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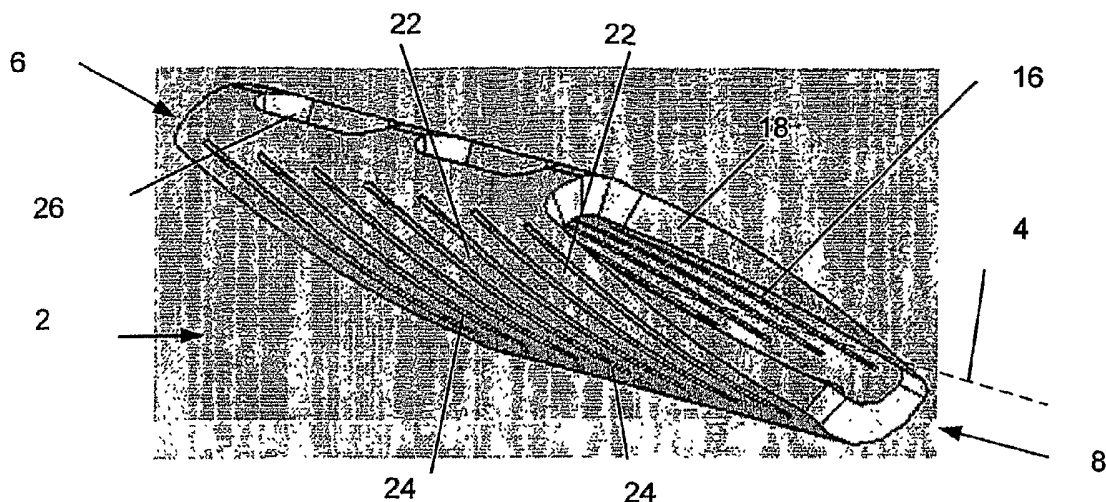
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(54) Title: EXPANDABLE SUPPORT DEVICE AND METHOD OF USE



(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. A method of repairing tissue is also disclosed. The device and method can be used to treat compression fractures. The compression fractures can be in the spine. The device can be deployed by compressing the device longitudinally resulting in radial expansion.

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TITLE OF THE INVENTION

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EXPANDABLE SUPPORT DEVICE AND METHOD OF USE

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7

CROSS-REFERENCE TO RELATED APPLICATIONS

8

[0001] This application claims the benefit of U.S. Provisional Application No.

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60/617,810, filed 12 October 2005, which is incorporated by reference herein in its

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entirety.

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BACKGROUND OF THE INVENTION

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1. Field of the Invention

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[0002] This invention relates to devices for providing support for biological tissue, for

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example to repair spinal compression fractures, and methods of using the same.

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2. Description of Related Art

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[0003] This invention relates to devices for providing support for biological tissue, for

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example to repair spinal compression fractures, and methods of using the same.

20

[0004] Vertebroplasty is an image-guided, minimally invasive, nonsurgical therapy

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used to strengthen a broken vertebra that has been weakened by disease, such as

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osteoporosis or cancer. Vertebroplasty is often used to treat compression fractures, such

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as those caused by osteoporosis, cancer, or stress.

24

[0005] Vertebroplasty is often performed on patients too elderly or frail to tolerate

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open spinal surgery, or with bones too weak for surgical spinal repair. Patients with

1 vertebral damage due to a malignant tumor may sometimes benefit from vertebroplasty.

2 The procedure can also be used in younger patients whose osteoporosis is caused by long-
3 term steroid treatment or a metabolic disorder.

4 **[0006]** Vertebroplasty can increase the patient's functional abilities, allow a return to
5 the previous level of activity, and prevent further vertebral collapse. Vertebroplasty
6 attempts to also alleviate the pain caused by a compression fracture.

7 **[0007]** Vertebroplasty is often accomplished by injecting an orthopedic cement
8 mixture through a needle into the fractured bone. The cement mixture can leak from the
9 bone, potentially entering a dangerous location such as the spinal canal. The cement
10 mixture, which is naturally viscous, is difficult to inject through small diameter needles,
11 and thus many practitioners choose to "thin out" the cement mixture to improve cement
12 injection, which ultimately exacerbates the leakage problems. The flow of the cement
13 liquid also naturally follows the path of least resistance once it enters the bone – naturally
14 along the cracks formed during the compression fracture. This further exacerbates the
15 leakage.

16 **[0008]** The mixture also fills or substantially fills the cavity of the compression
17 fracture and is limited to certain chemical composition, thereby limiting the amount of
18 otherwise beneficial compounds that can be added to the fracture zone to improve
19 healing. Further, a balloon must first be inserted in the compression fracture and the
20 vertebra must be expanded before the cement is injected into the newly formed space.

21 **[0009]** A vertebroplasty device and method that eliminates or reduces the risks and
22 complexity of the existing art is desired. A vertebroplasty device and method that is not
23 based on injecting a liquid directly into the compression fracture zone is desired.

24

25

SUMMARY OF THE INVENTION

1 [0010] An expandable support device that can be used to repair fractures and stabilize
2 hard tissue, such as via intra-vertebral or intervertebral deployment, is disclosed. The
3 expandable support device can have a longitudinal axis and a radial axis. The expandable
4 support device can be configured, for example by design of the cells, voids or holes in the
5 wall, to expand radially when compressed longitudinally. The expandable support device
6 can be made from an integral piece of metal.

7 [0011] A method for deploying an expandable support device in the spine is
8 disclosed. The expandable support device can be deployed, for example, by longitudinal
9 compression. The longitudinal compression can result in radial expansion of the
10 expandable support device. The expandable support device can be deployed in an
11 intravertebral site. The expandable support device can be deployed in an intervertebral
12 site.

13 [0012] A device (e.g., tool) for deploying an expandable support device is disclosed.
14 The tool can be configured to apply a compressive force on the expandable support
15 device along the expandable support device's longitudinal axis. The tool can be
16 configured to securely engage the expandable support device. The tool can be configured
17 to removably attach to opposing points at or near opposing longitudinal ends of the
18 expandable support device.

19

20

BRIEF DESCRIPTION OF THE DRAWINGS

21 [0013] Figure 1 is a side perspective view of an embodiment of the expandable
22 support device.

23 [0014] Figure 2 is a front view of the embodiment of the expandable support device
24 of Figure 1.

- 1 [0015] Figure 3 is a rear perspective view of the embodiment of the expandable
2 support device of Figure 1.
- 3 [0016] Figure 4 is a bottom view of the embodiment of the expandable support device
4 of Figure 1.
- 5 [0017] Figure 5 is a side view of the embodiment of the expandable support device of
6 Figure 1.
- 7 [0018] Figures 6 and 7 are side views of various embodiments of the expandable
8 support device.
- 9 [0019] Figure 8 is a side perspective view of an embodiment of the expandable
10 support device.
- 11 [0020] Figures 9 through 11 are front views of various embodiments of the
12 expandable support devices.
- 13 [0021] Figure 12 is a top perspective view of an embodiment of the expandable
14 support device.
- 15 [0022] Figure 13 is top view of the embodiment of the expandable support device of
16 Figure 12.
- 17 [0023] Figure 14 is a front view of the embodiment of the expandable support device
18 of Figure 12.
- 19 [0024] Figures 15 and 16 illustrate an embodiment of a method for using a delivery
20 system for the expandable support element.
- 21 [0025] Figures 17 through 19 illustrate an embodiment of a method for accessing a
22 damage site in the vertebra.
- 23 [0026] Figure 20 illustrates various embodiments of methods for deploying the
24 expandable support device to the vertebral column.

- 1 [0027] Figures 21 through 26 illustrate an embodiment of a method for deploying the
2 expandable support device into the damage site in the vertebra.
- 3 [0028] Figures 27 and 28 illustrate an embodiment of a deployment tool.
- 4 [0029] Figures 29 through 31 illustrate an embodiment of a method of expanding the
5 expandable support device using the deployment tool of Figures 27 and 28.
- 6 [0030] Figures 32 and 33 illustrate various embodiments of methods for expanding
7 the expandable support device.
- 8 [0031] Figures 34 and 35 illustrate various embodiments of the expandable support
9 device in an expanded configuration.
- 10 [0032] Figures 36 and 37 illustrate an embodiment of a method for deploying the
11 expandable support device into the damage site in the vertebra.
- 12 [0033] Figure 38 illustrates an embodiment of a method for deploying a second
13 expandable support device or locking pin in the damage site in the vertebra.
- 14 [0034] Figures 39 through 41 illustrate a method for deploying a second expandable
15 support device in the vertebra.
- 16 [0035] Figure 42 is a close-up view of an embodiment of section A-A of Figure 41.
- 17 [0036] Figure 43 illustrates an embodiment of the buttress.
- 18 [0037] Figures 44 through 46 illustrate various embodiments of section B-B of the
19 buttress of Figure 43.
- 20 [0038] Figures 47 through 49 illustrate an embodiment of a method for deploying the
21 buttress.
- 22 [0039] Figure 50 illustrates an embodiment of a method for deploying the buttress.
- 23 [0040] Figures 51 through 53 illustrate an embodiment of a method for deploying the
24 buttress
- 25 [0041] Figure 54 illustrates an embodiment of the buttress.

1 [0042] Figure 55 illustrates an embodiment of section C-C of the buttress of Figure
2 54.

3 [0043] Figure 56 illustrates an embodiment of a method for deploying the buttress.
4

5 DETAILED DESCRIPTION

6 [0044] Figures 1 through 5 illustrate an expandable support device 2, such as a stent,
7 that can be implanted in a bone, such as a compression fracture in a vertebra 60, or in soft
8 tissue, such as a herniated intervertebral disc 62. The expandable support device 2 can be
9 biocompatible. The expandable support device 2 can be used for tissue repair, for
10 example for repair bone fractures such as spinal compression fractures, and/or repairing
11 soft tissue damage, such as herniated vertebral discs 62. The expandable support device 2
12 can have any configuration, and be used for method, described in the P001 Patent
13 Application.

14 [0045] The expandable support device 2 can have a longitudinal axis 4. The
15 expandable support device 2 can have a first end 6 and a second end 8. The first end 6
16 can be substantially parallel with the second end 8. The longitudinal axis 4 can intersect
17 the first end 6 and the second end 8 at a first contracted intersection angle 10 and a second
18 contracted intersection angle 12, respectively, for example, when the expandable support
19 device 2 is in a contracted configuration (as shown). The expandable support device 2
20 can be hollow, for example along the longitudinal axis 4. The first end 6 can have a first
21 port 14. The second end 8 can have a second port 16. The first contracted intersection
22 angle 10 can be substantially equal to the second contracted intersection angle 12. The
23 contracted intersection angles can be from about 0° to about 90°, more narrowly from
24 about 5° to about 45°, yet more narrowly from about 10° to about 30°, for example about
25 20°.

1 [0046] The expandable support device 2 can have a wall 18. The outer and/or inner
2 surfaces of the wall 18 can be configured to increase friction or be capable of an
3 interference fit with another object, such as a second expandable support device 20. The
4 configurations to increase friction or be capable of an interference fit include teeth 162,
5 knurling, coating, or combinations thereof.

6 [0047] The wall 18 can have struts 22. The wall 18 can have about 8 struts 22 on
7 each side of the expandable support device 2. The struts 22 can be substantially parallel
8 to the first end 6 and/or the second end 8. The struts 22 can be separated from the other
9 struts 22 by wall openings 24. The expandable support device 2 can have about 7 wall
10 openings 24 on each side. The wall openings 24 can be substantially parallel to the first
11 end 6 and/or second end 8, for example when the expandable support device 2 is in a
12 contracted configuration. The expandable support device 2 can have ingrowth ports 26.

13 [0048] The expandable support device 2 can have a first port 14 and/or a second port
14 16. A hollow of the expandable support device 2 can be completely or partially coated
15 and/or filled with agents and/or a matrix as listed below.

16 [0049] The leading end of the expandable support device 2 can be sharpened. The
17 leading end can be used to help move tissue aside during implantation and deployment.
18 The leading end can be self-penetrating.

19 [0050] When in a contracted configuration, the expandable support device 2 can have
20 a contracted length 28 and a contracted height 30. The expanded length 126 can be from
21 about 0.318 cm (0.125 in.) to about 10 cm (4 in.), for example about 3.8 cm (1.5 in.). The
22 contracted height 30 can be from about 0.1 cm (0.05 in.) to about 3 cm (1 in.), for
23 example about 0.8 cm (0.3 in.).

24 [0051] Figure 6 illustrates that the expandable support device 2 can have shorter struts
25 22 than the struts 22 shown in Figures 1 through 5. The length of the struts 22 can be

1 from about 0.3 cm (0.1 in.) to about 5 cm (2 in.), for example about 2 cm (0.7 in.), also
2 for example about 1 cm (0.5 in.).

3 [0052] Figure 7 illustrates that the expandable support device 2 can have from about 2
4 struts 22 to about 50 struts 22, for example about 4 struts 22, also for example about 8
5 struts 22. The expandable support device 2 can have from about 1 wall opening 24 to
6 about 51 wall openings 24, for example about 3 wall openings 24, also for example about
7 7 wall openings 24.

8 [0053] Figure 8 illustrates that the expandable support device 2 can have a first pane
9 32, a second pane 34, a third pane 36, and a fourth pane 38. A first joint 40 can attach the
10 first pane 32 to the second pane 34. A second joint 42 can attach the second pane 34 to
11 the third pane 36. A third joint 44 can attach the third pane 36 to the fourth pane 38. The
12 joints can rotatably attach the panes. The joints can be separate from or integral with the
13 panes. Each pane can have struts 22 and wall openings 24. During use, the joints can
14 enable the panes to rotate in-plane, as shown by arrows 46.

15 [0054] Figures 9, 10 and 11 illustrate that the expandable support device 2, for
16 example as shown in Figure 8, can have a square or rectangular, circular, or polygonal
17 cross-section, respectively. Figure 11 shows the joints as nodes having a wider section
18 than the wall 18, but the joints can also have the same width or a smaller width than the
19 wall 18.

20 [0055] Figures 12 through 14 illustrate the expandable support device 2 that can have
21 a radius of curvature 48 along the longitudinal axis 4. The radius of curvature 48 can be
22 from about 1 mm (0.04 in.) to about 250 mm (10 in.), for example about 50 mm (2 in.).
23 (The wall 18 is shown sans panels or struts 22 for illustrative purposes.) The expandable
24 support device 2 can have at least one flat side, for example two flat sides. The two flat
25 sides can be on opposite sides of the expandable support device 2 from each other.

1 [0056] The expandable support devices 2 can have textured and/or porous surfaces
2 for example, to increase friction against bone surfaces, and/or promote tissue ingrowth.
3 The expandable support devices 2 can be coated with a bone growth factor, such as a
4 calcium base.

5 [0057] The expandable support device 2 can be covered by a thin metal screen. The
6 thin metal screen can expand and/or open when the expandable support device 2 expands.

7 [0058] Any or all elements of the expandable support device 2 and/or other devices or
8 apparatuses described herein can be made from, for example, a single or multiple
9 stainless steel alloys, nickel titanium alloys (e.g., Nitinol), cobalt-chrome alloys (e.g.,
10 ELGILOY® from Elgin Specialty Metals, Elgin, IL; CONICHROME® from Carpenter
11 Metals Corp., Wyomissing, PA), nickel-cobalt alloys (e.g., MP35N® from Magellan
12 Industrial Trading Company, Inc., Westport, CT), molybdenum alloys (e.g., molybdenum
13 TZM alloy, for example as disclosed in International Pub. No. WO 03/082363 A2,
14 published 9 October 2003, which is herein incorporated by reference in its entirety),
15 tungsten-rhenium alloys, for example, as disclosed in International Pub. No. WO
16 03/082363, polymers such as polyethylene terephthalate (PET)/polyester (e.g.,
17 DACRON® from E. I. Du Pont de Nemours and Company, Wilmington, DE),
18 polypropylene, (PET), polytetrafluoroethylene (PTFE), expanded PTFE (ePTFE),
19 polyether ketone (PEK), polyether ether ketone (PEEK), poly ether ketone ketone
20 (PEKK) (also poly aryl ether ketone ketone), nylon, polyether-block co-polyamide
21 polymers (e.g., PEBAX® from ATOFINA, Paris, France), aliphatic polyether polyurethanes
22 (e.g., TECOFLEX® from Thermedics Polymer Products, Wilmington, MA), polyvinyl
23 chloride (PVC), polyurethane, thermoplastic, fluorinated ethylene propylene (FEP),
24 absorbable or resorbable polymers such as polyglycolic acid (PGA), polylactic acid
25 (PLA), polycaprolactone (PCL), polyethyl acrylate (PEA), polydioxanone (PDS), and

1 pseudo-polyamino tyrosine-based acids, extruded collagen, silicone, zinc, echogenic,
2 radioactive, radiopaque materials, a biomaterial (e.g., cadaver tissue, collagen, allograft,
3 autograft, xenograft, bone cement, morselized bone, osteogenic powder, beads of bone)
4 any of the other materials listed herein or combinations thereof. Examples of radiopaque
5 materials are barium sulfate, zinc oxide, titanium, stainless steel, nickel-titanium alloys,
6 tantalum and gold.

7 **[0059]** Any or all elements of the expandable support device 2 and/or other devices or
8 apparatuses described herein, can be, have, and/or be completely or partially coated with
9 agents and/or a matrix a matrix for cell ingrowth or used with a fabric, for example a
10 covering (not shown) that acts as a matrix for cell ingrowth. The matrix and/or fabric can
11 be, for example, polyester (e.g., DACRON® from E. I. Du Pont de Nemours and
12 Company, Wilmington, DE), polypropylene, PTFE, ePTFE, nylon, extruded collagen,
13 silicone or combinations thereof.

14 **[0060]** The expandable support device 2 and/or elements of the expandable support
15 device 2 and/or other devices or apparatuses described herein and/or the fabric can be
16 filled, coated, layered and/or otherwise made with and/or from cements, fillers, glues,
17 and/or an agent delivery matrix known to one having ordinary skill in the art and/or a
18 therapeutic and/or diagnostic agent. Any of these cements and/or fillers and/or glues can
19 be osteogenic and osteoinductive growth factors.

20 **[0061]** Examples of such cements and/or fillers includes bone chips, demineralized bone
21 matrix (DBM), calcium sulfate, coralline hydroxyapatite, biocoral, tricalcium phosphate,
22 calcium phosphate, polymethyl methacrylate (PMMA), biodegradable ceramics, bioactive
23 glasses, hyaluronic acid, lactoferrin, bone morphogenic proteins (BMPs) such as
24 recombinant human bone morphogenetic proteins (rhBMPs), other materials described
25 herein, or combinations thereof.

1 **[0062]** The agents within these matrices can include any agent disclosed herein or
2 combinations thereof, including radioactive materials; radiopaque materials; cytogenic
3 agents; cytotoxic agents; cytostatic agents; thrombogenic agents, for example
4 polyurethane, cellulose acetate polymer mixed with bismuth trioxide, and ethylene vinyl
5 alcohol; lubricious, hydrophilic materials; phosphor cholene; anti-inflammatory agents,
6 for example non-steroidal anti-inflammatories (NSAIDs) such as cyclooxygenase-1
7 (COX-1) inhibitors (e.g., acetylsalicylic acid, for example ASPIRIN® from Bayer AG,
8 Leverkusen, Germany; ibuprofen, for example ADVIL® from Wyeth, Collegeville, PA;
9 indomethacin; mefenamic acid), COX-2 inhibitors (e.g., VIOXX® from Merck & Co.,
10 Inc., Whitehouse Station, NJ; CELEBREX® from Pharmacia Corp., Peapack, NJ; COX-1
11 inhibitors); immunosuppressive agents, for example Sirolimus (RAPAMUNE®, from
12 Wyeth, Collegeville, PA), or matrix metalloproteinase (MMP) inhibitors (e.g.,
13 tetracycline and tetracycline derivatives) that act early within the pathways of an
14 inflammatory response. Examples of other agents are provided in Walton et al, Inhibition
15 of Prostaglandin E₂ Synthesis in Abdominal Aortic Aneurysms, *Circulation*, July 6, 1999,
16 48-54; Tambiah et al, Provocation of Experimental Aortic Inflammation Mediators and
17 Chlamydia Pneumoniae, *Brit. J. Surgery* 88 (7), 935-940; Franklin et al, Uptake of
18 Tetracycline by Aortic Aneurysm Wall and Its Effect on Inflammation and Proteolysis,
19 *Brit. J. Surgery* 86 (6), 771-775; Xu et al, Sp1 Increases Expression of Cyclooxygenase-2
20 in Hypoxic Vascular Endothelium, *J. Biological Chemistry* 275 (32) 24583-24589; and
21 Pyo et al, Targeted Gene Disruption of Matrix Metalloproteinase-9 (Gelatinase B)
22 Suppresses Development of Experimental Abdominal Aortic Aneurysms, *J. Clinical*
23 *Investigation* 105 (11), 1641-1649 which are all incorporated by reference in their
24 entireties.

1 [0063] The expandable support devices 2 can be laser cut, and/or non-laser cut. The
2 expandable support device 2 can be laser cut in a partially opened pattern, then the
3 expandable support device 2 can be loaded (e.g., crimped) onto a deployment tool 50
4 (e.g., balloon). The loaded expandable support device 2 can have a smaller profile while
5 plastically deforming the struts 22 past their limits.

6 [0064] The expandable support device 2 can be longitudinally segmented. Multiple
7 expandable support devices 2 can be attached first end 6 to second end 8, and/or a single
8 expandable support device 2 can be severed longitudinally into multiple expandable
9 support devices 2.

10

11 METHOD OF USE

12 [0065] Figure 15 illustrates that the expandable support device 2 can be loaded in a
13 collapsed (i.e., contracted) configuration onto a deployment tool 50. The deployment tool
14 50 can have an expandable balloon 52 catheter 54 as known to those having an ordinary
15 level of skill in the art. The deployment tool 50 can have a catheter 54. The catheter 54
16 can have a fluid conduit 56. The fluid conduit 56 can be in fluid communication with a
17 balloon 52. The balloon 52 and the deployment tool 50 can be the balloon 52 and
18 deployment tool 50 as described by the P005 Patent Application. The balloon 52 can be
19 configured to receive a fluid pressure of at least about 5,000 kPa (50 atm), more narrowly
20 at least about 10,000 kPa (100 atm), for example at least about 14,000 kPa (140 atm).

21 [0066] The deployment tool 50 can be a pair of wedges, an expandable jack, other
22 expansion tools, or combinations thereof.

23 [0067] Figure 16 illustrates that the fluid pressure in the fluid conduit 56 and balloon
24 52 can increase, thereby inflating the balloon 52, as shown by arrows. The expandable
25 support device 2 can expand, for example, due to pressure from the balloon 52.

1 [0068] Figures 17 (side view) and 18 (top view) illustrates a vertebral column 58 that
2 can have one or more vertebra 60 separated from the other vertebra 60 by discs 62. The
3 vertebra 60 can have a damage site 64, for example a compression fracture.

4 [0069] An access tool 66 can be used to gain access to the damage site 64 and or
5 increase the size of the damage site 64 to allow deployment of the expandable support
6 device 2. The access tool 66 can be a rotating or vibrating drill 68 that can have a handle
7 70. The drill 68 can be operating, as shown by arrows 72. The drill 68 can then be
8 translated, as shown by arrow 74, toward and into the vertebra 60 so as to pass into the
9 damage site 64.

10 [0070] Figure 19 illustrates that the access tool 66 can be translated, as shown by
11 arrow 86, to remove tissue at the damage site 64. The access tool 66 can create an access
12 port 76 at the surface of the vertebra 60. The access port 76 can open to the damage site
13 64. The access tool 66 can then be removed from the vertebra 60.

14 [0071] Figure 20 illustrates that a first deployment tool (a) 78 can enter through the
15 subject's back. The first deployment tool (a) 78 can enter through a first incision (a) 80 in
16 the skin 82 on the posterior 84 side of the subject near the vertebral column 58. The first
17 deployment tool (a) 78 can be translated, as shown by arrow, to position a first
18 expandable support device (a) 88 into a first damage site (a) 90. The first access port (a)
19 92 can be on the posterior 84 side of the vertebra 60.

20 [0072] A second deployment tool (b) 94 can enter through a second incision (b) 96
21 (as shown) in the skin 82 on the posterior 84 or the first incision (a) 80. The second
22 deployment tool (b) 94 can be translated through muscle (not shown), around nerves 98,
23 the spinal cord 99, and anterior 100 of the vertebral column 58. The second deployment
24 tool (b) 94 can be steerable. The second deployment tool (b) 94 can be steered, as shown
25 by arrow 102, to align the distal tip of the second expandable support device (b) 104 with

1 a second access port (b) 106 on a second damage site (b) 108. The second access port (b)
2 106 can face anteriorly 100. The second deployment tool (b) 94 can translate, as shown
3 by arrow 110, to position the second expandable support device 20 in the second damage
4 site (b) 108.

5 **[0073]** The vertebra 60 can have multiple damage sites and expandable support
6 devices deployed therein. The expandable support devices can be deployed from the
7 anterior 100, posterior 84, both lateral, superior, inferior, any angle, or combinations of
8 the directions thereof.

9 **[0074]** Figures 21 and 22 illustrate translating, as shown by arrow, the deployment
10 tool 50 loaded with the expandable support device 2 through the access port 76 from the
11 anterior 100 side of the vertebral column 58. Figures 23 and 24 illustrate that the
12 deployment tool 50 can be deployed from the posterior 84 side of the vertebral column
13 58. The deployment tool 50 can be deployed off-center, for example, when approaching
14 the posterior 84 side of the vertebral column 58.

15 **[0075]** Figures 25 illustrates that deployment tool 50 can position the expandable
16 support device 2 in the vertebra 60 and into the damage site 64.

17 **[0076]** Figure 26 illustrates that the fluid pressure in the fluid conduit 56 and the
18 balloon 52 can increase, thereby inflating the balloon 52, as shown by arrows. The
19 expandable support device 2 can expand, for example, due to pressure from the balloon
20 52. The balloon 52 can be expanded until the expandable support device 2 is
21 substantially fixed to the vertebra 60. The balloon 52 and/or the expandable support
22 device 2 can reshape the vertebral column 58 to a more natural configuration during
23 expansion of the balloon 52.

24 **[0077]** Figure 27 illustrates that the deployment tool 50 can have a shaft 112 and a
25 sleeve 114. The shaft 112 can be slidably received, as shown by arrow, by the sleeve

1 114. The shaft 112 can have a first catch 116. The shaft 112 can have a relief 118 section
2 or an additional catch on a side opposite the first catch 116. The sleeve 114 can have a
3 second catch 120.

4 **[0078]** Figure 28 illustrates that the deployment tool 50 can have an actuator 122,
5 such as an ergonomic lever handle 70. The handle 70 can be attached to the sleeve 114.
6 When the shaft 112 is received in the sleeve 114, the actuator 122 can be attached to the
7 shaft 112. Applying a force to the actuator 122 can cause the shaft 112 to slide in the
8 sleeve 114.

9 **[0079]** Figure 29 illustrates that the expandable support device 2, for example in a
10 contracted configuration, can be loaded on the shaft 112. The first end 6 of the
11 expandable support device 2 can be received by and/or interference fit in the first catch
12 116. The second end 8 of the expandable support device 2 can be received by and/or
13 interference fit in the relief 118. The first and/or second end 8 of the expandable support
14 device 2 can be beveled. The beveled ends can be shaped to fit the first catch 116 and/or
15 relief 118.

16 **[0080]** Figure 30 illustrates that the shaft 112 can slide, as shown by arrow, relative to
17 the sleeve 114. The second end 8 of the expandable support device 2 can be received by
18 and/or engage the second catch 120. The second end 8 can interference fit the second
19 catch 120.

20 **[0081]** Figure 31 illustrates that the shaft 112 can be forcibly slid into the sleeve 114.
21 The expandable support device 2 can be squeezed between the first catch 116 and the
22 second catch 120. The expandable support device 2 can be resiliently and/or deformably
23 forced into an expanded configuration. The expandable support device 2 can be released
24 from the deployment tool 50, for example, by sliding the shaft 112 away from the sleeve
25 114.

1 [0082] Figure 32 illustrates that the expandable support device 2 can be expanded by
2 applying force, as shown by arrows, on the first end 6 and the second end 8, and by
3 directing the force toward the expandable support device 2. Figure 33 illustrates that the
4 expandable support device 2 can be expanded by applying force, as shown by arrows,
5 radially outward against the wall 18.

6 [0083] Figures 34 and 35 illustrate various embodiments of the expandable support
7 device 2 in an expanded configuration. The wall openings 24 can expand when the
8 expandable support device 2 is in an expanded configuration.

9 [0084] The expandable support device 2 can have an expanded height 124 and an
10 expanded length 126. The expanded height 124 can be from about 0.3 cm (0.1 in.) to
11 about 5 cm (2 in.), for example about 2 cm (0.6 in.). The expanded length 126 can be
12 from about 0.1 cm (0.05 in.) to about 3.8 cm (1.5 in.), for example about 3 cm (1 in.). The
13 expandable support device 2 can have first 128 and second 130 expanded intersection
14 angles. The first expanded intersecting angle can be substantially equal to the second
15 expanded intersecting angle. The expanded intersecting angles can be from about 45° to
16 about 135°, for example about 110°, also for example about 90°.

17 [0085] Figure 36 illustrates that the fluid pressure can be released from the balloon
18 52, and the balloon 52 can return to a pre-deployment configuration, leaving the
19 expandable support element substantially fixed to the vertebra 60 at the damage site 64.

20 [0086] The access port 76 can have an access port diameter 132. The access port
21 diameter 132 can be from about 1.5 mm (0.060 in.) to about 40 mm (2 in.), for example
22 about 8 mm (0.3 in.). The access port diameter 132 can be a result of the size of the
23 access tool 66. After the expandable support device 2 is deployed, the damage site 64 can
24 have a deployed diameter 134. The deployed diameter 134 can be from about 1.5 mm

1 (0.060 in.) to about 120 mm (4.7 in.), for example about 20 mm (0.8 in.). The deployed
2 diameter 134 can be greater than, equal to, or less than the access port diameter 132.

3 **[0087]** Figure 37 illustrates that the deployment tool 50 can be removed, as shown by
4 arrow, from the vertebra 60 after the expandable support device 2 is deployed.

5 **[0088]** Figure 38 illustrate that a second expandable support device 20 and/or locking
6 pin can be inserted, as shown by arrow 136, into the first deployed expandable support
7 device 88, for example, after the first expandable support device 138 is deployed in the
8 vertebra 60. The second expandable support device 20 and/or locking pin can prevent the
9 first expandable support device 138 from collapsing after the first expandable support
10 device 138 is deployed in the vertebra 60. The second expandable support device 20
11 and/or locking pin can form an interference fit with the expandable support device 2.

12 **[0089]** Figure 39 illustrates that the second expandable support device 20 can be
13 translated, as shown by arrow, into the first expandable support device 138. The first
14 expandable support device 138 can be in an expanded, contracted, or other configuration.
15 The second expandable support device 20 can be in an expanded, contracted, or other
16 configuration. The struts 22 and/or wall openings 24 of the first expandable support
17 device 138 can be angled in a substantially opposite direction to the struts 22 and/or wall
18 openings 24 of the second expandable support device 20.

19 **[0090]** Figure 40 illustrates that after the second expandable support device 20 is
20 inside the first expandable support device 138, the second expandable support device 20
21 can be subject to any or all of the expansion forces, as shown by arrows.

22 **[0091]** Figure 41 illustrates that the second expandable support device 20 can be in an
23 expanded configuration in the first expandable support device 138. The second
24 expandable support device 20 can be translated into the first expandable support device
25 138 and expanded, as shown in Figures 39 and 40. The second expandable support

1 device 20 can be in an expanded configuration and screwed or otherwise attached into the
2 first expandable support device 138.

3 **[0092]** Figure 42 illustrates that the first expandable support device 138 can be
4 rotatably attached to, or have an interference fit with, the second expandable support
5 device 20. The first expandable support device 138 can have first teeth 140, for example
6 on the inside surface of the wall 18. The second expandable support device 20 can have
7 second teeth 142, for example on the outside surface of the wall 18. The first teeth 140
8 can engage the second teeth 142.

9 **[0093]** Figure 43 illustrates a buttress 144. The buttress 144 can have a longitudinal
10 axis 4. The buttress 144 can have a tensioner 146. A first end 6 of the tensioner 146 can
11 be fixedly or removably attached a first end 6 of the buttress 144. A second end 8 of the
12 tensioner 146 can be fixedly or removably attached a second end 8 of the buttress 144.
13 The tensioner 146 can be in a relaxed configuration when the buttress 144 is in a relaxed
14 configuration. The tensioner 146 can create a tensile force between the first end 6 of the
15 buttress 144 and the second end 8 of the buttress 144 when the buttress 144 is in a
16 stressed configuration. The tensioner 146 can be, for example, a resilient wire, a coil,
17 spring, an elastic member, or combinations thereof.

18 **[0094]** The buttress 144 can have a coil 148. The coil 148 can have turns 150 of a
19 wire, ribbon, or other coiled element. Figures 44 through 46 illustrate that the coil 148
20 can be made from a wire, ribbon, or other coiled element having a circular, square, or
21 oval cross-section, respectively.

22 **[0095]** The buttress 144 can be a series of connected hoops.

23 **[0096]** Figure 47 illustrates that the buttress 144 can be loaded into a hollow
24 deployment tool 50 in a smear 152 (i.e., partially shear stressed) configuration. The
25 buttress 144 in the smear 152 configuration can have a relaxed first end 6, a stressed

1 smear 152 section, and a relaxed second end 8. The longitudinal axis 4 can be not
2 straight (i.e., non-linear) through the smear 152 section.

3 [0097] Figure 48 illustrates that part of the buttress 144 can be forced, as shown by
4 arrow, out of the deployment tool 50. The second end 8 can exit the deployment tool 50
5 before the remainder of the buttress 144. The smear 152 section can then partially relax.
6 The second end 8 can be positioned to a final location before the remainder of the buttress
7 144 is deployed from the deployment tool 50.

8 [0098] Figure 49 illustrates that the remainder of the buttress 144 can be forced, as
9 shown by arrow, out of the deployment tool 50. The smear 152 section can substantially
10 relax. The longitudinal axis 4 can return to a substantially relaxed and/or straight (i.e.,
11 linear) configuration.

12 [0099] Figure 50 illustrates that the buttress 144 can be deployed 154 in the
13 expandable support device 2, for example with the longitudinal axis 4 of the buttress 144
14 or the strongest orientation of the buttress 144 aligned substantially parallel with the
15 primary load bearing direction (e.g., along the axis of the spine) of the expandable
16 support device 2.

17 [00100] Figure 51 illustrates that the buttress 144 can be loaded into the hollow
18 deployment tool 50 with the longitudinal axis 4 of the buttress 144 substantially parallel
19 with the hollow length of the deployment tool 50. The entire length of the buttress 144
20 can be under shear stress.

21 [00101] Figure 52 illustrates that part of the buttress 144 can be forced, as shown by
22 arrow, out of the deployment tool 50. The second end 8 of the buttress 144 can exit the
23 deployment tool 50 before the remainder of the buttress 144. The tensioner 146 can apply
24 a tensile stress between the ends of the buttress 144, for example, forcing the deployed
25 second end 8 of the buttress 144 to “stand up straight”. The second end 8 of the buttress

1 144 can be positioned to a final location before the remainder of the buttress 144 is
2 deployed from the deployment tool 50.

3 **[00102]** Figure 53 illustrates that the remainder of the buttress 144 can be forced, as
4 shown by arrow, out of the deployment tool 50. The buttress 144 can substantially relax.

5 **[00103]** Figure 54 illustrates that the buttress 144 can have a first wedge 156 and a
6 second wedge 158. The first wedge 156 can contact the second wedge 158 at a
7 directionally locking interface 160. The directionally locking interface 160 can have
8 directional teeth 162.

9 **[0100]** Figure 55 illustrates that the first wedge 156 can be slidably attached to the
10 second wedge 158. The first wedge 156 can have a tongue 164. The second wedge 158
11 can have a groove 166. The tongue 164 can be slidably attached to the groove 166.

12 **[0101]** A gap 168 can be between the tongue 164 and the groove 166. The gap 168
13 can be wider than the height of the teeth 162. The gap 168 can be configured to allow the
14 first wedge 156 to be sufficiently distanced from the second wedge 158 so the teeth 162
15 on the first wedge 156 can be disengaged from the teeth 162 on the second wedge 158.

16 **[0102]** The buttress 144 in a compact configuration can be placed inside of the
17 longitudinal port 170 of the deployed expandable support device 2. Figure 56 illustrates
18 that the first wedge 156 can then be translated, as shown by arrows, relative to the second
19 wedge 158 along the directionally locking interface 160. The first wedge 156 can abut a
20 first side of the inside of the deployed expandable support device 2. The second wedge
21 158 can abut a second side of the inside of the deployed expandable support device 2.
22 The directionally interference fitting teeth 162 can prevent disengagement of the buttress
23 144. A stop 172 can limit the relative translation of the first wedge 156 and the second
24 wedge 158.

1 **[0103]** U.S. Provisional Patent Application Serial No. 60/612,001, titled
2 “EXPANDABLE SUPPORT DEVICE AND METHOD OF USE”, filed on 21 September
3 2004, is herein incorporated by reference in its entirety, and herein referred to as the P001
4 Patent Application. U.S. Provisional Patent Application Serial No. 60/611,972, titled
5 “BALLOON AND METHODS OF MAKING AND USING”, filed on 21 September
6 2004, is herein incorporated by reference in its entirety, and herein referred to as the P005
7 Patent Application. U.S. Provisional Patent Application titled “EXPANDABLE
8 SUPPORT DEVICE AND METHOD OF USE”, filed on 24 September 2004, attorney
9 docket no. SM P008 is herein incorporated by reference in its entirety, and herein referred
10 to as the P008 Patent Application. U.S. Provisional Patent Application titled
11 “SLIDABLE EXPANSION DEPLOYMENT DEVICE AND METHOD OF USING”,
12 filed on 24 September 2004, attorney docket no. SM P013 is herein incorporated by
13 reference in its entirety, and herein referred to as the P013 Patent Application. U.S.
14 Provisional Patent Application titled “EXPANDABLE SUPPORT DEVICE AND
15 METHOD OF USE”, filed on 24 September 2004, attorney docket no. SM P014 is herein
16 incorporated by reference in its entirety, and herein referred to as the P014 Patent
17 Application.

18 **[0104]** It is apparent to one skilled in the art that various changes and modifications
19 can be made to this disclosure, and equivalents employed, without departing from the
20 spirit and scope of the invention. Elements shown with any embodiment are exemplary
21 for the specific embodiment and can be used on other embodiments within this disclosure.

1

CLAIMS

2 We claim:

3 1. An expandable support device for performing completely implantable spinal repair,
4 comprising:

5 a longitudinal axis, a first end, and a second end;

6 wherein the device comprises a first configuration and a second configuration,

7 and wherein in the first configuration the first end is substantially parallel with the
8 second end, and the longitudinal axis intersects the first end at a first angle;

9 and wherein in the second configuration the first end is substantially parallel with
10 the second end, and the longitudinal axis intersects the first end at a second angle, and the
11 first angle is not equal to the second angle.

12

13 2. A method for deploying a spinal repair device having a longitudinal axis, a first end
14 and a second end, comprising:

15 delivering the spinal repair device into a target location;

16 expanding the spinal repair device, wherein expanding comprises applying a force
17 to the spinal repair device such that the first end and the second end angularly rotate with
18 respect to the longitudinal axis, and wherein the first end and the second end are
19 substantially parallel before the expanding and after the expanding.

20

21 3. A method for deploying a spinal repair device having a longitudinal axis, and a radial
22 axis, comprising:

23 delivering the spinal repair device into a target location;

24 radially expanding the spinal repair device, wherein radially expanding comprises
25 applying a force to the spinal repair device along the longitudinal axis, such that the

- 1 spinal repair device is compressed along the longitudinal axis by the force, and the spinal
2 repair device resultingly expands along the radial axis.
3
- 4 4. A device for deploying an expandable support device, comprising:
5 a first elongated member comprising a first catch; and
6 a second elongated member comprising a second catch;
7 wherein the first elongated member is configured to longitudinally slide along the
8 second elongated member, and wherein the first catch and the second catch are
9 configured to releasably attach to the expandable support device.
10
- 11 5. The device of Claim 4, wherein the first elongated member is a shaft.
12
- 13 6. The device of Claim 5, wherein the second elongated member is radially outside the
14 shaft

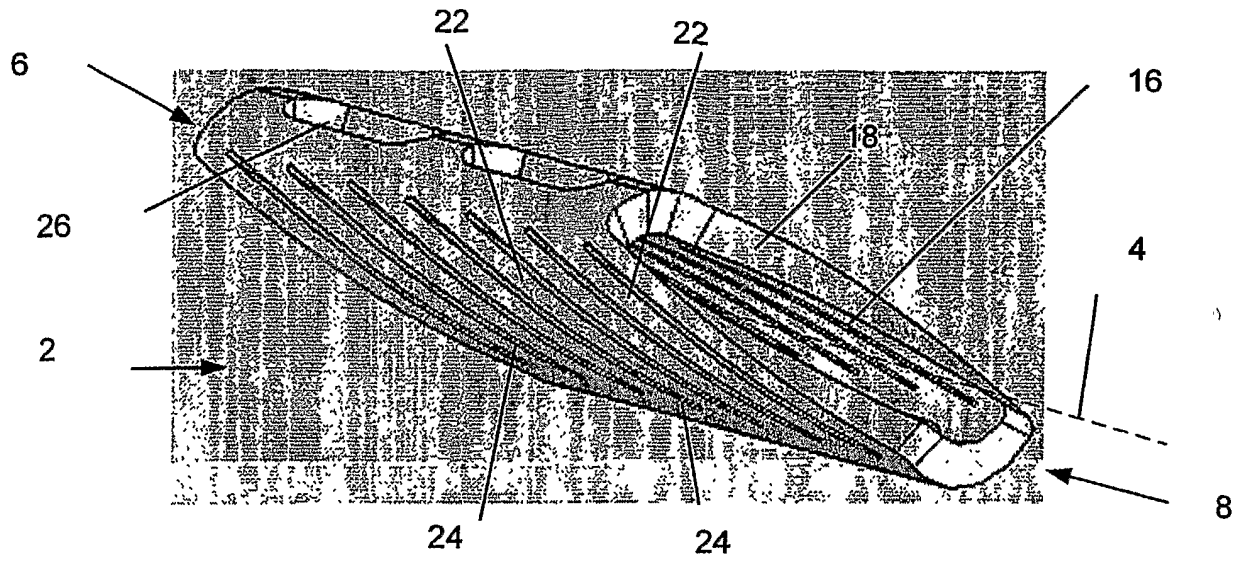


Fig. 1

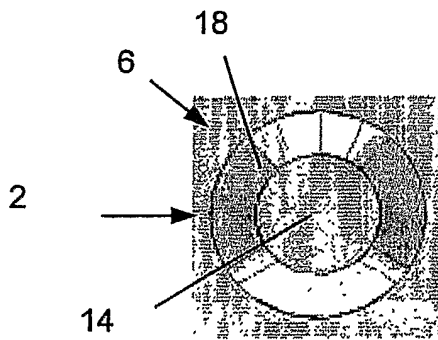


Fig. 2

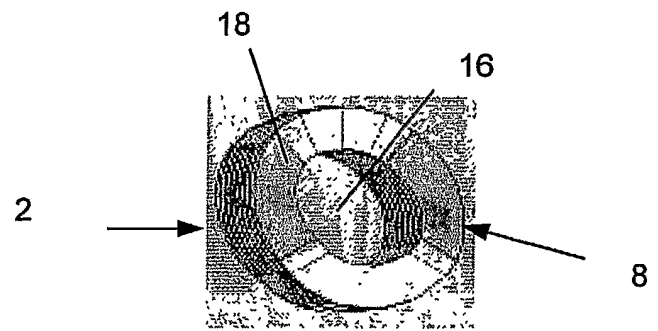


Fig. 3

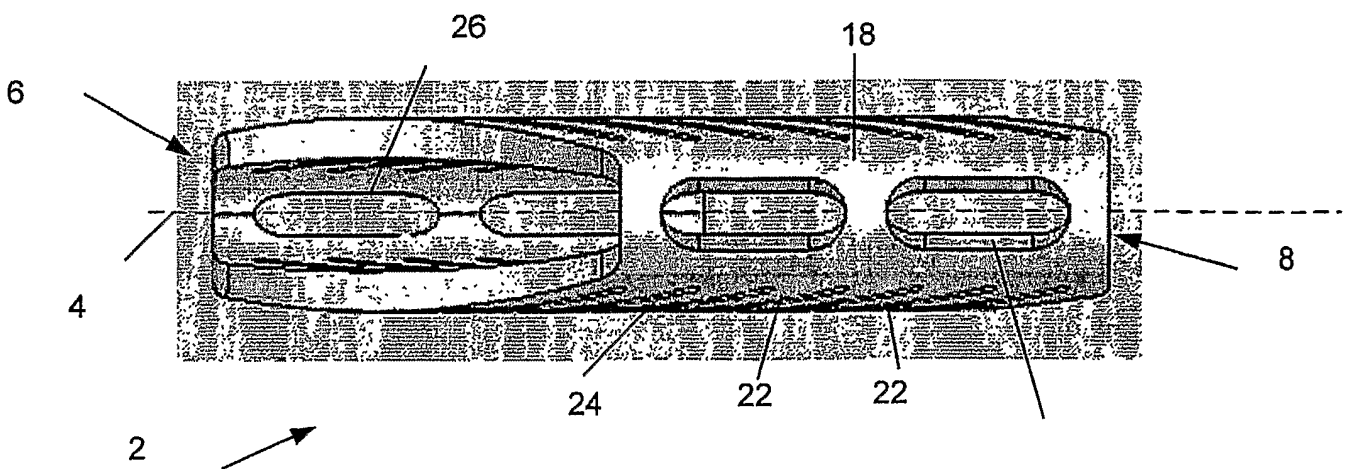
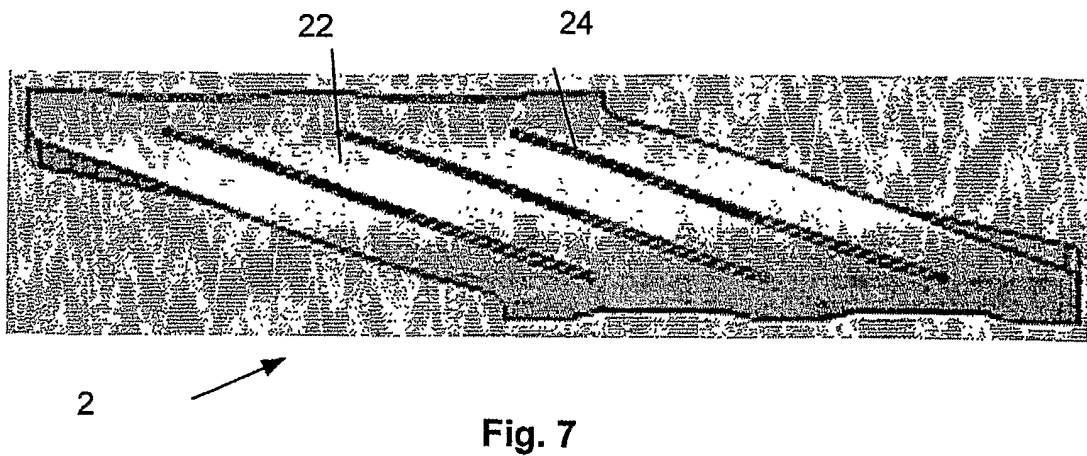
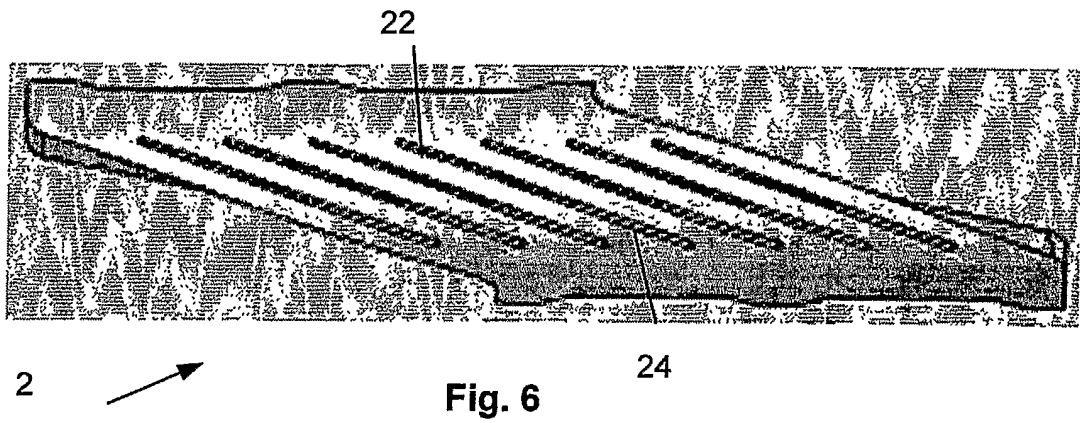
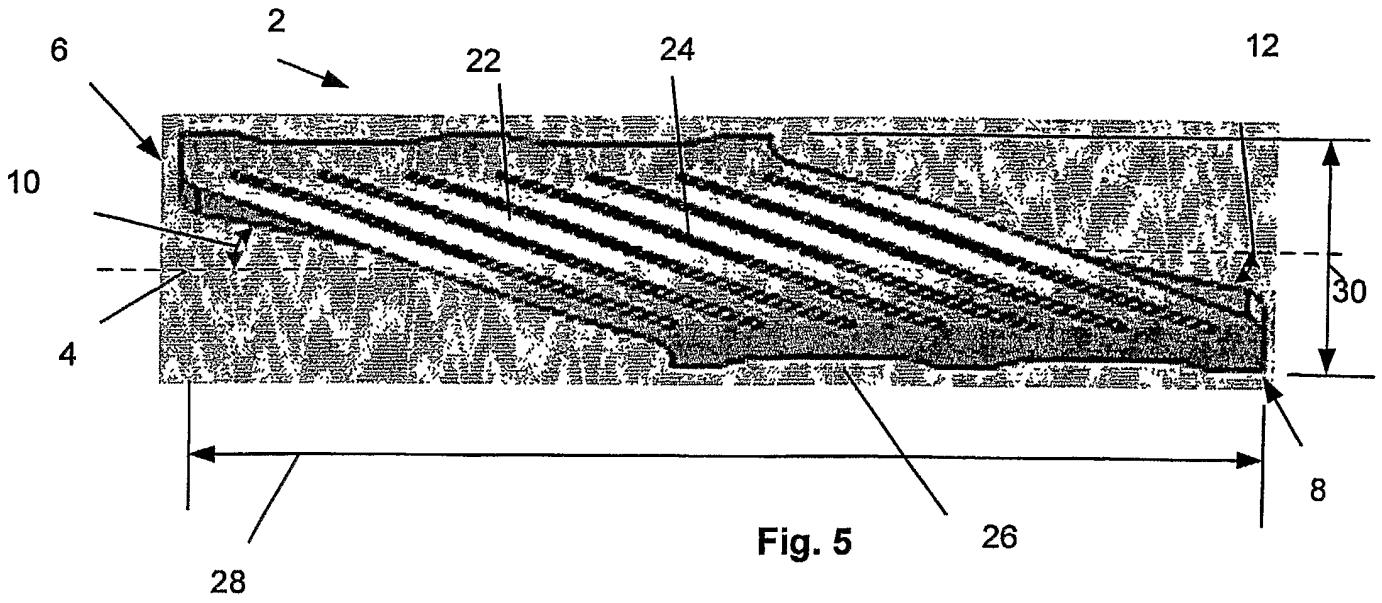


Fig. 4



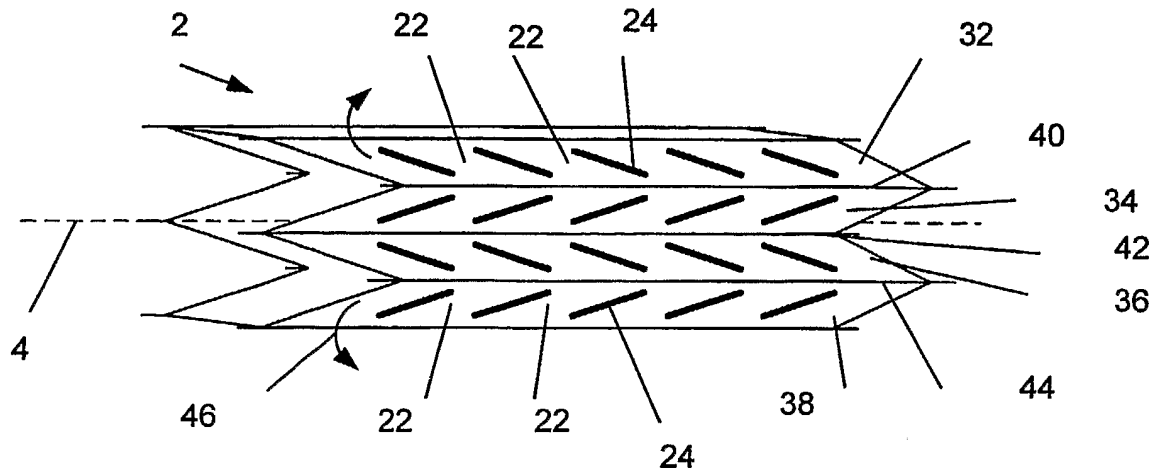


Fig. 8

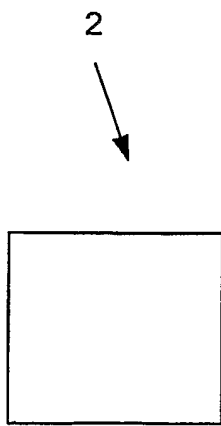


Fig. 9

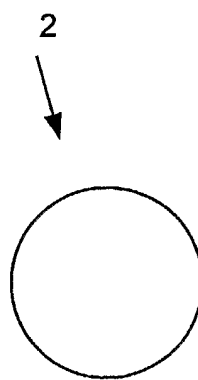


Fig. 10

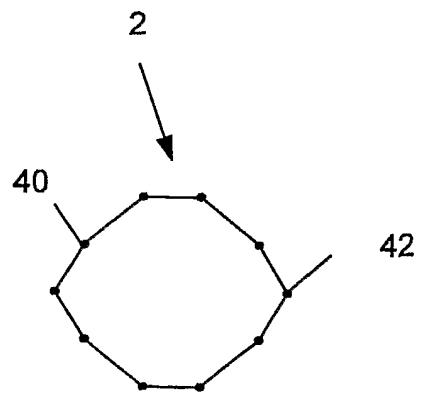


Fig. 11

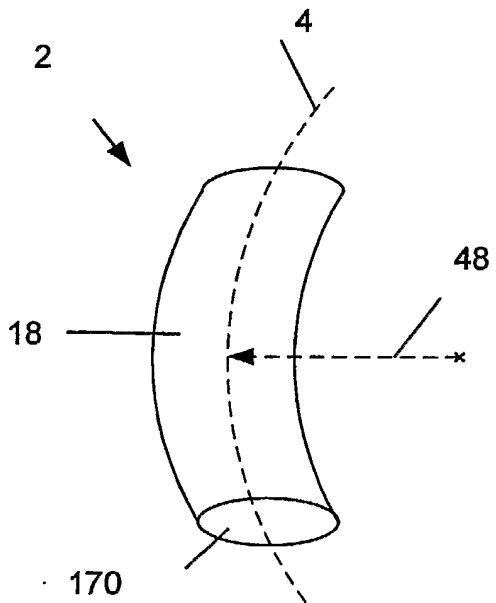


Fig. 12

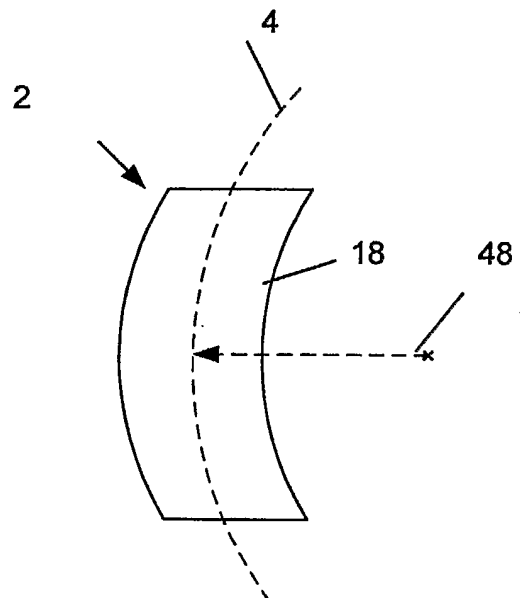


Fig. 13

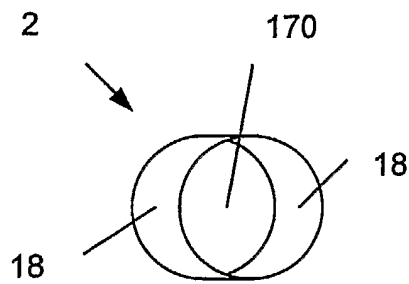
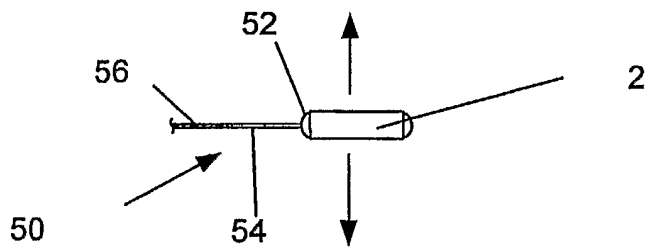
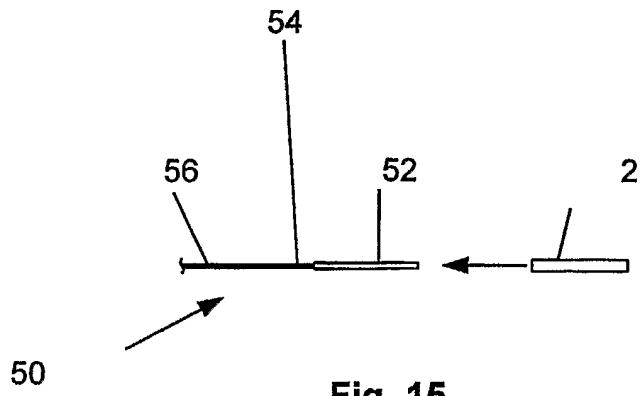


Fig. 14

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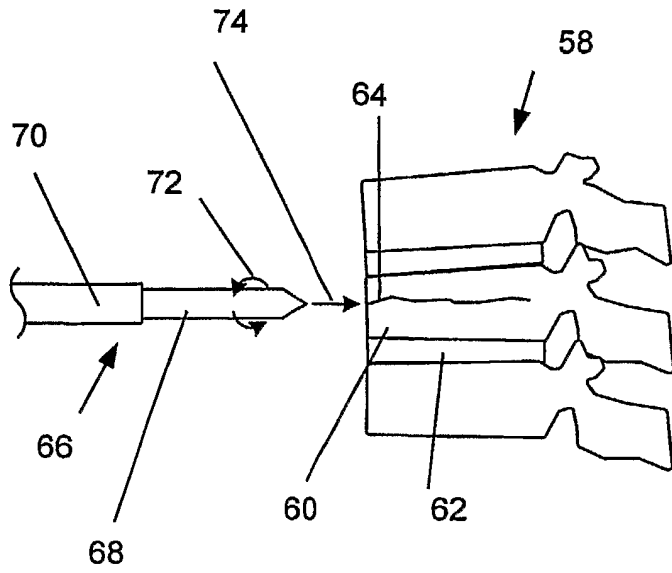


Fig. 17

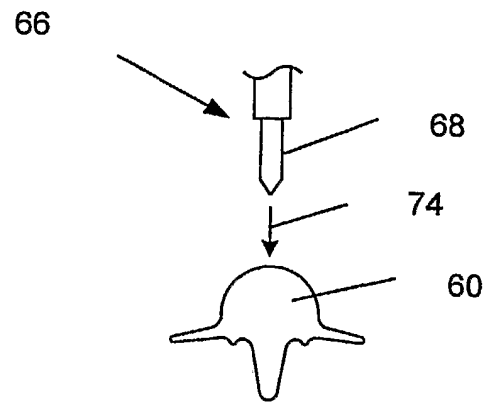


Fig. 18

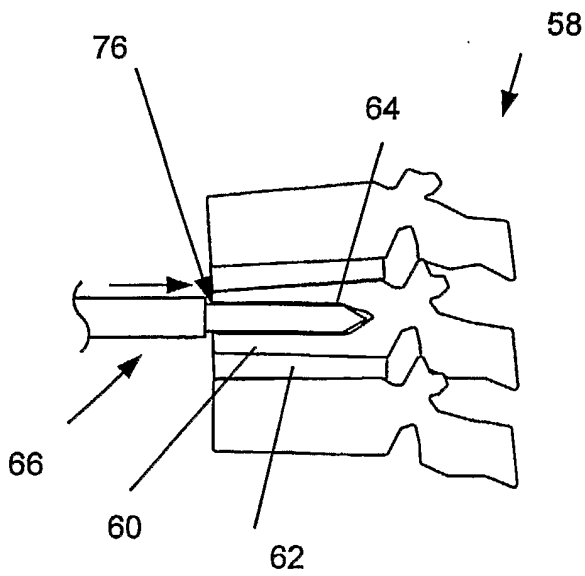


Fig. 19

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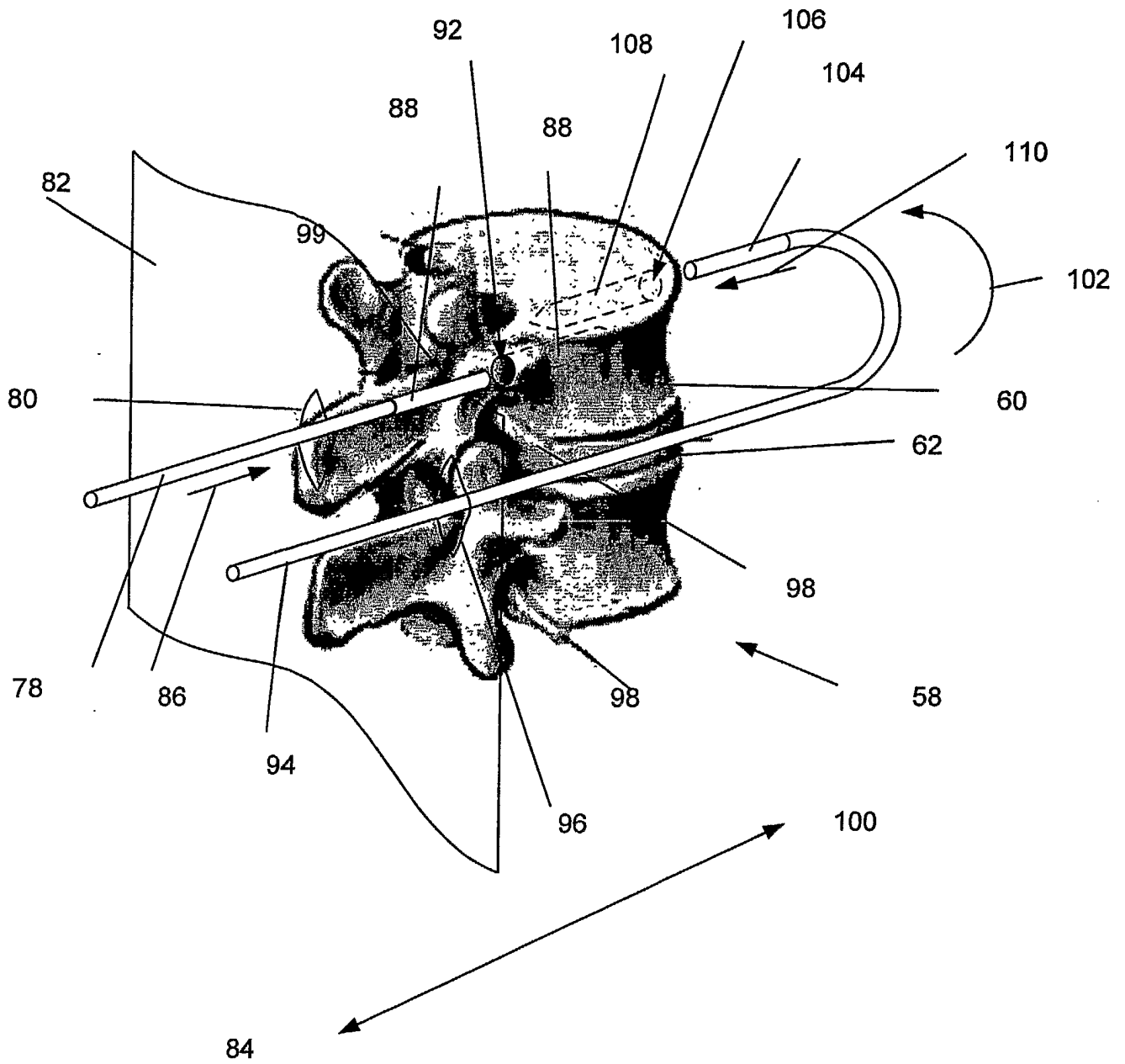


Fig. 20

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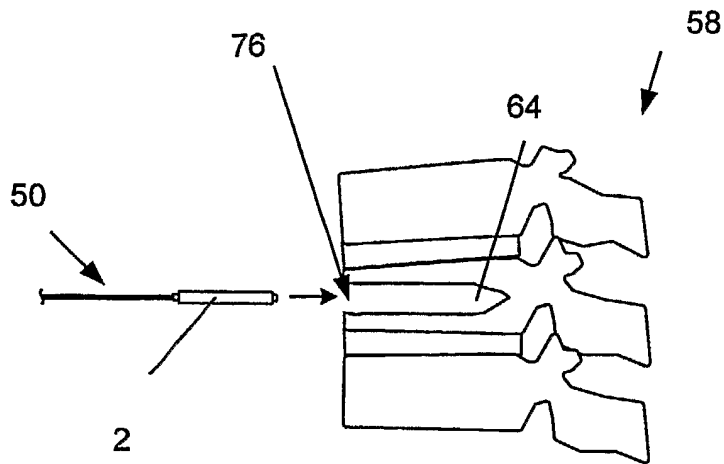


Fig. 21

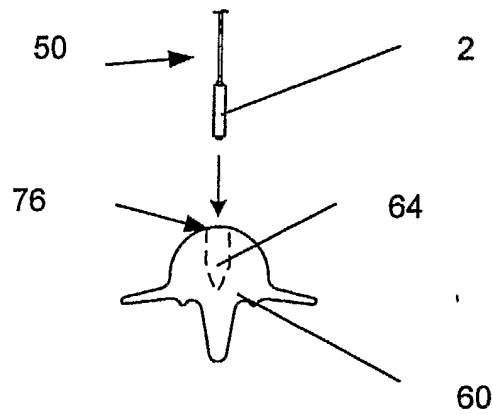


Fig. 22

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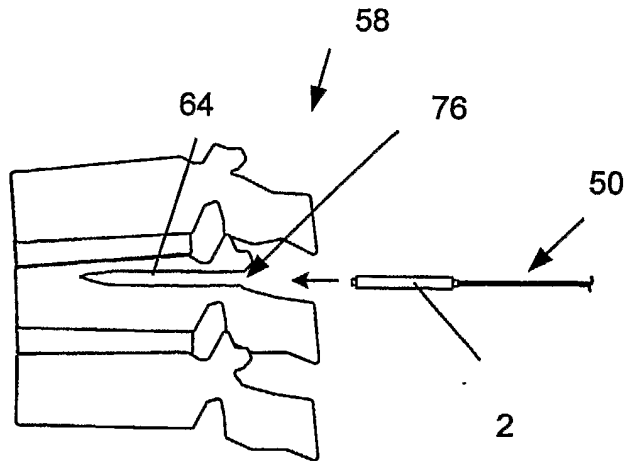


Fig. 23

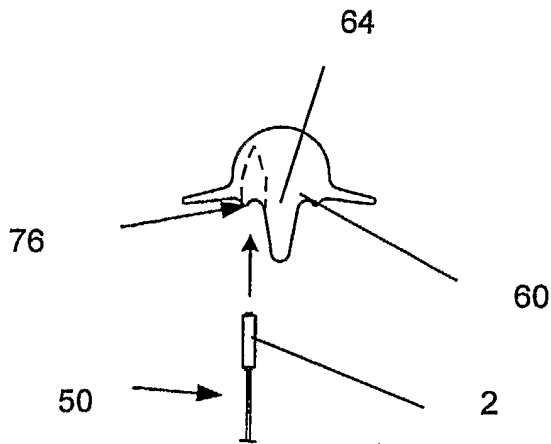


Fig. 24

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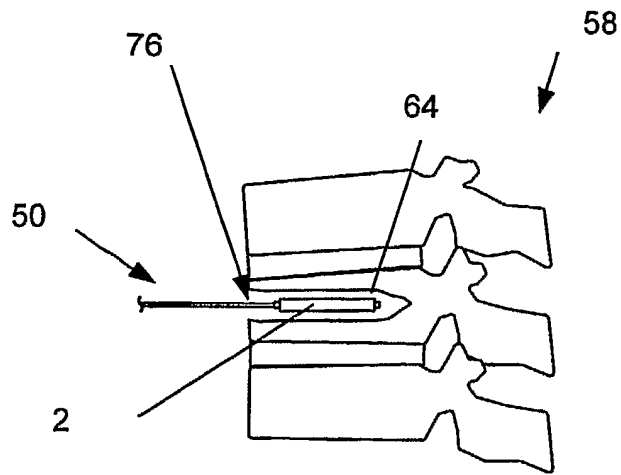


Fig. 25

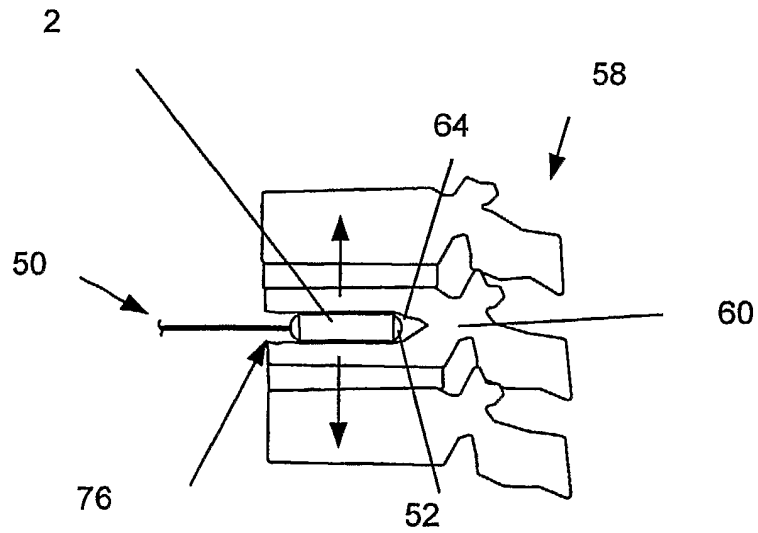


Fig. 26

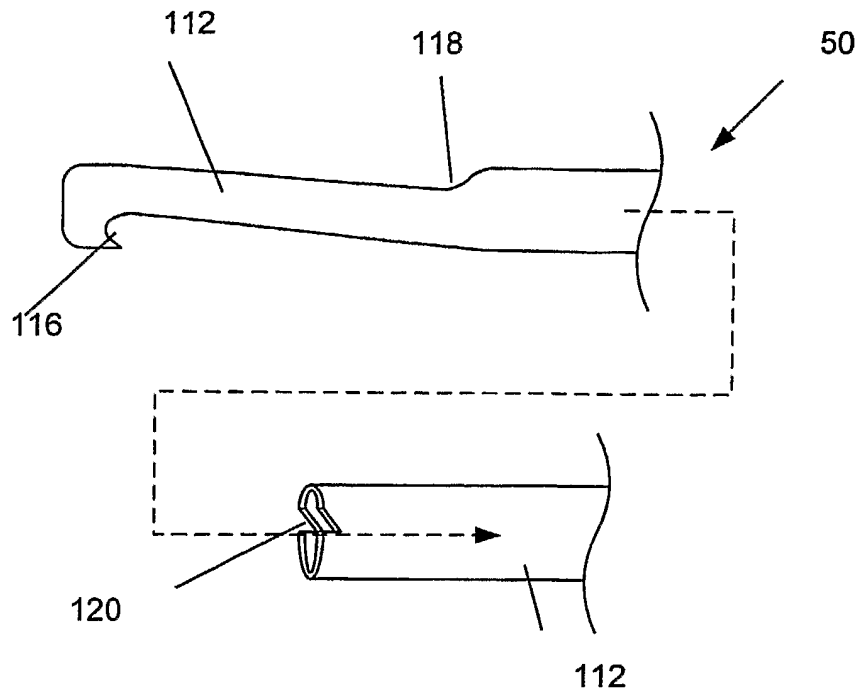


Fig. 27

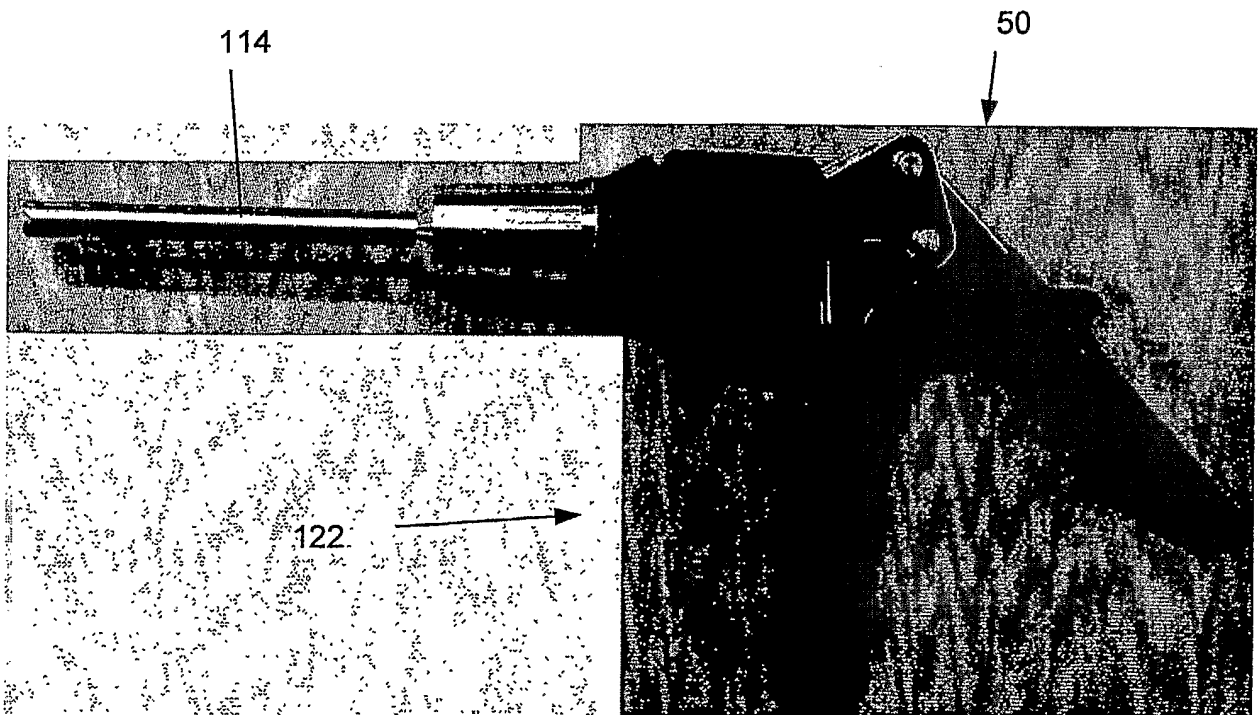


Fig. 28

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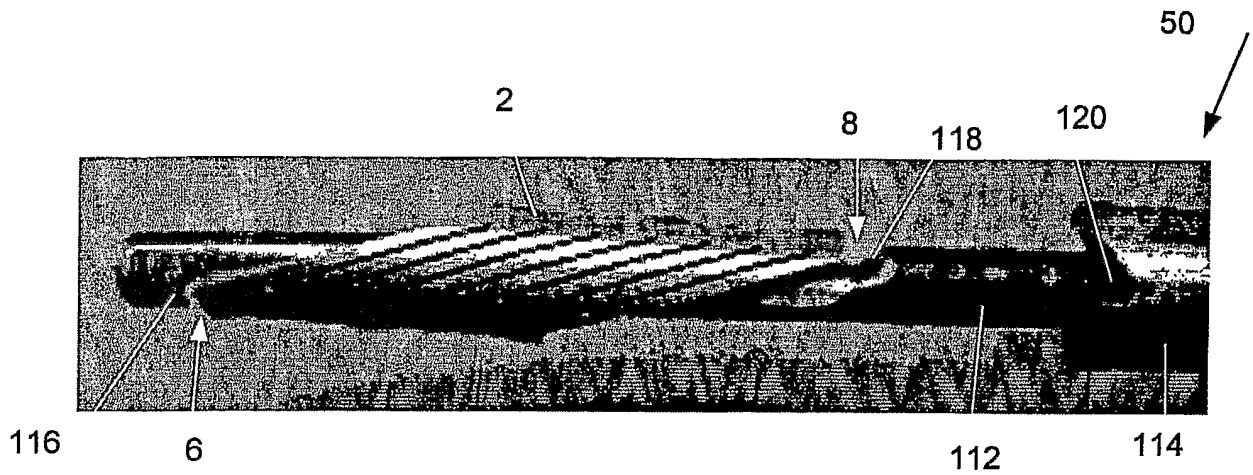


Fig. 29

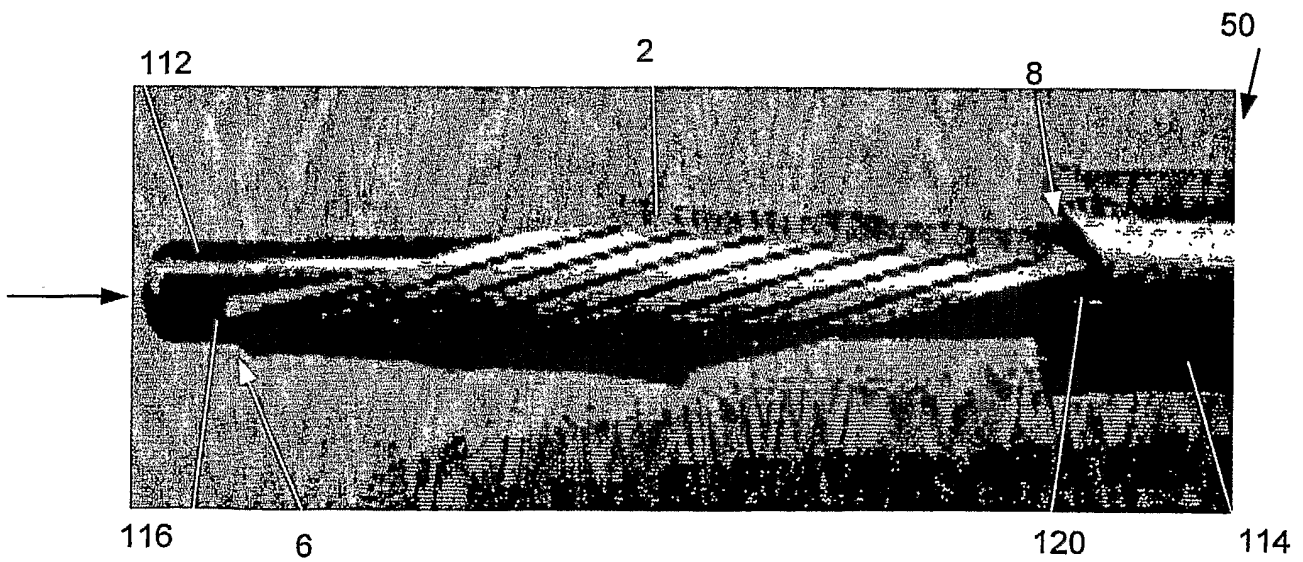


Fig. 30

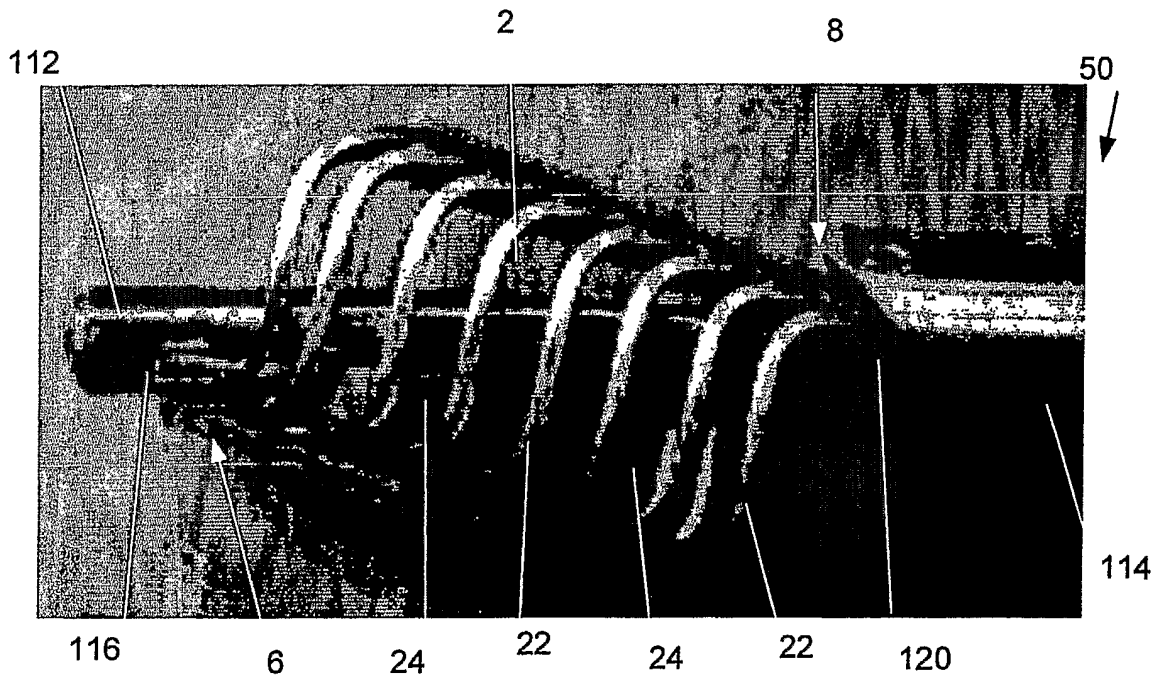


Fig. 31

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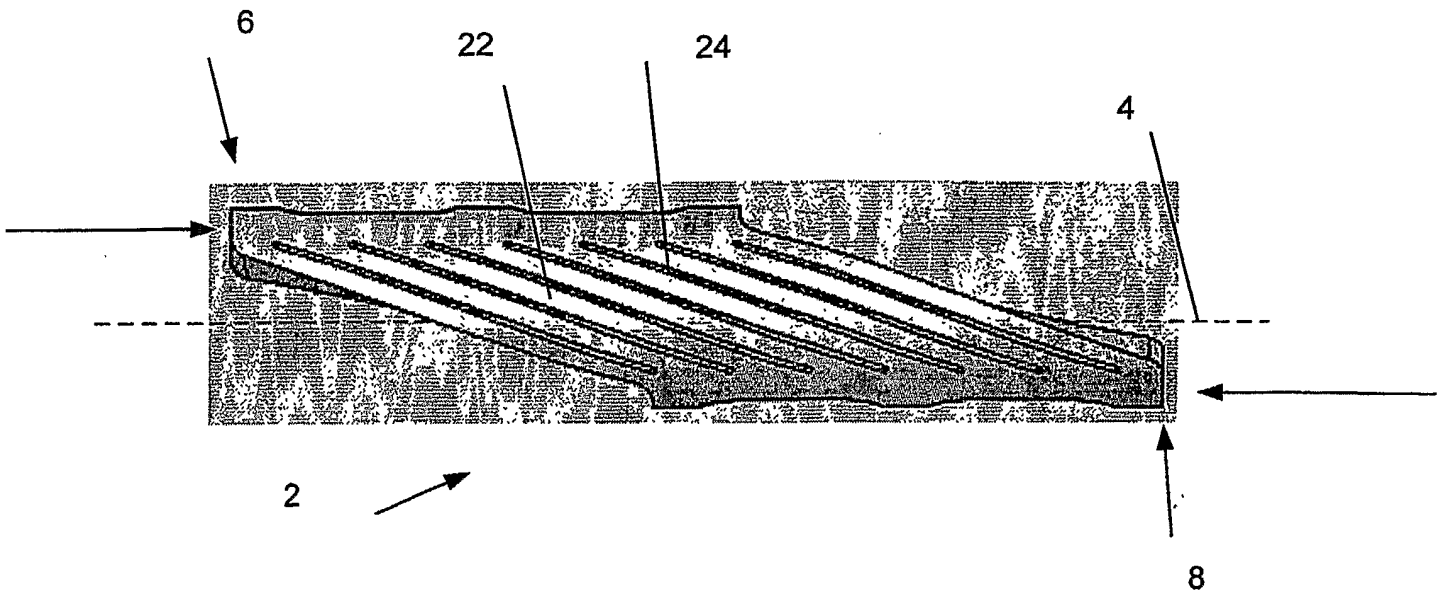


Fig. 32

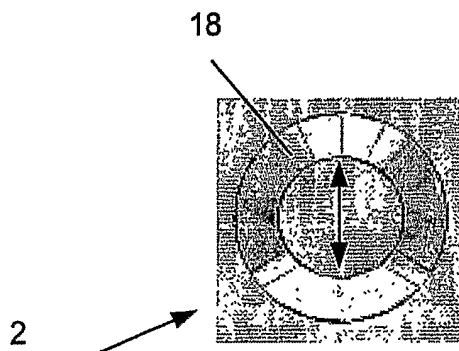
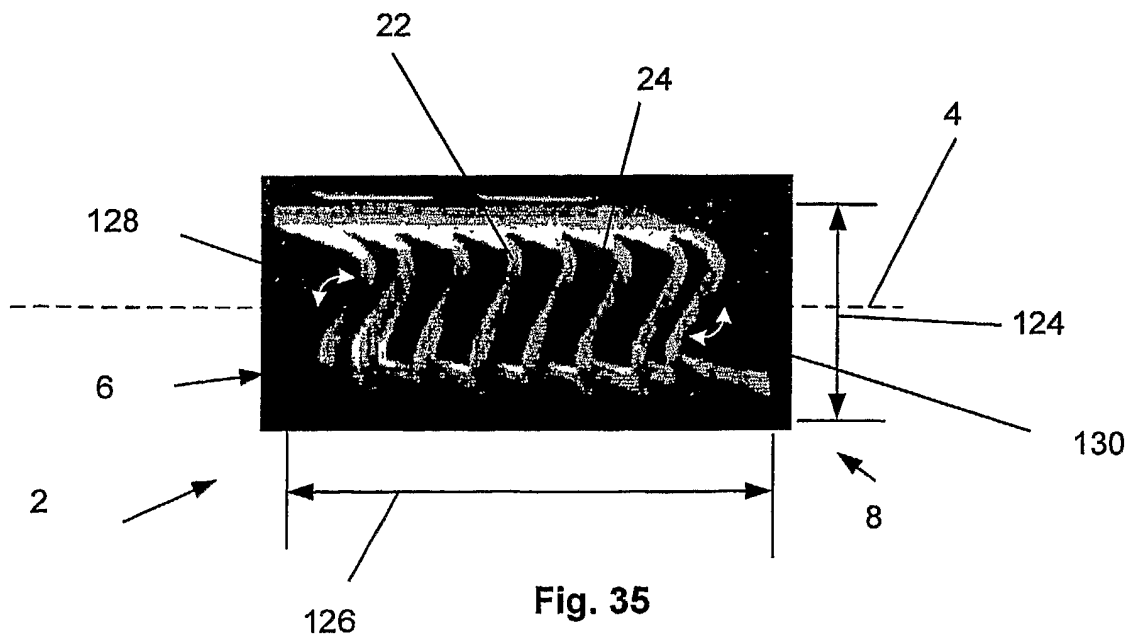
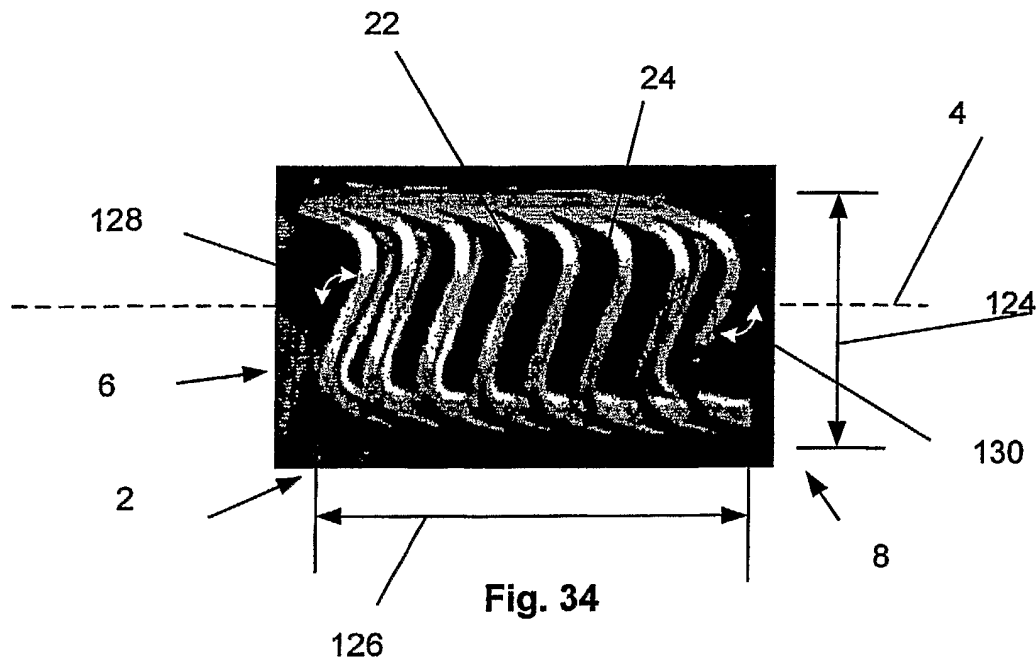


Fig. 33



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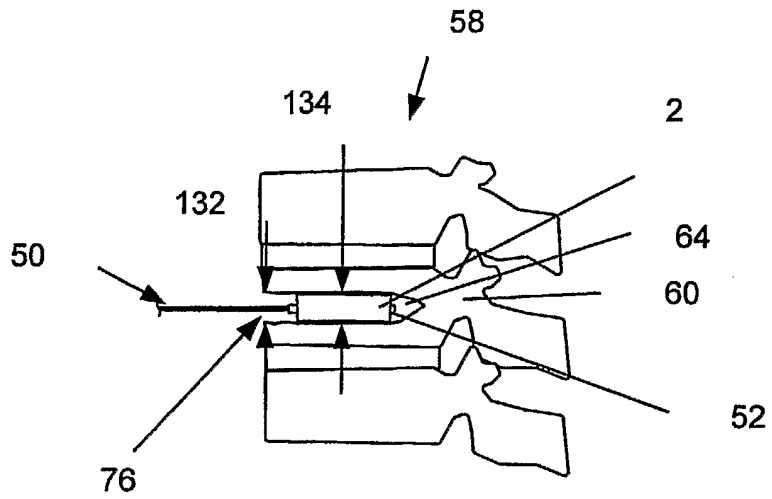


Fig. 36

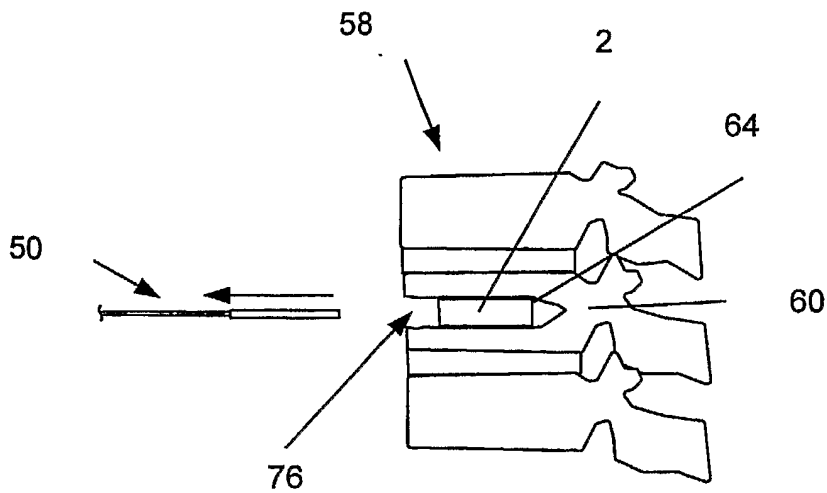


Fig. 37

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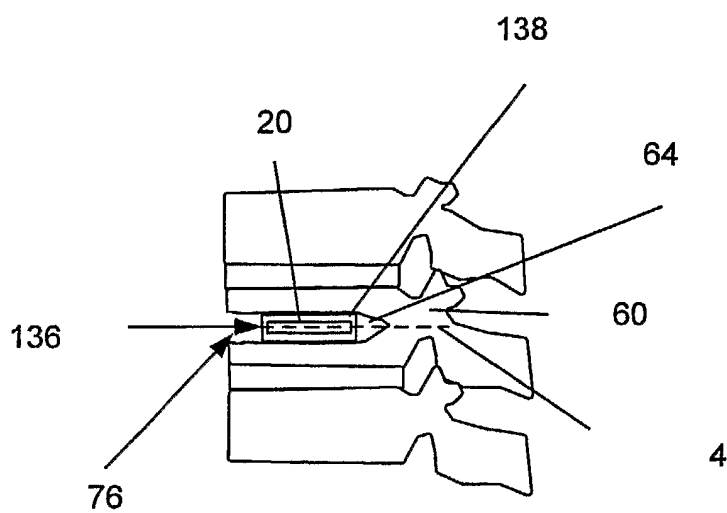


Fig. 38

18/22

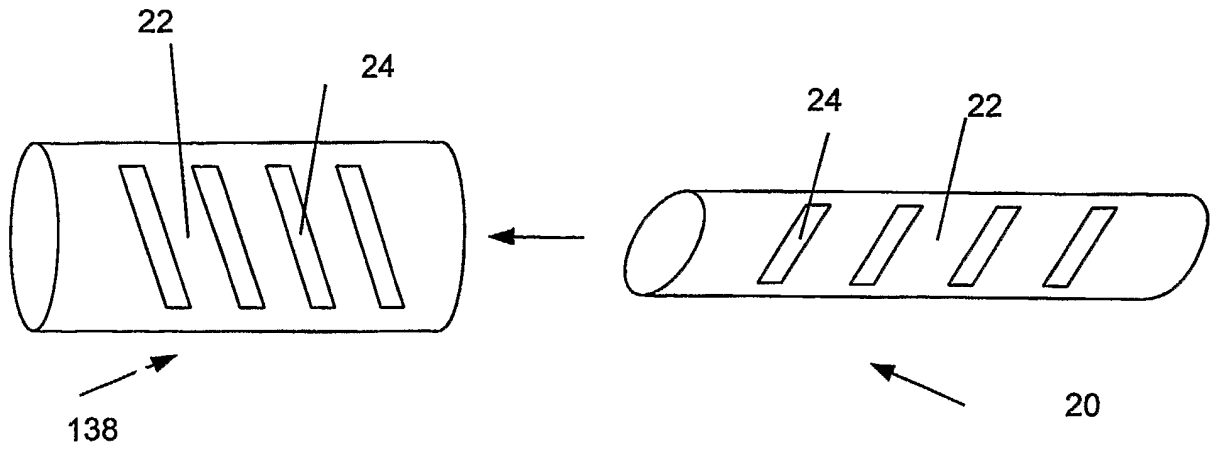


Fig. 39

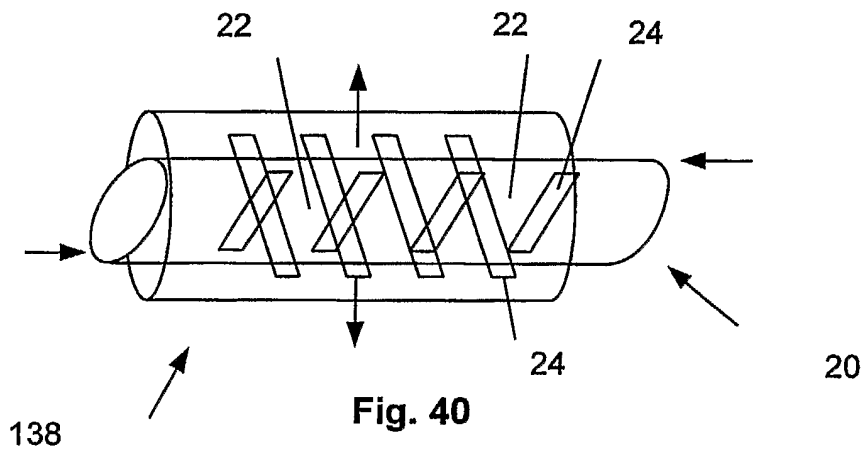


Fig. 40

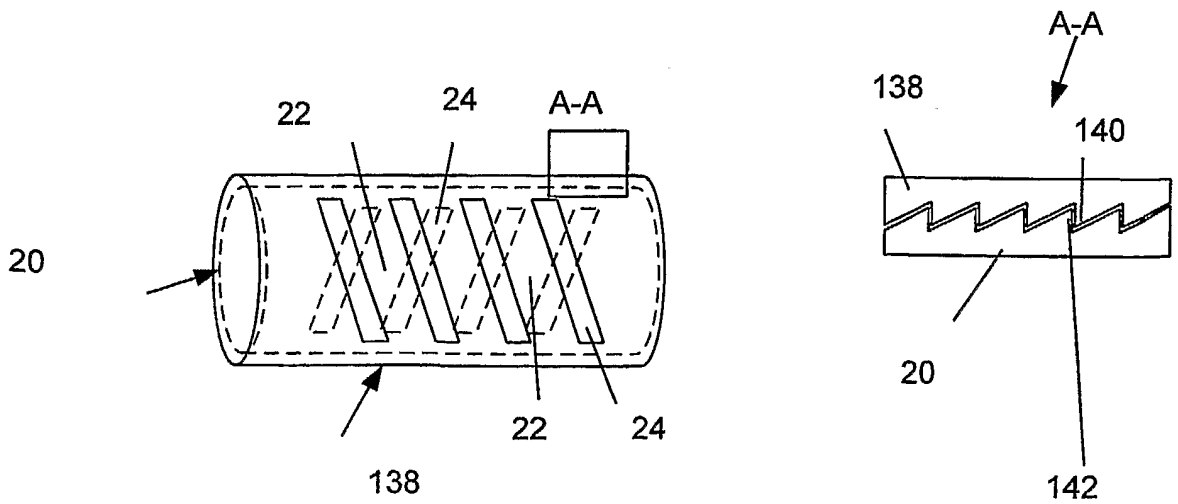


Fig. 41
SUBSTITUTE SHEET (RULE 26) Fig. 42

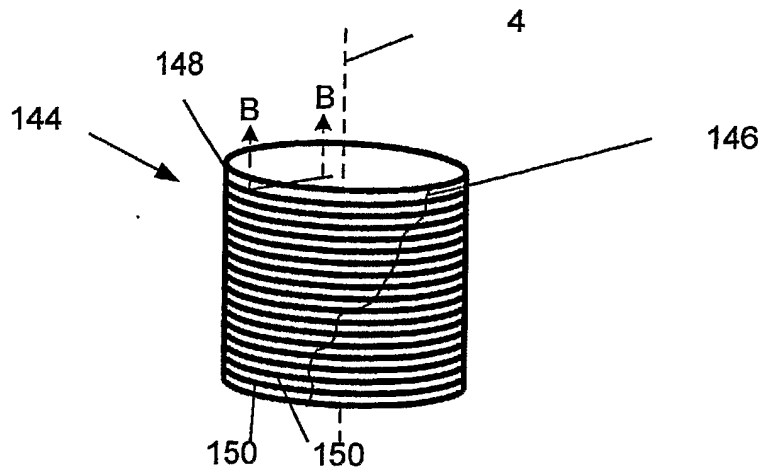


Fig. 43

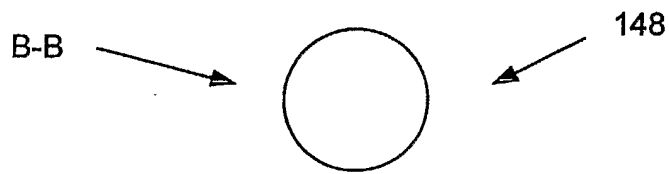


Fig. 44

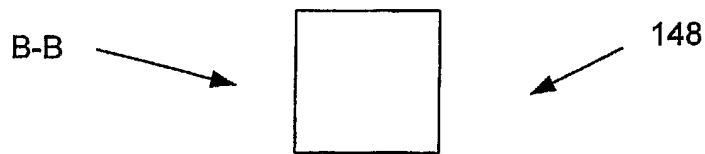


Fig. 45



Fig. 46

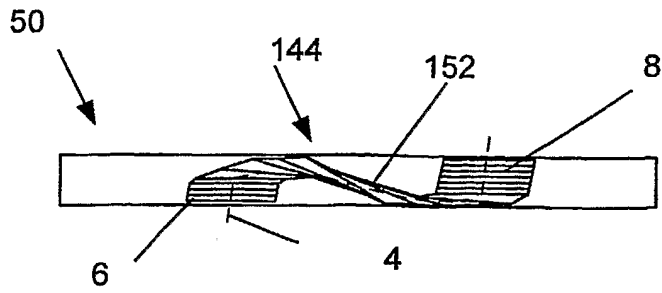


Fig. 47

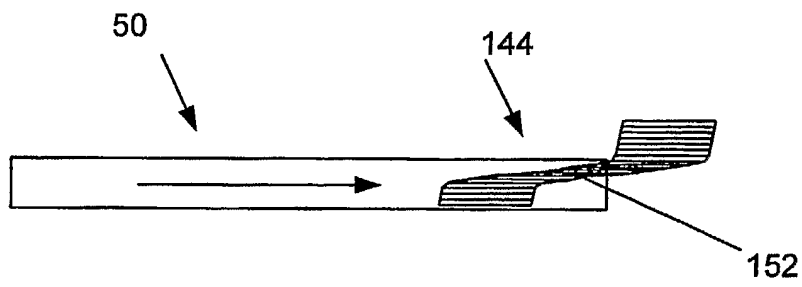


Fig. 48

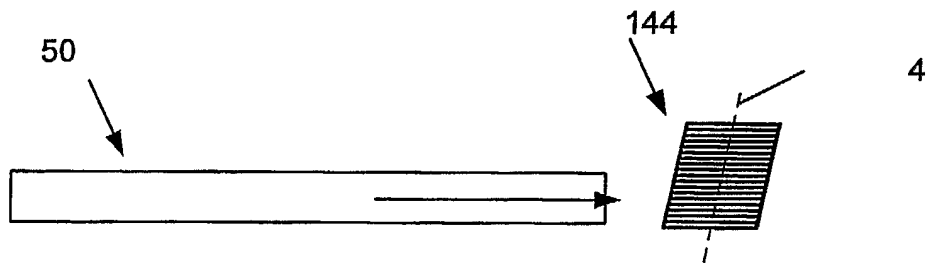


Fig. 49

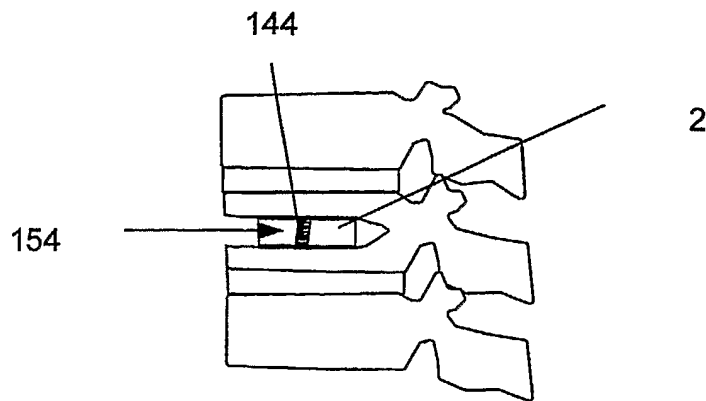


Fig. 50

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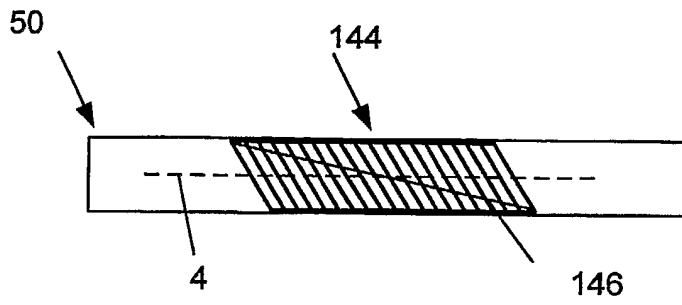


Fig. 51

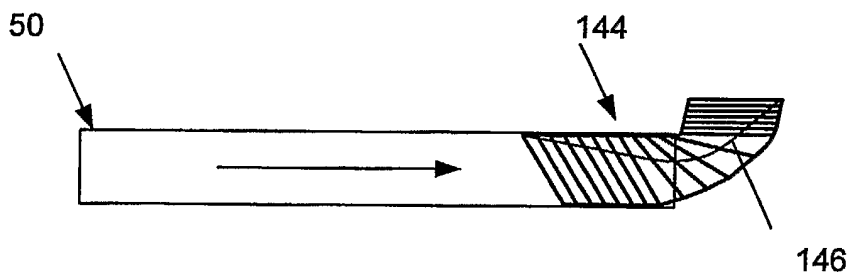


Fig. 52

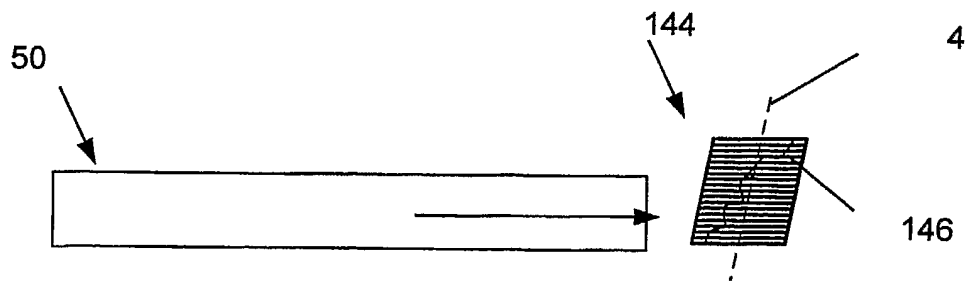


Fig. 53

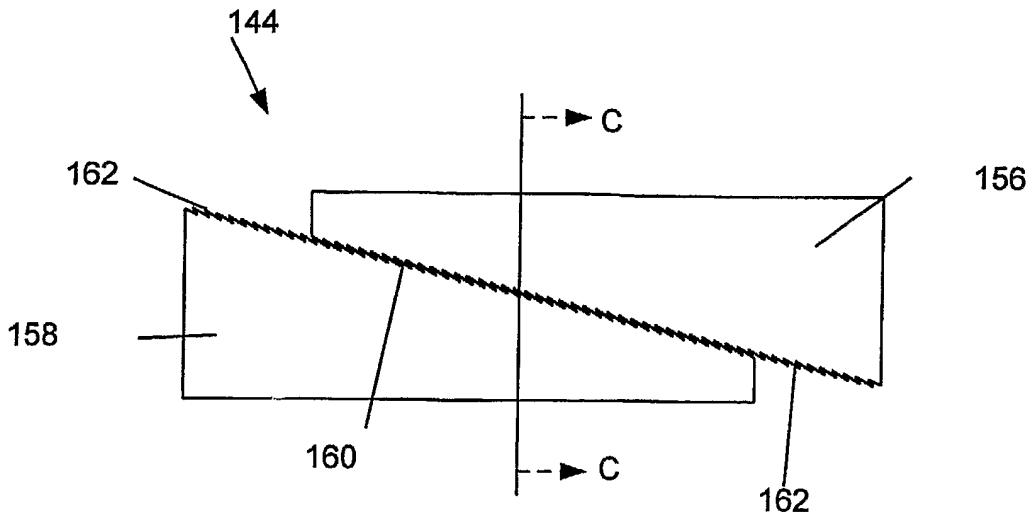


Fig. 54

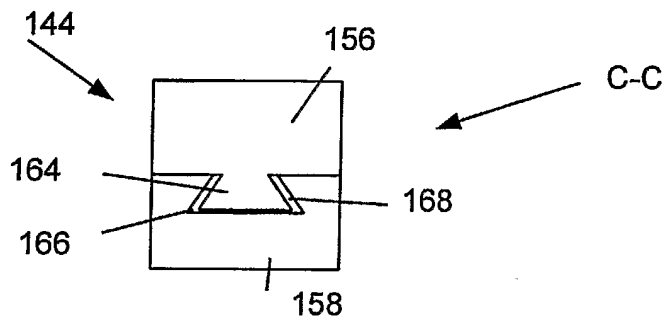


Fig. 55

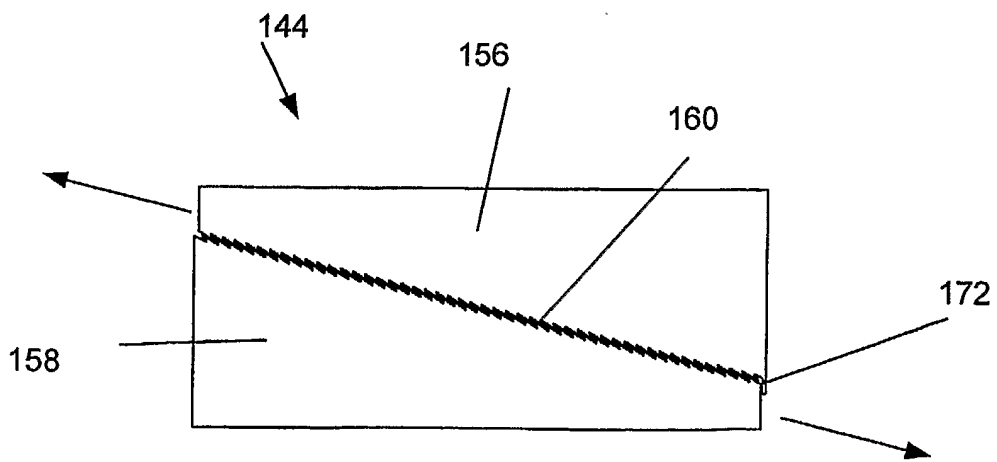


Fig. 56