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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
18 January 2007 (18.01.2007)

PCT

(10) International Publication Number
WO 2007/009107 A2

(51) International Patent Classification:
A61B 17/02 (2006.01)

(21) International Application Number:
PCT/US2006/027601

(22) International Filing Date: 14 July 2006 (14.07.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/699,576 14 July 2005 (14.07.2005) US
60/752,183 19 December 2005 (19.12.2005) US

(71) Applicant *(for all designated States except US)*: **STOUT MEDICAL GROUP, P.L.** [US/US]; 410 East Walnut, Suite 10, Perkasie, PA 18944 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **GREENHALGH, Scott, E.** [US/US]; 7943 Pleasant Avenue, Wyndmoor, PA 19038 (US). **ROMANO, John, Paul** [US/US]; 59 Skyline Drive, Chalfont, PA 18914 (US). **IGOE, Michael, P.** [US/US]; 448 Campus Drive, Perkasie, PA 18944 (US). **KIEFER, Robert** [US/US]; 50 S. 3rd Street, Apt. 107, Perkasie, PA 18944 (US).

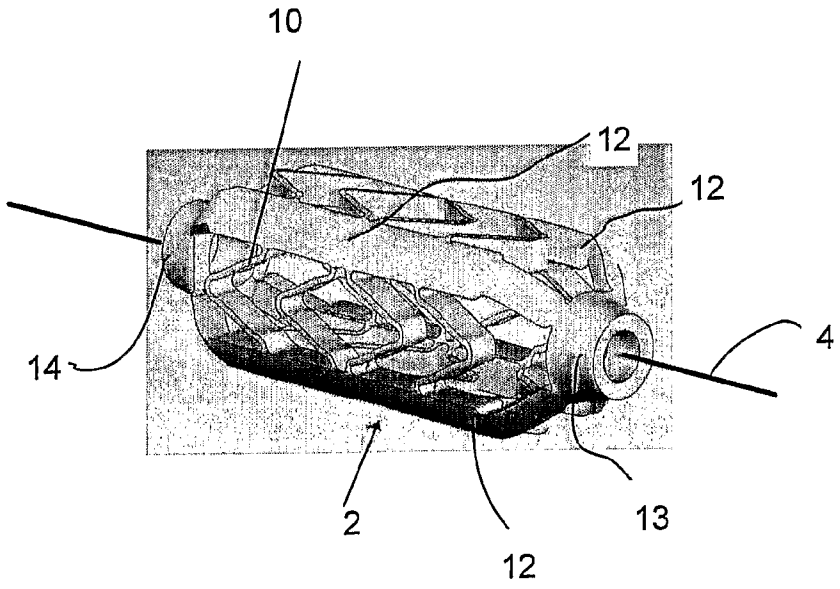
(74) Agent: **LEVINE, David, A.**; LEVINE BAGADE HAN LLP, 2483 East Bayshore Road, Suite 100, Palo Alto, CA 94303 (US).

(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, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, 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, RS, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, 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).

[Continued on next page]

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



(57) Abstract: An expandable support device for tissue repair is disclosed. The device can be used to repair hard or soft tissue, such as bone or vertebral discs. The device can have multiple flat sides that remain flat during expansion. A method of repairing tissue is also disclosed. Devices and methods for adjusting (e.g., removing, repositioning, resizing) deployed orthopedic expandable support devices are also disclosed. The expandable support devices can be engaged by an engagement device. The engagement device can longitudinally expand the expandable support device. The expandable support device can be longitudinally expanded until the expandable support device is substantially in a pre-deployed configuration. The expandable support device can be then be physically translated and/or rotated.

WO 2007/009107 A2

Published:
— *without international search report and to be republished upon receipt of that 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.

EXPANDABLE SUPPORT DEVICE AND METHOD OF USE

E. Skott Greenhalgh

John Paul Romano

Michael P. Igoe

Robert Kiefer

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application Nos. 60/699,576 filed 14 July 2005, and 60/752,183 filed 19 December 2005, which are herein incorporated by reference in their entireties.

BACKGROUND 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.

[0003] Vertebroplasty is an image-guided, minimally invasive, nonsurgical therapy used to strengthen a broken vertebra that has been weakened by disease, such as osteoporosis or cancer. Vertebroplasty is often used to treat compression fractures, such as those caused by osteoporosis, cancer, or stress.

[0004] Vertebroplasty is often performed on patients too elderly or frail to tolerate open spinal surgery, or with bones too weak for surgical spinal repair. Patients with vertebral damage due to a malignant tumor may sometimes benefit from vertebroplasty. The procedure can also be used in younger patients whose osteoporosis is caused by long-term steroid treatment or a metabolic disorder.

[0005] Vertebroplasty can increase the patient's functional abilities, allow a return to the previous level of activity, and prevent further vertebral collapse. Vertebroplasty attempts to also alleviate the pain caused by a compression fracture.

[0006] Vertebroplasty is often accomplished by injecting an orthopedic cement mixture through a needle into the fractured bone. The cement mixture can leak from the bone, potentially entering a dangerous location such as the spinal canal. The cement mixture, which is naturally viscous, is difficult to inject through small diameter needles, and thus many practitioners choose to "thin out" the cement mixture to improve cement injection, which ultimately exacerbates the leakage problems. The flow of the cement liquid also naturally follows the path of least resistance once it enters the bone – naturally along the cracks formed during the compression fracture. This further exacerbates the leakage.

[0007] The mixture also fills or substantially fills the cavity of the compression fracture and is limited to certain chemical composition, thereby limiting the amount of otherwise beneficial compounds that can be added to the fracture zone to improve healing. Further, a balloon must first be inserted in the compression fracture and the vertebra must be expanded before the cement is injected into the newly formed space.

[0008] A vertebroplasty device and method that eliminates or reduces the risks and complexity of the existing art is desired. A vertebroplasty device and method that is not based on injecting a liquid directly into the compression fracture zone is desired.

BRIEF SUMMARY OF THE INVENTION

[0009] An expandable support device for performing completely implantable spinal repair is disclosed. The device may include a near end portion and a far end portion with a number of backbone struts extending therebetween. The near and far end

portions may be closed or have passage openings. In one variation of the invention the end portions can be non-expandable and can cause the implant to form a tapered profile when expanded. Adjacent backbone struts in the implant can be connected by a number of deformable support struts. The adjacent backbone struts can be affixed together or integral (e.g., when laser cut from a tube or other extrusion type piece).

[0010] The structure of the implant device can permit expansion in a number of directions. Variations of the implant can assume different cross-sectional shapes , where such shapes include a square, rectangular, triangular, or any such type of polygon where the sides are defined by the adjacent backbone struts and associated connecting support struts. Furthermore, the shapes may also be rounded, tapered, rectangular (e.g., where the aspect ratio may not be 1 to 1.)

[0011] A method for repairing a damaged section of a spine is also disclosed. The method can include expanding an expandable support device in a treatment site such as a damaged section of bone (e.g., vertebra) or soft tissue (e.g., vertebral disc). The expandable support device can be loaded on a balloon during the expanding. The expansion of the device may be accomplished as described herein. For example, the expansion may include can include inflation of a balloon-type expansion device. Inflating the balloon can include inflating the balloon equal to or greater than about 5,000 kPa of internal pressure, or equal to or greater than about 10,000 kPa of internal pressure.

[0012] Expandable support devices for orthopedic applications, deployment tools and methods for using that same that can be deployed in a minimally invasive procedure are disclosed. For example, the expandable support devices can be deployed through 0.25 in. to 0.5 in. incisions. The expandable support devices can be, for example,

metal and/or polymer self-assembling, self-forming structures. Imaging modalities can be used to maneuver the expandable support device inside the patient.

[0013] Further, expandable support devices, deployment tools and methods are disclosed for removing, resizing, and repositioning the expandable support devices are disclosed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] Figure 1 illustrates a perspective view of a variation of the implant in an unexpanded configuration.

[0015] Figure 2 illustrates a perspective view of the variation of the implant of Figure 1 in an expanded configuration.

[0016] Figure 3 illustrates a side view of the variation of the implant of Figure 1.

[0017] Figure 4 shows a variation of the view along line 4-4 in Figure 3.

[0018] Figure 5 illustrates a side view of the variation of the implant of Figure 1 in an expanded configuration.

[0019] Figure 6 shows a variation of the view along line 6-6 in Figure 4

[0020] Figures 7 and 8 illustrate a variation of a method for using a delivery system for the expandable support element.

[0021] Figures 9 through 11 illustrate a variation of a method for accessing a treatment site in the vertebra.

[0022] Figure 12 illustrates various variations of methods for deploying the expandable support device to the vertebral column.

[0023] Figures 13 through 15 illustrate a variation of a method for deploying the expandable support device into the treatment site in the vertebra.

[0024] Figures 16 and 17 illustrate a variation of a method for deploying the expandable support device into the treatment site in the vertebra.

[0025] Figures 18 and 19 illustrate a variation of a method for deploying one or more expandable support devices into one or more treatment sites in the vertebra.

[0026] Figure 20 illustrates a variation of a method for deploying the expandable support device into the treatment site in the vertebra.

[0027] Figure 21 illustrates a variation of a method for deploying the expandable support device into the treatment site in the vertebra.

[0028] Figure 22 illustrates a variation of a method for deploying multiple expandable support devices into one or more treatment sites in the vertebra.

[0029] Figures 23 and 24 illustrate a variation of a method for deploying the expandable support device into the treatment site in the vertebra.

[0030] Figures 25 and 26 illustrate a variation of a method for deploying the expandable support device between vertebral bodies.

[0031] Figures 27 through 29 illustrate a variation of a method for adjusting and/or retracting the expandable support device with an engagement device.

[0032] Figures 30 through 32 illustrate a variation of a method for adjusting and/or retracting the expandable support device with an engagement device.

[0033] Figures 33 and 35 illustrate a variation of a method for splitting the expandable support device with an engagement device.

[0034] Figure 34 illustrates a variation of the engagement device having a cutting blade.

[0035] Figure 36 illustrates a variation of the expandable support device that has been slit.

[0036] Figure 37 illustrates a variation of a method for adjusting and/or retracting the expandable support device.

[0037] Figure 38 illustrates a cross-sectional view of a method for deploying the expandable support device in a bone.

[0038] Figures 39 through 41 illustrate a variation of a method for overdeploying the expandable support device.

[0039] Figures 42 through 46 illustrate a method for deploying the expandable support device.

DETAILED DESCRIPTION

[0040] Figures 1 and 2 illustrate a biocompatible implant used for tissue repair, including, but not limited to repair of bone fractures such as spinal compression fractures, and/or repairing soft tissue damage, such as herniated/diseased vertebral discs. The impant can be used to perform vertebroplasty, and/or the implant can be used as a partial and/or complete vertebra and/or vertebral disc replacement, and/or for vertebral fixation. The implant can be an expandable support device 2, for example a stent. The expandable support device 2 can have a longitudinal axis 4.

[0041] The expandable support devices 2 can be used to provide structural reinforcement from inside one or more bones, as a replacement for one or more bones, or between bones. The expandable support devices can be used for a variety of orthopedic locations, such as in the vertebral column, for example, to treat compression fractures. Examples of expandable support devices and methods for use of expandable support devices, as well as devices for deploying the expandable support devices include those disclosed in the following applications which are all incorporated herein in their entireties: PCT Application Nos. US2005/034115, filed

21 September 2005; US2005/034742, filed 26 September 2005; US2005/034728, filed 26 September 2005; US2005/037126, filed 12 October 2005; U.S. Provisional Application Nos. 60/675,543, filed 27 April 2005; 60/723,309, filed 4 October 2005; 60/675,512, filed 27 April 2005; 60/699,577, filed 14 July 2005; 60/699,576, filed 14 July 2005; and 60/752,183 filed 19 December 2005.

[0042] The expandable support device 2 can have a plurality of backbone struts 12. The backbone struts 12 can connect a near end portion 13 and a far end portion 14. The backbone struts 12 can each have a near end and a far end affixed to the respective end portions 13 and 14. The expandable support device 2 can be constructed of separate structures that are fixed, integrated or otherwise joined together. The expandable support device 2 can be fabricated from a uniform stock of material (e.g., via laser cutting or electrical discharge machining (EDM)). Adjacent backbone struts can be joined by a number of deformable support struts 10. The support struts 10 can have a thinner cross sectional thickness than most of the remainder of the stent. This feature allows for pre-determined deformation of the stent 2 to take place.

[0043] The support struts 10 may also serve to distribute load across the backbone strut. In such cases, the number of support struts will determine the degree to which the backbone struts are supported.

[0044] The expansion ratio of the expandable support device 2 can be, for example, about 3 or about 4 times the initial diameter of the expandable support device 2. The expansion ratio can be selected as required for the particular procedure. For example, in the pre-expanded configuration the expandable support device 2 can have an initial diameter of about 6.3 mm (0.25 in.), while in the expanded configuration, the diameter can be about 9.5 mm (0.37 in.). In a further example, the expandable

support device 2 can have an initial diameter of about 5 mm (0.2 in.), while in the expanded configuration, the diameter can be about 20 mm (0.8 in.).

[0045] In the pre-expanded configuration, the cross-sectional shape of the expandable support device 2 can be circular, triangular, oval, rectangular, square, or any type of polygon and/or rounded, and/or tapered shape. Upon expansion, the expandable support device 2 can form a polygon-type shape, or other shape as discussed herein.

[0046] Figure 2 illustrates that the expandable support device 2 can expand such that the backbone struts 12 can expand away from the longitudinal axis 4. The backbone struts 12 can remain substantially parallel to the axis 4. The support struts 10 can be configured to limit the expansion of the backbone struts 12. The backbone struts 12 can be configured to prevent the backbone struts 12 from buckling.

[0047] The adjacent backbone struts 12 and accompanying support struts 10 can form a side of the implant. Although the variation illustrated in Figures 1 through 6 shows four backbone struts 12, and four support struts 10 per adjacent backbone struts 12 (and therefore four faces), the inventive device can have three or more sides, for example with the requisite number of backbone supports. The cross sectional areas of the expandable support device 2, can include triangular shapes, square shapes, rectangular shapes, and any type of polygon-shaped structure, for example when the expandable support device 2 is in an expanded configuration. The longitudinal length of each side of the expandable support device 2 can be equal to the other sides or sides of the expandable support device 2. The longitudinal length of each side of the expandable support device 2 can be substantially different than the other sides or sides of the expandable support device 2.

[0048] Any portion of the expandable support device 2 can have one or more ingrowth ports (not shown). The ingrowth ports can be configured to encourage

biological tissue ingrowth therethrough during use. The ingrowth ports can be configured to releasably and/or fixedly attach to a deployment tool or other tool. The ingrowth ports can be configured to increase, and/or decrease, and/or focus pressure against the surrounding biological tissue during use. The ingrowth ports can be configured to increase and/or decrease the stiffness of either the backbone or support struts.

[0049] The expandable support device 2 can have any number of support struts 12. The support struts 12 can have a substantially "V"-like shape that deforms or expands as the implant expands, such as shown in Figure 2. The shape of the support struts 12 can be shapes other than the substantially "V"-like shape. The struts 12 can be configured as any shape to accommodate the expansion of the implant 2. Such shapes can include a substantially "U"-like shape, a substantially "W"-like configuration, an substantially "S"-like configuration. The struts can have a combination of configurations in the same expandable support device 2, for example, to time the expansion of portions of the implant or otherwise control the profile of the implant during expansion.

[0050] The expandable support device 2 can have a wall thickness from about 0.25 mm (0.098 in.) to about 5 mm (0.2 in.), for example about 1 mm (0.04 in.). The expandable support device 2 can have an inner diameter (e.g., between farthest opposing backbone structures). The inner diameter can be from about 1 mm (0.04 in.) to about 30 mm (1.2 in.), for example about 6 mm (0.2 in.). The wall thickness and/or the inner diameter can vary with respect to the length along the longitudinal axis 4. The wall thickness and/or the inner diameter can vary with respect to the angle formed with a plane parallel to the longitudinal axis 4. The wall thickness can be reduced at points where deformation is desired. For example, the wall thickness of

the support struts 12 can be reduced where the backbone structure meets the end portions.

[0051] Figure 3 illustrates that the implant 2 can have near and far end portions 13 and 14. The near and far end portions 13 and 14 can be attached to each backbone strut via a near and far end of the backbone strut 12.

[0052] Figure 4 illustrates a front view of the implant 2 taken along the line 4-4 of Figure 3. The end portions of the expandable support device 2 can have openings 16. The opening 16 can be threaded to accommodate a threaded member. One or both of the end portions can be solid which allows for filling of the expandable support device 2 with materials described herein. The end portions can be expandable. The end portions can be non-expandable (i.e., rigid).

[0053] Figure 5 illustrates that after expansion the backbone struts 18 can remain parallel to the longitudinal axis 4 and the ends of the backbone struts can form a taper with the near and far end portions 13 and 14.

[0054] Figure 6 illustrates a front view taken along the line 6-6 of Figure 5 of the expandable support device 2. The expandable support device 2 can have a square cross sectional shape as the backbone struts 12 remain parallel to the longitudinal axis 4.

[0055] The expandable support device 2 can have one or more protrusions on the surface of the expandable support device 2. The protrusions can have features such as tissue hooks, and/or barbs, and/or cleats. The protrusions can be integral with and/or fixedly or removably attached to the expandable support device 2. The expandable support device 2 can be configured (e.g., on the support struts 10 or other parts of the implant) to burrow into soft bone (e.g., cancellous or diseased), for example, until the device fully expands, or until the device hits the harder vertebral endplates.

[0056] Any or all elements of the expandable support device 2 and/or other devices or apparatuses described herein (e.g., including all deployment tools and their elements described below) can be made from, for example, a single or multiple stainless steel alloys, 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, aromatic polyesters, such as liquid crystal polymers (e.g., Vectran, from Kuraray Co., Ltd., Tokyo, Japan), ultra high molecular weight polyethylene (i.e., extended chain, high-modulus or high-performance polyethylene) fiber and/or yarn (e.g., SPECTRA® Fiber and SPECTRA® Guard, from Honeywell International, Inc., Morris Township, NJ, or DYNEEMA® from Royal DSM N.V., Heerlen, the Netherlands), polytetrafluoroethylene (PTFE), expanded PTFE (ePTFE), polyether ketone (PEK), polyether ether ketone (PEEK), poly ether ketone ketone (PEKK) (also poly aryl ether ketone ketone), 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), poly-L-glycolic acid (PLGA), polylactic acid (PLA), poly-L-lactic acid (PLLA),

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.

[0057] Any or all elements of the expandable support device 2 and/or other devices or apparatuses described herein (e.g., including all deployment tools and their elements described below), can be, have, and/or be completely or partially coated with agents and/or a matrix a matrix for cell ingrowth 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.

[0058] The expandable support device 2 and/or elements of the expandable support device 2 and/or other devices or apparatuses described herein (e.g., including all deployment tools and their elements described below) 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.

[0059] 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.

[0060] 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.

METHOD OF USE

[0061] Figure 7 illustrates that the expandable support device 2 can be loaded in a collapsed (i.e., contracted) configuration onto a deployment tool 38. The deployment tool 38 can have an expandable balloon catheter as known to those having an ordinary level of skill in the art. The deployment tool 38 can have a catheter 40. The catheter 40 can have a fluid conduit 42. The fluid conduit 42 can be in fluid communication with a balloon 44. The balloon 44 and the deployment tool 38 can be the balloon 44 and deployment tool 38 as described by PCT Application No. US2005/033965 filed 21 September 2005, which is herein incorporated by reference in its entirety. The balloon 44 can be configured to receive a fluid pressure of at least about 5,000 kPa (50 atm), more narrowly at least about 10,000 kPa (100 atm), for example at least about 14,000 kPa (140 atm).

[0062] The expandable support device 2 can be deployed and/or expanded with a force from a mechanical actuation device (e.g., as opposed to the balloon expansion). For example, the ends of the expandable support device 2 can move, or be moved, together to expand the backbone struts outward. The expandable support device 2 can be configured to be self-expand upon the removal of a restraint (e.g., when the expandable support device 2 is constructed from a resilient or super-elastic material). The expandable support device 2 can be made from a shape memory alloy that can have a pre-determined transition temperature such that expansion takes place due to temperature changes passively (e.g., from the patient's body heat) or actively (e.g.,

from thermal and/or electrical energy delivered to the expandable support device 2 from outside the patient) created during or after implantation.

[0063] The expandable support device 2 can be locked into the expanded configured with a locking structure (e.g., a center strut, ratchet type mechanism, screw, locking arm, combinations thereof) that can be integral with or separate from the remainder of the expandable support device 2. The expandable support device 2 can be "locked" into the expanded position by filing the expandable support device 2 with cement, filler (bone chips, calcium sulfate, coralline hydroxyapatite, Biocoral, tricalcium phosphate, calcium phosphate, PMMA, bone morphogenic proteins, other materials described herein, or combinations thereof.

[0064] The deployment tool 38 can be a pair of wedges, an expandable jack, other expansion tools, or combinations thereof.

[0065] Figure 8 illustrates that the fluid pressure in the fluid conduit 42 and balloon can increase, thereby inflating the balloon 44, as shown by arrows. The expandable support device 2 can expand, for example, due to pressure from the balloon 44.

[0066] Figures 9 (side view) and 10 (top view) illustrates a group of bones, such as vertebral column 46, that can have one or more bones, such as vertebra 48, separated from the other vertebra 48 by soft tissue, such as vertebral discs 50. The vertebra 48 can have a target or damage site 52, for example a compression fracture.

[0067] An access tool 54 can be used to gain access to the damage site 52 and or increase the size of the damage site 52 to allow deployment of the expandable support device 2. The access tool 54 can be a rotating or vibrating drill 56 that can have a handle 58. The drill 56 can be operating, as shown by arrows 60. The drill 56 can then be translated, as shown by arrow 62, toward and into the vertebra 48 so as to pass into the damage site 52.

[0068] Figure 11 illustrates that the access tool 54 can be translated, as shown by arrow, to remove tissue at the damage site 52. The access tool 54 can create an access port 64 at the surface of the vertebra 48. The access port 64 can open to the damage site 52. The access tool 54 can then be removed from the vertebra 48.

[0069] Figure 12 illustrates that a first deployment tool 38a can enter through the subject's back. The first deployment tool 38a can enter through a first incision 66a in skin 68 on the posterior side of the subject near the vertebral column 46. The first deployment tool 38a can be translated, as shown by arrow 70, to position a first expandable support device 2a into a first damage site 52a. The first access port 64a can be on the posterior side of the vertebra 48.

[0070] A second deployment tool 38b can enter through a second incision 66b (as shown) in the skin 68 on the posterior or the first incision 66a. The second deployment tool 38b can be translated through muscle (not shown), around nerves 72, and anterior of the vertebral column 46. The second deployment tool 38b can be steerable. The second deployment tool 38b can be steered, as shown by arrow 74, to align the distal tip of the second expandable support device 2b with a second access port 64b on a second damage site 52b. The second access port 64b can face anteriorly. The second deployment tool 38b can translate, as shown by arrow 76, to position the second expandable support device 2 in the second damage site 52b.

[0071] The vertebra 48 can have multiple damage sites 52 and expandable support devices 2 deployed therein. The expandable support devices 2 can be deployed from the anterior, posterior, either or both lateral, superior, inferior, any angle, or combinations of the directions thereof.

[0072] Figures 13 and 14 illustrate translating, as shown by arrow, the deployment tool 38 loaded with the expandable support device 2 through the access port 64.

Figure 15 illustrates locating the expandable support device 2 on the deployment tool 38 in the damage site 52.

[0073] Figures 16 and 17 illustrate that the deployment tool 38 can be deployed from the posterior side of the vertebral column 46. The deployment tool 38 can be deployed off-center, for example, when approaching the posterior side of the vertebral column 46.

[0074] Figures 18 and 19 illustrate that first and second deployment tools 38a and 38b can position and deploy first and second expandable support devices 2a and 2b simultaneously, and/or in the same vertebra 48 and into the same or different damage sites 52a and 52b.

[0075] Figure 20 illustrates that the fluid pressure in the fluid conduit 42 and the balloon 44 can increase, thereby inflating the balloon 44, as shown by arrows. The expandable support device 2 can expand, for example, due to pressure from the balloon 44. The balloon 44 can be expanded until the expandable support device 2 is substantially fixed to the vertebra 48. The balloon 44 and/or the expandable support device 2 can reshape the vertebral column 46 to a more natural configuration during expansion of the balloon 44.

[0076] Figure 21 illustrates that the access port 64 can be made close to the disc 50, for example when the damage site 52 is close to the disc 50. The deployment tool 38 can be inserted through the access port 64 and the expandable support device 2 can be deployed as described supra.

[0077] Figure 22, a front view of the vertebral column, illustrates that more than one expandable support device 2 can be deployed into a single vertebra 48. For example, a first expandable support device (not shown) can be inserted through a first access port 64a and deployed in a first damage site 52a, and a second expandable support

device (not shown) can be inserted through a first access port 64a and deployed in a second damage site 52b.

[0078] The first access port 64a can be substantially centered with respect to the first damage site 52a. The first expandable support device (not shown) can expand, as shown by arrows 78, substantially equidirectionally, aligned with the center of the first access port 64a. The second access port 64b can be substantially not centered with respect to the second damage site 52b. The second expandable support device (not shown) can substantially anchor to a side of the damage site 52 and/or the surface of the disc 50, and then expand, as shown by arrows 80, substantially directionally away from the disc 50.

[0079] Figure 23 illustrates that the fluid pressure can be released from the balloon 44, and the balloon 44 can return to a pre-deployment configuration, leaving the expandable support element substantially fixed to the vertebra 48 at the damage site 52.

[0080] The access port 64 can have an access port diameter 82. The access port diameter 82 can be from about 1.5 mm (0.060 in.) to about 40 mm (2 in.), for example about 8 mm (0.3 in.). The access port diameter 82 can be a result of the size of the access tool 54. After the expandable support device 2 is deployed, the damage site 52 can have a deployed diameter 84. The deployed diameter 84 can be from about 1.5 mm (0.060 in.) to about 120 mm (4.7 in.), for example about 20 mm (0.8 in.). The deployed diameter 84 can be greater than, equal to, or less than the access port diameter 82.

[0081] Figure 24 illustrates that the deployment tool 38 can be removed, as shown by arrow, from the vertebra 48 after the expandable support device 2 is deployed.

[0082] Figures 25 and 26 illustrate the expandable support device 2 can be placed between the vertebral bodies into a defect 52 of the vertebral disc. Figure 25 illustrates an anterior approach to inserting the expandable support member between vertebral bodies. Figure 26 illustrates a posterior approach to inserting the expandable support member. The expandable support member can also be inserted from a lateral approach.

[0083] The expandable support device 2 can be configured to create a cavity or otherwise displaces bone and/or tissue to form a space within the target sites during deployment (e.g., during radial expansion). For example, the struts of the expandable support device 2 can be configured so the radial expansion of the expandable support device 2 can move and/or compact bone/tissue. The struts can be configured to be narrow such that, on expansion, the struts move a relatively smaller amount of bone and/or tissue such that the struts do not compact the tissue.

[0084] After the expandable support device 2 has been initially deployed (i.e., inserted, and/or radially expanded) into the treatment site, the expandable support device 2 can be retracted, removed, resized, repositioned, and combinations thereof. The expandable support device 2 can be retracted and/or removed, and/or resized, and/or repositioned, for example, about 0 to about 2 months after initial deployment and/or the latest removal, and/or resizing, and/or repositioning.

[0085] Figure 27 illustrates that the deployment tool 38, such as an engagement device, can be configured to attach to the implanted expandable support device. The engagement device can have one or more engagement elements 100, such as first and second engagement elements 100a and 100b. The engagement elements 100 can be on the radial inside and/or radial outside of the engagement device. For example, the engagement elements can be on an inner rod 102 that can be translatably and/or

rotationally slidably attached to an outer handle 104. The engagement elements 100 can be a screw thread, a keyed slot, a toggle, ball and socket, an interference fit, a clip, a ratchet, a magnet, glue, an expanding anchor clip, an abutment, a hook, or combinations thereof. The engagement device can be the deployment device (e.g., the deployment tool or other device originally used to deploy the expandable support device 2).

[0086] Figure 27 illustrates that the engagement device 38 can attach to the expandable support device 2. The expandable support device 2 can be configured to releasably attach to the engagement elements 100 at discrete locations (e.g., along discrete lengths of the inner diameter of the expandable support device 2).

[0087] The first engagement element 100a can attach to the proximal end of the expandable support device 2. The first engagement element 100a can be an abutment. The second engagement element 100b can attach to the distal end of the expandable support device 2. The second engagement element 100b can be a threaded outer surface. The expandable support device 2 can have a threaded inner radius, for example, that can be configured to engage the threaded outer surface of the second engagement element 100b.

[0088] Figure 28 illustrates that a tensile force, as shown by arrows 106, can be applied to the ends of the expandable support device 2, for example, via the engagement device 38 and the first and second engagement elements 100a and 100b. For example, the inner rod 102 can be pushed distally while the outer handle 104 can be concurrently pulled proximally. The radius of the expandable support device 2 can contract, as shown by arrows 108.

[0089] Figure 29 illustrates that the tensile force, shown by arrows 106, can longitudinally expand the expandable support device. The expandable support device

can radially contract, for example, until the expandable support device 2 is in a configuration completely or substantially equivalent to the configuration of the expandable support device 2 before the original deployment of the expandable support device to the treatment site. For example, the expandable support device 2 can have a maximum outer radius that is equal to or smaller than the inner radius of the portion (e.g., the outer handle 104) of the deployment tool 38 into which the expandable support device 2 can be configured to retract.

[0090] The expandable support device 2 can be withdrawn from the target site, and/or retracted into the engagement device 38.

[0091] Figure 30 illustrates that the outer handle 104 can be a sheath and/or a sheath can be radially outside or inside of the outer handle 104. The sheath can have a sheath entry 110. The sheath entry 110 can be at the distal end of the sheath. The sheath entry 110 can have a hard material edge, and/or a slippery polymer edge, and/or a tapered edge, and/or an expanding slotted tube front edge, and/or a sacrificial (e.g., breakaway) edge.

[0092] Figure 31 illustrates that the sheath can be forced over the expandable support device 2, and/or the expandable support device 2 can be drawn, as shown by arrow 112, into the sheath.

[0093] Figure 31 illustrates that the expandable support device 2 can radially contract, as shown by arrows 114, as the expandable support device 2 is completely or partially translated (e.g., withdrawn, retracted), as shown by arrow 112, into the sheath. The radial contraction of the expandable support device 2 can be resilient or forced deformation.

[0094] Figure 32 illustrates that the expandable support device 2 can be completely withdrawn or retracted into the sheath. In a radially contracted configuration, the

outer radius of the expandable support device 2 can be about equal to and/or smaller than the inner radius of the sheath. The deployment tool 38 and expandable support device 2 can be removed from the target site.

[0095] Figure 33 illustrates a side view of the engagement device 38 deployed through the expandable support device 2. The engagement device 38 can be deployed extending through the expandable support device 2, for example through a center channel or port.

[0096] Figure 34 illustrates that the engagement device 38 can have an engagement element 100 that can be configured to unbuckle, tear, split, destroy, separate, cut, break or combinations thereof, the struts 10. The engagement element 100 can be a cutter saw 116, and/or otherwise have a bladed or sharp proximal side.

[0097] Figure 35 illustrates that the engagement device 38 can be longitudinally translated, as shown by arrow, for example, drawing the engagement element 100 through the struts 10. The engagement element 100 can unbuckle, tear, split, destroy, separate, cut, break or combinations thereof, the struts 10. The engagement element 100 can partially or completely collapse or buckle the expandable support device 2, for example within the target or treatment site (e.g., bone cavity).

[0098] Figure 36 illustrates that the expandable support device 2 can be separated into two or more expandable support device pieces 118. The expandable support device pieces 118 can be removed andor repositioned and/or resized individually and/or together from the target site.

[0099] Figure 37 illustrates a cross-sectional view of a method of adjusting the expandable support device similar to the method illustrated in Figures 27 through 29. The first engagement element 100a can be threading on the radial inside of the outer handle. The first engagement element 100a can be forced toward the second

engagement element 100b (e.g., by pushing the outer handle 104 distally and pulling the inner rod 102 proximally), for example to radially expand and longitudinally contract the expandable support device 2. The first engagement element 100a can be forced away from the second engagement element 100b (e.g., by pulling the outer handle 104 proximally and pushing the inner rod 102 distally), for example to radially contract and longitudinally expand the expandable support device 2

[0100] The deployment tool 38 can be rotatably attached to and detached from the expandable support device 2. The outer handle 104 can contact the expandable support device 2 by completely encircling the first engagement element 100a, and/or by discretely contacting the first engagement element 100a, for example with a set of individual radially translatable arms that can be detached from the first engagement element 100a by translating the arms radially outward (or inward if necessary) from the first engagement element 100a.

[0101] The outer handle 104 and inner rod 102 can be detached and/or reattached in any combination to the expandable support device 2. For example, the expandable support device 2 can be positioned in the target site. The expandable support device 2 can then be radially expanded (e.g., by applying a longitudinally compressive force). The inner rod 102 can then be detached from the expandable support device 2. The expandable support device 2 can be repositioned by manipulating the expandable support device 2 with the outer handle 104. The outer handle 104 can then be detached from the expandable support device 2 and the deployment tool can be withdrawn from the target site and/or the inner rod 102 can be reattached to the expandable support device 2 and the expandable support device can be radially expanded, and/or radially contracted, and/or repositioned within the target site, and/or removed from the target site.

[0102] Figure 38 illustrates a cross section of the expandable support device 2 implanted at a treatment site 52 in a bone 48. The expandable support device 2 can have one or more markers, such as a first marker 120a and/or a second marker 120b, attach to and/or be integral with the expandable support device 2. Any number of markers 120 can extend out of the bone 52. The markers 120 can be radiopaque and/or echogenic. The markers 120 can be used, for example, to locate the expandable support device 2 (e.g., once the bone 48 has regrown around the treatment site 52).

[0103] The expandable support device 2 can be configured to radially contract when a rotational (e.g., twisting) force is applied to the expandable support device 2. The expandable support device 2 can have a completely or partially coiled or otherwise spiral configuration. The expandable support device 2 can have a radius or height reduction based on a twisting effect.

[0104] The expandable support device 2 can be configured to be overdeployable. When the expandable support device 2 is overdeployed, the expandable support device 2 can return to a substantially pre-deployment configuration (e.g., having a pre-deployment radius, but in a different configuration otherwise).

[0105]

[0106] Figures 39 through 41 illustrate that the configuration of the struts 10 can cause the expandable support device 2 to have an overdeployment radius substantially equivalent to a pre-deployment radius 122. Figure 39 illustrates the expandable support device 2 in a pre-deployment configuration. A longitudinally compressive force, as shown by arrows 124, can be applied. Radial expansion, as shown by arrows 126, can begin, for example due to the longitudinally compressive force.

[0107] Figure 40 illustrates that when the expandable support device 2 is fully deployed, the expandable support device 2 has no radial expansion. The longitudinally compressive forces, as shown by arrows 124, can begin to force the struts longitudinally inward, for example beyond a configuration at the maximum radial expansion of the expandable support device 2. This overdeployment can cause a decrease in the radius of the expandable support device 2.

[0108] Figure 41 illustrates that when the expandable support device 2 is overdeployed, the expandable support device 2 can radially contract, as shown by arrows 128. The expandable support device 2 can have an overdeployment radius 130 substantially equivalent to, or less than, or greater than the pre-deployment radius 122.

[0109] Figure 42 illustrates that the expandable support device 2 can have a control element, such as internal control shaft 132. The internal control shaft 132 can be removably attached to the inner rod 102. The remainder of the expandable support element 2 can be removably and/or rotatably attached to the interenal control shaft 132.

[0110] The internal control shaft 132 can have the first and second engagement elements 100a and 100b. The expandable support element 2 can have discrete first and second receivers 136a and 136b configured to removably attach to the first and second engagement elements 100a and 100b, respectively. For example, the first and second receivers 136a and 136b can be threaded.

[0111] The first engagement element 100a can have a stop or brake thread 140, for example configured to interference fit the first receiver 136a.

[0112] In an undeployed or pre-deployed (e.g., radially contracted) configuration, the second engagement element 100b can be attached to the second receiver 136b. The first engagement element 100a can be unattached to the first receiver 136a.

[0113] Figure 43 illustrates that a compression force, shown by arrows 142, can be applied to the expandable support device 2. For example, the sliding rod 102 can be pulled proximally and the outside handle 104 can be pushed distally. The expandable support device 2 can be attached to the sliding rod 102 via the second engagement element 100b and the second receiver 136b. The expandable support device 2 can be attached to the outside handle 104 via abutting or otherwise engaging at the first receiver 136a or other element. The compression force can produce radial expansion, as shown by arrows 144, in the expandable support device 2.

[0114] Figure 44 illustrates that once the expandable support device 2 is substantially radial expanded, the inner rod can be rotated, as shown by arrow 146, with respect to the expandable support device 2 with the exception of the inner control shaft 148. (The expandable support device can be held rotationally stationary by the target site and/or by engagement between the outside handle and the expandable support device 2.) The inner control shaft 132 can rotate as shown by arrow 148. The rotation of the second engagement element 100b with respect to the second receiver 136b can force the control shaft 132 to translate, as shown by arrow 150, with respect to the expandable support device 2. The expandable support device 2 can radially expand during the translation shown by the arrow 150.

[0115] Figure 45 illustrates that during the translation shown by arrow 150 in Figure 44, the first engagement element 100a can engage the first receiver 136a. The second engagement element 100b can remain engaged to the second receiver 136b. The inner rod 102, control shaft 132, and first engagement element 136a can rotate with respect

to the remainder of the expandable support device 2, for example until a safety element, such as the brake thread 140, stops the rotation. The brake thread 140 can interference fit with the first receiver 136a. The brake thread 140 can provide sufficient resistance to friction fit with the first receiver 136a. The safety element (e.g., stop or brake thread) can be on the first and/or second engagement elements 100a and/or 100b and/or first and/or second receivers 136a and/or 136b.

[0116] Figure 46 illustrates that the inner control shaft 132 can be detached from the inner rod 102, for example at a coupling point 152. The coupling point 152 can include one or more detachable attachment elements, such as hooks, pegs and holes, thread knots and holes, radially translatable arms, teeth, threads, or combinations thereof. The inner control shaft 132 can have corresponding detachable attachment elements, such as threads 154. The threads can be in the same direction (e.g., with higher coefficients of friction) as the threads of the first and second engagement elements 100a and 100b, or counter-threaded with respect to the threads of the first and second engagement elements 100a and 100b. The coupling point 152 can be detached by deactivating or otherwise detaching the detachable attachment elements. For example, the inner rod 102 can be rotated or counter rotated as necessary, as shown by arrow. The inner control shaft 132 can remain rotationally fixed because, for example, the target site has substantially fixed the expandable support device and the brake thread 140 can fix the inner control shaft 132 to the expandable support device 2.

[0117] The deployment tool 38 can be removed from the target site. The expandable support device 2 can remain in the target site, for example, fixed in the deployed configuration (e.g., unable to substantially radially or longitudinally expand or contract) and/or bolstered by the inner control shaft 132. The deployment tool 38 can

re-engage the expandable support device 2 and the above steps can be reversed to radially contract and retract, reposition, and/or remove the expandable support device 2 in or from the target site.

[0118] The expandable support device 2 can have a mechanical key or locking bar that can fix the expandable support device 2 in an expanded or otherwise deployed configuration. When the key or locking bar is removed from the expandable support device 2, the expandable support device 2 can be repositioned, and/or removed and/or resized (e.g., deconstructed), for example, automatically, resiliently radially compressed.

[0119] The expandable support device can be subject to fatigue, for example, to increase material brittleness resulting in fracture. The fractured pieces of the expandable support device can be removed, for example, by suction and irrigation. The engagement element can be a small grabber or gripper. The engagement element can induce oscillating motion in the struts. The oscillating motion can cause strut fatigue and failure, for example in the struts and/or in the joints. The oscillating motion can be ultrasonic, mechanical, hydraulic, pneumatic, or combinations thereof.

[0120] The expandable support device 2 can have receiving elements to engage the engagement elements. For example, the receiving elements can be hooks, barbs, threads, flanges, wedge shaped slots, dovetails, hinges, key holes, or combinations thereof.

[0121] The expandable support device 2 can have a leader. The leader can be a heavy wire. The leader can guide the engagement device into and/or over the implant. The engagement device 38 can radially contract the implant, for example, using a method described herein. The engagement device 38 and/or another tool can drill or otherwise destroy bone and/or other tissue to access the expandable support device 2.

[0122] The tissue surrounding the expandable support device 2 can be destroyed (e.g., chemically and/or electrically and/or thermally, such as by cauterization or electro-cauterization). The expandable support device 2 can be removed and/or repositioned and/or resized once the surrounding tissue is completely or substantially destroyed.

[0123] The expandable support device 2 can be mechanically destroyed. For example, the expandable support device can be mechanically compressed, for example by applying external radially and/or axially (i.e., longitudinally) contracting jaws. A snipper and/or microgrinder and/or saw can mechanical destroy the expandable support device.

[0124] The expandable support device 2 can be chemically destroyed using RF energy. For example UV energy can be delivered to dissolve a plastic expandable support device.

[0125] The expandable support device 2 can be biodegradable. The expandable support device 2 can be made from biodegradable materials known to those having ordinary skill in the art. The expandable support device 2 can be made from a magnesium based alloy that can degrade or a biodegrading polymer for example, PGA, PLA, PLLA, PCL.

[0126] The expandable support device 2 can be configured to device designed to dissolve when exposed to selected materials (e.g., in solution). For example, acetone can be applied to the expandable support device (e.g., made from PMMA). The surrounding tissues can be protected and/or the expandable support device can be fluidly contained before the dissolving solution is applied.

[0127] The expandable support device 2 can be dissolved, for example, by exposing the expandable support device to an electrolyte and electricity.

[0128] Imaging methods can be used in combination with the methods for deploying the expandable support device described herein. For example, imaging methods can be used to guide the expandable support device during deployment. The expandable support device 2 can have imaging markers (e.g., echogenic, radiopaque), for example to signal the three-dimensinal orientation and location of the expandable support device during use of an imaging modality. Imaging modalities include ultrasound, magnetic resonance imaging (MRI, fMRI), computer tomography (CT scans) and computed axial tomography (CAT scans), radiographs (x-rays), fluoroscopy, diffuse optical tomography, elastography, electrical impedance tomography, optoacoustic imaging, positron emission tomography, and combinations thereof.

[0129] 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 expressed herein as singular or plural can be used in the alternative (i.e., singular as plural and plural as singular). Elements shown with any embodiment are exemplary for the specific embodiment and can be used in combination on or with other embodiments within this disclosure.

CLAIMS

We claim:

1. An expandable support device for placement within or between spinal vertebral bodies, comprising:

a near end portion, a far end portion and a longitudinal axis extending therebetween;

a plurality of backbone struts substantially parallel to the longitudinal axis, the backbone struts each having a near end integral with the near end portion and a far end integral with the far end portion;

a plurality of deformable support struts located between each adjacent backbone strut, such that each adjacent backbone strut and the respective support struts located therebetween form a plurality of sides of the device; and

where each support strut is deformable such that, upon radial expansion of the expandable support device, the adjacent backbone struts separate while the support struts deform.

2. The device of claim 1, where the plurality of deformable support struts prevents buckling of the backbone struts upon expansion of the device.

3. The device of claim 1, where upon radial expansion of the device the near end and far ends of the backbone struts do not expand as much as the remainder of the backbone strut such that they form a taper while the remainder of the backbone strut remain substantially parallel to the longitudinal axis.

4. The device of claim 1, further comprising at least one tissue ingrowth portion in at least one backbone strut.

5. The device of claim 1, further comprising a protrusion on a surface of the device, where the protrusion engages tissue when the device expands.

6. The device of claim 5, where the protrusion comprises a tissue hook, barbs, or cleat.

7. The device of claim 1, where the near end portion comprises an opening.

8. The device of claim 7, where the opening in the near end comprises a threaded portion for receipt of a threaded member.

9. The device of claim 1, where the near end portion is solid.

10. The device of claim 1, where the far end portion comprises an opening.

11. The device of claim 1, where the far end portion is solid.

12. The device of claim 1, where the near end portion is non-expandable.

13. The device of claim 1, where the far end portion is non-expandable.

14. The device of claim 1, comprising at least two support struts per adjacent backbone struts.

15. The device of claim 14, comprising at least four support struts per adjacent backbone struts.

16. The device of claim 1, comprising at least three backbone struts forming at least three sides of the implant.

17. The device of claim 16, comprising at least four backbone struts forming at least four sides of the implant.

18. The device of claim 1, where a cross sectional wall thickness of each support strut is less than a cross sectional wall thickness of the backbone strut so that the support strut deforms at a lower expansive force than the backbone strut.

19. The device of claim 1, where in the unexpanded state a cross section of the implant comprises a shape selected from the group consisting of a, a triangle, an oval, a rectangle, and a square.

20. The device of claim 19, where after expanded the cross section of the implant comprises a shape selected from the group consisting of a triangle, a rectangle, a square, and a polygon.

21. The device of claim 1, where after expansion a first minimum distance between two adjacent backbone struts on at least a first side of the implant is greater than a second minimum distance between two adjacent backbone struts on at least a second side of the implant, such that the sides of the implant are not uniform.

22. The device of claim 1, where the support struts comprise a shape selected from a group consisting of a v-shape, a u-shape, a w-shape, an s-shape, or a combination thereof.

23. The device of claim 1, where the implant comprises a material selected from the group consisting of a single or multiple stainless steel alloys, nickel titanium alloys, cobalt-chrome alloys, nickel-cobalt alloys, molybdenum alloys, tungsten-rhenium alloys, and a combination thereof.

24. The device of claim 1, where the implant comprises a polymer material.

25. The device of claim 24, where the polymer comprises a polyethylene teraphathalate, a polyester, a polypropylene, polytetrafluoroethylene, expanded PTFE, polyether ether ketone, nylon, polyether-block co-polyamide polymers, aliphatic polyether polyurethanes, polyvinyl chloride, polyurethane, thermoplastic, fluorinated ethylene propylene.

26. The device of claim 24, where the polymer comprises an absorbable or resorbable polymers selected from the group consisting of a polyglycolic acid (PGA), polylactic acid (PLA), polycaprolactone (PCL), polyethyl acrylate (PEA), polydioxanone (PDS), and pseudo-polyamino tyrosine-based acids, extruded collagen, and silicone.

27. The device of claim 1, further comprising an echogenic, radioactive, radiopaque materials, and a biomaterial.

28. The device of claim 1, further comprising an agent delivery matrix at least partially coating the implant.

29. The device of claim 28, where the agent comprises an agent selected from the group consisting of a radioactive material, a radiopaque material, a cytogenic agent, a cytotoxic agent, a cytostatic agent, a thrombogenic agent, an anti-inflammatory agent, an immunosuppressive agent, and a combination thereof.

30. A device for repairing the spine comprising:
an implant of any of claims 1-29, mounted on a balloon catheter.

31. A method for repairing a damaged section of a spine, comprising:
expanding an implant as in the damaged section, wherein the implant is loaded on a

balloon prior to expanding; and

wherein expanding comprises inflating a balloon.

32. The method of claim 31, wherein expanding comprises inflating the balloon equal to or greater than about 5,000 kPa of internal pressure.

33. The method of claim 31, wherein expanding comprises inflating the balloon equal to or greater than about 10,000 kPa of internal pressure.

34. A method for repairing a damaged section of a spine, comprising:

deploying an implant according to any of claims 1-29 into the damaged section;

expanding the expandable support device in the damaged section;

supporting the damaged section with the implant; and

leaving the implant in the damaged section.

35. The method of claim 34, wherein the damaged section is a vertebra.

36. The method of claim 34, wherein the damaged section is a vertebral disc.

37. The method of claim 36, wherein the damaged section is a vertebral disc annulus.

38. The method of claim 36, wherein the damaged section is a vertebral disc nucleus.

39. The method of claim 34, wherein expanding comprises inflating a balloon

40. The method of claim 39, wherein the expandable support device is loaded on the balloon during the expanding, and wherein expanding comprises inflating the balloon equal to or greater than about 5,000 kPa of internal pressure.

41. The method of claim 39, wherein expanding comprises inflating the balloon equal to or greater than about 10,000 kPa of internal pressure.

42. The method of claim 34, wherein further comprising inserting a substance into the expanded support device.

43. The method of claim 42, wherein the substance comprises a cement, filler (bone chips, calcium sulfate, coralline hydroxyapatite, Biocoral, tricalcium phosphate, calcium phosphate, PMMA, bone morphogenic proteins, or other similar materials.

44. The method of claim 34, wherein the expandable support device is locked into an expanded position using a strut, rachet-type mechanism, screw, or locking arm.

45. The method of claim 34, wherein expanding comprises moving the near end portion and the far end portion closer together.

46. The method of claim 34, where expanding the expandable support device comprises burrowing a portion of the expanded support device into tissue.

47. The method of claim 34, where the expandable support member comprises a steel, titanium, or a nickel-titanium.

48. The method of claim 34, where the expandable support member is constrained prior to expanding, and where upon removal of the constraint, the support member expands.

49. The method of claim 34, where the portions of the expandable support member are sized such that upon expanding the support member, tissue is displaced without compressing the tissue.

50. The method of claim 34, where expanding the expandable support member further includes creating a cavity in the body.

51. A method for adjusting an expandable support device deployed in an orthopedic treatment site, the method comprising:

engaging the expandable support device with an engagement device;

delivering a force through the engagement device to the expandable support device; and

contracting the expandable support device.

52. The method of Claim 51, further comprising withdrawing the expandable support device from the orthopedic treatment site.

53. The method of Claim 51, further comprising resizing the expandable support device within the orthopedic treatment site.

54. The method of Claim 51, further comprising repositioning the expandable support device within the orthopedic treatment site.

55. The method of Claim 51, wherein contracting comprises radially contracting.

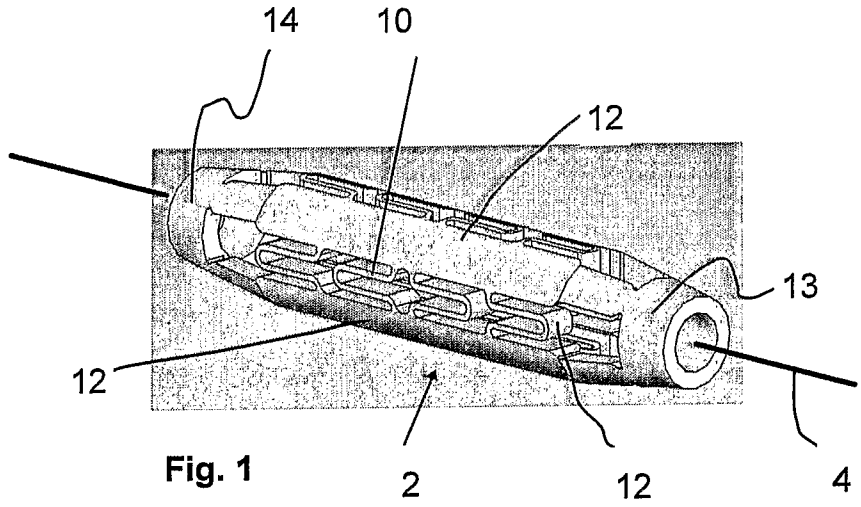


Fig. 1

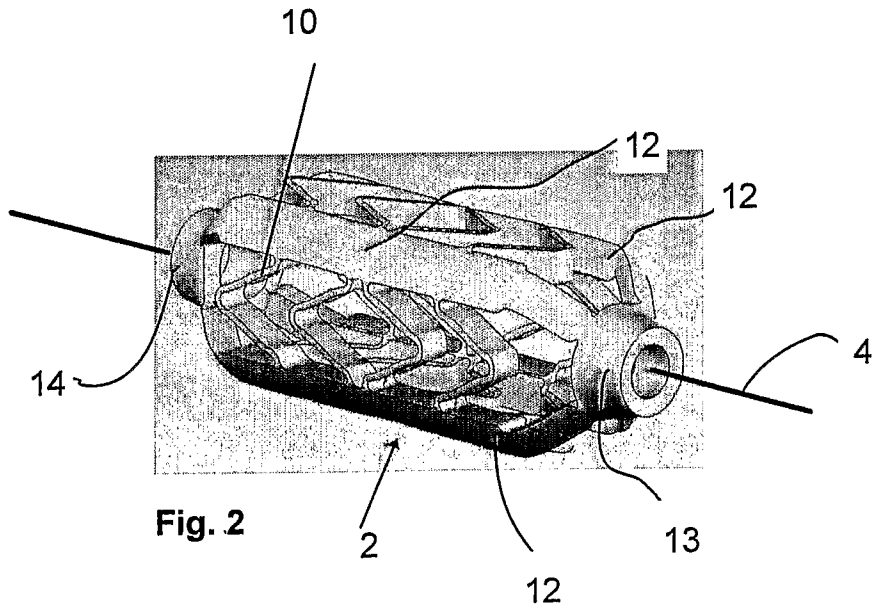


Fig. 2

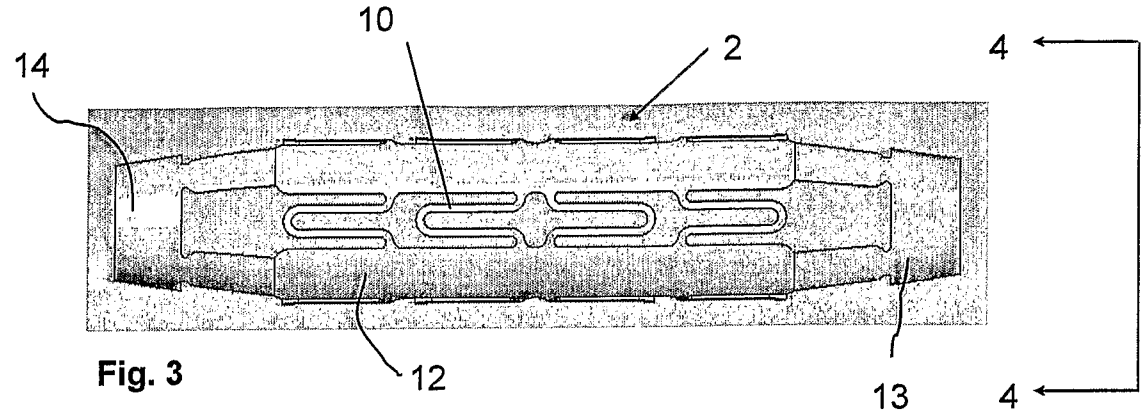


Fig. 3

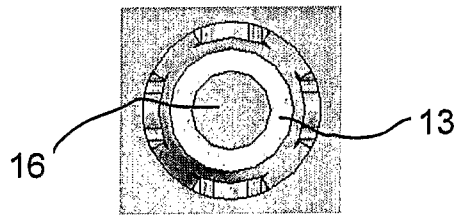


Fig. 4

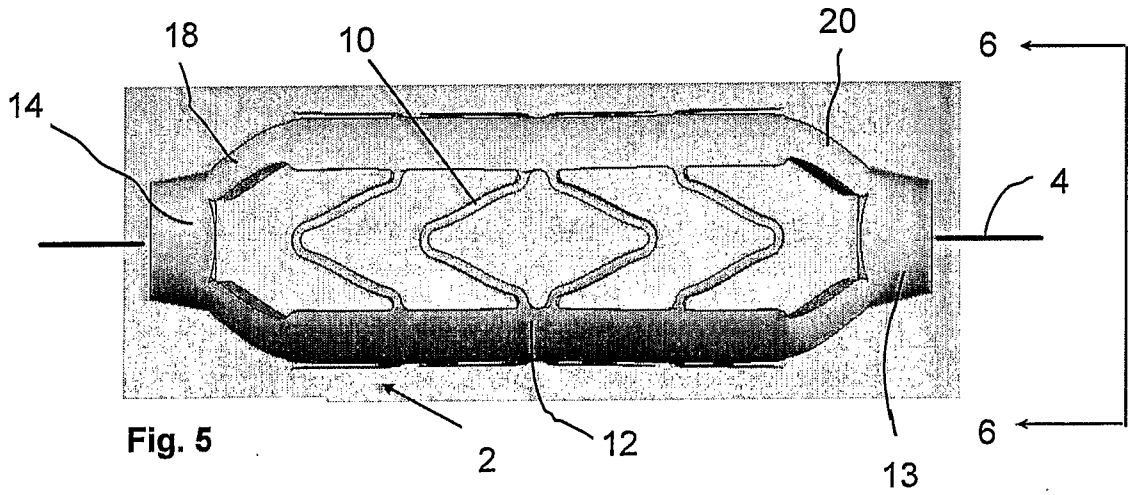


Fig. 5

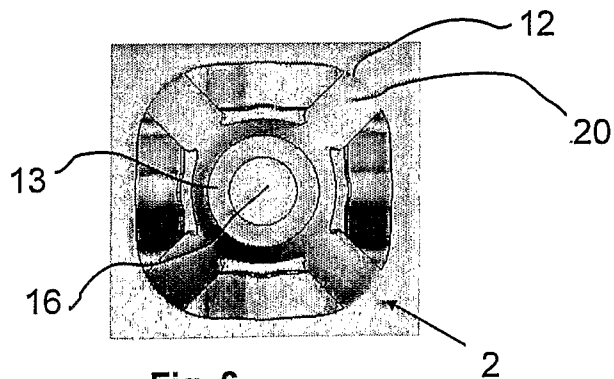


Fig. 6

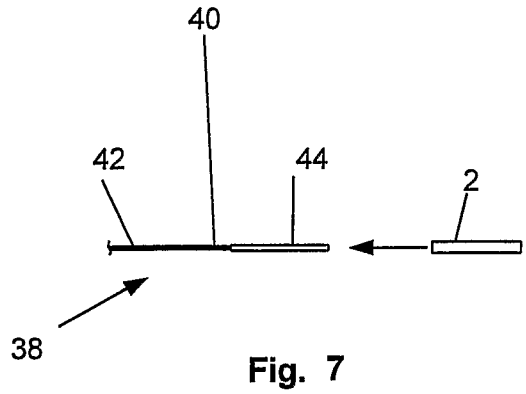


Fig. 7

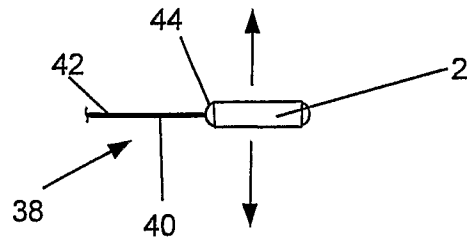


Fig. 8

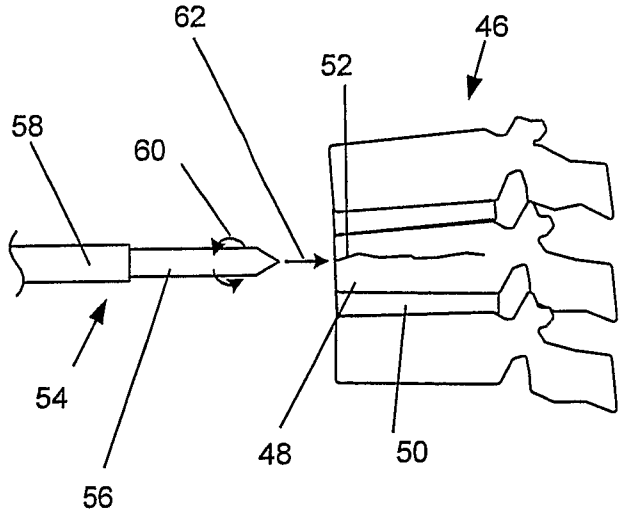


Fig. 9

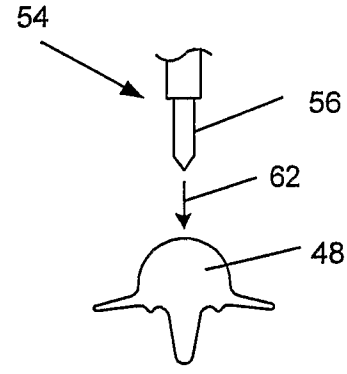


Fig. 10

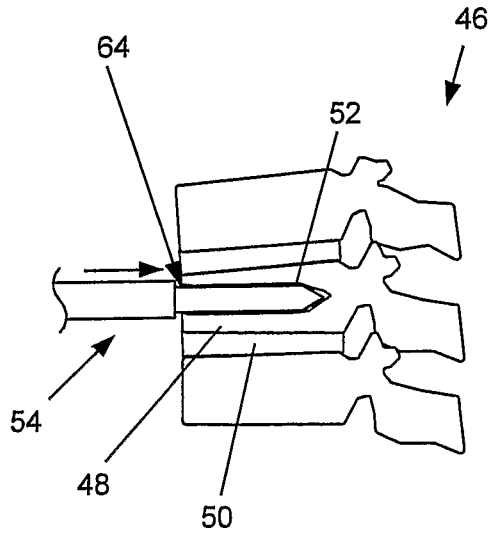


Fig. 11

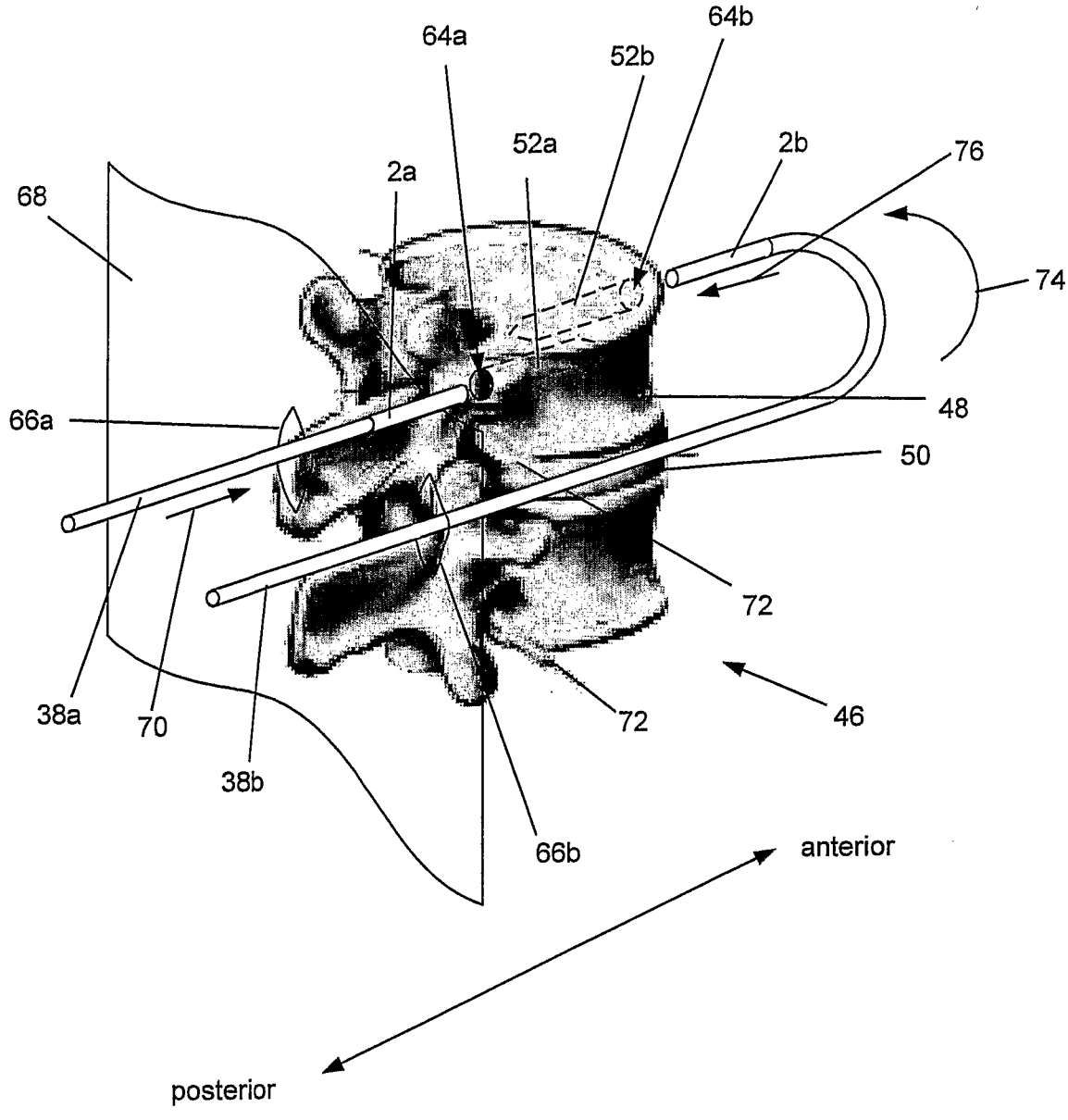

64a
64b
52b
52a
2b
76
2a
68
74
66a
48
50
72
38a
70
72
46
38b
66b
anterior
posterior

Fig. 12

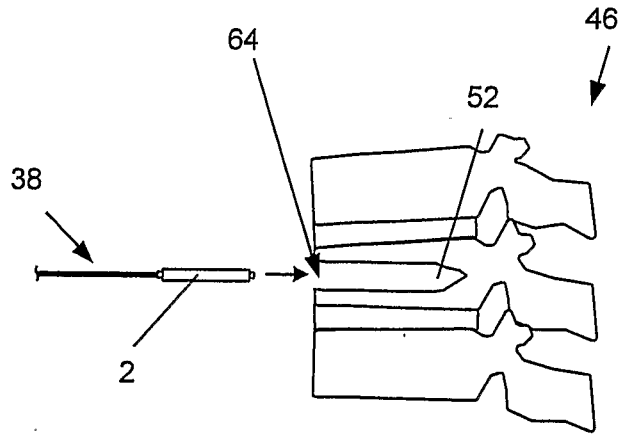


Fig. 13

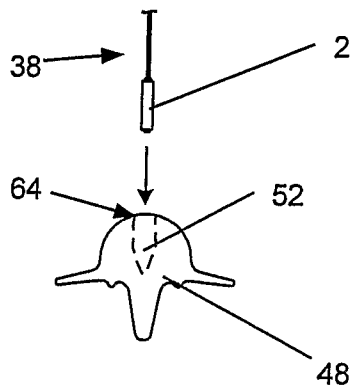


Fig. 14

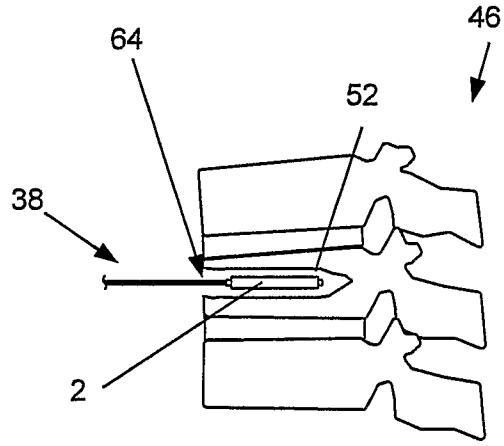


Fig. 15

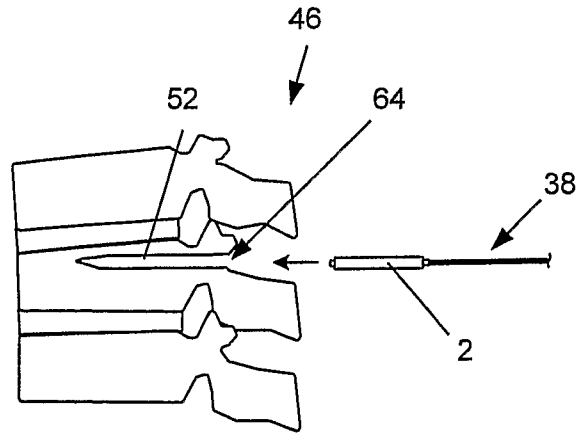


Fig. 16

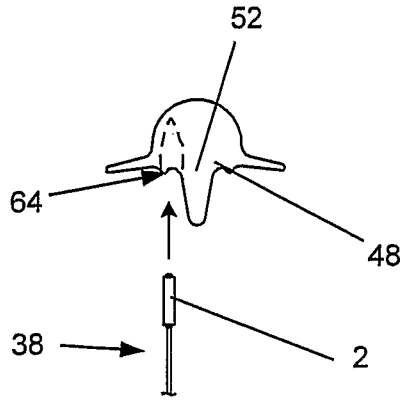


Fig. 17

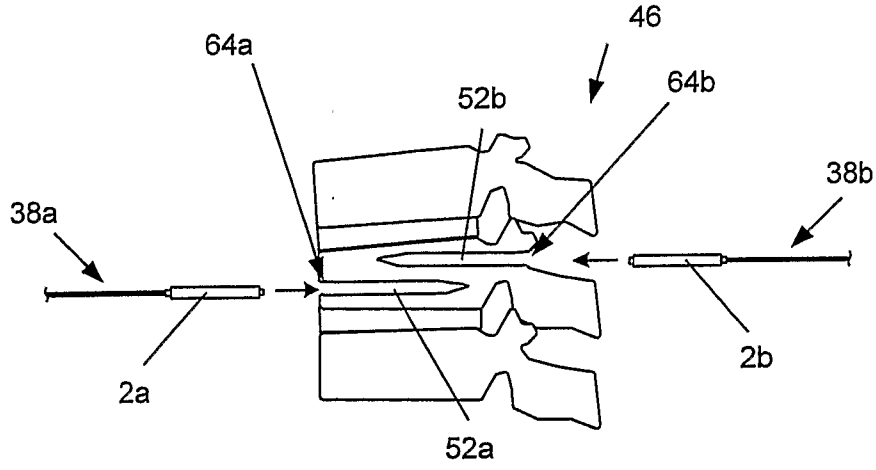


Fig. 18

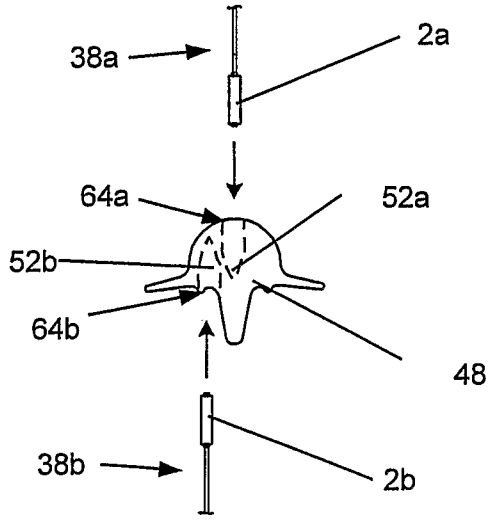


Fig. 19

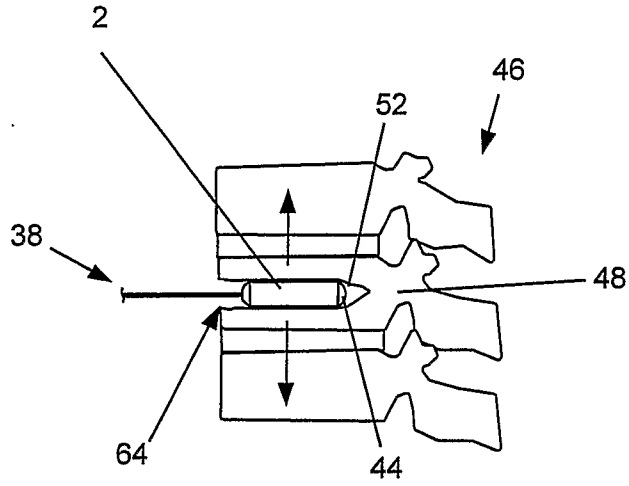


Fig. 20

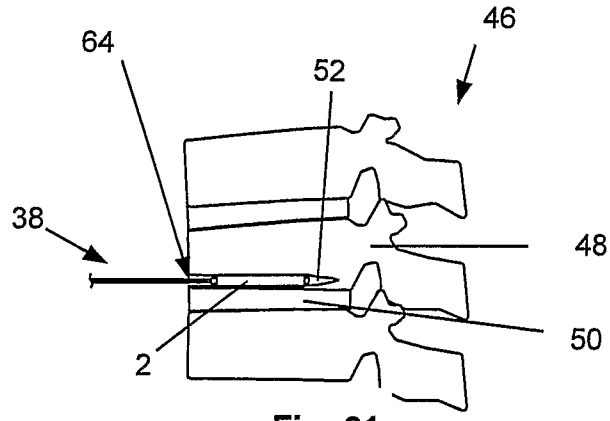


Fig. 21

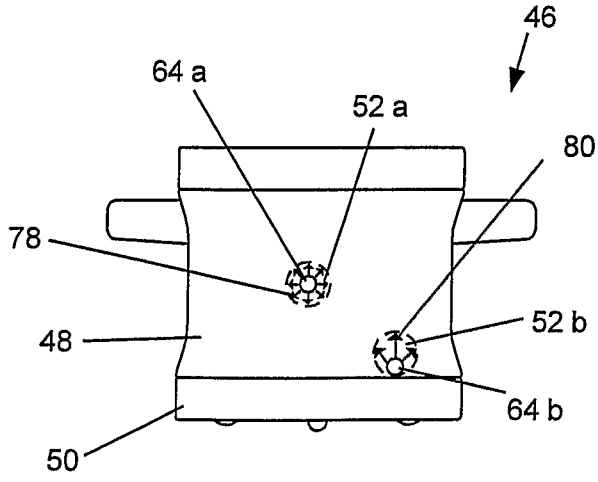


Fig. 22

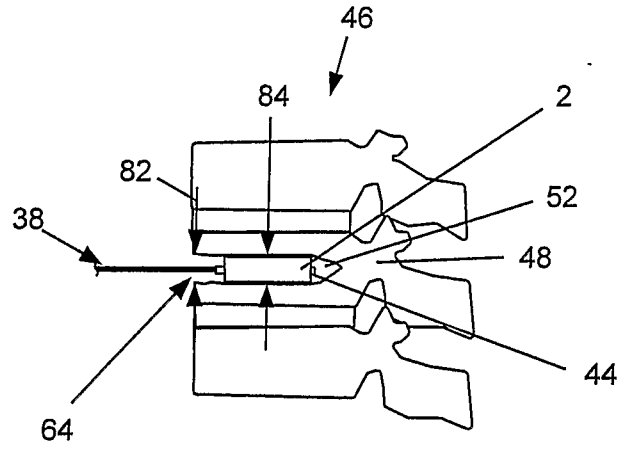


Fig. 23

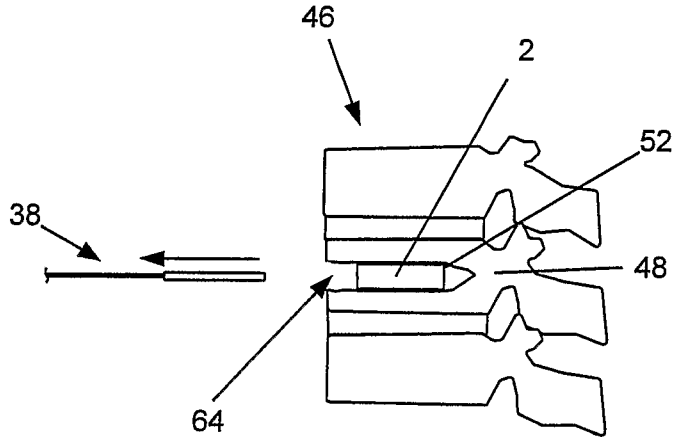


Fig. 24

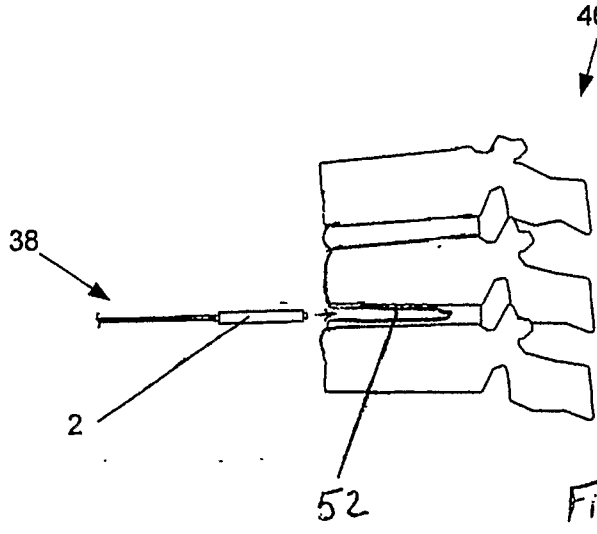


Fig. 25

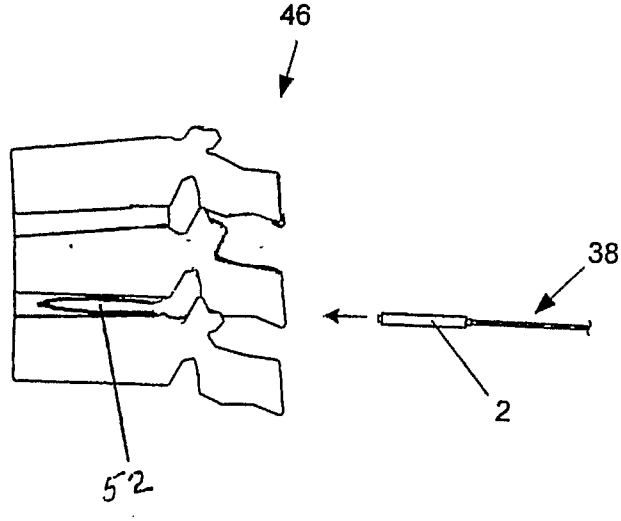


Fig. 26

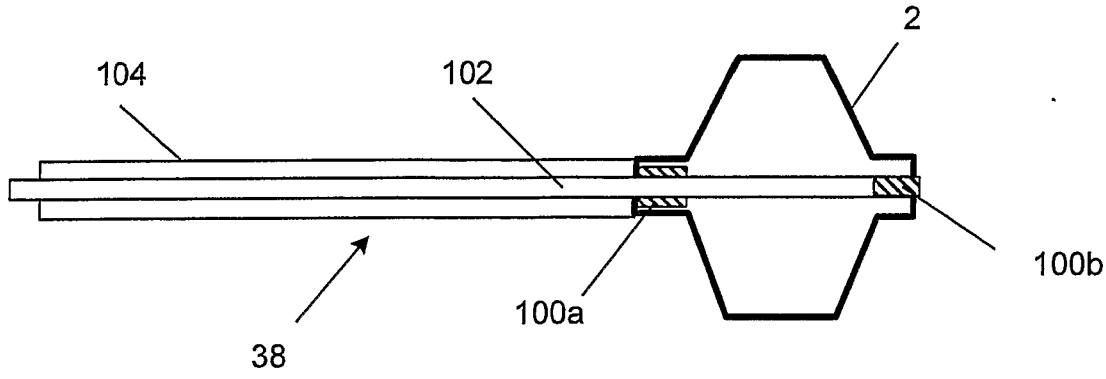


Figure 27

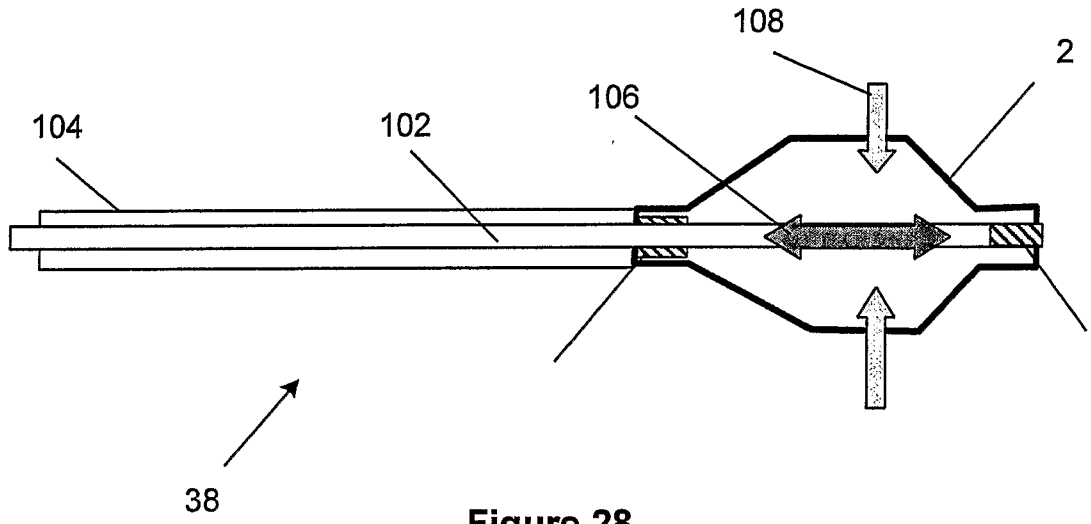


Figure 28

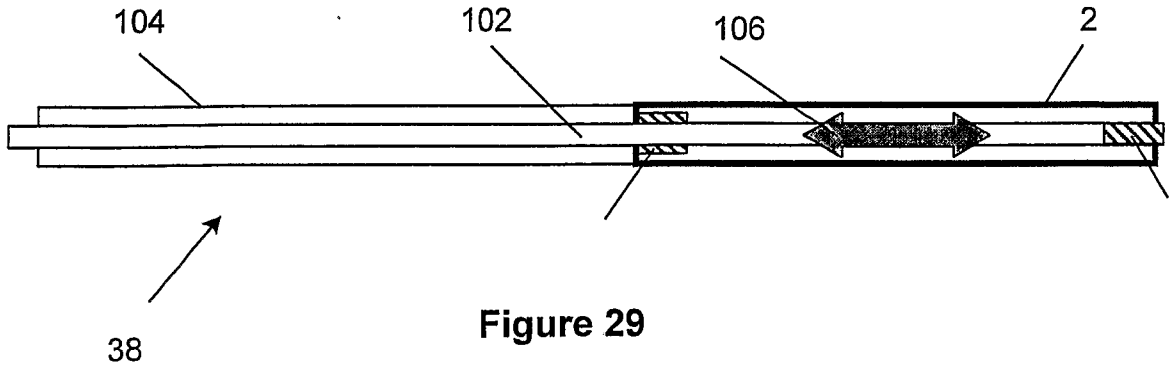


Figure 29

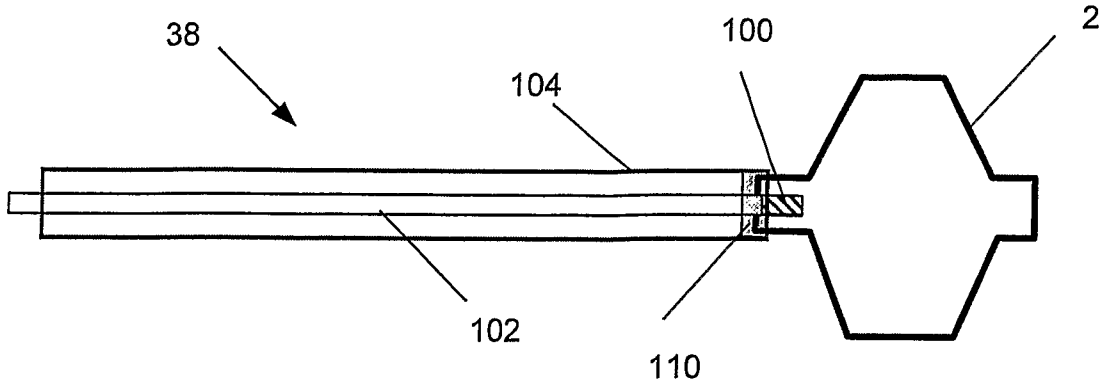


Figure 30

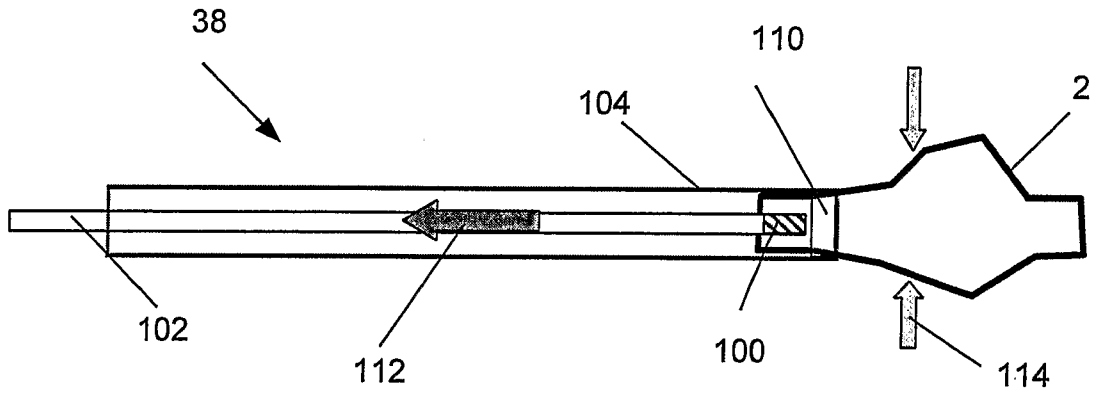


Figure 31

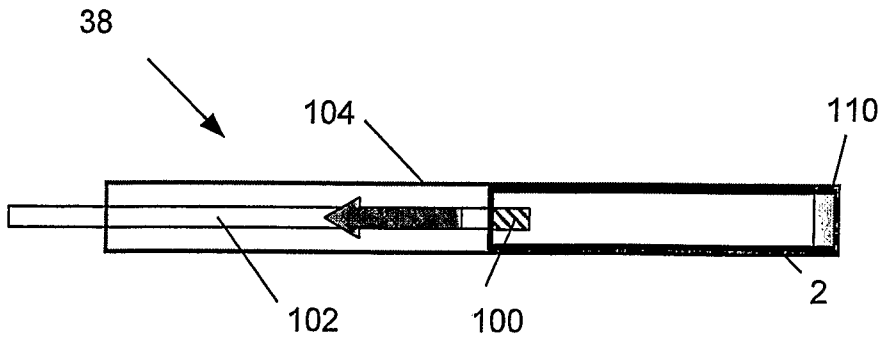


Figure 32

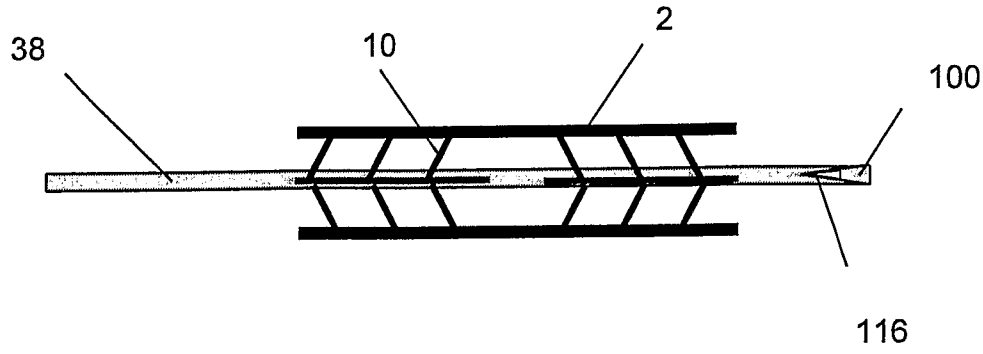


Figure 33

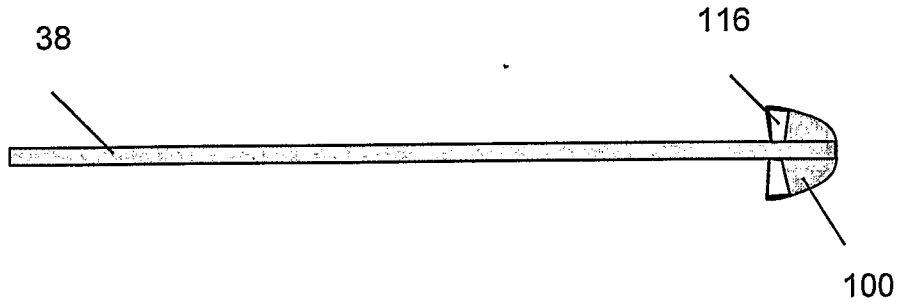


Figure 34

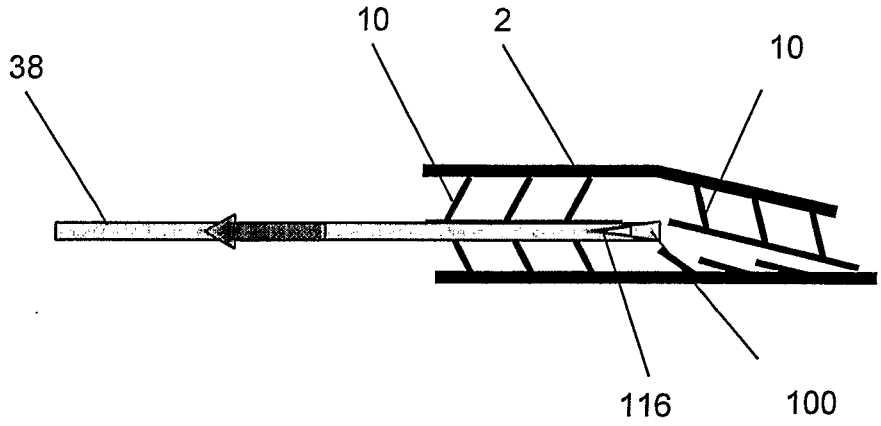


Figure 35

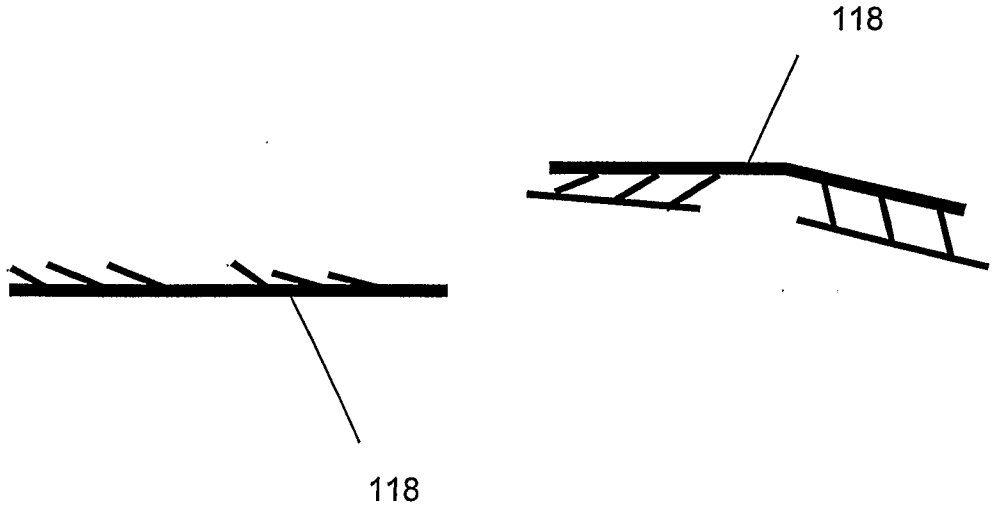


Figure 36

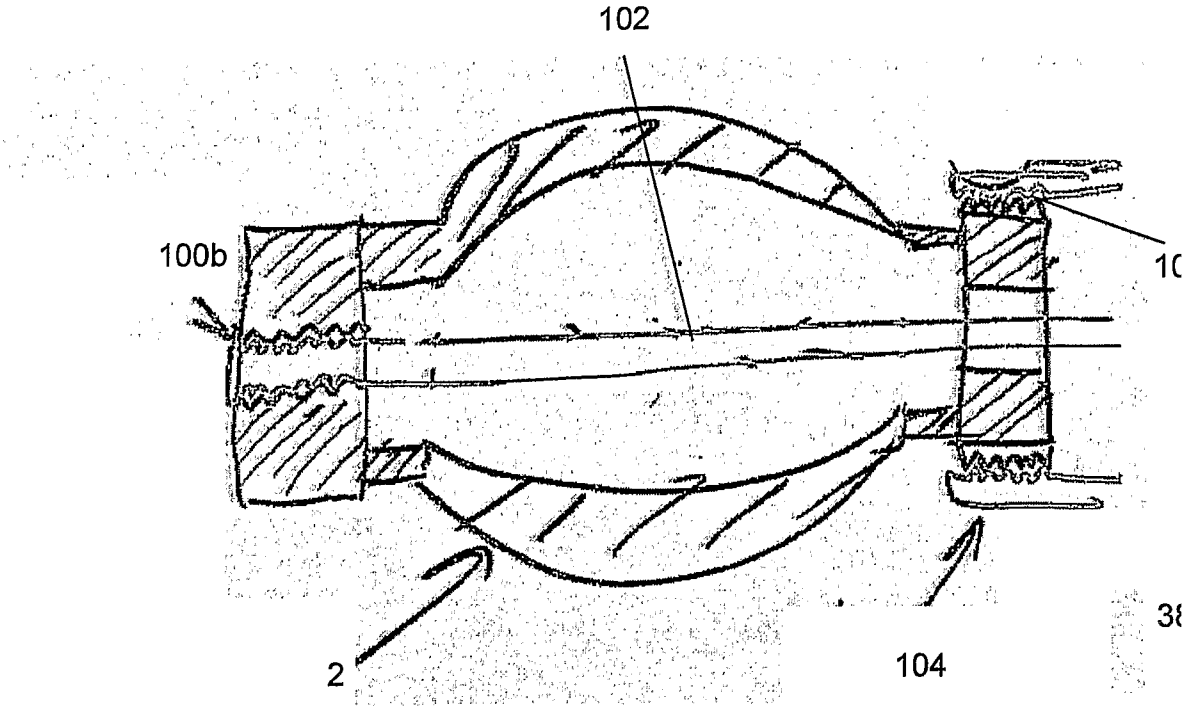


Figure 37

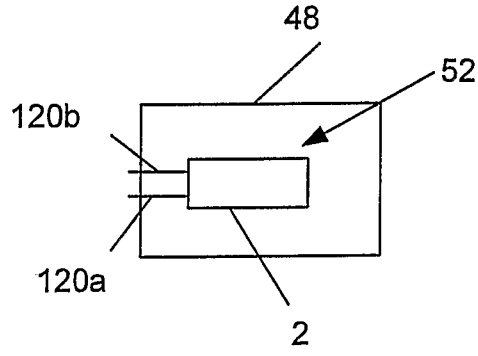


Figure 38

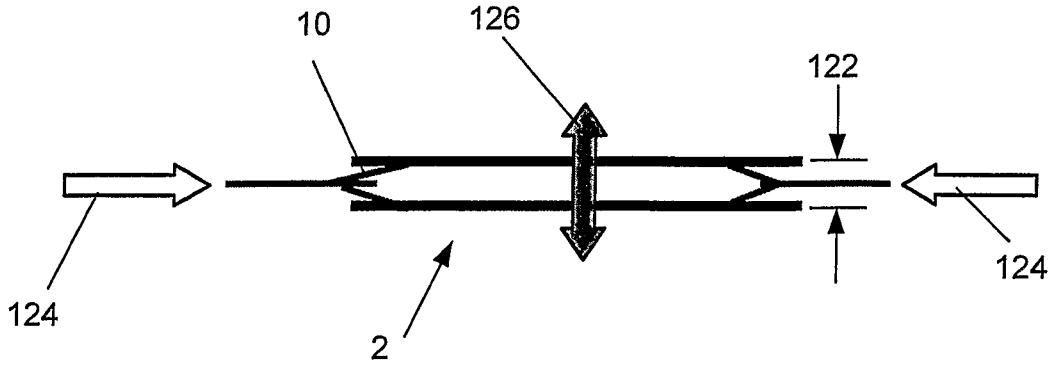


Figure 39

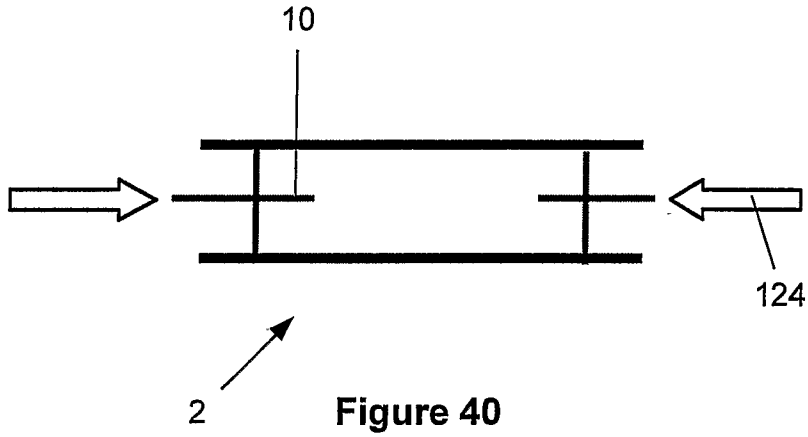


Figure 40

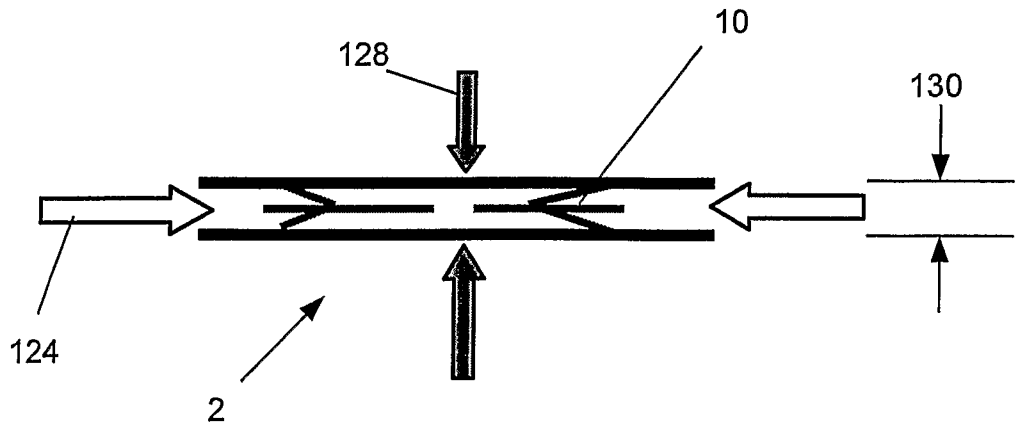


Figure 41

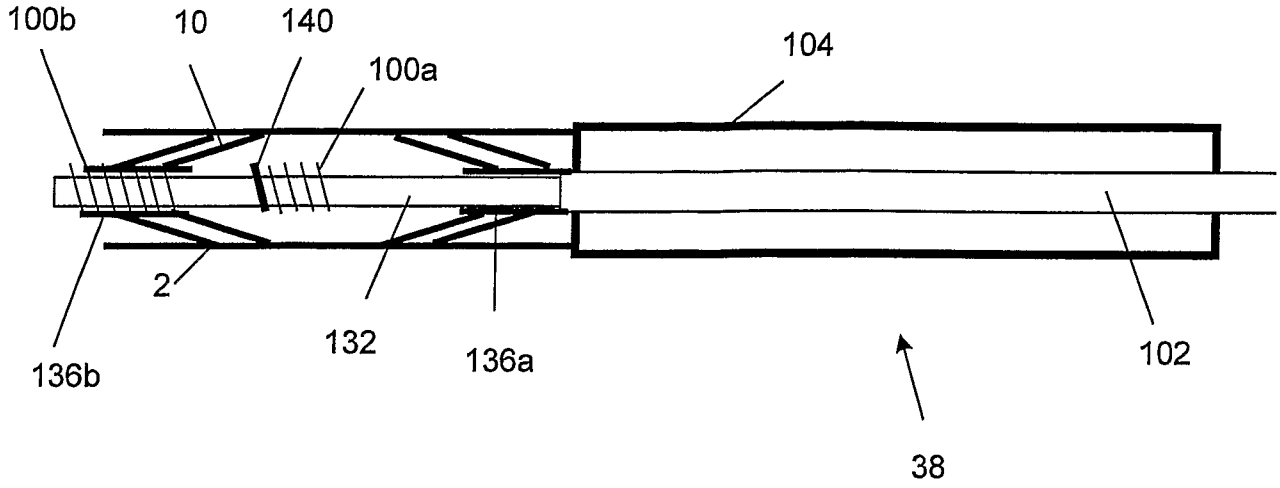


Figure 42

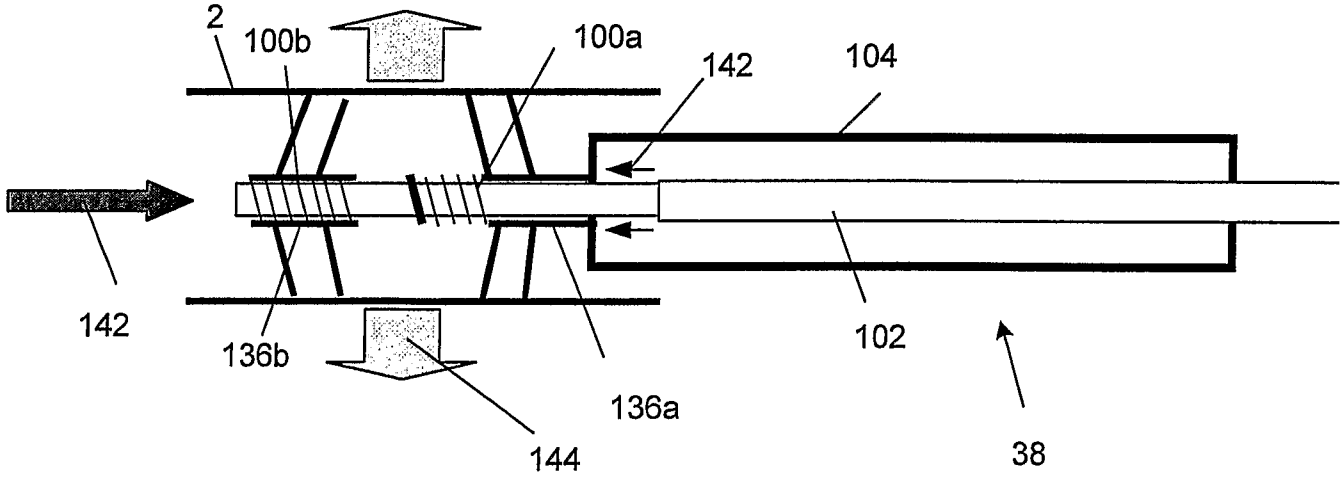


Figure 43

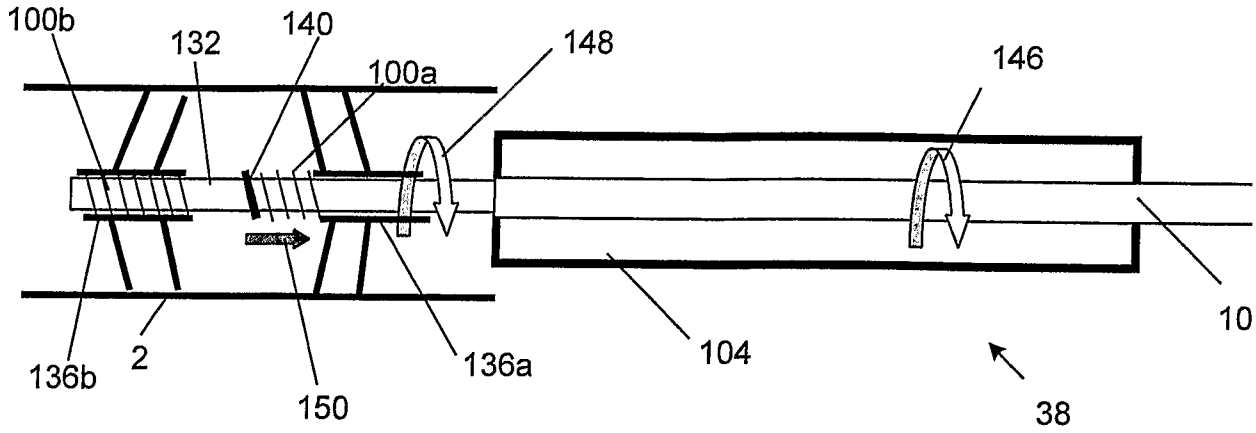


Figure 44

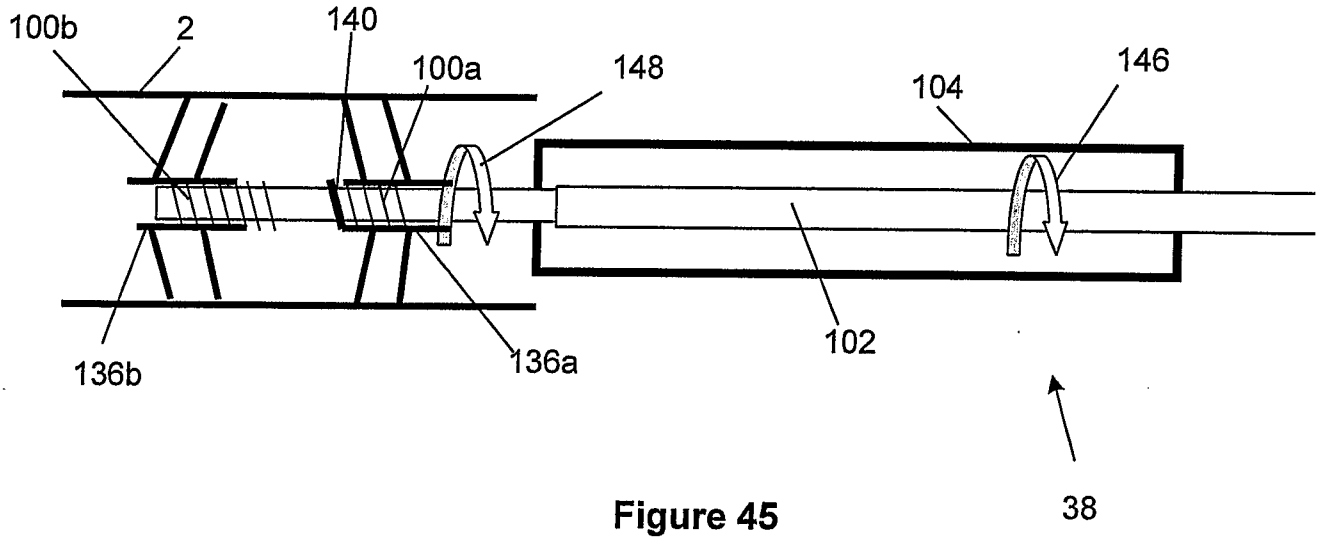


Figure 45

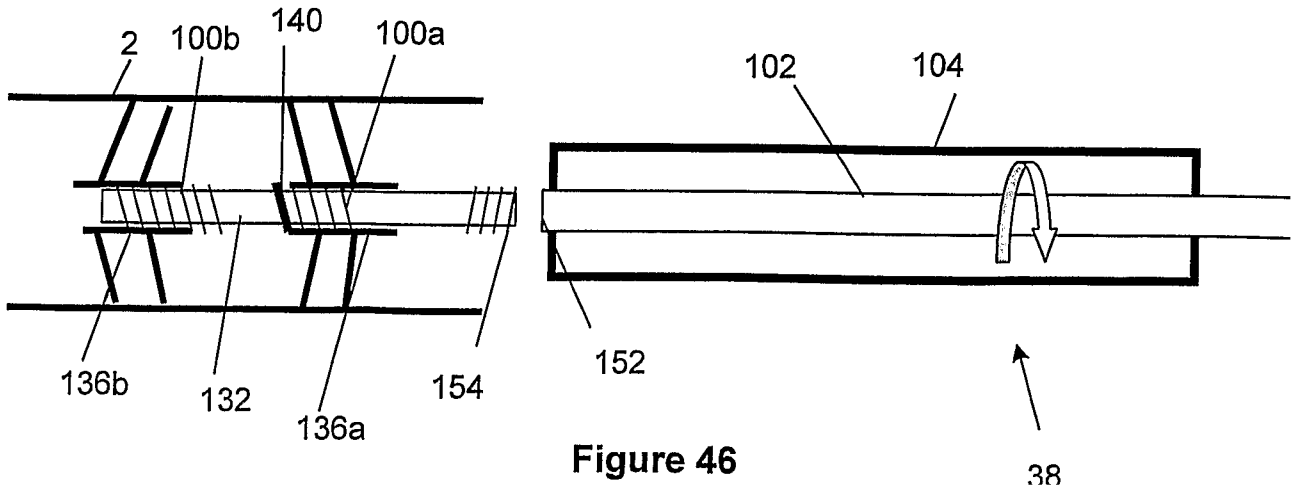


Figure 46