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(54) **DELIVERY CATHETER WITH FORWARD-LOOKING ULTRASOUNG IMAGING**

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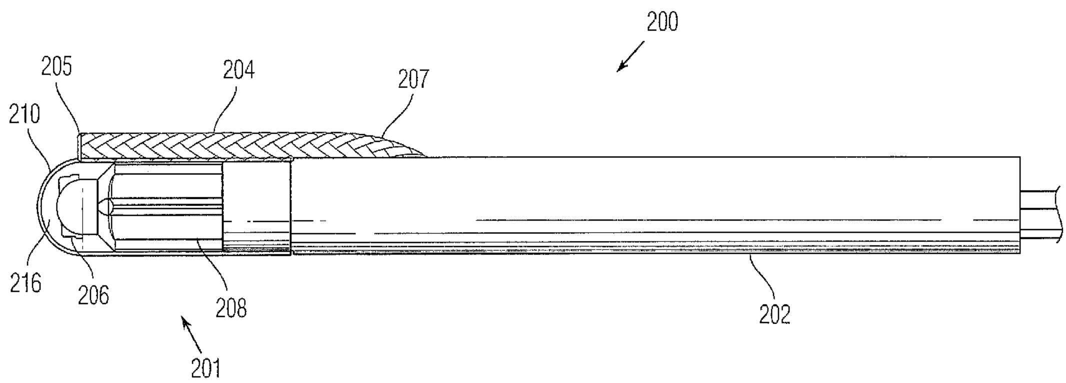
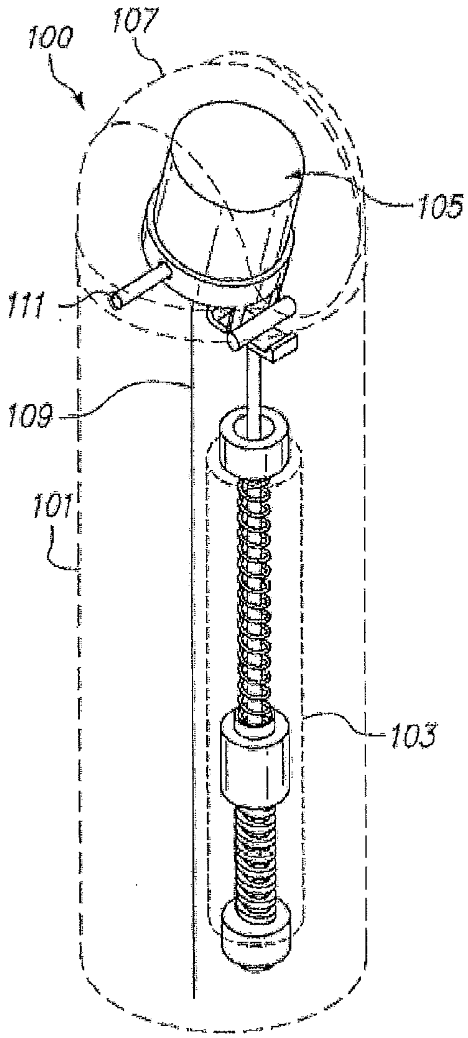
(57) **ABSTRACT**

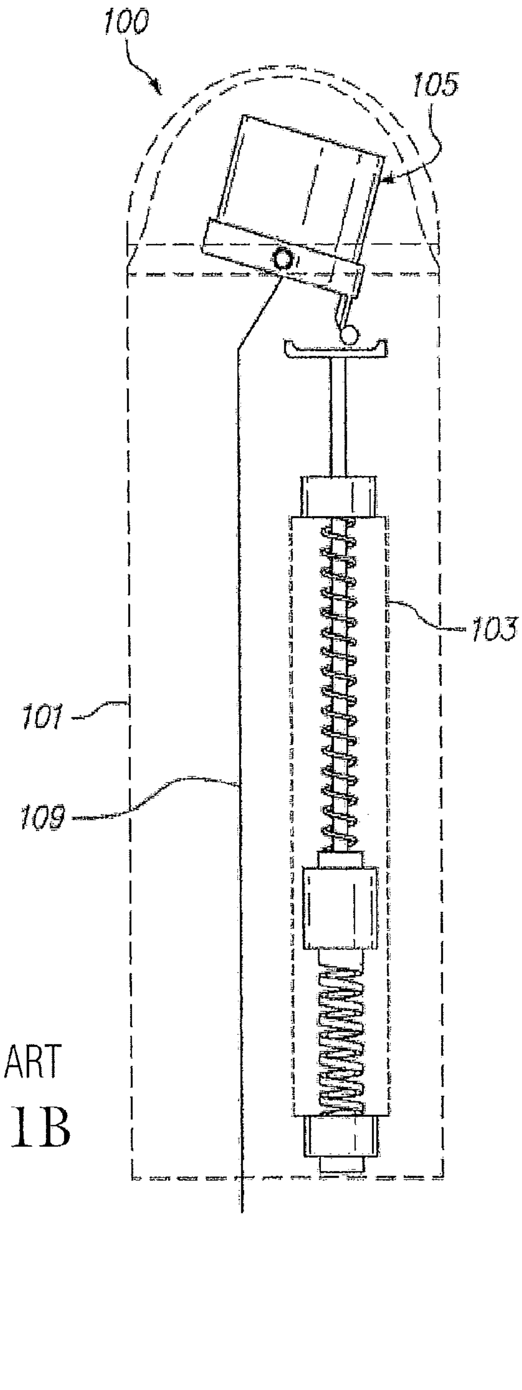
A catheter based medical device is provided for a percutaneous surgical procedure that provides forward-looking visualization and delivery of a medical device. The catheter includes a carriage at its distal end and an ultrasonic transducer is supported by the carriage. A conduit that has its proximal end disposed within the catheter and the conduit passes through the sidewall of the catheter proximate to the distal end of the catheter so that the distal end of the conduit is disposed on an exterior of the sidewall of the catheter. A medical device is deliverable through the lumen of the conduit and the ultrasonic transducer provides visualization of the medical device distally of the transducer.





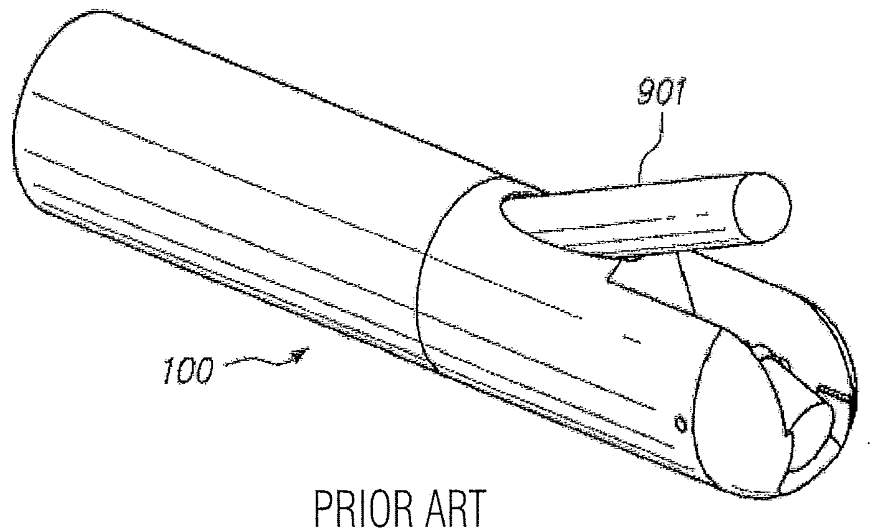
PRIOR ART

Fig. 1A

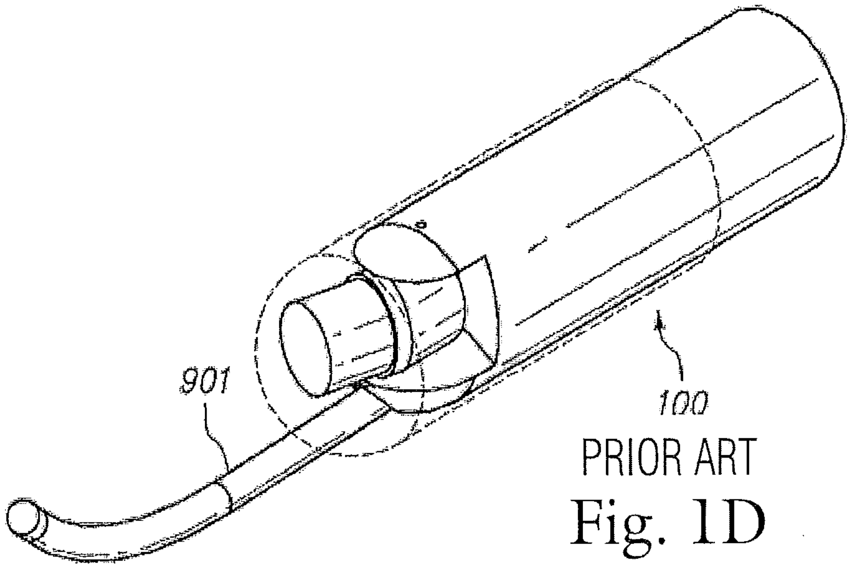


PRIOR ART

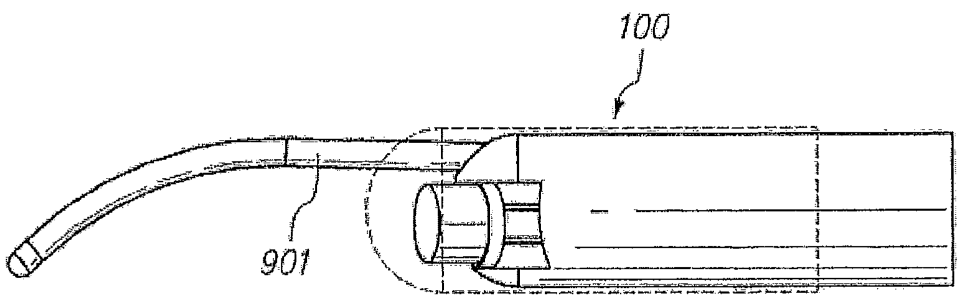
Fig. 1B



PRIOR ART
Fig. 1C



PRIOR ART
Fig. 1D



PRIOR ART
Fig. 1E

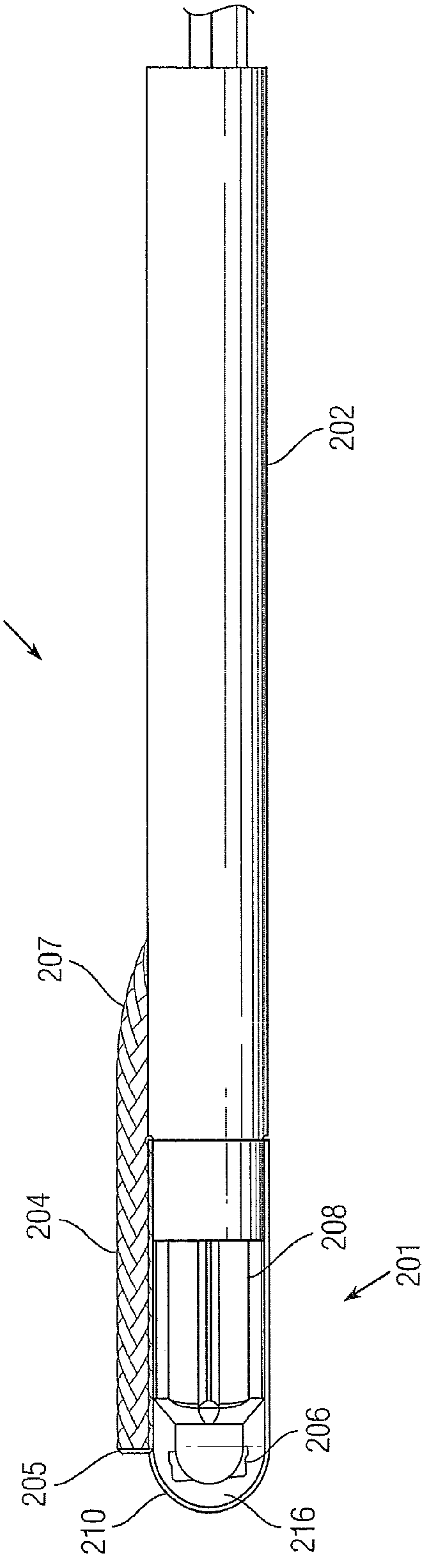


Fig. 2

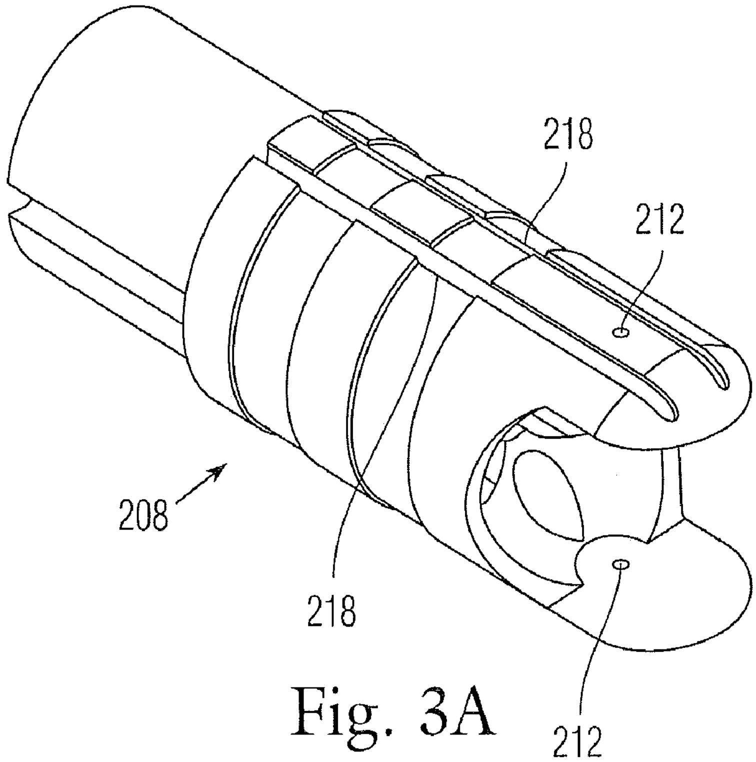


Fig. 3A

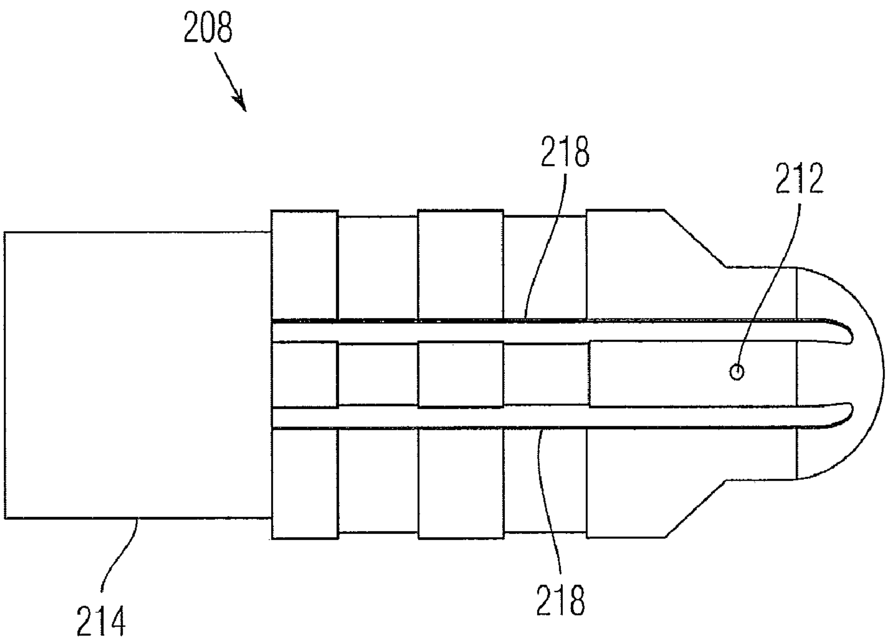


Fig. 3B

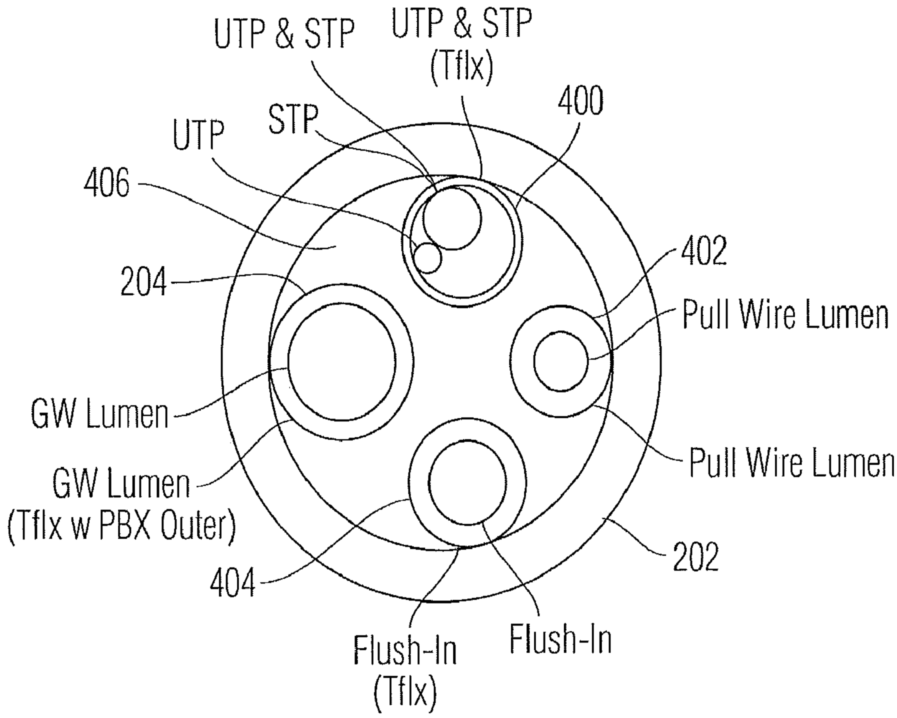

UTP & STP
UTP & STP
(Tflx)
400
STP
UTP
406
402
204
Pull Wire Lumen
GW Lumen
Pull Wire Lumen
GW Lumen
(Tflx w PBX Outer)
202
404
Flush-In
(Tflx)
Flush-In

Fig. 4A

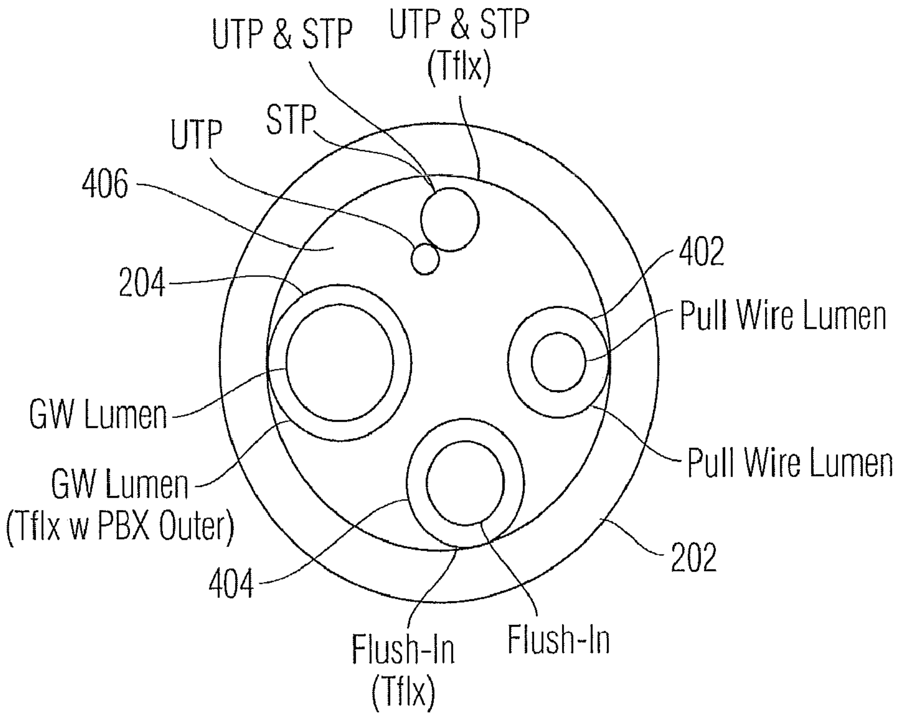

UTP & STP
UTP & STP
(Tflx)
STP
UTP
406
402
204
Pull Wire Lumen
GW Lumen
Pull Wire Lumen
GW Lumen
(Tflx w PBX Outer)
202
404
Flush-In
(Tflx)
Flush-In

Fig. 4B

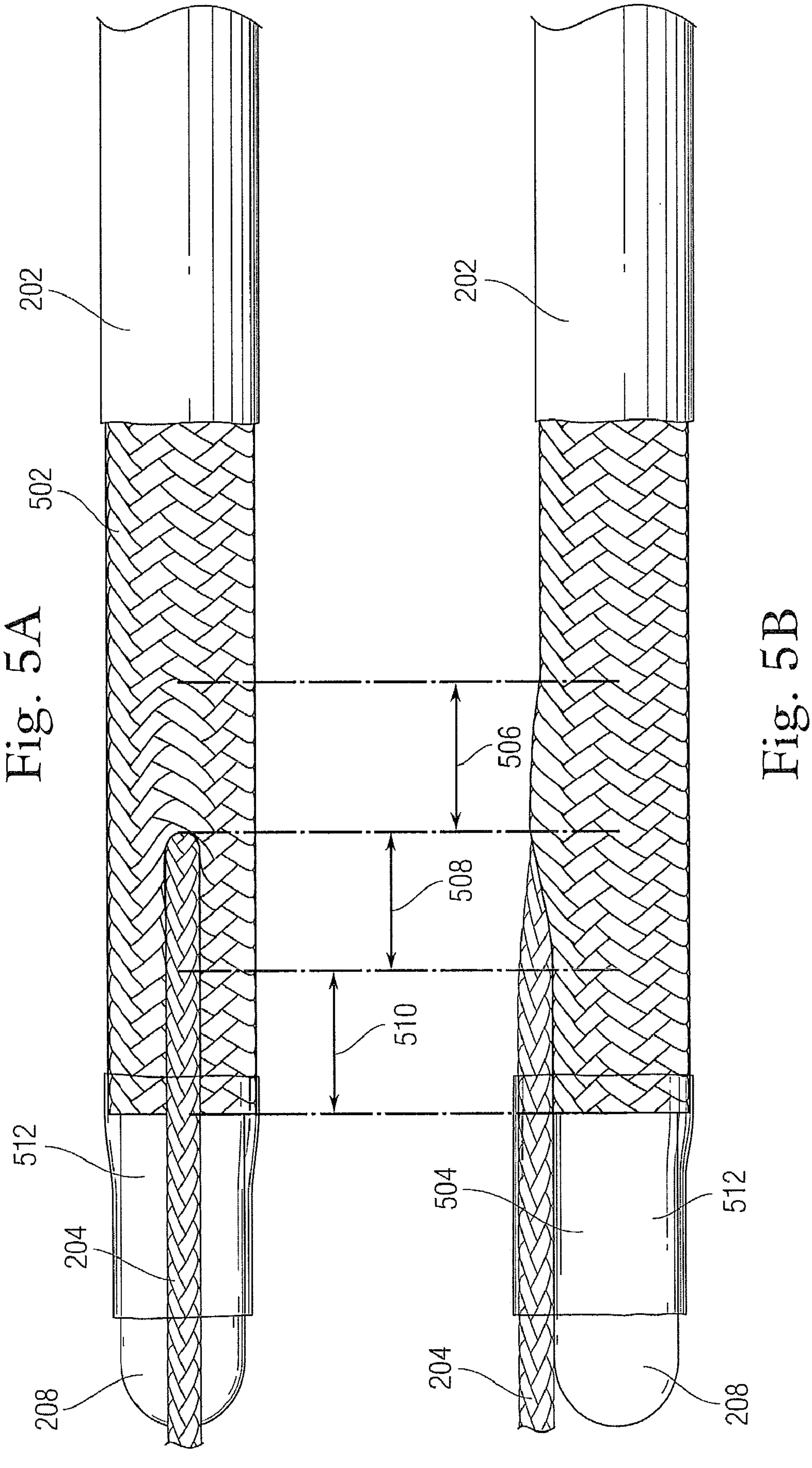


Fig. 5A

Fig. 5B

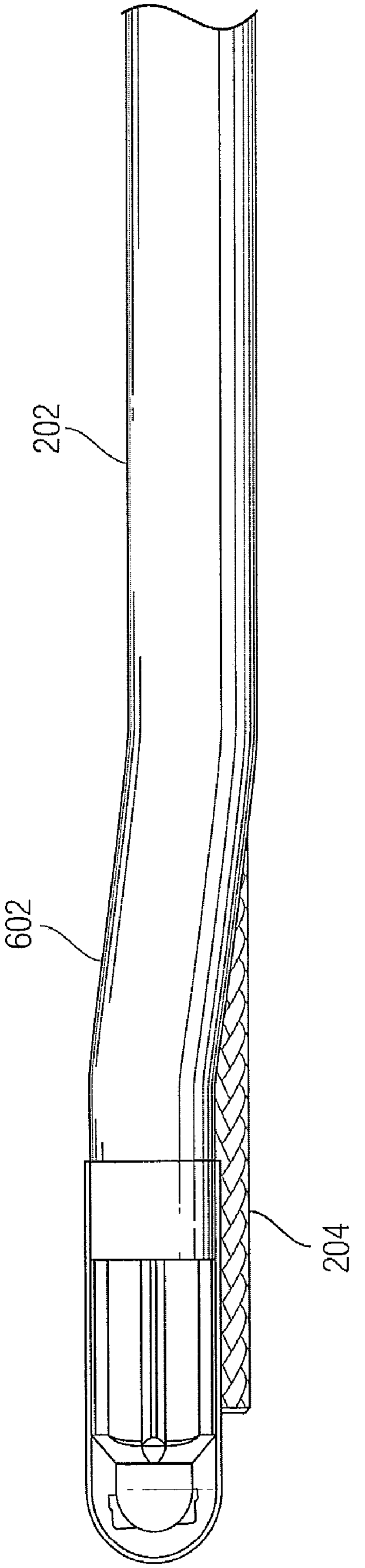


Fig. 6

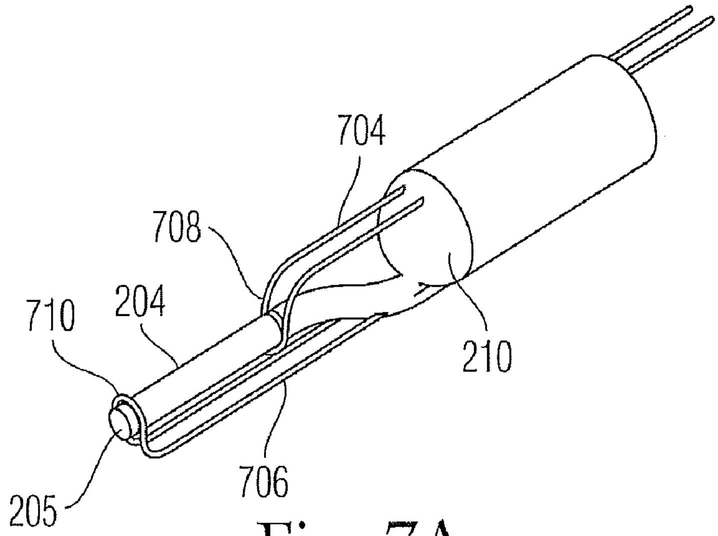


Fig. 7A

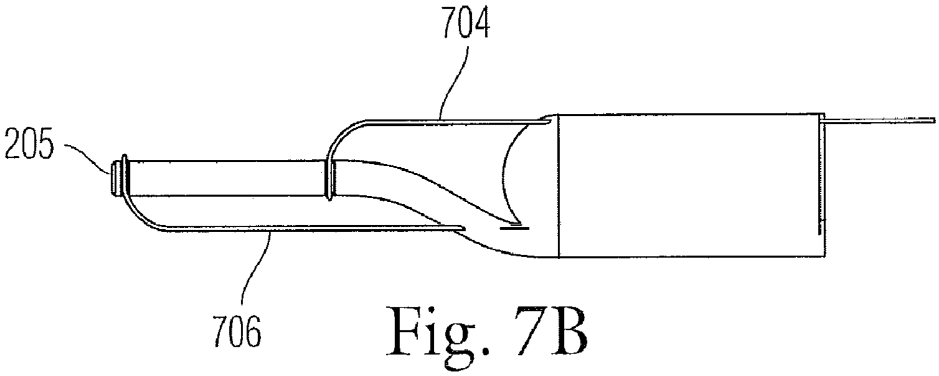


Fig. 7B

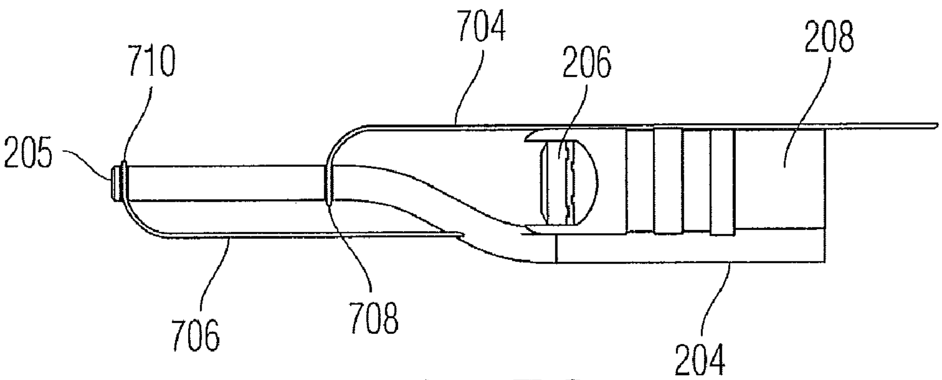


Fig. 7C

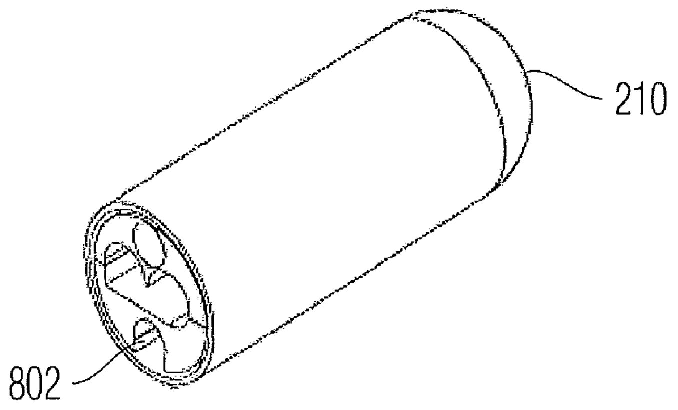


Fig. 8A

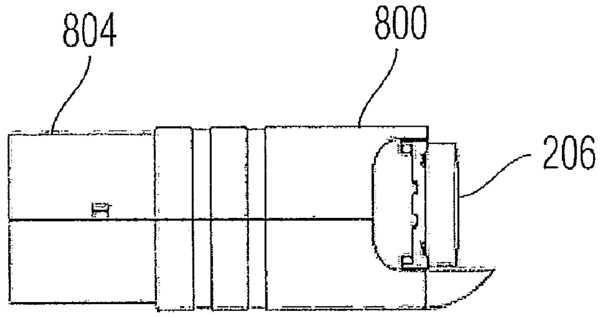


Fig. 8B

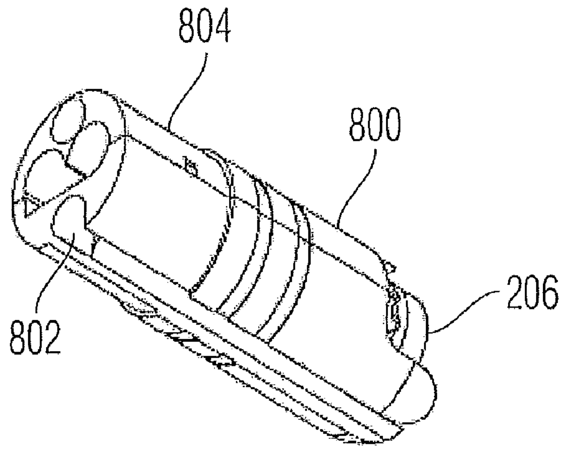


Fig. 8C

DELIVERY CATHETER WITH FORWARD-LOOKING ULTRASOUNG IMAGING

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the benefit of U.S. patent application Ser. No. 61/363,153, filed Jul. 9, 2010, which is hereby incorporated by reference in its entirety.

FIELD OF THE INVENTION

[0002] The invention relates to catheters providing forward-looking imaging and more specifically relates to catheters configured to provide forward-looking ultrasound imaging in combination with a portal adapted for forward-delivery of medical devices and/or other therapeutic agent(s)

BACKGROUND OF THE INVENTION

[0003] Percutaneous catheter based surgery is known for performing procedures on various tissues/organs within the body. Traditionally, during a procedure, clinicians rely on X-ray fluoroscopic images that comprise plane-view images showing the external shape of the silhouette of the lumen or cavity in the body/organ. Percutaneous catheter- and to provide intra-operative feedback. For example, in one particular procedure, the precise placement and desired expansion of stents can be improved as a result of simultaneous catheter-based imaging. Conventional intravascular imaging devices are large and not sufficiently flexible to be placed simultaneously with other devices.

[0004] In order to resolve these issues, an ultrasonic transducer device has been utilized for endovascular intervention to visualize the inside of the blood vessels. Certain current technology is based on one or more stationary ultrasound transducers or an arrangement for rotating a single transducer relative to the catheter. A problem with known devices of this type is that they are not well suited for use with other catheters, such as catheter-mounted interventional devices.

[0005] Additionally, many devices provide side-looking images which again is not well suited for providing guidance during invasive procedures. Forward-looking ultrasound imaging is essential in guiding an interventional device for treatment in a timely manner. For example, when implanting a heart pacemaker, electrical leads need to be implanted in precise locations. The present invention provides a solution that combines forward-looking imaging technology with the independent, concurrent delivery of an interventional catheter instrument.

BRIEF DESCRIPTION OF THE DRAWING FIGURES

[0006] FIG. **1**A is a partial cut-away perspective view of an ultrasonic transducer and actuator according to prior art;

[0007] FIG. **1**B is a partial cut-away side view of the ultrasonic transducer and actuator according to prior art;

[0008] FIG. **1**C is a perspective view of a forward-looking ultrasonic imaging device according to prior art;

[0009] FIG. **1**D is a partial cut-away perspective view of a forward-looking ultrasonic imaging device according to prior art;

[0010] FIG. **1**E is a partial cut-away side view of a forward-looking ultrasonic imaging device according to prior art;

[0011] FIG. **2** is a side view of a delivery catheter with forward-looking ultrasound imaging device according to an embodiment of the invention;

[0012] FIG. **3**A is a perspective view of a ultrasonic carriage device according to an embodiment of the invention;

[0013] FIG. **3**B is a top view of an ultrasonic carriage device according to an embodiment of the invention;

[0014] FIG. **4**A is a cross-section view of the delivery catheter of FIG. **2**;

[0015] FIG. **4**B is a variant cross-section view the delivery catheter of FIG. **2**;

[0016] FIG. **5**A is a top view of a delivery catheter with forward-looking ultrasound imaging device according to an embodiment of the invention;

[0017] FIG. **5**B is a side view of a delivery catheter with forward-looking ultrasound imaging device according to an embodiment of the invention;

[0018] FIG. **6** is a side view of a delivery catheter with forward-looking ultrasound imaging device according to an embodiment of the invention;

[0019] FIG. **7**A is a perspective view of an end of a delivery catheter with forward-looking ultrasound imaging device according to an embodiment of the invention;

[0020] FIG. **7**B is a side view of an end of a delivery catheter with forward-looking ultrasound imaging device according to an embodiment of the invention;

[0021] FIG. **7**C is a partial cut-away side view of an end of a delivery catheter with forward-looking ultrasound imaging device according to an embodiment of the invention;

[0022] FIG. **8**A is a perspective view of an end of a delivery catheter with forward-looking ultrasound imaging device according to an embodiment of the invention;

[0023] FIG. **8**B is a partial cut-away side view of an end of a delivery catheter with forward-looking ultrasound imaging device according to an embodiment of the invention; and

[0024] FIG. **8**C is a partial cut-away perspective view of an end of a delivery catheter with forward-looking ultrasound imaging device according to an embodiment of the invention.

DETAILED DESCRIPTION OF CERTAIN EMBODIMENTS OF THE INVENTION

[0025] Embodiments of the invention will now be described with reference to the accompanying drawing figures, wherein like numerals refer to like elements throughout. The terminology used in the description presented herein is not intended to be interpreted in any limited or restrictive manner simply because it is being utilized in conjunction with a detailed description of certain specific embodiments of the invention.

[0026] FIGS. **1**A and **1**B illustrate an embodiment of a forward-looking intravascular ultrasound device **100** capable of sweeping or scanning forward of the distal end of the device **100** to produce ultrasound images. As shown in FIG. **1**A, the device **100** includes an elongated body **101** having a distal end, a proximal end, and a longitudinal axis. The elongated body **101** is any size. In one embodiment, the elongated body **101** is small enough to fit inside a standard guide catheter with an inner diameter that is, is about, is not less than, is not less than about, is not more than, or is not more than about 12 Fr, 11 Fr, 10 Fr, 9 Fr, 8 Fr, 7 Fr, 6 Fr, 5 Fr, 4 Fr, 3 Fr, 2 Fr, 1 Fr, or falls within a range defined by, and including, any two of these values. Thus, the outside diameter of the elongated body **101** is preferably less than the inner diameter of the standard guide catheter in some embodiments.

[0027] The elongated body **101** has at least a portion **107** which is at least partially sonolucent (e.g., permits the passage of at least some ultrasound waves without absorbing or reflecting them back to their source). The portion **107** can be a window made of an ultrasound transparent material, a material which is partially or substantially transparent to ultrasound energy, or the portion **107** can be a window, opening, or aperture. In some embodiments, the entire elongated body **101** or the majority of the distal end of the elongated body **101** is formed of a substantially sonolucent material.

[0028] In some embodiments, portions of the elongate member **101** are solid and other portions, for example, the distal end, include housing portions capable of receiving other objects. Such housing portions can be tubular structures attached to the side of the distal end or attached to the distal end of the elongated body **101**. Other elongated bodies **101** are tubular and have one or more lumens capable of housing other objects in the distal end. The elongated body **101** shown in FIGS. **1**A and **1**B houses an ultrasound transducer element **105**, a local actuator **103**, a coupling member **111**, and an electrical wire **109**. In some embodiments, the electrical wire **109** is connected to the ultrasound transducer element **105** and wrapped at least partially around the coupling member **111**. In some embodiments, the transducer element **105** comprises, or is secured directly or indirectly to the coupling member **111**.

[0029] The local actuator **103** is configured to engage (e.g., contact, push, or pull) the ultrasound transducer element **105** and cause the ultrasound transducer element **105** to rotate in a first direction and/or a second direction counter to the first direction about an axis of rotation. In some embodiments, the axis of rotation is generally normal to the longitudinal axis. In some embodiments, the ultrasound transducer element **105** is directly connected or coupled with the elongated body **101** and configured to rotate relative to the elongated body **101** about an axis of rotation. In some embodiments, the axis of rotation is substantially parallel to the coupling member **111**. In other embodiments, the ultrasound transducer element **105** is coupled with a member **111** that extends from an interior surface of the elongated member **101** such that the ultrasound transducer element **105** rotates about the member **111**.

[0030] Further details of the forward-looking intravascular ultrasound device **100** are described in detail in PCT/US2009/044218, the contents of which are incorporated herein in its entirety as if set forth herein.

[0031] Turning now to FIG. **2**, this figure illustrates a medical device and or other therapeutic delivery and imaging tool **200** in accordance with an embodiment of the present invention. The tool **200** includes an elongate delivery catheter **202**, an elongate medical device conduit **204**, an ultrasonic transducer **206**, a carriage **208** that supports the ultrasonic transducer **206**, and a sonolucent acoustic window **210**. The elongate delivery catheter and the elongate medical device conduit are connected to one another at least at the distal end (as shown in FIG. **2**) and can be advanced as a unit into a person for forward-looking imaging while performing an intervention or diagnostic procedure using a device delivered through the elongate device conduit **204**. The delivery catheter **202** and the medical device conduit **204** each have a distal end, a proximal end, and a sidewall defining an interior lumen. The transducer **206** is similar to the transducer **105** and can be actuated via an actuator **103** as shown in FIGS. **1**A and **1**B. The tool **200** allows for the delivery of a medical device and/or therapeutic, such as a guide wire, needle, or other intravascular medical instrument/fluid/energy, through the medical device conduit **204** and the ultrasonic transducer **206** provides forward-looking imaging of target tissue to determine the position of the medical device relative to the target tissue. Each of the components of the tool **200** are described in more detail herein.

[0032] FIGS. **3**A and **3**B illustrate an embodiment of a carriage **208** for the ultrasonic transducer **105**, **206** (omitted from FIGS. **3**A and **3**B for clarity). The carriage **208** includes pivot holes **212** that accept a coupling member or pin. Alternatively, the carriage walls can include pin-like protrusions or posts that are coupled with the transducer. This structural arrangement allows the transducer **206** to rotate so the transducer can move along a sweep path (e.g., 120 degrees) to facilitate ultrasonic imaging.

[0033] The carriage **208** includes a shoulder **214** that permits the carriage **208** to be mounted on the distal end of the delivery catheter **202**. The delivery catheter **202** is placed over the shoulder **214** of the carriage **208** such that the carriage **208** is seated in the distal end portion of the deliver catheter **202**. FIG. **2** illustrates the carriage **208** mounted on the distal end of delivery catheter **202**. There are other means of coupling the carriage **208** to the distal end of the delivery catheter **202** and the use of shoulder **214** is just one example.

[0034] As shown in FIG. **2**, the acoustic window **210** is placed over the carriage **208** and extends over the portion of the delivery catheter **202** that is seated on the shoulder **214** of the carriage **208**. The acoustic window **210** is mounted in spaced relation to the ultrasonic transducer **206** so that the transducer **206** is capable of performing its sweeping motion free of interference by acoustic window **210**. This mounting arrangement of the acoustic window **210** results in a cavity **216** between the transducer **206** and the window **210**. In one embodiment, this cavity **216** is filled with saline or other fluid in order to facilitate transmission of the acoustic waves emitted from the transducer **206** through the saline in the cavity **216** and through the acoustic window **210**. It is desirable to maintain a fluid environment around the transducer **206** so that the effects of any boundary conditions are minimized. The ultrasonic energy, therefore, passes through the saline, then through the sonolucent acoustic window, into a blood cavity, to tissue, and back free of any air space, in a preferred implementation.

[0035] FIG. **4**A illustrates an interior portion of the delivery catheter **202** in which several lumens are located. An acoustic transducer lumen **400** provides a conduit for the electrical wire that is used to actuate a shape memory alloy (SMA) that causes the transducer **206** to move in its sweep path, according to one embodiment of the invention. The acoustic transducer lumen **400** also provides a conduit for the electrical data wire that transmits the signals produced by the transducer **206** to the proximal end of the delivery catheter **202**. The acoustic transducer lumen is optional and the electrical and data wires can be disposed in the interior lumen **406** of the catheter **202**, as shown in FIG. **4**B.

[0036] A steering wire lumen **402** provides a conduit for a steering wire that can be a pull wire or a push/pull wire that provides steering control for the distal end **201** of the tool **200**. The steering wire is anchored to either the carriage **208** or otherwise in a distal portion of the catheter **202**. Pushing or pulling the steering wire causes movement of the distal end **201** of the tool **200**. This allows the user to simultaneously manipulate the acoustic transducer **206** and the medical device conduit **204** because the medical device conduit is mounted in parallel to the axis of the carriage **208**. The steering wire permits the user to aim the acoustic transducer **206** and, therefore, a distal opening **205** opening of the medical device conduit **204** towards target tissue so that the user can visualize the target tissue and direct the opening **205** towards the visualized, target tissue for delivery of a medical device and/or other therapeutic agent to the target tissue. A steering mechanism (e.g. a handle) can impart both of the pulling and pushing forces (e.g., via a thumbwheel or slide connected to the proximal end of the steering wire(s)). Manipulating a steering wire to deflect the catheter **202** provides for macro-adjustment of the catheter **202**, the transducer **206**, and the opening **205** together. It is also possible to micro-adjust the conduit **204** and opening **205** via a separate conduit steering mechanism, as discussed below in connection with FIG. **7**, for example.

[0037] Optionally, a flush lumen **404** is located within the delivery catheter **202**. The flush lumen **404**, when provided, provides a conduit for the delivery of saline or other suitable fluid to the cavity **216** between the acoustic transducer **206** and the acoustic window **210**. A user injects saline into the flush lumen **404** at the proximal end of the flush lumen. The interior space **406** of the deliver catheter **202** that is not occupied by other lumens provides a return for the saline flush. Optionally, a separate lumen can be provided as a return for the flush. As the user continues to inject saline into the flush lumen **404**, cavity **216** fills with saline and injection of saline is continued until saline fills the interior space **406** of the delivery conduit **204** such that saline exits the proximal end of the delivery catheter **202**. This provides a fluid environment around the transducer **206** so as to minimize the effect of any boundary conditions, as noted above. Alternatively, a valve, such as a one-way valve or a two-way valve (similar to a valve of a Groshong catheter, for example), can be provided in the fluid flush path that maintains the fluid in the tip and surrounding the transducer **206**, which avoids the need to inject saline until it exits out the proximal end of the delivery catheter **202** because the fluid is maintained locally in the tip region. This can provide more space efficiency in the delivery catheter **202**. A port for injection of the fluid flush can optionally be provided in the side of the carriage or the distal end of the delivery catheter **202**. This arrangement eliminates the need for a flush lumen to run from the distal end to the proximal end of the delivery catheter **202**. The cavity **216** can also be pre-vacuumed and then saline is introduced into the cavity **216**. Introducing the saline into a vacuumed cavity eliminates air bubbles and aids in the filling of the cavity with saline without the need for a return flush.

[0038] The medical device conduit **204** is disposed within the delivery catheter along a portion of the deliver catheter **202** that is proximate the carriage **208**. The medical device conduit **204** provides a conduit for delivery of a medical device, for example, a guide wire, with at least one lumen that is fluidly separated from any saline or other fluid in the lumen of the delivery catheter **202**. As can be seen in FIG. **2**, the medical device conduit **204** transitions from the interior of the delivery catheter **202** to the exterior just proximal to the carriage **208**.

[0039] FIGS. **5**A and **5**B provide a detailed view of the transition of the medical device conduit **204** from the interior to the exterior of the deliver catheter **202**. In one embodiment, the delivery catheter **202** is made from PEBAX and includes an embedded braid **502**. The delivery catheter **202** can be formed of other medically compliant, flexible materials used to make catheters and can include a coil rather than a braid. In an embodiment, the medical device conduit **204** is also PEBAX and includes an embedded coil **504**. The medical device conduit **204** can be formed of other medically compliant, flexible materials used to make catheters and can include a braid rather than a coil. The medical device conduit **204** transitions from the interior to the exterior of the delivery catheter **202** in three transition zones **506**, **508**, and **510**. In the first transition zone **506**, the braid **502** of the delivery catheter **202** is generally intact and the medical device conduit **204** is disposed under the braid. In the second transition zone **508**, the medical device conduit **204** passes between and through the braids **502** of the delivery catheter **202** without the need to sever the braids. However, depending on the braid angle and weave pattern, the braids can be severed to assist the medical device conduit **204** to pass through the braids **502**. In the third transition zone **510**, the medical device conduit **204** is located on the exterior side of the braid **502** of the delivery catheter **202**. Through these three zones, the medical device conduit **204** transitions from an interior to an exterior of the delivery catheter **202** at a gradual angle so there are no tight bends in the medical device conduit. The delivery catheter **202** and the medical device conduit **204** can be heated together until the PEBAX of the delivery catheter **202** and the PEBAX of the medical device conduit **204** fuse together. The fusing of the two catheter and the conduit results in a fluid tight seal between the two catheters. This is accomplished without the need to use adhesive or other sealants. Adhesives or sealants can be used in addition to or as an alternative to the fusing of the catheter and conduit to provide a fluid tight seal. Providing the fluid tight seal maintains any saline within the interior of the delivery catheter **202** and prevents the saline from escaping into the patient. An optional jacket **512** is placed around the medical device conduit **204**, the carriage **208**, and a distal end portion of the delivery catheter **202**. The jacket **512**, which can be a polyethylene or other suitable material shrink wrap, secures the medical device conduit **204** adjacent the carriage **208** and runs parallel to the carriage **208** and the delivery catheter **202**.

[0040] Transitioning the medical device conduit **204** through the sidewall of the delivery catheter **202** provides the advantage that transition is very gradual, which eliminates sharp bends in the medical device conduit **204** that can impede the delivery of a medical device through the conduit **204**. The prior art device shown in FIGS. **1**C-**1**E, by contrast, shows a medical device **900** that is transitioned through the ultrasonic transducer carriage. This arrangement has several significant drawbacks. As can be seen in FIG. **1**C, the transition through the carriage is relatively sharp, and so deployment of an instrument through this sharp bend can be difficult and reduce any tactile response that the clinician otherwise may have as a result of contacting tissue after advancing an instrument through the carriage. The transition cannot be made more gradual without extending the length of the carriage because a more gradual transition requires a gently angled hole. As can be seen in FIG. **1**C, a more gently angled hole in the carriage would require a longer carriage in order to prevent the hole from interfering with the ultrasonic transducer. However, providing a longer carriage decreases the flexibility of the device because, unlike the flexible catheter materials in the arrangement of the present invention, the carriage itself is rigid. Thus, a longer carriage increases the difficulty to deploy the device through tortuous passages for percutaneous operations. In addition, passing a medical device through the carriage may interfere, abrade, or otherwise conflict with the and other elements that drive the ultrasonic transducer.

[0041] As shown in FIG. **2**, the medical device conduit **204** has a slight bend **207** as it transitions from the interior to the exterior of the delivery catheter **202**. In an alternative embodiment, as shown in FIG. **6**, the medical device conduit **204** remains straight as it transitions from the interior to the exterior of the delivery catheter **202**, and it is the delivery catheter **202** that has a bend **602**. This arrangement provides advantages by providing a medical device conduit **204** that is straight and avoids any impediments to deploying medical devices through a torturous path. It also maximizes the ability to push a medical device through the medical device conduit **204** without kinking. Meanwhile, by having the active mechanism for pivoting the transducer **206** co-located within the carriage **208** with the transducer, the delivery catheter **202** can accommodate the bend **602** without imparting a torque that otherwise could result from a remote coupling to a motive force at the catheter proximal end.

[0042] In the embodiment illustrated in FIGS. **7**A, **7**B, and **7**C, the medical device conduit **204** includes a distal extension portion that extends distally beyond the acoustic window **210**. This arrangement is advantageous because it defines a space between any tissue abutting the distal extension and the ultrasonic transducer **206** which provides for optimal imaging of the target tissue while concurrently supporting a medical device, via the extension portion of the medical device conduit **204**, beyond the transducer **206** itself. Maintaining the transducer **206** at a distance, for example, 10 to 25 mm, from the target tissue provides a larger imaging field of view. When the transducer is directly adjacent to the target tissue, the field of view is narrow and limited to a very small area. A narrow field of view is not desirable because it is difficult to perceive the location of the transducer and medical device conduit because the narrow field of view precludes visualization of anatomical landmarks in the patient. Providing the extension portion, however, provides a mechanism to ensure spacing of the transducer **206** from the target tissue while also allowing the opening **205** to be placed directly adjacent the target tissue.

[0043] Support struts **704** and **706** support the extension portion of the conduit **204** and maintain the device conduit **204** in a desired position relative to the transducer **206**. The support struts **704** and **706** maintain the extension portion of the conduit **204** concentrically located with the carriage **208** and in the field of view of the transducer **206**. As the transducer **206** sweeps back and forth during its operation, the position of the extension and the surrounding tissue is visualized. Accordingly, the position of the opening **205** through which a medical device is delivered (e.g., a guide wire) can be visualized so that a user can ensure accurate deployment of the medical device. The struts **704** and **706** are preferably a thin, flexible material, such as nitinol or laser cut from a hypotube, for example, so that they provide support to the extension portion of the conduit **204** while also being flexible enough to be deployed through a guide sheath into the heart without risk of tissue perforation. The struts **704** and **706** are formed with collar portions **708** and **710** that seat the extension portion of conduit **204**. Alternatively, the struts can be looped around the extension portion such that the conduit **204** is seated in the loops formed by the struts. The collars portions **708** and **710** can also be at least partially fused into the material of the sidewall (e.g., PEBAX) of the medical device conduit **204**. As can be seen in FIG. **3**, the carriage **208** can be formed with grooves **218** to seat the struts **704** and **706** to assist in anchoring the struts. FIG. **7** illustrate just one example of a strut arrangement, and other structural arrangements of struts can be used to support the conduit extension. For example, the struts can be coupled to single collar, the struts can each be a single wire construction, and a plurality of struts can be used and arranged in different positions depending on the anatomical structures and desired performance characteristics required for a particular medical procedure. In a variation, the proximal ends of the struts **704** and **706** extend proximally into the interior of the delivery catheter **202** and to the proximal end of the catheter (not shown). Imparting compression and/or tension force on the proximal ends of the struts causes a deflection at their distal ends. The deflection at the distal ends of the struts can be used for micro-adjustment of the extension portion of the medical device conduit **204**. Adjusting the extension portion of the medical device conduit **204** allows the user to direct the opening **205** of the conduit **204** without adjusting the position of the delivery catheter **202**. Accordingly, an instrument can be advanced independently of the positioning of the delivery catheter within an isolated lumen of the medical device conduit **204**, and thereafter the exit angle of the medical deliver catheter can be micro-adjusted. This can be done without adjusting the field of view of the transducer, if desired. Accordingly, manipulating a steering wire anchored to the carriage **208**, for example, provides for macro-adjustment of the distal end of the catheter **202**, the transducer **206**, and the medical device conduit **204** while manipulation of the struts provides for micro-adjustment of the conduit **204** without repositioning or dislodging the catheter **202**. In one arrangement, imparting a compressive force on strut **706** causes the opening **205** to bend in a direction toward strut **704**, and imparting a tensile force on strut **706** causes the opening **205** to bend in a direction away from strut **704**. Applying force to one of the two wires of a strut while keeping the other wire fixed or applying an opposite force to the other wire can be used to cause deflection in a direction that is in or out of the image plane of FIG. **7**B. A steering mechanism can impart both of these tensile and compressive forces at the same time (e.g., via a thumbwheel or slide connected to the proximal end of the struts).

[0044] In one example of use, a guide wire is passed through the mitral annulus of the heart using the tool **200**. The distal opening **205** of the medical device conduit **204** is positioned adjacent a ventricular side of the mitral annulus. The position of the distal opening is confirmed via the transducer **206** to ensure proper placement of the guide wire. Optionally, the distal opening **205** is positioned distal to the transducer **206** and spaced therefrom by the length of the struts so as to better ensure an optimal field of view for a mitral annulus procedure, namely, a spacing of about 10 mm from the tissue to provide ultrasound images that include the region between the transducer and the distal opening, as well as a view into the tissue itself to a depth of about 15 mm. The guide wire is inserted into the proximal end of the medical device conduit **204**. The wire is advanced toward the distal end of the delivery catheter **202** as the device conduit **204** transitions from an interior to an exterior of the delivery catheter **202**. The guide wire is further advanced into the extension portion of the device conduit **204**, when such an extension is provided. As the user advances the guide wire through the mitral annulus to the atrial side, the struts **704** and **706** of the extension portion maintain the position of the conduit **204** and the transducer **206** provides visualization of the positioning of the guide wire deployment. The struts **704** and **706** and the extension portion of the conduit **204** also provide support to the guide wire (or other medical device) as it manipulated and advanced. The extension portion of the conduit **204** further provides a structural guide as it is abutted against the target tissue that automatically maintains the imaging transducer an optimal distance from the target tissue for viewing.

[0045] In the embodiments shown in FIGS. **2**, **5**, **6**, and **7**, the medical device conduit **204** transitions from an interior to an exterior of the delivery catheter **202** and is disposed alongside the carriage **208**. In these embodiments, the device conduit **204** exits the delivery catheter **202** in order to go around and extend past the carriage **208**. In one embodiment as shown in FIG. **8**, a carriage **800** is provided with a trough **802** that seats the device conduit **204**. The trough **802** and the conduit **204** can be sized so that when the conduit is seated in the trough a fluid seal is formed. The device conduit **204** is seated in the trough **802** and then the delivery catheter is seated over the shoulder **804** of the carriage **800** and over the medical device conduit **204** with the device conduit disposed on the interior of the delivery catheter **202**. The medical device conduit **204** extends within the delivery catheter to a proximal end of the delivery catheter and, as such, can isolate any device within the delivery catheter from wires, fluids, and elements within the delivery catheter. The trough **802** allows the medical device conduit **204** to remain inside the interior of the delivery catheter **202** and eliminates the transition of the medical device conduit from the interior to the exterior of the delivery catheter **202** through the sidewall of the delivery catheter **202**. Therefore, there is no need to penetrate the sidewall of the catheter **202**. This arrangement provides several advantages over the prior art arrangements because it eliminates the need for a bend in the medical device conduit.

[0046] The acoustic window **210** includes a hole (not shown) that is substantially aligned with the trough **802**. The hole is sized to allow the medical device conduit **204** to seat in the hole. The sizing of the hole and the conduit can be such that seating of the medical device conduit **204** in the hole provides a fluid-tight seal. The seal prevents saline in the cavity **216** from escaping through the hole in the window. Adhesive can be applied to provide a fluid seal between the conduit **204** and the hole, in a variation of the foregoing. Additionally or alternatively, the materials of the conduit **204** and the window can be fused to provide sealing.

[0047] The medical device conduit **204** can terminate substantially flush with the acoustic window **210** or extend distally past the window **210**. This structural arrangement permits a medical device (e.g., guide wire, needle, etc.) to be deployed past the distal end of the acoustic window **210** and in the field of view of the transducer **206** for visualization of the medical device and the target tissue. In a further arrangement, the medical device conduit **204** has an extension to space its distal opening **205** ahead of the transducer window by a prescribed amount. The extension can include struts for support, as previously described. Preferably, the medical device conduit exits the carriage at a location that minimally interferes with the field of view provided by movement of the transducer **206**.

[0048] The invention and embodiments described herein can be used for a number of different surgical procedures and applications. For example, the device can provide direct visualization the transducer and delivery of needles and guide wire delivery systems through the conduit **204**. The device can be used for, among other procedures, mitral annulus penetration; transseptal procedures; arterial puncture; fine needle aspiration of the lungs; fine needle aspiration in gastrointestinal procedures; fine needle aspiration of the uterus, ovaries, etc. in genitourinary procedures. Other applications that can benefit from the use of the device include structural heart repair; valve repair; valve replacement; perivalvular leak closure; patent foramen ovale (PFO) closure; atrial septal defect (ASD) closure; ventricular septal defect (VSD) closure; transseptal needle delivery; left atrial appendage closure; electrode delivery; coil delivery; stem cell delivery; biologics delivery; tissue injection; vascular access & closure (e.g. femoral artery for cardiovascular procedure); vascular access catheter placement to optimize position for flow and to minimize turbulence/thrombus formation (e.g. dialysis catheter or PICC line); stent delivery; urinary tract therapy (e.g. kidney stones, incontinence implants); artificial insemination; vascular blockage (e.g. stroke); brain therapy (e.g. tumor); pain management; cerebrospinal access and closure; lymph system therapy (navigation of lymph ducts); gastrointestinal therapy; hepatic therapy; pancreatic therapy; natural orifice translumenal endoscopic surgery (NOTES) (e.g. access, closure, diagnostics, and therapy delivery, etc.); aortic and thoracic aneurism therapy (e.g. tissue assessment for stent anchor placement, peri-stent leakage, etc); renal artery access; tissue biopsy; musculoskeletal procedures (e.g. joint therapy); and ENT (Ear nose and throat) therapy, energy based therapy (e.g. cryogenic, infrared, radio frequency), for example. These are just a few of the procedures and applications in which the device may be used and are non-limiting examples.

[0049] While the invention has been described in connection with certain embodiments thereof, the invention is not limited to the described embodiments but rather is more broadly defined by the features recited in the claims below and equivalents of such features.

1. A catheter based medical device for a percutaneous surgical procedure that provides forward-looking visualization and delivery of a medical device, comprising:

a catheter having a distal end, a proximal end, and a sidewall defining an interior lumen;

a carriage supported by the distal end of the catheter;

an ultrasonic transducer supported by the carriage such that the transducer is free to move in a sweep path in order to provide visualization distally of the transducer;

a conduit having a proximal end, a distal end, and a sidewall defining a second interior lumen, the proximal end of the conduit being disposed within the interior lumen of the catheter and extending from proximal end of the catheter, wherein the conduit passes through the sidewall of the catheter proximate to the distal end of the catheter so that the distal end of the conduit is disposed on an exterior of the sidewall of the catheter; and

wherein a medical device is deliverable through the second interior lumen of the conduit and wherein the ultrasonic transducers provides visualization of the medical device distally of the transducer.

2. A catheter based medical device according to claim **1**, wherein the sidewall of the conduit is in fluid sealing engagement with the sidewall of the catheter at a location at which the conduit passes through the sidewall of the catheter.

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专利名称(译)	具有前视超声成像的输送导管		
公开(公告)号	US20120089022A1	公开(公告)日	2012-04-12
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[标]申请(专利权)人(译)	HOUSE MORGAN 史蒂芬叫		
申请(专利权)人(译)	HOUSE，MORGAN CAHALANE，史蒂芬		
当前申请(专利权)人(译)	MITRALIGN INC.		
[标]发明人	HOUSE MORGAN CAHALANE STEVEN		
发明人	HOUSE, MORGAN CAHALANE, STEVEN		
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摘要(译)

提供了一种基于导管的医疗装置，用于经皮外科手术，其提供医疗装置的前瞻性可视化和递送。导管在其远端包括托架，超声波换能器由托架支撑。一种导管，其近端设置在导管内，导管穿过导管的侧壁，靠近导管的远端，使得导管的远端设置在导管侧壁的外部。医疗装置可通过导管的内腔输送，并且超声换能器提供换能器远侧的医疗装置的可视化。