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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
1 December 2005 (01.12.2005)

PCT

(10) International Publication Number
WO 2005/112791 A2

(51) International Patent Classification[7]: A61B 17/08

(21) International Application Number:
PCT/US2005/016623

(22) International Filing Date: 12 May 2005 (12.05.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/844,247 12 May 2004 (12.05.2004) US

(71) Applicant and
(72) Inventor: **MODESITT, D., Bruce** [US/US]; 120 Wingate Ave., San Carlos, CA 94070 (US).

(74) Agent: **LEVINE, David, A.**; P.O. Box 61180, Palo Alto, CA 94306-1180 (US).

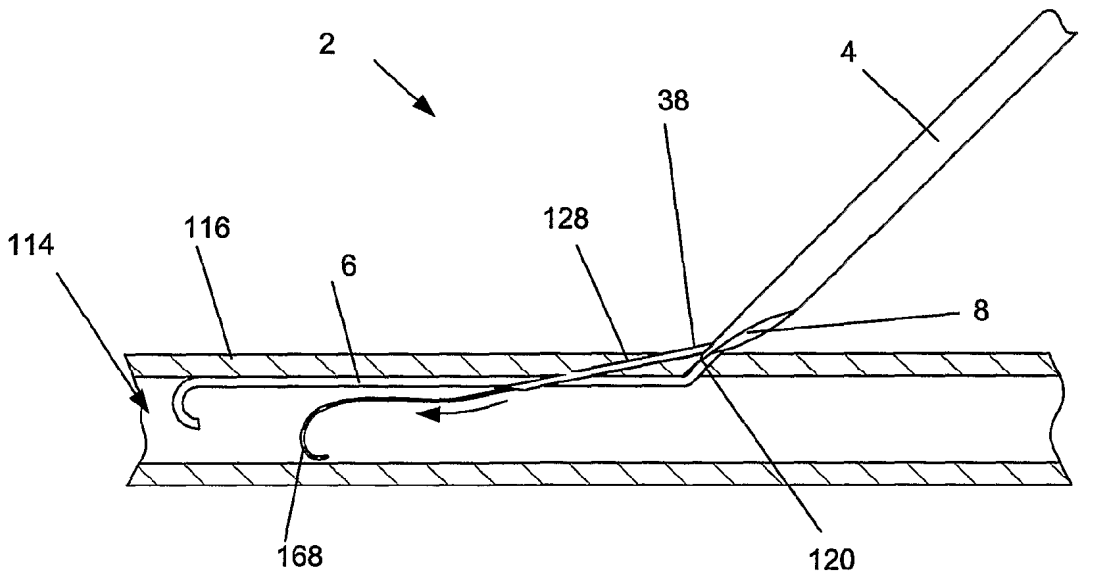
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK,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

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

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

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

(54) Title: ACCESS AND CLOSURE DEVICE AND METHOD



(57) **Abstract:** Devices and methods for accessing and closing vascular sites (114) are disclosed. Self-sealing closure devices (2) and methods are disclosed. A device (2) that can make a steep and controlled access path into a vascular lumen (114) is disclosed. Methods for using the device (2) are also disclosed.

WO 2005/112791 A2

TITLE OF THE INVENTION

ACCESS AND CLOSURE DEVICE AND METHOD

TECHNICAL FIELD

[0001] The present invention relates to the field of accessing a biological lumen and closing the access port thereby created.

BACKGROUND ART

[0002] A number of diagnostic and interventional vascular procedures are now performed translumenally, where a catheter is introduced to the vascular system at a convenient access location - such as the femoral, brachial, or subclavian arteries - and guided through the vascular system to a target location to perform therapy or diagnosis. When vascular access is no longer required, the catheter and other vascular access devices must be removed from the vascular entrance and bleeding at the puncture site must be stopped.

[0003] One common approach for providing hemostasis is to apply external force near and upstream from the puncture site, typically by manual compression. This method is time-consuming, frequently requiring one-half hour or more of compression before hemostasis. This procedure is uncomfortable for the patient and frequently requires administering analgesics. Excessive pressure can also present the risk of total occlusion of the blood vessel, resulting in ischemia and/or thrombosis.

[0004] After hemostasis is achieved by manual compression, the patient is required to remain recumbent for six to eighteen hours under observation to assure continued hemostasis. During this time bleeding from the vascular access wound can restart, potentially resulting in major complications. These complications may require blood transfusion and/or surgical intervention.

[0005] Bioabsorbable fasteners have also been used to stop bleeding. Generally, these approaches rely on the placement of a thrombogenic and bioabsorbable material, such as collagen, at the superficial arterial wall over the puncture site. This method generally presents difficulty locating the interface of the overlying tissue and the adventitial surface of the blood vessel. Implanting the fastener too far from the desired location can result in failure to provide hemostasis. If, however, the fastener

intrudes into the vascular lumen, thrombus can form on the fastener. Thrombus can embolize downstream and/or block normal blood flow at the thrombus site. Implanted fasteners can also cause infection and auto-immune reactions/rejections of the implant.

[0006] Suturing methods are also used to provide hemostasis after vascular access. The suture-applying device is introduced through the tissue tract with a distal end of the device located at the vascular puncture. Needles in the device draw suture through the blood vessel wall on opposite sides of the punctures, and the suture is secured directly over the adventitial surface of the blood vessel wall to close the vascular access wound.

[0007] To be successful, suturing methods need to be performed with a precise control. The needles need to be properly directed through the blood vessel wall so that the suture is well anchored in tissue to provide for tight closure. Suturing methods also require additional steps for the surgeon.

[0008] Due to the deficiencies of the above methods and devices, a need exists for a more reliable vascular closure method and device. There also exists a need for a vascular closure device and method that does not implant a foreign substance and is self-sealing. There also exists a need for a vascular closure device and method requiring no or few extra steps to close the vascular site.

DISCLOSURE OF INVENTION

[0009] A device for accessing a biological lumen is disclosed. The biological lumen has a lumen wall having a longitudinal lumen wall axis. The device has an elongated member that has a longitudinal member axis. The member is configured to access the lumen at a first angle. The first angle is defined by the longitudinal lumen wall axis and the longitudinal member axis. The first angle is less than about 19 degrees.

[0010] The first angle can be less than about 15 degrees. The first angle can be less than about 10 degrees. The device can also have an anchor. The anchor can be configured to hold the elongated member at a fixed angle with respect to the longitudinal lumen wall axis.

[0011] The device can also have a retainer. The retainer can be configured to hold the elongated member at a fixed angle with respect to the longitudinal lumen axis.

[0012] Another device for accessing a biological lumen is disclosed. The biological lumen has a lumen wall and a longitudinal lumen wall axis. The device has a first elongated member and a second elongated member. The first elongated member has a first elongated member axis. The second elongated member has a second elongated member axis. The second elongated member is configured so that the second elongated member axis is parallel to the longitudinal lumen wall axis.

[0013] The second elongated member can have a retainer. The retainer can have an inflatable member. The retainer can have a resilient member. The second elongated member can extend substantially adjacent to the lumen wall.

[0014] Also disclosed is a device for closing an opening on a biological lumen wall. The device has a longitudinal axis, a first force-applying member, a second force-applying member, and a resilient member. The resilient member provides to the first and the second force-applying members a force that is radially outward with respect to the longitudinal axis.

[0015] A method of accessing a blood vessel through a blood vessel wall is also disclosed. The blood vessel wall has a longitudinal wall axis. The method includes entering the vessel at an angle of less than about 19 degrees with respect to the longitudinal wall axis. The method also includes inserting a lumenal tool into the vessel.

[0016] Also disclosed is a method for accessing a biological lumen. The biological lumen has a lumen wall and a longitudinal lumen wall axis. The method includes inserting in the biological lumen a second elongated member. The second elongated member has a second elongated member axis. The method also includes aligning the second elongated member so that the second elongated member axis is substantially parallel to the longitudinal lumen wall axis. Further, the method includes inserting in the biological lumen a first elongated member comprising a first elongated member axis.

[0017] Additionally disclosed is a method of closing a vascular opening. The vascular opening has an inside surface and a longitudinal axis. The method includes inserting a device in the opening and applying a force to the inside surface. The force is directed in at least one radially outward direction from the longitudinal axis.

[0018] The method can include maintaining the force. The applying a force can include the device applying at least a part of the force. The applying of a force can include the device applying all of the force.

[0019] Also disclosed is a method for accessing and closing a blood vessel having a vessel wall. The vessel wall can have an inside surface and an outside surface. The method includes forming an arteriotomy and deploying a closure augmentation device in the arteriotomy. The closure augmentation device produces pressure on the inside surface and the outside surface.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] Figure 1 is a front perspective view of an embodiment of the arteriotomy device.

[0021] Figure 2 is a side view of the arteriotomy device of Figure 1.

[0022] Figure 3 is a close-up view of the arteriotomy device of Figure 1.

[0023] Figures 4 and 5 are close-up views of various embodiments of the anchor.

[0024] Figure 6 is a side perspective view of an embodiment of the arteriotomy device with the introduction device deployed.

[0025] Figure 7 is a close-up view of an embodiment of the arteriotomy device with the introduction device deployed.

[0026] Figures 8 and 9 are side views of various embodiments of the arteriotomy device with the introduction devices deployed.

[0027] Figure 10 is a bottom perspective view of an embodiment of the arteriotomy device.

[0028] Figure 11 is a side view of an embodiment of the arteriotomy device with the lumenal retainer deployed.

[0029] Figure 12 is a bottom perspective view of an embodiment of the arteriotomy device with the lumenal retainer deployed.

[0030] Figure 13 is a side perspective view of an embodiment of the arteriotomy device.

[0031] Figure 14 is a side perspective view of an embodiment of the arteriotomy device with the entry wall retainer deployed.

[0032] Figures 15 and 16 illustrate various embodiments of the tensioner.

[0033] Figures 17 and 18 illustrate various embodiments of the pressure clip.

[0034] Figures 19 and 20 illustrate various embodiments of the toggle.

[0035] Figure 21 illustrates a method for deploying the arteriotomy device in a cross-section of a lumen.

[0036] Figures 22 and 23 illustrate methods for deploying the retainers in a cross-section of a lumen.

[0037] Figures 24 and 25 illustrate a method for deploying the introduction device in a cross-section of a lumen.

[0038] Figure 26 illustrates a method for deploying a guidewire in a cross-section of a lumen.

[0039] Figures 27-30 illustrate a method for deploying the introduction device in a cross-section of a lumen.

[0040] Figure 31 illustrates a method for deploying a guidewire in a cross-section of a lumen.

[0041] Figure 32 illustrates a portion of an arteriotomized lumen.

[0042] Figure 33 illustrates section A-A of Figure 28.

[0043] Figures 34-36 illustrate a method for deploying a tensioner in a see-through portion of lumen wall.

[0044] Figures 37-40 illustrate methods for deploying various embodiments of the pressure clip in a cross-section of a lumen.

[0045] Figure 41 illustrates a method of using a suture on a portion of an arteriotomized lumen.

[0046] Figure 42 illustrates section B-B of Figure 41 with the out-of-section suture.

[0047] Figure 43 illustrates a method of using pledgets on a portion of an arteriotomized lumen.

[0048] Figure 44 illustrates section C-C of Figure 43.

[0049] Figure 45 illustrates an embodiment of the toggle deployment device in a first configuration.

[0050] Figure 46 is a close-up view of Figure 45.

[0051] Figure 47 illustrates an embodiment of the toggle deployment device in a second configuration.

[0052] Figure 48 is a close-up view of Figure 47.

[0053] Figure 49 illustrates a method of using the toggle deployment device in a cross-section of a lumen.

[0054] Figure 50 illustrates Figure 49 with a portion of the toggle deployment device shown in section D-D.

[0055] Figure 51 illustrates a method of using the toggle deployment device in a cross-section of a lumen.

[0056] Figure 52 illustrates Figure 51 with a portion of the toggle deployment device shown in section E-E.

[0057] Figures 53-55 illustrate a method of using the toggle deployment device in a cross-section of a lumen.

[0058] Figure 56 is a close-up view of Figure 55.

[0059] Figure 57 illustrates an embodiment of a deployed toggle in a cross-section of a lumen.

[0060] Figure 58 is a close-up view of Figure 59.

[0061] Figures 59-61 illustrate a method for deploying a toggle in a cross-section of a lumen.

[0062] Figure 62 is a close-up view of Figure 61.

[0063] Figure 63 illustrates a method for deploying a toggle in a cross-section of a lumen.

[0064] Figures 64-66 shown, in cross-section, a method for deploying the guidewire through an arteriotomy.

[0065] Figures 67 and 68 illustrate a method for attaching guidewire to the anchor.

DETAILED DESCRIPTION AND INDUSTRIAL APPLICABILITY

[0066] Figures 1 through 3 illustrate a device for accessing a biological lumen, such as an arteriotomy device 2. The arteriotomy device 2 can have a delivery guide 4. The delivery guide 4 can be slidably attached to an anchor 6. The anchor 6 can be rigid, flexible or combinations thereof. The anchor 6 can be resilient, deformable or combinations thereof. The anchor 6 can be retractable and extendable from the delivery guide 4. The delivery guide 4 can have an introducer lumen 8. The introducer lumen 8 can have an introducer lumen exit port 10. The introducer lumen exit port 10 can be on the surface of the delivery guide 4.

[0067] The anchor 6 can have an anchor angle section 12. The anchor 6 can have an anchor extension section 14, for example a guide eye sheath or an attachable

guidewire. The anchor extension section 14 can extend from the anchor angle section 12. The anchor extension section 14 can be separate from and attached to, or integral with, the anchor angle section 12.

[0068] The anchor angle section 12 can have an anchor angle first sub-section 16, an anchor bend 20 and an anchor angle second sub-section 18. The anchor angle first and/or second sub-sections 16 and/or 18 can be part of the anchor bend 20. The anchor bend 20 can have a sharp or gradual curve. The radius of curvature for the anchor bend 20 can be from about 0.1 mm (0.004 in.) to about 2.0 mm (0.079 in.).

[0069] The anchor angle first sub-section 16 can have an anchor angle first sub-section diameter 22 from about 0.38 mm (0.015 in.) to about 1.0 mm (0.039 in.), for example about 0.71 mm (0.028 in.). The anchor angle second sub-section 18 can have an anchor angle second sub-section diameter 24 from about 0.38 mm (0.015 in.) to about 1.0 mm (0.039 in.), for example about 0.71 mm (0.028 in.).

[0070] The anchor angle first sub-section 16 can have a delivery longitudinal axis 26. The anchor angle second sub-section 18 can have an anchor longitudinal axis 28. The intersection of the delivery longitudinal axis 26 and the anchor longitudinal axis 28 can be an anchoring angle 30. The anchoring angle 30 can be from about 20° to about 90°, more narrowly from about 30° to about 60°, for example about 45°.

[0071] Any or all elements of the arteriotomy device 2 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), 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 polyester (e.g., DACRON® from E. I. Du Pont de Nemours and Company, Wilmington, DE), polypropylene, 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), polydioxanone, and pseudo-polyamino tyrosine-based acids, extruded collagen, silicone, zinc, echogenic, radioactive, radiopaque materials or combinations thereof. Examples of radiopaque materials are barium sulfate, zinc oxide, titanium, stainless steel, nickel-titanium alloys, tantalum and gold.

[0072] Any or all elements of the arteriotomy device 2, including supplemental closure devices, such as tensioners, clips, toggles, sutures, 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.

[0073] The elements of the arteriotomy device 2 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.

[0074] Figure 4 illustrates that the anchor angle section 12 and the anchor extension section 14 can have a flexible elongated element. The flexible elongated element can be resilient and/or deformable. The flexible elongated element can have an integral, or multiple separate and fixedly attached, wound wire 32. The anchor angle section 12 can be in a sheath 34. Figure 5 illustrates that the anchor angle section 12 can have a wire coating 36, for example a lubricious coating and/or a coating made from urethane.

[0075] Figures 6 and 7 illustrate that the arteriotomy device 2 can have an introduction device 38. The introduction device 38 can be slidably attached to the introducer lumen 8. The introduction device 38 can have a hollow needle (as shown in Figure 6). The introduction device 38 can have a solid needle (as shown in Figure 7). The introduction device 38 can have a guidewire.

[0076] The introduction device 38 can have an introduction longitudinal axis 40. The intersection of the introduction longitudinal axis 40 and the anchor longitudinal axis 28 can be an introduction angle 42. The introduction angle 42 can be less than or equal to about 19°, more narrowly less than or equal to about 15°, yet more narrowly from about 5° to about 10°, for example about °10.

[0077] The introduction device 38 can have an introduction device diameter 44. The introduction device diameter 44 can be from about 0.25 mm (0.010 in.) to about 1.0 mm (0.039 in.), for example about 0.56 mm (0.022 in.).

[0078] Figures 8 and 9 illustrate that the arteriotomy device 2 can be configured so that the introduction device 38 can be deployed from the anchor 6. The anchor 6 can have an introduction device port 46. The introduction device 38 can be a hollow needle (as shown in Figure 8). When fully deployed, the introduction device 38 can contact the introducer lumen exit port 10. The introduction device 38 can be a channel between the introducer lumen 8 and the anchor 6. The anchor 6 can have a port (not shown) configured to communicate with the biological lumen and the

introduction device 38. The introduction device 38 can be a solid needle (as shown in Figure 9).

[0079] Figure 10 illustrates that a lumenal retainer 48 can have a first retracted configuration. The lumenal retainer 48 can be seated in a lumenal retainer port 50. The lumenal retainer port 50 can be in the anchor 6. The lumenal retainer 48 can be a wire, scaffold or stent - for example made from a deformable or resilient material, such as a shape memory alloy - an inflatable balloon, or combinations thereof. Intralumenal inflatable balloons, such as those inflated with saline solution or carbon dioxide, are known to those having ordinary skill in the art. The lumenal retainer 48 can extend into the delivery guide 4.

[0080] Figures 11 and 12 illustrate that the lumenal retainer 48 can have a second deployed configuration. Figure 11 shows that the lumenal retainer 48 can be a wire or balloon. Figure 12 shows that the lumenal retainer 48 can be a wire. In the deployed configuration, the lumenal retainer 48 can deploy away from the lumenal retainer port. The lumenal retainer 48 can have a lumenal retainer deployed diameter 52. The lumenal retainer deployed diameter 52 can be from about 2.54 mm (0.100 in.) to about 10.2 mm (0.400 in.), for example about 6.35 mm (0.250 in.).

[0081] Figure 13 illustrates that the arteriotomy device 2 can have an entry wall retainer port 54. The entry wall retainer port 54 can be at or near the anchor bend 20. The entry wall retainer port 54 can be at or near the anchor angle first sub-section 16. The entry wall retainer port 54 can be in fluid communication with a sensor or port (not shown) on or near the delivery guide 4 of the arteriotomy device 2.

[0082] Figure 14 illustrates that an entry wall retainer 56 can be deployed through the entry wall retainer port 54. The entry wall retainer 56 can have a first retracted configuration (as shown in Figure 13). The entry wall retainer 56 can have a second deployed configuration (as shown in Figure 14).

[0083] Figures 15 through 20 illustrate various supplemental closure devices. The supplemental closure devices can be completely or partially bioabsorbable, bioresorbable, bioadsorbable or combinations thereof. The supplemental closure devices can be made from homografts, heterografts or combinations thereof. The supplemental closure devices can be made from autografts, allografts or combinations thereof.

[0084] Figure 15 illustrates a tensioner 58. The tensioner 58 can be resilient, deformable, or combinations thereof. The tensioner 58 can have a tensioner longitudinal axis 60. The tensioner 58 can have a resilient element, such as a spring, for example a tensioner head 62. The tensioner head 62 can have a tensioner first shoulder 64. The tensioner head 62 can have a tensioner second shoulder 66. The tensioner first and second shoulders 64 and 66 can rotatably attached to a separate or integral tensioner first leg 68 and a separate or integral tensioner second leg 70, respectively. The tensioner first and second legs 68 and 70 can attach to tensioner first and second feet 72 and 74, respectively.

[0085] The tensioner legs 68 and 70 can have tensioner leg diameters 76. The tensioner leg diameters 76 can be from about 0.1 mm (0.005 in.) to about 0.76 mm (0.030 in.), for example about 0.38 mm (0.015 in.). The tensioner first and second legs 68 and 70 can have a tensioner inter-leg outer diameter 78. The tensioner inter-leg outer diameter 78 can be from about 1.3 mm (0.050 in.) to about 5.08 mm (0.200 in.), for example about 4.06 mm (0.160 in.). The tensioner shoulders 64 and/or 66 and/or the tensioner feet 72 and/or 74 can extend to a greater radius from the tensioner longitudinal axis 60 than their respective tensioner inter-leg radius.

[0086] Figure 16 illustrates a tensioner first strut 80 that can attach to the tensioner first leg 68 and the tensioner second leg 70. The tensioner first leg 68 can be resilient, deformable or combinations thereof. A tensioner second strut 82 can attach to the tensioner first leg 68 and the tensioner second leg 70. The tensioner second leg 70 can be resilient and/or deformable. The tensioner 58 can have no tensioner head 62. The tensioner 58 can have more than two tensioner struts 80 and 82.

[0087] Figure 17 illustrates a pressure clip 84. The pressure clip 84 can be resilient. The pressure clip 84 can be deformable. The pressure clip 84 can have a pressure clip longitudinal axis 86. The pressure clip 84 can have a pressure clip head 88. The pressure clip head 88 can be rotatably attached to a separate or integral pressure clip first leg 90. The pressure clip head 88 can be rotatably attached to a separate or integral pressure clip second leg 92. The pressure clip can have a pressure clip first end 94 and a pressure clip second end 96. The pressure clip first leg 90 can terminate in the pressure clip first end 94. The pressure clip second leg 92 can terminate in the pressure clip second end 96. The pressure clip first leg 90 and/or the pressure clip second leg 92 can be biased toward the pressure clip longitudinal axis 86.

[0088] Figure 18 illustrates the pressure clip 84 that can have a pressure clip sheath 98 slidably attached to the pressure clip second leg 92. The pressure clip first and/or second ends 94 and/or 96 can be pressure dissipaters, such as flat and/or curved portions, for example circular loops. The pressure clip first and/or second ends 94 and/or 96 can be resilient and/or deformable. The pressure clip first leg 90 can be rotatably attached to the pressure clip second leg 92. The pressure clip first leg 90 can be attached to the pressure clip second leg 92 via a rotatable, and/or deformable, and/or flexural joint in the pressure clip head 88.

[0089] Figure 19 illustrates a toggle 100. The toggle 100 can have a toggle first end 102. The toggle 100 can have a toggle second end 104. The toggle first and/or second ends 102 and/or 104 can be bars, dowels, rods, beams, or combinations thereof. The toggle 100 can have a filament 106. The filament 106 can be fixedly attached at a filament first end 107 to the toggle first end 102. The filament 106 can be fixedly attached at a filament second end 109 to the toggle second end 104. The filament 106 can be resilient or deformable. The filament 106 can be substantially flexible.

[0090] Figure 20 illustrates the toggle 100 that can have the filament 106 that can be slidably attached to the toggle second end 104 at a hole 108. The filament 106 can frictionally fit the hole 108. The filament 106 can have no pawls 110 (not shown in Figure 20). The filament 106 can interference fit the hole 108. The filament 106 can have one or more pawls 110. The hole 108 can have one or more notches 112. The notches 112 can be internal to the hole 108. The notches 112 and the pawls 110 can be configured to allow the toggle second end 104 to slide toward the toggle first end 102. The notches 112 and the pawls 110 can be configured to provide an interference fit when the toggle second end 104 is attempted to be moved away from the toggle first end 102.

METHOD OF MANUFACTURE

[0091] The elements of the arteriotomy device 2, including the supplemental closure devices, can be directly attached by, for example, melting, screwing, gluing, welding or use of an interference fit or pressure fit such as crimping, snapping, or combining methods thereof. The elements can be integrated, for example, molding, die cutting, laser cutting, electrical discharge machining (EDM) or stamping from a single piece

or material. Any other methods can be used as known to those having ordinary skill in the art.

[0092] Integrated parts can be made from pre-formed resilient materials, for example resilient alloys (e.g., Nitinol, ELGILOY®) that are preformed and biased into the post-deployment shape and then compressed into the deployment shape as known to those having ordinary skill in the art.

[0093] Any elements of the arteriotomy device 2, including the supplemental closure devices, or the arteriotomy device 2, including the supplemental closure devices, as a whole after assembly, can be coated by dip-coating, brush-coating or spray-coating methods known to one having ordinary skill in the art. For example, these methods can be used to coat the wound wire 32 with the wire coating 36 can be spray coated, dip-coated or brushed onto the wire 32.

[0094] One example of a method used to coat a medical device for vascular use is provided in U.S. Patent No. 6,358,556 by Ding et al. and hereby incorporated by reference in its entirety. Time release coating methods known to one having ordinary skill in the art can also be used to delay the release of an agent in the coating, for example the coatings on the supplemental closure devices.

[0095] The supplemental closure devices can be covered with a fabric, 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. Methods of covering an implantable device with fabric are known to those having ordinary skill in the art.

METHOD OF USE

[0096] Figure 21 illustrates a method of inserting the anchor 6 into a biological lumen 114, for example a blood vessel, such as a femoral artery. The biological lumen 114 can have a lumen wall 116 and a lumen wall surface 118. The anchor 6 can be inserted into the biological lumen 114 using a Seldinger technique, modified Seldinger technique, or other method known to one having ordinary skill in the art. The anchor 6 can create a first arteriotomy 120. The anchor 6 can be inserted into the lumen 114 so that the anchor angle second sub-section 18 can be substantially parallel with the lumen wall surface 118. The anchor 6 can be inserted into the lumen 114 so

that the anchor angle second sub-section 18 can be substantially in contact with the lumen wall surface 118.

[0097] Figure 22 illustrates a method of deploying, as shown by arrow, the lumenal retainer 48 from the first retracted configuration to the second deployed configuration. The lumenal retainer 48 can be deployed by extending a wire, scaffold or stent, or by inflating a balloon. When the lumenal retainer 48 is deployed, the anchor angle second sub-section 18 can be made substantially parallel with the lumen wall surface 118. When the lumenal retainer 48 is deployed, the anchor angle second sub-section 18 can be made to be substantially in contact with the lumen wall surface 118.

[0098] Figure 23 illustrates a method of deploying, as shown by arrow 122, the entry wall retainer 56 from the first retracted configuration to the second deployed configuration. When the lumenal retainer is in the second deployed configuration, the lumenal retainer 48 can be substantially parallel with the lumen wall surface 118. When the lumenal retainer is in the second deployed configuration, the lumenal retainer 48 can be substantially in contact with the lumen wall surface 118.

[0099] A proximal force, as shown by arrow 124, can be applied to the anchor 6, for example by being applied to the delivery guide 4. When the proximal force is applied, the anchor angle second sub-section 18 can be made substantially parallel with the lumen wall surface 118. When the proximal force is applied, the anchor angle second sub-section 18 can be made to be substantially in contact with the lumen wall surface 118.

[0100] Figures 24 and 25 illustrate a method for deploying the introduction device 38. The introduction device 38 can egress from the introducer lumen 8 and the introducer lumen exit port 10. As shown in Figure 24, the introduction device 38 can be pushed, as shown by arrow, into and through the lumen wall 116. The introduction device 38 can form a second arteriotomy 128. As shown in Figure 25, the introduction device 38 can be pushed, as shown by arrow, adjacent to or through the anchor 6. The anchor 6 can be configured to have ports suitable to allow the introduction device 38 to pass through the anchor 6. A tip of the introduction device 38 can enter the lumen 114.

[0101] The introduction device 38 can pass through an introduction run 132 and an introduction rise 134. The introduction run 132 can be the component of the length of the introduction device 38 in the lumen wall 116 that is parallel to the lumen wall 116.

The introduction run 132 can be the component of the length parallel to the lumen wall 116 between the opening of the second arteriotomy 128 on the outside of the lumen wall 116 and the opening of the second arteriotomy 128 on the inside lumen wall surface 118. The introduction run 132 can be from about 0.10 cm (0.010 in.) to about 3.810 cm (1.500 in.), for example about 0.64 cm (0.25 in.).

[0102] The introduction rise 134 can be the component of the length of the introduction device 38 in the lumen wall 116 that is perpendicular to the lumen wall 116. The introduction rise 134 can be the component of the length perpendicular to the lumen wall 116 between the opening of the second arteriotomy 128 on the outside of the lumen wall 116 and the opening of the second arteriotomy 128 on the inside lumen wall surface 118. The introduction rise 134 can be from about 0.51 mm (0.020 in.) to about 5.08 mm (0.200 in.), for example about 1.0 mm (0.040 in.). An introduction slope can be the ratio of the introduction rise 134 to the introduction run 132. The introduction slope can be from about $^1/_2$ to about $^1/_{40}$ or less, for example about $^1/_6$, also for example about $^1/_3$. The introduction slope can be, for examples, equal to or less than about $^1/_2$ or $^1/_3$, more narrowly equal to or less than about $^1/_3$ or $^1/_4$, yet more narrowly equal to or less than about $^1/_5$ or $^1/_6$, even still more narrowly than about equal to or less than about $^1/_{10}$.

[0103] The introduction rise 134 and the introduction run 132 can be components of an introduction vector. The introduction run 132 can be the component of the introduction vector parallel to the lumen wall 116. The introduction rise 134 can be the component of the introduction vector perpendicular to the lumen wall 116. The introduction vector can be a vector from an outer opening 136 to an inner opening 138. The outer opening 136 can be a temporary or permanent opening on the outside of the lumen wall 116 formed by the introduction device 38. The inner opening 138 can be a temporary or permanent opening on the inside of the vessel wall.

[0104] Figure 26 illustrates that the introduction device 38, for example a hollow needle, can act as a pathway for a lumenal tool, for example tools such as a guidewire 168, to be deployed, as shown by arrow, into the lumen 114. The introduction device 38, for example a solid needle, can be removed from the second arteriotomy 128 and the lumenal tool can be deployed through, for example, the introducer lumen exit port 10, and the second arteriotomy 128. The introduction device 38 can be the lumenal

tool, for example a guidewire. The introduction device 38 can be further deployed and used as a lumenal tool after passing through the lumen wall 116.

[0105] Figures 27 through 30 illustrates a method of deploying the introduction device 38 that can have a pre-formed bend. As shown in Figure 27, the arteriotomy device 2 can be configured to deploy the introduction device 38 at the introduction angle 42 from about 0° to about 5°, for example about 0°.

[0106] As shown in Figure 28, the introduction device 38 can be pushed, as shown by arrow, through the lumen wall 116. The introduction device 38 can cleave a plane in the lumen wall 116. The plane can be substantially parallel with the lumen wall surface 118. The introduction device 38 can be adjacent to the adventitia in a blood vessel. The introduction device 38 can be advanced along the subintimal or submedial cleavage plane in a blood vessel. Once the lumen wall has been cleaved, a subintimal angioplasty can be performed as known to one having ordinary skill in the art. Once the lumen wall has been cleaved, a remote endarterectomy can be performed as known to one having ordinary skill in the art. Bent and straight introduction devices 38 can be swapped during use to selectively cleave the lumen wall 116. Tools, such as guidewires, can be inserted through hollow introduction devices 38 to selectively cleave the lumen wall 116.

[0107] As shown in Figure 29, when the bend in the introduction device 38 moves into the lumen wall 116, the introduction device 38 can rotate, as shown by arrow, toward the biological lumen 114. As shown in Figure 30, the bend in the introduction device 38 can continue to rotate the introduction device 38 toward the biological lumen 114. As described infra, the introduction device 38 can enter the lumen 114. Figure 31 illustrates that the introduction device 38 that can have the bend can act as a pathway for a lumenal tool, as described infra.

[0108] An introducer sheath can be inserted over the guidewire 168 and/or the introduction device 38. The introducer sheath can be less than about 22 French (7.3 mm, 0.29 in. diameter) or less than the diameter of the lumen to which the introducer sheath is introduced. The introducer sheath can be, for examples, about 6 French (2.3 mm, 0.092 in. diameter), and about 8 French (2.67 mm, 0.105 in. diameter). The introducer sheath can be known to one having ordinary skill in the art, for example the introducer sheath described in U.S. Patent No. 5,183,464 to Dubrul, et al.

[0109] The introducer sheath can be inserted into the second arteriotomy 128. The introducer sheath can expand the second arteriotomy 128 to a workable size. The introducer sheath can be inserted into the second arteriotomy 128 before and/or after and/or concurrently with the supplemental closure device is deployed and/or other closure method is used.

[0110] Figures 32 and 33 illustrate an exemplary biological lumen 114 after the arteriotomy device 2 has been deployed to, and removed from, the biological lumen 114. The biological lumen 114 can have the first and second arteriotomies 120 and 128. The biological lumen 114 can have a second arteriotomy 128. The biological lumen 114 can have a first web 140 on one side of the arteriotomy (shown for the second arteriotomy 128), and a second web 142 on the opposite side of the arteriotomy 120 or 128. The natural pressure, shown by arrows, from the first and second webs 140 and 142 can self-seal the arteriotomy 120 or 128.

[0111] One or more supplemental closure devices can be deployed to the first and/or second arteriotomies 120 and/or 128. The supplemental closure devices can provide a force or restraint to aid hemostasis. The supplemental closure devices can be permanently or temporarily deployed. The supplemental closure devices can biodissolve after hemostasis is achieved and/or after the relevant arteriotomy 120 or 128 is substantially or completely healed. The force from the supplemental closure device can be maintained from about 15 minutes to about 24 hours or more, for example about 120 minutes.

[0112] Figure 34 illustrates a tensioner 58 in a compressed configuration. Compressive forces, shown by arrows, can compress the tensioner first and second legs 68 and 70. In a compressed configuration, the tensioner inter-leg outer diameter 78 can be from about 0.51 mm (0.020 in.) to about 2.54 mm (0.100 in.), for example about 1.5 mm (0.060 in.).

[0113] Figures 35 and 36 illustrate a method of deploying the tensioner 58. As shown in Figure 35, the tensioner 58 can be in a compressed configuration. The tensioner 58 can be exposed to the compressive forces, as shown by arrows 144. The compressive forces can be applied by a retractable sheath, clamps, other methods known to one having ordinary skill in the art, or combinations thereof. A deployment force, shown by arrow 146, can deploy the tensioner 58 into the arteriotomy 120 or 128.

[0114] The arteriotomy 120 or 128 can have an arteriotomy diameter 148. The arteriotomy diameter 148 can be from about 0.5 mm (0.020 in.) to about 400 mm (15 in.), yet a narrower range from about 1.0 mm (0.040 in.) to about 10.2 mm (0.400 in.), for example about 2.54 mm (0.100 in.). When in the compressed configuration, the tensioner inter-leg outer diameter 78 can be smaller than the arteriotomy diameter 148. The tensioner first and second shoulders 64 and 66 can be wide enough to interference fit with the arteriotomy 120 or 128. The tensioner first and second shoulders 64 and 66 can dissipate force on the lumen wall surface 118.

[0115] As shown in Figure 36, the compressive forces can be removed from the tensioner 58. The tensioner first and second leg 68 and 70 can expand, as shown by arrows. The tensioner 58 can force the arteriotomy 120 or 128 into a substantially or completely flat and/or closed and/or stretched configuration. The walls of the arteriotomy 120 or 128 can come into close contact.

[0116] The arteriotomy 120 or 128 can have an arteriotomy width 150 and an arteriotomy height 152. The arteriotomy width 150 can be about half the circumference of the arteriotomy 120 or 128. The arteriotomy width 150 can be from about 1.0 mm (0.040 in.) to about 10.2 mm (0.400 in.), for example about 4.06 mm (0.160 in.).

[0117] The arteriotomy height 152 can be about the tensioner leg diameter 76. The arteriotomy height 152 can be less than about 0.51 mm (0.020 in.), more narrowly, less than about 0.38 mm (0.015 in.). The arteriotomy height 152 can be from about 0.25 mm (0.010 in.) to about 1.3 mm (0.050 in.), for example about 0.38 mm (0.015 in.). The arteriotomy height 152 can be small enough to enable cell growth, blood clotting, acoustic sealing, heat sealing, gluing, enhanced self-sealing and combinations thereof across the arteriotomy 120 or 128.

[0118] The tensioner first and second shoulders 64 and 66 can be wide enough to interference fit with the arteriotomy 120 or 128. The tensioner first and second feet 72 and 74 can be wide enough to interference fit with the arteriotomy 120 or 128. The tensioner first and second feet 72 and 74 can dissipate force on the lumen wall surface 118.

[0119] The arteriotomy 120 or 128 can be plugged, and/or packed, and/or tamponed before, and/or concurrent with, and/or after using any of any of the supplemental closure devices infra and/or supra, the self-sealing closure method, or combinations

thereof. The plug, pack, tampon, or combinations thereof (not shown) can be made from gelfoam, collagen, other implantable and biocompatible tampon materials known to those having ordinary skill in the art, or combinations thereof.

[0120] Figures 37 through 40 illustrate deploying the pressure clip 84 to the arteriotomy 120 or 128. Figure 37 illustrates extending, and/or thinning, and/or straightening, and/or tensioning the pressure clip second end 96. The pressure clip sheath 98 can be translated, as shown by arrow, along the pressure clip second leg 92 and onto the pressure clip second end 96. The pressure clip 84 can be deployed to the arteriotomy after the pressure clip second end 96 is extended, and/or thinned, and/or straightened, and/or tensioned.

[0121] As shown in Figure 38, the pressure clip second leg 92 can be rotated with respect to the pressure clip head 88, so that the pressure clip second leg 92 and the pressure clip head 88 are substantially aligned. The pressure clip second leg 92 can be deployed, as shown by the arrow, through the first arteriotomy 120. The pressure clip second leg 92 can be deployed through the lumen wall 116 (e.g., if there is no existing first arteriotomy 120, if the first arteriotomy 120 is not suitably located with respect to the second arteriotomy 128).

[0122] Figure 39 illustrates contracting, and/or widening, and/or releasing and/or relaxing the pressure clip second end 96. The pressure clip sheath 98 can be translated, as shown by arrow, along the pressure clip second leg 92 and off of the pressure clip second end 96. The pressure clip second end 96 can be contracted, and/or widened, and/or released and/or relaxed after the pressure clip 84 is deployed to the arteriotomy.

[0123] As shown in Figure 40, after the pressure clip second leg 92 is deployed through the first arteriotomy 120, the pressure clip second leg 92 can be released or deformed so as to rotate with respect to the pressure clip head 88. The pressure clip head 88 can seat in the first arteriotomy 120. The pressure clip first and second legs 90 and 92 can apply force, as shown by arrows, to the first and second webs 140 and 142, respectively.

[0124] Figures 41 and 42 illustrate a method of deploying a stitch 154 surrounding and/or through the arteriotomy 120 or 128. The stitch 154 can be tightened to apply additional pressure to the arteriotomy 120 or 128. The stitch 154 can have a knot 156, or other tying configuration or device, for example a pledget or clamp.

[0125] Figures 43 and 44 illustrate a method of deploying the filament 106 adjacent to and/or through the arteriotomy 120 or 128. The filament 106 can be attached to a first pledget 158a by a first knot 156a or other tying configuration or device. The filament 106 can be attached to a second pledget 158b by a second knot 156b or other tying configuration or device. The first and second pledgets 158a and 158b can be other pressure diffusers known to one having ordinary skill in the art, such as the toggles 100 described infra and supra.

[0126] Figures 45 and 46 illustrate a toggle deployment device 159 that can be in a first retracted configuration. The toggle deployment device 159 can have a pressure check port 160. The pressure check port 160 can be in fluid communication with a sensor or port on or near the handle (not shown) of the toggle deployment device 159, such as an external lumen where blood flow can be observed, for example from flow from the end of an external tube or port and/or through a transparent or translucent window. The pressure check port 160 can facilitate deployment of the toggle deployment device 159 to a location where the pressure check port 160 is introduced to pressure, for example when the pressure check port 160 enters the biological lumen 114. The sensor or port on or near the handle of the toggle deployment device 159 will signal that the pressure check port 160 has been placed into the biological lumen 114 (e.g., by displaying a small amount of blood flow). The pressure check port 160 can be deployed into the biological lumen 114 and then withdrawn from the biological lumen 114 to the point where the lumen wall 116 just stops the pressure in the pressure check port 160. The entry wall retainer port 54 can additionally perform the function as described herein for the pressure check port 160. The toggle deployment device 159 can have a delivery needle port 161.

[0127] Figures 47 and 48 illustrate the toggle deployment device 159 that can be in a second delivery configuration. A delivery needle 162 can be slidably attached to the toggle deployment device 159. The delivery needle 162 can egress from the delivery needle port 161 when the toggle deployment device 159 is in the second delivery configuration.

[0128] Figures 49 and 50 illustrate that the toggle deployment device 159 can be deployed into the arteriotomy 120 or 128 at a location where the pressure check port 160 can be located in the biological lumen 114. The delivery needle port 161 can be in, or adjacent to, the lumen wall 116.

[0129] Figures 51 and 52 illustrate that the toggle deployment device 159 can be placed in the second delivery configuration. If the delivery needle port is in, or adjacent to, the lumen wall 116 when the toggle deployment device 159 is placed in the second delivery configuration, the delivery needle 162 can enter the lumen wall 116. For example, the delivery needle 162 can enter the second web 142. The delivery needle 162 can exit the second web 142 and enter, as shown by arrows, the biological lumen 114.

[0130] Figure 53 illustrates that a pusher 164 can be slidably attached to the delivery needle 162. The delivery needle 162 can have a needle tip port 166. The toggle 100 can be in the delivery needle 162. The toggle 100 can be configured in the delivery needle 162 such that the toggle first end 102 can be located on the needle tip port 166 -side of the pusher 164.

[0131] Figure 54 illustrates that the pusher 164 can be moved, as shown by arrow, toward the needle tip port 166. The delivery needle 162 can be moved back relative to the pusher 164, the pusher 164 can be moved forward relative to the delivery needle 162, or combinations thereof. The pusher 164 can push the toggle first end 102 out of the delivery needle 162. The pusher 164 can push the toggle first end 102 into the biological lumen 114.

[0132] Figures 55 and 56 illustrate that the toggle deployment device 159 can be in a first retracted configuration after deploying the toggle first end 102 into the biological lumen 114. When the delivery needle 162 retracts into the toggle deployment device 159, the toggle second end 104 can be in the toggle deployment device 159. The filament 106 can extend though the delivery needle port 161.

[0133] Figures 57 and 58 illustrate that the toggle 100 can be deployed across the lumen wall. When the toggle deployment device 159 is removed from the arteriotomy, the toggle second end 104 can deploy on the outside of the lumen wall 116 from the delivery needle port 161. The toggle first end 102 can form an interference fit with the lumen wall surface 118. The toggle second end 104 can form an interference fit with the outside of the lumen wall 116 or the surrounding tissue, such as subcutaneous tissue. The toggle second end 104 can be slidably translated along the filament 106 toward the lumen wall 116, for example for the toggle 100 illustrated in Figure 20. The length of the filament 106 on the opposite side of toggle

second end 104 from the toggle first end 102 can be cut, snapped, torn or otherwise removed.

[0134] Figures 59 through 63 illustrate a method for deploying the toggle 100. The delivery needle 162 can egress, as shown by arrow, from a toggle deployment delivery port 163. The toggle deployment delivery port 163 can be in the delivery guide 4. The delivery needle 162 can be advanced toward the lumen 114.

[0135] Figure 60 illustrates that the delivery needle 162 can be deployed through the lumen wall. When the delivery needle 162 is deployed through the lumen wall 116, the delivery needle can intersect, or pass adjacent to, the second arteriotomy.

[0136] Figures 61 and 62 illustrate that the pusher 164 can be advanced, as shown by arrow, through the delivery needle 162. The toggle first end 102 can egress from the needle tip port 166. The toggle first end 102 can deploy into the lumen 114.

[0137] Figure 63 illustrates that the delivery needle 162 can be retracted into the delivery guide 4 and/or the filament 106 can be pulled taught, both shown by arrow. The toggle first end 102 can form an interference fit with the lumen wall surface 118. The toggle second end 104 (not shown in Figure 63) can be slidably translated on the filament 106 down to, and form an interference fit with, the outside of the lumen wall 116. The length of the filament 106 on the opposite side of toggle second end 104 from the toggle first end 102 can be cut, snapped, torn or otherwise removed.

[0138] Figure 64 illustrates an introducer needle 165 that can have an end inserted, as shown by arrow, through the lumen wall 116 and into the lumen 114, for example by using the Seldinger technique. The introducer needle 165 can be hollow and/or have a longitudinal channel. Figure 65 illustrates that the guidewire 168 can be deployed, shown by arrows, through the hollow and/or longitudinal channel of the introducer needle 165.

[0139] Figure 66 illustrates that the introducer needle 165 can be removed, as shown by arrow, from the lumen wall 116. The guidewire 168 can remain substantially in place. After the introducer needle 165 is removed, a portion of the guidewire 168 can be outside the lumen 114 and another portion of the guidewire 168 can be inside the lumen 114.

[0140] Figure 67 illustrates a method of fixedly or slidably attaching the guidewire 168 to the anchor 6. A guidewire proximal end 170 can be placed in proximity to an anchor distal end 172. The guidewire proximal end 170 can then be attached, as

shown by arrows, to the anchor distal end 172. The guidewire proximal end 170 can be attached to the anchor distal end 172 while some or all of the guidewire 168 is in the lumen 114. The guidewire proximal end 170 can be configured to snap-fit, interference fit, slidably attach or combinations thereof, to the anchor 6. When the guidewire 168 is attached to the anchor 6, the guidewire 168 can act as the anchor extension section 14 and/or the lumenal tool. Figure 68 illustrates the guidewire 168 attached to the anchor 6.

[0141] Where applicable, the methods described supra for deploying any supplemental closure device can be used for deploying any of the other supplementary deployment device. 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

I claim:

1. A device for accessing a biological lumen having a lumen wall having a longitudinal lumen wall axis, the device comprising:

an elongated member comprising a longitudinal member axis, wherein the member is configured to access the lumen at a first angle, and wherein the first angle is defined by the longitudinal lumen wall axis and the longitudinal member axis, wherein the first angle is less than about 19 degrees.

2. The device of Claim 1, wherein the first angle is less than about 15 degrees.

3. The device of Claim 2, wherein the first angle is less than about 10 degrees.

4. The device of Claim 3, wherein the first angle is greater than about 5 degrees.

5. The device of Claim 1, further comprising an anchor.

6. The device of Claim 5, wherein the anchor is configured to hold the elongated member at a fixed angle with respect to the longitudinal lumen wall axis.

7. The device of Claim 1, further comprising a retainer.

8. The device of Claim 7, wherein the retainer is configured to hold the elongated member at a fixed angle with respect to the longitudinal lumen axis.

9. A device for accessing a biological lumen having a lumen wall and a longitudinal lumen wall axis, the device comprising:

a first elongated member comprising a first elongated member axis, and

a second elongated member comprising a second elongated member axis, wherein the second elongated member is configured so that the second elongated member axis is parallel to the longitudinal lumen wall axis.

10. The device of Claim 9, wherein the second elongated member comprises a retainer.

11. The device of Claim 10, wherein the retainer comprises an inflatable member.

12. The device of Claim 10, wherein the retainer comprises a resilient member.

13. The device of Claim 9, wherein the second elongated member extends substantially adjacent to the lumen wall.

14. A device for closing an opening on a biological lumen wall, comprising:
a longitudinal axis,
a first force-applying member,
a second force-applying member, and
a resilient member,
wherein the resilient member provides to the first and the second force-applying members an outward radial force with respect to the longitudinal axis.

15. The device of Claim 14, wherein the first force-applying member applies force in a first direction, and wherein the second force-applying member applies force in a second direction, and wherein the first direction is substantially opposite to the second direction.

16. A method of accessing a blood vessel through a blood vessel wall having a longitudinal wall axis, the method comprising:
entering the vessel at an angle of less than about 19 degrees with respect to the longitudinal wall axis, and
inserting a lumenal tool into the vessel.

17. The method of Claim 16, wherein the first angle is less than about 15 degrees.

18. The method of Claim 17, wherein the first angle is less than about 10 degrees.

19. The method of Claim 18, wherein the first angle is greater than about 5 degrees.

20. The method of Claim 16, further comprising aligning a device with the lumenal wall before the entering.

21. A method for accessing a biological lumen having a lumen wall and a longitudinal lumen wall axis, the method comprising:

inserting in the biological lumen a second elongated member comprising a second elongated member axis,

aligning the second elongated member so that the second elongated member axis is substantially parallel to the longitudinal lumen wall axis, and

inserting in the biological lumen a first elongated member comprising a first elongated member axis.

22. The method of Claim 21, wherein an angle between the first elongated member axis and the longitudinal lumen wall axis is less than about 15 degrees.

23. The method of Claim 22, wherein an angle between the first elongated member axis and the longitudinal lumen wall axis is less than about 10 degrees.

24. The method of Claim 21, wherein the second elongated member comprises a retainer, wherein the method further comprises extending the retainer.

25. The method of Claim 24, wherein the retainer comprises a resilient member.

26. The method of Claim 21, wherein the second elongated member comprises an inflatable member, the method further comprising inflating the inflatable member.

27. The method of Claim 21, wherein the second elongated member extends substantially adjacent to the lumen wall.

28. A method of closing a vascular opening, the vascular opening having an inside surface and a longitudinal axis, the method comprising:

inserting a device in the opening,

applying a force to the inside surface, wherein the force is directed in at least one radially outward direction from the longitudinal axis.

29. The method of Claim 28, further comprising maintaining the force.

30. The method of Claim 29, wherein maintaining comprises maintaining for less than about 120 minutes.

31. The method of Claim 28, wherein the applying a force comprises the device applying at least a part of the force.

32. The method of Claim 31, wherein the applying a force comprises the device applying all of the force.

33. A method for accessing and closing a blood vessel having a vessel wall, wherein the vessel wall has an inside surface and an outside surface, the method comprising:

forming an arteriotomy,

deploying a closure augmentation device in the arteriotomy, wherein the closure augmentation device produces pressure on the inside surface and the outside surface.

34. The method of Claim 33, wherein the closure augmentation device comprises a filament, and wherein the filament is in the arteriotomy.

35. The method of Claim 33, wherein the closure augmentation device comprises a pressure clip.

36. The method of Claim 33, wherein the closure augmentation device comprises a pledget.

37. The method of Claim 33, wherein the closure augmentation device comprises a toggle.

38. The method of Claim 33, wherein the closure augmentation device comprises a suture.

39. A method for accessing a blood vessel having a vessel wall, wherein the vessel wall has an inside and an outside, the method comprising:

forming an arteriotomy in the vessel wall, wherein the arteriotomy has an arteriotomy run and an arteriotomy rise, and wherein the arteriotomy rise is about equal to or less than one-third of the arteriotomy run, and

deploying vascular tools through the arteriotomy.

40. The method of Claim 39, wherein forming the arteriotomy further comprises deploying an introduction device through the vessel wall, and wherein the introduction device passes through the vessel wall at substantially various angles with respect to the vessel wall.

41. The method of Claim 39, wherein forming the arteriotomy further comprises deploying an introduction device through the vessel wall, and wherein the introduction device cleaves a plane in the lumen wall.

42. The method of Claim 41, wherein the plane can be substantially parallel with the lumen wall.

43. The method of Claim 41, wherein the blood vessel wall has an adventitia, and wherein the plane is adjacent to the adventitia.

44. The method of Claim 39, wherein the arteriotomy has an outside lumen wall opening and an inside lumen wall opening, and wherein the introduction run is the component of the length substantially parallel to the lumen wall between the outside lumen wall opening and the inside lumen wall opening.

45. The method of Claim 44, wherein the introduction rise is the component of the length substantially perpendicular to the lumen wall between the outside lumen wall opening and the inside lumen wall opening.

46. The method of Claim 39, wherein the arteriotomy rise is about equal to or less than one-fourth of the arteriotomy run.

47. The method of Claim 39, wherein the arteriotomy rise is about equal to or less than one-fifth of the arteriotomy run.

48. A method for accessing a blood vessel having a vessel wall, wherein the vessel wall has an inside and an outside, the method comprising:

deploying an introduction device to form an arteriotomy,

moving the introduction device through the vessel wall at a first angle with respect to the vessel wall,

moving the introduction device through the vessel wall at a second angle with respect to the vessel wall, and

entering the inside of the vessel wall with the introduction device.

49. The method of Claim 48, wherein the first angle or the second angle is less than about 5 degrees.

50. The method of Claim 48, wherein the first angle or the second angle is about 0 degrees.

51. The method of Claim 48, wherein the introduction device forms an outer opening on the outside of the vessel wall, and wherein the introduction device forms an inner opening on the inside of the vessel wall, and wherein a vector between the outer inner opening and the outer opening can comprise an introduction run and introduction rise, and wherein the ratio of the introduction rise to the introduction run can be equal to or less than about ½.

52. The method of Claim 51, wherein the ratio of the introduction rise to the introduction run can be equal to or less than about 1/3.

53. The method of Claim 51, wherein the ratio of the introduction rise to the introduction run can be equal to or less than about ¼.

54. The method of Claim 51, wherein the ratio of the introduction rise to the introduction run can be equal to or less than about $^1/_5$.

55. The method of Claim 51, wherein the ratio of the introduction rise to the introduction run can be equal to or less than about $^1/_6$.

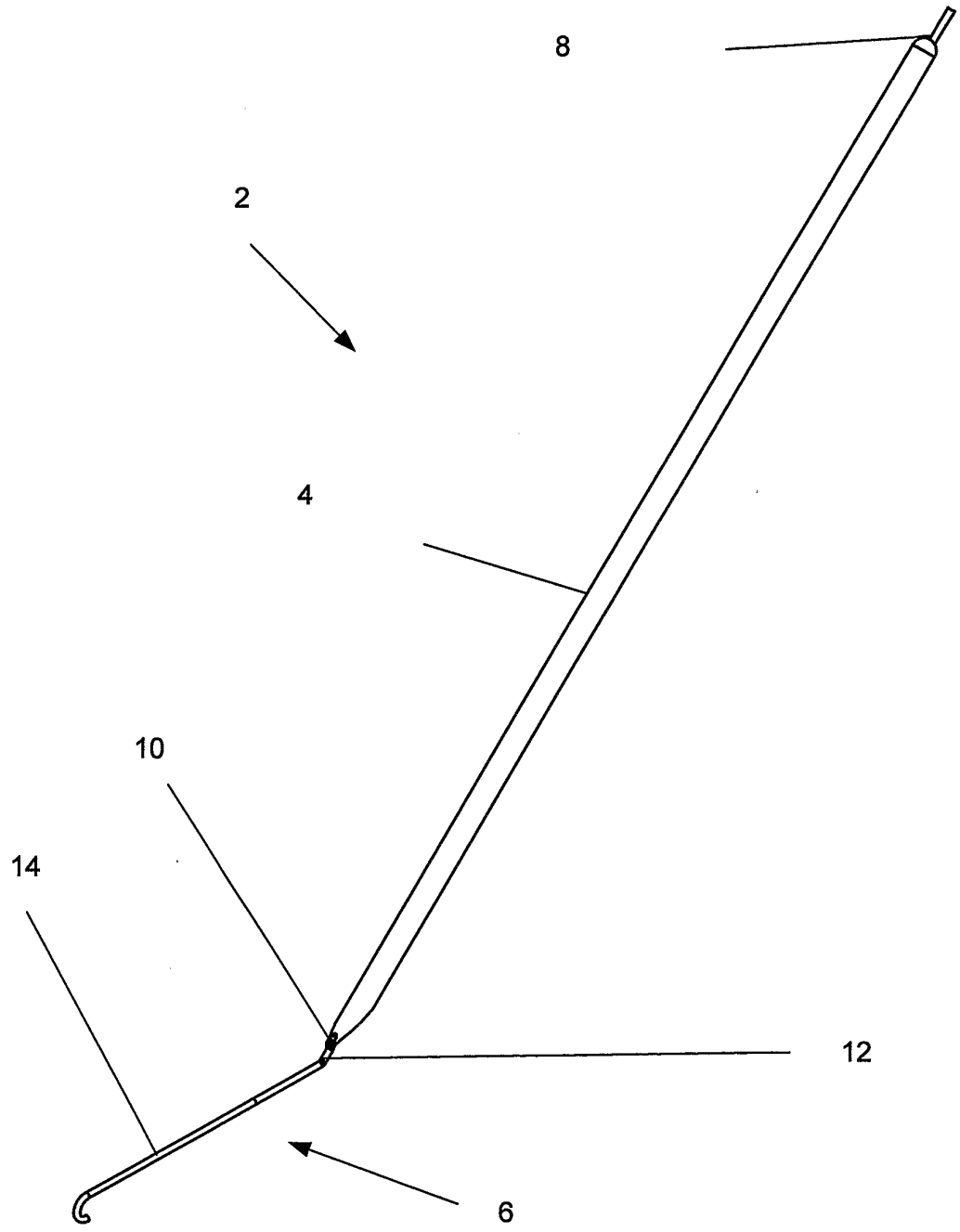


Fig. 1

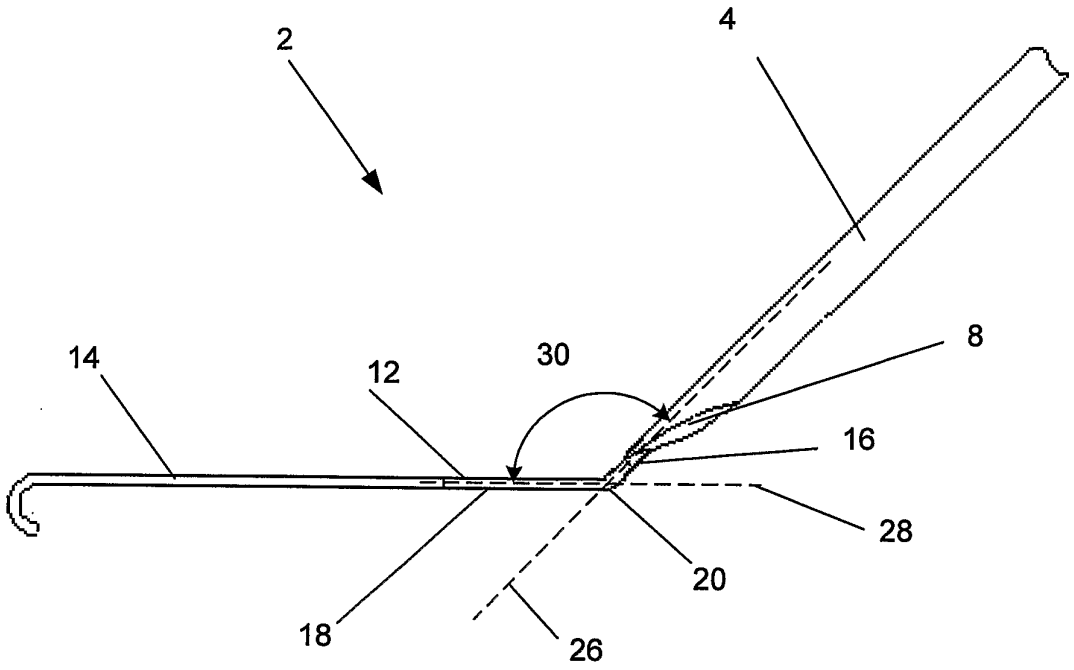


Fig. 2

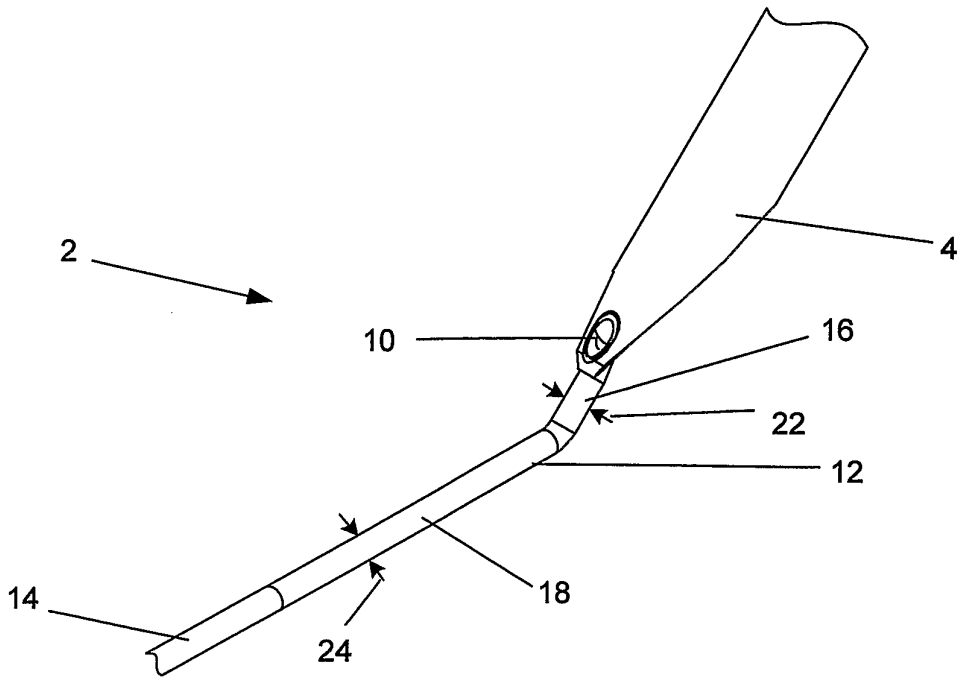


Fig. 3

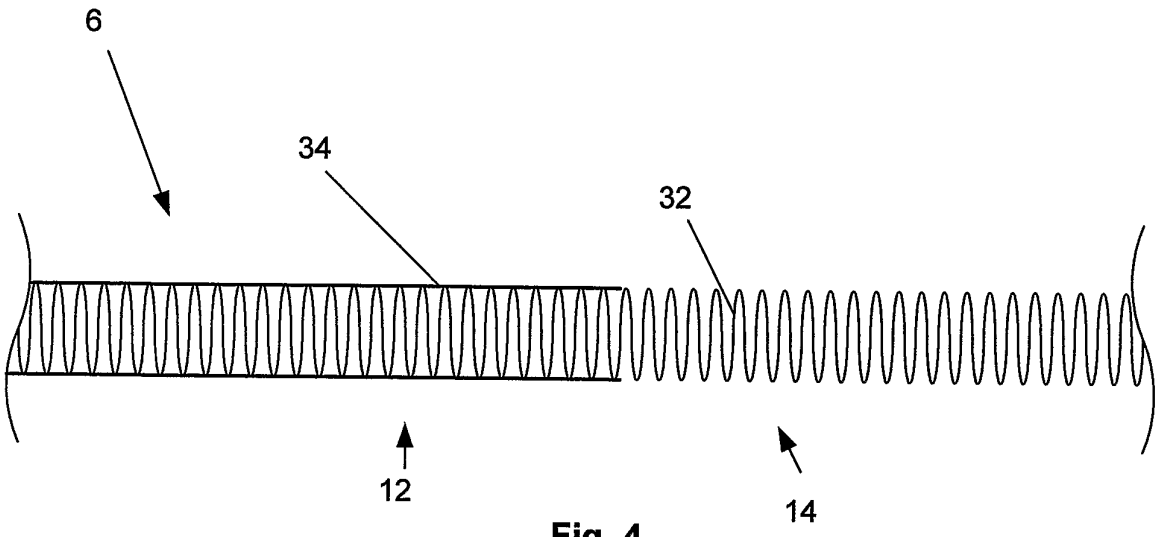


Fig. 4

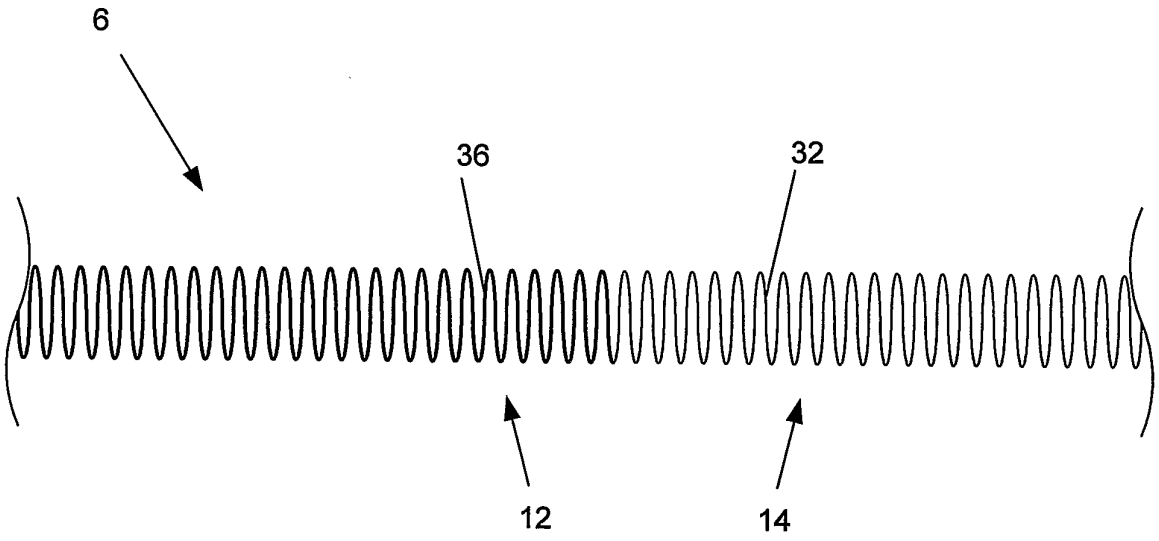


Fig. 5

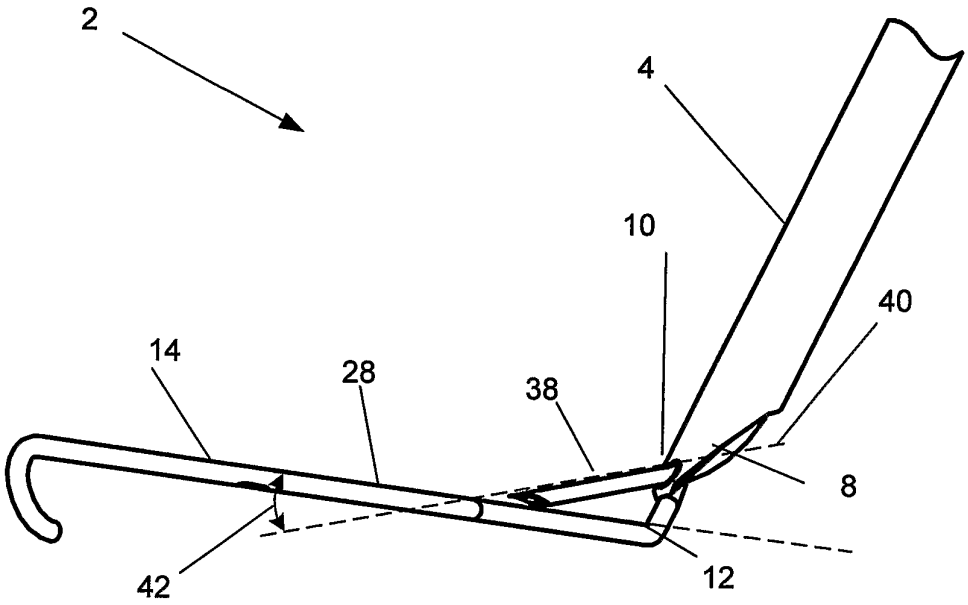


Fig. 6

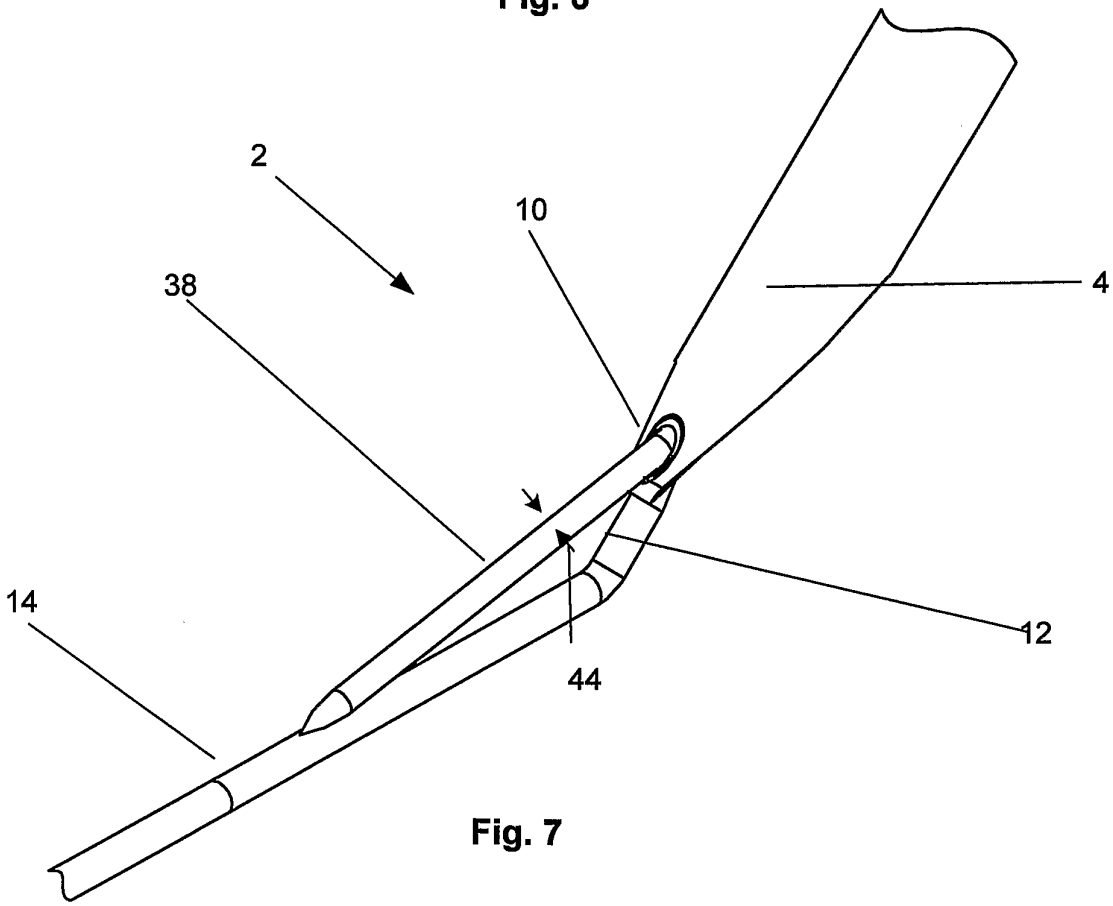


Fig. 7

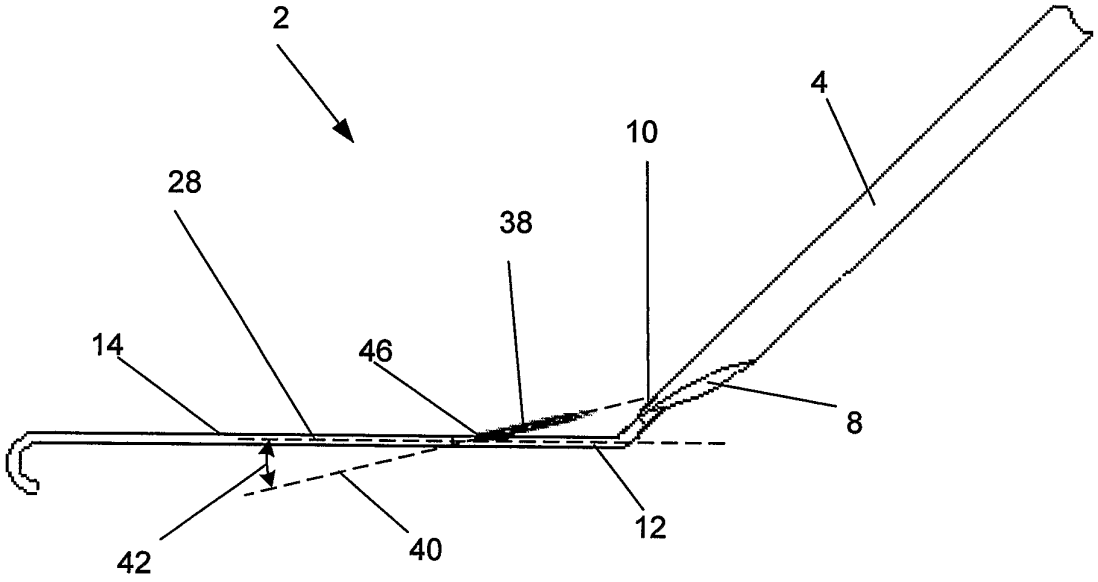


Fig. 8

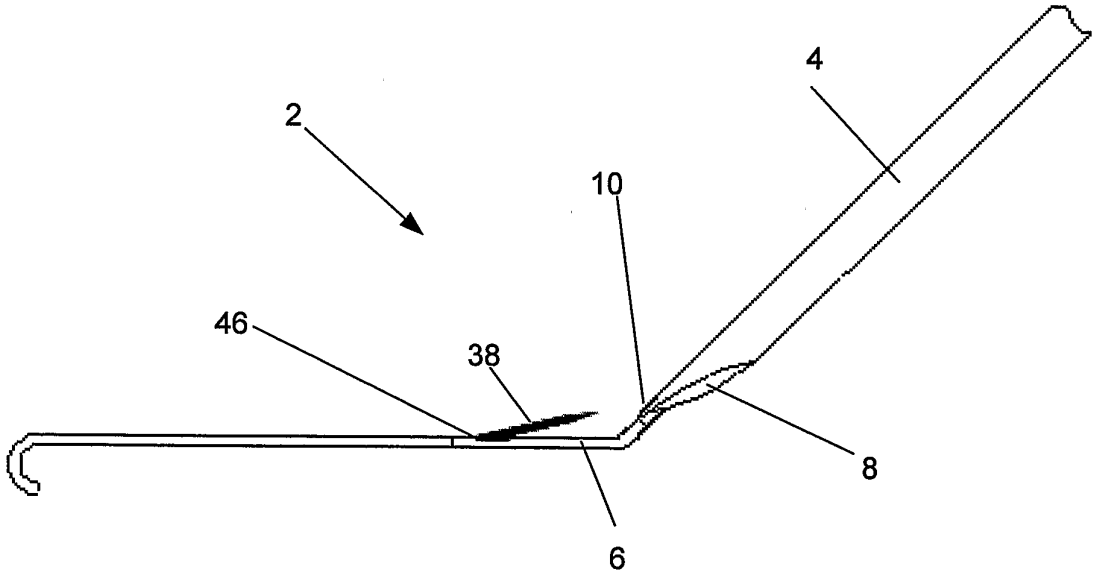


Fig. 9

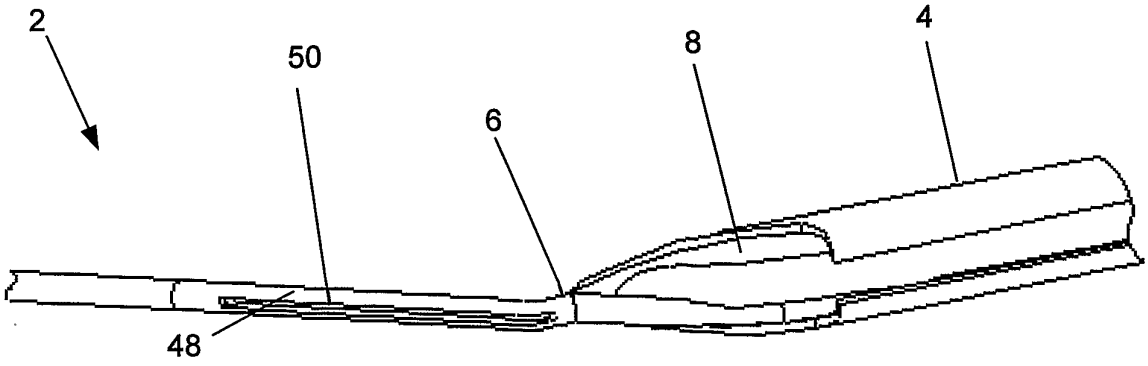


Fig. 10

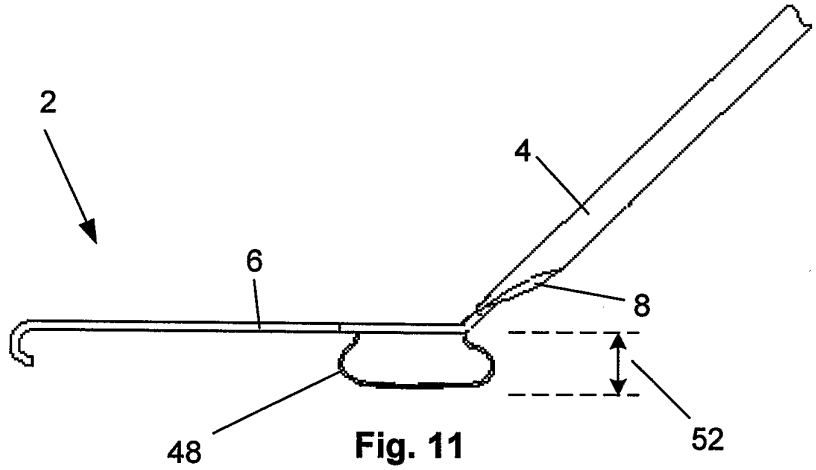


Fig. 11

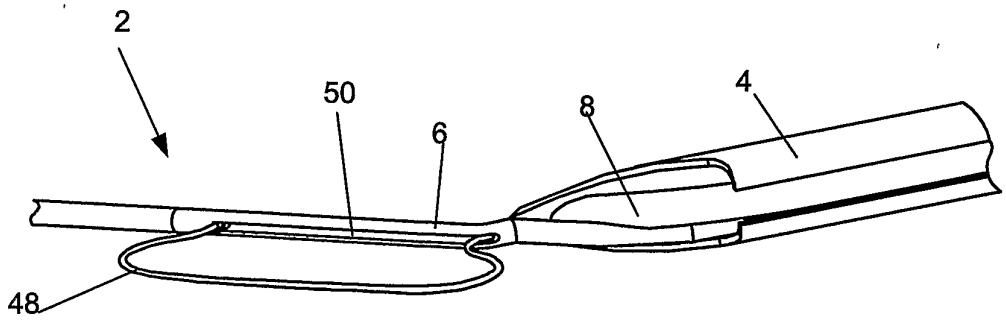


Fig. 12

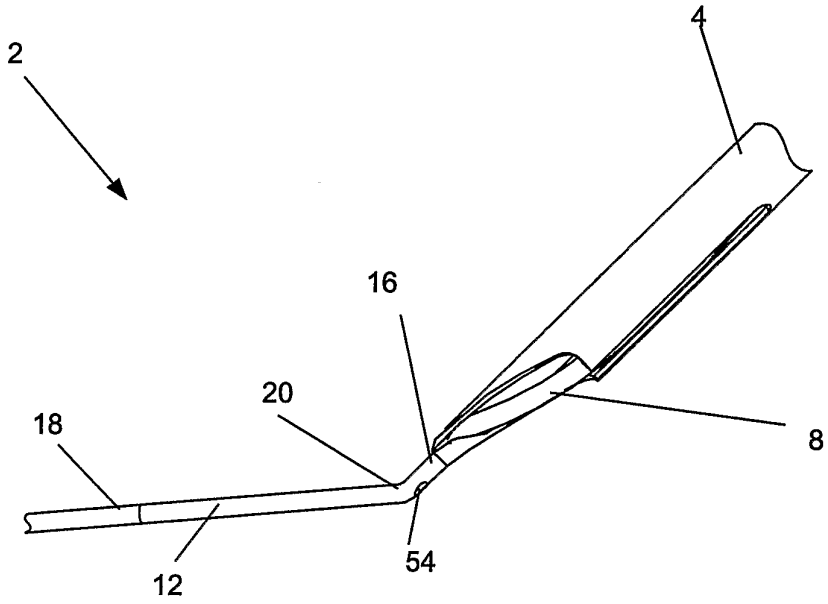


Fig. 13

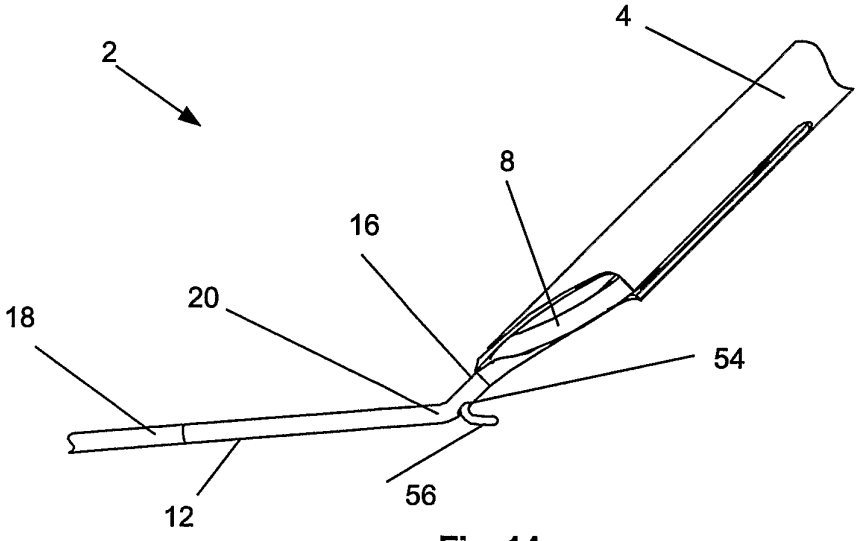


Fig. 14

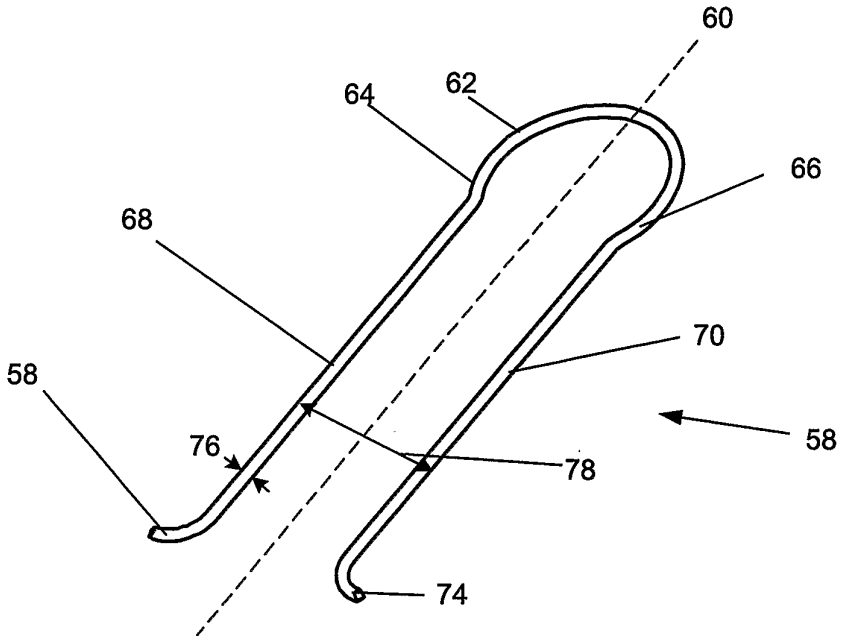


Fig. 15

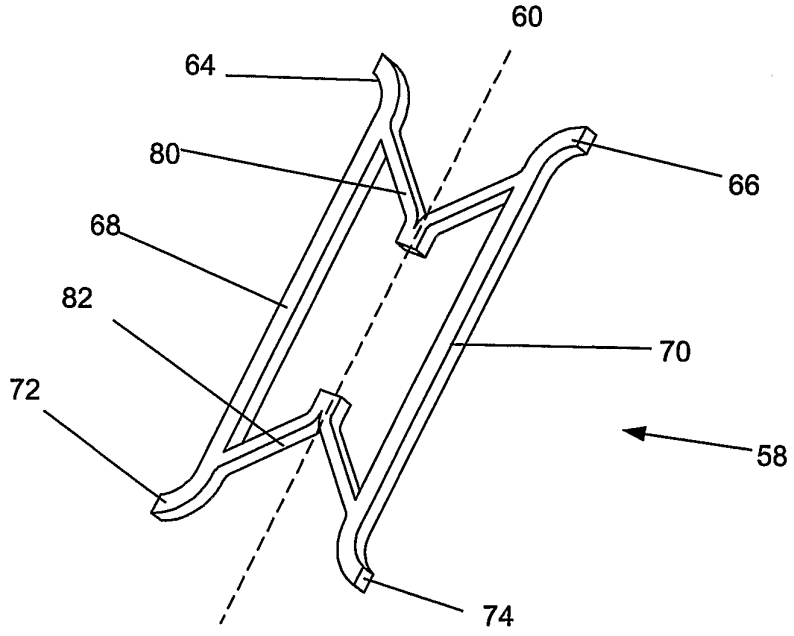


Fig. 16

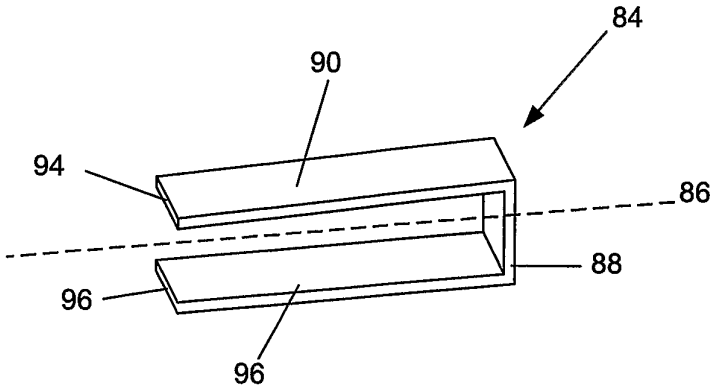


Fig. 17

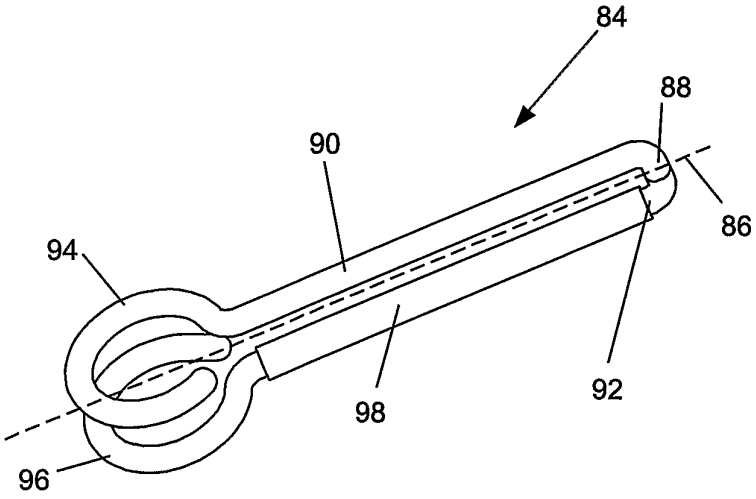


Fig. 18

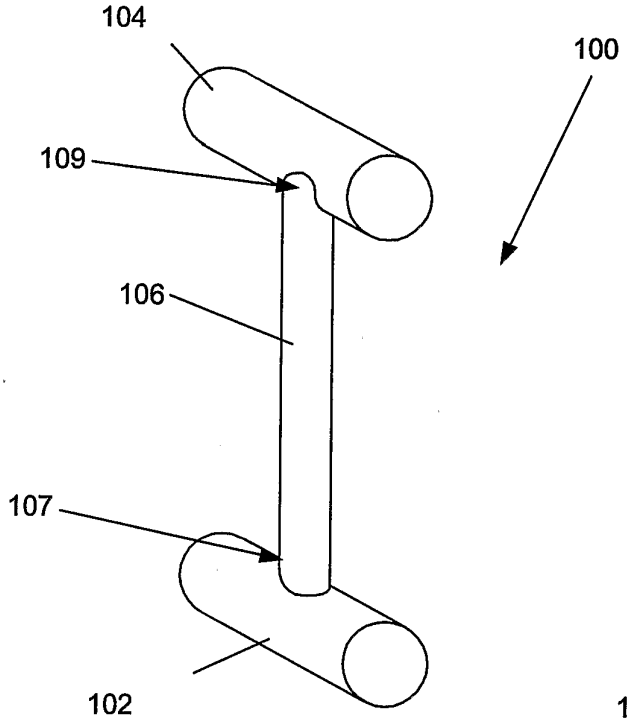

104
100
109
106
107
102

Fig. 19

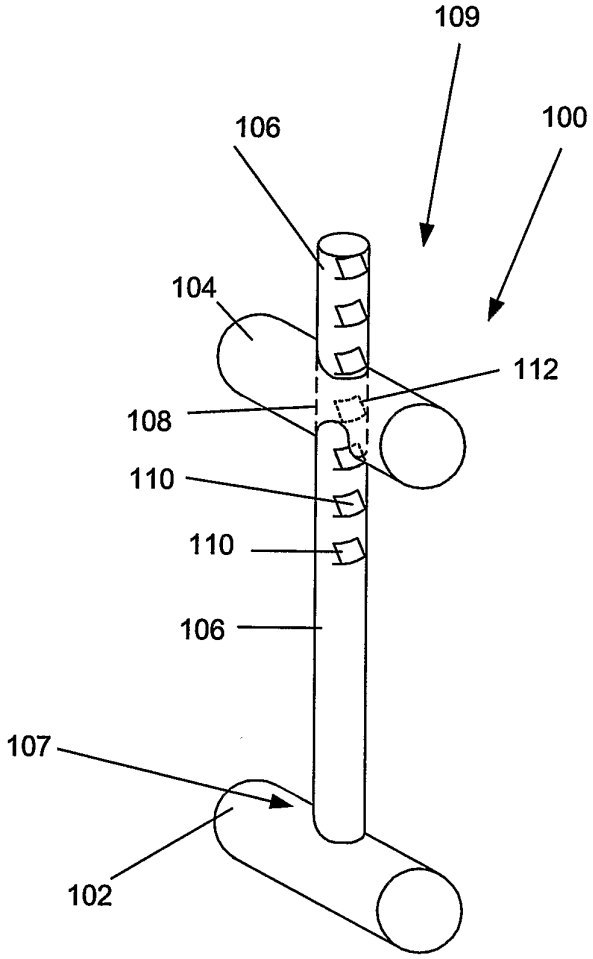

109
106
100
104
112
108
110
110
106
107
102

Fig. 20

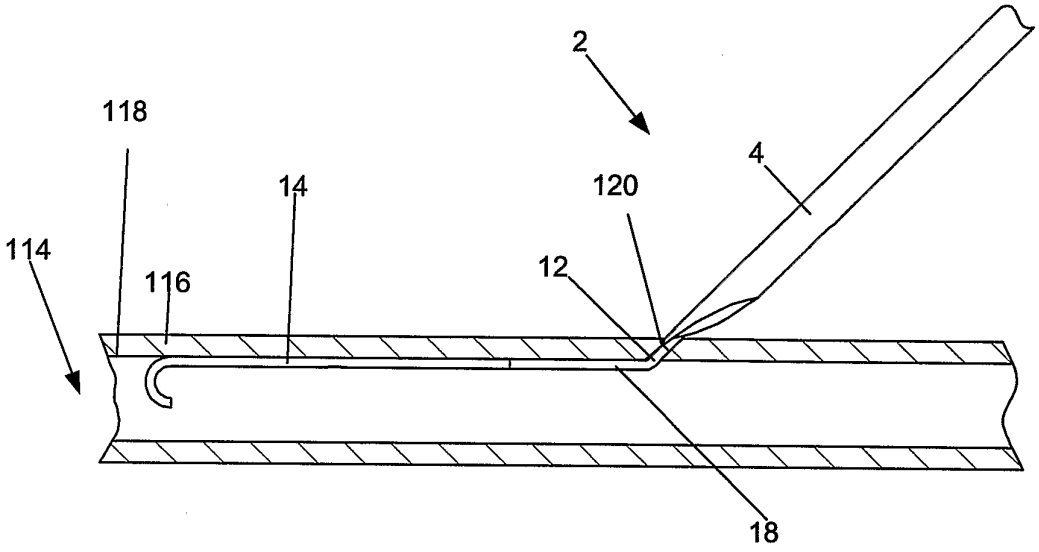


Fig. 21

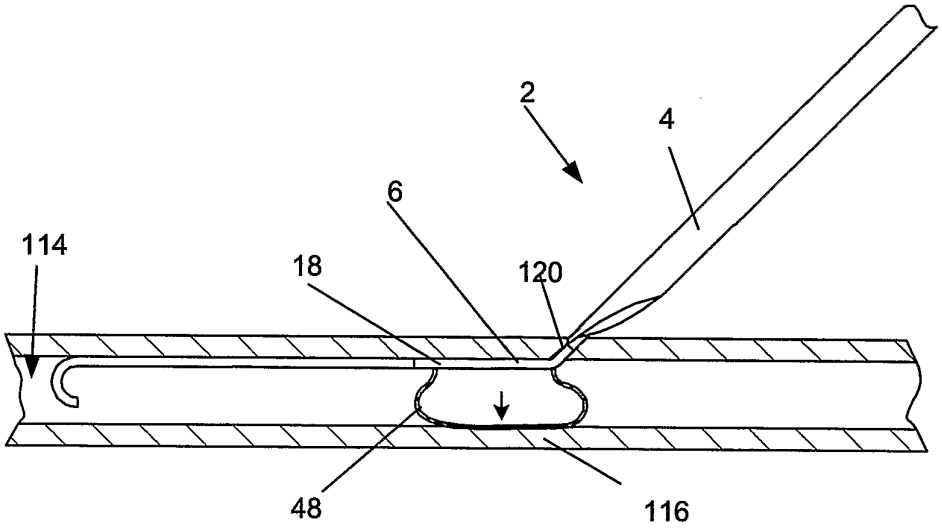


Fig. 22

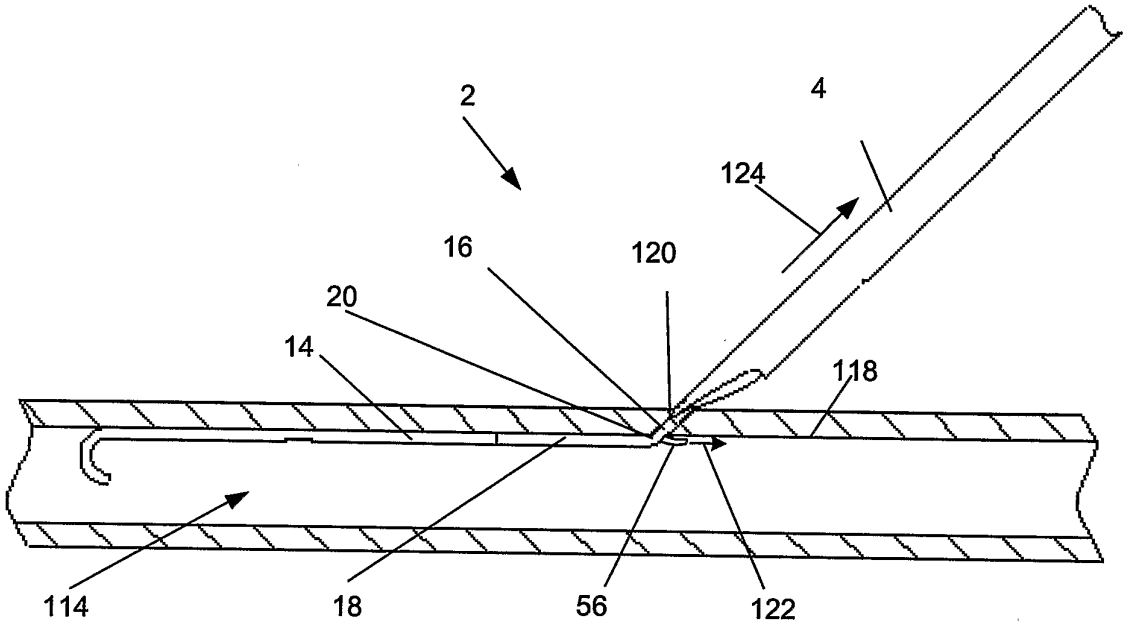


Fig. 23

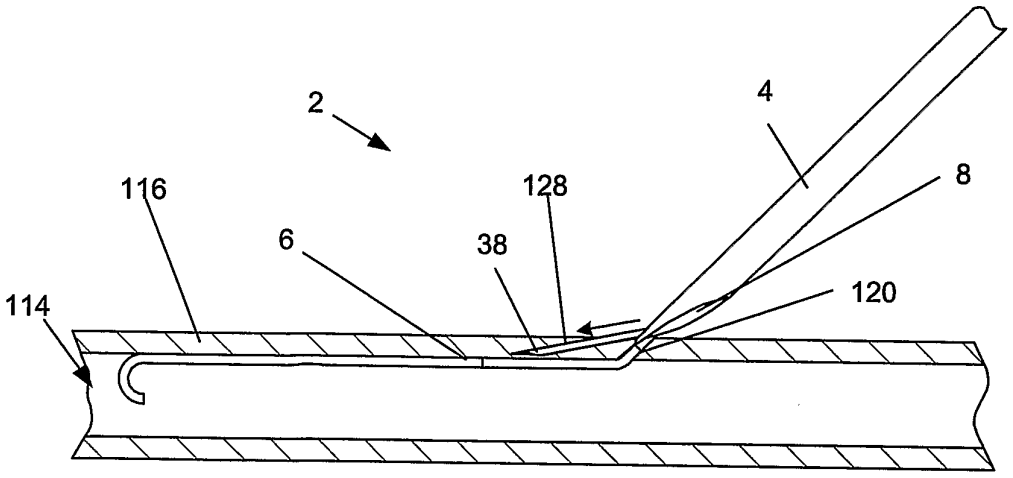


Fig. 24

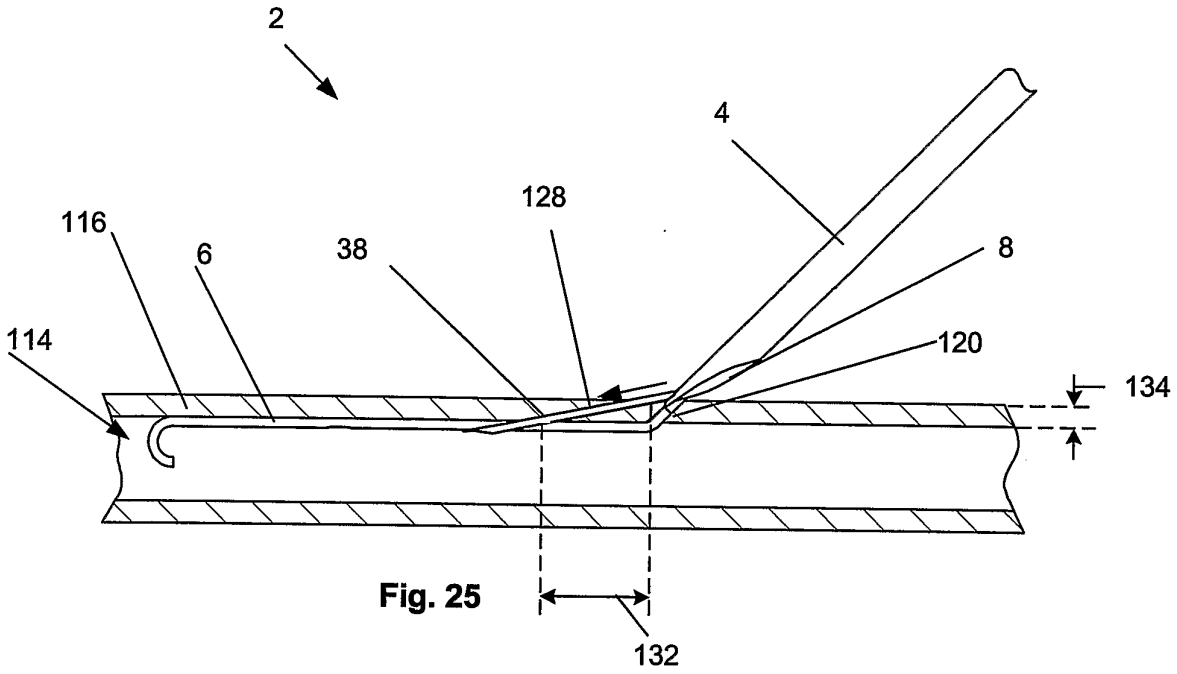


Fig. 25

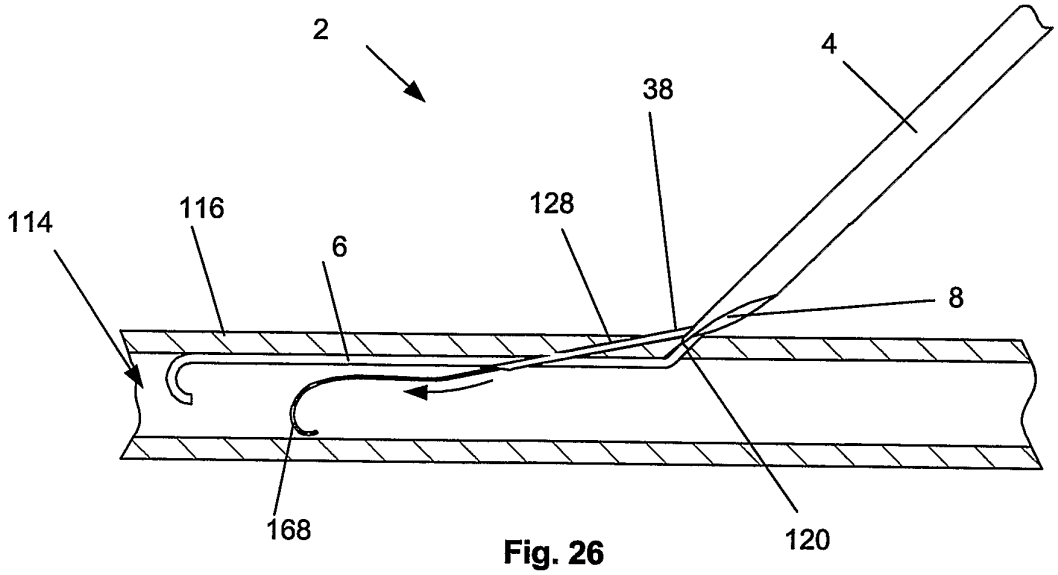


Fig. 26

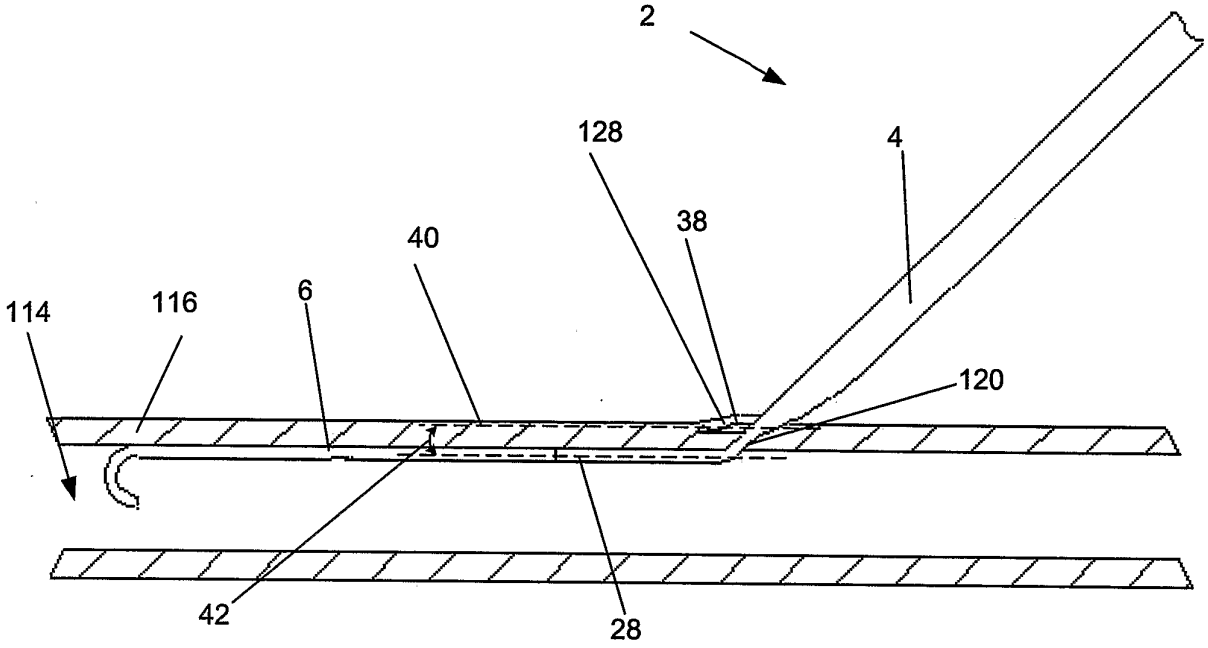


Fig. 27

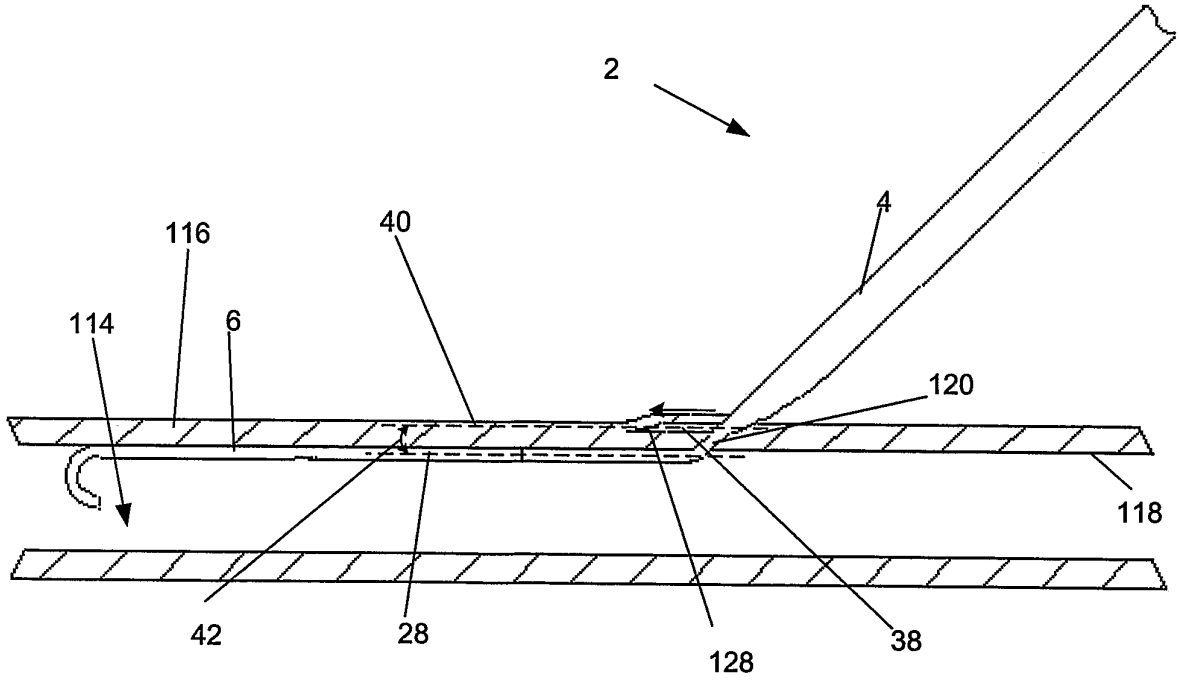


Fig. 28

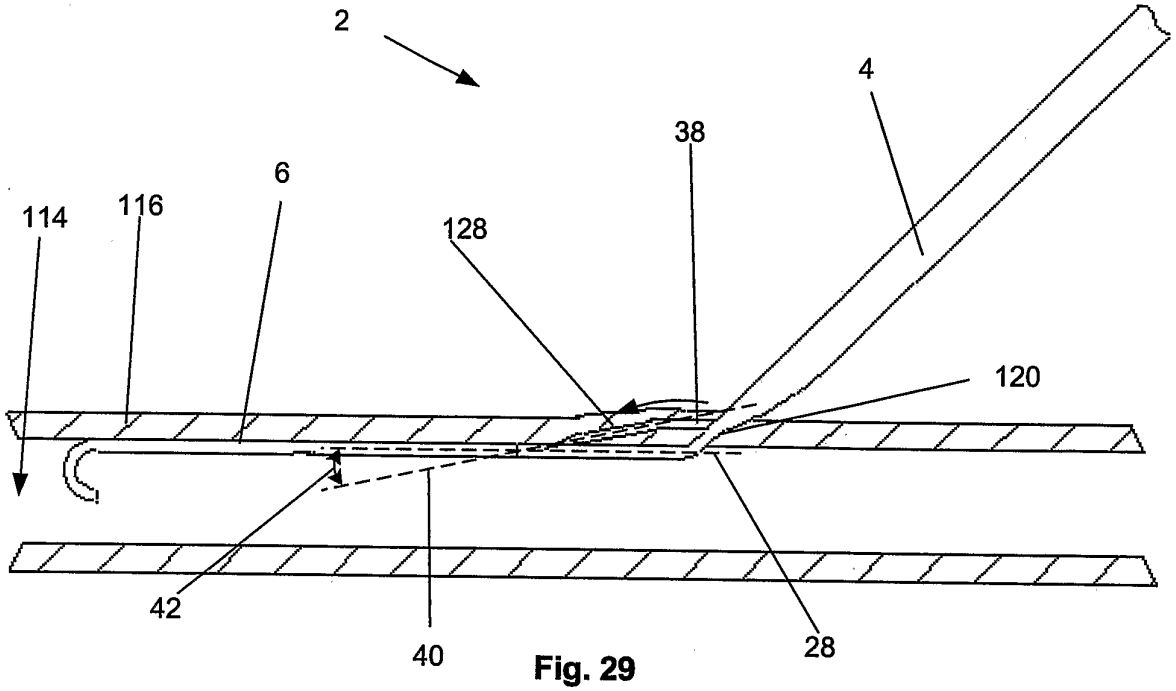

2
4
38
6
114
116
128
120
42
40
28

Fig. 29

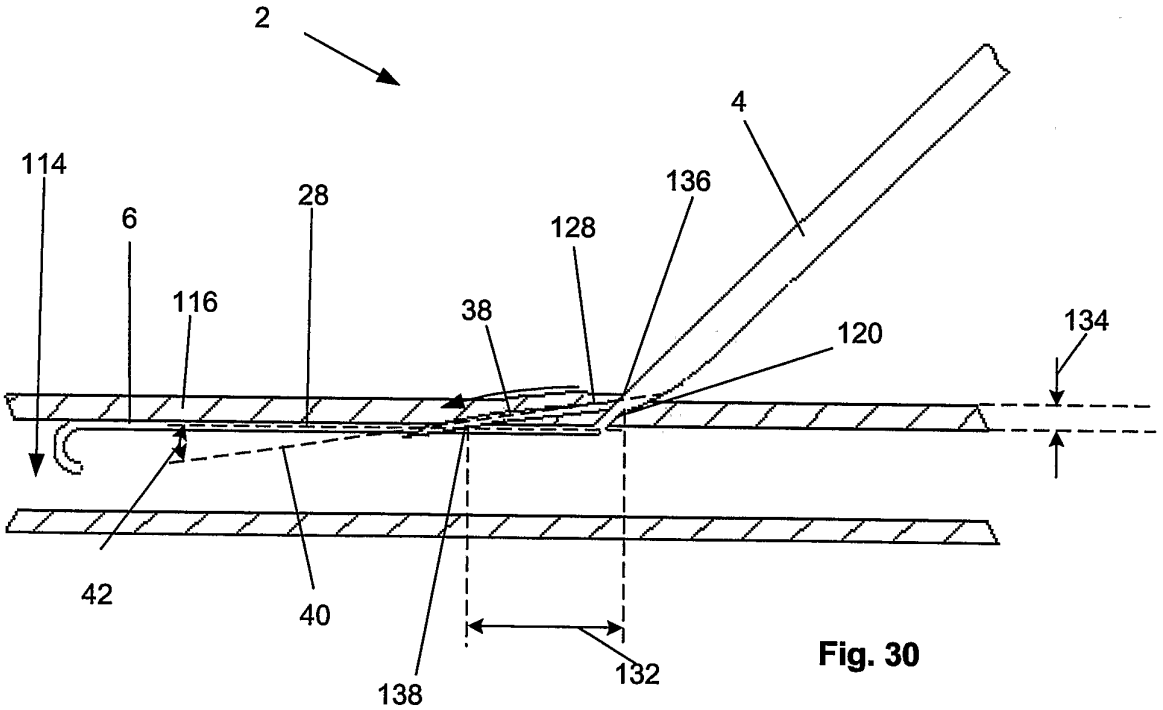

2
4
114
136
28
6
128
116
38
120
134
42
40
138
132

Fig. 30

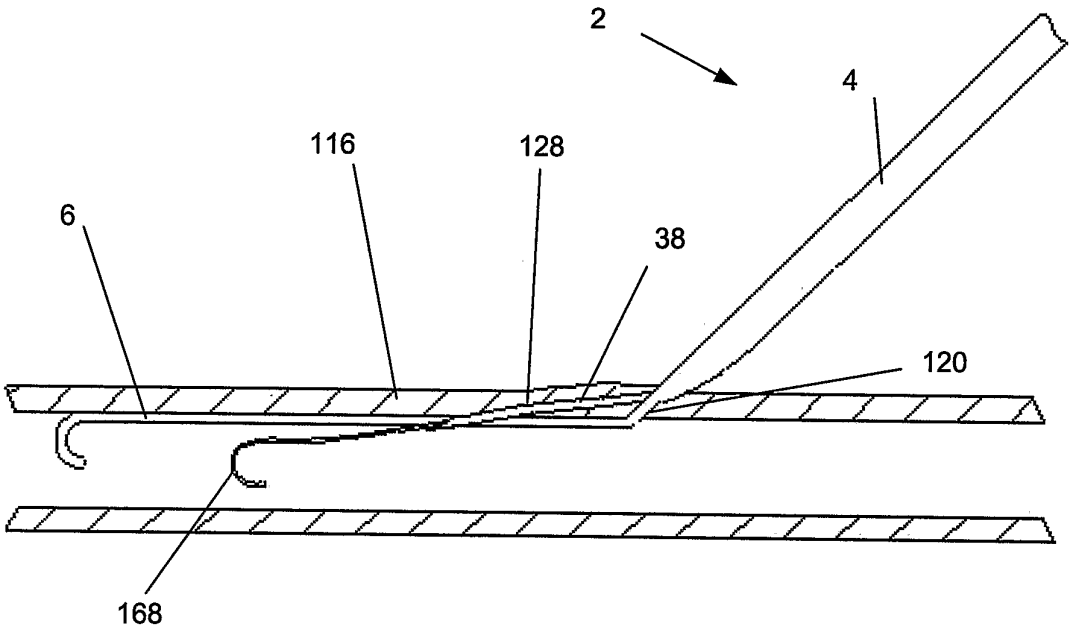


Fig. 31

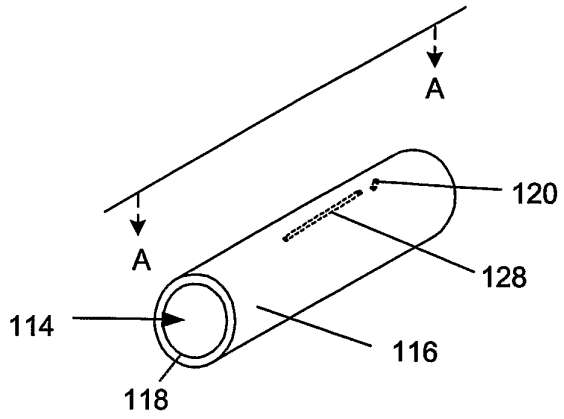


Fig. 32

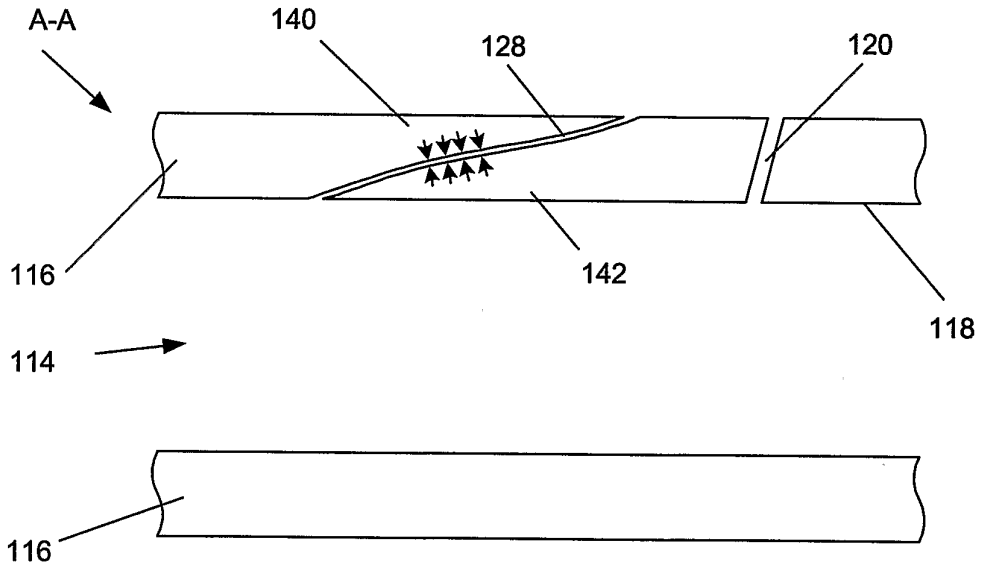


Fig. 33

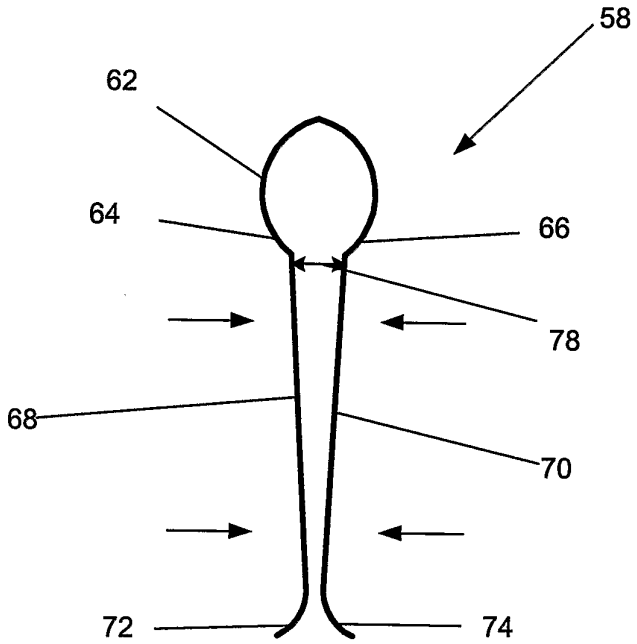


Fig. 34

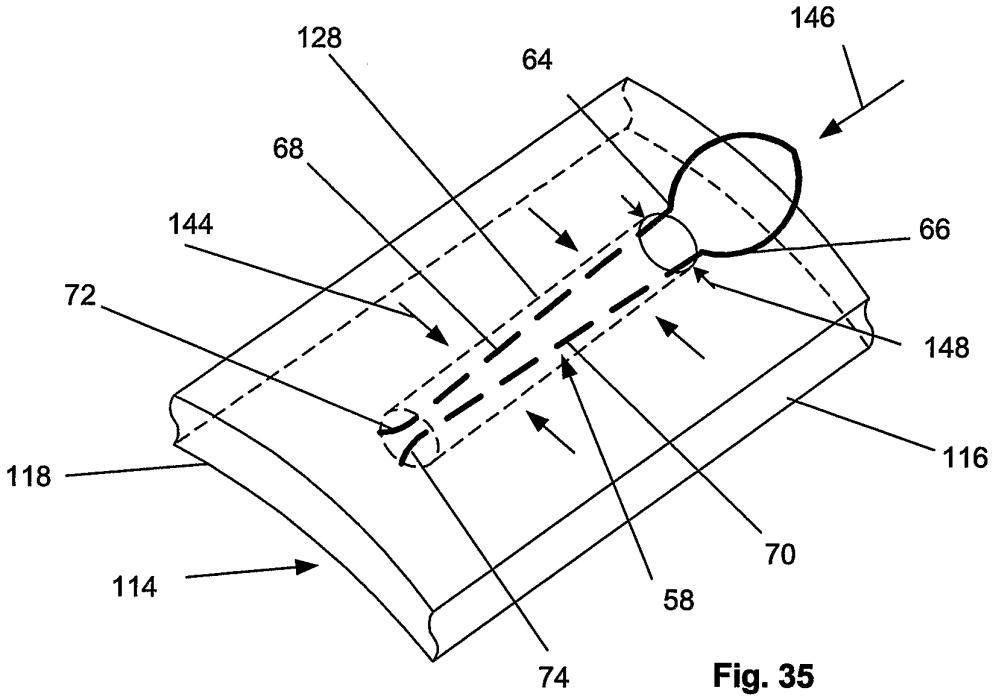

146
128
64
68
144
66
72
148
116
118
70
114
58
74

Fig. 35

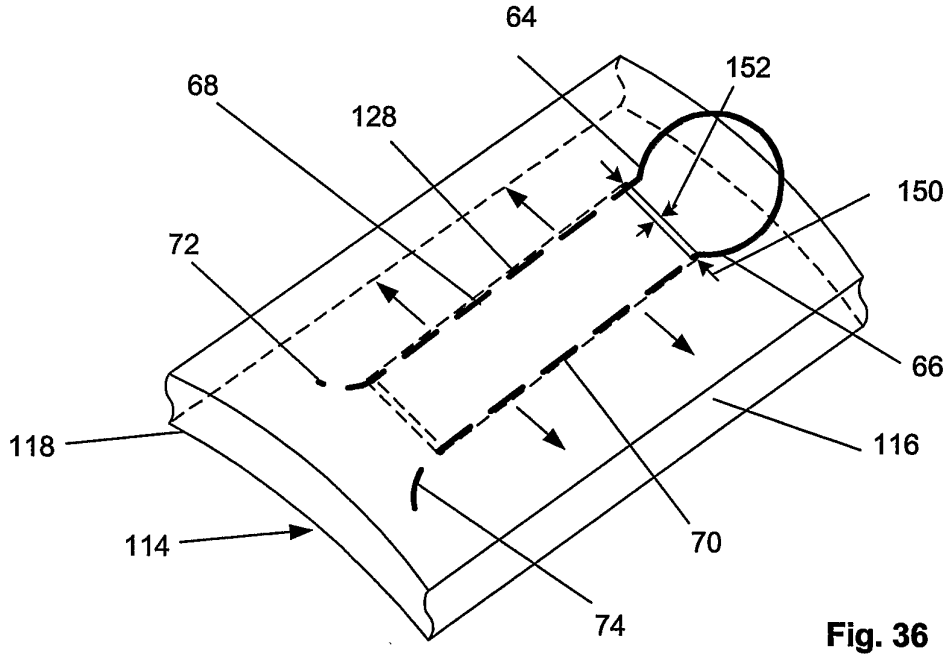

64
152
68
128
150
72
66
116
118
70
114
74

Fig. 36

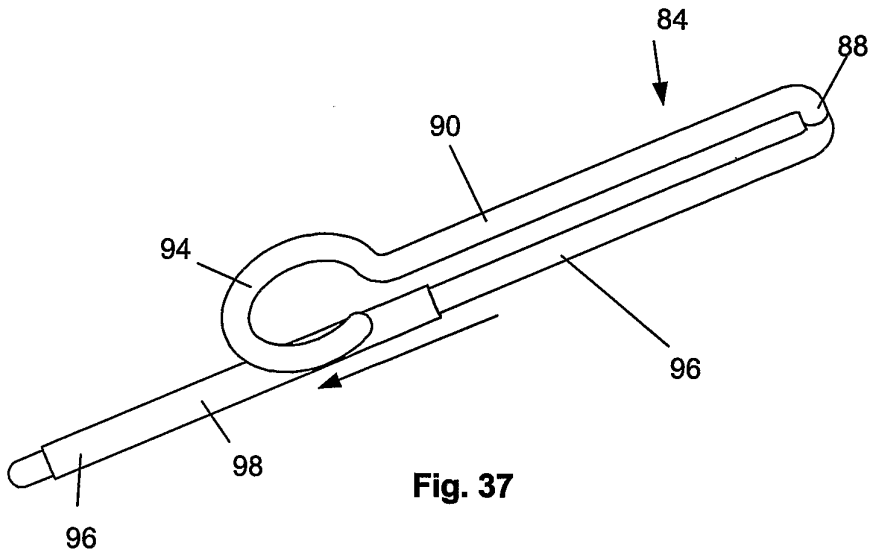


Fig. 37

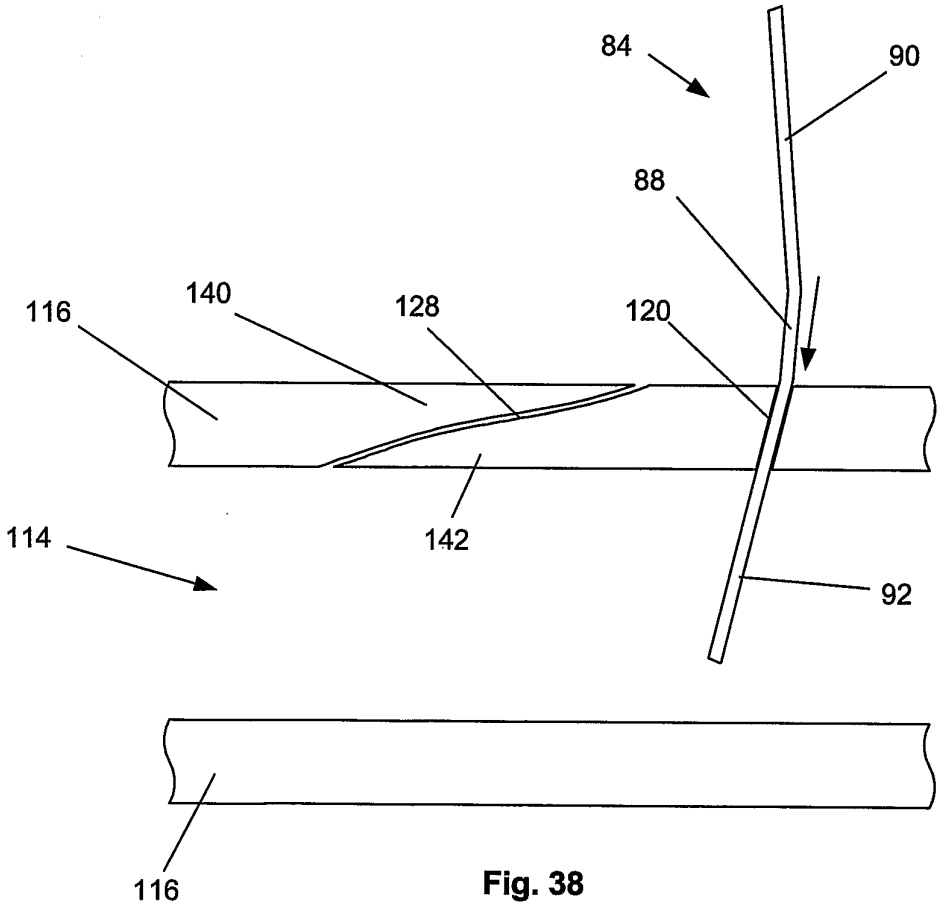


Fig. 38

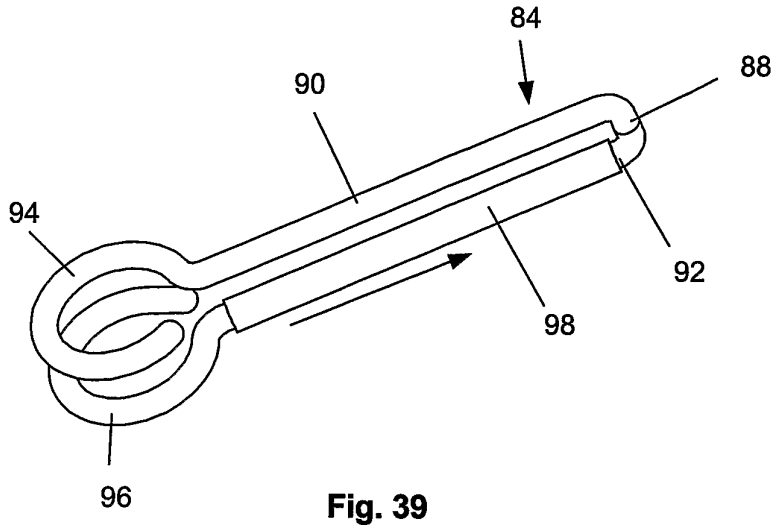


Fig. 39

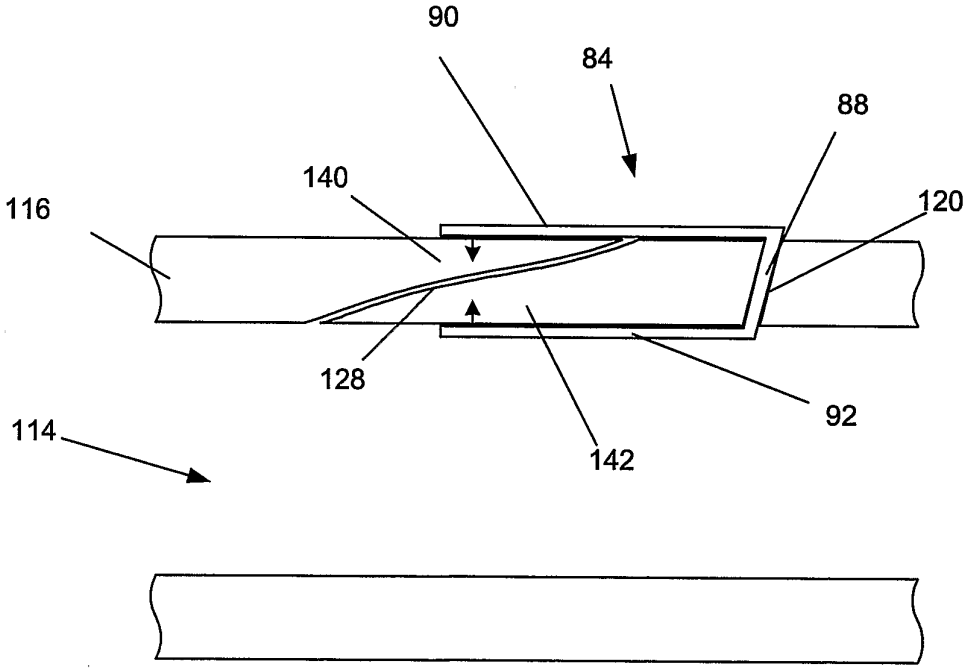


Fig. 40

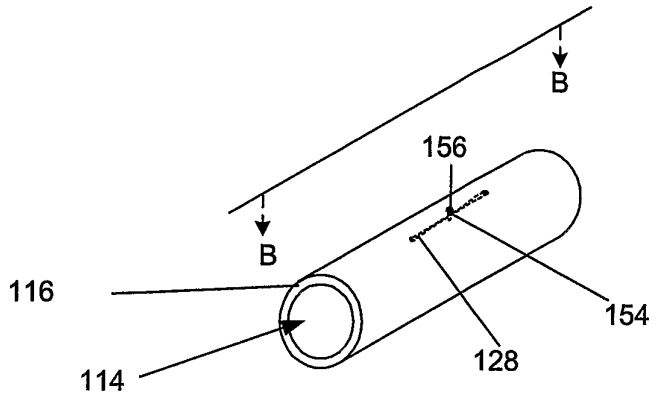


Fig. 41

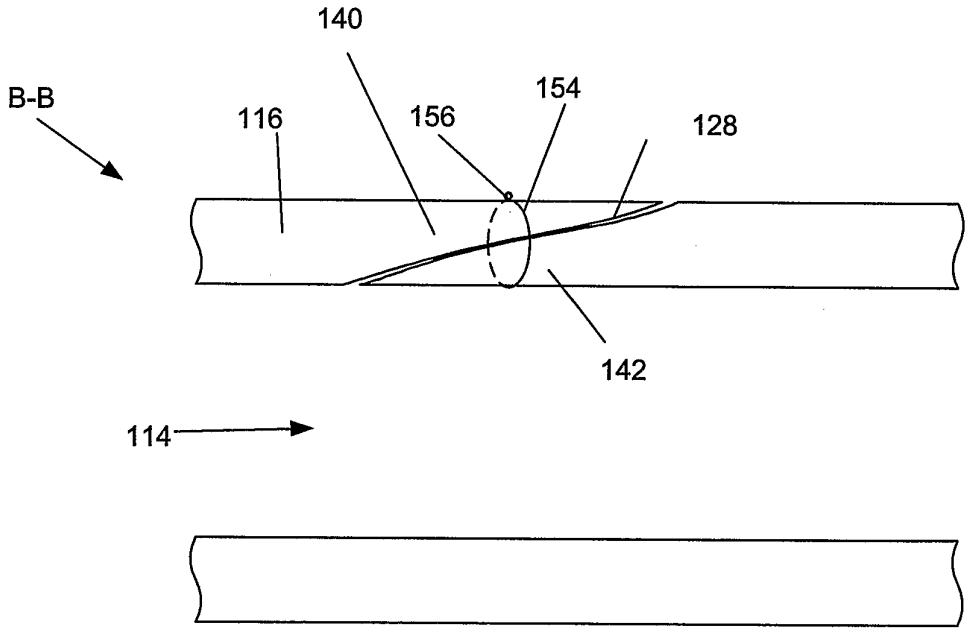


Fig. 42

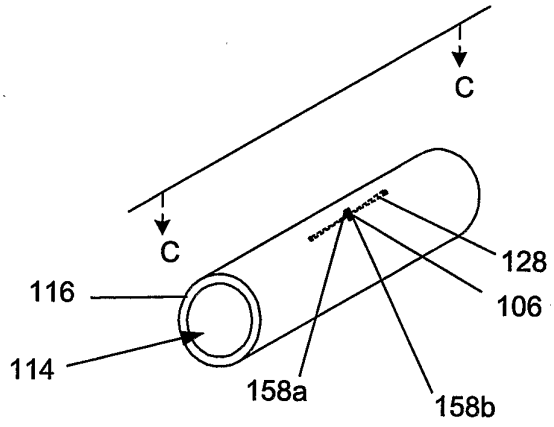

C
C
116
114
128
106
158a
158b

Fig. 43

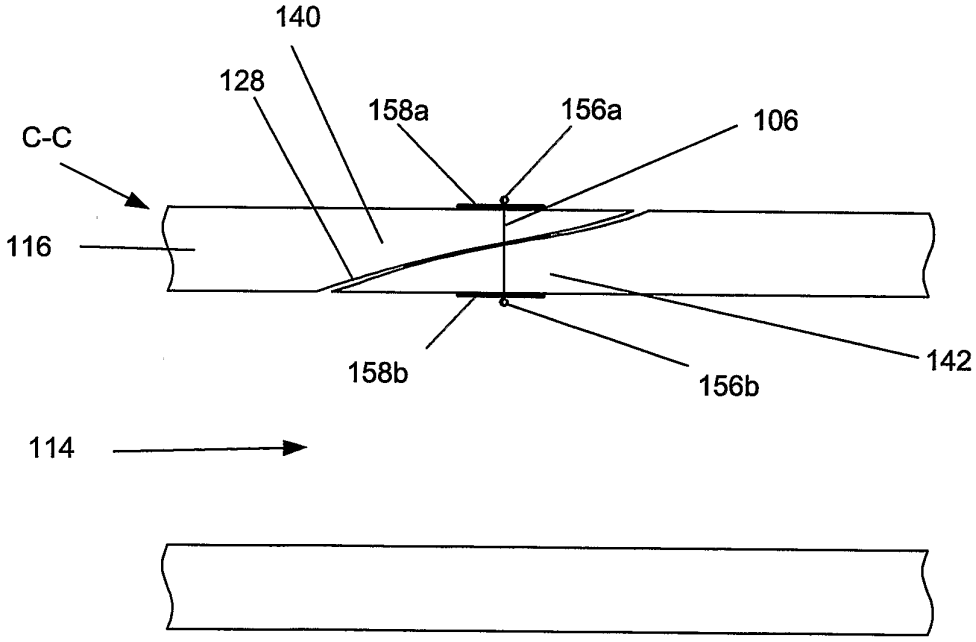

140
128
158a
156a
106
C-C
116
158b
156b
142
114

Fig. 44

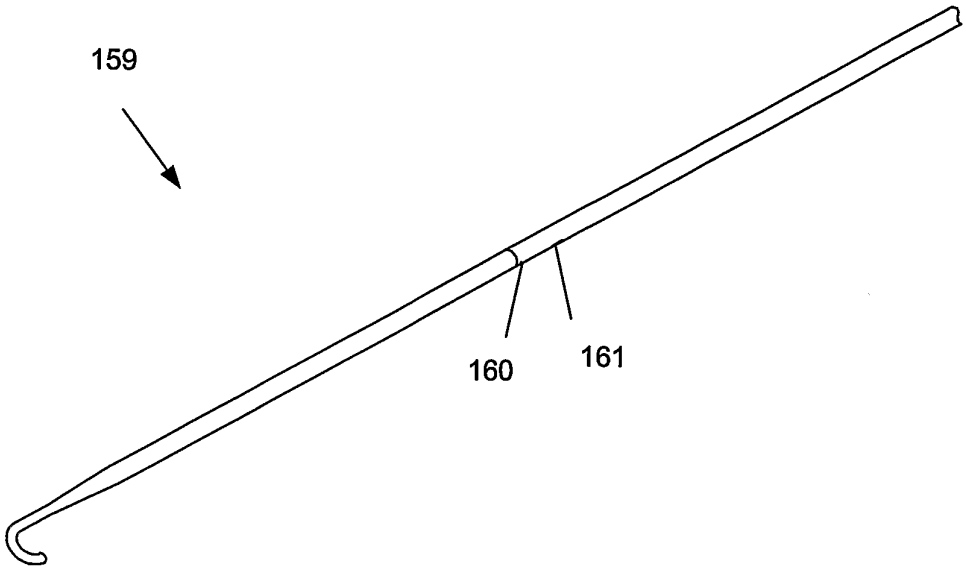


Fig. 45

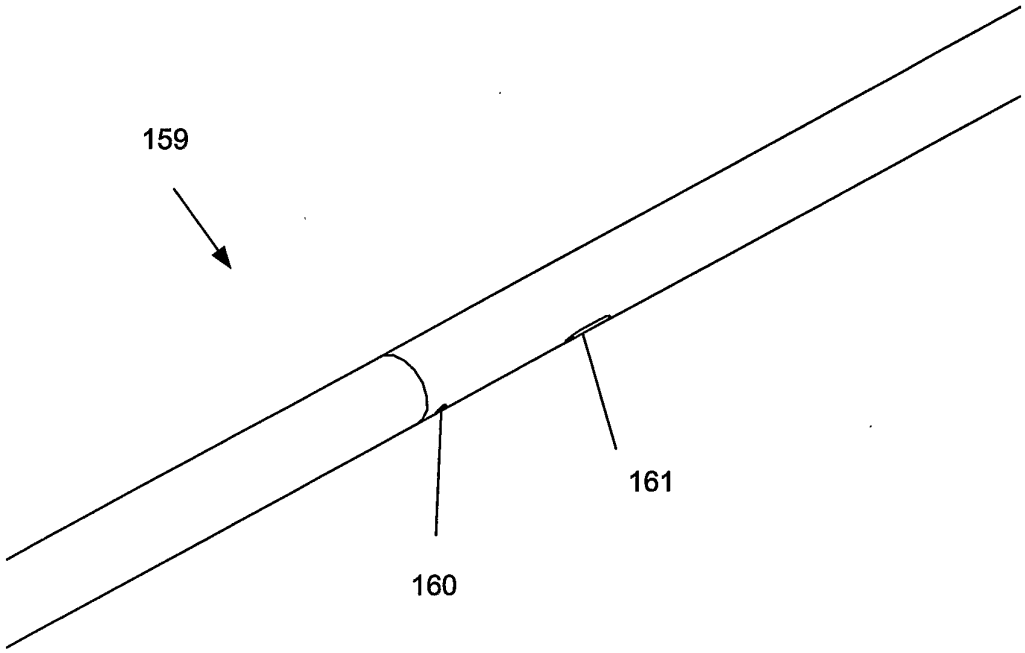


Fig. 46

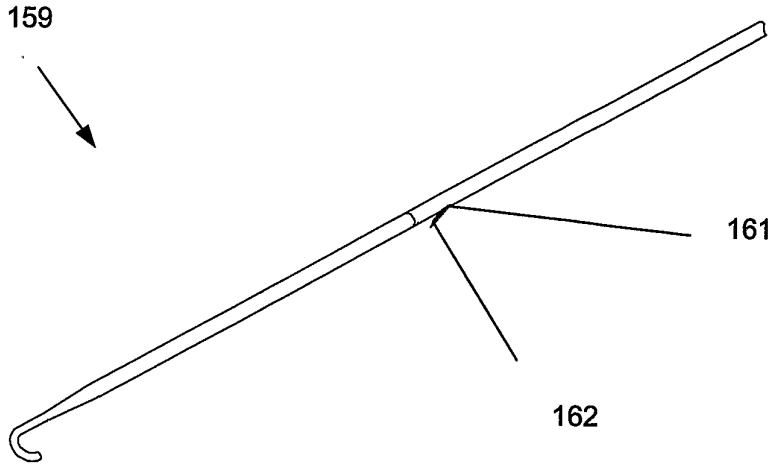


Fig. 47

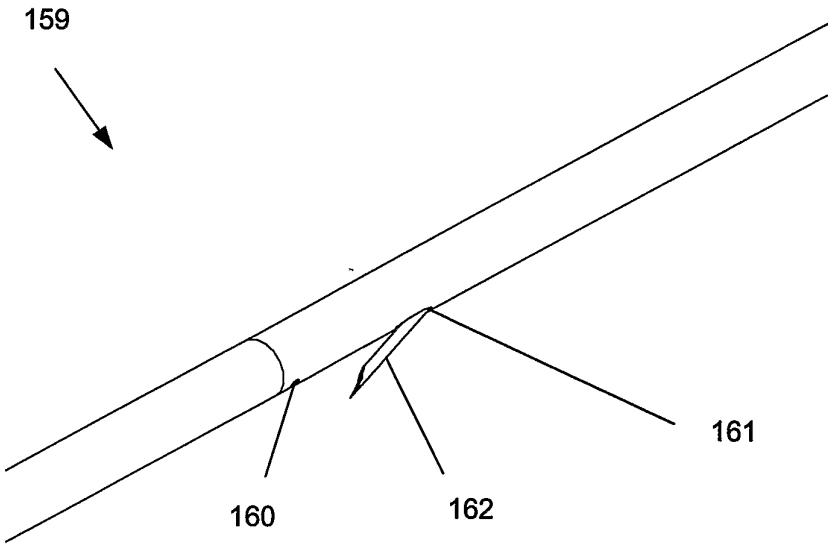


Fig. 48

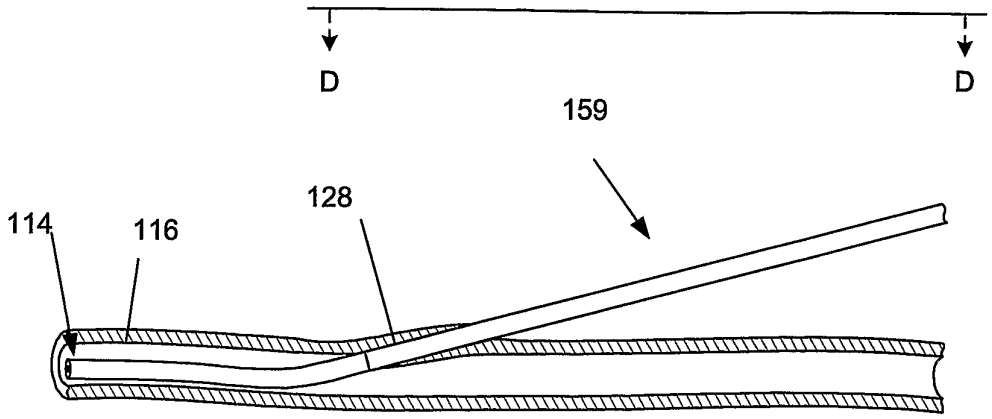


Fig. 49

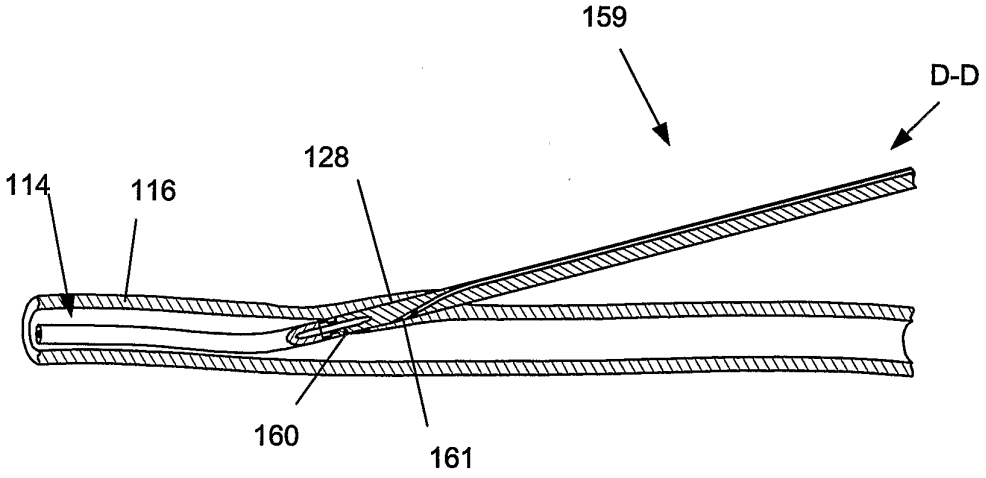


Fig. 50

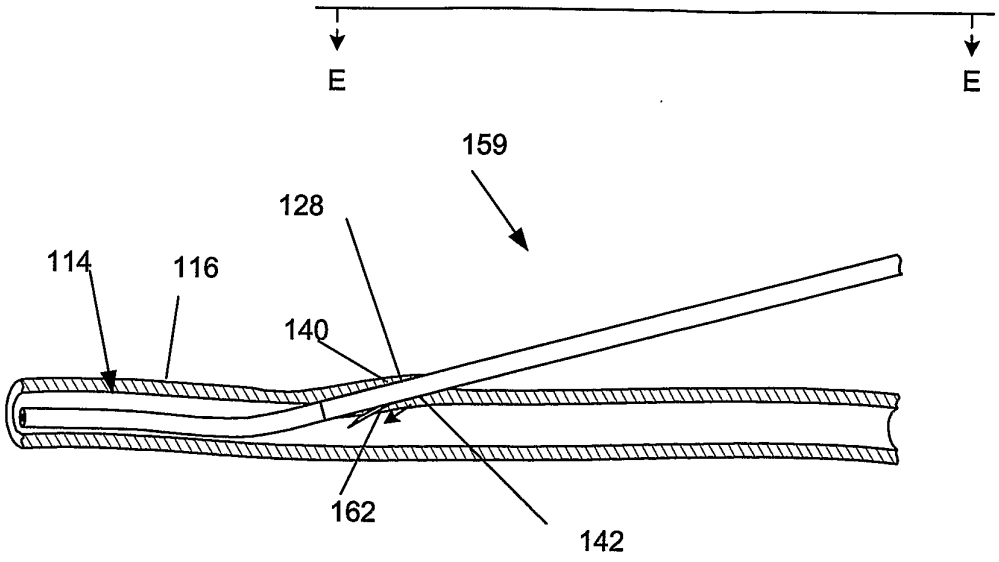


Fig. 51

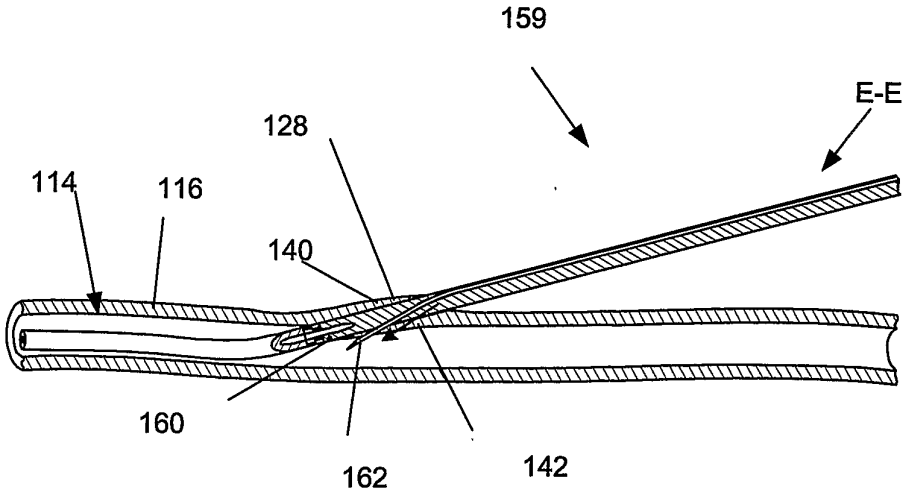


Fig. 52

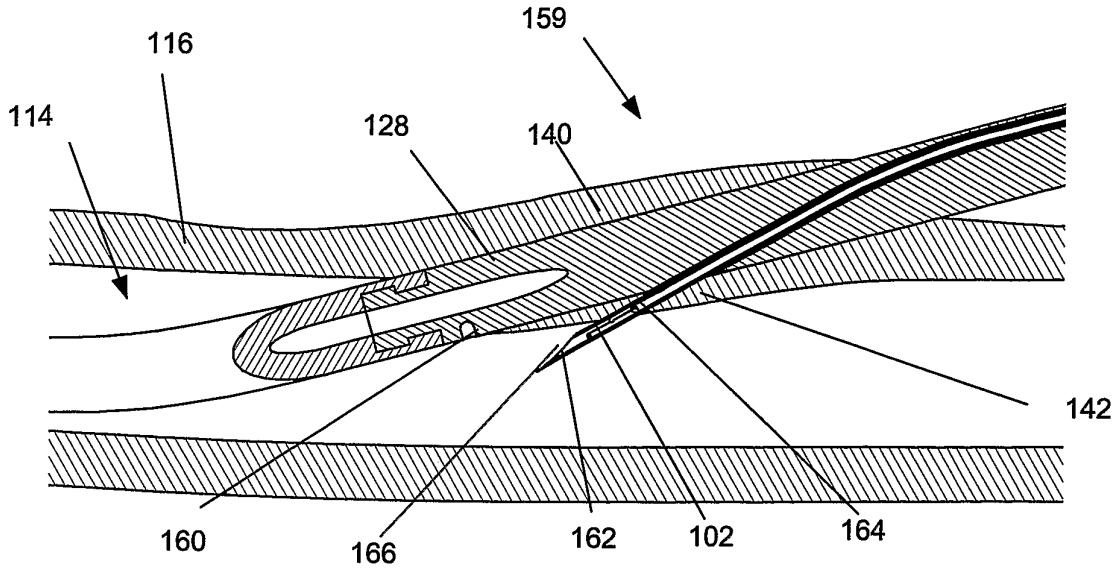

159
116
114
128
140
142
160
166
162
102
164

Fig. 53

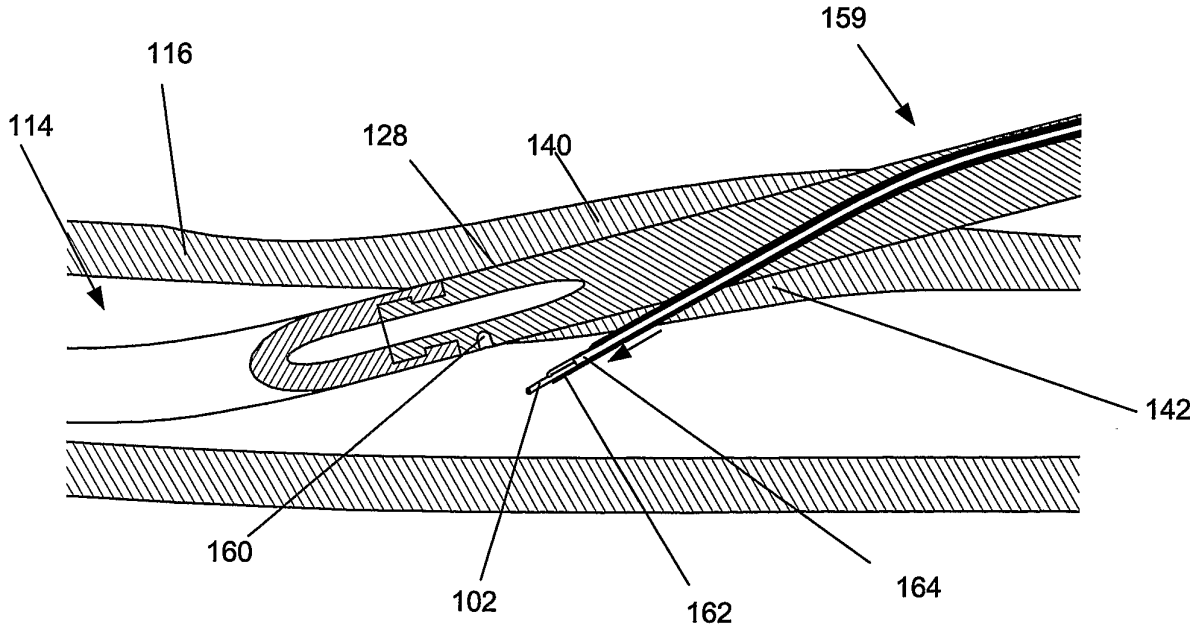

159
116
114
128
140
142
160
102
162
164

Fig. 54

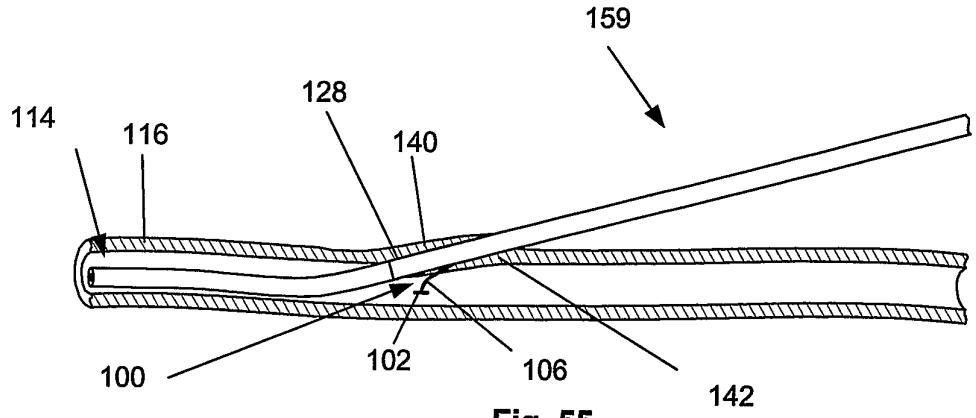

159
128
114
116
140
100
102
106
142

Fig. 55

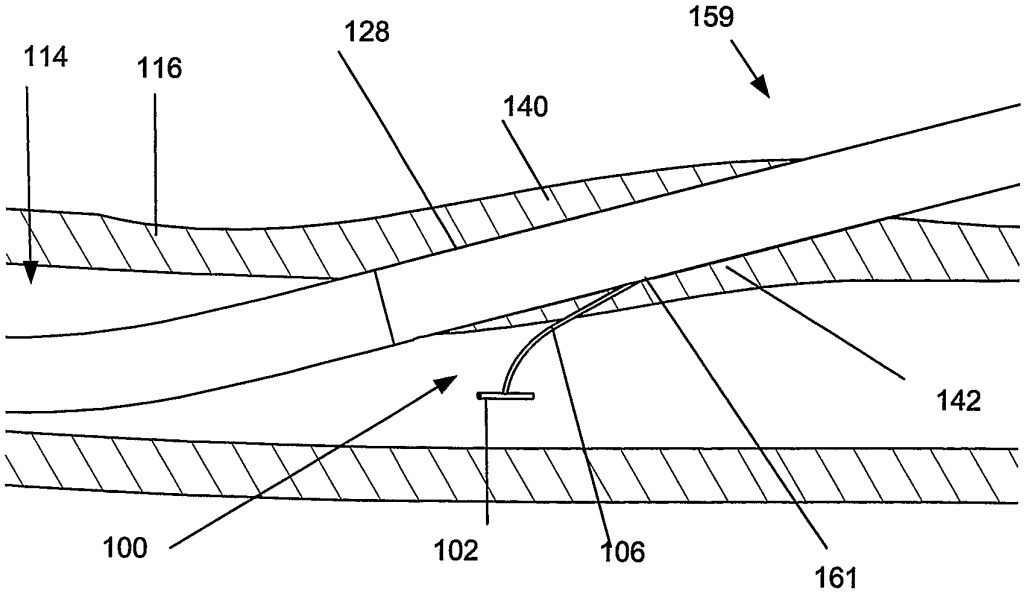

159
128
114
116
140
142
100
102
106
161

Fig. 56

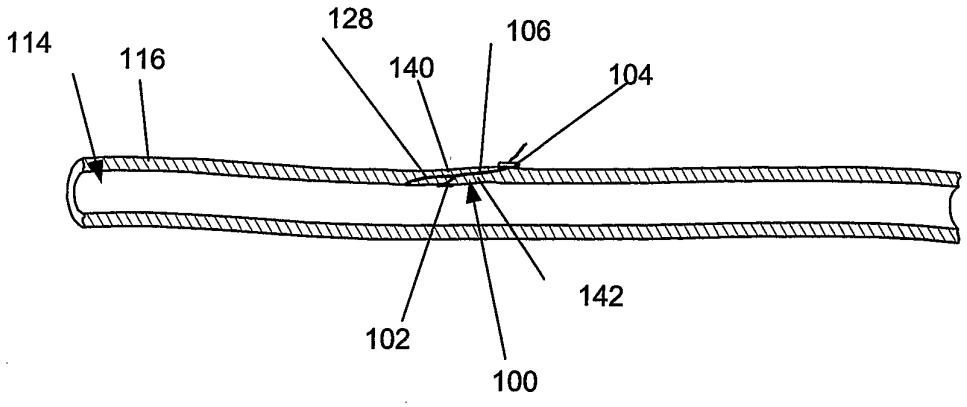

114
116
128
140
106
104
142
102
100

Fig. 57

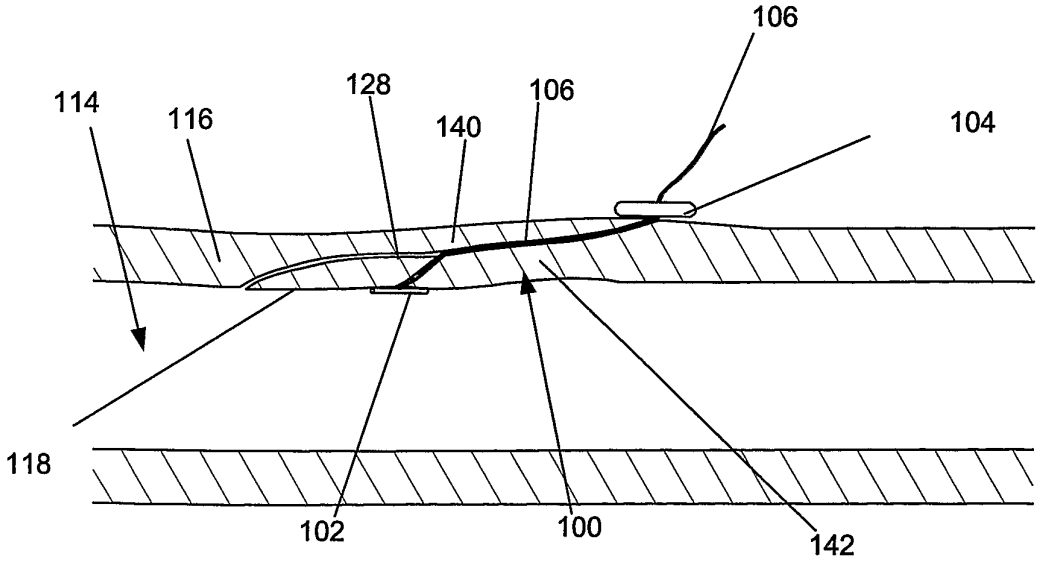

106
114
116
128
140
106
104
118
102
100
142

Fig. 58

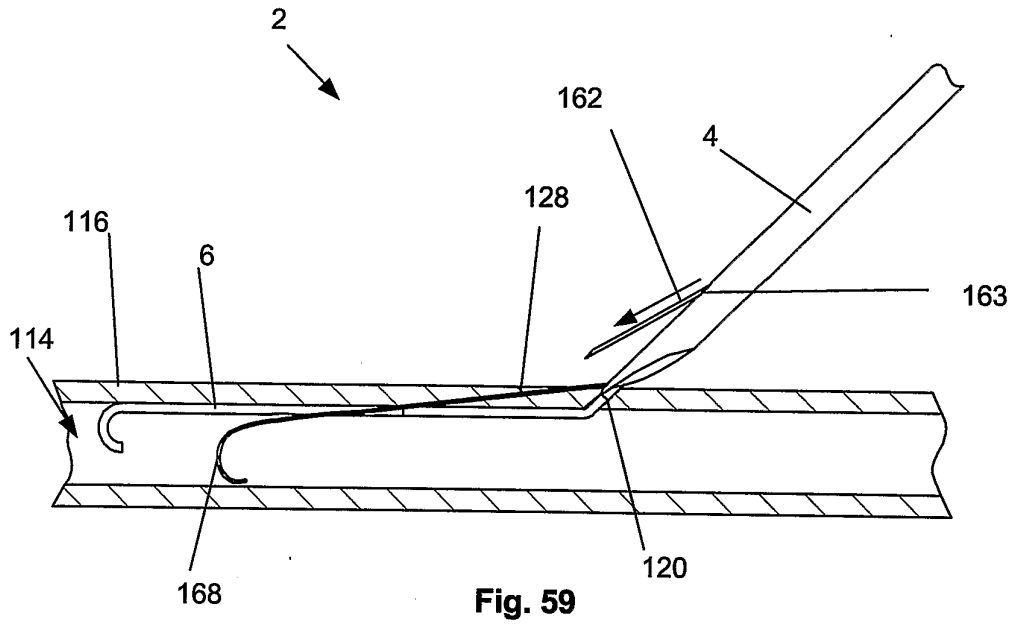


Fig. 59

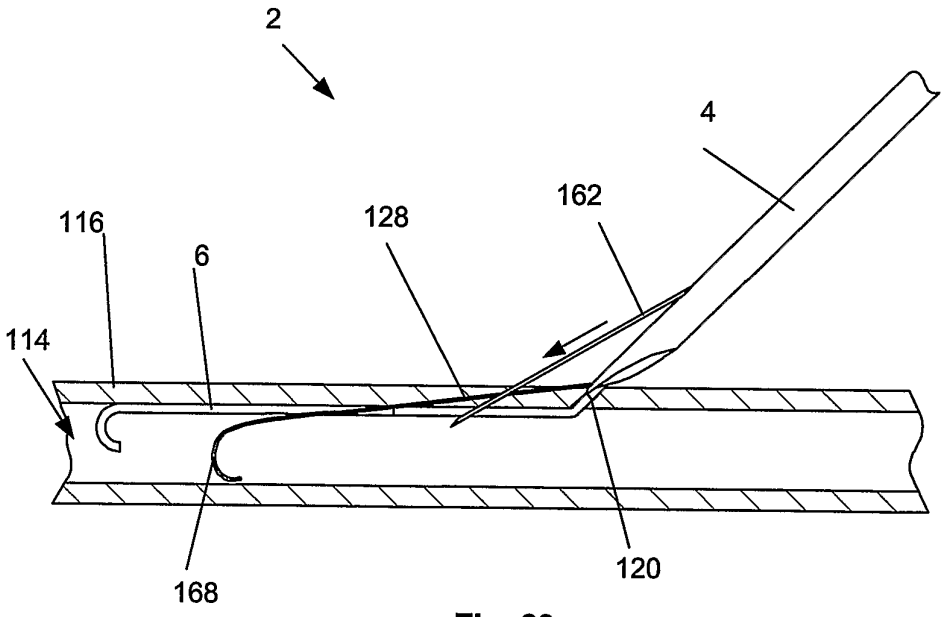


Fig. 60

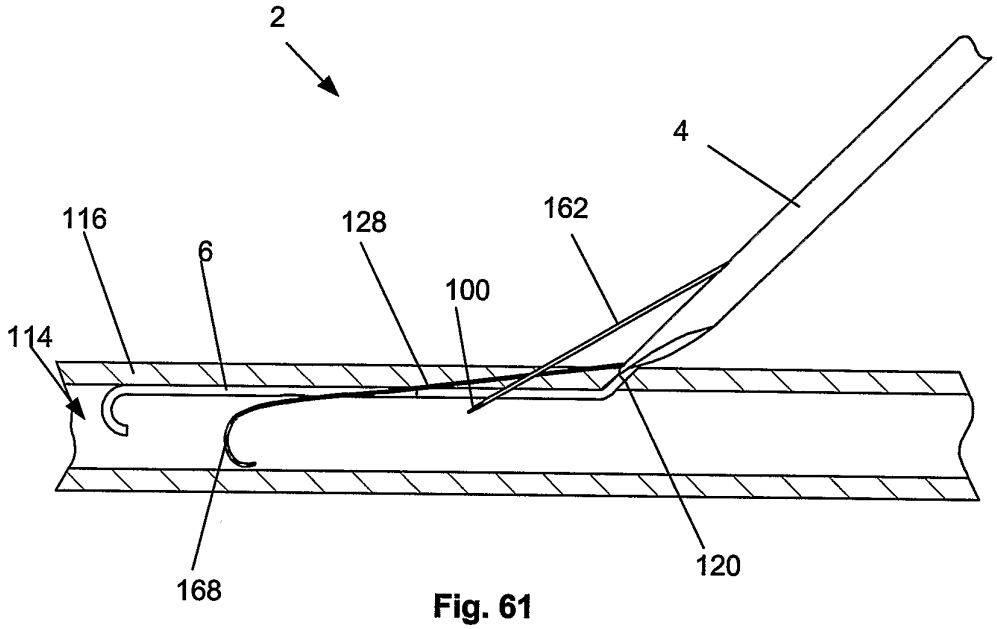

2
4
116
6
128
162
100
114
168
120

Fig. 61

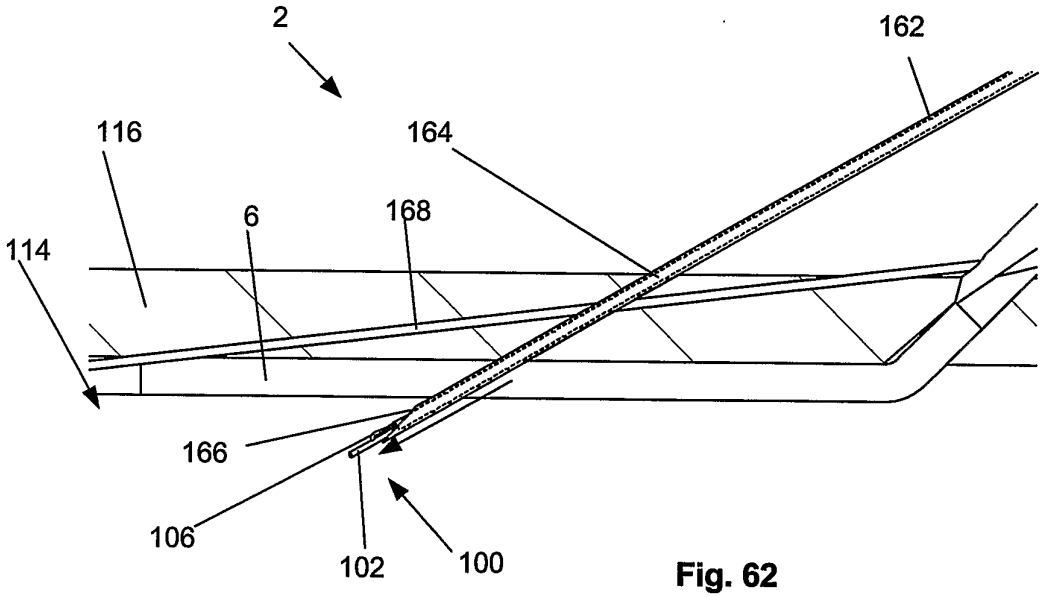

2
162
116
164
6
168
114
166
106
102
100

Fig. 62

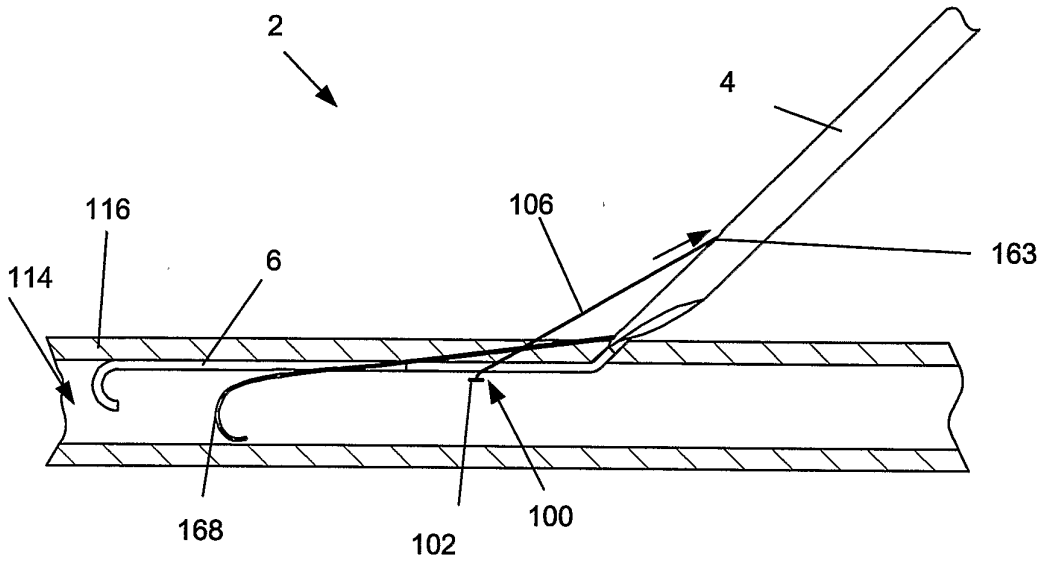


Fig. 63

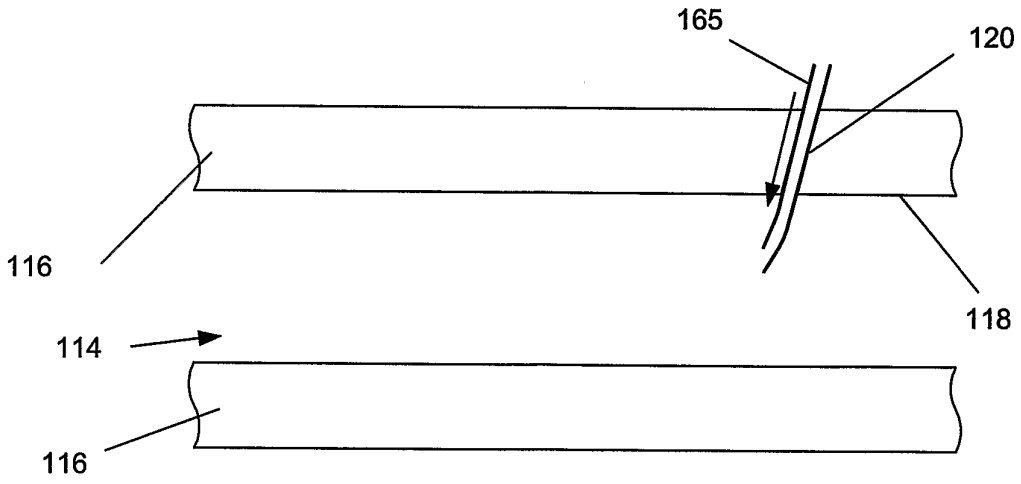


Fig. 64

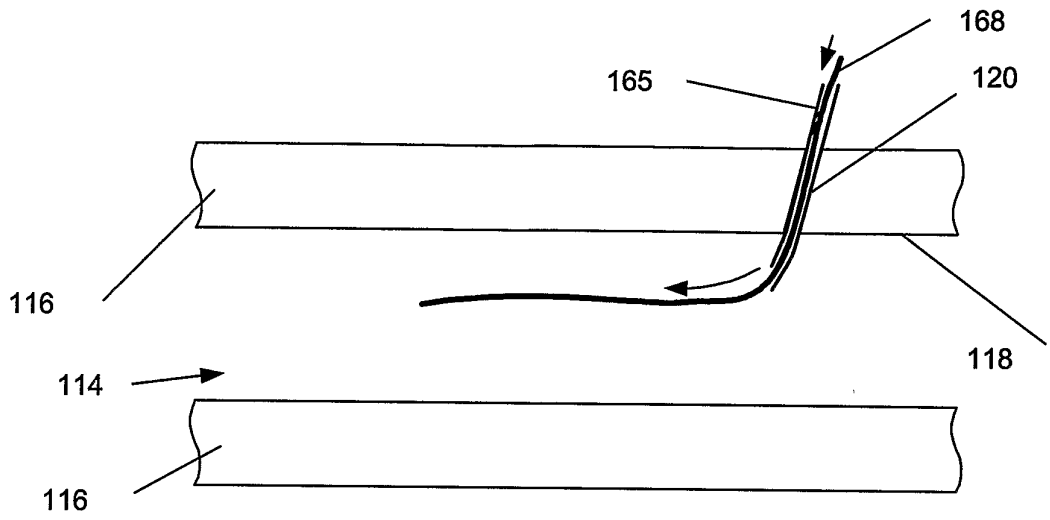


Fig. 65

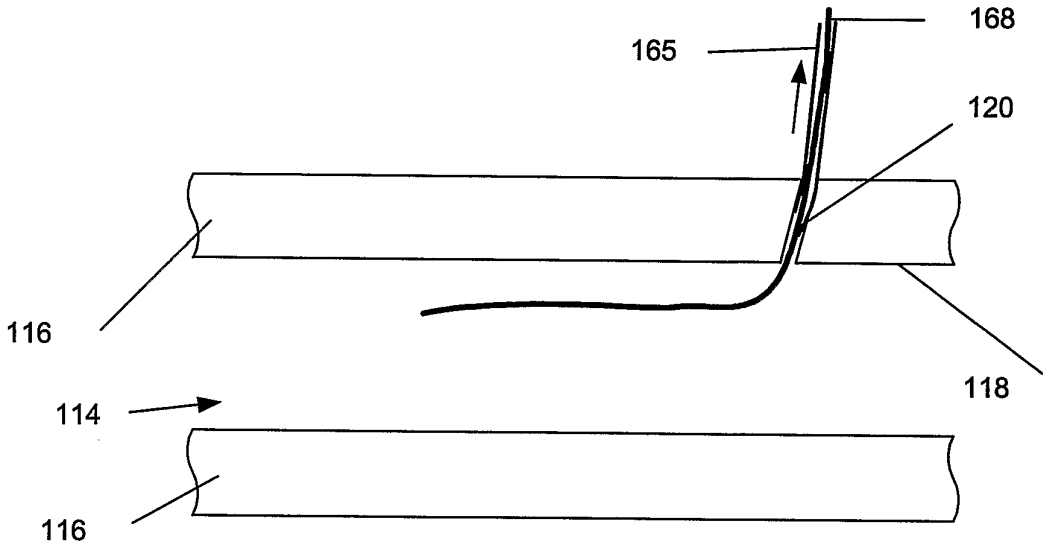


Fig. 66

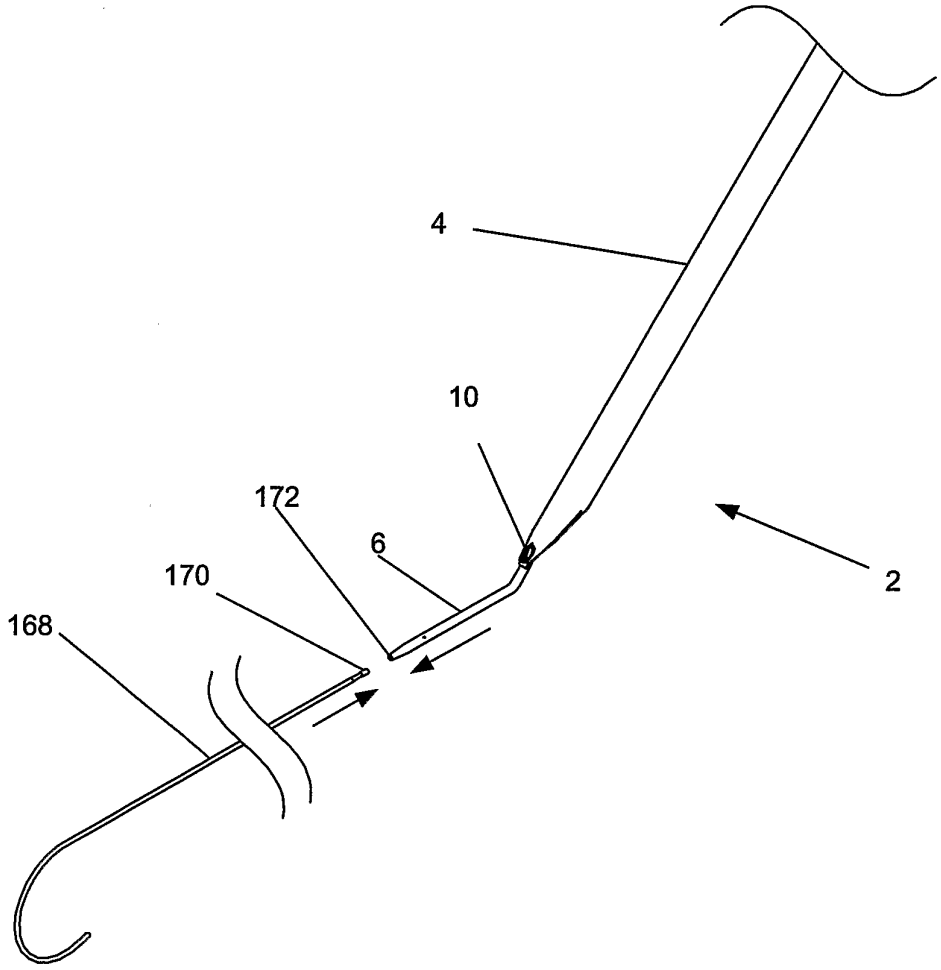


Fig. 67

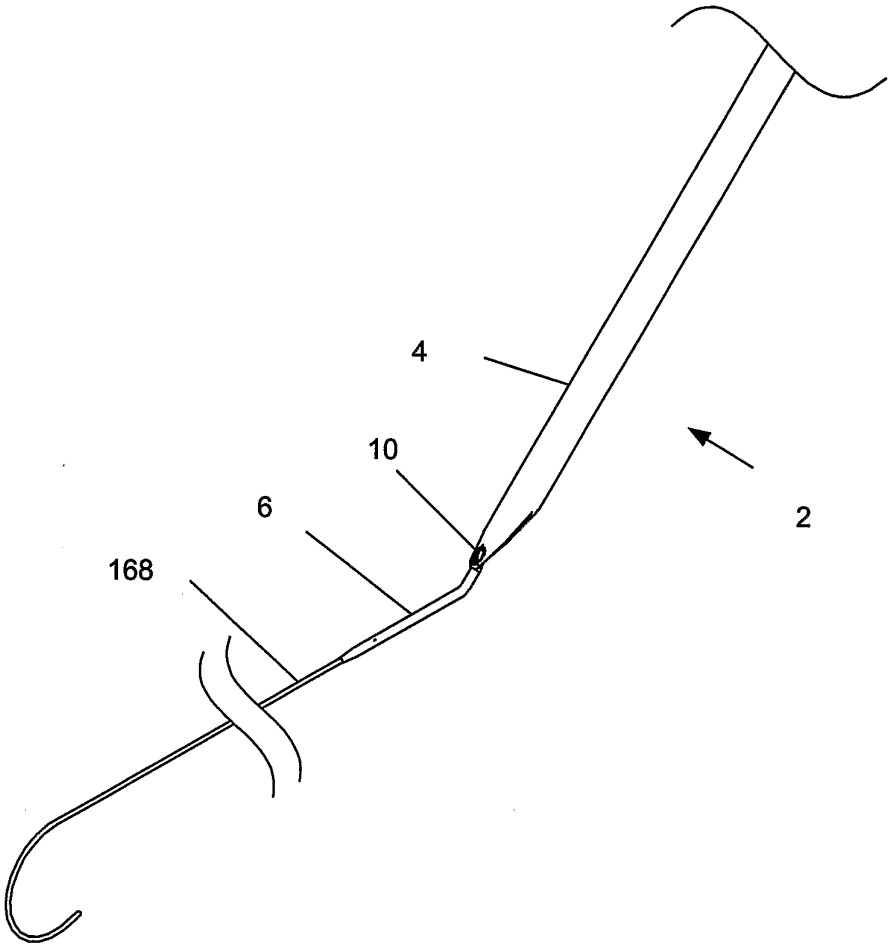


Fig. 68