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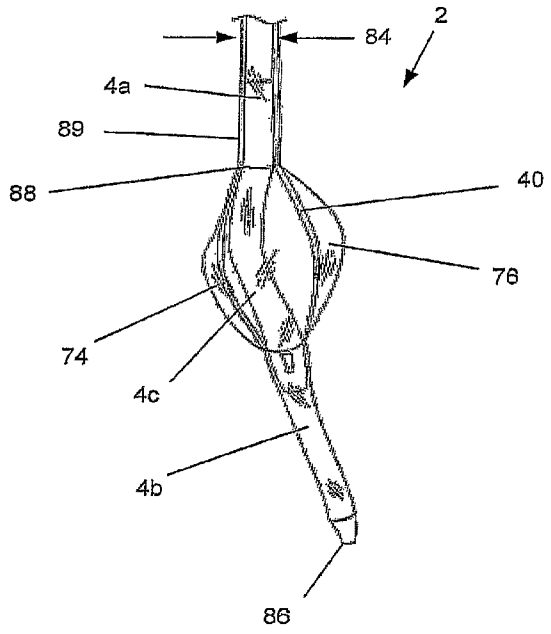

(57) Abstract: A surgical balloon is disclosed. The balloon can have or be attached to a longitudinal or transverse constraining band. The band can impair, restrain or deform radial expansion of a portion of the balloon during inflation. The balloon can be used in vascular procedures. The band can restrain a portion of the inflated balloon such that a channel exists between the restrained portion of the balloon and the vascular wall. Fluid can flow through the channel while the balloon is inflated in the vessel. The balloon can also be used to expand a support device. The balloon can be used to in an intrabone or interbone space to support bone.

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TITLE OF THE INVENTION

BALLOON AND METHODS OF MAKING AND USING

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CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Patent Application No. 60/740,792, filed 30 November 2005, which is incorporated by reference herein in its entirety.

BACKGROUND OF THE INVENTION

[0002] This invention relates to a high-strength balloon, and methods of making and using the same.

[0003] 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.

[0004] 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.

[0005] 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.

[0006] 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

[0007] An expansion device for use in surgical procedures is disclosed. The expansion device has a balloon with a constraining band. The band can attached to and/or integral with the balloon. The band can be oriented longitudinally, transverse, or at an angle to a longitudinal axis of the balloon. The balloon can have an inflated configuration where the band constrains a first length of the balloon near the band. The constraint can prevent the first length from radially expanding to the extent that the substantial remainder of the balloon radially expands. The band can be fabric. The band can be polymer.

[0008] The balloon can have a catheter section, other shaft, or other structural support longitudinally disposed inside of, outside of, or integrated with the balloon. The structural support can be mechanically reinforced. The structural support can be a fluid conduit. The structural support can be configured to allow a guidewire to pass therethrough. The structural support can be hollow, solid or combinations thereof.

[0009] The balloon can have a curvature (i.e., a curved configuration having a substantially non-zero radius of curvature). The balloon can have an internal tension

member. The balloon can have a cleat. The balloon can be in fluid communication with a catheter.

[0010] Also disclosed is a method for providing expansion forces at a target site during surgery with a balloon. The method also includes inflating the balloon. The method can include target sites that are in vessels, in intrabone and/or interbone spaces. The method can include deploying a prosthesis to the target site.

[0011] A method for expanding a balloon in a lumen and/or valve is also disclosed. The method includes expanding the balloon so that fluid flow along the lumen or across the valve can flow along one or more open channels formed between the balloon and lumen wall and/or valve annulus and/or leaflets.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] Figure 1 is a side view of an embodiment of the balloon attached to a catheter.

[0013] Figure 2 is a front view of the embodiment of the balloon of Figure 1.

[0014] Figure 3 is a side view of an embodiment of the balloon attached to a catheter.

[0015] Figure 4 illustrates an embodiment of section A-A of Figure 1.

[0016] Figure 5 illustrates an embodiment of section B-B of Figure 1.

[0017] Figure 6 illustrates an embodiment of section A-A of Figure 1.

[0018] Figure 7 illustrates an embodiment of section B-B of Figure 1.

[0019] Figure 8 illustrates an embodiment of section A-A of Figure 1.

[0020] Figures 9 through 11 are side views of various embodiments of the balloon attached to a catheter.

[0021] Figure 12 is a side view of an embodiment of the balloon attached to a catheter.

[0022] Figure 13 is a top view of the balloon and catheter of Figure 12.

[0023] Figures 14 through 16 are sectional views of various embodiments of the balloon connector and the balloon.

[0024] Figure 17 is a perspective and partial see-through view of an embodiment of the balloon attached to a catheter.

[0025] Figure 18 is a longitudinal front end view of the embodiment of Figure 17.

[0026] Figure 19 is a perspective and partial see-through view of an embodiment of the balloon attached to a catheter.

[0027] Figure 20 is a longitudinal front end view of the embodiment of Figure 19.

[0028] Figure 21 is a side perspective view of an embodiment of the balloon attached to a catheter.

[0029] Figure 22 is a longitudinal rear perspective view of the embodiment of Figure 21.

[0030] Figure 23 illustrates an embodiment of the balloon attached to a catheter in a first configuration.

[0031] Figure 24 illustrates the embodiment of Figure 23 in a second configuration.

[0032] Figure 25a is a top view an embodiment of the balloon attached to a catheter in a first configuration.

[0033] Figure 25b is a side view of the balloon attached to the catheter of Figure 25a.

[0034] Figure 26a is a top view of the balloon attached to the catheter of Figure 25a in a second configuration.

[0035] Figure 26b is a side view of the balloon attached to the catheter of Figure 26a.

[0036] Figure 26c is a front view of the balloon attached to the catheter of Figure 26a.

[0037] Figures 27 and 28a illustrate an embodiment of a method of using an embodiment of the balloon in the vasculature.

[0038] Figure 28b illustrates the expanded section Z-Z of Figure 28a.

[0039] Figure 29 is a perspective view of an embodiment of a method of using the balloon across a valve, with the valve shown in cross-section. For clarity, the catheter and the longitudinal ends of the balloon are not shown in Figures 29 through 31 and 33.

[0040] Figure 30 illustrates an embodiment of cross-section C-C of Figure 29.

[0041] Figure 31 is a perspective cross-section view of an embodiment of a method of using an embodiment of the balloon across a valve.

[0042] Figure 32a illustrates an embodiment of cross-section D-D of Figure 31.

[0043] Figure 32b illustrates the expanded section D1-D1 of Figure 32a.

[0044] Figure 33 is a perspective view of an embodiment of a method of using an embodiment of the balloon across a valve, with the valve shown in cross-section.

[0045] Figures 34 through 36 illustrate an embodiment of a method for using the balloon.

[0046] Figure 37 illustrates various embodiments of methods for using the balloon.

[0047] Figures 38 through 40 illustrate an embodiment of a method for using the balloon.

DETAILED DESCRIPTION

[0048] Figures 1 and 2 illustrate a hydraulic and/or pneumatic 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. One or more transverse axes (not shown) can be perpendicular to the longitudinal axis 6.

[0049] 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.

[0050] 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.

[0051] Figure 3 illustrates that the balloon 2 can have an 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.

[0052] 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.).

[0053] 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.

[0054] 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.

[0055] 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.

[0056] 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.

[0057] 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.

[0058] 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.

[0059] 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 thro.

ugh 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).

[0060] 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.

[0061] 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.

[0062] Figure 10 illustrates that the balloon 2 can have a band 40. The band 40 can be, for example, fabric (e.g., textile: woven, knitted, braided, or combinations thereof) and/or polymer. The band 40 can be slit films, injection molded, laser cut (e.g., tubes), or combinations thereof. The bands 40 can be one or more wires, one or more threads, sutures, ribbons, or combinations thereof. The bands 40 can be made from polyethylene teraphathalate (PET), 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), nylon, titanium, steel, cobalt-chrome alloys (e.g., ELGILOY® from Elgin Specialty Metals, Elgin, IL; CONICHROME® from Carpenter Metals Corp., Wyomissing, PA), a single or multiple stainless steel alloys, nickel titanium alloys, or combinations thereof. The band 40 can be soft and/or flexible, semi-rigid, or rigid. The band 40 can be expandable or non-expandable.

[0063] 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.

[0064] The band 40 can be placed at a narrowing in the balloon 2. The band 40 can be parallel with a transverse axis of the balloon 2, parallel with the longitudinal axis 6 of the balloon 2, or at an angle to the longitudinal 6 and transverse axes of the balloon 2. The band 40 can be fixedly attached to the catheter 4, for example the catheter 4 in the balloon 2. The balloon 2 can have multiple bands 40.

[0065] 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. The band 40 can have a band modulus of elasticity. The balloon 2 can have a balloon modulus of elasticity. The band modulus of elasticity can be greater than, equal to, or less than the balloon modulus of elasticity. For multiple bands 40 with one balloon 40, the multiple bands can have the same or various band moduli of elasticity.

[0066] 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.

[0067] 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.

[0068] 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.

[0069] 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).

[0070] 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.

[0071] 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.

[0072] The outer compression element 46 can be outside the balloon 2. The outer compression element 46 can be, for example, a rivet or plug.

[0073] 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.

[0074] 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.

[0075] Figures 17 and 18 illustrate that the balloon 2 can be subdivided into two or more segments, for example a balloon first segment 74 and a balloon second segment 76. The segments can each have one or more lobes. The band 40 can divide the balloon first segment 74 from the balloon second segment 76. The band 40 can shape or otherwise configure the balloon first segment 74 and/or balloon second segment 76. The balloon first segment 74 can be in fluid communication with the balloon second segment 76. The band 40 can extend longitudinally (as shown) along the balloon 2, and/or the band 40 can traverse the longitudinal axis 6, as shown in Figure 10.

[0076] In an expanded configuration, the balloon 2 can have a balloon expanded diameter 78. The balloon expanded diameter 78 can be from about 1 mm (0.04 in.) to about 40 mm (2 in.), more narrowly from about 2 mm (0.08 in.) to about 30 mm (1 in.), for example about 15 mm (0.59 in.).

[0077] Figures 19 and 20 illustrate that balloon can have a first 74, second 76, third 80 and fourth 82 segment. The segments can be configured symmetrically around the balloon 2. The band 40 can extend in multiple planes (e.g., horizontal and vertical),

and/or the balloon 2 can have multiple bands 40 (not shown) on top of one another bands 40.

[0078] Figures 21 and 22 illustrates that the catheter 4 can have a catheter first section 4a, a catheter second section 4b, and a catheter third section 4c. The catheter first section 4a can be attached to the balloon 2. The catheter second section 4b can have a catheter distal tip 86.

[0079] The catheter first section 4a can have a catheter first section diameter 84. The catheter first section diameter 84 can be from about 1 mm (0.04 in.) to about 25 mm (1.0 in.), for example, about 4.75 mm (0.187 in.).

[0080] The band 40 can be rigid, flexible, or combinations thereof. The band 40 can be deformable, resilient, or combinations thereof. The band 40 can locally (e.g., within a close proximity of the band) constrain (i.e., resist) radial expansion of the balloon 2 during use.

[0081] The band 40 can have a retaining loop 88 at one or both longitudinal ends. The retaining loop 88 can attach the band 40 to the catheter 4. The retaining loop 88 can circumscribe the inside and/or outside of the catheter 4 or be integral with the catheter 4.

[0082] The band 40 can have one or more retaining straps 89 at one or both longitudinal ends. The retaining straps 89 can attach the band 40 to the catheter 4. The retaining straps 89 can be substantially parallel with the longitudinal axis of the catheter 4. The retaining straps can be on the inside and/or outside of the catheter 4 or be integral with the catheter 4.

[0083] The band 40 can be separate and/or integral with the catheter 4. The band can have a first band segment 40a and a second band segment 40b. The first band segment 40a can be separate from or integral with the second band segment 40b.

[0084] The catheter 4 can be configured for fluids and/or a guidewire to pass through the entire length, or a section of the length, of the catheter 4. The catheter 4 can be hollow and/or solid. The catheter 4 can have one or more catheter lumen along all or a portion of the length of the catheter 4. The catheter 4 can have one or more optical fibers along all or a portion of the length of the catheter 4. The catheter 4 can have one or more conductive wires along all or a portion of the length of the catheter 4.

[0085] Figure 23 illustrates that the balloon 2 can be attached to the catheter 4 at a distal balloon connecter 12a and a proximal balloon connector 12b. The catheter third section 4c can be unreinforced.

[0086] Figure 24 illustrates that when the balloon 2 inflates during use, the balloon 2 radially expands, as shown by arrows 90. The radial expansion of the balloon 2 can cause a longitudinal shortening of the balloon 2. The longitudinal shortening of the balloon 2 can cause a compressive force, as shown by arrows 92, to be transmitted through the balloon connectors 12a and 12b to the catheter 4. The catheter 4 can buckle or kink in the catheter third section 4c. The catheter 4 can be configured to not obstruct flow inside the catheter 4 during buckling or kinking, for example, by the catheter 4 having a large enough internal diameter based on expected buckling or kinking.

[0087] Figures 25a and 25b illustrate that the catheter first section 4a, catheter second section 4b, catheter third section 4c, or combinations thereof, can be reinforced by a brace or other reinforcement. The reinforcement can be attached and/or integral with the catheter 4. The reinforcement can be interior, implanted, or exterior to the catheter 4. The reinforcement can be a coil, fiber mesh or weave, sleeve, sheath, rod, or combinations thereof. The reinforcement can be a configuration of the catheter 4. For example, the reinforcement can be longitudinal and/or transverse slotting, indentation, or corrugation of the catheter 4, for example along the catheter third section 4c.

[0088] Figures 26a and 26b illustrate that the reinforced catheter third section 4c can produce a support column force, as shown by arrows 94, for example in resistance to the compressive force, as shown by arrows 92. The reinforcement can prevent or otherwise minimize buckling or kinking in the catheter third section 4c.

[0089] Figure 26c illustrates that the retaining loop 88 can circumscribe or encircle the catheter 4.

[0090] As shown by Figures 25b and 26b, the longitudinal axis 6 can have a first configuration (e.g., curved (as shown) and/or straight) when the balloon 2 and catheter 4 are in a deflated configuration and a second configuration (e.g., straight (as shown) and/or curved) when the balloon 2 and catheter 4 are in an inflated configuration.

[0091] Any or all elements of the inflation device, including those elements listed with materials separately, 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), poly ester amide (PEA), 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.

[0092] Any or all elements of the inflation device, including those elements listed with materials separately, and/or other devices or apparatuses described herein, can be, have, and/or be completely or partially coated with agents and/or a matrix a matrix for cell ingrowth 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), poly ester amide (PEA), polypropylene, PTFE, ePTFE, nylon, extruded collagen, silicone, any other material disclosed herein, or combinations thereof.

[0093] The inflation device, including those elements listed with materials separately, and/or elements of the inflation device and/or other devices or apparatuses described herein and/or the fabric can be filled, coated, layered and/or otherwise made with and/or from cements, fillers, glues, and/or an agent delivery matrix known to one having ordinary skill in the art and/or a therapeutic and/or diagnostic agent. Any of these cements and/or fillers and/or glues can be osteogenic and osteoinductive growth factors.

[0094] 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.

[0095] 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

[0096] Figure 27 illustrates that the balloon 2 can be attached to a catheter 4 and positioned, as shown by arrow 96, into a lumen 98 at or adjacent to a treatment site 100. The lumen 98 can be a venous or arterial blood vessel (e.g., coronary or peripheral). The lumen 98 can have a damaged lumen wall 102 at the treatment site 100, for example as a symptom of atherosclerosis (e.g., stenosis, perhaps due to vascular plaque). The catheter 4 can be fixedly or removably attached to the balloon 2.

[0097] Figures 28a and 28b illustrate that the balloon 2 can be inflated, as shown by arrow 104. The balloon 2 can radially expand, as shown by arrows 90. The expanded balloon 2 can treat damaged the treatment site 100, for example by reconfiguring the lumen wall 102. The catheter 4 and balloon 2 can be removed from the treatment site 100 and lumen 98.

[0098] As shown in Figures 28a and 28b, the band 40 can constrain, retain or otherwise deform a portion of the balloon 2 or impair inflation of a portion of the balloon 2. The constraint or deformation can inhibit the radial expansion along the balloon 2 on one or more angles from longitudinal axis 6. The lumen 98 can have a channel 106 between a local area near the band 40 and the lumen wall 102. Fluid flow, shown by arrows 108, can flow in the channel 106 around the balloon 2 (i.e., between the balloon 2 and the lumen wall 102), for example when the balloon 2 is in an inflated configuration. The balloon 2 can retain one or more artificial or biological valvular leaflets (e.g., extending naturally from a blood vessel's valve or heart valves), for example, against the lumen wall 102, for example, when the balloon 2 is in an inflated configuration.

[0099] The catheter 4 can be separated from the balloon 2, and the balloon 2 can remain in the treatment site 100. The balloon 2 can be made from and/or filled with a biodegradable and or bioabsorbable material. The treatment site 100 can be an aneurysm. The aneurysm can be thoracic, abdominal, cerebral, coronary, or other vascular aneurysms. The aneurysm can be fusiform, saccular, a pseudoaneurysm, or combinations thereof. The balloon 2 can cover or be deployed into the aneurysm neck, for example minimizing and/or preventing fluid flow 108 into and/or out of the aneurysm. The balloon 2 can have a coating and/or a graft minimizing and/or preventing fluid flow 108 through the aneurysm neck. One or more balloons 2 with or without grafts can be deployed into the aneurysm.

[0100] Figures 29 and 30 illustrate that the balloon 2 can be positioned, as shown by arrow 110, at or adjacent to a valve 112. The valve 112 can have an annulus 114 and/or leaflets 116. The valve 12 can have a lumen wall 122. The valve 112 can be a vascular or heart valve, for example a stenotic mitral, aortic, tricuspid, or pulmonic valve.

[0101] As shown in Figure 31, the balloon 2 can be positioned to longitudinally overlap the annulus 114 and/or leaflets 116. The balloon 2 can then be inflated, for example causing the balloon to radially expand 90. The balloon 2 can have an expandable rim 118, for example, for structural support and/or for transmitting energy (e.g., RF energy) or force (e.g., abrasion) to the annulus 114. The expandable rim 118 can be separatable from the balloon 2. The expandable rim 118 can circumferentially lock during deployment.

[0102] As shown in Figures 32a and 32b, the balloon 2 can be inflated, for example causing radial expansion of the balloon 2. The balloon 2 can be configured to taper in the longitudinal middle of the balloon 2 during inflation 120, such as shown in Figures 31 and 32a. Also for example, the balloon 2 can be deformable, and/or separated from the catheter 4, and/or left wholly or partially as deployed.

[0103] As shown in Figures 32a and 32b, the band 40 can constrain, retain or otherwise deform a portion of the balloon 2 or impair inflation 120 of a portion of the balloon 2. The constraint or deformation can inhibit the radial expansion along the balloon 2 on one or more angles from longitudinal axis 6. The valve 112 can have a channel 106 between a local area near the band 40 and the valvular lumen wall 122. Fluid flow, shown by arrows 108, can flow in the channel 106 past the balloon 2 (i.e., between the balloon 2 and the valvular lumen wall 122), for example when the balloon 2 is in an inflated configuration. The balloon 2 can retain the leaflets 116, for example, against the valvular lumen wall 122, for example, when the balloon 2 is in an inflated configuration.

[0104] Figure 33 illustrates that the balloon 2 can be radially contracted (e.g., by deflating and/or applying a longitudinal tensile force, and/or a radial tensile force). The balloon 2 can be withdrawn from the valve 112, as shown by arrow 124.

[0105] The balloon 2 can be left in the valve 112 permanently or semi-permanently. The longitudinal ends of the balloon 2 can be removed. New leaflets can be attached to the expandable support device, for example at the attachment tabs 126 and/or expandable rim 118.

[0106] Figures 29, 30, 31 and 33 do not show the catheter 4 for clarity of illustration. Figure 31 does not show the longitudinal ends of the balloon 2 for clarity of illustration. Various figures herein illustrating the balloon 2 as having round or square longitudinal ends are non-limiting. The longitudinal ends of the balloon 2 can have round or square configuration or other known configurations.

[0107] The balloon 2 can be used for tissue distraction. One or more balloons 2 can be used concurrently on one application (i.e., patient, and/or at a single treatment site).

[0108] The balloon 2 can be used as a support and/or to separate bones, within, outside or between bones. Figure 34 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 No. 60/612,001, filed 21 September 2004, and PCT Application No. US2005/033965, filed 21 September 2005, which are herein incorporated by reference in their entireties.

[0109] Figure 35 illustrates that the balloon 2 can be inserted into a target site, such as an interbone, or intervertebral space. Figure 36 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.

[0110] Figure 37 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.

[0111] 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.

[0112] 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.

[0113] Figure 38 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.

[0114] Figure 39 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 40 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.

[0115] The deployment tools used herein can, for example, be the deployment tools disclosed herein, the deployment tool (i.e., including balloons) disclosed in U.S. Provisional Patent Application Nos. 60/611,972 filed 21 September 2004, 60/612,724 filed 24 September 2004, and 60/617,810 filed 12 October 2004, and PCT Applications Nos. US2005/033965, filed 21 September 2005, US2005/034742, filed 26 September 2005, and US2005/037126, filed 12 October 2005, which are all incorporated by reference herein in their entireties, or combinations thereof.

[0116] The balloon 2 can be used to deploy stents, scaffolds, expandable support devices, such as those disclosed in U.S. Provisional Patent Application No. 60/612,001, filed 21 September 2004, and PCT Application No. US2005/033965, filed 21 September 2005, which are 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 No. 60/612,001 and PCT Application No. US2005/033965.

[0117] The balloon 2 can be used to deploy vascular stents as known to those having ordinary skill in the art.

[0118] Any elements described herein as singular can be pluralized (i.e., anything described as "one" can be more than one). Any species element of a genus element can have the characteristics or elements of any other species element of that genus. The

above-described configurations, elements or complete assemblies and methods and their elements for carrying out the invention, and variations of aspects of the invention can be combined and modified with each other in any combination.

CLAIMS

We claim:

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

a balloon having a longitudinal axis and an expanded configuration, wherein a first cross-section of the balloon is substantially non-circular, wherein the first cross-section is substantially perpendicular to the longitudinal axis.

2. The device of Claim 1, wherein the first cross-section comprises a lobe.

3. The device of Claim 2, wherein the first cross-section comprises two lobes.

4. The device of Claim 3, wherein the first cross-section comprises four lobes.

5. The device of Claim 1, wherein the balloon further comprises a constraining band.

6. The device of Claim 5, wherein the constraining band is substantially parallel with the longitudinal axis of the balloon.

7. The device of Claim 5, wherein the constraining band has a band modulus of elasticity and the balloon has a balloon modulus of elasticity, and wherein the band modulus of elasticity is greater than the balloon modulus of elasticity.

8. The device of Claim 1, further comprising a conduit, wherein the conduit passes through the balloon.

9. The device of Claim 8, wherein the conduit comprises a structural reinforcement.

10. The device of Claim 9, wherein the structural reinforcement comprises a coil.

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

a balloon having a longitudinal axis, and

a constraining band along the balloon.

12. The device of Claim 11, wherein the constraining band is substantially parallel with the longitudinal axis.

13. The device of Claim 11, wherein the constraining band is radially exterior to the balloon.

14. The device of Claim 11, wherein the constraining band is integral with the balloon.

15. The device of Claim 11, wherein the constraining band has a band modulus of elasticity and the balloon has a balloon modulus of elasticity, and wherein the band modulus of elasticity is greater than the balloon modulus of elasticity.

16. A method for providing expansion forces in a biological lumen comprising a lumen wall, comprising:

deploying a balloon to the lumen,

inflating the balloon in the lumen, wherein the balloon expands to an inflated configuration, and wherein with the balloon in the inflated configuration, a flow channel forms between the balloon and the lumen wall.

17. The method of Claim 16, wherein forming the flow channel comprises constraining the balloon with an element.

18. The method of Claim 17, wherein the element comprises a constraining band.

19. The method of Claim 18, wherein the constraining band has a band modulus of elasticity and the balloon has a balloon modulus of elasticity, and wherein the band modulus of elasticity is greater than the balloon modulus of elasticity.

20. The method of Claim 16, wherein the constraining comprises forming the flow channel along a path substantially parallel with the longitudinal axis of the balloon.

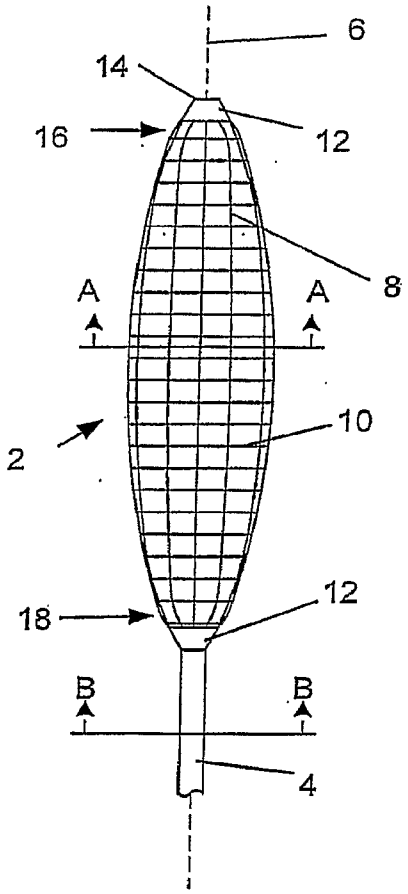

Fig. 1

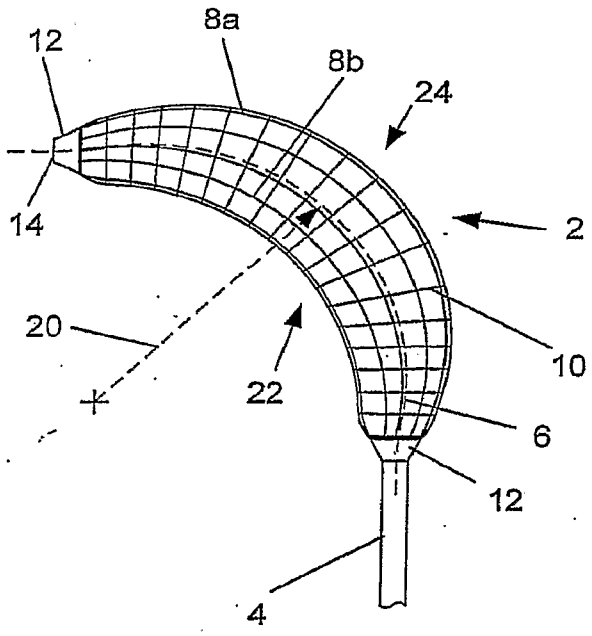

Fig. 3

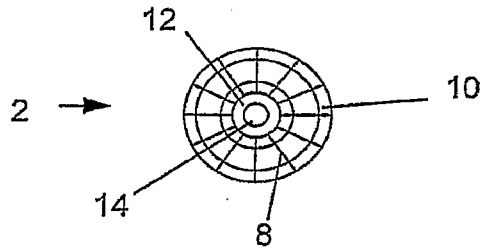

Fig. 2

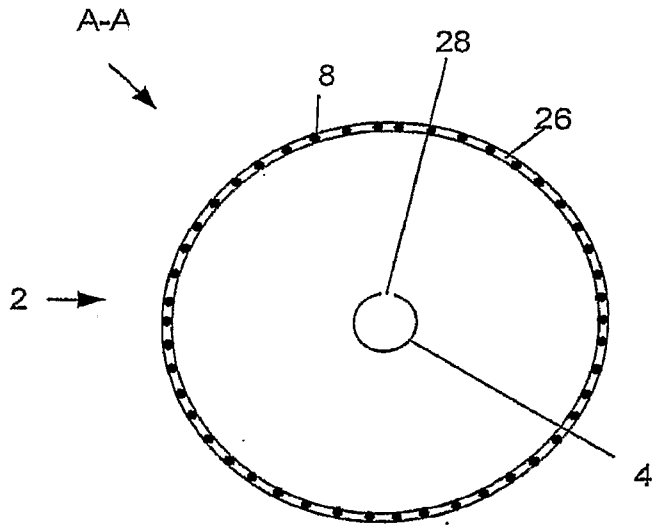

Fig. 4

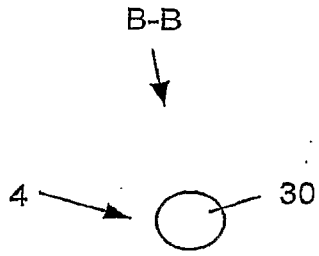

Fig. 5

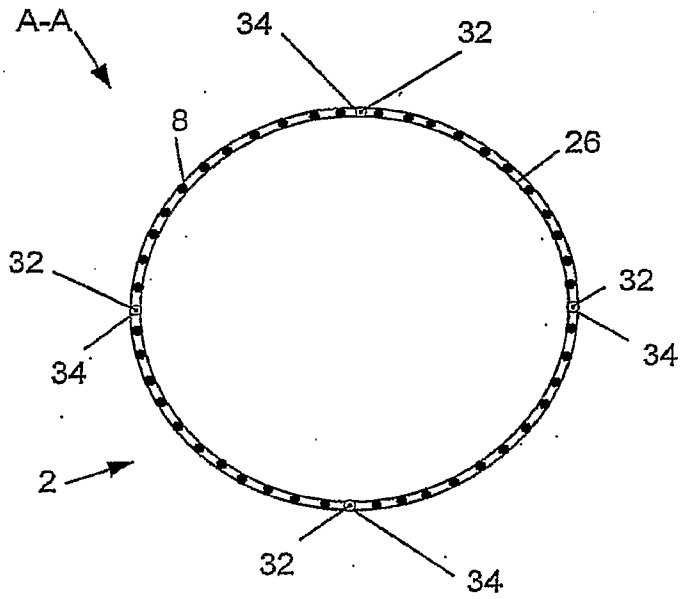

Fig. 6

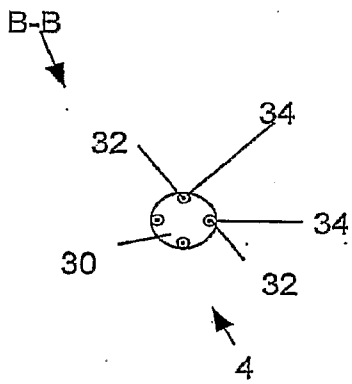

Fig. 7

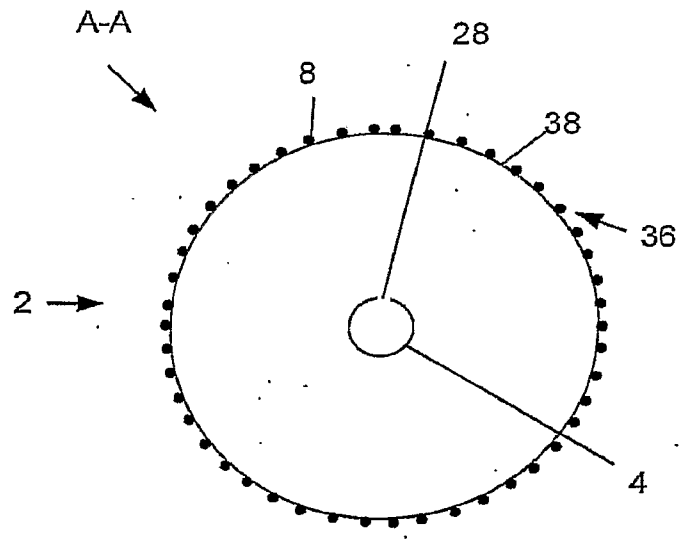

Fig. 8

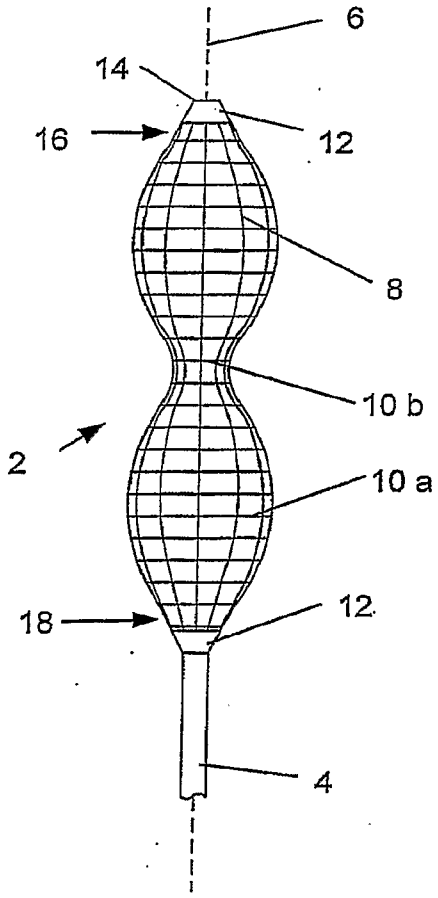

Fig. 9

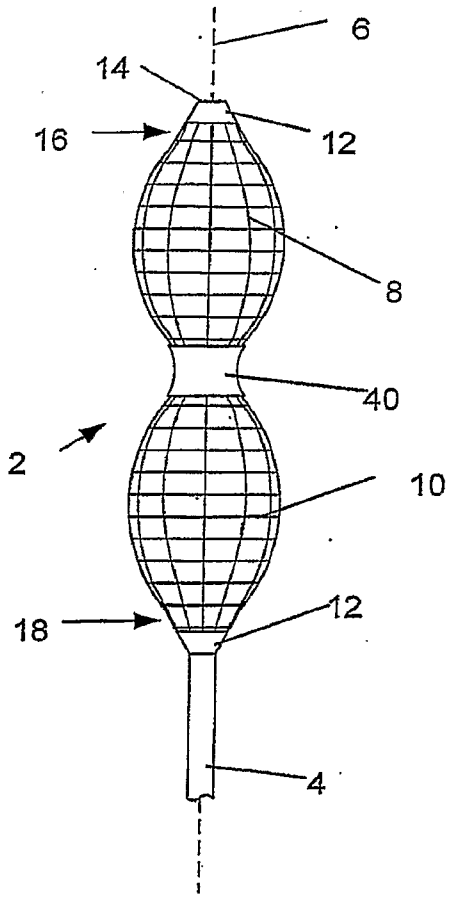

Fig. 10

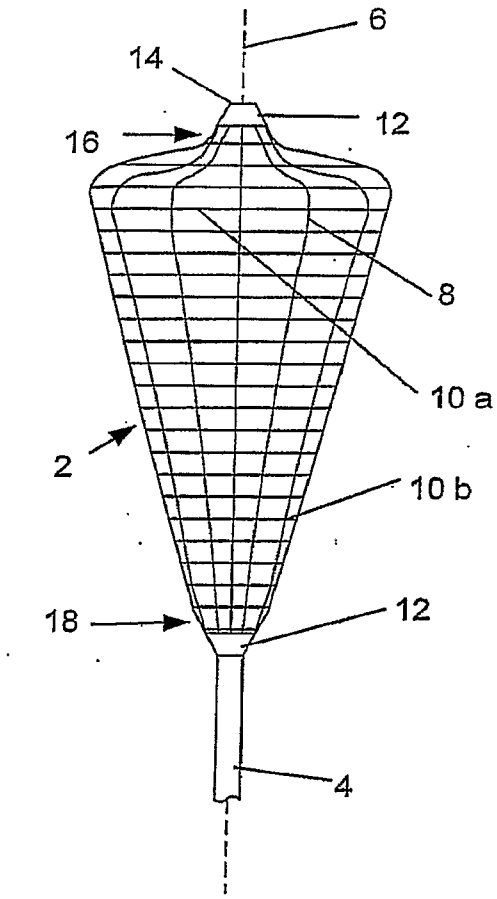

Fig. 11

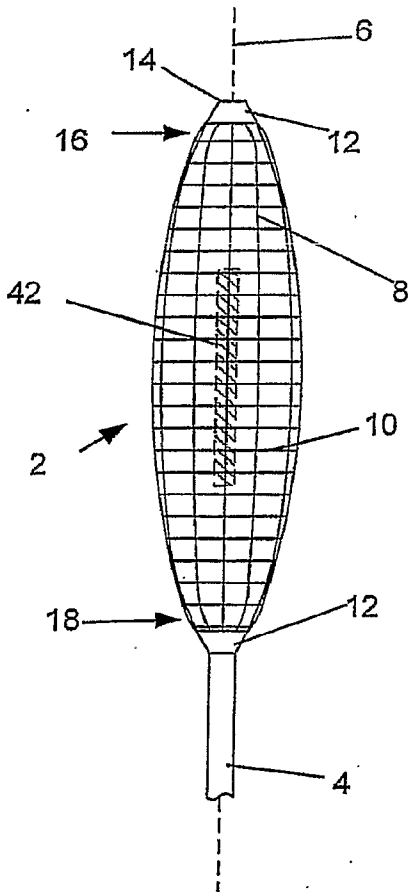

Fig. 12

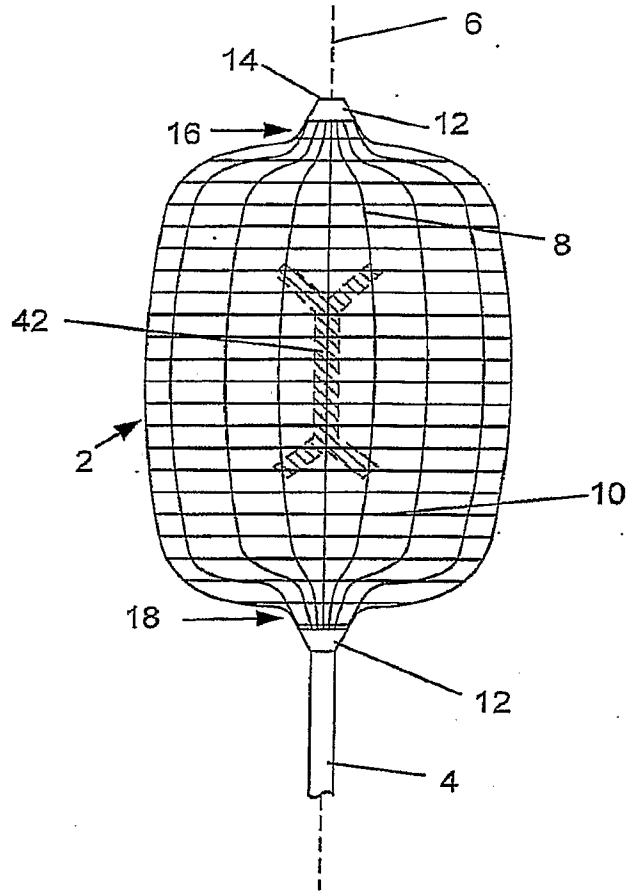

Fig. 13

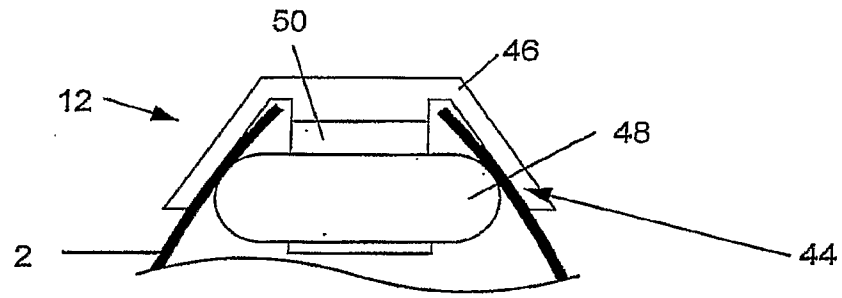

Fig. 14

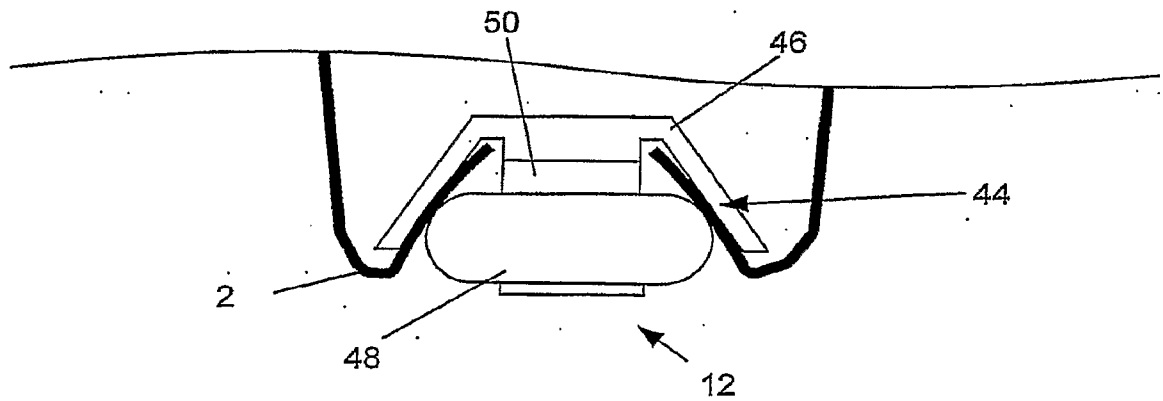

Fig. 15

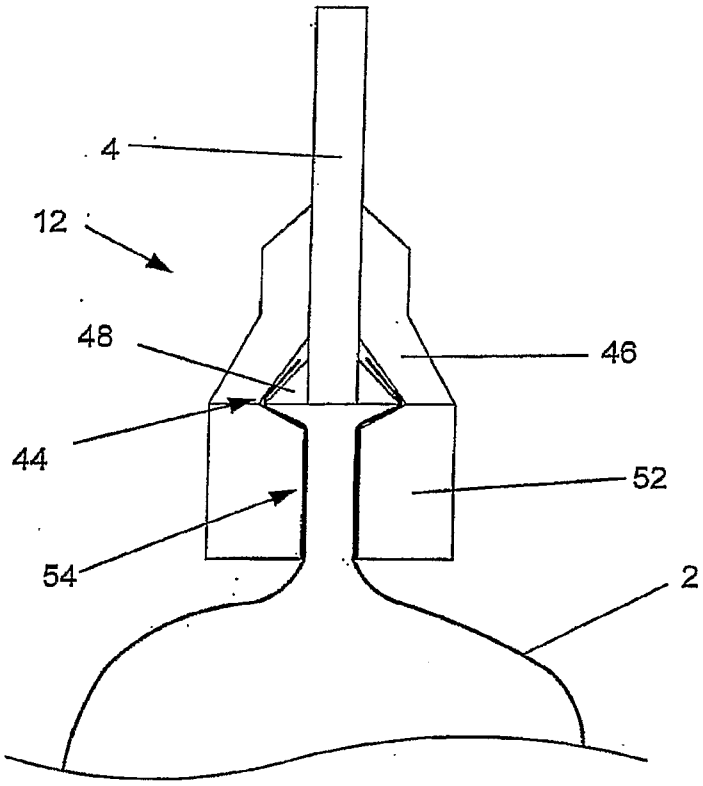

Fig. 16

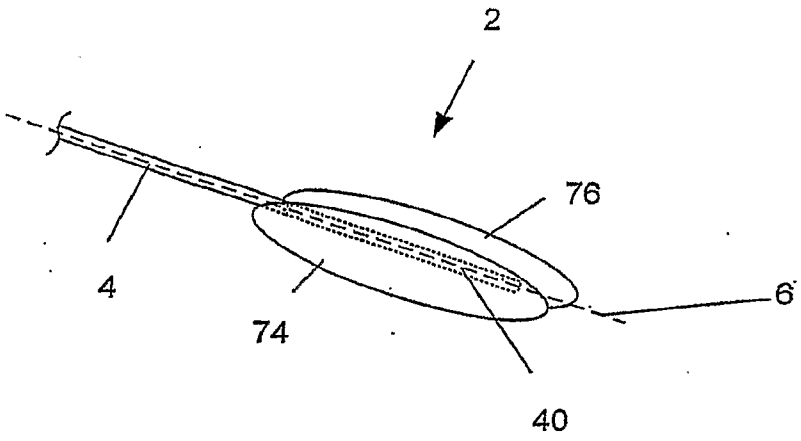

Fig. 17

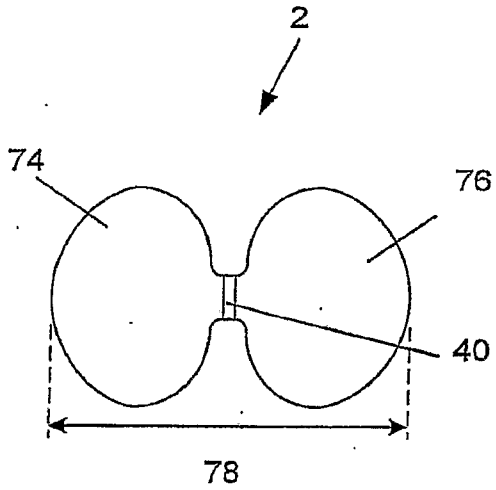

Fig. 18

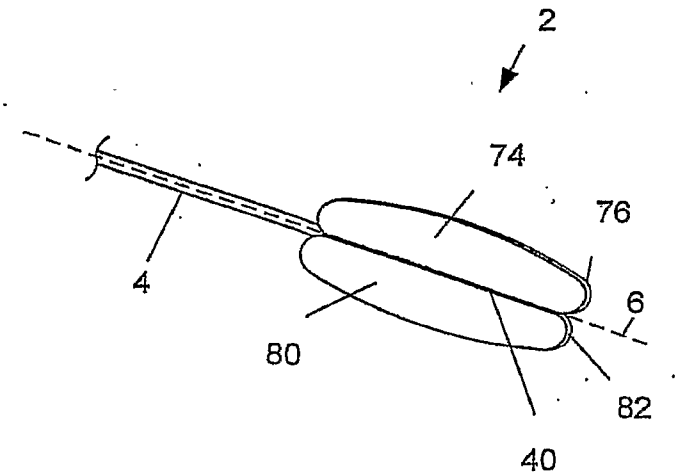

Fig. 19

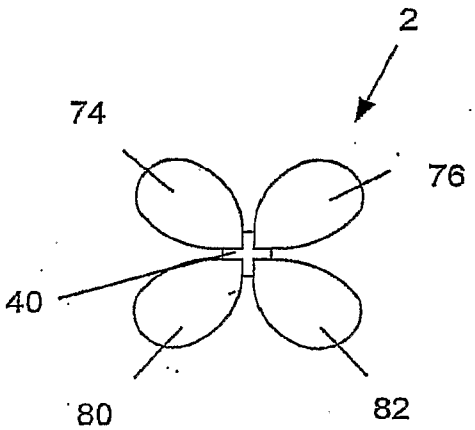

Fig. 20

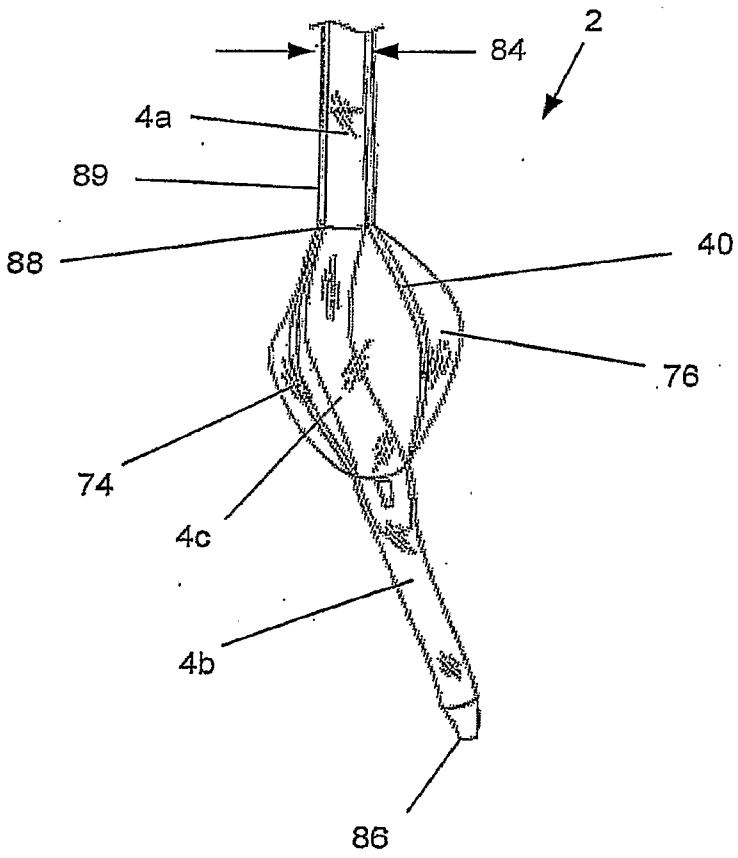

Fig. 21

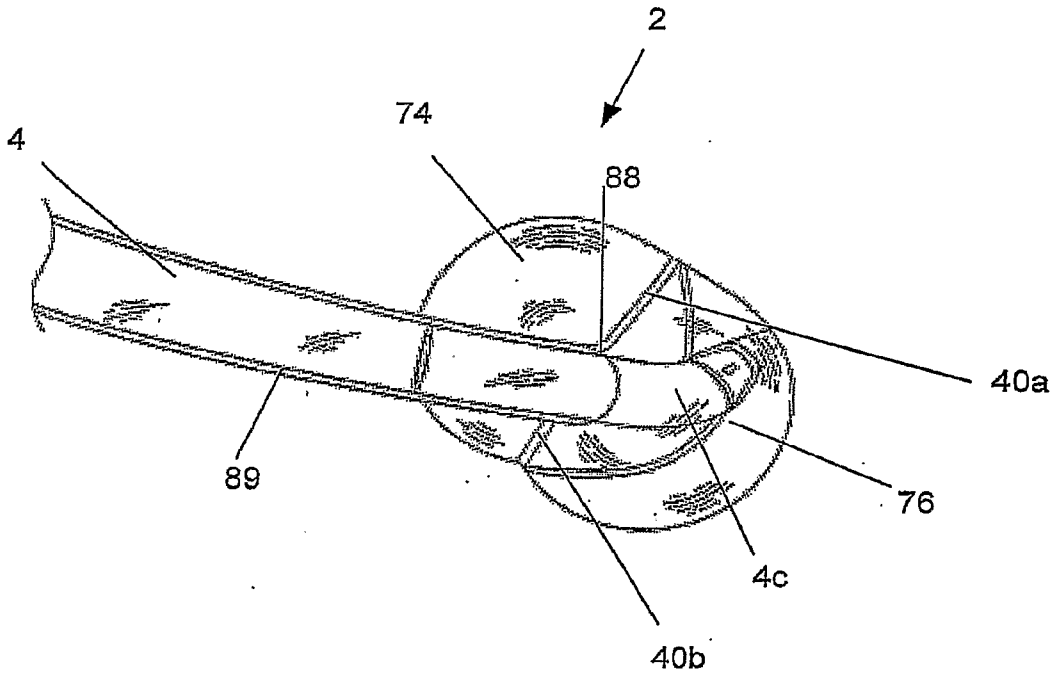

Fig. 22

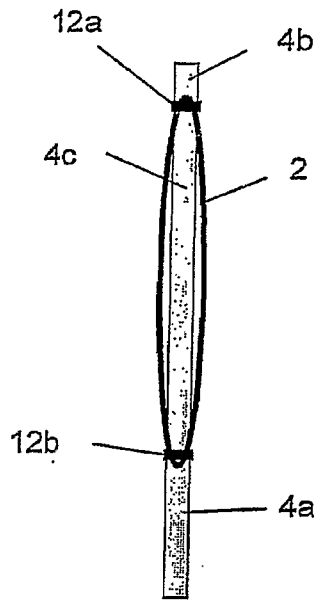

Fig. 23

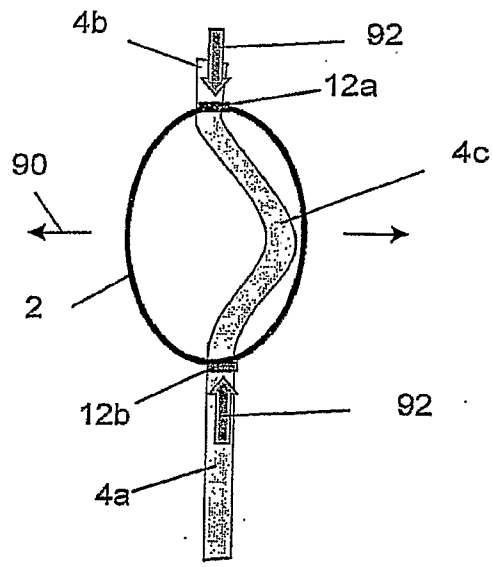

Fig. 24

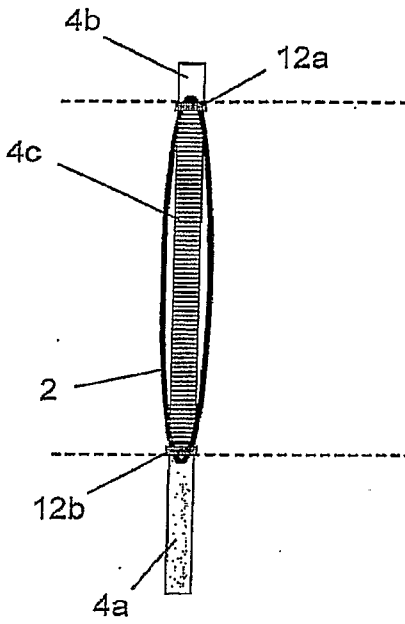

Fig. 25a

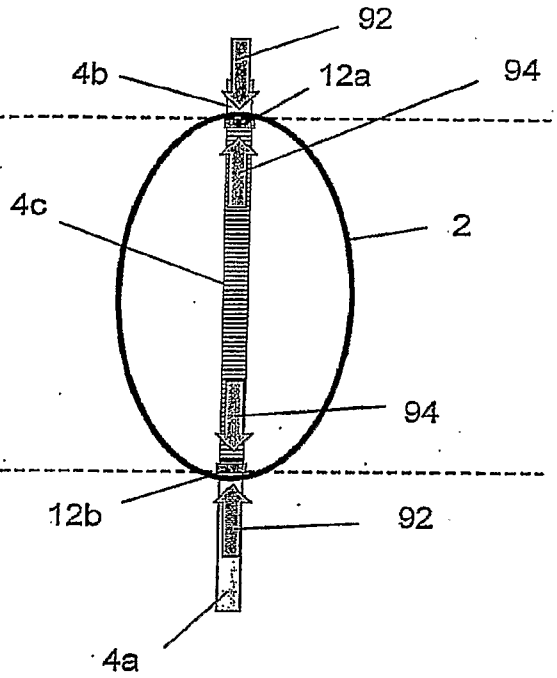

Fig. 26a

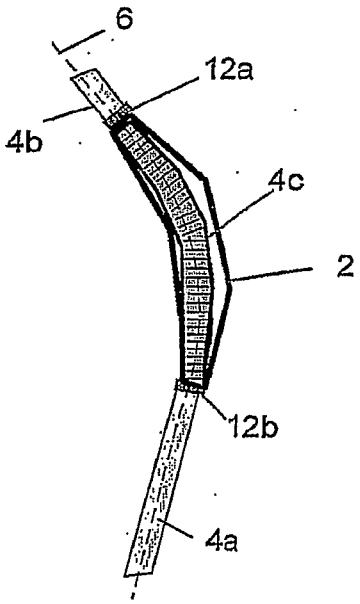

Fig. 25b

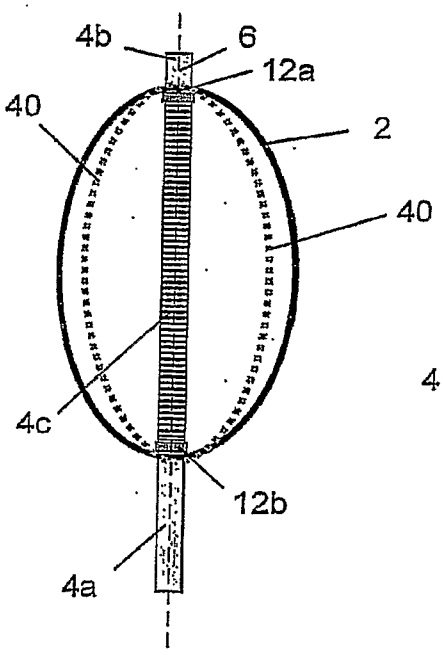

Fig. 26b

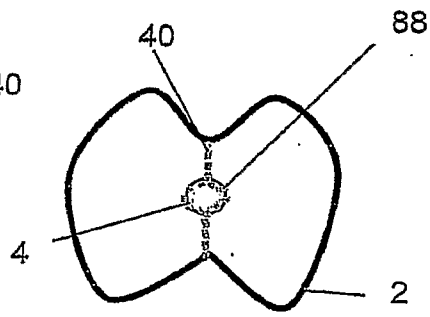

Fig. 26c

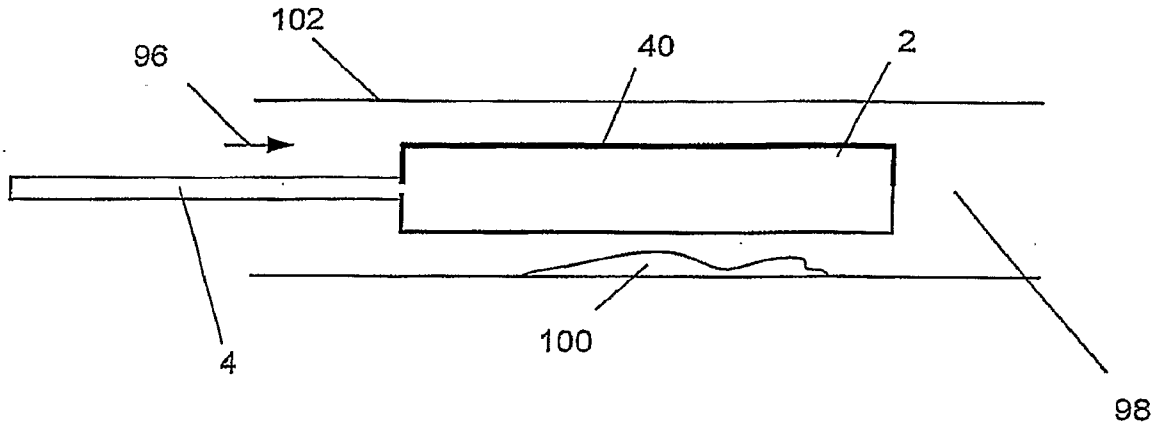

Fig. 27

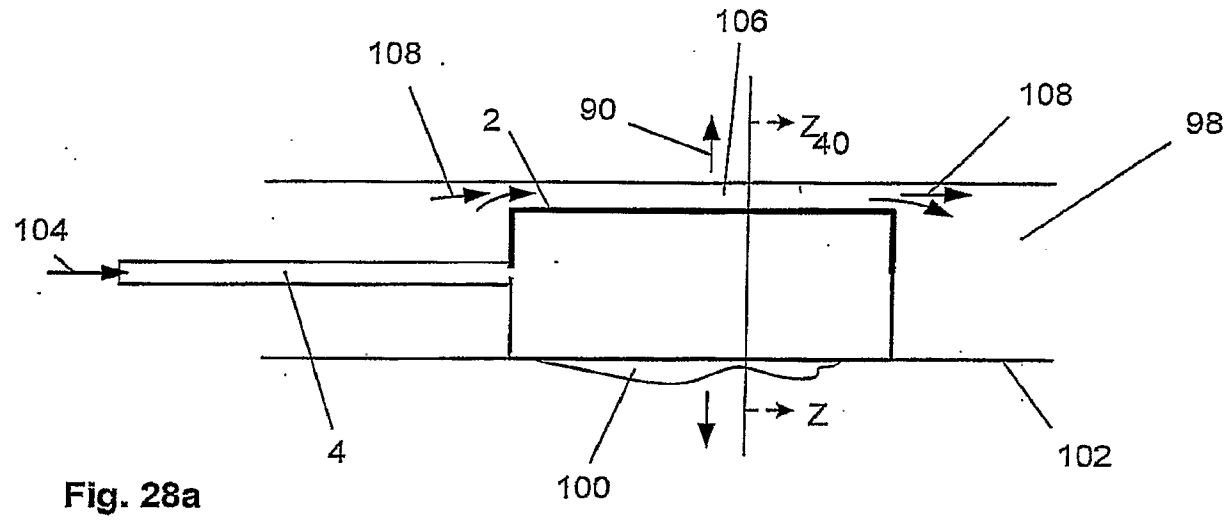

Fig. 28a

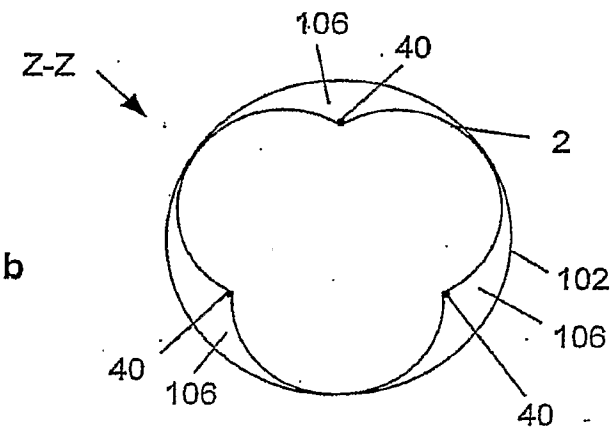

Fig. 28b

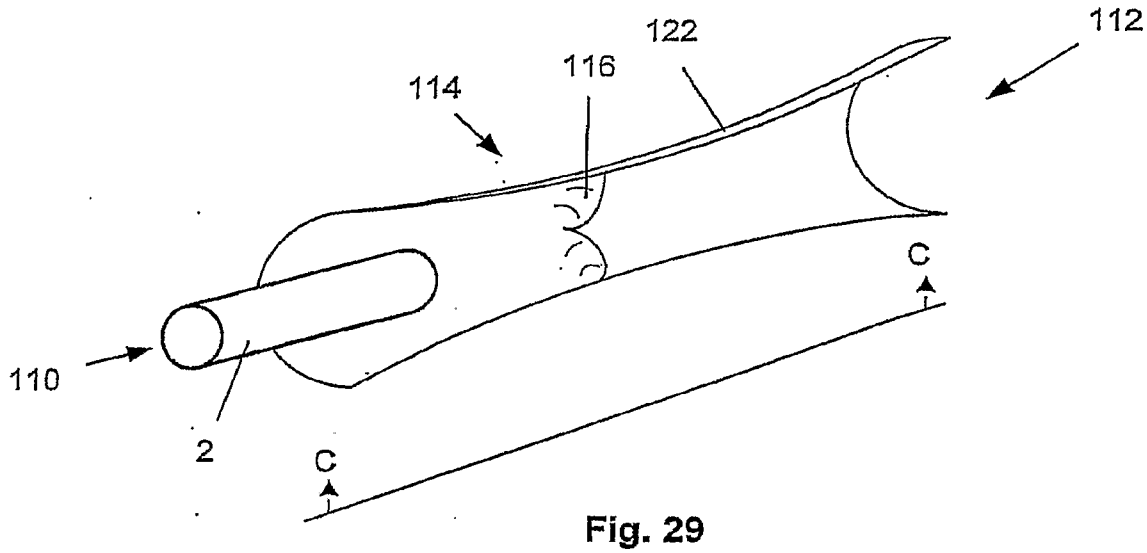

Fig. 29

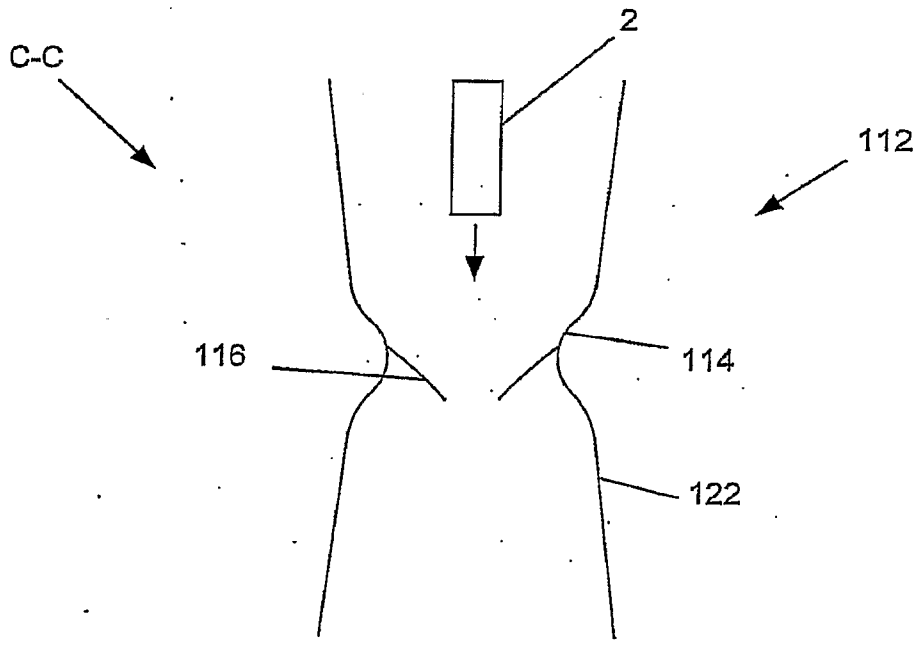

Fig. 30

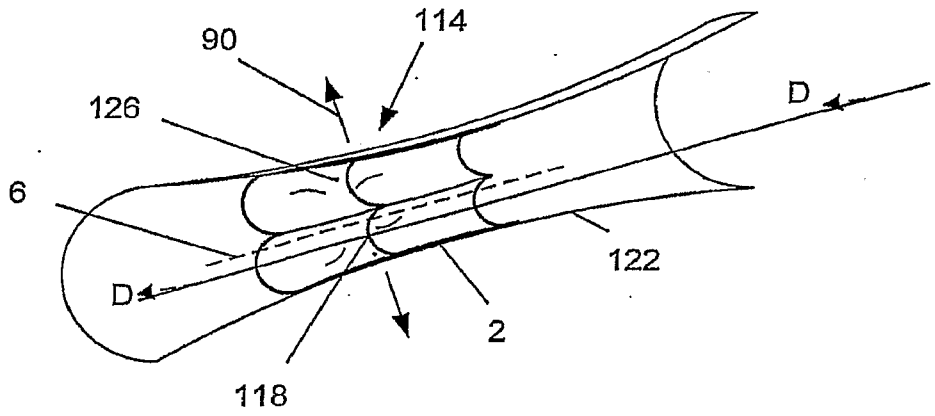

Fig. 31

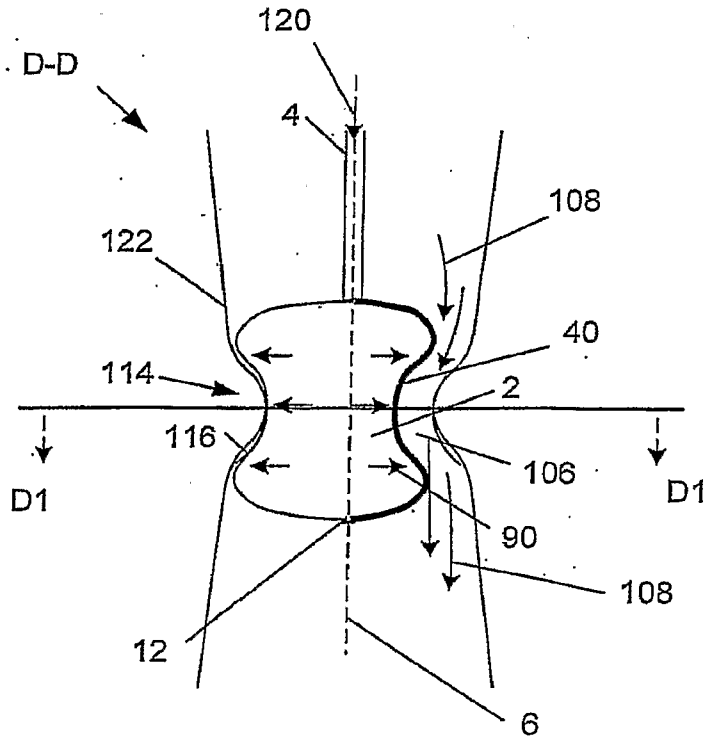

Fig. 32a

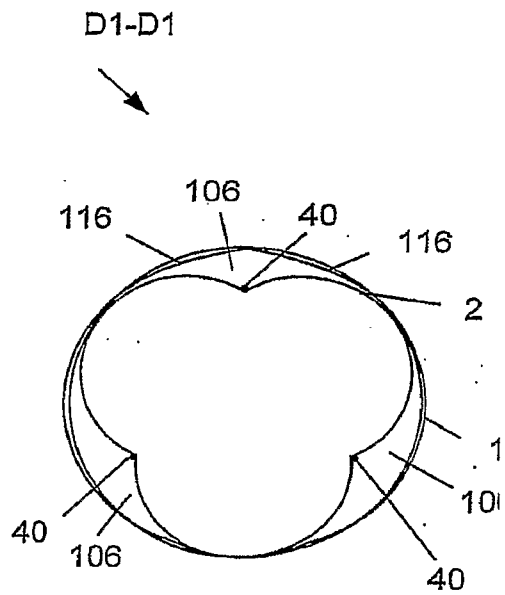

Fig. 32b

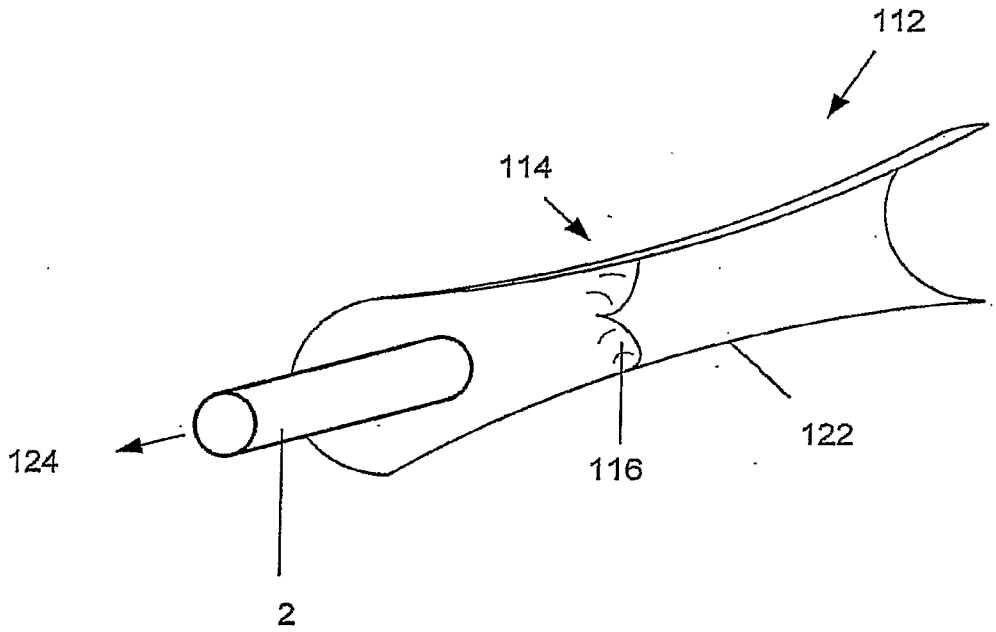

Fig. 33

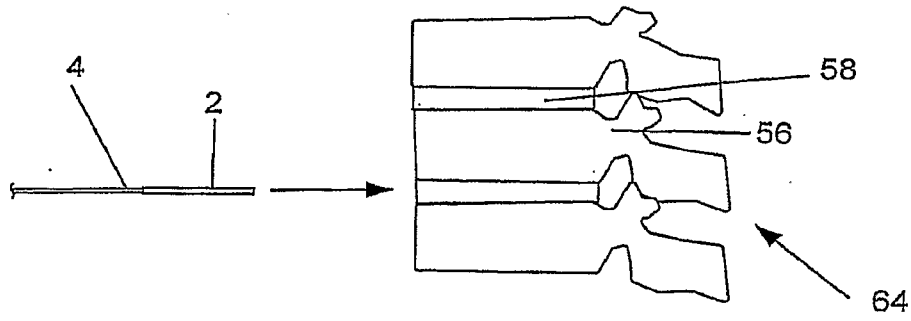

Fig. 34

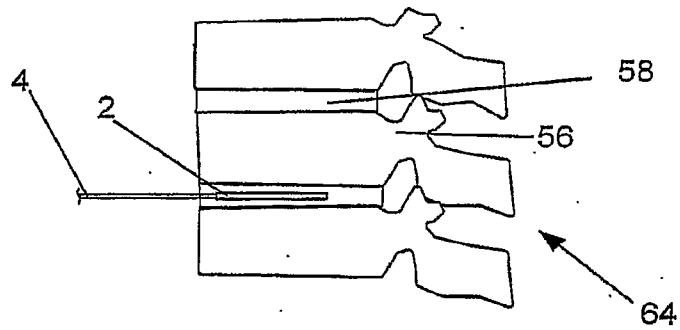

Fig. 35

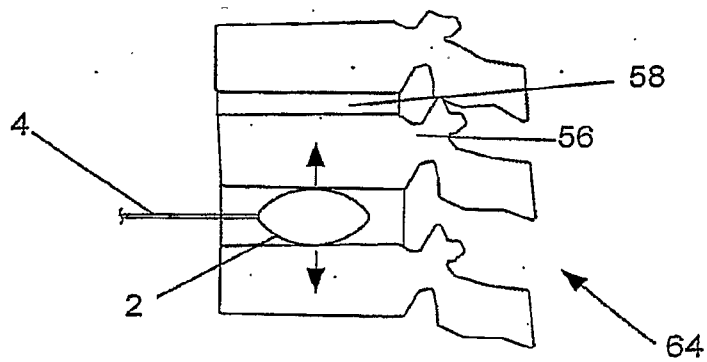

Fig. 36

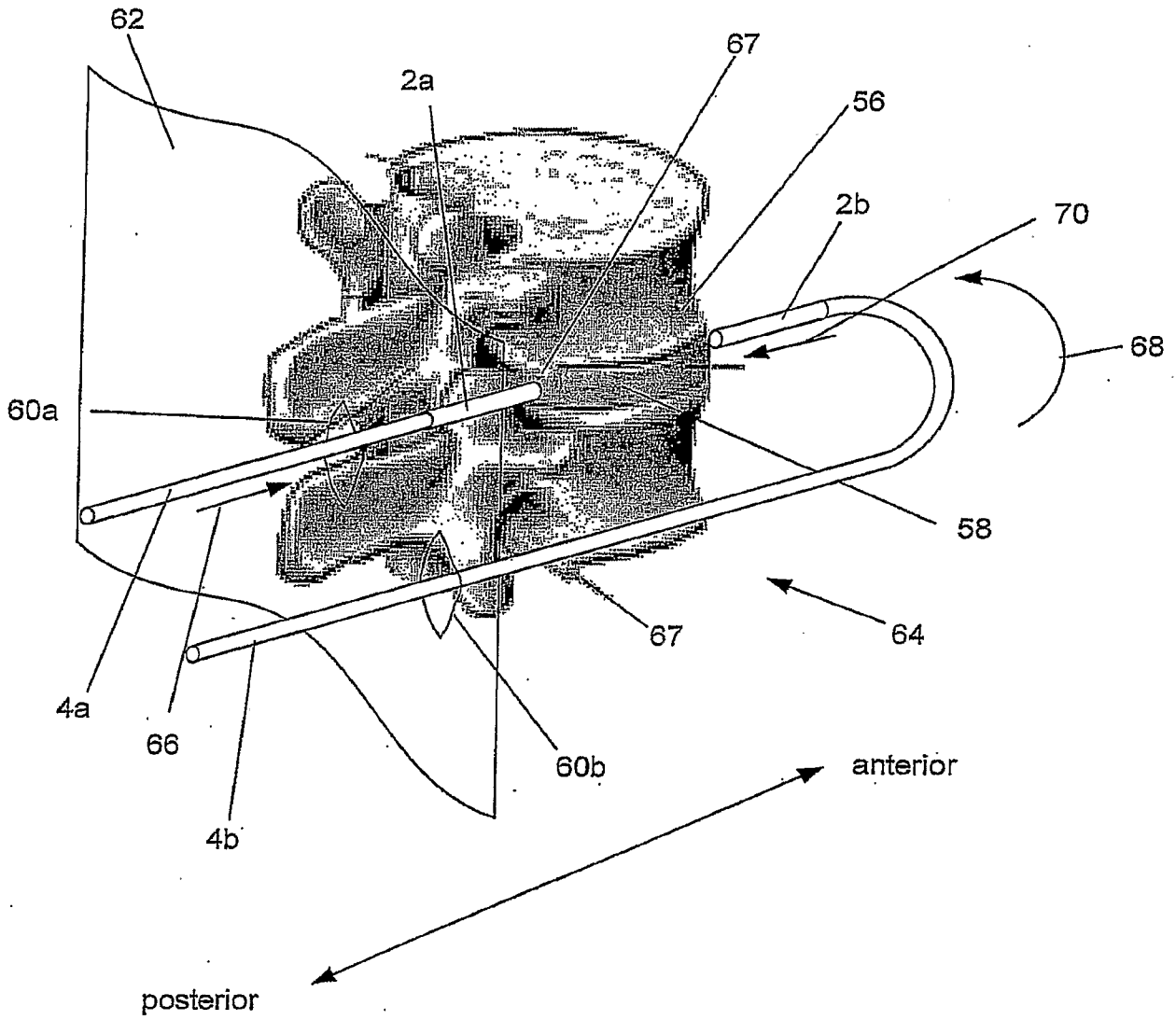

Fig. 37

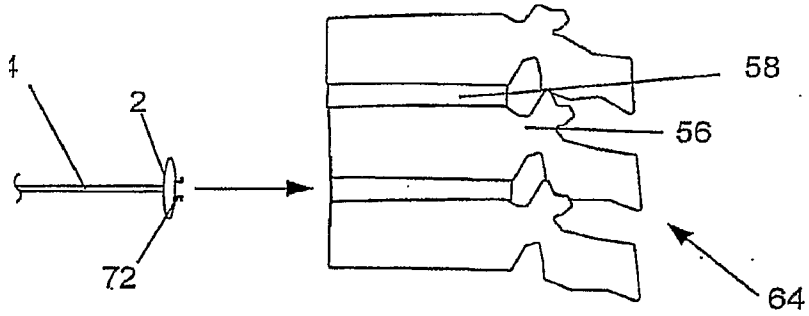

Fig. 38

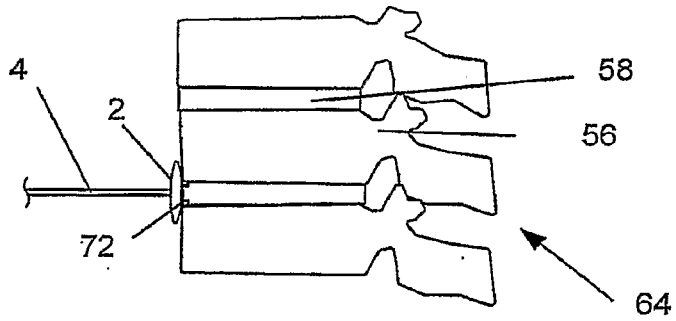

Fig. 39

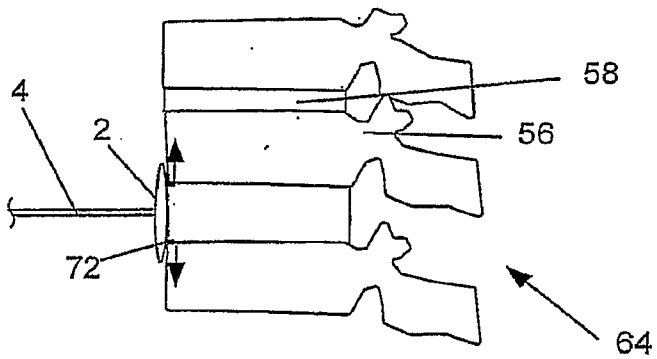

Fig. 40