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(54) **Title**: VERTEBRAL ROD SYSTEM AND METHODS OF USE

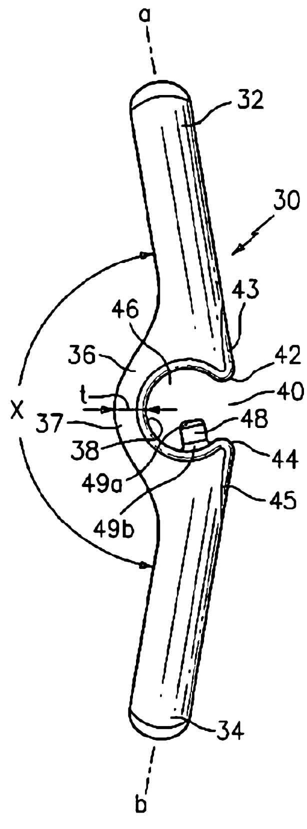

FIG. 3

(57) **Abstract**: A vertebral rod is provided having a first elongated section and a second elongated section. An intermediate section is disposed between the first section and the second section. The intermediate section has an inner surface that defines a first locking part. A resistance member has an exterior surface that defines a second locking part configured for engagement with the first locking part such that the resistance member is fixed with and engaging at least a portion of the inner surface.

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VERTEBRAL ROD SYSTEM AND METHODS OF USE

BACKGROUND

Spinal disorders such as degenerative disc disease, disc herniation, osteoporosis, spondylolisthesis, stenosis, scoliosis and other curvature abnormalities, kyphosis, tumor, and fracture may result from factors including trauma, disease and degenerative conditions caused by injury and aging. Spinal disorders typically result in symptoms including pain, nerve damage, and partial or complete loss of mobility.

Non-surgical treatments, such as medication, rehabilitation and exercise can be effective, however, may fail to relieve the symptoms associated with these disorders. Surgical treatment of these spinal disorders include discectomy, laminectomy, fusion and implantable prosthetics. As part of these surgical treatments, connecting elements such as vertebral rods are often used to provide stability to a treated region. During surgical treatment, one or more rods may be attached to the exterior of two or more vertebral members.

Rods redirect stresses away from a damaged or defective region while healing takes place to restore proper alignment and generally support the vertebral members. In some applications, rods are attached to the vertebral members without the use of implants or spinal fusion. Flexible connecting elements are also known that permit limited spinal motion of a spinal motion segment. Such flexible connecting elements can provide dynamic spinal support. While prior connecting elements have attempted to provide effective spinal stabilization, there remains a need for connecting elements that provide a dynamic stabilizing resistance to forces and permit motion of a spinal column segment(s) in flexion and extension while effectively stabilizing the spinal column segment(s) and the structural integrity of the connecting element.

Therefore, it would be desirable to provide a dynamic vertebral rod system, having flexion and extension capability, which provides stability while reducing stress on spinal elements. Desirably, the vertebral rod system includes a resistance member that provides resistance to motion and stress on the vertebral rod. It would be most desirable if the vertebral rod system includes a tension element to resist motion and stress. It would be highly desirable if characteristics such as rod stiffness, range of motion and fatigue strength of the system are adjustable.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present disclosure as it existed before the priority date of each claim of this application.

SUMMARY OF THE INVENTION

Accordingly, a dynamic vertebral rod system is provided, having flexion and extension capability, which provides stability while reducing stress on spinal elements. Desirably, the vertebral rod system includes a resistance member that provides resistance to motion and stress on the vertebral rod. It is contemplated that the vertebral rod system includes a tension element to resist motion and stress. It is further contemplated that characteristics such as rod stiffness, range of motion and fatigue strength of the vertebral rod system are adjustable. It is envisioned that the disclosed system may be employed as a posterior, anterior and/or lateral dynamic stabilization device. The components of the vertebral rod system are easily manufactured and assembled.

In one embodiment, there is provided a vertebral rod comprising: a first elongated section extending between a first end and a second end; a second elongated section extending between a first end and a second end, the second ends of the first and second sections being spaced apart from one another; an intermediate section disposed between the first section and the second section, the intermediate section having an inner surface that defines a first locking part, the inner surface defining a cavity comprising an opening between the second ends of the first and second sections; and a resistance member having an exterior surface that defines a second locking part configured for engagement with the first locking part such that the resistance member is fixed with and engaging at least a portion of the inner surface; wherein the cavity of the intermediate section has a maximum width that is greater than a width of the opening in the cavity, and wherein, when the second locking part is engaged with the first locking part, the resistance member substantially prevents closure of the opening of the cavity.

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In another embodiment, there is provided a vertebral rod comprising: a first elongated section extending between a first end and a second end; a second elongated section extending between a first end and a second end, the second section including at least a portion thereof having an arcuate configuration that defines a radius of curvature in a range of 20-400 mm; a flexible intermediate section disposed between the first section and the second section, the intermediate section having an arcuate inner surface that defines a cavity, the cavity comprising an opening between the second ends of the first and second sections, and that defines a locking part; and a bumper disposed within the cavity that provides increasing resistance to movement of the first and second sections from a first orientation, the bumper having an exterior surface that engages the locking part to retain the bumper in the cavity; wherein the cavity of the intermediate section has a maximum width that is greater than a width of the opening in the cavity, and wherein the bumper substantially prevents closure of the opening of the cavity.

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

In one embodiment, the vertebral rod system includes a dynamic vertebral rod with flexion and extension capabilities and methods of use. The vertebral rod includes upper and lower sections that are separated by a relatively flexible intermediate section. The intermediate section includes one or more members, and may have a variety of configurations to provide greater flexibility than the upper and lower sections. An elastic resistance member may be positioned within the intermediate section. The intermediate section and/or the elastic resistance member provide for variable resistance during movement of the upper and lower sections.

In an alternate embodiment, the resistance increases as the upper and lower sections move from a first orientation to a second orientation, which may include a load or forces applied to the sections in flexion and/or extension. In another embodiment, the extent of movement of the upper and lower sections is limited. The rod can be made of various materials including metals, polymers, ceramics and/or their composites. The elastic resistance member can be made of various polymers including silicone, polyurethane, silicone-polyurethane, polymeric rubbers and hydrogels.

In another embodiment, the rod is formed of a thermoplastic resin such as polyetheretherketone (PEEK), PEK, carbon-PEEK composite, PEEK-$BaSO_4$ and has a curved and flexible intermediate section encasing a polyurethane bumper. The upper and lower sections of the PEEK rod may be oval or round in cross-section. The intermediate section has a C-shape with the upper and lower sections connected near an open end of the intermediate section such that the overall length of the rod increases in spinal flexion and decreases in spinal extension.

In another alternate embodiment, a tension band such as a cable, tether, sleeve and/or jacket may be used to connect the upper and lower sections to limit motion and stress to the intermediate section in spinal extension. Rod stiffness, range of motion and fatigue strength can be adjustable. Other variations in rod configurations and materials are also contemplated to achieve similar flexion-extension capabilities.

In one embodiment, the vertebral rod can be manufactured via injection molding using a PEEK material and injection molding the bumper using a polyurethane material. Assembly includes inserting the bumper into the rod.

In an alternate embodiment, the intermediate section may be modified to modulate or change its stiffness or compliance, to correspondingly alter similar characteristics of the rod. Such modifications can include modifying the thickness of the cross-section of the rod; modifying the shape or profile of a particular cross-section of the rod; defining particular patterns in a surface of the rod such as a wave (or peak/valley), grooves, bumps, ribs, ridges; applying thermal treatment(s) to the rod; increasing resistance reinforcement of the rod with a tension band, tether or a cable. It is contemplated that the bumper can be of various sizes or shapes, such as cylindrical, spherical, rectangular or other regular or irregular shapes. It is further contemplated that the bumper can be fabricated from materials including polymers, elastomers, metals or ceramics or combinations thereof. Alternatively, the bumper can be solid, porous and may be designed to include patterns to modify modulus, stiffness or compliance. Various structure for securing the bumper with the rod are also contemplated, such as non-locking screws or other features.

Alternatively, the vertebral rod system can include a non-locking multi-axial screw and a rod having sections with end stops, which allow the vertebral rod to slide within the screw under flexion-extension motion to cooperate with the flexion/bending of the rod. The non-locking screw provides an anti-disengagement or non-slip out of the rod from the screw. Other anti-disengagement configurations, such as a longer end-cap, an end bumper, or stoppers to limit sliding or prevent the rod from slipping off the screw are also envisioned.

The rod may have an angled orientation or curvature and multiple/variable rod lengths to provide topping-off or trimming during surgery. It is envisioned that parameters of the rod system such as rod stiffness can be altered by modifying rod and/or bumper parameters such as material, material modulus, thickness, profile, component design and porosity. Accordingly, the vertebral rod system may be modular and/or adjustable by providing variable rod stiffness and/or bumper stiffness. It is contemplated that the rod has a static shear strength capable of resisting forces of at least 100 newtons (N), preferably at least 200N, and most preferably at least 400N, applied to the rod, with a rod deflection of at least 2 millimeters (mm), preferably at least 5mm, and at least 10mm without failure.

In one particular embodiment, in accordance with the principles of the present disclosure, a vertebral rod system is provided. The vertebral rod system includes a vertebral rod having a first elongated section, a second elongated section and an intermediate section disposed between the first section and the second section. The intermediate section has an inner surface that defines a first locking part. A resistance member has an exterior surface that defines a second locking part configured for engagement with the first locking part such that the resistance member is fixed with and engaging at least a portion of the inner surface. The first section may define a longitudinal axis disposed at an angle of less than 180 degrees from a longitudinal axis defined by the second section.

The intermediate section can be flexible relative to the first and second sections, and configured to provide variable resistance to movement of the first and second sections. The resistance member may be elastic and configured to provide variable resistance to movement of the first and second sections. The intermediate section may define an arcuate inner surface, the resistance member being configured to engage substantially all of the inner surface. The intermediate section may have a C-shaped configuration defining a correspondingly shaped inner surface and an open end, whereby the resistance member is configured to prevent and resist closing of the open end.

The first locking part can be a post projecting from the inner surface and the second locking part is an opening, such that the post is configured for mounting with the opening. The intermediate section can define an arcuate shape that includes a plurality of grooves disposed about a circumference thereof. The first section may have a first dimension of length and the second section has a second, greater dimension of length.

Alternatively, the vertebral rod system includes a tension element disposed about the first section and the second section for connection therebetween in a configuration to limit movement of the first and second sections. The tension element has an elongated band configuration including a first loop portion disposed about the first section and a second loop portion disposed about the second section.

In an alternate embodiment, the vertebral rod includes a first elongated section defining a first longitudinal axis. The second elongated section defines a second longitudinal axis and has at least a portion thereof with an arcuate configuration that defines a radius of curvature in a range of 20-400 mm. A flexible intermediate section is disposed between the first section and the second section. The intermediate section has an arcuate inner surface that defines a cavity and includes a locking part. A bumper is mounted with the locking part and is disposed within the cavity for engagement with the inner surface in a configuration that provides increasing resistance to movement of the first and second sections from the first orientation.

In another alternate embodiment, a vertebral rod system for attachment to vertebrae is provided. The system includes a vertebral rod having a first elongated section, a second elongated section and a flexible intermediate section disposed between the first section and the second section. The intermediate section has an inner surface that defines a cavity and includes a first locking part. A resistance member is disposed within the cavity having an exterior surface disposed for engagement with the inner surface. The exterior surface defines a second locking part configured for engagement with the first locking part such that the resistance member is fixed with the inner surface. A first fastening element is configured to attach the first section to vertebrae and a second fastening element is configured to attach the second section to adjacent vertebrae. The vertebral rod is configured to provide increasing resistance to movement of the first and second sections during flexion and extension of vertebrae from a first orientation.

The first fastening element may define a cavity configured for movable support of the first section. The first section includes a stop configured to prevent disengagement of the first section from the first fastening element. The second section can extend a length greater than the first section such that the second section extends across at least two intervertebral levels associated with the vertebrae, whereby the second fastening element and the third fastening element are configured to attach the second section to the vertebrae.

The vertebral rod system can include an elongated tension band disposed about the sections and including a first loop portion disposed about the first section and a second loop portion disposed about the second section in a configuration to limit movement of the sections from the first orientation.

BRIEF DESCRIPTION OF THE DRAWINGS

The present disclosure will become more readily apparent from the specific description accompanied by the following drawings, in which:

FIG. 1 is a perspective view of one particular embodiment of the vertebral rod system in accordance with the principles of the present disclosure;

FIG. 2 is a perspective view of a vertebral rod of the vertebral rod system shown in FIG. 1;

FIG. 3 is a side plan view of the vertebral rod shown in FIG. 2;

FIG. 4 is a perspective view of a resistance member of the vertebral rod system shown in FIG. 1;

FIG. 5 is a side, cross-section view of the resistance member taken along line 5-5 in FIG. 4;

FIG. 6 is a perspective view of a vertebral rod system of the present disclosure attached to vertebrae;

FIG. 7 is a lateral section view of the vertebral rod system of the present disclosure attached to vertebrae illustrating rod movement;

FIG. 8 is a side view of an alternate embodiment of the vertebral rod shown in FIG. 2;

FIG. 9 is a front view of another alternate embodiment of the vertebral rod shown in FIG. 2;

FIG. 10 is a side view of another alternate embodiment of the vertebral rod shown in FIG. 2;

FIG. 11 is a lateral section view of an alternate embodiment of the vertebral rod system employing the vertebral rod shown in FIG. 10 attached to vertebrae;

FIG. 12 is a side view of another alternate embodiment of the vertebral rod shown in FIG. 2;

FIG. 13 is a front view of an alternate embodiment of the vertebral rod shown in FIG. 11;

FIG. 14 is a side view of another alternate embodiment of the vertebral rod shown in FIG. 2;

FIG. 15 is a side view of another alternate embodiment of the vertebral rod shown in FIG. 2;

FIG. 16 is a side view of another alternate embodiment of the vertebral rod shown in FIG. 2;

FIG. 17 is a perspective view of another alternate embodiment of the vertebral rod shown in FIG. 2;

FIG. 18 is a perspective view of an alternate embodiment of the resistance member shown in FIG. 4;

FIG. 19 is a perspective view of another alternate embodiment of the resistance member shown in FIG. 4;

FIG. 20 is a perspective view of another alternate embodiment of the resistance member shown in FIG. 4;

FIG. 21 is a perspective view of another alternate embodiment of the resistance member shown in FIG. 4;

FIG. 22 is a lateral section view of an alternate embodiment of the vertebral rod system attached to vertebrae;

FIG. 23 is a side view of an alternate embodiment of the vertebral rod system employing the vertebral rod shown in FIG. 8;

FIG. 24 is a front view of the vertebral rod system shown in FIG. 23;

FIG. 25 is a side view of an alternate embodiment of the vertebral rod system employing the vertebral rod shown in FIG. 8;

FIG. 26 is a front view of the vertebral rod system shown in FIG. 25;

FIG. 27 is a side view of an alternate embodiment of the vertebral rod system employing the vertebral rod shown in FIG. 8;

FIG. 28 is a front view of the vertebral rod system shown in FIG. 27; and

FIGS. 29 – 43 are side views of alternate embodiments of locking parts of the vertebral rod system, in accordance with the principles of the present disclosure.

Like reference numerals indicate similar parts throughout the figures.

DETAILED DESCRIPTION OF THE INVENTION

The exemplary embodiments of the vertebral rod system and methods of use disclosed are discussed in terms of medical devices for the treatment of spinal disorders and more particularly, in terms of a dynamic vertebral rod system having flexion and extension capability. It is envisioned that the vertebral rod system and methods of use disclosed provide stability and maintains structural integrity while reducing stress on spinal elements. It is envisioned that the present disclosure may be employed to treat spinal disorders such as, for example, degenerative disc disease, disc herniation, osteoporosis, spondylolisthesis, stenosis, scoliosis and other curvature abnormalities, kyphosis, tumor and fractures. It is further envisioned that the present disclosure may be employed with surgical treatments including open surgery and minimally invasive procedures, of such disorders, such as, for example, discectomy, laminectomy, fusion, bone graft and implantable prosthetics. It is contemplated that the present disclosure may be employed with other osteal and bone related applications, including those associated with diagnostics and therapeutics. It is further contemplated that the disclosed vertebral rod system may be employed in a surgical treatment with a patient in a prone or supine position, employing a posterior, lateral or anterior approach. The present disclosure may be employed with procedures for treating the lumbar, cervical, thoracic and pelvic regions of a spinal column.

The present invention may be understood more readily by reference to the following detailed description of the invention taken in connection with the accompanying drawing figures, which form a part of this disclosure. It is to be understood that this invention is not limited to the specific devices, methods, conditions or parameters described and/or shown herein, and that the terminology used herein is for the purpose of describing particular embodiments by way of example only and is not intended to be limiting of the claimed invention. Also, as used in the specification and including the appended claims, the singular forms "a," "an," and "the" include the plural, and reference to a particular numerical value includes at least that particular value, unless the context clearly dictates otherwise. Ranges may be expressed herein as from "about" or "approximately" one particular value and/or to "about" or "approximately" another particular value. When such a range is expressed, another embodiment includes from the one particular value and/or to the other particular value. Similarly, when values are expressed as approximations, by use of the antecedent "about," it will be understood that the particular value forms another embodiment.

The following discussion includes a description of a vertebral rod system, related components and exemplary methods of employing the vertebral rod system in accordance with the principles of the present disclosure. Alternate embodiments are also disclosed. Reference will now be made in detail to the exemplary embodiments of the present disclosure, which are illustrated in the accompanying figures. Turning now to FIGS. 1-5, there is illustrated components of a vertebral rod system in accordance with the principles of the present disclosure.

The components of the vertebral rod system are fabricated from materials suitable for medical applications, including metals, polymers, ceramics, biocompatible materials and/or their composites, depending on the particular application and/or preference of a medical practitioner. For example, a vertebral rod of the vertebral rod system can be fabricated from materials such as titanium, thermoplastics such as polyaryletherketone (PAEK) including PEEK and PEK, carbon-PEEK composites, PEEK-$BaSO_4$ polymeric rubbers, biocompatible materials such as polymers including plastics, metals, ceramics and composites thereof, rigid polymers including polyphenylene, polyamide, polyimide, polyetherimide, polyethylene, epoxy; and different sections of the rod may have alternative material composites to achieve various desired characteristics such as strength, rigidity, elasticity, compliance biomechanical performance, durability and radiolucency or imaging preference. As a further example, a resistance member of the vertebral rod system may be fabricated from materials such as silicone, polyurethane, silicone-polyurethane, copolymers, polymeric rubbers, polyolefin rubbers, hydrogels, semi-rigid and rigid materials, and biocompatible materials such as elastomers, rubbers, thermoplastic elastomers, thermoset elastomers, elastomeric composites and plastics. One skilled in the art, however, will realize that such materials and fabrication methods suitable for assembly and manufacture, in accordance with the present disclosure, would be appropriate.

The vertebral rod system is configured for attachment to vertebrae (as shown, for example, in FIG. 6) during surgical treatment of a spinal disorder, examples of which are discussed herein. The vertebral rod system has a vertebral rod 30, which includes a first elongated section, such as, for example, upper section 32 that defines a longitudinal axis a. A second elongated section, such as, for example, lower section 34 defines a longitudinal axis b.

An intermediate section 36 is connected with sections 32, 34 and disposed therebetween as a joining section of the components of vertebral rod 30. It is envisioned that the components of vertebral rod 30 may be monolithically formed, integrally connected or arranged with attaching elements. Intermediate section 36 is flexible relative to sections 32, 34, and is configured to provide resistance to movement of sections 32, 34. It is envisioned that intermediate section 36 may provide increasing, variable, constant and/or decreasing resistance. It is contemplated that sections 32, 34, 36 can be variously dimensioned, for example, with regard to length, width, diameter and thickness. It is further contemplated that the respective cross-section of sections 32, 34, 36 may have various configurations, for example, round, oval, rectangular, irregular, uniform and non-uniform. Section 32 may have a different cross-sectional area, geometry, material or material property such as strength, modulus or flexibility relative to section 34.

Intermediate section 36 may have a variable thickness *t* (FIG. 3) according to the requirements of the particular application. It is envisioned that thickness *t* of intermediate section 36 may be in a range of 1-10 mm, preferably in a range of 2-8 mm, and most preferably in a range of 3-5 mm . It is further envisioned that the cross-sectional geometry or area of intermediate section 36 can be uniform, non-uniform, consistent or variable.

It is envisioned that intermediate section 36 may be configured as a flexible joint having a wide, narrow, round or irregular configuration. It is further envisioned that intermediate section 36 can be variously configured and dimensioned with regard to size, shape, thickness, geometry and material. Intermediate section 36 may also have one or a plurality of elements connecting sections 32, 34 such as spaced apart portions, staggered patterns and mesh. Intermediate section 36 may be fabricated from the same or alternative material to sections 32, 34. Intermediate section 36 may also have a different cross-sectional area, geometry or material property such as strength, modulus and flexibility relative to sections 32, 34. Intermediate section 36 may be connected to sections 32, 34 using various methods and structure including molding of a continuous component, mechanical fastening, adhesive bonding and combinations thereof. It is envisioned that intermediate section 36 has a flexible hinge configuration, which can be offset forward or backward relative to a central axis of rod 30 to modify the flexibility or stiffness of the vertebral rod system. It is further envisioned that particular parameters may be selected to modulate the flexibility or stiffness of the vertebral rod system including the cross-sectional area (or thickness) of intermediate section 36, material modulus that may correlate to the hardness of bumper 50 discussed below, modification of porosity in a range of 0 – 30 percent which may include modification of void volume in a range of 10 microns – 1mm, as well as rod material properties. These parameters allow modification of the properties or performance of the vertebral rod system such as strength, durability, flexibility (or stiffness), overall profile and the ability to employ a percutaneous approach, for a particular application.

Intermediate section 36 includes a flexible joint member 37, which has a C-shaped configuration and defines a corresponding shaped arcuate inner surface 38 and an open end 40. It is contemplated that joint member 37 may have alternative configurations such as U-shaped, V-shaped or W-shaped. It is further contemplated that vertebral rod 30 may include one or a plurality of intermediate sections 36 spaced along the length of rod 30. In embodiments including a plurality of sections 36, the multiple sections 36 may be disposed in similar, or alternative orientations such as aligned, non-aligned, offset, open end facing or not facing vertebrae and alternate angular orientation.

Upper section 32 is disposed adjacent to an upper portion 42 of open end 40 and the transition defines a front face 43. Lower section 34 is disposed adjacent a lower portion 44 and the transition defines a front face 45. Inner surface 38 defines a cavity 46 and a first locking part, such as, for example, a post 48. Post 48 has a first portion 49a, which is cylindrical, and a second portion 49b, which has an increasing diameter as post 48 transitions into surface 38, as shown in FIG. 3.

Cavity 46 is configured for disposal of a resistance member, such as, for example, a bumper 50, as shown in FIGS. 4 and 5. Bumper 50 has an exterior surface 52 that defines a second locking part, such as, for example, an opening 54. Opening 54 has a first portion 55a configured for receipt of portion 49a, and a second portion 55b having an increasing diameter and being configured for receipt of portion 49b. Opening 54 receives post 48 for fixed mounting of bumper 50 with vertebral rod 30 to lock these components of the vertebral rod system in place. It is contemplated that portions 49a, 49b may be variously configured and dimensioned, and portions 55a, 55b correspondingly configured and dimensioned for reception thereof. Portions 49a, 49b may be uniform in configuration and dimension. It is envisioned that the first locking part may include one or a plurality of elements, may be variously disposed about intermediate section 36, or employ fastening elements and adhesives, with the second locking part being correspondingly configured for engagement therewith.

Bumper 50 is elastic and configured to provide variable resistance to movement of sections 32, 34 and 36. It is contemplated that bumper 50 can provide increasing, variable, constant and/or decreasing resistance. Bumper 50 is disposed within cavity 46 and engages surface 38 in a close fitting engagement. Bumper 50 can be variously configured with regard to size, shape, for example, round, oblong, rectangular, triangular, spherical, and irregular shapes. It is envisioned that bumper 50 has a hardness in the range of 20 Shore A to 55 Shore D, and preferably between 70 and 90 Shore A. The material of bumper 50 can be solid or porous, homogeneous or heterogeneous, single polymer or a blend/composite of more than one polymer. It is contemplated that the resiliency of bumper 50 can prevent creep and improve shape recovery of the vertebral rod system. It is envisioned that bumper 50 is configured to prevent and/or resist closing of open end 40. Bumper 50 can be inserted with cavity 46 for assembly, or formed in situ by, for example, a pouch, bag or balloon with the bumper configuration being inserted into cavity 46 and injected with a curable material.

In a first orientation of vertebral rod 30, longitudinal axis a is disposed at an angle x relative to longitudinal axis b about joint member 37, as shown in FIG. 3. Angle x is desirably in a range of 135 degrees to less than 180 degrees, and most desirably in a range of 150 degrees to 160 degrees. Angle x may be equal to 180 degrees. It is contemplated that in the first orientation, no flexion or extension forces are applied to vertebral rod 30. As sections 32, 34, 36 move to a second orientation from the first orientation, flexion and/or extension forces are applied to vertebral rod 30. As such, bumper 50 engagingly interacts with intermediate section 36 in a configuration that provides increasing resistance to movement of sections 32, 34 from the first orientation to the second orientation. Movement of the components of the vertebral rod system between one or a plurality of orientations is contemplated and may include a range of increasing and decreasing levels of resistance of the components of the vertebral rod system.

In assembly, operation and use, the vertebral rod system is employed with a surgical procedure for treatment of a spinal disorder affecting a section of a spine of a patient, as discussed herein. The vertebral rod system may also be employed with other surgical procedures. In particular, the vertebral rod system is employed with a surgical procedure for treatment of a condition or injury of an affected section of the spine including vertebrae V, as shown in FIGS. 6 and 7. It is contemplated that the vertebral rod system is attached to vertebrae V for dynamic stabilization of the affected section of the spine to facilitate healing and therapeutic treatment, while providing flexion and extension capability.

In use, to treat the affected section of the spine, a medical practitioner obtains access to a surgical site including vertebra V in any appropriate manner, such as through incision and retraction of tissues. It is envisioned that the vertebral rod system may be used in any existing surgical method or technique including open surgery, mini-open surgery, minimally invasive surgery and percutaneous surgical implantation, whereby the vertebrae V is accessed through a micro-incision, or sleeve that provides a protected passageway to the area. Once access to the surgical site is obtained, the particular surgical procedure is performed for treating the spinal disorder. The vertebral rod system is then employed to augment the surgical treatment. The vertebral rod system can be delivered or implanted as a pre-assembled device or can be assembled in situ. The vertebral rod system may be completely or partially revised, removed or replaced, for example, replacing bumper 50 only, replacing rod 30 and bumper 50 and using the in-place fastening elements.

A first fastening element, such as, for example, fixation screw assembly 70 is configured to attach upper section 32 to vertebra V_1. A second fastening element, such as, for example, fixation screw assembly 71 is configured to attach lower section 34 to adjacent vertebra V_2. Pilot holes are made in vertebrae V_1, V_2 for receiving fixation screw assemblies 70, 71. Fixation screw assemblies 70, 71 include threaded bone engaging portions 72 that are inserted or otherwise connected to vertebrae V_1, V_2, according to the particular requirements of the surgical treatment. Fixation screw assemblies 70, 71 each have a head 74 with a bore, or through opening and a set screw 76, which is torqued on to sections 32, 34 to attach rod 30 in place with vertebrae V, as will be described.

As shown in FIG. 6, the vertebral rod system includes two axially aligned and spaced rods 30, with portions of sections 32, 34 extending through the bores of heads 74. Set screws 76 of each head 74 are torqued on the end portions of rods 30 to securely attach rods 30 with vertebrae V_1, V_2. Upon fixation of the vertebral rod system with vertebrae V, vertebral rod 30 is configured to provide increasing resistance to movement of sections 32, 34 during flexion and extension of the spine. For example, vertebral rod 30, as shown in FIG. 7A, is in an unloaded state, which corresponds to the first orientation discussed above, where there is no appreciable tensile or compressive loads on vertebrae V_1, V_2. In flexion and/or extension of vertebrae V caused by corresponding movement of the patient, rod 30 reacts with increasing resistance during movement of rod 30 to a second, third or more orientation(s).

In flexion, as shown in FIG. 7B, upper section 32 moves relative to section 34, in the direction of arrow F. Joint member 37 flexibly expands circumferentially about bumper 50 such that intermediate section 36 compresses bumper 50. This configuration increases resistance during flexion. In extension, as shown in FIG. 7C, upper section 32 moves relative to section 34, in the direction shown by arrow E. Joint member 37 flexibly compresses circumferentially about bumper 50. Inner surface 38 adjacent bumper 50 is in tension and the opposing edge of joint member 37 is in compression such that joint member 37 does not significantly compress bumper 50. Resistance is increased during extension. The increase of resistance during flexion and extension provides limited movement of vertebrae V for dynamic stabilization of the treated area of the spine.

The vertebral rod system can be used with various bone screws, pedicle screws or multi-axial screws (MAS) used in spinal surgery. It is contemplated that the vertebral rod system may be used with pedicle screws coated with an osteoconductive material such as hydroxyapatite and/or osteoinductive agent such as a bone morphogenic protein for enhanced bony fixation to facilitate motion of the treated spinal area. Rod 30 and bumper 50 can be made of radiolucent materials such as polymers. Radiomarkers may be included for identification under x-ray, fluoroscopy, CT or other imaging techniques. Metallic or ceramic radiomarkers, such as tantalum beads, tantalum pins, titanium pins, titanium endcaps and platinum wires can be used, such as being disposed at the end portions of rod 30 and/or along the length thereof adjacent joint member 37 or with bumper 50.

Referring to FIG. 8, in an alternate embodiment of vertebral rod 30, similar to that described with regard to FIGS. 1-3, upper section 32 and lower section 34 are disposed in an orientation such that longitudinal axis *a* is disposed at an angle *z* relative to longitudinal axis *b* about open end 40. Angle *z* is desirably in a range of 135 degrees to less than 180 degrees, and most desirably in a range of 150 degrees to 160 degrees. Angle z may be equal to 180 degrees. Referring to FIG. 9, in another alternate embodiment of vertebral rod 30, similar to that described, upper section 32 and lower section 34 are disposed in a laterally offset orientation such that longitudinal axis *a* is disposed at an angle *y* relative to longitudinal axis *b* about the side of intermediate section 36. Angle *y* is desirably in a range of 135 degrees to less than 180 degrees, and most desirably in a range at 150 degrees – 160 degrees. Angle y may be equal to 180 degrees. It is contemplated that the vertebral rod system may be disposed in an angular orientation according to the particular angle *z* and angle *y* such that rod 30 may offset both axially and laterally.

Referring to FIG. 10, an alternate embodiment of the vertebral rod system includes a vertebral rod 130, similar to vertebral rod 30 described with regard to FIGS. 1-3. Vertebral rod 130 includes an upper section 132, an intermediate section 136 and a lower section 134, similar to those sections described above. Upper section 132 has a first length and lower section 134 has a second, greater length. In a first orientation of vertebral rod 130, longitudinal axis *a* is disposed at an angle of 180 degrees relative to longitudinal axis *b*, about an open end 140. It is contemplated that longitudinal axis *a* may be disposed at

other angular orientations relative to longitudinal axis *b*, including those discussed herein.

Lower section 134 has an arcuate configuration and an increased length providing the ability to extend over two or more intervertebral elements. It is contemplated that the configuration of the vertebral rod system may provide dynamic or flexible stabilization over a plurality of intervertebral levels, including treated and untreated vertebral and intervertebral levels. It is further contemplated that lower section 134 provides a less flexible, or more rigid stabilization relative to upper section 132 and intermediate section 136. It is envisioned that lower section 134 may be attached with vertebrae across lower lumbar levels such as levels L5-S1. Lower section 134 may be cut or trimmed during a surgical procedure such that the size of vertebral rod 130 can be modified according to patient needs or the particular requirements of a surgical treatment or medical practitioner.

The arcuate configuration of lower section 134 has a radius of curvature *rr*. Desirably, the radius of curvature *rr* is in a range of 20-400 mm, preferably in a range of 50-200 mm, and most preferably in a range of 100-150 mm. In an alternate embodiment, upper section 132 can have an arcuate configuration and/or an increased length, similar to that described. An arcuately configured upper section 132 has a radius of curvature including those ranges discussed herein. It is contemplated that the arcuately configured section 132 may have an equivalent or non-equivalent radius, same or alternate orientation relative to lower section 134. It is further contemplated that upper section 132 may include a laterally offset orientation, similar to that discussed with regard to FIGS. 9 and 16.

Referring to FIG. 11, an alternate embodiment of the method of use of the vertebral rod system with a surgical procedure for treating a spinal disorder, similar to that described with regard to FIGS. 6 and 7, includes vertebral rod 130 discussed above. The vertebral rod system includes fixation screw assemblies 170, 171 and 173, which include threaded bone engaging portions 172 that are inserted or otherwise connected to vertebrae V_1, V_2 and V_3, according to the particular requirements of the surgical treatment. Fixation screw assemblies 170, 171 and 173 each have a head 174 with a through opening and a set screw 176, which is torqued on to vertebral rod 130 to attach rod 130 in place with vertebrae V.

Upper section 132 has a shorter rod length, relative to lower section 134. Fixation screw assembly 170 is torqued on to upper section 132 for attachment with vertebra V_1. Lower section 134 has a longer rod length that extends across intervertebral disc elements I_1 and I_2. Fixation screw assemblies 171, 173 are torqued on to lower section 134 for attachment with vertebrae V_2, V_3. Motion is preserved while providing stability to an untreated intervertebral level.

It is envisioned that upper section 132 and intermediate section 136 are used for lumbar levels such as L4-L5. It is contemplated that lower section 134 is used for a lower lumbar level, such as L5-S1. It is contemplated that vertebral rod 130 is configured such that lower section 134 can be cut or trimmed as desired during the surgical procedure. It is envisioned that the vertebral rod may be heat treated during surgery to obtain a best fit curvature or shape for the patient. It is further envisioned that vertebral rod 130 may include one or a plurality of intermediate sections 136 spaced along the length of rod 130, such as, for example, an additional section 136 being disposed between fixation screw assemblies 171 and 173. In embodiments including a plurality of sections 136, the multiple sections 136 may be disposed in similar, or alternative orientations such as aligned, non-aligned, offset, open end facing or not facing vertebrae and alternate angular orientation.

Referring to FIG. 12, in an alternate embodiment, vertebral rod 130 has a linearly configured lower section 234. In a first orientation of vertebral rod 130, upper section 132 defines longitudinal axis *a*, which is disposed at an angle *xx* relative to a longitudinal axis *b* of lower section 234, about an open end 140 of intermediate section 136. Angle *xx* is desirably in a range of 135 degrees to less than 180 degrees, and most desirably in a range of 150 degrees to 160 degrees. Angle *xx* may be equal to 180 degrees.

Referring to FIG. 13, in another alternate embodiment of vertebral rod 130, similar to that described with regard to FIG. 12, upper section 132 and lower section 234 are disposed in a laterally offset orientation such that axis *a* is disposed at angle *yy* relative to longitudinal axis *b* about the side of intermediate section 136. Angle *yy* is desirably in a range of 135 degrees to less than 180 degrees, and most desirably in a range of 150–160 degrees. Angle *yy* may be equal to 180 degrees. It is contemplated that the vertebral rod system may be disposed in an angular orientation according to the particular angle *xy* and angle *yy* such that rod 130 may offset both axially and laterally.

Referring to FIG. 14, in an alternate embodiment of vertebral rod 130, similar to that described with regard to FIG. 11, a lower section 334 has an arcuate configuration with a corresponding radius of curvature *r*. Desirably, the radius of curvature *r* is in a range of 20-400 mm, preferably in a range of 50-200 mm, and most preferably in a range of 100-150 mm.

Referring to FIG. 15, in another alternate embodiment of vertebral rod 130, similar to those described above, an upper section 432 has an arcuate configuration with a corresponding radius of curvature r_1. Desirably, the radius of curvature r_1 is in a range of20-400 mm, preferably in a range of 50-200 mm, and most preferably in a range of 100-150 mm. A lower section 434 has an undulating configuration with corresponding radii of curvature r_2, r_3. Radii r_2, r_3 are desirably in a range of 20-400 mm, preferably in a range of 50-200 mm, and most preferably in a range of 100-150 mm, and may be of equal value, non-equivalent or zero.

Referring to FIG. 16, in another alternate embodiment of vertebral rod 130 shown in FIG. 15, lower section 434 includes a laterally oriented curvature with a corresponding radius of curvature r_4, which is desirably in a range of 20-400 mm, preferably in a range of 50-200 mm, and most preferably in a range of 100-150 mm.

Referring to FIG. 17, in an alternate embodiment of vertebral rod 30, similar to that described with regard to FIGS. 1-3, an intermediate section 536 has an inner surface 538 that includes a plurality of grooves 580. Grooves 580 are transversely disposed about the circumference of inner surface 538. Intermediate section 538 has an exterior surface 582, which includes a plurality of grooves 584. Grooves 584 are transversely disposed about joint member 537. It is contemplated that one or a plurality of grooves may be defined in surfaces 538, 582. It is further contemplated that grooves 580, 584 may be oriented longitudinally. Grooves 580, 584 may be disposed on only one of surface 538 or surface 582. It is envisioned that the grooves may be staggered or discontinuous.

Referring to FIG. 18, in an alternate embodiment, bumper 50 is fabricated from a porous or foam material. In another alternate embodiment, bumper 50 has a gear surface configuration including teeth 660, as shown in FIG. 19. In another alternate embodiment, bumper 50 has a dumbbell configuration including elliptical surfaces 760, as shown in FIG. 20. In another alternate embodiment, bumper 50 has through holes 360, as shown in FIG. 21.

Referring to FIG. 22, in alternate embodiment of the vertebral rod system employing components similar to those described above, fixation screw assemblies 970, 971, similar to assemblies 70, 71, described above, are employed for attaching a vertebral rod 930, similar to rod 30 described above, to vertebrae V_1, V_2. Fixation screw assemblies 970, 971 include heads 974 configured for relative movement of rod 930 therein. Rod 930 includes an upper section 932 and a lower section 934, which are relatively moveable within the respective through openings of heads 974. Upper section 932 includes a stop 935 defined at an end portion thereof. Lower section 934 includes a stop 937 defined at an end portion thereof. Stops 935, 937 are configured to prevent disengagement of vertebral rod 930 from fixation screw assemblies 970, 971 during movement of vertebrae V_1, V_2 under flexion and extension. It is envisioned that assemblies 970, 971 include non-locking multi axial screws such that sections 932, 934 freely slide under applied tensile and compressive loads in connection with the flexion/extension of rod 930. Sections 932, 934 may include an elongated stop or end cap to limit sliding or further prevent rod 930 from slipping out of engagement with fixation screw assemblies 970, 971. Sections 932, 934 may also be torqued for fixation with set screws or the like.

Referring to FIGS. 23 and 24, in another alternate embodiment of the vertebral rod system including vertebral rod 30, similar to that described with regard to FIG. 8, a tension element, such as, for example, a band 1090 is disposed about upper section 32, lower section 34 and intermediate section 36 in a configuration to limit movement of sections 32, 34 from the first orientation. Band 1090 can be secured to ends of sections 32, 34 with crimp, attached lockcap, loop around a pin or tied knot. Band 1090 may include a tether or a cable and is desirably fabricated from an elastic material. Band 1090 augments resistance of rod 30 with regard to movement of sections 32, 34 in flexion/extension, as described above.

Referring to FIGS. 25 and 26, in an alternate embodiment of the vertebral rod system shown in FIGS. 23 and 24, a band 1190 includes a loop 1192 disposed about upper section 32 and a loop 1194 disposed about lower section 34. A central portion 1196 of band 1190 is disposed across open end 40. Referring to FIGS. 27 and 28, in another alternate embodiment of the vertebral rod system shown in FIGS. 23 and 24, a band is configured as a woven mesh 1290. Mesh 1290 includes a loop 1292 disposed about upper section 32 and a loop 1294 disposed about lower section 34. A central portion 1296 is disposed across open end 40. It is contemplated that mesh 1290 is fabricated from an elastic material.

Referring to FIGS. 29-43, the vertebral rod system can include alternate embodiments of the locking parts of intermediate section 36 and bumper 50, similar to that described with regard to FIGS. 1-3. As shown in FIG. 29, intermediate section 36 includes a first locking part, a conical shaped post 1348 and bumper 50 includes a second locking part, an opening 1354 configured for reception thereof and locking engagement of bumper 50 with vertebral rod 30. Alternatively, as shown in FIG. 30, intermediate section 36 includes a first locking part, a post 1448 having a barb 1449 and bumper 50 includes a second locking part, an opening 1454 configured for reception thereof and locking engagement of bumper 50 with vertebral rod 30. Alternatively, as shown in FIG. 31, intermediate section 36 includes a first locking part, a wedge shaped post 1548 and bumper 50 includes a second locking part, an opening 1554 configured for reception thereof and locking engagement of bumper 50 with vertebral rod 30.

Alternatively, as shown in FIG. 32, intermediate section 36 includes a first locking part, a conical shaped post 1648 disposed with joint member 37 and bumper 50 includes a second locking part, an opening 1654 configured for reception thereof and locking engagement of bumper 50 with vertebral rod 30. Alternatively, as shown in FIG. 33, intermediate section 36 includes a first locking part, a post 1748 having a dual hook 1749, disposed with joint member 37, and bumper 50 includes a second locking part, an opening 1754 configured for reception thereof and locking engagement of bumper 50 with vertebral rod 30. Alternatively, as shown in FIG. 34, intermediate section 36 includes a first locking part, a pin shaped post 1848 and bumper 50 includes a second locking part, an opening 1854 configured for reception thereof and locking engagement of bumper 50 with vertebral rod 30.

Alternatively, as shown in FIG. 35, intermediate section 36 includes a first locking part, a post 1948 extending from inner surface 38 and across a portion of open end 40. Bumper 50 includes a second locking part, an exterior surface 1952 having a recess 1953 configured for reception of post 1948 and locking engagement of bumper 50 with vertebral rod 30. Alternatively, as shown in FIG. 36, intermediate section 36 includes a first locking part, a tether 2048 connected adjacent faces 43, 45 and extending across open end 40.

Bumper 50 includes an exterior surface 2052 configured for engagement with tether 2048 such that bumper 50 is fixed with vertebral rod 30. Alternatively, as shown in FIG. 37, intermediate section 36 includes a first locking part, a tether 2148 connected adjacent a side portion thereof and extending across a lateral open portion of cavity 46. Bumper 50 includes an exterior surface 2152 configured for engagement with tether 2148 such that bumper 50 is fixed with vertebral rod 30.

Alternatively, as shown in FIG. 38, intermediate section 36 includes a first locking part, a tether 2248 connected adjacent faces 43, 45 and extending across a lateral open portion of cavity 46. Bumper 50 includes an exterior surface 2252 configured for engagement with tether 2248 such that bumper 50 is fixed with vertebral rod 30. Alternatively, as shown in FIG. 39, intermediate section 36 includes a first locking part, a tethered connection 2348 disposed on a lower side portion thereof. Bumper 50 includes a second locking part, a tethered connection 2354 in a tethered configuration with intermediate section 36 for locking engagement of bumper 50 with vertebral rod 30. Alternatively, as shown in FIG. 40, intermediate section 36 includes a first locking part, a tethered connection 2448 disposed on an upper side portion thereof. Bumper 50 includes a second locking part, a tethered connection 2454 in a tethered configuration with intermediate section 36 for locking engagement of bumper 50 with vertebral rod 30.

Alternatively, as shown in FIG. 41, the vertebral rod system includes a tether 2548 connected adjacent end portions of sections 32, 34 and extending across a lateral open portion of cavity 46. Bumper 50 includes an exterior surface 2552 configured for engagement with tether 2548 such that bumper 50 is fixed with vertebral rod 30. Alternatively, as shown in FIG. 42, intermediate section 36 includes a first locking part, a tether 2648 connected adjacent upper and lower portions of joint member 37 and extending across a lateral open portion of cavity 46. Bumper 50 includes an exterior surface 2652 configured for engagement with tether 2648 such that bumper 50 is fixed with vertebral rod 30. Alternatively, as shown in FIG. 43, intermediate section 36 includes a first locking part, a mesh 2748 disposed thereabout for capture of bumper 50. Bumper 50 includes an exterior surface 2752 configured for engagement with mesh 2748 such that bumper 50 is fixed with vertebral rod 30.

It will be understood that various modifications may be made to the embodiments disclosed herein. Therefore, the above description should not be construed as limiting, but merely as exemplification of the various embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

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WHAT IS CLAIMED IS:

1. A vertebral rod comprising:

a first elongated section extending between a first end and a second end;

a second elongated section extending between a first end and a second end, the second ends of the first and second sections being spaced apart from one another;

an intermediate section disposed between the first section and the second section, the intermediate section having an inner surface that defines a first locking part, the inner surface defining a cavity comprising an opening between the second ends of the first and second sections; and

a resistance member having an exterior surface that defines a second locking part configured for engagement with the first locking part such that the resistance member is fixed with and engaging at least a portion of the inner surface;

wherein the cavity of the intermediate section has a maximum width that is greater than a width of the opening in the cavity, and

wherein, when the second locking part is engaged with the first locking part, the resistance member substantially prevents closure of the opening of the cavity.

2. A vertebral rod according to Claim 1, wherein the resistance member has a hardness between 70 and 90 Shore A.

3. A vertebral rod according to Claim 1 or 2, wherein the intermediate section is flexible relative to the first and second sections, and configured to provide resistance to movement of the first and second sections.

4. A vertebral rod according to Claim 1, 2 or 3, wherein the resistance member is elastic and configured to provide resistance to movement of the first and second sections.

5. A vertebral rod according to any one of the preceding claims, wherein the intermediate section defines an arcuate inner surface, the resistance member being configured to engage substantially all of the inner surface.

6. A vertebral rod according to any one of the preceding Claims, wherein the intermediate section has a C-shaped configuration defining a correspondingly shaped inner surface.

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7. A vertebral rod according to any one of the preceding Claims, wherein the first section defines a longitudinal axis disposed at an angle of less than 180 degrees from a longitudinal axis defined by the second section.

8. A vertebral rod according to any one of the preceding Claims, wherein the cavity comprises a post projecting from the inner surface and the exterior surface of the resistance member comprises an aperture configured for disposal of the post to retain the resistance member in the cavity.

9. A vertebral rod according to any one of the preceding claims, wherein the second section has an arcuate configuration that defines a radius of curvature in a range of 20-400 mm.

10. A vertebral rod according to any one of the preceding claims, wherein the first section has a first dimension of length and the second section has a second, greater dimension of length.

11. A vertebral rod comprising:

a first elongated section extending between a first end and a second end;

a second elongated section extending between a first end and a second end, the second section including at least a portion thereof having an arcuate configuration that defines a radius of curvature in a range of 20-400 mm;

a flexible intermediate section disposed between the first section and the second section, the intermediate section having an arcuate inner surface that defines a cavity, the cavity comprising an opening between the second ends of the first and second sections, and that defines a locking part; and

a bumper disposed within the cavity that provides increasing resistance to movement of the first and second sections from a first orientation, the bumper having an exterior surface that engages the locking part to retain the bumper in the cavity;

wherein the cavity of the intermediate section has a maximum width that is greater than a width of the opening in the cavity, and

wherein the bumper substantially prevents closure of the opening of the cavity.

12. A vertebral rod according to Claim 11, wherein the bumper has a hardness

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between 70 and 90 Shore A.

13. A vertebral rod according to Claim 11 or 12, wherein the bumper is elastic.

14. A vertebral rod substantially as any one embodiment described herein with reference to the accompanying Figures.

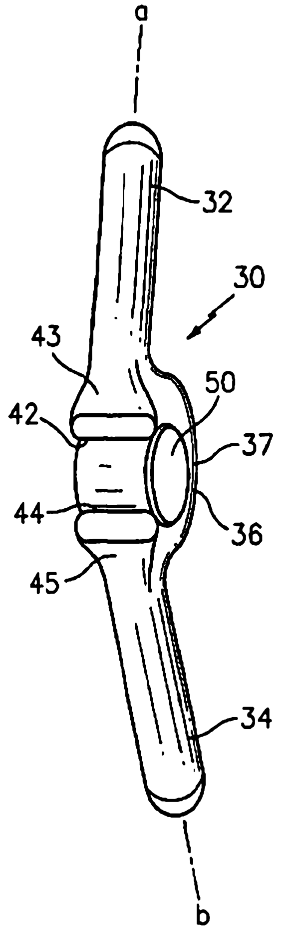

FIG. 1

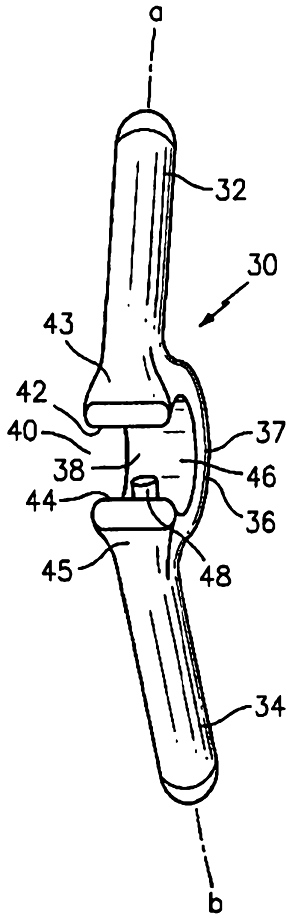

FIG. 2

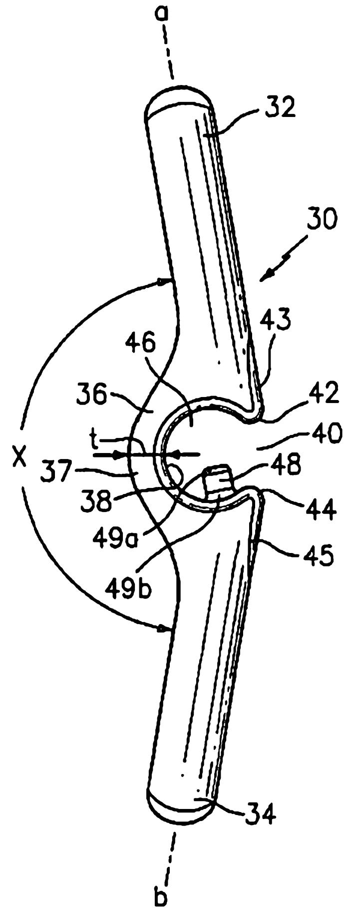

FIG. 3

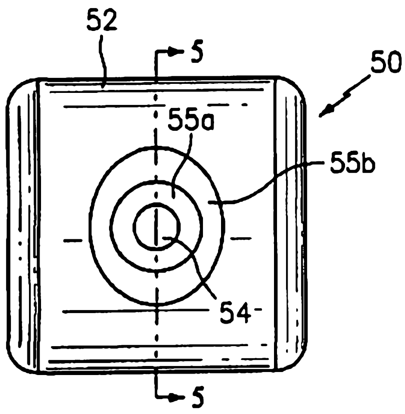

FIG. 4

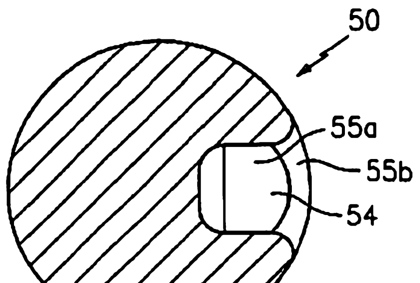

FIG. 5

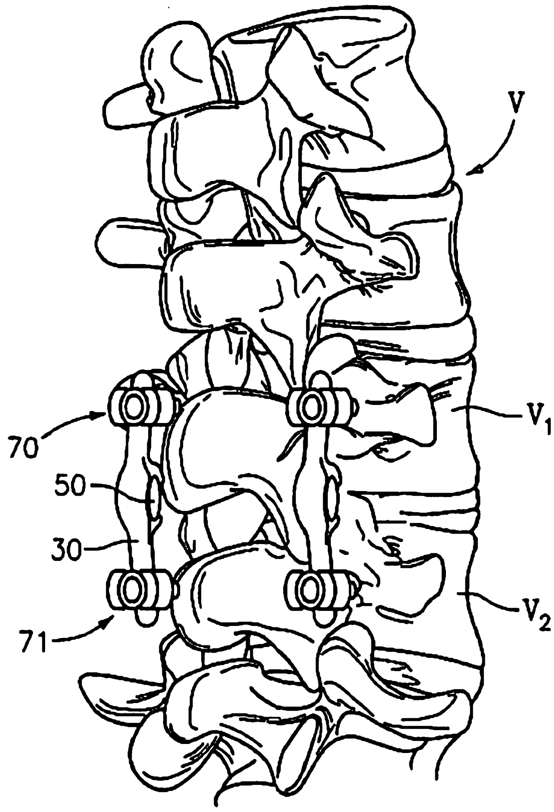

FIG. 6

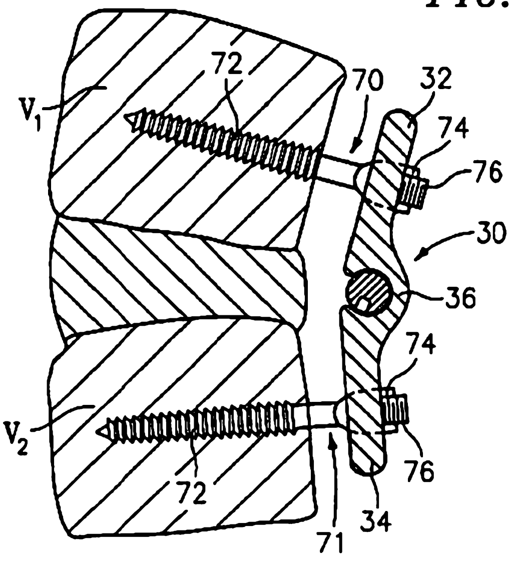

FIG. 7A

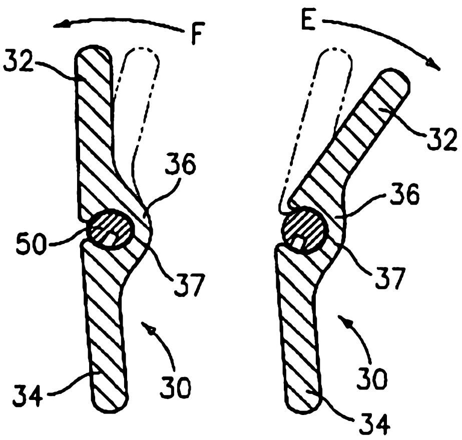

FIG. 7B *FIG. 7C*

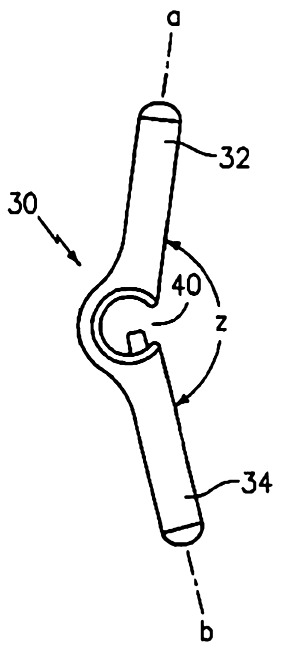

FIG. 8

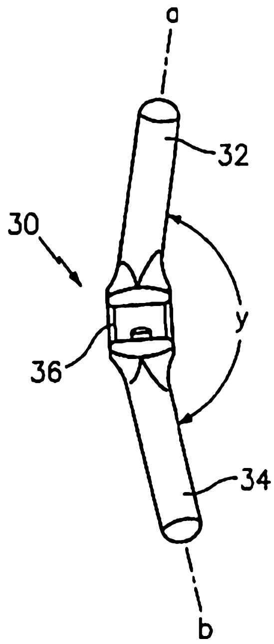

FIG. 9

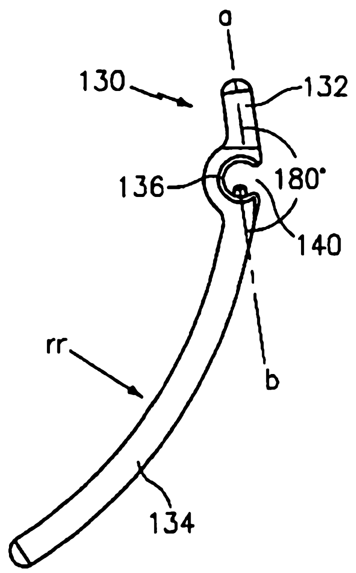

FIG. 10

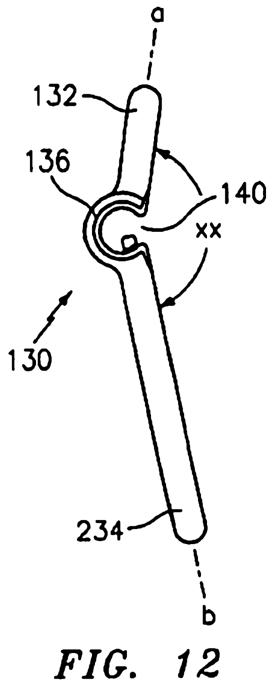

FIG. 12

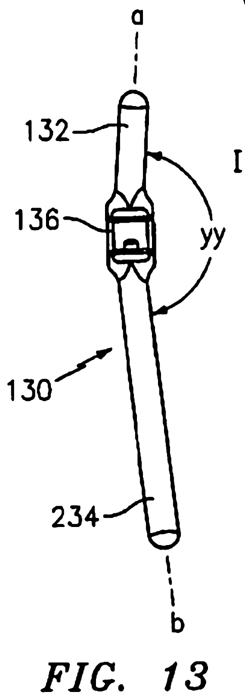

FIG. 13

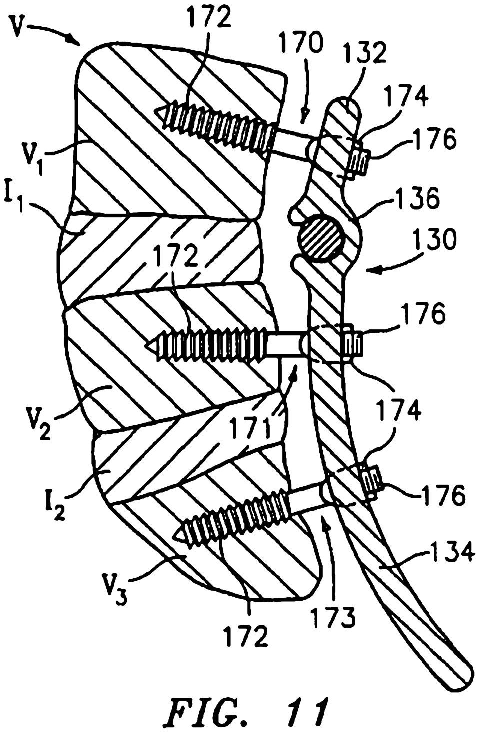

FIG. 11

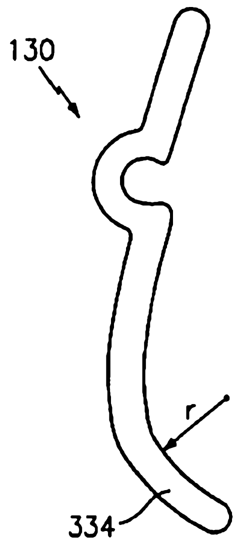

FIG. 14

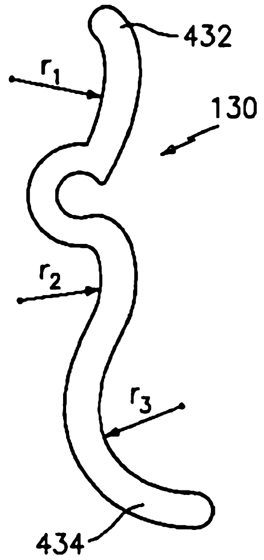

FIG. 15

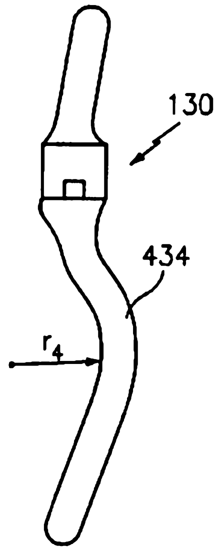

FIG. 16

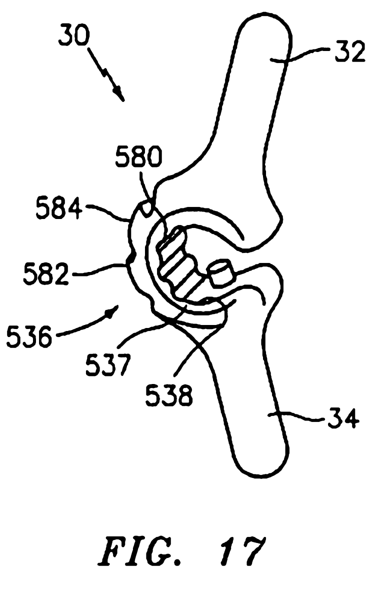

FIG. 17

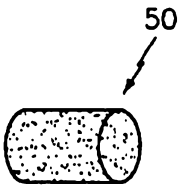

FIG. 18

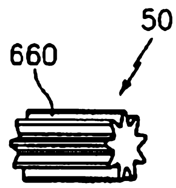

FIG. 19

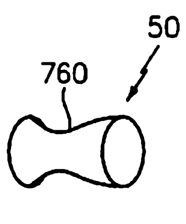

FIG. 20

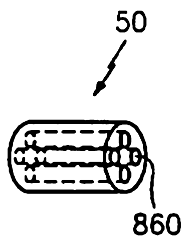

FIG. 21

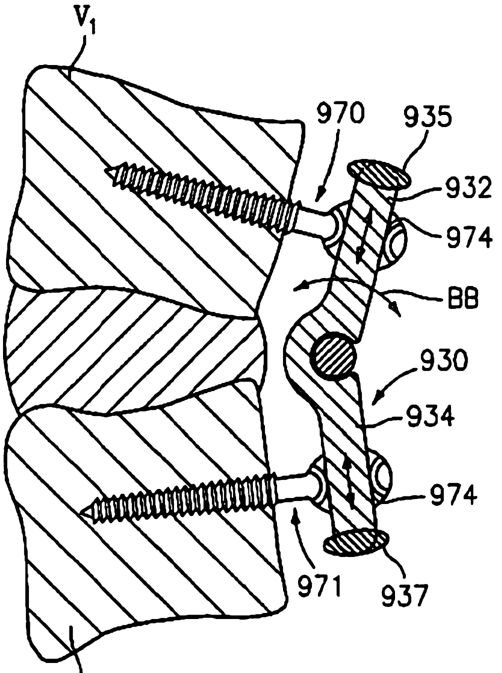

FIG. 22

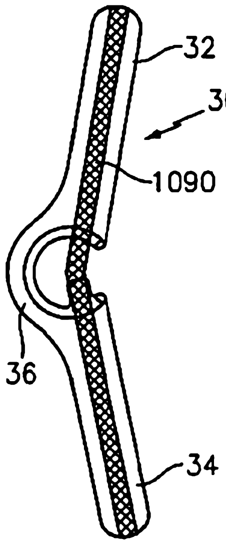

FIG. 23

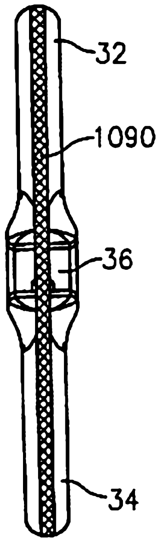

FIG. 24

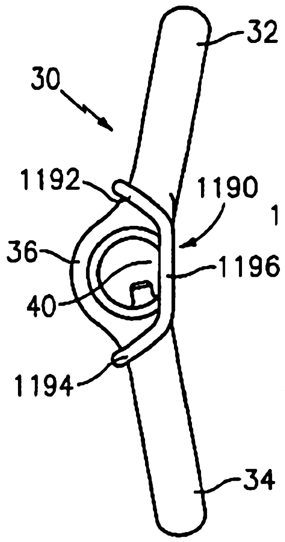

FIG. 25

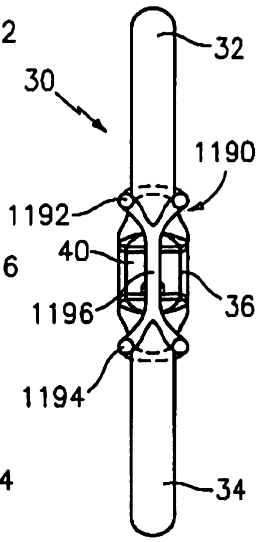

FIG. 26

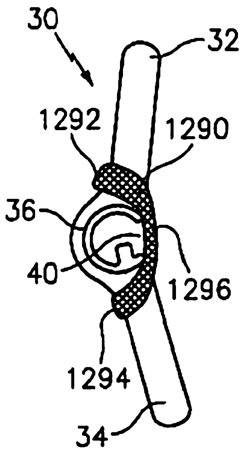

FIG. 27

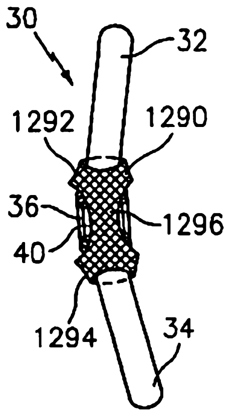

FIG. 28

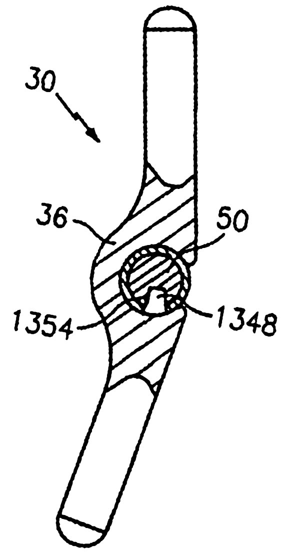

FIG. 29

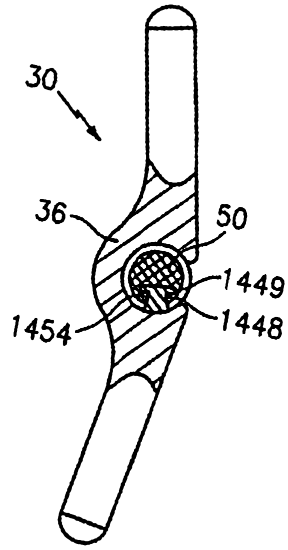

FIG. 30

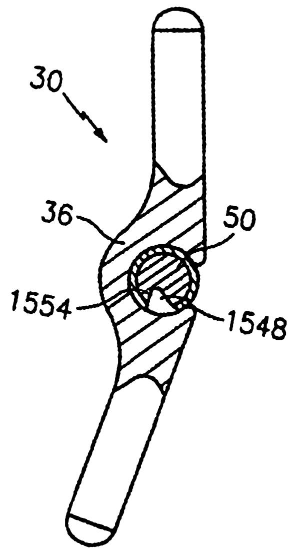

FIG. 31

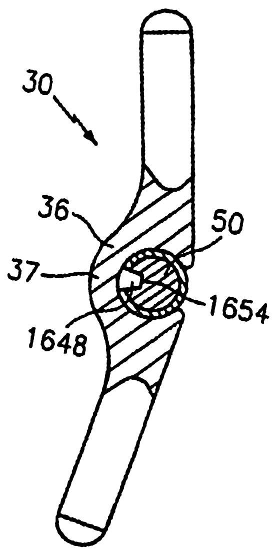

FIG. 32

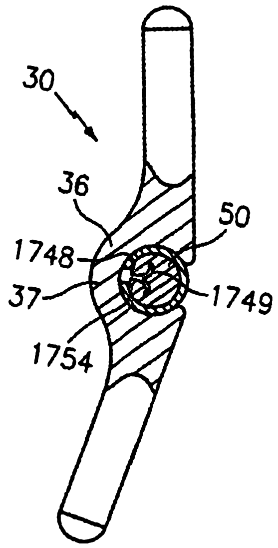

FIG. 33

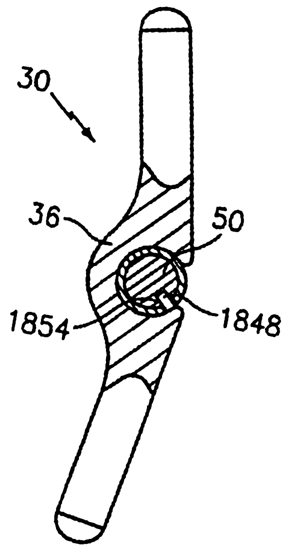

FIG. 34

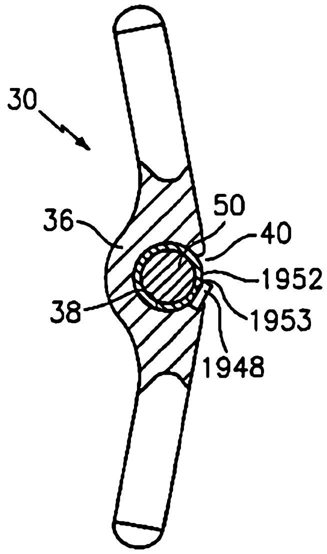

FIG. 35

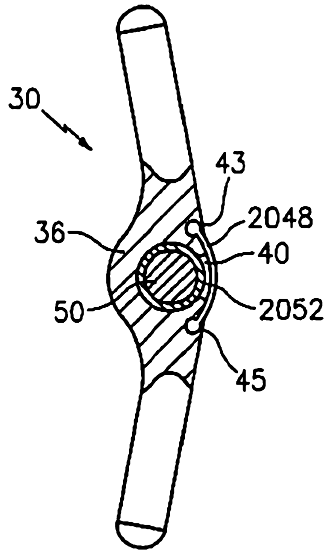

FIG. 36

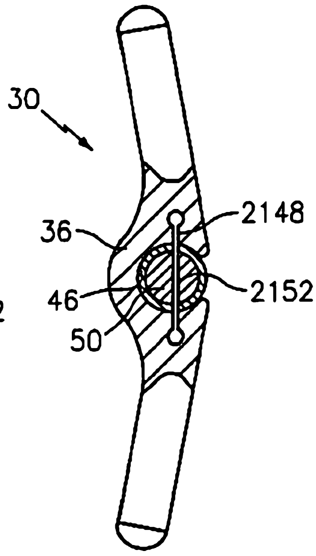

FIG. 37

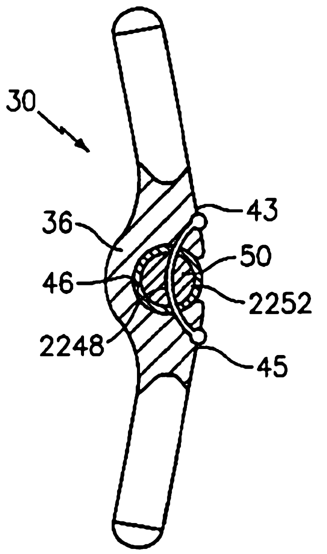

FIG. 38

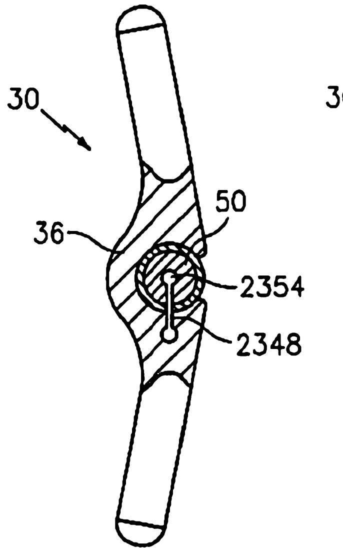

FIG. 39

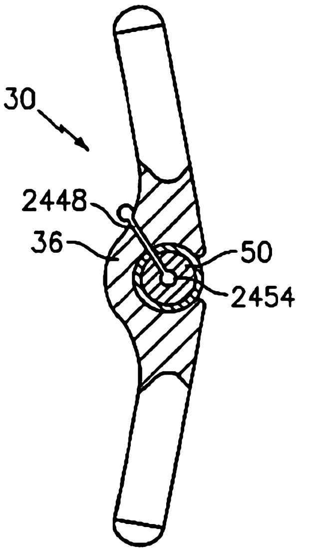

FIG. 40

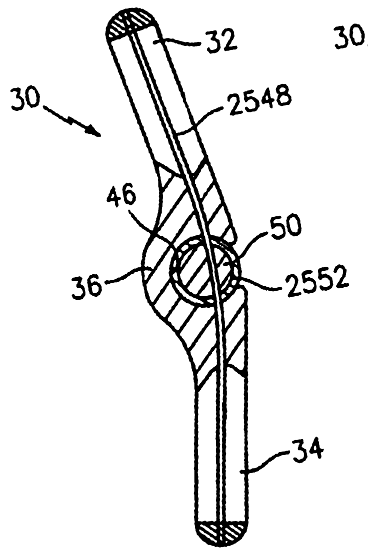

FIG. 41

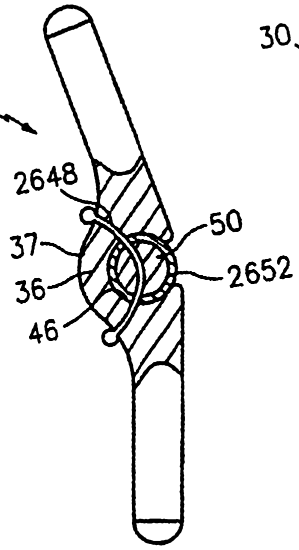

FIG. 42

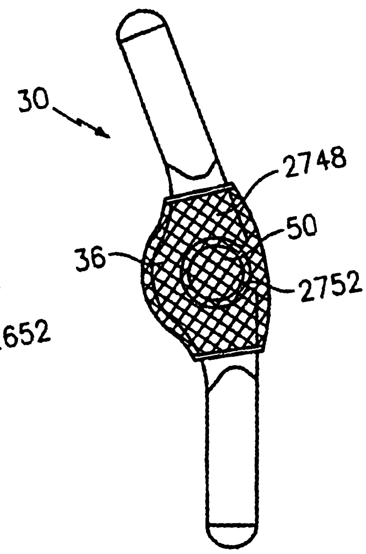

FIG. 43