

# United States Patent [19]

Levy et al.

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[54] PROSTHETIC TENDON

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[51] Int. Cl.<sup>4</sup> ..... A61F 1/00

[52] U.S. Cl. ..... 623/13; 128/92 C

[58] Field of Search ..... 128/335, 334, 92 C, 128/92 G, 22 R; 3/1, 1.4, 1.9, 1.91

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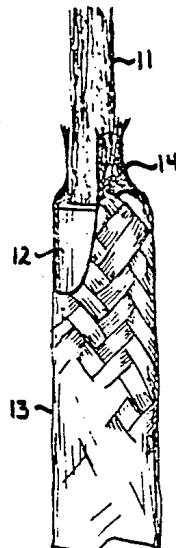
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Attorney, Agent, or Firm—Browdy and Neimark

[57] ABSTRACT

There is provided a tendon prosthesis comprising in combination an essentially tubular core of physiologically acceptable and mechanically strong fabric, embedded in a flexible polymer, which member is provided with a surrounding woven sleeve of a biodegradable fabric, said inner fabric core being exposed at both ends for attachment to the bone and muscle, and a process for the production of same which comprises stretching a knitted dacron strip to form an elliptical cross-section member, longitudinally open, embedding it in polymerizable silicon monomer, polymerizing same, weaving around same a sleeve from biodegradable filaments, and closing the sleeve at the two ends around exposed dacron core.

13 Claims, 11 Drawing Figures



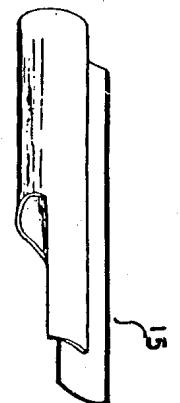


FIG. 1

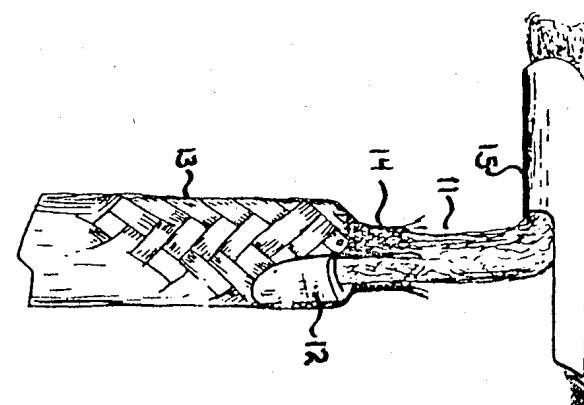


FIG. 2

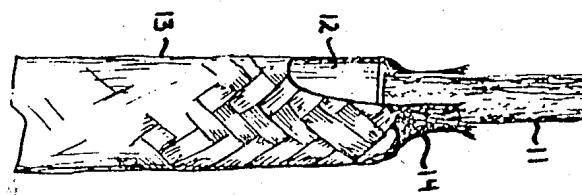


FIG. 3

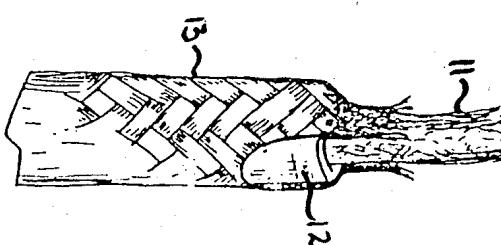


FIG. 4

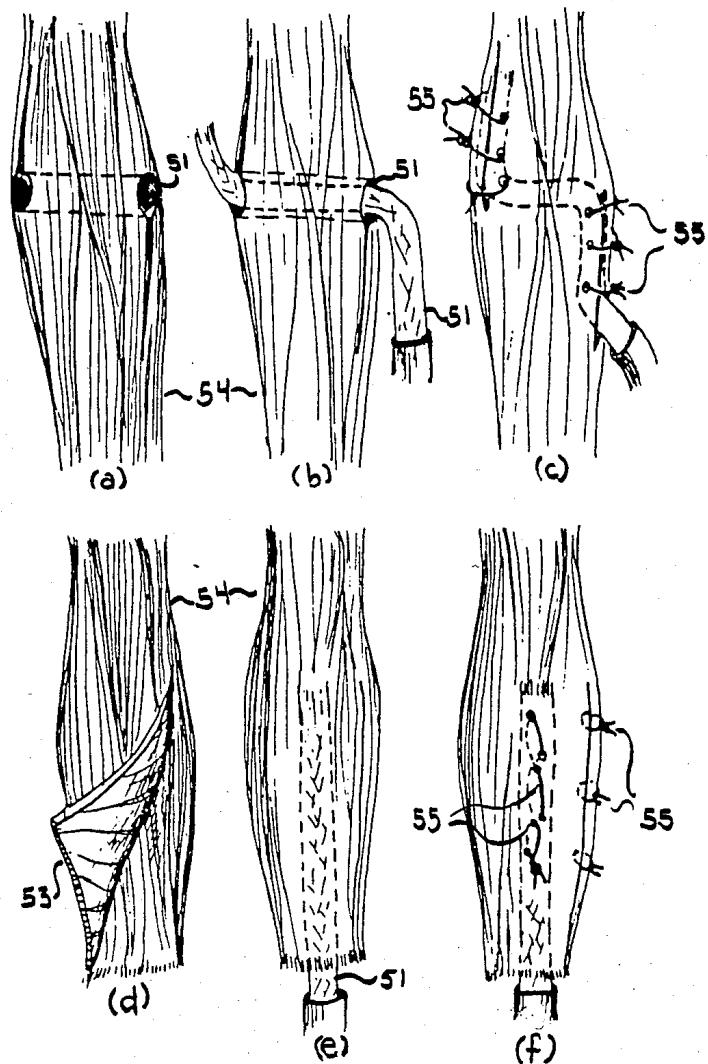


FIG. 5

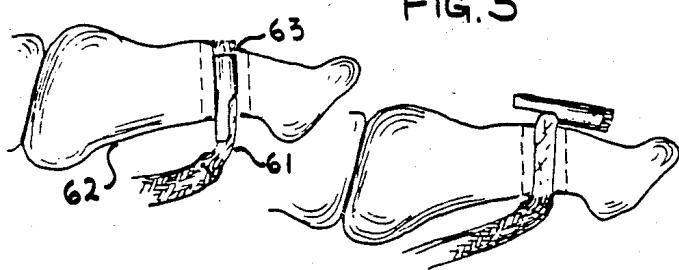


FIG. 6

## PROSTHETIC TENDON

## FIELD OF THE INVENTION

There is provided a tendon prosthesis with a biodegradable sleeve, a process for the production of same and its use in prosthesis in human and veterinary medicine.

## BACKGROUND OF THE INVENTION

The repair of damaged tendons, especially in the palm of the hand, as well as in other locations, causes severe problems. The conventional method of implantation of tendons in cases of severe injuries of the hand requires three surgical operations, namely, the implantation of a silicon rod; its removal after a period of about six weeks; and the insertion into the thus created tunnel of a tendon taken from a donor site of the body. In cases of attachment to a finger, there is created a "window" in the finger bone and inserting the end of the tendon into same, connecting it by means of a stainless steel wire which is tied to a button on the other side of the bone. The suture of flexor tendons in the palm of the hand, in the region called "no man's land" is often functionally unsuccessful due to adhesions of the tendon to neighboring tissues. This is the reason why substitution of a torn tendon by a new one is generally resorted to. In cases of destruction of tendons, these are replaced by donor tendons from other body sites or by prosthetic tendons. One of the more serious problems of prosthetic tendons (hereinafter PT), is their adhesion to surrounding tissues.

It is one of the objects of the present invention to overcome this problem, and to provide PT which are mechanically strong, can be implanted in one step, and which do not cause problems of adhesion.

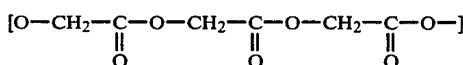
## SUMMARY OF THE INVENTION

There are provided prosthetic tendons (PT) which are implanted in a one-step surgical procedure, and which fulfill all the physiological requirements, without problems of adhesion to surrounding tissues, and which are provided with means for attachment to the bone (like finger phalanges) and other bones and to the muscle. There is also provided a process for the production of such PTs.

The novel prosthetic tendon comprises a core of a polymer fabric on which was cast a layer of silicon rubber or the like, which provides elasticity and a smooth movement of the tendon, said core of fabric and silicon rubber being encased in a sleeve of a biodegradable material. The sleeve is preferably a woven one, which provides adequate elasticity, and prevents the growth of surrounding tissue towards the silicon rubber. After being in place for a certain period of time, the said exterior sleeve undergoes enzymatic degradation and disappears. It thus serves as temporary spacer between the tendon and its surroundings, and the surrounding tissue subsequently develops into a tendon sheath which will be remote from the surface of the silicon rubber. The prosthetic member is provided with novel means of attachment to the bone.

There is also provided a method of production of such PT which comprises molding a core of suitable polymer, such as silicon rubber containing a strong synthetic fabric, and weaving on same a sleeve of a biodegradable material, and sealing same at its ends, to prevent unravelling and its sliding on the silicon core.

Advantageously, the PT is provided at one of its ends with means for attachment to a bone. According to a preferred embodiment, a rectangular elongated strip of Dacron or similar fabric of surgical grade, is tensioned, thus imparting to it a traverse section of open elliptical shape. There is provided a mold into which a polymerizable material is introduced, into which the said elliptical core is inserted, and which is polymerized, resulting in a layer of said polymer around said inner core. At this stage a sleeve of a biodegradable material is woven from fibers thereof. Good results were obtained by the use of 16 filaments of a polymer of polyglycolic acid (PGA), of the formula



which were woven to provide a tightly fitting sleeve, the ends of which were sealed by applying an elevated temperature of about 240° C. The outer sleeve and the enclosed silicon are terminated at a point before the insertions points, thus the two ends of the PT are of a smaller diameter than that of the main part of the PT. To one of the ends of the PT there is attached a member made of an inert metal, such as stainless steel of surgical grade, which is in the shape of an open cylinder surrounding the end of the PT, which is passed through a hole drilled in the bone to which the PT is to be attached, and which, after passage through said hole, is bent at a 90° angle to be flush with said bone, firmly anchoring the said end of the PT in place.

The PT is surgically implanted at one end in muscle, and during several weeks there takes place an ingrowth of fibrocytes and connective tissue into the pores of the Dacron fabric from each end, resulting in a biological bond between the PT and muscles. At the place where the PT is connected with the bone, the inner fabric remains exposed to permit ingrowth of bone tissue into said fabric, at which stage the said tendon is held in place by the said metal anchor. After this period of time, the material of the biodegradable sleeve undergoes degradation by the enzymes attacking it, and it gradually disappears, leaving a new tendon within the silicon layer, which is remote from the surrounding tissue.

The invention is illustrated with reference to the enclosed schematic drawings, which are not according to scale, and in which:

FIG. 1 is a perspective view of the anchor in open state;

FIG. 2 is a perspective view of part of a prosthesis of the invention with attached anchor;

FIG. 3 illustrates the sealing of the outer sleeve at its point of termination;

FIG. 4 shows part of the prosthesis, in partial section;

FIG. 5 (a), (b), (c), (d), (e) and (f) illustrates the insertion of such prosthesis in muscle; and

FIG. 6 illustrates the insertion and anchoring of the prosthesis in bone.

## DESCRIPTION OF THE PREFERRED EMBODIMENT

The prosthetic tendon (PT) has as backbone a strip of Dacron (Meadox Double Velour Dacron Fabric, Cat # 019136) Dacron is a registered trademark for a polyester made from polyethylene terephthalate. The Dacron backbone strip has a width of about 7 mm width is cut to the desired length. A typical length is from 50 to

about 150 mm. The strip is tensioned, and this imparts to it an open elliptical cross-section. There is provided a mold of adequate length and of elliptical cross-section, consisting of two half sections. The Dacron tube (open at its length) is introduced into a half mold which there has been previously introduced a quantity of silicon (Dow-Corning Sylgard 186 Silicon Elastomer). While the strip is maintained under tension by two holders, and the second part of the mold is filled with the same silicon, both portions of the resin being admixed with Sylgard 186 curing agent (1:10), after which the mold is closed and the silicon polymerized after removal of air by vacuum at 110° C. during 20 minutes. The mold is cooled, and the PT removed. Around the Darcon fabric there is thus provided a silicon coating, and around this there is woven a sleeve consisting of 16 filaments of polyglycolic acid (Davis and Geck 2/0 Dexon). The cross section of the complete PT is elliptical, about 3 mm width and about 1 mm height. The Dacron is exposed at both ends of the strand, and the outer sleeve is firmly closed around the Dacron core by application of heat of about 240° C., fusing the outer sleeve filaments.

The polymer from which the sleeve is made is biodegradable, and due to enzymatic degradation it disappears after a certain period of time.

As shown in FIGS. 2, 3, and 4, the prosthesis consists of an inner core of Darcon ribbon, in open elliptical form, 11, around which there is provided a layer of silicon 12, and which is provided with a sleeve 13 of biodegradable material, which sleeve is closed around the Dacron core at both ends, as shown at 14. For anchoring to a bone, there is provided a stainless steel member 15, shown in FIG. 1 and FIG. 2. This anchor is made from a tubular profile with a longitudinal opening. The Dacron fiber is inserted into the tubular member, and this is firmly attached to same by application of mechanical force. When the prosthetic tendon is to be attached to a bone, like a finger phalanx, a small hole is bored through same, slightly larger than the diameter of the tubular anchor, which is passed therethrough while being coaxial with the main portion of the tendon. After passage through the hole, the anchor is bent by 90° and thus anchored firmly in place as shown in FIG. 6 where the anchor 15 is shown during the passage stage and after being bent over. As shown in FIG. 5, the exposed Dacron core 51 is passed, via a hole 52 or flap 53, into the muscle 54, and sutured to it as shown in FIG. 5(c) and FIG. 5(f) by stitches 55. During some weeks there occurs an ingrowth of fibrocytes and connective tissue into this fabric and a biological bond is established. FIG. 6 illustrates the attachment of the exposed Dacron fabric 61 to bone 62 by insertion into a hole 63. The anchor illustrated with reference to FIG. 6 is of about 0.5 mm diameter, and the hole needs to be slightly larger. When bent over, a T-formed anchor is formed.

The PGA sleeve disappears after some weeks, and this sleeve prevents the adhesion of the surrounding tissue to the silicon tendon. It acts as spacer and isolator, and after its disappearance there results a tendon sheath surrounding the implant and remote from it. The rupture load was measured by an Instron device and was found to be about 10.400 Kg for the tendon, with elongation of 57%. The rupture load of the anchor-Dacron junction is about 2.5 Kg. Experiments carried out on turkeys showed that the tendon prosthesis of the invention fulfills all the physiological requirements, and preliminary experiments with humans confirm this.

Tendons of varying lengths (40, 70, 110 and 150 mm length) were produced and tested. All gave satisfactory results.

It is clear that the above description is by way of illustration only and that various modifications in the nature of the materials used and in the dimensions and arrangements of parts may be resorted to without departing from the scope and spirit of the invention.

We claim:

1. A tendon prosthesis consisting essentially of a tubular core of biocompatible fabric, embedded in a polymer which provides elasticity and prevents tissue ingrowth therethrough, said core being encased in a sleeve of biodegradable material, said biodegradable material being selected so as to prevent growth of surrounding tissue towards said core, and said core having fabric extending beyond said sleeve at both ends for attachment to the bone and muscle, whereby upon implantation the sleeve undergoes enzymatic degradation thus serving as a temporary spacer between the newly developed tendon sheath and the surface of the core structure.
2. A tendon prosthesis according to claim 1, wherein the inner core is an elliptical open tubular member of polyester fabric made from polyethylene terephthalate, which is embedded in silicon rubber, the outer sleeve being woven from filaments of polyglycolic acid (PGA).
3. A tendon prosthesis according to claim 1, further including a tubular anchor with a longitudinal opening, attached to the exposed fabric of said core extending beyond said sleeve, and adapted to pass through a hole in the bone and to be bent over to attach it firmly to the bone.
4. A tendon prosthesis according to claim 1, wherein said biocompatible fabric is composed of polyester fibers made from polyethylene terephthalate and said polymer is a silicon polymer, and wherein said core is the product of stretching a strip of said fabric of about 7 mm width, embedded in silicon polymer, so as to form an elliptical member having a major axis of about 3 mm and a minor axis of about 1 mm.
5. A tendon prosthesis according to claim 1, wherein said outer sleeve is closed around the inner fabric of said core at both ends of the prosthesis.
6. A tendon prosthesis in accordance with claim 1, wherein said biodegradable sleeve material is polyglycolic acid.
7. A tendon prosthesis in accordance with claim 1, wherein said biodegradable sleeve is woven.
8. A tendon prosthesis in accordance with claim 6, wherein said biodegradable sleeve is woven.
9. A tendon prosthesis in accordance with claim 1, wherein said core comprises a polyester fabric made from polyethylene terephthalate embedded in silicon polymer.
10. A process for producing a tendon prosthesis consisting essentially of a tubular core of biocompatible fabric, embedded in a polymer which provides elasticity and prevents tissue ingrowth therethrough, said core being encased in a sleeve of biodegradable material, said biodegradable material being selected so as to prevent growth of surrounding tissue towards said core, and said core having fabric extending beyond said sleeve at both ends for attachment to the bone and muscle, comprising stretching a knitted strip of biodegradable fabric to form a longitudinally open elliptical cross-section member, embedding said member in a polymerizable

monomer which upon polymerization becomes a polymer which provides elasticity and prevents tissue ingrowth therethrough, polymerizing said monomer, weaving around said polymer a sleeve from filaments of said biodegradable material, and closing the sleeve at the two ends around the exposed fabric core.

11. A process according to claim 10, wherein an anchor is attached to one of the ends of the exposed fabric core.

12. A process in accordance with claim 10, wherein

said biocompatible fabric comprises a polyester fabric made from polyethylene terephthalate and said polymer comprises a silicon polymer.

5 13. A process according to claim 12, wherein an anchor is attached to one of the ends of the exposed fabric core.

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## Bibliographic data: CA2202708 (A1) — 1997-10-30

### THREE-DIMENSIONAL BRAIDED COVERED STENT

**Inventor(s):** THOMPSON PAUL J [US] ± (THOMPSON, PAUL J)

**Applicant(s):** SCHNEIDER USA INC [US] ± (SCHNEIDER (USA) INC)

**Classification:** - **international:** A61F2/06; A61F2/90; D04C1/06; A61F2/00; A61F2/02; (IPC1-7): A61F2/04; A61L27/00  
- **cooperative:** A61F2/06 (EP); A61F2/90 (EP); D04C1/06 (EP, US); D04C3/36 (EP); D04C3/40 (EP); A61F2/0077 (EP); A61F2/07 (EP); A61F2/95 (EP); A61F2002/072 (EP); A61F2210/0004 (EP); A61F2210/0076 (EP); A61F2220/0008 (EP); A61F2220/0016 (EP); A61F2240/001 (EP); A61F2250/0067 (EP); A61F2250/0098 (EP); D10B2509/06 (EP)

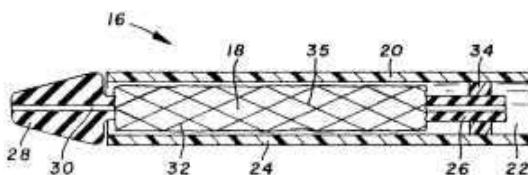
**Application number:** CA19972202708 19970415

**Priority number(s):** US19960640091 19960430

**Also published as:** CA2202708 (C) AT330562 (T) AU1992897 (A) AU729170 (B2)  
DE69736150 (T2) more

### Abstract of CA2202708 (A1)

A prosthesis (18, 108, 120) for transluminal implantation consists of a flexible tubular three-dimensionally braided structure of metal or polymeric monofilaments (32, 110, 126), and polymeric multifilament yarns (42). The prosthesis can be elastically deformed to reduce its diameter through axial elongation. The monofilaments and multifilament yarns are arranged in axially spaced apart helices, concentric on a common central axis of the prosthesis. The monofilaments are selectively shaped before their interbraiding with the multifilament yarns, either by an age-hardening or other heat-setting stage, or a cold-working stage that controllably plastically deforms the strands. The shaped structural strands cooperate to impart to the prosthesis its nominal shape and resilience. The textile strands cooperate to provide one or more layers of sheeting (40) that reduce permeability and thereby enhance the utility of the prosthesis as a vascular graft. An alternative embodiment prosthesis (132) includes elastically and plastically deformable structural strands (140), selectively plastically deformed by cold working, then three-dimensionally braided to form the prosthesis.



**FIG. 1**

## Description: CA2202708 (A1) — 1997-10-30

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### THREE-DIMENSIONAL BRAIDED COVERED STENT

#### Description of CA2202708 (C)

**A high quality text as facsimile in your desired language may be available amongst the following family members:**

AU729170 (B2) DE69736150 (T2) EP0804909 (A2) JPH1033692 (A) MX9703233 (A)  
US5718159 (A) US6342068 (B1)

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[0001] CA 02202708 1997-04-15 THREE-DIMENSIONAL BRAIDED COVERED STENT BACKGROUND OF THE INVENTION The present invention relates to body implantable devices, and more particularly to prostheses including stems and grafts intended for long term or permanent intraluminal fixation. A variety of patient treatment and diagnostic procedures involve the use of devices inserted into the body of a patient and intraluminally implanted. Among these devices are prostheses as disclosed in U.S. Patent No. 4,655,771 (Wallsten). These devices are flexible, tubular, braided structures formed of helically wound thread elements. A delivery catheter includes gripping members for securing a prosthesis to the catheter. In deployment, the gripping members and catheter are removed, allowing the prosthesis to assume a substantially cylindrical shape as it radially expands and substantially conforms to a blood vessel wall or other tissue. Metallic thread elements or strands are generally favored for applications requiring flexibility and effective resistance to radial compression after implantation. Metallic strands can be thermally formed by a moderately high temperature age-hardenirsg process while wound about a mandrel in the desired helical configuration. The strands cooperate to provide the requisite strength, due to their high modulus of elasticity. The flexibility of the strands also is important, as it permits a radial compression of the stent (by an axial elongation) that facilitates delivery of the stent through narrow blood vessels or other lumens toward the intended treatment site. Because the self-expanding device generally remains at least slightly radially compressed after fixation, its restoring force can provide acute fixation. The flexible stmt can accommodate a wider range of lumen diameters, reducing CA 02202708 1997-04-15 the need to precisely match the stmt and lumen as to size. The favorable combination of strength and flexibility is due to the properties of the strands themselves, and the arrangement of strands, i.e. the axial spacing between adjacent helical strands, the braiding angles of the strands, etc. Accordingly, conventional stems characteristically have an open mesh. construction as shown in Figures 2a (relaxed) and 2b (radially constrained). U.S. Patent No. 4,681,110 (Wiktor) discloses a flexible tubular liner, insertable into the aorta to treat an aneurisym. The liner is a tight weave of flexible plastic strands, designed to self-expand against the aneurisym to direct blood flow past the aneurisym. In this context, a tight weave is intended to minimize leakage, so that the liner can effectively shunt blood through to eliminate the aneurysmal sack from the blood path. Those of skill in the art have generally encountered difficulty in providing a device that simultaneously accommodates the competing needs of low permeability, and strength and flexibility for considerable radial compression and expansion. One known approach to counter this problem is a combination stent/grafft, in which a compliant but substantially fixed-radius

and tightly-woven graft is sutured or otherwise coupled to a radially expandable stent. The stent upon release is intended to radially expand to the graft diameter. This, however, generally requires a careful matching of the graft diameter with the lumen diameter at the treatment site. Otherwise, either an oversized graft is compressed between the stent and body tissue with undesirable folds or gathering of the graft material, or an undersized graft prevents the stent from expanding sufficiently to anchor the device. Several prosthesis constructions have been suggested, particularly involving three dimensional

CA 02202708 2003-06-04 ' 76286-2 braiding as disclosed in International Patent Publications No. W091/10766. For example, see International Patent Publication No. W092/16166, No. W094/06372, and No. W094/06373. These publications discuss composite grafts or other braided structures that combine different types of strands, e.g. multifilament yarns, monofilaments, fusible materials, and collagens. In all of these disclosures, the woven or braided structure is heat set after braiding to impart the desired nominal shape to the device. Accordingly, all strands and filaments must be compatible with the heat set conditions (primarily the high temperature), limiting the types of materials that can be interbraided into the device. Therefore, it is an object of the present invention to provide a three-dimensionally braided prosthesis including structural strands and other strands interbraided with the structural strands, in which the types of materials for such other strands are not limited by conditions necessary to thermally set or otherwise selectively shape the structural strands. Another object is to provide a process for three- dimensionally braiding a tubular prosthesis to provide a gradient in permeability, porosity, strength or other structural property in the radial direction. A further object is to provide, in a three- dimensional braiding process involving the interbraiding of multiple strands, a means for selectively cold-working a portion of the strands to predetermine a nominal shape of the interbraided structure. Yet another object is to provide an interbraided device incorporating the strength, resilience and range of diameters associated with stents, and the low permeability associated with grafts, adapted to incorporate a radial gradient in porosity or another characteristic.

CA 02202708 2003-06-04 ' 76286-2 \_g\_ SUMMARY OF THE INVENTION To achieve these and other objects, there is provided a process for making a prosthesis, including the following steps: providing a plurality of structural strands formed of structural material and having an original nominal shape; providing a plurality of compliant textile strands; altering the structural strands while they remain separate from the textile strands to impart to each of the structural strands a selected nominal shape in lieu of the original nominal shape; and after said altering, three-dimensionally braiding the textile strands and the altered structural strands into a three-dimensional integrated structure in which the structural strands together provide a tubular shape of the integrated structure and the textile strands form a textile sheeting supported by the structural strands and adapted to compliantly conform to changes from said tubular shape due to deformations of the structural strands. Preferably the braiding forms a latticework of the structural strands. Then, the textile strands are formed as one or more layers of textile sheeting supported by the latticework. A salient feature of the process is that the structural strands are selectively shaped, i.e. given their predetermined second nominal shapes, prior to the interbraiding step. Consequently, process conditions for selective shaping have virtually no impact on the textile

CA 02202708 2003-06-04 ' 76286-2 -4a- strands. This is particularly beneficial when the structural strands are metallic, e.g. formed of Elgiloy™ or another cobalt-based alloy, certain stainless steels, or a recovery metal such as Nitinol™ nickel-titanium alloy. These metals provide the desired strength and resiliency, yet when thermally shaped require temperatures far above the melting points typical of the multifilament yarns suitable for the textile strands. Certain polymers suitable for the structural strands likewise are advantageously shaped at temperatures unsuitably high for the textile strands. In either event, thermally setting or shaping the structural strands prior to interbraiding prevents this kind of

CA 02202708 2003-06-04 ' 76286-2 damage to the textile strands. In accordance with the present invention, structural strands may be selectively shaped by cold working as well. Certain resilient and ductile metals are particularly well suited to cold working. Examples of highly preferred alloys in this regard are discussed in U.S. Patent 5,891,191 entitled "Cobalt-Chromium-Molybdenum Alloy Stent and Stent-Graft", assigned to the assignee of this application and filed concurrently herewith. A primary advantage of cold working is the ability to incorporate the cold-working step and the braiding step into a continuous operation. In particular, each structural strand on its

way to a braiding station can be wrapped about a shaping pulley under sufficient tension to achieve the desired plastic deformation. Continuous shaping and braiding substantially reduce manufacturing cost. The structural strands can be formed into a variety of shapes, most preferably helical. The helices can be wound in a single direction so that the interstices are helical. More frequently, the structural strands are wound as two sets of helices running in opposite directions, to form a latticework in which the interstices are rhombic. The oppositely directed~helices can be interbraided, or can overlie one another, being interbraided only with the textile strands. The interbraided structure can incorporate further strands, for example of radiopaque material. The structure can incorporate one or more elastomeric strands running axially of the structure and fused to the structure along at least part of its axial length, thus to enhance radial self-expansion. As compared to structures formed by conventional two-dimensional braiding techniques, three-dimensionally braided structures tend to have a more even distribution of forces among the structural strands. Three- dimensional braiding enables a controlled structuring of

CA 02202708 1997-04-15 tubular prosthesis, for example to provide radial gradients in permeability, porosity, strength or other structural properties. A three-dimensionally braided structure with three or more discrete layers facilitates confining a latticework of structural strands to a medial layer, providing a textile cover on both sides of the latticework. The process can be augmented with several steps that enhance the utility of the prosthesis, such as coating the structural strands, the textile strands, or both. A heat setting step may be performed after braiding, when the textile strands are formed of a yarn amenable to heat setting. An adhesive can be applied to the ends of the integrated structure after braiding, to reduce unraveling. Another aspect of the present invention is a prosthesis. The prosthesis includes a three- dimensionally braided structure including a plurality of structural strands and a plurality of compliant textile strands. The structural strands are formed of a structural material having a tendency to assume a nominal shape when in a relaxed state. The structural strands further have respective selected nominal strand shapes imparted by at least one of: (i) a selective plastic deformation from an original nominal shape to the selected nominal shape; and (ii) a selective thermal setting including a heating of the structural strand to a temperature greater than a melting temperature of the textile strands while the structural strand is maintained in the selected nominal shape. The structural strands have selected orientations within the three-dimensionally braided structure, to impart a predetermined configuration to the structure. In a preferred prosthesis, the structural strands cooperate to form a latticework, and the textile strands cooperate to form one or more layers of textile sheeting supported by the latticework. Thus, the structural CA 02202708 1997-04-15 strength and resiliency of a self-expanding stent and the low permeability of a graft are combined in a single prosthesis. The structural strands preferably are monofilaments of metal, e.g. a stainless steel, an alloy including cobalt or an alloy including titanium. Alternatively the monofilaments are polymeric, constructed of materials including PET, polypropylene, PEEK, HDPE, polysulfone, acetyl, PTFE, FEP, polycarbonate urethane, and polyurethane. In either event the preferred textile strands are multifilament polymeric yarns. Suitable materials for the multifilament yarns include PET, polypropylene, polyurethane, polycarbonate urethane, HDPE (high density polyethylene), polyethylene, silicone, PTFE, ePTFE and polyolefin. Thus in accordance with the present invention, a three-dimensionally braided structure incorporating structural and textile strands is manufactured according to a process that enables a controlled shaping of the structural strands without adversely affecting the textile strands. The result is an intraluminal device with the favorable qualities of an open weave stent and of a tightly woven graft. The structural strands are shaped either thermally or by plastic deformation, before they are brought together with the textile strands for interbraiding. The interbraiding step involves all strands simultaneously, interweaving a compliant textile sheeting among the structural strands as the structural strands are formed into a latticework that defines the shape of the prosthesis. As a result, the textile sheeting is supported by the latticework and tends to conform to the shape of the latticework. The textile sheeting exhibits low permeability and high compliance, preventing leakage of blood or other fluids, yet readily accommodating radial contractions and expansions of the structural latticework.

CA 02202708 1997-04-15 -g- IN THE DRAWINGS For a further understanding of the above and other features and advantages, reference is made to the following detailed description and to the drawings, in which: Figure 1 is a partial side sectional view of a prosthesis constructed in accordance with the present invention, contained within a deployment device; Figures 2a and 2b illustrate an open weave stent consisting of

resilient metal structural strands in a two-dimensional braid; Figures 3 and 4 show the prosthesis of Figure 1 in a radially constrained state, and in a radially expanded state, respectively; Figure 5 schematically illustrates several discrete layers of the prosthesis formed by the three-dimensional braiding of multiple strands; Figure 6 is an enlarged partial view of Figure 3, with several outer layers removed, schematically illustrating an interbraiding of structural and textile strands in a medial layer of the prosthesis; Figures 7 shows the prosthesis of Figure 1 deployed within a vessel and spanning an aneurysm; Figures 8-10 schematically illustrate a process for manufacturing the prosthesis; Figures 11 and 12 schematically illustrate an alternative process for manufacturing the prosthesis; Figure 13 schematically illustrates a three-dimensional setup for braiding a prosthesis in a first example according to the present invention; Figure 14 schematically illustrates a three-dimensional setup for braiding the prosthesis in a second example according to the present invention; Figure 15 is an illustration of an alternative embodiment prosthesis; Figure 16 is an illustration of another alternative

CA 02202708 1997-04-15 embodiment prosthesis; and Figure 17 is an illustration of a further alternative embodiment prosthesis. **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS** Turning now to the drawings, there is shown in Figure 1 a deployment device 16 for delivering a prosthesis 18 to an intended fixation location or treatment site within a body lumen, and then controllably releasing the prosthesis for radial self-expansion and fixation within the lumen. The device includes an elongate and flexible outer catheter 20 constructed of a biocompatible polymer, e.g. polyurethane. A central lumen 22 runs the length of catheter 20. A distal portion 24 of the outer catheter surrounds prosthesis 18. An inner catheter 26 is contained within lumen 22 and runs along substantially the entire length of outer catheter 20. At the distal end of inner catheter 26 is a tapered distal tip 28. Prosthesis 18 surrounds inner catheter 26, and thus is confined between the inner and outer catheters. A lumen in the inner catheter can accommodate a flexible guidewire. Prosthesis 18, shown completely rather than in section, is a tubular braided structure including 25 helically wound monofilament structural strands 32 formed of a resilient material. In Figure 1, prosthesis 18 is elastically compressed into a reduced radius axially elongated delivery state. Outer catheter 20 confines the prosthesis, maintaining it in the delivery state against 30 an elastic restoring force. An annular detent 34, mounted to inner catheter 26, occupies a space between the inner and outer catheters to limit proximal travel of prosthesis 18 relative to the inner catheter. Thus, as outer catheter 20 is moved proximally relative to inner catheter 26, the detent prevents the prosthesis from moving with the outer catheter.

CA 02202708 1997-04-15 Catheters 20 and 26, while maintaining prosthesis 18 in the delivery configuration, are moved transluminally, through vasculature, to deliver the prosthesis to the intended treatment site. Once the prosthesis is positioned as intended, inner catheter 26 is held stationary, while outer catheter 20 is withdrawn proximally. Detent 34 prevents prosthesis 18 from moving proximally with the outer catheter, thus to maintain the prosthesis properly aligned as it progressively radially self-expands toward a relaxed state and into intimate contact with tissue at the treatment site. Because the prosthesis does not expand completely to the relaxed state, it exerts a residual force on the tissue that tends to maintain fixation of the prosthesis. At this point the prosthesis has a diameter much larger than the diameter of distal tip 28, so that the inner catheter and tip, along with the outer catheter, are easily proximally withdrawn. Prosthesis 18 resembles a radially self-expanding stent, in that it is well suited for radially compressed delivery and radial self-expansion. Accordingly, familiarity with radially self-expanding stems is useful in considering prosthesis 18. A conventional two-dimensionally braided radially self-expanding stent 21 is shown in Figures 2a and 2b. The stent consists of two oppositely directed and concentric sets of helically wound thread elements or wires 23. The wires can be formed of metal or a polymeric material and have good elastic recovery. Each wire is selectively shaped so that its nominal shape, i.e. its shape when in a relaxed state subject to no external stresses, is helical. Wires 23 cooperate to give the stent its nominal tubular shape. Adjacent helices in two opposite winding directions are spaced apart axially, resulting in rhombotic voids or interstices 25 with dimensions substantially larger than the wire diameters. The open-mesh construction, in

CA 02202708 2003-06-04 76286-2 combination with the resiliency and strength of the selectively shaped wires, enables and facilitates (a) elastic compression of the stent to a much smaller radius suitable for intraluminal delivery; (b) virtually instantaneous radial expansion of the stent when released at a treatment site; and (c) a sufficient

residual force to ensure acute fixation without hooks or barbs, although such fixation options may also be used. With reference to Figures 3 and 4 it can be appreciated that structural strands 32 form a latticework 35 of prosthesis 18. Like wires 23 of stent 2'1, strands 32 are arranged in two oppositely directed and concentric sets of helices, spaced apart axially from one another to define rhombotic interstices. Structural strands 32 further are similar to the stent wires in that they exhibit the requisite strength and elasticity, are biocompatible, resistant to fatigue and corrosion, and in vascular applications are hemocompatible as well. Materials meeting these needs include certain stainless "spring" steels, cobalt-based alloys, and alloys containing titanium. Several preferred cobalt-based TM alloys are sold under the brand names "Elgiloy", "Phynox" TM and "MP35N". Particularly preferred CoCrMo alloys are described in aforementioned U.S. Patent No. 5,891,191 entitled "Cobalt-Chromium-Molybdenum Alloy Stent and Stent Graft" (J. Stinson), assigned to the assignee of this application and filed concurrently herewith. These alloys contain less than about ~5 weight percent nickel, preferably less than about 2 weight percent nickel and more preferably no more than about 1 weight percent nickel. Chromium is preferably present in an amount between about 26.0 and 30.0 weight percent, and molybdenum preferably in an amount between about 5.0 and 7.0 weight percent. The alloys further can include nitrogen in an amount up to about 0.25 weight percent, and carbon in an amount up to about 0.35 weight percent.

CA 02202708 2003-06-04 ' 76286-2 Other elements, preferably in amounts no greater than about 1.0 weight percent, include iron, silicon, manganese, copper, phosphorous, sulfur and tungsten. The balance of the alloy in each case can be cobalt, preferably in an amount of at least 60.0 weight percent. Specific examples are described in this application. A preferred alloy of titanium is a recovery metal alloy of nickel and titanium, sold under the brand name "Nitinol". Other suitable titanium alloys include titanium-Zirconium-niobium alloys and a titanium-aluminum-vanadium alloy known as Ti-6A1-4V. Suitable polymeric monofilaments include PET, polypropylene, PEEK, HDPE, polysulfone, acetyl, PTFE, FEP, polycarbonate urethane, and polyurethane. Suitable polyurethanes and polycarbonate urethanes include those sold under the following brand names: Chronoflex AR, TM Chronoflex A1, Corethane, and Biomer. These monofilaments preferably have diameters in the range of about 0.002- 0.015 inches (0.051-0.38 mm). As seen in Figure 4, structural strands 32 intersect each other to define a braid angle  $\alpha$  which is bisected by a longitudinal axis 36 of the prosthesis. The braid angle, when prosthesis 18 is in the relaxed state, is in the range of about 60 to 150 degrees, and more preferably so to 140 degrees. As seen in Figure 3, radial compression of the prosthesis substantially reduces the braid angle. The braid angle largely determines the relationship between radial compression and axial elongation of the prosthesis. More particularly, smaller braid angles yield less axial shortening for a given amount of radial expansion. On the other hand, for a given strand size

CA 02202708 1997-04-15 and strength, a larger, braid angle imparts greater resistance to radial compression and more positive acute fixation. Accordingly a smaller braid angle generally requires a structural strand that is stronger, i.e. with a higher modulus of elasticity. Figure 5 schematically illustrates the manner in which multiple structural strands 32 and multiple textile strands 42 are interbraided with one another to form several discrete layers of prosthesis 18. These include an inner (radially inward) layer 44 consisting primarily of textile strands 42, an outer layer 46 also consisting primarily of the textile strands, and a medial layer 48 that incorporates the structural strands 32. Layers 44-48 are formed simultaneously in a single braiding operation that also interlocks the layers, in that at least one of the strands from each of the layers is braided into one of the other layers. In one preferred approach, inner layer 44 and outer layer 46 are formed substantially entirely of textile strands 42, while medial layer 48 is an interbraided combination of textile strands 42 and structural strands 32, e.g. at a one-to-one ratio, or two-to-one ratio in favor of the textile strands. Inner layer 44 includes a first set of its textile strands that extend into the medial layer, and a second set of its textile strands that extend through the medial layer into the outer layer, then back to the inner layer. These sets together can comprise a relatively small percentage of the textile strands of layer 44. Medial layer 48 and outer layer 46 similarly have sets of textile strands extending into the other layers. Thus there is a substantial intermingling among strands of the different layers for effective interlocking, although the layers remain distinct from one another in character. Textile strands 42 preferably are multifilament yarns, although they can be monofilaments. In either event the textile strands are much finer than the structural strands, ranging from about 10 to 400 denier. CA 02202708 2003-06-04 76286-2 Individual filaments of the multifilament yarns can

range from about 0.25 to about 10 denier. The multifilament yarns generally have a high degree of compliance, which may or may not include elasticity. Suitable materials include PET, polypropylene, polyurethane, polycarbonate urethane, HDPE, polyethylene, silicone, PTFE, ePTFE and polyolefin. One suitable high molecular weight polyethylene is sold under the brand name "Spectra". The fine textile strands are closely woven in layers 44, 46, and 48, and can be considered to form a textile sheeting or fabric 40 in each layer. Due to the fineness of textile strands 42 and a close or tight weave, the textile sheetings can be microporous, yet essentially impervious to body fluids. Also, the textile sheeting layers are highly compliant, conforming to changes in the shape of latticework 35 as prosthesis 18 either radially self-expands or is radially compressed. The shape of latticework 35 thus determines the shape of the prosthesis. In medial layer 48, the interstices 38 between adjacent structural strands in prosthesis 18 are occupied by textile sheeting or fabric. As seen in Figures 5 and 6, sheeting is formed of multiple textile strands 42 interbraided with one another and further interbraided with structural strands 32. Textile strands 42 also are provided in sets of oppositely directed helices, and intersect one another at the same braid angle a defined by the structural strands. Strands 32 and 42 are shown in Figure 6 in a one over one braiding pattern. However, it is to be appreciated that a variety of braiding patterns are known to those skilled in the art, and the pattern most suitable in a given instance depends on the desired structural characteristics and the materials involved. Thus, prosthesis 18 combines the favorable attributes of self-expanding stents and grafts. Latticework 35 provides radial compressibility, self-

CA 02202708 2003-06-04 76286-2 expansion over a wide range of radii and residual force for acute fixation, while textile sheetings 40 of layers 44-48 reduce permeability to the extent that the prosthesis is essentially impervious to blood and other body fluids. For these reasons, prosthesis 18 is particularly well suited to treating an aneurysm.

Figure 7 illustrates fixation of prosthesis 18 within a blood vessel having a vessel wall 50. Along the vessel wall is in an aneurysm 52. Opposite end regions 54 and 56 of the prosthesis have radially expanded into intimate contact with vessel wall 50 on opposite sides of the aneurysm. A medial region 58 of the prosthesis spans the aneurysm. End regions 54 and 56 effectively fix the prosthesis, due to the resilience and strength of the structural strand latticework. At the same time the prosthesis, because of textile sheetings 40, shunts blood past the aneurysm preventing any substantial leakage into the aneurysmal sack. A particularly favorable structure for prosthesis 18 has a medial layer 48 formed by interbraiding metallic structural strands with DacronM(polyester) multifilament yarns as the textile strands. The metal structural strands exhibit high strength in terms of elastic moduli. For example, stainless steels can have elastic moduli of about  $28-30 \times 10^6$  psi. Titanium and alloys of titanium tend to have elastic moduli in the range of  $15.4-16.6 \times 10^6$  psi. In contrast, polyethylene, for example, has an elastic modulus in the range of about  $0.02-0.055 \times 10^6$  psi, and other polymeric materials have elastic moduli in this order of magnitude. Accordingly, for a given strand diameter, helical diameter and helical pitch, a latticework of metallic strands is considerably more resistant to radial compression, and provides a greater residual force for acute fixation. The Dacron polyester multifilament yarn has a high elastic recovery and elongation (up to 36% for the polyester fiber) and a low elastic modulus, which ensure that textile sheeting 40

CA 02202708 1997-04-15 conforms to the latticework. This favorable composite structure cannot be manufactured by forming a braided structure on a mandrel, then heating the mandrel to thermally set the strands in their helical shapes. Thermally setting metallic structural strands entails heating the strands to temperatures up to about 1000 C. while the strands are maintained in the intended helical shape. Such temperatures are well above the melting points of polyesters and other materials most suitable for the multifilament yarn textile strands. Selectively shaping the structural strands is important in enhancing the predictability and control over prosthesis contractions and expansions, and also reduces any tendency of the prosthesis to unravel. To attain favorable characteristics of stems and grafts, prosthesis 18 can be fabricated according to several steps as illustrated in Figures 8-10. Figure 8 shows two structural strands (metal monofilaments) 32a and 32b, one from each set of oppositely directed structural strands, wound about a mandrel 60 and supported by respective bobbins 62 and 64. While just strands 32a and 32b are illustrated as a matter of convenience, it is to be appreciated that all of the structural strands are wound about the mandrel and maintained together for shaping. Only structural strands are present, however, as shaping occurs before interbraiding with the textile strands. Age-hardening is accomplished within a furnace 66 in a vacuum or a protective atmosphere.

Temperatures are within the range of about 350-1000 C., with the specific temperature depending on the structural material. The filaments overlie one another to form multiple intersections, one of which is indicated at 68. Bobbins, including 62 and 64, are set to tension their respective strands during age-hardening. The appropriate duration for age-hardening varies with materials and dimensions,

CA 02202708 1997-04-15 but can range from as brief as 30 seconds, to about 5 hours. After age-hardening, the structural strands are allowed to cool, whereupon each structural strand retains the helical shape as its nominal shape. In the context of elastic materials, "nominal shape" refers to the shape in a relaxed state, i.e. when under no external stress. The age-hardened metallic monofilaments are highly resilient, i.e. deformable under external stress, but elastically returning to the nominal shape when free of the external stress. The strands when constructed of a recovery metal are plastically deformable when maintained below an activation temperature, which for Nitinol can be below body temperature, i.e. below about 37~ C. When heated to the activation temperature or above, the structural strand returns to the selected nominal shape. In the context of recovery metal strands, "nominal shape" is the shape to which the strand returns when heated to at least the activation temperature. When structural strands 32 are thermoplastic rather than metallic monofilaments, multiple strands are thermally set in similar fashion. More particularly, with the thermoplastic monofilaments wound in opposite sets about mandrel 60, the strands are heated to a heat-forming temperature in the range of about 100 to 400 C., more preferably 150 to 2500 C., either within a furnace as previously described or by heating the mandrel. The strands are maintained at or above the heat-forming temperature for a duration generally shorter than that of thermally setting metal strands, i.e. from about 30 seconds to about 2 hours, or more preferably 5 to 15 minutes. Again, only the structural strands are shaped, and before they are interbraided with the textile strands. This sequence can be advantageous even when the structural strands and textile strands are formed of the same thermoplastic material, as it enables fabrication of a prosthesis in which only the structural strands are

CA 02202708 1997-04-15 thermally set. It is to be appreciated that the thermal setting process alters the structural strands, in the sense of changing their shapes from an original nominal shape to a selected nominal shape. Typically the original nominal shape is linear, with the selected nominal shape determined by the diameter of the mandrel and the pitch at which the structural strands are wound about the mandrel. Interbraiding of the structural and textile strands occurs after selective shaping. Figure 9 schematically illustrates a braiding apparatus 70 including a cylindrical carrier assembly 72 including several annular arrays of bobbins, two of the bobbins being indicated at 80a and Bob. The apparatus further includes a mandrel 78, centered within the cylindrical assembly and movable longitudinally relative to the assembly as indicated by the arrow. Figure 10 illustrates part of carrier assembly 72 in greater detail, to reveal five annular arrays or sets of carrier bobbins indicated at 80, 82, 84, 86 and 88. The sets are coaxial and axially spaced apart, each including forty-eight bobbins, twenty-four bobbins for respective clockwise and counterclockwise windings about mandrel 78. While those skilled in the art are acquainted with the use of braiding machinery, it is emphasized here that braiding apparatus 70 is configured as described in the aforementioned International Patent Publication No. W091/10766. Suitable braiding machinery is available from Albany International Research Company of Mansfield, Massachusetts. The equipment is used as follows: First, carrier assembly 72 is loaded by winding different strands onto different bobbins. The type of strand wound on each bobbin depends on the desired braiding pattern and ratio of structural strands to textile strands. All strands are drawn from their respective bobbins to mandrel 78, and braiding proceeds

CA 02202708 1997-04-15 by moving mandrel 78 longitudinally, while at the same time the bobbins are moved relative to one another as dictated by the desired pattern of braiding. The result is a simultaneous interbraiding of the structural and textile strands onto the mandrel, as indicated at 90. The mandrel determines the diameter of the braided structure. Mandrel longitudinal speed largely determines the braid angle. Prosthetic lengths are determined by the duration of braiding, or by cutting the braided structure to predetermined lengths upon its removal from the mandrel. The braiding process includes controlling the structural strands as to orientation during braiding, to ensure that the individual helices cooperate to provide the desired nominal tubular configuration for the resulting lattice work. Similar control of the textile strands is not necessary, due to their more compliant nature. Properly oriented structural strands diminish any unraveling tendency and result in more predictable contraction and

expansion of the prosthesis. Further, from Figure 6 it can be appreciated that the textile strands, in occupying the interstices between structural strands of layer 48, tend to maintain the structural strands in the desired configuration of intersecting helices.

Figure 11 schematically illustrates an alternative three-dimensional braiding apparatus 92 in which the structural strands are selectively shaped by cold working. In particular, a cylindrical carrier assembly 94 is mounted concentrically on a longitudinally movable mandrel 96. As before, the carrier assembly supports multiple bobbins in arrays including several concentric circular sets of bobbins, with two of the bobbins being indicated at 98 and 100. A structural strand 32 has been wound on the bobbin 98, while bobbin 100 carries a textile strand 42. The structural strand is not thermally shaped before braiding, and thus at first has a

CA 02202708 2003-06-04 76286-2 linear nominal shape. structural strand 32 is plastically deformed by cold working as it travels from bobbin 98 to the mandrel. A small diameter shaping pulley 102 and a larger diameter idler pulley 104 are disposed along the path traversed by strand 32. While pulleys 102 and 104 are shown in side elevation in Figure 11, it should be understand that in the actual braiding device pulley 102 is orthogonal to pulley 104 to effect the selected shaping of strand 32. Shaping pulley 102 exerts a bending stress on the moving structural strand trained about this pulley, particularly on radially outward portions of the strand. Bobbin 98 is supported on a carrier that includes a clutch (not shown) adjustable to adjust the tension applied to the strand, thereby to adjust the amount of bending stress. The tension is controlled so that the bending stress, at least along the radially outward portions of the strand along pulley 102, exceeds the yield stress of the material. The appropriate level of tension is in the range of about 200-1000 gms, depending on such factors as the material, the monofilament diameter and the bending radius about pulley 102. The result is a cold-working plastic deformation, represented as a hatched segment 106 in Figure 12. It is to be appreciated that segment 106 is greatly exaggerated and intended for illustration only. The actual plastic flow is less pronounced and continuous, and changes the nominal shape of the structural strand from linear to helical. Further in this connection, it is noted that pulley 102 would impart a curved nominal shape to the structural strand in any event, and that the helical nominal shape with the desired pitch is obtained through proper orientation of the pulley with respect to the carrier assembly while maintaining the desired tension in the strand. The CoCrMo alloys described in the aforementioned U.S. Patent No. 5,891,191 entitled "Cobalt-Chromium-Molybdenum Alloy Stent and Stent-Graft"

CA 02202708 1997-04-15 are particularly well suited for this approach. Although shaping pulleys and tensioning clutches are required only in~connection with the structural strands as shown, these components add complexity to the braiding apparatus. The advantage of this approach is that the selective shaping and braiding steps can occur closely in time and within a continuous process. In contrast, thermal shaping is followed by cooling the strands and winding the strands onto bobbins, and therefore involves processing in a batch mode. Figures 13-14 illustrate different carrier bobbin loading arrangements used in two of the following examples of the braiding process. Each example utilizes a 240 carrier multilayer interlock braider. The bobbins are arranged in five annular, coaxial and axially spaced apart sets or rows of forty-eight carrier bobbins each. Within each set, bobbins can be installed on the carriers in both clockwise and counterclockwise winding directions. In Figures 13 and 14 these sets are designated 80-88 as in Figure 10. In each case the metallic monofilaments are thermally shaped prior to braiding, although they can as well be shaped by plastic deformation. Exam 1p a 1: The bobbins of the carrier assembly (Figure 13) are loaded with two hundred and twenty-four textile strands of polyester, each being 70 denier and composed of forty- seven filaments. More particularly, all of the bobbins in sets 80, 82, 86 and 88 are loaded with the polyester yarn. These textile strands also are loaded onto thirty- two of the bobbins in central set 84. Of the remaining sixteen bobbins, eight bobbins installed on carriers in the clockwise direction, and eight bobbins installed in the counterclockwise direction, are loaded with sixteen structural strands. The structural strands are arranged symmetrically, in that in each direction, every third bobbin is loaded with one of the structural strands.

CA 02202708 1997-04-15 Each structural strand is an Elgiloy wire having a diameter of 0.0047 inches (0.12 mm). The strands are braided onto an 8 mm diameter round mandrel, with the braider operated to determine a braid angle of 110. The braid is formed to an adequate length, then removed from the mandrel. The result is a tubular three-dimensionally braided structure of the polyester yarn and metal monofilaments. The wire latticework forms a central or medial layer of the structure and is braided in

the two over two braiding pattern. Exam: As in Example 1, the textile strands are 70 denier polyester yarns composed of forty-seven filaments. One hundred and sixty-eight of the polyester yarn textile strands are loaded (Figure 14) as follows: onto all the bobbins of outer set 88, its adjacent set 86, and set 82. Twenty-four bobbins of central set 84 also are loaded with the polyester yarn. The remaining twenty-four bobbins of the central set are loaded with Elgiloy wire, again having a diameter of 0.0047 inches. Twelve of these bobbins are installed in the clockwise direction, and twelve in the counterclockwise direction, with every second bobbin being wound with a structural strand. All bobbins of inner set 80 are loaded with a 70 denier collagen fiber. The strands are braided onto an 8 mm diameter round mandrel, with the braider operated to determine a braid angle of 1100. The result is a tubular, three-dimensionally braided structure of the polyester yarn and metal monofilaments, with an inner layer of fibers consisting of the collagen and determining an inside diameter of the structure. The latticework consists of two concentric layers of helices wound in opposite directions. Example 3: As in Example 1, all the bobbins in sets 80, 82, 86 and 88 are loaded with the textile strands, each being a

CA 02202708 1997-04-15 70 denier polyester yarn composed of forty-seven filaments. In set 84 corresponding to a central layer of the finished structure, twenty-four of the carrier bobbins likewise are loaded with the polyester multifilament yarn. The remaining twenty-four bobbins are loaded with a 0.0047 inch diameter Elgiloy wire. In this case, all twenty-four bobbins installed in the clockwise direction are loaded with the Elgiloy wire. The strands are braided onto an 8 mm diameter round mandrel, with the braider operated to determine a braid angle of 110. This arrangement is not illustrated. The result is a tubular three-dimensionally braided structure of the polyester yarn and metal monofilaments. The wire latticework consists of spirals wound in the clockwise direction. Exam 1~: All of the carrier bobbins in sets 86 and 88 corresponding to outer layers of the finished structure, and in set 82 corresponding to a more inward layer, are loaded with a polyester yarn of 50 denier and composed of 34 filaments. Twenty-four of the bobbins in set 84 also are loaded with the 50 denier polyester yarn. The remaining twenty-four bobbins of set 84 are loaded with structural strands. Each structural strand is a 0.0055 inch (0.137 mm) diameter Nitinol wire. The Nitinol strands are preset into helices 8 mm in diameter. Twelve of the bobbins loaded with the Nitinol wire are installed in the clockwise direction at every other carrier position. The remaining twelve bobbins loaded with the wire are similarly installed in the counterclockwise direction. All forty-eight bobbins of set 80 are loaded with textile strands, each strand in this case being the 70 denier forty-seven filament polyester yarn. The strands are wound onto an 8 mm diameter round mandrel and the braider is operated to determine a braid angle of 110. The setup is not shown. The result is a tubular three-dimensionally braided

CA 02202708 2003-06-04 ' 76286-2 structure of the two types of polyester yarns and the metal monofilaments. The inner layer of fibers consists of the coarser (70 denier) polyester yarn. The coarser strands are more closely packed, in the sense that there is a greater proportion of surface area occupied by yarn as compared to interstices or openings between adjacent yarns. Thus there is a permeability gradient in the radial direction, with the inner layer of the finished structure being less permeable to fluids. The Nitinol latticework consists of two concentric layers of helices in opposite directions of winding. In all of these examples, the resulting prosthesis has water permeability comparable to that of a vascular graft, and can be constrained to a reduced diameter and allowed to expand like a radially self-expanding stent. The prosthesis fabricating processes can be enhanced to impart a variety of desired characteristics to the prosthesis. A prosthesis formed of helical structural strands interbraided with multifilament yarns forming textile sheetings can further incorporate a strand formed of a radiopaque material, e.g. tantalum. This improves the fluoroscopic imaging of the prosthesis at or near a treatment site. Other approaches to enhancing radiopacity include use of composite structural strands (e. g. wires with radiopaque cores), plated monofilaments, radiopaque inks and marker bands., Figure 15 illustrates a tubular three-dimensionally braided prosthesis 108 incorporating metal monofilaments 110 and several layers of textile sheeting or fabric, e.g. as indicated at 112, 114 and 116. The latticework is formed of two oppositely directed sets of helices, and further includes several polyurethane axial runners 118. The axial runners are braided using triaxial guide tubes as discussed in U.S. Patent No. 5,758,562 entitled "Process for Manufacturing Braided Composite Prosthesis" (P. Thompson), assigned to the assignee of this application, filed concurrently with this application CA 02202708 2003-06-04 76286-2 The axial runners improve radial recovery and reduce the tendency to unravel or fray. Another approach to reduce unraveling of the

prosthesis is to apply a silicone adhesive to the opposite ends, or to submerge the prosthesis ends into a solution of a polyurethane, a polycarbonate urethane, or a silicone, and a solvent having a low percentage of solids. Residual polyurethane, polycarbonate urethane or silicone remains after drying and tends to prevent unraveling. Figure 16 illustrates a three-dimensionally braided prosthesis 120 including an inner layer 122 consisting primarily of multifilament yarns, a medial layer 124 including polyester yarns and a latticework of structura I filaments 126, and an outer layer 128 consisting primarily of multifilament yarns. Several drug eluting strands, one of which is shown at 130, also are braided into the outer layer. The drug eluting strands can be coated or impregnated with steroids such as dexamethasone to reduce restenosis, or with heparin or coumadin to reduce thrombogenicity. Three-dimensional braiding facilitates concentration of the drug eluting strands within the outer layer of the prosthesis. Similarly, strands treated or coated for other properties can be concentrated in the prosthesis outer layer, e.g. to reduce friction, reduce inflammatory responses, and improve biocompatibility. Figure 17 illustrates a prosthesis 132 formed of layers 134, 136 and 138. These layers are formed entirely of structural strands 140, more particularly metallic monofilament strands, formed for example of a cobalt-based alloy. At least a portion of the strands, and more preferably all of the strands, are selectively shaped either thermally or by cold working as discussed above, before interbraiding. Prosthesis 132 is of open weave construction, more in the nature of a stent than a graft.

CA 02202708 1997-04-15 A salient feature of prosthesis 132, due to its multilayered, three-dimensional construction, is a more even distribution of forces throughout the stnt structure as compared to a two-dimensionally braided stent such as stnt 21. Moreover, since the multilayered stent incorporates several times the number of structural strands as stnt 21, assuming the same size, each of structural strands 140 can be substantially smaller in diameter than a typical wire 23. Yet, three- dimensionally braided stent 132 exhibits the same strength and resiliency, and in fact exhibits an improved resistance to radial compression due to the more even distribution of force. Yet another advantage lies in the fact that the multilayered stent, because of the smaller diameter structural filaments and despite their greater number, is compressible to a smaller delivery diameter than stnt 21. Further modifications to enhance utility for specific applications, include using a tapered mandrel for heat setting the structural strands, to form a tapered prosthesis. To reduce migration, prosthesis can be provided with flared ends, or may be braided with end portions that do not incorporate the multifilament yarns. Collagen, PGA and other biological or bioabsorbable materials can be substituted for portions of the monofilament or multifilament strands. Metallocene catalized polymers, e.g. polyolefins or polypropylene, and fluorination if desired, may also be incorporated. Finally, three-dimensional construction enables and facilitates several advantageous non-uniform prosthesis constructions. A latticework of structural strands can be confined within a medial layer, covered by inner and outer layers of textile sheeting. The outer layer can be formed with larger pores and greater permeability to encourage fibrotic ingrowth, while at the same time an inner layer can be microporous and essentially impervious

CA 02202708 2003-06-04 f 76286-2 to blood and other body fluids. Specially treated or coated strands can be concentrated or confined within either the outer layer or inner layer of the prosthesis. Thus, in accordance with the present invention, a prosthesis incorporates structural strands interbraided with layers of more tightly woven textile strands that reduce permeability. The structural strands are selectively shaped before their interbraiding with the textile strands, either by a thermal set or by selective plastic deformation, and in either event are shaped without adversely affecting the textile strands. Plastic deformation of structural strands by cold working is advantageous in permitting a continuous process of cold working followed by interbraiding. The result is an interbraided prosthesis incorporating the strength, resilience and range of radii associated with self-expanding stents, and the impermeability associated with vascular grafts. The scope of this disclosure is intended to comprehend the subject matter of the patent applications and publications identified herein.



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(54) WOVEN PROSTHESIS AND METHOD FOR  
MANUFACTURING THE SAME

Publication Classification

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(51) Int. Cl.

A61F 2/82

(2006.01)

(73) Assignee: MAQUET CARDIOVASCULAR  
LLC, Wayne, NJ (US)

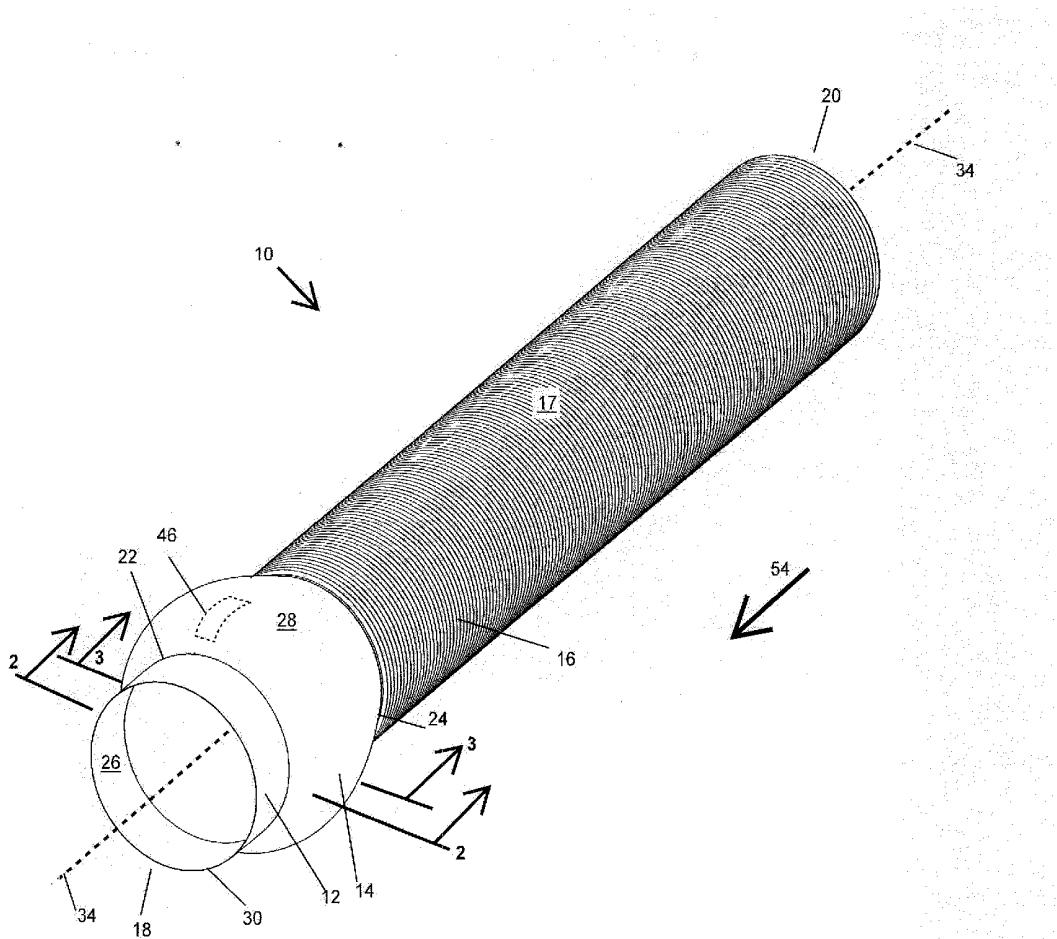
(52) U.S. Cl. .... 623/1.15

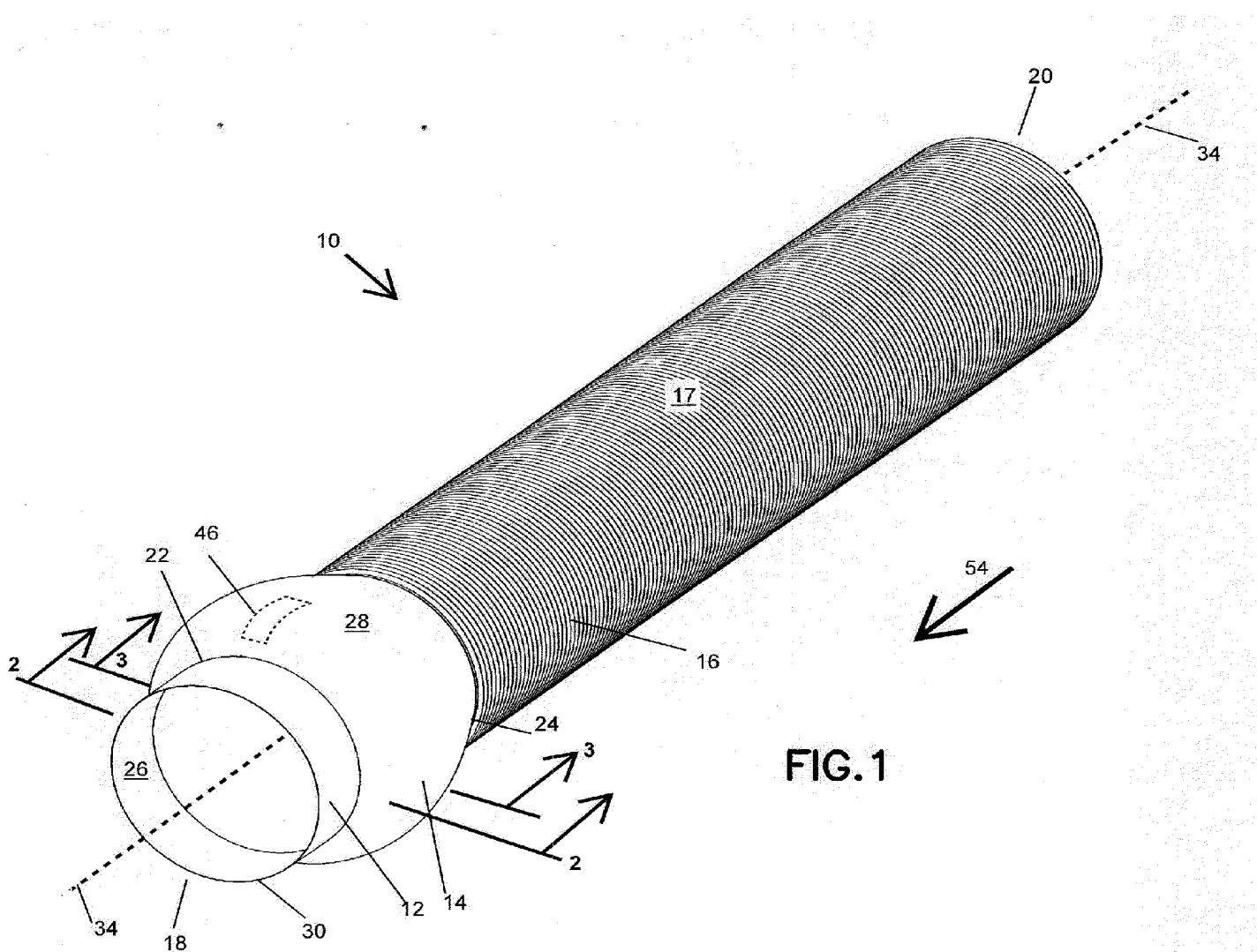
(21) Appl. No.: 12/978,382

(57) ABSTRACT

(22) Filed: Dec. 23, 2010

A woven prosthesis, such as a woven vascular graft, woven from warp and weft yarns. Velour warp yarns forming the prosthesis are selectively incorporated into a base layer of the prosthesis so as to provide a bulbous section without compromising the porosity of the prosthesis.





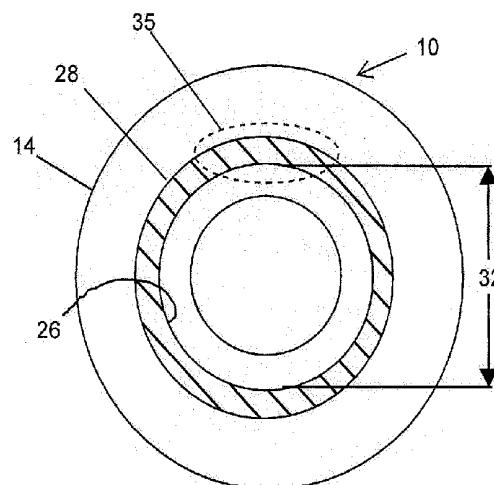


FIG. 2

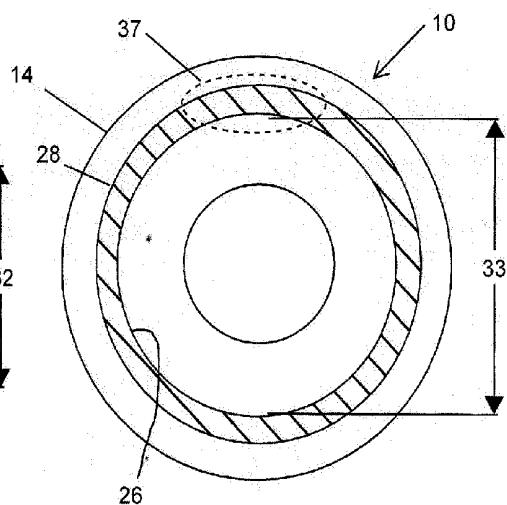


FIG. 3

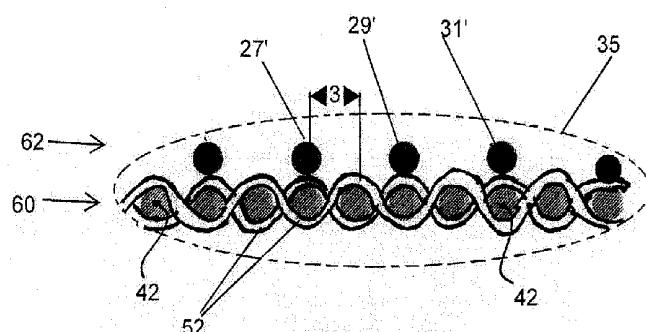


FIG. 4A

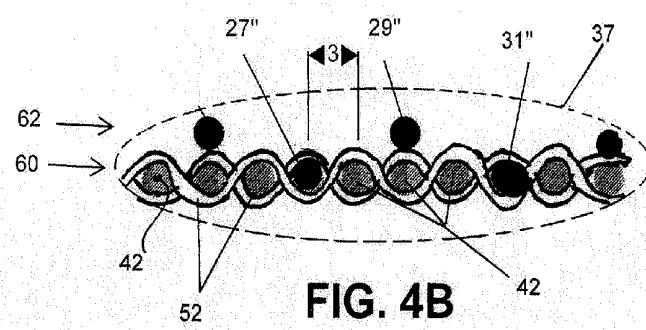


FIG. 4B

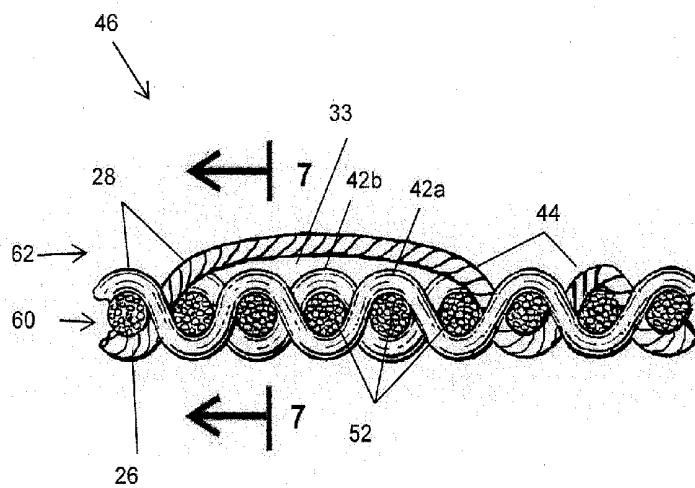
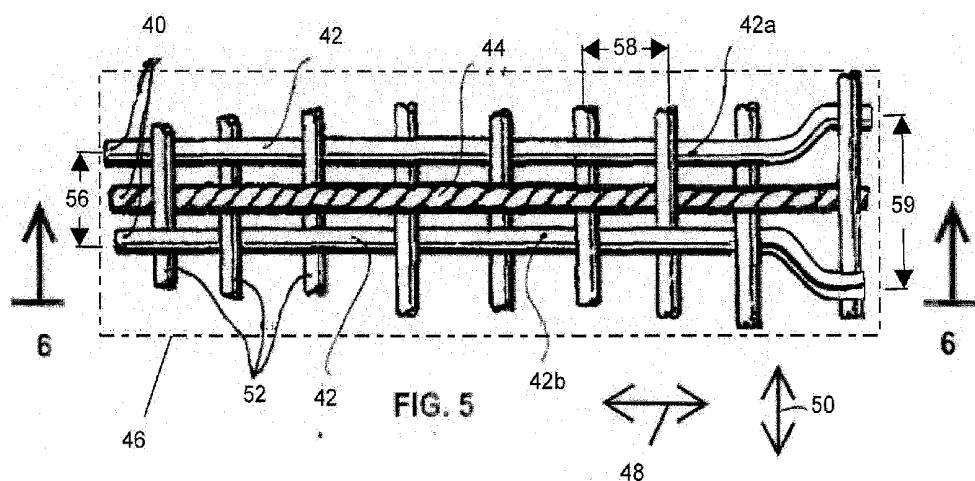


FIG. 6

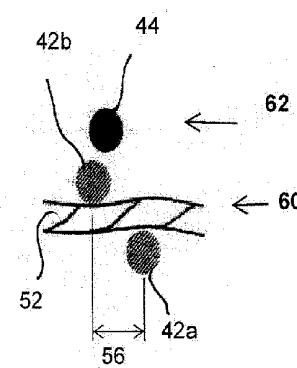
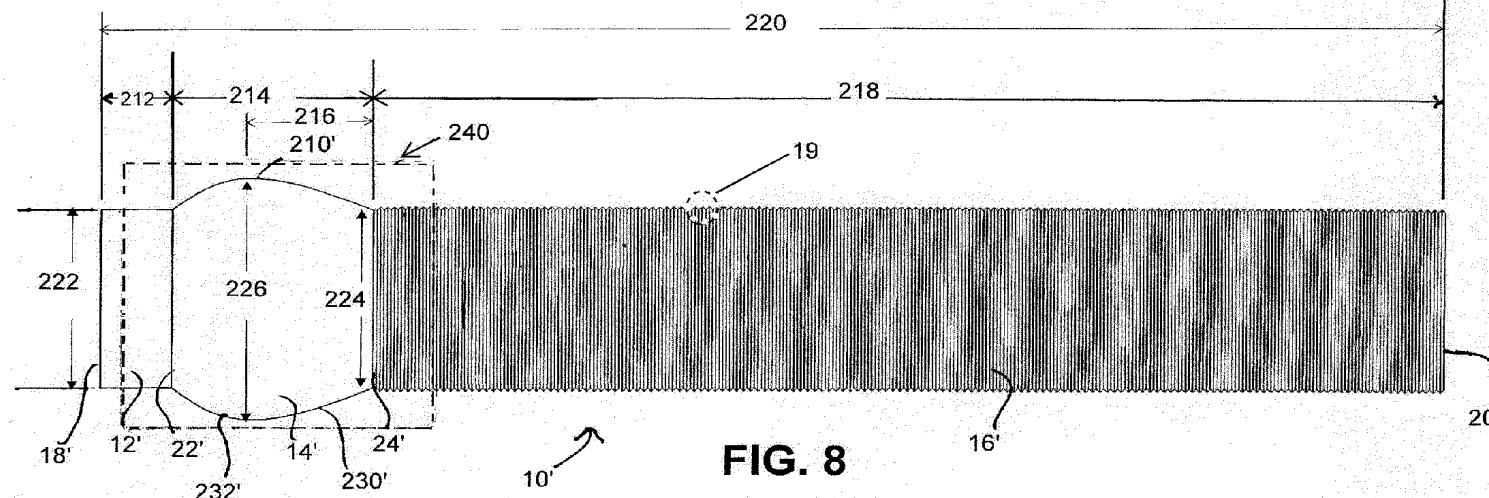
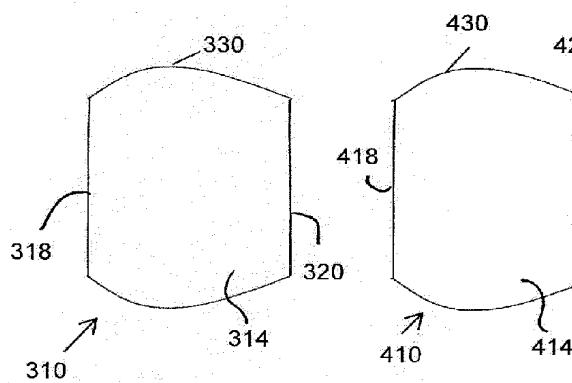


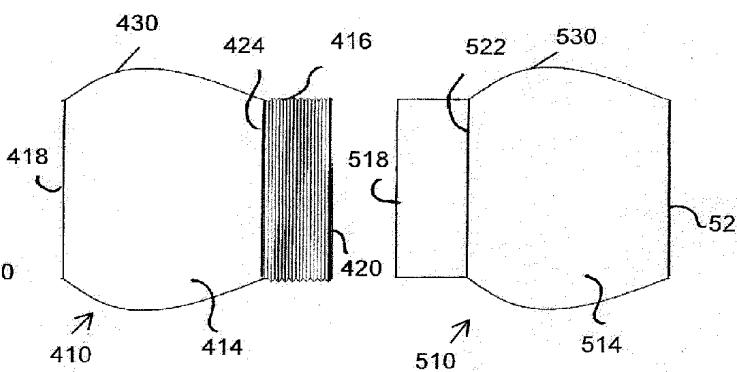
FIG. 7



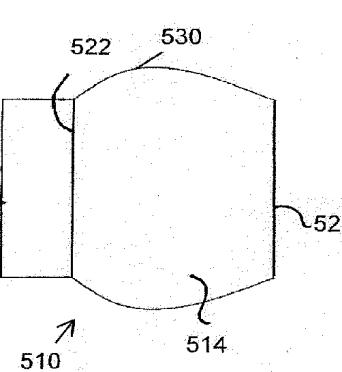
**FIG. 8**



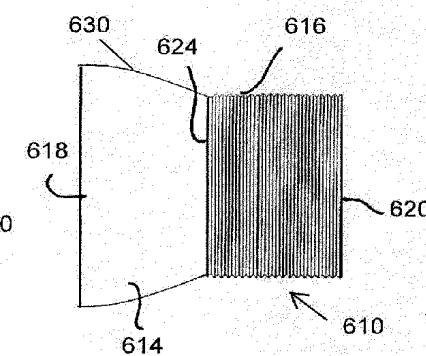
**FIG. 20**



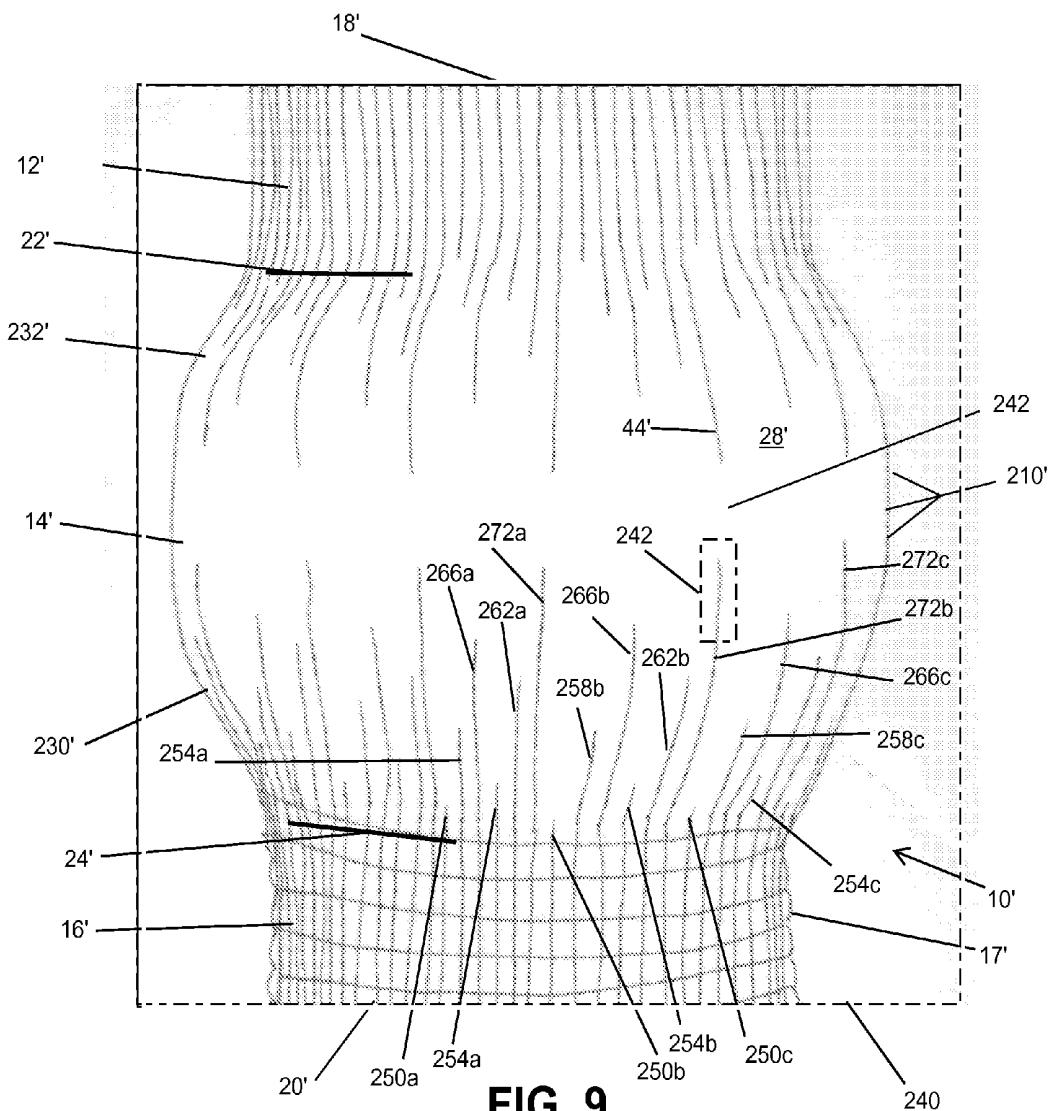
**FIG. 21**



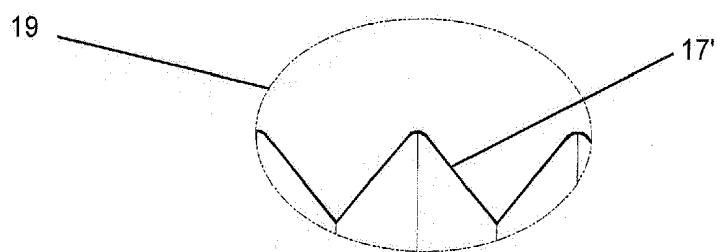
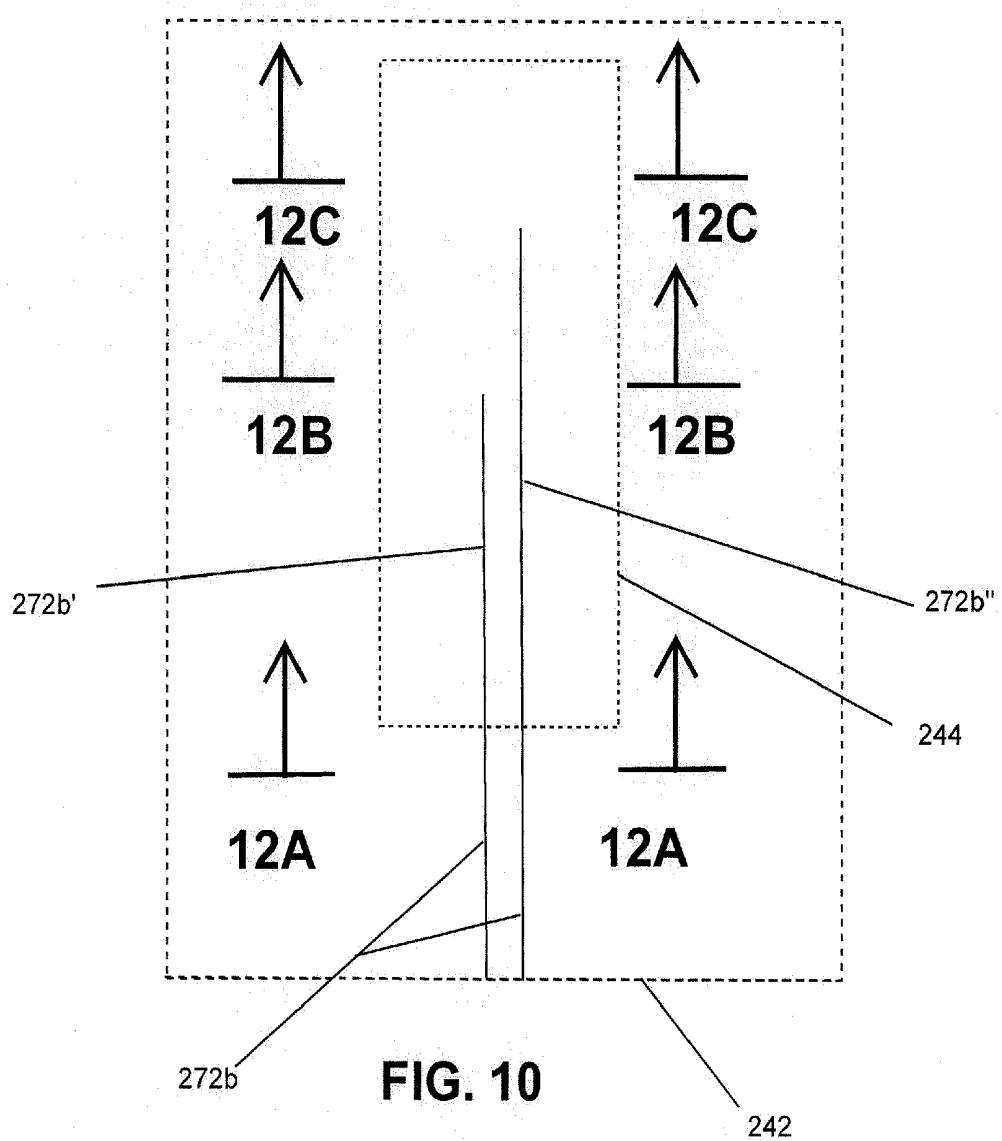
**FIG. 22**

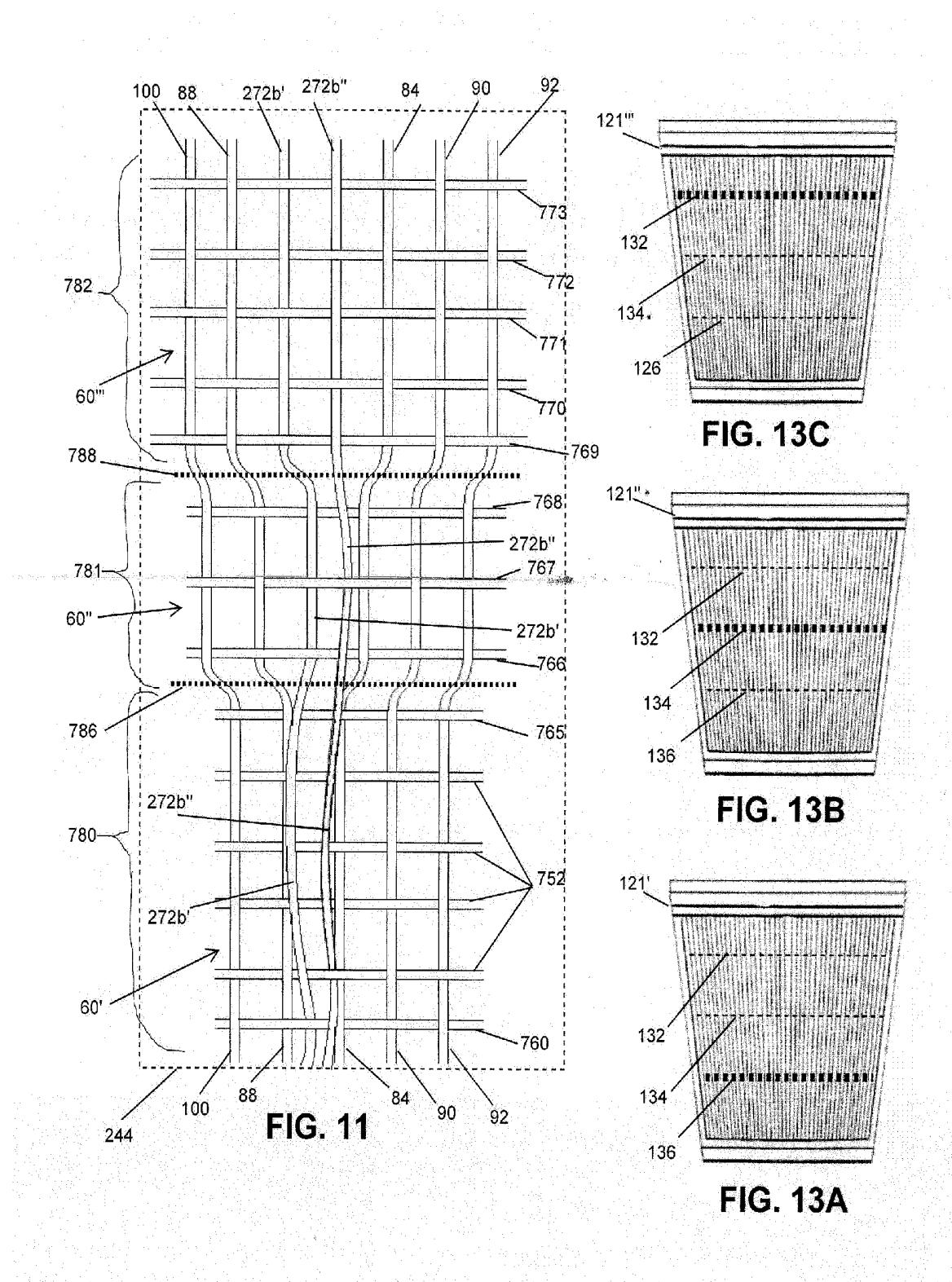


**FIG. 23**



**FIG. 9**





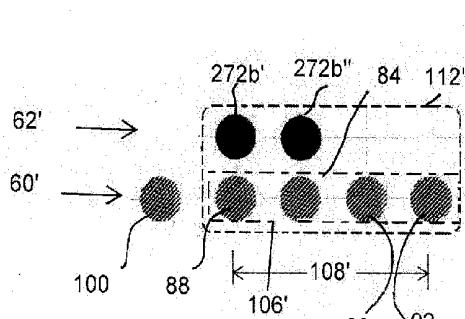


FIG. 12A

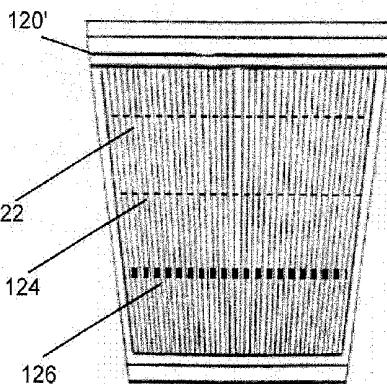


FIG. 14A

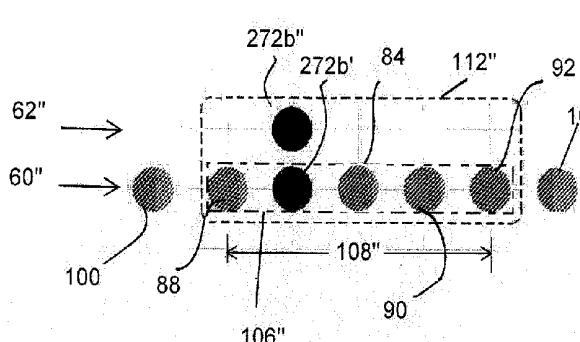


FIG. 12B

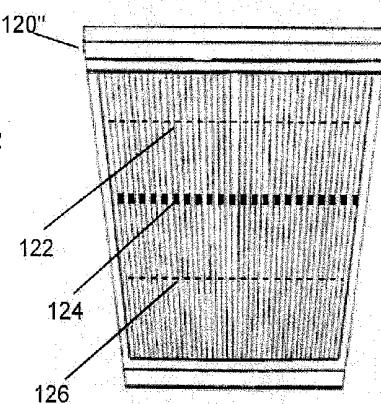


FIG. 14B

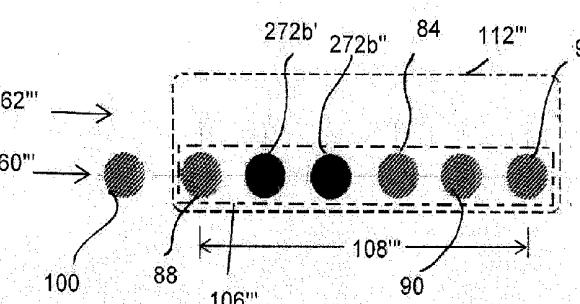


FIG. 12C

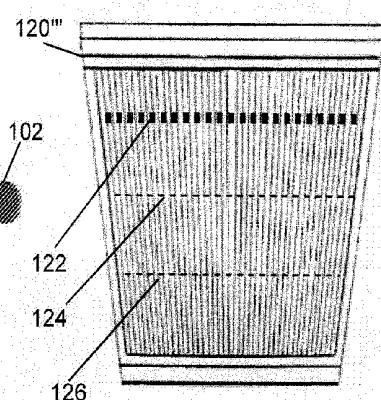
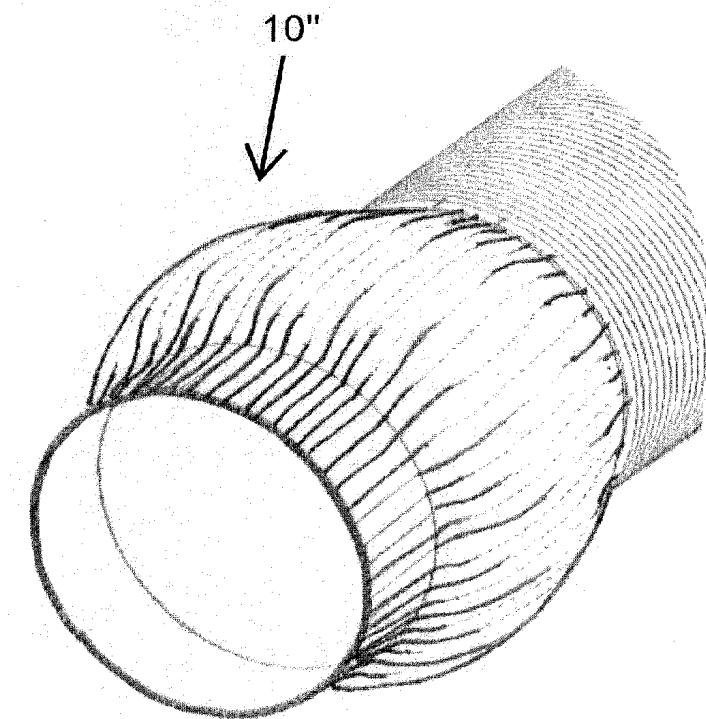
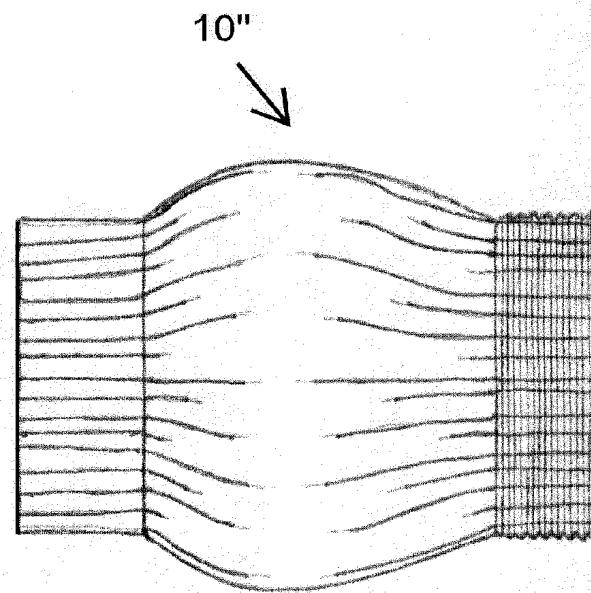


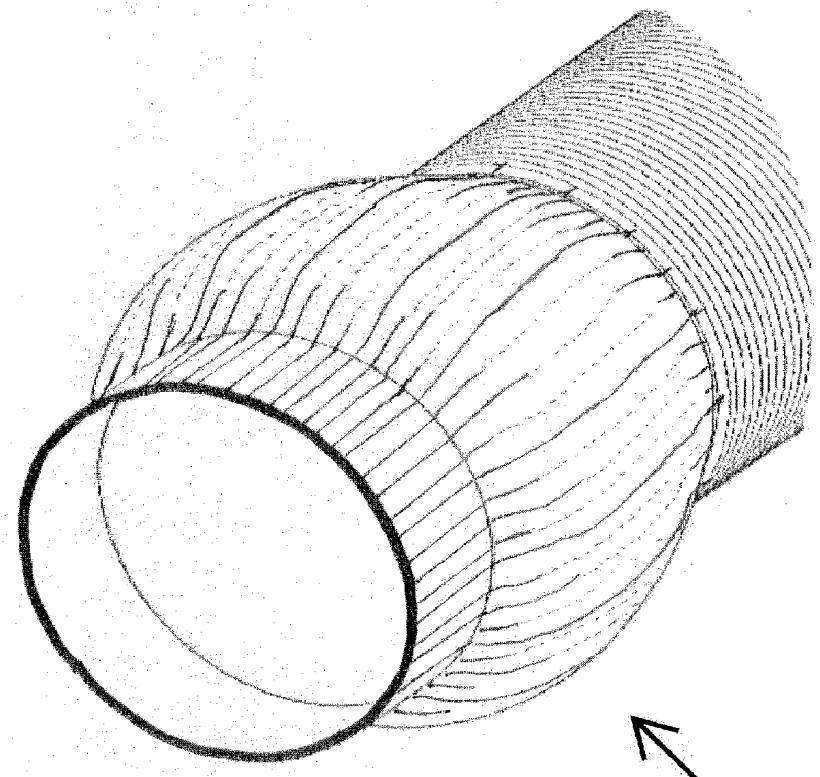
FIG. 14C



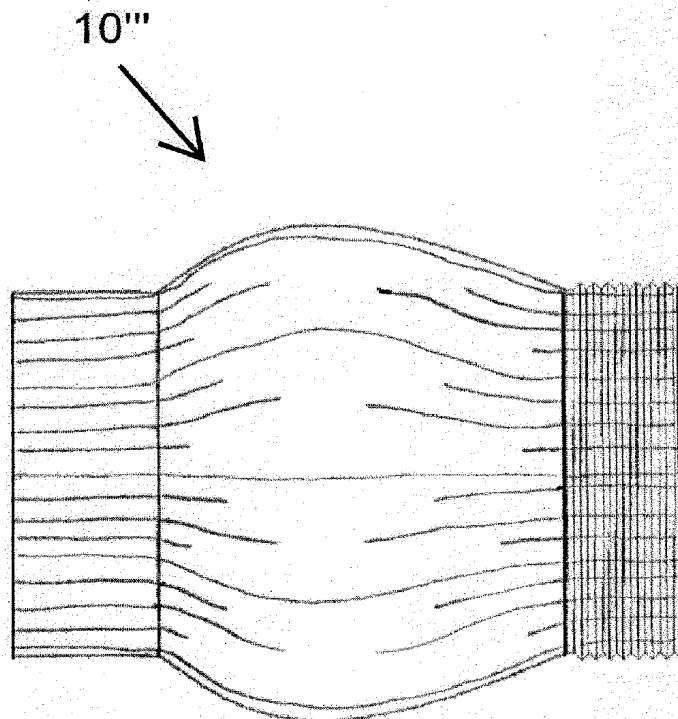
**FIG. 16A**



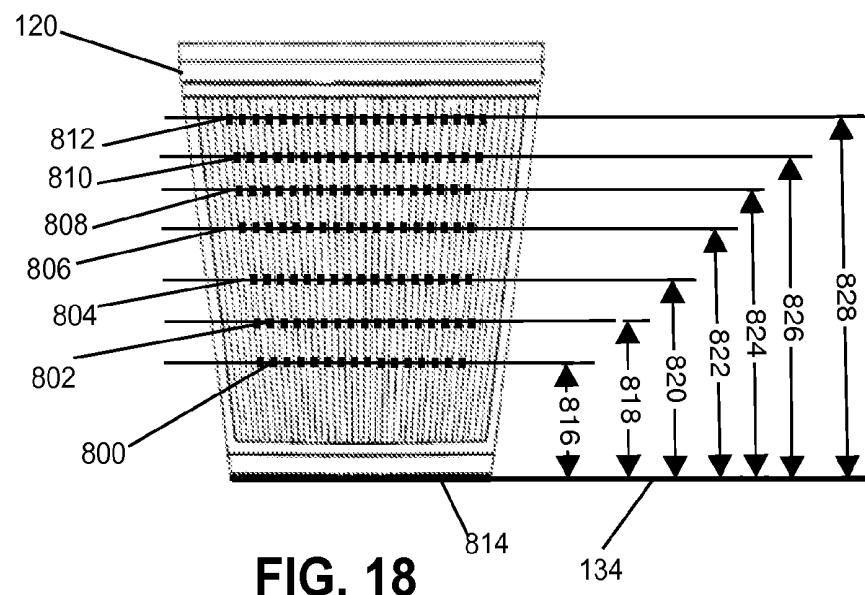
**FIG. 16B**



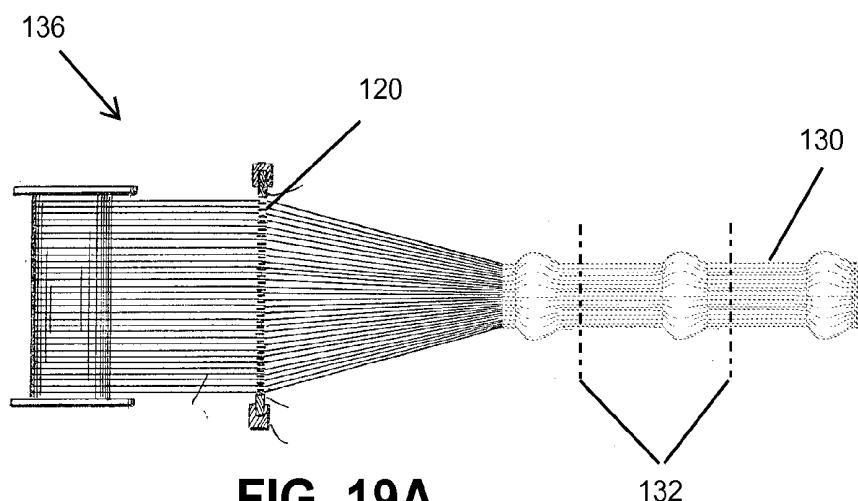
**FIG. 17A** 10"



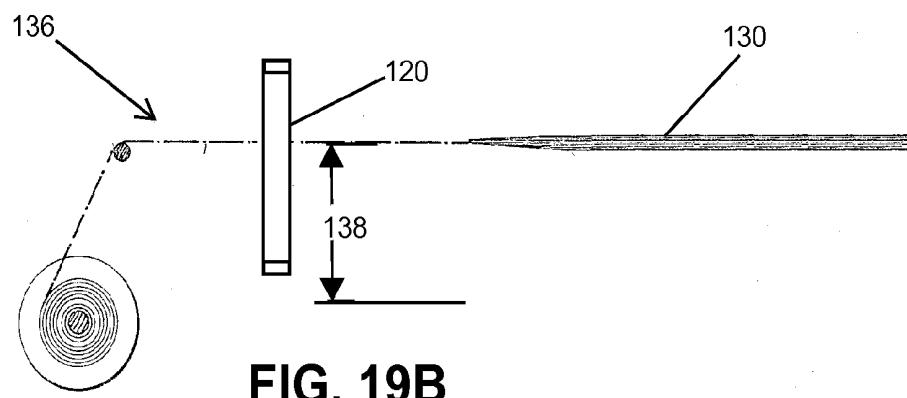
**FIG. 17B**



**FIG. 18**



**FIG. 19A**



**FIG. 19B**

**WOVEN PROSTHESIS AND METHOD FOR  
MANUFACTURING THE SAME****CROSS-REFERENCE TO RELATED  
APPLICATIONS**

[0001] Not applicable.

**STATEMENT REGARDING FEDERALLY  
SPONSORED RESEARCH OR DEVELOPMENT**

[0002] Not applicable.

**BACKGROUND OF THE INVENTION**

[0003] 1. Field of the Invention

[0004] The present invention relates to an implantable woven prosthesis and a method for manufacturing same. In an exemplary embodiment, the prosthesis is a tubular graft varying in diameter along its length. The prosthesis may be used, for example, by vascular or cardiovascular surgeons, for repairing portions of the cardiovascular system, including but not limited to all or portions of the ascending aorta, and aortic root. In an exemplary embodiment, the present invention may also be applicable to valve sparing and Bentall-type procedures.

[0005] 2. Description of Related Art

[0006] Tubular woven fabrics have been used for soft-tissue implantable prostheses to replace or repair damaged or diseased lumens in the body. Within the field of cardiothoracic surgery, for example, endoprostheses are used in the vascular system to prevent blood flow and pressure from rupturing a weakened or otherwise damaged section of the vessel. Such endoluminal conduits may be affixed in a specified location in the vessel by means of stents, hooks, sutures, or other mechanisms serving to secure the devices in place. Endoluminal tubular devices or conduits can also be used in other lumens in the body, such as in the esophagus and colon areas.

[0007] One area of specialty, replacement or repair of the aortic valve and/or the ascending aorta, in particular the sinuses of Valsalva, involves specialized and time consuming surgical procedures. These procedures have traditionally been performed with straight woven grafts. Although the procedures can be executed with a straight graft prosthesis, there is an increasing perception within the surgical community that vascular grafts incorporating bulges or bulbous portions to mimic the natural shape and profile of the human vasculature may be beneficial. Attempts to fabricate such grafts by others typically have caused problems in one or both of the areas of fabrication, surgical utility, and/or post operative patency.

[0008] For example, some fabrication attempts have involved post-weaving processing such as stitching, suturing, or the seaming of cut sections of corrugated fabrics together in a manner that results in a graft comprising a corrugated expandable middle section. Such a graft requires additional and costly manufacturing steps. Furthermore, the resulting graft can compromise surgical utility and ease of use for the surgeon, since a sufficiently flat and smooth surface is not provided for anastomosis to occur on a bulbous portion. Such deficiencies complicate anastomosis procedures.

[0009] Additionally, the "seams" or "junctions" where the multiple components are brought together create localized portions of graft rigidity, strength, and change in porosity not found in other portions of the graft. The resulting non-uniform nature of the underlying graft forces the surgeon to consider orientation of the graft prior to and during implan-

tation and/or anastomosis. This extra precaution required of the surgeon may distract him or her from other aspects of the surgery.

[0010] Furthermore, in vivo arterial pressure applied to grafts with corrugated bulbous sections may result in expanded shapes and dimensions that are drastically different when compared to the unpressurized state of such prosthesis commonly occurring during surgery. With such prostheses, the surgeon will therefore not be able to predict the in vivo performance of the prosthesis in terms of the clearance or engagement of valve leaflets with the inner sidewall of the prosthesis. Therefore, the surgeon may not fully appreciate how such a graft will function in vivo, and may not have any predictions as to long-term surgical success of the prosthetic thereby potentially jeopardizing the intended efficacy of the surgical procedure.

[0011] Other examples of fabricating prostheses for addressing problems relating to the ascending aorta and sinuses of Valsalva attempt to utilize shrinking characteristics of yarns in a controlled manner such that smaller diameter portions of a graft are created through the shrinking of weft yarns. While tapers may be able to be formed through such a procedure, concerns relating to suture retention strength as well as non-uniform porosity of the fabric structure can cause problems for surgeons and/or long term durability of the prosthesis, when used for repairing portions of the ascending aorta. Additionally, the fabricator of such prostheses will be limited through the shrink coefficients of the yarns to design geometries of sufficient taper required for mimicking the sinuses of Valsalva.

**SUMMARY OF THE INVENTION**

[0012] An implantable prosthesis according to an example embodiment of the present invention comprises a woven base comprising base warp yarns interwoven with weft yarn passes, the woven base at least partially forming smaller and larger diameter portions of the prosthesis and one or more velour yarns forming part of both the smaller and larger diameter portions. In at least a portion of the larger diameter portion at least one of the one or more velour yarns incorporated into the woven base and exhibiting a weave pattern consistent with the woven base.

[0013] According to an example embodiment, within the smaller diameter portion, the at least one of the one or more velour yarns is not incorporated into the woven base and does not exhibit a weave pattern consistent with the woven base.

[0014] According to an example embodiment, a spacing between the base warp yarns is maintained approximately the same in the smaller and larger diameter portions without adding additional warp yarns to the larger diameter portion beyond that in the smaller diameter portion.

[0015] According to an example embodiment, an increase in diameter of the prosthesis going from the smaller diameter portion to the larger diameter is effected by increasing spacing between the base warp yarns during weaving of the prosthesis.

[0016] According to an example embodiment, the spacing between the base warp yarns in the larger diameter portion is made smaller without reducing a diameter of the larger diameter portion by at least one of the one or more velour yarns incorporated into the woven base of the larger diameter portion.

[0017] According to an example embodiment, the prosthesis is a generally tubular graft and the larger diameter portion

lies within a portion of the graft varying in diameter along a longitudinal axis of the graft and the smaller diameter portion lies within a portion of the graft having a generally uniform diameter.

[0018] According to an example embodiment, the prosthesis is a generally tubular graft and the larger and smaller diameter portions lie within a portion of the prosthesis in diameter along a longitudinal axis of the graft.

[0019] According to an example embodiment, in at least a portion of the smaller diameter portion the one or more velour yarns exhibit a float that is entirely absent or smaller in the larger diameter portion.

[0020] According to an example embodiment, a spacing between the base warp yarns in the smaller diameter portion is within 30% of the size of the spacing in the larger diameter portion.

[0021] According to an example embodiment, a spacing between the base warp yarns in the smaller diameter portion is within 15% of the size of the spacing in the larger diameter portion.

[0022] According to an example embodiment, a spacing between the base warp yarns in the smaller diameter portion is within 10% of the size of the spacing in the larger diameter portion.

[0023] According to an example embodiment, the prosthesis comprises a quantity of the base warp yarns and velour yarns is the same in the larger diameter portion as the smaller diameter portion, and wherein the base warp yarns and the velour warp yarns are continuously woven between the smaller diameter portion and the larger diameter portion.

[0024] According to an example embodiment, the prosthesis comprises a secondary woven layer disposed over at least one of the smaller and larger diameter portions, and a portion of a yarn forming the secondary layer is incorporated into the base layer of the larger portion.

[0025] An implantable prosthesis according to an example embodiment of the present invention comprises, (i) a woven structure comprising warp yarns interwoven with weft passes, all or a portion of the warp yarns together with the weft passes form a woven base of the woven structure, (ii) a first portion of the woven structure is woven with a first set of the warp yarns, a first subset of the first set of the warp yarns interwoven with the weft passes forms the woven base in the first portion, two of the warp yarns in the first subset in the first portion are spaced apart from each other a first distance along a surface of the prosthesis, the first distance is greater than any spacing between any other pair of warp yarns in the first subset in the first portion along the surface of the prosthesis, (iii) a second portion of the woven structure is woven with the first set of the warp yarns, a second subset of the first set of the warp yarns interwoven with the weft passes forms the woven base in the second portion, two of the warp yarns in the first subset in the second portion are spaced apart from each other a second distance along the surface of the prosthesis, the second distance is greater than any spacing between any other pair of warp yarns in the first subset in the second portion along the surface of the prosthesis. The second distance is greater than the first distance, and the number of warp yarns in the first subset is smaller than the number of warp yarns in the second subset.

[0026] According to an example embodiment the portion of the warp yarns interwoven with the weft passes and disposed

in the woven base are arranged in a base weave pattern, and another portion of the warp yarns not disposed in the woven base are velour warp yarns.

[0027] According to an example embodiment the prosthesis is a generally tubular graft, the first portion having a first diameter along a longitudinal axis of the graft, the second portion having a second diameter along the longitudinal axis larger than the first diameter.

[0028] According to an example embodiment the first portion of warp yarns not in the first subset forming the woven base exhibit a float that is entirely absent or smaller in the second portion.

[0029] According to an example embodiment, the prosthesis has a first end and a second end, and essentially all the warp yarns are continuously woven between the first and second ends.

[0030] According to an example embodiment the prosthesis comprises a secondary woven structure disposed over at least one of the first and second portions, wherein a portion of a yarn forming the secondary woven structure is incorporated into the woven base of the secondary portion.

[0031] An example method for making a prosthesis according to the present invention comprises the steps of, (i) weaving a woven base from a set of warp yarns and at least one weft yarn pass the set of warp yarns comprises warp yarns woven as base warp yarns and warp yarns woven as non-base warp yarns, wherein the base warp yarns and weft yarn passes are woven into a base weave pattern, and the non-base warp yarns are woven with at least one weft yarn pass when not woven into a base weave pattern, (ii) incorporating into the woven base one or more of the non-base warp yarns, wherein the one or more non-base warp yarns assume a weave pattern consistent with all or portions of the base weave pattern.

[0032] According to an example embodiment the non-base warp yarns are velour yarns.

[0033] According to an example embodiment the woven base is configured to establish a smaller and larger diameter portion, and the larger diameter portion is capable of achieving a larger diameter than the smaller diameter portion. The larger diameter of the larger diameter portion is achieved by the step of incorporating into the woven base one or more velour yarns.

[0034] An example method for making the graft may further include the step of incorporating into the woven base one or more velour yarns exclusively utilizes velour yarns utilized as velour prior to being incorporated into the base weave pattern.

[0035] According to an example embodiment the larger diameter portion has a base warp density within a tolerance of 30% of a base warp density for the smaller diameter portion.

[0036] According to an example embodiment the larger diameter portion has a base warp density within a tolerance of 15% of a base warp density for the smaller diameter portion.

[0037] According to an example embodiment the larger diameter portion has a base warp density within a tolerance of 10% of a base warp density for the smaller diameter portion.

[0038] According to an example embodiment a variable reed is moved during the weaving step to provide for a varied diameter profile of the medical prosthesis.

[0039] An example method for making a prosthesis according to the present invention comprises the step of weaving a woven base comprising base warp yarns interwoven with weft yarn passes, the base at least partially forming smaller and larger diameter portions, and one or more velour yarns

forming part of both the smaller and larger diameter portions. The example method for making the prosthesis may further comprise weaving in at least a portion of the larger diameter portion at least one of the one or more velour yarns into the woven base to exhibit a weave pattern consistent with the woven base.

[0040] According to an example embodiment the at least one of the one or more velour yarns woven into the woven base of the larger diameter portion and exhibiting a weave pattern consistent with the woven base is not woven into the base of the smaller diameter portion.

[0041] An example method for making a prosthesis according to the present invention comprises the steps of, (i) weaving a variable diameter graft having a velour layer on at least a portion of the graft, comprising the step of changing a weave pattern of a warp yarn used to form the velour layer in a smaller diameter portion of the graft such that said warp yarn takes on a weave pattern and forms part of a base layer of a larger diameter portion of the graft.

[0042] An example method for making the prosthesis may further include the step of changing the weave pattern of the warp yarn as it transitions from the larger diameter portion to a second smaller diameter portion so as to form a velour layer on at least a portion of the second smaller diameter portion which is smaller in diameter than the larger diameter portion.

[0043] An example method for making the prosthesis may further include the step of shifting at least a pair of adjacent warp yarns used to form a base layer of the smaller diameter portion so as to increase a spacing between the adjacent warp yarn in the larger diameter portion.

[0044] According to an example embodiment a spacing between base warp yarns used to form the smaller diameter portion is within 30% of the size of a corresponding spacing between the same base warp yarns in the larger diameter portion.

[0045] According to an example embodiment a spacing between base warp yarns used to form the smaller diameter portion is within 15% of the size of a corresponding spacing between the same base warp yarns in the larger diameter portion.

[0046] An example method for making a prosthesis according to the present invention comprises the steps of, (i) forming a first portion of the prosthesis by interweaving base warp yarns, velour warp yarns, and one or more weft yarn passes, (ii) shifting at least a pair of adjacent base warp yarns so as to increase or decrease a spacing between them, and (iii) forming a base layer of a second portion of the prosthesis by weaving the one or more weft yarn passes with the at least a pair of shifted base warp yarns together with one or more of the velour warp yarns.

[0047] According to an example embodiment wherein the velour warp yarn exhibits a float in the first portion and no float or less of a float in the second portion.

[0048] According to an example embodiment, wherein the shifting is accomplished using a warp yarn guide device.

[0049] According to an example embodiment, the warp yarns pass through gaps in the warp yarn guide device and the spaces are spaced apart a distance greater than the spacing between the warp yarns in the first portion of the prosthesis.

[0050] According to an example embodiment, wherein the medical prosthesis is a generally tubular graft and the second portion of the graft has a larger diameter than the first portion of the graft.

[0051] According to an example embodiment, the shifting is incrementally increased or decreased along a longitudinal axis of the graft so as to effect a change in diameter of the prosthesis.

[0052] According to an example embodiment, wherein a spacing between the base warp yarns in the first portion is within 30% of the size of a corresponding spacing between the same base warp yarns in the second portion.

[0053] An example method for making the graft may further include the step of using at least one of the base warp yarns from the first portion in the second portion as a velour warp yarn and not as part of the base layer of the second portion.

[0054] According to an example embodiment, a quantity of the base warp yarns and velour warp yarns is the same for both the first portion and the second portion.

[0055] According to an example embodiment a quantity of the base warp yarns and velour warp yarns is consistent throughout the entire medical prosthesis.

[0056] An example method for weaving a prosthesis according to the present invention comprises the steps of, (i) weaving a woven base comprising base warp yarns interwoven with weft yarn passes, the base at least partially forming smaller and larger diameter portions of the prosthesis, one or more velour yarns forming part of both the smaller and larger diameter portions, and (ii) incorporating in at least a portion of the larger diameter portion at least one of the one or more velour yarns into the woven base so as to exhibit a weave pattern consistent with the woven base. According to an example embodiment, incorporating in step (ii) may not be in the smaller diameter portion.

[0057] An example method for weaving the prosthesis may further include the step of shifting at least a pair of adjacent warp yarns used to form a base layer of the smaller diameter portion so as to increase a spacing between said adjacent warp yarns in the larger diameter portion.

[0058] An example method for making an implantable medical prosthesis according to the present invention and comprising a woven structure comprising warp yarns interwoven with weft passes, all or a portion of the warp yarns together with the weft passes form a woven base of the woven structure, comprises the steps of, (i) weaving a first portion of the woven structure with a first set of the warp yarns, a first subset of the first set of the warp yarns interwoven with the weft passes forms the woven base in the first portion, two of the warp yarns in the first set in the first portion are spaced apart from each other a first distance along a surface of the prosthesis, the first distance is greater than any spacing between any other pair of warp yarns in the first set in the first portion along the surface of the prosthesis, and (ii) weaving a second portion of the woven structure with the first set of the warp yarns, a second subset of the first set of the warp yarns interwoven with the weft passes forms the woven base in the second portion, two of the warp yarns in the first set in the second portion are spaced apart from each other a second distance along the surface of the prosthesis, the second distance is greater than any spacing between any other pair of warp yarns in the first set in the second portion along the surface of the prosthesis.

[0059] An implantable prosthesis according to an example embodiment of the present invention comprises (i) a woven base comprising base warp yarns interwoven with weft yarn passes, the base at least partially forming smaller and larger diameter portions of the prosthesis, and (ii) one or more

additional warp yarns forming part of both the smaller and larger diameter portions. In at least a portion of the larger diameter portion but not the smaller diameter portion at least one of the one or more additional warp yarns incorporated into the woven base and exhibiting a weave pattern consistent with the woven base.

[0060] An implantable prosthesis according to an example embodiment of the present invention comprises a prosthesis comprising a woven base, the base forming all or part of the sidewall of a proximal tubular portion, a larger diameter portion, and a distal tubular portion, the larger diameter portion comprises a maximum diameter, the maximum diameter is 4 or more millimetres larger than a measured diameter within the proximal tubular portion, the larger diameter portion has a length between seventy five percent and one hundred fifty percent of the measured diameter within the proximal tubular portion, the proximal tubular portion and the larger diameter portion have a substantially uniform yarn to yarn spacing within the woven base for warp yarns woven with weft passes within the woven base.

[0061] According to an example embodiment the weft passes are woven with the same yarn material and shrinkage attributes throughout the proximal tubular portion, the larger diameter portion, and the distal tubular portion. The shrinkage attributes include coefficients of shrinkage.

[0062] According to an example embodiment the weft passes are woven with the same weft yarn throughout the proximal tubular portion, the larger diameter portion, and the distal tubular portion.

[0063] According to an example embodiment the larger diameter portion is seamlessly woven with the proximal tubular portion and the distal tubular portion.

[0064] According to an example embodiment the same quantity of warp yarns are used to form the proximal tubular portion, the larger diameter portion, and the distal tubular portion.

[0065] According to an example embodiment the larger diameter portion is configured to be dimensionally stable under pressurized conditions of 120 millimeters of Mercury.

[0066] According to an example embodiment the larger diameter portion is configured to maintain its diameter under fluidic pressurized conditions of 120 millimeters of Mercury.

[0067] According to an example embodiment the woven base at the maximum diameter of the larger diameter portion is free of at least one of corrugations, pleats, and crimps.

[0068] According to an example embodiment the larger diameter portion is dimensionally stable under pressurized conditions of 120 millimeters of Mercury.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0069] FIG. 1 is perspective view of a vascular graft according to an example embodiment of the present invention.

[0070] FIG. 2 is a cross sectional view taken along lines 2-2 in FIG. 1.

[0071] FIG. 3 is a cross sectional view taken along lines 3-3 in FIG. 1.

[0072] FIG. 4A is a partial sectional view of a portion of the graft of FIG. 2.

[0073] FIG. 4B is a partial sectional view of a portion of the graft in FIG. 3.

[0074] FIG. 5 is a magnified top view of a portion of the graft surface in FIG. 1.

[0075] FIG. 6 is a sectional view taken along lines 6-6 in FIG. 5.

[0076] FIG. 7 is a sectional view taken along lines 7-7 in FIG. 6.

[0077] FIG. 8 is an elevation view of a vascular graft according to an example embodiment the present invention.

[0078] FIG. 9 is a magnified view of a bulbous portion and adjacent portions of the graft of FIG. 8.

[0079] FIG. 10 is a magnified view taken of a portion of the graft as shown in FIG. 8 and FIG. 9.

[0080] FIG. 11 is a magnified view of a sub-portion of the portion illustrated in FIG. 10.

[0081] FIG. 12A is a sectional view taken along lines 12A-12A in FIG. 10.

[0082] FIG. 12B is a sectional view taken along lines 12B-12B in FIG. 10.

[0083] FIG. 12C is a sectional view taken along lines 12C-12C in FIG. 10.

[0084] FIG. 13A is an elevation view of a fan-shaped reed in a first position.

[0085] FIG. 13BA is an elevation view of a fan-shaped reed in a second position.

[0086] FIG. 13C is an elevation view of a fan-shaped reed in a third position.

[0087] FIG. 14A is an elevation view of a fan-shaped reed in a first position.

[0088] FIG. 14B is an elevation view of a fan-shaped reed in a second position.

[0089] FIG. 14C is an elevation view of a fan-shaped reed in a third position.

[0090] FIG. 15 is a magnified view of a portion of the graft in FIG. 8.

[0091] FIG. 16A is a perspective view of a graft according to an example embodiment of the present invention.

[0092] FIG. 16B is an elevation view of the graft of FIG. 16A.

[0093] FIG. 17A is a perspective view of a graft according to an example embodiment of the present invention.

[0094] FIG. 17B is an elevation view of the graft of FIG. 17A.

[0095] FIG. 18 is a front view of a fan-shaped reed.

[0096] FIG. 19A is an overhead view of a weaving station according to an example embodiment of the present invention.

[0097] FIG. 19B is a side view of the weaving station of FIG. 19A.

[0098] FIG. 20 is an elevation view of a graft according to an example embodiment of the present invention.

[0099] FIG. 21 is an elevation view of a graft according to an example embodiment of the present invention.

[0100] FIG. 22 is an elevation view of a graft according to an example embodiment of the present invention.

[0101] FIG. 23 is an elevation view of a graft according to an example embodiment of the present invention.

#### DETAILED DESCRIPTION OF THE PRESENT INVENTION

[0102] For purposes of the description hereinafter, the words "upper," "lower," "right," "left," "vertical," "horizontal," "top," "bottom," "lateral," "longitudinal," "axial," and like terms, if used, shall relate to the invention, as it is oriented in the drawing figures. When appropriate, the term "proximal" shall refer to the relative location of an aspect of a prosthesis, directed towards a heart such as a human heart, and the term distal shall refer to a relative location of an aspect of prosthesis in a direction away from a heart. It is to be

understood that the invention may assume many alternative variations and embodiments except where expressly specified to the contrary. It is also to be understood that the specific devices and embodiments illustrated in the accompanying drawings and described herein are simply example embodiments of the invention.

[0103] FIG. 1 illustrates a varied-diameter prosthesis 10 according to an example embodiment of the present invention configured, for example, as a replacement for the aortic root or ascending aorta. Prosthesis 10 includes a first woven tubular portion 12, a bulbous second woven portion 14, and a third woven tubular portion 16. Prosthesis 10 further comprises a proximal end 18, a distal end 20, and a sidewall 30 disposed therebetween. The sidewall 30 is continuously woven thereby using continuous warp yarns between the ends of the woven structure, such as the proximal 18 and distal end 20 without the need for cutting apart or welding together the warp yarns in between the ends. Other example configurations of the prosthesis 10 are illustrated in FIGS. 8, 16A, 16B, 17A, 17B, and 20 to 23.

[0104] The sidewall 30 of prosthesis 10 shown in FIG. 1 is configured to resist a predetermined level of blood leakage. The leakage rate may be controlled by adjusting the porosity of the sidewall 30 by, for example, adjusting the weave pattern, yarn spacing, yarn denier, and/or yarn tightness. Such attributes of sidewall 30 will provide for a uniform porosity sufficient to provide for tissue ingrowth, yet not cause or promote leakage. The porosity of sidewall 30 can be generally uniform throughout prosthesis 10 before and/or after an optional coating application. Coating applications including collagen or gel coatings may be employed depending on the desired configuration by the fabricator. Desirably, a porosity of sidewall 30 after a coating step may be less than 5 millilitres per centimeter squared per minute at 120 mm Hg. This may be measured using the Wesolowski method.

[0105] A variety of weave patterns may be employed. When warp yarns of the present disclosure engage consecutive weft passes, this is commonly known as a plain weave pattern. Additionally, when warp yarns skip, jump, or float over a plurality of weft passes (greater than the skip utilized in the base), these warp yarns are referred to as velour warp yarns and the weave pattern is referred to as a velour weave pattern. A variety of weave patterns may be chosen for both the base as well as portions other than the base, such as warp yarn patterns for those warp yarns not in the base. Examples of non-base warp yarn patterns include velour weave patterns for warp yarns not in the base. Velour weave patterns may include single velour, double velour, and others. Generally, the frequency of interlacing of weft pass is greater for warp yarns when in the base it is for warp yarns when in a non-base layer such as a velour layer.

[0106] Prosthesis 10 is generally elongate, and is woven with warp yarns arranged generally parallel to an axis 34 shown in FIG. 1. First and second tubular portions 12 and 16 are shown as straight tubular portions and are continuously interwoven with the bulbous portion 14 disposed between the tubular portions 12 and 16. The prosthesis 10, 10', 10", 10'', 310, 410, 510, 610 depicted in FIGS. 1, 8, 16A, 16B, 17A, 17B, and 20 to 23 represents just a few examples of the universe of complex contoured vascular prosthetic structures capable of being produced utilizing the techniques of the present invention, and other variations within the scope of the claimed invention are contemplated.

[0107] FIG. 2 illustrates a highly schematic cross section taken about line 2-2 in FIG. 1. The diameter of the prosthesis 10 at line 2-2 is labeled using reference number 32. As discussed further below, the prosthesis 10 as illustrated in FIG. 2 has already undergone processing steps so as to allow it to maintain this substantially self-supporting configuration. Prior to this processing, the prosthesis has a more flattened profile common to greiges.

[0108] FIG. 3 illustrates a highly schematic cross section taken about line 3-3 in FIG. 1. The diameter of the prosthesis 10 at line 3-3 is labelled using reference number 33. Line 3-3 intersects prosthesis 10 at a larger diameter than line 2-2, and thus the diameter 33 is larger in magnitude than the diameter 32.

[0109] FIG. 4A is a magnified view of a circumferential section 35 of prosthesis 10 shown in FIG. 2. Illustrated is a cross section of the sidewall, comprising a total of fifteen warp yarns 40, and two weft passes 52. A first set of warp yarns (fifteen as illustrated) are shown, ten of which are interwoven with a first set of weft passes 52 (two weft yarns as shown), and comprise a first subset of the first set or base layer 60. The term "base" is meant to be interchangeably used with the terms "base layer," "foundation," "ground" or "ground layer." The remaining warp yarns make up a second set of warp yarns, and are positioned outside the base layer 60, in a non-base layer, such as a velour layer 62. This second set comprises among the five non-base warp yarns, yarns 27', 29', and 31'. In this embodiment, the non-base velour layer provides a loose weave (relative to the base layer 60) allowing for tissue ingrowth into the prosthesis 10 during usage as a vascular conduit and, thus, functions as a velour layer.

[0110] Similar to FIG. 4A, FIG. 4B represents a magnified view of a circumferential section 37 of prosthesis 10 shown in FIG. 3 taken over the same arc as section 35. Illustrated is a cross section of the sidewall, including a total of thirteen warp yarns 40, and two weft passes 52. A first set of warp yarns 40 (thirteen as illustrated) are shown, ten of which are interwoven with a first set of weft passes 52 (two weft yarns as shown), and comprise a first subset of the first set or base layer 60. Two warp yarns of the first subset of the first set are warp yarns 27' and 31", which are the same warp yarns 27' and 31' illustrated in FIG. 4A, but now positioned in FIG. 4B as interwoven with weft passes 52 and in the base layer 60. The two warp yarns 27 and 31 have therefore been shifted from a first position in a non-base layer (velour layer 62) illustrated in FIG. 4A (as warp yarns 27' and 31'), to a base layer 60 illustrated in FIG. 4B (as warp yarns 27" and 31").

[0111] Despite the diameter increase between FIG. 2 and FIG. 3, it should be noted that a center-to-center distance or spacing 3 between adjacent warp yarns 40 in both FIGS. 4A and 4B is the same or approximately the same. The expanded diameter in the bulbous portion 14, therefore, does not come at the expense of increased prosthesis porosity in this portion 14, which can cause blood leakage as well as reduce suture integrity during procedures such as anastomosis. Rather, shifting warp yarns 27' and 31' in the non-base layer 62 into the base layer 60 during weaving of the prosthesis 10 allows for an increased diameter in the second woven portion 14 while still maintaining the yarn density, and thus porosity of the prosthesis 10, in this portion 14. Shifting the warp yarns 40 apart, absent any other intervention, necessarily decreases the yarn density of the prosthesis 10 in the bulbous portion 14.

[0112] In an exemplary embodiment, rather than shifting both yarns 27' and 31' into the base layer 60, only one of yarns

**27'** and **31'** may be shifted into the base layer. In this case, spacing between adjacent warp yarns will increase compared to that shown in FIGS. 4A and 4B. This may be desirable to the extent a reduced porosity is desired in the bulbous second portion 14 as compared to, for example, the first woven tubular portion 12, while still maintaining the porosity above a level allowing for blood leakage.

[0113] Throughout the present disclosure, including FIGS. 4A and 4B, when the warp yarns are located in a base layer of the prosthesis and have adopted a weave pattern or first weave pattern consistent with the base layer, the warp yarns when in the base layer **60** are referred to generically as base warp yarns. Furthermore, when the warp yarns are not in the base layer **60** and have not adopted the weave pattern of the base layer **60**, or have adopted a second weave pattern different from the first weave pattern, the warp yarns may be referred to within the present disclosure as non-base warp yarns, such as, but not limited to velour warp yarns. Some warp yarns may be positioned and/or woven as a base warp yarn throughout all or just a portion of the entire prosthetic structures described herein. Some warp yarns may be positioned and/or woven as a velour warp yarn throughout all or just a portion of the prosthetic structures described herein. Further, some warp yarns may serve as both velour warp yarns and base warp yarns and may transition between the two states by a transition or adjustment in weave pattern, or frequency of interlacing.

[0114] FIG. 5 is a magnified view of a portion **46** (circumscribed in dashed lines for reference only) of an external surface **28** of prosthesis **10** as shown in FIG. 1. Three warp yarns (generally referenced as warp yarns **40**) are shown woven with a plurality of weft passes **52**. The warp yarns extend in a direction correlating to arrows **48**, while the weft passes **52** extend in directions that correlate with arrows **50**. Other directions may be employed without departing from the spirit of the invention, and the directions shown are merely illustrative. Arrows **48** are generally consistent with the axis **34** in FIG. 1.

[0115] Of the warp yarns **40** illustrated in FIG. 5, two of the warp yarns **40** are base warp yarns **42** throughout the entire figure, and one of the warp yarns **44** exhibits behaviours of both a base warp yarn, such as warp yarns **42**, as well as a non-base warp yarn, such as a velour warp yarn. The non-base warp yarn **44** exhibits both a first weave pattern, i.e., a 5/1 velour pattern, and a second weave pattern, i.e., a 1/1 plain weave pattern. In the 5/1 velour pattern, the warp yarn **44** (shown cross hatched for illustrative purposes only) passes under a first weft pass **52** (first to the left in FIG. 5), and floats over five subsequent weft passes **52** before passing under the third to last right most weft pass **52**. After passing under the third to last right most weft pass **52**, warp yarn **44** transitions to a base warp yarn by adopting a repeating over and under 1/1 plain weave pattern for the remaining weft passes **52**.

[0116] Consistent with the above, base warp yarns **42a** and **42b** engage each of the nine subsequent weft passes **52** from left to right. Specifically, base warp yarn **42a** is positioned below the first weft pass while base warp yarn **42b** is positioned above the first weft pass. This pattern repeats such that all of the nine weft passes shown in FIG. 5 are interwoven with the first and second base warp yarns **42a**, **42b**.

[0117] On the right most side of portion **46**, where warp yarn **44** is woven/incorporated into the base **60**, and adopts a weave pattern consistent with the base (such as the 1/1 weave pattern shown for base warp yarns **42a**, **42b**), adjacent base

warp yarns **40** are shifted apart from each other in the base layer **60** and accommodate this incorporation. This relative shifting of the base warp yarns **40** in the base layer **60** as illustrated occur before the transition in weave pattern but may also occur at or after the transition in weave patterns. As detailed below, a warp yarn guide device (FIGS. 13A-13C and 14A-14C), such as a fan-shaped reed, may be used to adjust the spacing between the warp yarns **40**. When warp yarn **44** is moved into the base layer **60**, warp yarn **44** adopts the same weave pattern as one or both of base warp yarns **42a**, **42b**. Warp yarn **44**, when in the base layer **60**, is in-phase with base warp yarn **42a**, and out-of-phase with base warp yarn **42b**.

[0118] First warp yarn spacing **56** designates the space between adjacent base warp yarns **42a**, **42b** in the base layer **60** when additional warp yarns are not interwoven between the base warp yarns **42a**, **42b** with a weave pattern consistent with the base warp yarns **42a**, **42b**. Second warp yarn spacing **59** designates the larger center to center distance between adjacent warp yarns **42a**, **42b** in the base layer **60** to the right of portion **46** where the yarns **42a**, **42b** been shifted apart.

[0119] FIG. 6 illustrates a side view of portion **46** of external surface **28**, taken through lines **6-6** in FIG. 5. FIG. 6 illustrates how warp yarn **44** floats over five weft passes **52** as a velour warp yarn, engage, i.e., pass under, an additional weft pass (the sixth from the left), and change weave patterns to adopt a base weave pattern by floating above and below consecutive weft passes. While FIG. 6 demonstrates a gap or spacing **65** between warp yarn **44** and the base warp yarns **42** when warp yarn **44** is not in the base layer **60**, the warp yarn **44** may be woven in a manner such that no space or gap exists. Also, while FIG. 5 illustrates the warp yarn **44** only projecting from surface **28** (an outer surface of the prosthesis **10**), the velour warp yarn **44** may be flipped such that it projects only from an inner surface of the prosthesis, or optionally from both the inner and outer surfaces **26**, **28**. Further, while a float over five weft passes is illustrated other floats may be used as well.

[0120] FIG. 7 illustrates a cross sectional view taken through lines **7-7** of FIG. 6. First base warp yarn **42a** and second base warp yarn **42b** are shown to have different elevations, with a weft pass disposed therebetween, but they may also be arranged so as to be at the same elevation. A dashed line is included in FIG. 7 for illustrative purposes to distinguish between the base layer **60** below the dashed line and the non-base layer **62** above the dashed line.

[0121] As indicated above, base warp yarns **42a**, **42b** and the interposed weft passes **52** form the base layer **60** further illustrated in FIG. 7 and lateral distance **56** represents the center-to-center distance between the first and second warp yarns **42a**, **42b**. This distance **56** (see also FIG. 5) between adjacent warp base warp yarns may be adjusted, e.g., so as to make space for one or more velour warp yarns to be incorporated into the base layer **60** and adopt a weave pattern consistent with the base layer **60**. To the extent desirable, e.g., to control porosity, suture retention strength, or permeability to blood of the prosthesis, distance **56** may also be decreased when a base warp yarn moves out of the base layer **60** and adopts a weave pattern consistent with a non-base weave pattern, such as a velour weave pattern.

[0122] Warp yarns may be systematically moved from a first position in a non-base layer **62**, hence outside of base layer **60** of the woven structure, to a second position within the base layer **60**. In the first position, the warp yarns are

woven in a manner in which they engage weft passes, and may for example be woven in a velour-type manner, floating over a plurality of weft yarn passes, adopting a non-base **62** weave pattern such as a velour weave pattern. Alternatively, in the first position, the warp yarns may be woven in a layer not in the base, such as in a multi-layered or three dimensional fabric structure, wherein the base comprises one of the layers, and the other layer(s) may comprise the non-base layer **62**. In the second position, the warp yarns are woven into the base layer **60**, preferably in a manner whereby the warp yarns adopt or take on the weave pattern of the base **60**.

**[0123]** When the warp yarns are moved into the base of the woven structure, some or all of the base warp yarns may be moved laterally with respect to each other so that the warp yarn brought into the base has sufficient space to adopt a weave pattern consistent with the base, and also provide for a controlled base warp yarn density (e.g., a consistent warp yarn density). Warp yarn density is typically measured in warp yarns per given unit of length of fabric. For clarity, in the present disclosure, woven yarn density will relate to a given length of the woven structure that can be measured for instance in a generally taut state, i.e., drawn tight sufficient to remove slack. The density is measured as the quantity of yarns per given unit of length.

**[0124]** FIG. 8 illustrates an example embodiment of woven prosthesis **10'** of the present invention. Similar to FIG. 1, the prosthesis **10'** is illustrated as having a first tubular portion **12**,<sup>1</sup> a second bulbous portion **14**,<sup>1</sup> and a third portion **16**,<sup>1</sup>. The second tubular portion **16**, **16**' has a crimped surface **17**, **17**' but may also be non-crimped. The crimped surface **17**, **17**' can be circularly crimped, helically crimped, or configured with combinations thereof.

**[0125]** FIG. 9 is a magnified view of a portion of the prosthesis **10'** taken about a dashed line border **240**. As can be seen in FIG. 9, circumferentially spaced velour warp yarns **44**' are woven into the prosthesis **10'** and extend longitudinally along the prosthesis **10'**. The circumferential center-to-center spacing of the velour warp yarns **44**' is adjustable. Also adjustable, is the pattern in which the velour warp yarns **44**' are longitudinally transitioned into and out of the base layer **60** (FIGS. 12A-12C).

**[0126]** A plurality of groups of velour warp yarns (**250**, **254**, **258**, **262**, **266**, and **270**) are shown in FIG. 9. Each group is representative of a plurality of warp yarns that share a characteristic relating to the positioning of the groups of warp yarns. Shown for example in FIG. 9 are a plurality of groups, three of which are illustrated with suffixes a through c for the groups of velour warp yarn **250**, **254**, **258**, **262**, **266**, and **270**. A first group of velour warp yarns **250** is represented by velour warp yarns (or sets of velour warp yarns) **250a**, **250b**, and **250c**. These yarns may be brought into the base and adopt a weave pattern consistent with the base at the same or similar time during the weaving process. Subsequent to velour warp yarns **250a**, **250b**, and **250c** being moved into the base, additional velour warp yarns such as a second group of warp yarns **254** comprised of velour warp yarns **254a**, **254b**, and **254c** may be brought into the base. The process of moving one or more groups of velour warp yarns into the base intentionally correlates to the vertical positioning of reed **120** and can be used to maintain base warp yarn density, and control the diameter of the prosthesis such as to increase or decrease the diameter. This process as applied to groups of velour warp yarns **250** and **254** can be subsequently adapted to additional

groups, such as **258**, **262**, **266**, and **270**. This process, therefore, can be used to controllably expand the diameter.

**[0127]** FIG. 10 is a magnified view of a portion of the bulbous section **14'** shown in FIG. 9 and circumscribed by dashed line border **242** for illustration purposes. The portion circumscribed by dashed border **242** includes one of the many velour warp yarns **44**' spaced about and woven into prosthesis **10'**. In the magnified view of FIG. 10, it can be seen that the portion circumscribed by border **242** actually includes two velour warp yarns **272b**,<sup>1</sup> **272b**" that are closely spaced. FIG. 11 is a magnified view of the portion of the prosthesis **10'** circumscribed by dashed border **244**

**[0128]** FIGS. 12A, 12B, 12C are sectional views shown in FIG. 10 taken along lines 12A-12A, 12B-12B, and 12C-12C, respectively. For illustrative clarity, the weft yarns are not shown. As the prosthesis **10'** is woven, and as further detailed below, velour warp yarns **272b**,<sup>1</sup> **272b**" are progressively shifted from the velour layer **62**,<sup>1</sup> **62**", **62**"" into the base layer **60**,<sup>1</sup> **60**", **60**"" e.g., so as to maintain a warp yarn density of the base layer **60** while increasing a width **108**,<sup>1</sup> **108**", **108**"" defined by a first set of warp yarns **84**, **88**, **90**, **92**. This can be used in a repetitive manner throughout a prosthesis, to thereby produce a large diameter bulbous portion (such as bulbous portions **14**, **14**' illustrated in FIGS. 1 and 8), as well as manage porosity, warp yarn density, or other properties of a prosthesis.

**[0129]** Shown in FIG. 12A are a first set of warp yarns **112**' with six warp yarns in the set, however other quantities are possible. First set of warp yarns **112**' has a plurality of base warp yarns **84**, **88**, **90**, **92** in a base **60**' thereby defining a first subset **106**'. Additionally shown in a non-base layer, such as a velour layer **62**,<sup>1</sup> are one or more velour warp yarns **272b**,<sup>1</sup> **272b**.". Flanking or adjacent to each side of the first set of warp yarns within border **112**' are additional base warp yarns **100**, **102**. Two warp yarns within the first subset of warp yarns circumscribed by border **106**', are spaced apart from each other a first distance **108**,<sup>1</sup> a distance greater than the distance of any other pair of base warp yarns in the first subset circumscribed by border **106**'.

**[0130]** Pertaining to the warp yarns of FIG. 12A, a warp yarn guide device, such as a fan-shaped reed **120**,<sup>1</sup> may be used to control warp yarn spacing. As shown in FIG. 14A, fan shaped reed **120**' has, e.g., three positions (122, 124, and 126) where warp yarns intersect the reed **120**' to control spacing during weaving. Correlating to the warp yarns arranged in FIG. 12A, the position of fan shaped reed **120**' to facilitate the weave pattern of FIG. 11A is shown to be in a "high" position whereby the **120**' reed engages warp yarns at a low location **126**. The reed **120**' is progressively lowered (or raised depending on its orientation) so as to shift the base warp yarns **84**, **88**, **90**, **92** apart making space for the velour warp yarns **272b**,<sup>1</sup> **272b**" to be incorporated into the base layer **60**,<sup>1</sup> **60**", **60**"".

**[0131]** Shown in FIG. 12B is the first set of warp yarns from FIG. 12A with a different arrangement and circumscribe by dashed border **112**.". The first set of warp yarns in FIG. 12B differs from that of FIG. 12A in that velour warp yarn **272b**' has been shifted into the first subset **106**" or base layer **60**.". Therefore, in the first subset **106**" of the first set of warp yarns circumscribed by dashed border **112**," there are now five base warp yarns instead of four. Reed **120**" may be shifted to the middle position to shift the base warp yarns sufficiently to accommodate velour warp yarn **272b**' in the base layer **60**."

[0132] Reed 120<sup>"</sup> may be shifted even further to the low position illustrated in FIG. 14C so as to allow for incorporation of velour yarn 272b<sup>"</sup> to be incorporated in base layer 60,<sup>"</sup> as illustrated in FIG. 12C. In this state, the base layer 60<sup>"</sup> circumscribed by dashed line 106<sup>"</sup> holds six base warp yarns [0133] The distance 108<sup>"</sup> shown in FIG. 12C has increased to be greater than distances 108' and 108<sup>"</sup> shown in FIGS. 12A and 12B, respectively. Even though the distance 108<sup>"</sup> has increased, the warp yarn density of the base layer 106<sup>"</sup> is maintained relatively consistent with the warp yarn densities of one or both of the arrangements depicted in FIGS. 12A and 12B. Additionally, the velour warp yarn density in terms of velour warp yarns per given length, has decreased in FIG. 12C, i.e., to a magnitude of zero) when compared to one or both of FIGS. 12A and 12B. Warp yarn 272b<sup>"</sup> adopts the weave pattern of the base warp yarns circumscribed by border 106<sup>"</sup> depicted in FIG. 12C.

[0134] The warp yarns are guided by reed 120 through a variety of spacings (or dents) within the reed used to influence the woven width (or diameter) of the prosthesis 10.<sup>"</sup> As illustrated in FIG. 18, the spacings correlate with locations 800, 802, 804, 806, 808, 810, and 812, each location having a different offset (816, 818, 820, 822, 824, 826, and 828) respectively, from a datum 814 on the reed 120. For example, since warp yarn group 250 is shown to enter the base layer first (from the bottom or distal end 20<sup>'</sup> in FIG. 9), the portion of the prosthesis woven prior to group 250 being moved into the base relates to location 800 of fan shaped reed 120 spaced from a datum 814 on the reed a distance 816. When warp yarn group 250 moves into the base layer, the fan shaped reed moves to a second position causing warp yarns to engage a second location 802 on the fan shaped reed 120, spaced a distance 818 from the datum 814 on the reed. This relationship may continue for the remaining groups 254, 258, 262, 266, and 270 such that portions of the bulbous profile 230<sup>'</sup> in FIG. 9 can be controllably and repeatably formed.

[0135] In order to achieve both a flare and a taper, the process described above to expand the diameter can be reversed while still weaving in the same warp yarn direction. Therefore, warp yarns are shifted from a base layer into a non-base layer such as a velour layer when a taper is desired. The fan shaped reed will therefore be controlled to move in the opposite direction, causing the diameter of the bulbous portion 14<sup>'</sup> of prosthesis 10<sup>'</sup> to be reduced, thereby controllably forming the contour 232<sup>'</sup> illustrated in FIG. 9.

[0136] While FIGS. 12A through 12C illustrate a specific behaviour of a set of warp yarns applicable to many different woven structures, such as a woven conduit, the principles illustrated in FIGS. 12A through 12C may be replicated throughout portions of woven structures, including woven structures configured to be used as vascular prostheses, e.g., in which complex and varied diameters or contours are desired. Contoured shapes including cylindrical conduits may be formed and configured to represent the natural geometries and shapes of the vascular structure for humans and mammals. This can be accomplished without using yarns of different material attributes, such as shrinking attributes, including coefficients of shrinking. In alternative embodiments however, yarns of different coefficients of shrinking may be used.

[0137] Prosthesis 10<sup>'</sup> of FIG. 8 has a length 220 between twelve and thirty centimeters, although other lengths may be appropriate depending on the intended use. The second tubular portion 16<sup>'</sup> has a first length 218 greater than ten centime-

ters, preferably fifteen centimeters, but other lengths may be used. The first tubular portion 12<sup>'</sup> has a first tubular diameter 222 and a length 212, and the second tubular portion 16<sup>'</sup> has a second tubular diameter 224. A maximum diameter 226 is greater than the diameters of the first and second tubular portions 12<sup>'</sup> and 16<sup>'</sup> respectively, and is positioned within the bulbous portion 14.<sup>'</sup> The maximum diameter 226 is larger than the diameters 222 and 224 by four to sixteen millimeters, preferably six to ten millimeters, and most preferably by about eight millimetres, but this difference may be varied.

[0138] As further illustrated in FIG. 8, the maximum diameter 226 of bulbous portion 14<sup>'</sup> may be positioned to be closer to a first transition region 22<sup>'</sup> than a second transition region 24,<sup>'</sup> hence further from the second transition region 24<sup>'</sup> than the first transition region 22<sup>'</sup>. For example, the maximum diameter 226 may be positioned at a distance 216 from second transition region 24<sup>'</sup> such that the distance 216 is between 50% and 75%, or between 60% and 70%, or between 65% and 70% of the length 214 of the bulbous portion 14.<sup>'</sup> The woven length 214 of the bulbous portion 14<sup>'</sup> is configured to approximate the diameter 224 within a tolerance of plus or minus two millimeters, preferably one millimeter. The first tubular portion 12<sup>'</sup> is configured to have a length 212 measured from the first transition region 22<sup>'</sup> to the proximal end 18,<sup>'</sup> greater or equal to one centimeter. All of these dimensions are provided as examples, for they may vary, and they not intended to limit the scope of the invention.

[0139] The first transition region 22<sup>'</sup> represents the transition from the first tubular portion 12<sup>'</sup> to the bulbous portion 14,<sup>'</sup> while the second transition region 24<sup>'</sup> represents the transition from the bulbous portion 14<sup>'</sup> to the second tubular portion 16<sup>'</sup>. The bulbous portion 14<sup>'</sup> is woven to have a varied diameter profile and is configurable to have varying degrees of flaring and tapering, to mimic the natural anatomy, shape, dimensions, and intended blood flow dynamics of the aortic root for cardiothoracic surgery pertaining to the ascending aorta.

[0140] FIG. 9 illustrates a partial view of a woven prosthesis 10<sup>'</sup> embodiment representative of elements of the present disclosure, taken about border 240 of FIG. 8. Illustrated in FIG. 9 is a bulbous portion 14,<sup>'</sup> and adjacent thereto portions of the first tubular portion 12<sup>'</sup> and the second tubular portion 16<sup>'</sup>. Preferably, the first tubular portion 12<sup>'</sup> and the second tubular portion 16<sup>'</sup> have warp yarns continuously woven throughout the bulbous portion 14<sup>'</sup> into one, preferably both of the first and second tubular portions 12<sup>'</sup> and 16<sup>'</sup>. Other elements such as first transition region 22<sup>'</sup> and second transition region 24<sup>'</sup> are illustrated as well. The second transition region 24<sup>'</sup> may correlate with the sinotubular junction common to the anatomy of the ascending aorta.

[0141] The velour warp yarn density (quantity of velour warp yarns per given length of woven fabric) is shown to decrease when moving towards the maximum diameter portion of the bulbous portion 14,<sup>'</sup> and away from either the first or second transition regions 22<sup>'</sup> and 24<sup>'</sup>.

[0142] Additionally shown in FIG. 9, the second tubular portion 16<sup>'</sup> has a crimped surface 17.<sup>'</sup> This is shown more specifically in FIG. 15, taken about border 19 shown in FIG. 8. The crimped surface can be circularly or helically crimped.

[0143] Variations of the shape illustrated in FIG. 9 can be made, by controlling how many warp yarns are moved into the base, as well as controlling the movement and coordination of the fan-shaped reed 120. Additionally, variations can

be made by controlling how many weft passes will be woven with the warp yarns while the fan-shaped reed 120 is moving or stationary.

[0144] FIG. 11 illustrates the behaviour of the velour warp yarns 272b' and 272b" circumscribed by border 244 in FIG. 10. Velour warp yarns 272b' and 272b" are shown to adopt a 5/1 weave pattern in portion 780. The velour warp yarns 272b' and 272b" float over a plurality of weft passes 752 (depicted as yarns extending from left to right in FIG. 11). After floating over weft pass 765 and under weft pass 766, velour warp yarn 272b' is shown to adopt the weave pattern of base layer 60," 60," which in this example may be represented as a 1/1 weave pattern. Thereafter, velour warp yarn 272b' engages each of the weft passes 769 through 773. Fan shaped reed 120 adjusts from a first position 121' illustrated in FIG. 13A while weaving portion 780 to a second position 121" illustrated in FIG. 13B while weaving portion at or near transition point 786 (illustrated by a dashed horizontal line). In the first position (FIG. 13A) where the reed 121' has been moved to a top position, warp yarns engage the reed at a low portion 136 of the reed, and in the second position 121" (FIG. 13B), the reed has been moved to a middle position whereby warp yarns engage the reed at the middle portion 134 of the reed 121." Therefore, when velour warp yarn 272b' adopts the base weave pattern 60," 60," the warp yarn spacing in the base layer 60," 60" may be maintained.

[0145] Further illustrated in FIG. 11, velour warp yarn 272b" is shown to first adopt a 5/1 weave pattern in portion 780 and part of portion 781, and then adopt a weave pattern consistent with the base weave pattern in portion 782. This behaviour is similar to that of velour warp yarn 272b', but begins at a different weft pass. After floating over weft pass 766 and under weft pass 767, velour warp yarn 272b" is shown to adopt the weave pattern of a base layer 60," which in this example may be represented as a 1/1 weave pattern. Similar to velour warp yarn 272b', velour warp yarn 272b" engages each of the weft passes 769 through 773. Fan shaped reed 120 adjusts from a second position 121" illustrated in FIG. 13B to a third position 121"" illustrated in FIG. 13C at or near transition point 788 (illustrated by a dashed horizontal line). In the second position 121" (FIG. 13B), where the reed 121" has been moved to a middle position, warp yarns engage the reed at a middle portion 134 of the reed, and in the third position 121"" (FIG. 13C), the reed 121 ""has been moved to a bottom position whereby warp yarns engage the reed 121"" at the top portion 132 of the reed 121. Therefore, when velour warp yarn 272b" adopts the base weave pattern, the warp yarn spacing in the base layer 60"" may be maintained, and the overall width achieved by the same quantity of warp yarns from portion 780 has increased to increasingly wider portions 781 and 782.

[0146] A distance between the two outer most base warp yarns 100 (on the far left) and 92 (on the far right) increases in portion 781 and again in 782 while the woven portion circumscribed by border 244 maintains a fairly consistent warp yarn density.

[0147] FIG. 20 illustrates another example embodiment of the present invention. Prosthesis 310 comprises a proximal end 318, and a distal end 320, and a sidewall 330 disposed therebetween, preferably constructed through a weaving process. The sidewall 330 may be woven with a base layer and velour layer, as illustrated by example in FIGS. 12A through

12C. Such weaving processes used to provide prosthesis 310 may be consistent with the weaving of portions of prosthesis 10' described herein.

[0148] Prosthesis 310 is configured to have a size and shape in accordance with the bulbous portion of prosthesis 10.' Unlike prosthesis 10,' prosthesis 310 does not have first and second tubular portions 12,' 16.' Prosthesis 310 may be woven in a manner generally consistent with prosthesis 10.' Prosthesis 310 may be formed, for example, by cutting the bulbous portion 14' from prosthesis 10,' and utilizing the woven bulbous portion alone.

[0149] FIG. 21 illustrates a prosthesis 410 including a proximal end 418, and a distal end 420, and a sidewall 430 disposed therebetween, preferably constructed through a weaving process. The sidewall 430 may be woven with a base layer and velour layer, as illustrated by example in FIGS. 12A through 12C. Such weaving processes used to provide prosthesis 410 may be consistent with the weaving of portions of prosthesis 10' described herein.

[0150] Prosthesis 410 is configured to have a size and shape in accordance with the bulbous portion of prosthesis 10,' as well as the first tubular portion 12' of prosthesis 10.' Unlike prosthesis 10,' prosthesis 410 does not have a second tubular portion 16.' Prosthesis 410 may be woven in a manner generally consistent with prosthesis 10.' Prosthesis 410 may be formed by removing through cutting for instance, second tubular portion 16' from prosthesis 10,' and utilizing the remaining portion of prosthesis 10' not removed.

[0151] FIG. 22 illustrates a prosthesis 510 which comprises a proximal end 518, and a distal end 520, and a sidewall 530 disposed therebetween, preferably constructed through a weaving process. The sidewall 530 may be woven with a base layer and velour layer, as illustrated by example in FIGS. 12A through 12C. Such weaving processes used to provide prosthesis 510 may be consistent with the weaving of portions of prosthesis 10' described herein.

[0152] Prosthesis 510 is configured to have a size and shape in accordance with the bulbous portion of prosthesis 10,' as well as the first tubular portion 12' of prosthesis 10.' Unlike prosthesis 10,' prosthesis 510 does not have a second tubular portion 16.' Prosthesis 510 may be woven in a manner generally consistent with prosthesis 10.' Prosthesis 510 may be formed by removing through cutting for instance, second tubular portion 16' from prosthesis 10,' and utilizing the remaining portion of prosthesis 10' not removed.

[0153] FIG. 23 illustrates a prosthesis 610 which comprises a proximal end 618, and a distal end 620, and a sidewall 630 disposed therebetween, preferably constructed through a weaving process. The sidewall 630 may be woven with a base layer and velour layer, as illustrated by example in FIGS. 12A through 12C. Such weaving processes used to provide prosthesis 610 may be consistent with the weaving of portions of prosthesis 10' described herein.

[0154] Prosthesis 610 is configured to have a size and shape in accordance with a portion of the bulbous portion 14' of prosthesis 10,' as well as the second tubular portion 16' of prosthesis 10.' Unlike prosthesis 10,' prosthesis 610 does not have a first tubular portion 12,' nor does it have a proximal portion of the bulbous portion 14' of prosthesis 10.' Therefore, the bulbous portion of prosthesis 610 only expands outward in an increasing diameter configuration, such as a "flared" manner, flaring from the second tubular portion 616 towards the proximal portion 618. Prosthesis 610 may be woven in a manner generally consistent with prosthesis 10.' Prosthesis

**610** may be formed by removing through cutting for instance, the proximal portion of the bulbous portion **14**, through cutting for instance at the location of the maximum diameter **226** of prosthesis **10**' (FIG. 8), as well as the first tubular portion **12**' of prosthesis **10**', thereby utilizing the remaining portions of prosthesis **10**' not removed.

[0155] In order to accomplish the change in woven structure width along a weft yarn direction, or for tubular structures, the change in related diameters, the principles of weave pattern adjustment from a velour warp yarn to a base warp yarn, as described previously by example in relation to FIGS. 12A through 12C, and applicable to the finished prostheses illustrated for example in FIGS. 1, 8, 9, and 20 through 23, will be illustrated and further described.

[0156] It should be noted that embodiments of the invention may involve all velour warp yarns to move into the base as illustrated for example for prosthesis **10**" in FIGS. 16A and 16B only to emerge again. In other embodiments, such as the prosthesis **10**"" illustrated in FIGS. 17A and 17B, less than all of the velour warp yarns are moved into the base.

[0157] It should also be noted that many permutations of weave patterns may be employed to carry out the invention. For example, warp yarns not in the base may exist in a layer of a three dimensional fabric near or adjacent to the base, and then may be brought into the base. Alternatively, warp yarns not in the base may be of the many varieties of velour warp yarns such as single velour and double velour warp yarns. The single or double velour warp yarns may be brought into the base and adopt a weave pattern involving a higher frequency of interlacing when in the base than when not in the base. This may be fully or partially achieved by the movement of the velour warp yarns from a first position in which the velour warp yarn adopts a velour weave pattern, such as but not limited to a 5/1 velour weave pattern, and adjusts to a second weave pattern, such as a weave pattern consistent with the base, including but not limited to a 1/1, 6/4, or 6/3 weave pattern. Other weave patterns appropriate for the base include, for example, a 3/1 weave pattern, a 2/1 weave pattern, a 1/3 weave pattern, as well as a 1/4 weave pattern.

[0158] Additionally, it should be noted that by adjusting where the velour yarns transition into the base, the rate of expansion or contraction for the width of woven structure will be controllable, and enable different shapes and geometries to be fabricated.

#### Method of Manufacture And Fabrication

[0159] Prostheses consistent with and resulting from the methods of manufacture of the embodiments of the present invention may be constructed in a variety of specific ways. In certain embodiments, examples of the present invention may be manufactured in four steps comprising (i) a flat weaving step, (ii) a cutting step, (iii) a heat setting step, and (iv) a sterilization step. The heat setting step may be achieved in a two-step manner, first involving the application of heat through a crimping mandrel to crimp and corrugate certain portions of the surface of portions of the prosthesis, as well as a shaping step in which heat is applied to the prosthesis, whereby the prosthesis takes a "set" or "shape memory" in an expanded state through the usage of an expandable bladder configured to provide a shape consistent with the desired final shape of the prosthesis.

[0160] An example prosthesis according to the present invention, including prosthesis **10**, **10**," **10**," may be woven with a loom, e.g., a Jacquard-type loom **136**, and a warp yarn

guide device, e.g., fan-shaped reed **120**, as shown in FIGS. 18, 19A, and 19B. The warp yarns or threads (i.e., those yarns extending in the longitudinal direction) and one or more weft or fill yarns or threads (i.e., those yarns extending generally transverse to the longitudinal direction of the portion to be woven) are interlaced with one another in one or multiple predetermined weaving patterns. When weaving a conduit, as employed in various embodiments of the present invention, at the weaving station of the loom, the warp yarns are fed individually through heddles aligned transverse to the longitudinal direction on one of four or more shafts. The upward and downward movement of the shafts moves a preselected pattern of the warp yarns up and then down. In such an arrangement, two of the shafts move the warp yarns for forming the upper surface of the tubular conduit, and two of the shafts move the warp yarns for forming the lower surface of the tubular conduit. As the warp yarns on one shaft are drawn upwardly and the warp yarns on another shaft are drawn downwardly, the weft thread is shuttled in a first direction between those groups of warp yarns to weave the upper surface of the tubular conduit, thereby providing a weft pass of the weft yarn, also known as a machine pick. The weft yarn is then shuttled in a reverse direction between another group of upwardly and downwardly drawn warp yarns to weave the lower surface of the tubular conduit, thereby creating an additional weft pass or machine pick. The position of the shafts and thus the position of the warp yarns is then reversed and the weft thread is again shuttled between the groups of warp yarns, creating a plurality of weft passes, wherein the process continues resulting in a woven tubular shape.

[0161] As they approach the weaving station, the warp yarns are fed between the fingers of fan-shaped reed **120**, which aligns the yarns for weaving and which thus determines the ultimate shape of the woven article. Whereby weaving tubular articles having a substantially constant diameter is performed utilizing a conventional front reed which is fixed in place and which has evenly spaced fingers used to produce constant spacing between the warp yarns, reeds with varying spacing will be beneficial for carrying out the present invention but are not required. An example of such a reed has spacing between the fingers which is narrow at a first end or bottom end, and gradually increases toward the top end. In contrast to conventional reeds, the fan-shaped reed **120** is not held in a fixed position, but rather is moved upward or downward to alter yarn to yarn spacing in all or portions of the article being woven. For example, fan shaped reed **120**," **120**," **120**," as shown in FIGS. 14A-14C, may be moved upwards and downwards, causing warp yarns to engage the fan shaped reed **120**," **120**," **120**," at a plurality of elevations represented by dimensions **816** through **828** in FIG. 18, all with respect to a datum **134**. When the fan shaped reed is at its highest position, the warp yarns engage the reed at a low position such as that represented by location **800** in FIG. 18. Likewise, when the fan shaped reed is at its lowest position, the warp yarns engage the reed at a high location such as that represented by location **812** in FIG. 18. In the context of fabricating a tubular article consistent with certain embodiments of the present disclosure, the movement of the fan-shaped reed **120** provides for an adjustable diameter.

[0162] When programmed to coordinate with the specific manipulation or engagement of warp yarns, the spacing of warp yarns can be adjusted to provide for sufficient space such that one or more velour warp yarns may be brought into the base, and woven as a part of the base, thereby adopting a

weave pattern consistent with the base. The invention thereby enables a base warp yarn density to be held within a range or otherwise managed, such that the diameter of a tubular woven conduit may be selectively adjusted, without requiring an adjustment of the finished spacing of warp yarns within a base layer. Provided that a sufficient quantity of velour warp yarns are able to be brought into the base, controlled flaring and tapering of all or portions of a woven tubular conduit may therefore be provided.

[0163] When the reed 120 is gradually moved upwards as the weaving of the tubular conduit advances, the spacing between the warp yarns and, hence, the diameter of the tubular article being woven, see, e.g., greige 130 in FIG. 19A, will gradually be decreased. Similarly, when the reed 120 is gradually moved downward as the weaving of the tubular conduit advances, the spacing between the warp yarns will increase as will the diameter of the tubular article being woven. The rate of movement of the reed 120 will determine the taper of the article being woven, the faster the reed is moved, the larger the angle of taper, and the slower the reed is moved, the smaller the angle of taper. Moving the reed at a constant rate will produce a constant angle of taper. However, changing the rate of movement of the reed enables tubular articles to be formed with curved or changing angles of taper. It is noted that use of the reed is not required as the spacing between warp yarns may already be large enough to accommodate shifting of the non-base warp yarns, e.g., velour war yarns, into the base layer of the prosthesis.

[0164] When using a movable reed 120, it is initially held in a fixed lower position to weave a substantially uniform diameter tubular conduit. When a desired length of the tubular conduit has been reached, the reed 120 is drawn downwards in increments, providing additional spacing between certain warp yarns such that additional warp yarns may be moved from a first position in a velour layer to a second position in the base layer. This is done such that when the warp yarns are brought into the base layer, and adopt a weave pattern consistent with the base layer, as illustrated in FIGS. 12B-12C, for example, the resulting spacing between the warp yarns adjacent the additional warp yarn is increased. With each change for additional warp yarns to be brought into the base, the movement of the reed 120 will have to be evaluated to see if an adjustment is needed to provide sufficient spacing such that at a rate which would produce the desired angle of taper. The front reed is continued to be drawn downward as the weaving process continues until a woven fabric having the desired tubular configuration has been formed as the greige 130 represented for example in FIGS. 19A and 19B.

[0165] The weaving step utilized to fabricate embodiments of the present invention may be conducted for a given length of a woven structure. In accordance with embodiments of the present invention, a plurality of bulbous portions may be woven into a greige 130 shown in FIGS. 19A and 19B. A secondary cutting step may be employed at cutting locations 132 shown in FIG. 19A as dashed lines in order to section the woven structure to a length consistent with the desired intended usage of a prosthesis.

[0166] During further processing of the prosthesis, all or portions of the prosthesis of the present invention may be crimped to provide for "self supporting" qualities of the finished prosthesis, adding rigidity to the tubular prosthesis wherein the strength is needed to ensure proper cross sectional area for assured flow of blood through the conduits. Examples are disclosed by example in U.S. Pat. No. 3,945,

052 herein incorporated by reference. As illustrated in all the figures, neither the bulbous portion nor the collar or first woven portion 12,12' are crimped but they may be crimped in other embodiments. A benefit to not crimping these sections include, for example, being able to provide a surgeon locally flat or slightly curved surfaces beneficial for anastomosis and suturing. Providing a surface that has crimps, pleats, or corrugations in the bulbous portion 14, 14' and/or a collar, e.g., the proximal tubular woven portion 12, 12', may complicate suturing and anastomosis procedures as it is understood to be more convenient to suture and perform a proximal anastomosis on a flat or slightly curved surface rather than a non-uniform crimped, pleated, or corrugated surface.

[0167] The woven fabric or prosthesis 10, 10', 10", 10''' may be coated with a collagen or gel coating applied to entire length of the prosthesis for sealing purposes. Therefore, in addition to a uniform textile structural porosity capable of being achieved in a base layer (between warp yarns, weft yarns, and interwoven combinations thereof), a uniform functional porosity impacting permeability of the woven fabric to a fluid may additionally be achieved.

[0168] The prosthesis 10, 10', 10", 10''' may be sterilized from any of the sterilization process suitable for woven grafts, including gamma radiation or cobalt 60 radiation, ethylene oxide gas, or e-beam radiation as commonly known to one skilled in the art.

[0169] Materials useful for forming embodiments of the present invention include textile weaving products, for example, synthetic materials such as synthetic polymers. Synthetic yarns suitable for use in the present invention include, but are not limited to, polyesters, including polyethylene terephthalate polyesters (herein referred to as PET), polypropylenes (herein referred to as PP), polyethylenes, polyurethanes and polytetrafluoroethylenes (herein referred to as PTFE). The yarns may be of the monofilament, multifilament, spun type or combinations thereof. The yarns may also be flat, twisted or textured, and may have high, low or moderate shrinkage properties. Such yarn materials, for instance PET, are available from DuPont under the trade name of Dacron. The yarns may, for example, have a total denier in the range of 15 to 300, or in the range 100 to 200, and may also be about 140 denier but can have other sizes as well. The yarns may be comprised of single or multiple plies. An example yarn that may be utilized according to the present invention may be texturized and PET based, and comprises two plies, each having a denier of 70, the yarn having a total denier of 140.

[0170] The following two examples are to be illustrative of embodiments that relate to the present invention. They both relate to the formation of a bulbous prosthesis, consistent with prosthesis 10, 10' shown in FIGS. 1 and 8 respectively. Unless otherwise noted, the vascular prosthesis of all of the following examples were fabricated through flat-woven processes, arranged to achieve a tubular configuration using an electronic Jacquard weaving machine and a variable reed such as a fan-shaped reed.

#### EXAMPLE 1

[0171] In a first example of the present invention, an aortic prosthesis is constructed to have small diameter of approximately 32 millimeters, and a maximum diameter of approximately 40 millimeters. The prosthesis is constructed in accordance with the elements represented for instance in FIGS. 1 and 9.

[0172] A weft yarn material chosen for the present example is comprised of polyethylene terephthalate (PET) is provided having two plies of 70 denier per ply, thereby having a final denier of 140. A warp yarn material chosen for the present example is comprised of polyethylene terephthalate (PET) and is provided having two plies of 70 denier per ply, thereby having a final denier of 140. Either or both of the warp and weft yarn materials may be texturized or untexturized. A base weave pattern is chosen to be a plain weave pattern. It is determined that a velour layer will be woven to the outside of the base layer. The weave pattern chosen for the velour layer is a 5/1 pattern.

[0173] A constant weft yarn spacing is chosen to be used for the weaving of all woven portions of the prosthesis. Specifically, a weft yarn spacing of 66 yarns per inch (26 weft yarns per centimeter) is determined to be used for all woven portions of the prosthesis.

[0174] A total quantity of warp yarns is chosen based on a desired warp yarn density, positioning, and finished diameters, including the maximum diameter portion of the woven article. By way of example, a total of 703 warp yarns have been chosen.

[0175] When weaving the first portion 12, 12' and the third portions 16, 16' (both collar and crimped/corrugated sections respectively), the position of the reed 120 is set to its narrowest width in order to achieve a woven fabric tubular diameter of approximately 32 mm (or flat width 50.3 mm), and the total of 703 warp yarns are so divided into two groups. The first group includes 469 warp yarns to form the base layer, and the second group includes 234 warp yarns to form the velour layer of the first portion. Therefore, to achieve the intended tubular diameter of 32 millimeters, the warp spacing for the base layer is 118 yarns per inch (46 yarns per centimeter) when a 32 millimeter diameter portion is to be woven, and 59 velour warp yarns per inch (23 yarns per centimeter) for the velour layer. The average fabric warp spacing including both velour and base warp yarns is the sum of both layers, i.e., 177 yarns per inch (70 yarns per centimeter). The first tubular portion 12, 12' is woven with warp yarns acting as both base warp yarns and velour warp yarns to establish the first tubular portion 12, 12'.

[0176] The fan shaped reed 120 is gradually repositioned in steps during the weaving process to achieve the desired profile of the bulbous portion 14, 14'. This occurs in combination with the conversion of velour warp yarns into base warp yarns, until the maximum desired diameter is achieved.

[0177] When reaching the maximum diameter portion, the reed 120 is at its widest to facilitate maximum fabric tubular diameter of 40 mm (or flat width 62.8 mm), and the total of 703 warp yarns are so divided into two groups that 584 yarns now form the fabric base layer (for example, the inner surface), and 119 yarns form the velour layer or layers. As a result, the warp spacing for the ground layer 60, 60' is maintained as 118 yarns per inch (46), while the velour layer is reduced to 24 yarns per inch (9 yarns per centimeter) for the velour layer 62, 62".

## EXAMPLE 2

[0178] In a second example of the present invention, an aortic prosthesis is constructed to have small diameter of approximately 24 millimeters, and a maximum diameter of approximately 32 millimeters. The prosthesis is constructed in accordance with the elements represented for instance in FIGS. 1 and 9.

[0179] A weft yarn material chosen for the present example is comprised of polyethylene terephthalate (PET) is provided having two plies of 70 denier per ply, thereby having a final denier of 140. A warp yarn material chosen for the present example is comprised of polyethylene terephthalate (PET) and is provided having two plies of 70 denier per ply, thereby having a final denier of 140. Either or both of the warp and weft yarn materials may be texturized or untexturized. A base weave pattern is chosen to be a plain weave pattern. The velour layer 62, 62" can be woven to the outside of the base layer 60, 60." The weave pattern chosen for the velour layer is a 5/1 pattern.

[0180] A constant weft yarn spacing is chosen to be used for the weaving of all woven portions of the prosthesis 10, 10'. Specifically, a weft yarn spacing of 66 yarns per inch (26 weft yarns per centimeter) is determined to be used for all woven portions of the prosthesis 10, 10'.

[0181] A total quantity of warp yarns is chosen based on a desired warp yarn density, positioning, and finished diameters, including the maximum diameter portion of the woven article. By way of example, a total of 550 warp yarns have been chosen.

[0182] When weaving the first portion 12, 12' and the third portion 16, 16' (both corrugated and collar portions), the position of the reed 120 is set to narrowest width in order to achieve a woven fabric tubular diameter of approximately 24 mm (or flat width 37.7 mm), and the total of 550 warp yarns are so divided into two groups. The first group includes 367 warp yarns to form the base layer 60, 60," and the second group includes 183 warp yarns to form the velour layer 62, 62" of the first portion 12, 12'. Therefore, to achieve the intended tubular diameter of 24 millimeters, the warp spacing for the base layer 60, 60' is 124 yarns per inch (49 yarns per centimeter) when a 24 millimeter diameter portion is to be woven, and 62 velour warp yarns per inch (24 yarns per centimeter) for the velour layer 62, 62". The average fabric warp spacing including both velour and base warp yarns is the sum of both layers, (i.e., 177 yarns per inch, or 70 yarns per centimeter). The first tubular portion 12, 12' is woven with warp yarns acting as both base warp yarns and velour warp yarns to establish the first tubular portion 12, 12'. Again, the reed 120 is gradually repositioned in steps during the weaving process to achieve the desired profile of the bulbous portion 14, 14'. This occurs in combination with the conversion of velour warp yarns into base warp yarns, until the maximum desired diameter is achieved.

[0183] When reaching the maximum diameter portion, the reed 120 is at its widest to facilitate maximum fabric tubular diameter of 32 mm (or flat width 50.3 mm), and the total of 550 warp yarns are so divided into two groups that 491 yarns now form the fabric base layer 60, 60' (for example, the inner surface), and 59 yarns form the velour layer or layers 62, 62". As a result, the warp spacing for the ground layer 60, 60' is maintained as 124 yarns per inch (49 yarns per centimeter), while the velour layer 62, 62" is reduced to 15 yarns per inch (6 yarns per centimeter) for the velour layer.

[0184] After the maximum desired diameter is achieved, the diameter of the prosthesis 10, 10' is intentionally reduced or tapered by reversing the steps used to create the increased diameter. Specifically, warp yarns now in the base 60, 60' of the prosthesis 10, 10' are adjusted and moved out of the base 60, 60' to behave and perform as velour warp yarns. The spacing of the base warp yarns still within the base 60, 60' are adjusted to accommodate the removal of the warp yarn from

the base layer 60, 60' to the velour layer 62, 62', without significantly impacting the warp yarn spacing within the base 60, 60'.

[0185] As many apparently widely different embodiments of the present invention can be made without departing from the spirit and scope thereof, it is to be understood that the invention is not limited to the specific embodiments thereof except as defined in the appended claims.

1. An implantable medical prosthesis comprising:  
a woven base comprising base warp yarns interwoven with weft yarn passes, the woven base at least partially forming smaller and larger diameter portions of the prosthesis; and  
one or more velour yarns forming part of both the smaller and larger diameter portions;  
in at least a portion of the larger diameter portion at least one of the one or more velour yarns incorporated into the woven base and exhibiting a weave pattern consistent with the woven base.

2. The prosthesis of claim 1, wherein within the smaller diameter portion, the at least one of the one or more velour yarns is not incorporated into the woven base and does not exhibit a weave pattern consistent with the woven base.

3. The prosthesis of claim 1, wherein a spacing between the base warp yarns is maintained approximately the same in the smaller and larger diameter portions without adding additional warp yarns to the larger diameter portion beyond that in the smaller diameter portion.

4. The prosthesis of claim 1, wherein an increase in diameter of the prosthesis going from the smaller diameter portion to the larger diameter is effected by increasing spacing between the base warp yarns during weaving of the prosthesis.

5. The prosthesis of claim 3, wherein the spacing between the base warp yarns in the larger diameter portion is made smaller without reducing a diameter of the larger diameter portion by at least one of the one or more velour yarns incorporated into the woven base of the larger diameter portion.

6. The prosthesis of claim 1, wherein the prosthesis is a generally tubular graft and the larger diameter portion lies within a portion of the graft varying in diameter along a longitudinal axis of the graft and the smaller diameter portion lies within a portion of the graft having a generally uniform diameter.

7. The prosthesis of claim 1, wherein the prosthesis is a generally tubular graft and the larger and smaller diameter portions lie within a portion of the prosthesis in diameter along a longitudinal axis of the graft.

8. The prosthesis of claim 1, wherein in at least a portion of the smaller diameter portion the one or more velour yarns exhibit a float that is entirely absent or smaller in the larger diameter portion.

9. The prosthesis of claim 1, wherein a spacing between the base warp yarns in the smaller diameter portion is within 30% of the size of the spacing in the larger diameter portion.

10. The prosthesis of claim 1, wherein a quantity of the base warp yarns and velour yarns is the same in the larger diameter portion as the smaller diameter portion, and wherein the base warp yarns and the velour warp yarns are continuously woven between the smaller diameter portion and the larger diameter portion.

11. The prosthesis of claim 1, wherein the prosthesis comprises a secondary woven layer disposed over at least one of the smaller and larger diameter portions, and wherein a por-

tion of a yarn forming the secondary layer is incorporated into the base layer of the larger portion.

12. An implantable medical prosthesis comprising:  
a woven structure comprising warp yarns interwoven with weft passes, all or a portion of the warp yarns together with the weft passes form a woven base of the woven structure;  
a first portion of the woven structure is woven with a first set of the warp yarns, a first subset of the first set of the warp yarns interwoven with the weft passes forms the woven base in the first portion, two of the warp yarns in the first subset in the first portion are spaced apart from each other a first distance along a surface of the prosthesis, the first distance is greater than any spacing between any other pair of warp yarns in the first subset in the first portion along the surface of the prosthesis;  
a second portion of the woven structure is woven with the first set of the warp yarns, a second subset of the first set of the warp yarns interwoven with the weft passes forms the woven base in the second portion, two of the warp yarns in the first subset in the second portion are spaced apart from each other a second distance along the surface of the prosthesis, the second distance is greater than any spacing between any other pair of warp yarns in the first subset in the second portion along the surface of the prosthesis;  
wherein the second distance is greater than the first distance, and the number of warp yarns in the first subset is smaller than the number of warp yarns in the second subset.
13. The implantable medical prosthesis of claim 11, wherein the portion of the warp yarns interwoven with the weft passes and disposed in the woven base are arranged in a base weave pattern, and another portion of the warp yarns not disposed in the woven base are velour warp yarns.
14. The implantable medical prosthesis of claim 11, wherein the prosthesis is a generally tubular graft, the first portion having a first diameter along a longitudinal axis of the graft, the second portion having a second diameter along the longitudinal axis larger than the first diameter.
15. The implantable medical prosthesis of claim 11, wherein in the first portion of warp yarns not in the first subset forming the woven base exhibit a float that is entirely absent or smaller in the second portion.
16. The implantable medical prosthesis of claim 11, further comprising a first end and a second end, and wherein essentially all the warp yarns are continuously woven between the first and second ends.
17. The implantable medical prosthesis of claim 11, wherein the prosthesis comprises a secondary woven structure disposed over at least one of the first and second portions, wherein a portion of a yarn forming the secondary woven structure is incorporated into the woven base of the secondary portion.
18. A method for manufacturing an implantable medical prosthesis comprising:  
weaving a woven base from a set of warp yarns and at least one weft yarn pass the set of warp yarns comprises warp yarns woven as base warp yarns and warp yarns woven as non-base warp yarns, wherein the base warp yarns and weft yarn passes are woven into a base weave pattern, and the non-base warp yarns are woven with at least one weft yarn pass when not woven into a base weave pattern; and

incorporating into the woven base one or more of the non-base warp yarns, wherein the one or more non-base warp yarns assume a weave pattern consistent with all or portions of the base weave pattern.

**19.** The method of claim **19**, wherein the non-base warp yarns are velour yarns.

**20.** The method of claim **19**, wherein the woven base is configured to establish a smaller and larger diameter portion, the larger diameter portion capable of achieving a larger diameter than the smaller diameter portion, wherein the larger diameter of the larger diameter portion is achieved by the step of incorporating into the woven base one or more velour yarns.

**21.** The method of claim **19**, wherein the incorporating into the woven base one or more velour yarns exclusively utilizes velour yarns utilized as velour prior to being incorporated into the woven base.

**22.** The method of claim **20**, wherein the larger diameter portion has a base warp density within 30% of a base warp density for the smaller diameter portion.

**23.** The method of claim **19**, wherein a variable reed is moved during the weaving step to provide for a varied diameter profile of the medical prosthesis.

**24.** A method for manufacturing an implantable medical prosthesis comprising:

weaving a woven base comprising base warp yarns interwoven with weft yarn passes, the base at least partially forming smaller and larger diameter portions, one or more velour yarns forming part of both the smaller and larger diameter portions, weaving in at least a portion of the larger diameter portion at least one of the one or more

velour yarns into the woven base to exhibit a weave pattern consistent with the woven base.

**25.** The method for manufacturing an implantable prosthesis as claimed in claim **24**, wherein the at least one of the one or more velour yarns woven into the woven base of the larger diameter portion and exhibiting a weave pattern consistent with the woven base is not woven into the base of the smaller diameter portion.

**26.** A method for weaving a variable diameter graft having a velour layer on at least a portion of the graft, comprising the step of changing a weave pattern of a warp yarn used to form the velour layer in a smaller diameter portion of the graft such that said warp yarn takes on a weave pattern and forms part of a base layer of a larger diameter portion of the graft.

**27.** The method as claimed in claim **26**, further comprising the step of changing the weave pattern of the warp yarn as it transitions from the larger diameter portion to a second smaller diameter portion so as to form a velour layer on at least a portion of the second smaller diameter portion which is smaller in diameter than the larger diameter portion.

**28.** The method as claimed in claim **26**, further comprising the step of shifting at least a pair of adjacent warp yarns used to form a base layer of the smaller diameter portion so as to increase a spacing between said adjacent warp yarn in the larger diameter portion.

**29.** The method as claimed in claim **26**, wherein a spacing between base warp yarns used to form the smaller diameter portion is within 30% of the size of a corresponding spacing between the same base warp yarns in the larger diameter portion.

**30-53.** (canceled)

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**(64) SOFT-TISSUE TUBULAR PROSTHESES  
WITH SEAMED TRANSITIONS**

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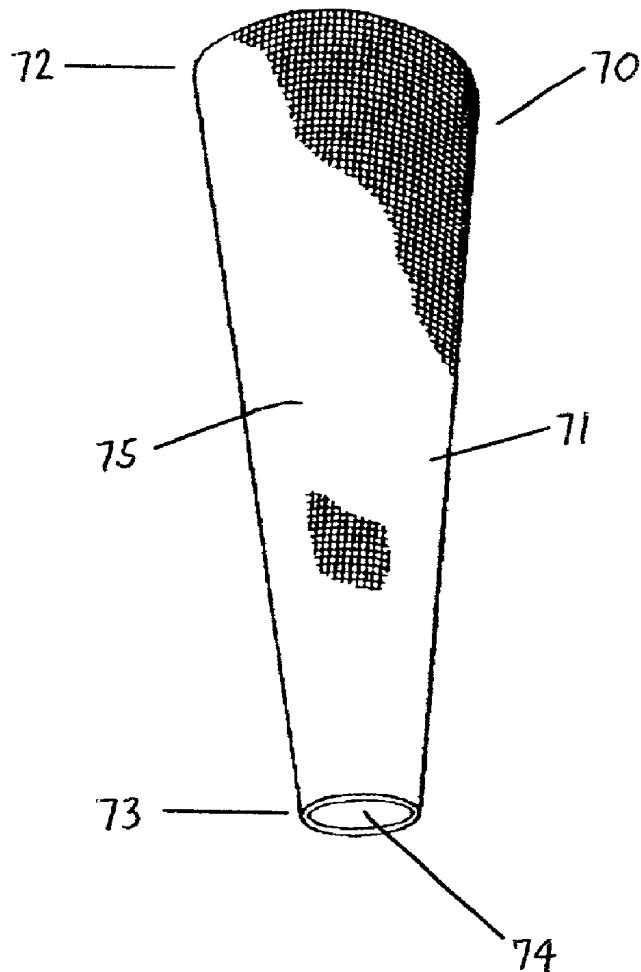
(63) Non-provisional of provisional application No. 60/248,989, filed on Nov. 15, 2000. Non-provisional of provisional application No. 60/249,066, filed on

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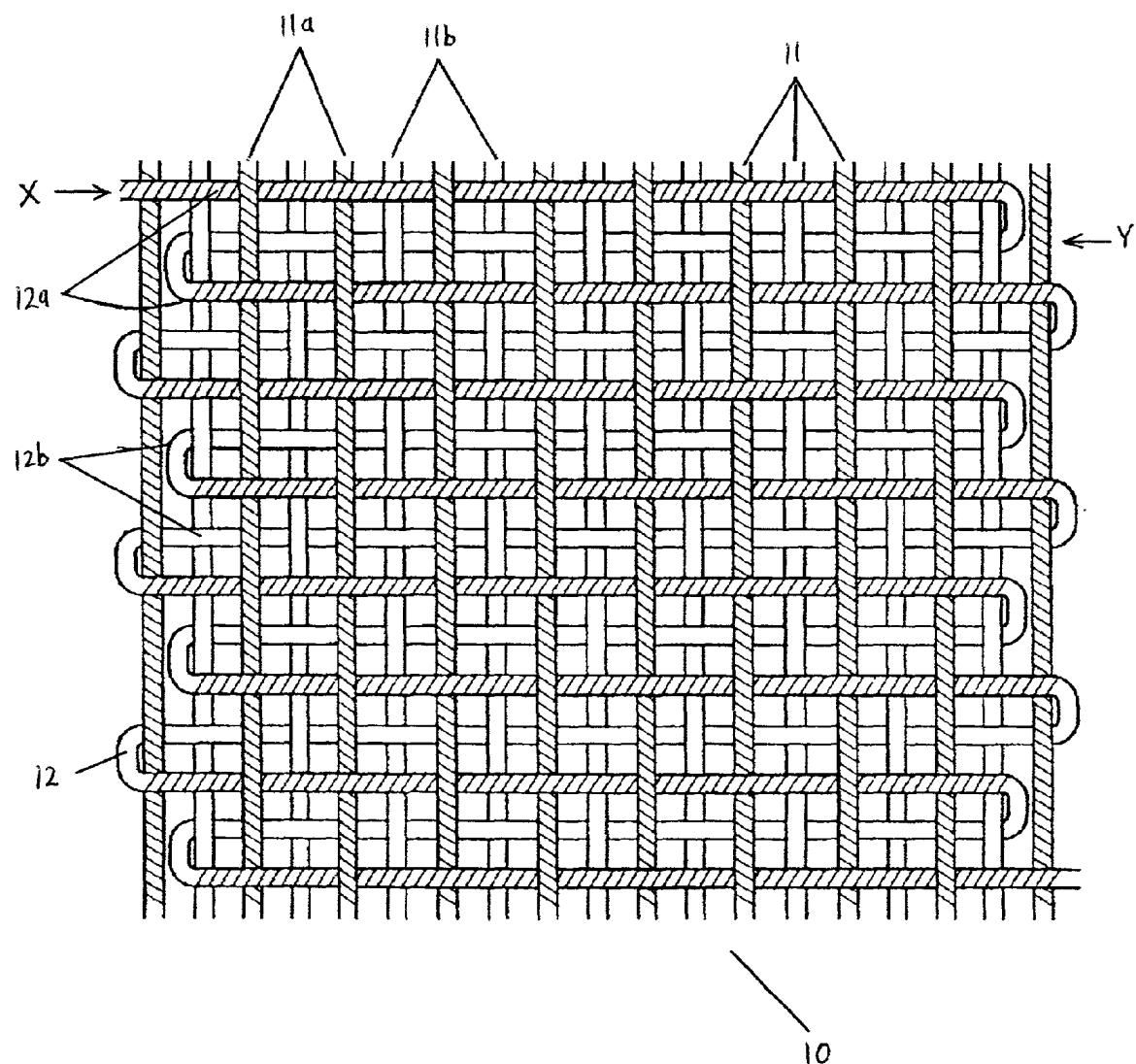
(51) **Int. Cl.<sup>7</sup>** ..... **A61F 2/06**  
(52) **U.S. Cl.** ..... **623/1.15**

**(57) ABSTRACT**

Single tubular woven or bifurcated prostheses are disclosed having varying diameters and tapered transitions. The prostheses comprise a seam along the tapered edges, thereby providing a substantially fluid-tight transition between sections or extents of the prostheses. The seam may be located at an edge where fabric of the prosthesis tapers from one diameter to a different diameter and/or at a point where the prosthesis splits such as a bifurcation. The seamed crotch may be used for tapered and non-tapered bifurcated grafts. The seam may be woven directly on a weaving loom or joined together after weaving is completed.

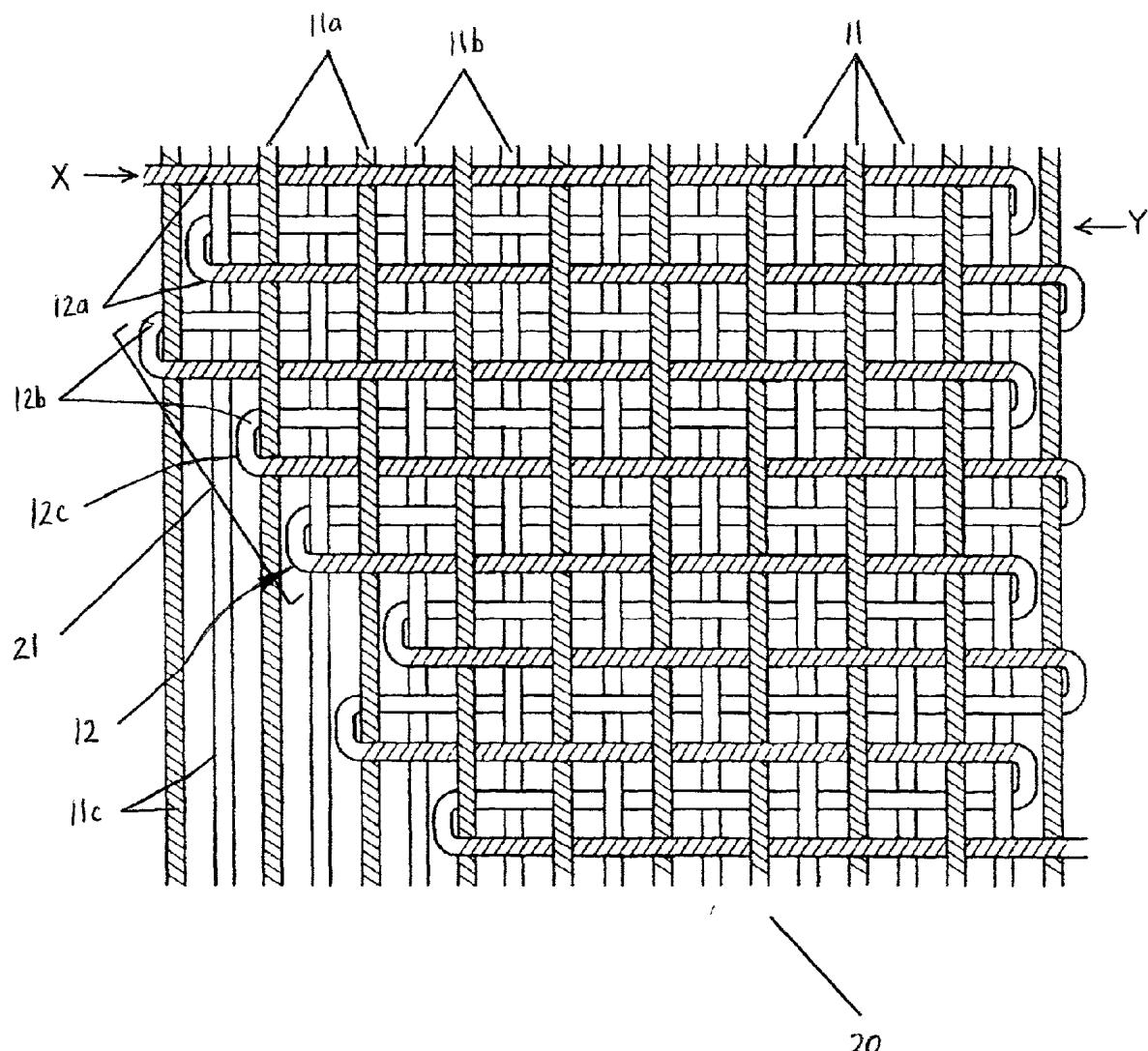


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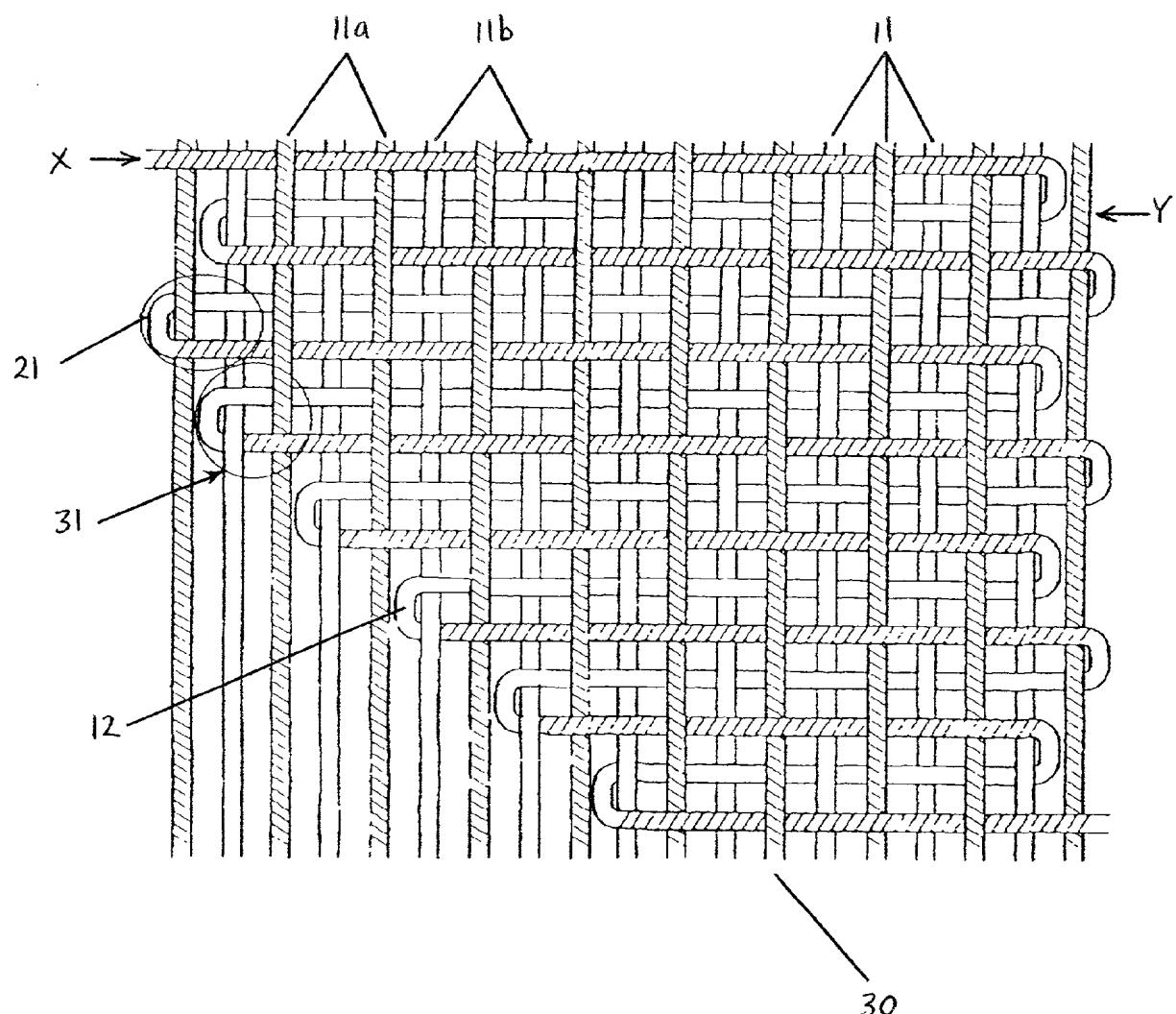


**FIG. 1**

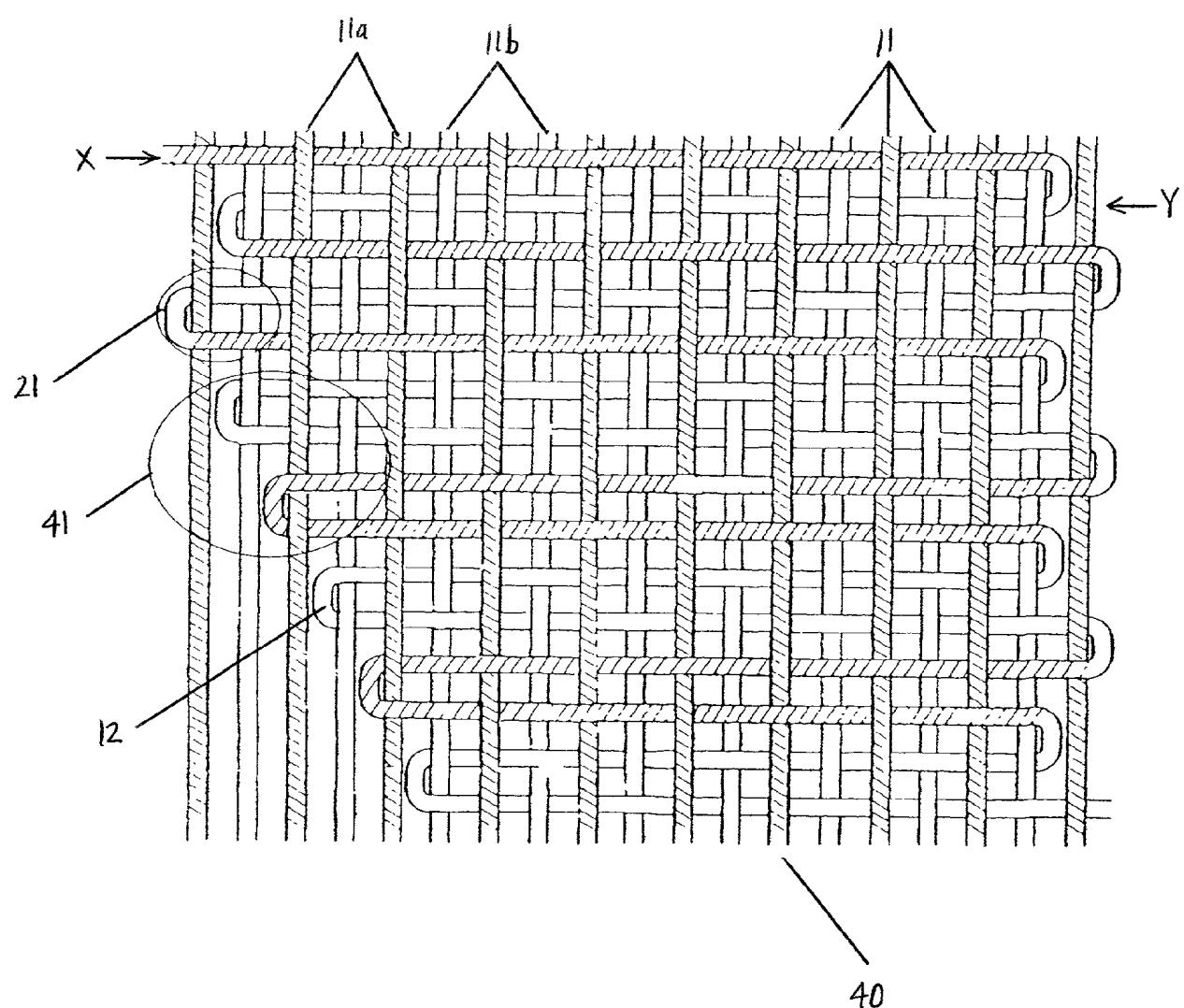
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**FIG. 2**

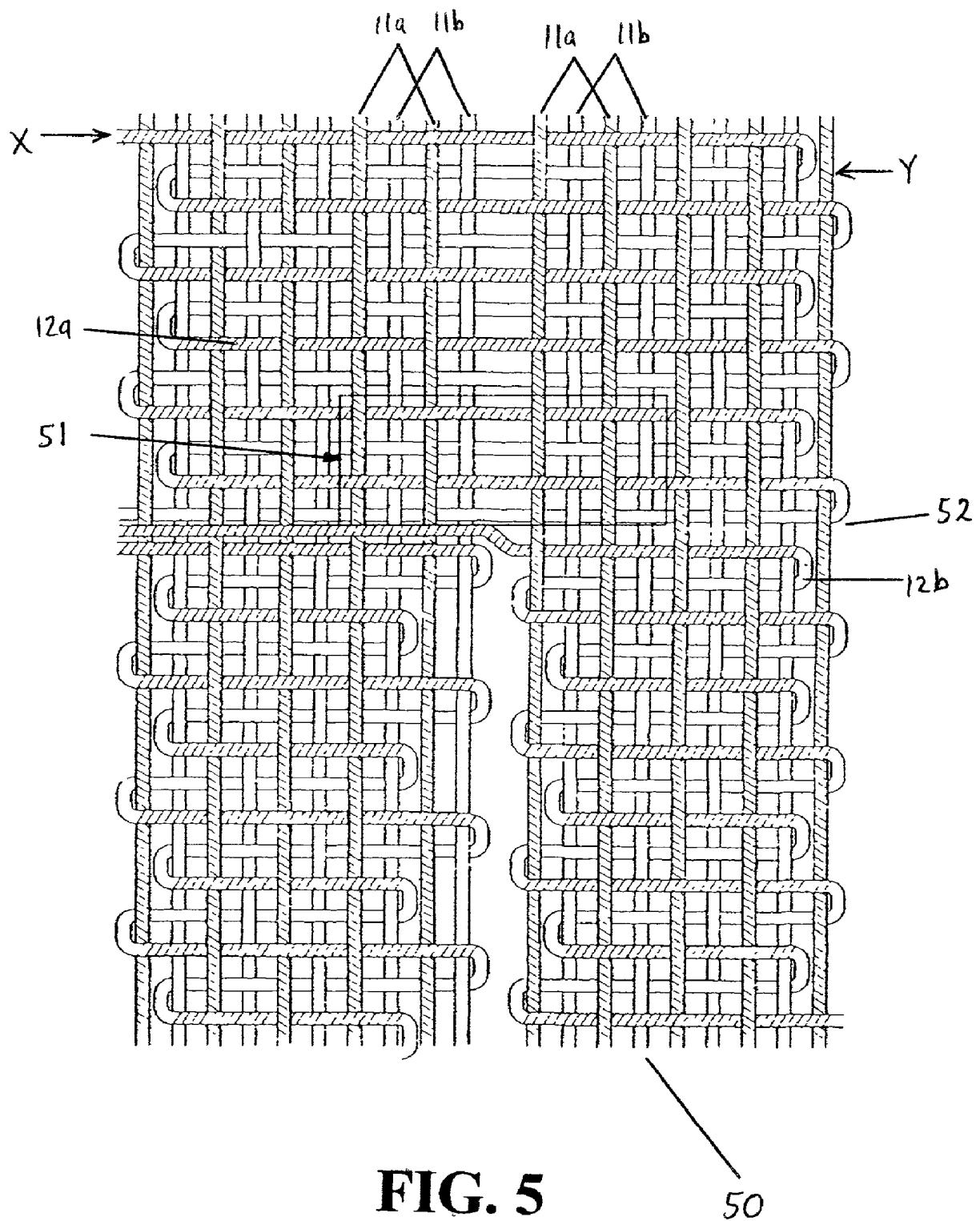


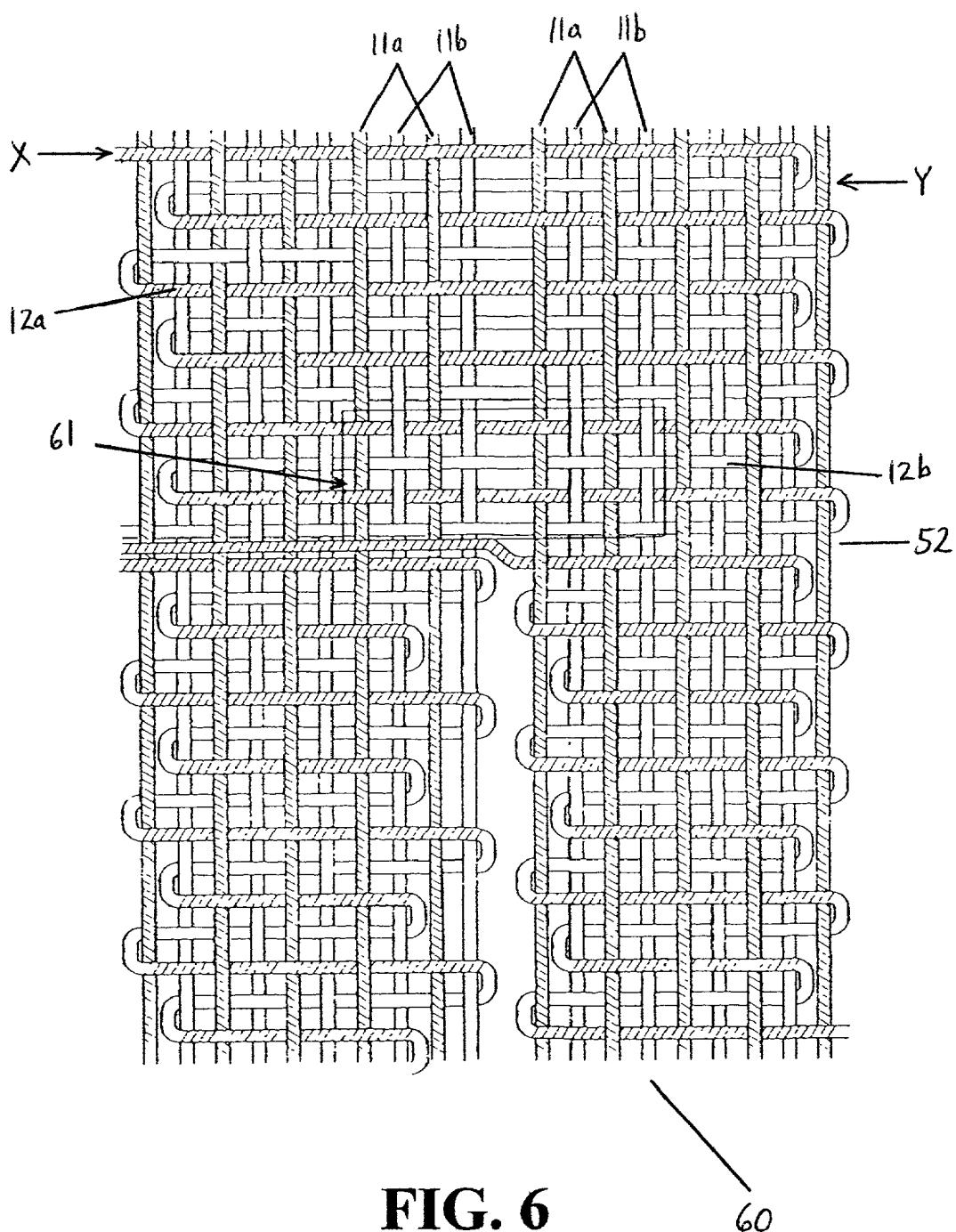
**FIG. 3**

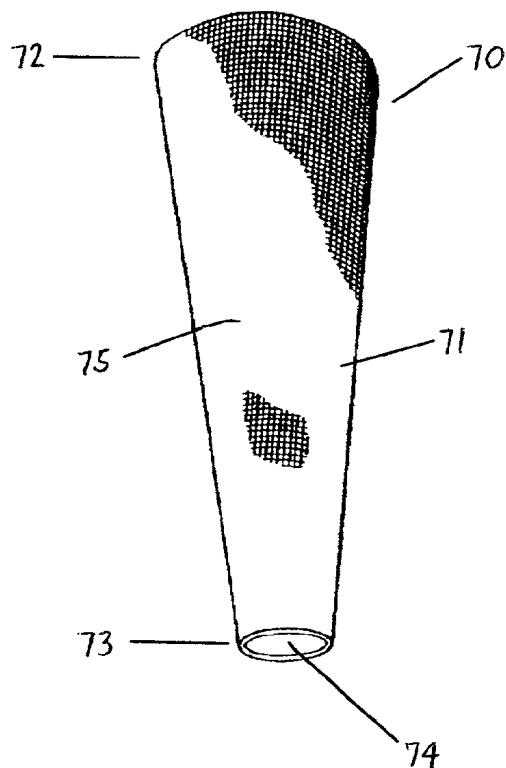


**FIG. 4**

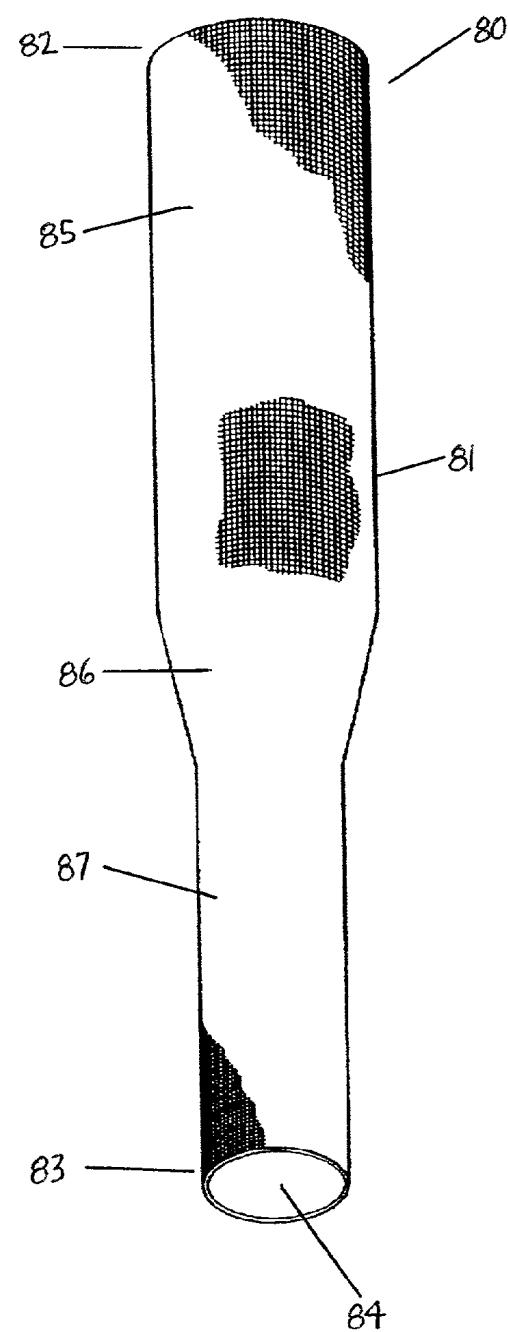
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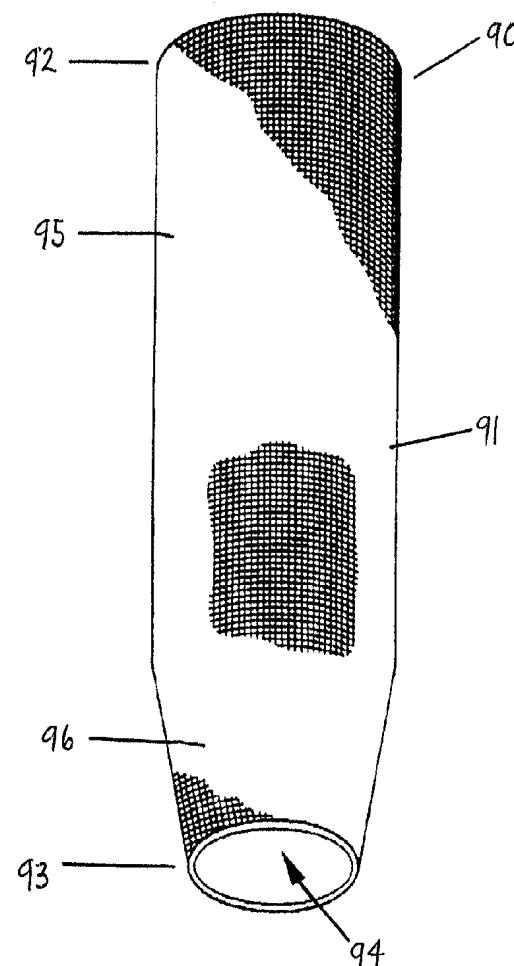




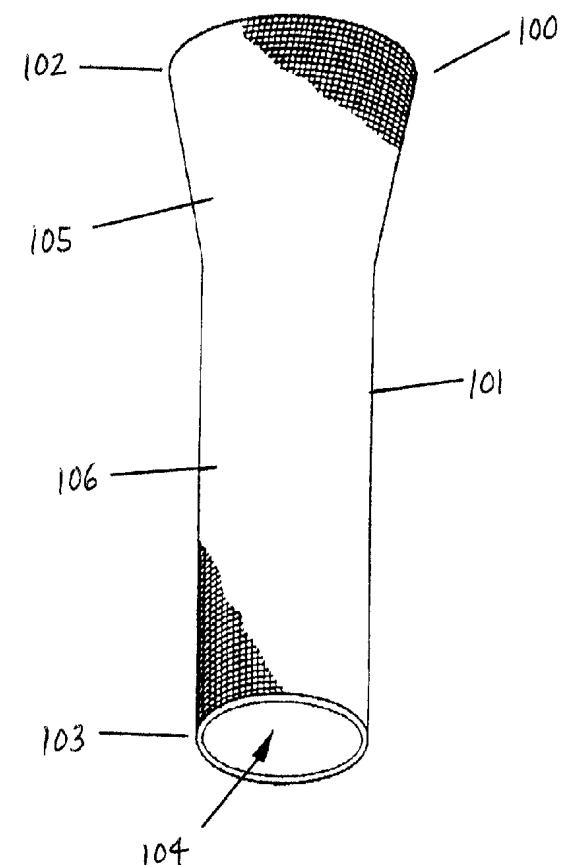
**FIG. 7**



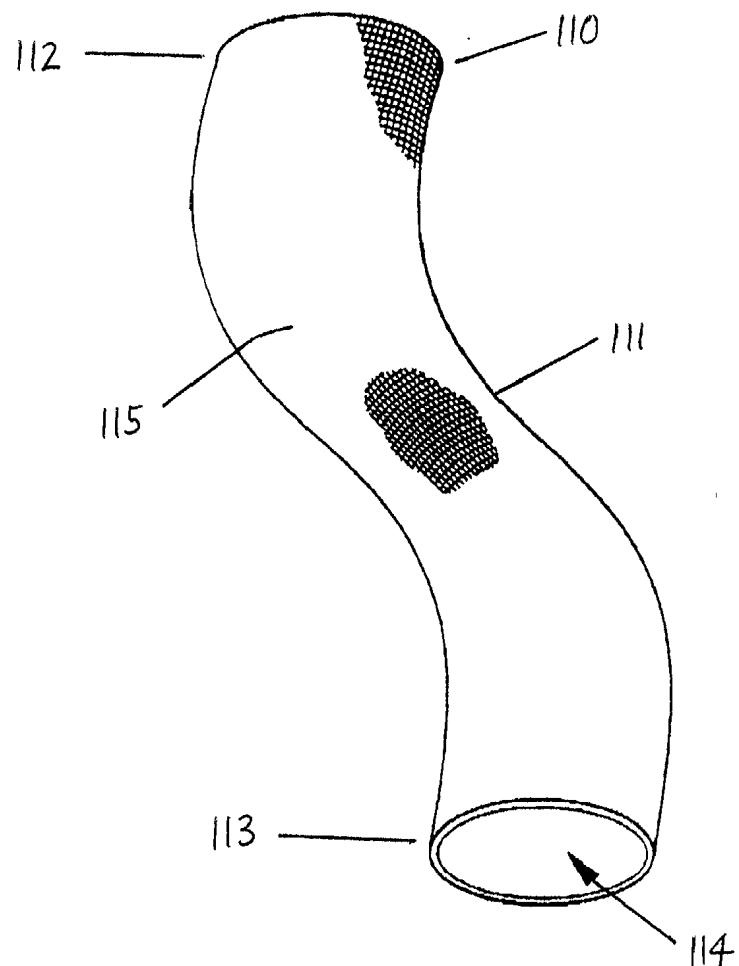
**FIG. 8**



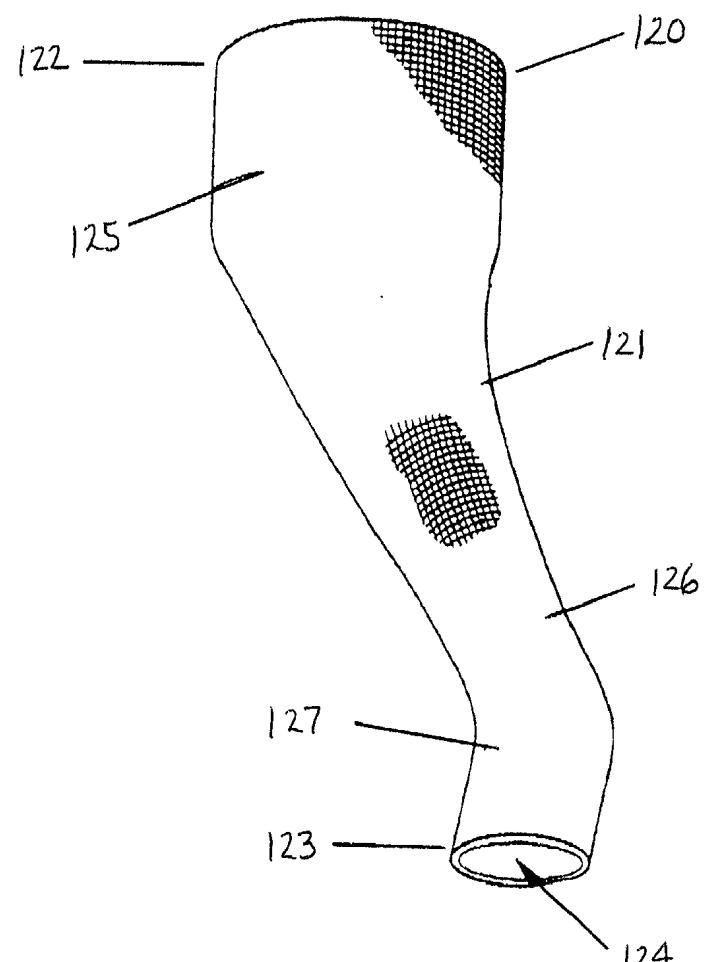
**FIG. 9**



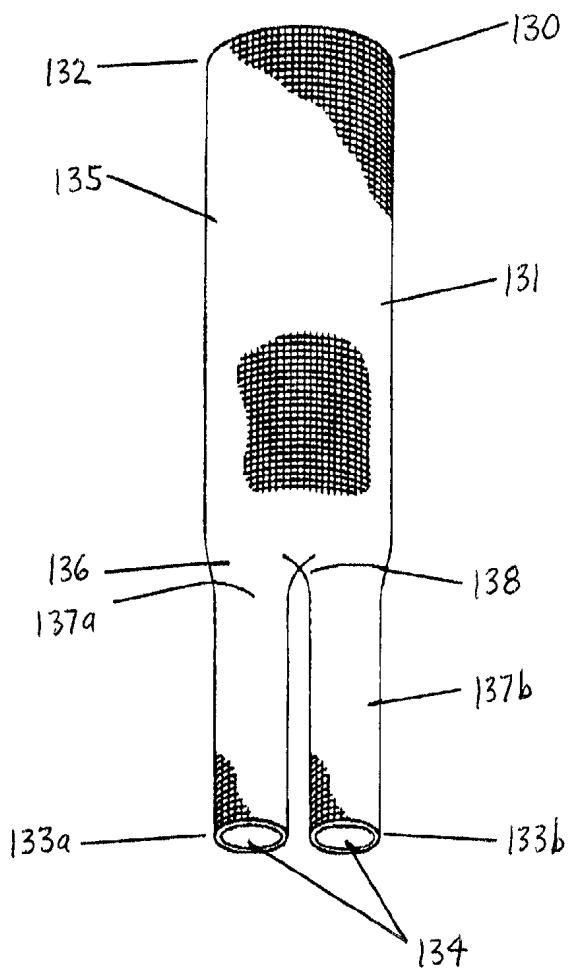
**FIG. 10**



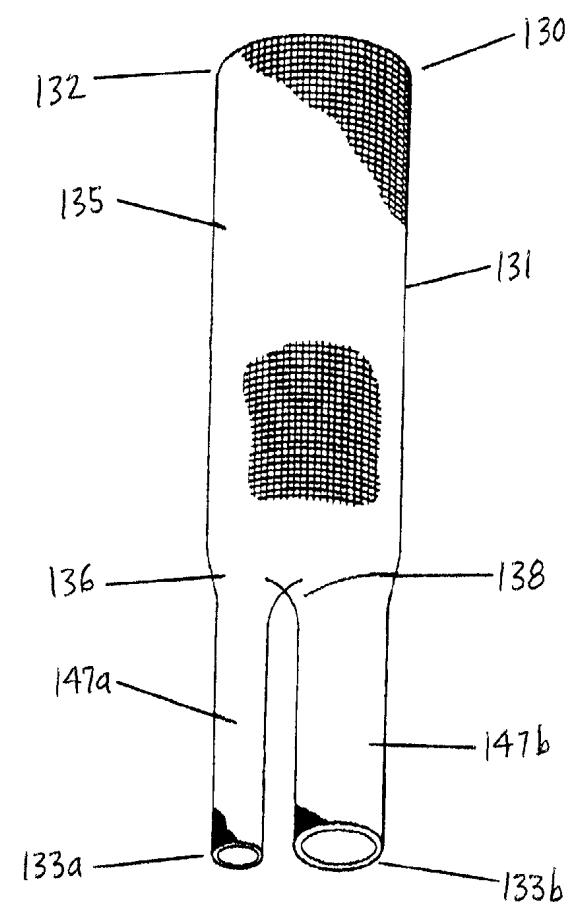
**FIG. 11**



**FIG. 12**



**FIG. 13**



**FIG. 14**

## SOFT-TISSUE TUBULAR PROSTHESES WITH SEAMED TRANSITIONS

### CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Applications Serial No. 60/248,989 filed Nov. 15, 2000; Serial No. 60/249,066 filed Nov. 15, 2000; and Serial No. 60/254,949 filed Dec. 12, 2000, which are incorporated by reference in their entirety.

### FIELD OF THE INVENTION

[0002] The present invention relates to tubular prostheses, and more particularly to tubular prostheses having varying diameters and/or branching segments, and methods for their manufacture. The prostheses of the present invention are advantageous for use in implantable endoluminal applications.

### BACKGROUND OF THE INVENTION

[0003] Tubular woven fabrics may be utilized for prostheses implantable in soft-tissue to replace or repair damaged or diseased vessels or passages in the body. A general discussion of different types of woven fabric prostheses is set forth in U.S. Pat. No. 5,800,514, issued Sep. 1, 1998, the disclosure of which is hereby incorporated herein by reference.

[0004] Applications for implantable prostheses include, but are not limited to, applications in the vascular system, urinary tract, gastrointestinal tract, endocrine system, and lymphatic system. In particular, endoprostheses are used in the vascular system to prevent blood flow from rupturing a weakened section of a vessel. Such endoluminal conduits are generally affixed in a specified location in a vessel by means of stents, hooks, and/or other mechanisms which serve to secure the device in place. Endoluminal tubular devices or conduits can also be used in other vessels and passages in the body, such as in the esophagus and colon.

[0005] Vascular grafts have been used successfully for many years to replace segments of a diseased vessel by open surgical methods. These techniques, however, require long and expensive procedures, which have a high degree of risk associated with them due to the complexity of the surgical procedures and risks of surgery in general. Presently, less invasive techniques for treating abnormal, diseased, and traumatized vessels have become more prominent because they present less risk to the patient and are less complex than open surgery. As an example of such a procedure, a physician will make an incision in the femoral artery and introduce an endoluminal device by means of a catheter delivery system to the precise location of the damaged or diseased vessel. The device generally includes a stent and graft combination, which is deployed from the delivery system and affixed in place usually by use of a balloon catheter. The balloon catheter is used to expand the stents which are attached to, and most often contained within, the graft portion. Expansion of the stent serves both to anchor the graft and to maintain the graft and the vessel lumen in an open state. In some cases, self-expanding stents or the like are used. Stents made from shape-memory materials, such as nitinol, are also employed, whereby radial expansion or contraction of the stent is designed to occur at specified temperatures.

[0006] Effective use of tubular endoluminal prostheses, however, requires a high degree of precision in the diameter of the tube, such that the outside diameter of the prosthesis matches the inside diameter of the body lumen very closely, thereby conforming the prosthesis to the internal surface of the vessel. Vessels and lumens in the body, however, often vary in diameter and shape from one point or segment to another. In addition, vessels sometimes define a tortuous path between two points along their length. This is particularly true with vessels in the vascular system. Thus, tubular endoprostheses which are generally singular in configuration cannot accurately conform to all portions of a vessel lumen which have such variations present. In an attempt to conform to a varying diameter and/or angled or ill-shaped vessel, a prosthesis wall will often require bunching, or gathering, within the lumen of the vessel. Bunching of a prosthesis wall into an unsmooth configuration generally creates a more turbulent environment for blood flow and presents an increased and long-term potential for thrombosis.

[0007] More recently, in recognition of certain problems in delivering and implanting endoluminal prostheses, a thinly woven graft was made, which is designed to closely fit the inner lumen of vessels. However, these grafts have been made in single lengths or bifurcated structures using traditional weaving techniques, which have specific limitations as to the final shape of the product. Also, in conventional weaving techniques, the transition from one diameter to another occurs at a single point in the weave, creating a sudden change in the weaving pattern of the fabric in bifurcated or multi-diameter grafts. Such sudden changes create voids and gaps in a prosthesis wall and are considered undesirable.

[0008] Conventional weaving processes are commonly employed to fabricate various tubular-shaped products. For example, implantable tubular prostheses which serve as conduits, such as vascular grafts, esophageal grafts, and the like, are commonly manufactured using tubular weaving techniques, wherein the tubular product is woven as a flat tube. In such weaving processes, yarns are interwoven in different directions to create the tubular fabric. For example, a set of warp yarns run lengthwise parallel to the selvages, or edge portions, and represent the width of the product being woven. Fill yarns run from selvage to selvage at right angles to the warp and are interlaced between the warp yarns. The fill yarn is woven along the length of the warp yarns, with each successive pass of the fill yarn across the warp yarns for each side of the tube representing one machine pick. Weaving one fill yarn along the entire circumference of the tube, i.e., one filling pick, requires two picks of the weaving machine. Thus, two machine picks represent one filling pick in a tubular woven structure. As such, in a conventional woven product, the fill yarn is woven along the length of the warp yarns for a multiple number of machine picks. The resulting woven product is defined in length by the number of filling picks of the fill yarn and defined in width by the number of warp yarns in which the fill yarn is woven between.

[0009] Conventional techniques of forming tubular shapes have required manual cutting and suturing of standard woven tubular prostheses to the desired size and shape. Woven tubular prostheses, such as vascular grafts, having tapered diameter sections or tailored shapes are typically

made by manual customization in the form of cutting, splicing, and/or tailoring with sutures.

[0010] Conventional grafts having more than one diameter are made by weaving separate grafts having different diameters and suturing the individual grafts together to make a continuous tube. The change in diameter between graft segments requires customized cutting to gradually transition from one diameter to another. For example, a surgeon may select a bifurcated graft having a 24 mm aortic section and equivalent 12 mm femoral sections for use in a patient. If one of the patient's femoral arteries is 10 mm in diameter, the surgeon would manually cut the appropriate femoral section and suture a seam along that section to form a leg more closely matching a 10 mm diameter. This customization requires cutting and suturing. Such customization relies heavily on the skill of the physician and allows little quality control in the final product. Customized grafts may not always be made in advance for a particular patient, since the requirements for such customization may not be known until the physician begins the procedure to introduce the device into the body. Additionally, suture seams take up considerable amounts of space when packed into a delivery capsule or other catheter-like device designed to deploy endoluminal prostheses.

[0011] Thus, conventional continuously woven bifurcated grafts suffer the disadvantages of gaps created at the bifurcation point between the prosthesis trunk and leg portions due to separation or splitting of the warp yarns, and featuring only leg portions having equal diameters. Different diameter leg portions could be accomplished only through customization. Such customization often requires manually cutting off one leg portion and suturing onto the trunk of another independently formed leg having a different diameter.

[0012] Complex shapes, such as tubular "S-shaped" or frustoconical-shaped woven sections have not been attempted using conventional weaving techniques due to the impracticability, intensive labor, and resulting high cost to the consumer. Indeed, such shaped tubes could not be woven practically using prior art techniques.

[0013] In addition to requiring manual cutting and sewing steps, manually customizing grafts often creates sutured seams that are disadvantageous in endoluminal prostheses, particularly because of the space that sutures occupy when tightly packed into a catheter delivery system. Furthermore, such seams disadvantageously contribute to irregularities in the surface of a graft, which may contact and possibly erode a weakened area of a vessel and/or increase the potential for thrombosis.

[0014] Recently, continuous flat-weaving techniques have been used to make graft diameter changes in a gradual manner, such that a tubular section transitions from one diameter to another diameter in a tapered fashion. U.S. Pat. No. 5,800,514 discloses a seamless tubular prosthesis and methods for producing seamless tubular prostheses. Techniques described in the patent permit the weaving of gradually-shaped tubular grafts in a continuous process to create seamless and void-free conduits for implantation in the body.

[0015] In general, U.S. Pat. No. 5,800,514 relates to flat-woven, implantable tubular prostheses, and in particular endoluminal grafts, which have been continuously woven to

form seamless tubular products having gradual changes in diameter along their length. Such seamless grafts include tubular sections of various shapes formed from gradual changes in the number of warp yarns engaged or disengaged with the fill yarns during the weaving process. Changes in diameter and/or shape of a graft are accomplished by gradually engaging and/or disengaging selected warp yarns with the fill yarns in the weave pattern. Similarly, a bifurcation is achieved by disengaging selected warp yarns in the area of the intended split. The gradual transition can be accomplished using electronic jacquard looms controlled by computer software. Such engaging and/or disengaging of warp yarns can change the diameter of the tube or graft in a manner which creates a seamless and gradual transition from one diameter to another. Additionally, such engagement and/or disengagement can be used to create tubular vascular prostheses and the like which have any number of shapes.

[0016] Despite the potential advances achieved by such prostheses and techniques, such seamless prostheses have several disadvantages. In particular, the weaving techniques that are utilized to produce the prostheses and render them seamless, produce voids and gaps in the tubular wall.

[0017] Thus, there remains a need for developing tubular prostheses having smooth transitions from one diameter to another diameter that avoid gaps and voids in the tubular wall of the graft and provide an improved barrier against leakage in transition areas. There is a need for tubular prostheses having smooth transitions without voids and gaps at points of branching, such as in a bifurcated graft. There is also a need for tubular prostheses which allow for an increased rate of transition in tapered areas so as to provide more acutely angled transitions. There is also a need for tubular prostheses having smooth transitions that do not have excessive seams, such as with a seam sutured in the field. Further, there is also a need for tubular prostheses having smooth transitions that can be produced in various shapes in an efficient and economical manner.

## SUMMARY OF THE INVENTION

[0018] The present invention provides a tubular woven prosthesis, a single or bifurcated tube, that can be produced with varying diameters and tapered transitions. The tapered portions are closed by joining edges of the tapered transitional portions together. Prostheses of the present invention comprise a seam, in the form of a hem or selvage, along tapered edges that closes or seals the prostheses without the voids and gaps found in prior art prostheses. In an embodiment, edges are woven together into a stitched seam directly on a weaving loom. In other embodiments, a tubular prosthesis is formed on a weaving machine and the tapered portion, or extent, is left open, or unwoven, in non-tubular fashion. The edges are joined post-weaving to form a tubular article. In still other embodiments, prostheses of the present invention comprise a seam at the point of a furcation split or crotch that closes or seals the tube to provide a substantially fluid-tight transition without the voids and gaps found in conventional prostheses.

[0019] In an embodiment of the present invention, a woven implantable tubular prosthesis is disclosed comprising: a plurality of warp yarns and fill yarns; a first tubular extent having a first diameter; a second tubular extent having

a second diameter different from the first diameter, and the first and second tubular extents are spaced apart to define a transition tubular extent therebetween. The prosthesis further comprises a tapered edge along the transition tubular extent formed by a weaving pattern having a graduated change in the number of warp yarns; and a seam along the tapered edge, wherein the seam provides a substantially fluid-tight transition between the first tubular extent and the second tubular extent. As such, a tubular extent of one diameter may be joined to another tubular extent of a different diameter, connecting the two tubular extents with a tapered transition element. The seam comprises top layer warp yarns and bottom layer warp yarns woven together along the tapered edge on a weaving loom. The diameter of the first tubular extent and the diameter of the second tubular extent is each defined by a different number of warp yarns.

[0020] In other embodiments of the present invention, the first and second tubular extents are spaced apart to define an open transition extent therebetween. The prosthesis further comprises an unwoven tapered edge along the open transition extent formed by a weaving pattern having a graduated change in the number of warp yarns.

[0021] In other embodiments, the tubular prosthesis further comprises a plurality of secondary tubular extents, each woven at a transition with the first tubular extent; and an open crotch formed at the transition between the first tubular extent and the plurality of secondary tubular extents. The open crotch is formed by a weaving pattern that disengages a predetermined number of warp yarns along the transition. The prosthesis further comprises a seam along the crotch, wherein the seam provides the transition between the first tubular extent and the plurality of secondary tubular extents with a substantially fluid-tight closure. The plurality of secondary tubular extents may comprise a pair of secondary tubular extents defining a bifurcated structure. Each of the pair of secondary tubular extents may have a different diameter or the same diameter.

[0022] In embodiments, the graduated change in the number of warp yarns includes disengagement of predetermined warp yarns from the weaving pattern. The high ratio of disengaged warp yarns to fill yarns in the present invention allows the tapered edge in a tubular prosthesis to have an angle greater than 45 degrees.

[0023] Embodiments of tubular prostheses in the present invention comprise various shapes, including a frustoconical shape, an "S" shape, an inward taper, and an outward flare, as well as other shapes needed for implantation in the body.

[0024] Prostheses of the present invention utilize various materials, depending on the intended use of the tubular prosthetic article. Such materials include warp yarns and fill yarns made from polyester, polypropylene, polyethylene, polyurethane, polytetrafluoroethylene, and mixtures thereof. Preferably, prostheses of the present invention are flat-woven.

[0025] In embodiments having an open transition extent and/or an open crotch, the seam includes a seam forming means to close the open transition extent into a tube after weaving is completed. The seam forming means comprises stitching sewn along the tapered edge, gluing, stapling, welding, and/or other means suitable for securely closing a tubular prosthesis seam.

[0026] In another aspect, the present invention includes a method of making a woven implantable tubular prosthesis, comprising: weaving a first tubular extent having a first diameter using a first predetermined number of warp yarns; weaving continuously from the first tubular extent a transition tubular extent formed by a weaving pattern having a graduated change in the first predetermined number of warp yarns to produce a tapered edge along the transition tubular extent; and weaving a second tubular extent continuously from the transition tubular extent using a second predetermined number of warp yarns. Such a method also includes creating a seam along the tapered edge, wherein the seam provides a substantially fluid-tight transition between the first tubular extent and the second tubular extent. Creating the seam further comprises weaving top layer warp yarns and bottom layer warp yarns together along the tapered edge on a weaving loom.

[0027] Methods of making a woven tubular prosthesis of the present invention include weaving a first tubular extent having a first diameter using a first predetermined number of warp yarns; weaving continuously from the first tubular extent an open transition extent formed by a weaving pattern having a graduated change in the first predetermined number of warp yarns to produce an unwoven tapered edge along the open transition extent; and weaving a second tubular extent continuously from the open transition extent using a second predetermined number of warp yarns. Such methods further include creating a seam along the tapered edge, wherein the seam provides a substantially fluid-tight transition between the first tubular extent and the second tubular extent. Embodiments of methods of the present invention include creating the seam using a seam forming means to close the open transition extent into a tube after weaving is completed. The seam forming means comprises sewing a seam along the tapered edge, or other means suitable for closing a seam on an implantable prosthesis.

[0028] Methods of the present invention also include making a woven tubular prosthesis, comprising: weaving a first tubular extent having a first diameter using a first predetermined number of warp yarns; weaving continuously from the first tubular extent an open transition formed by a weaving pattern that disengages a second predetermined number of warp yarns along the transition to produce an open crotch; and weaving a plurality of secondary tubular extents, each woven at a transition with the first tubular extent. Such methods also include creating a seam along the crotch, wherein the seam provides the transition between the first tubular extent and the plurality of secondary tubular extents with a substantially fluid-tight closure. Creating the seam further comprises using a seam forming means, such as sewing, to close the open crotch after weaving is completed. The seamed crotch may be used for tapered and non-tapered bifurcated grafts.

[0029] Tubular prostheses of the present invention differ from the tubular prostheses described in U.S. Pat. No. 5,800,514, insofar as the tubular prostheses of the present invention are not seamless. The seam portion in the tubular prostheses of the present invention is advantageous as it minimizes voids and gaps found along the tapered edges and at the bifurcation point of the tubular prostheses.

[0030] Features of a soft-tissue prosthesis with seamed transitions of the present invention may be accomplished

singularly or in combination in one or more of the embodiments of the present invention. As will be appreciated by those of ordinary skill in the art, the present invention has wide utility in a number of applications as illustrated by the variety of features and advantages discussed below.

[0031] A tubular prosthesis of the present invention and methods for making same provide numerous advantages over prior art tubular prostheses and methods. For example, the present invention advantageously provides tubular woven single or bifurcated prostheses that can be produced with varying diameters and tapered transitions. As a result, the present invention advantageously provides tubular prostheses in complex shapes.

[0032] Another advantage is that the present invention provides methods for producing tubular prostheses having seams at tapered edges in transition areas that allow for an increased rate of transition. Seamed edges of tapered portions of prostheses of the present invention have advantages over the seamless edges of the prior art, as seamed edges provide an improved barrier against leakage. In addition, prostheses of the present invention may comprise more abruptly tapered portions than the prostheses of the prior art, rendering the prostheses of the present invention more suitable for use in certain applications.

[0033] Another advantage is that tubular prostheses of the present invention having seams at transition areas, such as tapers and furcations, provide increased strength to the graft in those areas.

[0034] Yet another advantage is that tubular prostheses made according to the present invention have more uniform characteristics such as porosity, strength, flexibility, and thickness along the length of the prosthesis.

[0035] Embodiments of the tubular prostheses of the present invention can be as implantable endoluminal prostheses in cardiovascular, gastrointestinal, genitourinary, gynecologic, hepatobiliary, endocrine, otolaryngologic, pulmonary, and other intra- and inter-organ tracts, pathways, and/or luminal communications in the body. The prostheses may be curved, tapered, or otherwise adapted for use in different luminal pathways. The methods of the present invention may also be advantageous for creating split tubular fabrics for other applications.

[0036] As will be realized by those of skill in the art, many different embodiments of the tubular prosthesis of the present invention are possible. Additional uses, objects, advantages, and novel features of the invention are set forth in the detailed description that follows and will become more apparent to those skilled in the art upon examination of the following or by practice of the invention.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0037] FIG. 1 is a weaving schematic showing a conventional plain tubular weave pattern known in the art.

[0038] FIG. 2 is a weaving schematic depicting a prior art weaving pattern used in producing a tapered edge in a seamless tubular prosthesis.

[0039] FIG. 3 shows a woven seam weave pattern utilized in a method of the present invention to produce a tapered edge in a tubular prosthetic article in an embodiment of the present invention.

[0040] FIG. 4 shows an open edge weave pattern utilized in a method of the present invention to produce an open edge in a tubular prosthetic article in an embodiment of the present invention.

[0041] FIG. 5 shows an open crotch weave pattern that produces a tapered edge at a split in a prior art technique for making a tubular prosthesis.

[0042] FIG. 6 shows a stitched crotch weave pattern utilized in a method of the present invention to produce a stitched crotch in a tubular prosthetic article in an embodiment of the present invention.

[0043] FIG. 7 is a view of a frustoconical-shaped tubular prosthesis in an embodiment of the present invention.

[0044] FIG. 8 is a view of another shape of a tubular prosthesis in an embodiment of the present invention.

[0045] FIG. 9 is a view of another shape of a tubular prosthesis in an embodiment of the present invention.

[0046] FIG. 10 is a view of another shape of a tubular prosthesis in an embodiment of the present invention.

[0047] FIG. 11 is a view of a sinusoid-shaped tubular prosthesis in an embodiment of the present invention.

[0048] FIG. 12 is a view of another shape of a tubular prosthesis in an embodiment of the present invention.

[0049] FIG. 13 is a view of a bifurcated tubular prosthesis in an embodiment of the present invention.

[0050] FIG. 14 is a view of another bifurcated tubular prosthesis in an embodiment of the present invention.

#### DETAILED DESCRIPTION OF THE INVENTION

[0051] Embodiments of the present invention comprise a woven implantable tubular prosthesis having varying diameters and tapered transitions including a seam formed along a tapered edge or opening in a transition area. Seams of the present invention provide a substantially fluid-tight transition between a first tubular portion, or extent, and a second tubular extent. The seam may be located at an edge where fabric of the prosthesis tapers from one diameter to a different diameter and/or at a point where the prosthesis splits, such as with a bifurcation. An edge is defined as an outer limit of the graft width as taken along the longitudinal axis as the graft is flat-woven on the loom. In embodiments, the seam is stitched directly on a weaving loom by stitching the top and bottom fabric portions of a tubular prosthesis together. In other embodiments, the seam is joined together after weaving is completed.

[0052] Conventional weaving techniques can be incorporated in methods for producing embodiments of tubular prostheses of the present invention. Referring to the Figures, FIG. 1 shows a conventional plain tubular weave pattern 10 known in the art. Warp yarns 11 are further shown as 11a indicating they are in the top layer of the weave and 11b indicating their presence in the bottom layer of the weave. Top layer warp yarns 11a and bottom layer warp yarns 11b run in a lengthwise direction in the graft and define the width of the graft. Fill yarns 12 are further shown as top fill yarns 12a and bottom fill yarns 12b. These fill yarns are woven with the top and bottom warp yarns 11a and 11b as shown

in **FIG. 1** in a manner known in the art. For example, a filling yarn shuttle (not shown) passes across warp yarns **11** while selected warp yarns **11** are lifted according to a specific weave pattern. In electronic weaving machines, such weave patterns can be programmed into the machine using software. In a typical plain tubular weave as depicted in **FIG. 1**, the shuttle first weaves top fill yarn **12a** by passing across warp yarns **11** while certain warp yarns **11** are lifted. During travel of top fill yarns **12a**, in direction X, for weaving of the top tubular body portion, the bottom warp yarns **11b** are not lifted so as to prevent top fill yarns **12a** from interweaving with bottom warp yarns **11b**. Likewise, during passage of bottom fill yarns **12b**, in direction Y, for weaving of the bottom tubular body portion, the top warp yarns **11a** are always lifted such that bottom fill yarns **12b** are not interwoven with top warp yarns **11a**. The plain tubular weave pattern as just described can be used to form single portions of tubular prosthetic grafts of the present invention that have a constant diameter. This pattern is then modified by gradually engaging or disengaging warp yarns to create tapers and/or shapes.

**[0053]** **FIG. 2** is a weaving schematic depicting a prior art weaving pattern **20** used in producing a seamless tubular prosthesis, according to a technique set forth in U.S. Pat. No. 5,800,514 for producing a tapered edge in a tubular woven article. As shown in **FIG. 2**, the tapered edge **21** is formed by gradually disengaging the warp yarns **11a** and **11b**. Disengaging the warp yarns **11a** and **11b** is accomplished by dropping the desired warp yarns, for example warp yarns **11c**, such that the fill yarns **12** are not interwoven across the warp yarns **11** for that section of the pattern. This technique produces a tapered edge like tapered edge **21** in a tubular article. This type of dropping of warp yarns in a gradual manner forms the transitional portion of the graft. In continuous flat-weaving processes, the warp yarns are then re-engaged during the weave pattern once the transitional section has been completed.

**[0054]** As described, in the embodiments of the present invention, transition from one diameter to another diameter is accomplished by engaging and/or disengaging predetermined warp yarns from the weave pattern. Such disengaging or engaging of warp yarns can be gradual. However, such a transition can potentially be accomplished using any combination of numbers of warp yarns and fill yarns. A disadvantage of this recently developed technique is that in seamless tubular prostheses, the total number of warp yarns engaged and/or disengaged should not exceed a maximum of three warp yarns per four machine picks on each edge of the tubular flat-woven product in order to avoid gaps and voids at the transition. Tubular prostheses of the present invention eliminate this limitation on the rate of transition and the shallow angles resulting from such a gradual transition in seamless tubular prostheses.

**[0055]** **FIG. 3** shows a woven seam weave pattern **30** utilized in a method of the present invention to produce the edge **21** of a tubular prosthetic article in an embodiment of the present invention. As shown in **FIG. 3**, the tapered tubular edge **21** is formed by interweaving top layer warp yarns **11a** and bottom layer warp yarns **11b** together to form a seam, or "selvage," comprising a single layer fabric at the tapered edge **21**. A minimum of one warp yarn from each of the top and bottom layers is utilized to form the woven seam **31**. Additional warp yarns from either or both layers may be

utilized to increase the width of the seam **31**. The greater the number of warp yarns utilized the greater the size, or width, of the seam. In embodiments of the present invention, the size of the seam may be varied depending the intended end use of the tubular article. In embodiments utilizing a woven seam, as shown in **FIG. 3**, the seam can be made while the tubular prosthesis is still on the weaving loom.

**[0056]** **FIG. 4** shows an open edge weave pattern **40** utilized in a method of the present invention to produce an open edge **41** in a tubular article in an embodiment of the present invention. As shown in **FIG. 4**, the open tapered edge **41** is formed by causing the fill yarns **12** to remain on the same layer, either top or bottom, at the tapered tubular edge **21**. In embodiments utilizing an open edge weave pattern, as shown in **FIG. 4**, a seam is generally made after weaving is complete and the prosthesis is removed from the loom. The tapered edges may be sealed by sewing, welding, bonding, gluing, stapling, and/or other techniques suitable for sealing tubular prosthetic articles.

**[0057]** **FIG. 5** is an open crotch weave pattern **50** that produces a tapered edge at a split in a prior art technique for making a tubular prosthesis as set forth in U.S. Pat. No. 5,800,514, for producing a tapered edge in a tubular woven article. As shown in **FIG. 5**, the open crotch **51** at the bifurcation area **52** is formed by gradually disengaging warp yarns **11a** and **11b** from fill yarns **12a** and **12b**. The disengaging of the warp yarns **11a** and **11b** is accomplished by dropping the desired warp yarns **11a** and **11b** from the end of the tubular flat-woven graft such that the fill yarns **12a** and **12b** are not interwoven across the warp yarns **11a** and **11b** for that section of the pattern. Using this technique, a transition at the bifurcation area **52** is limited to a maximum disengagement rate of three warp yarns per four machine picks.

**[0058]** As shown in **FIG. 5**, in conventional manufacturing processes for tubular weaving of bifurcated grafts, it is necessary to split the number of warp yarns at the crotch area during the weaving process in order to split the tubular woven graft from a first tubular woven extent, such as a first aortic woven extent, into a plurality of secondary woven extents, such as first and second iliac woven extents. This splitting of warp yarns is necessary in order to accomplish the transition at the crotch **138**, as shown in **FIG. 13**, where the diameter of the graft transitions from a first inner diameter of the aortic woven extent **135**, to two separate inner diameters representing the first and second iliac woven extents **137a** and **137b**.

**[0059]** **FIG. 6** is a stitched crotch weave pattern **60** utilized in a method of the present invention to produce a stitched crotch **61** in a tubular article in an embodiment of the present invention. As shown in **FIG. 6**, the bifurcation area **52** is formed by interweaving top layer warp yarns **11a** and bottom layer warp yarns **11b** together with fill yarns **12a** and **12b** to form a seam, or "selvage," comprising a single layer fabric at the bifurcation edges. A minimum of one warp yarn from each layer is utilized. Additional warp yarns from either or both layers may be utilized to increase the width of the seam. The greater the number of warp yarns utilized the greater the width, or size, of the seam. In embodiments of the present invention, the size of the seam may be varied depending the intended end use of the tubular article.

**[0060]** In embodiments utilizing a stitched crotch weave pattern **60** as shown in **FIG. 4**, a seam is generally made

after weaving is complete and the prosthesis is removed from the loom. The edges at a crotch or bifurcation may be sealed by sewing, welding, bonding, gluing, stapling, and/or other techniques suitable for sealing tubular prosthetic articles.

[0061] FIGS. 7-14 illustrate tubular prostheses having various shapes and configurations in embodiments of the present invention. The weaving pattern is not shown to scale and the tapered portions comprise seams according to the present invention.

[0062] Referring to FIG. 7, a typical tubular woven textile graft 70 in accordance with the present invention is shown generally as a tapered graft in a generally frustoconical shape. Graft 70 is a textile product formed of a woven synthetic fabric. Graft 70 is depicted in one embodiment in FIG. 7 which includes a generally tubular body 71 having a first end 72 and an opposed second end 73, defining therebetween an inner lumen 74 which permits passage of blood through graft 70. Graft 70 includes continuous transitional woven extent 75 extending between first end 72 and second end 73, and extending along the entire length of graft 70. Graft 70 of FIG. 7 has a generally frustoconical shape, with first end 72 having a first tubular inner diameter and second end 73 having a second tubular inner diameter which is different than the inner diameter of first end 72. For example, first end 72 may have an inner diameter of 12 millimeters and second end 73 may have an inner diameter of 10 millimeters, with transitional woven portion 75 forming a gradual taper having successive changes in diameter throughout. As such, graft 70 gradually tapers from the 12 millimeter inner diameter of first end 72 to the 10 millimeter inner diameter of second end 73 along the length of transitional woven portion 75. The gradual tapering of transitional woven extent 75 is accomplished by gradually disengaging and/or engaging a selected number of warp yarns from the weaving pattern during weaving of the graft. Transitional woven extent 75 may include a seam along tapered edges to provide a substantially fluid-tight transition between first end 72 and second 73.

[0063] FIG. 8 shows a variation of the configuration of FIG. 7, with graft 80 in the form of a step-tapered graft having a tubular body 81 with a first end 82 and an opposed second end 83 defining an inner lumen 84 therebetween. In the embodiment of FIG. 8, graft 80 includes first woven extent 85 which defines a portion of tubular body 81 having a continuous first inner diameter and second woven extent 87 which defines a portion of tubular body 81 having a continuous second inner diameter which is different than the inner diameter of first woven extent 85. Graft 80 of FIG. 8 further includes transitional woven extent 86 adjacent and contiguous with first and second woven extents 85 and 87. In such an embodiment, graft 80 includes a constant diameter extending through first woven extent 85 and a constant diameter which is different than the inner diameter of first woven extent 85 which extends through second woven extent 87, and gradually tapers from the inner diameter of first woven extent 85 to the inner diameter of second woven extent 87 through the length of transitional woven extent 86. Transitional woven extent 86 may include a seam along tapered edges to provide a substantially fluid-tight transition between first woven extent 85 and second woven extent 87.

[0064] FIG. 9 shows another embodiment of the step-tapered configuration of FIG. 8, with graft 90 having a

tubular body 91 with a first end 92 and an opposed second end 93 defining an inner lumen 94 therebetween. In the embodiment of FIG. 9, graft 90 includes a first woven extent 95 and a transitional woven extent 96, with the first woven extent 95 defining first end 92 and including a continuous inner diameter along the length thereof, and the transitional woven extent 96 defining second end 93 and including a gradual taper such that graft 90 gradually tapers from the inner diameter of first woven extent 95 to a second diameter at second end 93 which is different than the inner diameter of first woven extent 95. It is contemplated that such gradual tapering can be either an inward taper or an outward, or flared, taper. Transitional woven extent 96 may include a seam along tapered edges to provide a substantially fluid-tight transition between first woven extent 95 and second end 93.

[0065] FIG. 10 shows another embodiment of the configuration of graft 70 of FIG. 7, with graft 100 having a tubular body 101 with a first end 102 and an opposed second end 103 defining an inner lumen 104 therebetween. In the embodiment of FIG. 10, graft 100 includes a transitional woven extent 105 and a second woven extent 106, with the transitional woven extent 105 defining first end 102 and the second woven extent 106 including a continuous inner diameter along the length thereof, and defining second end 103. Further, transitional woven extent 106 includes a gradual taper such that graft 100 gradually tapers outwardly from the inner diameter of first end 102 to a second diameter at second end 103 which is different than the inner diameter of first end 102. Transitional woven extent 105 may include a seam along tapered edges to provide a substantially fluid-tight transition between first end 102 and second woven extent 106.

[0066] FIG. 11 depicts a sinusoidal shaped graft 110 having a tubular body 111 with a first end 112 and an opposed second end 113 defining an inner lumen 114 therebetween. In the embodiment of FIG. 11, graft 110 includes a continuous first woven extent 115, with the first woven extent 115 defining both first and second ends 112 and 113. First woven extent 115 has a continuous inner diameter along the length thereof, such that first end 112 and second end 113 have the same inner diameter. Graft 110 is shaped along its length in an "S" configuration, with tubular body 111 gradually changing direction as warp yarns on one edge of graft 110 during the weaving process are engaged or disengaged while the same portion of tubular body 111 on the other edge of graft 110 equally changes in the same direction as warp yarns are engaged or disengaged at this edge. Thus, as warp yarns at one edge of the graft are disengaged as that edge and shape of the graft gradually curve, the corresponding warp yarns at the opposite edge on the same pick are engaged. As the "S" shape again changes direction, the opposite may be true, that is, warp yarns at a given pick on one edge may be engaging as corresponding warp yarns at the other edge on the same pick may be disengaging. In order to maintain a constant diameter, the warp yarns at each of the edges of the tubular graft must simultaneously change by additionally adding or engaging an equal number of warp yarns on one edge as the other edge loses or disengages warps. Thus, the total number of warp yarns within the tubular body wall remains constant during the weaving process. Continuous first woven extent 115 may

include a seam along tapered edges to provide a substantially fluid-tight transition between first end 112 and second end 113.

[0067] FIG. 12 shows an embodiment of the present invention having a variation of the sinusoidal-shaped graft 110 shown in FIG. 11. Graft 120 in FIG. 12 includes a tubular body 121 with a first end 122 and an opposed second end 123 defining an inner lumen 124 therebetween. In the embodiment of FIG. 7, graft 120 includes first woven extent 125 having a first inner diameter and second woven extent 127 having a second inner diameter which is different than the inner diameter of first woven extent 125. Graft 120 further includes a transitional woven extent 126 adjacent first and second woven extents 125 and 127. For example, first woven extent 125 may include a woven graft section having an inner diameter of 12 millimeters and second woven extent 127 may include a woven graft section having an inner diameter of 10 millimeters, with transitional woven extent 126 forming a gradual taper. As such, graft 120 gradually tapers from the 12 millimeter inner diameter of first woven extent 125 to the 10 millimeter inner diameter of second woven extent 127 along the length of transitional woven extent 126. Graft 120 is shaped along its length in an "S" configuration similar to the manner in FIG. 11, with tubular body 121 gradually tapering in on one side of graft 120 during the weaving process, while the same portion of tubular body 121 on the other side of graft 120 tapers outwardly. Transitional woven extent 126 may include a seam along tapered edges to provide a substantially fluid-tight transition between first woven extent 125 and second woven extent 127.

[0068] FIGS. 13 and 14 illustrate embodiments of tubular prostheses of the present invention comprising bifurcations. Referring to FIGS. 13 and 14, a typical tubular woven bifurcated graft 130 includes a generally tubular body 131 having a first end 132 and opposed second ends 133a and 133b, defining therebetween an inner lumen 134 which permits passage of blood once the bifurcated graft 130 is implanted in a blood vessel. Bifurcated graft 130 includes aortic woven extent 135 having a first inner diameter, and further includes first and second iliac woven tubular extents 137a and 137b, each having an inner diameter which is different than the inner diameter of aortic woven extent 135. The inner diameters of first and second iliac woven extents 137a and 137b can be the same as depicted in FIG. 13, or can be different as depicted in 147a and 147b of FIG. 14. Further, iliac woven extents 137a and 137b can be of the same general length as shown in FIGS. 13 and 14 or can be of different general lengths. Bifurcated graft 130 further includes bifurcated transitional woven extent 136 contiguous with aortic woven extent 135 and first and second iliac woven extents 137a and 137b at crotch 138, forming a bifurcated arch. Bifurcated transitional woven extent 136 forms a gradual taper such that bifurcated graft 130 gradually tapers from the inner diameter of aortic woven extent 135 to the inner diameters of first and second iliac woven extents 137a and 137b along the length of bifurcated transitional woven extent 136. The gradual tapering of bifurcated transitional woven extent 136 is accomplished by gradually disengaging and/or engaging a predetermined number of warp yarns from the weaving pattern during weaving of the graft, as discussed above. Bifurcated transitional woven extent 136 may include a seam along tapered edges to provide a substantially fluid-tight transition

between aortic woven extent 135 and first and second iliac tubular extents 137a and 137b.

[0069] Further, during weaving of bifurcated graft 130, two separate filling yarn shuttles (not shown) are required for weaving of the two distinct iliac woven extents 137a and 137b. To form the gradual transition in the crotch 138, the shuttle designated for weaving of iliac woven extent 137a selectively and gradually engages warp yarns designated for weaving of iliac woven extent 137b. Likewise, the shuttle designated for weaving iliac woven extent 137b selectively and gradually engages warp yarns designated for weaving of iliac woven extent 137a. In this manner, the crotch 138 is woven using a simultaneous tapering effect at the interface between the aortic woven extent 135 and iliac woven extents 137a and 137b. As such, a smooth contiguous surface transition is obtained.

[0070] While a variety of shapes and configurations are shown in the drawings and described herein, any tubular, flat-woven graft incorporating a gradually transitioning, continuously woven portion is contemplated by the present invention. The gradual tapering of the transitional woven portion or extent is accomplished in each of the embodiments by gradually disengaging and/or engaging a predetermined number of warp yarns from the weaving pattern during weaving of the graft as discussed above.

[0071] Any type of textile product can be used as the warp yarns and fill yarns of the present invention. Of particular usefulness in forming the woven prostheses of the present invention are synthetic materials such as thermoplastic polymers. Thermoplastic yarns suitable for use in the present invention include polyesters, polypropylenes, polyethylenes, polyurethanes, polytetrafluoroethylenes, as well as others. The yarns may be of the monofilament, multifilament, or spun type.

[0072] Yarns utilized in prostheses of the present invention comprise yarns known and generally utilized in the art for prostheses. In general, the selection of yarn will depend on the intended end use application of the tubular prosthesis. Yarns used in forming the woven grafts of the present invention may be flat, twisted or textured, and may have high, low or moderate shrinkage properties. Additionally, the yarn type and yarn denier can be selected to meet specific properties desired for the prosthesis such as porosity, flexibility and compliance. The yarn denier utilized in prostheses of the present invention includes a range of deniers from small to heavy.

[0073] Although the present invention has been described with reference to particular embodiments, it should be recognized that these embodiments are merely illustrative of the principles of the present invention. Those of ordinary skill in the art will appreciate that the soft-tissue prostheses with seamed transitions of the present invention may be constructed and implemented in other ways and embodiments. Accordingly, the description herein should not be read as limiting the present invention, as other embodiments also fall within the scope of the present invention.

What is claimed is:

1. A woven implantable tubular prosthesis, comprising:  
a plurality of warp yarns and fill yarns;  
a first tubular extent having a first diameter;

a second tubular extent having a second diameter different from the first diameter, the first and second tubular extents spaced apart to define a transition tubular extent therebetween;

a tapered edge along the transition tubular extent formed by a weaving pattern having a graduated change in the number of warp yarns; and

a seam along the tapered edge, wherein the seam provides a substantially fluid-tight transition between the first tubular extent and the second tubular extent.

**2.** The tubular prosthesis of claim 1, wherein the plurality of warp yarns further comprises top layer warp yarns and bottom layer warp yarns, wherein the seam comprises the top layer warp yarns and the bottom layer warp yarns woven together along the tapered edge.

**3.** The tubular prosthesis of claim 1, wherein the graduated change in the number of warp yarns comprises disengagement of a predetermined number of warp yarns from the weaving pattern.

**4.** The tubular prosthesis of claim 3, wherein the ratio of disengaged warp yarns to fill yarns causes the tapered edge to have an angle greater than 45 degrees.

**5.** The tubular prosthesis of claim 4, wherein the ratio of disengaged warp yarns to fill yarns causes the tapered edge to have approximately a 90 degree angle.

**6.** The tubular prosthesis of claim 1, wherein the first tubular extent first diameter and the second tubular extent second diameter is each defined by a different number of warp yarns.

**7.** The tubular prosthesis of claim 1, wherein the transition tubular extent comprises a frustoconical shape.

**8.** The tubular prosthesis of claim 1, wherein the transition tubular extent comprises an "S" shape.

**9.** The tubular prosthesis of claim 1, wherein the transition tubular extent comprises an inward taper.

**10.** The tubular prosthesis of claim 1, wherein the transition tubular extent comprises an outward flare.

**11.** The tubular prosthesis of claim 1, wherein the prosthesis is flat-woven.

**12.** The tubular prosthesis of claim 1, wherein the warp yarns and fill yarns comprise materials selected from the group consisting of polyester, polypropylene, polyethylene, polyurethane, polytetrafluoroethylene, and mixtures of any thereof.

**13.** A woven implantable tubular prosthesis, comprising:

a first tubular extent having a first predetermined number of warp yarns defining a constant first diameter along the first tubular extent;

a second transition tubular extent having a first end and a second end, the first end woven to the first tubular extent, the second transition tubular extent having at least a second predetermined number of warp yarns and having a graduated change in the number of warp yarns defining a second diameter different from the first diameter defining a weaving pattern incorporating a graduated transition along the second transition tubular extent;

a third tubular extent woven to the second end of the second transition tubular extent, the third tubular extent having a third predetermined number of warp yarns

defining a constant third diameter along the third tubular extent that is different than the first diameter and the second diameter;

a tapered edge along the second transition tubular extent formed by the graduated transition weaving pattern; and

a seam along the tapered edge, wherein the seam provides a substantially fluid-tight transition between the first tubular extent and the third tubular extent.

**14.** A woven implantable tubular prosthesis, comprising:

a plurality of warp yarns and fill yarns;

a first tubular extent having a first diameter;

a second tubular extent having a second diameter different from the first diameter, the first and second tubular extents spaced apart to define an open transition extent therebetween;

an unwoven tapered edge along the open transition extent formed by a weaving pattern having a graduated change in the number of warp yarns; and

a seam along the tapered edge, wherein the seam provides a substantially fluid-tight transition between the first tubular extent and the second tubular extent.

**15.** The tubular prosthesis of claim 14, wherein the seam comprises a seam forming means to close the open transition extent into a tube after weaving is completed.

**16.** The tubular prosthesis of claim 15, wherein the seam forming means comprises stitching sewn along the tapered edge.

**17.** The tubular prosthesis of claim 15, wherein the seam forming means comprises gluing.

**18.** The tubular prosthesis of claim 15, wherein the seam forming means comprises stapling.

**19.** The tubular prosthesis of claim 15, wherein the seam forming means comprises welding.

**20.** The tubular prosthesis of claim 14, wherein the graduated change in the number of warp yarns comprises disengagement of predetermined warp yarns from the weaving pattern.

**21.** The tubular prosthesis of claim 14, wherein the first tubular extent first diameter and the second tubular extent second diameter is each defined by a different number of warp yarns.

**22.** The tubular prosthesis of claim 14, wherein the transition tubular extent comprises a frustoconical shape.

**23.** The tubular prosthesis of claim 14, wherein the transition tubular extent comprises an "S" shape.

**24.** The tubular prosthesis of claim 14 wherein the transition tubular extent comprises an inward taper.

**25.** The tubular prosthesis of claim 14, wherein the transition tubular extent comprises an outward flare.

**26.** The tubular prosthesis of claim 14, wherein the prosthesis is flat-woven.

**27.** The tubular prosthesis of claim 14, wherein the warp yarns and fill yarns comprise materials selected from the group consisting of polyester, polypropylene, polyethylene, polyurethane, polytetrafluoroethylene, and mixtures thereof.

**28.** A woven implantable tubular prosthesis, comprising:

a plurality of warp yarns and fill yarns;

a first tubular extent having a first diameter;

- a plurality of secondary tubular extents, each woven at a transition with the first tubular extent;
- an open crotch formed at the transition between the first tubular extent and the plurality of secondary tubular extents by a weaving pattern that disengages a predetermined number of warp yarns along the transition; and
- a seam along the crotch, wherein the seam provides the transition between the first tubular extent and the plurality of secondary tubular extents with a substantially fluid-tight closure.
- 29.** The tubular prosthesis of claim 28, wherein the seam comprises a seam forming means to close the open crotch after weaving is completed.
- 30.** The tubular prosthesis of claim 29, wherein the seam forming means comprises stitching sewn along the crotch.
- 31.** The tubular prosthesis of claim 29, wherein the seam forming means comprises gluing.
- 32.** The tubular prosthesis of claim 29, wherein the seam forming means comprises stapling.
- 33.** The tubular prosthesis of claim 29, wherein the seam forming means comprises welding.
- 34.** The tubular prosthesis of claim 28, wherein the plurality of secondary tubular extents comprises a pair of secondary tubular extents defining a bifurcated structure.
- 35.** The tubular prosthesis of claim 34, wherein each of the pair of secondary tubular extents has a different diameter.
- 36.** The tubular prosthesis of claim 34, wherein each of the pair of secondary tubular extents has the same diameter.
- 37.** The tubular prosthesis of claim 28, wherein the prosthesis is flat-woven.
- 38.** The tubular prosthesis of claim 28, wherein the warp yarns and fill yarns comprise materials selected from the group consisting of polyester, polypropylene, polyethylene, polyurethane, polytetrafluoroethylene, and mixtures thereof.
- 39.** A method of making a woven implantable tubular prosthesis, comprising: weaving a first tubular extent having a first diameter using a first predetermined number of warp yarns;
- weaving continuously from the first tubular extent a transition tubular extent formed by a weaving pattern having a graduated change in the first predetermined number of warp yarns to produce a tapered edge along the transition tubular extent;
- weaving a second tubular extent continuously from the transition tubular extent using a second predetermined number of warp yarns; and
- creating a seam along the tapered edge, wherein the seam provides a substantially fluid-tight transition between the first tubular extent and the second tubular extent.
- 40.** The method of claim 39, the warp yarns further comprising top layer warp yarns and bottom layer warp yarns, wherein creating the seam further comprises weaving the top layer warp yarns and the bottom layer warp yarns together along the tapered edge on a weaving loom.
- 41.** The method of claim 39, wherein the graduated change in the number of warp yarns comprises disengaging predetermined warp yarns from the weaving pattern.
- 42.** A method of making a woven implantable tubular prosthesis, comprising:
- weaving a first tubular extent having a first diameter using a first predetermined number of warp yarns;
- weaving continuously from the first tubular extent an open transition extent formed by a weaving pattern having a graduated change in the first predetermined number of warp yarns to produce an unwoven tapered edge along the open transition extent;
- weaving a second tubular extent continuously from the open transition extent using a second predetermined number of warp yarns; and
- creating a seam along the tapered edge,
- wherein the seam provides a substantially fluid-tight transition between the first tubular extent and the second tubular extent.
- 43.** The method of claim 42, wherein creating the seam further comprises using a seam forming means to close the open transition extent into a tube after weaving is completed.
- 44.** The method of claim 43, wherein the seam forming means comprises sewing a seam along the tapered edge.
- 45.** The method of claim 42, wherein the graduated change in the number of warp yarns comprises disengaging predetermined warp yarns from the weaving pattern.
- 46.** A method of making a woven implantable tubular prosthesis, comprising:
- weaving a first tubular extent having a first diameter using a first predetermined number of warp yarns;
- weaving continuously from the first tubular extent an open transition formed by a weaving pattern that disengages a second predetermined number of warp yarns along the transition to produce an open crotch;
- weaving a plurality of secondary tubular extents, each woven at a transition with the first tubular extent; and
- creating a seam along the crotch,
- wherein the seam provides the transition between the first tubular extent and the plurality of secondary tubular extents with a substantially fluid-tight closure.
- 47.** The method of claim 46, wherein creating the seam further comprises using a seam forming means to close the open crotch after weaving is completed.
- 48.** The method of claim 47, wherein the seam forming means comprises sewing a seam to close the open crotch.
- 49.** The method of claim 46, wherein the plurality of secondary tubular extents comprises a pair of secondary tubular extents defining a bifurcated structure.
- 50.** The method of claim 49, wherein each of the pair of secondary tubular extents has a different diameter.
- 51.** The method of claim 49, wherein each of the pair of secondary tubular extents has the same diameter.

\* \* \* \* \*



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(54) **TUBULAR COMPRESSION ORTHOSIS FOR  
IMMOBILISING A LOWER LIMB AFTER A  
VENOUS SURGICAL PROCEDURE**

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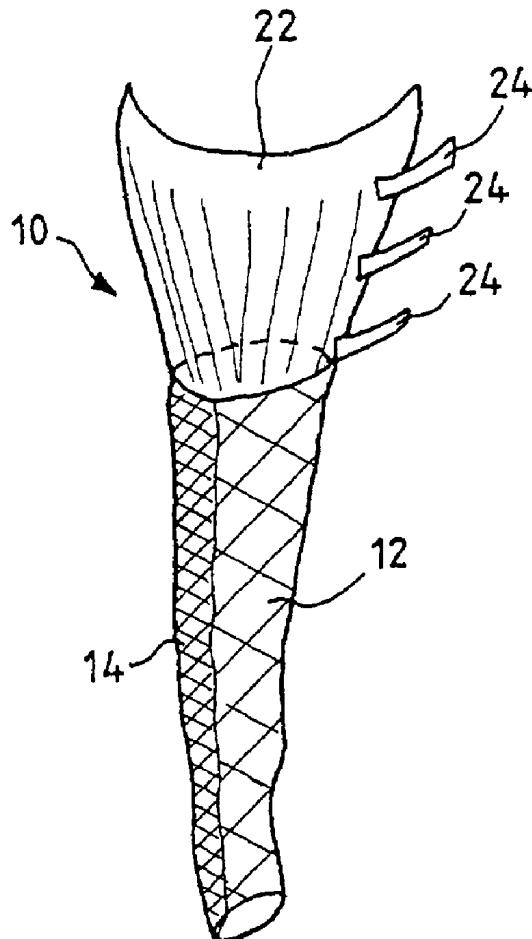
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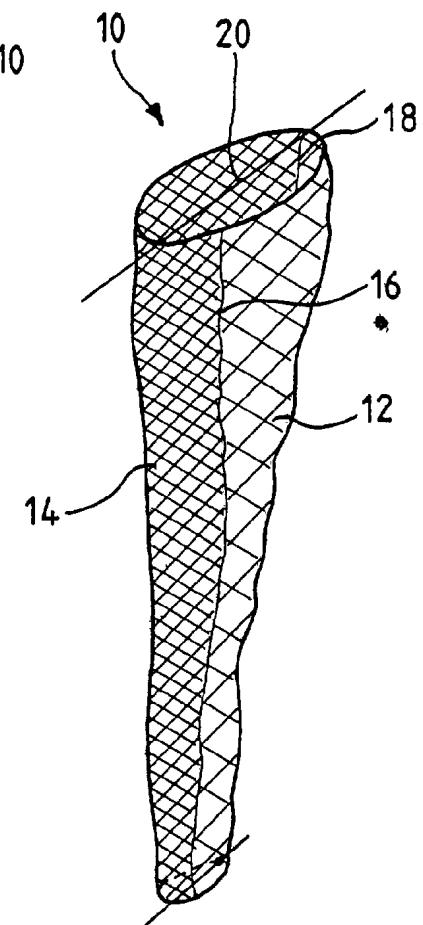
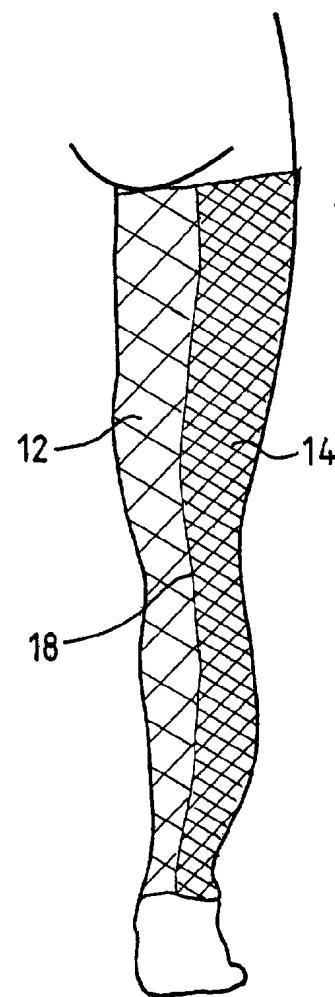
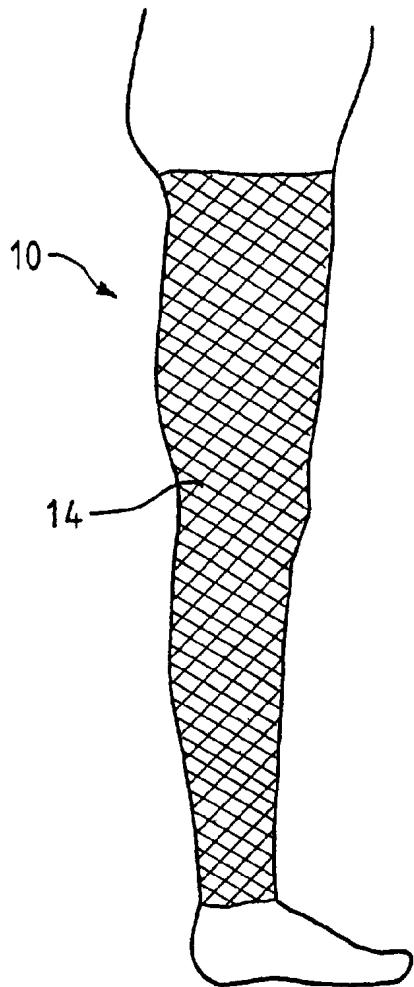
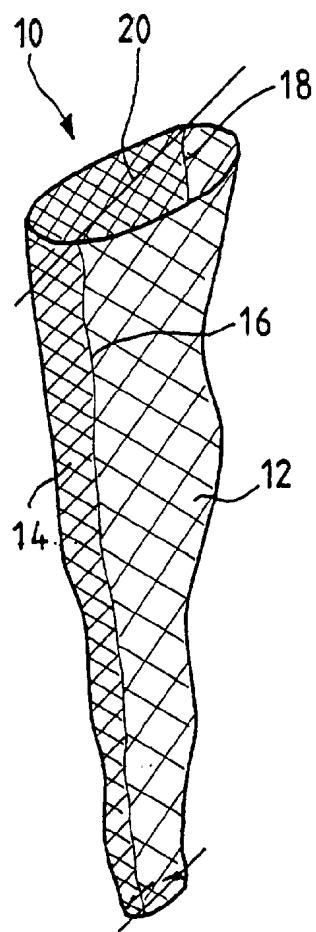
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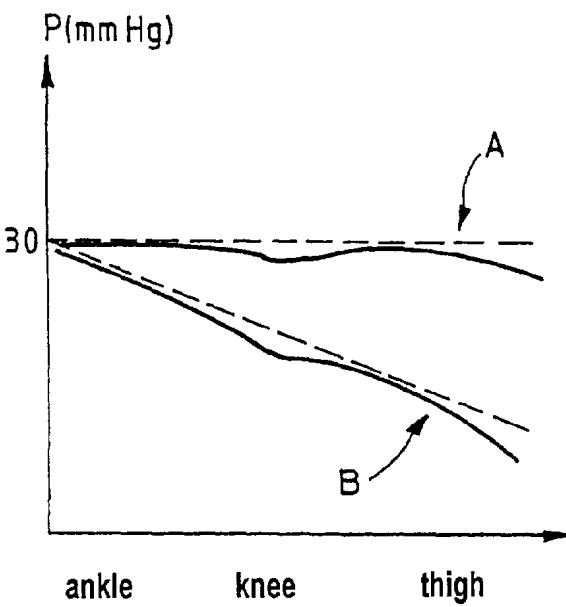
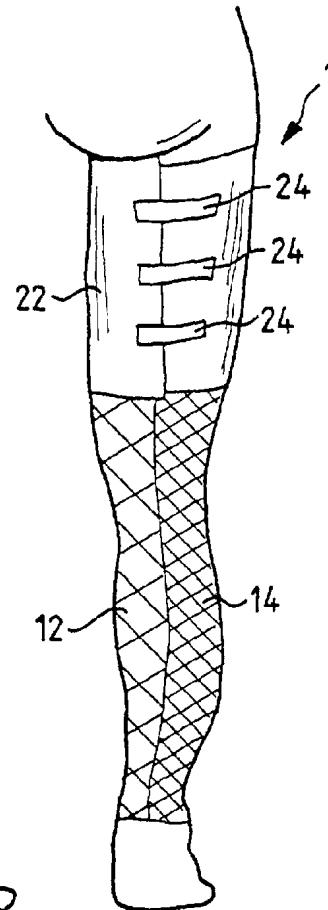
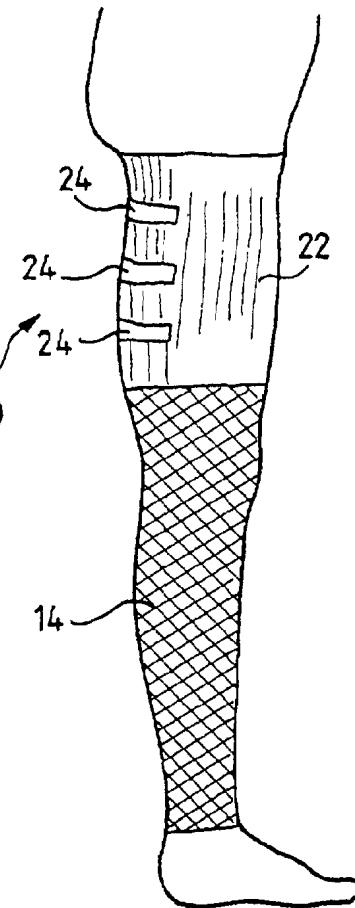
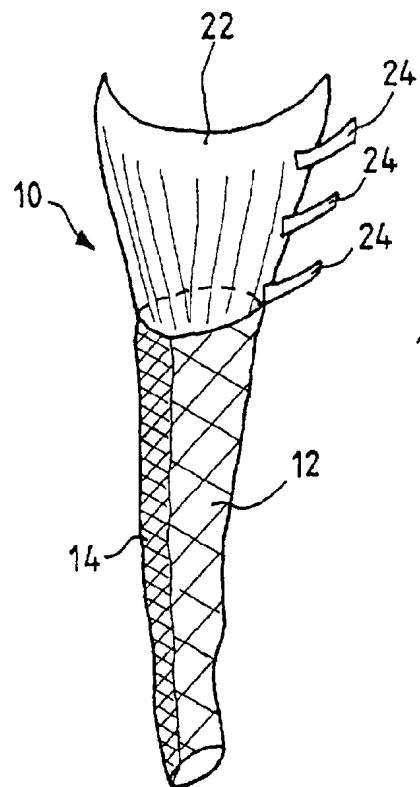
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(57) **ABSTRACT**

The orthosis comprises a compressive tubular portion (10) of knitted or woven fabric, of varying section that matches the profile of the lower limb, and in which the knit or weave structure is selected as a function of the peripheral dimensions of the lower limb so as to apply compression pressure of about 30 mmHg to 40 mmHg that is substantially constant along the length of the limb. The tubular portion extends from the foot to the top of the thigh and comprises a stretchable inner region (12) that is highly elastic and that is connected along two generator lines to an outer region (14) that is non-stretchable or poorly stretchable. The top end of the orthosis is also provided with a thigh sleeve (22) that is open along a generator line and that is provided with adjustable closure means (24).







## TUBULAR COMPRESSION ORTHOSIS FOR IMMOBILISING A LOWER LIMB AFTER A VENOUS SURGICAL PROCEDURE

[0001] The invention relates to the field of compressive orthoses for use in the immediate postoperative period after surgery of veins in the lower limbs.

[0002] Surgery of superficial veins comprises two main operations, both of which involve surgical removal of the diseased vein.

[0003] The first operation is known as "stripping" which comprises tearing out the vein axis of the inner or outer saphena on a wire. This operation is performed under an anesthetic which can be general, loco-regional, peridural, or under neuroleptanalgesia. It gives rise to significant damage to the collateral branches of the saphena which consequently bleed, giving rise to hematomas, which are painful and uncomfortable for patients in the hours and days following surgery.

[0004] The other technique in common use is outpatient phlebectomy, which is a surgical act that is less traumatizing than stripping (but which can also be performed in the context of stripping). This technique involves thorough exeresis of the superficial veins under outpatient conditions. The hematomas are smaller than with stripping, but the risk of immediate bleeding exists when the patient gets up, such risks being inherent to outpatient surgery.

[0005] In both cases, in order to reduce bleeding and attenuate the consequences thereof, immediately after surgery the surgeon applies compression very strongly to the operated limb so as to limit postoperative inflammation and bleeding.

[0006] In nearly all cases, such compression is applied at present using dry or adhesive bands.

[0007] That technique presents several drawbacks:

[0008] by its very nature it depends on the skill of the person performing it;

[0009] it is not possible to monitor the value and the uniformity of the pressure applied: as a result some bands run the risk of being too tight and therefore painful, or else not tight enough and therefore ineffective.

[0010] In practice, during the period immediately following surgery, it is found that patients generally suffer far more from bands that have been poorly put into place than they do from the operation itself.

[0011] Other methods of vascular surgery give rise to discomfort of the same kind, for example methods referred to as "conservative surgery" derived from conservative hemodynamic outpatient treatment for vein insufficiency (known in French under the initials CHIVA).

[0012] One of the objects of the invention is to propose an orthosis which, on being put into place immediately after an operation, serves to provide controlled and regular compression over the entire lower limb in a manner that does not depend on the skill of the person applying the orthosis, and that compresses sufficiently to limit postoperative inflammation and bleeding.

[0013] The bands that are currently in widespread use constitute the orthosis that is easiest to put into place, but as mentioned above, that is least suited to the purpose of applying compression.

[0014] It is possible, instead, to use some other existing type of orthosis, in particular medical elastic stockings. However such stockings apply pressure degressively, and in particular they apply little pressure to the thigh, whereas under postoperative conditions, it is specifically on the thigh where the pressure needs to be applied most strongly. Furthermore, such stockings are difficult to put on a patient who is unconscious because of general anesthesia and also because of the dressings that have been applied to the leg and that increase its volume.

[0015] The orthosis of the invention serves to mitigate all of those drawbacks.

[0016] Thus, the invention provides a tubular compressive orthosis for compressing a lower limb after vein surgery, in particular after outpatient phlebectomy or vein stripping, which orthosis comprises a compressive tubular portion of knitted or woven fabric, and of varying section matching the profile of the lower limb, and in which the structure of the knit or the weave is selected as a function of the peripheral dimensions of the lower limb so as to apply compression at a pressure which is substantially constant along the length of the limb.

[0017] According to various advantageous secondary characteristics:

[0018] the substantially constant compression pressure lies in the range 30 millimeters of mercury (mmHg) to 40 mmHg;

[0019] the orthosis is in the form of an open stocking, having no knitted heel or foot;

[0020] the tubular portion extends from the foot to the top of the thigh;

[0021] the tubular portion comprises a stretchable inner region that is highly elastic and that is connected along two generator lines, e.g. approximately diametrically opposite generator lines, to an outer region that is non-stretchable or poorly stretchable;

[0022] the top end of the tubular portion comprises a thigh sleeve that is open along a generator line and that is provided with adjustable closure means; and

[0023] the top and/or bottom ends of the orthosis are made of material that can be cut and that is run-resistant, so as to enable the orthosis to be cut to length when it is put into place.

[0024] The invention is described below in greater detail with reference to the accompanying drawings.

[0025] FIG. 1 shows an orthosis of the invention prior to being put into place.

[0026] FIGS. 2 and 3 are respectively a side view and a back view of the FIG. 1 orthosis in place on a lower limb.

[0027] FIG. 4 shows a variant of the FIG. 1 orthosis.

[0028] FIG. 5 shows an improvement applied to the FIG. 1 orthosis.

[0029] FIGS. 6 and 7 are respectively a side view and a back view of the improved orthosis of FIG. 5 put into place on a lower limb.

[0030] FIG. 8 is a graph showing the respective compression pressure profiles as obtained by an orthosis of the invention and by a conventional elastic stocking.

[0031] FIG. 1 shows the orthosis of the invention which is essentially in the form of a stocking that is open at the foot. More precisely, the orthosis 10 is in the form of a knitted tube of varying section that matches the shape of a leg, i.e. it tapers downwards, and it advantageously does not have a knitted foot or heel.

[0032] This orthosis is for covering the lower limb, as shown in FIGS. 2 and 3, from the foot to the top of the thigh.

[0033] It must be capable of exerting constant compressive pressure on the lower limb from the ankle to the thigh (unlike traditional elastic stockings which produce pressure that decreases going away from the ankle), and this pressure should be about 30 mmHg to 40 mmHg (40.0 hectopascals (hPa) to 53.2 hPa), thus enabling a regular and constant hemostatic effect to be exerted all along the lower limb.

[0034] The tubular orthosis 10 comprises two substantially semicylindrical portions 12 and 14 which extend along the entire length of the orthosis and which are connected together along two generator lines 16, 18 situated at opposite ends of a diameter 20.

[0035] The semicylindrical portion 12 that is situated on the inside of the leg is constituted by a reinforced elastic stitch, e.g. of the same type as that used on the seat face of pantyhose.

[0036] The semicylindrical portion 14 situated on the outside of the leg is knitted using a stitch that stretches little, i.e. a stitch with short elongation, so as to apply greater compression on the outer face.

[0037] The term "elasticity" is used herein in the sense that is conventional for textiles, i.e. to denote the ability of a textile material that has been stretched to return to its initial shape and dimensions once the deforming forces have been removed; this elasticity is expressed in percentage elongation relative to one meter at rest.

[0038] Elongation is said to be "short" (for a stitch that stretches little, such as that used in the portion 14) when maximum elongation is less than 70% (see in particular C. Gardon-Mollard and A.-A. Ramelet in "La Contention Médicale" [Medical compression], published by Masson, Paris, 1999, pp. 51-54) and elongation is said to be "medium" (an "elastic" stitch such as that used in the portion 12) when the maximum elongation lies in the range 70% to 140%.

[0039] Advantageously, the orthosis is manufactured in several sizes, typically three or four sizes of different diameters but having a single length, with the orthosis being fitted to the length of the patient's leg by cutting off excess length at each end. The orthosis should then be knitted, at least at both ends, with a stitch of the run-resistant type so as to avoid unraveling after it has been cut to length.

[0040] The stitch can be of the same type as is used in a conventional elastic stocking, e.g. the Varisma (registered

trademark) stocking produced by Innothéra Topic. It can be of the wfted, plain, pinched or floated micromesh, etc. type, all of which stitches are known per se to specialists in knitting techniques.

[0041] The yarn used for knitting the orthosis can be an elastane covered in cotton and polyamide, an elastane covered in polyamide without any cotton, or indeed a mixture of elastane and elastodiene (synthetic rubber latex). Nevertheless, the material advantageously includes a large fraction of cotton so as to be more effective in absorbing serosites and bleeding; it can also be selected so as to be washable and optionally reusable.

[0042] The orthosis of the invention is advantageously put into place using an accessory of the kind described in WO-A-99/44558 (Innothéra Topic International) which makes putting on and adjusting the orthosis simple, quick, and accurate, even in the presence of thick dressings and on a limb that is still anesthetized.

[0043] Naturally, a variety of variants can be envisaged.

[0044] In a first variant shown in FIG. 4, the outer semicylindrical portion 14 is of greater peripheral extent than the elastic inner portion 12, i.e. the two generator lines 16 and 18 where the portions are joined together both lie on the same side of a diameter 20.

[0045] Another variant consists not in knitting the orthosis but in making it up from two kinds of woven fabric presenting the same deformation characteristics as those described above, i.e. both a fabric having small elongation for the outer face 14 and an elastic fabric for the inner face 12. To avoid the drawbacks associated with lines of stitching, the two semicylindrical portions can be connected together using textile heat-sealing or high frequency methods, which are known per se.

[0046] An improvement shown in FIGS. 5 to 7 consists in providing the top portion of the orthosis in the form of a thigh sleeve that is not elastic but that is adjustable, e.g. made of woven fabric.

[0047] To make it easy to put on, this sleeve is open along a generator line as shown in FIG. 5. After the orthosis has been put on the leg, the practitioner presses the sleeve 22 against the top portion of the thigh and moves its two free edges towards each other by adjusting the tightening so as to apply the desired amount of compression to this region of the lower limb. The thigh sleeve 22 is then closed in the desired position, e.g. by means of self-fastening closure strips 24 which make it easy to adjust tightness, where necessary.

[0048] FIG. 8 is a graph showing the compression profile that is obtained using the orthosis of the invention, i.e. substantially constant profile A, in comparison with the degressive profile B that is obtained using a conventional elastic stocking. The dashed-line profiles are ideal profiles, while the continuous-line profiles represent real measurements. These measurements take account both of the shape of the knee which locally prevents regular pressure being applied, and also the fact that it is difficult to maintain pressure at the top of the thigh because of the large diameter of this region (Laplace's law).

1. A tubular compressive orthosis for compressing a lower limb after vein surgery, in particular after outpatient phle-

bectomy or vein stripping, the orthosis being characterized in that it comprises a compressive tubular portion (10) of knitted or woven fabric, and of varying section matching the profile of the lower limb, and in which the structure of the knit or the weave is selected as a function of the peripheral dimensions of the lower limb so as to apply compression at a pressure which is substantially constant along the length of the limb.

2. The orthosis of claim 1, in which the tubular portion (10) comprises a stretchable inner region (12) that is highly elastic and that is connected along two generator lines (16, 18) to an outer region (14) that is non-stretchable or poorly stretchable.

3. The orthosis of claim 2, in which the two generator lines (16, 18) interconnecting the inner and outer regions are approximately diametrically opposite.

4. The orthosis of claim 1, in which the substantially constant compression pressure lies in the range 30 mmHg to 40 mmHg.

5. The orthosis of claim 1, characterized in that it is in the form of an open stocking, having no knitted heel or foot.

6. The orthosis of claim 1, in which the tubular portion extends from the foot to the top of the thigh.

7. The orthosis of claim 1, in which the top end of the tubular portion comprises a thigh sleeve (22) that is open along a generator line and that is provided with adjustable closure means (24).

8. The orthosis of claim 1, in which the top and/or bottom ends of the orthosis are made of material that can be cut and that is run-resistant, so as to enable the orthosis to be cut to length when it is put into place.

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