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Percutaneous, ultrasound-guided introduction of medical devices

Abstract

Described are methods and systems and system components useful for percutaneously delivering or retrieving vascular implant devices, such as filters, utilizing intravenous ultrasound (IVUS) imaging alone or in combination with external (e.g. transabdominal) ultrasound or other imaging technology. Implants deliverable by such systems, such as vena cava or other vascular filters, can have two or more echogenic markers spaced at such a distance that they are separately discernible by IVUS and/or external ultrasound imaging.

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Background/Summary

REFERENCE TO RELATED APPLICATION (1) This application is a continuation U.S. patent application Ser. No. 13/731,313, filed Dec. 31, 2012 which is a continuation of International Application No. PCT/US2011/042670, filed Jun. 30, 2011, which claims the benefit of U.S. Provisional Patent Application Ser. No. 61/360,459 filed Jun. 30, 2010 and of U.S. Provisional Patent Application No. 61/406,418 filed Oct. 25, 2010, each entitled Percutaneous, Ultrasound-Guided Introduction of Medical Devices, and each of which is hereby incorporated herein by reference in its entirety.

BACKGROUND
(1) The present invention pertains generally to medical devices and systems for their introduction. In certain aspects, the invention relates to systems and methods for percutaneously introducing vascular devices such as vascular filters under ultrasound guidance, and to delivery components and implant features that are useful therein.
(2) Vascular devices are commonly percutaneously introduced under fluoroscopic guidance. For example, vena cava filters are most often placed under fluoroscopic guidance with the injection of contrast agent to provide a cavogram characterizing the site of intended implantation. Such fluoroscopic procedures must be performed in a specially equipped room such as an X-ray suite. This not only necessitates transport of an often critically ill patient to the suite but also adds significant expense to the procedure.
(3) Ultrasound imaging technology, including intravenous ultrasound (IVUS) imaging, has been used to some extent in the diagnosis and in the treatment of patients. However, the images generated with IVUS and other ultrasound technology are often more difficult to interpret for purposes of implant guidance, particularly for physicians or other health care providers who are more accustomed to fluoroscopic images.
(4) Needs exists for improved and/or alternative methods, systems and device features whereby the introduction of vascular devices such as vena cava filters can be guided under ultrasound imaging techniques. In certain of its aspects, the present invention is addressed to these needs.
SUMMARY
(5) In some embodiments, the present invention relates to methods and systems for percutaneously delivering or retrieving vascular implant devices, such as filters, utilizing intravenous ultrasound (IVUS) imaging alone or in combination with external (e.g. transabdominal) ultrasound imaging technology. Delivery systems of the invention can include distally-positioned echogenic markers and proximally-positioned visible indicia which together provide enhanced guidance during implant introduction. Implants deliverable by such systems, such as vena cava or other vascular filters, can have two or more echogenic markers spaced at such a distance that they are separately discernible by IVUS and/or external ultrasound imaging. Additional embodiments include IVUS-enabled catheters, IVUS-enabled sheaths, and IVUS-enabled vascular snares, useful for example in the placement or retrieval of vena cava filters, and IVUS-facilitated confirmation of device placement following deployment and systems therefor.
(6) Ultrasound-guiding systems and methods described herein can utilize a combination of IVUS and external (e.g. transabdonimal) ultrasound images, real-time-generated images and stored images (e.g. three-dimensional maps) generated using IVUS imaging, and/or a combination of IVUS images and displayed graphical markers generated by non-imaging techniques. Still further

aspects of the invention, and features and advantages thereof, will be apparent to those of ordinary skill in the art from the description herein.

Description

BRIEF DESCRIPTION OF THE FIGURES

(1) FIG. **1** is a perspective view of one embodiment of a filter device.

(2) FIG. **1**A is a partial cut-away view of another embodiment of a filter device.

(3) FIG. **1**B is a partial cut-away view of another embodiment of a filter device.

(4) FIG. **2** is a partial cut-away perspective view of one embodiment of an IVUS-enabled device delivery system.

(5) FIGS. **3**-**7** illustrate devices and steps used in certain embodiments for the delivery of a filter device.

(6) FIG. **8**-**10** illustrate devices and steps used in other embodiments for the delivery of a filter device.

(7) FIG. **11** provides a partial cut-away perspective view of one embodiment of an echogenically-marked vascular snare in position to capture a filter device.

(8) FIG. **12** provides a partial cut-away cross-sectional view of one embodiment of an echogenically-marked filter device within a retrieval sheath.

(9) FIG. **13** provides a partial cut-away cross-sectional view of one embodiment of an IVUS-enabled filter delivery system.

(10) FIG. **14** provides a partial cut-away cross-sectional view of another embodiment of an IVUS-enabled filter delivery system.

(11) FIG. **15** provides a schematic representation of an image-guided medical device delivery system.

(12) FIG. **16** provides illustrative IVUS-generated images useful for confirming the placement of a deployed filter device.

(13) FIG. **17** provides a perspective view of a spring collar position marking device in accordance with one embodiment of the invention.

DETAILED DESCRIPTION

(14) For the purpose of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended. Any alterations and further modifications in the described embodiments, and any further applications of the principles of the invention as described herein are contemplated as would normally occur to one skilled in the art to which the invention relates.

(15) As disclosed above, certain aspects of the invention relate to methods and systems that include features which enhance functionality and/or safety during delivery of the vascular devices using ultrasound imaging techniques. Additionally, aspects of the invention relate to vascular devices, and in particular embodiments vascular filters, including two or more echogenic markers located thereon, as well as percutaneous delivery or retrieval devices that include unique echogenic features and/or IVUS imaging capability.

(16) With reference now to FIG. **1**, shown is a vascular filter **20** in an expanded state. Vascular filter **20** as depicted is suitable for use as a vena cava filter in humans. Filter **20** includes a hub **21** having a plurality of primary struts **22** and plurality of secondary struts **23** emanating therefrom. In particular, in the depicted embodiment, filter **20** includes four primary struts **21** and eight secondary struts **23** extending from hub **21**. Hub **21** crimps together ends of struts **22** and **23** in a compact bundle extending generally along a central or longitudinal axis of filter **20**. The struts **22** and **23** can be formed of a superelastic metal alloy, such as a superelastic nickel-titanium (Ni—Ti)

alloy (e.g. Nitinol), stainless steel, or any other suitable material that will result in a self-expanding filter. The struts of filter **20** can provide a filter structure configured to trap embolic matter in the vascular vessel. Other filters of the invention can include alternate strut configurations or other member(s) positionable within the vessel to trap embolic matter.

(17) Filter **20** also includes a retrieval/delivery element including a generally straight elongate neck **24** connected to a reversely-turned hook **25**, with the hook terminating in ball component **26**. This retrieval/delivery feature can be used in retrieving and/or initially placing the filter **20**. Although neck **24** as illustrated is generally straight, it will be understood that other neck configurations, including curved configurations, can be used. Hub **21** includes a shoulder **27** or other feature, preferably extending around its entire circumference, that serves as an echogenic marker and thus generates an ultrasound image discernable from surrounding media or device components. In addition, ball component **26** effectively serves as such an echogenic marker.

(18) In the illustrated device, shoulder **27** and ball **26**, or other echogenic features in their place, are longitudinally spaced a distance "d" from one another sufficient to enable separate and discrete visualization of ball/marker **26** and shoulder/marker **27** by IVUS imaging, external ultrasound imaging, or both. In particular embodiments, when using IVUS imaging, distance "d" is sufficiently great that the IVUS probe for generating the IVUS image can be positioned within longitudinal distance "d" without picking up either ball/marker **26** or shoulder/marker **27** in the image. In this manner, the IVUS probe and other device components adjacent thereto (e.g. the tip of a snare catheter) can be reliably and recognizably positioned within longitudinal distance "d" by advancing or withdrawing the IVUS probe to separately view ball/marker **26** and shoulder/marker **27**, and then positioning the IVUS probe therebetween to a point where neither marker is visible in the IVUS image. The attending physician or other user can thereby develop confidence that the IVUS probe and device components nearby are properly positioned for action within the span of longitudinal distance "d". Illustratively, as discussed in greater detail below, a retrieval snare having an IVUS probe at or near its distal tip can be reliably positioned within longitudinal distance "d" for closure of a snare loop to capture the retrieval element of filter **20**. In addition or alternatively, distance "d" can be sufficiently large that marker **26** and marker **27** generate separate and discrete images using external (e.g. transabdominal) imaging techniques. External imaging can then be used to view the positioning of third echogenic marker, for example on another device such as the end of a snare, between marker **26** and **27**, for action within the span of distance "d". In certain embodiments, distance "d" is greater than 3 mm, for example in the range of 4 mm to 10 mm.

(19) Filter **20** may also have echogenic markers positioned on one or a plurality of its primary and/or secondary struts. These echogenic markers can for example be echogenic elements mounted around the struts, including for example sonically-reflective metal coils discernable by IVUS or external ultrasound (US) imaging, or cannular segments with dimpled, grooved or otherwise textured surfaces, or any other suitable echogenic structure. In the illustrated device, echogenic coils **28** are mounted around the primary struts **22**. Further, echogenic markers **28** can include projecting filaments such as whiskers or barbs **29**, which can serve to enhance interaction of the struts with the vessel walls, for example providing improved anchorage and/or resistance to strut migration through the vessel walls.

(20) Referring now to FIGS. **1**A and **1**B, shown are a partial cutaway views of additional embodiment of filters **20**A and **20**B of the invention, respectively. Except where described otherwise, filters **20**A and **20**B can have features that are the same as those of filter **20**. In filter **20**A, a delivery/retrieval element is provided that includes a shoulder **27**A on the hub as in filter **20**, and a generally straight neck portion **24**A connected to a terminating, larger-diameter ball component **25**A. Ball component **25**A is of sufficient dimension to serve as a graspable feature utilizing a vascular snare. Ball component **25**A also serves as an echogenic marker for the filter **20**A. In filter **20**B (FIG. **1**B), a delivery/retrieval element is provided that includes a shoulder **27**B

on the hub as in filter **20**, and a generally straight neck portion **24**B connected to a terminating closed hoop **25**B. Hoop **25**B defines an internal opening and is of sufficient dimension to serve as a graspable feature, for example utilizing a retrieval hook device. Hoop component **25**B also includes at least one echogenic marker thereon and in certain embodiments a plurality of echogenic markers (**25**B′, **25**B″, **25**B‴) which may for example be any echogenic structure, component or material described herein, attached to or integrally occurring within or upon the material of hoop **25**B.

(21) While FIGS. **1**, **1**A and **1**B illustrate specific retrieval elements for incorporation within the structure of the vascular filter, it will be understood that other retrieval structures or materials can also be used within aspects of the invention. For example, any attachment structure that can be engaged by mechanical elements and/or using field forces (e.g. magnetic), or by other means, can be used. In certain embodiments, as in the illustrated filters, the retrieval element of the filter can be configured to reside generally centrally in the vessel lumen when the filter is deployed.

(22) With reference to FIG. **2**, shown is a partial cutaway view of a system useful for implanting a vascular device such as a filter. System **40** includes a dilator **41** for percutaneous introduction, a guide device **42** such as a wire guide, and an outer delivery sheath **43**. Dilator **41** includes an IVUS probe **44** including one or more ultrasound transducers, such as piezoelectric crystal elements, for producing and/or receiving ultrasonic sound waves. IVUS probe **44** is preferably a transducer array with a plurality of ultrasound transducers, but can also be provided by a single rotating transducer as known. IVUS probe **44** and other IVUS elements disclosed herein can, for example, be configured to provide data for two-dimensional and/or three-dimensional IVUS images. IVUS probe **44** is connected electronically, such as by a wire and connector (not shown) positioned within or along dilator **41**, to an IVUS imaging system that may include a display device and a computer processor for processing data gathered by IVUS probe **44** and displaying images correlated thereto. Sheath **43** of system **40** includes a distal tip region having an echogenic marker **45** and a fluoroscopic marker **46**. Echogenic marker **45** and fluoroscopic marker **46** can be provided by the same physical structure or by differing physical structures.

(23) In one embodiment, the markers **45**/**46** are both provided by a radiopaque material, such as platinum, titanium, tungsten or another a metal (including alloys), positioned outside and/or within the material making up the body of the sheath **43**. Illustratively, a platinum structure, such as a platinum hoop or ring, can be attached around the outside of sheath **43** to provide a fluoroscopically-discernible marker. Such a radiopaque structure can also contain structural features rendering it effective as an echogenic marker. These features may for example include dimples, grooves, or other textured surface features rendering the marker material visually discernible by ultrasound imaging. The fluoroscopic and/or echogenic markers can also be provided by other structures or materials or combinations thereof. Illustratively, in one embodiment, the markers **45** and **46** can be located closely adjacent one another, with the fluoroscopic marker **46** provided by a radiopaque material such as a metal, and the echogenic marker **45** provided by a separate element with any of the patterned features as discussed hereinabove for echogenic markers, or containing internal materials or features that have an acoustic impedance that significantly differs from the surrounding media so as to be discernible by ultrasonic imaging. The incorporated features or materials can include for example gas-filled spaces embedded within polymeric materials (e.g. bubbles), or acoustic impedance-mismatched, sonically-reflective materials such as glass, ceramic, metal or other particles (e.g. beads) incorporated within or coated upon a polymeric material. For additional information about echogenic markers that can be used herein, reference can be made for example to U.S. Pat. No. 5,201,314.

(24) The markers **45**/**46** can be associated with sheath **43** in any suitable fashion including positioning on the outside, inside, within the body or wall of the sheath **43**, or combinations thereof. Sheath **43** also includes a more proximally located marking feature **47** that is visible to the eye of the user when positioned externally of the patient. Visible marking feature **47** in the

illustrated embodiment demarks the distance from locations within feature **47** to the distal tip of the sheath **43**. For these purposes, the marking feature **47** can include a plurality of visible marking features **48** spaced longitudinally from one another along the length of sheath **43**, such as lines, scores, or other markings partially or completely circumscribing the circumference of the sheath **43**. In the illustrated embodiment, the marking feature **47** also includes numeric markings **49** associated with markings **48** which numerically indicate the distance of the respective associated markings **48** from the tip of the sheath **43**. In one example, the marking feature **47** includes markings **48** offset longitudinally from one another by a regular distance such as 1 mm or 1 cm, and associated numerical markings **49** providing an indication of how many millimeters or centimeters, respectively, each marking **48** is spaced from the distal tip of the sheath **43**. The marking feature **47** is positioned along the length of the sheath **43** such that at least some of or the entire marking feature **47** will occur externally of the patient during use of the sheath **43** to deliver the filter or other vascular device. For these purposes, the marking feature **47** can for example be positioned so as to include markings at skin level at a percutaneous insertion site through which system **40** is introduced. In this regard, it will be understood that other reference points external of the patient against which the marking feature **47** can be reliably tracked during a procedure to determine the distance to the distal tip of the sheath may also be used. Fixed external reference points are particularly useful for these purposes.

(25) In one mode of use, the IVUS-enabled dilator **41** can be advanced within a vascular vessel of the patient along guide **42**, and the IVUS probe **44** can be operated to generate signals translated to images of features of the vessel. IVUS probe **44** can then be positioned to and image a target position to which it is desired to move the distal tip of the sheath **43**. Thereupon, the sheath **43** can be advanced coaxially along the dilator **41** until the distal tip of the sheath **43** detectably abuts or overlies IVUS probe **44** or regions proximate thereto. This detection can, for example, be by way of a tactile resistance to advancement of the sheath **43** over the IVUS probe **44** or some region or feature of sheath **43** proximate thereto, or by a change in an ultrasound image generated based signals from IVUS probe **44** due to the distal tip of the sheath **43** overlying some or all of IVUS probe **44** (for example, a change in the brightness of the image). This change in the image, in certain embodiments, can be enhanced by the presence of the echogenic marker **45** at the distal end region of sheath **43**. At this point, the user knows that the distal tip of the sheath **43** is in essentially the same target position as the IVUS probe **44**. Thereafter, the dilator **41** and guide **42** can be withdrawn from sheath **43**, and a delivery catheter or other delivery instrument for delivering the vascular device can be advanced through sheath **43**, while continuing to hold stable the position of the sheath **43** with its distal tip at the target position. In certain embodiments, the distal tip of the vascular implant to be deployed can then be aligned with the distal tip of the sheath **43** while maintaining the stable position of the sheath **43**, and sheath **43** can be withdrawn proximally a distance while holding stable the position of the delivery instrument to reliably deploy the vascular device at the target site.

(26) The alignment of the distal end of the vascular implant with the distal end of the sheath **43** can be accomplished in any suitable manner, including by tracking the position of the distal tip of the vascular implant ultrasonically (e.g. transabdominally with the assistance of a tip-located echogenic markers, such as marker **26** on filter **20** and marker **45** on sheath **43**) and/or through other means. In certain embodiments, the vascular device is carried by a delivery catheter or other instrument having a first visible marker that remains external of the patient and which aligns with an external reference point, such as the proximal end of the sheath **43** or a connected accessory (e.g. a Touhy-Borst adaptor), when the distal end of the vascular implant is at the distal tip of the sheath **43**. The delivery instrument may also include a second visible marker, proximal to the first visible marker, to which the sheath can be withdrawn, to signal a stage of deployment, e.g. when the vascular implant has been completely deployed out of the sheath. Other measures for accomplishing similar signaling alignments may also be used.

(27) The use of system **40** of FIG. **2** to deliver a vena cava filter to a patient will now be described with reference to FIGS. **3**-**7**. FIG. **3** shows system **40** having been introduced into the vena cava **50** through a percutaneous access site **51** in the right femoral vein of a patient. Right renal vein **52**A and left renal vein **52**B feed into the vena cava **50**, and in the illustrated embodiment it is desired to deploy a filter generally below the renal veins **52**A and **52**B, or "caudal" thereto. Depicted in FIG. **3** is dilator **41** advanced into vena cava **50** and at a position at which IVUS probe **44** can generate an image of at least the lowest-positioned renal vein, in most instances that being the right renal vein **52**A. Prior to reaching this position, the IVUS probe **44** can be used to generate images of vascular landmarks distal to the renal veins, for example the right atrium, the hepatic veins, or other features. In certain embodiments the IVUS probe **44** will have a longitudinal resolution such that an image showing both renal veins **52**A and **52**B can be obtained. Sheath **43** is also percutaneously inserted into the vena cava, which insertion may have been before, with, or after that of dilator **41**. The distal tip of sheath **43** is shown positioned well below the IVUS probe **44** so that it does not obscure IVUS probe **44** and thereby degrade generated image data. As can also be seen, the marking feature **47** includes at least portions remaining at skin level on the patient, and demarking the shaft distance from skin level to the distal tip of sheath **43**. Further, in the illustrated embodiment, a repositionable scale marker **54** is positioned about sheath **43** and can be advanced to locations within marker feature **47**. Scale marker **54** can include a stop or locking mechanism **55** which can be actuated to selectively release and secure the position of scale marker **54** along sheath **43**. Any suitable mechanism can be used for this purpose including, for example, spring actuated friction stops against the sheath **43**, tightenable screws or knobs which abut sheath **43** or cinch marker **54**, or the like.

(28) Referring to FIG. **17**, the marker **54** can comprise a spring collar **54**A, which itself represents another aspect of the invention, receivable around the sheath **43** (see illustrative FIG. **3**B; it will be understood that spring collar **54**A can also be used as marker **54** in other FIGs. in which marker **54** is shown). Spring collar **54**A includes a wire spring **120** with a wire coiled to provide one or more wire loops and preferably a plurality of wire loops **121**, which can be positioned adjacent to one another. Spring collar **54**A can also include a first wire segment **122** extending from the wire loop(s) **121** and a second wire segment **123** extending from the wire loop(s) **121**. In a relaxed (unstressed) condition, the segments **122** and **123** extend in directions that are radially offset from one another about a central axis "A" of the wire loop(s) **121**, preferably at an offset of less than about 140 degrees about central axis "A". The spring collar **54**A is configured such that the segments **122** and **123** can be moved radially toward one another, for example by squeezing them toward one another, to cause the internal diameter of the wire loop(s) **121** to increase in size in the resulting stressed condition of the spring collar **54**A. In this fashion, spring collar **54**A can be received around sheath **43** or another elongate, percutaneously introduced device, and can be sized to frictionally engage the outer surface of the sheath **43** or other device when in its relaxed condition or at least biasing toward its relaxed condition, and then frictionally disengage (or at least engage with less friction) when segments **122** and **123** are moved toward one another to increase the loop(s) diameter. This action can be used to facilitate repositioning the spring collar **54**A along the sheath **43** or other device by disengaging, moving and then re-engaging the spring collar **54**A. Other actions that reduce the diameter of loop(s) **121** may also be used, including for instance an action in which moving segments **122** and **123** toward one another causes such diameter to decrease while introducing stress into the spring collar. In such a design, for frictional engagement with the sheath **43** or other device, a feature for holding the segments **122** and **123** in position once the sheath/device is stressed and thereby engaged could be used, for example a clip or cap. The clip, cap or other feature could thereafter be removed or released to disengage the spring collar from the sheath **43**/device, move the spring collar, and then re-applied after squeezing segments **122** and **123** toward one another to re-engage the sheath/device.

(29) As illustrated in FIG. **17**, the spring collar **54**A can optionally include a molded plastic or other

jacket attached to and that at least partially covers the wire spring **120**. Such a jacket can be provided by one piece or optionally multiple pieces, and desirably includes at least tab portions connected respectively to each of the wire segments **122** and **123**, with the tab portions providing a widened (relative to the diameters of the wire segments **122** and **123**) area that can be used for manually gripping and manipulating the spring collar **54**A for the engagement/disengagement operations discussed above. In the illustrated embodiment, the jacket includes a first jacket piece **124** and a second jacket piece **125**. First and second jacket pieces **124**,**125** include respective tab portions **126**,**127** which define respective grooves **128**,**129** for receiving respective portions of wire segments **122**,**123**. Grooves **128** and **129** terminate along the lengths of tab portions **126** and **127**, and tab portions **126** and **127** include portions **130** and **131** outward of the grooves **128** and **129** which define respective apertures **132** and **133** for receiving outward end portions of the wire segments **122** and **123**. If desired, a bonding agent can be applied within apertures **132** and **133** or at other locations to help to secure the jacket pieces **124** and **125** to the wire spring **120**. Jacket pieces **124** and **125** can also include structures for jacketing the wire loop(s) **121** of the wire spring **120**. With reference to first jacket piece **124**, it includes a loop-covering portion **134** that includes one or more fingers **135**, preferably two or more fingers. Second jacket piece **125** includes a loop covering portion **136** that includes one or more fingers **137**, preferably two or more fingers. When jacket pieces **124** and **125** are assembled on the wire spring, finger(s) **135** and finger(s) **137** interleave but remain slidably disposed with respect to one another. In this fashion, when tab portions **126** and **127** are squeezed or otherwise forced toward one another to enlarge the loop(s) **121**, finger(s) **135** and **137** will slide relative to one another so as to decrease their extent of interleaved overlap while still providing a structure that generally surrounds the loop(s) **121**. Release of the tab portions **126** and **127** will then cause finger(s) **135** and **137** to slide again relative to one another so as to increase their extent of interleaved overlap while providing a loop(s)-surrounding structure. Jacket portions **124** and **125** can optionally each be monolithic pieces, as illustrated, providing both the respective tab portions and loop(s)-surrounding portions.

(30) When the spring collar **54**A or other scale marker **54** is frictionally engaged with the sheath **43** or other device, it can do so while compressing the sheath **43** or other device at a level which does not substantially deform the shape of the sheath **43** or other device (e.g. leaving open an internal lumen thereof) but which creates sufficient friction to resist movement of the collar **54**A or other marker **54** along the sheath **43** or other device during use. For example, such friction can be sufficient to require a force of greater than 2 Newtons applied to the engaged collar **54**A/marker **54** in the direction of the longitudinal axis of the sheath **43** or other device in order to cause sliding movement of the engaged collar **54**A/marker **54**, more preferably in the range of about 3 Newtons to 10 Newtons, and most preferably about 4 to about 5 Newtons. It will be understood that other force values could be utilized in varied circumstances depending for instance upon the particular percutaneously-introduced device and procedure requirements associated therewith. It will also be understood that the friction and resultant resistance to linear displacement of the engaged spring collar **54**A or other marker **54** can depend, for instance, upon the extent of surface contact, the surface characteristics and materials of construction of the collar or marker and those of the sheath or other percutaneous device, which can also be varied in achieving the desired result. The variation of these and other parameters will be within the purview of those skilled in the field given the teachings herein. Moreover, as shown in FIG. **3**C, in accordance with certain inventive embodiments, a spring collar **54**A or other biased marker **54** can be equipped with a retainer device **54**B that holds the collar **54**A or other marker **54** in an unrelaxed (or stressed) condition when received around the sheath **43** or other device. For example, the sheath or other device can be packaged or handled with the collar **54**A or other marker **54** received therearound, but equipped with the applied retainer device **54**B to disengage or reduce compression of the sheath **43** or other device by the collar **54**A or other marker **54**. In this fashion, potential deformation of the sheath **43** or other device over time, e.g. during storage prior to use, can be reduced or eliminated. As

illustrated, retainer device **54**B can be a cap in which tab portions **126** and **127** are received and held closer together than they would be in a relaxed condition of the collar **54**A, although other retainer elements or devices that resist return of the spring collar **54**A to its relaxed condition could also be used.

(31) Returning to a discussion of an illustrative procedure, with particular reference to FIG. **4**, while holding the position of IVUS probe **44** stationary, sheath **43** is advanced coaxially over dilator **41** until the distal tip of sheath **43** advances over IVUS probe **44**. This event can be sensed tactilely as discussed above, and/or through a change in the image generated by IVUS probe **44** due to being covered by the wall of sheath **43** (potentially enhanced by the presence of echogenic marker **46**, which can be configured to reflect ultrasonic energy sourced from the probe **44** within). At this point, the user knows that the distal tip of sheath **43** is positioned at the target position found with the IVUS probe **44**. The user can then reference the scale markings within the marking feature **47** that coincide with the skin level of the percutaneous insertion site **51**. A correlation can thereby be drawn between the positioning of the distal tip of the sheath **43** at the target site and a scale marking within marking feature **47**. Again, in one embodiment, such scale marking includes a numeric value correlating to the distance from the marking to the distal tip of sheath **43**. The repositionable scale marker **54**, when present, can also be advanced and secured to abut the percutaneous insertion site **51** with the distal tip of sheath **43** at this target position. The dilator **41** and if still present the wire guide can then be removed from the sheath **43** while holding the sheath stably in position with the distal tip of the sheath **43** at the target position.

(32) Referring now to FIGS. **5** and **6**, thereafter, a filter introducer system carrying filter **20** (FIG. **1**) is advanced into the sheath **43**. In FIG. **5**, shown is filter introducer system **60** advanced into sheath **43** to position the distal tip of filter **20** substantially at the distal tip of sheath **43**. As noted above, this positioning can be discerned in any suitable manner. In the embodiment shown, filter introducer **60** includes proximal, visible markers **62** and **63** spaced longitudinally from one another, and positioned on introducer **60** so as to remain external of the patient during the procedure. When the distal-most marker **62** aligns with a distal-most portion of the sheath **43**, or aligns with another identifiable reference associated with sheath **43**, the distal tip of filter **20** is aligned with the distal tip of sheath **43**.

(33) With reference now to FIGS. **5** and **6** together, at this point, sheath **43** can be withdrawn until the proximal end of sheath **43** (or the associated reference point) is flush with marker **63**, whereupon filter **20** is externalized from sheath **43** at the target location. In the illustrated embodiment, at this stage, the secondary legs **23** of filter **20** are deployed outwardly against the wall of the inferior vena cava **50**; however, the primary struts **22** remain engaged by retaining element **61**, such as a metal mount, located at the tip of introducer **60**. Retaining device **61** is actuatable from a position external of the patient to release primary struts **22** of filter **20**, for example by operating a button, switch, lever, or any other suitable mechanism. Such a mechanism is in use at present on the COOK® CLECT® filter set for femoral vein approach (William Cook Europe, Denmark), which mechanism can be used herein. Additionally, reference can be made to U.S. Pat. No. 5,324,304, which describes similar release mechanisms that can be used herein.

(34) After release of the primary struts **22** from the retaining element **61**, filter **20** fully deploys in vena cava **50**, and sheath **43** and any other percutaneously introduced devices can thereafter be withdrawn from the patient. Shown in FIG. **7** is an enlarged view of filter **20** as deployed within the inferior vena cava **50**, with both secondary struts **23** and primary struts **22** having expanded radially outwardly against the wall of vena cava **50**. With filter device **20** so deployed, in certain embodiments the echogenic markers **26** and **27** are sufficiently spaced to be viewed by transabdominal ultrasound as distinct images. Still further, in desirable embodiments, echogenic markers **28** are located on primary struts **22** so as to be positioned against the caval or other vessel wall when in the expanded, deployed condition. The position of echogenic markers **28** and thus of the associated strut regions can thus be confirmed with ultrasound images. As noted above, the

elongate generally straight filaments **29** extending from markers **28** can aid in the fixation of device **20** against the walls of vena cava **50** and/or can help to prevent migration of the struts **22** through the caval or other vessel wall.

(35) In advantageous operations, after deployment of the filter **20** from sheath **43** and release of the primary struts **22** from retaining device **61**, the filter introducer **60** is withdrawn while leaving sheath **43** percutaneously inserted. The guide **42** can then be reinserted through sheath **43** and an IVUS-enabled catheter such as dilator **41** can be reintroduced over the guide **42**. With the guide **42** extending into or beyond the filter **20**, the IVUS-enabled dilator **41** can be advanced within vena cava **50** and the IVUS probe **44** can be used in the generation of images to confirm the deployment position of filter **20**. In one mode, the IVUS images generated can be used to inspect the position of the primary struts **22** and/or secondary struts **23** against the wall of vena cava **50**. To facilitate this inspection, echogenic markers (e.g. **28**) positioned on struts **22** and/or **23** and configured to be apposed against the wall of vena cava **50** upon proper deployment of the filter **20** can be used to generate images from which such apposition can be confirmed or denied. The IVUS probe **44** can also if desired be advanced beyond filter **20** to generate an image of renal vein or veins **52**A and/or **52**B to confirm position of the filter **20** caudal thereto. After this inspection, and potentially also electronic storage of the confirming images for the patient record, the guide device **42** and IVUS-enabled dilator **41** can be withdrawn from the patient. For example, shown in FIG. **16** are images of a vena cava filter implanted in the vena cava of a sheep, obtained by advancing an IVUS-enabled catheter beyond the implanted filter and generating IVUS images during a pull-back of the catheter. Shown at the top is a projection image generated from a series of axial images, depicting the lower renal junction, the vena cava filter hook, the filter legs, and the ilio-caval bifurcation. The projection image has interpretive markings added by the user, in the form of color-coded vertical lines corresponding to anatomical landmarks and features of the implanted device. Desirably, the projection image or other IVUS-generated image(s) will depict the first and second ends of the device, which can optionally be marked on the image by the user. Shown at the bottom are axial IVUS images corresponding to the device features and anatomic landmarks discussed above and depicted in the projection image, and color coded to the vertical lines added to the projection image. These and other marking and/or indexing measures can be taken to add clarity to the interpretation of the image(s). Such an image or images can be obtained of an implanted vena cava filter or other vascular filter or other device, with accompanying physiologic landmarks from the patient, to confirm proper placement of the device following deployment. The optional presence of echogenic features on the device, e.g. on the filter hook and/or filter legs, can enhance the ability to visualize the device features in the confirming ultrasound images. The utilization of IVUS-generated device placement images to confirm the location of the implanted device after deployment, and for purposes of maintaining a patient medical record relating to the surgery, constitutes another embodiment of the invention and can be used in conjunction with any system or placement method described herein or otherwise. The collected IVUS data can be filtered to improve the IVUS image, for example by excluding data from certain segments or regions. For example, the projection image in FIG. **16** (top) was generated from data taken from the longitudinal volume depicted between the dotted lines in the left-most axial image found below. This technique and/or other filtering techniques can be used to improve the image quality given the teachings herein. The IVUS-generated images can be electronically stored in the patient record, e.g. using a data capture and storage system directly coupled to the IVUS device or system, or by otherwise transferring the electronic data to the patient record, and/or by retaining printouts or other “hard copy” version of the captured confirming images. In certain embodiments, the IVUS-generated image can serve as an alternative to any radiographic image (e.g. X-ray image) where no radiographic confirmation of placement is taken, and in other embodiments the IVUS-generated image can serve as an addition to a placement-confirming X-ray or other radiographic image in the patient record.

(36) FIGS. **7-9** illustrate an embodiment of a delivery system for a vascular device, such as a vascular filter, that is useful from an approach descending downwardly within the vena cava, e.g. through a percutaneous access site in the left or right jugular vein. System **70** has numerous features which correspond directly with features of system **40** discussed above, to which reference can be made for details. System **70** includes an IVUS-enabled dilator having an IVUS probe **78**, for percutaneous insertion through percutaneous access site **71**. System **70** includes a sheath **72** translatable coaxially over the dilator. An echogenic marker **73** is provided at the distal end of sheath **72**. Sheath **72** further includes an echogenic marker **74** spaced proximally of marker **73** a longitudinal distance **75**. Markers **73** and **74** can optionally include physically discrete or physically integrated fluoroscopic markers as discussed above. Longitudinal distance **75** corresponds to a desired distance for advancement of the distal tip of sheath **72** beyond IVUS probe **78** to position the sheath for deployment of a vascular device, as discussed in further detail below. Sheath **72** also includes a marking feature **76** corresponding to marking feature **47** of sheath **43**, desirably a numeric distance scale, as discussed above. It will be understood in this regard that the relative position of marking feature **76** along sheath **72** may differ from the position of marking feature **47** along sheath **43**, due to the differing distances from the respective percutaneous entry sites the target site. System **70** also includes a guide device **79** such as a wire guide. Shown in FIG. **7** is the dilator with the IVUS probe **78** in position to image and identify a location at or just below the renal veins **52**A and **52**B which feed into inferior vena cava **50**. This position is intended to be at or near the uppermost portion of the vascular implant when deployed. Sheath **72** is shown in FIG. **7** in position with its distal tip proximal of IVUS probe **78** for best viewing conditions.
(37) Referring now particularly to FIG. **8**, while holding the IVUS probe **78** in the target position, sheath **72** has been advanced along the dilator. In doing so, the advancement of the distal sheath tip over the IVUS probe **78** is recognizable by the user by a change in the generated IVUS image, which can be enhanced through the presence of an echogenic marker **73**. As the sheath **72** is advanced further, the user will again note a change in the IVUS image as the more proximal echogenic marker **74** arrives overtop the IVUS probe **78**. If desired, sheath **72** can be configured to also provide a tactile signal of this positioning. In this position, the distal tip of the sheath **72** has been advanced to a target location distal of the IVUS probe **78** from which pull-back of sheath **72** will be initiated for deployment of the implant. At this point also, the user can make visual reference to the visible marker feature **76** and in a particular embodiment to scale markings therein which align at skin level at the percutaneous entry site **71**, or with any other suitable location correlating to the position of the distal tip of the sheath **72**. While holding the sheath in position, potentially with continuing reference to the position of scale markings within the marking feature **76**, the dilator including IVUS probe **78** and the guide **79** can then be withdrawn.
(38) With reference now to FIG. **9**, a filter introducer **80** carrying filter **20** can then be inserted through sheath **72**. Filter **20** can for example be held by introducer **80** with a loop, hook or similar retaining device **84** located at the distal end of introducer **80** and engaging the hook of filter device **20**. Similar to system **40** above, filter introducer **80** includes proximally-positioned external visible markers **82** and **83** spaced longitudinally along the shaft of device **80**. The distal marker **82** aligns generally with a reference point, for instance the proximal end of sheath **72** or an element connected thereto, when the distal end of filter **20** is generally aligned with the distal tip of sheath **72**. After advancing filter introducer **80** to this position while holding sheath **72** in place, sheath **72** can be withdrawn proximally until the distal end of sheath **72** (or piece associated therewith) is generally flush with marker **83**, giving indication that the filter device **20** has been deployed from the distal opening of sheath **72**. Retaining device **84** can then be actuated to release filter device **20** from introducer **80**, thus leaving filter device **20** deployed within the inferior vena cava. Thereafter, if desired, the guide device **79** and the IVUS-enabled dilator can be re-introduced through sheath **72** and used to inspect the deployed filter **20** and the apposition of its struts against the caval wall. Echogenic markers **28** positioned on the primary struts **22** and/or the secondary struts **23** can

facilitate capturing images showing those markers at or against the wall of vessel **50** to provide assurance that the filter **20** has properly and completely deployed. The guide **79**, the dilator with IVUS probe **78** and if still present the sheath **72** can then be withdrawn from the patient.

(39) In additional aspects of the invention, provided are IVUS-enabled and/or echogenically-marked percutaneously-insertable devices that can be used in the retrieval or delivery of vascular filters or other implant devices. FIG. **11** is a partial cut-away view of a percutaneous vascular snare device **90** embodiment of the invention. Vascular snare **90** includes an elongate shaft **91** having an internal lumen and a snare loop **92**, for example made of a flexible filament(s) such as wire, which can be controllably deployed from and withdrawn into the lumen. Snare device **90** includes an echogenic marker **92** on at least a portion of the snare loop **92**. Echogenic marker **92** can include a grooved structure, a coil such as a wire coil, a dimpled and/or grooved structure such as dimpled and/or grooved cannula, or any other suitable echogenic structure or material as discussed herein. Further, marker **92** can be mounted over the wire or other elongate filament forming the snare loop **92**, or can be integrally formed into the wire or other elongate filament. Echogenic marker **92** is sized and configured to permit the deployment of the snare loop **92** smoothly out of and into the cannulated device **91** without substantial damage to either, so as to facilitate capturing devices with the snare. In certain embodiments, the snare device **90** includes an IVUS probe **94**. The IVUS probe **94** can be used in obtaining ultrasound-generated images of a device to be captured and potentially retrieved with snare device **90**. Still further, in some embodiments, the echogenic marker **93** of snare device **90** can be positioned on the snare loop **92**, and the snare loop can deploy to a configuration, such that at least a portion of the marker **93** can be imaged using an ultrasonic signal generated with the IVUS probe **94**. For these purposes, the snare loop **92** can deploy, at least in part, laterally from the lumen of the cannulated device **91**, so as to position at least a portion of the echogenic marker **93**, and potentially the entire marker **92**, within the range of longitudinal resolution of the IVUS probe **94**. In this manner, a user of snare device **90** can confirm deployment and position of the snare loop **92** in an open position by viewing images generated with IVUS probe **94**. For these purposes, the snare loop **92** can be deploy to an open condition in which at least a portion of echogenic marker **93** aligns longitudinally with at least a portion of IVUS probe **94**, or is longitudinally offset no more than about 3 mm therefrom. Echogenic marker **93** can, of course, also be visualized using an externally-generated (e.g. transabdominal) ultrasound image, to assist in guiding a capture or retrieval operation. Such external ultrasound imaging can also be used in conjunction with IVUS imaging derived from IVUS probe **94** in guiding the operation.

(40) With continued reference to FIG. **11** and also to FIG. **12**, in one mode, vascular snare **90** can be used to capture and retrieve an implanted vascular filter, for instance filter **20** described herein. External (e.g. transabdominal) ultrasound imaging can be used to discretely visualize echogenic markers **26** and **27** of filter **20** and echogenic marker **93** of snare device **20** (in an open condition) positioned therebetween and around neck **25** of filter **20**. Snare loop **92** can then be closed by withdrawing it into the cannulated shaft **91** so as to capture filter **20**, with the closed snare loop ultimately catching in hook **25**. Alternatively or in addition, when IVUS probe **94** is present, vascular snare **90** can be used in generating an IVUS image to discretely and sequentially visualize marker **27** and marker **26** of filter **20**, to guide positioning of the snare loop therebetween and around the neck **25** of the filter **20**, whereupon it can be closed to capture the filter **20**. After capture of the filter in the snare loop **92** in a closed condition, a cannulated retrieval device **95** (FIG. **12**) such as a catheter or sheath can be advanced over device **91** and over filter **20** to force struts **23** and **22** radially inwardly to retrieve the filter **20** into the cannulated retrieval device **95**. The snare **90**, filter **20** and cannulated retrieval device **95** can then be removed from the patient. Alternatively, such a capture and/or retrieval operation can be used to reposition the filter **20** after deployment.

(41) FIG. **13** illustrates another embodiment of an IVUS-enabled filter delivery system **100** of the invention. System **100** includes a filter delivery sheath **101** with filter **20** housed in a lumen thereof. Delivery sheath **101** can have all of the attributes of sheath **43** discussed hereinabove, including but

not limited to marking feature **47** and repositionable scale marker **54** (see, e.g., FIGS. **2**-**6**). Delivery sheath **101** also has an IVUS probe **102** mounted proximate its distal tip. As discussed above, wire(s) and connectors for powering IVUS transducer element **102** and for transmitting signal data can be suitably routed along sheath **101** embedded within shaft walls, within additional lumens thereof, or properly positioned and protected, may share a lumen with filter **20**. Any of these same arrangements or combinations thereof can be used for routing wire(s) and connectors for any of the IVUS probes disclosed herein. The presence of IVUS probe **102** on the implant delivery sheath **101** itself can eliminate the need to use a separate IVUS-enabled device (e.g., the IVUS-enabled dilator **41** discussed above), although in certain modes of use both types of IVUS-enabled devices could be used in guiding the device delivery.

(42) Delivery sheath **101** also includes an echogenic marker **103** and/or a fluoroscopic marker **104**. As discussed above, markers **103** and **104**, when both present, can be provided by a single structure or material with dual function, or by separate pieces or structures. The arrangements discussed above can be suitably used. IVUS-enabled filter delivery system **100** also includes a filter introducer device **105**, such as a catheter, having an elongate shaft **106** and a retaining element **107**, such as a metal mount, in which the ends of primary struts **22** of filter **20** are received, and are releasably held. The ends of primary struts **22** can be released from retaining element **107** upon actuation of a button, switch or other suitable mechanism of introducer device **105**, as discussed above for other embodiments.

(43) Delivery sheath **101** can be used to percutaneously deliver vena cava filter **20** to a position generally as shown in FIGS. **3**-**6**, with modification. To do so, sheath **101** can be percutaneously introduced (conventionally along with a dilator, which is then removed), e.g. through the right or left femoral vein, and advanced to a position to view the renal veins using the IVUS probe **102**. With the position of the probe **102** generally at or caudal to the lower renal vein (typically the right), the position of the sheath **101** can be noted (e.g. using visible scale markings corresponding to feature **47** above). Holding the sheath **101** in place, the filter introducer **105** can be used to advance the hook of filter **20** to the distal tip of the sheath **101**, for example using alignment of external, visible proximal marker **108** on introducer **105** with a feature on or associated with sheath **101** to signal that the distal tip of filter **20** is aligned with the distal tip of sheath **101**. The position of the distal tip of sheath **101** within the inferior vena cava can then be confirmed using the external (e.g. skin-level) visible scale markings on the sheath and/or using the IVUS probe **102** to visualize the renal vein(s) again. The sheath can then be pulled back to align the feature on or associated with sheath **101** with external, visible marker **109** to signal that filter **20** has been deployed from the distal opening of sheath **101**. The release actuator for retention device **107** can then be operated to release primary struts **22** of filter **20** to fully deploy the filter **20**.

(44) FIG. **14** illustrates still another embodiment of an IVUS-enabled filter delivery system **110** of the invention. System **110** includes a filter delivery sheath **111** with filter **20** housed in a lumen thereof. Delivery sheath **111** can have all of the attributes of sheaths discussed hereinabove, including but not limited to external visible marking features (e.g. **76**, FIGS. **8**-**10**) and a repositionable scale marker (e.g. **54**, FIGS. **2**-**6**). Delivery sheath **111** also has an IVUS probe **112** a distance proximal to its distal tip. The presence of IVUS probe **112** on the implant delivery sheath **111** itself can eliminate the need to use a separate IVUS-enabled device (e.g., an IVUS-enabled dilator as discussed above), although in certain modes of use both types of IVUS-enabled devices could be used in guiding the device delivery.

(45) Delivery sheath **111** also includes an echogenic marker **113** and/or a fluoroscopic marker **114** proximate its distal tip, the construction of which can be as discussed hereinabove. System **110** also includes a filter introducer device **115**, such as a catheter, having an elongate shaft **116** and a retaining element **117**, such as a hook, releasably engaging the hook of filter **20**. The hook of filter **20** can be released from retaining element **117** upon actuation of a button, switch or other suitable mechanism of introducer device **115**, as discussed above for other embodiments.

(46) Delivery sheath **111** can be used to percutaneously deliver vena cava filter **20** to a position generally as shown in FIGS. **8**-**10**, with modification. To do so, sheath **111** can be percutaneously introduced (conventionally along with a dilator, which is then removed), e.g. through the right or left jugular vein, and advanced to a position to view the renal veins using the IVUS probe **112**. With the position of the probe **112** generally at or caudal to the lower renal vein (typically the right), the position of the sheath **111** can be noted (e.g. using external visible scale markings corresponding to features **47** or **76** above). Due to the distance between IVUS probe **112** and the distal end of sheath, this position will place the distal end of sheath **111** well caudal the renal vein(s), at a position corresponding to the desired lowermost point of the deployed filter implant. In the illustrated embodiment, the distance from IVUS probe **112** to the distal sheath tip is approximately equal to or slightly greater than (e.g. up to about 130% of) the length of filter **20** when deployed. Holding the sheath **111** in place, the filter introducer **115** can be used to advance the distal leg ends of filter **20** to the distal tip of the sheath **111**, for example using alignment of external, visible proximal marker **118** with a feature on or associated with sheath **111** to signal that the distal tip of filter **20** is aligned with the distal tip of sheath **111**. The position of the distal tip of sheath **111** within the inferior vena cava can then be confirmed using the external (e.g. skin-level) visible scale markings on the sheath and/or using the IVUS probe **112** to again visualize the renal vein(s). The sheath can then be pulled back to align a feature on or associated with sheath **111** with external, visible marker **119** to signal that filter **20** has been deployed from the distal opening of sheath **111**. The release actuator for retention device **117** can then be operated to release the hook **25** of filter **20** to fully deploy the filter **20**.

(47) In additional embodiments, unique ultrasound image guidance methods and systems are provided. These methods and systems can be used in conjunction with implant devices and delivery/retrieval components discussed hereinabove, or with other devices or components. In one aspect, ultrasound guidance of percutaneous procedures can be provided using a combination of real time IVUS images and electronically-stored images. The electronically-stored images can, for example, be sequential images of a vessel acquired during pull-back of an IVUS probe (e.g., on IVUS-enabled dilators, sheaths or snares as discussed above) within the vessel, desirably at a constant speed, or generated images reconstructed from a plurality of such sequential images. Constant-speed pull-back devices for these purposes are known and commercially available. The generated, stored images can for example be three-dimensional or two-dimensional images of the length of vessel in which an implant such as a filter is to be deployed, reconstructed from a plurality of sequential, cross-sectional or otherwise segmental images of the vessel.

(48) With reference to FIG. **15**, provided is a schematic showing components of one embodiment of such a system. System **200** as depicted includes IVUS-enabled dilator **41** as described above (FIGS. **2**-**4**), although other IVUS-enabled devices such as the dilator of FIGS. **8**-**9**, snare **94** (FIG. **11**) or delivery sheaths **101** (FIG. **13**) or **111** (FIG. **14**) can be substituted for dilator **41**. Dilator **41** includes IVUS probe **44** and also includes a marking feature **47**A, which can be the same as marking feature **47** discussed hereinabove in connection with FIGS. **2**-**6**) and thus include individual scale markings **48** denoting a distance from the marking to a distal feature of dilator **41**, such as the distance from the individual scale marking to the IVUS probe **44**, and associated numerical markings **49**. Dilator is shown percutaneously inserted with scaled regions of marking feature **47**A occurring at skin level at entry site **51** on the patient.

(49) System **200** includes a computer processor **201**, which can also include an electronic memory storage for storing data and images. Computer processor **201** receives signal data from IVUS probe **44** via data transmission connection **202**, which can for example be a wired or wireless connection. Computer processor **201** generates ultrasound images of vessel **50** using the transmitted signal data. Processer **201** is electronically connected via connection **203** to a visual display device **204** such as a display monitor. Display device **204** displays two-dimensional, real time IVUS images **205** generated using IVUS probe **44**. In the depicted image **205**, shown are the left and right renal veins

generated by IVUS probe **44** positioned closely thereby. Display device **204** also displays an image **206** generated by reconstructing a plurality of previously-acquired two-dimensional, cross-sectional image data sets from IVUS probe **44**. Algorithms for these purposes are known and are also available in commercially available IVUS devices and associated software, including those available from Volcano Corporation (San Diego, CA, USA). The previously-acquired data sets for reconstructing image **206** can be obtained during a pull-back of dilator **41**, desirably at constant speed, during which IVUS image data are collected, desirably at regular time intervals. A pull-back device **206**A can be used for these purposes, embodiments of which are also commercially available from Volcano Corporation.

(50) In one embodiment, a graphical scale **207** is displayed on or in conjunction with image **206**. Scale **207** can have scale markings **208** which correlate to individual scale markings **48** on dilator **41**. Scale **207** can also have respective associated numerical markings **209** which correlate to respective associated numerical markings **49** on dilator **41**. Thus, for example, a scaled marker on graphical scale **207** that is numbered “10 cm” will align longitudinally on or next to image **206** at a point correlated to the longitudinal position of IVUS probe **44** when a corresponding “10 cm” scaled marker of marking feature **47**A occurs at skin level of entry site **51**. Reliable external reference points for marking feature **47**A other than skin level could also be used. In one manner of generating and locating graphical scale **207**, at the starting point for pull-back, a user can input to the processor **201** the numeric indicia **49** having associated marker **28** at skin level. Using time-elapsed and constant-speed information provided to processor **201** by pull-back device **206**A via connection **206**B, processor **201** can ascertain how far probe **44** has traveled when generating a given image data set to be incorporated in the reconstruction of image **206**, and can thereby accurately generate scale **207** in reference to the reconstructed image **206**. In other modes of accurately generating scale **207**, pull-back device **206**A can include a device for directly measuring the distance traveled by dilator **41** during the pull-back, for example by detecting revolutions of a roller wheel of known circumference, or any other suitable means, and can communicate traveled distances to processor **201** that correlate to images acquired. Alternatively, such a direct measuring device can be provided in a separate position-tracking device **212** which communicates similar information to processor **201** concerning dilator **41** shaft travel distance during image acquisition via connection **213**. As another alternative, during pull-back, a user can manually communicate shaft travel increments to processor **201** during image capture while watching marking feature **47**A as it moves past skin level or another reference point. These or other measures for accurately associating scale **207** with image **206** can be used.

(51) In certain embodiments, a graphical image **210** having features generally correlating to those of dilator **41** or the other device in use is displayed in association with image **206**, potentially also in combination with scale **207**. The graphical image **210** can include a graphical representation **211** of the IVUS probe **44**, the distal tip of the device in use, and/or other device features. The position and movement of the image **210** relative to image **206** can be correlated to the position of dilator **41** (or the other device in use) within the vessel **50**. This can be accomplished by inputting to processor **201** information related to shaft travel of dilator **41** during the procedure, starting from a known reference point which may for example be manually inputted by a user based upon visual observation of marking feature **47**A relative to skin level or another reference point, and/or may be a direct continuation of the above-described positional tracking of the device **41** during the pull-back/image acquisition phase, for which the original positional input information from the user at the start of pull-back may continue to serve as a known reference point. To track shaft travel, devices for directly measuring shaft travel (e.g. as a part of the pull-back device **206**A or a separate position-tracking device **23**), or manual entry by a user, can be used, as discussed above.

(52) In a different mode, sequential images that continue to be acquired by IVUS probe **41** during the procedure can be compared, using an appropriate algorithm and processor **201**, to prior-acquired images obtained to generate image **206**. The newly-acquired images can then be registered

to prior-acquired images of known position along image **206**, and the graphical image **210** can be positioned accordingly, e.g. by aligning graphical IVUS probe image **211** with the registered prior-acquired image.
(53) System **200** can also include an external ultrasound imaging probe **214** (e.g. a transabdominal probe) connected to processor **201** via transmission connection **215**. Alternatively or in addition to graphical images **207** and/or **210** discussed above, real-time external ultrasound images can be positionally registered to prior-acquired and generated IVUS image **206** and displayed therein or adjacent thereto, via appropriate fiduciary points established during the generation of IVUS image **206**, for example by fixing the position of probe **214** during the procedure and acquiring fiduciary points during the pull-back operation, such as the location of the starting and finishing positions of an externally-imaged echogenic marker (e.g. **45**, FIG. **2**) respectively at the start and end of the pull-back to generate image **206**. In this manner, historic IVUS data and real time external ultrasound data can be together used to guide a device delivery or retrieval operation. Of course, real-time IVUS data and images can also be used in conjunction with the historic IVUS data and real time external ultrasound data.
(54) The display **204** can also include patient-specific information **216** and date/time information **217**, as well as appropriate image descriptors **218** and **219**, or other standard system performance or setting information.
(55) In still further embodiments of the invention, systems and methods as described above which employ an ultrasound-emitting IVUS probe on a percutaneously-introduced device, can be used in conjunction with an external (e.g. transabdominal) ultrasound unit that is tuned to receive an ultrasound signal from the IVUS probe, and thereby detect the location of the IVUS probe as an "active" ultrasound marker in the system, or detect the location of a separate echogenic marker(s) on the introduced IVUS device or neighboring devices based upon the reflection by the separate marker(s) of the internally-generated IVUS signal. In this fashion the relative location of portions of the introduced device(s) can be detected with external ultrasound based on the IVUS-probe-generated, and potentially reflected, ultrasound signal. In addition or alternatively, the internally-generated IVUS probe signal can be received by the external ultrasound unit and processed to develop images of biological structures, thus providing an "inside out" ultrasound image generation system. In some embodiments, the external receipt and processing of the signals from the IVUS probe can be accomplished using an external ultrasound unit also used simultaneously or intermittently to emit and detect reflected ultrasound for development of ultrasound images, as discussed hereinabove. Alternatively, separate external ultrasound units can be used, one tuned to detect the IVUS probe-generated signals, and one functioning to generate images of biological structures and potentially other features of the introduced device from externally-generated ultrasound. In certain modes of practice, images or corresponding signals generated from both ultrasound emitted by the internal IVUS probe and by an external unit can be used together, either displayed as separate images to a user or processed and combined using an algorithm (e.g. with registration) to generate a single, enhanced image for display. Such processing can be achieved using a computer processor as described herein. Systems and methods as here described having images developed using IVUS probe-generated ultrasound that is detected externally, alone or in combination with externally-generated ultrasound, form additional embodiments of the invention whether used with the specific systems described in conjunction with the drawings above, or otherwise.
(56) It will be understood that although embodiments described herein are at times discussed in connection with the delivery of, or features of, a vascular filter and related sheath and/or catheter deployment devices, embodiments of the invention can likewise involve the delivery of, and features of, other percutaneously-deliverable vascular devices such as stents, stent valves, occluders, embolization devices, anastomosis devices, and the like. These and other permutations will be within the purview of those of ordinary skill in the art given the teachings herein.

(57) The use of the terms “a” and “an” and “the” and similar referents in the context of describing the invention (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range, unless otherwise indicated herein, and each separate value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g., “such as”) provided herein, is intended merely to better illuminate the invention and does not pose a limitation on the scope of the invention unless otherwise claimed. No language in the specification should be construed as indicating any non-claimed element as essential to the practice of the invention.
(58) Preferred embodiments of this invention are described herein, including the best mode known to the inventors for carrying out the invention. Of course, variations of those preferred embodiments will become apparent to those of ordinary skill in the art upon reading the foregoing description. The inventors expect skilled artisans to employ such variations as appropriate, and the inventors intend for the invention to be practiced otherwise than as specifically described herein. Accordingly, this invention includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described elements in all possible variations thereof is encompassed by the invention unless otherwise indicated herein or otherwise clearly contradicted by context. In addition, all publications cited herein are indicative of the abilities of those of ordinary skill in the art and are hereby incorporated by reference in their entirety as if individually incorporated by reference and fully set forth.

Claims

1. A system for ultrasound guidance, comprising: a computer processor for receiving signal data from an intravascular ultrasound probe mounted on an elongate percutaneously introducible device having a distal tip located distally of the intravascular ultrasound probe and generating ultrasound images using the signal data, wherein the intravascular ultrasound probe travels correspondingly with the elongate percutaneously introducible device; a visual display device electronically connected to the computer processor; and said computer processor and display device configured to display on the visual display device two-dimensional, real time images generated by the computer processor using the signal data simultaneously with and spaced from a three-dimensional image generated from prior-acquired intravascular ultrasound image signal data from the intravascular ultrasound probe, and wherein the computer processor and visual display device are configured to display within the three-dimensional image on the visual display a graphical image representing a position of the intravascular ultrasound probe, and wherein the computer processor is configured to perform a comparison of the two-dimensional, real time images to the prior-acquired intravascular ultrasound image signal data and to position the graphical image within the three-dimensional image based on the comparison, wherein the computer processor and visual display device are configured to display on the visual display device a reference scale, wherein the reference scale is generated from the prior-acquired three-dimensional ultrasound image and is correlated to the real time two-dimensional image.
2. The system of claim 1, wherein the three-dimensional image is generated by reconstructing a plurality of previously-acquired two-dimensional, cross-sectional image data sets from the intravascular ultrasound probe.
3. The system of claim 1, also including the elongate percutaneously introducible device.
4. The system of claim 1, arranged wherein the computer processor receives the signal data via a

wired data transmission connection.
5. The system of claim 1, arranged wherein the computer processor receives the signal data via a wireless data transmission connection.
6. The system of claim 1, wherein the visual display device comprises a display monitor.
7. The system of claim 3, wherein the elongate percutaneously introducible device is a dilator.
8. The system of claim 1, wherein the prior-acquired intravascular ultrasound image signal data comprises position-tracking data correlated to image data.
9. The system of claim 1, wherein the computer processor is configured to compare the two-dimensional, real time images to the prior-acquired intravascular ultrasound image signal data in order to at least one of (i) position the at least one of a reference scale and a graphical image and (ii) adjust the at least one of a reference scale and a graphical image.
10. The system of claim 1, also comprising an external ultrasound imaging probe connected to the computer processor.
11. The system of claim 10, wherein the computer processor and display device are configured to display real-time external ultrasound images positionally registered to the three-dimensional image.
12. The system of claim 10, wherein the external ultrasound imaging probe is tuned to receive an ultrasound signal from the intravascular ultrasound probe.
13. The system of claim 12, also comprising a second external ultrasound imaging probe.
14. The system of claim 1, for ultrasound guidance of the delivery of a percutaneously-deliverable vascular device, the system also comprising: the elongate percutaneously introducible device; a delivery catheter; and a percutaneously-deliverable vascular device received in the delivery catheter.
15. The system of claim 14, wherein the percutaneously-deliverable vascular device is a filter, stent, stent valve, occluder, embolization device, or anastomosis device.
16. The system of claim 1, also comprising the elongate percutaneously introducible device, and wherein the elongate percutaneously introducible device is a delivery sheath carrying a percutaneously deliverable vascular device configured for deployment from a distal opening at the distal tip of the delivery sheath.
17. The system of claim 16, wherein the graphical image also represents a position of the distal tip of the elongate percutaneously introducible device.
18. The system of claim 17, wherein the percutaneously deliverable vascular device is a filter, stent, stent valve, occluder, embolization device, or anastomosis device.
19. The system of claim 1, wherein the elongate percutaneously introducible device includes one or more visible markers on a proximal end of the device, and wherein said computer processor and display device are configured to correlate a position of the intravascular ultrasound probe on the reference scale with the one or more visible markers.