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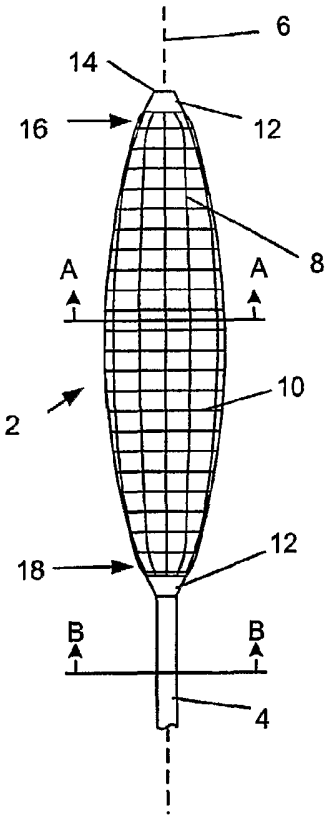
(54) Title: BALLOON AND METHODS OF MAKING AND USING



(57) Abstract: A surgical balloon is disclosed. The balloon can be woven, knitted or braided. The balloon can withstand extreme pressures relative to other surgical balloons. The balloon can have various geometries, including non-standard shapes. The balloon can be used to expand a support device. The balloon can be used to in an intrabone or interbone space to support bone. Methods of making and using the balloon are also disclosed.

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TITLE OF THE INVENTION

BALLOON AND METHODS OF MAKING AND USING

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BACKGROUND OF THE INVENTION

[0001] This invention relates to a high-strength balloon, and methods of making and using the same.

[0002] Expansion of generally cylindrical deformable stents is often carried out by inflation of a separate balloon located inside the stent during deployment. However, these balloons are made for angioplasty and deployment of relatively weak vascular stents.

[0003] For deployment of stronger orthopedic stents, typical deployment techniques include using mechanical leverage. Deployment balloons may require as much as 150 atm of pressure, far more than a sustainable pressure in a typical balloon used for vascular stent deployment or angioplasty. Not only must the walls of the balloon be made to withstand the extreme pressures, but the seams (e.g., often the ends) must be able to as well. Reinforced walls and seams are not present in typical angioplasty or vascular stent deployment balloons.

[0004] Further, mechanical deployment techniques for orthopedic strength stents limit the geometry of the stents that can be deployed through a minimally invasive procedure. Balloon deployment has not been an option for deployment of high-strength stents with non-standard geometries, not just because of the aforementioned strength requirements,

but also to achieve near such strengths, no such balloon would be sustainable with an alternate geometry to match the geometry of the stent.

[0005] Therefore, an invasive high strength balloon for use in deployment of high strength stents is desired. Further, an invasive high strength balloon that can expand into a non-standard geometry is desired.

BRIEF SUMMARY OF THE INVENTION

[0006] An expansion device for use in surgical procedures is disclosed. The expansion device has a balloon with an end. The balloon has yarns and fill. The yarns can be braided. The yarns can be knitted. The yarns can be woven. The fill can have a polymer. The balloon can have a balloon connector. The balloon connector can pressure seal the end of the balloon. The balloon can have a curvature (i.e., a curved configuration having a substantially non-zero radius of curvature). The balloon can have a fabric band. The balloon can have an internal tension member. The balloon can have a cleat. The balloon can be in fluid communication with a catheter.

[0007] Also disclosed is a method for providing expansion forces at a target site during surgery. The method includes deploying a balloon having an inside, and made with yarns and fill. The method also includes inflating the balloon. The method can include target sites that are in intrabone and/or interbone spaces. The method can include deploying a prosthesis to the target site. The method can also include inflating the balloon by applying at least about 5,000 kPa and/or 10,000 kPa, and/or 14,000 kPa, and/or 15,000 kPa of fluid pressure to the inside of the balloon.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] Figure 1 is a side view of an embodiment of the balloon attached to a catheter.

[0009] Figure 2 is a front view of the embodiment of the balloon of Figure 1.

[0010] Figure 3 is a side view of an embodiment of the balloon attached to a catheter.

[0011] Figure 4 illustrates an embodiment of section A-A of Figure 1.

[0012] Figure 5 illustrates an embodiment of section B-B of Figure 1.

[0013] Figure 6 illustrates an embodiment of section A-A of Figure 1.

[0014] Figure 7 illustrates an embodiment of section B-B of Figure 1.

[0015] Figure 8 illustrates an embodiment of section A-A of Figure 1.

[0016] Figures 9 through 11 are side views of various embodiments of the balloon attached to a catheter.

[0017] Figure 12 is a side view of an embodiment of the of the balloon attached to a catheter.

[0018] Figure 13 is a top view of the balloon and catheter of Figure 12.

[0019] Figures 14 through 16 are sectional views of various embodiments of the balloon connector and the balloon.

[0020] Figures 17 through 19 illustrate an embodiment of a method for using the balloon.

[0021] Figure 20 illustrates various embodiments of methods for using the balloon.

[0022] Figures 21 through 23 illustrate an embodiment of a method for using the balloon.

DETAILED DESCRIPTION

[0023] Figures 1 and 2 illustrates a hydraulic inflation device, such as a balloon 2 attached in fluid communication to a catheter 4, that can be used for invasive and non-invasive surgical procedures. The balloon 2 can be made from yarns. The yarns can be, for example, braided, knitted or woven (as shown). Using commonly known textile engineering principles, the fabric density, thickness, stiffness and elongation of the balloon 2 can be altered by one having an ordinary skill in the art. The yarns can be

impregnated, coated, dipped, or otherwise mixed with polymers, for example, to minimize fluid leakage through the balloon 2. For example, the material of the balloon 2 can be made as taught by U.S. Patent Application 09/974,220 filed on 9 October 2001, and included herein in its entirety. The balloon 2 can have a longitudinal axis 6.

[0024] The balloon 2 can have longitudinal, axial or warp yarns 8. The warp yarns 8 can be substantially parallel with the longitudinal axis 6. The balloon 2 can have latitudinal, transverse or weft yarns 10. The weft yarns 10 can be substantially perpendicular to the warp yarns 8.

[0025] The balloon 2 can be attached to the catheter 4 at balloon connectors 12. One or more balloon connectors 12 can attach the balloon 2 to the catheter 4 at a terminal end 14. The balloon 2 can have a fluid-tight seal against the balloon connectors 12. The balloon connectors 12 can provide a seal against the balloon 2 and not attach the balloon 2 to the catheter 4. The balloon 2 adjacent to the balloon connectors 12 can be configured in distal and proximal tapers 16 and 18. The distal taper 16 can be a different configuration that the proximal taper 18. The tapers 16 and 18 can be any configuration shown by the ends or cones disclosed by "Application of High-Pressure Balloons in the Medical Device Industry", Saab, M., Advanced Polymers, Inc. 1999 <http://www.advpoly.com/NewsData/BalloonPaper.pdf>, which is herein incorporated in its entirety.

[0026] Figure 3 illustrates that the balloon 2 can have a asymmetrical radius of curvature 20. The balloon 2 can have a curvature inside 22 and a curvature outside 24. The warp yarns 8, such as first warp yarn 8a, closer to the curvature outside 24 can have longer lengths than the warp yarns 8, such as second warp yarn 8b, closer to the curvature inside 22.

[0027] The radius of curvature 20 can be measured at the longitudinal axis 6. The radius of curvature 20 can be from about 1 mm (0.04 in.) to about 250 mm (10 in.), for example about 50 mm (2 in.).

[0028] Figure 4 illustrates that the balloon 2 can have warp yarns 8 and a fill 26. The combined warp yarns 8 and fill 26 can be substantially or completely leak-proof. Any yarns disclosed herein can be made from polyethylene teraphathalate (PET)/polyester (e.g., DACRON® from E. I. Du Pont de Nemours and Company, Wilmington, DE), nylon, liquid crystal polymer fibers such as VECTRAN® from Celanese Acetate, LLC, Kronberg/Taunus, Germany, KEVLAR® from E. I. Du Pont de Nemours and Company, Wilmington, DE, Spectra, metal filaments, such as steel, nickel titanium alloys (e.g., Nitinol), nickel-cobalt alloys (e.g., MP35N® from Magellan Industrial Trading Company, Inc., Westport, CT), or combinations thereof. Some or all yarns can be woven, braided or knitted into the balloon 2 under tension.

[0029] The fill 26 can be made from one or more polymers, such as an elastic polymer, for example LYCRA®, from E. I. Du Pont de Nemours and Company, Wilmington, DE, latex, polyurethane (PU), silicone, and polyether-block co-polyamide polymers (e.g., PEBAX® from ATOFINA, Paris, France); or non-oriented polymers, for example shrink tubing, or partially-oriented polymers like polyesters, or combinations thereof. The catheter 4 can have a fluid port 28 where the catheter 4 is in the balloon 2.

[0030] For example, the balloon 2 can be made by dipping woven VECTRAN® yarns into silicon resin and cured. The balloons 2 can be coated on the internal surface of the balloon 2, for example with a coating of silicone.

[0031] Figure 5 illustrates that the catheter 4 can have a hollow fluid channel 30. The fluid channel 30 can be in fluid communication with the balloon 2.

[0032] Figure 6 illustrates that the balloon can have one, two, three, four, or more steering wires 32. The steering wires 32 can slidably pass through hollow steering channels 34 in the balloon 2. The steering channels 34 can be fixedly attached to the catheter 4 and/or the balloon connector 12 at the terminal end 14.

[0033] The steering channels 34 can be attached to the inside or outside of the balloon 2. The steering channels 34 can be integrated with the balloon 2. For example the steering channels 34 can be braided, knitted, or woven (as shown) into the balloon 2.

[0034] Figure 7 illustrates that the steering wires 32 can slidably pass though the hollow steering channels 34 in or on the catheter 4. The steering wires 32 can terminate at a proximal end (not shown) of the catheter 4 in a steering control tool (not shown). The steering control tool can control the tensions in the individual steering wires 32, for example, causing a change in the balloon geometry and the direction of the terminal end 14. The steering wires 32 can be used to manipulate the balloon 2 and/or the catheter 4 through tortuous passages, for example, blood vessels or around nerves and into a location on the anterior spine (e.g., in a vertebra or intervertebral disc).

[0035] Figure 8 illustrates that the balloon can have a sheath 36 and a bladder 38. The bladder 38 can be substantially or completely leak-proof. The bladder 38 can be slidably in contact with the sheath 36. The bladder 38 can be fixedly attached (e.g., welded, stitched, stapled, pinch clipped, snapped) to the sheath 36. The sheath 36 can be made from yarns. The bladder 38 can be made from one or more polymers, such as an elastic polymer, for example LYCRA®, by from E. I. Du Pont de Nemours and Company, Wilmington, DE, latex, polyurethane (PU), silicone, and polyether-block co-polyamide polymers (e.g., PEBAX® from ATOFINA, Paris, France); or non-oriented polymers, for example shrink tubing, or partially-oriented polymers like polyesters, or combinations thereof. The sheath 36 can be configured to fit the shape of the bladder 38.

[0036] Figure 9 illustrates a "dog bone" configuration of the balloon 2. The balloon 2 can have a varying radius from the longitudinal axis 6 with respect to the length along the longitudinal axis 6. The length of the weft yarns 10 at a first length along the longitudinal axis 6, for example first weft yarn 10a, can be longer than the length of the weft yarns 10 at a second length along the longitudinal axis 6, for example second weft yarn 10b.

[0037] Figure 10 illustrates that the balloon 2 can have a band 40. The band 40 can be, for example, fabric and/or polymer. The band 40 can be soft and/or flexible, semi-rigid, or rigid. The band 40 can be attached by being resiliently pressed into or onto the balloon 2. The band 40 can be fixedly attached and/or integrated with the balloon 2. The band 40 can be placed at a narrowing in the balloon 2. The band 40 can be fixedly attached to the catheter 4, for example the catheter 4 in the balloon 2. The band 40 can be configured to restrict expansion of part or all of the balloon 2 during non-use, and/or, deflation, and/or inflation of the balloon 2.

[0038] Figure 11 illustrates a tapered configuration of the balloon 2. The balloon 2 can be in a conical, square, spherical, conical/square, conical square long, conical/spherical, long spherical, tapered, "dog bone", stepped, or combinations thereof configuration, as disclosed by "Application of High-Pressure Balloons in the Medical Device Industry", Saab, M., Advanced Polymers, Inc. 1999 <http://www.advpoly.com/NewsData/BalloonPaper.pdf>, previously incorporated by reference in its entirety.

[0039] Figures 12 and 13 illustrate that the balloon 2 can have an internal tension member 42. The internal tension member 42 can not expand when the balloon inflates, or can minimally expand when the balloon 2 inflates, or can expand less substantially less than if the balloon 2 did not have the internal tension member 42. The internal tension member 42 can be configured to increase the rigidity of the balloon 2.

[0040] The internal tension member 42 can be an area where opposite sides of the balloon 2 are sewn to each other. The internal tension member 42 can be an area where opposite sides of the balloon 2 are sewn to each other around the catheter 4. The internal tension member 42 can be an area where opposite sides of the balloon 2 are sewn to the catheter 4. The internal tension member 42 can be an area where opposite sides of the balloon 2 are sewn to an resilient or rigid element, for example made from metal and/or polymer. The balloon 2 can be substantially shorter and wider than other configurations of the balloon 2 shown herein.

[0041] Figure 14 illustrates that the balloon connector 12 can compress the balloon 2 between in one or more compression zones 44. The compression zone 44 can provide sufficient pressure to maintain attachment to, and a seal with, the balloon 2, for example, when the balloon 2 has an internal pressure less than or equal to about 15,000 kPa (150 atm), more narrowly less than or equal to about 14,000 kPa (140 atm), yet more narrowly less than or equal to about 10,000 kPa (100 atm), yet even more narrowly less than or equal to about 5,000 kPa (50 atm).

[0042] The balloon connector 12 can have an outer compression element 46 and/or an inner compression element 48. A compression element connector 50 can fixedly attach the inner compression element 48 to the outer compression element 46. The compression element connector 50 can increase and/or decrease tension between the inner compression element 48 and the outer compression element 46. The compression element connector 50 can be, for example, a screw or bolt and a threaded receptacle. The balloon 2 can be fixedly attached between the inner compression element 48 and the outer compression element 46.

[0043] The inner compression element 48 can be inside of the balloon 2. The inner compression element 48 can be free of significantly sharp edges exposed near the balloon

2, or exposed anywhere, during use. The inner compression element 48 can be configured to be substantially conical. The inner compression element 48 can be configured to be substantially oval or ovaloid, spherical or spheroid, toroid or combinations thereof.

[0044] The outer compression element 46 can be outside the balloon 2. The outer compression element 46 can be, for example, a rivet or plug.

[0045] Figure 15 illustrates that the inner compression element 48 can be outside of the balloon 2. The outer compression element 46 can be inside the balloon 2.

[0046] Figure 16 illustrates that the balloon connector 12 can have a controlled expansion section 52. The controlled expansion section 52 can be resilient. The controlled expansion section 52 can be configured to spread stress over a neck 54 of the balloon during expansion of the balloon 2, for example, thereby reducing pressure on the portion of the balloon 2 in the balloon connector 12. The controlled expansion section 52 can expand when the balloon 2 inflates. For example, the expansion of the controlled expansion section 52 can be caused by the pressure from the neck 54 of the balloon 2. The inner compression element 48 can be substantially conical.

[0047] Any or all elements of the balloon 2, catheter 4, band 40, internal tension member 42, and/or other devices or apparatuses described herein 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, (PET), polytetrafluoroethylene (PTFE), expanded PTFE (ePTFE), polyether ether ketone (PEEK), nylon, polyether-block co-polyamide polymers (e.g., PEBAX® from ATOFINA, Paris, France), aliphatic polyether polyurethanes (e.g., TECOFLEX® from Thermedics Polymer Products, Wilmington, MA), polyvinyl chloride (PVC), polyurethane, thermoplastic, fluorinated ethylene propylene (FEP), absorbable or resorbable polymers such as polyglycolic acid (PGA), polylactic acid (PLA), polycaprolactone (PCL), polyethyl acrylate (PEA), polydioxanone (PDS), and pseudo-polyamino tyrosine-based acids, extruded collagen, silicone, zinc, echogenic, radioactive, radiopaque materials, a biomaterial (e.g., cadaver tissue, collagen, allograft, autograft, xenograft, bone cement, morselized bone, osteogenic powder, beads of bone) any of the other materials listed herein or combinations thereof. Examples of radiopaque materials are barium sulfate, zinc oxide, titanium, stainless steel, nickel-titanium alloys, tantalum and gold.

[0048] Any or all elements of the balloon 2, catheter 4, band 40, internal tension member 42, and/or other devices or apparatuses described herein, can be or have 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.

[0049] The elements of the balloon 2, catheter 4, band 40, internal tension member 42, and/or other devices or apparatuses described herein and/or the fabric can be filled and/or coated with an agent delivery matrix known to one having ordinary skill in the art and/or a therapeutic and/or diagnostic agent. The agents within these matrices can include

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

[0050] The balloon 2 can be used as a support and/or to separate bones, within, outside or between bones. Figure 17 illustrates that the balloon 2 can be used on a series of bones such as the vertebral column (i.e., the spine) that can have vertebrae 56, and intervertebral discs 58. The balloon 2 can be loaded on a catheter 4. The balloon 2 can be translated, as shown by arrow, to a target site. The target site for the balloon 2 can be interbone or intrabone space, such as those disclosed in U.S. Provisional Patent Application titled "EXPANDABLE SUPPORT DEVICE AND METHOD OF USE", filed 21 September 2004, U.S. Patent Application No. 60/612,001, which is herein incorporated by reference in its entirety.

[0051] Figure 18 illustrates that the balloon 2 can be inserted into a target site, such as an interbone, or intervertebral space. Figure 19 illustrates that the balloon 2 can inflate once at a target site, such as intervertebral space. The balloon 2 can expand, as shown by arrows, for example due to increased internal fluid pressure. The increased internal fluid pressure can be delivered by the catheter 4. The balloon 2 can apply expansion forces to the surrounding bones, such as the vertebrae 56. The balloon 2 can be deployed between ribs to create sufficient access to the thorax, for example to gain access to the thorax, such as the heart, for surgical procedures.

[0052] Figure 20 illustrates that a first catheter 4 can enter through the subject's back. The first catheter 4 can enter through a first incision 60a in skin 62 on the posterior side of the subject near the vertebral column 64. The first catheter 4a can be translated, as shown by arrow 66, to position a first balloon 2a adjacent or into the disc 58 (as shown) or vertebra 56.

[0053] A second catheter 4b can enter through a second incision 60b (as shown) in the skin 62 on the posterior or through the first incision 60a. The second catheter 4b can be translated through muscle (not shown), around nerves 67, and anterior of the vertebral

column 46. The second catheter 4b can be steerable. The second catheter 4b can be steered, as shown by arrow 68, to align the distal tip of a second balloon 2b with the anterior side of the disc 58 or vertebra 56. The second catheter 4b can translate, as shown by arrow 70, to position the second balloon 2 in the disc 58 or vertebra 56.

[0054] The disc 58 or vertebra 56 can have multiple balloons 2 deployed therein. The balloons 2 can be deployed from the anterior, posterior, both lateral, superior, inferior, any angle, or combinations of the directions thereof. Multiple balloons 2 can be deployed sequentially and/or simultaneously.

[0055] Figure 21 illustrates that the balloon 2 can be attached to one or more cleats 72. The cleats 72 can extend from the balloon 2. The cleats 72 can have a surface (e.g., having hooks, barbs, feet) configured to maximize the ability to grip or grab other surfaces. The balloon 2 can be translated, as shown by arrow, to a target site.

[0056] Figure 22 illustrates that the balloon 2 can be positioned so that the cleats 72 can grip or grab one or more surfaces, such as the surfaces of adjacent vertebrae 56. Figure 23 illustrates that the balloon 2 can be inflated once the cleats 72 are positioned at a target site, such as in contact with, or adjacent to, the vertebrae 56. The balloon 2 can expand due to increased internal fluid pressure. The cleats 72 can apply expansion forces, as shown by arrows, to the surrounding bones, such as the vertebrae 56. The balloon 2 can be deployed between ribs to create sufficient access to the thorax, for example to gain access to the thorax, such as the heart, for surgical procedures.

[0057] The balloon 2 can be used to deploy stents, scaffolds, expandable support devices, such as those disclosed in U.S. Provisional Patent Application titled "EXPANDABLE SUPPORT DEVICE AND METHOD OF USE", filed 21 September 2004, U.S. Patent Application No. 60/612,001, which is incorporated by reference supra, or combinations thereof. The balloon 2 can be used to expand devices or anatomical tissues or elements

such as compression bone (e.g., vertebral) fractures, soft tissue failures (e.g., herniated intervertebral discs) and methods of deploying disclosed in U.S. Provisional Patent Application titled "EXPANDABLE SUPPORT DEVICE AND METHOD OF USE", filed 21 September 2004, U.S. Patent Application No. 60/612,001.

[0058] It is apparent to one skilled in the art that various changes and modifications can be made to this disclosure, and equivalents employed, without departing from the spirit and scope of the invention. Elements shown with any embodiment are exemplary for the specific embodiment and can be used on other embodiments within this disclosure.

CLAIMS

We claim:

1. An expansion device for use in surgical procedures comprising:

a balloon having a first end,

wherein the balloon comprises yarns and fill.

2. The device of Claim 1, wherein the yarns are braided.

3. The device of Claim 1, wherein the yarns are knitted.

4. The device of Claim 1, wherein the yarns are woven.

5. The device of Claim 1, wherein the fill comprises a polymer.

6. The device of Claim 1, wherein the balloon comprises a first balloon connector.

7. The device of Claim 6, herein the first balloon connector pressure seals the first end of the balloon.

8. The device of Claim 6, wherein the pressure seal comprises a compression seal.

9. The device of Claim 6, herein the balloon comprises a second balloon connector.

10. The device of Claim 8, wherein the balloon has a second end, and wherein the second balloon connector pressure seals the second end of the balloon.

11. The device of Claim 1, wherein the balloon has a curvature.

12. The device of Claim 11, wherein a radius of the curvature is greater than or equal to about 1 mm.

13. The device of Claim 11, wherein a radius of the curvature is greater than or equal to about 50 mm.

14. The device of Claim 13, wherein the radius of the curvature is less than or equal to about 250 mm.

15. The device of Claim 1, wherein the balloon further comprises a fabric band.

16. The device of Claim 1, wherein the balloon further comprises an internal tension member.

17. The device of Claim 1, wherein the balloon further comprises a cleat.

18. The device of Claim 1, further comprising a catheter in fluid communication with the balloon.

19. A method for providing expansion forces at a target site during surgery, comprising:

deploying a balloon to the target site, and wherein the balloon has an inside, and wherein the balloon comprises yarns and fill; and

inflating the balloon.

20. The method of Claim 19, wherein the fill comprises a polymer.

21. The method of Claim 19, wherein the target site comprises an intrabone space.

22. The method of Claim 19, wherein the target site comprises an interbone space.

23. The method of Claim 19, further comprising deploying a prosthesis to the target site.

24. The method of Claim 23, wherein the prosthesis comprises an expandable support device.

25. The method of Claim 23, wherein the prosthesis comprises a stent.

26. The method of Claim 23, wherein the prosthesis comprises a scaffold.

27. The method of Claim 23, further comprising loading the prosthesis on the balloon before the inflating.

28. The method of Claim 23, further comprising expanding the prosthesis.

29. The method of Claim 19, wherein inflating comprises applying at least about 5,000 kPa of fluid pressure to the inside of the balloon.

30. The method of Claim 19, wherein inflating comprises applying at least about 10,000 kPa of fluid pressure to the inside of the balloon.

31. The method of Claim 19, wherein inflating comprises applying at least about 14,000 kPa of fluid pressure to the inside of the balloon.

32. The method of Claim 19, wherein inflating comprises applying at least about 15,000 kPa of fluid pressure to the inside of the balloon.

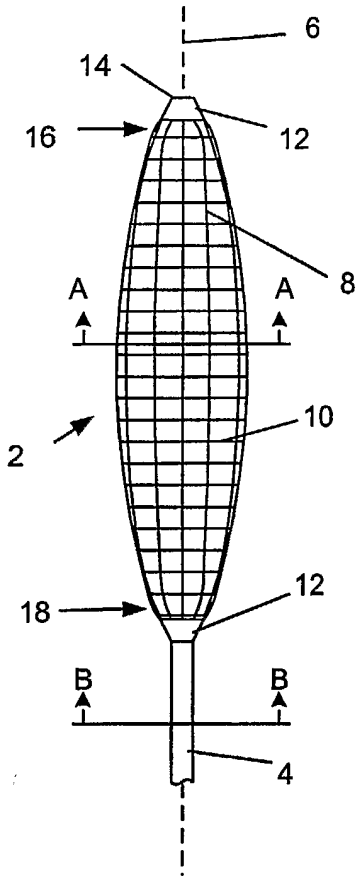


Fig. 1

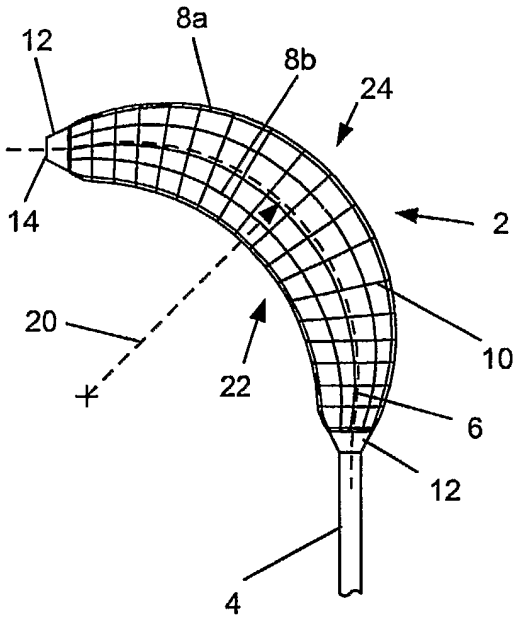


Fig. 3

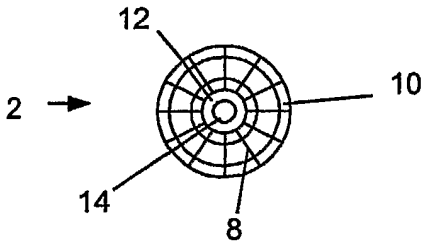


Fig. 2

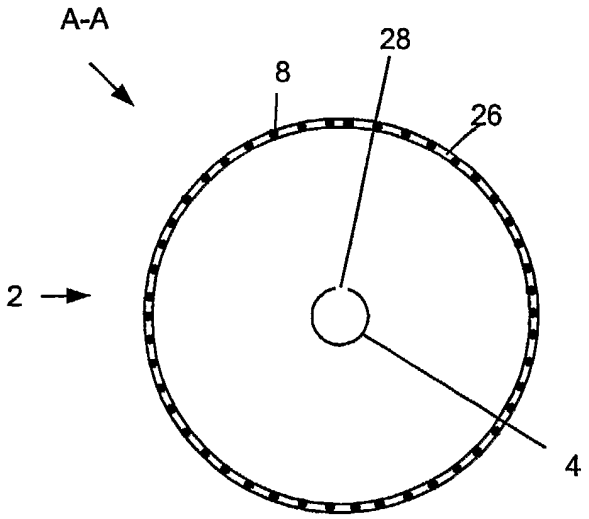


Fig. 4

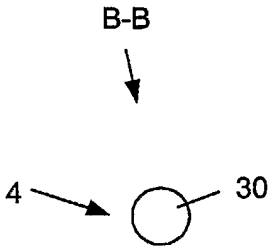
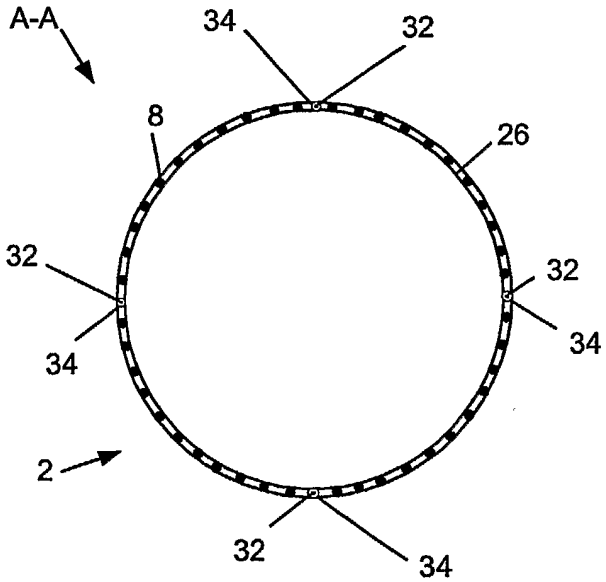


Fig. 5



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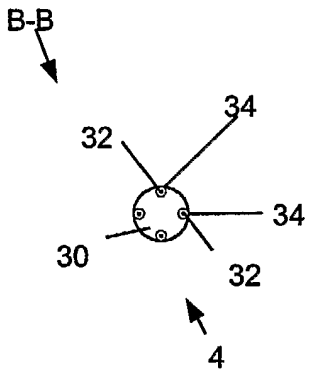

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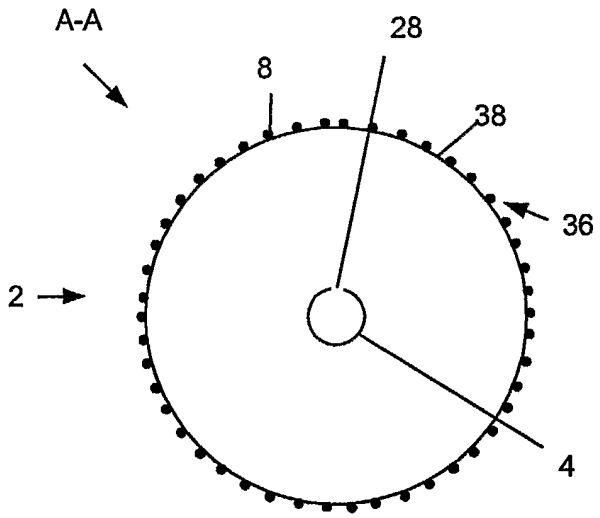


Fig. 8

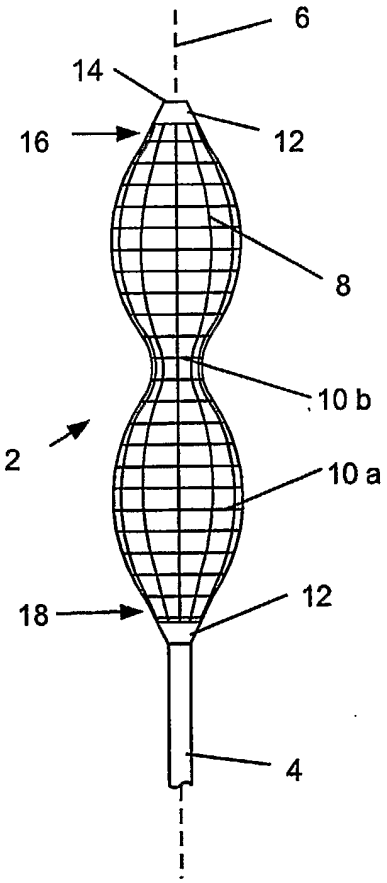


Fig. 9

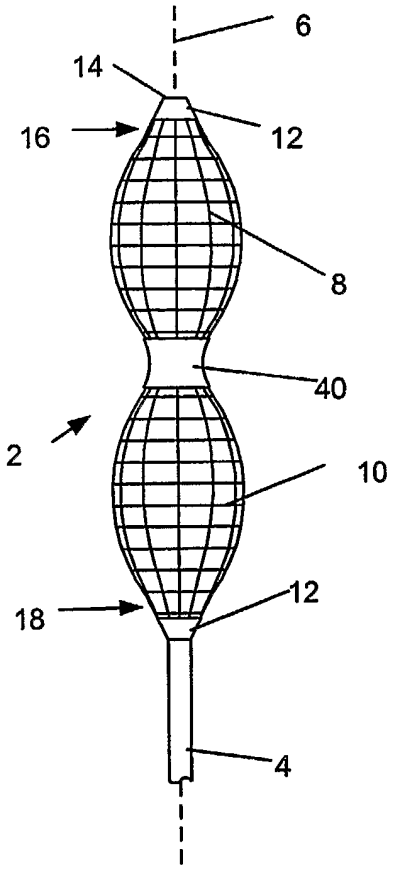


Fig. 10

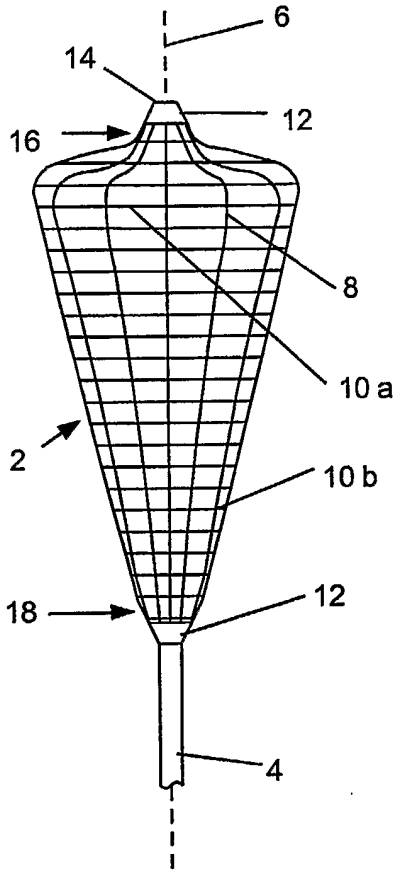


Fig. 11

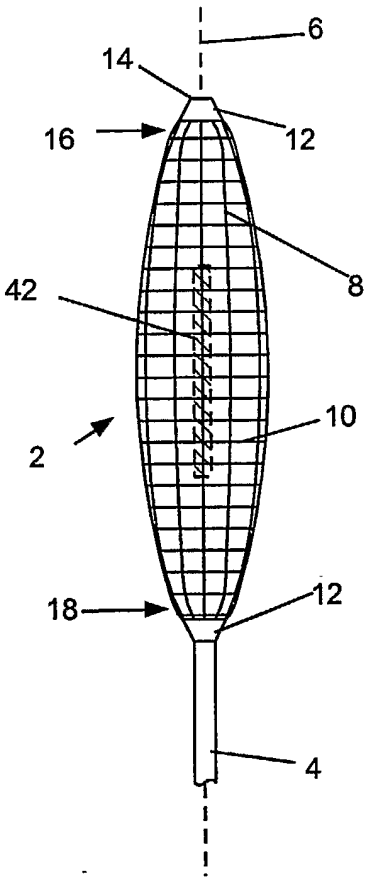


Fig. 12

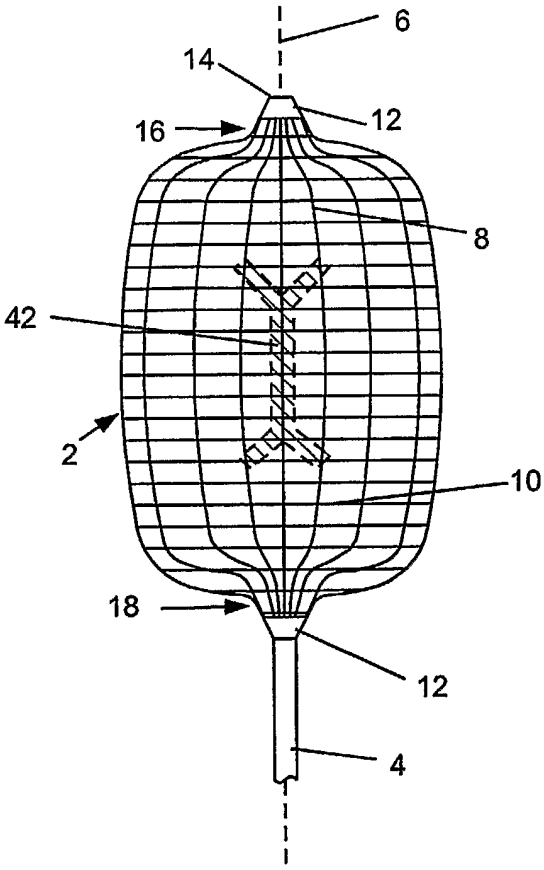


Fig. 13

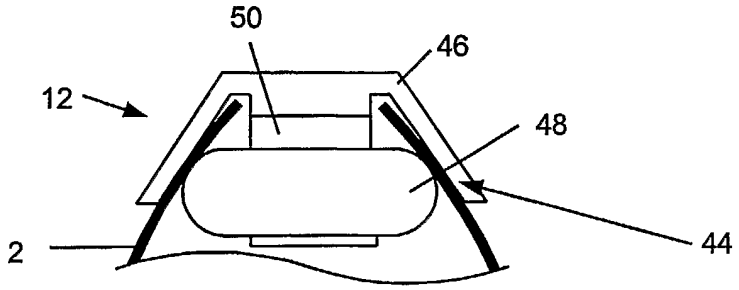


Fig. 14

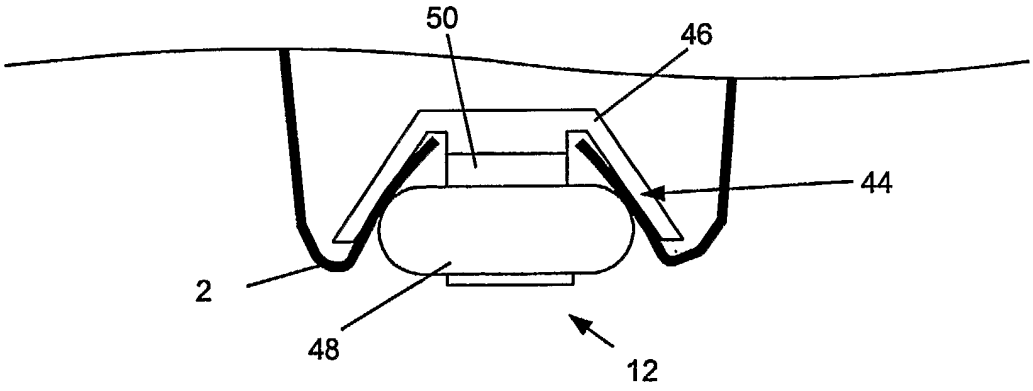
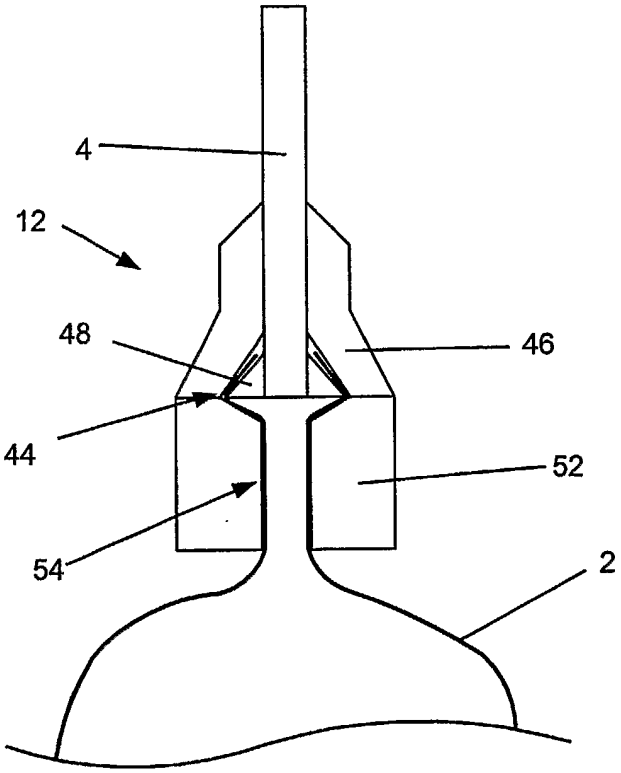


Fig. 15



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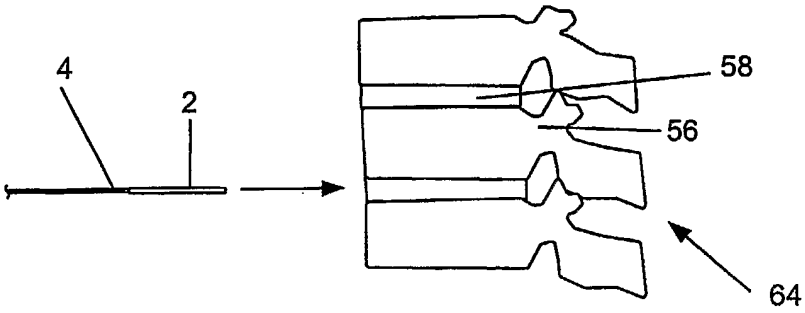

Fig. 17

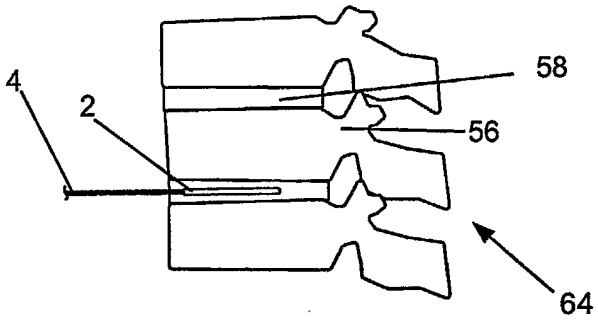

Fig. 18

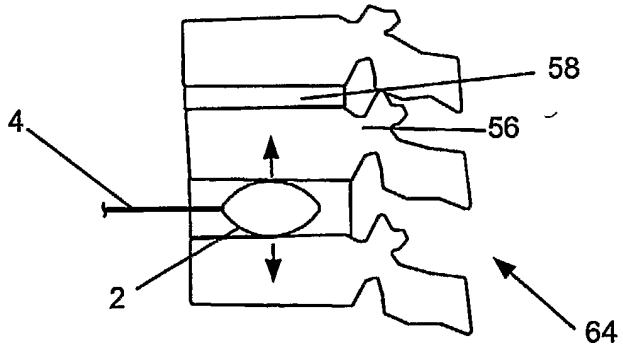

Fig. 19

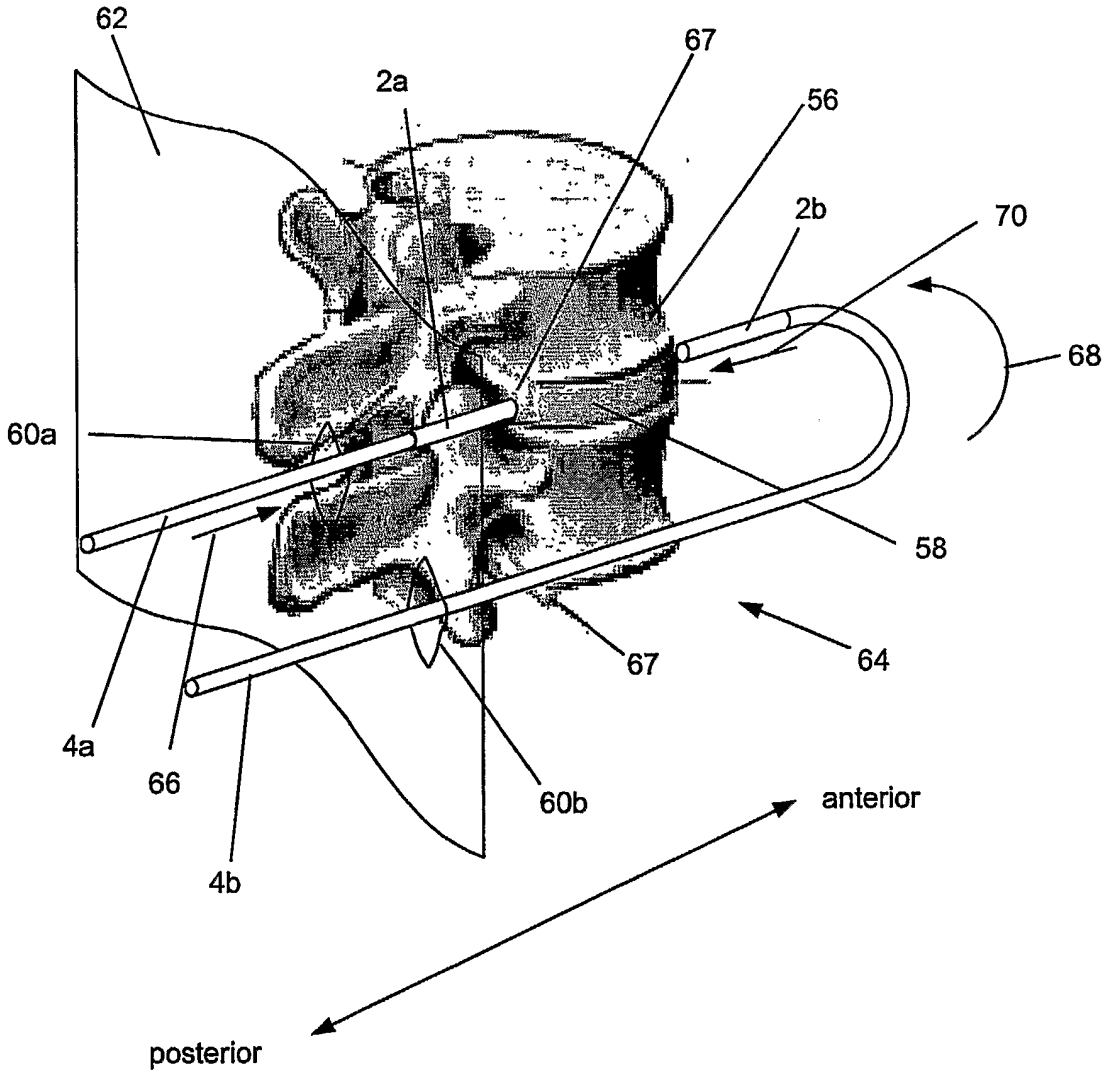

Fig. 20

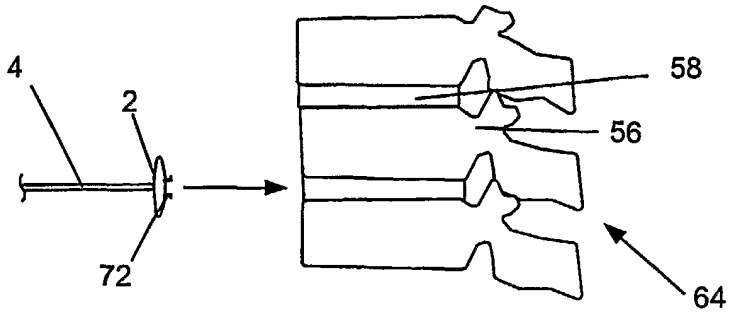

Fig. 21

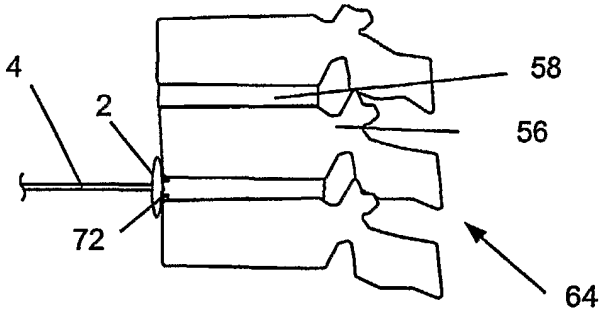

Fig. 22

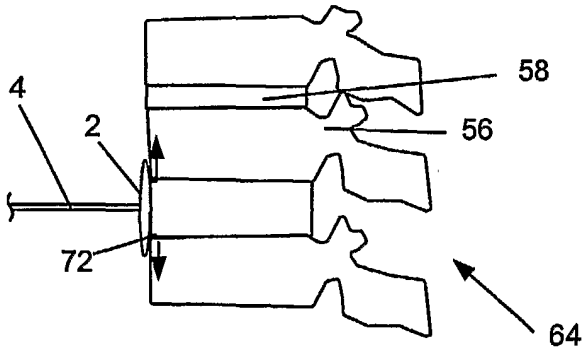

Fig. 23