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(54) **MAGNETORHEOLOGICAL FLUID COMPOSITIONS AND PROSTHETIC KNEES UTILIZING SAME**

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(52) **U.S. Cl.** 252/62.52

(58) **Field of Classification Search** 252/62.52; 623/24, 26, 39

See application file for complete search history.

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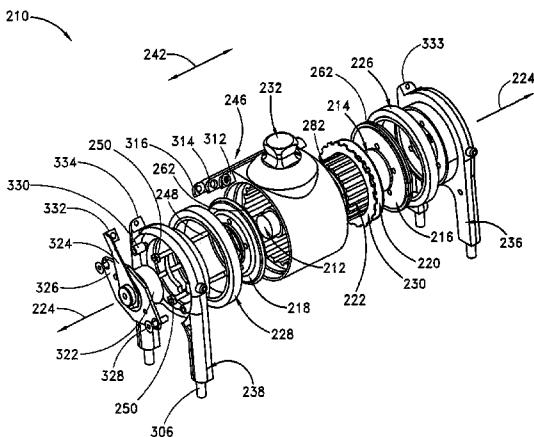
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(57)

ABSTRACT

The present invention relates in one embodiment to magnetorheological fluids utilized in prosthetic joints in general and, in particular, to magnetorheological fluids utilized in controllable braking systems for prosthetic knee joints. Preferred magnetorheological fluids of the present invention comprises polarizable iron particles, a carrier fluid, and optionally an additive. Preferred additives include, but are not limited to functionalized carrier fluids as well as derivatized fluoropolymers. Preferred carrier fluids include, but are not limited, to perfluorinated polyethers.

54 Claims, 8 Drawing Sheets



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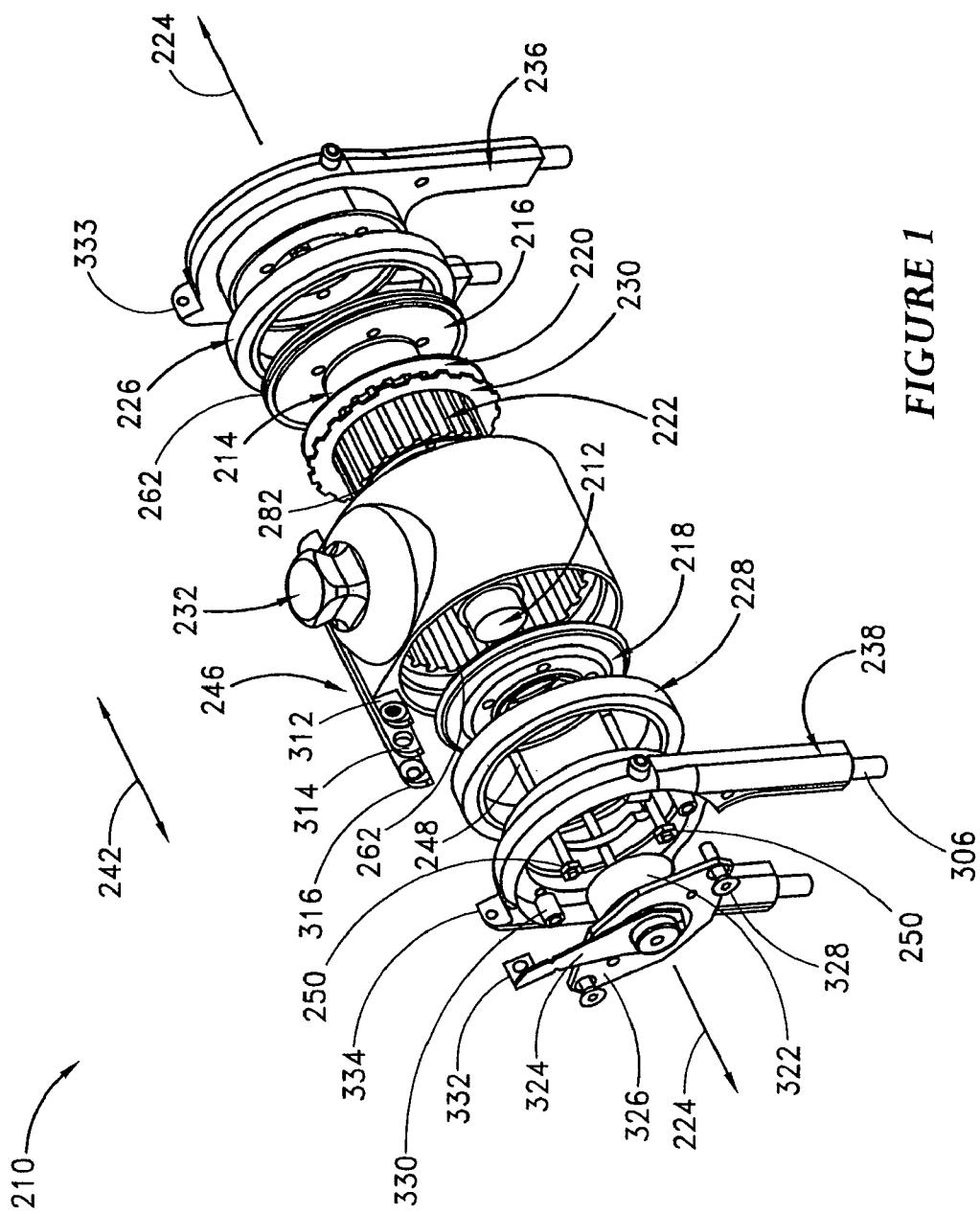
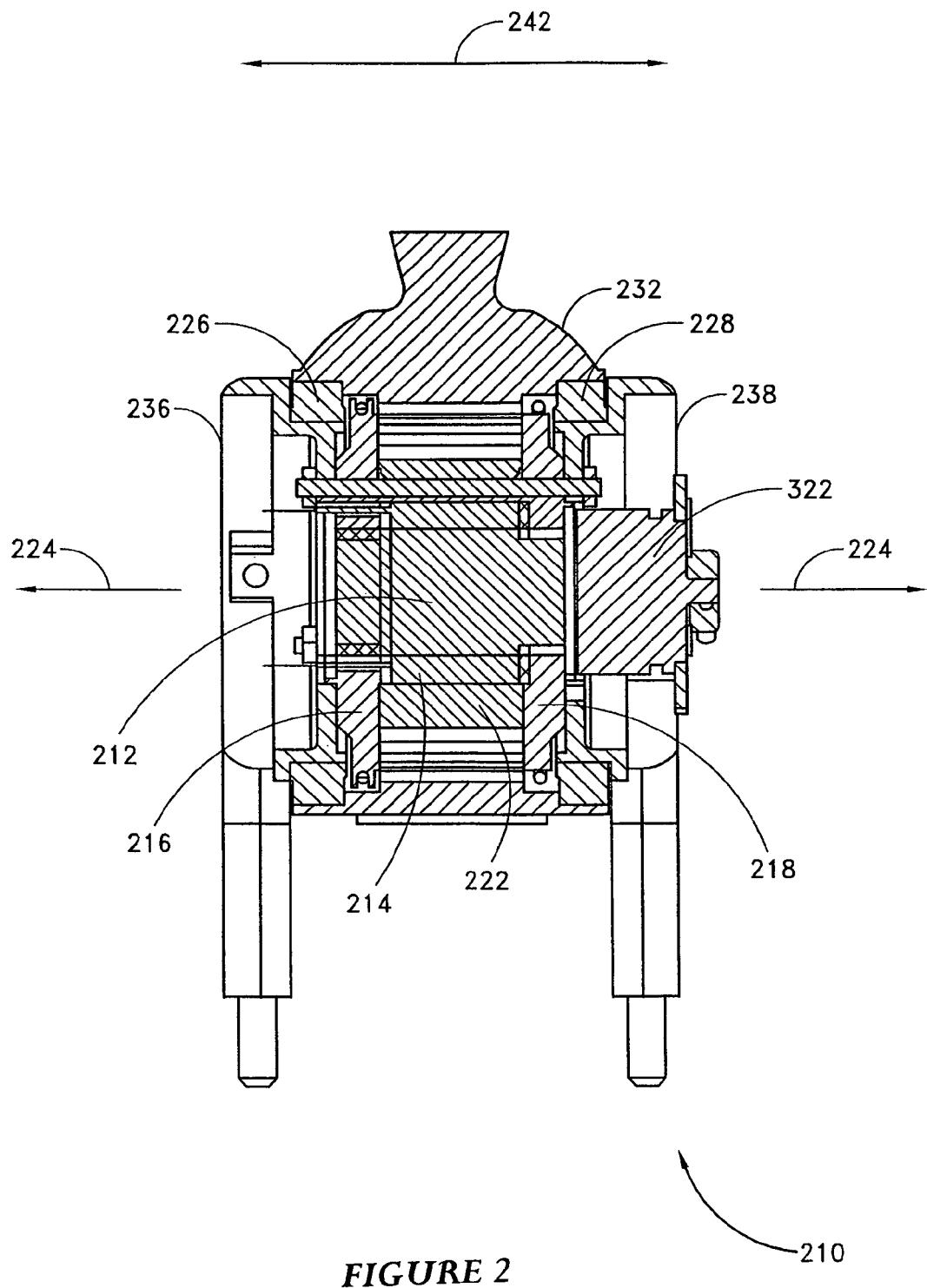


FIGURE 1



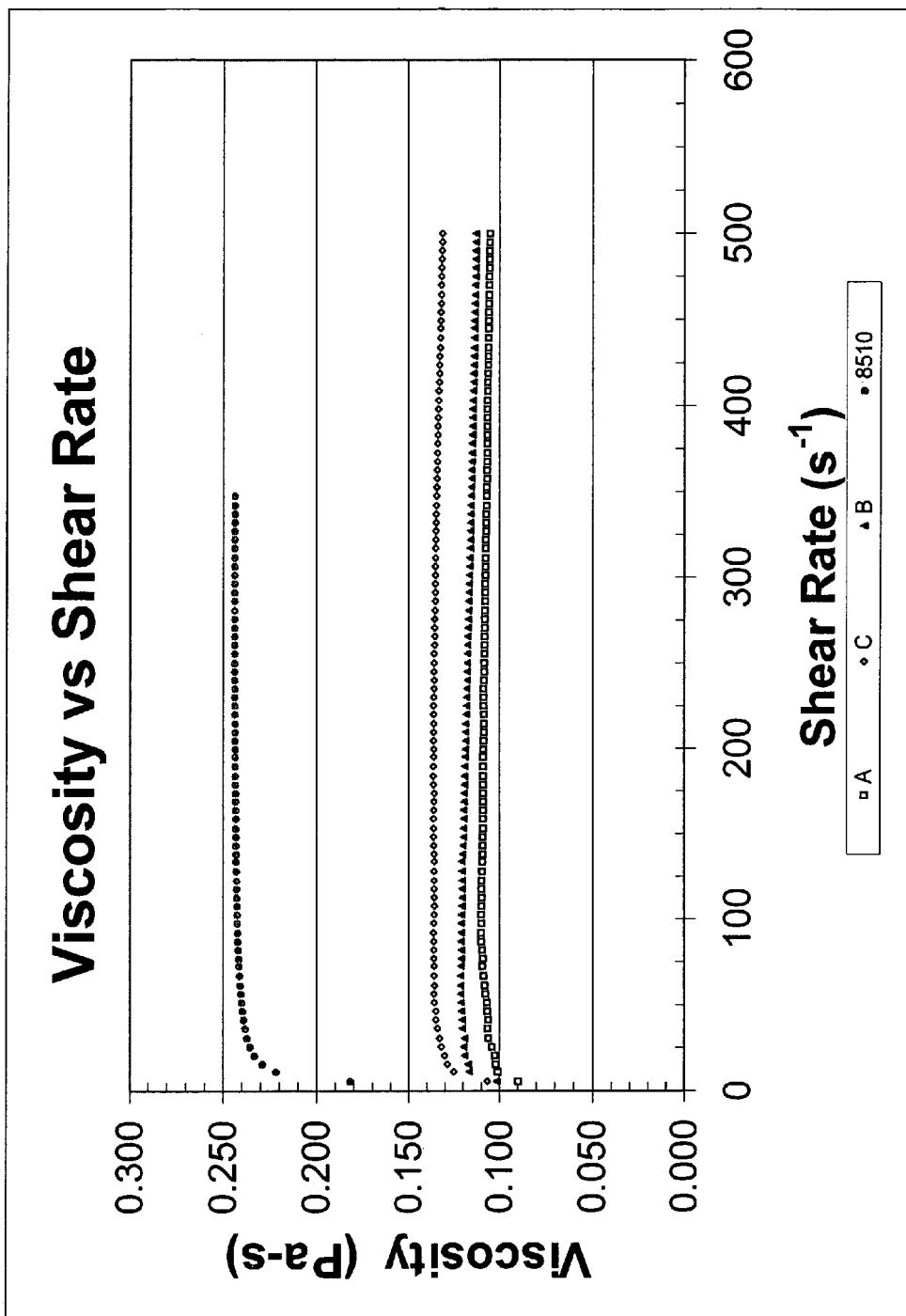


FIGURE 3

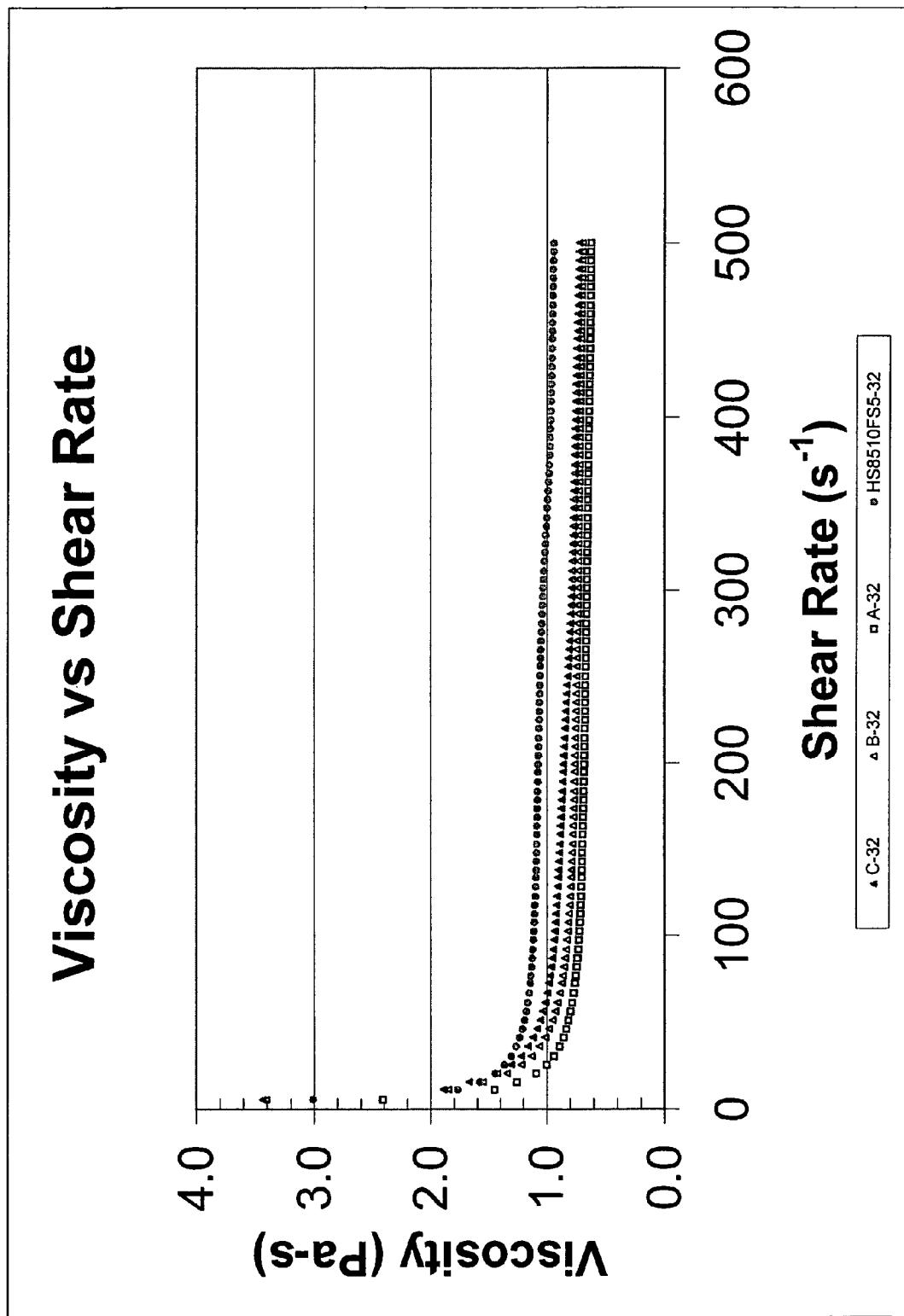


FIGURE 4

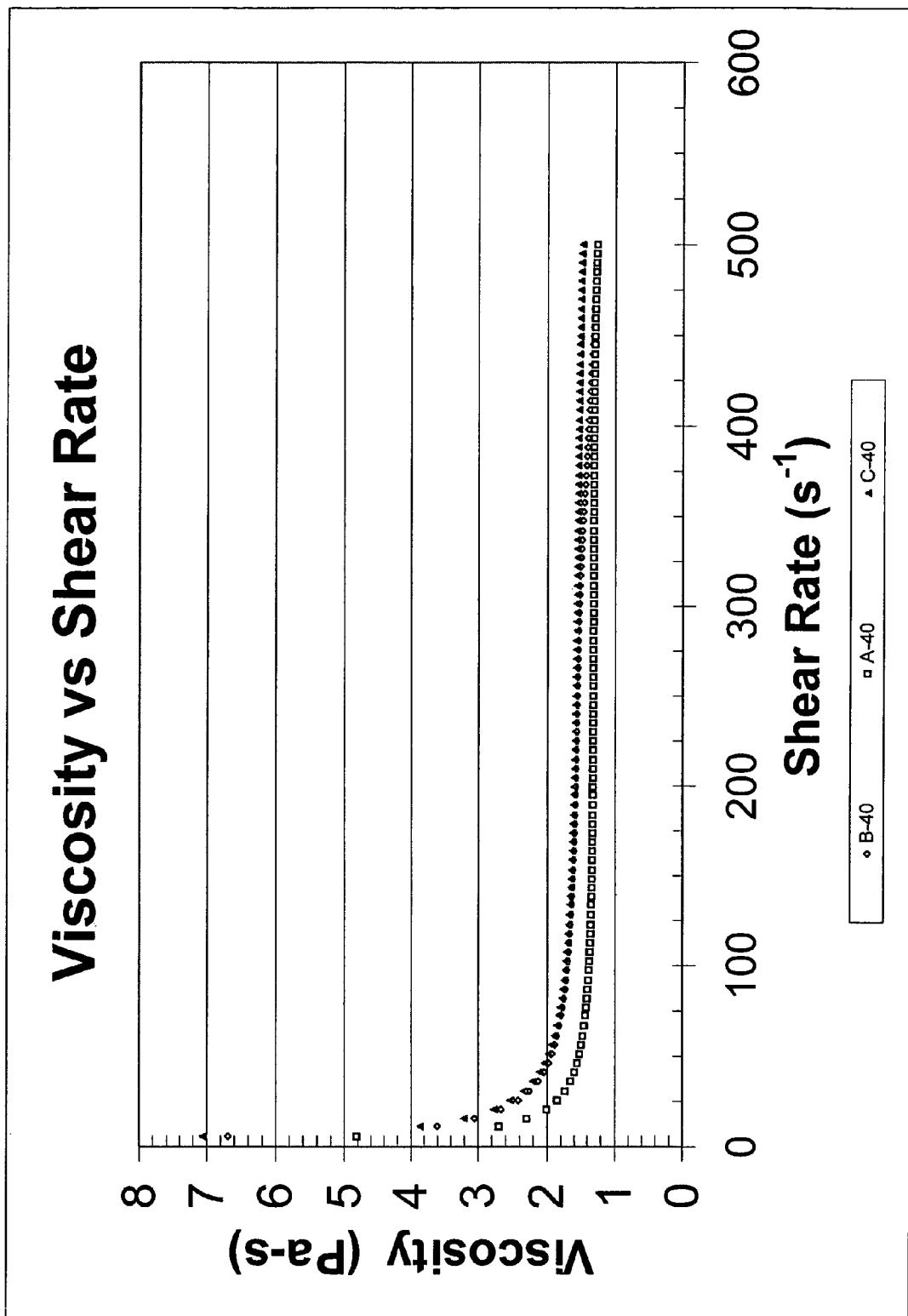
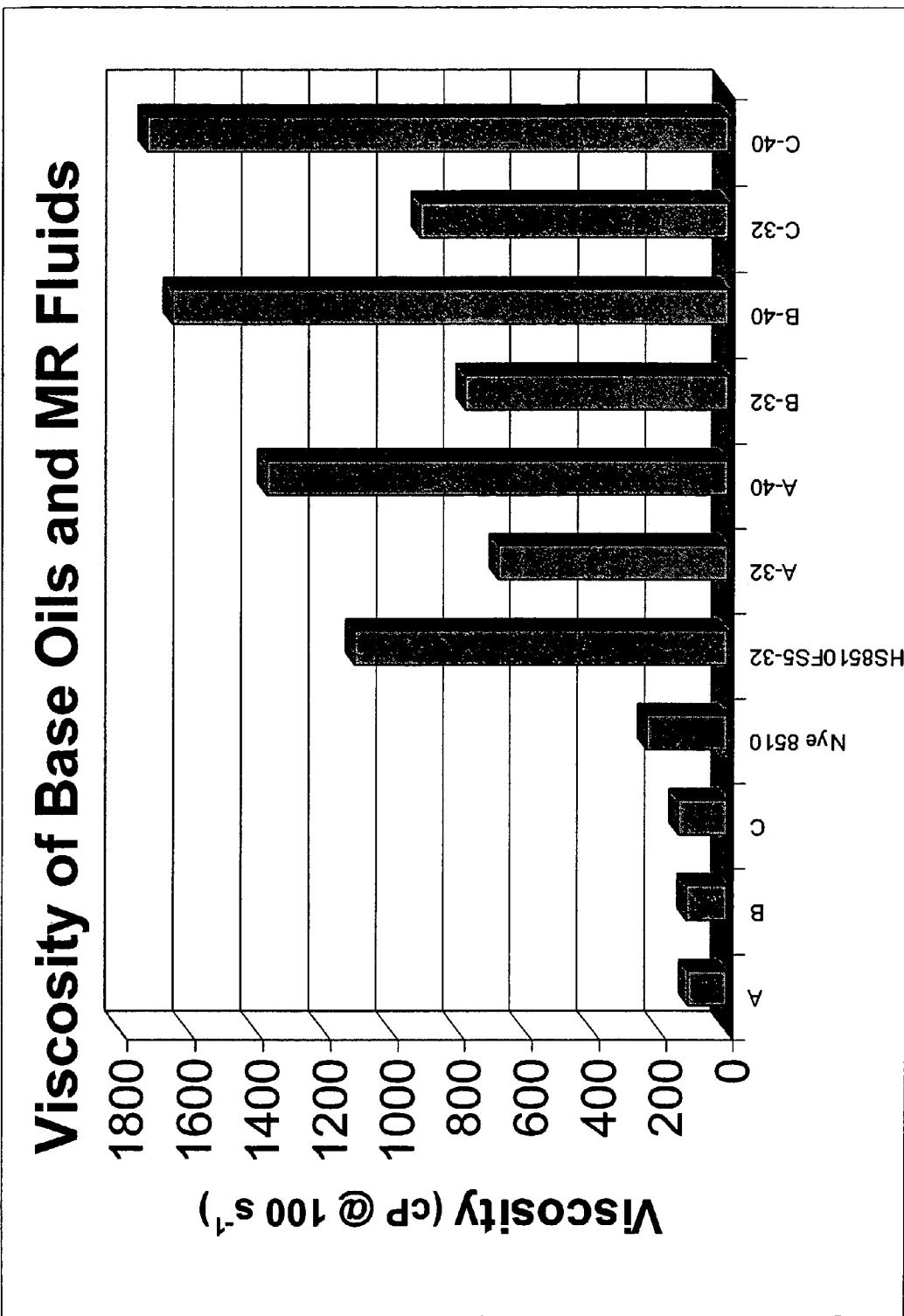


FIGURE 5



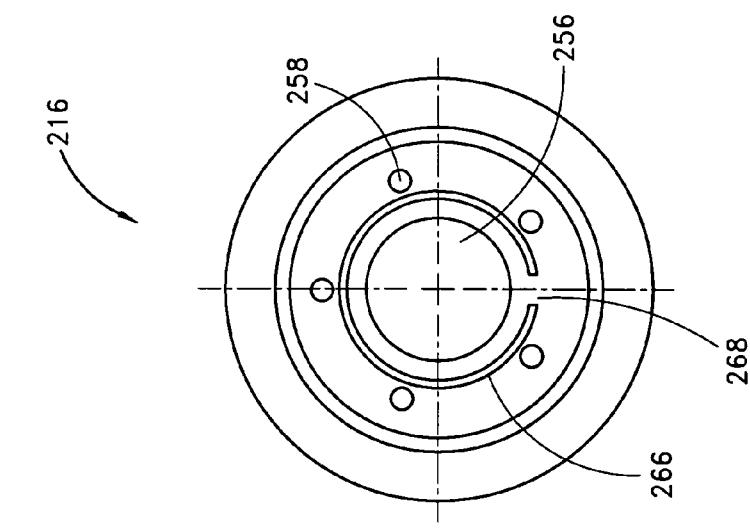


FIG. 8

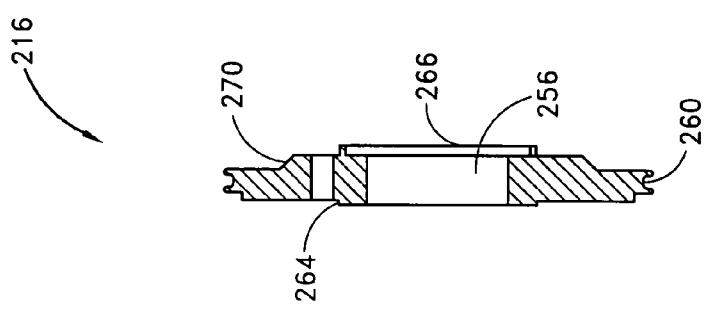


FIG. 9

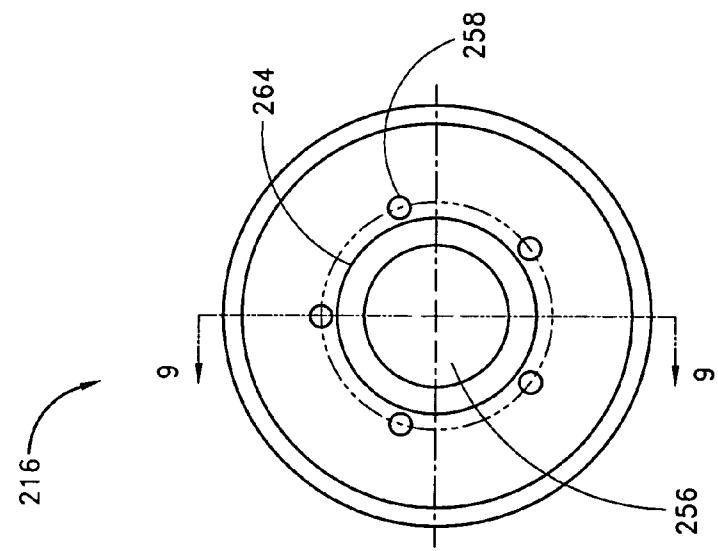


FIG. 7

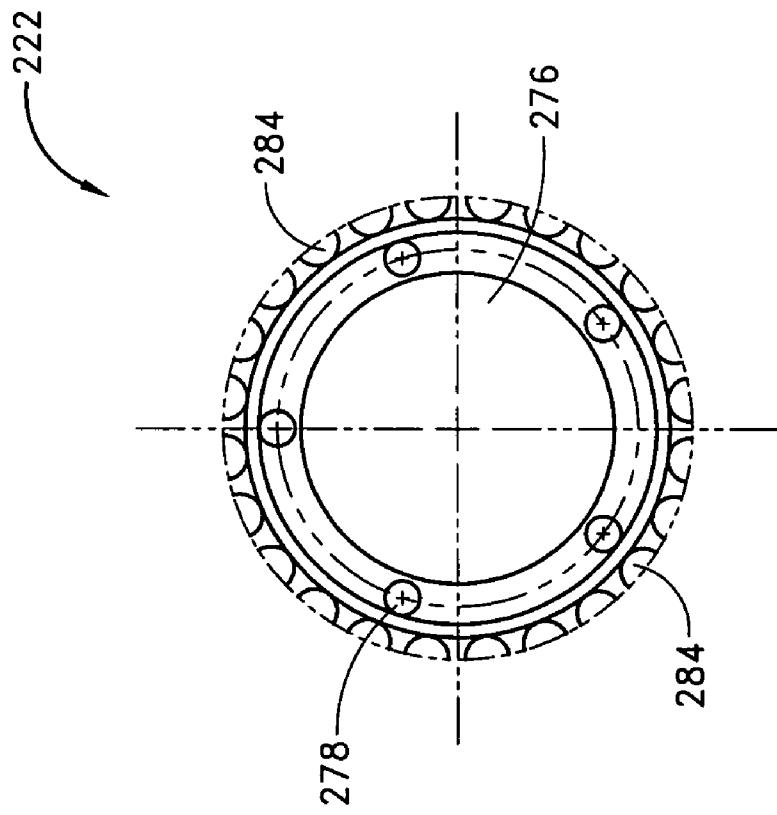


FIG. 10

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**MAGNETORHEOLOGICAL FLUID
COMPOSITIONS AND PROSTHETIC KNEES
UTILIZING SAME**

RELATED APPLICATIONS DATA

This application claims priority under 35 U.S.C. 119(e) from provisional application Ser. No. 60/467,722 filed May 2, 2003, the entirety of which is hereby incorporated by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates in one embodiment to magnetorheological fluids utilized in prosthetic joints in general and, in particular, to magnetorheological fluids utilized in controllable braking systems for prosthetic knee joints.

2. Description of the Related Art

Three types of variable-torque brakes have been employed in prosthetic knees in the past: (i) dry friction brakes where one material surface rubs against another surface with variable force; (ii) viscous torque brakes using hydraulic fluid squeezed through a variable sized orifice or flow restriction plate; and (iii) magnetorheological (MR) brakes or dampers where MR fluid (containing small iron particles suspended in the fluid) is squeezed through a fixed orifice or flow restriction plate, with viscosity of the fluid being varied in response to an applied magnetic field. Each of these technologies, as conventionally practiced in the field of prosthetics, can pose certain disadvantages.

Though dry friction brakes can generally provide a substantial torque range for their size, undesirably, they are often difficult to control. After extended use, the frictional pads tend to wear, thereby changing the frictional characteristics of the brake and the torque response for a given commanded torque. Disadvantageously, this can cause unreliable damping performance, and hence adversely affect the gait of the amputee and also cause discomfort to the amputee. Consequently, dry friction brakes may need frequent servicing and/or replacement which undesirably adds to the cost.

Under high loading conditions, viscous torque brakes are susceptible to leakage of hydraulic fluid and possibly other damage due to excessive pressure build-up. Disadvantageously, this can result in an irreversible state, since once the brake unit is overloaded it cannot return to normal. Therefore, such a viscous torque brake for a prosthetic joint is prone to catastrophic failure, and hence can be unreliable and detrimental to the safety of an amputee.

In certain MR brakes and dampers, the interaction of the MR fluid with the device causes increased pressure, seal deterioration, or a combination of the two. Another possible cause of these adverse effects is decomposition of the MR fluid. Once the seals fail or the MR fluid decomposes, the prosthetic knee is no longer suitable for use.

SUMMARY OF THE INVENTION

In accordance with preferred embodiments, there is provided a magnetorheological fluid (MR fluid) comprising polarizable particles, a carrier fluid, and optionally an additive. In one embodiment, the polarizable particles comprise iron particles ranging in size from about 0.1 to about 100 microns, preferably from about 0.2 to about 50 microns, from about 0.4 to about 10 microns, or from about 0.5 to

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about 9 microns, but also including about 0.3, 0.6, 0.7, 0.8, 0.9, 1, 2, 3, 4, 5, 6, 7, 8, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 40, 60, 70, 80, and 90 microns, and ranges encompassing such sizes. In certain embodiments, iron particles comprise from about 1 to about 60% (v/v) of the total MR fluid volume, preferably from about 10 to about 50% (v/v), from about 20 to about 40% (v/v), but also including about 5, 15, 25, 30, 35, 45, and 55% (v/v) and ranges encompassing such percentages.

10 Suitable candidates for carrier fluids include, but are not limited to, silicone, hydrocarbon, esters, ethers, fluorinated esters, fluorinated ethers, mineral oil, unsaturated hydrocarbons, and water based fluids. In one embodiment, a preferred carrier fluid comprises an aliphatic hydrocarbon. In another embodiment, a preferred carrier fluid comprises a perfluorinated polyether ("PFPE").

In one embodiment, a preferred additive comprises a functionalized fluoropolymer, including, but not limited to, a parafluoropropene and oxygen polymerized amide derivative.

15 In another embodiment, a preferred additive comprises a functionalized carrier fluid. Suitable candidates for mono-functionalized PFPE carrier fluid derivatives include, but are not limited to silane, phosphate, hydroxyl, carboxylic acid, alcohol and amine functions. Suitable candidates for difunctional PFPE carrier fluid derivatives include, but are not limited to, dihydroxyl, ethoxy ether, isocyanate, aromatic, ester and alcohol functions. In one embodiment, a preferred functionalized PFPE carrier fluid comprises a poly (hexafluoropropylene epoxide) with a carboxylic acid located on the terminal fluoromethylene group. In one embodiment, the additive comprises from about 0.1 to about 20% (v/v) of the carrier fluid, preferably from about 1 to about 15% (v/v), or from about 2 to about 10% (v/v), but also including about 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 25 8, 8.5, 9, 9.5, 11, 12, 13, 14, 16, 17, 18, and 19% (v/v) and ranges encompassing such percentages.

In one embodiment, a preferred MR fluid comprises about 28% (v/v) particles, and about 72% (v/v) fluid component wherein said fluid component comprises about 5% (v/v)

40 poly(hexafluoropropylene epoxide) with a carboxylic acid located on the terminal fluoromethylene group additive and about 95% (v/v) PFPE oil carrier fluid. In another embodiment, a preferred MR fluid comprises about 32% (v/v) particles, and about 68% (v/v) fluid component wherein said fluid component comprises about 5% (v/v) parafluoropropene and oxygen polymerized amide derivative additive and about 95% (v/v) PFPE oil carrier fluid. In another embodiment, a preferred MR fluid comprises about 32% (v/v) particles and about 68% (v/v) fluid component wherein said fluid component comprises about 5% (v/v) parafluoropropene and oxygen polymerized amide derivative additive and about 95% (v/v) PFPE oil carrier fluid. In embodiments containing PFPE oil, the PFPE oil may comprise substantially all one 45 50 55 60 PFPE oil or a mixture of one or more PFPE oils.

In one embodiment, an MR fluid is specifically designed for use in a shear mode device. For such a device, mechanically hard particles are desired. The carrier fluid also desirably experiences a less dramatic viscosity change over temperature changes as compared to other fluids. This may be measured in terms of a viscosity index (test method ASTM D-2270) with preferred carrier fluids having higher

viscosity indices. In one embodiment, preferred carrier fluids have viscosity indices preferably ranging from about 100 to about 340 based on kinematic viscosity at 104 and 212° F., from about 120 to about 320, from about 140 to about 300, but also including 160, 180, 200, 220, 240, 255, 260, 280, and ranges encompassing these amounts. One embodiment that accomplishes this includes a carrier fluid comprising one or more PFPE oils. For example, a preferred PFPE fluid, UNIFLOR™ 8510 has a viscosity index of 255. Without wishing to be bound by any theory, it is believed that preferred PFPE oils of certain embodiments demonstrate desirable viscosity indices due to their narrow distribution of molecular weights. Also, the MR fluid desirably does not produce a significant amount of vapor in a sealed chamber so as to interfere with the function of the device. In one embodiment, a fluid component comprising PFPE oil carrier fluid and a functionalized fluoropolymer additive provides this property. Without wishing to be bound by any theory, it is believed that preferred PFPE oils of certain embodiments are less volatile, i.e. lower vapor pressures than other oils, because they have much higher molecular weights, e.g. about 2,000 to about 15,000, and therefore do not produce a significant amount of vapor.

In addition, a shear mode device should provide sufficient torque, for example torque production in one embodiment may be about 0.1 to about 200 Newton-meters, more preferably about 0.3 to about 150 Newton-meters, even more preferably about 0.5 to about 100 Newton-meters, but also including about 0.8, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 20, 30, 40, 50, and 75 Newton-meters. In one embodiment, maintaining a sufficient ratio of particles, such as iron particles, to MR fluid provides for this. In one embodiment, a suitable ratio is achieved when the iron particles comprise from about 1 to about 60% (v/v) of the total MR fluid volume, preferably from about 10 to about 50% (v/v), more preferably from about 20 to about 40% (v/v), but also including about 5, 15, 25, 30, 35, 45, and 55% (v/v) and ranges encompassing these percentages.

In accordance with preferred embodiments, there is provided a MR fluid comprising polarizable particles, a carrier fluid, and optionally an additive for use in a prosthetic knee, for example, a knee as described in U.S. Patent Publication 2001/0029400A1. In one embodiment, the prosthetic knee comprises at least two adjacent surfaces adapted for shear movement relative to one another wherein the MR fluid is contained between said adjacent surfaces. In one embodiment, the MR fluid used in combination with the knee comprises PFPE oil carrier fluid and particles, such as polarizable particles described above. In one embodiment, the polarizable particles comprise iron particles ranging in size from about 0.1 to about 100 microns, preferably from about 0.2 to about 50 microns, more preferably from about 0.4 to about 10 microns, even more preferably from about 0.5 to about 9 microns, but also including about 0.3, 0.6, 0.7, 0.8, 0.9, 1, 2, 3, 4, 5, 6, 7, 8, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 40, 60, 70, 80, and 90 microns, and ranges encompassing these sizes. In certain embodiments, iron particles comprise from about 1 to about 60% (v/v) of the total MR fluid volume, preferably from about 10 to about 50% (v/v), more preferably from about 20 to about 40% (v/v), but also including about 5, 15, 25, 30, 35, 45, and 55% (v/v) and ranges encompassing such percentages.

In another embodiment, the MR fluid used in combination with a prosthetic knee optionally includes an additive. In one embodiment, a preferred additive comprises a functionalized fluoropolymer, more preferably a parafluoropropene and oxygen polymerized amide derivative. In another embodiment,

a preferred additive comprises a functionalized carrier fluid. Suitable candidates for monofunctionalized PFPE carrier fluid derivatives include, but are not limited to silane, phosphate, hydroxyl, carboxylic acid, alcohol and amine functions. Suitable candidates for difunctional PFPE carrier fluid derivatives include, but are not limited to, dihydroxyl, ethoxy ether, isocyanate, aromatic, ester and alcohol functions. In one embodiment, a preferred functionalized PFPE oil comprises a poly(hexafluoropropylene epoxide) with a carboxylic acid located on the terminal fluoromethylene group. In one embodiment, the additive comprises from about 0.1 to about 20% (v/v) of the carrier fluid, preferably from about 1 to about 15% (v/v), more preferably from about 2 to about 10% (v/v), but also including about 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 9.5, 11, 12, 13, 14, 16, 17, 18, and 19% (v/v), and ranges encompassing these amounts.

In another embodiment, the passage or cavity of the knee that holds the MR fluid contains a volume of about 1 to about 20 ml, preferably from about 2 to about 9 ml, more preferably from about 3 to about 8 ml, but also including about 4, 5, 6, and 7 ml, and ranges encompassing these volumes. In one embodiment, the MR fluid fills the cavity to about 70% of its capacity, but ranges from about 50 to about 100% as well about 55, 60, 65, 75, 80, 85, 90 and 90% and ranges encompassing these amounts are also acceptable.

In another embodiment, the MR fluid used in combination with a prosthetic knee in shear mode in one embodiment utilizes a MR fluid that is operable over a temperature range from about 10 to about 115° F., but also including about 20, 30, 40, 50, 60, 70, 80, 90, 100, and 110° F. Operability in one embodiment depends on viscosity, wherein the carrier fluid desirably has a viscosity at 104° F. of about 10 to about 100 cSt (centistokes), more preferably about 30 to about 80 cSt, even more preferably about 50 to about 70 cSt, but also including about 10, 20, 25, 35, 40, 45, 55, 60, 65, 75, 85, 90, and 95 cSt.

Desirably, operation of a prosthetic knee in shear mode in one embodiment preferably utilizes a carrier fluid with a pour point preferably ranging from about -70° C. to about -40° C., from about -65° C. to about -45° C., but also including about -50° C., -55° C., and -60° C., and ranges encompassing these temperatures. In another embodiment, operation of a prosthetic knee in shear mode preferably utilizes a carrier fluid with a percent volatility at 121° C. preferably ranging from about 0.01% to about 20%, from about 0.02% to about 15%, from 0.03% to about 12%, but also including about 0.05%, 0.08%, 0.1%, 0.2%, 0.3%, 0.4%, 0.5%, 0.7%, 0.9%, 1%, 3%, 5%, 7%, 9%, 17%, and ranges encompassing these percentages.

In one embodiment, a preferred MR fluid used in combination with a prosthetic knee in shear mode comprises about 28% (v/v) particles, and about 72% (v/v) fluid component wherein said fluid component comprises about 5% (v/v) poly(hexafluoropropylene epoxide) with a carboxylic acid located on the terminal fluoromethylene group additive and about 95% (v/v) PFPE oil carrier fluid. In another embodiment, a preferred MR fluid used in combination with a prosthetic knee in shear mode comprises about 32% (v/v) particles, and about 68% (v/v) fluid component wherein said fluid component comprises about 5% (v/v) poly(hexafluoropropylene epoxide) with a carboxylic acid located on the terminal fluoromethylene group additive and about 95% (v/v) PFPE oil carrier fluid. In another embodiment, a preferred MR fluid used in combination with a prosthetic knee in shear mode comprises about 28% (v/v) particles, and about 72% (v/v) fluid component wherein said fluid com-

ponent comprises about 5% (v/v) parafluoropropene and oxygen polymerized amide derivative additive and about 95% (v/v) PFPE oil carrier fluid. In another embodiment, a preferred MR fluid comprises about 32% (v/v) particles and about 68% (v/v) fluid component wherein said fluid component comprises about 5% (v/v) parafluoropropene and oxygen polymerized amide derivative additive and about 95% (v/v) PFPE oil carrier fluid. In embodiments containing PFPE oil, the PFPE oil may comprise substantially all one PFPE oil or a mixture of one or more PFPE oils.

All of these embodiments are intended to be within the scope of the invention herein disclosed. These and other embodiments of the present invention will become readily apparent to those skilled in the art from the following detailed description of the preferred embodiments having reference to the attached figures, the invention not being limited to any particular preferred embodiment(s) disclosed.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1 and 2 depict one embodiment of a prosthetic knee suitable for use in preferred embodiments. FIGS. 1 and 2 correspond to FIGS. 4 and 5, respectively, of U.S. Patent Publication 2001/0029400A1 (application Ser. No. 09/767,367), filed Jan. 22, 2001, entitled "ELECTRONICALLY CONTROLLED PROSTHETIC KNEE," the entire disclosure of which is hereby incorporated by reference herein. More specifically, the description of the drawings and the item numbers depicted in the drawings are described in detail in the above referenced patent publication. FIG. 1 is a detailed exploded perspective view of a magnetorheologically actuated prosthetic knee having features and advantages in accordance with one preferred embodiment of the present invention. FIG. 2 is a cross section view of the prosthetic knee of FIG. 1.

FIGS. 3-5 illustrate dynamic viscosity curves for various carrier oils and MR fluid samples.

FIG. 6 illustrates a comparison of the viscosities of various carrier oils and MR fluids.

FIG. 7 is a front view of one of the core side plates of FIG. 1 having features and advantages in accordance with one preferred embodiment of the present invention.

FIG. 8 is a rear view of the core side plate of FIG. 7.

FIG. 9 is a cross section view along line 11—11 of FIG. 7.

FIG. 10 is an end view of the inner spline of FIG. 1 having features and advantages in accordance with one preferred embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Disclosed herein are magnetorheological fluids (MR fluids) suitable for use in magnetorheological knee brakes or actuators. More particularly, the disclosed MR fluids may be applicable to prosthetic knee joints which operate in shear mode, for example, where the MR fluid is provided between adjacent surfaces, such as between parallel plates or in the annular space between inner and outer cylinders. Certain embodiments of a magnetorheological knee brake or actuator that may employ the MR fluids as described herein are described in U.S. Patent Publication 2001/0029400A1 (application Ser. No. 09/767,367), filed Jan. 22, 2001, entitled "ELECTRONICALLY CONTROLLED PROSTHETIC KNEE," the entire disclosure of which is hereby incorporated by reference herein. FIGS. 1 and 2, corresponding to FIGS. 4 and 5 of U.S. Patent Publication 2001/0029400A1,

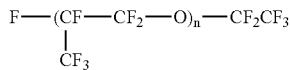
also depict one embodiment of a magnetorheological knee brake or actuator that may employ the MR fluids as described herein. Certain embodiments of a control scheme and system for magnetorheological knee brakes or actuators are described in copending U.S. Patent Publication 2002/0052663A1 (application Ser. No. 09/823,931), filed Mar. 29, 2001, entitled "SPEED-ADAPTIVE AND PATIENT-ADAPTIVE PROSTHETIC KNEE," the entire disclosure of which is hereby incorporated by reference herein. It will be appreciated, however, that the MR fluids as described herein may have applicability to other devices which utilize MR fluids, including but not limited to, other devices operating in a shear mode.

In one embodiment, the magnetorheological fluid preferably comprises a plurality of iron, ferrous or magnetic particles suspended in fluid. These suspended particles form torque producing chains in response to an applied magnetic field. Thus, the magnetorheological (MR) fluid undergoes a rheology or viscosity change or variation, which is dependent on the magnitude of the applied magnetic field. In turn, this variation in the bulk fluid viscosity determines the magnitude of the shearing force/stress or torque generated, and hence the level of damping or braking provided by the prosthetic knee or other device. Typically, the bulk viscosity of the MR fluid increases with increasing strength of the applied field. By controlling the magnitude of this magnetic field, the rotary motion of an artificial limb is rapidly and precisely adjusted and/or controlled, for example, to control the flexion and extension during swing and stance phases to provide a more natural and safe ambulation for the amputee. Preferably the MR fluid has one or more of the following properties: a high magnetic flux capacity and low magnetic remanence and low viscosity while having a large magnetic field induced shearing stress so that, advantageously, a prosthetic knee in one embodiment, provides a wide dynamic torque range.

In one embodiment, the MR fluid preferably comprises a carrier fluid with polarizable ferrous or iron particles. As used herein, the term carrier fluid is a broad term used in its ordinary sense and includes embodiments wherein the specific carrier fluids described below are the primary component and embodiments wherein the carrier fluid comprises these specific fluids as well as additives described below. In addition, embodiments wherein the additives described below are the primary carrier fluid are also contemplated. In one embodiment, such as when used between rotor-stator surfaces of U.S. 2001/0029400A1, these particles have a size on the order of a micron or a few microns. Ideally the MR fluid exhibits shear rate thinning behavior where MR fluid viscosity decreases with increasing shear rate. This advantageously minimizes the viscous torque due to shearing of the MR fluid between each rotor-stator pair under zero-field conditions (that is, when the electromagnet is not energized), and hence allows for a larger operating torque range. Further, in one embodiment MR fluids used in combination with a prosthetic knee desirably exhibit low off-state viscosity and therefore low off-state torque as torque is proportional to MR fluid viscosity. The viscosity of preferred MR fluids in certain embodiments may be altered by one or more of the following: increasing or decreasing the particle loading, including an additive, changing the carrier fluid, or mixing two or more carrier fluids.

Suitable candidates for carrier fluids include, but are not limited to, silicone, hydrocarbon, esters, ethers, fluorinated esters, fluorinated ethers, mineral oil unsaturated hydrocarbons, and water based fluids. In one embodiment, the carrier fluid comprises substantially all one fluid. In another

embodiment, the carrier fluid is a mixture of one or more carrier fluids. In one embodiment, the carrier fluid preferably comprises an aliphatic hydrocarbon. In another embodiment the carrier fluid preferably comprises a perfluorinated polyether (PFPE), also known as perfluoropolyether, perfluoroalkylether or perfluoropolyalkylether, fluid. In certain embodiments, a preferred PFPE oil comprises fluorine end capped branched homopolymers of hexafluoropropylene epoxide with the following chemical structure:



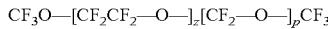
Where n=10–60

In another embodiment, a preferred PFPE oil comprises a branched PFPE containing pendent trifluoromethyl groups, ($-\text{CF}_3$), with the following structure:



Where n=5–65

In another embodiment, a preferred PFPE oil comprises a linear PFPE with the following structure:



Where the ratio of z:p is between about 0.5:1 and 2:1, and z+p is between about 40 and about 180. In another embodiment, a preferred PFPE oil comprises a linear PFPE with the following structure:



Where n=10–50

In another embodiment, a preferred PFPE oil comprises perfluoropropylpolyether. As presently contemplated preferred perfluorinated polyethers may be purchased from Nye Lubricants (Fairhaven, Mass., USA) and include, but are not limited to, UNIFLORTM 8510, UNIFLORTM 8130, UNIFLORTM 8140, UNIFLORTM 8730 and UNIFLORTM 8970. Suitable perfluorinated polyethers may also be purchased from E.I. du Pont de Nemours and Company, (Wilmington, Del., USA) and include, but are not limited to, Krytox® GPL-103, Krytox® L-65 oil, Krytox® XP 1A4 oil, Krytox® L-100, Krytox® 1525, Krytox® 1525S, and Krytox® 1531.

Other ingredients can be optionally added to the carrier fluids of preferred embodiments to enhance the performance properties of preferred carrier fluids. In some embodiments, preferred additives include, but are not limited to, functionalized carrier fluids. In embodiments comprising perfluorinated polyethers, desirable additives can also include, but are not limited to, functionalized PFPE oils as well as derivatized fluoropolymers. Suitable candidates for mono-functionalized PFPE derivatives include, but are not limited to, dihydroxyl, ethoxy ether, isocyanate, aromatic, ester and alcohol functions. More specifically, in one embodiment comprising perfluorinated polyethers, a preferred functionalized PFPE oil comprises a poly(hexafluoropropylene epoxide) with a carboxylic acid located on the terminal fluoromethylene group. As presently contemplated preferred functionalized PFPE oils are Krytox® 157 FSL and Krytox® 157 FSM available from E.I. du Pont de Nemours and Company, (Wilmington, Del., USA). In another embodiment, a preferred fluoropolymer comprises a parafluoropropene and oxygen polymerized amide derivative. As presently contem-

plated a preferred parafluoropropene and oxygen polymerized amide derivative additive is FOMBLIN DA 306 available from Solvay Solexis (Thorofare, N.J., USA).

Suitable candidates for polarizable ferrous or iron particles include, but are not limited to, particles ranging in size from about 0.1 to about 100 microns, preferably from about 0.2 to about 50 microns, more preferably from about 0.4 to about 10 microns, even more preferably from about 0.5 to about 9 microns, but also including about 0.3, 0.6, 0.7, 0.8, 0.9, 1, 2, 3, 4, 5, 6, 7, 8, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 40, 60, 70, 80, and 90 microns, and ranges encompassing these sizes. In certain embodiments, preferred particles are mechanically hard. As presently contemplated preferred iron particles are available from BASF AG (Ludwigshafen, Germany) and include, but are not limited to, BASF Carbonyl Iron Powder OM, BASF Carbonyl Iron Powder HQ, BASF Carbonyl Iron Powder HS, BASF Carbonyl Iron Powder EW, BASF Carbonyl Iron Powder HS-I, and BASF Carbonyl Iron Powder HL-1. Other suitable iron particles may also be purchased from ISP Corporation (Wayne, N.J., USA). Other suitable ferrous or iron particles well known to those of skill in the art may also be used. In related embodiments, particles comprising magnetic or ferrimagnetic materials other than iron may be used alone or in combination with iron-based particles.

In accordance with a preferred embodiment, the MR fluid composition comprises polarizable iron particles, PFPE carrier fluid, and an additive. In one embodiment, the iron particles comprise from about 1 to about 60% (v/v) of the total MR fluid volume, preferably from about 10 to about 50% (v/v), more preferably from about 20 to about 40% (v/v), but also including about 5, 15, 25, 30, 35, 45, and 55% (v/v) and ranges encompassing such percentages. To determine the weight of particles required to achieve the proper % (v/v), the required volume is multiplied by the density of the particles. In one embodiment, the additive comprises from about 0.1 to about 20% (v/v) of the carrier fluid, preferably from about 1 to about 15% (v/v), more preferably from about 2 to about 10% (v/v), but also including about 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 9.5, 11, 12, 13, 14, 16, 17, 18, and 19% (v/v) and ranges encompassing such percentages. For example, in one embodiment a preferred MR fluid comprises about 28% (v/v) iron particles and about 72% (v/v) fluid component wherein said fluid component comprises about 5% (v/v) a parafluoropropene and oxygen polymerized amide derivative additive and about 95% (v/v) PFPE carrier fluid. In another embodiment, a preferred MR fluid comprises about 32% (v/v) particles and about 68% (v/v) fluid component wherein said fluid component comprises about 5% (v/v) parafluoropropene and oxygen polymerized amide derivative additive and about 95% (v/v) PFPE oil carrier fluid. In another embodiment, a preferred MR fluid comprises about 28% (v/v) particles, and about 72% (v/v) fluid component wherein said fluid component comprises about 5% (v/v) poly(hexafluoropropylene epoxide) with a carboxylic acid located on the terminal fluoromethylene group additive and about 95% (v/v) PFPE oil carrier fluid. In another embodiment, a preferred MR fluid comprises about 32% (v/v) particles, and about 68% (v/v) fluid component wherein said fluid component comprises about 5% (v/v) poly(hexafluoropropylene epoxide) with a carboxylic acid located on the terminal fluoromethylene group additive and about 95% (v/v) PFPE oil carrier fluid. In embodiments containing PFPE oil, the PFPE oil may comprise substantially all one PFPE oil or a mixture of one or more PFPE oils.

The MR fluid ingredients may be combined in any order and mixed by any suitable means including, but not limited to, stirring, agitation, sonification or blending. In accordance with a preferred embodiment, additives are first mixed with carrier fluids and stirred. Carrier fluid is added to the iron particles and the ingredients are stirred. The particles are then dispersed using sonification. The resulting MR fluid is then heated. A detailed example is provided below in the example section.

When the MR fluids as described herein are used in combination with a prosthetic knee, for example, a knee as described in U.S. Patent Publication 2001/0029400A1, certain characteristics of the fluid as well as the knee may be desired. In one embodiment, such as shown in FIGS. 4 and 5 of U.S. 2001/0029400A1, a knee may contain a cavity or passage for holding MR fluid between a plurality of rotors and stators. The number of rotors and stators in certain embodiments may be increased or reduced in order to alter the off-state or low-end torque properties of the MR fluid used in combination with the knee. In one embodiment, the number of rotors and stators preferably range from about 50 to about 90, preferably from about 55 to about 70, but also including about 57, 59, 61, 63, 65, 67, and ranges encompassing these amounts. The knee cavity may contain a volume of about 1 to about 10 ml, preferably from about 2 to about 9 ml, more preferably from about 3 to about 8 ml, but also including about 4, 5, 6, and 7 ml. In one embodiment, the MR fluid fills the cavity to about 70% of its total volume, but may range from about 50 to about 100% as well about 55, 60, 65, 75, 80, 85, 90 and 90%. The MR fluid advantageously demonstrates one or more of the following: relatively low volatility, stable viscosity, thermal stability, and a stable composition. In addition, in certain embodiments it is desirable that the cavity or passage containing the MR fluid does not exhibit undesirable pressure levels. Without wishing to be bound by any theory, it is believed that an unsuitable fluid may release gases or volatilize causing pressure within the prosthetic knee to increase to an undesirable level. If the pressure is too high, the integrity of the prosthetic knee seals can be compromised. In certain embodiments it is desirable that a prosthetic knee utilizing a MR fluid produces torque of about 0.1 to about 200 Newton-meters, more preferably about 0.3 to about 150 Newton-meters, even more preferably about 0.5 to about 100 Newton-meters, but also including about 0.8, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 20, 30, 40, 50, and 75 Newton-meters.

Desirably, operation of a prosthetic knee in shear mode in one embodiment utilizes a MR fluid that is operable over a temperature range from about 10 to about 115° F., but also including about 20, 30, 40, 50, 60, 70, 80, 90, 100, and 110° F. Operability in one embodiment depends on viscosity, wherein the carrier fluid desirably has a viscosity at 104° F/ (40° C.) of about 10 to about 100 cSt, more preferably viscosity of about 30 to about 80 cSt, even more preferably viscosity of about 50 to about 70 cSt, but also including about 10, 20, 25, 35, 40, 45, 55, 60, 65, 75, 85, 90, and 95 cSt. The viscosity of preferred MR fluids in certain embodiments may be altered by one or more of the following: increasing or decreasing the particle loading, including an additive, changing the carrier oil, or mixing two or more carrier oils.

In one embodiment, an MR fluid is specifically designed for use in a shear mode device. For such a device, mechanically hard particles are desired. The carrier fluid also desirably experiences a less dramatic viscosity change over temperature changes as compared to other fluids. This may be measured in terms of a viscosity indices (test method

ASTM D-2270) with preferred carrier fluids having higher viscosity indices. In one embodiment, preferred carrier fluids have viscosity indices preferably ranging from about 100 to about 340 based on kinematic viscosity at 104 and 212° F., from about 120 to about 320, from about 140 to about 300, but also including 160, 180, 200, 220, 240, 255, 260, 280, and ranges encompassing these amounts. One embodiment that accomplishes this includes a carrier fluid comprising one or more PFPE oils. For example, a preferred PFPE fluid, UNIFLORTM 8510 has a viscosity index of 255. Without wishing to be bound by any theory, it is believed that preferred PFPE oils of certain embodiments demonstrate desirable viscosity indices due to their narrow distribution of molecular weights. Also, the MR fluid desirably does not produce a significant amount of vapor in a sealed chamber so as to interfere with the function of the device. In one embodiment, a fluid component comprising PFPE oil carrier fluid and a fluoropolymer additive provides this property. Without wishing to be bound by any theory, it is believed that preferred PFPE oils of certain embodiments are less volatile, i.e. lower vapor pressures than other oils, because they have much higher molecular weights, e.g. about 2,000 to about 15,000, and therefore do not produce a significant amount of vapor.

Desirably, operation of a prosthetic knee in shear mode in one embodiment preferably utilizes a carrier fluid with a pour point (test method ASTM D-97) preferably ranging from about -70° C. to about -40° C., from about -65° C. to about -45° C., but also including about -50° C., -55° C., -60° C., and ranges encompassing these temperatures. ASTM D-97 method defines "pour point" as the lowest temperature at which movement of an oil is observed. In another embodiment, operation of a prosthetic knee in shear mode preferably utilizes a carrier fluid with a percent volatility at 121° C. (test method ASTM D-972) preferably ranging from about 0.01% to about 20%, from about 0.02% to about 15%, from about 0.03% to about 12%, but also including about 0.05%, 0.08%, 0.1%, 0.2%, 0.3%, 0.4%, 0.5%, 0.7%, 0.9%, 1%, 3%, 5%, 7%, 9%, 17%, and ranges encompassing these percentages.

More specifically, when used in combination with a prosthetic knee as previously disclosed, desirable MR fluids for use in certain embodiments comprise a carrier fluid and polarizable particles. More specifically, in one embodiment used in combination with a prosthetic knee, the MR fluid comprises one or more PFPE oil carrier fluids and polarizable particles. In one embodiment, the iron particles comprise from about 1 to about 60% (v/v) of the total MR fluid volume, preferably from about 10 to about 50% (v/v), more preferably from about 20 to about 40% (v/v), but also including about 5, 15, 25, 30, 35, 45, and 55% (v/v), and ranges encompassing these percentages.

Other ingredients can be optionally added to the carrier fluids of preferred embodiments to enhance the performance properties of preferred carrier fluids. In some embodiments, preferred additives include, but are not limited to, functionalized carrier fluids. In embodiments comprising perfluorinated polyethers, desirable additives can also include, but are not limited to, functionalized PFPE oils as well as derivatized fluoropolymers. Suitable candidates for mono-functionalized PFPE derivatives include, but are not limited to silane, phosphate, hydroxyl, carboxylic acid, alcohol and amine functions. Suitable candidates for difunctional PFPE derivatives include, but are not limited to, dihydroxyl, ethoxy ether, isocyanate, aromatic, ester and alcohol functions. In some embodiments, functionalized perfluorinated polyether fluid additive comprises one or more functional

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groups selected from the group consisting of silane, phosphate, hydroxyl, carboxylic acid, amine, dihydroxyl, ethoxy ether, isocyanate, aromatic, ester and alcohol functions. More specifically, in one embodiment comprising perfluorinated polyethers, a preferred functionalized PFPE oil comprises a poly(hexafluoropropylene epoxide) with a carboxylic acid located on the terminal fluoromethylene group. As presently contemplated preferred functionalized PFPE oils are Krytox(157 FSL and Krytox.RTM. 157 FSM available from E.I. du Pont de Nemours and Company, (Wilmington, Del., USA). In another embodiment, a preferred fluoropolymer comprises a parafluoropropene and oxygen polymerized amide derivative. As presently contemplated a preferred parafluoropropene and oxygen polymerized amide derivative additive is FOMBLIN DA 306 available from Solvay Solexis (Thorofare, N.J., USA).

The ingredients may be combined in any order and mixed by any suitable means including, but not limited to, stirring, agitation, blending or sonification. In accordance with a preferred embodiment, the MR fluid is prepared as described above. Prior to loading into the prosthetic knee, the MR fluid is stirred under vacuum using a high speed stirrer to remove any dissolved gases. In a preferred embodiment, the MR fluid is heated to about 90 to about 160° F., more preferably to about 100 to about 150° F., even more preferably to about 110 to about 130° F., but also including about 95, 105, 115, 120, 122, 125, 135, 140, 145, and 155° F., under vacuum prior to loading into the prosthetic knee.

In another preferred embodiment, the MR fluid is heated at ambient pressure prior to being placed under vacuum. While under vacuum, agitation or stirring of the MR fluid is preferred but not required. After the MR fluid is released from the vacuum, the MR fluid is loaded into the prosthetic knee. The loading of the prosthetic knee involves adding the MR fluid to the knee and then placing the knee under vacuum. While under vacuum the knee is optionally agitated. To reduce the vacuum pressure, an inert gas is added into the vacuum chamber. Once, the vacuum is fully released, the prosthetic knee is removed and closed. The vacuum fill process should be carefully monitored as exiting air may blow enough MR fluid out of the funnel to require fluid volume replenishment.

EXAMPLES

Example 1

MR Fluid Preparation

To prepare the MR fluid, the additives were mixed with the carrier fluids and stirred. Carrier fluid was added to the iron particles and the ingredients were stirred. A Branson Digital Sonifier, Model 450, was used to disperse the iron particles in the carrier fluid. The MR fluid was then placed on the sonifier table, with the probe adjusted so that the majority of the probe was immersed in the MR fluid without touching the bottom of the mixture jar. The MR fluid was then sonicated for 1.5 minutes at 50% intensity while the sonifier table rotated. The MR fluid was checked periodically to ensure that the mixture did not become too hot. A fan was used to cool the MR fluid. Once the cycle was complete, the jar was rotated to wash down any particles that were adhered to the walls of the jar. The sonification step was then repeated two more times. Once complete, the MR fluid was removed from the sonifier and a final stir of the MR Fluid

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was performed to ensure that there were no clumps in the MR fluid. The MR fluid was then placed in an oven for two hours at 50° C.(122° F.).

Example 2

Prosthetic Knee MR Fluid Loading

When the MR fluids as described herein are used in combination with a prosthetic knee, for example, a knee as described in U.S. Patent Publication No. 2001/0029400A1, certain characteristics of the fluid as well as the knee may be desired. In one embodiment, such as shown in FIGS. 4 and 5 of U.S. 2001/0029400A1 and FIGS. 1 and 2 disclosed herein and described in further detail below, a knee may contain a cavity or passage for holding MR fluid between a plurality of rotors and stators. The number of rotors and stators in certain embodiments may be increased or reduced in order to alter the off-state or low-end torque properties of the MR fluid used in combination with the knee. In one embodiment, the number of rotors and stators preferably range from about 50 to about 90, preferably from about 55 to about 70, but also including about 57, 59, 61, 63, 65, 67, and ranges encompassing these amounts. The knee cavity may contain a volume of about 1 to about 10 ml, preferably from about 2 to about 9 ml, more preferably from about 3 to about 8 ml, but also including about 4, 5, 6, and 7 ml. In one embodiment, the MR fluid fills the cavity to about 70% of its total volume, but may range from about 50 to about 100% as well about 55, 60, 65, 75, 80, 85, 90 and 90%. The MR fluid advantageously demonstrates one or more of the following: relatively low volatility, stable viscosity, thermal stability, and a stable composition. In addition, in certain embodiments it is desirable that the cavity or passage containing the MR fluid does not exhibit undesirable pressure levels. Without wishing to be bound by any theory, it is believed that an unsuitable fluid may release gases or volatilize causing pressure within the prosthetic knee to increase to an undesirable level. If the pressure is too high, the integrity of the prosthetic knee seals can be compromised. In certain embodiments it is desirable that a prosthetic knee utilizing a MR fluid produces torque of about 0.1 to about 200 Newton-meters, more preferably about 0.3 to about 150 Newton-meters, even more preferably about 0.5 to about 100 Newton-meters, but also including about 0.8, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 20, 30, 40, 50, and 75 Newton-meters.

FIGS. 1 and 2 show a controllable rotary prosthetic knee joint 210 having features and advantages in accordance with one preferred embodiment of the present invention. The prosthetic knee 210 generates controllable dissipative forces preferably substantially along or about the knee axis of rotation 224.

The electronically controlled knee 210 generally comprises a generally central core 212 in mechanical communication with a pair of rotatable side plates 216, 218, an electromagnet 214, a plurality of blades or rotors 220 in mechanical communication with a rotatable inner spline 222, a plurality of blades or stators 230 in mechanical communication with a rotatable outer spline 232, a pair of ball bearings 226, 228 for transferring rotary motion to a pair of outer side walls or forks 236, 238. The rotation is substantially about the knee axis of rotation 224.

The plurality of rotors 220 and stators 230 are preferably interspersed in an alternating fashion and the gaps or micro-gaps between adjacent blades 220 and 230 comprise thin lubricating films of a magnetorheological (MR) fluid, which

thereby resides in the cavity or passage formed between the inner spline 222 and the outer spline 232. This preferred embodiment provides a controllable and reliable artificial knee joint, which advantageously has a wide dynamic torque range, by shearing the MR fluid in the multiple gaps or flux interfaces between adjacent rotors 220 and stators 230.

Preferably, end-threaded rods 248 and nuts 250 are used to secure selected components of the prosthetic knee 210, thereby allowing a straightforward assembly and disassembly procedure with a minimum of fasteners. Alternatively, or in addition, various other types of fasteners, for example, screws, pins, locks, clamps and the like, may be efficaciously utilized, as required or desired, giving due consideration to the goals of providing secure attachment, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

Preferably, the core 212 and associated side plates 216, 218 are formed of a magnetically soft material of high flux saturation density and high magnetic permeability. Thus, when the electromagnet 214 is actuated a magnetic field, circuit or path is generated or created within the knee joint 210. In one preferred embodiment, the magnetic field passes longitudinally (parallel to the axis of rotation 224) through the central core 212, radially through the side plate 218, laterally (parallel to lateral direction 242) through the interspersed set of rotors 220 and stators 230 and the magnetorheological (MR) fluid, and radially through the side plate 216. The orientation or positioning of the electromagnet 214 and the direction of current flow through it determines the polarity of the magnetic field, and thereby determines whether the magnetic field passes radially inwards or outwards through the side plate 218, and hence in the correspondingly opposite direction through the side plate 216. The portion of the magnetic field passing through the core 212 and side plates 216, 218 generally defines the magnetic return path while the active or functional magnetic field is generally defined by the magnetic path through the rotors 220, stators 230 and MR fluid residing therebetween.

FIGS 7-9 show one preferred embodiment of the core side plate or disk 216 of the prosthetic knee joint 210. The core side plate 216 preferably comprises a circular groove 260 to receive an O-ring 262 (FIG. 1), lip seal or gasket and the like. This provides a dynamic seal between the rotatable side plate 216 and the inner surface of the rotatable outer spline 232 and prevents leakage of MR fluid from the knee 210. The other side plate 218 is similarly configured to receive an O-ring 262 (FIG. 1) and provide a dynamic seal. In an alternative preferred embodiment, two grooves or flanges are provided on the inner surface of the outer spline 232 to receive O-rings or the like and provide a dynamic seal between the core side plates 216, 218 and the outer spline 232.

The O-rings 262 are fabricated from a suitable rubber material or the like such as Viton, Teflon and Neoprene among others. In one preferred embodiment, the O-rings 262 have an inner diameter of about 50 mm and a width of about 1.5 mm. In other preferred embodiments, the dynamic seals can be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing reliable seals, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

The inner surface of the core side plate 216 preferably has a generally circular shoulder or step 264 for aligning or locating with the inner spline 222 (FIG. 1). The outer surface of the core plate 216 preferably has a generally ring-shaped shoulder or step 266 for aligning or locating with the outer fork 236 (FIG. 1). Optionally, the step 266 may include a cut 268 to allow clearance space for electrical wires or leads. Other holes around the central cavity 256 may be provided

for passage of electrical wires or leads. Preferably, the outer surface of the core side plate 216 includes a tapered portion 270. This advantageously decreases weight, saves material and also provides clearance space to facilitate assembly.

5 The core side plate 216 is preferably fabricated from a material having a high saturation flux density, a high magnetic permeability and low coercivity. Advantageously, this facilitates in the construction of an artificial knee or brake that is compact and light weight, and also strong. In one 10 preferred embodiment, the core plate 216 comprises an integral unit. In another preferred embodiment, the core plate 216 is formed of laminated sheets to advantageously reduce or minimize eddy losses.

Preferably, the core plate 216 comprises an iron-cobalt 15 (FeCo) high magnetic saturation alloy. In one preferred embodiment, the core plate 216 comprises Vacoflux 50 as available from Vacuumschmelze of Hanau, Germany. In another preferred embodiment, the core plate 216 comprises Iron-Cobalt High Saturation Alloy (ASTM A-801 Type 1 Alloy). In yet another preferred embodiment, the core plate 20 216 comprises Vacoflux 17 as available from Vacuum-schmelze of Hanau, Germany. In a further preferred embodiment, the core plate 216 comprises Hiperco Alloy 50. In other preferred embodiments, the core plate 216 can be efficaciously fabricated from alternate soft magnetic materials or the like, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable prosthetic knee joint, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

30 In one preferred embodiment, the material comprising the core plate 216 has a saturation flux density of about 2.2 Tesla. Such a high saturation flux density is desirable because it allows a compact and light weight design. For example, if a material having a lower saturation flux density 35 was utilized, the cross-sectional area of the return path through the core plate 216 in the direction of the applied magnetic field would have to be increased to achieve the same dynamic torque range. In other preferred embodiments, the core side plate saturation flux density can be higher or lower, as needed or desired, giving due consideration 40 to the goals of providing a suitably compact, light weight and/or durable prosthetic knee joint, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

45 Preferably, the core side plate 216 is formed by machining followed by heat treatment in a hydrogen atmosphere to achieve optimal magnetic properties. In other preferred embodiments, the core side plate 216 can be efficaciously fabricated from other techniques, for example, casting, forging, molding, laminating, among others, as required or desired, giving due consideration to the goals of providing desired magnetic properties and a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

55 FIG. 10 shows one preferred embodiment of the inner spline 222 of the prosthetic knee joint 210. The inner spline 222 is preferably generally cylindrical in shape and comprises a substantially central cylindrical cavity or through hole 276 for receiving the electromagnet or magnetic coil 214 (FIG. 1). Alternatively, other suitable shapes for the inner spline 222 and cavity 276 may be efficaciously utilized, as needed or desired.

60 Preferably, the inner spline 222 comprises a plurality of approximately equally spaced longitudinal through holes 278 arranged in a generally circular fashion to receive end-threaded rods or bolts and the like to secure selected components of the prosthetic knee 210, such as the core side

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plates 216, 218 and the inner spline 222. These holes 278 are generally aligned with corresponding holes 258 of the core side plates 216, 218.

In one preferred embodiment, the inner spline 222 comprises five holes 278. In another preferred embodiment, the inner spline 222 comprises three holes 278. Alternatively, fewer or more holes 278 arranged in other fashions may be provided, as needed or desired.

The inner spline 222 preferably comprises a circular groove 260 at each end to receive respective O-rings 282 (FIG. 1) or gaskets and the like. This provides a static seal between the inner spline 222 and the side plates 216, 218, since these components rotate together during knee rotation, and prevents leakage of MR fluid from the knee 210. In an alternative preferred embodiment, a respective groove or flange is provided on the inner surfaces of either or both plates 216, 218 to receive O-rings or the like and provide a static seal.

The O-rings 282 are fabricated from a suitable rubber material or the like such as Viton, Teflon and Neoprene among others. In one preferred embodiment, the O-rings 282 have an inner diameter of about 30.5 mm (1.201 inches) and a width of about 0.76 mm (0.030 inches). In other preferred embodiments, the static seals can be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing reliable seals, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

The outer surface of the inner spline 222 preferably has a plurality of approximately equally spaced longitudinal grooves 284 which are adapted to engage corresponding teeth of the rotors 220. In one preferred embodiment, the grooves 284 are generally semi-circular in shape. In another preferred embodiment, the grooves 284 are generally rectangular or square shaped with rounded corners. In other preferred embodiments, the grooves 284 can be efficaciously shaped and/or configured in alternate manners, as required or desired, giving due consideration to the goals of providing reliable load transmission from the rotors 220 to the inner spline 222, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

The inner spline 222 is preferably fabricated from titanium or a titanium alloy, and more preferably from 16A1-14V titanium alloy. Advantageously, the use of titanium or titanium alloys provides a near zero magnetic permeability and a yet strong, hard surface with low weight to engage the rotors and transmit torque from them. An additional benefit is that the high resistivity of the material (titanium or titanium alloy) reduces energy losses due to induced eddy currents. In other preferred embodiments, the inner spline 222 can be efficaciously fabricated from other metals, alloys, plastics, ceramics among others, as required or desired, giving due consideration to the goals of providing an inner spline 222 of near zero magnetic permeability, and a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

Preferably, the inner spline 222 is formed by machining. In other preferred embodiments, the inner spline 222 can be efficaciously fabricated from other techniques, for example, casting, forging, molding, among others, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, the prosthetic knee 210 comprises an angle sensing potentiometer 322 (FIG. 1). The potentiometer 322 is connected to an arm 324 and a mounting plate 326. The mounting plate 326 is connected to the fork 238 utilizing screws 328 or the like and spacers 330. An

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end 332 of the arm 324 is mechanically connected to the angled outer surface 334 of the fork 238 utilizing suitable screws or the like.

In one preferred embodiment of the present invention, the prosthetic knee 210 further comprises an extension assist to help straighten the leg by urging or biasing the leg to extension by applying a controlled torque or force. Any one of a number of devices, such as a spring-loaded extension assist, as known in the art may be used in conjunction with the present invention.

The mounting forks 236, 238 (FIG. 1) of the magnetorheologically actuated prosthetic knee 210 are preferably in mechanical communication with the bearings 226, 228 respectively and transfer rotary motion to a pylon or artificial shin portion of the amputee. Threaded studs 306 or other suitable connectors or fasteners are used to facilitate connection of the mounting forks 236, 238 to a pylon or artificial shin portion of the amputee.

Preferably, the mounting forks 236, 238 are fabricated from anodized 7075-T6 aluminum alloy. In other preferred embodiments, the mounting forks 226, 238 can be efficaciously fabricated from other metals, alloys, plastics, ceramics among others, as required or desired, giving due consideration to the goals of providing suitably strong, durable, light weight and/or substantially non-magnetic mounting forks 226, 238, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, the mounting forks 236, 238 are formed by machining. In other preferred embodiments, the mounting forks 236, 238 can be efficaciously fabricated from other techniques, for example, casting, forging, molding, among others, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, and as shown in FIG. 1, the prosthetic knee 210 further comprises a flexion stop system or assembly comprising a cushioned stop or restraint assembly or system 246. The flexion stop system controls the maximum allowable flexion angle by physically limiting the rotation between the outer side forks 236, 238 and the outer spline 232, and hence the rotation of the knee joint. The stop system 246 (FIG. 1) generally comprises a plurality of stops, bands or strips 312, 314 and 316.

A measured volume of MR fluid was then transferred into a funnel inserted into the prosthetic knee actuator. The knee was placed in the vacuum chamber and the chamber was sealed with a bell jar. Vacuum was slowly drawn to 28" Hg. The knee was periodically agitated during this procedure.

The vacuum chamber was slowly filled with nitrogen gas to remove the vacuum. Vacuum was slowly released at about 2" Hg per 10 seconds. The knee was agitated to help force the fluid into the knee. Nitrogen was disconnected from the vacuum chamber when the gage read zero. The vacuum chamber was then unsealed and the knee was removed. The funnel was then removed from the knee. Care was taken so as to avoid tipping the knee during this process, which would have resulted in a release of the nitrogen head. The knee was closed by inserting the appropriate set screw with a torque of about 2.5 Nm applied to the screw.

Example 3

MR Fluid Settling Tests

Settling tests were conducted for thirteen different MR fluids. The rate of settling varied significantly and was found to be a function of iron particle size, the use of additives, and the viscosity of the fluids.

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Procedure for Settling Tests

MR fluids were formulated by adding carrier oil, with or without an additive, to a jar containing a weighed aliquot of carbonyl iron particles. For formulations containing an additive, the additive was blended with the carrier oil prior to mixing with the iron particles. The components were mixed by hand for several minutes and then the iron particles were dispersed using high frequency ultrasonic energy supplied by a Branson Digital Sonifier, Model 450. The fluids were subjected to 2–3 cycles of ultrasonic energy, each cycle having a duration of 1.5 minutes and power amplitude of approximately 50%. The fluids were then mixed again by hand to insure complete dispersion of the iron particles. Fluids were not degassed prior to starting the settling tests.

Approximately 8 mL of each of the well-mixed MR fluids were transferred to 10 mL graduated cylinders. The cylinders were closed by placing a ground glass stopper into the neck of each cylinder.

The initial volume of MR fluid was recorded and the volume of settled material was read and recorded at regular intervals for a period of twenty-one days. The fraction of settling was defined as the volume of carrier oil, which separated from the MR fluid and floated on the top of the MR fluid divided by the initial fluid volume.

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Example 4

Viscosity and Shear Rate Testing

Dynamic viscosity of three mixed carrier oils and six MR fluids made from the mixed carrier oils were measured as a function of shear rate. Viscosity measurements were performed at ambient temperature (22° C.) using a Rheometric Scientific (TA Instruments) RFS-II rheometer with a parallel plate sample cell. All samples were run in duplicate with approximately 1cc of sample. Five of the samples were rerun in duplicate on a second day due to incomplete mixing of the first samples.

Samples of mixed carrier fluids as well as MR fluids containing mixed carrier fluids were tested. The samples and viscosity measurements were as follows:

TABLE 2

Sample Name	Fluid Component %((v/v))	BASF HS particles %((v/v))	Viscosity (cP) at 100 s ⁻¹
A	100 ¹	0%	115
B	100 ²	0%	121
C	100 ³	0%	145
A-32	68 ¹	32%	681

TABLE 1

MR Fluids Tested					
MR Fluid	BASF Particle Type	Particle Loading (% (v/v) of total MR fluid)	Fluid Component (% (v/v) of total MR fluid)	Carrier Fluid (% (v/v) of total fluid component)	Dupont 157 FSL Additive (% (v/v) of total fluid component)
HQ81FS-28	HQ	28%	72%	95% Nye 8130	5%
HQ85FSL-28	HQ	28%	72%	95% Nye 8510	5%
HS67FSS-32	HS	32%	68%	63.7% Nye 8510; 31.3% Dupont GPL-103	5%
HS8510FSL-25	HS	25%	75%	95% Nye 8510	5%
HS8510FSL-28H	HS	28%	72%	95% Nye 8510	5%
HS85FS10-28	HS	28%	72%	90% Nye 8510	10%
HS85FS10-32	HS	32%	68%	90% Nye 8510	10%
HS85FS1-32	HS	32%	68%	99% Nye 8510	1%
HS85FSS-32	HS	32%	68%	95% Nye 8510	5%
OM8510-25	OM	25%	75%	100% Nye 8510	None
OM85-25-1	OM	25%	75%	99% Nye 8510	1%
OMP-25	OM	25%	75%	100% Nye 8130	None
OMPFA-25	OM	25%	75%	95% Nye 8130	5%

HQ Particle Size Ranges from about 0.5–2.0μ

HS Particle Size Ranges from about 1.5–3.5μ

OM Particle Size Ranges from about 2–9μ

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Results

In general the largest iron particles, OM grade, settled the fastest, especially when the viscosity of the fluid was reduced by including the Dupont 157 FSL additive in the formulation. However, the settling curves for the larger OM grade particles were initially steep and then leveled off after 10 to 14 days. Settling rates for the smaller iron particles, HS and HQ grade, were nearly linear over the twenty-one day test period.

Overall, MR fluids with lower settling rates demonstrated longer life and greater durability during subsequent bench testing in prosthetic knees. MR fluids with high settling rates produced hard caked settled iron particles. These fluids performed poorly in subsequent bench testing in prosthetic knees. MR fluids with low settling rates produce soft settled iron particles. These fluids generally performed well in subsequent prosthetic knee bench tests.

TABLE 2-continued

Sample Name	Fluid Component %((v/v))	BASF HS particles %((v/v))	Viscosity (cP) at 100 s ⁻¹
A-40	60 ¹	40%	1371
B-32	68 ²	32%	780
B-40	60 ²	40%	1651
C-32	68 ³	32%	917
C-40	60 ³	40%	1725

¹Fluid component consisting of 47.5% (v/v) Nye 8510 carrier fluid, 47.5% (v/v) Dupont GPL-103 carrier fluid; 5% (v/v) Dupont 157-FSL additive.

²Fluid component consisting of 63.7% (v/v) Nye 8510 carrier fluid, 31.3% (v/v) Dupont GPL-103 carrier fluid; 5% (v/v) Dupont 157-FSL additive.

³Fluid component consisting of 71.3% (v/v) Nye 8510 carrier fluid, 23.7% (v/v) Dupont GPL-103 carrier fluid; 5% (v/v) Dupont 157-FSL additive.

The dynamic viscosity curves which were measured at ambient temperature ($22^{\circ}\text{ C}.$), for the samples above are illustrated in FIGS. 3, 4, and 5. FIG. 3 represents the viscosity, η , versus shear rate cures for the three mixed carrier oils, A–C, and a sample of 100% ((v/v)) Nye 8510 oil. All of the mixed carrier had a lower viscosity than Nye 8510. The typical viscosity specification value for Nye 8510 oil is 65 cSt at $40^{\circ}\text{ C}.$, while the Dupont GPL-103 oil had a viscosity of 30 cSt at $40^{\circ}\text{ C}.$.

FIG. 4 represents the viscosity, η , versus shear rate curves for the three mixed carrier oil MR fluids containing 32% ((v/v)) of HS iron particles and a MR fluid which contains 100% Nye 8510 carrier oil and 32% ((v/v)) of HS iron. Viscosities of the mixed carrier oil MR fluids were less than the MR fluid containing only Nye 8510. This data demonstrated that it was possible to reduce the viscosity of a MR fluid by decreasing the viscosity of the carrier oil. Viscosity of the mixed carrier oil MR fluids was lowered in proportion to the amount of GPL-103, which was added to the carrier oil. The three mixed MR fluids exhibited Non-Newtonian behavior as the viscosity of these fluids changed continually with shear rate. The viscosity of these fluids was approximately six times that of the corresponding carrier oil at a shear rate of 100 s^{-1} .

FIG. 5 represents the viscosity, η , versus shear rate curves for the three mixed carrier oil MR fluids which contain 40% ((v/v)) of HS iron particles. The viscosities of these fluids were considerably larger than the viscosities of the MR fluids, which contained 32% ((v/v)) iron. Viscosity of the mixed carrier oil MR fluids containing 40% ((v/v)) iron was lower for the fluids with higher amounts of GPL-103, however, the viscosity curve for B-40 was higher than expected. This apparent anomaly was mostly likely caused by incomplete mixing of the viscous 40% ((v/v)) iron MR fluids prior to the viscosity measurements. The three MR fluids exhibited Non-Newtonian behavior as the viscosity of these fluids changed continually with shear rate. The viscosity of these fluids was approximately twelve times that of the corresponding carrier oil at a shear rate of 100 s^{-1} .

FIG. 6 summarizes the comparison of the viscosities of the three mixed carrier oils to Nye 8510 and the viscosities of the six mixed carrier oil MR fluids to that of a MR fluid containing only Nye 8510. Nye 8510 had a viscosity of 240

cP at 100 s^{-1} , while the three mixed carrier oils were well below 200 cP. The MR fluid which contained only Nye 8510 and 32% ((v/v)) iron, namely HS8510FSL-32, has a viscosity of 1,100 cP at 100 s^{-1} ¹, while the MR fluids containing mixed carrier oils and 32% ((v/v)) iron had viscosities of 680, 780 and 917 cP at 100 s^{-1} respectively, for the fluids which contain 50, 67 and 75% ((v/v)) of Nye 8510. Viscosity of the MR fluids containing 32% ((v/v)) iron increased with increasing amounts of the more viscous Nye 8510. Viscosity of the MR fluids containing 40% ((v/v)) iron also increased with increasing amounts of Nye 8510.

Results indicated that the three carrier oils exhibited near Newtonian behavior, while the six MR fluids all exhibited Non-Newtonian behavior. Viscosity of the MR fluids were shown to be a function of both iron loading and carrier oil viscosity. For MR fluids with 32% ((v/v)) iron loading the viscosity was approximately six times that of the corresponding carrier fluid. For MR fluids with 40% ((v/v)) iron loading the viscosity was about twelve times that of the corresponding carrier fluid. All of the MR fluids exhibited thinning i.e. a reduction in viscosity as a function of shear rate, especially at low shear rates.

Example 5

Prosthetic Knee Testing

Numerous prosthetics knees operating in shear mode were filled with various MR fluids and tested for fluid performance, low-end torque, cavity pressure, and overall durability of the knee. Testing was performed to simulate use of the knee by an amputee. The knees were tested using a custom made test bench in conjunction with LabVIEW data acquisition software (National Instruments). The test machine rotated the prosthetic knees at a rate of 32,000 cycles per day in order to simulate accelerated knee usage. Prosthetic knees of varying configurations were used with numerous MR fluid compositions. The goal was to achieve three million cycles without knee failure. Due to limited equipment, testing of several knees was cut short in order to test other fluids and/or knee configurations. The following table illustrates some of the testing.

TABLE 3

Fluid Name	Fluid Composition*	Fluid Performance	Duration of Test
OMPF-25	75% fluid component ¹ ; 25% BASF OM particles.	Unit ran smoothly, off state torque at end of test was 0.7 N-m. Applied field torque at end was 49 N-m.	2.2 million cycles
HS8510FSL-28	72% fluid component ² ; 28% BASF HS particles.	Unit ran well, off state torque at end of test was 0.8 N-m. Applied field torque at end was 33 N-m.	1.2 million cycles
HQ8510FSL-28	72% fluid component ² ; 28% BASF HQ particles.	Unit ran well, off state torque at 2.2 million cycles was 0.8 N-m. Applied field torque at 2.2 million cycles was 43 N-m.	2.4 million cycles
HS8510FSL-25	75% fluid component ² ; 25% BASF HS particles.	Unit ran well, off state torque at 800,000 cycles was 0.6 N-m. Applied field torque at 800,000 cycles was 40 N-m.	862,000 cycles
HS67FSL-32	68% fluid component ³ ; 32% BASF HS particles.	Two units, A1 and A2, produced improved initial applied field torque 47–50 N-m. Initial off state torque was in the range of 0.6–0.8 N-m. A1 at 433K was at 44 N-m. A2 at 290K was at 47 N-m.	A1 - 433K cycles. A2 - 290K cycles.

*All percentages are % (v/v).

¹Fluid component consisting of 100% Nye 8130 carrier fluid.

²Fluid component consisting of 95% Nye 8510 carrier fluid and 5% Dupont 157-FSL additive.

³Fluid component consisting of 63.7% Nye 8510 carrier fluid, 31.3% Dupont GPL-103 carrier fluid, and 5% Dupont 157-FSL additive.

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The various methods and techniques described above provide a number of ways to carry out the invention. Of course, it is to be understood that not necessarily all objectives or advantages described may be achieved in accordance with any particular embodiment described herein. Thus, for example, those skilled in the art will recognize that the composition may be made and the methods may be performed in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other objectives or advantages as may be taught or suggested herein.

Furthermore, the skilled artisan will recognize the interchangeability of various features from different embodiments. Similarly, the various features and steps discussed above, as well as other known equivalents for each such feature or step, can be mixed and matched by one of ordinary skill in this art to perform methods in accordance with principles described herein.

Although the invention has been disclosed in the context of certain embodiments and examples, it will be understood by those skilled in the art that the invention extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses and obvious modifications and equivalents thereof. Accordingly, the invention is not intended to be limited by the specific disclosures of preferred embodiments herein, but instead by reference to claims attached hereto.

What is claimed is:

1. A magnetorheological fluid comprising polarizable particles and a fluid component,

wherein the fluid component comprises a carrier fluid and an additive;

wherein the additive comprises a parafluoropropene and oxygen polymerized amide derivative.

2. The magnetorheological fluid of claim 1 wherein the polarizable particles comprise iron particles.

3. The magnetorheological fluid of claim 2 wherein the iron particles range in size from about 0.2 to about 50 microns.

4. The magnetorheological fluid of claim 3 wherein the iron particles range in size from about 0.4 to about 10 microns.

5. The magnetorheological fluid of claim 4 wherein the iron particles range in size from about 0.5 to about 9 microns.

6. The magnetorheological fluid of claim 2 wherein the iron particles comprise about 1 to about 60% (v/v) of the total magnetorheological fluid volume.

7. The magnetorheological fluid of claim 6 wherein the iron particles comprise about 10 to about 50% (v/v) of the total magnetorheological fluid volume.

8. The magnetorheological fluid of claim 7 wherein the iron particles comprise more preferably from about 20 to about 40% (v/v) of the total magnetorheological fluid volume.

9. The magnetorheological fluid of claim 1 wherein the carrier fluid is selected from the group consisting of silicone, hydrocarbon, esters, ethers, fluorinated esters, fluorinated ethers, mineral oil, unsaturated hydrocarbons, and combinations thereof.

10. The magnetorheological fluid of claim 9 wherein the carrier fluid comprises one or more perfluorinated polyethers.

11. The magnetorheological fluid of claim 1 wherein the additive comprises from about 0.1 to about 20% (v/v) of the fluid component.

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12. The magnetorheological fluid of claim 11 wherein the additive comprises from about 1 to about 15% (v/v) of the fluid component.

13. The magnetorheological fluid of claim 12 wherein the additive comprises from about 2 to about 10% (v/v) of the fluid component.

14. The magnetorheological fluid of claim 1 comprising: about 28% (v/v) iron particles; and about 72% (v/v) fluid component;
wherein said fluid component comprises about 5% (v/v) additive and about 95% (v/v) perfluorinated polyether carrier fluid.

15. The magnetorheological fluid of claim 1 wherein the magnetorheological fluid is operable over a temperature range from about 10 to about 115° F.

16. The magnetorheological fluid of claim 1 wherein the carrier fluid has a viscosity at 104° F. of about 10 to about 100 cSt.

17. The magnetorheological fluid of claim 16 wherein the carrier fluid has a viscosity at 104° F. of about 30 to about 80 cSt.

18. The magnetorheological fluid of claim 17 wherein the carrier fluid has a viscosity at 104° F. of about 50 to about 70 cSt.

19. The magnetorheological fluid of claim 1 wherein the carrier fluid has a viscosity index from about 100 to about 340 based on kinematic viscosity at 104 and 212° F.

20. The magnetorheological fluid of claim 19 wherein the carrier fluid has a viscosity index from about 120 to about 320 based on kinematic viscosity at 104 and 212° F.

21. The magnetorheological fluid of claim 1 wherein the carrier fluid has a pour point ranging from about -70° C. to about -40° C.

22. The magnetorheological fluid of claim 1 wherein the carrier fluid has a percent volatility at 121° C. ranging from about 0.01% to about 20%.

23. A magnetorheological fluid consisting of polarizable particles and a fluid component,

wherein the fluid component consists essentially of a carrier fluid and an additive;

wherein the carrier fluid consists essentially of one of the group consisting of silicone, hydrocarbon, esters, ethers, fluorinated esters, fluorinated ethers, mineral oil, and unsaturated hydrocarbons; and

wherein the additive consists essentially of a functionalized perfluorinated polyether fluid.

24. A magnetorheological fluid comprising polarizable particles and a fluid component

wherein the fluid component consists essentially of a carrier fluid and an additive;

wherein the carrier fluid consists essentially of one of the group consisting of silicone, hydrocarbon, esters, ethers, fluorinated esters, fluorinated ethers, mineral oil, and unsaturated hydrocarbons; and

wherein the additive consists essentially of a functionalized perfluorinated polyether fluid

wherein the functionalized perfluorinated polyether fluid additive comprises a poly(hexafluoropropylene epoxide) with a carboxylic acid located on the terminal fluoromethylene group.

25. The magnetorheological fluid of claim 24 wherein the polarizable particles comprise iron particles.

26. The magnetorheological fluid of claim 25 wherein the iron particles range in size from about 0.2 to about 50 microns.

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27. The magnetorheological fluid of claim **25** wherein the iron particles range in size from about 0.4 to about 10 microns.

28. The magnetorheological fluid of claim **25** wherein the iron particles range in size from about 0.5 to about 9 microns.

29. The magnetorheological fluid of claim **25** wherein the iron particles comprise about 1 to about 60% (v/v) of the total magnetorheological fluid volume.

30. The magnetorheological fluid of claim **29** wherein the iron particles comprise about 10 to about 50% (v/v) of the total magnetorheological fluid volume.

31. The magnetorheological fluid of claim **30** wherein the iron particles comprise more preferably from about 20 to about 40% (v/v) of the total magnetorheological fluid volume.

32. The magnetorheological fluid of claim **24** wherein the carrier fluid comprises one or more perfluorinated polyethers.

33. The magnetorheological fluid of claim **24** wherein the functionalized perfluorinated polyether fluid additive comprises one or more functional groups selected from the group consisting of silane, phosphate, hydroxyl, carboxylic acid, amine, dihydroxyl, ethoxy ether, isocyanate, aromatic, ester and alcohol functions.

34. The magnetorheological fluid of claim **24** wherein the additive comprises from about 0.1 to about 20% (v/v) of the fluid component.

35. The magnetorheological fluid of claim **34** wherein the additive comprises from about 1 to about 15% (v/v) of the fluid component.

36. The magnetorheological fluid of claim **35** wherein the additive comprises from about 2 to about 10% (v/v) of the fluid component.

37. A magnetorheological fluid comprising:
about 32% (v/v) polarizable iron particles; and
about 68% (v/v) fluid component;
wherein said fluid component consists essentially of about 5% (v/v) additive and about 95% (v/v) perfluorinated polyether carrier fluid;
wherein said additive consists essentially of poly(hexafluoropropylene epoxide) with a carboxylic acid located on the terminal fluoromethylene group.

38. The magnetorheological fluid of claim **37** wherein the iron particles range in size from about 0.2 to about 50 microns.

39. The magnetorheological fluid of claim **37** wherein the iron particles range in size from about 0.4 to about 10 microns.

40. The magnetorheological fluid of claim **37** wherein the iron particles range in size from about 0.5 to about 9 microns.

41. A magnetorheological fluid comprising polarizable particles and a fluid component,

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wherein the fluid component comprises a carrier fluid and an additive;

wherein the additive comprises poly(hexafluoropropylene epoxide) with a carboxylic acid located on the terminal fluoromethylene group.

42. The magnetorheological fluid of claim **41** wherein the polarizable particles comprise iron particles.

43. The magnetorheological fluid of claim **42** wherein the iron particles range in size from about 0.2 to about 50 microns.

44. The magnetorheological fluid of claim **42** wherein the iron particles range in size from about 0.4 to about 10 microns.

45. The magnetorheological fluid of claim **42** wherein the iron particles range in size from about 0.5 to about 9 microns.

46. The magnetorheological fluid of claim **42** wherein the iron particles comprise about 1 to about 60% (v/v) of the total magnetorheological fluid volume.

47. The magnetorheological fluid of claim **46** wherein the iron particles comprise about 10 to about 50% (v/v) of the total magnetorheological fluid volume.

48. The magnetorheological fluid of claim **47** wherein the iron particles comprise more preferably from about 20 to about 40% (v/v) of the total magnetorheological fluid volume.

49. The magnetorheological fluid of claim **41** wherein the carrier fluid is selected from the group consisting of silicone, hydrocarbon, esters, ethers, fluorinated esters, fluorinated ethers, mineral oil, unsaturated hydrocarbons, and combinations thereof.

50. The magnetorheological fluid of claim **49** wherein the carrier fluid comprises one or more perfluorinated polyethers.

51. The magnetorheological fluid of claim **41** wherein the additive comprises from about 0.1 to about 20% (v/v) of the fluid component.

52. The magnetorheological fluid of claim **51** wherein the additive comprises from about 1 to about 15% (v/v) of the fluid component.

53. The magnetorheological fluid of claim **52** wherein the additive comprises from about 2 to about 10% (v/v) of the fluid component.

54. The magnetorheological fluid of claim **41** comprising:
about 32% (v/v) iron particles; and
about 68% (v/v) fluid component;
wherein said fluid component comprises about 5% (v/v) additive and about 95% (v/v) perfluorinated polyether carrier fluid.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,101,487 B2
APPLICATION NO. : 10/722313
DATED : September 5, 2006
INVENTOR(S) : Henry Hsu et al.

Page 1 of 2

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In column 2, line 19, **delete** the word “parafluoropropene” and **insert** the word --perfluoropropene-- in its place.

In column 2, line 51, **delete** the word “parafluoropropene” and **insert** the word --perfluoropropene- in its place.

In column 2, line 56, **delete** the word “parafluoropropene” and **insert** the word --perfluoropropene-- in its place.

In column 3, line 66, **delete** the word “parafluoropropene” and **insert** the word --perfluoropropene-- in its place.

In column 5, line 1, **delete** the word “parafluoropropene” and **insert** the word --perfluoropropene-- in its place.

In column 5, line 6, **delete** the word “parafluoropropene” and **insert** the word --perfluoropropene-- in its place.

In column 7, line 66, **delete** the word “parafluoropropene” and **insert** the word --perfluoropropene-- in its place.

In column 8, line 1, **delete** the word “parafluoropropene” and **insert** the word --perfluoropropene-- in its place.

In column 8, line 46, **delete** the word “parafluoropropene” and **insert** the word --perfluoropropene-- in its place.

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Page 2 of 2

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In column 8, line 51, **delete** the word “parafluoropropene” and **insert** the word --perfluoropropene-- in its place.

In column 11, line 12, **delete** the word “parafluoropropene” and **insert** the word --perfluoropropene-- in its place.

In column 11, line 14, **delete** the word “parafluoropropene” and **insert** the word --perfluoropropene-- in its place.

In column 21, line 34, Claim 1, **delete** the word “parafluoropropene” and **insert** the word --perfluoropropene-- in its place.

Signed and Sealed this

Twentieth Day of March, 2007



JON W. DUDAS
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,101,487 B2
APPLICATION NO. : 10/722313
DATED : September 5, 2006
INVENTOR(S) : Henry Hsu et al.

Page 1 of 3

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

At column 7, line 56, please delete “dihydioxyl” and insert -- dihydroxyl --, therefor.

At column 7, line 58, before “More” please insert -- In some embodiments, functionalized perfluorinated polyether fluid additive comprises one or more functional groups selected from the group consisting of silane, phosphate, hydroxyl, carboxylic acid, amine, dihydroxyl, ethoxy ether, isocyanate, aromatic, ester and alcohol functions. --

At column 10, line 53 through column 11, line 17, please delete the paragraph beginning “Other ingredients can be optionally added . . .” and ending “available from Solvay Solexis (Thorofare, N.J., USA),” and insert the following paragraph therefor:

-- In another embodiment, the MR fluid used in combination with a prosthetic knee may optionally comprise an additive. Suitable additives include, but are not limited to, functionalized carrier fluids as well as fluoropolymers. In one embodiment, the iron particles comprise from about 1 to about 60 % (v/v) of the total MR fluid volume, preferably from about 10 to about 50% (v/v), more preferably from about 20 to about 40% (v/v), but also including about 5, 15, 25, 30, 35, 45, and 55 % (v/v), and ranges encompassing these amounts. In one embodiment, the additive comprises from about 0.1 to about 20 % (v/v) of the carrier fluid, preferably from about 1 to about 15 % (v/v), more preferably from about 2 to about 10 % (v/v), but also including 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 9.5, 11, 12, 13, 14, 16, 17, 18, and 19 % (v/v). For

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Page 2 of 3

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

example, in one embodiment a preferred MR fluid used in combination with a prosthetic knee in shear mode comprises about 32% (v/v) particles and about 68% (v/v) fluid component wherein said fluid component comprises about 5% (v/v) a perfluoropropene and oxygen polymerized amide derivative additive and about 95% (v/v) perfluorinated polyether carrier fluid. In another embodiment a preferred MR fluid used in combination with a prosthetic knee in shear mode comprises about 28% (v/v) particles and about 72% (v/v) fluid component wherein, said fluid component comprises about 5% (v/v) a perfluoropropene and oxygen polymerized amide derivative additive and about 95% (v/v) perfluorinated polyether carrier fluid. In another embodiment, a preferred MR fluid used in combination with a prosthetic knee in shear mode comprises about 32% (v/v) particles, and about 68% (v/v) fluid component wherein said fluid component comprises about 5% (v/v) poly(hexafluoropropylene epoxide) with a carboxylic acid located on the terminal fluoromethylene group additive and about 95% (v/v) PFPE oil carrier fluid. In another embodiment, a preferred MR fluid used in combination with a prosthetic knee in shear mode comprises about 28% (v/v) particles, and about 72 % (v/v) fluid component wherein said fluid component composes about 5% (v/v) poly(hexafluoropropylene epoxide) with a carboxylic acid located on the terminal fluoromethylene group additive and

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,101,487 B2
APPLICATION NO. : 10/722313
DATED : September 5, 2006
INVENTOR(S) : Henry Hsu et al.

Page 3 of 3

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

about 95% (v/v) PFPE oil carrier fluid. In embodiments containing PFPE oil,
the PFPE oil may comprise substantially all one PFPE oil or a mixture of one or
more PFPE oils. --

Signed and Sealed this

Twenty-sixth Day of August, 2008



JON W. DUDAS
Director of the United States Patent and Trademark Office



US007455696B2

(12) **United States Patent**
Bisbee, III et al.

(10) **Patent No.:** US 7,455,696 B2
(45) **Date of Patent:** Nov. 25, 2008

(54) **DYNAMIC SEALS FOR A PROSTHETIC KNEE**

(75) Inventors: **Charles R. Bisbee, III**, Mission Viejo, CA (US); **Henry H. Hsu**, Aliso Viejo, CA (US)

(73) Assignee: **Össur hf**, Reykjavik (IS)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 162 days.

(21) Appl. No.: **11/124,621**

(22) Filed: **May 6, 2005**

(65) **Prior Publication Data**

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Related U.S. Application Data

(60) Provisional application No. 60/624,986, filed on Nov. 3, 2004, provisional application No. 60/569,512, filed on May 7, 2004.

(51) **Int. Cl.**

A61F 2/64 (2006.01)
A61F 2/68 (2006.01)

(52) **U.S. Cl.** **623/45**

(58) **Field of Classification Search** **623/39-45**
See application file for complete search history.

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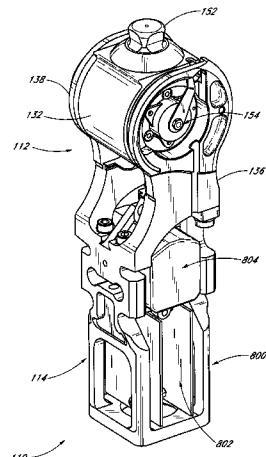
Primary Examiner—Bruce E. Snow

(74) Attorney, Agent, or Firm—Knobbe, Martens, Olson & Bear, LLP

(57) **ABSTRACT**

The invention in some embodiments relates to a dynamic seal for a prosthetic knee. The dynamic seal in one embodiment is utilized to seal a magnetorheological fluid comprising a liquid and solid particles within a chamber of the knee. The dynamic seal embodiments are specially configured with a pre-loaded tensioned garter spring which has a coil spacing that is at least as large as the size of the particles or maximum size of the particles in the magnetorheological fluid. Desirably, this allows the magnetorheological fluid particles to flow in and out of the dynamic seal without clogging the seal and advantageously provides for a reliable dynamic seal.

17 Claims, 103 Drawing Sheets



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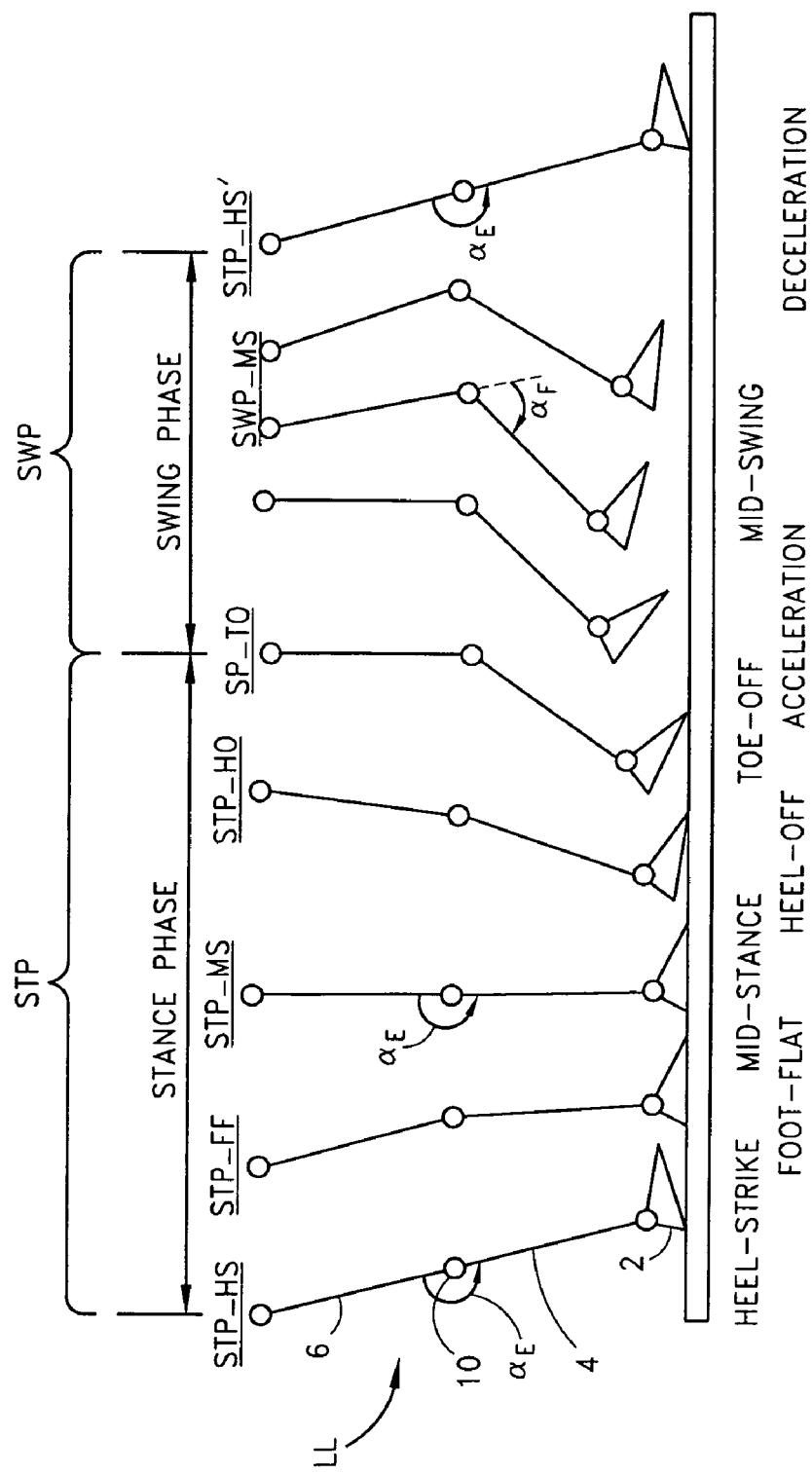


FIG. 1

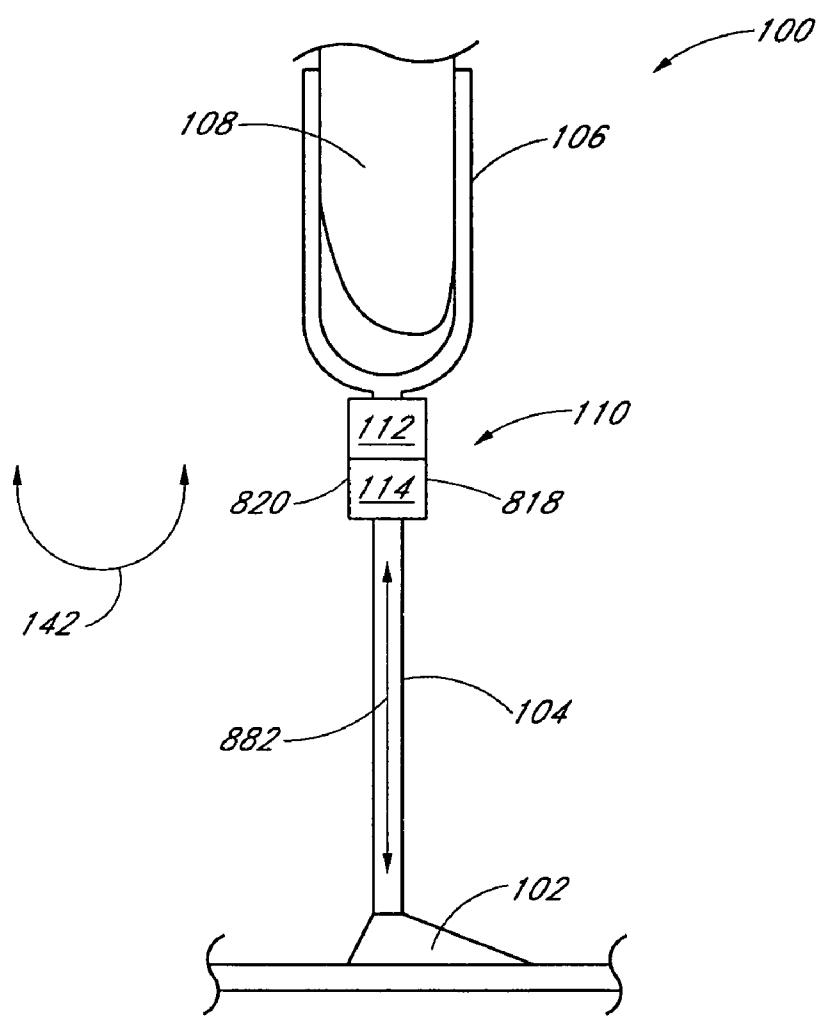


FIG. 2

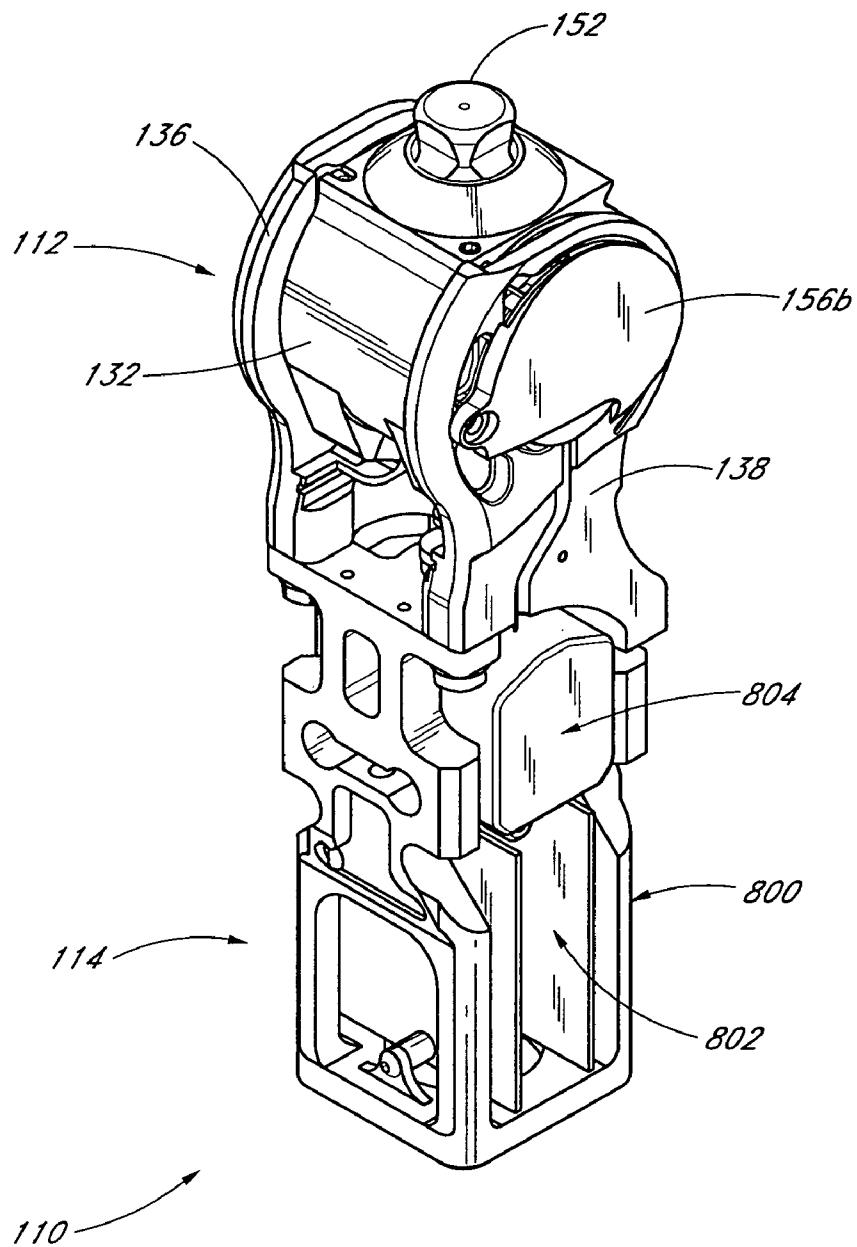


FIG. 3A

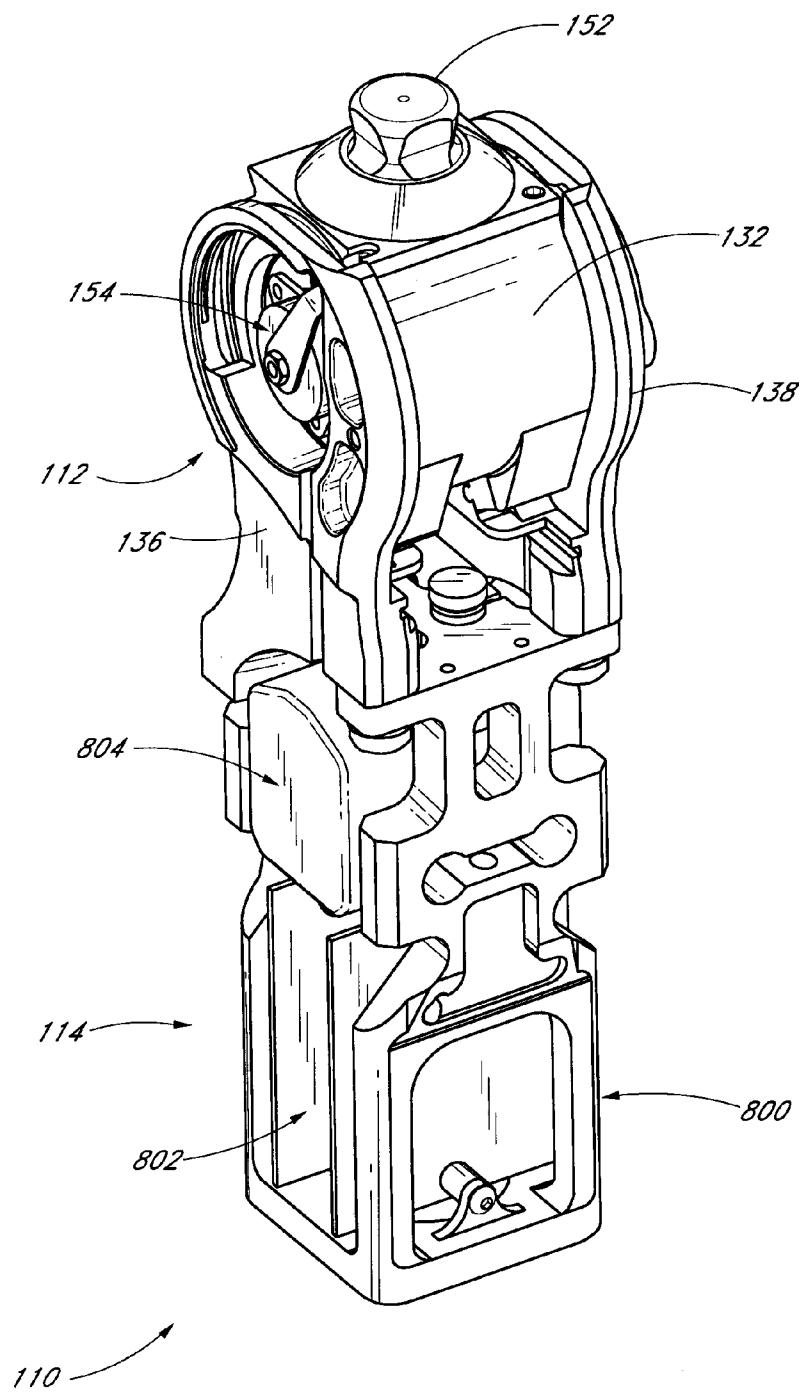


FIG. 3B

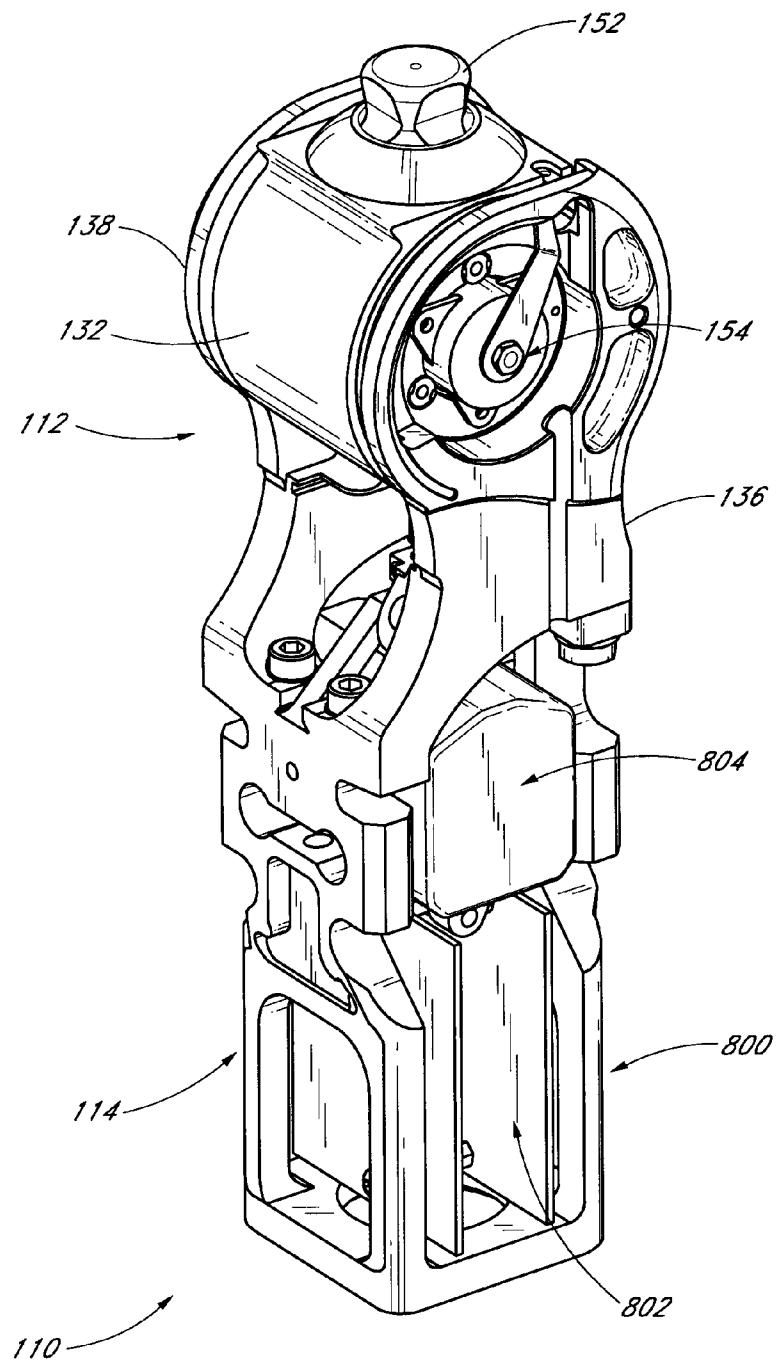


FIG. 3C

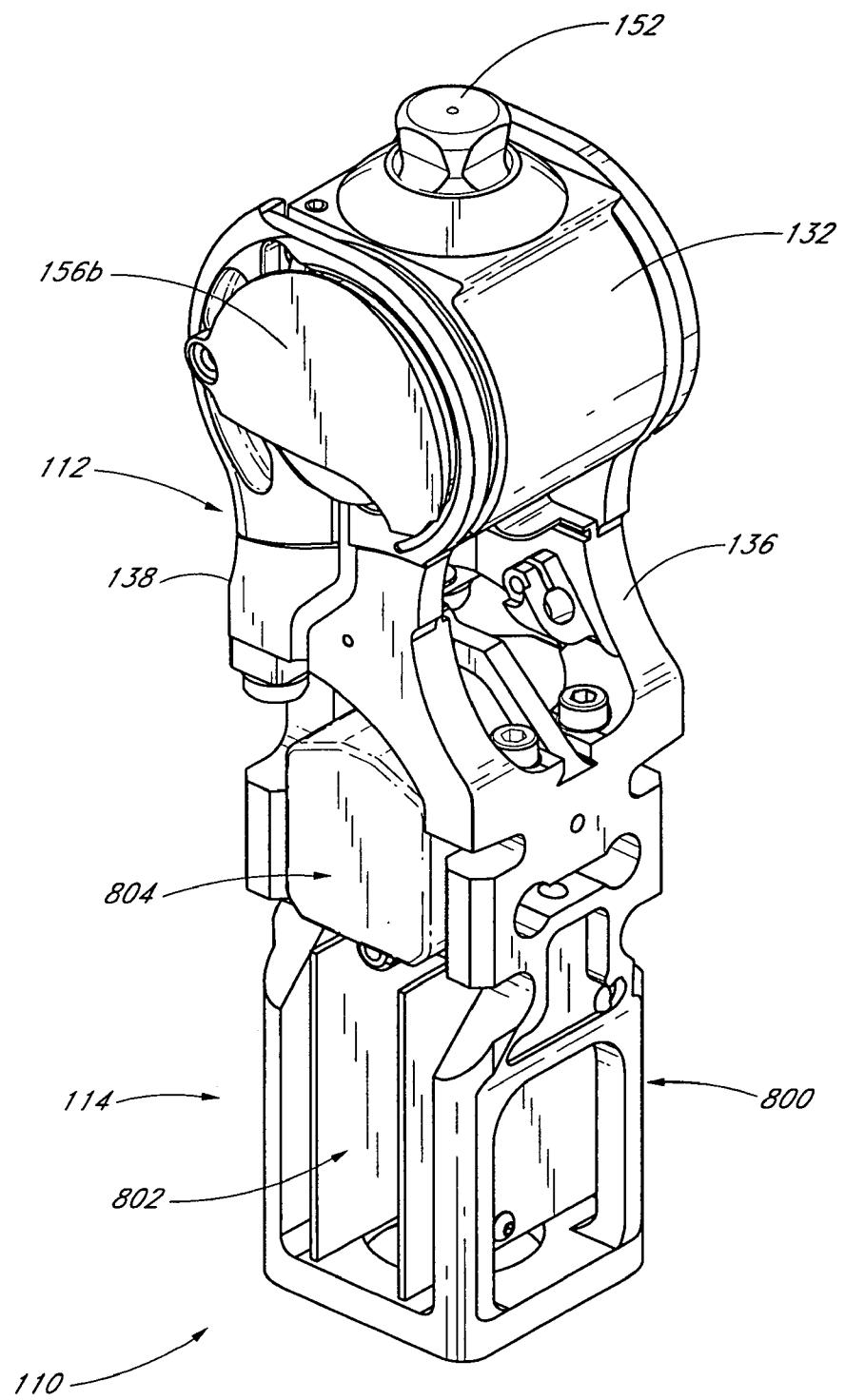


FIG. 3D

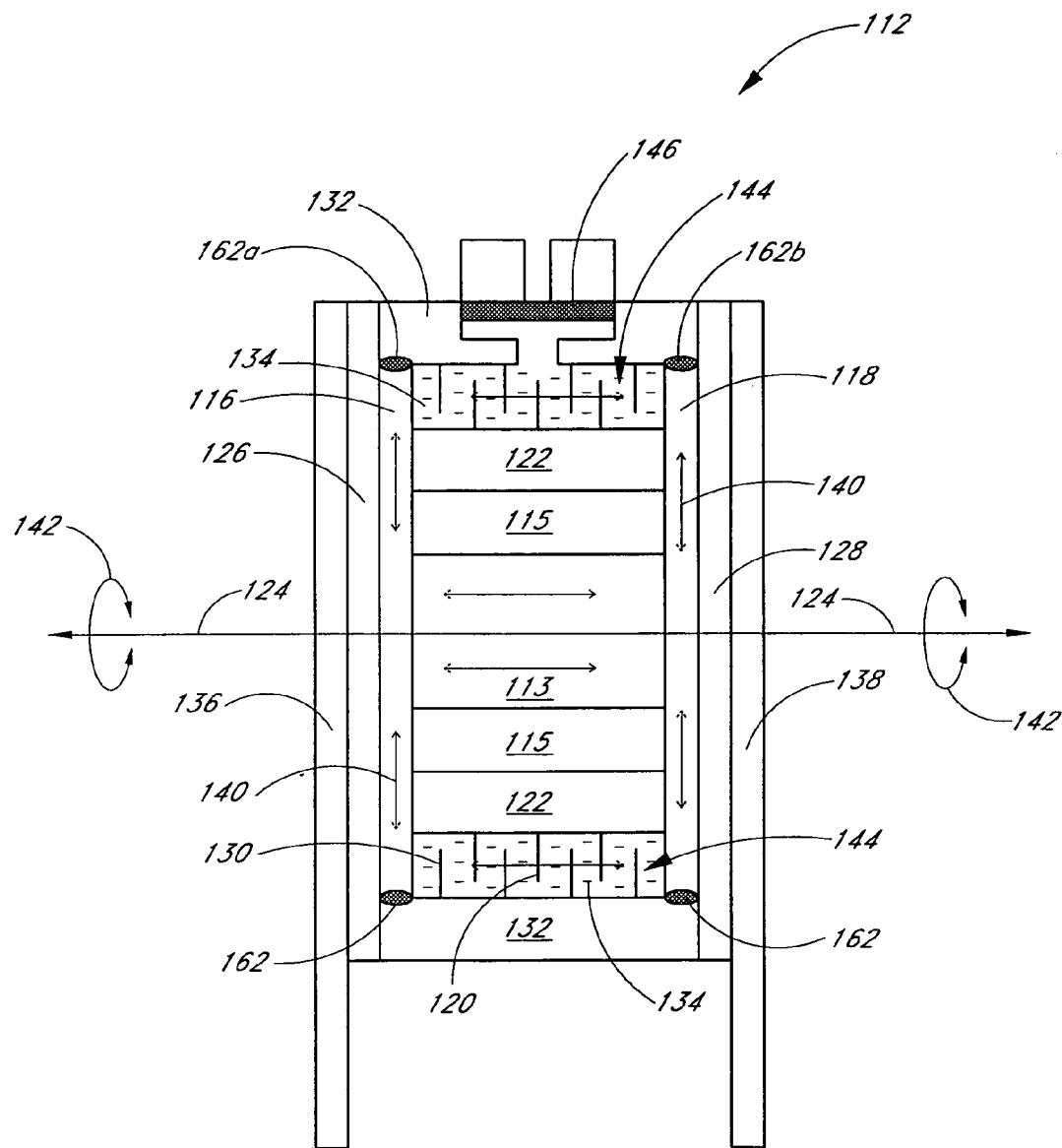


FIG. 4

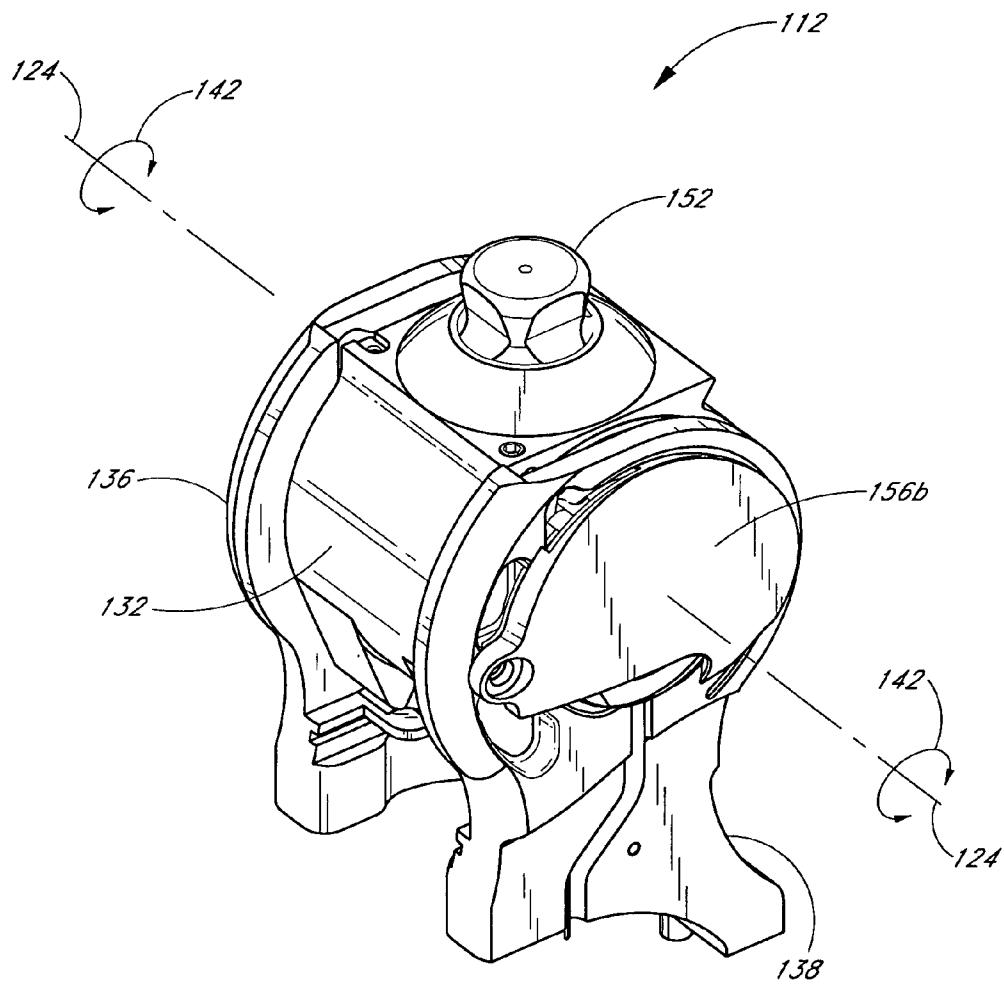


FIG. 5A

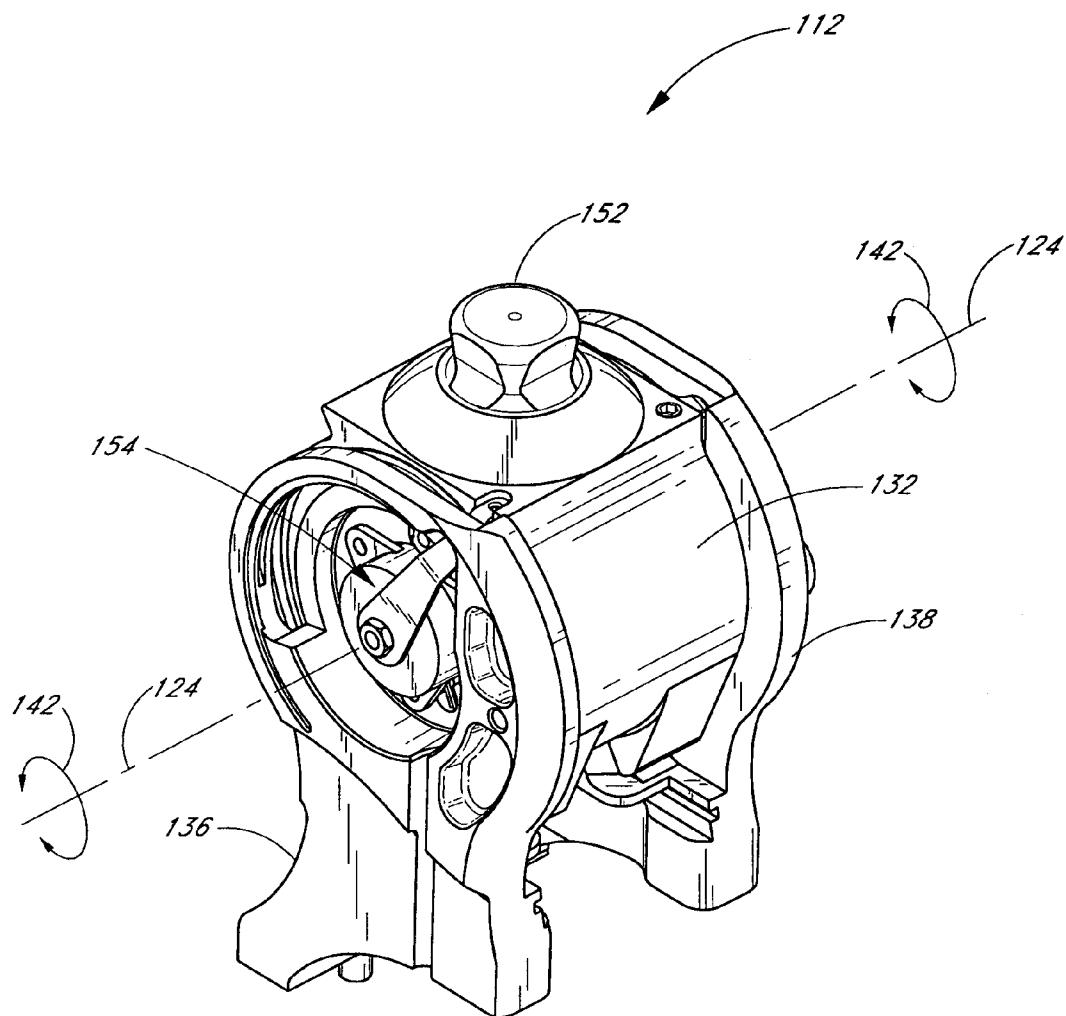


FIG. 5B

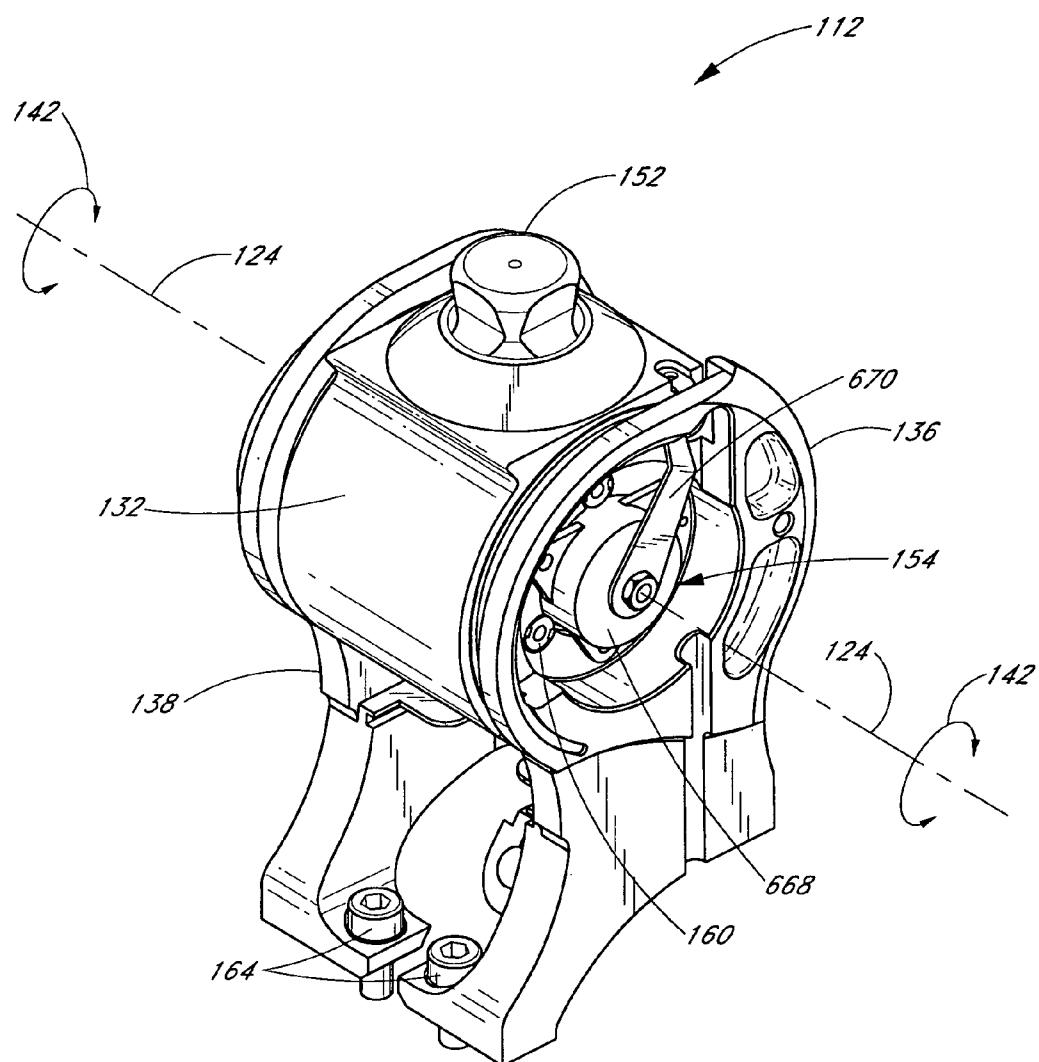


FIG. 5C

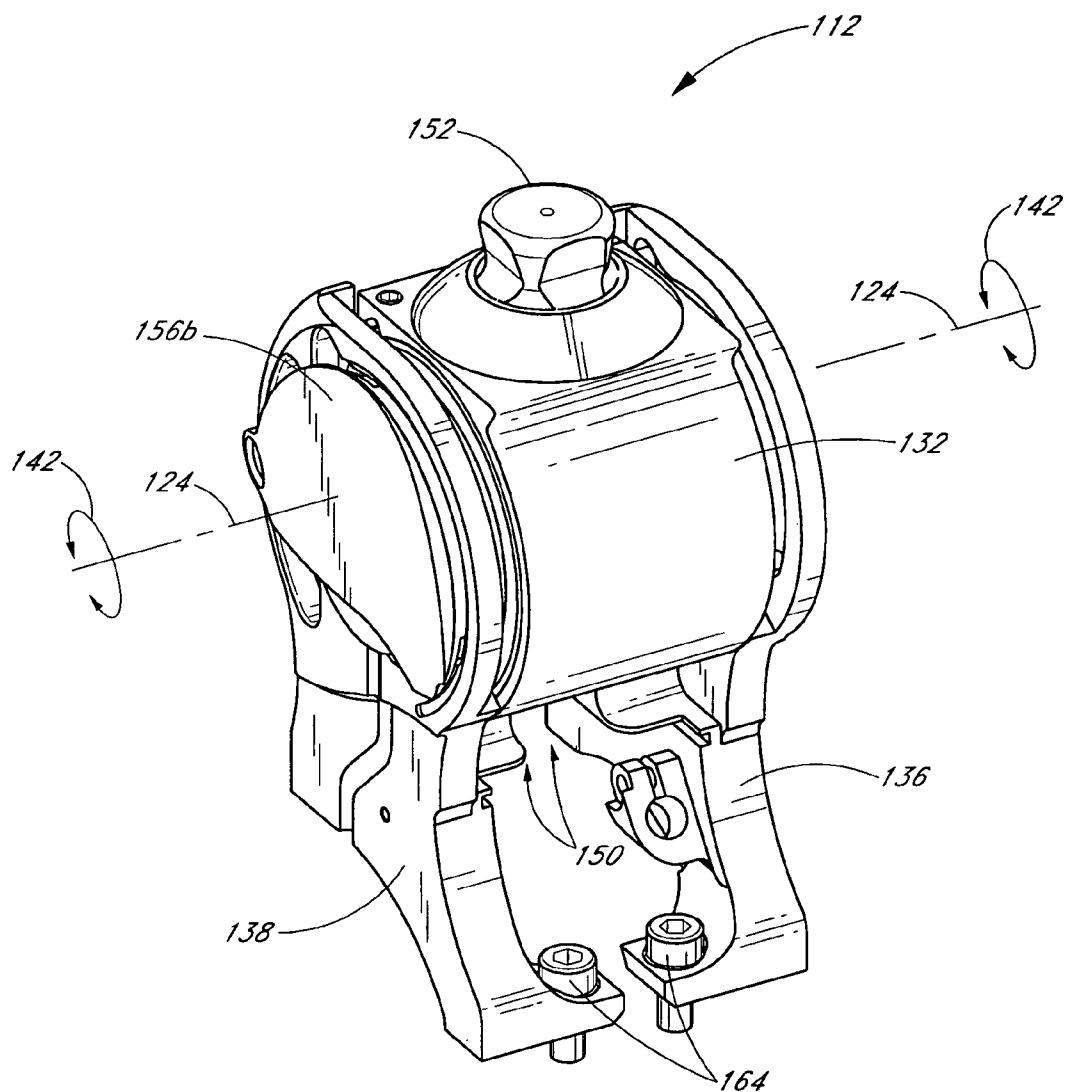


FIG. 5D

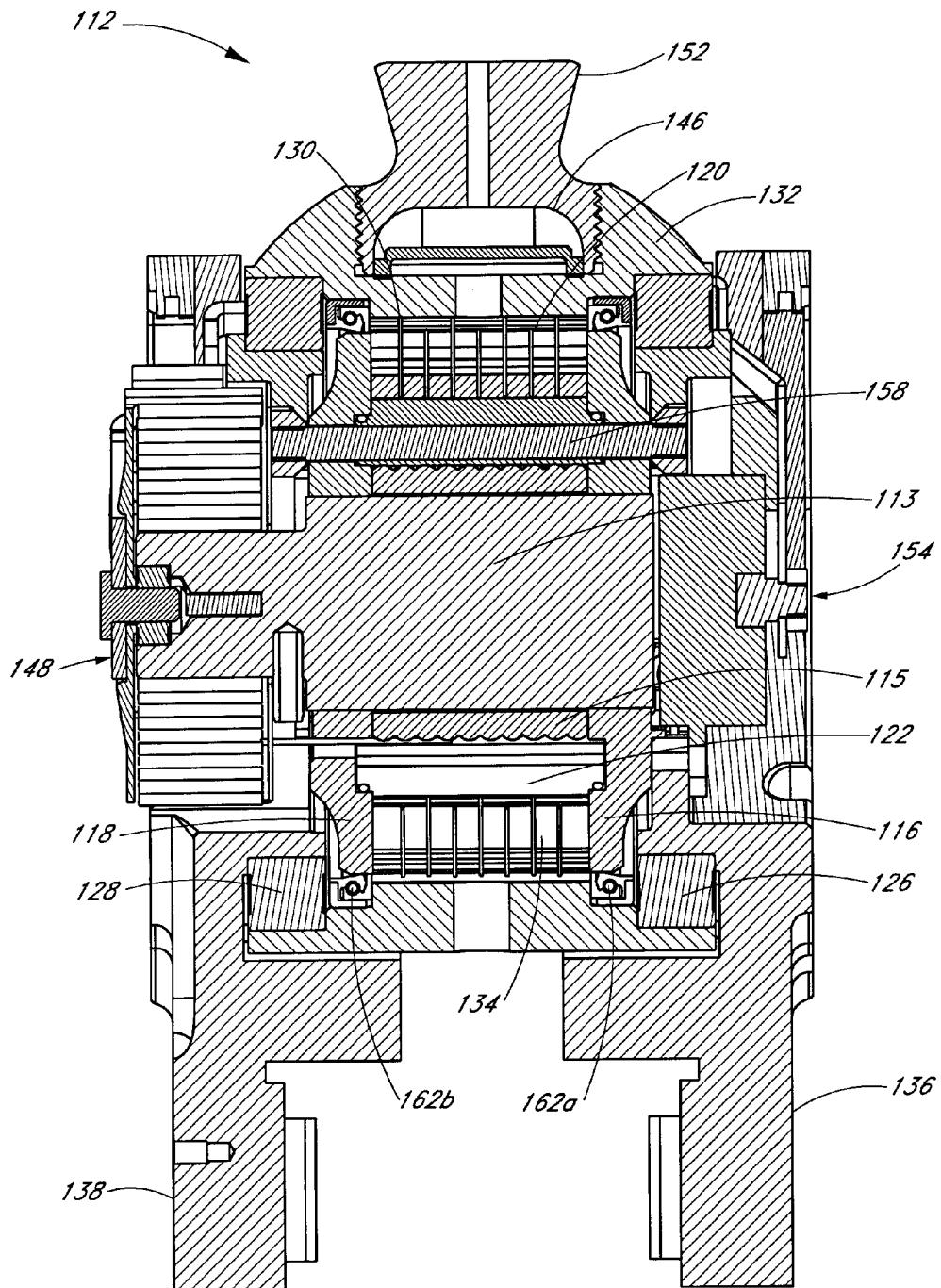


FIG. 5E

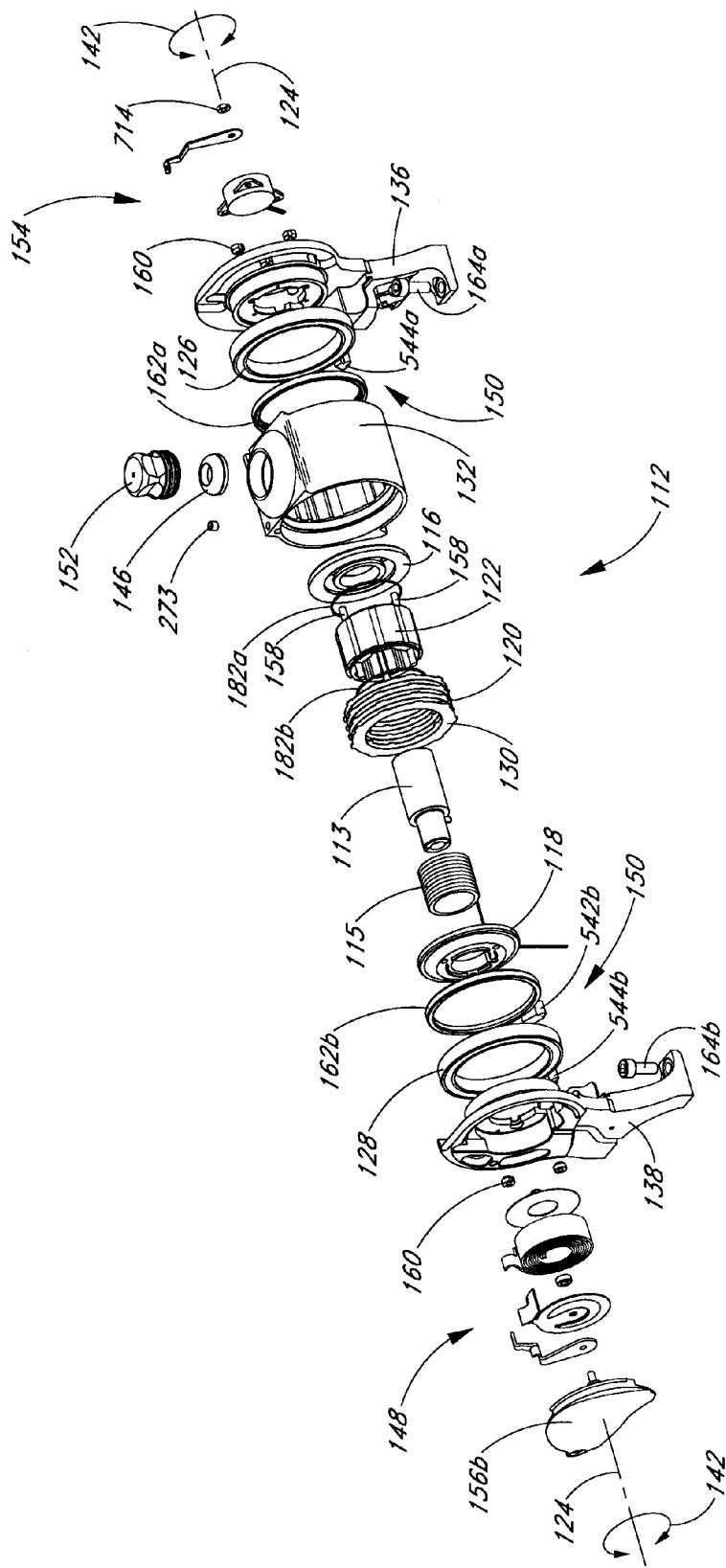


FIG. 6

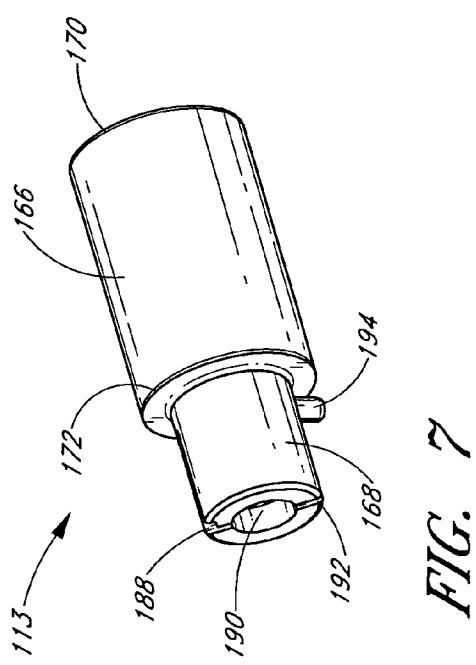


FIG. 7

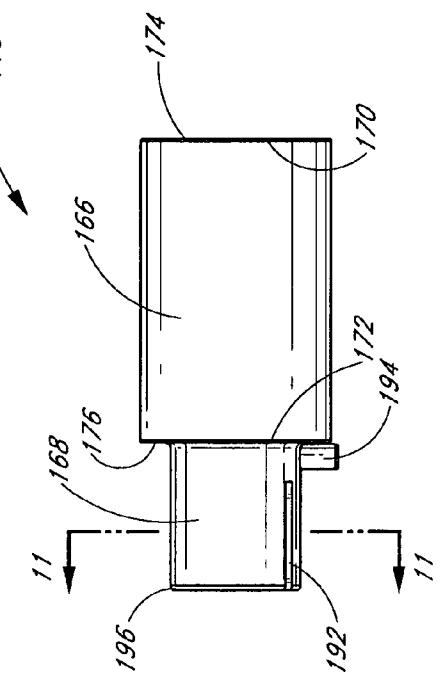


FIG. 8

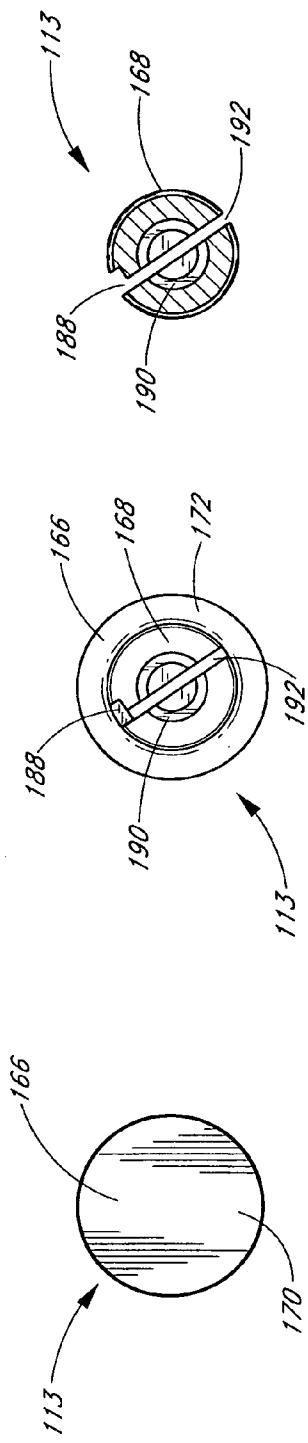


FIG. 9

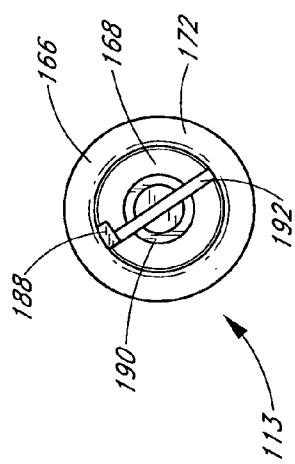


FIG. 10

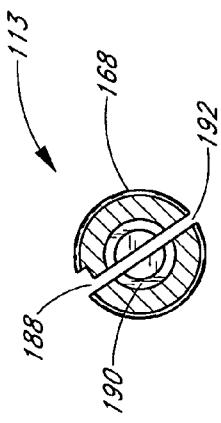


FIG. 11

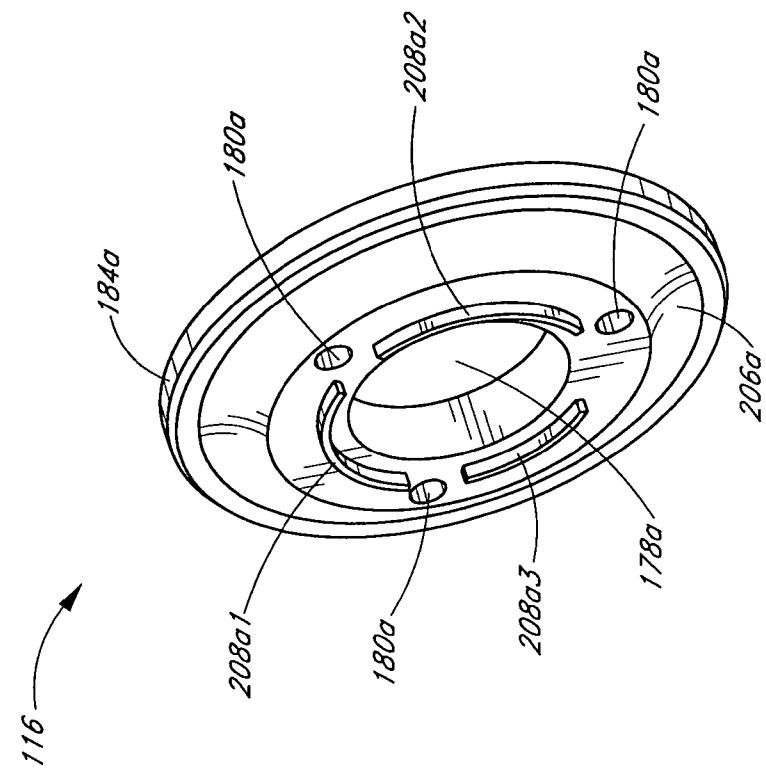


FIG. 13

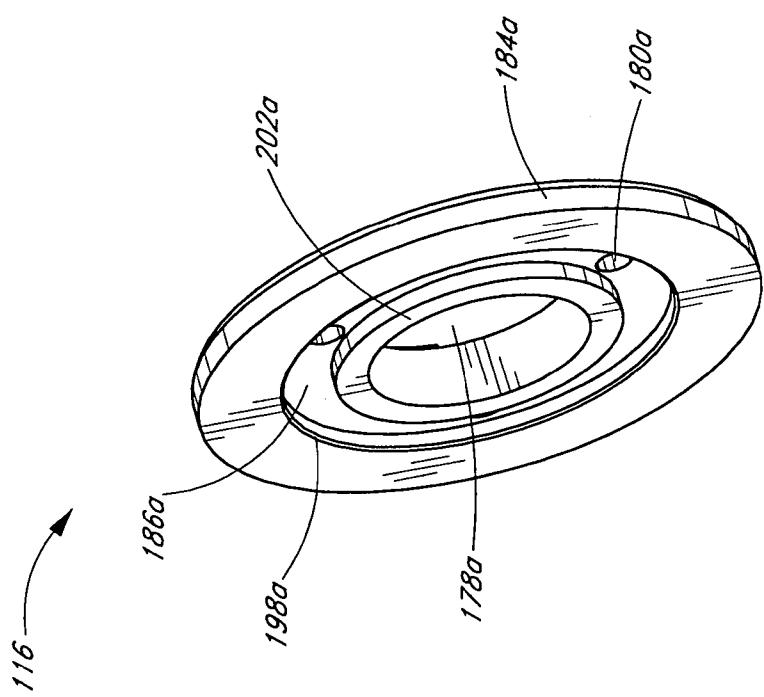


FIG. 12

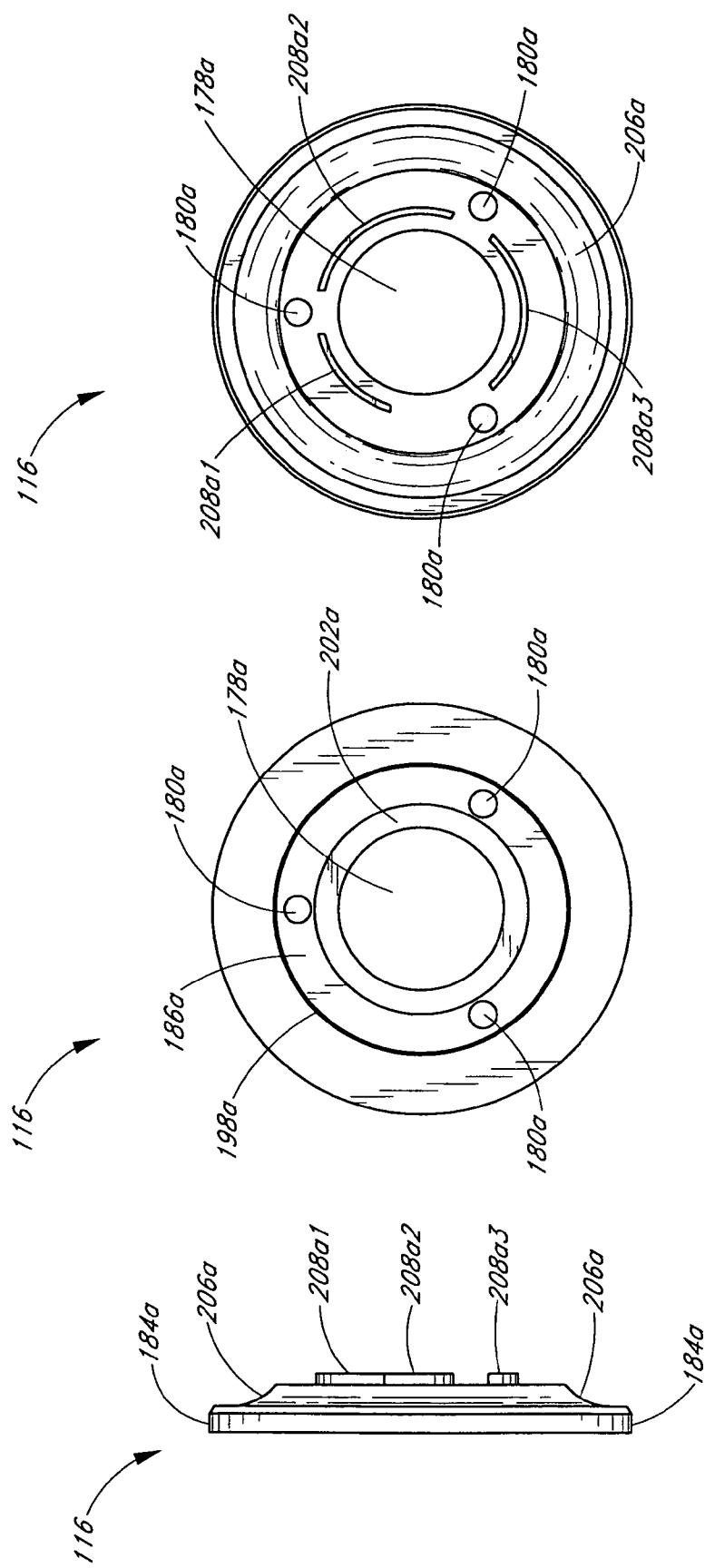


FIG. 14

FIG. 15

FIG. 16

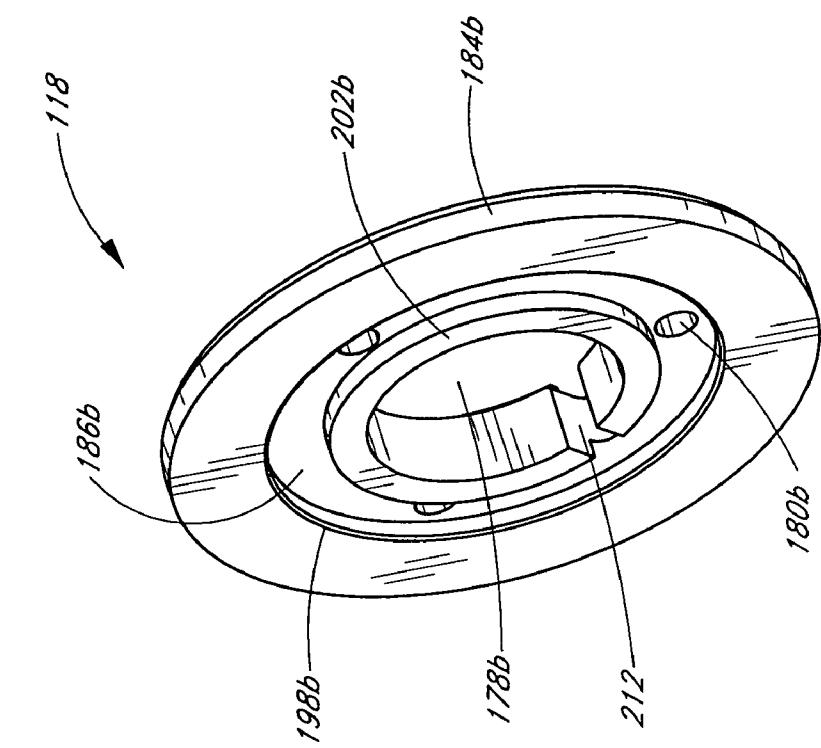


FIG. 18

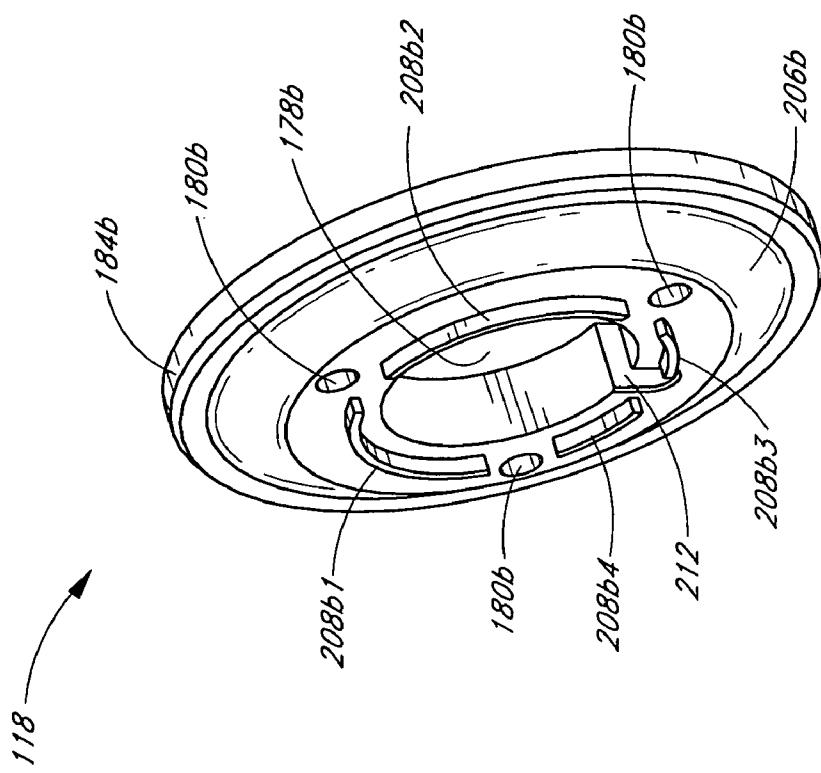


FIG. 17

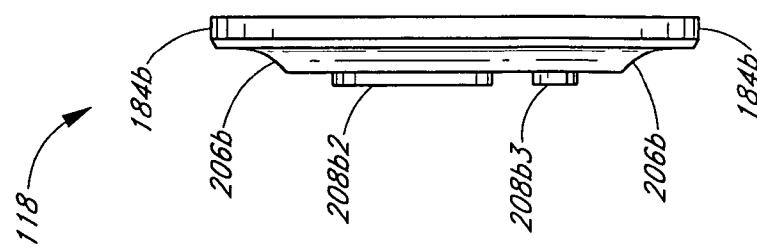
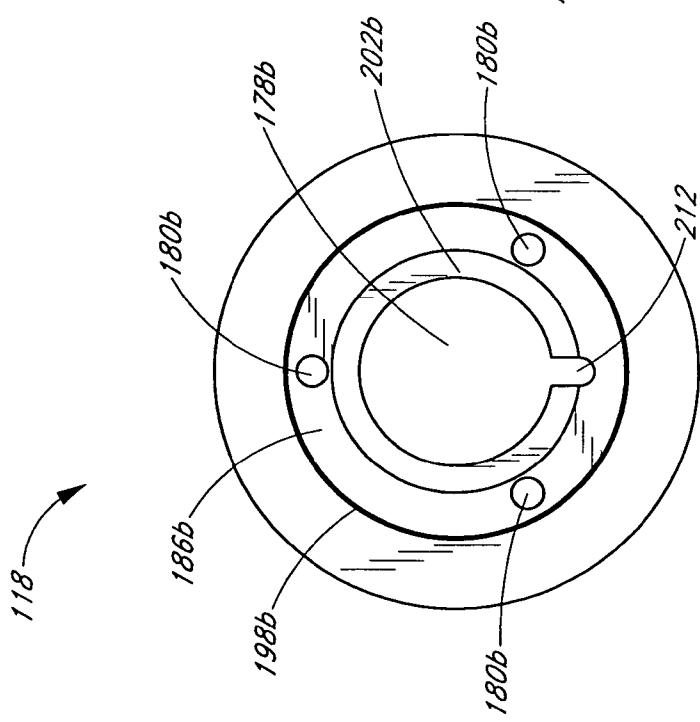
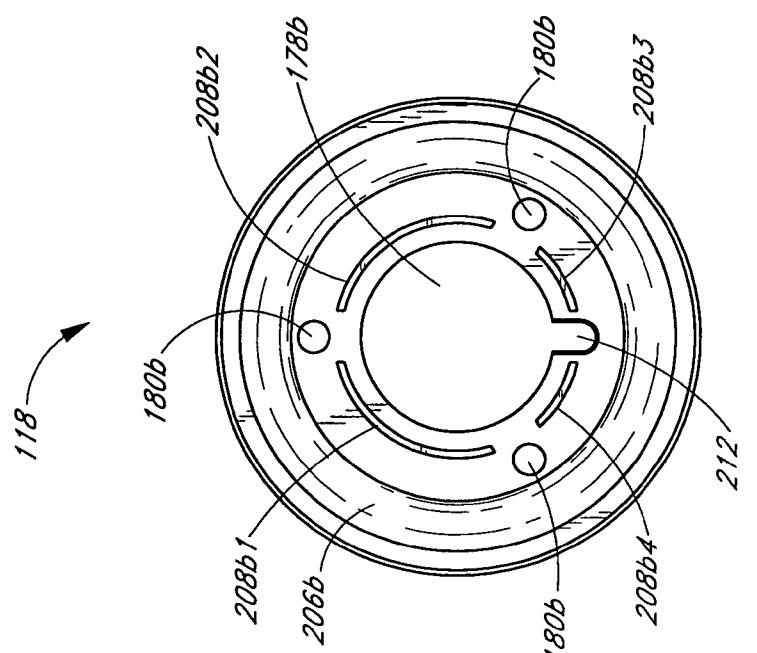


FIG. 20

FIG. 19

FIG. 21

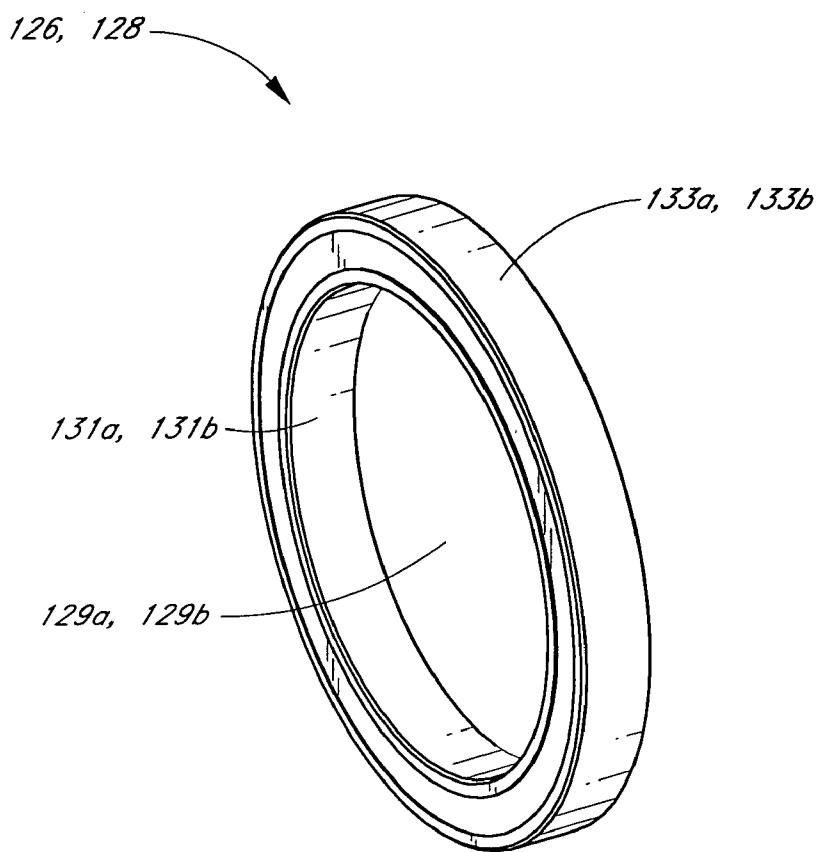


FIG. 22

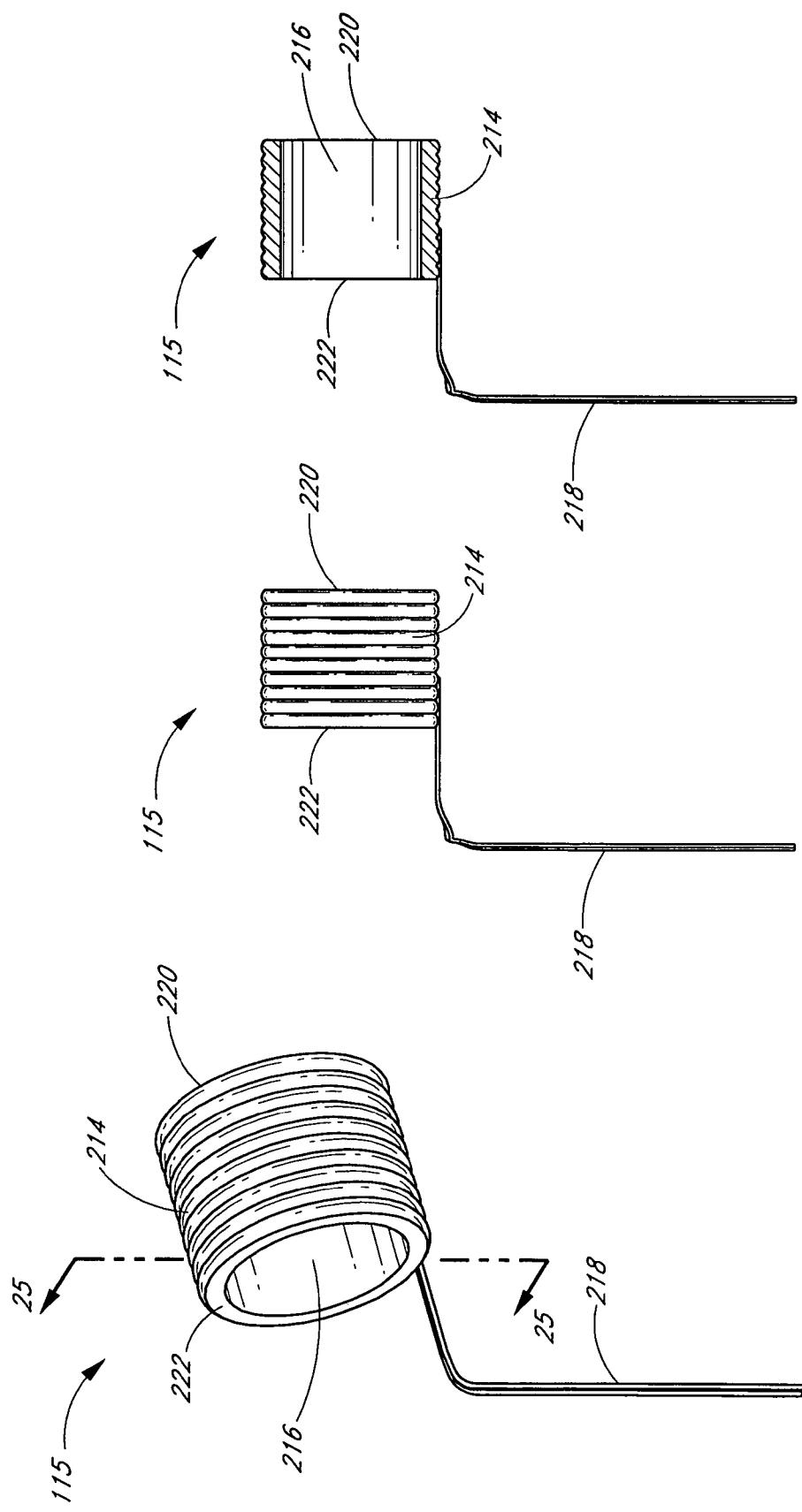


FIG. 23

FIG. 24

FIG. 25

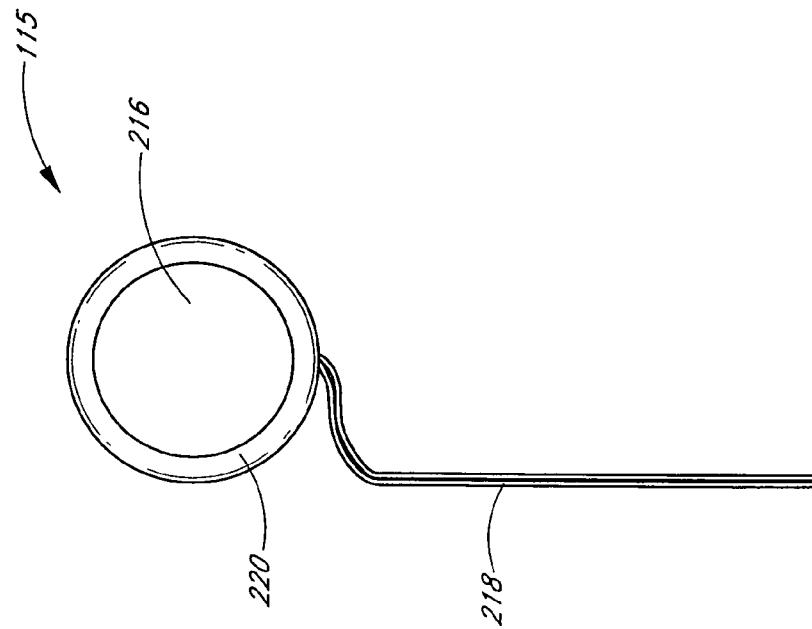


FIG. 27

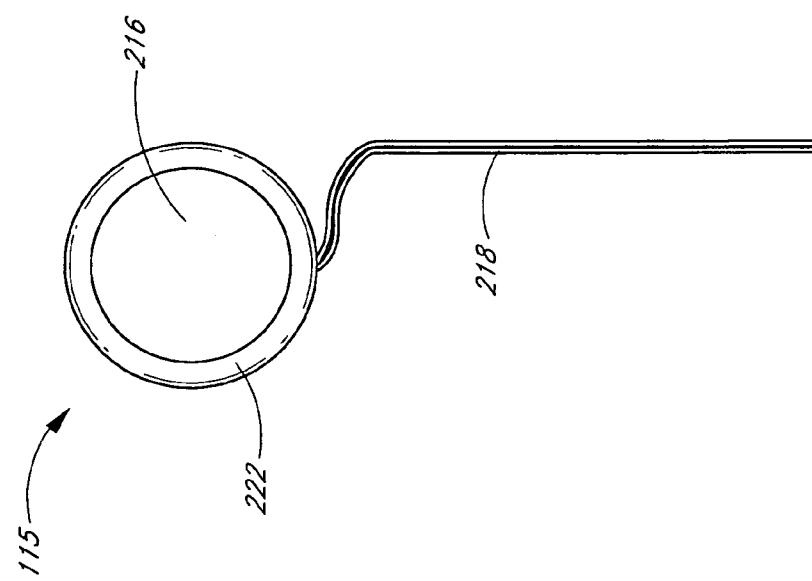


FIG. 26

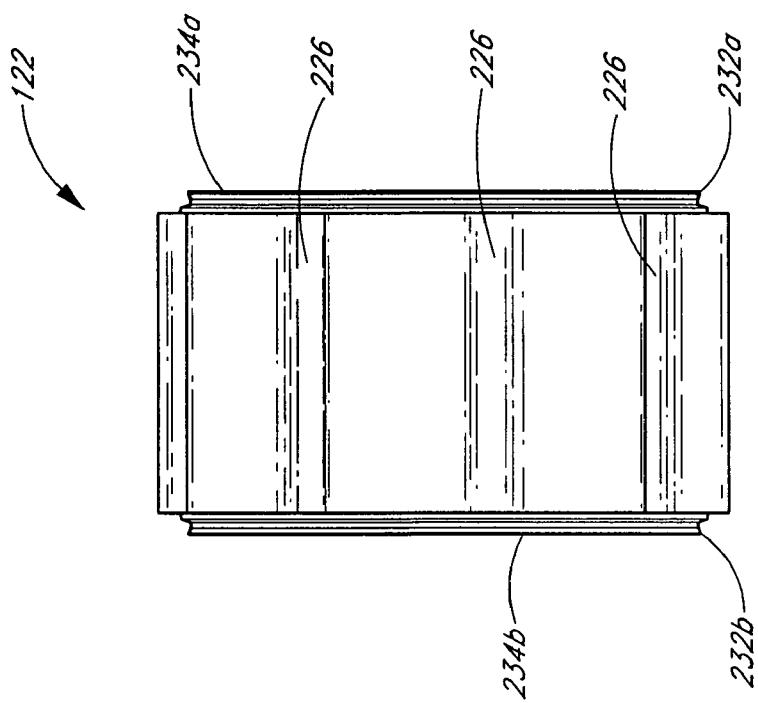


FIG. 29

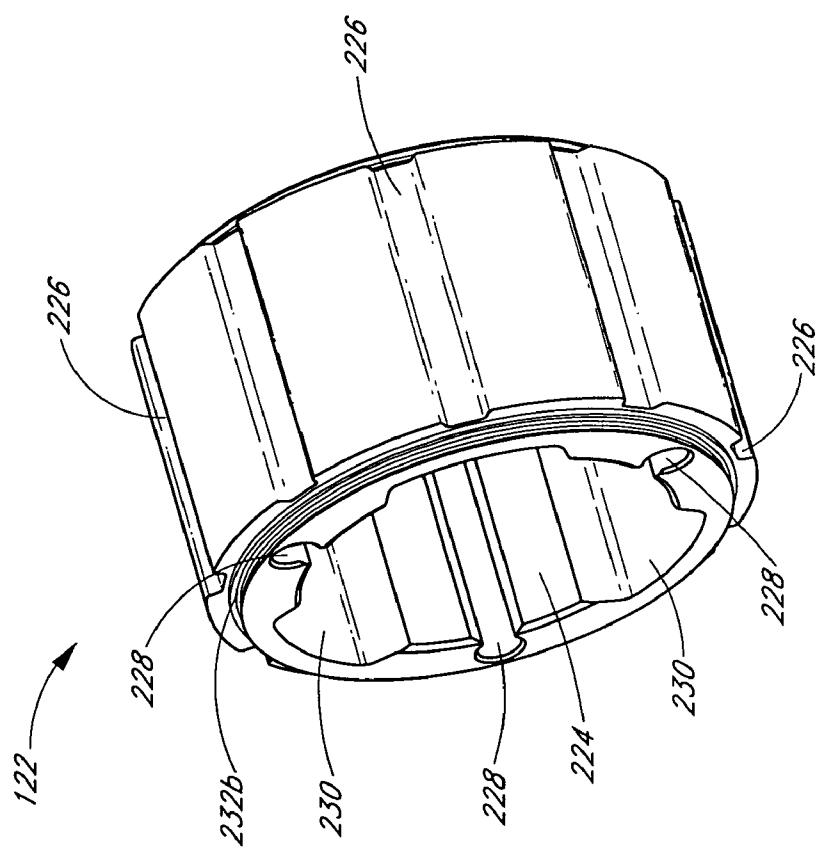


FIG. 28

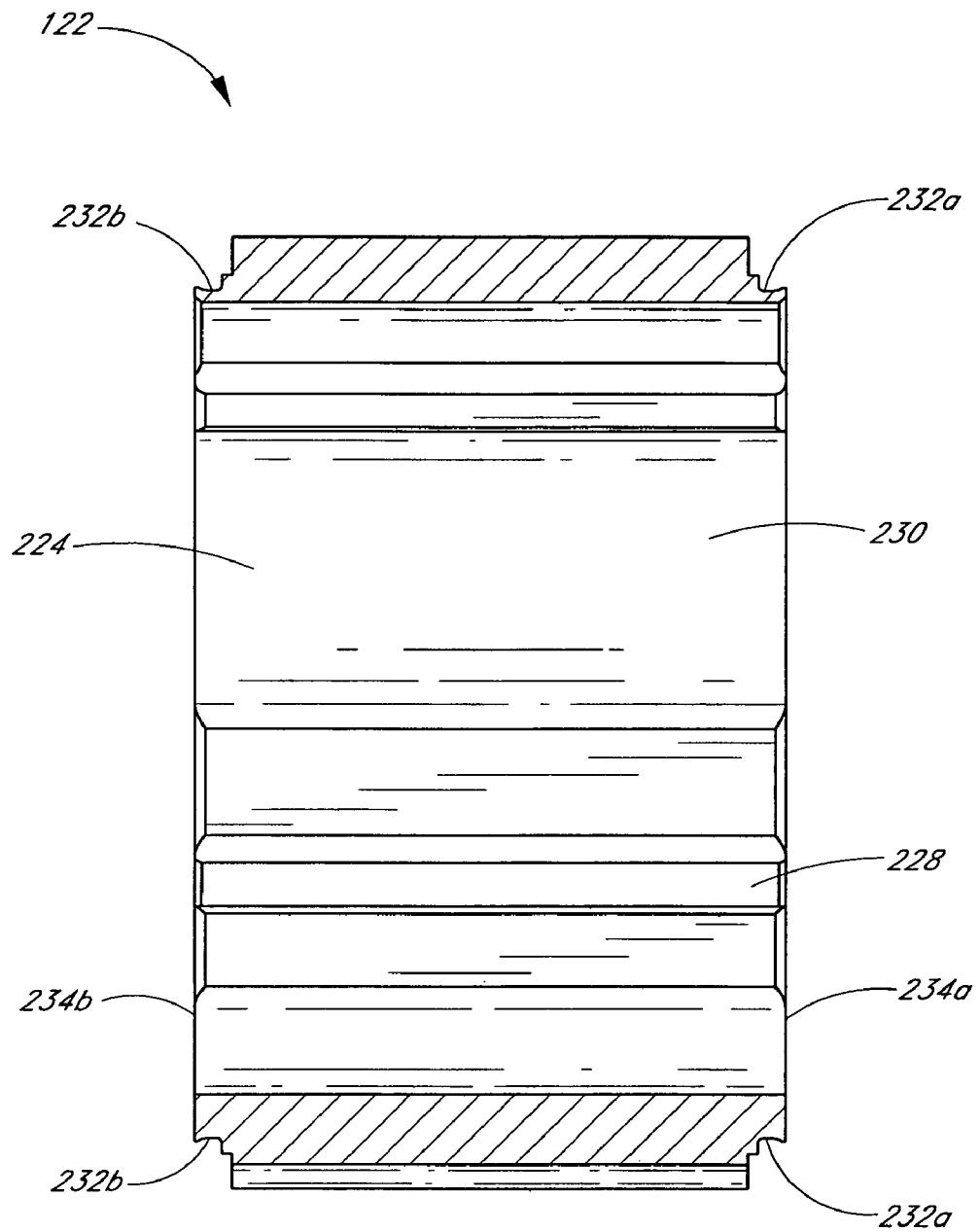


FIG. 30

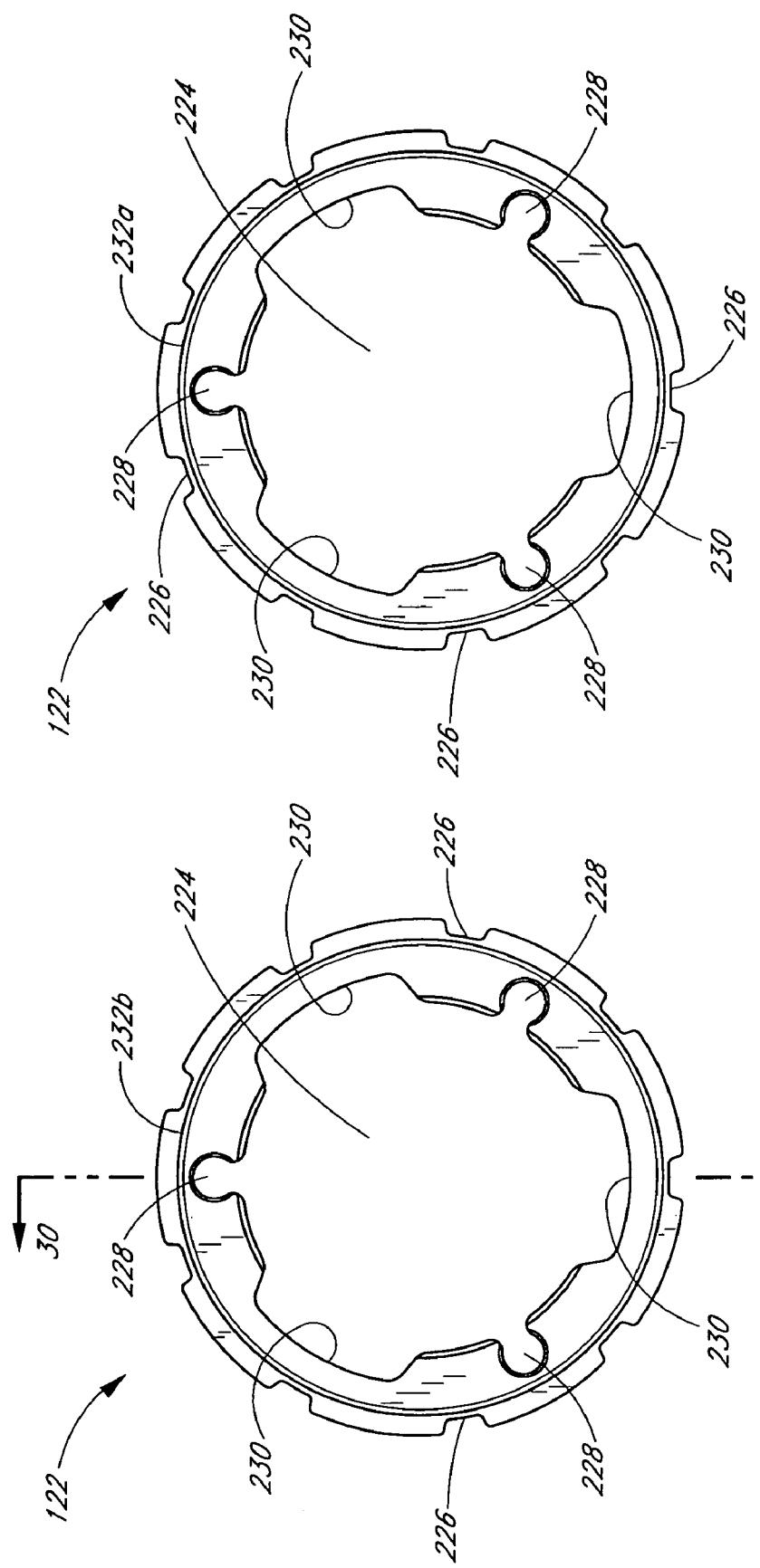
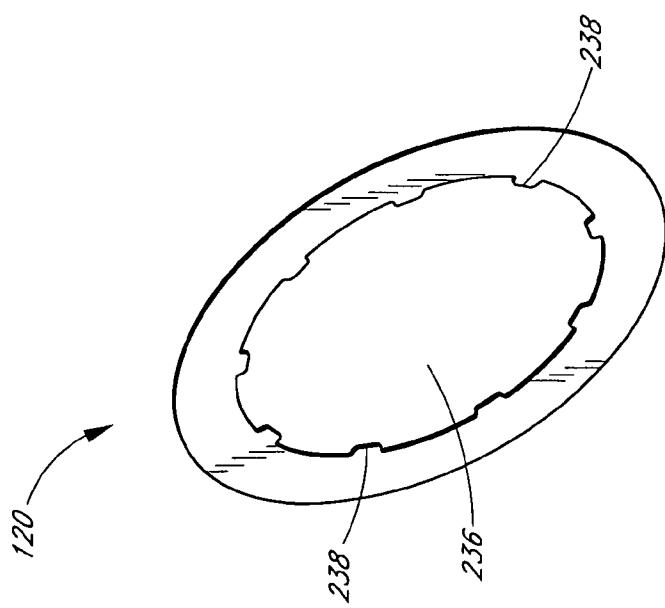
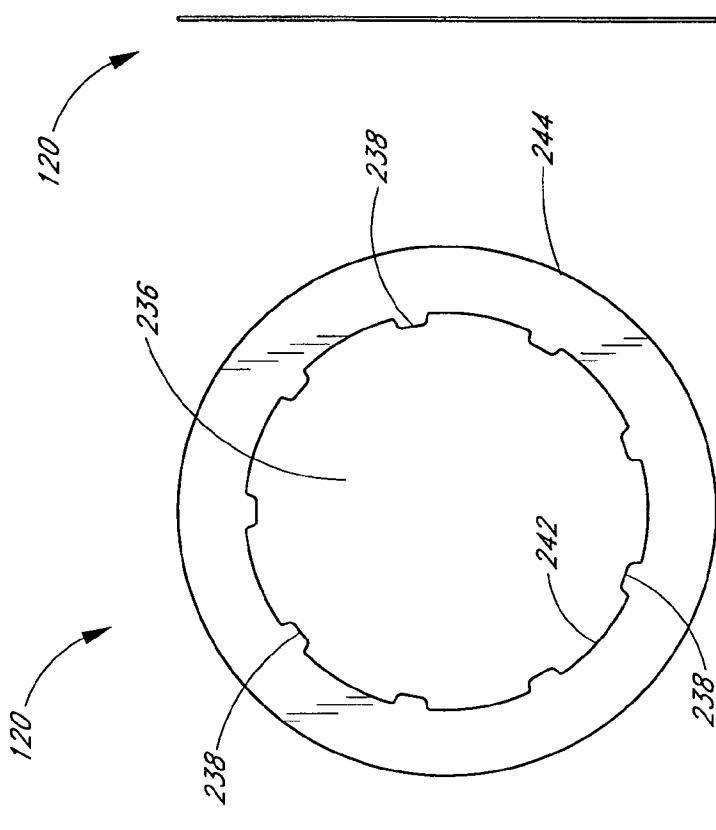


FIG. 31 FIG. 32

FIG. 35

FIG. 34

FIG. 33



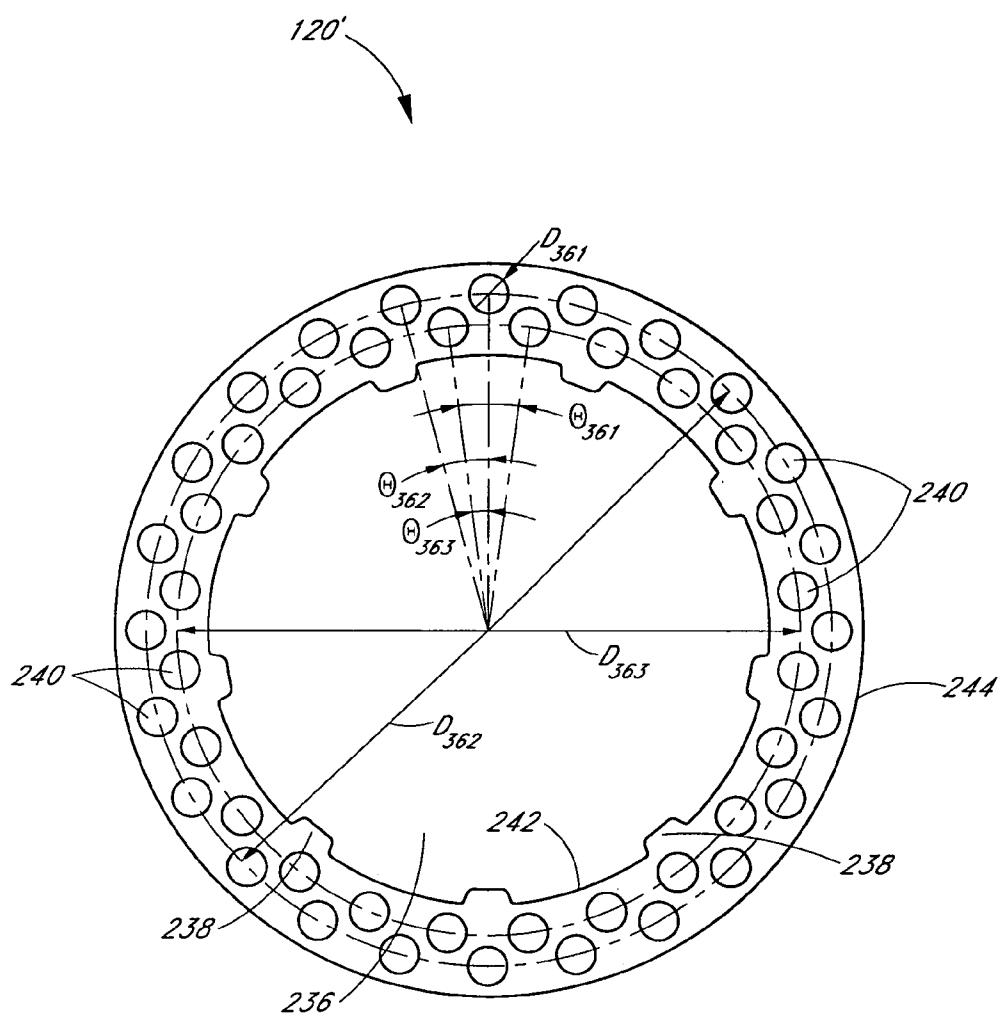


FIG. 36

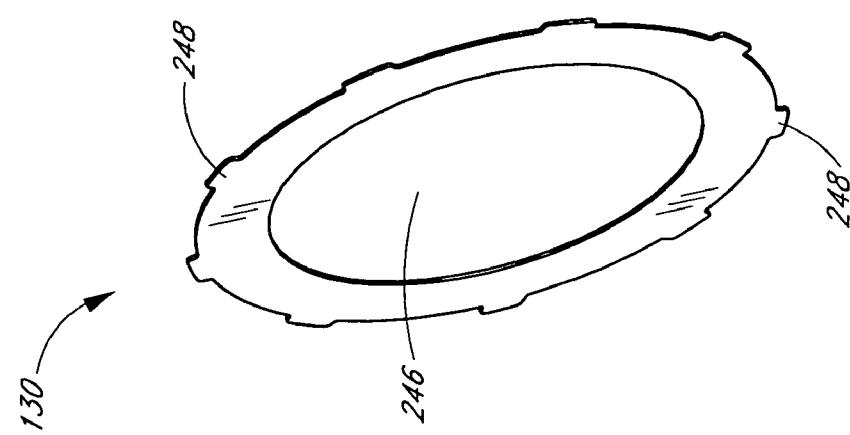
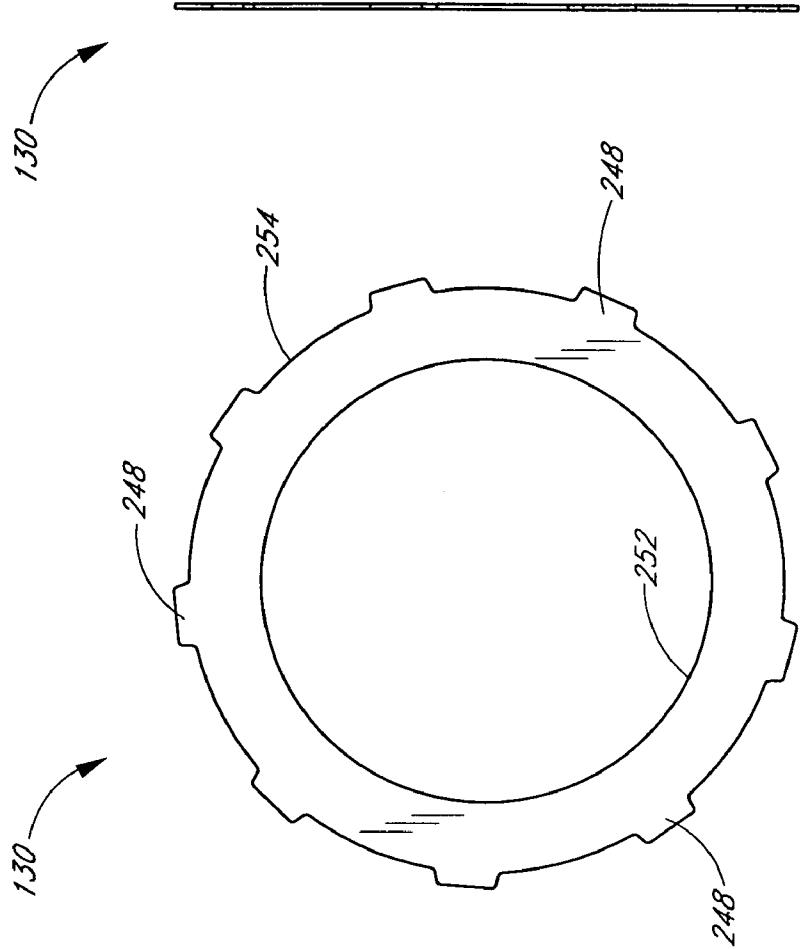


FIG. 39

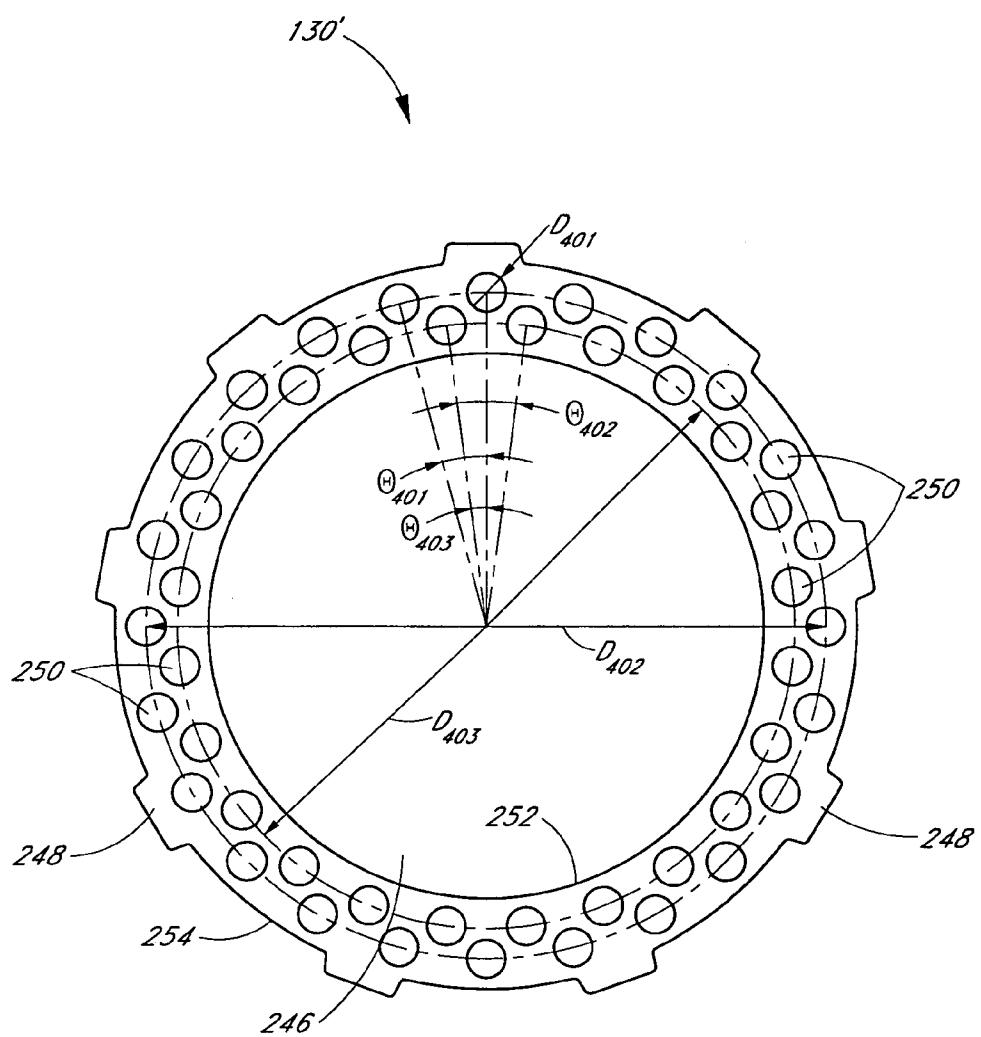


FIG. 40

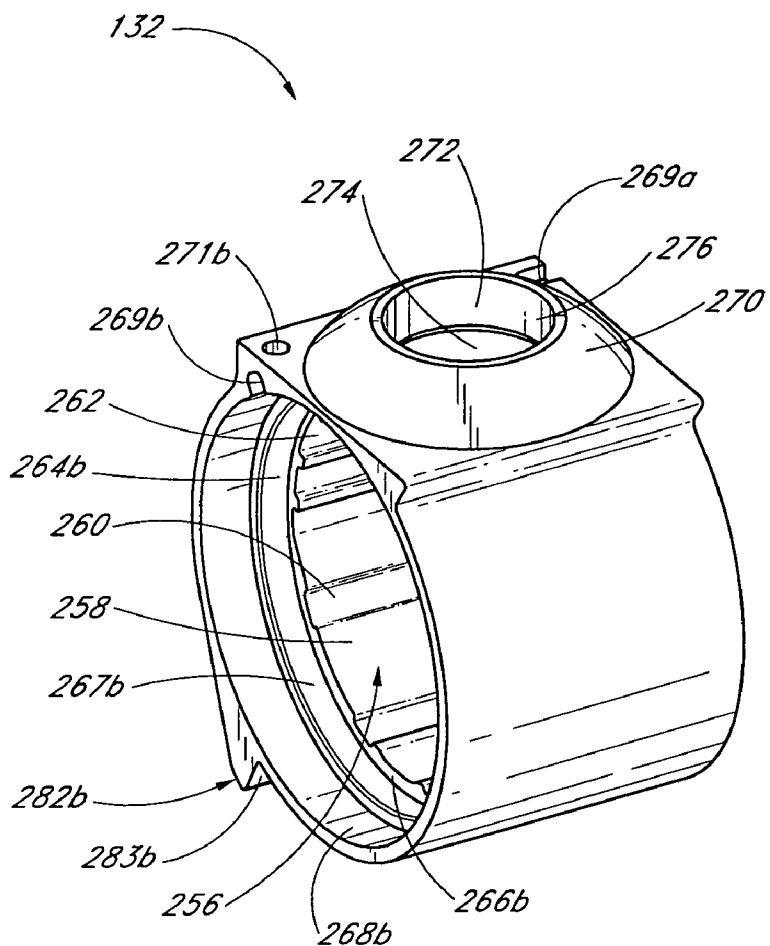


FIG. 41

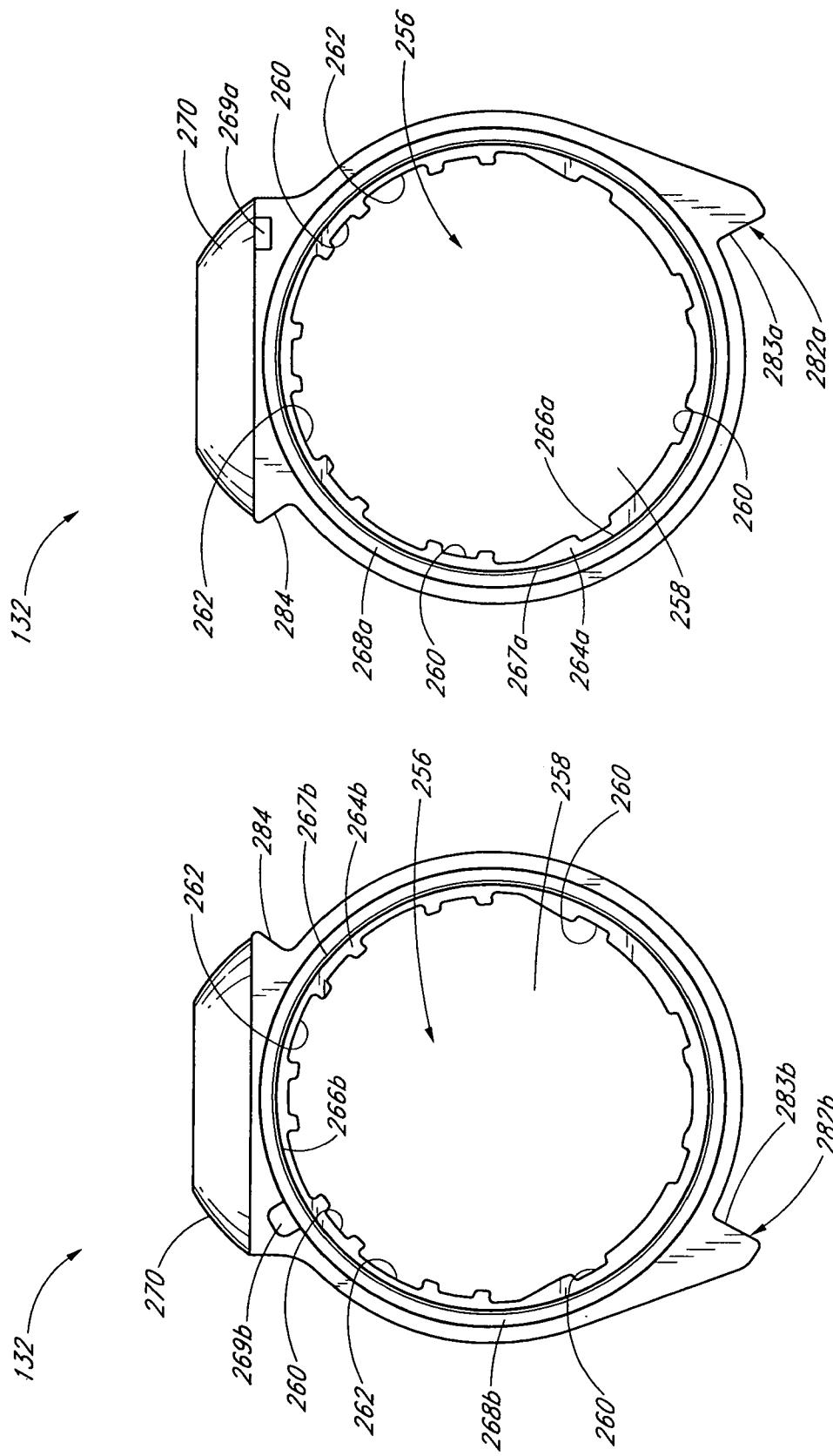


FIG. 42 FIG. 43

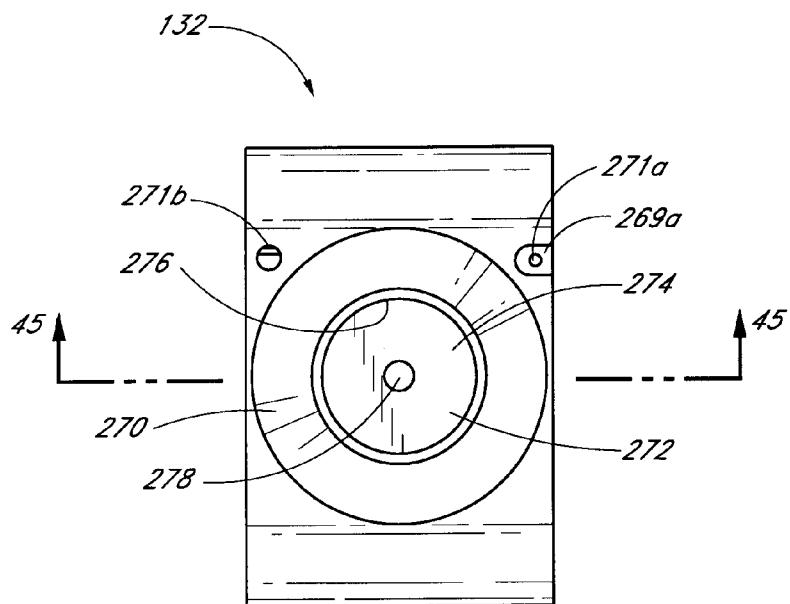


FIG. 44

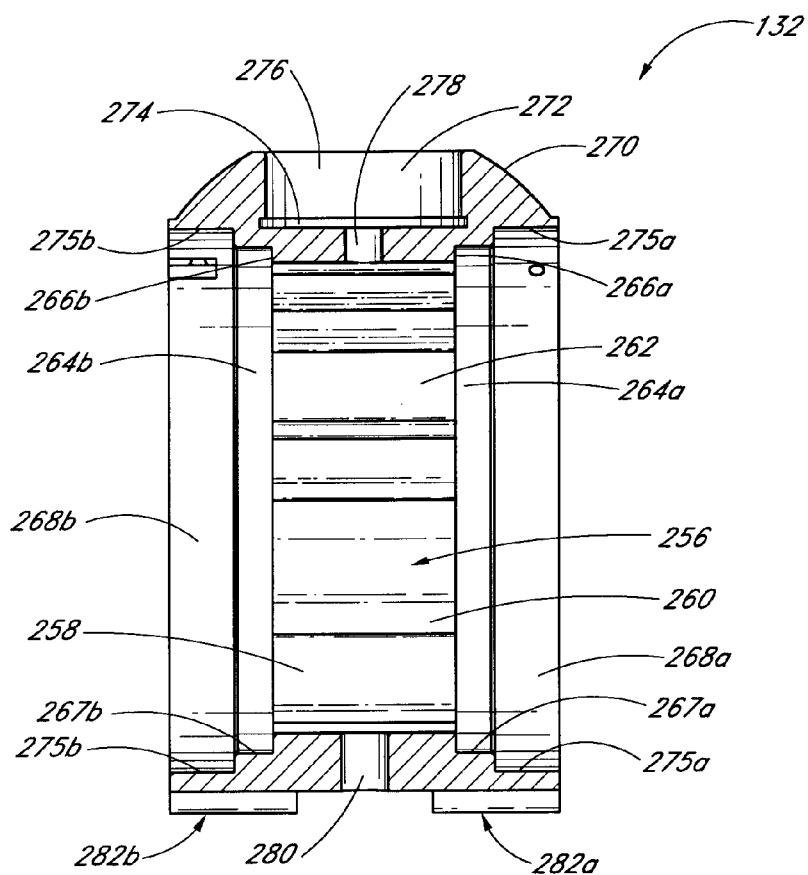
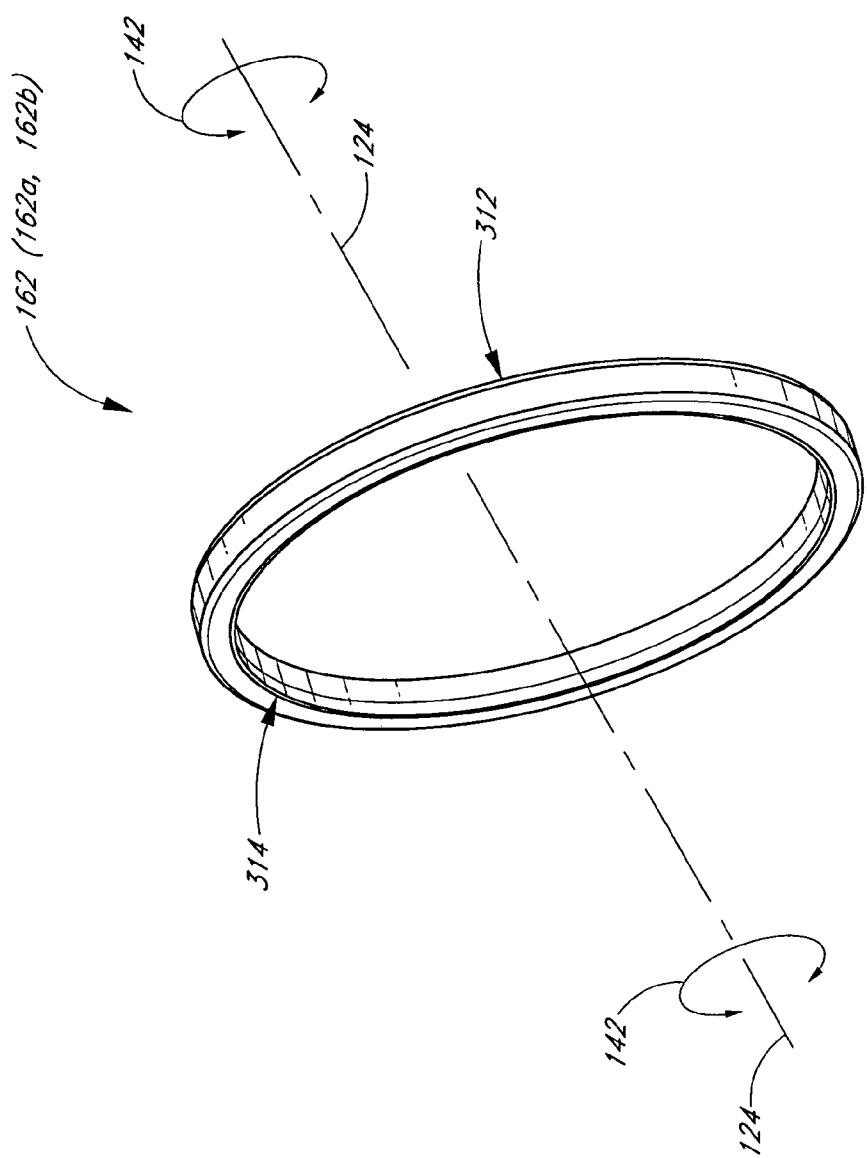


FIG. 45

FIG. 46

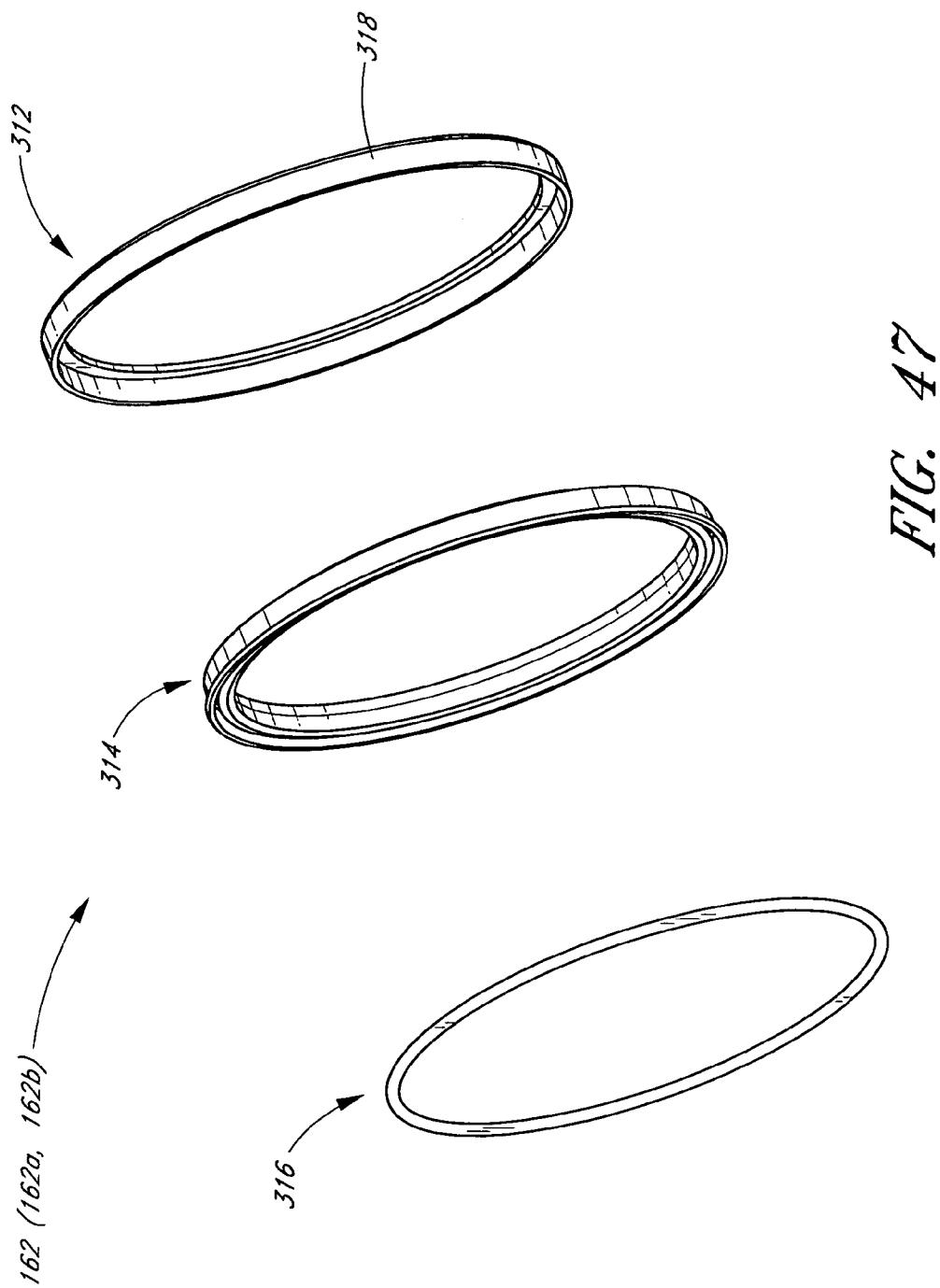
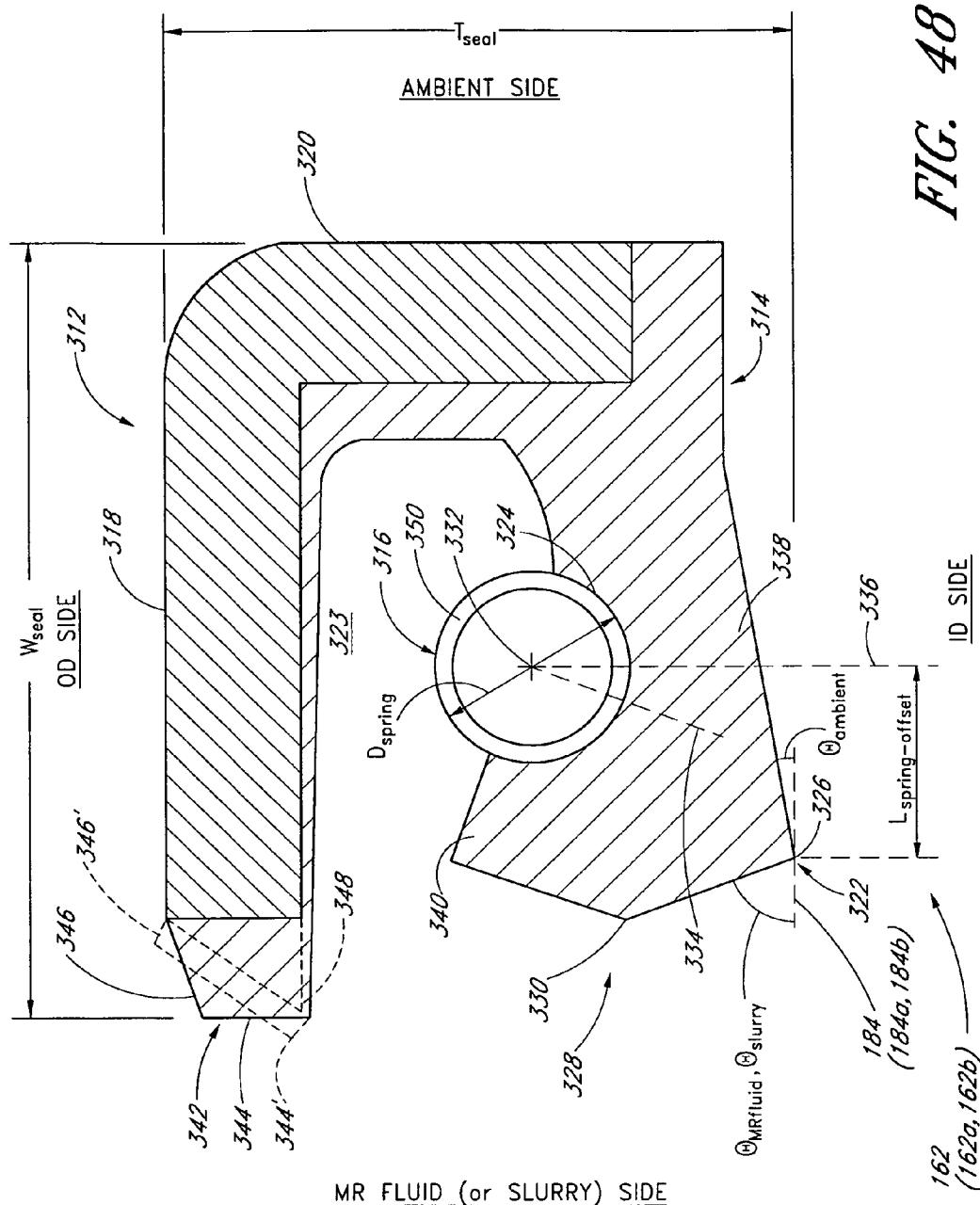


FIG. 47



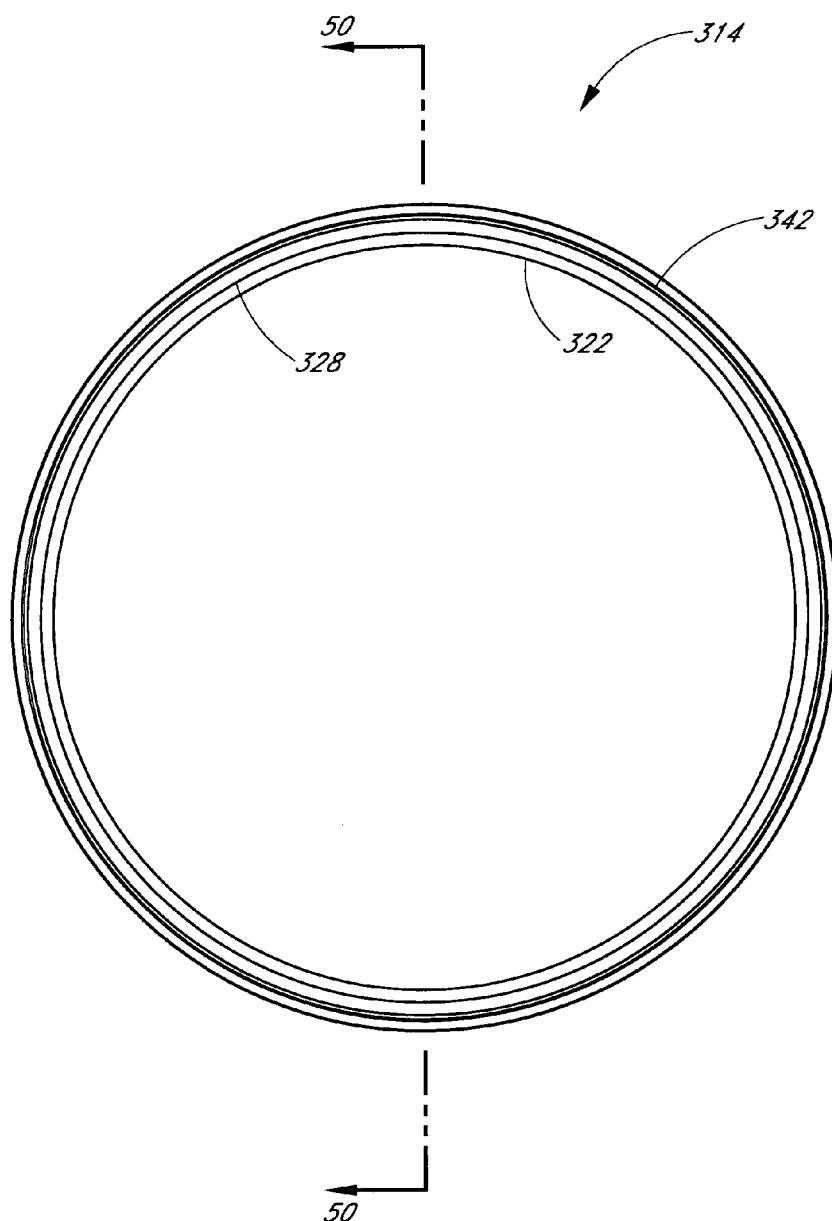


FIG. 49

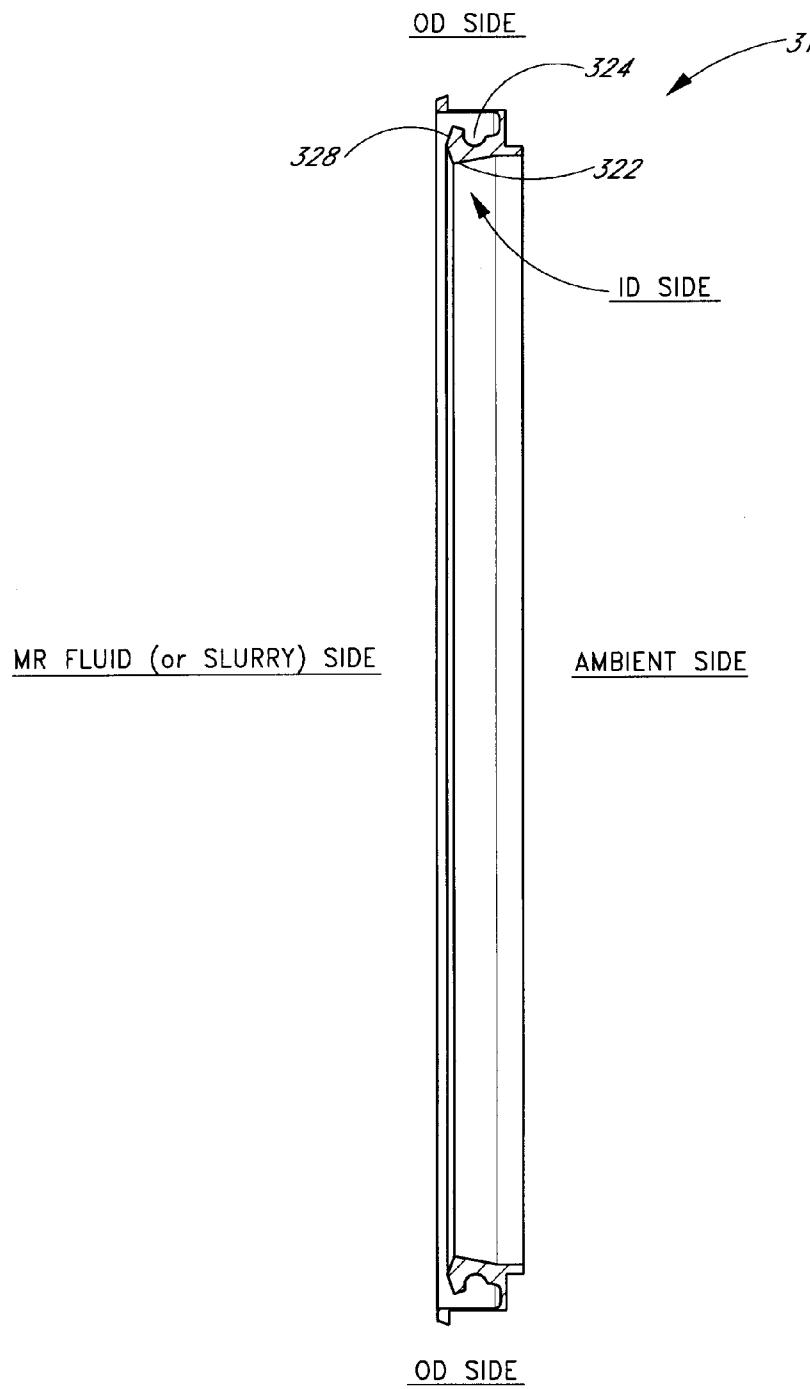


FIG. 50

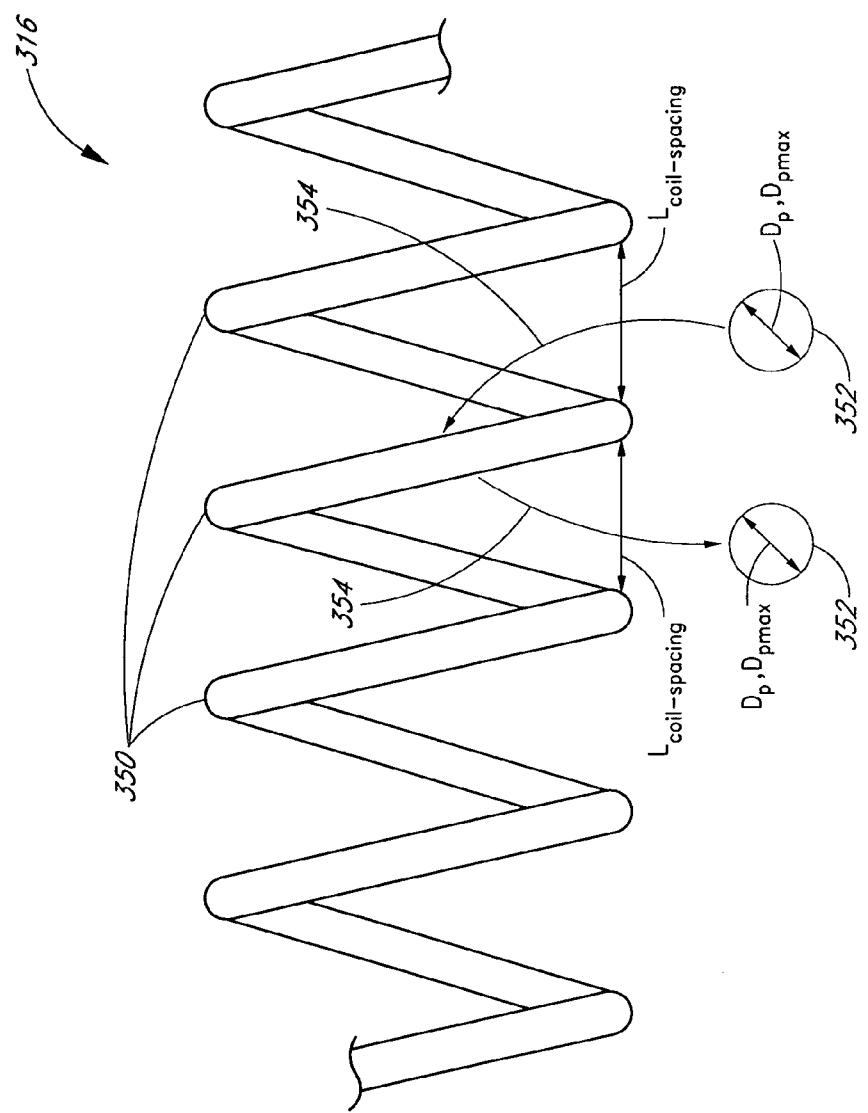
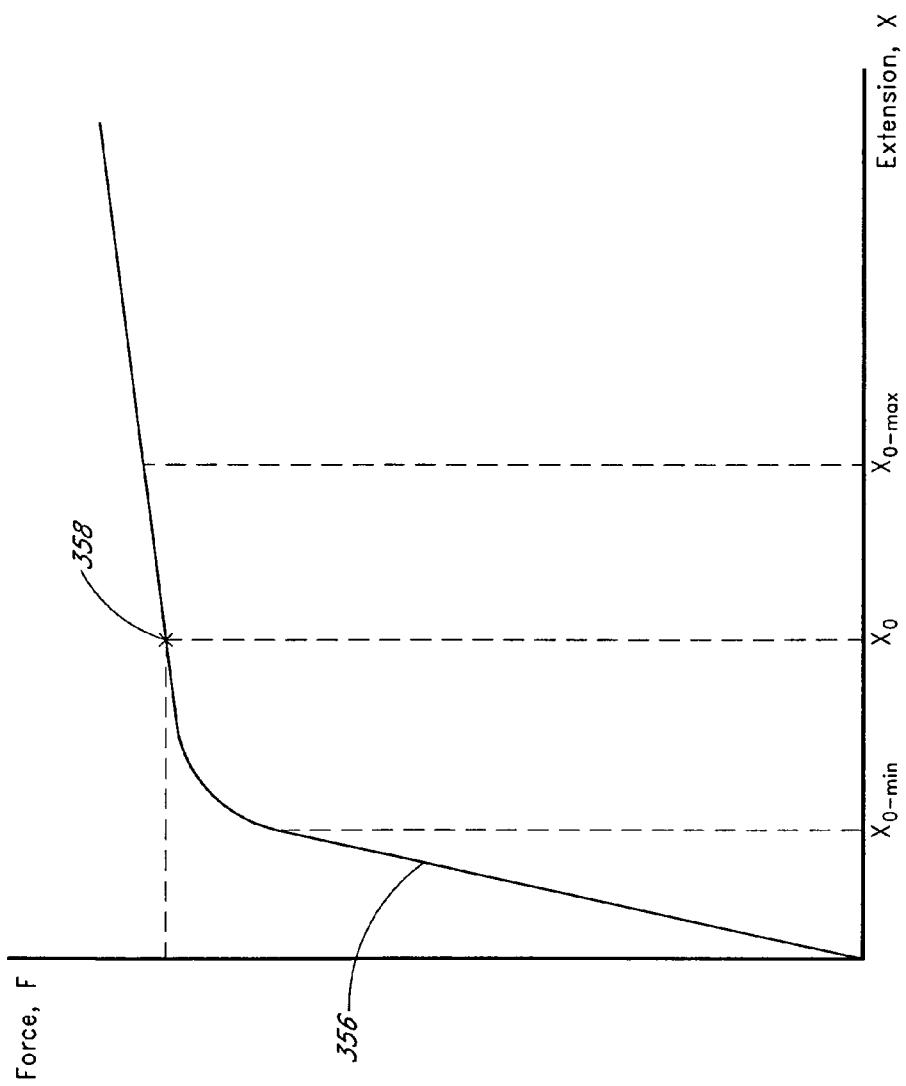


FIG. 51

FIG. 52



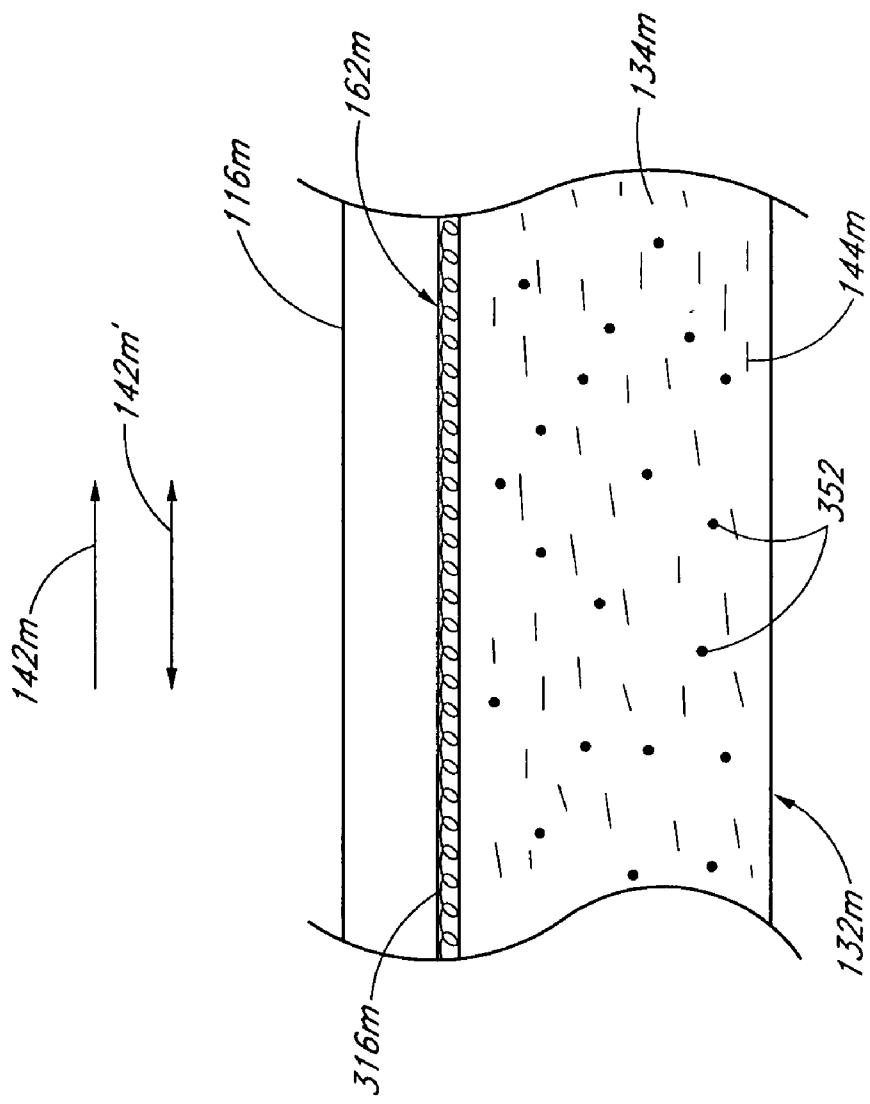


FIG. 53

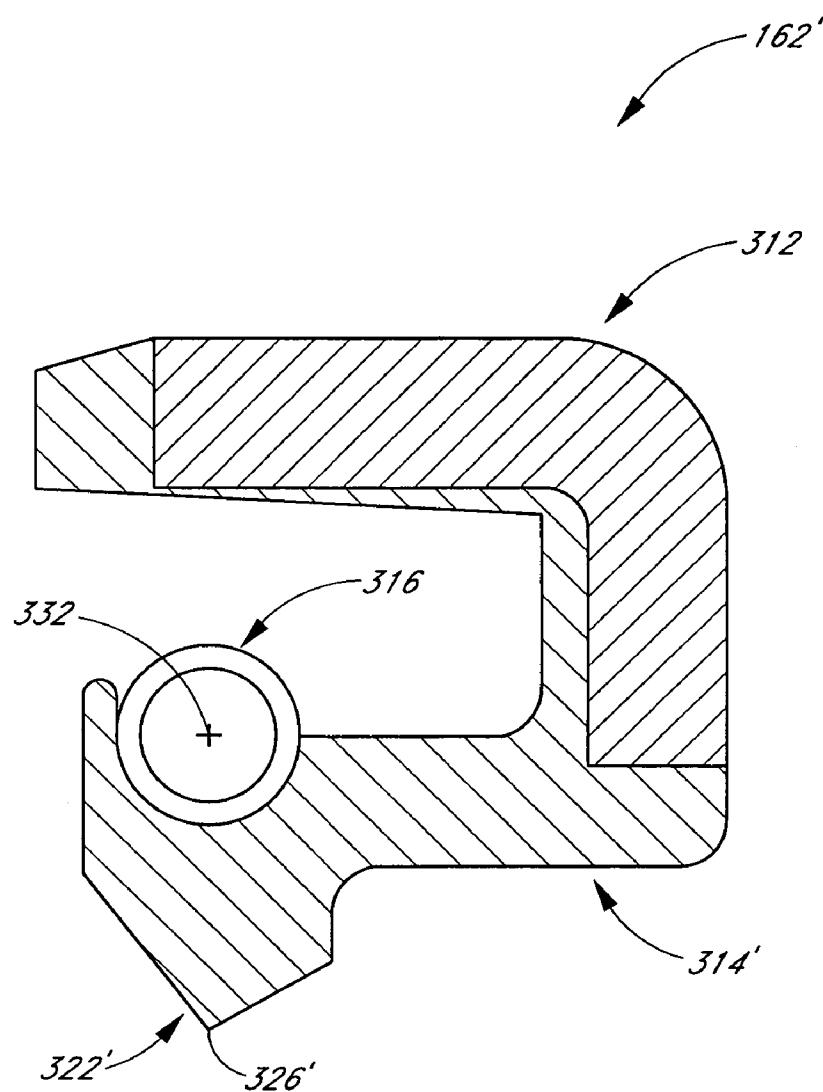
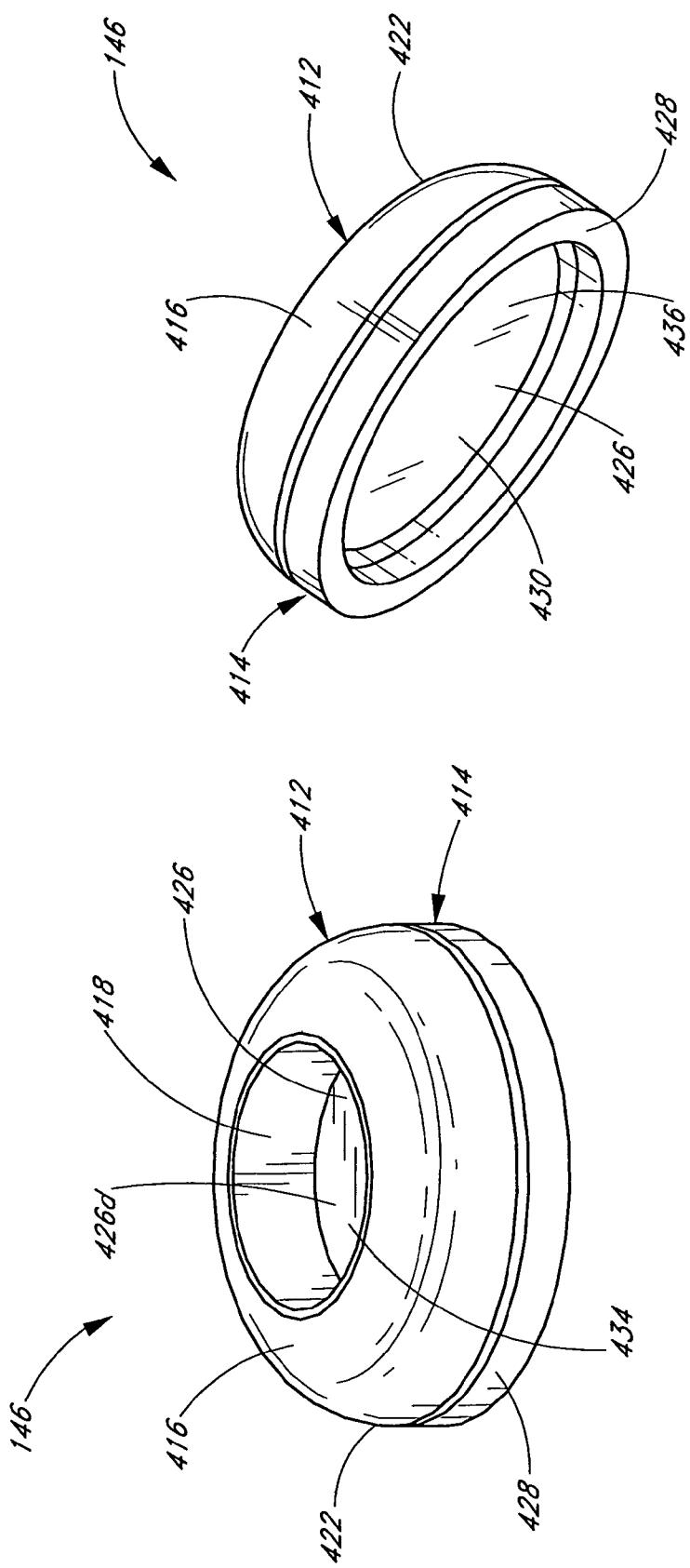


FIG. 54



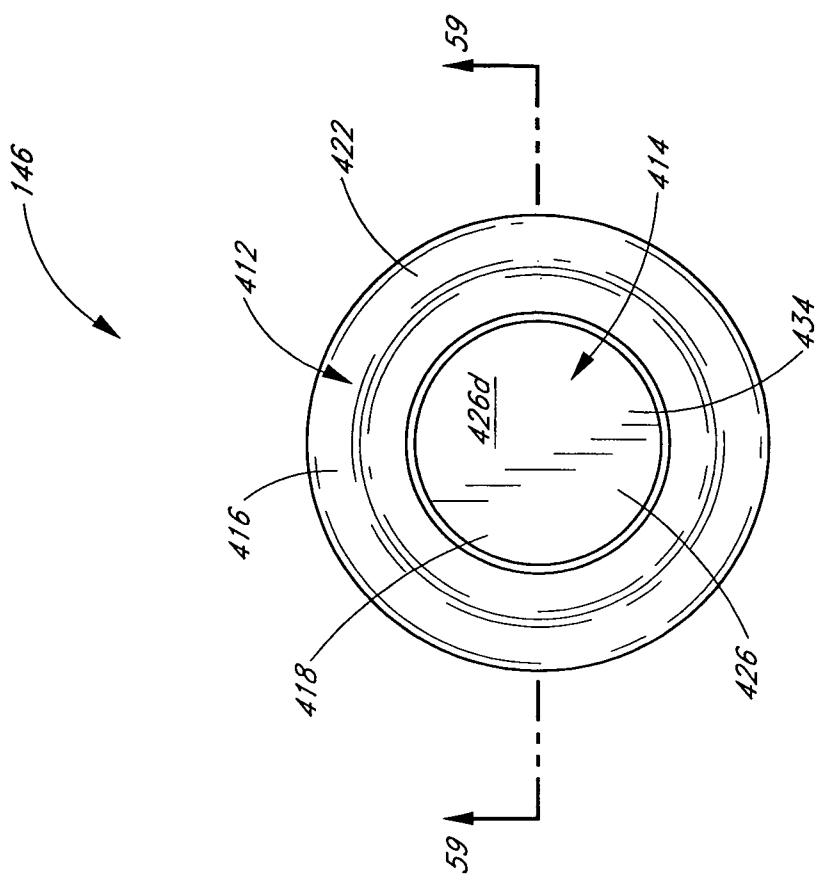


FIG. 58

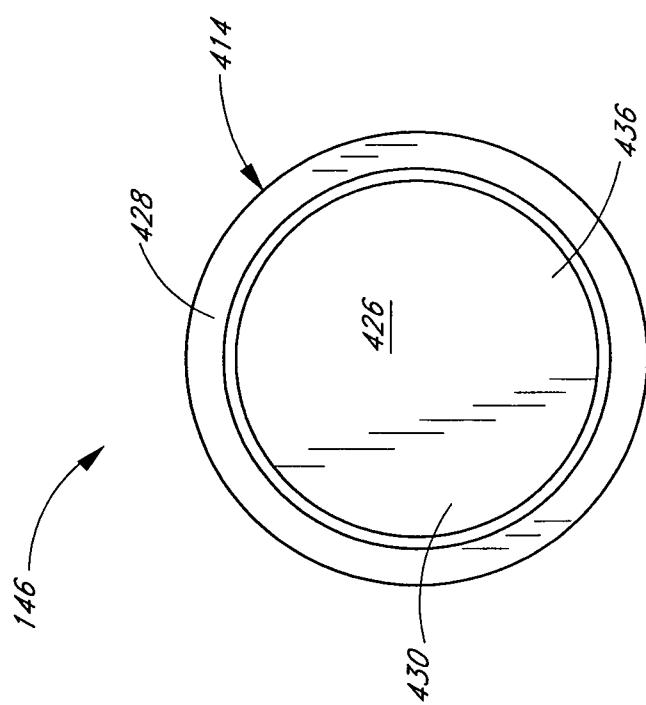


FIG. 57

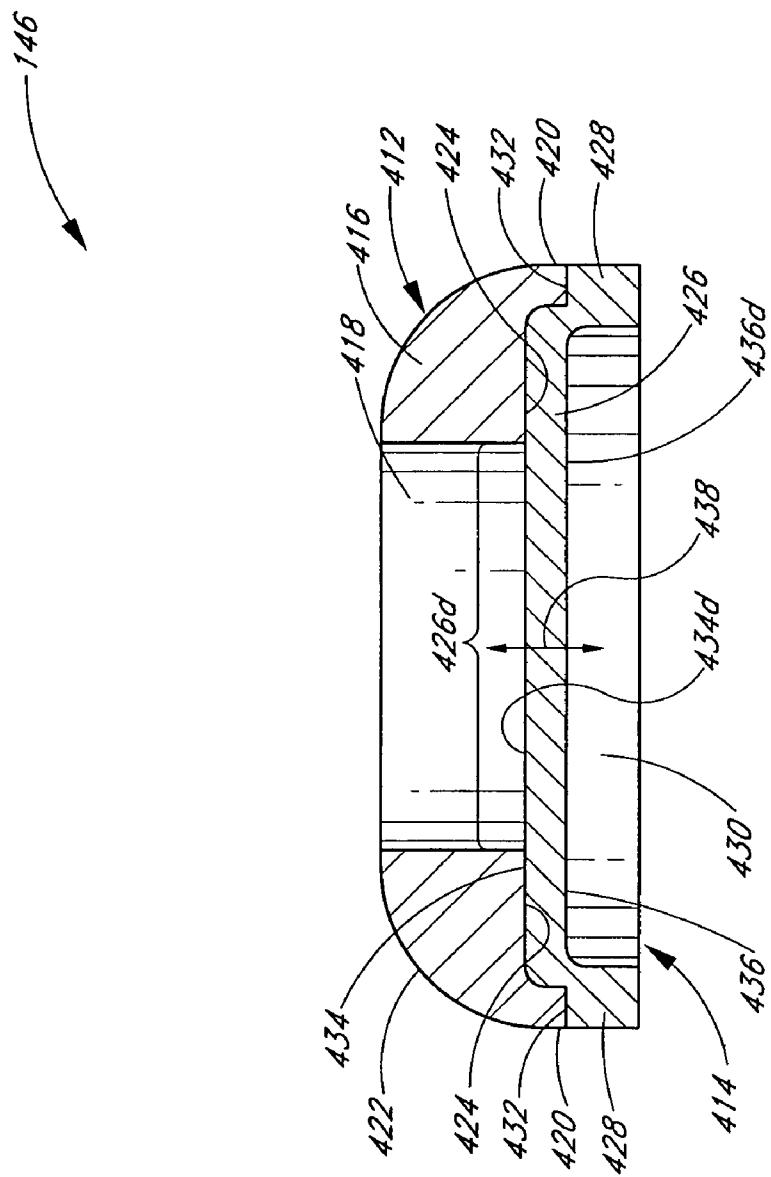


FIG. 59

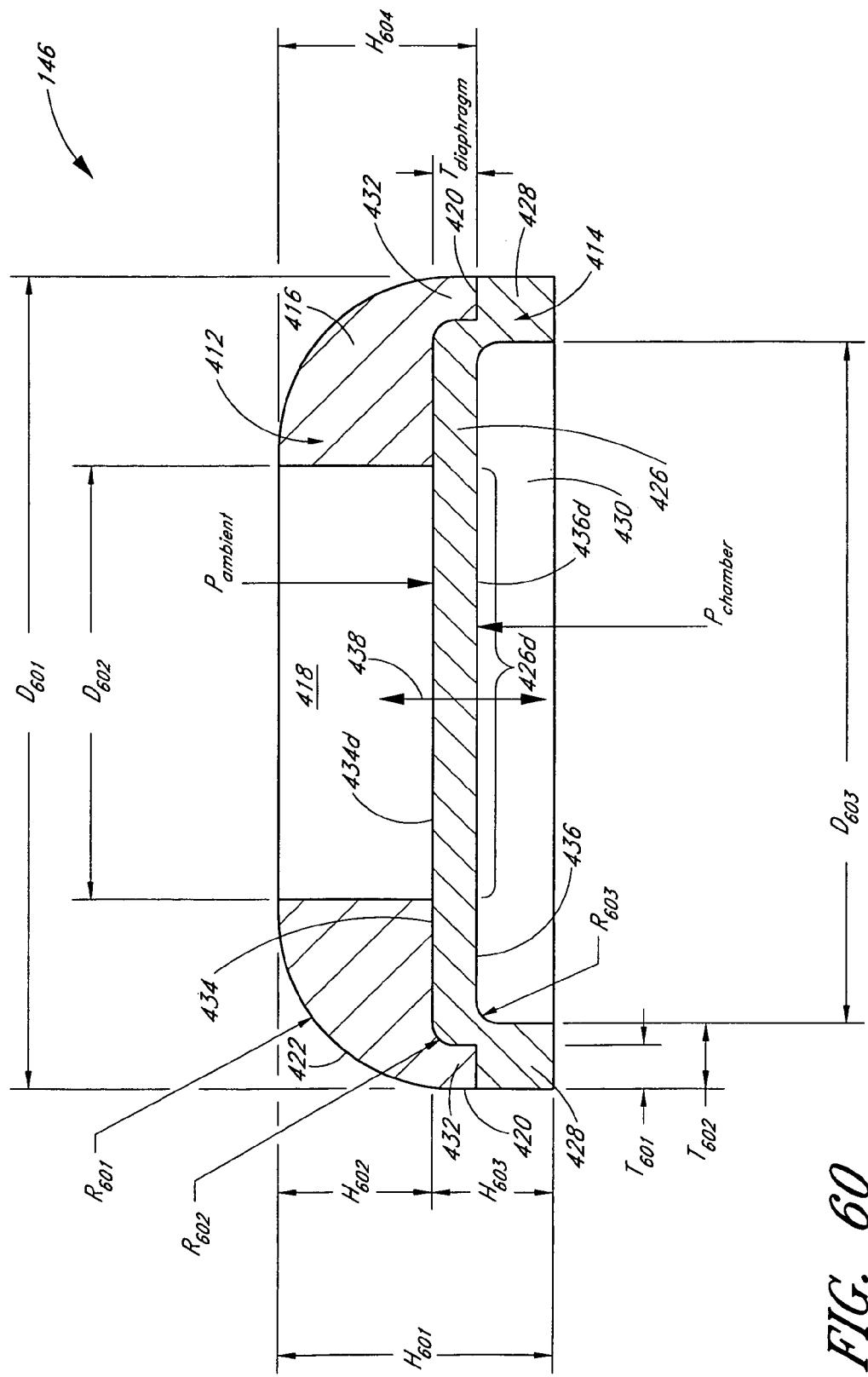


FIG. 60

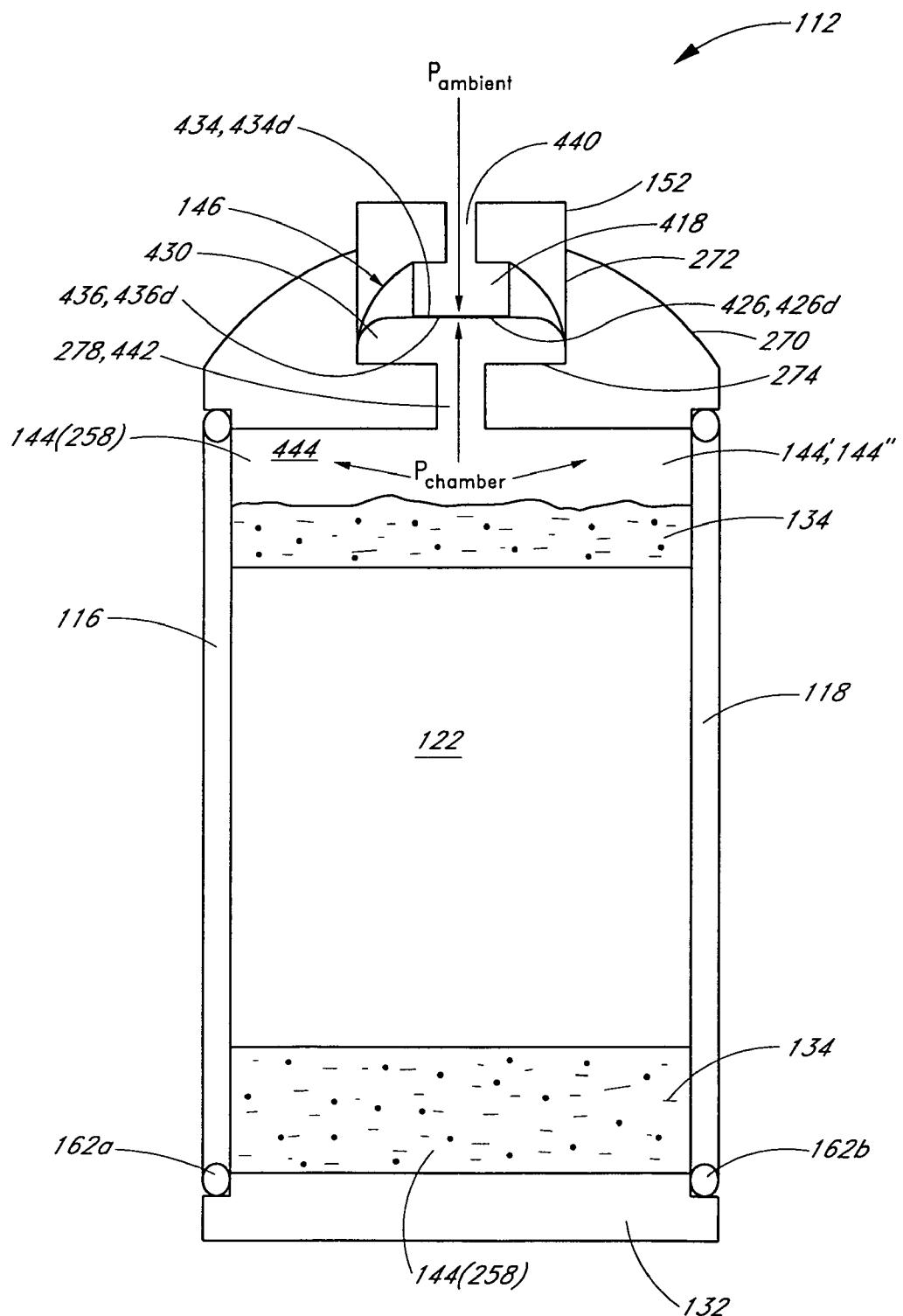
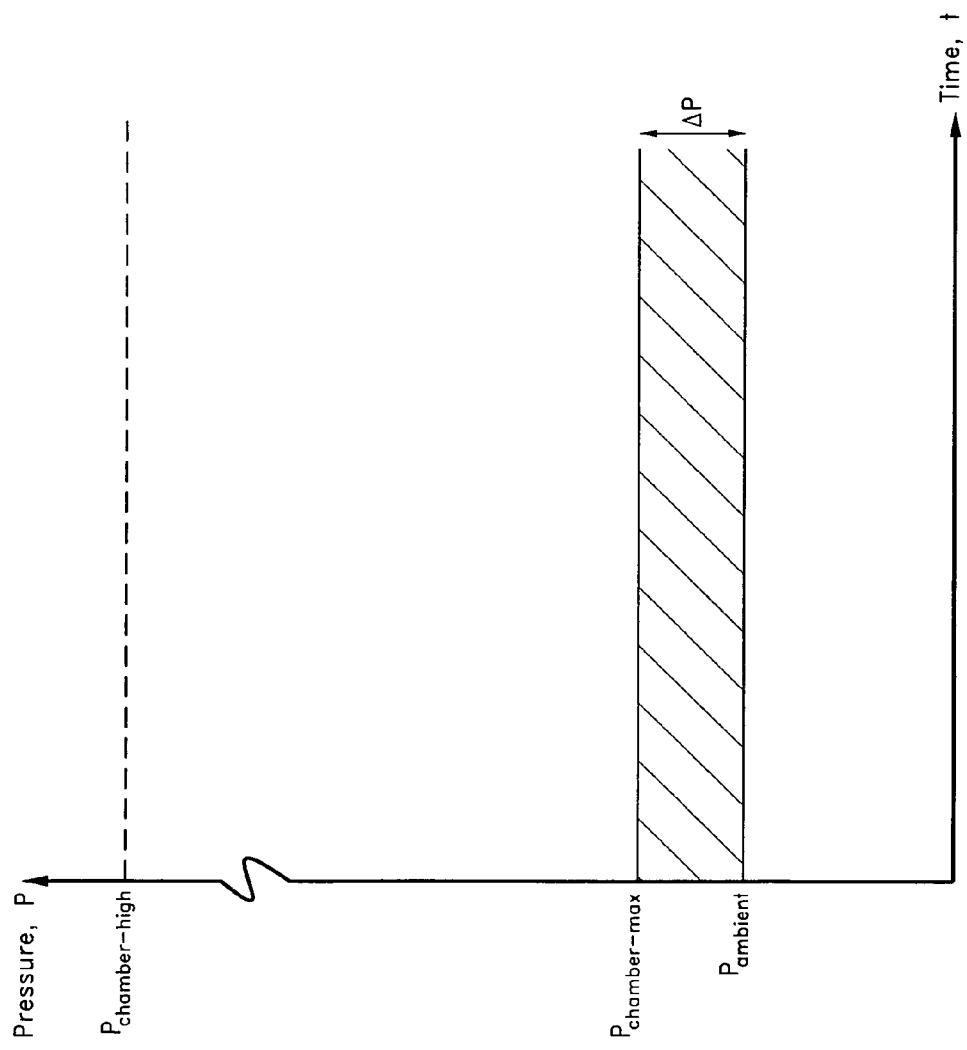


FIG. 61

FIG. 62



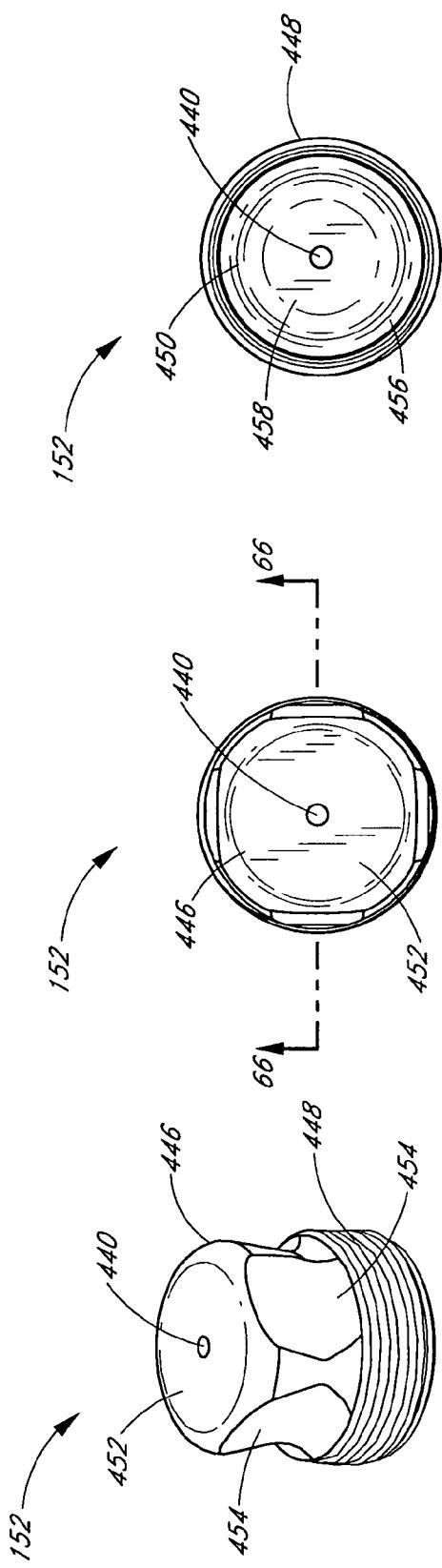


FIG. 63 FIG. 64 FIG. 65

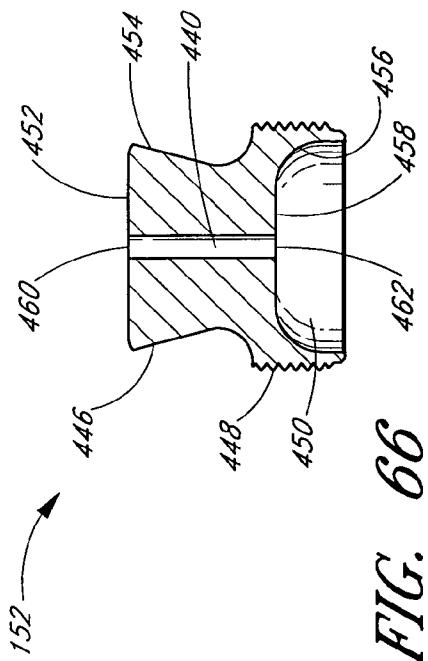


FIG. 66

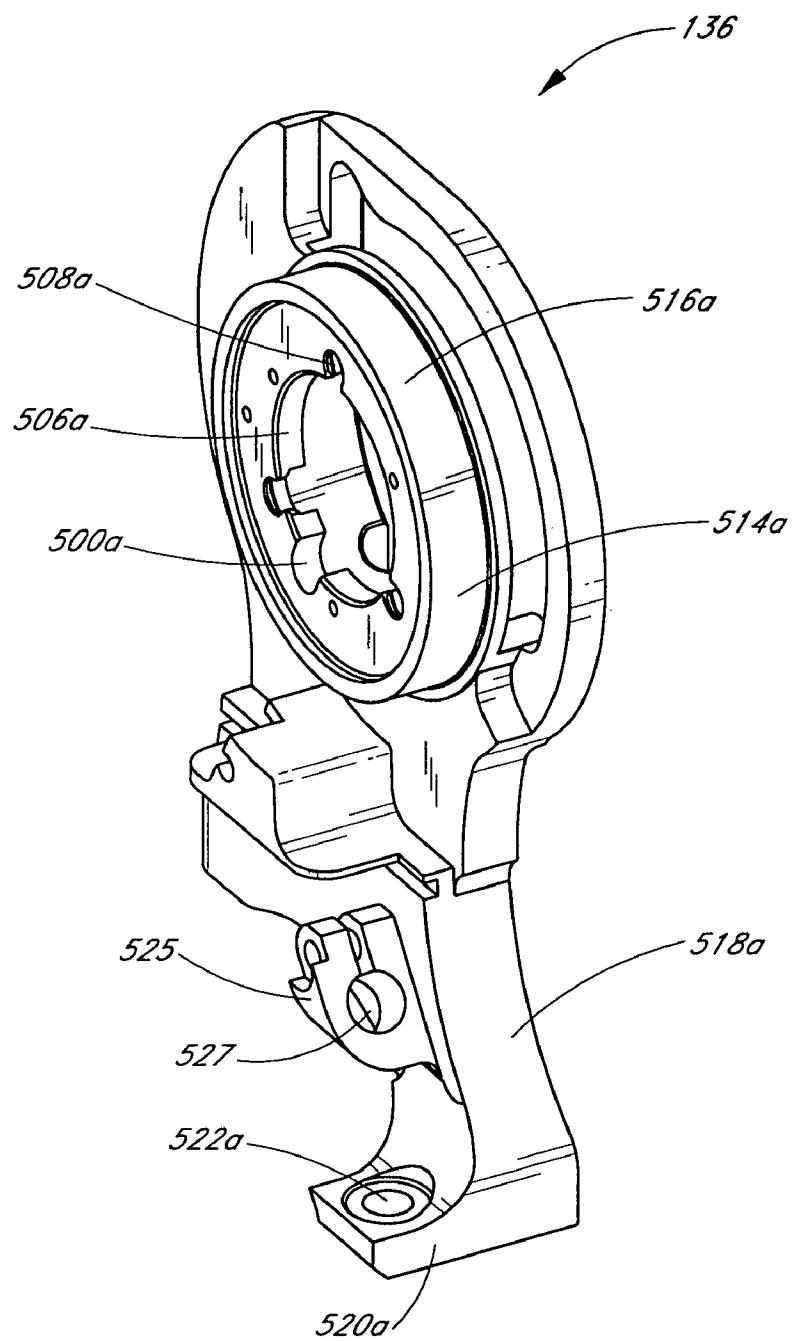


FIG. 67

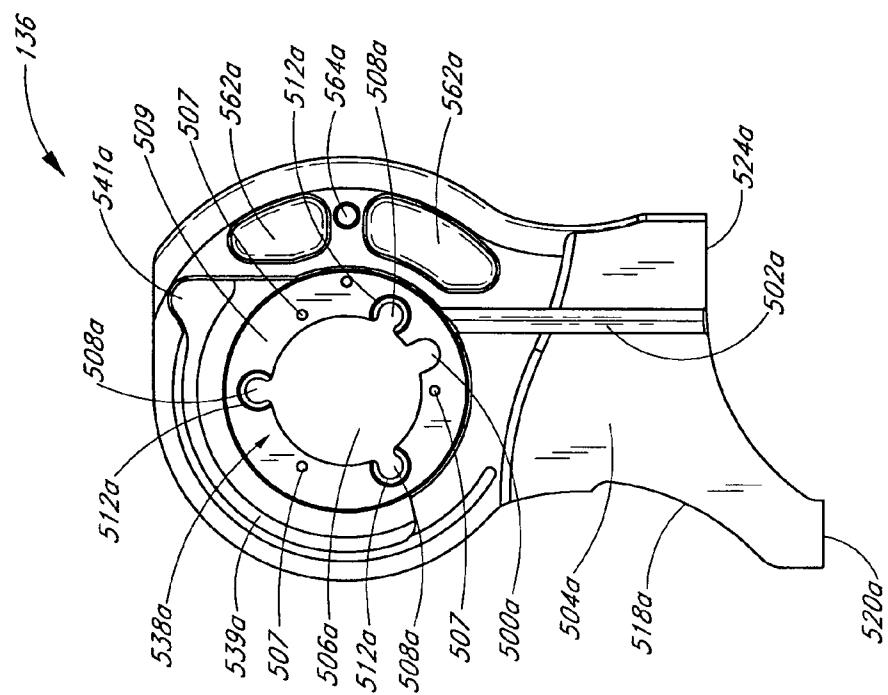


FIG. 69

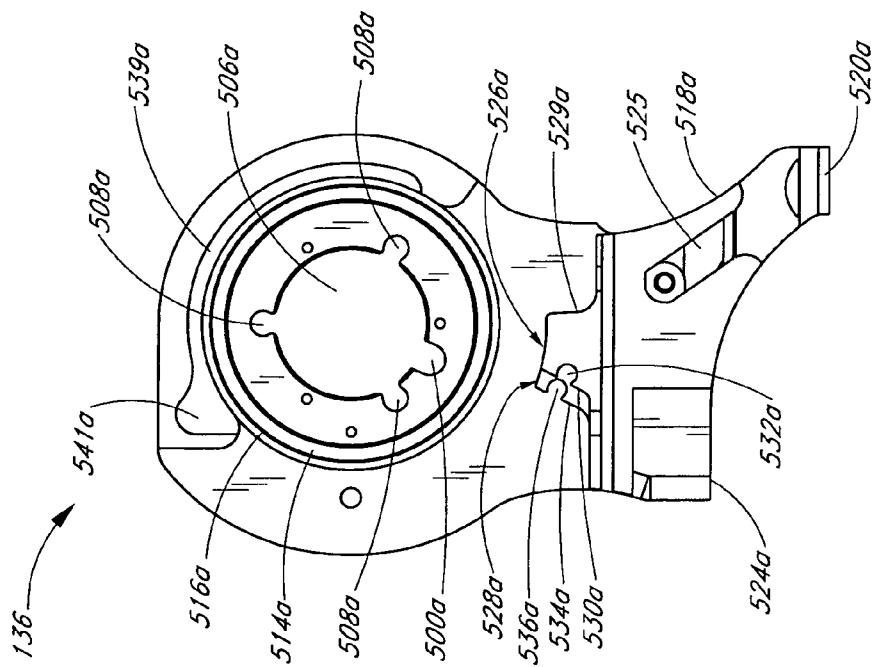


FIG. 68

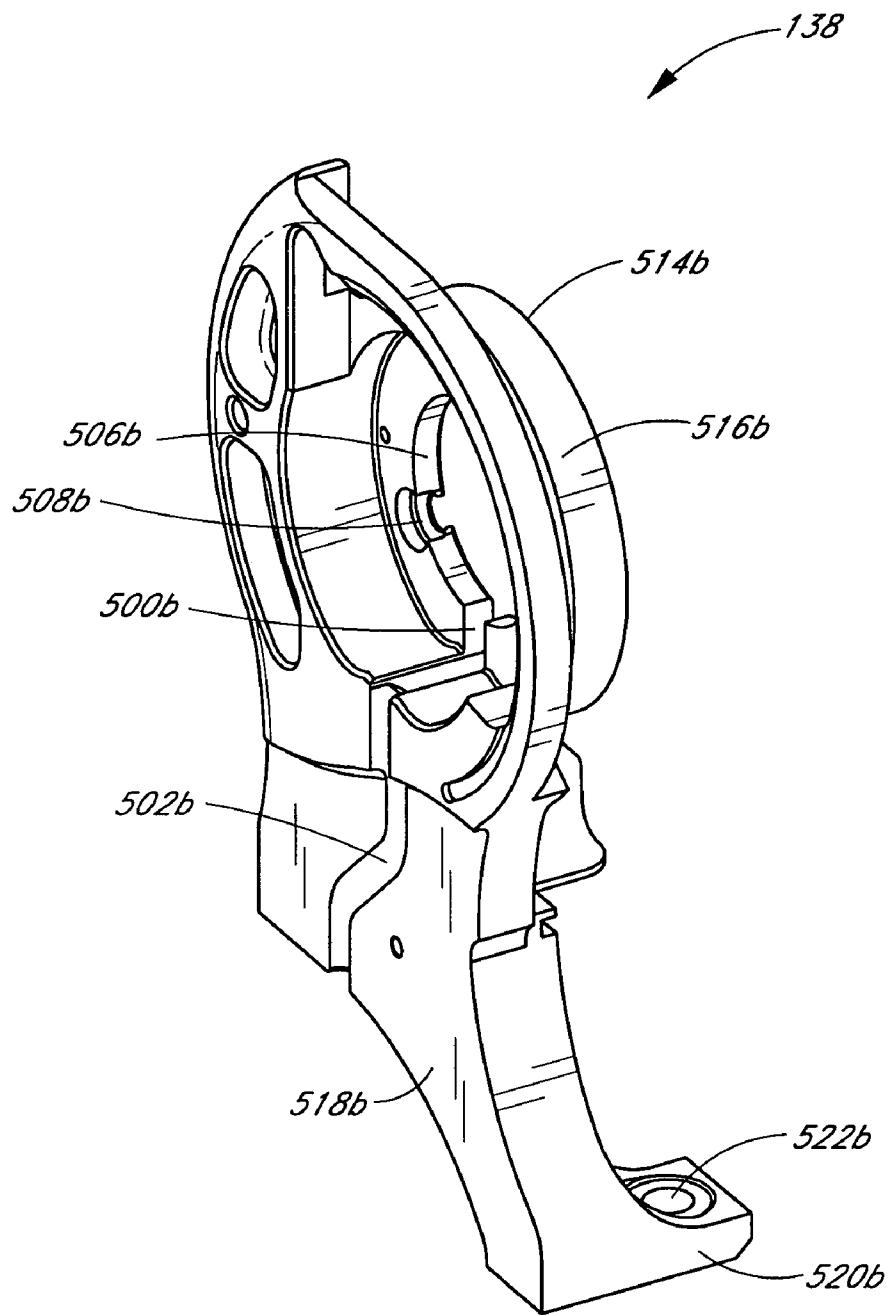


FIG. 70

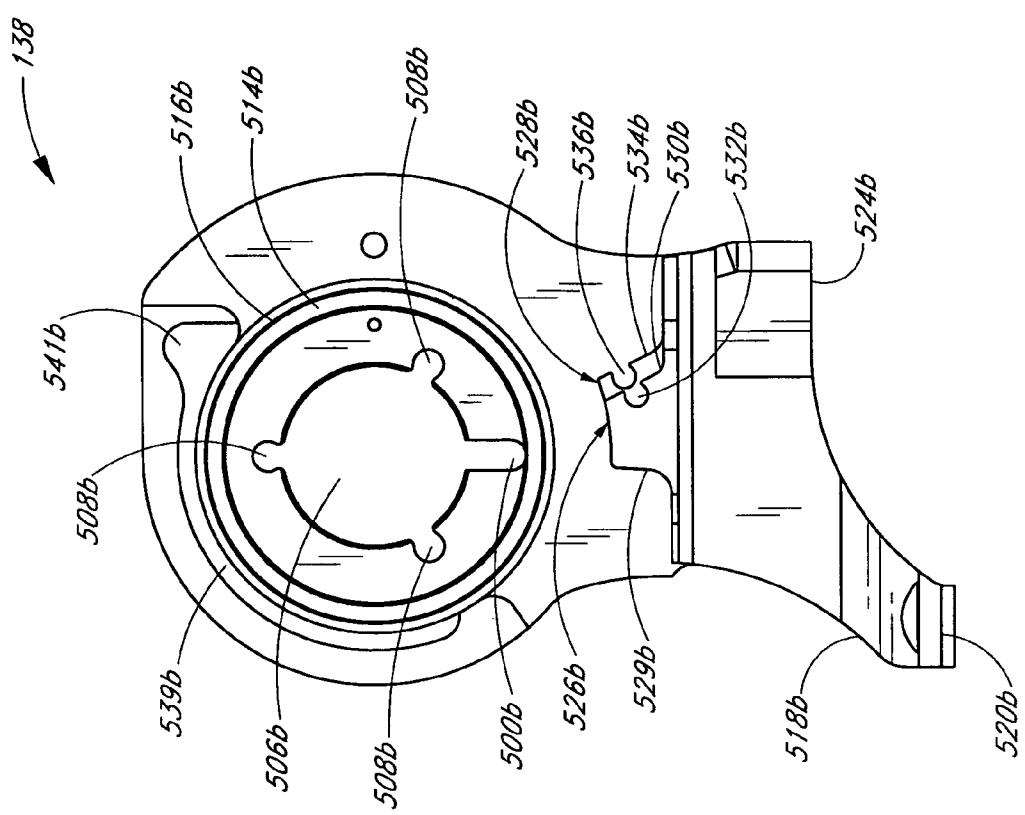


FIG. 71

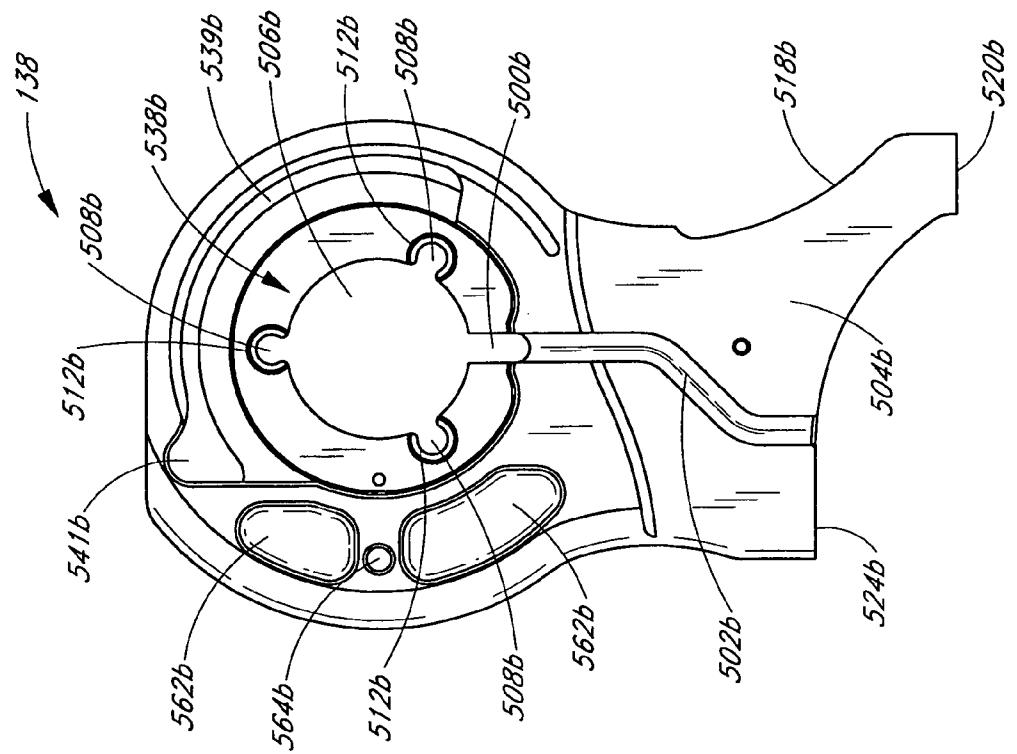
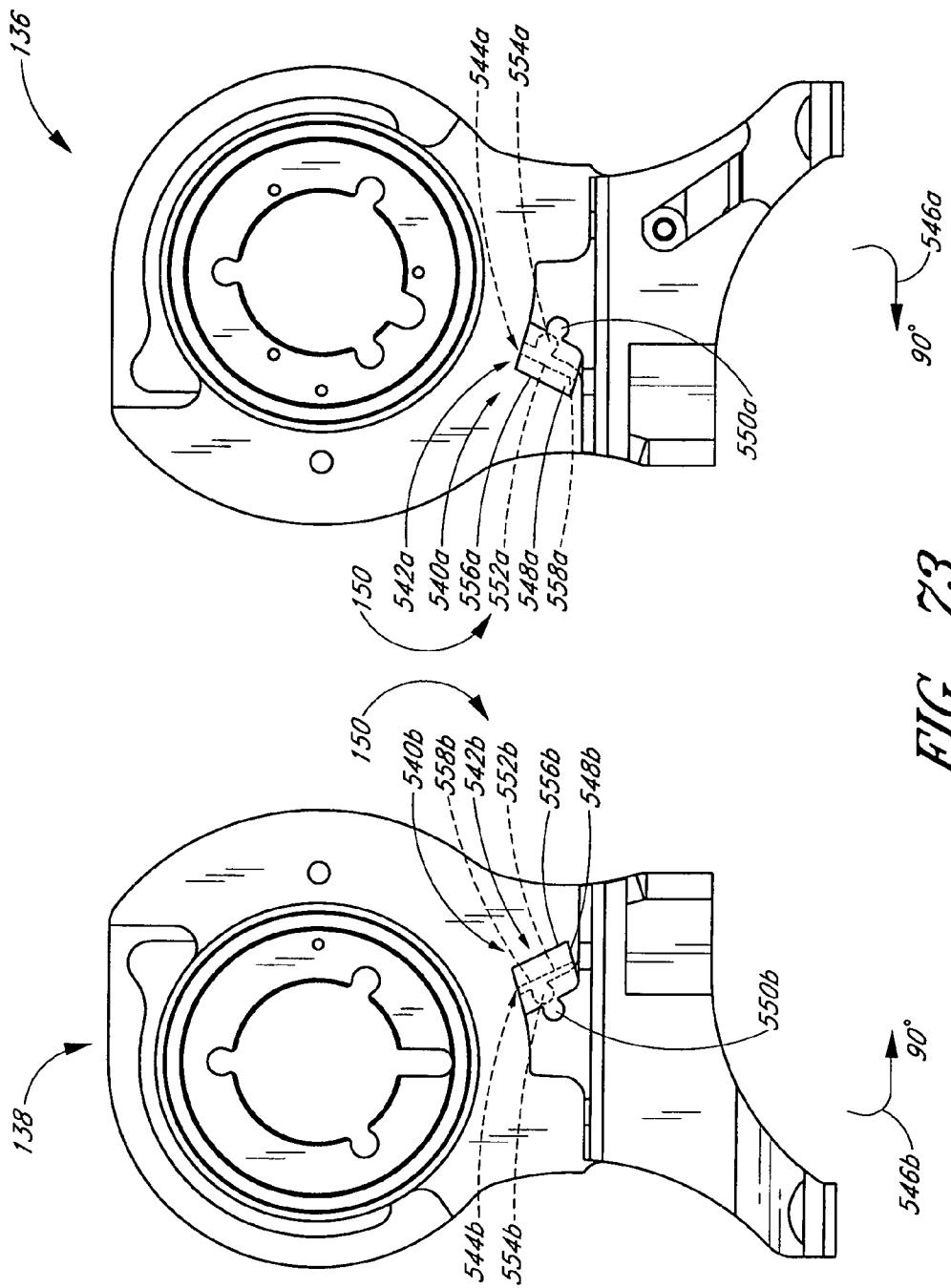


FIG. 72



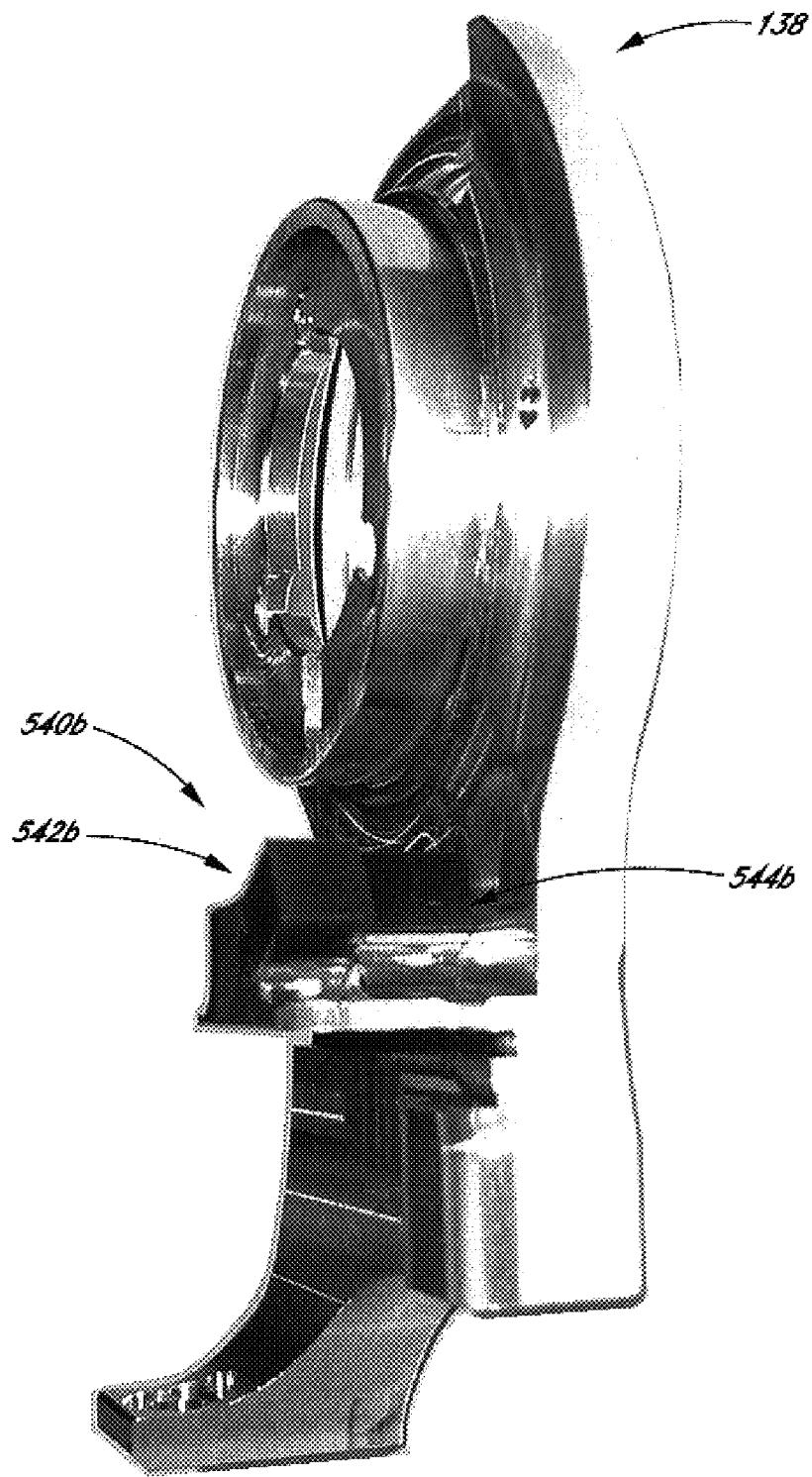


FIG. 74

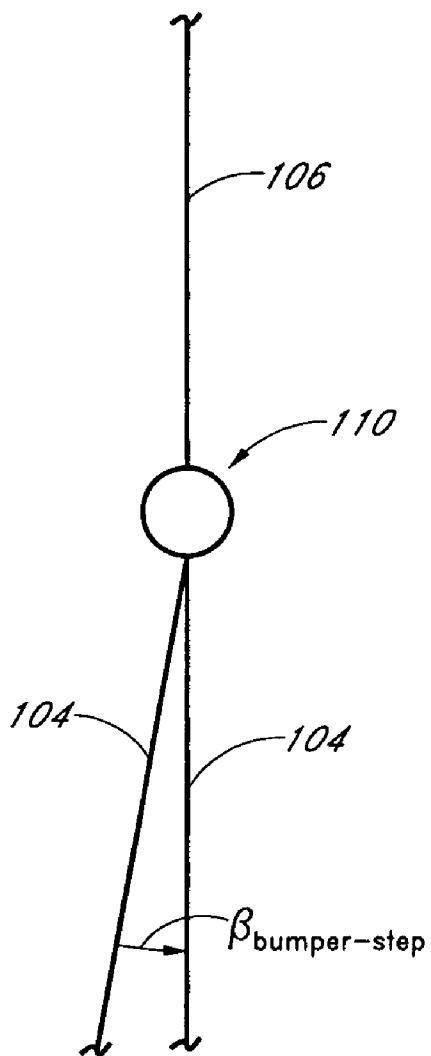


FIG. 75

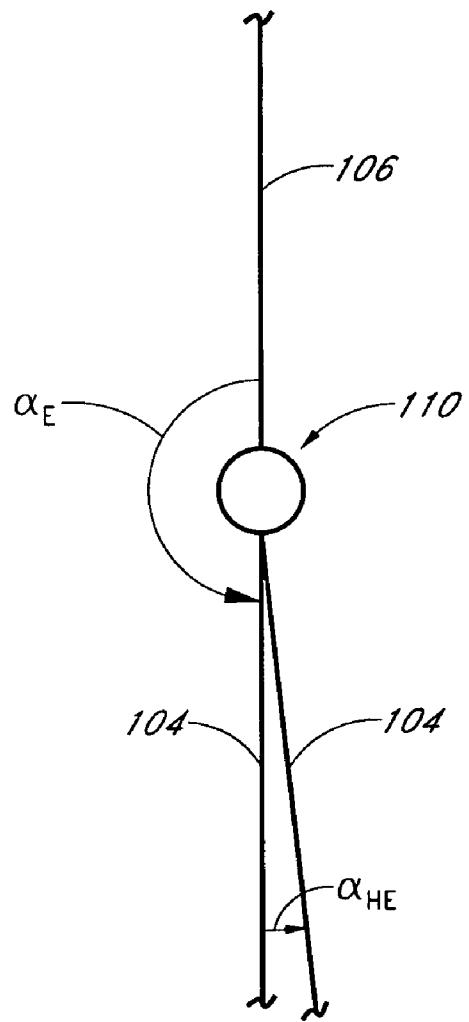


FIG. 76

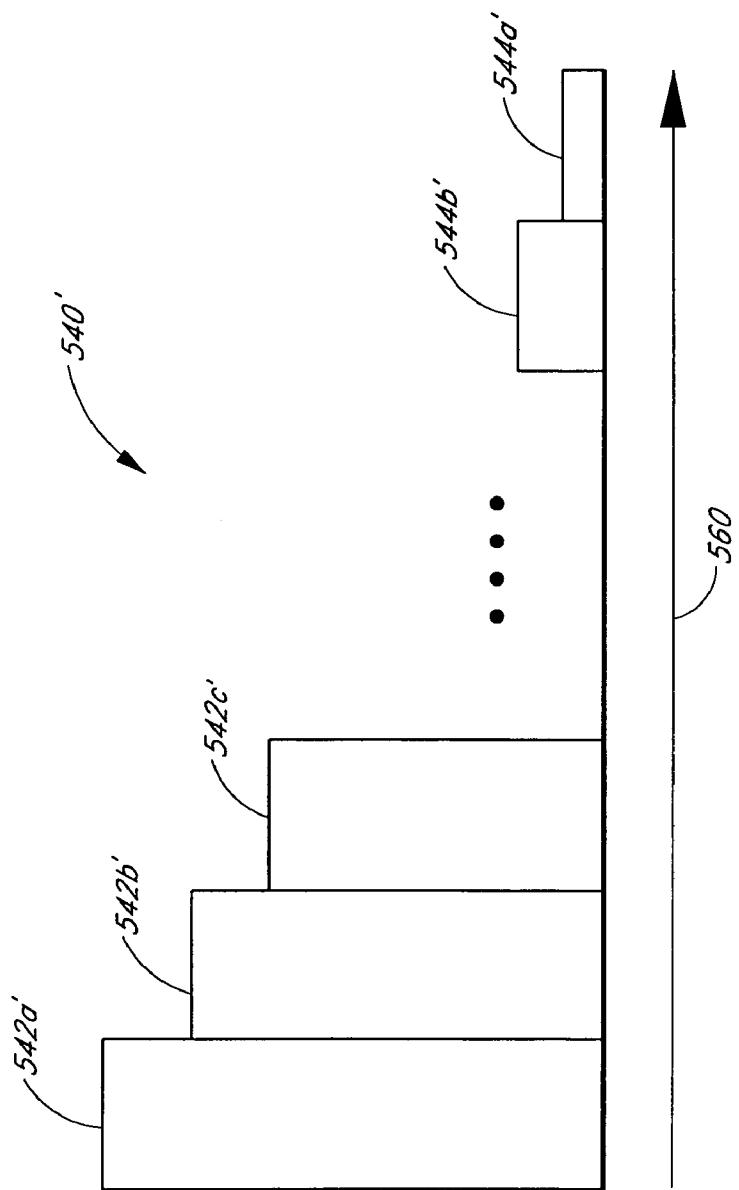


FIG. 77

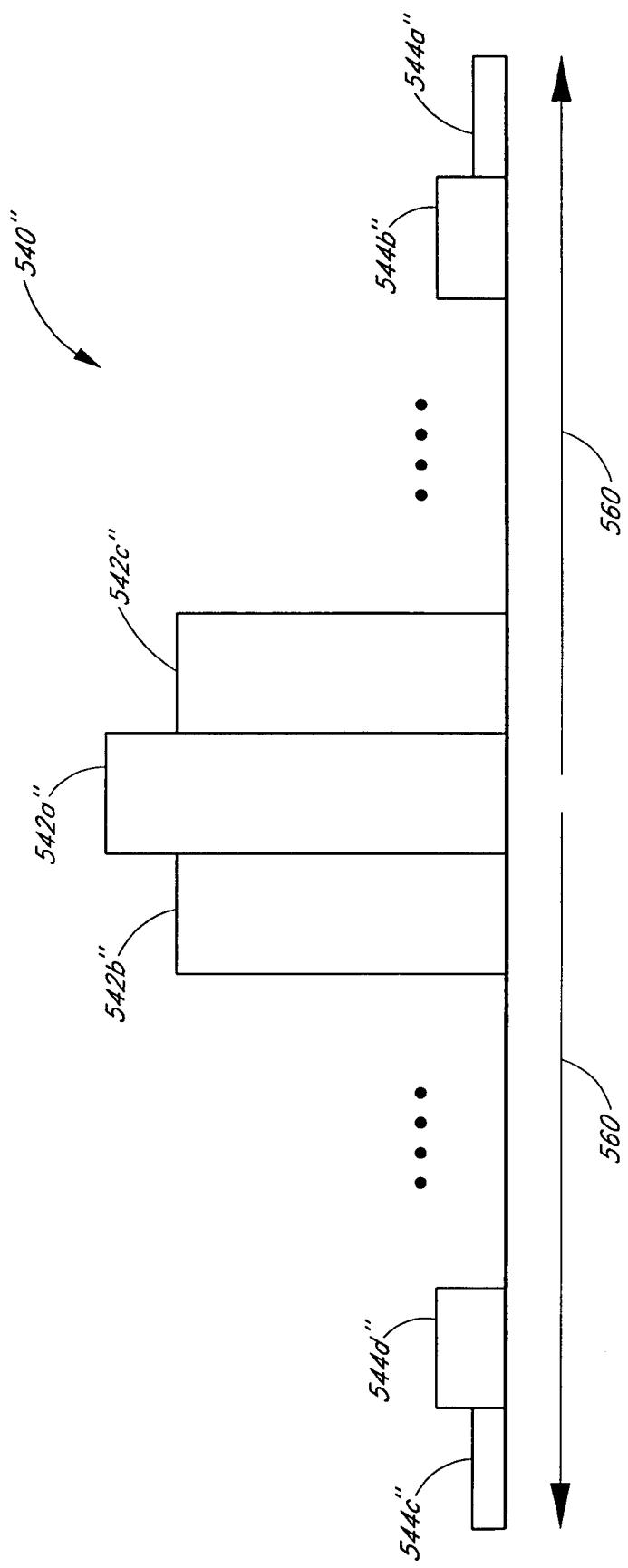


FIG. 78

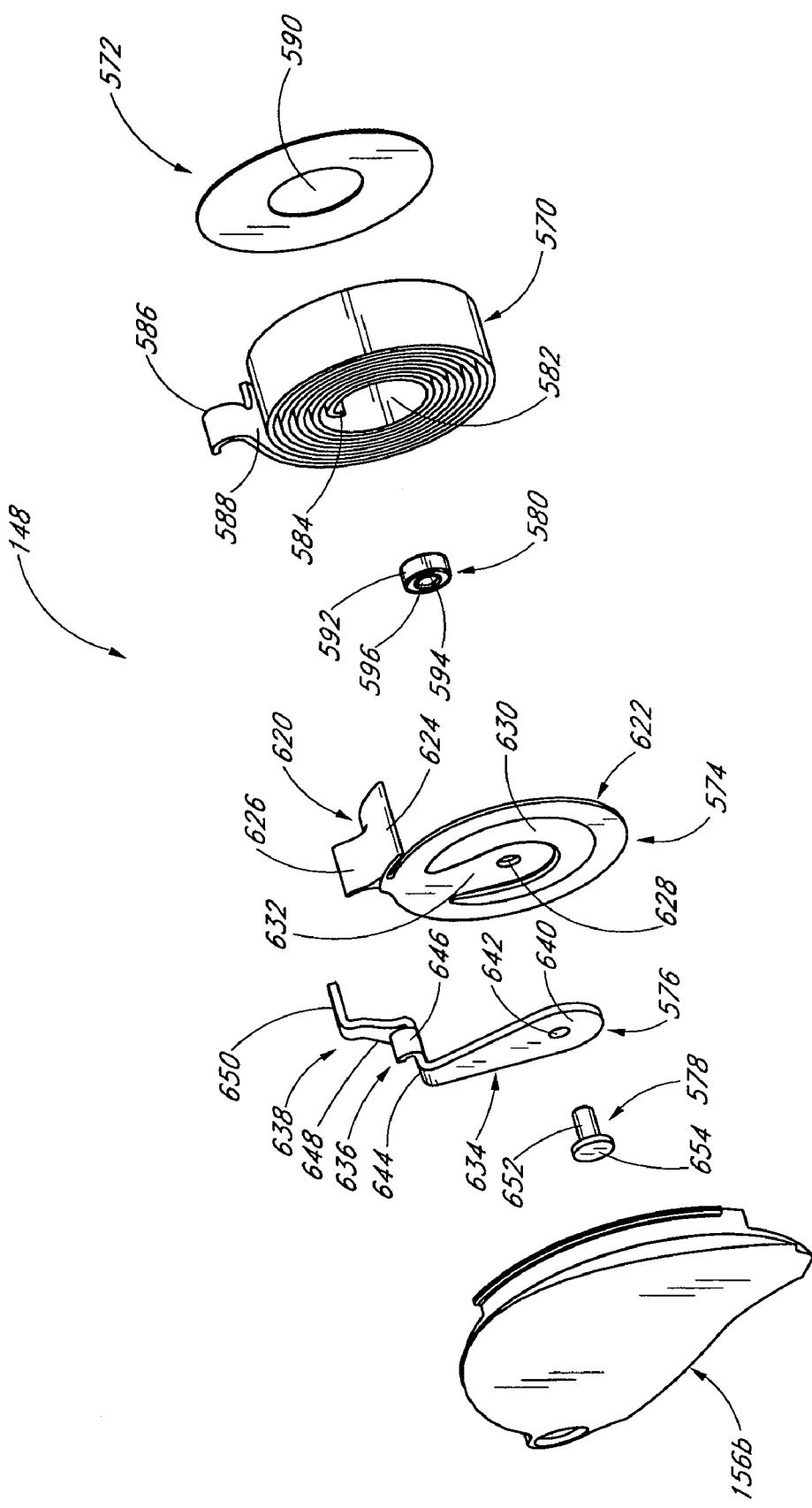


FIG. 79

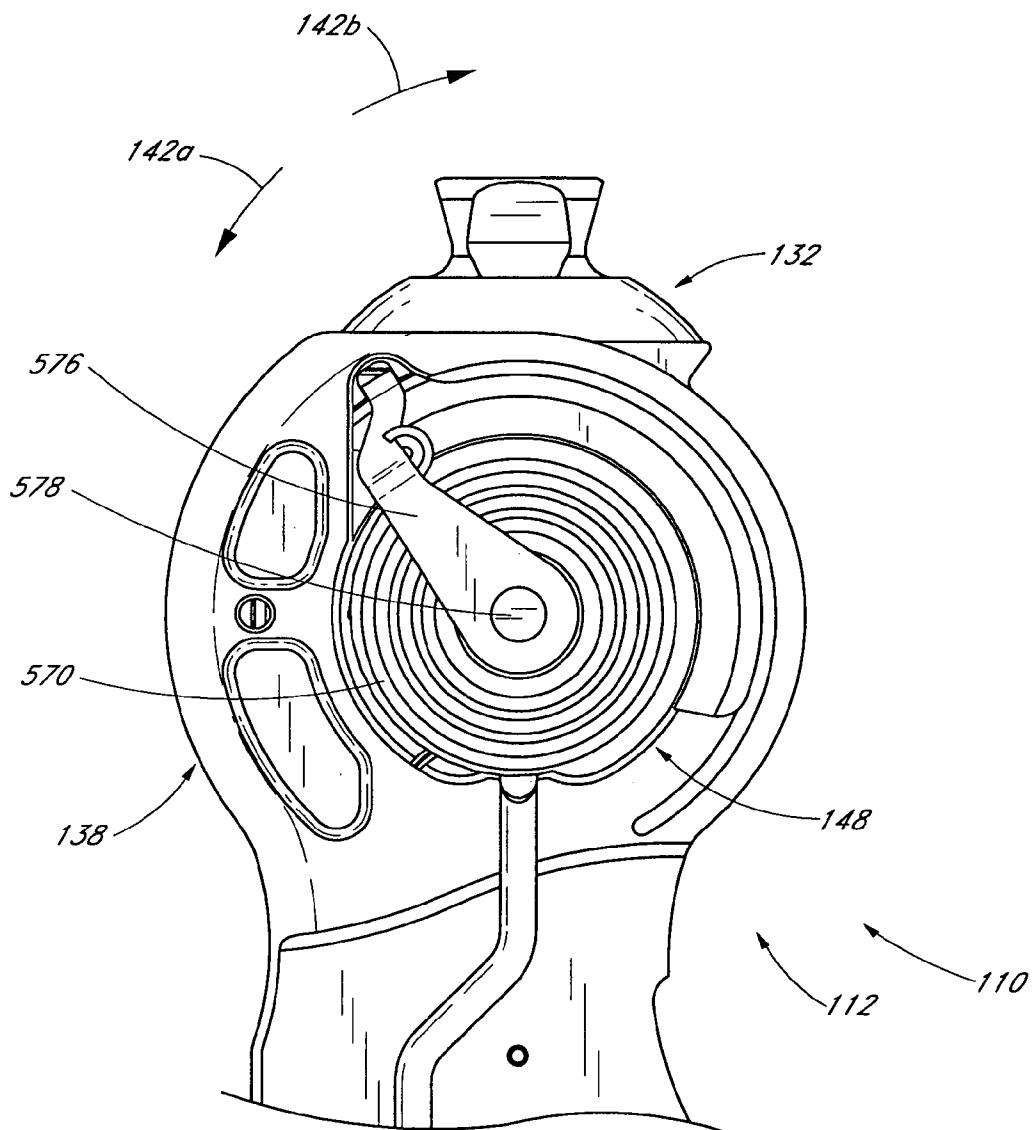


FIG. 80

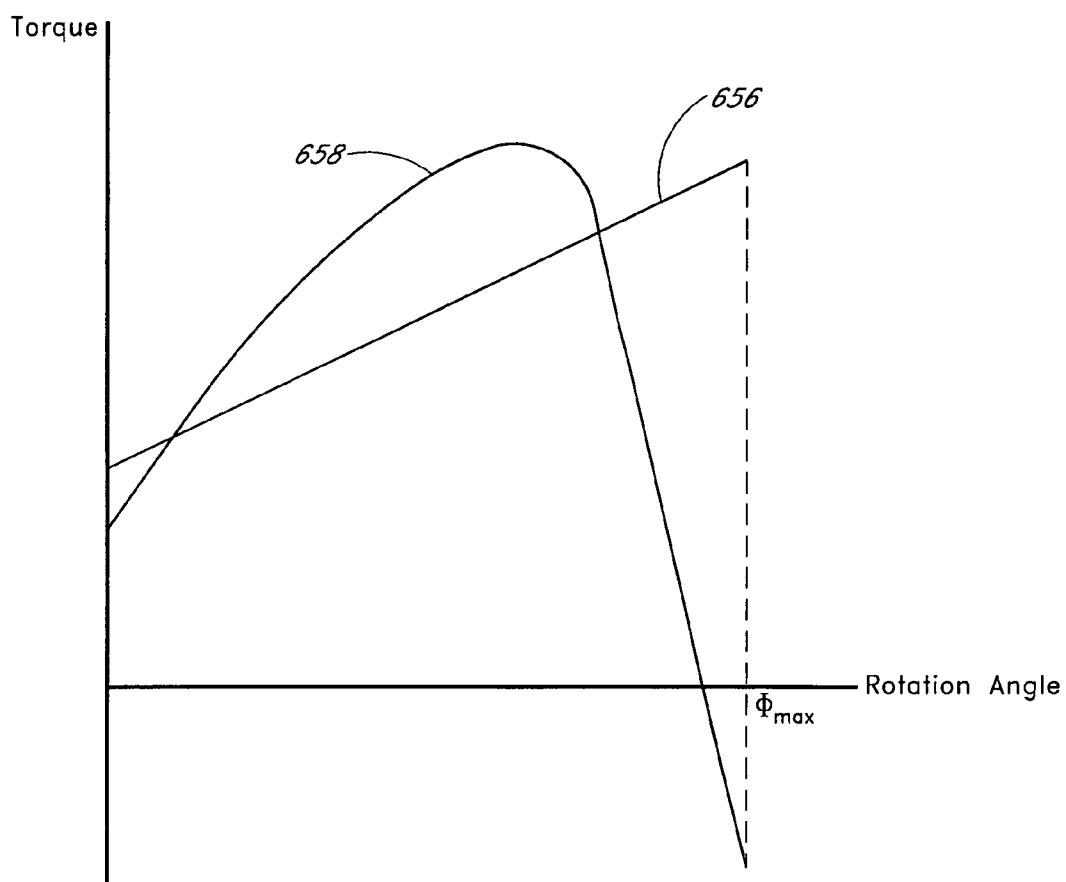


FIG. 81

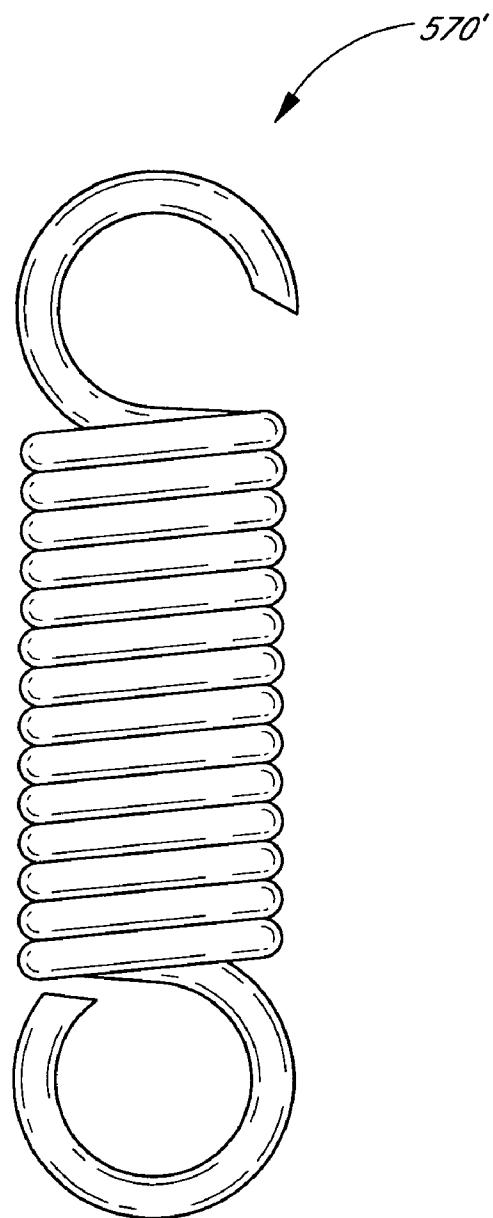


FIG. 82

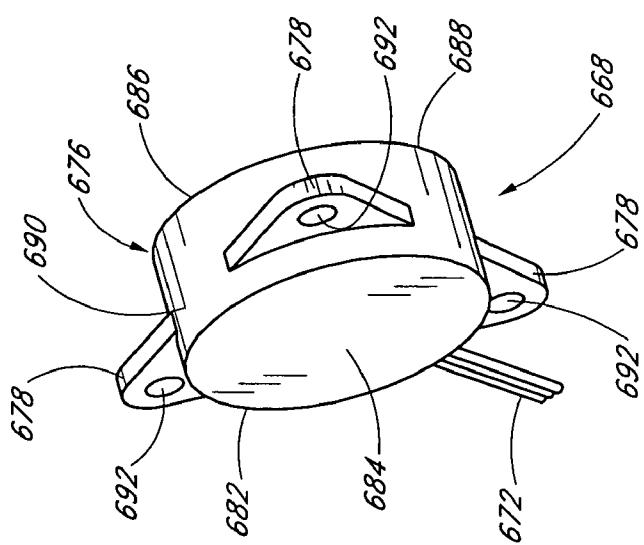
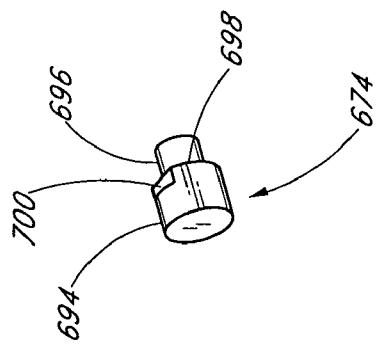
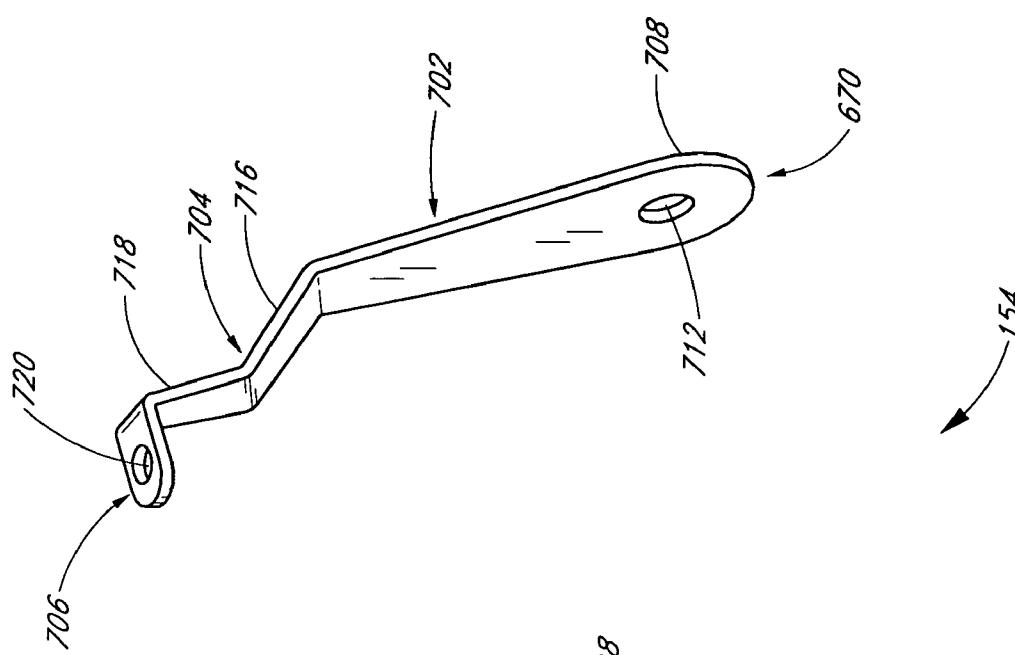


FIG. 83

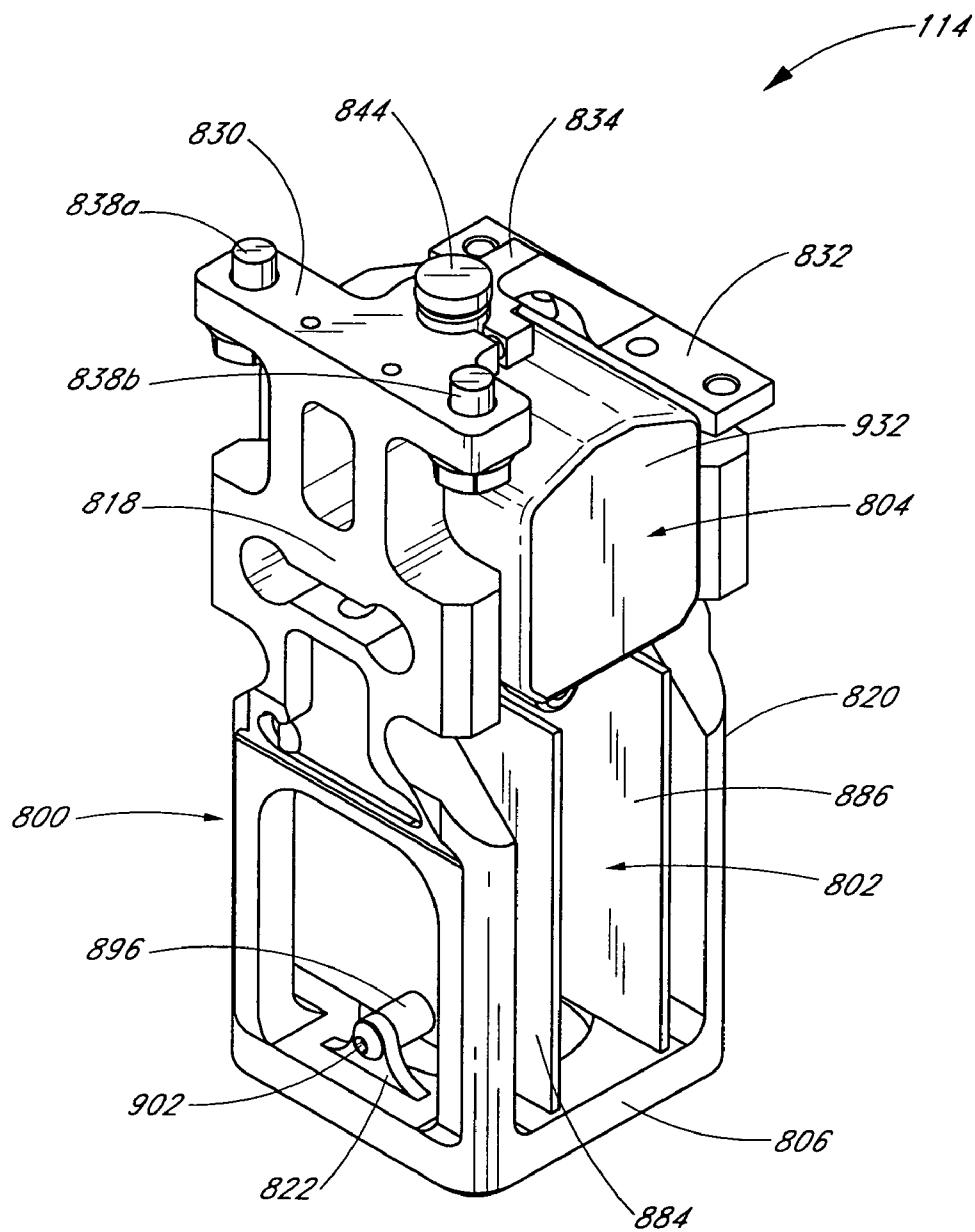


FIG. 84

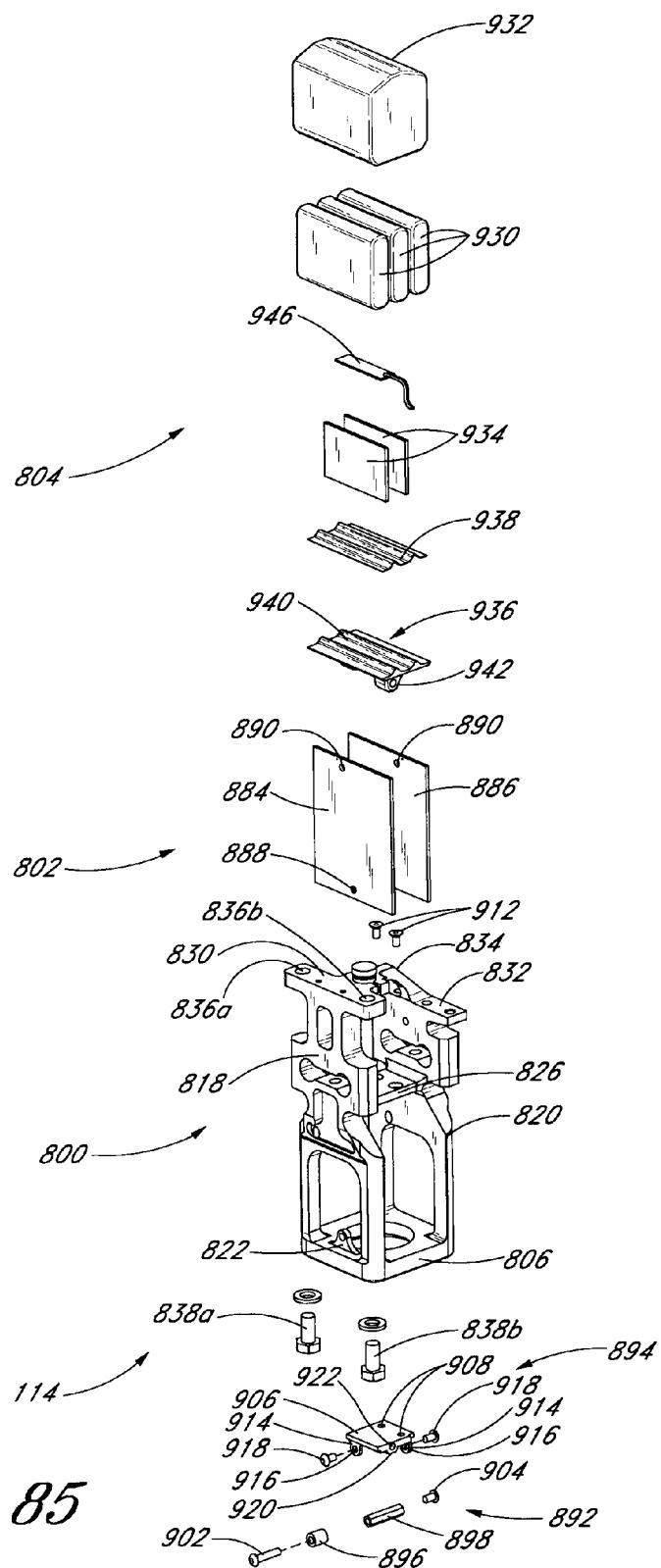


FIG. 85

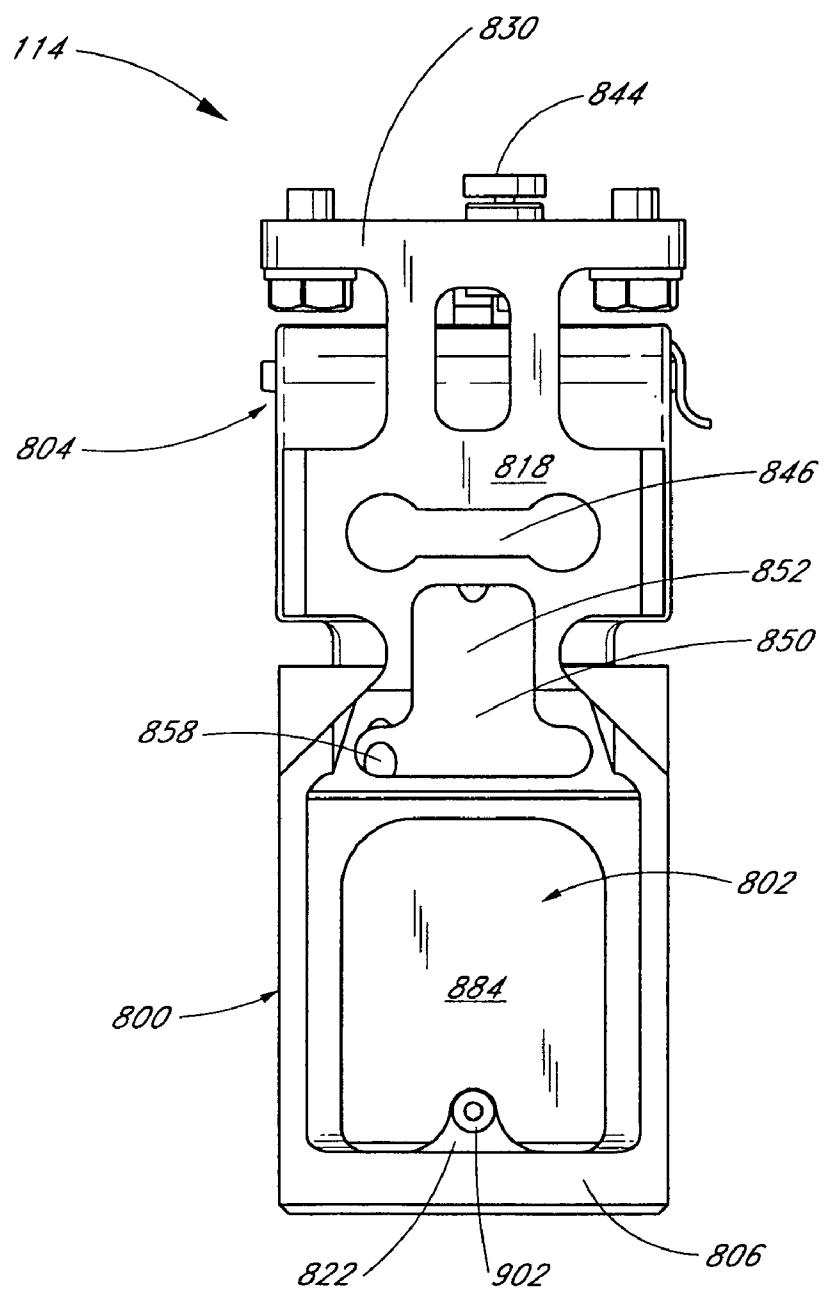


FIG. 86

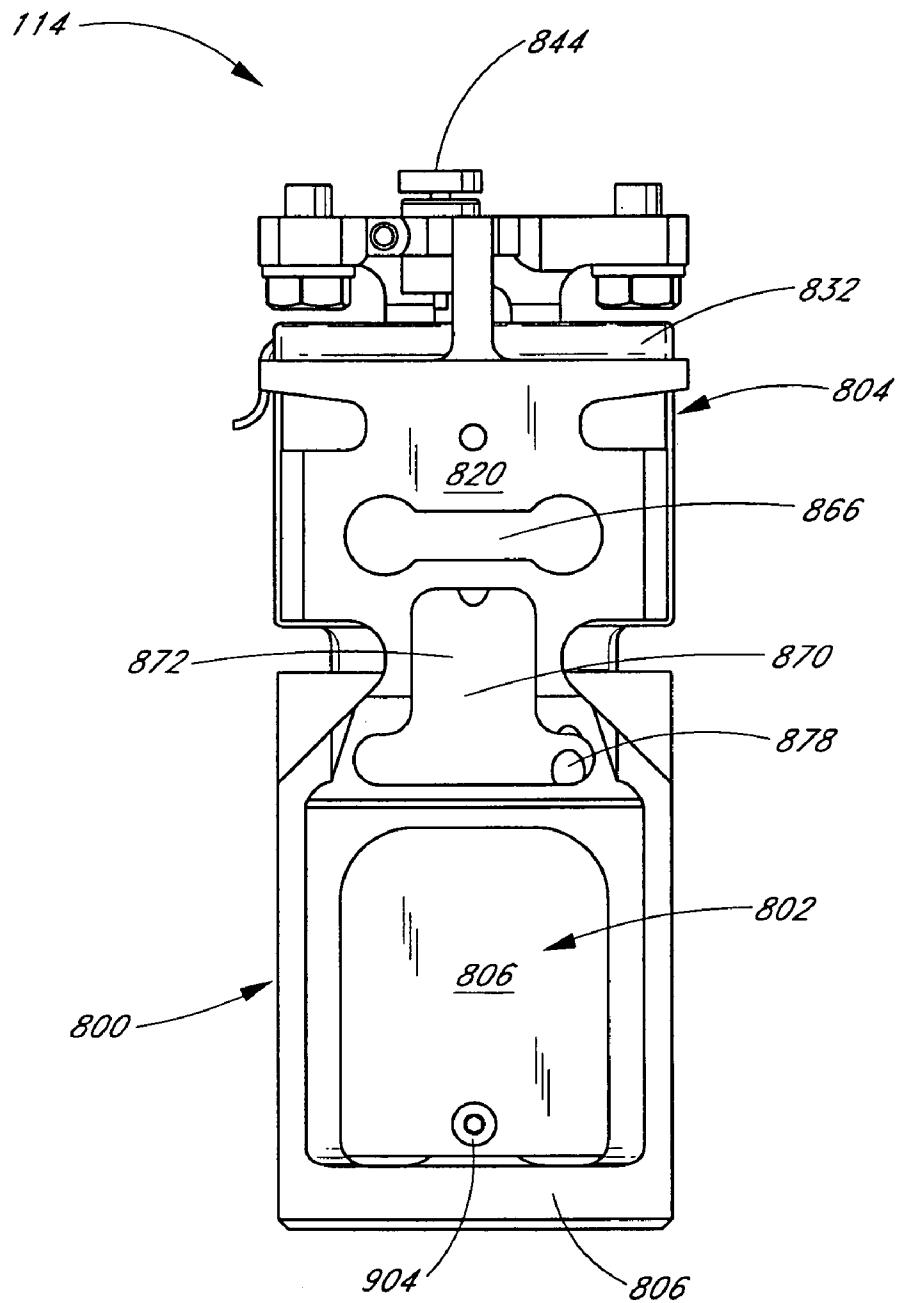


FIG. 87

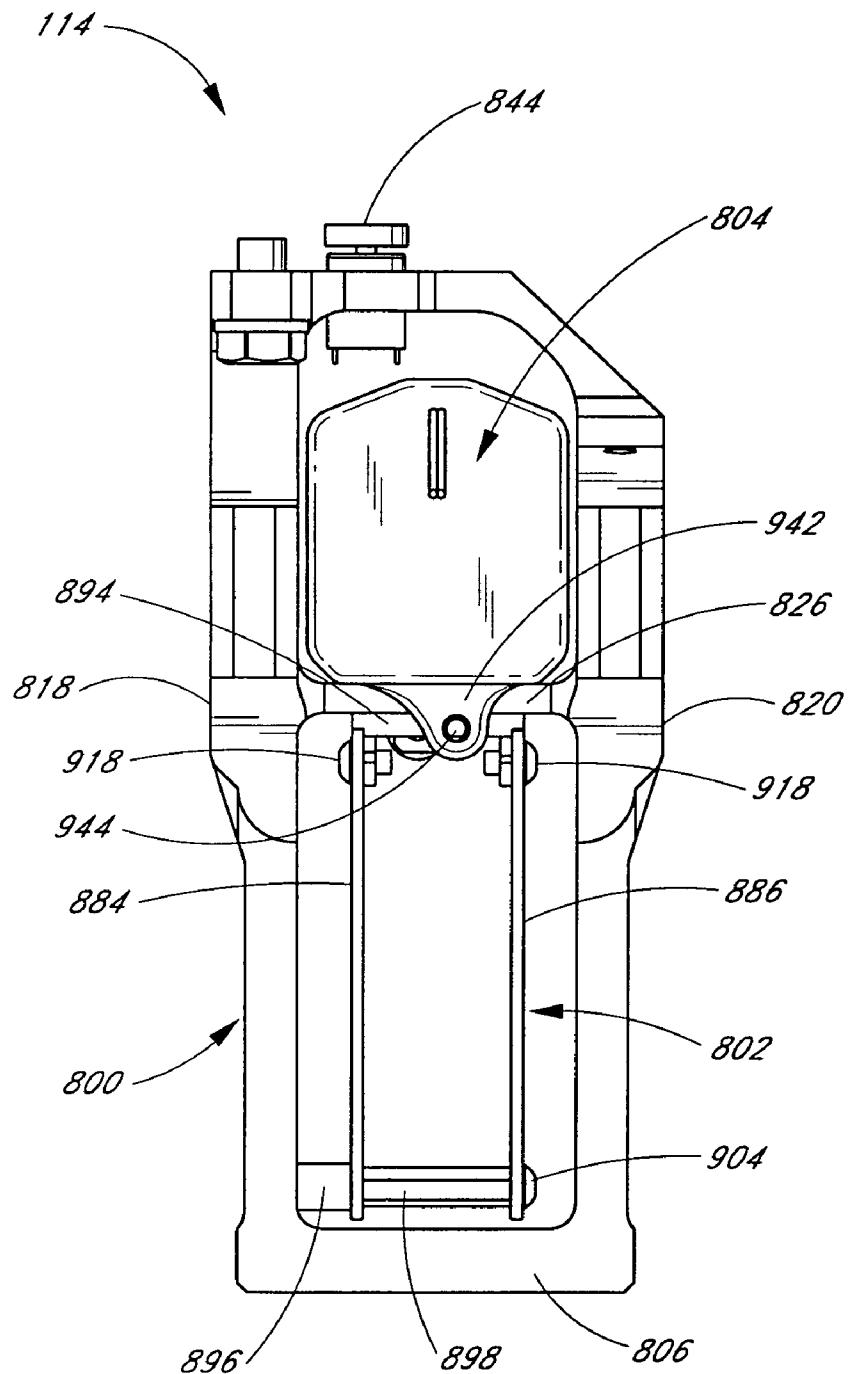


FIG. 88

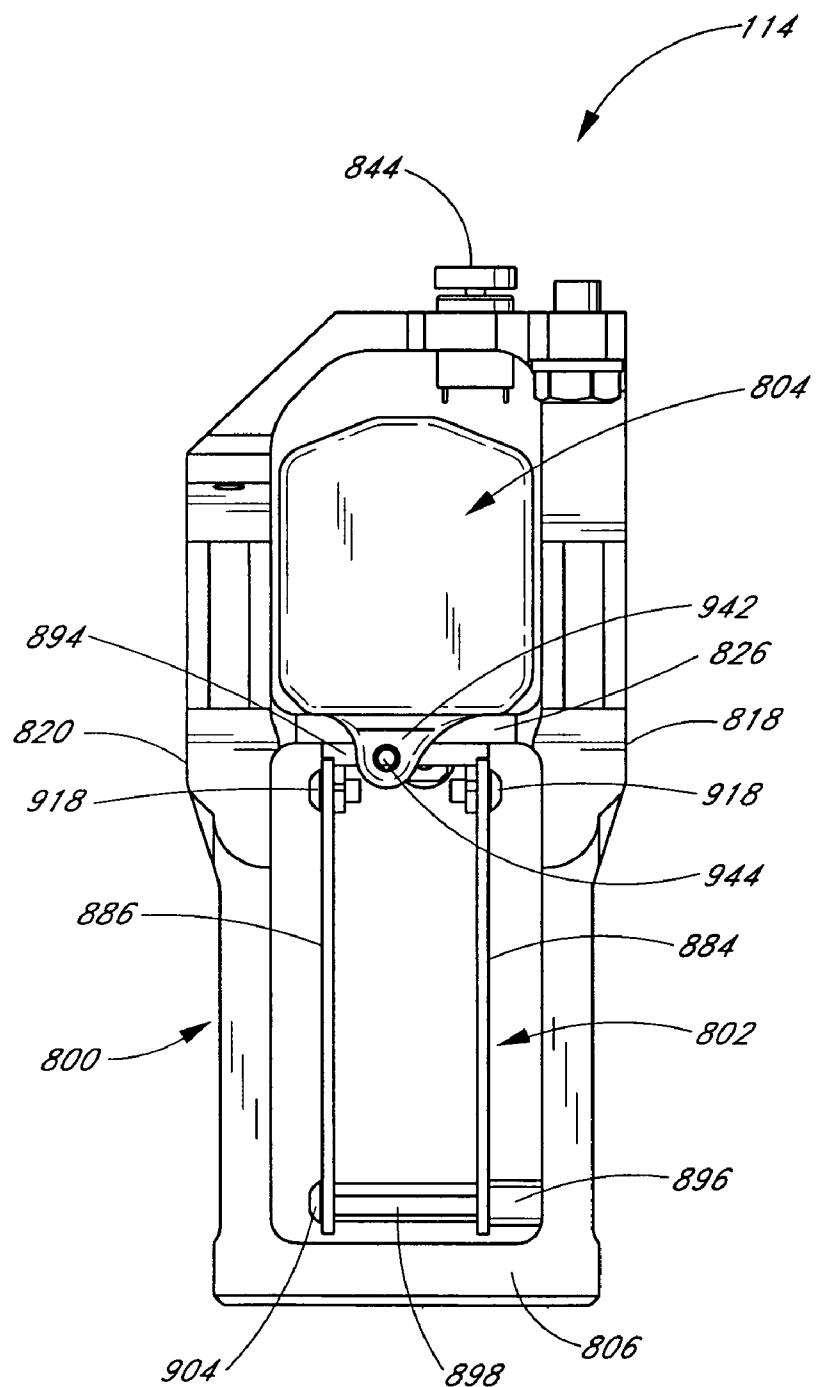


FIG. 89

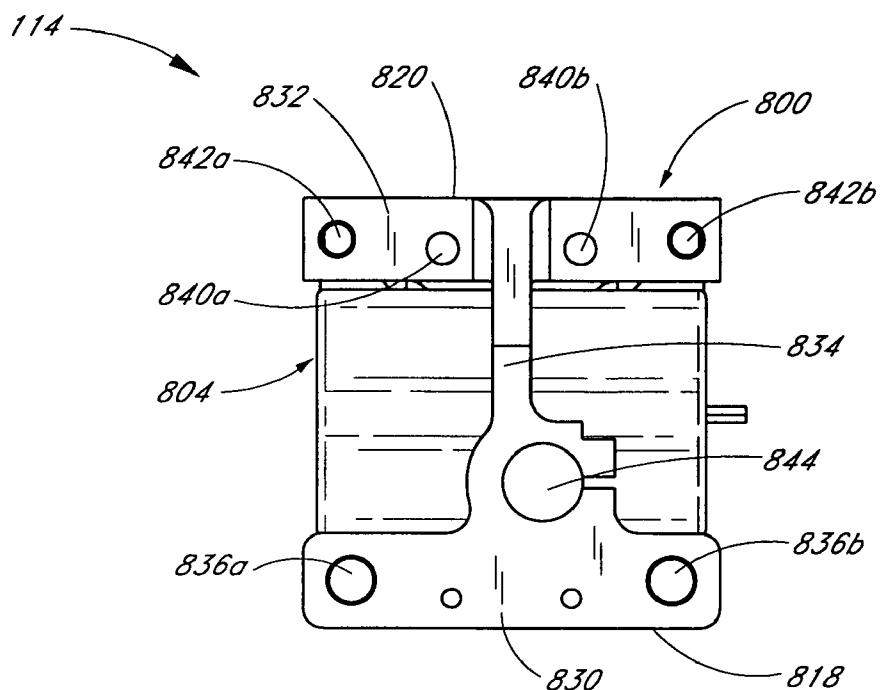


FIG. 90

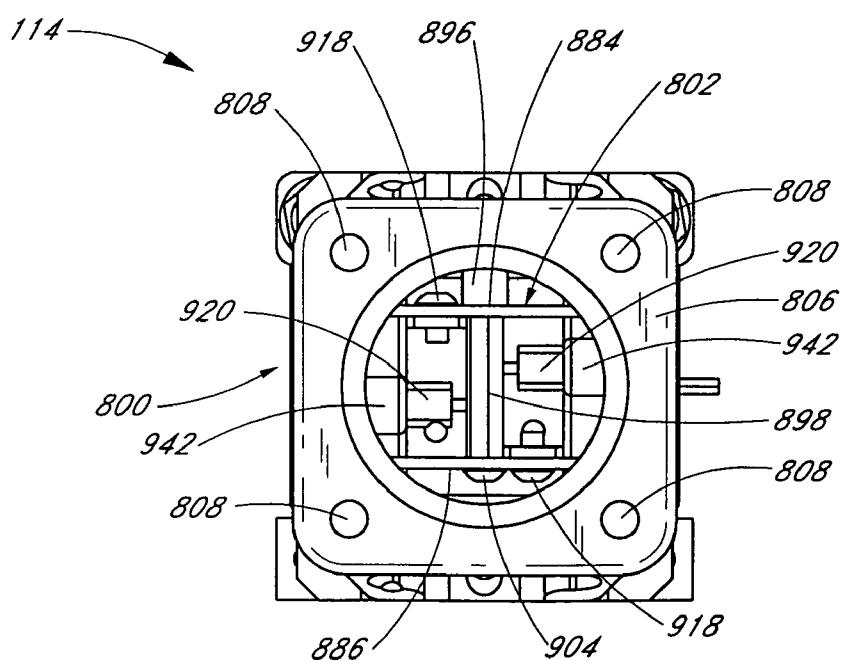


FIG. 91

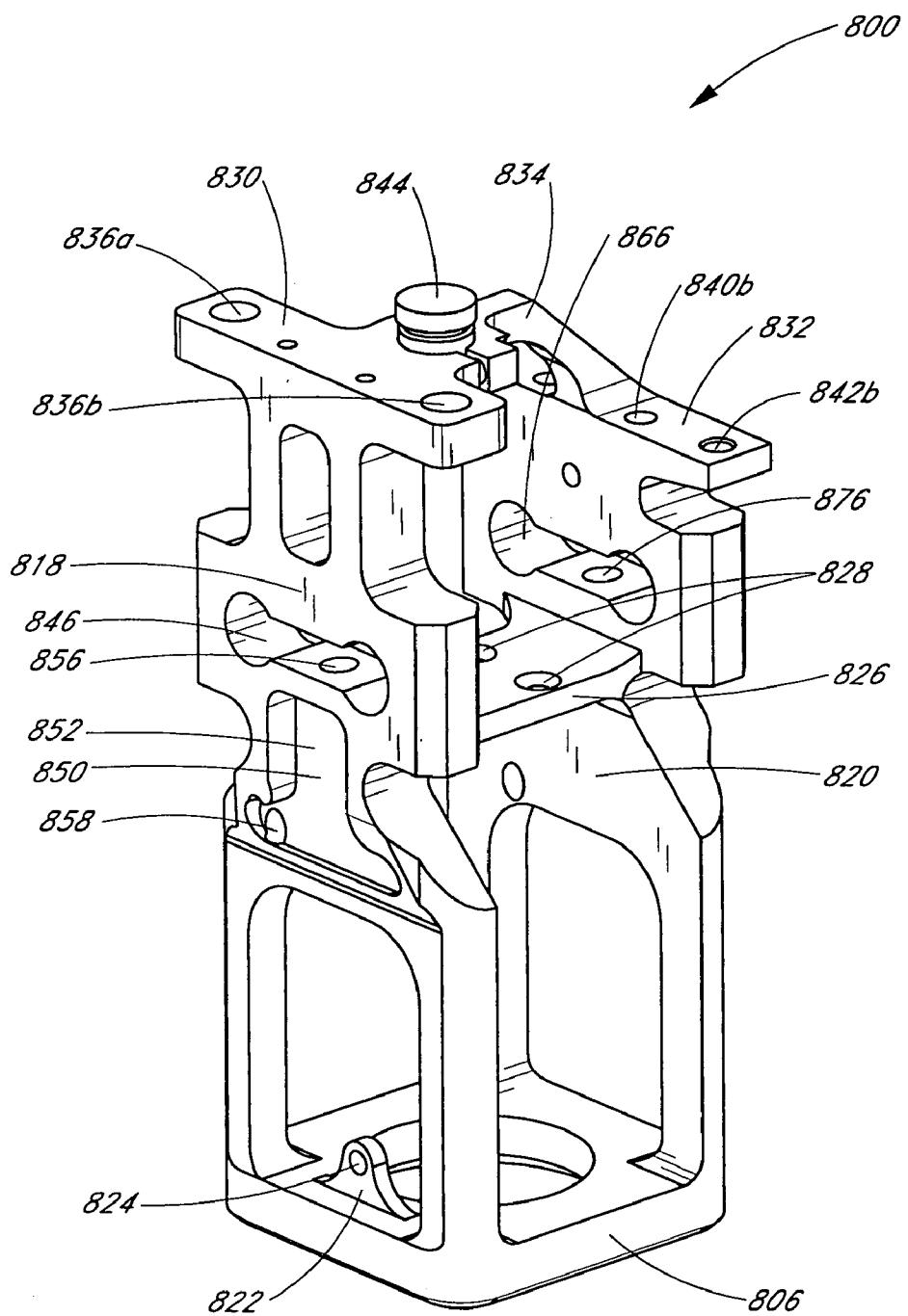


FIG. 92

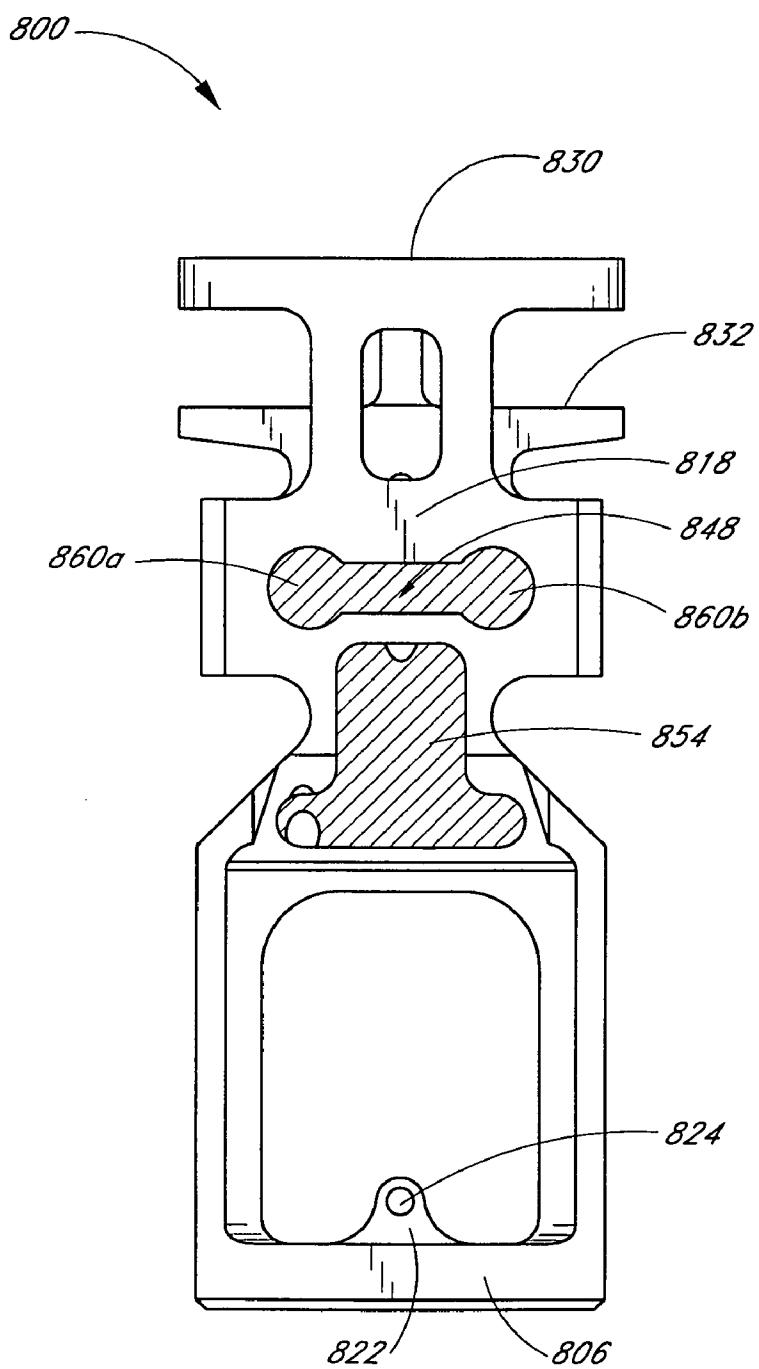


FIG. 93

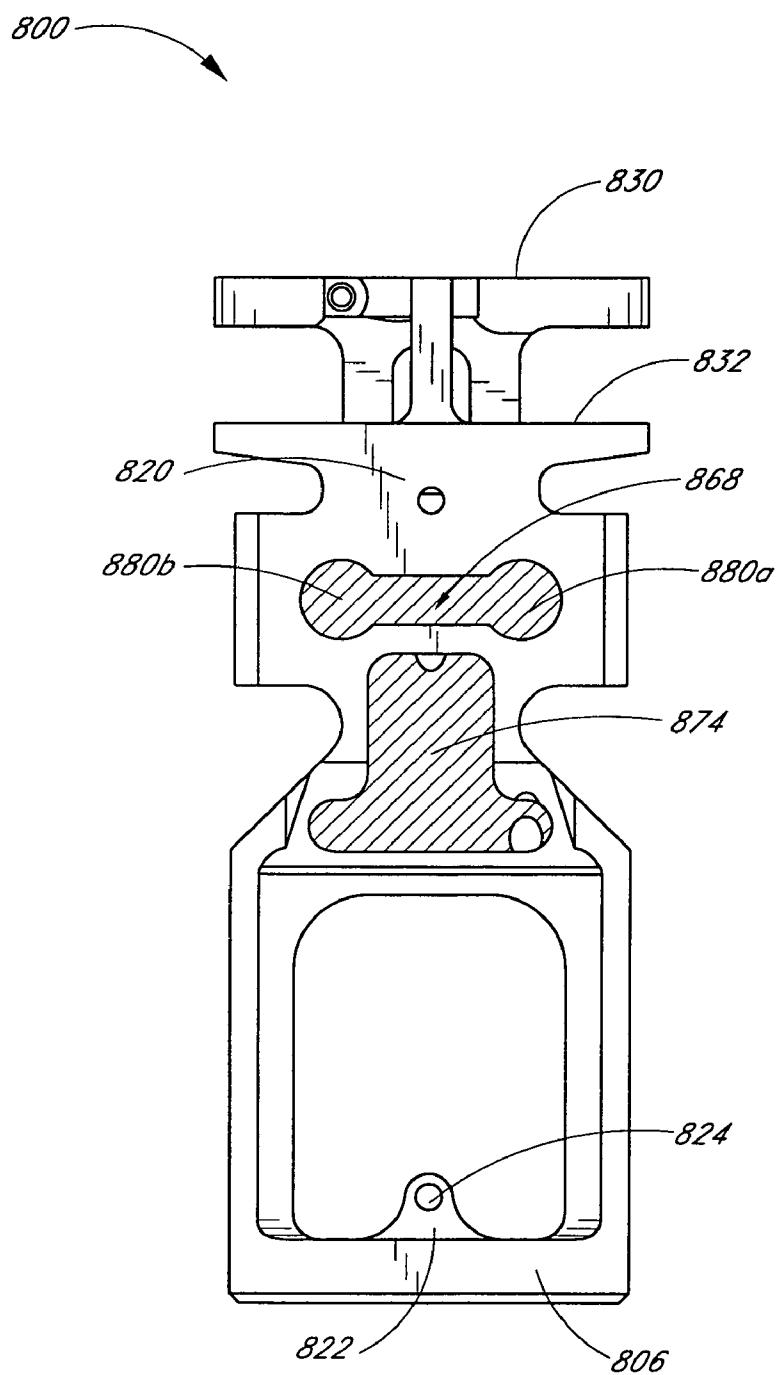


FIG. 94

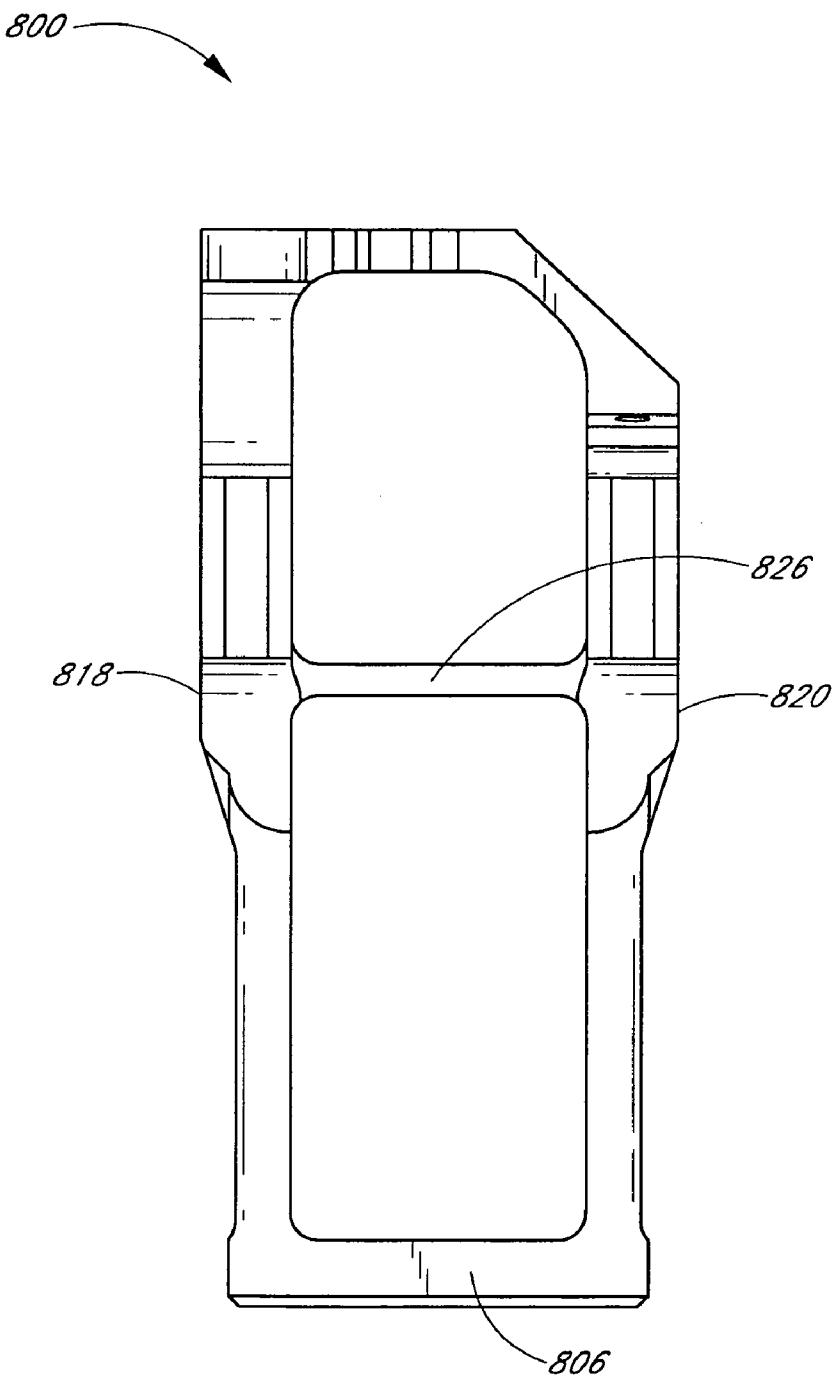


FIG. 95

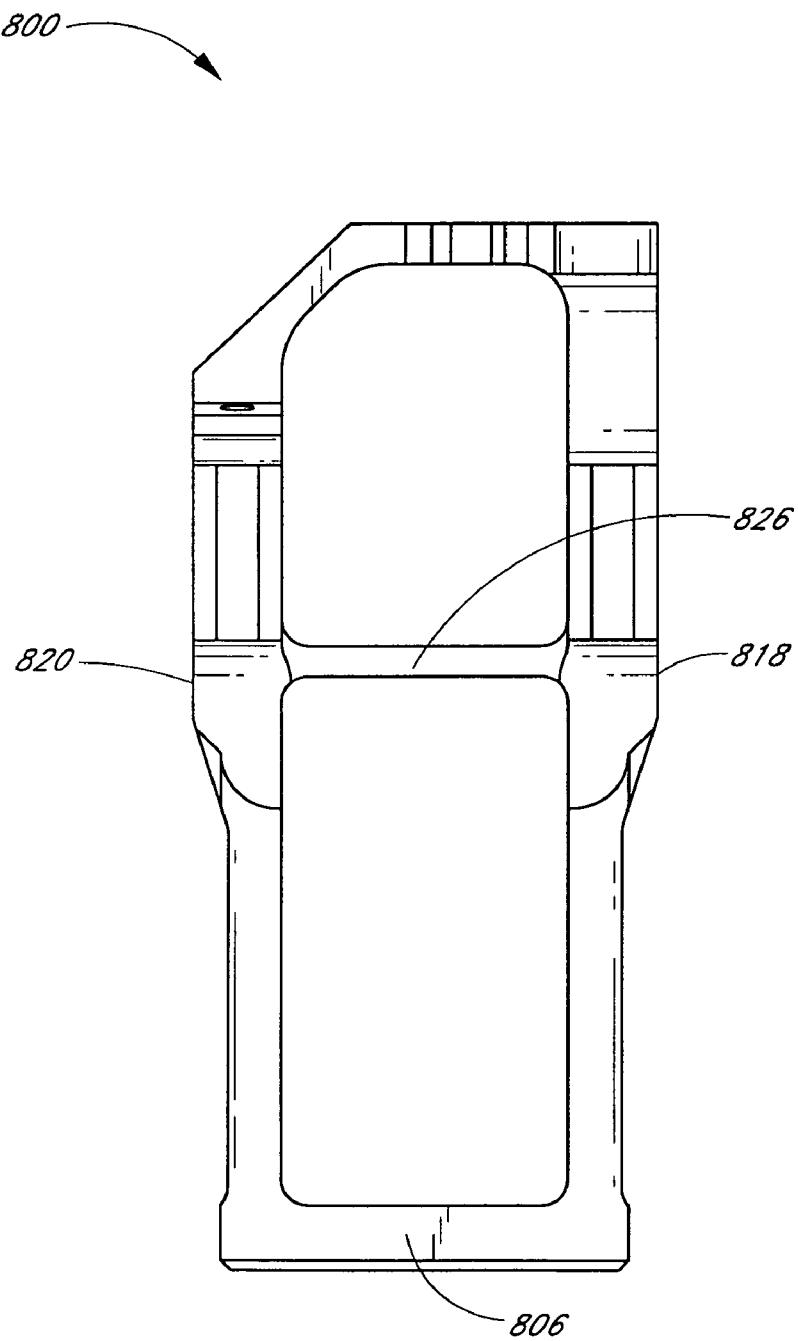


FIG. 96

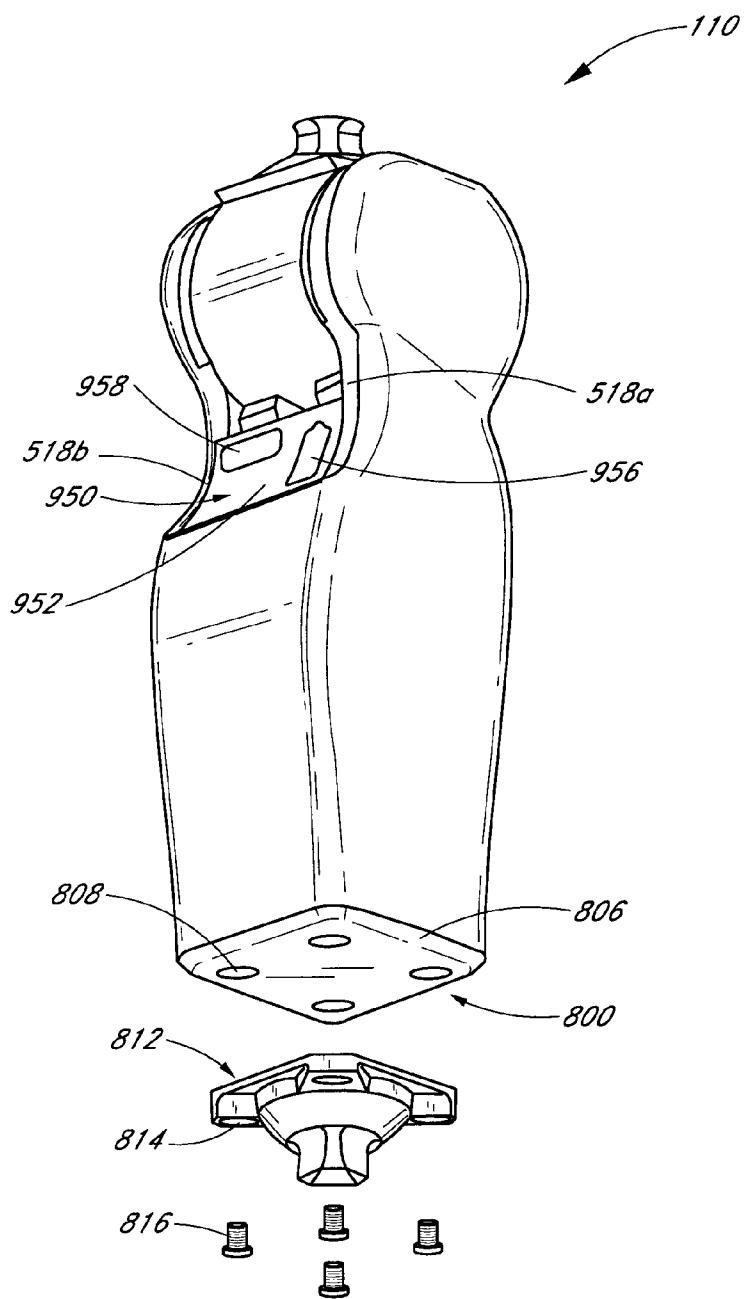


FIG. 97

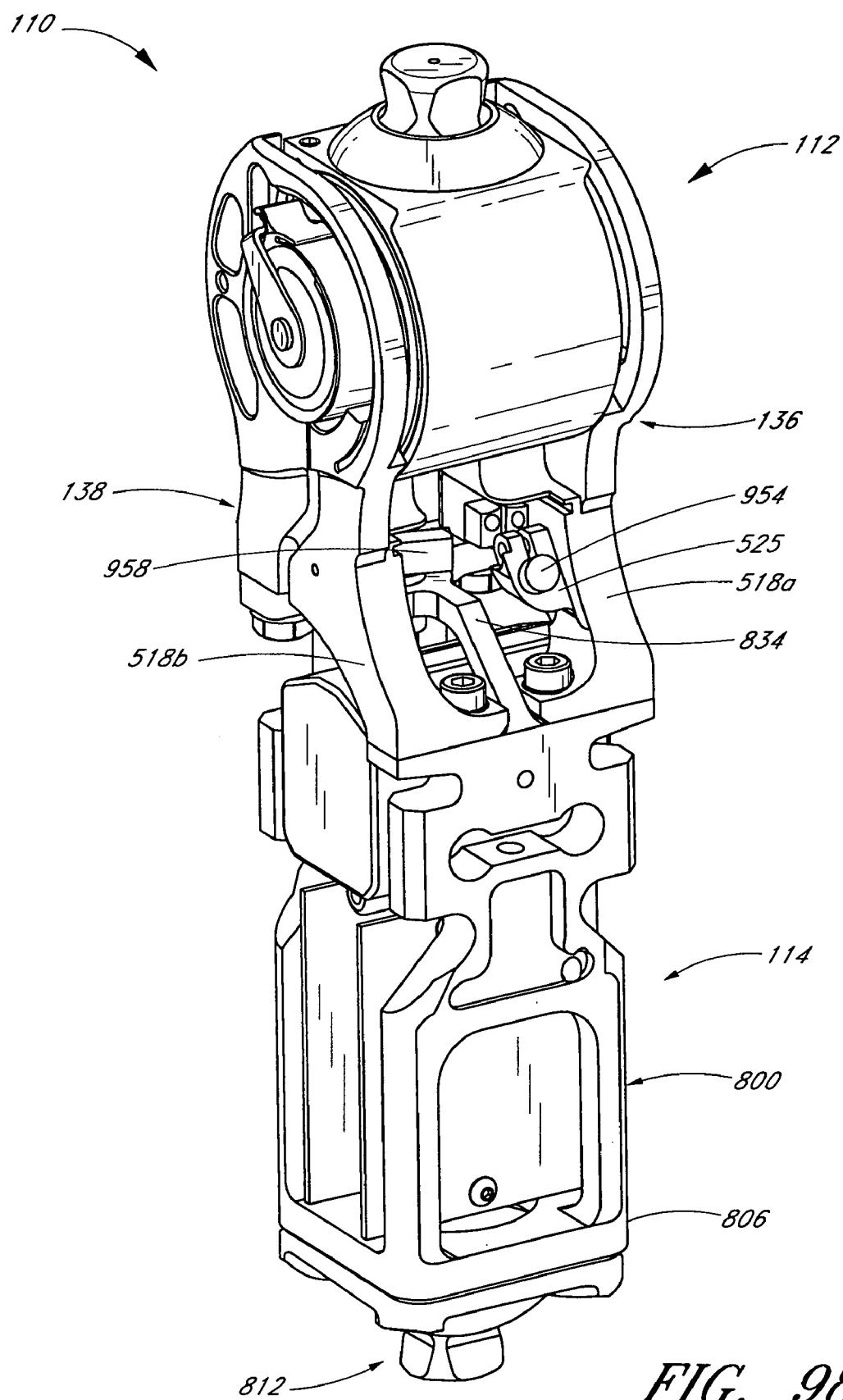


FIG. 98

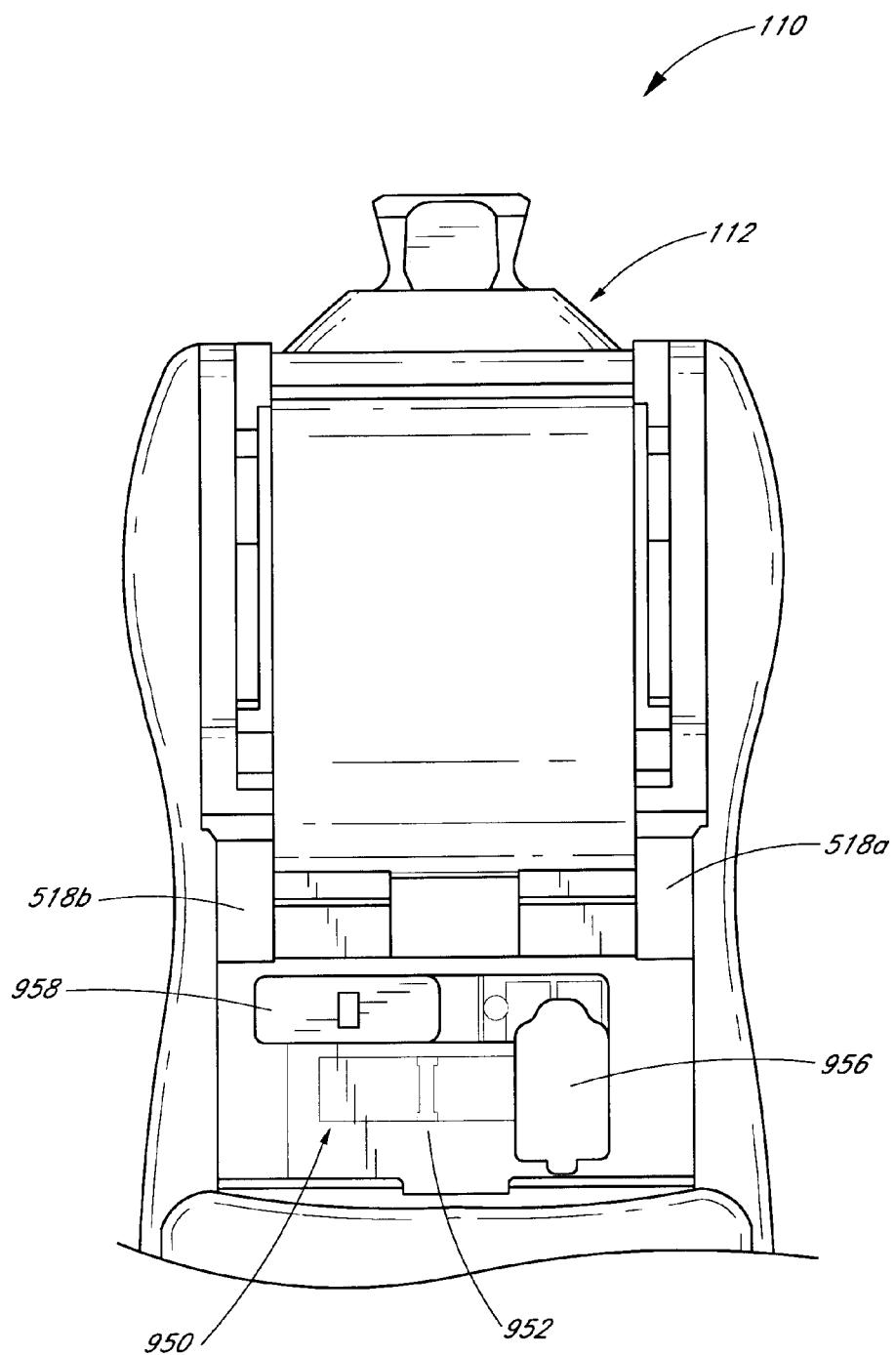


FIG. 99

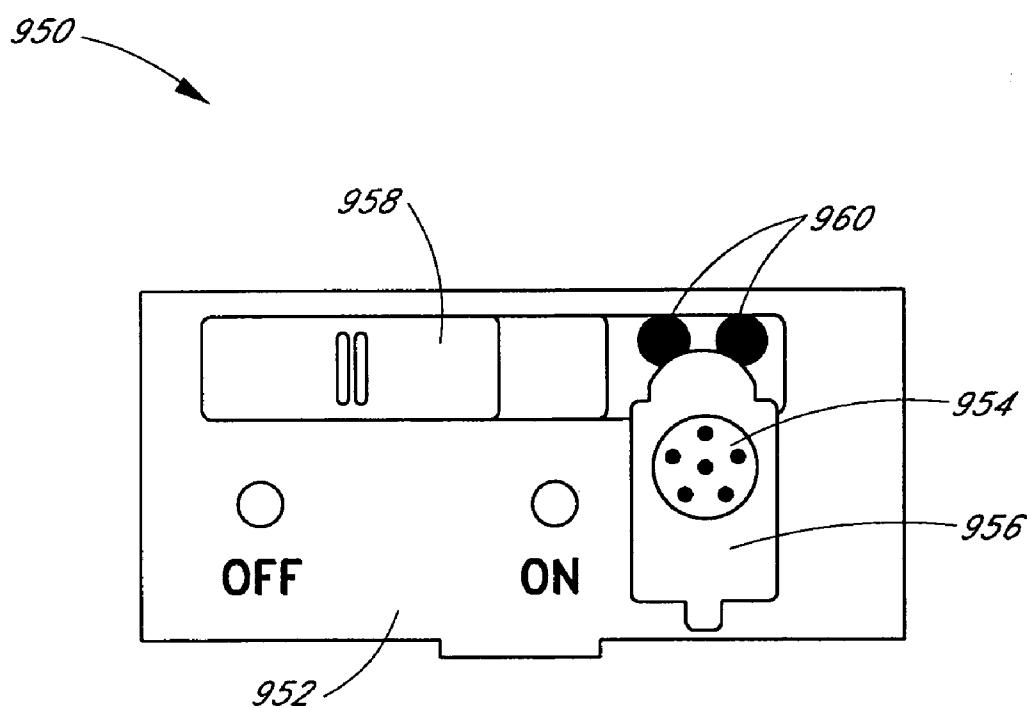


FIG. 100

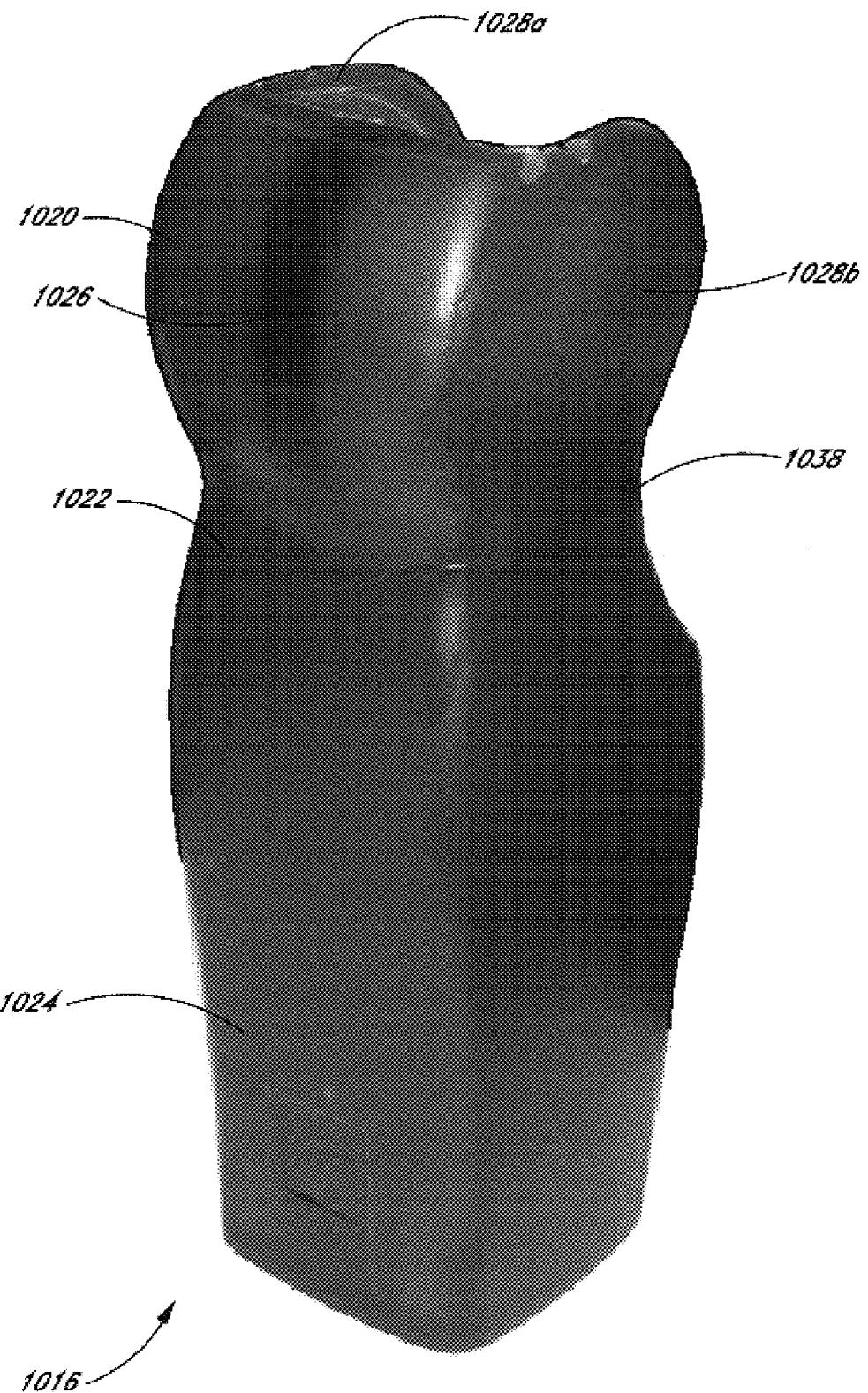


FIG. 101

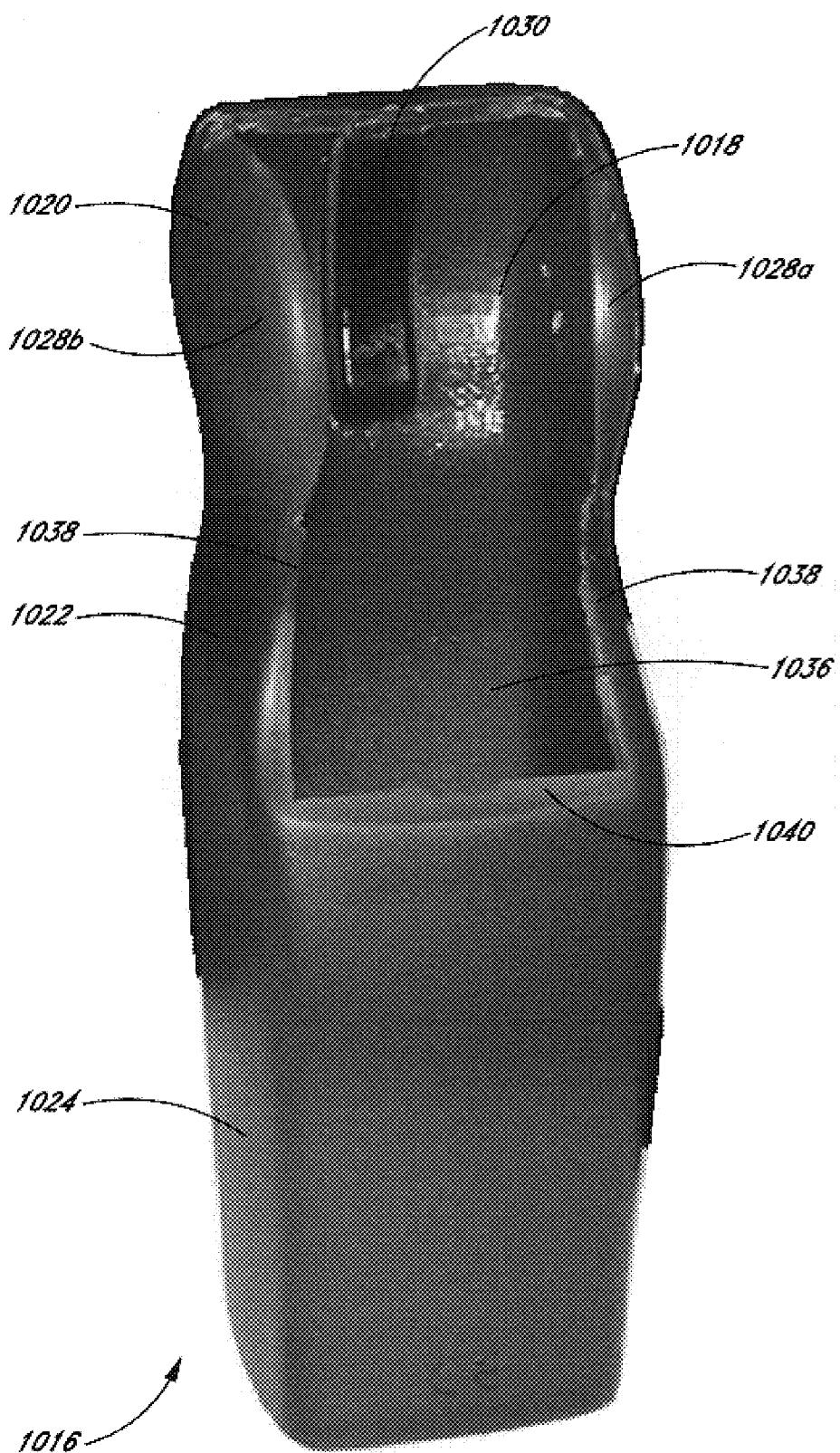


FIG. 102

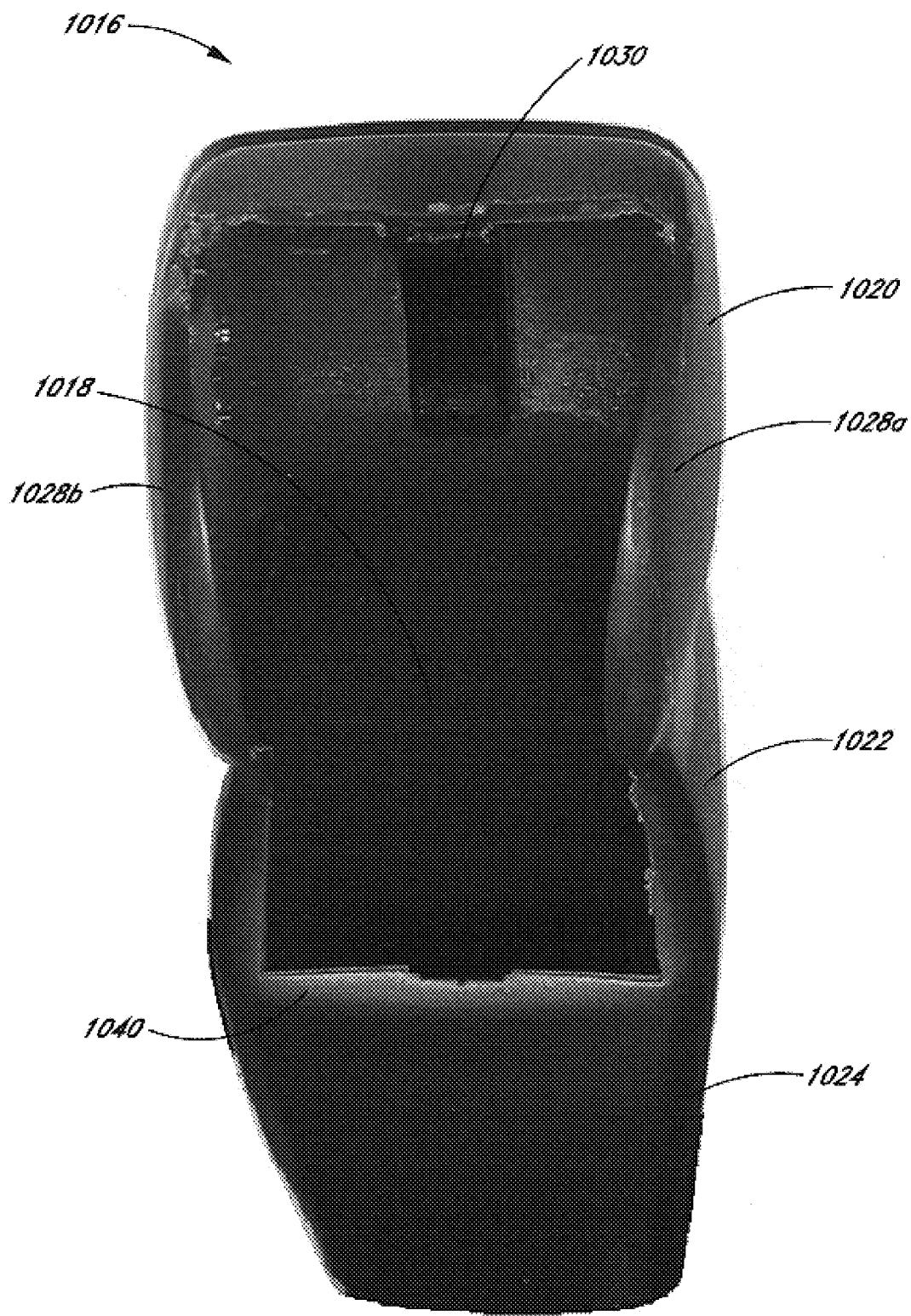


FIG. 103

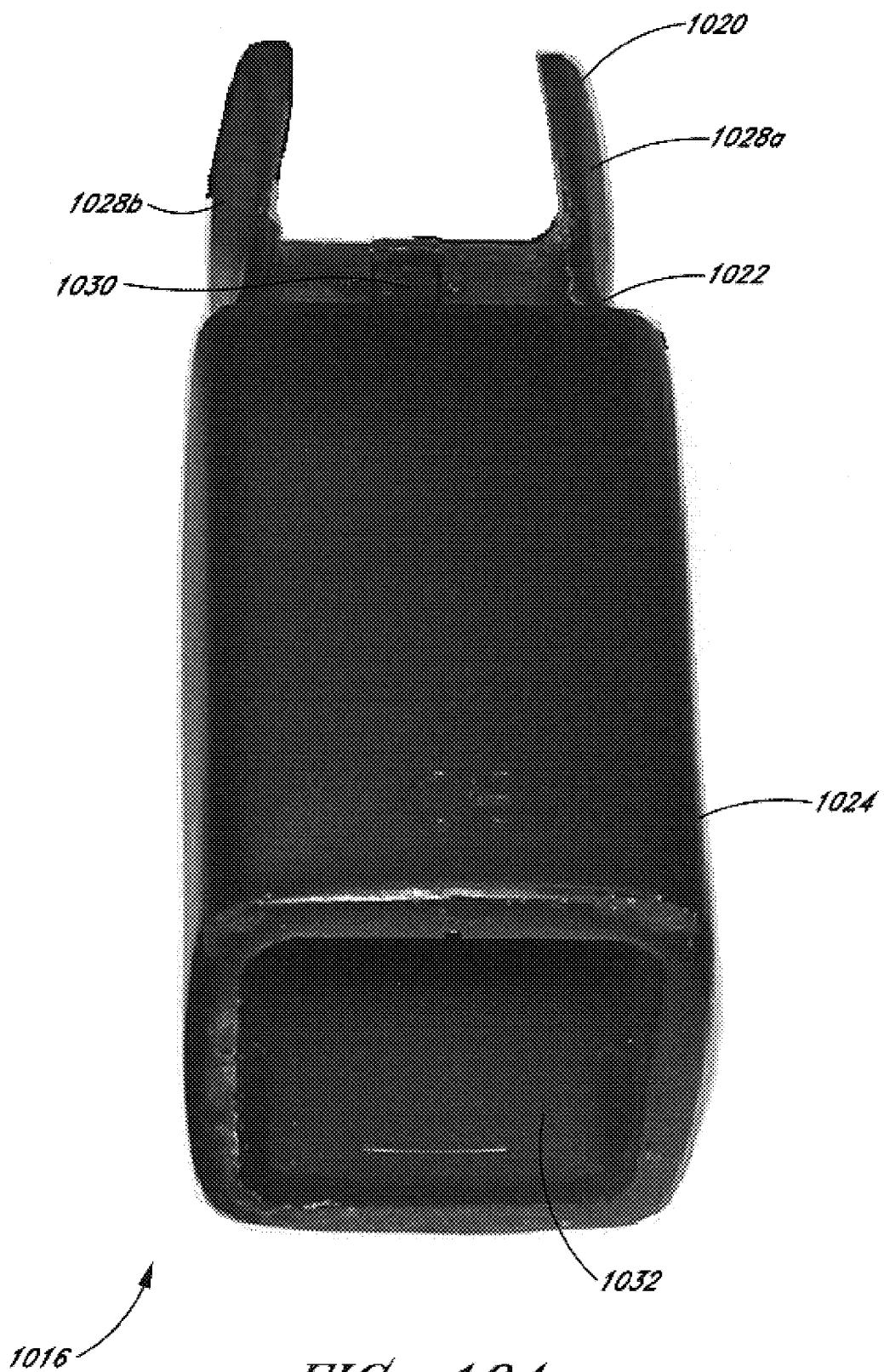


FIG. 104

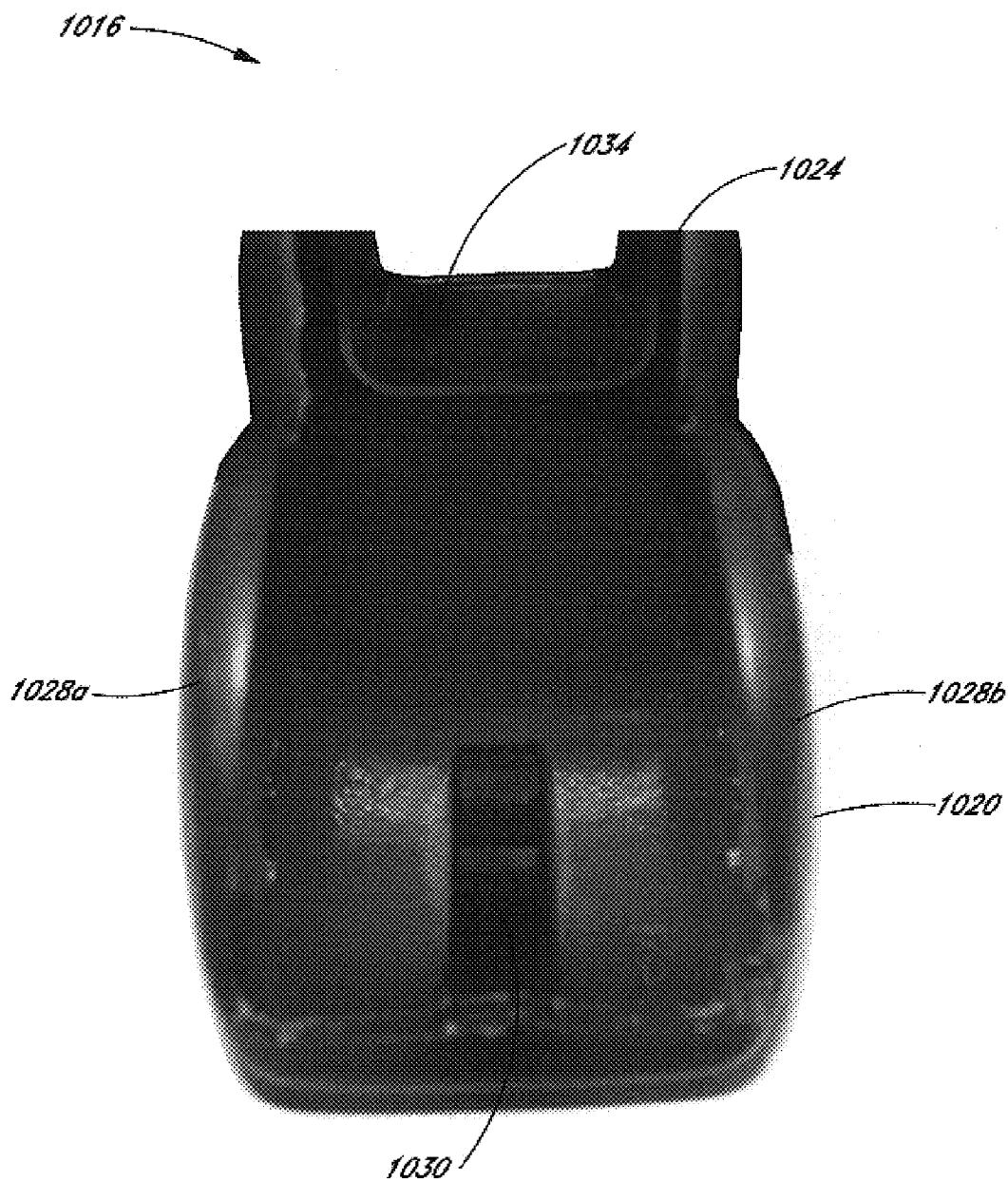


FIG. 105

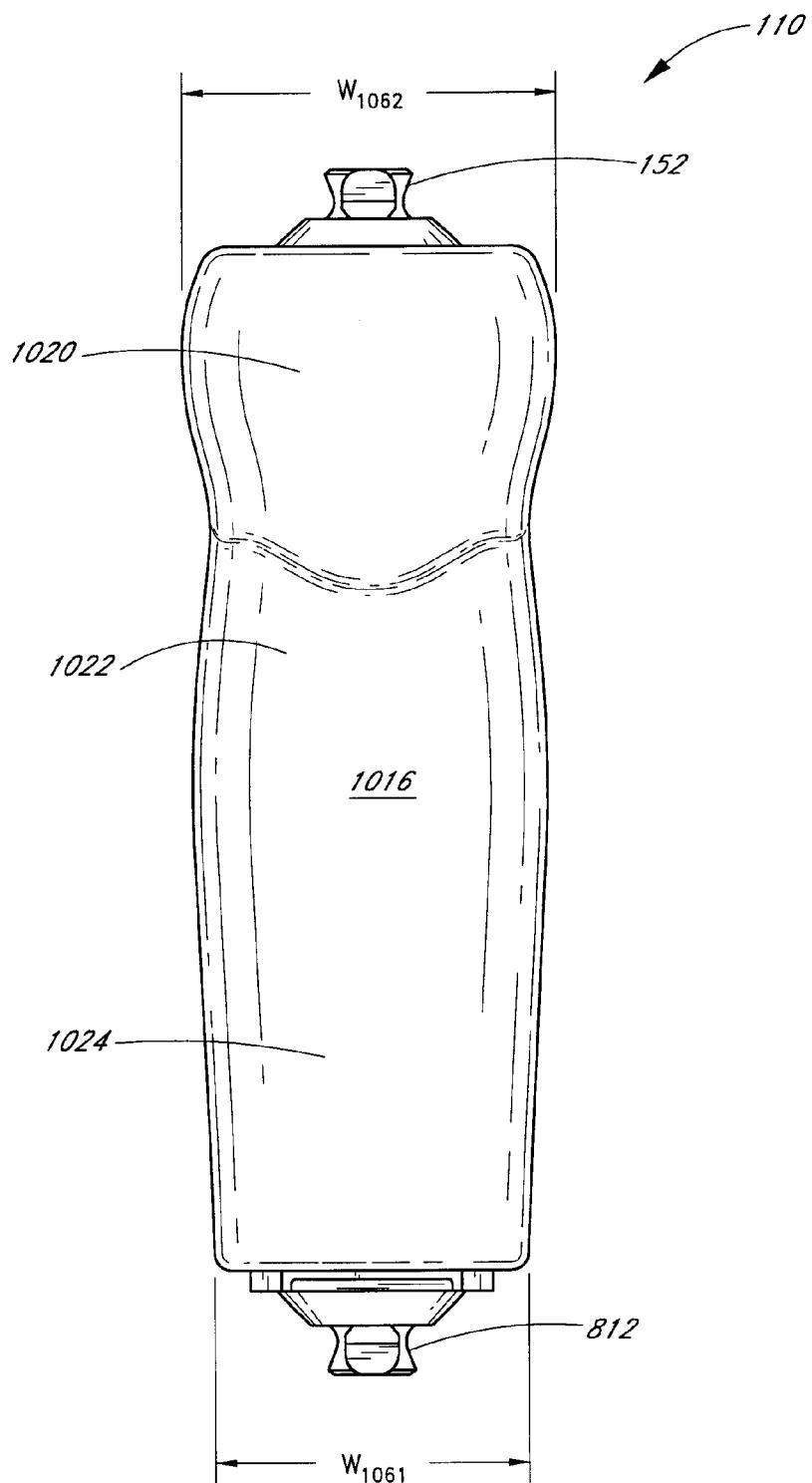


FIG. 106

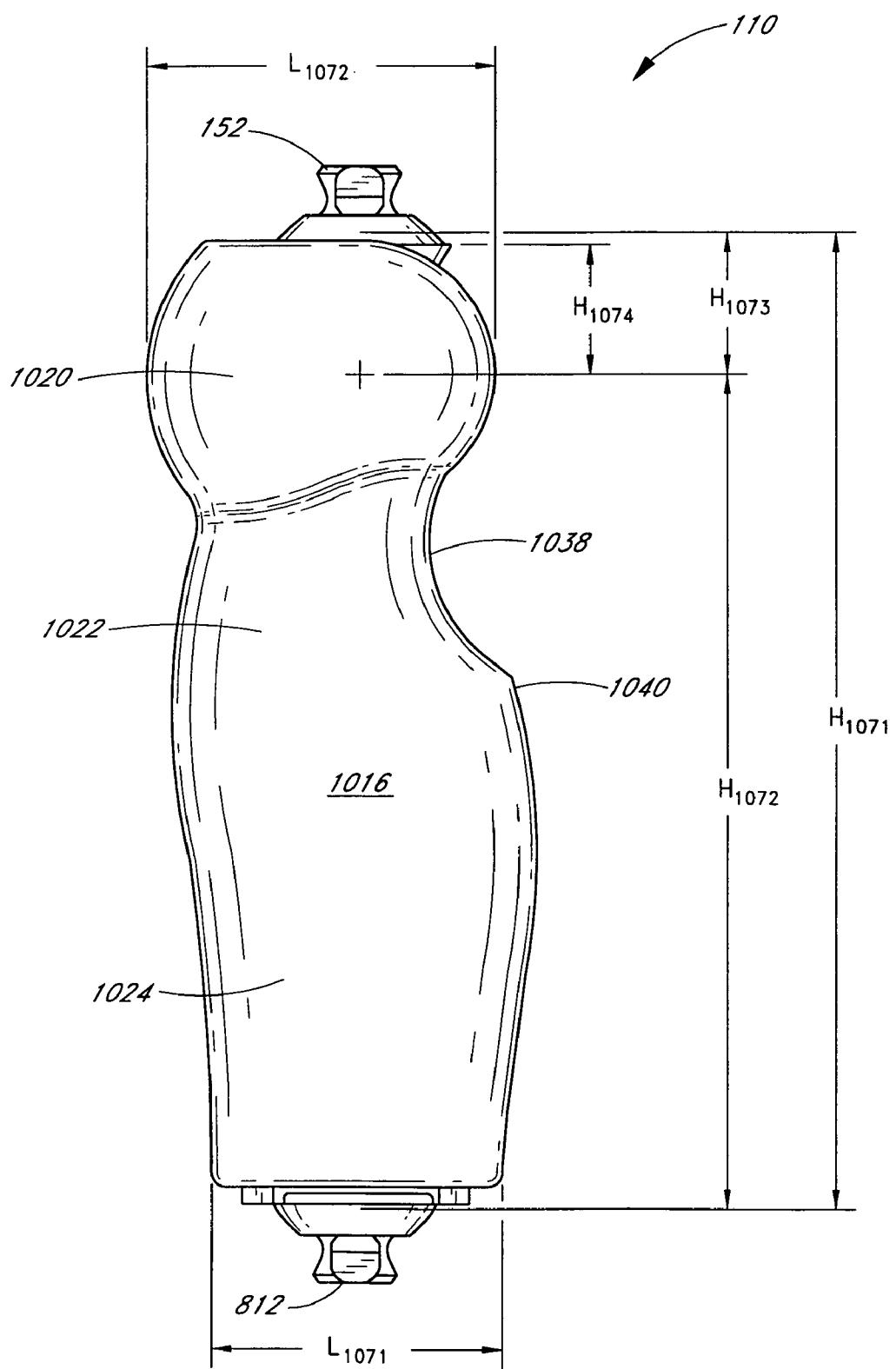


FIG. 107

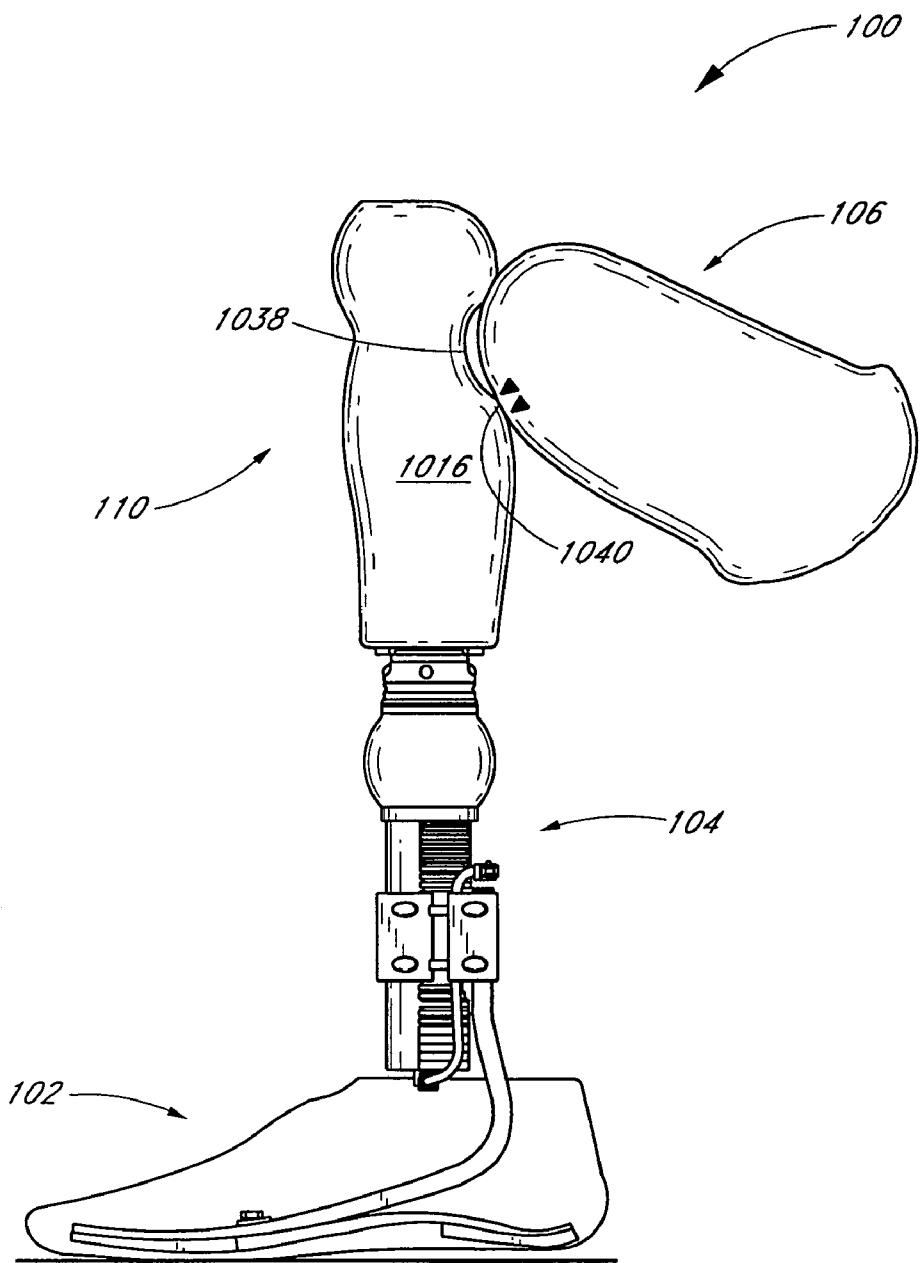


FIG. 108

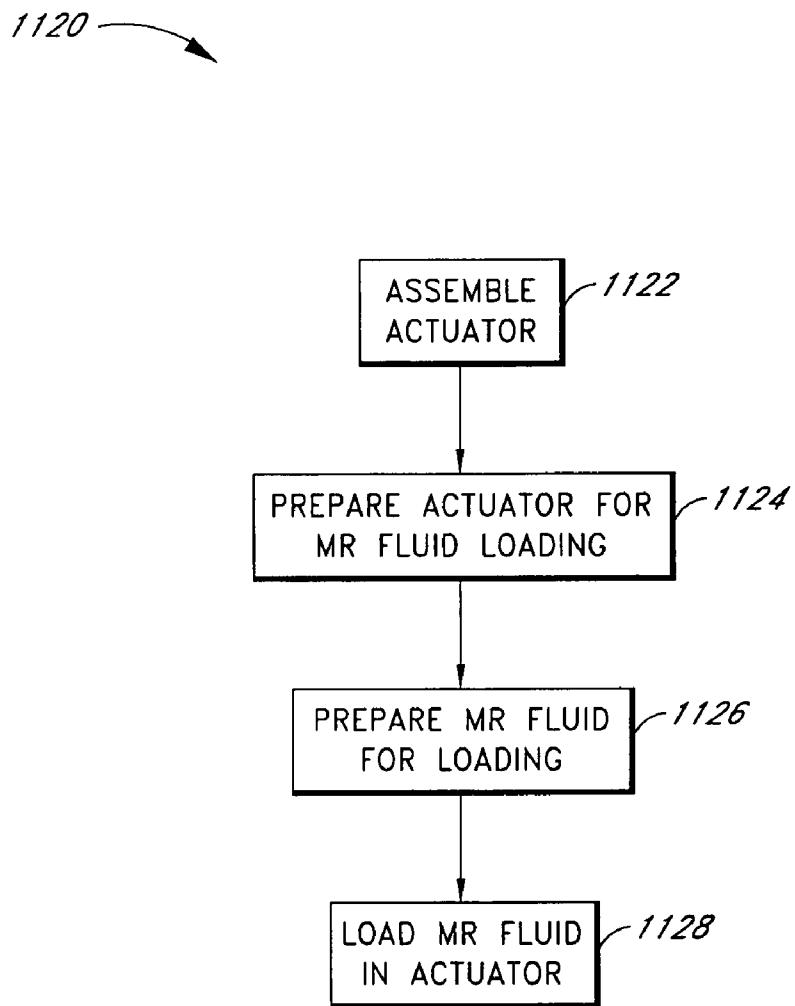


FIG. 109

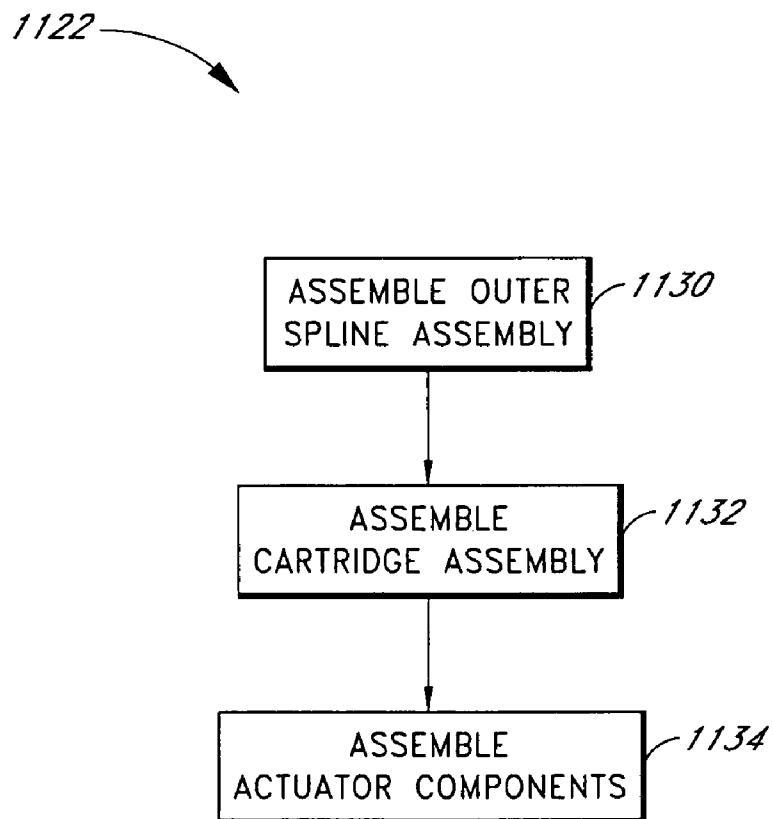


FIG. 110

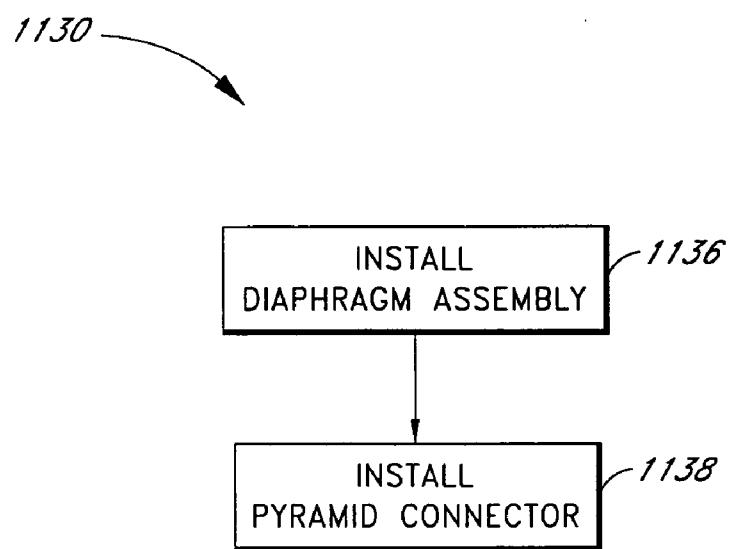


FIG. 111

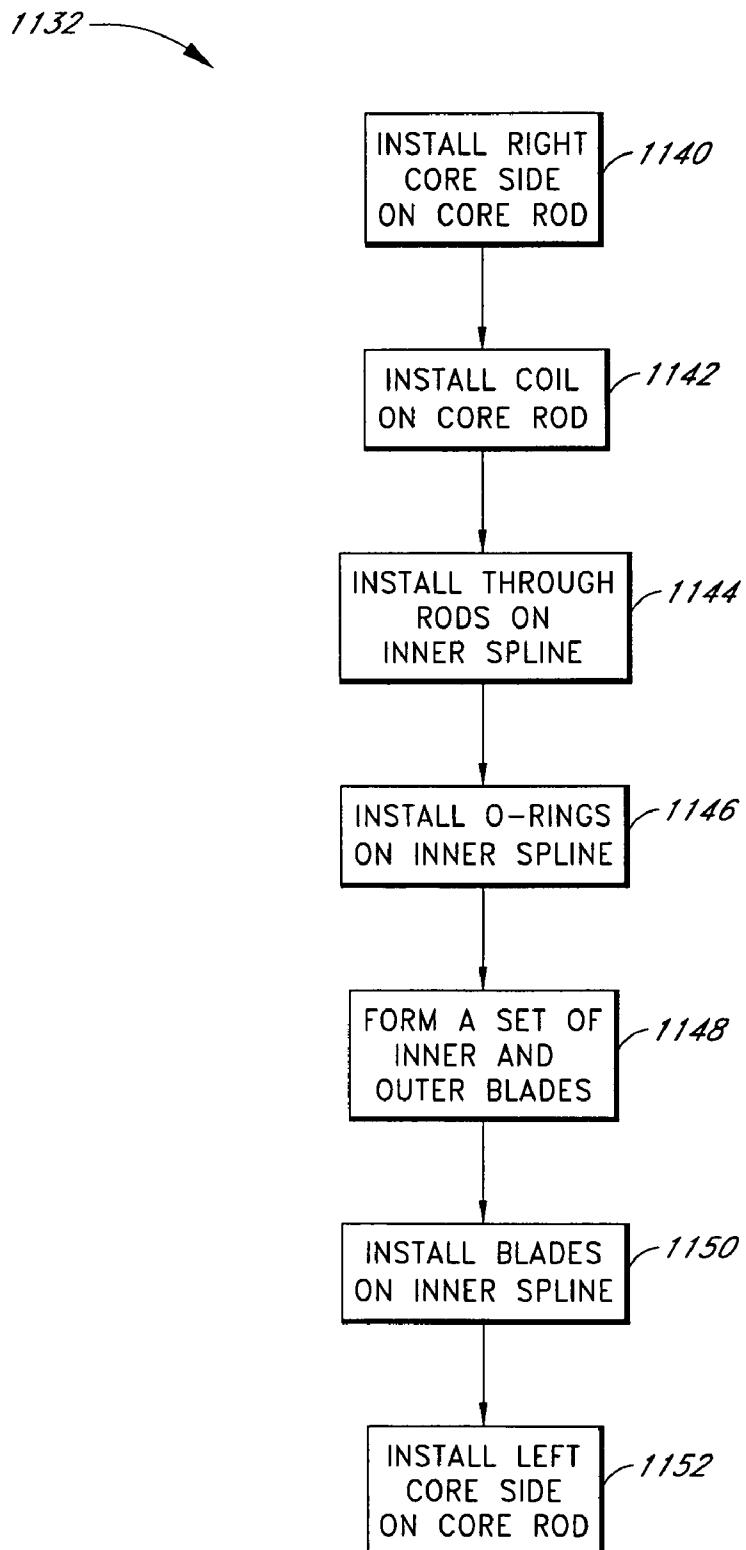


FIG. 112

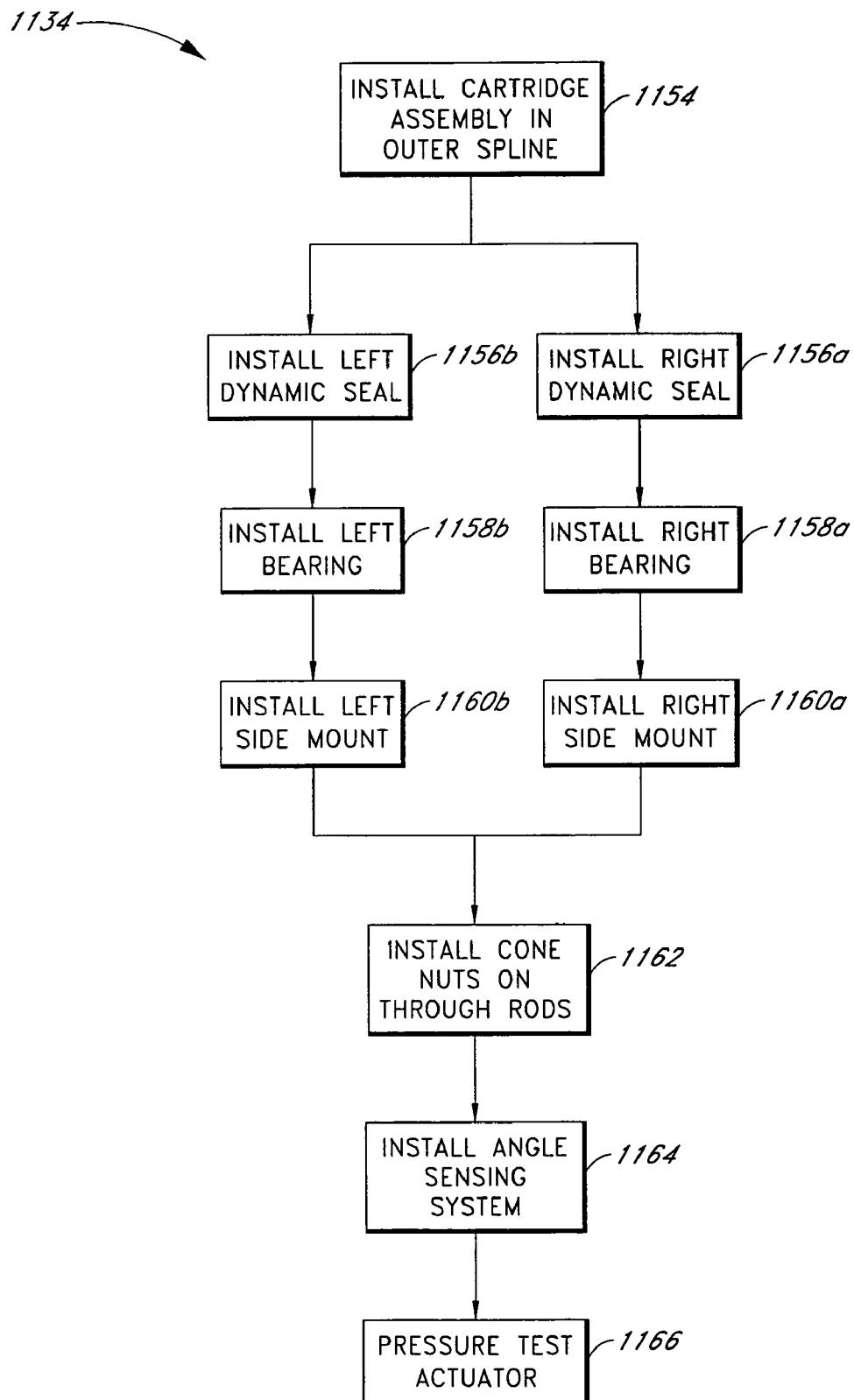


FIG. 113

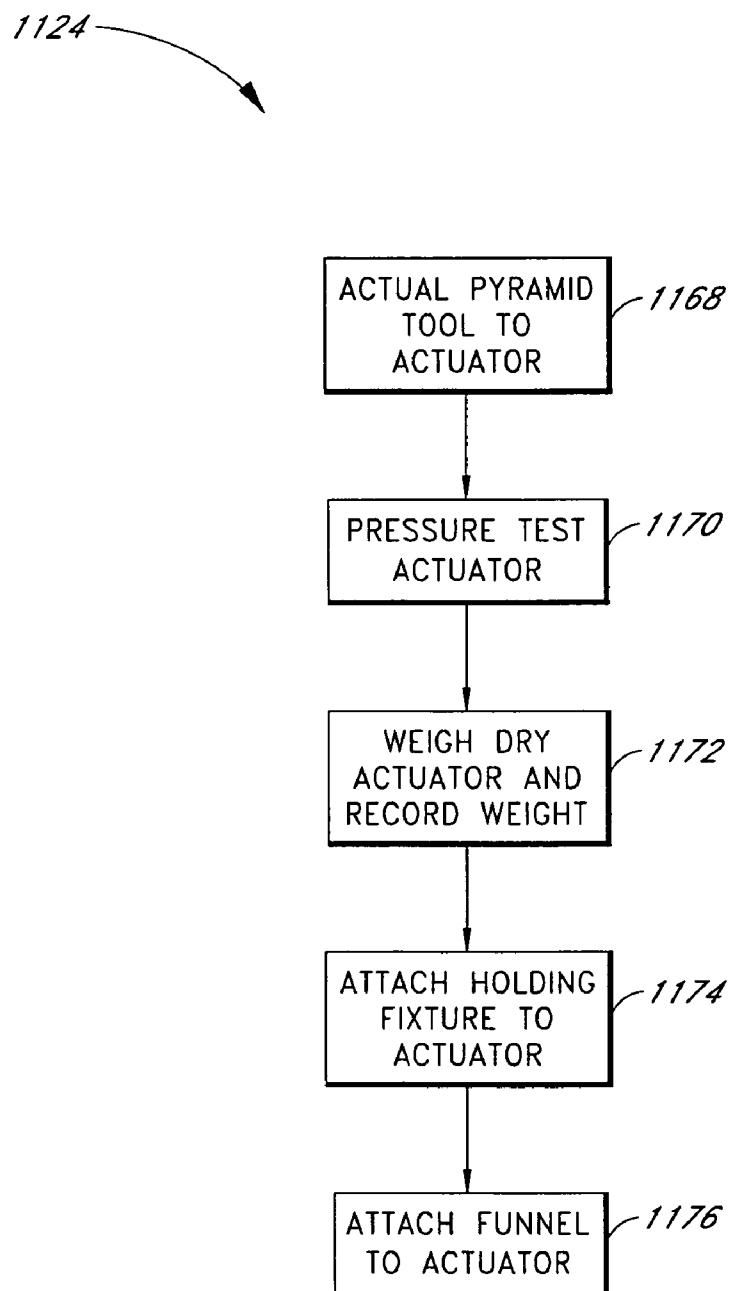


FIG. 114

Replacement Sheet
Reply to Office Action
of June 17, 2005

DYNAMIC SEALS FOR A PROSTHETIC KNEE

Bisbee et al.
Appl. No.: 11/124,621 Atty Docket: OSSUR.056A

93/103

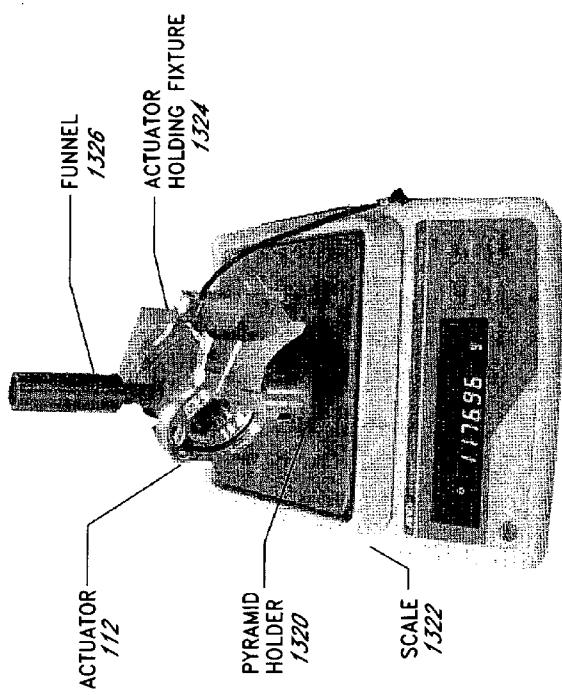


FIG. 115

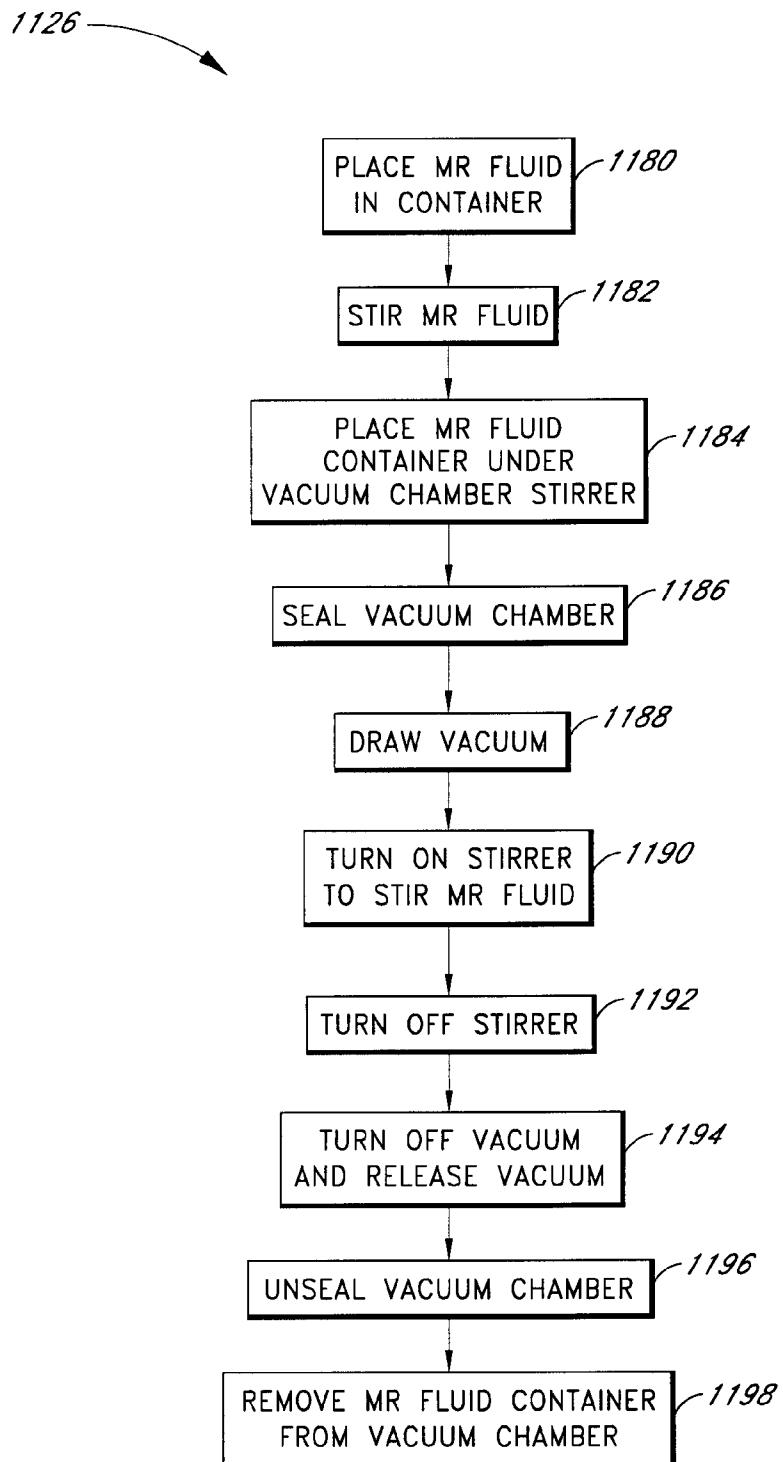


FIG. 116

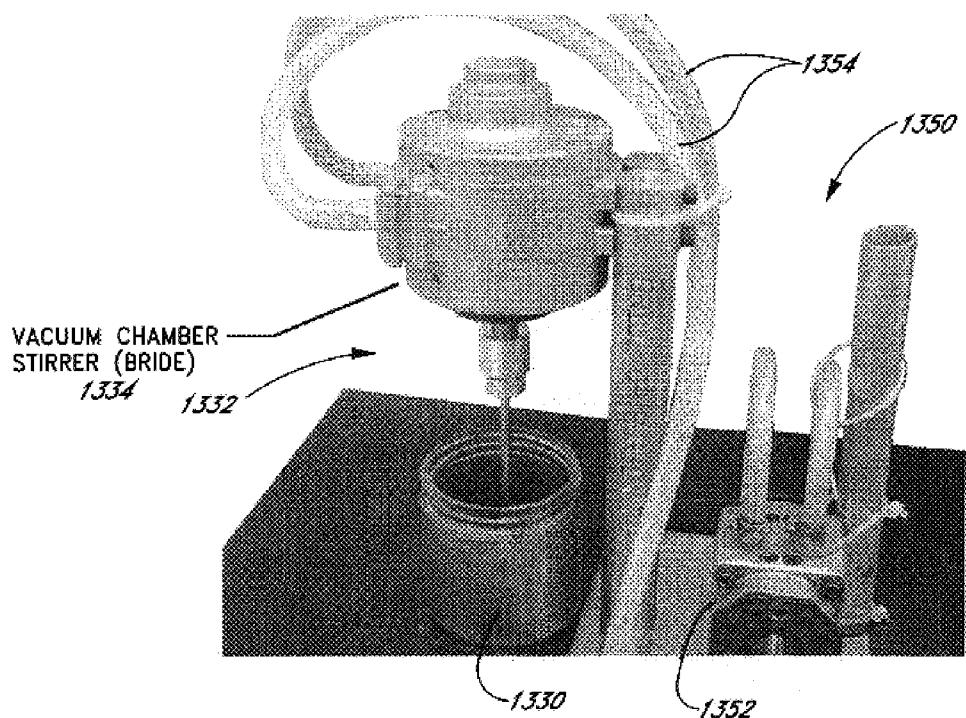


FIG. 117

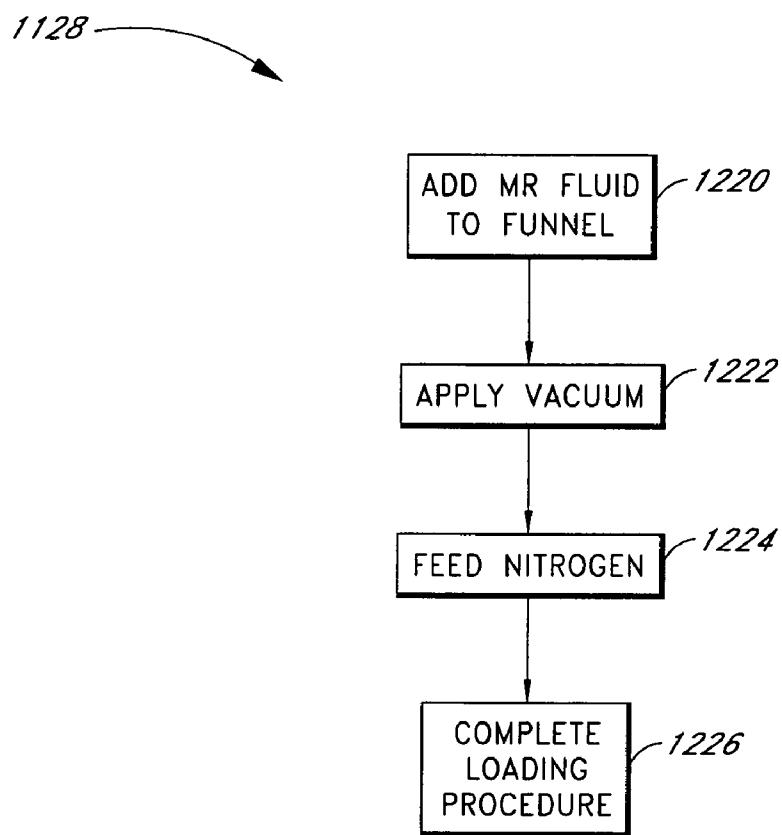


FIG. 118

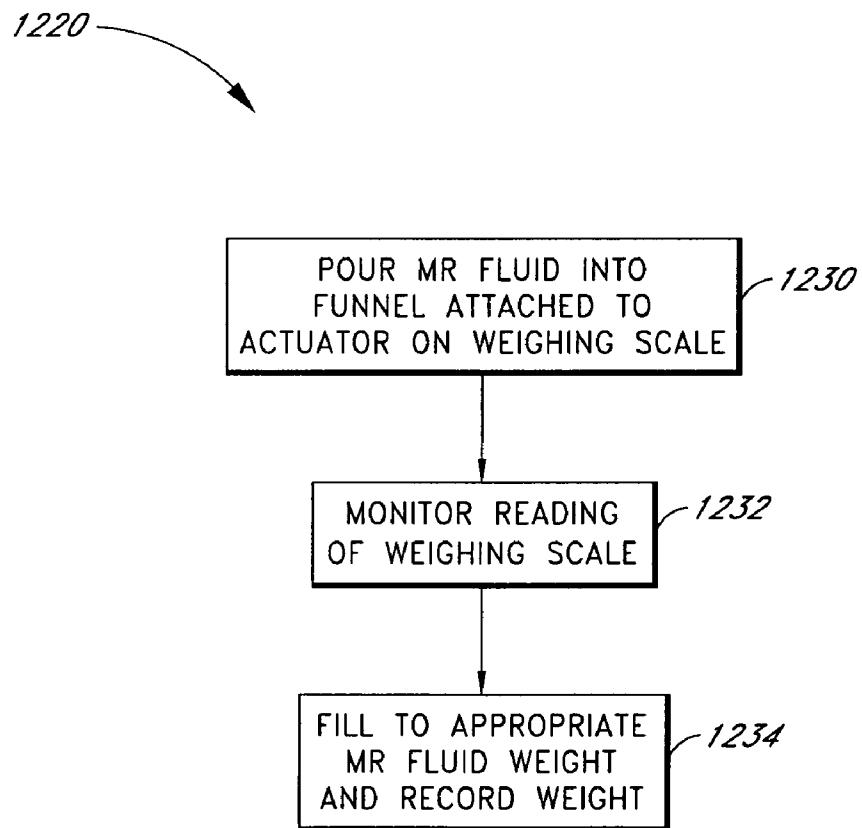


FIG. 119

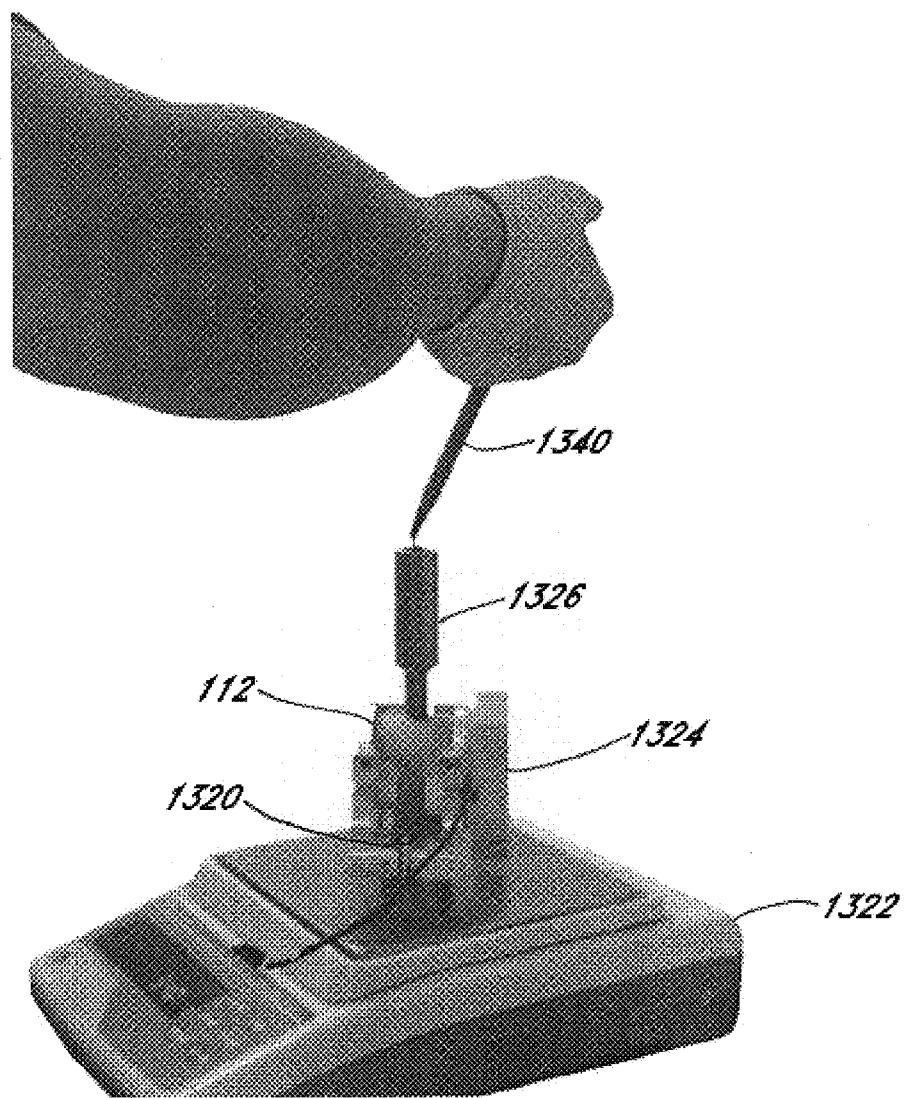


FIG. 120

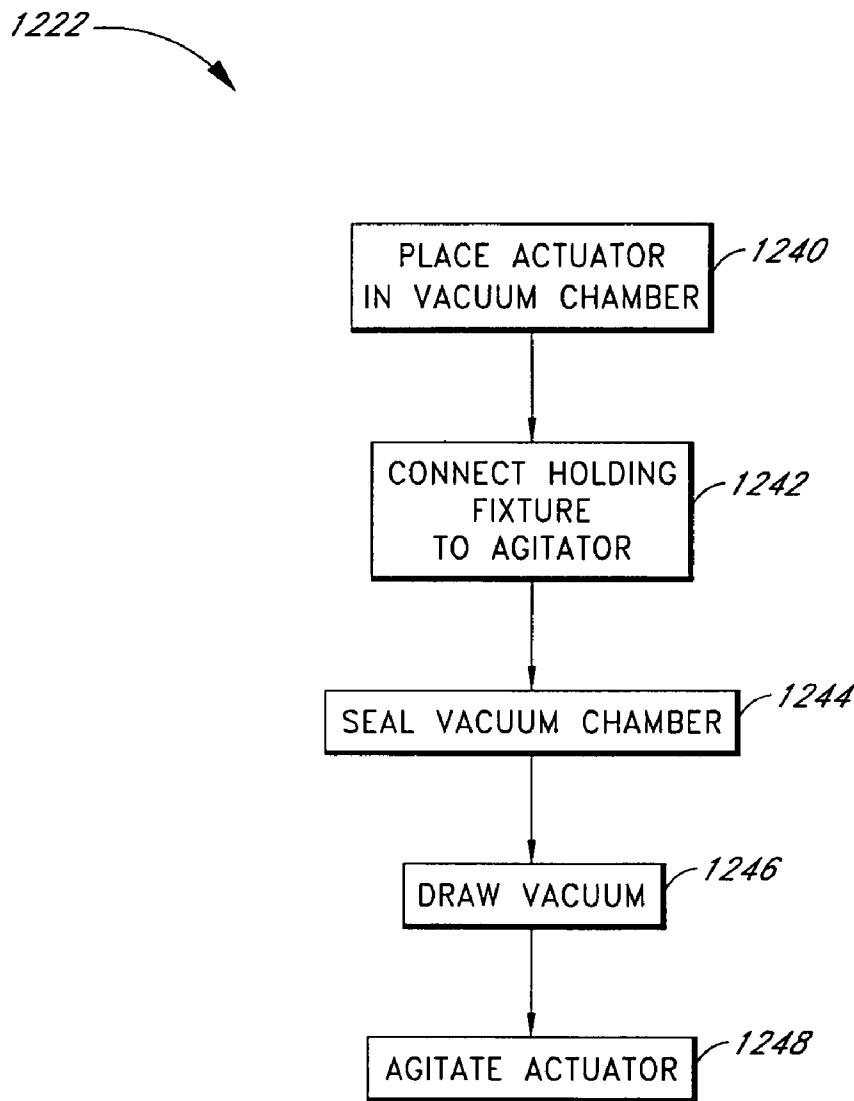


FIG. 121

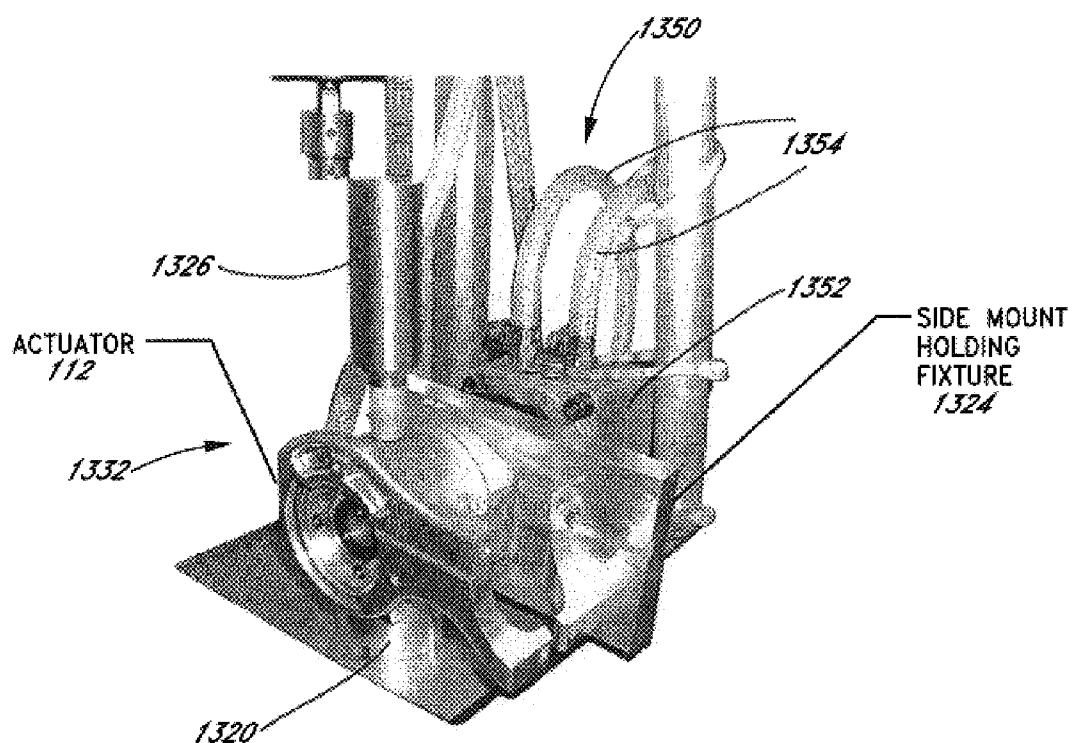


FIG. 122

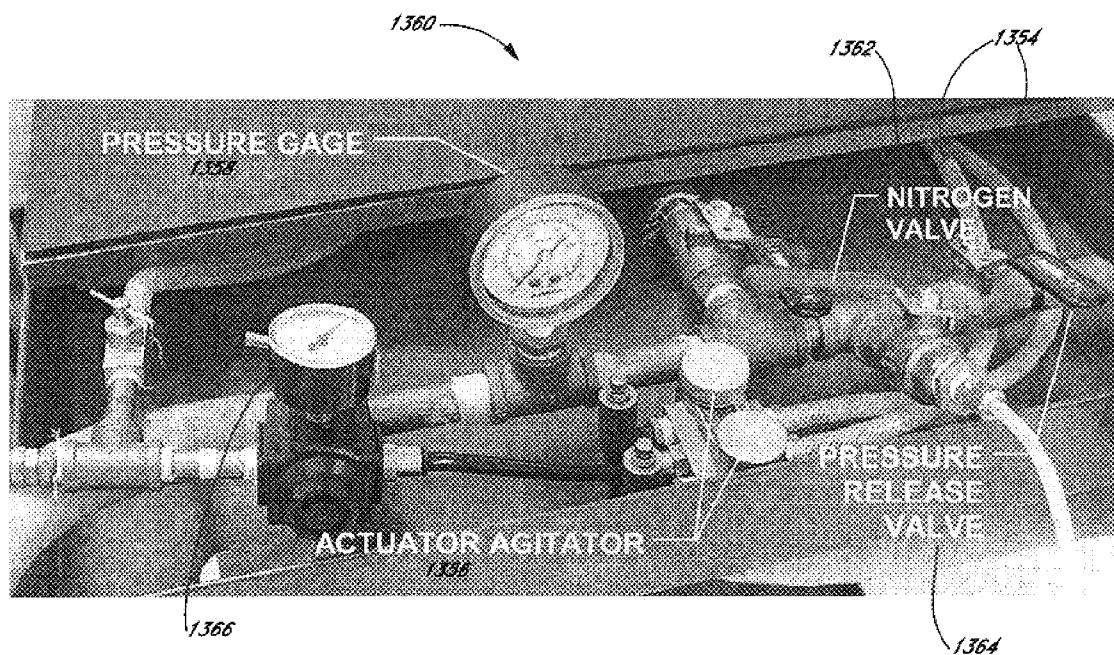


FIG. 123

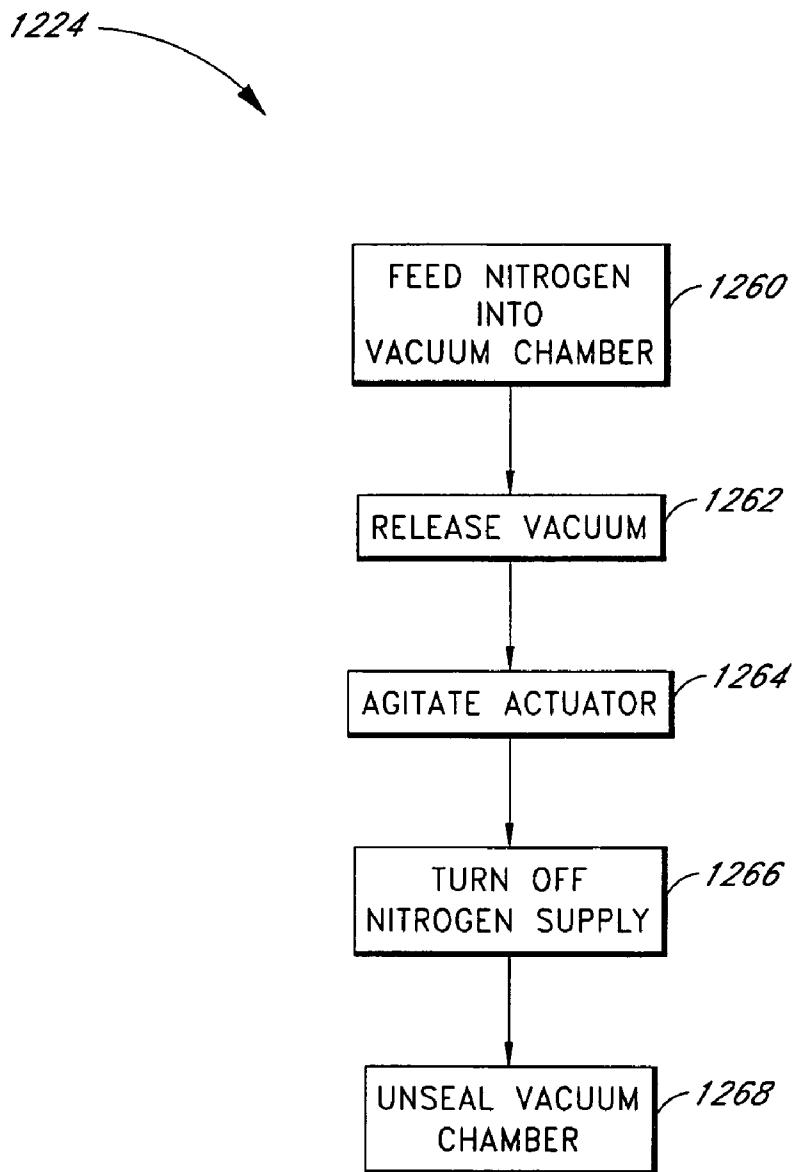
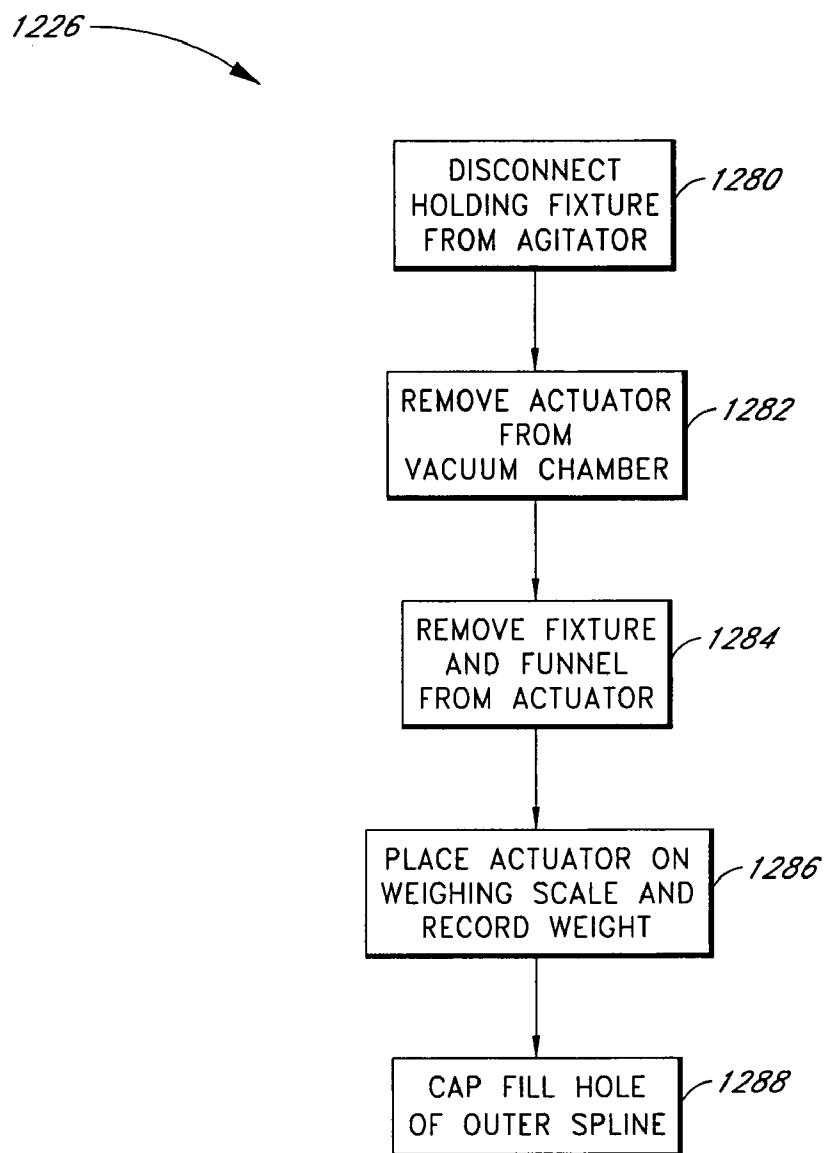


FIG. 124

*FIG. 125*

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DYNAMIC SEALS FOR A PROSTHETIC KNEE

RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Patent Application No. 60/569,512, filed May 7, 2004, and U.S. Provisional Patent Application No. 60/624,986, filed Nov. 3, 2004, the entirety of each one of which is hereby incorporated by reference herein.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates in one embodiment to dynamically sealing a slurry flow in general and, in particular, to a dynamic seal for sealing an actuator chamber of a prosthetic knee that contains a magnetorheological fluid comprising a liquid and solid particles.

2. Description of the Related Art

Three types of variable-torque brakes have been employed in prosthetic knees in the past: (i) dry friction brakes where one material surface rubs against another surface with variable force; (ii) viscous torque brakes using hydraulic fluid squeezed through a variable sized orifice or flow restriction plate; and (iii) magnetorheological (MR) brakes or dampers where MR fluid (containing small iron particles suspended in the fluid) is squeezed through a fixed orifice or flow restriction plate, with viscosity of the fluid being varied in response to an applied magnetic field. Each of these technologies, as conventionally practiced in the field of prosthetics, can pose certain disadvantages.

Though dry friction brakes can generally provide a substantial torque range for their size, undesirably, they are often difficult to control. After extended use, the frictional pads tend to wear, thereby changing the frictional characteristics of the brake and the torque response for a given commanded torque. Disadvantageously, this can cause unreliable damping performance, and hence adversely affect the gait of the amputee and also cause discomfort to the amputee. Consequently, dry friction brakes may need frequent servicing and/or replacement which undesirably adds to the cost.

Under high loading conditions, viscous torque brakes are susceptible to leakage of hydraulic fluid and possibly other damage due to excessive pressure build-up. Disadvantageously, this can result in an irreversible state, since once the brake unit is overloaded it cannot return to normal. Therefore, such a viscous torque brake for a prosthetic joint is prone to catastrophic failure, and hence can be unreliable and detrimental to the safety of an amputee.

In certain MR brakes and dampers, the interaction of the MR fluid with the device undesirably causes increased pressure, seal deterioration, or a combination of the two. Another possible cause of these adverse effects is decomposition of the MR fluid. Once the seals fail or the MR fluid decomposes, the prosthetic knee is no longer suitable for use.

SUMMARY OF THE INVENTION

The invention in some embodiments relates to a dynamic seal for a prosthetic knee. The dynamic seal in one embodiment is utilized to seal a magnetorheological fluid comprising a liquid and solid particles within a chamber of the knee. The dynamic seal embodiments are specially configured with a pre-loaded tensioned garter spring which has a coil spacing that is at least as large as the size of the particles or maximum size of the particles in the magnetorheological fluid. Desir-

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ably, this allows the magnetorheological fluid particles to flow in and out of the dynamic seal without clogging the seal and advantageously provides for a reliable dynamic seal.

Some embodiments relate to a device to be worn by a wearer at a knee location. The device generally comprises a housing, at least one side plate and at least one dynamic seal. The housing comprises a chamber containing a fluid that undergoes a rheology change in response to an applied energy field. The fluid comprises a mixture of solid particles and a liquid. The side plate is within the housing and forms a barrier to contain the fluid in the chamber. The dynamic seal is fitted between the housing and the side plate to contain the fluid in the chamber during relative rotation between the housing and the side plate. The dynamic seal has a tensioned spring with coils that are spaced by a distance at least as large as the largest size of the particles of the fluid.

Some embodiments relate to a device to be attached to a limb. The device generally comprises an actuator adapted to provide relative movement between two adjacent portions.

20 The actuator generally comprises a housing that comprises a chamber. The chamber contains a fluid that undergoes a rheology change in response to an applied energy field. The fluid comprises a mixture of solid particles and a liquid. The chamber is sealed with at least one dynamic seal. The dynamic seal has a tensioned spring with coils being spaced by a distance ($L_{coil-spacing}$) at least as large as the largest size (D_{pmax}) of the particles of the fluid so that the particles flow in and out of said spring.

Some embodiments relate to a device for sealingly containing a flowing fluid. The device generally comprises a housing that comprises a chamber. The chamber contains a fluid that flows in the chamber. The fluid comprises a mixture of solid particles and a liquid. The chamber is sealed with at least one dynamic seal. The dynamic seal has a tensioned spring with adjacent coils being spaced by a gap at least as large as the largest size of the particles of the fluid.

Some embodiments relate to a method of sealing a slurry flow. The method generally comprises providing a housing that comprises a chamber which contains a fluid that flows in the chamber. The fluid comprises a mixture of solid particles and a liquid. The chamber is dynamically sealed with at least one seal. The seal has a tensioned spring with coils that are spaced by a distance at least as large as the largest size of the particles of the fluid so that the particles flow through the spring.

For purposes of summarizing the invention, certain aspects, advantages and novel features of the invention have been described herein above. Of course, it is to be understood that not necessarily all such advantages may be achieved in accordance with any particular embodiment of the invention. Thus, the invention may be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught or suggested herein without necessarily achieving other advantages as may be taught or suggested herein.

All of these embodiments are intended to be within the scope of the invention herein disclosed. These and other embodiments of the invention will become readily apparent to those skilled in the art from the following detailed description of the preferred embodiments having reference to the attached figures, the invention not being limited to any particular preferred embodiment(s) disclosed.

BRIEF DESCRIPTION OF THE DRAWINGS

Having thus summarized the general nature of the invention and some of its features and advantages, certain preferred

embodiments and modifications thereof will become apparent to those skilled in the art from the detailed description herein having reference to the figures that follow, of which:

FIG. 1 is a simplified schematic view of one normal human locomotion cycle illustrating the various limb positions during stance and swing phases.

FIG. 2 is a simplified schematic view of a lower limb prosthetic assembly with an electronically controlled prosthetic knee illustrating features and advantages in accordance with an embodiment of the invention.

FIGS. 3A-3D are simplified perspective views of a prosthetic knee assembly illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 4 is a simplified schematic view of a magnetorheological actuator for a prosthetic knee depicting its general configuration and operation and illustrating features and advantages in accordance with an embodiment of the invention.

FIGS. 5A-5D are simplified perspective views of a magnetorheological actuator of the prosthetic knee assembly of FIGS. 3A-3D illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 5E is a simplified sectional view of a magnetorheological actuator of the prosthetic knee assembly of FIGS. 3A-3D illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 6 is a simplified exploded perspective view of the magnetorheological actuator of FIGS. 5A-5E illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 7 is a simplified perspective view of a core rod of the actuator of FIG. 6 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 8 is a simplified side view of the core rod of FIG. 7 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 9 is a simplified right end view of the core rod of FIG. 7 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 10 is a simplified left end view of the core rod of FIG. 7 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 11 is a simplified sectional view along line 11-11 of FIG. 8 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 12 is a simplified perspective view of a right core side of the actuator of FIG. 6 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 13 is another simplified perspective view of the right core side of FIG. 12 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 14 is a simplified side view of the right core side of FIG. 12 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 15 is a simplified front view of the right core side of FIG. 12 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 16 is a simplified rear view of the right core side of FIG. 12 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 17 is a simplified perspective view of a left core side of the actuator of FIG. 6 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 18 is another simplified perspective view of the left core side of FIG. 17 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 19 is a simplified side view of the left core side of FIG. 17 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 20 is a simplified front view of the left core side of FIG. 17 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 21 is a simplified rear view of the left core side of FIG. 17 illustrating features and advantages in accordance with an embodiment of the invention.

10 FIG. 22 is a simplified perspective view of a bearing of the actuator of FIG. 6 illustrating features and advantages in accordance with an embodiment of the invention.

15 FIG. 23 is a simplified perspective view of a magnetic coil of the actuator of FIG. 6 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 24 is a simplified side view of the magnetic coil of FIG. 23 illustrating features and advantages in accordance with an embodiment of the invention.

20 FIG. 25 is a simplified sectional view along line 25-25 of FIG. 23 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 26 is a simplified front end view of the magnetic coil of FIG. 23 illustrating features and advantages in accordance with an embodiment of the invention.

25 FIG. 27 is a simplified rear end view of the magnetic coil of FIG. 23 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 28 is a simplified perspective view of an inner spline of the actuator of FIG. 6 illustrating features and advantages in accordance with an embodiment of the invention.

30 FIG. 29 is a simplified side view of the inner spline of FIG. 28 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 30 is a simplified sectional view along line 30-30 of FIG. 31 illustrating features and advantages in accordance with an embodiment of the invention.

35 FIG. 31 is a simplified end view of the inner spline of FIG. 28 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 32 is a simplified opposite end view of the inner spline of FIG. 28 illustrating features and advantages in accordance with an embodiment of the invention.

40 FIG. 33 is a simplified perspective view of one of the inner rotors of the actuator of FIG. 6 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 34 is a simplified front (or rear) view of the inner rotor of FIG. 33 illustrating features and advantages in accordance with an embodiment of the invention.

45 FIG. 35 is a simplified side view of the inner rotor of FIG. 33 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 36 is a simplified front (or rear view) of an inner rotor illustrating features and advantages in accordance with another embodiment of the invention.

50 FIG. 37 is a simplified perspective view of one of the outer rotors of the actuator of FIG. 6 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 38 is a simplified front (or rear) view of the outer rotor of FIG. 37 illustrating features and advantages in accordance with an embodiment of the invention.

55 FIG. 39 is a simplified side view of the outer rotor of FIG. 37 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 40 is a simplified front (or rear view) of an outer rotor illustrating features and advantages in accordance with another embodiment of the invention.

FIG. 41 is a simplified perspective view of an outer spline of the actuator of FIG. 6 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 42 is a simplified end view of the outer spline of FIG. 41 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 43 is a simplified opposite end view of the outer spline of FIG. 41 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 44 is a simplified top view of the outer spline of FIG. 41 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 45 is a simplified sectional view along line 45-45 of FIG. 44 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 46 is a simplified perspective view of a dynamic seal of the actuator of FIG. 6 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 47 is a simplified exploded perspective view of the dynamic seal of FIG. 46 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 48 is a simplified cross-section view of the dynamic seal of FIG. 46 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 49 is a simplified front view of a lip seal element of the dynamic seal of FIG. 46 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 50 is a simplified sectional view along line 50-50 of FIG. 49 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 51 is a simplified schematic enlarged partial view of a garter spring of the dynamic seal of FIG. 46 showing the spacing between spring coils and illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 52 is simplified schematic deflection curve of a garter spring of the dynamic seal of FIG. 46 showing operational points and ranges and illustrating features and advantages in accordance with embodiments of the invention.

FIG. 53 is a simplified schematic view of a slurry flow arrangement with a dynamic seal illustrating features and advantages in accordance with a modified embodiment of the invention.

FIG. 54 is a simplified cross-section view of a dynamic seal of the actuator of FIG. 6 illustrating features and advantages in accordance with another embodiment of the invention.

FIG. 55 is a simplified perspective view of a diaphragm assembly of the actuator of FIG. 6 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 56 is another simplified perspective view of the diaphragm assembly of FIG. 55 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 57 is a simplified bottom view of the diaphragm assembly of FIG. 55 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 58 is a simplified top view of the diaphragm assembly of FIG. 55 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 59 is a simplified sectional view along line 59-59 of FIG. 58 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 60 is another simplified sectional view of the diaphragm assembly of FIG. 55 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 61 is a simplified schematic view of a prosthetic knee actuator pressure control system illustrating features and advantages in accordance with embodiments of the invention.

FIG. 62 is a simplified graphical representation of desirable pressure variation control provided by embodiments of the pressure control system of FIG. 61 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 63 is a simplified perspective view of a pyramid stud of the actuator of FIG. 6 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 64 is a simplified bottom view of the pyramid stud of FIG. 63 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 65 is a simplified top view of the pyramid stud of FIG. 63 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 66 is a simplified sectional view along line 66-66 of FIG. 65 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 67 is a simplified perspective view of a right side mount of the actuator of FIG. 6 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 68 is a simplified front (interior face) view of the right side mount of FIG. 67 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 69 is a simplified rear (exterior face) view of the right side mount of FIG. 67 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 70 is a simplified perspective view of a left side mount of the actuator of FIG. 6 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 71 is a simplified front (interior face) view of the left side mount of FIG. 70 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 72 is a simplified rear (exterior face) view of the left side mount of FIG. 70 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 73 is a simplified side (interior) view of a shock absorbing multi-stage bumper system of the actuator of FIG. 6 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 74 is a simplified perspective view of one multi-stage bumper assembly of the bumper system of FIG. 73 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 75 is a simplified schematic view of knee rotation during operation of the bumper system of FIG. 73 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 76 is a simplified schematic view of knee hyperextension during operation of the bumper system of FIG. 73 illustrating features and advantages in accordance with another embodiment of the invention.

FIG. 77 is a simplified schematic view of another shock absorbing multi-stage bumper system illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 78 is a simplified schematic view of yet another shock absorbing multi-stage bumper system illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 79 is a simplified exploded perspective view of an extension assist system of the actuator of FIG. 6 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 80 is a simplified partial side view of the extension assist system of FIG. 79 mounted on the actuator illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 81 is a simplified graphical representation of torque versus angle relationships for an extension assist spring of the actuator of FIG. 6 illustrating features and advantages in accordance with some embodiments of the invention.

FIG. 82 is a simplified side view of an extension spring for an extension assist system of the actuator of FIG. 6 illustrating features and advantages in accordance with another embodiment of the invention.

FIG. 83 is a simplified exploded perspective view of an angle sensing system of the actuator of FIG. 6 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 84 is a simplified perspective view of a frame and electronics assembly of the prosthetic knee assembly of FIGS. 3A-3D illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 85 is a simplified exploded perspective view of the assembly of FIG. 84 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 86 is a simplified front view of the assembly of FIG. 84 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 87 is a simplified rear view of the assembly of FIG. 84 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 88 is a simplified right side view of the assembly of FIG. 84 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 89 is a simplified left side view of the assembly of FIG. 84 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 90 is a simplified top view of the assembly of FIG. 84 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 91 is a simplified bottom view of the assembly of FIG. 84 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 92 is a simplified perspective view of a load cell frame of the assembly of FIG. 84 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 93 is a simplified front view of the load cell frame of FIG. 92 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 94 is a simplified rear view of the load cell frame of FIG. 92 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 95 is a simplified right side view of the load cell frame of FIG. 92 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 96 is a simplified left side view of the load cell frame of FIG. 92 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 97 is a simplified perspective view of a prosthetic knee assembly illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 98 is another simplified perspective view of a prosthetic knee assembly illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 99 is a simplified partial rear view of a prosthetic knee assembly illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 100 is a simplified schematic enlarged view of a control panel of the prosthetic knee assembly illustrating features and advantages in accordance with an embodiment of the invention.

5 FIG. 101 is a simplified perspective view of a prosthetic knee cover illustrating features and advantages in accordance with an embodiment of the invention.

10 FIG. 102 is another simplified perspective view the knee cover of FIG. 101 illustrating features and advantages in accordance with an embodiment of the invention.

15 FIG. 103 is yet another simplified perspective view the knee cover of FIG. 101 illustrating features and advantages in accordance with an embodiment of the invention.

20 FIG. 104 is still another simplified perspective view the knee cover of FIG. 101 illustrating features and advantages in accordance with an embodiment of the invention.

25 FIG. 105 is a further simplified perspective view the knee cover of FIG. 101 illustrating features and advantages in accordance with an embodiment of the invention.

30 FIG. 106 is a simplified front view of a prosthetic knee assembly including the knee cover of FIG. 101 illustrating features and advantages in accordance with an embodiment of the invention.

35 FIG. 107 is a simplified side view of the prosthetic knee assembly of FIG. 106 illustrating features and advantages in accordance with an embodiment of the invention.

40 FIG. 108 is a simplified view of a lower limb prosthetic assembly illustrating features and advantages in accordance with an embodiment of the invention.

45 FIG. 109 is a simplified schematic diagram of a method of assembling a prosthetic knee actuator and loading magnetorheological fluid in the actuator illustrating features and advantages in accordance with an embodiment of the invention.

50 FIG. 110 is a simplified schematic diagram of some acts of assembling the actuator of FIG. 109 illustrating features and advantages in accordance with an embodiment of the invention.

55 FIG. 111 is a simplified schematic diagram of some acts of assembling an outer spline assembly of the actuator of FIG. 110 illustrating features and advantages in accordance with an embodiment of the invention.

60 FIG. 112 is a simplified schematic diagram of some acts of assembling a cartridge assembly of the actuator of FIG. 110 illustrating features and advantages in accordance with an embodiment of the invention.

65 FIG. 113 is a simplified schematic diagram of some acts of assembling components of the actuator of FIG. 110 illustrating features and advantages in accordance with an embodiment of the invention.

70 FIG. 114 is a simplified schematic diagram of some acts of preparing the actuator of FIG. 109 for magnetorheological fluid loading illustrating features and advantages in accordance with an embodiment of the invention.

75 FIG. 115 is a simplified perspective view of the actuator of FIG. 114 on a weighing scale illustrating features and advantages in accordance with an embodiment of the invention.

80 FIG. 116 is a simplified schematic diagram of some acts of preparing the magnetorheological fluid of FIG. 109 for loading illustrating features and advantages in accordance with an embodiment of the invention.

85 FIG. 117 is a simplified perspective view of a stirrer for the magnetorheological fluid of FIG. 116 illustrating features and advantages in accordance with an embodiment of the invention.

90 FIG. 118 is a simplified schematic diagram of some acts of loading the magnetorheological fluid in the actuator of FIG.

109 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 119 is a simplified schematic diagram of some acts of adding the magnetorheological fluid to a funnel of FIG. 118 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 120 is a simplified perspective view of pouring the magnetorheological fluid in the funnel of FIG. 119 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 121 is a simplified schematic diagram of some acts of applying a vacuum to the magnetorheological fluid and actuator of FIG. 118 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 122 is a simplified perspective view of the actuator of FIG. 119 in a vacuum chamber illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 123 is a simplified perspective view of a vacuum table and gauges associated with the vacuum chamber of FIG. 122 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 124 is a simplified schematic diagram of some acts of feeding nitrogen to the actuator of FIG. 118 illustrating features and advantages in accordance with an embodiment of the invention.

FIG. 125 is a simplified schematic diagram of some acts of completing the loading of the magnetorheological fluid in the actuator of FIG. 118 illustrating features and advantages in accordance with an embodiment of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Some preferred embodiments of the invention described herein relate generally to prosthetic devices and, in particular, to magnetorheologically actuated controllable braking systems utilized in prosthetic knees for supporting an amputee that allow the amputee to move comfortably, safely and in a substantially natural and life-like manner in various dynamic and static states, terrains and topography.

While the description sets forth various embodiment specific details, it will be appreciated that the description is illustrative only and should not be construed in any way as limiting the invention. Furthermore, various applications of the invention, and modifications thereto, which may occur to those who are skilled in the art, are also encompassed by the general concepts described herein.

Understanding normal human walking/running provides the basis for the design and development of effective lower limb prostheses with controlled motion. Normal human locomotion or gait can be described as a series of rhythmical alternating movements of the limbs and trunk which result in the forward progression of the body's center of gravity.

One typical gait cycle, as schematically depicted in FIG. 1, comprises of the activity that occurs between heel strike of one lower limb LL and the subsequent heel strike of the same limb LL. The limb or leg LL generally comprises a foot 2 and a shin portion 4 coupled or articulated to a thigh portion 6 via a knee or knee joint 10. During a single gait cycle each lower limb or extremity passes through one stance or extended phase STP and one swing phase SWP.

The stance phase STP begins at heel-strike STP_HS when the heel touches the floor or supporting ground surface and the stance knee begins to flex slightly. This flexion allows for

shock absorption upon impact and also maintains the body's center of gravity at a more constant vertical level during stance.

Shortly after heel-strike STP_HS, the sole makes contact with the ground at the beginning of the foot-flat phase STP_FF. After maximum flexion is reached in the stance knee, the joint begins to extend again, until maximum extension is reached at mid-stance STP_MS as the body weight is swung directly over the supporting extremity and continues to 10 rotate over the foot.

As the body mass above the ankle continues to rotate forward, the heel lifts off the ground at heel-off STP_HO. Shortly after this, the body is propelled forward by the forceful action of the calf-muscles (push-off). The push-off phase 15 terminates when the entire foot rises from the ground at toe-off SP_TO.

During late stance, the knee of the supporting leg flexes in preparation for the foot leaving the ground for swing. This is typically referred to in the literature as "knee break". At this time, the adjacent foot strikes the ground and the body is in 20 "double support mode", that is, both the legs are supporting the body weight.

At toe-off SP_TO, as the hip is flexed and the knee reaches a certain angle at knee break, the foot leaves the ground and the knee continues to flex into the swing phase. During early swing the foot accelerates. After reaching maximum flexion at mid-swing SWP_MS, the knee begins to extend and the foot decelerates. After the knee has reached full extension, the foot once again is placed on the ground at heel-strike STP_HS' and the next walking cycle begins.

Typically, the anatomical position is the upright position, therefore flexion is a movement of a body part away from the extended or stance or anatomical position. Thus, bending of the knee is knee flexion. Extension is a movement of a limb towards the anatomical position, thus knee extension is a movement in the "straightening" direction.

During a typical normal walking progression on a generally level surface, the maximum flexion angle α_F varies 40 between about 70° and 80°. The maximum extension angle α_E is typically about or close to 180°. Thus, in level walking the normal human knee rotates through a range of approximately 70°-80° going from a position of full extension in early and mid stance to 70°-80° of flexion shortly after toe-off. In other situations, such as, in a sitting position, the maximum flexion angle α_F can be greater than about 70°-80° and up to, for example, about 140°-150°.

System Overview

FIG. 2 is a schematic illustration of an embodiment of a lower limb prosthetic assembly, system or prosthesis 100 including an electronically controlled active knee prosthetic assembly, system or prosthesis 110. As described in greater detail later herein, advantageously, the knee prosthesis 110 provides resistive forces to substantially simulate the position and motion of a natural knee joint during ambulation and/or other locomotory or stationary activities performed by an amputee. The prosthetic or artificial knee 110 is desirably safe, reliable and generally comfortable to use by the amputee.

The prosthetic lower limb 100 further includes an artificial or prosthetic foot 102 coupled or mechanically connected to a pylon, tube, shaft or shank portion 104 that connects to a distal or bottom portion of the prosthetic knee 110 and a residual limb or stump socket 106 that connects to a top or proximal end of the prosthetic knee 110. The stump socket 106 receives a residual limb or femur portion 108 of the

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amputee. A suitable pylon or the like can also be provided between the stump socket 106 and the prosthetic knee 110, as needed or desired.

Embodiments of the invention can be practiced with a wide variety of prosthetic feet. These include Flex-Foot® feet such as Ceterus™, LP Ceterus™, Vari-Flex®, LP Vari-Flex®, Talux® and Elation™. Some embodiments of suitable prosthetic feet and associated devices are disclosed in U.S. Pat. No. 5,181,932, issued Jan. 26, 1993, U.S. Pat. No. 5,181,933, issued Jan. 26, 1993, U.S. Pat. No. 5,728,177, issued Mar. 17, 1998, U.S. Pat. No. 5,766,265, issued Jun. 16, 1998, U.S. Pat. No. 5,800,569, issued Sep. 1, 1998, U.S. Pat. No. 6,511,512, issued Jan. 28, 2003, U.S. Patent Application Publication No. 2003/0093158, published May 15, 2003, U.S. patent application Ser. No. 10/642,125, filed Aug. 15, 2003, U.S. patent application Ser. No. 10/674,736, filed Sep. 30, 2003, and U.S. patent application Ser. No. 10/742,455, filed Dec. 18, 2003, the entirety of each one of which is hereby incorporated by reference herein.

The prosthetic knee 110 generally comprises a variable-torque magnetorheological (MR) actuator assembly or braking system 112 and a frame and electronics assembly or system 114 that also serves as a mount for the knee actuator 112 and facilitates in monitoring and controlling the operation of the knee actuator 112. The prosthetic knee system 110 desirably provides resistive forces to substantially simulate the position and motion of a natural knee joint during ambulation and/or other locomotory activities performed by the amputee.

Advantageously, the prosthetic knee 110 of embodiments of the invention permits the amputee to move and/or adapt comfortably and safely in a wide variety of circumstances. For example, during walking, running, sitting down, or when encountering subtle or drastic changes in the terrain, topography and environment or ambient conditions, such as, when the user lifts a suitcase or walks down a slope or encounters stairs, among others.

The prosthetic knee 110 provides stance control to limit buckling when weight is applied to the limb. In addition, the prosthetic knee 110 provides aerial swing control so that the knee reaches full extension just prior to or at heel-strike in a smooth and natural manner. Moreover, the prosthetic knee 110, by adjusting and/or fine tuning the range and/or magnitudes of the resistive torque level, can be adapted for use with a wide variety of patients having different body weights, heights and activity levels.

The prosthetic knee assembly 110 of embodiments of the invention has particular efficacy when used in conjunction with a trans-femoral (above-knee, A/N) amputee. In modified embodiments, the prosthetic knee joint 110 may be efficaciously adapted for use with a knee-disarticulation (K/D) amputee wherein the amputation is through the knee joint, as needed or desired.

FIGS. 3A-3D show a system overview of the prosthetic knee assembly 110 generally comprising the magnetorheological actuator assembly or system 112 and the frame and electronics assembly or system 114. The frame and electronics assembly 114 also provides power and communicates with the actuator assembly 112 via electrical signals. Each of these systems is described in greater detail below.

Magnetorheological Actuator

FIG. 4 shows a conceptual drawing of the rotary magnetorheological (MR) knee actuator or braking system 112 illustrating its general configuration and operation. More detailed drawings and description are provided later below

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herein. The knee actuator, damper or brake 112 can be considered a device that resists or controls motion or rotation.

The knee actuator 112 includes a substantially central core rod 113 substantially circumscribed or enveloped by an electromagnet or magnetic coil 115 and is mechanically coupled, communicated or connected with a pair of side plates or disks 116, 118. By passing a variable, controlled current through the coil 115, a variable magnetic field is created. As described further below, in some embodiments, the core rod 113 and core sides 116, 118 comprise a ferrous, magnetizable or magnetic material and the like.

The knee actuator 112 further includes a plurality of rotary inner blades, plates or rotors 120 mechanically coupled, communicated or connected with an inner spline 122. The inner spline 122 generally circumscribes or envelopes the electromagnetic coil or electromagnet 115 and is mechanically coupled, communicated or connected to the core side plates 116, 118.

In the illustrated embodiment, the inner blades 120 are substantially concentrically arranged about a knee actuator or brake axis of rotation 124. The inner spline 122 is rotatable about the knee joint axis of rotation 124, and hence so are the blades or rotors 120 and the core side plates 116, 118, as generally indicated by arrows 142. Rotation of the inner spline 122 corresponds to rotation or movement of the lower (below the knee) part of the leg. The inner spline 122, and hence the inner blades 120, are substantially irrotationally coupled to or nonrotatable with respect to the pylon 104.

The knee actuator 112 also comprises a plurality of rotary outer blades, plates or rotors 130 mechanically coupled, communicated or connected with an outer spline, housing, shell or rotor head 132. The outer spline 132 generally circumscribes or envelopes the inner spline 122 to form a fluid receiving chamber, cavity or passage 144 with the core side plates 116, 118 generally forming at least a portion of the side walls of the chamber 144.

In the illustrated embodiment, the outer blades 130 are substantially concentrically arranged about the axis of rotation 124. The outer spline 132 is rotatable about the knee joint axis of rotation 124, and hence so are the blades or rotors 130, as generally indicated by arrows 142. Rotation of the outer spline 132 corresponds to rotation or movement of the upper (above the knee) part of the leg, for example, the stump socket 106 (see FIG. 2).

As discussed further below, the outer spline 132 is mechanically coupled, communicated or connected to the stump socket 106 using a pyramid adapter or the like, thereby attaching the knee actuator 112 and the prosthetic knee 110 to the stump socket 106. The outer spline 132, and hence the outer blades 130, are substantially irrotationally coupled to or nonrotatable with respect to the stump socket 106 or residual limb 108.

The plurality of inner blades 120 and outer blades 130 are interspersed in an alternating fashion and extend into the chamber 144 that contains magnetorheological (MR) fluid 134. Gaps between adjacent blades 120 and 130 include the magnetorheological (MR) fluid 134. In one embodiment, the MR fluid 134 in the gaps or microgaps between adjacent inner blades 120 and outer blades 130 is in the form of thin lubricating films between adjacent blades 120 and 130.

During knee joint rotation, the MR fluid 134 in the plurality of gaps between the inner blades 120 and outer blades 130 is sheared to generate a damping torque to control the limb rotation. The rotary blades or disks 120 and 130 are preferably formed of a ferrous, magnetizable or magnetic material and the like. Shearing of the MR fluid 134 present between the

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core side plates 116, 118 and adjacent outer blades 130 can also contribute to the knee damping.

The knee actuator 112 comprises a pair of side mounts, walls or forks 136, 138 that are mechanically coupled, communicated or connected to the inner spline 122 and rotate with it about the knee joint axis of rotation 124, as generally indicated by arrows 142. The side mounts 136, 138 in combination with the outer spline 132 can be considered to form one main outer shell of the knee actuator 112. As discussed further below, the side mounts 136, 138 are connected to the frame and electronics assembly 114 which in turn is connected to a lower (below the knee) part of the leg, for example, the leg pylon 104 (see FIG. 2). Thus, rotation of the side mounts 136, 138 corresponds to rotation of the lower part of the leg.

In a modified embodiment, the connections of the outer spline 132 and side mounts 136, 138 to the upper and lower parts of the legs are reversed. For example, the outer spline 132 may be coupled to the lower leg rotation and the side mounts 136, 138 to the upper leg rotation.

The knee actuator 112 further includes a pair of bearings 126, 128 mechanically coupled, communicated or connected to the outer spline 132 and to respective side mounts, walls or forks 136, 138. The bearings 126, 128 are arranged so that they facilitate rotation of the outer spline 132 substantially independently of the rotation of the side mounts 136, 138.

The central core rod 113 and the electromagnet or coil 115 also rotate along with the rotation of the inner spline 122, the inner blades 120, the core side plates 116, 118 and the side mounts 136, 138. The outer blades 130 rotate together with the rotation of the outer spline 132. This also counter-rotates the inner and outer blades 120 and 130.

The inner blades 120 are substantially rotationally fixed relative to the inner spline 122 and the outer blades 130 are substantially rotationally fixed relative to the outer spline 132. The rotation of the inner blades 120, inner spline 122, outer blades 130 and outer spline 132 is substantially around or about the knee axis of rotation 124 as is the rotation of the core rod 113, core side plates 116, 118 and coil 115.

During various stages of locomotion or knee rotation, the inner blades 120 may rotate while the outer blades 130 are rotationally substantially stationary, or the outer blades 130 may rotate while the inner blades 120 are rotationally substantially stationary, or both the inner blades 120 and the outer blades 130 may rotate or be substantially rotationally stationary. Thus, relative rotational motion is created between the inner blades 120 and the outer blades 130 with the MR fluid 134 being sheared in the gaps between adjacent inner and outer blades 120 and 130. In one embodiment, to establish a frame of reference, it can be assumed that the outer spline 132 is stationary.

Actuation of the magnet or coil 115 causes a magnetic field, circuit or path 140 to be generated or created within the knee actuator 112. In one embodiment, the magnetic field 140 (as indicated by the solid arrowheads) passes laterally (generally parallel to the axis of rotation 124) through the central core rod 113, radially outwards through the core side plate 118, laterally (generally parallel to the axis of rotation 124 in a direction opposite to that through the core rod 113) through the interspersed set of inner blades 120 and outer blades 130 and the magnetorheological fluid 134, and radially inwards through the core side plate 116. As discussed further below, in another embodiment, the polarity of the magnetic field is reversed, and the magnetic field 140 (as indicated by the dashed arrowheads) passes laterally (generally parallel to the axis of rotation 124) through the central core rod 113, radially outwards through the core side plate 116, laterally (generally

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parallel to the axis of rotation 124 and in a direction opposite to that through the core rod 113) through the interspersed set of inner blades 120 and outer blades 130 and the magnetorheological fluid 134, and radially inwards through the core side plate 118.

The portion of the magnetic field 140 passing through the core rod 113 and side plates 116, 118 generally defines the magnetic return path. The active or functional magnetic field is generally defined by the magnetic path through the inner blades or rotors 120, the outer blades or rotors 130 and the MR fluid 134.

The magnetorheological (MR) fluid 134 is a field responsive (FR) fluid or medium that undergoes a rheology or viscosity change which is dependent on the magnitude of the applied magnetic field. In turn, this variation in fluid viscosity determines the magnitude of the shearing force/stress, torque or torsional resistance generated, and hence the level of damping provided by the knee actuator 112 and/or the prosthetic knee 110. The resistive braking effect is a function of the MR fluid viscosity which in turn is a function of the magnetic field. Thus, by controlling the magnitude of this magnetic field, the rotary motion of the artificial limb is controlled, for example, to control the flexion and extension during swing and stance phases to provide a more natural and safe ambulation for the amputee.

The MR fluid 134 generally comprises polarizable particles, a carrier fluid, and optionally an additive. In some embodiments, as described further below, the MR fluid 134 is specifically designed for use in a shear mode device, such as the prosthetic knee 110. For such a device, mechanically hard particles are desired. The carrier fluid also desirably experiences a less dramatic viscosity change over temperature changes as compared to other fluids.

In some embodiments, the MR fluid 134 has one or more of the following properties: a high magnetic flux capacity and low magnetic remanence and low viscosity while having a large magnetic field induced shearing stress. Advantageously, this allows the prosthetic knee 110 to provide a wide dynamic torque range.

In some embodiments, as described further below, the knee actuator 112 includes a pair of specially designed dynamic seals 162 (162a, 162b). The seals 162 run along rims of the respective side plates 116, 118 and provide a reliable dynamic seal between the side plates 116, 118 and the outer spline 132, thereby desirably allowing rotational motion while preventing leakage of the MR fluid 134 from the chamber 144. The specially designed dynamic seals 162 are configured so that the particles in the MR fluid 134 can flow in and out of the seals 162 (and, in particular, in some embodiments, as described further below, in and out of garter springs of the seals 162) without clogging them and thus advantageously preventing seal failure.

In one embodiment, as discussed further below, the rims of the core side plates 116, 118 are surface hardened to further improve dynamic seal performance. Advantageously, embodiments of the invention can have particular efficacy in providing substantially leak-proof sealing during handling and flow of small particle slurries by utilizing the specially designed dynamic seals 162.

In some embodiments, as described further below, the knee actuator 112 includes a flexible diaphragm assembly or device 146 in fluid communication with the MR fluid 134. The flexible device 146 advantageously prevents or mitigates undesirable pressure build up within the knee actuator 12, for example, due to fluid expansion or outgassing.

In some embodiments, as described further below, the chamber 144 is partially or not fully filled with the MR fluid

134 so that the remaining space contains a compressible gas that allows for fluid expansion and advantageously prevents or mitigates undesirable pressure build up. Also, when the MR fluid out gasses, it out gasses into the gas that is compressible and hence there is low pressure build up.

In some embodiments, as indicated above and also discussed further below, a degaussing technique is used to keep residual magnetism low by changing or reversing the current direction at selected intervals. Thus, the polarity and direction of the magnetic field **140** is reversed as indicated by the solid and dashed arrowheads. Advantageously, this allows the knee to "free-up" and desirably creates a low torque ability and wide dynamic torque range.

Advantageously, there is no or negligible pressure build up within the MR actuated prosthetic knee of embodiments of the invention. This substantially eliminates or reduces the chances of fluid leakage and failure of the knee, and hence desirably adds to the safety of the device.

Also advantageously, the multiple shearing surfaces or flux interfaces, provided by embodiments of the invention, behave like a torque multiplier and allow the viscous torque level to be stepped up to a desired maximum value without the use of an additional transmission or other auxiliary component.

For example, if two flux interfaces can provide a maximum viscous torque of about 1 N/m, then forty flux interfaces will be able to provide a viscous damping torque of about 40 N/m. In contrast, if a 40:1 step-up transmission is used to increase the viscous torque, disadvantageously, not only is the system reflected inertia magnified by a factor of about 1600, but the system weight, size and complexity are undesirably increased.

The multiple shearing surfaces or interfaces of embodiments of the prosthetic knee advantageously allow for a wide dynamic torque range to be achieved which permits safe and/or more natural ambulation for the patient. The low end torque is desirably kept to a minimal, in some embodiments, by a degaussing technique which allows the knee to swing substantially freely, as needed or desired.

Advantageously, the MR actuated prosthetic knee of embodiments of the invention provides a rapid and precise response. Again, this permits the patient to move in a safe and/or more natural manner.

FIGS. 5A-5E and 6 show different views of one embodiment of the prosthetic knee actuator assembly **112**. As noted above, the knee actuator **112** generally comprises the core rod **113** and core side plates **116**, **118**, the coil **115**, the inner blades **120** and the inner spline **122**, the bearings **126**, **128**, the outer blades **130** and the outer spline **132**, the side mounts **136**, **138**, the diaphragm assembly **146** and the dynamic seals **162**.

As described in greater detail below, the knee actuator **112** further comprises an extension assist assembly or system **148**, a shock absorbing or bumper assembly or system **150** on the side mounts **136**, **138**, a pyramid connector, adapter or stud **152** that facilitates connection to the stump socket **106** or the like, and a knee angle sensing or measuring assembly or system **154**. The knee actuator **112** also comprises a plurality of fastening through rods, dowels or studs **158** and associated cone nuts **160**, a pair of O-rings, seals or gaskets **182** that provide a seal between the inner spline **122** and associated core side plates **116**, **118**, and bolts **164** (**164a**, **164b**) that facilitate a rigid connection between the side mounts **136**, **138** and the frame and electronics assembly **114**.

The knee actuator **112** also comprises a pair of right and left protective side caps **156** (**156a**, **156b**). In the drawings only the left side cap **156b** is shown and the right side cap **156a** is substantially similar to the left side cap **156b**.

Core Rod

FIGS. 7-11 show different views of one embodiment of the core rod **113**. The core rod **113** generally includes a core or main body portion or section **166** that engages the core side plates **116**, **118** and a mandrel portion or section **168**.

The core portion **166** and the mandrel portion **168** are generally cylindrical in shape, though in modified embodiments other suitable shapes may be used with efficacy, as needed or desired. In the illustrated embodiment, the core portion **166** has an outer diameter that is greater than the outer diameter of the mandrel portion **168**.

The core or core portion **166** is part of the magnetic return path through the knee actuator **112**. The core portion **166** desirably has a substantially constant outer diameter along substantially its entire length. Advantageously, this improves the magnetic properties of the device by reducing or minimizing discontinuities in the magnetic field path.

The outer diameter of the core portion **166** is also dimensioned and configured such that the magnetic coil **115** fits over the core portion **166** with a suitably small tolerance fit. The core portion **166** is desirably compact so as to provide improved and/or suitable power efficiency. Advantageously, this also allows more coil turns in the coil **115** and allows higher and/or improved magnetic flux.

In one embodiment, the outer diameter of the core portion **166** is about 1.9 cm (3/4 inch). In another embodiment, the outer diameter of the core portion **166** is in the range from about 1.3 cm (1/2 inch) to about 2.5 cm (1 inch), including all values and sub-ranges therebetween. In modified embodiments, other suitable dimensions may be efficaciously utilized, as needed or desired.

The core portion **166** has a free end **170** and an opposed end **172** connected to the mandrel portion **168**. The free end **168** is dimensioned and configured to matingly engage the right core side **116**. The opposite end **172** is dimensioned and configured to matingly engage the left core side **118**. The core portion **166**, and hence the core rod **113**, rotate as the core side plates **116**, **118** rotate.

In one embodiment, and as best seen in FIG. 8, the core portion end **170** has a generally circumferential chamfered, beveled or tapered surface **174**. Advantageously, this facilitates mating engagement or mechanical connection with the right core side plate **116** utilizing a press fit technique.

The chamfer **174** desirably extends out through and beyond the right core side plate **116**. Thus, advantageously, the chamfer **174** does not adversely affect the magnetic field **140** or magnetic properties of the device. This is at least partially because discontinuities in the magnetic field path **140** are substantially prevented, minimized or reduced and the magnetic circuit **140** is not saturated due to the chamfer **174**, thereby providing higher flux.

In one embodiment, the core portion end **170** extends beyond the core side plate **116** by about 250 micrometers, microns or μm ($^{10}/_{1000}^{\text{th}}$ of an inch). In another embodiment, the core portion end **170** extends beyond the core side plate **116** by about 25 micrometers, microns or μm ($^{1}/_{1000}^{\text{th}}$ of an inch) to about 500 μm ($^{20}/_{1000}^{\text{th}}$ of an inch), including all values and sub-ranges therebetween. In modified embodiments, the core portion end **170** may extend a greater or lesser distance beyond the core side plate **116** with efficacy, as needed or desired.

In one embodiment, and as best seen in FIG. 8, the core portion end **172** has a generally circumferential chamfered, beveled or tapered surface **176**. Advantageously, this facilitates mating engagement or mechanical connection with the left core side plate **116** utilizing a press fit technique.

The chamfer 176 desirably extends out through and beyond the left core side plate 118. Thus, advantageously, the chamfer 176 does not adversely affect the magnetic field 140 or magnetic properties of the device. This is at least partially because discontinuities in the magnetic field path 140 are substantially prevented, minimized or reduced and the magnetic circuit 140 is not saturated due to the chamfer 176, thereby providing higher flux.

In one embodiment, the core portion end 172 extends beyond the core side plate 118 by about 250 micrometers, microns or μm ($^{10}/_{1000}^{\text{th}}$ of an inch). In another embodiment, the core portion end 172 extends beyond the core side plate 118 by about 25 micrometers, microns or μm ($^{1}/_{1000}^{\text{th}}$ of an inch) to about 500 μm ($^{20}/_{1000}^{\text{th}}$ of an inch), including all values and sub-ranges therebetween. In modified embodiments, the core portion end 172 may extend a greater or lesser distance beyond the core side plate 118 with efficacy, as needed or desired.

In one embodiment, the outer diameter of the mandrel portion 168 is dimensioned and configured such that a spring of the extension assist 148 fits over the mandrel portion 168 with a suitably small tolerance fit, as described further below. The mandrel portion 168 has a slot, notch or groove 188 that receives a portion, such as the inner leg, of the spring to desirably provide precision angular location setting between the mating parts. The mandrel portion 168 also comprises a generally circular inner bore 190 that receives a bearing or other rotary transmission device of the extension assist 148.

In the illustrated embodiment, the mandrel portion 168 includes a slot notch or groove 192 through which a cable or wire of the magnetic coil 115 passes through. Advantageously, this provides an exit for the magnetic coil cable and can also facilitate in keeping the magnetic coil cable in place and prevent undesirable motion or movement of the cable.

In one embodiment, the mandrel portion 168 has a pin 194 or the like that is received into a notch of the left core side plate 118 that facilitates in aligning the core rod 113 with one or both of the core side plates 116, 118. The notches 188, 192 may also facilitate in alignment. Other suitable markings, indicia and the like may be efficaciously used to facilitate in alignment and orientation of the various parts of the prosthetic knee device, as needed or desired.

In one embodiment, and as seen for example in FIG. 8, the mandrel portion 168 has at its free end a generally circumferential chamfered, beveled or tapered surface 196. Advantageously, this facilitates mating engagement or mechanical connection with the extension assist spring utilizing a press fit technique or the like.

The core rod 113 desirably comprises a magnetically soft material of high flux saturation density, high magnetic permeability and low coercivity. In one embodiment, the core rod 113 comprises an iron-cobalt (FeCo) alloy with about 17% to about 50% cobalt (Co), including all values and sub-ranges therebetween. Examples of suitable materials include, but are not limited to, VACOFLUX 17 and VACOFLUX 50 as available from Vacuumschmelze of Hanau, Germany.

In one embodiment, the core rod 113 is fabricated by first annealing in air and then machining to the desired dimensions and configuration. Advantageously, the air annealing is economical in cost and results in a suitable hardness (or softness) that is easier to machine. The machining desirably also removes any impurities (e.g., oxidation layer) that may be present or may have been introduced or formed on the surface of the material, since the impurities do not penetrate deeper than a depth of 1-2 mm or less, which is within the depth of machining.

In another embodiment, the core rod 113 is fabricated by annealing in a vacuum or partial vacuum. Optionally, hydrogen annealing, which prevents oxidation, may be used though this tends to be expensive.

In one embodiment, the annealing temperature is about 820° C. In one embodiment, the annealing time is about 4 hours to 10 hours in dry hydrogen. In one embodiment, the rate of cooling is about 100° C./hour until a temperature of about 200° C. is reached and at temperatures lower than that any cooling rate in any atmosphere may be used.

Core Side Plates

The core side plates or disks 116, 118, along with the core portion 166, are part of the magnetic return path through the knee actuator 112. The right core side plate 116 engages the free core end 170 and the left core side plate 118 engages the opposite core end 172. The skilled artisan will appreciate that the right and left side arrangements may be transposed, interchanged or reversed with efficacy, as needed or desired.

FIGS. 12-16 show different views of one embodiment of the right core side plate 116. The right side plate 116 is generally circular in shape and is rotatably fitted within the outer spline 132 such that there can be relative rotational motion between the right side plate 116 and the outer spline 132.

The right side plate 116 includes a substantially central circular cavity, opening or through hole 178a which substantially irrotationally mates with the core end 170. In modified embodiments, other suitable irrotationally interlocking shapes may be efficaciously utilized to provide for mating between the right side plate 116 and the core rod 113.

The mating engagement desirably utilizes an interference or press fit so that the right side plate 116 and the core rod 113 rotate together, in tandem or synchronously. As indicated above, in one embodiment, the chamfer 174 of the core end 170 extends beyond the plate cavity 178a so that it is substantially isolated from the magnetic circuit 140 through the device.

The right side plate 116 includes a plurality of generally equidistantly spaced circularly arranged through holes 180a. Each of the through holes 180a receives a respective one of the through rods 158. The holes 180a are radially outwardly offset relative to the cavity 178a.

The right side plate 116 has an outer peripheral rim or edge 184a which is generally circumferential and on which is rotatably fitted a respective one of the specially designed dynamic seals 162a. As described further below, this provides a dynamic seal between the rotatable right side plate 116 and the inner surface of the outer spline 132 thereby preventing leakage of MR fluid 134. In a modified embodiment, a groove, notch or the like may be provided to receive the dynamic seal 162a or a modified form of it.

In one embodiment, the outer rim 184a is surface hardened to protect the rim or edge 184a from any undesirable scratching or damage during use or, such as, for example, during assembly of the knee actuator 112. Thus, a hardened ring is provided on the seal wear surface that improves the reliability of the dynamic seal.

The surface hardening of the outer rim 184a can be performed by a number of techniques including, but not limited to, plasma coating and the like. In one embodiment, a titanium nitride surface coating or layer provides the desired surface hardening. The titanium nitride coating desirably has a hardness of about 63 HRC though in modified embodiments the hardness can be more or less.

The right side plate 116 has an inwardly facing generally annular recess 186a with an associated edge or chamfered,

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beveled or tapered surface **198a**. As described further below, the recess **186a** receives one end of the inner spline **122** to generally align and locate the engaging parts. The inner spline end sealingly contacts the surface **198a** via the O-ring **182a** at a circular location that is positioned slightly radially outwards from the circle formed by the through holes **180a**.

The right side plate **116** has an inwardly facing generally annular shoulder, step or surface **202a** that abuts against one end of the magnetic coil **115**. A coil protection washer or the like may be provided between the associated coil end and the shoulder **202a**, as needed or desired. A tapered surface or portion **206a** may be provided on the outer surface of the core plate **116** that advantageously preserves cross sectional path for magnetic flux and facilitates in evening out the magnetic flux as it travels through the side plate **116**. The tapered surface or portion **206a** can further decrease weight, save material and also provide clearance space to facilitate assembly.

In the illustrated embodiment, the outer surface of the right side plate **116** has one or more shoulders or steps **208a1**, **208a2**, **208a3** arranged in a generally circular or ring-like fashion for facilitating alignment and coupling with the right side mount **136**. Gaps or notches between the shoulders **208a1**, **208a2**, **208a3** may facilitate alignment during assembly of the knee device and may also provide clearance space, such as, for example, for wires, leads and the like. Other suitable markings or indicia may be efficaciously utilized to facilitate alignment and assembly, as needed or desired.

FIGS. 17-21 show different views of one embodiment of the left core side plate **118**. The left side plate **118** is generally circular in shape and is rotatably fitted within the outer spline **132** such that there can be relative rotational motion between the left side plate **118** and the outer spline **132**.

The left side plate **118** includes a substantially central circular cavity, opening or through hole **178b** which substantially irrotationally mates with the core end **172**. In modified embodiments, other suitable irrotationally interlocking shapes may be efficaciously utilized to provide for mating between the left side plate **118** and the core rod **113**.

The mating engagement desirably utilizes an interference or press fit so that the left side plate **118** and the core rod **113** rotate together, in tandem or synchronously. As indicated above, in one embodiment, the chamfer **176** of the core end **172** extends beyond the plate cavity **178b** so that it is substantially isolated from the magnetic circuit **140** through the device.

The left side plate **118** includes a plurality of generally equidistantly spaced circularly arranged through holes **180b**. Each of the through holes **180b** receives a respective one of the through rods **158**. The holes **180b** are radially outwardly offset relative to the cavity **178b**.

The left side plate **118** has an outer peripheral rim or edge **184b** which is generally circumferential and on which is rotatably fitted a respective one of the specially designed dynamic seals **162b**. As described further below, this provides a dynamic seal between the rotatable left side plate **118** and the inner surface of the outer spline **132** thereby preventing leakage of MR fluid **134**. In a modified embodiment, a groove, notch or the like may be provided to receive the dynamic seal **162b** or a modified form of it.

In one embodiment, the outer rim **184b** is surface hardened to protect the rim or edge **184b** from any undesirable scratching or damage during use or, such as, for example, during assembly of the knee actuator **112**. Thus, a hardened ring is provided on the seal wear surface that improves the reliability of the dynamic seal.

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The surface hardening of the outer rim **184b** can be performed by a number of techniques including, but not limited to, plasma coating and the like. In one embodiment, a titanium nitride surface coating or layer provides the desired surface hardening. The titanium nitride coating desirably has a hardness of about 63 HRC though in modified embodiments the hardness can be more or less.

The left side plate **118** has an inwardly facing generally annular recess **186b** with an associated edge or chamfered, beveled or tapered surface **198b**. As described further below, the recess **186b** receives one end of the inner spline **122** to generally align and locate the engaging parts. The inner spline end sealingly contacts the surface **198b** via the O-ring **182b** at a circular location that is positioned slightly radially outwards from the circle formed by the through holes **180b**.

The left side plate **118** has an inwardly facing generally annular shoulder, step or surface **202b** that abuts against one end of the magnetic coil **115**. A coil protection washer or the like may be provided between the associated coil end and the shoulder **202b**, as needed or desired. A tapered surface or portion **206b** may be provided on the outer surface of the core plate **118** that advantageously preserves cross sectional path for magnetic flux and facilitates in evening out the magnetic flux as it travels through the side plate **118**. The tapered surface or portion **206b** can further decrease weight, save material and also provide clearance space to facilitate assembly.

In the illustrated embodiment, the outer surface of the left side plate **118** has one or more shoulders or steps **208b1**, **208b2**, **208b3**, **208b4** arranged in a generally circular or ring-like fashion for facilitating alignment and coupling with the left side mount **138**. Gaps or notches between the shoulders **208b1**, **208b2**, **208b3**, **208b4** may facilitate alignment during assembly of the knee device and may also provide clearance space, such as, for example, for wires, leads and the like. Other suitable markings or indicia may be efficaciously utilized to facilitate alignment and assembly, as needed or desired.

In the illustrated embodiment, the left side plate **118** includes a notch, groove or recess **212** generally between the shoulders **208b3**, **208b4**. Advantageously, the notch **212** and the gap between the **208b3**, **208b4** provides clearance space for passage of a cable, lead or wire of the magnetic coil **115**. Alternatively, or in addition, a similar cable-receiving notch **45** may be provided on the right side plate **118**, as needed or desired.

The core side plates **116**, **118** desirably comprise a magnetically soft material of high flux saturation density, high magnetic permeability and low coercivity while maintaining suitable mechanical properties such as hardness, strength and ductility. In one embodiment, the core side plates **116**, **118** comprise an iron-cobalt (FeCo) alloy with about 50% iron (Fe) and about 50% cobalt (Co) such as VACODUR 50 as available from Vacuumschmelze of Hanau, Germany. VACODUR 50 has the desired magnetic properties and optimum mechanical properties including improved strength and ductility.

In modified embodiments, the core side plates **116**, **118** can comprise an iron-cobalt (FeCo) alloy with about 17% to about 50% cobalt (Co), including all values and sub-ranges therebetween. Examples of suitable materials include, but are not limited to, VACOFLUX 17 and VACOFLUX 50 as available from Vacuumschmelze of Hanau, Germany.

In one embodiment, the core side plates **116**, **118** are fabricated by first annealing in air and then machining to the desired dimensions and configuration. Advantageously, the air annealing is economical in cost and results in a suitable

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hardness (or softness) that is easier to machine. The machining desirably also removes any impurities (e.g., oxidation layer) that may be present or may have been introduced or formed on the surface of the material, since the impurities do not penetrate deeper than a depth of 1-2 mm or less, which is within the depth of machining.

In another embodiment, the core side plates 116, 118 are fabricated by annealing in a vacuum or partial vacuum. Optionally, hydrogen annealing, which prevents oxidation, may be used though this tends to be expensive.

In one embodiment, the annealing temperature is about 820° C. In one embodiment, the annealing time is about 4 hours to 10 hours in dry hydrogen. In one embodiment, the rate of cooling is about 100° C./hour until a temperature of about 200° C. is reached and at temperatures lower than that any cooling rate in any atmosphere may be used.

Bearings

FIG. 22 shows the bearings 126, 128 in accordance with one embodiment. The bearings 126, 128, in one embodiment, form a press fit with the outer spline 132 and the respective side mounts 136, 138. The bearings 126, 128 are arranged so that they facilitate rotation of the outer spline 132 substantially independently of the rotation of the side mounts 136, 138.

Each of the bearings 126, 128 generally comprises a respective central cavity 129a, 129b, a respective inner bearing surface 131a, 131b and an outer bearing surface. The inner bearing surfaces 131a, 131b are engaged with respective side mounts 136, 138 to facilitate rotation and the outer bearing surfaces 133a, 133b are engaged with the outer spline 132 to facilitate rotation.

The bearings 126, 128 can comprise any one of a number of suitable devices that transmit rotary motion and/or load while reducing frictional wear between the coupled components. In one embodiment, the bearings 126, 128 comprise ball bearings. In modified embodiments, the bearings 126, 128 can comprise any suitable combination of ball bearings, roller bearings, ball thrust bearings, roller thrust bearings, tapered roller bearings and the like, as needed or desired.

Magnetic Coil

FIGS. 23-27 show different views of one embodiment of the magnetic coil, electromagnetic or wire spool 115. In the illustrated embodiment, the magnetic coil 115 is without a bobbin or is bobbin-less and comprises copper wire or winding 214. Advantageously, the bobbin-less coil 115 has an increased relative proportion of copper which desirably results in improved performance efficiency and/or reduced electrical resistance.

The coil wire 214 is arranged in a generally circular arrangement and has a generally cylindrical cavity or through passage 216 which fits over the core portion 166 of the core rod 113 to mechanically connect the magnetic coil 115 and the core rod 113. Thus, as the core rod 113 (and core side plates 116, 118) rotate so does the magnetic coil 115. In one embodiment, the coil 115 forms a close slip fit with the core rod 113, for example, with a clearance of about $\frac{5}{1000}$ of an inch or less.

The coil wire 214 terminates in a power input or connection cable or lead wires 218 that is connected to a battery, power source or the like. The cable 218 is desirably shielded. The cable 218 passes through the mandrel portion slot 192 and the left side plate notch 212, along the left side mount 138 and finally connects to the frame and electronics assembly 114. A suitable connector or the like is provided at the free end of the cable 218 to facilitate connection to the frame and electronics assembly 114.

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The coil wire 214 has a pair of generally annular spaced opposed ends 220, 222 which are in mechanical communication with a respective one of the core side plate annular shoulders 202a, 202b. The coil ends 220, 222 may directly abut against respective shoulders 202a, 202b or coil protection washers (e.g. foam washers) may be placed between the coil ends 220, 222 and respective shoulders 202a, 202b, as needed or desired.

The coil wire 214 cross-section is generally circular or ellipsoidal. In a modified embodiment, the coil wire 214 cross-section is generally square or rectangular. The square or rectangular cross-section desirably provides for a higher packing efficiency though the cost can also be higher.

In another embodiment, a plurality of magnetic coils arranged in parallel are utilized to generate the magnetic field within the knee actuator 112. The multiple coil arrangement has an increased relative proportion of copper which desirably results in improved performance efficiency and/or reduced electrical resistance. The multiple coil arrangement can also provide enhanced frequency response characteristics.

Inner Spline

FIGS. 28-32 show different views of one embodiment of the rotary inner spline 122. The inner spline 122 generally circumscribes or envelopes the magnetic coil or electromagnet 115 and is coupled or mechanically connected to the side plates 116, 118. The inner blades or rotors 120 are fitted over the inner spline 122 and are generally concentrically arranged about the brake axis of rotation 124. The inner spline 122 is rotatable about the knee joint axis of rotation 124, and hence so are the blades or rotors 120 and the core side plates 116, 118. Rotation of the inner spline 122 corresponds to rotation or movement of the lower (below the knee) part of the leg.

In the illustrated embodiment, the inner spline 122 is generally cylindrical in shape and comprises a substantially central cylindrical cavity or through hole 224. The inner spline cavity 224 receives the electromagnet or magnetic coil 115 which is rotatable along with the inner spline 122.

The exterior surface of the inner spline 122 comprises a plurality of longitudinal grooves, notches, splines or keyways 226 that extend generally parallel to the axis of rotation 124 and securely engage or mate with corresponding teeth or keys of the inner blades 120. In the illustrated embodiment, the inner spline 122 comprises nine substantially equally spaced grooves 226. In modified embodiments, fewer or more teeth-engaging grooves arranged in other suitable manners may be efficaciously utilized, as needed or desired.

The grooves 226 are desirably generally rectangular or square shaped to facilitate reliable load or torque transmission between the inner spline 122 and the inner rotors 120. In modified embodiments, the grooves 226 may have other suitable shapes such as round, semi-circular, curved, polygonal, and combinations thereof among others, with efficacy, as needed or desired.

In the illustrated embodiment, the inner spline 122 includes three longitudinal dowel-receiving holes, cavities or passages 228 that are arranged substantially equidistantly and in a generally circular fashion. In modified embodiments, fewer or more dowel-receiving passages arranged in other suitable manners may be efficaciously utilized, as needed or desired.

The passages 228 are substantially aligned with the holes 180a, 180b of respective core side plates 116, 118. The passages 228 (and holes 180a, 180b) receive a respective one of the studs or rods 158 to secure selected components of the knee actuator 112, such as the core side plates 116, 118 and the inner spline 122.

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In the illustrated embodiment, the inner spline cavity 224 further includes a plurality of longitudinal recesses 230. The recesses 230 desirably serve to reduce the weight of the inner spline 122, and hence that of the knee actuator 112 and prosthetic knee 110.

In the illustrated embodiment, and as best seen in FIGS. 29 and 30, inner spline ends 234a, 234b each have a respective generally circular groove or flange 232a, 232b that receives a respective one of the O-rings or gaskets 182a, 182b. The inner spline ends 234a, 234b extend at least partially into the respective core side plate recesses 186a, 186b.

The O-rings 182a, 182b seal against respective side plate edges or surfaces 198a, 198b to form a static seal between the rotatable inner spline 122 and the rotatable core side plates 116, 118 since these components rotate together during knee rotation. The static seal desirably prevents leakage of MR fluid 134 from the knee actuator chamber 144 (see, for example, FIG. 4). In one embodiment, the O-rings 182 comprise Viton® which has desirable properties to operate with oils and the like. In modified embodiments, the O-rings 182 can comprise any one of a number of suitable seal-providing materials such as rubber, Teflon® and Neoprene among others, as needed or desired.

The inner spline 122 is desirably fabricated from titanium or a titanium alloy, such as 6Al-4V titanium alloy, to provide a non-ferrous yet strong, hard surface with low weight to engage the rotors 120 and transmit torque from them. Advantageously, the use of titanium or titanium alloys provides a near zero magnetic permeability and a yet strong, hard surface. An additional benefit is that the high resistivity of the material (titanium or titanium alloy) reduces energy losses due to induced eddy currents. In modified embodiments, the inner spline 122 can be efficaciously fabricated from other suitable metals, alloys, plastics, ceramics, among others, as required or desired.

The inner spline 122 is desirably formed by machining, such as wire electro-discharge machining (EDM). In another embodiment, the inner spline 122 is formed by broaching. In modified embodiments, the inner spline 122 can be efficaciously fabricated from other suitable techniques, for example, casting, forging, molding, laser processing, among others, as required or desired.

Inner Rotors

FIGS. 33-35 show different views of one embodiment of the rotary inner blades, plates or rotors 120. The inner blades 120 are mechanically coupled, communicated or connected with the inner spline 122 and are substantially concentrically arranged about the knee actuator or brake axis of rotation 124. The inner blades 120 rotate with the inner spline 122 about the axis of rotation 124.

In the illustrated embodiment, the inner blades 120 are generally circular in shape with an annular or ring shaped profile and a generally uniform and thin thickness. The blades 120 comprise a substantially central cavity or through hole 236 that receive the inner spline 122. The blades 120 have a plurality of inwardly extending teeth, splines or keys 238 on their inner edges or peripheries 242 that engage or mate with the inner spline grooves or key-ways 226 to secure the blades 120 to the inner spline 122.

In the illustrated embodiment, the inner blades 120 each comprise nine approximately equally spaced teeth 238 which are generally rectangular or square shaped to facilitate torque or load transmission between the blades 120 and the inner spline 122. In modified embodiments, the blades 120 may efficaciously comprise fewer or more teeth 238 arranged in

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other suitable manners and having modified shapes, such as other polygonal, semi-circular or curved configurations, as needed or desired.

The inner blades 120 desirably comprise a magnetically soft material of high flux saturation density, high magnetic permeability and low coercivity while maintaining suitable mechanical properties such as hardness, strength and ductility. The low coercivity advantageously results in minimal or low build-up of residual magnetism within the device. In one embodiment, the inner blades 120 comprise an iron-cobalt (FeCo) alloy with about 50% iron (Fe) and about 50% cobalt (Co) such as VACODUR 50 as available from Vacuum-schmelze of Hanau, Germany. VACODUR 50 has the desired magnetic properties and optimum mechanical properties including improved strength and ductility. In another embodiment, the inner blades 120 comprise spring steel which is desirably magnetically soft and mechanically hard to enhance durability and minimize wear.

In modified embodiments, the inner blades 120 may comprise other suitable materials that are magnetically soft and mechanically hard to enhance durability and minimize wear. These include blue temper steel and silicon steel.

The inner blades 120 are desirably formed by machining, such as wire electro-discharge machining (EDM). Advantageously, this permits a high degree of manufacturing precision and avoids or mitigates any undesirable backlash, jarring or play between the rotors 120 and inner spline 122 which may otherwise cause discomfort to the patient. In another embodiment, the inner blades 120 are formed by stamping. In yet another embodiment, the inner blades 120 are formed by laser processing. In modified embodiments, the inner blades 120 can be efficaciously fabricated from other suitable techniques, for example, casting, forging, molding, among others, as required or desired.

FIG. 36 shows an inner blade 120' in accordance with a modified embodiment. The inner blade 120' has a plurality of through holes 240. Alternatively, or in addition, cross channels may be provided at inner and/or outer edges 242, 244 of the blade 120'.

The holes 240 (and/or cross channels) impose a discontinuous path that can, in some embodiments, desirably improve magnetic properties of the knee device. In some embodiments, advantageously, the holes 240 (and/or cross channels) can improve the high-end torque, add to device life by increasing the MR fluid volume and improve power efficiency.

In the illustrated embodiment, the holes 240 are arranged in generally circular rows with a staggered configuration, though in modified embodiments other suitable hole arrangements may be efficaciously used, as needed or desired. In one embodiment, the hole diameter D₃₆₁ is about 2.71 mm (0.1065 inches), the outer row diameter D₃₆₂ is about 44.58 mm (1.755 inches), the inner row diameter D₃₆₃ is about 40.51 mm (1.595 inches), the angles θ₃₆₁ and θ₃₆₂ are about 15° and the angle θ₃₆₃ is about 7.5°. In modified embodiments, other suitable dimensions may be used with efficacy, as needed or desired.

In a modified embodiment, the rotors 120 have a generally polygonal inner periphery with multiple sides, for example, six, eight, twelve, etc., for interlocking with a mating configuration of the inner spline 122. This embodiment may or may not include the inner blade teeth 238.

Outer Rotors

FIGS. 37-39 show different views of one embodiment of the rotary outer blades, plates or rotors 130. The outer blades 130 are mechanically coupled, communicated or connected

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with an outer spline, housing, shell or rotor head 132 and are substantially concentrically arranged about the axis of rotation 124. The outer blades 130 rotate with the outer spline 132 about the axis of rotation 124.

In the illustrated embodiment, the outer blades 130 are generally circular in shape with an annular or ring shaped profile and a generally uniform and thin thickness. The blades 130 comprise a substantially central cavity or through hole 246 that non-contactingly receives the inner spline 122. The blades 130 have a plurality of outwardly extending teeth, splines or keys 248 on their outer edges or peripheries 254 that engage or mate with grooves or key-ways on the interior of the rotatable outer spline 132 to secure the blades 130 to the outer spline 132.

In the illustrated embodiment, the outer blades 130 each comprise nine approximately equally spaced teeth 248 which are generally rectangular or square shaped to facilitate engagement and torque or load transmission between the blades 130 and the outer spline 132. In modified embodiments, the blades 130 may efficaciously comprise fewer or more teeth 248 arranged in other suitable manners and having modified shapes, such as other polygonal, semi-circular or curved-configurations, as needed or desired.

The outer blades 130 desirably comprise a magnetically soft material of high flux saturation density, high magnetic permeability and low coercivity while maintaining suitable mechanical properties such as hardness, strength and ductility. The low coercivity advantageously results in minimal or low build-up of residual magnetism within the device. In one embodiment, the outer blades 130 comprise an iron-cobalt (FeCo) alloy with about 50% iron (Fe) and about 50% cobalt (Co) such as VACODUR 50 as available from Vacuum-schmelze of Hanau, Germany. VACODUR 50 has the desired magnetic properties and optimum mechanical properties including improved strength and ductility. In another embodiment, the outer blades 130 comprise spring steel which is desirably magnetically soft and mechanically hard to enhance durability and minimize wear.

In modified embodiments, the outer blades 130 may comprise other suitable materials that are magnetically soft and mechanically hard to enhance durability and minimize wear. These include blue temper steel and silicon steel.

The outer blades 130 are desirably formed by machining, such as wire electro-discharge machining (EDM). Advantageously, this permits a high degree of manufacturing precision and avoids or mitigates any undesirable backlash, jarring or play between the rotors 130 and outer spline 132 which may otherwise cause discomfort to the patient. In another embodiment, the outer blades 130 are formed by stamping. In yet another embodiment, the outer blades 130 are formed by laser processing. In modified embodiments, the outer blades 130 can be efficaciously fabricated from other suitable techniques, for example, casting, forging, molding, among others, as required or desired.

FIG. 40 shows an outer blade 130' in accordance with a modified embodiment. The outer blade 130' has a plurality of through holes 250. Alternatively, or in addition, cross channels may be provided at inner and/or outer edges 252, 254 of the blade 130'.

The holes 250 (and/or cross channels) impose a discontinuous path that can, in some embodiments, desirably improve magnetic properties of the knee device. In some embodiments, advantageously, the holes 250 (and/or cross channels) can improve the high-end torque, add to device life by increasing the MR fluid volume and improve power efficiency.

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In the illustrated embodiment, the holes 250 are arranged in generally circular rows with a staggered configuration, though in modified embodiments other suitable hole arrangements may be efficaciously used, as needed or desired. In one embodiment, the hole diameter D_{401} is about 2.71 mm (0.1065 inches), the outer row diameter D_{402} is about 44.58 mm (1.755 inches), the inner row diameter D_{403} is about 40.51 mm (1.595 inches), the angles θ_{401} and θ_{402} are about 15° and the angle θ_{403} is about 7.5°. In modified embodiments, other suitable dimensions may be used with efficacy, as needed or desired.

In a modified embodiment, the rotors 130 have a generally polygonal outer periphery with multiple sides, for example, six, eight, twelve, etc., for interlocking with a mating configuration of the outer spline 132. This embodiment may or may not include the outer blade teeth 248.

Rotor Arrangement and Spacing

The inner blades 120 and outer blades 130 are interspersed in an alternating fashion about the axis of rotation 124. The blades 120, 130 extend into the chamber 144 (see, for example, FIG. 4) that contains magnetorheological (MR) fluid 134. Gaps between adjacent blades 120 and 130 include the magnetorheological (MR) fluid 134. During knee joint rotation, the MR fluid 134 in the gaps between the inner blades 120 and outer blades 130 is sheared to generate a damping torque to control the limb rotation.

The inner blades 120 are substantially rotationally fixed relative to the inner spline 122 and the outer blades 130 are substantially rotationally fixed relative to the outer spline 132. The rotation of the inner blades 120, inner spline 122, outer blades 130 and outer spline 132 is substantially around or about the knee axis of rotation 124.

During various stages of locomotion or knee rotation, the inner blades 120 may rotate while the outer blades 130 are rotationally substantially stationary, or the outer blades 130 may rotate while the inner blades 120 are rotationally substantially stationary, or both the inner blades 120 and the outer blades 130 may rotate or be substantially rotationally stationary. Thus, relative rotational motion is created between the inner blades 120 and the outer blades 130 with the MR fluid 134 being sheared in the gaps between adjacent inner and outer blades 120 and 130.

The optimal blade gap size or spacing (G_b) depends on several factors. One factor is the size or diameter (D_p) of the particles of the MR fluid 134. The gap size (G_b) can be selected to optimize fluid longevity by being at least about the order of the particle size (D_p). Other factors include the thickness of the blades 120, 130 and the number of blades 120, 130.

It is also desirable to minimize the MR fluid gap between adjacent rotors 220 and stators 230 since the power needed to saturate the total MR fluid gap is a strong function of the gap size (G_b). Thus, advantageously, a smaller gap size renders the knee device more efficient and reduces power consumption.

In one embodiment, the gap size or blade spacing (G_b) is about 18 microns or μm (0.0007 inches). In another embodiment, gap size or blade spacing (G_b) is in the range from about 13 μm (0.0005 inches) to about 130 μm (0.005 inches), including all values and sub-ranges therebetween. In yet another embodiment, gap size or blade spacing (G_b) is in the range from about 5 μm (0.0002 inches) to about 250 μm (0.01 inches), including all values and sub-ranges therebetween. A more durable MR fluid, some embodiments of which are described in further detail below, desirably allows for a smaller gap size (G_b).

In one embodiment, the ratio of the gap size (G_b) and the particle size (D_p) is generally given by the following relationship, including all values and sub-ranges therebetween, with the upper limit of the range generally corresponding to the largest gap size and the smallest particle size:

$$1 \leq \frac{G_b}{D_p} \leq 650$$

In one embodiment, the knee actuator 112 comprises N_{outer} outer blades 130 and N_{inner} inner blades 120 where $N_{inner}=$ ($N_{outer}-1$) and N_{outer} and N_{inner} are positive integers. The outer blades 130 and the inner blades 120 alternate to form a blade stack or set with an outer blade 130 at the beginning and end of the blade stack. This results in N_{inner} number of flux interfaces and $(2 \times N_{inner})$ or $(N_{inner}+N_{outer}-1)$ fluid gaps between the blades 120 and 130 in which the magnetorheological (MR) fluid 134 resides. When the side plates 116, 118 are included in the configuration, this results in N_{outer} number of flux interfaces and $(2 \times N_{outer})$ or $(N_{inner}+N_{outer}+1)$ fluid gaps in which the magnetorheological (MR) fluid 134 resides.

In one embodiment, the knee actuator 112 comprises about 59 blades with 29 inner blades 120 and 30 outer blades 130. In another embodiment, the knee actuator 112 comprises about 61 blades with 30 inner blades 120 and 31 outer blades 130. In yet another embodiment, the knee actuator 112 comprises about 83 blades with 41 inner blades 120 and 42 outer blades 130. In still another embodiment, the knee actuator 112 comprises about 81 blades with 40 inner blades 120 and 41 outer blades 130. In a further embodiment, the knee actuator 112 comprises about 85 blades with 42 inner blades 120 and 43 outer blades 130. In modified embodiments, fewer or more blades 120, 130 may be efficaciously utilized, as needed or desired.

In one embodiment, the inner blades 120 have a thickness of about 0.2 mm (0.008 inches). In another embodiment, the inner blades 120 have a thickness of about 0.25 mm (0.010 inches). In yet another embodiment, the inner blades 120 have a thickness of about 0.3 mm (0.012 inches). In modified embodiments, other suitable dimensions and thickness may be efficaciously utilized, as needed or desired.

In one embodiment, the outer blades 130 have a thickness of about 0.2 mm (0.008 inches). In another embodiment, the outer blades 130 have a thickness of about 0.25 mm (0.010 inches). In yet another embodiment, the outer blades 130 have a thickness of about 0.3 mm (0.012 inches). In modified embodiments, other suitable dimensions and thickness may be efficaciously utilized, as needed or desired.

In some embodiments, the thickness of the inner blades 120 is greater than the thickness of the outer blades 130. In one embodiment, the inner blades 120 have a thickness of about 0.3 mm (0.012 inches) and the outer blades 130 have a thickness of about 0.25 mm (0.010 inches). In another embodiment, the inner blades 120 have a thickness of about 0.3 mm (0.012 inches) and the outer blades 130 have a thickness of about 0.2 mm (0.008 inches). In modified embodiments, other suitable dimensions and thickness may be efficaciously utilized, as needed or desired.

In one embodiment, the inner blades 120 have a thickness about 25% greater than the thickness of the outer blades 130. In another embodiment, the inner blades 120 have a thickness about 50% greater than the thickness of the outer blades 130. In yet another embodiment, the inner blades 120 have a thickness about 20% to about 60%, including all values and sub-ranges therebetween, greater than the thickness of the outer

blades 130. In modified embodiments, other suitable dimensions and thickness may be efficaciously utilized, as needed or desired.

The induced yield stress or viscous torque is proportional to the overlap area between an inner-outer blade pair multiplied by twice the number of inner blades. This desirably allows the viscous torque or yield stress to be increased or decreased by selecting or predetermining the number of blades 120, 130 and/or the overlap or mating surface area between adjacent blades 120, 130 and/or the gap size therebetween.

Outer Spline

FIGS. 41-45 show different views of one embodiment of the rotary outer spline, housing, shell or rotor head 132. The outer spline 132 generally circumscribes and houses the inner blades 120 and the inner spline 122 to form the fluid receiving chamber, cavity or passage 144. The inner spline 122 in turn generally circumscribes the magnetic coil 115 and the core portion 166.

The outer blades or rotors 130 are fitted within the outer spline 132 and rotate with the outer spline 132 about the axis of rotation 124. Rotation of the outer spline 132 corresponds to rotation or movement of the upper (above the knee) part of the leg, for example, the stump socket 106 (see FIG. 2).

In the illustrated embodiment, the outer spline 132 is generally cylindrical in shape and comprises a substantially central cylindrical cavity or through hole 256. The cavity 256 has a sealed interior chamber 258 that receives the inner spline 122 and forms the sealed outer annular MR fluid chamber 144 (see, for example, FIG. 4) in which the blades 120, 130 extend and rotate. The core side plates 116, 118 are positioned in the cavity 256 to generally form at least a portion of the side walls of the chamber 144 and the specially configured dynamic seals 162 reliably seal the device against undesirable leakage.

The surface of the interior chamber 256 (and/or fluid chamber 144) comprises a plurality of longitudinal grooves, notches, splines or key-ways 260 that extend generally parallel to the axis of rotation 124 and securely engage or mate with corresponding teeth or keys 248 of the outer blades 130. In the illustrated embodiment, the outer spline 132 comprises nine substantially equally spaced grooves 260. In modified embodiments, fewer or more teeth-engaging grooves arranged in other suitable manners may be efficaciously utilized, as needed or desired.

The grooves 260 are desirably generally rectangular or square shaped to facilitate reliable load or torque transmission between the outer spline 132 and the outer rotors 130. In modified embodiments, the grooves 260 may have other suitable shapes such as round, semi-circular, curved, polygonal, and combinations thereof among others, with efficacy, as needed or desired.

In the illustrated embodiment, the surface of the interior chamber 256 (and/or fluid chamber 144) comprises a plurality of cross channels 262 that extend generally parallel to the grooves 260. The channels 262 advantageously provide for increased volume of the interior chamber 256 (and/or fluid chamber 144), thereby permitting greater capacity to hold the MR fluid 134. The channels 262 are desirably positioned on the upper or top portion of the interior chamber 256 (and/or fluid chamber 144), thus substantially preventing any undesirable accumulation of particles of the MR fluid 134 therein.

The outer spline cavity 256 further includes a pair of generally circular recesses 264 (264a, 264b) on either side of the interior chamber interior chamber 256 (and/or fluid chamber 144) that receive a respective one of the core side plates 116, 118 and dynamic seals 162a, 162b. The recesses 264a, 264b

have respective seal engaging surfaces, flanges or shoulders 266a, 266b and 267a, 267b that abut against a respective one of the dynamic seals 162a, 162b, thereby preventing undesirable fluid leakage from the chamber 256. As discussed further below, the dynamic seals 162 rotate with the outer spline 132.

The outer spline cavity 256 further includes a pair of generally circular recesses 268 (268a, 268b) on either side of respective recesses 264a, 264b. The recesses 268a, 268b receive a respective one of the bearings 126, 128. The recesses 268a, 268b have respective bearing surfaces, flanges or shoulders 275a, 275b that engage respective outer bearing surfaces 133a, 133b of respective bearings 126, 128. In one embodiment, the bearings 126, 128 form a press fit within respective outer spline recesses 268a, 268b.

In one embodiment, the outer spline 132 includes, near its top end and proximate the right recess 268a, a slot, cavity or opening 269a that receives an arm portion of the angle sensor assembly 154, as described further below. In the illustrated embodiment, the slot 269a is generally rectangular or U-shaped though in modified other suitable shapes may be used, as needed or desired. A threaded hole 271a is in communication with the slot 269a and extends downwardly from the slot 269a for attaching the angle sensor arm portion therein.

In one embodiment, the outer spline 132 includes, near its top end and proximate the left recess 268b, a slot, cavity or opening 269b that receives an arm portion of the extension assist assembly 148, as described further below. In the illustrated embodiment, the slot 269b is generally rectangular or U-shaped though in modified embodiments other suitable shapes may be used, as needed or desired.

A threaded hole 271b is in communication with the slot 269b and extends downwardly towards the slot 269b. The threaded hole 271b engages a set screw 273 (see, for example, FIG. 6) or the like for securing the extension assist arm portion within the slot 269b.

The outer spline 132 has a generally frusto-conical or domed top end or portion 270 with a generally cylindrical central cavity or cup 272 with a base surface 274. The cavity 272 has a threaded side wall 276 with female threads or counter bores that engage corresponding male threads of the pyramid adapter 152 to connect the outer spline 132 and adapter 152.

The convex dome shape of the outer spline top end 270 desirably facilitates connection between the pyramid adapter 152 and the stump socket 106. The distal end of the stump socket 106 (or an annular connection member there at) can have a spherically concave distal edge with substantially the same radius of curvature as the convex dome of the outer spline top end 270. Thus, when the distal end of the stump socket 106 (or an annular connection member there at) is seated on the domed top end 270, it allows relative pivoting and rotation therebetween to provide proper orientation between the stump socket 106 and the outer spline 132 (and/or prosthetic knee 110).

The cavity 272, in some embodiments, houses the diaphragm assembly 146 which is in fluid communication with the chamber 144 (and/or chamber 258) via a port 278, described with respect FIGS. 55-62 below. The diaphragm assembly 146 is generally below the pyramid connector 152. As discussed further below, advantageously, the diaphragm assembly 146 prevents or mitigates undesirable pressure build up within chamber 144 (and/or chamber 258) and prevents undesirable fluid leakage.

In the illustrated embodiment, the outer spline 132 includes a bottom or lower threaded port or hole 280 in fluid communication with the chamber 144 (and/or chamber 258). As

discussed further below, in some embodiments, the port 280 is used to fill MR fluid 134 in to the chamber 144 (and/or chamber 258) utilizing an efficient and specially configured fill scheme. After the MR fluid 134 has been loaded into the actuator 112, the hole 280 is closed with a set screw or the like.

In the illustrated embodiment, the outer surface of the outer spline 132 comprises a pair of spaced stops or fangs 282 (282a, 282b) with respective engaging or contacting surfaces 283 (283a, 283b). At full knee extension, the stops 282a, 282b engage or contact the specially designed shock absorbing bumper assembly 150 to prevent further knee rotation. Similarly, one or more stops may be provided on the outer spline 132, for example, at 284, in conjunction with associated hard stops or bumper or bumper assemblies on the side mounts 136, 138 to control the maximum knee flexion to a predetermined flexion angle, as needed or desired.

In one embodiment, the outer spline 132 is fabricated from titanium or a titanium alloy, such as 6Al-4V titanium alloy, to provide a non-ferrous yet strong, hard surface with low weight to engage the rotors 130 and transmit torque from them. Advantageously, the use of titanium or titanium alloys provides a near zero magnetic permeability and a yet strong, hard surface. An additional benefit is that the high resistivity of the material (titanium or titanium alloy) reduces energy losses due to induced eddy currents.

In another embodiment, the outer spline 132 comprises anodized 7075-T6 aluminum alloy. Advantageously, the hard anodized aluminum alloy surface protects the surfaces of the outer spline grooves 260 against surface damage and hence eliminates or mitigates any backlash, jarring or play. In modified embodiments, the outer spline 132 can be efficaciously fabricated from other suitable metals, alloys, plastics, ceramics, among others, as required or desired. In one embodiment, the outer spline 132 is nickel plated.

The outer spline 132 is desirably formed by machining, such as wire electro-discharge machining (EDM). In another embodiment, the outer spline 132 is formed by broaching. In modified embodiments, the outer spline 132 can be efficaciously fabricated from other suitable techniques, for example, casting, forging, molding, laser processing, among others, as required or desired.

Dynamic Seals

FIGS. 46-48 show different views of one embodiment of the rotary dynamic "radial" seals 162 (162a, 162b). The dynamic seal 162 generally comprises a protective seal can, case, shell or housing 312, a seal element or lip seal 314 and an internal garter spring 316. FIGS. 49 and 50 show different views of one embodiment of the lip seal element 314.

As described further below, the dynamic seal 162 of embodiments of the invention is specially configured and designed with a pre-loaded tensioned garter spring 316 with predetermined coil spacing that is at least as large as the size of particles or maximum size of particles in the MR fluid 134. Desirably, this allows MR fluid particles to flow in and out of the dynamic seal 162 without clogging the seal and advantageously provides for a reliable dynamic seal.

The dynamic seals 162 of embodiments of the invention create a barrier between surfaces in relative motion which, in the prosthetic knee embodiments, are rotatable surfaces of the core side plates 116, 118 and the outer spline 132 to prevent leakage of MR fluid from the chamber 144 therebetween. At any given knee rotation, the core side plates 116, 118 may rotate while the outer spline 132 is rotationally fixed, or the outer spline 132 may rotate while the core side plates 116, 118

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are rotationally fixed, or the core side plates 116, 118 and the outer spline 132 may all rotate.

The dynamic seals 162a, 162b fit over a respective of the outer rims 184a, 184b (see, for example, FIGS. 14 and 19) of respective core side plates 116, 118 and rotate with the outer spline 132. The dynamic seals 162a, 162b are positioned in a respective one of the recesses or cavities 264a, 264b (see, for example, FIG. 45) of the rotatable outer spline 132.

In the illustrated embodiment, the seal case 312 is generally circular in shape and has a generally L-shaped cross section. The seal case 312 desirably provides rigidity to the dynamic seal 162.

As best seen in FIG. 48, the seal case 312 generally fits over the seal element 314 and is attached to it, for example, by bonding. The seal case 312 has an upper outer or OD surface 318 that generally defines the dynamic seal outer diameter (OD) and a rear outer surface 320 that faces away from the MR fluid side and towards the air, atmosphere or ambient side. In one embodiment, the seal case surfaces 318 of respective dynamic seals 162a, 162b form a press fit within a respective one of the outer spline surfaces 267a, 267b.

In one embodiment, the seal case 312 comprises stainless steel to provide the desired strength characteristics. In modified embodiments, the seal case 312 can be efficaciously fabricated from other suitable metals, alloys, plastics, ceramics, among others, as required or desired. In one embodiment, the seal case 312 is coated with a corrosion inhibitor to provide enhanced durability.

In one embodiment, the seal case 312 is fabricated by laser cutting a generally circular ring from a metal or alloy such as sheet steel. The rings are desirably roll-formed to prevent the finished seals from distorting when fabricating stresses are relieved by installation, age and temperature forces. The formed ring may be grit blasted to provide a suitable finish, as needed or desired, and coated with a bonding agent that provides suitable adhesion to the seal element material. In modified embodiments, the seal case 312 can be efficaciously fabricated from other suitable techniques, for example, machining, casting, forging, molding, laser processing, among others, as required or desired.

The seal element 314 is generally circular and has one or more sealing lips which provide for dynamic sealing. The seal element 314 has a generally circular spring-loaded seal lip 322 at the dynamic seal inner diameter (ID) and a garter spring cavity 323. The seal lip 322 is kept in position by the garter spring 316 which is housed in a generally circular internal groove or notch 324 generally above the seal lip 322. The groove 324 has a semi-circular cross section.

The seal lip 322 has a tip 326 at generally its inner-most diameter location. The seal lips 322 and their tips 326 of respective dynamic seals 162a, 162b dynamically engage or seal against a respective one of the generally circular outer rims 184a, 184b (see, for example, FIGS. 14 and 19) of respective core side plates 116, 118. The seal lips 322 are rotatable with the outer spline 132 and dynamically sealingly rotate over the core plate rims 184a, 184b.

In the illustrated embodiment of FIG. 48, the seal element 314 can include another generally circular seal lip 328 with a tip 330 facing the inner or MR fluid side. The core side plate rims 184a, 184b and the outer spline surfaces 266a, 266b are generally perpendicular to one another.

Referring in particular to the embodiment of FIG. 48, the configuration and arrangement of the seal lips 322, 328 and/or the groove 324 and/or the garter spring 316 can provide several advantages. One advantage is that the spring 316 provides optimized loading of the seal lip 322 and its tip 326 and enhanced seal performance.

In the illustrated embodiment of FIG. 48, the spring centerline 332 is offset relative to the tip 326 as generally denoted by $L_{spring-offset}$ and the centerline plane 334 of the spring groove 324 is skewed or not coincident with the plane 336

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through the circumference of the spring 316. In some embodiments, the former may also be stated as the tip 322 not being directly below the spring 316 or its centerline 332 while the latter may also be stated as the plane 334 being skewed or not perpendicular to the core plate rim surface 184 (184a, 184b).

One important advantage of providing the offset, generally denoted by length $L_{spring-offset}$, is that it allows for the use of a sharper, steeper or larger MR fluid side angle $\theta_{MRfluid}$ (or slurry side angle θ_{slurry}). The sharper angle $\theta_{MRfluid}$ (or θ_{slurry}) desirably creates a higher pressure or load point/area contact between the resilient tip 326 and the associated rim surface 184 during their relative motion, thereby desirably allowing for reliable and secure sealing.

In one embodiment, the angle $\theta_{MRfluid}$ (or θ_{slurry}) is about 70°. In another embodiment, the angle $\theta_{MRfluid}$ (or θ_{slurry}) is in the range from about 60° to about 75°, including all values and sub-ranges therebetween. In yet another embodiment, the angle $\theta_{MRfluid}$ (or θ_{slurry}) is in the range from about 45° to about 80°, including all values and sub-ranges therebetween. In modified embodiments, the angle $\theta_{MRfluid}$ (or θ_{slurry}) may 20 efficaciously be lower or higher, as needed or desired.

In one embodiment, the spring offset length $L_{spring-offset}$ is about the same as the garter spring cross-sectional diameter D_{spring} . In one embodiment, the offset length $L_{spring-offset}$ is about 1 mm (0.04 inches). In another embodiment, the offset length $L_{spring-offset}$ is in the range from about 0.5 mm to about 1.5 mm, including all values and sub-ranges therebetween. In yet another embodiment, the offset length $L_{spring-offset}$ is in the range from about 0.1 mm to about 2 mm, including all values and sub-ranges therebetween. In modified embodiments, the offset length $L_{spring-offset}$ may efficaciously be lower or higher, as needed or desired.

In the illustrated embodiment of FIG. 48, the seal lip 322 includes or is associated with support material 338 generally below, or closer to the dynamic seal inner diameter, than the spring 316 and/or the spring groove 324. The support material 338 desirably provides enhanced strength and/or improves the dynamic seal quality between the lip 322 and the associated core side plate rim 184.

In the illustrated embodiment of FIG. 48, a shallow or small air, atmosphere or ambient side angle $\theta_{ambient}$ is provided. Desirably, this improves the seal quality between the lip 322 and the associated core side plate rim 184 and/or may provide enhanced strength.

In one embodiment, the angle $\theta_{ambient}$ is about 10°. In another embodiment, the angle $\theta_{ambient}$ is in the range from about 7.5° to about 30°, including all values and sub-ranges therebetween. In yet another embodiment, the angle $\theta_{ambient}$ is in the range from about 5° to about 40°, including all values and sub-ranges therebetween. In modified embodiments, the angle $\theta_{ambient}$ may efficaciously be lower or higher, as needed or desired.

In the illustrated embodiment of FIG. 48, the seal lip 328 includes or is associated with support material 340 adjacent to the spring 316. The support material 340 is on the MR fluid side (or slurry side) and at least a portion of it is above, or closer to the dynamic seal outer diameter, than the spring centerline 332. Advantageously, the support 340 facilitates in keeping the tensioned, loaded or extended spring 316 in its place in the track or groove 324.

The seal element 314 further includes a support portion or structure 342 at generally the dynamic seal outer diameter (OD). The support structure has MR fluid (or slurry) facing surface 344 and an outer diameter side facing surface 346 that may be tapered.

The seal surfaces 344 of respective dynamic seals 162a, 162b engage or seal against a respective one of the generally circular surfaces 266a, 266b (see, for example, FIG. 45) of the outer spline 132. This engagement is substantially irrotational since the dynamic seals 162 rotate with the outer spline 132.

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The seal surfaces 346 of respective dynamic seals 182a, 182b may engage or seal against a respective one of the generally circular surfaces 267a, 267b (see, for example, FIG. 45) of the outer spline 132. This engagement is substantially irrotational since the dynamic seals 162 rotate with the outer spline 132.

As shown in phantom in FIG. 48, the seal portion 342 may include one or more generally circular sealing lips such as the seal lip 344' and the seal lip 346', as needed or desired. The seal case 312 may have a tip 348 associated with the seal portion 342 to provide enhanced rigidity, as needed or desired.

The seal lips 344' of respective dynamic seals 182a, 182b engage or seal against a respective one of the generally circular surfaces 266a, 266b of the outer spline 132. The seal lips 346' of respective dynamic seals 182a, 182b may engage or seal against a respective one of the generally circular surfaces 267a, 267b of the outer spline 132.

The seal element 314 desirably comprises a flexible material such as a rubber, an elastomer, an elastomeric compound or the like that provides suitable sealing characteristics. In one embodiment, the seal element 314 comprises Viton®. In another embodiment, the seal element 314 comprises Nitrile, sometimes referred to as NBR or BUNA-N. In modified embodiments, the seal element 314 can be efficaciously fabricated from other suitable materials such as Teflon®, Neoprene and the like, as required or desired.

In one embodiment, the seal element 314 comprises a material having a durometer (shore D) hardness of about 70. In another embodiment, the seal element 314 comprises a material having a durometer hardness in the range from about 65 to about 75, including all values and sub-ranges therebetween. In modified embodiments, other suitable hardnesses may efficaciously be used, as needed or desired.

In one embodiment, the seal element 314 is fabricated by molding. The seal element 314 is bonded to the steel case 312. In modified embodiments, the seal element 314 can be efficaciously fabricated utilizing other suitable techniques, as needed or desired.

The garter spring 316 is generally circular in overall shape and is fitted within the seal element groove 324. The garter spring 316 has a generally circular cross section with the spring centerline 332 and comprises a plurality of coils 350.

The garter spring 316 is tensioned and applies a pressure or load on the seal lip 322 and its tip 326 to provide a strong and reliable seal. In one embodiment, the garter spring 316 also applies pressure or load on the seal lip 328.

FIG. 51 schematically shows the coils 350 of the garter spring 316. The spring coils 350 are advantageously spaced by an optimal and/or predetermined spacing or gap ($L_{coil-spacing}$) so that they allow MR fluid (or slurry) particles 352 to flow or swim in and out (as generally denoted by arrows 354) of the coils 350 while maintaining a load that keeps the garter spring 316 mounted within the groove 324 and prevents undesirable displacement of the spring 316.

The pre-loaded or "stretched out" garter spring 316 has a coil gap $L_{coil-spacing}$ that is at least as large as the MR fluid (or

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slurry) particle size or diameter (D_p) or at least as large as the largest MR fluid (or slurry) particle size or diameter (D_{pmax}). The small particles 352 can gain access to the spring(s) 316 due to the small particle sizes involved, the dynamics of the rotational motion and the MR fluid vacuum fill techniques of embodiments of the invention (as described further below and used to fill the MR fluid in the knee actuator). The rotational engagement, as opposed to a static one, can allow the MR fluid 134 and its small particles 352 to contact the spring coils 350.

Advantageously, embodiments of the invention provide a dynamic seal 162 having the specially configured garter spring 316 with coil spacing $L_{coil-spacing}$ that desirably prevents the small particles 352 to get "stuck" within the spring coils 350, thereby desirably preventing seal deterioration or failure. This may be accomplished, for example, by shortening or adjusting the spring length or circumference and/or by increasing or adjusting the tensioning of the spring 316.

Fully covering the dynamic seal garter spring is not a feasible or practical way to protect it from clogging. One major disadvantage is that it is difficult and unfeasible to fabricate such a dynamic seal. Another major disadvantage is that during MR fluid loading procedures, such as the MR fluid vacuum loading conditions of embodiments of the invention (as described further below and used to fill the MR fluid in the knee actuator), the cover can undesirably expand, rupture and/or become dislodged which will render the seal inoperable. Embodiments of the invention provide a simple and elegant solution to overcome these advantages by optimizing the coil gap size $L_{coil-spacing}$, as described further below.

In some embodiments, the relationship between the coil gap or spacing size $L_{coil-spacing}$ and the MR fluid particle size or diameter D_p or the MR fluid maximum particle size or diameter D_{pmax} can generally be given by the following, where $k \geq 1$:

$$L_{coil-spacing} = kD_p$$

or

$$L_{coil-spacing} = kD_{pmax}$$

In one embodiment, k is about 1.25. In another embodiment, k is about 1.5. In yet another embodiment, k is about 2. In still another embodiment, k is in the range from about 1.2 to about 5, including all values and ranges therebetween. In a further embodiment, k is in the range from about 1.1 to about 10, including all values and ranges therebetween. In modified embodiments, other suitable values for k may be efficaciously used, as needed or desired.

The particle size and the particle size distribution may have a wide range of values, for example, from about 0.2 microns (μm) to about 50 μm . TABLE 1 below illustrates some exemplifying values and ranges for the gap size $L_{coil-spacing}$ for various values and ranges of k and the particle size D_p or the maximum particle size D_{pmax} within the MR fluid 134 or other slurry or multi-phase mixture.

TABLE 1

Some Embodiments of Values and Ranges of $L_{coil-spacing}$ or D_p or D_{pmax} in microns (μm)										
k	0.2	0.5	1	2	3	4	5	10	25	50
1.25	0.25	0.625	1.25	2.5	3.75	5	6.25	12.5	31.25	62.5
1.5	0.3	0.75	1.5	3	4.5	6	7.5	15	22.5	75
2	0.4	1	2	4	6	8	10	20	50	100

TABLE 1-continued

Some Embodiments of Values and Ranges of $L_{coil-spacing}$ or D_p or $D_{p,max}$ in microns (μm)										
k	0.2	0.5	1	2	3	4	5	10	25	50
1.2-5	0.24-1	0.6-2.5	1.2-5	2.4-10	3.6-15	4.8-20	6-25	12-50	30-125	60-250
1.1-10	0.22-2	0.55-5	1.1-10	2.2-20	3.3-30	4.4-40	5.5-50	11-100	27-250	55-500

FIG. 52 shows one graphical example of a deflection curve 356 of the garter spring 316. The deflection curve 356 schematically illustrates the relationship between the force or loading of the spring 316 and its extension or deflection distance. The garter spring 316 is tensioned to an optimum force value or range so that it provides the desired coil gap $L_{coil-spacing}$ that prevents the MR fluid (or slurry) particles 352 from clogging the spring 316 and while preventing excessive spring loading that may cause spring failure or cause the spring 316 from jumping out of its track or groove 324.

FIG. 52 schematically illustrates some suitable force-extension operational points and ranges for the spring 316. In one embodiment, the spring 316 is tensioned to operate at point 358 on the deflection curve 356 so that its extension is generally at point x_o . In another embodiment, the spring 316 may be tensioned over a range of points on the deflection curve 356 such that its extension is generally between the range x_{o-min} and x_{o-max} . In modified embodiments, other suitable spring loading operational points and ranges may be efficaciously used, giving due consideration to the goals of providing reliable dynamic seals, maintaining suitable coil spacing $L_{coil-spacing}$ and generally avoiding excessive loading, as needed or desired.

In one embodiment, the garter spring 316 is fabricated from an extension spring portion having a length of about 14.6 cm (5.75 inches). The spring portion is formed into the generally circular garter spring 316 and fitted with the seal element groove 324 to spring-load the seal element 314. In one embodiment, the spring centerline diameter is about 5 cm (1.96 inches) and the spring centerline circumference is about 15.7 cm (6.17 inches). In one embodiment, the spring cross section diameter D_{spring} is about 1.02 mm (0.04 inches). In modified embodiments, other suitable spring dimensions may be efficaciously utilized, as needed or desired.

In one embodiment, the garter spring 316 comprises stainless steel such as SAE 30302/30304 stainless steel. In modified embodiments, the garter spring 316 can be efficaciously fabricated from other suitable metals, alloys, plastics, ceramics, among others, as required or desired.

The inner diameter (ID) of the dynamic seals 162a, 162b is dimensioned so that they fit over respective outer diameters (or rims 184a, 184b) of respective core side plates 116, 118 and apply a radially inwards pressure or load to dynamically seal the MR fluid 134 (or slurry) within the knee device 112. The inner diameters of the dynamic seals 162a, 162b are slightly smaller than the respective outer diameters of the core side plates 116, 118 so that the seal garter springs 316 are tensioned (or their tension increases) when mounted on respective rims 162a, 162b.

In one embodiment, the inner diameter (ID) of the dynamic seals 162a, 162b is about 4.69 cm (1.846 inches) and the outer or rim diameter of the core side plates 116, 118 (or shafts) is about 4.80 cm (1.89 inches). In modified embodiments, other suitable dimensions may be efficaciously used, as needed or desired.

In one embodiment, the inner diameters of the dynamic seals 162a, 162b are about 2.5% smaller than the respective outer or rim diameters of the core side plates 116, 118. In another embodiment, the inner diameters of the dynamic seals 162a, 162b are about 2% to about 3%, including all values and sub-ranges therebetween, smaller than the respective outer or rim diameters of the core side plates 116, 118. In yet another embodiment, the inner diameters of the dynamic seals 162a, 162b are about 1% to about 5%, including all values and sub-ranges therebetween, smaller than the respective outer or rim diameters of the core side plates 116, 118. In modified embodiments, other suitable diameter and/or size variations may be efficaciously utilized, as needed or desired.

The outer diameter (OD) of the dynamic seals 162, 162b is dimensioned so that when the seals 162a, 162b are mounted on respective core side rims 184a, 184b the seals 162a, 162b form a press fit within respective recesses or housing bores 264a, 264b of the outer spline 132. More specifically, the outer surfaces 318 of the seal cases 312 form a press or interference fit with respective surfaces 267a, 267b of respective outer spline recesses or housing bores 264a, 264b.

In one embodiment, the outer diameter (ID) of the dynamic seals 162a, 162b is about 5.410 cm (2.130 inches) and the diameter of the housing bore surfaces 267a, 267b is about 5.398 cm (2.125 inches). In modified embodiments, other suitable dimensions may be efficaciously used, as needed or desired.

Referring in particular to FIG. 48, in one embodiment, the dynamic seal width W_{seal} is about 3.81 mm (0.15 inches). In one embodiment, the dynamic seal thickness T_{seal} is about 6.96 mm (0.274 inches). In modified embodiments, other suitable dimensions may be efficaciously used, as needed or desired.

In one embodiment, the contact path width between the seal lips 322 and respective core side plate rims 184a, 184b is in the range from about 102 microns or μm (0.004 inches) to about 152 μm (0.006 inches), including all values and sub-ranges therebetween. In another embodiment, the contact path width between the seal lips 322 and respective core side plate rims 184a, 184b is in the range from about 51 μm (0.002 inches) to about 254 μm (0.01 inches), including all values and sub-ranges therebetween. In yet another embodiment, the contact path width between the seal lips 322 and respective core side plate rims 184a, 184b is in the range from about 25 μm (0.001 inches) to about 508 μm (0.02 inches), including all values and sub-ranges therebetween. In modified embodiments, other suitable contact path widths may be efficaciously utilized, as needed or desired.

The “lip force” is generally defined as the force per unit length applied by the spring-loaded primary seal lips 322 on respective core side-plate rims 184a, 184b. In one embodiment, the lip force is in the range from about 0.5 Newtons/cm

or N/cm (0.3 lbs/inch) to about 0.7 N/cm (0.4 lbs/inch), including all values and sub-ranges therebetween. In another embodiment, the lip force is in the range from about 0.44 Newtons/cm or N/cm (0.25 lbs/inch) to about 1.75 N/cm (1 lbs/inch), including all values and sub-ranges therebetween. In yet another embodiment, the lip force is in the range from about 0.35 Newtons/cm or N/cm (0.2 lbs/inch) to about 3.5 N/cm (2 lbs/inch), including all values and sub-ranges therebetween. In modified embodiments, other suitable lip forces may be efficaciously utilized, as needed or desired.

During assembly, the dynamic seals 162a, 162b are mounted on respective rims 184a, 184b of respective core side plates 116, 118. The seals 162a, 162b are generally perpendicular to the outer diameter sealing surface of respective rims 184a, 184b.

In one embodiment, the inner diameters or sealing lips 322 of respective dynamic seals 162a, 162b are coated with grease such as silicone grease and the like prior to installation. Desirably, this facilitates the sealing lips 322 in sliding into place over respective rims 162a, 162b and protects the lips 322 during the initial run-in phase. If desired, other portions of the seal elements 314 may be coated with grease, as suitable.

As also discussed above, in one embodiment, the core plate outer rims 184a, 184b are surface hardened to protect the rims or edges 184a from any undesirable scratching or damage during use or assembly, such as during installation of the seals 162a, 162b. This rim hardening also advantageously improves the dynamic sealing between the seal lips 322 and respective rims 184a, 184b.

The dynamic seals 162a, 162b while mounted on respective core side plates 116, 118 are press fitted within respective outer spline recesses or housing bores 264a, 264b. The outer diameter surfaces of the dynamic seals 162a, 162b engage respective surfaces 267a, 267b of respective outer spline recesses 264a, 264b. More specifically, the outer surfaces 318 of the seal cases 312 form a press or interference fit with respective housing bore surfaces 267a, 267b.

In one embodiment, an impregnation sealant is applied to the joints or cracks between the outer diameter surfaces of the dynamic seals 162a, 162b and the respective engaging surfaces 267a, 267b of respective outer spline recesses 264a, 264b. Desirably, the impregnation sealant seals the small or microscopic voids at the interface between outer diameter surfaces of the dynamic seals 162a, 162b and the respective outer spline surfaces 267a, 267b.

In one embodiment, the impregnation sealant comprises Loctite® 990 impregnation sealant. The impregnation sealant flows into the small or microscopic voids, pores or openings at the interface between the outer diameter surfaces of the dynamic seals 162a, 162b and the respective outer spline surfaces 267a, 267b and cures to form a tough thermoset polymer that provides a reliable seal.

The impregnation sealant can be cured in an oven or at room temperature. In one embodiment, the sealant is cured in an oven for about 30 minutes at about 150° Fahrenheit (F). In another embodiment, the sealant is cured for about 3 hours under ambient conditions. In modified embodiments, other suitable curing times and temperatures may be efficaciously utilized, as needed or desired.

The dynamic seals 162a, 162b rotate with the rotation of the outer spline 132 and hence independently of the rotation of the core side plates 116, 118. The seal elements 314, and more particularly the primary seal lips 322, rotatably interact with and dynamically seal against the outer diameter surfaces of respective core side plate rims 184a, 184b as the knee joint rotates.

In embodiments of the prosthetic knee, the dynamic seals 162 contain the MR fluid 134, that is sheared during knee joint rotation, within the fluid chamber 144. The specially designed dynamic seals 162, including the specially configured garter springs 316, can also have application and use in other rotary configurations with slurry flows, solid particle and liquid flows, solid liquid two-phase flows or solid and liquid multi-phase flows.

Embodiments of the invention encompass providing dynamic seals and methods of handling small particle slurries and the like. For example, the dynamic seal(s) 162 can be used on a rotating shaft with a bearing and other rotary flow situations involving small particle slurries and the like. The small particles can range in size or diameter from about $\frac{1}{10}$ th of a micron to about a thousand microns, including all values and sub-ranges therebetween.

Modified embodiments of the dynamic seals may be used in linear, cartesian, axial and reciprocating flows involving small particle slurries and the like. These can include a piston-cylinder arrangement. The small particles can range in size or diameter from about $\frac{1}{10}$ th of a micron to about a thousand microns, including all values and sub-ranges therebetween.

FIG. 53 shows the use of a modified dynamic seal 162m in a linear or Cartesian geometry that may have a one- two- or three-dimensional flow. A slurry 134m, including small particles 352m, flows within a chamber 144m of a housing 132m and there is relative motion between a plate 116m and the housing 132m generally denoted by arrows 142m or 142m' (reciprocating motion).

The dynamic seal 162m is provided at the interface between the plate 116m and the housing 132m. As discussed above and herein, the specially designed dynamic seal 162m has a pre-loaded or "stretched out" garter spring 316m that has a coil gap $L_{coil-spacing}$ that is large enough for the slurry particles 352m to flow or swim in and out of the spring coils. The garter spring 316m may be kept tensioned by providing hooks or the like at its ends.

FIG. 54 shows a dynamic seal 162' in accordance with a modified embodiment. As shown in the figure, in this embodiment, the seal element 314' has modified features and includes a seal lip 322' with a tip 326' that is substantially directly below the garter spring 316 or the spring centerline 332.

45 Diaphragm Assembly

FIGS. 55-60 show different views of one embodiment of the diaphragm assembly or device 146. The diaphragm assembly 146 generally comprises a cap or dome portion 412 connected to a diaphragm or membrane portion 414.

The diaphragm assembly 146 of embodiments of the invention advantageously prevents or mitigates undesirable pressure build-up within the knee actuator 112 and more particularly in the sealed MR fluid chamber 144, thereby desirably providing a pressure control mechanism. The pressure build-up that the diaphragm assembly 146 facilitates in preventing or mitigating may occur, for example, due to MR fluid outgassing or expansion due to heat within the chamber 144.

The diaphragm assembly 146 is seated on the base surface 274 of the outer spline cavity 272 (see, for example, FIG. 45) and is generally above the MR fluid chamber 144. The diaphragm assembly 146 is sized and configured to generally fit within a cavity or recess of the pyramid connector 152, as discussed further below.

In the illustrated embodiment, the diaphragm assembly 146 and its features have generally circular, cylindrical, annu-

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lar or frusto-conical configurations. In modified embodiments other suitable shapes may be efficaciously utilized, as needed or desired.

The cap portion 412 supports the diaphragm portion 414 and, in one embodiment, comprises a substantially rigid material. The cap portion 412 generally comprises a convex dome 416, a generally central cavity or opening 418 and a lip 420.

The dome 416 is generally circular or annular and has a convex outer surface 422 sized and configured to engage or abut against a corresponding concave dome surface of the pyramid adapter 152, as also discussed further below. In one embodiment, grease, such as silicone grease or the like, is applied to one or both of the convex outer surface 422 and the concave dome surface of the pyramid adapter 152 to provide a reliable seal.

The opening 418 is generally circular or cylindrical. The opening or passage 418 has an open end that communicates with a through passage of the pyramid connector 152 (as discussed further below) exposed to ambient or atmospheric pressure and an opposite end that is closed by the diaphragm portion 414.

The lip 420 and a lower interior surface 424 (see FIG. 59) of the cap portion 412 engage or abut against the diaphragm portion 414. The lip 420 is generally circular or annular and is received in a generally circumferential recess of the diaphragm portion 414.

The flexible diaphragm portion 414 desirably prevents or mitigates undesirable pressure build-up in the sealed MR fluid chamber 144 and is in fluid communication with the MR fluid 134 and the chamber 144. The diaphragm portion 414 generally comprises a diaphragm or membrane 426, a lip 428, a generally central cavity 430 and a groove or recess 432.

The flexible diaphragm 426 is generally circular and is in the form of a membrane having a predetermined thickness. The diaphragm 426 has an upper or outer surface 434 and a generally opposed lower or inner surface 436 in communication with the diaphragm cavity 430.

The diaphragm 426 has a generally central diaphragm element section 426d (see, for example, FIGS. 55 and 58-60) that is deflectable to relieve pressure-build-up. The diaphragm element 426d is generally circular and, in one embodiment, has a generally uniform thickness. The thickness of the diaphragm element 426d is desirably such that it provides suitable flexibility (or resiliency) while maintaining sufficient structural strength.

The diaphragm element 426d has a corresponding upper or outer surface 434d and a lower or inner surface 436d. The generally annular portion of the diaphragm upper surface 434 that surrounds the deflectable upper surface 434d engages or is in contact with the cap lower surface 424.

The diaphragm lip 428 generally defines the circumference or periphery of the diaphragm cavity 430. The lip 428 is generally circular or annular and is seated on or engages base surface 274 of the outer spline cavity 272 (see, for example, FIG. 45). In one embodiment, grease, such as silicone grease or the like, is applied to the lip 428 to provide a reliable seal with the outer spline base surface 274 and/or the pyramid connector 152.

The groove 432 is generally circular or annular and runs around the diaphragm 426. The groove 432 receives the lip 420 of the cap portion 412 to facilitate alignment and connection between the cap portion 412 and diaphragm portion 414 of the diaphragm assembly.

The diaphragm cavity 430 is generally circular and has a closed end generally defined by the lower surface 436 and an opposed open end at the base surface 274 of the outer spline

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cavity 272. The diaphragm cavity 430 spaces the diaphragm lower surface 436 and the outer spline base surface 274. The diaphragm cavity 430 is in fluid communication with the outer spline port 278 and hence with the MR fluid chamber 144.

The opposed cavities 418 and 430 are on opposite sides of the deflectable diaphragm element 426d and are sealingly substantially isolated from one another. The cavity 418 is on the side of the diaphragm upper surface 434d and is exposed to ambient or atmospheric pressure $P_{ambient}$. The cavity 430 is on the side of the diaphragm lower surface 434d (or 434) and is exposed to the pressure $P_{chamber}$ in the MR fluid chamber 144.

Advantageously, the flexible diaphragm element 426d can deflect due to any undesirable pressure build-up within the chamber 144 and relieve and control the pressure therein to a suitable or predetermined value. This deflection is generally denoted by arrows 438 wherein an outward deflection is caused by a pressure increase and an inward deflection depicts a pressure decrease such as after a temporary pressure rise, for example, due to the cooling of the MR fluid and its contraction.

Desirably, the solid diaphragm element 426d provides a flexible medium that controls and limits undesirable pressure build-up in the knee actuator 112 and more particularly in the fluid chamber 144. This substantially prevents any adverse effect on the knee performance, for example, because of seal failure and fluid leakage.

Referring in particular to FIG. 60, in one embodiment, the diaphragm assembly diameter D_{601} is about 18.7 mm, the cap cavity diameter D_{602} is about 10 mm and the diaphragm cavity diameter D_{603} is about 15.7 mm. In modified embodiments, other suitable dimensions may be efficaciously used, as needed or desired.

In one embodiment, the diaphragm thickness $T_{diaphragm}$ is about 1 mm. In another embodiment, the diaphragm thickness $T_{diaphragm}$ is in the range from about 0.75 mm to about 1.5 mm, including all values and sub-ranges therebetween. In yet another embodiment, the diaphragm thickness $T_{diaphragm}$ is in the range from about 0.5 mm to about 3 mm, including all values and sub-ranges therebetween. In modified embodiments, other suitable dimensions may be efficaciously used, as needed or desired.

In one embodiment, the diaphragm assembly height H_{601} is about 6.25 mm to about 6.4 mm, the cap portion height H_{602} is about 3.5 mm, the diaphragm portion height H_{603} is about 2.75 mm to about 2.9 mm and the height H_{604} is about 4.5 mm. In modified embodiments, other suitable dimensions may be efficaciously used, as needed or desired.

In one embodiment, the cap portion lip thickness T_{601} is about 1 mm and the diaphragm portion lip thickness T_{602} is about 1.5 mm. In modified embodiments, other suitable dimensions may be efficaciously used, as needed or desired.

In one embodiment, the radius of curvature R_{601} is about 4 mm, the radius of curvature R_{602} is about 0.5 mm and the radius of curvature R_{603} is about 0.5 mm. In modified embodiments, other suitable dimensions may be efficaciously used, as needed or desired.

The cap portion 412 is desirably fabricated from a suitably strong material that can support the diaphragm portion 414. In one embodiment, the cap portion 412 comprises a strong, durable and tough polymer such as nylon, for example, nylon 66 having a Rockwell hardness of about 100. The nylon may be reinforced for enhanced performance, as needed or desired. In modified embodiments, other suitable materials may be efficaciously used, as needed or desired.

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The diaphragm portion 414 is desirably fabricated from a flexible and/or resilient material. In one embodiment, the diaphragm portion 414 comprises silicone (CF-13 or CF-15). In another embodiment, the diaphragm portion 414 comprises Vulkollan® polyurethane which desirably has a high tensile strength, high abrasion resistance and a Shore A hardness of about 70. In modified embodiments, other suitable materials may be efficaciously used, as needed or desired.

In one embodiment, the cap portion 412 is formed by machining and the diaphragm portion 414 is molded to the cap portion 412. In another embodiment, the cap portion 412 is formed by machining, the diaphragm portion 414 is formed by molding and the two are attached to one another, for example, adhesively or by using glue or the like.

In one embodiment, the diaphragm assembly 146 including the cap portion 412 and the diaphragm portion 414 are formed as an integral unit, for example, by molding. The diaphragm assembly 146 can comprise, for example, silicone. The diaphragm assembly 146 could be constructed so that the deflectable diaphragm element 426d is thin enough to be flexible yet strong and the other elements of the diaphragm assembly 146 are configured to comprise sufficient material to provide suitable rigidity, strength and/or durability, as needed or desired.

FIG. 61 schematically illustrates pressure control mechanisms of the knee actuator 112 in accordance with embodiments of the invention. The upper surface 434d of the deflectable diaphragm element 426d is exposed to ambient or atmospheric pressure $P_{ambient}$ through a pyramid passage 440 while the lower surface 436d is exposed to the pressure $P_{chamber}$ within the chamber 144. As discussed above and herein, the flexible diaphragm assembly 146 provides a pressure control mechanism in accordance with some embodiments.

The outer spline 132 generally circumscribes or envelopes the inner spline 122 to form the generally annular chamber 144 with the core side plates 116, 118 generally forming at least a portion of the side walls of the chamber 144. The sealed chamber 144 is a portion of the chamber 258 of the outer spline 132. The rotors 120, 130 (not shown in FIG. 61) extend into the chamber 144. The chamber 144 contains the MR fluid 134.

A sealed chamber 144' can also be defined as including the chamber 144 and the outer spline port 278. Another sealed chamber 144" may be defined as including the chamber 144, the port 278 and the diaphragm cavity 430 or portion 442 of the outer spline cavity 272 generally enclosed by the diaphragm portion 412 or diaphragm 426.

In some embodiments, the free space of the chamber 144 (or 144' or 144") is only partially filled with the MR fluid 134 (in one embodiment, about 1 milliliter) while the remaining space of the chamber 144, the outer spline port 278 and the outer spline cavity portion 442 is filled with a compressible gas 444 such as nitrogen, air and the like to provide a pressure control mechanism. Advantageously, the gas 444 provides a compressible medium that controls and limits undesirable pressure build-up in the knee actuator 112 and more particularly in the fluid chamber 144. This substantially prevents any adverse affect on the knee performance, for example, because of seal failure and fluid leakage.

As also indicated above, the pressure build-up that the compressible gas 444 facilitates in preventing or mitigating may occur, for example, due to MR fluid outgassing or expansion due to heat within the chamber 144. The gas 444 desirably compresses to maintain the desired pressure level.

In one embodiment, about 70% of the free space volume of the chamber 144 (or 144' or 144") is filled with MR fluid 134 and the remaining volume is filled with the compressible gas

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444. In another embodiment, about 65% to about 75%, including all values and sub-ranges therebetween, of the free space volume of the chamber 144 (or 144' or 144") is filled with MR fluid 134 and the remaining volume is filled with the compressible gas 444. In yet another embodiment, about 60% to about 80%, including all values and sub-ranges therebetween, of the free space volume of the chamber 144 (or 144' or 144") is filled with MR fluid 134 and the remaining volume is filled with the compressible gas 444. In still another embodiment, about 50% to about 90%, including all values and sub-ranges therebetween, of the free space volume of the chamber 144 (or 144' or 144") is filled with MR fluid 134 and the remaining volume is filled with the compressible gas 444. In modified embodiments, more or less of the chamber 144 (or 144' or 144") may be filled with MR fluid, as needed or desired.

In one embodiment, substantially all of the free space volume of the chamber 144 is filled with MR fluid 134 and the outer spline port 278 and the outer spline cavity portion 442 contain the compressible gas 444. In another embodiment, substantially all of the free space volume of the chamber 144 and the outer spline port 278 are filled with MR fluid 134 and the outer spline cavity portion 442 contains the compressible gas 444. Other suitable combinations of MR fluid volume and compressible gas volume may be efficaciously used, as needed or desired.

In one embodiment, the free space volume of the chamber 144 (or 144' or 144") is about 10 milliliters (mL). In another embodiment, the free space volume of the chamber 144 (or 144' or 144") is in the range from about 5 mL to about 15 mL, including all values and sub-ranges therebetween. In yet another embodiment, the free space volume of the chamber 144 (or 144' or 144") is in the range from about 1 mL to about 20 mL, including all values and sub-ranges therebetween. In modified embodiments, other suitable chamber volumes may be efficaciously utilized, as needed or desired.

Embodiments of the invention provide systems and methods of controlling or relieving pressure within a magnetorheologically actuated prosthetic knee 110. As schematically illustrated in FIG. 62, these embodiments control the pressure so that it does not generally exceed an upper limit or predetermined pressure $P_{chamber-max}$. Stated differently, these embodiments control the pressure variation to within generally a maximum or predetermined pressure differential ΔP from the ambient or atmospheric pressure $P_{ambient}$. Without any pressure control mechanisms, the chamber pressure can reach undesirably high values, $P_{chamber-high}$, which can adversely affect device performance, for example, by causing seal malfunction or failure.

Some embodiments control the sealed chamber pressure $P_{chamber}$ by utilizing the flexible diaphragm assembly 146 that includes a flexible solid medium such as the deflectable diaphragm element 426d to advantageously relieve undesirable pressure build-up. Some embodiments control the sealed chamber pressure $P_{chamber}$ by utilizing a compressible gaseous medium such as the compressible gas 444 (e.g., nitrogen, air or the like) to advantageously relieve undesirable pressure build-up. Some embodiments control the sealed chamber pressure $P_{chamber}$ by utilizing the flexible diaphragm assembly 146 in combination with the compressible gaseous medium so that the deflectable diaphragm element 426d and the compressible gas 444 both facilitate pressure control to advantageously relieve undesirable pressure build-up and, in some embodiment, are in fluid communication with one another and the MR fluid 134.

Pyramid Adapter

FIGS. 63-66 show different views of one embodiment of the pyramid connector, stud or adapter 152. The pyramid connector 152 generally comprises a proximal boss portion 446, a distal threaded portion 448 and a cavity, cup or recess 450 in fluid communication with the pyramid passage 440.

The pyramid connector 152 mechanically connects the outer spline 132 and the stump socket 106, thereby attaching the knee actuator 112 and the prosthetic knee 110 to the stump socket 106. The outer spline 132, and hence the outer blades 130, are substantially irrotationally coupled to or nonrotatable with respect to the stump socket 106 or residual limb 108. Stated differently, rotation of the outer spline 132 and the outer blades 130 generally corresponds to rotation of the stump socket 106 or residual limb 108.

The pyramid connector 152 is generally positioned over the diaphragm assembly 146 which is seated on the base surface 274 of the outer spline cavity 272 and generally within the cavity 272. The pyramid passage 440 exposes the upper surface 434d of the deflectable diaphragm element 426d to ambient or atmospheric pressure conditions and the pyramid cavity 450 sealingly fits over the convex dome surface 422 to advantageously facilitate the pressure control mechanism in accordance with some embodiments.

The boss portion 446 is generally frusto-pyramidal in shape and has a generally flat top surface 452. The frusto-pyramidal boss portion 446 has a plurality of angled faces 454 for receiving angled set screws or the like associated with the distal end of the stump socket 106 (or a suitable connection member there at). Once the set screws are tightened against respective angled faces 454 of the boss portion 446, the stump socket 106 will be locked in the desired orientation with respect to the outer spline 132.

The combination of the domed top portion 270 of the outer spline 132 and the frusto-pyramidal boss portion 446 distal end of the stump socket 106 (or a suitable connection member there at) advantageously provides for angular adjustments of the stump socket 106 (or a pylon assembly) with respect to the outer spline 132, and hence the knee actuator 112 and prosthetic knee 110.

The pyramid threaded portion 448 has male threads that engage female threads or counter bores of the threaded side wall 276 of the outer spline cavity or cup 272 to connect the outer spline 132 and adapter 152. The pyramid connector 152 is desirably bonded to the outer spline 132 to secure it in place, for example, by utilizing epoxy or the like on the respective mating male and/or female threads. During assembly, notches, markings, indicia and/or reference surfaces may be used for proper alignment and connection of the pyramid connector 152 to the domed top portion 270 of the outer spline 132.

The pyramid cavity 450 has a generally circular or annular concave domed surface 456 and a generally flat circular central surface 458. The cavity 450 is desirably sized and configured such that the diaphragm assembly 146 sealingly fits within it.

The concave inner domed surface 456 engages or abuts against the convex outer surface 422 of the diaphragm assembly cap portion 412 and, in some embodiments, also the diaphragm portion lip 428. In one embodiment, grease, such as silicone grease or the like, is applied to one or both of the convex outer surface 422 of the cap portion 412 and the concave dome surface 456 of the pyramid adapter 152 to provide a reliable seal. Grease, such as silicone grease or the like, may also be applied to any engaging surface of the diaphragm portion lip 428 and the concave dome surface 456 to provide a reliable seal. Advantageously, this facilitates in

sealing the MR fluid chamber 144 and isolate it from undesirable ambient or atmospheric exposure.

The flat surface 458 of the pyramid recess 450 is generally aligned with the open end of the passage 418 of the diaphragm assembly cap portion 412. The passage 418 communicates with the pyramid tube 440 that is exposed to ambient or atmospheric pressure.

The pyramid tubular passage 440 has one end 460 that opens at the boss portion surface 452 and a second opposed end 462 that opens at the cavity flat surface 458 such that the tubular passage 440 is in fluid communication with the upper surface 434d of the deflectable diaphragm element 426d. This exposes the upper surface 434d ambient or atmospheric pressure $P_{ambient}$. In modified embodiments, other tubular arrangements associated with the diaphragm assembly 146 and/or the pyramid connector 152 may be utilized to provide the desired pressure exposure, as needed or desired.

In one embodiment, the pyramid connector 152 comprises titanium or a titanium alloy. In another embodiment, the pyramid connector 152 comprises aluminum or an aluminum alloy. In modified embodiments, the pyramid connector 152 can be efficaciously fabricated from other suitable metals, alloys, plastics, ceramics, among others, as required or desired.

The pyramid connector 152 desirably allows for proper coupling and alignment between the outer spline 132 and the stump socket 106. The pyramid connector 152 also, in some embodiments, advantageously facilitates the pressure control mechanism embodiments of the diaphragm assembly 146 by providing housing space and selective exposure to ambient or atmospheric conditions while maintaining the seal integrity of the MR fluid chamber 144.

Side Mounts

The side mounts, walls or forks 136, 138 are mechanically coupled, communicated or connected to respective core side plates 116, 118 and the inner spline 122. The side mounts 136, 138 are further connected to the frame and electronics assembly 114 which in turn is connected to a lower (below the knee) part of the leg, for example, the leg pylon 104 (see FIG. 2). Thus, rotation of the side mounts 136, 138 corresponds to rotation or motion of the leg pylon 104.

FIGS. 67-69 show different views of one embodiment of the right side mount 136. The right mount 136 has a notch 500a through which a shielded cable or lead wires of the angle sensing system 154 passes. The right mount 136 has a groove 502a on its exterior surface or side 504a along which this cable runs and connects to the frame and electronics assembly 114.

The right mount 136 has a generally circular through cavity, hole or passage 506a. The cavity 506a is generally aligned with and fits over the shoulders or steps 208a1, 208a2, 208a3 (see, for example, FIG. 13) on the outer surface of the right core side plate 116. In one embodiment, the cavity 506a forms a close tolerance slip fit with the shoulders or steps 208a1, 208a2, 208a3.

In some embodiments, the cavity 506a also receives at least a portion of the angle sensing system 154 and a plurality of threaded holes 507 extend inwardly from side mount surface 509. The holes 507 receive screws or the like to facilitate connection to the angle sensing system 154. In the illustrated embodiment, three holes 507 are provided that are arranged substantially equidistantly and in a circular fashion around the cavity 506a.

The right side mount 136 includes a plurality of generally equidistantly spaced circularly arranged through holes 508a. Each of the through holes 508a receives a respective one of

the through rods 158. The holes 508a are generally radially outwardly offset relative to the cavity 506a. In the illustrated embodiment, the holes 508a and holes 507 are alternatingly interspersed and spaced to provide clearance space.

The holes 508a are substantially aligned with the holes 180a, 180b of respective core side plates 116, 118 and the passages 228 of the inner spline 122. The studs or rods 158 secure selected components of the knee actuator 112, such as the core side plates 116, 118, the inner spline 122 and the side mounts 136, 138.

As best seen in FIG. 69, the exteriorly or outwardly facing side of the right mount 136 has a plurality of recessed surfaces 512a with each generally circumscribing or surrounding a respective one of the holes 508a. Each of the recessed surfaces 512a receives a respective one of the cone nuts 160 or the like to secure the through rods 158 in place.

The right mount 136 includes an inwardly facing generally circular or annular ring 514a with a generally circular bearing surface 516a. The ring 514a is received within the cavity 129a of the right bearing 126 (see, for example, FIG. 22). The bearing surface 516a engages the inner bearing surface 131a of the right bearing 126. In one embodiment, the ring portion 514a forms a close tolerance slip fit within the right bearing 129a.

The right mount 136 includes a generally downwardly extending rear support or leg member 518a that connects to the frame and electronics assembly 114. The leg 518a has generally flat foot or seat member 520a with a through hole 522a that receives the bolt 164a (see, for example, FIG. 6) or the like to connect the rear portion of the right mount 136 to the frame and electronics assembly 114.

The right mount 136 has a threaded hole or the like at around 524a that receives a bolt or the like to connect the front portion of the right mount 136 to the frame and electronics assembly 114. The right side mount 136 may include another threaded hole substantially adjacent to the rear through hole 522a that receives a bolt or the like to further secure the connection between the right mount 136 and the frame and electronics assembly 114.

The side mount leg 518a, in one embodiment, includes a mount or support element 525 that supports a battery charging and system programming socket, port or receptacle, as described further below. The support 525 has a mounting hole 527 that receives the socket.

As best seen in FIG. 68, in some embodiments, the right side mount 136 includes a pair of substantially adjacent bumper mounts or supports 526a, 528a that facilitate in providing an extension stop system and shock absorption at substantially full knee extension, as discussed further below. The bumper mount 526a is inwardly offset relative to the bumper mount 528a. Stated differently, the bumper mount 528a is outwardly offset relative to the bumper mount 526a. In modified embodiments, this arrangement may be reversed, as needed or desired.

The bumper mount 526a includes a rearwardly slanting and generally flat surface 530a on which one bumper is seated. The bumper mount 526a has a female slot, recess or cavity 532a that receives a male portion of the bumper to facilitate alignment and connection therebetween.

The bumper mount 528a includes a rearwardly slanting and generally flat surface 534a on which a second bumper is seated. The bumper mount 528a has a female slot, recess or cavity 536a that receives a male portion of the bumper to facilitate alignment and connection therebetween.

In the illustrated embodiment, the right side mount 136 includes an exterior side recessed region or portion 538a and a curved generally C-shaped slot or opening 539a that desir-

ably provides clearance space for the knee angle sensing or measuring assembly or system 154 (see, for example, FIG. 6). The slot 539a may have a widened portion 541a at one closed end that is substantially aligned with the slot 269a (see, for example, FIG. 43) of the outer spline 132 to provide clearance space for assembly.

In the illustrated embodiment, the side mount 136 further includes a pair of relief pockets or cavities 562a that receive portions of a knee cover, as described further below. The side mount 136 has an opening or cavity 564a intermediate the pockets 562a that receives a connector pin or the like that facilitates attachment of the right side cap 156a.

The right mount 136 may include other recesses, holes, passages, slots, notches, contours and the like that can provide clearance space, alignment facilitation, connection features and component access, among other desirable characteristics. Material may be selectively removed at portions of the right mount 136 to advantageously provide device weight reduction while maintaining structural integrity, as needed or desired.

FIGS. 70-72 show different views of one embodiment of the left side mount 138. The left mount 138 has a notch 500b substantially aligned with the notch 212 of the left core side plate 118 through which the shielded cable or lead wires 218 (see, for example, FIG. 23) passes. The left mount 138 has a groove 502b on its exterior surface or side 504b along which the cable 218 runs and connects to the frame and electronics assembly 114. Advantageously, the notch 500b and groove 502b facilitate in keeping the cable 218 in position and prevent undesirable movement.

The left mount 138 has a generally circular through cavity, hole or passage 506b. The cavity 506b is generally aligned with and fits over the shoulders or steps 208b1, 208b2, 208b3, 208b4 (see, for example, FIG. 17) on the outer surface of the left core side plate 118. In one embodiment, the cavity 506b forms a close tolerance slip fit with the shoulders or steps 208b1, 208b2, 208b3.

The left side mount 138 includes a plurality of generally equidistantly spaced circularly arranged through holes 508b. Each of the through holes 508b receives a respective one of the through rods 158. The holes 508b are generally radially outwardly offset relative to the cavity 506b.

The holes 508b are substantially aligned with holes 508a of the right mount, the holes 180a, 180b of respective core side plates 116, 118 and the passages 228 of the inner spline 122. The studs or rods 158 pass through the holes 508b, the holes 508a, the holes 180a, 180b and the passages 228 to secure the core side plates 116, 118, the inner spline 122 and the side mounts 136, 138.

As best seen in FIG. 72, the exteriorly or outwardly facing side of the left mount 138 has a plurality of recessed surfaces 512b with each generally circumscribing or surrounding a respective one of the holes 508b. Each of the recessed surfaces 512b receives a respective one of the cone nuts 160 or the like to secure the through rods 158 in place.

The left mount 138 includes an inwardly facing generally circular or annular ring 514b with a generally circular bearing surface 516b. The ring 514b is received within the cavity 129b of the left bearing 128 (see, for example, FIG. 22). The bearing surface 516b engages the inner bearing surface 131b of the left bearing 128. In one embodiment, the ring portion 514b forms a close tolerance slip fit within the left bearing cavity 129b.

The left mount 138 includes a generally downwardly extending rear support or leg member 518b that connects to the frame and electronics assembly 114. The leg 518b has generally flat foot or seat member 520b with a through hole

522b that receives the bolt **164b** (see, for example, FIG. 6) or the like to connect the rear portion of the left mount **138** to the frame and electronics assembly **114**.

The left mount **138** has a threaded hole or the like at around **524b** that receives a bolt or the like to connect the front portion of the left mount **138** to the frame and electronics assembly **114**. The left side mount **138** may include another threaded hole substantially adjacent to the rear through hole **522b** that receives a bolt or the like to further secure the connection between the left mount **138** and the frame and electronics assembly **114**.

As best seen in FIG. 71, in some embodiments, the left side mount **138** includes a pair of substantially adjacent bumper mounts or supports **526b**, **528b** that facilitate in providing an extension stop system and shock absorption at substantially full knee extension, as discussed further below. The bumper mount **526b** is inwardly offset relative to the bumper mount **528b**. Stated differently, the bumper mount **528b** is outwardly offset relative to the bumper mount **526b**. In modified embodiments, this arrangement may be reversed, as needed or desired.

The bumper mount **526b** includes a rearwardly slanting and generally flat surface **530b** on which one bumper is seated. The bumper mount **526b** has a female slot, recess or cavity **532b** that receives a male portion of the bumper to facilitate alignment and connection therebetween.

The bumper mount **528b** includes a rearwardly slanting and generally flat surface **534b** on which a second bumper is seated. The bumper mount **528b** has a female slot, recess or cavity **536b** that receives a male portion of the bumper to facilitate alignment and connection therebetween.

In the illustrated embodiment, the left side mount **138** includes an exterior side recessed region or portion **538b** and a curved generally C-shaped slot or opening **539b** that desirably provide clearance space for the extension assist assembly or system **148** (see, for example, FIG. 6). The slot **539b** may have a widened portion **541b** at one closed end that is substantially aligned with the slot **269b** (see, for example, FIG. 42) of the outer spline **132** to provide clearance space for assembly.

In the illustrated embodiment, the side mount **138** further includes a pair of relief pockets or cavities **562b** that receive portions of a knee cover, as described further below. The side mount **138** has an opening or cavity **564b** intermediate the pockets **562b** that receives a connector pin or the like that facilitates attachment of the left side cap **156b**.

The left mount **138** may include other recesses, holes, passages, slots, notches, contours and the like that can provide clearance space, alignment facilitation, connection features and component access, among other desirable characteristics. Material may be selectively removed at portions of the left mount **138** to advantageously provide device weight reduction while maintaining structural integrity, as needed or desired.

In one embodiment, the side mounts **136**, **138** fabricated from an aluminum alloy such as anodized 7075-T6 aluminum alloy. In modified embodiments, the side mounts **136**, **138** can be efficaciously fabricated from other suitable metals, alloys, plastics, ceramics, among others, as required or desired.

The side mounts **136**, **138** are desirably formed by machining. In modified embodiments, the side mounts **136**, **138** can be efficaciously fabricated from other suitable techniques, for example, casting, forging, molding, laser processing, among others, as required or desired.

Multi-Stage Bumper System

Embodiments of the invention provide an extension stop system generally comprising the bumper system **150** on the side mounts **136**, **138** and the spaced stops **282** (**282a**, **282b**) of the outer spline **132**. At substantially full knee extension, the stops **282a**, **282b** engage or contact the specially designed shock absorbing bumper assembly **150** to prevent further knee rotation. Thus, the extension stop system controls the maximum allowable extension by physically limiting the rotation between the outer side mounts **136**, **138** and the outer spline **132**, and hence the rotation of the knee.

FIG. 73 shows one embodiment of the shock absorbing bumper system **150**. The bumper system generally comprises two bumper assemblies **540a**, **540b** with one each on a respective one of the side mounts **136**, **138**. FIG. 74 shows another view of the bumper assembly **540b** mounted on the left side mount **138**.

The side mounts **136**, **138** shown in FIG. 73 when in assembled form would be rotated by about 90° (as generally shown by arrows **546a**, **546b**) so that the bumper assemblies **540a**, **540b** face forwardly and are spaced and aligned with one another and the corresponding stops **282a**, **282b**. Advantageously, the bumper assemblies **540a**, **540b** provide a substantially smooth shock absorbing, cushioning and/or dissipating effect when engaged with respective stops **282a**, **282b** to substantially prevent or mitigate jarring or discomfort to the prosthetic knee wearer.

The right bumper assembly **540a** generally comprises a substantially soft and compressible first bumper **542a** and an adjacent substantially hard and rigid second bumper **544a**. The left bumper assembly **540b** generally comprises a substantially soft, resilient and compressible first bumper **542b** and an adjacent substantially hard and rigid second bumper **544b**.

The bumpers or stops **542a**, **544a** are attached to respective bumper supports **526a**, **528a** of the right side mount **136**. Thus, the bumper **542a** is inwardly offset relative to the bumper **544a**. Stated differently, the bumper **544a** is outwardly offset relative to the bumper **542a**. In modified embodiments, this arrangement may be reversed, as needed or desired.

The bumpers or stops **542b**, **544b** are attached to respective bumper supports **526b**, **528b** of the left side mount **138**. Thus, the bumper **542b** is inwardly offset relative to the bumper **544b**. Stated differently, the bumper **544b** is outwardly offset relative to the bumper **542b**. In modified embodiments, this arrangement may be reversed, as needed or desired.

The flexible bumper **542a** includes a generally main body portion or member **548a** that engages the outer spline stop **282a** at substantially full knee extension and a male locking portion or member **550a** that facilitates attachment to the bumper support **526a**. The bumper **544a** includes a generally main body portion or member **552a** that also engages the outer spline stop **282a** at substantially full knee extension and a male locking portion or member **554a** that facilitates attachment to the bumper support **528a**.

The flexible bumper **542b** includes a generally main body portion or member **548b** that engages the outer spline stop **282b** at substantially full knee extension and a male locking portion or member **550b** that facilitates attachment to the bumper support **526b**. The bumper **544b** includes a generally main body portion or member **552b** that also engages the outer spline stop **282b** at substantially full knee extension and a male locking portion or member **554b** that facilitates attachment to the bumper support **528b**.

The bumper element **548a** has a rear surface that is seated or rests on the generally flat surface **530a** of the bumper

support 526a of the right side mount 136. In the illustrated embodiment, the bumper element 548a is generally cubical in shape with generally rectangular sides. In modified embodiments, the bumper element 548a may be configured in other suitable polygonal or non-polygonal shapes with efficacy, as needed or desired.

The bumper element 552a has a rear surface that is seated or rests on the generally flat surface 534a of the bumper support 528a of the right side mount 136. In the illustrated embodiment, the bumper element 552a is generally cubical in shape with generally rectangular sides. In modified embodiments, the bumper element 552a may be configured in other suitable polygonal or non-polygonal shapes with efficacy, as needed or desired.

The bumper element 548b has a rear surface that is seated or rests on the generally flat surface 530b of the bumper support 526b of the left side mount 138. In the illustrated embodiment, the bumper element 548b is generally cubical in shape with generally rectangular sides. In modified embodiments, the bumper element 548b may be configured in other suitable polygonal or non-polygonal shapes with efficacy, as needed or desired.

The bumper element 552b has a rear surface that is seated or rests on the generally flat surface 534b of the bumper support 528b of the left side mount 138. In the illustrated embodiment, the bumper element 552b is generally cubical in shape with generally rectangular sides. In modified embodiments, the bumper element 552b may be configured in other suitable polygonal or non-polygonal shapes with efficacy, as needed or desired.

The soft bumper element 548a has a front face or surface 556a and the hard bumper element 552a has a front face or surface 558a that are arranged in a stepped fashion with the surface 556a extending forwardly with respect to the surface 558a. In the illustrated embodiment, the surfaces 556a, 558a are rearwardly slanted or angled such that they make substantially flush contact with the corresponding engaging surface 283a of the stop 282a of the outer spline 132.

The soft bumper element 548b has a front face or surface 556b and the hard bumper element 552b has a front face or surface 558b that are arranged in a stepped fashion with the surface 556b extending forwardly with respect to the surface 558b. In the illustrated embodiment, the surfaces 556b, 558b are rearwardly slanted or angled such that they make substantially flush contact with the corresponding engaging surface 283b of the stop 282b of the outer spline 132.

The male locking bumper element 550a is sized and configured to fit within the slot 532a of the bumper support 526a of the right side mount 136. In the illustrated embodiment, the male locking element 550a is generally cylindrical in shape with a generally circular cross section and a narrowed neck portion that facilitates interlocking within the slot 532a and inhibits undesirable removal or movement. In modified embodiments, other suitable polygonal or non-polygonal interlocking configurations may be efficaciously used, as needed or desired.

The male locking bumper element 550a is sized and configured to fit within the slot 536a of the bumper support 528a of the right side mount 136. In the illustrated embodiment, the male locking element 550a is generally cylindrical in shape with a generally circular cross section and a narrowed neck portion that facilitates interlocking within the slot 536a and inhibits undesirable removal or movement. In modified embodiments, other suitable polygonal or non-polygonal interlocking configurations may be efficaciously used, as needed or desired.

The male locking bumper element 550b is sized and configured to fit within the slot 532b of the bumper support 526b of the left side mount 138. In the illustrated embodiment, the male locking element 550b is generally cylindrical in shape with a generally circular cross section and a narrowed neck portion that facilitates interlocking within the slot 532b and inhibits undesirable removal or movement. In modified embodiments, other suitable polygonal or non-polygonal interlocking configurations may be efficaciously used, as needed or desired.

The male locking bumper element 554b is sized and configured to fit within the slot 536b of the bumper support 528b of the left side mount 138. In the illustrated embodiment, the male locking element 554b is generally cylindrical in shape with a generally circular cross section and a narrowed neck portion that facilitates interlocking within the slot 536b and inhibits undesirable removal or movement. In modified embodiments, other suitable polygonal or non-polygonal interlocking configurations may be efficaciously used, as needed or desired.

The bumpers 542a, 542b comprise a suitably soft, compressible and resilient material to provide the desired shock absorption properties. In one embodiment, the bumpers 542a, 542b comprise urethane such as a thermoplastic urethane (TPU). In modified embodiments, other suitable plastics and the like may be efficaciously utilized, as needed or desired.

In one embodiment, the bumpers 542a, 542b comprise a material having a Shore A hardness of about 90 A durometer. In another embodiment, the bumpers 542a, 542b comprise a material having a Shore A hardness of about 85 A durometer to about 95 A durometer, including all values and sub-ranges therebetween. In yet another embodiment, the bumpers 542a, 542b comprise a material having a Shore A hardness of about 80 A durometer to about 99 A durometer, including all values and sub-ranges therebetween. In modified embodiments, other suitable hardnesses may be efficaciously utilized, as needed or desired.

The bumpers 544a, 544b comprise a suitably hard and substantially rigid material to provide a hard stop for knee extension rotation. In one embodiment, the bumpers 544a, 544b comprise urethane such as a thermoplastic urethane (TPU). In modified embodiments, other suitable plastics and the like may be efficaciously utilized, as needed or desired. The use of urethane or the like advantageously avoids metal (alloy) to metal (alloy) contact and substantially prevents undesirable wear of the stops 282a, 282b.

In one embodiment, the bumpers 544a, 544b comprise a material having a Shore D hardness of about 75 D durometer. In another embodiment, the bumpers 544a, 544b comprise a material having a Shore D hardness of about 70 D durometer to about 80 D durometer, including all values and sub-ranges therebetween. In yet another embodiment, the bumpers 544a, 544b comprise a material having a Shore D hardness of about 60 D durometer to about 99 D durometer, including all values and sub-ranges therebetween. In modified embodiments, other suitable hardnesses may be efficaciously utilized, as needed or desired.

In one embodiment, the soft bumpers 542a, 542b are formed by molding. In modified embodiments, the bumpers 542a, 542b can be efficaciously fabricated from other suitable techniques, for example, casting, forging, machining, laser processing, among others, as required or desired.

In one embodiment, the hard bumpers 544a, 544b are formed by molding. In modified embodiments, the bumpers 544a, 544b can be efficaciously fabricated from other suitable techniques, for example, casting, forging, machining, laser processing, among others, as required or desired.

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During assembly of the bumper assemblies 540a, 540b on the respective side mounts 136, 138, in one embodiment, the hard bumpers 544a, 544b are first connected to respective bumper supports 528a, 528b. The male locking bumper elements 552a, 552b are slid into respective slots 536a, 536b to mount the hard bumpers 544a, 544b in place.

Similarly, the soft bumpers 542a, 542b are then connected to respective bumper supports 526a, 526b. The male locking bumper elements 550a, 550b are slid into respective slots 532a, 532b to mount the soft bumpers 542a, 542b in place.

In one embodiment, an adhesive such as Loctite® 495 which is a Loctite® cyanoacrylate ("Super Glue") or the like is used to secure the soft bumpers 542a, 542b to respective bumper supports 526a, 526b. The hard bumpers 544a, 544b are secured without an adhesive since the configuration of the interlocking features 552a, 552b and 532a, 532b and the positioning of the hard bumpers 544a, 544b between respective soft bumpers 542a, 542b and wall portions of respective side mounts 136, 138 prevents any undesirable movement of the hard bumpers 544a, 544b and keeps them in place. In modified embodiments, an adhesive such as Loctite® 495 which is a Loctite® cyanoacrylate ("Super Glue") or the like may be used to secure the hard bumpers 544a, 544b to respective bumper supports 528a, 528b, as needed or desired.

In operation of the extension stop system, at substantially full knee extension, the stops 282 (282a, 282b) contact the respective multi- or two-stage bumper assemblies 540 (540a, 540b). The stops 282a, 282b first contact respective soft bumpers 542a, 542b which are compressed as the knee rotates. The soft bumpers 542a, 542b stop compressing when the stops 282a, 282b contact respective hard bumpers 544a, 544b. This controls the limit of knee extension rotation and stops further knee extension. As the knee flexes, the soft bumpers 542a, 542b expand to substantially their original uncompressed state.

As schematically shown in FIG. 75, the knee rotation angle corresponding to when the stops 282 first engage the soft bumpers 542 and subsequently engage the hard bumpers 544 is generally given by $\beta_{bumper-step}$. This is due to the stepped configuration of the bumper assemblies 540 of embodiments of the invention.

In one embodiment, the angle $\beta_{bumper-step}$ is about 3°. In another embodiment, the angle $\beta_{bumper-step}$ is in the range from about 2° to about 4°, including all values and sub-ranges therebetween. In yet another embodiment, the angle $\beta_{bumper-step}$ is in the range from about 1° to about 5°, including all values and sub-ranges therebetween. In modified embodiments, $\beta_{bumper-step}$ may be higher or lower, as needed or desired.

Referring in particular to the schematic drawing of FIG. 76, in one embodiment, the shock absorbing bumper system 150 allows a maximum extension angle which is substantially the same as an anatomical extension angle α_E . The extension angle α_E typically is about 180° or close to it.

In another embodiment, the bumper system 150 allows a maximum extension angle which is slightly greater than α_E . This allows for a small degree of temporary knee hyperextension. The hyperextension angle is generally denoted by α_{HE} in FIG. 76.

In one embodiment, the hyperextension angle α_{HE} is about 1.5°. In another embodiment, the hyperextension angle α_{HE} is in the range from about 1° to about 2°, including all values and sub-ranges therebetween. In yet another embodiment, the hyperextension angle α_{HE} is in the range from about 0.5° to about 2.5°, including all values and sub-ranges therebetween. In modified embodiments, α_{HE} may be higher or lower, as needed or desired.

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As schematically illustrated in FIGS. 77 and 78, embodiments of the shock absorbing multi-stage bumper system may comprise bumper assemblies 540', 540" having more than two bumpers arranged in a generally side-by-side configuration. The bumper height (or relative operational height) generally varies with the properties of the bumper material, e.g., softness, compressibility, resilience, flexibility, hardness and rigidity.

The bumper assembly 540' of the embodiment of FIG. 77 generally comprises a plurality of bumpers 542a', 542b', 542c', 544a', 544b' and so on. The bumper assembly 540" of the embodiment of FIG. 77 generally comprises a plurality of bumpers 542a", 542b", 542c", 544a", 544b", 544c", 544d" and so on. In modified embodiments, the relatively soft bumpers 542', 542" and the relatively hard bumpers 544', 544" may be interspersed in any suitable manner, as needed or desired. For example, but not limited to, in a staggered, repetitive or alternating pattern or spaced from adjacent bumpers.

Referring to FIGS. 77 and 78, in one embodiment, the direction of arrows 560 generally denotes decreasing softness or increasing hardness. In another embodiment, the direction of arrows 560 generally denotes decreasing compressibility or increasing rigidity. In another embodiment, the direction of arrows 560 generally denotes decreasing resilience or flexibility.

Embodiments of the invention also provide a flexion stop system generally comprising a bumper system and one or more stops on the outer spline 132, for example, at 284. In one embodiment, the flexion stop system is generally similar to embodiments of the extension stop system and includes one or more shock absorbing multi-stage bumper assemblies that contact one or more respective stops at generally the maximum allowable knee flexion.

In one embodiment, hard stop 529a (FIG. 68) and 529b (FIG. 71) on respective side mounts 136, 138 contact one or more stops 284 of the outer spline 132 to control the maximum allowable knee flexion and provide a flexion stop system. In another embodiment, bumpers or bumper assemblies at about 529a (FIG. 68) and 529b (FIG. 71) on respective side mounts 136, 138 contact one or more stops 284 of the outer spline 132 to control the maximum allowable knee flexion and provide a flexion stop system.

The flexion stop system controls the maximum knee flexion to a predetermined flexion angle α_F . This is generally achieved by physically limiting the rotation between the side mounts 136, 138 and the outer spline 132, and hence the rotation of the knee joint.

In one embodiment, the flexion stop system is configured to allow a maximum flexion angle α_F of about 120°. In another embodiment, the flexion stop system is configured to allow a maximum flexion angle in the range from about 120° to about 140°-150°, including all values and sub-ranges therebetween. In modified embodiments, the maximum flexion angle α_F may be higher or lower, as needed or desired.

Studs and Cone Nuts

As best seen in the exploded view of FIG. 6, the knee actuator 112 comprises the fastening through rods, dowels or studs 158 which are end-threaded to threadably engage associated nuts 160 at each end. In one embodiment, three studs 158 each with two associated nuts 160 are utilized thereby allowing a straightforward assembly and disassembly procedure with a minimum of fasteners. In modified embodiments, other quantities of fastening studs may be utilized, as needed or desired.

The studs or rods 158 pass through the holes 508b of the left side mount 138, the holes 508a of the right side mount

136, the holes 180a, 180b of respective core side plates 116, 118 and the passages 228 of the inner spline 122. The studs 158 in combination with the nuts 160 secure the core side plates 116, 118, the inner spline 122 and the side mounts 136, 138 and clamp these components of the knee actuator 112 together.

The fastening studs 158 are desirably press fit within the passages 228. Advantageously, this reduces undesirable mechanical backlash and enhances torque transmission between the inner spline 122 (and rotors 120) and the side mounts 136, 138.

In one embodiment, the fastening studs 158 comprise a magnetic material. In a modified embodiment, the studs 158 comprise a non-magnetic material, such as stainless steel or the like, which may facilitate in substantially isolating the studs 158 from the magnetic path 140 (see, for example, FIG. 4) through the actuator 112 and can improve power efficiency.

The nuts 160 engage the respective end threads of the respective fastening studs 158 to clamp the core side plates 116, 118, the inner spline 122 and the side mounts 136, 138. A suitable adhesive or glue, such as Loctite® threadlocker or the like, can be applied to the end threads to provide a strong coupling between the studs 158 and corresponding nuts 160.

The right side nuts 160 are received in the corresponding recessed surfaces 512a (see, for example, FIG. 69) of the right side mount 136. The left side nuts 160 are received in the corresponding recessed surfaces 512b (see, for example, FIG. 72) of the left side mount 138.

In one embodiment, the nuts 160 comprise cone nuts. Advantageously, the use of cone nuts improves wear resistance and substantially prevents or reduces undesirable backlash.

The nuts 160 may also comprise lock nuts with self-locking features. In one embodiment, the nuts 160 may each have a torque-off head that shears off when the nuts 160 are tightened to a predetermined or desired torque. The nuts 160 may also have tamper resistant features so that they are not removable with a standard wrench or tool but with a special removal tool, thereby preventing undesirable disassembly.

Extension Assist System

In some embodiments, the prosthetic knee 110 comprises the extension assist assembly or system 148 to help straighten the leg by urging or biasing the leg to extension by applying a controlled torque or force. FIGS. 79 and 80 show different views of one embodiment of the extension assist system 148.

The extension assist system 148 facilitates knee extension and is particularly useful during swing phase extension. During the swing phase, the extension assist system 148 provides an urging force to encourage straightening of the knee or lower limb just before initial contact with a supporting or ground surface.

Though embodiments of the prosthetic knee actuator 112 can provide a low-end torque that is substantially zero or close to zero, thereby permitting substantially free swing phase extension, an extension assist can be advantageous in certain situations. For example, on stairs, the foot position is important on the step and the extension assist system 148 provides the desired momentum so that the foot lands properly on the supporting surface.

The extension assist system 148 is also advantageous when walking or moving at higher speeds. The extension assist system 148 can also advantageously reduce or prevent patient fatigue by providing additional momentum during extension.

The extension assist system 148 is generally mounted in the exterior side recessed region or portion 538b (see, for example, FIG. 72) of the left side mount 138. Advanta-

geously, the substantially internally mounted extension assist system 148 provides a reduced knee profile and protection for its components against undesirable side impact or contact. The extension assist system 148 generally comprises an internal spring 570, an inner shield or guard 572 on one side of the spring 570 and an outer shield or guard 574 on an opposed side of the spring 570, a rotatable arm 576, an axle 578 and a bearing 580.

In one embodiment, the spring 570 comprises a torsion or coil spring as shown, for example, in FIGS. 79 and 80. In modified embodiments, other types of springs, resilient, biasing or urging mechanisms, such as bands or the like and other devices capable of suitable energy storage and release may be utilized with efficacy, as needed or desired.

In one embodiment, the spring 570 is pre-loaded, that is, it has a selected pre-load in its rest or non-actuated state. In another embodiment, the spring 570 has a substantially zero pre-load in its rest or non-actuated state. The spring 570, in one analogy, may be thought of as being similar to an anatomical ligament.

The torsion spring 570 is generally circular or annular in shape and has a generally central circular or cylindrical cavity, passage or hole 582. The passage 582 has a diameter that is dimensioned and configured so that it fits over the outer diameter of the core mandrel portion 168 (see, for example, FIG. 7).

The spring 570 is generally positioned in the exterior side recessed region or portion 538b of the left side mount 138. The core mandrel portion 168 extends through the left side mount cavity 506b and into the left side mount recessed region 538b.

The spring 570 at its inner free end comprises an inner curved or bent hook, finger or leg 584. The inner finger 584 is received within or locked into the slot, notch or groove 188 of the core mandrel portion 168. In one embodiment, the inner finger 584 has a thickness that forms a press fit into the slot 188 of the core mandrel portion 168.

The spring 570 at its outer free end comprises an outer curved or bent hook, finger or leg 586. The outer finger 586 engages or locks with a portion of the arm 576, as described further below. As also described further below, the outer shield 574 is specially designed to cover a gap or slot 588 of the spring 570. The gap or slot 588 is present because of the spacing between the outermost spring coil and the adjacent spring coil. The gap or slot 588 is proximate to or adjacent the outer arm 586 and receives a portion of the outer shield 574.

The inner spring shield 572 is fitted over the core mandrel portion 168 and positioned interiorly relative to the spring 570. In the illustrated embodiment, the inner shield 572 is in the form of a generally circular annular disk with a cavity or hole 590 that is dimensioned and configured so that it fits over the outer diameter of the core mandrel portion 168.

The bearing 580 is fitted and positioned within the generally circular bore 190 (see, for example, FIG. 7) of the core mandrel portion 168. The bearing 580 comprises an outer bearing surface 592 that is coupled to the bore 190 and a generally circular cavity or hole 594 with an inner bearing surface 596 that is coupled to the axle 578. In one embodiment, Loctite® threadlocker, Loctite® retaining compound or the like is used to provide this coupling between the bearing 580 and the core mandrel portion 168 and the axle 578. The bearing 580 advantageously facilitates rotation of the core mandrel portion 168 and the axle 578 substantially independently of one another.

The outer spring shield 574 generally comprises a support portion or section 620 connected to a main body portion or section 622 positioned exteriorly relative to the spring 570. In

the illustrated embodiment, the main body portion 622 is in the form of a generally circular disk.

The shield support portion 620 generally comprises a pair of seats or shoulders 624, 626 that engage the spring 570. The first seat 624 is received within the gap, slot or spring portion 588 and the second seat 626 is positioned generally behind and abuts or engages the spring outer finger 586.

Advantageously, the specially designed outer shield 574 covers the spring gap 588 and prevents dirt and lint from getting between the coils of the spring 570. The shield 574 desirably also acts as a wiper to clean dirt and off of the outside diameter of the spring 570 as it rotates.

The shield main body portion 622 generally comprises a substantially central and circular hole or passage 628 through which the axle 578 extends. The hole 628 is substantially aligned with the bearing hole 594. In the illustrated embodiment, the main body portion 622 includes a curved generally C-shaped slot 630 that forms a radially extending portion or section 632 that is substantially aligned with and abuts or engages a portion of the arm 576. The C-shaped slot 630 desirably keys the shield 574 to the spring arm 576.

In one embodiment, the shield 574 comprises a small bearing standoff boss or land on the side of the shield 574 opposite the slot 630. The boss or land desirably facilitates in ensuring that axial loads are transmitted through the bearing 580 instead of causing rubbing which could adversely affect knee performance.

In one embodiment, the shield 574 comprises Delrin. In modified embodiments, other suitable materials may be used with efficacy, as needed or desired.

The spring arm 576 generally comprises a proximal main body portion or section 634, a medial portion or section 636 and a distal portion or section 638. In the illustrated embodiment, the arm 576 is generally in the form of an angled bar or plate.

The arm proximal portion 634 generally comprises a proximal end 640 with a substantially circular hole or passage 642 through which the axle 578 extends. The proximal portion is substantially aligned with and abuts or engages the outer shield portion 632. The hole 642 is substantially aligned with the outer shield hole 628 and the bearing hole 594.

The arm medial portion 636 is connected to the proximal portion 634 and generally comprises a seat or shoulder portion 644 and a curved or bent hook, finger or leg 646. The arm finger is substantially aligned with the spring outer finger 586. The spring outer finger 586 engages or locks with the arm finger 646.

The arm distal portion 638 is connected to the medial portion 636 and generally comprises an angled portion or section 648 and a distal end 650. The angled portion 648 extends generally interiorly and radially outwardly through the slot or opening 539b (see, for example, FIGS. 71 and 72) of the left side mount 138. The slot 539b desirably provided clearance space for rotation of the angled portion 539b.

The distal end 650 of the spring arm 576 is connected to the outer spline 132. The distal end 650 is dimensioned and configured so that it fits within the slot, cavity or opening 269b (see, for example, FIG. 41) of the outer spline 132. In one embodiment, the distal end 650 is generally rectangular or U-shaped though in modified other suitable shapes may be used, as needed or desired.

The set screw 273 (see, for example, FIG. 6) or the like engages the outer spline threaded hole 271b (see, for example, FIG. 41) and contacts or abuts the spring arm distal end 650 to securely connect it to the outer spline 132. In another embodiment, the distal end 650 may include a

threaded hole or the like that engages a connector pin to secure the distal end 650 to the outer spline 132.

The axle, pin, shaft or bar 578 generally comprises a shank portion 652 connected to a head or cap portion 654. The shank 652 extends through the arm hole 642, the outer shield hole 628 and into the bearing hole 594. The head 654 generally abuts the arm proximal end 640.

The shank 652 is coupled to the bearing hole 594 using Loctite® threadlocker or retaining compound. The shank 652 is press fitted in the arm hole 642 and the outer shield hole 628 such that the rotation of the shank 652 (and/or axle 578) generally corresponds to rotation of the arm 576 and the outer shield 574.

The extension assist system 148 operatively couples the spring 570 to both the core mandrel portion 168 and the outer spline 132. This coupling, connection or communication allows substantially independent actuation or tensioning of the spring 570 due to the rotation of the core mandrel portion 168 (and corresponding rotation of the side mount 138) and due to rotation of the outer spline 132.

FIG. 80 shows the prosthetic knee 110 in a substantially fully extended state. The arrows 142a, 142b generally depict the direction of knee rotation or flexion. The arrow 142a denotes the rotation or flexion of the side mount 138 (and hence the core mandrel portion 168) which generally corresponds to rotation of the lower leg pylon 104. The arrow 142b denotes the rotation or flexion of the outer spline 132 which generally corresponds to rotation of the upper leg socket 106.

The rotation of the core mandrel portion 168 in the direction 142a causes rotation of the spring inner finger 584 which is locked with the mandrel portion 168. This tensions or loads the spring 570 which thereby stores energy for subsequent release. The bearing 580 facilitates in the rotation of the mandrel portion 168 substantially independently of the axle 578. During knee extension or rotation in the opposite direction the spring 570 releases the stored energy thereby advantageously facilitating knee extension.

The rotation of the outer spline 132 in the direction 142b causes rotation of the spring arm 576 which is attached at its distal end 650 to the outer spline 132. This causes rotation of the spring outer finger 586 which is locked with or coupled to the arm 576 and this tensions or loads the spring 570 which thereby stores energy for subsequent release. The bearing 580 facilitates in the rotation of the axle 578, which is connected to the spring arm 576, substantially independently of the core mandrel portion 168. During knee extension or rotation in the opposite direction the spring 570 releases the stored energy thereby advantageously facilitating knee extension.

During energy storage, the spring 570 provides some degree of resistance to knee rotation. For example, during swing flexion, it is desirable to reach a certain target swing flexion angle. In this case, to allow the knee to swing substantially freely to reach the target angle, in one embodiment, a compromise or balance is provided for optimal performance.

The total resistance to swing flexion will be due to the actuator torque and the resistance due to the spring 570. In one embodiment, the actuator torque during swing flexion is passive (not electronically controlled, that is, with substantially zero magnetic field). The spring properties may be selected to achieve optimal performance. The passive torque can be manipulated to achieve optimal performance, for example, by adjusting the number of blades 120, 130 and/or the gap therebetween.

The spring 570 desirably has a suitably high fatigue life for enhanced durability. In one embodiment, the spring 570 has a fatigue life of at least one million cycles. In one embodiment, the spring 570 has a fatigue life of at least about 3-4 million

cycles. In modified embodiments, other suitable spring fatigue life properties may be utilized with efficacy, as needed or desired.

In one embodiment, the spring 570 has a diameter of about 3.8 cm (1.5 inches). In another embodiment, the spring 570 has a diameter of about 2.5 cm (1 inch) to about 5.1 cm (2 inches), including all values and sub-ranges therebetween. In one embodiment, the spring 570 comprises high carbon spring steel.

To achieve a high fatigue life, for a spring that has to survive an extremely high degree of rotation and, in one embodiment is relatively small and occupies a small space, the spring 570 is specially designed.

In some embodiments, a high fatigue life is achieved by altering the heat treatment of the spring 570 from the standard heat treatment process used by the spring manufacturer and by coating the spring 570 with an antifriction, anti-wear coating. Typically, springs made from high carbon spring steel are quenched and tempered after cold forming in order to achieve the desired strength and toughness of the material.

An analysis of conventional springs that had not performed well during fatigue testing revealed that impurities in the metal would congregate during the quench process causing dislocations in the metal lattice structure where cracks would initiate. To overcome this problem, the temperature of the quench bath is lowered so that the quench occurs in a much shorter time. This way, advantageously, the impurities do not have time to congregate and the metal lattice structure is much more homogeneous, thereby desirably providing a higher fatigue life for the spring 570.

In conventional coil springs of a small size that undergo a high degree of rotation, the friction forces between the spring coils are significant as the spring is loaded up. These friction forces can undesirably cause high wear rates and premature spring failure. In addition, the friction and rubbing between coils causes noise and wasted energy. With a suitable antifriction coating, in one study, the wear of the coated spring 570 over three million cycles was too small to be measured, the energy efficiency of the spring improved from about 80% to about 95%, and the noise was completely eliminated.

The extension assist system 148 of embodiments of the invention can be used to provide a wide range of extension assisting force or torque profiles which may be customized or fine-tuned to the specific needs of a patient. This may include the use of different spring sizes and different spring constants. The spring pre-load may be adjusted or fine-tuned using a tensioning screw or the like.

FIG. 81 shows some embodiments of extension assisting torque profiles as a function of rotation angle with maximum rotation angle being denoted by ϕ_{max} . In one embodiment, the torque profile is substantially linear as generally denoted by line or curve 656. The torque generally increases with increasing rotation angle. The torsion spring 570, in one embodiment, provides the linear torque profile 656.

In another embodiment, the torque profile is non-linear as generally denoted by line or curve 658. In this case, the torque initially increases with rotation angle and then decreases with the torque reversing direction after a certain point. A suitably mounted extension spring 570' (see FIG. 82), in one embodiment, provides the torque profile 658. The extension spring 570' can be mounted generally across the knee diameter.

One important design parameter is the total energy stored in the extension assist spring. This is generally represented by the area below the torque profile line or curve. Thus, the areas below respective curves 656 and 658 denote the total energy stored in the respective springs. Thus, advantageously,

springs with different variable torque profiles but substantially the same total energy storage characteristics may be used, as needed or desired.

In one embodiment, the spring 570 is capable of storing about 1.2 Joules over about 60° of knee flexion. In modified embodiments, the spring may have other suitable energy storing capabilities with efficacy, as needed or desired.

Angle Sensing System

In some embodiments, the prosthetic knee 110 comprises the knee angle sensor system or assembly 154 that measures the knee angle and communicates with the frame and electronics system 114. FIG. 83 shows an exploded perspective view of one embodiment of the knee angle sensor system 154.

The angle sensor system 154 is used to encode the absolute knee angle. The angle sensor system 154 desirably measures the degree to which a single degree-of-freedom knee joint is flexed or extended.

The angle sensor system 154 is generally mounted in the exterior side recessed region or portion 538a of the right side mount 136. Advantageously, the substantially internally mounted angle sensor system 154 provides a reduced knee profile and protection for its components against undesirable side impact or contact. The angle sensor system 154 generally comprises an angle sensor 668 and a rotatable arm 670 connected to the angle sensor 668 by a shaft, axle or pin 674.

A cable or lead wires 672 connect the angle sensor 668 to the frame and electronics assembly 114 for knee control purposes. A suitable connector or the like is provided at one end of the cable 672 to facilitate this interface. The cable 672 is desirably shielded.

The cable 672 passes through the notch 500a of the right side mount 136 and runs along the exterior surface groove 502a of the right side mount 136 (see, for example, FIG. 69) and connects to the frame and electronics assembly 114. Advantageously, the notch 500a and groove 502a facilitate in keeping the cable 672 in position and prevent undesirable movement.

In the illustrated embodiment, the angle sensor 668 generally comprises a substantially cylindrical housing 676 and a plurality of radially outwardly extending wings, mounts or connection members 678. The housing 676 generally comprises an inner portion or section 682 with an inner face or surface 684 and an outer portion or section 686 with an outer face or surface 688.

The inner and outer portions 682, 686 are generally separated by a plane passing through the wings 678. The inner and outer portions 682, 686 of the housing 676 also define a generally cylindrical or circular side, peripheral or circumferential face or surface 690. The housing inner portion 682 is sized and configured so that it fits within or extends into the cavity or recess 506a (see, for example, FIG. 69) of the right side mount 136.

The housing outer portion 686 (and shaft 680) are generally positioned within the recessed region or portion 538a (see, for example, FIG. 69) of the right side mount 136. The shaft 674 extends outwardly from the housing outer face 688 and is mechanically connected to the arm 670.

The wings or mounts 678 extend from the housing surface 690 and facilitate in connecting the angle sensor 668 to the right side mount 136. In the illustrated embodiment, the angle sensor 668 comprises three wings 678, though in modified embodiments fewer or more wings 678 may be efficaciously utilized, as needed or desired.

Each of the wings 678 comprises a through hole or cavity 692 that receive respective screws or the like to connect the angle sensor 668 to the right side mount 136. In the illustrated

embodiment, the holes 692 are arranged substantially equidistantly and in a circular fashion around the housing 676.

The wing holes 692 are substantially aligned with the threaded holes 507 (see, for example, FIG. 69) on the right side mount surface 509. Screws, connector pins or the like pass through respective holes 692 and threadably engage respective threaded holes 507 to secure or fasten the angle sensor 668 to the right side mount 136. A suitable adhesive or glue, such as Loctite® threadlocker or the like, can be utilized with the screws to provide a strong coupling between the angle sensor 668 and the right side mount 136.

The wings 678 abut against the surface 509 (see, for example, FIG. 69) of the right side mount 136. In the illustrated embodiment, the wings 678 and nuts 160 associated with the right side mount 136 are alternately interspersed and spaced to provide clearance space therebetween.

The shaft 674 has a proximal portion or section 694 and a distal portion or section 696 generally separated at a shoulder or step 698. The shaft 674 is rotatable and its proximal portion 694 extends through the housing 676 and more particularly through the housing outer face 688. The shaft proximal portion 694 connects to the angle sensor's inner componentry, such as electronics and the like, which is used to measure the knee angle.

A notch or groove 700 may be provided proximate the shoulder 698 to facilitate alignment or positioning. In one embodiment, a portion of the proximal section 694 that is proximal to the notch 700 extends into the sensor housing 676.

The shaft distal portion 696 is desirably threaded and connects to the arm 670. The shoulder 698 abuts against the rotatable arm 670 and facilitates in spacing it from the sensor housing 676.

The arm 670 is generally configured in the shape of a substantially flat angled bar and is operatively coupled to the right side mount 136 via the angle sensor 668 and to the outer spline 132. The arm 670 generally comprises a proximal main body portion or section 702, a medial portion or section 704 and a distal portion, section or end 706.

The arm proximal portion 702 has a proximal end 708 with a through hole or cavity 712. The shaft threaded portion 696 extends through the arm hole 712 and a nut 714 (see, for example, FIG. 6) or the like is engaged with the threaded portion 696 to securely connect the shaft 674 and arm 670. A suitable adhesive or glue, such as Loctite® threadlocker or the like, can be utilized with the threaded portion 696 and nut 714 to provide a strong coupling between the shaft 674 and arm 670.

The shaft shoulder 698 abuts against the arm proximal end 708 and spaces the arm proximal portion 702 from the sensor housing 676 and more particularly the housing outer surface 688. The arm proximal portion 702 extends generally radially outwardly and substantially parallel to the housing outer surface 688.

The medial portion 704 generally includes two connected sections or portions 716 and 718 that are angled relative to one another. The first section 716 is adjacent the arm proximal portion 702 and angled relative to it. The second section 718 is adjacent the arm distal end 706 and angled relative to it.

The arm section 716 extends generally radially outwards and laterally or longitudinally inwards. The arm section 716 passes through the curved generally C-shaped slot or opening 539a (see, for example, FIG. 69). The slot 539a desirably provides a rotational angular range of about 180° for the arm 670 (and the arm portion 716 extending through the slot 539a), though typically the maximum knee angle rotation is about 140°-150° and, in one embodiment, about 145°.

The medial second section 718 extends generally radially outwardly. The arm section 718 facilitates in aligning the arm distal end 706 with the slot, cavity or opening 269a (see, for example, FIGS. 43 and 44) of the outer spline 132.

The arm distal end 706 is received within the outer spline slot 269a. The distal end 706 has a through hole or cavity 720 that is substantially aligned with the threaded hole 271a (see, for example, FIG. 44) of the outer spline 132. A screw or the like extends through the hole 720 and is threadably engaged with the hole 271a to secure the arm distal end 706 to the outer spline 132. A suitable adhesive or glue, such as Loctite® threadlocker or the like, can be utilized with the threaded hole 271a and associated screw to provide a strong coupling between the arm 670 and the outer spline 132.

The distal end 706 is sized and configured to fit within the outer spline slot 269a, in one embodiment, in a generally close, tolerance fit. In the illustrated embodiment, the distal end 706 is generally rectangular or U-shaped though in modified other suitable shapes may be used, as needed or desired.

The angle sensor system 154 is operatively coupled, connected or communicated with the outer spline 132 and the right side mount 136. The angle sensor system 154 detects and measures the knee rotation angle and transmits it to the frame and electronics assembly 114 for knee control purposes.

The angle sensor system 154 measures the knee rotation angle when the outer spline 132 rotates, the right side mount 136 rotates or both rotate at the same time. As noted above and herein, rotation of the outer spline 132 corresponds to rotation of the outer rotors 130 and rotation of the right mount 136 (and left mount 138) corresponds to rotation of the inner rotors 120, inner spline 122, core rod 113 and core side plates 116, 118.

Rotation of the outer spline 132 causes rotation of the arm 670 which has its distal end 706 fixed to the outer spline 132. The arm portion 716 rotates or moves through the right side mount slot 539a. The rotation of the arm 670 results in rotation of the shaft 674 relative to the angle sensor 668 (and its internal componentry) which is used by the angle sensor 668 to measure the knee rotation angle.

Rotation of the right side mount 136 causes rotation of the angle sensor 668 since the sensor housing 676 is fixed to the right mount 136. The rotation of the angle sensor 668 is relative to the shaft 674 which is used by the angle sensor 668 to measure the knee rotation angle. When both the outer spline 132 and the right mount 136 rotate relative to one another, the angle sensor 668 uses the relative rotational positioning of the shaft 674 to measure the corresponding knee rotation angle.

In some embodiments, the signal from the knee angle sensor 668 is conditioned by amplification, band filtering and differentiation before being transmitted to a processor of the frame and electronics assembly 114. The differentiation is used to determine the rotational or angular velocity of the knee. The knee angular velocity signal further determines whether the knee is flexing or extending.

In one embodiment, the angle sensor 668 comprises a potentiometer. In modified embodiments, other suitable angle sensing devices, for example, optical or magnetic shaft encoders and the like, may be efficaciously used, as needed or desired.

In one embodiment, the angle sensor 668 comprises a 5 kiloOhm ($k\Omega$) precision potentiometer. A five volt power is supplied to one end of the potentiometer while the other end is held at ground. This provides a signal output proportional to a position between 0° and 180°. As indicated above, the maximum knee angle rotation is typically between about

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140°-150° and, in one embodiment, is controlled to about 145°. During assembly, the angle sensor system 154 is calibrated.

Frame and Electronics Assembly

FIGS. 84-91 show different views of one embodiment of the frame and electronics assembly 114. The frame and electronics assembly 114 facilitates in monitoring and controlling the operation of the knee actuator 112. The frame and electronics assembly 114 also provides power and communicates with the actuator assembly 112 via electrical signals.

The frame and electronics assembly 114 generally comprises a load cell pylon or frame 800, an electronic controller, control system or unit 802 and a power supply or battery system 804. FIGS. 92-96 show different views of one embodiment of the frame 800.

The frame 800 is connected to the knee actuator 112 and the lower pylon 104 (see, for example, FIG. 2). The frame 800 houses or supports the control system 802 and the battery system 804 and may also facilitate in shielding them and other associated electronic components and the like from the magnetic field generated by the knee actuator 112.

The frame 800 advantageously allows simple connections to foot and shock systems without the use of specialized pylons. Another advantage is the ability to change height or foot rotation without recalibration or system reset. Another benefit is that there is a low contribution to the prosthesis profile and hence this allows for increased number of foot options.

In one embodiment, the frame 800 is fabricated from aluminum or an aluminum alloy. In modified embodiments, other suitable metals, alloys, plastics, ceramics, among others, may be utilized with efficacy, as required or desired.

In the illustrated embodiment, the frame 800 is generally in the form of a three-dimensional rectangular structure. The frame 800 includes a base or distal portion or section 806 that has a plurality of threaded holes 808 (see, for example, FIG. 91) to facilitate connection to a lower leg pylon such as the pylon 104.

FIGS. 97 and 98 show a distal pyramid connector, adapter or stud 812 with through holes 814 aligned with a respective one of the frame holes 808. The pyramid connector 812 connects the prosthetic knee 110 to the pylon 104. Desirably, the pyramid connector 812 allows for proper coupling and alignment between the prosthetic knee 110 (and/or frame 800) and the pylon 104. In modified embodiments, other suitable connectors or the like may be efficaciously used, as needed or desired.

Bolts, screws 816 or the like pass through respective connector holes 814 and threadably engage respective frame holes 808 to attach the pyramid connector 812 to the frame base 806. A suitable adhesive or glue, such as Loctite® threadlocker or the like, can be applied to the threads to provide a strong coupling between the frame 800 and the pyramid connector 812.

In one embodiment, the pyramid connector 812 comprises titanium or a titanium alloy. In another embodiment, the pyramid connector 812 comprises aluminum or an aluminum alloy. In modified embodiments, the pyramid connector 812 can be efficaciously fabricated from other suitable metals, alloys, plastics, ceramics, among others, as required or desired.

The frame 800 includes a front side, portion or section 818 and a rear side, portion or section 820 between which the base 806 extends. In the illustrated embodiment, the right and left sides of the frame are generally open to facilitate, for

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example, device assembly and provide weight reduction while maintaining structural integrity.

The front side 818 has a support element or member 822 that facilitates in securing the control system 802 to the frame 800. The support element 822 has a through hole 824 that receives a screw or the like, as discussed further below.

The frame 800 includes a medial seat, platform or support element 826 that generally extends between the frame front and rear sides 818, 820. The platform 826 facilitates in supporting the control system 802 and battery system 804 in the frame 800. The support platform 826 has a pair of spaced through holes 828 that receives screws or the like, as described further below.

The frame 800 at around its top proximal end includes a front mount support 830 and a rear mount support that facilitate in connection to the knee actuator 112 and more particularly to the side mounts 136, 138. In the illustrated embodiment, the front support 830 is generally higher than the rear support 832 and the two are connected by a support element or member 834 that extends therebetween.

The front support 830 includes a pair of spaced through holes 836a, 836b that are aligned with respective threaded holes at respective front portions 524a, 524b (see, for example, FIGS. 68, 69, 71 and 72) of respective right and left side mounts 136, 138. Bolts, screws 838a, 838b or the like pass through respective holes 836a, 836b and threadably engage the respective threaded holes at respective side mount front portions 524a, 524b to connect the fronts of the frame 800 and the side mounts 136, 138.

The rear support 832 includes a pair spaced threaded holes 840a, 840b on either side of the support element 834 which are aligned with respective through holes 522a, 522b (see, for example, FIGS. 67 and 70) on respective feet or seats 520a, 520b of respective right and left side mounts 136, 138. The feet 520a, 520b are seated on the rear support 832. Bolts, screws 164a, 164b (see, for example, FIG. 6) or the like pass through respective holes 522a, 522b and threadably engage respective threaded holes 840a, 840b to connect the rears of the frame 800 and the side mounts 136, 138.

In one embodiment, the rear support 832 further includes another pair of spaced through holes 842a, 842b with one on either side of the holes 840a, 840b. The holes 842a, 842b are aligned with respective threaded holes provided on respective feet 520a, 520b. Screws or the like pass through respective holes 842a, 842b and threadably engage these respective threaded holes at respective side mount rear feet 520a, 520b to further connect and secure the rears of the frame 800 and the side mounts 136, 138.

In one embodiment, a vibrator motor 844 is mounted on the frame 800 at or proximate to the support element 834. The vibrator motor 844 is part of a vibrating warning system and is activated by signals from the control system 802 to alert or draw the attention of the wearer, as described further below.

The front side 818 of the frame 800 includes an aperture, window, cavity or opening 846 in which a front load force sensor 848 (see FIG. 93) is mounted. The frame front side 818 further includes a recess or cavity 850 with a recessed surface 852. An amplifier or signal amplification device 854 (see FIG. 93) is mounted in the recess 850 and is in electrical communication with the force sensor 848.

A passage 856 (see, for example, FIG. 92) through which a lead wire or the like passes connects or interfaces the force sensor 848 and the amplifier 854. An opening or hole 858 (see, for example, FIGS. 86 and 92) in the recessed surface 852 through which a lead wire or the like passes connects or interfaces the amplifier 854 and the control system 802.

In one embodiment, the front force sensor 848 comprises two strain gages 860a, 860b (see FIG. 93) mounted in the frame aperture 846. In modified embodiments, other suitable force or moment measurement sensors or devices may be efficaciously utilized, as needed or desired.

The rear side 818 of the frame 800 includes an aperture, window, cavity or opening 866 in which a rear load force sensor 868 (see FIG. 94) is mounted. The frame rear side 820 further includes a recess or cavity 870 with a recessed surface 872. An amplifier or signal amplification device 874 (see FIG. 94) is mounted in the recess 870 and is in electrical communication with the force sensor 868.

A passage 876 (see, for example, FIG. 92) through which a lead wire or the like passes connects or interfaces the force sensor 868 and the amplifier 874. An opening or hole 878 (see, for example, FIG. 87) in the recessed surface 872 through which a lead wire or the like passes connects or interfaces the amplifier 874 and the control system 802.

In one embodiment, the rear force sensor 868 comprises two strain gages 880a, 880b (see FIG. 94) mounted in the frame aperture 866. In modified embodiments, other suitable force or moment measurement sensors or devices may be efficaciously utilized, as needed or desired.

In one embodiment, the axial force sensors 848, 868 measure the component of force applied to the knee prosthesis 110 from the ground or other supporting surface in a direction substantially along or parallel to a shin longitudinal axis 882 (see, for example, FIG. 2). The force measurement is also used to determine whether the prosthetic foot 102 is on or off the ground or other supporting surface. That is, a zero axial force indicates that the foot 102 is not on the ground, for example, in the swing phase, while a non-zero axial force indicates that the foot 102 is on the ground, for example, in the stance phase.

In one embodiment, the measurements from the force sensors 848, 868 are used by the control system 802 to determine or compute the component of torque applied to the knee prosthesis 110 (and/or knee actuator 112) in substantially the knee rotation direction 142 (see, for example, FIG. 2). The moment measurement is also used to determine whether the applied knee moment is a flexion or extension moment and the direction of movement or knee rotation. For example, typically in normal walking, at heel strike a flexion moment is applied to the knee prosthesis 110, tending to flex the knee joint, and throughout late stance an extension moment is applied, tending to extend the joint.

In one embodiment, there is substantially no cross-talk between the front force sensor 848 and the rear force sensor 868. Advantageously, this provides for accurate measurement and differentiation or distinction between load on the front (toe-end) of the foot 102 and load on the rear (heel-end) of the foot 102.

In one embodiment, the four strain gages 860a, 860b, 880a, 880b are arranged in a wheatstone or standard bridge configuration. They are supplied with 5 volt power and produce an output or approximately 3 mv/v for each pound force of loading. Instrumentation amplifiers 854, 874 condition the bridge output and communicate it to the control system 802.

The frame 800 may include various recesses, windows holes, passages, slots, notches, contours and the like that can provide clearance space, alignment facilitation, connection features and component access, among other desirable characteristics. Material may be selectively removed at portions of the frame 800 to advantageously provide device weight reduction while maintaining structural integrity, as needed or desired.

The control system 802 is mounted within the frame 800. More particularly, in the illustrated embodiment, the control system 800 is generally above the frame base 806 and below the frame platform 826.

5 In the illustrated embodiment, the control system generally comprises two printed circuit boards (PCBs) 884 and 886. The front and rear circuit boards 884, 886 are spaced from one another and have the electronic control components, for example, a microprocessor, and associated components mounted thereon. In modified embodiments, fewer or more circuit boards or the like may be utilized with efficacy, as needed or desired.

Each of the circuit boards 884, 886 have respective bottom and top mounting holes 888, 890. The bottom holes 884 are engaged by a spacer system or assembly 892 and the top holes 886 are engaged by a mounting system or assembly 894 for securing the circuit boards 884, 886 in place within the frame 800.

15 The spacer system 892 generally comprises a pair of substantially aligned spacers 896, 898 and a pair of substantially aligned associated screws 902, 904 or the like. The spacer 896 is generally positioned between and abuts the frame support element 822 and the circuit board 884. The spacer 898 is generally positioned between and abuts the two circuit boards 884, 886. The spacers 896, 898 are substantially aligned with circuit board lower holes 888.

20 The screw 902 passes through the frame support hole 824 (see, for example, FIG. 92), the spacer 896 and the bottom hole 888 of the circuit board 884. The screw 902 is threadably engaged with the spacer 898 and may also threadably engage the spacer 896. The screw 904 passes through the bottom hole 888 of the second circuit board 886 and is threadably engaged with the spacer 898. In this manner, the spacer assembly 892 secures the lower portions of the circuit boards 884, 886 to the frame 800 and spaces the boards 884, 886.

25 The upper mounting system 894 generally connects the upper portions of the circuit boards 884, 886 and the battery system 804 to the frame platform 826. The mounting system 894 includes a generally flat plate or mount 906 with a pair of spaced holes 908 substantially aligned with respective through holes 828 (see, for example, FIG. 92) of the frame platform 826.

30 Screws 912 or the like pass through respective frame holes 828 and extend into respective mount holes 908 to secure the mount 906 to the frame platform 826. The screws 912 may threadably engage the holes 908 and/or associated nuts or the like may be used, as needed or desired.

35 In the illustrated embodiment, the mounting system 894 further comprises a pair of spaced and offset front and rear mounting support elements or members 914 with one each abutting (or adjacent to) respective circuit boards 884, 886. Each of the mounting elements 914 has a respective hole 916 substantially aligned with respective circuit board top holes 890.

40 Screws 918 or the like pass through respective circuit board holes 890 and extend into respective mount holes 916 to secure respective circuit boards 884, 886 to the mounting system 894 (and thereby frame platform 826). The screws 918 may threadably engage the mounting holes 916 and/or associated nuts or the like may be used, as needed or desired.

45 In the illustrated embodiment, the mounting system 894 further comprises a pair of spaced and offset right and left side mounting support elements or members 920 which facilitate mounting of the battery system 804 to the frame 800. Each of the mounting elements 920 has a respective hole 922, as described further below.

In one embodiment, the on-board control system 802 comprises a Motorola MC68HC912B32CFU8 microprocessor. The processor, in one embodiment, includes a Motorola HC12 compatible 16 bit processor, 32 Kilobytes flash eeprom, 768 byte eeprom, an 8 channel 10 bit AD converter, a serial peripheral interface (SPI), a serial communications interface (SCI), a programmable timer and pulse accumulators, a programmable pulse width modulator output, Motorola background mode debugging support, and programmable digital input-output (I/O) pins. In one embodiment, 32 Kilobytes of fast static ram are used.

The control system 802 comprises a controller to control the current through the magnetic coil 115 (see, for example, FIG. 6). In one embodiment, the current through the actuator coil 115 is controlled using a UCC3800 pulse width modulator controller.

In one embodiment, the control system 802 can control the coil current in the range from about 0 amperes to about 1.8 amperes in about hundred (100) increments, levels or steps. In modified embodiments, other current ranges and current control resolutions may be efficaciously utilized, as needed or desired.

As noted above, and also discussed further below, some embodiments provide for degaussing or demagnetization of the actuator blades 120, 130. The control system 802 includes a circuit that is designed to allow reversal of the current direction through the coil 115, thereby advantageously eliminating or mitigating undesirable residual magnetism build-up. Software control of this reversal allows demagnetization of the blades 120, 130 prior to situations where low torque is desirable.

In some embodiments, the control system 802 includes a warning system that is activated to alert or draw the attention of the wearer, as described further below. In embodiment, the control system 802 comprises an audible warning system. In another embodiment, the control system 802 comprises a vibrating warning system. In yet another embodiment, both audible and vibrating warning systems are used.

The power or battery system or pack 804 is generally positioned above and supported by the frame platform 826. The power system 804 provides electrical power to operate the various system components such as the control system 802.

As shown in FIG. 85, the power system 804 generally comprises a battery cell pack having one or more rechargeable batteries, battery cells or power sources 930. Advantageously, the power system 804 (and battery pack) are compact to facilitate in providing an overall compact knee design.

In one embodiment, the power system 804 comprises three batteries 930. In one embodiment, the batteries 930 comprise lithium ion batteries. In modified embodiments, other number of batteries and other suitable battery types may be efficaciously utilized, as needed or desired.

The power system 804 includes a cover 932 (see, for example, FIG. 85) or the like in which the batteries 930 are housed. In one embodiment, the cover 932 comprises heat shrink or the like. In modified embodiments, other suitable materials may be efficaciously used, as needed or desired.

The power system 804 includes one or more battery separators 934 (see, for example, FIG. 85) with one each between adjacent batteries 930. The separators 934 can comprise a cushioning adhesive material such as tape foam or the like to protect the batteries 930 and hold them in place.

The power system 804 includes a battery mount or support 936 (see, for example, FIG. 85) generally below the batteries 930 on which the batteries 930 are seated. An adhesive or

bonding tape 938 or the like may be provided intermediate the batteries 930 and the battery mount 936 to hold the batteries 930 in place.

The battery mount 936 has an upper contoured surface 940 that comprises channels, grooves or the like that facilitate alignment and positioning of the batteries 930 thereon. In the illustrated embodiment, the battery mount 936 comprises a pair of spaced and offset right and left side mounting elements or members 942. The mounting elements 942 extend out of the battery cover 932 and generally flank the frame platform 826 with the power system 804 seated generally thereon.

The mounting elements 942 abut against or are adjacent to respective mounting elements 920 of the mounting assembly 894. Each of the mounting elements 942 has a respective hole 944 aligned with a respective hole 922 of the mounting assembly 894.

Screws or the like pass through respective mounting holes 944 and respective mounting holes 922 to secure the power system 804 to the frame platform 826. The screws may threadably engage the holes 922 and/or the holes 944 and/or associated nuts or the like may be used, as needed or desired.

In one embodiment, the power system 804 produces an unregulated voltage of about 10 volts to about 12.5 volts, including all values and sub-ranges therebetween. The battery voltage, in one embodiment, is used to drive the magnetic coil current directly.

The power system 804 provides other voltages the electronics. These include, but are not limited to, voltage supplies of about 6 volts, about 5 volts, about 3.2 volts and about 2.5 volts.

In the illustrated embodiment, the battery system 804 comprises an internal protection circuit 946. The protection circuit 946 limits current to a predetermined maximum value.

In one embodiment, the protection circuit 946 limits current to about 2 amperes and momentarily shuts down the battery system 804 in the presence of higher current demands for safety purposes. The protection circuitry 946 also prevents overcharge of the battery system 804, for example, from highly discharged states.

The prosthetic knee 110 of embodiments of the invention desirably comprises an on-board battery charger for the power system 804. The input to the charger is, in one embodiment, a supply of about 18 volts and about 2 amperes. Medical grade power supplies may be used to provide the 18 volt source. The on-board charger controls the battery charging functions.

FIGS. 97-100 show different views of one embodiment of a charging, programming and power control panel or display 950 of the prosthetic knee assembly 110 (and/or the frame and electronics assembly 114). The control panel 950 communicates with the knee control system 802 which in turn communicates with the knee actuator 112, power system 804 and other associated electronics.

The control panel 950 is generally mounted on the rear of the prosthetic knee assembly 110 generally around the mechanical connection between the frame 800 and the side mounts 136, 138. More specifically, the control panel 950 is mounted between the rear legs 518a, 518b of respective side mounts 136, 138 and proximate to the frame upper support member 834.

The control panel 950 generally comprises a protective cover or shield 952, a port, socket or receptacle 954 with a protective cover 956, a power switch 958 and charging indicators 960. The control panel 950 may be interfaced with a separate circuit board that connects to the main control system 802.

The cover 952 can be raised to provide access to the port 954 and power switch 958 and then locked back into place. The cover 956 comprises a flexible material and may be transparent or at least partially transparent.

The port 954 is mounted in the cavity 527 of the right mount support 525 (see, for example, FIG. 67). The cover 956 protects the port 954 when it is not in use. The cover 956 can be selectively lifted to expose the port 954 and locked back down in position to shield the port 954. In the illustrated embodiment, the port 954 comprises a six pin socket that interfaces with a compatible plug from a cable or the like.

In one embodiment, the port 954 serves as both a charging port and a programming port. The battery charge is supplied from a suitable power source and the programming interface may be provided by a personal digital assistant (PDA) or the like. In modified embodiments, separate charging and programming ports may be used, as needed or desired.

In one embodiment, the prosthetic knee 110 may be remotely controlled and programmable. In one embodiment, the internet is used for communicating with the prosthetic knee 110, for example, to provide software upgrades or the like.

The power switch 958 is used to turn the prosthetic knee 110 on and off. In the illustrated embodiment, the power switch 958 comprises a sliding on-off switch. In modified embodiments, other suitable power switches such as push-button and the like may be efficaciously utilized, as needed or desired.

The charging indicators 960 show the status of battery charging. The charging indicators 960 may comprise blinking and steadily illuminated lights of different colors, for example, green and red, to indicate the charging status and on-off status.

The battery charging system, in some embodiments, disconnects the power system 804 from the control electronics 802 whenever the charger 954 is connected to a power source or a dummy charge plug is inserted into the charging receptacle 954. Thus, the knee 110 is off when connected to a charging source.

Embodiments of the invention provide convenient knee charging accessories that may be used, for example, at home, office, on the road or in an automobile. These include adapters, cables, plugs, sockets that may be easily connected to a power source (e.g. conventional wall outlet or automobile port) and interfaced with the charging port 954 of the prosthetic knee 110.

In one embodiment, the power or battery system 804 has an about 1,800 Milli-Amp-Hour (mAH) capacity. In another embodiment, the power or battery system 804 has an about 5,400 Milli-Amp-Hour (mAH) capacity.

In one embodiment, the power system or battery pack 804 comprises three battery cells 930 connected in series. In another embodiment, the power system or battery pack 804 comprises three battery cells 930 connected in parallel.

When the power system 804 is substantially fully charged, in one embodiment, the life of the charge is about 24 hours to about 48 hours depending on the level of the activity. The power system 804 desirably has a short charging time from substantially full discharge to substantially full charge. In one embodiment, the charging time is about 2.5 hours. In another embodiment, the charging time is in the range from about two (2) hours to about four (4) hours, including all values and sub-ranges therebetween. Partial usable charges occur much more rapidly.

Shroud

FIGS. 101-105 show different views of one embodiment of a prosthetic knee cover or shroud 1016. FIGS. 106 and 107 show different views of one embodiment of the prosthetic knee assembly 110 including the knee cover 1016. FIG. 108 shows one embodiment of the lower limb prosthetic assembly 100.

In one embodiment, the knee cover 1016 generally comprises an outer flexible skin, sheath, casing or jacket and an internal substantially rigid exoskeleton. The flexible skin carries substantially zero or only a small load that desirably facilitates accurate measurement of the load by the force sensors 848, 868. The substantially rigid exoskeleton which may comprise ribs, sleeves and the like desirably protects the internals of the knee against impact.

In one embodiment, the flexible skin comprises urethane. In modified embodiments, the skin may comprise other suitable flexible plastics or materials with efficacy, as needed or desired.

In one embodiment, the substantially rigid exoskeleton comprises a polycarbonate. In modified embodiments, the exoskeleton may comprise other suitable substantially rigid plastics or materials with efficacy, as needed or desired.

In one embodiment, the knee cover 1016 comprises at least a partially transparent material. In one embodiment, the knee cover 1016 comprises a material that is substantially blue in color.

The knee cover 1016 has a through passage that receives the knee actuator 112 and the frame and electronics assembly 114. The knee cover generally comprises a proximal or upper portion or section 1020 that substantially houses the actuator 112, a distal or lower portion or section 1024 that substantially houses the frame and electronics assembly 114 and a middle or medial section or portion 1022 that substantially houses the connection between the actuator 112 and the assembly 114.

The cover proximal portion 1020 generally comprises a front wall 1026 and a pair of spaced right and left side walls or ears 1028a and 1028b respectively. In the illustrated embodiment, the front wall 1026 is generally curved or semi-circular in shape.

The cover proximal portion 1020 comprises a substantially rigid and central internal ridge, rib or core 1030 that is connected to the front wall 1026. In the illustrated embodiment, the rib 1030 is generally curved or semi-circular in shape and is substantially centrally positioned between the side ears 1028a and 1028b. The rib 1030 advantageously provides clearance space on its sides for rotation or movement of the spaced outer spline stops or fangs 282 (282a, 292b).

Advantageously, the rigid rib 1030 provides support and protection, for example, during kneeling when the knee 110 rests on or contacts a surface. Typically, the rib 1030 is slightly spaced from the outer spline 132 so that it does not interfere with rotation of the outer spline 132. In one embodiment, the rib 1030 is integral with the flexible skin of the knee cover 1016 and comprises the same material as the skin.

The cover proximal portion 1120 has an open top end and rear that allows for attachment between the upper pyramid connector 152 and the stump socket 106 and clearance space for rotation (see, for example, FIGS. 106-108). The outer spline 132 rotates substantially independently of the knee cover 1016 while the rotation of the side mounts 136, 138 is coupled to the knee cover 1016, as described further below.

The knee cover ears 1028a, 1028b fit over respective right and left side caps 156a, 156b which are a part of the rigid exoskeleton that protects against impact. The right cap 156a

protects the angle sensor 154 and the left side cap 156b protects the extension assist 148.

Suitably placed grooves of the knee cover 1016 receive respective ribs or the like of the side caps 156 to connect the side caps 156 and the knee cover 1016 (and its proximal portion 1020). In one embodiment, the side cap ribs are substantially rigid. Adhesive or the like can be utilized to further secure this connection.

Locating bosses of the knee cover 1016 that extend inwardly from respective ears 1028a, 1028b are keyed with relief pockets 562a, 562b in the respective side mounts 136, 138. This further secures and aligns the knee cover 1016 (and its proximal portion 1020) with the side mounts 136, 138 and the actuator 112.

Since the knee cover 1016 (and its proximal portion 1020) are connected to the side mounts 136, 138 directly and via the side caps 156, the knee cover 1016 rotates along with the rotation of the side mounts 136, 138. As described further below, the knee cover 1016 is also connected to the frame and electronics assembly 114 which also rotates with the rotation of the side mounts 136, 138. Thus, rotation of the knee cover 1016 generally corresponds to that of the side mounts 136, 138, frame and electronics assembly 114 and the lower pylon 104.

The knee cover medial portion 1022 has a rear opening or open portion or face 1036 that desirably provides access to the control panel 950 (see, for example, FIG. 97). The medial portion has a rear arch portion (or arched edges) 1038 that advantageously provides clearance space for rotation of the stump socket 106 (see, for example, FIG. 108) such that it does not interfere with the control panel 950.

The knee cover distal portion 1024 is generally rectangular in shape. In one embodiment, the distal portion 1024 has an internal reinforcing sleeve or cover 1034 (see, for example, FIG. 105) that receives at least a portion of the frame and actuator assembly 114.

The distal portion 1024 has a distal end opening 1032 with a lip with a groove or the like that receives a lower edge or lip of the sleeve 1034 (see, for example, FIG. 104). Internal ribs or the like can be provided, for example, at the corners of the distal portion 1024 to facilitate connection of the sleeve 1034 therein. Adhesive or the like can be utilized to further secure this connection. These internal ribs not only hold the sleeve 1034 of the rigid exoskeleton in place, they also prevent the sleeve 1034 from banging against the frame 800 and making noise.

Pads or the like can be provided at selected positions between the sleeve 1034 and the frame and electronics assembly 114 for protection and/or mounting purposes. The pads may utilize a pressure sensitive adhesive backing or the like that facilitates attachment to the frame 800. The pads desirably prevent the sleeve 1034 from banging against the frame 800 and making noise.

FIG. 108 shows one knee rotation position where the stump socket 106 contacts a rear upper portion or edge 1040 of the knee cover distal portion 1024. This portion 1040 can include a protective thicker skin, padding, rib or the like to avoid undesirable contact between the socket 106 and the prosthetic knee 110.

Referring in particular to FIG. 106, in one embodiment, the width W_{1061} is about 65 mm (2 $\frac{1}{16}$ inches) and the width W_{1062} is about 75 mm (2 $\frac{5}{16}$ inches). In modified embodiments, other suitable dimensions may be efficaciously used, as needed or desired.

Referring in particular to FIG. 107, in one embodiment, the length L_{1071} is about 65 mm (2 $\frac{1}{16}$ inches), the length L_{1072} is about 78 mm (3 $\frac{1}{16}$ inches), the height H_{1071} is about 230 mm

(9 $\frac{1}{16}$ inches), the height H_{1072} is about 197 mm (7 $\frac{3}{4}$ inches), the height H_{1073} is about 32 mm (1 $\frac{3}{16}$ inches) to about 33 mm (1 $\frac{5}{16}$ inches) and the height H_{1074} is about 30 mm (1 $\frac{3}{16}$ inches). In modified embodiments, other suitable dimensions may be efficaciously used, as needed or desired.

Prosthetic Knee Operation

The prosthetic knee of embodiments of the invention provides high-speed instantly responsive control of knee movement, yet is robust and affordable for the amputee. The prosthetic knee embodiments advantageously provide enhanced security, energy efficiency, comfort, stability and optimized gait dynamics for amputees and simulate and/or closely recreate the dynamics of a natural knee joint.

The pressure control embodiments desirably maintain a zero or near zero pressure within the actuator thereby advantageously providing for long lifetime of use and low maintenance requirements. The dynamic seal embodiments are advantageous in providing reliable sealing and enhanced performance and reliability.

Another advantage is that the actuator weight is located more proximal in the knee thereby desirably providing a light-weight feel during swing phase. Yet another advantage is the ability to provide a low torque production during swing phase, thereby allowing for easy initiation of knee flexion.

During operation, the electromagnet or magnetic coil 114 is actuated, as needed, by a selected or predetermined electrical signal, voltage or current. This generates variable magnetic field that passes through blades 120, 130 and through the MR fluid or film therebetween to generate a variable damping torque (or rotary viscous or frictional resistance) which precisely and accurately controls the rotary motion of the knee joint.

Desirably, the prosthetic knee embodiments a rapid and precise response. Another advantage is that a wide dynamic torque or torsional resistance range can be provided with a small low-end torque.

In one embodiment, the actuator 112 provides a dynamic torque in the range from about 0.5 Newton-meters (N-m) to about 50 N-m, including all values and sub-ranges therebetween. In another embodiment, the actuator 112 provides a dynamic torque in the range from about 0.2 Newton-meters (N-m) to about 100 N-m, including all values and sub-ranges therebetween. In another embodiment, the actuator 112 provides a dynamic torque in the range from about 0.1 Newton-meters (N-m) to about 200 N-m, including all values and sub-ranges therebetween. In modified embodiments, other suitable dynamic torque ranges may be efficaciously provided, as needed or desired.

As noted above, some embodiments provide for degaussing or demagnetization of the actuator blades 120, 130. Advantageously, this allows the knee to "free-up" and desirably creates a low torque ability and wide dynamic torque range. Software control of this reversal allows demagnetization of the blades 120, 130 prior to situations where low torque is desirable.

The operation of the prosthetic knee 110 can be controlled by suitable software and hardware. Some control, degaussing, software and other operational embodiments are disclosed in U.S. patent application Ser. No. 11/077,177, filed Mar. 9, 2005, U.S. Provisional Patent Application No. 60/569,511, filed May 7, 2004, and U.S. Provisional Patent Application No. 60/572,996, filed May 19, 2004, each entitled, CONTROL SYSTEM AND METHOD FOR A PROSTHETIC KNEE, and U.S. Provisional Patent Application No. 60/551,717, filed Mar. 10, 2004, entitled, CONTROL SYSTEM FOR PROSTHETIC KNEE, the entirety of

each one of which is hereby incorporated by reference herein and each one of which is considered as part of this application.

Some prosthetic knees and control systems are disclosed in U.S. Pat. No. 6,764,520 B2, issued Jul. 20, 2004, and U.S. Pat. No. 6,610,101 B2, issued Aug. 26, 2003, the entirety of each one of which is hereby incorporated by reference herein.

MR Fluid Loading Procedure

FIGS. 109-125 describe embodiments of methods to assemble the knee actuator 112 and load the magnetorheological fluid 134 therein using a vacuum fill technique. Advantageously, this allows for an efficient (e.g., faster manufacturing speed) loading scheme and substantially uniform distribution of the MR fluid within the small gaps between the inner blades 120 and outer blades 130 which provides more consistent production.

The methods which are described and illustrated herein are not limited to the sequence of acts described, nor are they necessarily limited to the practice of all of the acts set forth. Other sequences of acts, or less than all of the acts, or simultaneous occurrence of the acts, may be utilized in practicing embodiments of the invention.

FIG. 109 shows one embodiment of a high-level flow chart, diagram or method 1120 of assembling at least a portion of the actuator 112 and loading MR fluid therein. It should be understood that any of the acts or steps disclosed, taught or suggested herein can each comprise a plurality of further acts or steps.

The method 1120 generally comprises acts or steps 1122, 1124, 1126 and 1128. The act 1122 generally comprises assembling at least a portion of the actuator 112, the act 1124 generally comprises preparing the actuator for loading of the MR fluid, the act 1126 generally comprises preparing the MR fluid for loading and the act 1128 generally comprises loading the MR fluid in the actuator 112. Each of these is discussed in further detail below.

FIG. 110 shows one embodiment of the act, step or method 1122 of assembling the actuator 112 in further detail in a flow chart or diagram format. The act 1122 generally comprises acts or steps 1130, 1132 and 1134. The act 1130 generally comprises assembling an outer spline assembly, the act 1132 generally comprises assembling a cartridge assembly and the act 1134 generally comprises assembling the outer spline assembly, the cartridge assembly and other actuator components. Each of these is discussed in further detail below.

FIG. 111 shows one embodiment of the act, step or method 1130 of assembling the outer spline assembly in further detail in a flow chart or diagram format. The act 1130 generally comprises acts or steps 1136 and 1138. The act 1136 generally comprises installing the diaphragm assembly 146 (see, for example, FIG. 6) and the act 1138 generally comprises installing the pyramid connector 152 (see, for example, FIG. 6). The diaphragm assembly 146 and pyramid connector 152 are installed with the outer spline 132 to form the outer spline assembly.

In one embodiment, the diaphragm assembly 146 is installed within the cavity 450 (see, for example, FIG. 66) of the pyramid connector 152 which is then attached to the top portion 270 (see, for example, FIG. 41) of the outer spline 132. In another embodiment, the diaphragm assembly 146 is installed within the top portion cavity 272 (see, for example, FIG. 41) of the outer spline 132 and the pyramid connector 152 is then attached to the outer spline top portion 270.

FIG. 112 shows one embodiment of the act, step or method 1132 of assembling the cartridge assembly in further detail in a flow chart or diagram format. The act 1132 generally com-

prises acts or steps 1140, 1142, 1144, 1146, 1148, 1150 and 1152. Each of these is discussed further below.

The act 1140 generally comprises installing the right core side 116 on the core rod 113 (see, for example, FIG. 6). The cavity 178a (see, for example, FIG. 13) of the right core side 116 is fitted substantially over the core portion end 170 (see, for example, FIG. 7).

The act 1142 generally comprises installing the coil 115 (see, for example, FIG. 6) over the core rod 113. The cavity 216 (see, for example, FIG. 23) of the coil 115 is fitted substantially over the core portion 166 (see, for example, FIG. 7) of the core rod 113.

The act 1144 generally comprises installing the through rods 158 on the inner spline 122 (see, for example, FIG. 6). The rods 158 are fitted through the passages 228 (see, for example, FIG. 28) of the inner spline 122.

The act 1146 generally comprises installing the O-rings 182 (see, for example, FIG. 6) on the inner spline 122. The right O-ring 182a is mounted in or on the inner spline groove or flange 232a and the left O-ring 182b is mounted in or on the inner spline groove or flange 232b (see, for example, FIG. 29).

The act 1148 generally comprises forming a set of inner blades 120 and outer blades 130 (see, for example, FIG. 6). A predetermined number of inner blades 120 and outer blades 130 is used to form the set. In one embodiment, the inner blades 120 and outer blades 130 are alternatingly interspersed.

The act 1150 generally comprises installing the inner blades 120 and outer blades 130 on the inner spline 130. More particularly, the inner blades 120 are fitted on the inner spline 130 with the inner blade teeth 238 (see, for example, FIG. 33) engaged with corresponding inner spline grooves 226 (see, for example, FIG. 28). The outer blades 130 are fitted within the outer spline 132, as described above and further below.

The act 1152 generally comprises installing the left core side 118 (see, for example, FIG. 6) on the core rod 113. The cavity 178b (see, for example, FIG. 17) of the left core side 118 is fitted substantially over the core portion end 172 (see, for example, FIG. 7). This substantially completes the assembly of the cartridge assembly.

FIG. 113 shows one embodiment of the act, step or method 1134 of assembling the outer spline assembly, the cartridge assembly and other actuator components in further detail in a flow chart or diagram format. The act 1134 generally comprises acts or steps 1154, 1156 (1156a, 1156b), 1158 (1158a, 1158b), 1160 (1160a, 1160b), 1162, 1164 and 1166. Each of these is discussed further below.

The act 1154 generally comprises installing the cartridge assembly in the outer spline 132. The outer blades 130 are fitted within the outer spline 132 with the outer blade teeth 248 (see, for example, FIG. 37) engaged with corresponding outer spline grooves 260 (see, for example, FIG. 41).

The act 1156a generally comprises installing the right dynamic seal 162a (see, for example, FIG. 6). The dynamic seal 162a is fitted between the right core side 116 and the outer spline 132.

The act 1156b generally comprises installing the left dynamic seal 162b (see, for example, FIG. 6). The dynamic seal 162b is fitted between the left core side 118 and the outer spline 132.

The act 1158a generally comprises installing the right bearing 126 (see, for example, FIG. 22) in the outer spline 132. The act 1158b generally comprises installing the left bearing 128 (see, for example, FIG. 22) in the outer spline 132.

The act 1160a generally comprises installing the right side mount 136 (see, for example, FIG. 6). The right side mount 136 is communicated with the right bearing 126.

The act 1160b generally comprises installing the left side mount 138 (see, for example, FIG. 6). The left side mount 138 is communicated with the left bearing 128.

The act 1162 generally comprises installing the nuts 160 (see, for example, FIG. 6) on respective through rods 158. The nuts 160 are tightened to clamp the inner spline 122, right core side 116, left core side 118, right side mount 136 and left side mount 138 to one another. The nuts 160 may initially be only partially tightened and then further tightened at a later assembly stage, as needed or desired.

The act 1164 generally comprises installing the angle sensing system 154 (see, for example, FIG. 6). The angle sensor 668 is mounted on the right side mount 136 and the arm 670 is connected to the sensor 668 and the outer spline 132.

The act 1166 generally comprises pressure testing the actuator 112 to check the seal integrity. An air pump or the like is connected to the outer spline chamber 258 (see, for example, FIG. 45) via the threaded port or hole 280 and the chamber 258 is pressurized to a predetermined pressure (e.g., 20 psi) for a predetermined time.

In one embodiment, the actuator 112 (e.g., outer spline 132 and side mounts 136, 138) is rotated during at least part of the pressure test. The pressure is monitored to confirm the seal integrity.

FIG. 114 shows one embodiment of the act, step or method 1124 of preparing the actuator 112 for MR fluid loading in further detail in a flow chart or diagram format. FIG. 115 shows one embodiment of a set-up or system to perform at least a portion of the act 1124.

The act 1124 generally comprises acts or steps 1168, 1170, 1172, 1174 and 1176. Each of these is discussed further below.

The act 1168 generally comprises attaching a pyramid tool or holder 1320 to the pyramid connector 152. The pyramid tool 1320 desirably allows the actuator 112 to be seated on a surface in a desired orientation.

The act 1170 generally comprises pressure testing the actuator 112. The act 1170 may be skipped if pressure testing has been recently performed in act 1166 (see FIG. 113). But, in some cases, for example, if the dry (without MR fluid) actuator has been kept in storage for a certain period, it is desirable to repeat the pressure testing in act 1170.

The act 1172 generally comprises weighing the dry actuator 112 and recording its weight. The pyramid tool 1320 may be used to seat the actuator 112 on a suitable weighing scale 1322 or the like.

The act 1174 generally comprises attaching a holding fixture 1324 to the actuator 112. The holding fixture 1324 allows the actuator to be mounted in a vacuum system, as described further below.

The act 1176 generally comprises attaching a funnel 1326 or the like to the actuator. The funnel 1326 is threadably attached to the threaded port or hole 280 of the outer spline 132 such that the funnel is substantially vertical to facilitate addition of the MR fluid, as described further below.

FIG. 116 shows one embodiment of the act, step or method 1126 of preparing the MR fluid for loading in further detail in a flow chart or diagram format. FIG. 117 shows one embodiment of a set-up or system to perform at least a portion of the act 1126.

The act 1126 generally comprises acts or steps 1180, 1182, 1184, 1186, 1188, 1190, 1192, 1194, 1196 and 1198. Each of these is discussed further below.

The act 1180 generally comprises placing the MR fluid in a container or receptacle 1330. A predetermined quantity of the MR fluid is added to the container 1330.

The act 1182 generally comprises stirring the MR fluid. A spatula or the like is used to stir the MR fluid, breaking up any visible clumps, so that the MR fluid has a substantially uniform consistency.

The act 1184 generally comprises placing the MR fluid container 1330 under a stirrer 1334 within a vacuum chamber 1332. The act 1186 generally comprises sealing the vacuum chamber 1332, for example, by using a bell jar or the like.

The act 1188 generally comprises drawing or applying a vacuum or partial vacuum. The vacuum or partial vacuum is applied (for example, by utilizing a pump, suction device or the like) for a predetermined time and pressure in the vacuum chamber 1332. The vacuum advantageously facilitates in degassing the MR fluid by extracting residual dissolved air or other gases in the MR fluid.

In one embodiment, the vacuum or partial vacuum is applied at about 29.4 inches mercury ("Hg) for about 30 minutes. In another embodiment, the vacuum or partial vacuum is applied at about 28 inches mercury ("Hg) for about 30 minutes. In yet another embodiment, the vacuum or partial vacuum is applied at about 28 inches mercury ("Hg) to about 29.4 inches mercury ("Hg) for about 30 minutes. The difference between this vacuum creating pressure value and the atmospheric or ambient pressure is the actual pressure in the vacuum chamber 1332. The vacuum creating pressure may also be considered a suction pressure. In modified embodiments, other suitable vacuum creating or suction pressures and times may be efficaciously utilized, as needed or desired.

The act 1190 generally comprises turning on the stirrer 1334 to stir the MR fluid in the container 1330 which is under the vacuum or partial vacuum. The stirring of the MR fluid is maintained for a predetermined time and/or until no bubbles are visible and further facilitates in degassing the MR fluid. In one embodiment, the stirrer 1334 is used to stir the MR fluid for about 30 minutes.

The act 1192 generally comprises turning off the stirrer 1334. The act 1194 generally comprises turning off the vacuum and slowly releasing the vacuum. The act 1196 generally comprises unsealing the vacuum chamber 1332. The act 1198 generally comprises removing the MR fluid container 1330 from the vacuum chamber 1332.

FIG. 118 shows one embodiment of the act, step or method 1128 of loading the MR fluid in the actuator 112 in further detail in a flow chart or diagram format. The act 1128 generally comprises acts or steps 1220, 1222, 1224 and 1226. Each of these is discussed further below.

FIG. 119 shows one embodiment of the act, step or method 1220 of adding the MR fluid to the funnel 1326 in further detail in a flow chart or diagram format. FIG. 120 shows one embodiment of a set-up or system to perform at least a portion of the act 1220.

The act 1220 generally comprises acts or steps 1230, 1232 and 1234. Each of these is discussed further below.

The act 1230 generally comprises pouring the MR fluid into the funnel 1326 attached to the actuator 112 on the weighing scale 1322. A suitable pipette 1340 or the like is used to transfer the prepared MR fluid from the container 1330 to the funnel 1326.

The act 1232 generally comprises monitoring the reading of the weighing scale 1322. The act 1234 generally comprises filling an appropriate and/or predetermined MR fluid weight (and/or volume) in the actuator 112 and recording the weight.

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In one embodiment, an extra quantity (e.g., one gram) of MR fluid is added to compensate for any fluid remaining in the funnel.

FIG. 121 shows one embodiment of the act, step or method 1222 of applying a vacuum or partial vacuum in further detail in a flow chart or diagram format. FIG. 122 shows one embodiment of a set-up or system to perform at least a portion of the act 1222. FIG. 123 shows one embodiment of a set-up or system generally comprising a vacuum table 1360 to perform at least a portion of the act 1222.

The act 1222 generally comprises acts or steps 1240, 1242, 1244, 1246 and 1248. Each of these is discussed further below.

The act 1240 generally comprises placing the actuator 112 in the vacuum chamber 1332. The pyramid tool 1320 is used to seat the actuator 112 and the funnel 1326 is oriented to be substantially vertical.

The act 1242 generally comprises connecting the holding fixture 1324 to an agitator system 1350. The agitator system 1350 generally comprises a mechanical agitator 1352 (e.g. air motor) connected to the holding fixture 1324 and driven by an actuator 1356 which, in one embodiment, controls the opening and closing of one or more valves associated with the actuation of the mechanical agitator 1352 (e.g. air motor). Cables or hydraulic/pneumatic lines connect the agitator 1352 and the actuator 1356. The holding fixture 1324 is bolted to the agitator 1352.

The act 1244 generally comprises sealing the vacuum chamber 1332, for example, by using a bell jar or the like. The act 1246 generally comprises drawing or applying a vacuum or partial vacuum. The vacuum is slowly applied (for example, by utilizing a pump, suction device or the like) for a predetermined time and pressure. This pressure is desirably chosen or selected such that it does not cause undesirable vaporization of the MR fluid but is appropriate to facilitate MR fluid loading.

In one embodiment, the vacuum or partial vacuum is applied at about 28 inches mercury (" Hg) for about 30 seconds. In another embodiment, the vacuum or partial vacuum is applied at about 29.4 inches mercury (" Hg) for about 30 seconds. In yet another embodiment, the vacuum or partial vacuum is applied at about 28 inches mercury (" Hg) to about 29.4 inches mercury (" Hg) for about 30 seconds. The difference between this vacuum creating pressure value and the atmospheric or ambient pressure is the actual pressure in the vacuum chamber 1332. The vacuum creating pressure may also be considered a suction pressure. In modified embodiments, other suitable vacuum creating or suction pressures and times may be efficaciously utilized, as needed or desired.

The vacuum advantageously creates a suction effect that draws MR fluid into the actuator 112 (outer spline 132) and desirably distributes it substantially uniformly in the gaps between the blades 120 and 130. Stated differently, the vacuum pulls air out of the chamber 144 by bubbling through the MR fluid.

The act 1248 generally comprises agitating the actuator 112. The agitator 1352 is actuated to rotate, for example, cyclically in a back and forth manner, the actuator 112. The agitation is performed periodically, for example, at a frequency of few times a minute.

Advantageously, this further facilitates in drawing the MR fluid into the actuator 112 as the fluid mixes or distributes as air bubbles out. In one embodiment, the actuator 112 is agitated for about 30 seconds. In modified embodiments, other suitable agitation times may be used with efficacy, as needed or desired. In one embodiment, the actuator agitation is synchronized with the application of vacuum or partial vacuum,

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for example, by applying the vacuum or partial vacuum and performing the actuator agitation over substantially the same time period. In one embodiment, the agitation frequency is about 10 times/minute or about 0.17 Hertz (Hz).

FIG. 124 shows one embodiment of the act, step or method 1224 of feeding nitrogen in further detail in a flow chart or diagram format. The act 1224 generally comprises acts or steps 1260, 1262, 1264, 1266 and 1268. Each of these is discussed further below.

The act 1260 generally comprises feeding nitrogen into the vacuum chamber 1332. In modified embodiments, other suitable inert, compressible gases may be efficaciously utilized, as needed or desired. In another embodiment, air is used.

The act 1262 generally comprises releasing the vacuum in the vacuum chamber 1332 as the nitrogen is fed to release the vacuum and facilitate in pushing the MR fluid down and into the chamber 144. In one embodiment, the vacuum is released slowly at about 2" Hg per 10 seconds.

The act 1264 generally comprises further agitating the actuator 112 to facilitate in forcing the MR fluid down and into the chamber 144. Advantageously, the nitrogen (inert, compressible gas) occupies the unfilled space within the actuator 112 (chamber 144) and facilitates in controlling undesirable pressure build-up, as discussed in further detail above.

The act 1266 generally comprises turning off the nitrogen supply once the vacuum has been released and the pressure has returned to substantially ambient conditions. The act 1268 generally comprises unsealing the vacuum chamber 1332. The cycle of vacuum filling, agitating and supplying an inert gas may be repeated more than once, as needed or desired.

The vacuum table 1360 (FIG. 123) may include a pressure gauge 1358 to monitor the pressure and various valves and the like to direct and control the flow paths. These may include a nitrogen feed valve 1362, a pressure release valve 1364, a pressure regulator 1366 associated with the actuator 1356 of the agitator 1352 (e.g. air motor), among others.

FIG. 125 shows one embodiment of the act, step or method 1226 of substantially completing the MR fluid loading procedure in further detail in a flow chart or diagram format. The act 1226 generally comprises acts or steps 1280, 1282, 1284, 1286 and 1288. Each of these is discussed further below.

The act 1280 generally comprises disconnecting the holding fixture 1324 from the agitator 1352. The act 1282 generally comprises removing the actuator 112 from the vacuum chamber 1332. The act 1284 generally comprises removing the fixture 1324 and the funnel 1326 from the actuator 112. The act 1286 generally comprises placing the actuator 112 on the weighing scale 1322 and recording the weight. Care is taken in handling the actuator 112 (for example, by avoiding tipping it) so that the nitrogen head in the chamber 144 is not released.

The actuator 112 can be pressure tested to check the seal integrity once the MR fluid has been loaded therein. An air pump or the like is connected to the outer spline chamber 258 (see, for example, FIG. 45) via the threaded port or hole 280 and the chamber 258 is pressurized to a predetermined pressure (e.g., 20 psi) for a predetermined time. Nitrogen or other inert gas that has been loaded into the actuator 112 may be used for the pressure test instead of air, as needed or desired.

The act 1288 generally comprises capping the threaded port or hole 280 of the outer spline 132 with a suitable threaded screw or plug. In one embodiment, a M6 3 mm set screw is used. A suitable adhesive or glue, such as Loctite® threadlocker or the like, can be applied to the threads to

provide a strong coupling. In one embodiment, a torque of about 2.5 N·m is applied to the set screw.

In one embodiment, the actuator 112 contains volume of about 5 milliliter (mL) of MR fluid. In another embodiment, the actuator 112 contains a volume in the range from about 4 mL to about 6 mL of MR fluid, including all values and sub-ranges therebetween. In yet another embodiment, the actuator 112 contains a volume in the range from about 2 mL to about 8 mL of MR fluid, including all values and sub-ranges therebetween. In yet another embodiment, the actuator 112 contains a volume in the range from about 1 mL to about 10 mL of MR fluid, including all values and sub-ranges therbetween. In modified embodiment, other suitable volumes of MR fluid may be efficaciously utilized, as needed or desired.

Magnetorheological Fluid

In some embodiments, the magnetorheological fluid comprises a plurality of iron, ferrous or magnetic particles suspended in fluid. These suspended particles form torque producing chains in response to an applied magnetic (energy) field. Thus, the magnetorheological (MR) fluid undergoes a rheology or viscosity change or variation which is dependent on the magnitude of the applied magnetic field. In turn, this variation in the bulk fluid viscosity determines the magnitude of the shearing force/stress or torque generated, and hence the level of damping or braking provided. Typically, the bulk viscosity of the MR fluid increases with increasing strength of the applied field. By controlling the magnitude of this magnetic field, the rotary motion of the artificial limb is rapidly and precisely adjusted and/or controlled, for example, to control the flexion and extension during swing and stance phases to provide a more natural and safe ambulation for the amputee.

The magnetorheological fluid used in conjunction with embodiments of the invention can comprise a wide variety of MR fluids or magnetically controlled or controllable mediums. Some embodiments of suitable MR fluids are disclosed in U.S. patent application Ser. No. 10/722,313, filed Nov. 25, 2003, which corresponds to U.S. Patent Application Publication No. 2004/0217324 A1, published Nov. 4, 2004, and U.S. Provisional Patent Application No. 60/467,722, filed May 2, 2003, both entitled MAGNETORHEOLOGICAL FLUID COMPOSITIONS AND PROSTHETIC KNEES UTILIZING SAME, the entirety of each one of which is hereby incorporated by reference herein and each one of which is considered as part of this application.

Embodiments of the invention can efficaciously utilize other field responsive (FR) fluids and mediums. In one embodiment, an electrorheological (ER) fluid is used whose rheology can be changed by an electric (energy) field. Thus, the electrorheological (ER) fluid undergoes a rheology or viscosity change or variation which is dependent on the magnitude of the applied electric field. Other suitable electronically or electrically controlled or controllable mediums may be efficaciously utilized, as needed or desired.

Embodiments of the invention and the concepts disclosed, taught or suggested herein can be used in conjunction with other types of prosthetic knees, control systems and other prosthetic devices and joints including ankles, feet, hips, elbows and wrists. Some embodiments of a prosthetic ankle, foot unit and control system are disclosed in U.S. Provisional Patent Application No. 60/544,259, filed Feb. 12, 2004, entitled LOWER LIMB PROSTHESIS WITH ANKLE-MOTION-CONTROLLED FOOT, U.S. Provisional Patent Application No. 60/588,232, filed Jul. 15, 2004, entitled PROSTHETIC OR ORTHOTIC SYSTEM WITH ANKLE-

MOTION-CONTROLLED FOOT, and U.S. patent application Ser. No. 11/056,344, filed Feb. 11, 2005, entitled SYSTEM AND METHOD FOR MOTION-CONTROLLED FOOT UNIT, the entirety of each one of which is hereby incorporated by reference herein and each one of which is considered as part of this application.

Embodiments of the invention and the concepts disclosed, taught or suggested herein can be used in conjunction with orthotic devices for bracing and/or supporting joints and muscles. The orthotic devices can be attached to the limb of a patient and can brace joints including knees, ankles, feet, hips, elbows and wrists. Embodiments of the invention and the concepts disclosed, taught or suggested herein can be used in conjunction with other muscle assist devices or muscle replacement devices and the like.

The methods which are described and illustrated herein are not limited to the sequence of acts described, nor are they necessarily limited to the practice of all of the acts set forth. Other sequences of acts, or less than all of the acts, or simultaneous occurrence of the acts, may be utilized in practicing embodiments of the invention.

From the foregoing description, it will be appreciated that novel approaches relating to prosthetic devices, pressure control and handling of slurries and fluids have been disclosed. While the components, techniques and aspects of the invention have been described with a certain degree of particularity, it is manifest that many changes may be made in the specific designs, constructions and methodology herein above described without departing from the spirit and scope of this disclosure.

While a number of preferred embodiments of the invention and variations thereof have been described in detail, other modifications and methods of using and medical applications for the same will be apparent to those of skill in the art. Accordingly, it should be understood that various applications, modifications, and substitutions may be made of equivalents without departing from the spirit of the invention or the scope of the claims.

Various modifications and applications of the invention may occur to those who are skilled in the art, without departing from the true spirit or scope of the invention. It should be understood that the invention is not limited to the embodiments set forth herein for purposes of exemplification, but is to be defined only by a fair reading of the appended claims, including the full range of equivalency to which each element thereof is entitled.

What is claimed is:

1. A prosthetic knee, comprising:
a housing comprising a chamber containing a magnetorheological fluid, said fluid comprising a mixture of solid particles and a liquid;

at least one side plate within said housing and forming a barrier to contain said fluid in said chamber; and

at least one dynamic seal fitted between said housing and said side plate to contain said fluid in said chamber during relative rotation between said housing and said side plate, said dynamic seal having a tensioned spring with coils being spaced by a distance at least as large as the largest size of said particles of said fluid;

wherein said side plate has a hardened outer rim that engages said dynamic seal, and wherein said outer rim has a coating of titanium nitride.

2. The prosthetic knee of claim 1, wherein said prosthetic knee comprises an actuator that shears said fluid.

3. The prosthetic knee of claim 1, wherein said prosthetic knee comprises two side plates with said fluid therebetween.

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4. The prosthetic knee of claim **3**, wherein said prosthetic knee comprises two of said dynamic seals with each engaged with a respective one of said side plates to dynamically seal said fluid therebetween.

5. The prosthetic knee of claim **1**, wherein said dynamic seal has a sealing lip that is loaded by said spring to apply pressure on said side plate.

6. The prosthetic knee of claim **5**, wherein said sealing lip has a tip that dynamically engages an outer rim of said side plate.

7. The prosthetic knee of claim **6**, wherein said tip is offset from said spring by a predetermined distance.

8. The prosthetic knee of claim **6**, wherein said sealing lip forms a fluid side angle with said outer rim and said angle is in the range from about 60° to about 75°.

9. The prosthetic knee of claim **6**, wherein said sealing lip forms an ambient side angle with said outer rim and said angle is in the range from about 7.5° to about 30°.

10. The prosthetic knee of claim **1**, wherein said particles have a maximum size in the range from about 2 μm to about 4 μm.

11. The prosthetic knee of claim **10**, wherein adjacent coils are spaced by a distance in the range from about 2.5 μm to about 40 μm.

12. The prosthetic knee of claim **1**, wherein said spring comprises a garter spring.

13. A prosthetic knee, comprising:

a housing comprising a chamber containing a magnetorheological fluid, said fluid comprising a mixture of solid particles and a liquid, the particles having a maximum size in the range from about 2 μm to about 4 μm;

at least two side plates forming a barrier to contain fluid in said chamber; and

at least two dynamic seals, each fitted between said housing and one of said side plates to contain said fluid in said chamber during relative rotation between said housing and said side plates, said dynamic seals comprising a tensioned spring with coils being spaced by a distance at least as large as the largest size of said particles of said fluid, in the range from about 2.5 μm to about 40 μm.

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14. The prosthetic knee of claim **13**, wherein said prosthetic knee comprises an actuator that shears said fluid.

15. The prosthetic knee of claim **13**, wherein said spring comprises a garter spring.

16. A prosthetic knee, comprising:

a housing comprising a chamber containing a magnetorheological fluid, said fluid comprising a mixture of solid particles and a liquid;

at least one side plate within said housing and forming a barrier to contain said fluid in said chamber; and

at least one dynamic seal fitted between said housing and said side plate to contain said fluid in said chamber during relative rotation between said housing and said side plate, said dynamic seal having a tensioned spring with coils being spaced by a distance at least as large as the largest size of said particles of said fluid;

wherein said particles have a maximum size in the range from about 2 μm to about 4 μm, and wherein adjacent coils are spaced by a distance in the range from about 2.5 μm to about 40 μm.

17. A prosthetic knee, comprising:

a housing comprising a chamber containing a magnetorheological fluid, said fluid comprising a mixture of solid particles and a liquid;

at least one side plate within said housing and forming a barrier to contain said fluid in said chamber; and

at least one dynamic seal fitted between said housing and said side plate to contain said fluid in said chamber during relative rotation between said housing and said side plate, said dynamic seal having a tensioned spring with coils being spaced by a distance at least as large as the largest size of said particles of said fluid;

wherein said dynamic seal has a sealing lip that is loaded by said spring to apply pressure on said side plate and said sealing lip has a tip that dynamically engages an outer rim of said side plate, and wherein said sealing lip forms a fluid side angle with said outer rim and said angle is in the range from about 60° to about 75°.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,455,696 B2
APPLICATION NO. : 11/124621
DATED : November 25, 2008
INVENTOR(S) : Charles R. Bisbee, III et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Drawings, at Sheet 93 of 103 (FIG. 115), lines 3-4, before "93/103" delete
"Replacement Sheet
Reply to Office Action
of June 17, 2005" *DYNAMIC SEALS FOR A PROSTHETIC KNEE
Bisbee et al.
Appl. No.: 11/124,621 Atty Docket: OSSUR.056A*".

At column 25, line 23, change "curved-configurations," to --curved configurations,--.

At column 26, line 58, change "inches):" to --inches).--.

At column 34 (below Table 1), line 1, change " $L_{coil,spacing}$ " to
-- $L_{coil-spacing}$ --.

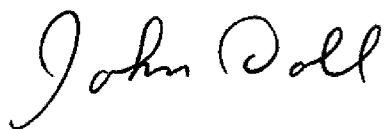
At column 35 (below Table 1-continued), line 1, change " $L_{coil,spacing}$ " to
-- $L_{coil-spacing}$ --.

At column 36, line 66, change "side-plate" to --side plate--.

At column 38, line 24 (Approx.), change "Cartesian" to --cartesian--.

Signed and Sealed this

Second Day of June, 2009



JOHN DOLL
Acting Director of the United States Patent and Trademark Office



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(19) **United States**
 (12) **Reissued Patent**
 Deffenbaugh et al.

(10) **Patent Number:** US RE42,903 E
 (45) **Date of Reissued Patent:** Nov. 8, 2011

(54) **ELECTRONICALLY CONTROLLED PROSTHETIC KNEE**

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(21) Appl. No.: **11/490,508**

(22) Filed: **Jul. 20, 2006**

Related U.S. Patent Documents

Reissue of:

(64) Patent No.: **6,764,520**
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U.S. Applications:

(60) Provisional application No. 60/177,108, filed on Jan. 20, 2000.

(51) **Int. Cl.**

A61F 2/48 (2006.01)

(52) **U.S. Cl.** **623/24; 623/26; 623/39**

(58) **Field of Classification Search** **623/24-27, 623/39-45, 47-56**

See application file for complete search history.

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Primary Examiner — Alvin J Stewart

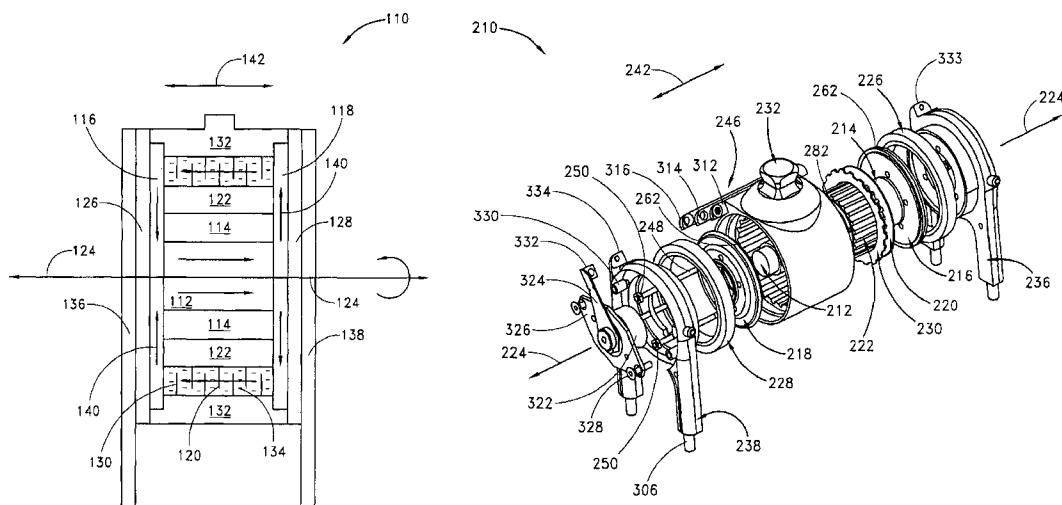
(74) *Attorney, Agent, or Firm* — Knobbe Martens Olson & Bear, LLP

(57)

ABSTRACT

The present invention relates to a variable-torque magnetorheologically actuated prosthetic knee which utilizes a plurality of interspersed and alternating rotors and stators to shear magnetorheological fluid in gaps formed therebetween. Advantageously, by operating in the “shear mode” there is substantially no or negligible fluid pressure buildup or change. Moreover, the multiple MR fluid gaps or flux interfaces desirably allow for the production of a large torque at low speed—eliminating the need for a transmission—and also for a wide dynamic torque range. One embodiment of the invention allows the rotors and/or stators to close the gaps therebetween to create a frictional torque component, thereby forming a “hybrid” braking system which provides a total torque or damping which is a combination of viscous torque and frictional torque.

64 Claims, 22 Drawing Sheets



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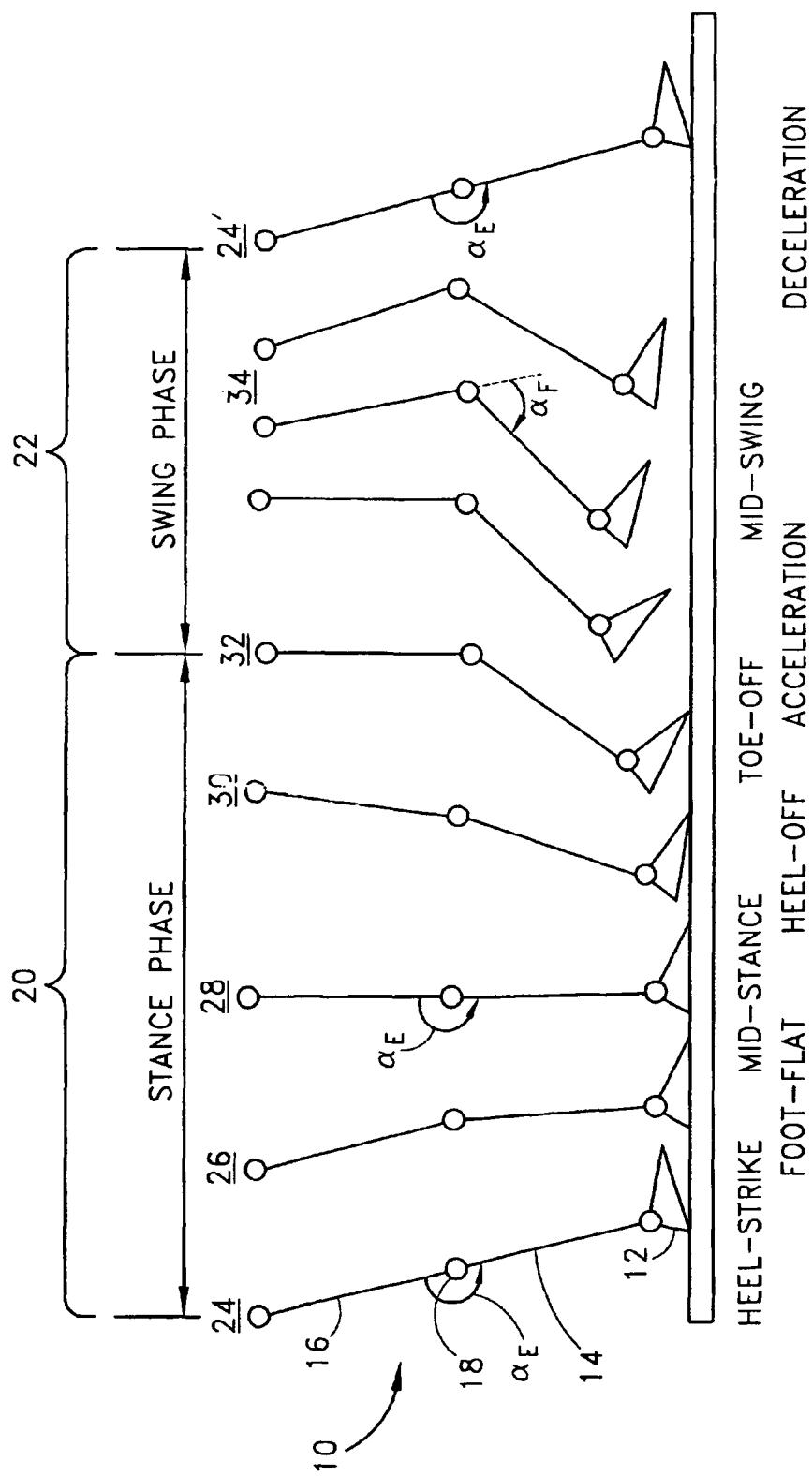


FIG. 1

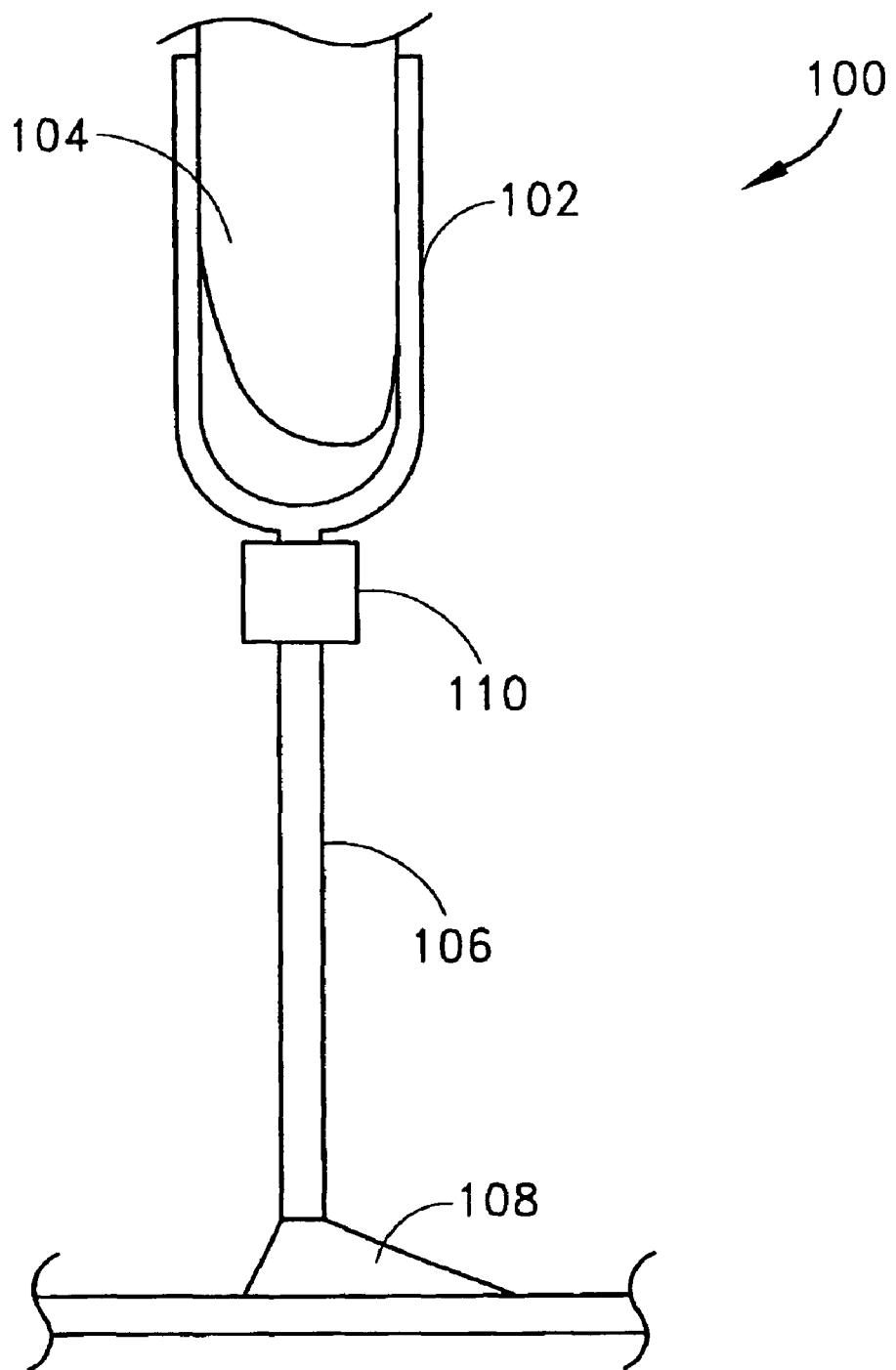


FIG. 2

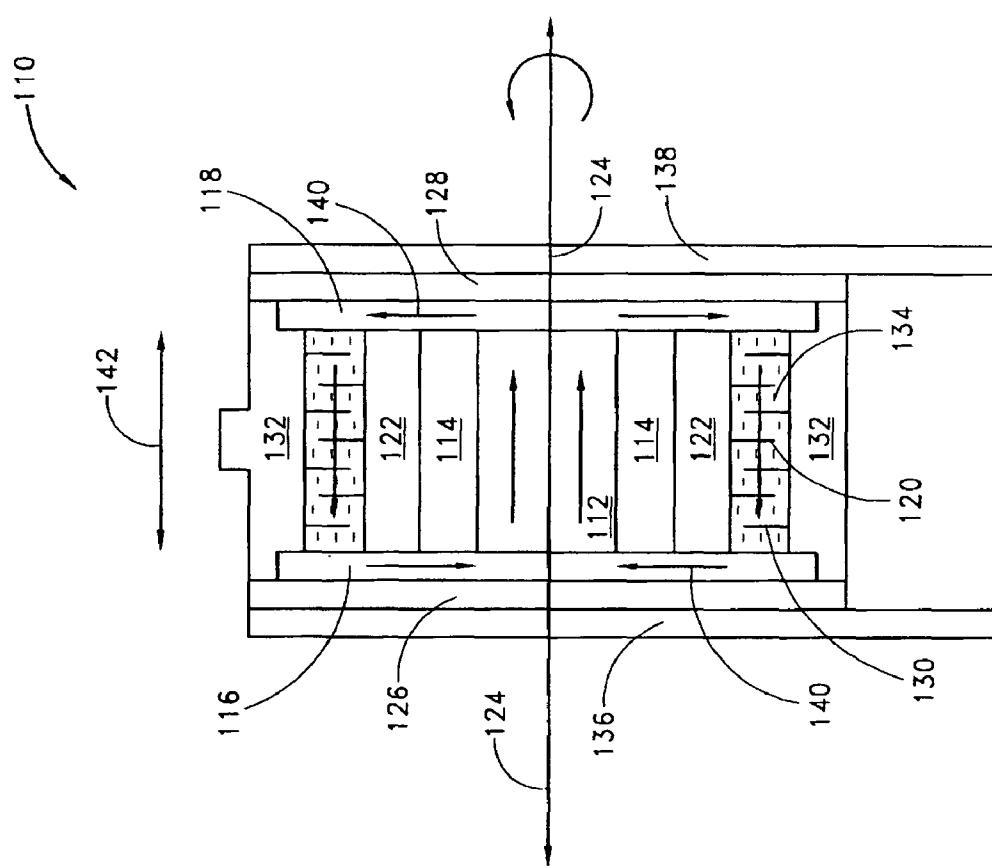


FIG. 3

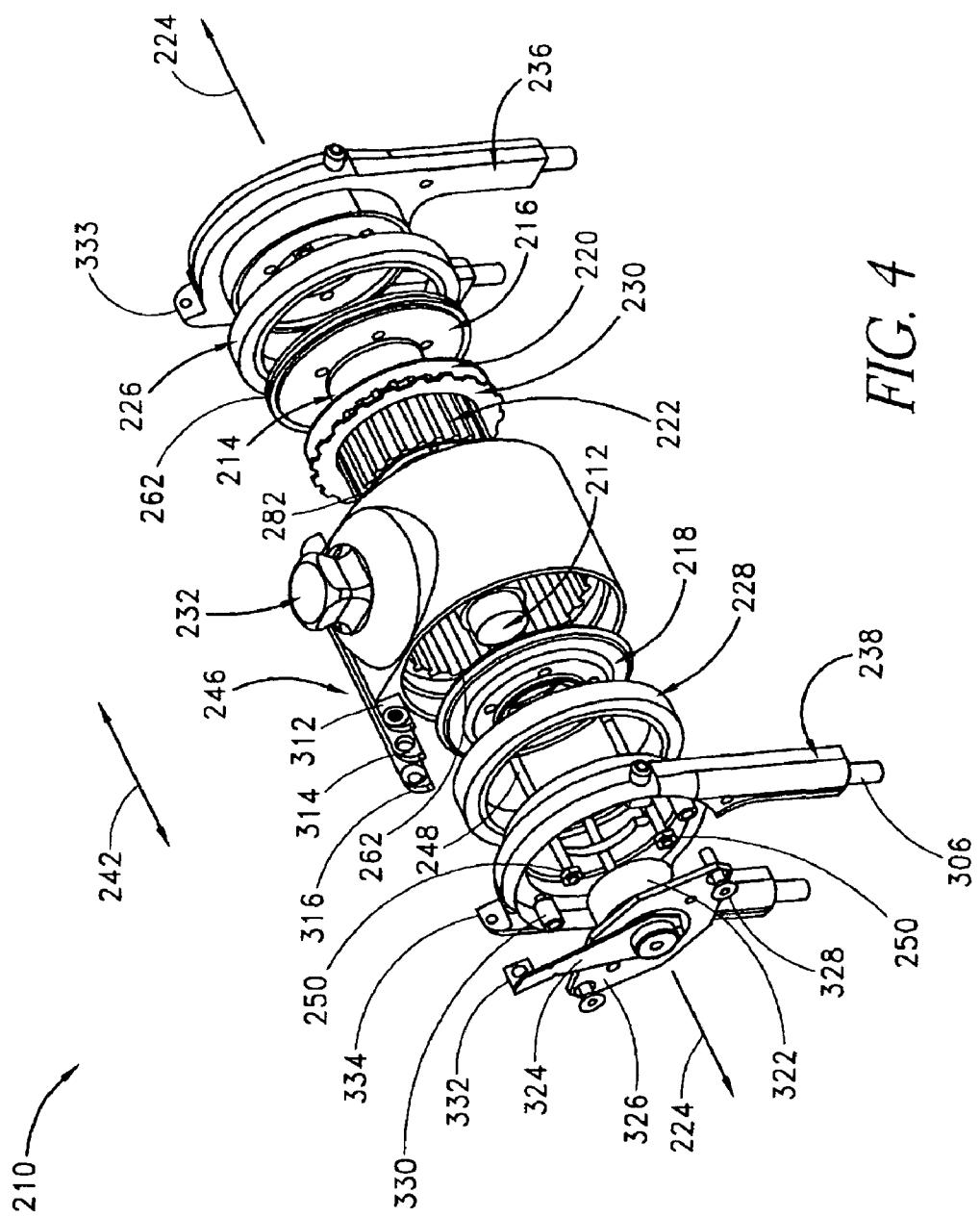
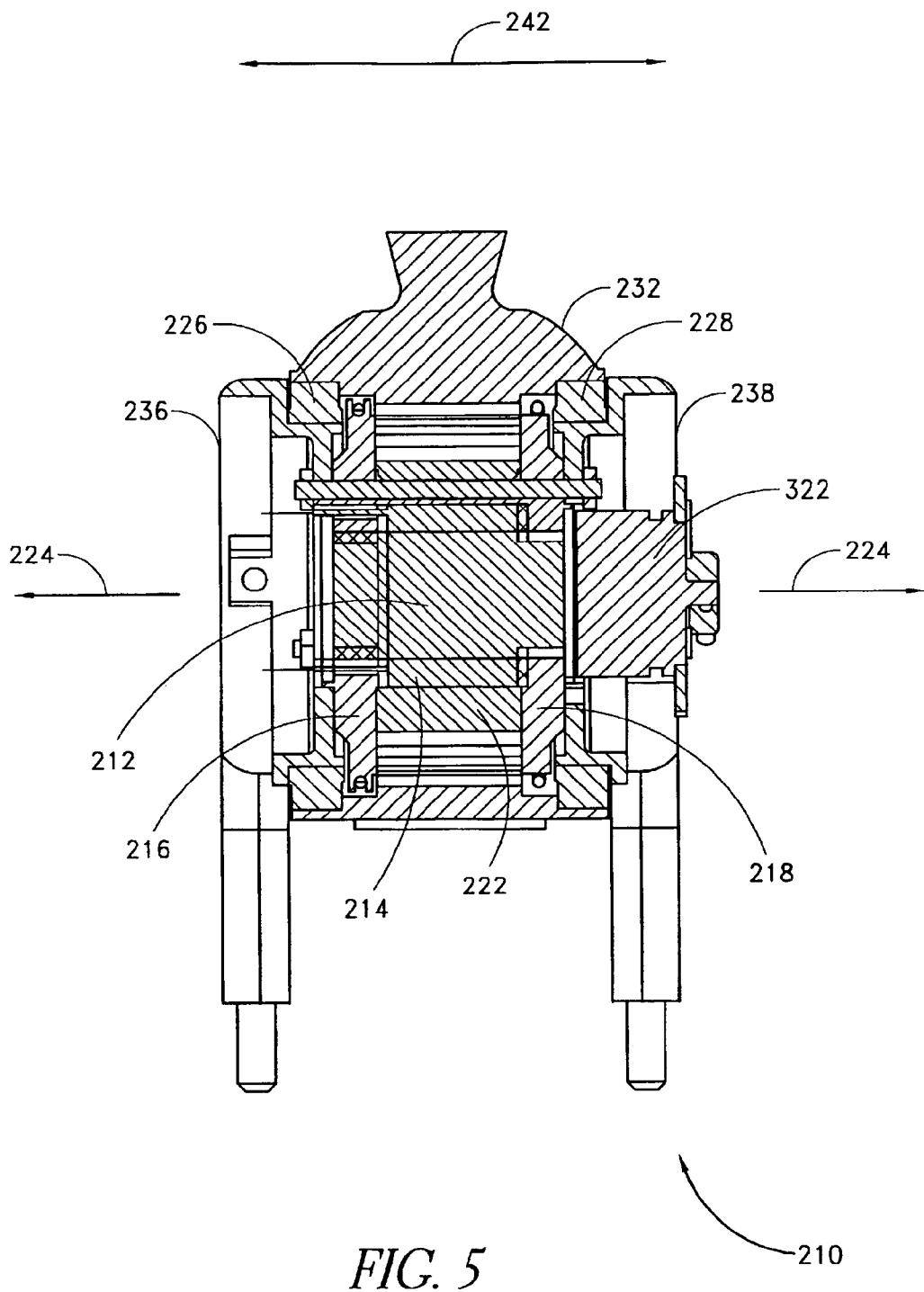
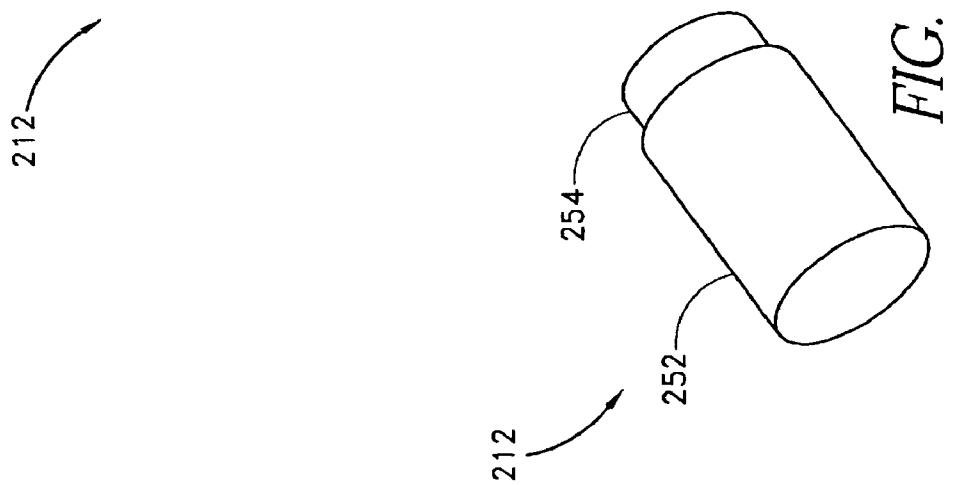
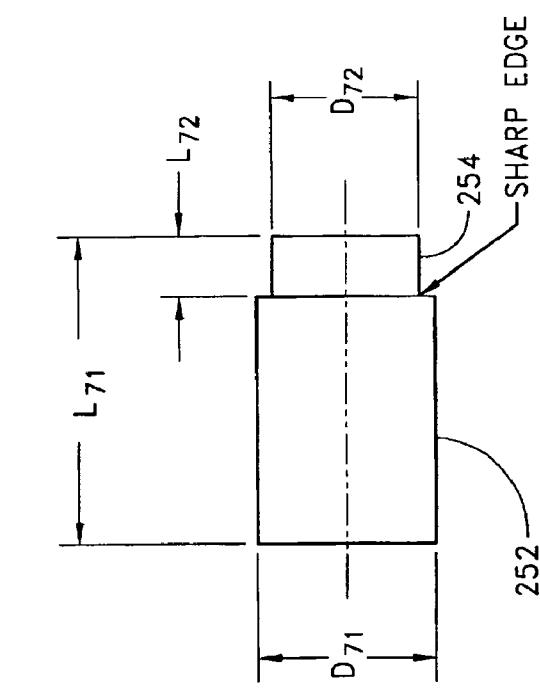
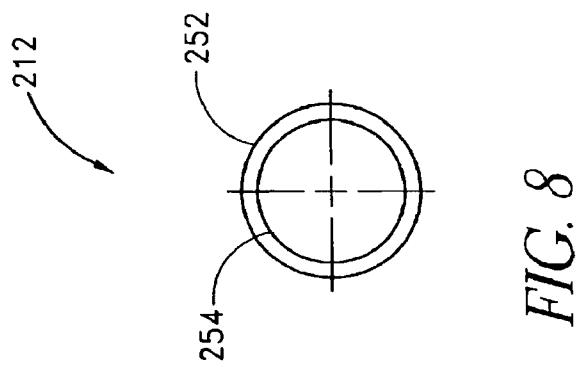


FIG. 4





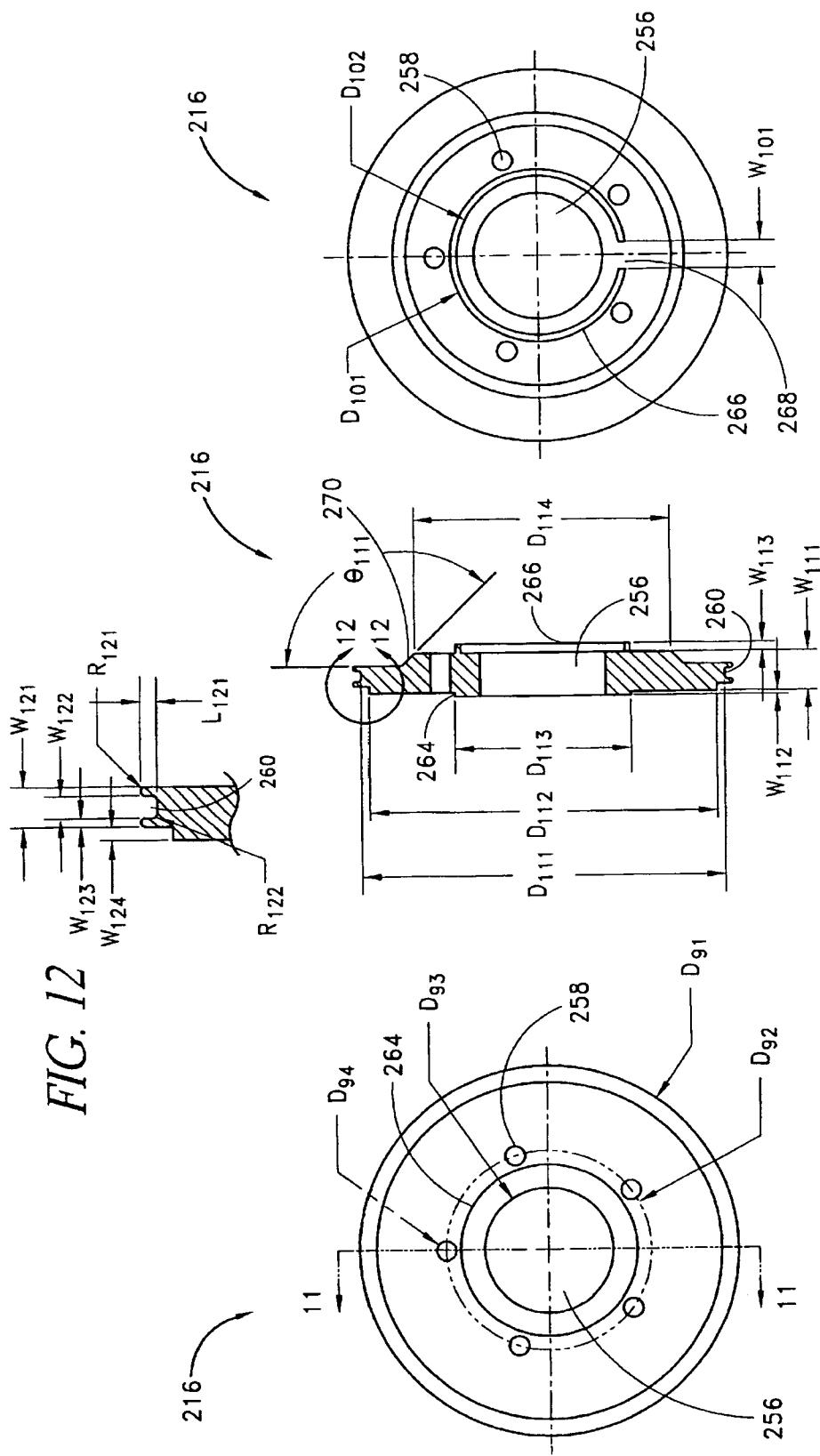


FIG. 9

FIG. 10

FIG. 11

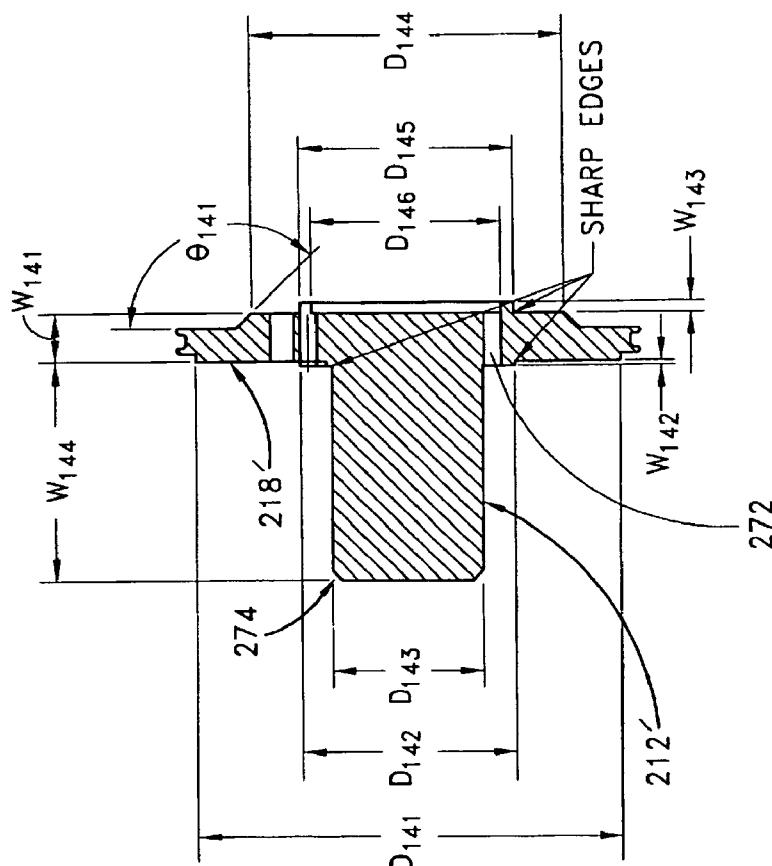


FIG. 14

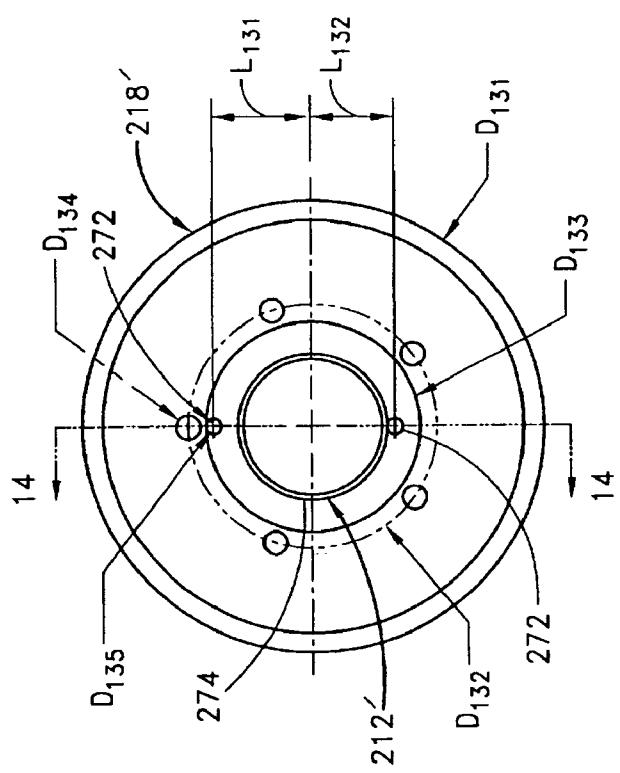
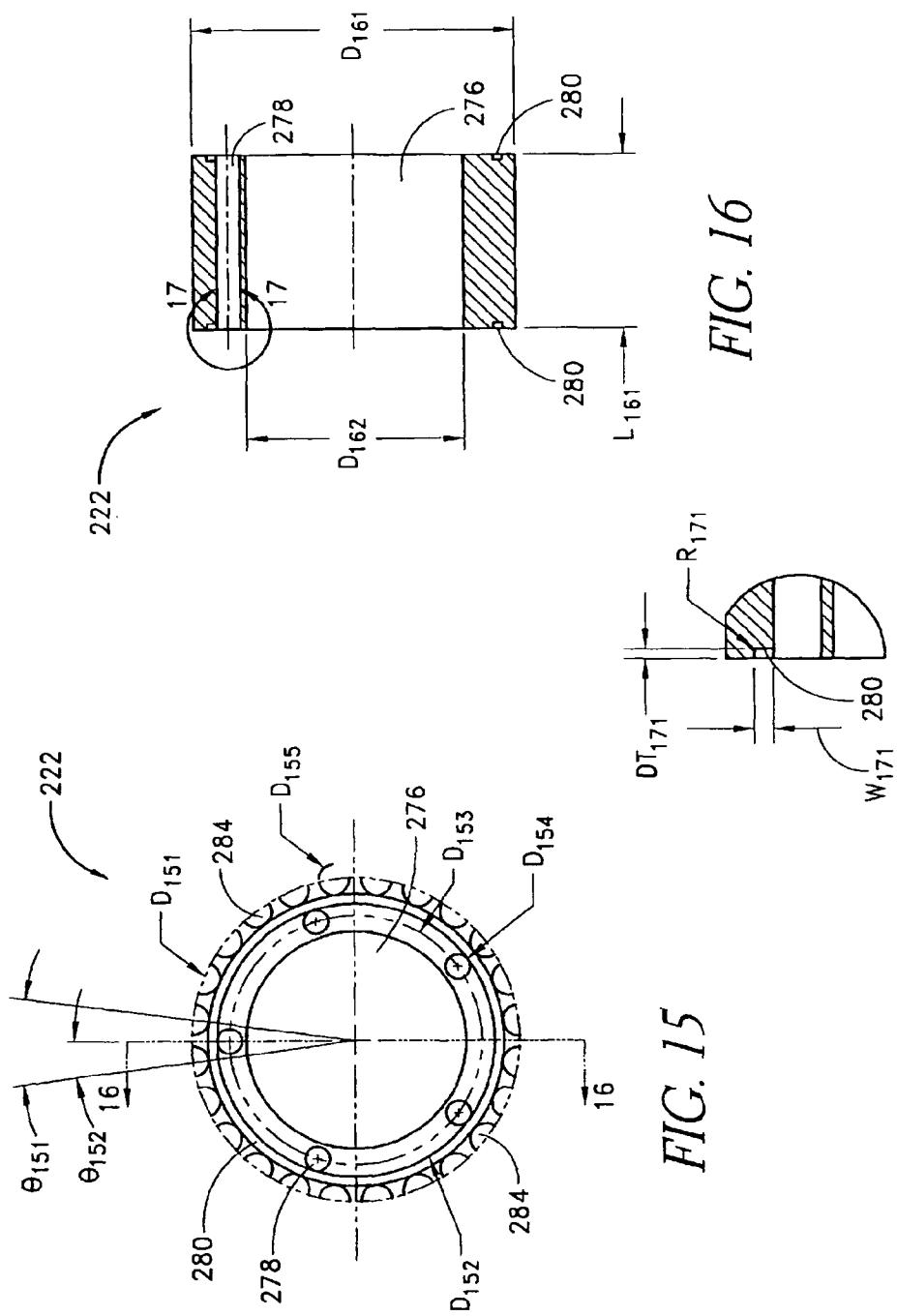


FIG. 13



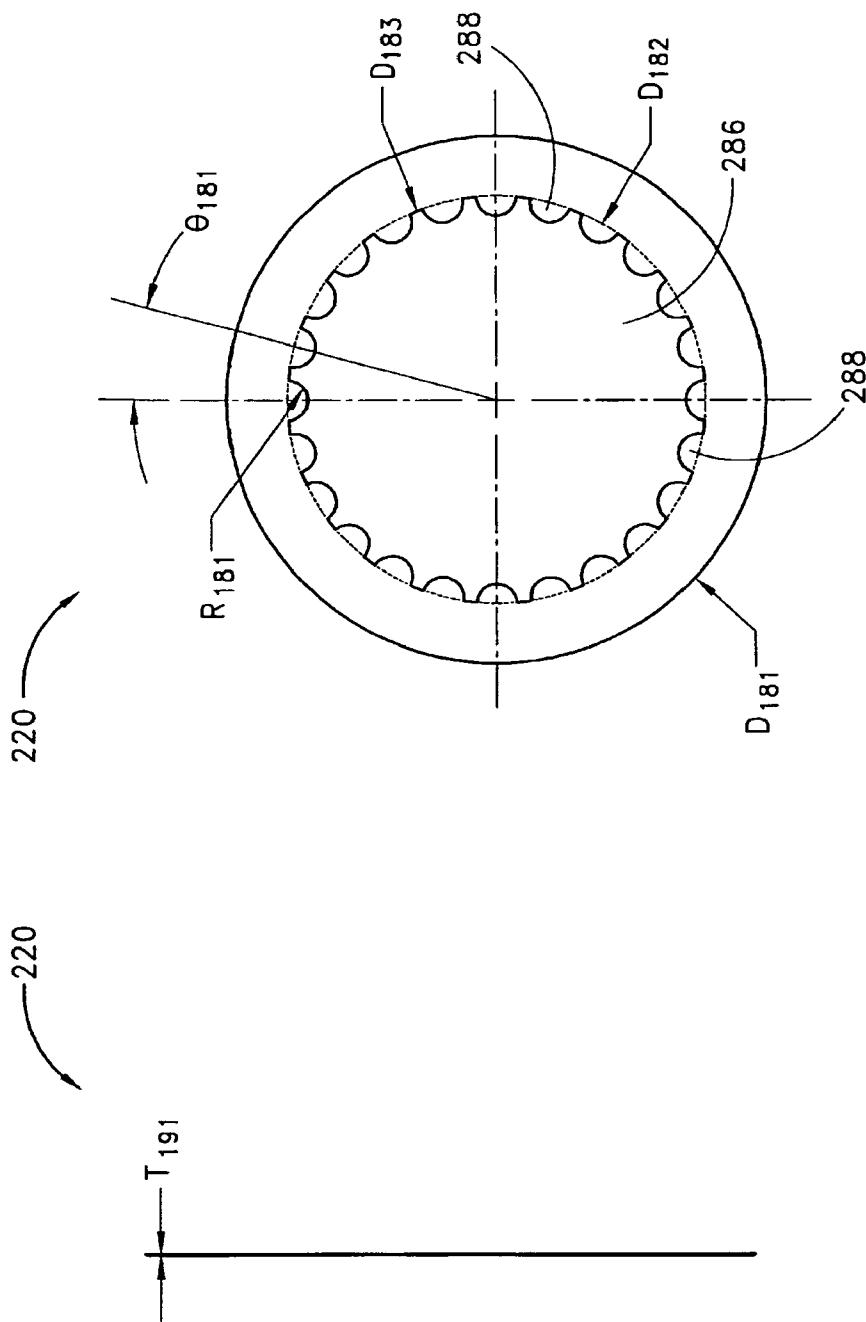
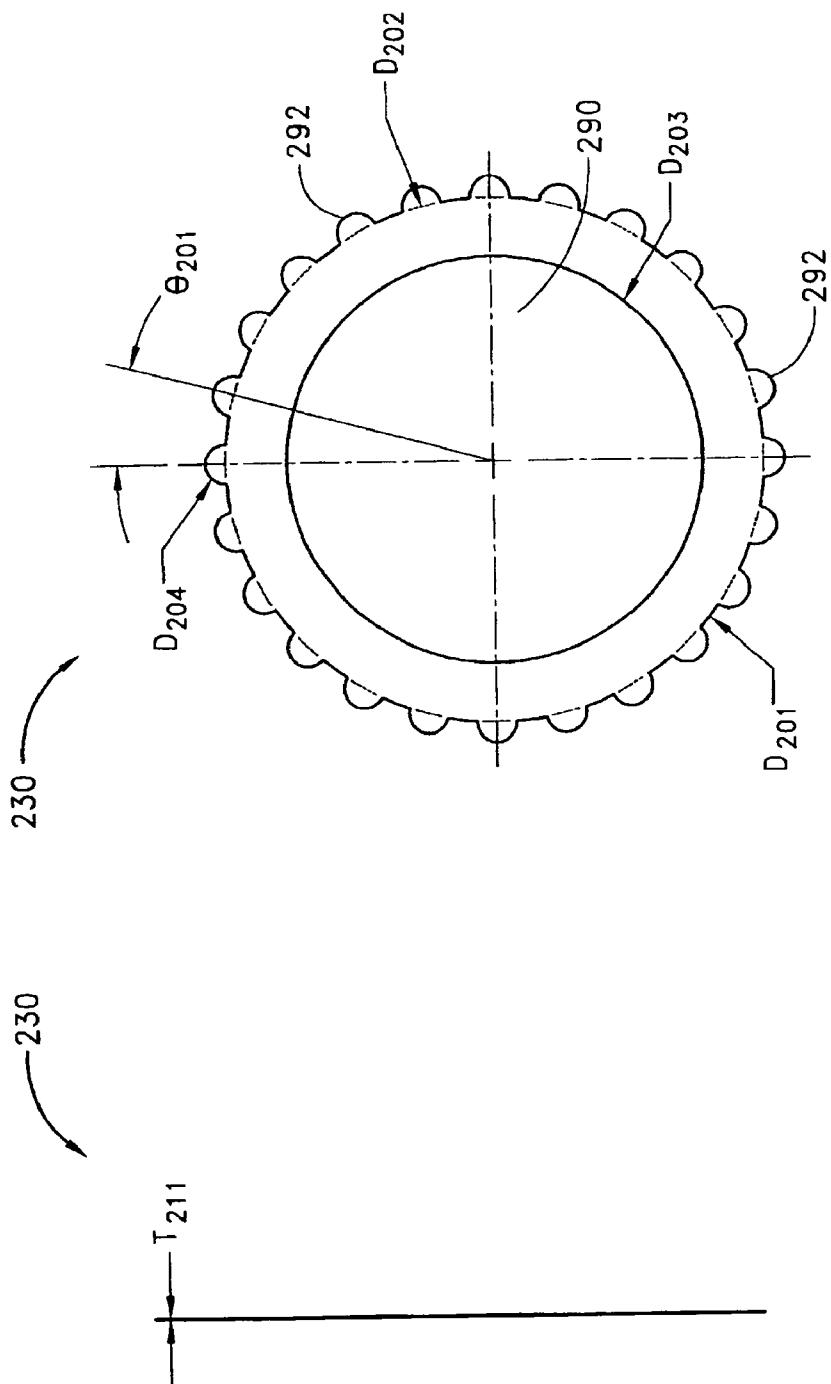


FIG. 18

FIG. 19



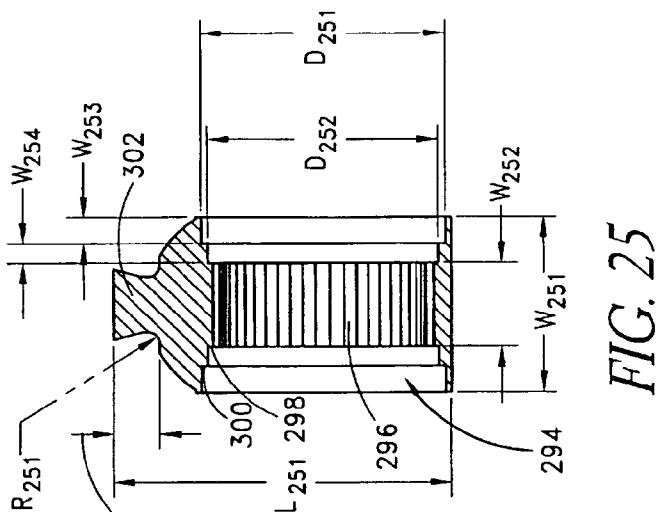
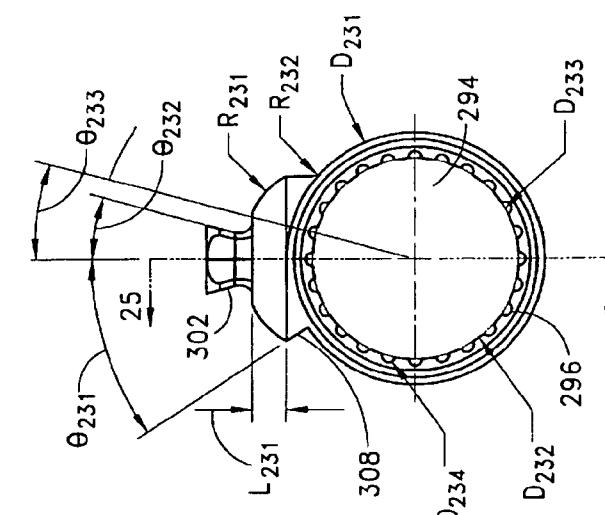
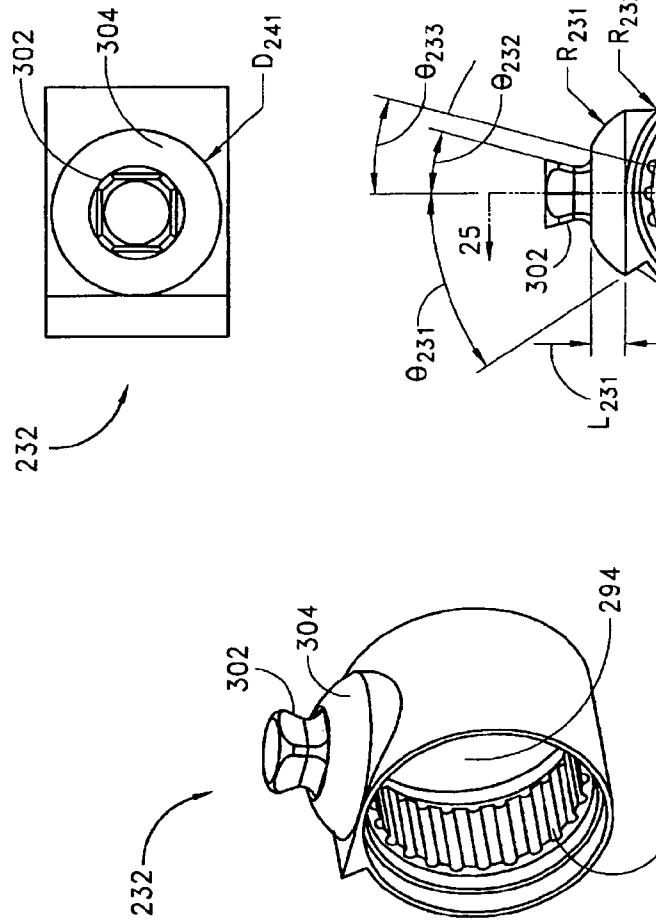
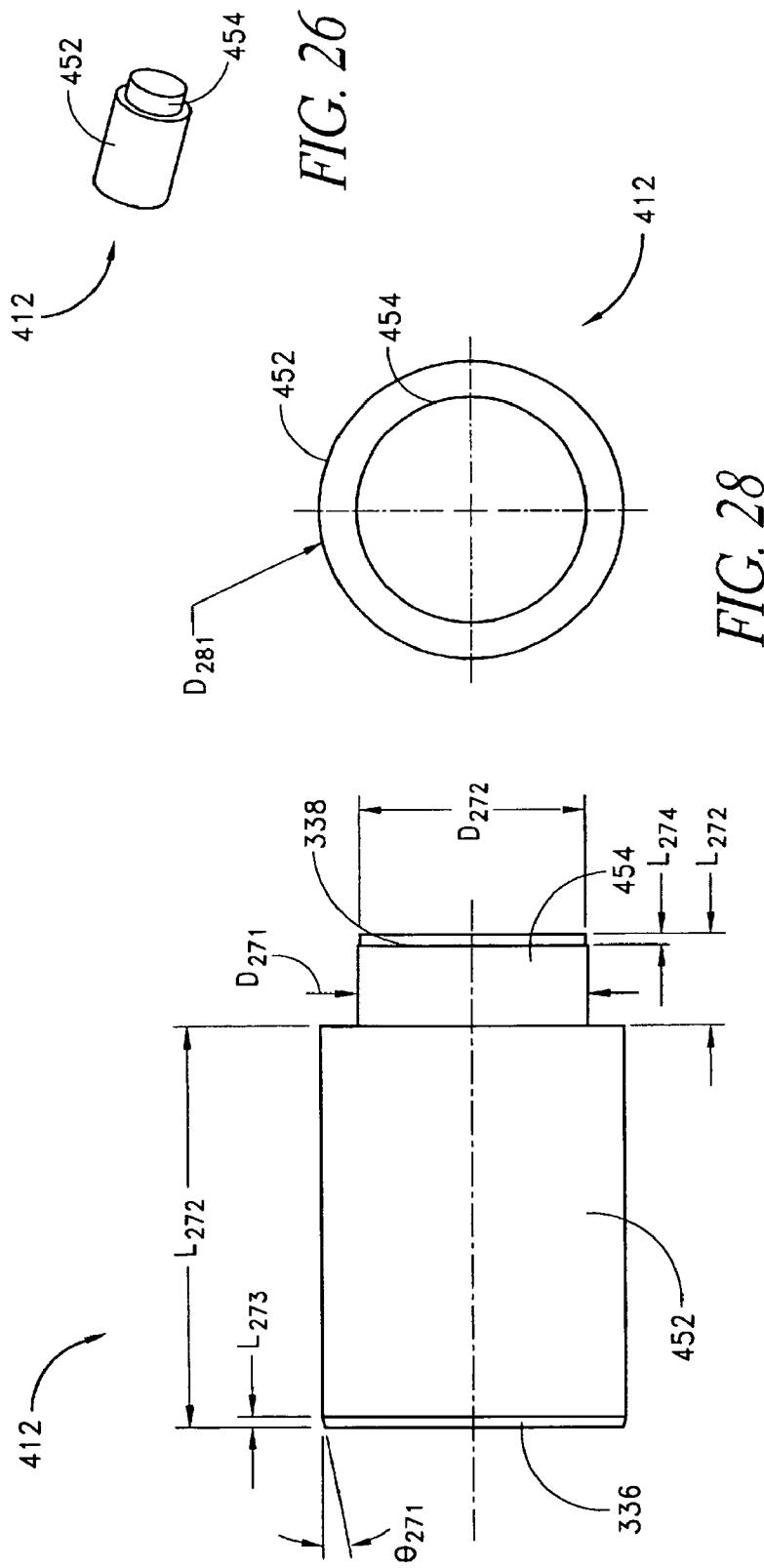
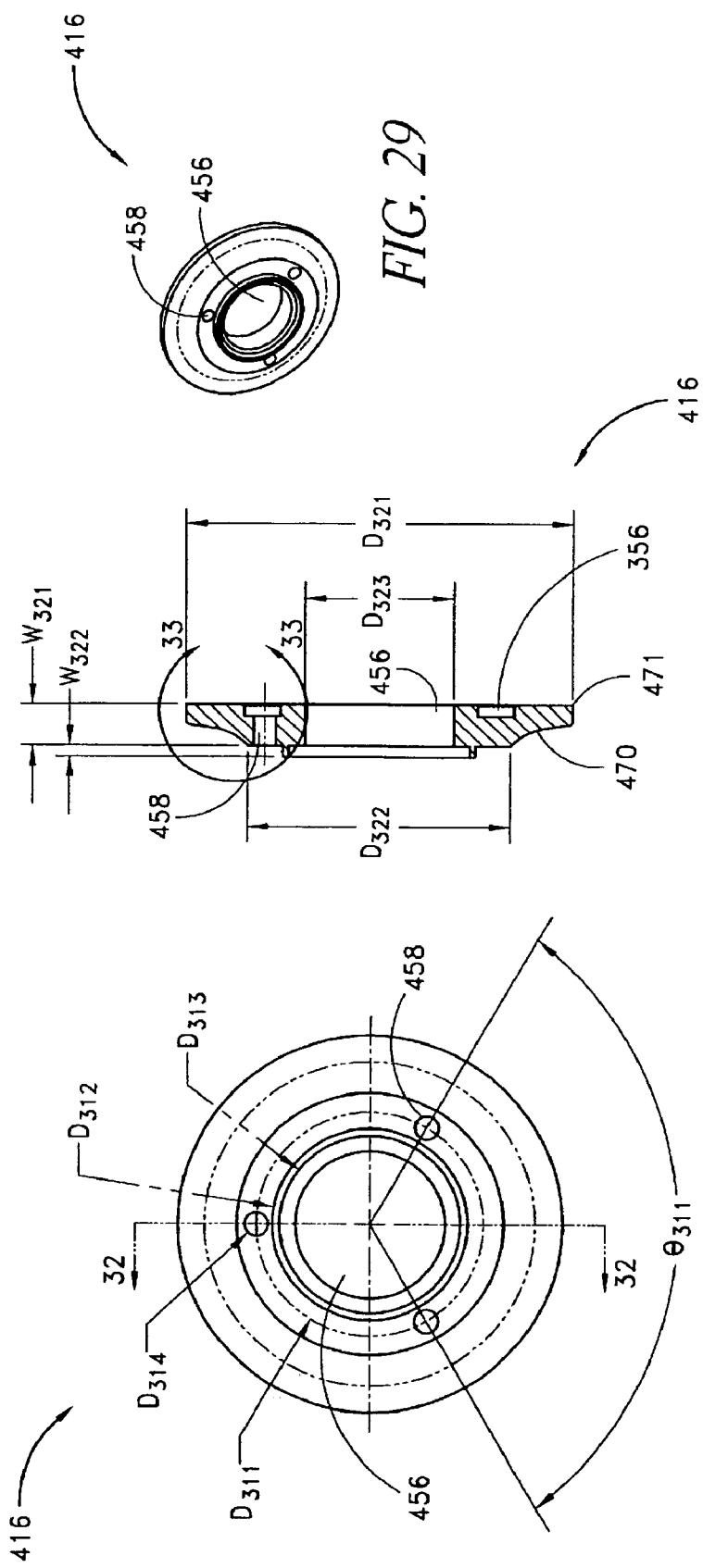


FIG. 25





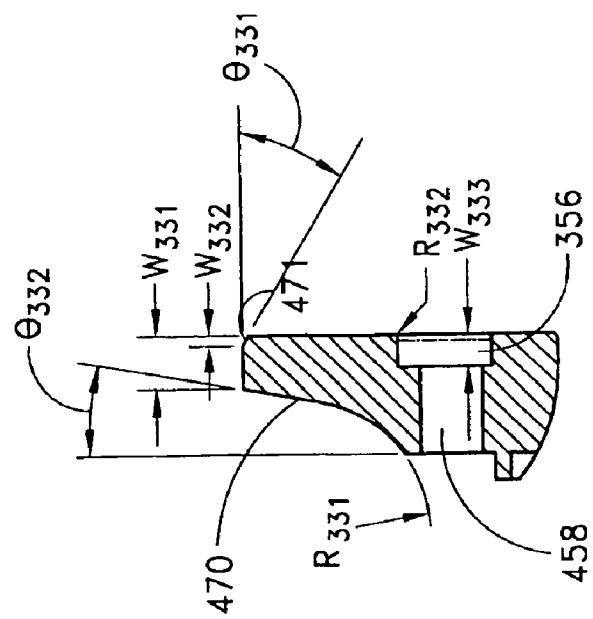


FIG. 33

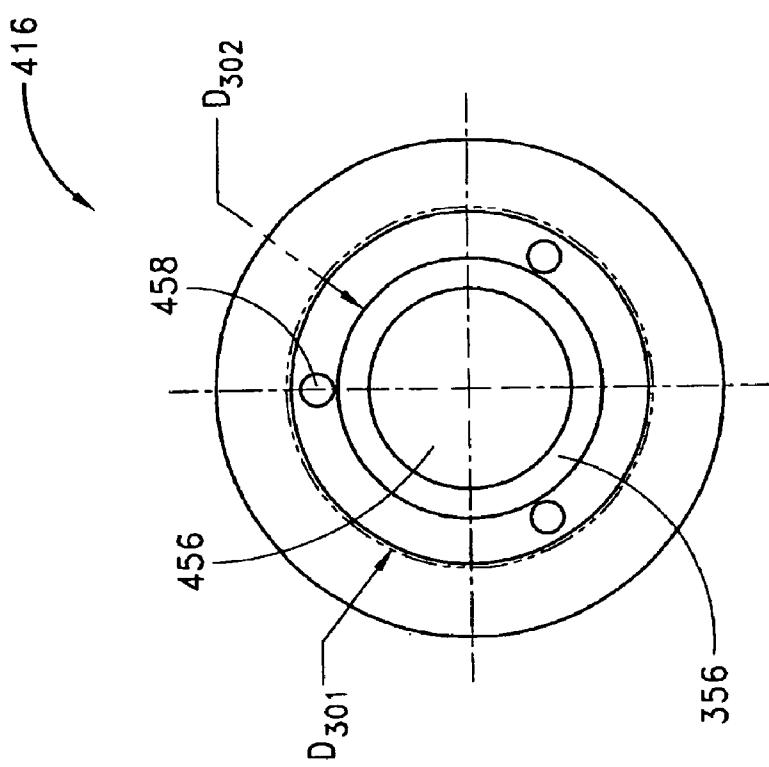


FIG. 30

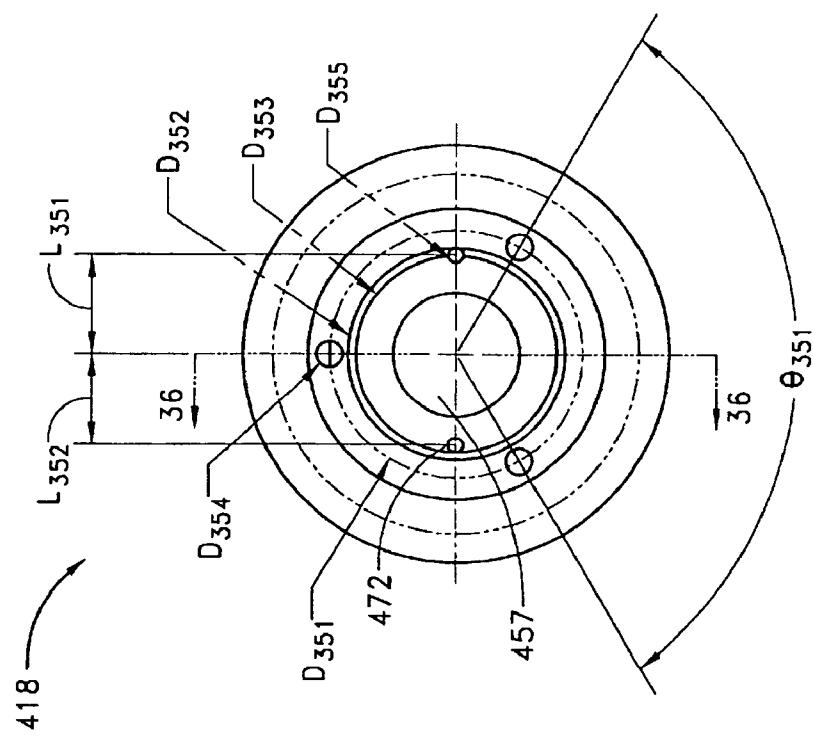
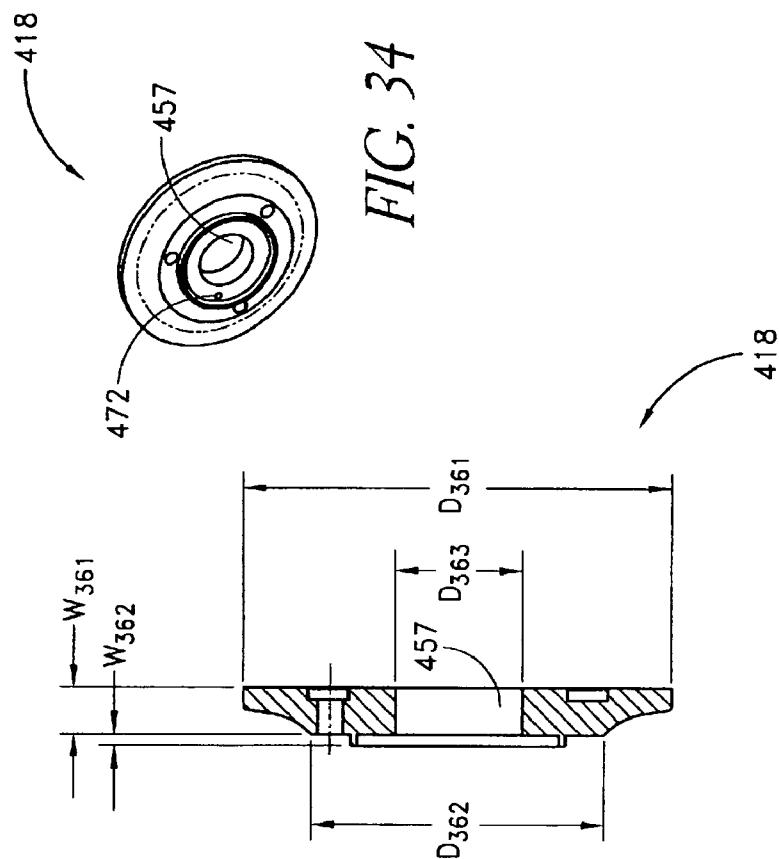
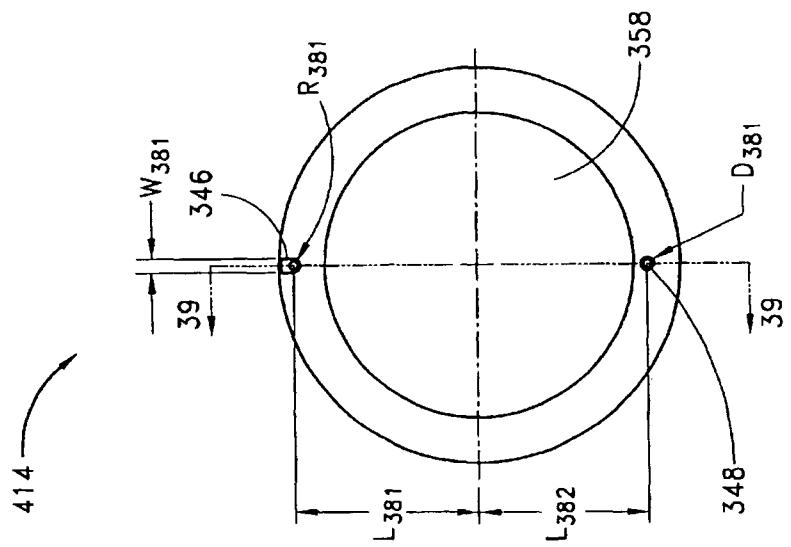
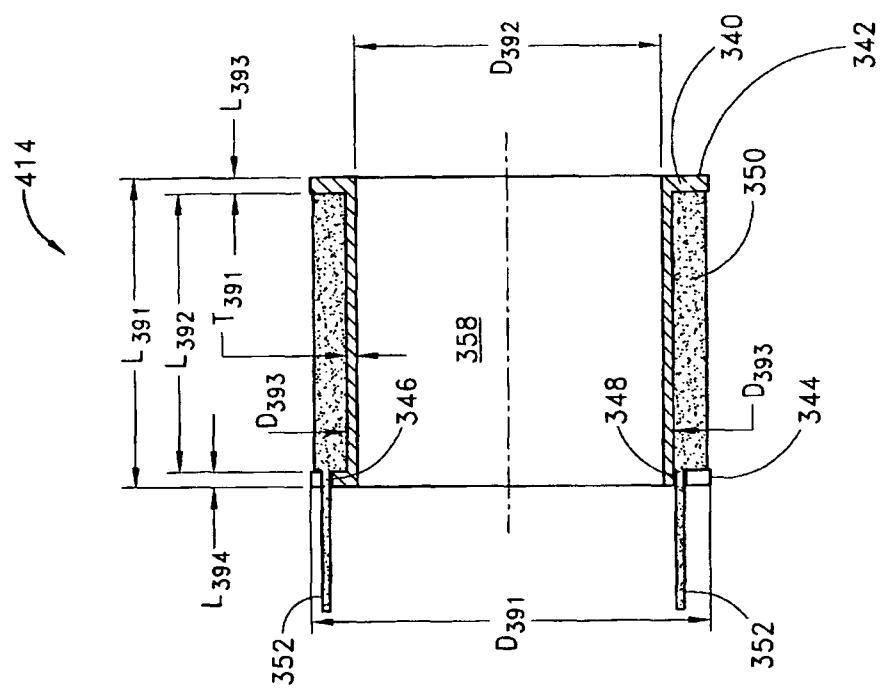
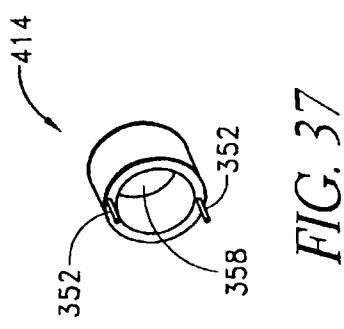


FIG. 36



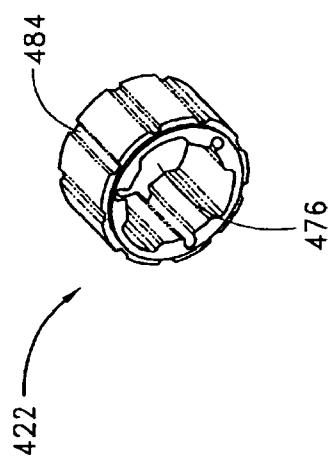


FIG. 40

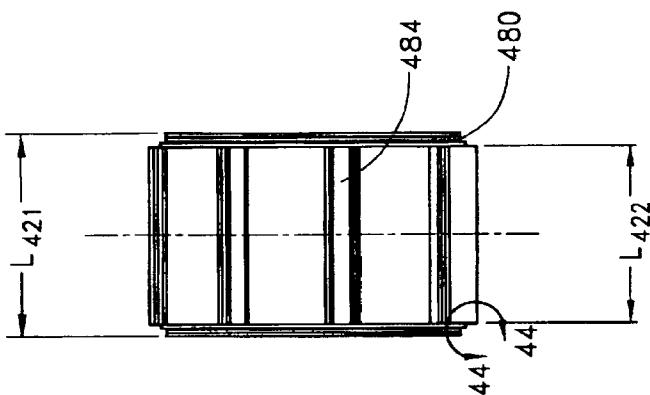


FIG. 42

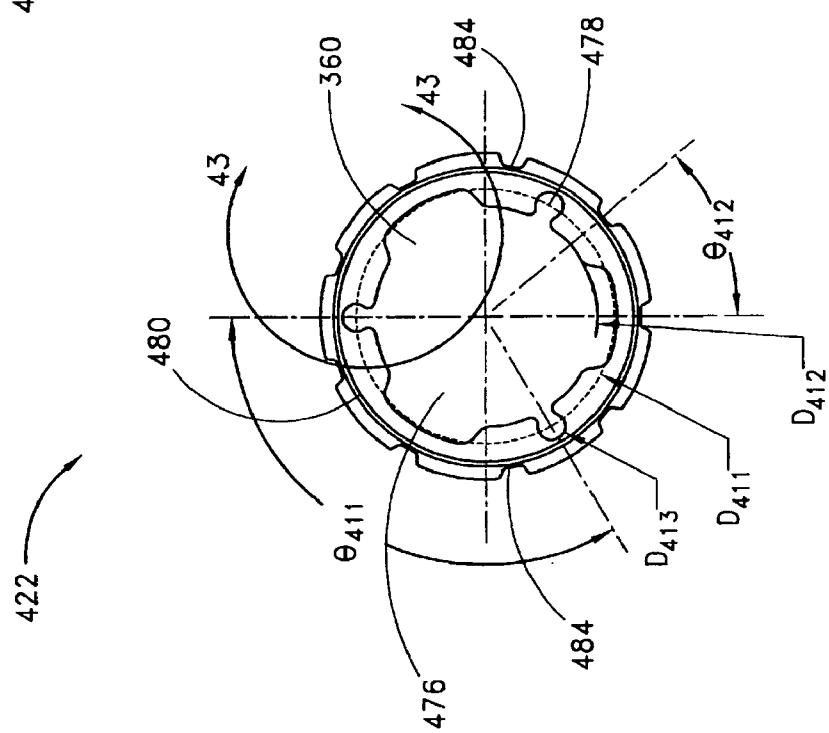


FIG. 41

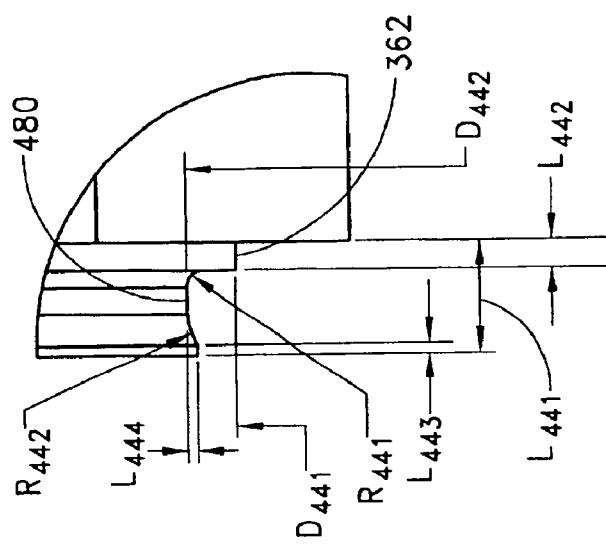


FIG. 44

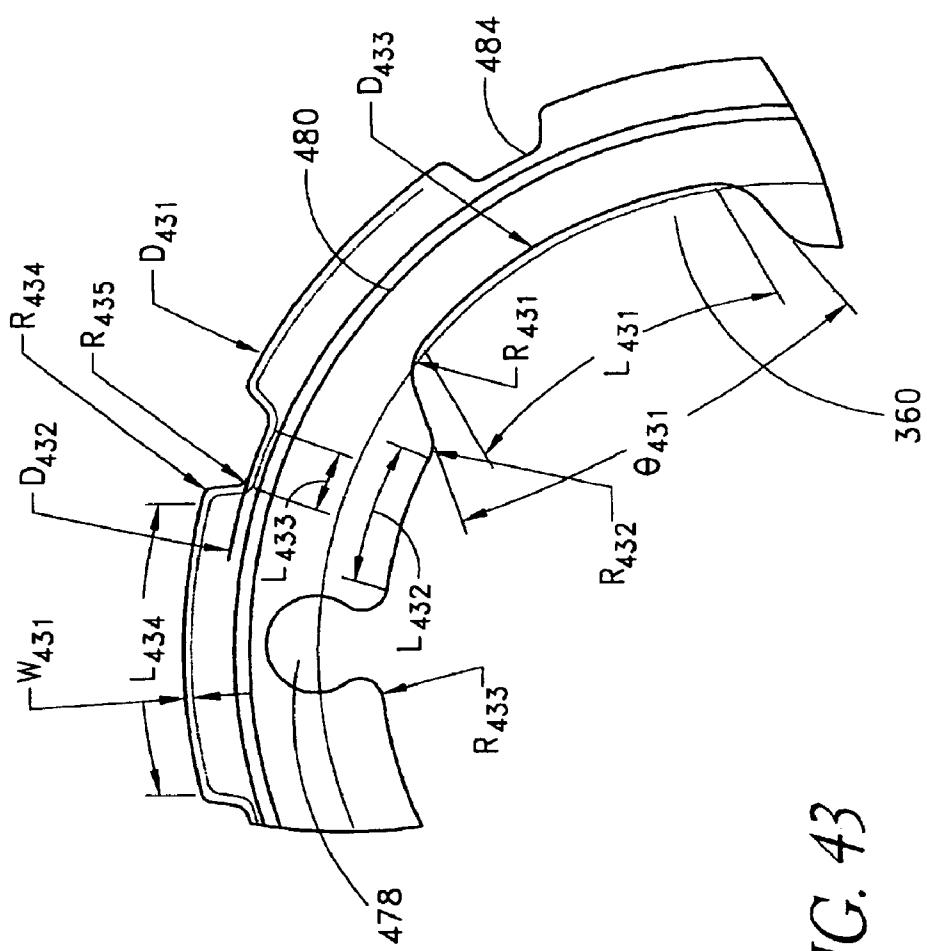


FIG. 43

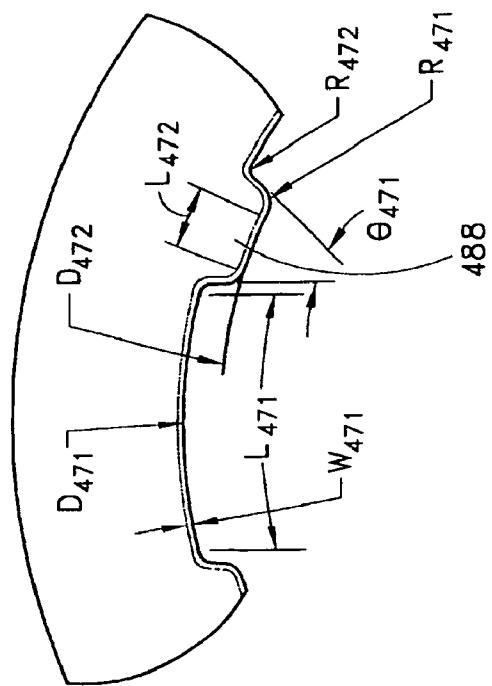
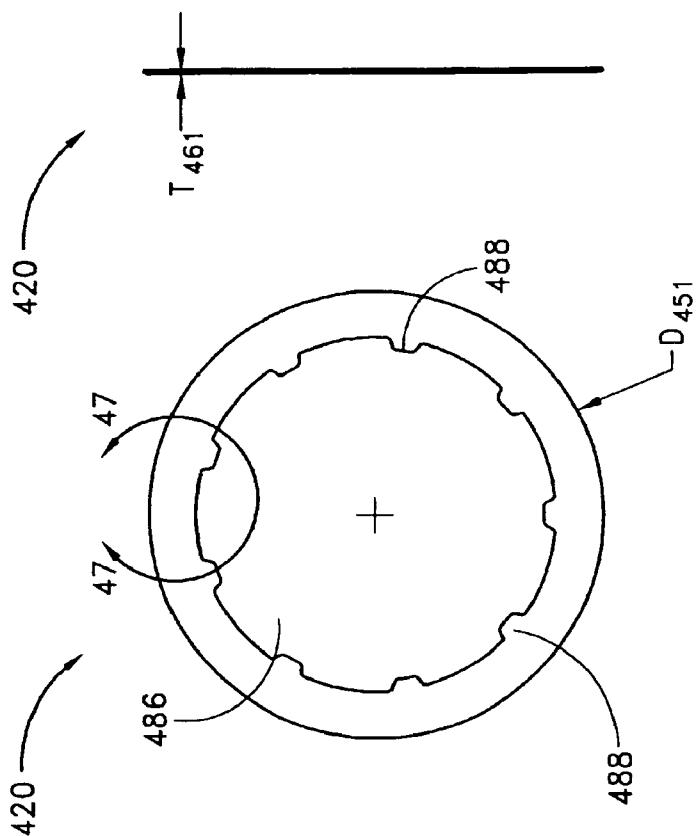


FIG. 47

FIG. 45
FIG. 46

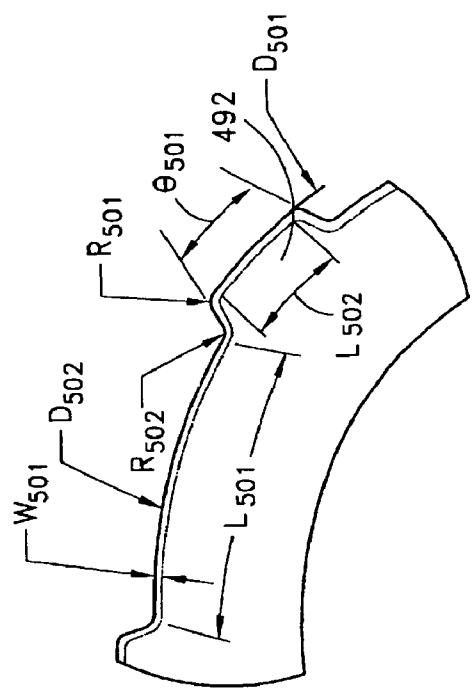


FIG. 50

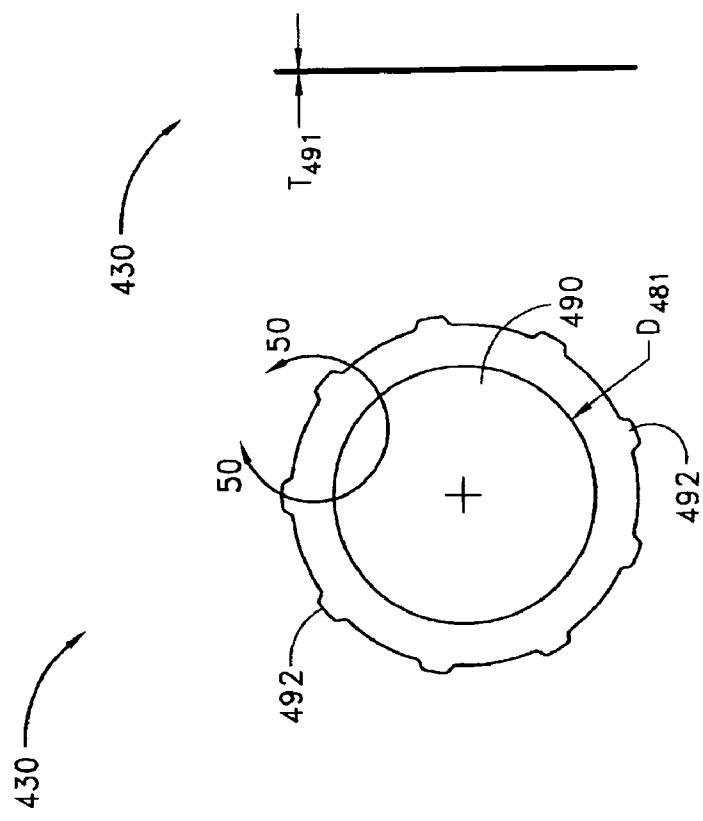


FIG. 48

FIG. 49

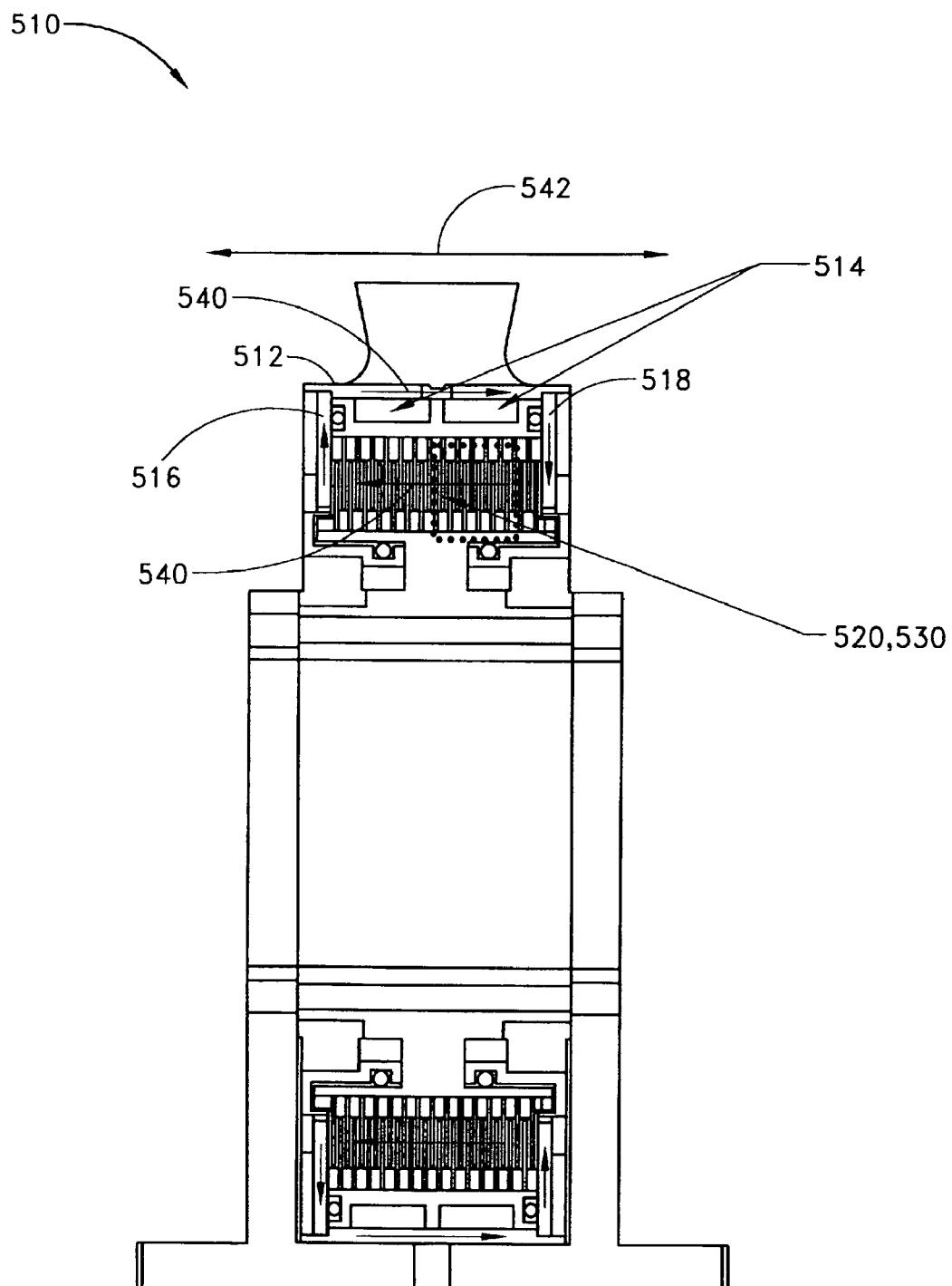


FIG. 51

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ELECTRONICALLY CONTROLLED
PROSTHETIC KNEE

Matter enclosed in heavy brackets [] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional application No. 60/177,108, filed Jan. 20, 2000, the entire disclosure of which is hereby incorporated by reference herein.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to prosthetic joints in general and, in particular, to controllable braking systems for prosthetic knee joints.

2. Description of the Related Art

Three types of variable-torque brakes have been employed in prosthetic knees in the past: (i) dry friction brakes where one material surface rubs against another surface with variable force; (ii) viscous torque brakes using hydraulic fluid squeezed through a variable sized orifice or flow restriction plate; and (iii) magnetorheological (MR) brakes or dampers where MR fluid (containing small iron particles suspended in the fluid) is squeezed through a fixed orifice or flow restriction plate, with viscosity of the fluid being varied in response to an applied magnetic field. Each of these technologies, as conventionally practiced in the field of prosthetics, can pose certain disadvantages.

Though dry friction brakes can generally provide a substantial torque range for their size, undesirably, they are often difficult to control. After extended use, the frictional pads tend to wear, thereby changing the frictional characteristics of the brake and the torque response for a given commanded torque. Disadvantageously, this can cause unreliable damping performance, and hence adversely affect the gait of the amputee and also cause discomfort to the amputee. Consequently, dry friction brakes may need frequent servicing and/or replacement which undesirably adds to the cost.

Under high loading conditions, viscous torque brakes are susceptible to leakage of hydraulic fluid and possibly other damage due to excessive pressure build-up. Disadvantageously, this can result in an irreversible state, since once the brake unit is overloaded it cannot return to normal. Therefore, such a viscous torque brake for a prosthetic joint is prone to catastrophic failure, and hence can be unreliable and detrimental to the safety of an amputee.

The term "valve mode" refers to the control of the flow of a MR fluid through an orifice by the application of a variable magnetic field perpendicular to the direction of the flow in place of the mechanical valve used in conventional viscous torque brakes. Disadvantageously, a MR brake operated in the "valve mode" also develops internal fluid pressure buildup, and hence is still susceptible to traditional pressure induced failure, thereby putting the amputee at risk.

SUMMARY OF THE INVENTION

Accordingly it is one important advantage of the present invention to overcome some or all of the above limitations by providing a variable-torque magnetorheologically actuated

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prosthetic knee which utilizes a plurality of interspersed and alternating rotors and stators to shear magnetorheological fluid in gaps formed therebetween. Advantageously, by operating in the "shear mode" there is substantially no or negligible fluid pressure buildup or change. Moreover, the multiple MR fluid gaps or flux interfaces desirably allow for the production of a large torque at low speed—eliminating the need for a transmission—and also for a wide dynamic torque range. One embodiment of the invention allows the rotors and/or stators to close the gaps therebetween to create a frictional torque component, thereby forming a "hybrid" braking system which provides a total torque or damping which is a combination of viscous torque and frictional torque.

In accordance with one preferred embodiment, a magnetorheologically actuated rotary prosthetic knee is provided for precisely and rapidly controlling lower limb movement. The prosthetic knee generally comprises a substantially central core and a pair of side plates, a plurality of interspersed and alternating magnetically soft rotors and magnetically soft stators, an electromagnet positioned between the core and the rotors and stators, and a pair of bearings. The core and the side plates are formed from a magnetically soft material to create a magnetic return path. The rotors and stators are arranged so as to form a plurality of gaps therebetween. The gaps contain a magnetorheological fluid which is sheared during knee rotation. The electromagnet is responsive to an electrical signal to generate a variable magnetic field to cause a controlled change in the viscosity of the magnetorheological fluid. The bearings are in rotary communication with the rotors and a shin portion of the lower limb to transfer rotary resistive torques from the prosthetic knee to the shin portion.

In accordance with another preferred embodiment, a controllable magnetorheological brake for an artificial knee is provided to dampen knee joint rotation. The magnetorheological knee generally comprises a plurality of alternately arranged and spaced magnetizable rotors and magnetizable stators, a magnetorheological fluid, and a magnet. The rotors and stators are concentrically configured about a longitudinal axis of rotation of the artificial knee. The magnetorheological fluid resides in a plurality of gaps formed between the rotors and the stators. The magnet is responsive to an applied voltage and adapted to generate a variable magnetic field which passes through the rotors, the stators and the magnetorheological fluid. The shearing of the magnetorheological fluid in the gaps between the rotors and the stators creates a variable torque output which precisely controls the rotation of the artificial knee.

In accordance with yet another preferred embodiment, an electronically controlled prosthetic knee is provided for generating a wide dynamic torque range. The prosthetic knee generally comprises a plurality of rotors, a plurality of stators, and a fluid adapted to undergo a rheology change in response to an applied magnetic field. The rotors comprise a ferrous material. The rotors are rotatable and laterally displaceable about a longitudinal axis of rotation of the prosthetic knee. The stators comprise a ferrous material and are alternately interspersed with the rotors to form gaps therebetween. The stators are laterally displaceable about the axis of rotation of the prosthetic knee. The fluid resides in the gaps formed between the rotors and the stators. Actuation of the magnetic field generates during knee rotation a controllable variable knee damping torque.

In accordance with a further preferred embodiment, a rotary prosthetic knee for an amputee is provided. The prosthetic knee generally comprises a rotatable inner spline, a plurality of rotors engaged with the inner spline, a plurality of

stators alternatingly interspersed with the rotors, an outer spline engaged with the stators, and a magnetically controlled medium residing in a plurality of sealed gaps between the rotors and the stators. The magnetically controlled medium is adapted to undergo a controlled bulk property change in response to an applied magnetic field such that the rotation of the rotors which shear the magnetically controlled medium is precisely controlled and the rotation of the prosthetic knee is variably damped to provide a substantially natural gait for the amputee.

In accordance with one preferred embodiment, a variable torque magnetorheological brake for a prosthetic knee is provided. The brake generally comprises a substantially central core, a first side plate connected to a first end of the core, a second side plate connected to a second end of the core and a rotatable and laterally displaceable blade positioned between the first side plate and the second side plate. The brake further comprises magnetorheological fluid in a pair of microgaps formed between the blade and the plates, and a magnet to generate a magnetic field such that a magnetic circuit is created through the core, the first side plate, the second side plate, the blade and the magnetorheological fluid. The microgaps have a size which is optimally minimized such that when the magnetic field has a zero value there is substantially no frictional contact between the blade and the side plates, thereby allowing the prosthetic knee to swing freely and provide a wide dynamic range.

In accordance with another preferred embodiment, a controllable rotary damper for an artificial knee is provided. The damper generally comprises a plurality of interspersed inner rotors and outer rotors, a plurality of magnetorheological fluid films, a pair of side plates and an electromagnet. The inner rotors and outer rotors are concentrically arranged about a longitudinal axis of the artificial knee. The magnetorheological fluid films are resident in a plurality of gaps between the inner rotors and the outer rotors. The pair of side plates sandwiches the inner rotors and the outer rotors with at least one of the side plates being laterally movable along the longitudinal axis of the artificial knee. The electromagnet is adapted to create a magnetic field through the inner rotors, the outer rotors, the magnetorheological fluid and the side plates. The relative rotation between the inner rotors and the outer rotors and the lateral movement of at least one of the side plates generates a variable damping torque to control the rotation of the artificial knee.

In accordance with one preferred embodiment, a prosthetic knee is provided. The prosthetic knee generally comprises a plurality of rotors, a plurality of stators and a fluid adapted to undergo a rheology change in response to an applied magnetic field. The rotors are rotatable about a longitudinal axis of the prosthetic knee. The stators are [alternating] *alternately* interspersed with the rotors to form gaps therebetween. The fluid resides in the gaps formed between the rotors and the stators. Controlled variation of the magnetic field varies the fluid rheology and shearing of the fluid caused by relative rotation between the rotors and stators during knee rotation generates a controllable variable knee torque.

For purposes of summarizing the invention and the advantages achieved over the prior art, certain objects and advantages of the invention have been described herein above. Of course, it is to be understood that not necessarily all such objects or advantages may be achieved in accordance with any particular embodiment of the invention. Thus, for example, those skilled in the art will recognize that the invention may be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught

herein without necessarily achieving other objects or advantages as may be taught or suggested herein.

All of these embodiments are intended to be within the scope of the invention herein disclosed. These and other embodiments of the present invention will become readily apparent to those skilled in the art from the following detailed description of the preferred embodiments having reference to the attached figures, the invention not being limited to any particular preferred embodiment(s) disclosed.

BRIEF DESCRIPTION OF THE DRAWINGS

Having thus summarized the general nature of the invention and its essential features and advantages, certain preferred embodiments and modifications thereof will become apparent to those skilled in the art from the detailed description herein having reference to the figures that follow, of which:

FIG. 1 is a schematic drawing of one normal human locomotion cycle illustrating the various limb positions during stance and swing phases;

FIG. 2 is a schematic illustration of a lower limb prosthetic assembly comprising an electronically controlled prosthetic knee and having features and advantages in accordance with one preferred embodiment of the present invention;

FIG. 3 is a simplified schematic drawing illustrating the general overall configuration of one preferred embodiment of the prosthetic knee of the present invention;

FIG. 4 is a detailed exploded perspective view of a magnetorheologically actuated prosthetic knee having features and advantages in accordance with one preferred embodiment of the present invention;

FIG. 5 is a cross section view of the prosthetic knee of FIG. 4;

FIG. 6 is a perspective view of the core of FIG. 4 having features and advantages in accordance with one preferred embodiment of the present invention;

FIG. 7 is a side view of the core of FIG. 6;

FIG. 8 is an end view of the core of FIG. 6;

FIG. 9 is a front view of one of the core side plates of FIG. 4 having features and advantages in accordance with one preferred embodiment of the present invention;

FIG. 10 is a rear view of the core side plate of FIG. 9;

FIG. 11 is a cross section view along line 11-11 of FIG. 9;

FIG. 12 is an enlarged view of region 12-12 of FIG. 11;

FIG. 13 is a front view of a combined core and associated side plate having features and advantages in accordance with one preferred embodiment of the present invention;

FIG. 14 is a cross section view along line 14-14 of FIG. 13;

FIG. 15 is an end view of the inner spline of FIG. 4 having features and advantages in accordance with one preferred embodiment of the present invention;

FIG. 16 is a cross section view along line 16-16 of FIG. 15;

FIG. 17 is an enlarged view of region 17-17 of FIG. 16;

FIG. 18 is a front view of one of the rotors of FIG. 4 having features and advantages in accordance with one preferred embodiment of the present invention;

FIG. 19 is a side view of the rotor of FIG. 18;

FIG. 20 is a front view of one of the stators of FIG. 4 having features and advantages in accordance with one preferred embodiment of the present invention;

FIG. 21 is a side view of the stator of FIG. 20;

FIG. 22 is a perspective view of the outer spline of FIG. 4 having features and advantages in accordance with one preferred embodiment of the present invention;

FIG. 23 is an end view of the outer spline of FIG. 22;

FIG. 24 is a top view of the outer spline of FIG. 22;

FIG. 25 is a cross section view along line 25-25 of FIG. 23;

FIG. 26 is a perspective view of a core having features and advantages in accordance with one preferred embodiment of the present invention;

FIG. 27 is a side view of the core of FIG. 26;

FIG. 28 is an end view of the core of FIG. 26;

FIG. 29 is a perspective view of a first core side plate having features and advantages in accordance with one preferred embodiment of the present invention;

FIG. 30 is a front view of the core side plate of FIG. 29;

FIG. 31 is a rear view of the core side plate of FIG. 29;

FIG. 32 is a cross section view along line 32-32 of FIG. 31;

FIG. 33 is an enlarged view of region 33-33 of FIG. 32;

FIG. 34 is a perspective view of a second core side plate having features and advantages in accordance with one preferred embodiment of the present invention;

FIG. 35 is a rear view of the core side plate of FIG. 34;

FIG. 36 is a cross section view along line 36-36 of FIG. 35;

FIG. 37 is a perspective view of a magnetic coil having features and advantages in accordance with one preferred embodiment of the present invention;

FIG. 38 is an end view of the magnetic coil of FIG. 34;

FIG. 39 is a cross section view along line 39-39 of FIG. 38;

FIG. 40 is a perspective view of an inner spline having features and advantages in accordance with one preferred embodiment of the present invention;

FIG. 41 is an end view of the inner spline of FIG. 40;

FIG. 42 is a side view of the inner spline of FIG. 40;

FIG. 43 is an enlarged view of region 43-43 of FIG. 41;

FIG. 44 is an enlarged view of region 44-44 of FIG. 42;

FIG. 45 is a front view of a rotor having features and advantages in accordance with one preferred embodiment of the present invention;

FIG. 46 is a side view of the rotor of FIG. 45;

FIG. 47 is an enlarged view of region 47-47 of FIG. 45;

FIG. 48 is a front view of a stator having features and advantages in accordance with one preferred embodiment of the present invention;

FIG. 49 is a side view of the stator of FIG. 48;

FIG. 50 is an enlarged view of region 50-50 of FIG. 48; and

FIG. 51 is a schematic cross section view of another preferred embodiment of a magnetorheologically actuated prosthetic knee in which the magnetic return path passes through the exterior of the knee.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Understanding normal human walking/running provides the basis for the design and development of effective lower limb prostheses with controlled motion. Normal human locomotion or gait can be described as a series of rhythmical alternating movements of the limbs and trunk which result in the forward progression of the body's center of gravity.

One typical gait cycle, as schematically depicted in FIG. 1, comprises of the activity that occurs between heel strike of one lower limb 10 and the subsequent heel strike of the same limb 10. The limb or leg 10 generally comprises a foot 12 and a shin portion 14 coupled or articulated to a thigh portion 16 via a knee or knee joint 18. During a single gait cycle each lower limb or extremity passes through one stance or extended phase 20 and one swing phase 22.

The stance phase 20 begins at heel-strike 24 when the heel touches the floor or supporting ground surface and the stance knee begins to flex slightly. This flexion allows for shock absorption upon impact and also maintains the body's center of gravity at a more constant vertical level during stance.

Shortly after heel-strike 24, the sole makes contact with the ground at the beginning of the foot-flat phase 26. After maximum flexion is reached in the stance knee, the joint begins to extend again, until maximum extension is reached at [mid-stance] mid-stance 28 as the body weight is swung directly over the supporting extremity and continues to rotate over the foot.

As the body mass above the ankle continues to rotate forward, the heel lifts off the ground at heel-off 30. Shortly after this, the body is propelled forward by the forceful action of the calf-muscles (push-off). The push-off phase terminates when the entire foot rises from the ground at toe-off 32.

During late stance, the knee of the supporting leg flexes in preparation for the foot leaving the ground for swing. This is typically referred to in the literature as "knee break". At this time, the adjacent foot strikes the ground and the body is in "double support mode", that is, both the legs are supporting the body weight.

At toe-off 32, as the hip is flexed and the knee reaches a certain angle at knee break, the foot leaves the ground and the knee continues to flex into the swing phase. During early swing the foot accelerates. After reaching maximum flexion at mid-swing 34, the knee begins to extend and the foot decelerates. After the knee has reached full extension, the foot once again is placed on the ground at heel-strike 24 and the next walking cycle begins.

Typically, the anatomical position is the upright position, therefore flexion is a movement of a body part away from the extended or stance or anatomical position. Thus, bending of the knee is knee flexion. Extension is a movement of a limb towards the anatomical position, thus knee extension is a movement in the "straightening" direction.

During a typical normal walking progression on a generally level surface, the maximum flexion angle α_F varies between about 70° and 80°. The maximum extension angle α_E is typically about or close to 180°. Thus, in level walking the normal human knee rotates through a range of approximately 70°-80° going from a position of full extension in early and mid stance to 70°-80° of flexion shortly after toe-off. In other situations, for example, in a sitting position, the maximum flexion angle α_F can be about 140°-150°.

System Overview

FIG. 2 is a schematic illustration of a lower limb prosthetic assembly or prosthesis 100 comprising an electronically controlled active knee prosthesis and having features and advantages in accordance with one preferred embodiment of the present invention. As described in greater detail later herein, preferably, the active knee prosthesis comprises a variable-torque magnetorheological (MR) braking system 110 for providing resistive forces to substantially simulate the position and motion of a natural knee joint during ambulation and/or other locomotory activities performed by the amputee. At one end the artificial knee 110 is coupled or mechanically connected to a residual limb socket 102 which receives a residual limb or femur portion 104 of the amputee while the other end of the prosthetic knee 110 is coupled or mechanically connected to a pylon or shank portion 106 which in turn is coupled or mechanically connected to a prosthetic or artificial foot 108.

Advantageously, the prosthetic knee joint 110 of the present invention permits the amputee to move and/or adapt comfortably and safely in a wide variety of circumstances. For example, during walking, running, sitting down, or when encountering subtle or drastic changes in the environment or ambient conditions, such as, when the user lifts a suitcase or walks down a slope.

The artificial knee joint 110 provides stance control to limit buckling when weight is applied to the limb. In addition, the prosthetic knee 110 provides aerial swing control so that the knee reaches full extension just prior to or at heel-strike in a smooth and natural manner. Moreover, the prosthetic knee 110, by adjusting and/or fine tuning the range and/or magnitudes of the resistive torque level, can be adapted for use with a wide variety of patients having different body weights, heights and activity levels.

Preferably, the artificial knee joint 110 of the present invention is used in conjunction with a trans-femoral (above-knee, A/N) amputee. Alternatively or optionally, the prosthetic knee joint 110 may be adapted for use with a knee-disarticulation (K/D) amputee where the amputation is through the knee joint, as needed or desired, giving due consideration to the goals of providing a substantially natural feeling and/or safe prosthetic device, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

FIG. 3 is a simplified schematic of a rotary prosthetic knee or magnetorheological (MR) braking system 110 in accordance with one preferred embodiment of the present invention. The knee actuator 110 includes a substantially central core 112 substantially circumscribed or enveloped by an electromagnet or magnetic coil 114 and in mechanical communication with a pair of side plates or disks 116, 118. By passing a variable, controlled current through the electromagnet 114, a variable magnetic field is created. Preferably, the core 112 and side plates 116, 118 are fabricated from a ferrous, magnetizable or magnetic material and the like. More preferably, the core 112 and side plates 116, 118 are fabricated from a magnetically soft material of high flux saturation density and high magnetic permeability.

The prosthetic knee 110 further includes a plurality of inner blades or plates 120 in mechanical communication with an inner spline 122. The inner spline 122 generally circumscribes or envelopes the electromagnet 114 and is coupled or mechanically connected to the side plates 116, 118. The blades 120 are preferably concentrically arranged about the brake axis of rotation 124. The inner spline 122 is preferably rotatable about the knee joint axis of rotation 124, and hence so are the blades or rotors 120 and the core side plates 116, 118. Rotation of the inner spline 122 corresponds to rotation or movement of the lower (below the knee) part of the leg.

The prosthetic knee 110 also comprises a plurality of outer blades or plates 130 in mechanical communication with an outer spline 132. The outer spline 132 generally circumscribes or envelopes the inner spline 122. The blades 130 are preferably concentrically arranged about the brake axis of rotation 124. The outer spline 132 is preferably rotatable about the knee joint axis of rotation 124, and hence so are the blades or stators 130. Rotation of the outer spline 132 corresponds to rotation or movement of the upper (above the knee) part of the leg. Preferably, the outer spline or housing 132 comprises means to facilitate connection of the prosthetic knee joint 110 to a suitable stump socket or the like. The outer spline 132, and hence the stators 130, are preferably substantially irrotationally coupled to or nonrotatable with respect to the stump socket or residual limb.

The plurality of rotors 120 and stators 130 are interspersed in an alternating fashion and the gaps between adjacent blades 120 and 130 comprise a magnetorheological (MR) fluid 134, which thereby resides in the cavity or passage formed between the inner spline 122 and the outer spline 132. In one preferred embodiment, the MR fluid 134 in the gaps or micro-gaps between adjacent rotors 120 and stators 130 is in the form of thin lubricating films between adjacent rotors 120 and

stators 130. Shearing of MR fluid present between the side plates 116, 118 and adjacent stators 130 can also contribute to the knee damping.

During knee joint rotation, the MR fluid in the plurality of gaps between the rotors 120 and stators 130 is sheared to generate a damping torque to control the limb rotation. The blades or disks 120 and 130 are preferably formed of a ferrous, magnetizable or magnetic material and the like. More preferably, the blades or disks 120 and 130 are formed of a material of as high magnetic permeability and magnetic softness as is mechanically practical.

The knee joint 110 further includes a pair of ball bearings 126, 128 coupled or connected to the respective side plates 116, 118. The ball bearings 126, 128 are further coupled or connected to respective side walls or mounting forks 136, 138. Thus, a rotary coupling is created between the inner spline 122 and the mounting forks 136, 138. The mounting forks 136, 138 in combination with the outer spline 132 form one main outer shell of the knee joint 110. Preferably, the side walls or mounting forks 136, 138 comprise means to facilitate connection of the prosthetic knee joint 110 to a suitable pylon, shank portion or the like, as described below.

Preferably, the central core 112 and the electromagnet 114 also rotate along with the rotation of the inner spline 122, the rotors 120, the core side plates 116, 118 and the mounting forks 136, 138. The stators 130 rotate together with the rotation of the outer spline 132.

The rotors 120 are rotationally fixed relative to the inner spline 122 and the stators 130 are rotationally fixed relative to the outer spline 132. During various stages of locomotion or knee rotation, and about the knee axis of rotation 124, the rotors 120 may rotate while the stators 130 are rotationally substantially stationary, or the stators 130 may rotate while the rotors 120 are rotationally substantially stationary, or both the rotors 120 and the stators 130 may rotate or be substantially rotationally stationary. The terms "rotor" and "stator" are used to distinguish the inner blades 120 and the outer blades 130, though both rotors 120 and stators 130 can rotate, and teach that relative rotational motion is created between the rotors 120 and the stators 130 (with MR fluid being sheared in the gaps between adjacent rotors 120 and stators 130). If desired, the blades 120 can be referred to as the "inner rotors" and the blades 130 as the "outer rotors."

Actuation of the magnet 114 causes a magnetic field, circuit or path 140 to be generated or created within the knee joint 110. In one preferred embodiment, the magnetic field 140 passes through the central core 112, radially outwards through the side plate 118, laterally through the interspersed set of rotors 120 and stators 130 and the magnetorheological fluid 134, and radially inwards through the side plate 116. The portion of the magnetic field 140 passing through the core 112 and side plates 116, 118 generally defines the magnetic return path while the active or functional magnetic field is generally defined by the magnetic path through the rotors 120, stators 130 and MR fluid 134.

The magnetorheological (MR) fluid 134 undergoes a rheology or viscosity change which is dependent on the magnitude of the applied magnetic field. In turn, this variation in fluid viscosity determines the magnitude of the shearing force/stress, torque or torsional resistance generated, and hence the level of damping provided by the prosthetic knee 110. Thus, by controlling the magnitude of this magnetic field, the rotary motion of the artificial limb is controlled, for example, to control the flexion and extension during swing and stance phases to provide a more natural and safe ambulation for the amputee.

In one preferred embodiment, the rotors 220 and/or stators 130 are displaceable in the lateral direction 142, and hence under the influence of a magnetic field can rub against adjacent rotors 220 and/or stators 130 with a variable force determined by the strength of the magnetic field to create a "hybrid" magnetorheological and frictional damping brake. In another preferred embodiment, the rotors 220 and stators 130 are laterally fixed in position relative to the splines 122 and 132, and hence the braking effect is substantially purely magnetorheological or viscous. Alternatively, some of the rotors 220 and/or stators 130 may be laterally fixed while others may be laterally displaceable, as required or desired, giving due consideration to the goals of providing a substantially natural feeling and/or safe prosthetic device, and/or of achieving one or more of the benefits and advantages as taught or suggested herein. In one embodiment, the side plates 116, 118 are laterally displaceable and contribute to the frictional damping due to frictional contact with adjacent stators 130.

Advantageously, by operating in the shear mode, there is no or negligible pressure build-up within the MR actuated prosthetic knee of the present invention. This substantially eliminates or reduces the chances of fluid leakage and failure of the knee, and hence desirably adds to the safety of the device.

Also advantageously, the multiple shearing surfaces or flux interfaces, provided by the preferred embodiments of the present invention, behave like a torque multiplier and allow the viscous torque level to be stepped up to a desired maximum value without the use of an additional transmission or other auxiliary component. For example, if two flux interfaces can provide a maximum viscous torque of about 1 N/m, then forty flux interfaces will be able to provide a viscous damping torque of about 40 N/m. In contrast, if a 40:1 step-up transmission is used to increase the viscous torque, disadvantageously, not only is the system reflected inertia magnified by a factor of about 1600, but the system weight, size and complexity are undesirably increased.

The multiple shearing surfaces or interfaces of the prosthetic knee of the preferred embodiments also advantageously allow for a wide dynamic torque range to be achieved which permits safe and/or more natural ambulation for the patient. Desirably, the MR actuated prosthetic knee of the preferred embodiments provides a rapid and precise response. Again, this permits the patient to move in a safe and/or more natural manner.

Magnetorheologically Actuated Prosthetic Knee

FIGS. 4 and 5 show a controllable rotary prosthetic knee joint 210 having features and advantages in accordance with one preferred embodiment of the present invention. The prosthetic knee 210 generates controllable dissipative forces preferably substantially along or about the knee axis of rotation 224.

The electronically controlled knee 210 generally comprises a generally central core 212 in mechanical communication with a pair of rotatable side plates 216, 218, an electromagnet 214, a plurality of blades or rotors 220 in mechanical communication with a rotatable inner spline 222, a plurality of blades or stators 230 in mechanical communication with a rotatable outer spline 232, a pair of ball bearings 226, 228 for transferring rotary motion to a pair of outer side walls or forks 236, 238. The rotation is substantially about the knee axis of rotation 224.

The plurality of rotors 220 and stators 230 are preferably interspersed in an alternating fashion and the gaps or micro-gaps between adjacent blades 220 and 230 comprise thin lubricating films of a magnetorheological (MR) fluid, which

thereby resides in the cavity or passage formed between the inner spline 222 and the outer spline 232. This preferred embodiment provides a controllable and reliable artificial knee joint, which advantageously has a wide dynamic torque range, by shearing the MR fluid in the multiple gaps or flux interfaces between adjacent rotors 220 and stators 230.

Preferably, end-threaded rods 248 and nuts 250 are used to secure selected components of the prosthetic knee 210, thereby allowing a straightforward assembly and disassembly procedure with a minimum of fasteners. Alternatively, or in addition, various other types of fasteners, for example, screws, pins, locks, clamps and the like, may be efficaciously utilized, as required or desired, giving due consideration to the goals of providing secure attachment, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

Core and Associated Side Plates (Magnetic Return Path)

Preferably, the core 212 and associated side plates 216, 218 are formed of a magnetically soft material of high flux saturation density and high magnetic permeability. Thus, when the electromagnet 214 is actuated a magnetic field, circuit or path is generated or created within the knee joint 210. In one preferred embodiment, the magnetic field passes longitudinally (parallel to the axis of rotation 224) through the central core 212, radially through the side plate 218, laterally (parallel to lateral direction 242) through the interspersed set of rotors 220 and stators 230 and the magnetorheological (MR) fluid, and radially through the side plate 216.

The orientation or positioning of the electromagnet 214 and the direction of current flow through it determines the polarity of the magnetic field, and thereby determines whether the magnetic field passes radially inwards or outwards through the side plate 218, and hence in the correspondingly opposite direction through the side plate 216. The portion of the magnetic field passing through the core 212 and side plates 216, 218 generally defines the magnetic return path while the active or functional magnetic field is generally defined by the magnetic path through the rotors 220, stators 230 and MR fluid residing therebetween.

FIGS. 6-8 show one preferred embodiment of the core 212 of the knee joint 210. The core 212 is preferably generally cylindrical in shape and comprises a pair of cylindrical portions 252, 254 with the core portion 252 having a diameter larger than that of the core portion 254. The core portion 252 is sized and configured to matingly engage a corresponding cavity of the core side plate 216 while the core portion 254 is sized and configured to matingly engage a corresponding cavity of the core side plate 218. Thus, the core 212 rotates as the core side plates 216, 218 rotate. In other preferred embodiments, the core 212 may be sized, shaped and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

The core 212 is preferably fabricated from a material having a high saturation flux density, a high magnetic permeability and low coercivity. Advantageously, this facilitates in the construction of an artificial knee or brake that is compact and light weight, and also strong. In one preferred embodiment, the core 212 comprises an integral unit. In another preferred embodiment, the core 212 is formed of laminated sheets to advantageously reduce or minimize eddy current losses.

Preferably, the core 212 comprises an iron-cobalt (FeCo) high magnetic saturation alloy. In one preferred embodiment, the core 212 comprises the Iron-Cobalt High Magnetic Saturation Alloy, ASTM A-801, Type 1 Alloy, which specifies a

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composition with about 50% cobalt. For example, the core 212 may comprise Hiperco Alloy 50®, Permendur V™ or Vanadium [Pemendur] *Permendur*, as available from Principal Metals, or Vacoflux 50 as available from Vacuum-schmelze of Hanau, Germany. In yet another preferred embodiment, the core 212 comprises a lower percentage of cobalt, for example, about 17%, available as Vacoflux 17 from Vacuum-schmelze of Hanau, Germany. In other preferred embodiments, the core 212 can be efficaciously fabricated from alternate materials of high magnetic saturation, high magnetic permeability and low coercivity, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable prosthetic knee joint, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, the material comprising the core 212 has a saturation flux density of about 2.2 Tesla. Such a high saturation flux density is desirable because it allows a compact and light weight design. For example, if a material having a lower saturation flux density was utilized, the cross-sectional area of the return path through the core 212 in the direction of the applied magnetic field would have to be increased to achieve the same maximum torque and dynamic torque range. In other preferred embodiments, the core saturation flux density can be higher or lower, as needed or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable prosthetic knee joint, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

Preferably, the core 212 is formed by machining followed by heat treatment in a hydrogen atmosphere to achieve optimal magnetic properties. In other preferred embodiments, the core 212 can be efficaciously fabricated from other techniques, for example, casting, forging, molding, laminating, among others, as required or desired, giving due consideration to the goals of providing desired magnetic properties and a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, and referring in particular to FIG. 7, the core 212 is dimensioned and configured such that the length L₇₁ is about 3.076 cm (1.211 inches), the length L₇₂ is about 0.61 cm (0.240 inches), the diameter D₇₁ is about 1.728 cm (0.6805 inches) and the diameter D₇₂ is about 1.424 cm (0.5605 inches). In another preferred embodiment, the diameter [D₇₁] D₇₁ and/or diameter D₇₂ is about 1.91 cm (0.750 inches). In other preferred embodiments, the core 212 may be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

FIGS. 9-12 show one preferred embodiment of the core side plate or disk 216 of the prosthetic knee joint 210. The side plate 216 is preferably generally circular in shape and comprises a substantially central circular cavity or through hole 256 for matingly engaging the free end of the core portion 252. Preferably, this mating attachment is via an interference fit. Alternatively, other suitable shapes for the side plate 216 and cavity 256 may be efficaciously utilized, as needed or desired.

In one preferred embodiment, the other core side plate or disk 218 is sized, shaped and configured substantially the same as the side plate 216 of FIGS. 9-12, except that the substantially central circular cavity of the core side plate 218 is sized, shaped and configured to matingly engage the core portion 254, preferably via an interference fit. Thus, for pur-

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poses of clarity and brevity of disclosure it is to be understood that a detailed description of the core side plate 216 will suffice and embody most of the corresponding features of the core side plate 218.

Preferably, the side plate 216 comprises a plurality of approximately equally spaced through holes 258 arranged in a generally circular fashion to receive end-threaded rods or bolts and the like to secure the various components of the prosthetic knee 210. In one preferred embodiment, the side plate 216 comprises five holes 258. In another preferred embodiment, the side plate 216 comprises three holes 258. Alternatively, fewer or more holes 258 arranged in other fashions may be provided, as needed or desired.

The core side plate 216 preferably comprises a circular groove 260 to receive an O-ring 262 (FIG. 4), lip seal or gasket and the like. This provides a dynamic seal between the rotatable side plate 216 and the inner surface of the rotatable outer spline 232 and prevents leakage of MR fluid from the knee 210. The other side plate 218 is similarly configured to receive an O-ring 262 (FIG. 4) and provide a dynamic seal. In an alternative preferred embodiment, two grooves or flanges are provided on the inner surface of the outer spline 232 to receive O-rings or the like and provide a dynamic seal between the core side plates 216, 218 and the outer spline 232.

The O-rings 262 are fabricated from a suitable rubber material or the like such as Viton, Teflon and Neoprene among others. In one preferred embodiment, the O-rings 262 have an inner diameter of about 50 mm and a width of about 1.5 mm. In other preferred embodiments, the dynamic seals can be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing reliable seals, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

The inner surface of the core side plate 216 preferably has a generally circular shoulder or step 264 for aligning or locating with the inner spline 222 (FIG. 4). The outer surface of the core plate 216 preferably has a generally ring-shaped shoulder or step 266 for aligning or locating with the outer fork 236 (FIG. 4). Optionally, the step 266 may include a cut 268 to allow clearance space for electrical wires or leads. Other holes around the central cavity 256 may be provided for passage of electrical wires or leads. Preferably, the outer surface of the core side plate 216 includes a tapered portion 270. This advantageously decreases weight, saves material and also provides clearance space to facilitate assembly.

The core side plate 216 is preferably fabricated from a material having a high saturation flux density, a high magnetic permeability and low coercivity. Advantageously, this facilitates in the construction of an artificial knee or brake that is compact and light weight, and also strong. In one preferred embodiment, the core plate 216 comprises an integral unit. In another preferred embodiment, the core plate 216 is formed of laminated sheets to advantageously reduce or minimize eddy losses.

Preferably, the core plate 216 comprises an iron-cobalt (FeCo) high magnetic saturation alloy. In one preferred embodiment, the core plate 216 comprises Iron-Cobalt High Saturation Alloy (ASTM A-801 Type 1 Alloy), which specifies a composition with about 50% cobalt. For example, the core [212] plate 216 may comprise Hiperco Alloy 50®, Permendur V™ or Vanadium [Pemendur] *Permendur*, as available from Principal Metals, or Vacoflux 50 as available from Vacuum-schmelze of Hanau, Germany. In yet another preferred embodiment, the core plate 216 comprises a lower percentage of cobalt, for example, about 17%, available as Vacoflux 17 from Vacuum-schmelze of Hanau, Germany. In

other preferred embodiments, the core plate 216 can be efficaciously fabricated from alternate soft magnetic materials or the like, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable prosthetic knee joint, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, the material comprising the core plate 216 has a saturation flux density of about 2.2 Tesla. Such a high saturation flux density is desirable because it allows a compact and light weight design. For example, if a material having a lower saturation flux density was utilized, the cross-sectional area of the return path through the core plate 216 in the direction of the applied magnetic field would have to be increased to achieve the same dynamic torque range. In other preferred embodiments, the core side plate saturation flux density can be higher or lower, as needed or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable prosthetic knee joint, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

Preferably, the core side plate 216 is formed by machining followed by heat treatment in a hydrogen atmosphere to achieve optimal magnetic properties. In other preferred embodiments, the core side plate 216 can be efficaciously fabricated from other techniques, for example, casting, forging, molding, laminating, among others, as required or desired, giving due consideration to the goals of providing desired magnetic properties and a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, and referring in particular to FIG. 9, the core side plate 216 is dimensioned and configured such that the major diameter D₉₁ is about 5.240 cm (2.063 inches), the blind-circle diameter D₉₂ is about 2.845 cm (1.120 inches), the diameter D₉₃ is about 1.727 cm (0.6800 inches) and the diameter D₉₄ is about 2.82 mm (0.111 inches). The diameter D₉₃ is preferably chosen to provide an interference fit between the central cavity 256 of the side plate 216 and the free end of the core portion 252. In another preferred embodiment, the diameter D₉₃ of the central cavity 256 is about 1.91 cm (0.750 inches). The corresponding central cavity of the other core side plate 218 has a diameter which is preferably chosen to provide an interference fit with the free end of the core portion 254. In other preferred embodiments, the core side plates 216, 218 may be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, and referring in particular to FIG. 10, the core side plate 216 is dimensioned and configured such that the diameter D₁₀₁ is about 2.43 cm (0.958 inches), the diameter D₁₀₂ is about 2.29 cm (0.900 inches) and the width W₁₀₁ is about 3.3 mm (0.13 inches). In other preferred embodiments, the core side plate 216 may be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, and referring in particular to FIG. 11, the core side plate 216 is dimensioned and configured such that the diameter D₁₁₁ is about 5.011 cm (1.973 inches), the diameter D₁₁₂ is about 4.801 cm (1.890 inches), the diameter D₁₁₃ is about 2.461 cm (0.969 inches), the diam-

eter D₁₁₄ is about 3.56 cm (1.40 inches), the width W₁₁₁ is about 5.59 mm (0.220 inches), the width W₁₁₂ is about 0.508 mm (0.020 inches), the width W₁₁₃ is about 1.27 mm (0.050 inches) and the angle θ₁₁₁ is about 135°. In other preferred embodiments, the core side plate 216 may be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, and referring in particular to FIG. 12, the core side plate 216 is dimensioned and configured such that the length L₁₂₁ is about 1.14 mm (0.045 inches), the width W₁₂₁ is about 2.79 mm (0.110 inches), the width W₁₂₂ is about 1.52 mm (0.060 inches), the width W₁₂₃ is about 0.64 mm (0.025 inches), the width W₁₂₄ is about 0.97 mm (0.038 inches), the radius of curvature R₁₂₁ is about 0.254 mm (0.010 inches) to about 0.127 mm (0.005 inches) and the radius of curvature R₁₂₂ is about 3.81 mm (0.15 inches). In other preferred embodiments, the core side plate 216 may be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

The core side plates 216, 218 are in mechanical communication with the pair of respective bearings 226, 228 (FIG. 4) for transferring rotary motion from the inner spline 222 (and hence rotors 220) to the pair of respective outer forks 236, 238 which in turn are mechanically connected to a pylon or prosthetic shin portion. Any one of a number of suitable bearings as known in the art may be used. In one preferred embodiment, the bearings 226, 228 comprise AST P/N B544DDXA ball bearings as available from The Torrington Company of Torrington, Conn.

The electromagnet or magnetic coil 214 (FIG. 4) generally circumscribes the core 212 and is preferably in mechanical communication with the core 212 and/or the core side plates 216, 218 so that the electromagnet 214 rotates along with the rotation of the core 212 and/or the core side plates 216, 218. The core 212 generally comprises a bobbin with winding or a coil. The number of turns or wraps of the winding is optimized. In one preferred embodiment, the winding comprises 340 turns or wraps. In other preferred embodiments fewer or more turns or wraps can be utilized with efficacy, as required or desired, giving due consideration to the goals of optimizing performance, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

The winding of the electromagnet 214 preferably comprises AWG 30 gauge copper magnet wire. In other preferred embodiments, the winding can comprise other types of materials with efficacy, as required or desired, giving due consideration to the goals of optimizing performance, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

FIGS. 13 and 14 show one preferred embodiment of a core 212' having an integrally formed core side plate 218' for use in conjunction with the MR actuated knee joint of the present invention. If desired both core side plates may be integrally formed with the core 212'. The embodiment of FIGS. 13-14 has several features which have already been discussed above. Thus, for purposes of clarity and brevity of disclosure it is to be understood that a limited discussion of this embodiment as set forth below is sufficient.

The side plate 218' comprises a pair of holes 272 which permit passage of electrical wires or leads. The end of the core

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218' has a tapered peripheral portion **274**. This taper **274** facilitates in matingly engaging the other side plate **216** via an interference fit.

In one preferred embodiment, and referring in particular to FIG. 13, the core **212'** and core side plate **218'** are dimensioned and configured such that the major diameter D_{131} is about 5.240 cm (2.063 inches), the blind-circle diameter D_{132} is about 2.845 cm (1.120 inches), the diameter D_{133} is about 2.46 cm (0.969 inches), the diameter D_{134} is about 2.82 mm (0.111 inches), the diameter D_{135} is about 1.78 mm (0.070 inches), the length L_{131} is about 11.2 mm (0.440 inches) and the length L_{132} is about 0.98 mm (0.385 inches). In other preferred embodiments, the core **212'** and core side plate **218'** may be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, and referring in particular to FIG. 14, the core **212'** and core side plate **218'** are dimensioned and configured such that the diameter D_{141} is about 4.801 cm (1.890 inches), the diameter D_{142} is about 2.461 cm (0.969 inches), the diameter D_{143} is about 1.728 cm (0.6805 inches), the diameter D_{144} is about 3.56 cm (1.40 inches), the diameter D_{145} is about 2.43 cm (0.958 inches), the diameter D_{146} is about 2.16 cm (0.849 inches), the width W_{141} is about 5.59 mm (0.220 inches), the width W_{142} is about 0.508 mm (0.020 inches), the width W_{143} is about 1.27 mm (0.050 inches), the width W_{144} is about 2.52 cm (0.991 inches), the angle θ_{141} is about 135° and the tapered portion **274** has a length of about 0.508 mm (0.02 inches) at an angle of about 45° . In another preferred embodiment, the diameter D_{143} is about 1.91 cm (0.750 inches). In other preferred embodiments, the core **212'** and core side plate **218'** may be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

Inner Spline

FIGS. 15-17 show one preferred embodiment of the inner spline **222** of the prosthetic knee joint **210**. The inner spline **222** is preferably generally cylindrical in shape and comprises a substantially central cylindrical cavity or through hole **276** for receiving the electromagnet or magnetic coil **214** (FIG. 4). Alternatively, other suitable shapes for the inner spline **222** and cavity **276** may be efficaciously utilized, as needed or desired.

Preferably, the inner spline **222** comprises a plurality of approximately equally spaced longitudinal through holes **278** arranged in a generally circular fashion to receive end-threaded rods or bolts and the like to secure selected components of the prosthetic knee **210**, such as the core side plates **216, 218** and the inner spline **222**. These holes **278** are generally aligned with corresponding holes **258** of the core side plates **216, 218**. In one preferred embodiment, the inner spline **222** comprises five holes **278**. In another preferred embodiment, the inner spline **222** comprises three holes **278**. Alternatively, fewer or more holes **278** arranged in other fashions may be provided, as needed or desired.

The inner spline **222** preferably comprises a circular groove **260** at each end to receive respective O-rings **282** (FIG. 4) or gaskets and the like. This provides a static seal between the inner spline **222** and the side plates **216, 218**, since these components rotate together during knee rotation, and prevents leakage of MR fluid from the knee **210**. In an alternative preferred embodiment, a respective groove or

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flange is provided on the inner surfaces of either or both plates **216, 218** to receive O-rings or the like and provide a static seal.

The O-rings **282** are fabricated from a suitable rubber material or the like such as Viton, Teflon and Neoprene among others. In one preferred embodiment, the O-rings **282** have an inner diameter of about 30.5 mm (1.201 inches) and a width of about 0.76 mm (0.030 inches). In other preferred embodiments, the static seals can be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing reliable seals, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

The outer surface of the inner spline **222** preferably has a plurality of approximately equally spaced longitudinal grooves **284** which are adapted to engage corresponding teeth of the rotors **220**. In one preferred embodiment, the grooves **284** are generally semi-circular in shape. In another preferred embodiment, the grooves **284** are generally rectangular or square shaped with rounded corners. In other preferred embodiments, the grooves **284** can be efficaciously shaped and/or configured in alternate manners, as required or desired, giving due consideration to the goals of providing reliable load transmission from the rotors **220** to the inner spline **222**, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

The inner spline **222** is preferably fabricated from titanium or a titanium alloy, and more preferably from [6Al-14V] 6A1-4V titanium alloy. Advantageously, the use of titanium or titanium alloys provides a near zero magnetic permeability and a yet strong, hard surface with low weight to engage the rotors and transmit torque from them. An additional benefit is that the high resistivity of the material (titanium or titanium alloy) reduces energy losses due to induced eddy currents. In other preferred embodiments, the inner spline **222** can be efficaciously fabricated from other metals, alloys, plastics, ceramics among others, as required or desired, giving due consideration to the goals of providing an inner spline **222** of near zero magnetic permeability, and a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

Preferably, the inner spline **222** is formed by machining. In other preferred embodiments, the inner spline **222** can be efficaciously fabricated from other techniques, for example, casting, forging, molding, among others, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, and referring in particular to FIG. 15, the inner spline **222** is dimensioned and configured such that the blind-circle major diameter D_{151} is about 3.673 cm (1.446 inches), the diameter D_{152} is about 3.119 cm (1.228 inches), the blind-circle diameter D_{153} is about 2.845 cm (1.120 inches), the hole diameter D_{114} is about 2.49 mm (0.098 inches), the groove curvature diameter D_{155} is about 3.18 mm (0.125 inches), the angle θ_{151} is typically about 15° and the angle θ_{152} is typically about 7.5° . In other preferred embodiments, the inner spline **222** may be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, and referring in particular to FIGS. 16 and 17, the inner spline **222** is dimensioned and

configured such that the major diameter D_{161} is about 3.632 cm (1.430 inches), the diameter D_{162} is about 2.464 cm (0.970 inches), the length L_{163} is about 1.96 cm (0.771 inches), the depth DT_{171} is about 0.51 mm (0.020 inches), the width W_{171} is about 1.02 mm (0.040 inches) and the radius of curvature R_{171} is between about 0.127 mm (0.005 inches) and 0.254 mm (0.010 inches). In other preferred embodiments, the inner spline 222 may be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

Rotors and Stators

FIGS. 18-19 show one preferred embodiment of one of the rotors or inner blades 220 of the prosthetic knee joint 210. The rotors 220 rotate with the rotation of the inner spline 222. The preferably annular or ring shaped thin rotor 220 is generally circular in shape and comprises a substantially central cavity or through hole 286 having a plurality of inwardly extending teeth 288 adapted to engage or mate with the inner spline grooves 284 (FIG. 15). Alternatively, the rotors 220 may be efficaciously shaped in other manners, as needed or desired.

In one preferred embodiment, the teeth 288 are generally semi-circular in shape. In another preferred embodiment, the teeth 288 are generally rectangular or square shaped with rounded corners. In other preferred embodiments, the teeth 288 can be efficaciously shaped and/or configured in alternate manners, as required or desired, giving due consideration to the goals of providing reliable load transmission from the rotors 220 to the inner spline 222, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

The rotors 220 are preferably fabricated from a magnetically soft material or the like which is mechanically hard to enhance durability and minimize wear. In one preferred embodiment, the rotors 220 are fabricated from blue temper steel. In another preferred embodiment, the rotors 220 are fabricated from non-grain oriented silicon steel (electric steel). In other preferred embodiments, the rotors 220 can be fabricated from alternate magnetically soft materials or the like with efficacy, as required or desired, giving due consideration to the goals of providing durable rotors 220, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

Preferably, the rotors 220 are fabricated from a material of moderate to high magnetic permeability, low or zero coercivity, and saturation flux density exceeding that of the magnetorheological fluid 134 (FIG. 3). Advantageously, this allows a compact, light weight design requiring less power dissipation in the electromagnet 214.

In one preferred embodiment, the rotors 220 are formed by wire electro-discharge machining (EDM). Advantageously, this permits a high degree of manufacturing precision and avoids or mitigates any backlash, jarring or play between the rotors 220 and inner spline 222 which may otherwise cause discomfort to the patient. In another preferred embodiment, the rotors 220 are formed by stamping techniques. In other preferred embodiments, the rotors 220 can be fabricated using alternate techniques with efficacy, as required or desired, giving due consideration to the goals of providing a natural and/or safe ambulation for the patient, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment of the invention the rotors 220 are laterally fixed in position relative to the inner spline 222. That is, they are not displaceable in the direction 242

(FIG. 4) along the brake longitudinal axis 224 (FIG. 4). For this embodiment, the rotors 220 can be attached to the inner spline 222 by injecting resin, glue or the like along teeth engagements, laser welding the rotors 220 to the inner spline 222, shrink or thermal fitting the rotors 220 to the inner spline 222, bonding the rotors 220 to the inner spline 222, or clamping the rotors 220 to the inner spline 222 among other techniques. Advantageously, this also eliminates or mitigates backlash, jarring or play between the rotors 220 and inner spline 222 which may otherwise cause discomfort to the patient.

In one preferred embodiment, and referring in particular to FIGS. 18-19, the rotors 220 are dimensioned and configured such that the major diameter D_{181} is about 4.80 cm (1.890 inches), the blind-circle diameter D_{182} is about 3.678 cm (1.448 inches), the diameter D_{183} is about 3.678 cm (1.448 inches), the tooth radius of curvature R_{181} is typically about 1.57 mm (0.062 inches), the angle θ_{181} is typically about 15° and the rotor thickness T_{191} is about 0.203 mm (0.008 inches).

In other preferred embodiments, the rotors 220 may be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

FIGS. 20-21 show one preferred embodiment of one of the stators or outer blades 230 of the prosthetic knee joint 210. The stators 230 rotate with the rotation of the outer spline 232. The preferably annular or ring shaped thin rotor 230 is generally circular in shape and comprises a substantially central cavity or through hole 290 adapted to non-contactingly receive the inner spline 222 and a plurality of outwardly extending teeth 292 on the stator outer periphery which are adapted to engage or mate with grooves on the interior of the outer spline 232. Alternatively, the stators 230 may be efficaciously shaped in other manners, as needed or desired.

In one preferred embodiment, the teeth 292 are generally semi-circular in shape. In another preferred embodiment, the teeth 292 are generally rectangular or square shaped with rounded corners. In other preferred embodiments, the teeth 292 can be efficaciously shaped and/or configured in alternate manners, as required or desired, giving due consideration to the goals of providing reliable engagement between the stators 230 to the outer spline 232, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

The stators 230 are preferably fabricated from a magnetically soft material or the like which is mechanically hard to enhance durability and minimize wear. In one preferred embodiment, the stators 230 are fabricated from blue temper steel. In another preferred embodiment, the stators 230 are fabricated from non-grain oriented silicon steel (electric steel). In other preferred embodiments, the stators 230 can be fabricated from alternate magnetically soft materials or the like with efficacy, as required or desired, giving due consideration to the goals of providing durable stators 230, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

Preferably, the stators 230 are fabricated from a material of moderate to high magnetic permeability, low or zero coercivity, and saturation flux density exceeding that of the magnetorheological fluid 134 (FIG. 3). Advantageously, this allows a compact, light weight design requiring less power dissipation in the electromagnet 214.

In one preferred embodiment, the stators 230 are formed by wire electro-discharge machining (EDM). Advantageously, this permits a high degree of manufacturing precision and

avoids or mitigates any backlash, jarring or play between the stators 230 and outer spline 232 which may otherwise cause discomfort to the patient. In another preferred embodiment, the stators 230 are formed by stamping techniques. In other preferred embodiments, the stators 230 can be fabricated using alternate techniques with efficacy, as required or desired, giving due consideration to the goals of providing a natural and/or safe ambulation for the patient, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment of the invention the stators 230 are laterally fixed in position relative to the outer spline 232. That is, they are not displaceable in the direction 242 (FIG. 4) along the brake longitudinal axis 224 (FIG. 4). For this embodiment, the stators 230 can be attached to the outer spline 232 by injecting resin, glue or the like along teeth engagements, laser welding the stators 230 to the outer spline 232, shrink or thermal fitting the stators 230 to the outer spline 232, bonding the stators 230 to the outer spline 232, or clamping the stators 230 to the outer spline 232 among other techniques. Advantageously, this also eliminates or mitigates backlash, jarring or play between the stators 230 and outer spline 232 which may otherwise cause discomfort to the patient.

In one preferred embodiment, and referring in particular to FIGS. 20-21, the stators 230 are dimensioned and configured such that the diameter D_{201} is about 4.811 cm (1.894 inches), the blind-circle diameter D_{202} is about 4.811 cm (1.894 inches), the diameter D_{203} is about 3.683 cm (1.450 inches), the tooth curvature diameter D_{204} is typically about 0.318 mm (0.125 inches), the angle θ_{201} is typically about 15° and the stator thickness T_{211} is about 0.203 mm (0.008 inches). In other preferred embodiments, the stators 230 may be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, the rotors 220 and/or stators 230 can slide or are displaceable in the lateral direction 242 (FIG. 4) along the knee or brake longitudinal axis 224 (FIG. 4). Thus, when a magnetic field passes through the stack of rotors 220 and stators 230 in a direction substantially perpendicular to each rotor and stator surface both frictional damping and MR damping develop in response to the applied field. The frictional damping is the result of rotor surfaces rubbing against or mechanically contacting adjacent stator surfaces. Frictional damping increases with increasing field strength because the magnetized rotors 220 and stators 230 attract one another and increase the normal force (in the direction of the longitudinal axis 224) between adjacent rotors 220 and stators 230. This creates a "hybrid" magnetorheological (viscous) and frictional damping brake mechanism in which the prosthetic knee 210 of the present invention operates.

In one preferred embodiment, the rotor-stator friction component contributes about 10% or less to the total knee torque. In other preferred embodiments, the friction component can efficaciously contribute more or less to the total knee torque, as required or desired, giving due consideration to the goals of providing a wide dynamic torque range, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, the prosthetic knee brake of the present invention is configured so that the one or both of the core side plates 216 and 218 can slide or are displaceable in the lateral direction 242 along the knee or brake longitudinal axis 224, and hence can contribute to the frictional damp-

ing. Preferably, each core side plate 216 or 218 creates a friction component that contributes about 20% or less to the total knee torque. In other preferred embodiments, the friction component can efficaciously contribute more or less to the total knee torque, as required or desired, giving due consideration to the goals of providing a wide dynamic torque range, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, the rotors 220 and stators 230 are laterally (in the direction 242) rigidly fixed or attached in position relative to the splines 222 and 232, and hence the braking effect is substantially purely magnetorheological. Hence, as magnetic field strength increases, the normal force between adjacent rotor and stator surfaces remains zero or substantially zero, and frictional damping does not contribute to the total knee torque. Advantageously, this improves the brake fatigue life since possible wear through friction is eliminated or reduced.

Alternatively, some of the rotors 220 and/or stators 230 may be laterally fixed while others may be laterally displaceable, as required or desired, giving due consideration to the goals of providing a substantially natural feeling and/or safe prosthetic device, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, the prosthetic knee 210 of the present invention comprises forty rotors 220 and forty one stators 230 interspersed in an alternating fashion. This results in forty flux interfaces or fluid gaps in which the magnetorheological (MR) fluid resides. In another preferred embodiment, the number of rotors 220 is about ten to one hundred, the number of stators 230 is about eleven to one hundred one so that the number of MR fluid to rotor interfaces which produce braking in the presence of a magnetic field is twice the number of rotors. In yet another preferred embodiment, the number of rotors 220 is in the range of one to one hundred. In a further preferred embodiment, the number of stators 230 is in the range of one to one hundred. In other preferred embodiments, the number of rotors 220, stators 230 and/or flux interfaces may be alternately selected with efficacy, as needed or desired, giving due consideration to the goals of providing a wide dynamic torque range, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

Advantageously, the induced yield stress or viscous torque is proportional to the overlap area between a rotor-stator pair multiplied by twice the number of rotors (the number of MR fluid to rotor interfaces which produce braking torque in the presence of a magnetic field). This desirably allows the viscous torque or yield stress to be increased or decreased by selecting or predetermining the number of rotors 220 and/or stators 230 and/or the overlap or mating surface area between adjacent rotors 220 and/or stators 230. Another advantage is that this permits control over the overall size, that is radial size and lateral size, of the MR actuated prosthetic knee 210. For example, the overall knee configuration may be made radially larger and laterally slimmer while providing the same viscous torque range by appropriate selection of the number of flux interfaces and the overlap area of the shearing surfaces.

It is desirable to minimize the MR fluid gap between adjacent rotors 220 and stators 230 since the power needed to saturate the total MR fluid gap is a strong function of the gap size. Thus, advantageously, a smaller gap size renders the MR actuated brake 210 more efficient and reduces power consumption.

Preferably, the MR fluid gap size is also selected so that in the absence of an applied magnetic field only a viscous damping force or torque component is present from the shearing of

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MR fluid between adjacent rotor and stator surfaces. That is, there is no frictional torque component between the rotors 220 and stators 230 under zero-field conditions.

Accordingly, in one preferred embodiment, the power required to saturate the MR fluid is lowered and the dynamic range of the knee is enhanced by minimizing the MR fluid gap size. In this embodiment, the gap is not reduced so much that, under zero-field conditions, a normal force acts between adjacent rotor and stator surfaces, causing frictional rubbing. The absence of friction between rotors and stators enables the knee joint to swing freely, thereby providing a wider dynamic range. As a note, the viscous damping at zero-field does not increase dramatically with decreasing fluid gap because the MR fluid exhibits a property known as shear rate thinning in which fluid viscosity decreases with increasing shear rate.

In one preferred embodiment, the MR fluid gap size or width between adjacent rotors 220 and stators 230 is about 40 microns (μm) or less. In another preferred embodiment, the MR fluid gap size or width between adjacent rotors 220 and stators 230 is in the range from about 10 μm to about 100 μm . In other preferred embodiments, the MR fluid gap size can be alternately dimensioned and/or configured with efficacy, as required or desired, giving due consideration to the goals of providing an energy efficient prosthetic knee 210 having a wide dynamic torque range, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, the prosthetic knee of the invention comprises a single stator or blade 230 coupled to the outer spline 232 and no rotors or blades 220. Thus, two MR fluid gaps are created between the blade 230 and the core side plates 216, 218. Preferably, the size of the MR fluid gaps is minimized, as discussed above.

In accordance with another preferred embodiment of the present invention, the disk or blade shaped rotors and stators are replaced by tubular rotors and stators. The tubular rotors and stators preferably comprise a plurality of thin concentrically arranged, alternately rotating and fixed ferrous (or magnetically soft) generally cylindrical tubes. The gaps between the tubes comprises a magnetorheological fluid which is sheared during knee rotation. The magnetic flux activating the MR fluid travels radially outwards. The magnetic return path is closed through a tubular outer ferrous (or magnetically soft) housing and an axially located central core. The viscous torque developed by such a device is the sum of the viscous torques developed between each tubular rotor and stator pair. To minimize weight, volume and energy consumption, preferably, the tubular rotors and stators are made as thin as possible within the constraints primarily of the loading by the magnetic fluid shearing and manufacturing cost. Optionally, one or more of the tubular rotors and/or stators may be radially displaceable to provide a friction component to the total knee torque.

Magnetorheological Fluid

As indicated above, the magnetorheological fluid preferably comprises a plurality of iron, ferrous or magnetic particles suspended in fluid. These suspended particles form torque producing chains in response to an applied magnetic field. Thus, the magnetorheological (MR) fluid undergoes a rheology or viscosity change or variation which is dependent on the magnitude of the applied magnetic field. In turn, this variation in the bulk fluid viscosity determines the magnitude of the shearing force/stress or torque generated, and hence the level of damping or braking provided by the prosthetic knee 210. Typically, the bulk viscosity of the MR fluid increases with increasing strength of the applied field. By controlling the magnitude of this magnetic field, the rotary motion of the artificial limb is rapidly and precisely adjusted and/or con-

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trolled, for example, to control the flexion and extension during swing and stance phases to provide a more natural and safe ambulation for the amputee.

The magnetorheological fluid used in conjunction with the prosthetic knee of the preferred embodiments of the present invention can comprise any one of a number of commercially available or known MR fluids or magnetically controlled mediums. Preferably, the MR fluid possesses a high magnetic flux capacity and low magnetic reluctance and low viscosity while having a large magnetic field induced shearing stress so that, advantageously, the prosthetic knee of the invention provides a wide dynamic torque range.

The MR fluid between the rotor-stator surfaces preferably comprises a carrier fluid with polarizable ferrous or iron particles having a size on the order of a micron or few microns. Ideally the carrier fluid exhibits shear rate thinning behavior where carrier fluid viscosity decreases with increasing shear rate. This advantageously minimizes the viscous torque due to shearing of the MR fluid between each rotor-stator pair under zero-field conditions (that is, when the electromagnet is not energized), and hence allows for a larger operating torque range. Suitable candidates for carrier fluid include silicone oil, hydrocarbon oil, and water based fluids among others.

Outer Spline and Mounting Forks

FIGS. 22-25 show one preferred embodiment of the outer spline 232 of the prosthetic knee joint 210. The outer spline 232 is preferably generally cylindrical in shape and comprises a substantially central cylindrical cavity or through hole 284 for receiving the stators 230, the core side plates 216, 218 and the bearings 226, 228. Alternatively, other suitable shapes for the outer spline 232 and cavity 294 may be efficaciously utilized, as needed or desired.

The central surface of the cavity 294 preferably has a plurality of approximately equally spaced longitudinal grooves 296 which are adapted to engage corresponding teeth 292 of the stators 230. In one preferred embodiment, the grooves 296 are generally semi-circular in shape. In another preferred embodiment, the grooves 296 are generally rectangular or square shaped with rounded corners. In other preferred embodiments, the grooves 296 can be efficaciously shaped and/or configured in alternate manners, as required or desired, giving due consideration to the goals of providing engagement between the stators 230 to the outer spline 232, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

The outer spline cavity 294 preferably has a pair of generally circular shoulders or steps 298 with one on either side of the grooves 296 for aligning or locating with respective cores side plates 216, 218. In one preferred embodiment, two generally circular grooves or flanges are provided within the cavity 294 to receive O-rings or the like and provide a dynamic seal between the rotatable outer spline 232 and the rotatable core side plates 216, 218. The outer spline cavity 294 preferably further includes pair of generally circular shoulders or steps 300 with one on either side of respective shoulders 298 for aligning or locating with respective bearings 226, 228.

In one preferred embodiment, the outer spline 232 includes a pyramid stub or connector 302 at its top end 304 for facilitating connection of the prosthetic knee 210 to a stump socket or residual limb of the amputee. The pyramid connector 302 preferably provides a substantially nonrotatable coupling between the stump socket or residual limb and the outer spline 232, and hence the stators 230. Alternatively, other suitable connectors and fittings may be efficaciously used, as required or desired, giving due consideration to the goals of providing

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reliable attachment between the prosthetic knee 210 and the residual limb of the amputee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, the pyramid stub 302 comprises titanium or a titanium alloy and the remainder of the outer spline 232 comprises anodized 7075-T6 aluminum alloy. Advantageously, the hard anodized aluminum alloy surface protects the surfaces of the outer spline grooves 296 against surface damage and hence eliminates or mitigates any backlash, jarring or play. In another preferred embodiment, the outer spline 232 is fabricated from titanium or a titanium alloy. In yet another preferred embodiment, the outer spline 232 is fabricated from anodized 7075-T6 aluminum alloy. In other preferred embodiments, the outer spline 232 can be efficaciously fabricated from other metals, alloys, plastics, ceramics among others, as required or desired, giving due consideration to the goals of providing a suitably strong, durable, light weight and/or substantially non-magnetic outer spline 232, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

Preferably, the outer spline 232 is formed by machining. In one preferred embodiment, a titanium or titanium block is threaded into a threaded cavity of the top end 304 of the outer spline 232, secured with Locktite and machined to form the pyramid stub 302, thereby allowing for proper juxtapositioning of the pyramid stub 302. In other preferred embodiments, the outer spline 232 can be efficaciously fabricated from other techniques, for example, casting, forging, molding, among others, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, and referring in particular to FIG. 23, the outer spline 232 is dimensioned and configured such that the major diameter D_{231} is about 5.994 cm (2.360 inches), the diameter D_{232} is about 4.813 cm (1.895 inches), the blind-circle diameter D_{233} is about 4.811 cm (1.894 inches), the groove curvature diameter D_{234} is about 3.20 mm (0.126 inches), the length L_{231} is about 8.0 mm (0.315 inches), the angle θ_{231} is about 33.7°, the angle θ^{232} is about 15°, the angle θ_{233} is about 15°, the radius of curvature R_{231} is about 2.40 cm (0.945 inches) and the radius of curvature R_{232} is about 0.762 mm (0.030 inches). In other preferred embodiments, the outer spline 232 may be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, and referring in particular to FIGS. 24-25, the outer spline 232 is dimensioned and configured such that the diameter D_{241} is about 4.00 cm (1.575 inches), the diameter D_{251} is about 5.715 cm (2.250 inches), the diameter D_{252} is about 5.398 cm (2.125 inches), the length L_{251} is about 7.861 cm (3.095 inches), the length L_{252} is about 1.067 cm (0.420 inches), the width W_{251} is about 4.171 cm (1.642 inches), the width W_{252} is about 1.958 cm (0.771 inches), the width W_{253} is about 6.35 mm (0.250 inches), the width W_{254} is about 4.72 mm (0.186 inches) and the radius of curvature R_{251} is about 3.05 mm (0.120 inches). In other preferred embodiments, the outer spline 232 may be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

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The mounting forks 236, 238 (FIG. 4) of the magnetorheologically actuated prosthetic knee 210 are preferably in mechanical communication with the bearings 226, 228 respectively and transfer rotary motion to a pylon or artificial shin portion of the amputee. Threaded studs 306 or other suitable connectors or fasteners are used to facilitate connection of the mounting forks 236, 238 to a pylon or artificial shin portion of the amputee.

Preferably, the mounting forks 236, 238 are fabricated from anodized 7075-T6 aluminum alloy. In other preferred embodiments, the mounting forks 226, 238 can be efficaciously fabricated from other metals, alloys, plastics, ceramics among others, as required or desired, giving due consideration to the goals of providing suitably strong, durable, light weight and/or substantially non-magnetic mounting forks 226, 238, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, the mounting forks 236, 238 are formed by machining. In other preferred embodiments, the mounting forks 236, 238 can be efficaciously fabricated from other techniques, for example, casting, forging, molding, among others, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, and as shown in FIG. 4, the prosthetic knee 210 further comprises a flexion stop system or assembly comprising a cushioned stop or restraint assembly 246. The flexion stop system controls the maximum allowable flexion angle by physically limiting the rotation between the outer side forks 236, 238 and the outer spline 232, and hence the rotation of the knee joint.

The stop system 246 (FIG. 4) generally comprises a plurality of stops, bands or strips 312, 314 and 316. The bands 312 and 314 are attached to an angled outer surface 308 (see FIG. 23) of the outer spline 232 using screws or the like. The band 316 is attached to angled outer surfaces 333, 334 of the side forks 236, 238, respectively, using screws or the like.

The prosthetic knee 210 is preferably configured so that at a predetermined maximum flexion angle the band 316 contacts or stops against the band 314 and prevents or restricts further knee rotation. Preferably, the band 314 comprises a resilient material to provide a shock absorbing, cushioning and/or dissipating effect. Similarly, the prosthetic knee of the preferred embodiments can comprise a shock absorbing extension stop, as needed or desired.

In one preferred embodiment, the flexion stop system of the present invention is configured to allow a maximum flexion angle of about 140°. In another preferred embodiment, the flexion stop system of the present invention is configured to allow a maximum flexion angle in the range from about 125° to about 150°. In other preferred embodiments, the maximum flexion angle can be efficaciously varied, as needed or desired, depending on the ambient conditions, activity and activity level, among other factors.

In one preferred embodiment, the stop 314 is fabricated from rubber and the stops 312, 316 are fabricated from titanium or a titanium alloy. In other preferred embodiments, the stops 312, 314, 316 can be efficaciously fabricated from other materials as required or desired, giving due consideration to the goals of providing a suitably strong, durable, light weight and/or cushioned flexion stop, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, the stops 312, 314, 316 have a major length of about 6.00 cm (2.363 inches) and a major

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width of about 5.99 mm (0.236 inches). In other preferred embodiments, the stops 312, 314, 316 may be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, the prosthetic knee 210 comprises an angle sensing potentiometer 322 (FIG. 4). The potentiometer 322 is connected to an arm 324 and a mounting plate 326. The mounting plate 326 is connected to the fork 238 utilizing screws 328 or the like and spacers 330. An end 332 of the arm 324 is mechanically connected to the angled outer surface 334 of the fork 238 utilizing suitable screws or the like.

In one preferred embodiment of the present invention, the prosthetic knee 210 further comprises an extension assist to help straighten the leg by urging or biasing the leg to extension by applying a controlled torque or force. Any one of a number of devices, such as a spring-loaded extension assist, as known in the art may be used in conjunction with the present invention.

Preferably, a feedback control system is provided to control and monitor the actuations of the magnetorheologically actuated prosthetic knee of the preferred embodiments of the present invention. The control system generally comprises a central controller or microprocessor and memory, one or more force, torque and angle sensors, a power source (such as a battery or the like) and other associated hardware and software. An outer housing or casing is preferably provided to house and/or protect the various components of the prosthetic knee of the preferred embodiments and the control system. A suitable cosmetic covering is also preferably provided over the outer housing.

Certain Operational Features and Advantages

The electronically controlled magnetorheologically actuated prosthetic knee of the preferred embodiments provides high-speed instantly responsive control of knee movement, yet is robust and affordable for the amputee. The preferred embodiments advantageously provide improved stability, gait balance and energy efficiency for amputees and simulates and/or closely recreates the dynamics of a natural knee joint.

During operation, the electromagnet or magnetic coil 214 is actuated, as needed, by a selected or predetermined electrical signal, voltage or current to generate an active variable magnetic field passing substantially perpendicularly to the plurality of rotor and stator surfaces and through the MR fluid or film between adjacent rotors 220 and stators 230 to generate a variable damping torque (or rotary resistive force) which precisely and accurately controls the rotary motion of the prosthetic knee 210. As discussed above, in accordance with one preferred embodiment, the torque comprises a frictional damping component.

Desirably, the MR actuated prosthetic knee 210 of the preferred embodiments provides a rapid and precise response. The materials in MR particles respond to the applied magnetic field within milliseconds, thereby allowing for real-time control of the fluid rheology and the knee motion. This facilitates in permitting the patient to move in a safe and/or more natural manner.

Advantageously, the viscous damping torque is generated by shearing of the MR fluid. Hence, there is no or negligible pressure build-up or change within the MR actuated prosthetic knee 210 of the present invention. This substantially eliminates or reduces the chances of fluid leakage and failure of the knee, and hence desirably adds to the safety. Moreover,

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costly and/or relatively complex components such as pressure bearings and the like need not be utilized to provide a reliable seal.

Another advantage is that the plurality of shearing surfaces or flux interfaces between adjacent rotors 220 and stators 230 behave like a torque multiplier and allow the viscous torque level (and/or frictional torque) to be stepped up to a desired maximum value without the use of an additional transmission or other auxiliary component. Moreover, the flexibility in selecting the overlap surface area between adjacent rotors 220 and stators 230 can also increase or decrease the maximum attainable viscous torque (and/or frictional torque). Thus, desirably a wide dynamic torque or torsional resistance range can be provided, as needed or desired, which adds to the versatility of the invention without adding substantially to system size, weight and complexity.

In one preferred embodiment, the prosthetic knee of the present invention provides a maximum dynamic torque of about 40 Newton-meters (N-m). In another preferred embodiment, the prosthetic knee of the present invention provides a dynamic torque in the range from about 0.5 N-m to about 40 N-m. In yet another preferred embodiment, the prosthetic knee of the present invention provides a dynamic torque in the range from about 1 N-m to about 50 N-m. In other preferred embodiments, the prosthetic knee of the present invention can provide other dynamic torque ranges with efficacy, as needed or desired, giving due consideration to the goals of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, the prosthetic knee of the present invention precisely controls the knee rotation, during extension and flexion phases, between full extension and a flexion angle of about 140°. In another preferred embodiment, the prosthetic knee of the present invention precisely controls the knee rotation, during extension and flexion phases, between full extension and a flexion angle in the range from about 125° to about 150°. In other preferred embodiments, the prosthetic knee of the present invention can provide other knee rotation ranges with efficacy, as needed or desired, giving due consideration to the goals of achieving one or more of the benefits and advantages as taught or suggested herein.

Also advantageously, the optimized thinness of the MR fluid gap between adjacent rotors 220 and stators 230 provides a higher maximum torque, a wider dynamic torque range and requires less energy consumption, preferably about 10 Watts or less. This adds to the efficiency and practicality of the MR actuated prosthetic knee 210 of the present invention and also saves on cost since a lower wattage and/or less complex power source can be used.

Other Preferred Embodiments

FIGS. 26 to 51 show several preferred embodiments having features and advantages in accordance with the present invention. For purposes of clarity and brevity of disclosure only certain features of these embodiments are discussed below and it is to be understood that other features are obvious from the drawings and/or are embodied in the description of the preferred embodiments as set forth above.

FIGS. 26-28 show one preferred embodiment of a substantially central core 412 of a magnetorheologically actuated prosthetic knee of the present invention. The core 412 preferably comprises a beveled or tapered surface 336 and a shoulder or step 338 at respective ends of respective core portions 452, 454 to facilitate mating engagement or mechanical connection with associated core side plates 416, 418 (shown in FIGS. 29-36). Thus, the core 412 rotates as the side plates 416, 418 rotate.

Preferably, the core 412 comprises an iron-cobalt (FeCo) high magnetic saturation alloy. In one preferred embodiment, the core 412 comprises Iron-Cobalt High Saturation Alloy (ASTM A-801 Type 1 Alloy), which specifies a composition with about 50% cobalt. For example, the core [212] 412 may comprise Hiperco Alloy 50®, Permendur V™ or Vanadium [Pemendur] *Permendur*, as available from Principal Metals, Vacoflux 50 as available from Vacuumschmelze of Hanau, Germany.

The core 412 is preferably formed by machining followed by heat treatment in a dry hydrogen atmosphere to achieve optimal magnetic properties. The core 412 is annealed in a dry hydrogen atmosphere preferably for about five hours at a temperature of about 820° Celsius. The core 412 is then cooled in a dry hydrogen atmosphere at about 150° Celsius/hour until a temperature of about 200° Celsius is reached. Care is taken to avoid contamination during heat treatment and any grease, oil, fingerprints and the like are removed using acetone or other suitable cleaning solvents. During heat treatment, the core 412 is preferably separated from the core side plates 416 and 418 to avoid any possible welding between the components.

In one preferred embodiment, and referring in particular to FIGS. 27 and 28, the core 412 is dimensioned and configured such that the length L₂₇₁ is about 2.517 cm (0.991 inches), the length L₂₇₂ is about 5.56 mm (0.220 inches), the length L₂₇₃ is about 0.51 mm (0.020 inches), the length L₂₇₄ is about 0.51 mm (0.020 inches), the diameter D₂₇₁ is about 1.424 cm (0.5605 inches), the diameter D₂₇₂ is about 1.415 cm (0.557 inches), the angle θ₂₇₁ is about 10° and the diameter D₂₈₁ is about 1.88 cm (0.740 inches). In other preferred embodiments, the core 412 may be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

FIGS. 29-33 show one preferred embodiment of a core side plate 416 of a magnetorheologically actuated prosthetic knee of the present invention. The core side plate 416 preferably comprises a substantially central cavity or through hole 456 adapted to matingly form an interference fit with the end of the core portion 452 (FIGS. 26-28) and three approximately equally spaced through holes 458 arranged in a generally circular fashion to receive bolts or the like to fasten the various components of the prosthetic knee. The core side plate 416 further comprises a generally circular groove or recess 356 adapted to engage or mechanically connect with a flange of the electromagnet 414 (FIGS. 37-39). Thus, the electromagnet or magnetic coil 414 rotates as the core side plate 416 rotates.

Preferably, tapers or tapered surfaces or portions 470, 471 are provided on respective outer and inner surfaces of the core side plate 416. This advantageously decreases weight, saves material and also provides clearance space to facilitate assembly. The rotatable core side plate 416 forms a dynamic seal with a rotatable outer spline utilizing an O-ring or the like provided within a groove or flange of the outer spline.

Preferably, the core side plate 416 comprises an iron-cobalt (FeCo) high magnetic saturation alloy. In one preferred embodiment, the core side plate 416 comprises Iron-Cobalt High Saturation Alloy (ASTM A-801 Type 1 Alloy), which specifies a composition with about 50% cobalt. For example, the core [212] side plate 416 may comprise Hiperco Alloy 50®, Permendur V™ or Vanadium [Pemendur] *Permendur*, as available from Principal Metals, Vacoflux 50 as available from Vacuumschmelze of Hanau, Germany.

The core side plate 416 is preferably formed by machining followed by heat treatment in a dry hydrogen atmosphere to achieve optimal magnetic properties. The core side plate 416 is annealed in a dry hydrogen atmosphere preferably for about five hours at a temperature of about 820° Celsius. The core side plate 416 is then cooled in a dry hydrogen atmosphere at about 150° Celsius/hour until a temperature of about 200° Celsius is reached. Care is taken to avoid contamination during heat treatment and any grease, oil, fingerprints and the like are removed using acetone or other suitable cleaning solvents. During heat treatment, the core side plate 416 is preferably separated from the core 412 to avoid any possible welding between the components.

In one preferred embodiment, and referring in particular to FIGS. 30-33, the core side plate 416 is dimensioned and configured such that the diameter D₃₀₁ is about 3.353 cm (1.320 inches), the diameter D₃₀₂ is about 2.461 cm (0.969 inches), the blind-circle diameter D₃₁₁ is about 2.845 cm (1.120 inches), the diameter D₃₁₂ is about 2.43 cm (0.958 inches), the diameter D₃₁₃ is about 2.29 cm (0.900 inches), the hole diameter D₃₁₄ is about 2.95 mm (0.116 inches), the angle θ₃₁₁ is typically 120°, the diameter D₃₂₁ is about 4.80 cm (1.890 inches), the diameter D₃₂₂ is about 3.30 cm (1.300 inches), the diameter D₃₂₃ is about 1.88 cm (0.740 inches), the width W₃₂₁ is about 5.59 mm (0.220 inches), the width W₃₂₂ is about 1.27 mm (0.050 inches), the width W₃₃₁ is about 2.54 mm (0.100 inches), the width W₃₃₂ is about 0.508 mm (0.020 inches), the width W₃₃₃ is about 1.52 mm (0.060 inches), the radius of curvature R₃₃₁ is about 6.35 mm (0.250 inches), the radius of curvature R₃₃₂ is about 0.254 mm (0.010 inches), the angle θ₃₃₁ is about 30° and the angle θ₃₃₂ is about 10°. In other preferred embodiments, the core side plate 416 may be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

FIGS. 34-36 show one preferred embodiment of a second core side plate 418 of a magnetorheologically actuated prosthetic knee of the present invention. The core side plate 418 is substantially the same as the first core side plate 416 except that it comprises a substantially central cavity or through hole 457 adapted to matingly form an interference fit with the end of the core portion 454 (FIGS. 26-28) and a pair of through holes 472 which permit passage of electrical wires or leads connected to an electromagnet or magnetic coil 414 (FIGS. 37-39) of the prosthetic knee of the present invention.

In one preferred embodiment, and referring in particular to FIGS. 35 and 36, the core side plate 418 is dimensioned and configured such that the length L₃₅₁ is about 1.14 cm (0.448 inches), the length L₃₅₂ is about 1.05 cm (0.413 inches), the hole diameter D₃₅₅ is about 1.78 mm (0.070 inches) and the diameter D₃₆₃ is about 1.42 cm (0.560 inches). The other dimensions D₃₅₁, D₃₅₂, D₃₅₃, D₃₅₄, θ₃₅₁, D₃₆₁, D₃₆₂, [W₃] 55 W₃₆₁ and W₃₆₂ are substantially the same as the dimensions D₃₁₁, D₃₁₂, D₃₁₃, D₃₁₄, θ₃₁₁, D₃₂₁, D₃₂₂, W₃₂₁ and W₃₂₂, respectively, as shown on FIGS. 31 and 32 and stated above for the first core side plate 416. In other preferred embodiments, the core side plate 418 may be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

FIGS. 37-39 show one preferred embodiment of an electromagnet, magnetic coil or wire spool 414 of a magnetorheologically actuated prosthetic knee of the present invention.

The magnetic coil 414 generally comprises a bobbin 340 having a pair of flanges 342, 344 at each end, winding 350 generally circumscribing the bobbin 340 and connected to electrical lead wires 352. A pair of slots or through holes 346, 348 in the bobbin flange 344 permit passage of the leads 352 which connect to a battery or other power source.

The magnetic coil 414 is preferably generally cylindrical in shape and has a generally cylindrical through passage 358 for receiving the core 412 (FIGS. 26-28) to mechanically connect the magnetic coil 414 to the core 412. The flanges 342 and 344 are received in grooves or recesses of respective side plates 416 and 418 (FIGS. 29-36) to mechanically connect the magnetic coil 414 to the side plates 416, 418. Thus, as the core side plates 416, 418 rotate so do the magnetic coil 414 and core 412.

Preferably, the bobbin 440 is fabricated from polyphenylene sulfide having a temperature rating of about 200° Celsius. The winding 350 preferably comprises three hundred and forty turns of 30 AWG copper wire having a resistance of about 8.03 ohms (Ω) and a power rating of about 13.7 watts at about 10.5 volts DC. The winding insulation comprises a suitable material having a temperature rating of about 155° Celsius. Preferably, the lead wires 352 comprise 24 AWG stranded wire about 8 inches long and covered with a teflon insulation with an about 0.25 inches section stripped and tinned.

In one preferred embodiment, and referring in particular to FIGS. 38 and 39, the electromagnet or magnetic coil 414 is dimensioned and configured such that the length L_{381} is about 1.138 cm (0.448 inches), the length L_{382} is about 1.05 cm (0.413 inches), the width W_{381} is about 0.762 mm (0.030 inches), the radius of curvature R_{381} is about 0.381 mm (0.015 inches), the diameter D_{381} is about 0.762 mm (0.030 inches), the diameter D_{391} is about 2.45 cm (0.965 inches), the diameter D_{392} is about 1.89 cm (0.745 inches), the diameter D_{393} is about 2.02 cm (0.795 inches), the length L_{391} is about 1.95 cm (0.766 inches), the length L_{392} is about 1.74 cm (0.686 inches), the length L_{393} is about 1.02 mm (0.040 inches), the length L_{394} is about 1.02 mm (0.040 inches) and the thickness T_{391} is about 0.635 mm (0.025 inches). In other preferred embodiments, the magnetic coil 414 may be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

FIGS. 40-44 show one preferred embodiment of an inner spline 422 of a magnetorheologically actuated prosthetic knee of the present invention. The inner spline 422 comprises a plurality of longitudinal grooves or notches 484 for engaging or mating with corresponding teeth of rotors 420 (FIGS. 45-47) and a substantially central cavity 476 for receiving the magnetic coil 414 (FIGS. 37-39). Preferably, the inner spline 422 comprises nine substantially equally spaced grooves 484 having a substantially rectangular or square shape with rounded corners.

The inner spline cavity 476 preferably includes three longitudinal cavities or passages 478 which are substantially aligned with the bolt-receiving holes of the core side plates 416, 418 (FIGS. 31 and 35). The passages 478 receive bolts or the like to fasten or secure the inner spline 422 and the core side plates 416, 418. The inner spline cavity 476 further includes a plurality of longitudinal recesses 360 which serve to reduce the weight of the inner spline 422, and hence that of the prosthetic knee.

The inner spline 422 preferably comprises a flange 480 at each end to receive an O-ring, gasket or the like to form a

static seal between the rotatable inner spline 422 and the rotatable core side plates 416, 418. An adjacent step, shoulder or flange 362 is also provided on each end to facilitate mounting of the O-rings or gaskets on the inner spline 422 during assembly of the prosthetic knee.

Preferably, the inner spline 422 is manufactured by wire electro-discharge machining (EDM). The inner spline 422 is preferably fabricated from titanium or a titanium alloy to provide a non-ferrous yet strong, hard surface with low weight to engage the rotors 420 and transmit torque from them. More preferably, the inner spline is fabricated from 6A1-4V titanium alloy.

In one preferred embodiment, and referring in particular to FIGS. 41-44, the inner spline 422 is dimensioned and configured such that the blind-circle diameter D_{411} is about 2.85 cm (1.120 inches), the diameter D_{412} is about 2.46 cm (0.970 inches), the passage diameter D_{413} is about 2.95 mm (0.116 inches), the angle θ_{411} is typically about 120°, the angle θ_{412} is typically about 40°, the length L_{421} is about 2.24 cm (0.881 inches), the length L_{422} is about 1.96 cm (0.771 inches), the curved length L_{431} is about 1.02 cm (0.402 inches), the curved length L_{432} is about 4.17 mm (0.164 inches), the curved length L_{433} is about 1.88 mm (0.074 inches), the curved length L_{434} is about 8.92 mm (0.351 inches), the major diameter D_{431} is about 3.63 cm (1.430 inches), the diameter D_{432} is about 3.43 cm (1.350 inches), the diameter D_{433} is about 2.90 cm (1.140 inches), the profile tolerance width W_{431} is about 0.0254 mm (0.001 inches), the radii of curvature $R_{431}, R_{432}, R_{433}, R_{434}, R_{435}$ are about 1.27 mm (0.050 inches), 1.27 mm (0.050 inches), 0.762 mm (0.030 inches), 0.381 mm (0.015 inches), 0.381 mm (0.015 inches), respectively, the angle θ_{431} is about 20°, the length L_{441} is about (0.055 inches), the length L_{442} is about 0.381 mm (0.015 inches), the length L_{443} is about 0.127 mm (0.005 inches), the length L_{444} is about 0.127 mm (0.005 inches), the diameter D_{441} is about 3.345 cm (1.317 inches), the diameter D_{442} is about 3.226 cm (1.270 inches), the radius of curvature R_{441} is about 0.20 mm (0.008 inches) and the radius of curvature R_{442} is about 0.51 mm (0.020 inches). In other preferred embodiments, the inner spline 422 may be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

FIGS. 45-47 show one preferred embodiment of one of the rotors or inner blades 420 of a magnetorheologically actuated prosthetic knee of the present invention. The preferably annular or ring shaped thin rotor 420 is generally circular in shape and comprises a substantially central cavity or through hole 486 having a plurality of inwardly extending teeth 488 adapted to engage or mate with the inner spline grooves 484 (FIG. 41). Preferably, the rotor 420 comprises nine approximately equally spaced teeth 488 which are generally rectangular or square shaped with rounded corners.

The rotors 420 are preferably fabricated from a mechanically hard, magnetically soft material that has a high saturation flux density. More preferably, the rotors 420 are fabricated from blue temper steel. The rotors 420 are preferably formed by wire electro-discharge machining (EDM). Advantageously, this permits a high degree of manufacturing precision and avoids or mitigates any backlash, jarring or play between the rotors 420 and inner spline 422 which may otherwise cause discomfort to the patient.

In one preferred embodiment, and referring in particular to FIGS. 45-47, the rotors 420 are dimensioned and configured such that the major outer diameter D_{451} is about 4.851 cm

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(1.910 inches), the thickness T_{461} is about 0.203 mm (0.008 inches), the curved length L_{471} is about 9.12 mm (0.359 inches), the curved length L_{472} is about 1.73 mm (0.068 inches), the major inner diameter D_{471} is about 3.642 cm (1.434 inches), the minor inner diameter D_{472} is about 3.439 cm (1.354 inches), the profile tolerance width W_{471} is about 0.0254 mm (0.001 inches), the radius of curvature R_{471} is about 0.508 mm (0.020 inches), the radius of curvature R_{472} is about 0.254 mm (0.010 inches) and the angle θ_{471} is about 40°. In other preferred embodiments, the rotors 420 may be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, the ratio between the rotor major outer diameter (D_{451}) and the rotor major inner diameter (D_{471}) is about 1.3. In another preferred embodiment, the ratio between the rotor major outer diameter (D_{451}) and the rotor major inner diameter (D_{471}) ranges between about 1.2 to about 5. In yet another preferred embodiment, the ratio between the rotor major outer diameter (D_{451}) and the rotor major inner diameter (D_{471}) ranges between about 1.1 to about 10. In other preferred embodiments, this ratio may be varied with efficacy, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

FIGS. 48-50 show one preferred embodiment of one of the stators or outer blades 430 of a magnetorheologically actuated prosthetic knee of the present invention. The preferably annular or ring shaped thin stator 430 is generally circular in shape and comprises a substantially central cavity or through hole 490 adapted to non-contactingly receive the inner spline 422 and a plurality of outwardly extending teeth 492 on the stator outer periphery which are adapted to engage or mate with grooves or notches on the interior of a rotatable outer spline of the prosthetic knee. Preferably, the stator 430 comprises nine approximately equally spaced teeth 492 which are generally rectangular or square shaped with rounded corners.

The stators 430 are preferably fabricated from a hard ferrous material that has a high saturation flux density. More preferably, the stators 430 are fabricated from blue temper steel. The stators 430 are preferably formed by wire electro-discharge machining (EDM). Advantageously, this permits a high degree of manufacturing precision and avoids or mitigates any backlash, jarring or play between the stators 430 and outer spline which may otherwise cause discomfort to the patient.

In one preferred embodiment, and referring in particular to FIGS. 48-50, the stators 430 are dimensioned and configured such that the major inner diameter D_{481} is about 3.658 cm (1.440 inches), the thickness T_{491} is about 0.203 mm (0.008 inches), the curved length L_{501} is about 1.18 cm (0.464 inches), the curved length L_{502} is about 3.66 mm (0.144 inches), the major outer diameter D_{501} is about 5.07 cm (1.996 inches), the minor outer diameter D_{502} is about 4.867 cm (1.916 inches), the profile tolerance width W_{501} is about 0.0254 mm (0.001 inches), the radius of curvature R_{501} is about 0.508 mm (0.020 inches), the radius of curvature R_{502} is about 0.254 mm (0.010 inches) and the angle θ_{501} is about 20°. In other preferred embodiments, the stators 430 may be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or

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durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

In one preferred embodiment, the ratio between the stator minor outer diameter (D_{502}) and the stator major inner diameter (D_{481}) is about 1.3. In another preferred embodiment, the ratio between the stator minor outer diameter (D_{502}) and the stator major inner diameter (D_{481}) ranges between about 1.2 to about 5. In yet another preferred embodiment, the ratio between the stator minor outer diameter (D_{502}) and the stator major inner diameter (D_{481}) ranges between about 1.1 to about 10. In other preferred embodiments, this ratio may be varied with efficacy, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

FIG. 51 shows a magnetorheologically actuated prosthetic knee 510 having features and advantages in accordance with another preferred embodiment of the present invention. In this embodiment, the magnetic return path passes through the exterior of the prosthetic knee 510. Such a configuration can allow for a more compact and/or light weight system design. Other suitable magnetic return paths can be selected or configured, as needed or desired, giving due consideration to the goals of achieving one or more of the benefits and advantages as taught or suggested herein.

Referring to FIG. 51, a magnetic field 540 is generated by the actuation of an electromagnet or magnetic coil 514 preferably positioned between a plurality of interspersed alternating rotors (inner blades) 520 and stators (outer blades) 530 and an outer magnetically soft housing or casing 512 of the prosthetic knee 510. The active portion of the magnetic field 540 passes (travelling substantially in the lateral direction 542) through the rotors 520, stators 530 and the magnetorheological fluid in the gaps therebetween. The return path of the magnetic field 540 passes radially outwards through a magnetically soft side plate 516, laterally through the knee exterior 512 and radially inwards through a second magnetically soft side plate 518.

While the components and techniques of the present invention have been described with a certain degree of particularity, it is manifest that many changes may be made in the specific designs, constructions and methodology hereinabove described without departing from the spirit and scope of this disclosure. It should be understood that the invention is not limited to the embodiments set forth herein for purposes of exemplification, but is to be defined only by a fair reading of the appended claims, including the full range of equivalency to which each element thereof is entitled.

What is claimed is:

1. A prosthetic knee, comprising:
a plurality of rotors being rotatable about a longitudinal axis of said prosthetic knee;
a plurality of stators alternately interspersed with said rotors to form gaps therebetween;
a fluid adapted to undergo a rheology change in response to an applied magnetic field and residing in said gaps formed between said rotors and said stators;
whereby, controlled variation of said magnetic field varies the fluid rheology and shearing of said fluid caused by relative rotation between said rotors and stators during knee rotation generates a controllable variable knee torque.
2. The prosthetic knee of claim 1, wherein said stators are rotatable about the longitudinal axis of said prosthetic knee.
3. The prosthetic knee of claim 1, wherein at least one of said rotors and said stators are laterally displaceable about the

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longitudinal axis of said prosthetic knee to create mechanical contact between adjacent rotors and stators to provide a frictional component to the torque.

4. The prosthetic knee of claim 1, wherein said rotors and said stators comprise a magnetically soft material.

5. The prosthetic knee of claim 1, wherein said rotors and said stators comprise generally annular disks.

6. The prosthetic knee of claim 5, wherein said rotors and said stators have a thickness of about 0.2 mm (0.008 inches).

7. The prosthetic knee of claim 1, wherein said plurality of rotors comprises hundred or less rotors and said plurality of stators comprises hundred or less stators.

8. The prosthetic knee of claim 7, wherein said plurality of rotors comprises forty rotors and said plurality of stators comprises forty one stators.

9. The prosthetic knee of claim 1, wherein said gaps between said rotors and said stators have a size in the range from about 10 microns (μm) to about 100 microns (μm).

10. The prosthetic knee of claim 9, wherein said gaps between said rotors and said stators have a size of about 40 microns (μm).

11. The prosthetic knee of claim 1, wherein said rotors and said stators comprise generally cylindrical tubes.

12. The prosthetic knee of claim 1, wherein said rotors and said stators comprise blue temper steel or silicon steel.

13. The prosthetic knee of claim 1, wherein said fluid comprises a magnetically controllable medium.

14. The prosthetic knee of claim 1, wherein said fluid comprises a magnetorheological fluid adapted to undergo a viscosity change in response to variation in said magnetic field.

15. The prosthetic knee of claim 1, further comprising a magnet to generate said magnetic field which passes through said rotors, said stators and said fluid.

16. The prosthetic knee of claim 1, further comprising a generally central core in mechanical communication with a pair of side plates to form a magnetic return path for said magnetic field.

17. The prosthetic knee of claim 16, wherein said core and said side plates comprise an iron-cobalt (FeCo) high magnetic saturation alloy.

18. The prosthetic knee of claim 16, wherein at least one of said side plates is laterally displaceable about the longitudinal axis of said prosthetic knee.

19. The prosthetic knee of claim 1, further comprising: a substantially central core and a pair of side plates formed from a magnetically soft material to create a magnetic return path; and

an electromagnet positioned between said core and said rotors and said stators and being responsive to an electrical signal to generate said magnetic field to cause a controlled change in the rheology of said fluid.

20. The prosthetic knee of claim 1, further comprising a rotatable inner spline with said rotors engaged with said inner spline.

21. The prosthetic knee of claim 20, wherein said inner spline comprises a plurality of longitudinal grooves and each of said rotors comprises a plurality of teeth matingly engaged with said longitudinal grooves of said inner spline.

22. The prosthetic knee of claim 20, wherein said inner spline comprises a titanium alloy.

23. The prosthetic knee of claim 20, further comprising a pair of bearings in rotary communication with said inner spline.

24. The prosthetic knee of claim 23, further comprising a pair of rotatable side mounting forks with each in mechanical

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communication with one of said bearings to facilitate connection of said prosthetic knee to a prosthetic shin.

25. The prosthetic knee of claim 1, further comprising an outer spline with said stators engaged with said outer spline.

5 26. The prosthetic knee of claim 25, wherein said outer spline comprises a plurality of longitudinal grooves and each of said stators comprises a plurality of teeth matingly engaged with said longitudinal grooves of said outer spline.

27. The prosthetic knee of claim 25, wherein said outer 10 spline comprises an anodized aluminum alloy.

28. The prosthetic knee of claim 25, wherein said outer spline comprises a pyramid stub to facilitate connection of said prosthetic knee to a residual limb socket.

15 29. The prosthetic knee of claim 1, further comprising a magnetic exterior portion and a pair of mechanically connected magnetic side plates to create a magnetic return path for said magnetic field.

30. The prosthetic knee of claim 1, further comprising a cushioned flexion stop system to control the maximum flexion of said prosthetic knee.

31. The prosthetic knee of claim 1, further comprising a cushioned extension stop system to control the maximum extension of said prosthetic knee.

32. The prosthetic knee of claim 1, further comprising an extension assist device for facilitating in extending said prosthetic knee.

33. The prosthetic knee of claim 1, further comprising a controller to control and monitor the actuations of said prosthetic knee.

34. A prosthetic assembly, comprising:
the prosthetic knee as recited in claim 1;
a stump socket in mechanical communication with said prosthetic knee and adapted to receive the residual limb of an amputee;

a prosthetic shin portion in mechanical communication with said prosthetic knee; and

a prosthetic foot in mechanical communication with said prosthetic shin portion.

35. A prosthetic device, comprising:
at least one rotor being actuatable about an axis of the device;
at least one stator being spaced from said at least one rotor and forming a gap therebetween; and
a fluid adapted to undergo a rheology change in response to an applied magnetic field and residing in said gap;
wherein controlled variation of said magnetic field varies the fluid rheology, and shearing of said fluid caused by relative rotation between said at least one rotor and said at least one stator during device rotation generates a controllable variable torque; and
wherein said prosthetic device comprises a prosthetic joint.

36. The prosthetic device of claim 35, wherein said at least one rotor is generally cylindrical.

37. The prosthetic device of claim 35, wherein said at least one stator is generally cylindrical.

38. The prosthetic device of claim 35, wherein said at least one rotor and said at least one stator are generally cylindrical.

39. The prosthetic device of claim 35, further comprising an outer housing.

60 40. The prosthetic device of claim 39, wherein said outer housing includes a connector for facilitating connection to a stump socket or a residual limb of an amputee.

41. The prosthetic device of claim 40, wherein said connector is a pyramid connector.

42. The prosthetic device of claim 35, wherein the joint is a prosthetic knee.

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43. The prosthetic device of claim 35, wherein said fluid comprises a magnetorheological fluid.

44. The prosthetic device of claim 35, further comprising at least one sensor for measuring an angle of rotation between said at least one rotor and said at least one stator.

45. The prosthetic device of claim 35, further comprising a microprocessor.

46. The prosthetic device of claim 35, in combination with a prosthetic foot mechanically coupled to the joint.

47. A prosthetic device system, comprising:
an outer generally cylindrical member comprising a substantially cylindrical cavity;

an inner generally cylindrical member provided within said substantially cylindrical cavity, wherein said inner and outer generally cylindrical members are rotatable about a device axis of rotation relative to one another;

a magnetorheological fluid residing in a cavity between said inner and outer generally cylindrical members; and

a connector at a top end of said outer generally cylindrical member for facilitating connection to a stump socket or a residual limb of an amputee;

wherein a damping torque to control device rotation is provided by shearing of said magnetorheological fluid; and

wherein said prosthetic device system comprises a prosthetic joint system.

48. The prosthetic device system of claim 47, wherein said connector is a pyramid connector.

49. The prosthetic device system of claim 47, wherein said inner generally cylindrical member is rotatable about a knee joint axis of rotation relative to said outer generally cylindrical member.

50. The prosthetic device system of claim 47, wherein said inner generally cylindrical member is mechanically connected to a prosthetic foot.

51. The prosthetic device system of claim 47, further comprising side walls for enclosing said magnetorheological fluid.

52. The prosthetic device system of claim 47, further comprising an electromagnet for applying a magnetic field to said magnetorheological fluid.

53. The prosthetic device system of claim 52, wherein said electromagnet is coupled to one of said generally cylindrical members.

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54. The prosthetic device system of claim 52, further comprising a power source connected with said electromagnet.

55. The prosthetic device system of claim 47, further comprising a feedback control system to control and monitor actuations of the prosthetic joint system.

56. The prosthetic device system of claim 47, further comprising at least one sensor for measuring an angle of rotation between said inner and outer generally cylindrical members.

57. The prosthetic device system of claim 47, further comprising a microprocessor and one or more sensors to provide control and monitor actuations of the prosthetic joint system.

58. The prosthetic device system of claim 47, wherein said magnetorheological fluid is sheared between adjacent cylinders.

59. A device to be worn by a wearer at a joint location, comprising:

a first surface;

a second surface spaced from said first surface to form a gap therebetween;

a fluid adapted to undergo a rheology change in response to an applied magnetic field and residing in said gap; and

at least one of said first surface and said second surface being movable relative to the other;

wherein, variation of said field varies the rheology of said fluid and shearing of said fluid caused by relative motion between said first and second surfaces generates a controllable variable damping of the device; and

wherein the device comprises a prosthetic device, and wherein said prosthetic device comprises a prosthetic joint.

60. The device of claim 59, wherein said prosthetic joint comprises a prosthetic knee.

61. The device of claim 59, wherein said fluid comprises a magnetorheological fluid.

62. The device of claim 59, wherein said fluid comprises a magnetically controllable medium.

63. The device of claim 59, wherein said first and second surfaces are generally cylindrical.

64. The device of claim 59, wherein said field varies the viscosity of said fluid.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : RE42,903 E
APPLICATION NO. : 11/490508
DATED : November 8, 2011
INVENTOR(S) : Bruce W. Deffenbaugh et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Specifications

In Column 1, Line 9, please insert the following:

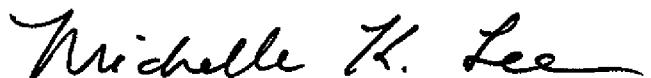
--Notice: More than one reissue application has been filed for the reissue of U.S. Patent No. 6,764,520 B2. The reissue applications include U.S. Patent Application No. 11/490,508, filed July 20, 2006 (the present, now issued, application) and U.S. Patent Application No. 13/273,081, filed October 13, 2011, which is a continuation of the present, now issued, application.--

In Column 6, Line 46, please change "and-having" to --and having--.

In Column 16, Line 34, please change "Currents." to --currents.--

In Column 23, Line 41, please change " θ^{232} " to -- θ_{232} --.

Signed and Sealed this
Twenty-ninth Day of April, 2014



Michelle K. Lee
Deputy Director of the United States Patent and Trademark Office



US005842547A

United States Patent

[19]

Carlson et al.

[11] **Patent Number:** 5,842,547[45] **Date of Patent:** Dec. 1, 1998[54] **CONTROLLABLE BRAKE**

[75] Inventors: **J. David Carlson**, Cary; **Douglas F. LeRoy**, Holly Springs, both of N.C.; **John C. Holzheimer**, Chagrin Falls, Ohio; **Donald R. Prindle**, North East; **Robert H. Marjoram**, Erie, both of Pa.

[73] Assignee: **Lord Corporation**, Cary, N.C.

[21] Appl. No.: 674,371

[22] Filed: Jul. 2, 1996

[51] Int. Cl.⁶ F16F 15/03

[52] U.S. Cl. 188/267; 192/21.5; 310/92

[58] Field of Search 188/267, 155, 188/290, 276, 161, 163, 164; 267/140.14; 192/21.5; 310/92, 93, 103, 105

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Primary Examiner—Robert J. Oberleitner

Assistant Examiner—Pamela J. Lipka

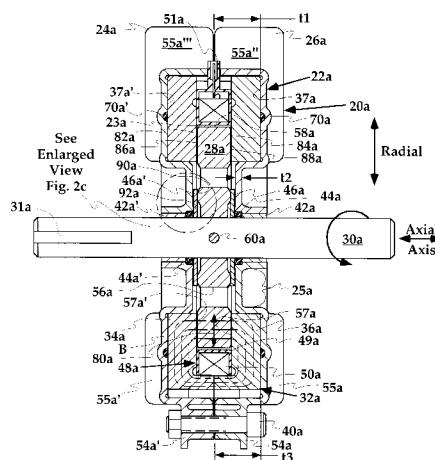
Attorney, Agent, or Firm—Randall S. Wayland

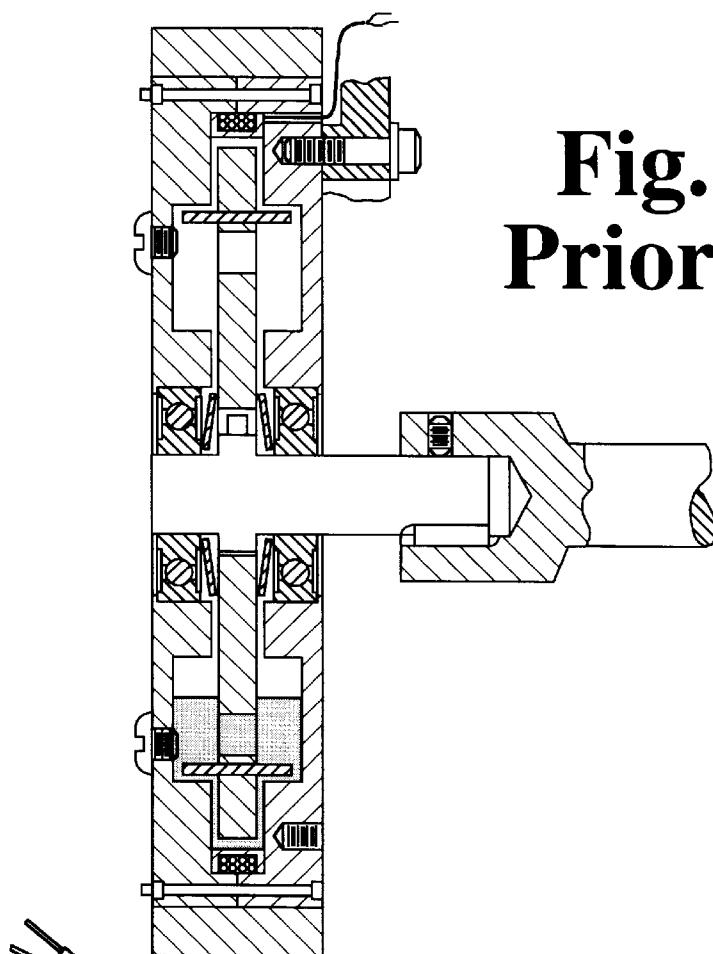
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ABSTRACT

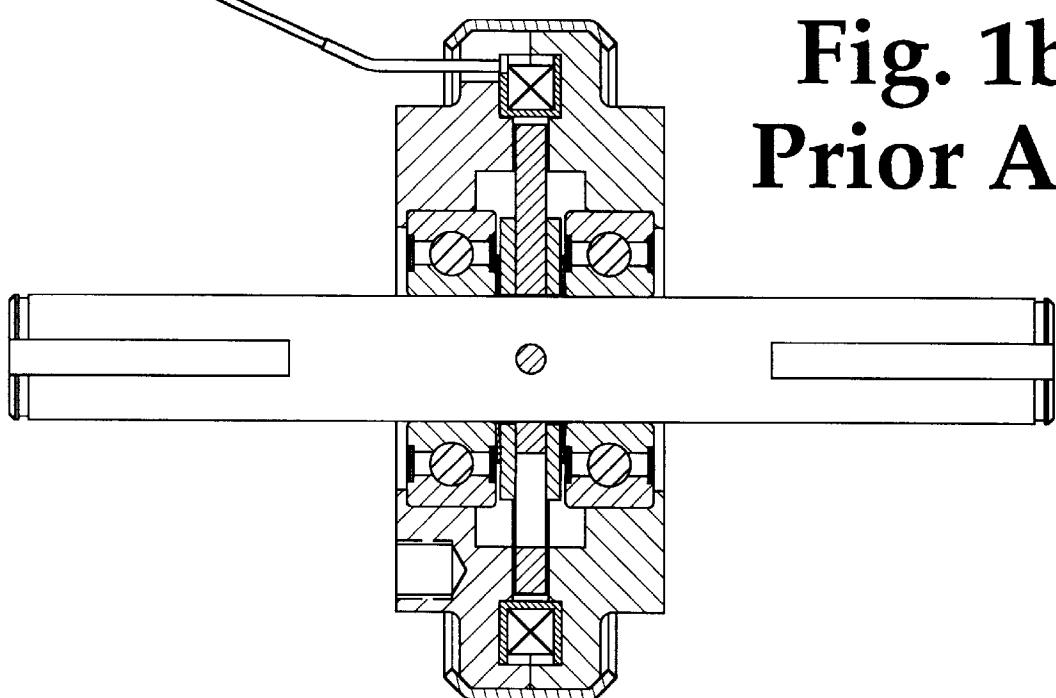
A controllable brake (20) including a rotor (28) supported by a shaft (30) which is rotatably supported by bushings (42) received in housing (22). A coil assembly (48) creates a magnetic field within a pole piece (32), which is preferably manufactured from a powdered metal material, which preferably has a density of between about 6.8 and 7.0 gm/cm. A magnetically-soft medium is contained within first and second gaps (86, 88) located between pole piece (32) and rotor (28). In one aspect, a magnetic saturation zone (25) reduces the propensity of magnetizing the shaft (30). In another, the pole halves (24, 26) are received in radially-spaced pole pockets (37) formed in the housing (22) and include an axial bias spring (70) to ensure intimate contact. In another aspect, a lip projection (76) traps fluid (23) between the lip projection (76) and shaft (30) and minimizes fluid exposure to the shaft seal (44). In another aspect, cooling fins (55) or a projection (53) restrains rotation of the housing (22). In another aspect, a spring (46) centers the rotor (28) relative to the housing (22).

24 Claims, 7 Drawing Sheets





**Fig. 1a
Prior Art**



**Fig. 1b
Prior Art**

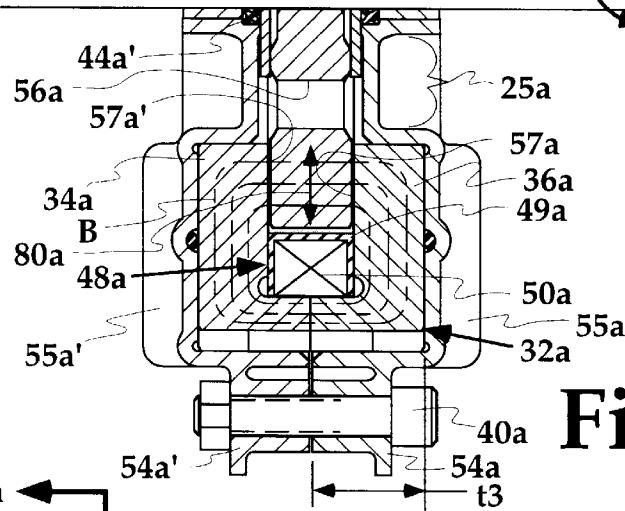
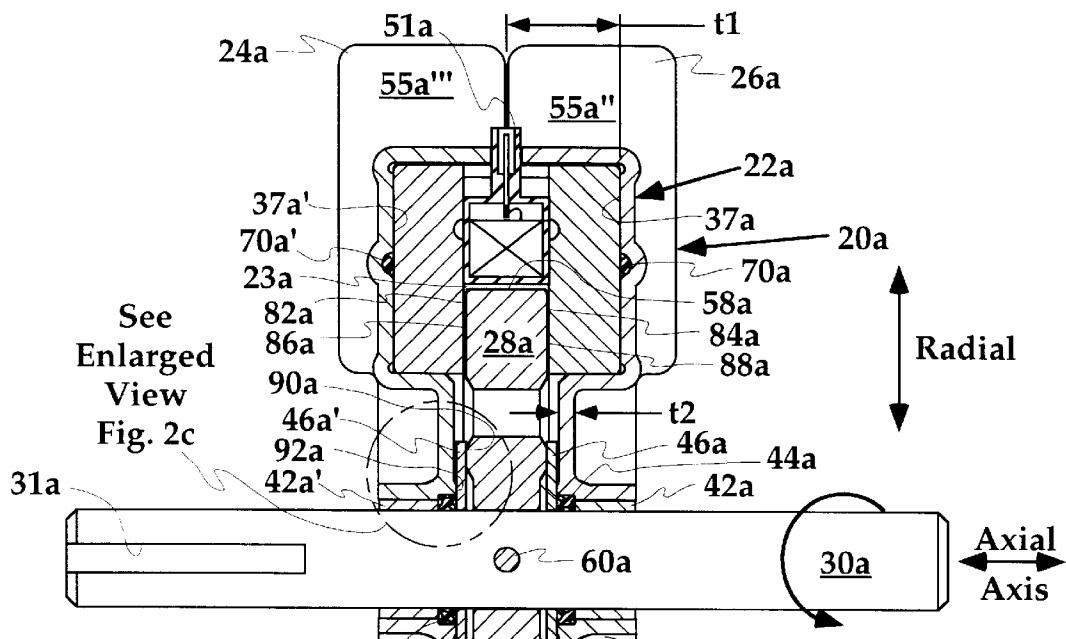


Fig. 2a

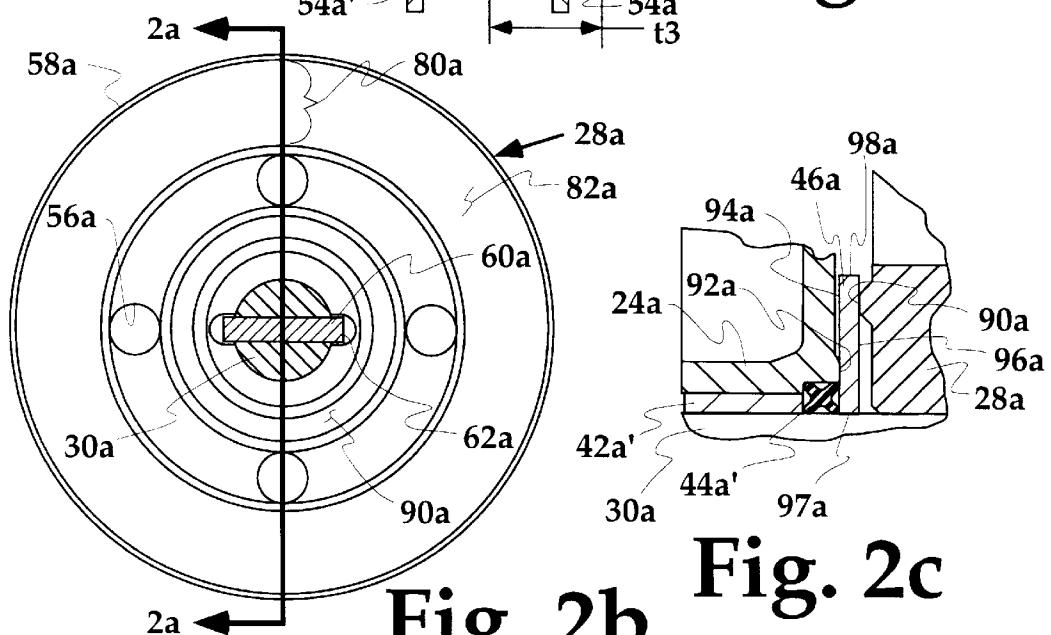


Fig. 2b Fig. 2c

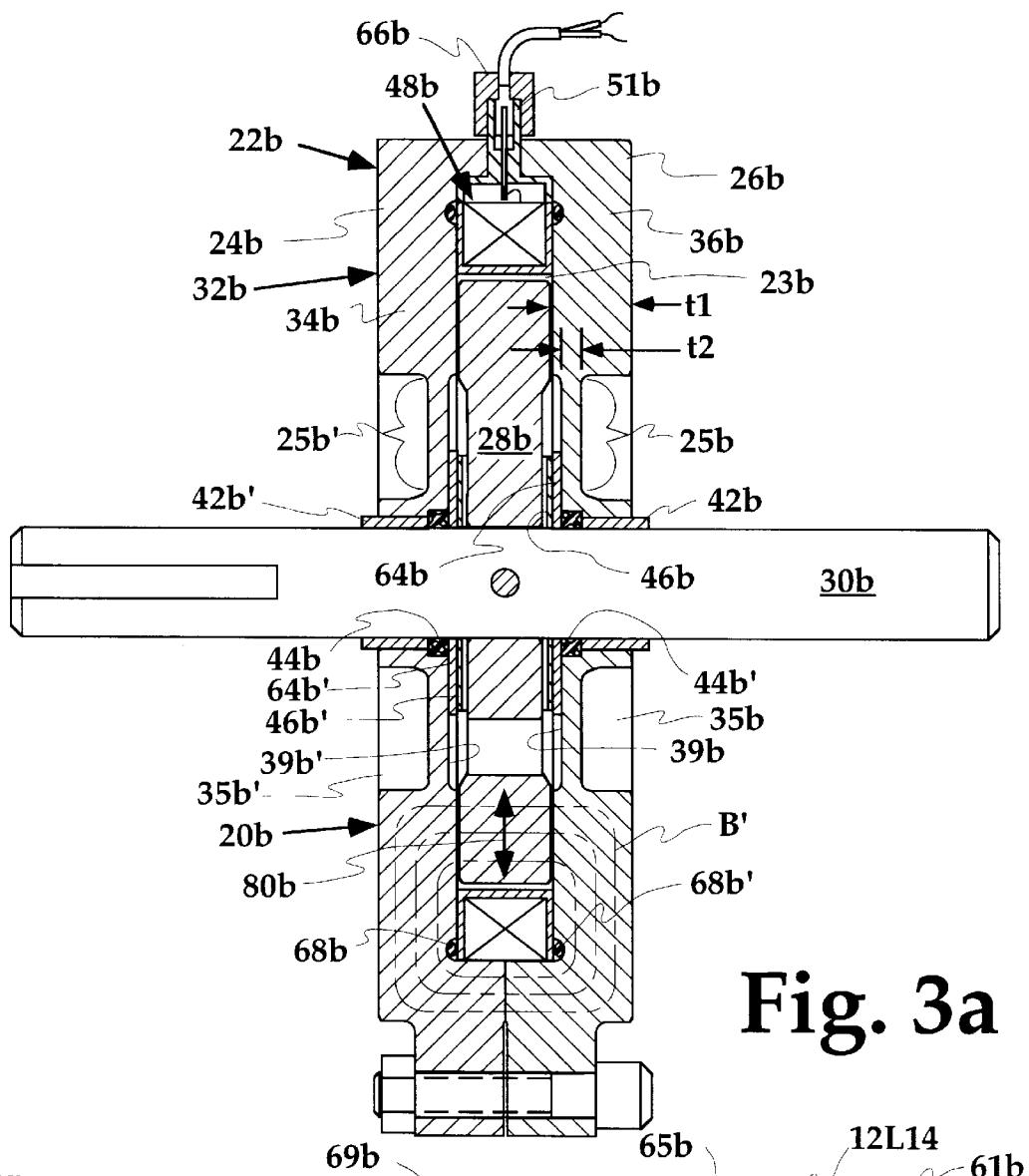


Fig. 3a

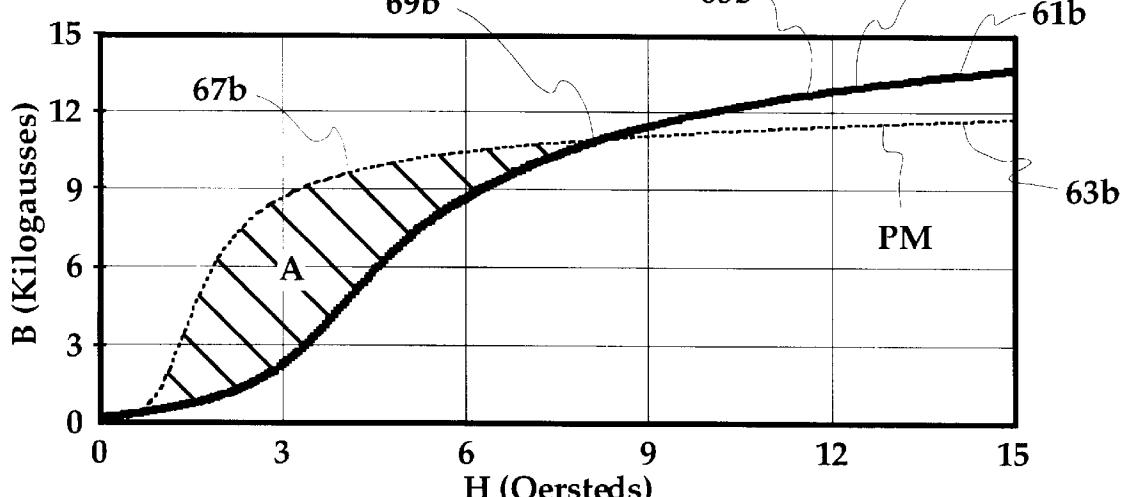


Fig. 3b

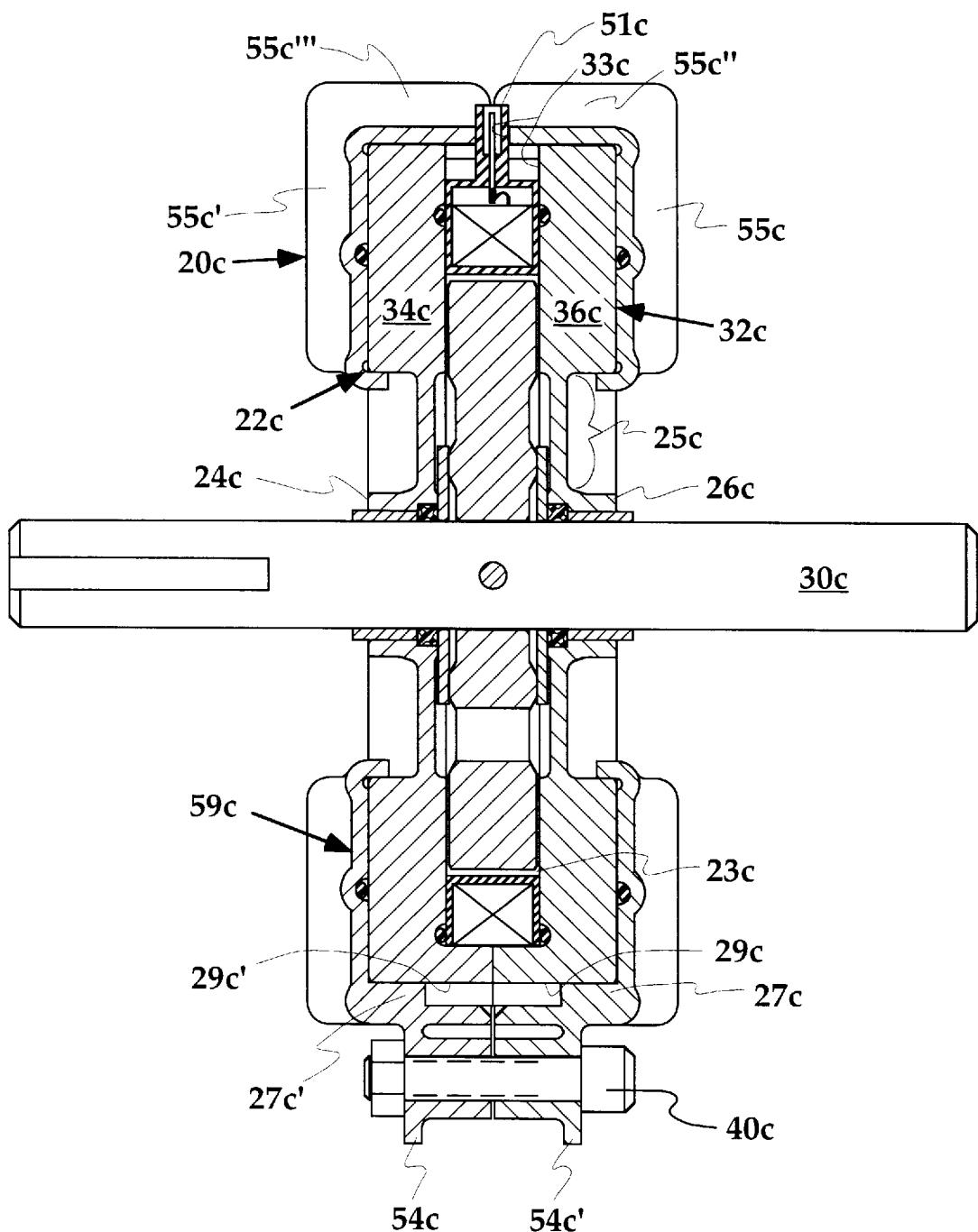
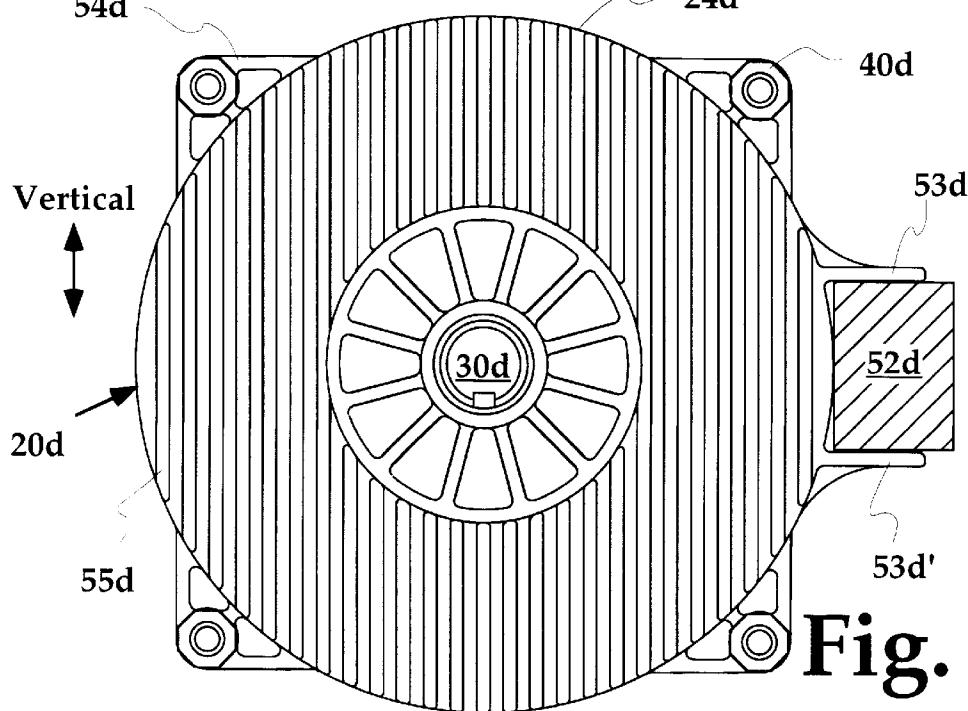
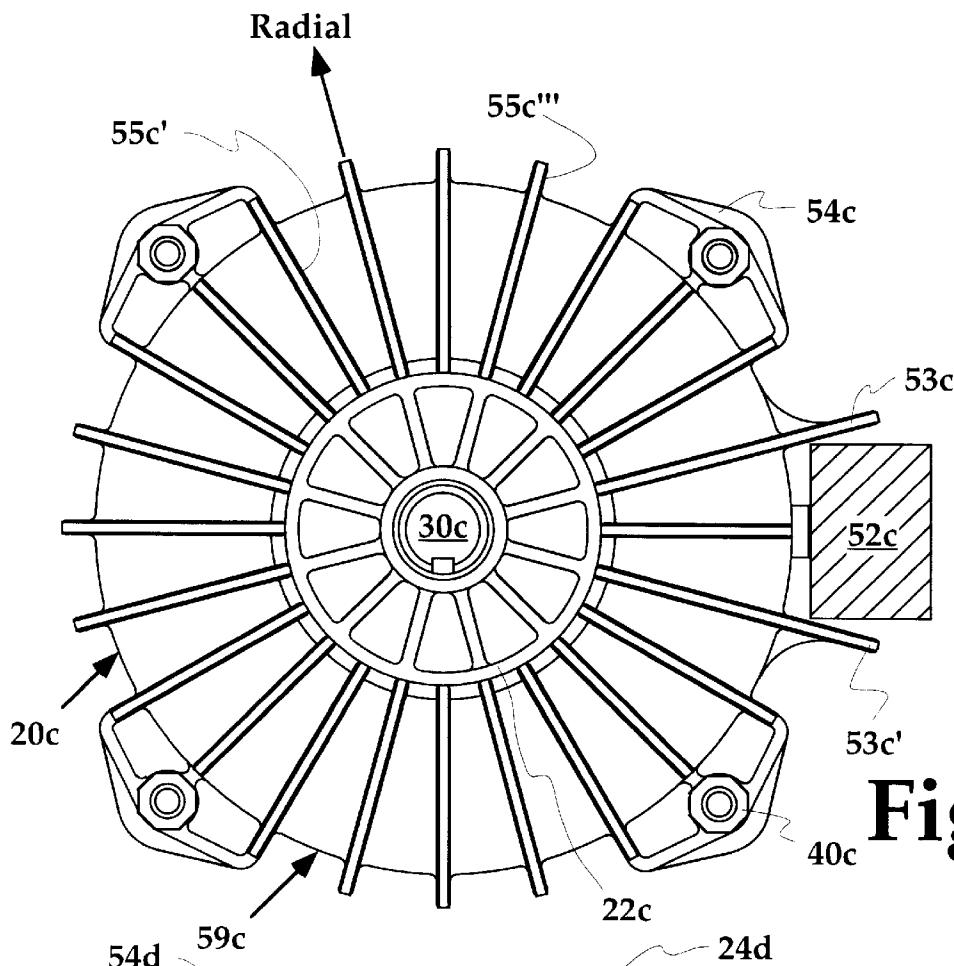


Fig. 4



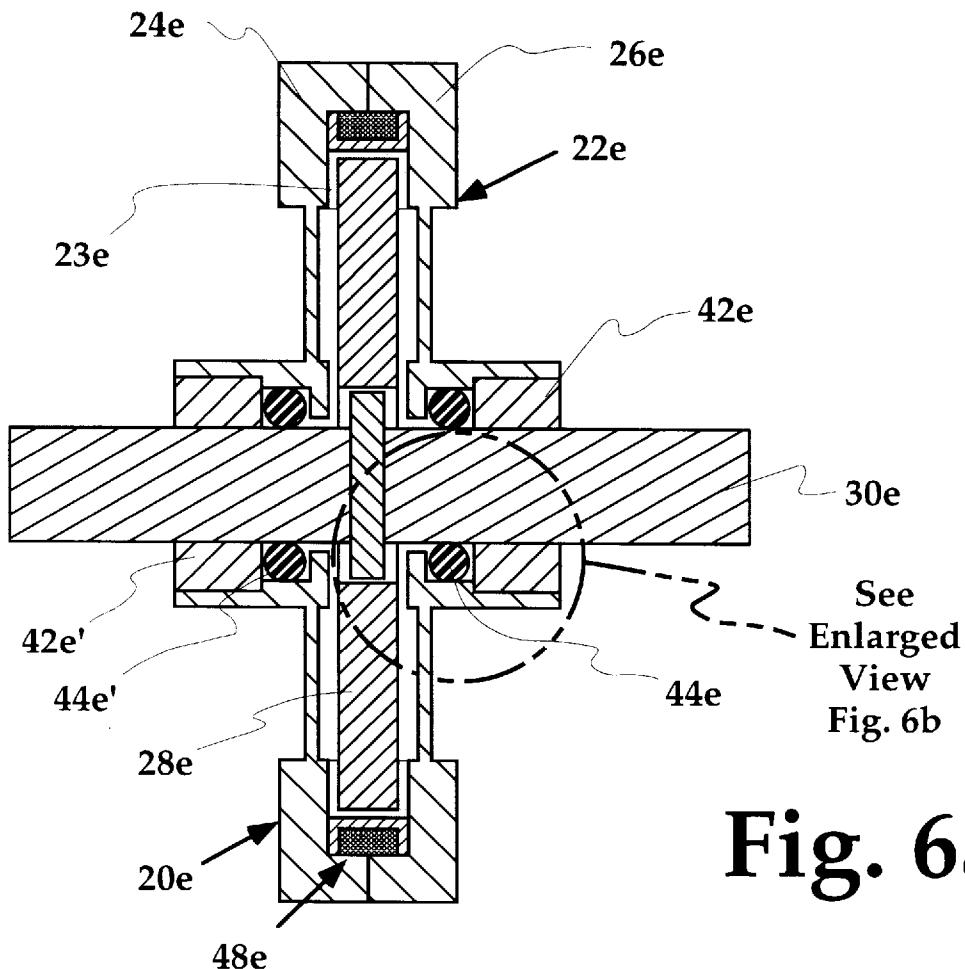


Fig. 6a

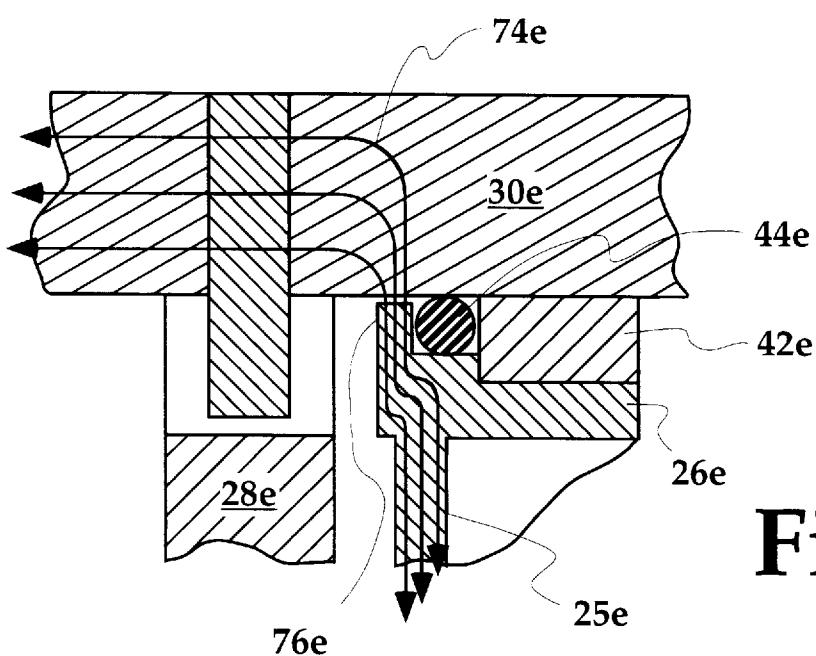


Fig. 6b

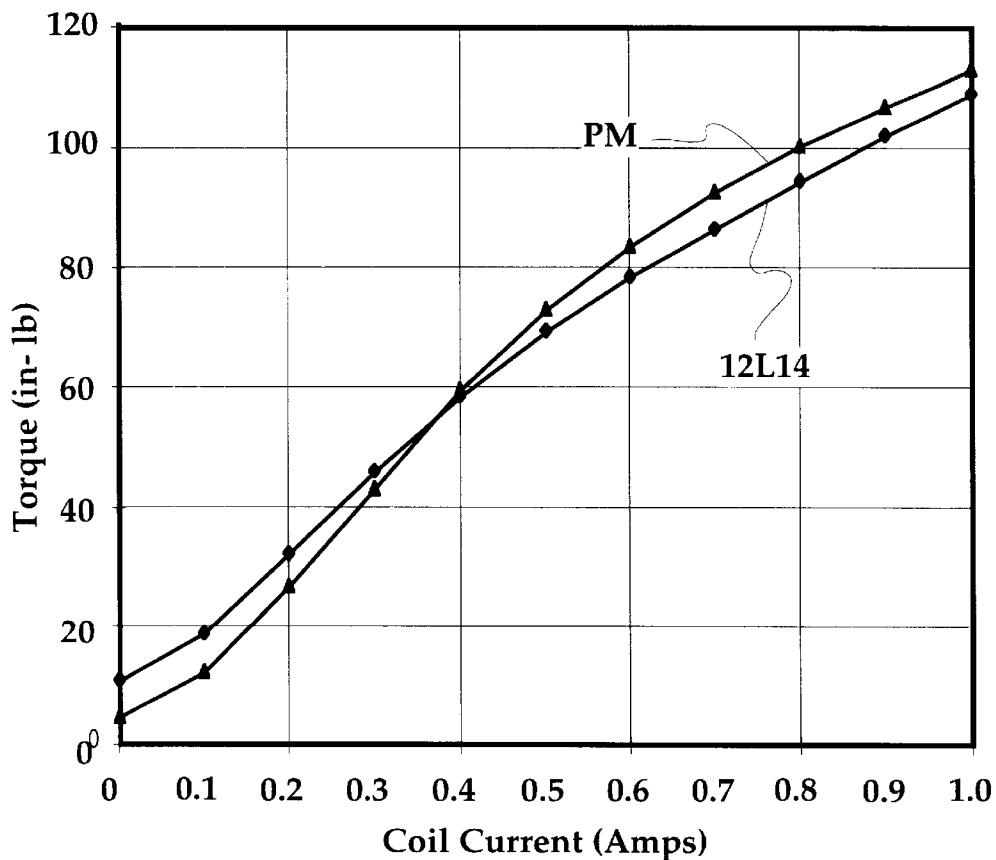


Fig. 7a

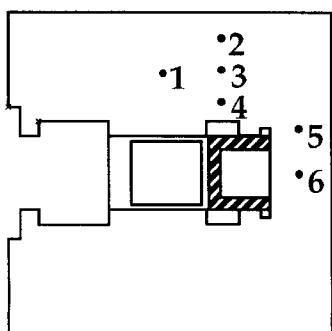


Fig. 7b

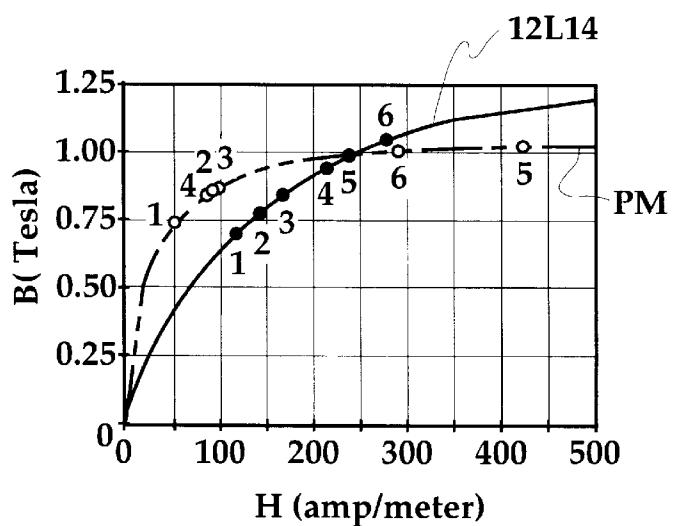


Fig. 7c

1**CONTROLLABLE BRAKE****FIELD OF THE INVENTION**

This invention relates to the area of controllable rotary acting devices. Specifically, the invention relates to the area of brakes for providing controllable torques and including a controllable magnetically-soft medium.

BACKGROUND OF THE INVENTION

Controllable devices generally include a controllable medium, such as an Electrorheological (ER) fluid, a Magnetorheological (MR) fluid, a ferrofluid, a dry magnetic particle material, or an electrophoretic material. Specifically, Magnetorheological (MR) fluid devices include a magnetorheological fluid, a medium which has magnetically-soft or paramagnetic particles suspended in a liquid carrier. MR dampers are known and include both rotary and linear acting varieties. Rotary devices can be used as brakes, clutches and the like, for providing variable torques while linear acting devices can be used for damping linear motion or for providing controllable dissipative forces along a specified axis.

MR devices have been found useful in a wide variety of applications. For example, MR dampers have been incorporated in vehicle engine mounts. One such device is taught in commonly assigned U.S. Pat. No. 5,398,917 to Carlson et al. In the mount, a rheological change of the MR fluid is used to control the engine motions by controlling the damping level therein. Other MR fluid devices are taught in the commonly assigned U.S. Pat. Nos. 5,284,330 and 5,277,281, both to Carlson et al., which describe axially-acting (linear) dampers and devices including sealless designs, respectively.

Copending applications Ser. No. 08/613,704 entitled "Portable Controllable Fluid Rehabilitation Devices" and Ser. No. 08/304,005 entitled "Magnetorheological Fluid Devices and Process of Controlling Force in Exercise Equipment Utilizing Same", both by Carlson et al., describe rotary dampers utilizing a controllable fluid for providing controllable forces in exercise machines and for portable devices for rehabilitation of injured limbs and the like.

Magnetically-controllable rotary dampers such as MR rotary dampers require highly magnetically permeable pole pieces for directing the magnetic flux across the working fluid gap(s) contained therein. In some cases there can be unwanted stray magnetic flux which can detract from the effectiveness of the damper. Stray or flanking flux paths can lead to a loss of efficiency because magnetic fields and associated field energy are developed where they are not needed or desired. This may cause remnant magnetism in any hard-magnetizable component present in the brake. This remnant magnetism can attract the magnetically-soft medium into areas where it may be undesirable to have it, for example, adjacent to the shaft seals. Constant exposure to a magnetically-soft medium, such as MR fluid, may cause premature failure of the shaft seals. Because of this stray flux, prior art shafts have been preferably made of a non-magnetic material. Notably, nonmagnetic shaft materials tend to be relatively expensive, thereby increasing the cost of the brake. Furthermore, prior art pole pieces have tended to be heavy and expensive in that they must be carefully designed to eliminate magnetic flux pinch or saturation points. Prior art pole piece materials have included wrought free-machining steels.

Furthermore, under conditions of continued use, the prior art brakes have experienced heat buildup problems. This

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leads to break down of the fluids and premature failure of the shaft seals. Therefore, there is a recognized need for a method and means for reducing wear of the seals in MR fluid brakes and for reducing the cost and weight of the pole pieces. In addition, smaller and more powerful brakes are always desired.

SUMMARY OF THE INVENTION

Therefore, given the benefits and drawbacks of the prior art controllable brakes including a magnetically-soft medium, the present invention is directed to a rotary brake which solves the seal wear, weight and cost problems associated with the prior art and also improves performance. In one aspect thereof, the brake includes powdered metal pole pieces. Initially, the use of powdered metal in the pole pieces was thought to be prohibitive because the brake would have to be made much thicker (physically larger) to accommodate the generally lower saturation magnetism of powdered metals. This is because of the fact that powdered metals are much less dense than wrought steel or Cold Rolled Steel (CRS) used in prior art pole pieces. It was thought by the inventors that to prevent magnetic saturation of the pole piece, the pole piece would have to be made as much as 30%-40% larger. Notably, no weight savings or performance increase was expected. However, the inventors discovered that because of the specific portion of the B/H curve which is operated upon for the present invention brake, the pole piece could be made the same size as the prior art wrought steel or Cold Rolled Steel (CRS) pole pieces. Furthermore, unexpectedly, the weight of the brake was reduced and the performance (torque rating) was increased.

In another aspect, preferably ring-like pole pieces are received within a pocket in a preferably non-magnetic housing and preferably includes cooling means formed radially or vertically thereon. The present invention brake minimizes the stray magnetic fields present in prior art devices and because the shaft is supported by a portion of the housing with low magnetic field density thereabouts, the shaft can be manufactured from a magnetic martensitic material, which reduces cost.

In another aspect, where the outer housing is manufactured entirely from powdered metal, a nonmagnetic bushing and/or a magnetic saturation zone acts as the mechanism to limit the exposure of the shaft to any stray magnetic fields. In yet another aspect, a noncontacting lip projection adjacent to the shaft seal causes any stray magnetic field present to be localized and attract the magnetically-soft medium between the shaft and lip projection, thereby preventing or minimizing the magnetically-soft medium from reaching the seal.

It is an unexpected advantage of the present invention that despite the use of powdered metal for the pole pieces, the size of the pole pieces, and thereby the size of the brake, unexpectedly does not have to be increased.

It is an unexpected advantage of the present invention that the brake is lighter than prior art brakes using wrought steel pole pieces.

It is an advantage of the present invention that the brake is less costly than prior art brakes using wrought steel pole pieces.

It is an advantage of the present invention that the brake may run cooler than prior art brakes thereby providing longer life of the fluid when an MR fluid is used.

It is an unexpected advantage of the present invention that the brake including powdered metal pole pieces performs better than prior art wrought brakes of the same size, in that

they can develop larger braking torques, have lower off states and can switch quicker.

It is an advantage of the present invention that the seals in the brake will last longer as a result of less exposure to the abrasive magnetically-soft medium.

The abovementioned and further aspects, features and advantages of the present invention will become apparent from the accompanying descriptions of the preferred embodiments and attached drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings which form a part of the specification, illustrate several embodiments of the present invention. The drawings and description together, serve to fully explain the invention. In the drawings,

FIG. 1a and FIG. 1b are partially cross-sectioned side views of prior art MR fluid brakes sold by LORD Corporation,

FIG. 2a is a partially cross-sectioned side view of a first embodiment of the present invention rotary brake including cooling fins, a preferably nonmagnetic housing supporting the shaft with pole pieces received within a pocket formed in the nonmagnetic housing that are spaced away from the shaft,

FIG. 2b is a partially cross-sectioned side view of the rotor and shaft assembly,

FIG. 2c is a partially cross-sectioned and enlarged side view of the spring assembly between rotor and housing,

FIG. 3a is a partially cross-sectioned side view of another embodiment of the present invention controllable brake including a powdered metal housing which preferably includes a magnetic saturation zone,

FIG. 3b is a graphical illustration of the B/H curves for the prior art (AISI 12L14) and powdered metal pole piece materials of the present invention,

FIG. 4 is a partially cross-sectioned side view of another embodiment of the present invention controllable brake with a preferably thermally conductive clamping assembly and including a pole piece and housing combination,

FIG. 5a is a frontal view of the FIG. 4 embodiment of the present invention rotary controllable fluid brake illustrating a radial starburst cooling fin pattern which uses at least one of the cooling fins as the means for restraining rotation of the housing,

FIG. 5b is a frontal view of another embodiment of the present invention rotary controllable brake illustrating a vertical cooling fin pattern which uses a projection from the housing as the means for restraining rotation,

FIG. 6a is a cross-sectioned side view of another embodiment of the present invention rotary controllable brake including localized stray field directing means adjacent to the shaft for suspending the magnetically-soft medium therebetween and minimizing the amount of magnetically-soft medium reaching the shaft seal,

FIG. 6b is an enlarged cross-sectioned side view of a portion of the FIG. 6a embodiment,

FIG. 7a is a graphical illustration of the unexpected performance improvement of the controllable brake with powdered metal pole pieces as compared to prior art wrought steel pole pieces (AISI 12L14),

FIG. 7b is a cross-sectioned view of a portion of the pole pieces (one side of the centerline) used in a magnetic analysis, showing the points of interest 1-6, and

FIG. 7c is a graphical illustration of the location of each point on the B/H curve comparing wrought 12L14 with Powdered metal.

DETAILED DESCRIPTION OF THE INVENTION

With reference to the various figures herein, where like reference characters are employed where possible to indicate like components, there is shown in FIG. 2a a rotary-acting controllable brake which in this description is a magnetorheological (MR) fluid brake 20a. It should be understood that the various aspects of the present invention are described with reference to a MR fluid brake 20a, however, the inventors indicate and expect the various aspects of the invention would have equal applicability to any controllable brake device that includes a magnetically-soft medium, for example, in a dry powdered metal particle brake or coupling.

The first embodiment of MR fluid brake 20a comprises a housing 22a, preferably having substantially identical first and second halves 24a and 26a, preferably disc-shaped rotor 28a, a rotatable shaft 30a preferably manufactured from a magnetically soft material which has an optional key slot 31a formed therein, a magnetically-soft yoke 32a preferably having substantially identical first and second pole piece halves 34a and 36a, bushings 42a and 42a' which are preferably porous, impregnated, and nonmagnetic and which radially support the shaft, elastomer seals 44a and 44a', preferably of the elastomer quad-ring variety, disc-like springs 46a and 46a' for centering the rotor 28a, a coil assembly 48a for generating a changeable magnetic field which includes a nylon bobbin 49a and multiple hoop wound wire coils 50a, an electrical connector 51a and fasteners 40a.

In more detail, the housing halves 24a and 26a may be manufactured from wrought steel, stamped steel, cast or machined aluminum, aluminum alloys or the like. Most preferable materials are cast aluminum or a zinc/aluminum alloy. Each half 24a and 26a preferably has a pole pocket 37a and 37a' formed therein and spaced radially outward from the shaft axis. The pockets 37a and 37a' are formed near its outermost radial portion for receiving ring-like pole piece halves 34a and 36a of the magnetically-soft yoke 32a therein. The inventors recognized that it is desirable to distance the magnetically-soft yoke 32a away from the shaft 30a. They determined that this minimizes the stray magnetic field/flux developed in the area adjacent the shaft 30a and minimizes magnetization of the shaft 30a. Magnetization of the shaft 30a or the components near the shaft 30a is undesirable as it will cause MR fluid 23a to be attracted to the magnetized areas near the shaft seals 44a and 44a' causing undesirable wear thereof. Spacing the magnetically-soft yoke 32a away from the shaft 30a prevents or minimizes magnetic stray magnetic field buildup in the area adjacent to the shaft 30a.

If aluminum or other nonmagnetic material is used, then that in combination with spacing the magnetically-soft yoke 32a radially outward from the shaft acts as a means for limiting the magnetic field at or near the shaft seals. Likewise, if steel or other like magnetic material is used for the housing, the magnetic flux saturation zone 25a having a thickness t2 in combination with spacing the magnetically-soft yoke 32a radially outward from the shaft limits the amount of stray magnetic field present in areas adjacent the shaft 30a. The housing 22a performs the functions of supporting the shaft 30a and creating a portion of the fluid containment. Housing 22a also includes projecting flange portions 54a and 54a', preferably of which there are three or four pair, which are equally spaced and which are bolted together via fasteners 40a, such as with socket-head cap screw and nut shown, to secure the assembly together. The

housing 22a also includes means to prevent rotation of the pole piece halves 34a and 36a relative to each other and relative to the housing halves 24a and 26a. One such means (a nub and receiving groove) preventing rotation is described with reference to FIG. 4. Further, the fasteners 40a could interact with localized cutouts or recesses formed in the radial outer periphery of pole pieces to restrain rotation thereof.

It was also discovered by the inventors that, under certain conditions, the axial dimension t1 of the pole piece halves 34a and 36a and the axial dimension t3 from the bottom of the pole pockets, e.g. 37a to the edge of the flanges 54a can lead to a situation where the pole piece halves 34a and 36a do not touch each other at their inside edges (contacting interface). This can dramatically affect the performance of the MR brake 20a. This is because if an axial gap is present at the juncture between the halves, it acts as a magnetic reluctance, reducing the flux density of the magnetic field within the magnetically-soft yoke 32a. The axial gap at the contacting interface of the pole halves 34a and 36a is caused by tolerance stackups, i.e., when the dimensions of the pole piece halves 34a and 36a, i.e., t2 are at the low end of their tolerance range and the pole pocket bottom-to-flange dimension, i.e., t3, is at the high end of its tolerance range. To solve this problem, the inventors have added axial spring bias means to force the two pole halves 34a and 36a together and into intimate contact upon assembly thereof. Generally it is also desirable to make t3 less than t1. This eliminates the possibility of any axial gap occurring at the contact interface between the two halves 34a and 36a. In this embodiment, the axial spring bias is achieved by means of compressing bias springs 70a and 70a', which are preferably elastomer o-rings. The o-rings described herein perform the dual function of: 1) sealing the interface between the pole halves 34a and 36a and the housing halves 24a and 26a, and 2) axial spring biasing the pole pieces 34a and 36a together. O-rings may be used adjacent the coil 48a to ensure sealing therearound also.

The portion of the housing 22a in contact with the magnetically-soft yoke 32a is preferably thin in cross-section and preferably includes cooling fins 55a, 55a', 55a'', and 55a''' located in the vicinity thereof to help dissipate the heat generated by continuous or semi-continuous rotation of the MR brake 20a. Furthermore, it is preferable to use a highly-thermally conductive and nonmagnetic material such as aluminum or copper. The cooling fins 55a, 55a', 55a'', and 55a''' are preferably arranged such that they extend in a generally radial direction and preferably in a starburst pattern or straight across (vertical) pattern as will be described with reference to FIG. 5a and FIG. 5b. Preferably, the cooling fins 55a, 55a', 55a'', and 55a''' extend both axially and radially away from the pole piece halves 34a and 36a.

The pole piece halves 34a and 36a of magnetically-soft yoke 32a are adapted for side-by-side axial assembly and preferably each has a ring-like shape and has an L-shaped cross-section at each cross-section cut (on either side of the center-line). The magnetically-soft yoke 32a comprising pole piece halves 34a and 36a in this, and all embodiments, are preferably manufactured from a powdered metal material having a high magnetic permeability and a density range of between about 6.4 gm/cm³ and about 7.2 gm/cm³. A more preferable range is between about 6.8 gm/cm³ to about 7.0 gm/cm³. Although, powdered metal materials are available in lower densities, it was determined by the inventors that going below 6.8 gm/cm³ is not desired, in most cases, because the low density will make the size of the device larger. Further going above 7.0 gm/cm³ adds to the cost

substantially. The powdered metal material is preferably selected from the group consisting of pure iron, low carbon irons, and iron with added phosphorus. Notably, it is preferable that the pole piece halve materials and other flux carrying elements are annealed per the heat treat recommendation outlined in the appendix of ASTM A848 to further increase permeability and lower sulfur, nitrogen and oxygen content. Most importantly, the materials used should have low carbon content.

Each pole piece half 34a and 36a has a recess 57a and 57a' formed therein, which together interact to form the recess which receives the working portion 80a of the rotor 28a. Receiving rotor 28a in the recess creates the first and second gaps 86a and 88a adjacent the working surface 80a which contain a sufficient volume of the MR fluid 23a therein. By way of example, and not to be considered limiting, the preferable MR fluid 23a for this embodiment, as for all embodiments described herein, includes small, preferably spherical, magnetically-soft particles, such as magnetite, carbonyl iron, iron alloys, iron nitrides, iron carbides, chromium dioxide, low carbon steel, silicon steel, nickel, cobalt or the like, having a nominal diameter of between about 1 and about 6 microns which are disbursed and suspended in a preferably low-viscosity liquid such as silicone oil, hydrocarbon oil, paraffin oil, mineral oil, chlorinated fluid, fluorinated fluid, kerosene, glycol, water or the like.

The rotor 28a includes first and second rotor surfaces 82a and 84a, working portion 80a, and an outer periphery 58a. Preferably, the rotor 28a is disc-like and the plane of the rotor surfaces 82a and 84a is substantially perpendicular to the axial axis of the shaft 30a, thereby first and second surfaces 82a and 84a are preferably parallel. The rotatable shaft 30a also preferably includes means for restraining rotation thereon, such as an optional key slot 31a, for preventing rotation relative to the coupling device/component the MR brake 20a is attached to. The working portion 80a of the rotor 28a is received within a cutout or recess 57a and 57a' preferably formed in each half 34a and 36a. The working portion 80a comprise a portion of the magnetic circuit in that the lines of flux B act through the working portion 80a of the rotor 28a. The rotor 28a is preferably manufactured from a PM material also. Although, the inventors had used PM for the rotors of prior art brakes, such as shown in FIG. 1a and FIG. 1b, it was not recognized that the magnetically-soft yoke 32a could be made from PM materials without a significant increase in its size. This is because the rotor is seldom a pinch point in the magnetic circuit. The pinch points (saturation points having high flux density or high B) are generally always located in the magnetically-soft yoke 32a. Generally this is because in disc-like rotors, the lines of flux act across the working section 80a of the rotor 28a. The flux density in the rotor 28a is approximately the same as in the first and second gaps 86a and 88a.

The means for generating the changeable magnetic field is preferably comprised of a coil assembly 48a further comprising a preferably nonmagnetic or nylon bobbin 49a and multiple hoop wound and insulated copper magnet wire 50a, by way of example and not to be considered limiting, between about 170 winds and about 250 winds. The coil assembly 48a is received in the recesses 57a and 57a' at the outermost portion thereof and at a position adjacent to the outer periphery 58a of the rotor 28a. The coil assembly 48a generates a changeable magnetic field within the magnetically-soft yoke 32a and, therefore, also in the gaps 86a and 88a, upon being electrically energized with DC

current. An estimate of the magnetic flux lines are generally shown as B. The lines of flux preferably act perpendicularly across the first and second gaps **86a** and **88a**. The exposure to the magnetic field causes a change in rheology, i.e., the particles within the MR fluid **23a** which become polarized and align into chains acting across the first and second gaps **86a** and **88a**. This rheology change causes an increase in torsional resistance between the housing **22a** and rotor **28a** at the working section **80a** thereof, with the resulting increased resistance to torsional rotation of the shaft **30a** relative to the housing **22a**. This provides the controllable resistance in the system which the MR brake **20a** is used, which for the embodiments described herein, can range up to about 220 in.-lb. of torque output.

The inner seal preventing escape of the MR fluid **23a** between the pole pieces **34a** and **36a** is preferably comprised of the flexible nylon bobbin **49a** itself or in combination with an RTV sealant. Most preferably, an o-ring seal is used to provide a positive seal even with worst-case tolerance stackup conditions. As discussed earlier, the spring bias **70a** and **70a'** provides an outer seal between the pole piece halves **34a** and **36a** and the housing halves **24a** and **26a**. Shaft seals **44a** and **44a'** seal against the shaft **30a**.

The rod-like shaft **30a** is preferably manufactured from a magnetic material such as CRS and is preferably radially supported by nonmagnetic bushings **42a** and **42a'**. Bushings **42a** and **42a'** are preferably manufactured from a nonmagnetic material. By way of example and not to be considered limiting, porous bronze, or the like which is preferably impregnated with a friction reducing material, such as grease, oil, perfluorinated polyethylene, or the like may be used. Alternatively plastic could be used. It was discovered by the inventors herein that making the bushing **42a** and **42a'** out of a nonmagnetic material helps considerably in reducing the stray magnetic flux exposed to the shaft **30a**.

As shown in FIG. 2b and FIG. 2c, the rotor **28a** attaches and interconnects to the shaft **30a** by way of pin **60a** inserted crosswise through shaft **30a** and which is received in at least one slot **62a** formed radially into the rotor **28a**. This restrains relative torsional rotation between the shaft and rotor **28a**. Notably, the rotor **28a** may still move axially a certain amount relative to the shaft **30a** as far as allowed before springs **46a** and **46a'** (FIG. 2a) and pin **60a** make contact. Adjacent to the ends of the bushings **42a** (FIG. 2a) and **42a'** are elastomer shaft seals **44a** and **44a'** of the elastomer quad-ring variety. Preferably, the seals **44a** (FIG. 2a) and **44a'** are molded from an approximately 60–90 durometer fluorocarbon elastomer and more preferably from an about 75 durometer fluorocarbon elastomer material. Bushings **42a** (FIG. 2a) and **42a'** and seals **44a** (FIG. 2a) and **44a'** are retained in appropriately sized bushing and seal glands formed in each of housing halves **24a** and **26a** (FIG. 2a).

FIG. 2c illustrates an enlarged view of one side of a spring assembly which functions to center the rotor **28a** and maintain the dimensions of first and second gaps **86a** and **88a** (FIG. 2a) at approximately equal thickness of, by way of example and not to be considered limiting, approximately 0.01–0.025 inch. In this view, the spring **46a**, which is preferably a disc-spring, flexibly suspends the rotor **28a** along the axial axis of the shaft **30a** and maintains the axial position of the rotor **28a** relative to the housing **22a** (FIG. 2a). The spring **46a** is preferably washer-like and is flexible and preferably manufactured from a flexible material, such as thin spring steel, or nylon. The spring **46a** includes first and second faces **94a** and **96a**, an inner diameter **97a** and an outer diameter **98a**. Rotor projection **90a** and housing projections **92a** contact the spring **46a** on faces **94a** and **96a**.

Preferably, during assembly, springs **46a** and **46a'** (FIG. 2a) are flexed slightly, for example, inner diameter **97a** axially relative to outer diameter **98a**. This functions to properly align and center the rotor **28a** relative to the housing **22a**.

FIG. 3a illustrates another embodiment of magnetorheological (MR) fluid brake **20b**, including a housing **22b** and magnetically-soft yoke **32b** combination where each pole piece half **24b** and **26b** is preferably entirely manufactured from a powdered metal material such as a magnetically-soft Powdered Iron Metal per ASTM A811 or Powdered Phosphorus Iron per ASTM A839. The housing **22b** and magnetically-soft yoke **32b** combination is preferably manufactured from substantially identical halves **24b** and **26b**. Each half **24b** and **26b** preferably includes pole piece halves **34b** and **36b**, relief pockets **39b** and **39b'** and magnetic saturation zones **25b** and **25b'**. The relief pockets **39b** and **39b'** help focus the magnetic field across the rotor **28b** as well as reduce the viscous drag on the portion of rotor **28b** away from the working portion **80b**. The magnetic saturation zone **25b** is generally a cored-out section which significantly reduces the cross-sectional area of the housing **22b** in the area adjacent the shaft **30b**, thus, it acts as a pinch or saturation point to limit the magnitude of the stray magnetic field present therein. This prevents any strong magnetic field from being generated in the area adjacent to the shaft seals **44b** and **44b'**. The inventors discovered it is desirable to reduce the thickness **t2** in the magnetic saturation zone **25b** to the smallest dimension possible, yet retaining sufficient strength to carry the torsional loads. Specifically, the dimension **t2** should be made less than $\frac{1}{3}$ and more preferably less than $\frac{1}{4}$ of **t1** to limit the degree of remnant magnetization of the shaft **30b**. Radial directed webs **35b** and **35b'** may be optionally included to add strength in the cored-out area. The webs **35b** and **35b'** (see similar webs in FIG. 5a) should preferably be as thin as practicable. Unexpectedly, even the use of thin nonmagnetic bushings also has a dramatic effect on reducing the level of stray magnetic flux exposed to the shaft **30b**.

Bushings **42b** and **42b'** which are preferably thin, non-magnetic and porous and lubricated bronze, radially support the shaft **30b** at housing halves **24b** and **26b**. With the use of the magnetic saturation zone **25b**, the shaft **30b** may be made of a less expensive magnetic martensitic material such as cold rolled steel or the like in place of more expensive nonmagnetic stainless steels. In a similar manner as the FIG. 2a embodiment, coil assembly **48b** functions as the means for generating the changeable magnetic field **B'** within the magnetically-soft yoke **32b** and within pole piece halves **34b** and **36b** and, thus, within gaps **86a** and **88a**. In this embodiment, the springs **46b** and **46b'** that center the rotor **28b** are wave-type springs, or the like. It should be understood that other springs could be used, for example, helical springs, conical springs, volute springs, Belleville springs, slotted washer springs, curved washer springs, and finger washer springs, or the like.

End washers **64b** and **64b'** are preferably manufactured from nylon or spring steel and serve the dual purposes of: 1) providing a lateral race for the shaft seals **44b** and **44b'** to act against, and 2) to provide a smooth surface for the springs **64b** and **64b'** to act against. Optional seals **68b** and **68b'** are preferably used to seal the escape of MR fluid **23b**. Connector **51b**, lead **66b**, and coil assembly **48b** comprise a portion of the electrical circuit. Generally, the MR brakes described herein are DC devices. A further description of the electrical circuitry needed to control such MR brake devices can be found in commonly assigned U.S. patent application Ser. No. 08/613,704 to Carlson, filed Mar. 11, 1996 and

entitled "Portable Controllable Fluid Rehabilitation Devices", which is hereby incorporated by reference herein.

FIG. 3b illustrates the B/H curve for materials compared in the magnetorheological (MR) fluid brake 20b. B stands for the magnetic flux density in tesla and H stands for the magnetic field in amp/meter. Curve 1 designated 61b illustrates the B/H curve for a free machining steel (12L14) whereas Curve 2 designated 63b illustrates the B/H curve for a 6.9 gm/cm³ density pure iron, powdered-metal material. Curve 1 has a knee 1 designated by 65b and curve 2 has a knee designated by 67b. Generally, the inventors recognize it is desirable to operate below the knee in any B/H curve, i.e., below saturation or at a lower applied magnetic field. As discovered by the inventors herein and as represented by the shaded area A, the use of powdered metal material for the poles will generate a significantly higher flux density for any current density below the knee in the curve. Therefore, translating into more torque resistance for any coil amperage provided to the MR brake 20b. This is true up to the cross over point 69b. Furthermore, use of powdered metal improves switching speed and provides less remnant magnetization of the magnetically-soft yoke 32b providing a lower off-state.

FIG. 4 illustrates another embodiment of the magnetorheological (MR) fluid brake 20c. In this embodiment, the magnetically-soft yoke 32c and housing 22c combination is preferably powdered metal material and includes pole piece halves 34c and 36c. The magnetically-soft yoke 32c carries the magnetic circuit and is integral with the housing 22c. The housing 22c supports the shaft 30c and forms the containment for the MR fluid 23c. Cooling fins 55c, 55c', 55c'', and 55c''' extend axially and radially away from the pole piece halves 34c and 36c and are included in a clamp assembly 59c. Halves or the clamp assembly 59c are secured together at projecting flange portions 54c and 54c' with fasteners 40c which secures housing halves 24c and 26c together. Nubs 27c and 27c' on clamp assembly 59c are received in grooves 29c and 29c' formed in pole piece halves 34c and 36c to prevent rotation of the pole piece halves 34c and 36c relative to the clamp assembly 59c. The electrical connector 51c is received in connector hole 33c, which is a hole through the magnetically-soft yoke 32c and clamp assembly at a single location on the periphery of the MR brake 20c.

FIG. 5a and FIG. 5b illustrates embodiments of magnetorheological (MR) fluid brakes 20c and 20d, respectfully. The FIG. 5a embodiment includes cooling fins 55c' which extend in the axial direction away from the pole piece 32c (FIG. 4) and cooling fin 55c''' which extends in the axial direction from the magnetically-soft yoke 32c (FIG. 4). The clamp assembly 59c is preferably manufactured from a material with good thermal conductivity such as aluminum, and functions to hold the pole piece halves 34c and 36c (FIG. 4) together and as a heat sink to efficiently carry the heat away from the magnetically-soft yoke 32c.

FIG. 6a and FIG. 6b illustrate another embodiment of the magnetorheological (MR) fluid brake 20e. This embodiment includes a housing 22e including first and second halves 24e and 26e, a rotor 28e, a coil assembly 48e, a shaft supported by bushings 42e and 42e', and shaft seals 44e and 44e'. In another novel aspect of the invention, stray field projecting means such as noncontacting lip projection 76e are used to direct any stray magnetic flux 74e. The lip projection 76e, which is preferably an integral part of the housing halves 24e and 26e, directs any stray magnetic flux 74e down through the lip projection 76e and into the shaft 30e. This causes a magnetically-soft medium, such as MR fluid 23e, to be attracted locally to that area, and puddle thereat. This builds

a barrier to further migration of the MR fluid 23e past the barrier and into the vicinity of seal 44e and 44e'. Therefore, it is surmised by the inventors that less exposure to MR fluid 23e, and the abrasive particles therein, will reduce the seal wear and prolong the useful life thereof.

FIG. 7a illustrates a performance curve for brakes having the geometry similar to the MR brake 20b embodiment of FIG. 3a and compares the performance of substantially identical brakes with wrought steel pole pieces and powdered metal pole pieces. In this figure, it is readily apparent that for 1.0 amps current input to the coil assembly, the powdered metal version designated PM generates up to about 4% more torsional resistance (torque in.-lb.) as compared to wrought steel (AISI 12L14) pole pieces of the exact same geometry. This result was unexpected at the time of the making of the invention. Further, it was found that the off-state is about 55% lower and the switching speed is higher with PM pole pieces as compared to wrought pole pieces.

FIG. 7b and FIG. 7c illustrate a cross-sectioned portion on one side of the centerline of an MR brake used in the analysis of, and the results of the performance comparison of an MR brake similar to the MR brake 20b using 6.9 gm/cm³ pure-iron powdered metal as indicated by the designation PM as compared to an identical cross-section using wrought steel (AISI 12L14).

While the preferred embodiments of the present invention have been described in detail, various modifications, alterations, changes and adaptations to the aforementioned may be made without departing from the spirit and scope of the present invention defined in the appended claims. It is intended that all such modifications, alterations and changes be considered part of the present invention.

What is claimed is:

1. A controllable brake, comprising
 - (a) a shaft,
 - (b) a rotor manufactured from a highly magnetically permeable material having first and second rotor surfaces, a working portion, and an outer periphery, said rotor being interconnected to said shaft to restrain relative rotation therebetween,
 - (c) a housing including a magnetically-soft yoke which is manufactured from a highly magnetically permeable powdered metal material, said magnetically-soft yoke having a recess formed therein, said recess receiving said working portion of said rotor and forming a first gap adjacent to said first rotor surface and a second gap adjacent to said second rotor surface, said housing including a portion shaped relatively thin compared to a part of the housing including the yoke, said portion formed adjacent the shaft for preventing magnetic field buildup at a shaft sealing area,
 - (d) a magnetically-soft medium contained within and at least partially filling said first and second gaps, and
 - (e) means for generating a changeable magnetic field adjacent to said magnetically-soft yoke, said changeable magnetic field being directed to cause said magnetically-soft medium within said first and second gaps to change rheology thereby causing a change in torsional resistance of said controllable brake when said means for generating a changeable magnetic field is energized.
2. A brake of claim 1 wherein said magnetically-soft medium is a magnetorheological fluid including magnetically-soft particles disbursed within a carrier liquid.
3. A brake of claim 1 wherein said means for generating a changeable magnetic field is a coil assembly.

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4. A brake of claim 1 wherein said magnetically-soft yoke is made from a first and second half and includes axial spring bias means for ensuring intimate contact between said first and second halves.

5. A brake of claim 1 wherein said magnetically soft-yoke includes a plurality of vertically oriented and laterally spaced convection cooling fins extending from an axial surface thereof.

6. A brake of claim 1 wherein a plurality of cooling fins each of said cooling fins including a first portion which extends radially outward from a radial peripheral portion of said magnetically-soft yoke and also a second portion which extends axially outward from an axial portion of said magnetically-soft yoke.

7. A brake of claim 1 wherein rotation of said housing relative to an attachment member is restrained by one restraint member selected from a group consisting of:

- i) at least one of a plurality of cooling fins, and
- ii) a radial projection extending from said housing.

8. A controllable brake, comprising:

- (a) a shaft having an axis of rotation,
- (b) a rotor manufactured from a highly magnetically permeable material having first and second rotor surfaces and an outer periphery, wherein said rotor interconnects to said shaft such that relative rotation is restrained therebetween,
- (c) a housing which radially supports said shaft, the housing being shaped with a hollow enclosed space providing a pocket radially spaced from said axis of rotation of said shaft,
- (d) a magnetically-soft yoke manufactured from a magnetically permeable material received within said pocket, said magnetically-soft yoke further having a recess therein, said recess receiving a working portion of said rotor and forming a first gap adjacent to said first rotor surface and a second gap adjacent to said second rotor surface,
- (e) a magnetically-soft medium contained within and at least partially filling said first and second gaps, and
- (f) a coil assembly adjacent to said magnetically-soft yoke for generating a changeable magnetic field therein which is directed by said magnetically-soft yoke to cause said magnetically-soft medium within said first and second gaps to change rheology thereby causing a change in torsional resistance of said controllable brake upon electrically energizing said coil assembly.

9. A brake of claim 8 wherein said magnetically controlled medium is a magnetorheological fluid including magnetically-soft particles disbursed within a carrier liquid.

10. A brake of claim 8 wherein said magnetically-soft yoke is manufactured from a powdered metal material.

11. A brake of claim 10 wherein said powdered metal material has a density range of between about 6.4 gm/cm³ and about 7.2 gm/cm³.

12. A brake of claim 10 wherein said powdered metal material is selected from a group consisting of pure iron, low carbon iron, and iron with added phosphorous.

13. A brake of claim 8 wherein at least one spring flexibly suspends said rotor along an axial axis and maintains an axial position of said rotor relative to said housing.

14. A brake of claim 13 wherein said rotor includes a rotor projection, said housing includes a housing projection, said at least one spring includes a first face which rests against said housing projection and a second face which rests against said rotor projection.

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15. A controllable brake, comprising:

- (a) a shaft,
- (b) a rotor manufactured from a highly magnetically permeable material having first and second rotor surfaces, a working portion, and an outer periphery, said rotor interconnects to said shaft restraining relative rotation therebetween,
- (c) a housing and magnetically-soft yoke combination manufactured from a magnetically permeable powdered metal material, said housing and magnetically-soft yoke combination having a recess formed therein, said recess receiving said working portion of said rotor therein and forming a first gap adjacent to said first rotor surface, and a second gap adjacent to said second rotor surface, said housing and magnetically-soft yoke combination including a thicker section at an outer radial portion adjacent to said working portion and a thinner section at an inner radial portion adjacent to said shaft,
- (d) a magnetically-soft medium including magnetically-soft particles contained in and at least partially filling said first and second gaps, and
- (e) a coil assembly adjacent to said housing and magnetically-soft yoke combination for generating a changeable magnetic field therein which is directed to cause said magnetically-soft medium within said first and second gaps to change rheology thereby causing a change in torsional resistance of said controllable brake upon electrically energizing said coil assembly.

16. A brake of claim 15 wherein said magnetically controlled medium is a magnetorheological fluid including magnetically-soft particles disbursed within a carrier liquid.

17. A brake of claim 15 further including a shaft seal for sealing around said shaft and wherein said housing and magnetically-soft yoke combination includes a magnetic saturation portion formed therein adjacent to said shaft to minimize a magnitude of said changeable magnetic field which is generated in an area adjacent to said shaft seal.

18. A brake of claim 15 wherein said housing and magnetically-soft yoke combination is manufactured from said powdered metal material having a density of between about 6.4 gm/cm³ and about 7.2 gm/cm³.

19. A brake of claim 15 wherein said powdered metal material is selected from a group consisting of pure iron, low carbon iron, and iron with added phosphorous.

20. A brake of claim 15 further including a shaft seal, wherein a noncontacting lip projection on said housing and magnetically-soft yoke combination in an area adjacent to said shaft seal provides a weak localized magnetic flux to retain some of said magnetically-soft medium between said noncontacting lip projection and said shaft.

21. A brake of claim 15 wherein at least one spring supports said rotor along an axial axis and maintains substantially equal thicknesses of said first gap and said second gap.

22. A brake of claim 15 wherein said rotor includes a rotor projection, said housing includes a housing projection, at least one spring is flexible and disc-like and includes an inner periphery which spring loads against said housing projection and an outer periphery which spring loads against said rotor projection.

23. A controllable brake, comprising:

- (a) a shaft,
- (b) a rotor manufactured from a highly magnetically permeable material having a working portion and a rotor projection, said rotor operatively coupled to said shaft to restrain relative rotation therebetween,

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- (c) a housing including a magnetically-soft yoke and a housing projection, said magnetically-soft yoke having a recess formed therein which receives said working portion of said rotor forming at least one gap,
- (d) a magnetically-soft medium contained within said at least one gap,⁵
- (e) means for generating a magnetic field within said magnetically-soft yoke, said magnetic field being directed to cause said magnetically-soft medium to change rheology thereby causing a change in torsional resistance of said controllable brake when said means for generating said magnetic field is energized, and
- (f) least one flexible disc-like spring having a first periphery which spring loads against said housing projection and a second periphery which spring loads against said rotor projection.¹⁰

24. A controllable brake, comprising:

- (a) a shaft,
- (b) a rotor manufactured from a highly magnetically permeable material having a working portion, said rotor operatively coupled to said shaft,²⁰

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- (c) a housing including an axial pocket formed therein,
- (d) a magnetically-soft yoke including first and second yoke halves received in said axial pocket, said magnetically-soft yoke having a recess formed therein which receives said working portion of said rotor forming at least one gap,
- (e) a magnetically-soft medium contained within said at least one gap,
- (f) means for generating a magnetic field within said magnetically-soft yoke, said magnetic field being directed across said gap to cause said magnetically-soft medium to change rheology thereby causing a change in torsional resistance of said controllable brake when said means for generating said magnetic field is energized, and
- (g) axial spring bias means interactive with said housing for ensuring intimate contact between said first and second yoke halves.

* * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,942,547
DATED : August 24, 1999
INVENTOR(S) : Gary R. Gustafson, David G. Powers, and Mark A. Wuonola

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 7,

Line 41, delete “-NHR₇” and replace with -- -NHR⁷--;
Line 42, delete “-NHR₇R₈” and replace with -- -NR⁷R⁸--;
Line 42, delete “=CH₂” and replace with -- =CH₂--;
Line 61, delete “-NHR₇” and replace with -- -NHR⁷--;
Line 62, delete “-NHR₇R₈” and replace with -- -NR⁷R⁸--;
Line 62, delete “=CH₂” and replace with -- =CH₂--;

Column 8,

Line 4, delete “and R¹⁰”;
Line 27, delete “R⁴” and replace with -- R⁴--;

Column 16,

Line 20; delete “Bis-2,5-dimethylpyrrolo-2-deoxystreptamine” and replace with -- Bis-2,5-dimethylpyrrolo-2-deoxystreptamine --;

Column 24,

Line 32, delete “preferably” and replace with -- preferably --;

Column 48,

Line 54, delete “-NHR⁷R⁸” and replace with -- -NR⁷R⁸--;

Column 49,

Line 10, delete “-NHR⁷R⁸” and replace with -- -NR⁷R⁸--;
Line 16, delete “,and R¹⁰”;

Signed and Sealed this

Second Day of October, 2001

Attest:

Nicholas P. Godici

Attesting Officer

NICHOLAS P. GODICI
Acting Director of the United States Patent and Trademark Office



US006423098B1

(12) **United States Patent**
Biedermann

(10) **Patent No.: US 6,423,098 B1**
(45) **Date of Patent: Jul. 23, 2002**

(54) **LEG PROSTHESIS WITH AN ARTIFICIAL KNEE JOINT PROVIDED WITH AN ADJUSTMENT DEVICE**

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(75) Inventor: **Lutz Biedermann, VS-Villingen (DE)**

(73) Assignee: **Biedermann Motech GmbH (DE)**

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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PCT Pub. Date: **Jun. 17, 1999**

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A61F 2/74

(52) U.S. Cl. **623/24; 623/26; 623/44**

(58) Field of Search 623/24-27, 39,
623/43-46, 57, 58

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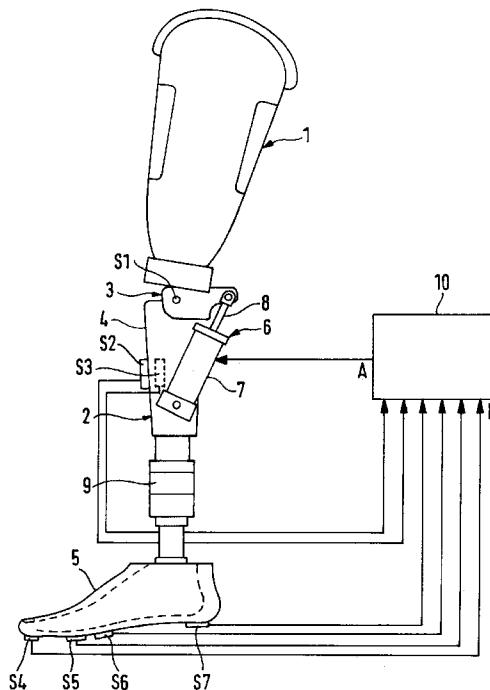
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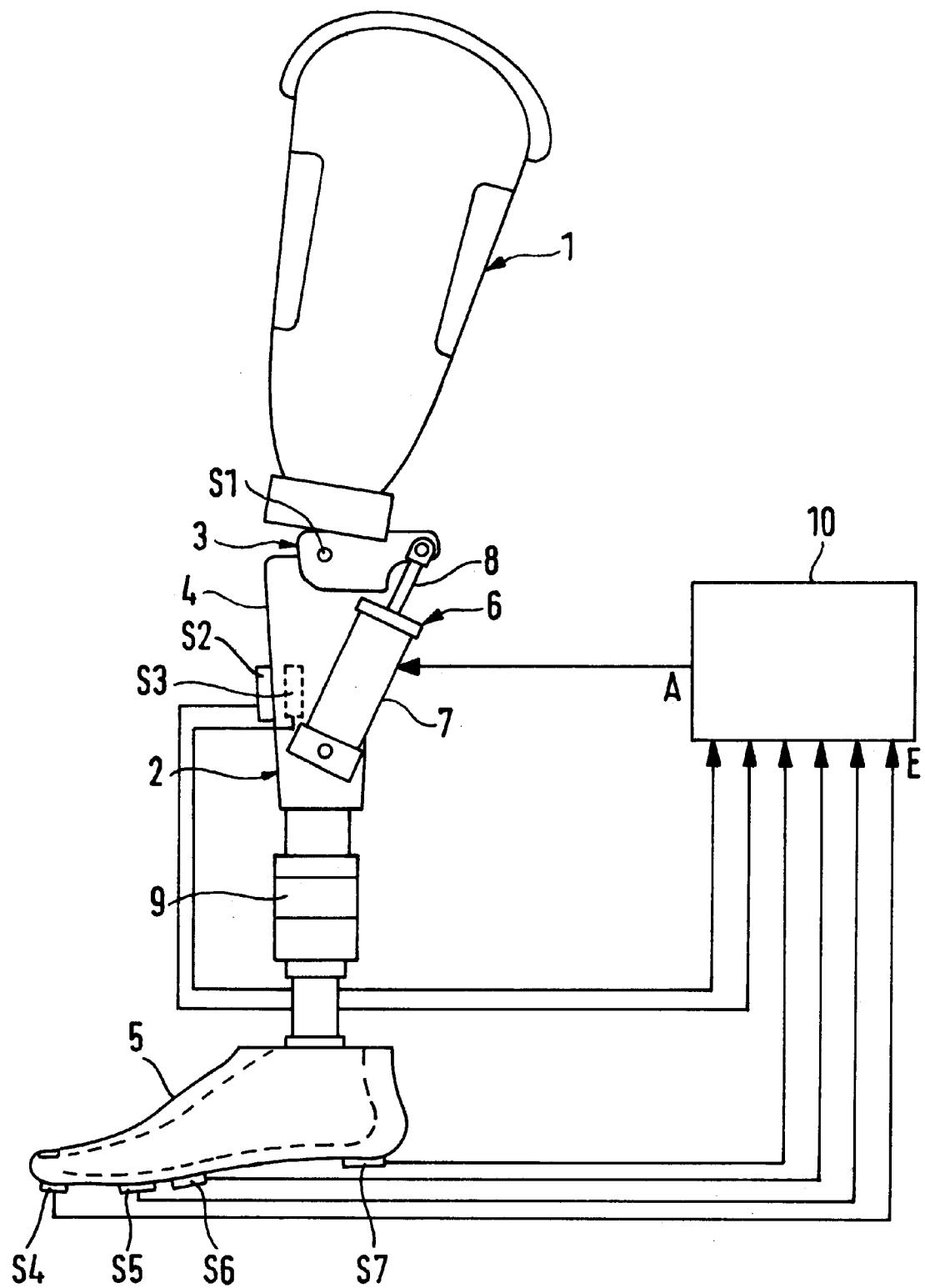
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ABSTRACT

A leg prosthesis having an artificial knee joint with swing phase control and recoil break comprises a damping member acting upon the knee joint, detectors for detecting force, knee angle and acceleration and a control unit for controlling the dampening degree of the damping member on the basis of the detected values. The damping characteristics of the damping member are varied in dependence on control signals produced by the control unit on the basis of a viscosity change of the magneto-rheological liquid.

9 Claims, 1 Drawing Sheet





LEG PROSTHESIS WITH AN ARTIFICIAL KNEE JOINT PROVIDED WITH AN ADJUSTMENT DEVICE

The invention relates to a leg prosthesis comprising an artificial knee joint having swing phase control and recoil brake wherein a control member provided at the knee joint controls the knee joint depending on control signals based on a viscosity change of a magneto-rheological liquid.

When walking with a prosthesis the thigh member is moved forward by the residual limb. The leg member may, owing to its mass inertia, bend back very far if the damping is not properly adjusted. The wearer of the prosthesis then has to wait until the prosthesis moves again in forward direction before putting the foot on the ground. This results in an unharmonious walking appearance, an unfavourable time characteristic and therefore poor wearing properties.

It is known to provide leg prostheses comprising an artificial knee joint with a damping member formed as a pneumatic or hydraulic cylinder for swing phase control and as a so-called recoil brake. The leg prosthesis is adapted to the wearer by means of a stationary walking pattern analysis system. The wearer of the prosthesis must do a test run, for example on a walking band, and the walking pattern is then subjectively evaluated by an orthopedic technician.

Taking also the subjective sensations of the wearer of the prosthesis into account, the various components of the prosthesis are then adapted and adjusted. The result of this adjustment is often inaccurate because it is based on subjective criteria. Further, later changes such as weight changes, temperature changes or changes of the ground conditions are not taken into consideration.

Moreover, the known damping members for artificial knee joints are disadvantageous in that they are unable to react in a sufficiently fast manner to an abrupt change of the walking dynamics.

It is the object of the invention to provide a leg prosthesis comprising an artificial knee joint with a swing phase control and a recoil brake, the leg prosthesis ensuring an always optimum operation which is adapted to the wearer as well as fast reaction to abrupt changes of the walking dynamics.

This object is achieved by a control based on a viscosity change of a magneto-rheological liquid and an automatic control producing control signals on the basis of detected values to automatically regulate the knee joint functions during the operation of the prosthesis.

Further features and advantages of the invention will be apparent from the description of an embodiment with reference to the FIGURE.

The FIGURE shows, in schematic representation, a leg prosthesis comprising an artificial knee joint with a swing phase control and a recoil brake and a corresponding control or regulation, respectively.

In conventional manner the prosthesis comprises a thigh member 1 and a leg member 2 and a knee joint 3 joining both members.

The leg member 2 comprises a shin part 4 having a lower leg tube 9 and a foot member 5 attached thereto. The foot member 5 comprises a leaf spring which is not shown in the FIGURE for allowing resilient steps. The thigh member 1 is formed for connection with the residual limb.

The knee joint 3 comprises a damping member in form of a hydraulic piston-cylinder device 6. The piston 7 of the piston-cylinder device 6 is connected to the shin part 4 and the piston rod 8 of the piston-cylinder device 6 is connected with the knee joint 3. The cylinder of the piston-cylinder

device is filled with a magneto-rheological liquid (MR fluid) having the characteristics of changing its viscosity within about 3 to 5 milliseconds when subjected to a magnetic field. The magneto-rheological liquid consists of a suspension of magnetizable particles having a size on the order of micrometers in oil. Under normal circumstances the consistency of a magneto-rheological liquid is similar to that of engine oil. When subjected to a magnetic field the viscosity abruptly increases whereby the change is proportional to the intensity of the magnetic field.

The piston 8 or the cylinder 7 of the piston-cylinder device 6 further comprises a solenoid which can be controlled by external signals and generates the magnetic field affecting the magneto-rheological liquid.

The leg prosthesis further comprises a number of sensors for detecting motion and force. A knee angle detector for detecting the knee angle is provided in the knee joint 3. Acceleration detectors are provided at the shin part 4. A head-on acceleration detector S2 serves for measuring the acceleration in walking direction, a lateral acceleration detector S3 serves for measuring the acceleration perpendicular to the walking direction. The acceleration detectors may be conventional acceleration detectors which are for example used in vehicle technology. Further, force detectors S4 to S7 are provided in the region of the foot sole. The force detector S4 is located in the region of the toes, the force detectors S5 and S6 are located in the region of the ball of the foot and the force detector S7 is located in the heel region. The detectors may be conventional force detectors, for example based on a compression spring. Alternatively, force sensors located within the lower leg tube 9 may be used.

The signal outputs of the detectors S1 to S7 are connected to one or several inputs E of a control or regulation unit 10.

The control unit comprises a CPU and a data memory. A program having an algorithm for processing the incoming signals of the sensors and for producing one or several output signals is provided in the data memory. A signal output A of the control unit 10 is connected with the piston-cylinder device 6 and especially with the solenoid provided within the piston.

In operation the control of the leg prosthesis works as follows.

The measurement data of the detectors S1 and S7 are transmitted to the control unit 10. Based on the measurement data control unit 10 produces control signals for the piston-cylinder device and transmits them to this device. Based on the control signals the solenoid produces a defined magnetic field which causes a determined viscosity change of the magneto-rheological liquid in the cylinder 7. By changing the viscosity the depth of immersion of the piston 9 into the cylinder 7 and therefore the damping effect can be correspondingly controlled. The damping change thereby occurs within a period of about 3 to 5 milliseconds. This is particularly advantageous when using the damping as recoil brake. If the wearer of the leg prosthesis stumbles, the leg member can be prevented in good time from folding up by the damping effect which immediately builds up.

The control unit, the detectors and the damping member are interconnected in a control circuit, i.e. the damping effect is adjusted during walking. This is advantageous, compared to a conventional prosthesis control, in that the prosthesis functions are adjusted in direct dependence on the natural walking pattern of the wearer of the prosthesis.

Modified embodiments are possible. More or less than the above-described detectors may be provided.

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In place of the piston-cylinder device having a cylinder with an axially displaceable piston therein a piston-cylinder device comprising a rotary piston may be used. The rotary piston can be provided with vanes having a defined resistance within the cylinder dependent on the viscosity of the magneto-rheological liquid. In this case, the piston rod is connected to a rotary shaft of the knee joint.

What is claimed is:

1. A leg prosthesis having an artificial knee joint with swing phase control and recoil brake, said prosthesis comprising:

means for producing control signals for controlling said knee joint; and

a control member controlling said knee joint on the basis of said control signals;

said control member comprising a damping member in the form of a piston cylinder device having a piston and a cylinder filled with a magneto-rheological liquid and means for changing the viscosity of said magneto-rheological liquid within the cylinder on the basis of said control signals, wherein a damping effect is provided by the piston in the cylinder.

2. The leg prosthesis of claim 1, said means for producing control signals comprising a detector provided at said leg prosthesis,

said detector including (A) a detector selected from the group consisting of (1) a force detector, (2) a knee angle detector or (3) an acceleration detector having a signal output, and (B) a control unit connected to said signal output of said detector for producing said control signals on the basis of the values of force, knee angle or acceleration detected by said detector.

3. The leg prosthesis of claim 2 comprising a detector selected from the group consisting of:

(1) a detector provided at the knee joint for detecting the knee angle,

(2) a detector provided in the region of a shin for detecting a lateral or forward acceleration, or

(3) a force detector provided at the sole.

4. The leg prosthesis of claim 2, further comprising a regulating unit for automatic regulation of the knee joint functions during the walking on the basis of the actually detected values of force, acceleration or knee angle, said regulation unit comprising said knee joint, said control unit and said control member.

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5. The leg prosthesis of claim 2, wherein said control unit is mounted to said leg prosthesis and fixedly connected to said control member.

6. The leg prosthesis of claim 1, wherein said means for changing the viscosity of said magneto-rheological liquid is a solenoid, and said control member controls said solenoid for varying the magnetic field produced by said solenoid on the basis of said control signals.

7. A leg prosthesis according to claim 1, said leg prosthesis further comprising:

at least one detector provided at said prosthesis for detection of force, knee angle or acceleration, said detector having a signal output; and

a control unit connected to said signal output for producing control signals on the basis of the values detected by said detector;

wherein said control member is provided at said knee joint for automatically controlling said knee joint on the basis of said control signals during operation of said prosthesis.

8. The leg prosthesis of claim 1, wherein said piston-cylinder device comprises an axially displaceable piston or a rotary piston.

9. A leg prosthesis having an artificial knee joint with swing phase control and recoil brake, said prosthesis comprising:

means for producing control signals for controlling said knee joint;

at least one detector provided at said prosthesis for detection of force, knee angle or acceleration, said detector having a signal output;

a control unit connected to said signal output for producing control signals on the basis of the values detected by said detector; and

a control member provided at said knee joint for automatically controlling said knee joint on the basis of said control signals during operation of said prosthesis;

said control member comprising a piston and a cylinder filled with a magneto-rheological liquid and means for changing the viscosity of said magneto-rheological liquid on the basis of said control signals, wherein said magneto-rheological liquid provides resistance within the cylinder, thereby providing a damping effect on the piston.

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