(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
29 June 2006 (29.06.2006)

PCT

(10) International Publication Number
WO 2006/068682 A1

(51) International Patent Classification:
A61B 17/60 (2006.01)

(21) International Application Number:
PCT/US2005/034728

(22) International Filing Date:
26 September 2005 (26.09.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/612,728 24 September 2004 (24.09.2004) US

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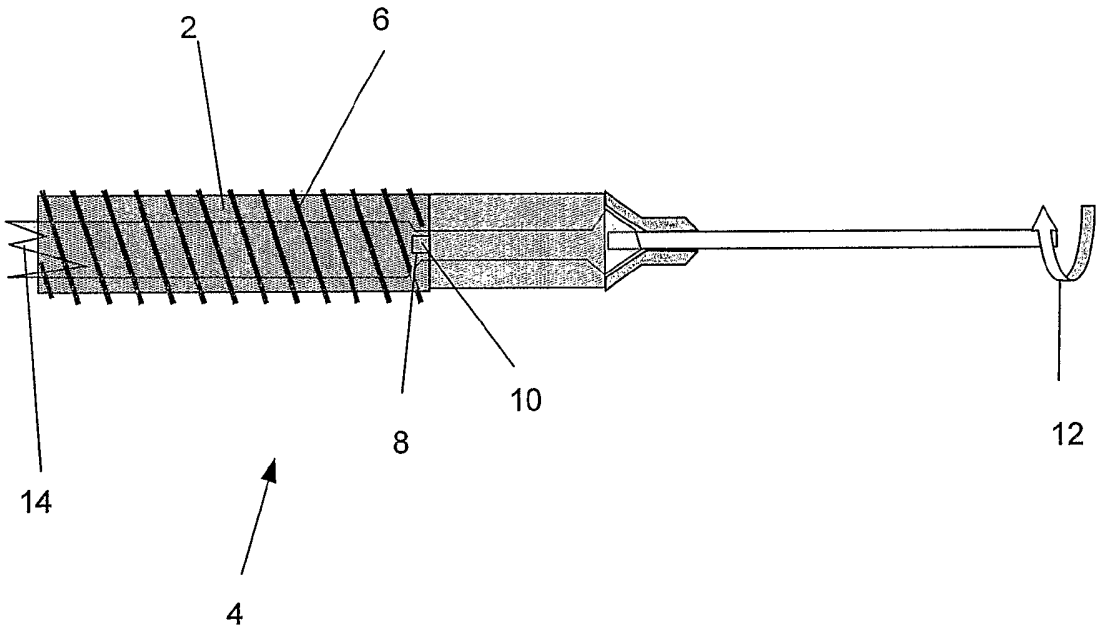
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) **Title:** EXPANDABLE SUPPORT DEVICE AND METHOD OF USE



(57) **Abstract:** An expandable support device and methods of using the expandable support device are disclosed. The expandable support device can be rotatably and inflatably deployed by a deployment tool. The deployment tool can engage a notch on the expandable support device and deliver a torque to the expndable support device. The deployment tool can inflate and expand the expandable support device.

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TITLE OF THE INVENTION

EXPANDABLE SUPPORT DEVICE AND METHOD OF USE

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CROSS–REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Application No. 60/612,728, filed 24 September 2004, which is incorporated by reference herein in its entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0002] This invention relates to devices for providing support for biological tissue, for example to repair spinal compression fractures, and methods of using the same.

2. Background of the Invention

[0003] In the human spine, the vertebral disc provides cushion between adjacent vertebrae. The disc sometimes becomes damaged or deteriorates due to age, disease, injury, or congenital defect. As a result, the vertebrae may also become compressed or otherwise damaged. Vertebrae may also become too closely spaced anteriorly, especially due to age, but also because of other factors that produce an undesired abnormal curvature of the spine with respect to lordosis or kyphosis. As one possible treatment, a patient may undergo surgery to place spacers or interbody devices between the vertebrae. These spacers provide proper spacing of the vertebrae and also promote fusion between

the vertebrae. Such devices are often referred to as a fusion cages or an intervertebral fusion device. To promote fusion, bone or bone fusion material is often placed about the interbody devices to promote growth of the bone between the vertebrae. Some procedures include packing bone fusion materials between one or more interbody devices to promote growth of bone. This is intended to create a fusion between the vertebrae.

[0004] In the past, interbody devices have typically been either generally rectangular or at least partially cylindrical and threaded. The cylindrical devices can be threadably received between and partially into the adjacent vertebrae. To accomplish this, the vertebrae are typically first spaced apart, and then a drill creates a partial bore (radiused channel) in facing surfaces of opposed vertebrae which allows this type of interbody device to be received between the vertebrae. Because of the space between the bones, the interbody device usually engages the bones only along an upper surface and a lower surface of the device. When the interbody device is of a cylindrical threaded type, the upper and lower surfaces are radiused relative to a front to rear axis and such are essentially designed to engage the portion of the vertebrae where bone is removed by boring to create an opening for the device.

[0005] Such interbody devices function well if they engage as much surface of the bone as possible. This provides support to the bone and reduces the chance of subsidence of the device into the bone, where subsidence results from contact pressure of the interbody spacer against an intervertebral surface of a vertebra. Subsidence can occur since part of the bone is somewhat spongy in nature, especially near the centers of the facing upper and lower surfaces of the vertebrae. The remainder of the structure of the intervertebral device mainly functions to support the two vertebral surfaces, unless the device is also

used as a cage within or around which to pack bone fusion material. Because it is also desirable in such structures to maintain weight and volume as low as possible in order to make the device more compatible with the body, it is also desirable to make the entire device as small and lightweight as possible, while maintaining strength. Devices with passthrough windows and other open core structures are limited in strength because of substantial open regions in the core or body of the device.

[0006] It is also desirable to minimize the amount of cutting into and reshaping of the vertebral bones to only that which is necessary to correct the structure and function of the spine. Thus, it is desirable to conform an interbody spacer to the shape of the vertebral surfaces of adjacent vertebrae, which surfaces are shallowly concave, rather than conform the vertebrae to the shape of the interbody spacer.

[0007] In view of the conditions noted above, there remains a need for an improved implant device and delivery system to assist in repair of spinal compression fractures as well as spinal fusion procedures.

SUMMARY OF THE INVETION

An expandable support device configured to fuse to surrounding tissue is disclosed. The expandable support device can be deployed into bone. The expandable support device can increase stability and reduce motion of the bones and/or the expndable support device. The expandable support device can have struts that can be blades configured to dig into the surrounding tissue when the expandable support device is rotatably deployed. The expandable support device can have one or more struts that are

thinner on the radial outside of the expandable support device and thicker on the radial inside of the expandable support device.

A deployment tool that can have a balloon configured to deploy an expandable support device is disclosed. The expandable support device can releasably attach (i.e., mate) with the deployment tool to enable the deployment tool to deploy the expandable support device into hard tissue, such as bone.

SUMMARY OF THE FIGURES

Figure 1 illustrates an embodiment of a deployment tool loaded with an embodiment of an expandable support device.

Figure 2 illustrates an embodiment of the expandable support device.

Figures 3 and 4 illustrate various embodiments of cross-section A-A of Figure 2.

Figures 5 through 8 illustrate various embodiments of the struts of Figure 4.

Figures 9 through 11 illustrate various embodiments of the expandable support device.

Figure 12 illustrates a side perspective view of an embodiment of the expandable support device.

Figure 13 illustrates an end view of the embodiment of the expandable support device of Figure 12.

Figure 14 illustrates a side perspective view of an embodiment of the expandable support device.

Figure 15 illustrates an end view of the embodiment of two expandable support devices of Figure 14.

DETAILED DESCRIPTION

[0008] U.S. Provisional Patent Application No. 60,612,001, titled "EXPANDABLE SUPPORT DEVICE AND METHOD OF USE", filed on 21 September 2004 is herein incorporated by reference in its entirety, and herein referred to as the P001 Patent Application. U.S. Provisional Patent Application No. 60/611,972, titled "BALLOON AND METHODS OF MAKING AND USING", filed on 21 September 2004 is herein incorporated by reference in its entirety, and herein referred to as the P005 Patent Application. U.S. Provisional Patent Application No. 60/612,723, titled "EXPANDABLE SUPPORT DEVICE AND METHOD OF USE", filed 24 September 2004 is herein incorporated by reference in its entirety, and herein referred to as the P008 Patent Application. U.S. Provisional Patent Application No. 60/612,724, titled "SLIDABLE EXPNASION DEPLOYMENT DEVICE AND METHOD OF USING", filed 24 September 2004 is herein incorporated by reference in its entirety, and herein referred to as the P013 Patent Application.

[0009] Figure 1 illustrates an expandable support device 2 loaded onto a deployment tool 4. The expandable support device 2 can have threads 6 in and/or on the surface of the expandable support device 2. The threads 6 can be in the direction necessary to deploy the expandable support device 2 into a bone, such as within and/or between vertebrae.

[0010] The expandable support device 2 can be balloon expandable and/or self-expandable. The expandable support device 2 can be resilient and/or deformable.

[0011] The expandable support device 2 can have a notch 8. The notch 8 can tightly interference fit a deployment driver head 10. The deployment tool 4 can be rotated, as

shown by arrow 12, during use. Rotation of the deployment tool 4 can cause the threads 6 to screw into a deployment site, such as a bone (e.g., a vertebra). The deployment tool 4 can also be otherwise used (e.g., by inflation of a deployment balloon 14 that is part of the deployment tool 4) to deploy the expandable support device 2, for example, after the expandable support device 2 is properly screwed into position. The threads 6 can be fixed in the deployment site, for example, during and/or after screwing the expandable support device 2 during use.

[0012] The balloon 14 on the deployment tool 4 can translate radial force loads directly to the expandable support device 2. The expandable support device 2 can have a maximum outer diameter equal or smaller the maximum outer diameter of the balloon 14.

[0013] The expandable support device 2 can be a stent. Figures 3 and 4 illustrates that th expandable support device 2 can have struts 16. The struts can have a circular or oval cross-section.

[0014] The struts 16 can be porous, for example, to allow tissue ingrowth into the strut 16 and fusion of the strut 16 to the surrounding tissue after implantation. The expandable support device 2 can have a first strut 16a and a second strut 16b. The first strut 16a can have a first porosity. The second strut 16b can have a second porosity. The first and second porosities can be equal. The first porosity can be greater than the second porosity. The porosity of the struts 16 can vary discretely and/or continuously around the perimeter or the expandable support device 2. The porosity of the struts 16 can vary discretely and/or continuously around the perimeter of the individual strut 16.

[0015] Figure 4 illustrates that some or all of the struts 16 can be narrower (i.e., thinner) on the side of the strut 16 that is radially outside of the expandable support device 2

compared to the side of the strut 16 that is radially inside the expandable support device 2. The strut 16 can become narrower relative to the radius with respect to the expandable support device 2. The thinner radial exterior of the struts 16 can imbed or poke into the surround tissue (e.g., bone) during deployment, for example, to increase the stability (i.e., minimize movement/motion, such as slipping out of the space and rolling) of the struts 16 in the bone, also for example to increase the depth of implantation (e.g., jamming) of the struts 16 into the surrounding tissue of the stent in the bone, for example, creating deflecting struts 16 (e.g., threads) that can imbed into the surrounding tissue (i.e., bone) after expansion of the expandable support device 2.

[0016] Figure 5 illustrates that the strut 16 can be configured to have a triangular cross-section. Figure 6 illustrates that the strut 16 can be configured to have a quadrilateral (e.g., trapezoidal) cross-section. Figure 7 illustrates that the strut 16 can have a sharp tip or barb on the radial exterior (i.e., with respect to the expandable support device 2) of the strut 16. Figure 18 illustrates that the strut 16 can have an exterior zone 18a and an interior zone 18b. The exterior zone 18a can have a first porosity. The interior zone 18b can have a second porosity. The first porosity can be greater, equal to, or less than the second porosity.

[0017] The expandable support device 2 can be tapered radially inward and/or radially outward at one or both ends 22a and 22b and/or along the middle 22c, for example as shown in Figures 2, 9 through 11, and the P008 Patent Application. The expandable support device 2 can be tapered, for example, by crimping on to the deployment tool 4, and/or by forming a bullet shape tip on the expandable support device 2. The expandable support device 2 can self tap into the deployment site (e.g., bone).

[0018] Figure 2 illustrates that the expandable support device 2 can have a first taper 20a at a first end 22a and a second taper 20b at a second end 22b. The first taper 20a can be radially inward. The second taper 20b can be radially inward. The middle 22c can have no taper.

[0019] Figure 9 illustrates that the first taper 20a can be radially inward and that the expandable support device 2 can have no second taper 20b. Figure 10 illustrates that the first taper 20a can be radially inward and that the second taper 20b can be radially outward. The second taper 20b can be a flare. Figure 11 illustrates that the second taper 20b can extend from the second end 22b to the first end 22a. The expandable support device 2 can be tapered radially inward and/or radially outward at any combination of the expandable support device ends and/or middle 22a, 22b, and/or 22c.

[0020] The expandable support device 2 can have a sharp end 22a or 22b. The sharp end can be used, for example, to push or hammer the expandable support device in place. The first end 22a can have a reinforced first end 22a and/or second end 22b, for example a reinforced first rim 24. The first end 22a and/or second end 22b (e.g., the first rim 24 and/or second rim) can be made from a different material than the middle 22c. The material of the first end 22a and/or second end 22b can be any of the materials described herein, for example, non-radiopaque, plastic (e.g., polyethylene (PE), polyethylene terephthalate (PET), Nylon, polyglycolic acid (PGA), ploy-L-lactic acid (PLLA)) ceramics, metals or combinations thereof. The struts 16 can be laser cut to create a mesh-like structure (e.g., many thin struts). The struts 16 can contain any of the agents or other materials described herein.

[0021] The expandable support device 2 can be porous and/or hollow. The expandable support device 2 can have a first hole 26 and/or a second hole. The first hole 26 can be at the first end 22a. The second hole can be at the second end 22b. The tissue (e.g., bone) carved out during deployment (e.g., during rotation, such as screwing, and/or translation) of the expandable support device 2 can fill the porous and/or hollow space within the expandable support device 2.

[0022] Figures 12 and 13 illustrate that the expandable support device 2 can have a square or rectangular cross-section with sharp or rounded edges. The expandable support device 2 can be round when contracted and square or rectangular when expanded. Figure 14 illustrates that the expandable support device 2 can have an oval or circular cross-section. Figure 15 illustrates that a first expandable support device 2a can be fixedly or removable attached to a second expandable support device 2b, for example at an attachment point or area 28. The attachment point or area 28 can be a weld, glue, snap, or combinations thereof. The first and second expandable support devices 2a and 2b can be held together by exterior forces alone.

[0023] Figure 16 illustrates the expandable support device 2 that can have an inverse thread, such as an engagement groove 30. The engagement groove 30 can be on the inner diameter of the expandable support device 2. The engagement groove 30 can be configured to engage an external engagement thread on the deployment tool 4. The expandable support device 2 can be or have any characteristics or features disclosed in the P001 Patent Application.

[0024] Figure 17 illustrates that the expandable support device can have a thread 6. The expandable support device 2 can be rotated during implantation to screw into an implant

site, such as a vertebra. The expandable support device 2 can have a thread 6 on the inside and/or outside diameter of the expandable support device 2.

[0025] Figures 18 and 19 illustrate that the thread 6 can be configured to allow rotation in a first direction and inhibit rotation in a second direction. Figure 18 shows that the thread 6 can have a ridge 32. The thread 6 can have uni-directional thread vertebrae 34. Figure 19 illustrates that uni-directional fins 36 can extend from the ridge 32.

[0026] Figure 20 illustrates that the expandable support device 2 can have a first thread 6a and a second thread 6b. The first thread 6a can be overlapping or non-overlapping (as shown) with the second thread 6b. The first thread 6a can have a first pitch, first thread shape, and first coefficient of friction. The second thread 6b can have a second pitch, second thread shape, and second coefficient of friction. The first pitch, first thread shape, and first coefficient of friction can be the same or different than the second pitch, second thread shape, and second coefficient of friction, respectively.

[0027] Figure 21 illustrates that the expandable support device 2 can have a substantially circular cross-section. The expandable support device 2 can have a longitudinal axis 38. Figure 22 illustrates that the struts 16 can be blades, tapping threads, cutting threads, or combinations thereof. The expandable support device 2 can have struts 16 that are blades, tapping threads, cutting threads, or combinations thereof and struts 16 that are not blades, tapping threads, cutting threads, or combinations thereof. The blade struts 16 can be straight blades. During deployment, such as during rotation of the expandable support device 2, the struts 16 can scoop out tissue (e.g., bone). The scooped out tissue can be held in the hollow interior of the expandable support device 2.

[0028] The struts 16 can be oriented unidirectionally. The struts 16 can be configured such that during rotation in a first direction, shown by arrow 40, the expandable support device 2 is minimally inhibited from rotating (i.e., easy to turn), and that during rotation in a second direction, shown by arrow 42, the rotation is resisted by the surrounding tissue and/or the expandable support device 2 can lock against the surrounding tissue. The struts 16 can be configured such that during rotation in a first direction, shown by arrow 40, the expandable support device 2 can be radially contracted, and that during rotation in a second direction, shown by arrow 42, the expandable support device 2 can be radially expanded.

[0029] Figure 23 illustrates that the struts 16 can be convex with respect to the longitudinal axis 38 at the center of the expandable support device 2. The struts 16 can be angled outward with respect to the circumference of the expandable support device 2. During a deployment rotation, similar to the rotation shown by arrow 42 of Figure 22, the struts 16 can anchor into the surrounding tissue.

[0030] Figure 24 illustrates that the struts 16 can be concave with respect to the longitudinal axis 38 at the center of the expandable support device 2. The struts 16 can be angled outward with respect to the circumference of the expandable support device 2. During a deployment rotation, similar to the rotation shown by arrow 42 of Figure 22, the struts 16 can scoop surrounding tissue into the expandable support device 2 and anchor into the remaining surrounding tissue.

[0031] The cross-sections of the expandable support device 2 can be substantially identical at cross-section C-C and D-D. Figures 24 and 25 illustrate that the cross-sections can vary between cross-section C-C and D-D. Figure 25 illustrates that the struts

16 can form a helix around the expandable support device 2. As shown in Figure 14, the expandable support device 2 can have a first strut 16a at top dead center. As shown in Figure 25, the first strut 16a can be at a twist angle 44 from top dead center.

[0032] The porous elements can be made from any materials described herein including, fabric surfaces, metals, sintered fabrics, sintered beads, acid etched surfaces, foamed metals, and combinations thereof.

[0033] The surface of any or all elements of the expandable support device and/or other devices or apparatuses described herein can be textured, for example with a rough surface to match trabecular bone.

[0034] Parts of the expandable support device 2 can be self expanding and some parts of the expandable support device 2 can be balloon expandable. Some or all of the self-expanding struts 16 can "poke" out with additional force when the stent is deployed. These struts 16 can, for example, help lock the expandable support device 2 in place, reduce motion, add stability, increase jamming of the stent in the bone, create deflecting threads or struts which then imbed in the surrounding tissue 9e.g., bone) after expansion of the expandable support device 2.

[0035] Figure 26 illustrates that a deployment extension 46 can enter through the subject's back. The first deployment extension 46a can enter through a first incision 48a in skin 50 on the posterior side of the subject near a vertebral column 52. The first deployment extension 46a can be translated, as shown by arrow 54, to position the first deployment tool 4a (e.g., loaded with the expandable support device 2) adjacent or into an intervertebral disc 56 (as shown) or vertebra 58.

[0036] A second deployment extension 46b (e.g., loaded with the expandable support device 2) can enter through a second incision 48b (as shown) in the skin 50 on the posterior or through the first incision 48a. The second deployment extension 46b can be translated through muscle (not shown), around nerves 60, and anterior of the vertebral column 52. The second deployment extension 46b can be steerable. The second deployment extension 46b can be steered, as shown by arrow 62, to align the distal tip of a second deployment tool 4b with the anterior side of the disc 56 or vertebra 58. The second deployment extension 46b can translate, as shown by arrow 54b, to position the second deployment tool 4b in the disc 56 or vertebra 58.

[0037] The disc 56 or vertebra 58 can have multiple expandable support devices 2 deployed therein. The expandable support devices 2 can be deployed from the anterior, posterior, both lateral, superior, inferior, any angle, or combinations of the directions thereof. Multiple expandable support devices 2 can be deployed sequentially and/or simultaneously.

[0038] Figures 27 through 29 illustrate various methods for using the expandable support device 2. Figure 27 illustrates that multiple, for example two, expandable support devices 2 can be implanted into a spine, for example a vertebra 58 (as shown) and/or intervertebral disc, in a substantially parallel and/or side-by-side configuration.

[0039] Figure 28 illustrates that the expandable support device can be implanted from and/or into a lateral portion of the vertebra (as shown) and/or intervertebral disc. Figure 28 illustrates that multiple expandable support devices can be implanted from and/or into anterior and/or lateral portions of the vertebra (as shown) and/or intervertebral disc. Curved expandable support devices can also be implanted into the spine, such that the

curve can prevent rolling the expandable support device during primary force application. (e.g., implantation as shown in Figure 29 can prevent rolling of the expandable support devices during spinal compression pressure.)

[0040] A pilot hole can be created and a tapping screw can be used to create a channel at the target site for the expandable support device 2. The tapping screw can be used to make a pilot hole at the target site for the expandable support device 2. The thread on the tapping screw can be used to scoop out bone and create arches for the expanded expandable support device 2 to sit in (e.g., for increased stability) once deployed. The carved-out tissue (e.g., bone) can be delivered into the expandable support device 2, for example, to promote ingrowth and fusion to surrounding tissue (e.g., bone).

[0041] The deployment tool 4 can deploy the expandable support device 2 by tapping or hammering the expandable support device 2 into the target site. The deployment tool 4 can deploy the expandable support device 2 by screwing the expandable support device 2 into the target site. The thread 6 and/or struts 16 can pull and/or lock the expndable support device 2 into the target site.

[0042] Figures 30a through 30c illustrate the expandable support device in a relaxed configuration. Figures 31a through 31c illustrate the expandable support device 2 in a contracted configuration, for example, due to rotation 42. Figures 32a through 32c illustrate the expandable support device in an expanded configuration, for example, due to rotation 40. Diameter 64 is a baseline diameter in a relaxed configuration, from which the contracted diameter and the expanded diameter can be viewed in reference.

[0043] Figures 33 and 34 illustrate that the expandable support device 2 and/or the first and second expandable support devices 2a and 2b can be deployed in a stable configuration in a single, or between vertebrae 58.

[0044] Figure 35 illustrates that the expandable support device 2 can be filled with agents, fillers 64, or other materials described herein including morselized bone, cement, hydroxy apatite, ceramic chips, and combinations thereof.

[0045] The fillers can be used to create the fusion environment. The fillers 64 can add to the compressive strength of the expandable support device 2. The ends of the expandable support device 2 can be closed after adding the filler 64.

[0046] During use, a small pilot hole can be created by a pilot tool to guide the expandable support device. The deployment tool can forcefully impact the deployment site, for example, to seat the stent before the screw is turned.

[0047] Any or all elements of the expandable support device and/or other devices or apparatuses described herein can be made from, for example, a single or multiple stainless steel alloys (e.g., Spring steel) , nickel titanium alloys (e.g., Nitinol), cobalt-chrome alloys (e.g., ELGILOY® from Elgin Specialty Metals, Elgin, IL; CONICHROME® from Carpenter Metals Corp., Wyomissing, PA), nickel-cobalt alloys (e.g., MP35N® from Magellan Industrial Trading Company, Inc., Westport, CT), molybdenum alloys (e.g., molybdenum TZM alloy, for example as disclosed in International Pub. No. WO 03/082363 A2, published 9 October 2003, which is herein incorporated by reference in its entirety), tungsten-rhenium alloys, for example, as disclosed in International Pub. No. WO 03/082363, polymers such as polyethylene teraphathalate (PET)/polyester (e.g., DACRON® from E. I. Du Pont de Nemours and

Company, Wilmington, DE), polypropylene, (PET), polytetrafluoroethylene (PTFE), expanded PTFE (ePTFE), polyether ether ketone (PEEK), nylon, polyether-block co-polyamide polymers (e.g., PEBAX® from ATOFINA, Paris, France), aliphatic polyether polyurethanes (e.g., TECOFLEX® from Thermedics Polymer Products, Wilmington, MA), polyvinyl chloride (PVC), polyurethane, thermoplastic, fluorinated ethylene propylene (FEP), absorbable or resorbable polymers such as polyglycolic acid (PGA), polylactic acid (PLA), polycaprolactone (PCL), polyethyl acrylate (PEA), polydioxanone (PDS), and pseudo-polyamino tyrosine-based acids, extruded collagen, silicone, zinc, echogenic, radioactive, radiopaque materials, a biomaterial (e.g., cadaver tissue, collagen, allograft, autograft, xenograft, bone cement, morselized bone, osteogenic powder, beads of bone) any of the other materials listed herein or combinations thereof. Examples of radiopaque materials are barium sulfate, zinc oxide, titanium, stainless steel, nickel-titanium alloys, tantalum and gold.

[0048] Any or all elements of the expandable support device 2 and/or other devices or apparatuses described herein, can be, have, and/or be completely or partially coated with agents and/or a matrix a matrix for cell ingrowth, a ceramic, a polymer, a biodegrading material, drugs or agents described herein, or used with a fabric, for example a covering (not shown) that acts as a matrix for cell ingrowth. The matrix and/or fabric can be, for example, polyester (e.g., DACRON® from E. I. Du Pont de Nemours and Company, Wilmington, DE), polypropylene, PTFE, ePTFE, nylon, extruded collagen, silicone or combinations thereof.

[0049] The expandable support device 2 and/or elements of the expandable support device and/or other devices or apparatuses described herein and/or the fabric can be

filled, coated, layered and/or otherwise made with and/or from cements, fillers, glues, and/or an agent delivery matrix known to one having ordinary skill in the art and/or a therapeutic and/or diagnostic agent. Any of these cements and/or fillers and/or glues can be osteogenic and osteoinductive growth factors.

[0050] Examples of such cements and/or fillers includes bone chips, demineralized bone matrix (DBM), calcium sulfate, coralline hydroxyapatite, biocoral, tricalcium phosphate, calcium phosphate, polymethyl methacrylate (PMMA), biodegradable ceramics, bioactive glasses, hyaluronic acid, lactoferrin, bone morphogenic proteins (BMPs) such as recombinant human bone morphogenetic proteins (rhBMPs), other materials described herein, or combinations thereof.

[0051] The agents within these matrices can include any agent disclosed herein or combinations thereof, including radioactive materials; radiopaque materials; cytogenic agents; cytotoxic agents; cytostatic agents; thrombogenic agents, for example polyurethane, cellulose acetate polymer mixed with bismuth trioxide, and ethylene vinyl alcohol; lubricious, hydrophilic materials; phosphor cholene; anti-inflammatory agents, for example non-steroidal anti-inflammatories (NSAIDs) such as cyclooxygenase-1 (COX-1) inhibitors (e.g., acetylsalicylic acid, for example ASPIRIN® from Bayer AG, Leverkusen, Germany; ibuprofen, for example ADVIL® from Wyeth, Collegeville, PA; indomethacin; mefenamic acid), COX-2 inhibitors (e.g., VIOXX® from Merck & Co., Inc., Whitehouse Station, NJ; CELEBREX® from Pharmacia Corp., Peapack, NJ; COX-1 inhibitors); immunosuppressive agents, for example Sirolimus (RAPAMUNE®, from Wyeth, Collegeville, PA), or matrix metalloproteinase (MMP) inhibitors (e.g., tetracycline and tetracycline derivatives) that act early within the pathways of an

inflammatory response. Examples of other agents are provided in Walton et al, Inhibition of Prostoglandin E_2 Synthesis in Abdominal Aortic Aneurysms, *Circulation*, July 6, 1999, 48-54; Tambiah et al, Provocation of Experimental Aortic Inflammation Mediators and Chlamydia Pneumoniae, *Brit. J. Surgery* 88 (7), 935-940; Franklin et al, Uptake of Tetracycline by Aortic Aneurysm Wall and Its Effect on Inflammation and Proteolysis, *Brit. J. Surgery* 86 (6), 771-775; Xu et al, Sp1 Increases Expression of Cyclooxygenase-2 in Hypoxic Vascular Endothelium, *J. Biological Chemistry* 275 (32) 24583-24589; and Pyo et al, Targeted Gene Disruption of Matrix Metalloproteinase-9 (Gelatinase B) Suppresses Development of Experimental Abdominal Aortic Aneurysms, *J. Clinical Investigation* 105 (11), 1641-1649 which are all incorporated by reference in their entireties.

[0100] It is apparent to one skilled in the art that various changes and modifications can be made to this disclosure, and equivalents employed, without departing from the spirit and scope of the invention. Elements shown with any embodiment are exemplary for the specific embodiment and can be used on other embodiments within this disclosure.

CLAIMS

We Claim:

1. A spinal implant deployment system comprising:

   a housing having a distal portion;

   an expandable spinal implant sized to fit between two adjacent vertebrae, the expandable spinal implant mounted on the distal portion of the housing, the expandable spinal implant having a first mating portion;

   a deployment driver head coupled to a shaft, where the deployment driver head engages the first mating portion such that rotation of the deployment driver causes rotation of the spinal implant; and

   a balloon attached to the housing and within the expandable implant such that expansion of the balloon causes expansion of the spinal implant.

2. The spinal implant deployment system of claim 0, further comprising a shaft coupled to the deployment driver head, such that rotation of the shaft causes rotation of the deployment head and expandable spinal implant.

3. The spinal implant deployment system of claim 0, where the first mating portion comprises a notch and the deployment driver head comprises a protrusion to fit the notch.

4. The spinal implant deployment system of claim 4, where the notch is sized to form an interference fit with the protrusion of the deployment driver head.

5. The spinal implant deployment system of claim 0, where the expandable spinal implant comprises an expandable body having an interior and exterior surfaces, where in a delivery state, the body is sized to fit between the two adjacent vertebrae, an external threading located on the exterior surface and extending along at least a portion thereof, where the exterior surface has threading.

6. The spinal fusion support device of claim5, where the expandable body comprises a tapered shape.

7. The spinal fusion support device of claim7, where the expandable body comprises a tapered shape at a first end and where the tapered shape comprises a radially outward tapered shape.

8. The spinal fusion support device of claim 7, where the expandable body comprises a tapered shape at a first end and where the tapered shape comprises a radially inward tapered shape.

9. The spinal fusion support device of claim 7, where the expandable body comprises a tapered shape at a first end and where the tapered shape comprises a radially outward tapered shape, and where the body further comprises a second end having a radially inward tapered shape.

10. The spinal fusion support device of claim 5, where the expandable body comprises a bullet shaped tip at a distal end.

11. The spinal fusion support device of claim 5, where the expandable body comprises a sharpened end having a tip such that upon sufficient force, the sharpened tip penetrates soft or hard tissue to seat the body.

12. The spinal fusion support device of claim 5, where the expandable body comprises a plurality of struts extending away from the body, where the struts have a sharpened end.

13. The spinal fusion support device of claim 5, where the exterior surface comprises a porous surface.

14. The spinal fusion support device of claim 13, where the porous surface comprises a porous material placed on the body.

15. The spinal fusion support device of claim 14, where the porous material comprises a material selected from a group consisting of fabric, metals, sintered fabric, sintered beads, acid etched, and foamed metals.

16. The spinal fusion support device of claim 15, where the fabric comprises polyester polypropylene, PTFE, ePTFE, nylon, extruded collagen, silicone or combinations thereof.

17. The spinal fusion support device of claim 13, where the body is hollow.

18. The spinal fusion support device of claim 13, where the porous surface comprises at least two sections where having different porosities.

19. The spinal fusion support device of claim 5, where upon expansion of the body, the body forms a non-circular cross sectional shape.

20. The spinal fusion support device of claim 5, where the expandable body comprises a non-circular cross sectional shape in the delivery state.

21. The spinal fusion support device of claim 5, further comprising a first tip located at an end of the body where the first tip comprises a first material and the body comprises a second material.

22. The spinal fusion support device of claim 21, where the first material comprises a material selected from the group consisting of a polymer, a ceramic, and a metal.

23. The spinal fusion support device of claim 21, where the first material comprises a non-radiopaque material.

24. The spinal fusion support device of claim 5, further comprising a second threading on an interior surface of the body.

25. The spinal fusion support device of claim 5, where the threading comprises a first pitch on a first portion of the body and a second pitch on a second portion of the body.

26. The spinal fusion support device of claim 5, where the threading is a self-tapping thread design such that it self-taps into vertebral bone.

27. The spinal fusion support device of claim 26, where the self-tapping thread design comprises a portion of the threading that extends from the body such that rotation of the body in a first direction cuts tissue while rotation in a second direction is prevented by the threading extending from the body.

28. The spinal fusion support device of claim 5, where the body comprises a helical pattern.

29. The spinal fusion support device of claim 5, where the body is coated with a material selected from a group consisting of a ceramic, a polymer, a drug, and a combination thereof.

30. The spinal fusion support device of claim 5, where the expandable body is self-expanding.

31. The spinal fusion support device of claim 31, where the expandable body comprises a material selected from a shape memory alloy, and spring steel.

32. The spinal fusion support device of claim 5, where the expandable body comprises a metal selected from a group consisting of a single or multiple stainless steel alloy, nickel titanium alloys, cobalt-chrome alloys, nickel-cobalt alloys, molybdenum alloys, and tungsten-rhenium alloy.

33. The spinal fusion support device of claim 5, where the expandable body comprises a polymer selected from a group consisting of polyethylene teraphathalate (PET), polyester, polypropylene, PET, polytetrafluoroethylene (PTFE), expanded PTFE (ePTFE), polyether ether ketone (PEEK), nylon, polyether-block co-polyamide polymers, aliphatic polyether polyurethanes, polyvinyl chloride (PVC), polyurethane, thermoplastic, fluorinated ethylene propylene (FEP), polyglycolic acid (PGA), polylactic acid (PLA), polycaprolactone (PCL), polyethyl acrylate (PEA), polydioxanone (PDS), and pseudo-polyamino tyrosine-based acids, extruded collagen, and silicone.

34. The spinal fusion support device of claim 5, where the expandable body is coated with an agent delivery matrix.

35. The spinal fusion support device of claim 34, where the agent delivery matrix comprises an agent selected from the group consisting of a radioactive material, a cytogenic agent, a cytotoxic agent, cytostatic agent, thrombogenic agent, phosphor cholene, anti-inflammatory agent, immunosuppressive agent, and matrix metalloproteinase (MMP) inhibitors.

36. A spinal fusion support device comprising:

an expandable body having an interior and exterior surfaces, where in a delivery state, the body is sized to fit between adjacent vertebrae,

an external threading located on the exterior surface and extending along at least a portion thereof;

where the exterior surface has threading.

37. The spinal fusion support device of claim 36, where the expandable body comprises a tapered shape.

38. The spinal fusion support device of claim 37, where the expandable body comprises a tapered shape at a first end and where the tapered shape comprises a radially outward tapered shape.

39. The spinal fusion support device of claim 37, where the expandable body comprises a tapered shape at a first end and where the tapered shape comprises a radially inward tapered shape.

40. The spinal fusion support device of claim 37, where the expandable body comprises a tapered shape at a first end and where the tapered shape comprises a radially outward tapered shape, and where the body further comprises a second end having a radially inward tapered shape.

41. The spinal fusion support device of claim 36, where the expandable body comprises a bullet shaped tip at a distal end.

42. The spinal fusion support device of claim 36, where the expandable body comprises a sharpened end having a tip such that upon sufficient force, the sharpened tip penetrates soft or hard tissue to seat the body.

43. The spinal fusion support device of claim 42, where the expandable body comprises a plurality of struts extending away from the body, where the struts have a sharpened end.

44. The spinal fusion support device of claim 36, where the exterior surface comprises a porous surface.

45. The spinal fusion support device of claim 44, where the porous surface comprises a porous material placed on the body.

46. The spinal fusion support device of claim 45, where the porous material comprises a material selected from a group consisting of fabric, metals, sintered fabric, sintered beads, acid etched, and foamed metals.

47. The spinal fusion support device of claim 46, where the fabric comprises polyester polypropylene, PTFE, ePTFE, nylon, extruded collagen, silicone or combinations thereof.

48. The spinal fusion support device of claim 44, where the body is hollow.

49. The spinal fusion support device of claim 44, where the porous surface comprises at least two sections where having different porosities.

50. The spinal fusion support device of claim 36, where upon expansion of the body, the body forms a non-circular cross sectional shape.

51. The spinal fusion support device of claim 36, where the expandable body comprises a non-circular cross sectional shape in the delivery state.

52. The spinal fusion support device of claim 36, further comprising a first tip located at an end of the body where the first tip comprises a first material and the body comprises a second material.

53. The spinal fusion support device of claim 52, where the first material comprises a material selected from the group consisting of a polymer, a ceramic, and a metal.

54. The spinal fusion support device of claim 52, where the first material comprises a non-radiopaque material.

55. The spinal fusion support device of claim 36, further comprising a second threading on an interior surface of the body.

56. The spinal fusion support device of claim 36, where the threading comprises a first pitch on a first portion of the body and a second pitch on a second portion of the body.

57. The spinal fusion support device of claim 36, where the threading is a self-tapping thread design such that it self-taps into vertebral bone.

58. The spinal fusion support device of claim 57, where the self-tapping thread design comprises a portion of the threading that extends from the body such that rotation of the body in a first direction cuts tissue while rotation in a second direction is prevented by the threading extending from the body.

59. The spinal fusion support device of claim 36, where the body comprises a helical pattern.

60. The spinal fusion support device of claim 36, where the body is coated with a material selected from a group consisting of a ceramic, a polymer, a drug, and a combination thereof.

61. The spinal fusion support device of claim 36, where the expandable body is self-expanding.

62. The spinal fusion support device of claim 61, where the expandable body comprises a material selected from a shape memory alloy, and spring steel.

63. The spinal fusion support device of claim 36, where the expandable body comprises a metal selected from a group consisting of a single or multiple stainless steel alloy, nickel titanium alloys, cobalt-chrome alloys, nickel-cobalt alloys, molybdenum alloys, and tungsten-rhenium alloy.

64. The spinal fusion support device of claim 36, where the expandable body comprises a polymer selected from a group consisting of polyethylene teraphathalate (PET),

polyester, polypropylene, PET, polytetrafluoroethylene (PTFE), expanded PTFE (ePTFE), polyether ether ketone (PEEK), nylon, polyether-block co-polyamide polymers, aliphatic polyether polyurethanes, polyvinyl chloride (PVC), polyurethane, thermoplastic, fluorinated ethylene propylene (FEP), polyglycolic acid (PGA), polylactic acid (PLA), polycaprolactone (PCL), polyethyl acrylate (PEA), polydioxanone (PDS), and pseudo-polyamino tyrosine-based acids, extruded collagen, and silicone.

65. The spinal fusion support device of claim 36, where the expandable body is coated with an agent delivery matrix.

66. The spinal fusion support device of claim 65, where the agent delivery matrix comprises an agent selected from the group consisting of a radioactive material, a cytogenic agent, a cytotoxic agent, cytostatic agent, thrombogenic agent, phosphor cholene, anti-inflammatory agent, immunosuppressive agent, and matrix metalloproteinase (MMP) inhibitors.

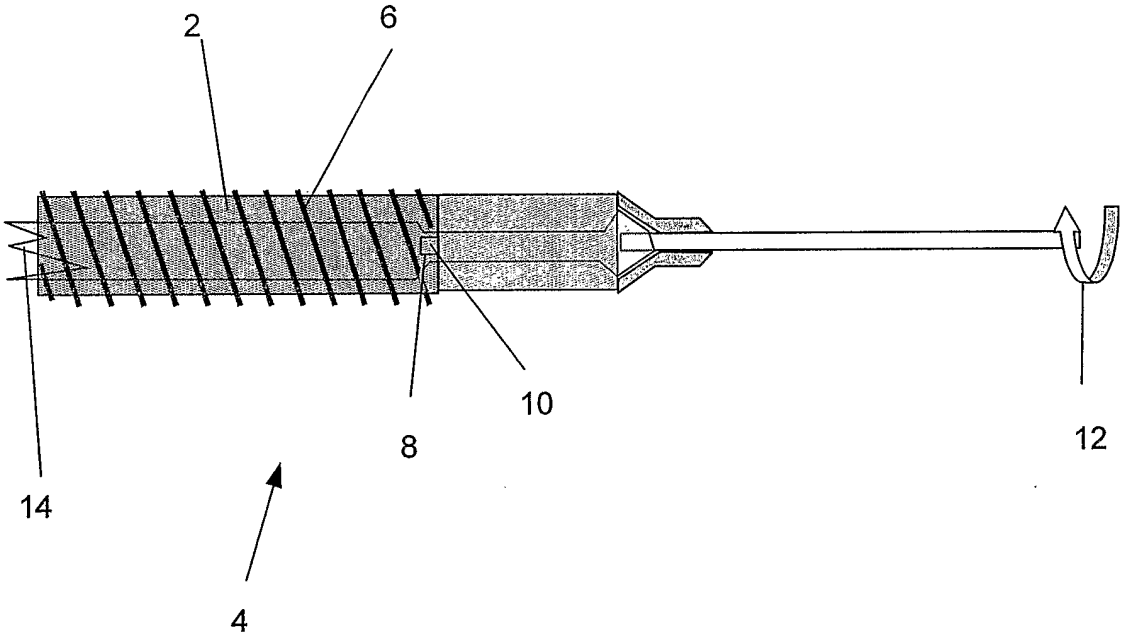

Fig. 1

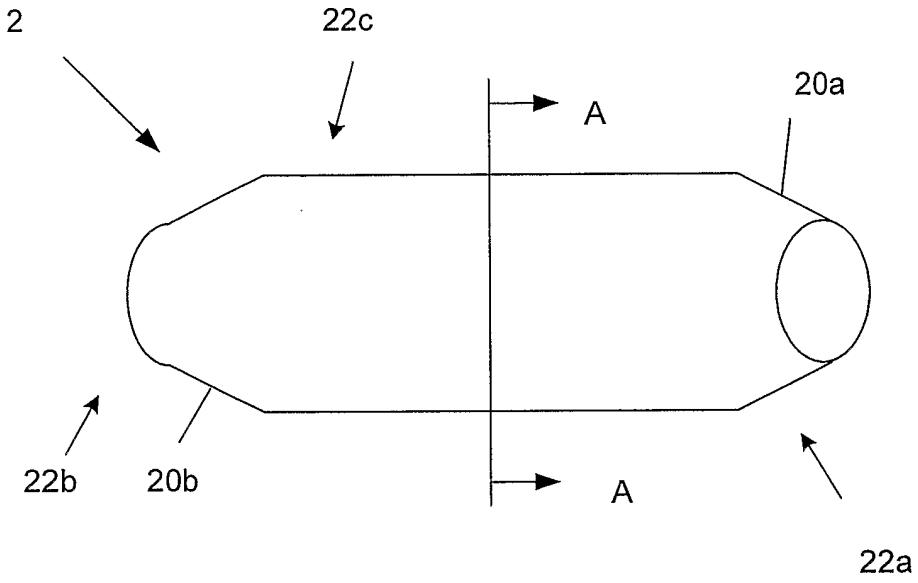

Fig. 2

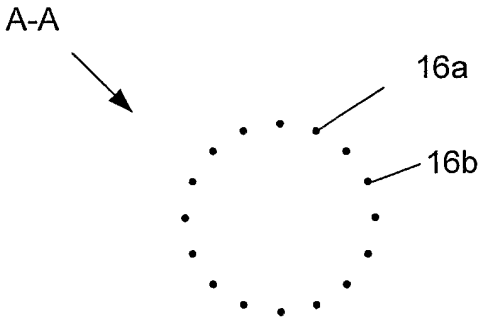

Fig. 3

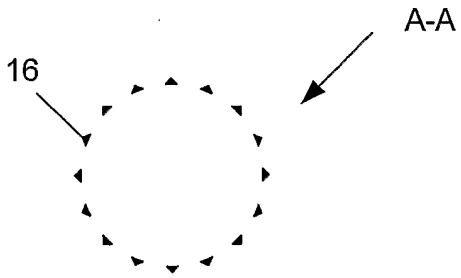

Fig. 4

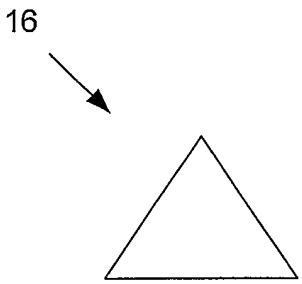

Fig. 5

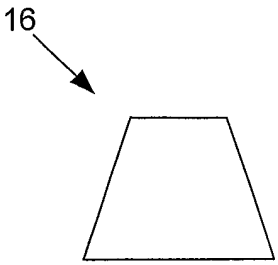

Fig. 6

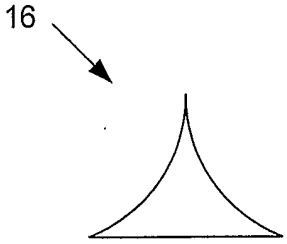

Fig. 7

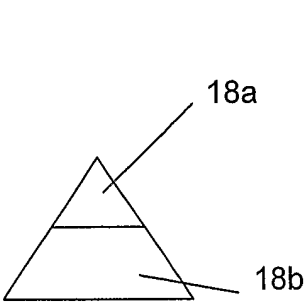

Fig. 8

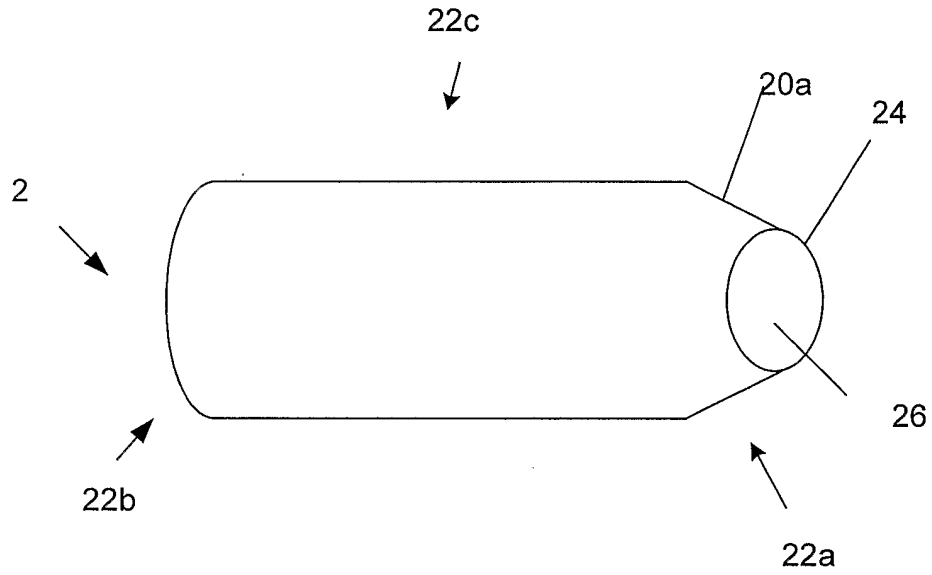

Fig. 9

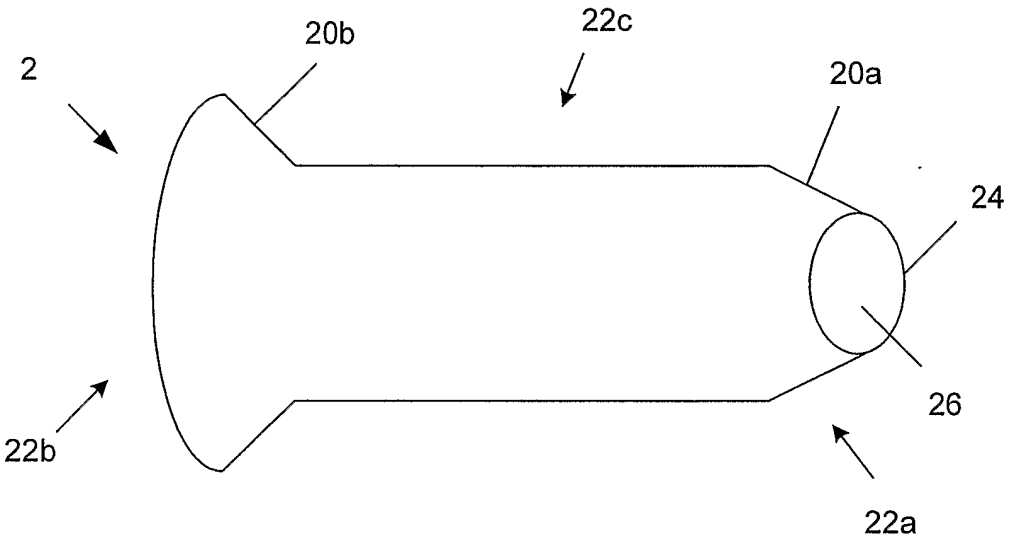

Fig. 10

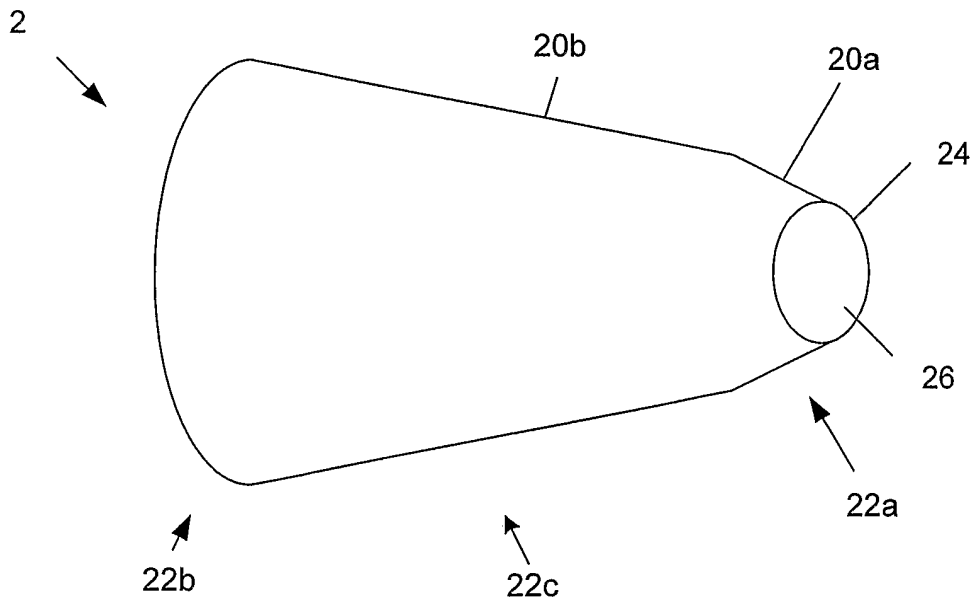

Fig. 11

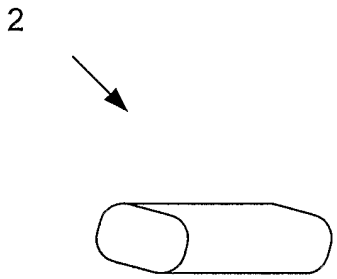

Fig. 12

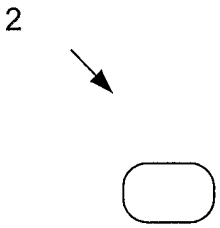

Fig. 13

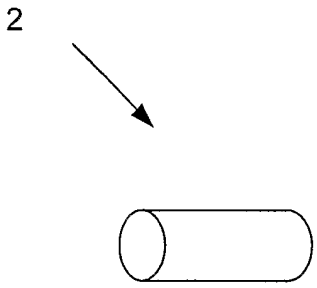

Fig. 14

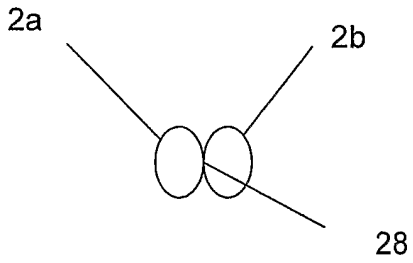

Fig. 15

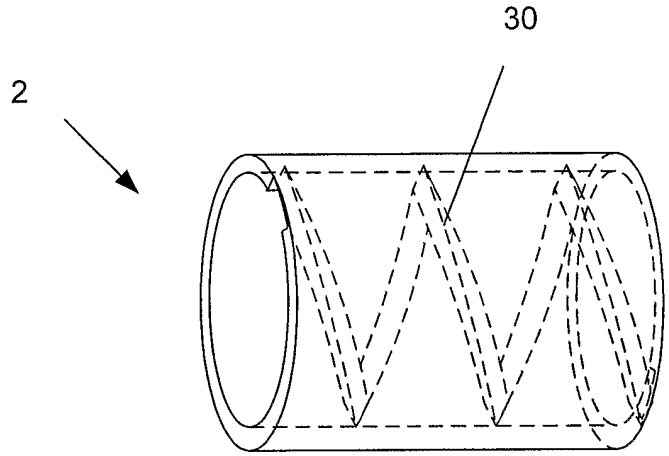

Fig. 16

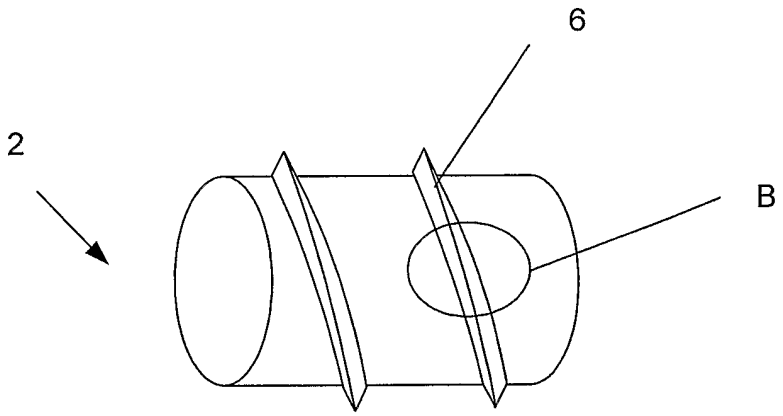

Fig. 17

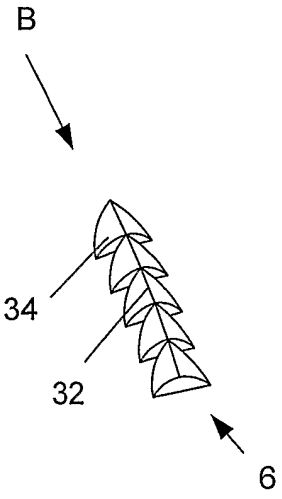

Fig. 18

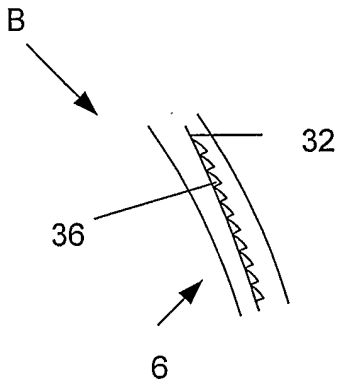

Fig. 19

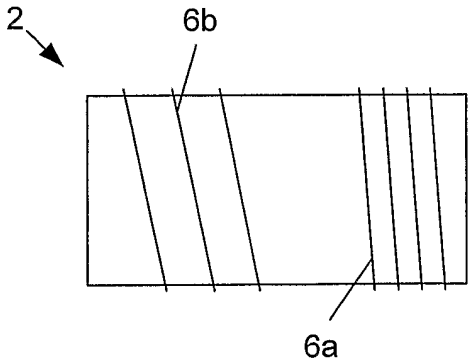

Fig. 20

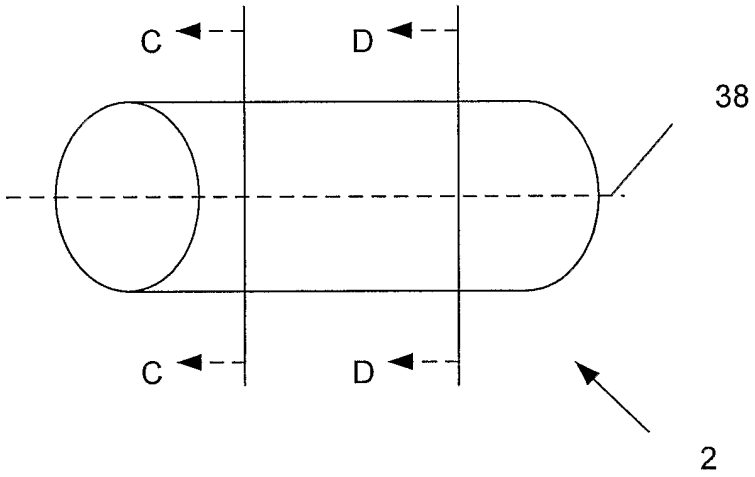

Fig. 21

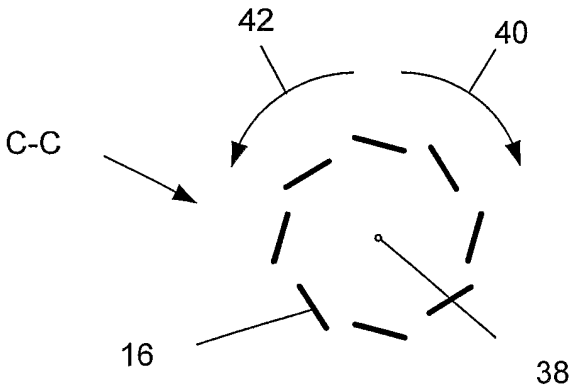

Fig. 22

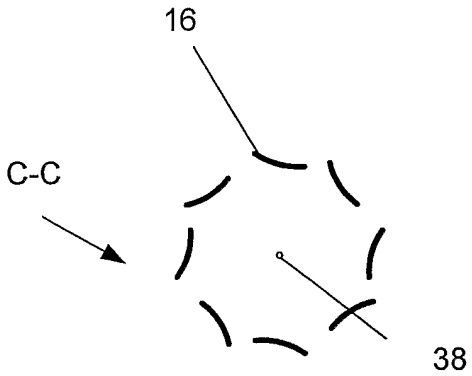

Fig. 23

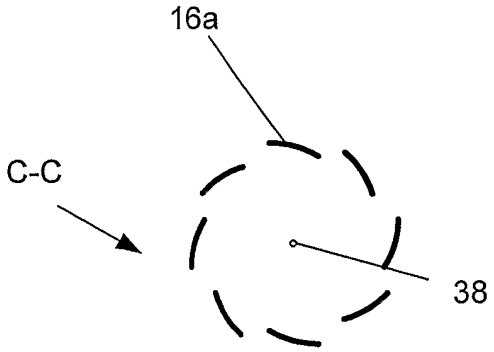

Fig. 24

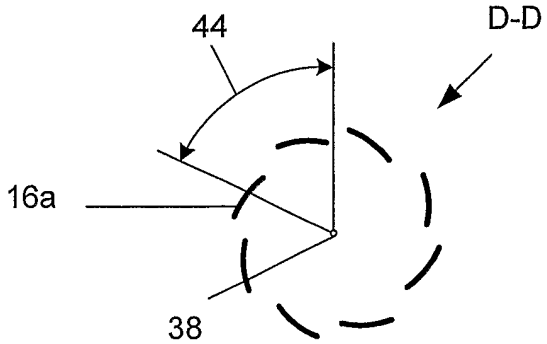

Fig. 25

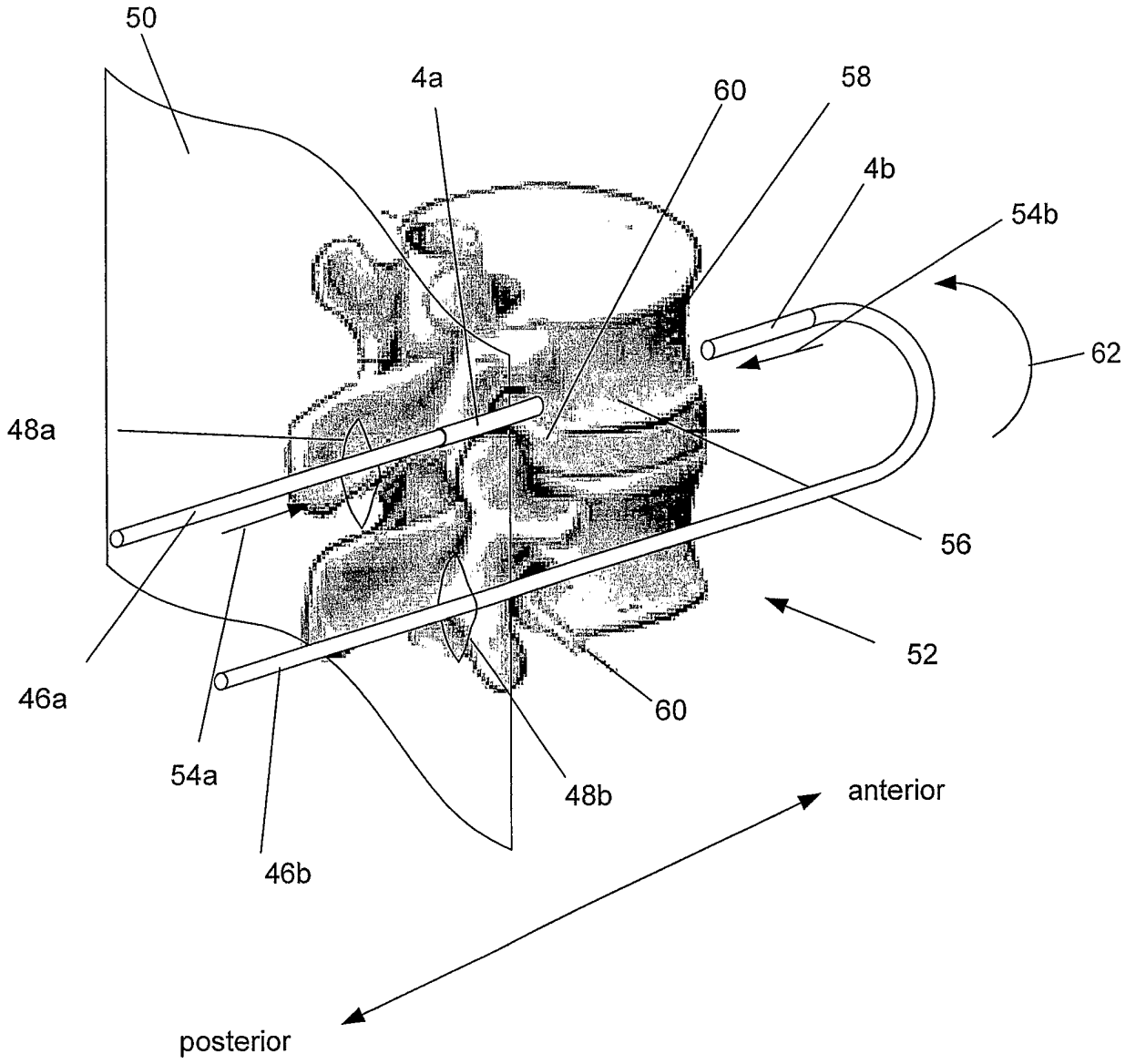
50
4a
60
58
4b
54b
62
48a
56
52
46a
60
54a
48b
anterior
46b
posterior

Fig. 26

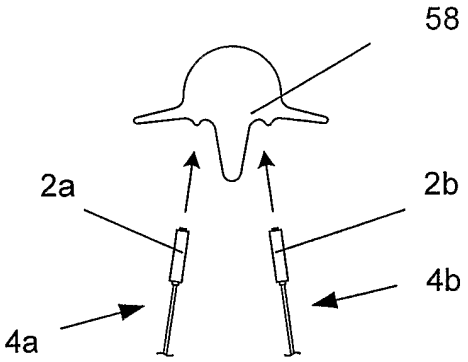

Fig. 27

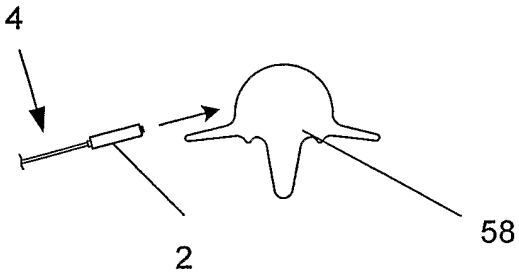

Fig. 28

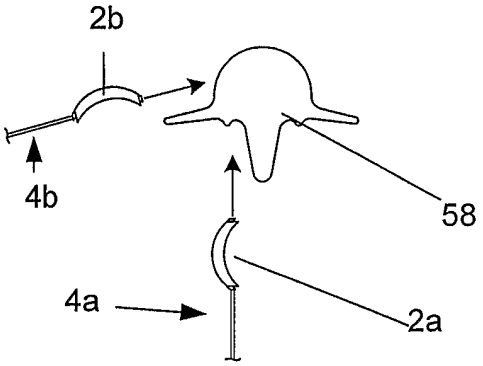

Fig. 29

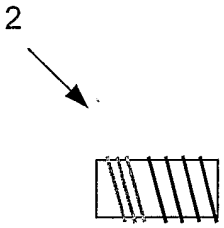

Fig. 30a

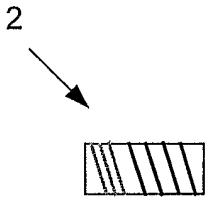

Fig. 31a

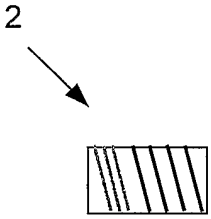

Fig. 32a

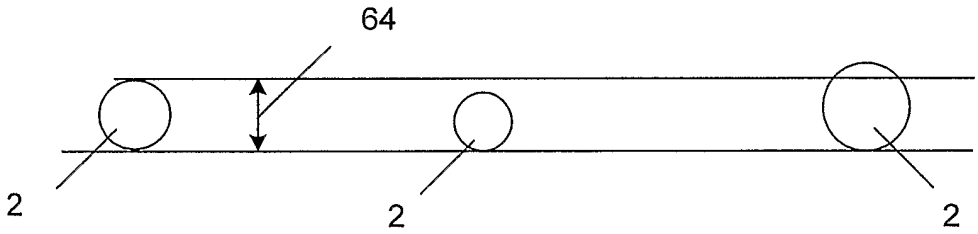

Fig. 30b

Fig. 31b

Fig. 32b

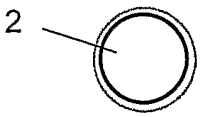

Fig. 30c

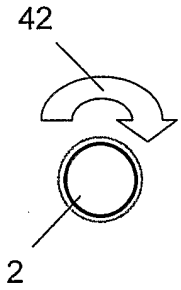

Fig. 31c

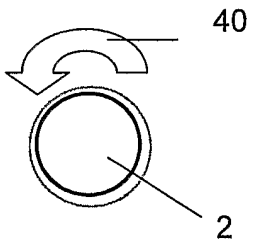

Fig. 32c

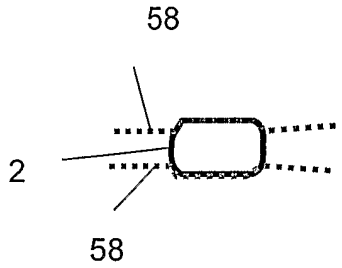

Fig. 33

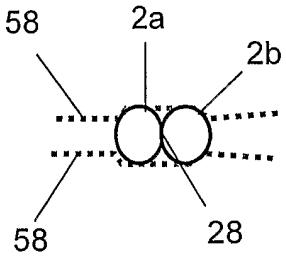

Fig. 34

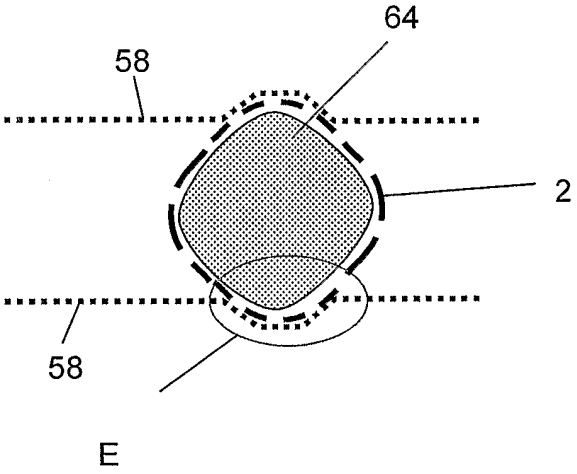

Fig. 35

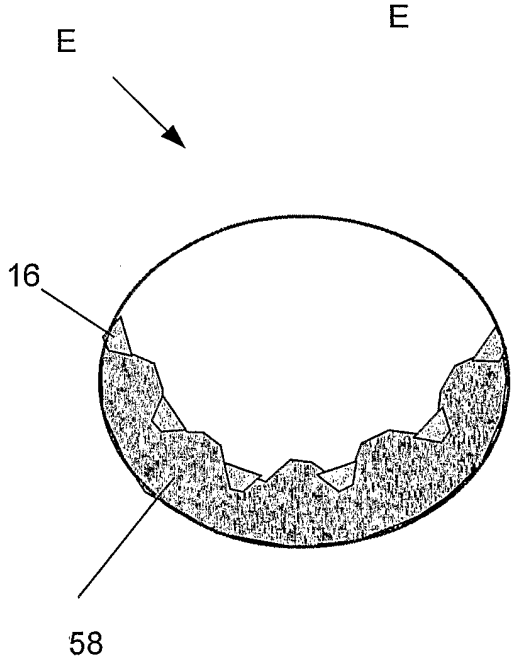

Fig. 36

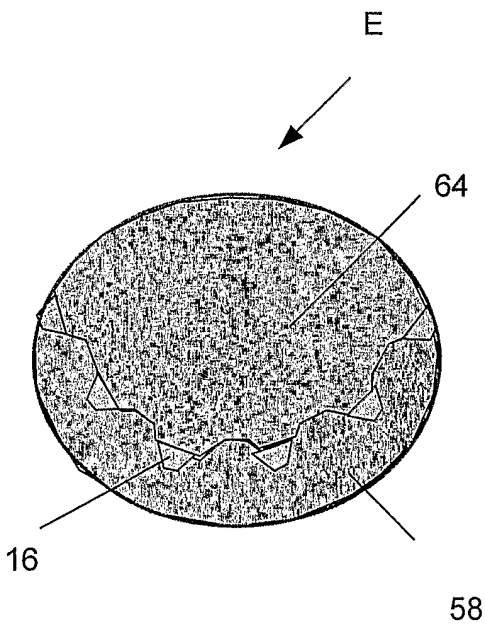

Fig. 37

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/34728

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) : A61B 17/60
US CL : 606/99
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 606/99, 86, 105; 600/3, 7; 623/17.11, 17.12, 17.13, 17.14, 17.15, 17.16

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,863,284 A (KLEIN) 26 January 1999 (26.01.1999), See whole document.	1-66
X	US 6,695,760 B1 (WINKLER et al) 24 February 2004 (24.02.2004), See whole document.	1-66
A	US 5,484,384 A (FEARNOT) 16 January 1996 (16.01.1996), See whole document.	1-66
A	US 2003/0199979 A1 (MCGUCKIN) 23 October 2003 (23.10.2003), See whole document.	1-66

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
04 February 2006 (04.02.2006)

Date of mailing of the international search report
27 FEB 2006

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