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(71) Applicant (for all designated States except US): **WAR-SAW ORTHOPEDIC, INC.** [US/US]; 2500 Silveus Crossing, 2500 Silveus Crossing, Warsaw, Indiana 46581 (US).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **TRIEU, Hai, H.** [US/US]; 1323 Graystone Lane, Cordova, Minnesota 38016 (US).

(74) Agents: **JOHNSON, Noreen, C.** et al.; 710 Medtronic Parkway MS LC340, Minneapolis, Minnesota 55432 (US).

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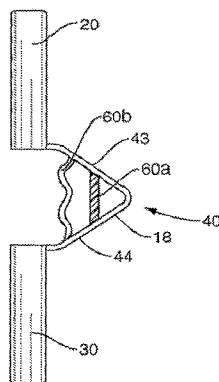
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(54) Title: VERTEBRAL RODS AND METHODS OF USE



(57) Abstract: The present application is directed to vertebral rods and methods of use. In one embodiment, the rod includes upper (20) and lower (30) sections that are separated by an intermediate section (40). The intermediate section may include one or more members, and may have a variety of configurations. An elastic member (60) may be positioned within the intermediate section. The intermediate section and the elastic member may provide for variable resistance during movement of the upper and lower sections. In one embodiment, the resistance increases the further away the upper and lower sections move from a first orientation. In one embodiment, the extent of movement of the upper and lower sections is limited.

WO 2007/090015 A1

VERTEBRAL RODS AND METHODS OF USE

Background

Vertebral rods are often used in the surgical treatment of spinal disorders such as degenerative disc disease, disc herniations, scoliosis or other curvature abnormalities, and fractures. Different types of surgical treatments are used. In some cases, spinal fusion is indicated to inhibit relative motion between vertebral members. In other cases, dynamic implants are used to preserve motion between vertebral members. For either type of surgical treatment, one or more rods may be attached to the exterior of two or more vertebral members, whether it is at a posterior, anterior, or lateral side of the vertebral members. In other embodiments, rods are attached to the vertebral members without the use of dynamic implants or spinal fusion.

Rods may redirect stresses over a wider area away from a damaged or defective region and restore the spine to its proper alignment. Rods may also increase loading on interbody constructs, decrease stress transfer to adjacent vertebral members while bone-graft healing takes place, and generally support the vertebral members.

Summary

The present application is directed to vertebral rods and methods of use. In one embodiment, the rod includes upper and lower sections that are separated by an intermediate section. The intermediate section may include one or more members, and may have a variety of configurations. An elastic member may be positioned within the intermediate section. The intermediate section and the elastic member may provide for variable resistance during movement of the upper and lower sections. In one embodiment, the resistance increases the further away the upper and lower sections move from a first orientation. In one embodiment, the extent of movement of the upper and lower sections is limited.

Brief Description of the Drawings

Figure 1A is a perspective view illustrating a rod according to one embodiment.

Figure 1B is a front view illustrating a rod according to one embodiment.

Figure 2 is a perspective view of a pair of rods attached to vertebral members according to one embodiment.

Figure 3 is a side view illustrating a rod according to one embodiment.

Figure 4 is a side view illustrating a rod according to one embodiment.

Figure 5 is a side view illustrating a rod according to one embodiment.

Figures 6A-H are side views illustrating a rod according to various embodiment.

Figures 7A-F are cross section views of an elastic member according to various embodiments.

Figure 8 is a side view illustrating a rod according to one embodiment.

Figure 9 is a side view illustrating a rod according to one embodiment.

Figure 10 is a cross section view of a rod according to one embodiment.

Figure 11A is a side view illustrating a rod according to one embodiment.

Figure 11B is a side view illustrating a rod according to one embodiment.

Figure 12 is a side view illustrating a rod according to one embodiment.

Figure 13 is a side view illustrating a rod according to one embodiment.

Figure 14 is a side view illustrating a rod according to one embodiment.

Figure 15A is a side view illustrating a rod in a first position according to one embodiment.

Figure 15B is a side view illustrating a rod in a second position according to one embodiment.

Figure 16 is a side view illustrating a rod and a sleeve according to one embodiment.

Figure 17 is a side view illustrating a rod according to one embodiment.

Figure 18 is a side view illustrating a rod according to one embodiment.

Detailed Description

The present application is directed to vertebral rods and methods of supporting one or more vertebral members. The rod may include upper and lower sections and an

intermediate section. An elastic member may be positioned at the intermediate section. The elastic member may have a variety of orientations, sizes, shapes, densities, modulus of elasticity, and other material properties depending upon the desired displacement between the upper and lower sections. The elastic member and/or the intermediate section may be elastically flexible to exert a stabilizing force during movement of the vertebral members.

Figure 1A illustrates a side perspective view and Figure 1B illustrates a front view of one embodiment of the rod 10. The rod 10 includes an upper section 20 and a lower section 30 separated by an intermediate section 40. An elastic member 60 may be positioned to work in combination with the intermediate section 40 to provide axial and lateral flexibility.

In one embodiment, the intermediate section 40 and elastic member 60 provide variable resistance during movement of the vertebral members 100. The resistance may provide dynamic stabilization during a normal range of motion from the neutral position during flexion, extension, lateral bending, and rotation. The resistance may be caused by placing the intermediate section 40 and elastic member 60 in compression or tension. Further, these elements may switch between compression and tension during movement of the vertebral members. The stiffness of the intermediate section 40 and elastic member 60 may further limit the range of motion beyond a predetermined amount.

Figure 2 illustrates one embodiment of two rods 10 attached to vertebral members 100. In this embodiment, the rods 10 are positioned at a posterior side of the spine, on opposite sides of the spinous processes 101. Rods 10 may be attached to a spine at other locations, including lateral and anterior locations. Rods 10 may also be attached at various sections of the spine, including the base of the skull and to vertebral members 100 in the cervical, thoracic, lumbar, and sacral regions. Thus, the illustration in Figure 2 is provided merely as a representative example of one embodiment. It is further well understood that a single rod 10 may be used for supporting the vertebral members 100.

In the embodiment of Figure 2, the rods 10 are secured to the vertebral members 100 by pedicle assemblies comprising a pedicle screw 12 including a receiver 14 and a retaining cap 13. The outer surface of each rod 10 is grasped, clamped, or otherwise secured within the receiver 14 and maintained in position by the retaining cap 13. Other mechanisms for securing rods 10 to the vertebral members 100 include hooks, cables, and other such devices. Further, examples of other types of retaining hardware include

threaded caps, screws, and pins. Rods 10 are also attached to plates in other configurations. Thus, the exemplary assemblies shown in Figure 2 are merely representative of one type of attachment mechanism.

Upper and lower sections 20, 30 may have a variety of shapes, sizes, and physical properties. In one embodiment, the upper and lower sections 20, 30 are substantially identical. In one embodiment, one or both of the sections 20, 30 are substantially cylindrical including an extended length and a circular cross sectional shape. In one embodiment, one or both of the sections 20, 30 are substantially rigid. One or both sections 20, 30 may be substantially straight, include a continuous curve, or include one or more discrete curved sections.

The intermediate section 40 is positioned between the upper and lower sections 20, 30. In one embodiment, the intermediate section 40 and upper and lower sections 20, 30 are constructed of a single piece including a folded or curved configuration. In other embodiments, intermediate section 40 is attached to the upper and lower sections 20, 30. Figure 3 illustrates one embodiment with the intermediate section 40 constructed of a separate member 41 that is attached to the sections 20, 30. Member 41 is attached to the upper section 20 with one or more fasteners 16. Embodiments of fasteners 16 may include rivets, pins, screws, etc. In the embodiment of Figure 3, member 41 is attached to the lower section 30 in another manner, such as with adhesives, welding, brazing, etc. Intermediate section 40 may be constructed from one or more members 41. In the embodiment of Figure 3, intermediate section 40 is constructed from a single member 41.

The embodiment of Figure 4 illustrates the intermediate section 40 constructed of two separate members 41a, 41b. In this embodiment, first member 41a is connected with section 20, and second member 41b is connected with section 30. Members 41a, 41b are connected together in a manner as described above.

Intermediate section 40 may have a variety of widths. In the embodiment of Figure 1B, intermediate section 40 has a width w that is greater than a width w' of the upper and lower sections 20, 30. In other embodiments, the width w of the intermediate section 40 is less than or equal to the width w' of the sections 20, 30. In one embodiment, the width w of the intermediate section 40 is up to four times the width of the sections 20, 30. The width w of the intermediate section 40 may vary, as illustrated in the embodiment of Figure 1B. In another embodiment, the width w is substantially constant.

Intermediate section 40 may also be positioned at a variety of locations relative to the sections 20, 30. In one embodiment as illustrated in Figure 3, intermediate section 40 is laterally offset from the sections 20, 30. In another embodiment as illustrated in Figure 6A, intermediate section 40 is axially aligned with the sections 20, 30.

In one embodiment, intermediate section 40 may comprise a member 18 including a first section 43 and a second section 44. First and second sections 43, 44 may comprise the entirety of or a limited portion of the member 18. In one embodiment as illustrated in Figure 4, intermediate section 40 has substantially planar first and second sections 43, 44. In other embodiments, intermediate section 40 has a curved shape as illustrated in Figure 5. In various other embodiments such as illustrated in Figure 3, intermediate section 40 has a combination of planar and curved shapes.

In some embodiments, intermediate section 40 is constructed from a single member 18. Figures 6A and 6B illustrate embodiments with the intermediate section 40 comprised of a single member 18 including a curved shape. Figures 6C, 6D, and 6E illustrate embodiments having an intermediate section 40 comprised of a single member 18 including planar and curved sections.

Embodiments of the intermediate section 40 may include multiple members 18. Figure 6F illustrates an embodiment with a curved first member 18a and a second member 18b. Figures 6G and 6H illustrate embodiments with first and second members 18a, 18b each including curved and planar sections. In embodiments having multiple members 18, members 18 may be constructed from a single piece, or multiple different pieces fastened together. Further, the multiple members 18 may be spaced apart, or in close proximity. Support members 18 may also have an overlapping configuration. The overlap may be in a horizontal direction, vertical direction, or both. Member 18 of Figure 6A and members 18a and 18b of Figure 6G illustrate embodiments having vertical overlap with multiple sections of each of these members overlapping vertical between the sections 20, 30.

Member 18 of Figures 6B, 6C, and 6E also includes vertical overlap. Member 18 of Figure 6D illustrates an embodiment of horizontal overlap. Horizontal overlap occurs when a line perpendicular to the axis of sections 20 and 30 extends through the member at least twice. Some embodiments feature both horizontal and vertical overlap. Intermediate sections 40 comprising multiple members 18 include horizontal overlap due to the

construction. Each of the members 18a, 18b may themselves include horizontal and/or vertical overlap.

In one embodiment as illustrated in Figure 1A, the intermediate section 40 includes an open side 70. In different embodiments, the open side 70 faces in anterior or posterior directions. In one embodiment, an interior section is formed between the multiple members 18 that comprise the intermediate section 40. The interior section may have two sides enclosed by the members 18. In one embodiment, the lateral sides of the interior section 70 are open. In another embodiment, the interior section 70 is completely enclosed.

Multiple intermediate sections 40 may be positioned along the length of the rod 10. In one embodiment as illustrated in Figure 2, each rod 10 includes two separate intermediate sections 40. The intermediate sections 40 may include the same or different sizes, shapes, and constructions. A middle section 42 may be positioned along the length of the rod 10 between the intermediate sections 40. In one embodiment, middle section 42 is constructed in a manner as described above for the upper and lower sections 20, 30.

Upper and lower sections 20, 30, and the intermediate section 40 may be constructed of a variety of materials including metals, polymers, ceramics, and combinations thereof. Examples of metals include titanium, titanium alloys such as nickel-titanium, stainless steel, and cobalt chromium. Examples of polymers include silicone, silicone-polyurethane copolymer, polyolefin rubber, PEEK, PEEK-carbon composites, polyimide, polyetherimide, polyurethane, and combinations thereof. Examples of polyurethanes include thermoplastic polyurethanes, aliphatic polyurethanes, segmented polyurethanes, hydrophilic polyurethanes, polyether-urethane, polycarbonate-urethane, silicone polyetherurethane, polyvinyl alcohol hydrogel, polyacrylamide hydrogel, and polyacrylic hydrogel. Examples of ceramics include calcium phosphate, hydroxyapatite, HAPCP, alumina, and zirconium.

The intermediate section 40 may provide resistance to movement of the upper and lower sections 20, 30. Movement of one or both of the sections 20, 30 may cause deformation of the intermediate section 40. In one embodiment, the resistance is substantially constant during movement of the sections 20, 30. In another embodiment, the resistance increases when one or both of the sections 20, 30 move farther away from a first, neutral position. The shape of the intermediate section 40 may also affect the

resistance. In one embodiment, relative movement between the sections 20, 30 in a first direction causes a first amount of resistance, and movement in a second, opposite direction causes a second, different amount of resistance. In one embodiment, the differences in resistance may be used to restriction motion of the vertebral members 100 in one direction (e.g., flexion) more than in a second direction (e.g., extension).

An elastic member 60 may be positioned within the intermediate section 40 and has a stiffness to provide resistance to movement of the sections 20, 30. The elastic member 60 may share the load applied to the rod 10 and may prevent fatigue failure of the intermediate section 40. The elastic member 60 may impose a substantially linear or non-linear resistance to resist movement of the sections 20, 30.

Elastic member 60 may be constructed of a variety of different materials. Member 60 may be resilient and change shape during movement of the sections 20, 30. Examples of such materials include elastic or rubbery polymers, hydrogels or other hydrophilic polymers, or composites thereof. Particularly suitable elastomers include silicone, polyurethane, copolymers of silicone and polyurethane, polyolefins, such as polyisobutylene and polyisoprene, neoprene, nitrile, vulcanized rubber and combinations thereof. Examples of polyurethanes include thermoplastic polyurethanes, aliphatic polyurethanes, segmented polyurethanes, hydrophilic polyurethanes, polyether-urethane, polycarbonate-urethane and silicone polyetherurethane. Other suitable hydrophilic polymers include polyvinyl alcohol hydrogel, polyacrylamide hydrogel, polyacrylic hydrogel, poly(N-vinyl-2-pyrrolidone hydrogel, polyhydroxyethyl methacrylate hydrogel, and naturally occurring materials such as collagen and polysaccharides, such as hyaluronic acid and cross-linked carboxyl-containing polysaccharides, and combinations thereof.

In one embodiment, elastic member 60 is connected to the intermediate section 40. The elastic member 60 may be connected with mechanical fasteners such as screws, pins, rivets, tethers, sleeves, cables, etc. In another embodiment, elastic member 60 is connected with an adhesive. In one embodiment, the intermediate section 40 includes a roughened surface, ridges, teeth, etc. to maintain the position of the elastic member 60. In one embodiment, the elastic member 60 has a shape that attaches to the intermediate section 40. In a specific embodiment, elastic member 60 includes a dovetail recess that attaches with an extension that extends from the intermediate section 40.

In one embodiment, elastic member 60 is connected to both the first and second sections 43, 44 of the intermediate section 40. When connected to both sections 43, 44, the elastic member 60 provides resistance to both inward and outward movement that may occur during flexion, extension, lateral bending, and rotation. During inward movement of the sections 20, 30, elastic member 60 is compressed and provides a resistance to the inward movement. During outward movement of the sections 20, 30, the elastic member 60 is placed in tension to provide resistance. In one embodiment, the elastic member 60 is placed in compression during extension of the vertebral members and placed in tension during flexion.

In one embodiment with the elastic member 60 connected to one of the first and second sections 43, 44, the elastic member 60 provides resistance to inward movement. However, the elastic member 60 may not be placed in tension during outward movement of the sections 20, 30 and the resistance to this movement is limited to the intermediate section 40.

In various embodiments, elastic member 60 is constructed from a single member as illustrated in Figures 7A-7D. Figure 7A illustrates one embodiment having an elastic member 60 with a substantially rectangular shape. Figure 7B illustrates a substantially C-shaped elastic member 60 with the base facing away from the support member 18. Figure 7C illustrates an elastic member 60 having a rectangular first surface that contacts the second section 44 and four planar sidewalls that taper upwards. Figure 7D illustrates an embodiment having an irregular, non-symmetrical shape.

Elastic member 60 may further include two or more separate members. The separate members may have the same construction, or may be constructed of different materials each having a different stiffness. Figure 7E illustrates an embodiment having three separate elastic members 60a, 60b, 60c. Each elastic member 60a, 60b, 60c is independent and has a substantially circular shape that may be cylindrical, spherical, or conical. Figure 7F illustrates an embodiment having a first elastic member 60a that extends around a second elastic member 60b. In one embodiment, elastic members 60a, 60b are connected together.

In a neutral condition with no external forces on the rod 10, the elastic member 60 may have a variety of heights H. In one embodiment, the height H is sized for the member 60 to extend between and contact both sections 43, 44. In one embodiment, the height H

may be substantially the same throughout the elastic member 60. In other embodiments as illustrated in Figures 8 and 9, the height H may vary along the elastic member 60. Figure 8 includes elastic member 60 having a height H that decreases away from the support member 18, and Figure 9 includes the elastic member 60 having a height H that increases away from the support member 18.

The device 10 may provide a variable resistance to deformation. The variable resistance may cause less resistance to initial amounts of vertebral movement, but apply greater forces to reduce larger vertebral movements. By way of example, the device 10 may be designed to provide little resistance during an initial amount of movement of the sections 20, 30. Larger amounts of resistance may be applied to the vertebral members when the sections 20, 30 move beyond the initial amount. In some embodiments, the stiffness of the elastic member 60 and intermediate section 40 increases with additional amounts of movement. The amount of resistance applied by each member increases the further they move away from the original, first position.

Variable resistance to inward movement may also result from the height of the elastic member 60. In one embodiment, the height H is less than the height of the opening 70 (i.e., the member 60 does not contact both sections 43, 44). The resistance to the initial movement of the sections 20, 30 is isolated to the intermediate section 40. The elastic member 60 does not affect the stiffness until it is contacted by two sections 43, 44 of the intermediate section 40 and begins to elastically deform. In one embodiment, deformation is limited to the intermediate section 40 during an amount of initial section movement. Movement beyond this initial amount causes the sections 43, 44 to begin deforming the elastic member 60 in addition to continued deformation of the intermediate section 40 resulting in greater stiffness of the device and more resistance to additional movement. The shape and size of the elastic member 60 may further cause variable resistance to deformation. Greater amounts of contact between the sections 43, 44 and the elastic member 60 may result in greater amounts of resistance. By way of example using the embodiments of Figures 8 and 9, the peaked shapes of the elastic members 60 provides less resistance during initial amounts of inward movement of the sections 43, 44. Additional inward movement of the sections 43, 44 results in deformation of larger amounts of the elastic member 60 resulting in greater resistance.

Variable resistance may also be provided by multiple elastic elements. Figure 10 illustrates an embodiment having two intermediate sections 40. A first intermediate section 40 includes two separate elastic members 60a and 60b. During inward movement of the sections 43a, 43b, the inner elastic member 60a is initially contacted thus causing a first amount of resistance. The second elastic member 60b is not contacted by section 43a until the member 60a is compressed beyond a predetermined amount. This compression then causes the elastic member 60b to deform resulting in additional amounts of resistance. The second intermediate 40 section includes a single elastic member constructed of first and second materials 60c, 60d having different stiffnesses. Initial compression of the sections 43b, 44b causes deformation of the first material 60c resulting in a first resistance. Additional compression causes deformation of the first and second materials 60c, 60d which together provide additional resistance.

Figures 11A and 11B illustrate another embodiment having first and second members 60a, 60b positioned between the sections 43, 44. As illustrated in Figure 11A, member 60b has a greater length and is in a slackened configuration when the rod 10 is in a neutral orientation with no external forces. An initial outward movement of the sections 43, 44 is resisted initially by the first member 60a and the intermediate section 40. As the sections 43, 44 move further outward, member 60b is pulled tight. Movement beyond this amount causes the member 60b to be stretched and further movement is opposed by the combination of the first and second members 60a, 60b and the intermediate section 40.

Members 60a, 60b may be constructed of the same or different materials. In one embodiment, member 60b is constructed of an inelastic material and acts as a limiter to control the extent of outward movement. In this embodiment, the sections 43, 44 are moved apart an amount until the member 60b is pulled tight. The inelastic nature of the member 60b then prevents further outward movement of the sections 43, 44 beyond this amount. In one embodiment, member 60b immediately restricts further motion once it is pulled tight, such as occurs with a metallic member. In another embodiment, member 60b provides for a small amount of additional outward movement after being pulled tight prior to stopping further movement. An example includes a woven fabric that expands a slight amount after the member 60b has been pulled tight.

The limiter member 60b as illustrated in the embodiments of Figures 11A and 11B may be constructed of a variety of materials including metals, polymers, and ceramics.

Examples of metals may include titanium and stainless steel. Examples of polymers may include fibers and textile-based products that are woven or braided. An example of a ceramic is a carbon fiber in a braided configuration.

Elastic member 60 may fill varying amounts of the space between the sections 20, 30. In one embodiment, member 60 fills a limited amount of the intermediate section 40. In another embodiment as illustrated in Figure 12, elastic member 60 substantially fills the entirety of the interior section 70. In this embodiment, voids 78 are positioned within the elastic member 60. In one embodiment, voids 78 include a specific shape and size to control the supporting abilities of the elastic member 60. Voids 78 may be substantially free of material, or may be filled with a material that is different than that of the elastic member 60. As illustrated in Figure 12, voids 78 may be positioned within the interior of the elastic member 60, or may be positioned along one edge as illustrated in Figure 13.

A limiter may prevent movement of the sections 20, 30 beyond a predetermined amount. Figure 14 illustrates one embodiment having a rigid limiting member 79 positioned within the intermediate section 40 between the sections 43, 44. Movement of one or both sections 20, 30 may cause inward movement of the sections 43, 44 and cause deformation of the elastic member 60. At a predetermined amount of movement, section 43 contacts a top edge of limiting member 79 that prevents further inward movement. Limiting member 79 may have a variety of different shapes and orientations.

Another limiting embodiment is illustrated in Figures 15A and 15B. Arms 92, 93 are positioned opposite from sections 43 and 44. Arms 92, 93 include edges that are spaced apart forming a gap 49 in a first position such as in a neutral state as illustrated in Figure 15A. This allows for a limited amount of inward movement of the sections 43, 44 during vertebral movement. At a predetermined amount of inward movement, edges contact together as illustrated in Figure 15B and further inward movement is prevented.

In one embodiment as illustrated in Figure 16, a sleeve 85 extends around the intermediate section 40. In one embodiment, sleeve 85 functions to maintain the elastic material 60 within the intermediate section 40. Sleeve 85 may further provide resistance to movement of the sections 20, 30. In one embodiment, sleeve 85 applies resistance to outward movement of the intermediate section 40. Sleeve 85 may be constructed from materials that are elastic, semi-elastic, or inelastic. Sleeve 85 may be solid, such as

constructed from silicone, may be braided or woven, such as a polyester braid or weave, or may be a combination of different materials and constructions.

Tethers 150 may also be used to provide additional resistance to device 10. In one embodiment as illustrated in the embodiments of Figure 17, tether 150 extends across the open side 70 and is attached to the first and second sections 20, 30. Tether 150 provides resistance during outward movement of the sections 20, 30. In other embodiments, multiple tethers 150 extend across the open side 70. Tethers 150 may have a variety of widths and shapes depending upon the context of use. In one embodiment, tether 150 is constructed of an elastic material that stretches upon movement of the vertebral members 100. In one embodiment, tether 150 is constructed of an inelastic material to prevent movement beyond a predetermined amount. In another embodiment, one or more tethers 150 are connected to the elastic member 60. In one embodiment, the tether 150 is completely contained within the elastic member 60. In one embodiment, tether 150 is positioned completely or in part on the exterior surface of the elastic member 60. In another embodiment, tether 150 extends outward from the elastic member 60. The tether or tethers 150 connected to the elastic member 60 may provide additional resistance during vertebral movement.

Figure 18 illustrates another embodiment with the elastic member 60 contacting the upper and lower sections 20, 30. In one embodiment, elastic member 60 is spaced away from the member 18. In another embodiment, elastic member 60 is also in contact with the member 18.

When the elastic member 60 is formed from an elastic material, such as a hydrogel, or other similar hydrophilic material, it may deliver desired pharmacological agents. In one embodiment, the pharmacological agents are delivered during deformation of the elastic member 60. The pharmacological agent may be a one used for treating various spinal conditions, including degenerative disc disease, spinal arthritis, spinal infection, spinal tumor and osteoporosis. Such agents include antibiotics, analgesics, anti-inflammatory drugs, including steroids, and combinations thereof. Other such agents are well known to the skilled artisan. These agents are also used in therapeutically effective amounts. Such amounts may be determined by the skilled artisan depending on the specific case.

In one embodiment, the elastic member 60 is attached to the intermediate member 40 to move between positions of tension and compression. During a first motion of the vertebral members 100, the elastic member 60 is placed in compression to provide resistance to the movement. During a second motion of the vertebral members 100, the elastic member 60 is placed in tension to provide resistance to the motion. In one embodiment, the intermediate section 40 is in sequence placed in compression and tension during vertebral movement.

Spatially relative terms such as “under”, “below”, “lower”, “over”, “upper”, and the like, are used for ease of description to explain the positioning of one element relative to a second element. These terms are intended to encompass different orientations of the device in addition to different orientations than those depicted in the figures. Further, terms such as “first”, “second”, and the like, are also used to describe various elements, regions, sections, etc and are also not intended to be limiting. Like terms refer to like elements throughout the description.

As used herein, the terms “having”, “containing”, “including”, “comprising” and the like are open ended terms that indicate the presence of stated elements or features, but do not preclude additional elements or features. The articles “a”, “an” and “the” are intended to include the plural as well as the singular, unless the context clearly indicates otherwise.

The present invention may be carried out in other specific ways than those herein set forth without departing from the scope and essential characteristics of the invention. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive, and all changes coming within the meaning and equivalency range of the appended claims are intended to be embraced therein.

Claims

What is claimed is:

1. A vertebral rod comprising:
 - a first elongated section;
 - a second elongated section;
 - an intermediate section positioned between the first and second sections, the intermediate section comprising a member with a turn and an upper section and a lower section; and
 - an elastic member positioned within the intermediate section;
 - the intermediate section and elastic member configured to provide variable resistance to movement of the first and second sections.
2. The rod of claim 1, wherein the first section and the second section comprise a common cross sectional shape.
3. The rod of claim 1, further comprising a second intermediate section and a middle member, the middle member positioned between the intermediate section and the second intermediate section, the second intermediate section providing a second variable resistance that is different than the variable resistance of the intermediate section.
4. The rod of claim 3, wherein the middle member has a common cross sectional shape with the first and second sections.
5. The rod of claim 1, wherein the intermediate section further comprises a plurality of turns.
6. The rod of claim 1, wherein the intermediate section comprises a second member comprising a first end attached to the first section and a second end attached to the second section, the second member being spaced from the member.
7. The rod of claim 1, wherein the elastic member is attached both of the upper and lower sections of the intermediate section.

8. The rod of claim 1, further comprising a second elastic member positioned within the intermediate section between the upper and lower sections.

5 9. The rod of claim 1, further comprising a sleeve that extends around at least a portion of the intermediate section to maintain the elastic material within the intermediate section.

10 10. The rod of claim 1, further comprising a tether that extends across the intermediate section and is attached to the first and second sections, the tether retarding outward movement of the first and second sections.

15 11. The rod of claim 1, wherein the elastic member is constructed from the group consisting of silicone, polyurethane, copolymers of silicone and polyurethane, and polyolefins.

12. A vertebral rod comprising:

a first section;

a second section;

20 an intermediate section positioned between the first and second sections, the intermediate section comprising a member with a turn and an upper section and a lower section; and

an elastic member positioned within the intermediate section between the upper and lower sections;

25 the intermediate section movable between a first position with the upper and lower sections spaced a first distance apart, and a second position with the upper and lower sections spaced a second, different distance apart, the elastic member applying a force in the second position to return the intermediate section towards the first position.

30 13. The rod of claim 12, wherein the intermediate section and elastic member are configured to provide increasing resistance as the intermediate section moves from the first position towards the second position.

16

14. The rod of claim 12, wherein the second distance is less than the first distance and the elastic member is in compression in the second position.

15. The rod of claim 14, wherein the elastic member is spaced from one of the upper and lower sections in the first position, and in contact with each of the upper and lower sections in the second position.

16. The rod of claim 12, wherein the second distance is greater than the first distance and the elastic member is in tension in the second position.

17. The rod of claim 16, wherein the elastic member is connected to each of the upper and lower sections.

18. The rod of claim 12, wherein the elastic material is deformable and has a first shape when the intermediate section is in the first position and a second different shape when the intermediate section is in the second position.

19. The rod of claim 18, wherein the elastic material further comprises a pharmacological agent, deformation of the elastic material from the first shape to the second shape causes the pharmacological agent to be distributed.

20. A vertebral rod comprising:

an upper section;

a lower section;

an intermediate section extending between the upper and lower sections, the intermediate section comprising first and second members;

an interior section formed between the first and second members; and

an elastic member positioned within the interior section;

the first and second members and the elastic member providing resistance to movement of the upper and lower sections.

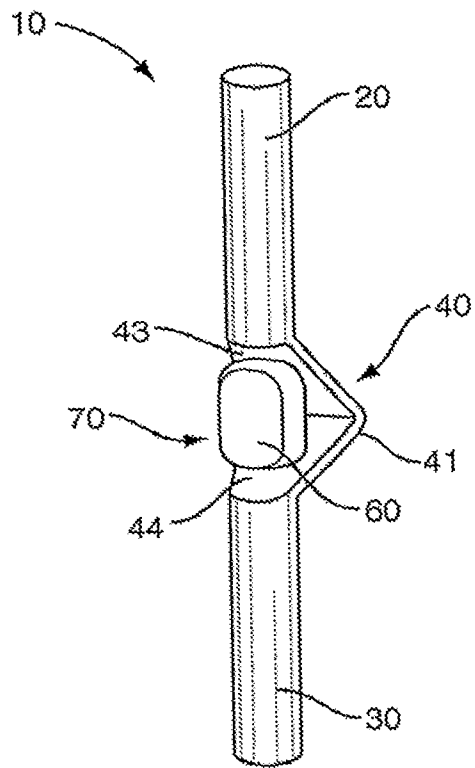


FIG. 1A

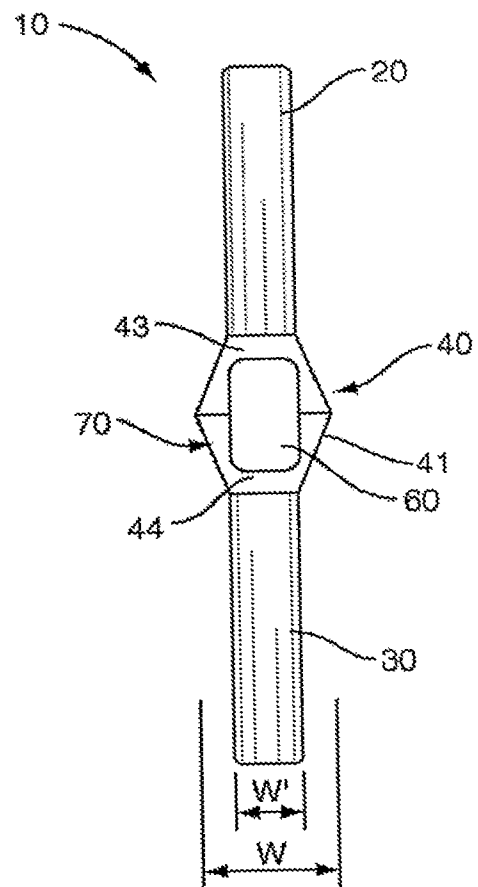


FIG. 1B

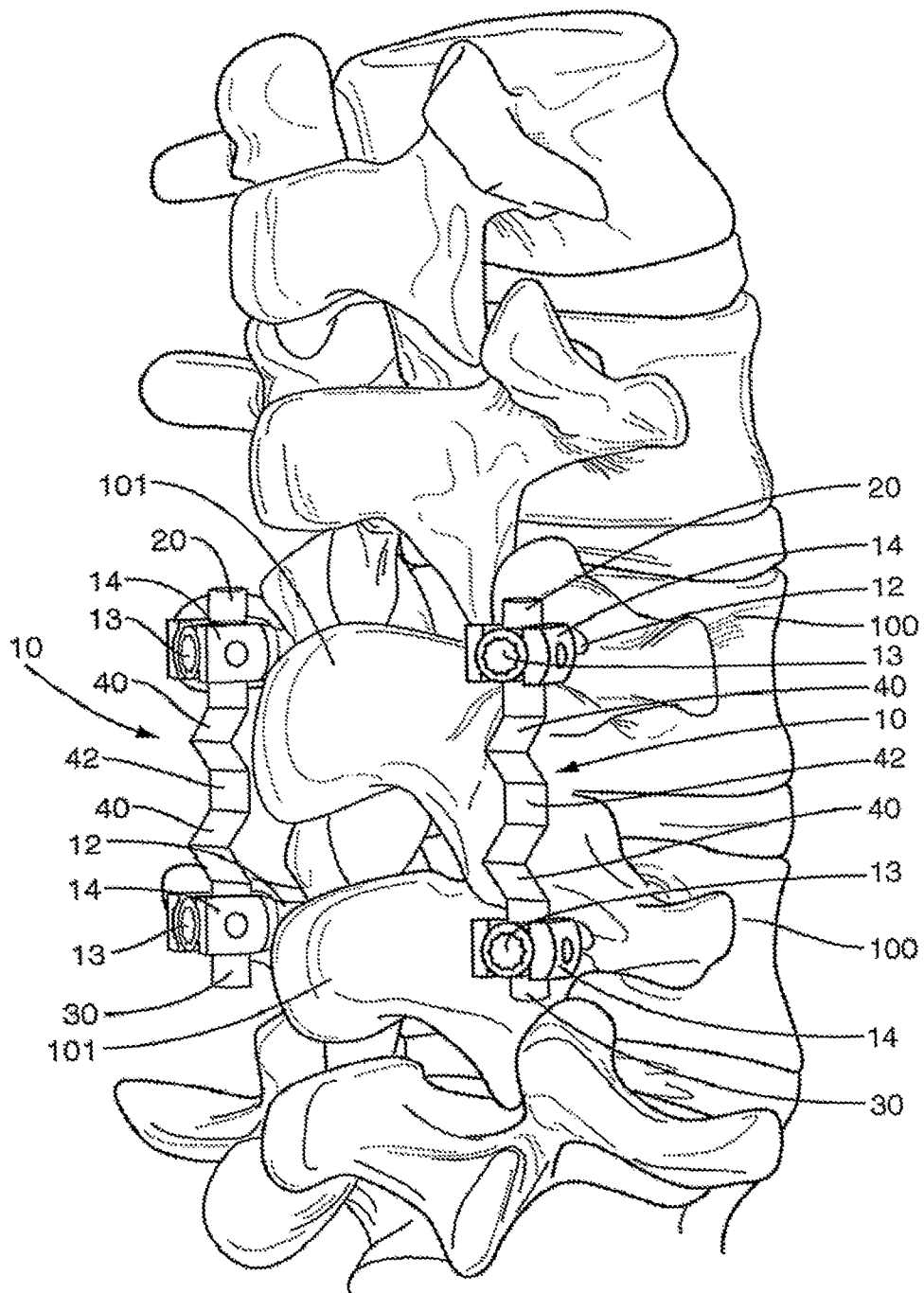


FIG. 2

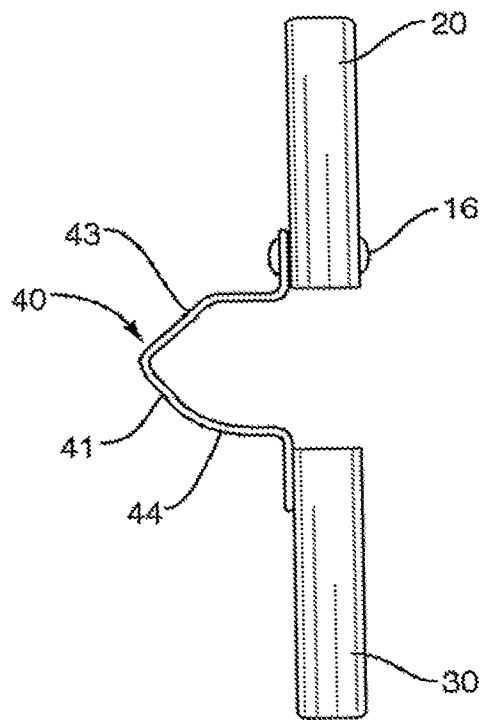


FIG. 3

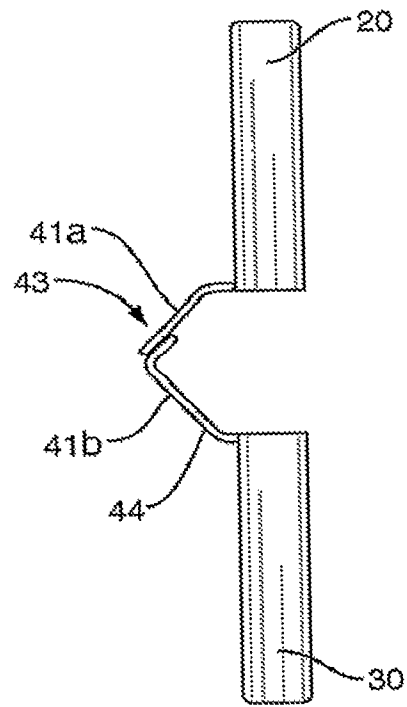


FIG. 4

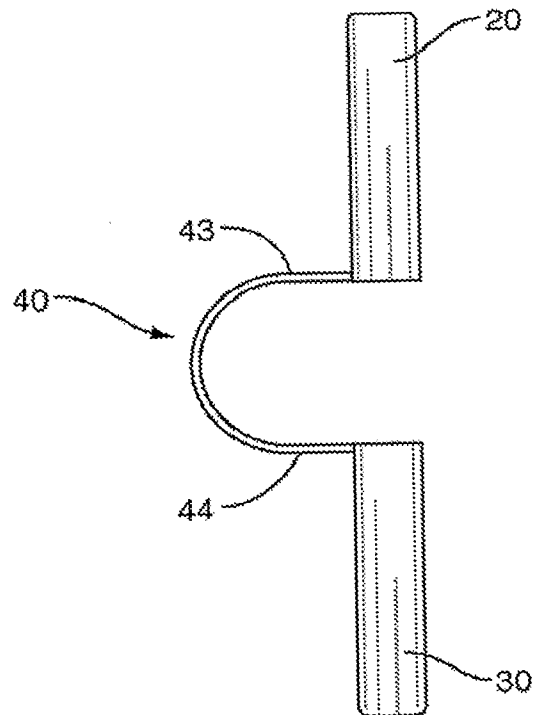


FIG. 5

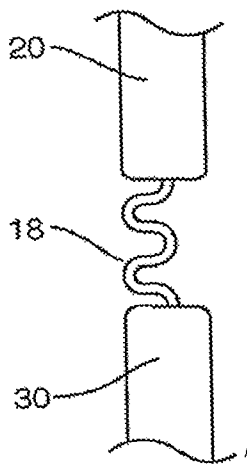


FIG. 6A

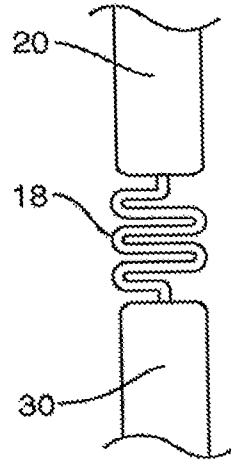


FIG. 6B

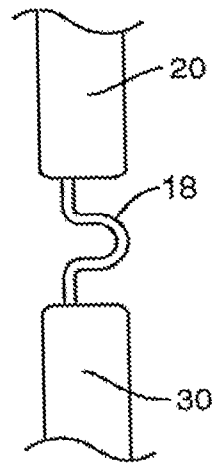


FIG. 6C

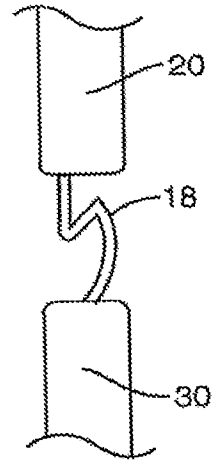


FIG. 6D

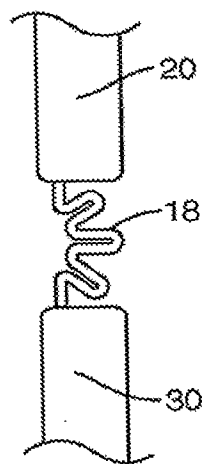


FIG. 6E

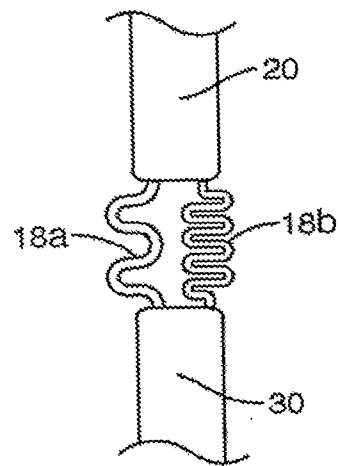


FIG. 6F

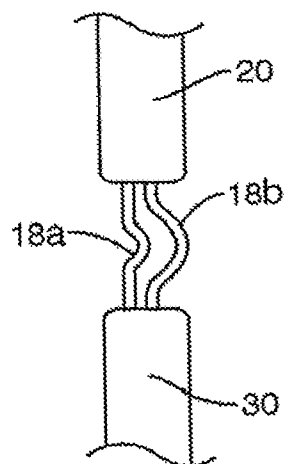


FIG. 6G

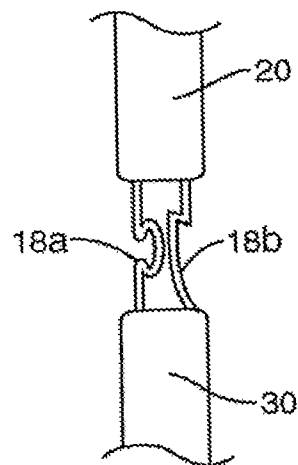


FIG. 6H

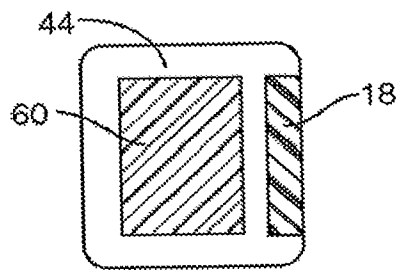


FIG. 7A

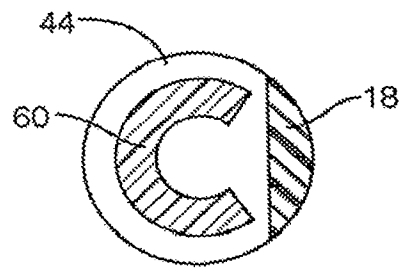


FIG. 7B

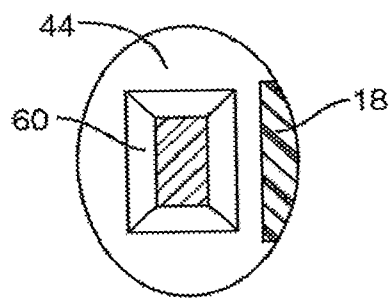


FIG. 7C

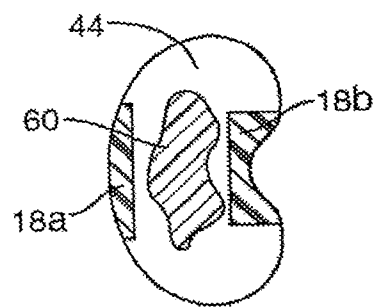


FIG. 7D

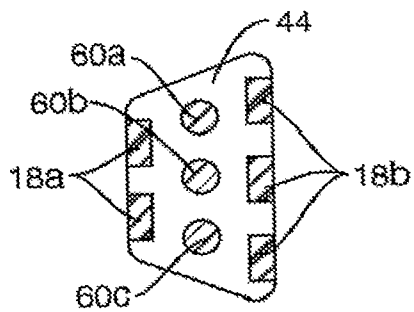


FIG. 7E

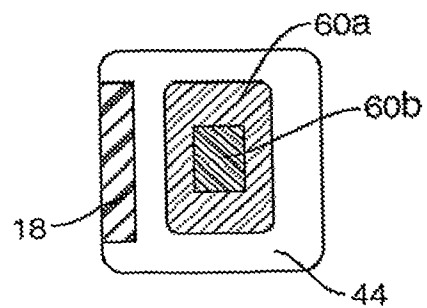


FIG. 7F

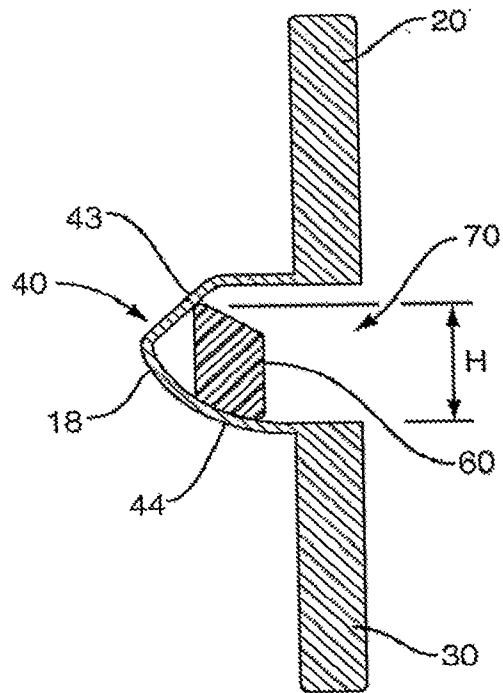


FIG. 8

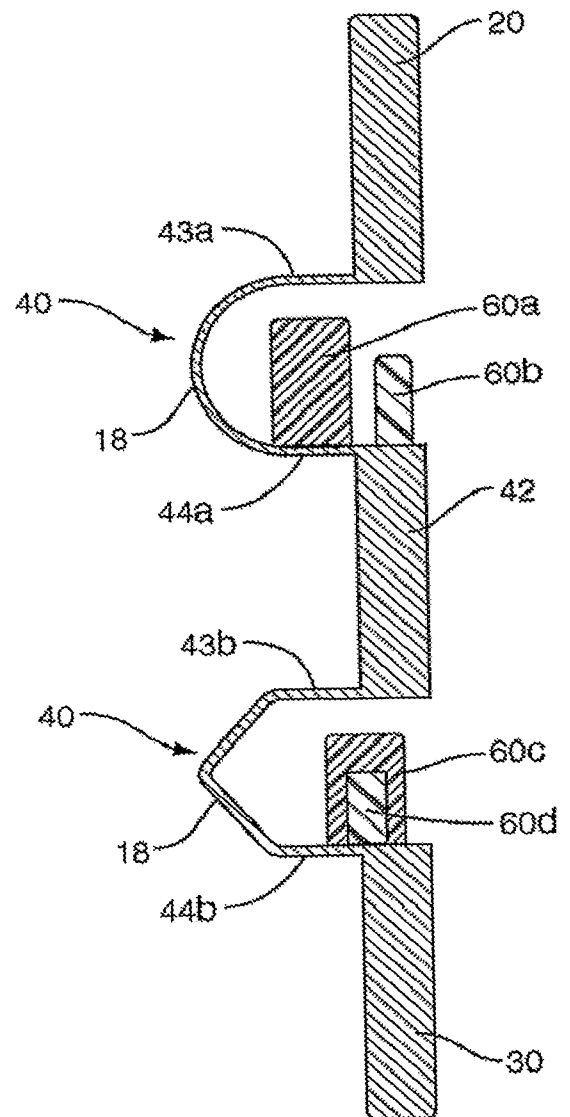
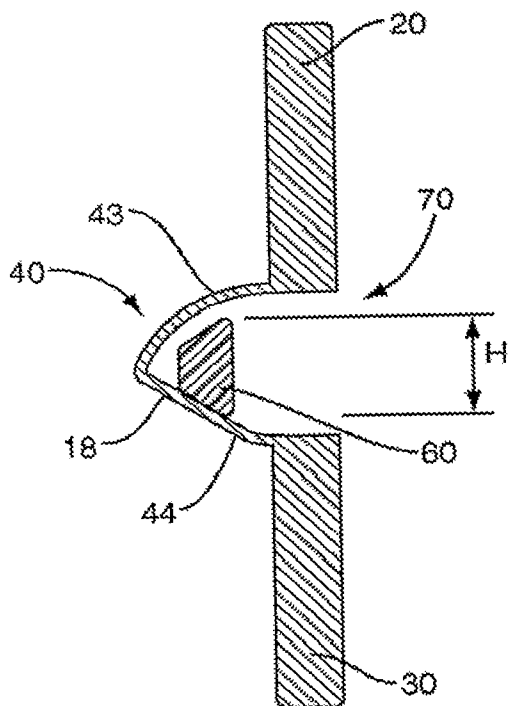


FIG. 10

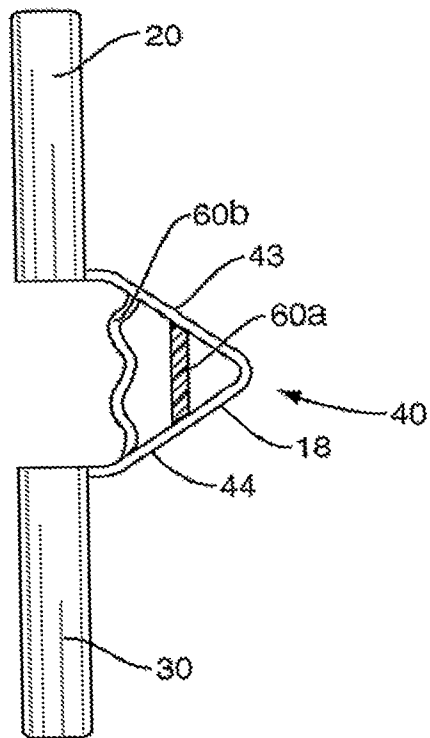


FIG. 11A

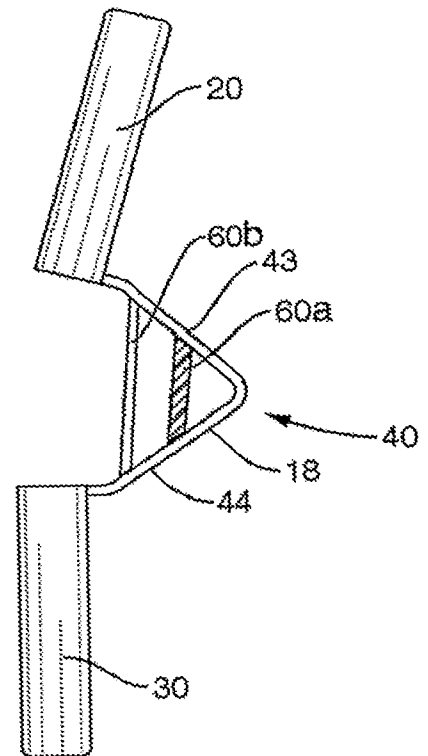


FIG. 11B

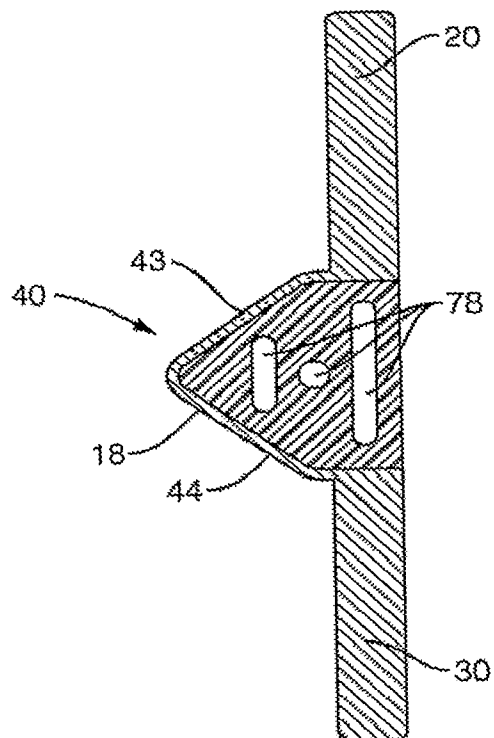


FIG. 12

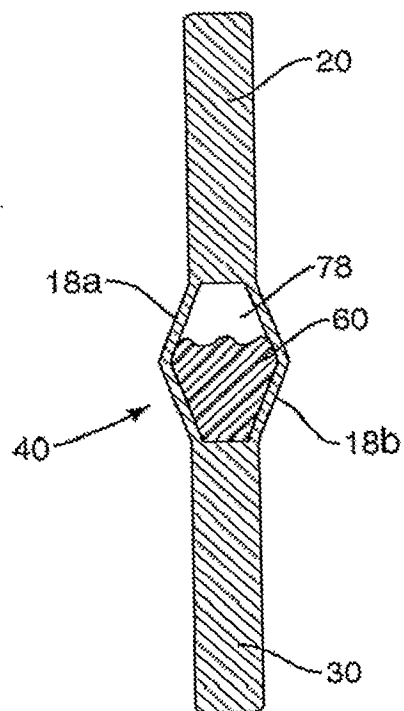


FIG. 13

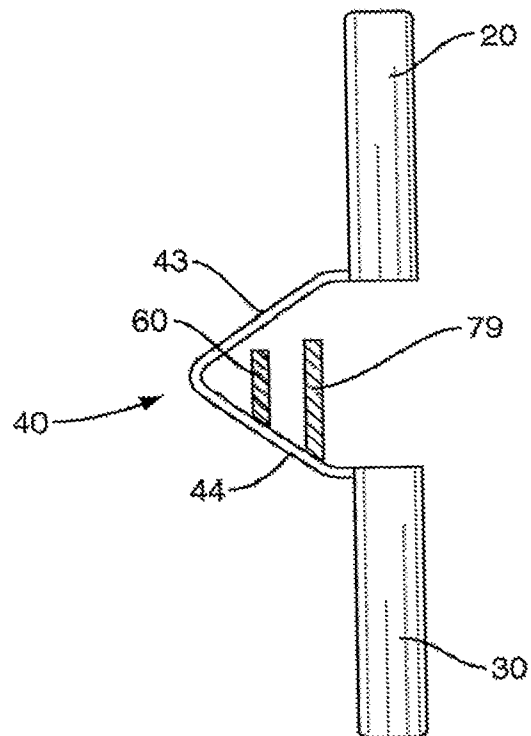


FIG. 14

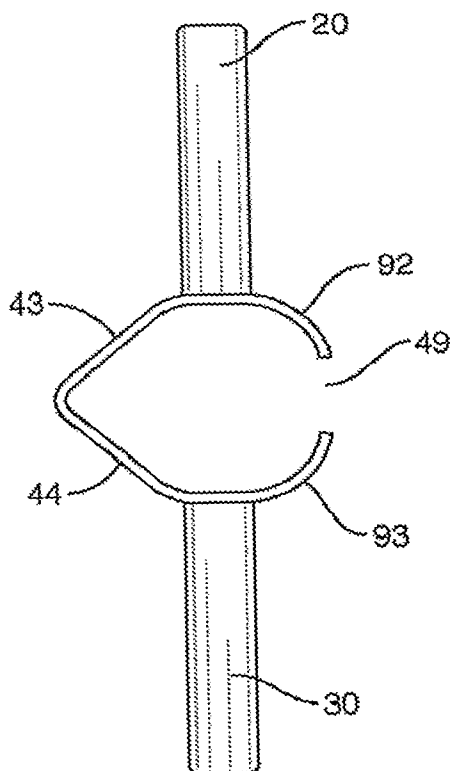


FIG. 15A

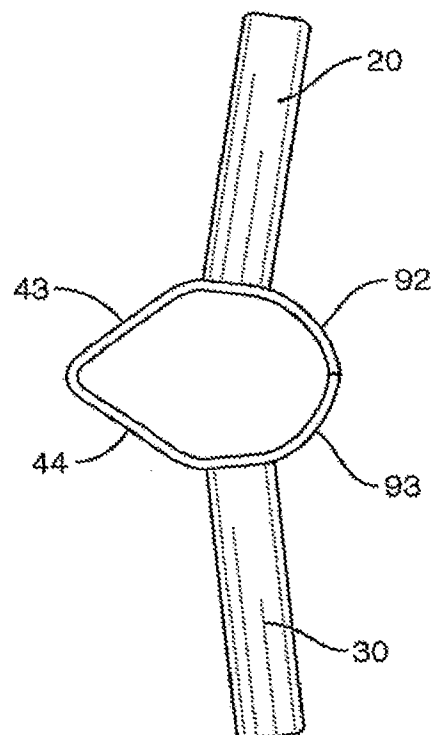


FIG. 15B

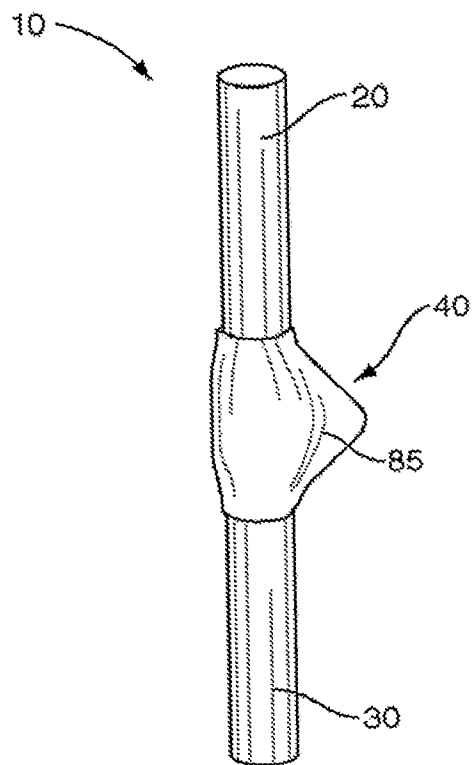


FIG. 16

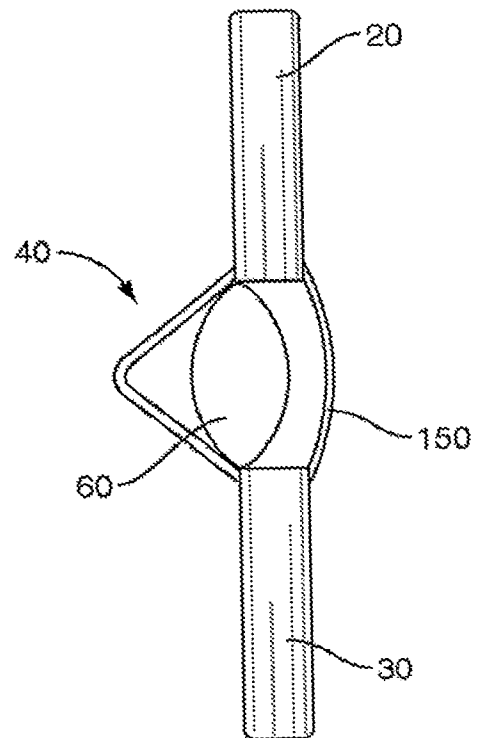


FIG. 17

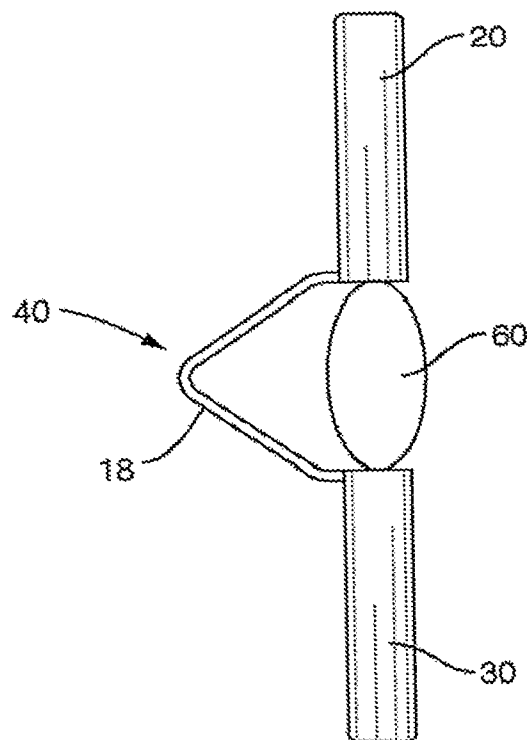


FIG. 18

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/060966

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/70

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|----------------------------|
| X | US 2005/085815 A1 (HARMS JURGEN [DE] ET AL) 21 April 2005 (2005-04-21) figures 4a,8 paragraphs [0065], [0066], [0068], [0070], [0085], [0091] ----- | 1-7, 12-14, 17,18,26 |
| X | US 2005/277922 A1 (TRIEU HAI H [US] ET AL) 15 December 2005 (2005-12-15) paragraphs [0024], [0029] - [0031], [0035] - [0040], [0042], [0043], [0048] figures 6,7,9,13,14 ----- -/-- | 1-9, 11-14, 17,18,26 |

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☒ See patent family annex.

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Date of the actual completion of the international search

4 June 2007

Date of mailing of the international search report

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European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|---|------------------------------|
| X | WO 2004/105577 A (GLOBUS MEDICAL [US]; DAVID C PAUL [US]; ANDREW LEE [US]) 9 December 2004 (2004-12-09) figures 1,2,12,21 page 8, lines 17-20 page 11, lines 5-8,27-30 page 19, line 26 - page 20, line 17 page 25, lines 24-28 ----- | 1,2,7, 11-13, 17,18,26 |
| X | FR 2 844 180 A1 (SPINEVISION [FR]) 12 March 2004 (2004-03-12) figure 7 page 10, lines 3-14 page 11, line 30 - page 12, line 14 page 13, line 20 - page 14, line 5 ----- | 1-7,9, 12,13,26 |
| X | WO 2004/089244 A (RITLAND STEPHEN [US]) 21 October 2004 (2004-10-21) figures 9,10 page 10, line 20 - page 11, line 5 page 12, line 1 - page 14, line 8 ----- | 1,2,12, 13, 16-18,26 |
| A | US 2005/171540 A1 (LIM ROY [US] ET AL) 4 August 2005 (2005-08-04) figures 36-42 paragraphs [0106], [0109] - [0113] ----- | 1,2,10, 12,26 |
| A | US 5 540 688 A (NAVAS FERNAND [FR]) 30 July 1996 (1996-07-30) figures 8-10 column 4, line 61 - column 5, line 46 ----- | 1,9,12, 26 |

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2007/060966

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---------------------|---|--|
| US 2005085815 A1 | 21-04-2005 | DE 10348329 B3 EP 1523949 A1 JP 2005118569 A | 17-02-2005 20-04-2005 12-05-2005 |
| US 2005277922 A1 | 15-12-2005 | AU 2005253991 A1 EP 1776052 A1 WO 2005122925 A1 | 29-12-2005 25-04-2007 29-12-2005 |
| WO 2004105577 A | 09-12-2004 | EP 1628563 A2 JP 2007502692 T KR 20060073536 A US 2006041259 A1 | 01-03-2006 15-02-2007 28-06-2006 23-02-2006 |
| FR 2844180 A1 | 12-03-2004 | AT 345740 T AU 2003296319 A1 EP 1536735 A1 WO 2004024011 A1 US 2006142758 A1 | 15-12-2006 30-04-2004 08-06-2005 25-03-2004 29-06-2006 |
| WO 2004089244 A | 21-10-2004 | AU 2004228019 A1 CA 2520741 A1 CN 1798528 A EP 1613224 A2 JP 2006521903 T KR 20060012270 A | 21-10-2004 21-10-2004 05-07-2006 11-01-2006 28-09-2006 07-02-2006 |
| US 2005171540 A1 | 04-08-2005 | EP 1718230 A2 US 2006264942 A1 WO 2005074828 A2 | 08-11-2006 23-11-2006 18-08-2005 |
| US 5540688 A | 30-07-1996 | NONE | |