US 20080146939A1

(19) United States

(12) Patent Application Publication

(10) Pub. No.: US 2008/0146939 A1

(43) Pub. Date: Jun. 19, 2008

McMorrow et al.

(54) **APPARATUS AND METHOD FOR IMAGE GUIDED INSERTION AND REMOVAL OF A CANNULA OR NEEDLE**

(76) Inventors: **Gerald McMorrow**, Kirkland, WA (US); **Steven J. Shankle**, Kirkland, WA (US); **Russell A. Garrison**, Redmond, WA (US)

Correspondence Address:
BLACK LOWE & GRAHAM, PLLC
701 FIFTH AVENUE, SUITE 4800
SEATTLE, WA 98104

(21) Appl. No.: **11/925,873**

(22) Filed: **Oct. 27, 2007**

Related U.S. Application Data

(63) Continuation of application No. 11/258,592, filed on Oct. 24, 2005, which is a continuation-in-part of application No. PCT/US03/24368, filed on Aug. 1, 2003, said application No. 11/258,592 is a continuation-in-part of application No. PCT/US03/14785, filed on May 9, 2003, which is a continuation of application No. 10/165,556, filed on Jun. 7, 2002, now Pat. No. 6,676,605, said application No. 11/258,592 is a continuation-in-part of application No. 10/888,735, filed on Jul. 9, 2004, now abandoned, which is a continuation-in-part of application No. 10/633,186, filed on Jul. 31, 2003, now Pat. No. 7,004,904, which is a continuation-in-part of application No. 10/443,126, filed on May 20, 2003, now Pat. No. 7,041,059.

(60) Provisional application No. 60/621,349, filed on Oct. 22, 2004, provisional application No. 60/423,881, filed on Nov. 5, 2002, provisional application No. 60/423,881, filed on Nov. 5, 2002, provisional application No. 60/400,624, filed on Aug. 2, 2002, provisional application No. 60/470,525, filed on May 12, 2003.

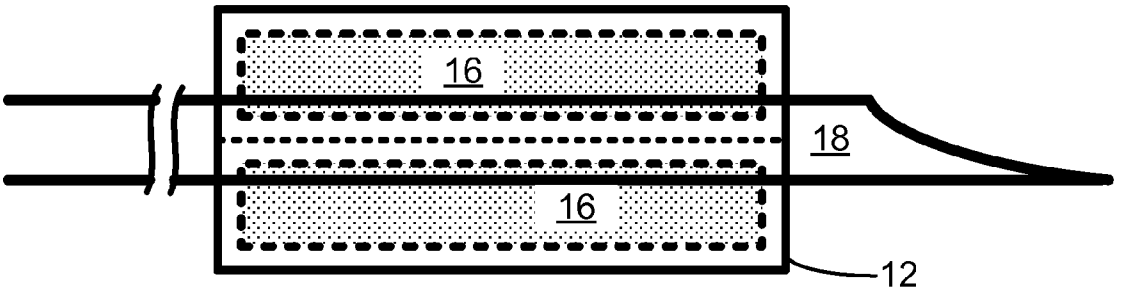
Publication Classification

(51) **Int. Cl.**
A61B 8/00 (2006.01)

(52) **U.S. Cl.** **600/462**

(57) **ABSTRACT**

A means for holding a selected cannula such that the cannula is controllably restricted in motion in all but one line, but still able to slide along the line relatively freely. The motion restricting force may be selectively varied, thereby allowing an unrestricted separation of the cannula and the holding/guide device.



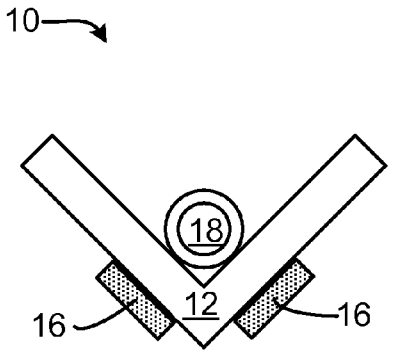


Fig. 1A

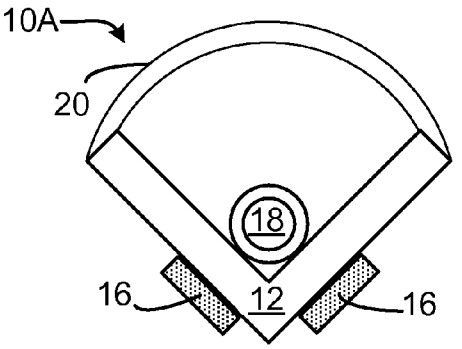


Fig. 1B

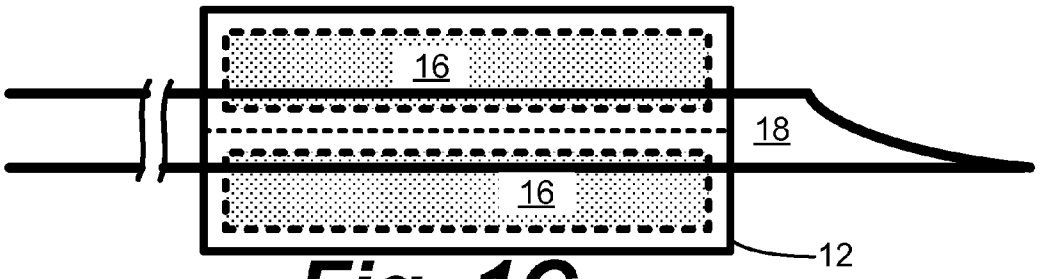


Fig. 1C

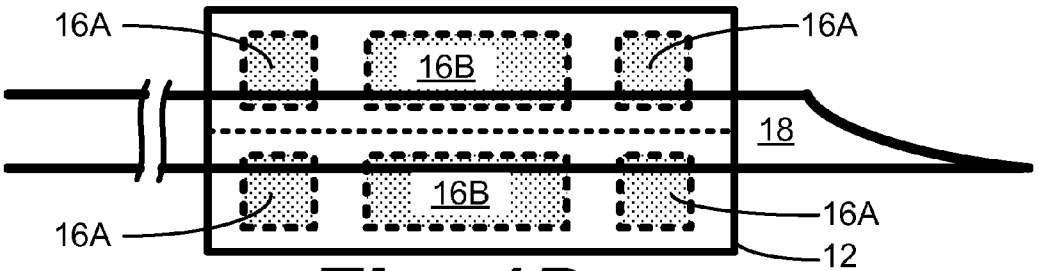


Fig. 1D

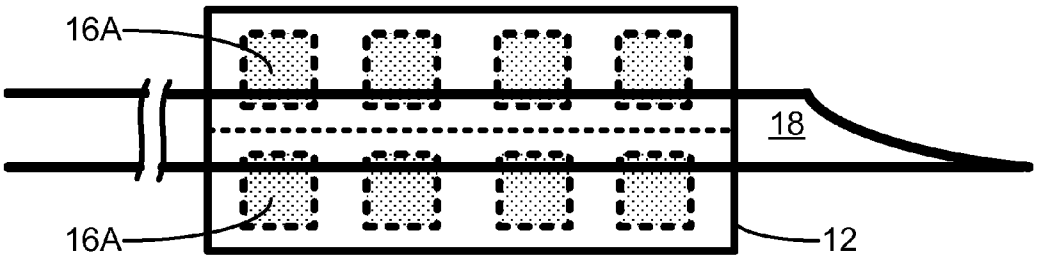


Fig. 1E

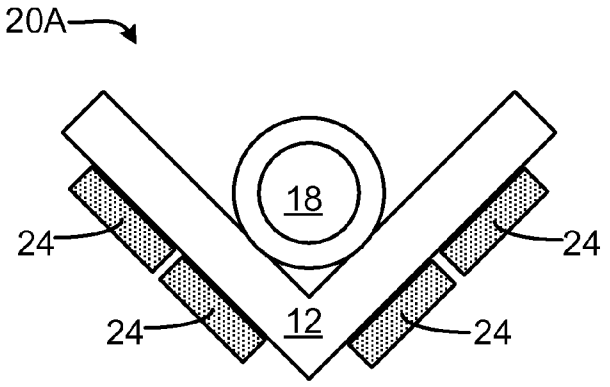


Fig. 2A

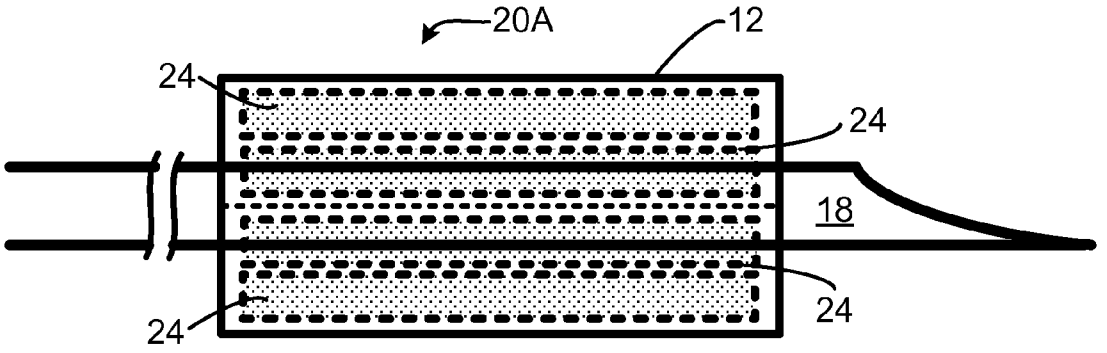


Fig. 2B

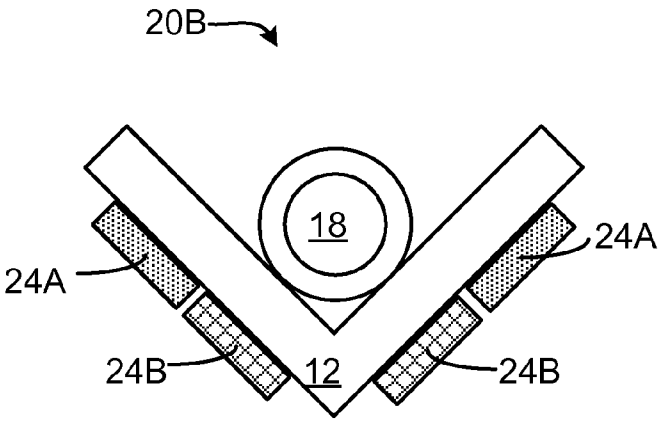


Fig. 3A

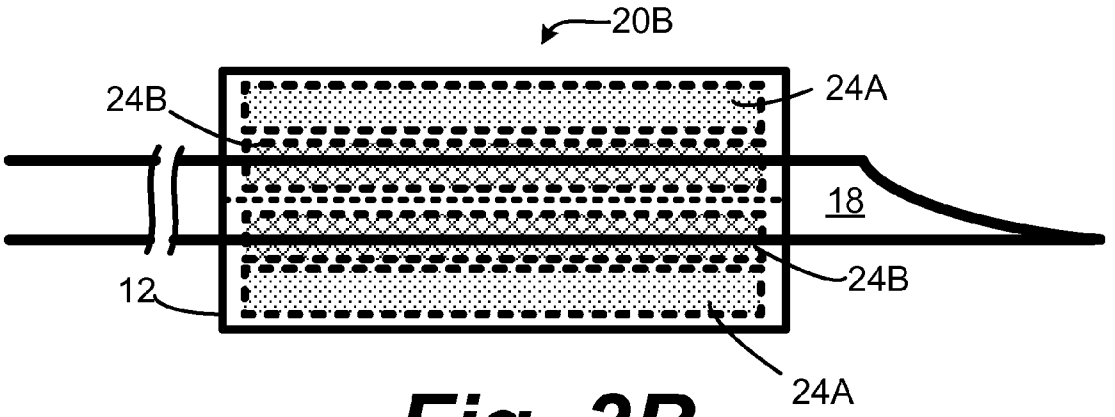


Fig. 3B

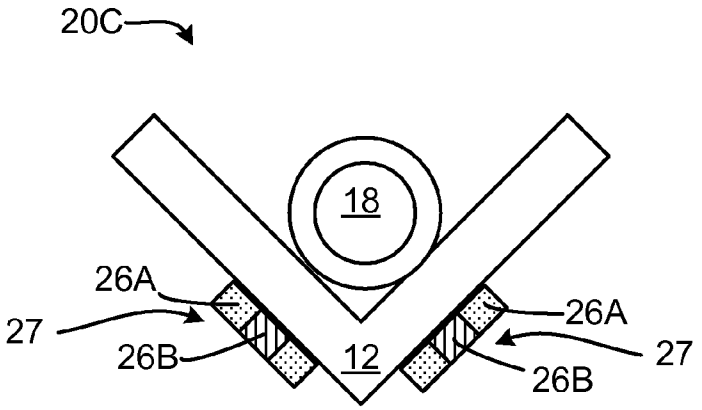


Fig. 4A

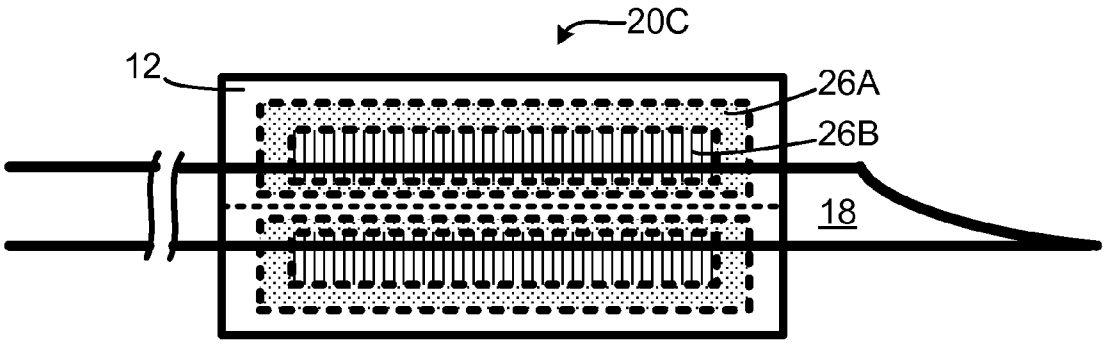


Fig. 4B

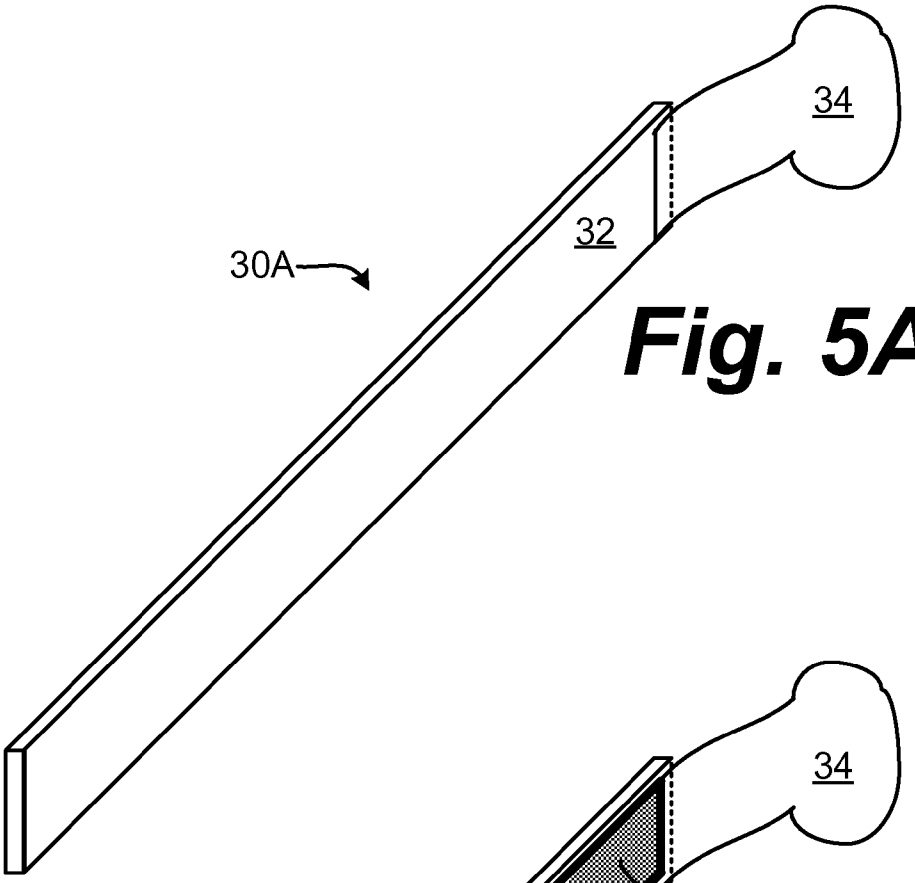


Fig. 5A

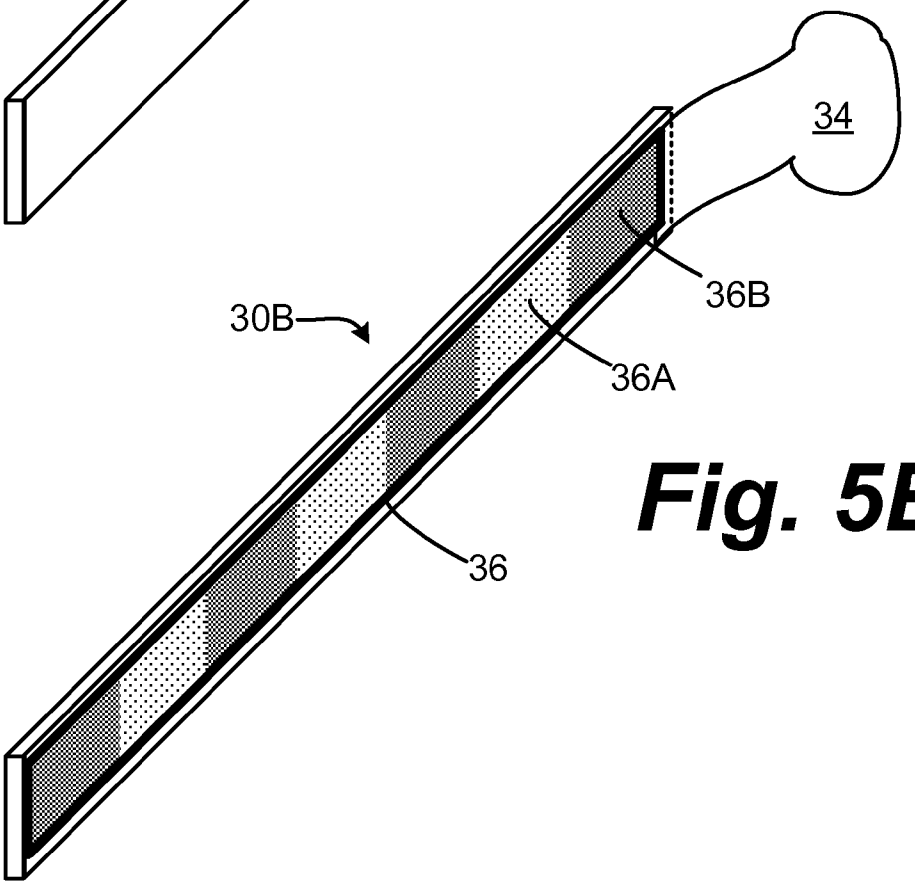


Fig. 5B

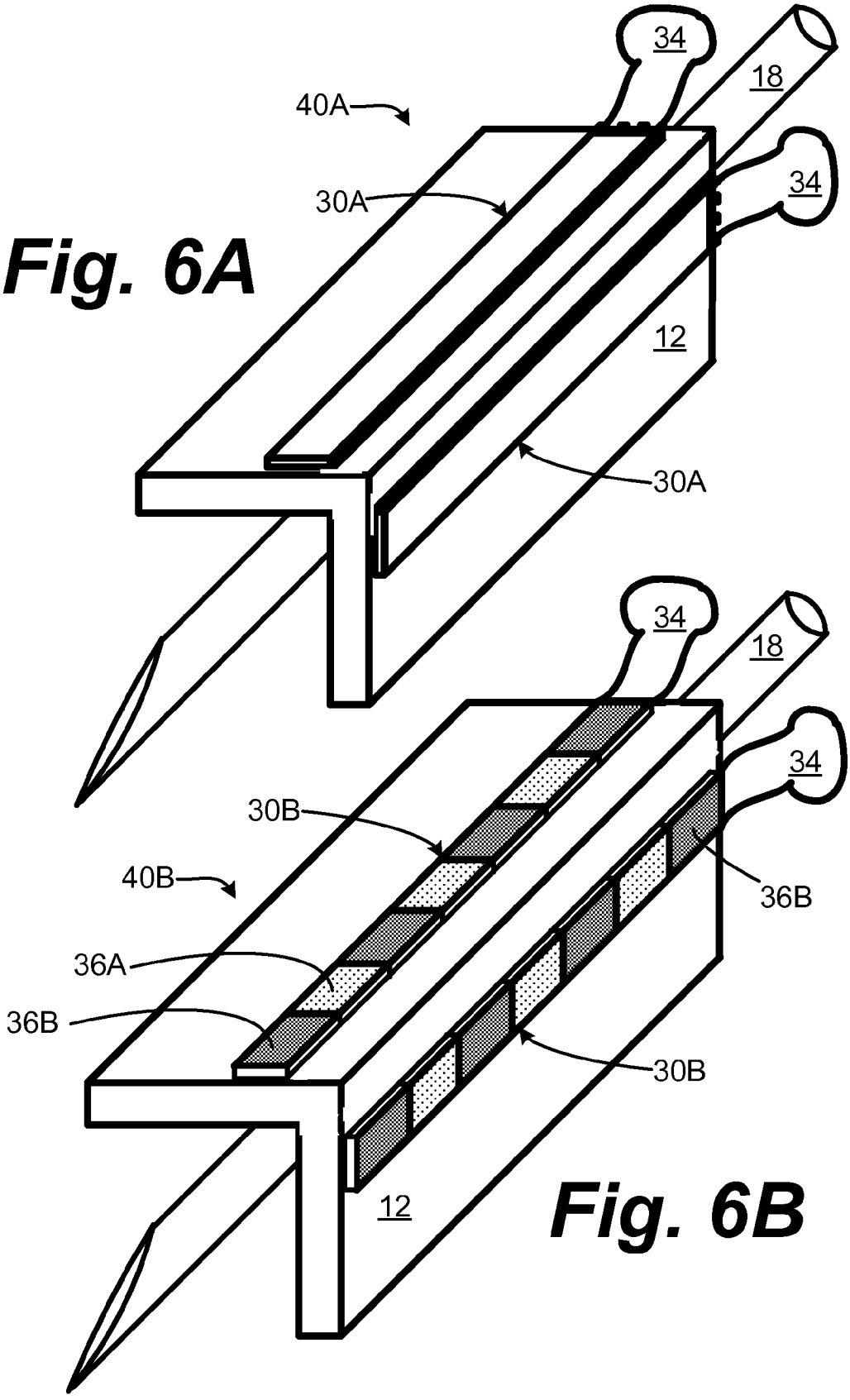


Fig. 6A

Fig. 6B

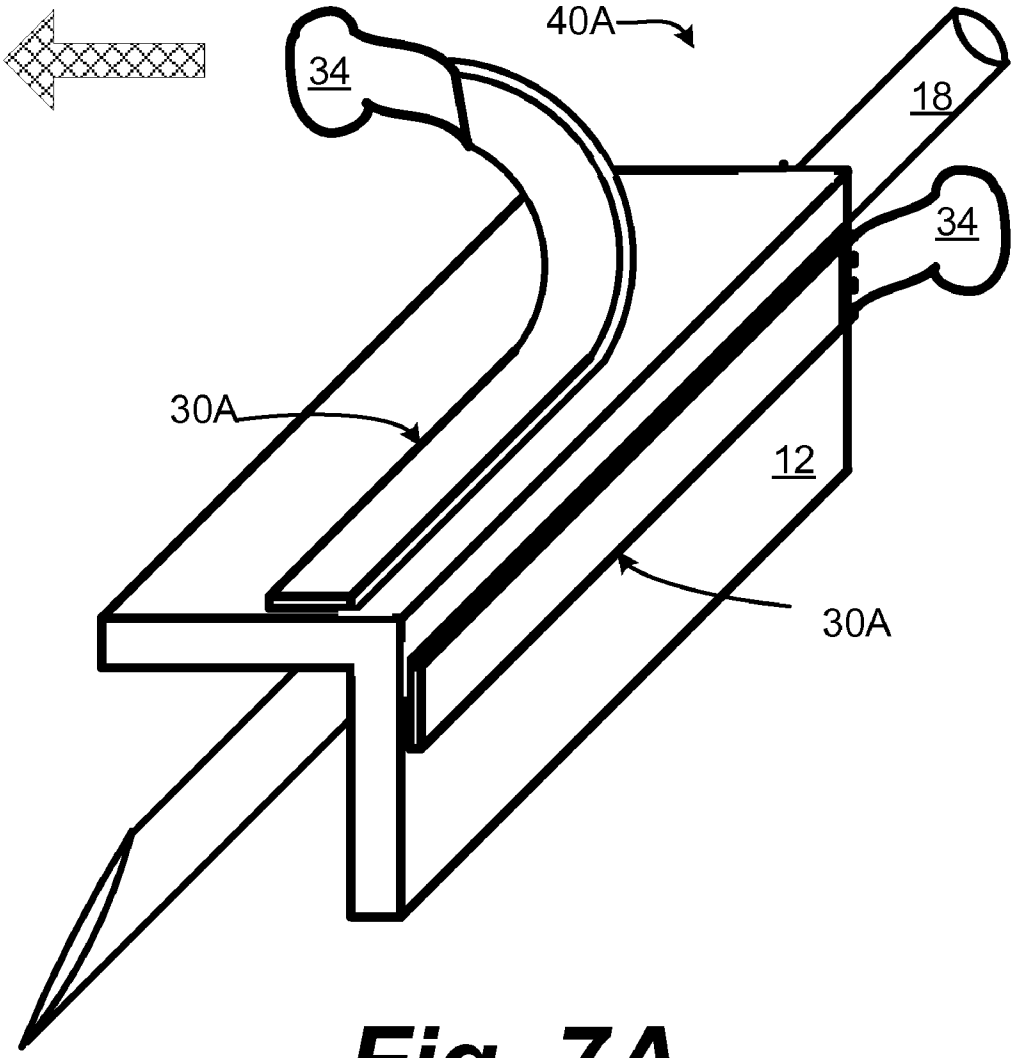


Fig. 7A

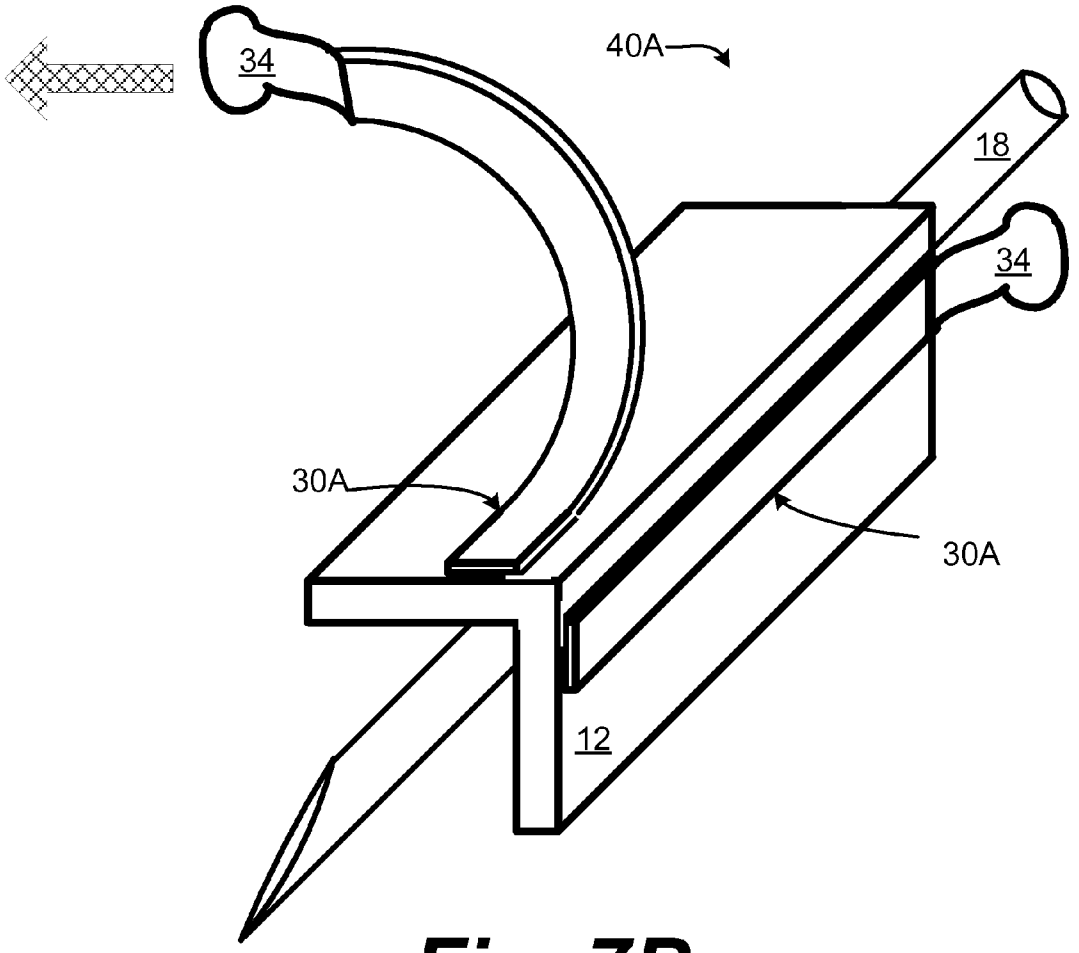


Fig. 7B

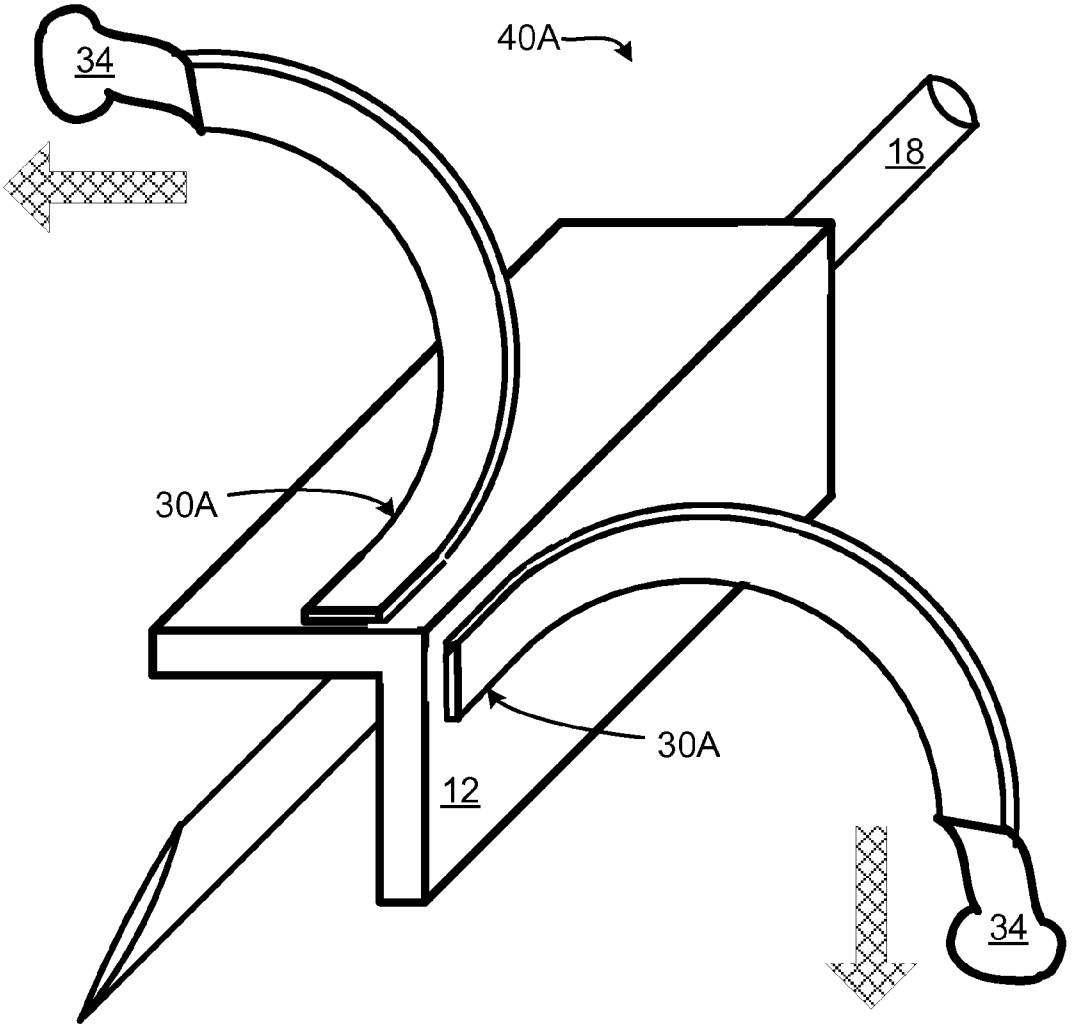


Fig. 7C

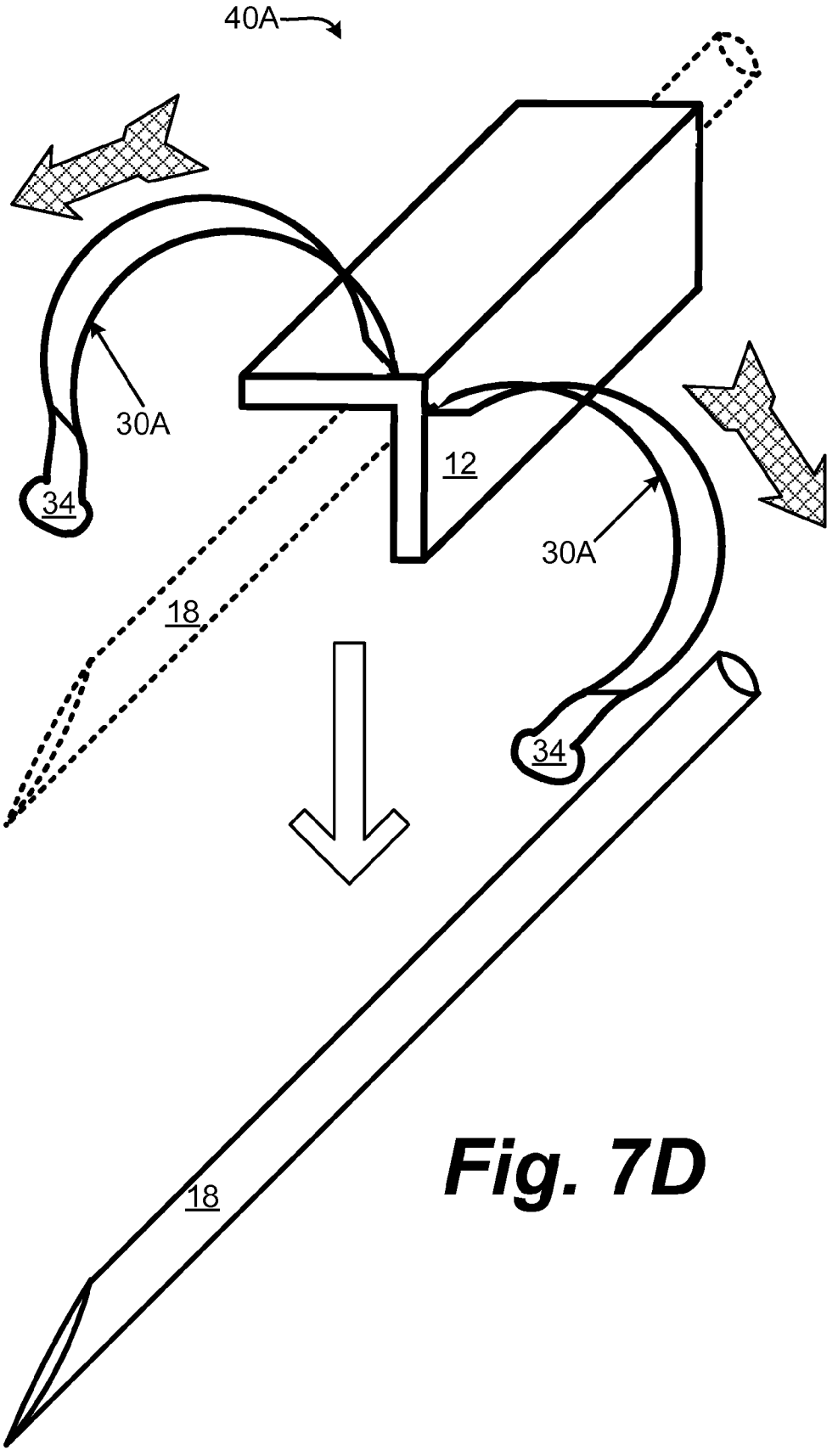


Fig. 7D

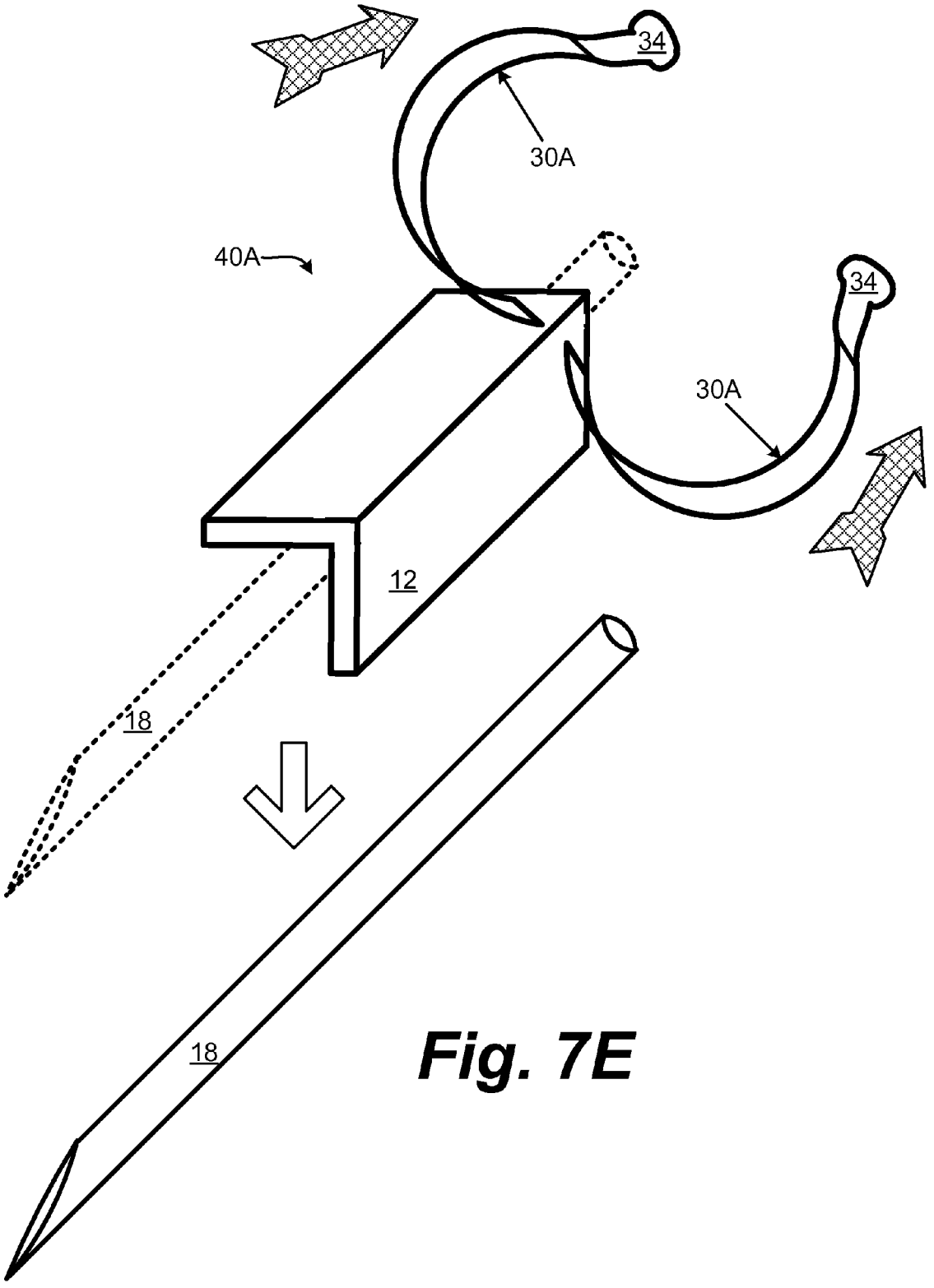


Fig. 7E

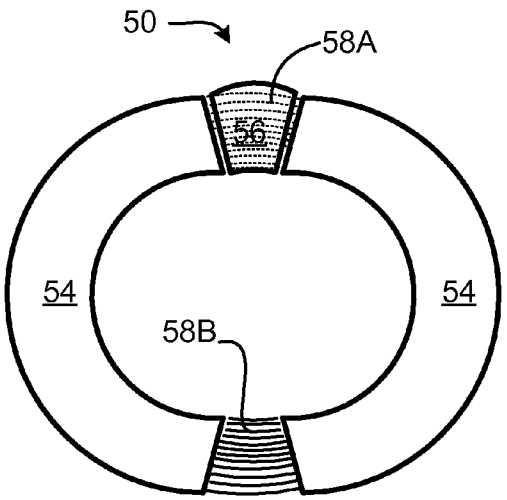


Fig. 8A

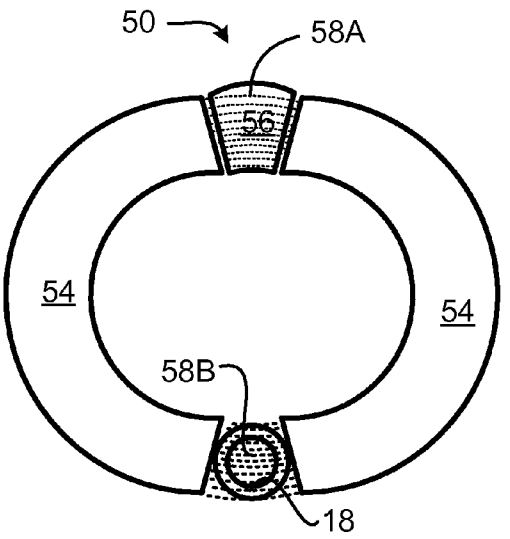


Fig. 8B

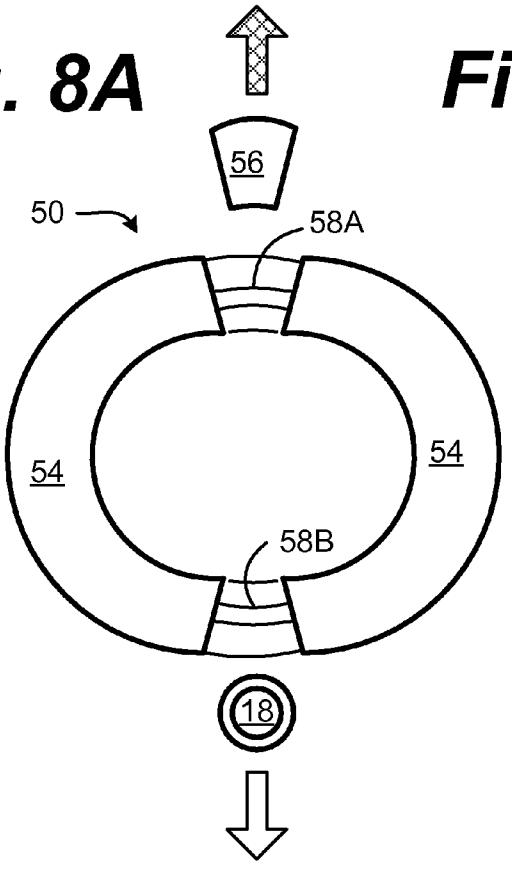


Fig. 8C

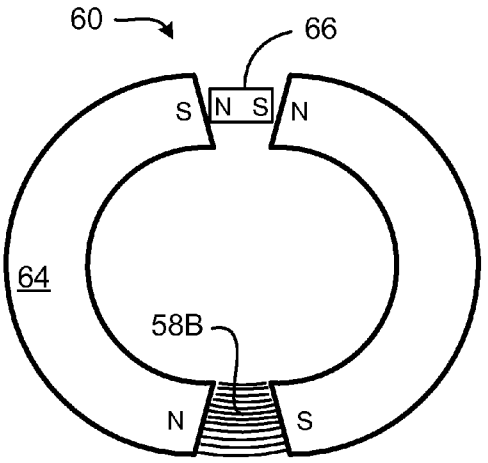


Fig. 9A

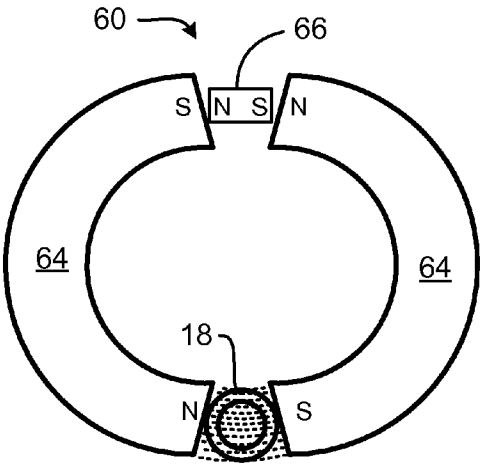


Fig. 9B

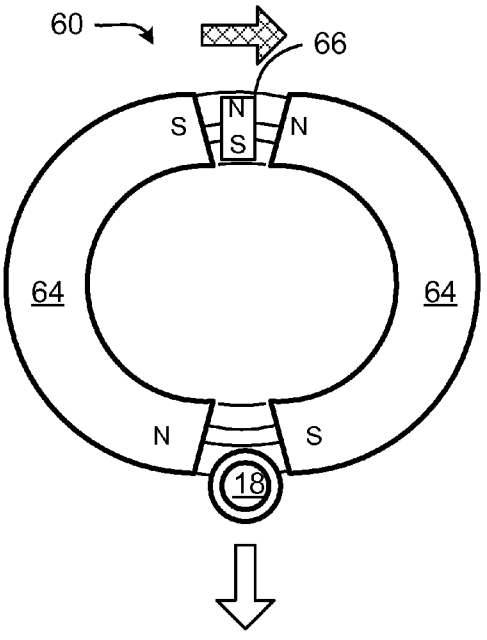


Fig. 9C

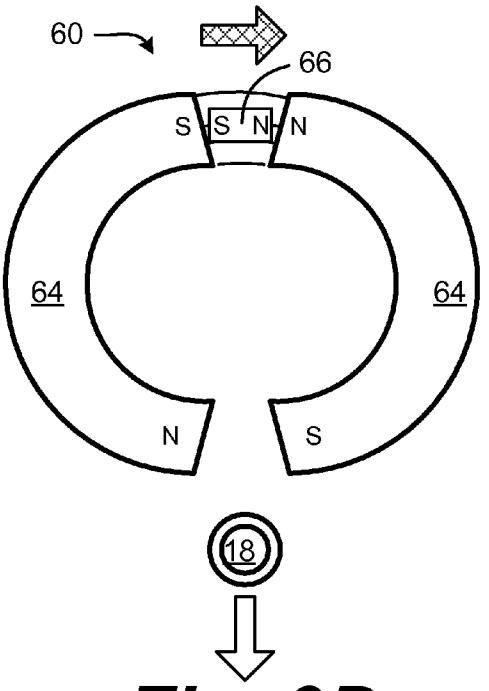


Fig. 9D

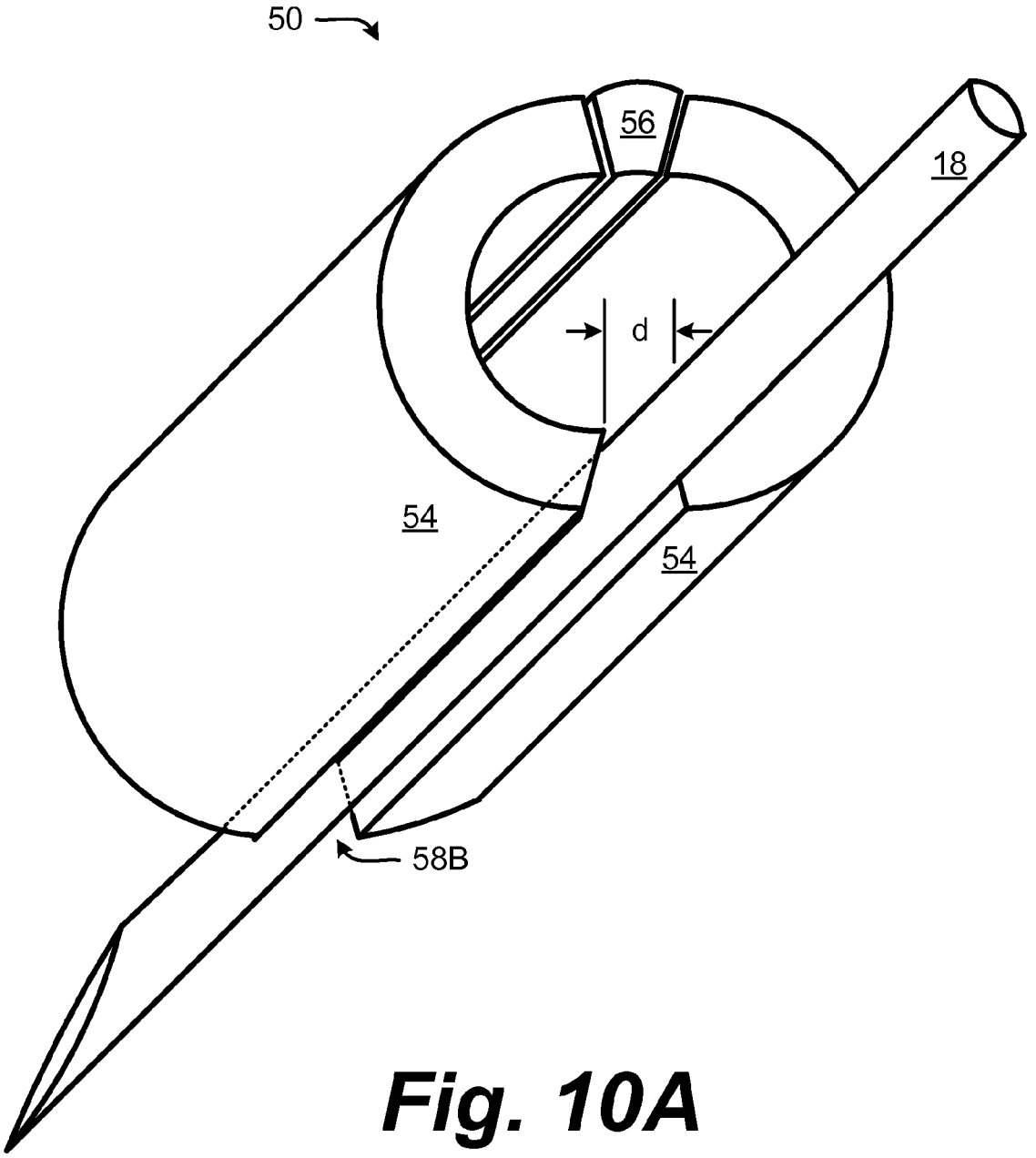


Fig. 10A

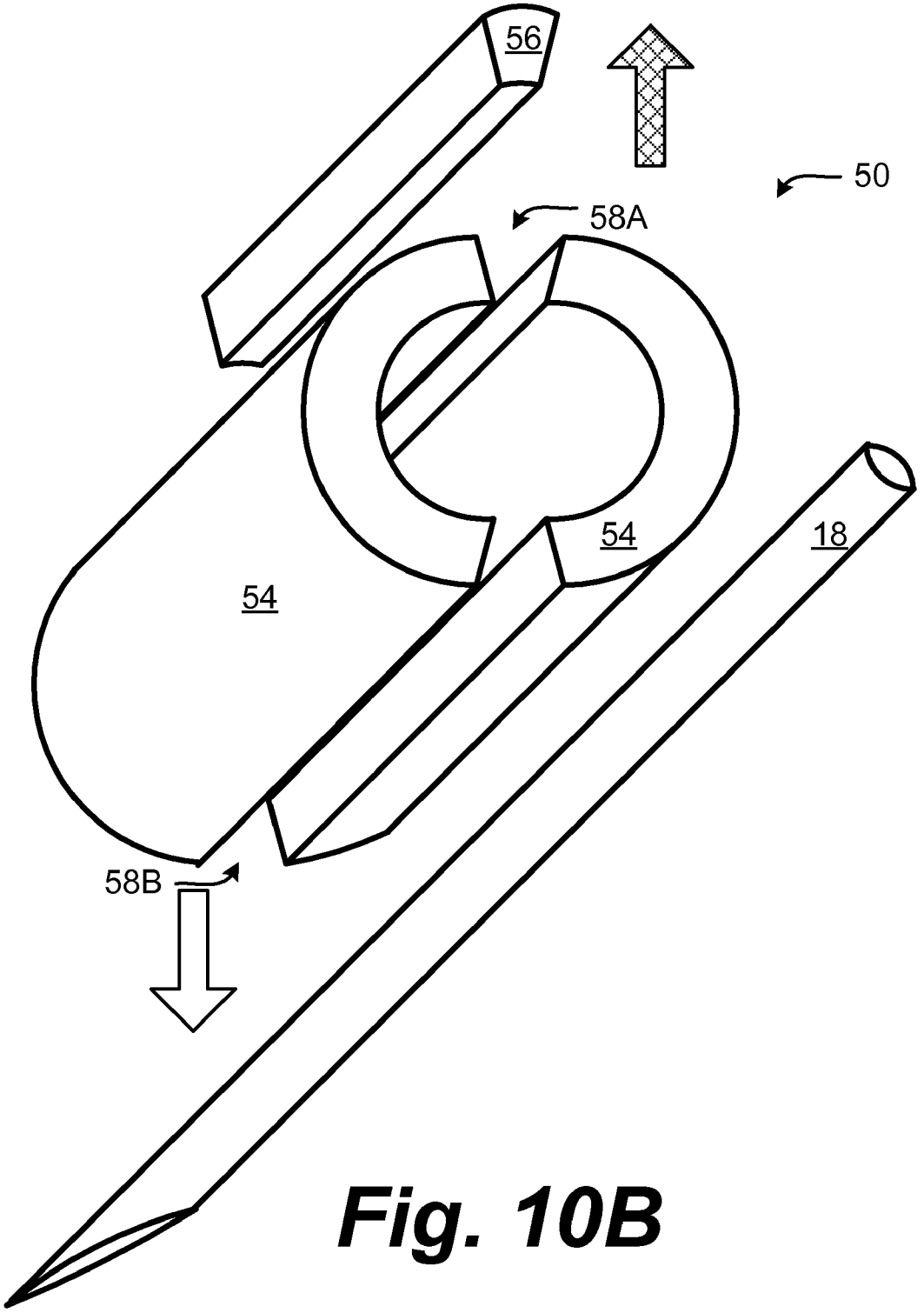


Fig. 10B

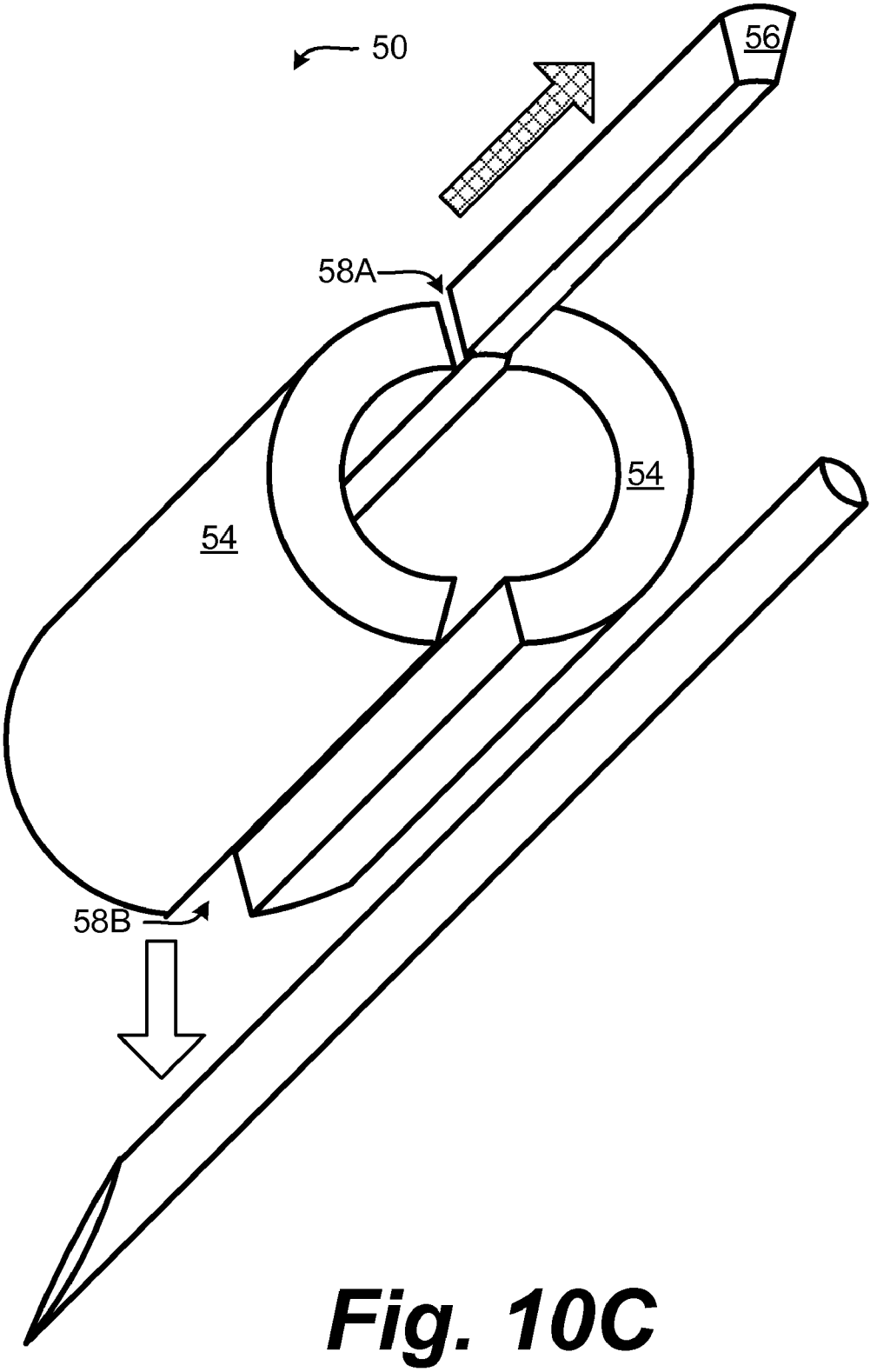


Fig. 10C

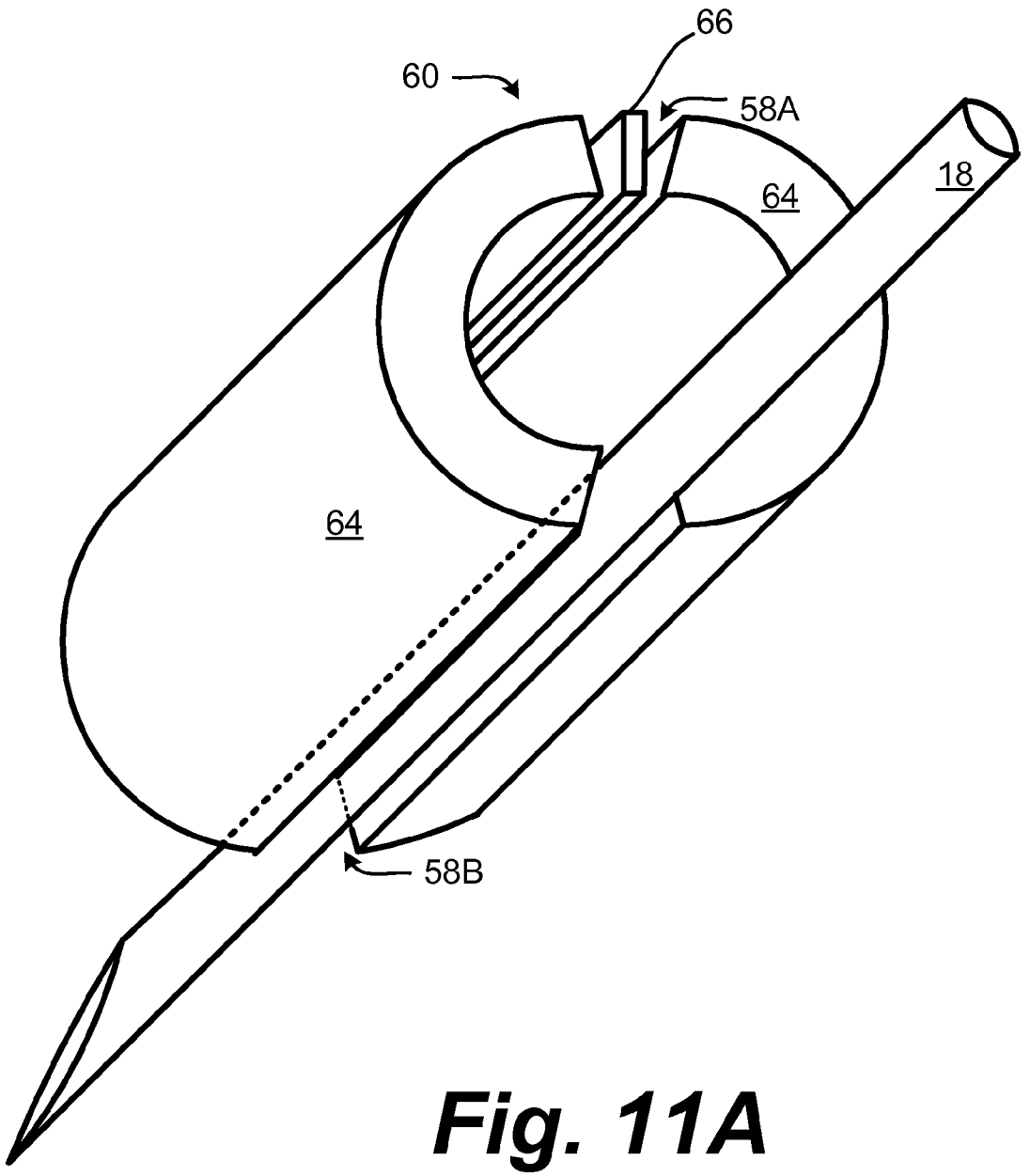


Fig. 11A

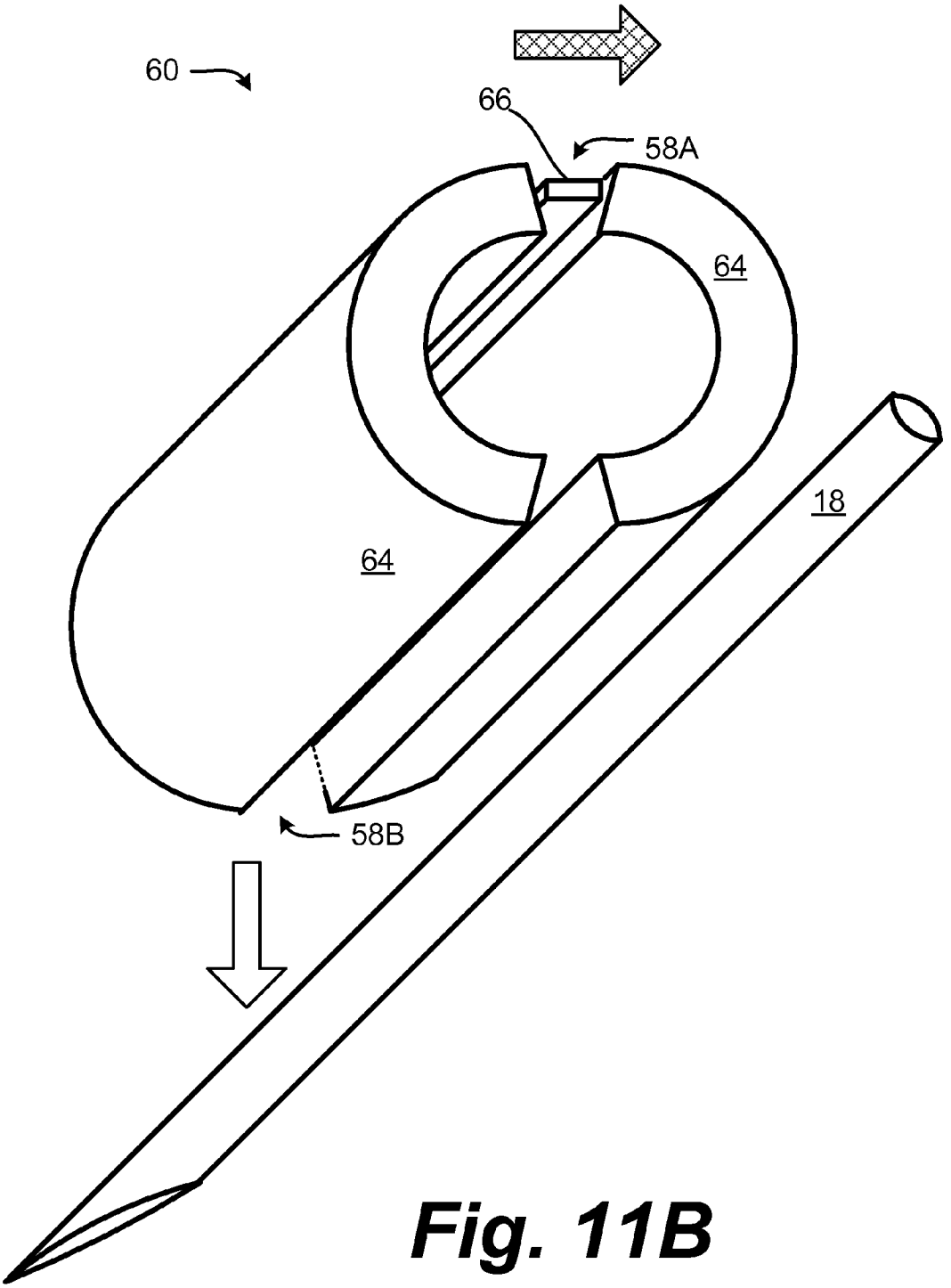


Fig. 11B

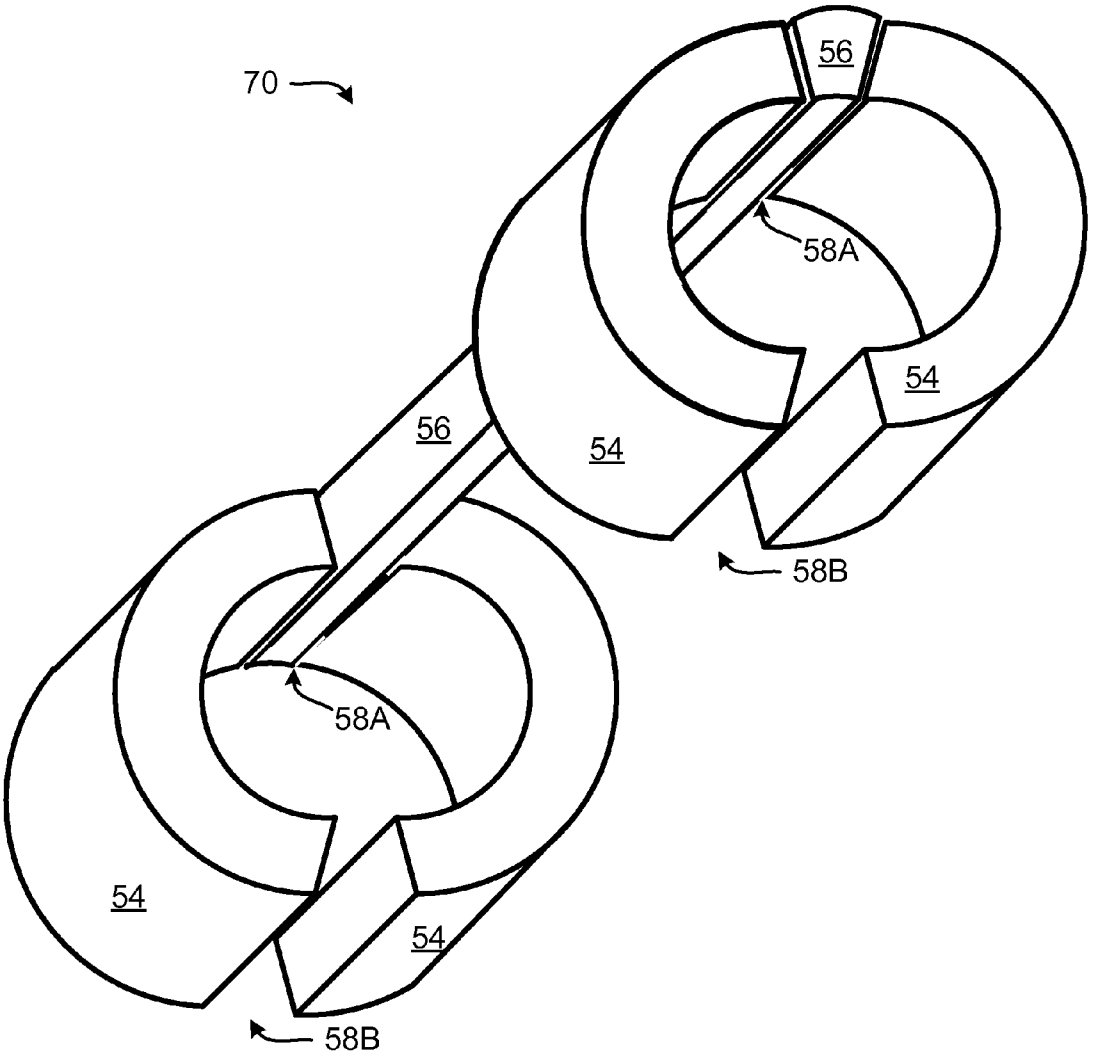


Fig. 12A

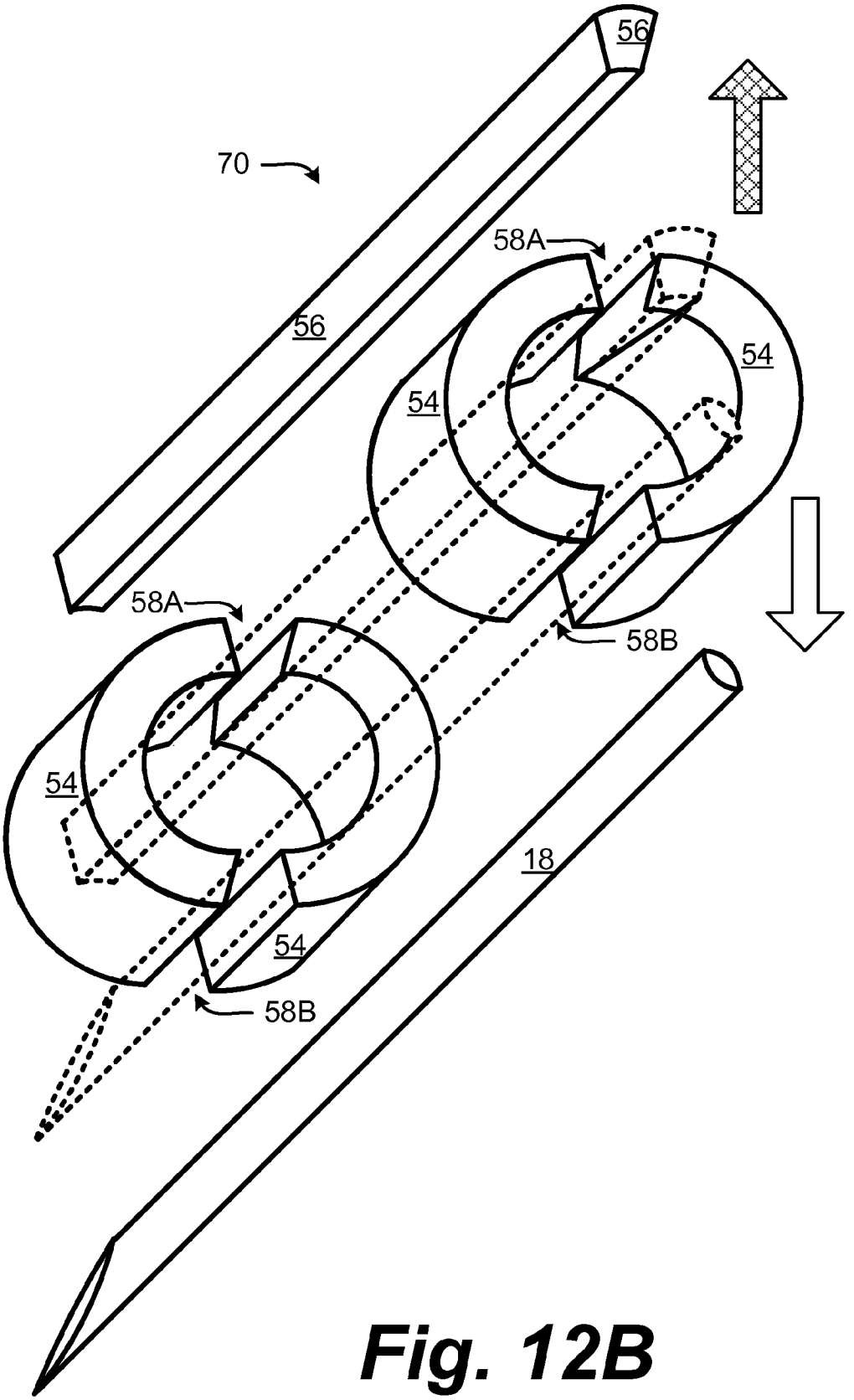


Fig. 12B

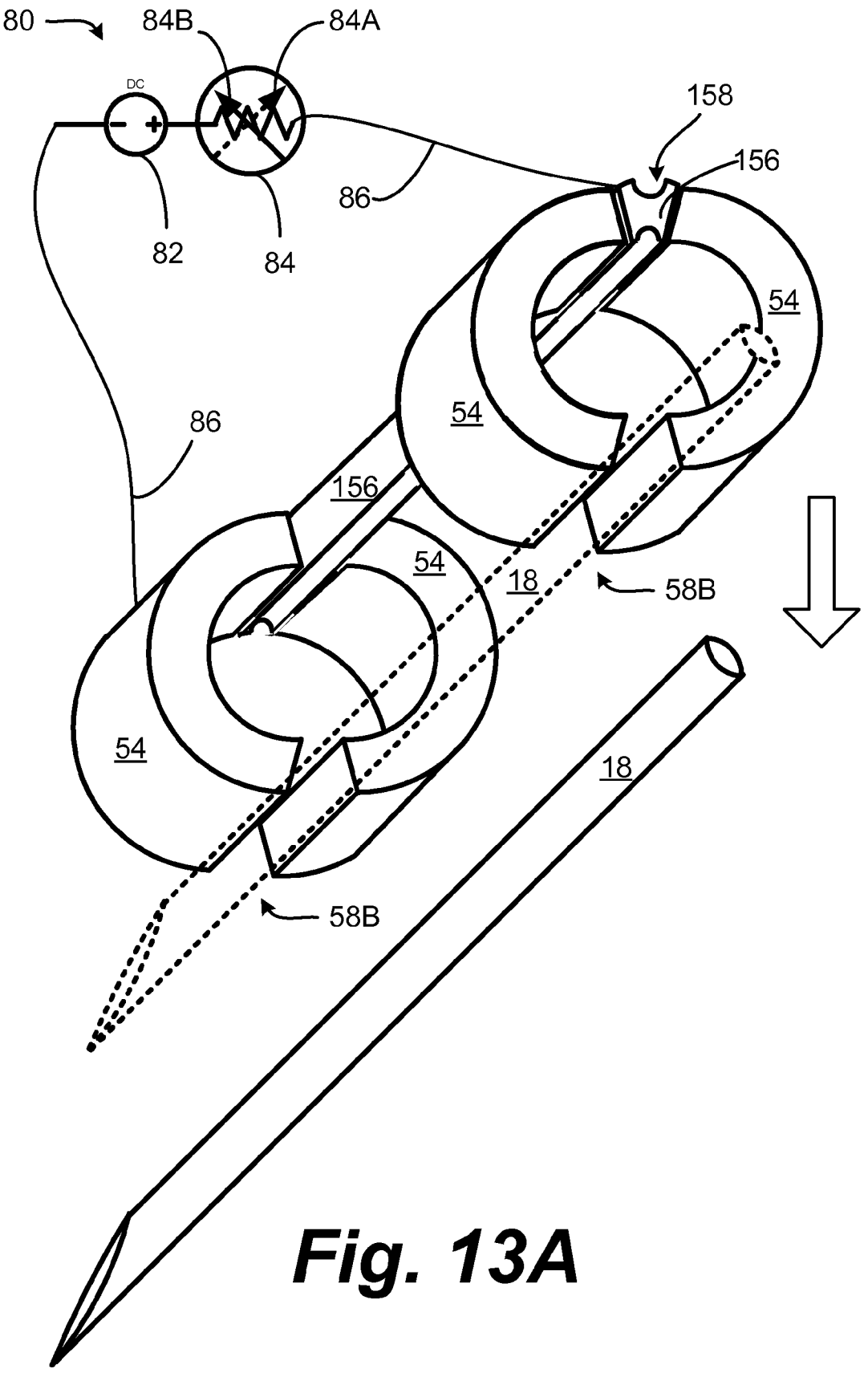


Fig. 13A

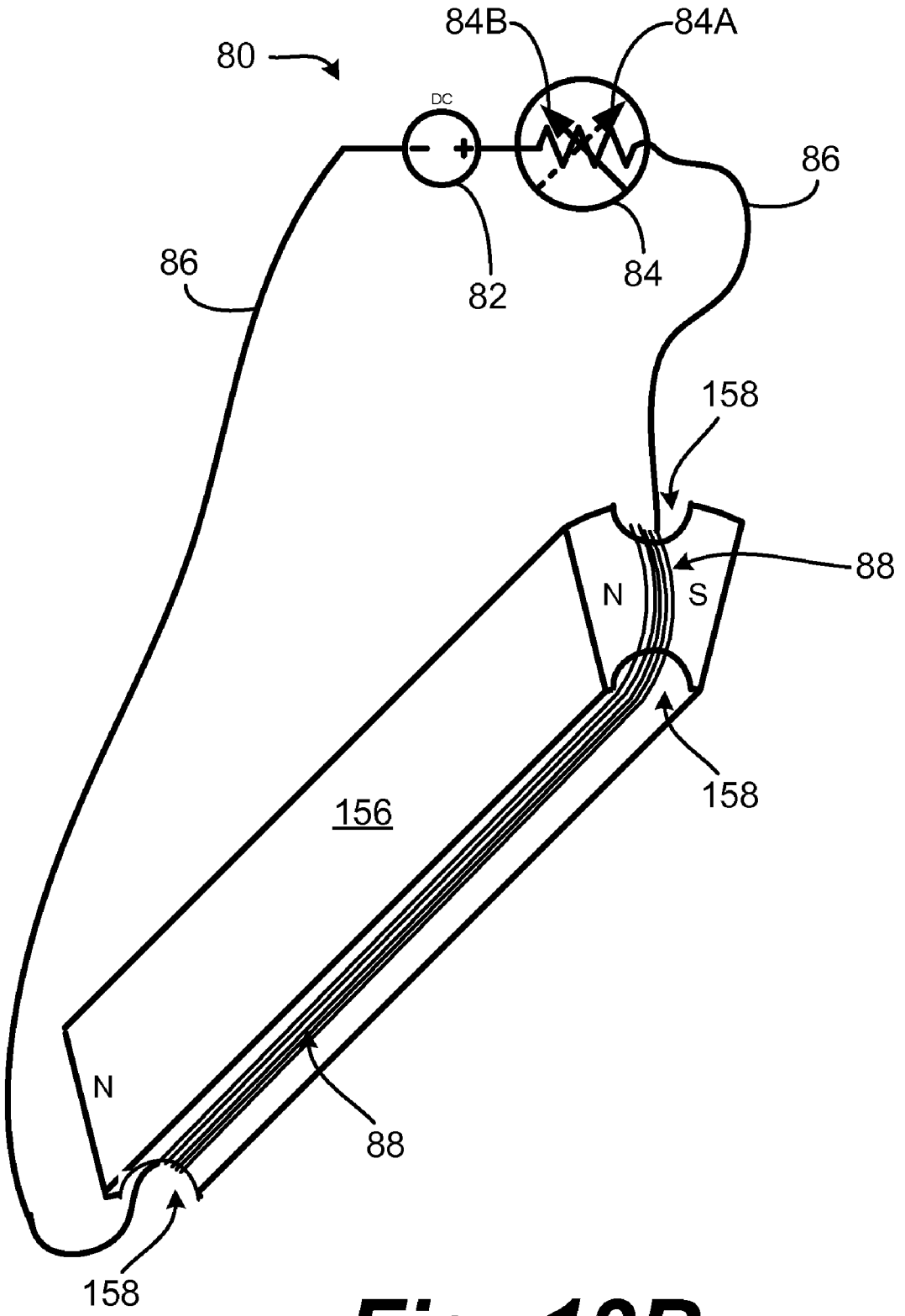


Fig. 13B

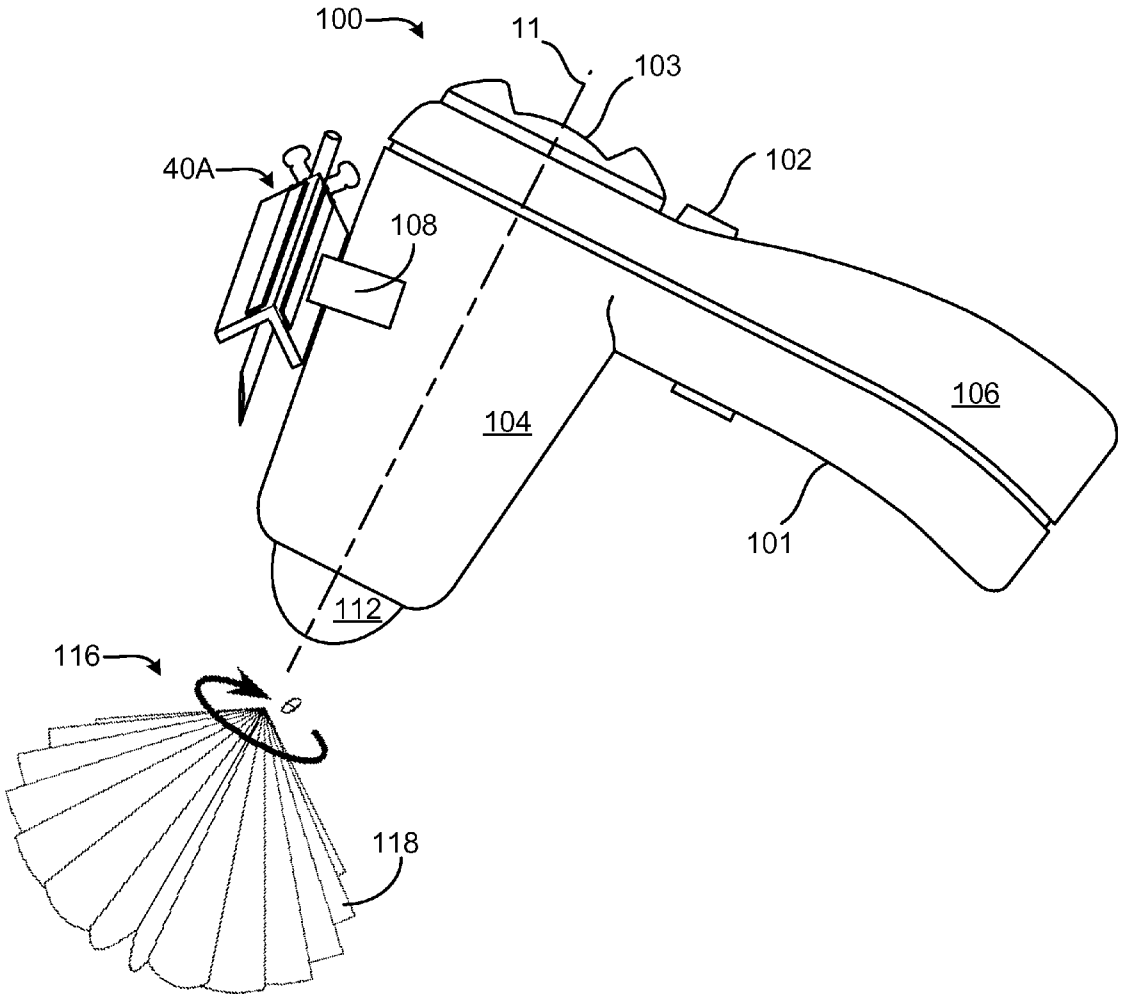


Fig. 14

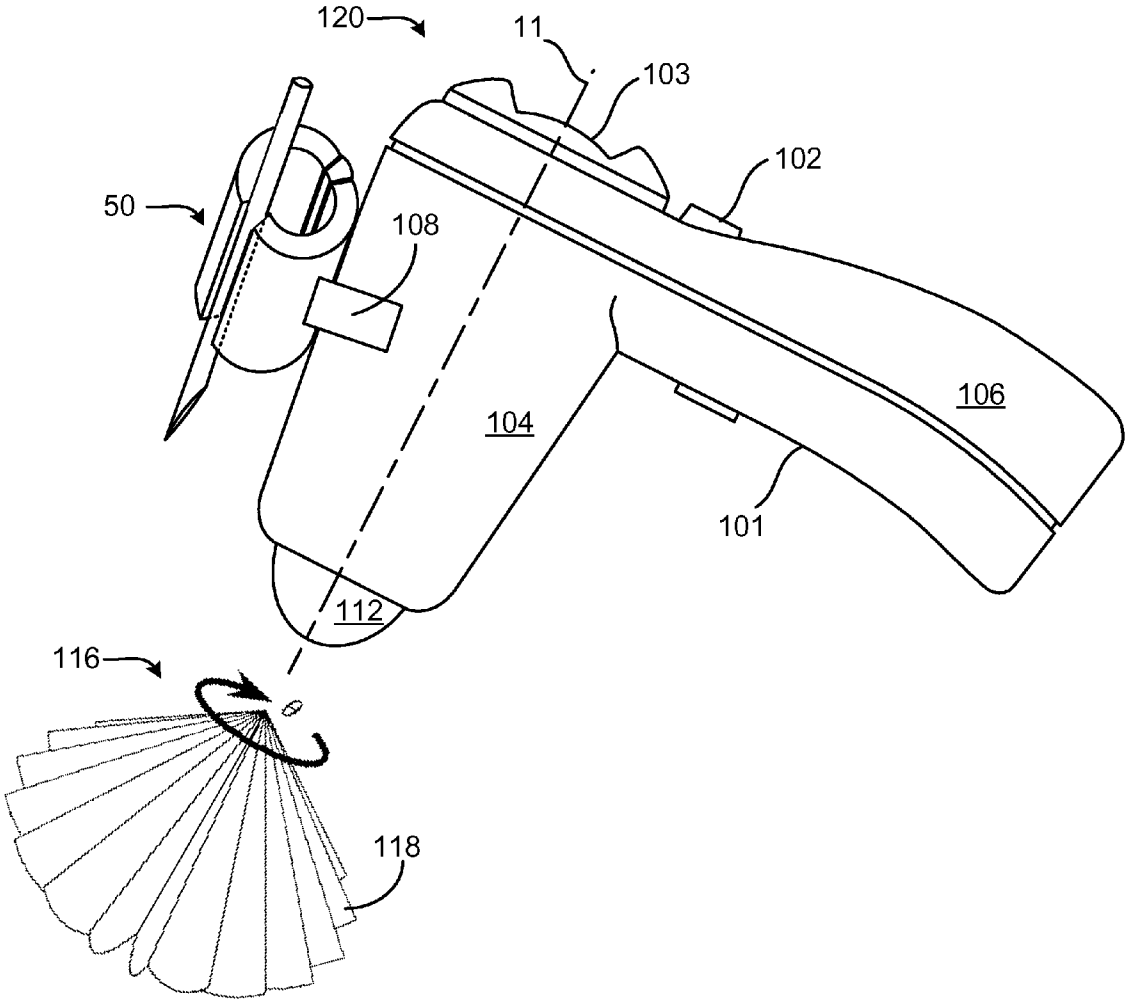


Fig. 15

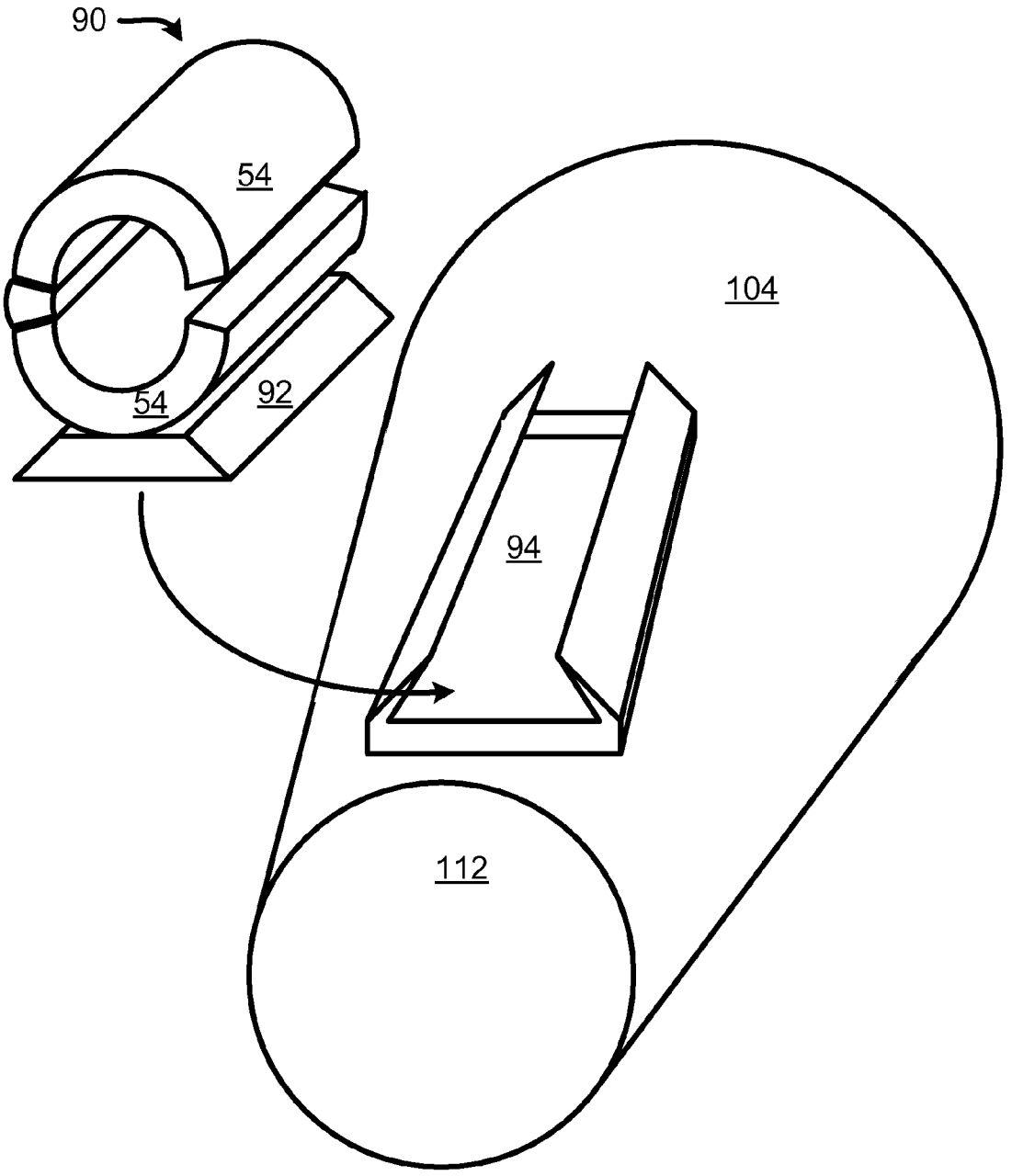


Fig. 16

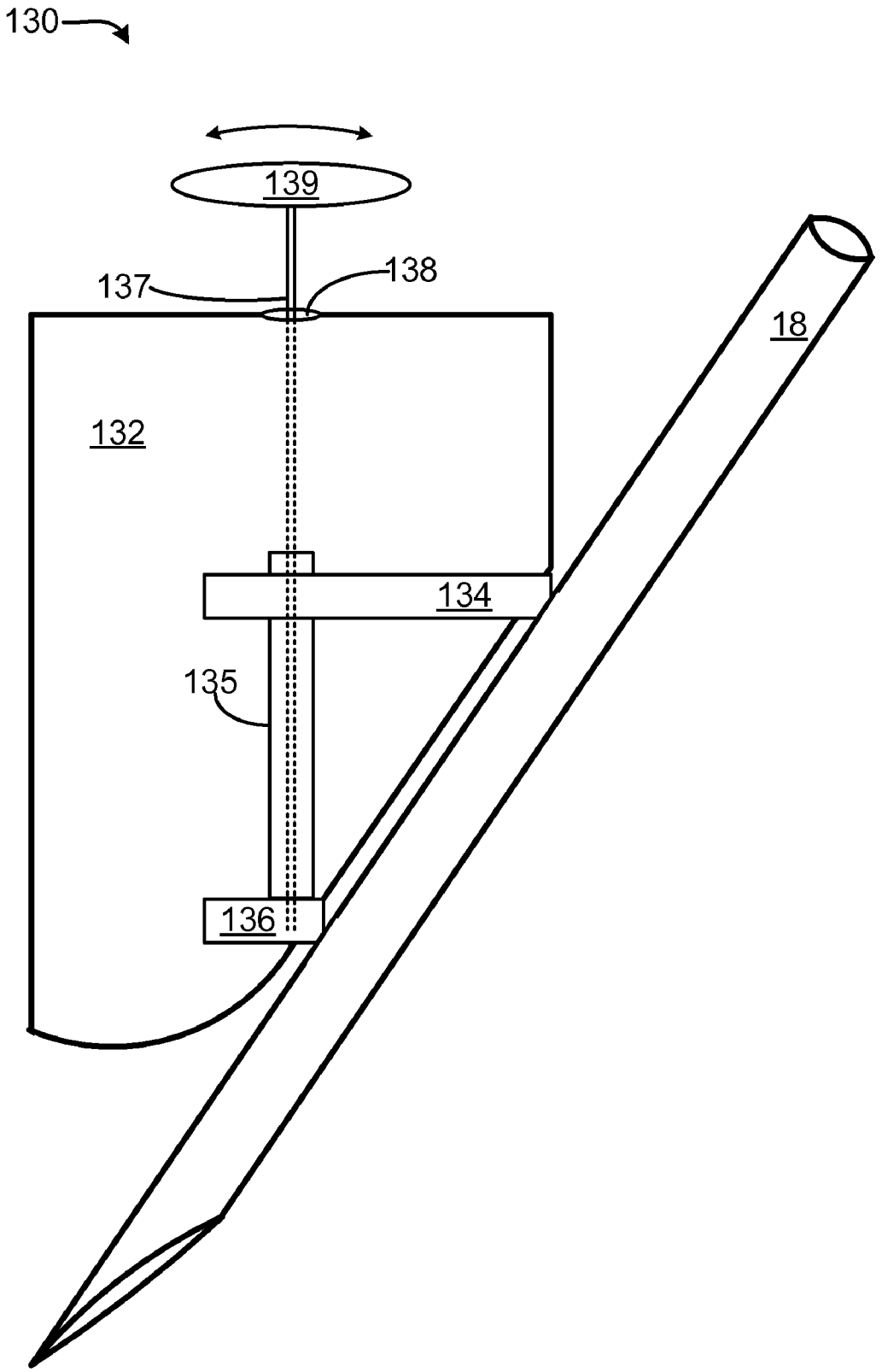


Fig. 17

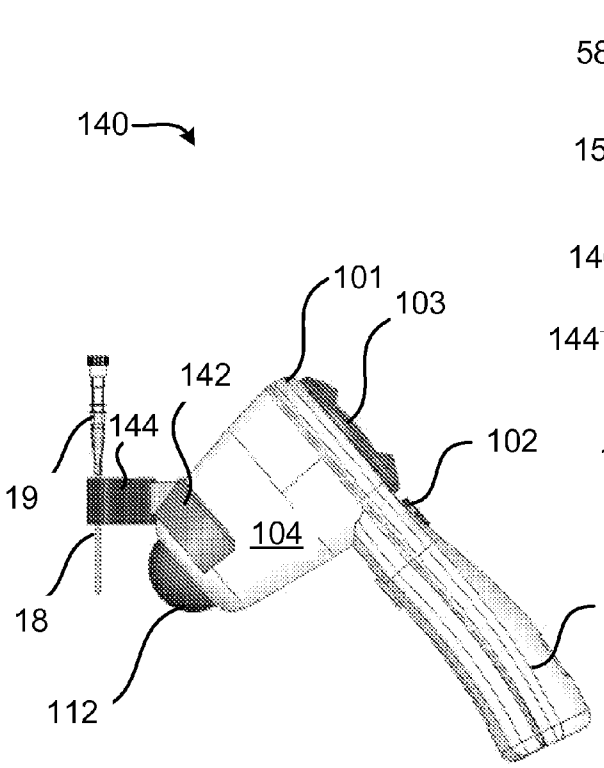


Fig. 18A

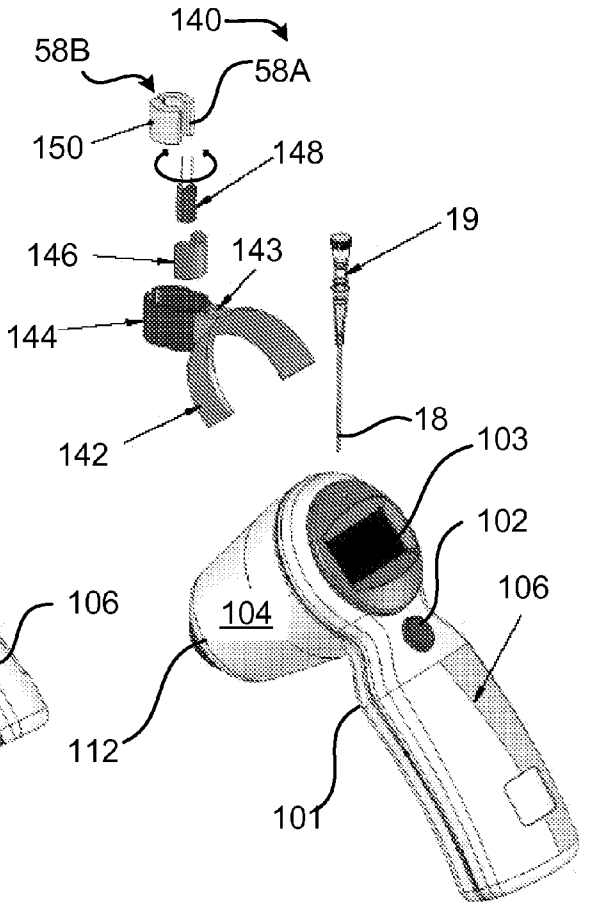


Fig. 18B

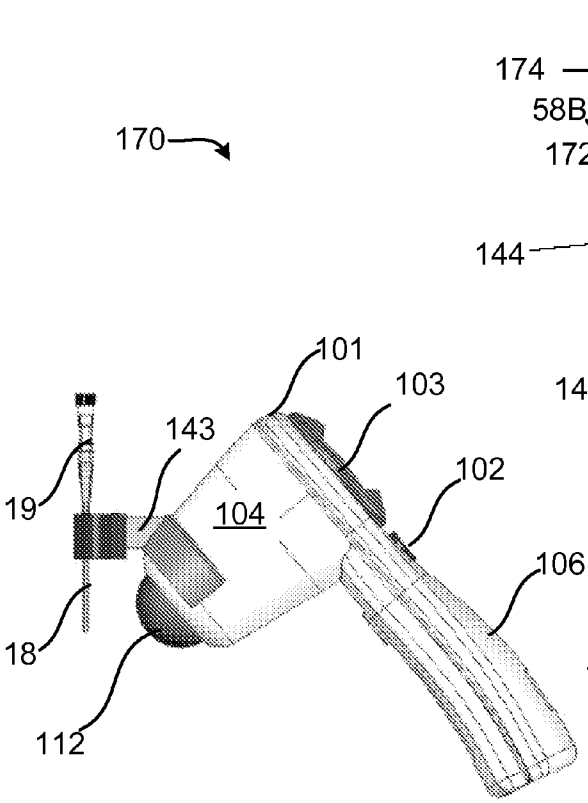


Fig. 19A

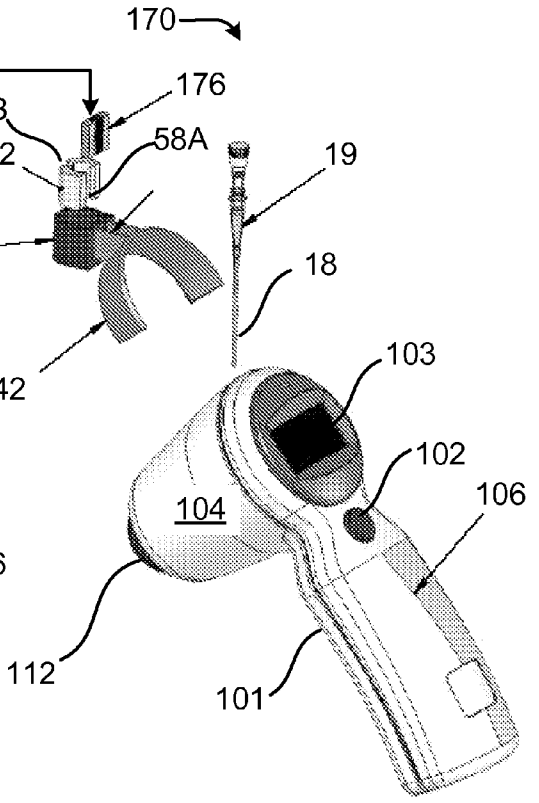


Fig. 19B

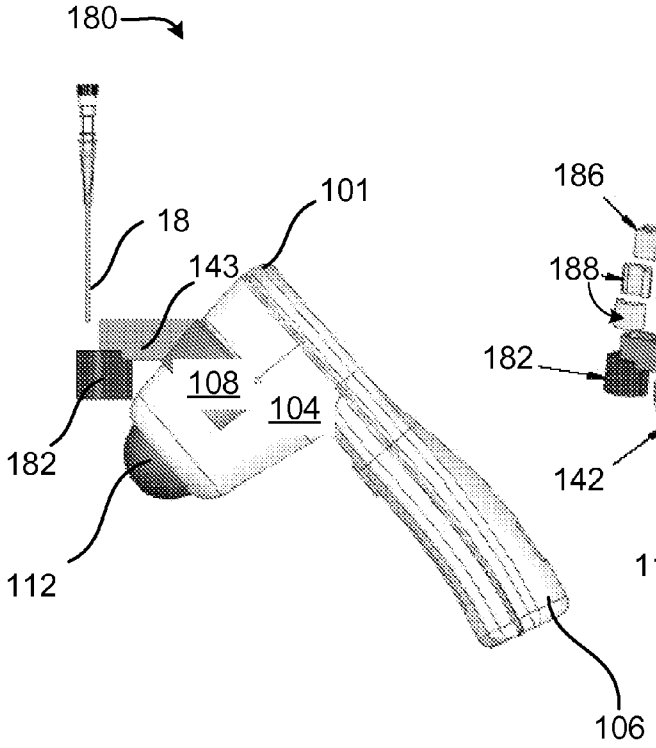


Fig. 20A

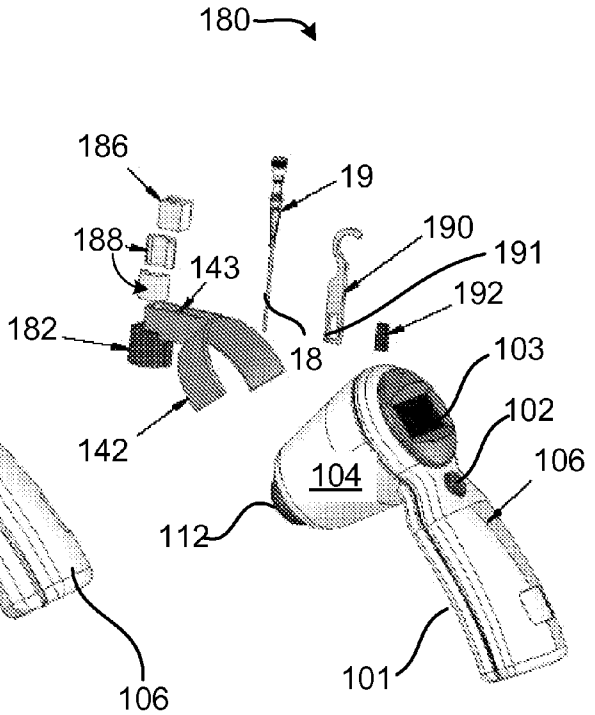


Fig. 20B

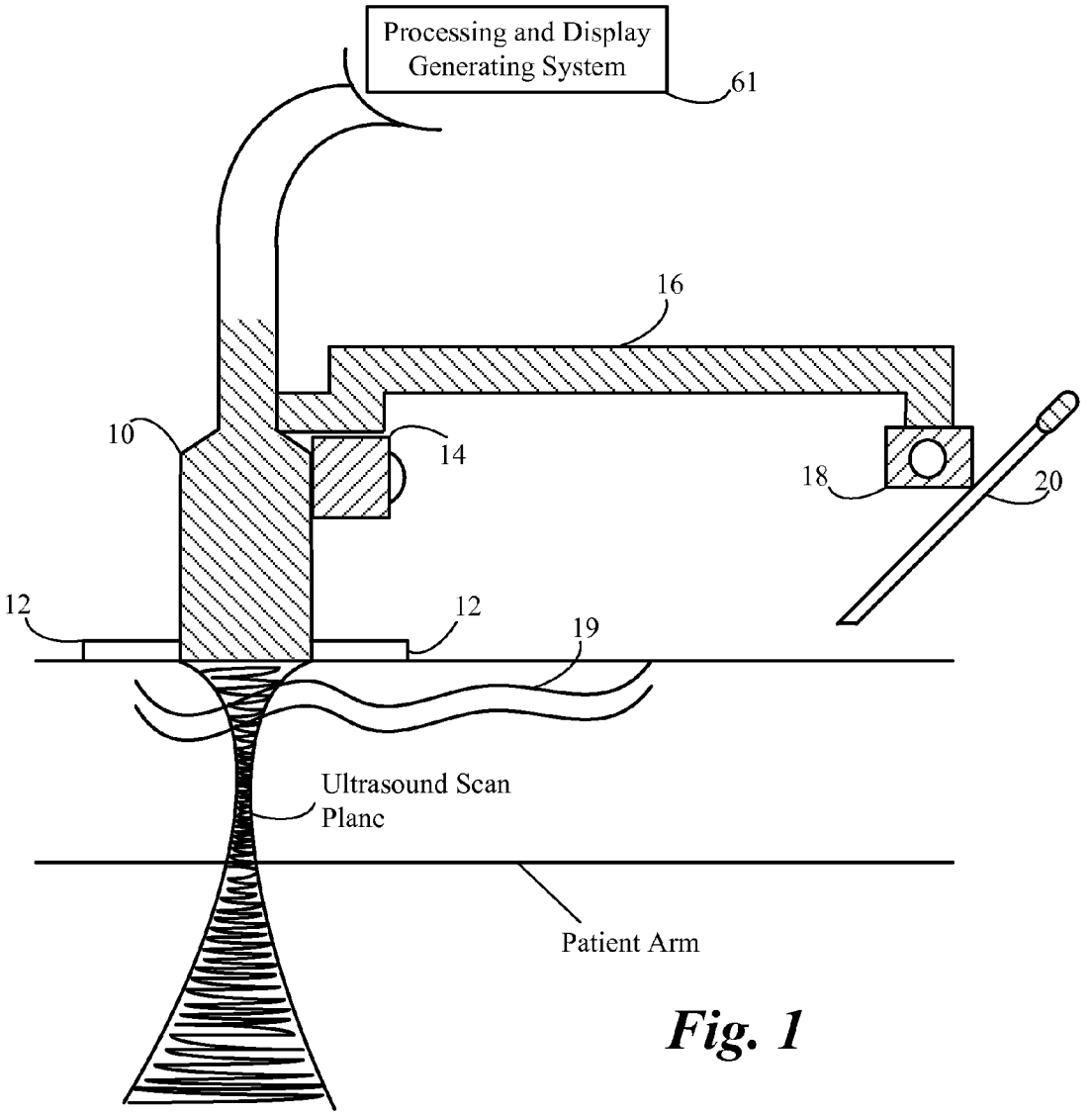

Processing and Display Generating System
61
16
10
14
18
20
12
12
19
Ultrasound Scan Planc
Patient Arm

Fig. 1

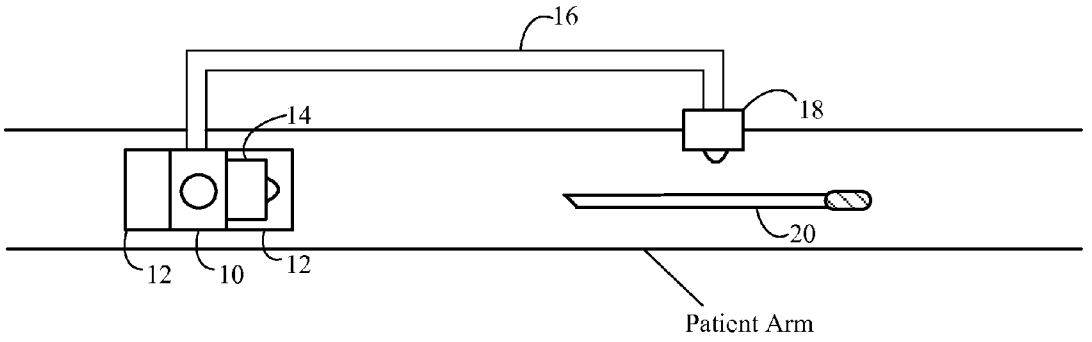


Fig. 2

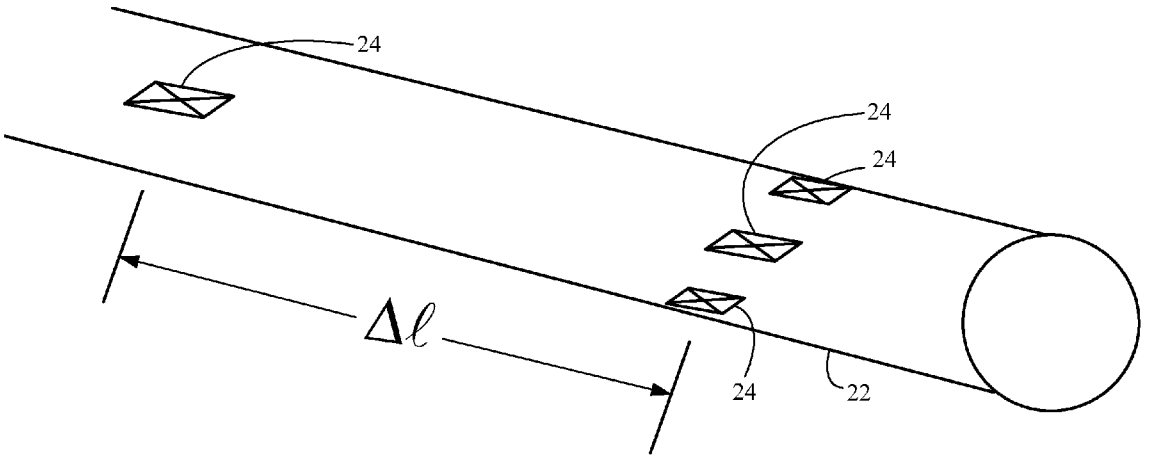


Fig. 3

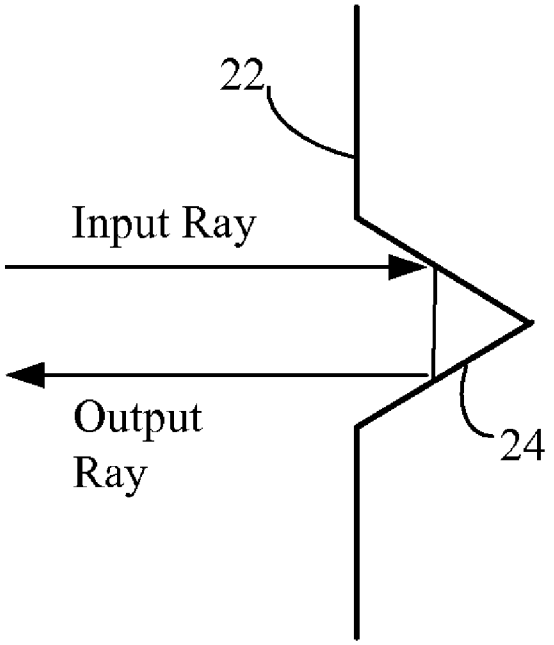


Fig. 4A

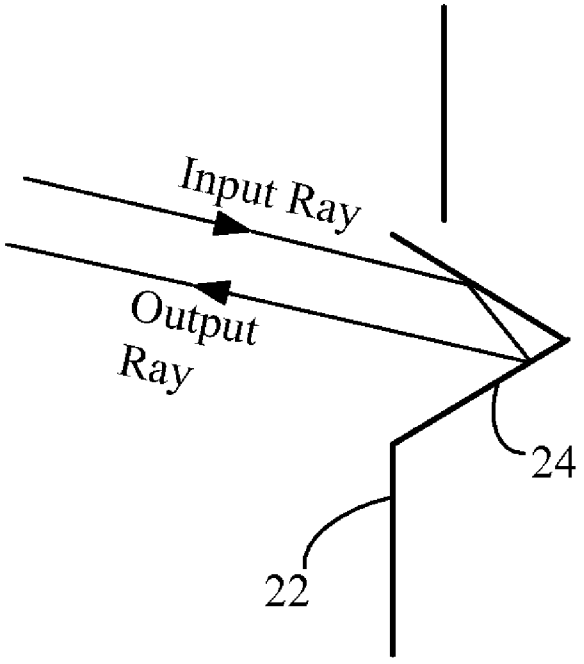


Fig. 4B

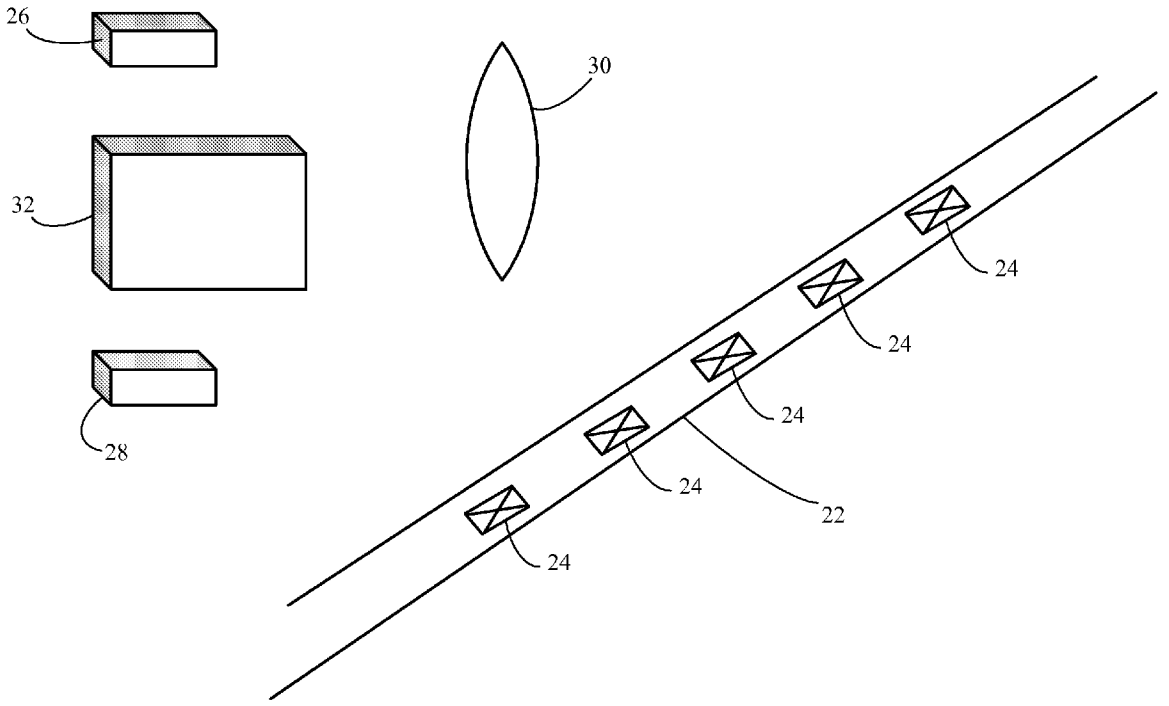


Fig. 5

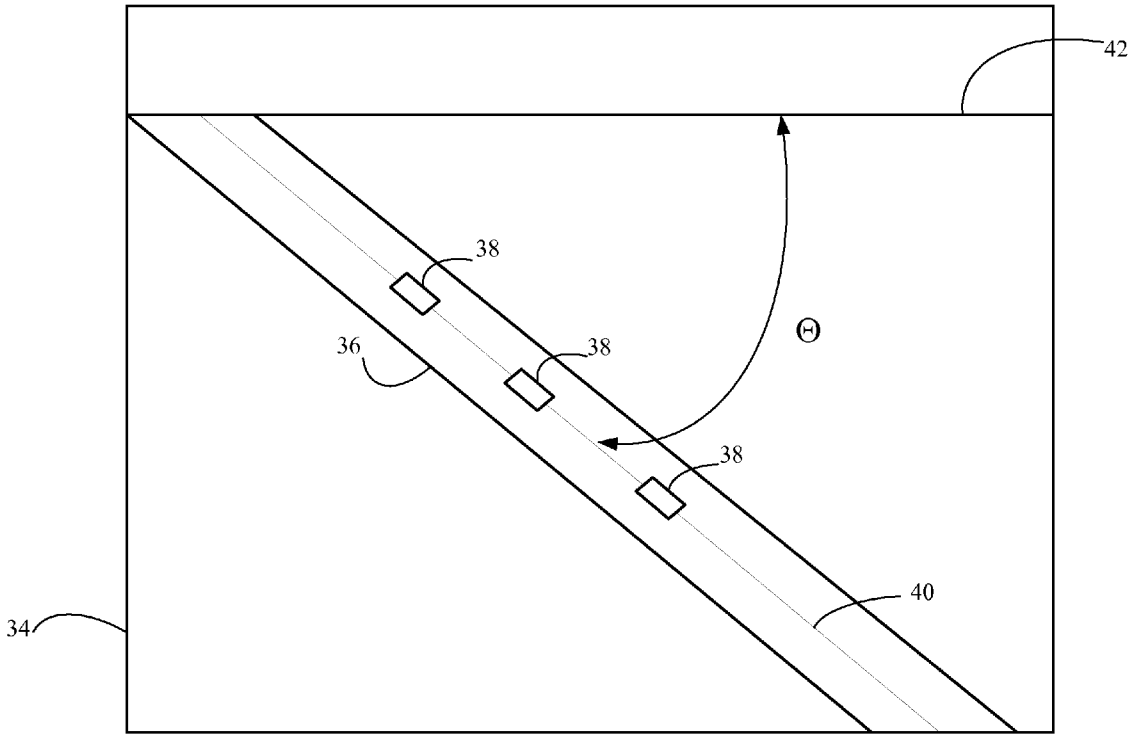


Fig. 6

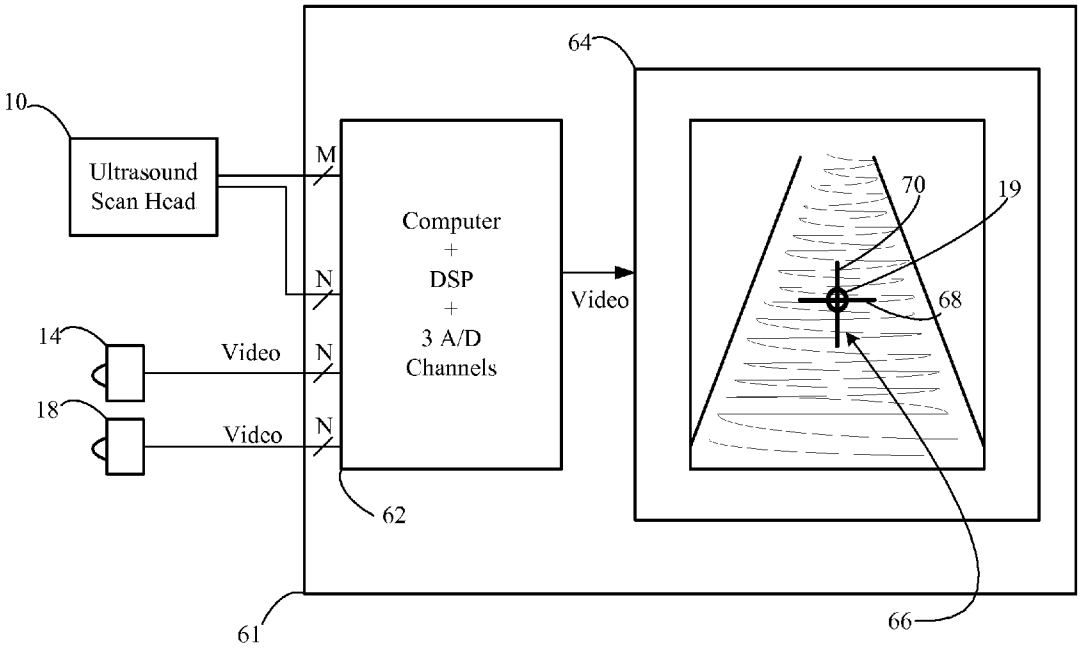

10
Ultrasound
Scan Head
M
N
14
Video
N
18
Video
N
Computer
+
DSP
+
3 A/D
Channels
62
Video
64
70
19
68
66
61

Fig. 7

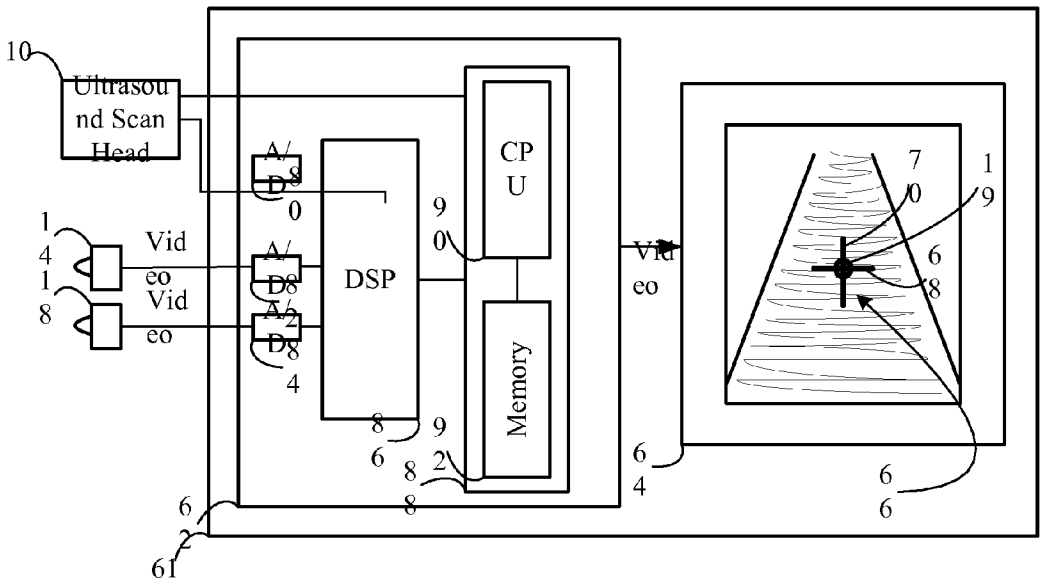

10
Ultrasou
nd Scan
Head
A/
D
DSP
CP
U
Memory
Vid
eo
Vid
eo
Vid
eo
DSP
Memory

Fig. 8

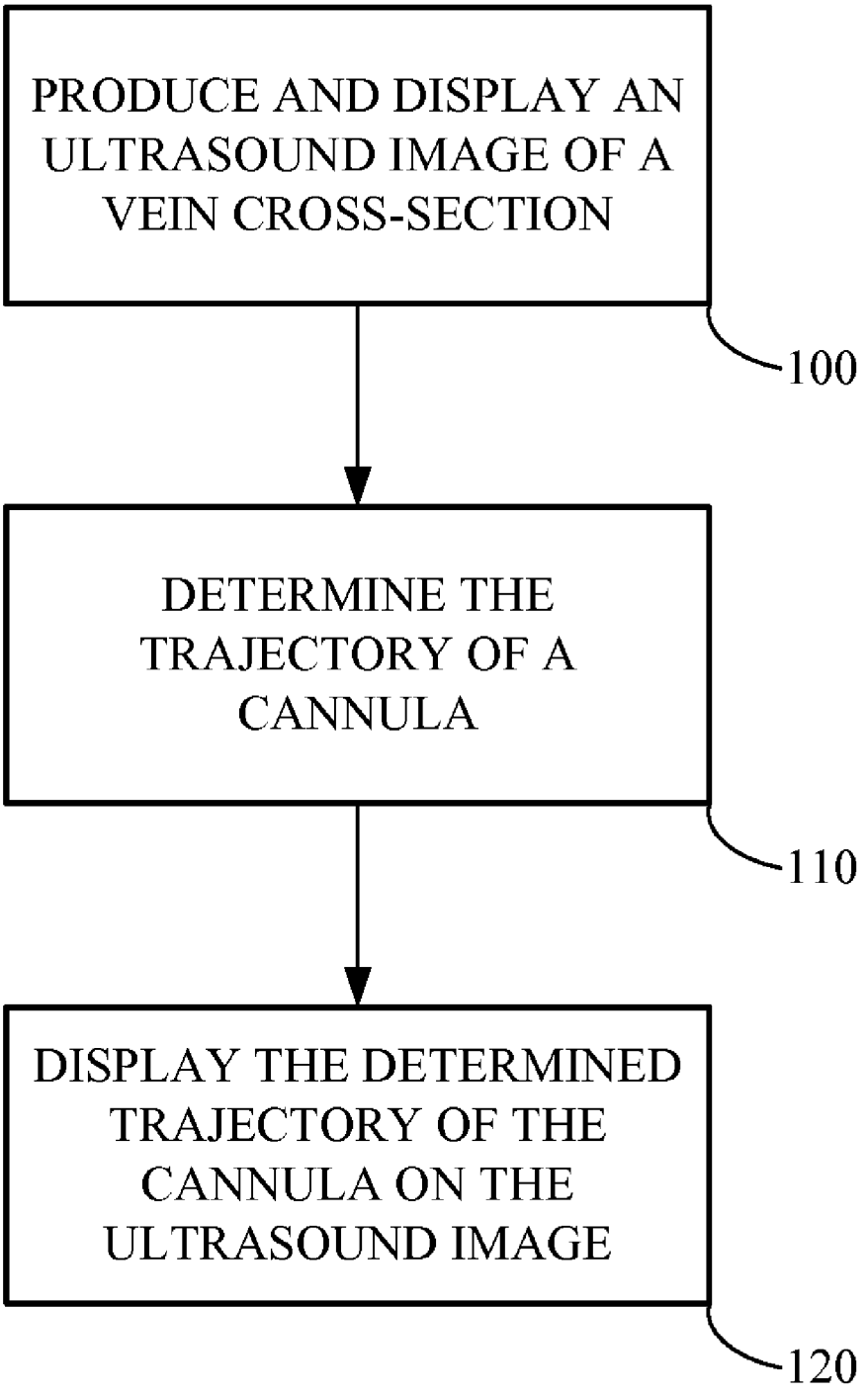

PRODUCE AND DISPLAY AN ULTRASOUND IMAGE OF A VEIN CROSS-SECTION
100
DETERMINE THE TRAJECTORY OF A CANNULA
110
DISPLAY THE DETERMINED TRAJECTORY OF THE CANNULA ON THE ULTRASOUND IMAGE
120

Fig. 9

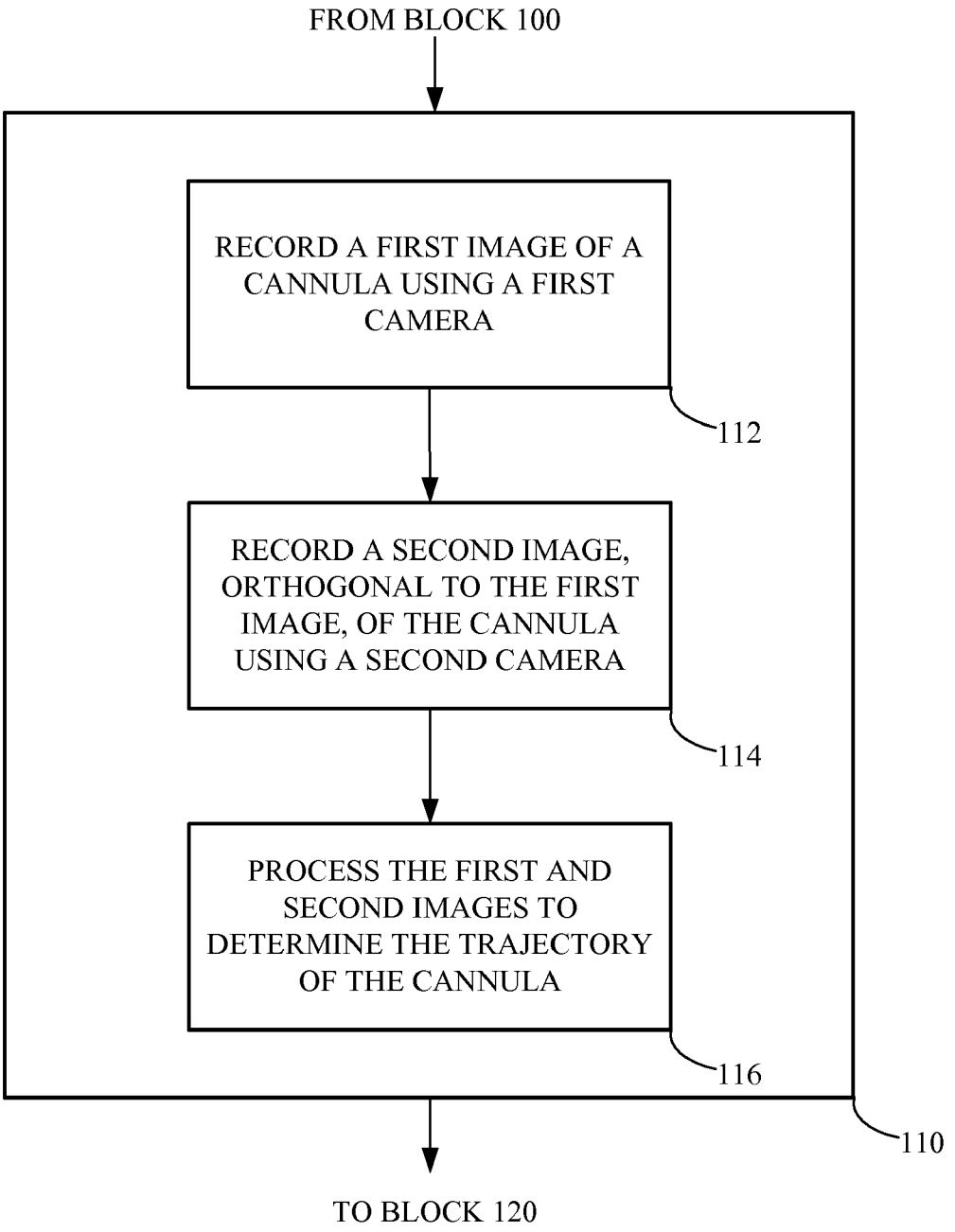

FROM BLOCK 100
RECORD A FIRST IMAGE OF A CANNULA USING A FIRST CAMERA
112
RECORD A SECOND IMAGE, ORTHOGONAL TO THE FIRST IMAGE, OF THE CANNULA USING A SECOND CAMERA
114
PROCESS THE FIRST AND SECOND IMAGES TO DETERMINE THE TRAJECTORY OF THE CANNULA
116
110
TO BLOCK 120

Fig. 10

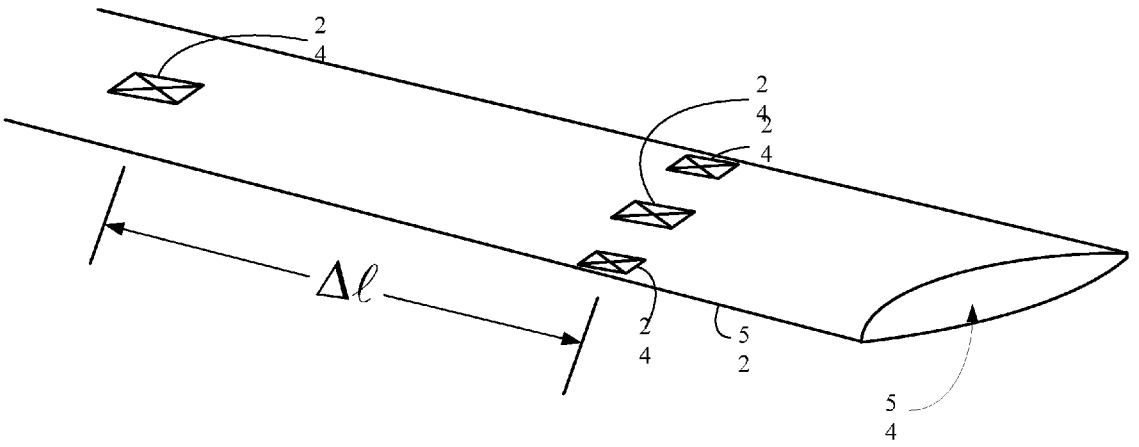


Fig. 11

APPARATUS AND METHOD FOR IMAGE GUIDED INSERTION AND REMOVAL OF A CANNULA OR NEEDLE

FIELD OF THE INVENTION

[0001] This invention relates to a magnetic system for manipulating the placement of a needle or cannula in a biologic subject.

BACKGROUND OF THE INVENTION

[0002] The following applications are incorporated by reference as if fully set forth herein: U.S. application Ser. Nos. 11/258,592 filed Oct. 24, 2005 and 11/874,824 filed Oct. 18, 2007.

[0003] Unsuccessful insertion and/or removal of a cannula, a needle, or other similar devices into vascular tissue may cause vascular wall damage that may lead to serious complications or even death. Image guided placement of a cannula or needle into the vascular tissue reduces the risk of injury and increases the confidence of healthcare providers in using the foregoing devices. Current image guided placement methods generally use a guidance system having a mechanical means for holding specific cannula or needle sizes. The motion and force required to disengage the cannula from the guidance system may, however, contribute to a vessel wall injury, which may result in extravasation. Complications arising from extravasation resulting in morbidity are well documented. Therefore, there is a need for image guided placement of a cannula or needle into vascular tissue while still allowing a health care practitioner to use standard "free" insertion procedures that do not require a guidance system to hold the cannula or needle.

SUMMARY OF THE INVENTION

[0004] This invention relates to a magnetic system for manipulating the placement of a needle or cannula for the purposes of positioning via image devices into an artery, vein, or other body cavity and releasing the cannula once the placement is successfully completed.

[0005] The invention provides a means for holding a selected cannula such that the cannula is controllably restricted in motion in all but one line, but still able to slide along that line relatively freely. The motion restricting force may be selectively varied, thereby allowing an unrestricted separation of the cannula and the holding/guide device.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] Embodiments of the present invention are described in detail below with reference to the following drawings.

[0007] FIG. **1** is a cross-sectional view of a first embodiment;

[0008] FIG. **1**B is an alternate embodiment of the first embodiment;

[0009] FIG. **1**C is a plan view of the first embodiment;

[0010] FIG. **1**D is a plan view of another embodiment;

[0011] FIG. **1**E is a plan view of yet another embodiment;

[0012] FIG. **2**A is a cross-sectional view of a second embodiment;

[0013] FIG. **2**B is a plan view of the second embodiment;

[0014] FIG. **3**A is a cross-sectional view of an alternate embodiment of the second embodiment;

[0015] FIG. **3**B is a plan view of the alternate embodiment of the second embodiment;

[0016] FIG. **4**A is a third embodiment of the invention;

[0017] FIG. **4**B is a plan view of the third embodiment;

[0018] FIG. **5**A is an embodiment of a magnetic strip;

[0019] FIG. **5**B is an alternate embodiment of the magnetic strip;

[0020] FIG. **6**A is an embodiment of a magnetic guide assembly having the embodiments of FIG. **5**A;

[0021] FIG. **6**B is an alternate embodiment of a magnetic guide assembly having the magnetic strip embodiments of FIG. **5**B;

[0022] FIG. **7**A schematically depicts removing a strip from the device depicted in FIG. **6**A;

[0023] FIG. **7**B is a progression of the strip removal of FIG. **7**A;

[0024] FIG. **7**C is a continuation of strip removal of FIG. **7**B;

[0025] FIG. **7**D is near complete removal of the strips from the magnetic guidance device;

[0026] FIG. **7**E is an alternate arrangement of the magnetic strips to the magnetic guidance device;

[0027] FIG. **8**A is a cross-section of a fifth embodiment in the form of a magnet-ferrite core assembly;

[0028] FIG. **8**B depicts the assembly of FIG. **8**A in cross-section holding a cannula in a gap;

[0029] FIG. **8**C depicts the assembly of FIG. **8**A in cross-section where removal of the magnet causes release of the cannula;

[0030] FIG. **9**A is an alternate embodiment of the magnet-ferrite core assembly of FIG. **8**A;

[0031] FIG. **9**B depicts the alternate embodiment of FIG. **9**A magnetically holding a cannula;

[0032] FIG. **9**C schematically shows in cross-section the release of the cannula from the assembly of FIG. **9**A.

[0033] FIG. **9**D shows the complete release of the cannula from the assembly of FIG. **9**A;

[0034] FIG. **10**A is an isometric view of the magnetic core assembly of FIG. **8**A;

[0035] FIG. **10**B is a schematic isometric depiction of the operation of the magnet core assembly of FIG. **8**A;

[0036] FIG. **10**C is a schematic depiction of the operation of the magnet core assembly of FIG. **8**A;

[0037] FIG. **11**A is an alternate embodiment of an isometric view of the alternate embodiment depicted in FIG. **9**A;

[0038] FIG. **11**B depicts an operation of the embodiment shown in FIG. **11**A;

[0039] FIG. **12**A is an alternate embodiment of a pair of magnet core assemblies of FIG. **8**A;

[0040] FIG. **12**B is an isometric view of a schematic operation of an embodiment of FIG. **12**A;

[0041] FIG. **13**A is an isometric view schematically depicting an electro magnetic embodiment of FIG. **12**A;

[0042] FIG. **13**B is an isometric view schematically depicting the electromagnet of FIG. **13**A;

[0043] FIG. **14** illustrates in a partial isometric and side view of a V-Block configured needle guidance device mounted to an ultrasound transceiver;

[0044] FIG. **15** illustrates in a partial isometric and side view of a magnet-ferrite core configured needle guidance device mounted to an ultrasound transceiver;

[0045] FIG. **16** is an alternate embodiment of FIG. **8**A for detachably attaching a magnet-ferrite needle guidance to an ultrasound transducer housing;

[0046] FIG. **17** is an alternate embodiment of FIG. **12**A mounted to a transducer housing;

[0047] FIG. **18**A is a side view of an ultrasound scanner having a magnetic guide assembly;

[0048] FIG. **18**B is an isometric view and exploded view of components of the device of FIG. **18**A;

[0049] FIG. **19**A is a side view of alternate embodiment of FIG. **18**A utilizing a rotating magnet;

[0050] FIG. **19**B is an isometric view and exploded view of components of the device of FIG. **19**A;

[0051] FIG. **20**A is a side view of alternate embodiment of FIG. **19**A utilizing a pulling magnet; and

[0052] FIG. **20**B is an isometric view and exploded view of components of the device of FIG. **20**A.

[0053] FIGS. **1** and **2** are diagrams showing one embodiment of the present invention;

[0054] FIG. **3** is a diagram showing additional detail for a needle shaft to be used with one embodiment of the invention;

[0055] FIGS. **4**A and **4**B are diagrams showing close-up views of surface features of the needle shaft shown in FIG. **3**;

[0056] FIG. **5** is a diagram showing imaging components for use with the needle shaft shown in FIG. **3**;

[0057] FIG. **6** is a diagram showing a representation of an image produced by the imaging components shown in FIG. **5**;

[0058] FIG. **7** is a system diagram of an embodiment of the present invention;

[0059] FIG. **8** is a system diagram of an example embodiment showing additional detail for one of the components shown in FIG. **2**;

[0060] FIGS. **9-10** are flowcharts of a method of displaying the trajectory of a cannula in accordance with an embodiment of the present invention; and

[0061] FIG. **11** schematically depicts an alternative embodiment of a needle having a distribution of reflectors located near a bevel of the needle.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0062] The present invention relates to an apparatus and a method for image guided insertion and removal of a cannula or needle. Many specific details of certain embodiments of the invention are set forth in the following description and in FIGS. **1** through **20**B to provide a thorough understanding of such embodiments. One skilled in the art, however, will understand that the present invention may have additional embodiments, or that the present invention may be practiced without several of the details described in the following description.

[0063] FIG. **1**A is a schematic cross-section view of a needle/cannula guide device **10** according to an embodiment of the invention. The needle/cannula guide device **10** includes a V-block **12** that supports a needle or cannula **18**. The V-block **12** includes two opposing sections that are coupled to each other at an apex. Magnetic strips **16** are positioned on an exterior portion of the V-block **12** that magnetically retain the cannula **18** within the V-block **12**. Accordingly, the V-block **12** may be fabricated from a suitably non-magnetic material, so that magnetic fields generated by the magnet strips **16** retain the metal needle **18** in the V-block **12**. The non-magnetic material of the V-block **12** may be comprised of a low friction polymeric material such as, for example, Teflon®, Nylon®, or Delrin®. Alternatively, it may be comprised of a ferromagnetic material that may similarly convey the magnetic fields generated by the magnets **16**. The magnets **16** may be fixedly coupled to the V-block **12**. Alternately, the magnets **16** may be removably coupled to the V-block **12**.

[0064] FIG. **1**B is a schematic cross-section view of a needle/cannula guide device **10**A according to another embodiment of the invention. Many of the details of the present embodiment have been described in detail in connection with the embodiment shown in FIG. **1**A, and in the interest of brevity, will not be described further. The guide device **10**A includes a foil wrapper **20** or other suitable wrapper materials that substantially encloses the cannula **18**. The wrapper **20** may be subjected to sterilization procedures so that the assembly **10**A may be sterilized by autoclaving, irradiation, or other known chemical processes. The foil wrapper **20** is generally sealably coupled to the V-block **12** so that the cannula **18** is substantially isolated from contaminants, yet is configured to be easily removed from the V-block **12**.

[0065] FIGS. **1**C, D, and E illustrate alternate embodiments of the cannula guide devices **10** and **10**A, as shown in FIG. **1**A and FIG. **1**B, respectively.

[0066] FIG. **1**C is a plan view of the devices **10** and **10**A where the cannula **18** is positioned in the V-block **12** and is held in position by the magnets **16**, which extend uninterrupted along a length of the V-block **12**. FIG. **1**D is a plan view of the devices **10** and **10**A that shows a first set of magnets **16**A positioned on first selected portions of the V-block **12**, and a second set of magnets **16**B that are positioned on second selected portions of the V-block **12**. As shown in FIG. **1**D, the second set **16**B may be positioned between the first set **16**A. FIG. **1**E is a plan view of the devices **10** and **10**A that shows magnets **16**A interruptably positioned on the V-block **12**. Although the magnets **16**, **16**A and **16**B are generally depicted in FIG. **1**C, FIG. **1**D AND FIG. **1**E as rectangular, it is understood that the magnets **16**, **16**A and **16**B may have any regular shape.

[0067] FIGS. **2**A and **2**B are cross sectional and plan views, respectively, of a cannula guide device **20**A according to another embodiment of the invention. In FIG. **2**A, the V-block **12** includes four magnet strips **24**, positioned on each arm of the V-block **12** that are used to generate a retaining force on the needle **18**. Referring now also to FIG. **2**B, the placement of the magnets **24** on the V-block **12** advantageously permit the V-block **12** to accommodate a variety of needle diameters.

[0068] FIGS. **3**A and **3**B are cross sectional and plan views, respectively, of a cannula guide device **20**B according to still another embodiment of the invention. The device **20**B includes magnets **24**B that are operable to generate an attractive force that is different from magnets **24**A. Accordingly, the magnets **24**B may generate a greater attractive force on the needle **18** than the magnets **24**A. Alternately, the magnets **24**A may generate a greater attractive than the magnets **24**B.

[0069] FIGS. **4**A and **4**B are cross sectional and plan views, respectively, of a cannula guide device **20**C according to still yet another embodiment of the invention. The device **20**C includes a unitary magnet strips **27** having regions that generate different attractive forces on the needle **18**. Accordingly, the unitary magnetic strips **27** include a first magnetic strip portion **26**A and a second magnetic strip portion **26**B. The attractive force generated by the portion **26**A may be greater than the attractive force generated by the portion **26**B, or the attractive force generated by the portion **26**B may be greater than the attractive force generated by the portion **26**A.

[0070] FIGS. **5**A and **5**B are isometric views, respectively, of magnetic strips **30**A and **30**B that may be removably coupled to the V-block **12** (FIG. **1**A). The magnetic strips **30**A and **30**B include a tab **34** configured to apply a pulling force to the strips **30**A and **30**B. Referring now in particular to FIG.

5A, a unitary magnetic element **32** is positioned on the strip **30**A that generates a relatively uniform attractive force on the needle **18** (not shown). Magnetic strip **30**B shown in FIG. **5**B includes a magnetic element **36** that also includes magnetic portions **36**A and **36**B that are configured to generate different attractive forces on the needle **18** (not shown). The magnetic strips **30**A and **30**B may also include an adhesive material that is operable to retain the strips **30**A and **30**B onto external surfaces of the V-block **12**.

[0071] FIGS. **6**A and **6**B are respective isometric views of needle guidance devices **40**A and **40**B. In FIG. **6**A, the needle guidance device **40**A includes the magnetic strips **30**A as shown in FIG. **5**A that are positioned on the exterior of the V-block **12**. The attractive force of the magnetic strips **30**A magnetically holds the needle **18** within an inner portion of the V-block **12**. In FIG. **6**B, the needle guidance device **40**B includes the magnetic strip **30**B of FIG. **5**B positioned on the V-block **12**.

[0072] FIGS. **7**A-**7**E are isometric views of the needle guidance device **40**A that will be used to a method of using the needle guidance device **40**A according to another embodiment of the invention. FIG. **7**A and FIG. **7**B show a first selected one of the magnetic strips **30**A being progressively removed from the V-block **12**. The first selected one of the strips **30**A may be removed by a user by grasping the tab **34** and applying a pulling force on the tab **34** in the direction shown. Accordingly, the attractive force on the needle **18** is also progressively reduced. A selected length of the strip **30**A may be removed so that a desired attractive force acting on the needle **18** is attained. Referring now to FIG. **7**C, a second selected one of the strips **30**A may be removed by grasping the tab **34** and applying a pulling force on the tab **34** in a suitable direction. As a result, the attractive force on the needle **18** is still further reduced. Although FIGS. **7**A through **7**C show a single magnetic strip applied to external surfaces of the V-block **12**, more than one magnetic strip may be present on an external surface of the V-block **12**.

[0073] Referring now to FIG. **7**D, when the first selected strip and the second selected strip are removed to a desired degree, the needle **18** may be separated from the V-block **12**.

[0074] As shown in FIG. **7**E, the magnetic strips **30**A may be positioned on the V-block **12** so that the strips **30**A are oriented oppositely to those shown in FIGS. **7**A through **7**D.

[0075] FIGS. **8**A-**8**C are respective cross sectional views of a needle guidance device **50** according to yet another embodiment of the invention. The needle guidance device **50** includes a pair of opposing metal cores **54** having a gap **58**A and a gap **58**B between the ferromagnetic cores **54**. The metal cores **54** are generally semi-circularly shaped and may be made of any metal or metal alloy suitable for conveying a magnetic field, such as a ferromagnetic or ferrite material. A magnet **56** is removably positionable within a selected one of the gaps **58**A and **58**B. For purposes of illustration, the magnet **56** is positioned in the gap **56**A. When the magnet **56** is positioned within a selected one of the gaps **58**A and **58**B, a magnetic field is communicated along the cores **54** from the gap **58**A to the gap **58**B. The gap **58**B is configured to accept a needle **18** so that the needle **18** will be retained in the gap **58**B by the magnetic fields communicated from gap **56**A. As shown in FIG. **8**A, the lines of the magnetic force are conveyed across the space **58**B. Referring briefly now to FIG. **8**B, the needle **18** is held within the gap **58**B. Accordingly, the needle **18** will be retained within the gap **58**B while the magnet **56** is positioned within gap **58**A. The gap **58**B progressively narrows to accommodate needles having variable diameters. Turning now to FIG. **8**C, as the magnet **56** is moved outwardly from the gap **58**A of the needle guidance device **50**, the magnetic field spanning the gap **58**B is correspondingly reduced. Accordingly, the needle **18** positioned within the gap **58**B may be gradually released from the needle guidance device **50**.

[0076] FIGS. **9**A-**9**D are respective cross sectional views of a needle guidance device **60** according to yet still another embodiment of the invention. With reference now to FIG. **9**A, the needle guidance device **60** includes a magnet **66** that is configured to be rotated within the gap **58**A. In FIG. **9**A, the magnet **66** is shown in a first position so that the magnetic lines of force are communicated along the ferromagnetic cores **54**. Accordingly, a magnetic field is established within the gap **58**B, so that the needle **18** is retained within the gap **58**B, as shown in FIG. **9**B. In FIG. **9**C, the magnet **66** is rotated to a second position so that the magnetic lines of force are generally directed away from the ferromagnetic cores **54**. Accordingly, the attractive force that retains the needle **18** within the gap **58**B is reduced so that the needle **18** may be moved away from the gap **58**B.

[0077] FIG. **10**A is an isometric view of the needle guidance device **50** of FIGS. **8**A through **8**C. In this schematic view, the needle **18** is held into the gap **58**B by the magnetic field generated by the magnet **56**. The needle **18** is retained from moving through the gap **58**B and into an internal region of the device **50** by providing beveled walls within the gap **58**B that have a minimum distance "d" so that the beveled walls interfere with further movement of the needle **18** through the gap **58**B since the distance "d" is generally selected to be smaller than a diameter of the needle **18**. Referring now to FIG. **10**B, method of disengagement of the needle **18** from the gap **58**B is shown. The disengagement of the needle **18** from the needle guidance device **50** includes moving the magnet **56** upwardly and away from the cores **54**. Correspondingly, a reduction in magnetic holding force occurs within the gap **58**B so that the needle **18** may be removed from the needle guidance device **50**.

[0078] FIG. **10**C shows an alternate method for disengagement of the needle **18** from the needle guidance device **50**. Moving the magnet **56** longitudinally along the gap **58**A so that the magnetic force across the gap **58**B is proportionately reduced effects the disengagement of the needle **18**. Depending upon the relative strength of the magnet **56**, the composition of the cores **54** and the material used to fabricate the needle, a user removing the magnet **56** may find that the magnetic holding force is sufficiently reduced to permit non-injurious disengagement of the needle **18** from the gap **58**B of the needle guidance device **50** when the magnet **56** is only partially disengaged from the gap **58**A. Alternately, the user may be required to completely remove the magnet **56** from the gap **58**A in order to release the needle **18** from the device **50**.

[0079] FIG. **11**A is an isometric view of the needle guidance device **60** that shows the needle **18** held in position by the rotating magnet **66**. In this case, the rotatable magnet **66** is in the vertical position within the gap **58**A, and the magnetic forces hold the needle **18** within the gap **58**B.

[0080] FIG. **11**B shows a completion of the disengagement process from FIG. **11**A. The rotatable magnet **66** is rotated to a horizontal position as indicated by the crosshatched arrow within the gap **58**A. This rotation causes either a reduction of retentive magnetic forces spanning across the gap **58**B or

generation of repulsive forces. As indicated by the downward arrow, the needle **18** becomes disengagable from the needle guidance device **60** and eventually separates from the gap **58**B.

[0081] FIG. **12**A is an isometric view of a needle guidance device **70**, according to another embodiment of the invention. The device **70** includes two ferromagnetic core assemblies **54** that are longitudinally spaced apart and share a common movable permanent magnet **56** configured to engage respective gaps **58**A in the core assemblies **54**. The magnet **56** may either be slidably disengaged from each ferromagnetic core assembly **54** either longitudinally or it may be removed from the gap **58**A by moving the magnet **56** in a radial direction and away from the core assemblies **54**. In either event, the progressive removal of permanent magnet **56** from the respective gaps **58**A causes a progressive reduction in magnetic fields across the gaps **58**B. Accordingly, a user may advantageously select a suitable retentive force for the needle **18**.

[0082] FIG. **12**B shows a disengagement of the operation in the orthogonal displacement. Here, the needle guidance device **70** is in a disengagement process where the permanent magnet **56** is removed 90° orthogonal to the spaces **58**A, to each ferrite core assembly **54**. Removal as previously mentioned of a permanent magnet **56** causes a diminution magnetic retentive forces across the gap **58**B resulting in a progressively easier disengagement force to be affected to the needle **18**.

[0083] FIG. **13**A shows a needle guidance **80** being an electromagnetic alternate embodiment to the permanent magnet embodiment **70**. This electromagnetic embodiment **80** includes a DC power assembly that has a power source **82**, a variable resistor **84** connected to the power source **82**, in communication with a coil winding (not shown—see FIG. **13**B below) electrically connected with the source **82** and resistor **84** via a wire **86**. The wire **86** is connected with the coil winding (not shown) that is wrapped within the groove **158** of the electromagnet **156**. The electromagnet **156** is a non-permanent electromagnet that respectfully occupies the spaces **58**A of metal cores **54**. The dashed arrow **84**A within the variable resistor **84** shows a resistor position when there is sufficient power that is delivered to the core winding occupying the grove **158** to induce a magnetic field of sufficient strength to hold the needle **18** across respective gaps **58**B of each iron or other metal core assembly **54** that is able to convey the magnetic flux fields generated by the electromagnet **156**. Reducing the power indicated by the solid arrow **84**B resistor position progressively causes a reduction of magnetic force due to the diminution of current and/or voltage applied to the windings occupying the grove **158**. Eventually the magnetic power is progressively lessened such that an applied disengagement force by a user permits the removal or non-injurious disengagement of the needle **18**, as indicated by the downward arrow, from the gaps **58**B of the guidance device **80**.

[0084] FIG. **13**B is an isometric view schematically depicting the electromagnet of FIG. **13**A. Within the grooves **158** of the he electromagnet **156** is a coil winding **88**. Application of electrical power by the DC power supply **82** through the variable resistor **84** results in a magnetic force generated by the electromagnet **156** in proportion to the amount of electrical power delivered to the coil winding **88**. North, N and South, S poles are formed along the electromagnet **156**. As the power is gradually lessened between the **84**A and **84**B resistor positions, the retentive magnetic force field generated along the electromagnet **156** is accordingly lessened.

[0085] As previously described for the removal of the magnetic strip embodiments and the permanent magnets and the electromagnet needle guidance devices as previously described provides a means for holding a selected cannula such that the cannula is controllably restricted in motion substantially along one dimension. The user may either manipulate the amount of magnetic strips to vary the magnetic power by the permanent magnets or adjust power to electromagnets so that a user may progressively overcome the retentive forces still applied to the needle **18** and effect the extraction or disengagement of the needle **18** from the respective needle guidance devices in a non-injurious way from a patient or other subject.

[0086] FIGS. **14**-**20**B are partial isometric views that depict various embodiments of the present invention coupled to an ultrasound transceiver **100**. In the description that follows, it is understood that the various embodiments may be removably coupled to the ultrasound transceiver **100**, or they may be permanently coupled to the transceiver **100**. It is also understood that, although an ultrasound transceiver is described in the following description and shown in the following figures, the various embodiments may also be incorporated into other imaging devices.

[0087] FIG. **14** is a partial isometric side view the V-Block **40**A of FIG. **6**A and FIG. **6**B coupled to an ultrasound transceiver **101** to form an assembly **100**. The ultrasound transceiver **101** has the needle guidance device **40**A coupled to a transducer housing **104** of the transceiver **101** using a bridge **108**. The needle guidance device **40**A may be fixedly coupled to the housing **104**, or the device **40**A may be removably coupled to the housing **104**. In either case, the transceiver **100** also includes a trigger **102**, a display **103**, a handle **106**, and a transducer dome **112**. Upon pressing the trigger **102**, an ultrasound scancone **116** emanates from the transducer dome **112** that penetrates a subject or patient. The scancone **116** is comprised of a radial array of scan planes **118**. Within the scanplane **118** are scanlines (not shown) that may be evenly or unevenly spaced. Alternatively, the scancone **116** may be comprised of an array of wedged distributed scancones or an array of 3D-distributed scanlines that are not necessarily confined to a given scan plane **118**. As shown, the scancone **116** is radiates about the transducer axis **11** that bisects the transducer housing **104** and dome **112**.

[0088] FIG. **15** is a partial isometric, side view of the needle guidance device **50** of FIG. **8**A, FIG. **8**B and FIG. **8**C coupled to the ultrasound transceiver **101** to form an assembly **120**. The ultrasound transceiver **101** has the needle guidance device **50** mounted to the transducer housing **104** using the bridge **108** of FIG. **14**. The device **50** may be fixedly or removably coupled to the housing **104**. A scan cone **116** is similarly projected from the transceiver **101**. Various aiming aids may be placed on the needle guidance device **50** to assist a user in aiming the insertion of a needle that is held by a magnetic force to slide within the gap **58**B.

[0089] FIG. **16** is a partial isometric view of a needle guidance device **90** that may be removably coupled to the housing **104** of an ultrasound transceiver **101**, according to another embodiment of the invention. The needle guidance device **90** is attached to an engagement wedge **92**. The engagement wedge **92** slidably and removably attaches with the slot holder **94** that is positioned on a selected portion of the housing **104**. Various aiming aids may be placed on the needle

guidance device **90** to assist a user in aiming the insertion of a needle that is held by a magnetic force to slide within the gap **58**B.

[0090] FIG. **17** is a partial isometric view of a needle guidance device **130** according to another embodiment of the invention. The device **130** is configured to be positioned within a transceiver housing **132**. A pair of magnets **134** and **136** are positioned on a rotational shaft **137** that projects into the housing **132**. The magnets **134** and **136** provide an attractive force on the needle **18** when the magnets **134** and **136** are aligned with the needle **18**. When the magnets **134** and **136** are rotated away from alignment (by manually rotating a wheel **139** coupled to the shaft **138**) with the needle **18**, the attractive force on the needle **18** is reduced, thus allowing the needle **18** to be moved relative to the housing **132**.

[0091] FIG. **18**A is a side view of an ultrasound scanner having a magnetic guide assembly **144**, according to an embodiment of the invention. The guidance assembly **144** includes the transceiver **101** in which a needle **18** with reservoir **19** is held within a ferrite housing **144**. The ferrite housing **144** is secured to transducer housing **104** by a clip-on clasp **142**.

[0092] FIG. **18**B is an isometric view and exploded view of components of the assembly **144** of FIG. **18**A. In the exploded view, the guidance assembly **144** is seen in greater detail. The ferrite housing **144** receives ferrite cores **146** and **150**. Rotable within the space defined by the ferrite core **146** and gap **58**A of ferrite cores **150** is a rotatable magnet **148**. Located between the clip-on clasp **142** and the ferrite housing **144** is an articulating bridge **143**. The articulating bridge **143** allows the user to alter the entry angle of the needle **18** into the patient relative to the transducer axis **11** as illustrated in FIG. **14**. Rotating the magnet **148** alters the magnetic holding power to gap **58**B between ferrite cores **150**.

[0093] FIG. **19**A is a side view of alternate embodiment shown in FIG. **18**A that uses a sliding magnet. A guidance assembly **170** includes the transceiver **101** in which a needle **18** with reservoir **19** is held within a ferrite housing **145**. The ferrite housing **145** is secured to transducer housing **104** by a clip-on clasp **142** and articulating bridge **143**. The ferrite housing **145** is configured to receive three components.

[0094] FIG. **19**B is an isometric view and exploded view of the components of the device **170** of FIG. **19**A. In the exploded view the guidance assembly **170** is seen in greater detail. The ferrite housing **145** receives two ferrite cores **172** and a slidable magnet **176**. The slidable magnet **176** is moveable within the space **56**A defined by the ferrite cores **172**. Opposite the space **56**A is space **56**B that receives the needle **18**. The articulating bridge **143** allows the user to alter the entry angle of the needle **18** into the patient or subject relative to the transducer axis **11** as illustrated in FIG. **14**. Sliding the magnet **176** alters the magnetic holding power to gap **58**B between ferrite cores **172**.

[0095] FIG. **20**A is a side view of alternate embodiment of the device **170** of FIG. **19**A utilizing a pulling magnet. A guidance assembly **180** includes the transceiver **101** in which a needle **18** with reservoir **19** is held within a ferrite housing **182**. The ferrite housing **182** is secured to transducer housing **104** by a clip-on clasp **142** and articulating bridge **143**. The ferrite housing **145** is configured to receive three components.

[0096] FIG. **20**B is an isometric view and exploded view of components of the device **180** of FIG. **20**A. In the exploded view the guidance assembly **180** is seen in greater detail. The ferrite housing **182** receives two ferrite cores **188** and a trigger receiver **186**. The trigger receiver **186** receivers the trigger **190** that has a magnet frame **191**. The magnet frame **191** retains the magnet **192**. The magnet **192** is snap-fitted into the magnet frame **191** of the trigger **190**. The magnet-loaded trigger **190** is slidably placed into the trigger receiver **186**. The trigger receiver **186** guides the magnet-loaded trigger **190** within the gap **58**B defined by the two ferrite cores **188**. Pulling the magnet-loaded trigger **190** alters the magnetic holding power to gap **58**B receiving the needle **18** located opposite the gap **58**A between ferrite cores **188**.

[0097] An example embodiment includes a system and method using single or multiple cameras for tracking and displaying the movement of a needle or cannula before and/or during insertion into a blood vessel or other sub-dermal structure and subsequent movements therein. A needle or a cannula-fitted needle may be detachably mounted to an ultrasound transceiver in signal communication with a computer system and display configured to generate ultrasound-acquired images and process images received from the single or multiple cameras. Along the external surfaces of the needle or cannula may be fitted optical reflectors that may be discernable in the camera images. The ultrasound transceiver may be secured against a subject's dermal area adjacent to a subdermal region of interest (ROI). Optical signals may be reflected towards the single or multiple cameras by the needle or cannula embedded reflectors and conveyed to the computer system and display. The trajectories of the needle or cannula movements may be determined by data analysis of the reflector signals detected by the cameras. The trajectories of needle or cannula having one or more reflectors may be overlaid onto the ultrasound images to provide alignment coordinates for insertion of the needle or cannula fitted needle into the ROI along a determined trajectory.

[0098] An example embodiment of the present invention generally includes an ultrasound probe attached to a first camera and a second camera. The example embodiment also generally includes a processing and display generating system that may be in signal communication with the ultrasound probe, the first camera, and/or the second camera. Typically, a user of the system scans tissue containing a target vein using the ultrasound probe and a cross-sectional image of the target vein may be displayed. The first camera captures and/or records a first image of a medical object to be inserted, such as a cannula for example, in a first direction and the second camera captures and/or records a second image of the cannula in a second direction orthogonal to the first direction. The first and/or the second images may be processed by the processing and display generating system along with the relative positions of the ultrasound probe, the first camera, and/or the second camera to determine the trajectory of the cannula. A representation of the determined trajectory of the cannula may be then displayed on the ultrasound image.

[0099] FIG. **1** is a diagram illustrating a side view of one embodiment of the present invention. A two-dimensional (2D) ultrasound probe **10** may be attached to a first camera **14** that takes images in a first direction. The ultrasound probe **10** may be also attached to a second camera **18** via a member **16**. In other embodiments, the member **16** may link the first camera **14** to the second camera **18** or the member **16** may be absent, with the second camera **18** being directly attached to a specially configured ultrasound probe. The second camera **18** may be oriented such that the second camera **18** takes images in a second direction that may be orthogonal to the first direction of the images taken by the first camera **14**. The

placement of the cameras **14**, **18** may be such that they can both take images of a cannula **20** when the cannula **20** may be placed before the cameras **14**, **18**. A needle may also be used in place of a cannula. The cameras **14**, **18** and the ultrasound probe **10** may be geometrically interlocked such that the cannula **20** trajectory can be related to an ultrasound image. In FIG. **1**, the second camera **18** may be behind the cannula **20** when looking into the plane of the page. In an embodiment, the cameras **14**, **18** take images at a rapid frame rate of approximately 30 frames per second. The ultrasound probe **10** and/or the cameras **14**, **18** may be in signal communication with a processing and display generating system **61** described in FIGS. **7** and **8** below.

[0100] In typical operation, a user first employs the ultrasound probe **10** and the processing and display generating system **61** to generate a cross-sectional image of a patient's arm tissue containing a vein to be cannulated ("target vein") **19**. This could be done by one of the methods disclosed in the patents, patent publications and/or patent applications which are herein incorporated by reference, such as, for example, U.S. patent application Ser. No. 11/460,182 filed Jul. 26, 2006. The user then identifies the target vein **19** in the image using methods such as simple compression which differentiates between arteries and/or veins by using the fact that veins collapse easily while arteries do not. After the user has identified the target vein **19**, the ultrasound probe **10** may be affixed to the patient's arm over the previously identified target vein **19** using a magnetic tape material **12**, for example. The ultrasound probe **10** and the processing and display generating system **61** continue to generate a 2D cross-sectional image of the tissue containing the target vein **19**. Images from the cameras **14**, **18** may be provided to the processing and display generating system **61** as the cannula **20** may be approaching and/or entering the arm of the patient.

[0101] The processing and display generating system **61** locates the cannula **20** in the images provided by the cameras **14**, **18** and determines the projected location at which the cannula **20** will penetrate the cross-sectional ultrasound image being displayed. The trajectory of the cannula **20** may be determined in some embodiments by using image processing to identify bright spots corresponding to micro reflectors previously machined into the shaft of the cannula **20** or a needle used alone or in combination with the cannula **20**. Image processing uses the bright spots to determine the angles of the cannula **20** relative to the cameras **14**, **18** and then generates a projected trajectory by using the determined angles and/or the known positions of the cameras **14**, **18** in relation to the ultrasound probe **10**. In other embodiments, determination of the cannula **20** trajectory may be performed using edge-detection algorithms in combination with the known positions of the cameras **14**, **18** in relation to the ultrasound probe **10**, for example.

[0102] The projected location may be indicated on the displayed image as a computer-generated cross-hair **66** (shown in FIG. **7**), the intersection of which may be where the cannula **20** is projected to penetrate the image. In other embodiments, the projected location may be depicted using a representation other than a cross-hair. When the cannula **20** does penetrate the cross-sectional plane of the scan produced by the ultrasound probe **10**, the ultrasound image confirms that the cannula **20** penetrated at the location of the cross-hair **66**. This gives the user a real-time ultrasound image of the target vein **19** with an overlaid real-time computer-generated image of the position in the ultrasound image that the cannula **20** will penetrate. This allows the user to adjust the location and/or angle of the cannula **20** before and/or during insertion to increase the likelihood they will penetrate the target vein **19**. In other embodiments, the ultrasound image and/or the computer-generated cross-hair may be displayed in near real-time. In an example embodiment, this allows a user to employ normal "free" insertion procedures while having the added knowledge of knowing where the cannula **20** trajectory will lead.

[0103] FIG. **2** is a diagram illustrating a top view of the embodiment shown in FIG. **1**. It is more easily seen from this view that the second camera **18** may be positioned behind the cannula **20**. The positioning of the cameras **14**, **18** relative to the cannula **20** allows the cameras **14**, **18** to capture images of the cannula **20** from two different directions, thus making it easier to determine the trajectory of the cannula **20**.

[0104] FIG. **3** is diagram showing additional detail for a needle shaft **22** to be used with one embodiment of the invention. The needle shaft **22** includes a plurality of micro corner reflectors **24**. The micro corner reflectors **24** may be cut into, or otherwise affixed to or embedded in, the needle shaft **22** at defined intervals Δl in symmetrical patterns about the circumference of the needle shaft **22**. The micro corner reflectors **24** could be cut with a laser, for example.

[0105] FIGS. **4**A and **4**B are diagrams showing close-up views of surface features of the needle shaft **22** shown in FIG. **3**. FIG. **4**A shows a first input ray with a first incident angle of approximately 90° striking one of the micro corner reflectors **24** on the needle shaft **22**. A first output ray is shown exiting the micro corner reflector **24** in a direction toward the source of the first input ray. FIG. **4**B shows a second input ray with a second incident angle other than 90° striking a micro corner reflector **25** on the needle shaft **22**. A second output ray is shown exiting the micro corner reflector **25** in a direction toward the source of the second input ray. FIGS. **4**A and **4**B illustrate that the micro corner reflectors **24**, **25** are useful because they tend to reflect an output ray in the direction from which an input ray originated.

[0106] FIG. **5** is a diagram showing imaging components for use with the needle shaft **22** shown in FIG. **3** in accordance with an example embodiment of the invention. The imaging components are shown to include a first light source **26**, a second light source **28**, a lens **30**, and a sensor chip **32**. The first and/or second light sources **26**, **28** may be light emitting diodes (LEDs), for example. In an example embodiment, the light sources **26**, **28** are infra-red LEDs. Use of an infra-red source is advantageous because it is not visible to the human eye, but when an image of the needle shaft **22** is recorded, the image can show strong bright dots where the micro corner reflectors **24** may be located because silicon sensor chips are sensitive to infra-red light and the micro corner reflectors **24** tend to reflect output rays in the direction from which input rays originate, as discussed with reference to FIGS. **4**A and **4**B. In alternative embodiments, a single light source may be used. Although not shown, the sensor chip **32** may be encased in a housing behind the lens **30** and the sensor chip **32** and light sources **26**, **28** may be in electrical communication with the processing and display generating system **61** shown in FIG. **7** below. The sensor chip **32** and/or the lens **30** form a part of the first and second cameras **14**, **18** in some embodiments. In an example embodiment, the light sources **26**, **28** may be pulsed on at the time the sensor chip **32** captures an image. In other embodiments, the light sources **26**, **28** may be left on during video image capture.

[0107] FIG. **6** is a diagram showing a representation of an image **34** produced by the imaging components shown in FIG. **5**. The image **34** may include a needle shaft image **36** that corresponds to a portion of the needle shaft **22** shown in FIG. **5**. The image **34** also may include a series of bright dots **38** running along the center of the needle shaft image **36** that correspond to the micro corner reflectors **24** shown in FIG. **5**. A center line **40** is shown in FIG. **6** that runs through the center of the bright dots **38**. The center line **40** may not appear in the actual image generated by the imaging components, but is shown in the diagram to illustrate how an angle theta (θ) could be obtained by image processing to recognize the bright dots **38** and determine a line through them. The angle theta represents the degree to which the needle shaft **22** may be inclined with respect to a reference line **42** that may be related to the fixed position of the sensor chip **32**.

[0108] FIG. **7** is a system diagram of an embodiment of the present invention and shows additional detail for the processing and display generating system **61** in accordance with an example embodiment of the invention. The ultrasound probe **10** is shown connected to the processing and display generating system via M control lines and N data lines. The M and N variables are for convenience and appear simply to indicate that the connections may be composed of one or more transmission paths. The control lines allow the processing and display generating system **61** to direct the ultrasound probe **10** to properly perform an ultrasound scan and the data lines allow responses from the ultrasound scan to be transmitted to the processing and display generating system **61**. The first and second cameras **14**, **18** are also each shown to be connected to the processing and display generating system **61** via N lines. Although the same variable N is used, it is simply indicating that one or more lines may be present, not that each device with a label of N lines has the same number of lines.

[0109] The processing and display generating system **61** may be composed of a display **64** and a block **62** containing a computer, a digital signal processor (DSP), and analog to digital (A/D) converters. As discussed for FIG. **1**, the display **64** can display a cross-sectional ultrasound image. The computer-generated cross hair **66** is shown over a representation of a cross-sectional view of the target vein **19** in FIG. **7**. The cross hair **66** consists of an x-crosshair **68** and a z-crosshair **70**. The DSP and the computer in the block **62** use images from the first camera **14** to determine the plane in which the cannula **20** will penetrate the ultrasound image and then write the z-crosshair **70** on the ultrasound image provided to the display **64**. Similarly, the DSP and the computer in the block **62** use images from the second camera **18**, which may be orthogonal to the images provided by the first camera **14** as discussed for FIG. **1**, to write the x-crosshair **68** on the ultrasound image. In other embodiments, the DSP and the computer in the block **62** may use images from both the first camera **14** and the second camera **18** to write each of the x-crosshair **68** and the z-crosshair **70** on the ultrasound image. In still other examples, images from the cameras **14**, **18** may be used separately or in combination to write the crosshairs **68**, **70** or other representations of where the cannula **20** is projected to penetrate the ultrasound image.

[0110] FIG. **8** is a system diagram of an example embodiment showing additional detail for the block **62** shown in FIG. **2**. The block **62** includes a first A/D converter **80**, a second A/D converter **82**, and a third A/D converter **84**. The first A/D converter **80** receives signals from the ultrasound probe **10** and converts them to digital information that may be provided to a DSP **86**. The second and third A/D converters **82**, **84** receive signals from the first and second cameras **14**, **18** respectively and convert the signals to digital information that may be provided to the DSP **86**. In alternative embodiments, some or all of the A/D converters are not present. For example, video from the cameras **14**, **18** may be provided to the DSP **86** directly in digital form rather than being created in analog form before passing through A/D converters **82**, **84**. The DSP **86** may be in data communication with a computer **88** that includes a central processing unit (CPU) **90** in data communication with a memory component **92**. The computer **88** may be in signal communication with the ultrasound probe **10** and may be able to control the ultrasound probe **10** using this connection. The computer **88** may be also connected to the display **64** and may produce a video signal used to drive the display **64**. In still other examples, other hardware components may be used. A field programmable gate array (FPGA) may be used in place of the DSP, for example. Or, an application specific integrated circuit (ASIC) may replace one or more components.

[0111] FIG. **9** is a flowchart of a process of displaying the trajectory of a cannula in accordance with an embodiment of the present invention. The process is illustrated as a set of operations shown as discrete blocks. The process may be implemented in any suitable hardware, software, firmware, or combination thereof. As such the process may be implemented in computer-executable instructions that can be transferred from one computer to a second computer via a communications medium. The order in which the operations are described is not to be necessarily construed as a limitation. First, at a block **100**, an ultrasound image of a vein cross-section may be produced and/or displayed. Next, at a block **110**, the trajectory of a cannula may be determined. Then, at a block **120**, the determined trajectory of the cannula may be displayed on the ultrasound image.

[0112] FIG. **10** is a flowchart of a process showing additional detail for the block **110** depicted in FIG. **9**. The process is illustrated as a set of operations shown as discrete blocks. The process may be implemented in any suitable hardware, software, firmware, or combination thereof. As such the process may be implemented in computer-executable instructions that can be transferred from one computer to a second computer via a communications medium. The order in which the operations are described is not to be necessarily construed as a limitation. The block **110** includes a block **112** where a first image of a cannula may be recorded using a first camera. Next, at a block **114**, a second image of the cannula orthogonal to the first image of the cannula may be recorded using a second camera. Then, at a block **116**, the first and second images may be processed to determine the trajectory of the cannula.

[0113] FIG. **11** schematically depicts an alternative embodiment of a needle having a distribution of reflectors located near the bevel of the needle. A needle shaft **52** includes a bevel **54** that may be pointed for penetration into the skin to reach the lumen of a blood vessel. The needle shaft **52** also includes a plurality of micro corner reflectors **24**. The micro corner reflectors **24** may be cut into the needle shaft **52** at defined intervals Δl in symmetrical patterns about the circumference of the needle shaft **52**. In an example, the micro corner reflectors **24** may be cut with a laser and serve to provide light reflective surfaces for monitoring the insertion and/or tracking of the trajectory of the bevel **54** into the blood vessel during the initial penetration stages of the needle **52** into the skin and/or tracking of the bevel **54** motion during guidance procedures.

[0114] While the preferred embodiment of the invention has been illustrated and described, as noted above, many changes can be made without departing from the spirit and scope of the invention. For example, a three-dimensional ultrasound system could be used rather than a 2D system. In addition, different numbers of cameras could be used along with image processing that determines the cannula **20** trajectory based on the number of cameras used. The two cameras **14**, **18** could also be placed in a non-orthogonal relationship so long as the image processing was adjusted to properly determine the orientation and/or projected trajectory of the cannula **20**. The radiation emitting from the light sources **26**, **28** may be of a frequency and intensity that may be sufficiently penetrating in tissue to permit reflection of sub-dermal located reflectors **24** to the detector sensor **32**. The sensor **32** may be suitably filtered to optimize detection of sub-dermal reflected radiation from the reflectors **24** so that sub-dermal trajectory tracking of the needles **22**, **52** or cannulas **20** having one or more reflectors **24** may be achieved. Also, an embodiment of the invention could be used for needles and/or other devices such as trocars, stylets, or catheters which are to be inserted in the body of a patient. Additionally, an embodiment of the invention could be used in places other than arm veins. Regions of the patient's body other than an arm could be used and/or biological structures other than veins may be the focus of interest.

[0115] While various embodiments of the invention have been illustrated and described, as noted above, many changes can be made without departing from the spirit and scope of the invention. For example, electromagnetic strips may be removably attached to V-blocks and the magnetic power controlled by an electric circuit applied to the electromagnetic strips. Permanent magnets used in the various embodiments may be of any metal able to generate and communicate a magnetic force, for example, Iron, Iron alloys, and Neodymnium based magnets. Accordingly, the scope of the invention is not limited by the disclosure of the preferred embodiment. Instead, the invention should be determined entirely by reference to the claims that follow.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. An imaging guided device for placing a cannula attached to a magnetically responsive needle at a targeted location, the device comprising:

an imaging probe operationally configured with imaging system to present an image;

an attachment connected with the imaging probe, the attachment comprising:

a block having at least one magnet to releasably retain the needle by alternating the magnetic force of the magnet applied to the needle,

wherein the needle is inserted to and removed from the targeted location as determined in the image at a user adjusted retentive magnetic force, leaving the cannula in place at the targeted location after removal of the needle.

2. The device of claim **1**, wherein the magnet comprises at least one removable strip.

3. The device of claim **1**, wherein the magnet comprises two removable strips approximately orthogonal to each other.

4. The device of claim **3**, wherein the removable strip includes a plurality of magnets having substantially similar magnetic power.

5. The device of claim **3**, wherein the removable strip includes a plurality of magnets having substantially different magnetic power.

6. The device of claim **5**, wherein the removable strip includes an inner magnetic core and an outer magnetic perimeter.

7. The device of claim **1**, wherein the magnet includes a ferrite core having a first gap to engage a moveable magnet bar and a second gap to receive the magnetically responsive needle.

8. The device of claim **7**, wherein the moveable magnet bar is slidable within the first gap.

9. The device of claim **7**, wherein the moveable magnet bar is translocatable from the first gap.

10. The device of claim **7**, wherein the moveable magnet bar is rotatable within the first gap.

11. The device of claim **1**, wherein the magnet includes a magnetic core having a first gap to engage a moveable magnet bar and a second gap to receive the magnetically responsive needle.

12. The device of claim **11**, wherein the moveable magnet bar is rotatable within the first gap.

13. A system for visualizing a medical object trajectory comprising:

a processing and display generating system;

an ultrasound probe for scanning tissue in signal communication with the processing and display generating system; and

at least one camera for capturing at least one image of a medical object in signal communication with the processing and display generating system,

wherein the processing and display generating system is configured to process signals received from the ultrasound probe, display an ultrasound image of the tissue, process signals received from the at least one camera to determine a trajectory of the medical object, and display a representation of the determined trajectory of the medical object on the ultrasound image.

14. The system of claim **13**, wherein the at least one camera includes a first camera that takes images of the medical object in a first direction and a second camera that takes images of the medical object in a second direction.

15. The system of claim **14**, wherein the first and second cameras are in a fixed position relative to the ultrasound probe.

16. The system of claim **15**, wherein the second direction is orthogonal to the first direction.

17. The system of claim **14**, wherein the medical object includes a cannula.

18. The system of claim **14**, wherein the medical object includes a plurality of reflectors and wherein the processing and display generating system is configured to determine a trajectory of the medical object based on light reflected by the plurality of reflectors.

19. The system of claim **18**, wherein the medical object includes a needle having a bevel, at least one of the reflectors is located near the bevel, and the processing and display generating system is configured to determine a trajectory of the bevel.

20. The system of claim **19**, wherein the processing and display generating system is configured to display a cross-sectional image of a target vein located within the scanned tissue on the ultrasound image and wherein the processing

and display generating system is configured to display a representation of the determined trajectory of the medical object on the ultrasound image.

21. The system of claim **20**, wherein the representation of the determined trajectory includes cross-hairs.

22. The system of claim **21**, further comprising an illumination source for illuminating the medical object during image capture.

23. The system of claim **22**, wherein the illumination source includes infrared light emitting diodes.

24. The system of claim **14**, wherein at least one of the first and second cameras are configured to capture images of a portion of the medical object when the portion is in a subdermal location.

25. A method for visualizing a medical object trajectory comprising:

scanning tissue using an ultrasound probe;

displaying an ultrasound image of the tissue;

capturing at least one image of a medical object using at least one camera;

processing the at least one image to determine a trajectory of the medical object; and

displaying a representation of the determined trajectory of the medical object on the ultrasound image.

* * * * *