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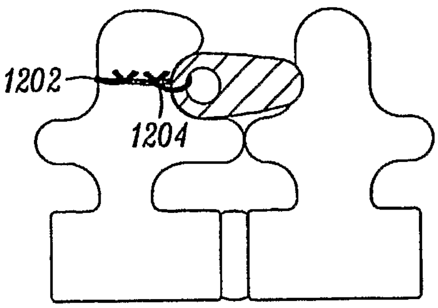
(54) **Title:** METHODS AND APPARATUS FOR TREATING SPINAL STENOSIS



(57) **Abstract:** Surgical implants are configured for placement posteriorly to a spinal canal between vertebral bodies to distract the spine and enlarge the spinal canal. In preferred embodiments the device permits spinal flexion while limiting spinal extension, thereby providing an effective treatment for treating spinal stenosis without the need for laminectomy. Invention may be used in cervical, thoracic, or lumbar spine. Numerous embodiments are disclosed, including elongated, length-adjustable components coupled to adjacent vertebral bodies using pedicle screws. Preferred embodiments, however, teach a device configured for placement between adjacentvertebral bodies and adapted to fuse to the lamina, facet, spinous process or other posterior elements of a single vertebra. Various mechanisms, including shape, porosity, tethers, and bone-growth promoting substances may be used to enhance fusion. Tether may be a wire, cable, suture, or other single or multi-filament member. Preferably, device forms a pseudo-joint in conjunction with the non-fused vertebra. Alternatively, device could be fused to the caudal vertebra or both the cranial and caudal vertebra.

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METHODS AND APPARATUS FOR TREATING SPINAL STENOSIS

CROSS REFERENCE TO RELATED APPLICATIONS

The present invention is an International Patent Application and claims the benefit of priority from commonly owned and co-pending U.S. Non-Provisional Patent Application Serial No. 11/051,692, entitled "Methods and Apparatus for Treating Spinal Stenonis" and filed on February 4, 2005 (which claims priority from US Provisional Patent Application Serial No. 60/629,018, filed November 18, 2004), the entire contents of which is hereby expressly incorporated by reference into this disclosure as if set forth in its entirety herein.

FIELD OF THE INVENTION

This invention relates generally to spine surgery and, in particular, to methods and apparatus for treating spinal stenosis.

BACKGROUND OF THE INVENTION

Spinal stenosis is a narrowing of spaces in the spine, results in pressure on the spinal cord and/or nerve roots. This disorder usually involves the narrowing of one or more of the following: (1) the canal in the center of the vertebral column through which the spinal cord and nerve roots run, (2) the canals at the base or roots of nerves branching out from the spinal cord, or (3) the openings between vertebrae through which nerves leave the spine and go to other parts of the body.

Pressure on the lower part of the spinal cord, or on nerve roots branching out from that area, may give rise to pain or numbness in the legs. Pressure on the upper part of the spinal cord (that is, the neck area) may produce similar symptoms in the shoulders, or even the legs. The condition generally occurs in patients who are in their last decade or decades of life.

Laminectomy, which involves removing bone, the lamina, from the vertebrae, is the most common surgical treatment for spinal stenosis. Laminectomy enlarges the spinal canal, thus relieving the pressure on compressed nerves. Surgical burs, drills, punches, and chisels are used during the procedure.

Surgeons risk injuring the nerves or the spinal cord as they enlarge the spinal canal. In addition, elderly patients frequently have co-morbidities that increase the risk of laminectomy. Complications of laminectomy include increased back pain, infection, nerve injury, blood clots, paralysis, prolonged recovery, and death.

Lumbar fusion is frequently preformed in-conjunction with laminectomy. Current fusion techniques require abrasion of large surfaces of bone. Bone bleeds during and after abrasion. Current fusion techniques increase the risk of spinal stenosis procedures. Fusion also prolongs patient recovery following spinal stenosis surgery.

Patients and surgeons would welcome less invasive treatments for spinal stenosis.

SUMMARY OF THE INVENTION

This invention is directed to surgical apparatus for treating spinal stenosis, without the need for laminectomy. Broadly the invention resides in a device configured for placement posteriorly to a spinal canal between vertebral bodies to distract the spine and enlarge the spinal canal. In the preferred embodiments the device permits spinal flexion while limiting spinal extension, thereby providing an effective treatment for treating spinal stenosis. The invention may be used in the cervical, thoracic, or lumbar spine.

Numerous embodiments are disclosed, including elongated, length-adjustable components coupled to adjacent vertebral bodies using pedicle screws. The preferred embodiments, however, teach a device configured for placement between adjacent vertebrae and adapted to fuse to the lamina, facet, spinous process or other posterior elements of a single vertebra. Various mechanisms, including shape, porosity, tethers, and bone-growth promoting substances may be used to enhance fusion. The tether may be a wire, cable, suture, allograft tissue, or other single or multi-filament member. Preferably, the device forms a pseudo-joint in conjunction with the non-fused vertebra.

Alternatively, the device could be fused to the caudal vertebra or both the cranial and caudal vertebrae.

In certain embodiments at least a portion of the device is constructed from bone. For example, the device may be constructed from the shaft of the clavicle, rib, humerus, radius, ulna, metacarpal, phalanx, femur, tibia, fibula, or metatarsal bone. The device includes a slot or indent to receive a portion of a spinous process or other vertebral feature to enhance fusion. The device may contain one or more bone-growth promoting substances such as BMP1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14 ... n, demineralized bone matrix, allograft cancellous bone, autograft bone, hydroxy appetite, coral or other highly porous substance.

An elastic, synthetic ligament or allograft ligament may me provided as part of the invention. The device may be configured to surround or clamp to a single spinous process, or include optional projections extending along the sides of a spinous process. The device may include spring-like or shape-memory properties. The device may have an asymmetric cross section or other shape to wedge or distract the spinous processes upon insertion. The may include a generally V-, U-, or C-shaped device configured to fit between the lamina of one vertebra and the spinous process and or lamina of an adjacent vertebra, and my be customized at the time of surgery.

The devices according to this invention may be made of any suitable material, including titanium, chrome-cobalt, stainless steel, polymers, liquid metals, shape-memory materials, ceramics, or human tissue. The device may be made of an in-situ curing material. The device could be customized to fit between the spinous processes. Bone or bone-growth material could be added top the device after the device cures.

Devices according to the invention may be constructed of bone, including allograft bone, PEEK (polyaryletherketone), or ceramic. Devices according to the invention may also me made of other biocompatible materials such as Polyphenolsulfone, Polysulfone, Acetal (Delrin), UHMW Polyethylene, and composites of these materials and carbon fibers. Alternative materials include bioresorbable materials such as polylactic acid (PLA), polyglycolic acid (PGA), poly (ortho esters), poly(glycolide-co-trimethylene carbonate), poly-L-lactide-co-6-caprolactone, polyanhydrides, poly-n-dioxanone, and poly(PHB-hydroxyvaleric acid).

Certain devices according to the invention are designed to withstand loads of at least 90N, and are preferably provided in a number of sizes. For example, the cranial-to-caudal dimensions could vary from 6mm-24mm in 2mm increments. The ventral-to-dorsal dimensions could also vary from 6mm-24mm, also in 2mm increments. The left-to-right dimensions could vary from 10-50mm, again in 2mm increments. Multi-level devices, similar to the embodiment shown in Figure 35D would be supplied in larger dimensions.

BRIEF DESCRIPTION OF THE DRAWINGS

Figures 1A-1B are lateral views of a novel device of the invention;

Figures 1C-1D are end views of a novel vertebral screw and a cross-section of the threaded portion of the rod and threaded end component shown in Figure 1A;

Figure 1E is an end view of an alternative embodiment of the screw shown in Figure 1C;

Figures 1F-1I are lateral and cross-sectional views of the device shown in Figure 1A and the screws of the embodiment shown in Figure 1C;

Figures 2A-2C are lateral and exploded views of an alternative embodiment of the invention;

Figures 2D-2E are end and side views of the screw and fastening component shown in Figure 2C;

Figures 3A-3C are lateral and top views of an alternative embodiment of the device shown in Figure 2A;

Figures 3D-3E are enlarged views of the top of various hinge joints of the type shown in Figure 3C;

Figure 3F is a lateral view of the device shown in Figure 3B and vertebral screws;

Figures 4A-4C are lateral views of an alternative embodiment of a vertebral screw and a portion of the device shown in Figure 3B;

Figures 5A-5D a re lateral views of an alternative embodiment of the device shown in Figure 2A (contracted position in Fig. 5B);

Figure 6A is an oblique view of an alternative embodiment of the invention;

Figure 6B is a lateral view of a portion of the spine;

Figure 6C is a lateral view of a portion of the spine and the embodiment of the invention shown in Figure 6A;

Figure 6D is a lateral view of a portion of the spine and the device shown in Figure 6A;

Figures 6E-6H are oblique views of a cancellous bone block, a shaft of long bone, and the combination;

Figure 6I is lateral view of a portion of the spine and a sagittal cross-section of the embodiment of the device shown in Figure 6A;

Figure 7A is an oblique view of a portion of a shaft of a long bone;

Figure 7B is an oblique view of portion of a shaft of a shaped long bone;

Figure 7C is a lateral view of the spine and the embodiment of the invention shown in Figure 7B;

Figure 7D is an oblique view of a piece of bone;

Figure 7E is an end view of the device shown in Figure 7A and the bone shown in Figure 7D;

Figure 7F is a lateral view of a portion of the spine and a sagittal cross-section of the embodiment of the device shown in Figure 7E;

Figures 8A-8C are end views of alternative shapes of the device shown in Figure 7B;

Figures 9A-9B are oblique and top views of an alternative embodiment of the device shown in Figure 6A;

Figure 9C is a lateral view of a portion of the spine and the embodiment of the invention shown in Figure 9A;

Figure 10A is an oblique drawing of an alternative embodiment of the invention related to that shown in Figure 6A;

Figures 10B-10F are lateral, dorsal, and sagittal coronal cross-sectional views of a portion of the spine and the embodiment of the invention of the type shown in Figure 10A;

Figures 11A-11B are dorsal views of the embodiment of the invention shown in Figure 10F in the spine;

Figures 12A-12B are lateral and dorsal views of the spine and the embodiment of the invention shown in Figure 11A;

Figures 12C-12D are lateral views of the embodiment of the invention shown in Figure 12A in the spine using alternate coupling techniques;

Figures 13A-13B are lateral and dorsal views of the spine and the embodiment of the invention shown in Figure 10B;

Figures 14A-14C are lateral and dorsal views of the spine and an alternative embodiment of the invention shown in Figure 13A;

Figure 14D is a dorsal view of the spine and an alternative embodiment of the invention shown in Figure 14C;

Figures 15-19 are lateral and dorsal views of the spine and the embodiment of the invention shown in Figure 10A using alternate coupling techniques;

Figures 20A-20B are dorsal and lateral views of the spine and an alternative embodiment of a device related to that shown in Figure 17;

Figures 21A-21B are dorsal views of the spine and an alternative embodiment of the invention related to that shown in Figure 20A;

Figure 22 is a lateral view of the spine and an alternative embodiment of the invention related to that shown in Figure 12A;

Figures 23A-23B are lateral and dorsal views of the spine and an alternative embodiment of the invention shown in Figure 22;

Figures 24A-24B are dorsal views of the spine and an alternative embodiment of the invention related to that shown in Figure 23B;

Figures 25A-25B are lateral and dorsal views of the spine and an alternative embodiment of the invention related to that shown in Figure 12A;

Figures 26A-26B are lateral and dorsal views of the spine and an alternative embodiment of the invention related to that shown in Figure 25A;

Figure 26C is a sagittal cross-section of an alternative embodiment of the invention related to that shown in Figure 26B;

Figures 27A-27B are lateral and dorsal views of an alternative embodiment of the device related to that shown in Figure 26A;

Figurse 28A-28C are lateral views of the spine and the embodiment of the invention shown in Figure 10A showing an "insert and rotate" manner of introduction;

Figure 29 is a lateral view of the spine, the embodiment of the invention shown in Figure 12A, and a device to help prevent extrusion of the spinous process spacer;

Figure 30 is a view of the caudal aspect of the cranial vertebra shown in Figure 28C;

Figure 31 shows a dorsal view of the spine;

Figure 32A is a lateral view of the spine and the embodiment of the invention shown in Figure 12A;

Figure 32B is a lateral view of the spine and an alternative embodiment of the invention related to that shown in Figure 32A;

Figure 32C is a lateral view of the spine and an alternative multilevel embodiment of the invention related to that shown in Figure 32B;

Figure 33 is a lateral view of the spine and an alternative multilevel embodiment of the invention related to that shown in Figure 32C;

Figure 34 is a lateral view of the spine and an alternative embodiment of the invention related to that shown in Figure 12A;

Figures 35A-35B are lateral and dorsal views of the spine and an alternative multilevel embodiment of the invention related to that shown in Figure 20B;

Figure 35C is a dorsal view of an alternative embodiment of the invention related to that shown in Figure 20B;

Figure 35D is a dorsal view of the spine and a three-level version of the device shown in Figure 35B;

Figure 36A is a dorsal exploded view of the spine and an alternative embodiment of the device related to that shown in Figure 35B;

Figure 36B is dorsal view of the spine and the embodiment of the invention shown in Figure 36A;

Figure 37 is a lateral view of the spine and an alternative embodiment of the invention related to that shown in Figure 33;

Figures 38A-38B are lateral views of spine and an alternative embodiment of the invention related to that shown in Figure 12A;

Figure 38C is a lateral view of the spine and an alternative embodiment of the invention related to that shown in Figure 38B;

Figures 39A-39B are dorsal views of an alternative embodiment of the invention related to that shown in Figure 38C;

Figures 40A-40B are dorsal views of an alternative embodiment of the device related to that shown in Figure 39A;

Figure 40C is a lateral view of the spine and the embodiment of the device shown in Figure 40B being introduced;

Figures 41A-41C are oblique, lateral and dorsal views of an alternative embodiment of the invention related to that shown in Figure 10A;

Figure 42 is an oblique view of an alternative embodiment of the invention related to that shown in Figure 41C;

Figures 43A-43B are oblique views of an alternative embodiment of the invention related to that shown in Figure 41A;

Figures 44A-44B are oblique views of an alternative embodiment of the invention related to that shown in Figure 43A;

Figure 45 is an oblique view of an alternative embodiment of the invention related to that shown in Figure 44B;

Figure 46 is an oblique view of an alternative embodiment of the invention related to that shown in Figure 45;

Figures 47A-47B are oblique views of an alternative embodiment of the invention related to that shown in Figure 46;

Figures 48A-48B are oblique views of an alternative embodiment of the invention related to that shown in Figure 47A;

Figures 49A-49B are lateral views of an alternative embodiment of the invention related to that shown in Figure 10A;

Figure 49C is a lateral view of an alternative embodiment of the invention related to that shown in Figure 49A;

Figures 50A-50B are lateral and dorsal views of an alternative embodiment of the device related to that shown in Figure 49C;

Figure 50C is an oblique view of bones shaped to be connected in an alternative method according to the invention;

Figure 50D is a lateral view of an alternative embodiment of the device related to that shown in Figure 49C;

Figure 51A is an oblique view of an alternative embodiment of the invention related to that shown in Figure 10A;

Figures 51B-51C are dorsal and caudal views of the spine and the embodiment of the invention shown in Figure 51A;

Figure 52 is a dorsal view of the spine and an alternative embodiment of the invention related to that shown in Figure 51B;

Figure 53 is a dorsal view of the spine and an alternative embodiment of the invention related to that shown in Figure 52;

Figures 54A-54B are lateral and dorsal views of the spine and an alternative embodiment of the invention related to that shown in Figure 53;

Figure 55 is a dorsal view of the spine and an alternative embodiment of the device shown in Figure 54B;

Figures 56A-56B are dorsal and lateral views of the spine and an alternative embodiment of the invention related to that shown in Figure 10A;

Figure 57 is a dorsal view of the spine and an alternative embodiment of the invention related to that shown in Figure 56A;

Figure 58 is a lateral view of the spine and an alternative embodiment of the invention related to that shown in Figure 10A;

Figure 59 is a lateral view of the spine and the embodiment of the invention shown in Figure 10A;

Figures 60A-60B are lateral views of the spine and an alternative embodiment of the invention related to that shown in Figure 10A;

Figure 61 is a lateral view of the spine and an alternative embodiment of the invention related to that shown in Figure 10A;

Figures 62A-62B are dorsal views of the spine and an alternative embodiment of the invention related to that shown in Figure 10C;

Figures 63A-63B are lateral views of the spine and an alternative embodiment of the invention related to that shown in Figure 62A;

Figures 64A-64B are lateral views of the spine and an alternative embodiment of the invention related to that shown in Figure 63B;

Figures 65A-65B are dorsal views of an alternative embodiment of the invention related to that shown in Figure 10A;

Figures 66A-66B are oblique views of an alternative embodiment of the invention related to that shown in Figure 41A;

Figure 67 is a dorsal view of the spine and an alternative embodiment of the invention related to that shown in Figure 10A;

Figure 68 is a lateral view of the spine and an alternative embodiment of the device related to that shown in Figure 12A;

Figures 69A-69B are dorsal views of an alternative embodiment of the invention related to that shown in Figure 10A;

Figures 70A-70B are dorsal views of an alternative embodiment of the invention related to that shown in Figure 69A;

Figure 71 is a lateral view of the spine and an alternative embodiment of the invention related to that shown in Figure 45;

Figure 72A is lateral view of a knife-like instrument;

Figure 72B is a lateral view of the spine and the cutting tool shown in Figure 72A;

Figure 73A is a lateral view of a tool used to distract the spinous processes;

Figure 73B is a view of the one end of the distracting tool shown in Figure 73A;

Figure 73C is a lateral view of the tool shown in Figure 72A;

Figure 73D is a view of the dorsal aspect of two adjacent spinous processes and the end of the tool shown in Figure 73C;

Figure 73E is a dorsal view of two adjacent spinous processes and the tips of the tool shown in Figure 73D;

Figure 74A is a lateral view of a measuring tool;

Figure 74B is a view of a gauge that may be used on the handle of the instrument shown in Figure 74A;

Figure 75 is an oblique view of a sleeve;

Figures 76A-76B are lateral and dorsal views of the spine and the embodiment of the invention shown in Figure 12A;

Figures 77A-77B are lateral views of the distal region of an instrument;

Figure 77C is a lateral view of the distal region of the instrument shown in Figure 77A and a device according to the invention;

Figure 78A is a lateral view of the tip of a distractor tool;

Figure 78B is a dorsal view of the tips of two spinous processes and the tip of the distractor tool shown in Figure 78A;

Figures 79A-79B are dorsal views of the tip of a spinous process, a cross-section of a tool, and a cable;

Figures 80A-80C are lateral, dorsal, and cranial views of the spine and an alternative embodiment of the invention related to that shown in Figure 12A;

Figure 81 is a lateral view of the spine and an alternative embodiment of the invention related to that shown in Figure 80A;

Figure 82 is a caudal view including an alternative embodiment of the invention related to that shown in Figure 81;

Figure 83 is a caudal view including an alternative embodiment of the invention related to that shown in Figure 82;

Figure 84 is a lateral view of the spine and an alternative embodiment of the invention related to that shown in Figure 37;

Figure 85 is a dorsal view of the spine and an alternative embodiment of the invention shown in Figure 80A;

Figure 86 is a dorsal view of the spine and an alternative embodiment of the invention related to that shown in Figure 85;

Figures 87A-87B are dorsal views of the spine and an alternative embodiment of the invention related to that shown in Figure 85;

Figures 88A-88B are lateral and dorsal views of the spine an alternative embodiment of the invention related to that shown in Figure 20A;

Figures 89A-89B are lateral and dorsal views of the spine and an alternative embodiment of the invention related to that shown in Figure 88A;

Figures 90 is an exploded oblique view of an alternative embodiment of the invention related to that shown in Figure 10A;

Figures 90B-90D are various views of the assembled device shown in Figure 90A;

Figures 91A-91B are dorsal and coronal cross-sectional views of the spine and an alternative embodiment of the invention related to that shown in Figure 12A;

Figure 92A is an oblique view of a shim-like device;

Figure 92B is an exploded lateral view of the spine, shims, and an alternative embodiment of the invention related to that shown in Figure 89A;

Figure 92C is a dorsal view of the spine and the embodiment of the invention shown in Figure 92B;

Figures 93A-93B are lateral and dorsal views of the spine and an alternative embodiment of the invention related to that shown in Figure 61;

Figure 93C is a dorsal view of the spine and an alternative embodiment of the invention related to that shown in Figure 93B;

Figures 94A-94B are front and side views of the embodiment of the invention shown Figure 10A and a novel insertion tool;

Figures 94C-94H are lateral, dorsal, and cross-sectional views of the insertion tool shown in Figure 94B during use introducing the embodiment of the invention of Figure 10A into the spine;

Figures 95A-95D are lateral, dorsal, and cranial views of the spine, the embodiment of the invention shown in Figure 10A, and a second impactor tool;

Figures 96A-96B are cranial and lateral views of an alternative embodiment of the invention related to that shown in Figure 94A;

Figures 97A-97B are lateral and cranial views of an alternative embodiment of the invention related to that shown in Figure 73A;

Figure 97C is an oblique view of the embodiment of the invention shown in Figure 97A and one arm of a McCulloch retractor;

Figures 98A-98B are oblique and lateral views of an alternative embodiment of the invention related to that shown in Figure 20A;

Figures 99A-99B are dorsal and lateral views of the spine and an alternative embodiment of the invention including rods that connect components placed between spinous processes;

Figures 100A-100C are oblique, dorsal, and lateral views of an alternative embodiment of the invention related to that drawn in Figure 97A; and

Figures 101A-101C are coronal and sagittal cross sectional views and lateral views of an alternative embodiment of the invention drawn in Figure 93B.

DETAILED DESCRIPTION OF THE INVENTION

Figure 1A is a lateral view of a three-component device used to treat spinal stenosis, drawn in its extended position. The central rod component 102 is threaded 104, 106 on both ends. One end of the component has left-handed threads. The other end of the rod component has right-handed threads. Bolt-like components 108, 110 are threaded onto the ends of the rod component. As discussed in further detail below, the rod component is coupled to pedicle screws then adjusted to force the screws apart. This permits spinal flexion, but limits spinal extension, thereby distracting the spine and enlarging the spinal canal.

Figure 1B is a lateral view of the device of Figure 1A drawn in its contracted position. Tools are used to prevent rotation of the end components. A wrench may be used to rotate the rod component placed on flats 112. Rotating the rod component, while preventing rotation of the end components, causes the end components to advance along the treaded portions of the rod, simultaneously.

Figure 1C is an end view of a vertebral screw 120 and a cross section of the threaded portion 104 of the rod, which passes through an opening 122 in the screw. Figure 1D is an end view of the screw drawn in Figure 1C and a cross section of the threaded end component 110 drawn in Figure 1A. The larger diameter of the end component prevents the component from passing through the opening in the screw.

Figure 1E is an end view of an alternative embodiment of a screw having a mechanism 130 that permits a connector ring 132 to swivel about a shaft 134 of the screw.

Figure 1F is a lateral view of the device drawn in Figure 1A and the screws of the embodiment drawn in Figure 1C. The device is drawn in its extended position. The narrow diameters of the treaded portions of the rod component permit the device to be inserted through the openings in the screws. Figure 1G is a lateral view of the embodiment of the device drawn in Figure 1F. The rod-like device has been inserted into the screws. Figure 1H is a lateral view of the device drawn in Figure 1G. The device is drawn in its contracted position. Rotation of the rod-like component advances the end bolt-like components into the screws. The large diameter of the end components prevents the tightened rod component from passing through the slot-like openings in the screws.

Figure 1I is a sagittal cross section of the device drawn in Figure 1H. The hemispherical ends 140, 142 of the rod component 102 articulate with the donut-like opening of the screws. The drawing illustrates the spherical cross section of the connector portion of the screws. The cooperation between the rod component and the screws prevent the heads of the screws from approaching one another. The enlargements at the ends of the assembled device may also be used to limit spinal flexion. The devices according to this invention may be made of any suitable material, including titanium, chrome-cobalt, stainless steel, polymers, liquid metals, shape-memory materials, ceramics, or human tissue. The device may also include a spring component. For example, a coil spring could be placed around the rod component.

The following disclosure describes how the device may be used to enlarge the spinal canal. The screws are placed into the pedicles of adjacent vertebrae, or into vertebrae spaced apart by at least one intermediate vertebra. The rod component is installed, and the enlargements at the ends of the bolt-like end components prevent the assembled rod from dissociating from the screws. A rod component of the appropriate length is selected to force the screws apart. This distracts the spine and enlarges the spinal canal as the heads of the screws separate. The circular openings in the screws enable the screws to slide along the end components. This permits spinal flexion, but limits spinal extension, which enlarges the spinal canal. Spinal flexion occurs as the screws advance along the end components. Spinal extension decreases the diameter of the spinal canal and decreases the size of the neuroforamina.

Figure 2A is a lateral view of an alternative embodiment of the invention which has two rod-like components 202, 204. The rod components have a turnbuckle to allow lengthening and shortening of the rods. Each turnbuckle further includes a nut 206, 208 that permits the rod to be locked in a particular length. One end of the rod component is shaped somewhat like the end component drawn in Figure 1F. The rods are connected to one another by a cable 210.

Figure 2B is an exploded view of the device drawn in Figure 2A and an alternative embodiment of the vertebral screws, each using a ring-like closure mechanism 220, 222, 224. Figure 2C is a lateral view of the device drawn in Figure 2B. The device has been drawn in an assembled configuration. Figure 2D is an exploded end view of the screw 219 and a fastening component 220.

Figure 2E is end view of the screw and fastening component drawn in Figure 2D and a cross section of the rod-like device drawn in Figure 2C. The fastening component may be made of a shape memory material. Alternatively, the fastening component may be made of an elastic material that is stretched prior to inserting the component. The fastening ring contracts after it is placed over the head of the screw.

Figure 3A is a lateral view of an alternative embodiment of the invention, wherein the rod-like components are connected by a hinge joint 302. Figure 3B is a lateral view of the embodiment of the device drawn in Figure 3A. The rods are drawn in a different position than drawn in Figure 3A. Figure 3C is a view of the top of the device drawn in Figure 3B. Figure 3D is an enlarged view of the top of the hinge joint drawn in Figure 3C.

Figure 3E is an enlarged view of the top of an alternative hinge joint 310 oriented in a direction 312 that is not perpendicular to the axis 314 of the rod components. Figure 3F is a lateral view of the device drawn in Figure 3B and vertebral screws 320, 322, 324.

Figure 4A is an exploded lateral view of an alternative vertebral screw and a hinged device that passes through an angled slot 402 in the screw when the rods 404, 406 are angled properly. Figure 4B is a lateral view of the device with the rods area angled to pass the rods through the slot in the screw. Figure 4C is a lateral view of the device with the rods oriented such that they will not pass through the slot in the screw.

Figure 5A is a lateral view of an alternative embodiment wherein rod-like components 502, 504 are threaded over an elastic cord 506. The end components 508, 510 are connected to the elastic cord. The device is drawn in its extended position. The elastic cord is stretched in the extended position. Figure 5B is a lateral view of the device drawn in its contracted position. Figure 5C is an exploded view of the device drawn in Figure 5A and vertebral screws 512, 514, 516. The elastic cord passes through the slots in the vertebral screws. Figure 5D is a lateral view of the assembled device drawn in Figure 5C.

Figure 6A is an oblique view of an alternative embodiment of the invention in the form of a cylindrical device 602 having two slots 604, 606 in sides of the device. The ends of the tube shaped device may by open. Figure 6B is a lateral view of a portion of the spine. The supraspinous ligament 610 is attached to the dorsal surface of the spinous processes 612, 614 of two consecutive vertebrae. The interspinous ligament 620 courses between the spinous processes of the vertebrae. The intervertebral disc is depicted at 622 and the neuroforamina at 624.

Figure 6C is a lateral view of a portion of the spine and the device of Figure 6A, which has been wedged between the spinous processes. The supraspinous and interspinous ligaments have been removed. The device forces the spinous processes apart. The spine flexes as the spinous processes are forced apart. The neuroforamina and the spinal canal are enlarged as the spine is flexed. The device holds the vertebrae in a flexed position. The device may be made of any suitable materials, including bone, metals, ceramics, or polymers. For example, the device may be made from an allograft shaft of a long bone such as the humerus, tibia, fibula, radius, ulna, or femur. Alternatively, the device may be made of material known as PEEK.

Figure 6D is a lateral view of a portion of the spine and the device drawn in Figure 6A. The device has been filled with a material that promotes bone growth. For example, the device may be filled with bone, BMP soaked collagen sponges, or demineralized bone matrix. The device may fuse with one or both of the spinous processes. The device does not fuse with other portions of the vertebrae. For example, the device does not fuse across to the lamina of the vertebrae. The lamina of the vertebrae remain their normal size and shape. The lack of fusion across the lamina facilitates future surgical "decompression" procedures. The interspinous has been reconstructed. The area of the drawing at 630 represents the reconstructed interspinous ligament. Allograft tendon may be used to reconstruct the interspinous ligament. Other materials such as Gortex, Dacron, Marlex or other non-absorbable material may be used to reconstruct the interspinous ligament.

Figure 6E is an oblique view of a cancellous bone block 640 which may be placed into the device drawn of Figure 5A. Figure 6F is an oblique view of a section of the shaft 642 of a long bone. Figure 6G is an oblique view of a section of the shaft of a long bone and a cancellous bone block. The cancellous bone block has been placed into the cortical bone ring. Figure 6H is an oblique view showing two slots machined into the sides of the cortical bone ring. As with the embodiment of Figure 6A, the slots are shaped to fit over at least a portion of the spinous processes.

Figure 6I is lateral view of a portion of the spine and a sagittal cross section of the embodiment of the device drawn in Figure 6A or 6H. The dotted lines represent the outline of the cortical ring. The drawing illustrates holes 660, 662 in the spinous processes receive an allograft tendon. Allograft tissue could also be wrapped around the cranial aspect of the cranial spinous process and the caudal aspect of the caudal spinous process.

Figure 7A is an oblique view of a portion of a shaft of a long bone. Figure 7B is an oblique view of portion of a shaft of a long bone that has been machined to fit between two spinous processes. The bone has been machined to insert the device at an orientation ninety degrees to the orientation drawn in Figure 6I. Figure 7C is a lateral view of the spine and the device of Figure 7B which has been inserted between the spinous processes.

Figure 7D is an oblique view of a piece of bone with teeth machined or otherwise formed to facilitate insertion in a first direction and resist extrusion in a direction 180 degrees from the first direction. Figure 7E is an end view of the device drawn in Figure 7A and the bone drawn in Figure 7D which has been inserted into the device drawn in Figure 7B. The bone of Figure 7D may be fastened to the device of Figure 7B.

Figure 7F is a lateral view of a portion of the spine and a sagittal cross section of the embodiment of the device drawn in Figure 7E. The dotted lines represent the outline of the periphery of the device.

Figure 8A is an end view of an alternative shape of the device drawn in Figure 7B. Figure 8B is an end view of an alternative shape of the device drawn in Figure 8A. Figure 8C is an end view of an alternative shape of the device drawn in Figure 8B. Alternative shapes are possible, including solid forms.

Figure 9A is an oblique view of an alternative embodiment of the invention which has a single slot 902 on one side of the device 900. Figure 9B is a view of the top of the embodiment of the invention drawn in Figure 8A. Figure 9C is a lateral view of a portion of the spine and the embodiment of the invention drawn in Figure 9A. The device straddles a single spinous process 920. This embodiment of the device is designed to fuse to a single spinous process. Fusion to a single spinous process allows spinal flexion, but limits spinal extension. The invention anticipates embodiments of the device that do not fuse to either spinous process.

Figure 10A is an oblique drawing of an alternative embodiment of the invention related to that shown in Figure 6A. The device has chambers 1002, 1004 in the left and right sides of the cranial portion which may be filled with a material that promotes the growth of bone into the device. One or more openings may connect the two chambers.

The cranial end of the device also has openings that extend into the chambers. The openings provide a path for cells to migrate into the chambers.

The device has a notch 1010 on its cranial side which may or may not have teeth. The notch accommodates the Spinous Process (SP) of the cranial vertebra. The caudal end 1012 of the device preferably includes a concavity. As with the embodiment of Figure 6C, the device may be made of bone including allograft bone, metal such as titanium, PEEK (polyaryletherketone), or ceramic. Devices according to the invention may also me made of other biocompatible materials such as Polyphenolsulfone, Polysulfone, Acetal (Delrin), UHMW Polyethylene, and composites of these materials and carbon fibers. Alternative materials include bioresorbable materials such as polylactic acid (PLA), polyglycolic acid (PGA), poly (ortho esters), poly(glycolide-co-trimethylene carbonate), poly-L-lactide-co-6-caprolactone, polyanhydrides, poly-n-dioxanone, and poly(PHB-hydroxyvaleric acid).

Devices according to the invention are designed to withstand loads of at least 90N, and are preferably provided in a number of sizes. For example, the cranial-to-caudal dimensions could vary from 6mm-24mm in 2mm increments. The ventral-to-dorsal dimensions could also vary from 6mm-24mm, also in 2mm increments. The left-to-right dimensions could vary from 10-50mm, again in 2mm increments. Multi-level devices, similar to the embodiment shown in Figure 35D would be supplied in larger dimensions.

Figure 10B is a lateral view of a portion of the spine and the embodiment of the invention shown in Figure 10A. The device fits between the SP of two adjacent vertebrae 1020, 1022. The device distracts the spinous processes 1024, 1026. The device also causes relative flexion of the spine at the area of the spine treated with the device. The device has been filled with a bone growth promoting substance 1030. The bone growth material has also been applied to the lamina 1032 of the cranial vertebra 1020. A portion of the lamina of the cranial vertebra has been decorticated to facilitate migration of cells from the patient's bone to the bone growth material. The device is designed to fuse to the cranial vertebra. The lack of bone growth material at the caudal end of the device inhibits fusion to the caudal vertebra.

Figure 10C is a dorsal view of a portion of the spine and the embodiment of the invention shown in Figure 10A. The SP 1026 of the caudal vertebra 1022 fits into the concavity 1012 on the caudal end of the device. The SP 1024 of the cranial vertebra 1020 fits into the notch 1010 on the cranial end of the device. Bone growth material 1032 is shown in the cranial aspect of the device and the lamina, SP, and facets of the cranial vertebra.

Figure 10D is a sagittal cross section of the embodiment of the invention shown in Figure 10B and a lateral view of the spine. The bone growth material 1032 can be seen extending from the lamina and SP of the cranial vertebra into one of the chambers in the device. The bone growth material extends through the slots in the cranial aspect of the device and through the openings on the left and the right sides of the device.

Figure 10E is a sagittal cross section of the embodiment of the invention shown in Figure 10D and a lateral view of the spine. The spine has been flexed. A gap 1040 can be seen between the SP of the caudal vertebra and the caudal end of the device.

Figure 10F is a coronal cross section of the embodiment of the invention shown in Figure 10E and the spine. The device is seated between the spinous processes of the cranial and caudal vertebrae. The chambers that house the bone growth material can be seen on the left and right sides of the device. Bone growth material 1032 can be seen passing through the slots on the cranial aspect of the device. An opening could connect the chambers in the left and the right sides of the device.

Figure 11A is a dorsal view of the embodiment of the invention shown in Figure 10F and the spine. Figure 11B is a dorsal view of the embodiment of the invention shown in Figure 11A and the spine. The spine has been flexed beyond the flexion caused by the device. A gap 1040 forms between the device and the caudal SP. The device is fused to the cranial vertebra. Alternatively, the device could be fused to the caudal vertebra or both the cranial and caudal vertebrae.

Figure 12A is a lateral view of the spine and the embodiment of the invention shown in Figure 10A. The device has been connected to the SP of the cranial vertebra. A cable, strap, cable tie, wire, cord, suture or other member 1202 has been wrapped around the base or waist of the SP. Second and third strap members 1204, 1206 pass between the SP and the loop around the SP. The second and third strap members are looped through holes 1208, 1210 on the left and right sides of the cranial aspect of the device. The device is forced into the SP, lamina, and/or facet joints of the cranial vertebra. The strapping method prevents migration of the device. The strapping method also prevents or restricts movement between the device and the cranial vertebrae. Reducing movement between the device and the cranial vertebra facilitates fusion to the cranial vertebra. The caudal end of embodiments of the device that are made of allograft bone could be treated to discourage fusion between the device and the caudal vertebra. For example, bone wax could be applied to the caudal end of the allograft device. Alternatively, the caudal end of the device could be covered with an allograft soft tissue, such as fascia, to inhibit bone growth to the device. Synthetic materials could also be used to inhibit bone growth to a portion of the device.

Figure 12B is a dorsal view of the embodiment of the invention shown in Figure 12A and the spine. A cable 1202 has been wrapped around the SP 1224 of the cranial vertebra. The second and third cables 1204, 1206 can be seen passing through the left and right sides of the device. The second and third cables also pass between the SP and the first cable. The cable that is looped around the SP of the cranial vertebra is preferably passed between the interspinous ligament and the cranial aspect of the SP.

Figure 12C is a lateral view of the spine and the embodiment of the invention wherein a fourth cable, strap, cable tie, wire, cord, suture or other member 1242 has been passed around the SP 1224 of the cranial vertebra and through the device. The fastening devices are preferably made of non-absorbable material. Alternatively, fastening member 1242 could pass through a set of holes in the ventral portion of the device.

Figure 12D is a lateral view of the spine and an embodiment of the invention wherein a fourth member 1252 has been passed around the SP 1226 of the caudal vertebra and through the device. The fourth cable may be tightly tied or loosely tied to permit movement between the caudal vertebra and the device.

Figure 13A is a lateral view of the spine and an embodiment of the invention wherein a screw, nail, or pin 1302 has been passed through the SP 1326 of the caudal vertebra. A member 1304 has been passed through the device and around the SP 1326 of the caudal vertebra. The cable and the pin prevent migration of the device. The cable and the pin also prevent or restrict movement between the device and the caudal vertebra. The device and the fastening method are designed to fuse the device to only the caudal vertebra. The caudal aspect of the device has holes that extend from the lamina and SP of the caudal vertebra to the chambers inside the device. Bone growth material is placed into the device and over the caudal vertebra. The lamina and/or the SP of the caudal vertebra could be decorticated to promote fusion. Figure 13B is a dorsal view of the embodiment of the invention shown in Figure 13A and the spine.

Figure 14A is a lateral view of the spine and an alternative embodiment of the invention wherein screws 1402, 1404 pass through the caudal aspect of the device. A screw, pin, or nail 1406 also passes through the SP 1426 of the caudal vertebra. Note that transverse pin 1406 passes dorsal to one of the screws and ventral to the other screw. Figure 14B is a dorsal view of the embodiment of the invention shown in Figure 14A and the spine.

Figure 14C is a dorsal view of the spine and an embodiment of the invention wherein optional cables, sutures, wires, cable ties or like members 1420, 1422 have been wrapped around the screws and the pin. Bone growth material has been placed over the caudal aspect of the device and the SP and lamina of the caudal vertebra.

Figure 14D is a dorsal view of the spine and an alternative embodiment of the invention wherein crossing screws 1420, 1432 pass through the device.

Figure 15 is a lateral view of the spine showing an alternative method is used to fasten a device according to the invention to the cranial vertebra. A wire, cable, suture, or other single or multi-filament member 1502 is passed through the device and around or through screws 1504 placed into the pedicles of the cranial vertebra.

Figure 16 is a dorsal view of the spine showing an alternative method used to fasten a device according to the invention to the cranial vertebra. A wire, cable, suture, or other single or multi-filament member 1602 is passed through the device and around the transverse processes 1620, 1622 of the cranial vertebra.

Figure 17 is a dorsal view of the spine showing an alternative method used to fasten a device according to the invention to the cranial vertebra. A screw 1702 is passed through the device and through the cranial SP 1724. Alternatively, screws could be passed through the SP and the left and right sides of the device. The left and right sides of the device are preferably tapered.

Figure 18 is a lateral view of the spine illustrating an alternative method used to fasten a device according to the invention to the cranial vertebra. Member 1802 passes through the left and right sides of the device. The member also passes around the lamina of the cranial vertebra.

Figure 19 is a lateral view of the spine showing an alternative method used to fasten a device according to the invention to the cranial vertebra. Members 1902, 1904 pass through the left and right sides of the device. The members also pass around the cranial vertebra just cranial to the inferior facet joints 1920.

Figure 20A is a dorsal view of the spine and an alternative embodiment of the invention including a device 2002 that surrounds the SP of the cranial vertebra. The device impinges against the cranial aspect of the caudal vertebra. The device may be held in place by a pin 2004 that passes through the SP 2024 of the cranial vertebra. Figure 20B is a lateral view of the spine and the embodiment of the invention shown in Figure 20A. The device is preferably designed to fuse to the cranial vertebra.

Figure 21A is a dorsal view of the spine and an alternative embodiment of the invention 2102 which clamps to the cranial aspect of the SP of the caudal vertebra 2126. The device may also clamp to the cranial vertebra 2124, or both the caudal and cranial. The device may have spring properties that clamp the device to the SP. Alternatively, the device could be made of a shape memory material such as a Nitinol. The device could contract as it reacts to temperature change. Figure 21B is a dorsal view of the spine and the embodiment of the invention shown in Figure 21A. The device was shown in its clamped or contracted shape.

Figure 22 is a lateral view of the spine and an alternative embodiment of the invention 2202 attached to the SP 2226 of the caudal vertebra. A hinge joint 2204 connects the fastener to the portion of the device that contains the bone growth material. A screw 2206 passes through the fastener component and the SP.

Figure 23A is a lateral view of the spine and an alternative embodiment of the invention 2302 attached to the SP 2326 of the caudal vertebra. The device has a component 2306 that houses the bone growth material and a fastening component 2308. Figure 23B is a dorsal view of the spine and the embodiment of the invention shown in Figure 23A. A hook 2310 from the fastening component is placed over the caudal aspect of the SP of the caudal vertebra. The fastening component may be connected to the component that contains the bone growth material via a ratchet mechanism. The ratchet mechanism locks the components after the components are compressed together.

Figure 24A is an exploded dorsal view of the spine and an alternative embodiment of the invention including a spring-like clip 2402 that connects the device to the SP of the vertebra. Figure 24B is a dorsal view of the spine and the embodiment of the invention shown in Figure 24A. The spring-like component has been connected to the component 2406 that houses the bone growth material.

Figure 25A is a lateral view of the spine and an alternative embodiment of the invention having projections 2502, 2504 that extend from the left and right sides of the cranial portion of the device. The projections have concavities that may receive bone growth promoting substances. The projections lie over the lamina of the cranial vertebra. The lamina may be decorticated to facilitate fusion between the device and the cranial vertebra. Figure 25B is a dorsal view of the spine and the embodiment of the invention shown in Figure 25A.

Figure 26A is a lateral view of the spine and an alternative embodiment of the invention which has projections 2602, 2604 that extend from the left and right sides of the cranial portion of the device. Bone growth promoting substance has been packed around the projections. The projections have bristles that help hold the bone growth material. Figure 26B is dorsal view of the spine and the embodiment of the invention shown in Figure 26A. Figure 26C is a sagittal cross section of an alternative embodiment of the invention shown in Figure 26B. The projections 2602/4 swivel in holes on the cranial portion of the device.

Figure 27A is a lateral view of an alternative embodiment of the invention, wherein projections 2702, 2704 from the cranial aspect of the device are connected to the component 2706 that houses the bone growth material via hinge joints. Figure 27B is a dorsal view of the spine and the embodiment of the invention shown in Figure 27A. The projections are preferably perforated to promote bone growth for a firmer attachment. Whereas a friction-fit or the use of soft tissues such as ligaments may weaken with time, fusion provides a more permanent attachment mechanism.

Figure 28A is a lateral view of the spine illustrating one method of inserting a device according to the invention, including that shown in Figure 10A. The spinous processes 2802, 2804 of the cranial and caudal vertebra are distracted as the wedge-shaped device is forced between the spinous processes. In Figure 28B the spinous processes have been distracted by the device. In Figure 28C the device has been rotated 90 degrees. The spinous processes have been further distracted as the device cams open the interspinous space.

Figure 29 is a lateral view of the spine along with an embodiment of the invention, such as that shown in Figure 12A, including a device 2900 to help prevent extrusion of the spinous process spacer. The accessory device 2902 is strapped at 2904 to the SP of the cranial vertebra. A pin 2906 is placed through the SP dorsal to the strap 2904 of the accessory device 2902. The accessory device 2902 impinges against the dorsal aspect of the spacer device 2920 if the spacer device 2920 migrates in a dorsal direction.

Figure 30 is a view of the caudal aspect of the cranial vertebra shown in Figure 28C. The shaded area of the drawing represents possible contact points of the spinous process spacer shown in Figure 12A. The spinous process spacer may contact the SP, lamina, and/or inferior facets of the cranial vertebra. Figure 31 is a dorsal view of the spine. The shaded areas represent possible contact points of the spinous process spacer (SPS). The areas could be decorticated to promote fusion of the spinous process spacer to either or both vertebrae.

Figure 32A is a lateral view of the spine and the embodiment of the invention shown in Figure 12A. Spinous process spacers are used to distract two levels of the spine. Three or more spinous process spacers could be used to distract three or more levels of the spine. Figure 32B is a lateral view of the spine and a variation of the embodiment of the invention shown in Figure 32A. The caudal aspect of the cranial SPS has a concavity 3202. The strap 3204 from the caudal SPS 3200 fits in the concavity of the cranial SPS. The concavity avoids impingement of the strap from the caudal SPS between the cranial SPS and the intermediate SP.

Figure 32C is a lateral view of the spine and an alternative, multilevel embodiment of the invention. The cranial strap 3220 from the caudal SPS is passed through an opening in the cranial SPS. The method avoids impingement of the strap from the caudal SPS and the intermediate SP.

Figure 33 is a lateral view of the spine and an alternative, multilevel embodiment of the invention wherein SPS devices are connected to the cranial and caudal aspects of the SP of the intermediate vertebra. Both SPS devices 3302, 3304 are preferably fused to only the intermediate vertebra 3310. Cables are passed from the left and right sides of both SPS devices. The cables 3320, 3322 from the lateral aspects of the SPSs also pass through a cable 3340 wrapped around the SP of the intermediate vertebra.

Figure 34 is a lateral view of the spine and an alternative embodiment of the invention shown in Figure 12A. The strap that surrounds the SPS is widened along the cranial aspect of the SP.

Figure 35A is a lateral view of the spine and an alternative, multilevel embodiment of the invention related to that shown in Figure 20B. The device distracts two adjacent levels of the spine. Allograft bone embodiments of the device could be treated to prevent fusion to the SP of the cranial and caudal vertebrae. For example, the cranial and caudal aspects of the device could be covered with bone wax, polymer, or other substance that inhibits bone growth to the device. The ends of the device could be constructed of only cortical bone. The center of the device is designed to fuse to the posterior elements of the intermediate vertebra. The center portion of an allograft bone device could include cortical and cancellous bone. Bone-growth-promoting substances could be placed between the device and the posterior elements of the intermediate vertebra. The posterior elements of the intermediate vertebra could be decorticated to facilitate fusion. The posterior elements of the vertebrae caudal and cranial to the device would not be decorticated.

Figure 35B is a dorsal view of the spine and the embodiment of the invention shown in Figure 35A. The device distracts two levels of the spine. The device preferably allows spinal flexion, but limits spinal extension at both levels of the spine.

Figure 35C is a dorsal view of an alternative embodiment of the invention related to that shown in Figure 20B. The two-component device is snapped together around a SP. The device may be held together through components 3540, 3542 that plastically deform when they area assembled. Alternatively the components could be made of a shape memory material such as Nitinol. Figure 35D is a dorsal view of the spine and a three-level embodiment of the device shown in Figure 35B.

Figure 36A is a dorsal, exploded view of the spine and an alternative embodiment of the invention related to that shown in Figure 35B. The device has a slot 3602 that accommodates more than one SP. Figure 36B is dorsal view of the spine and the embodiment of the invention shown in Figure 36A, wherein a cross member 3604 has been fastened to the device. The cross member 3604 fits between two adjacent spinous processes.

Figure 37 is a lateral view of the spine and an alternative embodiment of the invention related to that shown in Figure 33. A SPS 3702 has been connected to the caudal aspect of the cranial vertebra 3704 and a SPS 3710 has been connected to the cranial aspect of the caudal vertebra 3712 in a two-level construct. The cranial SPS is preferably fused to the cranial vertebra and the caudal SPS is preferable fused to the caudal vertebra. The arrangement keeps each SPS from impinging on the strap of an adjacent SPS.

Figure 38A is an exploded lateral view of spine and an alternative embodiment of the invention related to that shown in Figure 12A. A component 3802 is attached to the dorsal aspect of the SPS. The two components 3802, 3804 have teeth along their mating surfaces. The teeth interdigitate to prevent movement of one component relative to the other component. A screw 3810 is used to connect the two components. The dorsal component 3810 helps prevent the SPS 3804 from rotating about the coronal axis of the spine. Rotation of the SPS about the coronal axis of the spine could reduce the distraction of the vertebrae. Figure 38B is a lateral view of the spine and the embodiment of the invention shown in Figure 38A. The assembled device has been attached to the SP using the technique taught with reference to Figure 12A.

Figure 38C is a lateral view of the spine and an alternative embodiment of the invention including a dorsal component 3830 attached to the SPS with a cable 3832. The dorsal component has a chamber. Bone or bone-growth promoting substances may be added to the chambers in both components of the device. Holes may pass between the chambers of both components.

Figure 39A is a dorsal view of an alternative embodiment of the invention with components 3902, 3904 seen on the left and right sides of the device which slide along a slot 3906 formed across the dorsal surface of the SPS. The lateral locations of the dorsal components prevent the dorsal components from impinging against the spinous processes during rotation of the device. As taught in reference to Figure 28C, rotation of the SPS in the coronal axis of the spine cams open the interspace.

Figure 39B is a dorsal view of the embodiment of the invention shown in Figure 39A. The components 3902, 3904 on the dorsal aspect of the device have been moved to the center of the device 3900. The dorsal components may be reversibly connected together. The components could snap together via portions of the components that plastically deform. Alternatively, the components could fasten together using shape-memory materials. The dorsal components are snapped together after the SPS is rotated to cam open the interspace. The connected dorsal components strike the spinous processes if the SPS is rotated after the components are connected. The configuration of the device prevents loss of distraction as the SPS is unable to rotate from the "cam" position.

Figure 40A is a dorsal view of an alternative embodiment of the invention which has two projections 4002, 4004 on the dorsal aspect of the device 4000. Figure 40B is a dorsal view of the embodiment of the invention shown in Figure 40A. A cord 4010 has been wrapped around the projections on the dorsal aspect of the device. The cord is preferably an elastic band. Figure 40C is a lateral view of the spine and the embodiment of the device shown in Figure 40B. The band 4010 controls rotation of the device about the coronal axis of the spine. The band strikes the SP if the SPS is rotated about the coronal axis of the spine. The SPS may be rotated about the coronal aspect of the spine before the band is added to the device. The band is added to the device after the SPS is rotated into place.

Figure 41A is an exploded oblique view of an alternative embodiment of the invention may of allograft bone. The large cylinder 4102 could be made from the shaft of a long bone. The tibia, humerus, femur, radius, ulna, fibula, metatarsal, metacarpal, rib, pelvic bone, phalanges or other bones may be used to construct the device.

Figure 41B is a lateral view of the embodiment of the device shown in Figure 41A. A bone dowel 4104 has been placed through holes in the bone components 4110, 4112 that project from the cylinder shaped bone. The bone dowel holds the assembled bone SPS together. Figure 41C is a dorsal view of the embodiment of the invention shown in Figure 41B.

Figure 42 is an oblique view of an alternative embodiment of the invention machined from the shaft of a single long bone. The ventral aspect 4204 of the SPS 4202 is open. The large opening on the ventral aspect of the SPS prevents the SPS from protruding into the spinal canal. Holes such as 4210 are drilled into the sides of the device. The holes can be used attach the SPS to the spine with suture or cables.

Figure 43A is an exploded oblique view of an alternative embodiment of the invention similar to that shown in Figure 41A. Figure 43B is an oblique view of the device shown in Figure 43B. Bone dowels 4302, 4304 are used to hold a rectangular or trapezoid shaped bone piece 4306 within a cylinder shaped bone 4308. The central bone component acts as a beam or column to strength the cylindrical bone.

Figure 44A is an exploded oblique view of an alternative embodiment of the invention similar to that shown in Figure 43A. Figure 44B is an oblique view of the SPS shown in Figure 44A. A smaller bone 4402 is placed inside a larger bone 4404. The bones are held together with a bone dowel, screw, nail, staple, or other component 4406. For example, a portion of the shaft of a metatarsal bone could be placed inside a portion of the humerus.

Figure 45 is an oblique view of an alternative embodiment of the invention shown in Figure 44B. The device is manufactured by assembling the shafts of two bones 4502, 4504 that have been split along their longitudinal axes. The bones may be held together by bone dowels or other components 4506. The radius of one side of the assembled SPS is larger than the radius of the other side of the SPS.

Figure 46 is an oblique view of an alternative embodiment wherein the shaft of a first bone 4602 has been placed into a portion of the shaft 4604 of a second bone. The larger bone has been split along its longitudinal axis. The smaller one projects through the opening in the larger bone. The assembled SPS can be held together with bone dowels or other fastening mechanism 4706.

Figure 47A is an exploded, oblique view of an alternative embodiment of the invention. Figure 47B is an oblique view of the embodiment of the invention shown in Figure 47A. Projections 4702, 4704 from one bone component 4710 fit into slots (not visible) in a second bone component 4720. Two or three pieces of bone are used to assemble the completed device, as shown in Figure 47B. Other shapes of the assembled SPS can be manufactured by assembling more than three bones.

Figure 48A is an exploded oblique view of an alternative embodiment of the invention wherein a first bone component 4802 is inserted into a slot of a second bone component 4804. Figure 48B is an oblique view of the embodiment of the SPS shown in Figure 48A. The bone components may be held together with bone pins 4806 on either slide of the slot within one of the bones. The shape of the SPS manufactured from two bones may be varied by changing the size of the bone components or the location and/or size of the slots within one of the components. Alternatively, the device could be manufactured with more than two bone components. For example a first bone component could be manufactured with two slots to receive two other bone components. A composite device could be constructed with bone and one or more other materials. For example, the device could be assembled from components made of bone and components made of PEEK.

Figure 49A is lateral view of an alternative embodiment of the invention related to that shown in Figure 10A. Figure 49B is an exploded lateral view of the embodiment of the device shown in Figure 49A. The device is assembled from pieces of bone 4904 that are stacked, machined, and pinned together. The pieces of bone are preferably pinned together with other pieces of bone 4910. Figure 49C is a lateral view of an alternative embodiment of the invention similar to that shown in Figure 49A. The pieces of bone have teeth 4920 on the dorsal and ventral surfaces where the pieces of bone contact with one another. The teeth interdigitate to improve the strength of the assembled bone SPS device.

Figure 50A is lateral view of an alternative embodiment related to the device shown in Figure 49C which is assembled from multiple pieces of bone. The device may be constructed from machined pieces of cortical bone 5002 and pieces of cancellous bone 5004. Cortical bone is used to enable the device to receive loads from the vertebrae, whereas cancellous bone is used to facilitate fusion of the device to a single vertebra.

Figure 50B is a dorsal view of the embodiment of the invention wherein the bone components are pinned together. Projections 5010 from bones fit into recesses in other bone components.

Figure 50C is an oblique view of bones shaped to be connected in an alternative method than used in the device shown in Figure 50A. Rectangular projections 5020 and slots 5022 are machined into the bones.

Figure 50D is a lateral view of an alternative embodiment which has been constructed by assembling bones shaped like the bones in Figure 50C. The pieces of bone may be assembled much like the pieces of wood are assembled in Jenga puzzles. The assembled bones could be pinned to hold the bones together.

Figure 51A is an oblique view of an alternative embodiment of the invention related to that shown in Figure 10A. Figure 51B is a dorsal view of the spine and the embodiment of the invention shown in Figure 51A. The V- or U-shaped device 5102 is designed to fit between the SP of the L5 vertebra and the sacrum. Screws 5104, 5106 connect the device to the sacrum. Bone-growth promoting material is placed over or in the device. Bone-growth material is also preferably placed on to the sacrum. The device is designed to fuse to the sacrum. The device may be made of bone, metal, ceramic, polymers, or other material. Figure 51C is a caudal view of the embodiment of the device shown in Figure 51A. Screws 5104, 5106 may be seen within the device. The screws may course in different directions. For example, the screws may converge. The device may be used in other levels of the spine. The screws may be placed into the pedicles of the vertebrae.

Figure 52 is dorsal view of the spine and an alternative embodiment of the invention 5202 similar to that shown in Figure 51B, which is connected to screws 5204, 5206 placed into the pedicles of the vertebra. The device may be made of metal, bone, ceramic, or polymers. The device may be fused to one of the vertebrae. Alternatively, the device may be used without promoting fusion to either vertebra.

Figure 53 is a dorsal view of the spine and a version of the invention shown in Figure 52. The device 5302 has been connected to screws 5304, 5306 placed into the pedicles of one of vertebrae 5310. The device is designed for use in patients who have undergone removal of one or more spinous processes. A "bumper" component 5312 has been placed over a component that courses from one pedicle screw to the other pedicle screw. The various components may be made of a polymer, metal, or bone.

Figure 54A is a lateral view of the spine and an alternative embodiment of the invention shown in Figure 53. Screws 5404, 5406 are placed into the pedicles of vertebrae 5410. The screws are placed through portions of the superior facets of the caudal vertebra. The inferior facets of the cranial vertebra impinge against the screws. The screws are placed after the spine is flexed. The screws allow spinal flexion but limit spinal extension.

Figure 55 is a dorsal view of the spine and an embodiment of the invention 5500 shown in Figure 10A having been placed between the spinous processes 5502, 5504 of two vertebrae. The bone growth material extends into the facet joints between the two vertebrae. The bone growth material and the subsequent fusion mass cooperate with the SPS device to limit spinal extension.

Figure 56A is a dorsal view of the spine and an alternative embodiment of the invention wherein paired devices 5602, 5604 are placed along the left and right sides of the dorsal aspect of the vertebrae. Figure 56B is a lateral view of the spine and the embodiment of the invention shown in Figure 56A. The devices fit over the caudal aspect of the lamina of the cranial vertebra and the cranial aspect of the lamina of the caudal vertebra.

Figure 57 is a dorsal view of the spine and an alternative embodiment of the invention 5702 adapted to fit over the caudal aspect of the lamina 5704 of the cranial vertebra and the SP and/or lamina of the caudal vertebra 5706. The device distracts the vertebra and limits extension of the spine.

Figure 58 is a lateral view of the spine and an alternative embodiment of the invention related to that shown in Figure 10A. The dorsal and ventral surfaces of the cranial end of the device have concavities 5802, 5804 to receive bone-growth-promoting material (not shown).

Figure 59 is a lateral view of the spine and the embodiment of the invention related to that shown in Figure 10A. A tube 5902 passes from a hole in the pedicle 5904 of the vertebra to the concavity 5906 of the device 5908. The tube 5902 facilitates the migration of cells from the body or pedicle of the vertebra to the bone growth promoting material. Alternatively, cells obtained from aspirating the vertebra or other bone may be added to the bone growth material in the device.

Figure 60A is a lateral view of the spine and an exploded, lateral view of an alternative embodiment of the invention including a semi-cylindrical component 6002 with a hinge joint 6004 is placed between the spinous processes of two adjacent vertebrae 6010, 6012. Figure 60B is a lateral view of the spine and the embodiment of the invention shown in Figure 60A. A rod 6020 has been placed into the hinged semi-cylindrical component. The rod component expands the hinged component and distracts the spine. Spring-like properties of the hinged component or shape-memory properties of the components could be used to fasten the components.

Figure 61 is a lateral view of the spine and an alternative embodiment of the invention related to that shown in Figure 10A. A component 6102 attached to one SP impinges against a component 6104 attached to a SP of an adjacent vertebra. The components may be attached to the spinous processes using the method taught in Figure 12A. The components could be made of metal, polymers, ceramic, bone, fabric or combinations thereof.

Figure 62A is a dorsal view of the spine and a further alternative embodiment of the invention related to that shown in Figure 10C. Two wedge-shaped components 6202, 6204 are connected and inserted between the spinous processes of two adjacent vertebrae. Figure 62B is a dorsal view of the spine and the embodiment of the invention shown in Figure 62A. The wedge components 6202, 6204 have been urged together so as to increase the width of the device in the cranial-to-caudal direction, thereby distracting the vertebra. The components could be drawn together with screws. Alternatively, the components could be forced together with pliers. The components could be locked in the compressed position using screws or other fasteners, plastic deformation technology, or shape-memory technology.

Figure 63A is a lateral view of the spine and a variation of the embodiment of the invention shown in Figure 62A. Figure 63B is a lateral view of the spine and the embodiment of the device shown in Figure 63A. Two components 6302, 6304 are compressed together after placing the device between the spinous processes 6310, 6312 of adjacent vertebrae. The device distracts the spine as the components are forced together. The components may be locked in their compressed position.

Figure 64A is a lateral view of the spine and different configuration of the invention shown in Figure 63B. Figure 64B is a lateral view of the spine and the embodiment of the invention shown in Figure 64A. The device distracts the spine as the components 6402, 6404 are forced apart. The components may be locked in their extended position.

Figure 65A is a dorsal view of an alternative embodiment of the invention related to that shown in Figure 10A. Figure 65B is a dorsal view of the embodiment of the device shown in Figure 65A. The two components 6502, 6504 of the device articulate at the joint between the components. The positions of the components may be changed by rotating one component relative to the second component. A screw 6510 may be used to lock the components in a desired position.

Figure 66A is an exploded oblique view of an alternative embodiment of the invention related to that shown in Figure 41A. The device is preferably made of bone. Figure 66B is an oblique view of the device shown in Figure 66A. Projections 6602, 6604 from the central component 6610 are forced into holes 6620, 6622 in the lateral components 6630, 6632.

Figure 67 is a dorsal view of the spine and an alternative embodiment of the invention related to that shown in Figure 10A. The cranial aspect of the device 6702 is made of a resorbable material designed to resorb after the device fuses to one of the vertebrae.

Figure 68 is a lateral view of the spine and an alternative embodiment of the device related to that shown in Figure 12A. A compressible, resilient or elastic component 6802 is attached to the caudal end of the device. The component 6802 dampens loads across the device.

Figure 69A is a dorsal view of an alternative embodiment of the invention. Components 6902, 6904 on the left and right side of the device are connected with a hinge joint 6906. The components are also connected with one or more elastic bands. Compression on the caudal end of the device hinge the two components open. The device dampens loads applied by the spinous processes. Figure 69B is a dorsal view of the device shown in Figure 69A. The device has been partially opened to show the bands 6910.

Figure 70A is a dorsal view of an alternative embodiment of the invention similar to that shown in Figure 69A. Figure 70B is a dorsal view of the device shown in Figure 70A. The components 7002, 7004 on the left and right sides of the device are connected with two or more elastic cords 7010, 7012. The device is shown in its opened position. The device may be opened by forces from the spinous process adjacent to the device. The device dampens loads applied by the spinous processes.

Figure 71 is a lateral view of the spine and an alternative embodiment of the invention utilizing components preferably made from the shafts of bones. The bone components 7102, 7104 may be pinned in the configuration illustrated in the figure.

Figure 72A is lateral view of a knife-like instrument 7202 that may be used to cut the ligaments between the spinous processes. The cutting surface of the knife is shown at 7210. Figure 72B is a lateral view of the spine and the cutting tool shown in Figure 72A. The device 7202 has partially severed the interspinous ligament 7210. The device cuts the ligament as it is pulled away from the spinal canal.

Figure 73A is a lateral view of a tool 7302 used to distract the spinous processes. Figure 73B is a view of the one end of the distracting tool shown in Figure 73A. Fabric or elastic bands 7310, 7312 connect the tips 7330, 7332, 7334, 7336 of the tool.

Figure 73C is a lateral view of the tool, and Figure 73D is a view of the dorsal aspect of two adjacent spinous processes and the end of the tool shown in Figure 73C. The fabric bands 7310, 7312 fit between the spinous processes 7340, 7342. The thin bands conform to the shape of the spinous processes while applying pressure over a large area. The flexibility and the size bands protect the spinous processes from injury during spinal distraction.

Figure 73E is a dorsal view of two adjacent spinous processes and the tips of the tool shown in Figure 73D. The drawing illustrates the tool distracting the spinous processes 7340, 7342. The handle of the tool may include a gauge (not shown) that measures the force applied to the tool or the distance the tips of the tools have opened. The method may include distracting the spinous processes a certain distance (for example, 5mm), a certain percent (for example 20%) or until a certain amount of force is applied (for example, 20 inch/ pounds).

Figure 74A is a lateral view of a measuring tool 7400 having tips 7402, 7404 that are placed into the interspinous space. The tool may be used to distract the spinous processes and measure the distance between the spinous processes. The information may be used to determine the proper size of the device to be inserted between the spinous processes. Figure 74B is a view of a gauge 7410 used on the handle of the instrument shown in Figure 74A. The gauge suggests the proper size of the SPS device to insert between the spinous processes.

Figure 75 is an oblique view of a sleeve 7500 according to the invention that may be placed over the cables used in embodiments of the invention including that shown in Figure 12A.

Figure 76A is a lateral view of the spine and the embodiment of the invention shown in Figure 12A. A cable 7602 has been looped around the SP of the cranial vertebra. The cable also surrounds cable 7604 loops that attach to the left and right sides of the device 1200. The cables on the left and right sides of the device are tightened after the device is placed between the spinous processes. Figure 76B is a dorsal view of the spine and the embodiment of the invention shown in Figure 76A.

Figure 77A is a lateral view of the tip of an instrument 7702 that may be used to hold the SPS device. Figure 77B is a lateral view of the tip of the instrument shown in Figure 77A. A retractable member 7704 is shown in its retracted position. Figure 77C is a lateral view of the tip of the tool shown in Figure 77A and a SPS device. A projection 7710 from the tool is placed into a hole on the lateral side of the SPS device. The retractable arm 7704 passes over the other side of the SPS, thus holding the SPS device in the tool.

Figure 78A is a lateral view of the tip 7802 of a distractor tool 7804 according to the invention. Figure 78B is a dorsal view of the tips of two spinous processes 7810, 7812 and the tip of the distractor tool shown in Figure 78A. The wedge shaped distractor tool is forced between adjacent spinous processes to wedge the spinous processes open.

Figure 79A is a dorsal view of the tip of a SP 7902, a cross section of an inventive tool 7904, and a cable 7906. The tool is used to prevent over tightening the lower cable in the embodiment of the invention shown in Figure 12D. Figure 79B is a dorsal view of the tip of a SP, the cross section of the tool shown in Figure 79A and a cable. The tool has been rotated 90 degrees. Rotating the tool allows removal of the tool. Removing the tool provides sufficient slack in the cable to allow the SPS device to move away from the caudal vertebra.

Figure 80A is a lateral view of the spine and an alternative embodiment of the invention related to that shown in Figure 12A. The SPS 8002 is attached to the dorsal portion of the SP 8004 of the cranial vertebra. A cable, cord, wire suture or other flexible member(s) 8010 pass through a hole 8012 in the SP. The flexible member "bridle" 8020 also attaches to the left and right sides of the SPS. For example, a cable could pass through hole(s) 8030 in the SPS. This dorsal cable and attachment mechanism prevents the SPS from migrating into the spinal canal. The invention may be particularly helpful in patients treated with unilateral or bilateral laminotomies and/or partial facetectomies. A portion of the caudal end of the lamina is removed during laminotomies. The medial portions of the facet area removed during partial facetectomies. Facetectomy and laminotomy enlarge the spinal canal. The invention helps prevent SPSs from falling into the enlarged opening into the spinal canal. A sleeve could be used to increase the surface area of the cable. The sleeve could fit over the cable where the cable passes through the hole in the SP. Alternatively, a grommet could be placed into the hole in the SP.

Figure 80B is a dorsal view of the spine and the embodiment of the invention shown in Figure 80A. The bridle cable 8010 passes from one side of the SPS, through a hole in the SP, to the other side of the SPS. The cables and methods illustrated in Figure 12A were not shown to better illustrate the bridle cable. Figure 80C is a cranial view of the embodiment of the SPS shown in Figure 80A. The circles 8040, 8042 on the left and right sides of the dorsal portion of the SPS are designed to accept the ends of the bridle cable.

Figure 81 is a lateral view of the spine and an alternative embodiment of the invention wherein a portion 8102 of the SPS 8104 extends over the dorsal aspect of the SP. The dorsal aspect of the SP could be notched to help prevent the SPS from sliding off of the SP. Alternatively, the SPS may have a projection that extends over the SP of the caudal vertebra or the spinous processes of the cranial and the caudal vertebrae. Additional embodiments may use a harness, bridle, or mesh that extends from the left and right sides of the SPS and over one or more spinous processes. Alternatively, the invention could use a single member that extends from one side of the SPS to the SP. The unilateral embodiment of the invention is preferably placed on the side of the unilateral "hemi" laminotomy.

Figure 82 is a caudal view of a SPS and an alternative embodiment of the invention related to that shown in Figure 81. A projection including a hook 8202 from the SPS 8204 passes through a hole in the SP 8210.

Figure 83 is a caudal view of an alternative embodiment of the invention similar to that shown in Figure 82. Cables or other members 8302, 8304 pass from the sides of the SPS 8300 to a member 8310 that was placed into a hole in the SP. The cables or other members that pass through the SP could be made of bone, metal, ceramic, plastic, or other material. The component 8310 that passes through a hole in the SP preferably is made of a material that allows the patient's bone to grow into the component.

Figure 84 is a lateral view of the spine and a variation of the embodiment of the invention shown in Figure 37. The cable that connects the caudal SPS to the SP of the intermediate vertebra passes through a hole 8406 in the SP of the intermediate vertebra 8410. The hole in the SP is preferably located in the center of the SP. Alternatively, the cable could pass through another portion of the intermediate vertebra. For example, the cable could pass through holes in the lamina.

Figure 85 is a dorsal view of the spine and an alternative embodiment of the invention related to that shown in Figure 80A. The SPS 8502 has a projection 8504 from the cranial portion of the device. The projection extends over a portion of the lamina cranial to laminotomy defect. Projections could extend from the left and right sides of the SPS. A unilateral projection could extend from the SPS on the side of the laminectomy. Alternatively, a unilateral projection could extend from the SPS on the side contralateral to the laminectomy. Figure 86 is a dorsal view of the spine and an alternative configuration of the invention shown in Figure 85. The projection 8602 from the cranial portion of the SPS is connected to a screw 8604. The screw is preferably placed into on of the pedicles of the cranial vertebra.

Figure 87A is a dorsal view of the spine and an alternative embodiment of the invention related to that shown in Figure 85. The drawing illustrates a retractable projection member 8702 in its retracted position. Figure 87B is a dorsal view of the spine and the embodiment of the SPS shown in Figure 87A. The member 8702 is shown in its extended position. The projection member may locked in the extended position.

Figure 88A is a lateral view of the spine an alternative embodiment of the invention related to that shown in Figure 20A. The SPS device 8802 has two or more holes or chambers 8810 that may be filled with bone or bone growth promoting material. The device could be attached to the spine in the method taught in reference to Figure 12A. As with most other embodiments described herein, the device may be constructed of bone, metal, polymer, ceramic, or other material. The circle with dots represents a chamber in the side of the device. Figure 88B is a dorsal view of the spine and the embodiment of the invention shown in Figure 88A.

Figure 89A is a lateral view of the spine and an alternative embodiment of the invention related to that shown in Figure 88A. The device 8800 fits over SP 8802 and distracts two sets of adjacent spinous processes. Pin 8804 may be used to hold the device in place, and holes/apertures 8810 may be provided for bone ingrowth. Figure 89B is a dorsal view of the spine and the embodiment of the invention shown in Figure 89A.

Figure 90A is an exploded oblique view of an alternative embodiment of the invention related to that shown in Figure 10A. Openings 9002, 9004 on the left and right side of the device 9000 may be optionally closed with additional components 9012, 9014. The additional components may be screwed into the openings in the sides of the device. Alternative mechanisms may be used to fasten the side components to the device. Bone or bone-growth promoting substances may be placed into the device before fastening the side components. Tether fastening components may be passed through the bone in-growth holes on the cranial portion of the device.

The bone in-growth holes are limited to the cranial portion of the assembled device. Alternatively, the in-growth holes may be limited to the caudal portion of the device, the ventral portion of the device, the dorsal portion of the device, or any combination of two, three, or more portions of the device. The invention may also include one component device that does not have holes on the left and/or the right sides of the device. Figure 90B is a lateral view of the assembled device shown in Figure 90A. Figure 90C is an anterior view of the assembled device shown in Figure 90B. Figure 90D is coronal cross section of the assembled device shown in Figure 90C.

Figure 91A is a dorsal view of the spine and an alternative embodiment of the invention related to that shown in Figure 12A. Components 9102, 9104 from one end of the device 9100 pass over the cranial end of the cranial SP or the caudal aspect of the SP caudal to the device. The components may be tightened to force the device against the SP or lamina. Forcing the device against the SP, or lamina, eliminates movement between the device and the posterior elements of the spine the device is attached to.

Figure 91B is a coronal cross section of the spine and the embodiment of the device shown in Figure 91A. The fixation components may be locked in the tightened position. For example, the fixation components may include nuts 9110, 9112 that is threaded onto the component. The loose fit between the fixation component and the device allow the fixation components to swivel within the holes of the device. The device may have spherical recesses to receive the nuts of the fixation components.

Figure 92A is an oblique view of a shim-like device 9200 used to improve the fit between an interspinous device and the SP. The device is preferably made of bone. A portion of the device may be removed after the device is inserted between the interspinous device and the SP. The shim may also be made of metal, polymers (including PEEK), ceramic, or other material. The shims may be supplied in many different sizes and shapes.

Figure 92B is an exploded lateral view of the spine, shims 9200, 9200', and an alternative embodiment of the invention similar to that shown in Figure 89A. Shims 9200, 9200' fit between the SPS and the SP 9210. The SPS is designed to fuse to the posterior elements of the intermediate vertebra. The cranial and caudal ends of the device are sloped to fit the lamina of the cranial and caudal vertebra, respectively.

Figure 92C is a dorsal view of the spine and the embodiment of the invention shown in Figure 92B. A shim 9200 can be seen between the lateral aspect of the SP and the SPS and a shim 9200' can be seen between the caudal aspect of the SP and the SPS. Bone or bone growth promoting material may be placed in the openings between the SPS, the SP and the shims. Bone or bone-growth promoting substances may also be placed in the chambers of the SPS, over the SPS, and around the posterior elements of the intermediate vertebra. The hole in the device may be customized at the time of surgery. For example, surgeons could use power burs to enlarge the hole in the device. The enlarged hole would enable surgeons to place the device over abnormally large or deformed spinous processes.

Figure 93A is a lateral view of the spine and an alternative embodiment of the invention (see also Figure 61). The two components 9300, 9302 of the device have chambers 9310, 9312. Bone or bone-growth promoting substances may be placed in the chambers and between each component and the SP the component partially surrounds. The cranial component 9300 is designed to fuse to the SP of the cranial vertebra. The caudal component 9302 is designed to fuse to the SP of the caudal vertebra.

Figure 93B is a dorsal view of the spine and the embodiment of the invention shown in Figure 93A. The components cooperate to limit spinal extension, lateral bending, and/or axial rotation. The components allow spinal flexion. The device decreases the loads across the facet joints. Decreasing the loads may decrease back pain from arthritic facet joints.

The articulating surfaces of the components may be shaped in many different ways without departing from the spirit of the invention. Figure 93C is a dorsal view of the spine and an alternative embodiment of the invention wherein the articulating surfaces of the components 9330, 9332 are shaped differently.

Figure 94A is a view of the cranial side of the embodiment of the SPS shown Figure 10A and a tool 9400 used to facilitate insertion of the SPS. The tool has two components. An impactor component 9402 passes through a cylindrical opening in a second component 9404. The SPS 9440 fits into a U-shaped opening in the side of the second component 9404. A projection (not visible) from the tip of the impactor component fits into a hole in the dorsal side of the SPS. A projection (also not visible) from the base of the U of the second component fits into a hole on the side of the SPS.

The ventral surface of the SPS lies on one of the arms of the U-shaped component. The impactor component pistons inside the second component. The impactor component is advanced into the hole of the SPS to reversibly lock the SPS in the instrument. The impactor component can be reversibly locked in the second component. For example, a spring-loaded ring could be moved from one position to the next to reversibly lock the two components. Alternatively, a nut could be advanced along the impactor component to reversibly lock the impactor component to the second component. Figure 94B is a side view of the embodiment of the invention shown in Figure 94A. The ventral arm 9450 of the U-shaped end of the second component is wedge-shaped in cross section.

Figure 94C is a lateral view of the spine and the embodiment of the invention shown in Figure 94B. Figure 94D is a lateral view of the spine and the embodiment of the invention shown in Figure 94C. The tool and the SPS are impacted between adjacent spinous processes. The wedge-shaped end of the tool separates the spinous processes as the tool is advanced between the spinous processes. The impactor component of the tool may be struck with a mallet to advance the tool and the SPS between the spinous processes.

Figure 94E is an exploded lateral view of the spine and the embodiment of the invention shown in Figure 94D. The tool has been removed from the SPS. The SPS maintains distraction of the spinous processes. Distraction of the spinous processes by the SPS enables the wedge-shaped end of the tool to be easily removed from between the spinous processes. The impactor component of the tool is withdrawn from the SPS to enable the U-shaped second component to slide off the SPS. Figure 94F is an exploded view of the caudal end of a vertebra, a SPS, and the embodiment of the tool shown in Figure 94E. The tool 9400 has been removed from the SPS 9440.

Figure 94G is a dorsal view of the spine and the embodiment of the invention shown in Figure 94F. The impactor component of the tool was not shown. Projections 9460, 9462 from the cranial and/or caudal sides of the U-shaped component of the tool fit along the sides of the Spinous processes. The projections help center the SPS between the spinous processes. Alternatively, two projections may project from both the cranial and caudal sides of the tool. The projects could straddle both sides of the spinous processes cranial and caudal to the SPS. The notch in the SPS also helps center the SPS relative to the spinous processes.

Figure 94H is a cross section of the embodiment of the invention shown in Figure 94A. The impactor component is depicted at 9460, and the SPS is shown at 9462. The component with the wedge component is represented at 9400.

Figure 95A is a lateral view of the spine, the embodiment of the SPS shown in Figure 10A, and a second impactor tool 9502 used to advance the SPS 9504 towards the spinal canal. The tool may used after initial placement of the SPS by the tool shown in Figure 94A. Figure 95B is a dorsal view of the spine and the embodiment of the invention shown in Figure 95A. Like the tool shown in Figure 94G, optional projections 9560, 9562 help center the SPS in the sagittal plane of the spine. Figure 95C is a lateral view of the tool shown in Figure 95A. The projection 9570 from the ventral end of the tool fits into a hole in the dorsal side of the SPS. Figure 95D is a view of the cranial side of the tool shown in Figure 95C.

Figure 96A is a cranial view of an alternative configuration of the invention shown in Figure 94A, wherein the arm 9602 that connects the wedge component to the shaft of the instrument passes cranial to the SPS. Alternatively, the connecting arm may pass on the caudal side of the SPS. The piston component is threaded into the shaft of the second component. A nut 9620 may used to reversibly lock the components together. The SPS is represented by the area of the drawing with vertical and horizontal lines. Figure 96B is a lateral view of the embodiment of the invention shown in Figure 96B.

Figure 97A is a lateral view of an alternative embodiment of the invention related to that shown in Figure 73A. L-shaped components 9702, 9704 fit over the arms of distraction or retraction devices. For example, the L-shaped components may fit over the arms of a "McCulloch" retractor (V. Mueller Company). Flexible bands are indicated at 9706, 9708. The distraction components could be designed to fit into other instruments such as the "Caspari Distractor".

Figure 97B is an exploded cranial view of the embodiment of the invention shown in Figure 97A. The flexible band 9706 fits over the arms of the distraction component. Screws 9720, 9722 may be used to prevent the flexible band from sliding off the distraction component. Alternatively, a Velcro strap could be placed over the arms of the distraction component. Figure 97C is an oblique view of the embodiment of the invention shown in Figure 97A and one arm 9770 of a McCulloch retractor. The square shaped opening in the instrument fits over the square shaped arm 9770 of the retractor.

Figure 98A is an exploded oblique view of an alternative embodiment of the invention related to that shown in Figure 20A. A spacer component is placed over a spinous process. A dowel-like component 9802 is placed through an opening 9804 on the side of the device 9806, after the device is placed over the spinous process. The dowel component may locked into the spacer component. For example, the dowel component may be oval in cross section. Alternatively the oval dowel component could be cammed to lock the two components together.

Figure 98B is an oblique view of an assembled device of the embodiment shown in Figure 98A. Figure 98C is a lateral view of the spine and the embodiment of the invention shown in Figure 98A. The dowel component narrows the hole in the spacer component. The tip of the SP 9810 is too large to fit through the narrowed hole in the SPS. The dowel component may also increase apply pressure to the SP.

Figure 99A is a dorsal view of the spine and an alternative embodiment of the invention including rods 9902, 9904 that connect components placed between spinous processes. One or more of the interspinous components may prevent spinal extension through the level the interspinous component was placed.

Figure 99B is an exploded dorsal view of the embodiment of the invention drawn in Figure 99B. The rods may have spherical enlargements 9906, 9908 on one end of the rods. The spherical enlargements of the rods articulate with spherical concavities 9910, 9912 in one of the interspinous components. Set screws hold the rods in the interspinous components. The spherical articulation between the rods and the interspinous components allow the rods to be collinear or in a non-collinear alignment. The interspinous components may be tightened over the intermediate SP.

Figure 99C is a lateral view of the spine and the embodiment of the invention drawn in Figure 99B. The holes in the interspinous components may be filled with bone or a bone- growth-promoting substance. The interspinous components may fuse to the posterior elements of the intermediate vertebra.

Figure 100A is an oblique view of an alternative embodiment of the invention related to that drawn in Figure 97A. Figure 100B is a dorsal view of the embodiment of the invention drawn in Figure 100A. A band 9920 has been placed through slots 9922, 9924 in the arms 9926, 9928 of the device. The band is preferably flexible. The band may be made of plastic, metal, or fibrous material. For example, a plastic cable tie could be used. The large fastening end of the cable would prevent the first end of the cable from passing completely through one arm of the device. The fastening end of a second cable tie could be affixed to the second end of the cable tie, after the second end of the cable tie is passed through the second slot in the device. The large ends cable tie trap the cable tie within the device. Figure 100C is a lateral view of the embodiment of the device drawn in Figure 100B.

Figure 101A is a coronal cross section of an alternative embodiment of the invention drawn in Figure 93B. Rigid components 9930, 9932 are attached to adjacent spinous processes 9940, 9942. The fastening bands were not drawn on the component attached to the caudal SP. A flexible member 9950 is placed between the rigid components. The flexible component is preferably trapped between the rigid components without attaching to either component. The rigid components may have chambers filled with bone or bone-growth-promoting substances. The rigid components could fuse to the spinous processes. The flexible component may be made polymers, including elastomers or hydrogels. Alternatively, the intermediate component could be made of polyethylene. The polyethylene component could be attached to one of the rigid components. The large surface area of the rigid components enables transfer of loads across a larger area of the polymer component than can be transferred by the SP alone. The rigid components also surround a portion of the spinous processes. The configuration of the rigid components permits insertion of a polymer component that is larger than the space between the spinous processes. The device permits load transfer through large portions of large polymer components. The longevity of the polymer component is increased by the use of larger polymer components and by the transfer of loads through large portions of the polymer component. The polymer component could dampen the loads between the rigid components.

Figure 101B is sagittal cross section of the embodiment of the device drawn in Figure 101A. The areas of the drawing with closely spaced lines represent the rigid components. The area 9950' represents a portion of the polymer component. The device is configured to allow motion between the rigid components and contain the polymer component. The polymer component could be made of more than one material or of the same material with different durometers. For example, the transverse component of the polymer component may have more tensile strength than the lateral portions of the polymer component. Figure 101C is a lateral view of the spine and the embodiment of the device drawn in Figure 101A.

We claim:

1. Surgical apparatus for treating spinal stenosis, comprising:

a device configured for placement between vertebra posteriorly to a spinal canal; and adapted to fuse to a single vertebra; and

the device being operative to distract the spine and enlarge the spinal canal.

2. The surgical apparatus of claim 1, wherein the device permits spinal flexion while limiting spinal extension.

3. The surgical apparatus of claim 1, wherein the device includes:

an elongated component loosely coupled to adjacent vertebral bodies using pedicle screws.

4. The surgical apparatus of claim 1, wherein the device is configured for placement between adjacent spinous processes.

5. The surgical apparatus of claim 1, wherein:

the device is configured for placement between adjacent spinous processes; and

a structure to promote fusion to only one of the spinous processes.

6. The surgical apparatus of claim 1, wherein:

the device is configured for placement between adjacent spinous processes; and

a surface to promote bony ingrowth in conjunction with only one of the spinous processes.

7. The surgical apparatus of claim 1, wherein:

the device is configured for placement between adjacent spinous processes; and

one or more holes to promote bony ingrowth in conjunction with only one of the spinous processes.

8. The surgical apparatus of claim 1, wherein:

the device is configured for placement between adjacent spinous processes and fusion to only one of spinous processes; and

a shape on a portion of the device to form a pseudo-joint in conjunction with the non-fused spinous process.

9. The surgical apparatus of claim 1, further including a flexible member that passes around or through a spinous process to promote fusion thereto.

10. The surgical apparatus of claim 1, wherein at least a portion of the device is constructed from bone.

11. The surgical apparatus of claim 1, wherein at least a portion of the device is constructed from the shaft of the clavicle, rib, humerus, radius, ulna, metacarpal, phalanx, femur, tibia, fibula, or metatarsal bone.

12. The surgical apparatus of claim 1, wherein the device includes a slot or indent to receive a portion of a spinous process to fuse thereto.

13. The surgical apparatus of claim 1, wherein the device contains one or more bone-growth promoting substances.

14. The surgical apparatus of claim 1, wherein the devices contains one or more of the following:

BMP1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, n,
demineralized bone matrix,
allograft cancellous bone,
autograft bone,
hydroxy appetite,
coral or other highly porous substance.

15. The surgical apparatus of claim 1, further including an elastic synthetic ligament or allograft tissue that connects two adjacent spinous processes.

16. The surgical apparatus of claim 1, wherein the device is adapted fuse to the lamina, facet, or other posterior elements of a single vertebra.

17. The surgical apparatus of claim 1, wherein the device surrounds a single spinous process.

18. The surgical apparatus of claim 1, wherein the device clamps to a single spinous process.

19. The surgical apparatus of claim 1, wherein the device includes spring-like or shape-memory properties.

20. The surgical apparatus of claim 1, wherein the device includes projections extending along the sides of a spinous process.

21. The device of claim 1, wherein the device has asymmetric oval cross section.

22. The device of claim 1, wherein the device wedges apart the spinous processes upon insertion.

23. The device of claim 1, wherein the device distracts the spinous processes through rotation.

24. The device of claim 1, wherein the device is a generally V-, U-, or C-shaped device configured to fit between the lamina of one vertebra and the spinous process and or lamina of an adjacent vertebra.

25. The device of claim 1, wherein the size or shape of the device is customized at the time of surgery.

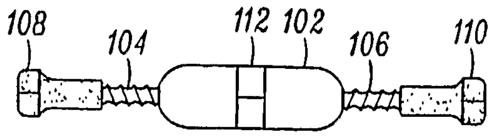


FIG. 1A

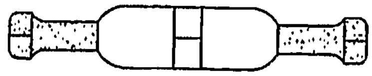


FIG. 1B

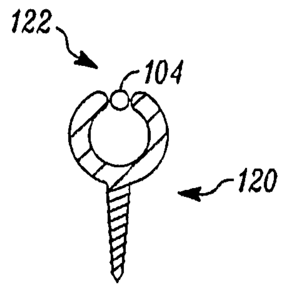


FIG. 1C

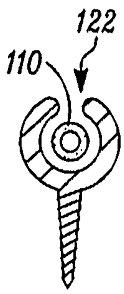


FIG. 1D

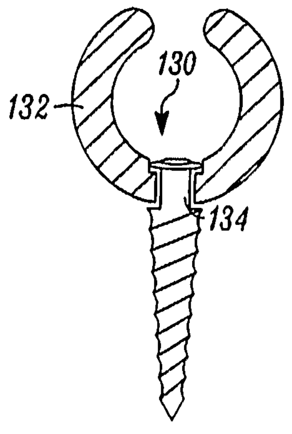


FIG. 1E

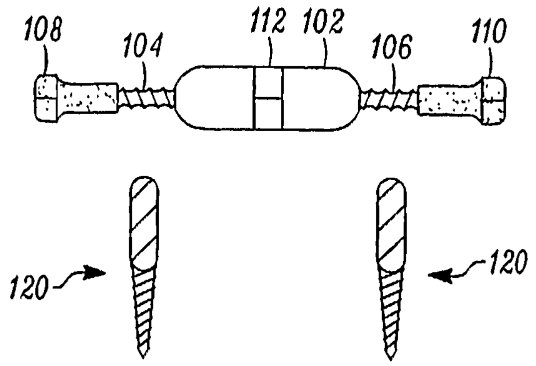


FIG. 1F

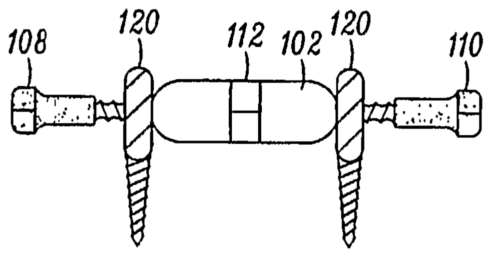


FIG. 1G

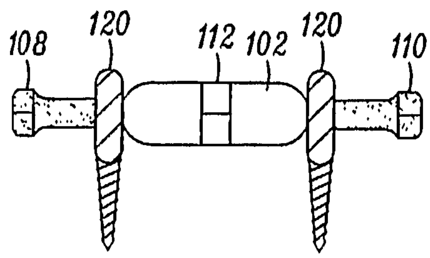


FIG. 1H

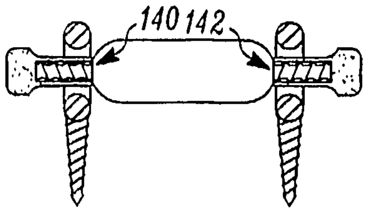


FIG. 1I

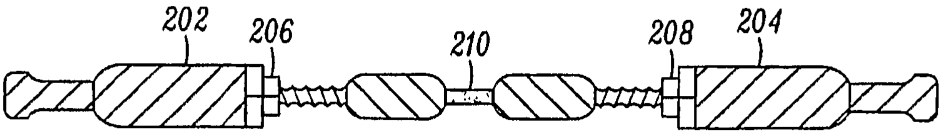


FIG. 2A

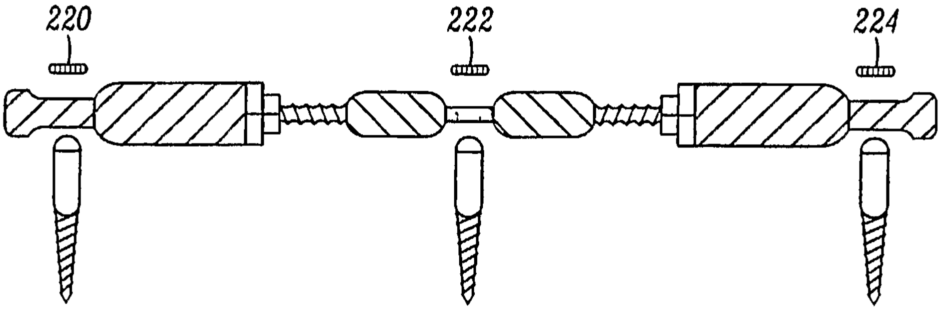


FIG. 2B

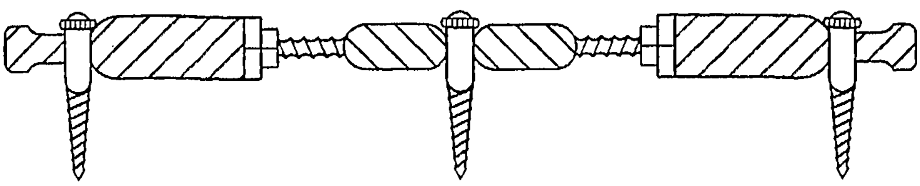


FIG. 2C

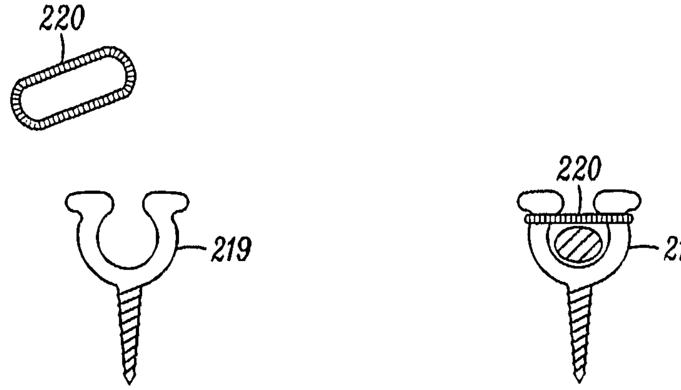


FIG. 2D FIG. 2E

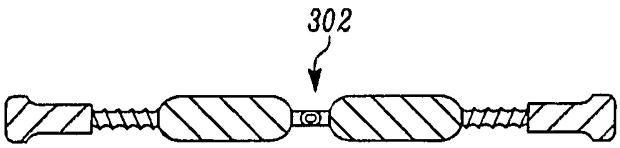


FIG. 3A

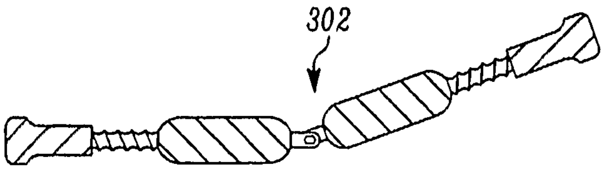


FIG. 3B

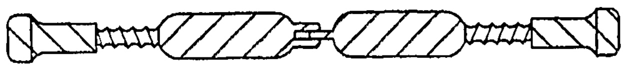


FIG. 3C

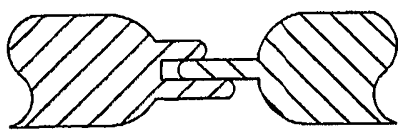


FIG. 3D

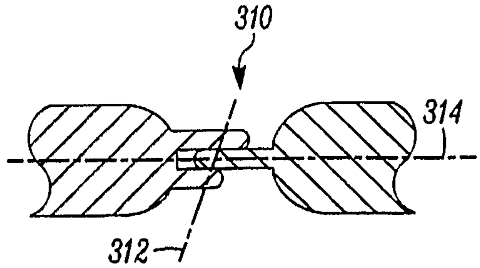


FIG. 3E

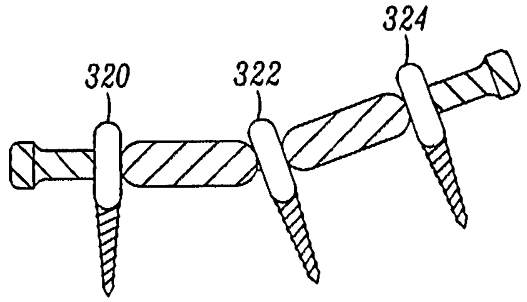


FIG. 3F

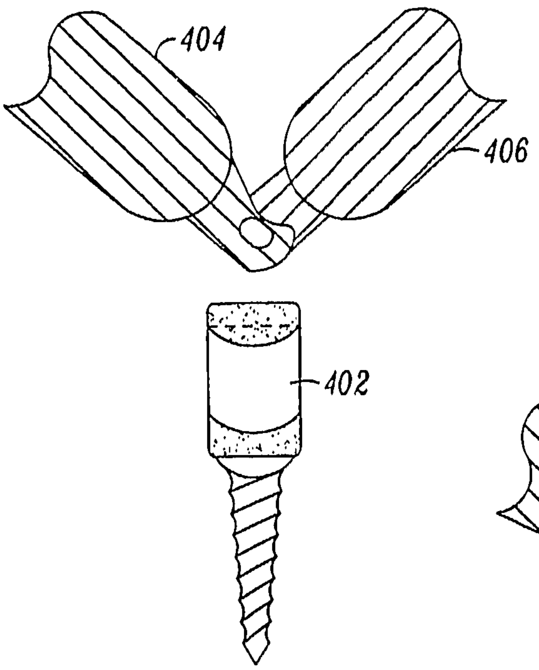


FIG. 4A

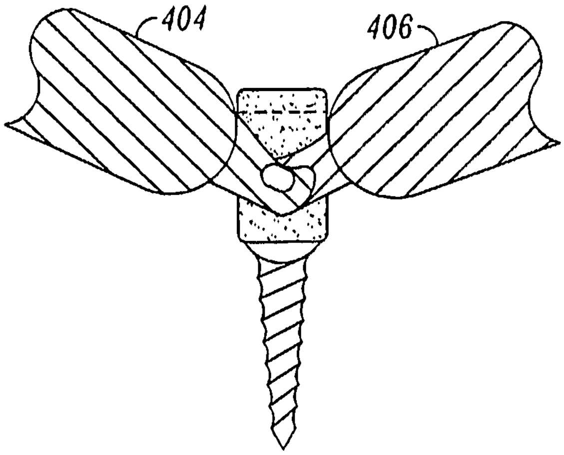


FIG. 4B

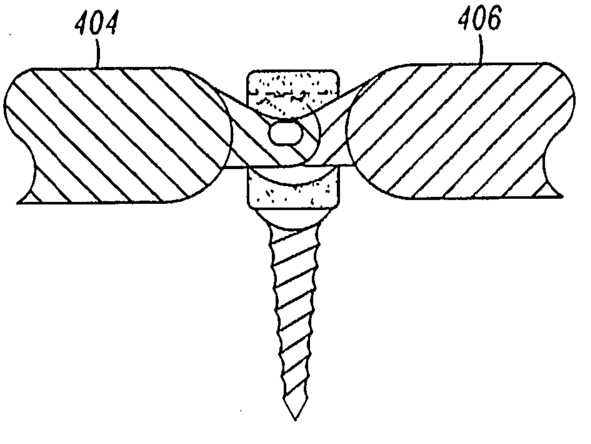


FIG. 4C

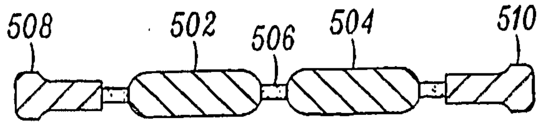


FIG. 5A

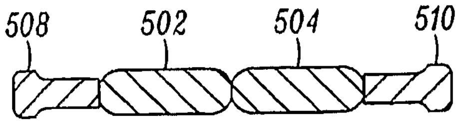


FIG. 5B

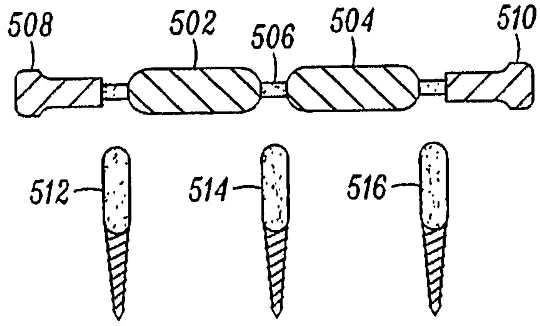


FIG. 5C

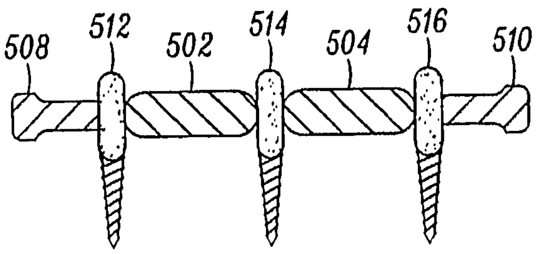


FIG. 5D

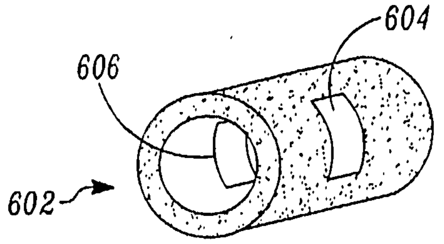


FIG. 6A

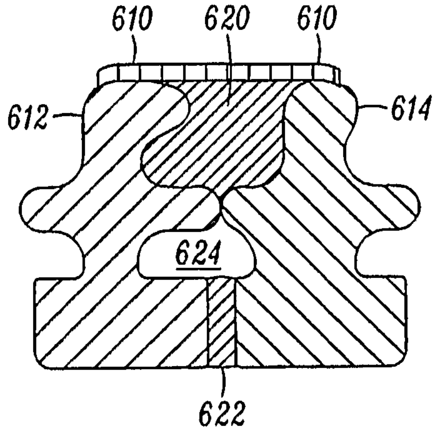


FIG. 6B

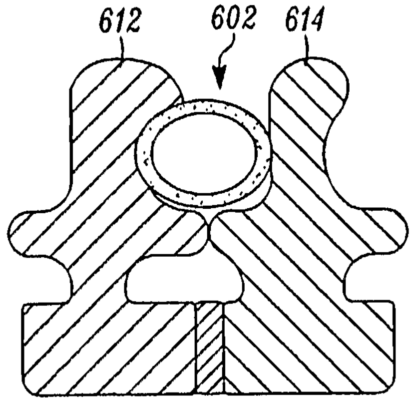


FIG. 6C

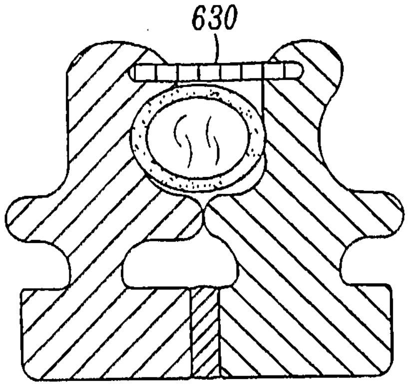


FIG. 6D

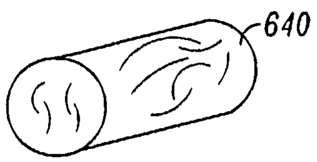


FIG. 6E

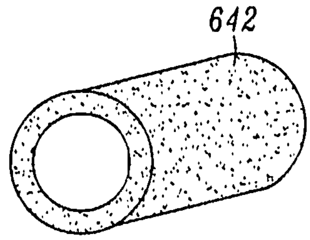


FIG. 6F

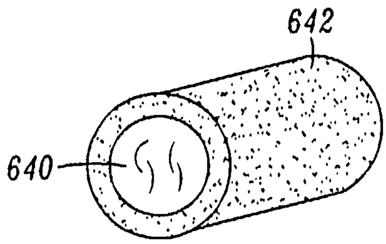


FIG. 6G

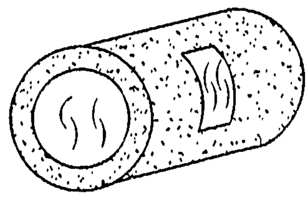


FIG. 6H

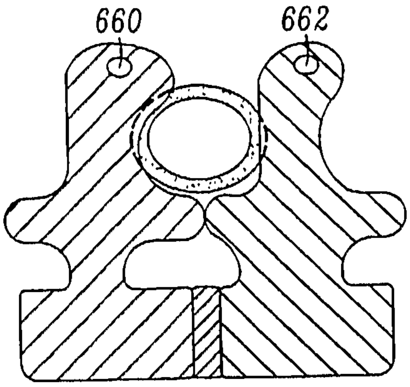


FIG. 6I

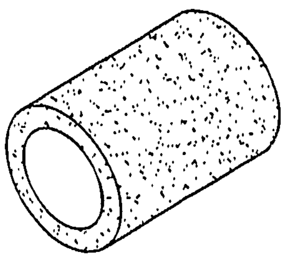


FIG. 7A

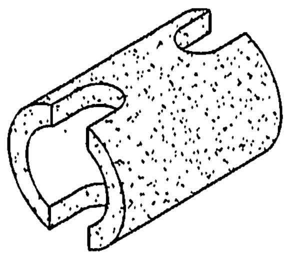


FIG. 7B

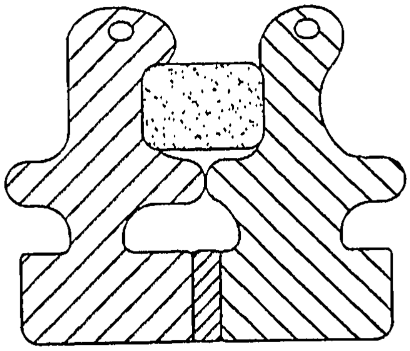


FIG. 7C

FIG. 7D

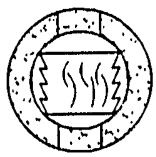


FIG. 7E

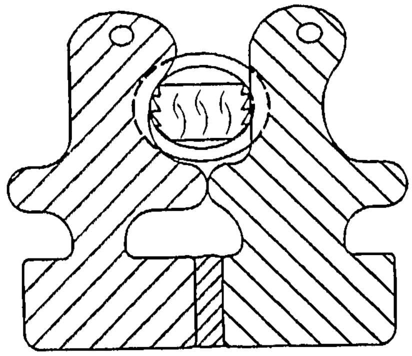


FIG. 7F

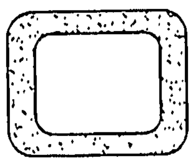


FIG. 8A

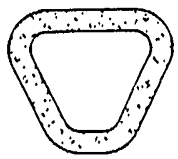


FIG. 8B

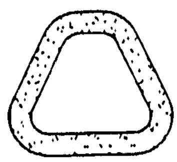


FIG. 8C

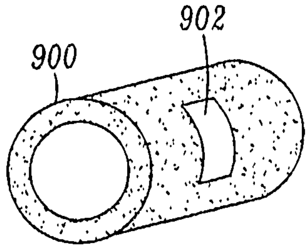


FIG. 9A

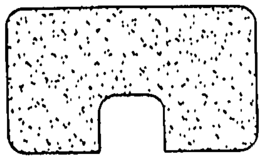


FIG. 9B

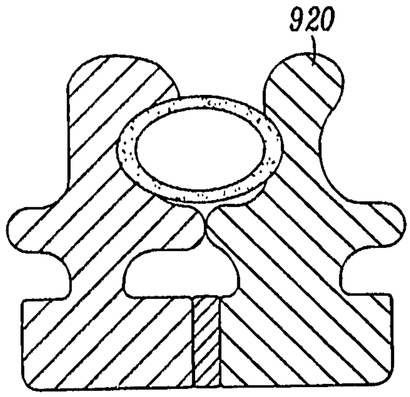


FIG. 9C

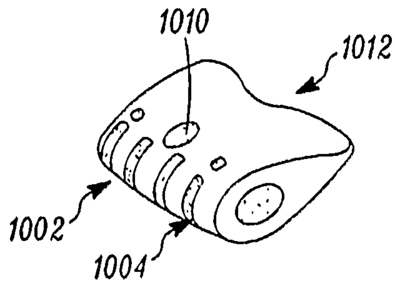


FIG. 10A

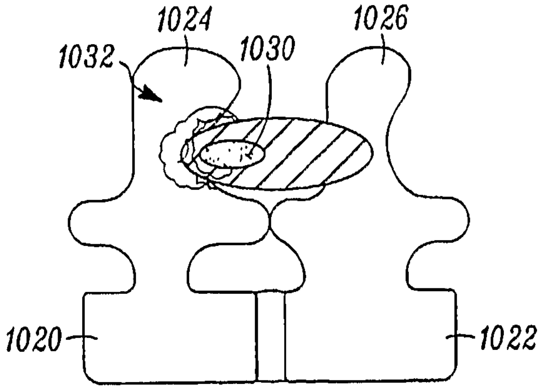


FIG. 10B

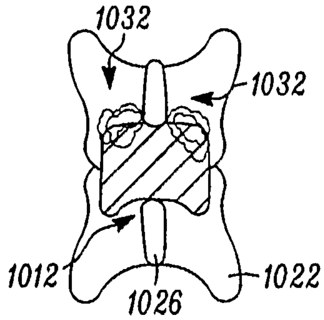


FIG. 10C

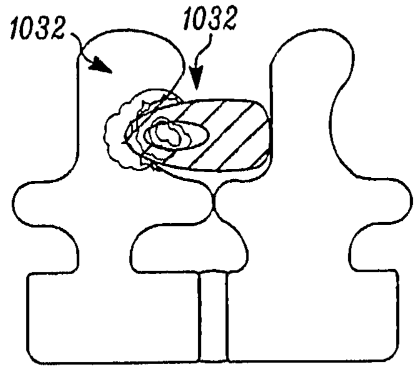


FIG. 10D

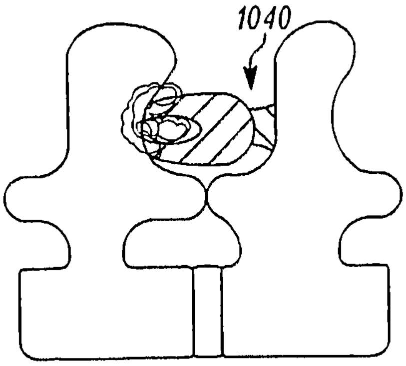


FIG. 10E

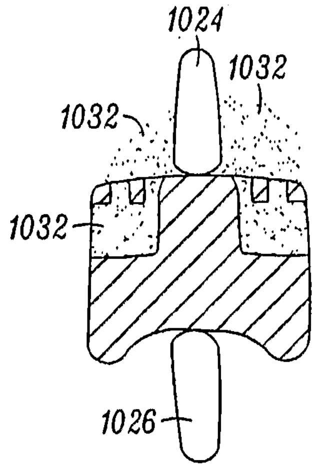


FIG. 10F

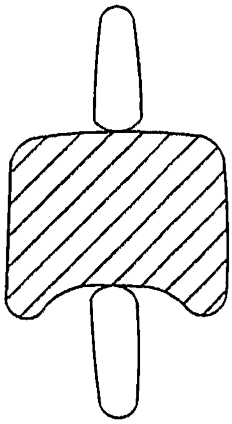


FIG. 11A

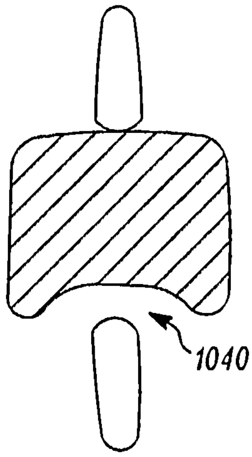


FIG. 11B

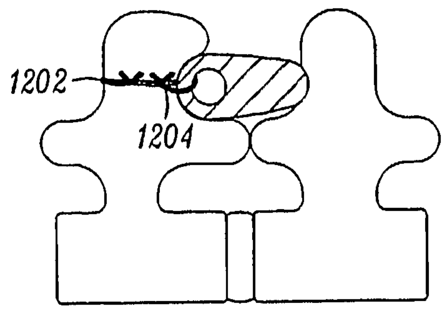


FIG. 12A

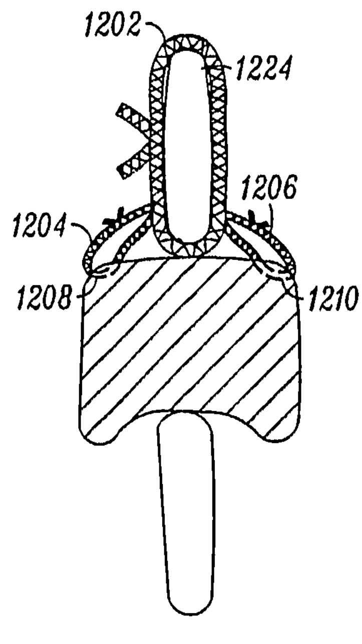


FIG. 12B

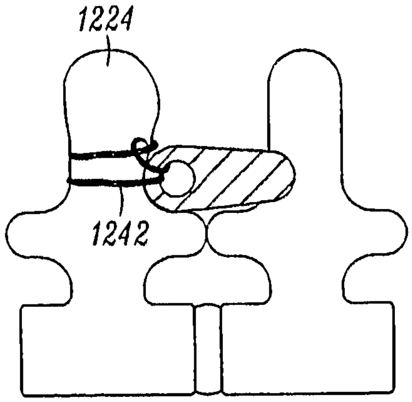


FIG. 12C

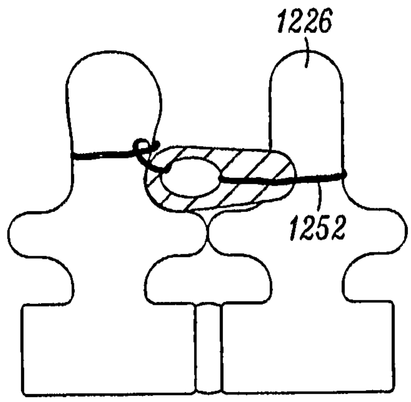


FIG. 12D

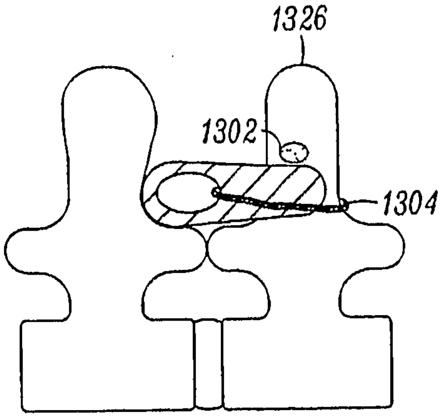


FIG. 13A

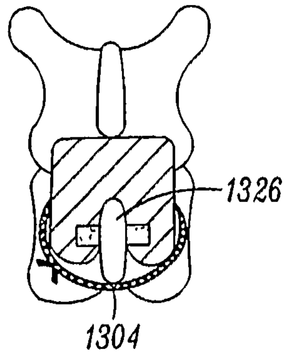


FIG. 13B

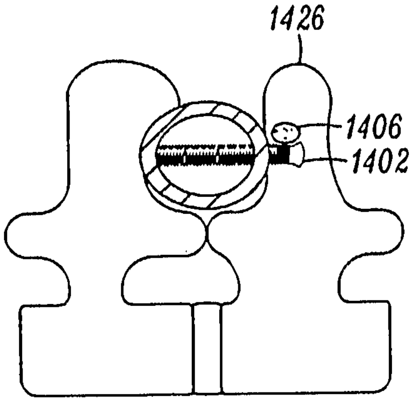


FIG. 14A

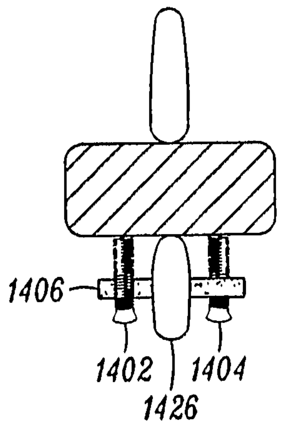


FIG. 14B

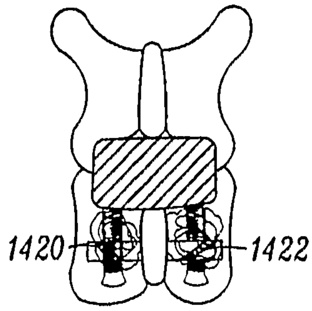


FIG. 14C

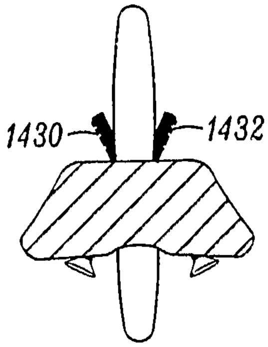


FIG. 14D

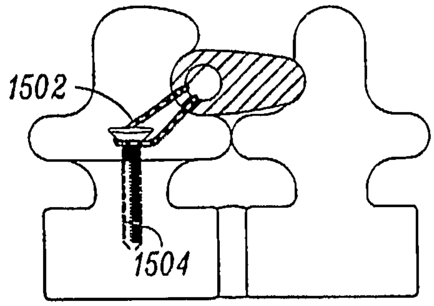


FIG. 15

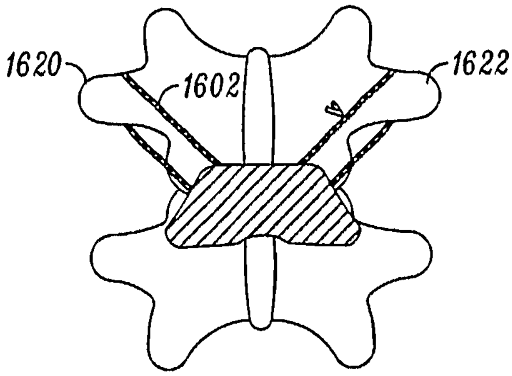


FIG. 16

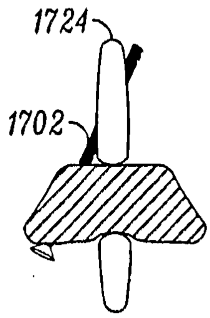


FIG. 17

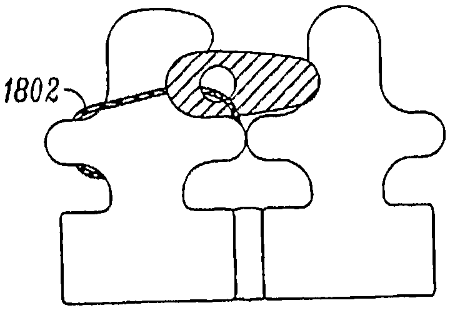


FIG. 18

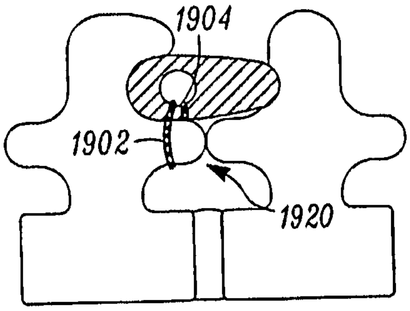


FIG. 19

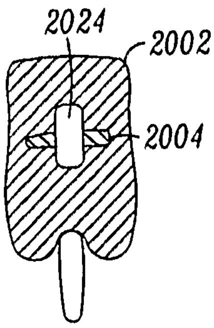


FIG. 20A

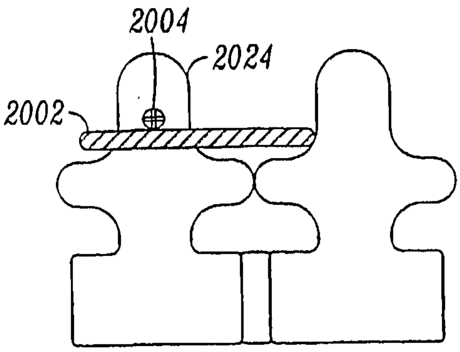


FIG. 20B

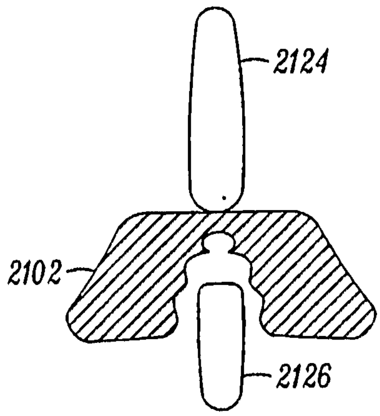


FIG. 21A

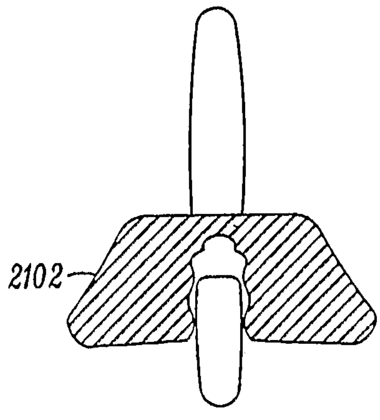


FIG. 21B

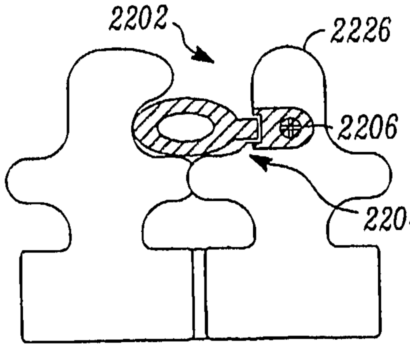


FIG. 22

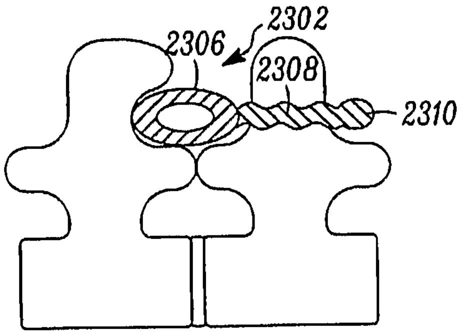


FIG. 23A

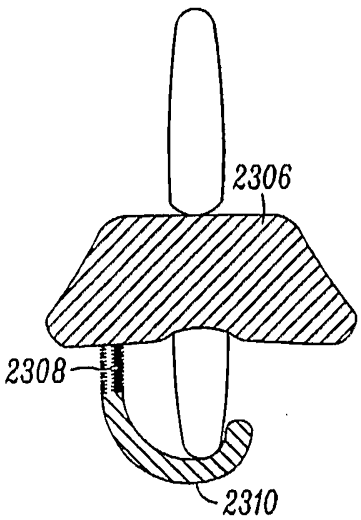


FIG. 23B

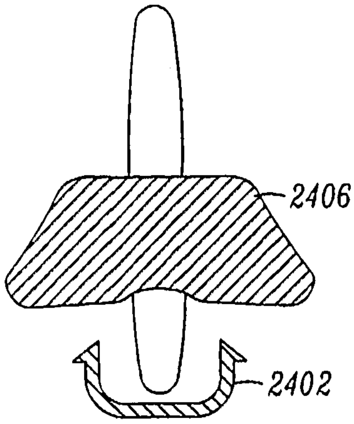


FIG. 24A

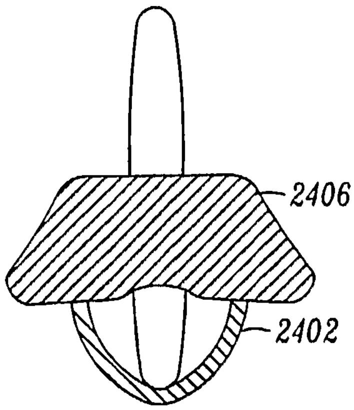


FIG. 24B

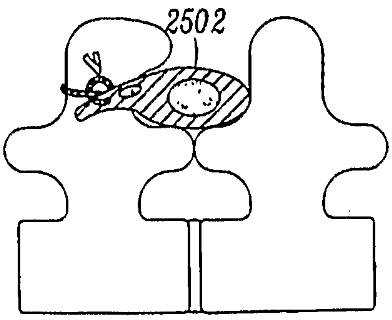


FIG. 25A

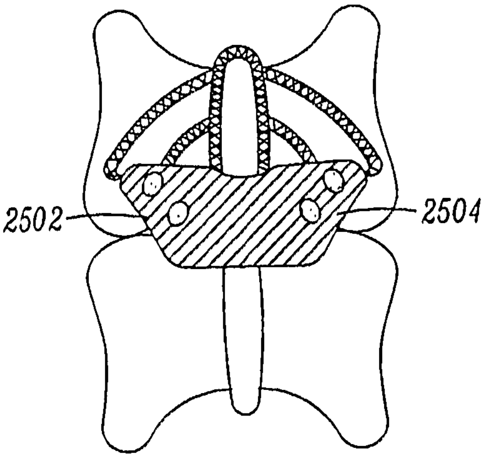


FIG. 25B

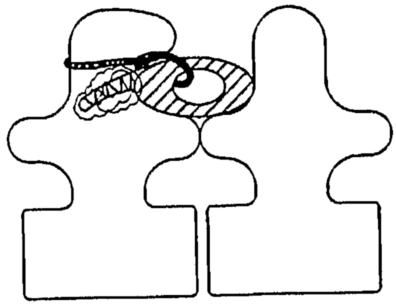


FIG. 26A

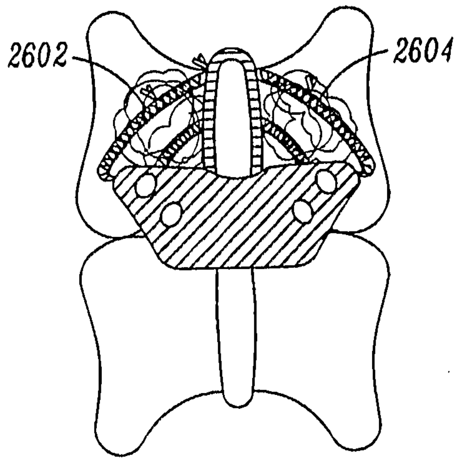


FIG. 26B

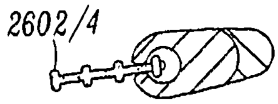


FIG. 26C

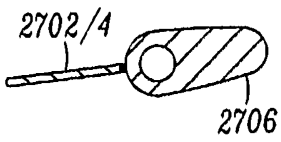


FIG. 27A

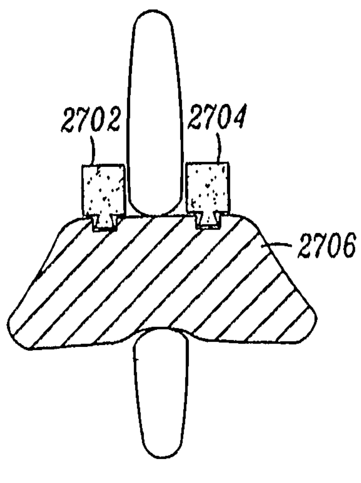


FIG. 27B

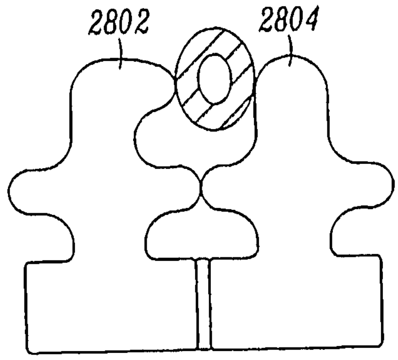


FIG. 28A

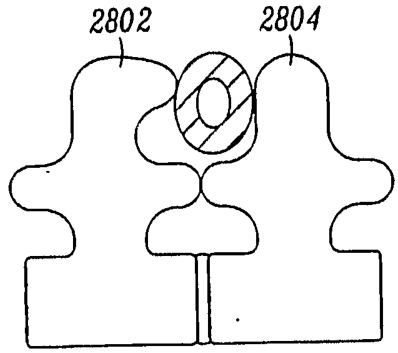


FIG. 28B

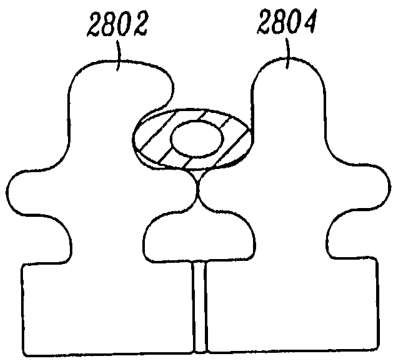


FIG. 28C

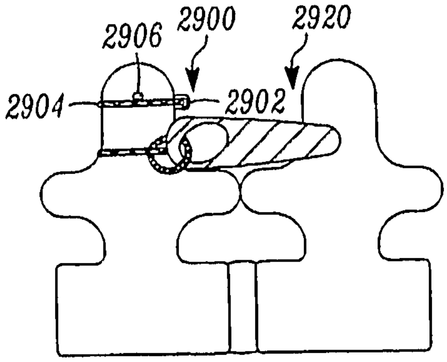


FIG. 29

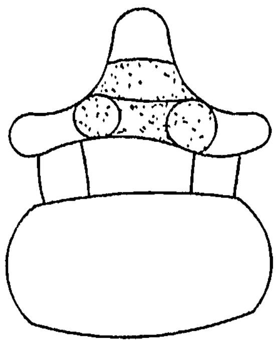


FIG. 30

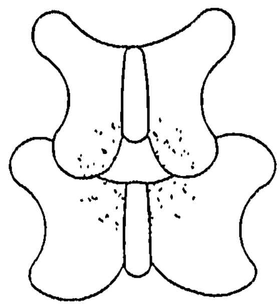


FIG. 31

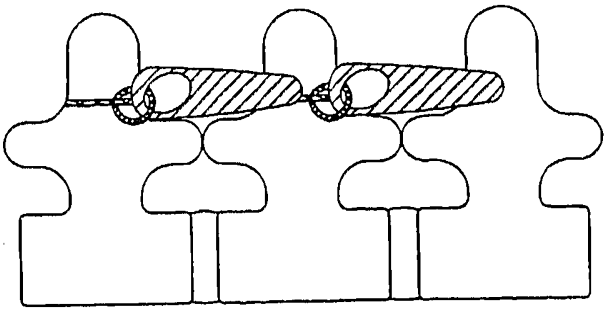


FIG. 32A

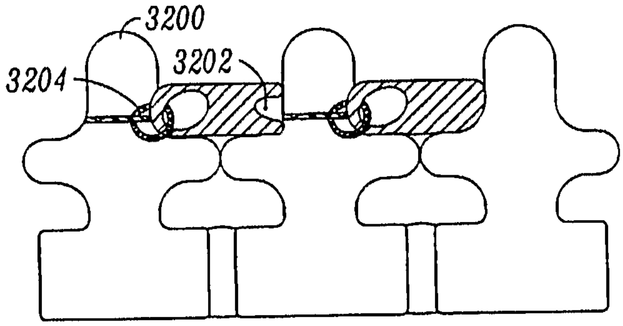


FIG. 32B

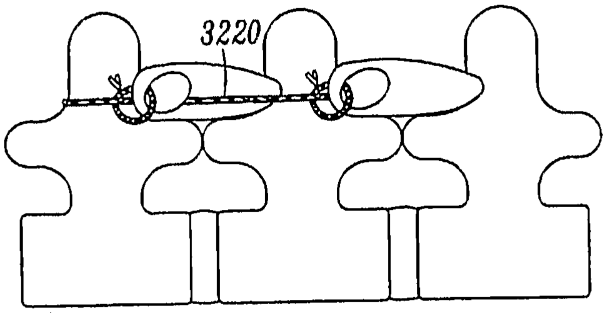


FIG. 32C

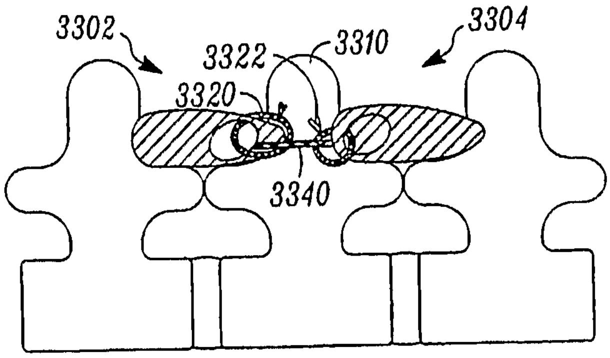


FIG. 33

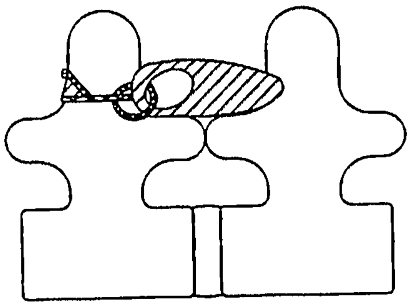


FIG. 34

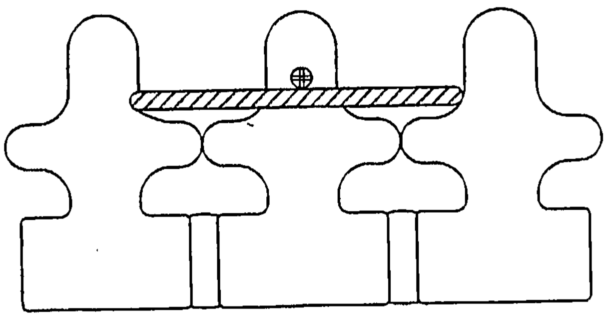


FIG. 35A

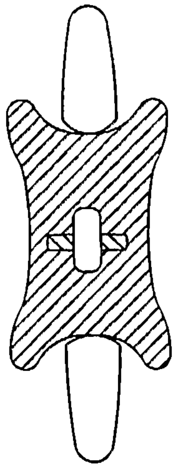


FIG. 35B

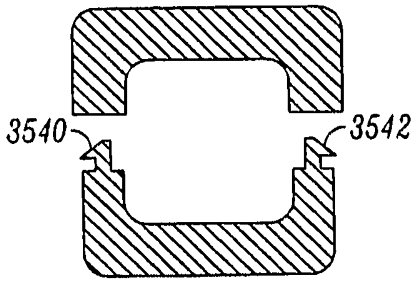


FIG. 35C

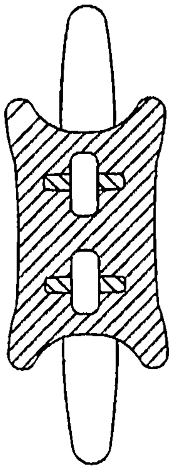


FIG. 35D

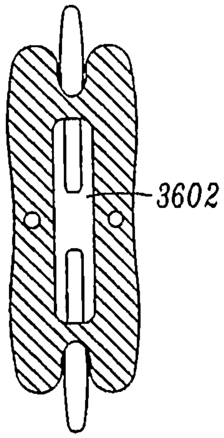


FIG. 36A

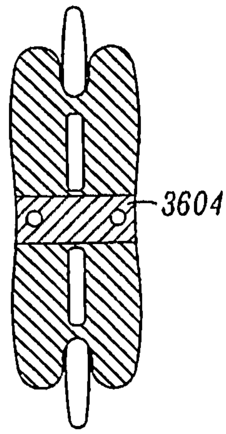


FIG. 36B

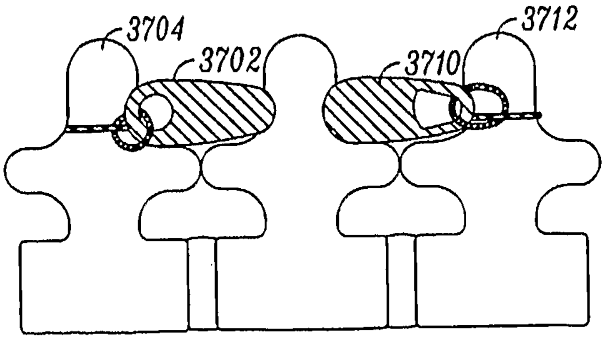


FIG. 37

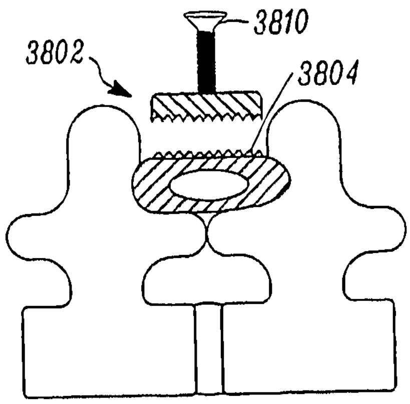


FIG. 38A

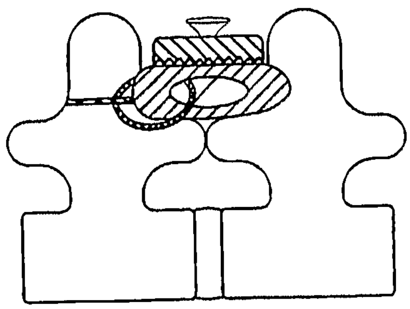


FIG. 38B

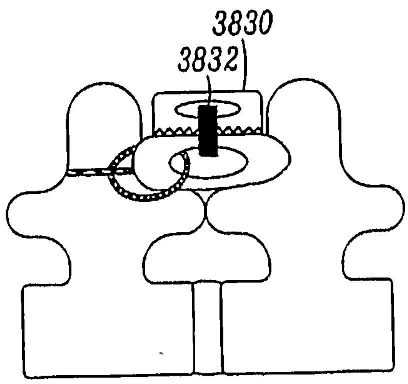


FIG. 38C

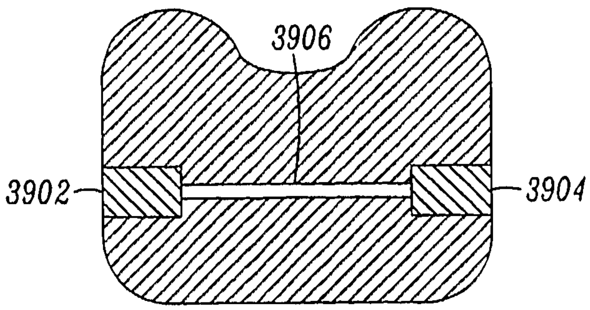


FIG. 39A

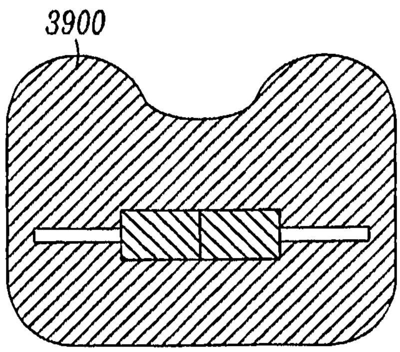


FIG. 39B

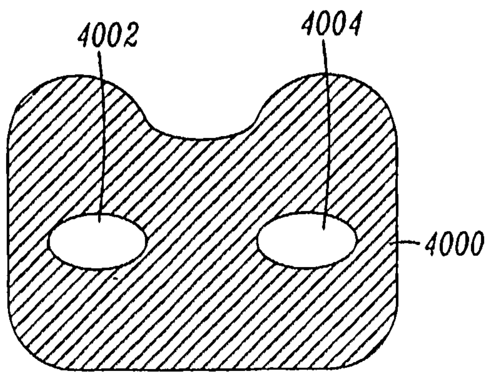


FIG. 40A

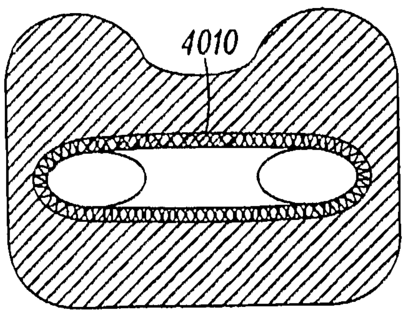


FIG. 40B

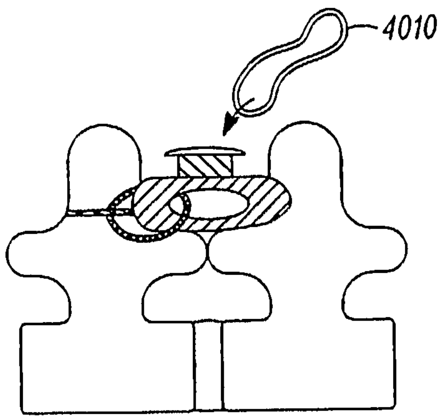


FIG. 40C

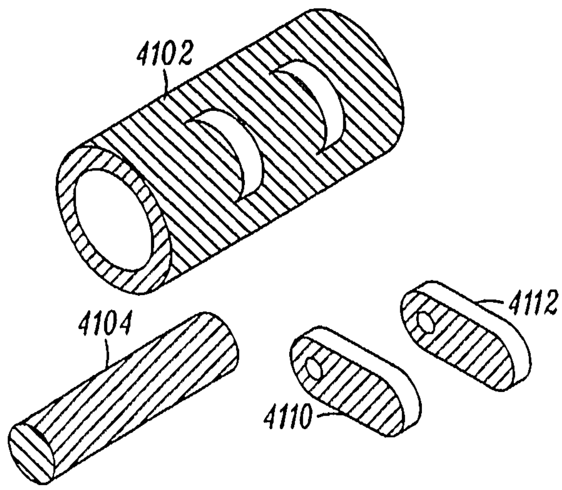


FIG. 41A

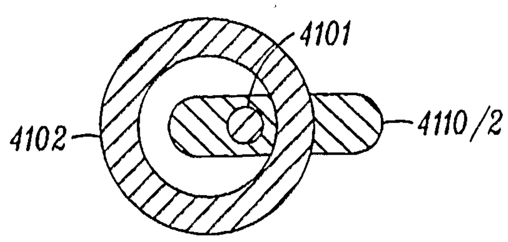


FIG. 41B

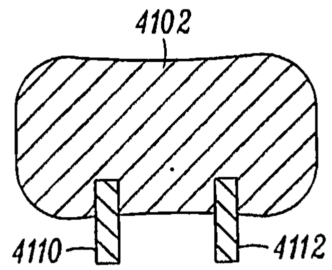


FIG. 41C

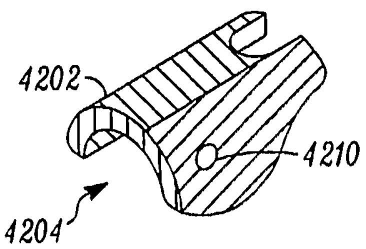


FIG. 42

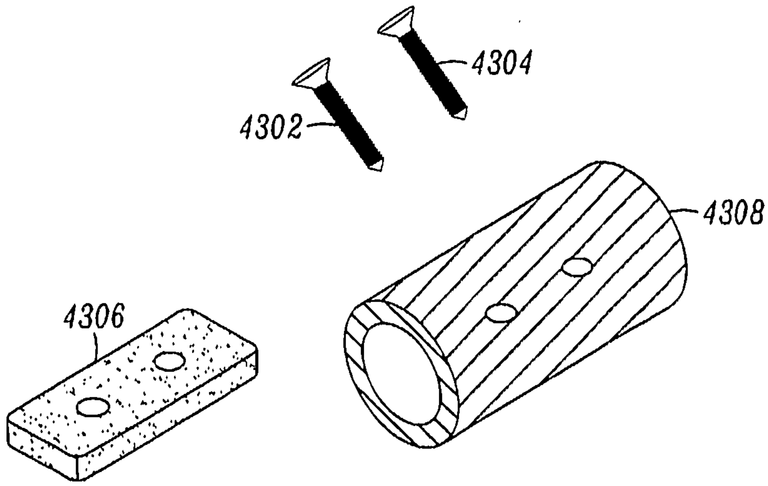


FIG. 43A

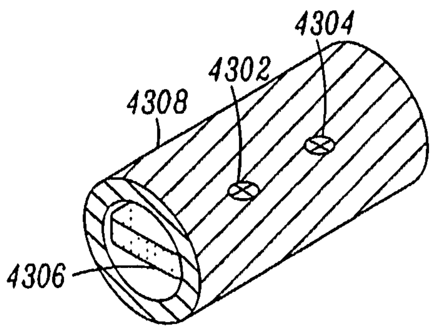


FIG. 43B

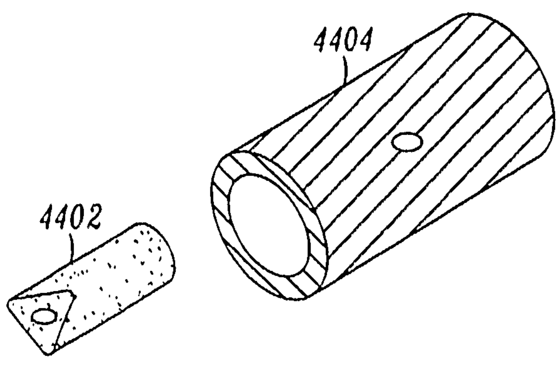


FIG. 44A

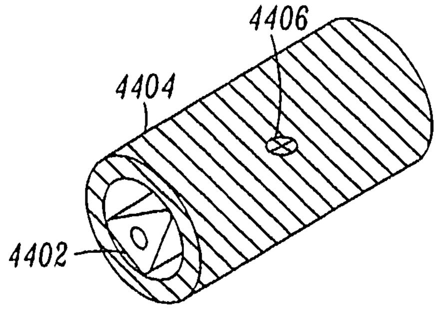


FIG. 44B

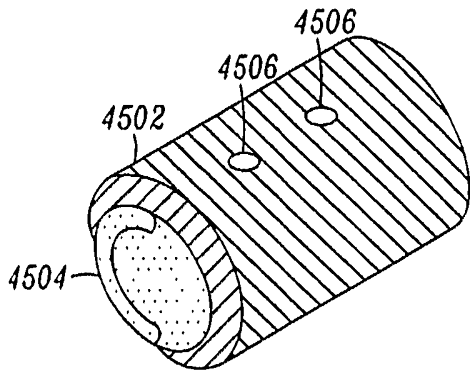


FIG. 45

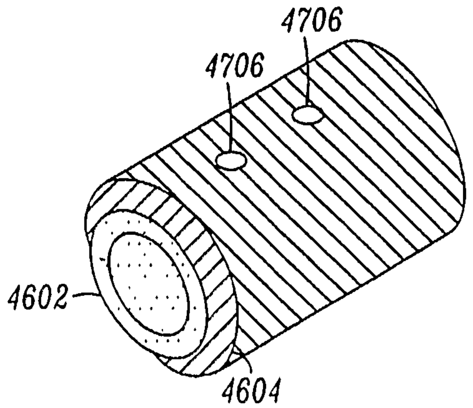


FIG. 46

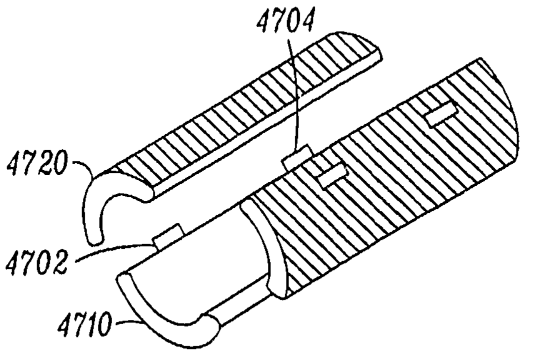


FIG. 47A

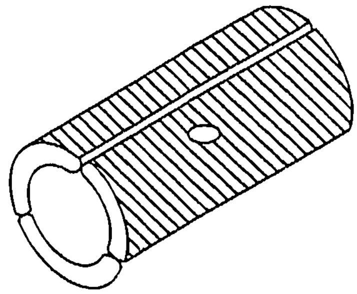
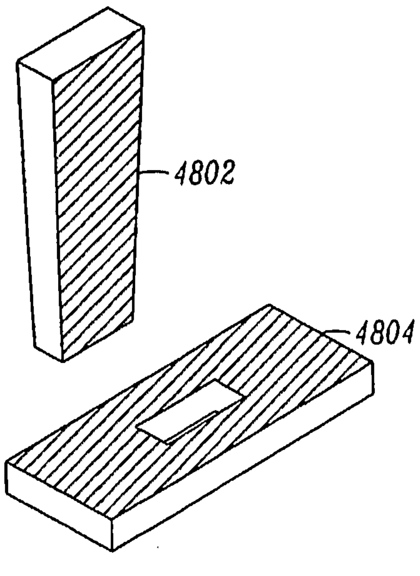


FIG. 47B



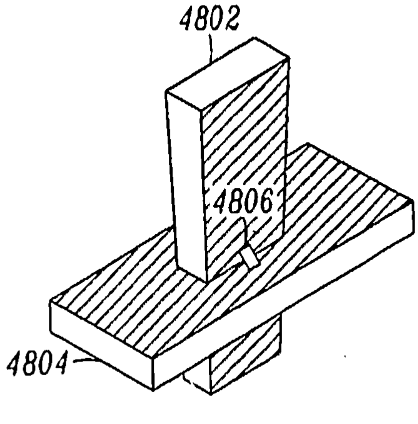


FIG. 48A

FIG. 48B

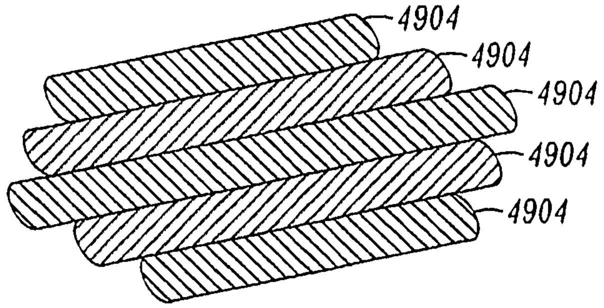


FIG. 49A

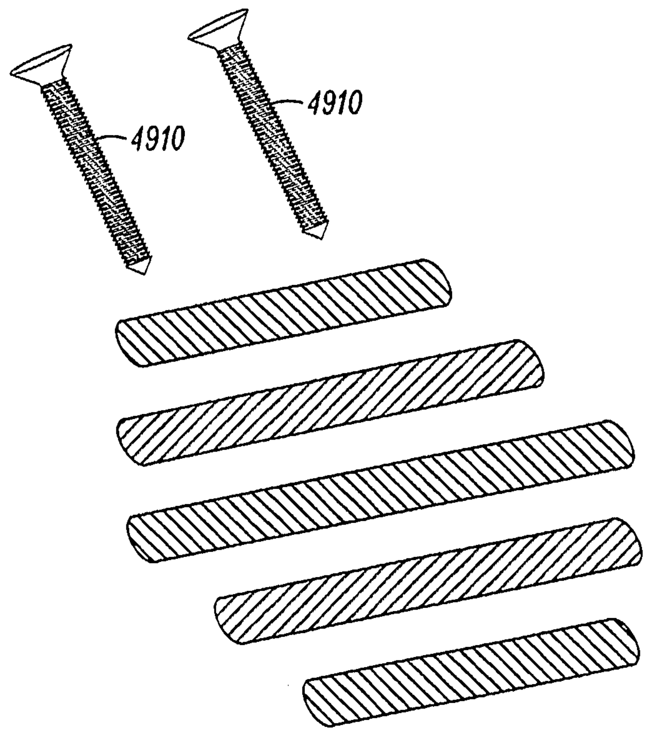


FIG. 49B

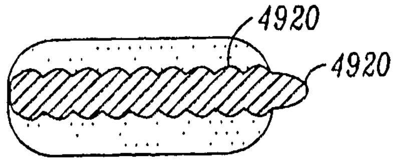


FIG. 49C

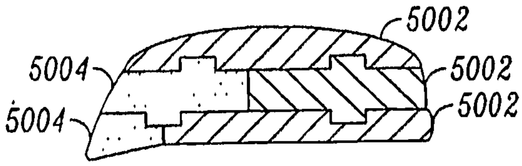


FIG. 50A

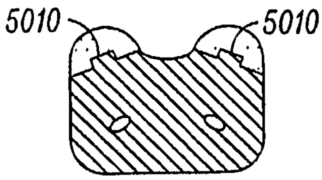


FIG. 50B

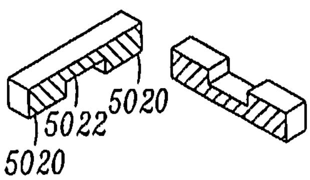


FIG. 50C

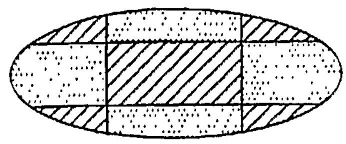


FIG. 50D

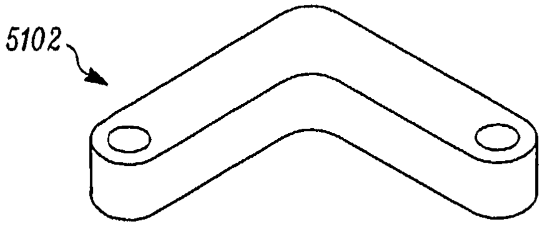


FIG. 51A

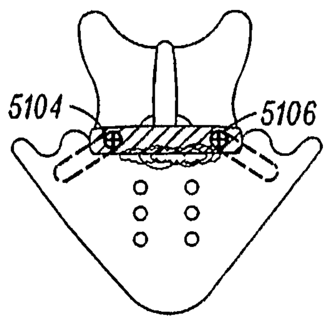


FIG. 51B

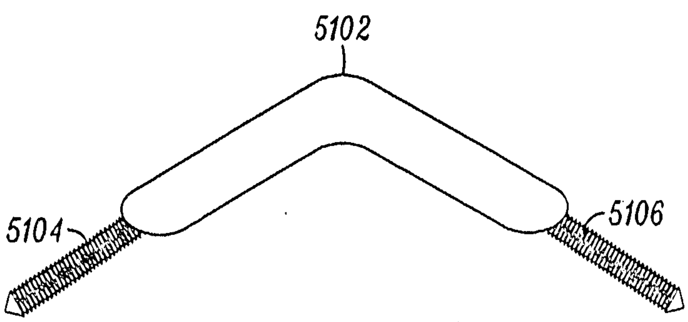


FIG. 51C

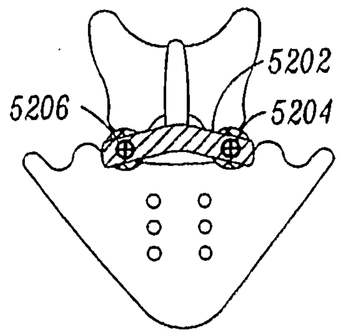


FIG. 52

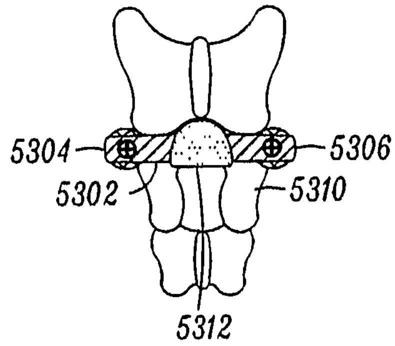


FIG. 53

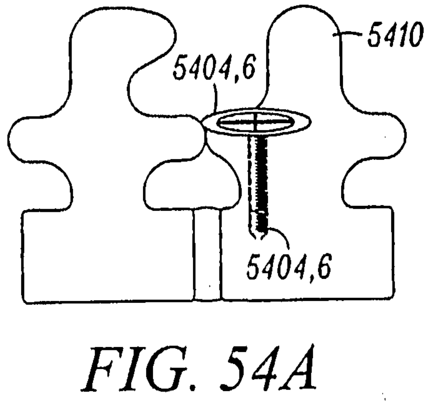


FIG. 54A

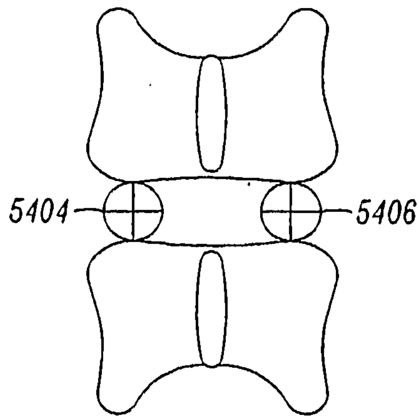


FIG. 54B

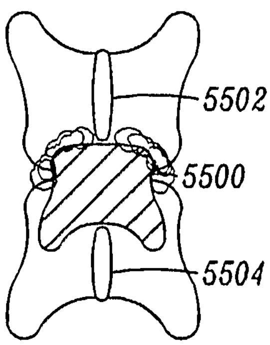


FIG. 55

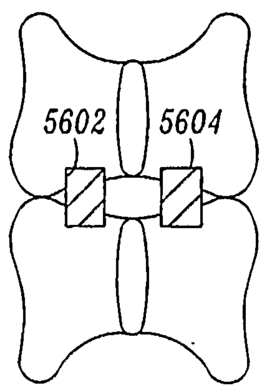


FIG. 56A

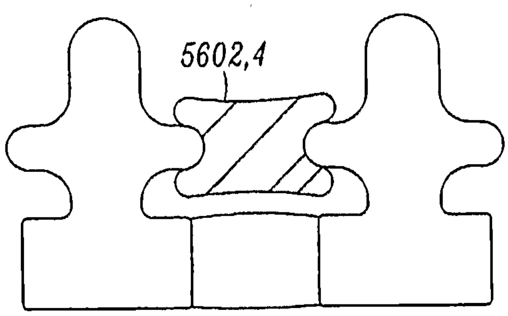


FIG. 56B

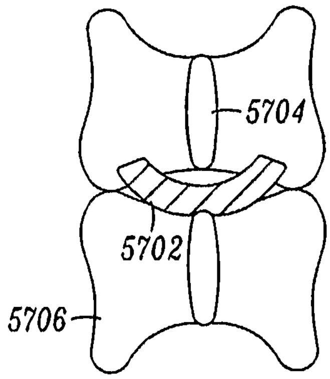


FIG. 57

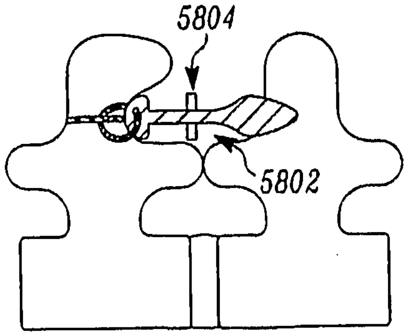


FIG. 58

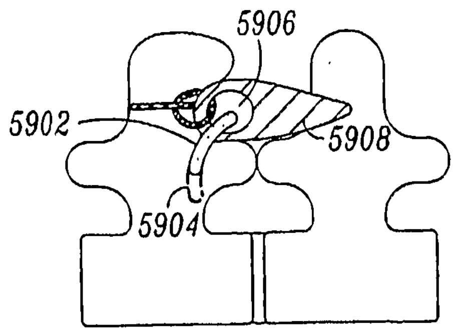


FIG. 59

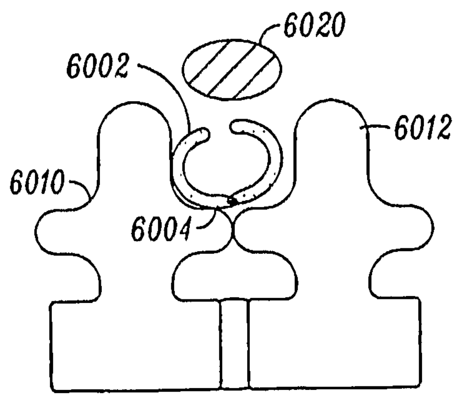


FIG. 60A

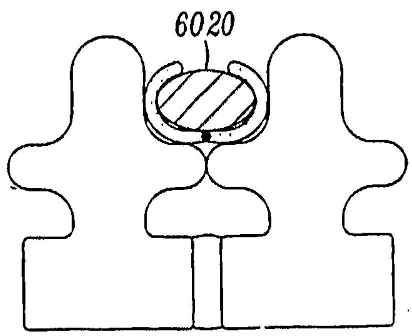


FIG. 50B

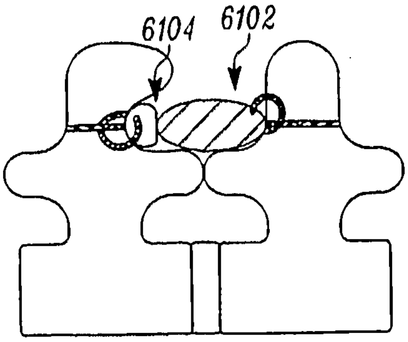


FIG. 61

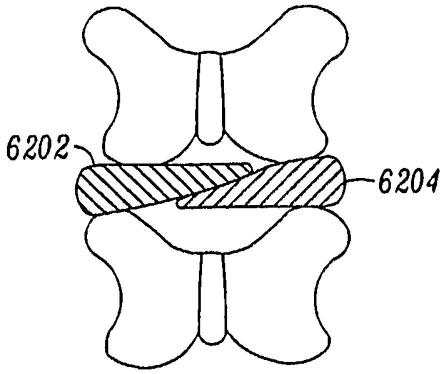


FIG. 62A

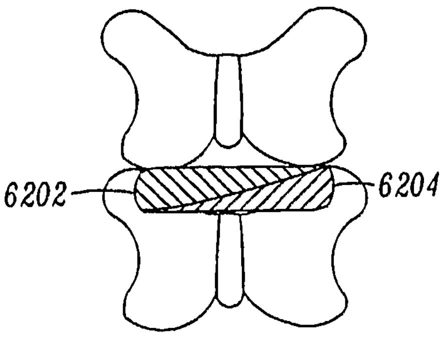


FIG. 62B

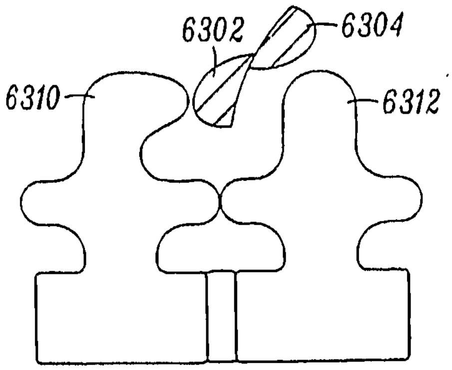


FIG. 63A

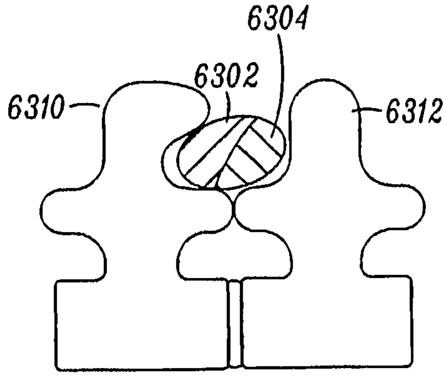


FIG. 63B

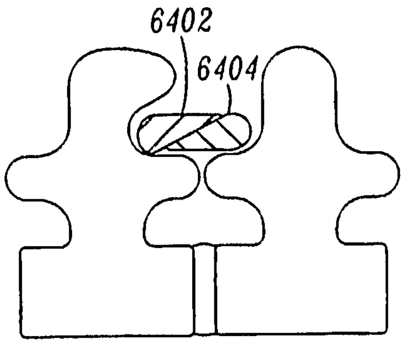


FIG. 64A

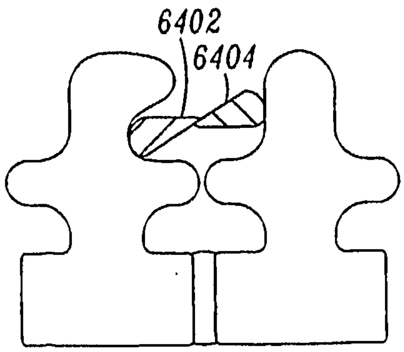


FIG. 64B

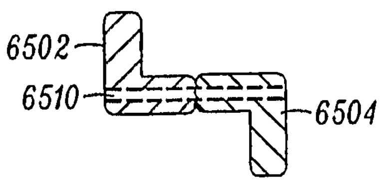


FIG. 65A

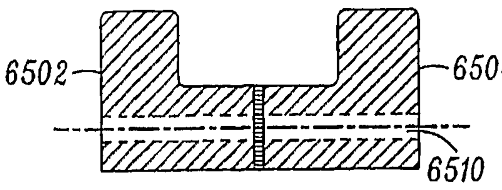


FIG. 65B

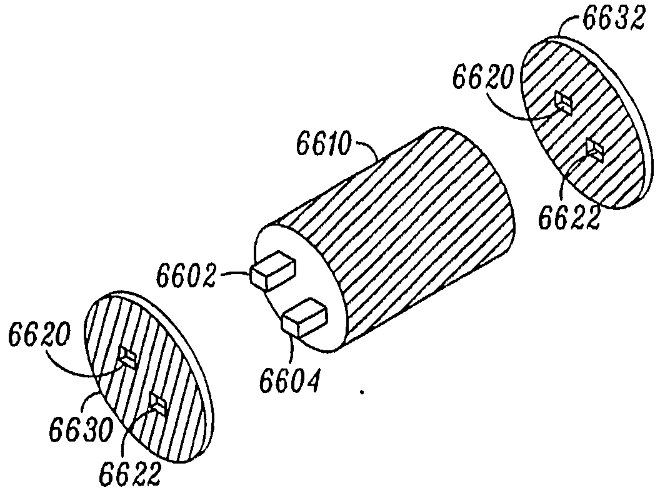


FIG. 66A

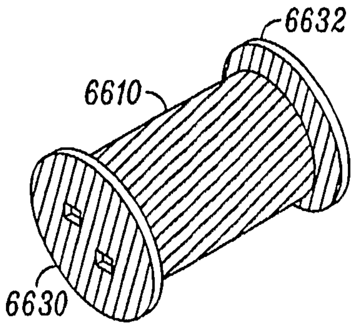


FIG. 66B

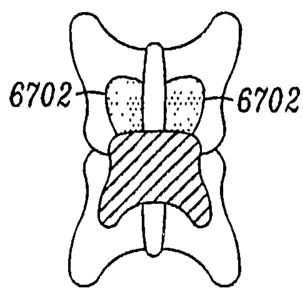


FIG. 67

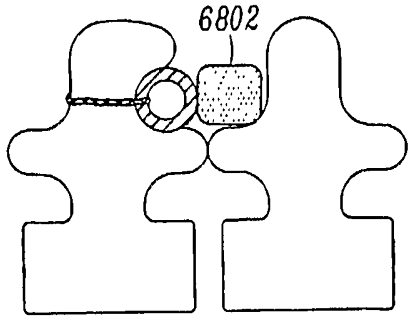


FIG. 68

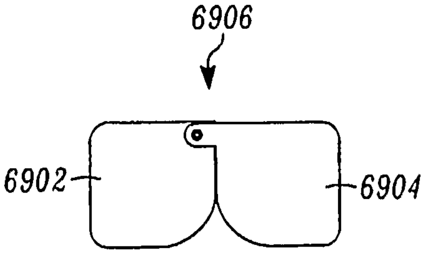


FIG. 69A

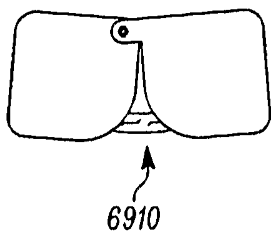


FIG. 69B

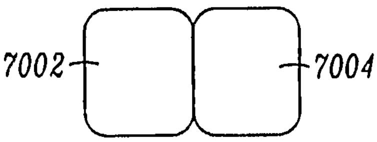


FIG. 70A

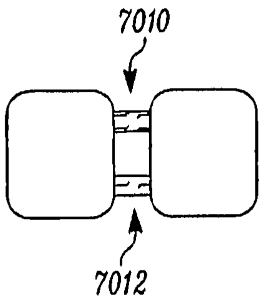


FIG.70B

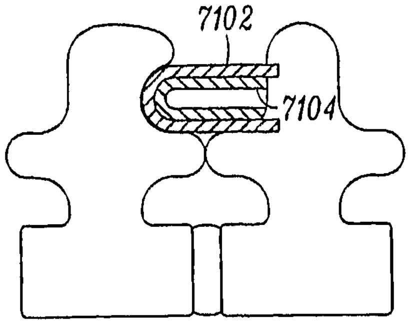


FIG. 71

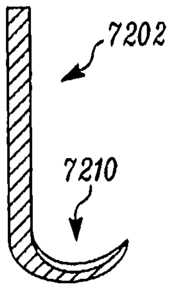


FIG. 72A

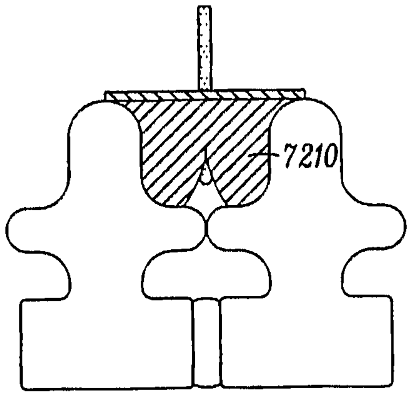


FIG. 72B

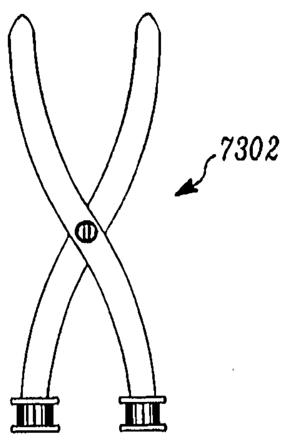


FIG. 73A

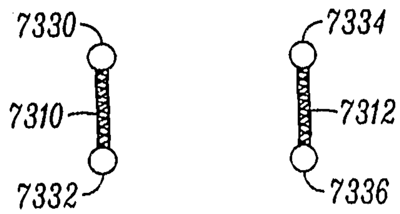


FIG. 73B

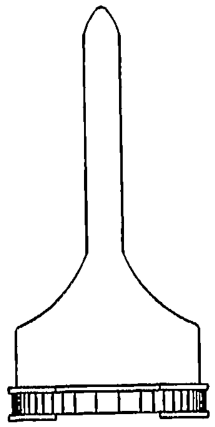


FIG. 73C

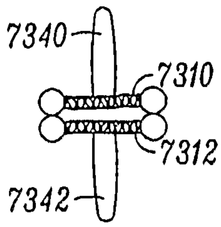


FIG. 73D

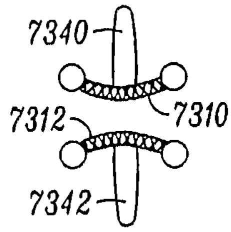


FIG. 73E

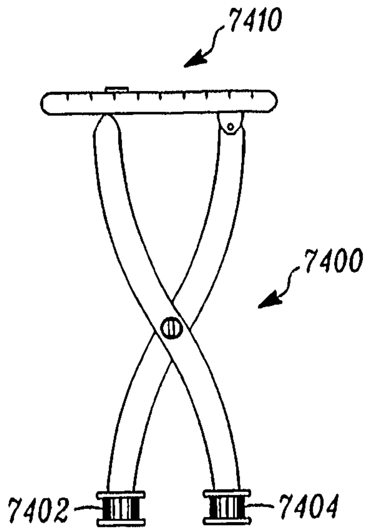


FIG. 74A

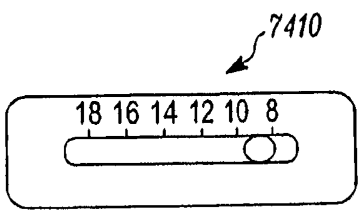


FIG. 74B

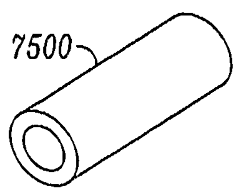


FIG. 75

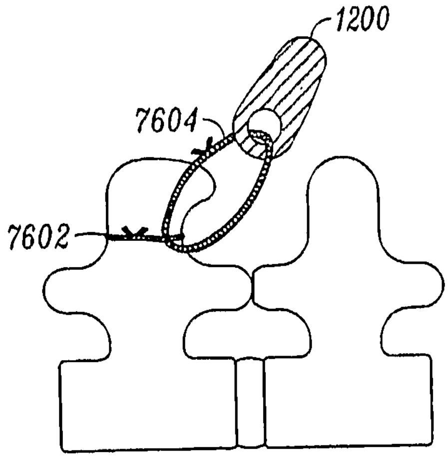


FIG. 76A

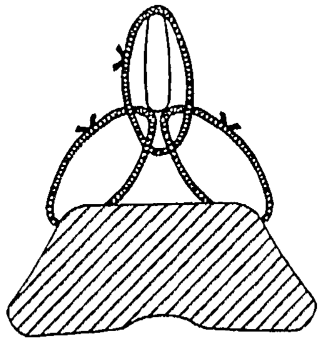


FIG. 76B

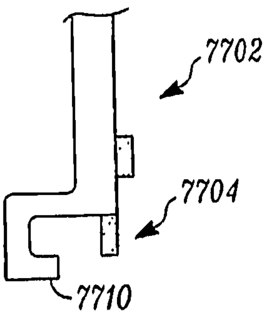


FIG. 77A

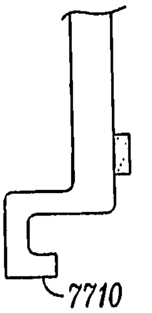


FIG. 77B

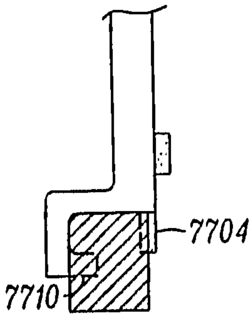


FIG. 77C

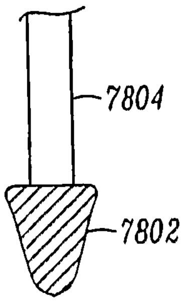


FIG. 78A

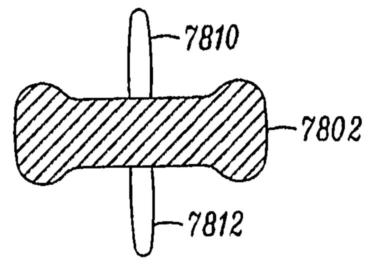


FIG. 78B

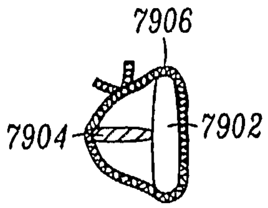


FIG. 79A

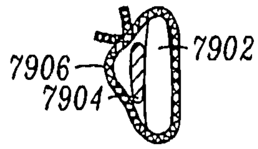


FIG. 79B

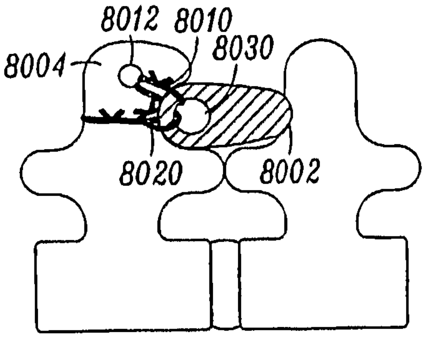


FIG. 80A

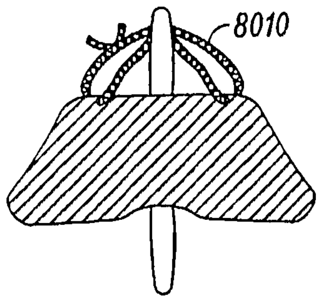


FIG. 80B

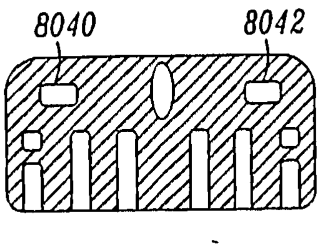


FIG. 80C

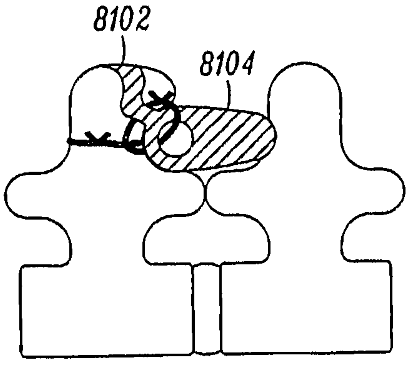


FIG. 81

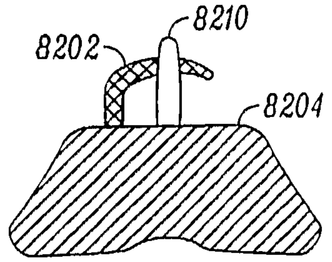


FIG. 82

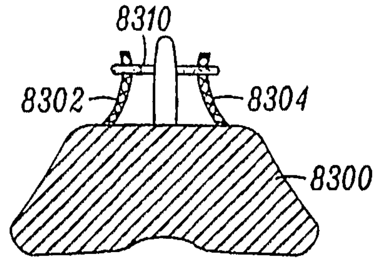


FIG. 83

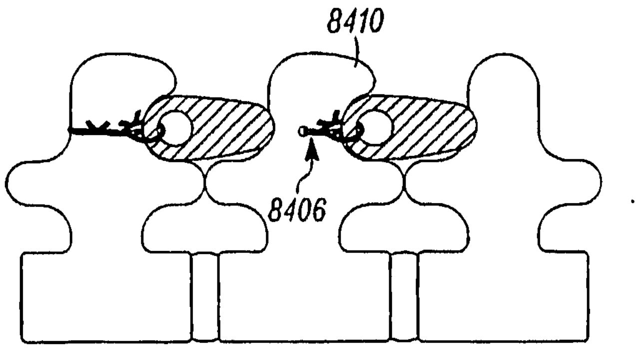


FIG. 84

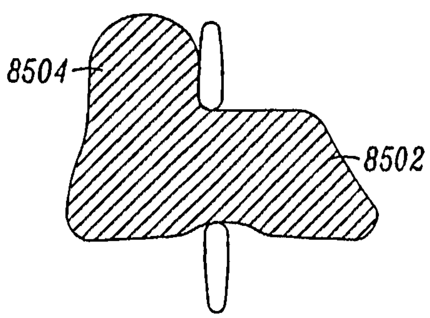


FIG. 85

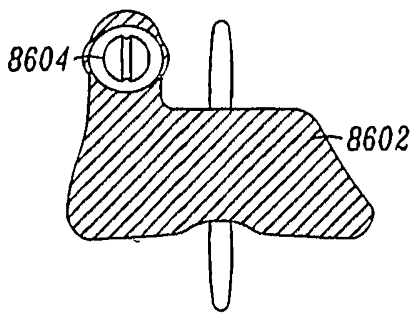


FIG. 86

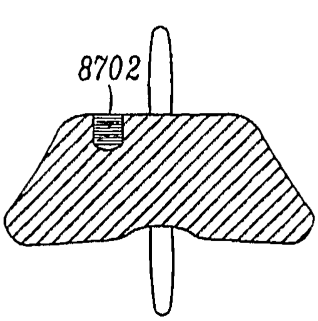


FIG. 87A

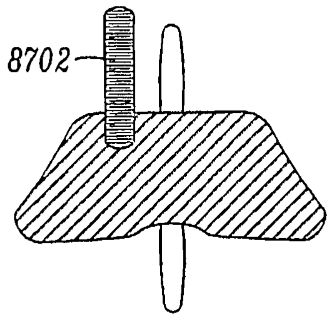


FIG. 87B

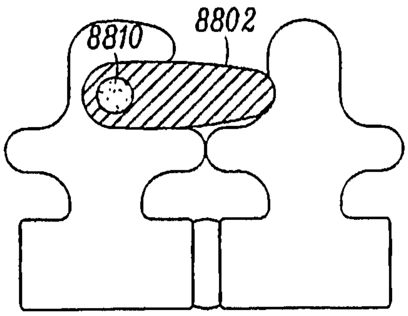


FIG. 88A

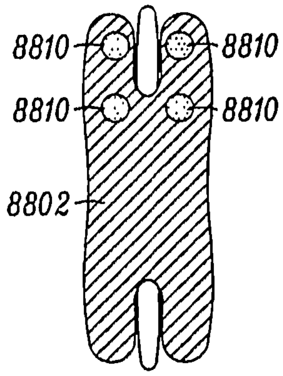


FIG. 88B

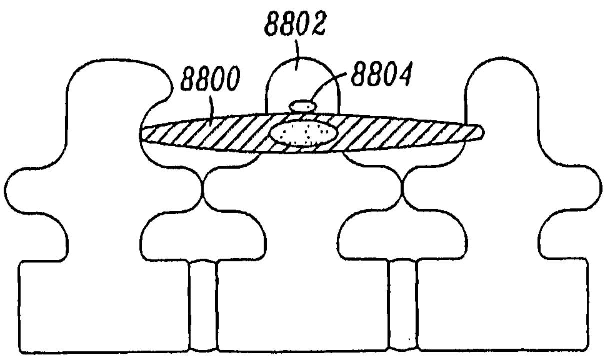


FIG. 89A

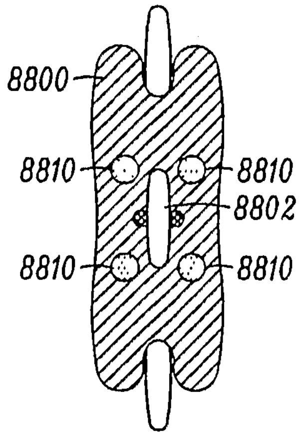


FIG. 89B

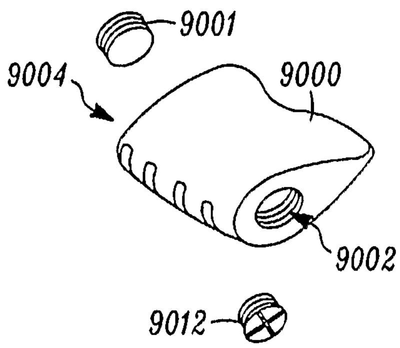


FIG. 90A

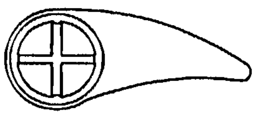


FIG. 90B

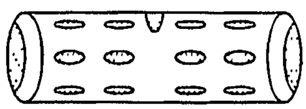


FIG. 90C

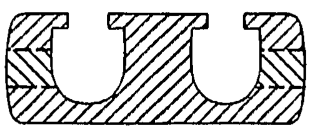


FIG. 90D

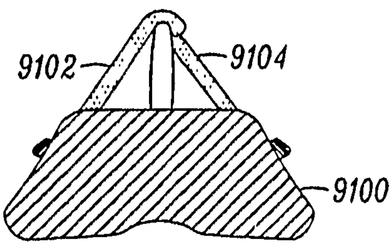


FIG. 91A

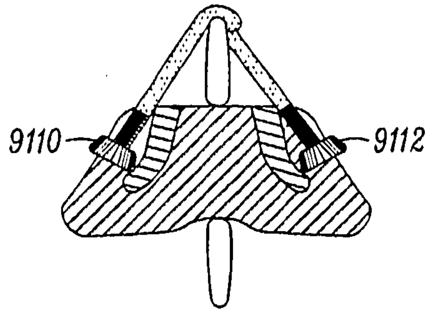


FIG. 91B

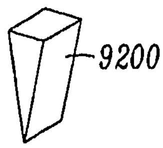


FIG. 92A

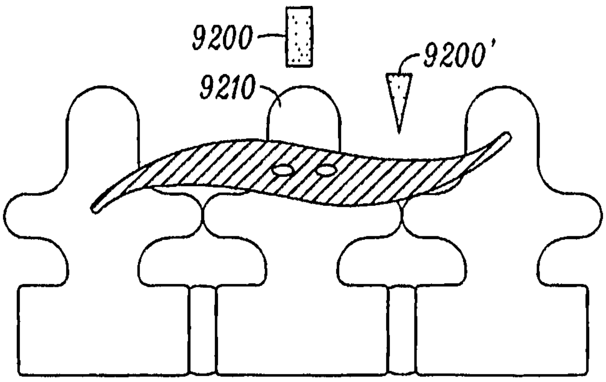


FIG. 92B

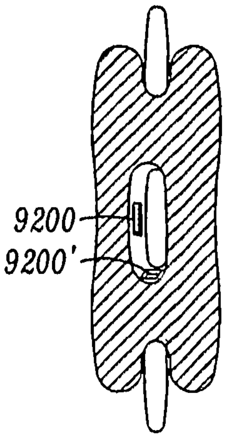


FIG. 92C

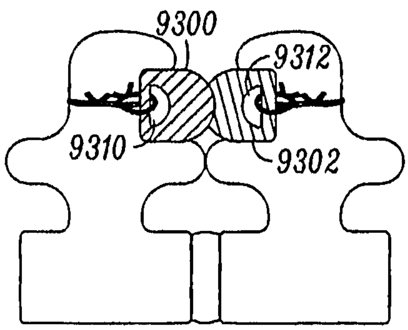


FIG. 93A

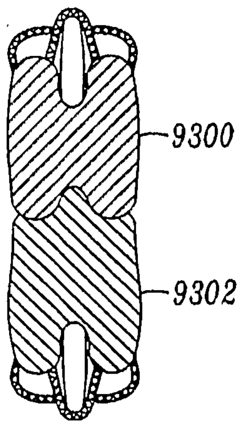


FIG. 93B

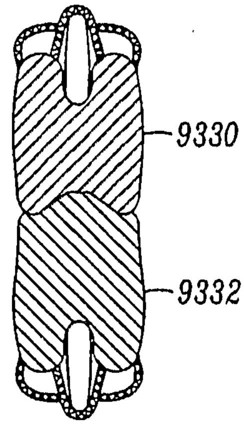


FIG. 93C

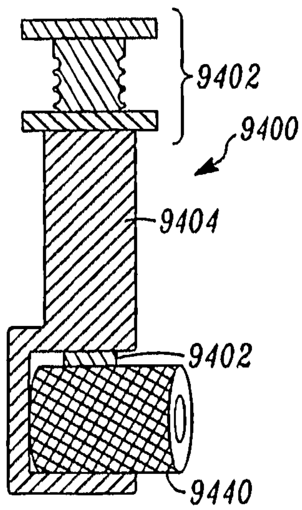


FIG. 94A

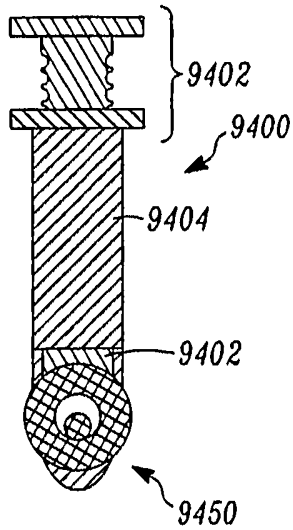


FIG. 94B

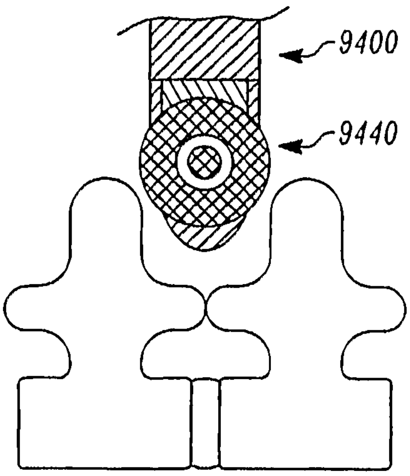


FIG. 94C

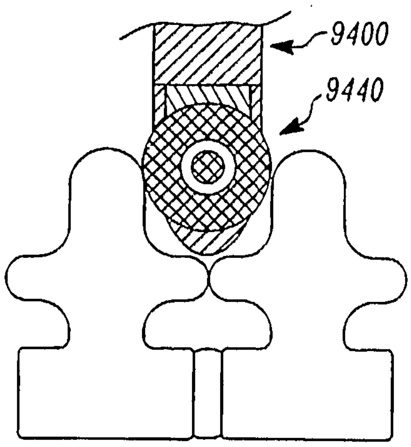


FIG. 94D

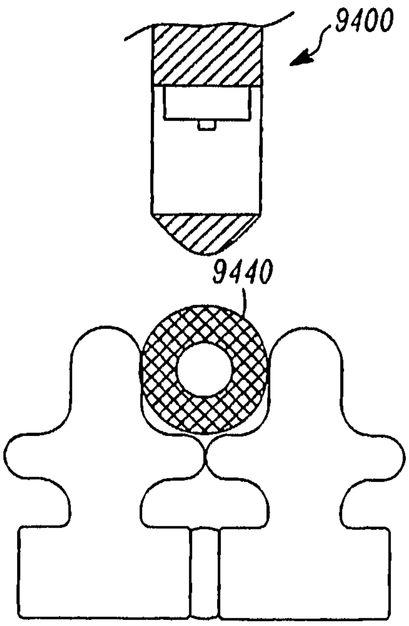


FIG. 94E

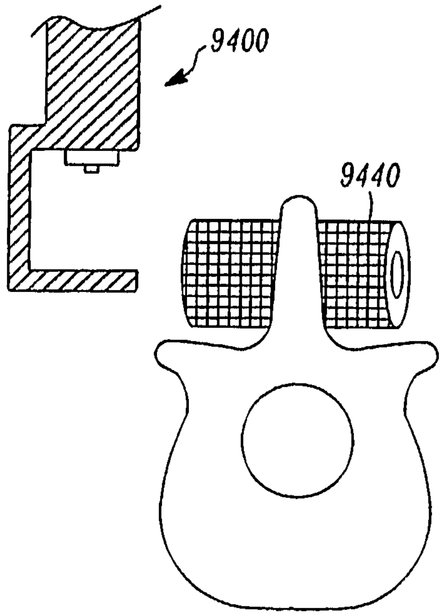


FIG. 94F

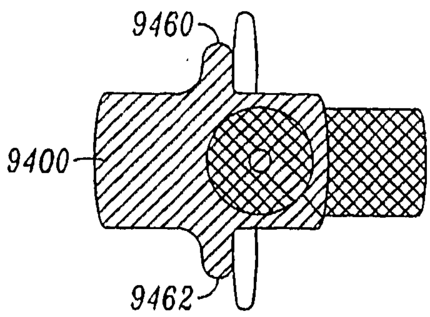


FIG. 94G

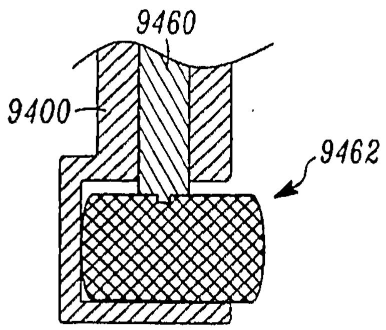


FIG. 94H

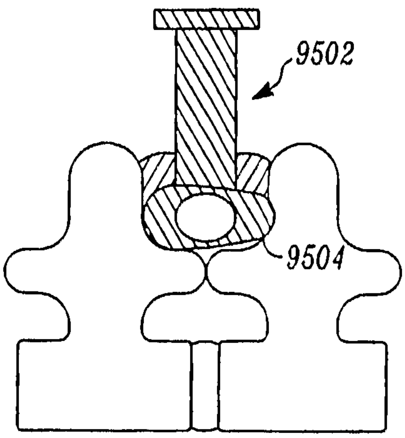


FIG. 95A

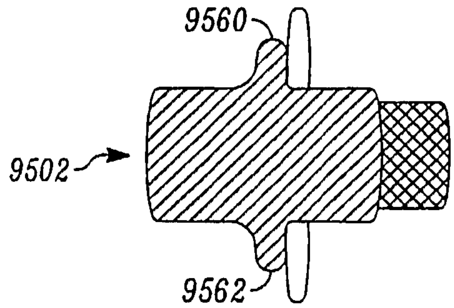


FIG. 95B

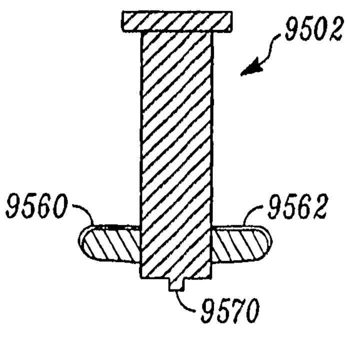


FIG. 95C

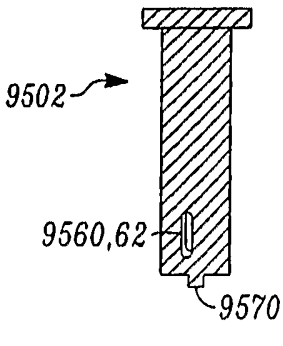


FIG. 95D

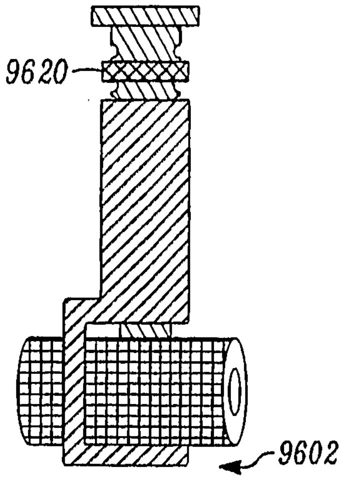


FIG. 96A

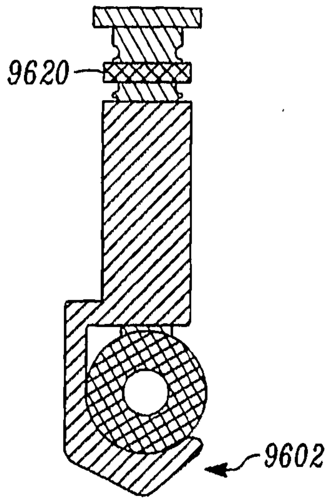


FIG. 96B

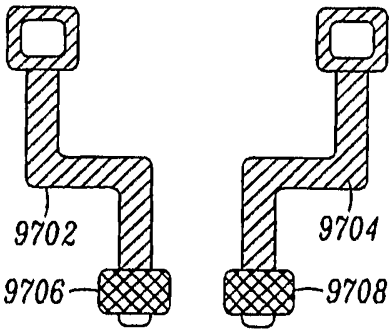


FIG. 97A

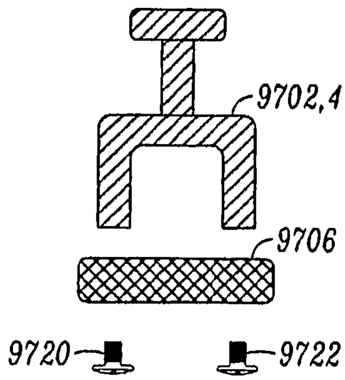


FIG. 97B

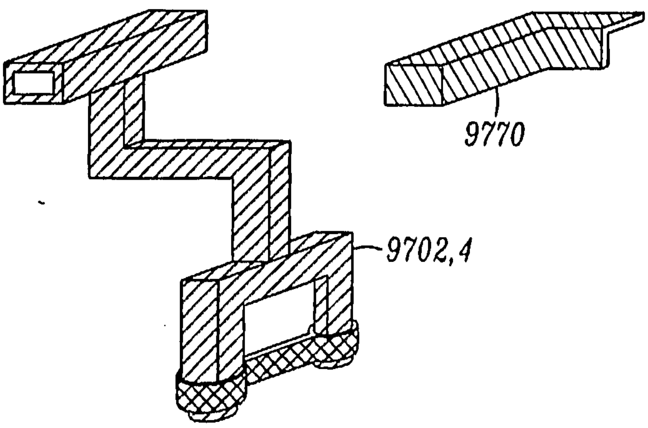


FIG. 97C

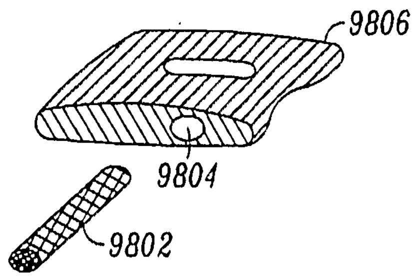


FIG. 98A

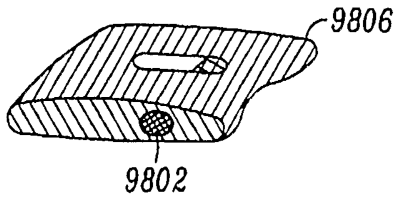


FIG. 98B

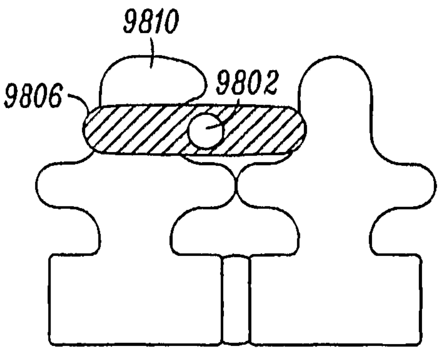


FIG. 98C

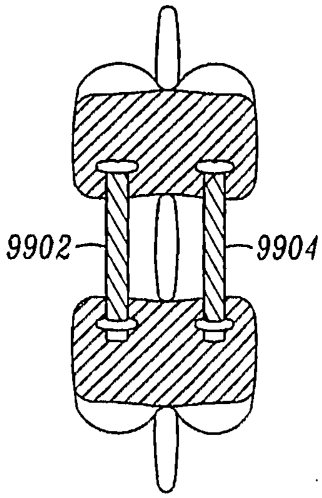


FIG. 99A

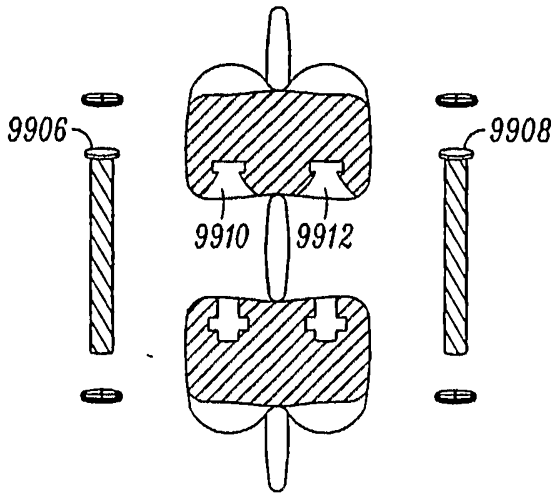


FIG. 99B

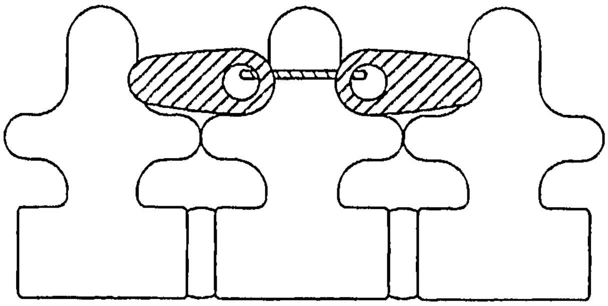


FIG. 99C

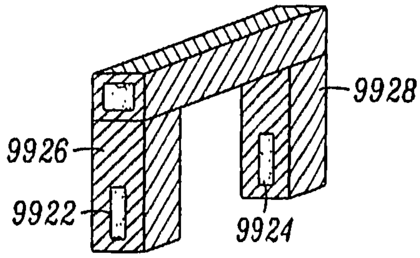


FIG. 100A

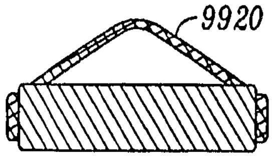


FIG. 100B

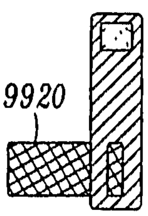


FIG. 100C

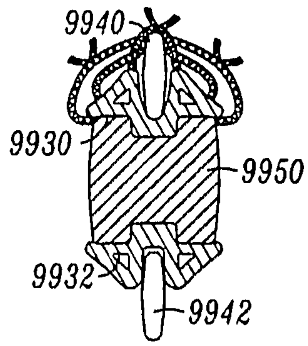


FIG. 101A

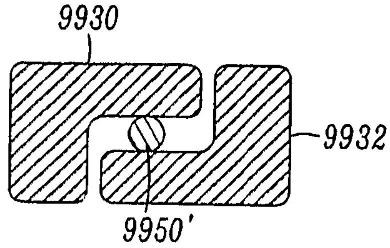


FIG. 101B

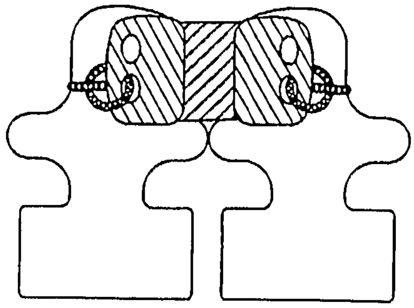


FIG. 101C