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(54) Title: PERCUTANEOUS SPINAL IMPLANTS AND METHODS

(57) Abstract: An apparatus includes an elongate member having a proximal portion configured to be deformed from a first configuration to a second configuration. The elongate member has a distal portion configured to be deformed from a first configuration to a second configuration. A non-expanding central portion is positioned between the proximal portion and the distal portion. The non-expanding central portion is configured to engage adjacent spinous processes. An apparatus includes a first clamp having a first end and a second end. The second end of the first clamp is configured to engage a first spinous process. A second clamp has a first end and a second end. The second end of the second clamp is configured to engage a second spinous process spaced apart from the first spinous process. A connector is coupled to the first end of the first clamp and the first end of the second clamp.

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PERCUTANEOUS SPINAL IMPLANTS AND METHODS

Cross-Reference to Related Applications

[001] This application claims priority to U.S. Patent Application Serial No. 11/059,526, entitled "Apparatus and Method for Treatment of Spinal Conditions," filed February 17, 2005; U.S. Provisional Application Serial No. 60/695,836 entitled "Percutaneous Spinal Implants and Methods," filed July 1, 2005; U.S. Patent Application Serial No. 11/252,879, entitled "Percutaneous Spinal Implants and Methods," filed October 19, 2005; and U.S. Patent Application Serial No. 11/252,880, entitled "Percutaneous Spinal Implants and Methods," filed October 19, 2005.

Background

[002] The invention relates generally to the treatment of spinal conditions, and more particularly, to the treatment of spinal compression using percutaneous spinal implants for implantation between adjacent spinous processes.

[003] A back condition that impacts many individuals is spinal stenosis. Spinal stenosis is a progressive narrowing of the spinal canal that causes compression of the spinal cord. Each vertebra in the spinal column has an opening that extends through it. The openings are aligned vertically to form the spinal canal. The spinal cord runs through the spinal canal. As the spinal canal narrows, the spinal cord and nerve roots extending from the spinal cord and between adjacent vertebrae are compressed and may become inflamed. Spinal stenosis can cause pain, weakness, numbness, burning sensations, tingling, and in particularly severe cases, may cause loss of bladder or bowel function, or paralysis. The legs, calves and buttocks are most commonly affected by spinal stenosis, however, the shoulders and arms may also be affected.

[004] Mild cases of spinal stenosis may be treated with rest or restricted activity, non-steroidal anti-inflammatory drugs (e.g., aspirin), corticosteroid injections (epidural steroids), and /or physical therapy. Some patients find that bending forward, sitting or lying down may help relieve the pain. This may be due to bending forward creates

more vertebral space, which may temporarily relieve nerve compression. Because spinal stenosis is a progressive disease, the source of pressure may have to be surgically corrected (decompressive laminectomy) as the patient has increasing pain. The surgical procedure can remove bone and other tissues that have impinged upon the spinal canal or put pressure on the spinal cord. Two adjacent vertebrae may also be fused during the surgical procedure to prevent an area of instability, improper alignment or slippage, such as that caused by spondylolisthesis. Surgical decompression can relieve pressure on the spinal cord or spinal nerve by widening the spinal canal to create more space. This procedure requires that the patient be given a general anesthesia as an incision is made in the patient to access the spine to remove the areas that are contributing to the pressure. This procedure, however, may result in blood loss and an increased chance of significant complications, and usually results in an extended hospital stay.

[005] Minimally invasive procedures have been developed to provide access to the space between adjacent spinous processes such that major surgery is not required. Such known procedures, however, may not be suitable in conditions where the spinous processes are severely compressed. Moreover, such procedures typically involve large or multiple incisions.

[006] Thus, a need exists for improvements in the treatment of spinal conditions such as spinal stenosis.

Summary of the Invention

[007] In one embodiment, apparatus includes an elongate member having a proximal portion configured to be deformed from a first configuration to a second configuration. The elongate member has a distal portion configured to be deformed from a first configuration to a second configuration. A non-expanding central portion is positioned between the proximal portion and the distal portion. The non-expanding central portion is configured to engage adjacent spinous processes.

[008] In another embodiment, apparatus includes a guide shaft, an expansion member coupled to the guide shaft, and an actuator. The expansion member is

configured to impart a force from within an interior of an implant to deform the implant. The actuator is coupled to the expansion member, the actuator is configured to move the expansion member from a first position to a second position.

[009] In yet another embodiment, apparatus includes a first clamp having a first end and a second end. The second end of the first clamp is configured to engage a first spinous process. A second clamp has a first end and a second end. The second end of the second clamp is configured to engage a second spinous process spaced apart from the first spinous process. A connector is coupled to the first end of the first clamp and the first end of the second clamp.

Brief Description of the Drawings

[0010] FIG. 1 is a schematic illustration of a posterior view of a medical device according to an embodiment of the invention in a first configuration adjacent two adjacent spinous processes.

[0011] FIG. 2 is a schematic illustration of a posterior view of a medical device according to an embodiment of the invention in a second configuration adjacent two adjacent spinous processes.

[0012] FIG. 3 is a schematic illustration of a deforming element according to an embodiment of the invention in a first configuration.

[0013] FIG. 4 is a schematic illustration of a side view of the expanding element illustrated in FIG. 3.

[0014] FIG. 5 is a side view of a medical device according to an embodiment of the invention in a first configuration.

[0015] FIG. 6 is a side view of the medical device illustrated in FIG. 5 in a second configuration.

[0016] FIG. 7 is a perspective view of a medical device according to an embodiment of the invention in a first configuration.

[0017] FIG. 8 is a posterior view of a medical device according to an embodiment of the invention, a portion of which is in a second configuration.

[0018] FIG. 9 is a posterior view of the medical device illustrated in FIG. 7 fully deployed in the second configuration.

[0019] FIG. 10 is a front plan view of the medical device illustrated in FIG. 7 in the second configuration.

[0020] FIG. 11 is a cross-sectional, side view of a medical device according to another embodiment of the invention in a first configuration.

[0021] FIG. 12 is a cross sectional, side view of the medical device illustrated in FIG. 11 in a partially expanded configuration.

[0022] FIG. 13 is a posterior view of the medical device illustrated in FIG. 11 inserted between adjacent spinous processes in a second configuration.

[0023] FIG. 14 is a lateral view of the medical device illustrated in FIG. 11 inserted between adjacent spinous processes in a second configuration.

[0024] FIG. 15 is a perspective view of an implant expansion device according to an embodiment of the invention.

[0025] FIG. 15A is a cross-sectional view of a portion of the device illustrated in FIG. 15, taken along line A-A in FIG. 15.

[0026] FIG. 15B is a cross-sectional view of a portion of the device illustrated in FIG. 15, taken along line B-B in FIG. 15.

[0027] FIG. 16 is an alternative perspective view of the implant expansion device illustrated in FIG. 15.

[0028] FIG. 17 is a perspective view of a portion of the implant expansion device illustrated in FIG. 15.

[0029] FIG. 18 is a perspective view of an implant expansion device according to an embodiment of the invention in a first position.

[0030] FIG. 19 is a perspective view of the implant expansion device illustrated in FIG. 18 in a second position.

[0031] FIG. 20 is a partial cross-sectional illustration of the implant expansion device as illustrated in FIG. 18 inserted in a spinal implant.

[0032] FIG. 21 is a partial cross-sectional illustration of the implant expansion device as illustrated in FIG. 19 inserted in a spinal implant.

[0033] FIG. 22 is a side view of a partially expanded spinal implant.

[0034] FIG. 23 is a side view of an expanded spinal implant.

[0035] FIG. 24 is a cross-sectional, side view of an implant expansion device according to an alternative embodiment of the invention in a first configuration.

[0036] FIG. 25 is a cross-sectional, side view of the implant expansion device illustrated in FIG. 24 in a second configuration.

[0037] FIG. 26 is a cross-sectional, plan view of an implant expansion device according to a further embodiment of the invention in a first configuration.

[0038] FIG. 27 is a partial side view of an implant for use with the implant expansion device illustrated in FIG. 26.

[0039] FIG. 28 is a cross-sectional, plan view of the implant expansion device illustrated in FIG. 26 in a second configuration.

[0040] FIG. 29 is a cross-sectional, plan view of an implant expansion device according to another embodiment of the invention in a first configuration.

[0041] FIG. 30 is a cross-sectional, side view of the implant expansion device illustrated in FIG. 29.

[0042] FIGS. 31 and 32 illustrate a posterior view of a spinal implant expandable by an expansion device implant expander according to another embodiment of the invention in a first configuration and a second configuration, respectively.

[0043] FIG. 33 illustrates a cross-sectional, side view of a spinal implant according to an embodiment of the invention.

[0044] FIG. 34 is a cross-sectional, side view and FIG. 35 is a side view of an implant expansion device according to an embodiment of the invention for use with the spinal implant illustrated in FIG. 33.

[0045] FIGS. 36 and 37 illustrate the use of the implant expansion device illustrated in FIGS. 34 and 35 with the spinal implant illustrated in FIG. 33.

[0046] FIG. 38 is a schematic illustration of an apparatus according to an embodiment of the invention.

[0047] FIG. 39 is a front plan view of an apparatus according to an embodiment of the invention and a portion of a spine.

[0048] FIG. 40 is a cross-sectional view of a component of the apparatus and the portion of the spine illustrated in FIG. 39, taken along line 40-40 in FIG. 39.

[0049] FIG. 41 is a side plan view of the apparatus illustrated in FIG. 39.

[0050] FIG. 42 is a side plan view of a component of the apparatus illustrated in FIG. 39.

[0051] FIG. 43 is a front plan view of the component of the apparatus illustrated in FIG. 42.

[0052] FIG. 44 is a partial cross-sectional view of a detachable trocar tip for use with an apparatus according to an embodiment of the invention in a first configuration.

[0053] FIG. 45 is a partial cross-sectional view of the detachable trocar tip for use with the apparatus according to an embodiment of the invention in a second configuration.

[0054] FIG. 46 is a partial exploded view of a detachable trocar tip for use with the apparatus according to an embodiment of the invention.

[0055] FIG. 47 is a side plan view of a medical device according to another embodiment of the invention.

[0056] FIG. 48 is a perspective view of a medical device according to another embodiment of the invention.

[0057] FIG. 49a is a perspective view of an apparatus according to an embodiment of the invention.

[0058] FIG. 49b is an exploded view of a portion of the apparatus illustrated in FIG. 49a.

[0059] FIG. 49c is an exploded view of a portion of the apparatus illustrated in FIG. 49a.

[0060] FIG. 50 is a perspective view of a spacer configured to be inserted between adjacent spinous processes according to an embodiment of the invention.

[0061] FIG. 51 is a side view of a spacer according to an embodiment of the invention in a first configuration inserted between adjacent spinous processes.

[0062] FIG. 52 is a side view of the spacer illustrated in FIG. 49 in a second configuration inserted between adjacent spinous processes.

[0063] FIGS. 53-55 are illustrations of spacers according to alternative embodiments of the invention.

[0064] FIG. 56 is a side view of a spacer according to an alternative embodiment of the invention in a first configuration.

[0065] FIG. 57 is a side view of the spacer illustrated in FIG. 56 in a second configuration inserted between adjacent spinous processes.

[0066] FIG. 58 is a side view of a spacer according to a further alternative embodiment of the invention inserted between adjacent spinous processes.

[0067] FIG. 59 is a side view of a spacer according to another alternative embodiment of the invention inserted between adjacent spinous processes.

[0068] FIGS. 60A – 60D are schematic illustrations of a posterior view of a medical device according to an embodiment of the invention in a first configuration (FIG. 60A), a second (FIGS. 60B and 60D) configuration and a third configuration (FIG. 60C).

[0069] FIGS. 61A – 61C are schematic illustrations of a posterior view of a medical device according to an embodiment of the invention in a first configuration, a second configuration and a third configuration, respectively.

[0070] FIGS. 62A – 62F are posterior views of a medical device according to an embodiment of the invention inserted between adjacent spinous processes in a first lateral position and a second lateral position.

[0071] FIG. 63 is a lateral view of the medical device illustrated in FIGS. 62A – 62F inserted between adjacent spinous processes in a second configuration.

[0072] FIG. 64 is a lateral view of a medical device according to an embodiment of the invention inserted between adjacent spinous processes in a second configuration.

[0073] FIGS. 65A and 65B are front views of a medical device according to an embodiment of the invention in a first configuration and a second configuration, respectively.

[0074] FIG. 66A is a schematic illustration of a posterior view of a medical device according to an embodiment of the invention in a first configuration disposed between two adjacent spinous processes.

[0075] FIG. 66B is a schematic illustration of a posterior view of a medical device according to an embodiment of the invention in a second configuration disposed between two adjacent spinous processes.

[0076] FIGS. 67A and 67B are perspective views of a medical device according to an embodiment of the invention in a first configuration and a second configuration, respectively.

[0077] FIG. 68 is a posterior view of the medical device illustrated in FIGS. 67A and 67B disposed between adjacent spinous processes in a second configuration.

[0078] FIG. 69 is a lateral view taken from a proximal perspective A-A of the medical device illustrated in FIG. 68 disposed between adjacent spinous processes in a second configuration.

[0079] FIG. 70 is a cross-sectional front view of the medical device illustrated in FIGS. 67A and 67B in a second configuration.

[0080] FIG. 71 is a cross-sectional plan view taken along section A-A of the medical device illustrated in FIGS. 67A and 67B in a second configuration.

[0081] FIG. 72 is a cross-sectional front view of a medical device according to an embodiment of the invention in a second configuration.

[0082] FIGS. 73A and 73B are cross-sectional plan views taken along section A-A of the medical device illustrated in FIG. 72 in a second configuration and a first configuration, respectively.

[0083] FIG. 74 is a cross-sectional front view of a medical device according to an embodiment of the invention in a second configuration.

[0084] FIGS. 75A through 75C are cross-sectional plan views taken along section A-A of the medical device illustrated in FIG. 74 in a second configuration, a first configuration, and a third configuration respectively.

[0085] FIGS. 76A and 76B are cross-sectional front views of a medical device according to an embodiment of the invention in a second configuration and a first configuration, respectively.

[0086] FIG. 77 is a cross-sectional front view of a medical device according to an embodiment of the invention in a second configuration.

[0087] FIG. 78 is a cross-sectional plan view taken along section A-A of the medical device illustrated in FIG. 77 in a second configuration.

[0088] FIGS. 79A and 79B are perspective views of a medical device according to an embodiment of the invention in a second configuration and a first configuration, respectively.

[0089] FIGS. 80A and 80B are lateral views of a medical device according to an embodiment of the invention in a first configuration and a second configuration, respectively.

[0090] FIGS. 81A and 81B are perspective views of the medical device illustrated in FIGS. 80A and 80B in a first configuration and a second configuration, respectively.

[0091] FIG. 82 is a cross-sectional plan view of the medical device illustrated in FIGS. 80A and 80B in a second configuration.

[0092] FIG. 83 is a schematic illustration of a medical device according to an embodiment of the invention in a collapsed configuration adjacent two spinous processes.

[0093] FIG. 84 is a schematic illustration of the medical device of FIG. 83 in an expanded configuration adjacent two spinous processes.

[0094] FIG. 85 is a side perspective view of an implant according to an embodiment of the invention in an expanded configuration.

[0095] FIG. 86 is a side perspective view of the implant of FIG. 85 shown in a collapsed configuration.

[0096] FIG. 87 is a side perspective view of the medical device of FIG. 85 shown in a collapsed configuration.

[0097] FIG. 88 is a side view of a deployment tool according to an embodiment of the invention.

[0098] FIG. 89 is a side view of a portion of the deployment tool of FIG. 88 shown in a first configuration.

[0099] FIG. 90 is a side view of the portion of the deployment tool of FIG. 89 shown in a second configuration.

[00100] FIG. 91 is a side view of a portion of the deployment tool of FIG. 89 and the implant of FIG. 85 with the implant shown in an expanded configuration.

[00101] FIG. 92 is a cross-sectional view of the portion of the deployment tool and implant shown in FIG. 91.

[00102] FIG. 93 is a cross-sectional view of the deployment tool and implant of FIG. 91 with the implant shown in a collapsed configuration positioned between adjacent spinous processes.

[00103] FIG. 94 is a side view of a portion of a medical device according to an embodiment of the invention illustrating an engaging portion in an extended configuration and positioned adjacent a spinous process.

[00104] FIG. 95 is a side view of the portion of the medical device of FIG. 94 illustrating the engaging portion in a partially collapsed configuration.

[00105] FIG. 96 is a side view of the portion of the medical device of FIG. 94 illustrating the engaging portion in the extended configuration after being inserted past the spinous process.

[00106] FIG. 97 is a side perspective view of the implant of FIG. 85 shown rotated about a longitudinal axis of the implant.

[00107] FIG. 98 is a side perspective view of an implant according to another embodiment of the invention.

[00108] FIG. 99 is a side view of a deployment tool according to another embodiment of the invention.

[00109] FIG. 100 is a side view of a deployment tool according to another embodiment of the invention.

[00110] FIG. 101 is a side view of a deployment tool according to another embodiment of the invention.

[00111] FIG. 102 is a side view of a deployment tool according to another embodiment of the invention.

[00112] FIG. 103 is a flow chart of a method according to an embodiment of the invention.

[00113] FIG. 104 is a schematic illustration of a posterior view of a medical device according to an embodiment of the invention in a first configuration adjacent two adjacent spinous processes.

[00114] FIG. 105 is a schematic illustration of a posterior view of a medical device according to an embodiment of the invention in a second configuration adjacent two adjacent spinous processes.

[00115] FIG. 106 is a schematic illustration of a deforming element according to an embodiment of the invention in a first configuration.

[00116] FIG. 107 is a schematic illustration of a side view of the expanding element illustrated in FIG. 106.

[00117] FIG. 108 is a side cross-sectional view of a medical device according to an embodiment of the invention in a first configuration.

[00118] FIG. 109 is a side cross-sectional view of the medical device illustrated in FIG. 108 in a second configuration.

[00119] FIG. 110 is a cross-sectional side view of a medical device and an actuator according to an embodiment of the invention with a portion of the medical device deployed in a second configuration.

[00120] FIG. 111 is a side cross-sectional view of a medical device and an actuator according to an embodiment of the invention with the medical device fully deployed in the second configuration.

[00121] FIG. 112 is a side cross-sectional view of a medical device according to another embodiment of the invention in a first configuration.

[00122] FIG. 113 is a side cross-sectional view of the medical device illustrated in FIG. 112 in a second configuration.

[00123] FIG. 114 is a side cross-sectional view of a medical device and an actuator according to an embodiment of the invention with a portion of the medical device moved back to its first configuration.

[00124] FIG. 115 is a side cross-sectional view of a medical device and an actuator according to an embodiment of the invention with the medical device moved back to its first configuration.

[00125] FIG. 116 is a side cross-sectional view of a medical device and an actuator according to an embodiment of the invention with a portion of the medical device moved back to its first configuration.

[00126] FIG. 117 is a side cross-sectional view of a medical device and an actuator according to an embodiment of the invention with the medical device moved back to its first configuration.

[00127] FIG. 118 is a side perspective view of an implant according to an embodiment of the invention shown in a collapsed configuration.

[00128] FIG. 119 is a cross-sectional view of the implant of FIG. 118 taken along line 23-23.

[00129] FIG. 120 is a cross-sectional view of the implant of FIG. 118 shown in an expanded configuration.

Detailed Description

[00130] As used in this specification and the appended claims, the singular forms “a,” “an” and “the” include plural referents unless the context clearly dictates otherwise. Thus, for example, the term “a member” is intended to mean a single member or a combination of members, “a material” is intended to mean one or more materials, or a combination thereof. Furthermore, the words “proximal” and “distal” refer to direction closer to and away from, respectively, an operator (e.g., surgeon, physician, nurse, technician, etc.) who would insert the medical device into the patient, with the tip-end (i.e., distal end) of the device inserted inside a patient’s body first. Thus, for example, the implant end first inserted inside the patient’s body would be the distal end of the implant, while the implant end to last enter the patient’s body would be the proximal end of the implant.

[00131] In one embodiment, apparatus includes an elongate member having a proximal portion configured to be deformed from a first configuration to a second configuration under, for example, an axial load or a radial load. The elongate member has a distal portion configured to be deformed from a first configuration to a second configuration under, for example, an axial load or a radial load. A non-expanding central portion is positioned between the proximal portion and the distal portion. The non-expanding central portion is configured to engage adjacent spinous processes.

[00132] In some embodiments of the invention, the elongate member can have multiple portions that each move from a first configuration to a second configuration,

either simultaneously or serially. Additionally, the device, or portions thereof, can be in many positions during the movement from the first configuration to the second configuration. For ease of reference, the entire device is referred to as being in either a first configuration or a second configuration.

[00133] FIG. 1 is a schematic illustration of a medical device according to an embodiment of the invention adjacent two adjacent spinous processes. The medical device 10 includes a proximal portion 12, a distal portion 14 and a central portion 16. The medical device 10 has a first configuration in which it can be inserted between adjacent spinous processes S. The central portion 16 is configured to contact the spinous processes S to prevent over-extension/compression of the spinous processes S. In some embodiments, the central portion 16 does not substantially distract the adjacent spinous processes S. In other embodiments, the central portion 16 does not distract the adjacent spinous processes S.

[00134] In the first configuration, the proximal portion 12, the distal portion 14 and the central portion 16 are coaxial (i.e., share a common longitudinal axis). In some embodiments, the proximal portion 12, the distal portion 14 and the central portion 16 define a tube having a constant inner diameter. In other embodiments, the proximal portion 12, the distal portion 14 and the central portion 16 define a tube having a constant outer diameter and/or inner diameter.

[00135] The medical device 10 can be moved from the first configuration to a second configuration as illustrated in FIG. 2. In the second configuration, the proximal portion 12 and the distal portion 14 are positioned to limit lateral movement of the device 10 with respect to the spinous processes S. The proximal portion 12 and the distal portion 14 are configured to engage the spinous process (i.e., either directly or through surrounding tissue) in the second configuration. For purposes of clarity, the tissue surrounding the spinous processes S is not illustrated.

[00136] In some embodiments, the proximal portion 12, the distal portion 14 and the central portion 16 are monolithically formed. In other embodiments, one or more of the proximal portion 12, the distal portion 14 and the central portion 16 are separate

components that can be coupled together to form the medical device 10. For example, the proximal portion 12 and distal portion 14 can be monolithically formed and the central portion can be a separate component that is coupled thereto.

[00137] In use, the spinous processes S can be distracted prior to inserting the medical device 10. Distraction of spinous processes is discussed below. When the spinous processes are distracted, a trocar can be used to define an access passage for the medical device 10. In some embodiments, the trocar can be used to define the passage as well as distract the spinous processes S. Once an access passage is defined, the medical device 10 is inserted percutaneously and advanced between the spinous processes, distal end 14 first, until the central portion 16 is located between the spinous processes S. Once the medical device 10 is in place between the spinous processes, the proximal portion 12 and the distal portion 14 are moved to the second configuration, either serially or simultaneously.

[00138] In some embodiments, the medical device 10 is inserted percutaneously (i.e., through an opening in the skin) and in a minimally invasive manner. For example, as discussed in detail herein, the size of portions of the implant is expanded after the implant is inserted between the spinous processes. Once expanded, the size of the expanded portions of the implant is greater than the size of the opening. For example, the size of the opening/incision in the skin may be between 3 millimeters in length and 25 millimeters in length. In some embodiments, the size of the implant in the expanded configuration is between 3 and 25 millimeters.

[00139] FIG. 3 is a schematic illustration of a deformable element 18 that is representative of the characteristics of, for example, the distal portion 14 of the medical device 10 in a first configuration. The deformable member 18 includes cutouts A, B, C along its length to define weak points that allow the deformable member 18 to deform in a predetermined manner. Depending upon the depth d of the cutouts A, B, C and the width w of the throats T1, T2, T3, the manner in which the deformable member 18 deforms under an applied load can be controlled and varied. Additionally, depending upon the length L between the cutouts A, B, C (i.e., the length of the material between

the cutouts) the manner in which the deformable member 18 deforms can be controlled and varied.

[00140] FIG. 4 is a schematic illustration of the expansion properties of the deformable member 18 illustrated in FIG. 3. When a load is applied, for example, in the direction indicated by arrow X, the deformable member 18 deforms in a predetermined manner based on the characteristics of the deformable member 18 as described above. As illustrated in FIG. 4, the deformable member 18 deforms most at cutouts B and C due to the configuration of the cutout C and the short distance between cutouts B and C. In some embodiments, the length of the deformable member 18 between cutouts B and C is sized to fit adjacent a spinous process.

[00141] The deformable member 18 is stiffer at cutout A due to the shallow depth of cutout A. As indicated in FIG. 4, a smooth transition is defined by the deformable member 18 between cutouts A and B. Such a smooth transition causes less stress on the tissue surrounding a spinous process than a more drastic transition such as between cutouts B and C. The dimensions and configuration of the deformable member 18 can also determine the timing of the deformation at the various cutouts. The weaker (i.e., deeper and wider) cutouts deform before the stronger (i.e., shallower and narrower) cutouts.

[00142] FIGS. 5 and 6 illustrate a spinal implant 100 in a first configuration and second configuration, respectively. As shown in FIG. 5, the spinal implant 100 is collapsed in a first configuration and can be inserted between adjacent spinous processes. The spinal implant 100 has a first expandable portion 110, a second expandable portion 120 and a central portion 150. The first expandable portion 110 has a first end 112 and a second end 1140. The second expandable portion 120 has a first end 122 and a second end 124. The central portion 150 is coupled between second end 1140 and first end 122. In some embodiment, the spinal implant 100 is monolithically formed.

[00143] The first expandable portion 110, the second expandable portion 120 and the central portion 150 have a common longitudinal axis A along the length of spinal

implant 100. The central portion 150 can have the same inner diameter as first expandable portion 110 and the second expandable portion 120. In some embodiments, the outer diameter of the central portion 150 is smaller than the outer diameter of the first expandable portion 110 and the second expandable portion 120.

[00144] In use, spinal implant 100 is inserted percutaneously between adjacent spinous processes. The first expandable portion 110 is inserted first and is moved past the spinous processes until the central portion 150 is positioned between the spinous processes. The outer diameter of the central portion 150 can be slightly smaller than the space between the spinous processes to account for surrounding ligaments and tissue. In some embodiments, the central portion directly contacts the spinous processes between which it is positioned. In some embodiments, the central portion of spinal implant 100 is a fixed size and is not compressible or expandable.

[00145] The first expandable portion 110 includes expanding members 115, 117 and 119. Between the expanding members 115, 117, 119, openings 111 are defined. As discussed above, the size and shape of the openings 111 influence the manner in which the expanding members 115, 117, 119 deform when an axial load is applied. The second expandable portion 120 includes expanding members 125, 127 and 129. Between the expanding members 125, 127, 129, openings 121 are defined. As discussed above, the size and shape of the openings 121 influence the manner in which the expanding members 125, 127, 129 deform when an axial load is applied.

[00146] When an axial load is applied to the spinal implant 100, the spinal implant 100 expands to a second configuration as illustrated in FIG. 6. In the second configuration, first end 112 and second end 1140 of the first expandable portion 110 move towards each other and expanding members 115, 117, 119 project substantially laterally away from the longitudinal axis A. Likewise, first end 122 and second end 124 of the second expandable portion 120 move towards one another and expanding members 125, 127, 129 project laterally away from the longitudinal axis A. The expanding members 115, 117, 119, 125, 127, 129 in the second configuration form projections that extend to positions adjacent to the spinous processes between which the

spinal implant 100 is inserted. In the second configuration, the expanding members 115, 117, 119, 125, 127, 129 inhibit lateral movement of the spinal implant 100, while the central portion 150 prevents the adjacent spinous processes from moving together any closer than the distance defined by the diameter of the central portion 150.

[00147] A spinal implant 200 according to an embodiment of the invention is illustrated in FIGS. 7-9 in various configurations. Spinal implant 200 is illustrated in a completely collapsed configuration in FIG. 7 and can be inserted between adjacent spinous processes. The spinal implant 200 has a first expandable portion 210, a second expandable portion 220 and a central portion 250. The first expandable portion 210 has a first end 212 and a second end 214. The second expandable portion 220 has a first end 222 and a second end 224. The central portion 250 is coupled between second end 214 and first end 222.

[00148] The first expandable portion 210, the second expandable portion 220 and the central portion 250 have a common longitudinal axis A along the length of spinal implant 200. The central portion 250 can have the same inner diameter as first expandable portion 210 and the second expandable portion 220. The outer diameter of the central portion 250 is greater than the outer diameter of the first expandable portion 210 and the second expandable portion 220. The central portion 250 can be monolithically formed with the first expandable portion 210 and the second expandable portion 220 or can be a separately formed sleeve coupled thereto or thereupon.

[00149] In use, spinal implant 200 is inserted percutaneously between adjacent spinous processes S. The first expandable portion 210 is inserted first and is moved past the spinous processes S until the central portion 250 is positioned between the spinous processes S. The outer diameter of the central portion 250 can be slightly smaller than the space between the spinous processes S to account for surrounding ligaments and tissue. In some embodiments, the central portion 250 directly contacts the spinous processes S between which it is positioned. In some embodiments, the central portion 250 of spinal implant 200 is a fixed size and is not compressible or

expandable. In other embodiments, the central portion 250 can compress to conform to the shape of the spinous processes.

[00150] The first expandable portion 210 includes expanding members 215, 217 and 219. Between the expanding members 215, 217, 219, openings 211 are defined. As discussed above, the size and shape of the openings 211 influence the manner in which the expanding members 215, 217, 219 deform when an axial load is applied. Each expanding member 215, 217, 219 of the first expandable portion 210 includes a tab 213 extending into the opening 211 and an opposing mating slot 218. In some embodiments, the first end 212 of the first expandable portion 210 is rounded to facilitate insertion of the spinal implant 200.

[00151] The second expandable portion 220 includes expanding members 225, 227 and 229. Between the expanding members 225, 227, 229, openings 221 are defined. As discussed above, the size and shape of the openings 221 influence the manner in which the expanding members 225, 227, 229 deform when an axial load is applied. Each expanding member 225, 227, 229 of the second expandable portion 220 includes a tab 223 extending into the opening 221 and an opposing mating slot 228.

[00152] When an axial load is applied to the spinal implant 200, the spinal implant moves to a partially expanded configuration as illustrated in FIG. 8. In the partially expanded configuration, first end 222 and second end 224 of the second expandable portion 220 move towards one another and expanding members 225, 227, 229 project laterally away from the longitudinal axis A. To prevent the second expandable portion 220 from over-expanding, the tab 223 engages slot 228 and acts as a positive stop. As the axial load continues to be imparted to the spinal implant 200 after the tab 223 engages slot 228, the load is transferred to the first expandable portion 210. Accordingly, the first end 212 and the second end 214 then move towards one another until tab 213 engages slot 218 in the fully expanded configuration illustrated in FIG. 9. In the second configuration, expanding members 215, 217, 219 project laterally away from the longitudinal axis A. In some alternative embodiments, the first expandable portion and the second expandable portion expand simultaneously under an axial load.

[00153] The order of expansion of the spinal implant 200 can be controlled by varying the size of openings 211 and 221. For example, in the embodiments shown in FIGS. 7-9, the opening 221 is slightly larger than the opening 211. Accordingly, the notches 226 are slightly larger than the notches 216. As discussed above with respect to FIGS. 3 and 4, for this reason, the second expandable portion 220 will expand before the first expandable portion 210 under an axial load.

[00154] In the second configuration, the expanding members 215, 217, 219, 225, 227, 229 form projections that extend adjacent the spinous processes S. Once in the second configuration, the expanding members 215, 217, 219, 225, 227, 229 inhibit lateral movement of the spinal implant 200, while the central portion 250 prevents the adjacent spinous processes from moving together any closer than the distance defined by the diameter of the central portion 250.

[00155] The portion P of each of the expanding members 215, 217, 219, 225, 227, 229 proximal to the spinous process S expands such that portion P is substantially parallel to the spinous process S. The portion D of each of the expanding members 215, 217, 219, 225, 227, 229 distal from the spinous process S is angled such that less tension is imparted to the surrounding tissue.

[00156] In the second configuration, the expanding members 225, 227, 229 are separate by approximately 120 degrees from an axial view as illustrated in FIG. 10. While three expanding members are illustrated, two or more expanding members may be used and arranged in an overlapping or interleaved fashion when multiple implants 200 are inserted between multiple adjacent spinous processes. Additionally, regardless of the number of expanding members provided, the adjacent expanding members need not be separated by equal angles or distances.

[00157] The spinal implant 200 is deformed by a compressive force imparted substantially along the longitudinal axis A of the spinal implant 200. The compressive force is imparted, for example, by attaching a rod (not illustrated) to the first end 212 of the first expandable portion 210 and drawing the rod along the longitudinal axis while imparting an opposing force against the second end 224 of the second expandable

portion 220. The opposing forces result in a compressive force causing the spinal implant 200 to expand as discussed above.

[00158] The rod used to impart compressive force to the spinal implant 200 can be removably coupled to the spinal implant 200. For example, the spinal implant 200 can include threads 208 at the first end 212 of the first expandable portion 210. The force opposing that imparted by the rod can be applied by using a push bar (not illustrated) that is removably coupled to the second end 224 of the second expandable portion 220. The push rod can be aligned with the spinal implant 200 by an alignment notch 206 at the second end 224. The spinal implant 200 can also be deformed in a variety of other ways, examples of which are discussed in detail below.

[00159] FIGS. 11-14 illustrate a spinal implant 300 according to an embodiment of the invention. Spinal implant 300 includes an elongated tube 310 configured to be positioned between adjacent spinous processes S and having a first end 312 and a second end 314. The elongated tube 310 has longitudinal slots 311 defined along its length at predetermined locations. The slots 311 are configured to allow portions of the elongated tube 310 to expand outwardly to form projections 317. An inflatable member 350 is disposed about the elongated tube between adjacent sets of slots 311.

[00160] The inflatable member 350 is configured to be positioned between adjacent spinous processes S as illustrated in FIGS. 11-14. Once inserted between the adjacent spinous processes, the inflatable member 350 is inflated with a liquid and/or a gas, which can be, for example, a biocompatible material. The inflatable member 350 is inflated to maintain the spinal implant 300 in position between the spinous processes S. In some embodiments, the inflatable member 350 is configured to at least partially distract the spinous processes S when inflated. The inflatable member 350 can be inflated to varied dimensions to account for different spacing between spinous processes S.

[00161] The inflatable member 350 can be inflated via an inflation tube 370 inserted through the spinal implant 300 once spinal implant 300 is in position between the spinous processes S. Either before or after the inflatable member 350 is inflated, the

projections 317 are expanded. To expand the projections 317, an axial force is applied to the spinal implant 300 using draw bar 320, which is coupled to the first end 312 of the spinal implant 300.

[00162] As the draw bar 320 is pulled, the axial load causes the projections 317 to buckle outwardly, thereby preventing the spinal implant from lateral movement with respect to the spinous processes S. FIG. 12 is an illustration of the spinal implant 300 during deformation, the projections 317 being only partially formed. Although illustrated as deforming simultaneously, the slots 311 alternatively can be dimensioned such that the deformation occurs at different times as described above. Once the spinal implant is in the expanded configuration (see FIG. 13), the draw bar 320 is removed from the elongated tube 310.

[00163] The orientation of the spinal implant 300 need not be such that two projections are substantially parallel to the axis of the portion of the spine to which they are adjacent as illustrated in FIG. 14. For example, the spinal implant 300 can be oriented such that each of the projections 317 is at a 45 degree angle with respect to the spinal axis.

[00164] The spinal implants 100, 200, 300 can be deformed from their first configuration to their second configuration using a variety of expansion devices. For example, portions of the spinal implants 100, 200, 300, as well as other types of implants I, can be deformed using expansion devices described below. While various types of implants I are illustrated, the various expansion devices described can be used with any of the implants described herein.

[00165] FIGS. 15-17 illustrate an embodiment of an expansion device 1500. The expansion device 1500 includes a guide handle 1510, a knob assembly 1515, an upper housing 1517 a shaft 1520 and an implant support portion 1530. The expansion device 1500 is used to insert an implant (not illustrated) in between adjacent spinous processes and expand the implant such that it is maintained in position between the spinous processes as described above. Both the guide handle 1510 and the knob assembly 1515 can be grasped to manipulate the expansion device 1500 to insert the implant. While

no particular implant is illustrated in FIGS. 15-17 for purposes of clarity, an implant such as, for example, implant 200 can be used with the expansion device 1500 (see FIG. 7).

[00166] The implant support portion 1530 slidably receives the implant over a surface of rod 1532. The implant slides over rod 1532 until it is received within a recess 1534 as best illustrated in FIG. 15B. The implant is threadedly coupled to implant support portion 1530 using a threaded rod 1570. The threaded rod 1570 is coupled within the actuator knob 1550 using a thrust bearing 1552. An alignment protrusion 1536 is disposed inside the recess 1534 and is configured to mate with a corresponding notch on the implant to ensure proper positioning of the implant.

[00167] Upper housing 1517 threadedly receives shaft 1520 as best illustrated in FIG. 15A. Upper housing includes internal threads 1519 that mate with external threads 1521 on shaft 1520. Actuator knob 1550 is coupled to the upper housing 1517 such that when actuator knob 1550 is turned in the direction indicated by arrows E, the shaft 1520 moves axially towards the distal end of the device 1500 as the threaded rod 1570 acts as a draw bar and opposes the movement of the implant in the distal direction. In other words, when the implant is inserted between adjacent spinous processes, the actuator knob 1515 is turned and the distal end of the shaft 1520 imparts an axial force against the proximal end of the implant. Simultaneously, the threaded rod 1570 causes an opposing force in the proximal direction.

[00168] The forces imparted by the shaft 1520 and the threaded rod 1570 cause portions of the implant to expand in a transverse configuration such that the implant is maintained in position between the spinous processes as described above.

[00169] Once the implant is in position and fully expanded, the release knob 1560 is turned in the direction indicated by arrow R to unscrew the threaded rod 1570 from the implant. The expansion device can then be removed.

[00170] FIG. 18 illustrates a portion of expansion device 400 in a collapsed configuration. Expansion device 400 can be used to selectively form protrusions on the

implant I (not illustrated in FIG. 18) at desired locations. The expansion device 400 includes a guide shaft 410, which can guide the expansion device 400 into the implant I and a cam actuator 450 mounted thereto and positionable into an eccentric position. The expansion device 400 has a longitudinal axis A and the cam actuator 450 has a cam axis C that is laterally offset from the longitudinal axis A by a distance d. FIG. 19 illustrates the expansion device 400 in the expanded configuration with the cam actuator 450 having been rotated about the cam axis C.

[00171] The expansion device 400 can be inserted into an implant I through an implant holder H as illustrated in FIG. 20. The implant holder H is coupled to the implant and is configured to hold the implant in position while the expansion device 400 is being manipulated to deform the implant I. Once the implant I is satisfactorily deformed, the implant holder H can be detached from the implant I and removed from the patient, leaving the implant I behind.

[00172] Referring to FIGS. 20 and 21, the expansion device 400 includes a handle 420 that is used to deploy the cam actuator 450. When the handle 420 is rotated, the cam actuator 450 is deployed and deforms the implant I. Once the cam actuator 450 is fully deployed (e.g., 180 degrees from its original position) and locked in place, the entire expansion device 400 is rotated to deform the implant I around the circumference of implant I. The cam actuator 450 circumscribes a locus of points that is outside the original diameter of the implant I, forming the projection P (see FIG. 22). The expansion device 400 can be rotated either by grasping the guide shaft 410 or by using the handle 420 after it has been locked in place.

[00173] The expansion device 400 can be used to form multiple projections P. Once a first projection P is formed, the cam actuator 450 can be rotated back to its first configuration and the expansion device 400 advanced through the implant I to a second position. When the expansion device 400 is appropriately positioned, the cam actuator 450 can again be deployed and the expansion device 400 rotated to form a second projection P (see FIG. 23). In some embodiments, the implant I is positioned between

adjacent spinous processes and the projections P are formed on the sides of the spinous processes to prevent lateral (i.e., axial) displacement of the implant I.

[00174] An alternative expansion device 500 is illustrated in FIGS. 24 and 25. FIG. 24 illustrates the expansion device 500 in a first configuration and FIG. 25 illustrates the expansion device 500 in a second configuration. The expansion device 500 includes a guide shaft 510 that is inserted into an implant I. An axial cam shaft actuator 520 is slidably disposed within the guide shaft 520. The axial cam shaft actuator 520 has a sloped recess 530 to receive a movable object 550. When the cam shaft actuator 520 is moved, the movable object 550 is displaced along the sloped recess 530 until it protrudes through an opening 540 in the guide shaft 510.

[00175] The movable object 550 is configured to displace a portion of the implant I, thereby forming a projection P. Multiple movable objects 550 can be used around the circumference of the guide shaft 510 to form a radially extending protrusions P around the circumference of the implant I. Additionally, the protrusions can be formed at multiple locations along the length of the implant I by advancing the expansion device 500 along the length of the implant to a second position as discussed above. Alternatively, the expansion device can have multiple recesses that displace other sets of movable objects.

[00176] In alternative embodiments, the expansion device can also serve as an implant. For example, the expansion device 500 can be inserted between adjacent spinous processes S, the movable objects moved out through openings 540, and the expansion device 500 left behind in the body. In such an embodiment, the movable objects prevent the expansion device 500 from lateral movement with respect to the spinous processes S.

[00177] In another alternative embodiment, rather than having openings 540 in the expansion device 500, the movable objects 550 can be positioned against a weaker (e.g., thinner) portion of the wall of the expansion device and move that portion of the expansion device 500 to a protruded configuration.

[00178] Another alternative expansion device 600 is illustrated in FIGS. 26-28. FIG. 26 illustrates the expansion device 600 in a first configuration and FIG. 28 illustrates the expansion device in a second configuration. The expansion device 600 includes a guide shaft 610 that is inserted into an implant I. The guide shaft 610 has openings 640 defined therein. An axial cam shaft actuator 620 is rotatably coupled within the guide shaft 610. Displaceable objects 650 are positioned within the guide shaft 610 and are configured to protrude through the openings 640 in the guide shaft 610. When the cam shaft actuator 620 is rotated approximately 90 degrees, the movable objects 650 move through the openings 640 and deform the implant I, forming the projection P. Alternatively, the expansion device can have multiple cams that displace other sets of movable objects.

[00179] Multiple movable objects 650 can be used around the circumference of the guide shaft 610 to form radially extending protrusions P around the implant I. Additionally, the protrusions can be formed at multiple locations along the length of the implant I by advancing the expansion device 600 along the length of the implant I to a second position as discussed above.

[00180] An implant expansion device 700 is illustrated in FIGS. 29 and 30. The implant expansion device 700 is configured to be inserted into an implant I. The implant 700 includes a guide shaft 710 coupled to a housing 770. A cam actuator 720 is rotatably mounted within the housing 770 and includes arms 790 that extend in opposite directions from one another. The cam actuator 720 is rotated using rod 722.

[00181] As the cam actuator 720 rotates, the arms 790 engage movable objects 750. The movable objects 750 are configured to project out of the housing 770 when the cam actuator is rotated in a clockwise manner. Once the movable objects 750 are fully extended, they engage the implant I and the expansion device 700 can be rotated a complete revolution to form a protrusion in the implant I.

[00182] After one protrusion is formed, the rod 722 can be rotated counterclockwise to disengage the movable objects 750 from the implant I. Once disengaged, the

expansion device 700 can be advanced to another location within the implant I as discussed above.

[00183] In some other embodiments, the implant I can be balloon actuated. FIG. 31 illustrates an implant I positioned between adjacent spinous processes S. A balloon actuator 800 is inserted into the implant I and expanded as illustrated in FIG. 32 to move the implant I to its expanded configuration. Once expanded, the balloon actuator 800 can be deflated and removed, leaving the implant I in an expanded configuration.

[00184] In some embodiments, the balloon actuator 800 can have multiple lobes, one that expands on each side of the spinous process S. In other embodiments, multiple balloon actuators 800 can be used to expand the implant I.

[00185] FIG. 33 is a cross-sectional view of an expandable implant 900 that can be expanded using an expansion device 950, illustrated in FIGS. 34-37. The implant 900 has an elongated body portion 910 having a first end 901 and a second end 902. The first end 901 has an externally threaded portion 911 and the second end 902 has an internally threaded portion 912. The implant 900 has a first outer diameter D1 at the externally threaded portion 911 and a second outer diameter D2, which is wider than the first outer diameter D1.

[00186] The expansion device 950 includes a draw bar 960 and a compression bar 970. In some embodiments, the compression bar 970 defines a channel 975 having internal threads 971 to mate with the externally threaded portion 911 of the implant 900 (see FIG. 34). The draw bar 960 has external threads 961 to mate with the internally threaded portion 912 of implant 900.

[00187] In use, the compression bar 970 is coupled to the first end 901 of the implant 900 and abuts the implant 900 at the transition between the first outer diameter D1 and the second outer diameter D2, which serves as a stop for the compression bar 970. In some embodiments, the outer diameter of the entire implant 900 is substantially constant and the inner diameter of the compression bar 970 narrows to serve as the stop for the compression bar 970. With the compression bar 970 in place, the draw bar 960

is inserted through the channel 975 and is coupled to the second end 902 of the implant 900 via the internally threaded portion 912 of implant 900 (see FIG. 35). Once the compression bar 970 and the draw bar 960 are coupled to the implant 900, the draw bar 960 can be pulled while imparting an opposing force on the compression bar 970 to expand the implant 900 (see FIG. 36). When the implant 900 is fully expanded, the compression bar 970 and the draw bar 960 are removed and the implant is left behind in the body.

[00188] With the expansion devices described herein, the location of protrusions can be selected in vivo, rather than having predetermined expansion locations. Such a configuration reduces the need to have multiple sizes of spacers available. Additionally, the timing of the deployment of the protrusions can be varied.

[00189] The various implants 100, 200, 300 described herein can be made from, for example, stainless steel, plastic, polyetheretherketone (PEEK), carbon fiber, ultra-high molecular weight (UHMW) polyethylene, etc. The material can have a tensile strength similar to or higher than that of bone.

[00190] In other embodiments of the invention, an apparatus includes a first clamp having a first end and a second end. The second end of the first clamp is configured to engage a first spinous process. A second clamp has a first end and a second end. The second end of the second clamp is configured to engage a second spinous process spaced apart from the first spinous process. A connector is coupled to the first end of the first clamp and the first end of the second clamp.

[00191] FIG. 38 is a schematic illustration of a medical device according to an embodiment of the invention attached to two adjacent spinous processes. The apparatus 1010 includes a first clamp 1012 configured to be coupled to a first spinous process S and a second clamp 1014 configured to be coupled to a second spinous process S. The first clamp 1012 and the second clamp 1014 are configured to be moved apart from one another in the direction indicated by arrows X. As the first clamp 1012 and the second clamp 1014 are moved apart, an opening between adjacent spinous processes S expands. An insert 1050 can be inserted between the spinous

processes S in the direction indicated by arrow Y to maintain the opening between the spinous processes S. The clamps 1012, 1014 engage the spinous processes S with sufficient force such that when the clamps 1012, 1014 are spread apart, they cause lateral displacement of the spinous processes S.

[00192] FIG. 39 is a side view of a medical device according to an embodiment of the invention coupled to a portion of a spine. The tissue surrounding the spine is not illustrated for the sake of clarity. The medical device 1000 includes a first clamp 1100 and a second clamp 1200. The first clamp 1100 has a proximal end 1120 and a distal end 1140. The distal end 1140 of the first clamp 1100 is configured to engage a first spinous process S. The second clamp 1200 has a first end 1220 and a second end 1240. The second end 1240 of the second clamp 1200 is configured to engage a second spinous process S that is spaced apart from the first spinous process S.

[00193] A connector 1300 is coupled to the proximal end 1120 of the first clamp 1100 and the first end 1220 of the second clamp 1200. The position of the connector 1300 relative to the first clamp 1100 and the second clamp 1200 can be adjusted such that the distance between the first clamp 1100 and the second clamp 1200 can be adjusted. In other words, the connector 1300 is reconfigurable between a first configuration and a second configuration. The first clamp 1100 is a first distance from the second clamp 1200 when the connector 1300 is in its first configuration and is a second distance from the second clamp 1200 when the connector 1300 is in its second configuration.

[00194] Referring to FIG. 40, in which the first clamp 1100 is illustrated, the first clamp 1100 includes a first jaw 1150 and a second jaw 1130 opposite the first jaw 1150. The first jaw 1150 and the second jaw 1130 are configured to be movable between a first configuration and a second configuration. The first jaw 1150 and the second jaw 1130 are closer together in the second configuration than in the first configuration. In the second configuration, the first jaw 1150 and the second jaw 1130 engage the spinous process S with sufficient force to substantially maintain the orientation of the first clamp 1100 and the second clamp 1200 with respect to the

spinous process S when the connector 1300 is moved to its second configuration, thereby spreading the spinous processes S. The second clamp 1200 has a similar configuration, but is not illustrated for ease of reference. The material of the jaws 1150, 1130 are such that they can sufficiently engage the spinous processes S as described, but to not damage the spinous processes. Adequate materials include, for example, stainless steel, polyetheretherketone (PEEK), carbon fiber, ultra-high molecular weight (UHMW) polyethylene, etc. The material can have a tensile strength similar to or higher than that of bone. In some embodiments, the clamp 1200 can be manufactured from stainless steel and a coating and/or an over-mold or over-layer of PEEK or carbon fiber can be applied to the jaws 1150, 1130.

[00195] In some embodiments, the medical device 100 is used to spread adjacent spinous processes of severely compressed vertebrae. Additionally, the medical device 100 stabilizes the spinous processes during procedures without penetrating the vertebrae.

[00196] In some embodiments, the first clamp 1100 includes a first arm 1170 and a second arm 1180 and a tension member 1160. The first arm 1170 and second arm 1180 can be resiliently coupled such that as tension member 1160 is advanced towards the distal end 1140 of the clamp 1100, the first arm 1170 and the second arm 1180 are moved towards one another, but as the tension member 1160 is moved away from the distal end 1140 of the clamp 1100, the first arm 1170 and the second arm 1180 return to their default position (i.e., spaced apart).

[00197] The tension member 1160 is configured to move the first jaw 1150 and the second jaw 1130 between their first configuration and their second configuration as the first arm 1170 and the second arm 1180 move towards one another. As the tension member 1160 is moved towards the first jaw 1150 and the second jaw 1130, the first jaw 1150 and the second jaw 1130 engage the spinous process S. In some applications, a distal end 1140 of the clamp 1100 is positioned adjacent the lamina L of the vertebra to which it is coupled. In some embodiments, the clamp 1100 is attached close to the

lamina L to minimize the lever arm on the spinous process. The distal end 1140 of clamp 1100 need not penetrate the lamina L.

[00198] In an alternative embodiment, the tension member includes threads that engage threads on the first clamp. In such an embodiment, the tension member is moved along the length of the first clamp by turning the tension member. Returning to FIG. 40, the tension member 1160 may optionally include a tapered portion 1190 that matingly engages a tapered portion 1110 of first clamp 1100. Such a configuration can ensure appropriate distribution of the forces to the spinous process S. The second clamp 1200 is similarly configured and includes a tension member 126 and opposing jaws.

[00199] A swing arm 1700 is pivotably coupled to the connector 1300 between the first clamp 1100 and the second clamp 1200. The swing arm 1700 has an arcuate portion 173 and travels along a range of motion. The arcuate portion 173 of the swing arm 1700 has a first end 1750 and a second end 1770.

[00200] As best seen in FIGS. 41 and 42, the second end 1770 of the arcuate portion 173 of swing arm 1700 is configured to receive a working tool 1840, such as, for example, a pointed trocar tip. The swing arm 1700 defines an opening 1740 in which at least a portion of the working tool 1840 is received. In some embodiments, the opening 1740 extends along the entire length of the arcuate portion 173 between the first end 1750 and the second end 1770. In some embodiments, an optional handle 190 can be coupled to the first clamp 1100 and/or the second clamp 1200 to facilitate insertion of the clamps 1100, 1200 and increase stability of the apparatus 1000 during use.

[00201] The working tool 1840 is coupled to a guide wire 1860. The guide wire 1860 has a first end 1810 and a second end 1830. The second end 1830 of the guide wire 1860 is coupled to the working tool 1840. A retainer 1820 (discussed in detail below) is coupled to the first end 1810 of the guide wire 1860 and is configured to maintain the position of the working tool 1840 with respect to the swing arm 1700. The retainer 1820 is matingly received in a recess 1720 in the swing arm 1700. The guide wire 1860 is received in the opening 1740 defined in the swing arm 1700. The guide

wire is received in the opening 1740 through a channel 1760 defined in the swing arm 1700 as best seen in FIG. 43. In some alternative embodiments, the guide wire does not extend through the opening 1740 of the swing arm 1700. In yet other alternative embodiments, the guide wire is not present.

[00202] FIGS. 44 and 45 illustrate the retainer 1820 in a first configuration and a second configuration, respectively. The retainer 1820 includes a housing 1880 that defines an opening 1870 through which guide wire 1860 is movably disposed. The guide wire 1860 is coupled to a retention member 1830. The retention member 1830 is biased towards a first end 1890 of housing 1880 by a spring 1850. The spring 1850 is between a second end 1810 of the housing 1880 and the retention member 1830.

[00203] In use, when the retainer 1850 is in the first configuration (FIG. 44), the working tool is maintained in the swing arm 1700. When the retainer 1820 is moved to its second configuration (FIG. 45), the working tool 1840 can be removed from the swing arm 1700. When moved to the second configuration, the retainer 1820 is displaced a distance d , thereby increasing the effective length of the guide wire 1860, allowing movement of the working tool 1840 with respect to the end of the swing arm 1700. In some embodiments, the distance d is approximately the same as the length of the portion of the working tool 1840 received in the swing arm 1700.

[00204] As shown in FIG. 46, a working tool 1840' is inserted into an opening 1740' defined by a swing arm 1700'. The swing arm 1700' includes a projection 1920 within opening 1740' that mates with a recess 1970 on working tool 1840'.

[00205] Returning to FIGS. 39-42, in use, a first clamp 1100 is inserted through a body B and coupled to a spinous process S. The tension member 1160 is moved towards the distal end 1140 of the first clamp to engage the first jaw 1150 and the second jaw 1130 with the spinous process S. The second clamp 1200 is then inserted and similarly coupled to the adjacent spinous process S. The connector 1300 is actuated to increase the distance between the first clamp 1100 and the second clamp 1200, thereby separating the adjacent spinous processes S. Once the spinous processes S are separated, the swing arm 1700 is moved through its range of motion M.

[00206] The swing arm 1700 is moved from a location outside a body B through a range of motion M (see, e.g., FIG. 41). The swing arm 1700 enters the body B and moves through range of motion M until it is at target T (see, e.g., FIG. 39) between adjacent spinous processes S.

[00207] The movement of the swing arm 1700 into the body defines a path within the tissue (not illustrated). The tissue is penetrated by a pointed projection (i.e., working tool 1840). The path M defined by the swing arm 1700 includes the target T between the adjacent spinous processes S. Once the path is defined, the swing arm 1700 can be removed and a spacer 500 (see FIG. 49), discussed in detail below, can be inserted between the adjacent spinous processes S. In some embodiments of the invention, the spacer 5000 can be removably attached to the swing arm 1700, inserted into the body and then removed from the swing arm 1700.

[00208] A medical device 2000 according to an embodiment of the invention is illustrated in FIG. 47. Medical device 2000 includes a handle 2900 coupled to an arm 2700. The arm 2700 has a first end 2750 and a second end 2770 and defines an opening 2740 along its length. A working tool 2840 can be received within opening 2740 adjacent the second end 2770. The arm 2700 also includes a recess 2720 to receive a retainer (not illustrated) similar to retainer 1850 discussed above. Medical device 2000 is inserted between adjacent spinous process in a manner similar to swing arm 1700 discussed above. The depth and placement of the arm 2700, however is determined by the user of the medical device 2000. Such a medical device can be used with or without the benefit of the clamps 1100, 1200 discussed above. In other words, the medical device 2000 can be inserted between adjacent spinous processes S without first separating the spinous processes S.

[00209] A medical device according to another embodiment of the invention is illustrated in FIG. 48. Medical device 2010 is a distraction tool having a handle 2011, a curved shaft 2020 and a distraction portion 2030. The distraction portion 2030 includes a pointed tip 2032 and an insertion position indicator 2034. The medical device 2010 is inserted into a patient's back and moved in between adjacent spinous processes from

the side of the spinous processes (i.e., a posterior-lateral approach). The configuration of the curved shaft 2020 assists in the use of a lateral approach to the spinous processes. The distraction portion 2030 defines a path through the patient's tissue and between the adjacent spinous processes.

[00210] The position indicator 2034 can be a physical ridge or detent such that the physician can identify through tactile sensation when the medical device 2010 has been inserted an appropriate distance (e.g., when the position indicator 2034 engages the spinous processes). The position indicator 2034 can alternatively be a radioopaque strip that can be imaged using a fluoroscope. As a further alternative, multiple fluoroscopic markings (not illustrated) can be placed on the shaft 2020 within the distraction portion 2030. The markings can be imaged to determine the spacing between the spinous processes and/or the position of the distraction portion 2030 relative to the spinous processes. Once the spinous processes are adequately distracted, the medical device 2010 is removed. After the medical device 2010 is removed, an implant (not illustrated in FIG. 48) is positioned between spinous processes using an insertion tool to limit the minimum distance between the spinous processes during their range of motion.

[00211] An alternative swing arm 1700'' for use with medical device 100 according to an embodiment of the invention is illustrated in FIGS. 49a-49c. As best seen in FIGS. 49a and 45c, the second end 1770'' of swing arm 1700'' is configured to receive a working tool 1840'', such as, for example, a pointed trocar tip. The swing arm 1700'' defines an opening 1740'' in which at least a portion of the working tool 1840'' is received. In some embodiments, the opening 1740'' extends along the entire length of the swing arm 1700'' between the first end 1750'' and the second end 1770'' to define a passageway or lumen. The opening 1740'' is slightly larger than the diameter of the working tool 1840'' such that the working tool 1840'' is positioned within the opening 1740'' during use.

[00212] The working tool 1840'' is coupled to a wire 1860''. The wire 1860'' has a first end 1810'' and a second end 1830''. The second end 1830'' of the wire 1860'' is coupled to the working tool 1840''. A retainer 1820'' (discussed in detail below) is

coupled to the first end 1810'' of the wire 1860'' and is configured to maintain the position of the working tool 1840'' with respect to the swing arm 1700''. In some embodiments, the wire 1860'' is substantially rigid such that the working tool 1840'' is not retracted into the opening 1740'' when force is imparted against the working tool 1840''.

[00213] The retainer 1820'' is received in a recess 1720'' in the swing arm 1700''. The retainer 1820'' is maintained in the recess 1720'' using threaded fasteners 173''. In some alternative embodiments, the wire 1860'' does not extend through the opening 1740'' of the swing arm 1700''. In yet other alternative embodiments, the wire 1860'' is not present.

[00214] FIGS. 50-59 illustrate various spacers 5000 that can be inserted between adjacent spinous processes S. Once the spacer 5000 is inserted between the spinous processes S, depending upon the type of spacer 5000, the spacer 5000 can be deformed to be held in place. For example, in some embodiments, a balloon actuator 5500 can be inserted into the spacer and expanded, thereby expanding the ends of the spacer 5000 to retain the spacer 5000 between the spinous processes S (see, e.g., FIGS 50, 52 and 56). Once the spacer 5000 is expanded, the balloon actuator 5500 can be deflated and removed (see, e.g., FIG. 57).

[00215] In some embodiments of the invention, the spacer 5000 includes an end portion 5750 that includes a recess 5970 that is configured to mate with the projection 1920 on swing arm 1700' (see FIG. 46).

[00216] In another embodiment, a method includes percutaneously inserting into a body an expandable member having a first configuration, a second configuration and a third configuration. The expandable member includes a support portion and a retention portion. The support portion has a longitudinal axis and is configured to be disposed between adjacent spinous processes. The retention portion is configured to limit movement of the support portion along the longitudinal axis. When the expandable member is in the first configuration, it is disposed in a first location between the adjacent spinous processes. The expandable member is then expanded from the first

configuration to the second configuration. The expandable member is then contracted from the second configuration to the third configuration and disposed in a second location, the second location being different from the first location.

[00217] In some embodiments, an apparatus includes an expandable member having a support portion, a retention portion, a first configuration, and a second configuration. The support portion has a longitudinal axis and is configured to be disposed between adjacent spinous processes. The retention portion is disposed adjacent to the support portion and is configured to limit movement of the support portion along the longitudinal axis. When in the first configuration, the expandable member has a first volume. When in the second configuration, the expandable member has a second volume, the second volume being greater than the first volume. The expandable member is configured to move from the first configuration to the second configuration and to move from the second configuration to the first configuration.

[00218] In some embodiments, the apparatus includes a sensor coupled to the expandable member. The sensor can be, for example, a strain gauge sensor or a piezoelectric sensor that measures a force applied to the expandable member and/or a pressure of a fluid within the expandable member.

[00219] In some embodiments, an apparatus includes a substantially rigid support member, a first expandable member and a second expandable member. The support member is configured to be disposed between adjacent spinous processes. The first expandable member is coupled to a proximal portion of the support member and has a first configuration in which it has a first volume and a second configuration in which it has a second volume, which is greater than the first volume. Similarly, the second expandable member is coupled to a distal portion of the support member and has a first configuration in which it has a first volume and a second configuration in which it has a second volume, which is greater than the first volume.

[00220] FIGS. 60A – 60D are schematic illustrations of a posterior view of a medical device 4000 according to an embodiment of the invention positioned adjacent two adjacent spinous processes S in a first configuration (FIG. 60A), a second configuration

(FIGS. 60B and 60D) and a third configuration (FIG. 60C). The medical device 4000 includes an expandable member 4002 having an inner area (not shown) and an outer surface 4010. The outer surface 4010 is configured to be disposed between the spinous processes S to prevent over-extension/compression of the spinous processes S. In some embodiments, the expandable member 4002 distracts the adjacent spinous processes S. In other embodiments, the expandable member 4002 does not distract the adjacent spinous processes S.

[00221] The expandable member 4002 has a first configuration, a second configuration and a third configuration. When in each configuration, the expandable member 4002 has an associated volume. As illustrated in FIG. 60A, the first configuration represents a substantially contracted condition in which the expandable member 4002 has a minimal volume. When the expandable member 4002 is in the first configuration, the medical device 4000 is inserted between the adjacent spinous processes S. As illustrated in FIGS. 60B and 60D, the second configuration represents an expanded condition in which the expandable member 4002 has a large volume. When the expandable member 4002 is in the second configuration, the outer surface 4010 of the medical device 4000 contacts the adjacent spinous processes S during at least a portion of the range of motion of the spinous processes. As illustrated in FIG. 60C, the third configuration represents a partially expanded condition in which the expandable member 4002 has a volume between that associated with the first configuration and that associated with the second configuration. When the expandable member 4002 is in the third configuration, the medical device 4000 can be repositioned between the adjacent spinous processes, as indicated by the arrow in FIG. 60C. The medical device can then be subsequently re-expanded into the second configuration, as illustrated in FIG. 60D.

[00222] FIGS. 61A – 61C are schematic illustrations of a posterior view of the medical device 4000 positioned adjacent two adjacent spinous processes S in a first configuration, a second configuration and a third configuration, respectively. As described above, when the expandable member 4002 is in the first configuration, the medical device 4000 is inserted between the adjacent spinous processes S. The

expandable member 4002 is then expanded to the second configuration, in which the outer surface 4010 of the medical device 4000 is disposed between the adjacent spinous processes S. The expandable member 4002 is then contracted to the third configuration to facilitate removal of the medical device 4000, as shown in FIG. 61C. In some embodiments, the third configuration can be the same as the first configuration.

[00223] In use, the adjacent spinous processes S can be distracted prior to inserting the medical device 4000 into a body. Distraction of spinous processes described herein. When the spinous processes S are distracted, a trocar (not shown) can be used to define an access passageway (not shown) for the medical device 4000. In some embodiments, the trocar can be used to define the passage as well as to distract the spinous processes S. Once an access passageway is defined, the medical device 4000 is inserted percutaneously and advanced between the spinous processes S and placed in the desired position between the adjacent spinous processes S. Once the medical device 4000 is in the desired position, the expandable member is expanded to the second condition, causing the outer surface 4010 to engage the spinous processes S.

[00224] In some embodiments, the adjacent spinous processes can be distracted by a first expandable member (not shown) configured to distract bone. Upon distraction, the first expandable member is contracted and removed from the body. The medical device 4000 is then inserted percutaneously, advanced between the spinous processes S, placed in the desired position and expanded, as described above.

[00225] In some embodiments, the medical device 4000 is inserted percutaneously (i.e., through an opening in the skin) and in a minimally-invasive manner. For example, as discussed in detail herein, the overall sizes of portions of the medical device 4000 are increased by transitioning the expandable member 4002 from the first configuration to the second configuration after the medical device 4000 is inserted between the adjacent spinous processes S. When in the expanded second configuration, the sizes of portions of the medical device 4000 are greater than the size of the opening. For example, the size of the opening/incision in the skin can be between 3 millimeters in length and 25 millimeters in length across the opening. In some embodiments, the size of the medical

device 4000 in the expanded second configuration is between 3 and 25 millimeters across the opening.

[00226] FIGS. 62A – 62F are posterior views of a spinal implant 4100 according to an embodiment of the invention inserted between adjacent spinous processes S in a first lateral position (FIG. 62C) and a second lateral position (FIG. 62E). The spinal implant 4100 includes an expandable member 4102, a sensor 4112 and a valve 4132. The expandable member 4102 has an inner area (not shown), an outer surface 4110, a support portion 4118, a proximal retention portion 4114 and a distal retention portion 4116. The expandable member 4102 is repeatably positionable in a first configuration (FIG. 62B), a second configuration (FIGS. 62C, 62E and 62F) and a third configuration (FIG. 62D). When in each configuration, the expandable member 4102 has an associated volume, as will be discussed below.

[00227] In use, the spinal implant 4100 is positioned in the substantially contracted first configuration during insertion and/or removal (see FIG. 62B). As discussed above, the spinal implant 4100 is inserted percutaneously between adjacent spinous processes S. The distal retention portion 4116 of the expandable member 4102 is inserted first and is moved past the spinous processes S until the support portion 4118 is positioned between the spinous processes S. When in the first configuration, the support portion 4118 can be sized to account for ligaments and tissue surrounding the spinous processes S. For purposes of clarity, such surrounding ligaments and tissue are not illustrated.

[00228] As illustrated in FIG. 62C, once in position, the expandable member 4102 is expanded into the second configuration by conveying a fluid (not shown) from an area outside of the expandable member 4102 to the inner area of the expandable member 4102. The fluid is conveyed by an expansion tool 4130, such as a catheter, that is matingly coupled to the valve 4132. The valve 4132 can be any valve suitable for sealably connecting the inner area of the expandable member 4102 to an area outside of the expandable member 4102. For example, in some embodiments, the valve 4132 can be, for example a poppet valve, a pinch valve or a two-way check valve. In other

embodiments, the valve includes a coupling portion (not shown) configured to allow the expansion tool 4130 to be repeatably coupled to and removed from the valve 4132. For example, in some embodiments, the valve 4132 can include a threaded portion configured to matingly couple the expansion tool 4130 and the valve 4132.

[00229] The fluid is configured to retain fluidic properties while resident in the inner area of the expandable member 4102. In this manner, the spinal implant 4100 can be repeatably transitioned from the expanded second configuration to the first configuration and/or the third configuration by removing the fluid from the inner area of the expandable member 4102. In some embodiments, the fluid can be a biocompatible liquid having constant or nearly constant properties. Such liquids can include, for example, saline solution. In other embodiments, the fluid can be a biocompatible liquid configured to have material properties that change over time while still retaining fluidic properties sufficient to allow removal of the fluid. For example, the viscosity of a fluid can be increased by adding a curing agent or the like. In this manner, the fluid can provide both the requisite structural support while retaining the ability to be removed from the inner area of the expandable member 4102 via the valve 4132. In yet other embodiments, the fluid can be a biocompatible gas.

[00230] The outer surface 4110 of the support portion 4118 can distract the adjacent spinous processes S as the expandable member 4102 expands to the second configuration, as indicated by the arrows shown in FIG. 62C. In some embodiments, the support portion 4118 does not distract the adjacent spinous processes S. For example, as discussed above, the adjacent spinous processes S can be distracted by a trocar and/or any other device suitable for distraction.

[00231] When in the second configuration, the outer surface 4110 of the support portion 4118 is configured to engage the spinous processes S for at least a portion of the range of motion of the spinous processes S to prevent over-extension/compression of the spinous processes S. In some embodiments, the engagement of the spinous processes S by the outer surface 4110 of the support portion 4118 is not continuous, but occurs upon spinal extension.

[00232] When in the second configuration, the proximal retention portion 4114 and the distal retention portion 4116 each have a size S1 (shown in FIG. 63) that is greater than the vertical distance D1 (shown in FIG. 63) between the spinous processes. In this manner, the proximal retention portion 4114 and the distal retention portion 4116 are disposed adjacent the sides of spinous processes S (i.e., either through direct contact or through surrounding tissue), thereby limiting movement of the spinal implant 4100 laterally along a longitudinal axis of the support portion 4118.

[00233] The expandable member 4102 can be made from any number of biocompatible materials, such as, for example, PET, Nylons, cross-linked Polyethylene, Polyurethanes, and PVC. In some embodiments, the chosen material can be substantially inelastic, thereby forming a low-compliant expandable member 4102. In other embodiments, the chosen material can have a higher elasticity, thereby forming a high-compliant expandable member 4102. In yet other embodiments, the expandable member 4102 can be made from a combination of materials such that one portion of the expandable member 4102, such as the support portion 4118, can be low-compliant while other portions of the expandable member 4102, such as the proximal retention portion 4114 and/or distal retention portion 4116 are more highly compliant. In yet other embodiments, a portion of the expandable member 4102 can include a rigid, inflexible material to provide structural stiffness. For example, the support portion 4118 can be constructed of a composite material that includes a rigid, inflexible material to facilitate distraction of the adjacent spinous processes.

[00234] In some embodiments, the expandable member 4102 includes a radiopaque material, such as bismuth, to facilitate tracking the position of the spinal implant 4100 during insertion and/or repositioning. In other embodiments, the fluid used to expand the expandable member 4102 includes a radiopaque tracer to facilitate tracking the position of the spinal implant 4100.

[00235] In the illustrated embodiment, the spinal implant 4100 includes a sensor 4112 coupled to the expandable member 4102. In some embodiments, the sensor 4112 is a strain gauge sensor that measures a force applied to the support portion 4118 of the

expandable member 4102. The sensor 4112 can include multiple strain gauges to facilitate measuring multiple force quantities, such as a compressive force and/or a tensile force. In other embodiments, the sensor 4112 is a variable capacitance type pressure sensor configured to measure a force and/or a pressure of the fluid contained within the inner portion of the expandable member 4102. In yet other embodiments, the sensor 4112 is a piezoelectric sensor that measures a pressure of the fluid contained within the inner portion of the expandable member 4102. In still other embodiments, the spinal implant 4100 can include multiple sensors 4112 located at various locations to provide a spatial profile of the force and/or pressure applied to the expandable member 4102. In this manner, a practitioner can detect changes in the patient's condition, such those that may result in a loosening of the spinal implant 4100.

[00236] In some embodiments, the sensor 4112 can be remotely controlled by an external induction device. For example, an external radio frequency (RF) transmitter (not shown) can be used to supply power to and communicate with the sensor 4112. In other embodiments, an external acoustic signal transmitter (not shown) can be used to supply power to and communicate with the sensor 4112. In such an arrangement, for example, the sensor can include a pressure sensor, of the types described above, for measuring a pressure; an acoustic transducers, and an energy storage device. The acoustic transducer converts energy between electrical energy and acoustic energy. The energy storage device stores the electrical energy converted by the acoustic transducer and supplies the electrical energy to support the operation of the pressure sensor. In this manner, acoustic energy from an external source can be received and converted into electrical energy used to power the pressure sensor. Similarly, an electrical signal output from the pressure sensor can be converted into acoustic energy and transmitted to an external source.

[00237] At times, the spinal implant 4100 may need to be repositioned. Such repositioning can be required, for example, to optimize the lateral position of the support portion 4118 during the insertion process. In other instances, the spinal implant 4100 can require repositioning subsequent to the insertion process to accommodate changes in the conditions of the patient. In yet other instances, the spinal implant 4100

can be removed from the patient. To allow for such repositioning and/or removal, the spinal implant is repeatably positionable in the first configuration, the second configuration and/or the third configuration. In FIG. 62D, for example, the expandable member 4102 is contracted to the third configuration by removing all or a portion of the fluid contained in the inner area, as described above. In this manner, the spinal implant 4100 can be repositioned in a lateral direction, as indicated by the arrow. Once in the desired position, the expandable member is reexpanded to the second condition as described above. Finally, as shown in FIG. 62F, the expansion tool 4130 is removed from the valve 4132.

[00238] FIG. 63 is a lateral view of the spinal implant 4100 illustrated in FIGS. 62A – 62F inserted between adjacent spinous processes S in a second configuration. Although FIG. 63 only shows the proximal retention portion 4114 of the expandable member 4102, it should be understood that the distal retention portion 4116 has characteristics and functionality similar to those described below for proximal retention portion 4114. As illustrated, the proximal retention portion 4114 has a size S1 that is greater than the vertical distance D1 between the spinous processes S. In this manner, the proximal retention portion 4114 and the distal retention portion 4116 limit the lateral movement of the spinal implant 4100 when in the second configuration, as discussed above.

[00239] FIG. 64 is a lateral view of a spinal implant 4200 according to an embodiment of the invention inserted between adjacent spinous processes and in a second configuration. Similar to the spinal implant 4100 discussed above, the spinal implant 4200 includes an expandable member 4202 and a valve 4232. The expandable member 4202 has a support portion (not shown), a proximal retention portion 4214 and a distal retention portion (not shown). The expandable member 4202 is repeatably positionable in a first configuration, a second configuration and/or a third configuration. When in each configuration, the expandable member 4202 has an associated volume, as discussed above.

[00240] In the illustrated embodiment, the proximal retention portion 4214 of the expandable member 4202 has a first radial extension 4236, a second radial extension 4238 and a third radial extension 4240. As illustrated, the distance S1 between the ends of the radial extensions is greater than the vertical distance D1 between the spinous processes S. In this manner, the proximal retention portion 4214 and the distal retention portion limit the lateral movement of the spinal implant 4200 when in the second configuration. In some embodiments, the proximal retention portion and the distal retention portion can assume a variety of different shapes.

[00241] FIGS. 65A and 65B are front views of a spinal implant 4300 according to an embodiment of the invention in a first configuration and a second configuration, respectively. The spinal implant 4300 includes a proximal expandable member 4304, a distal expandable member 4306, a support member 4308, a sensor 4312 and a valve 4332. The support member 4308 has an inner area (not shown) and an outer surface 4310. The outer surface 4310 is configured to contact the spinous processes (not shown). In some embodiments, the support member 4308 distracts the adjacent spinous processes. In other embodiments, the support member 4308 does not distract the adjacent spinous processes. In yet other embodiments, the engagement of the spinous processes by the support member 4308 is not continuous, but occurs upon spinal extension.

[00242] The support member 4308 has a proximal portion 4324, to which the proximal expandable member 4304 is coupled, and a distal portion 4326, to which the distal expandable member 4306 is coupled. The proximal expandable member 4304 and the distal expandable member 4306 are each repeatably positionable in a first configuration (FIG. 65A) and a second configuration (FIG. 65B). As described above, the first configuration represents a substantially contracted condition in which the proximal expandable member 4304 and the distal expandable member 4306 each have a minimal volume. When the spinal implant 4300 is in the first configuration, it can be inserted, repositioned and/or removed. In the illustrated embodiment, the proximal expandable member 4304 and the distal expandable member 4306 are each contained within the inner area of the support member 4308 when the spinal implant 4300 is in

the first configuration. In some embodiments, the proximal expandable member 4304 and the distal expandable member 4306 are not contained within the support member 4308.

[00243] Conversely, the second configuration represents an expanded condition in which the proximal expandable member 4304 and the distal expandable member 4306 each have a large volume. When the spinal implant 4300 is in the second configuration, the proximal expandable member 4304 and the distal expandable member 4306 each have a size that is greater than the vertical distance between the spinous processes, as described above. In this manner, the proximal expandable member 4304 and the distal expandable member 4306 engage the spinous processes, thereby limiting the lateral movement of the spinal implant 4300.

[00244] The proximal expandable member 4304 and the distal expandable member 4306 are expanded into the second configuration by conveying a fluid (not shown) from an area outside of each expandable member 4304, 4306 to an inner area defined by each expandable member 4304, 4306. The fluid is conveyed through a valve 4332, as described above. In the illustrated embodiment, the inner area of the proximal expandable member 4304, the inner area of the distal expandable member 4306 and the inner area of the support member 4308 are in fluid communication with each other to form a single inner area. As such, the fluid can be conveyed to both the inner area of the proximal expandable member 4304 and the inner area of the distal expandable member 4306 by a single valve 4332. In some embodiments, the inner areas of the proximal expandable member 4304 and the distal expandable member 4306 are not in fluid communication. In such an arrangement, each expandable member can be independently transformed between configurations.

[00245] The support member 4308 can be made from any number of biocompatible materials, such as, for example, stainless steel, plastic, polyetheretherketone (PEEK), carbon fiber, ultra-high molecular weight (UHMW) polyethylene, and the like. The material of the support member 4308 can have a tensile strength similar to or higher than that of bone. In some embodiments, the support member 4308 is substantially

rigid. In other embodiments, the support member 4308 or portions thereof is elastically deformable, thereby allowing it to conform to the shape of the spinous processes. In yet other embodiments, the support member 4308 includes a radiopaque material, such as bismuth, to facilitate tracking the position of the spinal implant 4300 during insertion and/or repositioning.

[00246] The proximal expandable member 4304 and the distal expandable member 4306 can be made from any number of biocompatible materials, as discussed above. The proximal expandable member 4304 and the distal expandable member 4306 can be coupled to the support member by an suitable means, such as a biocompatible adhesive.

[00247] In the illustrated embodiment, the spinal implant 4300 includes a sensor 4312 coupled to the support member 4308. As described above, the sensor 4312 can be configured to measure multiple force quantities and/or a pressure of the fluid contained within the proximal expandable member 4304 and the distal expandable member 4306.

[00248] In another embodiment, the apparatus includes a support member, a proximal retention member, and a distal retention member. The support member is configured to be disposed between adjacent spinous processes. The proximal retention member has a first configuration in which the proximal retention member is substantially disposed within a proximal portion of the support member and a second configuration in which a portion of the proximal retention member is disposed outside of the support member. The distal retention member has a first configuration in which the distal retention member is substantially disposed within a distal portion of the support member and a second configuration in which a portion of the distal retention member is disposed outside of the support member.

[00249] In some embodiments, each of the proximal retention member and the distal retention member includes a first elongate member and a second elongate member. The second elongate member is configured to be slidably disposed within the first elongate member. The support member includes a side wall defining a multiple openings, each opening being configured to receive a portion of at least one of the first elongate member or the second elongate member therethrough.

[00250] In some embodiments, each of the proximal retention member and the distal retention member includes an elongate member having a longitudinal axis and a rotating member having a longitudinal axis normal to the longitudinal axis of the elongate member. A portion of the elongate member is flexible in a direction normal to its longitudinal axis. The rotating member is coupled to the elongate member and configured to rotate about its longitudinal axis, thereby moving the elongate member along its longitudinal axis.

[00251] In some embodiments, a method includes percutaneously inserting into a body a support member configured to be disposed between adjacent spinous processes. The support member defines an inner area and an opening substantially normal to the longitudinal axis that connects the inner area and an area outside the support member. The support member includes a retention member having a first configuration in which the retention member is substantially disposed within the inner area, and a second configuration in which a portion of the retention member is disposed through the opening to the area outside the support member. The support member is disposed to a location between the adjacent spinous processes when retention member is in the first configuration. The retention member is moved from the first configuration to the second configuration.

[00252] Although specific portions of the apparatus, such as one or more retention members, are configured to move between a first, a second configuration and/or a third configuration, for ease of reference, the entire apparatus may be referred to as being in a first configuration, a second configuration and/or a third configuration. However, one of ordinary skill in the art having the benefit of this disclosure would appreciate that the apparatus may be configured to include four or more configurations. Additionally, in some embodiments, the apparatus can be in many positions during the movement between the first, second and/or third configurations. For ease of reference, the apparatus is referred to as being in either a first configuration, a second configuration or a third configuration. Finally, in some embodiments, although an apparatus includes one or more retention members, the figures and accompanying description may show and describe only a single retention member. In such instances, it should be understood

that the description of a single retention member applies to some or all other retention members that may be included in the embodiment.

[00253] FIGS. 66A and 66B are schematic illustrations of a posterior view of a medical device 3000 according to an embodiment of the invention disposed between two adjacent spinous processes S in a first configuration and a second configuration, respectively. The medical device 3000 includes a support member 3002, a proximal retention member 3010 and a distal retention member 3012. The support member 3002 has a proximal portion 3004 and a distal portion 3006, and is configured to be disposed between the spinous processes S to prevent over-extension/compression of the spinous processes S. In some embodiments, the support member 3002 distracts the adjacent spinous processes S. In other embodiments, the support member 3002 does not distract the adjacent spinous processes S.

[00254] The proximal retention member 3010 has a first configuration in which it is substantially disposed within the proximal portion 3004 of the support member 3002, as illustrated in FIG. 66A. Similarly, the distal retention member 3012 has a first configuration in which it is substantially disposed within the distal portion 3006 of the support member 3002. When the proximal retention member 3010 and the distal retention member 3012 are each in their respective first configuration, the medical device 3000 can be inserted between the adjacent spinous processes S.

[00255] The proximal retention member 3010 can be moved from the first configuration to a second configuration in which a portion of it is disposed outside of the support member 3002, as illustrated in FIG. 66B. Similarly, the distal retention member 3012 can be moved from the first configuration to a second configuration. When each is in their respective second configuration, the proximal retention member 3010 and the distal retention member 3012 limit lateral movement of the support member 3002 with respect to the spinous processes S by contacting the spinous processes S (i.e., either directly or through surrounding tissue). For purposes of clarity, the tissue surrounding the spinous processes S is not illustrated.

[00256] In use, the adjacent spinous processes S can be distracted prior to inserting the medical device 3000 into the patient. When the spinous processes S are distracted, a trocar (not shown in FIGS. 66A or 66B) can be used to define an access passageway (not shown in FIGS. 66A and 66B) for the medical device 3000. In some embodiments, the trocar can be used to define the passage as well as to distract the spinous processes S.

[00257] Once an access passageway is defined, the medical device 3000 is inserted percutaneously and advanced, distal portion 3006 first, between the spinous processes S. The medical device 3000 can be inserted from the side of the spinous processes S (i.e., a posterior-lateral approach). The use of a curved shaft assists in the use of a lateral approach to the spinous processes S. Once the medical device 3000 is in place between the spinous processes S, the proximal retention member 3010 and the distal retention member 3012 are moved to their second configurations, either serially or simultaneously. In this manner, lateral movement of the support member 3002 with respect to the spinous processes S is limited.

[00258] When it is desirable to change the position of the medical device 3000, the proximal retention member 3010 and the distal retention member 3012 are moved back to their first configurations, thereby allowing the support member 3002 to be moved laterally. Once the support member 3002 is repositioned, the medical device 3000 can be returned to the second configuration. Similarly, when it is desirable to remove the medical device 3000, proximal retention member 3010 and the distal retention member 3012 are moved to their first configurations, thereby allowing the support member 3002 to be removed.

[00259] In some embodiments, the medical device 3000 is inserted percutaneously (i.e., through an opening in the skin) and in a minimally-invasive manner. For example, as discussed in detail herein, the overall sizes of portions of the medical device 3000 can be increased by moving the proximal retention member 3010 and the distal retention member 3012 to their respective second configurations after the medical device 3000 is inserted between the adjacent spinous processes S. When in the

expanded second configuration, the sizes of portions of the medical device 3000 can be greater than the size of the opening. For example, the size of the opening/incision in the skin can be between 3 millimeters in length and 25 millimeters in length across the opening. In some embodiments, the size of the medical device 3000 in the expanded second configuration is between 3 and 25 millimeters across the opening.

[00260] FIGS. 67A, 67B, 68 – 71 illustrate a spinal implant 3100 according to an embodiment of the invention. FIGS. 67A and 67B are perspective views of the spinal implant 3100 in a first configuration and a second configuration, respectively. The spinal implant 3100 includes a support member 3102, a proximal retention member 3110 and a distal retention member 3112. The support member 3102 is positioned between adjacent spinous processes S, as illustrated in FIGS. 68 and 69. As shown in FIGS. 67A and 67B, the proximal retention member 3110 and the distal retention member 3112 are each repeatably positionable in a first configuration in which they are substantially disposed within the support member 3102 (FIG. 67A), and a second configuration in which a portion of each retention member 3110, 3112 is disposed outside of the support member 3102 (FIG. 67B). When the spinal implant 3100 is in the first configuration, it can be inserted between the adjacent spinous processes S, repositioned between the adjacent spinous processes and/or removed from the patient. When the spinal implant 3100 is in the second configuration, its lateral movement is limited, thereby allowing the desired position of the support member 3102 to be maintained.

[00261] In some embodiments, the support member 3102 distracts the adjacent spinous processes S. In other embodiments, the support member 3102 does not distract the adjacent spinous processes S. In yet other embodiments, the engagement of the spinous processes S by the support member 3102 is not continuous, but occurs upon spinal extension.

[00262] The support member 3102 can be made from any number of biocompatible materials, such as, for example, stainless steel, plastic, polyetheretherketone (PEEK), carbon fiber, ultra-high molecular weight (UHMW) polyethylene, and the like. The

material of the support member 3102 can have a tensile strength similar to or higher than that of bone. In some embodiments, the support member 3102 is substantially rigid. In other embodiments, the support member 3102 or portions thereof is elastically deformable, thereby allowing it to conform to the shape of the spinous processes. In yet other embodiments, the support member 3102 includes a radiopaque material, such as bismuth, to facilitate tracking the position of the spinal implant 3100 during insertion and/or repositioning.

[00263] In the illustrated embodiment, the spinal implant 3100 includes a sensor 3124 coupled to the support member 3102. In some embodiments, the sensor 3124 is a strain gauge sensor that measures a force applied to the support member 3102. In some embodiments, the sensor 3124 can include multiple strain gauges to facilitate measuring multiple force quantities, such as a compressive force and/or a bending moment. In other embodiments, the sensor 3124 is a variable capacitance type pressure sensor configured to measure a force and/or a pressure applied to the support member 3102. In yet other embodiments, the sensor 3124 is a piezoelectric sensor that measures a force and/or a pressure applied to the support member 3102. In still other embodiments, the spinal implant 3100 can include multiple sensors located at various locations to provide a spatial profile of the force and/or pressure applied to the support member 3102. In this manner, a practitioner can detect changes in the patient's condition, such those that may result in a loosening of the spinal implant.

[00264] In some embodiments, the sensor 3124 can be remotely controlled by an external induction device. For example, an external radio frequency (RF) transmitter (not shown) can be used to supply power to and communicate with the sensor 3124. In other embodiments, an external acoustic signal transmitter (not shown) can be used to supply power to and communicate with the sensor 3124. In such an arrangement, for example, the sensor can include a pressure sensor, of the types described above, for measuring a pressure; an acoustic transducers, and an energy storage device. The acoustic transducer converts energy between electrical energy and acoustic energy. The energy storage device stores the electrical energy converted by the acoustic transducer and supplies the electrical energy to support the operation of the pressure sensor. In this

manner, acoustic energy from an external source can be received and converted into electrical energy used to power the pressure sensor. Similarly, an electrical signal output from the pressure sensor can be converted into acoustic energy and transmitted to an external source.

[00265] The support member 3102 includes a sidewall 3108 that defines an inner area 3120 and multiple openings 3114 that connect the inner area 3120 to an area outside of the support member 3102. When the spinal implant 3100 is in the first configuration, the proximal retention member 3110 and the distal retention member 3112 are substantially disposed within the inner area 3120 of the support member 3102, as shown in FIG. 67A. When the spinal implant 3100 is in the second configuration, a portion of each of the proximal retention member 3110 and the distal retention member 3112 extends through the openings 3114 to an area outside of the support member 3102. In the second configuration, the proximal retention member 3110 and the distal retention member 3112 engage the adjacent spinous processes, thereby limiting lateral movement of the spinal implant 3100.

[00266] The proximal retention member 3110 includes a first elongate member 3130 and a second elongate member 3132. Similarly, the distal retention member 3112 includes a first elongate member 3131 and a second elongate member 3133. As illustrated in FIG. 71, which shows is a cross-sectional plan view of the proximal portion 3104 of the support member 3102, the first elongate member 3130 is slidably disposed within a pocket 3134 defined by the second elongate member 3132. A biasing member 3136, such as a spring or an elastic member, is disposed within the pocket 3134 and is coupled to the first elongate member 3130 and the second elongate member 3132. In this manner, the retention members can be biased in the second configuration. In other embodiments, the biasing member 3136 can be configured to bias the retention members in the first configuration. In yet other embodiments, the retention members do not include a biasing member, but instead use other mechanisms to retain a desired configuration. Such mechanisms can include, for example, mating tabs and slots configured to lockably engage when the retention members are in a desired configuration.

[00267] In use, the spinal implant 3100 is positioned in the first configuration during insertion, removal or repositioning. As discussed above, the spinal implant 3100 is inserted percutaneously between adjacent spinous processes. The distal portion 3106 of the support member 3102 is inserted first and is moved past the spinous processes until the support member 3102 is positioned between the spinous processes. The support member 3102 can be sized to account for ligaments and tissue surrounding the spinous processes S. In some embodiments, the support member 3102 contacts the spinous processes between which it is positioned during a portion of the range of motion of the spinous processes S. In some embodiments, the support member 3102 of spinal implant 3100 is a fixed size and is not compressible or expandable. In yet other embodiments, the support member 3102 can compress to conform to the shape of the spinous processes S. Similarly, in some embodiments, the proximal retention member 3110 and the distal retention member 3112 are substantially rigid. In other embodiments, the retention members or portions thereof are elastically deformable, thereby allowing them to conform to the shape of the spinous processes.

[00268] In the illustrated embodiment, the spinal implant 3100 is held in the first configuration by an insertion tool (not shown) that overcomes the force exerted by the biasing member 3136, thereby disposing a portion of the first elongate member 3130 within the pocket 3134 of the second elongate member 3132. In this manner, the spinal implant 3100 can be repeatedly moved from the first configuration to the second configuration, thereby allowing it to be repositioned and/or removed percutaneously. As illustrated in FIG. 70, the first elongate member 3130 and the second elongate member 3132 each include notches 3138 configured to receive a portion of the insertion tool. When the insertion tool is released, the biasing member 3136 is free to extend, thereby displacing a portion of the first elongate member 3130 out of the pocket 3134 of the second elongate member 3132. In this manner, portions of both the first elongate member 3130 and the second elongate member 3132 are extended through the adjacent openings 3114 and to an area outside of the support member 3102. In some embodiments, the proximal retention member 3110 and the distal retention member 3112 are transitioned between their respective first and second configurations

simultaneously. In other embodiments, the proximal retention member 3110 and the distal retention member 3112 are transitioned between their first and second configurations serially.

[00269] As illustrated, the first elongate member 3130 and the second elongate member 3132 each include one or more tabs 3140 that engage the side wall 3108 of the support member 3102 when in the second configuration, thereby ensuring that the first and second elongate members remain coupled to each other and that portions of the first and second elongate members remain suitably disposed within the support member 3102. In other embodiments, the first elongate member 3130 and the second elongate member 3132 are coupled to each other by other suitable mechanisms, such as mating tabs and slots configured to engage when the retention member reaches a predetermined limit of extension.

[00270] FIGS. 72, 73A and 73B are cross-sectional views of a spinal implant 3200 according to an embodiment of the invention. FIG. 72 illustrates a cross-sectional front view of the spinal implant 3200 in a second configuration, while FIGS. 73A and 73B illustrate a cross-sectional plan view of the spinal implant 3200 in the second configuration and a first configuration, respectively. The illustrated spinal implant 3200 includes a support member 3202, a retention member 3210 and a rotating member 3250. Although shown and described as including only a single retention member 3210, some embodiments can include one or more additional retention members having characteristics and functionality similar to those described for the retention member 3210.

[00271] As shown in FIGS. 73A and 73B, the retention member 3210 is repeatably positionable in a first configuration in which it is substantially disposed within the support member 3202, and a second configuration in which a portion the retention member 3210 is disposed outside of the support member 3102. When the spinal implant 3200 is in the first configuration, it can be inserted between adjacent spinous processes, repositioned between adjacent spinous processes and/or removed from the patient. When the spinal implant 3200 is in the second configuration, its lateral

movement is limited, thereby allowing the desired position of the support member 3202 to be maintained.

[00272] The support member 3202 includes a sidewall 3208 that defines an inner area 3220 and multiple openings 3214 that connect the inner area 3220 to an area outside of the support member 3202. When the spinal implant 3200 is in the first configuration, the retention member 3210 is substantially disposed within the inner area 3220 of the support member 3202, as shown in FIG. 73B. When the spinal implant 3200 is in the second configuration, a portion of the proximal retention member 3210 extends through the openings 3214 to an area outside of the support member 3202. In the second configuration, the retention member 3210 is disposed adjacent the spinous processes, thereby limiting lateral movement of the spinal implant 3200.

[00273] The retention member 3210 includes an elongate member 3228 having two end portions 3244, a central portion 3242, and a longitudinal axis L1 (shown in FIG. 72). A portion of the elongate member 3228 is flexible such that it can be wound along the rotating member 3250, as described below. In some embodiments, the elongate member 3228 is monolithically formed such that it is flexible enough to be wound along the rotating member 3250 yet rigid enough to limit lateral movement of the support member 3202 when positioned in the second configuration. In other embodiments, the elongate member 3228 includes separate components that are coupled together to form the elongate member 3228. For example, the central portion 3242 of the elongate member 3228 can be a distinct component having a greater amount of flexibility, while the end portions 3244 can be distinct components having a greater amount of rigidity.

[00274] In the illustrated embodiment, elongate member 3228 has one or more tabs 3240 that engage the side wall 3208 of the support member 3202 when in the second configuration, thereby ensuring that the elongate member 3228 does not freely extend entirely outside of the support member 3202. In other embodiments, a portion of the elongate member 3228 is retained within the support member 3202 by other suitable mechanisms. For example, the width of the central portion 3242 of the elongate

member 3228 can be greater than the width of the openings 3214, thereby ensuring that a portion of the elongate member 3228 will remain within the support member 3202.

[00275] The rotating member 3250 defines an outer surface 3252 and a slot 3254 through which the elongate member 3228 is disposed. The rotating member 3250 has a longitudinal axis L2 (shown in FIG. 72) about which it rotates. As illustrated in FIG. 73B, as the rotating member 3250 rotates, the elongate member 3228 is wound along the outer surface 3252 of the rotating member 3250. This causes the elongate member 3228 to move along its longitudinal axis L1, thereby causing the end portions 3244 of the elongate member 3228 to be retracted inwardly through the openings 3214. In this manner, the retention member 3210 can be repeatedly transitioned between the first configuration and the second configuration.

[00276] In some embodiments, the rotating member 3250 is rotated using an insertion tool (not shown) that includes a ratchet mechanism. The insertion tool can rotate the rotating member 3250 in a number of different ways, such as, for example, manually, pneumatically or electronically.

[00277] FIGS. 74 and 75A – 75C are cross-sectional views of a spinal implant 3300 according to an embodiment of the invention. FIG. 74 illustrates a cross-sectional front view of the spinal implant 3300 in a second configuration, while FIGS. 75A – 75C illustrate a cross-sectional plan view of the spinal implant 3300 in the second configuration, a first configuration, and a third configuration, respectively. The illustrated spinal implant 3300 includes a support member 3302 and a retention member 3310. Although shown and described as including only a single retention member 3310, some embodiments can include one or more additional retention members having characteristics and functionality similar to those described for the retention member 3310.

[00278] As shown in FIGS. 75A – 75C, the retention member 3310 is repeatably positionable in a first configuration, a second configuration and a third configuration. A portion the retention member 3310 is disposed outside of the support member 3302 when positioned in the second configuration. The retention member 3310 is

substantially disposed within the support member 3202 when positioned in each of the first and third configurations. As illustrated in FIGS. 75B and 75C, the orientation of the retention member 3310 differs between the first and third configurations. In this manner, the position of the spinal implant 3300 can be positioned appropriately depending on the direction in which it is being moved. For example, the spinal implant 3300 may be positioned in the first configuration to facilitate lateral movement of the support member 3302 in a distal direction, such as during insertion. Conversely, the spinal implant 3300 may be positioned in the third configuration to facilitate lateral movement of the support member 3302 in a proximal direction, such as during removal.

[00279] The support member 3302 includes a sidewall 3308 that defines an inner area 3320 and multiple openings 3314 that connect the inner area 3320 to an area outside of the support member 3302. When the spinal implant 3300 is in the second configuration, a portion of the proximal retention member 3310 extends through the openings 3314 to an area outside of the support member 3302.

[00280] The retention member 3310 includes a first elongate member 3330, a second elongate member 3332, and a hinge 3360 having a longitudinal axis L2 (shown in FIG. 74). Each of the first elongate member 3330 and the second elongate member 3332 has a distal end portion 3344 that extends through the openings 3314 when the spinal implant 3300 is in the second configuration and a proximal end portion 3346 that is pivotally coupled to the hinge 3360. In use, the hinge 3360 moves in a direction normal to its longitudinal axis L2, as indicated by the arrows in FIGS. 75B and 75C. The motion of the hinge is guided by a slot 3362 defined by the side wall 3308 of the support member 3302. The movement of the hinge 3360 allows the each of the first elongate member 3330 and the second elongate member 3332 to rotate about the longitudinal axis L2 of the hinge 3360, thereby positioning the distal end portion 3344 of each elongate member substantially within the inner area 3320 of the support member 3302.

[00281] In some embodiments, the slot 3362 includes detents or any other suitable mechanism (not shown) to maintain the hinge 3360 in the desired position. In other

embodiments the hinge 3360 includes a biasing member (not shown) configured to bias the hinge 3360 in one of the first, second, or third configurations. In yet other embodiments, the elongate members include other suitable mechanisms to retain the retention member in a desired configuration. Such mechanisms can include, for example, mating tabs and slots configured to lockably engage when the elongate members are in a desired configuration.

[00282] In some embodiments, the first elongate member 3330 and the second elongate member 3332 are monolithically formed of a substantially rigid material. In other embodiments, the first elongate member 3330 and the second elongate member 3332 include separate components having different material properties. For example, the distal end portion 3344 can be formed from a material having a greater amount of flexibility, while the proximal end portion 3346 can be formed from a substantially rigid material. In this manner, movement of the spinal implant 3300 is not restricted when a portion of the of the distal end portion 3344 protrudes from the openings 3314 in either the first configuration or the third configuration.

[00283] FIGS. 76A and 76B are cross-sectional front views of a spinal implant 3400 according to an embodiment of the invention. The illustrated spinal implant 3400 includes a support member 3402, a retention member 3410 and a rotating member 3450. As shown in FIGS. 76A and 76B, the retention member 3410 is repeatably positionable in a first configuration in which it is substantially disposed within the support member 3402, and a second configuration in which a portion the retention member 3410 is disposed outside of the support member 3402. Although shown and described as including only a single retention member 3410, some embodiments include one or more additional retention members having characteristics and functionality similar to those described for the retention member 3410.

[00284] The support member 3402 includes a sidewall 3408 that defines an inner area 3420 and multiple openings 3414 that connect the inner area 3420 to an area outside of the support member 3402. When the spinal implant 3400 is in the second

configuration, a portion of the proximal retention member 3410 extends through the openings 3414 to an area outside of the support member 3402.

[00285] The retention member 3410 includes a first elongate member 3430 and a second elongate member 3432, each having a distal end portion 3444 that extends through the openings 3414 when the spinal implant 3400 is in the second configuration, a proximal end portion 3446, and a longitudinal axis L1. As illustrated, the proximal end portions 3446 are coupled by two elastic members 3468, such as a spring or an elastic band. In some embodiments, the proximal end portions 3446 are coupled by a single elastic member. In other embodiments, the proximal end portions 3446 are indirectly coupled via the rotating member 3450. In such an arrangement, for example, a biasing member can be placed between the sidewall of the support member and each elongate member, thereby biasing each elongate member against the rotating member.

[00286] In the illustrated embodiment, the elongate members each include one or more tabs 3440 that engage the side wall 3408 of the support member 3402 when in the second configuration, thereby ensuring that the elongate members 3430, 3432 does not freely extend entirely outside of the support member 3402. In other embodiments, the elongate members do not include tabs, but are retained within the support member 3402 solely by the elastic members 3468. In yet other embodiments, the width of a portion of the elongate members can be greater than the width of the openings 3414, thereby ensuring that the elongate members will remain within the support member 3402.

[00287] The rotating member 3450 defines an outer surface 3452 having an eccentric shape and includes a longitudinal axis (not shown) about which it rotates. As illustrated in FIGS. 76A and 76B, as the rotating member 3450 rotates about its longitudinal axis, a portion of the proximal end portion 3446 of the first elongate member 3430 and the second elongate member 3432 engage the outer surface 3452 of the rotating member 3250. This causes the first elongate member 3430 and the second elongate member 3432 to move along their respective longitudinal axes L1, thereby causing the end portions 3444 of each elongate member to be extended outwardly through the openings 3414, as indicated by the arrows in FIG. 76A. In this manner, the retention member

3410 can be repeatedly transitioned between the first configuration and the second configuration.

[00288] In some embodiments, the rotating member 3450 is rotated using an insertion tool (not shown) that includes a ratchet mechanism. The insertion tool can rotate the rotating member 3450 in a number of different ways, such as, for example, manually, pneumatically or electronically.

[00289] FIGS. 77 and 78 illustrate a spinal implant 3500 according to an embodiment of the invention. FIG. 77 is a cross-sectional front view of the spinal implant 3500 in a second configuration. FIG. 78 is a cross-sectional plan view of the spinal implant 3500 taken along section A-A. The spinal implant 3500 includes a support member 3502 and a retention member 3510. Although only shown as being in a second or expanded configuration, it is understood from the previous descriptions that the retention member 3510 is repeatably positionable in a first configuration in which it is substantially disposed within the support member 3502, and the second configuration in which a portion the retention member 3510 is disposed outside of the support member 3502.

[00290] As illustrated, the retention member 3510 includes a first elongate member 3530 and a second elongate member 3532. The first elongate member 3530 is slidably disposed within a pocket 3534 defined by the second elongate member 3532. The first elongate member 3530 and the second elongate member 3532 each include one or more tabs 3540 that are coupled to the side wall 3508 of the support member 3502 by one or more biasing members 3536. In this manner, the retention member 3510 is biased in the first or retracted configuration. In other embodiments, the biasing members 3536 can be configured to bias the retention member 3510 in the second configuration. In yet other embodiments, the retention member 3510 is not retained by a biasing member 3536, but rather uses other suitable mechanisms to retain the desired configuration.

[00291] In use, the retention member 3510 is transitioned from the first configuration to the second configuration by supplying a pressurized fluid (not shown) to the pocket 3534 via valve 3570. The pressure exerted by the fluid on each of the first elongate member 3530 and the second elongate member 3532 overcomes the force exerted by

the biasing members 3536, thereby causing a portion the first elongate member 3530 to extend outwardly from the pocket 3534 of the second elongate member 3132, thereby allowing a portion of each elongate member to extend through the adjacent openings 3514 and to an area outside of the support member 3502. Similarly, the retention member 3510 is transitioned from the second configuration to the first configuration by opening the valve 3570 and relieving the pressure within the pocket 3534. In this manner, the spinal implant 3500 can be repeatedly moved from the first configuration to the second configuration, thereby allowing it to be repositioned and/or removed percutaneously.

[00292] FIGS. 79A and 79B illustrate perspective views of a spinal implant 3600 according to an embodiment of the invention. The spinal implant 3600 includes a support member 3602, a proximal retention member 3610, a distal retention member 3612, and an elastic member 3668. The support member 3602 defines a longitudinal axis L1 and has a sidewall 3608 that defines an inner area 3620 and has an outer surface 3616. As illustrated in FIG. 79B, the outer surface 3616 defines an area A normal to the longitudinal axis L1. As shown, the proximal retention member 3610 and the distal retention member 3612 are each repeatably positionable in a first configuration in which they are substantially disposed within the area A (FIG. 79B), and a second configuration in which a portion of each retention member 3610, 3612 is disposed outside of the area A (FIG. 79A).

[00293] As illustrated, the proximal retention member 3610 and the distal retention member 3612 are coupled by the elastic member 3668, a portion of which is disposed within the inner area 3620 of the support member 3602. In the illustrated embodiment, the elastic member 3668 has a sidewall 3674 that defines a lumen 3676. In other embodiments, the elastic member can be, for example, a spring, an elastic band, or any other suitable device for elastically coupling the proximal retention member 3610 and the distal retention member 3612.

[00294] The proximal retention member 3610 includes a first elongate member 3630 and a second elongate member 3632, each of which are pivotally coupled to a

connection member 3678 by a hinge 3660. Similarly, the distal retention member 3612 includes a first elongate member 3631 and a second elongate member 3633 each of which are pivotally coupled to a connection member 3678 by a hinge 3660.

[00295] As illustrated in FIG. 79A, when the spinal implant 3600 is in the second configuration, the elastic member 3668 exerts a biasing force on each connection member 3678, thereby causing the connection members 3678 to remain adjacent to the support member 3602. In this configuration, the first elongate member 3630 and the second elongate member 3632 are fully extended. The spinal implant 3600 is transitioned from the second configuration to the first configuration by stretching the elastic member 3668, which allows the connection members 3678 to be disposed apart from the support member 3602, thereby allowing the elongate members to move within the area A, as illustrated in FIG. 79B. The support member 3602 includes slots 3672 in which the end portion of each elongate member can be disposed to maintain the spinal implant 3600 in the first configuration.

[00296] The elastic member 3668 can be stretched by an insertion tool (not shown), a portion of which can be configured to be disposed within the lumen 3676 of the elastic member 3668. For example, a first portion of an insertion tool can engage the connection member 3678 of the proximal retention member 3610 while a second portion of the insertion tool can engage the connection member 3678 of the distal retention member 3612. The tool can then be configured to exert an outward force on each of the connection members 3678, thereby stretching the elastic member 3668 and allowing the spinal implant to transition from the second configuration to the first configuration.

[00297] While the spinal implants are shown and described above as having one or more retention members that extend substantially symmetrically from a support member when in a second configuration, in some embodiments, a spinal implant includes a retention member that extends asymmetrically from a support member when in a second configuration. For example, FIGS. 80 – 82 illustrate a spinal implant 3700 according to an embodiment of the invention that includes a proximal retention member

3710 and a distal retention member 3712 that extend asymmetrically from a support member 3702. As shown in FIGS. 80 and 81, the proximal retention member 3710 and the distal retention member 3712 are each repeatably positionable in a first configuration in which they are substantially disposed within the support member 3702, and a second configuration in which a portion each is disposed outside of the support member 3702.

[00298] The support member 3702 includes a sidewall 3708 that defines an inner area 3720 and two openings 3714 that connect the inner area 3720 to an area outside of the support member 3702. When the spinal implant 3700 is in the second configuration, a portion of the proximal retention member 3710 and a portion of the distal retention member 3712 extend through the openings 3714 to an area outside of the support member 3702.

[00299] In the illustrated embodiment, the proximal retention member 3710 and the distal retention member 3712 each include a first end portion 3746 and a second end portion 3744. The first end portions 3746 of the proximal retention member 3710 and the distal retention member 3712 are coupled by a connecting member 3782 that has a longitudinal axis L1 (shown in FIG. 77). In some embodiments, the connecting member 3782, the proximal retention member 3710 and the distal retention member 3712 are separate components that are coupled together to form the illustrated structure. In other embodiments, the connecting member 3782, the proximal retention member 3710 and the distal retention member 3712 are monolithically formed.

[00300] The connecting member 3782 defines a longitudinal axis L1, about which it rotates. As illustrated, as the connecting member 3782 rotates, the proximal retention member 3710 and the distal retention member 3712 also rotate, thereby causing the end portions 3744 of the proximal retention member 3710 and the distal retention member 3712 to extend outwardly through the openings 3714. In this manner, the retention member 3210 can be repeatedly transitioned between the first configuration and the second configuration.

[00301] In some embodiments, the connecting member 3782 is rotated using an insertion tool (not shown) that includes a ratchet mechanism. The insertion tool can rotate the connecting member 3782 in a number of different ways, such as, for example, manually, pneumatically or electronically.

[00302] In one embodiment, an apparatus includes a first body coupled to a second body. The first body and the second body collectively are configured to be releasably coupled to an implant device configured to be disposed between adjacent spinous processes. A first engaging portion is coupled to the first body, and a second engaging portion is coupled to the second body. The first engaging portion and/or the second engaging portion is configured to be received within a first opening defined by the implant device. The first body configured to be moved relative to the second body such that a distance between the first engaging portion and the second engaging portion is moved between a first distance and a second distance, and simultaneously a length of the implant device is moved between a first length and a second length.

[00303] In another embodiment, a kit includes an implant that is reconfigurable between an expanded configuration and a collapsed configuration while disposed between adjacent spinous processes. The implant has a longitudinal axis and defines an opening. A deployment tool is configured to be releasably coupled to the implant. The deployment tool includes an engaging portion configured to be removably received within the opening of the implant and extend in a transverse direction relative to the longitudinal axis when the deployment tool is coupled to the implant. The deployment tool is configured to move the implant between the collapsed configuration and the expanded configuration while the implant is disposed between the adjacent spinous processes.

[00304] FIGS. 83 and 84 are schematic illustrations of a medical device according to an embodiment of the invention positioned between two adjacent spinous processes. FIG. 83 illustrates the medical device in a first configuration, and FIG. 84 illustrates the medical device in a second configuration. The medical device 6000 includes an implant 6010 and a deployment tool 6020. The implant 6010 includes a distal portion

6012, a proximal portion 6014, and a central portion 6016. The implant 6010 is configured to be inserted between adjacent spinous processes S. The central portion 6016 is configured to contact and provide a minimum spacing between the spinous processes S when adjacent spinous processes S move toward each other during their range of motion to prevent over-extension/compression of the spinous processes S. In some embodiments, the central portion 6016 does not substantially distract the adjacent spinous processes S. In other embodiments, the central portion 6016 does distract the adjacent spinous processes S. The implant 6010 and the deployment tool 6020 can each be inserted into a patient's back and moved in between adjacent spinous processes from the side of the spinous processes (i.e., a posterior-lateral approach). The use of a curved insertion shaft assists in the use of a lateral approach to the spinous processes S.

[00305] The implant 6010 has a collapsed configuration in which the proximal portion 6014, the distal portion 6012 and the central portion 6016 share a common longitudinal axis. In some embodiments, the proximal portion 6014, the distal portion 6012 and the central portion 6016 define a tube having a constant inner diameter. In other embodiments, the proximal portion 6014, the distal portion 6012 and the central portion 6016 define a tube having a constant outer diameter and/or inner diameter. In yet other embodiments, the proximal portion 6014, the distal portion 6012 and/or the central portion 6016 have different inner diameters and/or outer diameters.

[00306] The implant 6010 can be moved from the collapsed configuration to an expanded configuration, as illustrated in FIG. 84. In the expanded configuration, the proximal portion 6014 and the distal portion 6012 each have a larger outer perimeter (e.g., outer diameter) than when in the collapsed configuration, and the proximal portion 6014 and the distal portion 6012 each have a larger outer perimeter (e.g., outer diameter) than the central portion 6016. In the expanded configuration, the proximal portion 6014 and the distal portion 6012 are positioned to limit lateral movement of the implant 6010 with respect to the spinous processes S. The proximal portion 6014 and the distal portion 6012 are configured to engage the spinous process (i.e., either directly or through surrounding tissue and depending upon the relative position of the adjacent

spinous processes S) in the expanded configuration. For purposes of clarity, the tissue surrounding the spinous processes S is not illustrated.

[00307] In some embodiments, the proximal portion 6014, the distal portion 6012 and the central portion 6016 are monolithically formed. In other embodiments, one or more of the proximal portion 6014, the distal portion 6012 and/or the central portion 6016 are separate components that can be coupled together to form the implant 6010. For example, the proximal portion 6014 and distal portion 6012 can be monolithically formed and the central portion 6016 can be a separate component that is coupled thereto. These various portions can be coupled, for example, by a friction fit, welding, adhesive, etc.

[00308] The implant 6010 is configured to be coupled to the deployment tool 6020. The deployment tool 6020 includes an elongate member 6022 and two or more engaging portions 6024. In the embodiment shown in FIGS. 83 and 84, there are two engaging portions 6024-1 and 6024-2 shown, but it should be understood that more than two engaging portions 6024 can be included. The elongate member 6022 can include a first body portion 6026 coupled to a second body portion 6028. In some embodiments, the first body portion 6026 is threadedly coupled to the second body portion 6028. The first body portion 6026 and the second body portion 6028 are configured to be moved relative to each other. For example, a threaded connection between the first body portion 6026 and the second body portion 6028 can be used to decrease or increase a distance between the first body portion 6026 and the second body portion 6028. The first body portion 6026 and the second body portion 6028 can be a variety of different shapes and sizes, and can be the same shape and/or size, or have a different shape and/or size than each other. For example, in some embodiments, the first body portion includes a straight distal end and a straight proximal end, and the second body portion includes a straight proximal end and a curved or rounded distal end. The curved distal end can assist with the insertion of the deployment tool into a lumen of an implant and also with the insertion of the medical device into a portion of a patient's body.

[00309] The first engaging portion 6024-1 can be coupled to the first body portion 6026 and the second engaging portion 6024-2 can be coupled to the second body portion 6028. The engaging portions 6024 can be, for example, substantially rectangular, square, circular, oval, semi-circular, or quarter-moon shaped. The engaging portions 6024, can be spring-loaded devices coupled to the elongate member 6022 of the deployment tool 6020, such that the engaging portions 6024 are biased into a position transverse to a longitudinal axis A defined by the elongate member 6022 and extending from an outer surface of the elongate member 6022. Upon force exerted on the engaging portions 6024, the engaging portions 6024 can be moved or collapsed to a position substantially below the outer surface of the elongate member 6022. The engaging portions 6024 can alternatively be coupled to an actuator (not shown) configured to move the engaging portions 6024 from a position transverse to the longitudinal axis A and extending from an outer surface of the elongate member 6022, to a position substantially below the outer surface of the elongate member 6022.

[00310] FIGS. 94-96 illustrate the movement of an engaging portion 6024 as it passes by a spinous process S when an implant and deployment tool (collectively also referred to as medical device) are coupled together and being inserted between adjacent spinous processes. In some cases, as the medical device is being inserted, an engaging portion 6024 extending from a proximal portion of an implant may come into contact with a spinous process (or other tissue). To allow the engaging portion 6024 to pass by the spinous process, the engaging portion 6024 can be moved downward (as described above) so as to clear the spinous process. FIG. 94 illustrates an engaging portion 6024 having a spring-biased construction. The engaging portion 6024 includes a curved portion 6048 that initially contacts the spinous process S as the medical device is being inserted adjacent a spinous process S. As the curved portion 6048 contacts the spinous process S, the engaging portion 6024 is moved downward at least partially into an interior of the implant 6010, as shown in FIG. 95. The engaging portion 6024 moves back to an extended position (e.g., extending transversely from a surface of the implant 6010) after the engaging portion clears the spinous process S, as shown in FIG. 96, due to the bias of the spring (not shown).

[00311] The deployment tool 6020 can be used to move the implant 6010 from the collapsed configuration to the expanded configuration, and vice versa, as will be discussed in more detail below. The first body portion 6026 and the second body portion 6028 are collectively configured to be inserted at least partially into a lumen (not shown in FIGS. 83 and 84) of the implant 6010, such that at least one engaging portion 6024 extends through an opening (not shown in FIGS. 83 and 84) defined by the implant 6010. The implant 6010 can be configured with one or more such openings, each of which is configured to receive an engaging portion 6024 disposed on the elongate member 6022 (e.g., the first body portion 6026 or the second body portion 6028). The openings defined by the implant 6010 can be, for example, the openings can be circular, oval, square, rectangular, etc. FIG. 85 illustrates an example of an implant 6110 defining curved rectangular openings 6136, and FIG. 98 illustrates an implant 6310 defining curved round or circular openings 6336.

[00312] The openings are at least partially defined by an edge (not shown in FIGS. 83 and 84) on the implant 6010. The engaging portions 6024 on the deployment tool 6020 include a surface (not shown in FIGS. 83 and 84) that is configured to engage or contact the edge of the openings of the implant 6010 when the elongate member 6022 is inserted into the lumen of the implant 6010.

[00313] In use, the spinous processes S can be distracted prior to inserting the implant 6010. When the spinous processes are distracted, a trocar can be used to define an access passage for the implant 6010. In some embodiments, the trocar can be used to define the passage as well as distract the spinous processes S. Once an access passage is defined, the implant 6010 can be inserted percutaneously and advanced between the spinous processes, distal end 6012 first, until the central portion 6016 is located between the spinous processes S. In some embodiments, the implant 6010 can be coupled to the deployment tool 6020 prior to being inserted between the adjacent spinous processes. In other embodiments, the implant 6010 can be inserted between adjacent spinous processes without being coupled to the deployment tool 6020. In the latter configuration, after the implant 6010 is disposed between the adjacent spinous

processes, the deployment tool 6020 can be inserted into the lumen defined by the implant 6010.

[00314] Once the implant 6010 is in place between the spinous processes, and the deployment tool 6020 is in position within the lumen of the implant 6010, the implant 6010 can be moved to the second configuration (i.e., the expanded configuration) by actuating the deployment tool 6020. For example, when the deployment tool 6020 is inserted into the lumen of the implant 6010, the first body portion 6026 is positioned at a first distance from the second body portion 6028, and the first engaging portion 6024-1 is positioned at a first distance from the second engaging portion 6024-2, as shown in FIG. 83. The deployment tool 6020 can then be actuated at a proximal end portion (e.g., by turning a handle) (not shown in FIGS. 83 and 84) causing the threaded coupling between the first body portion 6026 and the second body portion 6028 to move the first body portion 6026 and the second body portion 6028 towards each other such that the first body portion 6026 is now at a second distance (closer) from the second body portion 6028, as shown in FIG. 84. This movement likewise moves the first engaging portion 6024-1 and the second engaging portion 6024-2 to a closer position relative to each other. For example, in FIG. 83, the first engaging portion 6024-1 is positioned at a distance from the second engaging portion 6024-2 that is greater than a distance between the first engaging portion 6024-1 and the second engaging portion 6024-2 shown in FIG. 84.

[00315] As the engaging portions 6024-1 and 6024-2 are moved relative to each other, the surface (described above and described in more detail below) on the engaging portions 6024 imparts a force on the edge (described above and described in more detail below) of the opening defined by the implant causing the implant to move from the collapsed configuration to the expanded configuration.

[00316] The deployment tool 6020 is configured such that the deployment tool 6020 can be removed from the implant 6010 after the implant has been moved to the expanded configuration. The implant can remain disposed between the spinous processes indefinitely or removed as needed. For example, the deployment tool 6020

can be reinserted into the lumen of the implant 6010 and actuated in an opposite direction to cause the implant 6010 to be moved from the expanded configuration back to the collapsed configuration. In the collapsed configuration, the implant can be removed from the patient's body or repositioned to a new location between the spinous processes.

[00317] In some embodiments, the implant 6010 is inserted percutaneously (i.e., through an opening in the skin) and in a minimally-invasive manner. For example, as discussed in detail herein, the sizes of portions of the implant are expanded after the implant is inserted between the spinous processes. Once expanded, the sizes of the expanded portions of the implant are greater than the size of the opening. For example, the size of the opening/incision in the skin can be between 3 millimeters in length and 25 millimeters in length across the opening. In some embodiments, the size of the implant in the expanded configuration is between 3 and 25 millimeters across the opening.

[00318] FIGS. 85-87 illustrate an implant according to an embodiment of the invention. An implant 6110 includes a proximal portion 6114, a distal portion 6112, and a central portion 6116. The implant 6110 also defines multiple openings 6132 on an outer surface of the implant 6110. The openings 6132 are in communication with a lumen 6158 (shown in FIG. 92) defined by the implant 6110. The openings 6132 are partially defined by a first edge 6136 and a second edge 6138. The implant 6110 includes expandable portions disposed at the distal portion 6112 and the proximal portion 6114. The expandable portions 6140 can be coupled to the implant 6110 or formed integral with the implant 6110, as shown in FIG. 97. As shown in FIG. 97, elongated slots 6134 can be defined on an outer surface of the implant 6110. The elongated slots 6134 create weakened areas on the implant 6110 that allow the expandable portions 6140 to fold when exposed to axial force, forming extensions 6142, as shown in FIG. 86.

[00319] The implant 6110 can be inserted between adjacent spinous processes (not shown) in a collapsed configuration, as shown in FIG. 85, and then moved to an

expanded configuration, as shown in FIG. 86. The implant 6110 can then be moved back to a collapsed configuration as shown in FIG. 87, which illustrates the expandable portions 6140 in a partially collapsed configuration. Although FIG. 87 shows a partially collapsed configuration, in some embodiments, the implant can be moved back to the collapsed configuration as shown in FIG. 85.

[00320] To move the implant 6110 from the collapsed configuration to the expanded configuration, and vice versa, a deployment tool, as described above and as shown in FIGS. 88-90, can be used. The deployment tool 6120 includes an elongate member 6122 coupled to a handle 6144. The elongate member 6122 includes a first body portion 6126 coupled to a second body portion 6128 through a threaded coupling 6150. A pair of engaging portions 6124-1 are disposed on the first body portion 6126, and a pair of engaging portions 6124-2 are disposed on the second body portion 6128. The engaging portions 6124-1 and 6124-2 (also collectively referred to as engaging portions 6124) include a surface 6146 and a rounded portion 6148. The threaded coupling 6150 between the first body portion 6126 and the second body portion 6128 is used to move the first body portion 6126 and the second body portion 6128 such that a distance between the first body portion 6126 and the second body portion 6128 is changed. For example, FIG. 89 illustrates a first distance d-1 between the first body portion 6126 and the second body portion 6128, and FIG. 90 illustrates a second distance d-2 between the first body portion 6126 and the second body portion 6128. As shown in FIGS. 89 and 90, as the distance between the first body portion 6126 and the second body portion 6128 is changed, a distance between the engaging portions 6124-1 and 6124-2 is also changed.

[00321] In use, the first body portion 6126 and the second body portion 6128 are collectively disposed within the lumen 6158 of the implant 6110, such that the engaging portions 6124 extend through the openings 6132 and transverse to an axis B defined by the implant 6110, as shown in FIGS. 91-93. In this position, the surface 6146 of the engaging portions 6124 is configured to contact the edge 6136 of the openings 6132. FIGS. 91 and 92 illustrate the first body portion 6126 and the second body portion 6128 disposed within the lumen of the implant 6110, when the implant is in a collapsed

configuration. In this position, the first body portion 6126 is at a first distance from the second body portion 6128, the engaging portions 6124-1 are at a first distance from the engaging portions 6124-2, and the implant has a first length L-1.

[00322] When the implant is positioned between spinous processes S, the deployment tool 6120 can be actuated to move the implant 6110 to the expanded configuration, as shown in FIG. 93. When the deployment tool 6120 is actuated, the first body portion 6126 is moved closer to the second body portion 6128, and the engaging portions 6124-1 are moved closer to the engaging portions 6124-2. When this occurs, the surface 6146 on the engaging portions 6124 impart a force on the edge 6136 of the openings 6132, which axially compresses the implant 6110 until the implant 6110 has a second length L-2, as shown in FIG. 93.

[00323] To move the implant 6110 back to the collapsed configuration, the deployment tool 6120 can be reconfigured such that the surface 6146 of the engaging portions 6124 are positioned facing an opposite direction and configured to contact the edge 6138 of the implant 6110, as shown in FIG. 102. In some embodiments, the engaging portions 6124 can be, for example, removed and re-coupled to the elongate member 6122 (e.g., the first body portion 6126 and the second body portion 6128) such that the same engaging portions 6124 are simply repositioned. In other embodiments, a second deployment tool can be used having engaging portions positioned in the opposite direction. In either case, the deployment tool is inserted into the lumen 6158 of the implant 6110 as done previously, such that the engaging portions 6124 extend through the openings 6132 of the implant 6110 and the surface 6146 contacts the edge 6136 of the implant 6110. The deployment tool 6120 is then actuated in an opposite direction (e.g., turned in an opposite direction) such that the first body portion 6126 and the second body portion 6128 are threadedly moved further away from each other. In doing so, the engaging portions 6124-1 are moved further away from the engaging portions 6124-2, and the surface 6146 of the engaging portions 6124 impart a force on the edge 6138 (instead of edge of 6136) of openings 6132, which moves the implant 6110 back to the collapsed or straightened configuration. Thus, the implant described in all of the embodiments of the invention can be repeatedly moved between the

collapsed and expanded configurations as necessary to insert, reposition or remove the implant as desired.

[00324] FIG. 99 illustrates a deployment tool according to another embodiment of the invention. A deployment tool 6220 includes an elongate member 6222 having a first body portion 6226 coupled to a second body portion 6228 through a threaded coupling 6250. In this embodiment, the deployment tool 6220 includes two sets of four (8 total) engaging portions 6224 (only six engaging portions are shown in FIG. 99). A first set of engaging portions 6224-1 are coupled to the first body portion 6226, and a second set of engaging portions 6224-2 are coupled to the second body portion 6228. The engaging portions 6224 include a first surface 6246 and a second surface 6252. When the deployment tool 6220 is coupled to an implant, the first surface 6246 is configured to contact an edge of an opening defined on the implant (such as edge 6136 on implant 6110), and the second surface 6252 is configured to contact an opposite edge on the opening defined by the implant (such as edge 6138 on implant 6110).

[00325] Thus, in this embodiment, the deployment tool 6220 can be inserted into an implant and used to move the implant between a collapsed configuration and an expanded configuration without having to reposition the engaging portions 6224, or use a second deployment tool. To move the implant from a collapsed configuration to an expanded configuration, the deployment tool 6220 is actuated in a first direction. To move the implant back to the collapsed configuration, the deployment tool 6220 is actuated in an opposite direction (e.g., turned in an opposite direction). When the deployment tool 6220 is actuated to move the implant from the collapsed configuration to the expanded configuration, the surface 6246 of the engaging portions 6224 impart a force on an edge of an opening (e.g., edge 6136 on implant 6110), causing the implant to be axially compressed, as previously described. When the deployment tool 6220 is actuated to move the implant from the expanded configuration to the collapsed configuration, the surface 6252 of the engaging portions 6224 imparts a force on an opposite edge of the opening (e.g., edge 6138 on implant 6110), causing the implant to be substantially straightened as previously described.

[00326] FIG. 100 illustrates a deployment tool according to another embodiment of the invention. A deployment tool 6420 is similar to the deployment tool 6220 described above, except in this embodiment, there are only two sets of two engaging portions 6424 (4 total). The engaging portions 6424 are similar to the engaging portions 6224 except the engaging portions 6424 are substantially rectangular shaped. The engaging portions 6424 include a surface 6446 configured to contact an edge of an opening defined by an implant, and a surface 6452 configured to contact an opposite edge of the opening defined by the implant.

[00327] FIG. 101 illustrates a deployment tool according to yet another embodiment of the invention. A deployment tool 6520 is similarly constructed and functions similarly to the previous embodiments. The deployment tool 6520 includes an elongate member 6522 that includes a first body portion 6526 and a second body portion 6528. In this embodiment, the first body portion 6526 and the second body portion 6528 are smaller than illustrated in the previous embodiments, and engaging portions 6524 are coupled to the first body portion 6526 and the second body portion 6528 that are more elongate than previously shown.

[00328] A kit according to an embodiment of the invention can include at least one implant and at least one deployment tool as described above. For example, a kit can include an implant and two deployment tools, one deployment tool configured to be used to move the implant from a collapsed configuration to an expanded configuration, and another deployment tool configured to be used to move the implant from the expanded configuration to the collapsed configuration. Alternatively, a kit can include a single deployment tool have multiple engaging portions as described herein, that can be releasably coupled to an elongate member of a deployment tool. For example, one type or style of engaging portion can be used to move the implant from a collapsed configuration to an expanded configuration, and another type or style of engaging portion can be used to move the implant from the expanded configuration to the collapsed configuration. The kit can include engaging portions having one of a variety of different shapes and sizes, such that a user can select a particular engaging portion(s) for use in a particular application.

[00329] FIGS. 118-120 illustrate an implant according to another embodiment of the invention. An implant 6610 includes an outer shell 6670 having a distal portion 6612, a proximal portion 6614, and a central portion 6616. The implant 6610 can be moved between a collapsed configuration as shown in FIGS. 118 and 119, and an expanded configuration, as shown in FIG. 120. The proximal portion 6614 and the distal portion 6612 include expandable portions 6640 that form extensions 6642 that extend radially from the outer shell 6670 when the implant 6610 is in the expanded configuration.

[00330] The implant 6610 also includes an inner core 6672 disposed within a lumen 6658 defined by the outer shell 6670. The inner core 6672 can be constructed to provide increased compressive strength to the central portion 6616 of the outer shell 6670. In some embodiments, the inner core 6672 can define a lumen, while in other embodiments, the inner core 6672 can have a substantially solid construction. The inner core 6672 can be coupled to the central portion 6616 of the outer shell 6670 by, for example, a friction fit. The inner core 6672 can have a length such that the inner core 6672 is disposed within the lumen 6658 along substantially the entire length of the outer shell 6670 or only a portion of the length of the outer shell 6670. The inner core 6672 is also coupled to the distal portion 6612 of the outer shell 6670 with a coupling member 6674.

[00331] The coupling member 6674 can be, for example, a threaded coupling that can be used to move the implant 6610 between the collapsed configuration and the expanded configuration. For example, when the implant 6610 is disposed between adjacent spinous processes, a device can be used to turn the coupling member 6674 in a first direction such that an axial force is imparted on the distal portion 6612 of the outer shell 6610 in a proximal direction, and the distal portion 6612 is drawn toward the proximal portion 6614. In doing this, the outer shell 6670 will fold or bend as described in previous embodiments, and the implant 6610 will be moved to the expanded configuration. To move the implant 6610 from the expanded configuration to the collapsed configuration, the coupling member 6674 is turned in an opposite direction to impart an axial force on the distal portion 6612 of the outer shell 6610 in a

distal direction, moving the distal portion 6612 distally, and moving the implant 6610 to the collapsed configuration.

[00332] FIG. 103 is a flow chart illustrating a method according to an embodiment of the invention. A method includes at 6060, percutaneously disposing an expandable member at a first location between adjacent spinous processes within a body of a patient while the expandable member is in a collapsed configuration. The expandable member is coupled to a deployment tool that includes an engaging portion configured to be received through an opening defined by the expandable member. In other embodiments, the deployment tool can be coupled to the implant after the implant has been disposed between the spinous processes. After the implant has been disposed between the adjacent spinous processes, the expandable member can be moved from the collapsed configuration to an expanded configuration at 6062. To do this, the deployment tool can be actuated while the expandable member is disposed between the adjacent spinous processes such that the engaging portion of the deployment tool imparts a force to a first location on the expandable member and causes the expandable member to move from the collapsed configuration to an expanded configuration. After actuating the deployment tool such that the expandable member is moved from the collapsed configuration to the expanded configuration, the deployment tool can optionally be removed from the expandable member, at 6064. In embodiments where the deployment tool has been removed, the deployment tool can be subsequently reinserted into the expandable member.

[00333] At 6066, after the deployment tool has been actuated to move the implant from the collapsed configuration to the expanded configuration, the deployment tool can be actuated again such that the engaging portion imparts a force to a second location on the expandable member different from the first location on the expandable member, and the implant is moved from the expanded configuration to the collapsed configuration.

[00334] After actuating the deployment tool such that the expandable member is moved from the expanded configuration to the collapsed configuration, the expandable

member can optionally be disposed at a second location between the adjacent spinous processes different from the first location, at 6068. In some embodiments, after the deployment tool is actuated such that the expandable member is moved from the expanded configuration to the collapsed configuration, the expandable member can optionally be disposed at a second location outside of the body of the patient, at 6070.

[00335] The various implants and deployment tools described herein can be constructed with various biocompatible materials such as, for example, titanium, titanium alloyed, surgical steel, biocompatible metal alloys, stainless steel, plastic, polyetheretherketone (PEEK), carbon fiber, ultra-high molecular weight (UHMW) polyethylene, biocompatible polymeric materials, etc. The material of a central portion of the implant can have, for example, a compressive strength similar to or higher than that of bone. In one embodiment, the central portion of the implant, which is placed between the two adjacent spinous processes, is configured with a material having an elastic modulus higher than the elastic modulus of the bone, which forms the spinous processes. In another embodiment, the central portion of the implant is configured with a material having a higher elastic modulus than the materials used to configure the distal and proximal portions of the implant. For example, the central portion of the implant may have an elastic modulus higher than bone, while the proximal and distal portions have a lower elastic modulus than bone. In yet another embodiment, where the implant is configured with an outer shell and an inner core. The outer shell can be configured with material having a higher elastic modulus than the inner core (e.g., outer shell is made with titanium alloyed, while the inner core is made with a polymeric material). Alternatively, the outer shell can be configured with a material having a lower elastic modulus than the inner core (e.g., the outer shell is made with a polymeric material while the inner core is made with a titanium alloyed material).

[00336] An apparatus includes an elongate member having a proximal portion configured to be repeatedly moved between a first configuration and a second configuration under, for example, an axial load or a radial load. The elongate member has a distal portion configured to be moved from a first configuration to a second configuration under, for example, an axial load or a radial load. A non-expanding

central portion is positioned between the proximal portion and the distal portion. The non-expanding central portion is configured to engage adjacent spinous processes upon spinal extension.

[00337] In some embodiments, the elongate member can have multiple portions that each move from a first configuration to a second configuration, either simultaneously or serially. Additionally, the device, or portions thereof, can be configured into many intermediate positions during the movement between the first configuration and the second configuration. For ease of reference, the entire device is referred to as being in either a first configuration or a second configuration although it should be understood that the device and/or portions thereof have a range of motion that includes many configuration including the first configuration and the second configuration.

[00338] FIG. 104 is a schematic illustration of a medical device according to an embodiment of the invention adjacent two adjacent spinous processes. The medical device 7010 includes a proximal portion 7012, a distal portion 7014 and a central portion 7016. The medical device 7010 has a first configuration in which it can be inserted between adjacent spinous processes S or removed from between adjacent spinous processes S. The central portion 7016 is configured to contact the spinous processes S to prevent over-extension/compression of the spinous processes S. In some embodiments, the central portion 7016 does not substantially distract the adjacent spinous processes S. In other embodiments, the central portion 7016 does not distract the adjacent spinous processes S. The medical device 7010 is inserted into a patient's back and moved in between adjacent spinous processes from the side of the spinous processes (i.e., a posterior-lateral approach). The use of a curved insertion shaft assists in the use of a lateral approach to the spinous processes S.

[00339] In the first configuration, the proximal portion 7012, the distal portion 7014 and the central portion 7016 share a common longitudinal axis. In other embodiments, these portions do not share a common longitudinal axis. In some embodiments, the proximal portion 7012, the distal portion 7014 and the central portion 7016 define a tube having a constant inner diameter. In other embodiments, the proximal portion

7012, the distal portion 7014 and the central portion 7016 define a tube having a constant outer diameter and/or inner diameter. In yet other embodiments, the proximal portion 7012, the distal portion 7014 and/or the central portion 7016 have different inner diameters and/or outer diameters.

[00340] The medical device 7010 can be moved from the first configuration to a second configuration as illustrated in FIG. 105. In the second configuration, the proximal portion 7012 and the distal portion 7014 are positioned to limit lateral movement of the device 7010 with respect to the spinous processes S. The proximal portion 7012 and the distal portion 7014 are configured to engage the spinous process (i.e., either directly or through surrounding tissue) in the second configuration. For purposes of clarity, the tissue surrounding the spinous processes S is not illustrated. Note the medical device and/or its portions can engage the spinous processes S during all or just a portion of the range of motion of the spinous processes S associated with the patient's movements.

[00341] In some embodiments, the proximal portion 7012, the distal portion 7014 and the central portion 7016 are monolithically formed. In other embodiments, one or more of the proximal portion 7012, the distal portion 7014 and the central portion 7016 are separate components that can be coupled together to form the medical device 7010. For example, the proximal portion 7012 and distal portion 7014 can be monolithically formed and the central portion 7016 can be a separate component that is coupled thereto. The proximal portion 7012, the distal portion 7014 and the central portion 7016 can be the same or different materials. These various portions can be coupled, for example, by a friction fit, welding, adhesive, etc.

[00342] In use, the spinous processes S can be distracted prior to inserting the medical device 7010. Distraction of spinous processes is described herein. When the spinous processes are distracted, a trocar can be used to define an access passage for the medical device 7010. In some embodiments, the trocar can be used to define the passage as well as distract the spinous processes S. Once an access passage is defined, the medical device 7010 is inserted percutaneously and advanced between the spinous

processes, distal end 7014 first, until the central portion 7016 is located between the spinous processes S. Once the medical device 7010 is in place between the spinous processes, the proximal portion 7012 and the distal portion 7014 are moved to the second configuration, either serially or simultaneously.

[00343] In some embodiments, the medical device 7010 is inserted percutaneously (i.e., through an opening in the skin) and in a minimally-invasive manner. For example, as discussed in detail herein, when inserted, the sizes of portions of the implant are smaller than the size of the opening. The sizes of portions of the implant are expanded after the implant is inserted between the spinous processes. Once expanded, the sizes of the expanded portions of the implant are greater than the size of the opening. When collapsed, the sizes of portions of the spinal implant are again smaller than the size of the opening. For example, the size of the opening/incision in the skin can be between 3 millimeters in length and 25 millimeters in length across the opening. In some embodiments, the size of the implant in the expanded configuration is between 3 and 25 millimeters across the opening.

[00344] In some embodiments, the proximal portion 7012 and the distal portion 7014 can be moved back to their original configuration or substantially close to their original configuration and either repositioned between the adjacent spinous processes or removed from the body in which they were inserted.

[00345] FIG. 106 is a schematic illustration of a deformable element 7018 that is representative of the characteristics of, for example, the distal portion 7014 of the medical device 7010 in a first configuration. The deformable member 7018 includes cutouts A, B, C along its length to define weak points that allow the deformable member 7018 to deform in a predetermined manner. Depending upon the depth d of the cutouts A, B, C and the width w of the throats T1, T2, T3, the manner in which the deformable member 7018 deforms under an applied load can be controlled and varied. Additionally, depending upon the length L between the cutouts A, B, C (i.e., the length of the material between the cutouts), the manner in which the deformable member 7018 deforms can be controlled and varied.

[00346] FIG. 107 is a schematic illustration of the expansion properties of the deformable member 7018 illustrated in FIG. 106. When a load is applied, for example, in the direction indicated by arrow X, the deformable member 7018 deforms in a predetermined manner based on the characteristics of the deformable member 7018 as described above. As illustrated in FIG. 107, the deformable member 7018 deforms most at cutouts B and C due to the configuration of the cutout C and the short distance between cutouts B and C. In some embodiments, the length of the deformable member 7018 between cutouts B and C is sized to fit one side of adjacent spinous processes.

[00347] The deformable member 7018 is stiffer at cutout A due to the shallow depth of cutout A. As indicated in FIG. 107, a smooth transition is defined by the deformable member 7018 between cutouts A and B. Such a smooth transition causes less stress on the tissue surrounding a side of adjacent spinous processes than a more drastic transition (i.e., a steeper angled wall) such as between cutouts B and C. The dimensions and configuration of the deformable member 7018 can also determine the timing of the deformation at the various cutouts. The weaker (i.e., deeper and wider) cutouts deform before the stronger (i.e., shallower and narrower) cutouts.

[00348] FIGS. 108 and 109 illustrate a spinal implant 7100 in a first configuration and second configuration, respectively. As shown in FIG. 108, the spinal implant 7100 is collapsed in a first configuration and can be inserted between adjacent spinous processes. The spinal implant 7100 has a first deformable portion 7110, a second deformable portion 7120 and a central, non-deformable portion 7150. The first deformable portion 7110 has a first end 7112 and a second end 7114. The second deformable portion 7120 has a first end 7122 and a second end 7124. The central portion 7150 is coupled between second end 7114 and first end 7122. In some embodiments, the spinal implant 7100 is monolithically formed.

[00349] The first deformable portion 7110, the second deformable portion 7120 and the central portion 7150 have a common longitudinal axis A along the length of spinal implant 7100. The central portion 7150 can have the same inner diameter as first deformable portion 7110 and the second deformable portion 7120. In some

embodiments, the outer diameter of the central portion 7150 is smaller than the outer diameter of the first deformable portion 7110 and the second deformable portion 7120.

[00350] In use, spinal implant 7100 is inserted percutaneously between adjacent spinous processes. The first deformable portion 7110 is inserted first and is moved past the spinous processes until the central portion 7150 is positioned between the spinous processes. The outer diameter of the central portion 7150 can be slightly smaller than the space between the spinous processes to account for surrounding ligaments and tissue. In some embodiments, the central portion 7150 directly contacts the spinous processes between which it is positioned. In some embodiments, the central portion of spinal implant 7100 is a fixed size and is not compressible or expandable. Note the spinal implant 7100 and/or the first deformable portion 7110, second deformable portion 7120, and central portion 7150 can engage the spinous processes during all or just a portion of the range of motion of the spinous processes associated with the patient's movement.

[00351] The first deformable portion 7110 includes, for example, expanding members 7115, and 7117. Between the expanding members 7115, 7117, openings (not illustrated) are defined. As discussed above, the size and shape of the openings influence the manner in which the expanding members 7115, 7117 deform when an axial load is applied. The second deformable portion 7120 includes expanding members 7125 and 7127. Between the expanding members 7125, 7127, openings (not illustrated) are defined. As discussed above, the sizes and shapes of the openings influence the manner in which the expanding members 7125, 7127 deform when an axial load is applied.

[00352] When an axial load is applied to the spinal implant 7100, the spinal implant 7100 expands to a second configuration as illustrated in FIG. 109. In the second configuration, first end 7112 and second end 7114 of the first deformable portion 7110 move towards each other and expanding members 7115, 7117 project substantially laterally away from the longitudinal axis A. Likewise, first end 7122 and second end 7124 of the second deformable portion 7120 move towards one another and expanding

members 7125, 7127 project laterally away from the longitudinal axis A. The expanding members 7115, 7117, 7125, 7127 in the second configuration form projections that extend to positions adjacent to the spinous processes between which the spinal implant 7100 is inserted. In the second configuration, the expanding members 7115, 7117, 7125, 7127 inhibit lateral movement of the spinal implant 7100, while the central portion 7150 prevents the adjacent spinous processes from moving together any closer than the distance defined by the diameter of the central portion 7150 during spinal extension.

[00353] The first end 7112 of the first deformable portion 7110 defines a threaded opening 7113. The central portion 7150 defines a second threaded opening 7155. The second end 7124 of the second deformable portion 7120 defines a third threaded opening 7123. The threaded openings 7113, 7155, 7123 receive portions of an actuator 7200 (see FIG. 110) to move the first deformable portion 7110 and the second deformable portion 7120 between their respective first configurations and second configurations as described in greater detail herein. In some embodiments, the first threaded opening 7113 has a greater diameter than the second threaded opening 7155 and the third threaded opening 7123 (see FIGS. 108-111). In some embodiments the second threaded opening 7155 and the third threaded opening 7123 have the same diameter (see FIGS. 108-111). In other embodiments, the first threaded opening 7113' and the second threaded opening 7155' have the same diameter (see FIGS. 112-115) and the third threaded opening 7123' has a smaller diameter than the first threaded opening and the second threaded opening. The threaded openings 7113, 7155, 7123, 7113', 7155', 7123' are coaxially aligned. In other embodiments, the threaded openings can be any combination of different or the same sizes.

[00354] The spinal implant 7100 is deformed by a compressive force imparted substantially along the longitudinal axis A of the spinal implant 7100. As illustrated in FIG. 110, the compressive force is imparted to the first deformable portion 7110 by actuator 7200. The actuator includes a first portion 7210 and a second portion 7220 movably received within first portion 7210. In some embodiments, the second portion 7220 is slidably received within the first portion 7210. In other embodiments, the first

portion 7210 and the second portion 7220 are threadedly coupled. Each of the first portion 7210 and the second portion 7220 is provided with external threads 7212 and 7222, respectively, to engage the threaded openings 7113, 7155, 7123, 7113', 7155', 7123'.

[00355] As illustrated in FIG. 110, the compressive force is imparted to the first deformable portion 7110, for example, by attaching the threaded portion 7212 to the first threaded opening 7113, attaching the threaded portion 7222 to the second threaded opening 7155 of the central portion 7150, and drawing the second portion 7220 along the longitudinal axis A while imparting an opposing force against the first end 7112 of the first deformable portion 7110. The opposing force results in a compressive force causing the spinal implant 7100 to expand as discussed above.

[00356] Once the first deformable portion 7110 is moved to its second configuration, the threaded portion 7222 is threaded through the second threaded opening 7155 and threadedly coupled to the third threaded opening 7123. A compressive force is imparted to the second deformable portion 7120 of the spinal implant 7100 by drawing the second portion 7220 of the actuator in the direction indicated by the arrow F while applying an opposing force using the first portion 7210 of the actuator against the spinal implant 7100. The opposing forces result in a compressive force causing the spinal implant to expand as illustrated in FIG. 111.

[00357] In some embodiments, the first deformable portion 7110 and the second deformable portion 7120 can be expanded simultaneously when the second portion 7220 of the actuator is coupled to the third threaded opening 7123 and the first portion 7210 is coupled to the first threaded opening 7113 and a compressive force is applied.

[00358] In embodiments in which the first threaded opening 7113' has the same diameter as the second threaded opening 7155' (best seen, for example, in FIGS. 112 and 113), the first threaded portion 7212 can be threadedly coupled to the second threaded opening 7155' and the second threaded portion 7222 can be threadedly coupled to the third threaded opening 7123'. A compressive force is then applied between the central portion 7150 and the second end 7124 of the second deformable

portion 7120. Once the second deformable portion 7120 is in its second configuration, the first threaded portion 7212 can be threadedly coupled to the first threaded opening 7113' and the first deformable portion 7110 can be deformed into its second configuration.

[00359] After each of the first deformable portion 7110 and the second deformable portion 7120 are moved to the second expanded configuration, they subsequently can each be moved back to the first collapsed configuration by applying a force in the opposite direction along longitudinal axis A as illustrated, for example, in FIGS. 114-115. In this example, as discussed above, the spinal implant 7100 illustrated in FIGS. 112-115 has a first threaded opening 7113' that has the same diameter as the second threaded opening 7155'.

[00360] With the first threaded portion 7212 coupled to the second threaded opening 7155' and the second threaded portion 7222 coupled to the third threaded opening 7123', the second portion 7220 of the actuator 7200 is moved in the direction indicated by arrow F to move the second deformable portion 7120 to its first collapsed configuration.

[00361] The first threaded portion 7212 is then coupled to the first threaded opening 7113' and the second portion 7220 of actuator 7200 is again moved in the direction of arrow F to move the first deformable portion 7110 to its first collapsed configuration. When the entire spinal implant 7100 has been completely collapsed, the spinal implant 7100 can be repositioned between the spinous processes, or removed from its position between the spinous processes and removed from the body in which it was previously inserted. In some embodiments, the first deformable portion 7110 and the second deformable portion 7120 are not completely collapsed, but are instead moved to a configuration between fully expanded and fully collapsed. In this manner the spinal implant 7100 may be repositioned or removed without being completely collapsed.

[00362] In some embodiments, the first deformable portion 7110 and the second deformable portion 7120 can be moved between the first and second configuration using a balloon as an actuator. As illustrated in FIG. 116, the second deformable

portion 7120 is then moved from the second configuration to the first configuration by imparting a longitudinal force resulting from the inflation of a balloon 7300 with liquid and/or gas. As the balloon 7300 is inflated, it is forced against the central portion 7150 and the second end 7124 of the second deformable portion 7120. The force imparted by the balloon 7300 is generally in the direction indicated by the arrow F. In some embodiments, the balloon 7300 is a low-compliant balloon that is configured to expand to a predefined shape such that a force is imparted primarily in a substantially longitudinal direction indicated by arrow F.

[00363] After the second deformable portion 7120 is moved substantially to its collapsed configuration, the balloon 7300 is deflated and moved into the first deformable portion 7110. The balloon 7300 is then inflated as illustrated in FIG. 117 to impart a force in the direction indicated by arrow F. In some embodiments, the same balloon 7300 is used to collapse both the first deformable portion 7110 and the second deformable portion 7120. In other embodiments, a different balloon is used for each portion 7110, 7120. Once the entire implant 7100 is moved to the first configuration, the balloon is deflated and removed. In some embodiments, the balloon 7300 remains in the spinal implant 7100, and the spinal implant 7100 and the balloon 7300 are removed simultaneously.

[00364] In some embodiments, the shaft on which the balloon is coupled has external threads (not illustrated) to mate with the first threaded opening 7113, 7113' and/or the second threaded opening 7155, 7155'. In other embodiments, neither the openings nor the shaft on which the balloon is coupled are threaded. In yet other embodiments, the balloon 7300 is inserted through the first portion 7210 of the actuator 7200. Alternatively, the actuator 7200 and the balloon 7300 can be used in conjunction with the spinal implant to expand and/or contract the first deformable portion 7110 and the second deformable portion 7120.

[00365] In other embodiments, there are no threaded openings defined in the spinal implant 7100. For example, the spinal implant can have multiple actuator-engaging portions that are not threaded, but are rather contact or bearing surfaces for various

types of actuators. For example, an actuator (not illustrated) can be configured to grasp an outer surface of the spinal implant while simultaneously imparting a force against the distal portion of the spinal implant to move the implant to a collapsed configuration.

[00366] The spinal implant 7100 can be made from, for example, stainless steel, plastic, polyetheretherketone (PEEK), carbon fiber, ultra-high molecular weight (UHMW) polyethylene, etc. or some combination thereof. For example, the first deformable portion and the second deformable portion can be made from one material and the non-expanding central portion can be made from a different material. The material of such a non-expanding central portion can have a tensile strength similar to or higher than that of bone.

[00367] While various embodiments of the invention have been described above, it should be understood that they have been presented by way of example only, and not limitation. Where methods and steps described above indicate certain events occurring in certain order, those of ordinary skill in the art having the benefit of this disclosure would recognize that the ordering of certain steps may be modified and that such modifications are in accordance with the variations of the invention. Additionally, certain of the steps may be performed concurrently in a parallel process when possible, as well as performed sequentially as described above. Thus, the breadth and scope of the invention should not be limited by any of the above-described embodiments, but should be defined only in accordance with the following claims and their equivalents. While the invention has been particularly shown and described with reference to specific embodiments thereof, it will be understood that various changes in form and details may be made.

[00368] For example, although the embodiments above are primarily described as being spinal implants configured to be positioned between adjacent spinous processes, in alternative embodiments, the implants are configured to be positioned adjacent any bone, tissue or other bodily structure where it is desirable to maintain spacing while preventing axial or longitudinal movement of the implant.

[00369] While the implants described herein were primarily described as not distracting adjacent spinous processes, in alternative embodiments, the implants can be configured to expand to distract adjacent spinous processes.

[00370] Although described as being inserted directly between adjacent spinous processes, in alternative embodiments, the implants described above can be delivered through a cannula.

[00371] For example, although the swing arm 1700 is described as having an arcuate portion, in alternative embodiments of the invention, the entire swing arm 1700 may have an arcuate configuration. Additionally, the opening defined in the swing arm 1700 may extend the entire length of the swing arm 1700.

[00372] Although the swing arm 1700 is described and illustrated as having a circular opening at its end, in alternative embodiments, the opening can be any shape and the shape of the portion of the working tool and/or spacer can be shaped to be matingly engage the opening of the swing arm.

[00373] Although the connection between the swing arm and the working tool are shown with the swing arm being the female component and the working tool being the male component, in alternative embodiments, the orientation of the male/female relationship may be reversed.

[00374] Although the first arm 1170 and second arm 1180 of the first clamp 1100 are described as being resiliently coupled, in alternative embodiments of the invention, the first arm 1170 and the second arm 1180 are pivotably or hingedly coupled.

[00375] Although the first clamp and second clamp are disclosed as having jaws that engage opposite sides of a spinous process, in alternative embodiments, the first clamp and second clamp may include other configurations to engage the spinous process such as, for example, suction, adhesive, pins/projections, etc.

[00376] While the first clamp and second clamp are disclosed as being movable with respect to one another, in alternative embodiments, the first clamp or the second clamp may be fixed in position, with the other clamp moving relative to the fixed clamp.

[00377] While the first arm and the second arm of the clamp are shown as being resiliently biased apart from one another, in alternative embodiments, the first arm and the second arm can be manually moved towards and away from one another using a different configuration (e.g., scissor configuration).

[00378] Although embodiments are disclosed that illustrate the wire being coupled to the swing arm using a retainer, in alternative embodiments, a retainer need not be used. The wire can be coupled to the swing arm using other retention methods, such as, for example, a slit in which the wire can be clamped.

[00379] Additionally, although the working tool 1840 is disclosed as a trocar tip, the working tool may be any working tool such as, for example, a spacer, a balloon actuator, a bone tamp, etc.

[00380] Although the embodiments above are primarily described as being spinal implants configured to be positioned between adjacent spinous processes, in alternative embodiments, the implants are configured to be positioned adjacent any bone, tissue or other bodily structure where it is desirable to maintain spacing while preventing axial or longitudinal movement of the implant.

[00381] While the implants described herein were primarily described as not distracting adjacent spinous processes, in alternative embodiments, the implants can be configured to expand to distract adjacent spinous processes.

[00382] Although described as being inserted directly between adjacent spinous processes, in alternative embodiments, the implants described above can be delivered through a cannula.

[00383] Although the actuator used to move the spinal implant from the expanded configuration to the collapsed configuration is described as a rod assembly or a balloon,

in alternative embodiments the actuator can be any device configured to impart a longitudinal force sufficient to move the implant to its collapsed configuration. For example, the actuator can be a piston/cylinder assembly, a ratchet assembly, or the like.

Claims

1. An apparatus, comprising:
an expandable elongate member configured to be deformed from a first configuration to a second configuration to cause expansion of at least a portion of the expandable elongate member.
2. The apparatus of claim 1, wherein the expandable elongate member has
a proximal portion configured to be deformed from a first configuration to a second configuration to cause expansion of at least a section of the proximal portion;
a distal portion configured to be deformed from a first configuration to a second configuration to cause expansion of at least a section of the distal portion; and
a central portion between the proximal portion and the distal portion, the non-expanding central portion configured to engage adjacent spinous processes.
3. The apparatus of claim 2, wherein the non-expanding central portion is configured to engage the adjacent spinous processes upon spinal expansion.
4. The apparatus of claim 2, wherein the proximal portion, the distal portion and the central portion are monolithically formed.
5. The apparatus of claim 2, wherein the proximal portion is configured to deform to its second configuration before the distal portion deforms to its second configuration.
6. The apparatus of claim 2, wherein the proximal portion includes a first surface and a second surface that are spaced apart in the first configuration and matingly engage in the second configuration, the first surface and the second surface configured to restrict further deformation of the proximal portion once matingly engaged.
7. The apparatus of claim 2, wherein the proximal portion, the distal portion and the central portion together form a tube having a substantially constant inner diameter.

8. The apparatus of claim 2, wherein the elongate member is configured to be inserted between adjacent spinous processes percutaneously.

9. The apparatus of claim 2, wherein the proximal portion has a plurality of projections configured to extend outwardly from the elongate member in the second configuration.

10. The apparatus of claim 2, wherein the distal portion has a plurality of projections configured to extend outwardly from the elongate member in the second configuration.

11. The apparatus of claim 2, wherein the proximal portion and the distal portion each have a plurality of projections configured to extend outwardly from the elongate member in the second configuration, at least one projection from the plurality of projections being asymmetrical about an axis of the at least one projection.

12. The apparatus of claim 2, wherein the proximal portion and the distal portion deform from the first configuration to the second configuration substantially without distraction of the adjacent spinous processes.

13. The apparatus of claim 1, wherein the expandable elongate member is configured to deform from the first configuration to the second configuration under an axial load.

14. The apparatus of claim 1, wherein the expandable elongate member is configured to be inserted between adjacent spinous processes through an opening in a body.

15. The apparatus of claim 1, wherein the deformable proximal portion and the deformable distal portion are movable between the first configuration and the second configuration under an axially applied load.
16. The apparatus of claim 1, wherein the expandable elongate member is configured to change from the first configuration to the second configuration substantially without distracting bone.
17. The apparatus of claim 2, wherein the size of the proximal portion in the second configuration and the distal portion in the second configuration is greater than 1 millimeter.
18. The apparatus of claim 2, wherein the central portion is non-expandable.
19. The apparatus of claim 2, wherein the proximal portion and the distal portion are actuatable at different times.
20. The apparatus of claim 2, wherein the proximal portion in the second configuration includes at least two projections disposed adjacent to a side of the adjacent spinous processes, a distance defined between a distal end of a first projection from the at least two and a distal end of a second projection from the at least two projections being greater than a space between the adjacent spinous processes.
21. The apparatus of claim 2, wherein the proximal portion includes a plurality of slits, the plurality of slits configured to define at least two projections when the proximal portion is in the second configuration.
22. The apparatus of claim 2, wherein the proximal portion and the distal portion are mechanically actuatable.
23. The apparatus of claim 2, wherein the proximal portion, the distal portion and the central portion are monolithically formed.

24. The apparatus of claim 2, wherein the proximal portion, the distal portion and the central portion are physically distinct components.
25. The apparatus of claim 2, wherein the central portion is configured to be inflated.
22. The apparatus of claim 1, further comprising:
an actuator;
a guide shaft coupled to the actuator and configured to be coupled to the expandable elongate member.
23. The apparatus of 22, further comprising:
an expansion member coupled to the guide shaft, the expansion member being configured to impart a force from within an interior of the expandable elongate member to deform the expandable elongate member.
the actuator coupled to the expansion member, the actuator configured to move the expansion member from a first position to a second position.
24. The apparatus of claim 23, wherein the expansion member is configured to deform the expandable elongate member when at least a portion of the expandable elongate member is positioned between adjacent spinous processes.
25. The apparatus of claim 23, wherein the guide shaft has a proximal end and a distal end, the expansion member being coupled to the distal end.
26. The apparatus of claim 23, wherein the expansion member is rotatable about an axis of rotation that is substantially parallel to a longitudinal axis of the guide shaft, the axis of rotation of the expansion member being spaced apart from the longitudinal axis of the guide shaft.
27. The apparatus of claim 23, wherein the actuator is movable in a direction parallel to a longitudinal axis of the guide shaft, and

the expansion member is configured to be displaced in a direction substantially perpendicular to the longitudinal axis.

28. The apparatus of claim 23, wherein the guide shaft defines an opening configured to receive the expansion member, the expansion member being retracted in the first configuration and configured to extend beyond an outer surface of the guide shaft in the second configuration.

29. The apparatus of claim 23, wherein the actuator is configured to rotate about an axis of rotation, the axis of rotation being coaxial with a longitudinal axis of the guide shaft, and

the actuator is configured to displace the expansion member in a direction substantially perpendicular to the longitudinal axis when the actuator is rotated.

30. The apparatus of claim 23, wherein the expansion member is one expansion member from a plurality of expansion members.

31. The apparatus of claim 22, wherein the expansion member is a first expansion member from a plurality of expansion members, the first expansion member is movable in a first direction and a second expansion member is movable in a second direction different from the first direction.

32. The apparatus of claim 1, further comprising:

a guide shaft configured to be inserted in the expandable elongate member, the expandable elongate member having a diameter;

an expansion device coupled to the guide shaft, the expansion device configured to be moved between a first configuration and a second configuration, the expansion device in the second configuration configured to circumscribe a locus of points outside the diameter of the expandable elongate member; and

an actuator coupled to the expansion device, the actuator configured to move the expansion device from the first position to the second position.

33. The apparatus of claim 32, wherein the expansion device is rotatably coupled to the guide shaft.

34. The apparatus of claim 32, wherein the expansion device is slidably coupled to the guide shaft.

35. The apparatus of claim 32, wherein the expansion device is rotatable about an axis of rotation that is substantially parallel to a longitudinal axis of the guide shaft, the axis of rotation of the expansion device being spaced apart from the longitudinal axis of the guide shaft.

36. The apparatus of claim 32, wherein the actuator is movable in a direction parallel to a longitudinal axis of the guide shaft, and
the expansion device is configured to be displaced in a direction substantially perpendicular to the longitudinal axis.

37. The apparatus of claim 1, wherein the expandable elongate member is configured to be disposed between adjacent spinous processes, the apparatus further comprising:

a valve coupled to the expandable elongate member.

38. The apparatus of claim 37, wherein the valve is configured to convey a fluid from an area outside of the expandable elongate member to an inner area defined by the expandable elongate member and to convey the fluid from the inner area to the area outside of the expandable elongate member.

39. The apparatus of claim 37, wherein the valve includes a radiopaque material.

40. The apparatus of claim 37, wherein the valve is configured to be removably coupled to a tool configured to convey a fluid to the valve.

41. The apparatus of claim 37, wherein the valve is configured to be removably coupled to and recoupleable to a tool configured to convey a fluid to the valve.
42. The apparatus of claim 37, wherein:
the expandable elongate member has a first configuration in which the expandable elongate member has a first volume and a second configuration in which the expandable elongate member has a second volume, the second volume being greater than the first volume; and
the expandable elongate member is configured to move from the first configuration to the second configuration and to move from the second configuration to the first configuration.
43. The apparatus of claim 37, wherein the expandable elongate member has a support portion configured to be disposed between the adjacent spinous processes, the support portion having a longitudinal axis and a retention portion disposed adjacent to the support portion, the retention portion being configured to limit movement of the support portion along the longitudinal axis.
44. The apparatus of claim 37, wherein the expandable elongate member include a low-compliant material.
45. The apparatus of claim 1, further comprising:
a first body coupled to a second body, the first body and the second body collectively configured to be releasably coupled to the expandable elongate member configured to be disposed between adjacent spinous processes;
a first engaging portion coupled to the first body; and
a second engaging portion coupled to the second body, at least one of the first engaging portion or the second engaging portion configured to be received within a first opening defined by the expandable elongate member,

the first body configured to be moved relative to the second body such that a distance between the first engaging portion and the second engaging portion is moved between a first distance and a second distance and simultaneously a length of the expandable elongate member is moved between a first length and a second length.

46. The apparatus of claim 45, wherein the first length of the expandable elongate member is less than the second length of the expandable elongate member, and the first distance between the first engaging portion and the second engaging portion is less than the second distance between the first engaging portion and the second engaging portion.

47. The apparatus of claim 45, wherein the first length of the expandable elongate member is greater than the second length of the expandable elongate member, and the first distance between the first engaging portion and the second engaging portion is greater than the second distance between the first engaging portion and the second engaging portion.

48. The apparatus of claim 45, wherein the other of the at least one of the first engaging portion or the second engaging portion is configured to be received within a second opening defined by the expandable elongate member.

49. The apparatus of claim 45, wherein the first engaging portion and the second engaging portion are each spring loaded.

50. The apparatus of claim 45, wherein the first engaging portion and the second engaging portion each include a surface configured to impart a force on the expandable elongate member to move the expandable elongate member between the first length and the second length.

51. The apparatus of claim 1, wherein the expandable elongate member having a proximal portion configured to move from a first configuration to a second configuration and from the second configuration to the first configuration, at least a

section of the proximal portion being collapsed in the first configuration and expanded in the second configuration;

a distal portion configured to move from a first configuration to a second configuration and from the second configuration to the first configuration, at least a section of the distal portion being collapsed in the first configuration and expanded in the second configuration; and

a central portion between the proximal portion and the distal portion, the central portion configured to be disposed between adjacent spinous processes upon spinal extension, a material of the central portion being different than a material of the proximal portion and the distal portion.

52. An apparatus, comprising:

an elongate member having

a proximal portion configured to be deformed from a first configuration to a second configuration to cause expansion of at least a section of the proximal portion;

a distal portion configured to be deformed from a first configuration to a second configuration to cause expansion of at least a section of the distal portion; and

a non-expanding central portion between the proximal portion and the distal portion, the non-expanding central portion configured to engage adjacent spinous processes.

53. The apparatus of claim 52, wherein the non-expanding central portion is configured to engage the adjacent spinous processes upon spinal expansion.

54. The apparatus of claim 52, wherein the proximal portion, the distal portion and the central portion are monolithically formed.

55. The apparatus of claim 52, wherein the proximal portion is configured to deform to its second configuration before the distal portion deforms to its second configuration.

56. The apparatus of claim 52, wherein the proximal portion includes a first surface and a second surface that are spaced apart in the first configuration and matingly engage in the second configuration, the first surface and the second surface configured to restrict further deformation of the proximal portion once matingly engaged.

57. The apparatus of claim 52, wherein the proximal portion, the distal portion and the central portion together form a tube having a substantially constant inner diameter.

58. The apparatus of claim 52, wherein the elongate member is configured to be inserted between adjacent spinous processes percutaneously.

59. The apparatus of claim 52, wherein the proximal portion has a plurality of projections configured to extend outwardly from the elongate member in the second configuration.

60. The apparatus of claim 52, wherein the distal portion has a plurality of projections configured to extend outwardly from the elongate member in the second configuration.

61. The apparatus of claim 52, wherein the proximal portion and the distal portion each have a plurality of projections configured to extend outwardly from the elongate member in the second configuration, at least one projection from the plurality of projections being asymmetrical about an axis of the at least one projection.

62. The apparatus of claim 52, wherein the proximal portion and the distal portion deform from the first configuration to the second configuration substantially without distraction of the adjacent spinous processes.

63. The apparatus of claim 52, wherein the proximal portion and the distal portion are configured to deform from the first configuration to the second configuration under an axial load.

64. An apparatus, comprising:

an elongate member including a deformable distal portion and a deformable proximal portion, the deformable distal portion and the deformable proximal portion each having a first configuration for insertion of the elongate member between adjacent spinous processes and a second configuration defining at least two projections disposed substantially adjacent to a side of the adjacent spinous processes,

the at least two projections of the deformable distal portion and the at least two projections of the deformable proximal portion configured to substantially maintain a lateral position relative to the adjacent spinous processes.

65. The apparatus of claim 64, wherein the deformable proximal portion is configured to deform before the deformable distal portion.

66. The apparatus of claim 64, wherein the elongate member is configured to be inserted between adjacent spinous processes through an opening in a body, the opening being smaller than a diameter of the at least two projections.

67. The apparatus of claim 64, wherein the deformable proximal portion and the deformable distal portion are movable between the first configuration and the second configuration under an axially applied load.

68. An apparatus, comprising:

an elongate body including

a first deformable portion configured to be inserted through an opening in a body, the first deformable portion having a first configuration for insertion between adjacent spinous processes and a second configuration, the size of the first deformable portion in the second configuration being greater than a size of the opening;

a second deformable portion configured to be inserted through the opening in the body, the second deformable portion having a first configuration and a second configuration, the size of the second portion in the second configuration being greater than the size of the opening; and

a central portion disposed between the first deformable portion and the second deformable portion, the first deformable portion and the second deformable portion are each configured to change from the first configuration to the second configuration substantially without distracting bone.

69. The apparatus of claim 68, wherein the size of the first portion in the second configuration and the second portion in the second configuration is greater than 1 millimeter.

70. The apparatus of claim 68, wherein the central portion is non-expandable.

71. The apparatus of claim 68, wherein the first deformable portion and the second deformable portion are actuatable at different times.

72. The apparatus of claim 68, wherein the first deformable portion in the second configuration includes at least two projections disposed adjacent to a side of the adjacent spinous processes, a distance defined between a distal end of a first projection from the at least two and a distal end of a second projection from the at least two projections being greater than a space between the adjacent spinous processes.

73. The apparatus of claim 68, wherein the first deformable portion includes a plurality of slits, the plurality of slits configured to define at least two projections when the first deformable portion is in the second configuration.

74. The apparatus of claim 68, wherein the first deformable portion and the second deformable portion are mechanically actuatable.

75. The apparatus of claim 68, wherein the first deformable portion, the second deformable portion and the central portion are monolithically formed.

76. The apparatus of claim 68, wherein the first deformable portion, the second deformable portion and the central portion are physically distinct components.

77. The apparatus of claim 68, wherein the central portion is configured to be inflated.

78. An apparatus comprising:
a handle;
a shaft coupled to the handle; and
a distraction element coupled to the shaft.

79. An apparatus, comprising:
a guide shaft;
an expansion member coupled to the guide shaft, the expansion member being configured to impart a force from within an interior of an implant to deform the implant; and
an actuator coupled to the expansion member, the actuator configured to move the expansion member from a first position to a second position.

80. The apparatus of claim 79, wherein the expansion member is configured to deform the implant when at least a portion of the implant is positioned between adjacent spinous processes.

81. The apparatus of claim 79, wherein the guide shaft has a proximal end and a distal end, the movable object being coupled to the distal end.

82. The apparatus of claim 79, wherein the expansion member is rotatable about an axis of rotation that is substantially parallel to a longitudinal axis of the guide shaft, the axis of rotation of the expansion member being spaced apart from the longitudinal axis of the guide shaft.

83. The apparatus of claim 79, wherein the actuator is movable in a direction parallel to a longitudinal axis of the guide shaft, and

the expansion member is configured to be displaced in a direction substantially perpendicular to the longitudinal axis.

84. The apparatus of claim 79, wherein the guide shaft defines an opening configured to receive the expansion member, the expansion member being retracted in the first configuration and configured to extend beyond an outer surface of the guide shaft in the second configuration.

85. The apparatus of claim 79, wherein the actuator is configured to rotate about an axis of rotation, the axis of rotation being coaxial with a longitudinal axis of the guide shaft, and

the actuator is configured to displace the expansion member in a direction substantially perpendicular to the longitudinal axis when the actuator is rotated.

86. The apparatus of claim 79, wherein the expansion member is one expansion member from a plurality of expansion members.

87. The apparatus of claim 79, wherein the expansion member is a first expansion member from a plurality of expansion members, the first expansion member is movable in a first direction and a second expansion member is movable in a second direction different from the first direction.

88. An apparatus, comprising:

a guide shaft configured to be inserted in an implant having a diameter;

an expansion device coupled to the guide shaft, the expansion device configured to be moved between a first configuration and a second configuration, the expansion device in the second configuration configured to circumscribe a locus of points outside the diameter of the implant; and

an actuator coupled to the expansion device, the actuator configured to move the expansion device from the first position to the second position.

89. The apparatus of claim 88, wherein the expansion device is rotatably coupled to the guide shaft.

90. The apparatus of claim 88, wherein the expansion device is slidably coupled to the guide shaft.

91. The apparatus of claim 88, wherein the expansion device is moved from the first position to the second position when at least a portion of the implant is positioned between adjacent spinous processes.

92. The apparatus of claim 88, wherein the expansion device is rotatable about an axis of rotation that is substantially parallel to a longitudinal axis of the guide shaft, the axis of rotation of the expansion device being spaced apart from the longitudinal axis of the guide shaft.

93. The apparatus of claim 88, wherein the actuator is movable in a direction parallel to a longitudinal axis of the guide shaft, and
the expansion device is configured to be displaced in a direction substantially perpendicular to the longitudinal axis.

94. The apparatus of claim 88, wherein the actuator is configured to rotate about an axis of rotation, the axis of rotation being coaxial with a longitudinal axis of the guide shaft, and
the actuator is configured to displace the expansion device in a direction substantially perpendicular to the longitudinal axis when the actuator is rotated.

95. An apparatus, comprising:

an expansion device movable between a first configuration and a second configuration, the expansion device in the second configuration configured to deform the spinal implant;

a guide shaft configured to be inserted in a spinal implant when the expansion device is in the first configuration; and

an actuator rotatably coupled with respect to the guide shaft and configured to move the expansion device between the first configuration and the second configuration.

96. The apparatus of claim 95, wherein the guide shaft is configured to be rotated independently of the actuator.

97. The apparatus of claim 95, wherein the expansion device is configured to move in a first direction when the actuator is rotated in a first direction and the expansion device is configured to move in a second direction when the actuator is moved in a second direction.

98. A method, comprising:

moving an expansion device from a first configuration to a second configuration while disposed within a spinal implant, the expansion device in the second configuration configured to deform the spinal implant; and

moving the expansion device from the second configuration to the first configuration after the moving from the first configuration, the expansion device in the first configuration being substantially disengaged from the spinal implant, the spinal implant remaining deformed after the moving from the first configuration and after the moving from the second configuration.

99. The method of claim 98, wherein the moving from the first configuration and the moving from the second configuration are performed while the expansion device is disposed at a first location within the spinal implant, the method further comprising:

repositioning the expansion device to a second location within the spinal implant; and

moving the expansion device from the first configuration to the second configuration.

100. An apparatus, comprising:

a first clamp having a first end and a second end, the second end of the first clamp configured to engage a first spinous process;

a second clamp having a first end and a second end, the second end of the second clamp configured to engage a second spinous process spaced apart from the first spinous process; and

a connector coupled to the first end of the first clamp and the first end of the second clamp.

101. The apparatus of claim 100, wherein the connector is reconfigurable between a first position and a second position, the first clamp being a first distance from the second clamp when the connector is in the first position and being a second distance from the second clamp when the connector is in the second position.

102. The apparatus of claim 100, wherein the second end of the first clamp includes a first jaw and a second jaw opposite the first jaw, the first jaw and the second jaw configured to be movable between a first configuration and a second configuration, the first jaw and second jaw being closer together in the second configuration than in the first configuration.

103. The apparatus of claim 100, the first clamp including a first jaw and a second jaw at the second end, the apparatus further comprising a tension member coupled to the first connector, a distance between the first jaw and the second jaw being changed based on a movement of the tension member.

104. The apparatus of claim 100, wherein the first clamp includes a first arm and a second arm, the first arm being pivotably coupled to the second arm, the first arm being separable from the second arm at the second end.

105. The apparatus of claim 100, further comprising:
a swing arm pivotably coupled to the connector, the swing arm having a predefined range of motion.

106. The apparatus of claim 100, further comprising:
a swing arm pivotably coupled to the connector, the swing arm having a first end and a second end, the second end of the swing arm configured to receive a working tool.

107. The apparatus of claim 100, further comprising:
a swing arm pivotably coupled to the connector, the swing arm having a first end and a second end, the second end of the swing arm including a pointed projection, the pointed projection configured to define a pathway in tissue.

108. The apparatus of claim 100, further comprising:
a swing arm having a first end and a second end, the first end of the swing arm pivotably coupled to the connector, the swing arm defining an opening along its length;
a working tool configured to engage the second end of the swing arm;
a guide wire having a first end and a second end, the second end of the guide wire coupled to the working tool, the opening of the swing arm configured to receive the guide wire; and
a retainer coupled to the second end of the guide wire, the retainer configured to be removably coupled to the swing arm.

109. The apparatus of claim 100, further comprising:

a swing arm having a substantially arcuate shape, the swing arm having a range of motion including a position between the first spinous process and the second spinous process when the swing arm is pivotably coupled to the connector.

110. An apparatus, comprising:

an arcuate body portion having a first end and a second end, a side wall extending between the first end and the second end, the side wall defining a passageway between the first end and the second end;

a working tool configured to engage the second end;

a guide wire having a first end and second end, the first end of the guide wire coupled to the working tool, the guide wire configured to be received in the opening;
and

a retainer coupled to the second end of the guide wire, the retainer configured to be removably coupled to the body portion adjacent the first end of the apparatus.

111. The apparatus of claim 110, wherein the side wall defines a slot along its length between the first end and the second end.

112. The apparatus of claim 110, further comprising a working tool removably coupled to the second end, the working tool being one from a plurality of interchangeable working tools.

113. A method, comprising:

coupling a first clamp to a first spinous process;

coupling a second clamp to a second spinous process spaced apart from the first spinous process; and

changing a distance between the first spinous process and the second spinous process based on a movement of at least one of the first clamp and the second clamp.

114. The method of claim 113, further comprising:

inserting a portion of a swing arm between the first spinous process and the second spinous process after the coupling the first clamp, the coupling the second clamp and the changing the distance.

115. The method of claim 113, further comprising:

inserting a swing arm at a position between the first spinous process and the second spinous process after the coupling the first clamp, the coupling the second clamp and the changing the distance; and

inserting a spacer at the position.

116. The method of claim 113, further comprising:

defining a path that includes a position between the first spinous process and the second spinous process; and

inserting along the path a spacer configured to be located at the position.

117. A method, comprising:

moving an arcuate body between adjacent spinous processes of a vertebra to define an opening within tissue disposed between the adjacent spinous processes, the arcuate body having a second end portion configured to receive a working tool;

removing the arcuate body from the opening;

coupling a spacer to the arcuate body; and

inserting the spacer in the opening using the arcuate body.

118. A method comprising:

percutaneously inserting into a body an expandable member having a support portion and a retention portion, the support portion having a longitudinal axis and being configured to be disposed between adjacent spinous processes, the retention portion being configured to limit movement of the support portion along the longitudinal axis, the expandable member having a first configuration, a second configuration and a third configuration;

disposing the expandable member in a first location between the adjacent spinous processes when the expandable member is in the first configuration;
expanding the expandable member from the first configuration to the second configuration;
contracting the expandable member from the second configuration to the third configuration; and
disposing the expandable member in a second location, the second location being different from the first location.

119. The method of claim 118, wherein the second location is a location outside of the body.

120. The method of claim 118, wherein the second location is a location between the adjacent spinous processes.

121. The method of claim 118, wherein the second location is a location between the adjacent spinous processes, the method further comprising expanding the expandable member from the third configuration to the second configuration after the expandable member has been disposed in the second location.

122. The method of claim 118, wherein:

the expandable member has a first volume when the expandable member is in the first configuration;

the expandable member has a second volume when the expandable member is in the second configuration, the second volume being greater than the first volume; and

the expandable member has a third volume when the expandable member is in the third configuration, the third volume being between the first volume and the second volume.

123. The method of claim 118, wherein:

the expandable member has a first volume when the expandable member is in the first configuration;

the expandable member has a second volume when the expandable member is in the second configuration, the second volume being greater than the first volume; and

the expandable member has a third volume when the expandable member is in the third configuration, the third volume being the same as the first volume.

124. The method of claim 118, wherein the expandable member is configured to distract the adjacent spinous processes when the expandable member is in the second configuration.

125. The method of claim 118, wherein:

the expandable member is expanded from the first configuration to the second configuration by conveying a fluid into an inner area defined by the expandable member, the fluid being configured to retain fluidic properties; and

the expandable member is contracted from the second configuration to the third configuration by removing the fluid from the inner area.

126. The method of claim 118, wherein:

the expandable member is expanded from the first configuration to the second configuration by conveying a fluid into an inner area defined by the expandable member, the fluid being at least one of a liquid or a gas; and

the expandable member is contracted from the second configuration to the third configuration by removing the fluid from the inner area.

127. The method of claim 118, wherein the expandable member is a low compliant expandable member.

128. The method of claim 118, further comprising measuring at least one of a pressure or a force on the expandable member via a sensor disposed within the expandable member.

129. An apparatus, comprising:
an expandable member having
a support portion configured to be disposed between adjacent spinous processes, the support portion having a longitudinal axis;
a retention portion disposed adjacent to the support portion, the retention portion being configured to limit movement of the support portion along the longitudinal axis;
a first configuration in which the expandable member has a first volume;
and
a second configuration in which the expandable member has a second volume, the second volume being greater than the first volume, the expandable member configured to move from the first configuration to the second configuration and to move from the second configuration to the first configuration.
130. The apparatus of claim 129, wherein the support portion is configured to distract the adjacent spinous processes.
131. The apparatus of claim 129, wherein retention portion is a first retention portion, the expandable member further including a second retention portion disposed opposite the first retention portion and adjacent to the support portion, the second retention portion configured to limit movement of the support portion along the longitudinal axis.
132. The apparatus of claim 129, further comprising a sensor coupled to the expandable member, the sensor being configured to measure at least one of a pressure or a force.
133. The apparatus of claim 129, wherein the expandable member defines an inner area, the apparatus further comprising a valve defining a conduit in fluid communication with the inner area and an area outside of the expandable member.

134. The apparatus of claim 129, wherein the expandable member includes a radiopaque material.

135. The apparatus of claim 129, wherein the expandable member is configured to be inserted percutaneously between the adjacent spinous processes when in the first configuration.

136. The apparatus of claim 129, wherein at least one of the support portion or the retention portion include a low-compliant material.

137. An apparatus, comprising:

a support member configured to be disposed between adjacent spinous processes, the support member being substantially rigid;

a first expandable member coupled to a proximal portion of the support member, the first expandable member having a first configuration in which the first expandable member has a first volume and a second configuration in which the first expandable member has a second volume, the second volume being greater than the first volume; and

a second expandable member coupled to a distal portion of the support member, the second expandable member having a first configuration in which the second expandable member has a first volume and a second configuration in which the second expandable member has a second volume, the second volume of the second expandable member being greater than the first volume of the second expandable member.

138. The apparatus of claim 127, wherein the support member is configured to distract the adjacent spinous processes.

139. The apparatus of claim 127, wherein the support member is configured to contact the adjacent spinous processes upon spinal extension.

140. The apparatus of claim 127, wherein each of the first expandable member and the second expandable member are configured to be repeatedly transitioned between their respective first configuration and second configuration.

141. The apparatus of claim 127, wherein
the first expandable member defines an inner area; and
the second expandable member defines an inner area, the inner area of the second expandable member being in fluid communication with the inner area of the first expandable member.

142. An apparatus, comprising:
an expandable member configured to be disposed between adjacent spinous processes; and
a valve coupled to the expandable member.

143. The apparatus of claim 142, wherein the valve is configured to convey a fluid from an area outside of the expandable member to an inner area defined by the expandable member and to convey the fluid from the inner area to the area outside of the expandable member.

144. The apparatus of claim 142, wherein the valve includes a radiopaque material.

145. The apparatus of claim 142, wherein the valve is configured to be removably coupled to a tool configured to convey a fluid to the valve.

146. The apparatus of claim 142, wherein the valve is configured to be removably coupled to and recoupleable to a tool configured to convey a fluid to the valve.

147. The apparatus of claim 142, wherein:

the expandable member has a first configuration in which the expandable member has a first volume and a second configuration in which the expandable member has a second volume, the second volume being greater than the first volume; and

the expandable member is configured to move from the first configuration to the second configuration and to move from the second configuration to the first configuration.

148. The apparatus of claim 142, wherein the expandable member has a support portion configured to be disposed between the adjacent spinous processes, the support portion having a longitudinal axis and a retention portion disposed adjacent to the support portion, the retention portion being configured to limit movement of the support portion along the longitudinal axis.

149. The apparatus of claim 142, wherein the expandable member include a low-compliant material.

150. A kit, comprising:

an expandable member configured to be disposed between adjacent spinous processes, the expandable member including a valve; and

a catheter defining a lumen configured to convey a fluid, the catheter having a proximal end and a distal end, the distal end being coupleable to the valve.

151. An apparatus, comprising:

a support member configured to be disposed between adjacent spinous processes;

a proximal retention member having a first configuration in which the proximal retention member is substantially disposed within a proximal portion of the support member and a second configuration in which a portion of the proximal retention member is disposed outside of the support member; and

a distal retention member having a first configuration in which the distal retention member is substantially disposed within a distal portion of the support

member and a second configuration in which a portion of the distal retention member is disposed outside of the support member.

152. The apparatus of claim 151, wherein the support member is configured to contact the adjacent spinous processes upon spinal extension.

153. The apparatus of claim 151, further comprising a sensor coupled to the support member, the sensor being configured to measure at least one of a pressure or a force.

154. The apparatus of claim 151, wherein the support member is configured to be inserted between the adjacent spinous processes percutaneously.

155. The apparatus of claim 151, wherein:

the proximal retention member is configured to move from the first configuration to the second configuration and from the second configuration to the first configuration; and

the distal retention member is configured to move from the first configuration to the second configuration and from the second configuration to the first configuration.

156. The apparatus of claim 151, wherein:

the proximal retention member is configured to move to its own first configuration and the distal retention member is configured to move to its own first configuration substantially simultaneously; and

the proximal retention member is configured to move to its own second configuration and the distal retention member is configured to move to its own second configuration substantially simultaneously.

157. The apparatus of claim 151, wherein:

each of the proximal retention member and the distal retention member includes a first elongate member and a second elongate member configured to be slidably disposed within the first elongate member; and

the support member includes a side wall defining a plurality of openings, each opening from the plurality of openings being configured to receive a portion of at least one of the first elongate member or the second elongate member from at least one of the proximal retention member or the distal retention member therethrough.

158. The apparatus of claim 151, wherein:

each of the proximal retention member and the distal retention member includes

a first elongate member,

a second elongate member configured to be slidably disposed within the first elongate member, and

a biasing member coupled to the first elongate member and the second elongate member, the biasing member configured to retain each of the proximal retention member and the distal retention member in either one of the first configuration and the second configuration; and

the support member includes a side wall defining a plurality of openings, each opening from the plurality of openings being configured to receive a portion of at least one of the first elongate member and the second elongate member from at least one of the proximal retention member or the distal retention member therethrough.

159. The apparatus of claim 151, wherein each of the proximal retention member and the distal retention member includes:

an elongate member having a longitudinal axis, a portion of the elongate member being flexible in a direction normal to the longitudinal axis of the elongate member, and

a rotating member having a longitudinal axis normal to the longitudinal axis of the elongate member, the rotating member being coupled to the elongate member and configured to rotate about the longitudinal axis of the rotating member to move the elongate member along the longitudinal axis of the elongate member.

160. The apparatus of claim 151, wherein each of the proximal retention member and the distal retention member includes:

a first elongate member having a longitudinal axis,
a second elongate member having a longitudinal axis coaxial with the longitudinal axis of the first elongate member, and
an eccentric rotating member having an outer surface, a portion of the outer surface configured to contact a portion of each of the first elongate member and the second elongate member, the eccentric rotating member being configured to rotate such that each of the first elongate member and the second elongate member each move between their respective first configuration and the second configuration.

161. The apparatus of claim 151, wherein:

each of the proximal retention member and the distal retention member includes
a first elongate member configured to extend through a first opening defined in the support member,
a second elongate member configured to extend through a second opening defined in the support member, and
a hinge having a longitudinal axis, the hinge configured to pivotally couple the first elongate member and the second elongate member along the longitudinal axis and to move in a direction normal to the longitudinal axis such that each of the first elongate member and the second elongate member moves between the first configuration and the second configuration.

162. The apparatus of claim 151, wherein:

the proximal retention member is configured to be positioned in a third configuration in which the proximal retention member is substantially disposed within the proximal portion of the support member, the third configuration being different than the first configuration; and
the distal retention member is configured to be positioned in a third configuration in which the distal retention member is substantially disposed within the distal portion of the support member, the third configuration being different than the first configuration.

163. An apparatus, comprising:

a support member including a side wall having an outer surface, at least a portion of the outer surface being configured to be disposed between adjacent spinous processes, the outer surface defining an area normal to a longitudinal axis of the support member;

a proximal retention member having a first configuration in which the proximal retention member is disposed within the area and a second configuration in which a portion of the proximal retention member is disposed outside of the area; and

a distal retention member having a first configuration in which the distal retention member is disposed within the area and a second configuration in which a portion of the distal retention member is disposed outside of the area.

164. The apparatus of claim 163, wherein a portion of each of the proximal retention member and the distal retention member is configured to be disposed outside of the support member.

165. The apparatus of claim 163, further comprising an elastic member coupled to the proximal retention member and the distal retention member, the elastic member configured to retain each of the proximal retention member and the distal retention member in either one of the first configuration and the second configuration.

166. The apparatus of claim 163, wherein the support member is configured to be inserted between the adjacent spinous processes percutaneously.

167. An apparatus, comprising:

a support member configured to be percutaneously inserted into a body and disposed between adjacent spinous processes, the support member having a longitudinal axis and a side wall, the side wall being substantially parallel to the longitudinal axis and defining an inner area and an opening that connects the inner area and an area outside the support member; and

a retention member having a first configuration in which the retention member is substantially disposed within the inner area and a second configuration in which a

portion of the retention member is disposed through the opening to the area outside the support member.

168. A method, comprising:

percutaneously inserting into a body a support member configured to be disposed between adjacent spinous processes, the support member having a longitudinal axis and a side wall, the side wall being substantially parallel to the longitudinal axis and defining an inner area and an opening that connects the inner area and an area outside the support member, the support member including a retention member having a first configuration in which the retention member is substantially disposed within the inner area, and a second configuration in which a portion of the retention member is disposed through the opening to the area outside the support member;

disposing the support member to a location between the adjacent spinous processes when retention member is in the first configuration; and

moving the retention member from the first configuration to the second configuration.

169. The method of claim 168, wherein the location is a first location, the method further comprising:

moving the retention member from the second configuration to the first configuration; and

disposing the support member in a second location, the second location being different from the first location.

170. The method of claim 168, wherein the location is a first location, the method further comprising:

moving the retention member from the second configuration to the first configuration;

disposing the support member in a second location, the second location being between the adjacent spinous processes and different from the first location; and

moving the retention member from the first configuration to the second configuration after the support member has been disposed in the second location.

171. The method of claim 168, further comprising:

moving the retention member from the second configuration to the first configuration; and

disposing the support member in a second location, the second location being outside of the body.

172. An apparatus, comprising:

a support member configured to be disposed between adjacent spinous processes, the support member having a longitudinal axis; and

a retention member coupled to the support member, the retention member having a longitudinal axis that is normal to the longitudinal axis of the support member, the retention member being configured to move along its longitudinal axis from a first configuration to a second configuration.

173. The apparatus of claim 172, wherein:

the retention member is configured to allow movement of the support member along the longitudinal axis of the support member when in the first configuration; and

the retention member is configured to limit movement of the support member along the longitudinal axis of the support member when in the second configuration.

174. The apparatus of claim 172, wherein the retention member is configured to contact the adjacent spinous processes when in the second configuration.

175. The apparatus of claim 172, wherein:

the support member includes a side wall that defines an inner area and an opening that connects the inner area and an area outside the support member;

the retention member is substantially disposed within the inner area when in the first configuration; and

a portion of the retention member is disposed through the opening to the area outside the support member when in the second configuration.

176. An apparatus, comprising:

a first body coupled to a second body, the first body and the second body collectively configured to be releasably coupled to an implant device configured to be disposed between adjacent spinous processes;

a first engaging portion coupled to the first body; and

a second engaging portion coupled to the second body, at least one of the first engaging portion or the second engaging portion configured to be received within a first opening defined by the implant device,

the first body configured to be moved relative to the second body such that a distance between the first engaging portion and the second engaging portion is moved between a first distance and a second distance and simultaneously a length of the implant device is moved between a first length and a second length.

177. The apparatus of claim 176, wherein the first length of the implant device is less than the second length of the implant device, and the first distance between the first engaging portion and the second engaging portion is less than the second distance between the first engaging portion and the second engaging portion.

178. The apparatus of claim 176, wherein the first length of the implant device is greater than the second length of the implant device, and the first distance between the first engaging portion and the second engaging portion is greater than the second distance between the first engaging portion and the second engaging portion.

179. The apparatus of claim 176, wherein the other of the at least one of the first engaging portion or the second engaging portion is configured to be received within a second opening defined by the implant device.

180. The apparatus of claim 176, wherein the first engaging portion and the second engaging portion are each spring loaded.

181. The apparatus of claim 176, wherein the first engaging portion and the second engaging portion each include a surface configured to impart a force on the implant device to move the implant device between the first length and the second length.

182. A method, comprising:

inserting a distal portion of the apparatus according to claim 126 into tissue while the implant device is positioned at least partially over the apparatus with the first body and the second body of the apparatus positioned at least partially within a lumen of the implant device; and

positioning the implant device between adjacent spinous processes.

183. The method according to claim 182, further comprising:

securing the implant device between the adjacent spinous processes.

184. The method according to claim 182, further comprising:

moving the first body relative to the second body to apply an axial load on the implant device.

185. An apparatus, comprising:

an elongate body, the distal portion of the elongate body configured for insertion into a lumen of an implant device, the distal portion of the elongate body configured to apply an axial load on the implant device to deform at least a portion of the implant device, the implant device configured for placement between adjacent spinous processes.

186. The apparatus of claim 185, wherein the implant device includes a central portion configured to distract the adjacent spinous processes, an expandable distal portion and an expandable proximal portion.

187. The apparatus of claim 186, wherein the distal portion of the elongate body is configured to apply the axial load to expand the expandable distal portion and the expandable proximal portion of the implant device.

188. The apparatus of claim 186, wherein the distal portion of the elongate body is configured to apply the axial load to simultaneously expand the expandable distal portion and the expandable proximal portion of the implant device.

189. The apparatus of claim 186, wherein distal portion of the elongate body is configured to apply the axial load to expand the expandable distal portion and the expandable proximal portion of the implant device sequentially.

190. The apparatus of claim 185, wherein the distal portion of the elongate body includes a plurality of radially extended protrusions configured to engage the implant device.

191. The apparatus of claim 190, wherein each radially extended protrusion from the plurality of radially extended protrusions are configured for insertion into a corresponding opening defined by the implant device.

192. The apparatus of claim 185, wherein the distal portion of the elongate body is configured with a curvature to allow a user to insert the distal portion of the elongate body percutaneously into tissue and position the distal portion of the elongate body between adjacent spinous processes while maneuvering the proximal portion of the elongate body outside the tissue.

193. A kit, comprising:
an implant being reconfigurable between an expanded configuration and a collapsed configuration while disposed between adjacent spinous processes, the implant having a longitudinal axis and defining an opening; and

a deployment tool configured to be releasably coupled to the implant, the deployment tool including an engaging portion configured to be removably received within the opening of the implant and extend in a transverse direction relative to the longitudinal axis when the deployment tool is coupled to the implant, the deployment tool configured to move the implant between the collapsed configuration and the expanded configuration while the implant is disposed between the adjacent spinous processes.

194. The kit of claim 193, wherein the engaging portion includes a surface configured to impart a force on an edge of the opening of the implant when the deployment tool moves the implant from the collapsed configuration to the expanded configuration.

195. The kit of claim 193, wherein when the implant is in the expanded configuration, a first portion of the implant is configured to contact the adjacent spinous processes during at least a portion of a range of motion of the adjacent spinous processes, and a second portion of the implant is configured to retain the implant between the adjacent spinous processes.

196. The kit of claim 193, wherein the deployment tool is a first deployment tool configured to move the implant from the collapsed configuration to the expanded configuration, the kit further comprising:

a second deployment tool configured to move the implant from the expanded configuration to the collapsed configuration.

197. The kit of claim 193, wherein the opening is a first opening from a plurality of openings defined by the implant, the kit further comprising:

a plurality of engaging portions configured to be coupled to the deployment tool, each engaging portion from the plurality of engaging portions having a surface configured to engage an edge of an opening from the plurality of openings defined by the implant.

198. The kit of claim 193, wherein the implant is configured to distract adjacent spinous processes when the implant is in the expanded configuration.

199. A method, comprising:

percutaneously disposing an expandable member at a first location between adjacent spinous processes within a body while the expandable member is in a collapsed configuration;

actuating a deployment tool coupled to the expandable member while the expandable member is disposed between the adjacent spinous processes such that an engaging portion of the deployment tool imparts a force on the expandable member causing the expandable member to move from the collapsed configuration to an expanded configuration; and

actuating the deployment tool such that the engaging portion imparts a force on the expandable member causing the expandable member to move from the expanded configuration to the collapsed configuration.

200. The method of claim 199, further comprising:

coupling the expandable member to the deployment tool, such that the engaging portion of the deployment tool is received through an opening defined by the expandable member.

201. The method of claim 199, wherein the engaging portion imparts a force to a first location on the expandable member causing the expandable member to move from the collapsed configuration to the expanded configuration, and the engaging portion imparts a force to a second location on the expandable member different from the first location on the expandable member to cause the expandable member to move from the expanded configuration to the collapsed configuration.

202. The method of claim 199, further comprising:

after the actuating the deployment tool such that the expandable member is moved from the expanded configuration to the collapsed configuration, disposing the expandable member at a second location between the adjacent spinous processes different from the first location while the expandable member is in the collapsed configuration.

203. The method of claim 199, further comprising:

after the actuating the deployment tool such that the expandable member is moved from the collapsed configuration to the expanded configuration, removing the deployment tool from the expandable member.

204. The method of claim 199, further comprising:

after the actuating the deployment tool such that the expandable member is moved from the expanded configuration to the collapsed configuration, disposing the expandable member at a second location outside of the body while the expandable member is in the collapsed configuration.

205. A method, comprising:

disposing a distal portion of a tool percutaneously into a body;
engaging an implant device positioned between adjacent spinous processes; and
collapsing the implant device.

206. The method of claim 205, further comprising:

after the collapsing, removing the implant device from the pateint's body.

207. The method of claim 205, further comprising:

after the collapsing, re-positioning the implant device between the adjacent spinous processes.

208. The method of claim 205, wherein the engaging the implant device includes inserting the distal portion of the tool into a lumen of the implant device.

209. The method of claim 205, wherein the engaging the implant device includes disposing a protrusion coupled to the tool through an opening defined by the implant device.

210. The method of claim 205, wherein the collapsing the implant device includes applying an axial force on the implant device to collapse the implant device.

211. The method of claim 205, wherein the implant device includes a central portion configured to be disposed between the adjacent spinous processes, an expandable distal portion and an expandable proximal portion.

212. An apparatus, comprising:

an implant having an expandable portion and defining at least one opening through an outer surface, the expandable portion having a collapsed configuration and an expanded configuration; and

a deployment tool configured to be coupled to the implant, the deployment tool including a plurality of protrusions, at least one protrusion from the plurality of protrusions configured to be removably received through the at least one opening when the deployment tool is coupled to the implant, the at least one protrusion from the plurality of protrusions configured to be moved from a first position relative to a second protrusion from the plurality of protrusions to a second position relative to the second protrusion from the plurality of protrusions such that the expandable portion is moved between the collapsed configuration and the expanded configuration.

213. The apparatus of claim 212, wherein the at least one opening is a first opening, the second protrusion from the plurality of protrusions is configured to be removably received through a second opening from the at least one opening.

214. The apparatus of claim 212, wherein the deployment tool includes a first body and a second body, the first protrusion from the plurality of protrusions being coupled

to the first body, the second protrusion from the plurality of protrusions being coupled to the second body.

215. The apparatus of claim 212, wherein a distance between the at least one protrusion from the plurality of protrusions and the second protrusion from the plurality of protrusions when the expandable portion is in the collapsed configuration is greater than a distance between the at least one protrusion from the plurality of protrusions and the second protrusion from the plurality of protrusions when the expandable portion is in the expanded configuration.

216. The apparatus of claim 212, wherein the at least one opening on the implant is defined in part by an edge, the at least one protrusion includes a surface configured to impart a force on the edge to move the expandable portion between the collapsed configuration and the expanded configuration.

217. The apparatus of claim 212, wherein when the expandable portion is in the expanded configuration, a portion of the implant is configured to contact the adjacent spinous processes during at least a portion of a range of motion of the adjacent spinous processes and the expandable portion is configured to retain the implant between the adjacent spinous processes.

218. The apparatus of claim 212, wherein a portion of the implant is configured to distract the adjacent spinous processes when the expandable portion is in the expanded configuration.

219. An apparatus, comprising:

a first body coupled to a second body, the first body and the second body collectively configured to be releasably coupled to an implant device configured to be disposed between adjacent spinous processes;

a first engaging portion coupled to the first body; and

a second engaging portion coupled to the second body, at least one of the first engaging portion or the second engaging portion configured to be received within a first opening defined by the implant device,

the first body configured to be moved relative to the second body such that a distance between the first engaging portion and the second engaging portion is moved between a first distance and a second distance and simultaneously the implant device is moved between an expanded configuration and a collapsed configuration.

220. An apparatus, comprising:

a first body coupled to a second body, the first body and the second body collectively configured to be releasably coupled to an implant device configured to be disposed between adjacent spinous processes;

a first engaging portion coupled to the first body; and

a second engaging portion coupled to the second body, at least one of the first engaging portion or the second engaging portion configured to be received within a first opening defined by the implant device,

the first engaging portion and the second engaging portion each have a first configuration in which the first engaging portion and the second engaging portion are configured to move the implant from a collapsed configuration to an expanded configuration, and a second configuration in which the first engaging portion and the second engaging portion are configured to move the implant from the expanded configuration to the collapsed configuration.

221. An apparatus, comprising:

an elongate member having

a proximal portion configured to move from a first configuration to a second configuration and from the second configuration to the first configuration, at least a section of the proximal portion being collapsed in the first configuration and expanded in the second configuration;

a distal portion configured to move from a first configuration to a second configuration and from the second configuration to the first configuration, at least a

section of the distal portion being collapsed in the first configuration and expanded in the second configuration; and

a non-expanding central portion between the proximal portion and the distal portion, the non-expanding central portion configured to be disposed between adjacent spinous processes upon spinal extension.

222. The apparatus of claim 221, further comprising:

a proximal end defining a threaded opening; and

a distal end defining a threaded opening, the threaded opening at the proximal end and the threaded opening at the distal end each being configured to receive a portion of an actuator to cause the elongate member to move between the first configuration and the second configuration.

223. The apparatus of claim 221, further comprising:

a proximal actuator-engaging portion; and

a distal actuator-engaging portion, the proximal actuator-engaging portion and the distal actuator-engaging portion each being configured to receive a portion of an actuator to cause the elongate member to move between the first configuration and the second configuration under an axial load.

224. The apparatus of claim 221, further comprising:

a proximal actuator-engaging portion;

a distal actuator-engaging portion; and

a central actuator-engaging portion defined by the non-expanding central portion, the proximal actuator-engaging portion, the central actuator-engaging portion and the distal actuator-engaging portion each being configured to receive a portion of an actuator to cause the elongate member to move between the first configuration and the second configuration.

225. The apparatus of claim 221, further comprising:

a proximal actuator-engaging portion;

a distal actuator-engaging portion; and

a central actuator-engaging portion defined by the non-expanding central portion, the proximal actuator-engaging portion, the central actuator-engaging portion and the distal actuator-engaging portion each being configured to receive a portion of an actuator to cause the proximal portion to move between the first configuration and the second configuration under an applied load between the proximal actuator-engaging portion and the central actuator-engaging portion, and to cause the distal portion to move between the first configuration and the second configuration under an applied load between the distal actuator-engaging portion and the central actuator-engaging portion.

226. The apparatus of claim 221, wherein the elongate member is configured to be inserted between adjacent spinous processes when the proximal portion and the distal portion are each in the first configuration.

227. The apparatus of claim 221, wherein the proximal portion and the distal portion are configured to be moved from the second configuration to the first configuration under an axial load.

228. The apparatus of claim 221, further comprising:

an actuator having a first portion and a second portion;

a proximal actuator-engaging portion configured to receive the first portion of the actuator; and

a distal actuator-engaging portion configured to receive the second portion of the actuator, the first portion of the actuator and the second portion of the actuator configured to move relative to one another in a first direction to cause the elongate member to move to the second configuration and move relative to one another in a second direction to cause the elongate member to move to the first configuration from the second configuration.

229. The apparatus of claim 221, wherein the proximal portion and the distal portion are formed from a first material and the non-expanding central portion is formed from a second material different from the first material.

230. The apparatus of claim 221, wherein the proximal portion is configured to deform to its second configuration before the distal portion deforms to its second configuration.

231. The apparatus of claim 221, wherein the proximal portion has a plurality of projections configured to extend outwardly from the elongate member in the second configuration.

232. The apparatus of claim 221, wherein the proximal portion and the distal portion are configured to deform from the first configuration to the second configuration under a first axial load applied in a first direction, and the proximal portion and the distal portion are configured to move from the second configuration to the first configuration under a second axial load applied in a second direction, the second direction being substantially opposite the first direction.

233. The apparatus of claim 221, wherein the proximal portion and the distal portion are configured to deform from the second configuration to the first configuration by an axially applied load imparted using a low-compliant balloon.

234. A method of placing an implant in a body, comprising inserting the apparatus according to claim 171 between two adjacent spinous processes in the body.

235. A method, comprising:

inserting percutaneously into a body an elongate member including a proximal end portion and a distal end portion;

moving a section of the proximal end portion from a first configuration to a second configuration;

moving a section of the distal end portion from a first configuration to a second configuration;

moving the section of the proximal end portion from its second configuration to a third configuration; and

moving the section of the distal end portion from its second configuration to a third configuration.

236. The method of claim 235, wherein the moving the section of the proximal end portion to its second configuration occurs substantially simultaneously as the moving the section of the distal end portion to its second configuration.

237. The method of claim 235, wherein the first configuration of the proximal end portion substantially corresponds to the third configuration of the proximal end portion, and the first configuration of the distal end portion substantially corresponds to the third configuration of the distal end portion.

238. The method of claim 235, wherein the first configuration of the proximal end portion differs from the third configuration of the proximal end portion, and the first configuration of the distal end portion differs from the third configuration of the distal end portion.

239. The method of claim 235, wherein the moving the section of the proximal end portion to its third configuration and the moving the section of the distal end portion to its third configuration includes imparting an axial load to the elongate member.

240. The method of claim 235, further comprising:

coupling an actuator to the elongate member at a first location and a second location before the inserting;

separating the actuator from the elongate member after the moving the section of the proximal end portion from its first configuration to its second configuration and

the moving the section of the distal end portion from its first configuration to its second configuration; and

coupling the actuator to the elongate member before the moving the section of the proximal end portion from its second configuration to its third configuration and the moving the section of the distal end portion from its second configuration to its third configuration.

241. The method of claim 235, further comprising:

after moving the section of the proximal end to its third configuration and moving the section of the distal end portion to its third configuration, removing the elongate member from the body.

242. The method of claim 235, further comprising after the moving the section of the proximal end portion to its third configuration and the moving the distal end portion to its third configuration, removing the elongate member.

243. An apparatus, comprising:

an elongate member having

a proximal portion defining a first actuator-engaging portion, the proximal portion configured to move from a first configuration to a second configuration and from the second configuration to the first configuration,

a non-expanding central portion defining a second actuator-engaging portion, and

a distal portion defining a third actuator-engaging portion, the distal portion configured to move from a first configuration to a second configuration and from the second configuration to the first configuration, the elongate member configured to be disposed in tissue.

244. The apparatus of claim 243, the first actuator-engaging portion being a first threaded opening, the second actuator portion being a second threaded opening and the

third actuator-engaging portion being a third threaded opening, wherein a diameter of the first threaded opening is different from a diameter of the third threaded opening.

245. The apparatus of claim 243, the first actuator-engaging portion being a first threaded opening, the second actuator portion being a second threaded opening and the third actuator-engaging portion being a third threaded opening, wherein the first threaded opening, the second threaded opening and the third threaded opening are each configured to receive at least a portion of an actuator.

246. An apparatus, comprising:

an elongate member configured to be disposed in tissue having

a proximal portion configured to move from a first configuration to a second configuration under a first axial load applied in a first direction and to move from the second configuration to the first configuration under a second axial load applied in a second direction substantially opposite the first direction,

a central portion, and

a distal portion configured to move from a first configuration to a second configuration under a third axial load applied in the first direction and to move from the second configuration to the first configuration under a fourth axial load applied in the second direction.

247. The apparatus of claim 246, wherein the first axial load and the third axial load are the same axial load.

248. The apparatus of claim 246, wherein the second axial load and the fourth axial load are the same axial load.

249. A device, comprising:

a center portion configured for placement between two adjacent spinous processes;

an expandable distal portion configured to prevent the distal portion from moving through an opening between the two adjacent spinous processes when the center portion is positioned between the two adjacent spinous processes;

an expandable proximal portion configured to prevent the proximal portion from moving through the opening between the two adjacent spinous processes when the center portion is positioned between the two adjacent spinous processes.

250. The device of claim 249, wherein the expandable distal portion is further configured to be collapsible after expansion, such that once collapsed the distal portion can move through the opening between the two spinous processes.

251. The device of claim 249, wherein the expandable distal portion is further configured to be collapsible after expansion by applying an axial load, such that once collapsed the distal portion can move through the opening between the two spinous processes.

252. The device of claim 249, wherein the expandable distal portion is further configured to be collapsible after expansion by applying an axial load using a rod slidably disposed in an opening defined by the device, such that once collapsed the distal portion can move through the opening between the two spinous processes.

253. The device of claim 249, wherein the expandable distal portion is further configured to be collapsible after expansion by applying an axial load using a rod threadably coupled to the device, such that once collapsed the distal portion can move through the opening between the two spinous processes.

254. The device of claim 249, wherein the expandable distal portion is further configured to be collapsible after expansion by applying an axial load using an expandable body disposed in an opening defined by the device, such that once collapsed the distal portion can move through the opening between the two spinous processes.

255. The device of claim 249, wherein the expandable distal portion is further configured to be collapsible after expansion by applying an axial load using a balloon disposed in an opening defined by the device, such that once collapsed the distal portion can move through the opening between the two spinous processes.

256. An apparatus, comprising:

an elongate member having

a proximal portion configured to move from a first configuration to a second configuration and from the second configuration to the first configuration, at least a section of the proximal portion being collapsed in the first configuration and expanded in the second configuration;

a distal portion configured to move from a first configuration to a second configuration and from the second configuration to the first configuration, at least a section of the distal portion being collapsed in the first configuration and expanded in the second configuration; and

a central portion between the proximal portion and the distal portion, the central portion configured to be disposed between adjacent spinous processes upon spinal extension, a material of the central portion being different than a material of the proximal portion and the distal portion.

257. The apparatus of claim 256, further comprising:

a proximal actuator-engaging portion; and

a distal actuator-engaging portion, the proximal actuator-engaging portion and the distal actuator-engaging portion each being configured to receive at least a portion of an actuator to cause the elongate member to move between the first configuration and the second configuration under an axial load.

258. The apparatus of claim 256, wherein the proximal portion is configured to receive a balloon actuator to cause the proximal portion to move from its second configuration to its first configuration when the balloon actuator is inflated.

259. The apparatus of claim 256, wherein the proximal portion and the distal portion are configured to deform from the second configuration to the first configuration by an axially applied load imparted by an expansion of a low-compliant balloon.

260. The apparatus of claim 256, further comprising:

an actuator having a shaft and an expandable portion coupled to the shaft, the expandable portion configured to expand within the distal portion to cause the distal portion to move from its second configuration to its first configuration.

261. The apparatus of claim 256, further comprising:

an actuator having a shaft and an expandable portion coupled to the shaft, the expandable portion configured to expand within the proximal portion to cause the proximal portion to move from its second configuration to its first configuration.

262. The apparatus of claim 256, the material of the proximal portion and the material of the distal portion are configured to deform in response to an axially applied load imparted by an expansion of a low-compliant balloon.

263. The apparatus of claim 256, wherein the proximal portion and the distal portion are configured to deform from the first configuration to the second configuration under a first axial load applied in a first direction, and the proximal portion and the distal portion are configured to move from the second configuration to the first configuration under a second axial load applied in a second direction, the second direction being substantially opposite the first direction.

264. A method, comprising:

inserting an expandable member into an elongate member, the elongate member including a proximal end portion having a section in an expanded configuration and a distal end portion having a section in an expanded configuration; and

expanding the expandable member in a longitudinal to cause the section of the distal end portion to move from its expanded configuration to a collapsed configuration.

265. The method of claim 264, further comprising:

expanding the expandable member in a longitudinal direction to cause the section of the proximal end portion to move from its expanded configuration to a collapsed configuration.

266. The method of claim 264, further comprising removing the expandable member from the elongate member after at least one of the proximal end portion is in the collapsed configuration and the distal end portion is in the collapsed configuration.

267. The method of claim 264, wherein the expanding the expandable member includes inflating a balloon.

268. The method of claim 264, wherein the expanding the expandable member includes actuating a piston.

269. The method of claim 264, further comprising:

coupling the expandable member to the elongate member such that the expandable member is within the proximal portion before the expanding the expandable member to cause the section of the proximal end portion to move from its expanded configuration to a collapsed configuration;

separating the expandable member from the elongate member after the expanding the expandable member to cause the section of the proximal end portion to move from its expanded configuration to a collapsed configuration; and

coupling the expandable member to the elongate member such that the expandable member is within the distal portion before the expanding the expandable member to cause the section of the distal end portion to move from its expanded configuration to a collapsed configuration.

270. A kit, comprising:

an elongate member having

a proximal portion configured to move from a first configuration to a second configuration and from the second configuration to the first configuration, at least a section of the proximal portion being collapsed in the first configuration and expanded in the second configuration;

a distal portion configured to move from a first configuration to a second configuration and from the second configuration to the first configuration, at least a section of the distal portion being collapsed in the first configuration and expanded in the second configuration; and

a central portion between the proximal portion and the distal portion, the central portion configured to be disposed between adjacent spinous processes upon spinal extension, the central portion being a different material than a material of the proximal portion and the distal portion; and

an actuator configured to move the section of the proximal portion to its first configuration from its second configuration and move the section of the distal portion to its first configuration from its second configuration.

271. The kit of claim 270, wherein the actuator includes a balloon.

272. The kit of claim 270, wherein the actuator includes a piston and cylinder assembly.

273. The kit of claim 270, wherein the actuator is hydraulically actuated.

274. The kit of claim 270, wherein

the proximal portion defines a volume when the proximal portion is in the first configuration, and

the actuator is configured to define a volume when the actuator is in a collapsed configuration and define a volume when the actuator is in an expanded configuration, the volume of the actuator when in its expanded configuration substantially corresponding to the volume of the proximal portion when in its first configuration.

275. The kit of claim 270, wherein

the distal portion defines a volume when the distal portion is in the first configuration, and

the actuator is configured to define a volume when the actuator is in a collapsed configuration and define a volume when the actuator is in an expanded configuration, the volume of the actuator when in its expanded configuration substantially corresponding to the volume of the distal portion when in its first configuration.

276. The kit of claim 270, wherein the actuator is configured to be inserted in the elongate member subsequent to placement of the elongate member between adjacent spinous processes.

277. The kit of claim 270, wherein the actuator is configured to removably engage the elongate member.

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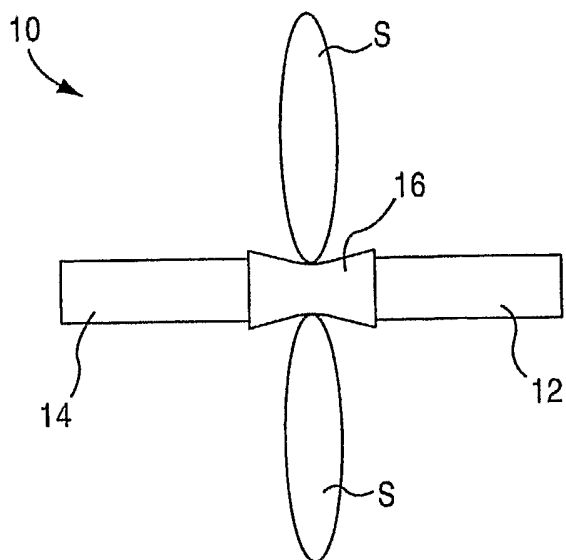


FIG. 1

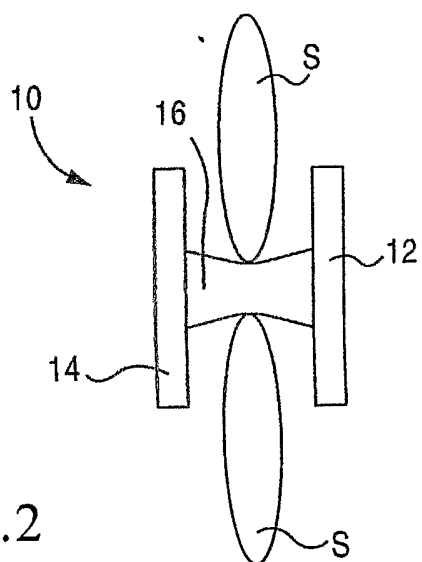


FIG. 2

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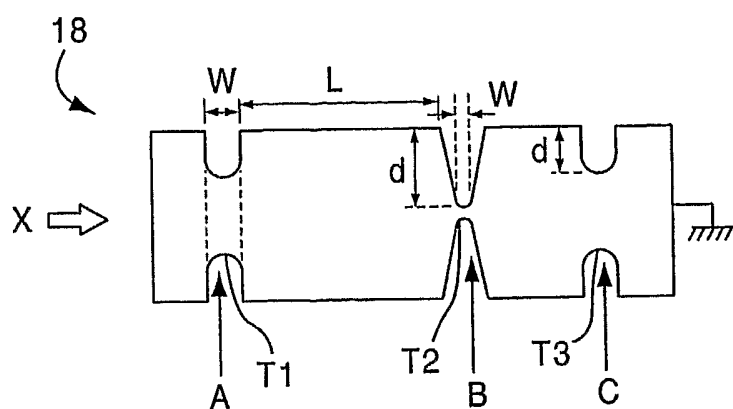


FIG. 3

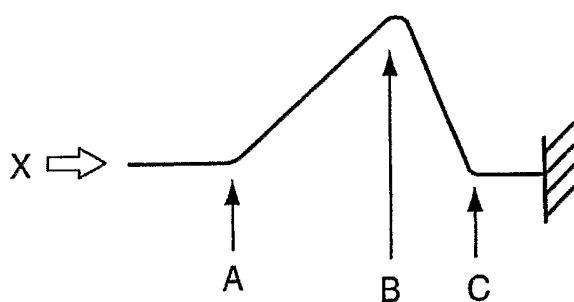


FIG. 4

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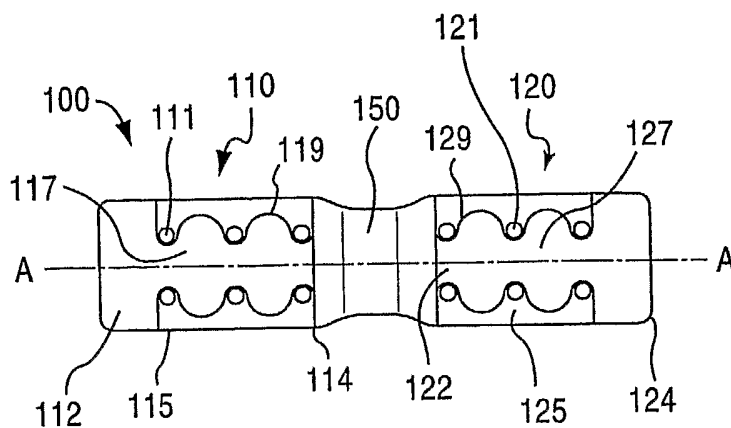


FIG. 5

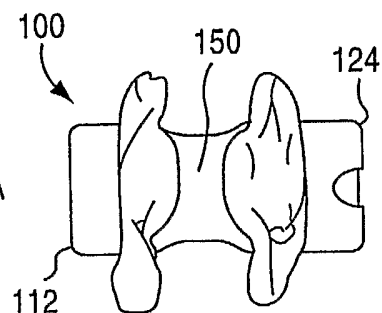


FIG. 6

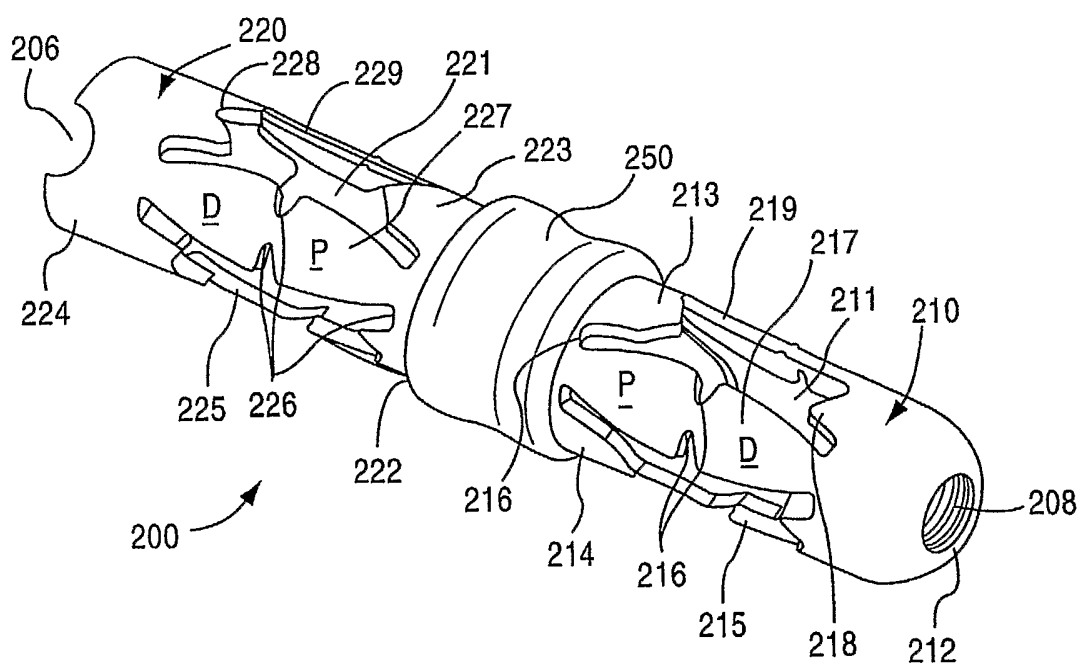


FIG. 7

SUBSTITUTE SHEET (RULE 26)

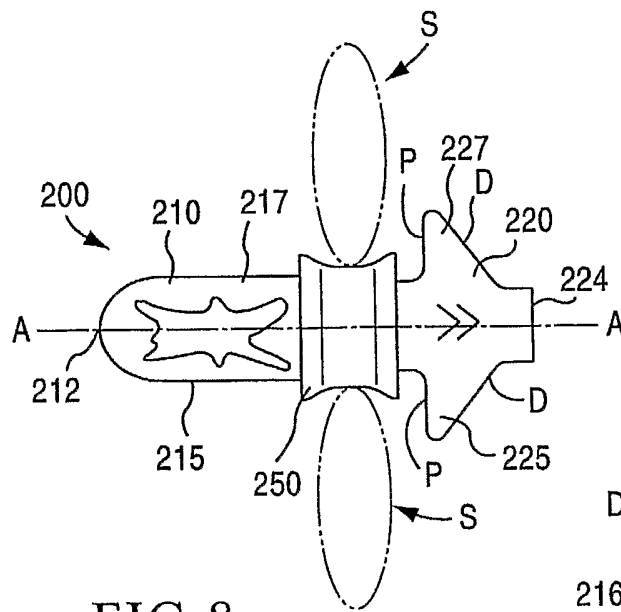


FIG. 8

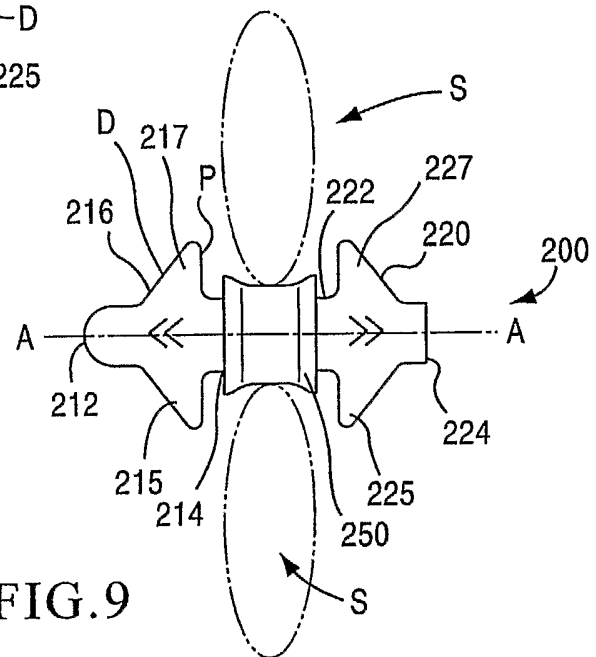


FIG. 9

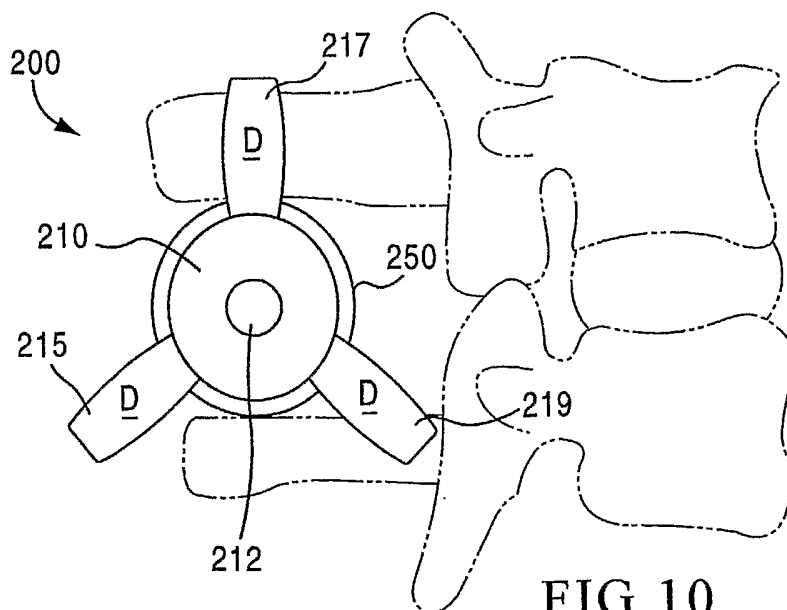


FIG. 10

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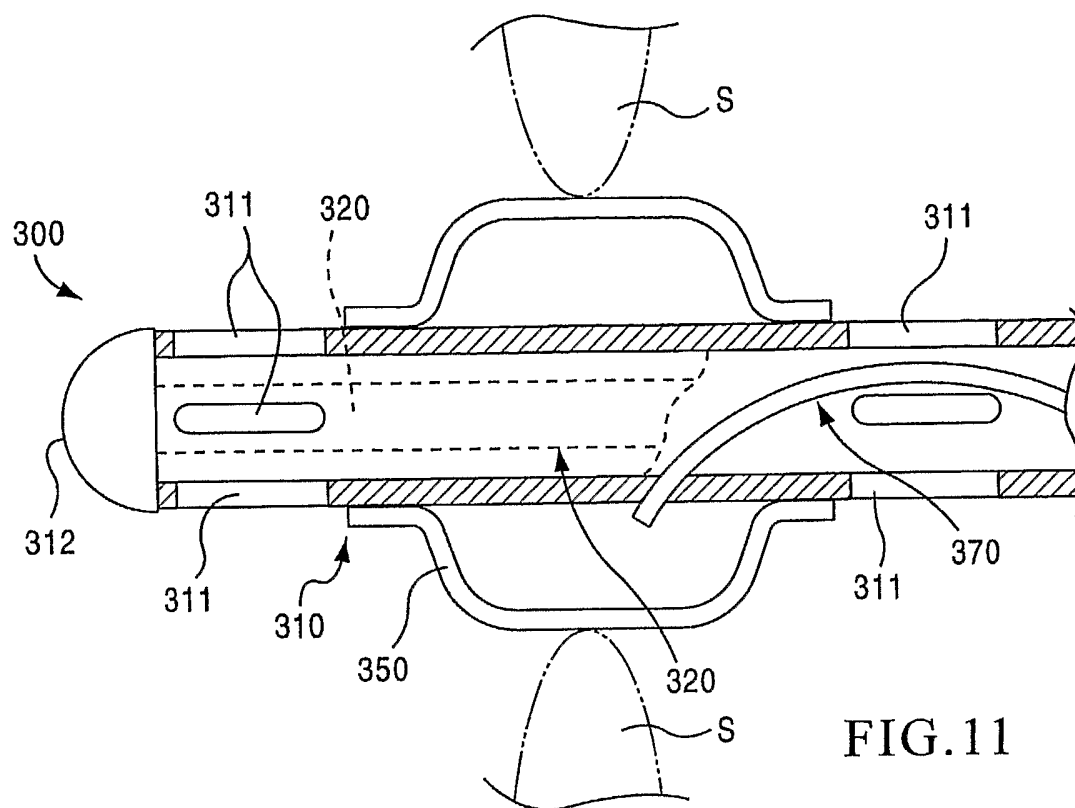


FIG. 11

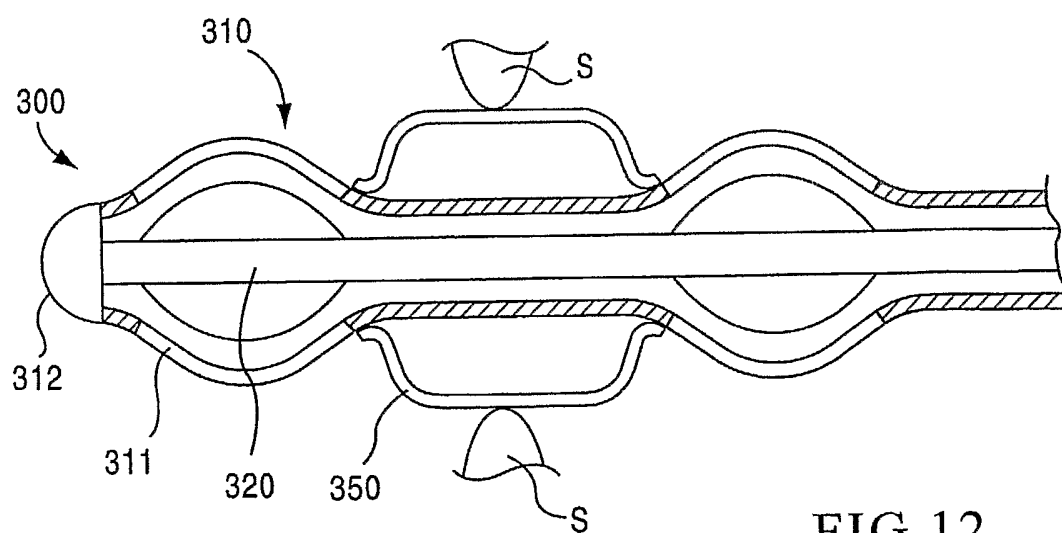


FIG. 12

FIG.13

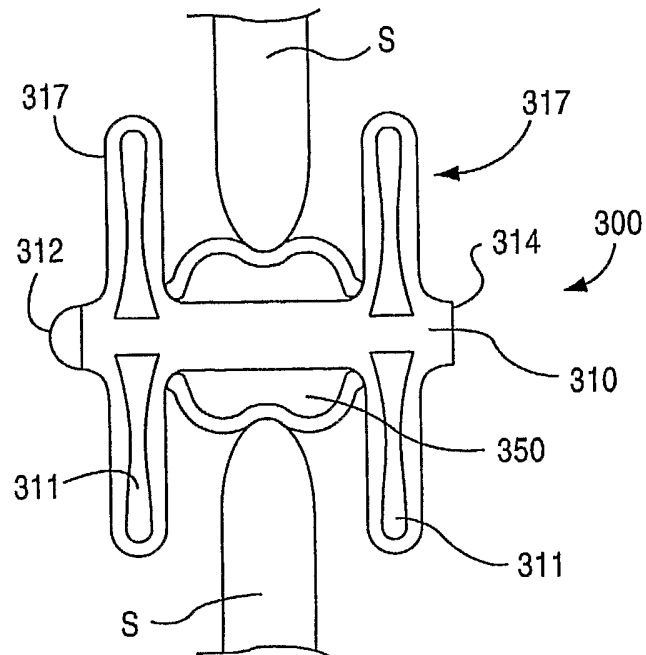
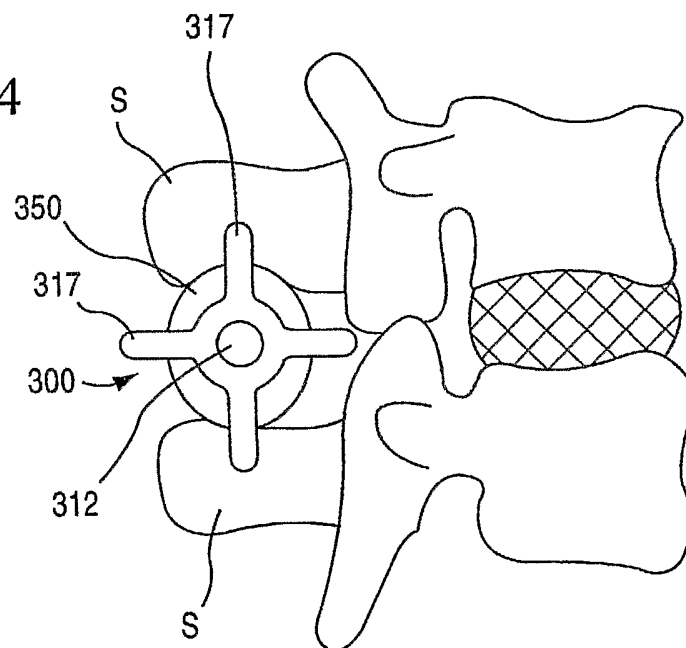
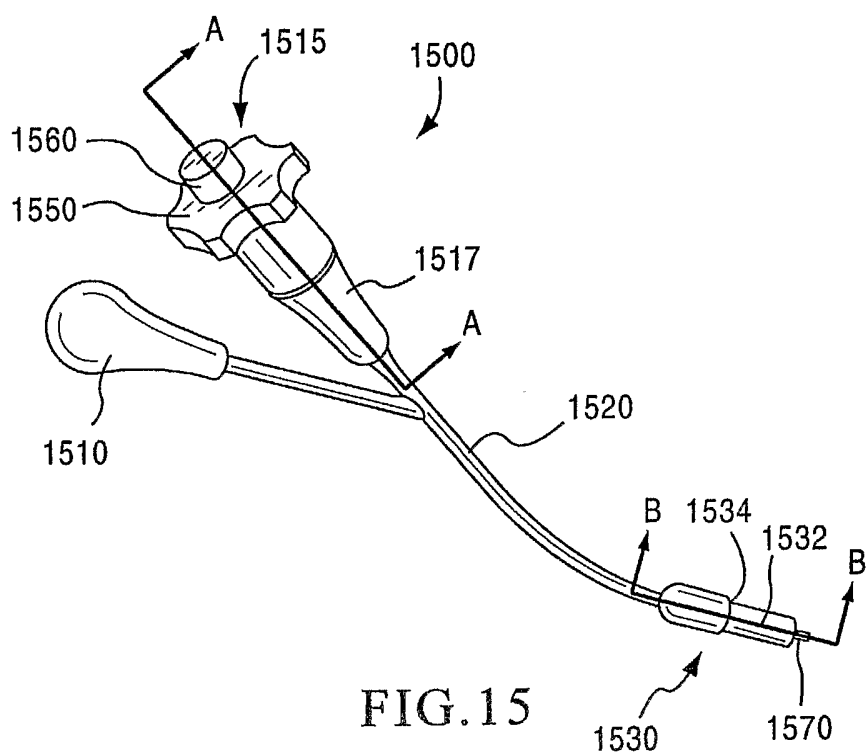


FIG.14



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SUBSTITUTE SHEET (RULE 26)

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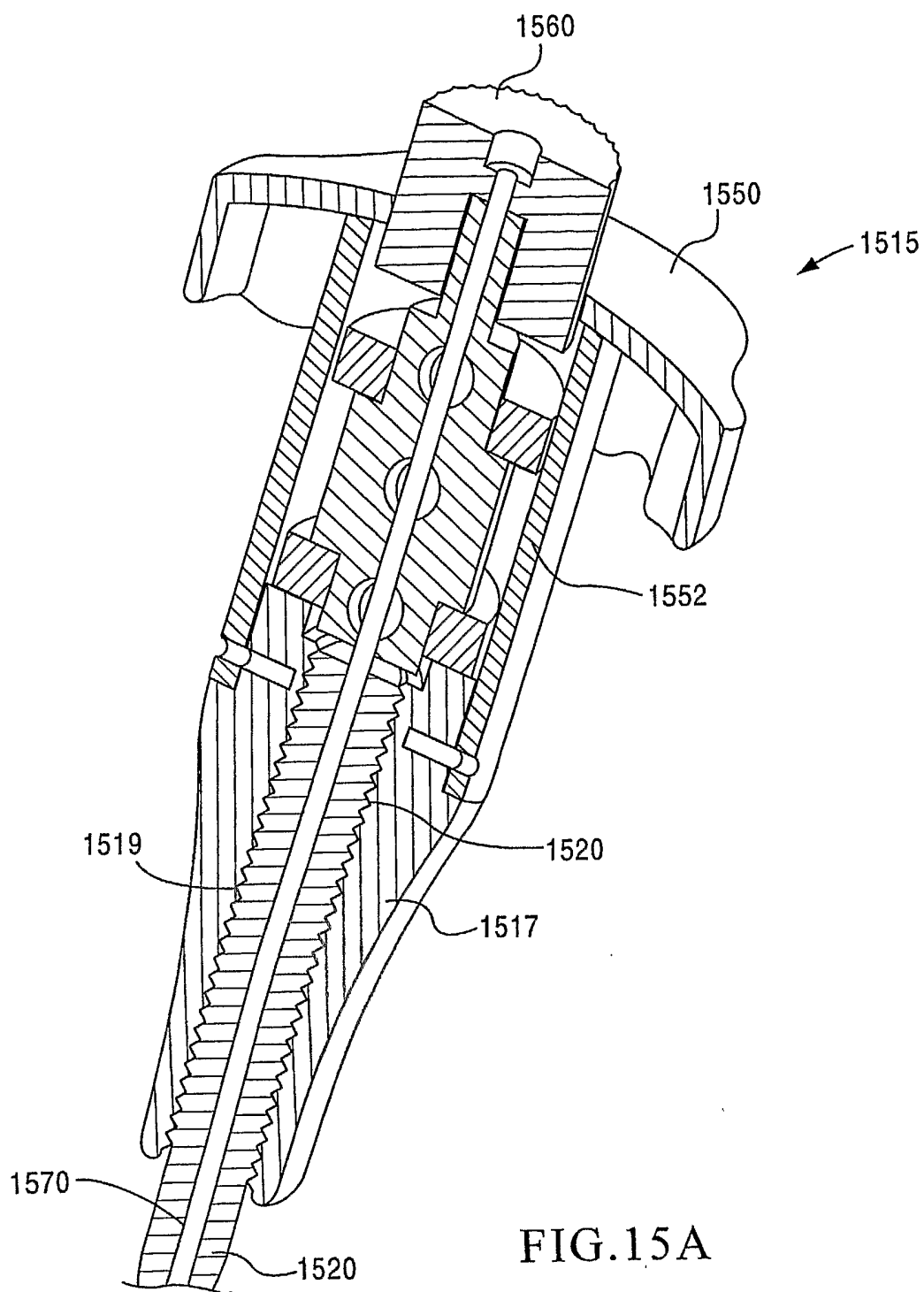


FIG. 15A

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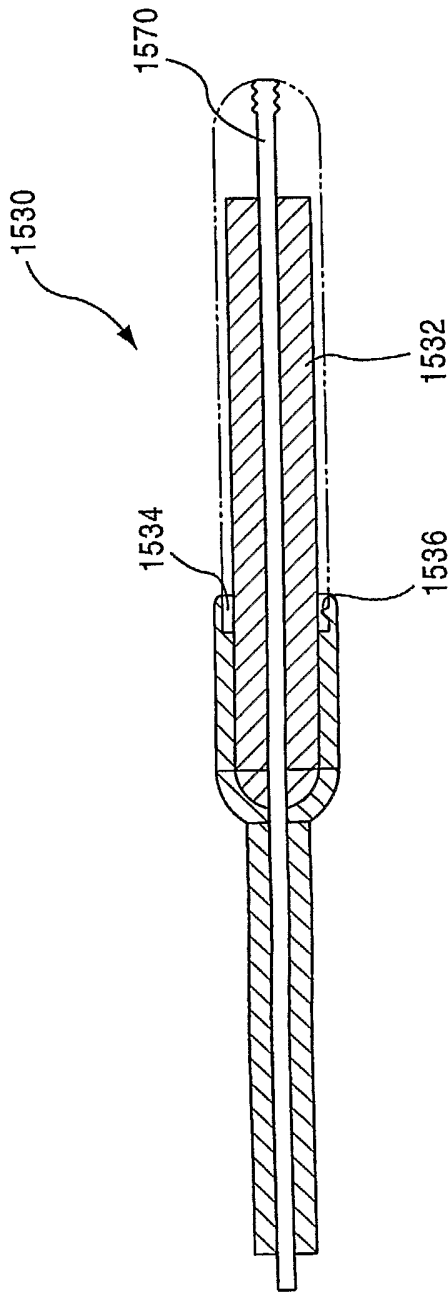


FIG. 15B

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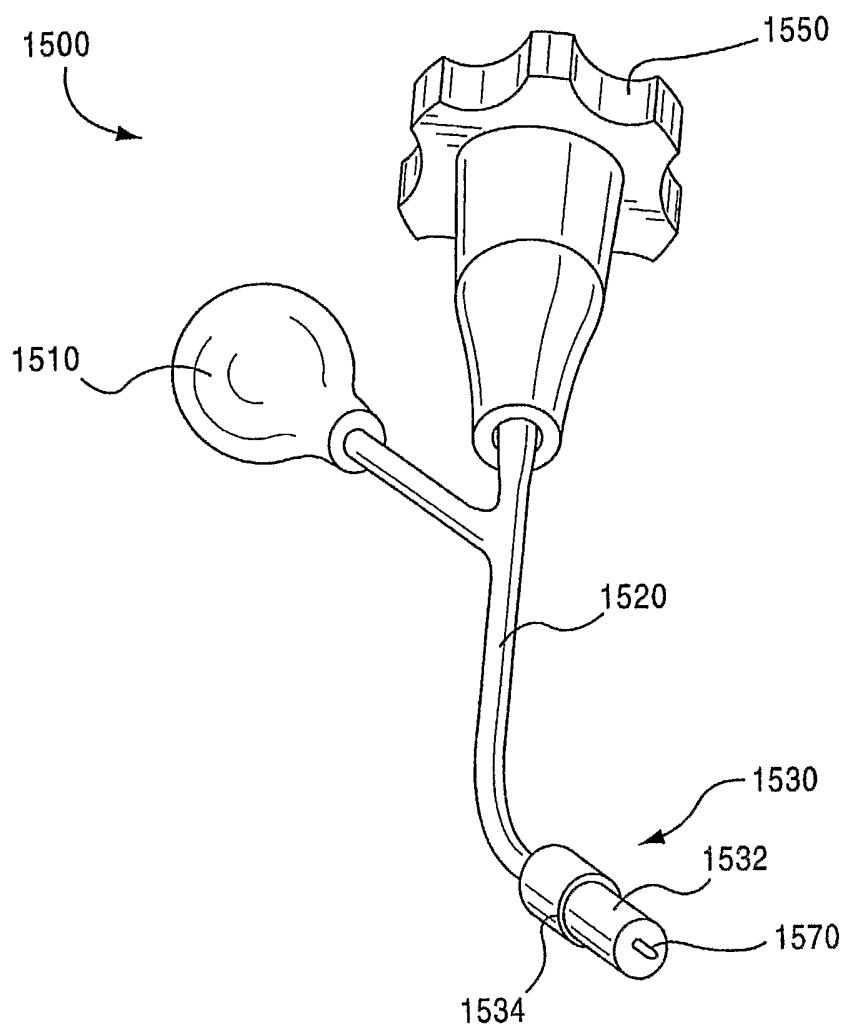


FIG.16

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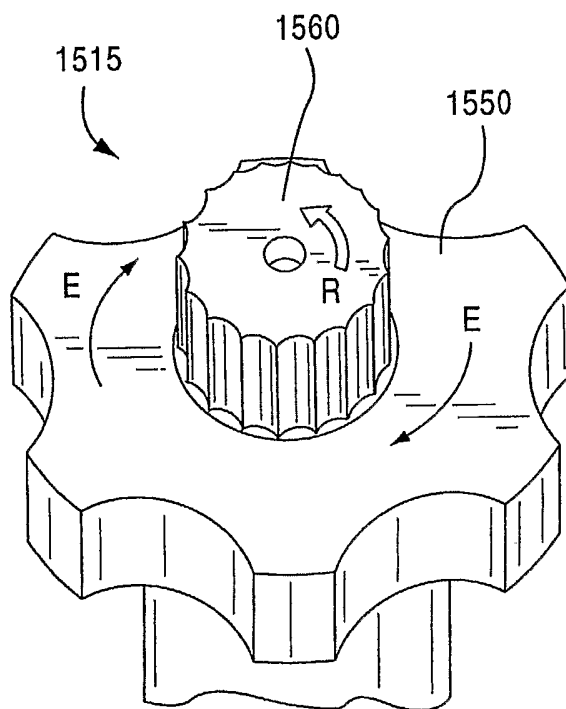


FIG.17

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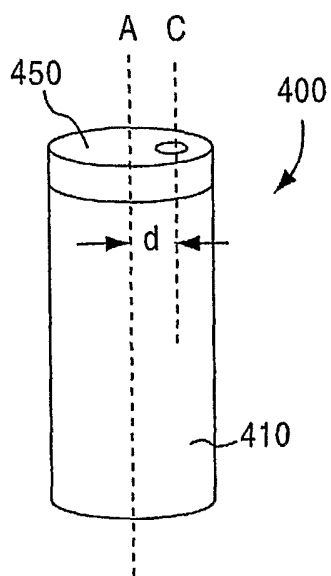


FIG. 18

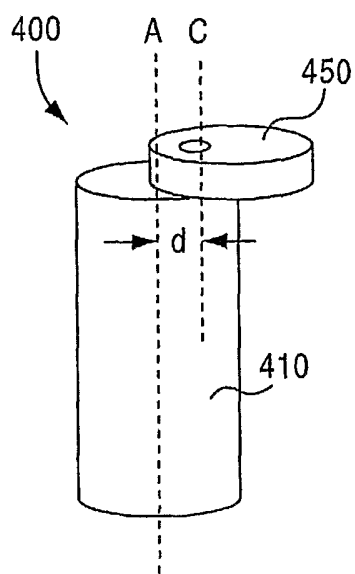


FIG. 19

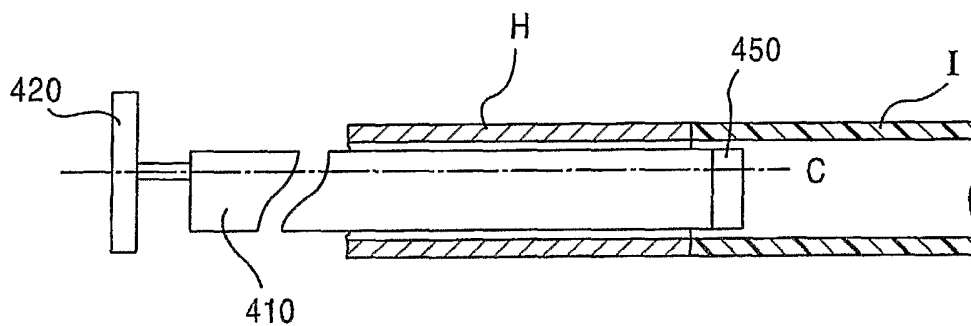


FIG. 20

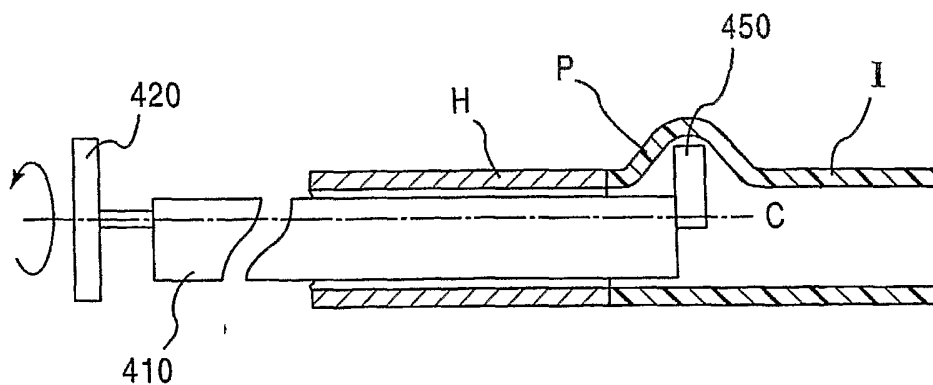


FIG. 21

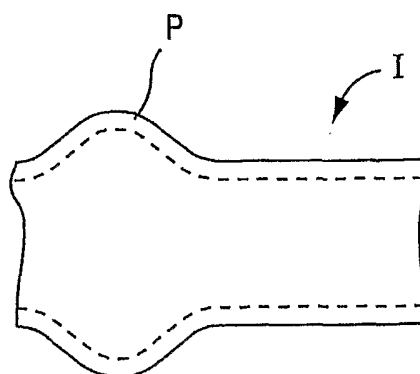


FIG. 22

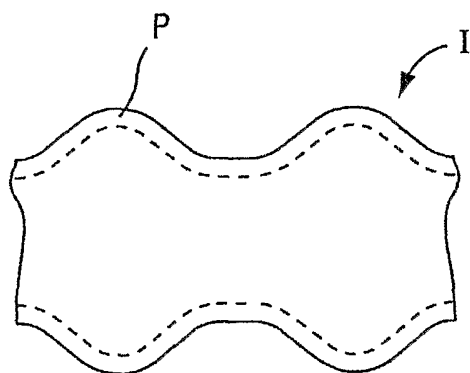


FIG. 23

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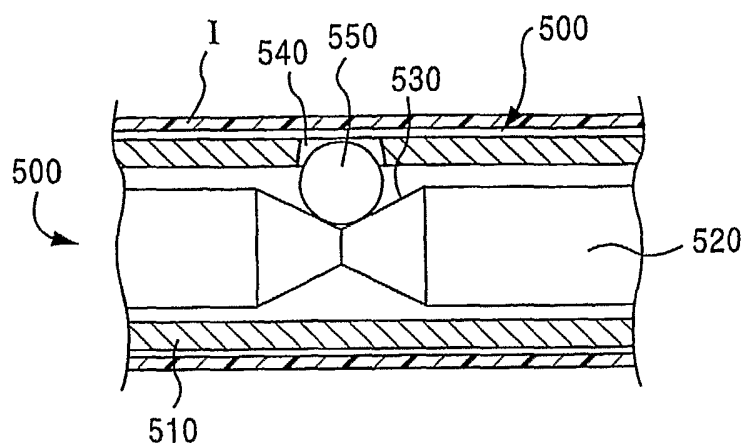


FIG. 24

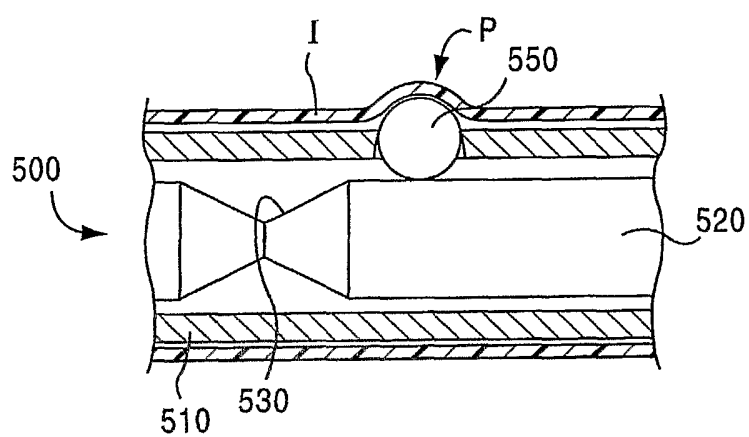


FIG. 25

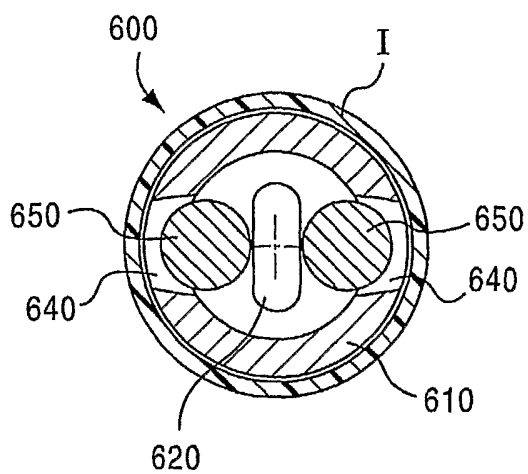


FIG. 26

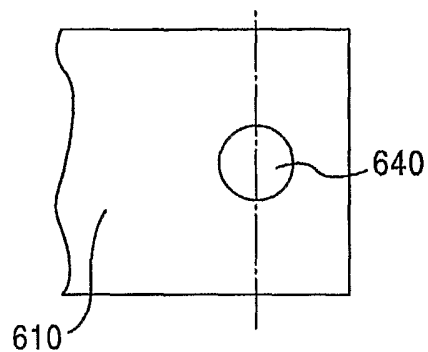


FIG. 27

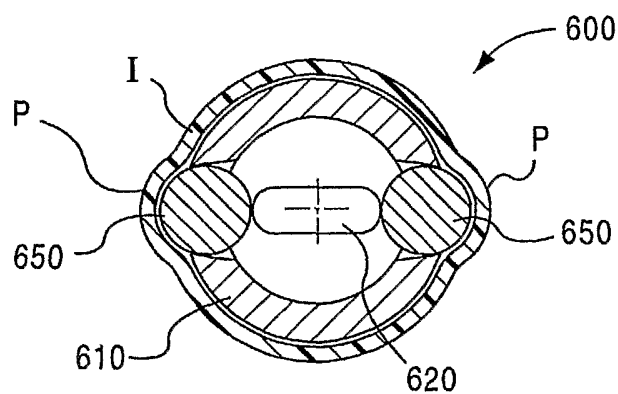
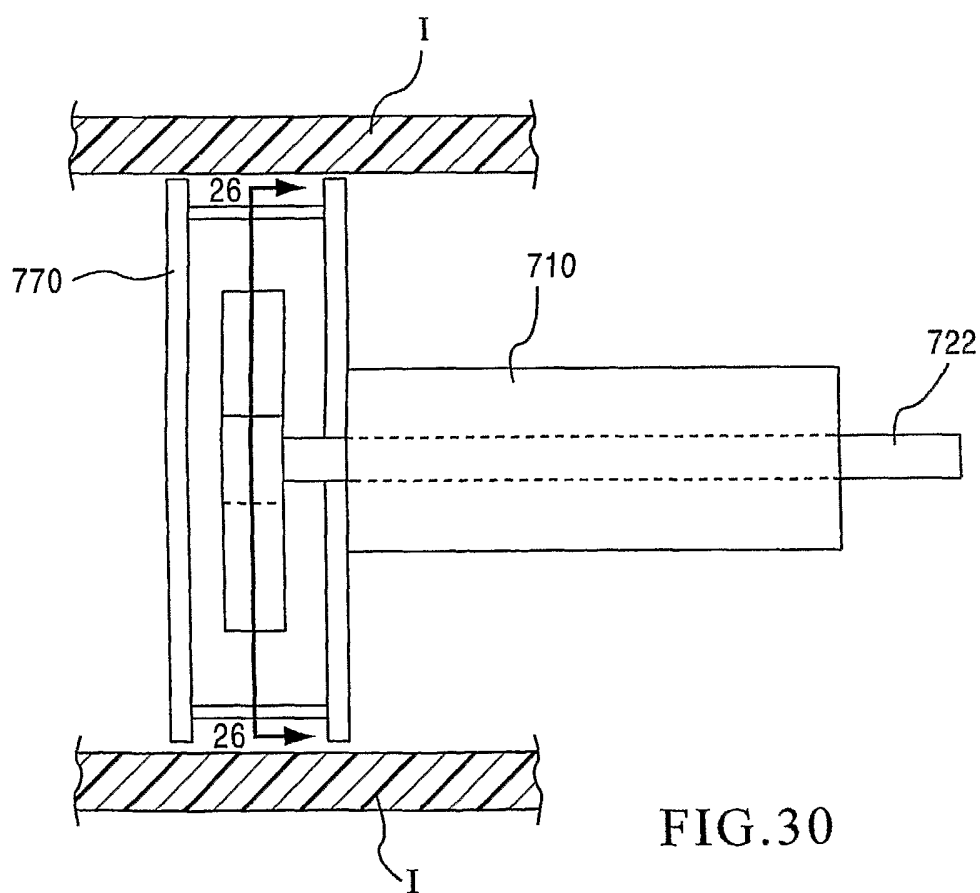
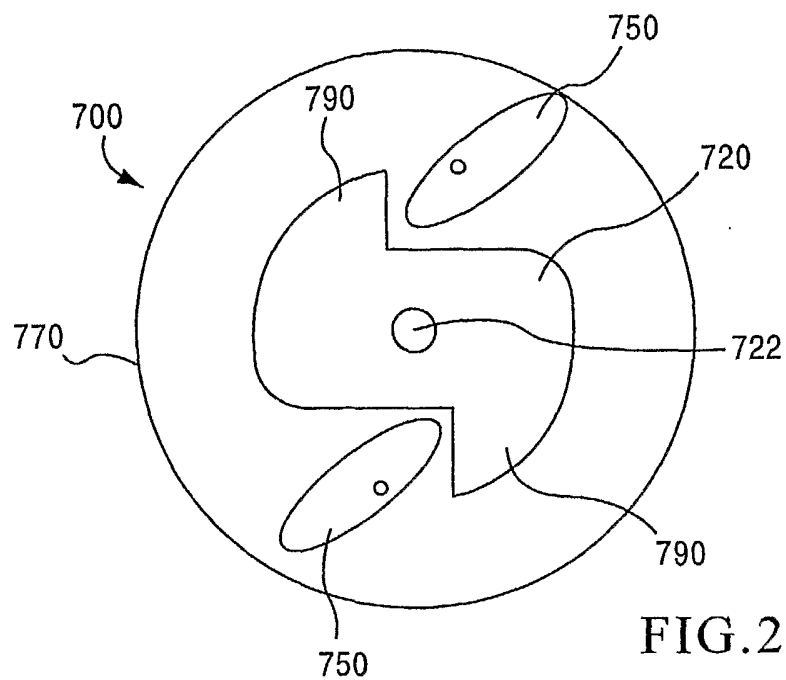


FIG. 28



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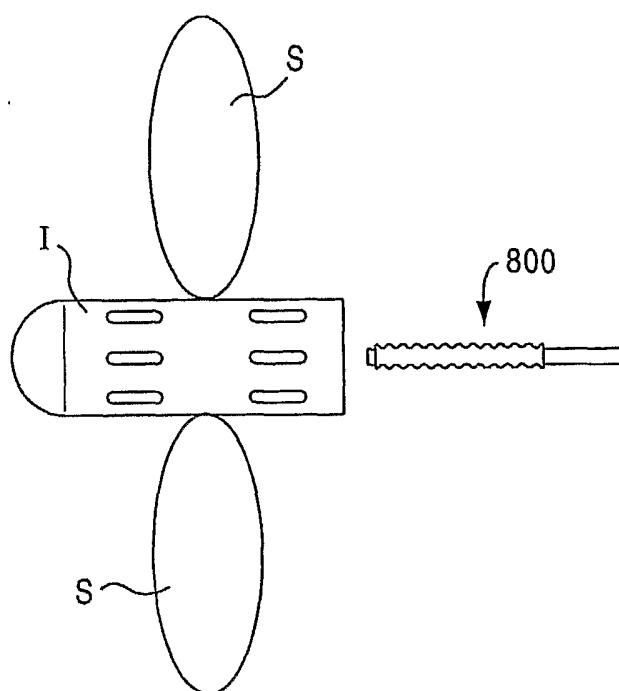


FIG. 31

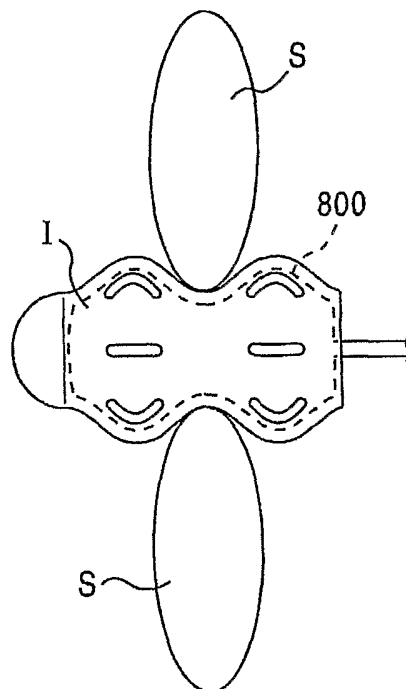


FIG. 32

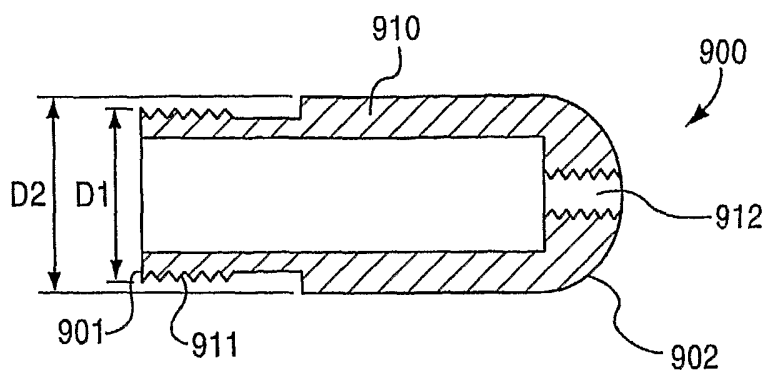


FIG. 33

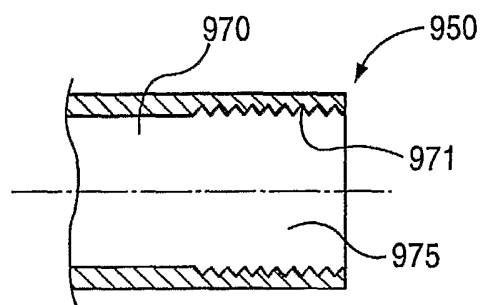


FIG. 34

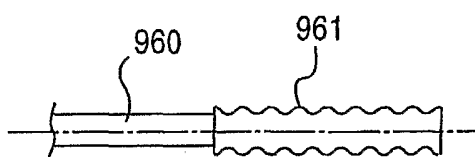


FIG. 35

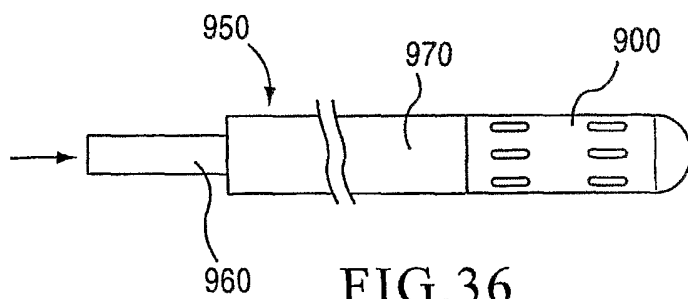


FIG. 36

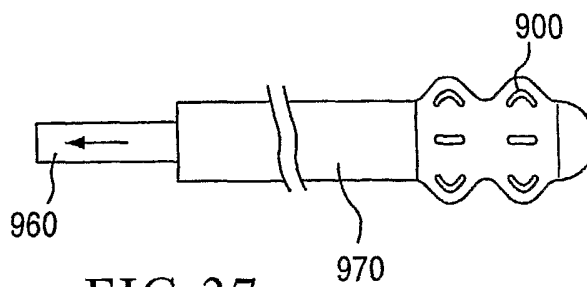


FIG. 37

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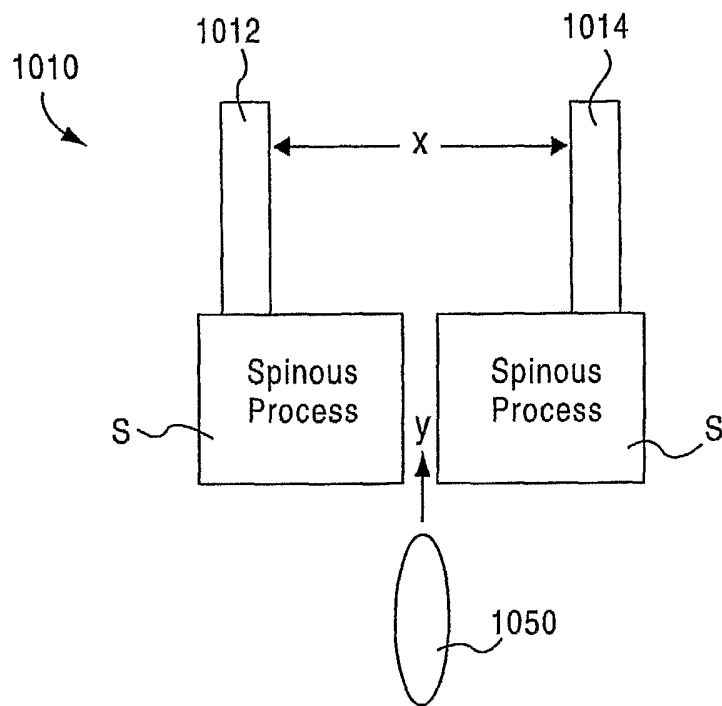


FIG.38

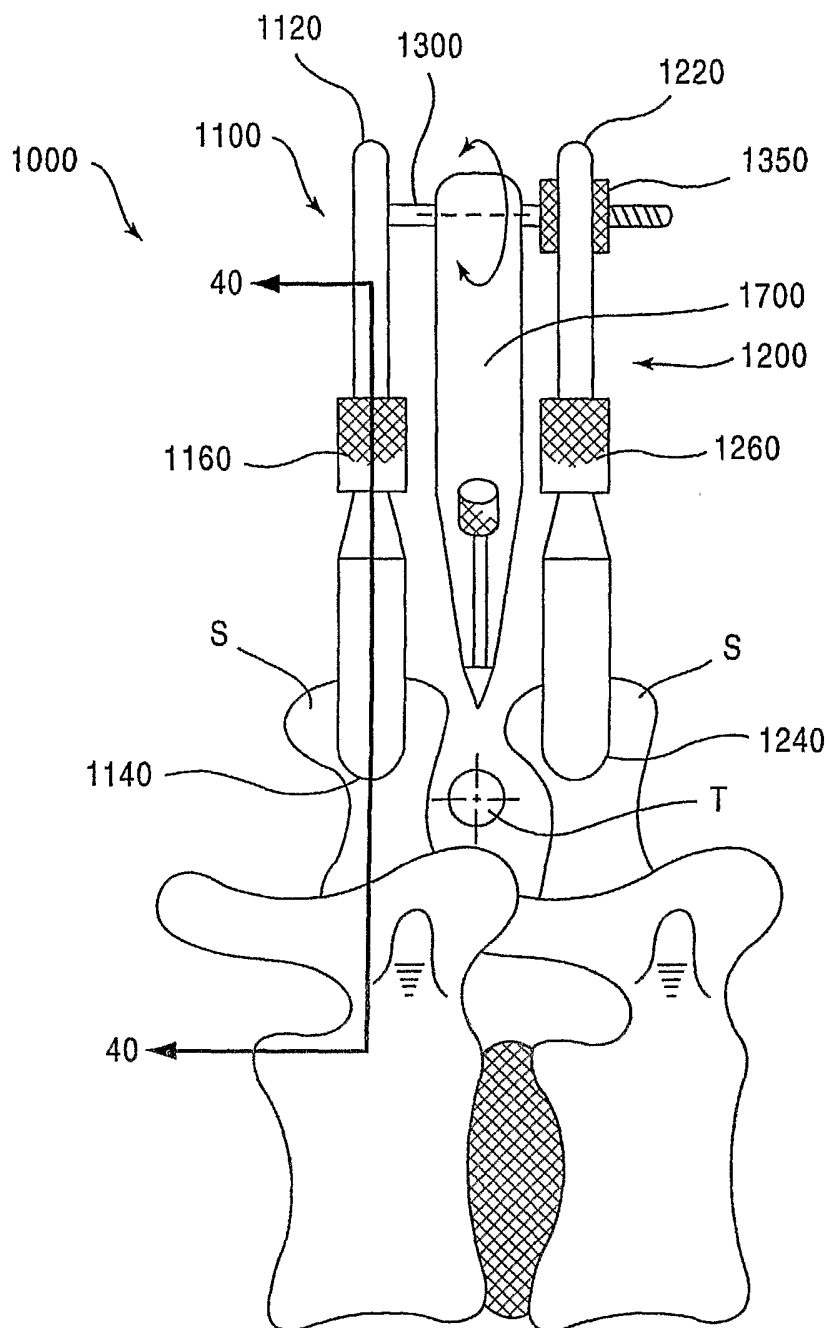


FIG.39

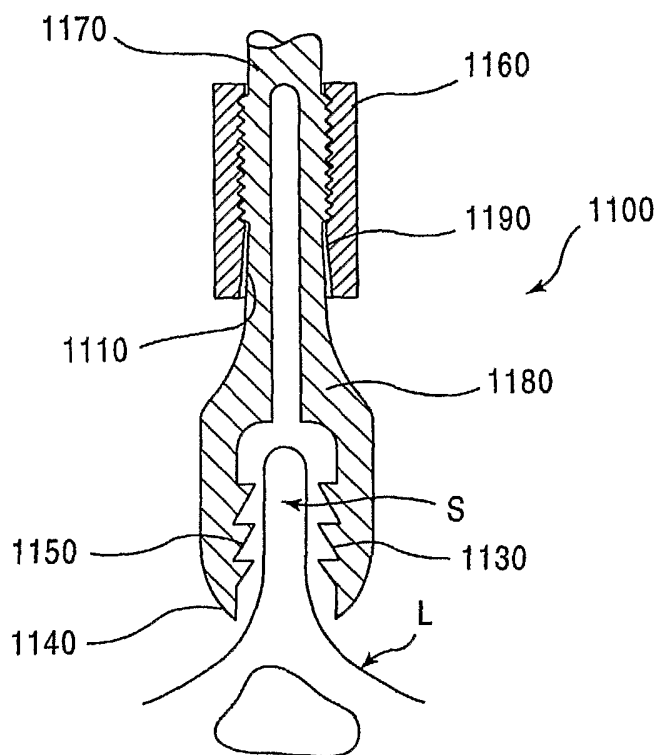


FIG. 40

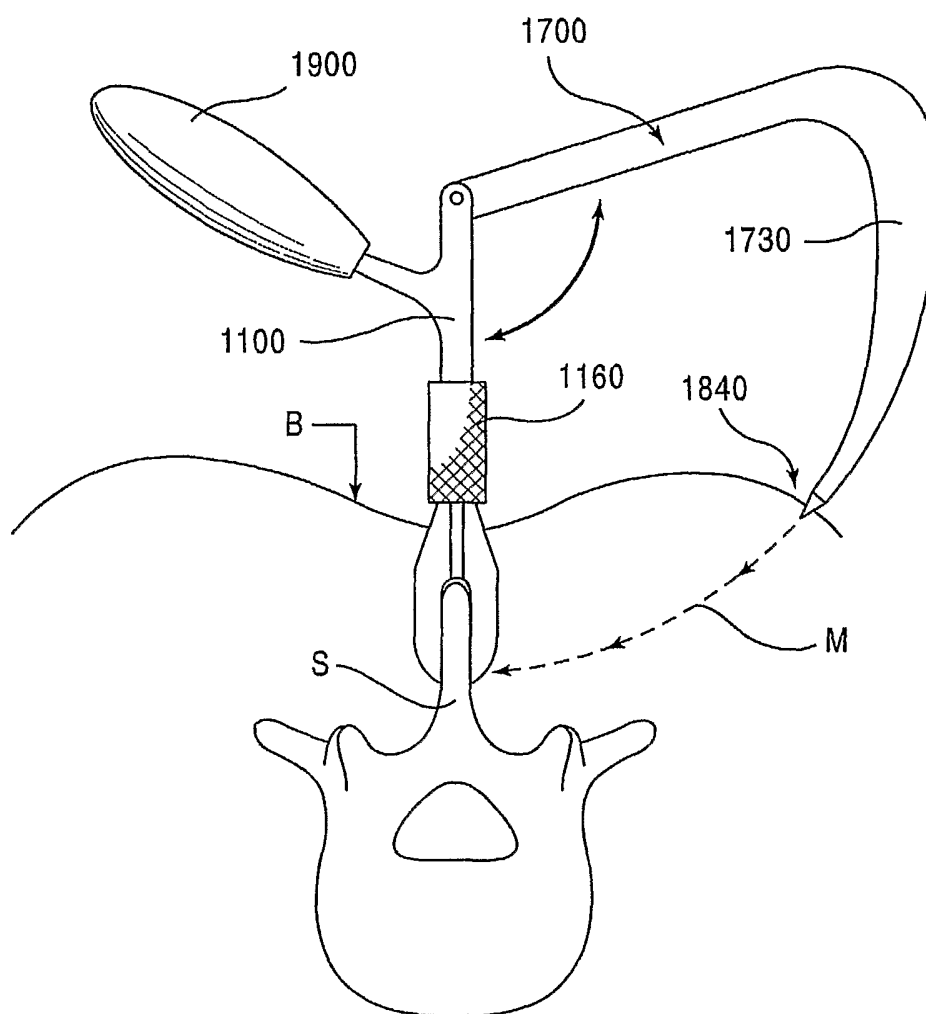


FIG. 41

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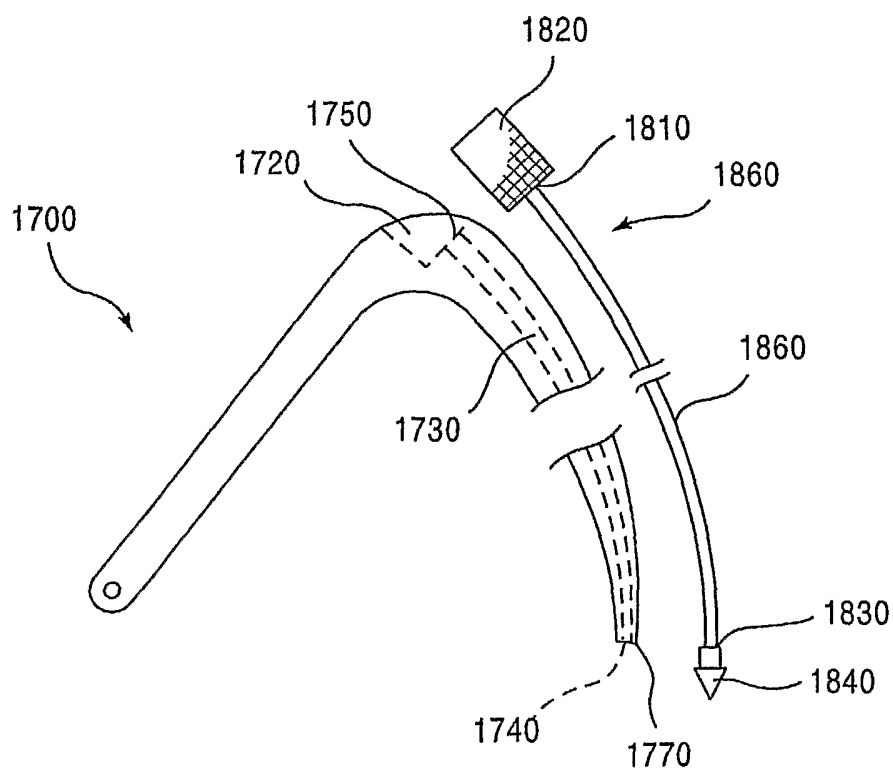


FIG. 42

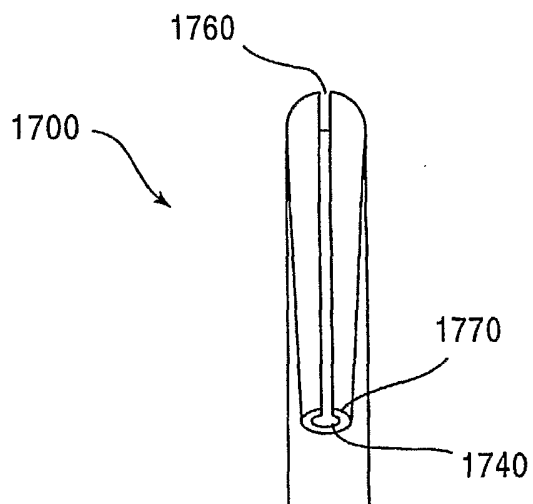


FIG. 43

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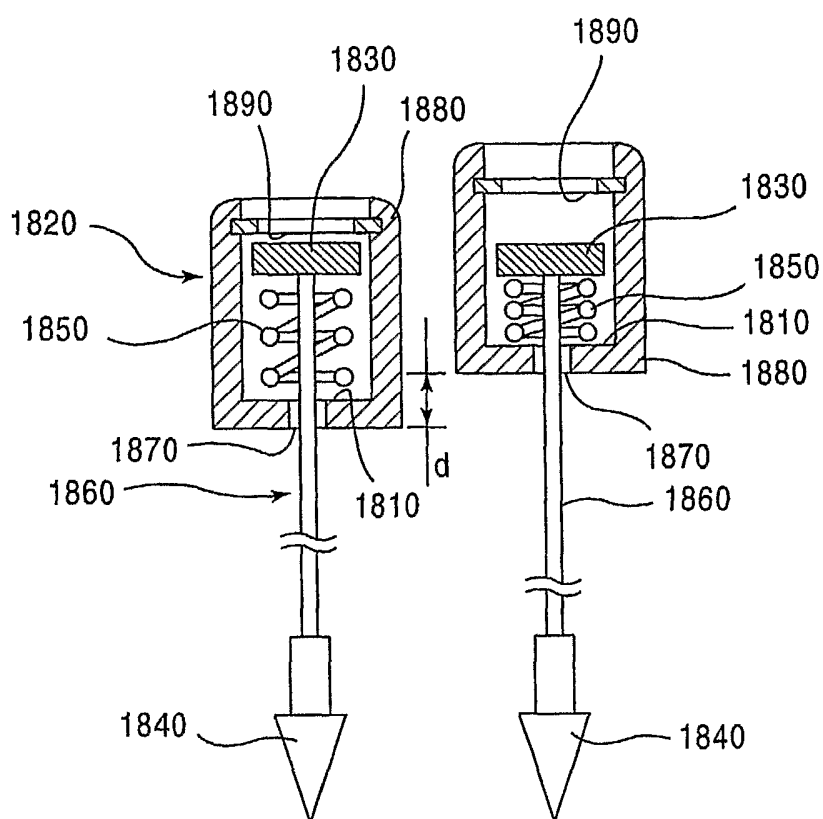


FIG. 44

FIG. 45

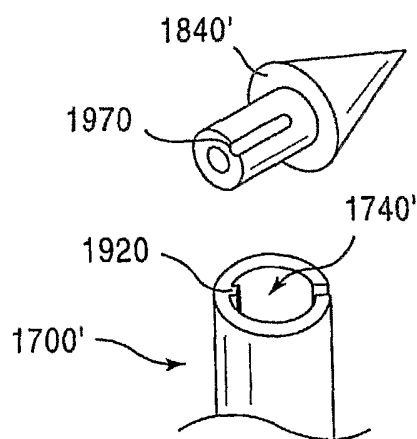


FIG. 46

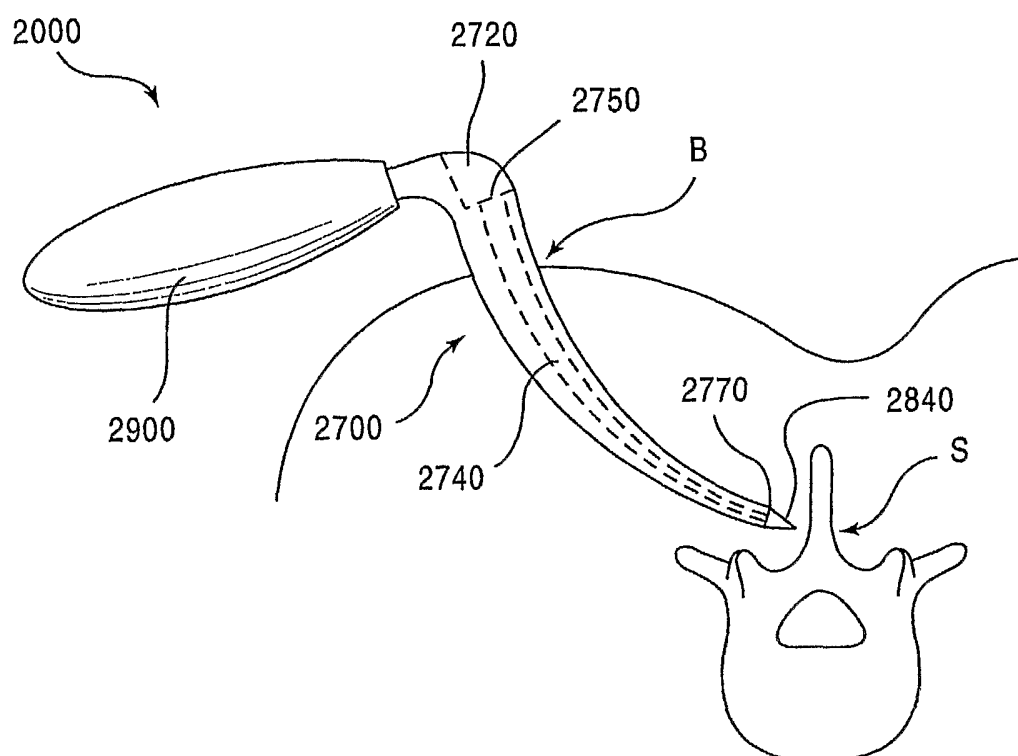


FIG.47

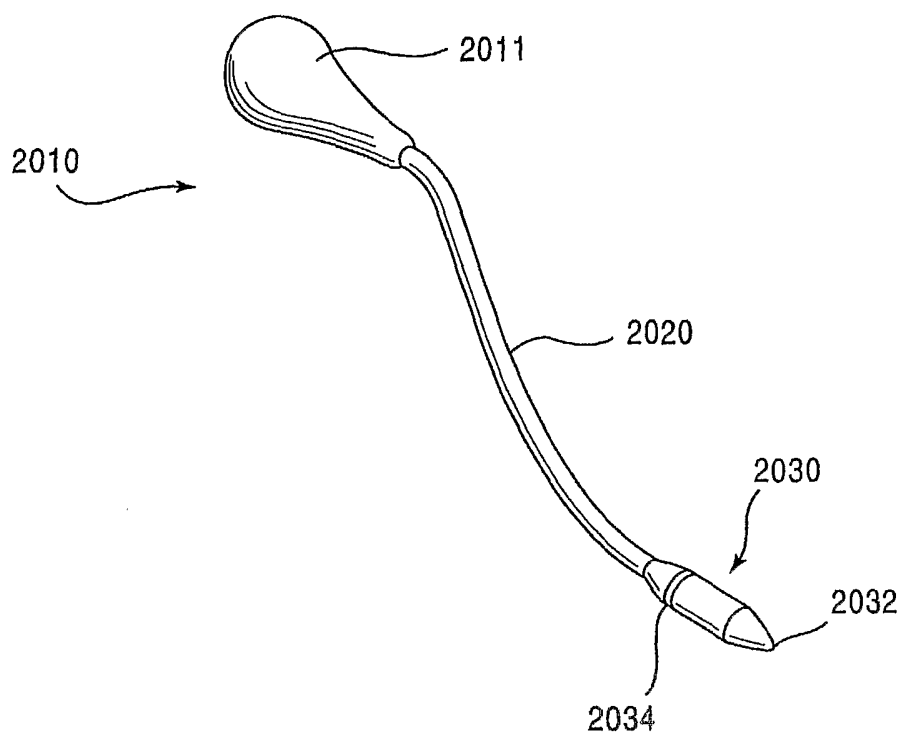


FIG. 48

FIG.49A

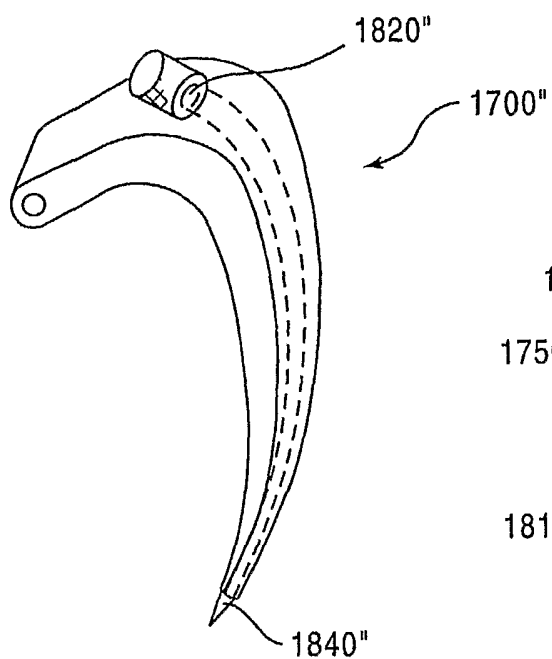


FIG.49B

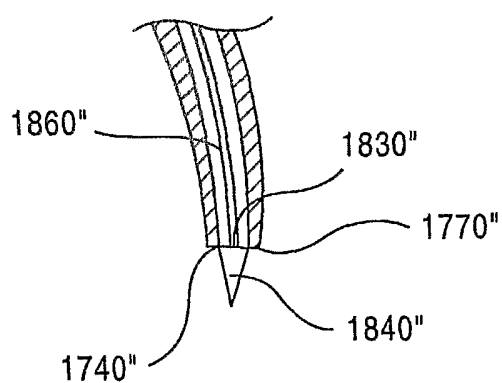
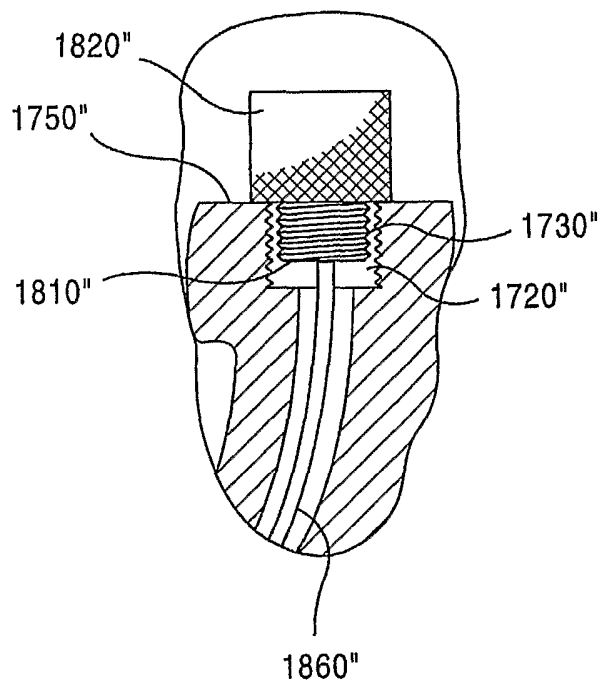
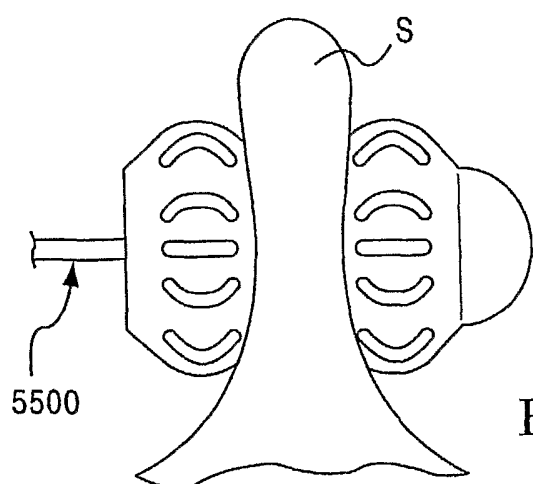
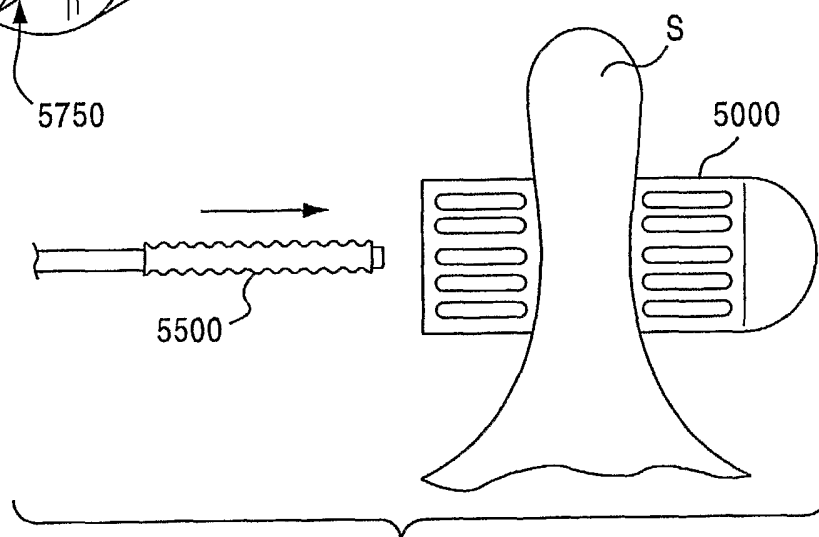
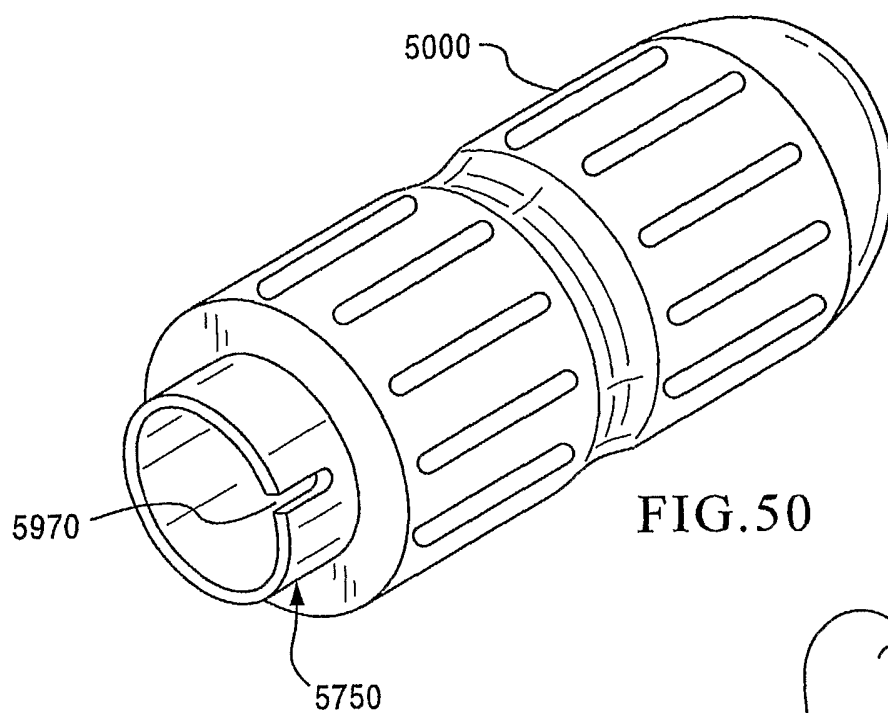


FIG.49C



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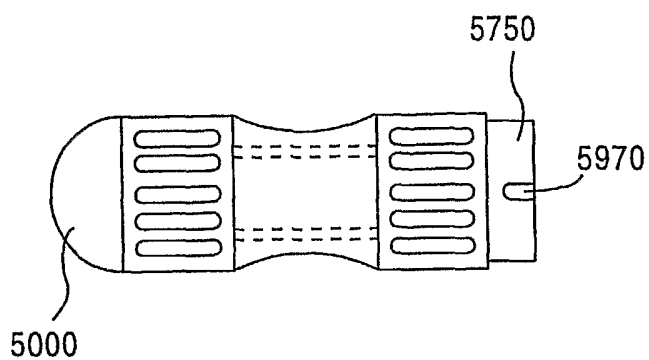


FIG. 53

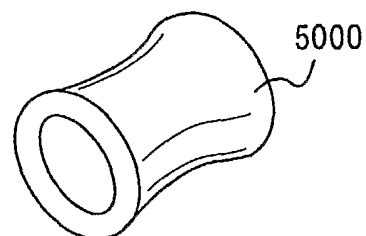


FIG. 54

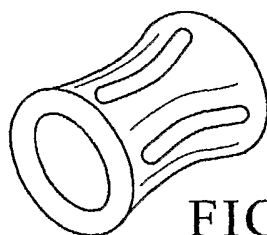


FIG. 55

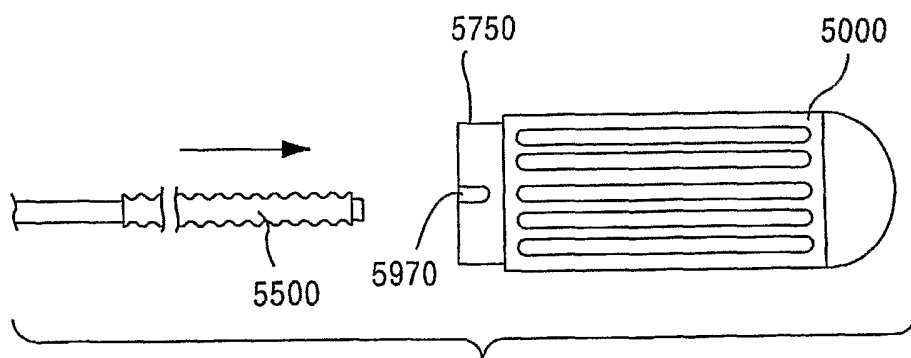


FIG. 56

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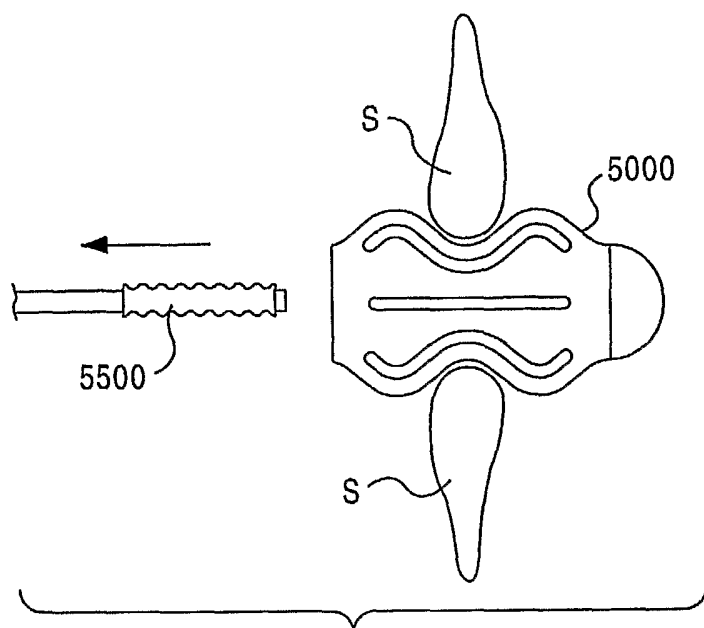


FIG. 57

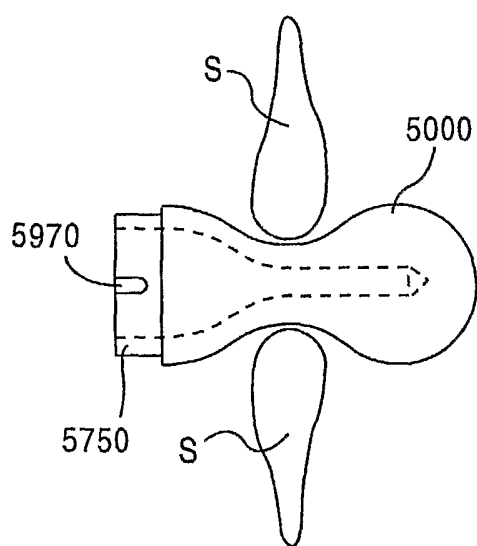


FIG. 58

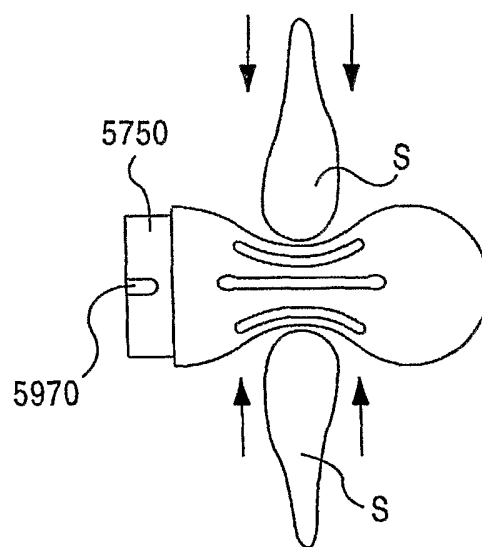


FIG. 59

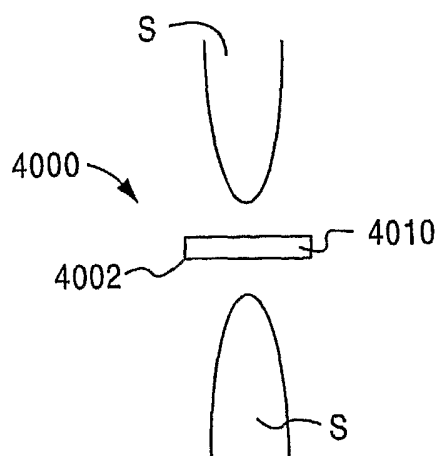


FIG. 60A

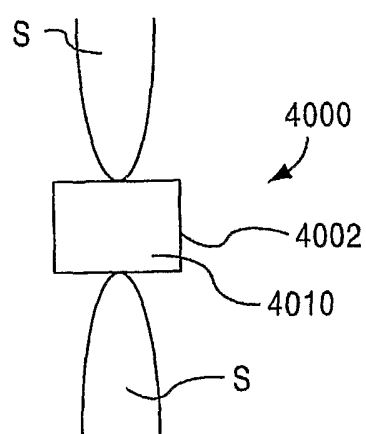


FIG. 60B

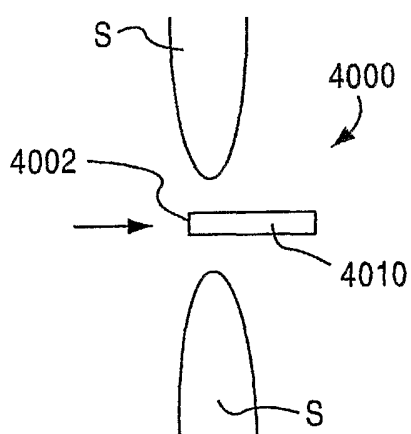


FIG. 60C

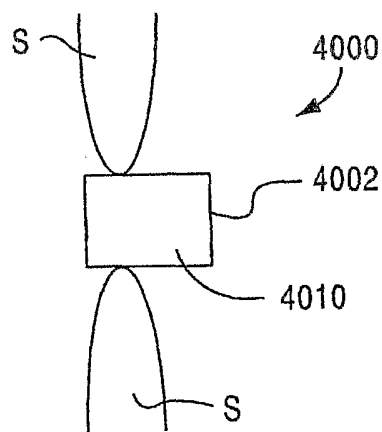


FIG. 60D

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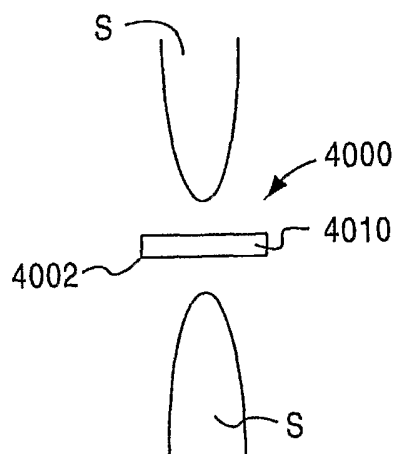


FIG. 61A

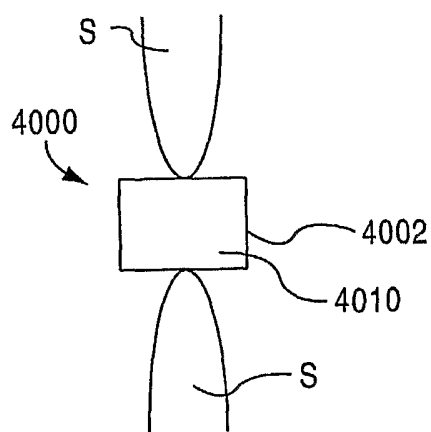


FIG. 61B

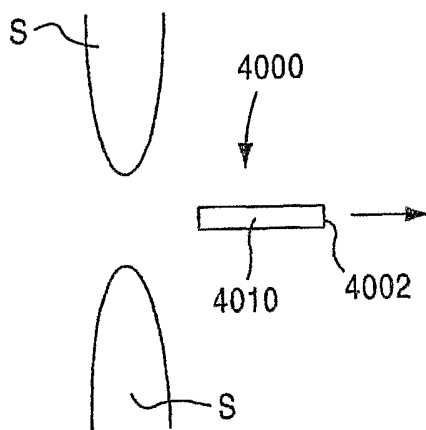


FIG. 61C

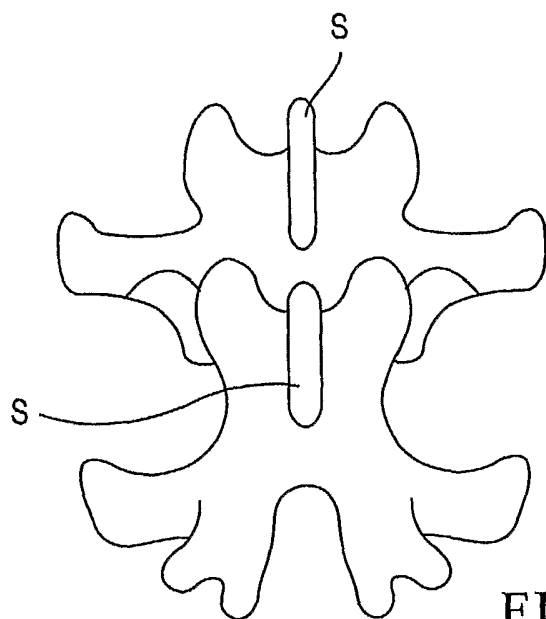


FIG. 62A

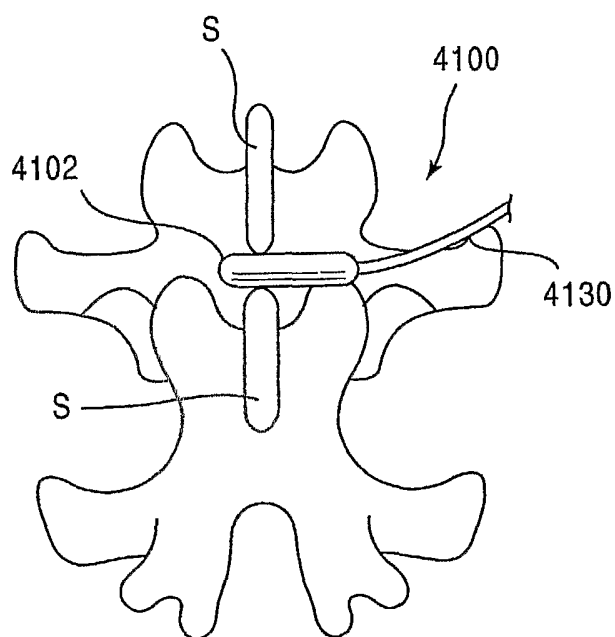
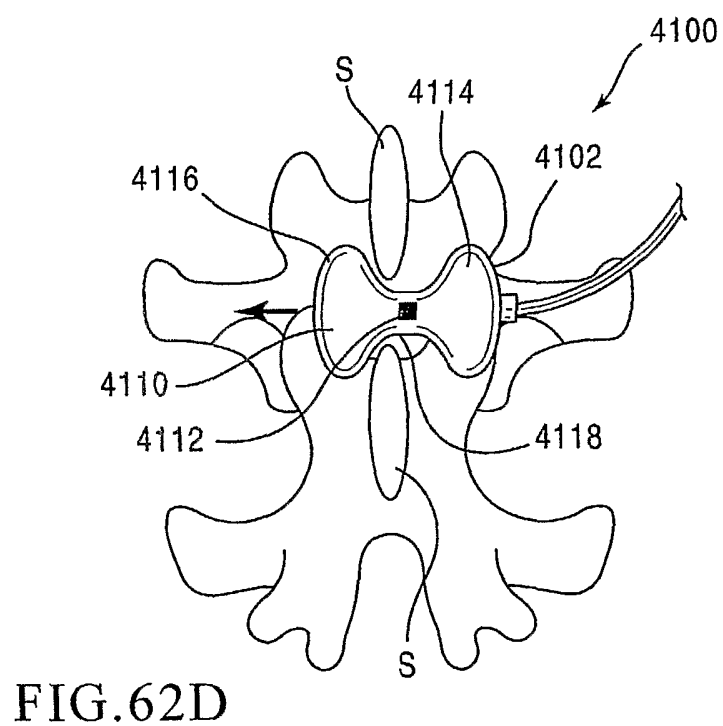
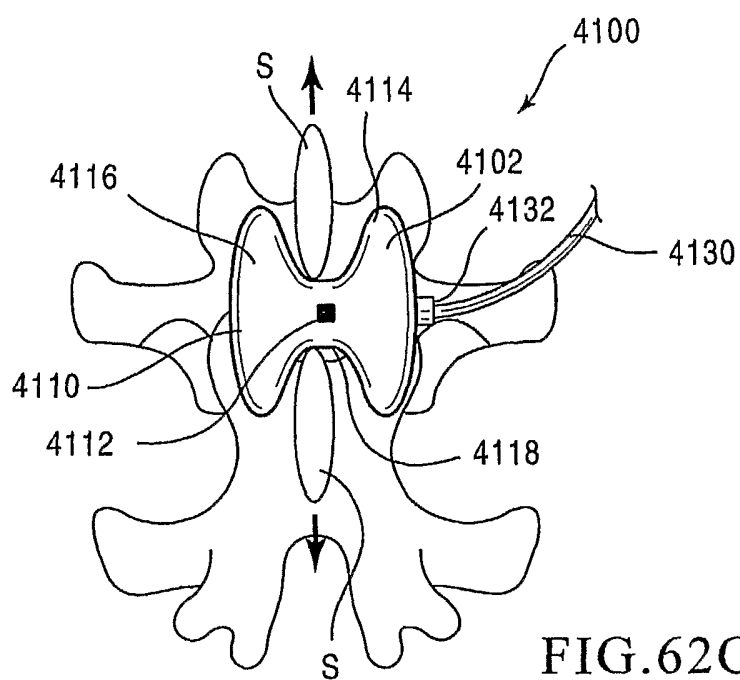


FIG. 62B

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SUBSTITUTE SHEET (RULE 26)

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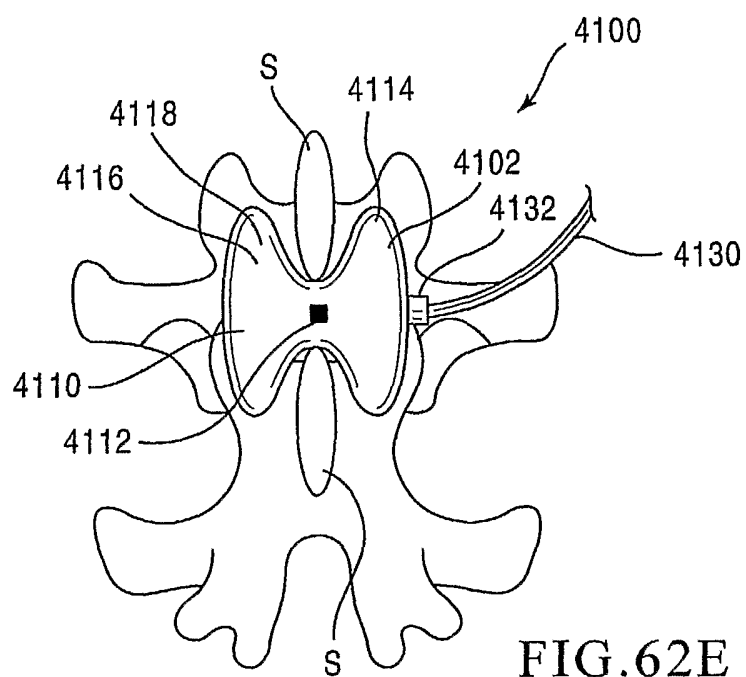


FIG. 62E

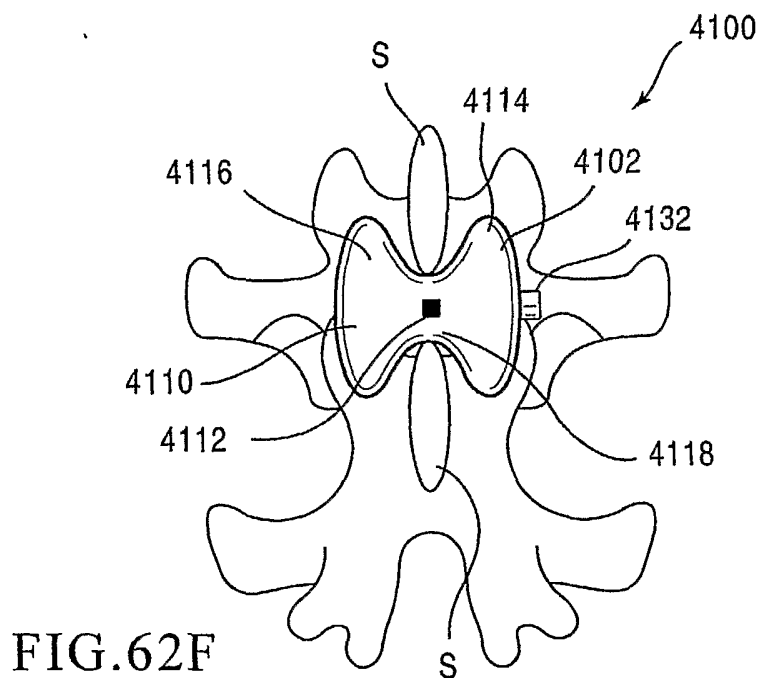


FIG. 62F

SUBSTITUTE SHEET (RULE 26)

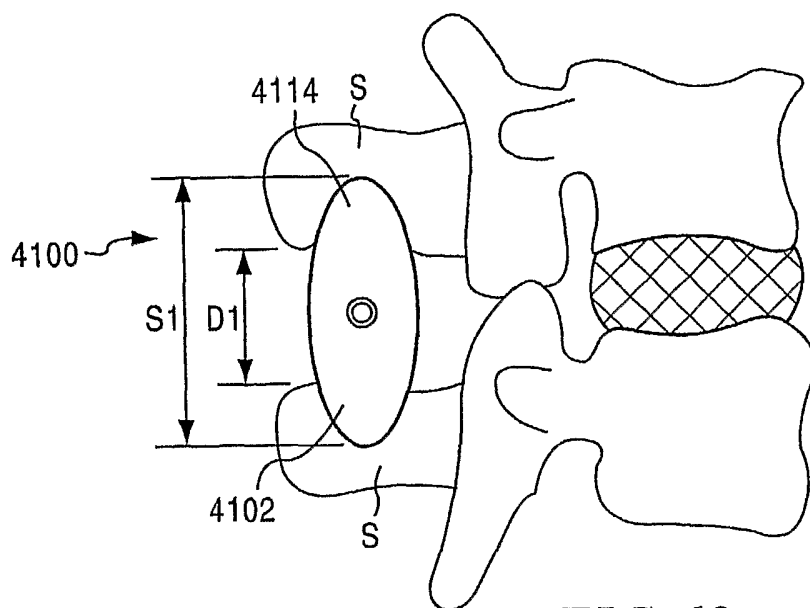


FIG. 63

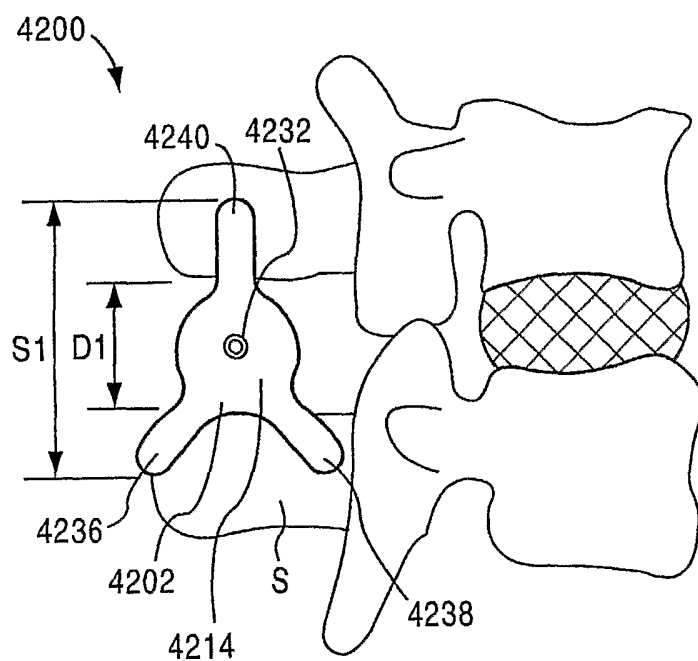


FIG. 64

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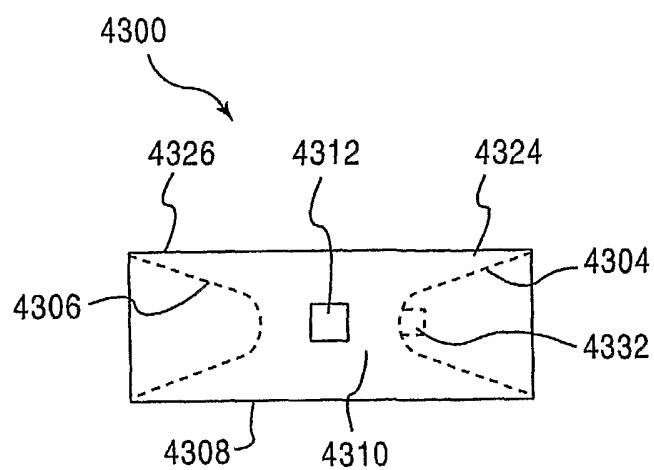


FIG. 65A

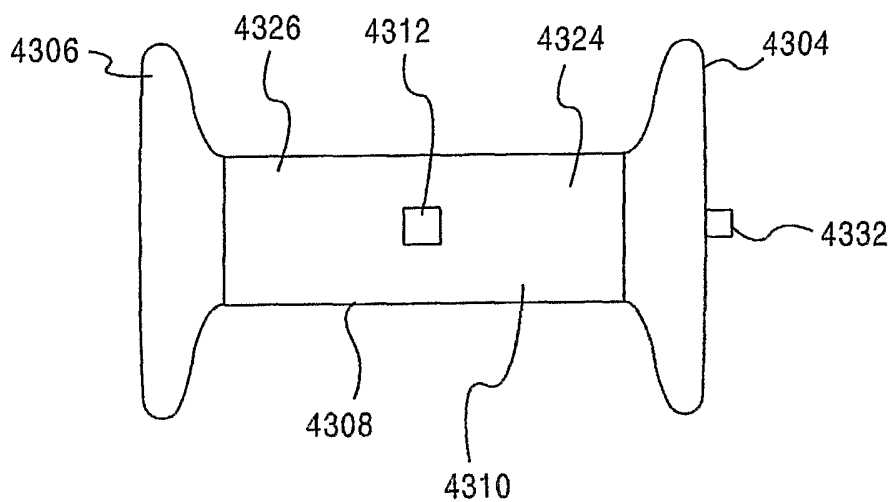


FIG. 65B

SUBSTITUTE SHEET (RULE 26)

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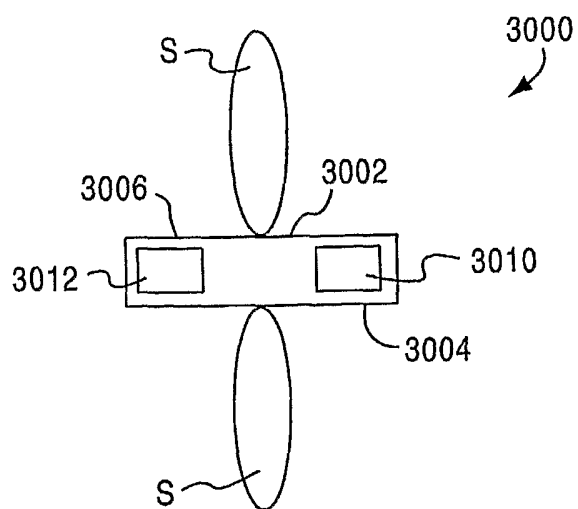


FIG. 66A

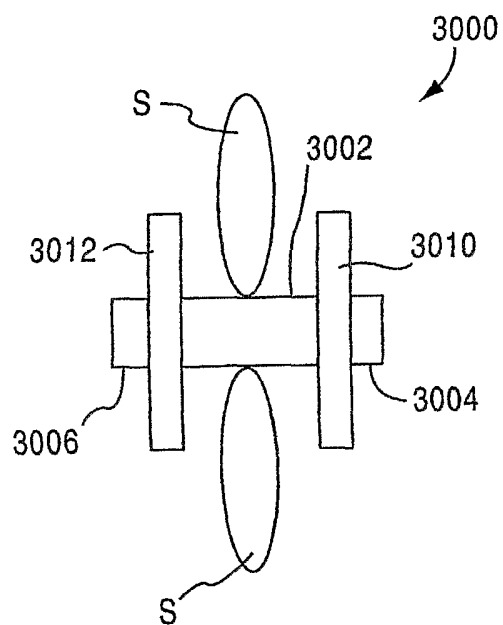
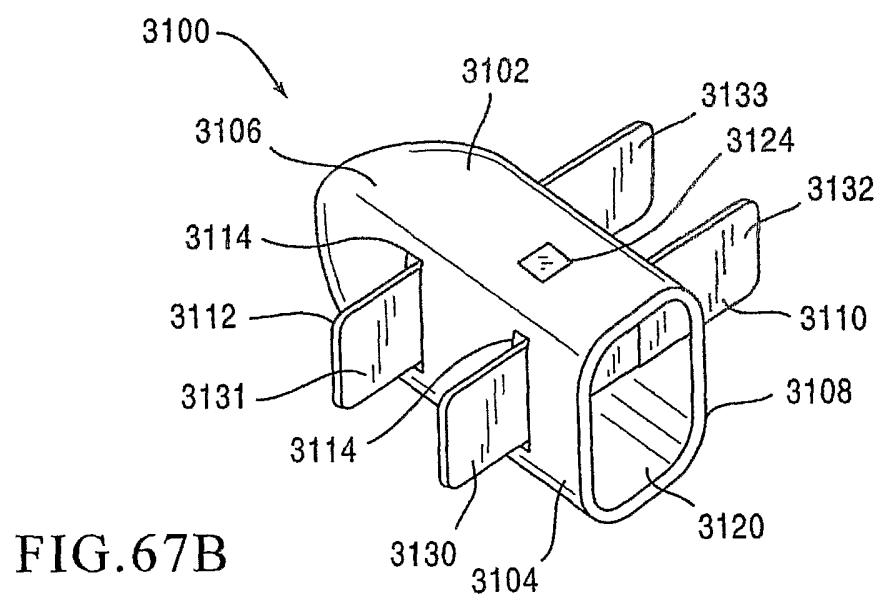
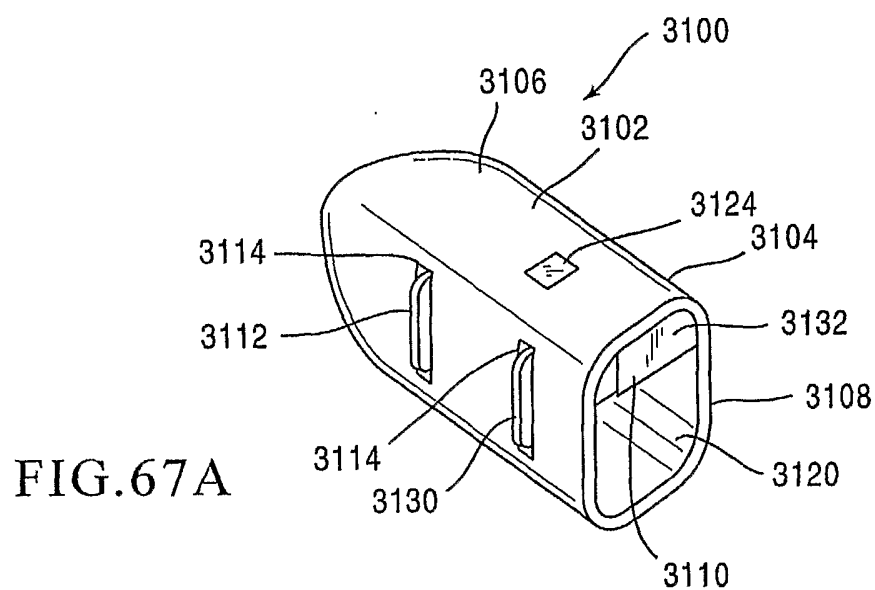


FIG. 66B

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SUBSTITUTE SHEET (RULE 26)

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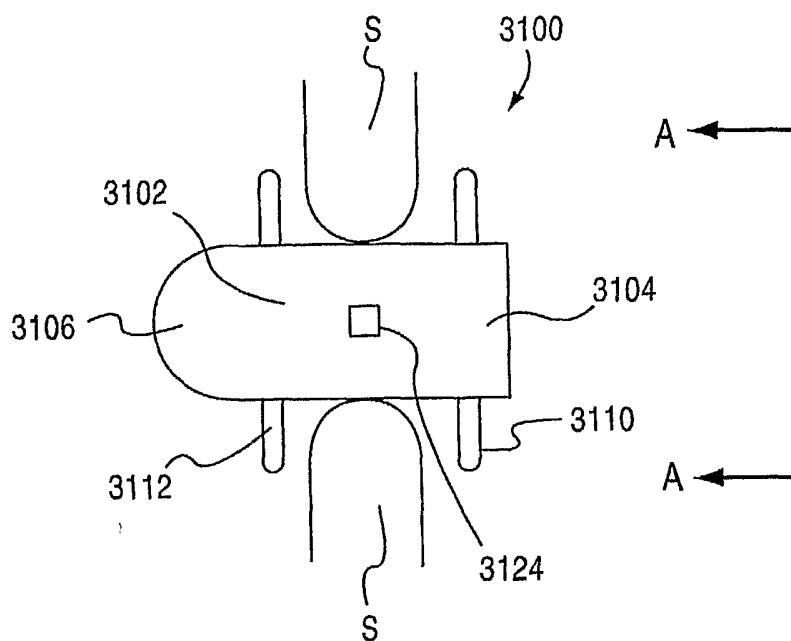


FIG. 68

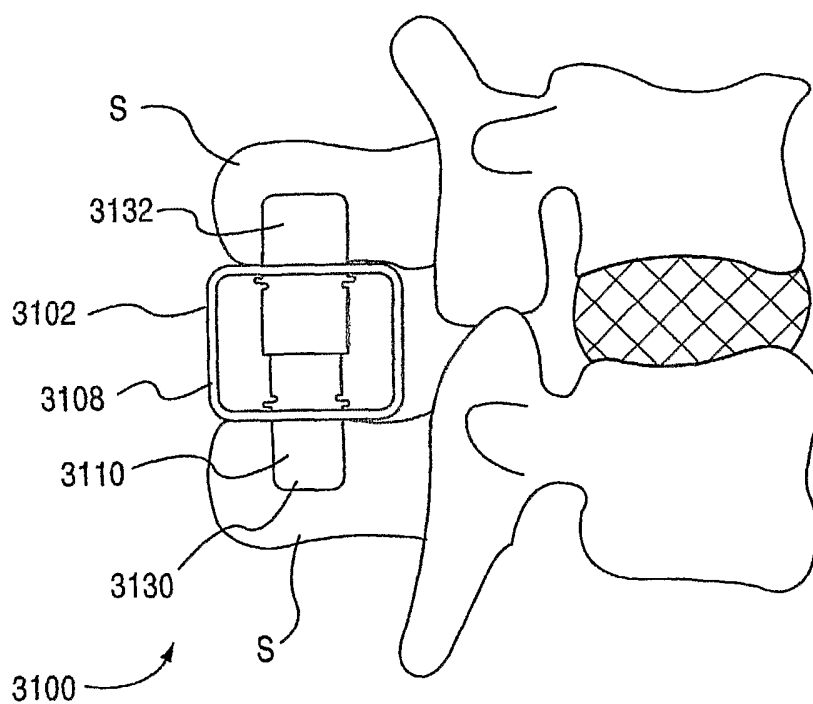


FIG. 69

SUBSTITUTE SHEET (RULE 26)

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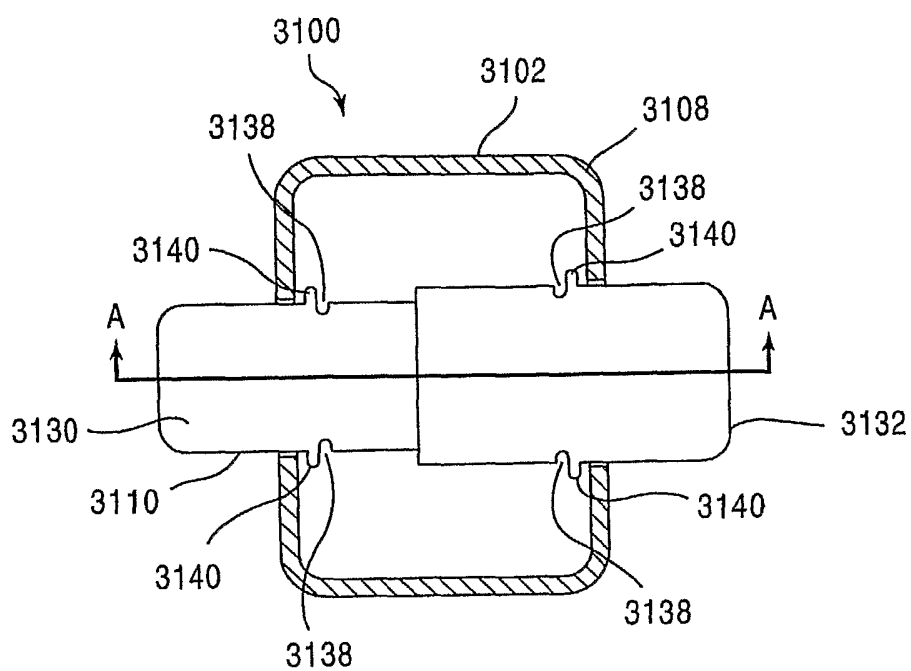


FIG. 70

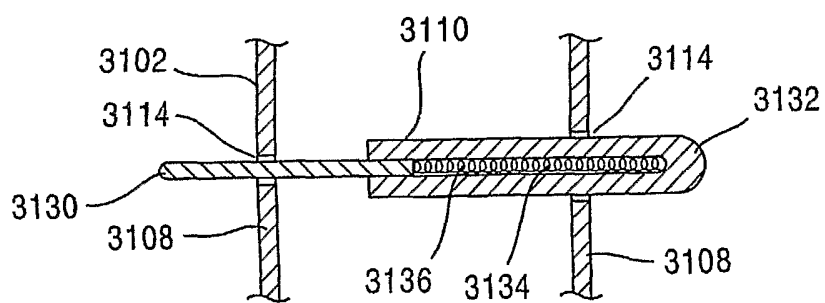


FIG.71

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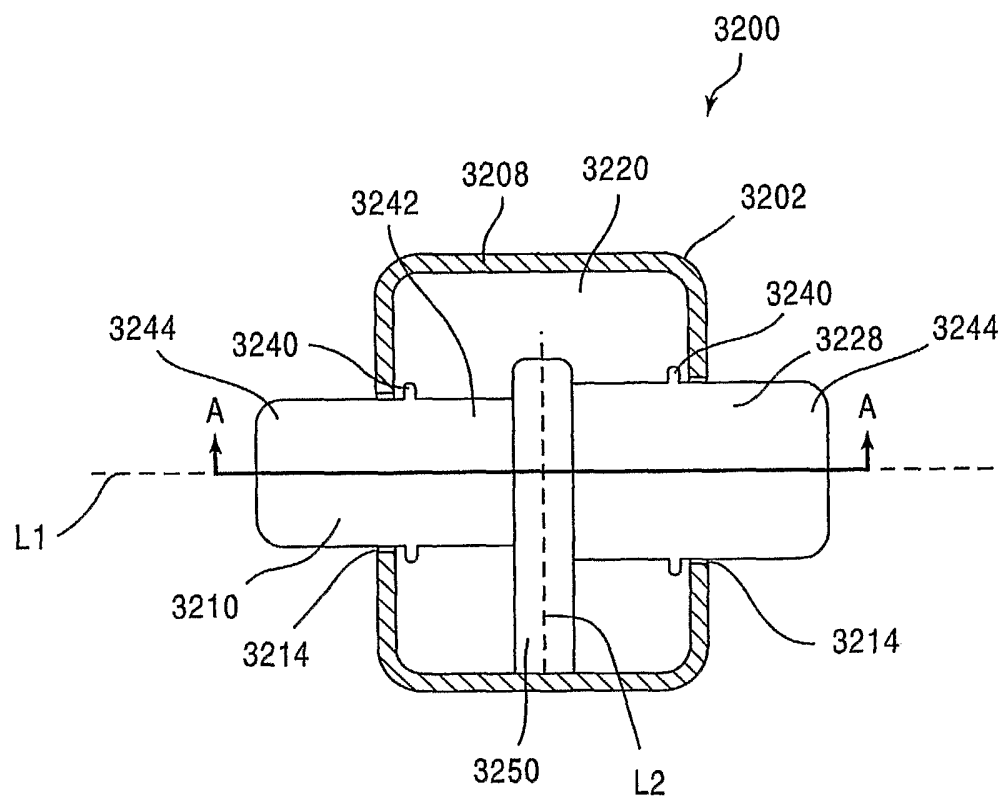


FIG.72

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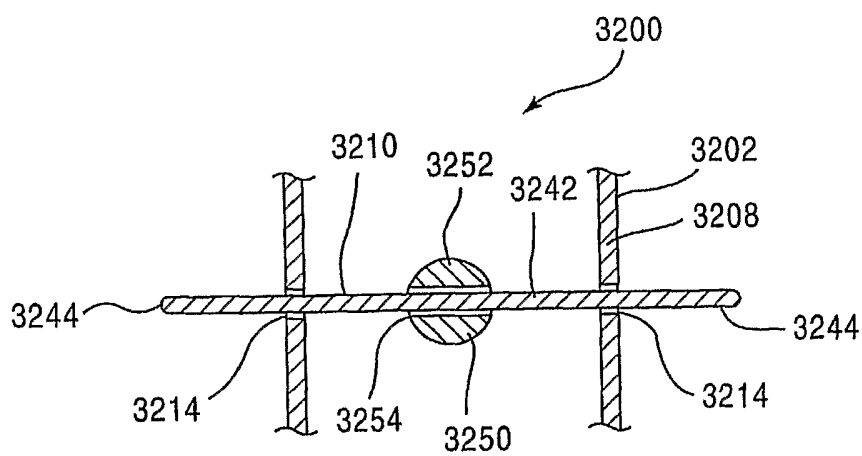


FIG. 73A

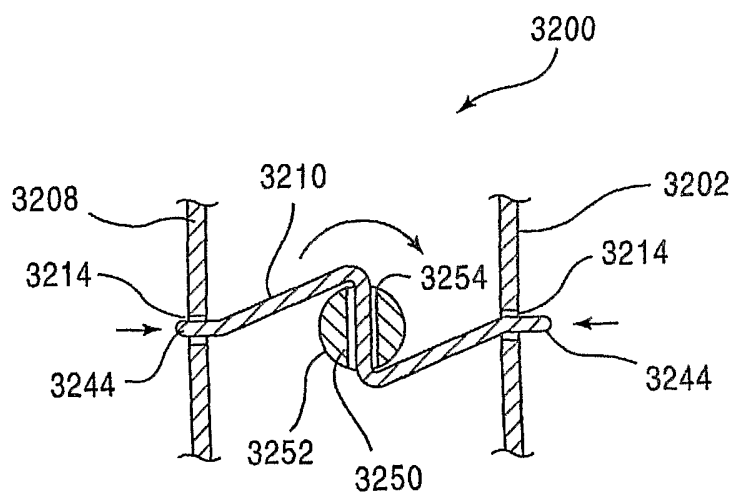


FIG. 73B

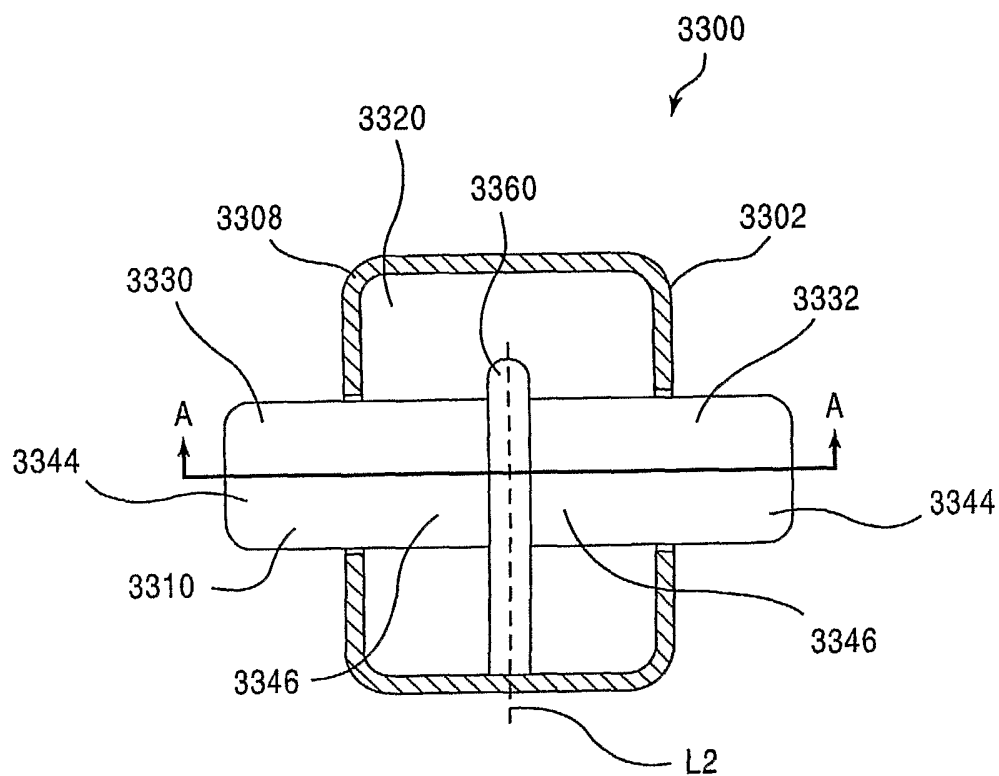


FIG. 74

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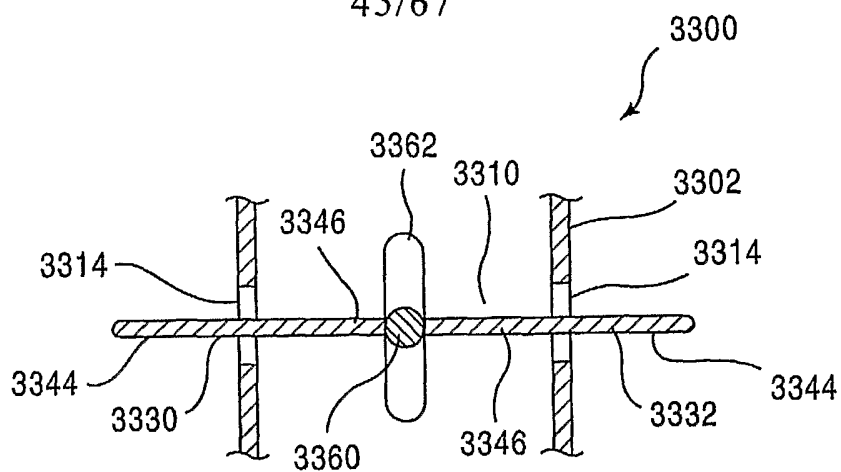


FIG. 75A

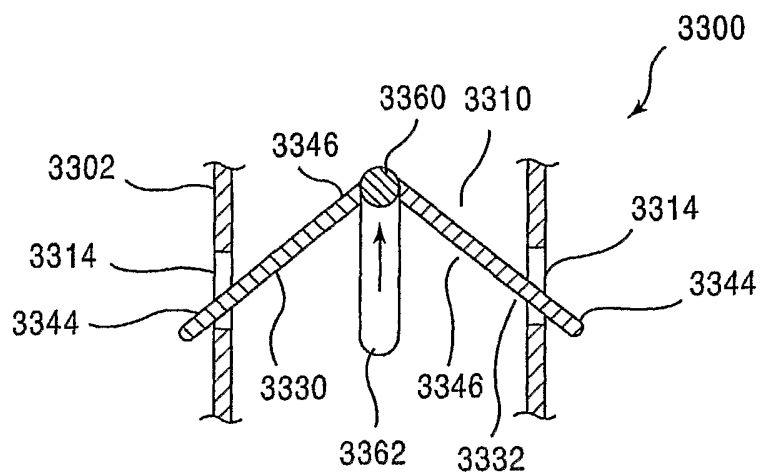


FIG. 75B

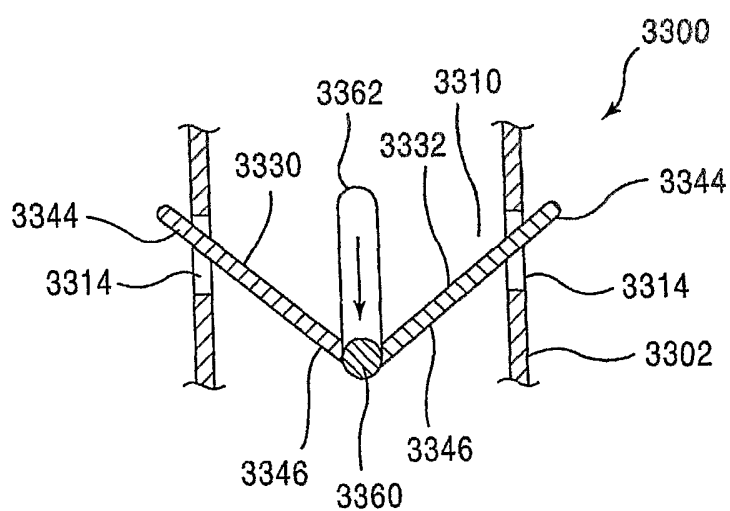


FIG. 75C

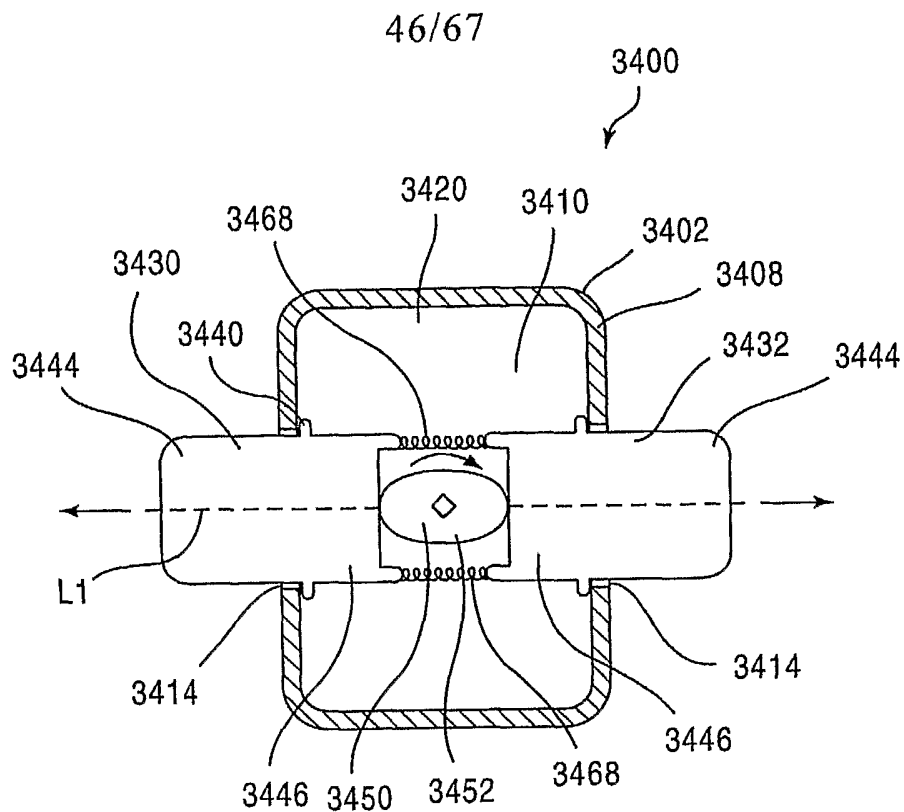


FIG. 76A

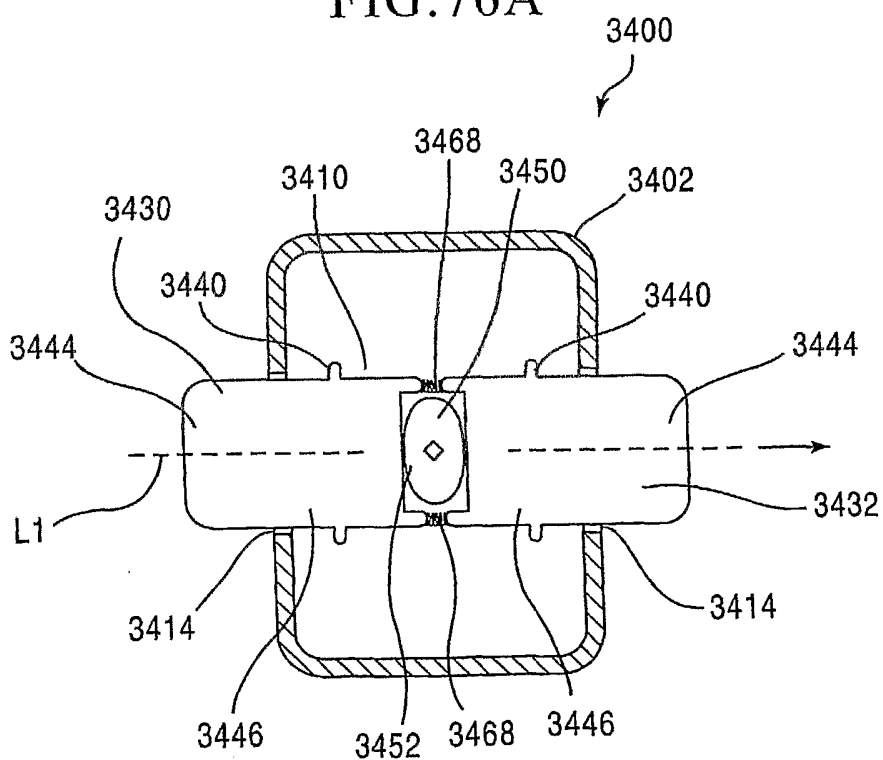


FIG. 76B

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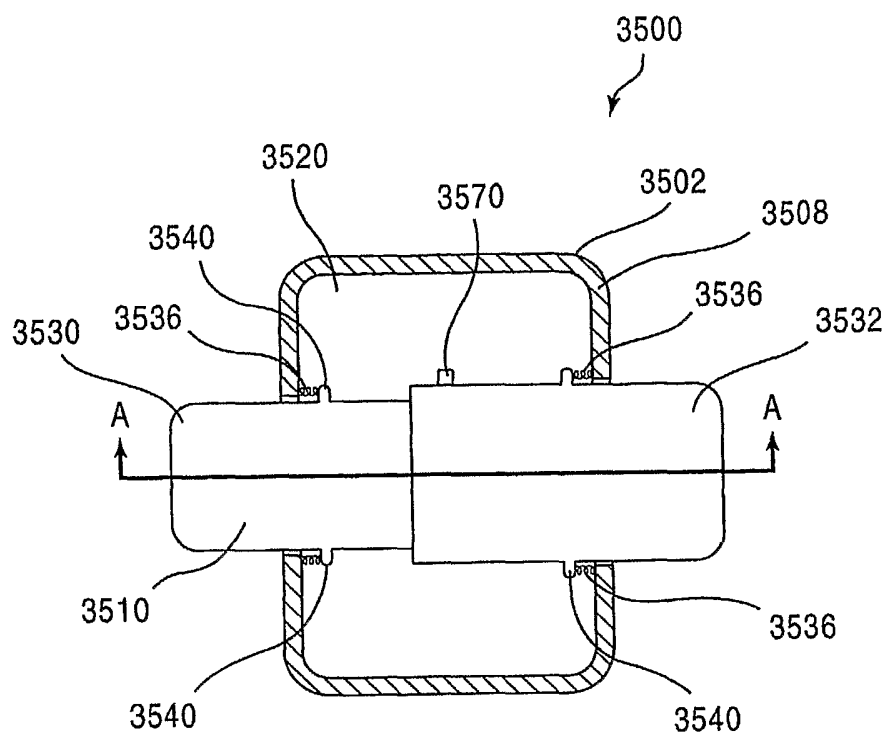


FIG.77

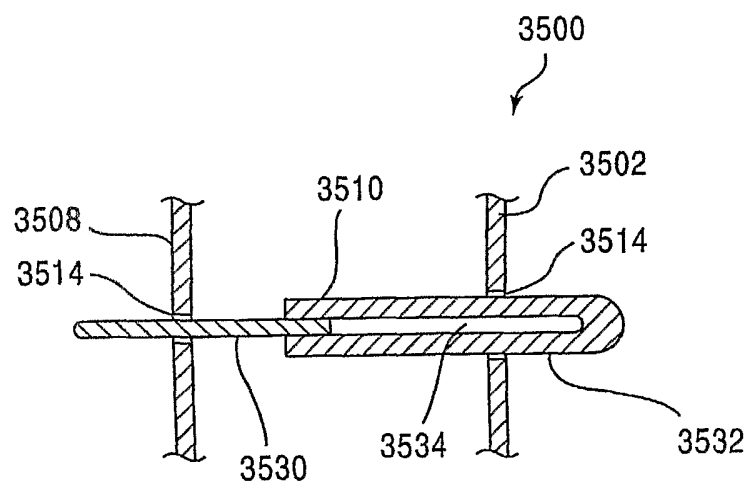
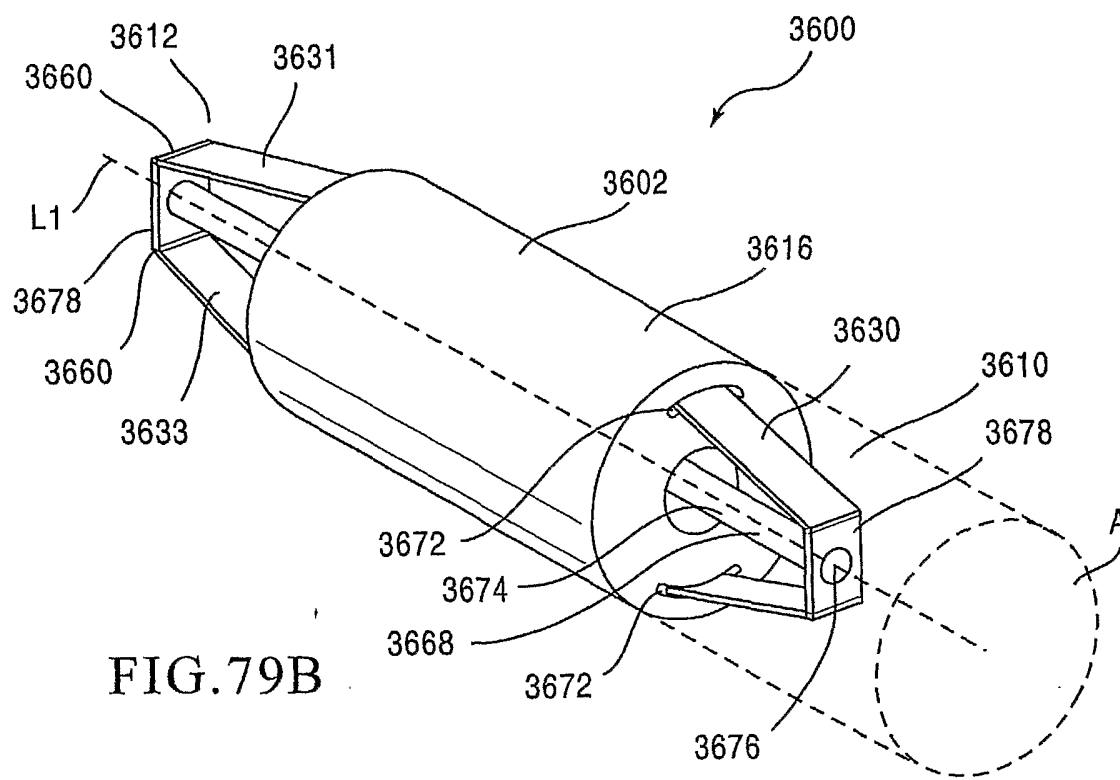
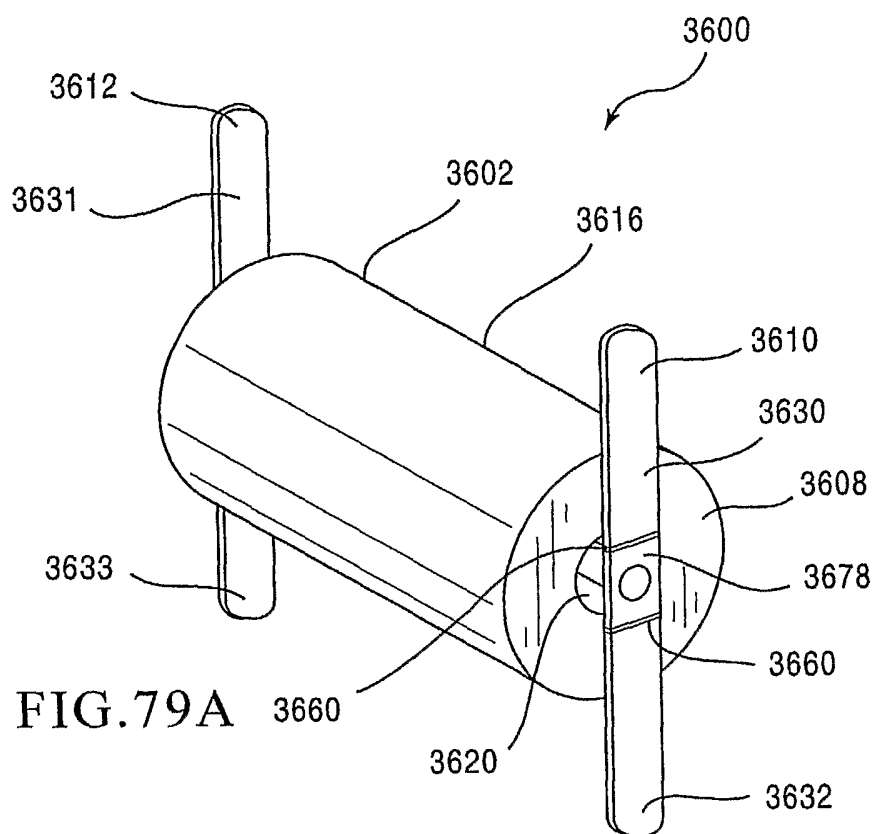


FIG.78

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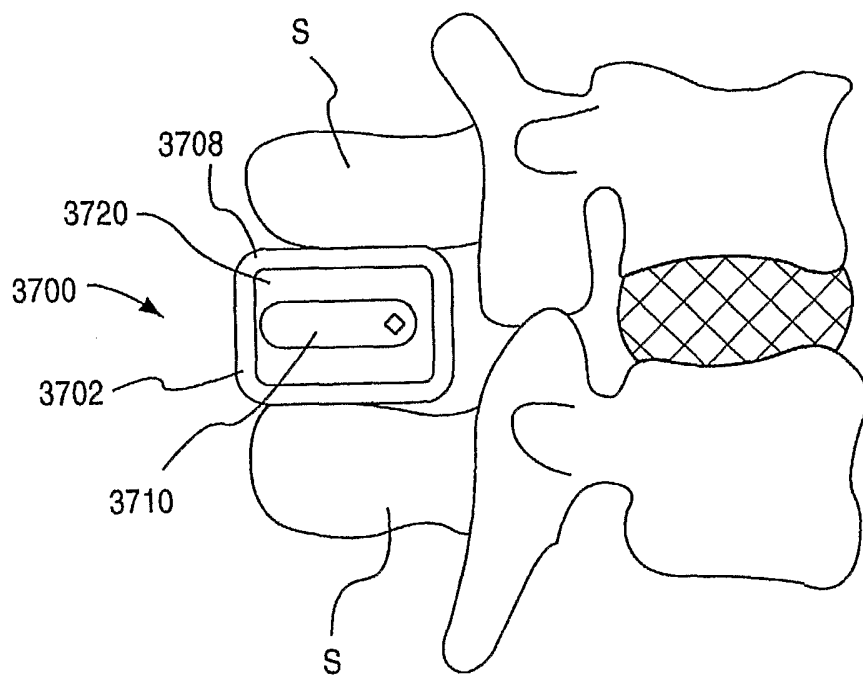


FIG. 80A

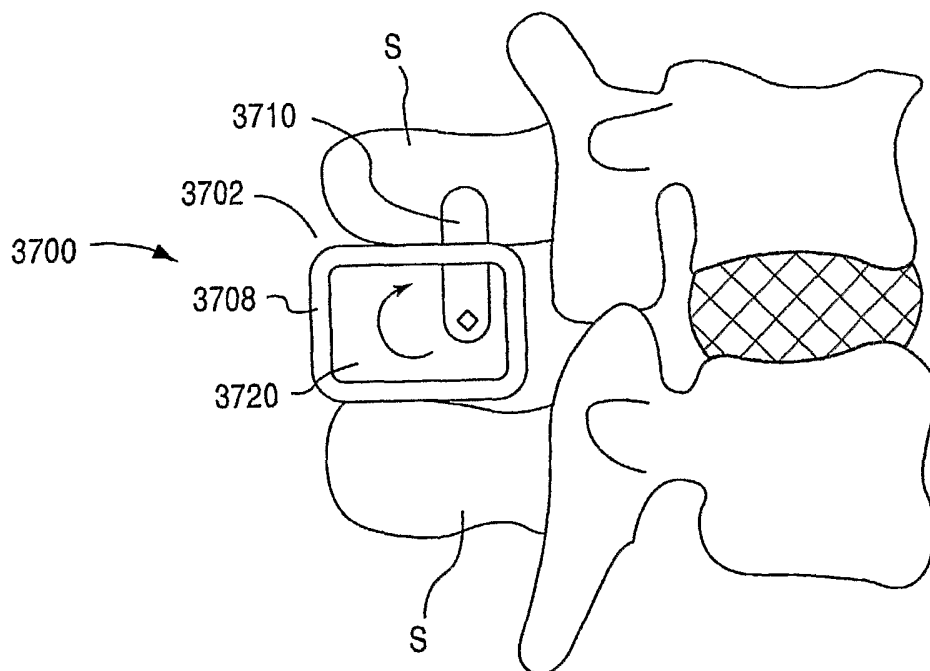


FIG. 80B

SUBSTITUTE SHEET (RULE 26)

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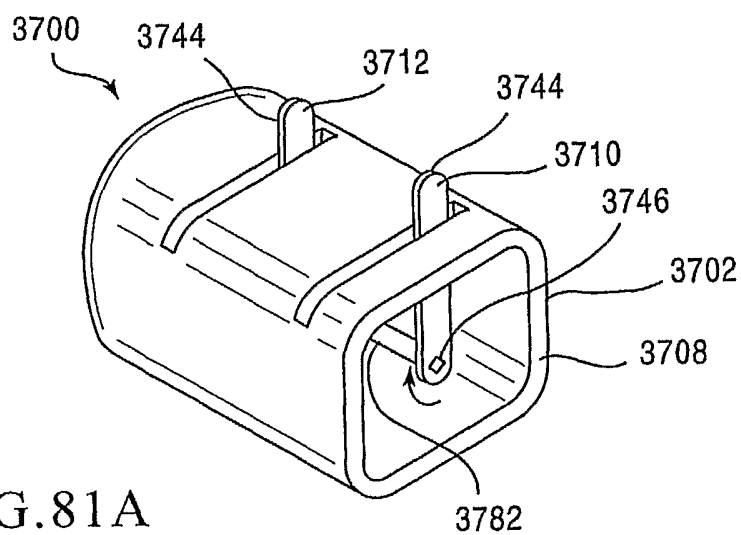


FIG. 81A

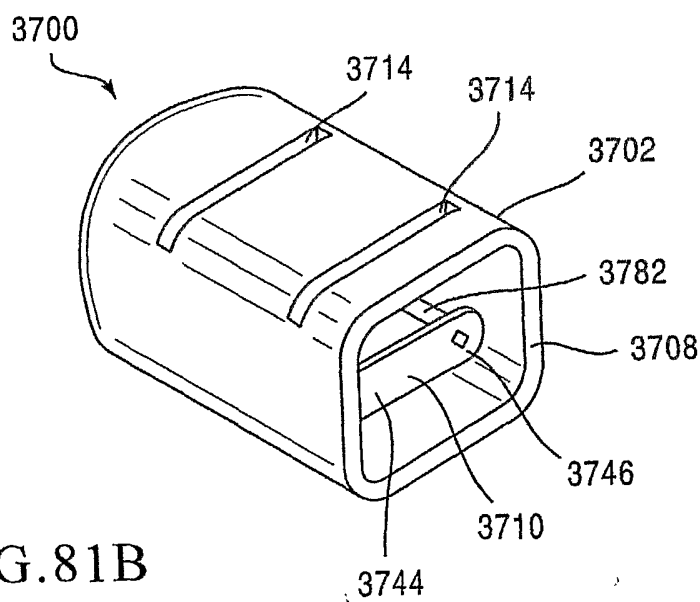


FIG. 81B

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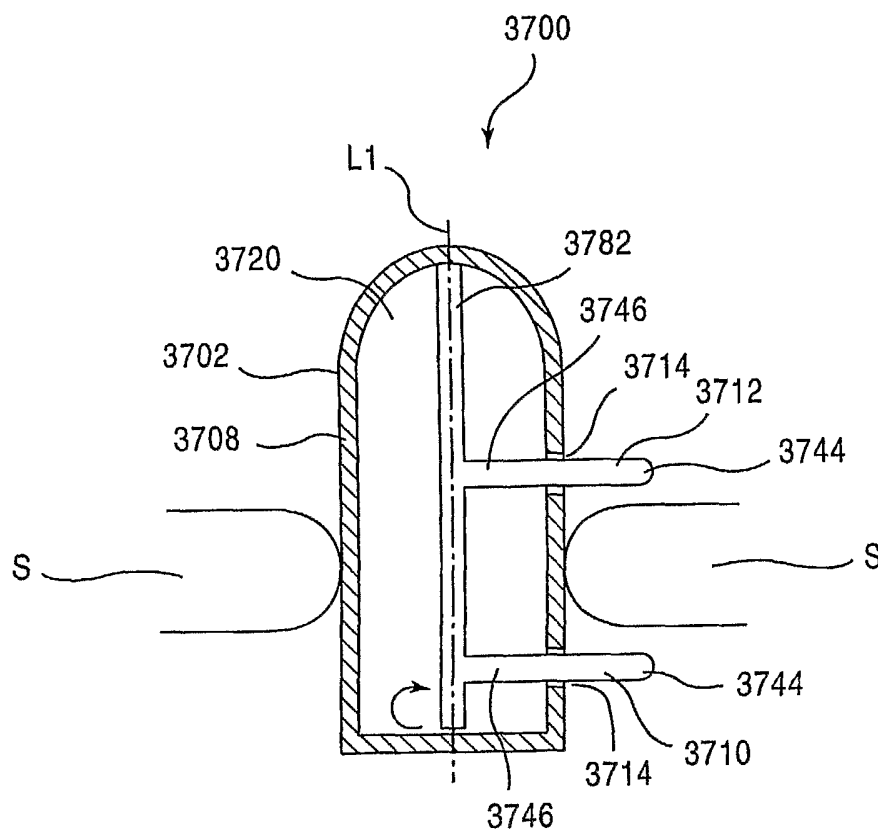


FIG.82

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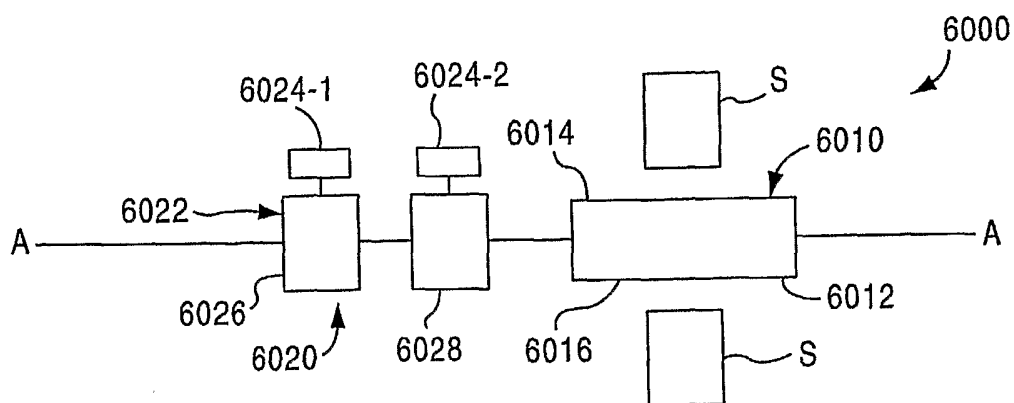


FIG. 83

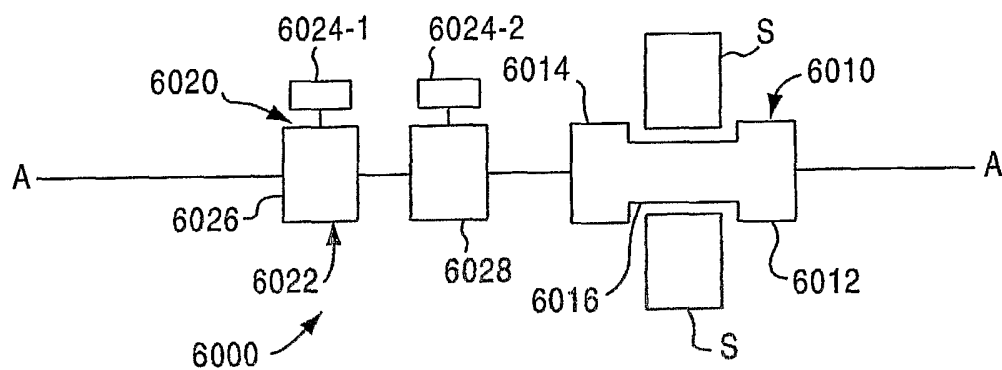


FIG. 84

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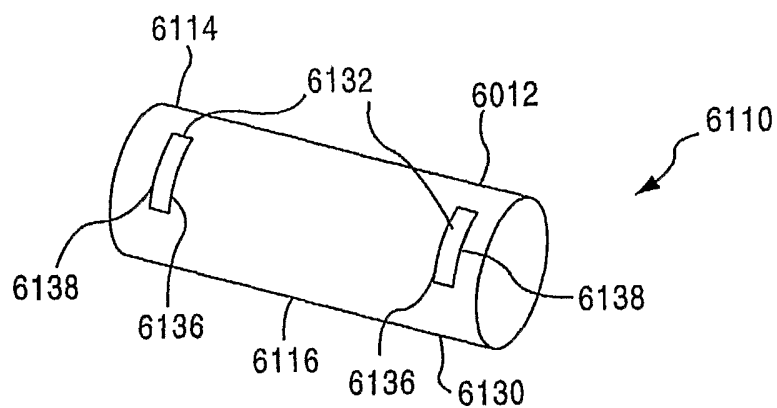


FIG. 85

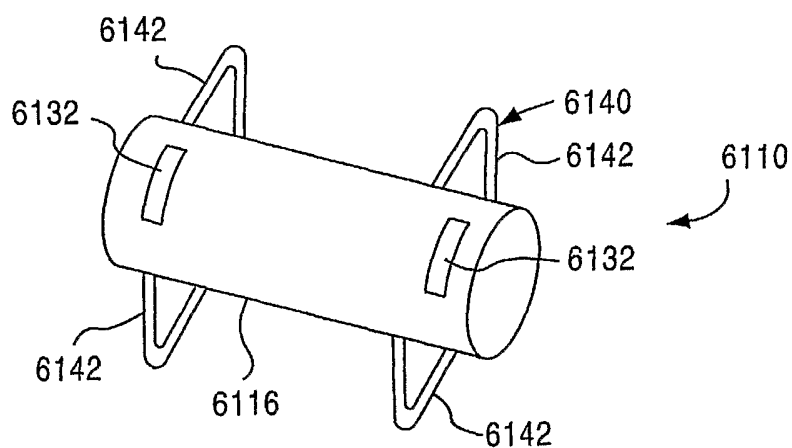


FIG. 86

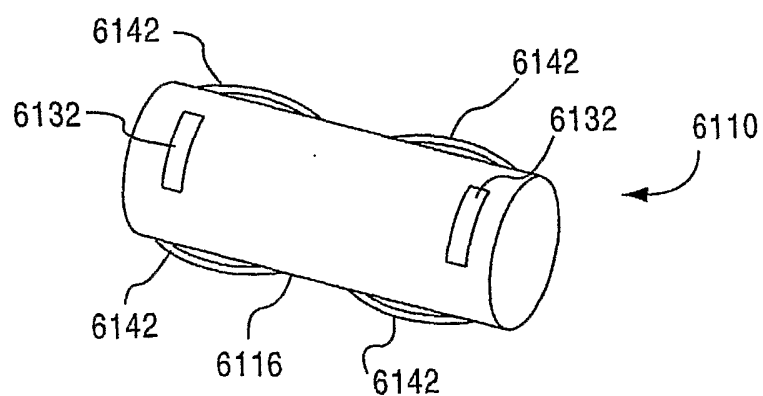
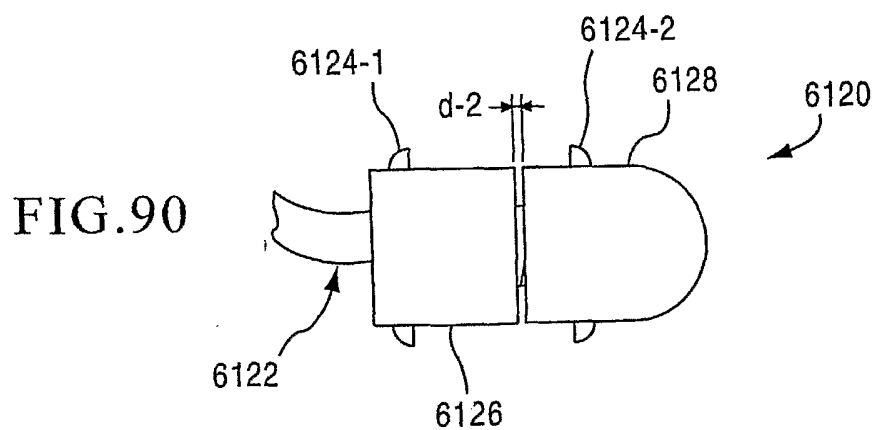
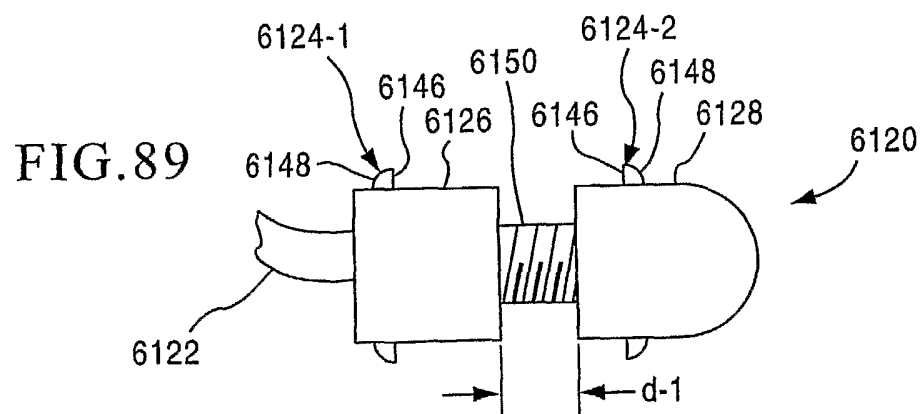
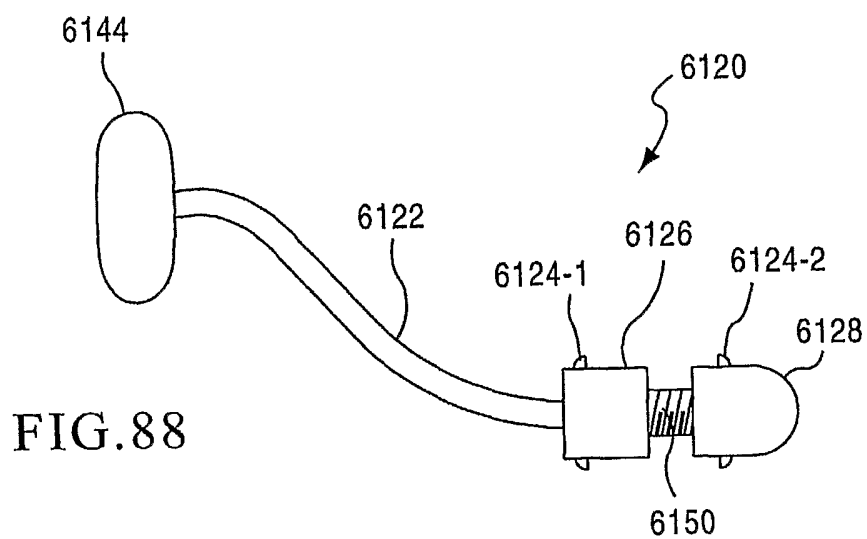


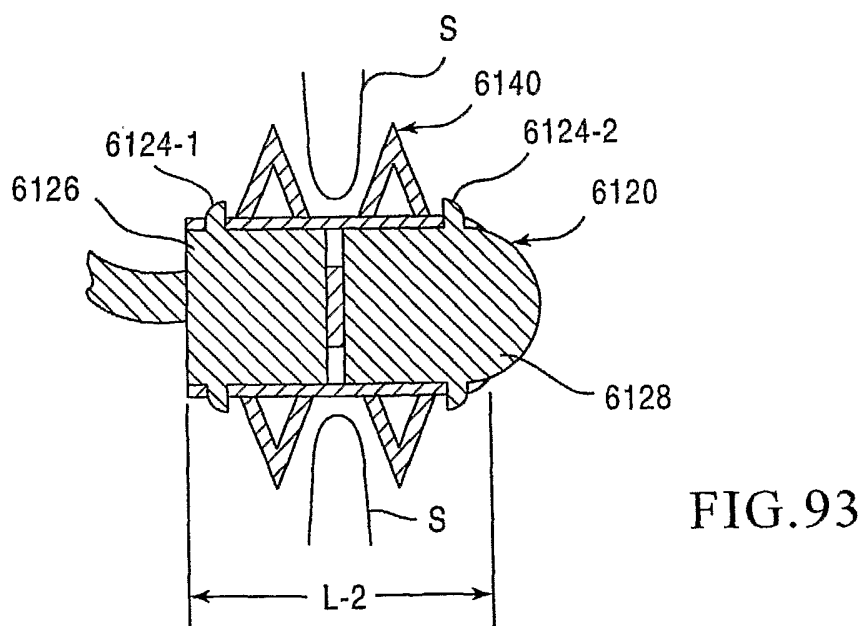
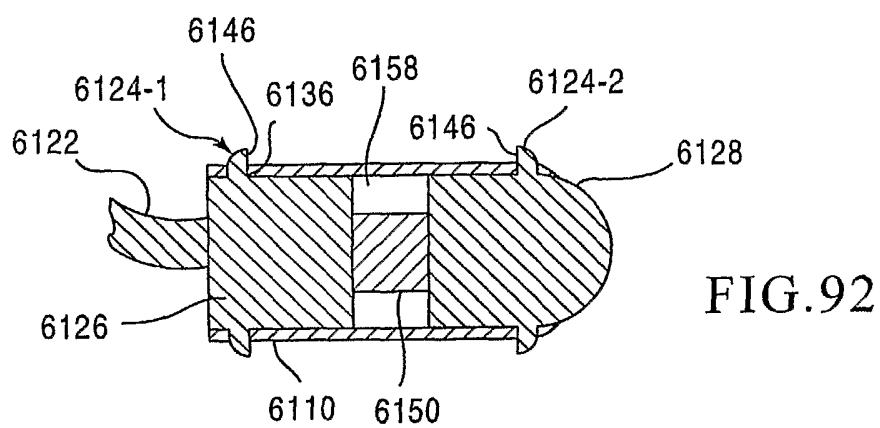
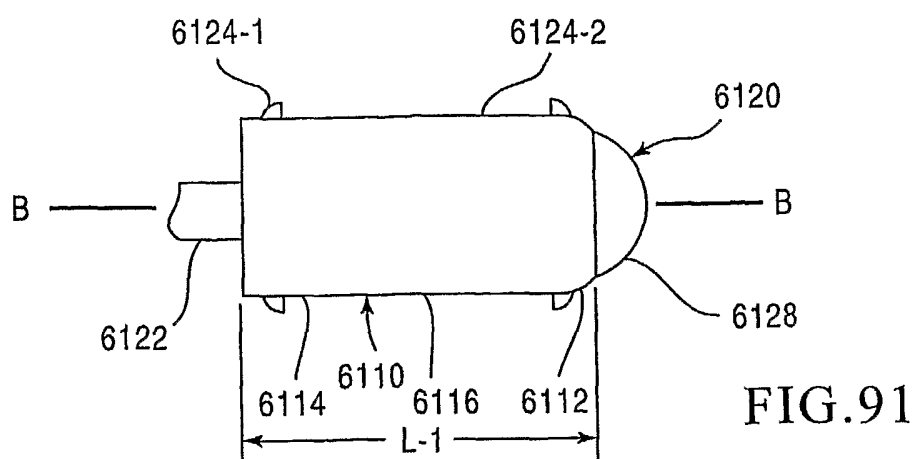
FIG. 87

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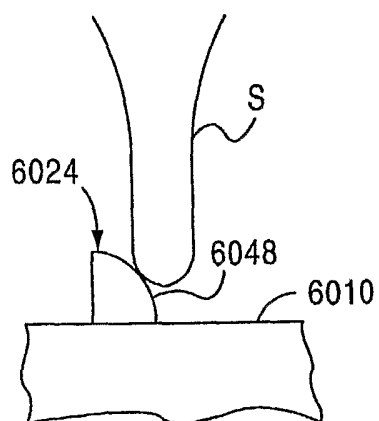


FIG. 94

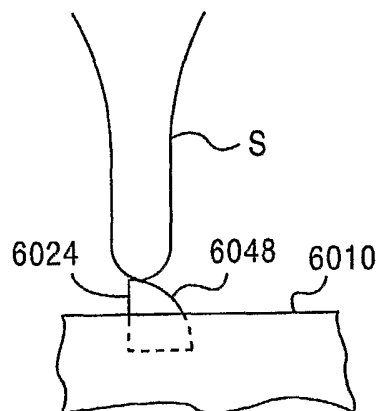


FIG. 95

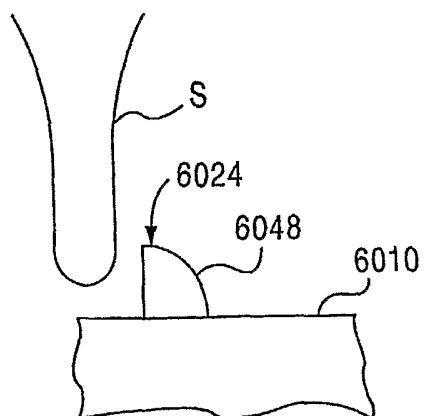


FIG. 96

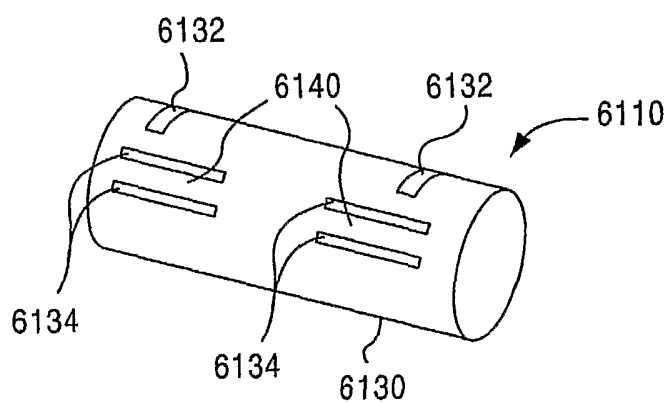


FIG. 97

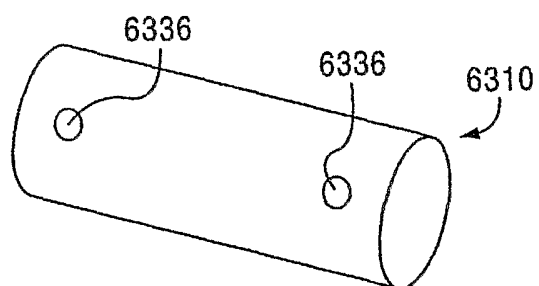


FIG. 98

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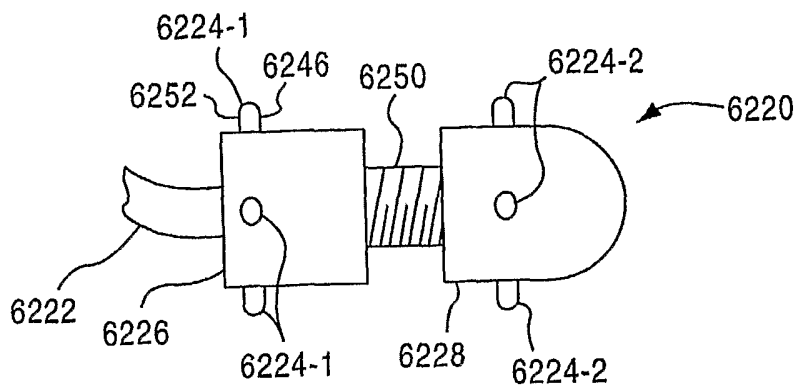


FIG. 99

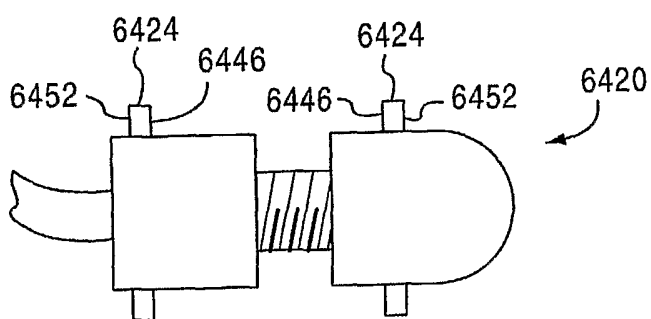


FIG. 100

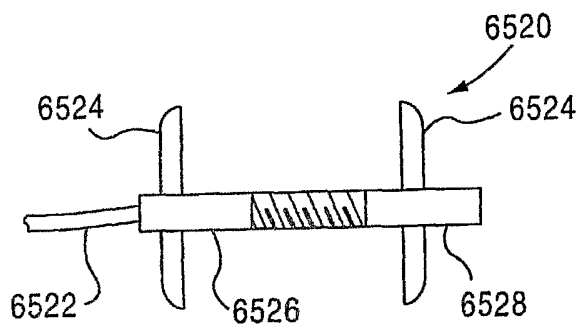


FIG. 101

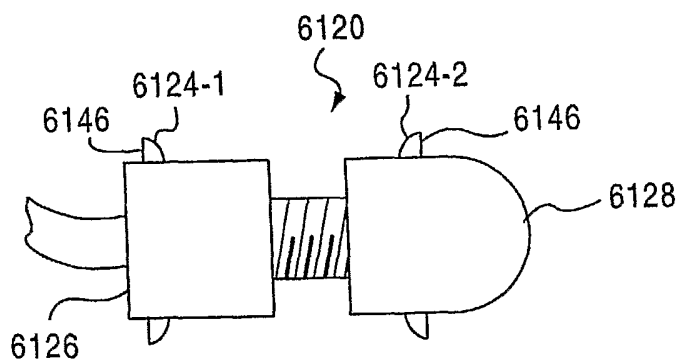


FIG. 102

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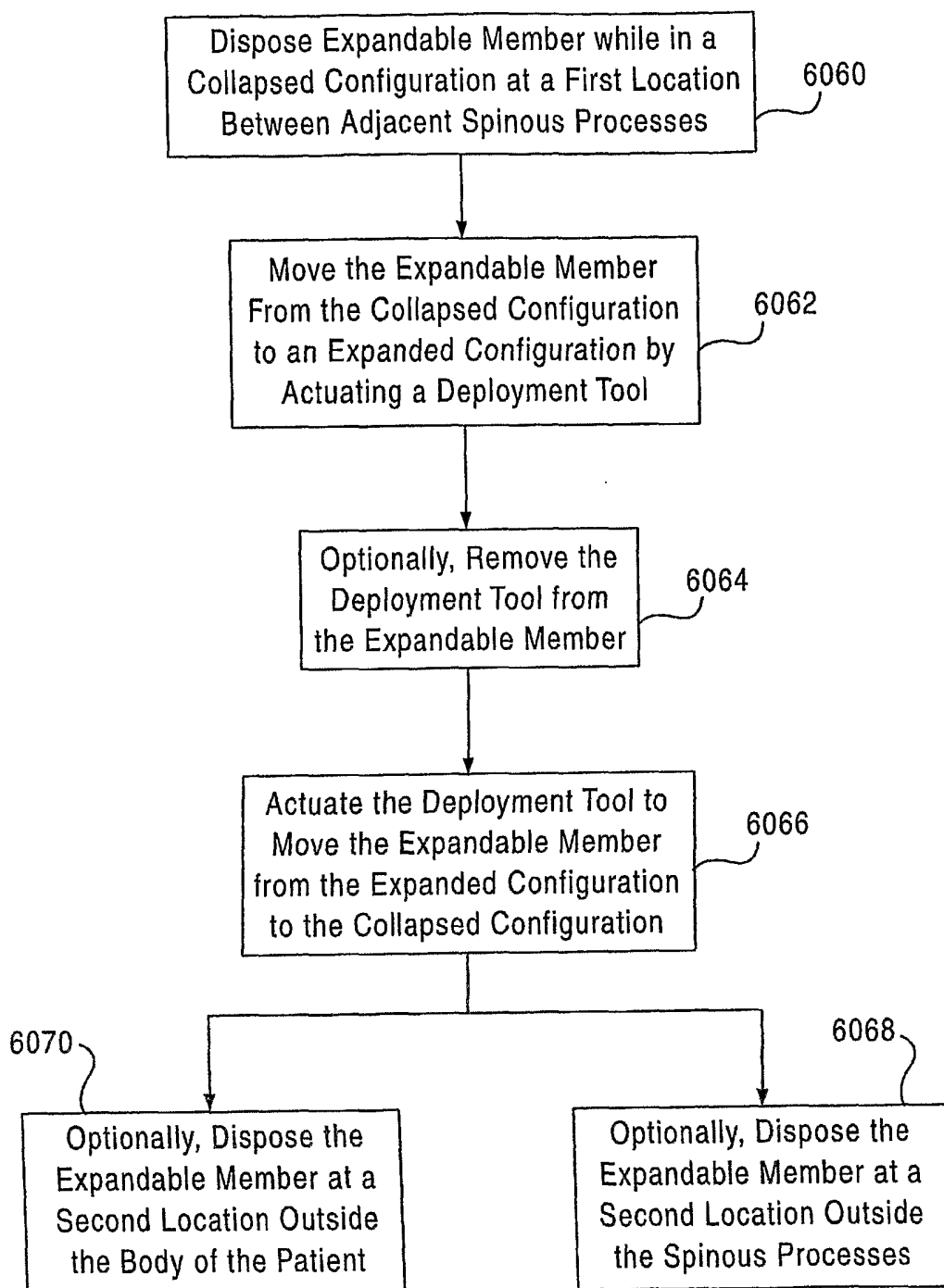


FIG.103

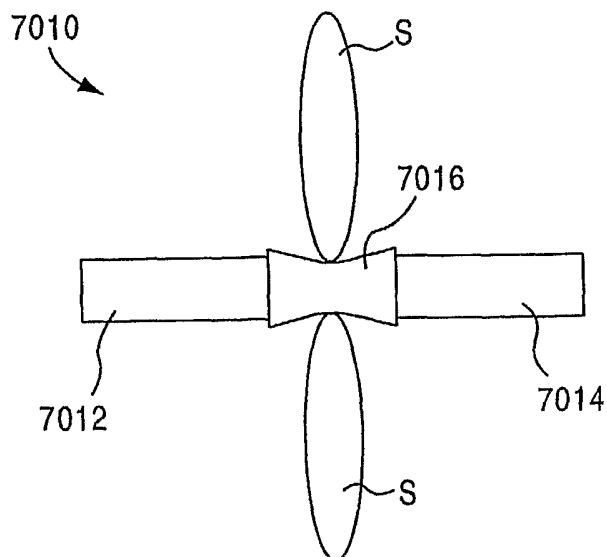


FIG. 104

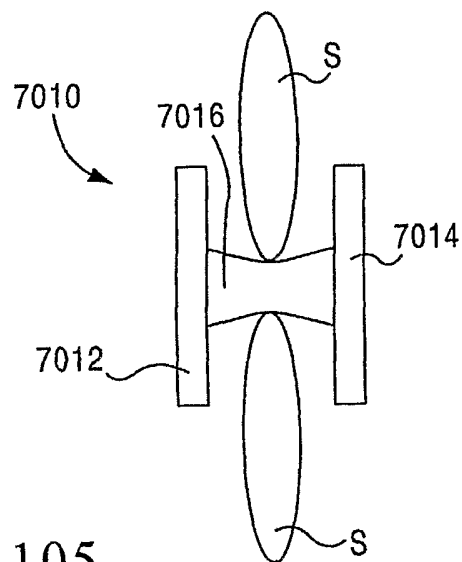


FIG. 105

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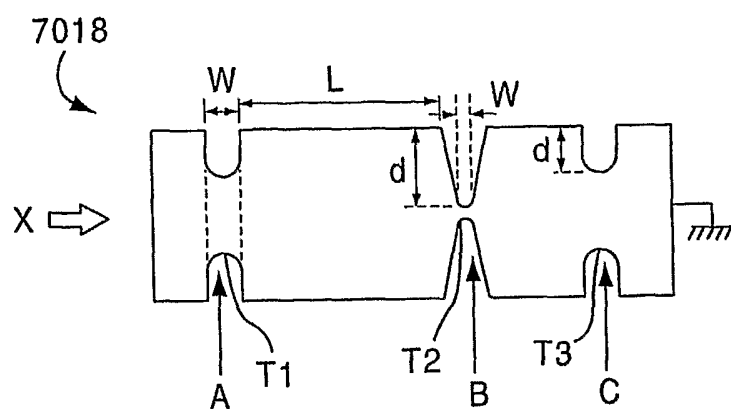


FIG.106

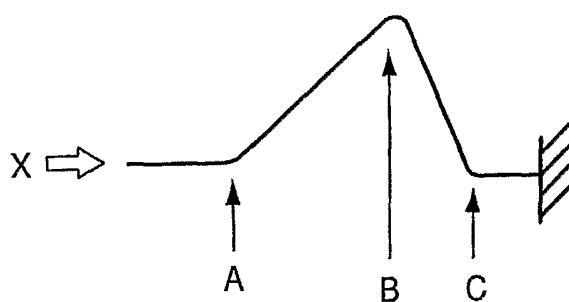


FIG.107

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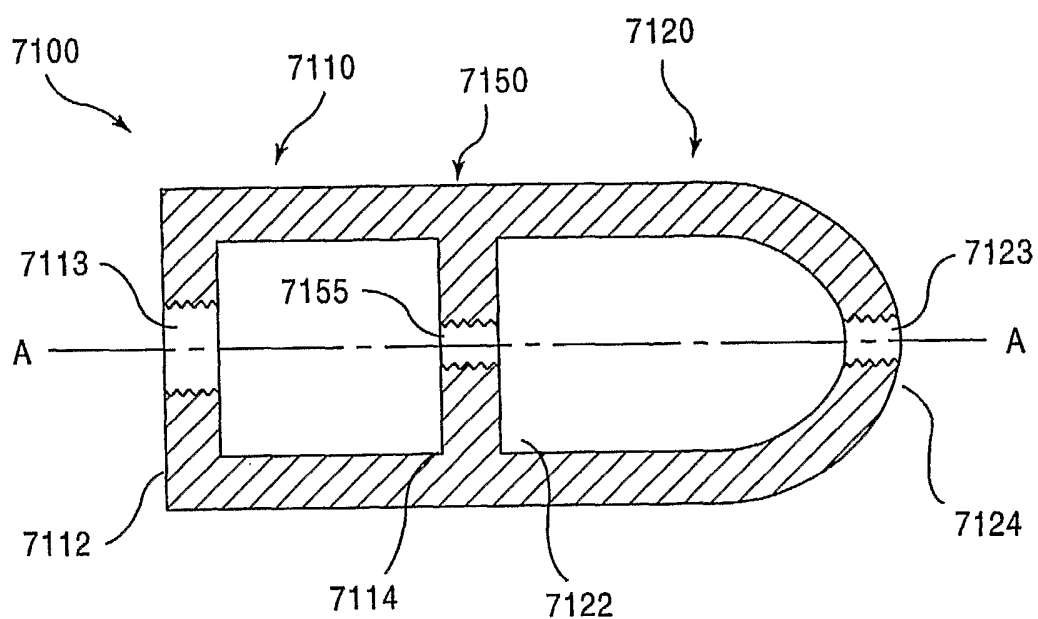


FIG. 108

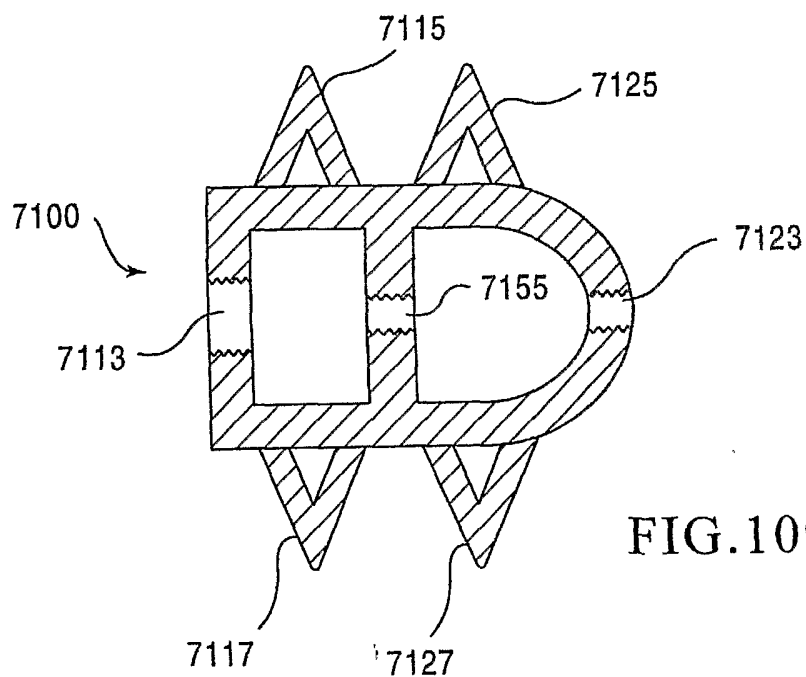


FIG. 109

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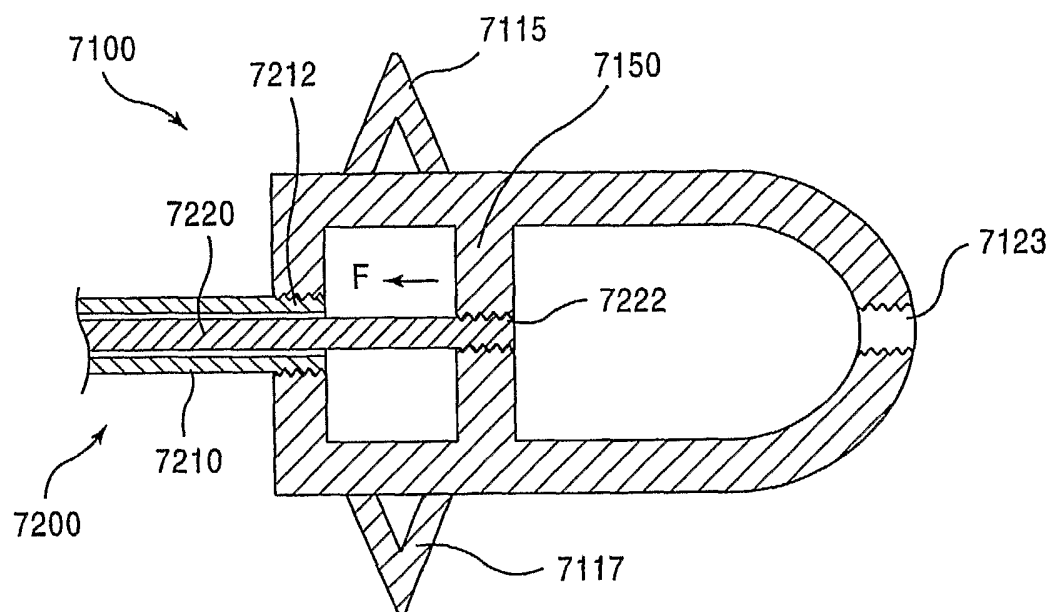


FIG. 110

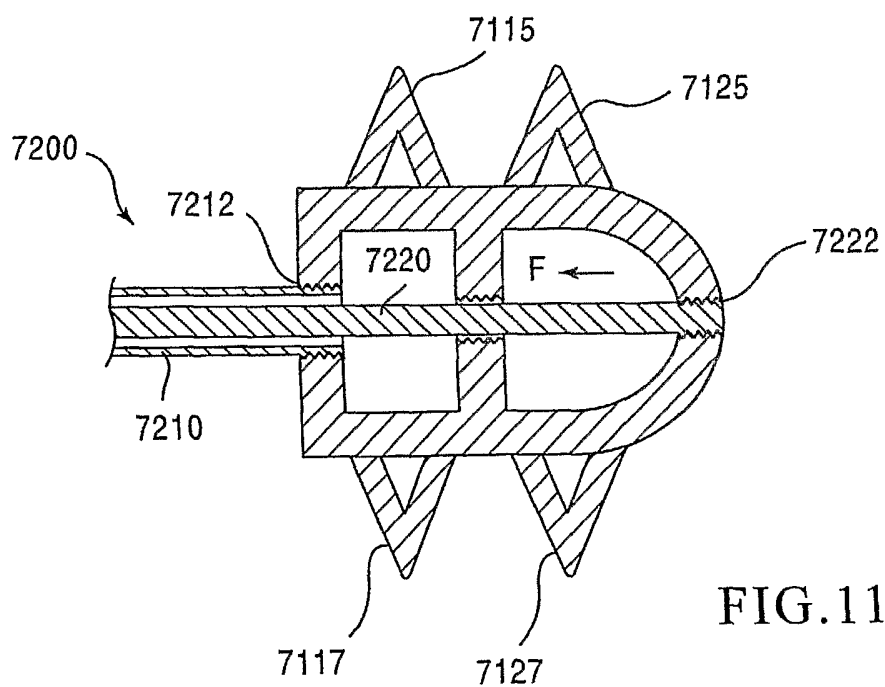


FIG. 111

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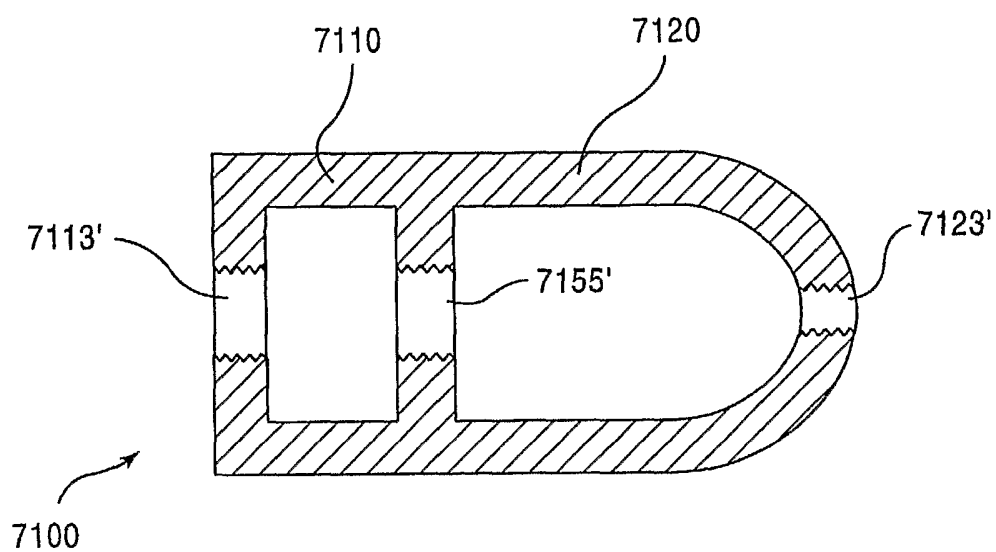


FIG. 112

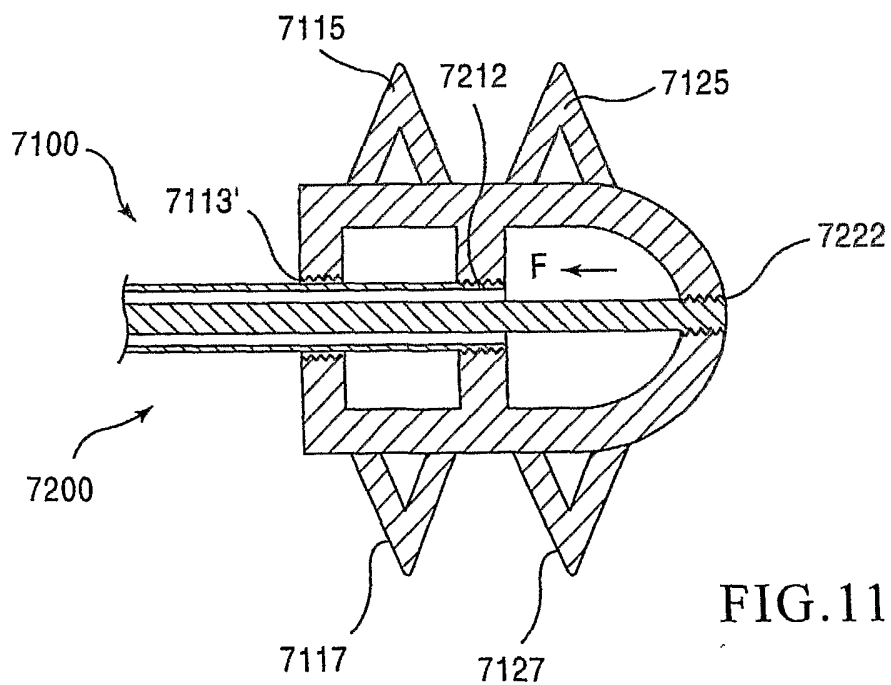
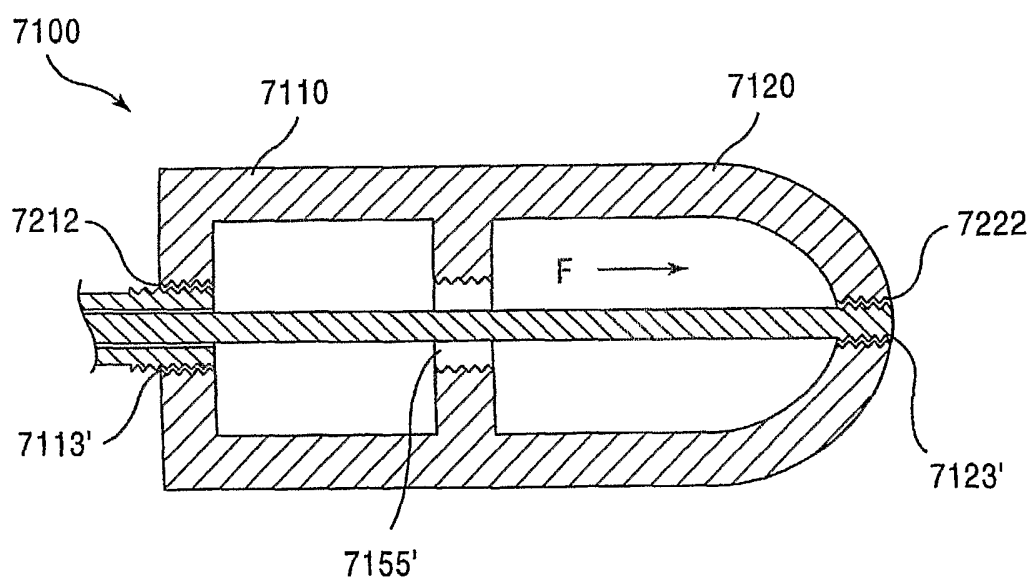
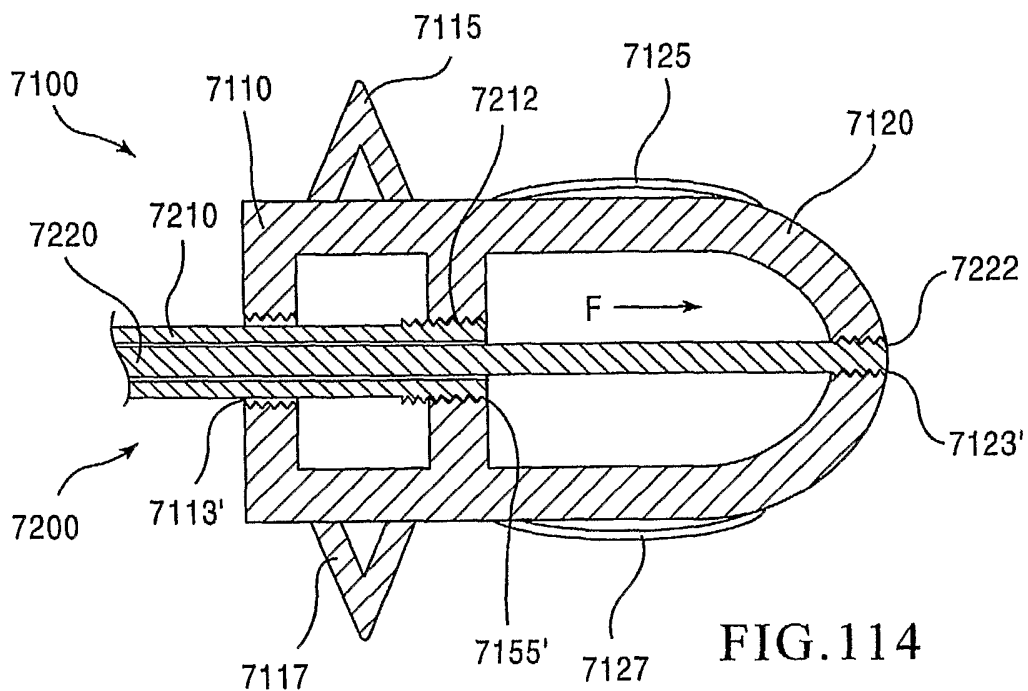


FIG. 113

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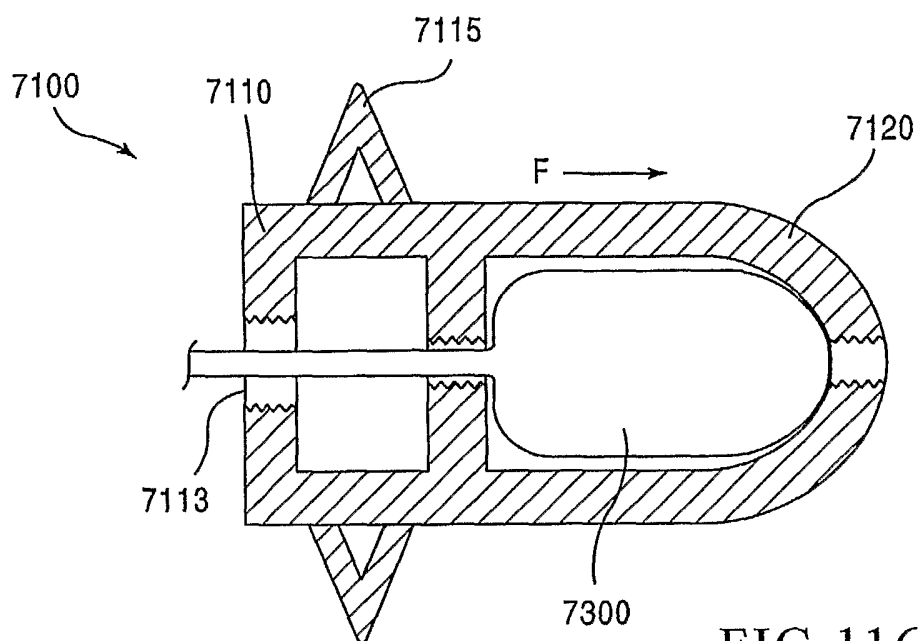


FIG. 116

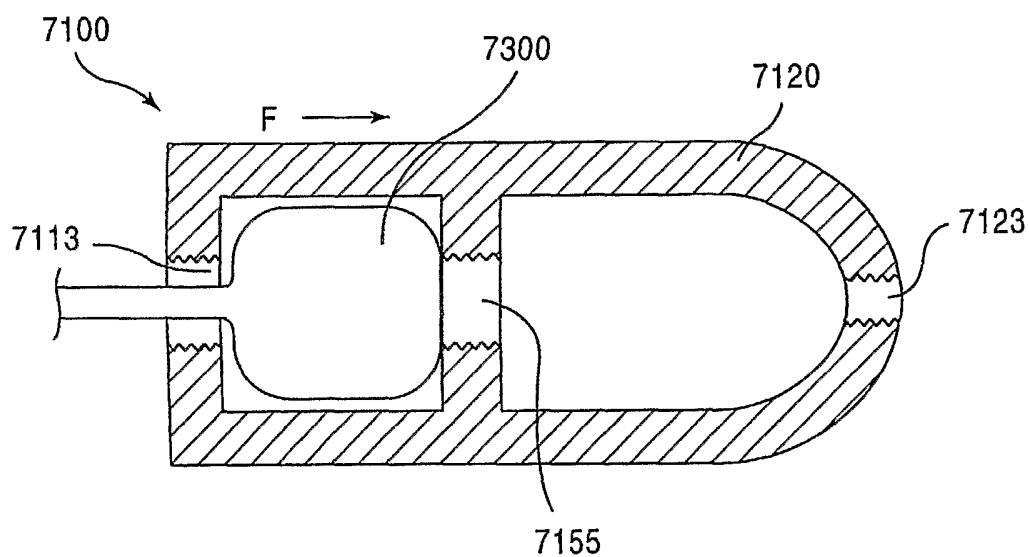


FIG. 117

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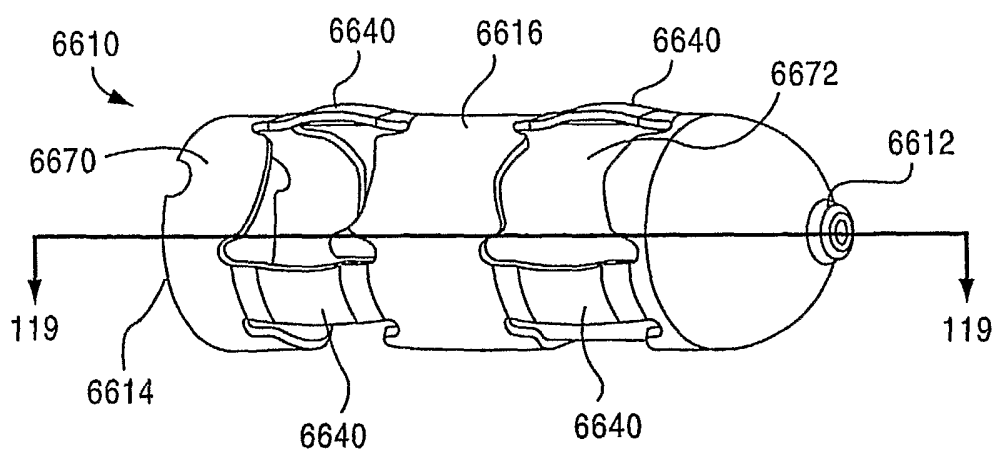


FIG. 118

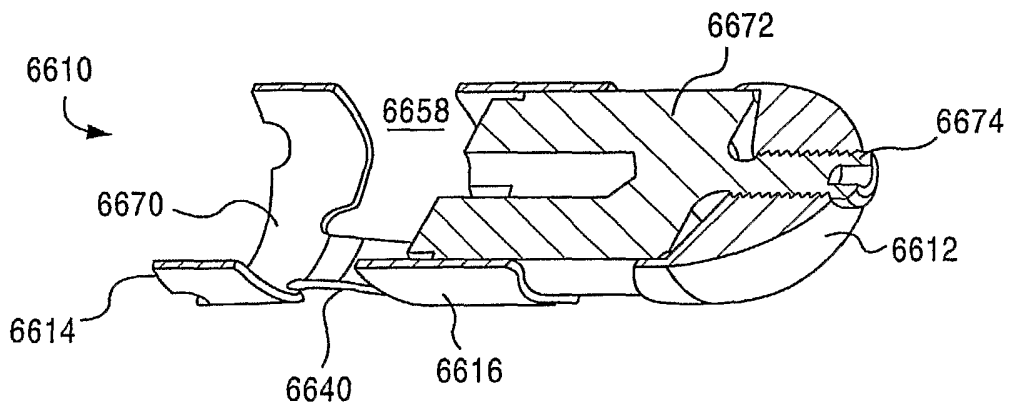


FIG. 119

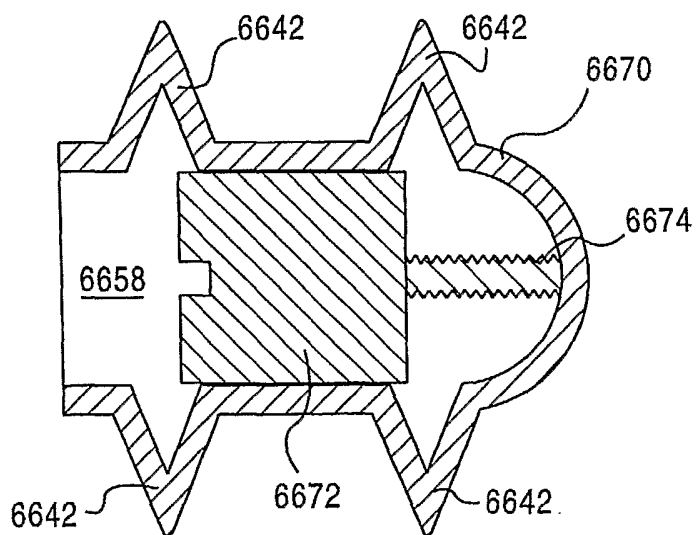


FIG. 120