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(54) **ADJUSTABLE MAGNETIC DEVICES AND METHODS OF USING SAME**

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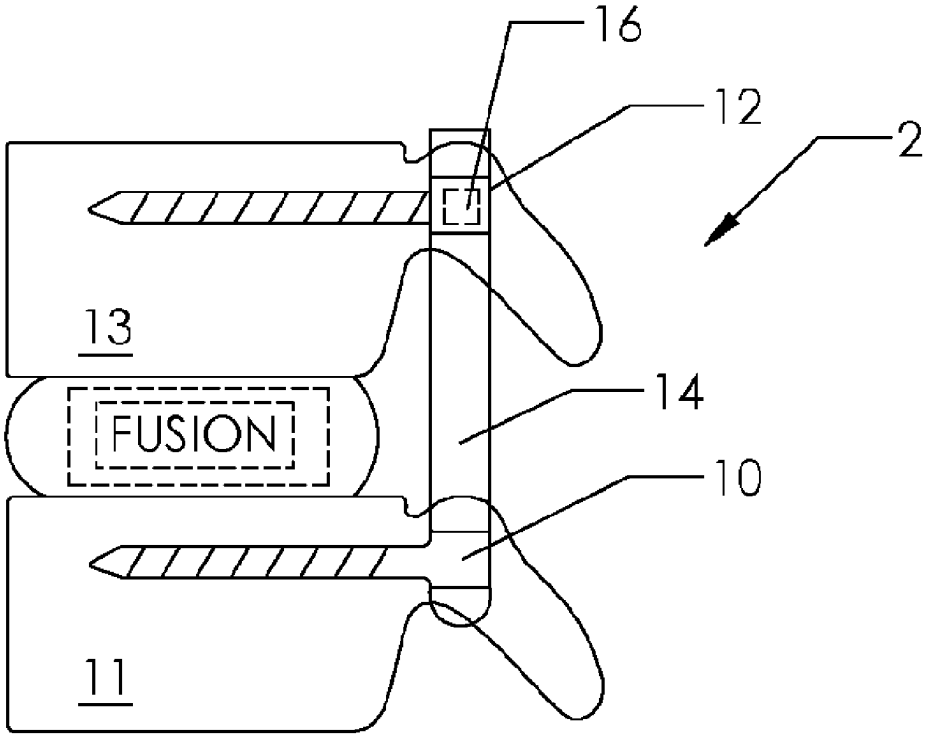
(57) **ABSTRACT**

A system includes a first pedicle screw, a second pedicle screw, and an adjustable rod having an outer housing coupled to one of the first pedicle screw and the second pedicle screw, the outer housing having a threaded shaft secured to one end thereof extending along an interior portion thereof. The system farther includes a hollow magnetic assembly disposed within the outer housing and having a magnetic element disposed therein, the hollow magnetic assembly having an internal threaded surface engaged with the threaded shaft, the magnetic assembly being coupled to the other of the first pedicle screw and the second pedicle screw, wherein the hollow magnetic assembly rotates in response to an externally applied magnetic field to thereby lengthen or shorten the distance between the first pedicle screw and the second pedicle screw.



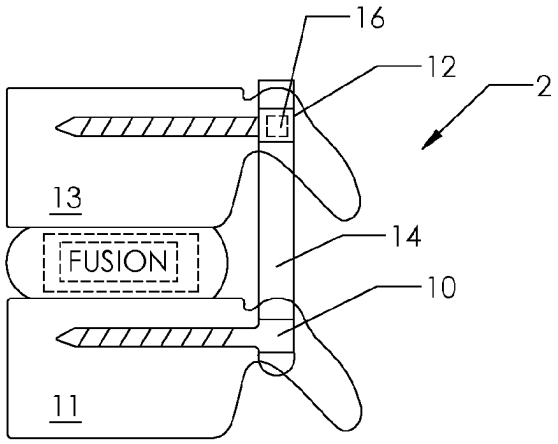


FIG. 1A

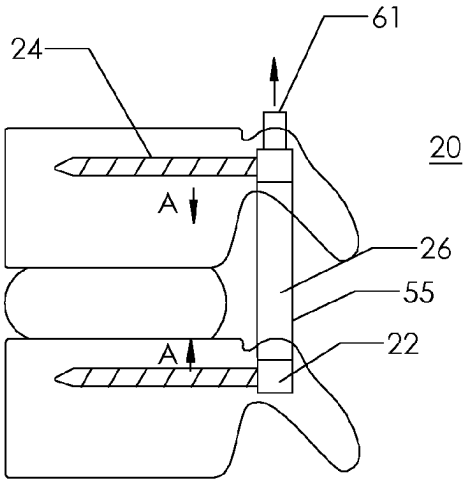


FIG. 2A

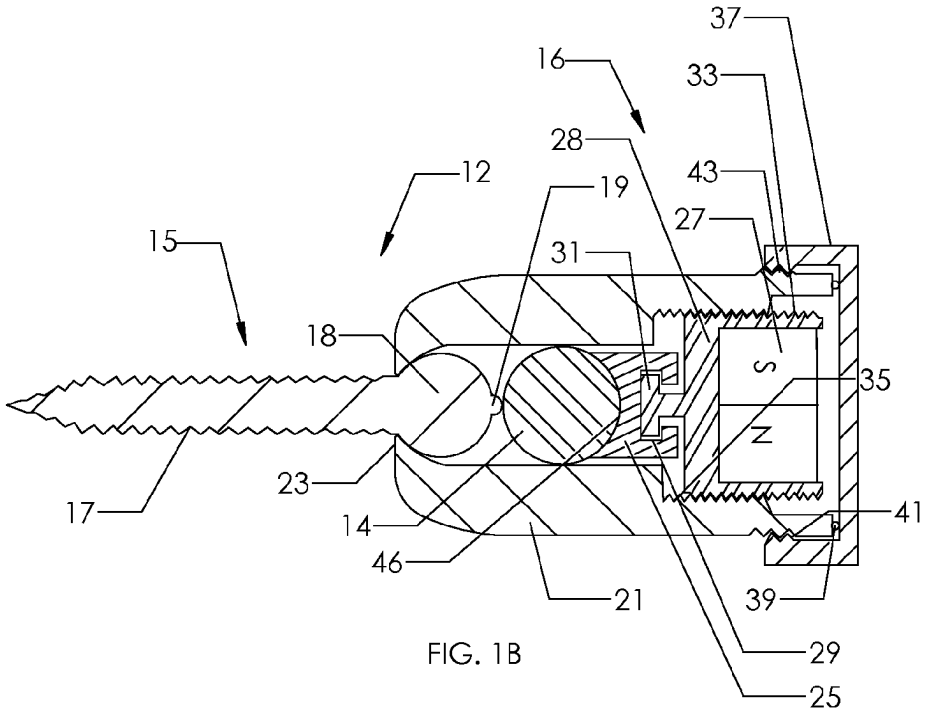

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FIG. 1B

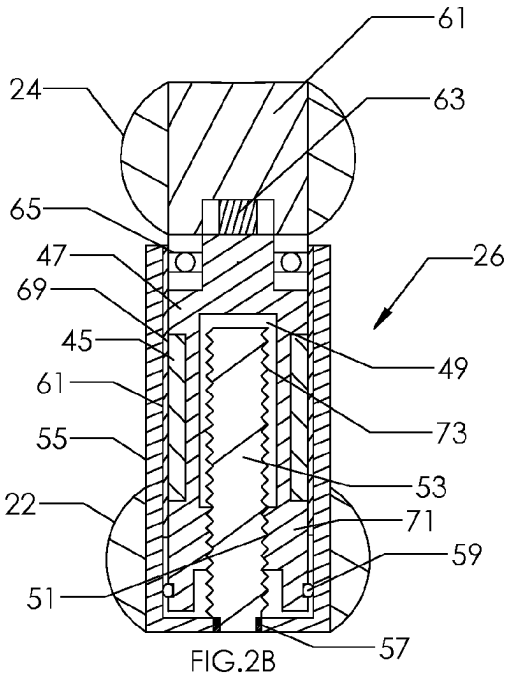
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FIG.2B

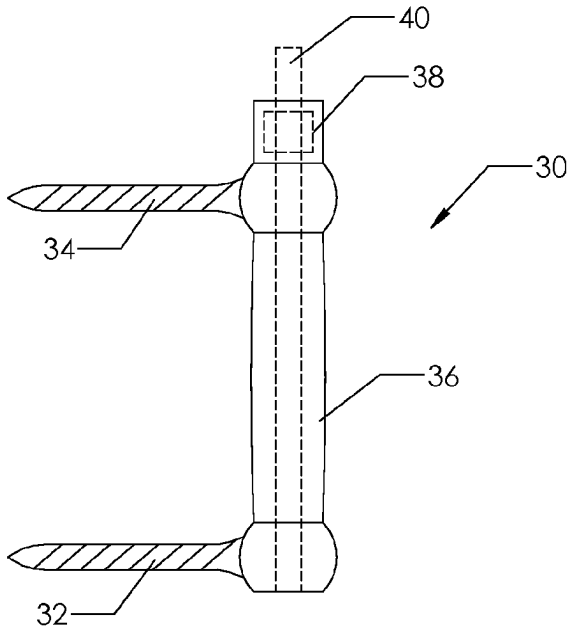

FIG. 3

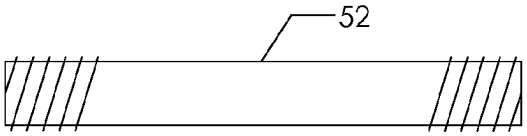

FIG. 4A

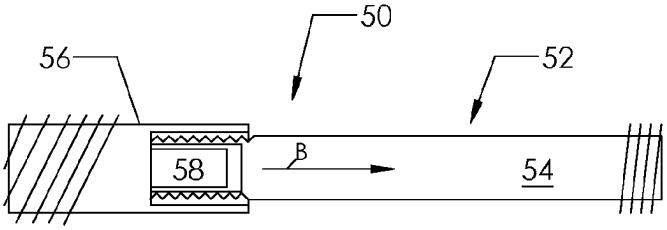

FIG. 4B

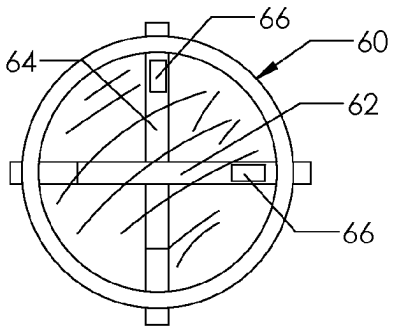

FIG. 5

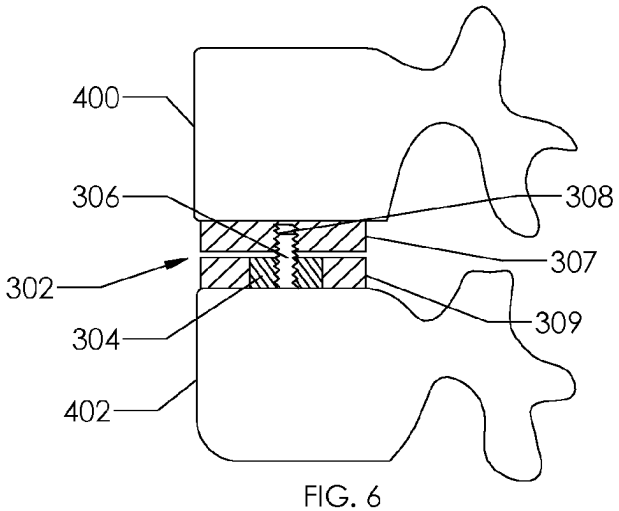
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FIG. 6

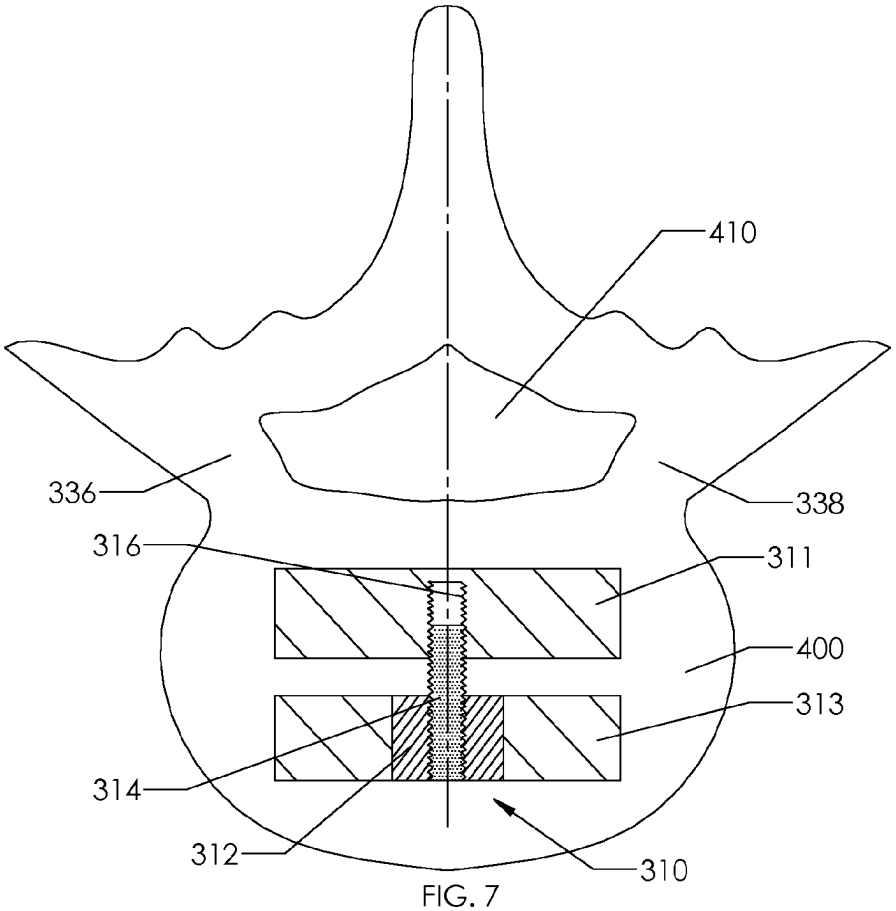
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FIG. 7

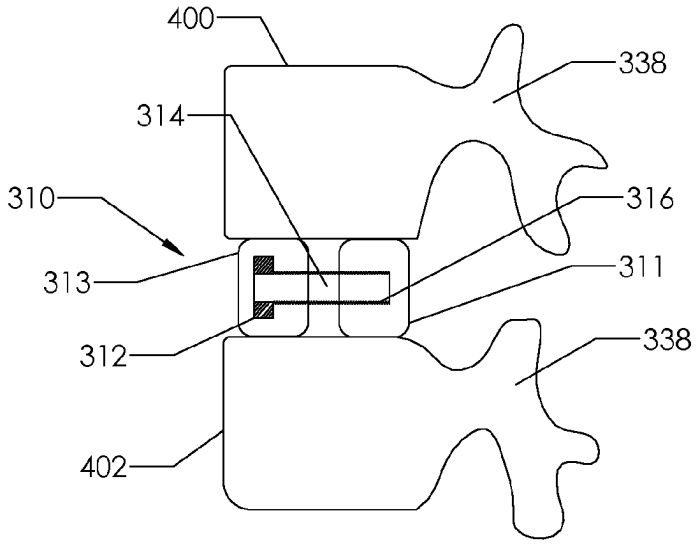

FIG. 8

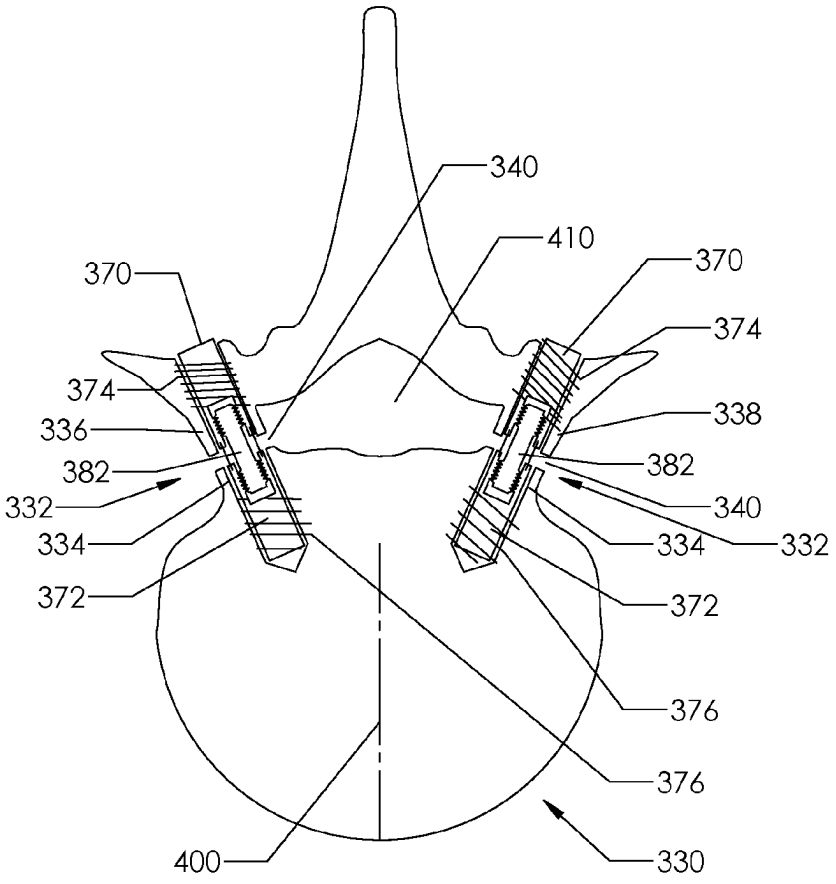
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FIG. 9

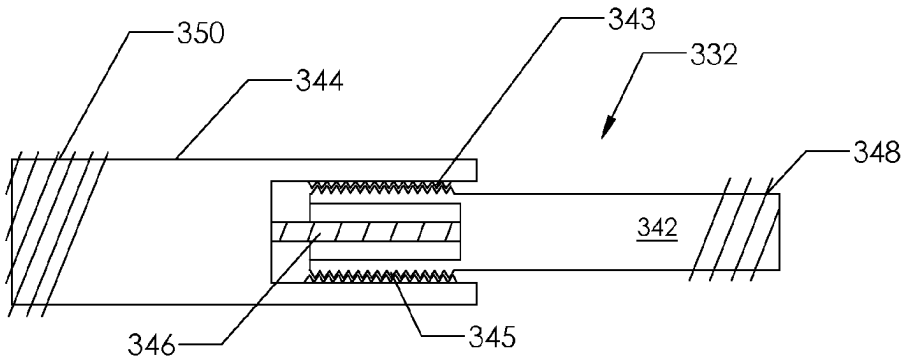

FIG. 10

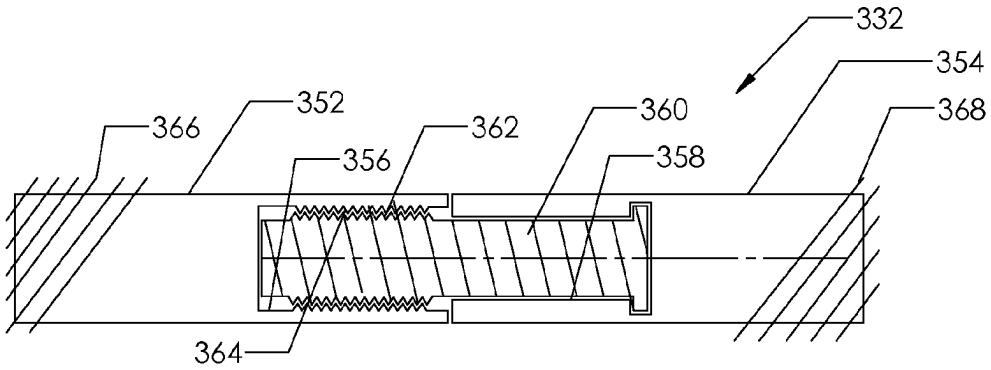

FIG. 11

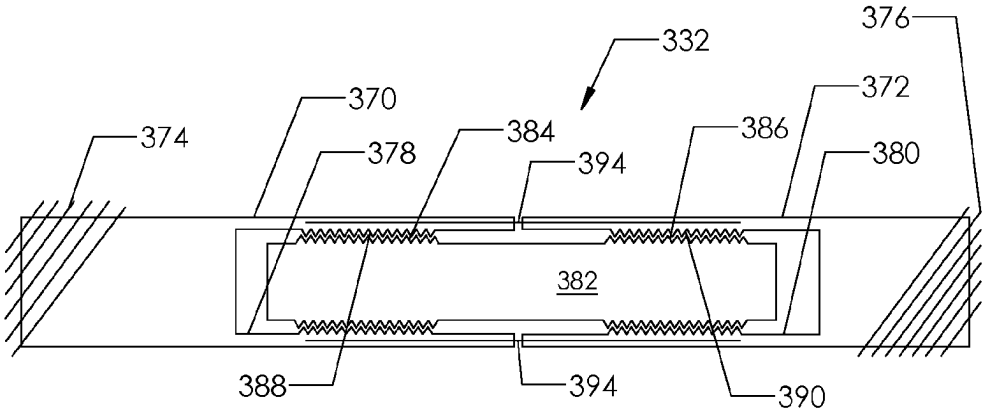

FIG. 12

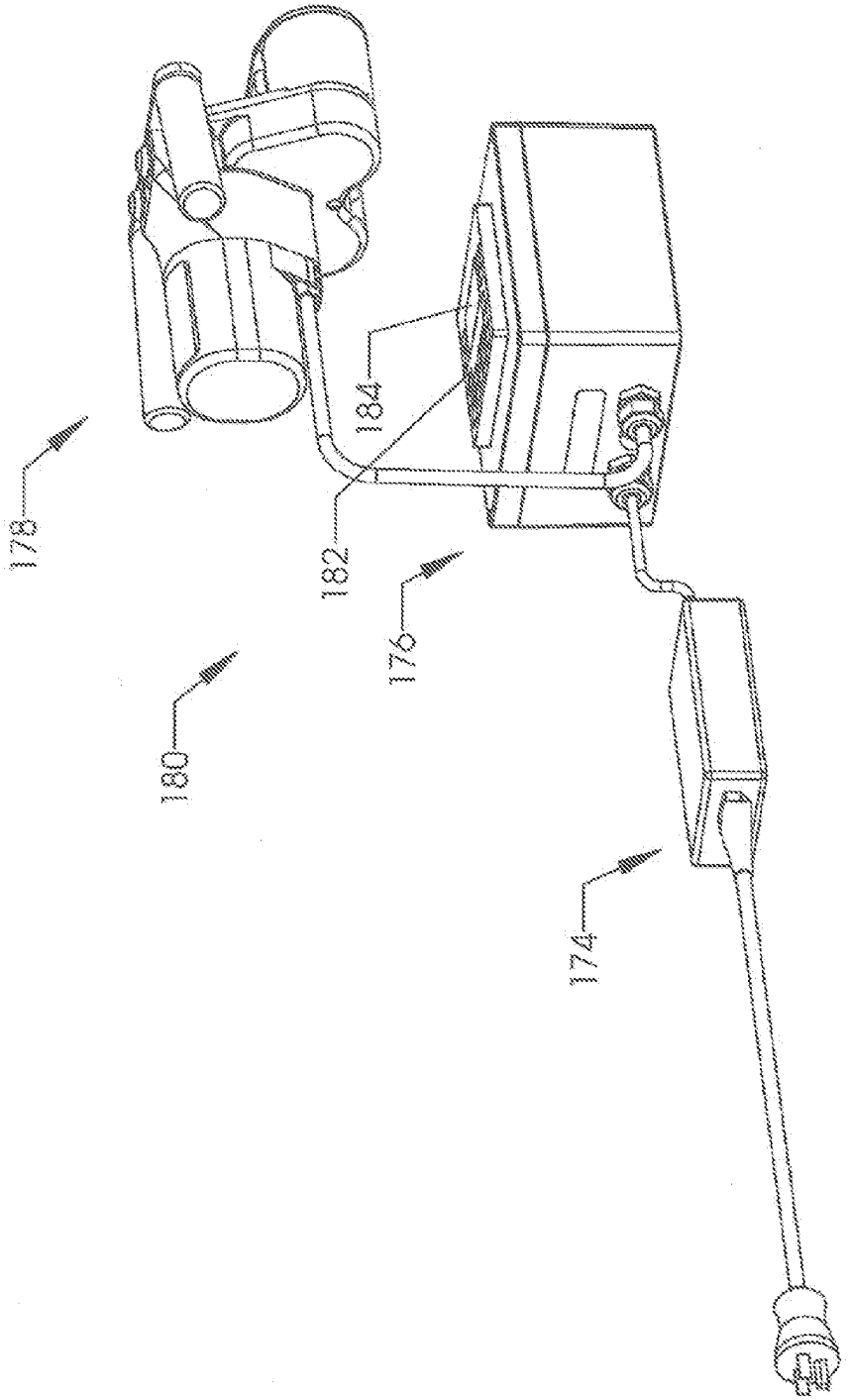

FIG. 13

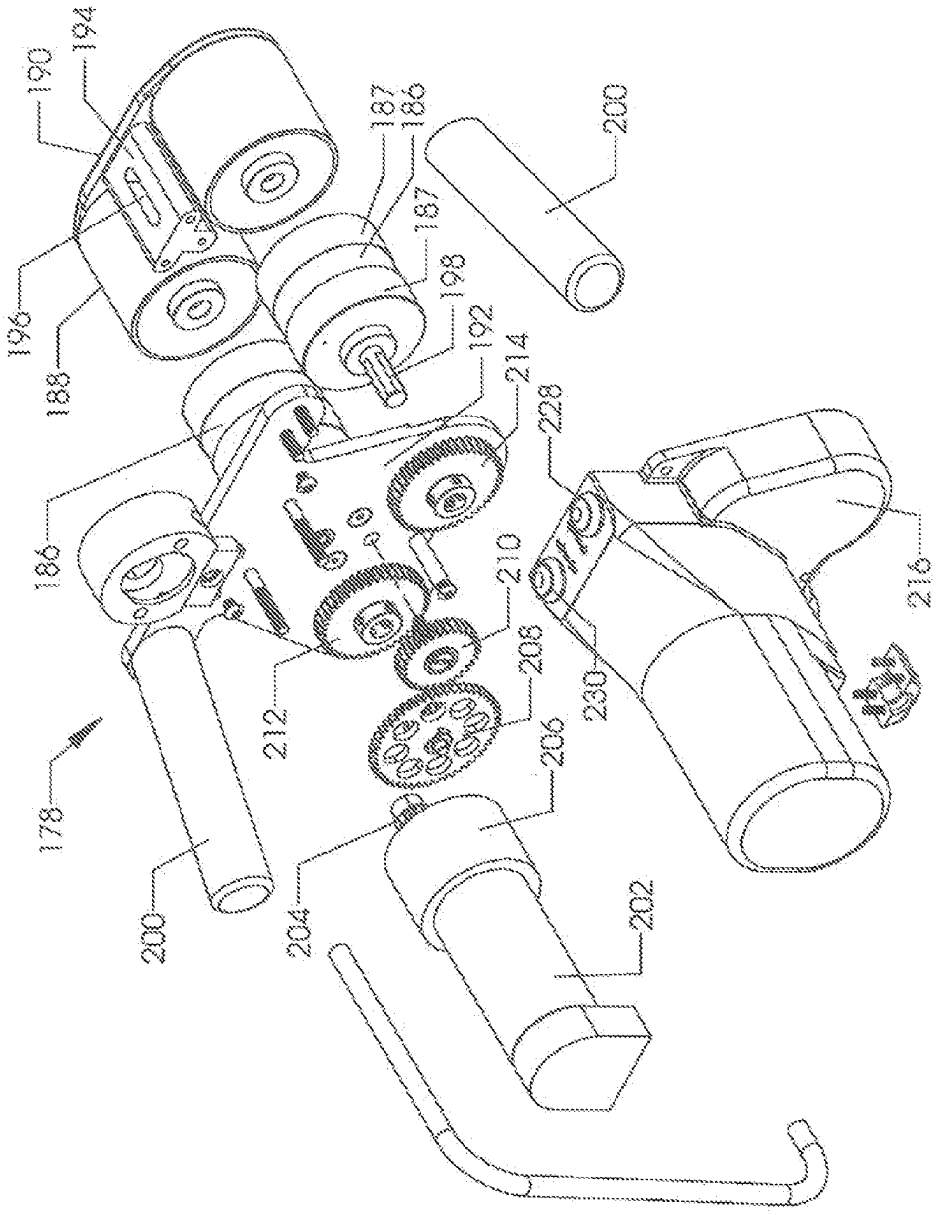
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FIG. 14

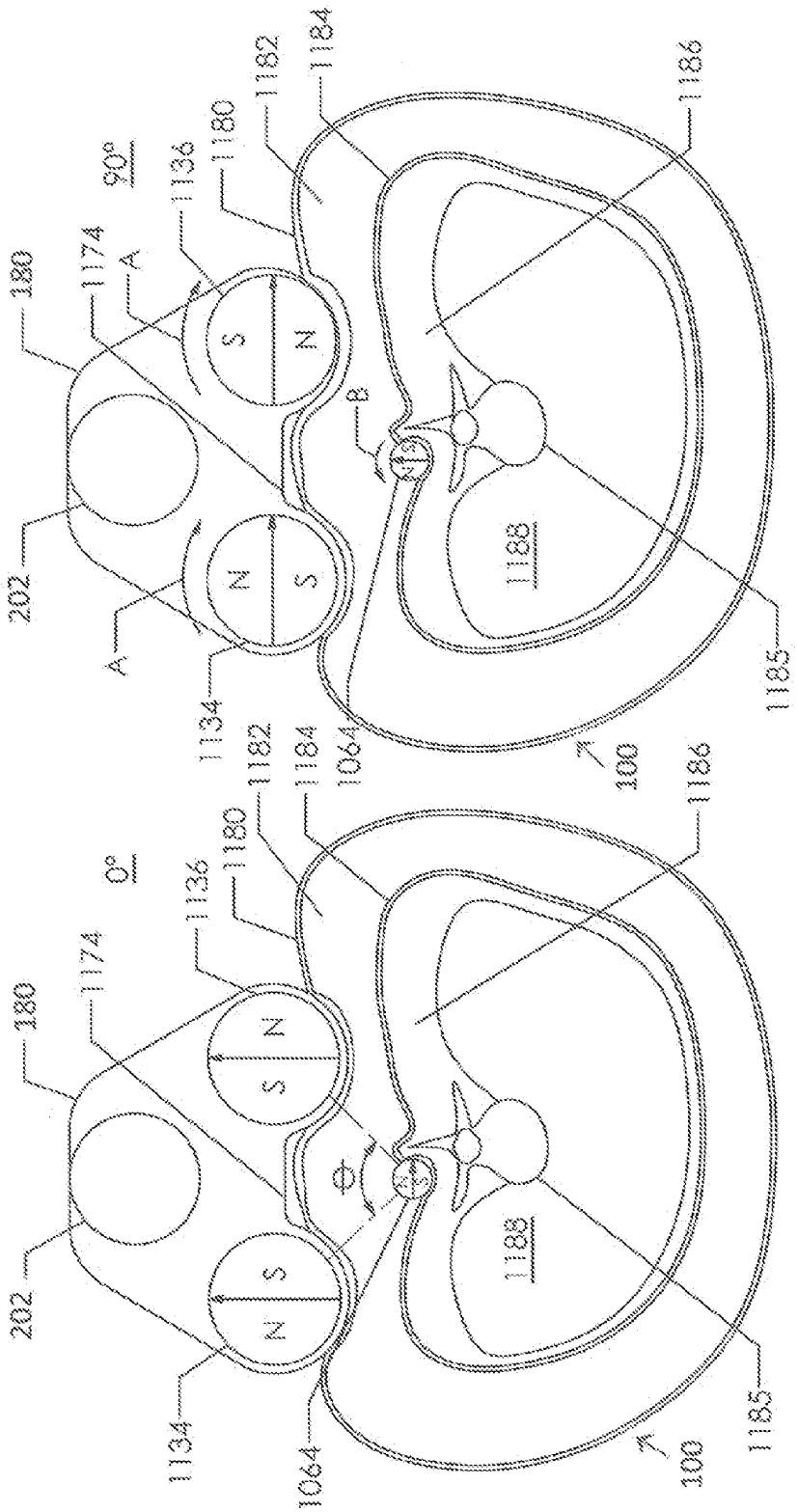
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FIG. 15

FIG. 16

ADJUSTABLE MAGNETIC DEVICES AND METHODS OF USING SAME

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation of U.S. patent application Ser. No. 18/440,266, filed on Feb. 13, 2024 and published as US 2024-0180593, which is a continuation of U.S. patent application Ser. No. 17/352,485, filed on Jun. 21, 2021 and now U.S. Pat. No. 11,918,255, which is a divisional of U.S. patent application Ser. No. 16/297,257, filed Mar. 8, 2019 and now U.S. Pat. No. 11,123,107, which is a continuation of U.S. patent application Ser. No. 14/449,761, filed Aug. 1, 2014 and now U.S. Pat. No. 10,265,101, which is a continuation of U.S. patent application Ser. No. 14/301,238, filed Jun. 10, 2014 and now U.S. Pat. No. 10,349,982, which is a continuation of U.S. patent application Ser. No. 14/355,202, filed Apr. 29, 2014 and now U.S. Pat. No. 10,016,220, which is a US national stage entry under 35 USC 371 of international patent application no. PCT/US2012/062696, filed Oct. 31, 2012, which claims the benefit of U.S. provisional patent application No. 61/567,936, filed Dec. 7, 2011 and US provisional application no. 61/554,389, filed Nov. 1, 2011. Any and all applications for which a foreign or domestic priority claim is identified above and/or in the Application Data Sheet as filed with the present application are hereby incorporated by reference under 37 CFR 1.57.

FIELD OF THE INVENTION

[0002] The field of the invention generally relates to medical devices for treating spinal conditions.

BACKGROUND OF THE INVENTION

[0003] Degenerative disc disease affects 65 million Americans. Up to 85% of the population over the age of 50 will suffer from back pain each year. Degenerative disc disease (DDD) is part of the natural process of growing older. Unfortunately as we age, our intervertebral discs lose their flexibility, elasticity, and shock absorbing characteristics. The ligaments that surround the disc, called the annulus fibrosis, become brittle and they are more easily torn. At the same time, the soft gel-like center of the disc, called the nucleus pulposus, starts to dry out and shrink. The combination of damage to the intervertebral discs, the development of bone spurs, and a gradual thickening of the ligaments that support the spine can all contribute to degenerative arthritis of the lumbar spine.

[0004] When degenerative disc disease becomes painful or symptomatic, it can cause several different symptoms, including back pain, leg pain, and weakness that are due to compression of the nerve roots. These symptoms are caused by the fact that worn out discs are a source of pain because they do not function as well as they once did, and as they shrink, the space available for the nerve roots also shrinks. As the discs between the intervertebral bodies start to wear out, the entire lumbar spine becomes less flexible. As a result, people complain of back pain and stiffness, especially towards the end of the day.

[0005] Depending on the severity and the condition, there are many ways to treat DDD patients, with fusion being the most common surgical option. The estimated number of thoracolumbar fixation procedures in 2009 was 250,000. Surgery for degenerative disc disease usually involves removing the damaged disc. In some cases, the bone is then permanently joined or fused to protect the spinal cord. There are many different techniques and approaches to a fusion procedure. Some of the most common are ALIFs, PLIFs, TLIFs, XLIFs (lateral), etc. Almost all of these techniques now involve some sort of interbody fusion device supplemented with posterior fixation (i.e., 360 fusion).

[0006] Another spinal malady that commonly affects patients is stenosis of the spine. Stenosis is related to the degeneration of the spine and typically presents itself in later life. Spinal stenosis can occur in a variety of ways in the spine. Most of the cases of stenosis occur in the lumbar region (i.e., lower back) of the spine, although stenosis is also common in the cervical region of the spine. Central stenosis is a choking of the central canal that compresses the nerve tissue within the spinal canal. Lateral stenosis occurs due to the trapping or compression of nerves after it has left the spinal canal. This can be caused by bony spur protrusions, bulging, or herniated discs.

SUMMARY OF THE INVENTION

[0007] In one embodiment, a system includes a first pedicle screw, a second pedicle screw, and an adjustable rod having an outer housing coupled to one of the first pedicle screw and the second pedicle screw, the outer housing having a threaded shaft secured to one end thereof extending along an interior portion thereof The system further includes a hollow magnetic assembly disposed within the outer housing and having a magnetic element disposed therein, the hollow magnetic assembly having an internal threaded surface engaged with the threaded shaft, the magnetic assembly being coupled to the other of the first pedicle screw and the second pedicle screw, wherein the hollow magnetic assembly rotates in response to an externally applied magnetic field to thereby lengthen or shorten the distance between the first pedicle screw and the second pedicle screw.

[0008] In another embodiment, a method for adjusting the amount of compression between two vertebral bodies includes securing a first pedicle screw to a first vertebra, securing a second pedicle screw to a second vertebra, and securing an adjustable rod between the first pedicle screw and the second pedicle screw, the adjustable rod having an outer housing coupled to the first pedicle screw, the outer housing having a threaded shaft secured to one end thereof extending along an interior portion thereof, the adjustable rod further having a hollow magnetic assembly disposed within the outer housing and having a magnetic element disposed therein, the hollow magnetic assembly having an internal threaded surface engaged with the threaded shaft, the magnetic assembly being coupled to the second pedicle screw. The method further includes applying an external magnetic field to the adjustable rod to rotate the magnetic element.

[0009] In another embodiment, a system includes a first pedicle screw having a shank and a head, a second pedicle screw having a shank and a head, and a rod placed between the first pedicle screw and the second pedicle screw and contained within a housing. The system further includes a magnetic actuator disposed within the housing and associated with one of the first and second pedicle screws, the magnetic actuator having a rotatable magnetic element coupled to a bushing, the rotatable magnetic element configured to move relative to the housing in response to an

externally applied magnetic field, wherein movement in a first direction frictionally engages the rod between the pedicle screw head and the bushing and wherein movement in a second direction disengages the rod from the pedicle screw head and the bushing.

[0010] In another embodiment, a system includes a first pedicle screw, a second pedicle screw, and a flexible spacer configured for placement between the first and second pedicle screws, the flexible spacer configured to adjust a compression or tension force between the first pedicle screw and second pedicle screw in response to an externally applied magnetic field.

[0011] In another embodiment, a device includes an interbody screw having first and second portions, the first portion having a threaded end and the second portion having a threaded end, at least one of the first and second portions being axially moveable with respect to the other in response to an externally applied magnetic field.

[0012] In another embodiment, an artificial disc device includes a body portion, a first adjustable member, and a second adjustable member arranged generally orthogonal to the first adjustable member, where the first and second adjustable members are configured to adjust a COR of the body portion in two orthogonal dimensions in response to an externally applied magnetic field.

[0013] In another embodiment, a distraction device interposed between two vertebral bodies includes first and second portions, one of the portions including a permanent magnet configured to rotate in response to an externally applied non-invasive magnetic field, the permanent magnet operatively coupled to a screw whereby rotation in one direction increases the height between the first and second portions.

[0014] In another embodiment, a distraction device implanted in a single vertebral body includes first and second portions, one of the portions including a permanent magnet configured to rotate in response to an externally applied non-invasive magnetic field, the permanent magnet operatively coupled to a screw whereby rotation in one direction increases the width between the first and second portions.

[0015] In another embodiment, a method of adjusting the spinal canal includes forming first and second bores into a vertebral body, making pedicle cuts to separate a portion of the vertebral body from the pedicles, and securing first and second distraction devices within the first and second bores. The method further includes applying a non-invasive magnetic field to the first and second distraction devices to expand the spinal canal.

[0016] In another embodiment, a system for adjusting the spinal canal includes a drilling tool for drilling first and second bores into a vertebral body, a cutting tool for making first and second pedicle cuts to separate a portion of the vertebral body from associated pedicles, and first and second distraction devices configured for placement within the first and second bores. The system further includes an external adjustment device configured to apply a non-invasive magnetic field to the first and second distraction devices, whereby the non-invasive magnetic field distracts both the first and second distraction devices.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] FIG. **1**A illustrates one embodiment of a pedicle screw system for fusion.

[0018] FIG. **1**B illustrates a sectional view of a pedicle screw of the pedicle screw system of FIG. **1**A.

[0019] FIG. **2**A illustrates another embodiment of a pedicle screw system for fusion applications.

[0020] FIG. **2**B illustrates a sectional view of the pedicle screw system of FIG. **2**A.

[0021] FIG. **3** illustrates another embodiment of a dynamic rod embodiment.

[0022] FIG. **4**A illustrates a screw.

[0023] FIG. **4**B illustrates an interbody device according to another embodiment.

[0024] FIG. **5** illustrates an artificial disc embodiment.

[0025] FIG. **6** illustrates one embodiment of a distraction device used for vertebral body height adjustment.

[0026] FIG. **7** illustrates a top view of one embodiment of a distraction device used for vertebral body width adjustment.

[0027] FIG. **8** illustrates a side view of the embodiment of FIG. **7**.

[0028] FIG. **9** illustrates an embodiment of a system that includes multiple distraction devices for the selective and incremental expansion of the spinal column.

[0029] FIG. **10** illustrates an embodiment of one type of distraction device.

[0030] FIG. **11** illustrates an embodiment of another type of distraction device.

[0031] FIG. **12** illustrates an embodiment of another type of distraction device. Two of these devices are illustrated in the system of FIG. **9**.

[0032] FIG. **13** illustrates a perspective view of an external adjustment device.

[0033] FIG. **14** illustrates an exploded view of the magnetic handpiece of the external adjustment device of FIG. **13**.

[0034] FIG. **15** illustrates a first orientation of two magnets of the external adjustment device in relation to an implanted magnet.

[0035] FIG. **16** illustrates a second orientation of the two magnets of the external adjustment device in relation to the implanted magnet.

DETAILED DESCRIPTION

[0036] FIG. **1**A illustrates a side view of a pedicle screw-based system **2** for the stabilization of the spine during fusion. The device includes a first pedicle screw **10** disposed in a first vertebral body **11**, a second pedicle screw **12** disposed in a second vertebral body **13**, and a rod **14** located between the first pedicle screw **10** and the second pedicle screw **12**. The rod **14** is fixedly secured at one end to the first pedicle screw **10**. The opposing end of the rod **14** is selectively coupled/de-coupled to the second pedicle screw **12** using a magnetic actuator **16**, seen in more detail in FIG. **1**B. The second pedicle screw **12** includes a screw body **15** having a shank **17** and a spherical head **18**. Spherical head **18** has a contact surface **19** which serves as a point of contact when the second pedicle screw **12** is coupled to the rod **14**. As seen in FIG. **1**B, the system **2** includes a housing **21** having an end or lip **23** for engaging with the spherical head **18** of the screw body **15** and maintaining the screw body **15** in a particular orientation in relation to the housing **21** when the second pedicle screw **12** is coupled to the rod **14**. The system **2** includes a magnetic element **28** having a radially-poled magnet **27** bonded within the magnetic element **28**. One end of the magnetic element **28** has a coupler **31** which

fits into a cavity **29** of a bushing **25**. The bushing **25** has a saddle-shaped surface **46** that is shaped to engage with a side surface of the rod **14**. The magnetic element **28** can rotate freely with respect to the bushing **25**, but the coupler **31** transfers axial movement of the magnetic element **28** to axial movement of the bushing **25** when the coupler **31** makes contact with the bushing **25** inside the cavity **29**. The magnetic element **28** includes male threads **33** that engage with corresponding female threads **35** located within an inner surface of the housing **21**. As seen in FIG. **1**B, the magnetic actuator actuates in a direction that is generally perpendicular to the axis of the rod **14**. In this manner, the rod **14** is pinched between the bushing **25** and the head **18** of the pedicle screw **12**.

[0037] The magnetic actuator **16** can be selectively mechanically engaged or disengaged to the second pedicle screw **12** using an externally applied moving magnetic field. For example, one or more rotating or cycling magnets disposed outside the body can be used to selectively engage or disengage the rod **14** to the second pedicle screw **12** by pinching the rod **14** between the bushing **25** and the contact surface **19** of the spherical head **18** of the second pedicle screw **12**. The radially-poled magnet **27** may be made from a rare earth magnet, for example, Neodymium-Iron-Boron. Because the radially-poled magnet **27** and, thus, magnetic element **28** are non-invasively rotated by the moving magnetic field, the bushing **25** is moved axially to frictionally grip the rod **14** between the contact surface **19** of the spherical head **18** and the bushing **25**. A cap **37** having female threads **41** is screwed over male threads **43** of the housing **21** to protect the inner contents. As seen in FIG. **1**B, an O-ring seal **39** seals the cap **37** to the housing **21**. For example, after a fusion procedure has been performed to fuse vertebral bodies **11**, **13** together, the subject undergoes radiographic imaging. At this point, the second pedicle screw **12** is engaged with the rod **14**. Once evidence of anterior fusion is seen, an external magnetic field is applied (e.g., rotating magnetic field) to disengage or de-couple the second pedicle screw **12** from the rod **14**. The pedicle screws **10**, **12** are no longer providing support and allow posterior movement. This will prevent stress shielding and reduce stresses on adjacent levels. Stress shielding refers to the reduction in bone density (osteopenia) as a result of removal of normal stress from the bone by an implant (for instance, the femoral component of a hip prosthesis). This is because by Wolff's law, bone in a healthy person or animal will remodel in response to the loads it is placed under. Therefore, if the loading on a bone decreases, the bone will become less dense and weaker because there is no stimulus for continued remodeling that is required to maintain bone mass.

[0038] This technology could be utilized to "decouple" the rod/screw interface to minimize or eliminate the stress shielding post fusion. This decoupling could provide the same benefit as surgical removal but without the need for a reoperation to remove the hardware post fusion. The stress shielding of the fused level may also contribute to adjacent level disease. If the screws/rods were decoupled, there is the possibility that the fused level would induce less stress on the adjacent level and minimize adjacent level disease. Once disengaged, an external magnetic field may be applied again to once again engage the second pedicle screw **12** to the rod **14**, locking in a new configuration with a lower stress.

[0039] Alternatively, the device may be implanted into two vertebral bodies **10**, **12** that have not been fused. This embodiment provides support and possible height restoration while the injured and/or diseased spinal segment heals. As healing occurs, the same or similar device can be used to introduce motion back to the spinal segment in the manner of an internal brace. If pain recurs, the surgeon can re-tighten pedicle screws to support the spine again. Initial implantation of the pedicle screws/rods can be set either rigid or flexible. The flexibility is adjusted post-operatively either increased or decreased based on the patient healing and pain levels.

[0040] FIGS. **2**A and **2**B illustrate another system **20** to control the loading of an interbody fusion to better promote fusion. Traditional pedicle screws may offload discs substantially. There is a general consensus in the medical community that fusion requires some degree of compression to fully form. The system **20** described herein includes two pedicle screws **22**, **24** that are connected together via an adjustable rod **26**. The adjustable rod **26** is able to shorten (direction of facing arrows A) to apply a compressive load to the vertebral bodies to aid in fusion. The adjustable rod **26** may also be lengthened to reduce this compressive load. The system **20** may be adjusted repeatedly to apply multiple applications of a compressive load to the vertebral bodies if needed. For this system **20**, interbody and pedicle screw fixation are conducted as normal, however, the two pedicle screws **22**, **24** are interconnected to one another via the adjustable rod **26**. The adjustable rod **26** includes an outer housing **55** that is secured to the pedicle screw **22** and includes a threaded shaft **53** that is fixedly secured to one end thereof and extends inwardly within the outer housing **55**. The adjustable rod **26** further includes a hollow magnetic assembly **69** that is disposed within the outer housing **55** and includes a hollow magnetic element **45** disposed therein, the hollow magnetic assembly **69** having an internal threaded surface **51** engaged with external threads **73** of the threaded shaft **53**, the magnetic assembly **69** being coupled to the other of the first pedicle screw and the second pedicle screw.

[0041] The hollow magnetic element **45** is preferably a radially-poled hollow magnet and effectuates rotation of the hollow magnetic assembly **69** that, for example, rotates in response to an externally applied moving magnetic field. The hollow magnetic assembly **69** may be formed by the hollow magnetic element **45** contained on or within a rotatable cylinder **47**. The rotatable cylinder **47** has a hollow cavity **49** into or on which is bonded a nut **71** that contains the threaded surface **51**. The nut **71** includes internal threads **51** that engage with a correspondingly threaded shaft **53** which is fixedly attached to the outer housing **55**, for example, at weld joint **57**. The outer diameter of the rotatable cylinder **47** may include an optional O-ring **59**, which seals to the inner diameter of the outer housing **55**. The rotatable cylinder **47** is longitudinally locked to the inner shaft **61** via a rotational coupling or swivel **63**. A first pedicle screw **22** is attached to the outer housing **55** and a second pedicle screw **24** is attached to the inner shaft **61** during surgery. The inner shaft **61** is telescopically adjustable within the outer housing **55**. The rotation of the radially-poled hollow magnetic element **45** contained in or on the rotatable cylinder **47** of the adjustable rod **26** is then translated into axial shortening or lengthening of the adjustable rod **26**. A thrust bearing **65** is held between inner shaft **61** and rotatable cylinder **47**, and supports the axial load if the

adjustable rod **26** is adjusted in compression (applying distraction between vertebral bodies). An externally applied magnetic field may be applied using an external adjustment device of the type described herein.

[0042] Once implanted in the subject, if radiographic evidence of non-fusion or pseudo-fusion exists, then the surgeon can adjust the pressure on the fusion site by shortening the adjustable rod **26** and thereby moving the pedicle screws **22**, **24** closer to one another to apply a compressive force between the vertebral bodies. The amount of shortening of the adjustable rod **26** will vary the degree of compression applied to the vertebral bodies. An alternative manner of assessing the degree of fusion is by supplying a strain gauge or other force measurement sensor on the adjustable rod, and non-invasively assessing the level of this force over time.

[0043] FIG. **3** illustrates another embodiment of a system **30** that includes two pedicle screws **32**, **34** and a flexible body or spacer **36** that separates the two pedicle screws **32**, **34**. The flexible spacer **36** has at one end a magnetic element **38** that interfaces with a cord or rod **40** that extends within the flexible spacer **36**. Movement of the magnetic element **38** (e.g., rotation) in response to an applied external magnetic field sets the tensions of the cord or rod **40** and pedicle screws **32**, **34**. Thus, the tension of the cord or rod **40** as well as the flexible spacer **36** can be controlled in a non-invasive manner. The tension on the cord or rod **40** may be adjusted by the externally applied magnetic field, in order to limit or delimit the amount of motion.

[0044] FIG. **4**B illustrates another embodiment of a system **50** that includes an adjustable screw **52** with threads on opposing ends much in the manner of a Herbert screw (FIG. **4**A). The pitch of each threaded end is different from each other. In this embodiment, as seen in FIG. **4**B, a single adjustable screw **52** includes a moveable segment or portion **54** that moves axially relative to a second segment or portion **56**. An internal magnet **58** disposed in the adjustable screw **52** rotates in response to an applied external magnetic field thereby causing axial movement of the moveable segment **54** relative to the other portion **56**. For example, the adjustable screw **52** can increase in length (arrow B), thereby creating distraction between vertebral bodies. The degree of distraction (or compression) can be altered as needed. This system **50** may be used in conjunction with fusion applications where adjustment is needed to apply compression or other forces to the fused vertebra. This is also useful in two level procedures to adjust one or both levels as this is very difficult to control using current devices and methods.

[0045] FIG. **5** illustrates another embodiment of an artificial disc **60** that is adjustable in two directions. A significant effort has gone on into the development of artificial discs. A key design feature of almost all artificial discs is to mimic the natural motion of the spine. A critical feature of artificial discs is the center of rotation (COR) and where it is located. While much work has gone into precisely calculating the COR of implants, in practice, trying to place the artificial disc and lining up the COR is nearly impossible. Quite often the surgeon has missed placement, either lateral/medial and/or anterior/posterior. This misplacement is very difficult or impossible to correct.

[0046] There is a need post-implantation of an artificial disc to adjust the COR. FIG. **5** illustrates one such artificial disc **60** that includes an x-y adjustment feature built therein. The adjustment feature includes two orthogonal adjustment members **62**, **64** that are able to move the body of the artificial disc **60** in the x and y directions. The adjustment members may lengthen or shorten based on a rotational magnet **66** contained in each adjustment member. Application of an external magnetic field is able to adjust each adjustment member. Preferably, each adjustment member can be independently adjusted by a single external adjustment device.

[0047] Ideally, the adjustment would be done with the aid of a fluoroscope. The medial to lateral positioning is relatively straight forward and can be done while the patient is in a standing position. For the A/P positioning, the patient could go through flexion and extension motion and the surgeon can monitor the movement of the vertebra relative to the disc and adjust accordingly. This would ensure ideal alignment of the COR of the implant.

[0048] FIG. **6** illustrates a distraction device **302** configured for distraction between a first vertebral body **400** and a second vertebral body **402**. Intervertebral disks can degenerate, bulge, herniate or thin, and cause accompanying back pain. In this embodiment, the distraction device **302** is inserted between adjacent vertebral bodies **400**, **402** and using an external adjustment device (described below) is used to adjust the height of the distraction device **302** to the desired level. This distraction device **302** can distract the vertebral body (e.g., vertebral body **400**) to the correct height. Subsidence is a common problem resulting in the loss of disc height over time. After implantation, the distraction device **302** can be adjusted post-operatively using an external adjustment device to restore disc height. The adjustments may be performed intermittently or periodically as required. The adjustments are preferably made after implantation but prior to complete fusion of the affected vertebral bodies.

[0049] The distraction device **302** contains a first portion **307** and a second portion **309** and an internal, permanent magnet **304** that can be rotated in response to an applied external magnetic field via an external adjustment device **180** as seen in FIGS. **13** and **14**. internal magnet **304** is coupled to lead screw **306** so that rotation motion changes the displacement between lead screw **306** and the female thread **308** inside the first portion **307** of the distraction device **302** (although the configuration could be reversed). Rotation of the lead screw **306** in one direction causes the first portion **307** and the second portion **309** to separate from one another, thereby increasing the height between the same and the attached vertebral bodies **400**, **402**. Rotation of the lead screw **306** in the opposite direction causes the first portion **307** and the second portion **309** to move closer together, thereby decreasing the height between the same and the attached vertebral bodies **400**, **402**.

[0050] FIGS. **7** and **8** illustrate another embodiment of a distraction device **310**. This embodiment of the distraction device **310** is used for width adjustment. A wider interbody device provides better clinical results by providing additional stability and minimizing subsidence issues. In this embodiment, the distraction device **310** has a fixed height but can be distracted using an external adjustment device **180** like that seen in FIGS. **13** and **14** to provide a variable width. The distraction device **310** of FIGS. **7** and **8** is oriented between a first vertebral body **400** and a second vertebral body **402**, as best seen in FIG. **8**, and is generally perpendicular with the orientation of the device **302** of FIG. **6**. Distraction of the device **310** will expand the width

between the vertebral bodies **400**, **102**. Like the prior embodiment, there is a first portion **311** and a second portion **313** and an internal, permanent magnet **312** that can be rotated in response to an applied external magnetic field via an external adjustment device **180**. The internal magnet **312** is coupled to a lead screw **314** so that rotational motion changes displacement between lead screw **314** and a female thread **316** located inside the first portion **311** of the distraction device **310**. The distraction device **310** has a fixed height which provides for a small interbody implant to be inserted. However, the adjustability of the width of the distraction device **310** and the vertebral bodies **400**, **402** containing the same provides for increased stability. Also illustrated are pedicles **336**, **338** and the spinal canal **410**. The distraction device **310** generally distracts in a direction that is substantially perpendicular to the longitudinal axis of the spinal canal **410**.

[0051] FIG. **9** illustrates another embodiment of a system **330** that includes multiple distraction devices **332** for the selective and incremental expansion of the spinal canal **410**. In this embodiment, two distraction devices **332** are located within respective bores **334** formed in each pedicle **336**, **338** of a single vertebral body **400**. The bores **334** may be formed using conventional drilling tools and techniques. After the bores **334** have been formed, circumferential pedicle cuts **340** are made in each pedicle **336**, **338** (i.e., osteotomy). The circumferential pedicle cuts **340** are made by a rotating cutting tool such as a burr (not shown) that is placed within each bore **334**. The circumferential pedicle cuts **340**, once made, completely separate a portion of the vertebral body **400** from the respective pedicles **336**, **338**. The two distraction devices **332** are secured within the respective bores **334**. The distraction devices **332** may be secured using an adhesive, cement, threads that engage bone tissue or fasteners (e.g., screws or the like).

[0052] Utilizing the Ilizarov technique of bone lengthening, only a small gap in each pedicle **336**, **338** is left after installation of the distraction devices **332**. As the cut pedicles **336**, **338** begin to grow back together, each distraction device **332** is expanded incrementally at a rate of approximately one (1) millimeter per day. Each incremental expansion of the distraction devices **332** progressively opens up the spinal canal **410**. This is accomplished using the external adjustment device **180** described herein. The adjustments are performed while the subject is awake to provide feedback regarding symptom relief. For example, after adjustment, the subject may move his or her spine through one or more motions to determine the degree to which expansion of the spinal canal **410** has reduced discomfort or pain. Additional adjustments of the distraction devices **332** may be made daily or periodically until the spinal canal **410** has been opened up enough to provide the subject with the desired amount of pain or discomfort relief. As part of the periodic adjustment, the subject may go through one or more range of motions to give direct feedback on pain and discomfort levels. Once the desired endpoint has been reached, additional adjustments can be stopped, at which point the cut pedicles **336**, **338** will undergo a period of consolidation and fully form into a solid bone mass. FIG. **9** illustrates distraction devices **332** of the type illustrated in FIG. **12** secured within bores **34**, although other distraction devices **332** may be used in connection with the procedure.

[0053] FIG. **10** illustrates one embodiment of a distraction device **332** that includes a moveable segment or portion **342** that moves axially relative to a second segment or portion **344**. An axially-poled internal magnet **346** disposed in the distraction device **332** rotates in response to an applied external magnetic field thereby causing axial movement of the moveable segment **342** relative to the other portion **344**. The moveable segment **342** contains threads **343** on a portion thereof that interface with corresponding threads **345** disposed on the second portion **344**. Rotation of the moveable segment **42** relative to the second portion **44** results in axial displacement of the distraction device **332**. For example, the distraction device **332** can increase in length (arrow B), thereby creating a distraction force. The degree of distraction (or compression) can be altered as needed. Threads **348**, **350** are located at the respective ends of the moveable segment **342** and the second portion **344** which can be used to engage bone tissue.

[0054] FIG. **11** illustrates another embodiment of a distraction device **332**. The distraction device **332** includes first and second portions **352**, **354** that include respective recesses **356**, **358** that contain a rotatable, axially-poled permanent magnet **360**. The permanent magnet **360** is coupled to or may include a threaded portion **362** that engages with corresponding threads **364** in one of the first and second portions **352**, **354**. Rotation of the rotatable permanent magnet **360** extends the first and second portions **352**, **354** away from one another, thereby increasing the distraction force. As seen in FIG. **11**, the ends of the first and second portions **352**, **354** may include threads **366**, **368** which can be used to engage bone tissue within each bore **334**.

[0055] FIG. **12** illustrates another embodiment of a distraction device **332**. The distraction device **332** includes first and second portions **370**, **372** each having respective threads **374**, **376** at an end thereof for mounting the distraction device **332** within each bore **334** as described above. The first and second portions **370**, **372** include respective recesses **378**, **380** that contain a rotatable permanent magnet **382**. The permanent magnet **382** is coupled to or may include two threaded portions **384**, **386** that engage with corresponding threads **388**, **390** in the first and second portions **370**, **372**. In the embodiment of FIG. **12**, the distraction device **332** includes one or more guides **394** that extend between the first and second portions **370**, **372**. The guides **394** prevent relative rotation between the first and second portions **370**, **372** yet still permit elongation of the distraction device **332**. For example, a plurality of guides **394** could be located circumferentially about the first and second portions **370**, **372** to prevent relative rotation.

[0056] FIG. **13** illustrates an external adjustment device **180** which is used to non-invasively adjust the devices and systems described herein. The external adjustment device **180** includes a magnetic handpiece **178**, a control box **176** and a power supply **174**. The control box **176** includes a control panel **182** having one or more controls (buttons, switches or tactile, motion, audio or light sensors) and a display **184**. The display **184** may be visual, auditory, tactile, the like or some combination of the aforementioned features. The external adjustment device **180** may contain software which allows programming by the physician.

[0057] FIG. **14** shows the detail of the magnetic handpiece **178** of the external adjustment device **180**. As seen in FIG. **14**, there are two (2) magnets **186** that have a cylindrical shape. The magnets **186** are made from rare earth magnets. The magnets **186** are bonded or otherwise secured within

magnetic cups **187**. The magnetic cups **187** include a shaft **198** which is attached to a first magnet gear **212** and a second magnet gear **214**, respectively. The orientation of the poles of each the two magnets **186** are maintained in relation to each other by means of the gearing system (by use of center gear **210**, which meshes with both first magnet gear **212** and second magnet gear **214**).

[0058] The components of the magnetic handpiece **178** are held together between a magnet plate **190** and a front plate **192**. Most of the components are protected by a cover **216**. The magnets **186** rotate within a static magnet cover **188**, so that the magnetic handpiece **178** may be rested directly on the patient, while not imparting any motion to the external surfaces of the patient Prior to distracting the intramedullary lengthening device **110**, the operator places the magnetic handpiece **178** over the patient near the location of the cylindrical magnet **134**. A magnet standoff **194** that is interposed between the two magnets **186** contains a viewing window **196** to aid in the placement. For instance, a mark made on the patient's skin at the appropriate location with an indelible marker may be viewed through the viewing window **196**. To perform a distraction, the operator holds the magnetic handpiece **178** by its handles **200** and depresses a distract switch **228**, causing motor **202** to drive in a first direction. The motor **202** has a gear box **206** which causes the rotational speed of an output gear **204** to be different from the rotational speed of the motor **202** (for example, a slower speed). The output gear **204** then turns a reduction gear **208** which meshes with center gear **210**, causing it to turn at a different rotational speed than the reduction gear **208**. The center gear **210** meshes with both the first magnet gear **212** and the second magnet gear **214** turning them at a rate which is identical to each other. Depending on the portion of the body where the magnets **186** of the external adjustment device **180** are located, it is desired that this rate be controlled, to minimize the resulting induced current density imparted by magnet **186** and cylindrical magnet **134** though the tissues and fluids of the body. For example, a magnet rotational speed of 60 RPM or less is contemplated although other speeds may be used, such as 35 RPM or less. At any time, the distraction may be lessened by depressing the retract switch **230**. For example, if the patient feels significant pain, or numbness in the area holding the device.

[0059] FIGS. **15** and **16** illustrate the progression of the magnets **186** (individually numbered **1134** and **1136**) and the implanted magnet **1064** that is located within the distraction device during use. Implanted magnet **1064** is shown for illustration purposes. Implanted magnet **1064** is one possible embodiment of the magnetic element described herein. FIGS. **15** and **16** illustrate the external adjustment device **180** being disposed against the external surface of the patient's skin **1180** adjacent the spine. In the non-invasive adjustment procedure depicted, the patient **100** lies in a prone position, and the external adjustment device **180** is placed upon the patient's back. However, the adjustment is conceived possible with the patient in supine or standing positions. The external adjustment device **180** is placed against the skin **1180** in this manner to remotely rotate the implanted magnet **1064**. As explained herein, rotation of the implanted magnet **1064** is translated into linear motion to controllably adjust the distraction device.

[0060] As seen in FIGS. **15** and **16**, the external adjustment device **180** may be pressed down on the patient's skin **1180** with some degree of force such that skin **1180** and other tissue, such as the underlying layer of fat **1182**, are pressed or forced into the recess **1174** of the external adjustment device **180**. FIGS. **15** and **16** show the magnetic orientation of the implanted magnet **1064** as it rotates in response to rotation of the permanent magnets **1134**, **1136** of the external adjustment device **180**.

[0061] With reference to FIG. **15**, the implanted magnet **1064** is shown being oriented with respect to the two permanent magnets **1134**, **1136** via an angle θ. This angle θ may depend on a number of factors including, for instance, the separation distance between the two permanent magnets **1134**, **1136**, the location or depth of where the implanted magnet **1064** is located, the degree of force at which the external adjustment device **180** is pushed against the patient's skin. Generally, in applications including some obese patients, the angle θ should be at or around 90° to achieve maximum drivability (e.g., torque).

[0062] FIG. **15** illustrates the initial position of the two permanent magnets **1134**, **1136** and the implanted magnet **1064**. This represents the initial or starting location (e.g., 0° position as indicated). Of course, it should be understood that, during actual use, the particular orientation of the two permanent magnets **1134**, **1136** and the implanted magnet **1064** will vary and likely will not have the starting orientation as illustrated in FIG. **15**. In the starting location illustrated in FIG. **15**, the two permanent magnets **1134**, **1136** are oriented with their poles in an N-S/S-N arrangement. The implanted magnet **1064** is, however, oriented generally perpendicular to the poles of the two permanent magnets **1134**, **1136**.

[0063] FIG. **16** illustrates the orientation of the two permanent magnets **1134**, **1136** and the implanted magnet **1064** after the two permanent magnets **1134**, **1136** have rotated through 90°. The two permanent magnets **1134**, **1136** rotate in the direction of arrow A (e.g., clockwise) while the implanted magnet **1064** rotates in the opposite direction (e.g., counter clockwise) represented by arrow B. It should be understood that the two permanent magnets **1134**, **1136** may rotate in the counter clockwise direction while the implanted magnet **1064** may rotate in the clockwise direction.

[0064] During operation of the external adjustment device **180**, the permanent magnets **1134**, **1136** may be driven to rotate the implanted magnet **1064** through one or more full rotations in either direction to increase or decrease distraction of the device as needed. Of course, the permanent magnets **1134**, **1136** may be driven to rotate the implanted magnet **1064** through a partial rotation as well (e.g., ¼, ⅛, 1/16, etc.). The use of two magnets **1134**, **1136** is preferred over a single external magnet because the implanted magnet **1064** may not be oriented perfectly at the start of rotation, so one external magnet **1134**, **1136** may not be able to deliver its maximum torque, which depends on the orientation of the internal driven magnet **1064** to some degree. However, when two (2) external magnets (**1134**, **1136**) are used, one of the two, **1134** or **1136**, will have an orientation relative to the internal driven magnet **1064** that is better or more optimal than the other. In addition, the torques imparted by each external magnet **1134**, **1136** are additive.

[0065] While embodiments of the present invention have been shown and described, various modifications may be made without departing from the scope of the present invention. As one example, the devices described herein may be used to lengthen or reform a number of other bones

such as the mandible or the cranium. The invention, therefore, should not be limited, except to the following claims, and their equivalents.

1. An adjustable screw comprising:
a stationary portion having a proximal end and a distal end;
a moveable portion having a proximal end and a distal end, the proximal end of the moveable portion coupled to the proximal end of the stationary portion to form an elongate screw body;
an internal magnet disposed in the proximal end of the moveable portion and configured to rotate in response to an applied external magnetic field, causing axial movement of the moveable portion relative to the stationary portion.

2. The adjustable screw of claim **1**, wherein the distal end of the stationary portion comprises threads and the distal end of the moveable portion comprises threads.

3. The adjustable screw of claim **2**, wherein the threads on the distal end of the stationary portion have a pitch that is different than a pitch of the threads of the distal end of the moveable portion.

4. The adjustable screw of claim **1**, wherein, when the applied external magnetic field causes the internal magnet to rotate in a first direction, the moveable portion moves axially relative to the stationary portion such that a distance between the distal end of the moveable portion and the distal end of the stationary portion increases.

5. The adjustable screw of claim **1**, wherein, when the applied external magnetic field causes the internal magnet to rotate in a second direction, the moveable portion moves axially relative to the stationary portion such that a distance between the distal end of the moveable portion and the distal end of the stationary portion decreases.

6. The adjustable screw of claim **1**, wherein the adjustable screw is used for a spinal fusion and the adjustable screw is used to apply compression to adjacent vertebrae.

7. The adjustable screw of claim **1**, wherein the adjustable screw is used for a two-level spinal fusion.

8. An adjustable screw system comprising:
an external adjustment device; and
an adjustable screw comprising:
a stationary portion having a proximal end and a distal end;
a moveable portion having a proximal end and a distal end, the proximal end of the moveable portion coupled to the proximal end of the stationary portion to form an elongate screw body; and
an internal magnet disposed in the proximal end of the moveable portion and configured to rotate in response to an external magnetic field applied by the external adjustment device, causing axial movement of the moveable portion relative to the stationary portion.

9. The adjustable screw system of claim **8**, wherein the distal end of the stationary portion comprises threads and the distal end of the moveable portion comprises threads.

10. The adjustable screw system of claim **9**, wherein the threads on the distal end of the stationary portion have a pitch that is different than a pitch of the threads of the distal end of the moveable portion.

11. The adjustable screw system of claim **8**, wherein, when the external magnetic field causes the internal magnet to rotate in a first direction, the moveable portion moves axially relative to the stationary portion such that a distance between the distal end of the moveable portion and the distal end of the stationary portion increases.

12. The adjustable screw system of claim **8**, wherein, when the external magnetic field causes the internal magnet to rotate in a second direction, the moveable portion moves axially relative to the stationary portion such that a distance between the distal end of the moveable portion and the distal end of the stationary portion decreases.

13. The adjustable screw system of claim **8**, wherein the adjustable screw is used for a spinal fusion and the adjustable screw is used to apply compression to adjacent vertebrae.

14. The adjustable screw system of claim **8**, wherein the adjustable screw is used for a two-level spinal fusion.

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