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(54) **ULTRASOUND IMAGING GUIDEWIRE
WITH STATIC CENTRAL CORE AND TIP**

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U.S.C. 154(b) by 0 days.

This patent is subject to a terminal dis-
claimer.

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Apr. 27, 2001, now Pat. No. 6,585,654, which is a
continuation of application No. 09/625,168, filed on
Jul. 25, 2000, now Pat. No. 6,248,076, which is a
continuation of application No. 09/393,507, filed on
Sep. 10, 1999, now Pat. No. 6,171,250, which is a
continuation of application No. 08/939,867, filed on
Sep. 29, 1997, now Pat. No. 5,951,480.

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(52) **U.S. Cl.** **600/463**

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600/585

See application file for complete search history.

(Continued)

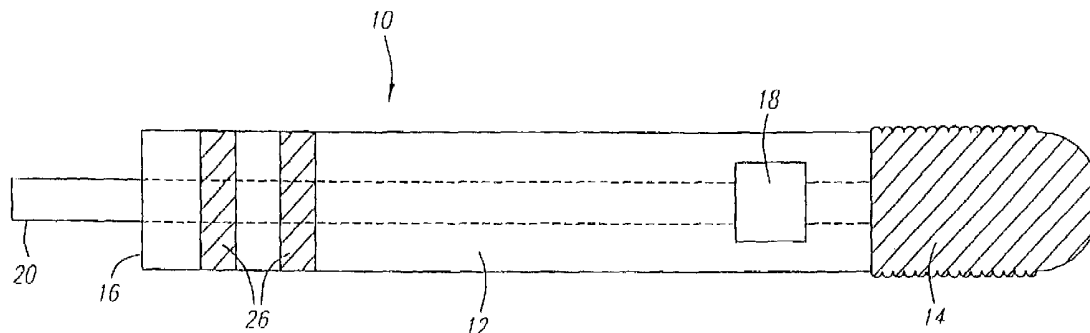
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(57) **ABSTRACT**

An ultrasound imaging guidewire, that is inserted into a patient's body. The guidewire has a static central core and an imaging guidewire body comprising an acoustical scanning device. The acoustical scanning device can be rotated to obtain 360 degree acoustical images of a site of interest in the patients body. Furthermore, the imaging guidewire includes a connector that permits the imaging guidewire body to be disengaged from the static central core tip so that the imaging guidewire body can be axially translated to obtain multi-position imaging. The imaging guidewire body is axially translated without losing the original guidewire positioning because the static central core maintains its position in the patient's body.

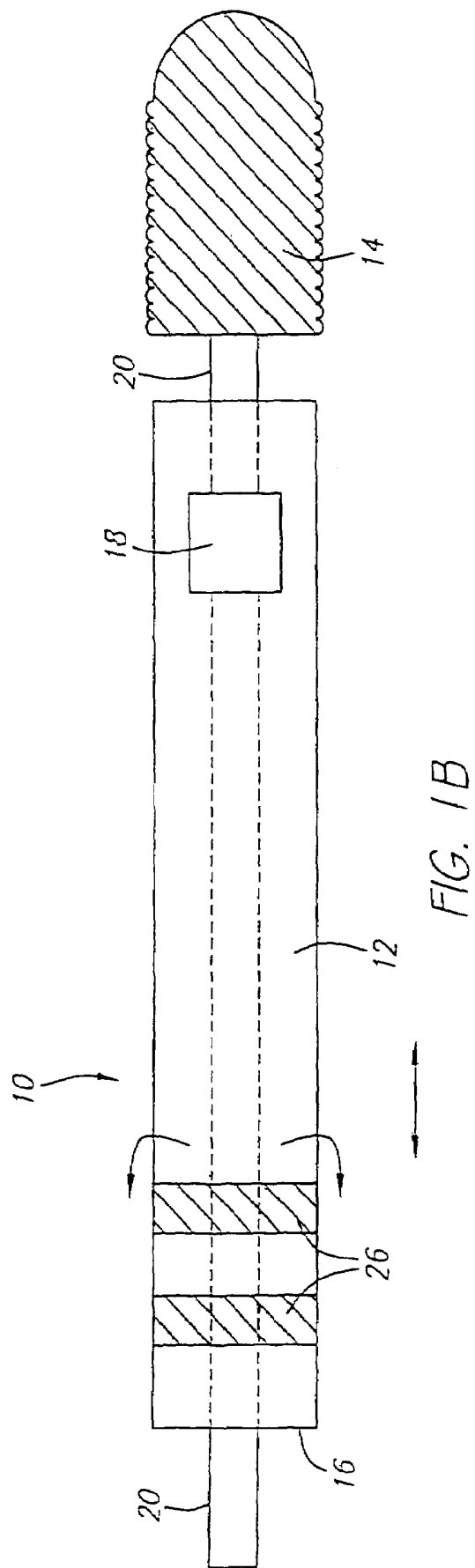
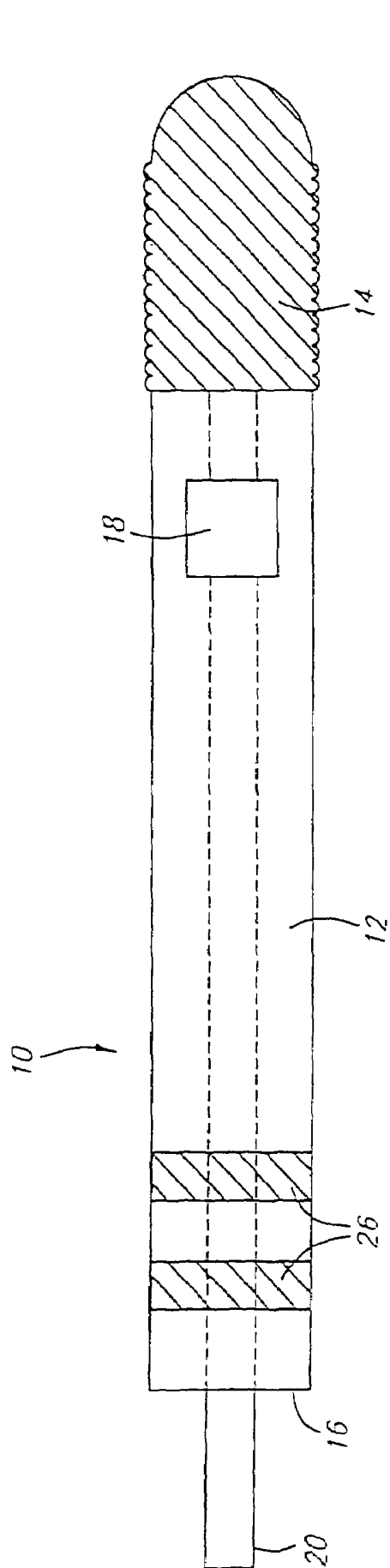
11 Claims, 5 Drawing Sheets



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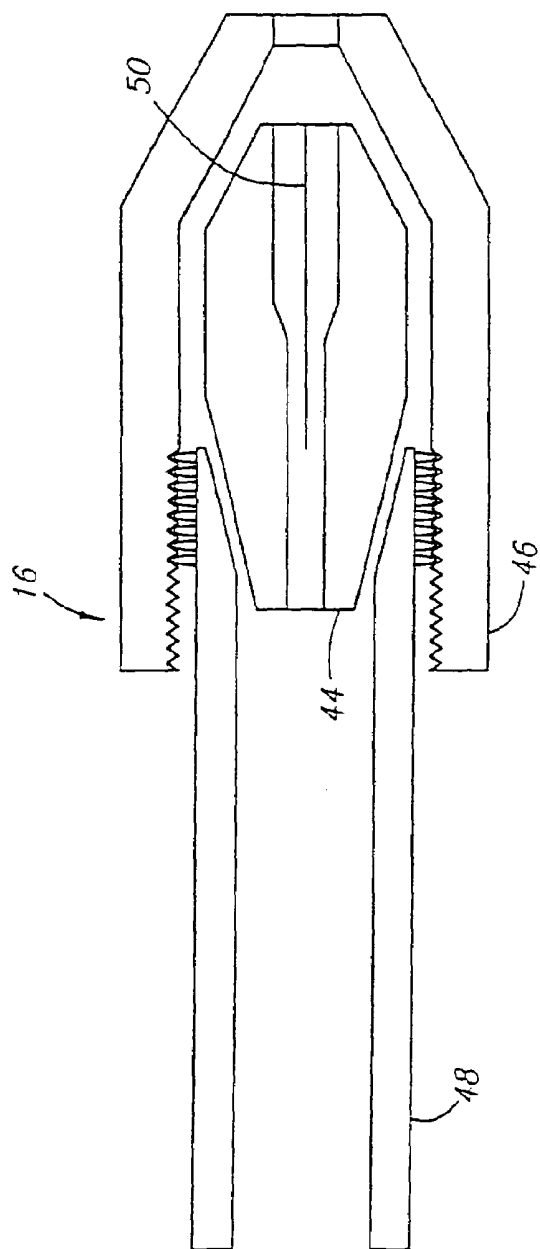


FIG. 2A

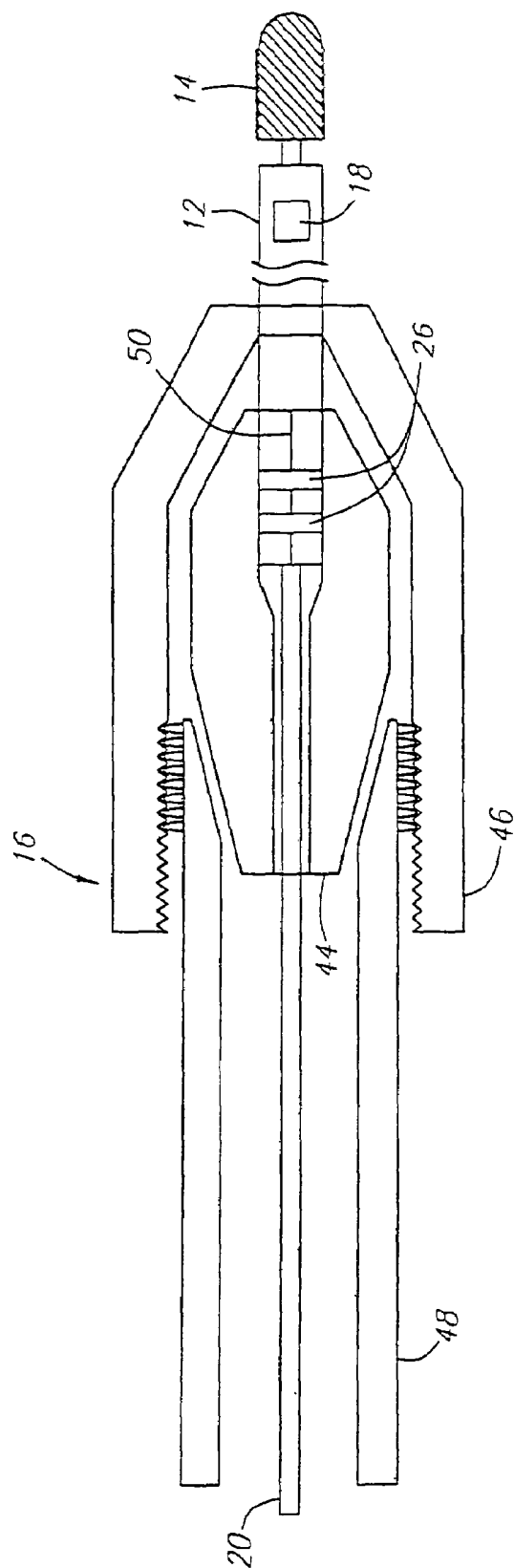


FIG. 2B

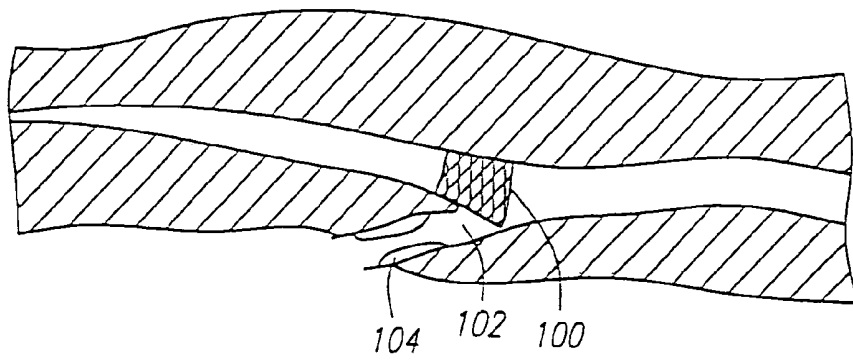


FIG. 3

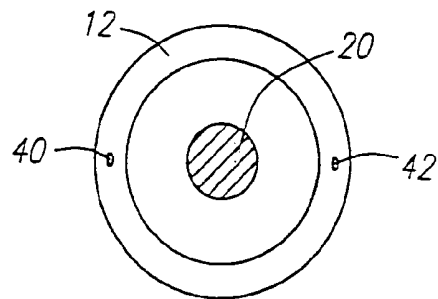


FIG. 4A

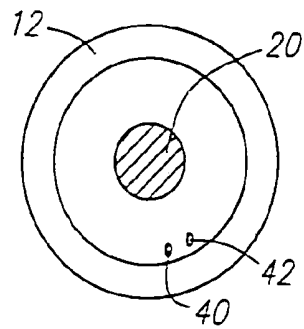


FIG. 4B

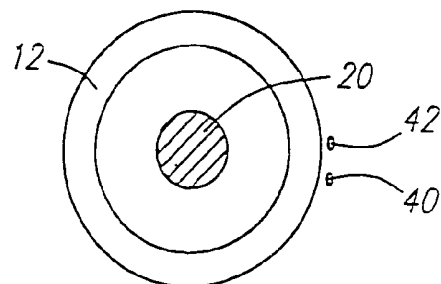


FIG. 4C

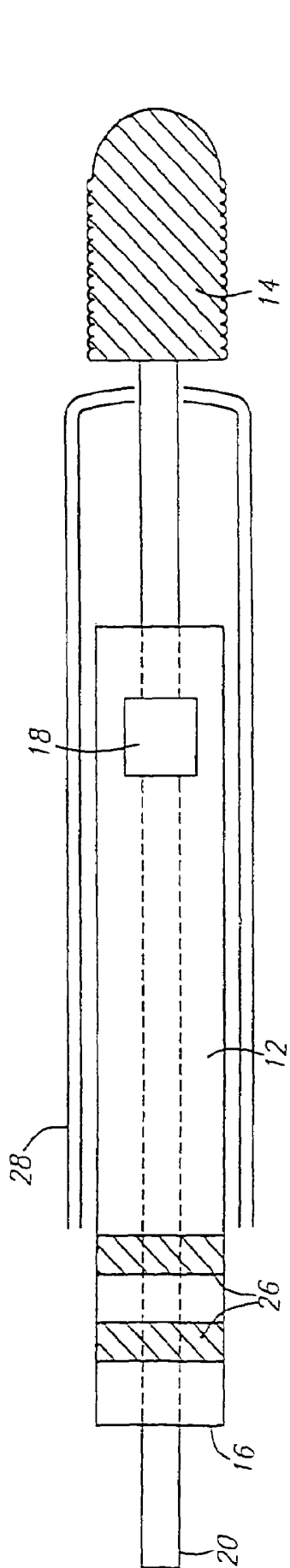


FIG. 5

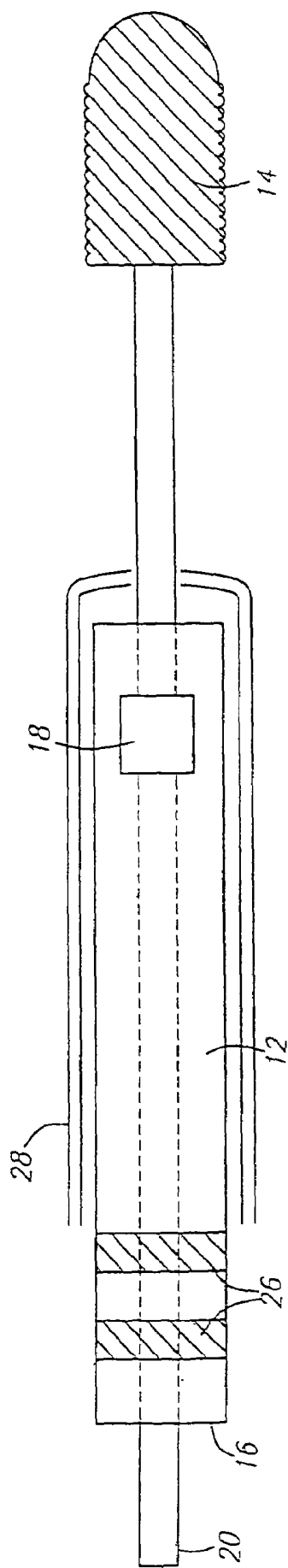


FIG. 6

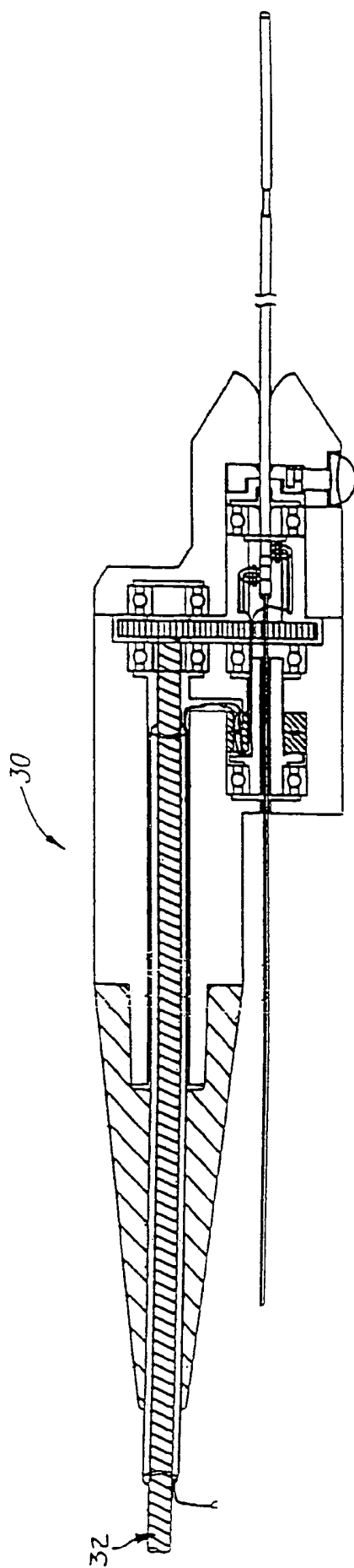


FIG. 7

ULTRASOUND IMAGING GUIDEWIRE WITH STATIC CENTRAL CORE AND TIP

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 10/405,586, now U.S. Pat. No. 6,770,035, filed on Apr. 1, 2003, which is a continuation of Ser. No. 09/844,644, now U.S. Pat. No. 6,585,654, filed on Apr. 27, 2001, which is a continuation of Ser. No. 09/625,168 now U.S. Pat. No. 6,248,076, filed on Jul. 25, 2000, which is a continuation of Ser. No. 09/393,507, now U.S. Pat. No. 6,171,250, filed on Sep. 10, 1999, which is a continuation of Ser. No. 08/939,867, now U.S. Pat. No. 5,951,480, filed on Sep. 29, 1997.

FIELD OF THE INVENTION

This invention relates to medical guidewires typically used by physicians to gain access to restricted regions of the body and over which therapeutic devices are passed for insertion to a site of interest. Specifically, the invention relates to an ultrasound imaging guidewire with a detachable imaging guidewire body and a stationary central core.

BACKGROUND OF THE INVENTION

Many surgeries involve the insertion of guidewires into a patient's body. The guidewire may be inserted into the digestive tract, urethra, blood vessels, heart chamber, a body cavity such as the abdominal cavity, or a hollow organ. Typically, an artery is the vessel of interest. The artery could be a relatively large peripheral vessel, a relatively small proximal coronary artery, or an artery of any size in between. The guidewire may include an imaging portion that permits close examination of the site of interest by means of ultrasonic waves. An ultrasonic imaging guidewire may permit the user to obtain 360 degree (i.e., cross-sectional) acoustic images of the vessel wall to, for example, determine the tissue morphology state of a site of interest, position a therapeutic device, monitor the progress of treatment or observe the site after treatment to determine the course of further treatment.

Often, the guidewire must be positioned at a predetermined site after passing through a complex network of blood vessels. Such placement may require a considerable amount of time. Furthermore, the difficulty and time required for guidewire placement increases with increasing vessel occlusion at later stages of disease. Thus, placement of the guidewire can be a time-consuming and difficult task.

Accordingly, once the physician has taken the time to correctly place the guidewire, it is preferable to maintain the guidewire position. However, it is also desirable to obtain images of the diseased area which may require that the guidewire be axially translated to view the site of interest. Hence, after the physician places the guidewire, the physician needs to move the imaging guidewire back and forth to make a correct diagnosis of the lesion morphology. The problem with advancements and pullbacks of the imaging guidewire is that the physician may lose the correct placement of the guidewire, and have to spend additional time repositioning the guidewire. Thus, there currently exists a need to maintain guidewire positioning while permitting multi-position, real-time imaging.

Furthermore, the back-and-forth movement of the guidewire may damage the patient's vessels. Therefore, there currently exists a need to provide safer guidewire imaging.

A significant problem encountered by physicians is the proper positioning of stents. Stents are often used to prevent lumen closure following bypass surgery and to treat acute vessel closure after angioplasty. It is often extremely difficult for a physician to accurately determine the correct location to deploy a stent, particularly at a bifurcating vessel. Incorrect placement of a stent can lead to "stent jail" and is demonstrated in FIG. 3. As shown in FIG. 3, if the stent **100** is incorrectly placed at a bifurcating vessel location **102**, the stent **100** may block the vessel **102** and the physician can no longer access that vessel **102**. This is particularly dangerous if the vessel **102** becomes diseased, such as at **104**, and access is needed for therapy. Thus, there currently exists a need for easier, multi-position, ultrasonic imaging of the site of interest to assist in accurate placement of a stent.

There also currently exists a need to provide improved imaging capabilities, without losing proper guidewire positioning, so as to efficiently locate the site of interest, to properly position therapeutic catheters such as an angioplasty balloon, and to observe continuously the site or sites of interest. There also exists a need to decrease the complexity and to save time associated with the ultrasonic imaging procedure.

SUMMARY OF THE INVENTION

Accordingly, a general object of the present invention is to provide an apparatus and method for permitting multi-position, ultrasonic imaging without losing correct guidewire positioning.

A further object of this invention is to provide a faster imaging guidewire procedure, and to eliminate the complexity associated with the ultrasonic imaging guidewire procedure.

Another object of this invention is to prevent harm to a patient's vessels by eliminating the back and forth movement of the guidewire tip.

In order to achieve the above objects of the present invention, an ultrasound imaging guidewire is provided with a connector to permit a static central core to be temporarily detached from an imaging guidewire body of a guidewire. A method is also provided to permit efficient and accurate imaging of the site of interest. The method includes the step of inserting a guidewire with an imaging guidewire body and a static central core into a patient's body at a particular site of interest. Next, the imaging guidewire body is rotated at the site of interest to obtain acoustical images. Finally, the imaging guidewire body of the guidewire is axially translated to further obtain images of the site or sites of interest, without axially translating the static central core.

Additional objects, advantages, aspects and features of the present invention will further become apparent to persons skilled in the art from a study of the following description and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A is an elevational view of an ultrasound imaging guidewire.

FIG. 1B is an elevational, view of the ultrasound imaging guidewire in a disengaged position.

FIG. 2A shows a torquer.

FIG. 2B shows a torquer with an imaging guidewire body and static central core.

FIG. 3 is a cross-sectional view of a bifurcating blood vessel with a stent incorrectly placed causing "stent jail."

FIGS. 4A–4C depict alternative methods of adhering wires to the imaging guidewire body.

FIG. 5 is an elevational view of the ultrasound imaging guidewire with a sheath that does not translate axially with the imaging guidewire body.

FIG. 6 is an elevational view of the ultrasound imaging guidewire with a sheath that does translate axially with the imaging guidewire body.

FIG. 7 shows a motor drive adapter which interfaces with an extension wire by offsetting the rotational axis of the extension wire.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIGS. 1 and 2, the present invention is directed to an ultrasound imaging guidewire 10. The guidewire 10 must have sufficient pushability and torque transmission ability to traverse a tortuous anatomy of blood vessels. Pushability means the characteristics of the guidewire 10 that can reliably transmit a pushing force given by the operator at the proximal end of the guidewire to the distal end thereof. Torque transmission ability means the characteristics that can reliably transmit rotational force applied to the proximal end of the guidewire to the distal end thereof. The imaging guidewire body 12 exhibits uniform, suitable axial and lateral stiffness and torquability up to a desired distal region, where the stiffness gradually changes to a floppy tip 14. The guidewire enables predictable torquing and pushability from proximal regions to the distal floppy tip 14 as is required for proper functioning as a guidewire.

Ultrasound imaging guidewire 10 includes an imaging guidewire body 12 which houses a rotatable transducer assembly 18, a static central core structure 20, a floppy tip assembly 14, a proximal connector 16 for disengaging the floppy tip 14 and static central core 20 from the imaging guidewire body 12, and electrical connectors 26 for coupling to a motor drive adapter 30 (shown in FIG. 7). The imaging guidewire body 12 has an outside diameter of approximately 0.035 inch. The overall length of ultrasonic guidewire 10 varies from approximately 40 cm to 300 cm.

The imaging guidewire is adapted for passage through a long, narrow body lumen such as a restricted, tortuous blood vessel. With ultrasound guidewire 10 inserted into a particular lumen of a patient's body, rotation of transducer assembly 18 by a motor drive adapter 30 connected to an ultrasound control system allows real-time, 360 degree ultrasonic images to be obtained of the body lumen. The control system processes data supplied by rotating transducer assembly 18 and displays real-time ultrasound images on a display device.

Imaging Guidewire Body

The imaging guidewire body 12 is formed from a substantially hollow tube designed to provide sufficient tensile strength and lateral stiffness to enable the guidewire 12 to maneuver a tortuous path. The body 12 also transmits torque to provide a substantially one-to-one correspondence between rotation of the proximal and distal ends of the tube to permit accurate imaging. As one skilled in the art would understand, the guidewire body 12 can be formed by a number of different materials including a metal alloy such as

Nitinol or stainless steel. In an alternative embodiment, the imaging guidewire body 12 is made of a composite material such as carbon fiber. In the preferred embodiment, a Nitinol hypotube is used because it minimizes kinking, transmits a high amount of torque, and is a memory metal that retains its shape after being bent. The imaging guidewire body 12 may have varying lengths from approximately 30 cm to 150 cm.

The imaging guidewire body 12 comprises an ultrasonic transducer assembly 18. As the transducer assembly 18 rotates, it provides 360 degree scanning of the lumen wall surrounding the transducer assembly 18. The transducer assembly 18 is adhesively bonded to the imaging guidewire body 12.

The transducer assembly 18 includes a piezoelectric crystal (PZT) with a matching layer on one side and a backing layer formed of acoustically absorbent material on the other side. The transducer assembly 18 in one embodiment maybe "air-backed" so as to increase the efficiency of the transducer. The ultrasound signal does not transmit through the air backing so therefore it is reflected entirely forward which increases the efficiency of the transducer. As one of skill in the art would understand, however, the transducer assembly 18 can be manufactured using alternate materials and designs.

At the proximal end of the imaging guidewire body 12, a pair of electrical connectors 26 are provided that couple a detachable motor drive adapter 30 (see FIG. 7) to a coaxial cable located inside the ultrasonic imaging guidewire 10. The coaxial cable includes an inner wire and an outer wire which are wrapped around each other. Proximal to the transducer assembly 18, the inner and outer wires are separated so that the inner wire is connected to the front of the transducer 18 and the outer wire is connected to the back of the transducer 18.

There are a number of alternative methods of adhering the wires to the imaging guidewire body. In one embodiment, shown in FIG. 4A, the wires 40, 42 are buried in the wall of the imaging guidewire body 12. In FIG. 4B, an alternate method of adhering the wires 40, 42 to the inside wall of the imaging guidewire body 12 is shown. The wires 40, 42 can be spread throughout the inside wall to eliminate any detrimental effects on uniform rotation of the guidewire body 12. In another embodiment shown in FIG. 4C, the wires 40, 42 are adhered to the outside wall of the imaging guidewire body 12. The wires may comprise flexleads which are flat and assist in meeting size constraints of the body 12. An adhesive may be added to the wires 40, 42 to prevent their movement or the interaction between the static central core 20 and the wires 40, 42. It should be noted that the orientation and placement of the wires 40, 42 is for exemplary purposes only. As one of ordinary skill in the art would understand, the wires 40, 42 can be placed anywhere around the circumference of the imaging guidewire body 12.

Static Central Core and Floppy Tip

The present invention comprises a static central core 20 occupying substantially the cross-section of the guidewire 10 throughout the imaging guidewire body 12 and distal of the transducer assembly 18. The static central core 20 is formed from stainless steel or Nitinol. This static central core 20 enhances lateral and axial stiffness, and minimizes the possibility of kinking of the imaging guidewire body 12.

The static central core 20 is welded to the floppy tip 14 which is radiopaque. In an alternative embodiment, only part of the floppy tip 14 is radiopaque. The floppy tip 14 is formed from a coil stacked upon itself that is soft and pliable

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so that it will minimize damage to the patient's vessels when it is being positioned in the patient's body. Furthermore, the floppy tip **14** is formable so that the physician can reshape the distal tip to assist in maneuvering the imaging guidewire **10** through the patient's vessels. The floppy tip **14** is formed from a heavy metal such as gold, platinum or iridium.

In an alternative embodiment the static central core **20** is an extended version that permits over-the-wire catheter exchange. In another alternative embodiment, the extended static central core **20** has a connector to attach or detach additional length to or from the static central core **20**.

Sheath Covering the Imaging Guidewire Body

When the imaging guidewire body **12** is positioned in certain areas of the body, such as the aorta, a sheath is needed to provide safety. The sheath **28** is designed with a preferably thin material because it is necessary to be able to obtain ultrasound images through the sheath **28**. Additionally, the sheath **28** must be nonkinkable and sufficiently strong to be maneuvered through a patient's body.

If a sheath **28** is employed to surround the imaging guidewire body **12**, a fluid such as blood or saline must be filled between the sheath **28** and the imaging guidewire body **12** to prevent air bubbles. It is desirable to eliminate air bubbles, because an air bubble will degrade the image quality. This is because the acoustical waves emitted from the transducer **18** do not travel through air. Therefore, a fluid that allows acoustical waves to be transmitted must be flushed into the sheath. As shown in FIG. 5, there is a gap between the imaging guidewire body **12** and the sheath **28**, and thus that gap must be flushed with a fluid. There are a number of known fluid alternatives for filling the area between the sheath **28** and the body **12** including saline and blood. There are also alternative methods for inserting the fluid. One such method is to have apertures along the perimeter of the sheath **28** that permit fluid to enter the sheath **28** from the patient's body. Alternatively a fluid such as saline is inserted into the sheath **28** at the proximal end of the sheath **28**, such as by a syringe. In another embodiment, a vacuum is created at the proximal end which causes the blood to be sucked up and into the desired area between the sheath **28** and the guidewire body **12**. Alternatively, the fluid is distally filled into the sheath **28**. Furthermore, to assist in any of these fluid flushing processes, a hydrophilic coating can be placed on both the inner and outer walls of the sheath which provides smoother fluid absorption. In one embodiment, the sheath **28** is covered with an anti-coagulant coating because blood clots may degrade the ultrasound image quality.

As shown in FIG. 5, in one embodiment, the sheath **28** stays in place, never rotating or translating axially. In another embodiment, as shown in FIG. 6, although the sheath **28** does not rotate, it does translate axially with the static central core **20**. The proximal connector **16** establishes the lateral positioning of the sheath **28** and the imaging body **12**.

The sheath **28** can be made of a number of different materials including polyethylene, silicon rubber or any acoustically transparent material. Optionally, for the embodiment of the sheath **28** that translates axially with the imaging body **12**, the sheath may be made of a stronger material or reinforced with metal braids. The reinforced material is not placed opposite the transducer assembly **18** so as to not interfere with the transmission of acoustical waves from the transducer assembly **18**. Also the material of

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the sheath **28** may be thinned out at the transducer position to permit an increase in transducer size (and therefore to permit better imaging).

Proximal Connector for Disengaging the Imaging Guidewire Body from the Static Central Core

As shown in FIGS. 1A and 1B, the proximal connector **16** permits the imaging guidewire body **12** and its transducer assembly **18** to be disengaged from the floppy tip **14**. When the transducer assembly **18** is disengaged from the floppy tip **14**, as shown in FIG. 1B, the user can obtain acoustical images of the site or sites of interest while maintaining the proper guidewire position. The ability to disengage the transducer assembly **18** enables the user to easily obtain multi-position images of the patient's vessels or other sites of interest. The user may both advance and withdraw the detachable transducer assembly **18** during the real-time imaging to more accurately position transducer assembly **18** at the site of interest, e.g., a region stenosed with plaque. The proximal connector **16** is used to disengage the transducer assembly **18** from the floppy tip **14**. A torquer can be used to hold the static central core **20** and the imaging body **12** together, as well as assisting the physician in turning or rotating the guidewire. Furthermore, in an alternative embodiment, the proximal connector **16** can be part of the motor drive adapter **30**.

FIG. 2A shows the preferred embodiment of the proximal connector **16**. One of ordinary skill in the art, however, would understand that the proximal connector **16** can be implemented with alternate designs. The proximal connector **16** includes a slotted collet **44**. When the slotted collet **44** is uncompressed, the ultrasound imaging guidewire body **12** and static central core **20** are fed into the proximal connector **16**, through the threaded collar **46** and into the slotted collet **44**. When the slotted collet **44** is compressed, the imaging guidewire body **12** and static central core **20** are locked together to act as a standard guidewire, as shown in FIG. 2B. The slotted collet **44** is compressed by turning the threaded collar **46** which forces the slotted collet **44** into the tapered handle **48**.

When compressed, the slotted collet **44** is shaped so as to tightly engage the guidewire body **12** and static central core **20**. Hence, the compression of slotted collet **44** fixes the guidewire body's position relative to the static central core's position. The slotted collet **44** is also sized so that the static central core **20** passes entirely through the slotted collet **44**, past the distal end of the tapered handle **48**. Furthermore, the slotted collet **44** is sized so that the imaging guidewire body **12** is only partially inserted into the collet **44**. When uncompressed, the slotted collet **44** is also sized such that the radial clearance is minimal between the imaging guidewire body **12** and its respective bore in the collet **44**. Similarly, the slotted collet **44** is sized such that the radial clearance is minimal between the static central core **20** and its respective bore in the collet **44**. In an alternative embodiment, the partial slot **50** of the collet **44** can be extended to the distal end of the collet **44** thereby creating a two-piece collet.

Connection between the Motor Drive Unit and the Imaging Guidewire

At the most proximal portion of the imaging guidewire **10**, a motor drive adapter **30** enables connection and subsequent disconnection of the ultrasonic imaging guidewire **10** to a motor drive unit for obtaining ultrasonic images. The motor drive unit adapter **30** has three primary goals, first to provide a sterile connection to the guidewire **10**, second to provide a mechanical connection to the guidewire **10**, and third to provide an electrical connection.

A problem is encountered when connecting the motor drive unit to the guidewire 10 because the motor drive unit is not sterile. Thus, if the guidewire 10 is plugged directly into the motor drive unit, then at least the sterility of the proximal end of the guidewire 10 is compromised. This is particularly a problem when the user performs a catheter exchange over the non-sterile proximal end of the guidewire 10. A solution is to have a disposable adapter which will interface with the non-sterile motor drive unit. Such a disposable motor drive adapter 30 is shown in FIG. 7. In the embodiment shown in FIG. 7, the entire device shown is sterile and preferably disposable. The motor drive adapter 30 includes an umbilical drive shaft 32 which makes it easier to couple the guidewire 10 and the motor drive unit. FIG. 7 permits an extension guidewire to be used because the motor drive adapter 30 has a hole at the proximal end where the extended portion of the extension guidewire is fed through. Furthermore, the extension guidewire 10 has its rotational axis offset from the rotational axis of the umbilical drive shaft 32 which is connected to the motor drive unit.

One skilled in the art would understand that numerous methods can be employed to create a mechanical connection. The mechanical connection needs to provide a firm grip on the rotating guidewire 10 so that there will be no slippage. The mechanical connection also needs to insure that the rotation from the motor drive adapter is transmitted smoothly to the guidewire 10, so that the guidewire 10 rotates smoothly. In one embodiment, there is a physical depression at one end of the motor drive adapter 30. Once the motor drive adapter engages the guidewire 10, it forces the guidewire 10 to rotate. Alternatively the motor drive adapter 30 does not have a physical depression, but engages the guidewire 10 with sufficient tightness to ensure that the guidewire 10 rotates smoothly. In another embodiment, two rubber wheels surround the guidewire 16. One rubber wheel is rotated in one direction, while the second rubber wheel is rotated in another direction. Meanwhile the imaging guidewire 10 spins in between the two rubber wheels. In the preferred embodiment, a multi-leaved spring arrangement is used to provide a mechanical connection between the guidewire 10 and the motor drive adapter 30.

An electrical connection that allows ultrasonic energy to be transmitted from motor drive adapter 30 to the wires 40, 42 inside the guidewire body 12 is provided by electrical connectors 26. In one embodiment, the electrical connectors 26 are formed by gold bands that are coupled to the motor drive adapter 30. The electrical connection aspect of the motor drive adapter 30 can be implemented using many different techniques, as one of skill in the art would understand. One method is to have a slipping contact that rubs on the rotating guidewire 10.

Another method uses electrodes on the rubber-wheel embodiment. In the preferred embodiment, non-slipping contacts with a rotary transformer are used.

The motor drive unit adapter 30 can be in a number of different forms including hollow, where the guidewire 10 is end loaded. In the preferred embodiment, the motor drive

unit adapter 30 is clam-shelled shaped, so that the guidewire 10 can be side loaded. The side-loaded version is the preferred embodiment because it obviates the need to thread the guidewire 10 in and out and therefore makes it easier to load and unload.

While a presently-preferred embodiment of the invention has been disclosed, it will be obvious to those skilled in the art that numerous changes may be made without departing from the spirit or scope of the invention. It is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as being illustrative and not limiting. The invention, therefore, is not to be limited except in accordance with the below claims.

The invention claimed is:

1. A medical device, comprising:
 - a guidewire body having an inner lumen configured to slidably receive a core member, the guidewire body comprising an ultrasonic transducer located within a distal region thereof;
 - the core member comprising a distal tip member located at a distal end thereof, wherein the guidewire body is rotatable about the core member and translatable along the core member and wherein translation of the guidewire body along the core member is limited in a first direction by the distal tip member; and
 - a sheath member having an inner lumen and an open distal end, the inner lumen configured to slidably receive the guidewire body and the open distal end configured to allow the core member to slide therethrough.
2. The device of claim 1, wherein a side wall of the sheath member has a thin section and a relatively thicker section, the thin section being located in a position corresponding to the position of the transducer.
3. The device of claim 2, wherein the thin section extends around the circumference of the sheath member.
4. The device of claim 2, wherein the relatively thicker section comprises a reinforcing material.
5. The device of claim 1, wherein the sheath member has an open proximal end coupled to a vacuum configured to draw a fluid into a gap region between the sheath and the guidewire body.
6. The device of claim 5, wherein the open distal end of the sheath is configured to allow the fluid to be drawn therethrough.
7. The device of claim 5, wherein at least one aperture is located along the length of the sheath, the aperture being configured to allow the fluid to be drawn therethrough.
8. The device of claim 5, wherein the fluid is blood.
9. The device of claim 5, wherein the sheath comprises an anti-coagulant coating on the surface of the inner lumen.
10. The device of claim 1, wherein the distal tip member is radiopaque.
11. The device of claim 1, wherein the distal end of the sheath is tapered such that the open distal end is smaller than the distal tip member.

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专利名称(译)	超声成像导丝具有静态中心核心和尖端		
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摘要(译)

超声成像导丝，插入患者体内。导丝具有静态中心核心和包括声学扫描装置的成像导丝主体。可以旋转声学扫描装置以获得患者身体中感兴趣部位的360度声学图像。此外，成像导丝包括连接器，该连接器允许成像导丝主体从静态中心芯尖脱离，使得成像导丝主体可以轴向平移以获得多位置成像。成像导丝主体轴向平移而不会失去原始导丝定位，因为静态中心核心保持其在患者体内的位置。

