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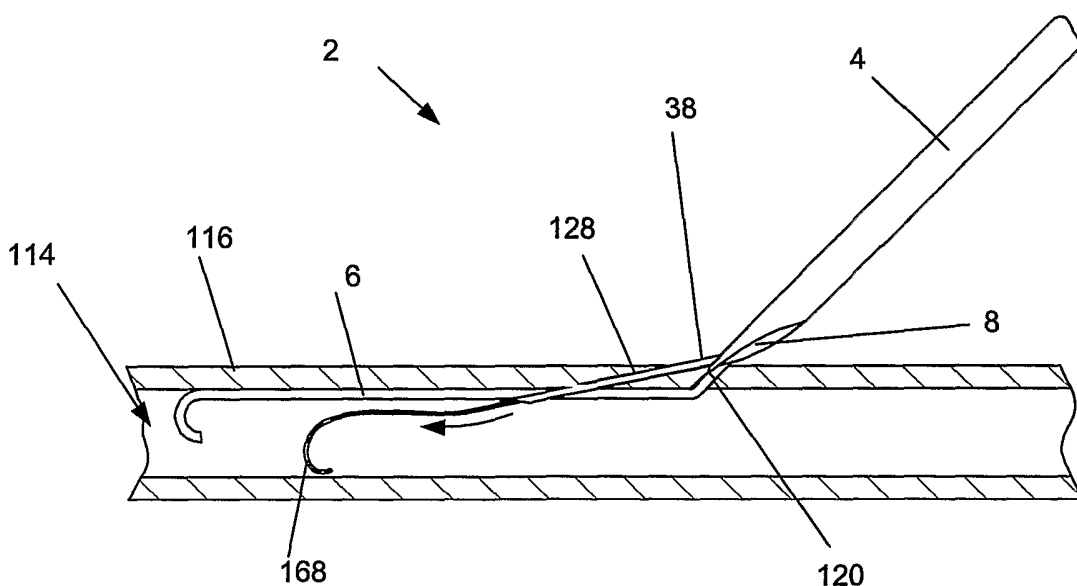
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(54) Title: ACCESS AND CLOSURE DEVICE AND METHOD



(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.

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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 transluminally, 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

1 intrudes into the vascular lumen, thrombus can form on the fastener. Thrombus can
2 embolize downstream and/or block normal blood flow at the thrombus site.

3 Implanted fasteners can also cause infection and auto-immune reactions/rejections of
4 the implant.

5 [0006] Suturing methods are also used to provide hemostasis after vascular access.
6 The suture-applying device is introduced through the tissue tract with a distal end of
7 the device located at the vascular puncture. Needles in the device draw suture
8 through the blood vessel wall on opposite sides of the punctures, and the suture is
9 secured directly over the adventitial surface of the blood vessel wall to close the
10 vascular access wound.

11 [0007] To be successful, suturing methods need to be performed with a precise
12 control. The needles need to be properly directed through the blood vessel wall so
13 that the suture is well anchored in tissue to provide for tight closure. Suturing
14 methods also require additional steps for the surgeon.

15 [0008] Due to the deficiencies of the above methods and devices, a need exists for a
16 more reliable vascular closure method and device. There also exists a need for a
17 vascular closure device and method that does not implant a foreign substance and is
18 self-sealing. There also exists a need for a vascular closure device and method
19 requiring no or few extra steps to close the vascular site.

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DISCLOSURE OF INVENTION

22 [0009] A device for accessing a biological lumen is disclosed. The biological lumen
23 has a lumen wall having a longitudinal lumen wall axis. The device has an elongated
24 member that has a longitudinal member axis. The member is configured to access the
25 lumen at a first angle. The first angle is defined by the longitudinal lumen wall axis
26 and the longitudinal member axis. The first angle is less than about 19 degrees.

27 [0010] The first angle can be less than about 15 degrees. The first angle can be less
28 than about 10 degrees. The device can also have an anchor. The anchor can be
29 configured to hold the elongated member at a fixed angle with respect to the
30 longitudinal lumen wall axis.

31 [0011] The device can also have a retainer. The retainer can be configured to hold the
32 elongated member at a fixed angle with respect to the longitudinal lumen axis.

1 [0012] Another device for accessing a biological lumen is disclosed. The biological
2 lumen has a lumen wall and a longitudinal lumen wall axis. The device has a first
3 elongated member and a second elongated member. The first elongated member has a
4 first elongated member axis. The second elongated member has a second elongated
5 member axis. The second elongated member is configured so that the second
6 elongated member axis is parallel to the longitudinal lumen wall axis.

7 [0013] The second elongated member can have a retainer. The retainer can have an
8 inflatable member. The retainer can have a resilient member. The second elongated
9 member can extend substantially adjacent to the lumen wall.

10 [0014] Also disclosed is a device for closing an opening on a biological lumen wall.
11 The device has a longitudinal axis, a first force-applying member, a second force-
12 applying member, and a resilient member. The resilient member provides to the first
13 and the second force-applying members a force that is radially outward with respect
14 to the longitudinal axis.

15 [0015] A method of accessing a blood vessel through a blood vessel wall is also
16 disclosed. The blood vessel wall has a longitudinal wall axis. The method includes
17 entering the vessel at an angle of less than about 19 degrees with respect to the
18 longitudinal wall axis. The method also includes inserting a luminal tool into the
19 vessel.

20 [0016] Also disclosed is a method for accessing a biological lumen. The biological
21 lumen has a lumen wall and a longitudinal lumen wall axis. The method includes
22 inserting in the biological lumen a second elongated member. The second elongated
23 member has a second elongated member axis. The method also includes aligning the
24 second elongated member so that the second elongated member axis is substantially
25 parallel to the longitudinal lumen wall axis. Further, the method includes inserting in
26 the biological lumen a first elongated member comprising a first elongated member
27 axis.

28 [0017] Additionally disclosed is a method of closing a vascular opening. The
29 vascular opening has an inside surface and a longitudinal axis. The method includes
30 inserting a device in the opening and applying a force to the inside surface. The force
31 is directed in at least one radially outward direction from the longitudinal axis.

1 [0018] The method can include maintaining the force. The applying a force can
2 include the device applying at least a part of the force. The applying of a force can
3 include the device applying all of the force.

4 [0019] Also disclosed is a method for accessing and closing a blood vessel having a
5 vessel wall. The vessel wall can have an inside surface and an outside surface. The
6 method includes forming an arteriotomy and deploying a closure augmentation device
7 in the arteriotomy. The closure augmentation device produces pressure on the inside
8 surface and the outside surface.

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BRIEF DESCRIPTION OF THE DRAWINGS

11 [0020] Figure 1 is a front perspective view of an embodiment of the arteriotomy
12 device.

13 [0021] Figure 2 is a side view of the arteriotomy device of Figure 1.

14 [0022] Figure 3 is a close-up view of the arteriotomy device of Figure 1.

15 [0023] Figures 4 and 5 are close-up views of various embodiments of the anchor.

16 [0024] Figure 6 is a side perspective view of an embodiment of the arteriotomy
17 device with the introduction device deployed.

18 [0025] Figure 7 is a close-up view of an embodiment of the arteriotomy device with
19 the introduction device deployed.

20 [0026] Figures 8 and 9 are side views of various embodiments of the arteriotomy
21 device with the introduction devices deployed.

22 [0027] Figure 10 is a bottom perspective view of an embodiment of the arteriotomy
23 device.

24 [0028] Figure 11 is a side view of an embodiment of the arteriotomy device with the
25 luminal retainer deployed.

26 [0029] Figure 12 is a bottom perspective view of an embodiment of the arteriotomy
27 device with the luminal retainer deployed.

28 [0030] Figure 13 is a side perspective view of an embodiment of the arteriotomy
29 device.

30 [0031] Figure 14 is a side perspective view of an embodiment of the arteriotomy
31 device with the entry wall retainer deployed.

32 [0032] Figures 15 and 16 illustrate various embodiments of the tensioner.

33 [0033] Figures 17 and 18 illustrate various embodiments of the pressure clip.

- 1 [0034] Figures 19 and 20 illustrate various embodiments of the toggle.
- 2 [0035] Figure 21 illustrates a method for deploying the arteriotomy device in a cross-
3 section of a lumen.
- 4 [0036] Figures 22 and 23 illustrate methods for deploying the retainers in a cross-
5 section of a lumen.
- 6 [0037] Figures 24 and 25 illustrate a method for deploying the introduction device in
7 a cross-section of a lumen.
- 8 [0038] Figure 26 illustrates a method for deploying a guidewire in a cross-section of a
9 lumen.
- 10 [0039] Figures 27-30 illustrate a method for deploying the introduction device in a
11 cross-section of a lumen.
- 12 [0040] Figure 31 illustrates a method for deploying a guidewire in a cross-section of a
13 lumen.
- 14 [0041] Figure 32 illustrates a portion of an arteriotomized lumen.
- 15 [0042] Figure 33 illustrates section A-A of Figure 28.
- 16 [0043] Figures 34-36 illustrate a method for deploying a tensioner in a see-through
17 portion of lumen wall.
- 18 [0044] Figures 37-40 illustrate methods for deploying various embodiments of the
19 pressure clip in a cross-section of a lumen.
- 20 [0045] Figure 41 illustrates a method of using a suture on a portion of an
21 arteriotomized lumen.
- 22 [0046] Figure 42 illustrates section B-B of Figure 41 with the out-of-section suture.
- 23 [0047] Figure 43 illustrates a method of using pledgets on a portion of an
24 arteriotomized lumen.
- 25 [0048] Figure 44 illustrates section C-C of Figure 43.
- 26 [0049] Figure 45 illustrates an embodiment of the toggle deployment device in a first
27 configuration.
- 28 [0050] Figure 46 is a close-up view of Figure 45.
- 29 [0051] Figure 47 illustrates an embodiment of the toggle deployment device in a
30 second configuration.
- 31 [0052] Figure 48 is a close-up view of Figure 47.
- 32 [0053] Figure 49 illustrates a method of using the toggle deployment device in a
33 cross-section of a lumen.

1 [0054] Figure 50 illustrates Figure 49 with a portion of the toggle deployment device
2 shown in section D-D.

3 [0055] Figure 51 illustrates a method of using the toggle deployment device in a
4 cross-section of a lumen.

5 [0056] Figure 52 illustrates Figure 51 with a portion of the toggle deployment device
6 shown in section E-E.

7 [0057] Figures 53-55 illustrate a method of using the toggle deployment device in a
8 cross-section of a lumen.

9 [0058] Figure 56 is a close-up view of Figure 55.

10 [0059] Figure 57 illustrates an embodiment of a deployed toggle in a cross-section of
11 a lumen.

12 [0060] Figure 58 is a close-up view of Figure 59.

13 [0061] Figures 59-61 illustrate a method for deploying a toggle in a cross-section of a
14 lumen.

15 [0062] Figure 62 is a close-up view of Figure 61.

16 [0063] Figure 63 illustrates a method for deploying a toggle in a cross-section of a
17 lumen.

18 [0064] Figures 64-66 shown, in cross-section, a method for deploying the guidewire
19 through an arteriotomy.

20 [0065] Figures 67 and 68 illustrate a method for attaching guidewire to the anchor.
21

22 DETAILED DESCRIPTION

23 AND INDUSTRIAL APPLICABILITY

24 [0066] Figures 1 through 3 illustrate a device for accessing a biological lumen, such
25 as an arteriotomy device 2. The arteriotomy device 2 can have a delivery guide 4.

26 The delivery guide 4 can be slidably attached to an anchor 6. The anchor 6 can be
27 rigid, flexible or combinations thereof. The anchor 6 can be resilient, deformable or
28 combinations thereof. The anchor 6 can be retractable and extendable from the
29 delivery guide 4. The delivery guide 4 can have an introducer lumen 8. The
30 introducer lumen 8 can have an introducer lumen exit port 10. The introducer lumen
31 exit port 10 can be on the surface of the delivery guide 4.

32 [0067] The anchor 6 can have an anchor angle section 12. The anchor 6 can have an
33 anchor extension section 14, for example a guide eye sheath or an attachable

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

4 [0068] The anchor angle section 12 can have an anchor angle first sub-section 16, an
5 anchor bend 20 and an anchor angle second sub-section 18. The anchor angle first
6 and/or second sub-sections 16 and/or 18 can be part of the anchor bend 20. The
7 anchor bend 20 can have a sharp or gradual curve. The radius of curvature for the
8 anchor bend 20 can be from about 0.1 mm (0.004 in.) to about 2.0 mm (0.079 in.).

9 [0069] The anchor angle first sub-section 16 can have an anchor angle first sub-
10 section diameter 22 from about 0.38 mm (0.015 in.) to about 1.0 mm (0.039 in.), for
11 example about 0.71 mm (0.028 in.). The anchor angle second sub-section 18 can
12 have an anchor angle second sub-section diameter 24 from about 0.38 mm (0.015 in.)
13 to about 1.0 mm (0.039 in.), for example about 0.71 mm (0.028 in.).

14 [0070] The anchor angle first sub-section 16 can have a delivery longitudinal axis 26.
15 The anchor angle second sub-section 18 can have an anchor longitudinal axis 28. The
16 intersection of the delivery longitudinal axis 26 and the anchor longitudinal axis 28
17 can be an anchoring angle 30. The anchoring angle 30 can be from about 20° to about
18 90°, more narrowly from about 30° to about 60°, for example about 45°.

19 [0071] Any or all elements of the arteriotomy device 2 or other devices or
20 apparatuses described herein can be made from, for example, a single or multiple
21 stainless steel alloys, nickel titanium alloys (e.g., Nitinol), cobalt-chrome alloys (e.g.,
22 ELGILOY® from Elgin Specialty Metals, Elgin, IL; CONICHROME® from
23 Carpenter Metals Corp., Wyomissing, PA), molybdenum alloys (e.g., molybdenum
24 TZM alloy, for example as disclosed in International Pub. No. WO 03/082363 A2,
25 published 9 October 2003, which is herein incorporated by reference in its entirety),
26 tungsten-rhenium alloys, for example, as disclosed in International Pub. No. WO
27 03/082363, polymers such as polyester (e.g., DACRON® from E. I. Du Pont de
28 Nemours and Company, Wilmington, DE), polypropylene, polytetrafluoroethylene
29 (PTFE), expanded PTFE (ePTFE), polyether ether ketone (PEEK), nylon, polyether-
30 block co-polyamide polymers (e.g., PEBAX® from ATOFINA, Paris, France),
31 aliphatic polyether polyurethanes (e.g., TECOFLEX® from Thermedics Polymer
32 Products, Wilmington, MA), polyvinyl chloride (PVC), polyurethane, thermoplastic,
33 fluorinated ethylene propylene (FEP), absorbable or resorbable polymers such as

1 polyglycolic acid (PGA), polylactic acid (PLA), polydioxanone, and pseudo-
2 polyamino tyrosine-based acids, extruded collagen, silicone, zinc, echogenic,
3 radioactive, radiopaque materials or combinations thereof. Examples of radiopaque
4 materials are barium sulfate, zinc oxide, titanium, stainless steel, nickel-titanium
5 alloys, tantalum and gold.

6 [0072] Any or all elements of the arteriotomy device 2, including supplemental
7 closure devices, such as tensioners, clips, toggles, sutures, or other devices or
8 apparatuses described herein can be or have a matrix for cell ingrowth or used with a
9 fabric, for example a covering (not shown) that acts as a matrix for cell ingrowth. The
10 matrix and/or fabric can be, for example, polyester (e.g., DACRON® from E. I. du
11 Pont de Nemours and Company, Wilmington, DE), polypropylene, PTFE, ePTFE,
12 nylon, extruded collagen, silicone or combinations thereof.

13 [0073] The elements of the arteriotomy device 2 and/or the fabric can be filled and/or
14 coated with an agent delivery matrix known to one having ordinary skill in the art
15 and/or a therapeutic and/or diagnostic agent. The agents within these matrices can
16 include radioactive materials; radiopaque materials; cytogenic agents; cytotoxic
17 agents; cytostatic agents; thrombogenic agents, for example polyurethane, cellulose
18 acetate polymer mixed with bismuth trioxide, and ethylene vinyl alcohol; lubricious,
19 hydrophilic materials; phosphor cholene; anti-inflammatory agents, for example non-
20 steroidal anti-inflammatories (NSAIDs) such as cyclooxygenase-1 (COX-1) inhibitors
21 (e.g., acetylsalicylic acid, for example ASPIRIN® from Bayer AG, Leverkusen,
22 Germany; ibuprofen, for example ADVIL® from Wyeth, Collegeville, PA;
23 indomethacin; mefenamic acid), COX-2 inhibitors (e.g., VIOXX® from Merck &
24 Co., Inc., Whitehouse Station, NJ; CELEBREX® from Pharmacia Corp., Peapack,
25 NJ; COX-1 inhibitors); immunosuppressive agents, for example Sirolimus
26 (RAPAMUNE®, from Wyeth, , Collegeville, PA), or matrix metalloproteinase
27 (MMP) inhibitors (e.g., tetracycline and tetracycline derivatives) that act early within
28 the pathways of an inflammatory response. Examples of other agents are provided in
29 Walton et al, Inhibition of Prostaglandin E₂ Synthesis in Abdominal Aortic
30 Aneurysms, *Circulation*, July 6, 1999, 48-54; Tambiah et al, Provocation of
31 Experimental Aortic Inflammation Mediators and Chlamydia Pneumoniae, *Brit. J.*
32 *Surgery* 88 (7), 935-940; Franklin et al, Uptake of Tetracycline by Aortic Aneurysm
33 Wall and Its Effect on Inflammation and Proteolysis, *Brit. J. Surgery* 86 (6), 771-775;

1 Xu et al, Sp1 Increases Expression of Cyclooxygenase-2 in Hypoxic Vascular
2 Endothelium, *J. Biological Chemistry* 275 (32) 24583-24589; and Pyo et al, Targeted
3 Gene Disruption of Matrix Metalloproteinase-9 (Gelatinase B) Suppresses
4 Development of Experimental Abdominal Aortic Aneurysms, *J. Clinical Investigation*
5 105 (11), 1641-1649 which are all incorporated by reference in their entireties.
6 [0074] Figure 4 illustrates that the anchor angle section 12 and the anchor extension
7 section 14 can have a flexible elongated element. The flexible elongated element can
8 be resilient and/or deformable. The flexible elongated element can have an integral,
9 or multiple separate and fixedly attached, wound wire 32. The anchor angle section
10 12 can be in a sheath 34. Figure 5 illustrates that the anchor angle section 12 can have
11 a wire coating 36, for example a lubricious coating and/or a coating made from
12 urethane.

13 [0075] Figures 6 and 7 illustrate that the arteriotomy device 2 can have an
14 introduction device 38. The introduction device 38 can be slidably attached to the
15 introducer lumen 8. The introduction device 38 can have a hollow needle (as shown
16 in Figure 6). The introduction device 38 can have a solid needle (as shown in Figure
17 7). The introduction device 38 can have a guidewire.

18 [0076] The introduction device 38 can have an introduction longitudinal axis 40. The
19 intersection of the introduction longitudinal axis 40 and the anchor longitudinal axis
20 28 can be an introduction angle 42. The introduction angle 42 can be less than or
21 equal to about 19°, more narrowly less than or equal to about 15°, yet more narrowly
22 from about 5° to about 10°, for example about 10°.

23 [0077] The introduction device 38 can have an introduction device diameter 44. The
24 introduction device diameter 44 can be from about 0.25 mm (0.010 in.) to about 1.0
25 mm (0.039 in.), for example about 0.56 mm (0.022 in.).

26 [0078] Figures 8 and 9 illustrate that the arteriotomy device 2 can be configured so
27 that the introduction device 38 can be deployed from the anchor 6. The anchor 6 can
28 have an introduction device port 46. The introduction device 38 can be a hollow
29 needle (as shown in Figure 8). When fully deployed, the introduction device 38 can
30 contact the introducer lumen exit port 10. The introduction device 38 can be a
31 channel between the introducer lumen 8 and the anchor 6. The anchor 6 can have a
32 port (not shown) configured to communicate with the biological lumen and the

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

3 [0079] Figure 10 illustrates that a luminal retainer 48 can have a first retracted
4 configuration. The luminal retainer 48 can be seated in a luminal retainer port 50.
5 The luminal retainer port 50 can be in the anchor 6. The luminal retainer 48 can be a
6 wire, scaffold or stent - for example made from a deformable or resilient material,
7 such as a shape memory alloy - an inflatable balloon, or combinations thereof.
8 Intraluminal inflatable balloons, such as those inflated with saline solution or carbon
9 dioxide, are known to those having ordinary skill in the art. The luminal retainer 48
10 can extend into the delivery guide 4.

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

18 [0081] Figure 13 illustrates that the arteriotomy device 2 can have an entry wall
19 retainer port 54. The entry wall retainer port 54 can be at or near the anchor bend 20.
20 The entry wall retainer port 54 can be at or near the anchor angle first sub-section 16.
21 The entry wall retainer port 54 can be in fluid communication with a sensor or port
22 (not shown) on or near the delivery guide 4 of the arteriotomy device 2.

23 [0082] Figure 14 illustrates that an entry wall retainer 56 can be deployed through the
24 entry wall retainer port 54. The entry wall retainer 56 can have a first retracted
25 configuration (as shown in Figure 13). The entry wall retainer 56 can have a second
26 deployed configuration (as shown in Figure 14).

27 [0083] Figures 15 through 20 illustrate various supplemental closure devices. The
28 supplemental closure devices can be completely or partially bioabsorbable,
29 bioresorbable, bioadsorbable or combinations thereof. The supplemental closure
30 devices can be made from homografts, heterografts or combinations thereof. The
31 supplemental closure devices can be made from autografts, allografts or combinations
32 thereof.

1 [0084] Figure 15 illustrates a tensioner 58. The tensioner 58 can be resilient,
2 deformable, or combinations thereof. The tensioner 58 can have a tensioner
3 longitudinal axis 60. The tensioner 58 can have a resilient element, such as a spring,
4 for example a tensioner head 62. The tensioner head 62 can have a tensioner first
5 shoulder 64. The tensioner head 62 can have a tensioner second shoulder 66. The
6 tensioner first and second shoulders 64 and 66 can rotatably attached to a separate or
7 integral tensioner first leg 68 and a separate or integral tensioner second leg 70,
8 respectively. The tensioner first and second legs 68 and 70 can attach to tensioner
9 first and second feet 72 and 74, respectively.

10 [0085] The tensioner legs 68 and 70 can have tensioner leg diameters 76. The
11 tensioner leg diameters 76 can be from about 0.1 mm (0.005 in.) to about 0.76 mm
12 (0.030 in.), for example about 0.38 mm (0.015 in.). The tensioner first and second
13 legs 68 and 70 can have a tensioner inter-leg outer diameter 78. The tensioner inter-
14 leg outer diameter 78 can be from about 1.3 mm (0.050 in.) to about 5.08 mm (0.200
15 in.), for example about 4.06 mm (0.160 in.). The tensioner shoulders 64 and/or 66
16 and/or the tensioner feet 72 and/or 74 can extend to a greater radius from the tensioner
17 longitudinal axis 60 than their respective tensioner inter-leg radius.

18 [0086] Figure 16 illustrates a tensioner first strut 80 that can attach to the tensioner
19 first leg 68 and the tensioner second leg 70. The tensioner first leg 68 can be resilient,
20 deformable or combinations thereof. A tensioner second strut 82 can attach to the
21 tensioner first leg 68 and the tensioner second leg 70. The tensioner second leg 70
22 can be resilient and/or deformable. The tensioner 58 can have no tensioner head 62.
23 The tensioner 58 can have more than two tensioner struts 80 and 82.

24 [0087] Figure 17 illustrates a pressure clip 84. The pressure clip 84 can be resilient.
25 The pressure clip 84 can be deformable. The pressure clip 84 can have a pressure clip
26 longitudinal axis 86. The pressure clip 84 can have a pressure clip head 88. The
27 pressure clip head 88 can be rotatably attached to a separate or integral pressure clip
28 first leg 90. The pressure clip head 88 can be rotatably attached to a separate or
29 integral pressure clip second leg 92. The pressure clip can have a pressure clip first
30 end 94 and a pressure clip second end 96. The pressure clip first leg 90 can terminate
31 in the pressure clip first end 94. The pressure clip second leg 92 can terminate in the
32 pressure clip second end 96. The pressure clip first leg 90 and/or the pressure clip
33 second leg 92 can be biased toward the pressure clip longitudinal axis 86.

1 [0088] Figure 18 illustrates the pressure clip 84 that can have a pressure clip sheath
2 98 slidably attached to the pressure clip second leg 92. The pressure clip first and/or
3 second ends 94 and/or 96 can be pressure dissipaters, such as flat and/or curved
4 portions, for example circular loops. The pressure clip first and/or second ends 94
5 and/or 96 can be resilient and/or deformable. The pressure clip first leg 90 can be
6 rotatably attached to the pressure clip second leg 92. The pressure clip first leg 90 can
7 be attached to the pressure clip second leg 92 via a rotatable, and/or deformable,
8 and/or flexural joint in the pressure clip head 88.

9 [0089] Figure 19 illustrates a toggle 100. The toggle 100 can have a toggle first end
10 102. The toggle 100 can have a toggle second end 104. The toggle first and/or
11 second ends 102 and/or 104 can be bars, dowels, rods, beams, or combinations
12 thereof. The toggle 100 can have a filament 106. The filament 106 can be fixedly
13 attached at a filament first end 107 to the toggle first end 102. The filament 106 can
14 be fixedly attached at a filament second end 109 to the toggle second end 104. The
15 filament 106 can be resilient or deformable. The filament 106 can be substantially
16 flexible.

17 [0090] Figure 20 illustrates the toggle 100 that can have the filament 106 that can be
18 slidably attached to the toggle second end 104 at a hole 108. The filament 106 can
19 frictionally fit the hole 108. The filament 106 can have no pawls 110 (not shown in
20 Figure 20). The filament 106 can interference fit the hole 108. The filament 106 can
21 have one or more pawls 110. The hole 108 can have one or more notches 112. The
22 notches 112 can be internal to the hole 108. The notches 112 and the pawls 110 can
23 be configured to allow the toggle second end 104 to slide toward the toggle first end
24 102. The notches 112 and the pawls 110 can be configured to provide an interference
25 fit when the toggle second end 104 is attempted to be moved away from the toggle
26 first end 102.

27

28 METHOD OF MANUFACTURE

29 [0091] The elements of the arteriotomy device 2, including the supplemental closure
30 devices, can be directly attached by, for example, melting, screwing, gluing, welding
31 or use of an interference fit or pressure fit such as crimping, snapping, or combining
32 methods thereof. The elements can be integrated, for example, molding, die cutting,
33 laser cutting, electrical discharge machining (EDM) or stamping from a single piece

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

3 **[0092]** Integrated parts can be made from pre-formed resilient materials, for example
4 resilient alloys (e.g., Nitinol, ELGILOY®) that are preformed and biased into the
5 post-deployment shape and then compressed into the deployment shape as known to
6 those having ordinary skill in the art.

7 **[0093]** Any elements of the arteriotomy device 2, including the supplemental closure
8 devices, or the arteriotomy device 2, including the supplemental closure devices, as a
9 whole after assembly, can be coated by dip-coating, brush-coating or spray-coating
10 methods known to one having ordinary skill in the art. For example, these methods
11 can be used to coat the wound wire 32 with the wire coating 36 can be spray coated,
12 dip-coated or brushed onto the wire 32.

13 **[0094]** One example of a method used to coat a medical device for vascular use is
14 provided in U.S. Patent No. 6,358,556 by Ding et al. and hereby incorporated by
15 reference in its entirety. Time release coating methods known to one having ordinary
16 skill in the art can also be used to delay the release of an agent in the coating, for
17 example the coatings on the supplemental closure devices.

18 **[0095]** The supplemental closure devices can be covered with a fabric, for example
19 polyester (e.g., DACRON® from E. I. du Pont de Nemours and Company,
20 Wilmington, DE), polypropylene, PTFE, ePTFE, nylon, extruded collagen, silicone or
21 combinations thereof. Methods of covering an implantable device with fabric are
22 known to those having ordinary skill in the art.

23

24 METHOD OF USE

25 **[0096]** Figure 21 illustrates a method of inserting the anchor 6 into a biological lumen
26 114, for example a blood vessel, such as a femoral artery. The biological lumen 114
27 can have a lumen wall 116 and a lumen wall surface 118. The anchor 6 can be
28 inserted into the biological lumen 114 using a Seldinger technique, modified
29 Seldinger technique, or other method known to one having ordinary skill in the art.
30 The anchor 6 can create a first arteriotomy 120. The anchor 6 can be inserted into the
31 lumen 114 so that the anchor angle second sub-section 18 can be substantially parallel
32 with the lumen wall surface 118. The anchor 6 can be inserted into the lumen 114 so

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

3 **[0097]** Figure 22 illustrates a method of deploying, as shown by arrow, the luminal
4 retainer 48 from the first retracted configuration to the second deployed configuration.
5 The luminal retainer 48 can be deployed by extending a wire, scaffold or stent, or by
6 inflating a balloon. When the luminal retainer 48 is deployed, the anchor angle
7 second sub-section 18 can be made substantially parallel with the lumen wall surface
8 118. When the luminal retainer 48 is deployed, the anchor angle second sub-section
9 18 can be made to be substantially in contact with the lumen wall surface 118.

10 **[0098]** Figure 23 illustrates a method of deploying, as shown by arrow 122, the entry
11 wall retainer 56 from the first retracted configuration to the second deployed
12 configuration. When the luminal retainer is in the second deployed configuration, the
13 luminal retainer 48 can be substantially parallel with the lumen wall surface 118.
14 When the luminal retainer is in the second deployed configuration, the luminal
15 retainer 48 can be substantially in contact with the lumen wall surface 118.

16 **[0099]** A proximal force, as shown by arrow 124, can be applied to the anchor 6, for
17 example by being applied to the delivery guide 4. When the proximal force is
18 applied, the anchor angle second sub-section 18 can be made substantially parallel
19 with the lumen wall surface 118. When the proximal force is applied, the anchor
20 angle second sub-section 18 can be made to be substantially in contact with the lumen
21 wall surface 118.

22 **[0100]** Figures 24 and 25 illustrate a method for deploying the introduction device 38.
23 The introduction device 38 can egress from the introducer lumen 8 and the introducer
24 lumen exit port 10. As shown in Figure 24, the introduction device 38 can be pushed,
25 as shown by arrow, into and through the lumen wall 116. The introduction device 38
26 can form a second arteriotomy 128. As shown in Figure 25, the introduction device
27 38 can be pushed, as shown by arrow, adjacent to or through the anchor 6. The
28 anchor 6 can be configured to have ports suitable to allow the introduction device 38
29 to pass through the anchor 6. A tip of the introduction device 38 can enter the lumen
30 114.

31 **[0101]** The introduction device 38 can pass through an introduction run 132 and an
32 introduction rise 134. The introduction run 132 can be the component of the length of
33 the introduction device 38 in the lumen wall 116 that is parallel to the lumen wall 116.

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

6 **[0102]** The introduction rise 134 can be the component of the length of the
7 introduction device 38 in the lumen wall 116 that is perpendicular to the lumen wall
8 116. The introduction rise 134 can be the component of the length perpendicular to
9 the lumen wall 116 between the opening of the second arteriotomy 128 on the outside
10 of the lumen wall 116 and the opening of the second arteriotomy 128 on the inside
11 lumen wall surface 118. The introduction rise 134 can be from about 0.51 mm (0.020
12 in.) to about 5.08 mm (0.200 in.), for example about 1.0 mm (0.040 in.). An
13 introduction slope can be the ratio of the introduction rise 134 to the introduction run
14 132. The introduction slope can be from about $\frac{1}{2}$ to about $\frac{1}{40}$ or less, for example
15 about $\frac{1}{6}$, also for example about $\frac{1}{3}$. The introduction slope can be, for examples,
16 equal to or less than about $\frac{1}{2}$ or $\frac{1}{3}$, more narrowly equal to or less than about $\frac{1}{3}$ or
17 $\frac{1}{4}$, yet more narrowly equal to or less than about $\frac{1}{5}$ or $\frac{1}{6}$, even still more narrowly
18 than about equal to or less than about $\frac{1}{10}$.

19 **[0103]** The introduction rise 134 and the introduction run 132 can be components of
20 an introduction vector. The introduction run 132 can be the component of the
21 introduction vector parallel to the lumen wall 116. The introduction rise 134 can be
22 the component of the introduction vector perpendicular to the lumen wall 116. The
23 introduction vector can be a vector from an outer opening 136 to an inner opening
24 138. The outer opening 136 can be a temporary or permanent opening on the outside
25 of the lumen wall 116 formed by the introduction device 38. The inner opening 138
26 can be a temporary or permanent opening on the inside of the vessel wall.

27 **[0104]** Figure 26 illustrates that the introduction device 38, for example a hollow
28 needle, can act as a pathway for a luminal tool, for example tools such as a guidewire
29 168, to be deployed, as shown by arrow, into the lumen 114. The introduction device
30 38, for example a solid needle, can be removed from the second arteriotomy 128 and
31 the luminal tool can be deployed through, for example, the introducer lumen exit port
32 10, and the second arteriotomy 128. The introduction device 38 can be the luminal

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

3 [0105] Figures 27 through 30 illustrates a method of deploying the introduction
4 device 38 that can have a pre-formed bend. As shown in Figure 27, the arteriotomy
5 device 2 can be configured to deploy the introduction device 38 at the introduction
6 angle 42 from about 0° to about 5°, for example about 0°.

7 [0106] As shown in Figure 28, the introduction device 38 can be pushed, as shown by
8 arrow, through the lumen wall 116. The introduction device 38 can cleave a plane in
9 the lumen wall 116. The plane can be substantially parallel with the lumen wall
10 surface 118. The introduction device 38 can be adjacent to the adventitia in a blood
11 vessel. The introduction device 38 can be advanced along the subintimal or
12 submedial cleavage plane in a blood vessel. Once the lumen wall has been cleaved, a
13 subintimal angioplasty can be performed as known to one having ordinary skill in the
14 art. Once the lumen wall has been cleaved, a remote endarterectomy can be
15 performed as known to one having ordinary skill in the art. Bent and straight
16 introduction devices 38 can be swapped during use to selectively cleave the lumen
17 wall 116. Tools, such as guidewires, can be inserted through hollow introduction
18 devices 38 to selectively cleave the lumen wall 116.

19 [0107] As shown in Figure 29, when the bend in the introduction device 38 moves
20 into the lumen wall 116, the introduction device 38 can rotate, as shown by arrow,
21 toward the biological lumen 114. As shown in Figure 30, the bend in the introduction
22 device 38 can continue to rotate the introduction device 38 toward the biological
23 lumen 114. As described infra, the introduction device 38 can enter the lumen 114.
24 Figure 31 illustrates that the introduction device 38 that can have the bend can act as a
25 pathway for a luminal tool, as described infra.

26 [0108] An introducer sheath can be inserted over the guidewire 168 and/or the
27 introduction device 38. The introducer sheath can be less than about 22 French (7.3
28 mm, 0.29 in. diameter) or less than the diameter of the lumen to which the introducer
29 sheath is introduced. The introducer sheath can be, for examples, about 6 French (2.3
30 mm, 0.092 in. diameter), and about 8 French (2.67 mm, 0.105 in. diameter). The
31 introducer sheath can be known to one having ordinary skill in the art, for example the
32 introducer sheath described in U.S. Patent No. 5,183,464 to Dubrul, et al.

1 [0109] The introducer sheath can be inserted into the second arteriotomy 128. The
2 introducer sheath can expand the second arteriotomy 128 to a workable size. The
3 introducer sheath can be inserted into the second arteriotomy 128 before and/or after
4 and/or concurrently with the supplemental closure device is deployed and/or other
5 closure method is used.

6 [0110] Figures 32 and 33 illustrate an exemplary biological lumen 114 after the
7 arteriotomy device 2 has been deployed to, and removed from, the biological lumen
8 114. The biological lumen 114 can have the first and second arteriotomies 120 and
9 128. The biological lumen 114 can have a second arteriotomy 128. The biological
10 lumen 114 can have a first web 140 on one side of the arteriotomy (shown for the
11 second arteriotomy 128), and a second web 142 on the opposite side of the
12 arteriotomy 120 or 128. The natural pressure, shown by arrows, from the first and
13 second webs 140 and 142 can self-seal the arteriotomy 120 or 128.

14 [0111] One or more supplemental closure devices can be deployed to the first and/or
15 second arteriotomies 120 and/or 128. The supplemental closure devices can provide a
16 force or restraint to aid hemostasis. The supplemental closure devices can be
17 permanently or temporarily deployed. The supplemental closure devices can
18 biodissolve after hemostasis is achieved and/or after the relevant arteriotomy 120 or
19 128 is substantially or completely healed. The force from the supplemental closure
20 device can be maintained from about 15 minutes to about 24 hours or more, for
21 example about 120 minutes.

22 [0112] Figure 34 illustrates a tensioner 58 in a compressed configuration.
23 Compressive forces, shown by arrows, can compress the tensioner first and second
24 legs 68 and 70. In a compressed configuration, the tensioner inter-leg outer diameter
25 78 can be from about 0.51 mm (0.020 in.) to about 2.54 mm (0.100 in.), for example
26 about 1.5 mm (0.060 in.).

27 [0113] Figures 35 and 36 illustrate a method of deploying the tensioner 58. As shown
28 in Figure 35, the tensioner 58 can be in a compressed configuration. The tensioner 58
29 can be exposed to the compressive forces, as shown by arrows 144. The compressive
30 forces can be applied by a retractable sheath, clamps, other methods known to one
31 having ordinary skill in the art, or combinations thereof. A deployment force, shown
32 by arrow 146, can deploy the tensioner 58 into the arteriotomy 120 or 128.

1 [0114] The arteriotomy 120 or 128 can have an arteriotomy diameter 148. The
2 arteriotomy diameter 148 can be from about 0.5 mm (0.020 in.) to about 400 mm (15
3 in.), yet a narrower range from about 1.0 mm (0.040 in.) to about 10.2 mm (0.400 in.),
4 for example about 2.54 mm (0.100 in.). When in the compressed configuration, the
5 tensioner inter-leg outer diameter 78 can be smaller than the arteriotomy diameter
6 148. The tensioner first and second shoulders 64 and 66 can be wide enough to
7 interference fit with the arteriotomy 120 or 128. The tensioner first and second
8 shoulders 64 and 66 can dissipate force on the lumen wall surface 118.

9 [0115] As shown in Figure 36, the compressive forces can be removed from the
10 tensioner 58. The tensioner first and second leg 68 and 70 can expand, as shown by
11 arrows. The tensioner 58 can force the arteriotomy 120 or 128 into a substantially or
12 completely flat and/or closed and/or stretched configuration. The walls of the
13 arteriotomy 120 or 128 can come into close contact.

14 [0116] The arteriotomy 120 or 128 can have an arteriotomy width 150 and an
15 arteriotomy height 152. The arteriotomy width 150 can be about half the
16 circumference of the arteriotomy 120 or 128. The arteriotomy width 150 can be from
17 about 1.0 mm (0.040 in.) to about 10.2 mm (0.400 in.), for example about 4.06 mm
18 (0.160 in.).

19 [0117] The arteriotomy height 152 can be about the tensioner leg diameter 76. The
20 arteriotomy height 152 can be less than about 0.51 mm (0.020 in.), more narrowly,
21 less than about 0.38 mm (0.015 in.). The arteriotomy height 152 can be from about
22 0.25 mm (0.010 in.) to about 1.3 mm (0.050 in.), for example about 0.38 mm (0.015
23 in.). The arteriotomy height 152 can be small enough to enable cell growth, blood
24 clotting, acoustic sealing, heat sealing, gluing, enhanced self-sealing and
25 combinations thereof across the arteriotomy 120 or 128.

26 [0118] The tensioner first and second shoulders 64 and 66 can be wide enough to
27 interference fit with the arteriotomy 120 or 128. The tensioner first and second feet
28 72 and 74 can be wide enough to interference fit with the arteriotomy 120 or 128.
29 The tensioner first and second feet 72 and 74 can dissipate force on the lumen wall
30 surface 118.

31 [0119] The arteriotomy 120 or 128 can be plugged, and/or packed, and/or tamponed
32 before, and/or concurrent with, and/or after using any of any of the supplemental
33 closure devices infra and/or supra, the self-sealing closure method, or combinations

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

4 **[0120]** Figures 37 through 40 illustrate deploying the pressure clip 84 to the
5 arteriotomy 120 or 128. Figure 37 illustrates extending, and/or thinning, and/or
6 straightening, and/or tensioning the pressure clip second end 96. The pressure clip
7 sheath 98 can be translated, as shown by arrow, along the pressure clip second leg 92
8 and onto the pressure clip second end 96. The pressure clip 84 can be deployed to the
9 arteriotomy after the pressure clip second end 96 is extended, and/or thinned, and/or
10 straightened, and/or tensioned.

11 **[0121]** As shown in Figure 38, the pressure clip second leg 92 can be rotated with
12 respect to the pressure clip head 88, so that the pressure clip second leg 92 and the
13 pressure clip head 88 are substantially aligned. The pressure clip second leg 92 can
14 be deployed, as shown by the arrow, through the first arteriotomy 120. The pressure
15 clip second leg 92 can be deployed through the lumen wall 116 (e.g., if there is no
16 existing first arteriotomy 120, if the first arteriotomy 120 is not suitably located with
17 respect to the second arteriotomy 128).

18 **[0122]** Figure 39 illustrates contracting, and/or widening, and/or releasing and/or
19 relaxing the pressure clip second end 96. The pressure clip sheath 98 can be
20 translated, as shown by arrow, along the pressure clip second leg 92 and off of the
21 pressure clip second end 96. The pressure clip second end 96 can be contracted,
22 and/or widened, and/or released and/or relaxed after the pressure clip 84 is deployed
23 to the arteriotomy.

24 **[0123]** As shown in Figure 40, after the pressure clip second leg 92 is deployed
25 through the first arteriotomy 120, the pressure clip second leg 92 can be released or
26 deformed so as to rotate with respect to the pressure clip head 88. The pressure clip
27 head 88 can seat in the first arteriotomy 120. The pressure clip first and second legs
28 90 and 92 can apply force, as shown by arrows, to the first and second webs 140 and
29 142, respectively.

30 **[0124]** Figures 41 and 42 illustrate a method of deploying a stitch 154 surrounding
31 and/or through the arteriotomy 120 or 128. The stitch 154 can be tightened to apply
32 additional pressure to the arteriotomy 120 or 128. The stitch 154 can have a knot 156,
33 or other tying configuration or device, for example a pledget or clamp.

1 [0125] Figures 43 and 44 illustrate a method of deploying the filament 106 adjacent
2 to and/or through the arteriotomy 120 or 128. The filament 106 can be attached to a
3 first pledget 158a by a first knot 156a or other tying configuration or device. The
4 filament 106 can be attached to a second pledget 158b by a second knot 156b or other
5 tying configuration or device. The first and second pledgets 158a and 158b can be
6 other pressure diffusers known to one having ordinary skill in the art, such as the
7 toggles 100 described infra and supra.

8 [0126] Figures 45 and 46 illustrate a toggle deployment device 159 that can be in a
9 first retracted configuration. The toggle deployment device 159 can have a pressure
10 check port 160. The pressure check port 160 can be in fluid communication with a
11 sensor or port on or near the handle (not shown) of the toggle deployment device 159,
12 such as an external lumen where blood flow can be observed, for example from flow
13 from the end of an external tube or port and/or through a transparent or translucent
14 window. The pressure check port 160 can facilitate deployment of the toggle
15 deployment device 159 to a location where the pressure check port 160 is introduced
16 to pressure, for example when the pressure check port 160 enters the biological lumen
17 114. The sensor or port on or near the handle of the toggle deployment device 159
18 will signal that the pressure check port 160 has been placed into the biological lumen
19 114 (e.g., by displaying a small amount of blood flow). The pressure check port 160
20 can be deployed into the biological lumen 114 and then withdrawn from the
21 biological lumen 114 to the point where the lumen wall 116 just stops the pressure in
22 the pressure check port 160. The entry wall retainer port 54 can additionally perform
23 the function as described herein for the pressure check port 160. The toggle
24 deployment device 159 can have a delivery needle port 161.

25 [0127] Figures 47 and 48 illustrate the toggle deployment device 159 that can be in a
26 second delivery configuration. A delivery needle 162 can be slidably attached to the
27 toggle deployment device 159. The delivery needle 162 can egress from the delivery
28 needle port 161 when the toggle deployment device 159 is in the second delivery
29 configuration.

30 [0128] Figures 49 and 50 illustrate that the toggle deployment device 159 can be
31 deployed into the arteriotomy 120 or 128 at a location where the pressure check port
32 160 can be located in the biological lumen 114. The delivery needle port 161 can be
33 in, or adjacent to, the lumen wall 116.

1 [0129] Figures 51 and 52 illustrate that the toggle deployment device 159 can be
2 placed in the second delivery configuration. If the delivery needle port is in, or
3 adjacent to, the lumen wall 116 when the toggle deployment device 159 is placed in
4 the second delivery configuration, the delivery needle 162 can enter the lumen wall
5 116. For example, the delivery needle 162 can enter the second web 142. The
6 delivery needle 162 can exit the second web 142 and enter, as shown by arrows, the
7 biological lumen 114.

8 [0130] Figure 53 illustrates that a pusher 164 can be slidably attached to the delivery
9 needle 162. The delivery needle 162 can have a needle tip port 166. The toggle 100
10 can be in the delivery needle 162. The toggle 100 can be configured in the delivery
11 needle 162 such that the toggle first end 102 can be located on the needle tip port 166
12 -side of the pusher 164.

13 [0131] Figure 54 illustrates that the pusher 164 can be moved, as shown by arrow,
14 toward the needle tip port 166. The delivery needle 162 can be moved back relative
15 to the pusher 164, the pusher 164 can be moved forward relative to the delivery
16 needle 162, or combinations thereof. The pusher 164 can push the toggle first end
17 102 out of the delivery needle 162. The pusher 164 can push the toggle first end 102
18 into the biological lumen 114.

19 [0132] Figures 55 and 56 illustrate that the toggle deployment device 159 can be in a
20 first retracted configuration after deploying the toggle first end 102 into the biological
21 lumen 114. When the delivery needle 162 retracts into the toggle deployment device
22 159, the toggle second end 104 can be in the toggle deployment device 159. The
23 filament 106 can extend through the delivery needle port 161.

24 [0133] Figures 57 and 58 illustrate that the toggle 100 can be deployed across the
25 lumen wall. When the toggle deployment device 159 is removed from the
26 arteriotomy, the toggle second end 104 can deploy on the outside of the lumen wall
27 116 from the delivery needle port 161. The toggle first end 102 can form an
28 interference fit with the lumen wall surface 118. The toggle second end 104 can form
29 an interference fit with the outside of the lumen wall 116 or the surrounding tissue,
30 such as subcutaneous tissue. The toggle second end 104 can be slidably translated
31 along the filament 106 toward the lumen wall 116, for example for the toggle 100
32 illustrated in Figure 20. The length of the filament 106 on the opposite side of toggle

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

3 [0134] Figures 59 through 63 illustrate a method for deploying the toggle 100. The
4 delivery needle 162 can egress, as shown by arrow, from a toggle deployment
5 delivery port 163. The toggle deployment delivery port 163 can be in the delivery
6 guide 4. The delivery needle 162 can be advanced toward the lumen 114.

7 [0135] Figure 60 illustrates that the delivery needle 162 can be deployed through the
8 lumen wall. When the delivery needle 162 is deployed through the lumen wall 116,
9 the delivery needle can intersect, or pass adjacent to, the second arteriotomy.

10 [0136] Figures 61 and 62 illustrate that the pusher 164 can be advanced, as shown by
11 arrow, through the delivery needle 162. The toggle first end 102 can egress from the
12 needle tip port 166. The toggle first end 102 can deploy into the lumen 114.

13 [0137] Figure 63 illustrates that the delivery needle 162 can be retracted into the
14 delivery guide 4 and/or the filament 106 can be pulled taught, both shown by arrow.
15 The toggle first end 102 can form an interference fit with the lumen wall surface 118.
16 The toggle second end 104 (not shown in Figure 63) can be slidably translated on the
17 filament 106 down to, and form an interference fit with, the outside of the lumen wall
18 116. The length of the filament 106 on the opposite side of toggle second end 104
19 from the toggle first end 102 can be cut, snapped, torn or otherwise removed.

20 [0138] Figure 64 illustrates an introducer needle 165 that can have an end inserted, as
21 shown by arrow, through the lumen wall 116 and into the lumen 114, for example by
22 using the Seldinger technique. The introducer needle 165 can be hollow and/or have
23 a longitudinal channel. Figure 65 illustrates that the guidewire 168 can be deployed,
24 shown by arrows, through the hollow and/or longitudinal channel of the introducer
25 needle 165.

26 [0139] Figure 66 illustrates that the introducer needle 165 can be removed, as shown
27 by arrow, from the lumen wall 116. The guidewire 168 can remain substantially in
28 place. After the introducer needle 165 is removed, a portion of the guidewire 168 can
29 be outside the lumen 114 and another portion of the guidewire 168 can be inside the
30 lumen 114.

31 [0140] Figure 67 illustrates a method of fixedly or slidably attaching the guidewire
32 168 to the anchor 6. A guidewire proximal end 170 can be placed in proximity to an
33 anchor distal end 172. The guidewire proximal end 170 can then be attached, as

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

8 **[0141]** Where applicable, the methods described supra for deploying any
9 supplemental closure device can be used for deploying any of the other supplementary
10 deployment device. It is apparent to one skilled in the art that various changes and
11 modifications can be made to this disclosure, and equivalents employed, without
12 departing from the spirit and scope of the invention. Elements shown with any
13 embodiment are exemplary for the specific embodiment and can be used on other
14 embodiments within this disclosure.

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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.

- 1 10. The device of Claim 9, wherein the second elongated member comprises a
2 retainer.
3
- 4 11. The device of Claim 10, wherein the retainer comprises an inflatable member.
5
- 6 12. The device of Claim 10, wherein the retainer comprises a resilient member.
7
- 8 13. The device of Claim 9, wherein the second elongated member extends
9 substantially adjacent to the lumen wall.
10
- 11 14. A device for closing an opening on a biological lumen wall, comprising:
12 a longitudinal axis,
13 a first force-applying member,
14 a second force-applying member, and
15 a resilient member,
16 wherein the resilient member provides to the first and the second force-applying
17 members an outward radial force with respect to the longitudinal axis.
18
- 19 15. The device of Claim 14, wherein the first force-applying member applies force in
20 a first direction, and wherein the second force-applying member applies force in a
21 second direction, and wherein the first direction is substantially opposite to the second
22 direction.
23
- 24 16. A method of accessing a blood vessel through a blood vessel wall having a
25 longitudinal wall axis, the method comprising:
26 entering the vessel at an angle of less than about 19 degrees with respect to the
27 longitudinal wall axis, and
28 inserting a luminal tool into the vessel.
29
- 30 17. The method of Claim 16, wherein the first angle is less than about 15 degrees.
31
- 32 18. The method of Claim 17, wherein the first angle is less than about 10 degrees.
33

- 1 19. The method of Claim 18, wherein the first angle is greater than about 5 degrees.
2
- 3 20. The method of Claim 16, further comprising aligning a device with the luminal
4 wall before the entering.
5
- 6 21. A method for accessing a biological lumen having a lumen wall and a
7 longitudinal lumen wall axis, the method comprising:
8 inserting in the biological lumen a second elongated member comprising a
9 second elongated member axis,
10 aligning the second elongated member so that the second elongated member
11 axis is substantially parallel to the longitudinal lumen wall axis, and
12 inserting in the biological lumen a first elongated member comprising a first
13 elongated member axis.
14
- 15 22. The method of Claim 21, wherein an angle between the first elongated member
16 axis and the longitudinal lumen wall axis is less than about 15 degrees.
17
- 18 23. The method of Claim 22, wherein an angle between the first elongated member
19 axis and the longitudinal lumen wall axis is less than about 10 degrees.
20
- 21 24. The method of Claim 21, wherein the second elongated member comprises a
22 retainer, wherein the method further comprises extending the retainer.
23
- 24 25. The method of Claim 24, wherein the retainer comprises a resilient member.
25
- 26 26. The method of Claim 21, wherein the second elongated member comprises an
27 inflatable member, the method further comprising inflating the inflatable member.
28
- 29 27. The method of Claim 21, wherein the second elongated member extends
30 substantially adjacent to the lumen wall.
31
- 32 28. A method of closing a vascular opening, the vascular opening having an inside
33 surface and a longitudinal axis, the method comprising:

- 1 inserting a device in the opening,
2 applying a force to the inside surface, wherein the force is directed in at least
3 one radially outward direction from the longitudinal axis.
4
- 5 29. The method of Claim 28, further comprising maintaining the force.
6
- 7 30. The method of Claim 29, wherein maintaining comprises maintaining for less
8 than about 120 minutes.
9
- 10 31. The method of Claim 28, wherein the applying a force comprises the device
11 applying at least a part of the force.
12
- 13 32. The method of Claim 31, wherein the applying a force comprises the device
14 applying all of the force.
15
- 16 33. A method for accessing and closing a blood vessel having a vessel wall, wherein
17 the vessel wall has an inside surface and an outside surface, the method comprising:
18 forming an arteriotomy,
19 deploying a closure augmentation device in the arteriotomy, wherein the
20 closure augmentation device produces pressure on the inside surface and the outside
21 surface.
22
- 23 34. The method of Claim 33, wherein the closure augmentation device comprises a
24 filament, and wherein the filament is in the arteriotomy.
25
- 26 35. The method of Claim 33, wherein the closure augmentation device comprises a
27 pressure clip.
28
- 29 36. The method of Claim 33, wherein the closure augmentation device comprises a
30 pledget.
31
- 32 37. The method of Claim 33, wherein the closure augmentation device comprises a
33 toggle.

1

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

4

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

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

10 deploying vascular tools through the arteriotomy.

11

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

16

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

20

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

23

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

26

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

31

- 1 45. The method of Claim 44, wherein the introduction rise is the component of the
2 length substantially perpendicular to the lumen wall between the outside lumen wall
3 opening and the inside lumen wall opening.
4
- 5 46. The method of Claim 39, wherein the arteriotomy rise is about equal to or less
6 than one-fourth of the arteriotomy run.
7
- 8 47. The method of Claim 39, wherein the arteriotomy rise is about equal to or less
9 than one-fifth of the arteriotomy run.
10
- 11 48. A method for accessing a blood vessel having a vessel wall, wherein the vessel
12 wall has an inside and an outside, the method comprising:
13 deploying an introduction device to form an arteriotomy,
14 moving the introduction device through the vessel wall at a first angle with
15 respect to the vessel wall,
16 moving the introduction device through the vessel wall at a second angle with
17 respect to the vessel wall, and
18 entering the inside of the vessel wall with the introduction device.
19
- 20 49. The method of Claim 48, wherein the first angle or the second angle is less than
21 about 5 degrees.
22
- 23 50. The method of Claim 48, wherein the first angle or the second angle is about 0
24 degrees.
25
- 26 51. The method of Claim 48, wherein the introduction device forms an outer opening
27 on the outside of the vessel wall, and wherein the introduction device forms an inner
28 opening on the inside of the vessel wall, and wherein a vector between the outer inner
29 opening and the outer opening can comprise an introduction run and introduction rise,
30 and wherein the ratio of the introduction rise to the introduction run can be equal to or
31 less than about $\frac{1}{2}$.
32

I

- 1 52. The method of Claim 51, wherein the ratio of the introduction rise to the
2 introduction run can be equal to or less than about $1/3$.
3
- 4 53. The method of Claim 51, wherein the ratio of the introduction rise to the
5 introduction run can be equal to or less than about $1/4$.
6
- 7 54. The method of Claim 51, wherein the ratio of the introduction rise to the
8 introduction run can be equal to or less than about $1/5$.
9
- 10 55. The method of Claim 51, wherein the ratio of the introduction rise to the
11 introduction run can be equal to or less than about $1/6$.
12

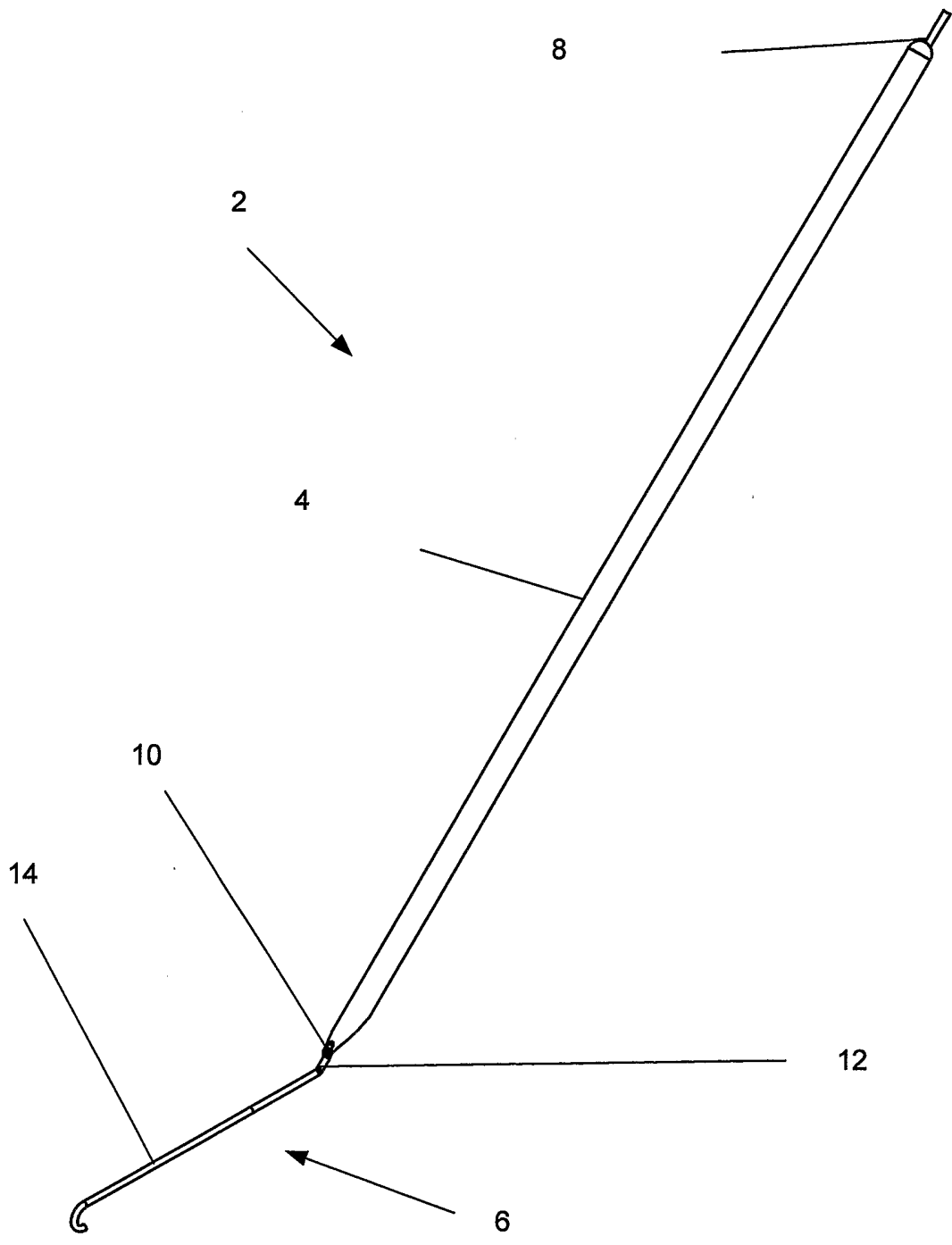


Fig. 1

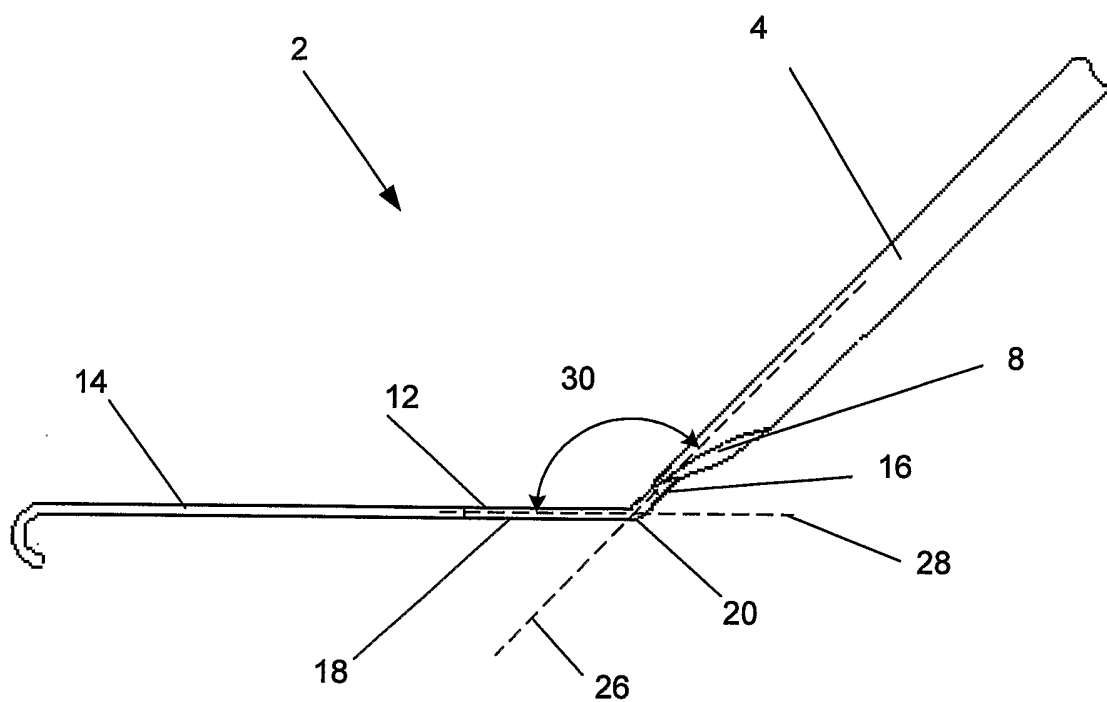


Fig. 2

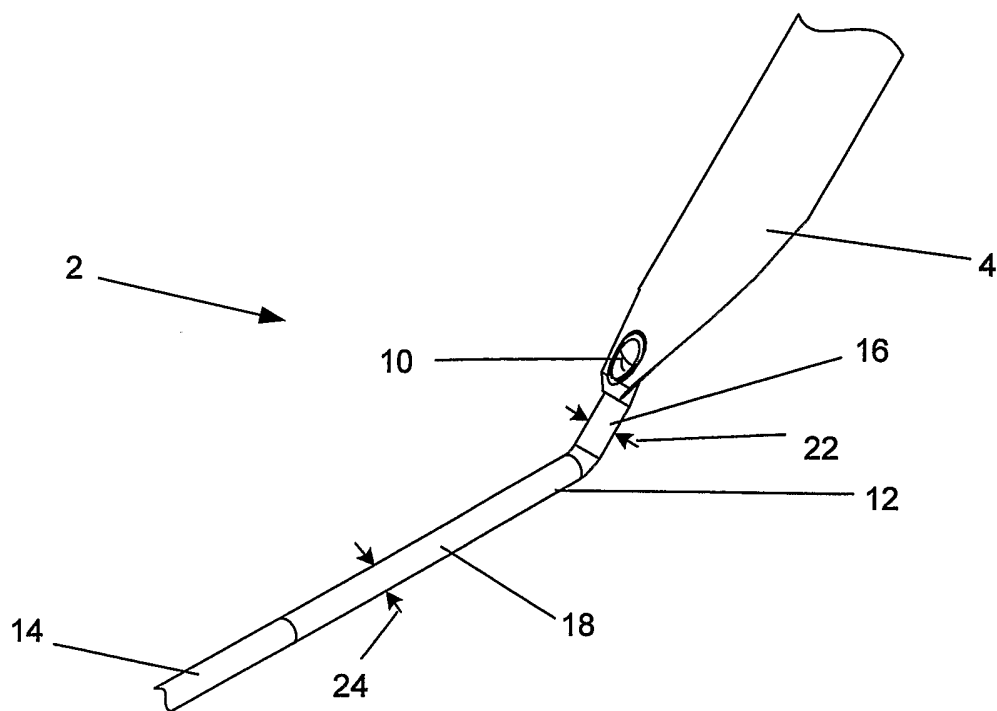


Fig. 3

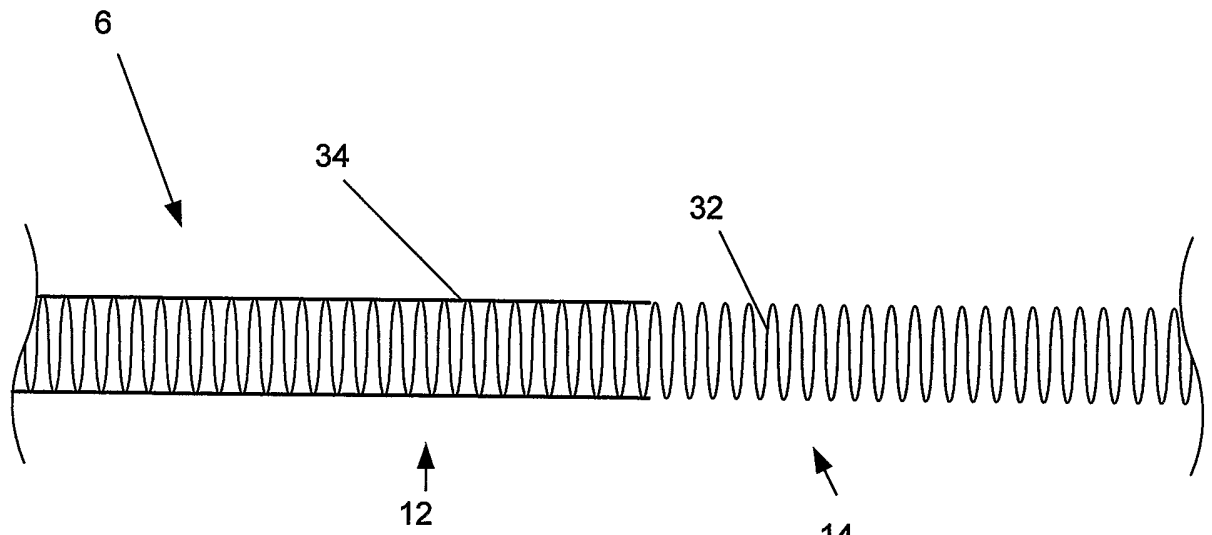


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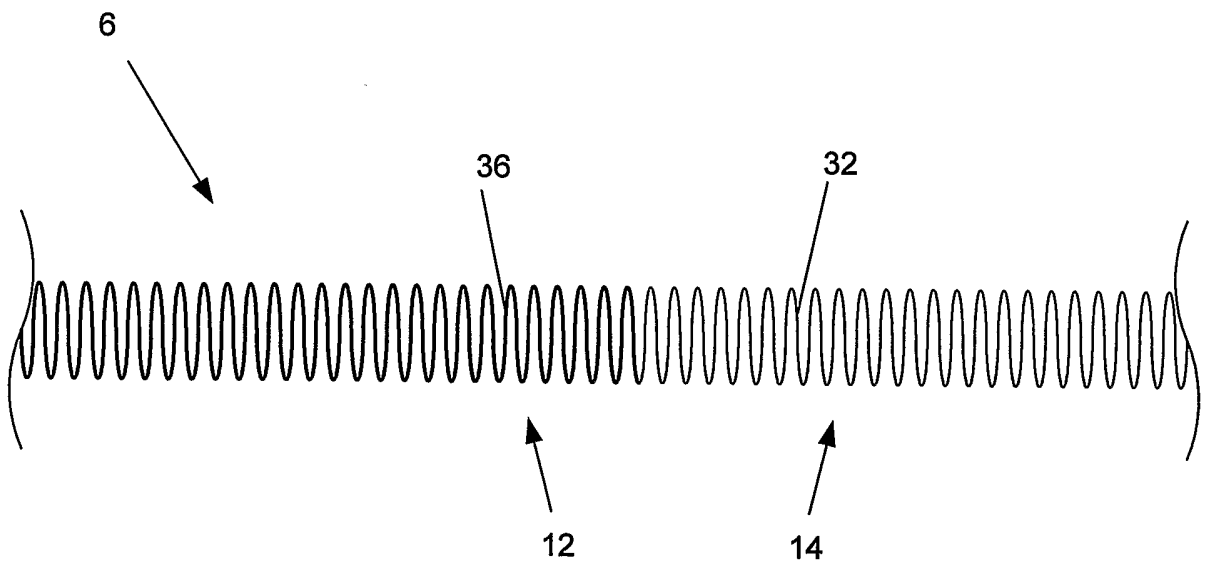


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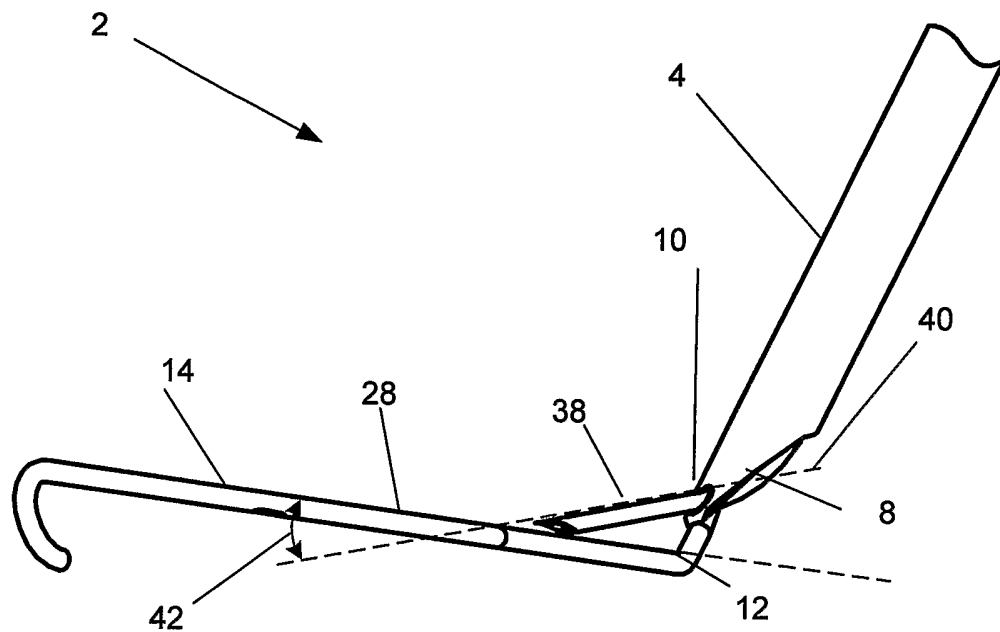


Fig. 6

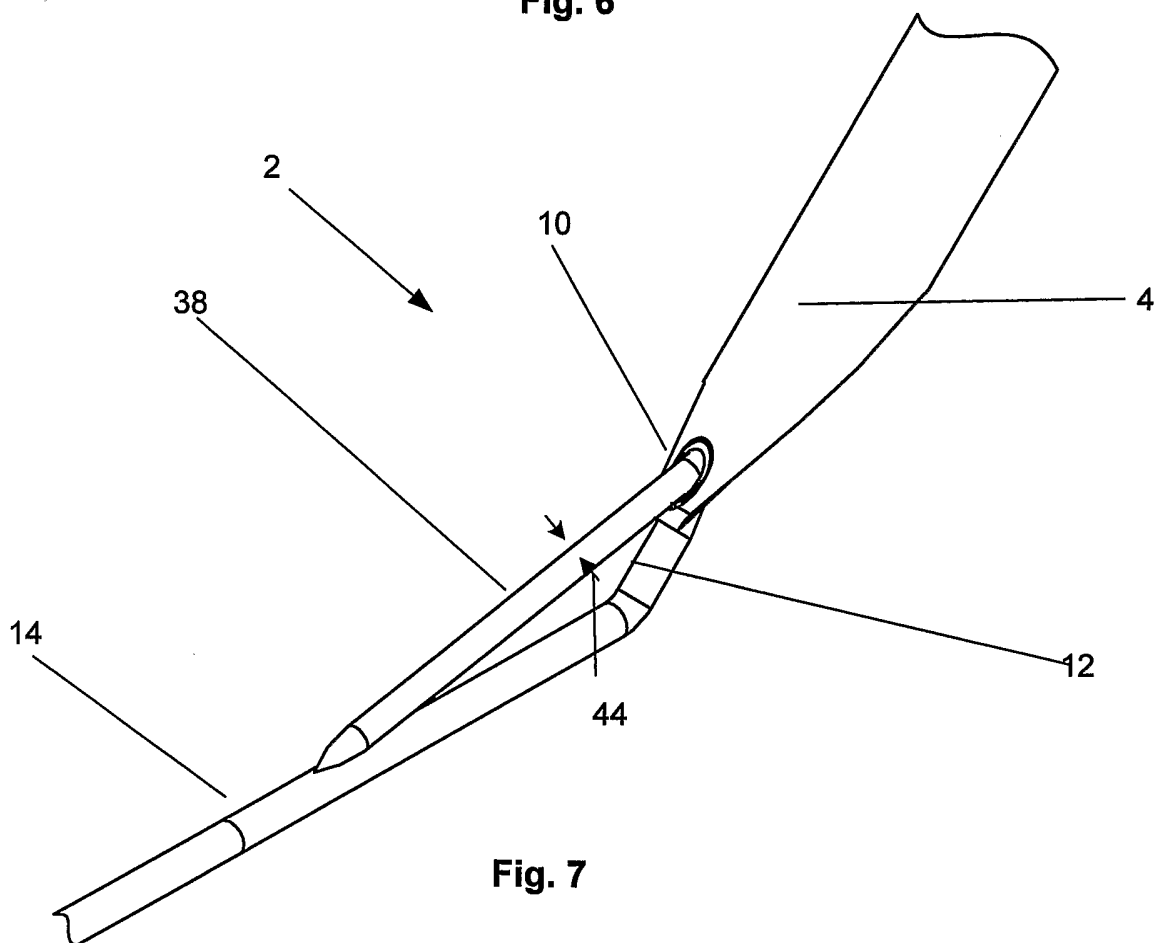


Fig. 7

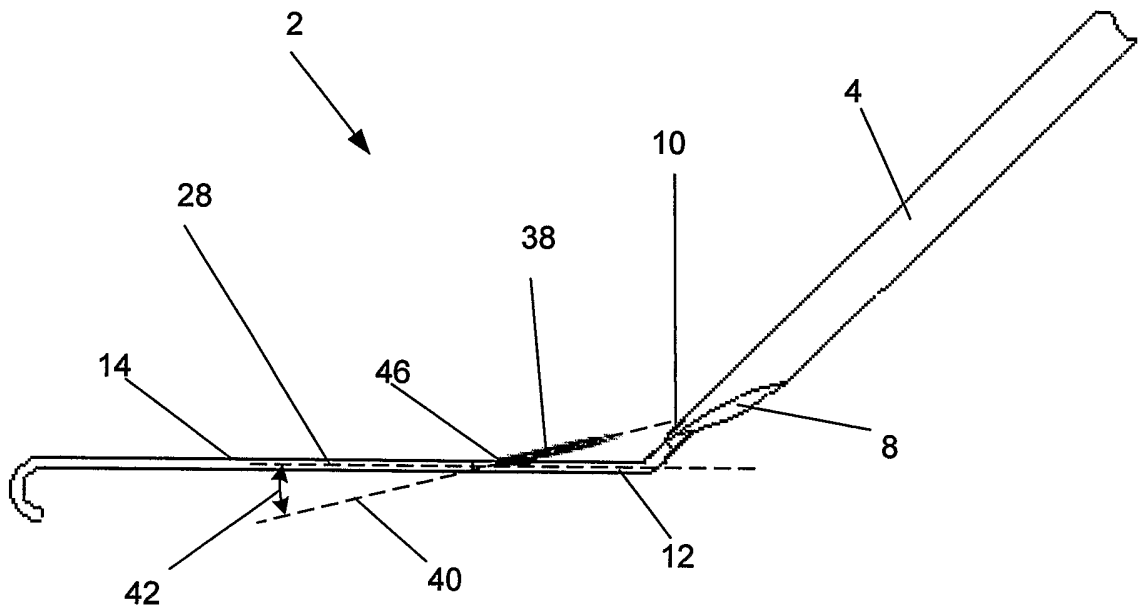


Fig. 8

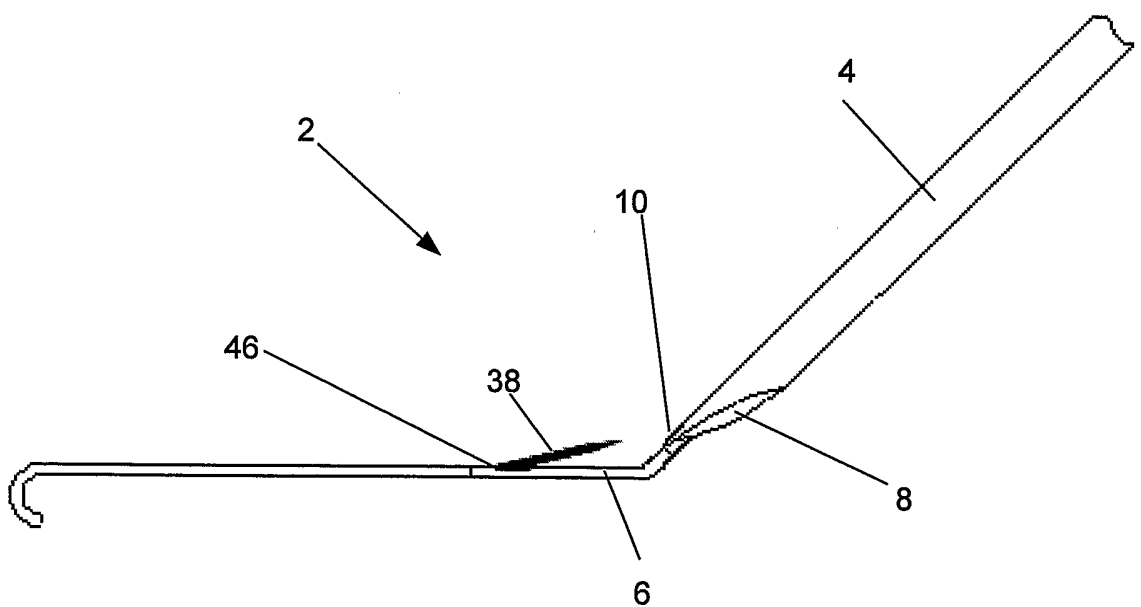


Fig. 9

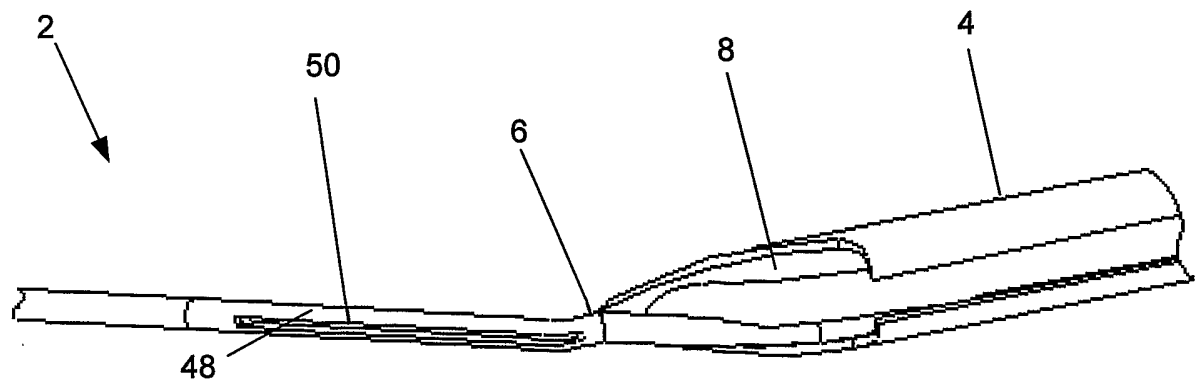


Fig. 10

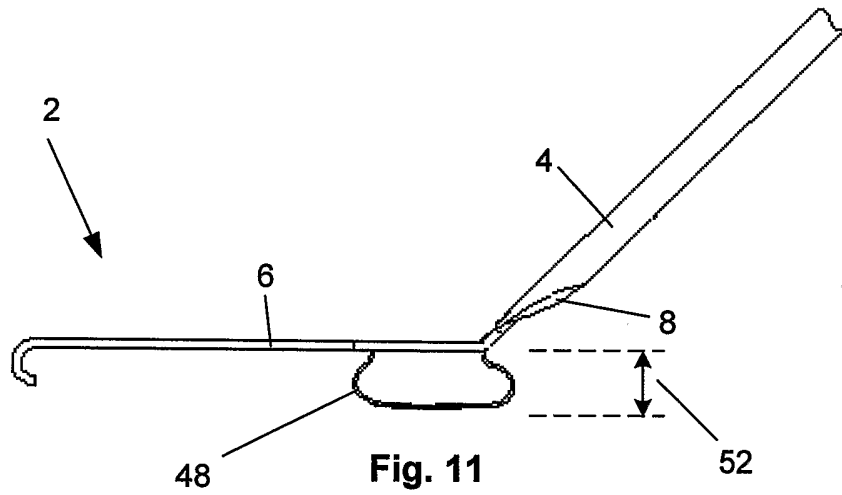


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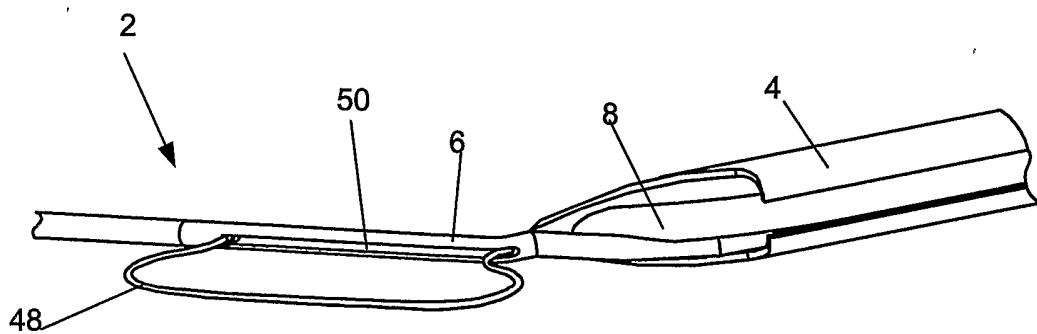


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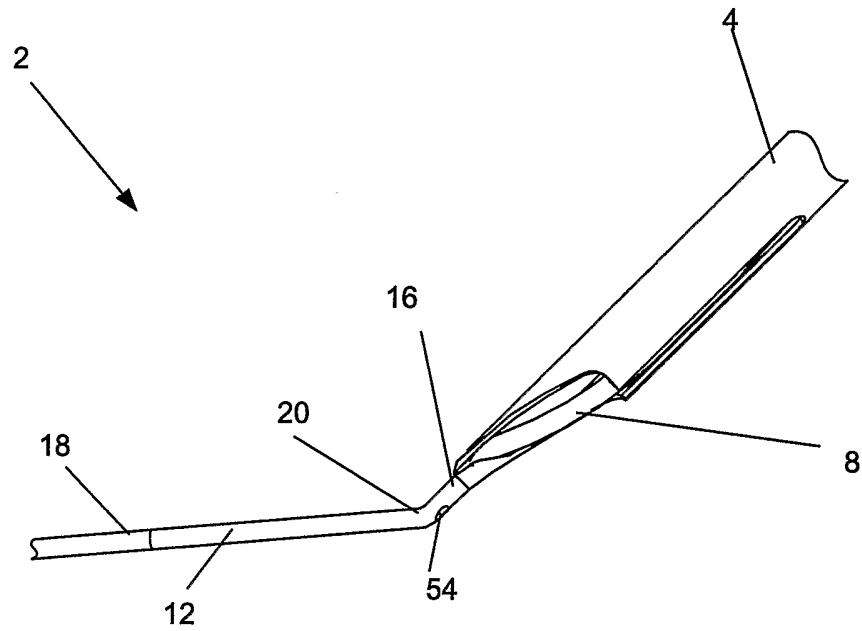


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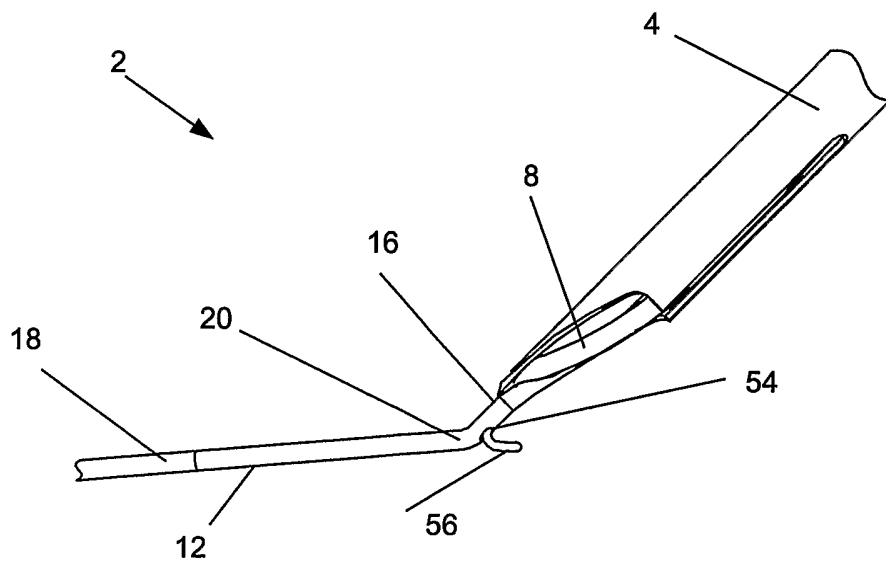


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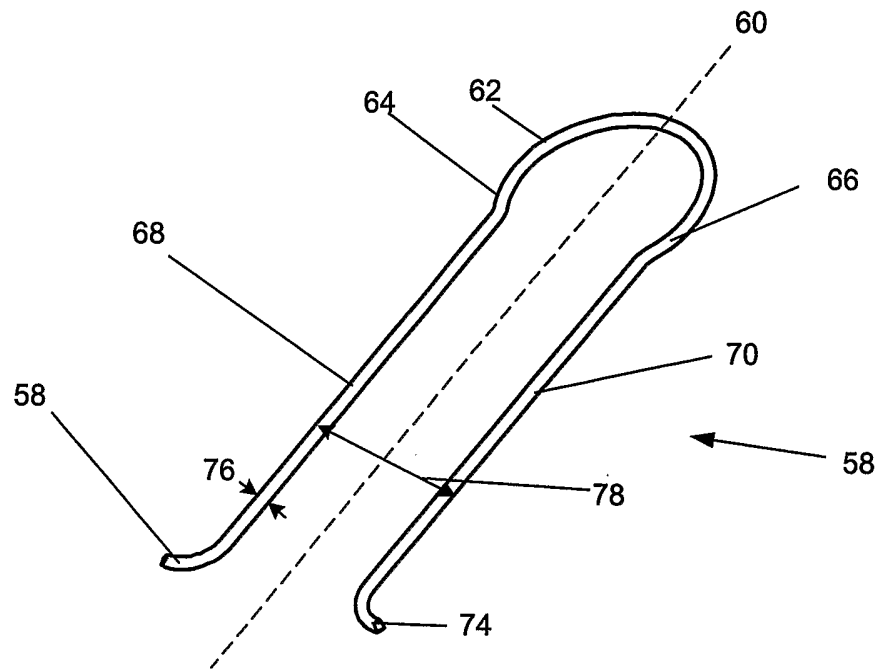


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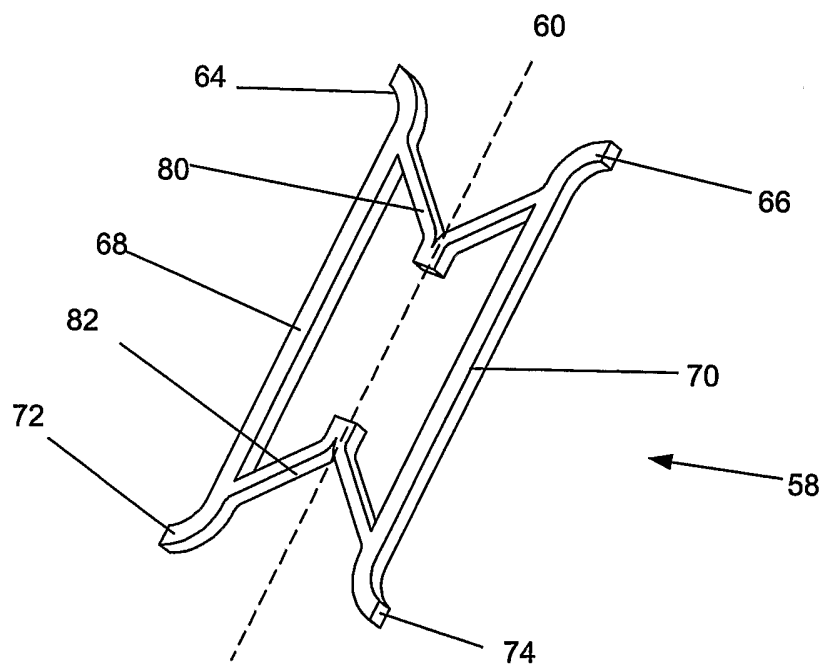


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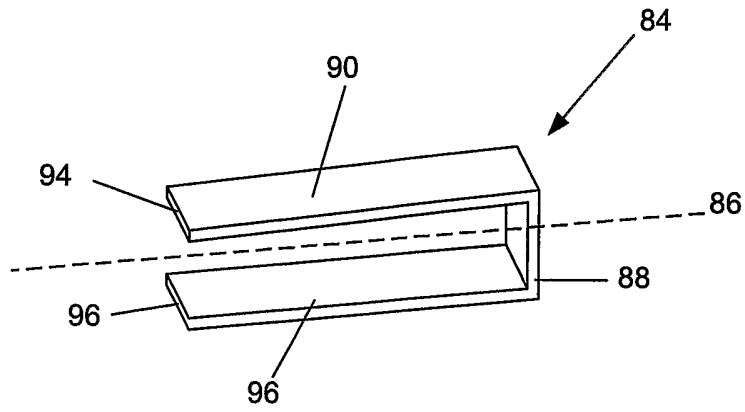


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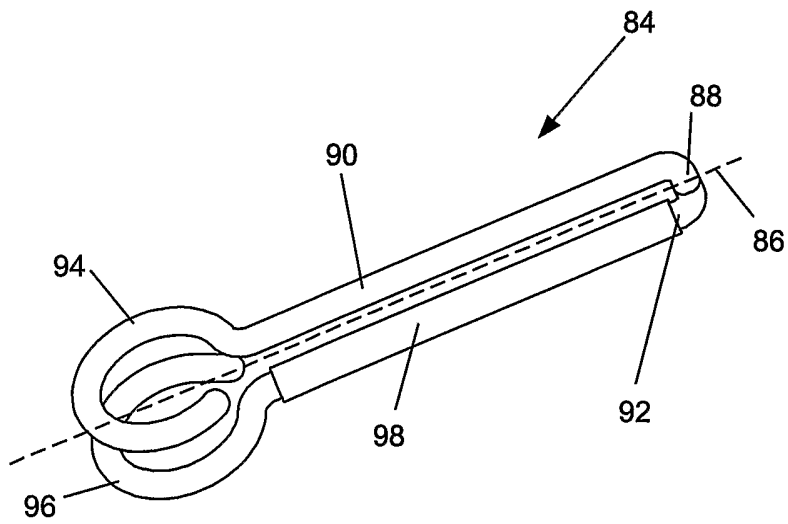


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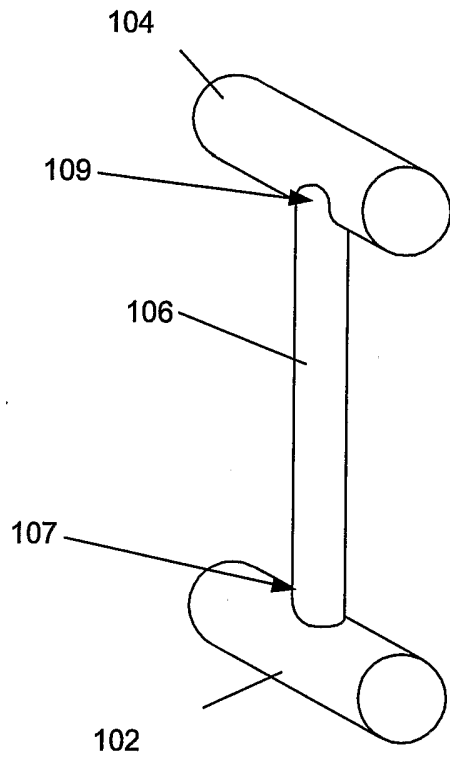


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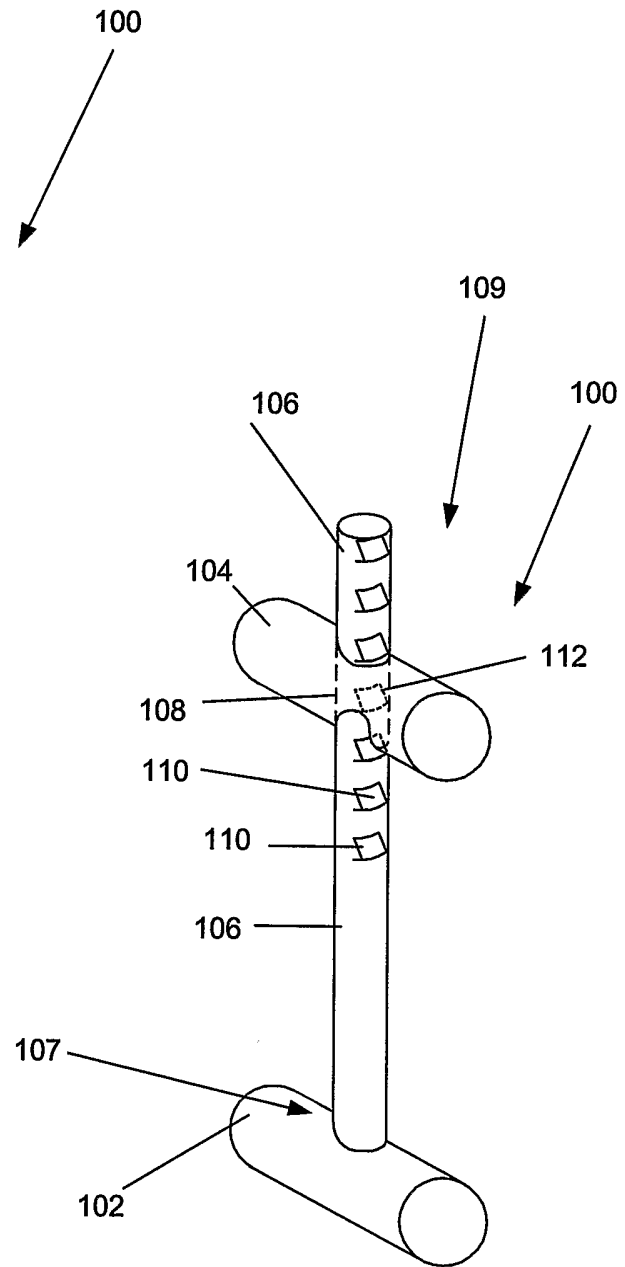


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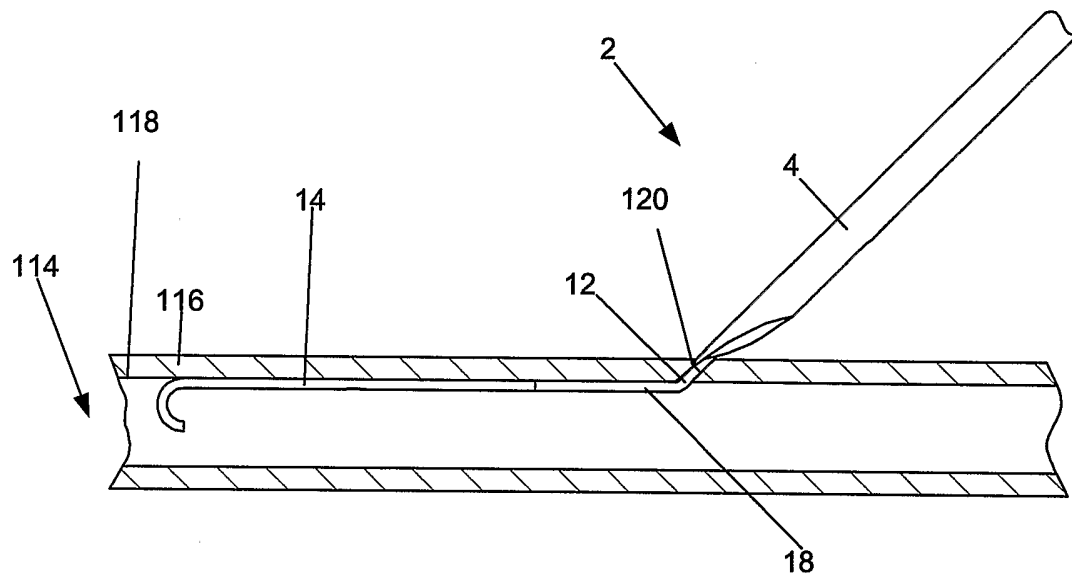


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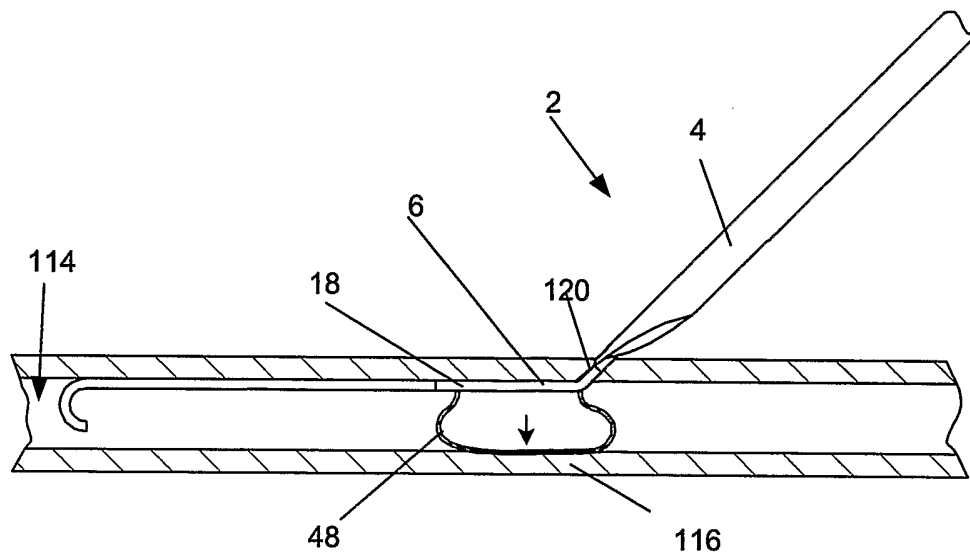


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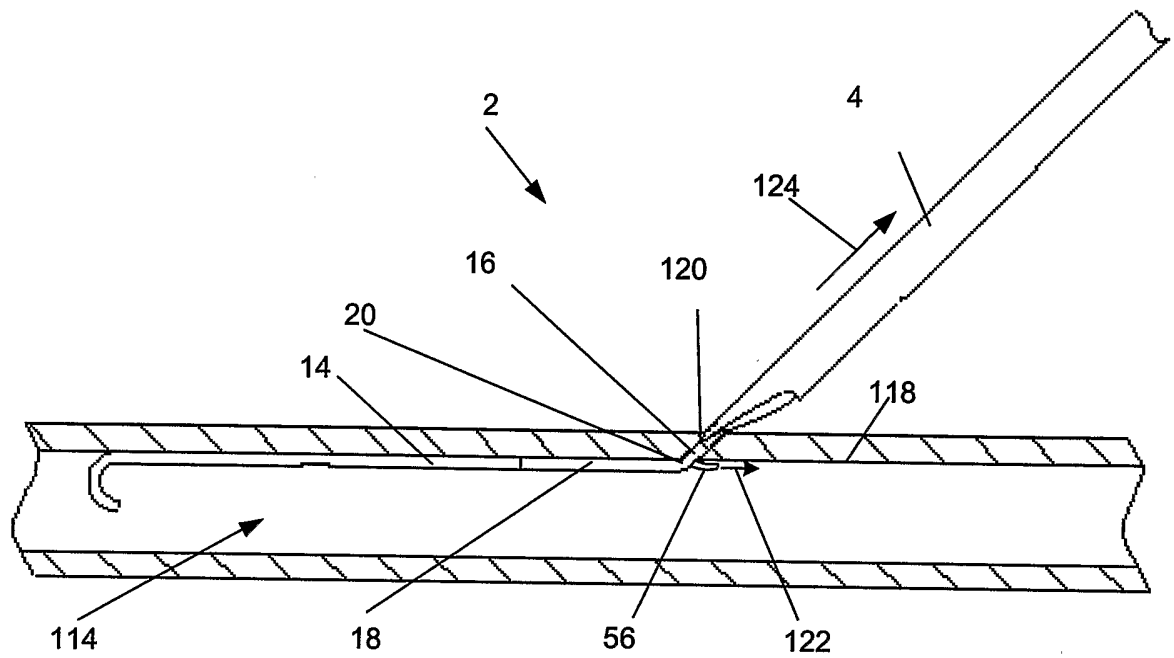


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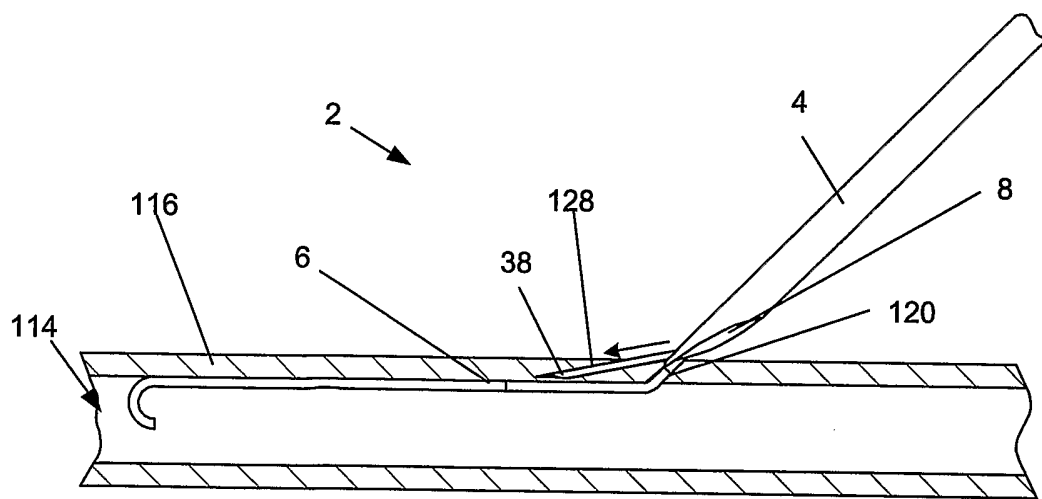
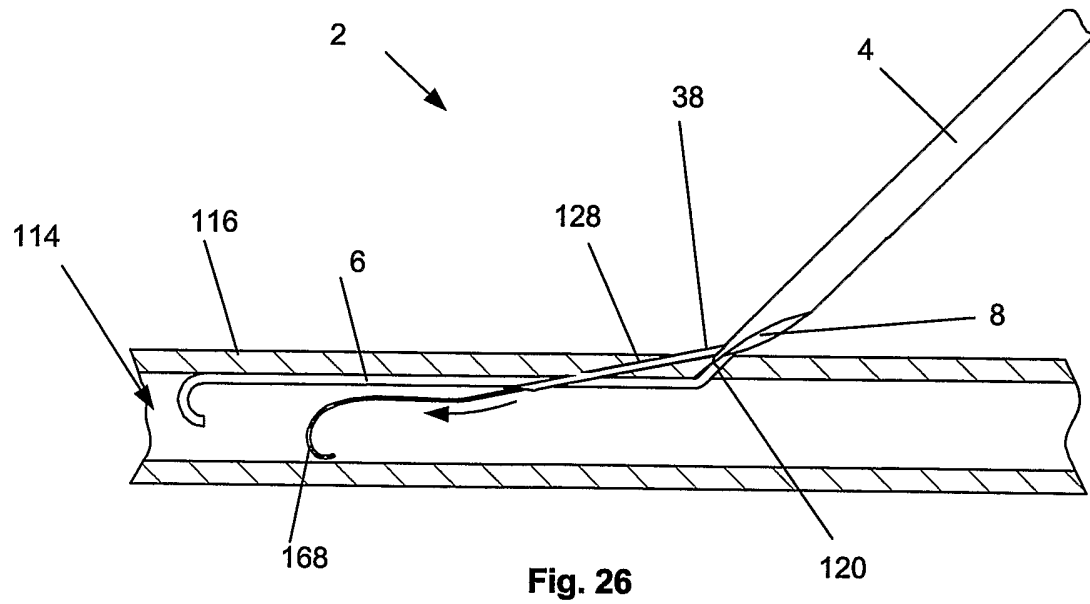
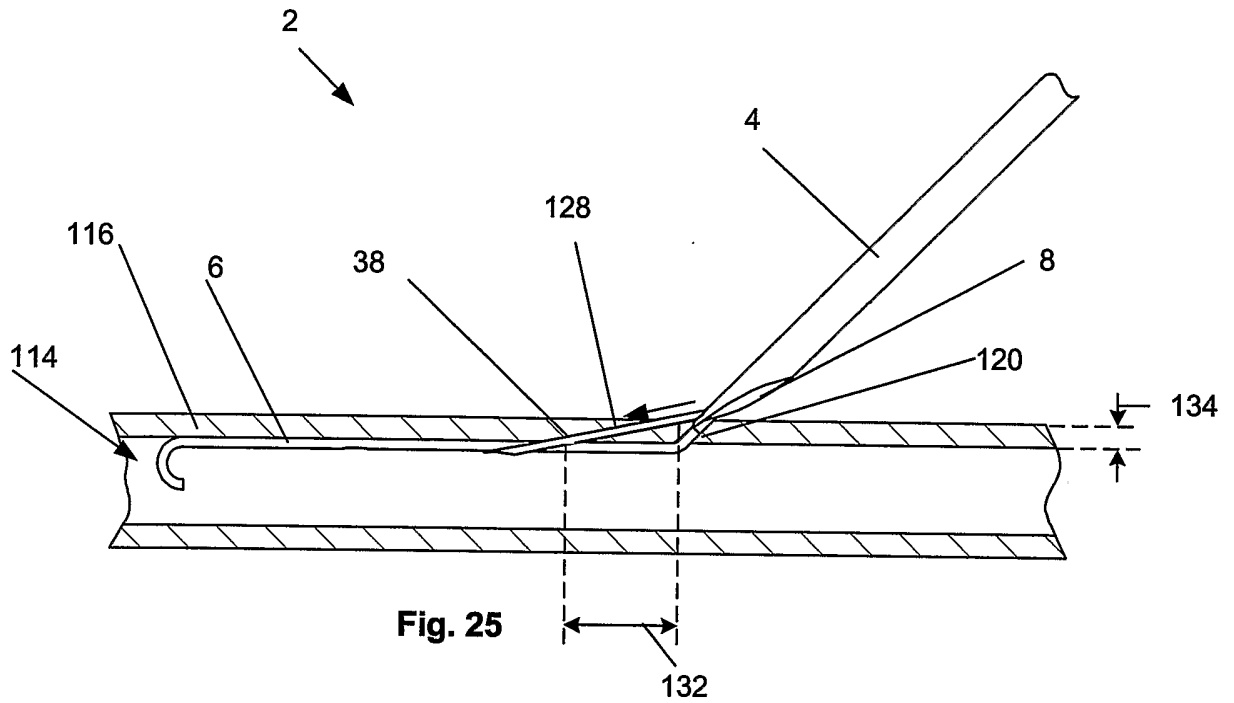


Fig. 24



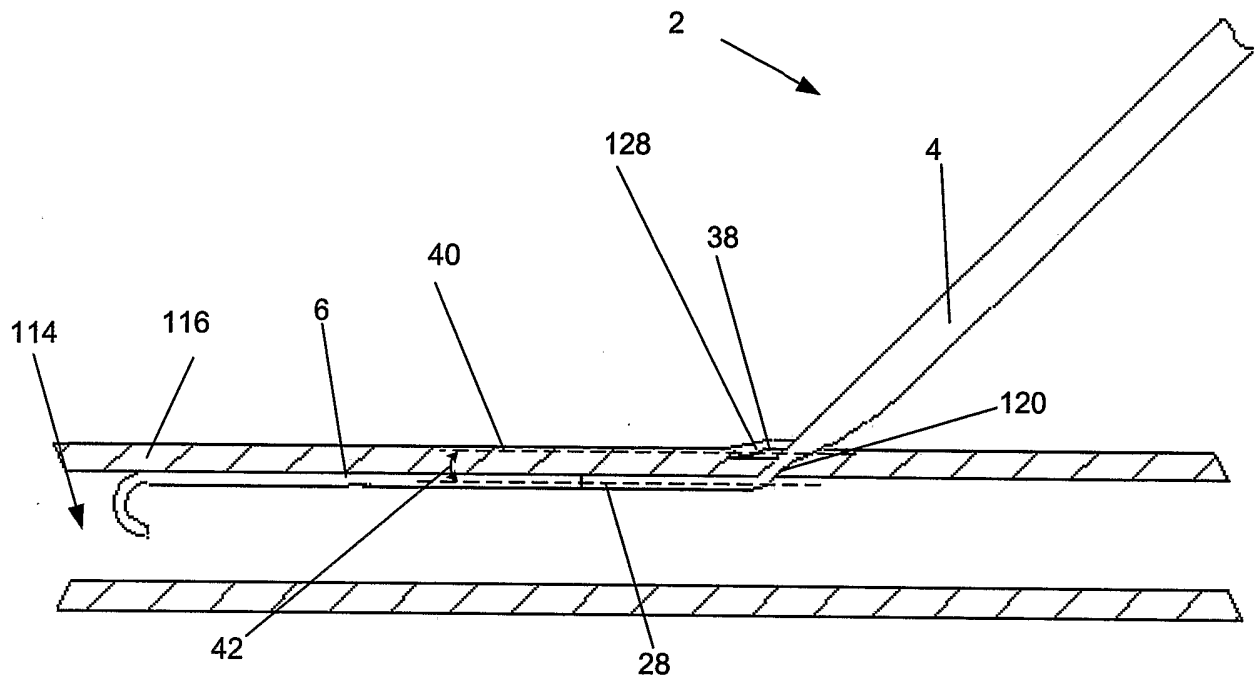


Fig. 27

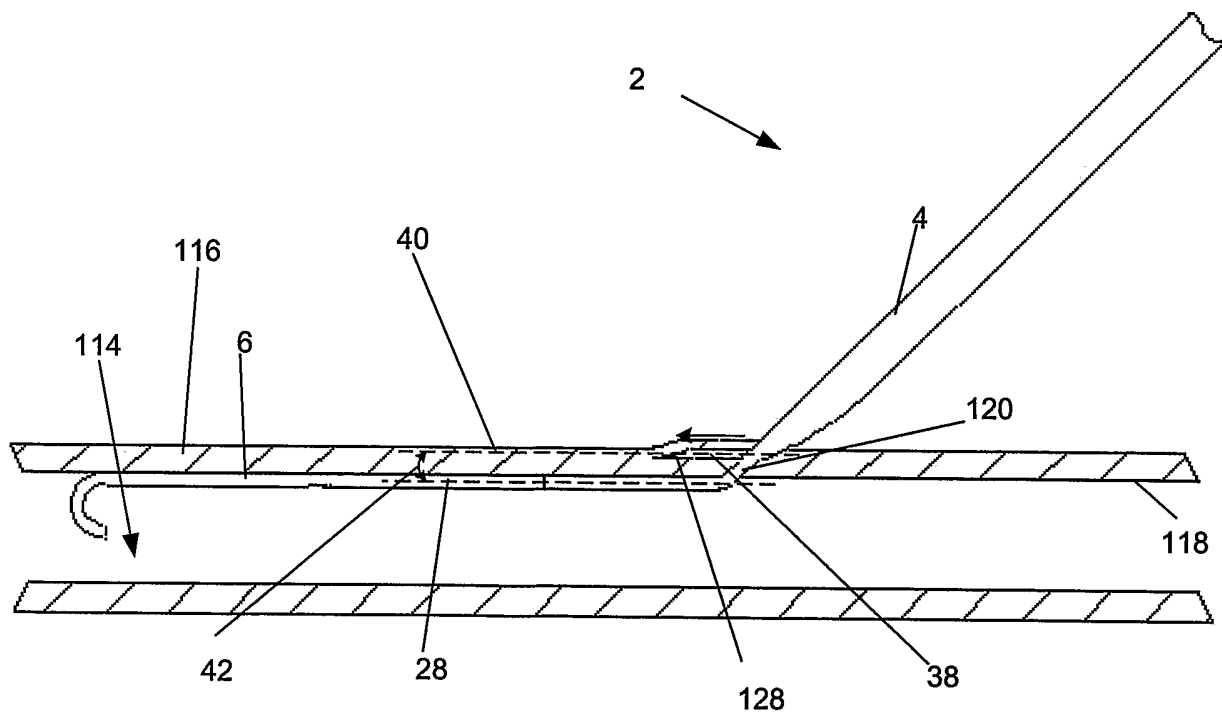


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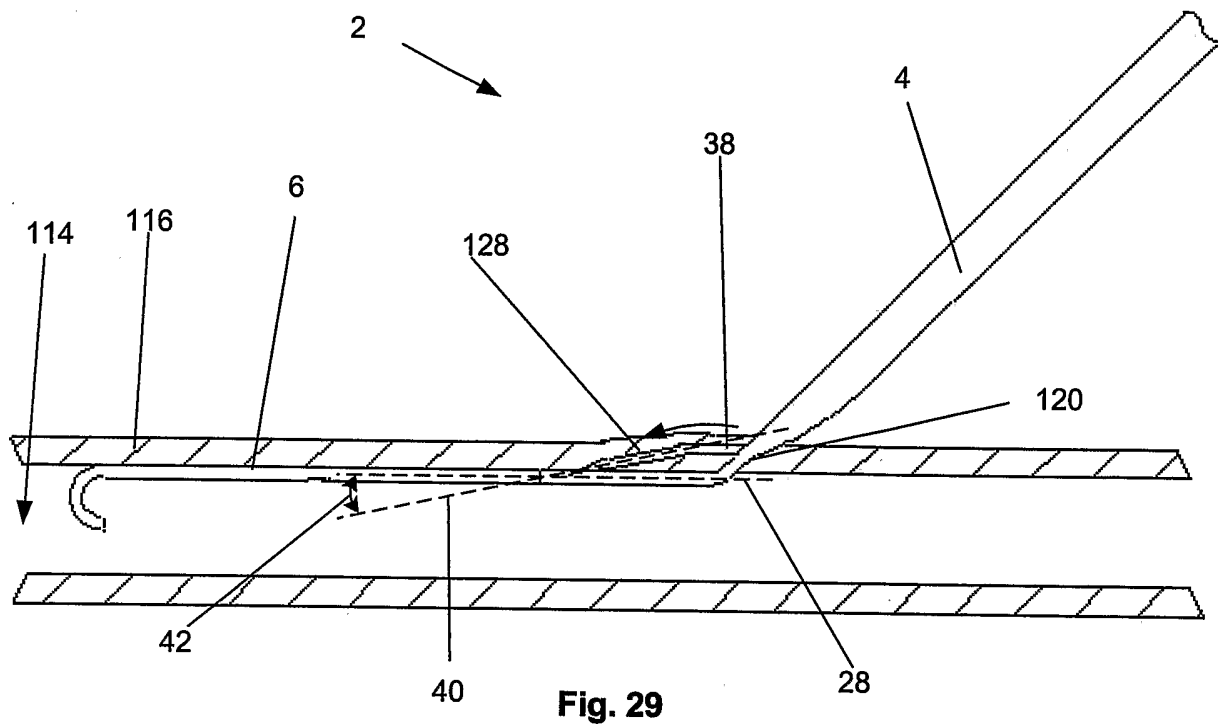


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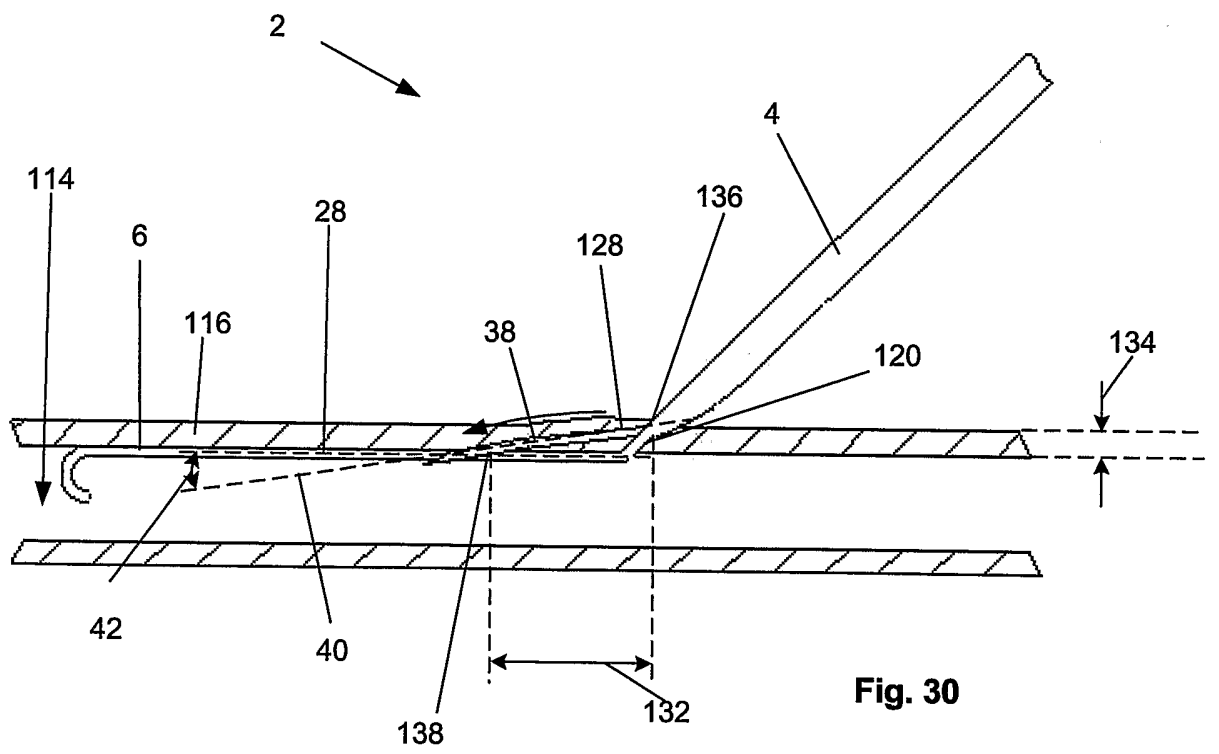


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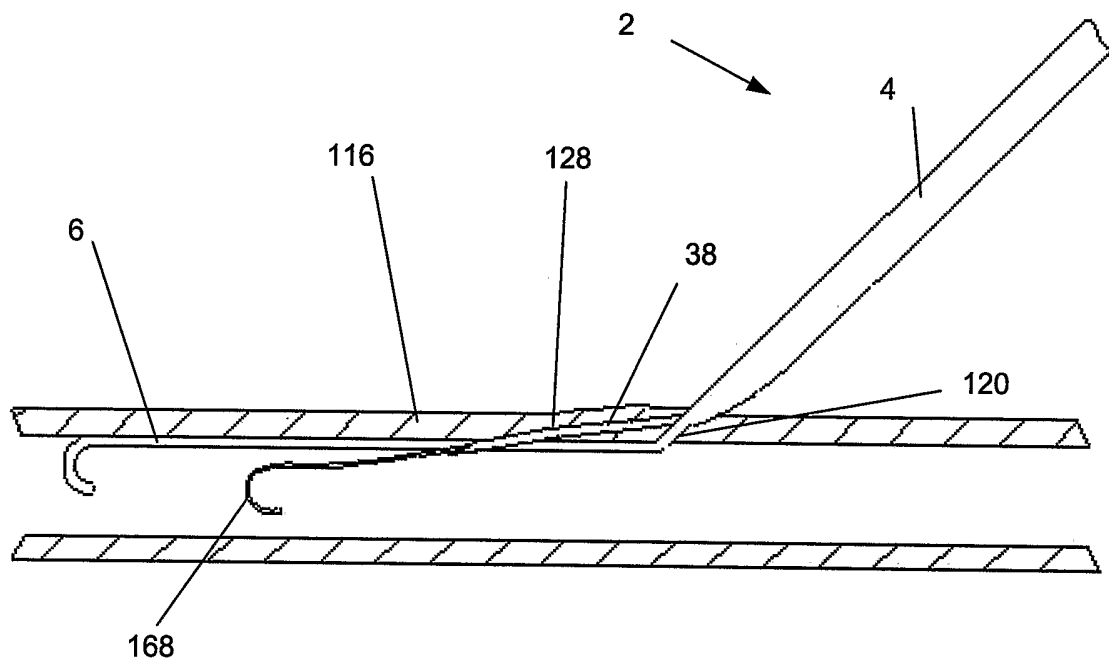


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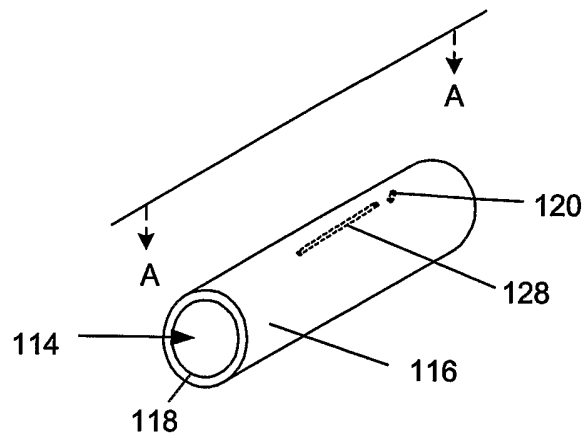


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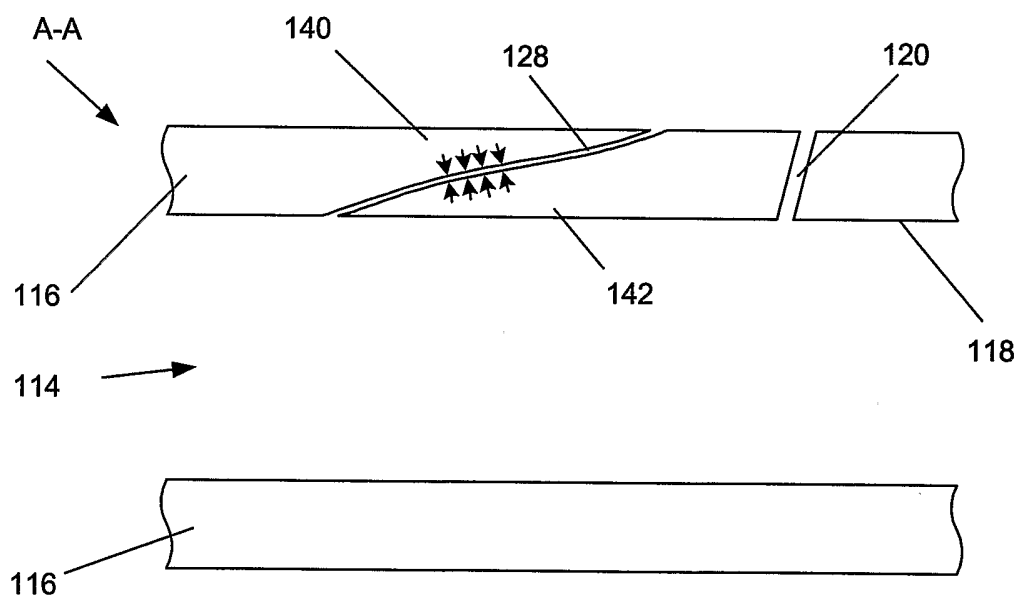


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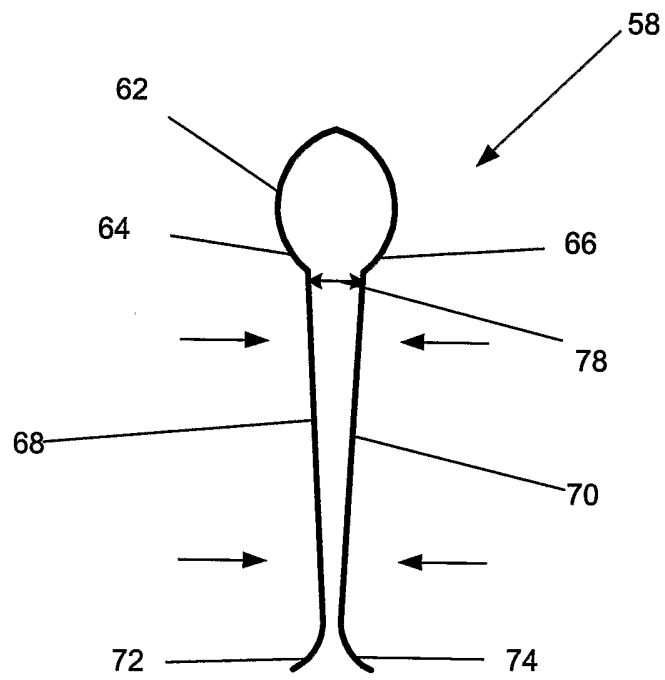


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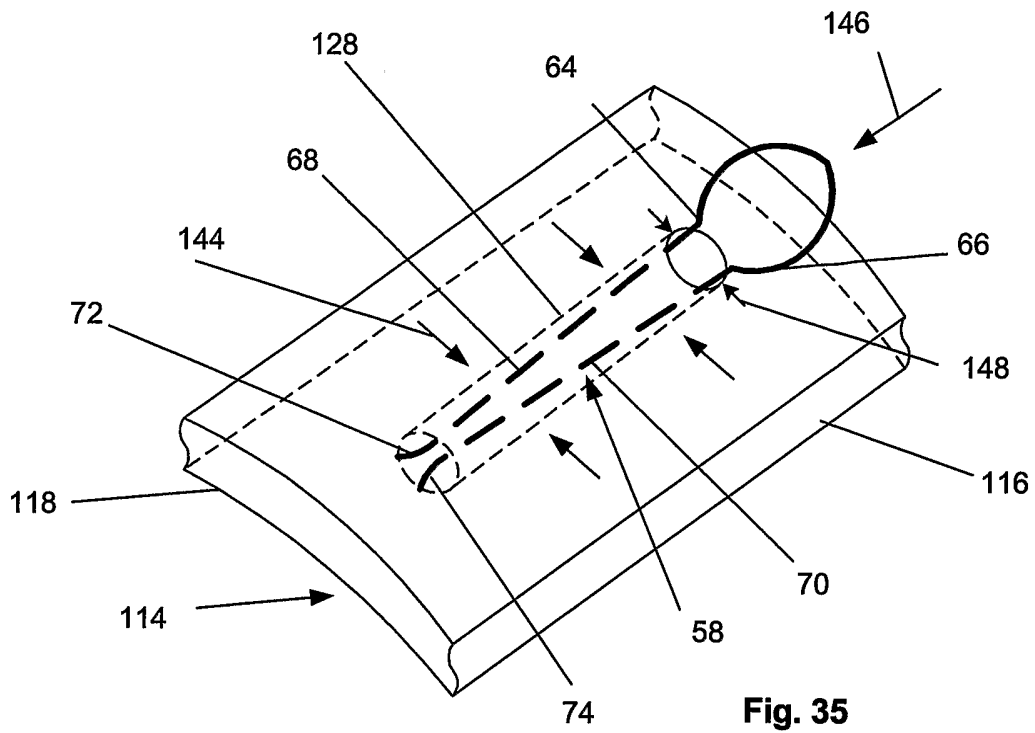


Fig. 35

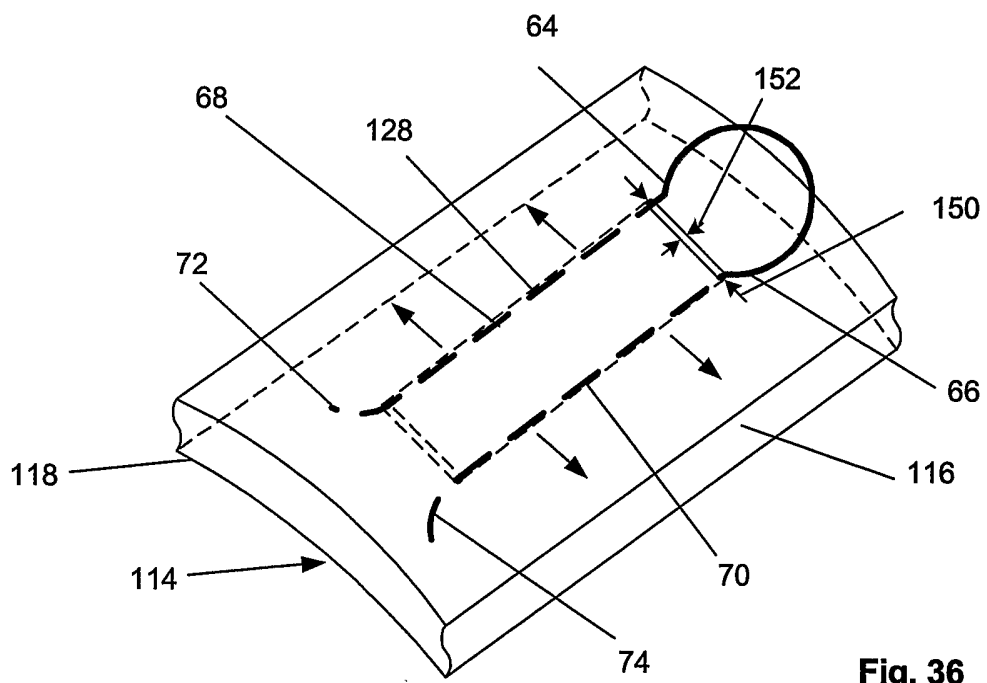
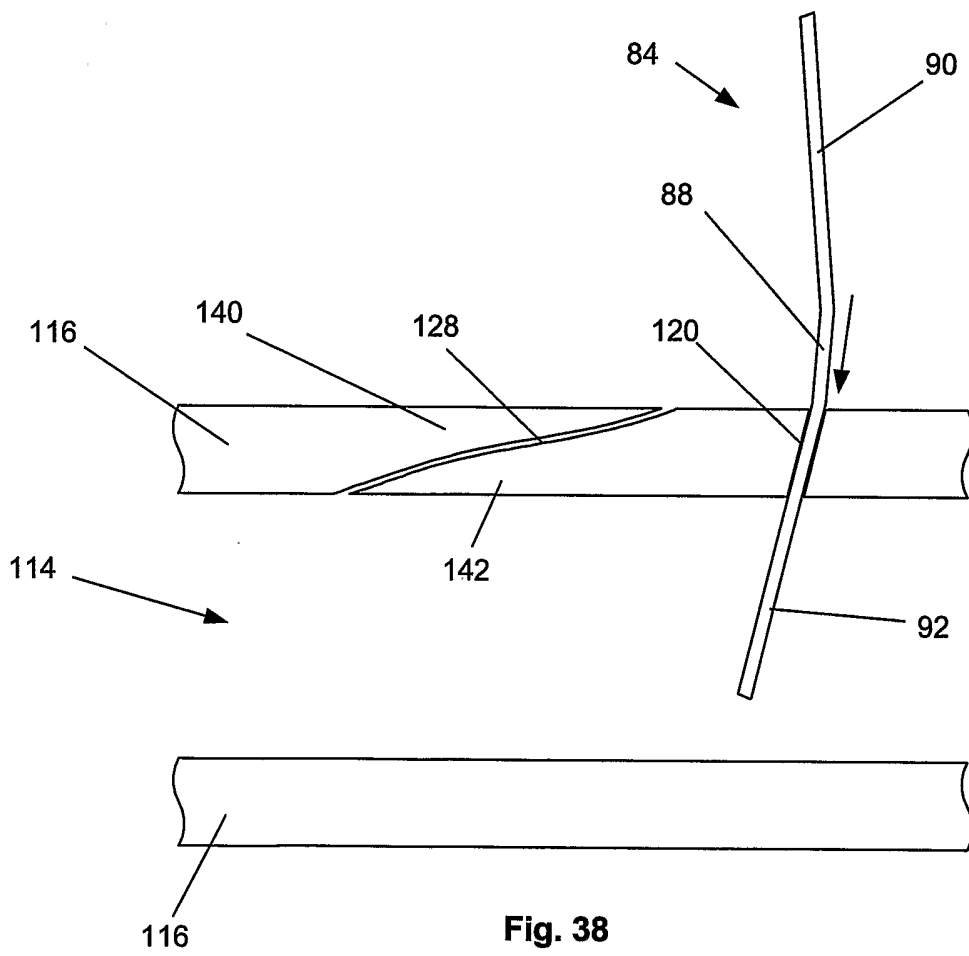
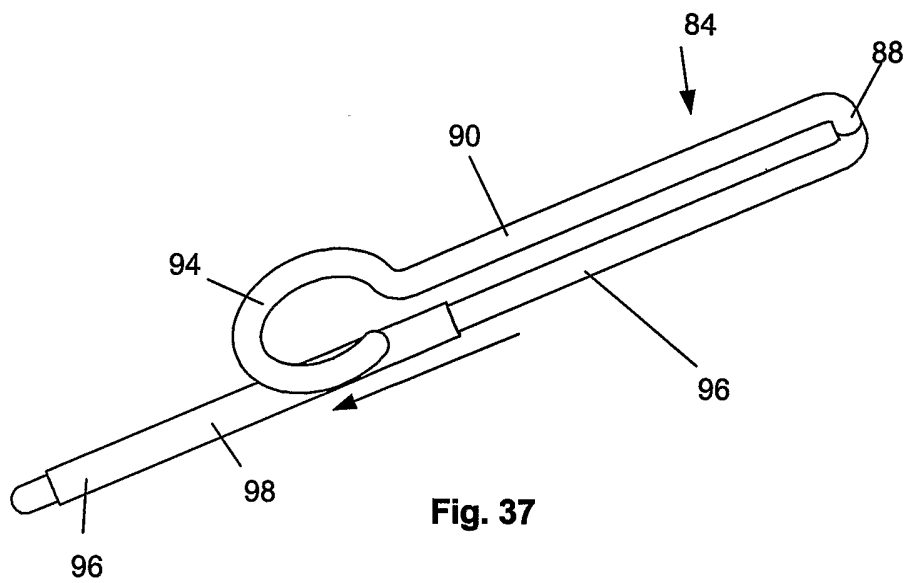
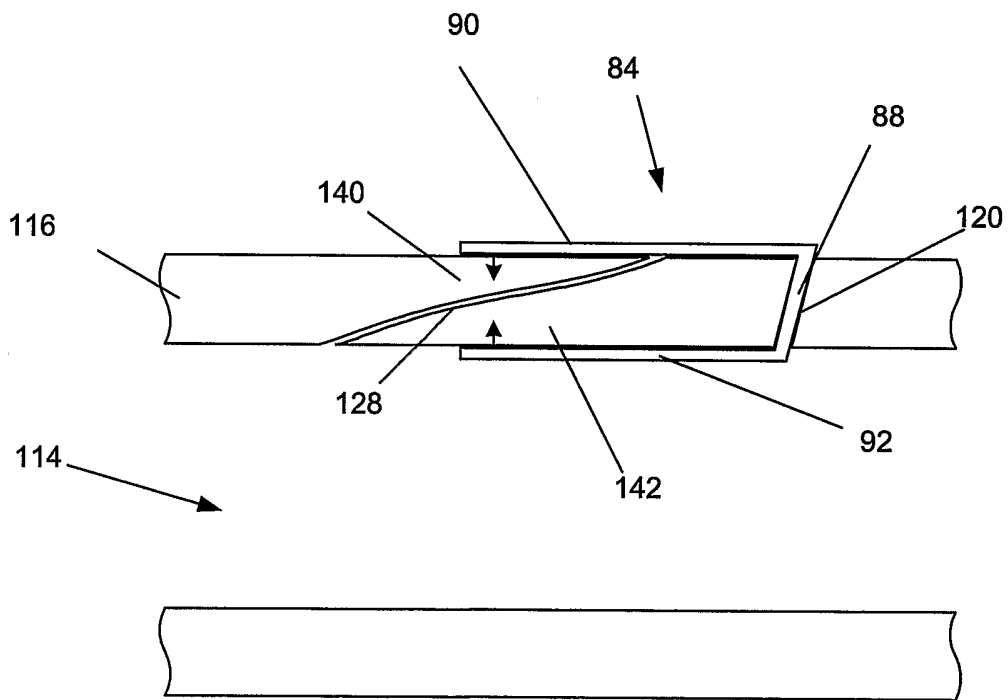
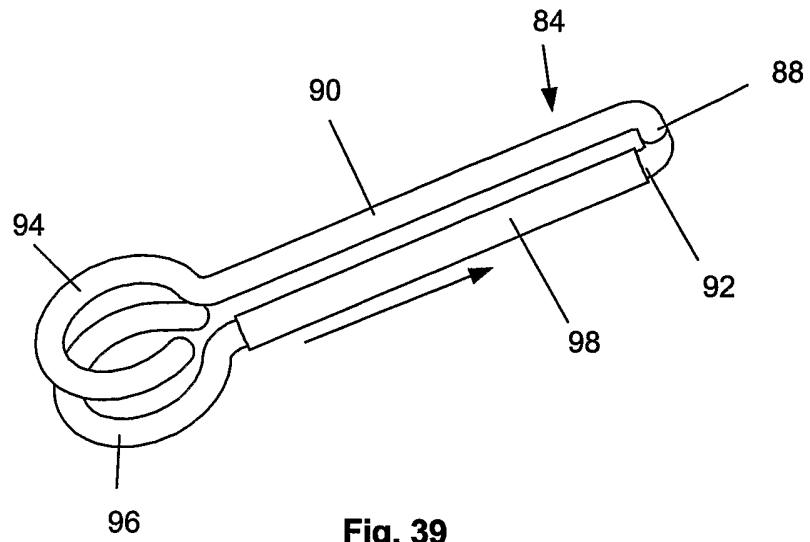


Fig. 36





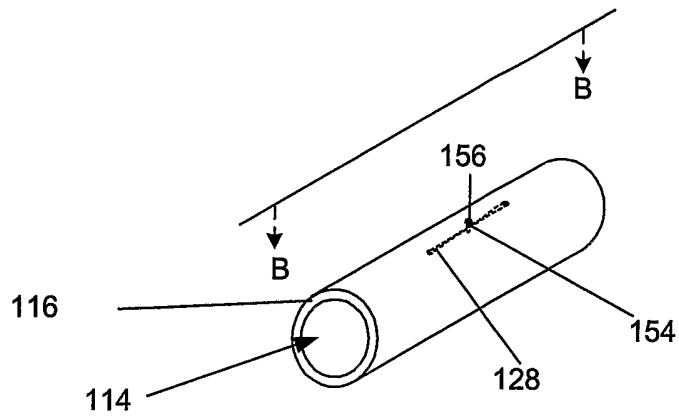


Fig. 41

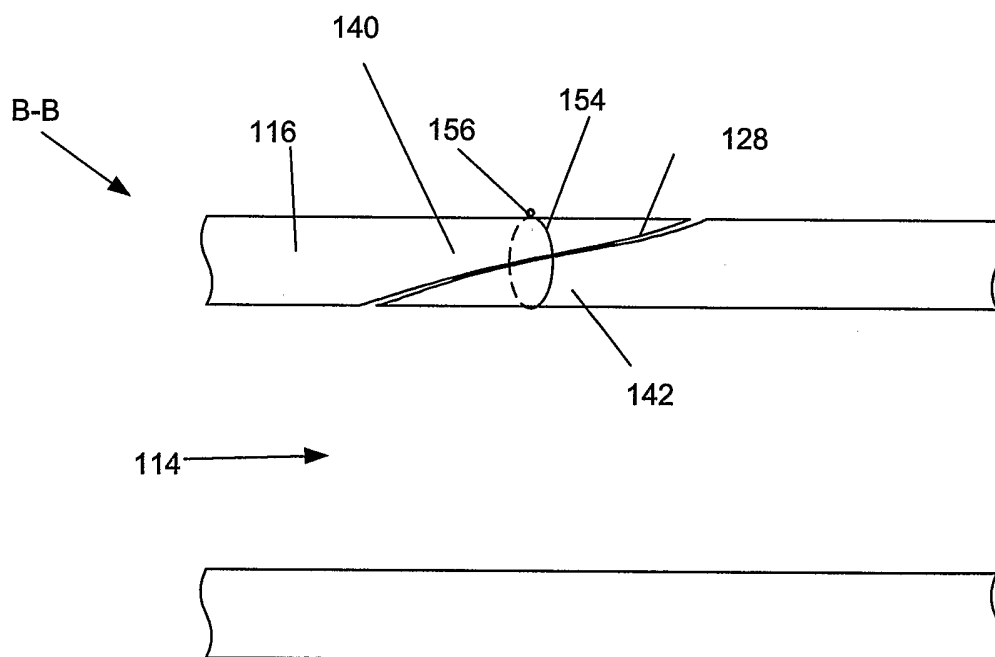


Fig. 42

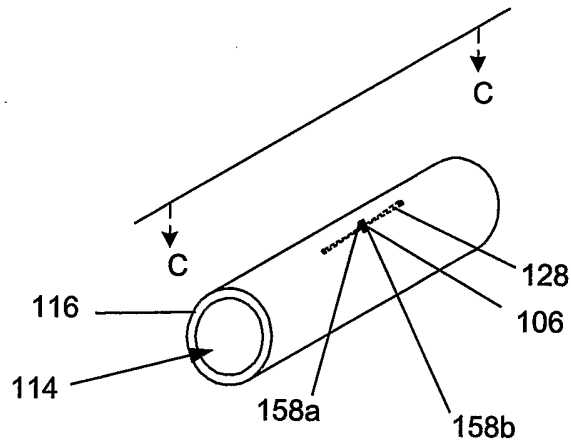


Fig. 43

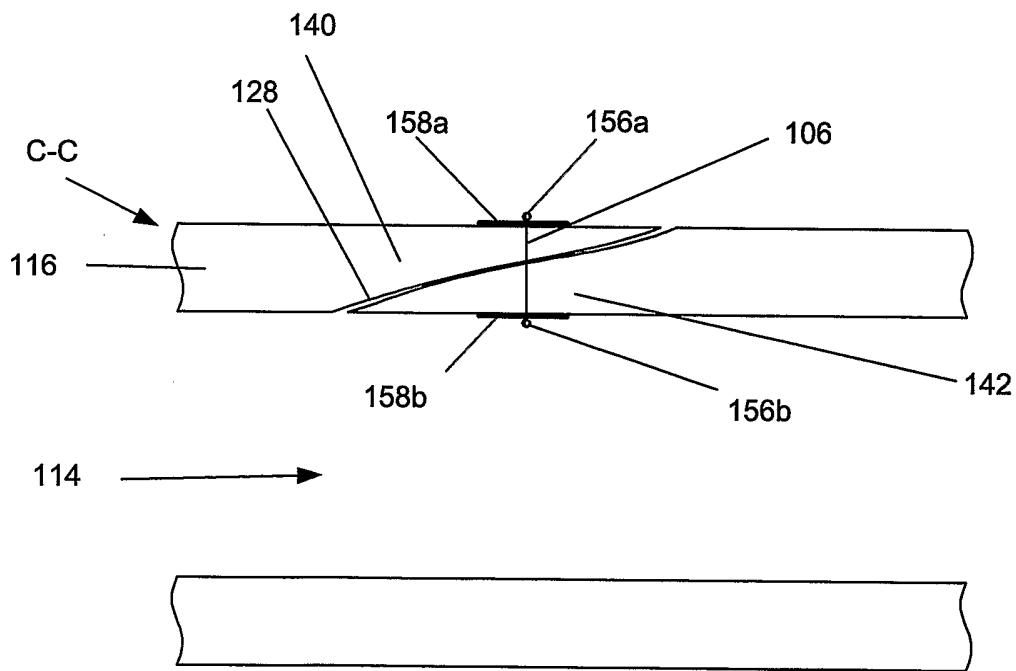


Fig. 44

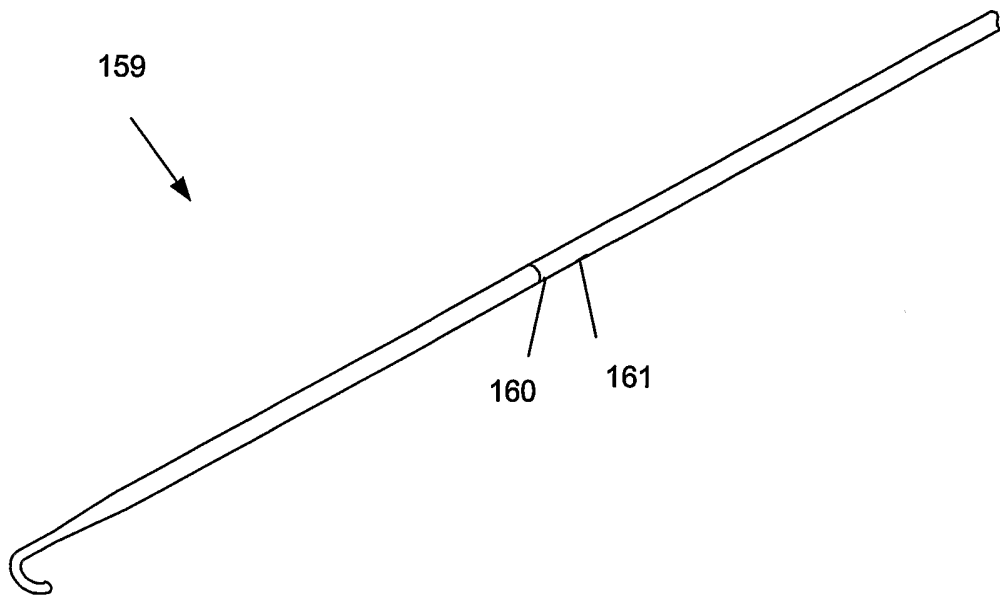


Fig. 45

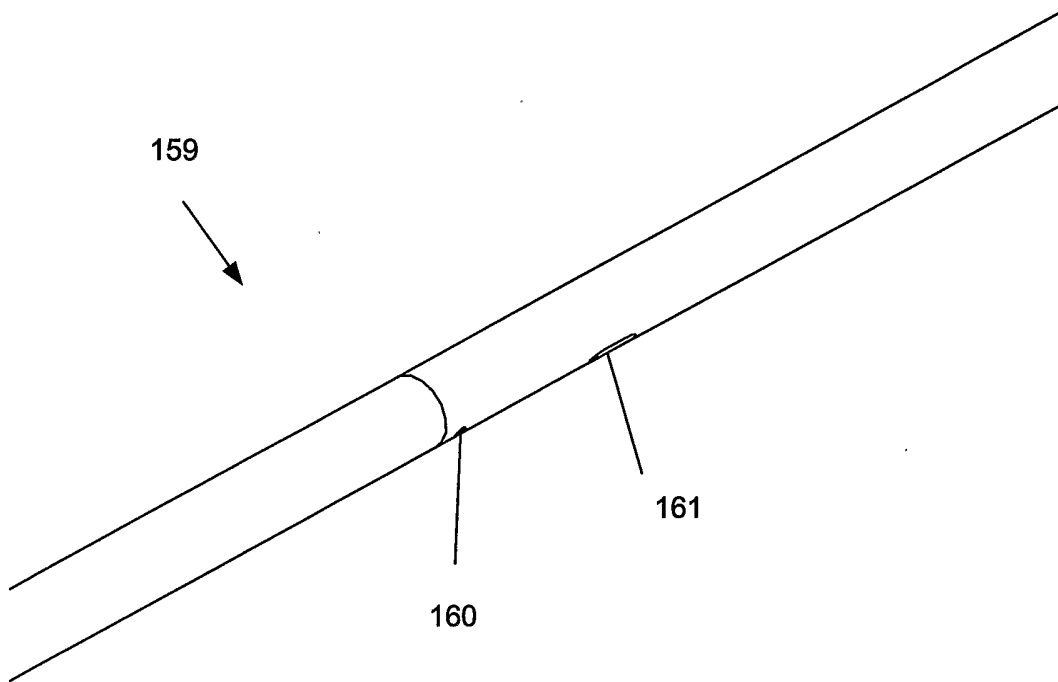


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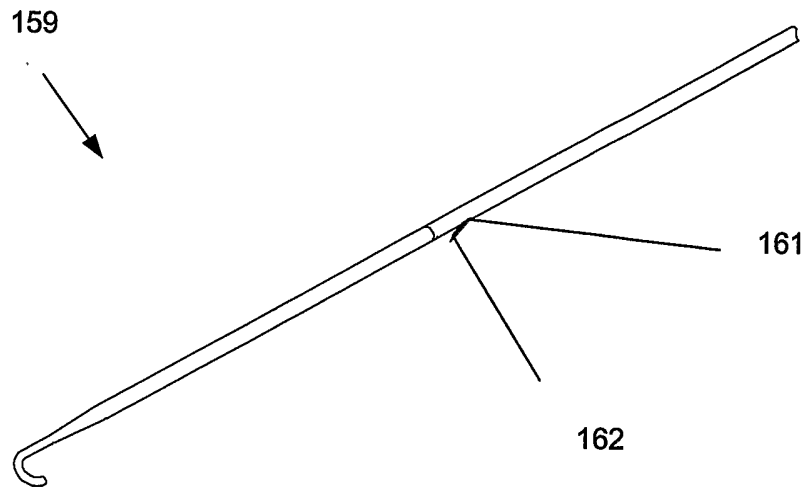


Fig. 47

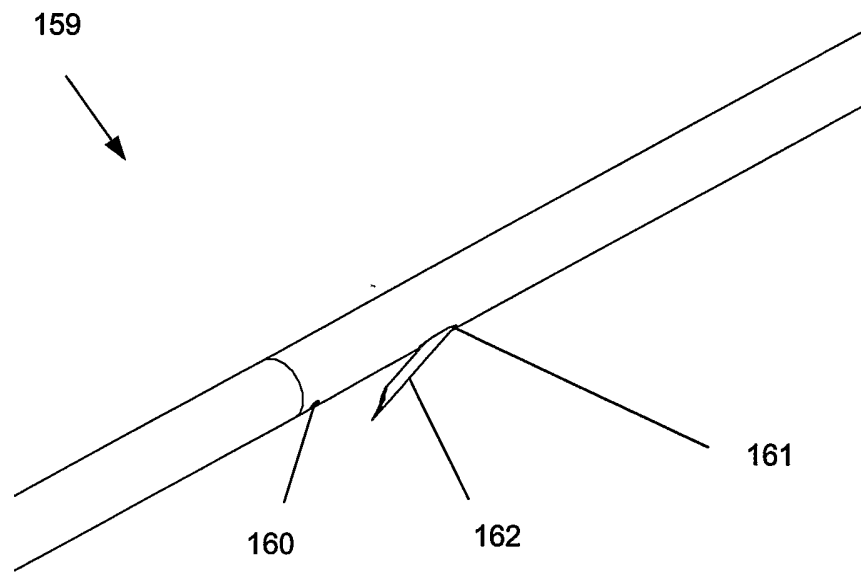


Fig. 48

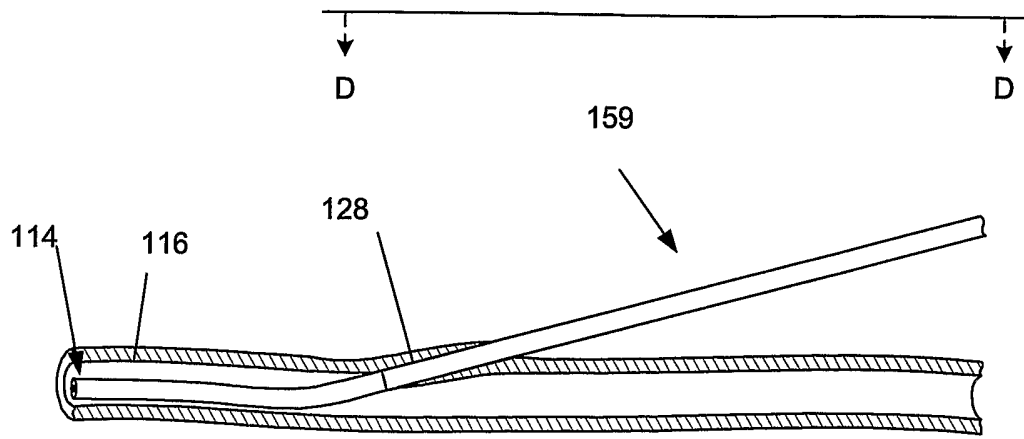


Fig. 49

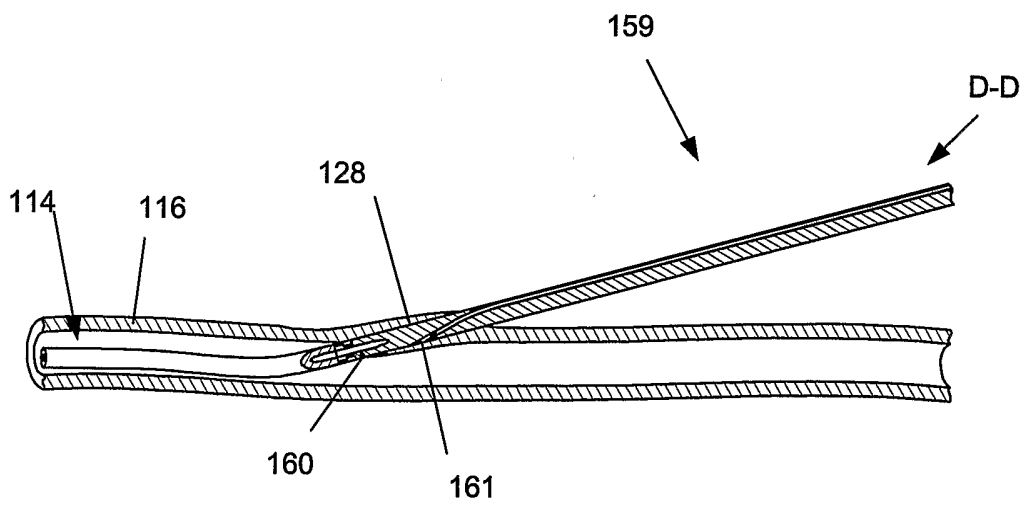


Fig. 50

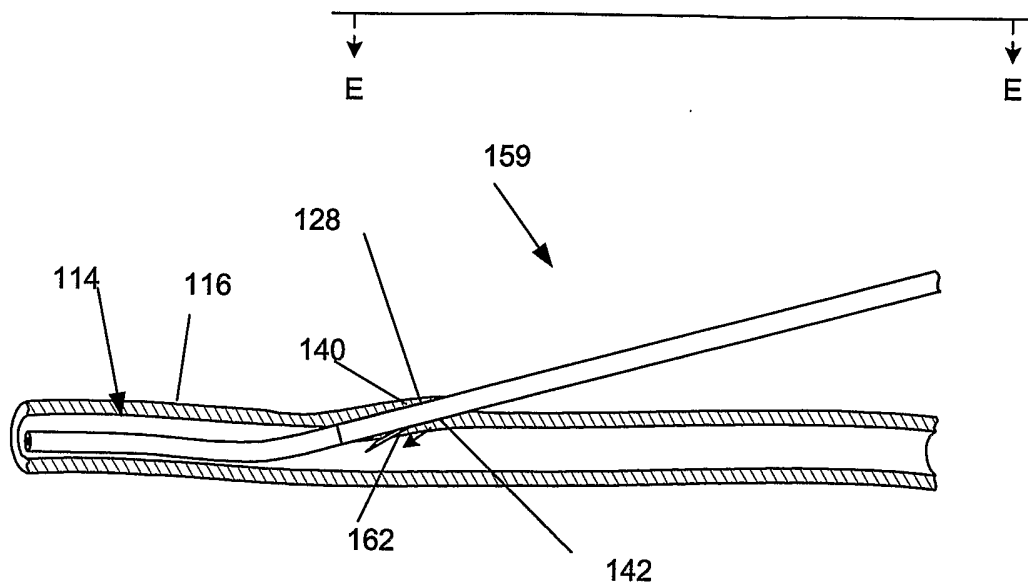


Fig. 51

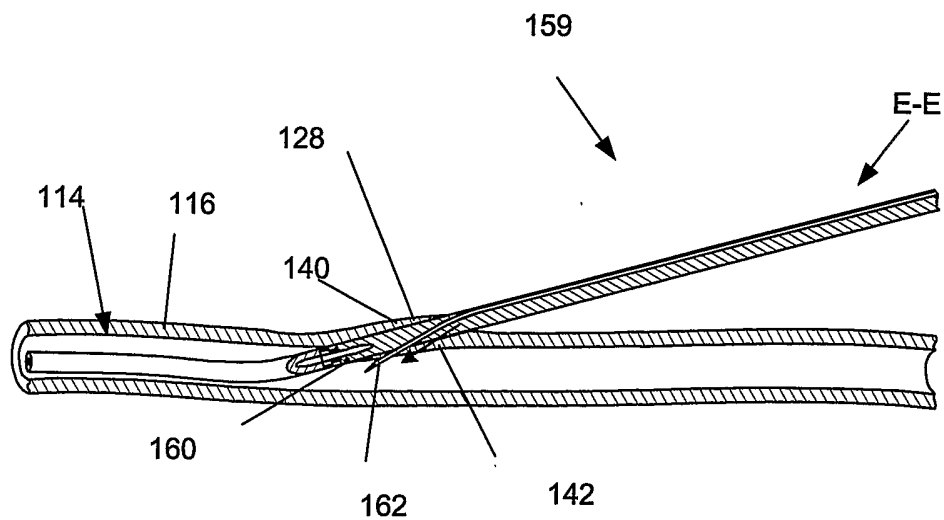


Fig. 52

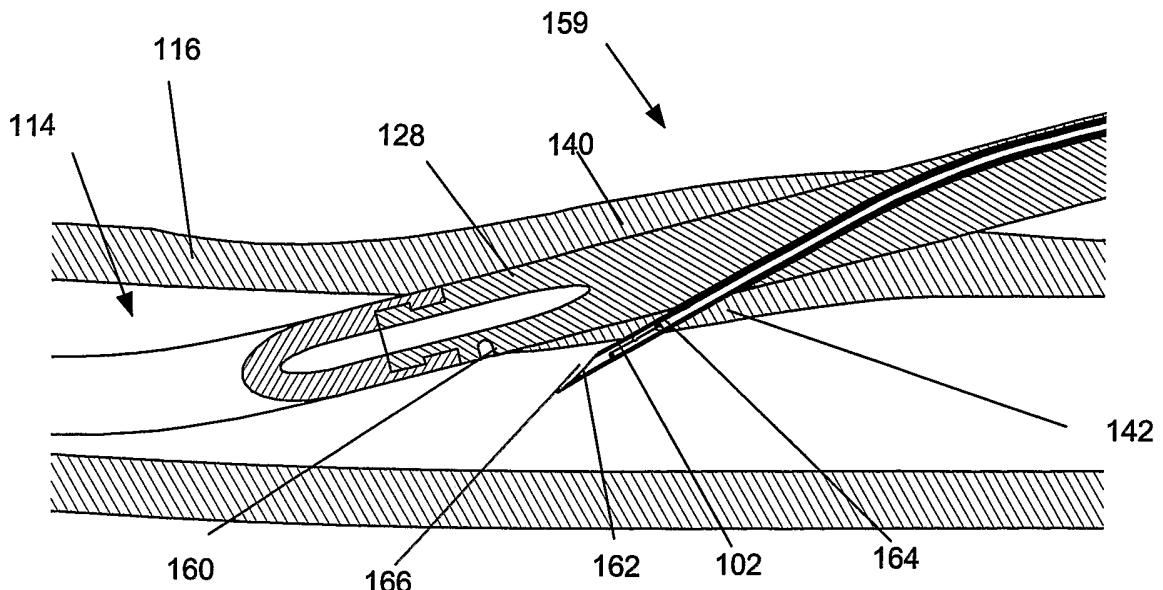


Fig. 53

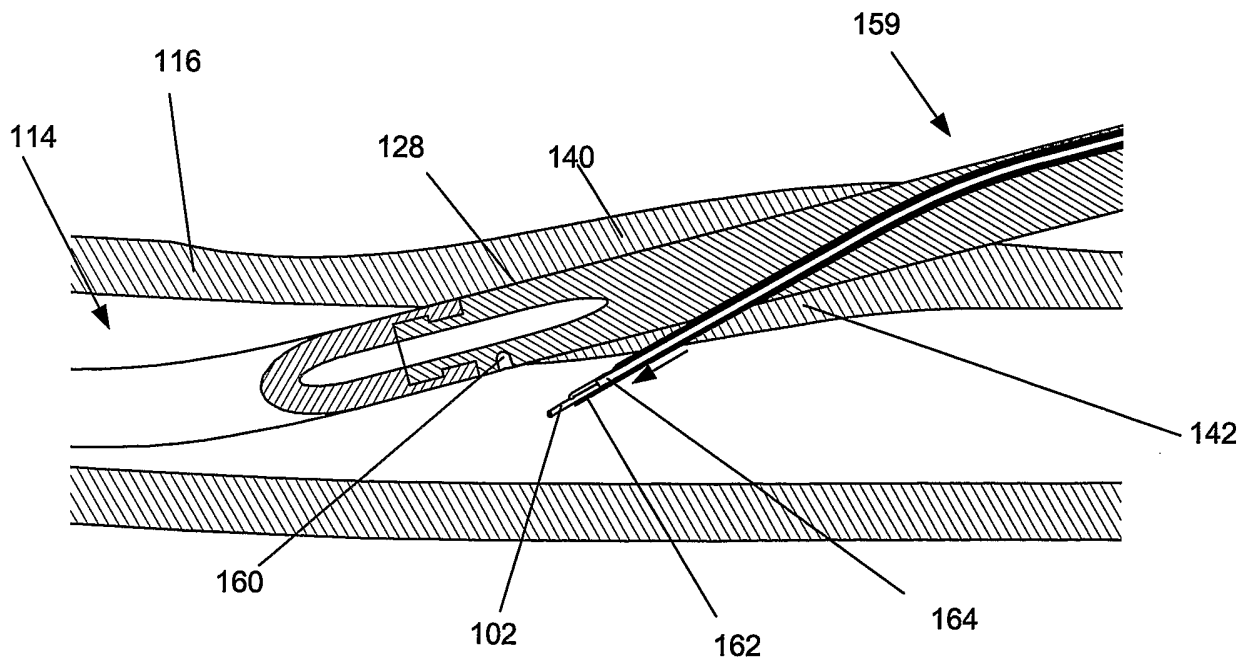


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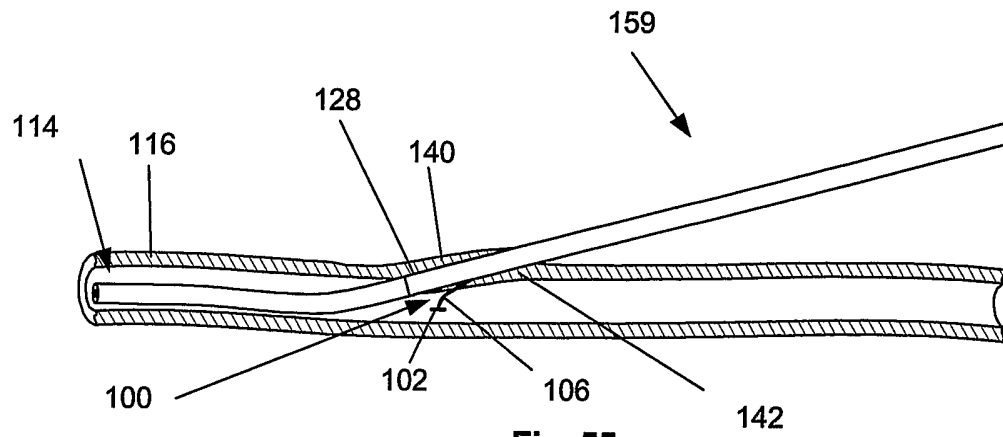


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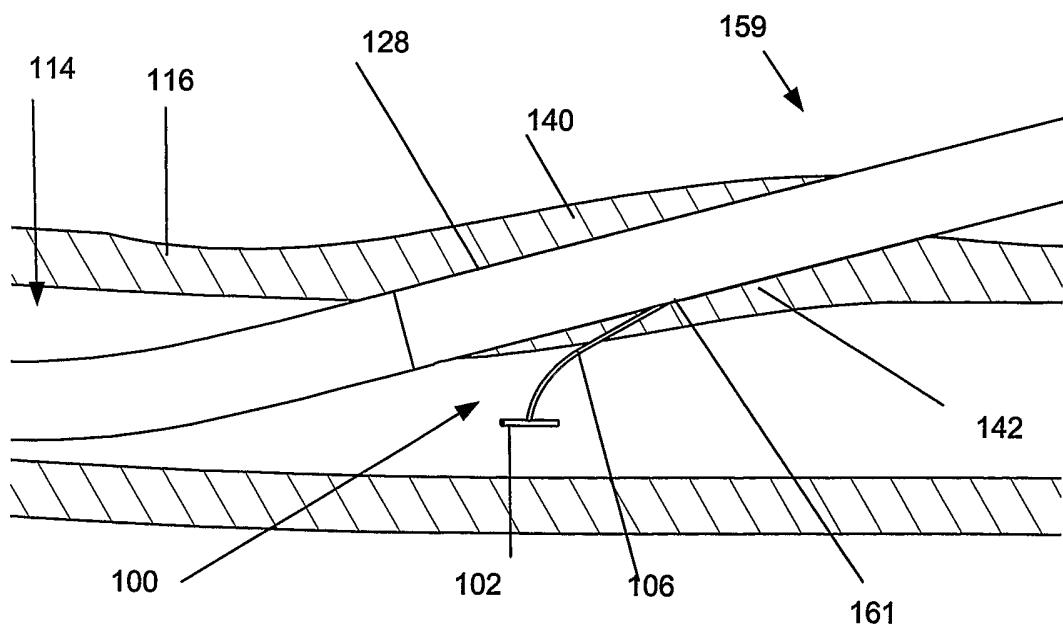


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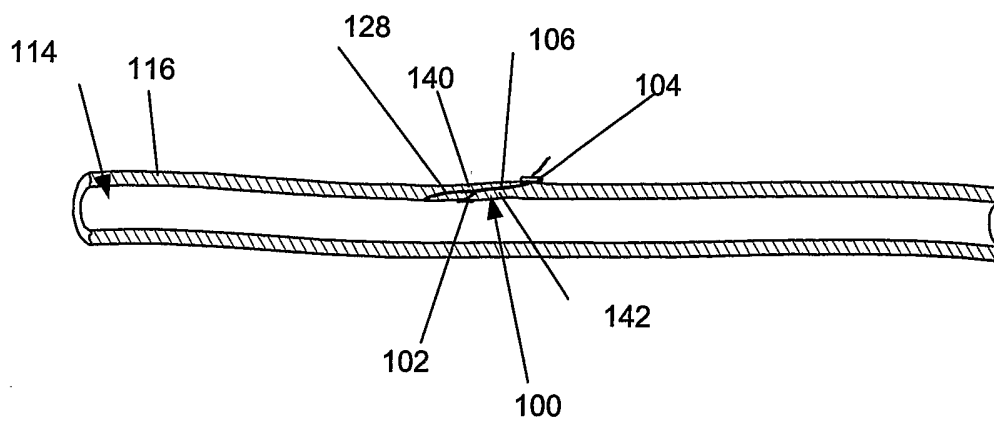


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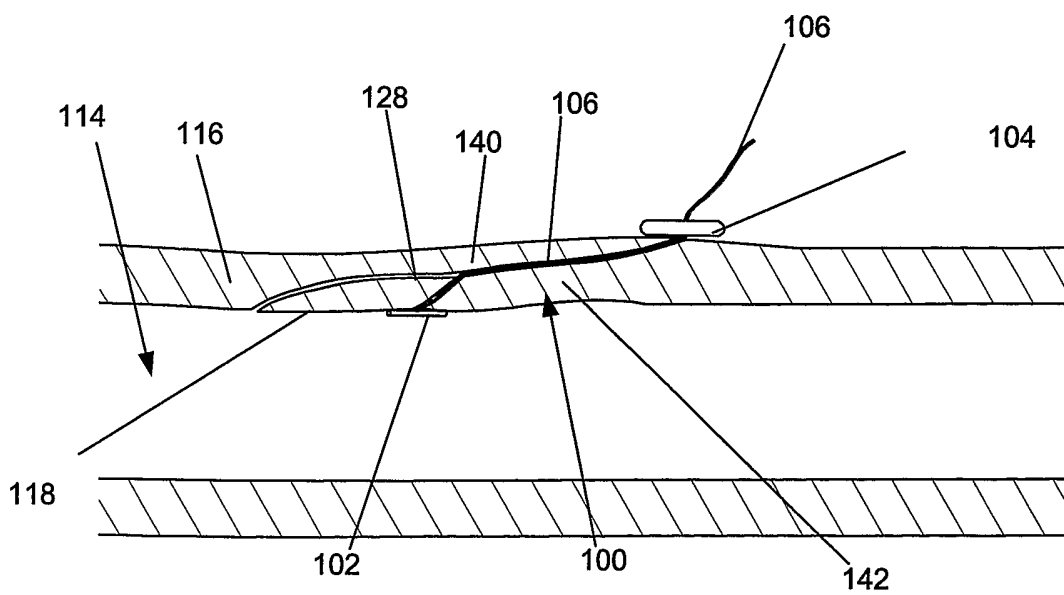


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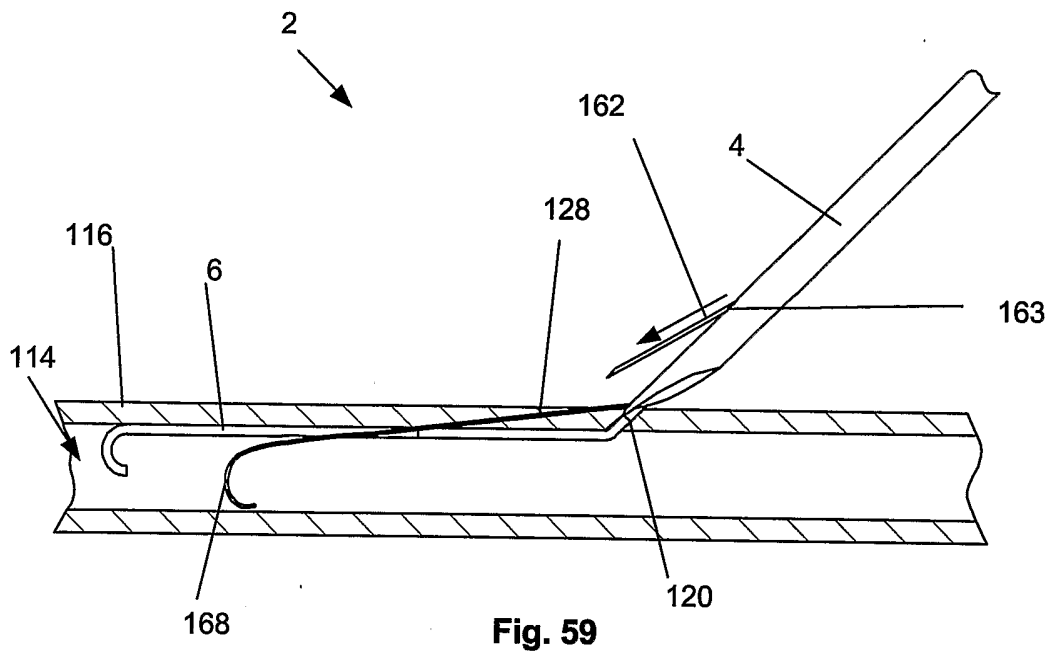


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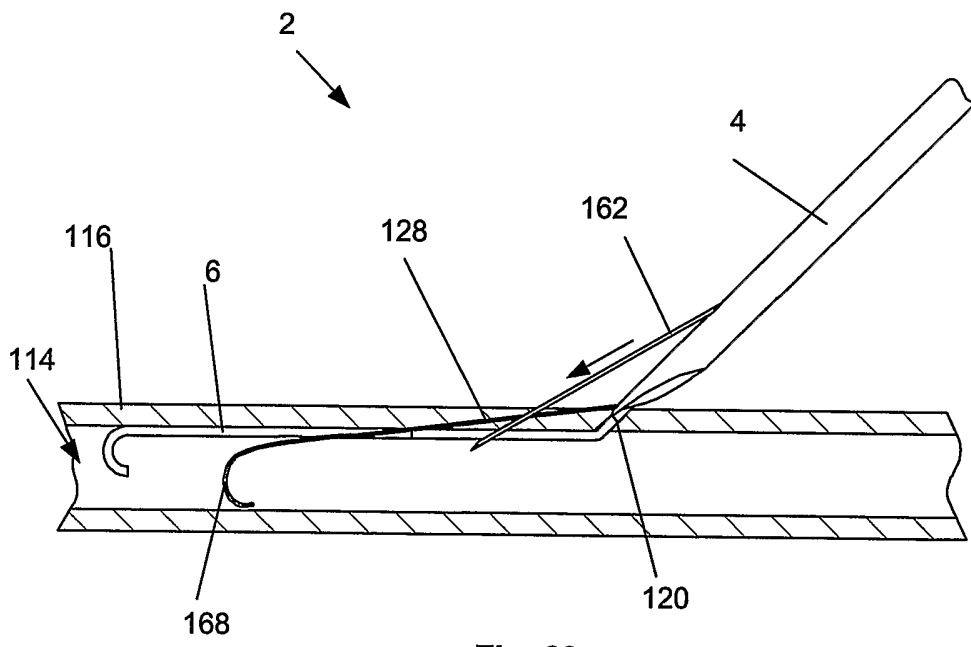


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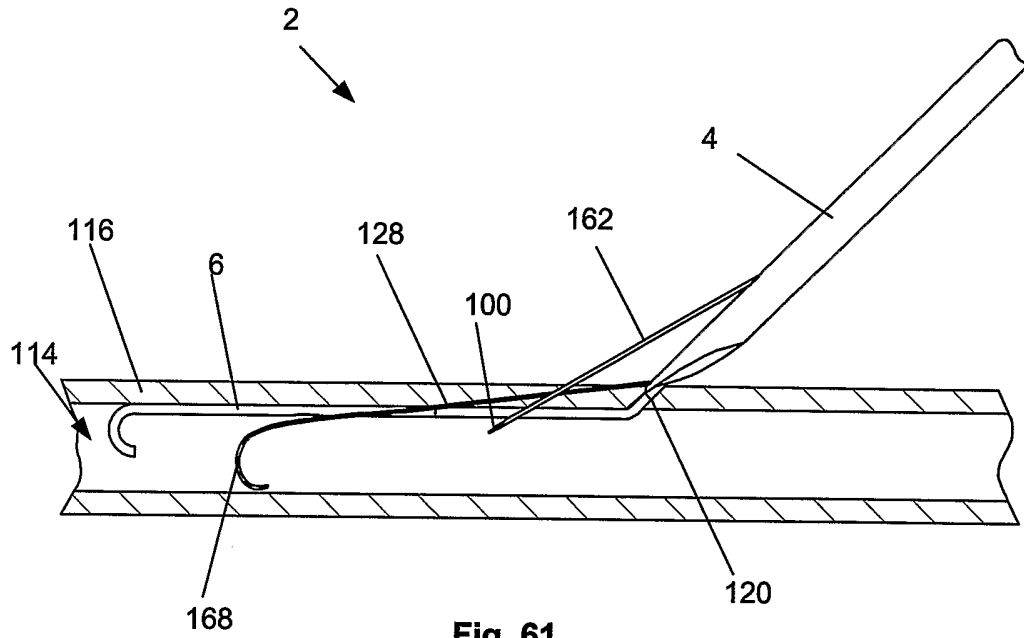


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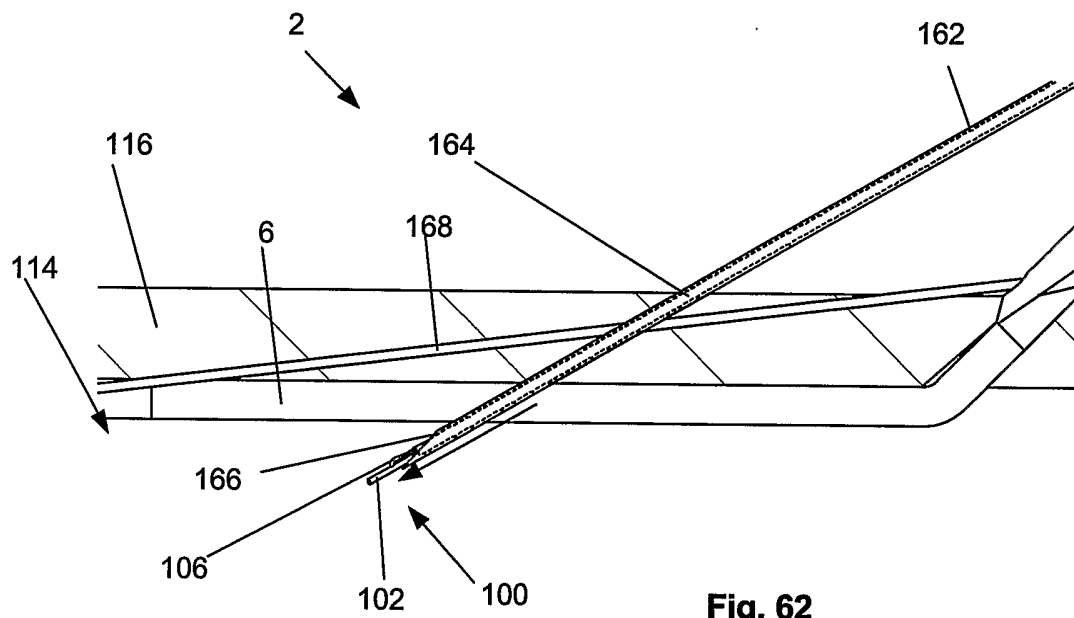


Fig. 62

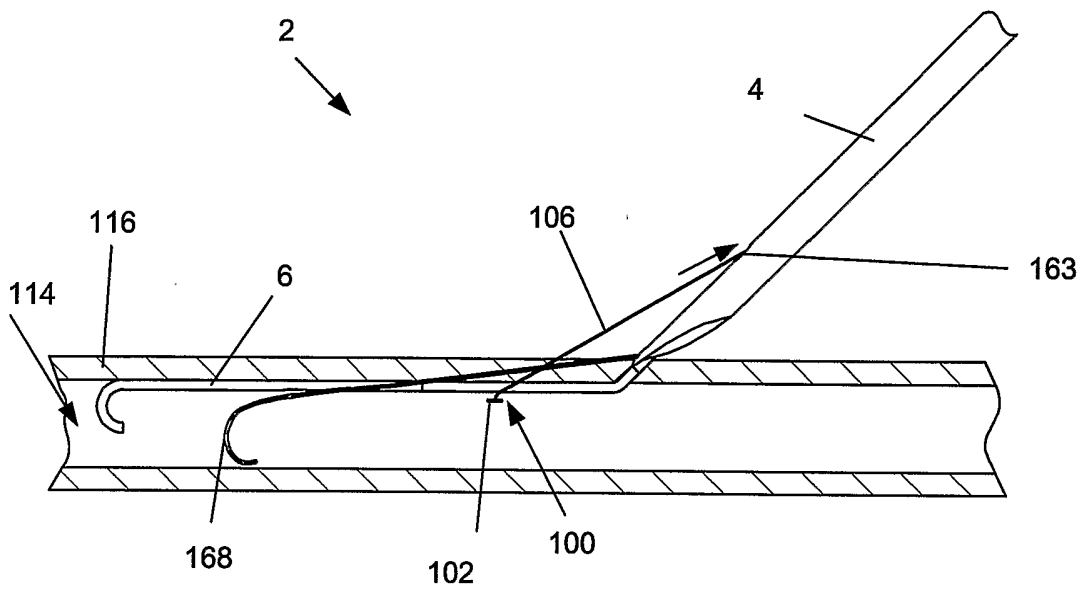


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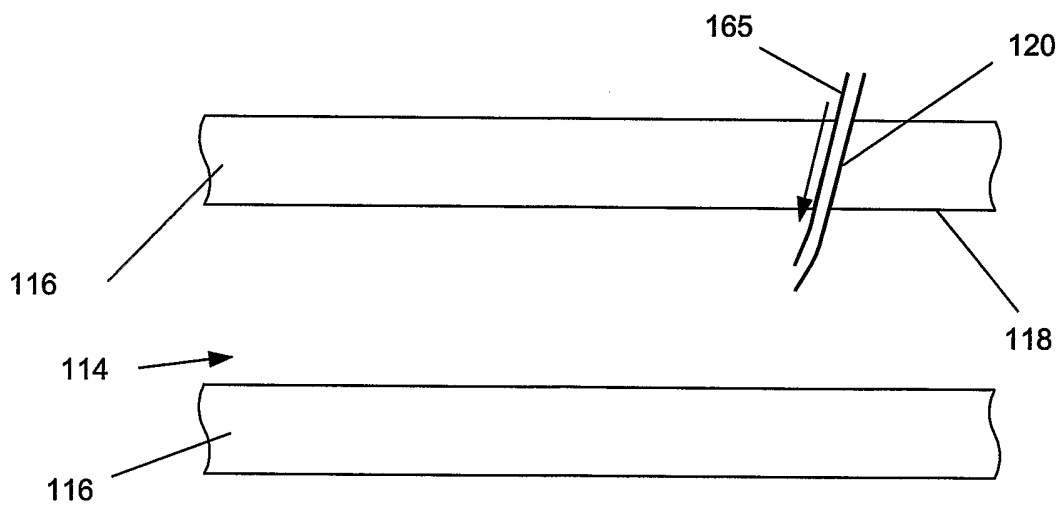


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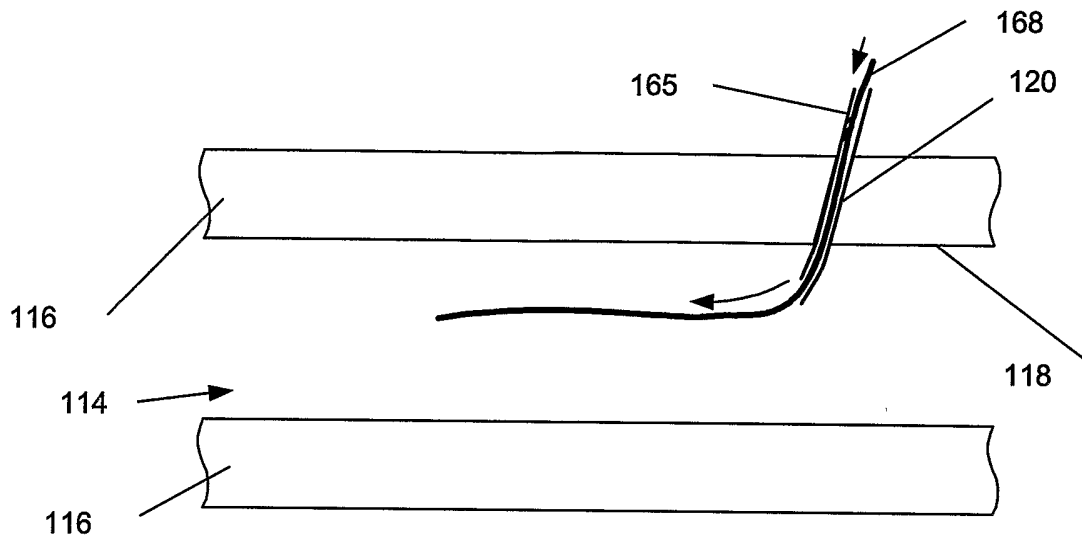


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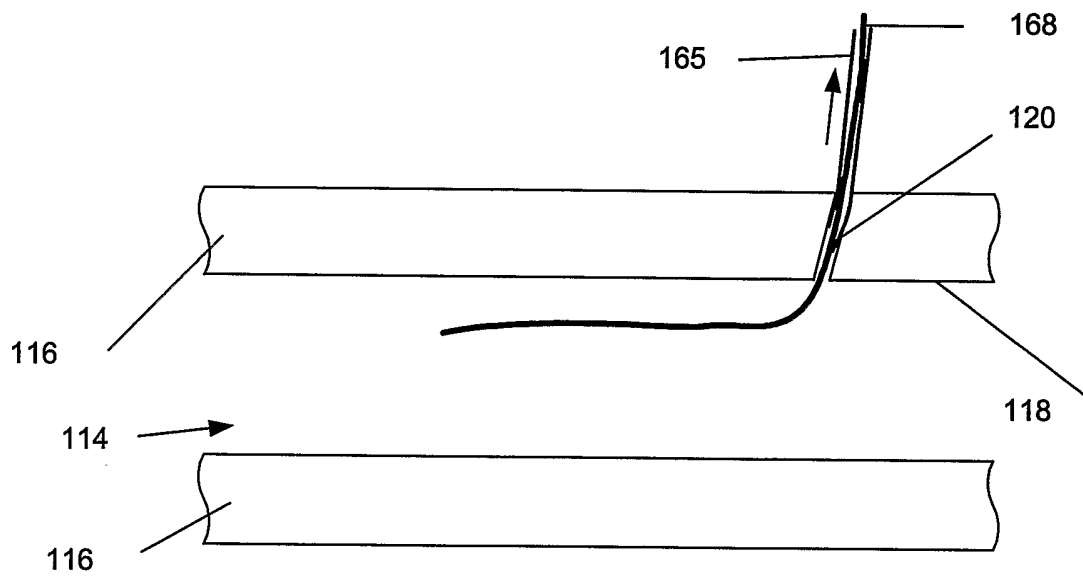


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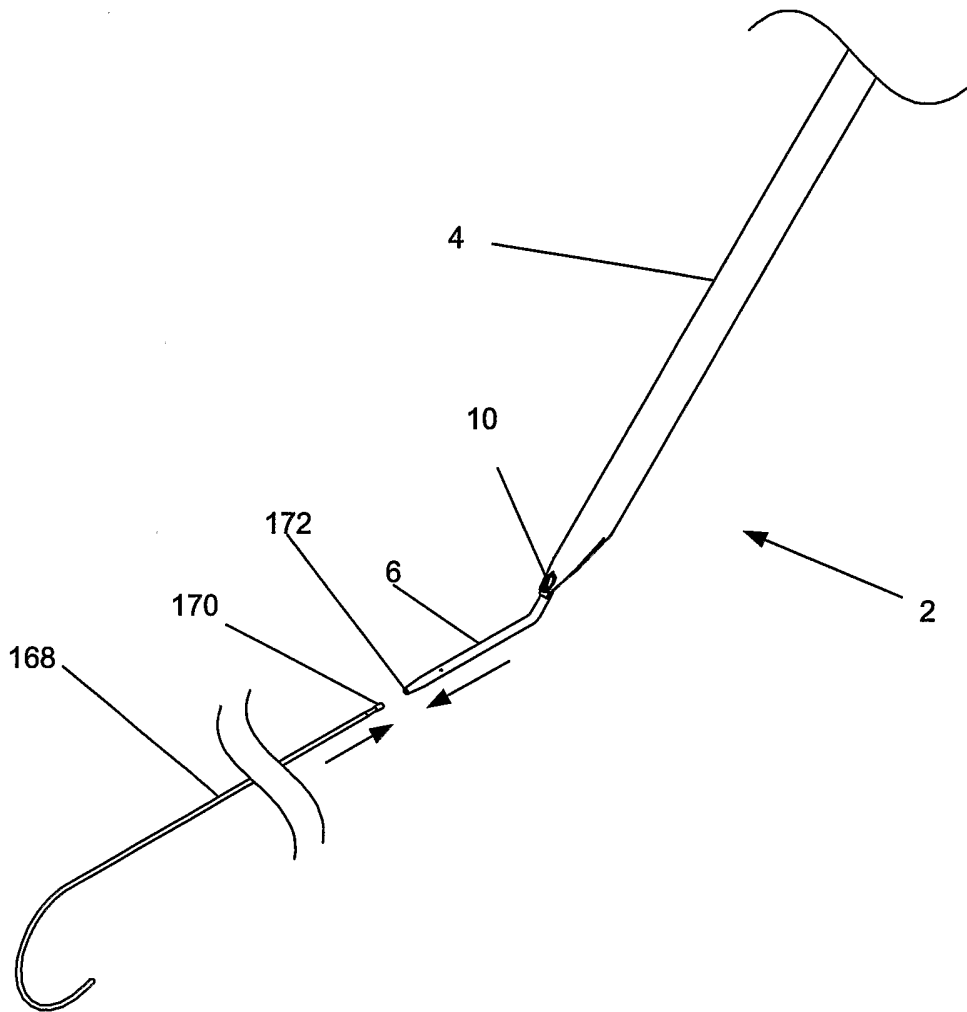


Fig. 67

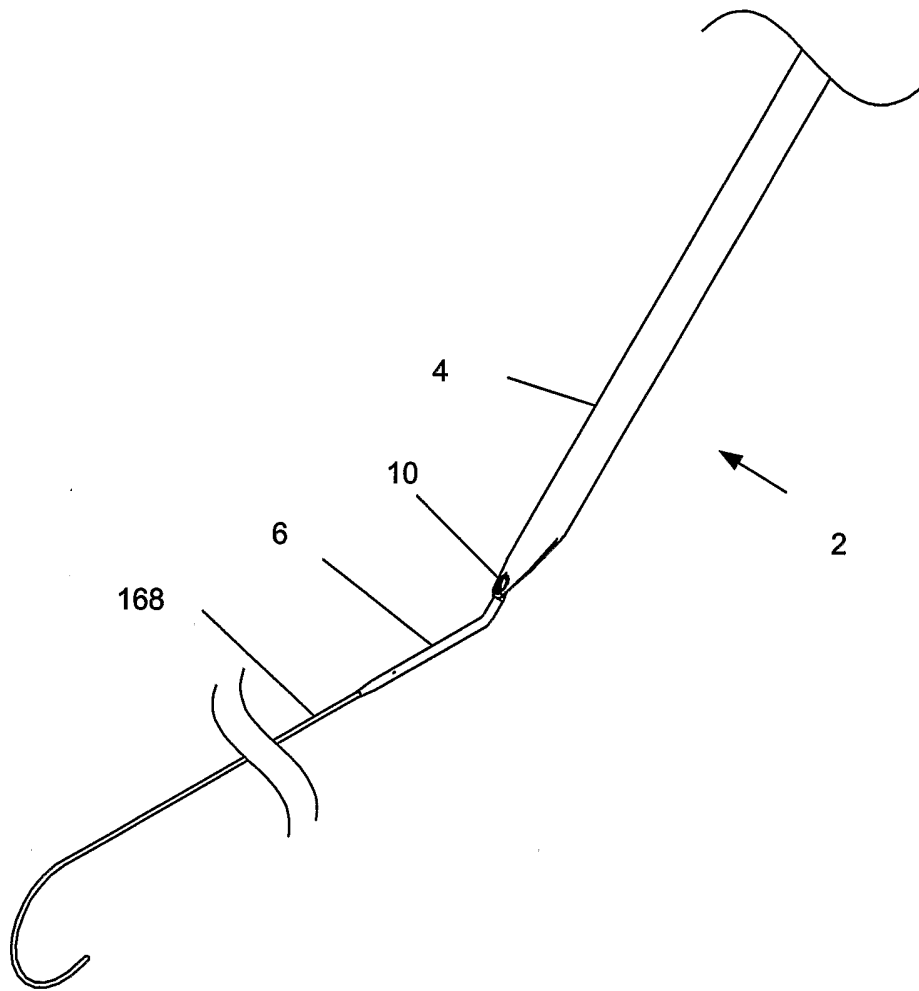


Fig. 68