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(54) **RETRIEVAL AND CENTERING DEVICE AND METHOD WITH PRESSURE AND ULTRASOUND FEATURES**

(71) Applicant: **CRUX BIOMEDICAL, INC.**, San Diego, CA (US)

(72) Inventors: **Jeremy Stigall**, San Diego, CA (US); **Eric Johnson**, Woodside, CA (US)

(21) Appl. No.: **14/858,466**

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Related U.S. Application Data

(63) Continuation-in-part of application No. 14/777,224, filed on Sep. 15, 2015, filed as application No. PCT/US14/30392 on Mar. 17, 2014.

(60) Provisional application No. 61/794,016, filed on Mar. 15, 2013, provisional application No. 62/052,406, filed on Sep. 18, 2014.

Publication Classification

(51) **Int. Cl.**

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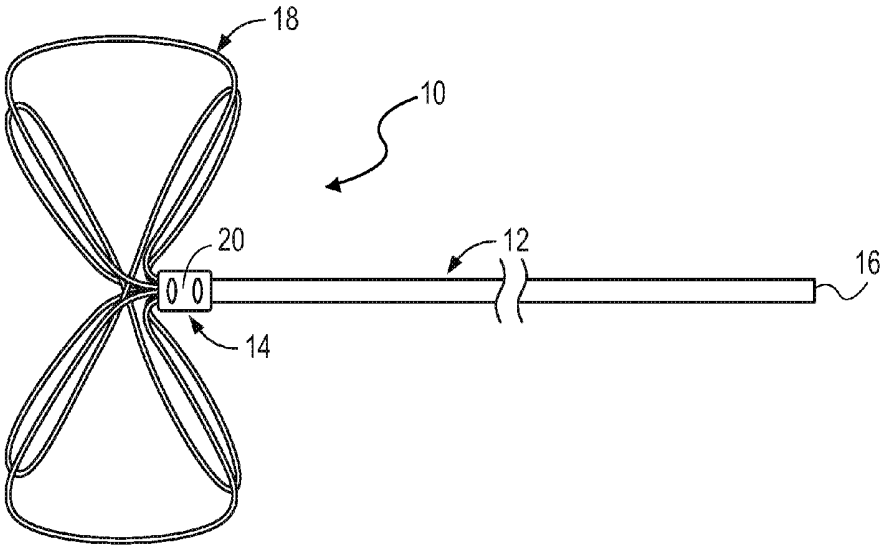
A61B 19/00	(2006.01)
A61B 8/12	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 17/221*** (2013.01); ***A61B 8/12*** (2013.01); ***A61F 2/01*** (2013.01); ***A61B 19/56*** (2013.01); *A61B 2017/22035* (2013.01)

(57) **ABSTRACT**

The present invention relates generally to devices and methods for retrieving or manipulating objects within a lumen. More specifically, embodiments of the invention relate to devices and methods for retrieving or manipulating medical devices from a body lumen. One embodiment of the present invention provides a retrieval device having a retrieval snare and an ultrasound transducer to assist in the intravascular navigation of the device. The device enables a user to capture a foreign object located within the human anatomy, grasp said object in a controlled manner, and retrieve and remove said object from the human anatomy.



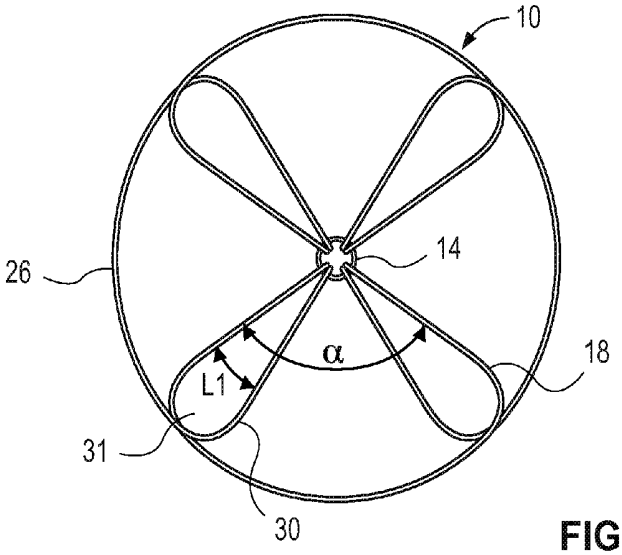


FIG. 1A

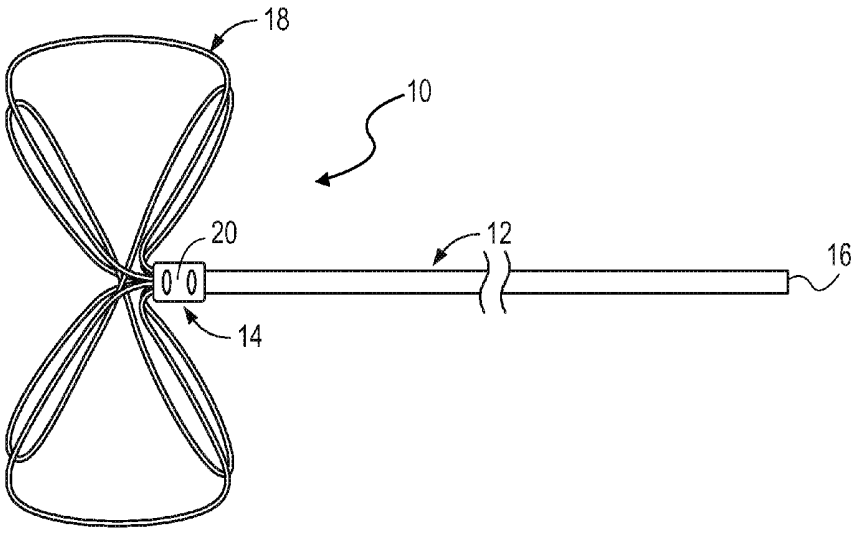


FIG. 1B

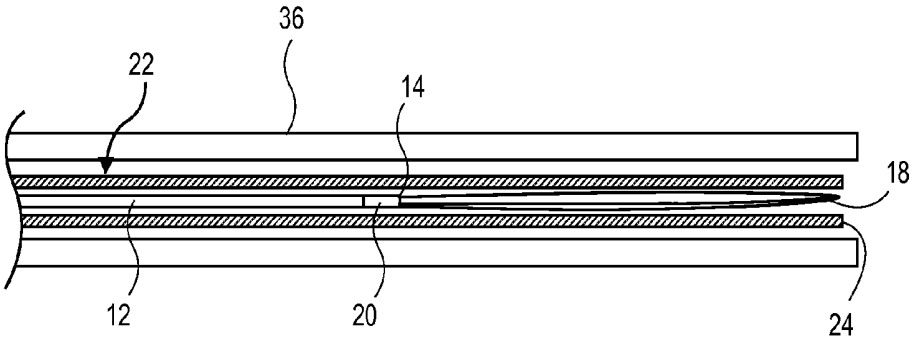


FIG. 1C

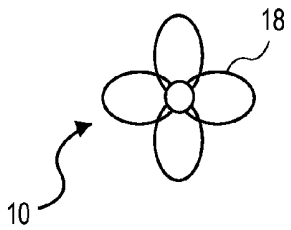


FIG. 1D

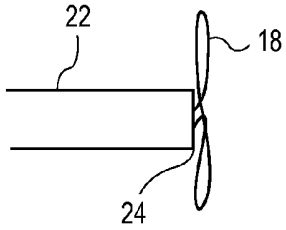


FIG. 1E

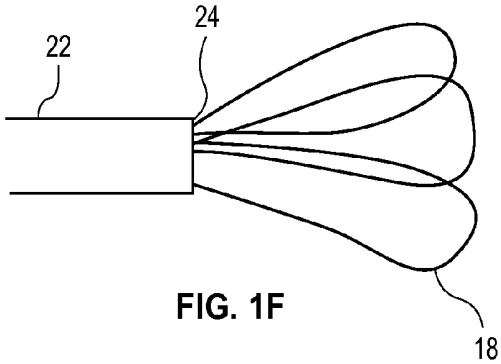


FIG. 1F

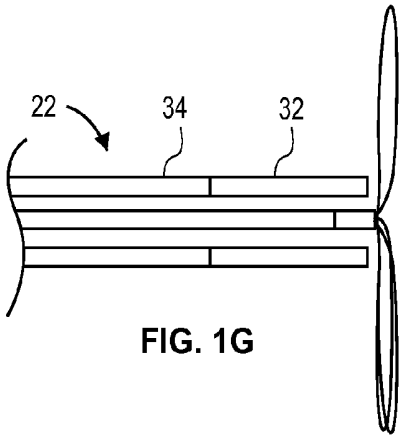


FIG. 1G

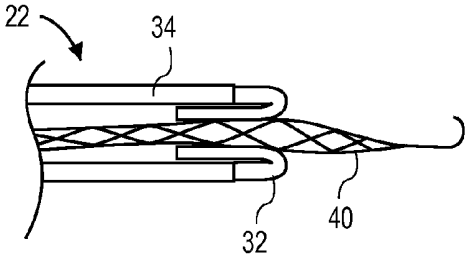


FIG. 1H

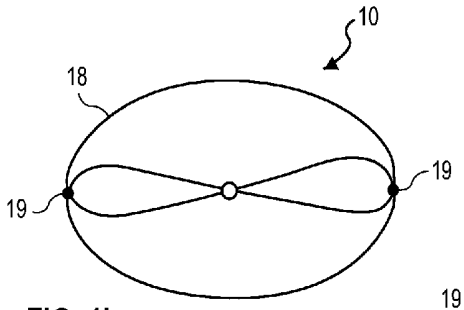


FIG. 1I

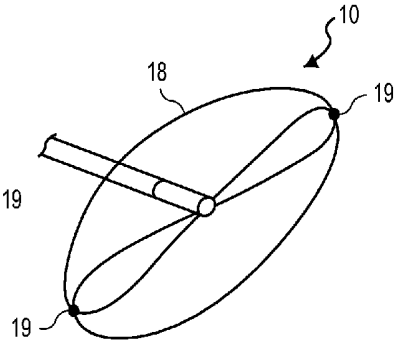


FIG. 1J

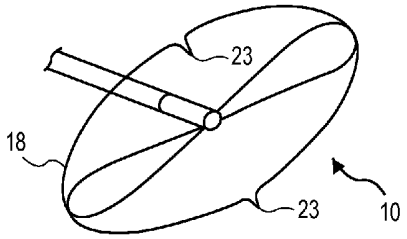


FIG. 1K

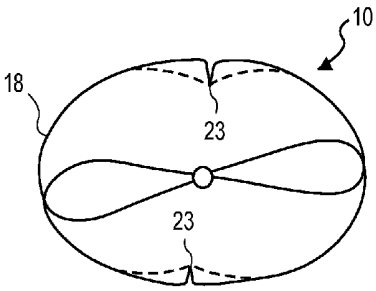


FIG. 1L

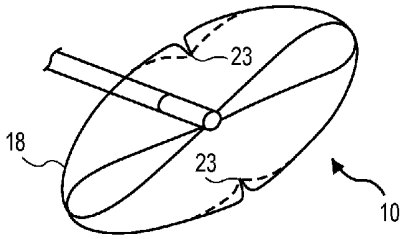


FIG. 1M

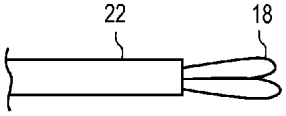


FIG. 1N

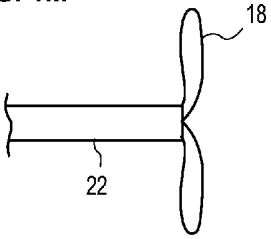


FIG. 1O

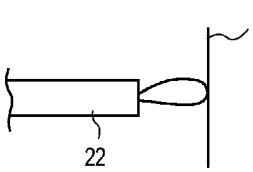


FIG. 1P

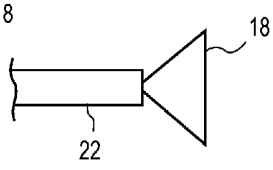


FIG. 1Q

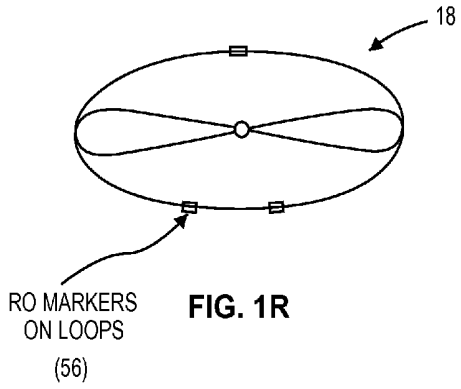


FIG. 1R

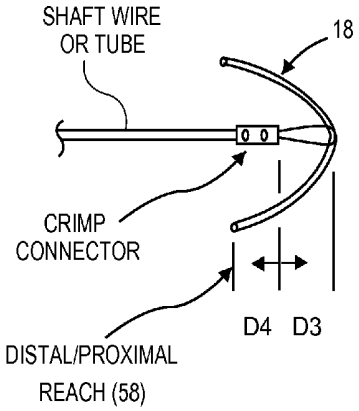


FIG. 1S

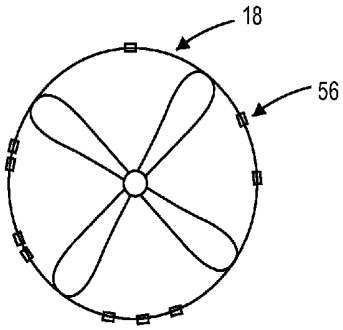


FIG. 1T

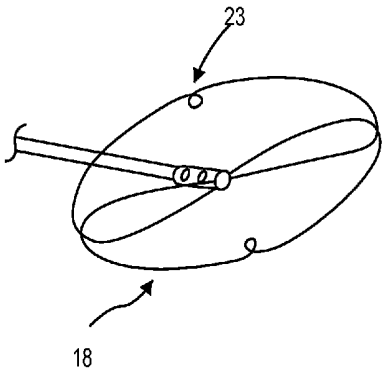


FIG. 1U

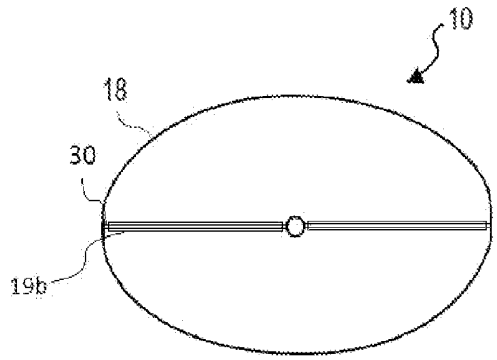


FIG. 1V

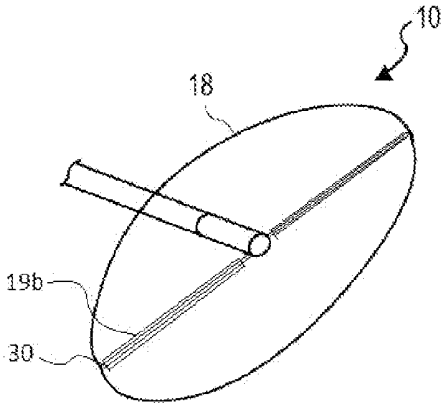


FIG. 1W

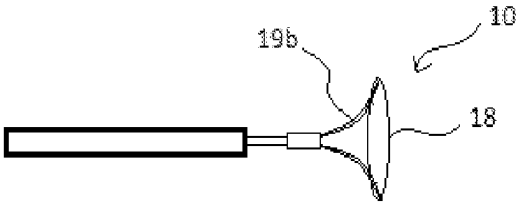


FIG. 1X

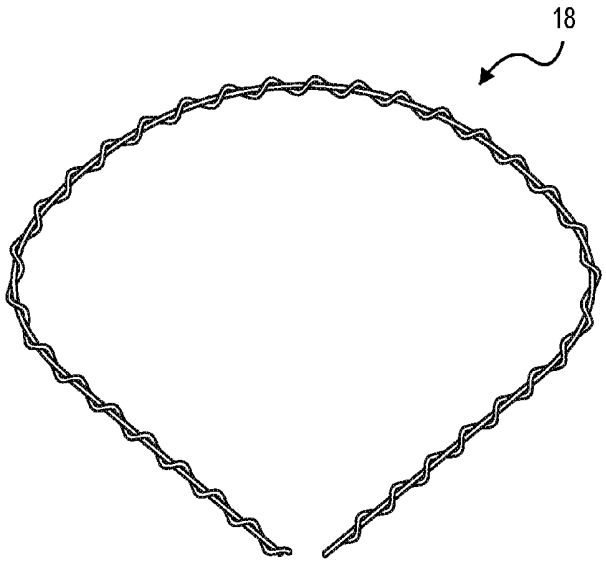


FIG. 2A

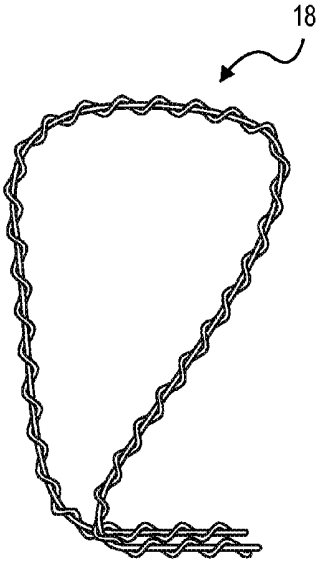


FIG. 2B

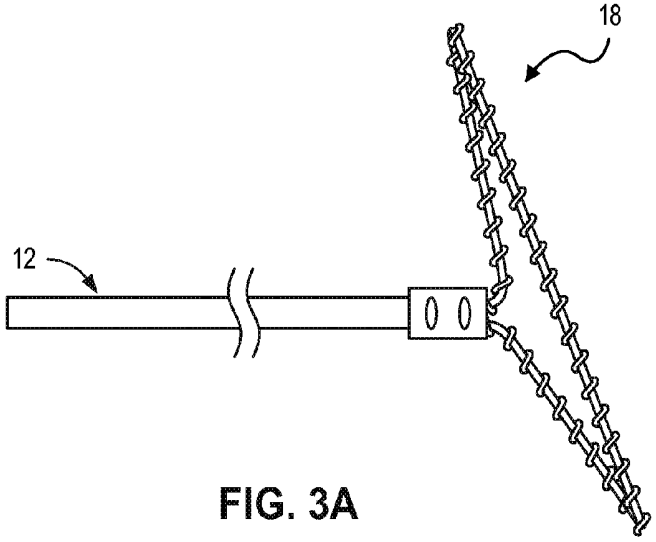


FIG. 3A

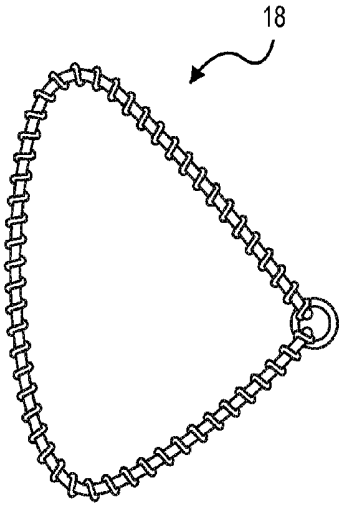


FIG. 3B

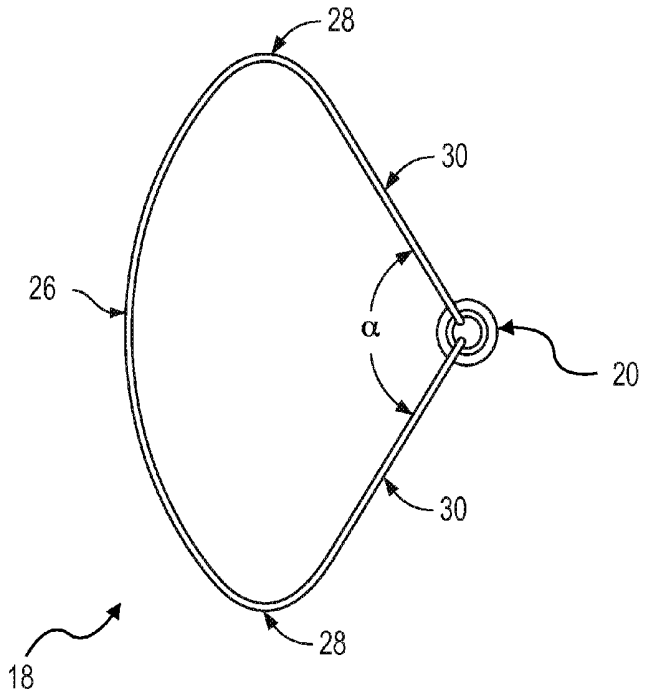


FIG. 4

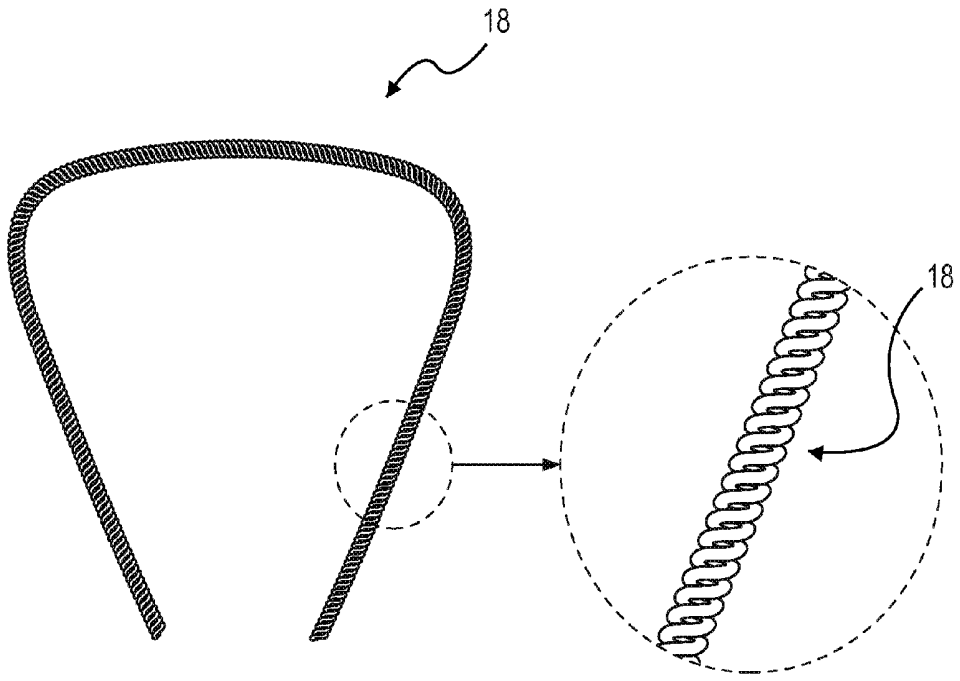


FIG. 5A FIG. 5B

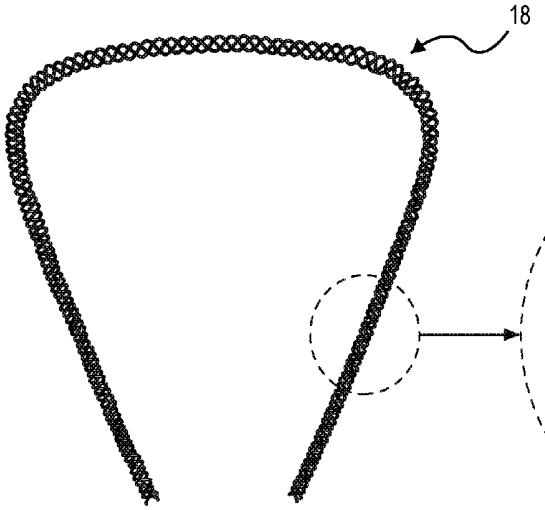


FIG. 6A

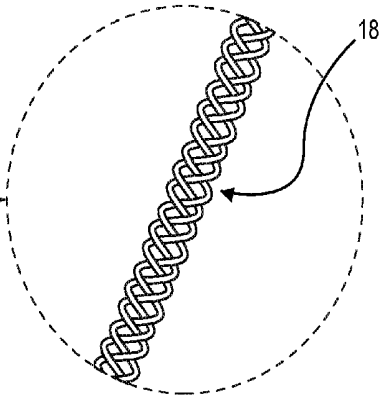


FIG. 6B

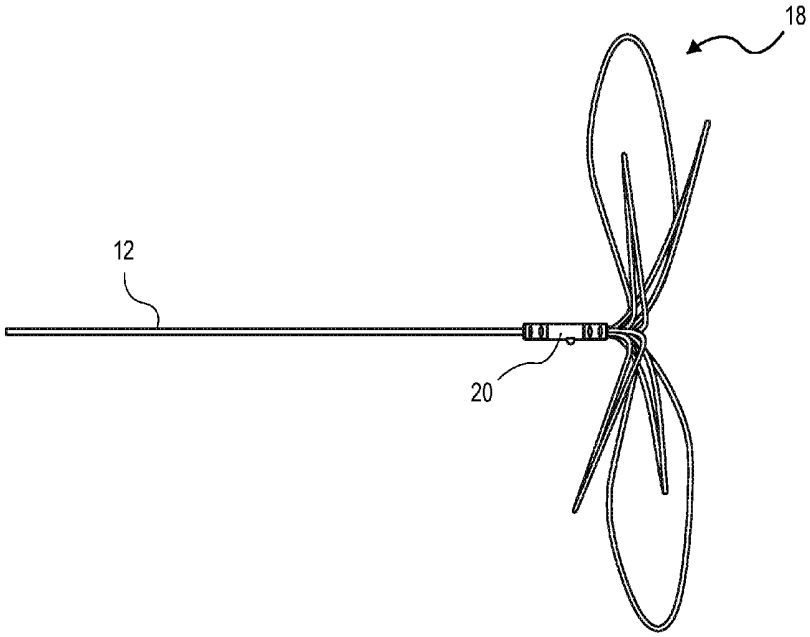


FIG. 7

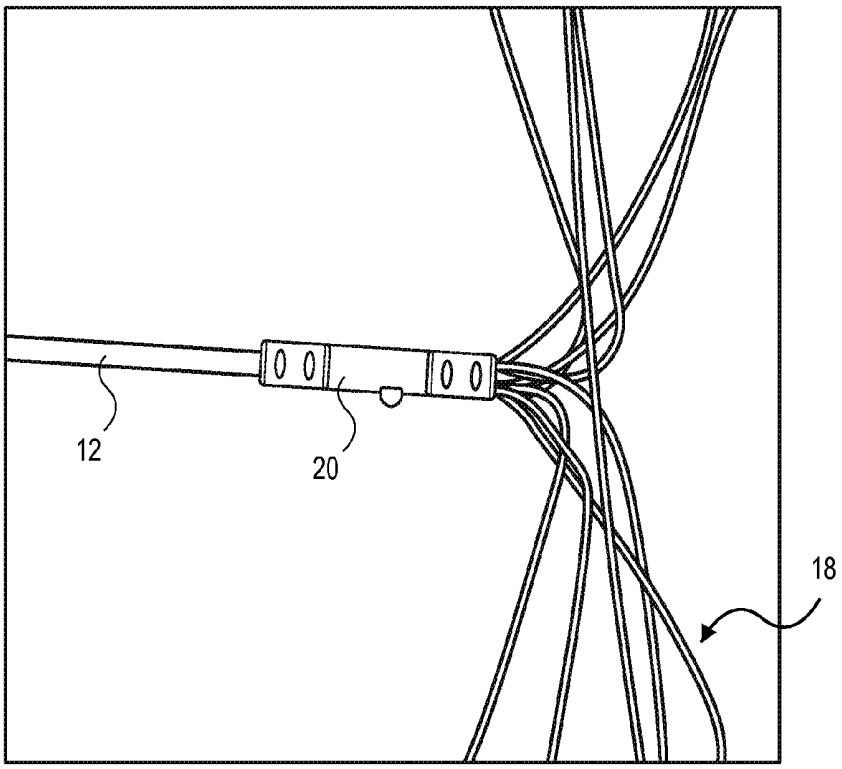


FIG. 8

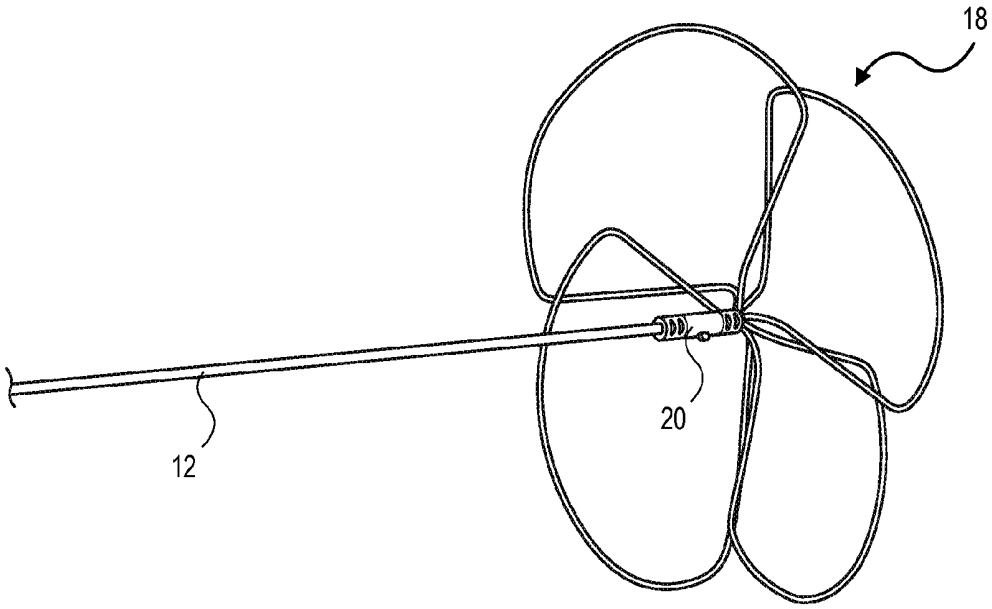


FIG. 9

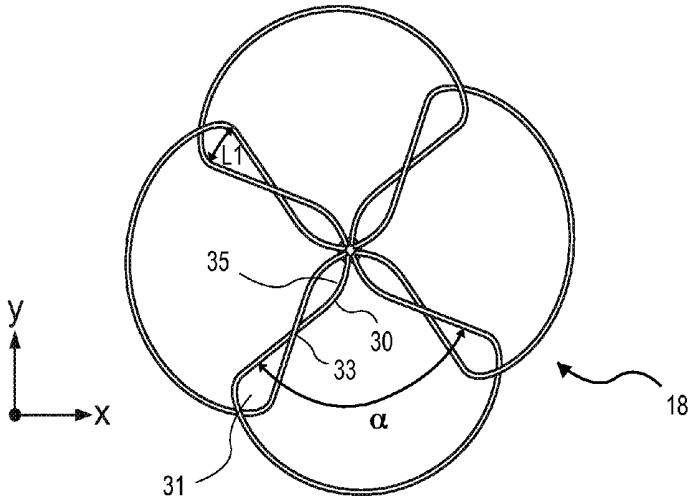


FIG. 10

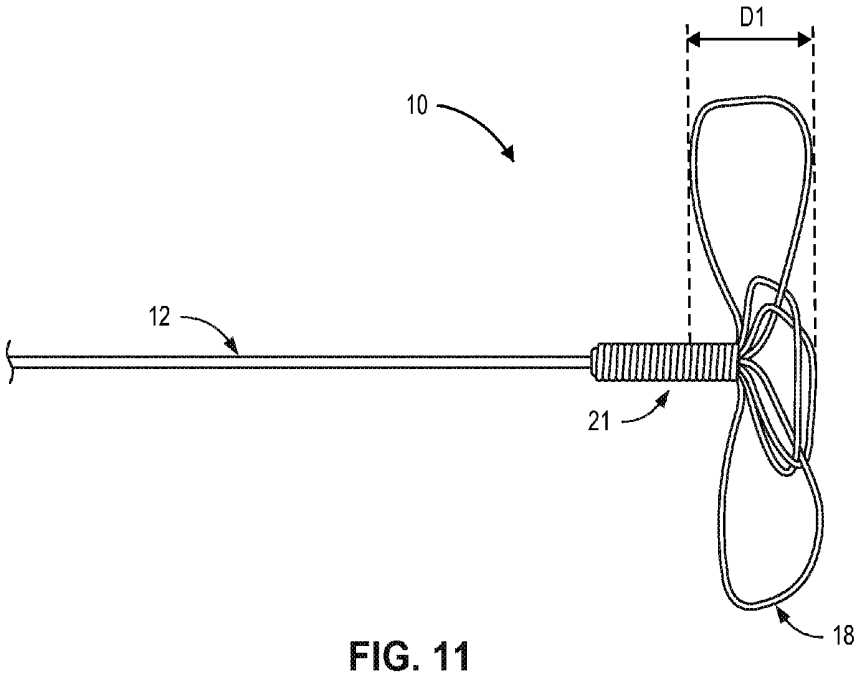


FIG. 11

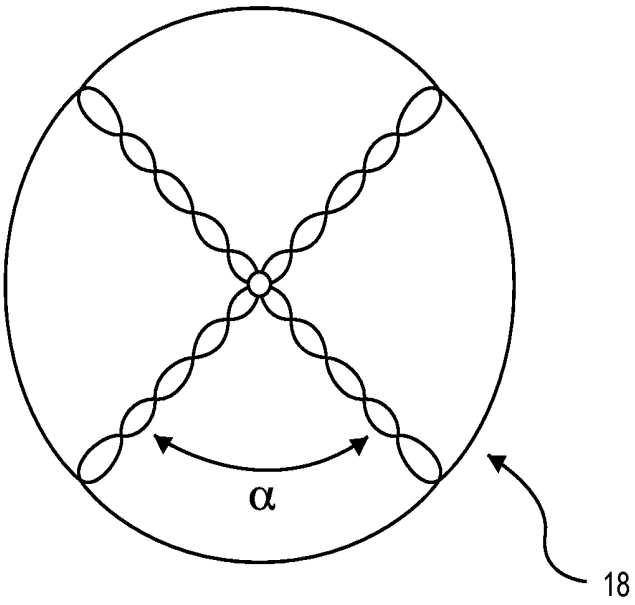


FIG. 10A

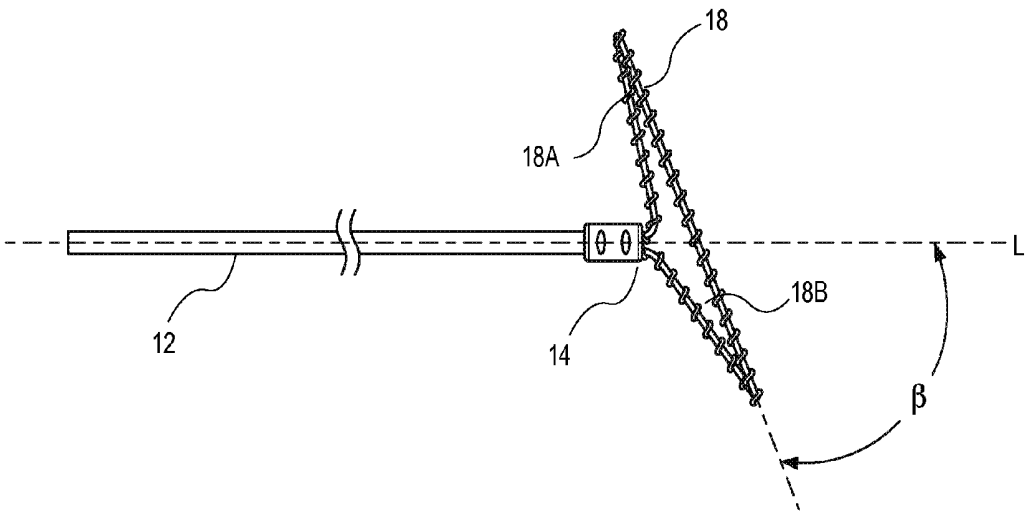


FIG. 12

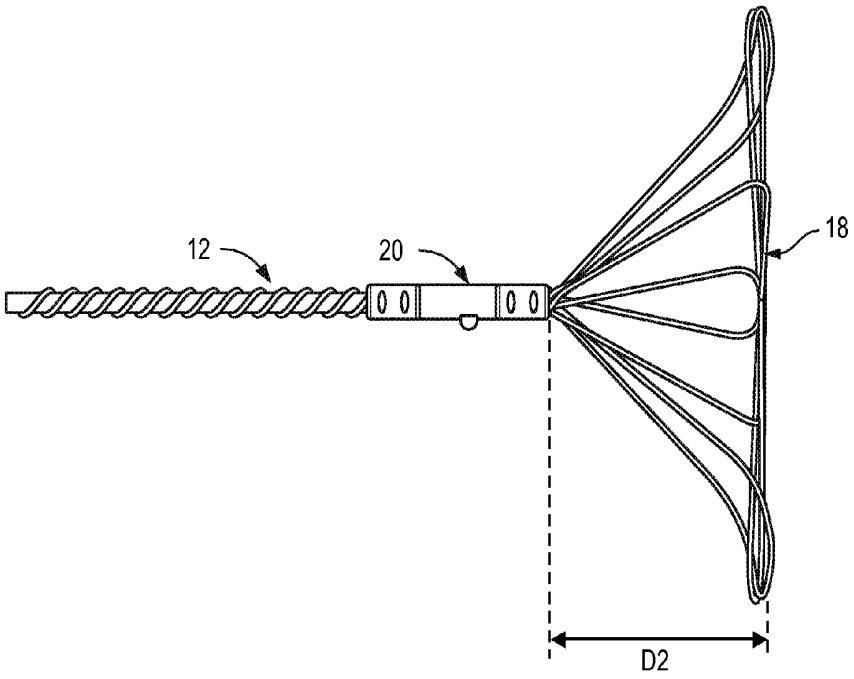


FIG. 13

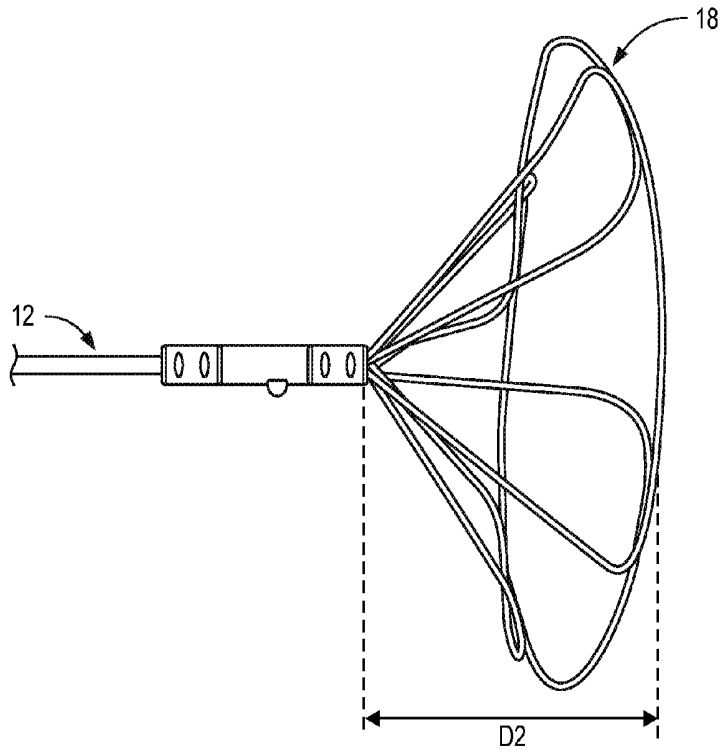


FIG. 14

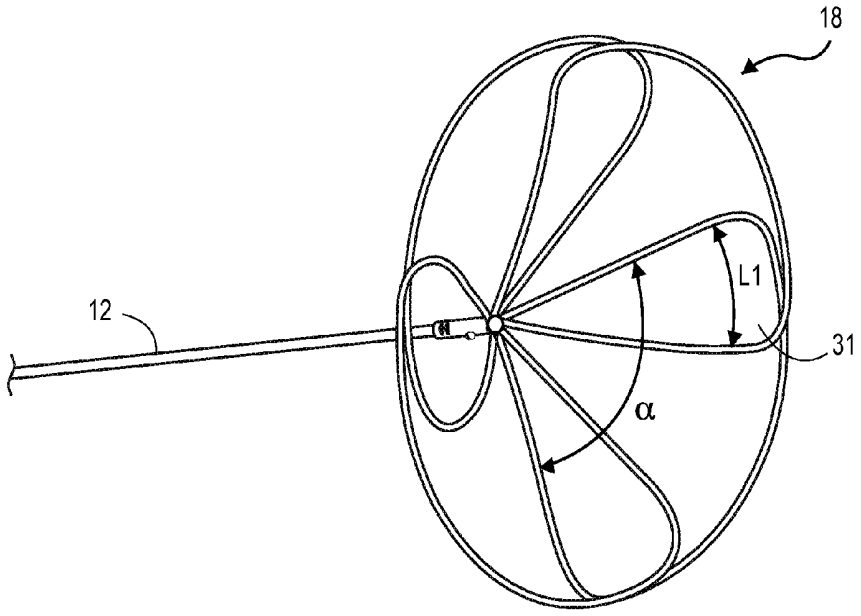


FIG. 15

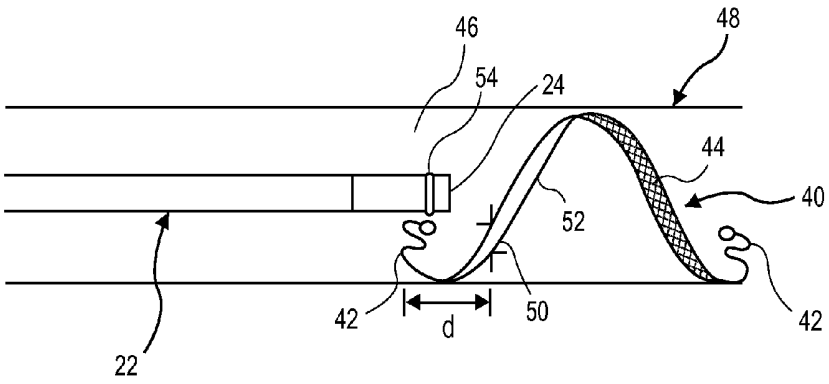


FIG. 16

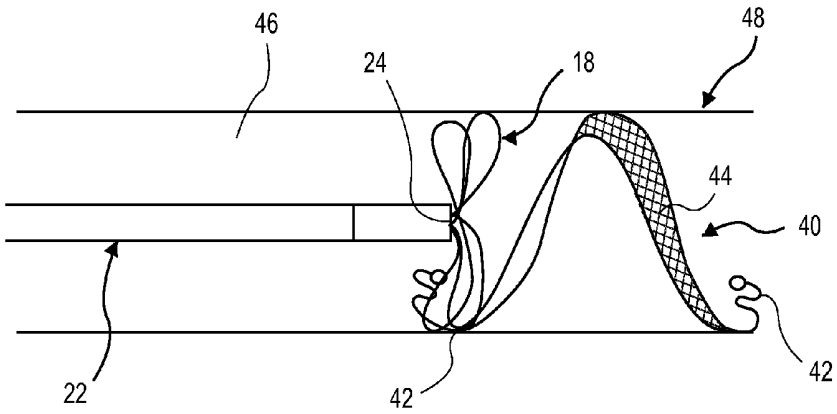


FIG. 17

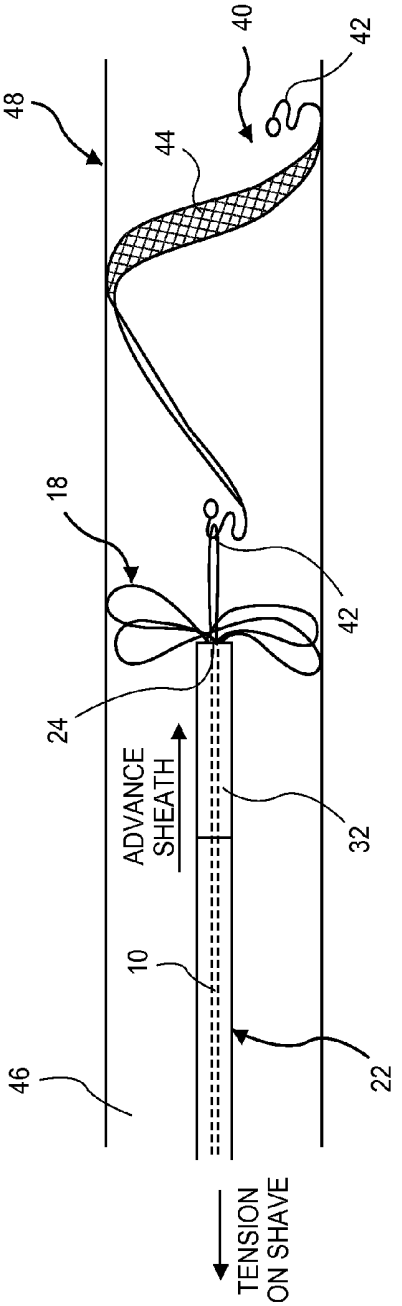

48
40
42
44
18
42
24
ADVANCE SHEATH
32
10
46
22
TENSION ON SHAVE

FIG. 18

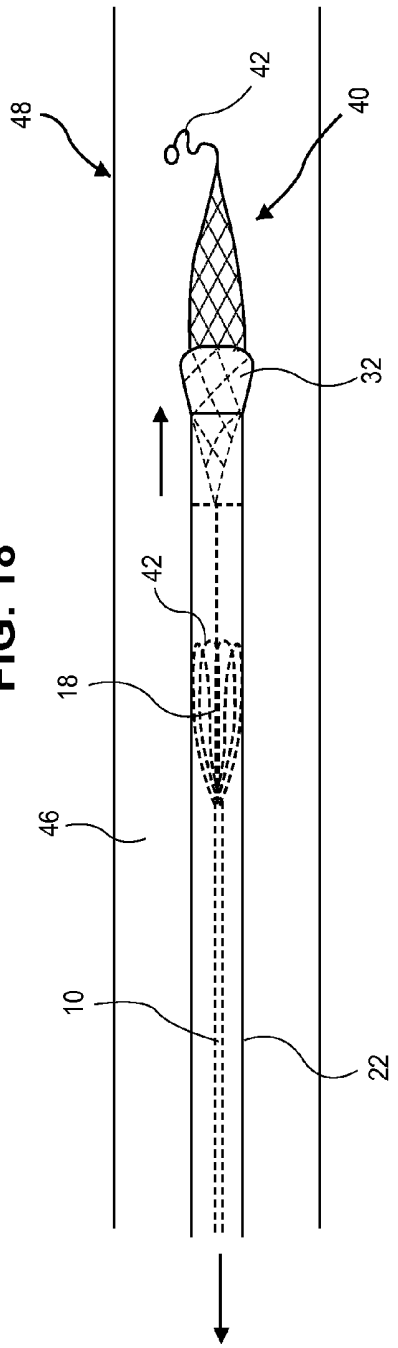

48
42
40
32
42
18
46
10
22

FIG. 19

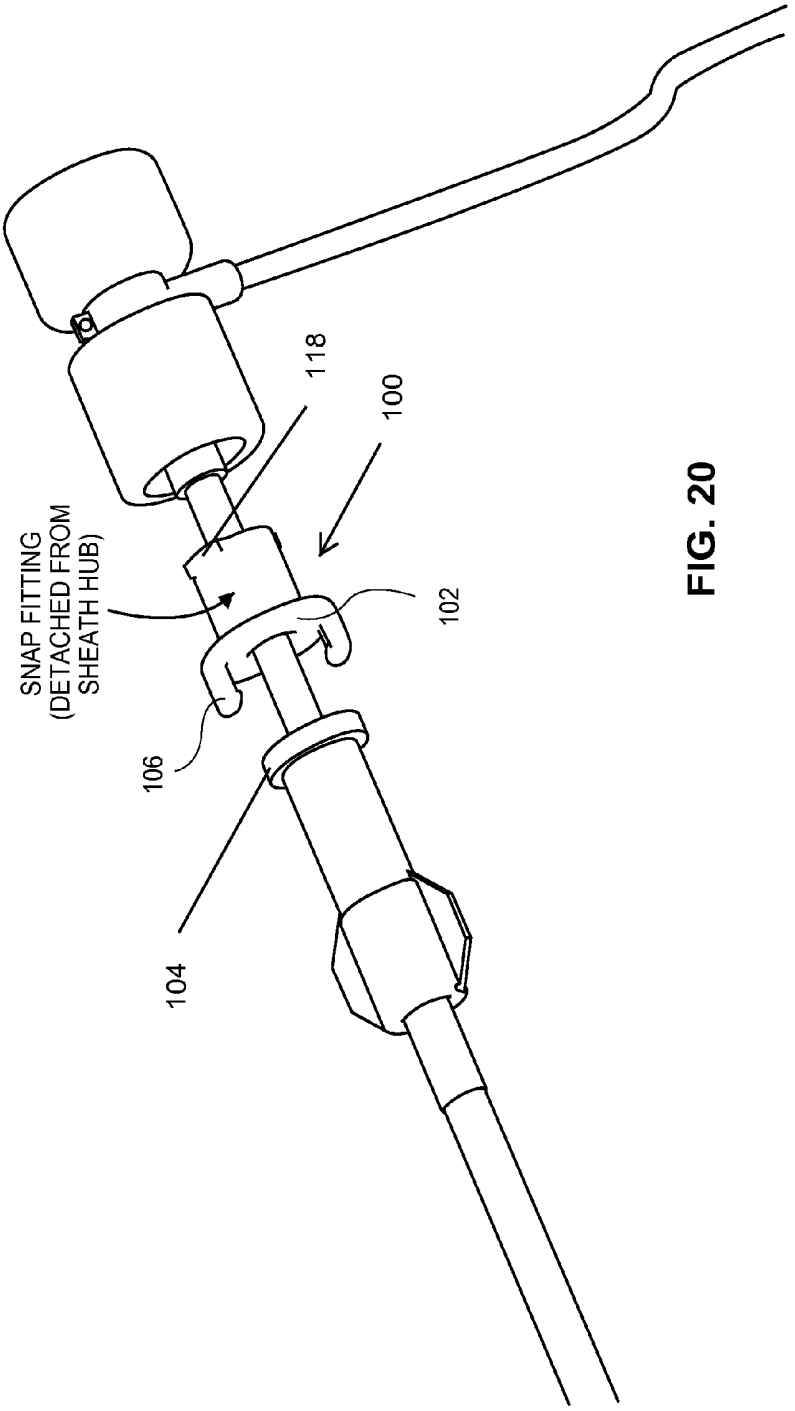


FIG. 20

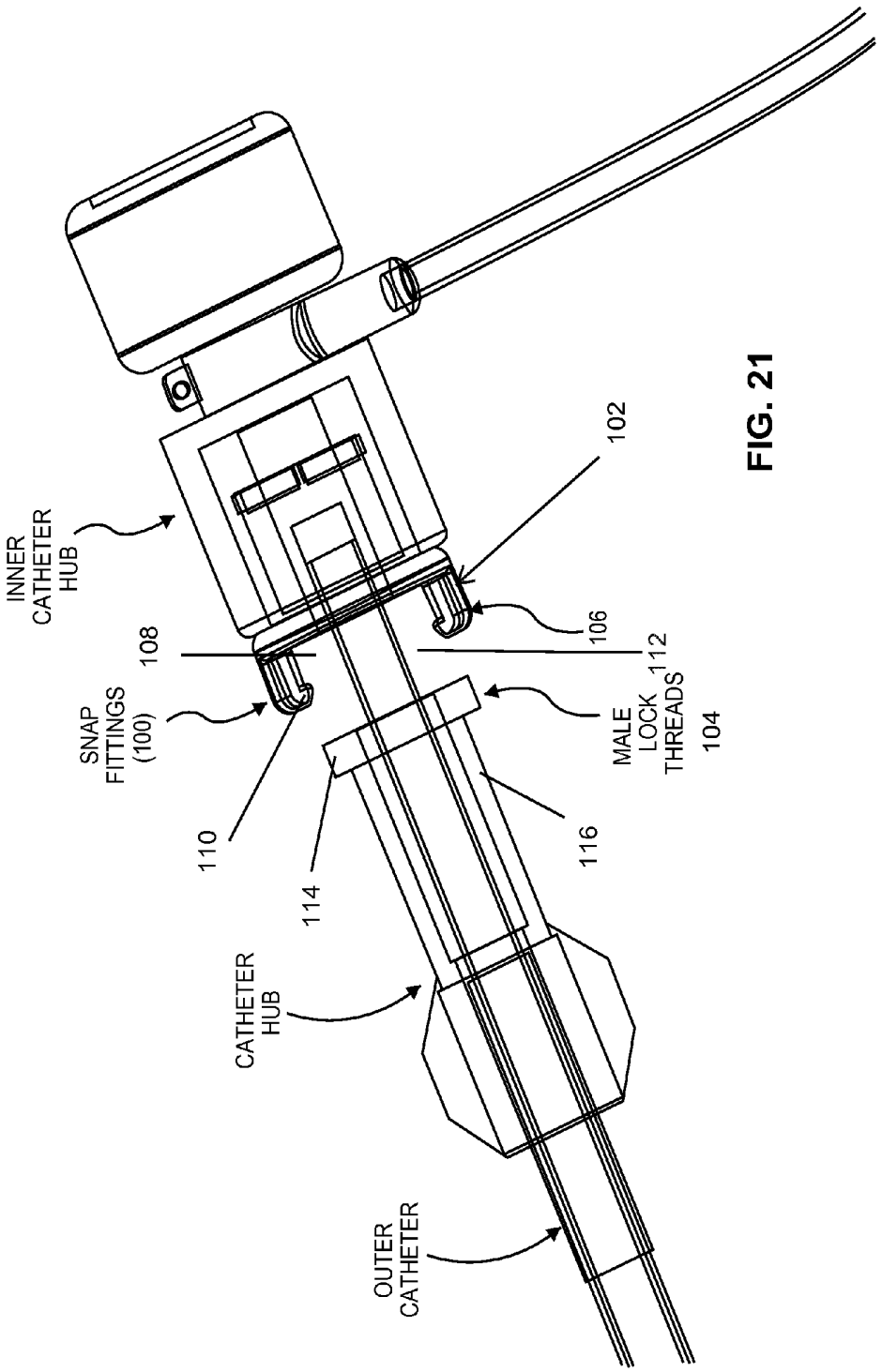

INNER CATHETER HUB
102
108
106
112
SNAP FITTINGS (100)
MALE LOCK THREADS
104
110
114
116
CATHETER HUB
OUTER CATHETER

FIG. 21

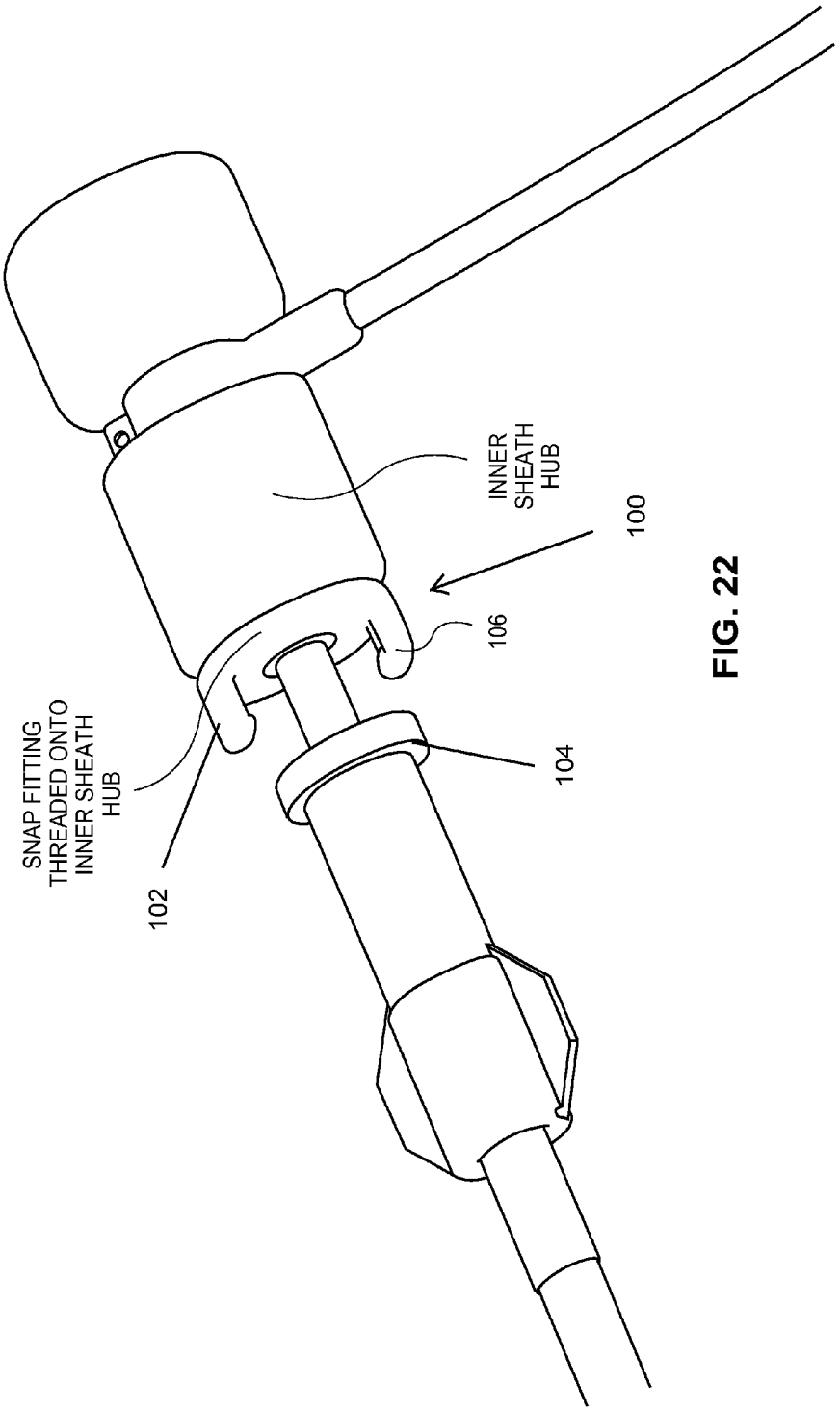

INNER SHEATH HUB
100
106
104
SNAP FITTING THREADED ONTO INNER SHEATH HUB
102

FIG. 22

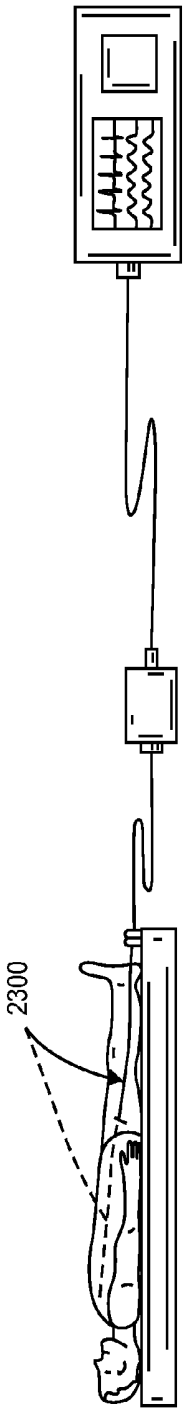


FIG. 23A

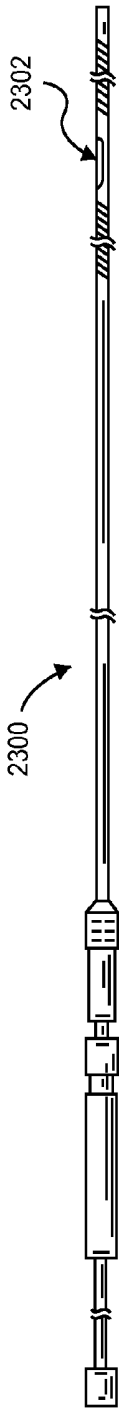


FIG. 23B

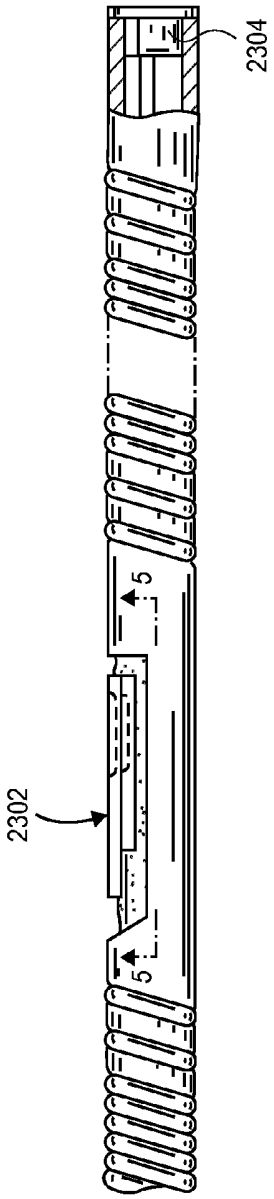


FIG. 23C

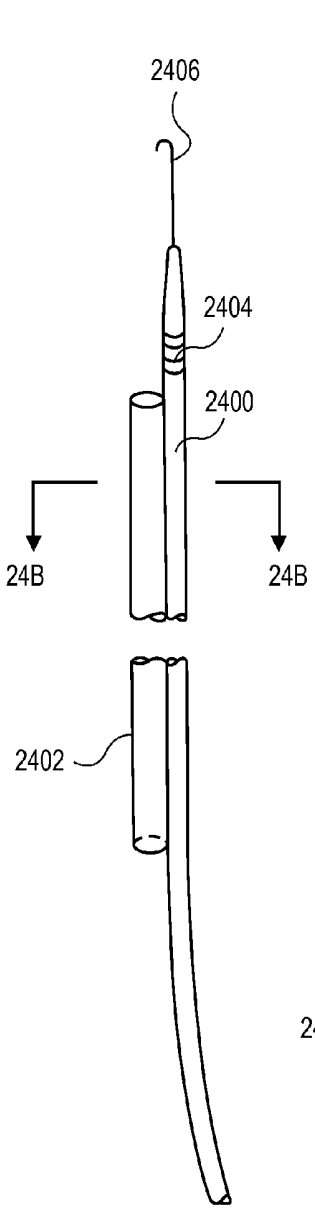


FIG. 24A

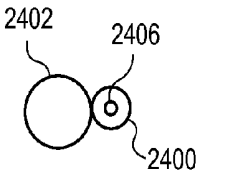


FIG. 24B

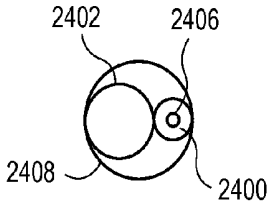


FIG. 24D

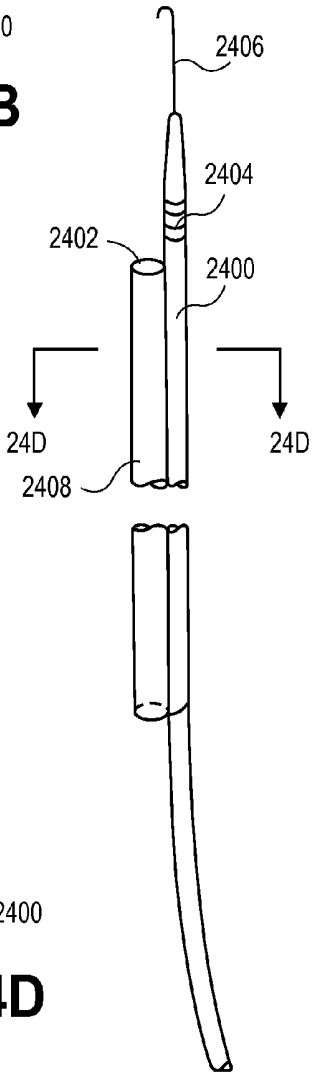
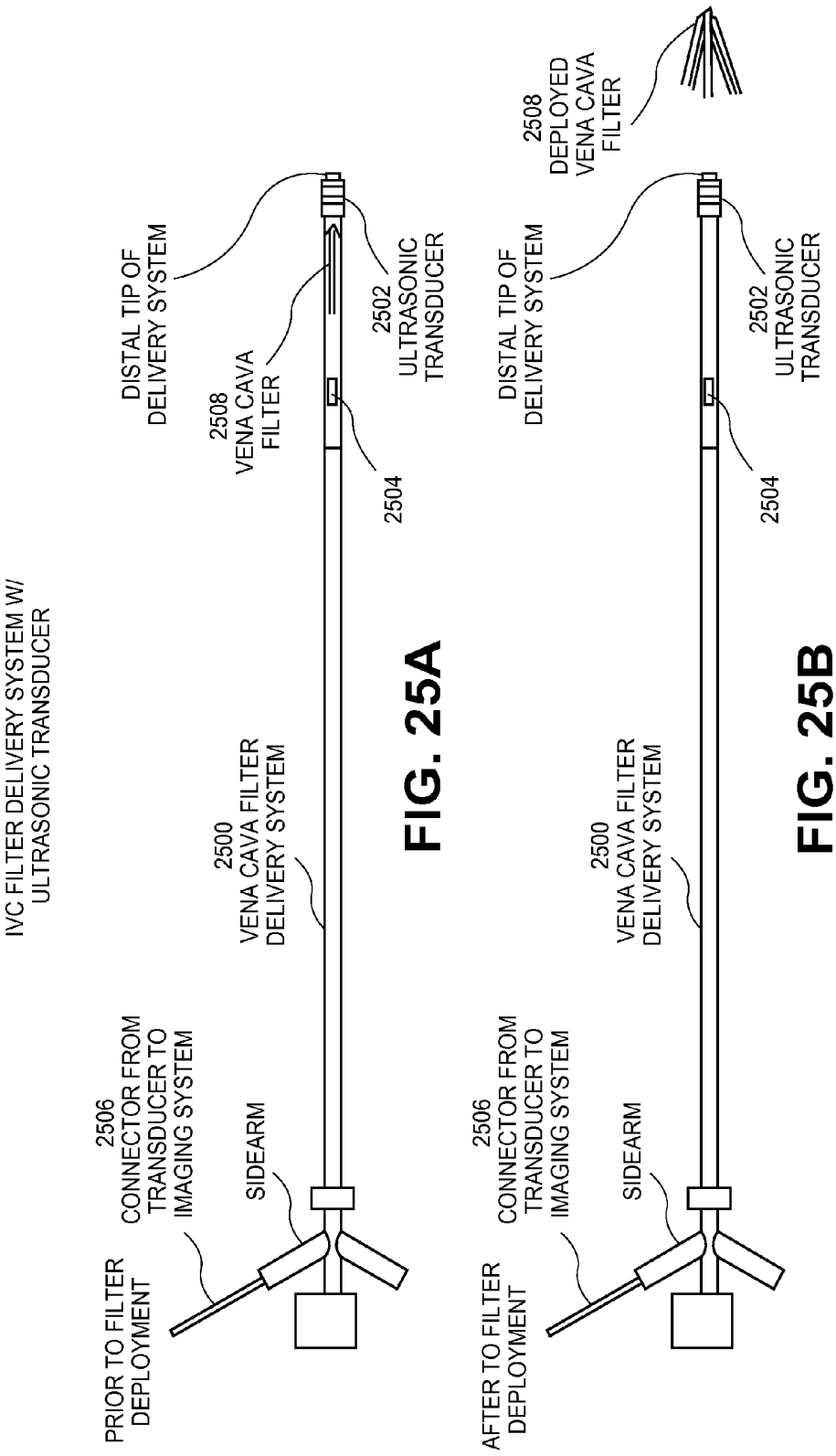


FIG. 24C


IVC FILTER DELIVERY SYSTEM W/
ULTRASONIC TRANSDUCER
PRIOR TO FILTER
DEPLOYMENT
2506
CONNECTOR FROM
TRANSDUCER TO
IMAGING SYSTEM
SIDEARM
2500
VENA CAVA FILTER
DELIVERY SYSTEM
DISTAL TIP OF
DELIVERY SYSTEM
2508
VENA CAVA
FILTER
2502
ULTRASONIC
TRANSDUCER
2504
FIG. 25A
AFTER TO FILTER
DEPLOYMENT
2506
CONNECTOR FROM
TRANSDUCER TO
IMAGING SYSTEM
SIDEARM
2500
VENA CAVA FILTER
DELIVERY SYSTEM
DISTAL TIP OF
DELIVERY SYSTEM
2508
DEPLOYED
VENA CAVA
FILTER
2502
ULTRASONIC
TRANSDUCER
2504
FIG. 25B

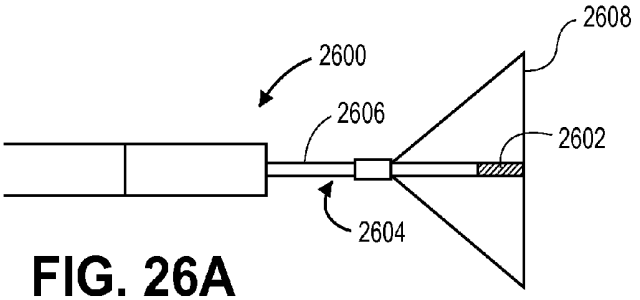


FIG. 26A

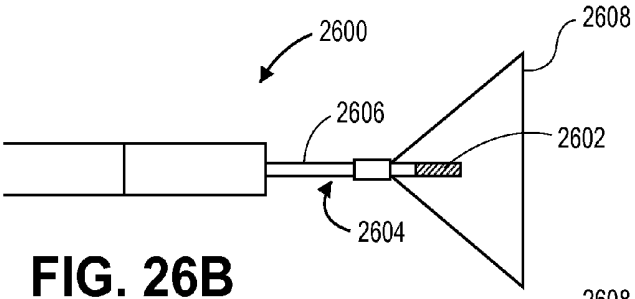


FIG. 26B

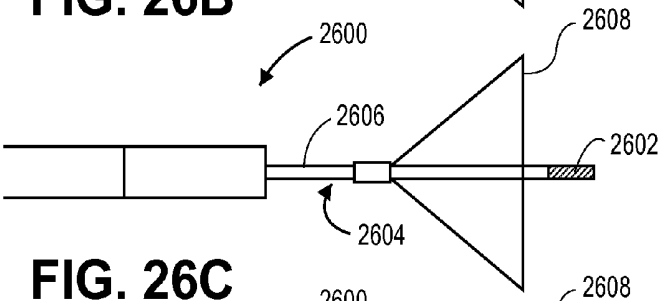


FIG. 26C

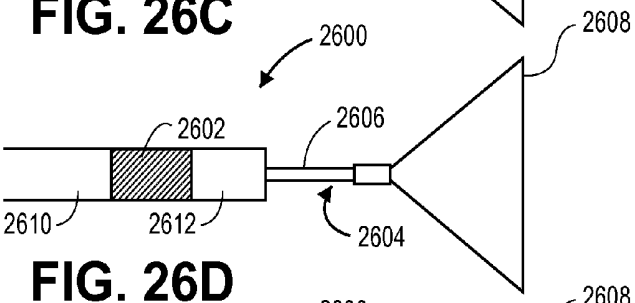


FIG. 26D

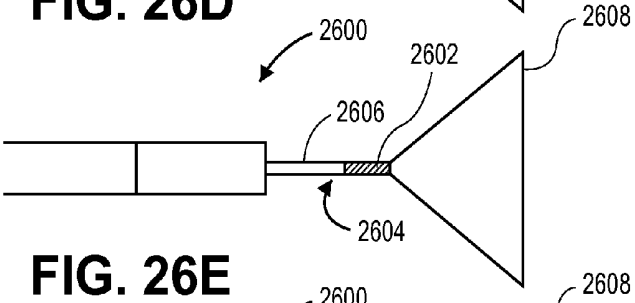


FIG. 26E

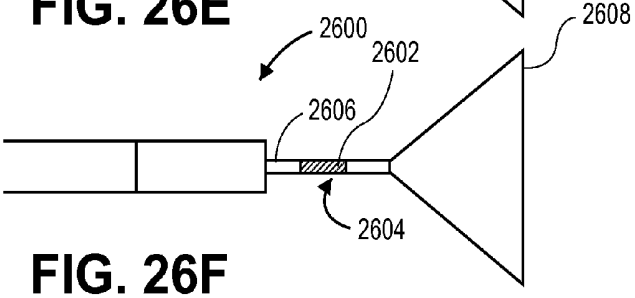


FIG. 26F

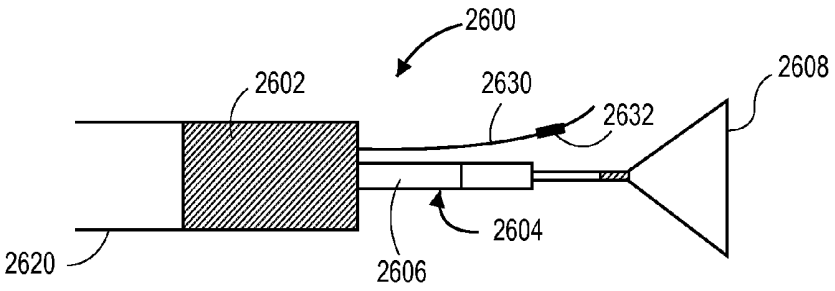


FIG. 26G

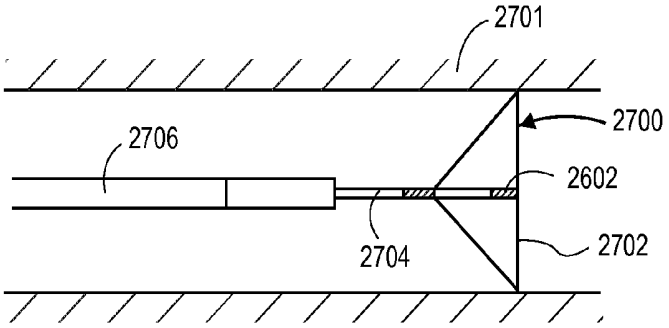


FIG. 27A

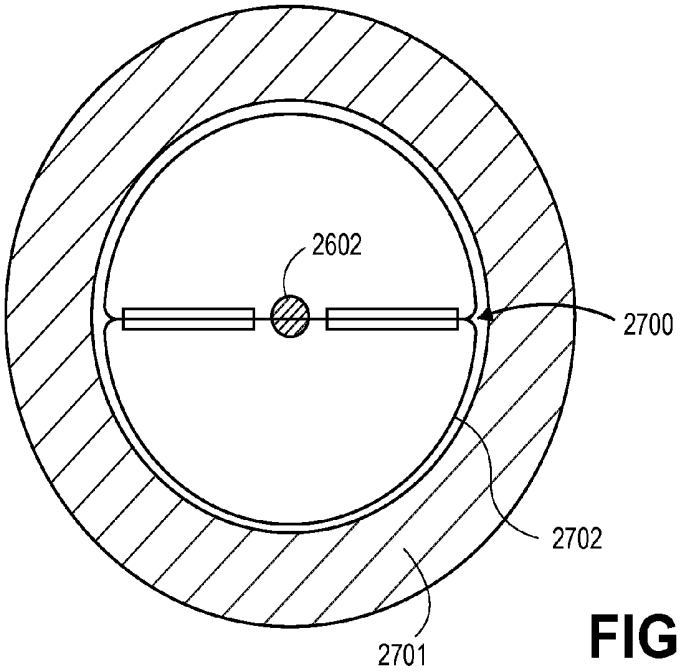


FIG. 27B

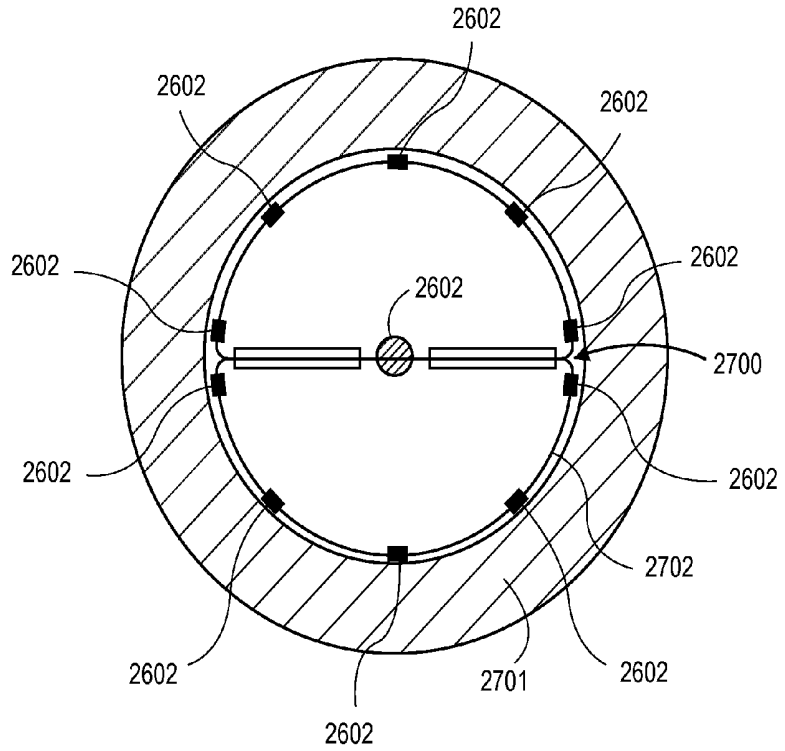

2602
2602
2602
2602
2602
2602
2700
2602
2602
2702
2602
2701
2602

FIG. 27C

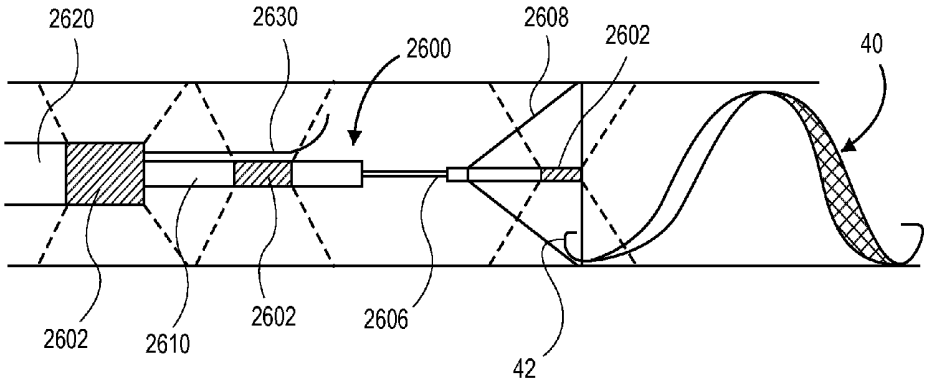


FIG. 28

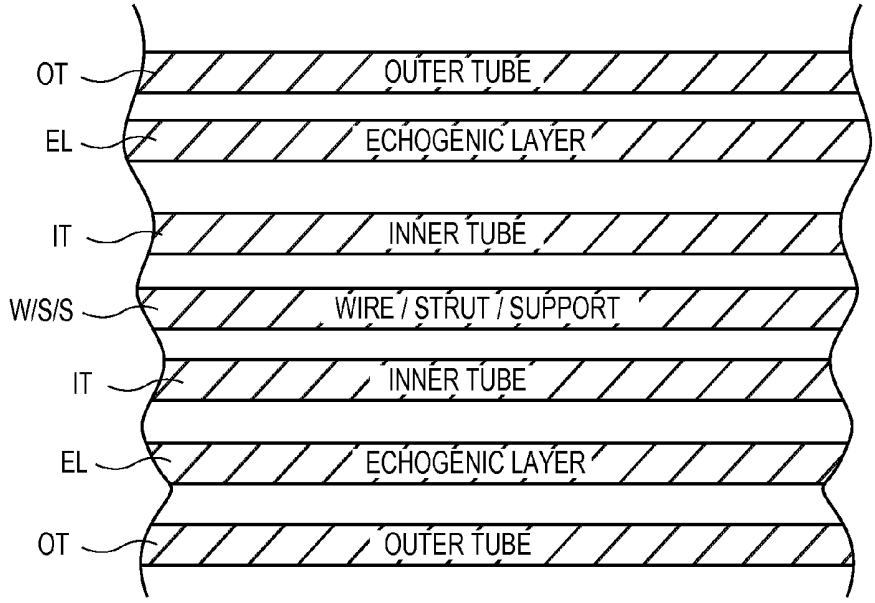
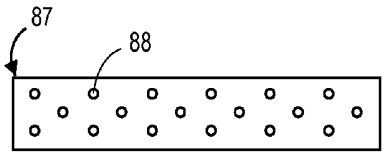
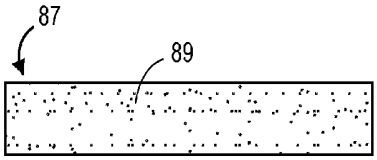

OT
OUTER TUBE
EL
ECHOGENIC LAYER
IT
INNER TUBE
W/S/S
WIRE / STRUT / SUPPORT
IT
INNER TUBE
EL
ECHOGENIC LAYER
OT
OUTER TUBE

FIG. 29



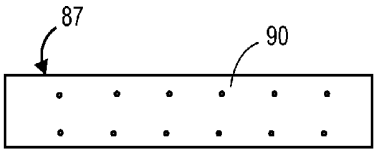
TUBE WITH LASER DRILLED HOLES

FIG. 30



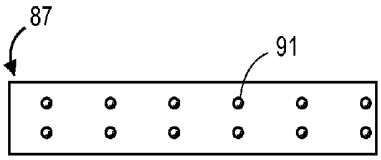
TUBE WITH ROUGH SURFACE
RAISED FEATURES

FIG. 31



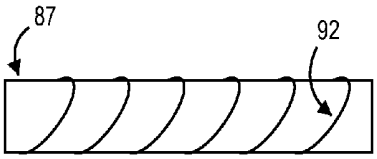
TUBE WITH BUBBLES

FIG. 32



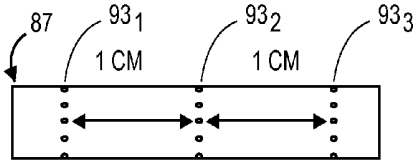
DIMPLES IN TUBE

FIG. 33



TUBE SANDWICH WITH
COIL/BRAID

FIG. 34



MEASUREMENT

FIG. 35

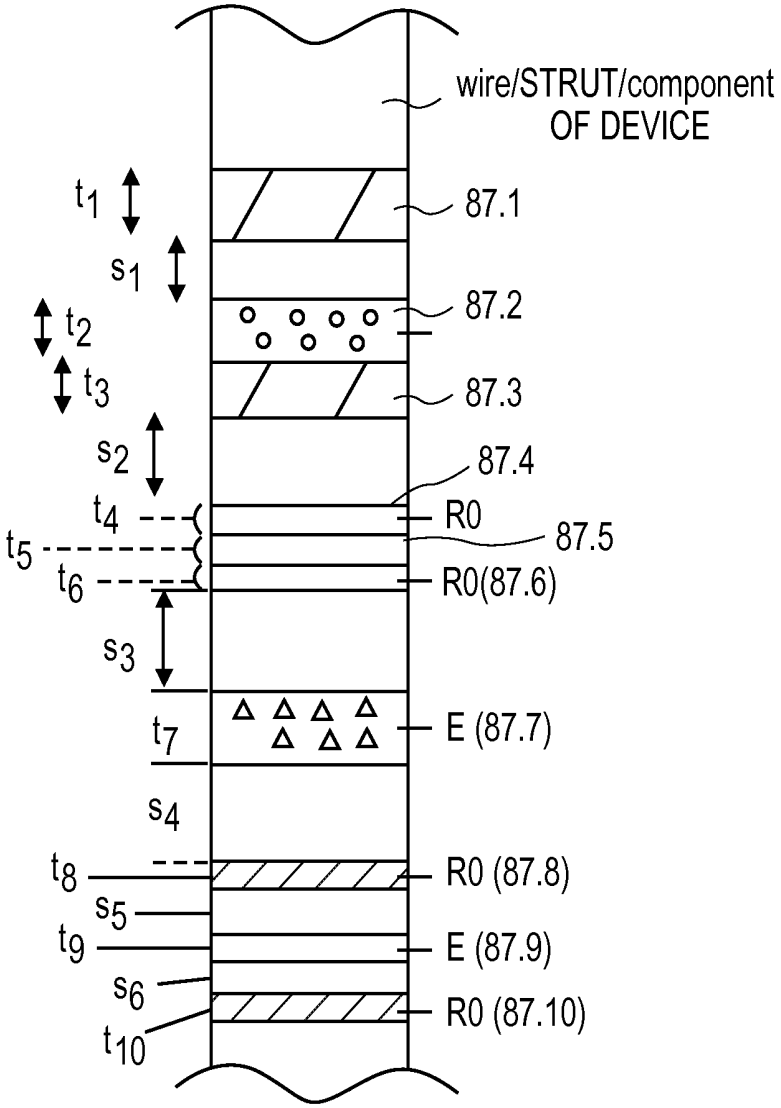

wire/STRUT/component
OF DEVICE
t1
87.1
s1
87.2
t2
t3
87.3
s2
87.4
t4
R0
87.5
t5
t6
R0(87.6)
s3
t7
E (87.7)
s4
t8
R0 (87.8)
s5
t9
E (87.9)
s6
R0 (87.10)
t10

FIG. 36

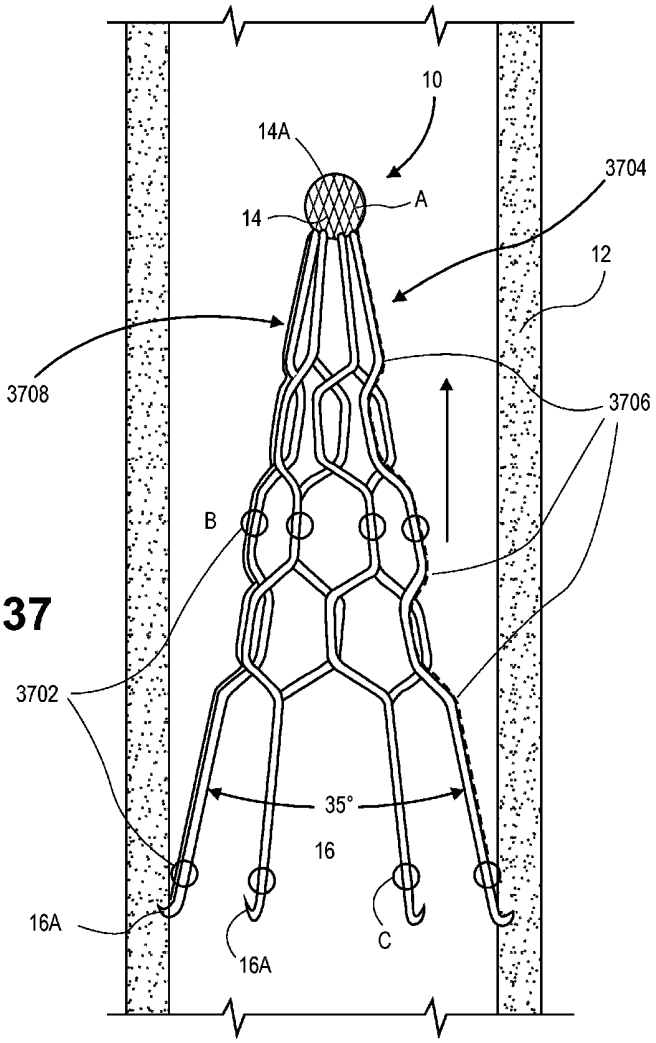


FIG. 37

FIG. 38

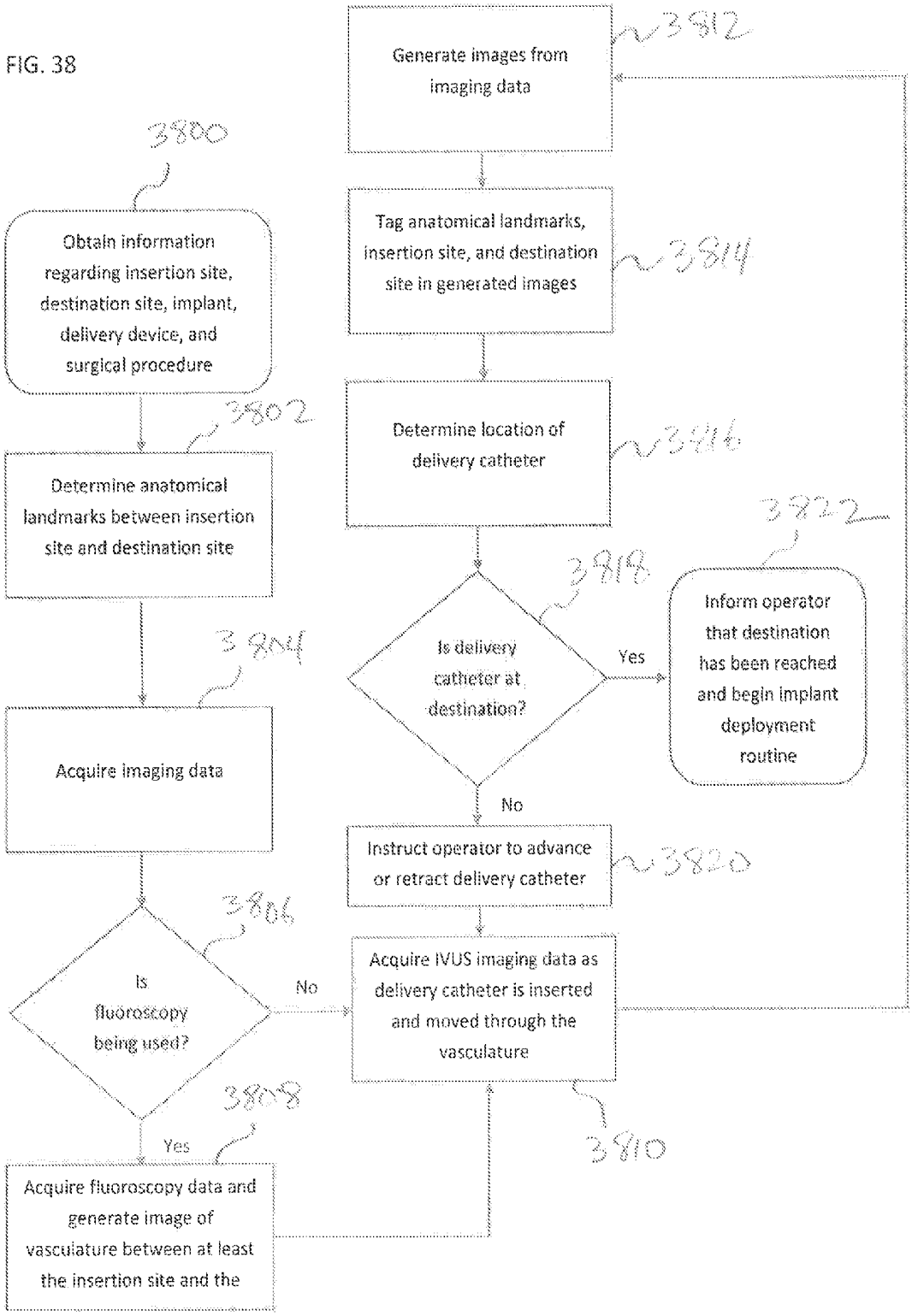
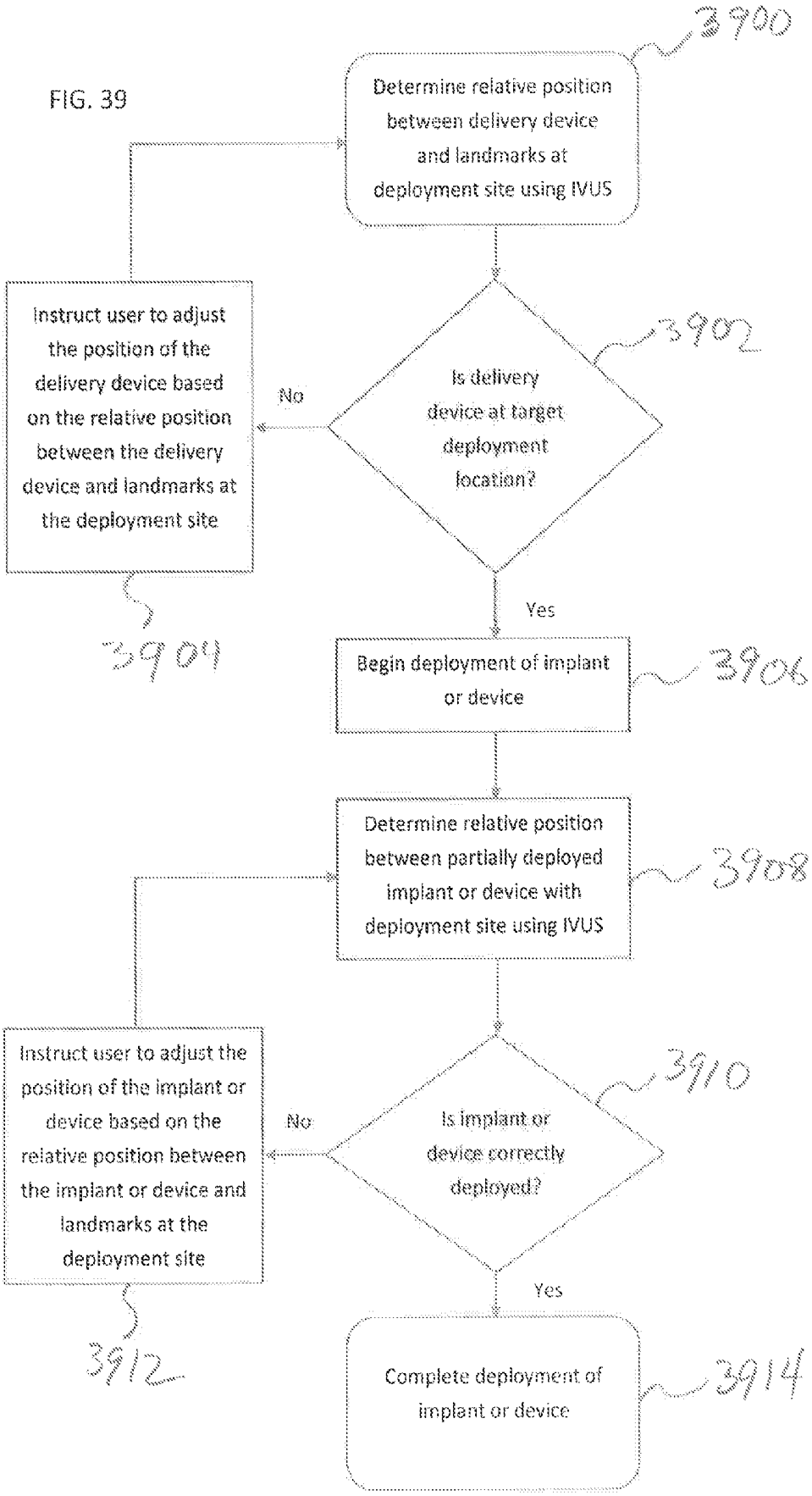

3800
Obtain information regarding insertion site, destination site, implant, delivery device, and surgical procedure
3802
Determine anatomical landmarks between insertion site and destination site
3804
Acquire imaging data
3806
Is fluoroscopy being used?
No
Yes
3808
Acquire fluoroscopy data and generate image of vasculature between at least the insertion site and the
3810
Acquire IVUS imaging data as delivery catheter is inserted and moved through the vasculature
3812
Generate images from imaging data
3814
Tag anatomical landmarks, insertion site, and destination site in generated images
3816
Determine location of delivery catheter
3818
Is delivery catheter at destination?
Yes
No
3820
Instruct operator to advance or retract delivery catheter
3822
Inform operator that destination has been reached and begin implant deployment routine

FIG. 39


3900
Determine relative position between delivery device and landmarks at deployment site using IVUS
3902
Is delivery device at target deployment location?
No
Instruct user to adjust the position of the delivery device based on the relative position between the delivery device and landmarks at the deployment site
3904
Yes
Begin deployment of implant or device
3906
Determine relative position between partially deployed implant or device with deployment site using IVUS
3908
3910
Is implant or device correctly deployed?
No
Instruct user to adjust the position of the implant or device based on the relative position between the implant or device and landmarks at the deployment site
3912
Yes
Complete deployment of implant or device
3914

RETRIEVAL AND CENTERING DEVICE AND METHOD WITH PRESSURE AND ULTRASOUND FEATURES

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation in part of U.S. patent application Ser. No. 14/777,224 filed on Sep. 15, 2015, which claims the benefit of PCT Application No. PCT/US2014/030392 filed on Mar. 17, 2014, which claims priority to U.S. Provisional Application No. 61/794,016 filed on Mar. 15, 2013. This application also claims priority to U.S. Provisional Application No. 62/052,406 filed on Sep. 18, 2014.

INCORPORATION BY REFERENCE

[0002] All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

[0003] The following patent is herein incorporated by reference in its entirety: U.S. patent application Ser. No. 11/969,827 titled, "ENDOLUMINAL FILTER WITH FIXATION" filed on Jan. 4, 2009.

FIELD

[0004] Embodiments of the invention relate generally to devices and methods for retrieving or manipulating objects within a lumen. More specifically, embodiments of the invention relate to devices and methods for retrieving or manipulating medical devices from a body lumen and use of an ultrasound transducer to assist with navigation of the device.

BACKGROUND

[0005] Embolic protection is utilized throughout the vasculature to prevent the potentially fatal passage of embolic material in the bloodstream to smaller vessels where it can obstruct blood flow. The dislodgement of embolic material is often associated with procedures which open blood vessels to restore natural blood flow such as stenting, angioplasty, arthrectomy, endarterectomy or thrombectomy. Used as an adjunct to these procedures, embolic protection devices trap debris and provide a means for removal for the body.

[0006] One widely used embolic protection application is the placement of filtration means in the vena cava. Vena cava filters (VCF) prevent the passage of thrombus from the deep veins of the legs into the blood stream and ultimately to the lungs. This condition is known as deep vein thrombosis (DVT), which can cause a potentially fatal condition known as pulmonary embolism (PE).

[0007] The next advancement in filters added the element of recoverability. Retrievable filters were designed to allow removal from the patient subsequent to initial placement. These filters can incorporate retrieval features that can be grasped and/or secured by a retrieval device, such as a snare based retrieval device. Grasping the retrieval feature using a snare generally requires the user to manipulate the snare over the retrieval feature, which can be difficult due to a variety of factors, such as retrieval feature geometry and location within the lumen, the structure and properties of the snare, and ability to visualize the retrieval feature and/or snare using a real-time visualization technique such as fluoroscopy.

[0008] Accordingly, it would be desirable to have an improved retrieval device that would facilitate engagement with a retrieval feature on a device making retrieval and/or manipulation of the device easier and faster to complete.

SUMMARY OF THE DISCLOSURE

[0009] The present invention relates generally to devices and methods for retrieving or manipulating objects within a lumen. More specifically, embodiments of the invention relate to devices and methods for retrieving or manipulating medical devices from a body lumen.

[0010] One embodiment of the present invention provides a novel and improved retrieval snare. The snare includes a snare wire, having a distal end and a proximal end, for use in the human anatomy, such as but not limited to blood vessels, pulmonary airways, reproductive anatomy, gastrointestinal anatomy, and organs such as the bladder, kidneys or lungs. The device enables a user to capture a foreign object located within the human anatomy, grasp said object in a controlled manner, and retrieve and remove said object from the human anatomy. Examples of foreign objects which might be removed from the human anatomy include implants such as stents, guidewires, leads, sheaths, filters, and valves, and organic objects such as kidney stones or calcified emboli. Other areas where embodiments of the snare can be used include, for example, removal and/or repositioning of distal protection devices that are used in a variety of medical procedures such as carotid stenting and percutaneous aortic valve replacement; and abdominal aortic aneurysm and thoracic aortic aneurysm devices. For example, a snare can be used to capture a vena cava filter and pull it into a retrieval sheath for removal from the patient. The snare is advanced through one or more retrieval sheaths, up to the site of a deployed filter. The snare is then deployed into the vessel, and engaged with the filter. Finally, the snare is held under tension while the sheath is advanced over said filter, collapsing it into the ID of said sheath. Another example is the use of a snare to grasp and extract loose kidney stones from a patient's kidneys. The snare is advanced through one or more sheaths, up to the site of the loose kidney stone. The snare is then deployed and engaged with the stone. Next, the snare is pulled into the sheath, drawing the stone into the distal ID of said sheath.

[0011] In some embodiments, a system for retrieving an object from a lumen is provided having a retrieval snare and an ultrasound transducer to assist in the intravascular navigation of the device. The system includes a retrieval device having a sheath configured to fit within the lumen, the sheath having a proximal end and a distal end. The device also includes a snare slidably disposed within the sheath, with the snare having a shaft with a longitudinal axis, a proximal end and a distal end and a plurality of loop elements in connection with the distal end of the shaft. The device further includes an intravascular ultrasound transducer located on the distal end of the sheath or shaft. A user interface configured to receive input from an operator regarding a surgical procedure including an insertion site and a destination site is also includes, as is a display. The device further includes a processor programmed to receive input from the user interface regarding the surgical procedure, determine anatomical landmarks between the insertion site and the destination site, receive an intravascular ultrasound signal from the intravascular ultrasound transducer, process the intravascular ultrasound signal into an image, and send the image to the display.

[0012] In some embodiments, the processor is further programmed to identify any anatomical landmarks in the image and tag the anatomical landmarks in the displayed image.

[0013] In some embodiments, the processor is further programmed to determine a location of the retrieval device based on the identified anatomical landmarks in the image.

[0014] In some embodiments, the processor is further programmed to determine whether the location is the destination site.

[0015] In some embodiments, the processor is further programmed to send a visual indicator to the display when the location has been determined to be the destination site.

[0016] In some embodiments, the visual indicator is color coded.

[0017] In some embodiments, the processor is further programmed to determine an orientation of the retrieval device with respect to anatomical landmarks using the processed intravascular ultrasound imaging signal.

[0018] In some embodiments, the processor is further programmed generate instructions for adjusting the position of the retrieval device based on the determined orientation of the retrieval device.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0020] FIG. **1**A is an axial view of the distal end of one embodiment of the snare device, showing the loop elements which substantially form a complete circle about the axis of the shaft. The edges of each loop overlap adjacent loops to ensure a substantially continuous circular pattern.

[0021] FIG. **1**B is a side perspective view of the snare device shown in FIG. **1**A, showing the loop elements such that the plurality of loop elements has an axial reach both proximal and distal the distal end of the shaft.

[0022] FIG. **1**C is a side cross-sectional view of a stowed snare within both an outer sheath and an inner sheath.

[0023] FIGS. **1**D-**1**F illustrate the various deployment stages of the loop elements of one embodiment of the snare. FIGS. **1**D and **1**E illustrate an initial deployment stage of the loop elements, while FIG. **1**F illustrates an intermediate deployment stage of the loop elements.

[0024] FIGS. **1**G and **1**H illustrate the flexible distal tip portion of the sheath with a deployed snare (FIG. **1**G) and a partially stowed snare (FIG. **1**H).

[0025] FIGS. **1**I-**1**J illustrate snare embodiments having two loop elements with a substantially elliptical or oblong fully deployed configuration.

[0026] FIGS. **1**K-**1**M illustrate snare embodiments having two loop elements with a substantially elliptical or oblong fully deployed configuration and a loop collapse facilitator.

[0027] FIGS. **1**N-**1**Q illustrate the stages of deployment of an embodiment of a snare with two loop elements.

[0028] FIG. **1**R illustrates a snare embodiment having two loop elements with a substantially elliptical or oblong fully deployed configuration, and a plurality of radiopaque markers disposed on each loop in different patterns, to differentiate each loop element fluoroscopically.

[0029] FIG. **1**S is a side view of a snare embodiment having two loop elements with a substantially elliptical or oblong fully deployed configuration, showing the loop elements having both a distal and proximal reach.

[0030] FIG. **1**T illustrates a snare embodiment having four loop elements in a substantially circular fully deployed configuration, and a plurality of radiopaque markers disposed on each loop in different patterns, to differentiate each loop element fluoroscopically.

[0031] FIG. **1**U illustrates another snare embodiment having two loop elements with a substantially elliptical or oblong fully deployed configuration and a loop collapse facilitator.

[0032] FIGS. **1**V-**1**X illustrate another snare embodiment having two loop elements that are fastened together at the swage and attached together with sleeves.

[0033] FIG. **2**A is an end view of an embodiment of a single loop element, using a single nitinol wire wrapped with a single radiopaque platinum wire.

[0034] FIG. **2**B is a perspective view of the single loop element shown in FIG. **2**A.

[0035] FIG. **3**A is a side view of another embodiment of a single loop on the end of a snare device, to illustrate the relative geometry of the loop elements.

[0036] FIG. **3**B is an end view of the single loop shown in FIG. **3**A.

[0037] FIG. **4** is an end view of a loop element and a hypo tube, to illustrate the D shape or pie shape geometry of the loop element features.

[0038] FIG. **5**A is an end view of an embodiment of a single loop element, using a plurality of wires which are twisted together to form a strand.

[0039] FIG. **5**B is a close up view of a portion of the single loop element strand shown in FIG. **5**A.

[0040] FIG. **6**A illustrates an embodiment of a single loop element, using a plurality of wires which are braided together to form a strand.

[0041] FIG. **6**B illustrates a close up view of a portion of the single loop element strand shown in FIG. **6**A.

[0042] FIG. **7** is a side view of an embodiment of a snare device using single wire loop elements, and a steel hypo tube which attaches the loops to the shaft via a crimp process.

[0043] FIG. **8** is a close up view of the snare device shown in FIG. **7**, further illustrating the steel hypo tube which attaches the loops to the shaft via a crimp process.

[0044] FIG. **9** is a perspective view of the snare device shown in FIG. **7**.

[0045] FIG. **10** is an end view of the snare device shown in FIG. **7**. The view illustrates how the loops overlap laterally, with the outer perimeter forming a circular shape.

[0046] FIG. **10**A is an end view of another embodiment of a snare device. The view illustrates how the loop elements are twisted together laterally, with the outer perimeter forming a circular shape.

[0047] FIG. **11** is a side view of an embodiment of a snare assembly, where the loop elements are attached to the shaft element with a wire coil.

[0048] FIG. **12** is a side view of an embodiment of the shaft, hypo tube, and a single loop element for illustrative purposes. The actual snare device can have a plurality of loop elements. The view illustrates an embodiment of the loop element wherein the angle of the radius portion of the loop element is typically about 45 degrees from the central axis of the hypo tube component.

[0049] FIG. **13** is a side view of an alternate embodiment of the snare device where the shaft is made from a twisted strand, and the loop elements form a circular shape in a single plane 90 degrees from the axis of the shaft.

[0050] FIG. **14** is a horizontal isometric view of the alternate embodiment shown in FIG. **13**, illustrating the flat circular shape of the outer perimeter of the snare loops.

[0051] FIG. **15** is a frontal angled view of the alternate embodiment shown in FIG. **13**, illustrating the circular shape of the snare outer perimeter, as well as the straight portions of each loop overlapping the adjacent loop to form a closed circle with no gaps about the perimeter.

[0052] FIGS. **16-19** illustrate embodiments of methods of using any of the snares **10** disclosed herein.

[0053] FIGS. **20-22** illustrate embodiments of a snap fitting that can be used with the snare.

[0054] FIGS. **23**A-**23**C illustrate an embodiment of guidewire having both a pressure sensor and an IVUS transducer.

[0055] FIGS. **24**A-**24**D illustrate two embodiments of an intravascular ultrasound catheter joined together in parallel with a catheter.

[0056] FIGS. **25**A and **25**B illustrate an embodiment of a filter delivery system where the pressure sensor and/or IVUS transducer are integrated into a delivery catheter, a retrieval catheter or a device itself.

[0057] FIGS. **26**A-**26**G illustrate various embodiments of a retrieval system having an ultrasound transducer incorporated into a sheath or a snare.

[0058] FIGS. **27**A-**27**C illustrate various embodiments of a centering device that positions an ultrasound transducer in the center of a lumen, or alternatively, places an array of ultrasound transducers around the periphery of the lumen.

[0059] FIG. **28** illustrates a method of using a retrieval system having one or more ultrasound transducers to retrieve a filter from a body lumen.

[0060] FIG. **29** is a section view of a wire strut or support element of a filter (w/s/s) having multiple segments in a concentric arrangement.

[0061] FIG. **30** is an embodiment of a segment having one or a plurality of laser drilled holes formed therein.

[0062] FIG. **31** is an embodiment of a segment having one or a plurality of raised features or alternatively roughed portions formed thereon.

[0063] FIG. **32** is an embodiment of a segment having one or a plurality of bubbles formed therein.

[0064] FIG. **33** is an embodiment of a segment having one or a plurality of dimples formed therein.

[0065] FIG. **34** is an embodiment of a segment having a coil or braided structure within or about the segment.

[0066] FIG. **35** is an embodiment of a segment having a plurality of echogenic markers arrayed in rings about the segment to provide an indication of measurement via the spacing between adjacent rings.

[0067] FIG. **36** illustrates various alternative configurations for a segment used alone or in conjunction with other segments.

[0068] FIG. **37** is a view of an exemplary filter illustrating various alternative aspects of providing a filter with improved echogenic characteristics.

[0069] FIG. **38** is a flow chart illustrating an embodiment of a method of navigating the distal protection device through the vasculature.

[0070] FIG. **39** is a flow chart illustrating an embodiment of a method of deploying the distal protection device at a deployment site.

DETAILED DESCRIPTION

[0071] As illustrated in FIGS. **1**A and **1**B, an embodiment of a retrieval device **10**, such as a snare, includes a primary or main shaft **12**, having a distal end **14** and a proximal end **16**. At the distal end **14** of the shaft **12** is a plurality of loop elements **18**. In some embodiments, the device **10** can typically have at least two loop elements **18**, but can have three or more loop elements **18**. These loop elements **18** are attached proximally to the distal end **14** of the shaft **12** via a hypo tube component **20**, and can be free and independent at their distalmost ends. In other embodiments, the distal ends of the loop elements **18** can be fastened or connected to adjacent loop elements using, for example, loop connectors, as described in more detail below. The loops **18** can be of a polymeric or metallic material, and are typically radiopaque and flexible.

[0072] The loop elements **18** can have a region of overlap **31**, with a span L**1**, between the adjacent loop elements. In some embodiments, L**1** can be less than about 5, 10, 15, 20, 25, 30, 35, 40 or 45 degrees. In some embodiments, L**1** can be between about 0 to 45 degrees, or about 0 to 15 degrees. The span of radial or circumferential coverage by each loop element **18** can be defined by the angle α between the two spoke elements **30** of the loop element **18**, as shown in FIG. **1**A and FIG. **4**. In some embodiments, angle α depends on the number of loop elements **18** and the amount of loop element overlap, L**1**. For example, in some embodiments, angle α can be determined approximately by dividing 360 degrees by the number of loop elements and then adding the amount of overlap, L**1**. Thus, for a four loop element snare embodiment with 10 degrees of overlap between each loop element, angle α equals approximately 100 degrees. For a two loop element snare embodiment with 10 degrees of overlap, angle α equals about 190 degrees. In other embodiments, the radial or circumferential coverage of the loop elements can be different while still providing complete radial or circumferential coverage. For example, in a four loop element embodiment with 10 degrees overlap, two loop elements can have an angle α of about 130 degrees while the other two loop elements can have an angle α of about 70 degrees.

[0073] The shape and flexibility of the loop elements **18** allows them to collapse and/or fold down easily into, for example, a 7Fr or smaller sheath catheter **22** during loading of the device **10** into the sheath **22** and/or during deployment of the device **10** from the sheath **22** and retraction of the device **10** into the sheath **22**, as illustrated in FIG. **1**C. In some embodiments, an additional outer sheath **36** can be used to provide additional column strength. In some embodiments, the outer sheath **36** can be a braided sheath, while the inner sheath **22** can be a coiled sheath, which can be more flexible that the braided sheath. The outer sheath **36** can be used with any of the embodiments disclosed herein.

[0074] In some embodiments, as illustrated in FIGS. **1**G and **1**H, the sheath **22**, which can be used in a single sheath embodiment or as an inner sheath in a double sheath embodiment, can have a soft, flexible and elastic distal tip portion **32** that can expand over a foreign object, such as a filter **40**, that is being pulled into the sheath **22**. In addition, the flexible distal tip portion **32** can evert when the foreign object and/or deployed loop elements **18** are retracted back into the sheath **22**. When the flexible distal tip portion **32** inverts, it can form

a ramp-like structure that facilitates the retraction of the filter **40** and the loop elements **18** back into the sheath **22**. The main portion **34** of the sheath **22** can have stiffer column strength than the flexible distal tip portion **32** in order to tolerate the relatively high levels of force that can be generated while pulling out embedded filters with the device **10**. In some embodiments, as mentioned above, an outer sheath can be used to provide additional column strength if needed.

[0075] In some embodiments, the distal tip portion **32** of the sheath **22** can be radiopaque and/or include a radiopaque marker. For example, in some embodiments, the polymer forming the distal tip portion **32** can be doped with radiopaque elements or compounds, such as barium, tantalum, tungsten, palladium, platinum or iridium based compounds or elements. Alternatively or in addition to the radiopaque doping, a single or plurality of radiopaque markers, such as a radiopaque marker band made of the radiopaque elements or compounds described herein, can be incorporated into the distal tip portion **32**. In some embodiments, the radiopaque marker band can be offset approximately 1-10 mm, or about 3-mm from the distal end of the sheath **22**, so as to not interfere with the elasticity and eversion of the distal tip portion **32** during the capture process. The radiopaque doping and/or marker allow the operator to visualize the location of the distal tip portion **32** of the sheath **22** during insertion, advancement, and positioning of the sheath **22** near the foreign object within the lumen. This allows the operator to accurately and precisely advance and position the tip of sheath **22** to the foreign object. In some embodiments where an outer sheath is combined with the retrieval sheath, each sheath can employ different radiopaque marker patterns to allow the operator to differentiate between the two sheaths fluoroscopically.

[0076] In addition, the marker offset can also function as an alignment feature which aids the operator in positioning the distal end of the sheath **22** in the proper location relative to the foreign object to be retrieved. For example, the foreign object can be a filter **40** with a frame **52**, a plurality of anchors **50** on the frame **40** and a retrieval element **42** as illustrated in FIGS. **16-19**. In some embodiments, deployment of the loop elements **18** is ideally distal the retrieval element **42** but proximal the anchor **50** closest to the retrieval element **42**, which can be achieved be lining up the marker band **54** with an element or feature on the filter **40**, such as the retrieval element **42**, for example. The distance d between the retrieval element **42** and the anchor **50** can serve as a design constraint for loop element **18** deployments, where the loop elements **18** can be designed to deploy with an axial reach of less than the distance d between the retrieval element **42** and the anchor **50** or other feature on the filter **40**. FIGS. **16-19** are more fully described below.

[0077] In some embodiments, the shaft **12** is straight and can be made of polymeric or metallic material, for example. The shaft **12** can be made of a solid design such as a wire, but can alternatively be hollow to facilitate passage of secondary devices through a lumen in the shaft **12**. The shaft **12** can be of a single wire or element, but can also be constructed of a plurality of wires or elements which can be braided, twisted or stranded into a single shaft **12**. The shaft **12** provides a means by which the user can advance, manipulate, and retract the distal end **14** of the device to capture and remove a foreign object from the human body. Typically, the user manipulates the device **10** at the proximal end **16**, which is typically outside of the human anatomy. By manipulating the shaft **12**, the motion is translated to the distal end **14** of the device **10**, which in turn causes the loop elements **18** to move within the human anatomy. This motion allows the loop elements **18** to catch on the foreign object to be removed from the body. Consequently, the shaft **12** can be designed to have sufficient stiffness, flexibility, pushability and torqueability to accomplish the functions described herein. In some embodiments, a single wire shaft can provide sufficient stiffness, flexibility, pushability and torqueability. In other embodiments, a multiple wire shaft can provide sufficient stiffness, flexibility, pushability and torqueability.

[0078] In some embodiments, a hypo tube **20** attaches the loop elements **18** to the shaft **12**. The hypo tube **20** has an inner diameter and an outer diameter, and is typically sized such that the shaft **12** and all of the loop elements **18** can fit within the inner diameter of the hypo tube **20**. The inner diameter is sized such that there is adequate interference between the hypo tube **20** and the shaft **12** and the loop elements **18**, so that the hypo tube **20** can be swaged or crimped circumferentially, mechanically locking the loop elements **18** and shaft **12** together. Additionally, the hypo tube can be radially shaped into a non-circular shape, such as but not limited to a hexagon or square or other rectilinear shape, to further facilitate mechanical fit and locking of said shaft **12** and loop elements **18**. In some embodiments, the length of the hypo tube **20** is about at least two times its outer diameter, but can be as short as one times its outer diameter, or as long as twenty times its outer diameter. The loop elements **18** can also be attached to the shaft **12** via welding, soldering, capturing within a coil, or potting within a polymeric or rigid adhesive form, for example.

[0079] In some embodiments, the loop elements **18** have a geometric shape which allows them to deploy in a staged manner, where the shape and effective diameter of the snare **10** is dependent upon how far the snare **10** is deployed out of the sheath **22**. In a first deployment stage as shown in FIG. **1**D, the loops **18** are initially deployed from the sheath **22** and expand, each with a semi-circular shape, a semi-oval shape, or semi-oblong shape, for example, and the effective diameter of the snare **10** is smaller than the effective diameter when the snare **10** is fully deployed. In some embodiments such as a four loop elements **18** embodiment, the snare geometry in the first deployment stage resembles a cloverleaf shape. In some embodiments, as illustrated in FIG. **1**E, the cloverleaf shaped loops **18** extend substantially transversely from the shaft **12** and sheath **22**. In a second deployment stage as shown in FIG. **1**F, the loops **18** extend further from the sheath **22**. In some embodiments, in the second deployment stage the loops **18** extend both transversely and axially from the distal end **24** of the sheath **22**, thereby providing the snare **10** with extended axial reach in this configuration. In a third deployment stage as illustrated in FIG. **1**A, the loops **18** fully expand, reaching the full effective diameter of the snare **10**. The snare **10** geometry in the third deployment stage can resemble a substantially complete circle, when viewed along the longitudinal axis of the snare **10** to yield an end view as shown in FIG. **1**A, with spoke elements that lead from the circle towards the central hypo tube attachment point. The circle geometry created by the radial edge portions of the loop elements **18** eliminates or reduces gaps between the loop elements **18**, which can make it easier for the operator to engage a retrieval element on a foreign object with the snare **10**, especially when the retrieval element is located near or around the periphery of the lumen.

[0080] To facilitate engagement of the loop elements **18** with the retrieval element, the loop elements **18**, when fully deployed, can be sized to conform approximately to the inner diameter of the lumen in which the foreign object is located. This allows full or substantially full apposition between the loop elements **18** and the full circumference of the lumen wall, which enhances the ability of the snare **10** to capture the retrieving element. In some embodiments, the geometry of the fully deployed loop elements **18** can be substantially elliptical, oval or oblong in order to conform to a lumen with a substantially elliptical, oval or oblong cross-sectional geometry. In these embodiments, the major axis of the elliptical or oblong geometry can be sized to conform approximately to the inner diameter of the lumen in which the foreign object is located. In general terms, the geometry of the fully deployed loop elements **18** can substantially match the geometry of the lumen.

[0081] For example, the vena cava may have a generally elliptical or oblong cross-sectional geometry. For use in the vena cava, a snare **10** with loop elements **18** having a substantially elliptical or oblong fully deployed configuration can be used advantageously, as shown in FIGS. **1**I-**1**M, which illustrate snare **10** embodiments having two loop elements **18**. In other embodiments, more than two loop elements **18**, such as 3, 4 or more loop elements, can be used. By matching the geometry of the deployed loop elements **18** with the geometry of the lumen, full circumferential apposition with the lumen wall can be more readily achieved. In addition, an elliptical or oblong snare **10**, which can have a major axis and a minor axis, can be used in lumens having a wide range of sizes because the major axis of the snare can be rotated to provide greater wall to wall reach when needed. Additionally, the loop elements **18** can exhibit both distal and proximal reach, by forming the shape of said loops with a proximally biased curve **58**, as shown in FIG. **1**S. In some embodiments, the distal reach, D**3**, is up to about 10 mm, and the proximal reach, D**4**, is up to about 10 mm, where distal reach and proximal reach are in reference to the distal end of the shaft **12**. In other embodiments, D**3** and D**4** can be greater than or less than the values recited above.

[0082] In some embodiments, each individual loop element **18** can employ a single or plurality of radiopaque markers **56**, such that each loop element **18** has a different quantity of radiopaque markers **56**, or a different pattern of radiopaque markers **56**, to allow the operator to visually differentiate and identify each loop element **18** fluoroscopically, as shown in FIGS. **1**R and **1**T. For example, as illustrated in FIG. **1**R, one loop element **18** has a single radiopaque marker **56** while the other loop element **18** has two radiopaque markers **56**. Similarly, in FIG. **1**T, the first loop element **18** has one radiopaque marker **56**; the second loop element **18** has two radiopaque markers **56**; the third loop element **18** has three radiopaque markers **56**; and the fourth loop element **18** has four radiopaque markers **56**.

[0083] In some embodiments, the loop elements **18** can be attached or connected together using a variety of techniques, as illustrated in FIGS. **11** and **1**J. For example, the loop elements **18** can be connected together by loop connectors **19** which can be made from a piece of wire, metal, plastic or polymer that can be wrapped, twisted, crimped, molded or formed around the two loop elements **18** at, for example, crossover junctions between the loop elements **18**. Other techniques for connecting the loop elements **18** together can be used, such as welding or applying adhesives. Alternatively, as shown in FIGS. **1**V-**1**X, the loop elements **18** can be connected together by loop connectors **19***b* which can be sleeves that are wrapped around or otherwise disposed around the adjacent spoke portions **30** of the loop elements **18**. The sleeves can be made of a variety of materials, such as heat shrinkable flexible plastic tubing through which the spokes can be disposed and then secured together by shrinking the tubing around the spokes. For example, the sleeves can be made of PTFE or another biocompatible polymer. The sleeves can provide additional structural stability to the loop elements **18** and allow the loop elements **18** to be advanced or retracted in unison. Without the sleeves, the loop elements **18** may become separated, with for example one loop element facing substantially proximally and the other loop facing substantially distally, which makes control of the snare more difficult and also makes visualization of the snare and object to be retrieved more difficult. Therefore, addition of flexible sleeves, can improve control and visualization of the loop elements during the retrieval process, while still permitting the loop elements to flex and bend and be deployed and manipulated by the user. Additionally, the spoke portions **30** can be twisted together to attach the loop elements **18** together, as shown in FIG. **10**A. For example, the spoke portions **30** of adjacent loop elements **18** can be twisted together. Attaching or connecting the loop elements **18** together can reduce the likelihood of unwanted or unintentional loop eversion or loop displacement that can occur during loop deployment, loop manipulation within the lumen and loop retraction.

[0084] In some embodiments, the loop elements **18** can include a single or plurality of loop collapse facilitator **23** features, as shown in FIGS. **1**K-**1**M, that facilitates collapse of the loop elements **18** when the loop elements **18**, are retracted back into the sheath **22** or when the sheath **22** is advanced over the loop elements **18**. The loop collapse facilitator **23** can be a preformed crimp or fold in the loop element **18** that serves as a collapse or folding point for the loop element **18** and therefore initiates or facilitates collapse of the loop element **18** when compressive forces are applied to the loop element **18**. In some embodiments, each loop element **18** can have at least one loop collapse facilitator **23**.

[0085] In addition, the loop collapse facilitator **23** can be oriented in a variety ways. For example, the loop collapse facilitators **23** can be pointed or extend either in a distal direction, as shown in FIG. **1**K or a proximal direction (not shown), such that the circumference of the loop elements **18** in the deployed configuration when viewed axially remains in the same shape, such as elliptical, oval or oblong, as compared to embodiments without the loop collapse facilitators **23**, as shown in FIG. **1**I. In other embodiments, the loop collapse facilitators **23** can be pointed or extend radially inwards as shown in FIGS. **1**L and **1**M, such that the circumference of the loop elements **18** in the deployed configuration when viewed axially remains in substantially the same shape, such as elliptical, oval or oblong, as compared to embodiments without the loop collapse facilitators **23**, as shown in FIG. **1**L. In other embodiments, the loop collapse facilitators **23** can be pointed or extend radially inwards as shown in the dotted lines in FIGS. **1**L and **1**M, such that the circumference of the loop elements **18** in the deployed configuration when viewed axially still remains substantially the same shape, such as elliptical, oval or oblong, but also includes a radially inward indentation, which can be arcuate and taper to a point that extends radially inwards. The size of the indentation can

be controlled by the size of the loop collapse facilitator **23** as well as the shape of the taper, as illustrated by the dotted lines and solid lines representing the loop collapse facilitator in FIGS. **1**L and **1**M. In some embodiments, the loop collapse facilitator **23** can be oriented both distally or proximally as well as radially. In some embodiments, the loop collapse facilitator **23** can employ a loop geometry which provides a hinge point to allow the loop element **18** to fold down and collapse with low force, as shown in FIG. **1**U.

[0086] FIGS. **1**N-**1**Q illustrate the stages of deployment of an embodiment of a snare **10** with two loop elements **18**. As shown in FIG. **1**N, during the initial or first deployment stage, the loop elements **18** extend axially out of the sheath **22**, thereby providing axial reach to the snare **10** in this configuration, which is suitable as described herein for guide wire retrieval or pacemaker lead retrieval, for example. More generally, this configuration is particularly suitable to retrieve an elongate object that is oriented transversely to the snare axis. In a second deployment stage, the loop elements **18** change from an axial orientation to a transverse or radial orientation, as shown in FIG. **1**O, in which the snare **10** has little or minimal axial reach. This configuration may be suitable when the space between the retrieval feature or object and another structure is small and more can more easily be accessed by loop elements with little or minimal axial reach. In the third or full deployment stage, as illustrated in FIGS. **1**P and **1**Q, the loop elements **18** are fully deployed, forming a circumference that is shaped to conform to the shape of the lumen, such as circular, elliptical, oval, oblong, or any other suitable shape, as illustrated in FIGS. **1**I-**1**M. In the third deployment stage, the snare **10** can have some axial reach and full radial reach which can be configured to provide full circumferential apposition with the lumen wall. The axial reach in the third deployment stage can be increased or decreased to enhance capture of the foreign object, such as a filter, as described herein.

[0087] The diameters of the wires can be 0.002"-0.007" each. The wires can be tightly wound together, and then formed into a loop element **18** of the desired shape. The loop element **18** outer radiused edge portion **26** can be angled such that the span of the radiused edge portion **26** is at angle of between about 45 degrees and 90 degrees, relative to the axis of the shaft **12**.

[0088] The loop element **18** of one embodiment, as illustrated in FIGS. **2**A and **2**B is made of at least two wires, which are tightly gathered in a twisted configuration, where at least one of the wires is a shape memory nickel titanium wire, and at least one of the wires is of a radiopaque platinum wire. In some embodiments, the twisted configuration can be advantageous over the braided configuration, when a specific stiffness property of the loop elements **18** is desired, by varying the number of wires and wire diameter used in the strand. In some embodiments, the loop element **18** includes 2 shape memory nickel titanium wires and two radiopaque platinum wires. Other materials can be used in place of the nickel titanium and/or radiopaque platinum wires. For example, the nickel titanium alloy, such as Nitinol, can be replaced with a stainless steel wire or polymeric wire. In addition, the radiopaque wire can be replaced with another radiopaque material, such as a platinum-iridium wire, a palladium wire, a gold wire, a tantalum wire, a tantalum-tungsten wire, and the like. In addition, these radiopaque materials can be incorporated into polymeric materials directly or a modified form, such as a salt for example. The radiopaque materials can be bonded or attached to the non-opaque wire in a variety of ways, including wrapping or braiding the radiopaque wire with the non-radiopaque wire together, or by attaching marker bands to the non-radiopaque wire, or by cladding the non-radiopaque wire with the radiopaque material, for example. In many embodiments, the use of various radiopaque markers can be used to indicate the relative location and orientation of the deployed snare **10** in the target area.

[0089] FIGS. **3**A and **3**B depict a view of one embodiment, where just one loop element **18** is shown attached to the shaft **12** for the sake of clarity. The embodiment shown in FIGS. **3**A and **3**B can have a plurality of loop elements **18**, such as two, three, or four loop elements **18**, or more than four loop elements **18** as described herein. A snare **10** with more loop elements **18** will have more spoke portions **30** that can engage with the foreign object, which may aid in retrieval of the foreign object. However, an increased number of loop elements **18** may obscure real-time imaging of the snare elements and foreign object, making it more difficult for the operator to correctly identify all the loop elements **18** on the screen, which may interfere with efficient manipulation of the snare **10**. In addition, a snare **10** with too many loop elements **18** can end up having a larger compressed diameter due to the many loop elements **18** that are attached to the shaft **12** via, for example, a hypo tube **20** swage connection, as discussed below. As more loop elements **18** are swaged to the hypo tube **20**, the diameter of the hypo tube **20** increases in order to accommodate the additional loop elements **20**. Increasing the compressed diameter of the snare **10** is generally undesirable for many minimally invasive techniques with which the snare **10** can be used because a larger device requires a larger percutaneous incision, which increases the pain and recovery time for the patient.

[0090] In contrast, in some embodiments a snare **10** with fewer loop elements **18**, such as two loop elements **18**, can be more easily visualized using real time imaging techniques, thereby allowing the operator to accurately identify each loop element **18** and therefore efficiently manipulate the position and orientation of the snare with respect to the foreign object. The two loop element embodiment, as discussed above, can still be capable of achieving complete or substantial circumferential apposition with the lumen wall. In some embodiments with too few loop elements **18**, such as a single loop element, the single loop element can be too floppy, and a floppy loop element **18** can be difficult to precisely manipulate and position, making grasping a small retrieval element on a foreign object more difficult.

[0091] FIGS. **3**A and **3**B illustrate the shape of the loop element **18** from two angles; a transverse side view in FIG. **3**A and a front axial view in FIG. **3**B. The shaft **12** can be attached to the hypo tube **20** via swaging. The hypo tube **20** can also be swaged to the loop element **18**. The loop element **18** can be made from a strand of four wires, two Nitinol wires and two platinum wires.

[0092] FIG. **4** is an axial view of an embodiment of a loop element **18** and a hypo tube **20**. The shape of the loop element **18** includes a radiused edge portion **26** which shares its radial center with the center axis of the hypo tube **20**. The radiused edge portion **26** is bounded at each end by a radiused corner feature **28**, which transitions the radiused edge portion **26** into two straight spoke portions **30**. These straight spoke portions **30** are typically the radius length from the central axis of the hypo tube **20** to the radiused edge portion **26** of the loop element **18**. In some embodiments, the straight spoke portions **30** are set at an angle α of approximately 90 degrees, and

radiate from the central axis of the hypo tube **20** to the outer radius of the radiused edge portion **26** of the loop element **18**.

[0093] The loop elements **18** have a geometry that enables them to catch easily on foreign objects in the human anatomy. In some embodiments as shown in FIG. **4**, the loop element **18** has a "D" shape which resembles a pie slice with rounded corners, when viewed axially along the device axis. This D shape includes a radiused edge portion **26**, which shares a radial center with the axis of the shaft of the device. The radiused edge portion **26** is bounded at either end by a radiused corner portion **28** which transitions the radiused edge portion **26** into two straight spoke portions **30**. In some embodiments, the radiused corner portion **28** bends about 90 degrees towards the central axis of the shaft **12**.

[0094] In some embodiments, the two straight spoke portions **30**, which radiate from the central axis of the hypo tube to the outer radius of the radiused edge portion **26**, are set at an angle α of about 90 degrees, for a snare **10** with four loop elements **18**. In some embodiments, the angle α between the two straight spoke portions **30** can be less than 90 degrees when, for example, the snare **10** has more than four loop elements **18**, such as an angle of about 60 degrees for a snare **10** with six loop elements **18**, or an angle of about 72 degrees for a snare **10** with 5 loop elements. To generalize, in some embodiments, the angle in degrees between the straight spoke portions **30** can be determined by dividing 360 by the number of loop elements **18** in the snare **10**. This results in a configuration where the loop elements **18** cover an entire circle of space when viewed along the axial axis. Therefore, in an embodiment of the snare **10** with three loop elements **18**, the angle between the two straight spoke 30 portions can be about 120 degrees. In some embodiments, the angle α between the straight spoke portions **30** can be greater than as determined using the formula set forth above, which results in an overlap of portions of the loop elements **18** with adjacent loop elements **18**. In some embodiments, the angle between the two straight spoke 30 portions is greater than the value calculated in the formula set forth above, where an angle of about 5 to 15 degrees ensures that there is minimal or no gap about the perimeter of the snare, to form a closed circle.

[0095] In some embodiments, from a transverse view, the large radiused edge portion **26** of the loop element **18** can be angled between about 90 degrees and about 30 degrees relative to the axis of the shaft **12** of the device **10**, as shown in FIG. **12**. This edge can also be substantially or exactly 90 degrees from the shaft axis, forming a flat, single plane circle when viewed transversely, as shown in FIG. **13**.

[0096] In other embodiments, from a transverse view, the large radiused edge portion **26** of the loop element **18** can be angled at an angle f**3** that is from about 5 to 45 degrees relative to the longitudinal axis L of the shaft **12** of the device **10**, as shown in FIGS. **3**A and **12**. Such a configuration where the radiused edge portion **26** is angled less than 90 degrees results in a propeller like configuration where the loop element **18** has a pitch and axial reach both proximal and distal the end of the shaft **12** and/or sheath **22**. As illustrated in FIG. **12**, the loop element **18** has a portion proximal to the distal most portion of the shaft and a portion distal to the distal most portion of the shaft, as shown by the dotted line which divides loop element **18** into the proximal portion **18**A and the distal portion **18**B. In addition, the propeller configuration can result in the opening of the loop elements **18** being oriented in both a plane transverse to the snare axis and a plane parallel to the snare axis.

[0097] In these embodiments, the axial deployment length at full deployment of the loop elements **18** is relatively short when compared to some prior art devices which resemble the intermediate deployment configuration illustrated in FIG. **1**F for some embodiments. A long axial deployment length can be beneficial in some situations, such as capturing a guide wire that is oriented generally transversely to the snare **10**, or capturing a retrieval element on a foreign object when the retrieval element is located at or near the center of the lumen. A short axial deployment length can be beneficial in other situations, such as capturing a retrieval element that is located at or near the periphery of the lumen. In some embodiments, loop elements **18** with a long axial deployment length can inadvertently capture structural elements on the foreign object, such as frame anchors on a filter, rather than the retrieval element which is specifically designed to be engaged by the snare. When a structural element such as a frame anchor is captured instead of the retrieval element, the filter may not be able to be withdrawn into the sheath **22** and be removed. In addition, the loop elements **18** may get tangled up with the frame anchors and other structural elements more easily when the axial length is long. This can be a problem with some prior art devices, such as the EN Snare® retrieval device, which has a long axial reach. For at least these reasons, a short deployment length can be advantageous over a long deployment length in certain situations. In some embodiments, the axial deployment length of the loop elements **18** can be less than the distance between the retrieval element and the support member or anchor of the filter, thereby reducing the likelihood that the loop elements **18** will inadvertently engage the anchors on the support members. In some embodiments, the axial deployment length of the loop elements **18** can be less than the distance between the retrieval element and the support member crossover or the material capture structure of the filter. In some embodiments, the axial deployment length of the loop elements **18** can be less than the distance between the retrieval element and any structure on the filter in which the loop elements can get entangled with or that interfere with the function of the loop elements **18**.

[0098] In addition to the axial deployment length, loop elements of prior art devices lack substantially complete circumferential apposition with the vessel wall, which makes it difficult to retrieve objects near the periphery of the blood vessel lumen. In contrast, embodiments of the snare disclosed herein achieve substantially complete circumferential apposition which facilitates retrieval of objections, such as retrieval elements on filters, that are located near the periphery of the blood vessel lumen.

[0099] FIGS. **5**A and **5**B illustrates an embodiment of a loop element **18** made of four round wires, which are tightly gathered in a twisted configuration, where two of the wires are of shape memory nickel titanium wire, and two of the wires are of a radiopaque platinum wire. The diameters of the wires can be about 0.004" each. The wires are tightly wound together, and then formed into a loop shape. In some embodiments, the loop outer radius is angled such that the span of the radius is at angle of between about 45 degrees and 90 degrees, relative to the axis of the shaft. FIGS. **6**A and **6**B illustrates a similar embodiment of a loop element **18** made of four wires, except that the wires are braided together rather than twisted together to form the loop element **18**.

[0100] One alternate embodiment of the device **10**, illustrated in FIGS. **7-10**, includes a series of loop element structures **18** mounted in a substantially circular geometry when

viewed along the longitudinal axis. In some embodiments, the loop elements **18** extend substantially transversely with respect to the longitudinal axis. In some embodiments, the outer circular perimeter defined by the loop elements **18** is substantially continuous and does not have gaps. In some embodiments, the overlap **31** between the loop elements **18** is as described above for FIG. **1**A, where the overlap **31** covers a pie shaped region that extends from the outer circumference of the loop elements to the center where the loop elements are attached to the shaft. In other embodiments, the overlap **31** between the loop elements **18** can change as the loop elements **18** are further extended out of the sheath. For example, as shown in FIG. **10**, the loop elements **18** can have an overlap **31** that occurs over approximately the middle to distal portion of the loop elements **18**. As illustrated in FIG. **10**, the overlap **31** begins at crossover points **33** between the spokes **30** of the loop elements **18**. In some embodiments, as the loop elements **18** are retracted back into the sheath, the crossover points **33** move closer towards the center, until the crossover points merge into the center, resulting in an overlap configuration similar to that illustrated in FIG. **1**A. In addition to the variable overlap regions, the embodiment illustrated in FIG. **10** has interior gap portions **35** between the loop elements. These interior gap portions **35** extend radially inwards from the crossover points **33**, and can decrease in size and disappear as the loop elements **18** are retracted back into the sheath. In these embodiments, the loop elements **18** can have a radial span that can be defined by the angle α, and an overlap with a span L**1**, similar to that described above for FIG. **1**A. In these embodiments and in others, the overlap portions can also act as additional snaring portions which increase the likelihood that a portion of the device engages the object to be retrieved.

[0101] In some embodiments, the loop elements **18** can be attached to a shaft **12** via a swaged or crimped hypo tube **20**. These loop elements **18** can be made of two or more wires, including at least one Nitinol wire and at least one platinum wire. As illustrated in FIGS. **7-10**, in some embodiments the most distal part of the device **10** can be the loop elements **18** because the device **10** does not have a distally extending control member that can be found in some prior art devices, such as the grasping device disclosed in U.S. Pat. No. 7,753,918. In some embodiments, the presence of a control member may interfere with retrieval of the foreign object, such as a filter, by getting entangled with the filter, making it advantageous for some embodiments to not have a distally extending control member. In some embodiments, the loop elements **18** can be angled or have a pitch with respect to the longitudinal axis.

[0102] FIG. **11** illustrates another embodiment of the snare **10** where the loop elements **18** are attached to the shaft **12** with a wire coil **21**. In some embodiments, the wire coil **21** can be a separate wire that can be wrapped around the proximal portions of the loop elements **18**. In other embodiments, the proximal portions of the loop elements **18** can be wrapped around the distal end of the shaft **12** in order to form the wire coil **21**. As additionally shown in FIG. **11**, the loop elements **18** can extend axially, or in other words, have an axial depth, D**1**, that can be between about 1 to 10 mm. This axial reach allows loop elements **18** to effect capture of an object, such as a retrieval element of a filter, via rotation about the longitudinal axis of the snare. In some embodiments, the axial depth, D**1**, is less than the distance between a retrieval element on a filter and the closest anchor to the retrieval element, as further described below.

[0103] Another alternate embodiment, as illustrated in FIGS. **13-15**, utilizes a twisted strand shaft **12** made of four 0.010" Nitinol wires. This shaft **12** is attached to twisted strand loops elements **18** using a hypo tube **20** using silver solder, for example. After full deployment, the loop elements **18** form a substantially circular geometry which is in a single plane typically 90 degrees from the axis of the shaft **12**. In some embodiments, as illustrated, the loop elements **18** extend both transversely and axially with respect to the longitudinal axis of the shaft **12**, forming a cone-like structure with a circular base defined by the distal edge portions of the loop elements **18**. The axial reach, D**2**, or extension of the circular portion past the distal end of the shaft can vary and can depend on and be less than, for example, the distance between the retrieval element and a particular filter structure, such as an anchor, support member, support member crossover, or material capture structure of the filter, as further described herein. The axial reach, D**2**, can be between about 1 to 10 mm. In addition, the loop elements **18** can a region of overlap **31** and can have a radial or circumferential span defined by the angle α, as described above with reference to FIGS. **1**A and **4**.

[0104] In some embodiments, this design offers several key features and capabilities, for example:

[0105] 1. Loop Design

[0106] The design of the loop elements allows for deployment in different size lumens, and can conform to variations in lumen anatomy such as tapering, curvature, and angulations. This conformance feature can also enable the device to achieve full radial apposition with the target lumen regardless of lumen diameter or circularity. The loop configuration allows the device to catch a foreign object no matter where the object is located within the luminal space, since the loops reach full radial apposition within the lumen. The design of the elements allows the snare to fit into a very small guiding sheath, facilitating navigation through tortuous anatomies. The angled design of the loop radius allows the device to have axial reach both distal and proximal to the point where the loops are attached to the shaft, enabling the loops to locate foreign objects with minimal forward and backward axial manipulation of the device by the user. The non-angled design of the loop radius allows the device to have a flat, single plane circle geometry, enabling the loops to locate foreign objects with which may be against the vessel wall or partially embedded in the vessel wall. The loops can be made radiopaque, which allows visualization of the loop under fluoroscopy. Additionally, each individual loop element can employ a single or plurality of radiopaque markers such that each loop element has a different quantity of radiopaque markers, or a different pattern of radiopaque markers, to allow the operator to visually differentiate and identify each loop element fluoroscopically.

[0107] 2. Shaft Design

[0108] The diameter and mechanical properties of the shaft, such as tensile strength, stiffness and/or elasticity, allows the user to manipulate the loops easily, by transferring axial and torsional motion from the proximal end of the device down to the distal end of the device. The diameter of the shaft allows for it to fit within a small diameter guiding sheath. The diameter of the shaft provides tensile support and strength to allow for high forces that may be required for

removing a foreign object from the human anatomy. The shaft can be either solid or hollow, allowing the passage of devices, such as a guidewire, through the shaft. The shaft can be of a single element such as a wire, or a construction of a plurality of elements which are braided or stranded together. The shaft can be of a radiopaque material, to facilitate fluoroscopic visualization.

[0109] 3. Hypo Tube Design

[0110] The inner diameter of the hypo tube allows the loop wires and shaft wire to fit snugly within the inner diameter, to facilitate mechanical swaging, soldering, or crimping of said hypo tube, mechanically locking the elements together. The outer diameter of the hypo tube provides adequate wall thickness to allow mechanical swaging or crimping of the hypo tube to provide a strong mechanical attachment, without cracking the hypo tube. The hypo tube can be of a radiopaque material, to facilitate fluoroscopic visualization. Additionally, the hypo tube can be radially shaped into a non-circular shape, such as but not limited to a hexagon or square or rectilinear shape, to further facilitate mechanical fit and locking of the shaft and loop elements.

[0111] In some embodiments, the fundamental design elements which achieve these features include, for example: (1) a plurality of loop elements, which are attached to a shaft via a hypo tube; (2) loops which are designed to be flexible and radiopaque; (3) loops which can be collapsed within a guiding catheter, and deployed outside of the guiding catheter; (4) loops which can reach full circular apposition within the luminal space in a human body; (5) loops which are attached to a shaft distally, which extend laterally towards the wall of the vessel of a human body; (6) loops which are angled relative to the axis of the shaft, typically less than 91 degrees and typically greater than 1 degrees; (7) loops which employ an attachment that is typically a crimped or swaged hypo tube; (8) a shaft which is attached to the loops; (9) a shaft having a diameter allows it to fit within a small diameter guiding catheter; (10) a shaft which can be either solid or hollow; (11) a shaft made of a material which can be polymeric, or can be of a metal such as but not limited to nickel titanium; and (12) a shaft having a length designed to enable the user to position the loops at a desired location to remove a foreign object from a human body.

[0112] In some embodiments, the snare device **10** is designed for placement into a guiding sheath **22**, being advanced through said sheath **22**, deploying near a foreign object located within the human anatomy, capturing said object, and removing the object from the human anatomy. The shape of the loop elements **18** allows them to conform to the diameter of the vessel in which they are deployed into, allowing easier capture of the foreign body with less manipulation.

[0113] The device **10** enables a user to capture a foreign object located within the human anatomy, grasp said object in a controlled manner, and retrieve and remove said object from the human anatomy. Examples of foreign objects which might be removed from the human anatomy include implants such as stents, guidewires, leads, filters, and valves, and organic objects such as kidney stones or calcified emboli. For example, a snare **10** can be used to capture a vena cava filter and pull it into a retrieval sheath **22** for removal from the patient.

[0114] FIGS. **16-19** illustrate embodiments of methods of using any of the snares **10** disclosed herein. As shown in FIG. **16**, the snare **10** can be advanced through one or more retrieval sheaths **22** and up to the site of a deployed filter **40**, which, for example, can be located within the lumen **46** of a blood vessel **48**. In some embodiments, the snare **10** can be pre-loaded into a sheath **22** which can be inserted into the patient via a minimally invasive procedure, such as a percutaneous insertion technique. In some embodiments, the distal end **24** of the sheath **22** can be advanced to or proximally to the retrieval element **42** of the filter **40**. In some embodiments, the distal end **24** of the sheath **22** is advanced just past, i.e. just distal, the retrieval element **42**, taking care to avoid advancing the distal end **24** into the other elements of the filter **40**, such as the filter portion **44** or anchors **50** on the filter frame **52**, which would indicate that the distal end **24** had been advanced too far. In some embodiments, the distal end **24** is advanced to a location distal the retrieval element **42** and proximal the anchors **50** closest the retrieval element **42**. In some embodiments, the sheath **22** includes a radiopaque marker **54** located near the distal end **24** of the sheath **22** that facilitates alignment of the distal end **24** with respect to the filter **40**. For example, the operator can align the radiopaque marker on the sheath **22** with the radiopaque retrieval element **42** of the filter **40** under fluoroscopy, which results in the distal end **24** of the sheath being correctly positioned for loop element **18** deployment, which in some embodiments as described herein is located between the retrieval element **42** and the anchor **50** closest to the retrieval element.

[0115] As illustrated in FIG. **17**, the snare **10** is then deployed into the vessel **48**. As described above, deployment of the snare **10** can include three deployment phases. In some embodiments, deployment of the snare **10** can include less than three deployment phases, such as one or two deployment phases, while in other embodiments, deployment of the snare **10** can include more than three deployment phases. FIG. **17** illustrates full deployment of the snare **10** into the vessel **48** with the loop elements **18** in a propeller-like configuration that provides some axial reach both proximal and distal to the distal end **24** of the sheath **22**. In some embodiments, the axial reach in the distal direction can be less than the distance d between the retrieval element **42** and anchor **50**, thereby reducing the likelihood that the loop elements **18** become entangled with or caught on the anchor elements **50** of the filter during loop element **18** deployment and manipulation. In some embodiments, the distance d can be between about 5 to 20 mm The region between the retrieval element **42** and the anchor **50** forms a zone of action in which the loop elements **18** can be deployed and manipulated to effect capture of the retrieval element **42**. In some embodiments, the loop elements **18** can have a pitch like the blades of a propeller such that the openings of the loop elements **18** are oriented in both a plane transverse to the snare **10** axis and a plane parallel to the snare axis. This allows the loop elements **18** to capture the retrieval element **42** either by moving the loop elements **18** axially in a proximal or distal direction or by rotating the loop elements **18** about the snare axis. In some embodiments, the loop elements **18** are deployed distal the retrieval element **42** and proximal the support member of the filter, such that the loop elements **18** achieve substantial apposition with the full circumference of the lumen wall, which is advantageous for capturing retrieval elements located near the periphery of the lumen. The deployed loop elements **18** can be withdrawn or retracted proximally to engage the retrieval element.

[0116] FIGS. **18-19** illustrate the loop element **18** engaged with the retrieval element **42** of the filter **40** and the subsequent collapse of the filter **40** into the sheath **22**. After the

retrieval element **42** is secured, the snare **10** is held under tension while the sheath **22** is advanced over the filter **40**, thereby collapsing the filter **40** into the ID of the sheath **22**. In some embodiments using both an inner sheath **22** and an outer sheath, the retrieval element **42**, and optionally a portion of the filter **40**, is first retracted or pulled into an inner sheath **22**, in order to secure the filter **40** to the snare **10** and to prevent or reduce unfurling of the tail portion of the filter **40**, before the outer sheath is advanced over the rest of the filter **40**.

[0117] As the sheath **22** is advanced over the filter **40**, the flexible distal tip portion **32** of the sheath **22** can expand and invert over the filter **40**, providing a ramp in which the filter **40** can be drawn into the sheath **22**. In some embodiments, the inversion of the distal tip portion **32** can be initiated by contact with specific structures on the filter, such as the retrieval element and/or anchors on the filter frame. In some embodiments, the snare **10** can be retracted in the proximal direction while the sheath **22** is advanced in the distal direction to capture the filter **40** within the sheath **22**. In other embodiments, the snare **10** can be retracted in the proximal direction while the sheath **22** is held relatively immobile, i.e. neither advanced nor retracted, to capture the filter **40** within the sheath **22**. In some embodiments, the entire filter **40** can be retracted into or captured by the inner sheath.

[0118] Another example is the use of a snare **10** to grasp and extract loose kidney stones from a patient's kidneys. The snare **10** is advanced through one or more sheaths **22**, up to the site of the loose kidney stone. The snare **10** is then deployed and engaged with the stone. Next, the snare **10** is pulled into the sheath **22**, or the sheath **22** advanced over the snare **10**, drawing the stone into the distal ID of said sheath **22**.

[0119] As described above, the retrieval system can include a plurality of different components, such as a guide wire, a snare **10**, an inner sheath and an outer sheath **22**. The proximal ends of these components are generally located outside the patient's body so that the operator can manipulate each of the components by grasping the proximal portion of the components and moving the component in a proximal or distal direction. Often, the proximal portions or ends of the components are or can be reversibly secured or fixed to one another in a proximal handle portion, using a rotatable or twist fitting, such as a luer lock, for example. Because one hand of the operator is often used to manipulate the component, only one hand is free to disconnect or connect the fittings, which can be difficult to do for a rotatable luer lock fitting. In addition, the twisting or rotation of the twist fitting can lead to unintentional and undesired twisting or rotation of the snare device.

[0120] Therefore, it would be advantageous to provide fittings that can more easily be manipulated with one hand, such as a snap fitting, as illustrated in FIGS. **20-22**. The snap fitting **100** comprises a female connector **102** and a male connector **104**. In some embodiments, the female connector **102** can have a plurality of flexible latch portions **106** that define an opening **112** and enclose a receptacle **108** that is configured to receive the male connector **104**. For example, the female connector **102** can have 2, 3, 4 or more latch portions **106**. The distal end of each flexible latch portion **106** can include a retaining feature **110** that projects radially inwards and functions to secure the male connector **104** within the receptacle **108**. The male connector **104** comprises a distal portion **114** that is configured to fit through the opening **112** and within the receptacle **108**. The male connector **104** can also include a narrow stem portion **116** that has a diameter less than the diameter of the opening **112**. In some embodiments, the distal portion **114** and/or the latch portions **106** can be tapered towards the outer or inner edge in order to present an angled surface to the opening **112** that can aid in widening the opening **112** by pushing apart the latch portions **106**.

[0121] These snap fittings **100** can be integrated into the proximal ends of the various components described herein, and well as other components that can be used with the retrieval system. Alternatively, the snap fittings **100** can be made into luer lock adaptors, or other connector adaptors such as screw adaptors, that allow the operator to convert a luer lock fitting, or other fitting, into a snap fitting, as illustrated in FIGS. **20-22**. In some embodiments, the device can include an outer catheter with an outer catheter hub and an inner catheter with an inner catheter hub. The female connector **102** of the snap fitting **100** can include a locking feature **118**, such as a luer lock fitting, that allows it to reversibly attach to the inner catheter hub. The outer catheter hub can include the male connector **104**, which can be integrated into the outer catheter hub as illustrated, or can be reversibly attached as described above for the female connector **102**. In some embodiments, all the components are locked together during insertion.

[0122] In some embodiments, the proximal gripping portions of the components can include an indicator that identifies which component the operator is gripping, thereby reducing the confusion that can occur in locating the corresponding proximal gripping portion for the desired component. In some embodiments, the gripping portion can include a visual indicator. For example, the different components can have color coded gripping portions, or can be labeled with, for example, an easily read symbol or the name of the component. In some embodiments, the gripping portion can include a tactile indicator that allows the operator to distinguish between the different components without having to look at the gripping portions, which allows the operator to maintain visual focus on more important matters, such as real-time imaging of the retrieval system within the patient provided through fluoroscopy. For example, one component can have a smooth gripping portion, another component can have a rough or knurled gripping portion, and another component can have a dimpled or ridged gripping portion. Each component can have a different tactile pattern to provide tactile contrast between the components.

[0123] Retrieval Device with IVUS and Pressure

[0124] In some embodiments, a pressure sensor and/or an intravascular ultrasound (IVUS) transducer can be added to or incorporated into the delivery system and method. The pressure sensor can be used to measure the pressure at various positions within the vasculature, which can be used to determine blood flow, while the intravascular ultrasound (IVUS) transducer can be used to measure fluid flow and/or provide imaging within the vessel. In some embodiments, the pressure sensor and/or IVUS transducer can be incorporated into the guidewire at one or more locations, such as the distal end or distal portion of a guidewire, as described in U.S. Pat. No. 8,277,386, U.S. Pat. No. 6,106,476 and U.S. Pat. No. 6,780,157 which are hereby incorporated by reference in their entireties for all purposes, as well as being incorporated into intermediate and proximal portions of the guidewire. The guidewire with the pressure sensor and/or the IVUS transducer can be used much like a normal guidewire to help navigate the delivery device through the vasculature, with the added benefit of providing pressure measurements and ultrasound imaging to help in the navigation, to visualize the

device placement site, and to monitor and ensure proper device deployment. In some embodiments, the IVUS transducer generates image slices as it is advanced and retracted which can then be assembled together to form a three dimensional reconstruction of the vasculature and/or the device within the vasculature. In some embodiments, the guidewire with the pressure sensor and/or IVUS transducer can be fastened to a catheter in a similar manner to that described below for a catheter having a pressure sensor and/or IVUS transducer that is fastened to another catheter.

[0125] FIGS. **23**A-**23**C illustrate an example of a guidewire **2300** having both a pressure sensor **2302** and an IVUS transducer **2304** located at the distal portion of the guidewire **2300**. In some embodiments, the pressure sensor **2302** can be made from a semiconductor material, such as silicon, that is formed into a diaphragm and can be located proximally of the distal tip, while the IVUS transducer **2304** can be located at the distal tip of the guidewire **2304**.

[0126] In some embodiments, the pressure sensor and/or IVUS transducer can be located on a catheter in a similar configuration to the guidewire. For example, the IVUS transducer can be located on the distal tip of the catheter while the pressure sensor(s) can be located proximally of the IVUS transducer at one or more locations along the catheter body, from the distal portion of the catheter to an intermediate portion of the catheter to the proximal portion of the catheter. The pressure and/or imaging catheter can be used in parallel with the delivery or retrieval device or any other catheter that is inserted into the vasculature. In some embodiments, the pressure and/or imaging catheter can be fastened to the delivery or retrieval device or other catheter by, for example, enclosing both catheters in a sheath or larger catheter or by fusing the two catheters together. For example, U.S. Pat. No. 6,645,152 and U.S. Pat. No. 6,440,077, both to Jung et al. and hereby incorporated by reference in their entireties for all purposes, discloses an intravascular ultrasound catheter joined together in parallel with a vena cava filter delivery device to guide placement of the filter in the vena cava. The pressure and/or imaging catheter can be used for the same purposes as the pressure and/or imaging guidewire.

[0127] FIGS. **24**A-**24**D illustrate two embodiments of an intravascular ultrasound catheter **2400** joined together in parallel with a catheter **2402** that can be used, for example, to deliver a device to a location with the vasculature, such as a vena cava filter to the vena cava. The intravascular ultrasound catheter **2400** can have an IVUS transducer **2404** located on the distal portion of the IVUS catheter **2400**. The IVUS transducer **2404** can be a solid state transducer that is disk shaped or cylindrically shaped with a hole to allow passage of a guidewire **2406** or other device through the IVUS catheter **2400**. As shown in FIGS. **24**A and **24**B, the IVUS catheter **2400** and the delivery catheter **2402** can be joined together in parallel without a sheath by adhering or fusing the two catheters together. FIGS. **24**C and **24**D illustrate the same IVUS catheter **2400** and delivery catheter **2402** fastened together using a sheath **2408**.

[0128] In some embodiments as illustrated in FIGS. **25**A and **25**B, the pressure sensor and/or IVUS transducer can be integrated into the delivery or retrieval catheter **2500** or device itself. For example, the IVUS transducer **2502** can be integrated into the distal tip or end of the catheter **2500** or device. The pressure sensor **2504** can be located on a distal portion of the catheter shaft proximally of the IVUS tranducer **2502**. A wire can extend from the IVUS transducer **2502** and/or pressure sensor **2504** to one or more connectors **2506** located at the proximal end of the catheter **2500**. The connector(s) **2506** can be used to connect the IVUS transducer **2502** and/or pressure sensor **2504** to an imaging system and/or processing system. In the illustrated embodiment, the catheter **2500** can be used to deliver a vena cava filter **2508** to the vena cava. The catheter **2500** can additionally have a telescoping sleeve or pusher rod to deploy the vena cava filter **2508**, or alternatively, the outer catheter sheath can be retracted to deployed the filter. The IVUS transducer can provide positioning guidance and determine the relative location of the filter by advancing and retracting the IVUS transducer **2502** on the catheter **2500** to generate a plurality of image slices that can be assembled to reconstruct a three dimensional image.

[0129] Use of the ultrasound imaging system allows the operator to deliver the device without fluoroscopy or using less fluoroscopy, thereby reducing the radiation exposure to the patient, while allowing more accurate evaluation of the vasculature, aiding placement of the device and allowing confirmation that device placement was proper. The imaging can be used to aid in the deployment of the filters or other devices. The imaging can also be used to aid in the retrieval of the deployed devices by providing visualization of, for example, the retrieval features on the deployed device and of the retrieval features, such as loops on a snare, of the retrieval device. The vasculature and implant location can be imaged prior to deployment, after deployment and/or during deployment. The imaging can be used during the retrieval process. The imaging can be used to aid in positioning of the filter or device within the vasculature. The imaging can be used to image the deployment location and determine the appropriate sizing of the filter or other device. The imaging can be used to help estimate treatment duration.

[0130] Although an imaging systems described above have been ultrasound based, other imaging systems can be used instead or in addition. For example, the imaging system can be based on intravascular ultrasound (IVUS), Forward-Looking IVUS (FLIVUS), optical coherence tomography (OCT), piezoelectric micro-machined ultrasound traducer (PMUT), and FACT.

[0131] Imaging System and Method for Navigation

[0132] One or more imaging modalities can be used to assist the navigation of the catheter and/or retrieval device through the vasculature and to assist in the surgical procedure at the surgical site. For example, fluoroscopy can be used to determine the location of the catheter and/or retrieval device in the vasculature and to assist in navigation. However, fluoroscopy involves the exposure of the patient to x-rays, which over time may increase the risk to a variety of diseases such as cancer, and may also cause burns to tissue such as the skin. The long procedure times for some operations can exacerbate these problems. In addition, medical personnel can also be exposed to incidental x-rays. Although the incidental exposure to the medical personnel is much lower than the patient during a given procedure, the numerous procedures using fluoroscopy conducted by the medical personnel during the course of the year can result in significant x-ray exposure to the medical personnel over time.

[0133] Therefore, the use of an additional or alternative imaging modality, such as intravascular ultrasound (IVUS) imaging, can be used to assist in navigation and assist in the surgical procedure at the surgical site, which can allow the use of fluoroscopy to be reduced, thereby lowering the x-ray

exposure to both the patient and medical personnel. Another imaging modality that can be used is optical coherence tomography (OCT). Although the following embodiments have been described primarily using IVUS imaging, OCT imaging can be used by adding a fiber optic element and optical sensor to the catheter.

[0134] The multiple imaging modalities can generate different images that can be displayed separately on one or more displays and/or overlayed and combined or coregistered into a single image and for display on a single display.

[0135] In some embodiments, the imaging devices can be in communication with a computer system having a processor for executing instructions and software, memory for storing the instructions and software, one or more input devices such as a keyboard and mouse, and a display.

[0136] FIG. **38** illustrates an embodiment of a method of navigating the delivery device and/or retrieval device from the insertion site to the destination site. In some embodiments, the method can be implemented by software that is executed on a computing device. At step **3800**, the software and computing device can obtain information from the operator regarding the insertion site, implant or therapeutic device, delivery device, retrieval device, and surgical procedure.

[0137] For example, the software can be imaging software that is designed for use to assist in various surgical procedures. For example, the imaging software can include a representative digital model of the cardiovascular system that includes all the blood vessels and the structures of the heart. In addition, the software can include a list of standard surgical procedures and allow the creation of custom surgical procedures, which can be a modification of the standard surgical procedures or can be created from scratch. The surgical procedures in the software contain information regarding the insertion site, the path of travel through the vasculature, the destination, and information regarding the performance of the procedure itself. For example, the surgical procedure can be linked to various instructions for use (IFU) associated with the devices used in the procedure. Also, given a particular insertion site and destination, the imaging software can anticipate the pathway through the vasculature that the surgeon will likely navigate and can determine the anatomical landmarks between the insertion site and destination site, as shown in step **3802**. For example, the software can identify the vessel junctions that the guidewire, catheter, guide sheath, or other device will encounter and pass as it is advanced from the insertion site to the destination.

[0138] The software can also have information regarding the device and/or implant, such as the size and shape of the device and/or implant, the echogenic markings on the device and/or implant, the fluoroscopic markings on the device and/or implant, and the like. In one aspect, the various markings on the device and/or implant may be adapted and configured as an identification designation. In one embodiment, the identification designation includes a color designation selected by the user of provided by the system. For example, one or more markers in a distal portion of may be in a first color, a mid-portion may be in a second color and in a proximal portion in still a third color. In contrast to designating regions of the device and/or implant, the user or the system may designate individual markers each with a different color or grouped into zones of color. In still another aspect, the entire model or representation of the implant or device or portion thereof may be in color to permit easier identification in the navigation display. In still other embodiments, the color of all or a portion of the device/implant or the color indicated for one or more markers is determined by whether or not the device/implant or marker is in a proper or expected position or in an improper or unexpected position. In one embodiment, proper or expected positions may display as green, improper positions as red and unexpected or indeterminate positions as yellow. In each of the above examples, colors are exemplary of a kind of identification designation and other indicia such as numbers, letters, pictograms (e.g., check marks, X, thumb up, thumb down and the like) may be used.

[0139] The software can also have information regarding the delivery device and/or retrieval device including whether the delivery device and/or retrieval device is equipped with one or more IVUS transducers, pressure sensors, and the like. In some embodiments, the imaging software can construct a two dimensional and/or three dimensional reconstruction of the patient's vasculature in real time using the acquired imaging data from the one or more imagining modalities, as shown in step **3804**. For example, in steps **3806** and **3808**, fluoroscopy, if used, can be used to construct an initial two dimensional reconstruction of the patient's circulatory system and vasculature between at least the insertion site and the destination site. In addition, echocardiography, such as trans-esophageal echocardiography (TEE) and trans-thoracic echocardiography (TTE), can be used to generate images and/or determine blood velocity and tissue velocity. An intravascular imaging modality, such as IVUS and/or OCT, can be used to generate a two dimensional and/or three dimensional reconstruction of the patient's circulatory system and vasculature as the imaging device is moved through the vasculature, as shown in steps **3810** and **3812**. The images can have an included scale that allows the distance between the vessels and other anatomical markers to be determined. The imaging device can have an outside surface with length or distance markings that allow the surgeon to determine what length of the imaging device has been inserted into the patient. In addition, the outside surface of the imaging device can include a longitudinal line along its length that allows the rotational orientation of the device to be determined.

[0140] Imaging data can be acquired as the imaging device is advanced through the vasculature, and also while the imaging device is retracted in reverse. In some embodiments, it can be desirable to scan a portion of the vasculature one or more times, such as two or three times for example, in order to enhance the resolution and/or accuracy of the reconstructed image.

[0141] In some embodiments, the imaging software can detect the presence of vessel junctions and/or other landmarks. In addition, as stated above, given a particular insertion site and destination, the imaging software can anticipate the pathway through the vasculature that the surgeon will likely navigate, and therefore, the software can identify the vessel junctions and/or other landmarks that the guidewire, catheter, guide sheath, or other device will encounter and pass as it is advanced from the insertion site to the destination. In some embodiments, for each detected vessel junction or other anatomical landmark, the imaging software can preliminarily tag, assign or suggest the name of the detected vessel junction and/or other landmark, as shown in step **3814**. The surgeon can accept the recommendation of the imaging software, or can override the recommendation by assigning a different vessel or landmark name to the detected vessel junction and/or other landmark. In some embodiments, the software can provide the recommended name along with one or more

alternative names for the detected vessel junction and/or other landmark, and the surgeon can select the recommended name or alternative name with a single mouse click or keyboard click. The recommendations can be placed over the image of the detected vessel junction and/or landmark. In addition or alternatively, the surgeon can be provided a list of potential names identified by the imaging software that can be selected by the surgeon. The surgeon can click or drag the name on top of the detected vessel junction and/or other anatomical landmark. In addition, the surgeon can manually enter in a name for the vessel junction and/or anatomical landmark, if, for example, the name does not appear in the recommendation or list. As the surgeon confirms and locks in the names of each detected vessel junction and/or other anatomical landmark, the imaging software can reevaluate and update its recommendations. The recommendations from the imaging software can be based on the insertion site, the destination, the anticipated pathway through the vasculature, the length of the device that has been inserted into the vasculature, the flow rate of blood, the blood pressure, the vessel diameter, the distance between other vessel junctions and/or anatomical landmarks, and the distance from and/or relative position to a confirmed or locked vessel junction and/or anatomical landmark.

[0142] This imaging procedure involving the identification of the vessel junctions and/or anatomical landmarks can be done either as a preliminary step before the catheter, which can be or include the retrieval device described herein, is inserted, or can be done concurrently with a catheter that doubles as an imaging device. In some embodiments, the guidewire and/or guide sheath and/or the catheter can include an imaging device, such as an imaging IVUS transducer located at the distal portion or tip of the device. The identified vessel junctions and/or anatomical landmarks can assist the surgeon in navigation the device through the vasculature to the destination site.

[0143] In some embodiments, the destination site, or a plurality of destination sites, can also be imaged in detail to assist the surgeon in accurately placing the device in the vasculature. For example, the femoral vein, the renal veins, and the inferior vena cave, for example, can be imaged along with other branch vessels. The locations of the vessels, the size and shapes of the vessel openings, the spacing between the openings, and the junction between vessels can be imagined and determined by the system and method.

[0144] In step **3816**, the location of the delivery catheter can be determined. In some embodiments, the system can determine the location of the delivery catheter and/or retrieval device using one or more of the following: identification of anatomical landmarks in a previous step, the length of the delivery device that has been inserted into the vasculature, identification by the user, and identification of the implant or object to be removed. If the delivery catheter and/or retrieval device is not at the destination site, the system and software can instruct the operator to advance, retract, and/or rotate the delivery catheter and/or retrieval device, as shown in step **3820**, based on the determined location of the delivery catheter and/or retrieval device. After or as the delivery catheter and/or retrieval device is moved through the vasculature, the system again acquires IVUS imaging data, as shown in step **3810**. As shown in FIG. **38**, the system and method enters a loop until the system and method determines that the delivery catheter and/or retrieval device is at the destination site in step **3818**. When the system and method determines that the delivery catheter and/or retrieval device is at the destination site, the operator can be informed, through a visual and/or audible notification for example, that the destination has been reached and that deployment of the implant or device can begin, as shown in step **3822**.

[0145] Imaging Systems and Methods for Device Deployment

[0146] In some embodiments, the software can further include a module for assisting in the deployment of the implant or device. As described above, the user can select a medical procedure from a list or menu, at either the prompting of the software, or by manually selecting the option from a menu.

[0147] Each preprogrammed medical procedure includes information regarding the standard procedure steps, including for example, the access points, the typical routes of navigation, the equipment required or recommended, and information regarding the echogenic implant, including models of the implant and color sections or other identification designations described above. The user can be presented with a plurality of fields which each present one aspect of the medical procedure. For example, one field can present access points and can present as a default the most common access point typically used in the medical procedure. If the user desires to use a different access point, the user can click on the access point field to select from a plurality of different predetermined access points, or can manually customize an access point by dragging a marker over a schematic drawing of the human body or a representation of the patient's vasculature generated by patient specific imaging data.

[0148] For a given procedure, the destination is generally known, and therefore, the navigation route through the vasculature can be determined by the system based on the access point and the destination, as described above.

[0149] Another field can allow the user to select the implant being used in the medical procedure from a predetermined list. The software can be preprogrammed with all the features of the various implants, including size, three-dimensional shape, location of echogenic features, pattern of echogenic features, and nature of the echogenic features. Additionally or optionally, one or more of the identification designations associated with the device may be preprogrammed or provided by the user such that the display information relating to the position, orientation or placement of an implant is provided according to the user's preferred color or other identification designation. Once the particular implant to be used is selected, the system will be able to automatically identify the implant and its location and orientation within the vasculature using one or more imaging modalities, such as IVUS imaging or FLIVUS imaging, by identifying the various features of implant in the ultrasound imaging data and mapping the data to a model of the implant that is prestored in the software database. By determining the three dimensional location of each of these features within the vasculature, the location and orientation of the implant or device within the vasculature can be determined. The output presented to the user may also be updated to include one or more of the device identification designations.

[0150] The imaging system can also be used to image the deployment or retrieval site and can automatically identify the anatomical structures of interest, such as the inferior vena cava and the renal veins. The system can provide real-time imaging and implant deployment guidance by imaging the implant throughout the deployment procedure, displaying the real-time images to the user that includes a reconstruction of

the deployment site and the current implant location and orientation within the deployment site, the current retrieval device location and orientation, and by providing instructions or recommendations to the user to achieve correct device deployment. The real time display may also be updated to include one or more identification designations or changes to an identification designation depending upon the stage of the procedure, user actions or other factors.

[0151] For example, FIG. **39** illustrates an embodiment of a deployment procedure, which can begin after the destination site has been reached. In step **3900**, the system and software can determine the relative position between the delivery device and/or retrieval device and one or more landmarks at the deployment site using IVUS and/or other imaging modalities. Based on the determined relative position, the system and software can determine whether the delivery device and/or retrieval device is at the target deployment location, as shown in step **3902**. If the delivery device and/or retrieval device is not at the target deployment location, the operator can be instructed to adjust the position of the delivery device and/or retrieval device based on the relative position between the delivery device and landmarks at the deployment site, as shown in step **3904**. After the operator adjusts the position of the delivery device and/or retrieval device, the method can then loop back to step **3900** by again determining the relative position of the delivery device and/or retrieval device to the landmarks. This portion of the procedure is an iterative loop for fine tuning the position and orientation of the delivery device and/or retrieval device before deployment of the implant or device that terminates when the delivery device and/or retrieval device is determined by the system and software to be at the target deployment location. Optionally or additionally, one or more identification designations may be updated or altered depending on the result of the operator action, adjustments to the device or subsequent determination (s) of the system.

[0152] When the delivery device is determined to be at the target deployment location, as shown in step **3906**, the operator can be instructed to begin deployment of the device or implant. During deployment of the device or implant, the system and software can determine the relative position between the partially deployed implant or device with the deployment site using IVUS, as shown in step **3908**. The system and method can then determine whether the implant or device is correctly deployed based on the previous determination in step **3908**. If the system and method determines that the implant or device is not correctly placed, the system and method can instruct the user to adjust the position of the implant or device based on the relative position between the implant or device and landmarks at the deployment site, as shown in step **3912**. The system and method then loops back to step **3908**. This loop can continue until the system and method determines that the implant or device is correctly deployed, upon which the system and method can instruct the user to complete the deployment of the implant or device, as shown in step **3614**. Optionally or additionally, one or more identification designations may be updated or altered depending on the result of the operator action, adjustments to the device or subsequent determination(s) of the system. When the delivery device is determined to be at the target deployment location, as shown in step **3906**, the operator can be instructed to begin deployment of the device or implant. During deployment of the device or implant, the system and software can determine the relative position between the partially deployed implant or device with the deployment site using IVUS, as shown in step **3908**. The system and method can then determine whether the implant or device is correctly deployed based on the previous determination in step **3908**. If the system and method determines that the implant or device is not correctly placed, the system and method can instruct the user to adjust the position of the implant or device based on the relative position between the implant or device and landmarks at the deployment site, as shown in step **3912**. The system and method then loops back to step **3908**. This loop can continue until the system and method determines that the implant or device is correctly deployed, upon which the system and method can instruct the user to complete the deployment of the implant or device, as shown in step **3914**.

[0153] FIGS. **26**A-**26**G illustrate various embodiments of a retrieval device and/or system **2600** that can include an IVUS transducer **2602** for imaging a deployed device, such as a filter, within the lumen of a vessel. In some embodiments, the retrieval system **2600** can have a plurality of IVUS transducers **2602** located in any of the positions as described herein. In some embodiments, as described above, the retrieval system **2600** includes a snare **2604** having shaft **2606** and a plurality of loop elements **2608** attached to the distal portion of the shaft **2606**. In some embodiments, the loop elements **2608** extend both axially and radially outwards.

[0154] In some embodiments, as illustrated in FIGS. **26**A-**26**C, the loop elements **2608** can be attached to the shaft **2606** proximally of the distal end of the shaft. An IVUS transducer **2602** can be located on the distal end of the shaft **2606**. As shown in FIG. **26**A, the loop elements **2608** can be attached to the shaft **2606** such that the distal ends of the loop elements **2608** when fully deployed are aligned or substantially aligned with the IVUS transducer **2602**. In other embodiments, as illustrated in FIG. **26**B, the distal ends of the loop elements **2608** when fully deployed are located distally of the IVUS transducer **2602**. In other embodiments, as illustrated in FIG. **26**C, the distal ends of the loop elements **2608** when fully deployed are located proximally of the IVUS transducer **2602**. These configurations can be used to optimize both the ability of the IVUS transducer to image the retrieval feature of the filter and the ability to align the distal end of the loop elements **2608** with the retrieval feature of the filter. A variety of factors can dictate which configuration is appropriate, such as the configuration of the retrieval feature and the imaging capability and configuration of the IVUS transducer **2602**. For example, for an IVUS transducer **2602** designed to image predominately in the radial direction, it may be desirable to align the IVUS transducer **2602** with the distal end of the loop elements **2608** as shown in FIG. **26**A. Alternatively, if the IVUS transducer **2602** is configured to image in a more forward looking direction, i.e. FLIVUS, it may be desireable to place the IVUS transducer **2602** proximally of the distal end of the loop elements **2608**, as shown in FIG. **26**B.

[0155] In some embodiments, as illustrated in FIG. **26**D, the IVUS transducer **2602** can be located on the distal portion of the retrieval sheath **2610**. In some embodiments, the IVUS transducer can be located proximally of the flexible, invertable tip portion **2612** of the retrieval sheath **2610**. In other embodiments, the IVUS transducer **2602** can be located at the distal tip in place of the flexible, invertable tip portion **2612**.

[0156] In some embodiments, as illustrated in FIGS. **26**E and **26**F, the IVUS transducer **2602** can be located on the shaft **2606** of the snare **2604**. The IVUS transducer **2602** can be located on the distal end of the shaft **2606** around the connec-

tion between the loop elements **2608** and the shaft **2606**, as shown in FIG. **26**E. In some embodiments, the IVUS transducer **2602** can be located on the distal portion of the shaft **2606** proximally of the connection **2614** between the loop elements **2608** and the shaft **2606**, as shown in FIG. **26**F.

[0157] In some embodiments, as illustrated in FIG. **26**G, the IVUS transducer **2602** can be located on the distal end of a guide catheter **2620** in which the retrieval system **2600** can be inserted through. A guidewire **2630**, with an optional pressure sensor **2632**, can be used in conjunction with the guide catheter **2620** and IVUS transducer **2602** to navigate through the vasculature to the deployed filter or device.

[0158] In some embodiments, as illustrated in FIGS. **27**A-**27**C, the loop elements of the snare can function as a centering device **2700** that positions the IVUS transducer **2602** in the central portion of the lumen of the vessel **2701**. In some embodiments, keeping the IVUS transducer **2602** centered within the lumen of the vessel **2701** maintains or enhances the imaging quality of the IVUS transducer **2602**. The centering device **2700** can have two or more loop elements **2702** that extend radially outwards from the catheter or elongate member **2704** that carries the IVUS transducer **2602**. For example, the centering device **2700** can have 2, 3, 4, 5, 6, 7, or 8 loop elements **2702**. The loop elements **2702** can be attached to the catheter or elongate member **2704** in various locations and configurations as described above for the attachment of the snare loop elements **2608** to the snare shaft **2606**. In some embodiments, the loop elements **2702** extend radially outwards with little axial extension. In other embodiments, the loop elements **2702** extend radially outwards and also axially in a distal and/or proximal direction. In some embodiments, a sheath **2706** can be used to cover the loop elements **2702** when the centering device **2700** is in a stowed configuration. The sheath **2706** can be retracted or the elongate member **2704** can be advanced relative to the sheath **2706** in order to deploy the loop elements **2704** in a deployed configuration. In some embodiments, the degree or amount of radial deployment of the loop elements **2702** can be controlled be controlling the amount the sheath **2706** is retracted or the elongate member **2704** is advanced. Therefore, for example, in a smaller vessel, the sheath **2706** can be retracted to a lesser amount than in a larger vessel, thereby resulting in radial deployment of the loop elements **2706** to an appropriate degree suitable for the smaller vessel.

[0159] As illustrated in FIG. **27**C, the loop elements **2608** can additionally or alternatively be used to position an array of IVUS transducers **2602** around the periphery of the lumen and along or proximate the lumen wall. In some embodiments, the IVUS transducers **2602** can be integrated into wire based loop elements **2608** to form the array. The IVUS transducers can be placed on the distal portions of the loop element that is configured to abut against the lumen wall. In some embodiments, the IVUS transducers can be spaced evenly around the lumen wall when deployed. This array of IVUS transducers can be used to generate a sharp image of the tissue/lumen interface, along with any objects located within or near the tissue/lumen interface, such as a retrieval feature of a device that is located against or proximate the lumen wall.

[0160] FIG. **28** illustrates a method of using a retrieval system **2600** having one or more IVUS transducers **2602** to retrieve a filter **40** from a body lumen. IVUS transducers **2602** can be located on the snare shaft **2606**, the retrieval sheath **2610** and/or the guide catheter **2620**, as described above. For example, a guidewire **2630** and the guide catheter **2620** can be inserted into the vessel through the a peripheral vessel, such as the femoral vein, for example, and navigated using IVUS imaging and/or fluoroscopy to the filter **40** location in, for example, the inferior vena cava. The retrieval device **2600** can be inserted through the guide catheter **2620** and IVUS imaging using any one of the IVUS transducers **2602** can be used to determine the location and orientation of the retrieval feature **42** on the filter. For example, the IVUS transducer **2602** on the distal end of the shaft **2602** can be used to align the distal end of the loop elements **2608** with the retrieval feature **42** of the filter **40**, ensuring proper capture of the retrieval feature **42** with the retrieval device. If needed, the loop elements **2608** can be rotated to effect capture of the retrieval feature **42**.

[0161] In some embodiments, the echogenicity of the loop elements **2608** can be increased by employing twists or braids of two or more wires to form the loops. In some embodiments, an echogenic material can be used to coat the loop elements **2608** and other parts of the snare. For example, various echogenic features as described below can be incorporated into the loop elements **2608** and any other feature of the retrieval system **2600**. In addition, echogenic materials and features can be incorporated into the filter device, as described below, in order to enhance its retrievability under IVUS imaging.

[0162] Filters are more complex structures in contrast to the relatively simple designs found in catheters and needles. In a more complex device like a filter there is a need to identify specific portions within the device during some medical procedures. In addition, it would be advantageous as well to determine the orientation of the device including components within the device to one another (as used for determining deployment, retrieval and the various intermediate stages thereof) as well as the overall filter orientation to the surrounding lumen or vessel. In contrast to the conventional techniques using location of the tip or start or end of the entire length, a more complex structure such as a filter position, orientation or relative placement information would yield specific benefits. In some cases, aspects, portions or attributes of the overall filter or filter components or portions will enable more useful determinations about the filter in relation to the physiological environment. In one aspect, an intravascular ultrasound (IVUS) catheter and processing system or signal processing algorithm is used to confirm filter sizing selection, guidance for filter placement, filter implantation steps, filter and/or vessel measuring using IVUS before during and/or after steps to confirm sizing selection and fit is appropriate under the physiologic environment and for confirmation and/or documentation of proper sizing selection, placement, engagement or degree of engagement of fixation elements (if present), clot burden, orientation and/or deployment in a patient or physician medical record.

[0163] In one aspect, embodiments of the present invention are directed toward medical devices having a complex shape or that are configured to move from stowed to deployed configurations that may also have specific orientation and placement criteria for proper use in a lumen, vessel or hollow organ. One such complex device is an IVC filter. Aspects of the present invention include such devices employed within the human body which have enhanced ultrasound visibility by virtue of incorporation of an echogenic material using any of the techniques described herein alone or in any combination.

[0164] In one aspect, there are described herein various alternative filter designs for increasing the echogenicity of the

filter. A filter with enhanced echogenic characteristics may include one or more than one of: (a) a modification to one or more components of the filter to enhance the echogenic characteristics of the component; (b) formation of dimples into a component surface of sufficient number and scaled to a suitable size, shape, orientation and pattern for use with intravascular ultrasound systems; (c) protrusions formed in, placed on or joined to a filter surface; (d) roughening one or more surfaces of a filter, for example using a chemical process, a laser or bead blasting technique; and (e) altering one or more steps of a filter manufacturing technique to introduce cavities, voids or pockets to locally modify or adapt one or more acoustic reflection characteristics to improve echogenicity in one or more specific regions of a filter. One example of the manufacturing alteration is to introduce gaps between the segments of tubing or coverings whereby the gap provides the echogenic enhancement. In addition, cavities, voids, pockets, dimples, gaps and the like may be left empty or, optionally, filed, partially filed or lined with any of the echogenic materials described herein.

[0165] In one aspect, there are provided embodiments of a filter having enhanced echogenic characteristics in or related to at least one or a portion of: an proximal end, a distal end, a terminal proximal end, a terminal distal end, a retrieval feature, an atraumatic tip on a retrieval feature, a mid-strut region, a leg or strut portion having at least one orientation attribute to another portion of the filter, an indicia of a location of a fixation element or a retrieval feature, a location on a portion of the filter selected such that in use with a particular fixation element the marker in a location that indicates that the fixation element is fully deployed into a wall of a lumen or portion of a vessel or hollow organ (i.e., the marker is against the lumen wall or nearly so when the fixation element is fully engaged. As such, see the marker against the wall indicates proper deployment, spaced from or not visible would indicate, respectively, not fully engaged or over penetration); a portion of the distal tip and/or an elongated portion. The above described methods may also be applied to the other techniques and alternatives described herein.

[0166] In still further embodiments, a portion, component or aspect of an intraluminal filter may have enhanced echogenic attributes by applying a coating or sleeve containing one or more of the echogenic materials disclosed herein or fabricated according to any of the techniques or having any of the attributes to enhance echogenic qualities as described herein. In some aspects, the enhanced echogenic attributes are provided by the incorporation into, application onto or within a component or portion of a filter one or more echogenic materials or echogenic markers in a specific configuration, location, orientation or pattern on the filter.

[0167] Enhanced echogenic markers or locations may be devised and placed for use individually or in combinations such as to facilitate the identification to an IVUS system or ultrasound imaging modality an indication or signature for a specific location on a filter, such as, for example, a retrieval feature, a terminal proximal end, a terminal distal end, a location of a fixation element or a location of some other indicia that identifies a specific aspect of a particular filter design. In addition or alternatively, two or more enhanced echogenic markers or portions may be used in combination to provide additional information about a filter such as orientation with in a vessel, confirmation of deployment or a portion of a deployment sequence, confirmation of final placement, confirmation of migration or lack of migration, confirmation of retrieval or progress in a retrieval sequence and the like according to the various processes and used for filters within the vasculature or in lumens of the body. In another specific embodiment, the use of IVUS techniques with embodiment of the echogenic enhanced filters describe herein may also be used to measure the diameter of the vessel at specific device locations indicated by the echogenic markers during or after deployment or retrieval of a filter.

[0168] In still further aspects, the use of IVUS techniques with embodiment of the echogenic enhanced filters describe herein may also be used to determine, detect or indicate inadequate dilation, adequate dilation, filter expansion, degree of filter expansion, filter—vessel engagement and degree or engagement, strut/leg/anchor position and other attributes relating to the interaction between the filter and the surrounding physiological environment.

[0169] Still further, the echogenic markers are positioned with regard to the likely or planned positioning of the IVUS transducer and/or likely pathways for acoustic energy used by the imaging system. By way of example, if the IVUS transducer is forward looking, then those forward looking aspects of the filter will be provided with the enhanced echogenic aspects. In another example, if the IVUS transducer is cylindrically shaped and will be positioned through the interior portion of a filter then the filter will be provided with enhanced echogenic aspects on interior surfaces or portions that would receive acoustic energy from such as transducer in such a position. Other modifications are within the scope of the invention based on the particular style of IVUS transducer used, the position relative to the filter and the placement and type of echogenic feature incorporated into the filter. Put another way, the echogenic enhancements of the filters described herein are selected, designed and positioned on the filter with regard to the IVUS sensor type, acquisition mode and position relative to the filter. Additional details in the use of IVUS with filters is further described in U.S. Pat. Nos. 6,645,152 and 6,440,077, both of which are incorporated herein by reference in their entirety for all purposes.

[0170] In one aspect, the placement and signature of such enhanced echogenic markers are discernible to a human user viewing an ultrasound output alone or in combination with being discernible to a computer system configured for the processing of an ultrasound return including a return from the enhanced echogenic filter. Additional aspects of the formation and use of echogenic materials is made with reference to the following US Patents and Patent Publications, each of which is incorporated herein by reference in its entirety: US 2010/0130963; US 2004/0230119; U.S. Pat. Nos. 5,327,891; 5,921,933; 5,081,997; 5,289,831; 5,201,314; 4,276,885; 4,572,203; 4,718,433; 4,442,843; 4,401,124; 4,265,251; 4,466,442; and 4,718,433.

[0171] In various alternatives, the echogenic material may either be applied to a portion of or a component of a filter in any of a number of different techniques.

[0172] In one example, an echogenic component or additive is applied to or incorporated into a filter or portion of a filter as a selective coating applied to a portion or component of a filter.

[0173] In one example, an echogenic component or additive is applied to or incorporated into a filter or portion of a filter as a mold formed to be placed over or joined to a portion of component of a filter.

[0174] In one example, an echogenic component or additive is applied to or incorporated into a filter or portion of a

filter as an extruded sleeve formed in a continuous segment to cover a portion or component of a filter. In one embodiment, one of the inner tubular member or the outer sleeve or coating may be fabricated of a material according to the present invention, having increased echogenicity, with the other of the inner tubular member fabricated of a biocompatible polymer such as polyurethane or silicone rubber, for example.

[0175] In one example, an echogenic component or additive is applied to or incorporated into a filter or portion of a filter as a compound or two layer structure comprising an inner tube and an outer tube or sleeve with one or both of the tubes made from or including or incorporating one or more echogenic materials or modifications as described herein. In addition or alternatively one or both sleeves, tubes described herein may include or encapsulate an echogenic marker or component of specific shape or geometry, for example, as in the case of a tube structure having within the sidewall of the tubing a coiled structure. In one aspect, the coiled structure is made from an echogenic material and the windings are provided in a manner that is useful in any of the aspects of the filter described herein. The coil may have a particular size or variation in size, pitch or variation in pitch or other attribute useful in providing an echo identifiable aspect of the filter property being determined. In one specific embodiment, the dimensions of the coil or other echogenic material has dimensions selected for increasing acoustic reflection with regard to the resolution or processing algorithms used in the imaging ultrasound system.

[0176] In one example, an echogenic component or additive is applied to or incorporated into a filter or portion of a filter as a braided structure incorporated into a compound or two layer structure comprising an inner tube and an outer tube or sleeve with one or both of the tubes made from or including or incorporating one or more braid comprising echogenic materials or modifications as described herein. In addition or alternatively one or both sleeves, tubes described herein may include or encapsulate an braid formed into an echogenic marker or component of specific shape or geometry, for example, as in the case of a tube structure having within the sidewall of the tubing a braided structure. In one aspect, the braided structure is made from an echogenic material and the braided is a small diameter that is when wound around the tubes or sleeve or directly onto a portion of or component of a filter. The winding pattern and spacing of the braided materials are provided in a manner that is useful in any of the aspects of the filter described herein. The braid may have a particular braid strand composition, structure, size or variation in size, pitch or variation in pitch or other attribute useful in providing an echo identifiable aspect of the filter property being determined. One or more of the strands in the braid may be formed from an echogenic material. One or more of the strands may be formed from a material having improved radiopaque characteristic. One or more of the strands may be formed from a material having both echogenic and radiopaque properties. The strands of a braid may be combined using any of the above described strand characteristics.

[0177] In another alternative, in still another example, an echogenic component or additive is applied to or incorporated into a filter or portion of a filter as the a series of short segments placed adjacent to one another along a portion or component of a filter in either a close packed or spaced arrangement. In another embodiment, the spacing or voids between adjacent segments may also be adjusted or selected so as to enhance echogenic capabilities of the filter using the material difference introduced by the spacings or voids.

[0178] In another alternative, in still another example, an echogenic component or additive is applied to or incorporated into a filter or portion of a filter as a tubing or sleeve suited to heat shrink operations. In one aspect, there is a manufacturing or assembly steps of sliding one or more sleeves over portion of the filter then apply heat to shrink down the segment about the portion of the filter. In particular, various embodiments provide for the specific placement of such a shrink fit tubing having enhanced echogenic characteristics as described herein. It is to be appreciated that the sleeves, segment or tubes may be provided from or have echogenic modifications or elements incorporated into suitable materials such as, for example, ePTFE, PTFe, PET, PVDF, PFA, FEP and other suitable polymers. Still further, these and other materials may be formed in shapes other than tubes but may also take the form of strands, lines, fibers and filaments to be applied in accordance with the echogenic enhancement techniques described herein. In some embodiments, the tubes or segments applied to a filter may have the same or different composition as well as have the same width or different widths. In one aspect, the width or thickness of a plurality of bands is used to provide a code or information about the filter. The use of echogenic bands of different widths is a marking technique similar to the way that different size and color rings on a resistor are arranged in a pattern to describe the resistor's value.

[0179] In another alternative, in still another example, an echogenic component or additive is applied to or incorporated into a filter or portion of a filter is extruded over a portion of or a component of the filter.

[0180] In another alternative, in still another example, an echogenic component or additive is applied to or incorporated into a filter or portion of a filter is by bonding an echogenic material or components to the filter using a suitable adhesive or bonding technique.

[0181] In any of the above described configurations, the portion or component of the filter may be modified with dimples, grooves, pockets, voids. In other aspects, there may be one or more full or partial circumferential recesses, rings, surface diffraction gratings or other surface features to selectively enhance or provide an echogenic property in that portion of the filter, to aid in or foster the application of the echogenic materials. In still further aspects, any of above described surface modifications may also be used to uniquely identify a portion of a filter or any of the above in any combination.

[0182] In still further aspects of any of the above echogenic markers or attributes the thickness of the sleeve or coating or component may decrease at its proximal and distal ends to provide for a smooth outer surface. As yet an additional alternative, a coating, marker or other echogenic material may extend proximally to or closely adjacent to the distal end or the distal end or both of the filter component or filtering device.

[0183] In still other alternatives or combinations, some filter design embodiments alter components of the filter to enhance echogenicity such as, for example, material selection to incorporate echogenic materials. Examples of echogenic materials include palladium, palladium-iridium or other alloys of echogenic materials.

[0184] In some embodiments, echogenic microbubbles are provided in a portion of a filter to enhance the acoustic reflec-

tions of that aspect of the filter. Echogenic microbubbles may be prepared by any convenient means and introduced into the component or portion thereof or by a coating or sleeve or shell or other transferring means or mixed with a polymer or other suitable base compound prior to extension of extrusion, molding casting or other technique. The echogenic microbubbles may be pre-prepared or prepared inside the component or element or marker as appropriate. Aspects of the preparation or use of microbubbles are described in U.S. Pat. Nos. 5,327,891; 4,265,251; 4,442,843; 4,466,442; 4,276,885; 4,572,203; 4,718,433 and 4,442,843. By way of example, echogenic microbubbles can be obtained by introducing a gas, e.g. carbon dioxide, into a viscous sugar solution at a temperature above the crystallization temperature of the sugar, followed by cooling and entrapment of the gas in the sugar crystals. Microbubbles can be formed in gelatin and introduced into a component or portion of a device. Microbubbles can also be produced by mixing a surfactant, viscous liquid and gas bubbles or gas forming compound, e.g. carbonic acid salt, under conditions where microbubbles are formed.

[0185] In still further alternatives, there is also the incorporation of dual mode materials (radiopaque and echogenic) into a polymer then used to form part of, be applied or otherwise incorporated with a filter device as described herein. Some of these polymer compounds may be fabricated to enhance aging and shelf life and have other beneficial attributes. In one aspect, a filter or portion thereof includes one or more selected segments that are constructed using visibility materials compounded with one or more polymeric materials that make the selected segments visible using both fluoroscopy and ultrasonic imaging. In one specific example, the visibility material may take the form of tungsten and/or tungsten carbide particles dispersed within a polymeric material. In one specific aspect, the radiopaque and echogenic material includes tungsten and/or tungsten carbide particles distributed within a base polymeric material.

[0186] In one embodiment, a portion of or a component of a filter includes or has been modified to have an inner layer including a radiopaque and echogenic material. In one alternative, the radiopaque and echo genic material includes particles distributed within a base polymeric material (i.e., a first polymeric material) including a polyether block amide; and an outer layer including an additional polymeric material (i.e., a second polymeric material). In certain embodiments, the additional polymeric material is a thermoplastic elastomer. Optionally, the additional polymeric material is more resistant to hydrolysis and/or oxidation than the base polymeric material.

[0187] In still further aspects, a component, a portion or an element added to a filter may be regarded as an echogenic body member that is a part of an echogenic filter to be sonically imaged. The echogenic body member is at least partially made up of a composite material which is echogenically imageable in the patient, such as by the use of ultrasonic imaging equipment used either within the patient or external to the patient. In one aspect, a composite material includes matrix material with discrete acoustic reflective particles embedded in matrix material. In one aspect, the matrix material is a biocompatible plastic. Examples of suitable plastics may include urethane, ethylene, silicone, polyethylene, tetrafluorethylene. In one aspect, a matrix is a formable, pliable material which may be molded and/or extruded to a variety of shapes, depending upon a specific application. The sound reflective particles are embedded in matrix material. Particles are, by way of example, made of a hard material, such as small glass particles that are solid or filled with an acoustically reflective medium. In one aspect, glass particles having a generally spherical shape forming glass microspheres. Glass microspheres with an outer diameter of about 5 microns is one acceptable size. Other sized particles may be utilized as, for example, ranging between 1 and 50 microns and beyond. Particles sized below the resolution size of the imaging ultrasound system in use may be arranged into patterns of sufficient size and orientation to the acoustic waves that result in a discernible feature by the imaging ultrasound system. Furthermore, the particles do not necessarily have to be spherical, or may be partially spherical. Still further, the shape of the particle could be altered to enhance acoustic reflection by presenting different shapes of particles, sizes of particles and combinations thereof to modify acoustic characteristics of the matrix material. By way of example, the particles may be shaped into an "Ordered array." "Ordered arrays" can take the form of a macrostructure from individual parts that may be patterned or unpatterned in the form of spheres, colloids, beads, ovals, squares, rectangles, fibers, wires, rods, shells, thin films, or planar surface. In contrast, a "disordered array" lacks substantial macrostructure.

[0188] By way of example, an echogenic marker may comprise particles that individually are below the resolution of the imaging ultrasound system. The echogenic marker is the combination of these below imaging ultrasound resolution particles in combination, in 1D, 2D or 3D patterns, in graphic arrays, or in machine readable combinations to make a signature. Based on the specific characteristics of the combination of particles, the acoustic returns from an echogenic marker or combination of echogenic markers may be visually perceptible in a display for interpretation by a user or may be detected and interpreted by one or more acoustic reflection or spectral processing algorithms within a imaging ultrasound processing system.

[0189] In one aspect, the echogenic material is fabricated by incorporating nanometer sized particles of sonically reflective materials, for example iron oxide, titanium oxide or zinc oxide into a biocompatible polymer. In one method of fabrication, the acoustically reflective particles are mixed with a powdered thermoplastic or thermosetting material such as a polyether amide, a polyurethane or an epoxy, or polyvinylchloride followed by thermal processing of the mixture to provide a material of increased sonic reflectance which may be applied as a coating on medical devices of the type discussed above or may be incorporated as a structural component of the medical devices as described herein.

[0190] In still further embodiments and aspects, the particles included to provide echogenic enhancements may be selected, arranged or incorporated to provide acoustically geometrically tuned nanostructures, microstructures or macrostructures. The particles provided herein are formable in all shapes currently known or to be created for acoustic reflection enhancement. In non-limiting examples, the nano-, micro- or macro-particles are shaped as spheres, ovals, cylinders, squares, rectangles, rods, stars, tubes, pyramids, stars, prisms, triangles, branches, plates or comprised of an acoustically reflective surface or where one or more surfaces is adapted such as by roughening or dimpling or other technique used to alter acoustic reflection properties. In non-limiting examples, the particles comprise shapes and properties such as plates,

solid shells, hollow shells, rods, rice shaped, spheres, fibers, wires, pyramids, prisms, or a combination thereof.

[0191] In one specific aspect, a partially spherical surface may be provided on the outside and/or the inside of particles, as for example a particle with a hollow spherical space therein. Particles are made up of a different material than the matrix. While desiring not to be bound by theory, it is believed that a spherical shape provides for sound reflections at a variety of angles regardless of the direction from which the ultrasonic sound waves are emanating from, and accordingly, are more likely to reflect at least a portion of the transmitted signal back to the ultrasonic receiver to generate an image. Since many of matrix materials available are relatively ultrasonically transparent in a patient, sound reflective particles provide adequate reflection. The use of a composite, rather than a solution, provides adequate size for acoustic reflection off of the discrete particles embedded in the matrix. As indicated, a variety of materials may be utilized for the sound reflective particles, such as aluminum, hard plastic ceramics, and, metal and/or metal alloys particles, and the like. Additionally, liquids, gases, gels, microencapsulants, and/or suspensions in the matrix may alternatively be used either alone or in combination, so long as they form a composite with the desired ultrasonically reflective characteristic.

[0192] Any of the above embodiments, alternatives or filter modifications to enhance echogenic characteristics may also be designed or implemented in such a way as to provide an echogenic identifiable or unique trait or acoustic reflection signature that may be registered by a human operator looking at a display or identified using signal processing techniques of a return containing acoustic reflections from the filter in an imaging ultrasound system. In one example, there is a surface of the filter having one or more echo registerable or identifiable feature, mark or indication in a position useful for determining one or more of: a location of an end of a filter; a location of a fixation element on a filter; a location of a retrieval feature on a filter; an orientation of one or more of a leg, a strut, a filter or an end of a filter relative to another of a leg, a strut, a filter or an end or the orientation of the overall filter to a lumen, vessel or hollow organ in a body. Moreover, in another widely applicable aspect of providing enhanced imaging characteristics to a filter as described herein, the characteristic or modification—however added or incorporated into the filter—enable a filter, a filter component or a specified portion of a filter to be more readily imaged by intravascular ultrasound as described herein. In still another aspect, the characteristics or modification to the filter are oriented and positioned in order to facilitate IVUS imaging via an IVUS probe borne by a filter deployment or retrieval catheter, snare, or other implement provided to facilitate the use of intravascular filters.

[0193] FIG. **29** is a section view of a wire strut or support element of a filter (w/s/s) having multiple segments in a concentric arrangement. In this illustrative embodiment, the wire is encased in alternating tube segments. There is an inner tube (IT) directly adjacent to the wire. There is an echogenic segment layer (EL) adjacent to the inner layer. The inner tube may be selected to act as bonding layer to increase adhesion between the echogenic layer and the filter wire, strut or support member. In this embodiment, there is an outer tube (OT) over the echogenic layer. In alternative configurations, either or both of the inner tube or the outer tube may be omitted. The echogenic layer is a segment having one or more of the echogenic characteristics described herein.

[0194] FIGS. **30-35** provide various exemplary embodiments of a segment **87** having one or a plurality of one or more than one type of echogenic characteristic, property or feature added thereto. Each of the illustrated echogenic adaptations applied to segment **87** along with segment **87** itself may be sized, scaled and/or shaped as described herein as needed based upon the requirements of the portion of the filter and the echogenic characteristic.

[0195] FIG. **30** is an embodiment of a segment **87** having one or a plurality of laser drilled holes **88** formed therein. The diameter and the shape of the holes may be selected based upon the size of the filter or filter component to which the segment **87** will be attached. The holes **88** may be completely through the wall of the segment or only partially through the wall. The holes **88** may be formed in any pattern, spacing or orientation as described herein.

[0196] FIG. **31** is an embodiment of a segment **87** having one or a plurality of raised features or alternatively roughed portions **89** formed thereon. The size and shape of the raised features or the roughness of the surface may be selected based upon the size of the filter or filter component to which the segment **87** will be attached. The raised features or portions of roughness **89** may be formed in any pattern, spacing or orientation as described herein.

[0197] FIG. **32** is an embodiment of a segment **87** having one or a plurality of bubbles **90** formed therein. The size, shape, pattern, and manner of incorporating one bubble **90** or a plurality of bubbles **90** into the segment **87** may be selected based upon the size of the filter or filter component to which the segment **87** will be attached. The bubbles **90** may be formed within the segment sidewall, near the surface of the segment sidewall or near the inner surface of the sidewall. The bubble or bubbles **90** may be formed in any pattern, spacing or orientation as described herein.

[0198] FIG. **33** is an embodiment of a segment **87** having one or a plurality of dimples **91** formed therein. The diameter and the shape of the dimples may be selected based upon the size of the filter or filter component to which the segment **87** will be attached. The dimples **91** may be formed in any pattern, spacing or orientation as described herein.

[0199] FIG. **34** is an embodiment of a segment **87** having a coil or braided structure **92** within or about the segment **87**. The size, shape, pattern, and manner of incorporating the coil or braid **92** into the segment **87** may be selected based upon the size of the filter or filter component to which the segment **87** will be attached. The coil or braid **92** may be formed within the segment sidewall, near the surface of the segment sidewall or near the inner surface of the sidewall. The coil or braid **92** may be part of a sandwich structure as illustrated and described in FIG. **29**. The coil or braid **92** may be formed in any pattern, spacing or orientation as described herein to enhance the echogenic characteristics of the filter or filter portion attached to the segment **87**. The coil or braid **92** may be continuous along the entire length of a segment **87** or, alternatively, the coil or braid **92** may be in short lengths selected so that a plurality of coils or braids are provided within a single segment **87**.

[0200] FIG. **35** is an embodiment of a segment **87** having a plurality of echogenic markers **93** arrayed in rings **93.1**, **93.2** and **93.3**. For purposes of illustration the rings are shown in an orientation that is generally orthogonal to the central longitudinal axis of the segment **87**. The rings are shown with a sample spacing of 1 cm between them. The spacing may be any suitable distance based on the factors described herein

such as filter size and physiological environment. Similarly, the rings may be angled in other orientations relative to the longitudinal axis of the segment. For example, some ring may be in one angular orientation while other rings may be in a different angular orientation where the angular orientation or patent of orientation is utilized to provide one or more of the filter functionality or echogenic characteristics described herein. In some specific configurations, the spacing and sizes used are in the millimeter range. In some specific configurations, the spacing and sizes are in the micron range. In some specific configurations, the size and/or spacing of a ring or between adjacent rings are in a combination of mm and micron ranges for sizes, spacings and features. The size and spacing of the echogenic markers **93** may be selected based upon the size of the filter or filter component to which the segment **87** will be attached. The markers **93** may be formed in any pattern, spacing or orientation as described herein in order to facilitate a measurement using the markers. Still further, the markers **93.1**, **93.2** and **93.3** may be utilized for provide for other filter characteristics as described herein.

[0201] FIG. **36** illustrates various alternative configurations for a segment used alone or in conjunction with other segments. The segments are illustrated along an exemplary wire, strut, or component of a filtering device. The segments may have different characteristics to enable the segment to be more readily imaged by a medical imaging modality used externally, internally or intraluminally. In one aspect, the segment characteristics are selected to provide for imaging enhancements for a filter being used within a vein or an artery. In another aspect, the segments may have different characteristics to enable the segment to be readily imaged by intravascular ultrasound as described herein. In still another aspect, the segments are oriented and positioned in order to facilitate IVUS imaging via an IVUS probe borne by a filter deployment or retrieval catheter, snare, or other implement. In one illustrative embodiment, the segments are selected and arrayed to facilitate imaging utilizing IVUS and an external medical imaging modality. In one exemplary embodiment, the external imaging modality is x-ray.

[0202] Also illustrated in FIG. **36** is the use of a combination of different echogenic characteristics (designated E) and radio-opaque characteristics (designated RO). These characteristics may be any of those described herein in any combination. The echogenic characteristic of a segment may be the same as another segment in a grouping such as in the E segments **87.9** and **87.5**. Alternatively, the echogenic characteristic of a segment may be different from those in an adjacent group as with segments **87.2**, **87.5** and **87.7**.

[0203] FIG. **36** also illustrates not only that different characteristic and properties of segments may be used but also how variable segment dimensions may be used to aid in echogenic enhancement of a filter. As illustrated, the segments have different widths or thicknesses as indicated along the longitudinal axis of the wire, strut or component. As such, FIG. **36** illustrates a series of imagine enhancing segments **87.1**-**87.10** having a variety of width or thickness values t**1**-t**10**. In one embodiment, the segments are configured as short rings or bands. The thickness of segments in groups may be similar as illustrated in segments **87.1**, **87.2** and **87.3** where the thicknesses t**1**, t**2** and t**3** are about the same. Similarly, segments **87.4**, **87.5** and **87.6** illustrate segments of similar width or thickness where t**4**, t**5** and t**6** are about the same value. Similarly, segments **87.8**, **87.9** and **87.10** illustrate segments of similar width or thickness where t**8**, t**9** and t**10** are about the same value.

[0204] FIG. **36** also illustrates how segments within a group or groups of segments may have a variety of different spacing (s**1**-s**6**) to provide enhancements to a filter for improving medical imaging modality characteristics. For example, in the segment grouping of 87.1, 87.2 and 87.3, there is a spacing s**1** between segment **87.1** and segment **87.2** but then no spacing between segments **87.2** and **87.3**. A spacing s**2** is shown between segment **87.3** but then no spacing in the combination segment grouping formed by segments **87.4**, **87.5** and **87.6**. A spacing of s**3** is shown between the three segment combination of 87.4, 87.5 and 87.6 to the single segment **87.7**. The single segment **87.7** is spaced apart by spacing s**4** from the equally sized (i.e., t**8**=t**9**=00) and equally spaced (i.e., s**5**=s**6**) group of segments **87.8**, **87.9** and **87.10**. It is to be appreciated that in various alternative embodiments, the spacing used in groups of segments or between groups of segments may be the same or variable.

[0205] FIG. **37** is a view of an exemplary filter illustrating various alternative aspects of providing a filter with improved echogenic characteristics. The filter illustrated is a conical filter. It is to be appreciated that the filter of FIG. **37** is merely representative of one type of filter. It is to be appreciated that the various alternative enhancement, modifications and treatments described herein may be provided to any intravascular or intraluminal filter. The exemplary filter is dividing into three general sections A, B and C. Sections A, B and C may be the same type of enhancement or have an enhancement different from one another section. In addition, the type of enhancement in each section may be the same or different from one another in detection, response or appearance under ultrasound. In addition, a tag, feature or enhancement may be different within a section. Circles **3702** are used to indicate exemplary locations for an echogenic feature, tag, marker or modification to an enhanced filter **10**. The illustrative embodiment in FIG. **37** also illustrates a continuous echogenic layer, feature or modification or treatment **3708**. The illustrative embodiment in FIG. **37** also illustrates an echogenic attribute on/near an inflection point **3706** in an enhanced filter structure **10**. The illustrative embodiment in FIG. **37** also illustrates a segmented echogenic layer, feature or modification or treatment **3704** on an enhanced filter structure **10**. Section A is considered the apex, tip, distal portion or terminal end depending upon filter configuration. Section B is considered the mid-strut, middle, filtration portion, debris capture portion, or thrombus collection or lysing portion depending upon specific filter configuration. Section C is considered the rear portion, proximal portion, proximal terminal portion, anchor, fixation or perforation portion depending upon a specific filter configuration. It is to be appreciated as well that the echogenic features, tags, markers or modifications illustrated for sections A, B and/or C may be of the same type or different types depending upon the echogenic signature or attribute intended for that section, group or sections or filter. As such, the echogenic features, tags, markers or modifications for a particular section may be selected from any of the various alternatives described herein.

[0206] Echogenic characteristics may be added to each of the sections based on the type of function being measured or characterized. For example, echogenic markers, features or tags may be added to Section A in order to provide, for example: identification of the terminal end, end portion or

retrieval portion of a filter. Echogenic characteristics of Section A may also be used for determinations related to Section A specifically or the filter generally of filter position, positioning, attitude within the lumen, localization of the filter within the vasculature and other traits common to the characterization of intravascular devices. For example, echogenic markers, features or tags may be added to Section B in order to provide, for example: identification of the mid strut portion, middle or capture region. Echogenic characteristics of Section B may also be used for determinations related to Section B such as for sizing, centering, symmetry of implantation, placement, apposition of implant to vessel walls, clot burden, deployment status or completion, gauge of filter capacity and/or filter contents as well as filter position, positioning, attitude within the lumen, localization of the filter within the vasculature and other traits common to the characterization of intravascular devices. For example, echogenic markers, features or tags may be added to Section C in order to provide, for example: identification of the rear portion, terminal end, retrieval feature, anchor location or depth of insertion, perforation indication or other aspects of the rear or proximal portion of a filter. Echogenic characteristics of Section C may also be used for determinations related to Section C such as for sizing, centering, symmetry of implantation or placement of legs struts and the like, as well as for determination of wall apposition, anchor penetration or perforation. Still further, the markers or tags may be added to aid in determining or evaluating filter position, positioning, attitude within the lumen, localization of the filter within the vasculature and other traits common to the characterization of intravascular devices.

[0207] A filter having enhanced echogenic properties is illustrated in FIG. **37** as it appears when it is in operative position within the vasculature. In one specific aspect the filter is in use in a large blood vessel. One exemplary vessel is the vena cava. Still further, a modified filter may be employed in a different vein or even an artery. The filter is designated generally by reference numeral **10**, and the wall of the blood vessel in which it is located is designated by reference numeral **12**. The filter **10** includes an apical hub **14** of overall egg-shaped or tear drop configuration and which has a generally hemispherically shaped end portion **14***a*.

[0208] The filter **10** includes a plurality of elongated legs **16** which are of equal length and are identically configured to each other. The legs **16** are collectively arrayed in a conical geometric configuration so that the legs converge to the apical hub **14**, and are symmetrically spaced about a central axis extending through the hub. Each of the legs is of equal diameter over its entire length and is made of a relatively resilient material, such as tempered stainless steel wire or the like. In addition to the echogenic attributes described herein, the legs may be coated with a polymeric, synthetic resin material having anti-thrombogenic properties. FIG. **37** illustrates an echogenic marker at the tip **14**. Exemplary continuous echogenic layers, features or modifications are also illustrated along one or more legs of the filter. In addition, FIG. **37** illustrates the use of echogenic tags, features or markers at, along or near inflection points in a filter element or component. In addition, FIG. **37** illustrates to application of echogenic markers, tags or features near the fixation elements of the filter.

[0209] In still other alternative embodiments, there is provided a material capture structure having one or more echogenic enhancements alone or in combination with radiopaque enhancements. In one aspect, the filter structure used in a filter includes both echogenic and radio opaque enhancements.

[0210] An one aspect, the filter includes material capture structure in the IVC filter will be viewable under fluoroscopic and ultrasound imaging modalities, including appropriate echogenic characteristics to enhance the view of the status or condition of the material capture structure while using IVUS. Enabling the material capture structure to be viewed will allow the physician to appropriately center and verify placement of a filter.

[0211] In one aspect, the filter elements or structures are doped to incorporate one or more of echogenic or radio opaque materials or treatments. In one aspect, the membrane, filaments or strands or other structures used to form the filter structure or webbing of the filter includes a radiopaque material having high echogenic properties, such as tungsten or gold, but not limited to either.

[0212] In other embodiments, one or more membranes, filaments or portions of a filament within a material capture structure includes one or more non-metallic echogenic features, such as those described elsewhere in this specification. For example, a membrane or filament or portion thereof may include air pockets either added to the material or by the use of materials with entrained air or gas that are used. Another example may include a membrane with a plurality of holes. In one embodiment, an ePTFE suture has echogenic properties due to air content of the ePTFE material. In other aspects, a suture material or a filament or polymer strand may also include dimpled/roughened/matrix/sponge materials, additives, or modifications to provide or enhance the overall echogenic nature of the suture, filament, material or material capture structure, in whole or in part.

[0213] In one aspect, these additional materials may assist the physician in centering or placing a filter within a vessel. In another aspect, this improvement is used in conjunction with IVUS will enable the adequate viewing of the filter portion of the filter and will allow for co-registration of filter placement along with an accurate entry/removal of the catheter through the webbing of the filter.

[0214] The advantages of this inventive aspect of a filter include, for example and not limitation, filter placement, accurate representation of filter location, ease of introducing/retracting catheter, more viewable space for more accurate assessments, ability to co-register filter location with IVUS and/or ability to better place filter in desired location.

[0215] Still other aspects of the use of the innovative filter include, for example, deployment of filters, positioning of filters, sizing of filters, and estimated treatment lengths as well as suture and/or material capture structure visibility. In still other aspects of the use of the innovative filter include, for example, deployment of a vena cava filter, positioning of an IVC filter, sizing of an IVC filter, and estimated treatment lengths as well as enhanced suture visibility.

[0216] In one embodiment, there is an IVC filter delivery system with an enclosed IVC filter. This filter would have a mesh, suture, web or other material capture structure suited to the anticipated filter use. The mesh, suture, web or other material capture structure has one or more components that is doped with a highly radiopaque material for better visibility under flouro and good echogenicity for better viewing under IVUS guidance. In still further alternative embodiments, the techniques described above may be applied to one or more material capture structure described in U.S. Patent Applica-

tion Publication US 2008/0147111 entitled "Endoluminal Filter with Fixation" filed Jun. 4, 2008 as U.S. patent application Ser. No. 11/969,827, (the "'7111 publication") incorporated herein by reference in its entirety for all purposes. In one particular aspect, the filament/strand/suture **461** shown in FIG. 58 of the '7111 publication may be coated or doped as described above alone or in combination with the illustrated pharmacological coating **466**.

[0217] In some embodiments, the snare handle portion can include snare deployment indicators, such as detents, that allow the operator to easily identify and achieve the different stages of snare deployment described above. For example, the operator can deploy the snare using the snare handle until the snare handle reaches a first indicator, which signifies that the snare is deployed in the first deployment stage. The operator can then further deploy the snare using the snare handle until the snare handle reaches a second indicator, which signifies that the snare is deployed in the second or intermediate deployment stage. Then the operator can further deploy the snare using the snare handle until the snare handle reaches a third indicator, which signifies that the snare is fully deployed. In some embodiments, there is a snare deployment indicator for each stage of snare deployment. In some embodiments, the loop elements of the snare have different configurations in each of the different deployment stages as, for example, described above. For example, deployment indicators can be provided to allow the operator to deploy the snare in stages as described above with respect to FIGS. **1**D-**1**G and FIGS. **1**N-**1**Q. As described above, a deployment stage corresponding to loop elements having an axial configuration can be particularly suited for retrieval of guidewires, leads, and other objects that are positioned transversely with respect to the snare axis. The fully deployed configuration can be particularly suitable for devices that have been designed for retrieval with the snare, such that markers can be used to align the snare with the object to be retrieved. In addition, the fully deployed configuration is particularly suitable for retrieving objects that are located near or proximate the lumen wall.

[0218] While described in various embodiments for retrieval of filters and other medical devices and objects, the sheath and snare designs may also be used to retrieve other filter devices, other embolic protection devices, and other objects. For example, filter devices and other devices described in commonly assigned, and concurrently filed U.S. Provisional Patent Application Ser. No. 61/586,661 (Attorney Docket Number 10253-701.102) is incorporated herein by reference in its entirety and for all purposes.

[0219] It is understood that this disclosure, in many respects, is only illustrative of the numerous alternative filtering device embodiments of the present invention. Changes may be made in the details, particularly in matters of shape, size, material and arrangement of various filtering device components without exceeding the scope of the various embodiments of the invention. Those skilled in the art will appreciate that the exemplary embodiments and descriptions thereof are merely illustrative of the invention as a whole. While several principles of the invention are made clear in the exemplary embodiments described above, those skilled in the art will appreciate that modifications of the structure, arrangement, proportions, elements, materials and methods of use, may be utilized in the practice of the invention, and otherwise, which are particularly adapted to specific environments and operative requirements without departing from the scope of the invention. In addition, while certain features and elements have been described in connection with particular embodiments, those skilled in the art will appreciate that those features and elements can be combined with the other embodiments disclosed herein.

What is claimed is:

1. A system for retrieving an object from a lumen defined by a lumen wall, the system comprising:
- a retrieval device comprising:
  - a sheath configured to fit within the lumen, the sheath having a proximal end and a distal end;
  - a snare slidably disposed within the sheath, the snare having a shaft with a longitudinal axis, a proximal end and a distal end and a plurality of loop elements in connection with the distal end of the shaft; and
  - an intravascular ultrasound transducer located on the distal end of the sheath or shaft;
  - a user interface configured to receive input from an operator regarding a surgical procedure including an insertion site and a destination site;
- a display;
- a processor programmed to:
  - receive input from the user interface regarding the surgical procedure;
  - determine anatomical landmarks between the insertion site and the destination site;
  - receive an intravascular ultrasound signal from the intravascular ultrasound transducer;
  - process the intravascular ultrasound signal into an image; and
  - send the image to the display.

2. The system of claim **1**, wherein the processor is further programmed to:
- identify any anatomical landmarks in the image; and
- tag the anatomical landmarks in the displayed image.

3. The system of claim **2**, wherein the processor is further programmed to:
- determine a location of the retrieval device based on the identified anatomical landmarks in the image.

4. The system of claim **3**, wherein the processor is further programmed to:
- determine whether the location is the destination site.

5. The system of claim **4**, wherein the processor is further programmed to:
- send a visual indicator to the display when the location has been determined to be the destination site.

6. The system of claim **5**, wherein the visual indicator is color coded.

7. The system of claim **1**, wherein the processor is further programmed to:
- determine an orientation of the retrieval device with respect to the object using the processed intravascular ultrasound imaging signal.

8. The system of claim **7**, wherein the processor is further programmed to:
- generate instructions for adjusting the position of the retrieval device based on the determined orientation of the retrieval device.

9. A system for retrieving an object from a lumen comprising:
- a retrieval device comprising:
  - a sheath configured to fit within the lumen, the sheath having a proximal end, a distal end and a radiopaque marker offset from the distal end;

a snare disposed within the sheath, the snare having a shaft with a longitudinal axis, a proximal end and a distal end and a plurality of loop elements in connection with the distal end of the shaft, wherein the plurality of loop elements has a collapsed configuration within the sheath and at least one deployed configuration outside the sheath, wherein the plurality of loop elements are configured to be deployed through an opening at the distal end of the sheath, wherein the at least one deployed configuration includes an initial deployed configuration in which the plurality of loop elements are deployed substantially transversely with respect to the longitudinal axis; and

an intravascular ultrasound transducer located at the distal end of the sheath.

10. The system of claim **9**, wherein the processor is further programmed to:

identify any anatomical landmarks in the image; and

tag the anatomical landmarks in the displayed image.

11. The system of claim **10**, wherein the processor is further programmed to:

determine a location of the retrieval device based on the identified anatomical landmarks in the image.

12. The system of claim **11**, wherein the processor is further programmed to:

determine whether the location is the destination site.

13. The system of claim **12**, wherein the processor is further programmed to:

send a visual indicator to the display when the location has been determined to be the destination site.

14. The system of claim **13**, wherein the visual indicator is color coded.

15. The system of claim **9**, wherein the processor is further programmed to:

determine an orientation of the retrieval device with respect to the object using the processed intravascular ultrasound imaging signal.

16. The system of claim **15**, wherein the processor is further programmed to:

generate instructions for adjusting the position of the retrieval device based on the determined orientation of the retrieval device.

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[标]申请(专利权)人(译)	CRUX生物医学		
申请(专利权)人(译)	CRUX生物医学，INC.		
当前申请(专利权)人(译)	CRUX生物医学，INC.		
[标]发明人	STIGALL JEREMY JOHNSON ERIC		
发明人	STIGALL, JEREMY JOHNSON, ERIC		
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摘要(译)

本发明一般涉及用于在腔内检索或操纵物体的装置和方法。更具体地，本发明的实施例涉及用于从体腔取回或操纵医疗装置的装置和方法。本发明的一个实施例提供了一种具有检索圈套和超声换能器的检索装置，以辅助该装置的血管内导航。该装置使用户能够捕获位于人体解剖结构内的异物，以受控方式抓住所述物体，并从人体解剖结构中取回和移除所述物体。