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(54) MINIATURE ACTUATOR MECHANISM FOR INTRAVASCULAR IMAGING

MINIATUR-STELLGLIEDMECHANISMUS FÜR DIE INTRAVASKULÄRE BILDGEBUNG

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Description

[0001] The present invention concerns a miniature actuator which is useful in intravascular imaging devices including intravascular ultrasound (IVUS), and optical coherence tomography (OCT). The miniature actuator mechanism and ultrasound or OCT imaging device is embedded in an elongate member such as an intravascular guide wire or catheter to provide imaging guidance in various interventional applications. Also disclosed is a reflector-based ultrasound imaging device created to minimize the overall scale of the imaging device, as well as ultrasound transducers having multiple transducer crystals to increase the field of view of the device while maintaining its small size.

[0002] Coronary artery disease is very serious and often requires an emergency operation to save lives. The main cause of coronary artery disease is the accumulation of plaques inside artery, which eventually occludes blood vessels. Several solutions are available, e.g., balloon angioplasty, rotational atherectomy, and intravascular stents, to open up the clogged section, which is called stenosis. Traditionally, during the operation, surgeons rely on X-ray fluoroscopic images that are basically planary images showing the external shape of the silhouette of the lumen of blood vessels. Unfortunately, with X-ray fluoroscopic images, there is a great deal of uncertainty about the exact extent and orientation of the atherosclerotic lesions responsible for the occlusion, making it difficult to find the exact location of the stenosis. In addition, though it is known that restenosis can occur at the same place, it is difficult to check the condition inside the vessels after surgery. Similarly, intravascular imaging would prove valuable during interventional procedures as an aid to navigation and for intraoperative feedback. For example, the precise placement and appropriate expansion of stents would benefit from concurrent intravascular imaging. Existing intravascular imaging devices are too large and insufficiently flexible to be placed simultaneously with other devices.

[0003] In order to resolve these issues, an ultrasonic transducer device has been utilized for endovascular intervention to visualize the inside of the blood vessels. To date, the current technology is mostly based on one or more stationary ultrasound transducers or rotating a single transducer in parallel to the blood vessels by means of a rotating shaft which extends through the length of the catheter to a motor or other rotary device located outside the patient. These devices have limitations in incorporating other interventional devices into a combination device for therapeutic aspects. They require a large space inside catheter such that there is not enough room to accommodate other interventional devices. Also due to the nature of the rotating shaft, the distal end of the catheter is very stiff and it is hard to go through tortuous arteries. The high speed rotating shaft also contributes to distorted non-uniform images when imaging a tortuous path in the vasculature. OCT has also been utilized to visualize the intravascular space based on differential reflectance, but like the existing ultrasound devices, most rely on a rotating fiber optic which extends along the length of the device. This approach also has problems, including for example the manipulation, spinning and scanning motion required with respect to a delicate glass or polycarbonate optical fiber; the actuator mechanism located outside the patient and tip located inside the patient are significantly distant from one another, leading to inefficiencies and control issues arising from the torque created by a long, spinning member; and remote mechanical manipulation and a long spinning element distort the image due to non-uniform rotational distortion. Given the numerous difficulties with current intravascular imaging devices, there is a need for improved intravascular imaging devices.

[0004] US 6 592 526 B1 discloses an side-looking intravascular ultrasound apparatus comprising an elongate member having a proximal end and a distal end, wherein a portion of said distal end is transparent to ultrasound energy, an ultrasound transducer disposed in said distal end and oriented to transmit ultrasound energy through said ultrasound energy transparent portion of said distal end at an angle of about 90° relative to a longitudinal axis of said elongate member and an actuator mechanism means for providing cyclical motion to said ultrasound transducer disposed in said distal end. The actuator mechanism means comprises a distal tip and a pair of opposing nitinol actuators disposed circumferentially around the distal end of the elongate member, the actuators comprising a nitinol element, a mount top, a mount bottom and two connections, one for connecting the mount bottom to the elongate member and one for connecting the mount top to the distal tip. The nitinol element of the first nitinol actuator form a first SMA actuator, the nitinol element of the second nitinol actuator a deformable component, the distal tip a movable element, the mount bottom of the nitinol element of the first nitinol actuator a first anchor and the mount bottom of the nitinol element of the second nitinol actuator a second anchor. The first SMA actuator is connected to the first anchor and the movable element, the deformable component is connected to the second anchor and the movable element and the anchor elements are secured relative to the elongate member.

[0005] The present invention is directed to a side-looking intravascular ultraground / optical coherence tomography apparatus according to the independent claims.

[0006] One embodiment of the invention is a side-looking intravascular ultrasound apparatus comprising an elongate member having a proximal end and a distal end, where at least a portion of the distal end is at least transparent to ultrasound energy; an actuator mechanism disposed in the distal end, the actuator mechanism comprising a first anchor, a second anchor, at least one movable element, a first SMA actuator connected to the first anchor and a movable element, and a deformable component connected to the second anchor and at least one movable element, where the anchor elements are secured relative to the elongate member, and an ultrasound transducer connected to the movable element, the transducer oriented to transmit ultrasound energy through the ultrasound transparent portion of the distal end at an angle of between about 15° to about 165° relative to a longitudinal axis of the elongate member, where the first SMA actuator has an activated and a deactivated state; and where the movable element and transducer move in a first direction relative to the elongate member upon activation of the first SMA actuator. In another embodiment of the apparatus, the deformable component comprises a second SMA actuator, where the second actuator has an activated and a deactivated state; and where activation of the second SMA actuator following deactivation of the first SMA actuator moves the movable element and transducer relative to the elongate member in a second direction of movement which is counter to the first direction of movement. In yet another embodiment of the apparatus, the deformable component is elastic or superelastic; where the deformable component has a relaxed state and a deformed state; where the deformable component is in a relaxed state when the first SMA actuator is deactivated; where the movement of the movable element and transducer in the first direction upon activation of the first SMA actuator deforms the elastic or superelastic deformable component; and where following deactivation of the first SMA actuator, the elastic or superelastic deformable component substantially returns to the relaxed state, the movable element and transducer moving in a second direction of movement which is counter to the first direction of movement.

[0007] In another embodiment of the apparatus described herein, the first and second direction of movement is rotational about the longitudinal axis of the elongate member, or substantially parallel to the longitudinal axis of the elongate member. In some embodiments, the elongate member is a guide wire. In some embodiments the apparatus further comprises a lumen traversing the longitudinal axis of the elongate member; and wires disposed in the lumen to electrically connect the transducer, first SMA and optionally the deformable component to one or more devices at the proximal end of the elongate member. In some embodiments the device is an ultrasound signal processor. In some embodiments the apparatus further comprises a second ultrasound transducer connected to the movable element. In some embodiments of the apparatus, the angle is between about 80° and about 110°; in some embodiments the diameter of the distal end of the elongate member is not more than about 0.1524 cm (0.060 inches).

[0008] Some embodiments of the apparatus of further comprise a connecting arm, the connecting arm connecting the ultrasound transducer to a movable element; where the movable element, connecting arm and transducer move in a first direction relative to the elongate member upon activation of the first SMA actuator. In some embodiments of the apparatus, the deformable component comprises a second SMA actuator; where the second actuator has an activated and a deactivated state; and where activation of the second SMA actuator following deactivation of the first SMA actuator moves the movable element, connector and transducer relative to the elongate member in a second direction of movement which is counter to the first direction of movement. In some embodiments the deformable component is elastic or superelastic; where the deformable component has a relaxed state and a deformed state; where the deformable component is in a relaxed state when the first SMA actuator is deactivated; where the movement of the movable element, connecting arm and transducer in the first direction upon activation of the first SMA actuator deforms the elastic or superelastic deformable component; and where following deactivation of the first SMA actuator, the elastic or superelastic deformable component substantially returns to the relaxed state, the movable element, connecting arm and transducer moving in a second direction of movement which is counter to the first direction of movement.

[0009] In some embodiments, the rotational motion is between about 1 and about 400 degrees, and the longitudinal motion is from about 1mm to about 20mm. Some embodiments further comprise a second ultrasound transducer connected to a movable element. In some embodiments, the ultrasound transducer further comprises at least two ultrasound crystals. In some embodiments, the transducer is oriented to transmit ultrasound energy through the ultrasound transparent portion of the distal end at an angle of between about 80° and about 110° relative to a longitudinal axis of the elongate member.

[0010] Another embodiment is a side-looking intravascular ultrasound apparatus comprising an elongate member having a proximal end and a distal end, where at least a portion of the distal end is transparent to ultrasound energy; an actuator mechanism disposed in the distal end, the actuator mechanism comprising a first anchor, a second anchor, a movable element, a first SMA actuator connected to the first anchor and the movable element, and a deformable component connected to the second anchor and the movable element, where the anchor elements are secured relative to the elongate member; a connecting arm and an ultrasound energy reflector, where the connecting arm connects the ultrasound energy reflector to a moveable element; and an ultrasound transducer disposed in the distal end of the elongate member; where the ultrasound transducer and the ultrasound energy reflector are oriented to transmit ultrasound energy through the ultrasound transparent portion of the distal end at an angle of between about 15° to about 165° relative to a longitudinal axis of the elongate member; where the first SMA actuator has an activated and a deactivated state; and where the movable element, connecting arm, and ultrasound energy reflector move in a first direction relative to the elongate member upon activation of the first SMA actuator. In some embodiments the deformable component comprises a second SMA actuator; where the second actuator has an activated and a deactivated state; and where activation of the second SMA actuator following deactivation of the first SMA moves the movable element, connecting arm and reflector relative to the elongate member in a second direction which is counter to the first direction of movement. In some embodiments the deformable component is elastic or superelastic; where the deformable component has a relaxed state and a deformed state; where the deformable component is in a relaxed state when the first SMA actuator is deactivated; where the movement of the movable element, connecting arm and reflector in the first direction upon activation of the first SMA actuator deforms the elastic or superelastic deformable component; and where following deactivation of the first SMA actuator, the elastic or superelastic deformable component substantially returns to the relaxed state, the movable element, connecting element and reflector moving in a second direction of movement which is counter to the first direction of movement. Some embodiments further comprise a second ultrasound energy reflector connected to a movable element. In some embodiments, the ultrasound transducer and the ultrasound energy reflector are oriented to transmit ultrasound energy through the ultrasound transparent portion of the distal end at an angle of between about 80° and about 110° relative to a longitudinal axis of the elongate member

[0011] Also disclosed is a method for visualizing the interior of a patient's vasculature, the method comprising inserting the distal end of an apparatus disclosed herein into the vasculature of a patient; generating an ultrasound signal from the transducer; generating a cyclical movement of the movable element and ultrasound transducer by alternating the activation and deactivation of the first SMA and optionally the deformable component, such that the movable element and ultrasound transducer are moved in the first and the second direction; receiving an ultrasonic signal reflected from the interior of the vasculature on the transducer; and producing an image from the reflected signal. In some examples of the method, the cyclical movement of the movable element and ultrasound transducer is generated by alternating the activation of the first SMA and the second SMA, such that the movable element and ultrasound transducer are moved in the first and the second direction.

[0012] Another example of the method for visualizing the interior of a patient's vasculature comprises inserting the distal end of an apparatus described herein into the vasculature of a patient; generating an ultrasound signal from the transducer; generating a cyclical movement of the movable element, connecting arm and ultrasound transducer by alternating the activation and deactivation of the first SMA and optionally the deformable component, such that the movable element, connecting arm and ultrasound transducer are moved in the first and the second direction; receiving an ultrasonic signal reflected from the interior of the vasculature on the transducer; and producing an image from the reflected signal. In some examples of the method, the cyclical movement of the movable element, connecting arm and ultrasound transducer is generated by alternating the activation of the first SMA and the second SMA, such that the movable element, connecting arm and ultrasound transducer are moved in the first and the second direction.

[0013] Another example of the method for visualizing the interior of a patient's vasculature comprises inserting the distal end of an apparatus described herein into the vasculature of a patient; generating an ultrasound signal from the transducer; generating a cyclical movement of the movable element, connecting arm and ultrasound energy reflector by alternating the activation of the first SMA and the second SMA, such that the movable element, connecting arm and ultrasound energy reflector are moved in the first and the second direction; receiving an ultrasonic signal reflected from the interior of the vasculature on the transducer; and producing an image from the reflected signal. In some examples, the cyclical movement of the movable element, connecting arm and ultrasound energy reflector are generated by alternating the activation of the first SMA and the second SMA, such that the movable element, connecting arm and ultrasound energy reflector are moved in the first and the second direction.

[0014] Another embodiment of the apparatus comprises an elongate member having a proximal end and a distal end, where at least a portion of the distal end is transparent to ultrasound energy; an ultrasound transducer disposed in the distal end; and an actuator mechanism means for providing cyclical motion to the transducer disposed in the distal end; where the transducer is oriented to transmit ultrasound energy through the ultrasound transparent portion of the distal end at an angle of between about 15° to about 165° relative to a longitudinal axis of the elongate member. The actuator mechanism means comprises a first anchor, a second anchor, a movable element, a first SMA actuator connected to the first anchor and the movable element, and a deformable component connected to the second anchor and the movable element, where the anchor elements are secured relative to the elongate member.

[0015] Another embodiment of the invention is a side-looking intravascular optical coherence tomography apparatus comprising an elongate member having a proximal end and a distal end, where at least a portion of the distal end is at least partially transparent to light energy; an actuator mechanism disposed in the distal end, the actuator mechanism comprising a first anchor, a second anchor, at least one movable element, a first SMA actuator connected to the first anchor and at least one movable element, and a deformable component connected to the second anchor and at least on movable element, where the anchor elements are secured relative to the elongate member; an optical fiber having a proximal and a distal end, the distal end of the optical fiber disposed in the distal end of the elongate member substantially parallel to a longitudinal axis of the elongate member; and a reflector connected to the movable element, the reflector oriented to reflect light energy from a distal tip of the optical fiber through the transparent portion of the distal end at an angle of between about 15° to about 165° relative to the longitudinal axis of the elongate member; where the first SMA actuator has an activated and a deactivated state; and where the movable element and mirror move in a first direction relative to the elongate member upon activation of the first SMA actuator. In another embodiment the deformable component comprises a second SMA actuator; where the second actuator has an activated and a deactivated state; and where activation of the second SMA actuator following deactivation of the first SMA actuator moves the movable element and reflector relative to the elongate member in a second direction of movement which is counter to the first direction of movement. In some embodiments the deformable component is elastic or superelastic; where the deformable component has a relaxed state and a deformed state; where the deformable component is in a relaxed state when the first SMA actuator is deactivated; where the movement of the movable element and reflector in the first direction upon activation of the first SMA actuator deforms the elastic or superelastic deformable component; and where following deactivation of the first SMA, the elastic or superelastic deformable component substantially returns to the relaxed state, the movable element and reflector moving in a second direction of movement which is counter to the first direction of movement.

[0016] In some embodiments, the first and second direction of movement is rotational about the longitudinal axis of the elongate member, or substantially parallel to the longitudinal axis of the elongate member. In some embodiments the elongate member is a guide wire. Another embodiment further comprises a lumen traversing the longitudinal axis of the elongate member; and wires disposed in the lumen to electrically connect the first SMA actuator and optionally the deformable component to one or more devices at the proximal end of the elongate member. In some embodiments the device is a signal processor.

[0017] In some embodiments the reflector is oriented to reflect light energy from a distal tip of the optical fiber through the transparent portion of the distal end at an angle of between about 80° and about 110° relative to the longitudinal axis of the elongate member. In some embodiments the diameter of the distal end of the elongate member is not more than about 0.1524 cm, (0.060 inches).

[0018] Another embodiment further comprises a connecting arm; the connecting arm connecting the reflector to a movable element; where the movable element, connecting arm and reflector move in a first direction relative to the elongate member upon activation of the first SMA actuator. In some embodiments the deformable component comprises a second SMA actuator; where the second actuator has an activated and a deactivated state; and where activation of the second SMA actuator following deactivation of the first SMA actuator moves the movable element, connecting arm and reflector relative to the elongate member in a second direction of movement which is counter to the first direction of movement. In some embodiments the deformable component is elastic or superelastic, and has a relaxed and deformed state; where the deformable component is in a relaxed state when the first SMA actuator is deactivated; where the movement of the movable element, connecting arm and reflector in the first direction upon activation of the first SMA actuator deforms the elastic or superelastic deformable component; and where following deactivation of the first SMA actuator, the elastic or superelastic deformable component substantially returns to the relaxed state, the movable element, connecting arm and reflector moving in a second direction of movement which is counter to the first direction of movement.

[0019] Another embodiment is a side-looking intravascular optical coherence tomography apparatus comprising an elongate member having a proximal end and a distal end, where at least a portion of the distal end is transparent to light energy; an actuator mechanism disposed in the distal end, the actuator mechanism comprising a first anchor, a second anchor, a movable element, a first SMA actuator connected to the first anchor and the movable element, and a deformable component connected to the second anchor and the movable element, where the anchor elements are secured relative to the elongate member; an optical fiber having a proximal and a distal end, the distal end of the optical fiber disposed in the distal end of the elongate member substantially parallel to a longitudinal axis of the elongate member, the moveable element connected to the distal end of the optical fiber; a reflector connected to a distal tip of the optical fiber, the reflector oriented to reflect light energy from the distal tip of the optical fiber through the transparent portion of the distal end at an angle between about 15° to about 165° relative to the longitudinal axis of the elongate member; where the first SMA actuator has an activated and a deactivated state; and where the movable element, distal tip of the optical fiber and the reflector move in a first direction relative to the elongate member upon activation of the first SMA actuator. In some embodiments the deformable component comprises a second SMA actuator; where the second actuator has an activated and a deactivated state; and where activation of the second SMA actuator following deactivation of the first SMA actuator moves the movable element, distal tip of the optical fiber and the reflector relative to the elongate member in a second direction which is counter to the first direction of movement. In some embodiments the deformable component is elastic or superelastic, and has a relaxed and deformed state; where the deformable component is in a relaxed state when the first SMA actuator is deactivated; where the movement of the movable element, distal tip of the optical fiber and the reflector in the first direction upon activation of the first

SMA deforms the elastic or superelastic deformable component; and where following deactivation of the first SMA actuator, the elastic or superelastic deformable component substantially returns to the relaxed state, the movable element, distal tip of the optical fiber and the reflector moving in a second direction of movement which is counter to the first direction of movement.

[0020] Also disclosed is a method for visualizing the interior of a patient's vasculature, the method comprising inserting the distal end of an apparatus disclosed herein into the vasculature of a patient; generating a cyclical movement of the movable element and reflector by alternating the activation and deactivation of the first SMA actuator and optionally the deformable component, such that the movable element and reflector are moved in the first and the second direction; transmitting light energy from the proximal end of the optical fiber to the distal tip, reflecting the energy on the reflector; receiving light energy reflected from the interior of the vasculature on reflector and reflecting the energy on the distal tip of the optical fiber; transmitting the energy from the distal tip of the optical fiber to the proximal end of the fiber; producing an image from the reflected energy. In some examples, the cyclical movement of the movable element and reflector is generated by alternating the activation of the first SMA actuator and the second SMA actuator, such that the movable element and reflector are moved in the first and the second direction.

[0021] Also disclosed is a method for visualizing the interior of a patient's vasculature, the method comprising inserting the distal end of an apparatus described herein into the vasculature of a patient; generating a cyclical movement of the movable element, connecting arm and reflector by alternating the activation and deactivation of the first SMA actuator and optionally the deformable component, such that the movable element, connecting arm and reflector are moved in the first and the second direction; transmitting light energy from the proximal end of the optical fiber to the distal tip, reflecting the energy on the reflector; receiving light energy reflected from the interior of the vasculature on reflector and reflecting the energy on the distal tip of the optical fiber; transmitting the energy from the distal tip of the optical fiber to the proximal end of the fiber; and producing an image from the reflected energy. In some examples the cyclical movement of the movable element, connecting arm and reflector is generated by alternating the activation of the first SMA actuator and the second SMA actuator, such that the movable element, connecting arm and reflector are moved in the first and the second direction.

[0022] Also disclosed is a method for visualizing the interior of a patient's vasculature, the method comprising inserting the distal end of an apparatus disclosed herein into the vasculature of a patient; generating a cyclical movement of the movable element, distal tip of the optical fiber and the reflector by alternating the activation and deactivation of the first SMA actuator and optionally the deformable component, such that the movable element, distal tip of the optical fiber and the reflector are moved in the first and the second direction; transmitting light energy from the proximal end of the optical fiber to the distal tip, reflecting the energy on the reflector; receiving light energy reflected from the interior of the vasculature on reflector and reflecting the energy on the distal tip of the optical fiber; transmitting the energy from the distal tip of the optical fiber to the proximal end of the fiber; and producing an image from the reflected energy. In some embodiments the cyclical movement of the movable element, distal tip of the optical fiber and the reflector is generated by alternating the activation of the first SMA actuator and the second SMA actuator, such that the movable element, distal tip of the optical fiber and the reflector are moved in the first and the second direction.

[0023] Another embodiment is a side-looking intravascular optical coherence tomography apparatus comprising an elongate member having a proximal end and a distal end, where at least a portion of the distal end is transparent to light energy; an optical fiber having a distal end, the distal end of the optical fiber disposed in the distal end of the elongate member; a reflector means disposed in the distal end of the elongate member; and an actuator mechanism means for providing cyclical motion to the reflector; where the reflector and distal end of the optical fiber is oriented to transmit light energy through the light transparent portion of the distal end of the elongate member at an angle of between about 15° to about 165° relative to a longitudinal axis of the elongate member. The actuator mechanism means comprises a first anchor, a second anchor, a movable element, a first SMA actuator connected to the first anchor and the movable element and a deformable component connected to the second anchor and the movable element, where the anchor elements are secured relative to the elongate member.

[0024] Figure 1 is a partial cut-away perspective view showing an embodiment of the actuator mechanism of the present invention and an ultrasound transducer disposed in the distal end of an elongate member.

[0025] Figures 2a and 2b are perspective views illustrating rotational motion of the actuator mechanism shown in FIG. 1, while Figures 2c and 2d illustrate longitudinal motion of the actuator mechanism shown in FIG. 1.

[0026] Figure 3 is a perspective view showing an embodiment of the actuator mechanism of the present invention connected to an ultrasound transducer by a connecting arm.

[0027] Figure 4 is a perspective view of the device of FIG. 3 disposed in the distal end of an elongate member having an ultrasound transparent window.

[0028] Figure 5 is a perspective view of the distal end of an elongate member with an actuator mechanism and ultrasound transducer structure disposed therein.

[0029] Figure 6 is a perspective view of the distal end of an elongate member with an actuator mechanism and two ultrasound support structures stacked orthogonally.

[0030] Figure 7 is a perspective view showing an actuator mechanism with an ultrasound reflector connected by a connecting arm, with an ultrasound transducer aligned with the reflector.

[0031] Figure 8 is a partial cut-away perspective view showing the device of FIG. 7 housed in the distal end of an elongate member with an ultrasound transparent window.

[0032] Figure 9 is a schematic drawing of an optical coherence tomography device with an actuator mechanism, a reflector and an optical fiber disposed in an elongate member having a transparent window.

[0033] Figure 10 is a schematic drawing of another embodiment of an optical coherence tomography device with an actuator mechanism connected to an optical fiber with a reflector on its distal end, disposed in an elongate member having an transparent window.

[0034] Figure 11 is a schematic drawing of another embodiment of an optical coherence tomography device with an actuator mechanism, a reflector and an optical fiber disposed in an elongate member having a transparent window.

[0035] Figures 12a, 12b, and 12c are schematic drawings illustrating ultrasound transducers having one, two, or three individual transducer crystals, respectively. Figures 12d, 12e, and 12f illustrate the field of view obtained by rotating the transducers of FIGs. 12a, 12b, and 12c, respectively.

[0036] Figures 13a and 13b are perspective views showing two tubular structures each with a built-in compliant mechanism in different design configuration.

[0037] Figure 14 is a perspective view showing an ultrasound transducer coupled to a micromanipulator having the compliant structure of FIG. 13a and two SMA actuators configured to actuate the compliant mechanism thereof.

[0038] The present invention relates to imaging devices for intravascular imaging, although the present invention is not limited to this preferred application. Imaging of the intravascular space, particularly the interior walls of the vasculature can be accomplished by a number of different means. Two of the most common are the use of ultrasound energy, commonly known as intravascular ultrasound (IVUS) and optical coherence tomography (OCT). Both of these methods are optimized when the instruments (IVUS or OCT) used for imaging a particular portion of the vasculature are repeatedly swept over the area being imaged.

[0039] To address the limitations in current devices, a new intravascular imaging device is described based on a Shape Memory Alloy (SMA) actuator mechanism embedded inside an elongate member such as a guide wire or catheter. The present invention utilizes a novel SMA mechanism to provide side-looking imaging by providing movement for an ultrasound transducer or OCT element Since this novel SMA actuator mechanism can be easily fabricated in micro-scale using laser machining or other fabrication techniques, it provides an advantage over existing imaging devices because it offers the ability to miniaturize the overall size of the device, while the use of multiple transducer crystals maximizes field of view. The small dimensions of the actuator mechanism of the invention allows for the diameter of the elongate member in which it is housed to be very small. The outside diameter of the elongate member, such as a guide wire or catheter containing an imaging device described herein can be as small as from about 0.0050" to about 0.060" outside diameter. The outside diameter for elongate members can be larger when the imaging device is combined with other interventional devices, although the outside diameter of these devices can be as small as 0.. 060" or smaller. Current catheters containing IVUS range from 0.70mm to 3mm in outside diameter.

[0040] Because the device does not require a rotating shaft or fiber optic along the length of the catheter, it also allows for a more flexible catheter or guide wire, and provides room for other interventional devices. In addition, it eliminates the problems mentioned above with current OCT technology because it does not require rotating the entire length of the optical fiber. This invention simplifies the manufacture and operation of OCT by allowing a straight fiber optic directed by an independent, oscillating reflector or prism controlled by the actuator mechanism located only in the distal tip of the device. A variation uses the actuator mechanism to rotate only the distal end of the optical fiber, eliminating the need to spin the entire fiber via a remote mechanism.

[0041] In a preferred embodiment, an ultrasound reflector can be implemented together with the SMA actuator mechanism. This has an advantage over the prior art because it eliminates the rotational load required to rotate a transducer and accompanying electrical wiring, further reducing size and increasing the amount of movement provided by the actuator, which in turn increases the field of view provided by the device. This preferred embodiment also increases imaging quality by allowing for a thicker backing layer for the ultrasound transducer, since the backing layer does not affect the diameter of the device. This in turn improves the signal-to-noise characteristics of the device and thus improves image quality. In addition, because the transducer does not need to be rotated, this also removes a constraint on the size of the backing layer.

[0042] As used herein, elongate member includes any thin, long, flexible structure which can be inserted into the vasculature of a patient. Elongate members include, for example, intravascular catheters and guide wires. The actuator mechanism is disposed in the distal end of the elongate member. As used herein, "distal end" of the elongate member includes any portion of the elongate member from the mid-point to the distal tip. As elongate members can be solid, some will include a housing portion at the distal end for receiving the actuator mechanism. Such housing portions can be tubular structures attached to the side of the distal end or attached to the distal end of the elongate member. Other elongate members are tubular and have one or more lumens in which the actuator mechanism can be housed at the distal end.

[0043] "Connected" and variations thereof as used herein includes direct connections, such as being glued or otherwise fastened directly to, on, within, etc. another element, as well as indirect connections where one or more elements are disposed between the connected elements.

[0044] "Secured" and variations thereof as used includes methods by which an element is directly secured to another element, such as being glued or otherwise fastened directly to, on, within, etc. another element, as well as indirect means of securing two elements together where one or more elements are disposed between the secured elements.

[0045] Movements which are counter are movements in the opposite direction. For example, if the movable element is rotated clockwise, rotation in a counterclockwise direction is a movement which is counter to the clockwise rotation Similarly, if the movable element is moved substantially parallel to the longitudinal axis of the elongate member in a distal direction, movement substantially parallel to the longitudinal axis in a proximal direction is a counter movement.

[0046] As used herein, "light" or "light energy" encompasses electromagnetic radiation in the wavelength range including infrared, visible, ultraviolet, and X rays. The preferred range of wavelengths for OCT is from about 400nm to about 1400nm. For intravascular applications, the preferred wavelength is about 1200 to about 1400nm. Optical fibers include fibers of any material which can be used to transmit light energy from one end of the fiber to the other.

[0047] "Reflector" as used herein encompasses any material which reflects or refracts a substantial portion of the ultrasound or light energy directed at it. In some embodiments of the OCT device the reflector is a mirror. In others, it is a prism. This allows refractive optical coherence tomography (as opposed to reflective tomography using a mirror.) The prism can also be designed to replace the lens typically required at the distal tip of the optical fiber.

[0048] Embodiments of the invention will now be described with reference to the accompanying 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. Furthermore, embodiments of the invention can include several novel features, no single one of which is solely responsible for its desirable attributes or which is essential to practicing the inventions herein described.

[0049] Figure 1 illustrates a novel actuator mechanism **10** for achieving the sweeping or scanning motion used for IVUS or OCT imaging. FIG. 1 shows an actuator mechanism **10,** which is housed in the distal end of an elongate member **11,** with the longitudinal axis of the actuator mechanism **10** oriented substantially parallel to the longitudinal axis of the elongate member **11.** The elongate member **11** will be described in greater detail below with reference to FIG. 4. The actuator mechanism **10** includes a first anchor **12** and a second anchor **14** which are secured relative to the interior of the elongate member **11** to anchor the actuator mechanism **10** to the distal end of elongate member **11** such that the anchors **12** and **14** cannot move relative to elongate member **11.** The actuator mechanism **10** also has a movable element **16** which is not secured relative to the elongate member **11,** and which is free to move in at least one range of motion relative to the anchors **12** and **14** and elongate member **11.**

[0050] The first anchor **12** is connected to the movable element **16** by a shape memory alloy (SMA) actuator **20** which moves movable element **16** when activated as described in more detail below. The SMA actuator **20** can be fabricated from any known material with shape memory characteristics, the preferred material being nitinol. In an alternative embodiment the actuator mechanism **10** can be fabricated without from a single tubing using any material with shape memory characteristics, incorporating the first anchor **12,** second anchor **14,** moveable element **16,** SMA actuator **20** and deformable component **22** (described below). As known by those of skill in the art, SMAs can be fabricated to take on a predetermined shape when activated. Activation of an SMA actuator consists of heating the SMA such that it adopts its trained shape. Typically, this is accomplished by applying an electric current across the SMA element. Deactivation of an SMA actuator includes turning off current to SMA, such that it returns to its pliable state as it cools. Activation of the SMA to its trained shape results in a force which can be utilized as an actuator. As one of skill in the art will recognize, the disclosed SMA actuator **20** can take numerous shapes and configurations in addition to the helical shape shown in FIG. 1. For example it could be linear, or more than one (e.g. 2, 3, 4 or more) SMA elements could be used to make the SMA actuator **20.**

[0051] The second anchor **14** is connected to the movable element **16** by a deformable component **22.** The deformable component **22** is made from materials which are not rigid, including elastic and superelastic, and nonelastic materials. Deformable materials include trained and untrained SMAs. Elastic alloys include, but are not limited to, stainless steel and titanium alloy, and superelastic alloys include but are not limited to, nitinol, Cu-Al-Ni, Cu-Al, Cu-Zn-Al, Ti-V and Ti-Nb alloy.

[0052] In an alternative embodiment, one or both of the anchors **12** and **14** are eliminated, and one end the SMA actuator **20** and/or the deformable component **22** are secured directly to the elongate member **11.** Also one or both of the anchors **12** and **14** are secured indirectly to the elongate member **11** through additional elements such as an intermediate housing for the actuator mechanism **10.** In addition, the SMA actuator **20** and/or deformable component **22** can be connected to either of, or both the anchor **12** or **14** and the movable element **16** through additional elements - they need not be directly connected to the anchor or movable element as shown. Alternatively, the moveable element **16** can include, or have an additional element(s) connected thereto, that extend over or within the anchors **12** and/or **14** with enough clearance such that the additional element(s) supports the movement of the moveable element **16** and help to align it relative to the anchors **12** and **14 -** this alignment provides precise and uniform motion in the elongate member **11.**

[0053] In the embodiment illustrated in FIG. 1, an ultrasound transducer **24** is connected to the movable element of the actuator mechanism by being disposed on the moveable element.

[0054] In addition, while FIG. 1 shows only a single moveable element, multiple moveable elements are possible. For example, the SMA actuator **20** could be connected to a first moveable element, and the deformable component **22** could be connected to a second moveable element, with the transducer **24** disposed between the two moveable elements. Alternatively, the moveable element(s) can be eliminated and the SMA actuator **20** and the deformable component 22 can be attached directly to the ultrasound transducer **24.**

[0055] In the embodiment shown in FIG. 1, the ultrasound transducer **24** is oriented such that it transmits ultrasound energy at an angle of about 90° relative to the longitudinal axes of the actuator mechanism **10** and elongate member **11.** The angle of orientation of the ultrasound transducer **24** relative to the longitudinal axes can be any angle between about 15° and about 165°, with the preferred angle for side-looking ultrasound being between about 80° and about 110°. Angles contemplated include about 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 105, 110, 115, 120, 125, 130, 135, 140, 145, 150, 155, 160, and about 165 degrees, or can fall within a range between any two of these values. For example, 15 (or 165, depending on orientation) degrees are preferred for forward-looking ultrasound imaging applications.

[0056] Housed in the elongate member **11,** the actuator **10** shown in FIG. 1 can be used to generate movement of the moveable element **16** as shown in FIG. 2. By activating the SMA actuator **20,** a force is generated which displaces the moveable element **16** and transducer **24** in a first direction since the anchor **12** is secured relative to the elongate member (not shown). FIG. 2a illustrates movement in a first direction, indicated by the arrow, which is rotational about the longitudinal axis of the actuator mechanism **10.** FIG. 2c illustrates a movement in a first direction, indicated by the arrow, which is substantially parallel to the longitudinal axis of the actuator mechanism **10.** The direction of movement generated by activation of the SMA actuator **20** will depend on configuration of the SMA actuator **20** relative to the anchor **12** and moveable element **16,** as well as the shape which is trained into the SMA actuator **20.** For example, the SMA actuator **20** shown in FIG. 2a is trained to twist when activated, while the SMA actuator **20'** shown in FIG. 2c is trained to contract. A combination of rotational and longitudinal movements is possible as well, for example by using an SMA actuator trained to twist and extend or contract, or by using a combination of SMA elements or actuators. For example, two or more SMA actuators could be linked in series.

[0057] FIGs. 2b and 2d illustrate counter movements in a second direction, indicated by the arrows, which provides an oscillating movement to the moveable element **16** and transducer **24.** This counter movement is provided by the deformable component **22** or **22′**, preferably when the SMA actuator **20** or **20′** is deactivated. The deformable component **22** can be any elastic or superelastic material, or a second SMA actuator. The deformable component is in a relaxed state when the SMA actuator **20** or **20′** is in the deactivated state. When the first SMA actuator **20** or **20′** is activated, as shown in FIGs. 2a and 2c, the deformable component **22** or **22'** is deformed by the movement of the moveable element **16** since the second anchor **14** is secured relative to the elongate member (not shown).

[0058] In an embodiment where the deformable component **22** or **22′** is an elastic or superelastic material, the energy stored in the deformable component **22** or **22′** when it is in its deformed state shown in FIGs. 2a and 2c moves the moveable element **16** and transducer **24** to the position shown in FIGs. 2b and 2d when the first SMA **20** or **20′** is deactivated. This movement in the second direction, indicated by the arrow, is counter to the movement in the first direction. By alternately activating and deactivating the first SMA 20 or **20′**, a cyclical movement of the moveable element **16** and transducer **24** will result. This cyclical movement can be rotational about the longitudinal axis of the of the actuator mechanism **10** as shown in FIGs. 2a and 2b, or approximately parallel to the longitudinal axis of the actuator mechanism **10** as shown in FIGs. 2c and 2d, or a combination of rotational and longitudinal movement (not shown).

[0059] In a preferred embodiment, the deformable component **22** or **22'** is a second SMA actuator that is trained to move the moveable element **16** and transducer **24** in a second direction which is counter the movement in the first direction caused by activation of the first SMA actuator **20** or **20'.** In this embodiment, the cyclical motion is generated by the alternating activation of the first SMA actuator **20** or **20'** and the second SMA actuator **22** or **22′**. The activation of the first SMA actuator **20** or **20'** deforms the second SMA actuator **22** or **22'** which is in its inactive state, as illustrated in FIGs. 2a and 2c. The first SMA actuator **20** or **20'** is deactivated and the second actuator SMA **22** or **22'** is activated, causing the deformation of the first SMA actuator **20** or **20'** and the movement of the moveable element **16** and transducer **24** as illustrated in FIGs. 2b and 2d.

[0060] Figure 3 shows another embodiment of the invention including the actuator mechanism **10** illustrated in FIGs. 1 and 2. As in FIG. 1, the actuator mechanism **10** in FIG. 3 includes a first anchor **12,** a second anchor **14,** a movable element **16.** The first anchor **12** is connected to the movable element **16** by a SMA actuator **20.** The second anchor **14** is connected to the movable element **16** by a deformable component **22.** In the embodiment illustrated in FIG. 3, the ultrasound transducer **24** is connected to the moveable element **16** by a connecting arm **26,** such that movement of the moveable element **16** results in movement of the ultrasound transducer **24** and connecting arm **26.** The movement of the moveable element **16** is generated as described above and illustrated in FIG. 2. In an alternate embodiment, the portion of the connecting arm **26** that is shown extending past the moveable element **16** and passing through the second anchor **14** is removed. The connecting arm **26** can have a lumen (not shown), and optionally wires can pass through the lumen to connect the transducer **24** to an ultrasound signal generator and processor located at the proximal end of the elongate member in which the actuator mechanism and transducer are housed. While the actuator mechanism **10** is illustrated as having the SMA actuator **20** in closer proximity to the transducer **24** than the deformable component **22,** one of skill in the art will readily appreciate that the actuator mechanism **10** can be oriented such that the location of the SMA actuator **20** and the deformable component **22** are reversed.

[0061] In several embodiments disclosed herein, the connecting arm **26** is shown passing through the center of the anchor **12** and **14** and moveable element **16.** One of skill in the art will recognize that it is not necessary to locate the connecting arm **26** along the longitudinal axis of the actuator mechanism **10.** For example, the connecting arm **26** could be located on an exterior surface of the moveable element **16,** and the anchor **12** could have a cut-out to allow the movement of the connecting arm **26** over the anchor **12.** In addition, it can be desirable to provide structural supports for the moveable element **16** to stabilize its movement within the elongate member.

[0062] Figure 4 illustrates an elongate member **30** which has a distal end **32** in which the actuator mechanism and ultrasound transducer **34** are housed. The distal end **32** of the elongate member **30** has at least a portion **36** of the elongate member which is transparent to ultrasound energy. The ultrasound transducer **34** is oriented to transmit and receive ultrasound energy through this portion **36.** The ultrasound transparent portion **36** can be a window made of an ultrasound transparent material, a material which is partially or substantially transparent to ultrasound energy, or the window can be a cutout such that there is no material between the transducer and the outside environment. The portion **36** is desirable where the distal end **32** of the elongate member **30** is made of a substance that absorbs ultrasound energy. In an alternative embodiment, the entire distal end **32** or elongate member **30** is transparent to ultrasound energy.

[0063] Figure 5 illustrates the distal end **40** of an elongate member, where all but the distal tip **41** of the elongate member is transparent so that the actuator mechanism **42** housed in the distal end **40** is visible. The actuator mechanism **42** is similar to the one illustrated in FIG. 3, with the addition of support members **44** disposed within the anchors **46.** The support members **44** support the connecting arm **50,** which connects the moveable element **52** and ultrasound transducer structure **54,** acting to stabilize the movements of the connecting arm **50** and moveable element **52.** The connecting arm **50** is free to rotate or slide within the support members **44,** but not the moveable element **52.** The support members **44** can be separate elements as shown in FIG. 5, or the anchors **46** can be fabricated to perform the function of the support members **44.** The actuator mechanism **42** is used to generate movement of the moveable element **52,** connecting arm **50** and ultrasound transducer structure **54** in the manner described above in reference to FIG. 2. The connecting arm **50** and moveable element **52** can be a single piece. In another embodiment, the moveable element **52** is eliminated, and the SMA actuator **62** and deformable component **64** are attached directly to the connecting arm **50.**

[0064] In the embodiment shown in FIG. 5, the ultrasound transducer structure **54** has two ultrasound transducer crystals **56** and **56'** for sending and receiving the ultrasound signal, which share a common backing **60.** The backing **60** provides support for the transducer crystals **56** and **56′**, as well as a barrier to absorb the ultrasound energy emitted by the back face of the transducer crystals **56** and **56′**. By using two transducer crystals **56** and **56′**, more of the interior wall of the vasculature or other structure can be imaged by a device of approximately the same size.

[0065] Figure 6 shows another embodiment wherein there are two ultrasound support structures **70** and **70′** stacked orthogonally, with each transducer support structure **70** and **70'** having two transducer crystals **72** and **72'** sharing a common backing **74** and **74'.** This configuration allows for an even larger field of view, as each transducer crystal **72** and **72'** generates a signal oriented in a different direction. One of skill in the art will recognize that the ultrasound support structures **70** and **70'** can be oriented to each other at any desirable angle. Additionally, the transducer crystals **72** and **72'** can be oriented on the support structures **70** and **70′** and with respect to each other in alternate configurations. Preferred embodiments of ultrasound transducers having more than one transducer crystal are described in more detail below and in reference to FIG. 12.

[0066] Figure 7 illustrates a preferred embodiment of the current invention. Shown in FIG.7 is an actuator mechanism **80** which has two anchors **82** and **82′**, a moveable element **84** connected to the anchor **82** and **82'** by an SMA actuator **86** and a deformable component **90.** A connecting arm **92** connects the moveable element **84** to an ultrasound energy reflector **94.** The reflector **94** has a surface **96** which is oriented to reflect ultrasound energy to and from an ultrasound transducer **100.** Movement of the moveable element **84,** connecting arm **92** and reflector **94** can be achieved as described above, with reference to FIG. 2. In another embodiment, the actuator mechanism **80** is configured to move the reflector **94** substantially parallel to the longitudinal axis of the actuator mechanism **80,** as described above. One of skill in the art will recognize that to maximize longitudinal movement, a space can be introduced between the anchor **82'** and the ultrasound energy reflector **94** to allow the reflector **94** to move in a proximal and distal direction. As discussed above, the orientation of the actuator mechanism **80** could be reversed such that SMA actuator **86** is closer to the reflector **94**, and the deformable component 86 is more distant.

[0067] In the embodiment shown in FIG. 7, the transducer **100** and reflector **94** are oriented such that ultrasound energy is reflected from the transducer away from the device at an orthogonal angle, about 90°, relative to the longitudinal axes of the actuator mechanism **80** and elongate member (not shown). The angle of the reflector can be changed so that the ultrasound energy transmitted to and from the ultrasound transducer is at an angle between about between about 15° and about 165°, with the preferred angle for side-looking ultrasound being between about 80° and about 110°. Angles contemplated include about 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 105, 110, 115, 120, 125, 130, 135, 140, 145, 150, 155, 160, and about 165 degrees, or can fall within a range between any two of these values. By decreasing the angle between the surface of the reflector and the surface of the transducer, the ultrasound energy will be reflected in a more forward-looking direction, that is toward the distal tip of the device. This can be useful in some applications where it is desirable to image the area in front of the device, such as when navigating a tortuous path through a blockage in the vasculature.

[0068] In the embodiment shown in FIG. 7, the reflector **94** can be shaped for specific purposes. For example, the surface **96** can be concave to focus the ultrasound beam into a smaller beam for certain imaging requirements. In other embodiments the surface is convex. In other embodiments, the reflector **94** has more than one reflective surface.

[0069] Figure 8 is a partial cut-away view which illustrates the device of FIG. 7 housed in the distal end **102** of an elongate member. A portion of the distal end housing the actuator mechanism **80** is cut away to show the actuator mechanism **80.** The portion of the distal end adjacent to the reflector **94** is a window **104** which is transparent to ultrasound energy. This permits ultrasound energy to be transmitted to and from the ultrasound transducer **100** through the distal end **102** of the elongate member. Alternatively, the configuration of the actuator mechanism **80** and the transducer **100** can be reversed - the actuator mechanism **80** is housed in the distal end of the elongate member and the transducer is located closer to the proximal end of the device.

[0070] Figure 9 is a schematic diagram of another embodiment of the current invention, where the imaging apparatus uses optical coherence tomography. OCT relies on light emitted from a fiber optic which is directed to the surface of the vasculature being imaged. The imaged surface reflects light back to the device where the same or another fiber optic transmits the signal to a processor outside the patient. Based on differential reflectance of the surface, and image is formed from the signal. FIG. 9 illustrates an actuator mechanism **110** similar to the ones disclosed in the previous figures, which has two anchors **112** and **112',** a moveable element **114** connected to the anchors **112** and **112'** by an SMA actuator **116** and a deformable component **120.** A connecting arm **122** connects the moveable element **114** to a reflector **124.** The reflector has a surface **126** which is oriented to reflect light energy to and from an optical fiber **130.** The actuator mechanism **110,** connecting arm **122,** reflector **124** and fiber optic **130** are advantageously housed in the distal end of an elongate member **132.** The apparatus further includes a window **134** that is transparent to light energy, located at the distal end of the elongate member **132.**

[0071] While the connecting arm **122** is free to move relative to the anchors **112** and **112',** it is secured to the moveable element **114.** Movement of the moveable element **114,** connecting arm **122** and reflector **124** can be achieved as described above with reference to FIG. 2. Rotational movement of the reflector **124** about the longitudinal axes of the actuator mechanism **110** and elongate member **132** is illustrated by the arrow in FIG. 9. In another embodiment, the actuator mechanism **110** is configured to move the reflector 124 substantially parallel to the longitudinal axes, as previously described. Also as discussed above, the connecting arm 122 can be supported by the anchors 112 and 112' or support elements disposed in the anchors. One of skill in the art will recognize that the connecting arm 122 and moveable element 114 can be fabricated from a single piece of material, or be separate pieces secured together, for example by glue, welding, snap-fit, or frictional forces due to a tight fit. These are examples only, and are not limiting. In an alternative embodiment, the SMA actuator 116 and deformable component 120 are attached directly to the connecting arm 122.

[0072] Since the optical fiber 130 is stationary and not mounted on the actuator mechanism 110, it eliminates the rotational load associated with conventional OCT devices which require rotating the entire length of the optical fiber. As a result, the actuator mechanism can potentially generate a wider range of motion due to the smaller load associated with the connecting arm **122** and reflector **124.** Since the OCT imaging device is based on a sweeping reflector, the fiber optic is can remain motionless, reducing or eliminating image distortion and issues associated with the torque generated by the spinning optical fiber.

[0073] The reflector **124** can be shaped for specific purposes. For example, the surface **126** can be concave to focus the coherent light into a smaller beam for certain imaging requirements. In other embodiments the surface is convex. The surface **126** can be designed to replace the lens typically attached to the end of a fiber optic when used for OCT. In this case the reflector **124** is used to focus the coherent light at the distance needed to image the vasculature, and the lens is not necessary. In some embodiments the reflector **124** is a mirror, in others, it is a prism. A prism allows refractive optical coherence tomography (as opposed to reflective tomography using a mirror.) The prism can also be designed to replace the lens typically required at the distal tip of the optical fiber. In other embodiments, the reflector **124** has more than one reflective surface. In another embodiment, one or more additional optical fibers and/or reflectors are provided to increase the field of view, or to provide different wavelengths of light.

[0074] Figure 10 is a schematic of another embodiment of the invention where the actuator mechanism **140** rotates the distal end of the fiber optic used for OCT. FIG. 10 illustrates an actuator mechanism **140** which has two anchors **142** and **142',** a moveable element **144** connected to the anchors **142** and **142′** by an SMA actuator **146** and a deformable component **150.** The moveable element **144** is secured to the distal end of a fiber optic **154** by, for example but not limited to, crimping, glue, welding, snap-fit, set screw, or frictional forces due to a tight fit. The optical fiber **154** which has a prism **156** or other reflective surface mounted on its distal tip. The prism **156** has a surface oriented to refract light energy to and from the optical fiber **154** as illustrated by the arrows. The actuator mechanism **140,** fiber optic **154** and prism **156** are shown housed in the distal end of an elongate member **160.** In the embodiment shown in FIG. 10, a portion of the distal end of the elongate member is a window **162** that is transparent to light energy.

[0075] While the optical fiber **154** is free to move relative to the anchors **142** and **142′**, it is secured to the moveable element **144.** Movement of the moveable element **144** can be achieved as described above, and as illustrated in FIG. 2. Because the moveable element **144** is secured to the fiber optic **154,** rotational movement of the moveable element as illustrated by the arrow in FIG. 10 results in rotational movement of the distal end of the fiber optic **154** and prism **156** about the longitudinal axis of the elongate member.

[0076] The sweeping motion of the actuator mechanism **140** creates a scanning pattern and can achieve a field of views in a range of angles, depending upon the strain characteristics of the optical fiber **154.** This produces the required scanning motion for OCT imaging without requiring the rotation of the entire fiber optic and the highspeed mechanical rotator in the proximal end of the device. In another embodiment, one or more additional actuator mechanisms are spaced along the fiber optic from the distal end toward the proximal end, increasing the rotational displacement of the distal end or the entire length of the optical fiber, and distributing the rotational load generated along the length of the optical fiber.

[0077] FIG. 11 is a schematic illustration of an actuator mechanism **170,** which has two anchors **172** and **172′**, a moveable element **174** connected to the anchors **172** and **172′** by an SMA actuator **176** and a deformable component **180.** A reflector **182** is mounted on the moveable element **174.** The reflector has a surface **184** which is oriented to reflect light energy to and from an optical fiber **186.** An optional support structure **190** stabilizes the moveable element **174.** The actuator mechanism **170,** reflector **182** and fiber optic **186** are shown housed in the distal end of an elongate member **192** as shown in FIG. 9. The actuator mechanism provides cyclical movement of the moveable element **174** and reflector **182** as described previously.

[0078] Figures 9, 10 and 11 illustrate a reflector or prism oriented such that light energy is reflected from the fiber optic away from the device at an orthogonal angle, about 90°, relative to the longitudinal axes of the actuator mechanism and elongate member. The angle of the reflector can be changed so that the light energy transmitted to and from the fiber optic is at an angle between about 15° and about 165° relative to the longitudinal axis of the device, with the preferred angle being between about 80° and about 110°. Angles contemplated include about 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 105, 110, 115, 120, 125, 130, 135, 140, 145, 150, 155, 160, and about 165 degrees, or can fall within a range between any two of these values. By adjusting the angle between the reflective surface of the reflector or prism and the end of the fiber optic, the light can be reflected in a more forward-looking direction, that is toward the distal tip of the device. This can be useful in some applications where it is desirable to image the area in front of the device, such as when navigating a tortuous path through a blockage in the vasculature.

[0079] As described herein, at least a portion of the elongate member is transparent to ultrasound energy or light energy. This includes a window made of an ultrasound or light energy transparent material, a material which is partially or substantially transparent to ultrasound or light energy, or the window can be a cut-out such that there is no material between the transducer, reflector or prism and the outside environment. In other embodiments the entire distal end or elongate member is transparent.

[0080] The actuator described herein can be made very small, such that the actuator has a diameter/width between about 5μm and about 1000μm, with the preferred size being between about 5μm and about 100μm. The actuator preferably has a diameter or width of, or of about, 5, 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 200, 300, 400, 500, 600, 700, 800, 900, or 1000 μm, or is at least about, 5, 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 200, 300, 400, 500, 600, 700, 800, 900, or 1000 μm, or is no more than about 5, 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 200, 300, 400, 500, 600, 700, 800, 900, or 1000 μm, or can fall within a range between any two of these values. The range of lengths preferred for the actuator is quite broad, and depends on the application. For rotational motion, the length of the actuator mechanism can be from about 20μm to about 10mm, with the preferred size being from about 200μm to about 10mm. For longitudinal motion, the length of the actuator can be from about 100μm to about 20mm, with the preferred length being from about 1mm to about 20mm. The actuator preferably has a length of, or of about, 20, 30, 40, 50, 60, 70, 80, 90, 100, 200, 300, 400, 500, 600, 700, 800, 900 μm, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, or 20 mm, or is at least about, 20, 30, 40, 50, 60, 70, 80, 90, 100, 200, 300, 400, 500, 600, 700, 800, 900 μm, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, or 20 mm, or is no more than about 20, 30, 40, 50, 60, 70, 80, 90, 100, 200, 300, 400, 500, 600, 700, 800, 900 μm, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, or 20 mm, or can fall within a range between any two of these values.

[0081] The outside diameter of the elongate member, such as a guide wire or catheter containing an imaging device described herein can be as small as from about 0.005" to about 0.100" outside diameter. Preferably, the outside diameter of the elongate member is, or is about 0.5, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, or 100 hundredths of an inch, or is at least about, 0.5, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, or 100 hundredths of an inch, or is no more than about 0.5, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, or 100 hundredths of an inch, or can fall within a range between any two of these values.

[0082] The range of motion generated by the actuator mechanism described herein will vary depending of the application. Rotational motion can be in a range from about 1 or 2 degrees up to about 400 degrees, depending on the area of interest. Angles of rotational displacement generated by the actuator mechanism are, or are about, 1, 2, 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 105, 110, 115, 120, 125, 130, 135, 140, 145, 150, 155, 160, 165, 170, 175, 180, 190, 195, 200, 205, 210, 215, 220, 225, 230, 235, 240, 245, 250, 255, 260, 265, 270, 275, 280, 285, 290, 295, 300, 305, 310, 315, 320, 325, 330, 335, 340, 345, 350, 355, 360, 365, 370, 375, 380, 385, 390, 395, or 400 degrees, or at least about 1, 2, 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 105, 110, 115, 120, 125, 130, 135, 140, 145, 150, 155, 160, 165, 170, 175, 180, 190, 195, 200, 205, 210, 215, 220, 225, 230, 235, 240, 245, 250, 255, 260, 265, 270, 275, 280, 285, 290, 295, 300, 305, 310, 315, 320, 325, 330, 335, 340, 345, 350, 355, 360, 365, 370, 375, 380, 385, 390, 395, or 400 degrees, or no more than 1, 2, 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 105, 110, 115, 120, 125, 130, 135, 140, 145, 150, 155, 160, 165, 170, 175, 180, 190, 195, 200, 205, 210, 215, 220, 225, 230, 235, 240, 245, 250, 255, 260, 265, 270, 275, 280, 285, 290, 295, 300, 305, 310, 315, 320, 325, 330, 335, 340, 345, 350, 355, 360, 365, 370, 375, 380, 385, 390, 395, or 400 degrees, or can fall within a range between any two of these values. By adjusting the power and/or duration of the activation signal to one or more of the SMA actuators, the degree of rotation or length of longitudinal displacement can be adjusted while the device is in the patient, allowing the operator to adjustably define a specific image field of view. The preferred range of rotational displacement generated by the actuator device is from about 25 to 360 degrees. In addition, it is possible to use the device of the invention for singe point interrogation for optical coherence reflectometry or Doppler effect measurements.

[0083] The amount of longitudinal displacement generated by the actuator mechanism is also dependent on the length of the area of interest. The length of longitudinal displacement can be from about 100μm to about 30mm or more. The length of longitudinal displacement generated by the actuator mechanism preferably is, or is about 100, 200, 300, 400, 500, 600, 700, 800, 900 μm, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, or 30 mm, or is at least about, 100, 200, 300, 400, 500, 600, 700, 800, 900 μm, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, or 30 mm, or is no more than about 100, 200, 300, 400, 500, 600, 700, 800, 900 μm, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, or 30 mm, or can fall within a range between any two of these values.

[0084] The frequency of the motion generated by the actuator mechanism can range from about 1Hz to about 100Hz. The preferred frequency of motion is between about 8Hz and 30Hz. The frequency of movement generated by the actuator mechanism is, or is about, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, or 100 Hz, or at least about 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, or 100 Hz, or no more than about 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, or 100 Hz, or can fall within a range between any two of these values.

[0085] In some embodiments, the actuator mechanism disclosed herein is made without any mechanical joints.

[0086] When the actuator described above is used to generate movement of an ultrasound transducer, the area imaged by a single transducer is limited by the range of movement the actuator can generate. One way to achieve a larger field of view is to use multiple transducer crystals. The prior art discloses phased array devices where individual crystal transducers are used in combination to generate an ultrasound wave for imaging. In these prior art devices, the individual crystals are mounted on separate backings and are not capable of individually producing an ultrasound signal for imaging. In contrast, the individual transducer crystals used in the transducers of the instant are preferably mounted on a shared backing and are preferably capable of individually producing an ultrasound signal for imaging.

[0087] As used herein, transducer crystal or crystal transducer refers to the material used to produce and/or receive the ultrasound signal. Materials used for making the transducer crystal are known in the art and include quartz and ceramics such as barium titanate or lead zirconate titanate. Ultrasound transducer crystals for IVUS utilize frequencies from about 5 MHz to about 60MHz, with the preferred range being from about 20MHz to about 45MHz.

[0088] Ultrasound crystals are preferably substantially rectangular, square, elliptical, or circular, although any shape that produces a functional ultrasound transducer is contemplated. As used herein, the top and bottom edge of a transducer crystal are defined by substantially parallel lines bounding the transducer, a first and second side edge are defined by a second set of substantially parallel lines bounding the transducer, where the lines defining the top and bottom edges are substantially perpendicular to the lines defining the first and second side edges. As defined herein, ellipses, circles, irregular shapes, etc. can have top, bottom, first and second edges.

[0089] Figure 12 illustrates a schematic of ultrasound transducers having one, two or three crystal transducers. The dashed lines shown in FIG. 12 represent the direction the ultrasound energy is transmitted and received from the transducer crystals. FIG. 12a shows an ultrasound transducer **200** having one crystal transducer **202** on a backing structure **204.** The backing material can be any material known to those in the art which absorbs ultrasound energy radiated from the transducer crystals back face. FIG. 12b shows an ultrasound transducer **210** having two crystal transducers **212** and **214** on a single backing structure **216.** FIG. 12c shows an ultrasound transducer **220** having three crystal transducers **222, 224** and **226** on a single backing structure **228.**

[0090] FIGs. 12d, 12e, and 12f show the range of fields of view with the different configurations of transducers shown in FIG. 12a, 12b and 12c, respectively. As an example, assume that the actuator mechanism (not shown) used to move the transducer can generate 60° rotational motion. With a single transducer as shown in FIGs. 12a, rotation of the ultrasound transducer **200** through 60° will provide a 60° field of view as shown in FIG. 12d, where the crystal transducer **202** is shown at the two extremes of the range of motion (the backing **204** is excluded for clarity.) If two transducers **212** and **214** are arranged with a 60° angle between their respective fields of view as shown in FIG. 12b, rotating the transducer structure **210** through 60° as shown by the two positions illustrated in FIG. 12e will provide a field of view totaling 120° with the same actuator. Similarly, three-transducers configured with a 60° angle between each crystal transducer **222, 224** and **226** as shown in FIG. 12c will have a field of view equivalent to 180° if the transducer is rotated through 60° as shown in FIG. 12f.

[0091] Although a 60° angle between the beams of the transducer crystals is shown in FIG. 12, any angle between 0° (equivalent to the field of view provided by a large crystal) and 180° is encompassed by the present invention. Angles encompassed by the invention include about 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 105, 110, 115, 120, 125, 130, 135, 140, 145, 150, 155, 160, 165, 170, 175, and about 180 degrees, or can fall within a range between any two of these values. In some embodiments, the angles defined by the adjacent pairs of crystals are not equal. For example, where three crystals are used, the angle defined by the third crystal and the second crystal can be different than the angle defined by the first crystal and the second crystal. The angle between the faces of the transducer crystals is preferably about the same as the degrees of deflection which can be achieved by the actuator mechanism. This maximizes field of view without significant overlap or gaps between the individual fields of view for each transducer crystal. For example, if two crystal transducers **212** and **214** are aligned at 60° as illustrated in FIG. 12b, but the actuator can only rotate the transducer structure by 30°, there will be a gap of approximately 30° between the fields of view generated by each transducer crystal. Similarly, if the actuator can rotate through 90°, there will be a 30° field of view overlap between the two fields of view generated by each transducer crystal. While an overlap or gap in the fields of view can be desirable in some applications, the preferred embodiment provides for minimal gaps or overlaps. Importantly, the individual transducer crystals are placed with their edges adjacent or touching, such that the size of any gap between the fields of view of the individual crystal transducers is minimized and significantly reduced. In a preferred embodiment, the individual transducer crystals are configured such that any gap between the individual fields of view are substantially eliminated. This provides an improved image quality.

[0092] While FIG. 12 illustrates an ultrasound transducer with 1, 2, or 3 crystals, more crystals can be used. Also contemplated are ultrasound transducers with 4, 5, 6, 7, 8, 9, or 10 transducer crystals. The crystals can be arranged on a single backing device, or on multiple backing devices as illustrated in FIG. 6. For single crystal transducers the diameter of the crystal if circular shaped, or width if rectangular shaped, is preferably from about 10μm to about 10mm, and more preferably from about 100μm to about 1mm. For transducers with multiple crystals, the combined diameter or width of the individual crystals is preferably from about 10μm to about 10mm, and more preferably from about 100μm to about 1mm. Preferably, the diameter or width of the individual crystals on a given transducer is approximately equal, although crystals of different diameters or widths can be combined.

The individual transducer crystals preferably have a diameter or width of, or of about, 100, 200, 300, 400, 500, 600, 700, 800, 900, or 1000 μm, or are at least about, 100, 200, 300, 400, 500, 600, 700, 800, 900, or 1000 μm, or are no more than about 100, 200, 300, 400, 500, 600, 700, 800, 900, or 1000 μm, or can fall within a range between any two of these values.

[0093] In another embodiment, the multiple transducer configurations disclosed herein are utilized in a device in which the actuator is configured to provide longitudinal, rather than rotational motion, for example as shown in FIGs. 2c and 2d. As with the rotational movement illustrated in FIG. 12, combining multiple transducers with longitudinal motion can also provide a larger field of view with the same actuator.

[0094] The multiple transducer configuration disclosed herein can also be used for forward looking ultrasound devices. Providing a 180° field of view allows ultrasound imaging with the capability of side-looking as well as forward-looking in a single device. A preferred forward looking device is disclosed in U.S. Patent Publication No. US-2004-0056751-A1. Other forward looking devices include those disclosed in U.S. Patent Nos. 5,379,772 and 5,377,685. As used herein, a pivot point is a point around which the transducer is rotated, and includes mechanical joints, for example those disclosed in U.S. Patent No. 5,379,772, FIGs. 2, 5, and 6. While the aforementioned forward looking devices disclose a single crystal transducer, applicants have discovered that transducers having multiple crystals dramatically increase the field of view. As was described with reference to side-looking devices, the multiple crystal transducers are disposed on the actuator mechanism.

[0095] U.S. Patent Publication No. US-2004-0056751-A1 discloses an elastic or superelastic material utilized as a structural material for a micromanipulator. In principle, when a compliant mechanism is deformed with an actuator, strain energy is stored inside the underlying structure during deformation (elastic and plastic). The stored energy is then directly utilized to produce a bias force to return the structure to its original shape. However, an elastic material such as stainless steel can also be utilized as a structural material for compliant mechanisms

[0096] According to an aspect of the disclosure, a Nd: YAG laser is implemented in the fabrication of the compliant structure out of a tube. A tubular nitinol structure with compliant mechanism was successfully fabricated using laser machining with a laser beam size of about 30μm. The outer diameter of the tube is about 800μm and the wall thickness is about 75μm. Actual feature size is about 25μm, which is mostly limited by the size of the laser beam. Thus, by reducing the beam size, resolution of the laser machining can be enhanced.

[0097] To shape a nitinol structure, there are three fabrication processes currently commercially available: chemical etching, laser machining and micromechanical cutting. However, these two processes are not able to precisely control etching depth. Thus, it is very difficult to have a variation in thickness and, consequently, the thickness of the mechanism determines the substrate thickness. This presents another issue in design, which is structural rigidity. For instance, if the substrate thickness is on the order of tens of microns, the supporting structure also starts deflecting as the mechanism moves. This deflection at the supporting structure, which is supposed to be fixed, directly contributes to loss of output displacement. Structural rigidity is mostly a shape factor, which is related to flexural modulus, EI. Considering the structural rigidity, a tube shape is more attractive than a plate form.

[0098] Figure 13a illustrates an exemplary tubular structure 1200a with a built-in compliant mechanism **1201a.** Figure 13b illustrates another exemplary tubular structure **1200b** with a built-in compliant mechanism **1201b** in a helical configuration having helix **1291** and helix **1292** intertwined in a "double helix"-like fashion. The mechanism design can be any shape and/or configuration as long as it utilizes structural compliance (elasticity and/or superelasticity) as a main design parameter. Similarly, as one skilled in the art would appreciate, the rest of the tubular structure can be in any suitable configuration, size, and length, etc., optimized for a particular application and thus is not limited to what is shown here. Moreover, in addition to nitinol, other flexible, resilient biocompatible metal or polymer materials can also be utilized as long as they have reversible structural behaviors, i.e., have elastic and/or superelastic behaviors while actuated.

[0099] As illustrated in Figure 13b, compliant mechanisms can be in a "double helix" configuration. U.S. Patent Publication No. US-2004-0056751-A1 teaches that it is desirable with the disclosed invention that any bending strain of the compliant mechanisms is distributed substantially evenly along their entire lengths. This reduces peak strain, which in various embodiments, can be, 4% or less, 3% or less, 2% or less and 1% or less. The "double helix" configuration provides greater symmetry in motion and provides a more even bending It is desired that the stiffness of compliant mechanisms in different directions be substantially the same.

[0100] In various embodiments, the elastic bending strength of the compliant mechanisms is customized in order to match with that of the actuators. In some embodiments, the actuators have slightly stiffer elastic bending strengths than those of the compliant mechanisms. In one embodiment, the compliant mechanisms are stiffer than the actuators when the actuators are relaxed, and the compliant mechanisms are softer than the actuators when the actuators are active. It is desirable to provide compliant mechanisms in configurations, such as those of the "double helix" configurations, that have as little stress concentration as possible.

[0101] According to the invention disclosed in U.S. Patent Publication No. US-2004-0056751-A1, the strain of a compliant mechanism is distributed, while minimizing the occurrence of strain location. The mechanical characterization of a compliant mechanism can be tuned by modifications in, (i) stiffness, (ii) peak strain (maximum strain), (iii) size, (iv) fatigue life, and the like. In one embodiment, the upper limit of strain is no more than 4%. The bending stiffness depends on actual application. By way of illustration, and without limitation, the bending stiffness of a compliant mechanism can be at least .5 N-mm and no more than 10 N-mm. In various embodiments, compliant mechanisms are stiffer than the imaging device. The associated actuators are also stiffer than the imaging device. The actuators need a longer thermal time constant than the imagining device.

[0102] Figure 14 schematically shows, according to an aspect of the invention disclosed in U.S. Patent Publication No. US-2004-0056751-A1, a micromanipulator **1300** tightly coupled with an ultrasound transducer **1310** for image scanning. Micromanipulator **1300,** as well as the other embodiments of micromanipulators disclosed herein, provide for steering, viewing and treatment at sites within vessels of the body, as well as for industrial applications.

[0103] The micromanipulator **1300** enables the ultrasound transducer **1310** to be directly coupled to the compliant mechanisms **1301.** In this fashion, the rotational center of the transducer **1310** for the scanning motion is substantially closer to the rotational axis of the mechanism **1301.** In an embodiment, SMAs are implemented as main actuators **1320** for the micromanipulator **1300.** To allow the SMAs **1320** be attached thereto, the micromanipulator **1300** might have one or more attachment points or built-in micro structures such as welding-enabling structures **1302** as shown in a cross-sectional view A-A and clamping-enabling structures **1302'** as shown in another cross-sectional view A'-A'. In some embodiments, the SMAs **1320** are attached to the compliant apparatus via the one or more attachment points or welding-enabling structure **1302** using a laser having a laser beam size of about 200 μm or less. In some embodiments, the SMAs **1320** are fastened to the compliant apparatus via the built-in clamping-enabling structures **1302'.**

[0104] The compliant mechanisms **1301** are actuated with SMA **1320** actuators based on shape memory effects including contraction as well as rotation motion to maximize output displacement. As one skilled in the art can appreciate, the SMA actuators can be in any shape such as wire, spring, coil, etc. and thus is not limited to what is shown.

[0105] Another aspect related to the current invention is a method for visualizing the interior of a patient's vasculature, or other structure with a lumen. The method comprises inserting the inserting the distal end of the elongate member of any of the apparatuses disclosed herein into the vasculature of a patient. The distal end is advanced through the vasculature, optionally under the guidance of x-ray fluoroscopic imaging to the location of the blockage, legion, or other area to be imaged. Alternatively, the imaging device can be used instead of or in addition to the x-ray fluoroscopic imaging to guide the device through the vasculature.

[0106] To generate an image, an ultrasound signal generator/processor located outside the patient is activated, generating an ultrasound signal from the ultrasound transducer. The actuator mechanism described herein is used to generate a cyclical movement of the ultrasound transducer or reflector as described above. In the case of OCT, the fiber optic is used to transmit a light signal from a signal processor unit outside the patient to the distal tip of the optical fiber. The reflector, prism, or distal end of the optical fiber is moved in a cyclical motion by the actuator mechanism as described herein. The cyclical movement sweeps the ultrasound or light energy over the area being imaged. The ultrasound or light energy is reflected back to the ultrasound transducer or fiber optic, respectively. The signal is then transmitted to the proximal end of the device where it is processed to produce an image.

[0107] In some embodiments of the current invention, the elongate member has one or more lumens along the longitudinal axis of the elongate member. The lumen(s) can be used to house the actuator mechanism, compliant mechanism, optical fiber and other devices described herein. The lumen(s) can also be used to house wiring which connects the ultrasound transducer(s) and SMA actuator(s) disposed in the distal end of the elongate member to devices located adjacent to the proximal end of the elongate member. These devices include, for example, other components of an ultrasound or OCT imaging system, such as an ultrasound or light source generator, receiver and computer located near the proximal end of the elongate member. In some embodiments, the imaging device of the invention is connected wirelessly to one or more components of the imaging system. The ultrasound imaging device of the invention is optionally configured to provide real-time imaging of the environment at the distal end of the elongate member. Other devices include a signal generator for controlling the activation of the SMA actuators.

[0108] The lumen(s) can also be used to flush the distal end of the ultrasound device with fluid. This fluid can improve the ultrasound signal, can be used to flush the area around the IVUS imaging device to ensure that the area is free of debris or bubbles which would interfere with the performance of the ultrasound device, and cool the ultrasound transducer and/or the SMA actuators. In an embodiment with using one or more lumens to flush the distal end of any of the devices described herein, it is desirable to provide a means for the fluid to circulate through the area around the ultrasound transducer, such as another lumen to return the fluid to the proximal end of the elongate member, or an opening in the distal end of the elongate member so that the fluid can escape. Optionally, a fluid pump can be attached to the proximal end of the elongate member to facilitate fluid circulation through the lumen(s). In another embodiment, the distal end of the elongate member contains fluid which is sealed or injected in the distal end and/or a lumen of the elongate member.

[0109] In another embodiment, SMA actuators can be used to bend or steer the distal end of the elongate members disclosed herein to allow the user to reduce the distance between the distal end of the device and image target. In the case of intravascular OCT this reduces the artifact caused by blood between the image acquisition device and the vessel wall by bringing the imaging portion of the device closer to the wall itself. Similar to current intravascular ultrasound system (IVUS), local actuators can provide the pull-back motion of the imaging tip, so it can control precisely the pull-back of the distal imaging tip and generate three-dimensional images of the blood vessel.

[0110] As discussed above, the angle or orientation of the ultrasound transducer or reflector, or the OCT reflector or prism can determine where the imaging energy is directed. For some applications, these elements direct the energy generally orthogonally from the longitudinal axis of the device. For other applications, these elements can be oriented to direct the imaging energy toward the distal tip of the device, resembling forward looking devices, or toward the proximal end of the device. In another embodiment of the invention, an additional SMA actuator is incorporated into the device to actively move the transducer, reflector or prism and change the imaging plane adaptively. This active angle control can provide side-looking and forward-looking as needed with a single imaging device.

[0111] In another embodiment, the IVUS system described herein and the OCT device described herein are combined in a single elongate member to provide both IVUS and OCT imaging in a single, compact device.

[0112] In another embodiment, the imaging devices disclosed herein are integrated into the distal end of a guide wire's rigid section, but proximal to the coil structure that defines the distal tip of a guidewire.

[0113] In another embodiment, the imaging devices described herein are combined with one or more therapeutic or interventional devices, for example, but not limited to, devices for stent placement and deployment, balloon angioplasty, directional atherectomy, cardiac ablation, PFO (patent foramen ovule) closure, transvascular re-entry, trans-septal punch, and CTO (chronic total occlusion) crossing.

[0114] The foregoing description details certain embodiments of the invention. It will be appreciated, however, that no matter how detailed the foregoing appears in text, the invention can be practiced in many ways. As is also stated above, it should be noted that the use of particular terminology when describing certain features or aspects of the invention should not be taken to imply that the terminology is being re-defined herein to be restricted to including any specific characteristics of the features or aspects of the invention with which that terminology is associated. The scope of the invention should therefore be construed in accordance with the appended claims and any equivalents thereof.

Claims

1. A side-looking intravascular ultrasound apparatus comprising:

    an elongate member (11) having a proximal end and a distal end, wherein at least a portion of said distal end is transparent to ultrasound energy;
    an ultrasound transducer disposed in said distal end; and
    an actuator mechanism (10) means for providing cyclical motion to said transducer disposed in said distal end;
    wherein a longitudinal axis of said actuator mechanism is oriented substantially parallel to a longitudinal axis of the elongate member;
    wherein said transducer is oriented to transmits ultrasound energy through said ultrasound transparent portion of said distal end at an angle of between about 15° to about 165° relative to a longitudinal axis of said elongate member,
    wherein said actuator mechanism means comprises a first anchor (12), a second anchor (14), a movable element (16), a first SMA actuator (20), connected to said first anchor and said movable element, and a deformable component (22) connected to said second anchor and said movable element, wherein said anchor elements are secured to and do not move relative to said elongate member; and
    wherein said first anchor, said second anchor, said movable element, said first SMA actuator, and said deformable component of said actuator mechanism are disposed along the longitudinal axis that is oriented substantially parallel to the longitudinal axis of said elongate member.

2. The apparatus of claim 1, wherein said apparatus has only one ultrasound transducer on said movable element.

3. The apparatus of claim 1, wherein said apparatus has only two ultrasound transducers on said movable element.

4. The apparatus of claim 1, wherein said apparatus has only three ultrasound transducers on said movable element.

5. The side-looking intravascular ultrasound apparatus of claim 1,
    wherein the ultrasound transducer is connected to said movable element;

wherein said first SMA actuator has an activated and a deactivated state; and
wherein said movable element and transducer move in a first direction relative to the elongate member and said first and second anchors upon activation of said first SMA actuator.

6. The apparatus of claim 5, wherein said deformable component comprises a second SMA actuator;
wherein said second actuator has an activated and a deactivated state; and
wherein activation of said second SMA actuator following deactivation of said first SMA actuator moves said movable element and transducer relative to the elongate member and said first and second anchors in a second direction of movement which is counter to said first direction of movement.

7. The apparatus of claim 5, wherein said deformable component is elastic or superelastic;
wherein said deformable component has a relaxed state and a deformed state;
wherein said deformable component is in a relaxed state when said first SMA actuator is deactivated;
wherein said movement of said movable element and transducer in said first direction upon activation of said first SMA actuator deforms said elastic or superelastic deformable component; and
wherein following deactivation of said first SMA actuator, said elastic or superelastic deformable component substantially returns to said relaxed state, said movable element and transducer moving in a second direction of movement which is counter to said first direction of movement.

8. The apparatus of claim 5 further comprising:

a lumen traversing the longitudinal axis of the elongate member; and
wires disposed in said lumen to electrically connect said transducer, first SMA actuator and optionally said deformable component to one or more devices at the proximal end of said elongate member.

9. The apparatus of claim 8, wherein said device is an ultrasound signal processor.

10. The apparatus of claim 5, further comprising a second ultrasound transducer connected to said movable element.

11. The apparatus of claim 5, further comprising a connecting arm (26),
said connecting arm connecting said ultrasound transducers to the movable element;
wherein said movable element, connecting arm and transducer move in a first direction relative to the elongate member and said first and second anchors upon activation of said first SMA actuator.

12. The apparatus of claim 11, wherein said deformable component comprises a second SMA actuator;
wherein said second actuator has an activated and a deactivated state; and
wherein activation of said second SMA actuator following deactivation of said first SMA actuator moves said movable element, connector and transducer relative to the elongate member and said first and second anchors in a second direction of movement which is counter to said first direction of movement.

13. The apparatus of claim 11, wherein said deformable component is elastic or superelastic;
wherein said deformable component has a relaxed state and a deformed state;
wherein said deformable component is in a relaxed state when said first SMA actuator is deactivated;
wherein said movement of said movable element, connecting arm and transducer in said first direction upon activation of said first SMA actuator deforms said elastic or superelastic deformable component; and
wherein following deactivation of said first SMA actuator, said elastic or superelastic, deformable component substantially returns to said relaxed state, said movable element, connecting arm and transducer moving in a second direction of movement which is counter to said first direction of movement.

14. The apparatus of claim 11, further comprising a second ultrasound transducer connected to a movable element.

15. The apparatus of claim 11, wherein said ultrasound transducer further comprises at least two ultrasound crystals.

16. A side-looking intravascular ultrasound apparatus comprising:

an elongate member having a proximal end and a distal end, wherein at least a portion of said distal end is transparent to ultrasound energy;
an actuator mechanism (80) disposed in said distal end, said actuator mechanism comprising a first anchor (82), a second anchor (82'), a movable element (84), a first SMA actuator (86) connected to said first anchor and said movable element, and a deformable component (90) connected to said second anchor and said movable element, wherein said anchor elements are secured to and do not move relative to said elongate member;
wherein said first anchor, said second anchor, said at least one movable element, said first

SMA actuator, and said deformable component of said actuator mechanism are disposed along a longitudinal axis that is oriented substantially parallel to a longitudinal axis of said elongate member;
a connecting arm (92) and an ultrasound energy reflector, wherein said connecting arm connects said ultrasound energy reflector to the movable element; and
an ultrasound transducer disposed in said distal end of said elongate member;
wherein said ultrasound transducer and said ultrasound energy reflector are oriented to transmit ultrasound energy through said ultrasound transparent portion of said distal end at an angle of between about 15° to about 165° relative to a longitudinal axis of said elongate member;
wherein said first SMA actuator has an activated and a deactivated state; and
wherein said movable element, connecting arm, and ultrasound energy reflector move in a first direction relative to the elongate member and said first and second anchors upon activation of said first SMA actuator.

17. The apparatus of claim 16, wherein said connecting arm and said movable element are a single piece.

18. The apparatus of claim 16, wherein said deformable component comprises a second SMA actuator;
wherein said second actuator has an activated and a deactivated state; and
wherein activation of said second SMA actuator following deactivation of said first SMA actuator moves said movable element, connecting arm and reflector relative to the elongate member in a second direction which is counter to said first direction of movement.

19. The apparatus of claim 16, wherein said deformable component is elastic or superelastic;
wherein said deformable component has a relaxed state and a deformed state;
wherein said deformable component is in a relaxed state when said first SMA actuator is deactivated;
wherein said movement of said movable element, connecting arm and reflector in said first direction upon activation of said first SMA actuator deforms said elastic or superelastic deformable component; and
wherein following deactivation of said first SMA actuator, said elastic or superelastic deformable component substantially returns to said relaxed state, said movable element, connecting element and reflector moving in a second direction, of movement which is counter to said first direction of movement.

20. The apparatus of claim 16, further comprising a second ultrasound energy reflector connected to a movable element.

21. A side-looking intravascular optical coherence tomography apparatus comprising:

an elongate member having a proximal end and a distal end, wherein at least a portion of said distal end is transparent to light energy;
an optical fiber (130) having a distal end, said distal end of said optical fiber disposed in said distal end of said elongate member;
a reflector means (124) disposed in said distal end of said elongate member and
an actuator mechanism (110) means for providing cyclical motion to said reflector;
wherein a longitudinal axis of said actuator mechanism is oriented substantially parallel to a longitudinal axis of the elongate member; and
wherein said reflector and distal end of said optical fiber is oriented to transmit light energy through said light transparent portion of said distal end of said elongate member at an angle of between about 15° to about 165° relative to a longitudinal axis of said elongate member,
wherein said actuator mechanism means comprises a first anchor (112), a second anchor (112), a movable element (114), a first SMA actuator (116) connected to said first anchor and said movable element, and a deformable component connected to said second anchor and said movable element, wherein said anchor elements are secured to and do not move relative to said elongate member;
wherein said first anchor, said second anchor, said movable element, said first SMA actuator, and said deformable component of said actuator mechanism are disposed along the longitudinal axis that is oriented substantially parallel to the longitudinal axis of said elongate member.

22. The side-looking intravascular optical coherence tomography apparatus of claim 21, wherein
the actuator mechanism means is disposed in said distal end of said elongate members ,
wherein said distal end of said optical fiber is disposed in said distal end of said elongate member substantially parallel to a longitudinal axis of said elongate member;
wherein the reflector is connected to said movable element;
wherein said first SMA actuator has an activated and a deactivated state; and
wherein said movable element and reflector move in a first direction relative to the elongate member and said first and second anchors upon activation of said first SMA actuator.

23. The apparatus of claim 22, wherein said deformable component comprises a second SMA actuator; wherein said second acruator has an activated and a deactivated state; and wherein activation of said second SMA actuator following deactivation of said first SMA actuator moves said movable element and reflector relative to the elongate .member and said first and second anchors in a second direction of movement which is counter to said first direction of movement.

24. The apparatus of claim 22, wherein said deformable component is elastic or superelastic; wherein said deformable component has a relaxed state and a deformed state; wherein said deformable component is in a relaxed state when said first SMA actuator is deactivated; wherein said movement of said movable element and reflector in said first direction upon activation of said first SMA actuator deforms said elastic or superelastic deformable component; and wherein following deactivation of said first SMA, said elastic or superelastic deformable component substantially returns to said relaxed state, said movable element and reflector moving in a second direction of movement which is counter to said first direction of movement.

25. The apparatus of claim 22, further comprising:

a lumen traversing the longitudinal axis of the elongate member; and wires disposed in said lumen to electrically connect said first SMA actuator and optionally said deformable component to one or more devices at the proximal end of said elongate member.

26. The apparatus or claim 25, wherein said device is a signal processor.

27. The apparatus of claim 22, further comprising a connecting arm (122), said connecting arm connecting said reflector to the movable element; wherein said movable element, connecting arm and reflector move in a first direction relative to the elongate member and said first and second anchors upon activation of said first SMA actuator.

28. The apparatus of claim 27, wherein said movable element and said connecting arm are a single piece.

29. The apparatus of claim 27, wherein said deformable component comprises a second SMA actuator, wherein said second actuator has an activated and a deactivated state; and wherein activation of said second SMA actuator following deactivation of said first SMA actuator moves said movable element, connecting arm and reflector relative to the elongate member and said first and second anchors in a second direction of movement which is counter to said first direction of movement.

30. The apparatus of claim 27, wherein said deformable component is elastic or superelastic, and has a relaxed and deformed state; wherein said deformable component is in a relaxed state when said first SMA actuator is deactivated; wherein said movement of said movable element, connecting arm and reflector in said first direction upon activation of said first SMA actuator deforms said elastic or superelastic deformable component; and wherein following deactivation of said first SMA actuator, said elastic or superelastic deformable component substantially returns to said relaxed state, said movable element, connecting arm and reflector moving in a second direction of movement which is counter to said first direction of movement.

31. The side-looking intravascular optical coherence tomography apparatus of claim 21, wherein the actuator mechanism means is disposed in said distal end of said elongate member; wherein said distal end of said optical fiber is disposed in said distal end of said elongate member substantially parallel to a longitudinal axis of said elongate member, said movable element connected to said distal end of said optical fiber; wherein the reflector is connected to a distal tip of said optical fiber, said reflector oriented to reflect light energy from said distal tip of said optical fiber through said transparent portion of said distal end at an angle between about 15° to about 165° relative to said longitudinal axis of said elongate member; wherein said first SMA actuator has an activated and a deactivated state; and wherein said movable element, distal tip of said optical fiber and said reflector move in a first direction relative to the elongate member and said first and second anchors upon activation of said first SMA actuator.

32. The apparatus of claim 31, wherein said deformable component comprises a second SMA actuator; wherein said second actuator has an activated and a deactivated state; and wherein activation of said second SMA actuator following deactivation of said first SMA actuator moves said movable element, distal tip of said optical fiber and said reflector relative to the elongate member and said first and second anchors in a second direction which is counter to said first direction of movement.

33. The apparatus of claim 31, wherein said deformable component is elastic or superelastic, and has a re-

laxed and deformed state;
wherein said deformable component is in a relaxed state when said first SMA actuator is deactivated;
wherein said movement of said movable element, distal tip of said optical fiber and said reflector in said first direction upon activation of said first SMA deforms said elastic or superelastic deformable component; and
wherein following deactivation of said first SMA actuator, said elastic or superelastic deformable component substantially returns to said relaxed state, said movable element, distal tip of said optical fiber and said reflector moving in a second direction of movement which is counter to said first direction of movement.

34. The apparatus of any of claims 1-33, wherein said first and second direction of movement, or said cyclical movement, is rotational about the longitudinal axis of said elongate member, or substantially parallel to the longitudinal axis of said elongate member.

35. The apparatus of claim 34, wherein said first and second direction of movement, or said cyclical movement, is rotational about the longitudinal axis of said elongate member.

36. The apparatus of claim 34, wherein said first and second direction of movement, or said cyclical movement, is substantially parallel to the longitudinal axis of said elongate member.

37. The apparatus of claim 34, wherein said rotational motion is between about 1 and about 400 degrees, and said longitudinal motion is from about 1 mm to about 20 mm.

38. The apparatus of claim 37, wherein said angle is between about 80° and about 110°.

39. The apparatus of any of claims 1-38, wherein said elongate member is a guide wire.

40. The apparatus of any of claims 1-39, wherein the diameter of said distal end of said elongate member is not more than about 0.1524 cm (0.060 inches).

Patentansprüche

1. Intravaskuläre Seitensicht-Ultraschallvorrichtung, die aufweist:

ein längliches Glied (11) mit einem proximalen Ende und einem distalen Ende, wobei mindestens ein Abschnitt des distalen Endes für Ultraschallenergie transparent ist;
einen Ultraschalltransducer, der im distalen Ende angeordnet ist; und
eine Antriebsmechanismuseinrichtung (10) zur Bereitstellung einer zyklischen Bewegung für den im distalen Ende angeordneten Transducer;
wobei eine Längsachse des Antriebsmechanismus im Wesentlichen parallel zu einer Längsachse des länglichen Glieds orientiert ist;
wobei der Transducer orientiert ist, Ultraschallenergie durch den für Ultraschall transparenten Abschnitt des distalen Endes unter einem Winkel von zwischen etwa 15° und etwa 165° relativ zu einer Längsachse des länglichen Glieds zu senden,
wobei die Antriebsmechanismuseinrichtung eine erste Verankerung (12), eine zweite Verankerung (14), ein bewegliches Element (16), ein erstes Formgedächtnislegierungsantriebselement (20), das mit der ersten Verankerung und dem beweglichen Element verbunden ist, und eine verformbare Komponente (22) aufweist, die mit der zweiten Verankerung und dem beweglichen Element verbunden ist, wobei die Verankerungselemente am länglichen Glied befestigt sind und sich relativ dazu nicht bewegen; und
wobei die erste Verankerung, die zweite Verankerung, das bewegliche Element, das erste Formgedächtnislegierungsantriebselement
und die verformbare Komponente des Antriebsmechanismus entlang der Längsachse angeordnet sind, die im Wesentlichen parallel zur Längsachse des länglichen Glieds orientiert ist.

2. Vorrichtung nach Anspruch 1, wobei die Vorrichtung nur einen Ultraschalltransducer am beweglichen Element aufweist.

3. Vorrichtung nach Anspruch 1, wobei die Vorrichtung nur zwei Ultraschalltransducer am beweglichen Element aufweist.

4. Vorrichtung nach Anspruch 1, wobei die Vorrichtung nur drei Ultraschalltransducer am beweglichen Element aufweist.

5. Intravaskuläre Seitensicht-Ultraschallvorrichtung nach Anspruch 1,
wobei der Ultraschalltransducer mit dem beweglichen Element verbunden ist;
wobei das erste Formgedächtnislegierungsantriebselement einen aktivierten und einen deaktivierten Zustand aufweist; und
wobei sich das bewegliche Element und der Transducer bei einer Aktivierung des ersten Formgedächtnislegierungsantriebselements relativ zum länglichen Glied und zur ersten und zweiten Verankerung in eine erste Richtung bewegen.

6. Vorrichtung nach Anspruch 5, wobei die verformbare Komponente ein zweites Formgedächtnislegierungsantriebselement aufweist;
wobei das zweite Antriebselement einen aktivierten und einen deaktivierten Zustand aufweist; und
wobei eine Aktivierung des zweiten Formgedächtnislegierungsantriebselements anschließend an eine Deaktivierung des ersten Formgedächtnislegierungsantriebselements das bewegliche Element und den Transducer relativ zum länglichen Glied und zur ersten und zweiten Verankerung in eine zweite Bewegungsrichtung bewegt, die zur ersten Bewegungsrichtung entgegengesetzt ist.

7. Vorrichtung nach Anspruch 5, wobei die verformbare Komponente elastisch oder superelastisch ist;
wobei die verformbare Komponente einen entspannten Zustand und einen verformten Zustand aufweist;
wobei sich die verformbare Komponente in einem entspannten Zustand befindet, wenn das erste Formgedächtnislegierungsantriebselement deaktiviert ist;
wobei die Bewegung des beweglichen Elements und des Transducers in die erste Richtung bei einer Aktivierung des ersten Formgedächtnislegierungsantriebselements die elastische oder superelastische verformbare Komponente verformt; und
wobei anschließend an eine Deaktivierung des ersten Formgedächtnislegierungsantriebselements die elastische oder superelastische verformbare Komponente im Wesentlichen in den entspannten Zustand zurückkehrt, wobei sich das bewegliche Element und der Transducer in eine zweite Bewegungsrichtung bewegen, die zur ersten Bewegungsrichtung entgegengesetzt ist.

8. Vorrichtung nach Anspruch 5, die ferner aufweist:

ein Lumen, das die Längsachse des länglichen Glieds durchquert, und
im Lumen angeordnete Drähte, um den Transducer, das erste Formgedächtnislegierungsantriebselement und optional die verformbare Komponente mit einem oder mehreren Bauteilen am proximalen Ende des länglichen Glieds elektrisch zu verbinden.

9. Vorrichtung nach Anspruch 8, wobei das Bauteil ein Ultraschallsignalprozessor ist.

10. Vorrichtung nach Anspruch 5, die ferner einen zweiten Ultraschalltransducer aufweist, der mit dem beweglichen Element verbunden ist.

11. Vorrichtung nach Anspruch 5, die ferner einen Verbindungsarm (26) aufweist;
wobei der Verbindungsarm den Ultraschalltransducer mit dem beweglichen Element verbindet;
wobei sich das bewegliche Element, der Verbindungsarm und der Transducer bei einer Aktivierung des ersten Formgedächtnislegierungsantriebselements relativ zum länglichen Glied und zur ersten und zweiten Verankerung in eine erste Richtung bewegen.

12. Vorrichtung nach Anspruch 11, wobei die verformbare Komponente ein zweites Formgedächtnislegierungsantriebselement aufweist,
wobei das zweite Antriebselement einen aktivierten und einen deaktivierten Zustand aufweist; und
wobei eine Aktivierung des zweiten Formgedächtnislegierungsantriebselements anschließend an eine Deaktivierung des ersten Formgedächtnislegierungsantriebselements das bewegliche Element, den Verbinder und den Transducer relativ zum länglichen Glied und zur ersten und zweiten Verankerung in eine zweite Bewegungsrichtung bewegt, die zur ersten Bewegungsrichtung entgegengesetzt ist.

13. Vorrichtung nach Anspruch 11, wobei die verformbare Komponente elastisch oder superelastisch ist;
wobei die verformbare Komponente einen entspannten Zustand und einen verformten Zustand aufweist;
wobei sich die verformbare Komponente in einem entspannten Zustand befindet, wenn das erste Formgedächtnislegierungsantriebselement deaktiviert ist;
wobei die Bewegung des beweglichen Elements, des Verbindungsarms und des Transducers in die erste Richtung bei einer Aktivierung des ersten Formgedächtnislegierungsantriebselements die elastische oder superelastische verformbare Komponente verformt; und
wobei anschließend an eine Deaktivierung des ersten Formgedächtnislegierungsantriebselements die elastische oder superelastische verformbare Komponente im Wesentlichen in den entspannten Zustand zurückkehrt, wobei sich das bewegliche Element, der Verbindungsarm und der Transducer in eine zweite Bewegungsrichtung bewegen, die zur ersten Bewegungsrichtung entgegengesetzt ist.

14. Vorrichtung nach Anspruch 11, die ferner einen zweiten Ultraschalltransducer aufweist, der mit einem beweglichen Element verbunden ist.

15. Vorrichtung nach Anspruch 11, wobei der Ultraschalltransducer ferner mindestens zwei Ultraschallkristalle aufweist.

16. Intravaskuläre Seitensicht-Ultraschallvorrichtung, die aufweist:

ein längliches Glied mit einem proximalen Ende

und einem distalen Ende, wobei mindestens ein Abschnitt des distalen Endes für Ultraschallenergie transparent ist;
einen Antriebsmechanismus (80), der im distalen Ende angeordnet ist, wobei der Antriebsmechanismus eine erste Verankerung (82), eine zweite Verankerung (82'), ein bewegliches Element (84), ein erstes Formgedächtnislegierungsantriebselement (86), das mit der ersten Verankerung und dem beweglichen Element verbunden ist, und eine verformbare Komponente (90) aufweist, die mit der zweiten Verankerung und dem beweglichen Element verbunden ist, wobei die Verankerungselemente am länglichen Glied befestigt sind und sich relativ dazu nicht bewegen;
wobei die erste Verankerung, die zweite Verankerung, das mindestens eine bewegliche Element, das erste Formgedächtnislegierungsantriebselement und die verformbare Komponente des Antriebsmechanismus längs einer Längsachse angeordnet sind, die im Wesentlichen parallel zu einer Längsachse des länglichen Glieds orientiert ist;
einen Verbindungsarm (92) und einen Ultraschallenergiereflektor, wobei der Verbindungsarm den Ultraschallenergiereflektor mit dem beweglichen Element verbindet; und
einen Ultraschalltransducer, der im distalen Ende des länglichen Glieds angeordnet ist;
wobei der Ultraschalltransducer und der Ultraschallenergiereflektor orientiert sind, Ultraschallenergie durch den für Ultraschall transparenten Abschnitt des distalen Endes unter einem Winkel von zwischen etwa 15° und etwa 165° relativ zu einer Längsachse des länglichen Glieds zu senden;
wobei das erste Formgedächtnislegierungsantriebselement einen aktivierten und einen deaktivierten Zustand aufweist; und
wobei sich das bewegliche Element, der Verbindungsarm und der Ultraschallenergiereflektor bei einer Aktivierung des ersten Formgedächtnislegierungsantriebselements in eine erste Richtung relativ zum länglichen Glied und zur ersten und zweiten Verankerung bewegen.

17. Vorrichtung nach Anspruch 16, wobei der Verbindungsarm und das bewegliche Element aus einem einzigen Stück bestehen.

18. Vorrichtung nach Anspruch 16, wobei die verformbare Komponente ein zweites Formgedächtnislegierungsantriebselement aufweist;
wobei das zweite Antriebselement einen aktivierten und einen deaktivierten Zustand aufweist; und
wobei eine Aktivierung des zweiten Formgedächtnislegierungsantriebselements anschließend an eine Deaktivierung des ersten Formgedächtnislegierungsantriebselements das bewegliche Element, den Verbindungsarm und den Reflektor relativ zum länglichen Glied in eine zweite Richtung bewegt, die zur ersten Bewegungsrichtung entgegengesetzt ist.

19. Vorrichtung nach Anspruch 16, wobei die verformbare Komponente elastisch oder superelastisch ist;
wobei die verformbare Komponente einen entspannten Zustand und einen verformten Zustand aufweist;
wobei sich die verformbare Komponente in einem entspannten Zustand befindet, wenn das erste Formgedächtnislegierungsantriebselement deaktiviert ist;
wobei die Bewegung des beweglichen Elements, des Verbindungsarms und des Reflektors in die erste Richtung bei einer Aktivierung des ersten Formgedächtnislegierungsantriebselements die elastische oder superelastische verformbare Komponente verformt; und
wobei anschließend an eine Deaktivierung des ersten Formgedächtnislegierungsantriebselements die elastische oder superelastische verformbare Komponente im Wesentlichen in den entspannten Zustand zurückkehrt, wobei sich das bewegliche Element, das Verbindungselement und der Reflektor in eine zweite Bewegungsrichtung bewegen, die zur ersten Bewegungsrichtung entgegengesetzt ist.

20. Vorrichtung nach Anspruch 16, die ferner einen zweiten Ultraschallenergiereflektor aufweist, der mit einem beweglichen Element verbunden ist.

21. Intravaskuläre optische Seitensicht-Kohärenztomographievorrichtung, die aufweist:

ein längliches Glied mit einem proximalen Ende und einem distalen Ende, wobei mindestens ein Abschnitt des distalen Endes für Lichtenergie transparent ist;
eine optische Faser (130) mit einem distalen Ende, wobei das distale Ende der optischen Faser im distalen Ende des länglichen Glieds angeordnet ist;
eine Reflektoreinrichtung (124), die im distalen Ende des länglichen Glieds angeordnet ist; und
eine Antriebsmechanismuseinrichtung (110) zur Bereitstellung einer zyklischen Bewegung für den Reflektor;
wobei eine Längsachse des Antriebsmechanismus im Wesentlichen parallel zu einer Längsachse des länglichen Glieds orientiert ist, und
wobei der Reflektor und das distale Ende der optischen Faser orientiert sind, Lichtenergie durch den für Licht transparenten Abschnitt des distalen Endes des länglichen Glieds unter einem Winkel von zwischen etwa 15° und etwa

165° relativ zu einer Längsachse des länglichen Glieds zu senden,
wobei die Antriebsmechanismuseinrichtung eine erste Verankerung (112), eine zweite Verankerung (112'), ein bewegliches Element (114), ein erstes Formgedächtnislegierungsantriebselement (116), das mit der ersten Verankerung und dem beweglichen Element verbunden ist, und eine verformbare Komponente aufweist, die mit der zweiten Verankerung und dem beweglichen Element verbunden ist, wobei die Verankerungselemente am länglichen Glied befestigt sind und sich relativ dazu nicht bewegen;
wobei die erste Verankerung, die zweite Verankerung, das bewegliche Element, das erste Formgedächtnislegierungsantriebselement und die verformbare Komponente des Antriebsmechanismus längs der Längsachse angeordnet sind, die im Wesentlichen parallel zur Längsachse des länglichen Glieds orientiert ist.

22. Intravaskuläre optische Seitensicht-Kohärenztomographievorrichtung nach Anspruch 21, wobei
die Antriebsmechanismuseinrichtung im distalen Ende des länglichen Glieds angeordnet ist;
wobei das distale Ende der optischen Faser im distalen Ende des länglichen Glieds im Wesentlichen parallel zu einer Längsachse des länglichen Glieds angeordnet ist;
wobei der Reflektor mit dem beweglichen Element verbunden ist;
wobei das erste Formgedächtnislegierungsantriebselement einen aktivierten und einen deaktivierten Zustand aufweist; und
wobei sich das bewegliche Element und der Reflektor bei einer Aktivierung des ersten Formgedächtnislegierungsantriebselements in eine erste Richtung relativ zum länglichen Glied und zur ersten und zweiten Verankerung bewegen.

23. Vorrichtung nach Anspruch 22, wobei die verformbare Komponente ein zweites Formgedächtnislegierungsantriebselement aufweist,
wobei das zweite Antriebselement einen aktivierten und einen deaktivierten Zustand aufweist; und
wobei eine Aktivierung des zweiten Formgedächtnislegierungsantriebselements anschließend an eine Deaktivierung des ersten Formgedächtnislegierungsantriebselements das bewegliche Element und den Reflektor relativ zum länglichen Glied und zur ersten und zweiten Verankerung in eine zweite Bewegungsrichtung bewegt, die zur ersten Bewegungsrichtung entgegengesetzt ist.

24. Vorrichtung nach Anspruch 22, wobei die verformbare Komponente elastisch oder superelastisch ist;
wobei die verformbare Komponente einen entspannten Zustand und einen verformten Zustand aufweist;
wobei sich die verformbare Komponente in einem entspannten Zustand befindet, wenn das erste Formgedächtnislegierungsantriebselement deaktiviert ist;
wobei die Bewegung des beweglichen Elements und des Reflektors in die erste Richtung bei einer Aktivierung des ersten Formgedächtnislegierungsantriebselements die elastische oder superelastische verformbare Komponente verformt; und wobei anschließend an eine Deaktivierung der ersten Formgedächtnislegierung die elastische oder superelastische verformbare Komponente im Wesentlichen in den entspannten Zustand zurückkehrt, wobei sich das bewegliche Element und der Reflektor in eine zweite Bewegungsrichtung bewegen, die zur ersten Bewegungsrichtung entgegengesetzt ist.

25. Vorrichtung nach Anspruch 22, die ferner aufweist:

ein Lumen, das die Längsachse des länglichen Glieds durchquert; und
im Lumen angeordnete Drähte, um das erste Formgedächtnislegierungsantriebselement und optional die verformbare Komponente mit einem oder mehreren Bauteilen am proximalen Ende des länglichen Glieds elektrisch zu verbinden.

26. Vorrichtung nach Anspruch 25, wobei das Bauteil ein Signalprozessor ist.

27. Vorrichtung nach Anspruch 22, die ferner einen Verbindungsarm (122) aufweist;
wobei der Verbindungsarm den Reflektor mit dem beweglichen Element verbindet;
wobei sich das bewegliche Element, der Verbindungsarm und der Reflektor bei einer Aktivierung des ersten Formgedächtnislegierungsantriebselements in eine erste Richtung relativ zum länglichen Glied und zur ersten und zweiten Verankerung bewegen.

28. Vorrichtung nach Anspruch 27, wobei das bewegliche Element und der Verbindungsarm aus einem einzigen Stück bestehen.

29. Vorrichtung nach Anspruch 27, wobei die verformbare Komponente ein zweites Formgedächtnislegierungsantriebselement aufweist;
wobei das zweite Antriebselement einen aktivierten und einen deaktivierten Zustand aufweist; und
wobei eine Aktivierung des zweiten Formgedächtnislegierungsantriebselements anschließend an eine Deaktivierung des ersten Formgedächtnislegierungsantriebselements das bewegliche Element, den Verbindungsarm und Reflektor relativ zum länglichen Glied und zur ersten und zweiten Verankerung

in eine zweite Bewegungsrichtung bewegt, die zur ersten Bewegungsrichtung entgegengesetzt ist.

30. Vorrichtung nach Anspruch 27, wobei die verformbare Komponente elastisch oder superelastisch ist und einen entspannten und einen verformten Zustand aufweist;
wobei sich die verformbare Komponente in einem entspannten Zustand befindet, wenn das erste Formgedächtnislegierungsantriebselement deaktiviert ist;
wobei die Bewegung des beweglichen Elements, des Verbindungsarms und des Reflektors in die erste Richtung bei einer Aktivierung des ersten Formgedächtnislegierungsantriebselements die elastische oder superelastische verformbare Komponente verformt; und
wobei anschließend an eine Deaktivierung des ersten Formgedächtnislegierungsantriebselements die elastische oder superelastische verformbare Komponente im Wesentlichen in den entspannten Zustand zurückkehrt, wobei sich das bewegliche Element, der Verbindungsarm und der Reflektor in eine zweite Bewegungsrichtung bewegen, die zur ersten Bewegungsrichtung entgegengesetzt ist.

31. Intravaskuläre optische Seitensicht-Kohärenztomographievorrichtung nach Anspruch 21, wobei
die Antriebsmechanismuseinrichtung im distalen Ende des länglichen Glieds angeordnet ist;
wobei das distale Ende der optischen Faser im distalen Ende des länglichen Glieds im Wesentlichen parallel zu einer Längsachse des länglichen Glieds angeordnet ist, wobei das bewegliche Element mit dem distalen Ende der optischen Faser verbunden ist;
wobei der Reflektor mit einer distalen Spitze der optischen Faser verbunden ist und der Reflektor orientiert ist, Lichtenergie von der distalen Spitze der optischen Faser durch den transparenten Abschnitt des distalen Endes unter einem Winkel zwischen etwa 15° und etwa 165° relativ zur Längsachse des länglichen Glieds zu reflektieren;
wobei das erste Formgedächtnislegierungsantriebselement einen aktivierten und einen deaktivierten Zustand aufweist; und
wobei sich das bewegliche Element, die distale Spitze der optischen Faser und der Reflektor in eine erste Richtung relativ zum länglichen Glied und zur ersten und zweiten Verankerung bei einer Aktivierung des ersten Formgedächtnislegierungsantriebselements bewegen.

32. Vorrichtung nach Anspruch 31, wobei die verformbare Komponente ein zweites Formgedächtnislegierungsantriebselement aufweist,
wobei das zweite Antriebselement einen aktivierten und einen deaktivierten Zustand aufweist; und
wobei eine Aktivierung des zweiten Formgedächtnislegierungsantriebselements anschließend an eine Deaktivierung des ersten Formgedächtnislegierungsantriebselements das bewegliche Element, die distale Spitze der optischen Faser und den Reflektor relativ zum länglichen Glied und zur ersten und zweiten Verankerung in eine zweite Richtung bewegt, die zur ersten Bewegungsrichtung entgegengesetzt ist.

33. Vorrichtung nach Anspruch 31, wobei die verformbare Komponente elastisch oder superelastisch ist und einen entspannten und verformten Zustand aufweist;
wobei sich die verformbare Komponente in einem entspannten Zustand befindet, wenn das erste Formgedächtnislegierungsantriebselement deaktiviert ist;
wobei die Bewegung des beweglichen Elements, der distalen Spitze der optischen Faser und des Reflektors in die erste Richtung bei einer Aktivierung der ersten Formgedächtnislegierung die elastische oder superelastische verformbare Komponente verformt; und
wobei anschließend an eine Deaktivierung des ersten Formgedächtnislegierungsantriebselements die elastische oder superelastische verformbare Komponente im Wesentlichen in den entspannten Zustand zurückkehrt, wobei sich das bewegliche Element, die distale Spitze der optischen Faser und der Reflektor in eine zweite Bewegungsrichtung bewegen, die zur ersten Bewegungsrichtung entgegengesetzt ist.

34. Vorrichtung nach einem der Ansprüche 1-33, wobei die erste und zweite Bewegungsrichtung oder die zyklische Bewegung um die Längsachse des länglichen Glieds rotierend oder im Wesentlichen parallel zur Längsachse des länglichen Glieds verlaufen.

35. Vorrichtung nach Anspruch 34, wobei die erste und zweite Bewegungsrichtung oder die zyklische Bewegung um die Längsachse des länglichen Glieds rotierend verlaufen.

36. Vorrichtung nach Anspruch 34, wobei die erste und zweite Bewegungsrichtung oder die zyklische Bewegung im Wesentlichen parallel zur Längsachse des länglichen Glieds verlaufen.

37. Vorrichtung nach Anspruch 34, wobei die Rotationsbewegung zwischen etwa 1 und etwa 400 Grad beträgt, und die Längsbewegung von etwa 1 mm bis etwa 20 mm beträgt.

38. Vorrichtung nach Anspruch 37, wobei der Winkel zwischen etwa 80° und etwa 110° liegt.

39. Vorrichtung nach einem der Ansprüche 1-38, wobei das längliche Glied ein Führungsdraht ist.

40. Vorrichtung nach einem der Ansprüche 1-39, wobei der Durchmesser des distalen Endes des länglichen Glieds nicht mehr als etwa 0,1524 cm (0,060 Inch) beträgt.

Revendications

1. Appareil d'imagerie latérale intravasculaire à ultrasons, comprenant:

un élément oblong (11) ayant une extrémité proximale et une extrémité distale, au moins une partie de l'extrémité distale étant perméable à l'énergie ultrasonique;
un transducteur d'ultrasons disposé dans l'extrémité distale; et
un moyen à mécanisme actionneur (10) destiné à imprimer un mouvement cyclique au transducteur disposé dans l'extrémité distale;
où un axe longitudinal du mécanisme actionneur est aligné sensiblement parallèlement à un axe longitudinal de l'élément oblong;
où le transducteur est orienté pour transmettre l'énergie ultrasonique à travers la partie perméable aux ultrasons de l'extrémité distale suivant un angle compris entre environ 15° et environ 165° par rapport à un axe longitudinal de l'élément oblong,
où le moyen à mécanisme actionneur comprend un premier ancrage (12), un deuxième ancrage (14), un élément mobile (16), un premier actionneur (20) à alliage à mémoire de forme raccordé au premier ancrage et à l'élément mobile, et un composant déformable (22) raccordé au deuxième ancrage et à l'élément mobile, les éléments d'ancrage étant fixé à l'élément oblong et n'étant pas mobiles par rapport à celui-ci; et
où le premier ancrage, le deuxième ancrage, l'élément mobile, le premier actionneur à alliage à mémoire de forme, et le composant déformable du mécanisme actionneur sont disposés le long d'un axe longitudinal aligné sensiblement parallèlement à l'axe longitudinal de l'élément oblong.

2. Appareil selon la revendication 1, où ledit appareil ne comporte qu'un seul transducteur d'ultrasons sur l'élément mobile.

3. Appareil selon la revendication 1, où ledit appareil ne comporte que deux transducteurs d'ultrasons sur l'élément mobile.

4. Appareil selon la revendication 1, où ledit appareil ne comporte que trois transducteurs d'ultrasons sur l'élément mobile.

5. Appareil d'imagerie latérale intravasculaire à ultrasons selon la revendication 1,
où le transducteur d'ultrasons est raccordé à l'élément mobile;
où le premier actionneur à alliage à mémoire de forme présente un état d'activation et un état de désactivation; et où l'élément mobile et le transducteur se déplacent dans une première direction par rapport à l'élément oblong et au premier et au deuxième ancrages par activation du premier actionneur à alliage à mémoire de forme.

6. Appareil selon la revendication 5, où le composant déformable comprend un deuxième actionneur à alliage à mémoire de forme;
où le deuxième actionneur présente un état d'activation et un état de désactivation; et
où après la désactivation du premier actionneur à alliage à mémoire de forme l'activation du deuxième actionneur à alliage à mémoire de forme déplace l'élément mobile et le transducteur par rapport à l'élément oblong et au premier et au deuxième ancrages dans une deuxième direction de déplacement opposée à la première direction de déplacement.

7. Appareil selon la revendication 5, où le composant déformable est élastique ou superélastique;
où le composant déformable présente un état de relâchement et un état de déformation;
où le composant déformable est dans un état de relâchement quand le premier actionneur à alliage à mémoire de forme est désactivé;
où le déplacement de l'élément mobile et du transducteur dans la première direction par activation du premier actionneur à alliage à mémoire de forme déforme le composant déformable élastique ou superélastique; et
où après la désactivation du premier actionneur à alliage à mémoire de forme, le composant déformable élastique ou superélastique retourne sensiblement vers l'état de relâchement, l'élément mobile et le transducteur se déplaçant dans une deuxième direction de déplacement opposée à la première direction de déplacement.

8. Appareil selon la revendication 5, comprenant en outre:

une lumière passant par l'axe longitudinal de l'élément oblong; et
des fils disposés dans la lumière pour relier électriquement le transducteur, le premier actionneur à alliage à mémoire de forme et, en option, le composant déformable à un ou plusieurs dispositifs à l'extrémité proximale de l'élément

oblong.

9. Appareil selon la revendication 8, où ledit dispositif est un processeur de signaux ultrasoniques.

10. Appareil selon la revendication 5, comprenant en outre un deuxième transducteur ultrasonique raccordé à l'élément mobile.

11. Appareil selon la revendication 5, comprenant en outre un bras de liaison (26);
ledit bras de liaison reliant le transducteur d'ultrasons à l'élément mobile;
l'élément mobile, le bras de liaison et le transducteur se déplaçant dans la première direction par rapport à l'élément oblong et au premier et au deuxième ancrages par activation du premier actionneur à alliage à mémoire de forme.

12. Appareil selon la revendication 11, où le composant déformable comprend un deuxième actionneur à alliage à mémoire de forme,
où le deuxième actionneur présente un état d'activation et un état de désactivation; et
où après la désactivation du premier actionneur à alliage à mémoire de forme l'activation du deuxième actionneur à alliage à mémoire de forme déplace l'élément mobile, le connecteur et le transducteur par rapport à l'élément oblong et au premier et au deuxième ancrages dans une deuxième direction de déplacement opposée à la première direction de déplacement.

13. Appareil selon la revendication 11, où le composant déformable est élastique ou superélastique;
où le composant déformable présente un état de relâchement et un état de déformation;
où le composant déformable est dans un état de relâchement quand le premier actionneur à alliage à mémoire de forme est désactivé;
où le déplacement de l'élément mobile, du bras de liaison et du transducteur dans la première direction par activation du premier actionneur à alliage à mémoire de forme déforme le composant déformable élastique ou superélastique; et
où après la désactivation du premier actionneur à alliage à mémoire de forme, le composant déformable élastique ou superélastique retourne sensiblement vers l'état de relâchement, l'élément mobile, le bras de liaison et le transducteur se déplaçant dans une deuxième direction de déplacement opposée à la première direction de déplacement.

14. Appareil selon la revendication 11, comprenant en outre un deuxième transducteur d'ultrasons raccordé à un élément mobile.

15. Appareil selon la revendication 11, où le transducteur d'ultrasons comprend en outre au moins deux cristaux à ultrasons.

16. Appareil d'imagerie latérale intravasculaire à ultrasons, comprenant:

un élément oblong ayant une extrémité proximale et une extrémité distale, où au moins une partie de l'extrémité distale est perméable à l'énergie ultrasonique;
un mécanisme actionneur (80) disposé dans l'extrémité distale, ledit mécanisme actionneur comportant un premier ancrage (82), un deuxième ancrage (82'), un élément mobile (84), un premier actionneur (86) à alliage à mémoire de forme raccordé au premier ancrage et à l'élément mobile, et un composant déformable (90) raccordé au deuxième ancrage et à l'élément mobile, les éléments d'ancrage étant fixés à l'élément oblong et n'étant pas mobiles par rapport à celui-ci;
où le premier ancrage, le deuxième ancrage, le ou les éléments mobiles, le premier actionneur à alliage à mémoire de forme, et le composant déformable du mécanisme actionneur sont disposés le long d'un axe longitudinal aligné sensiblement parallèlement à un axe longitudinal de l'élément oblong;
un bras de liaison (92) et un réflecteur d'énergie ultrasonique, le bras de liaison reliant le réflecteur d'énergie ultrasonique à l'élément mobile; et
un transducteur d'ultrasons disposé dans l'extrémité distale de l'élément oblong;
où le transducteur d'ultrasons et le réflecteur d'énergie ultrasonique sont orientés pour transmettre l'énergie ultrasonique à travers la partie perméable aux ultrasons de l'extrémité distale suivant un angle compris entre environ 15° et environ 165° par rapport à un axe longitudinal de l'élément oblong;
où le premier actionneur à alliage à mémoire de forme présente un état d'activation et un état de désactivation; et
où l'élément mobile, le bras de liaison, et le réflecteur d'énergie ultrasonique se déplacent dans une première direction par rapport à l'élément oblong et au premier et au deuxième ancrages par activation du premier actionneur à alliage à mémoire de forme.

17. Appareil selon la revendication 16, où le bras de liaison et l'élément mobile sont une seule pièce.

18. Appareil selon la revendication 16, où le composant déformable comprend un deuxième actionneur à alliage à mémoire de forme;
où le deuxième actionneur présente un état d'acti-

vation et un état de désactivation; et
où par activation du deuxième actionneur à alliage à mémoire de forme consécutive à la désactivation du premier actionneur à alliage à mémoire de forme, l'élément mobile, le bras de liaison et le réflecteur se déplacent par rapport à l'élément oblong dans une deuxième direction opposée à la première direction de déplacement.

19. Appareil selon la revendication 16, où le composant déformable est élastique ou superélastique;
où le composant déformable présente un état de relâchement et un état de déformation;
où le composant déformable est dans un état de relâchement quand le premier actionneur à alliage à mémoire de forme est désactivé;
où le déplacement de l'élément mobile, du bras de liaison et du réflecteur dans la première direction par activation du premier actionneur à alliage à mémoire de forme déforme le composant déformable élastique ou superélastique; et
où après la désactivation du premier actionneur à alliage à mémoire de forme, le composant déformable élastique ou superélastique retourne sensiblement vers l'état de relâchement, l'élément mobile, l'élément de liaison et le réflecteur se déplaçant dans une deuxième direction de déplacement opposée à la première direction de déplacement.

20. Appareil selon la revendication 16, comprenant en outre un deuxième réflecteur d'énergie ultrasonique raccordé à un élément mobile.

21. Appareil d'imagerie latérale intravasculaire à tomographie par cohérence optique, comprenant:

un élément oblong ayant une extrémité proximale et une extrémité distale, au moins une partie de l'extrémité distale étant perméable à l'énergie lumineuse;
une fibre optique (130) ayant une extrémité distale, ladite extrémité distale de la fibre optique étant disposée dans l'extrémité distale de l'élément oblong;
un moyen réflecteur (124) disposé dans l'extrémité distale de l'élément oblong; et
un moyen à mécanisme actionneur (110) destiné à imprimer un mouvement cyclique au réflecteur;
où un axe longitudinal du mécanisme actionneur est aligné sensiblement parallèlement à un axe longitudinal de l'élément oblong; et
où le réflecteur et l'extrémité distale de la fibre optique sont orientés pour transmettre l'énergie lumineuse à travers la partie perméable à la lumière de l'extrémité distale de l'élément oblong suivant un angle compris entre environ 15° et environ 165° par rapport à un axe longitudinal de l'élément oblong,
où le moyen à mécanisme actionneur comprend un premier ancrage (112), un deuxième ancrage (112'), un élément mobile (114), un premier actionneur (116) à alliage à mémoire de forme raccordé au premier ancrage et à l'élément mobile, et un composant déformable raccordé au deuxième ancrage et à l'élément mobile, les éléments d'ancrage étant fixés à l'élément oblong et n'étant pas mobiles par rapport à celui-ci;
où le premier ancrage, le deuxième ancrage, l'élément mobile, le premier actionneur à alliage à mémoire de forme, et le composant déformable du mécanisme actionneur sont disposés le long de l'axe longitudinal aligné sensiblement parallèlement à l'axe longitudinal de l'élément oblong.

22. Appareil d'imagerie latérale intravasculaire à tomographie par cohérence optique selon la revendication 21,
où le moyen à mécanisme actionneur est disposé dans l'extrémité distale de l'élément oblong;
où l'extrémité distale de la fibre optique est disposée dans l'extrémité distale de l'élément oblong sensiblement parallèlement à un axe longitudinal de l'élément oblong;
où le réflecteur est raccordé à l'élément mobile;
où le premier actionneur à alliage à mémoire de forme présente un état d'activation et un état de désactivation; et où l'élément mobile et le réflecteur se déplacent dans une première direction par rapport à l'élément oblong et au premier et au deuxième ancrages par activation du premier actionneur à alliage à mémoire de forme.

23. Appareil selon la revendication 22, où le composant déformable comprend un deuxième actionneur à alliage à mémoire de forme,
où le deuxième actionneur présente un état d'activation et un état de désactivation; et
où par activation du deuxième actionneur à alliage à mémoire de forme consécutive à la désactivation du premier actionneur à alliage à mémoire de forme, l'élément mobile et le réflecteur se déplacent par rapport à l'élément oblong et au premier et au deuxième ancrages dans une deuxième direction de déplacement opposée à la première direction de déplacement.

24. Appareil selon la revendication 22, où le composant déformable est élastique ou superélastique;
où le composant déformable présente un état de relâchement et un état de déformation;
où le composant déformable est dans un état de relâchement quand le premier actionneur à alliage à mémoire de forme est désactivé;
où le déplacement de l'élément mobile et du réflec-

teur dans la première direction par activation du premier actionneur à alliage à mémoire de forme déforme le composant déformable élastique ou superélastique; et
où après la désactivation du premier actionneur à alliage à mémoire de forme, le composant déformable élastique ou superélastique retourne sensiblement vers l'état de relâchement, l'élément mobile et le réflecteur se déplaçant dans une deuxième direction de déplacement opposée à la première direction de déplacement.

25. Appareil selon la revendication 22, comprenant en outre :

une lumière passant par l'axe longitudinal de l'élément oblong; et
des fils disposés dans la lumière pour relier électriquement le premier actionneur à alliage à mémoire de forme et, en option, le composant déformable à un ou plusieurs dispositifs à l'extrémité proximale de l'élément oblong.

26. Appareil selon la revendication 25, où ledit dispositif est un processeur de signaux.

27. Appareil selon la revendication 22, comprenant en outre un bras de liaison (122);
ledit bras de liaison reliant le réflecteur à l'élément mobile;
l'élément mobile, le bras de liaison et le réflecteur se déplaçant dans une première direction par rapport à l'élément oblong et au premier et au deuxième ancrages par activation du premier actionneur à alliage à mémoire de forme.

28. Appareil selon la revendication 27, où l'élément mobile et le bras de liaison sont une seule pièce.

29. Appareil selon la revendication 27, où le composant déformable comprend un deuxième actionneur à alliage à mémoire de forme;
où le deuxième actionneur présente un état d'activation et un état de désactivation; et
où par activation du deuxième actionneur à alliage à mémoire de forme consécutive à la désactivation du premier actionneur à alliage à mémoire de forme, l'élément mobile, le bras de liaison et le réflecteur se déplacent par rapport à l'élément oblong et au premier et au deuxième ancrages dans une deuxième direction de déplacement opposée à la première direction de déplacement.

30. Appareil selon la revendication 27, où le composant déformable est élastique ou superélastique, et présente un état de relâchement et un état de déformation;
où le composant déformable est dans un état de relâchement quand le premier actionneur à alliage à mémoire de forme est désactivé;
où le déplacement de l'élément mobile, du bras de liaison et du réflecteur dans la première direction par activation du premier actionneur à alliage à mémoire de forme déforme le composant déformable élastique ou superélastique; et
où après la désactivation du premier actionneur à alliage à mémoire de forme, le composant déformable élastique ou superélastique retourne sensiblement vers l'état de relâchement, l'élément mobile, le bras de liaison et le réflecteur se déplaçant dans une deuxième direction de déplacement opposée à la première direction de déplacement.

31. Appareil d'imagerie latérale intravasculaire à tomographie par cohérence optique selon la revendication 21,
où le moyen à mécanisme actionneur est disposé dans l'extrémité distale de l'élément oblong;
où l'extrémité distale de la fibre optique est disposée dans l'extrémité distale de l'élément oblong sensiblement parallèlement à un axe longitudinal de l'élément oblong, l'élément mobile étant raccordé à l'extrémité distale de la fibre optique;
où le réflecteur est raccordé à un bout distal de la fibre optique, ledit réflecteur étant orienté pour réfléchir l'énergie lumineuse du bout distal de la fibre optique à travers la partie perméable à la lumière de l'extrémité distale suivant un angle compris entre environ 15° et environ 165° par rapport à l'axe longitudinal de l'élément oblong;
où le premier actionneur à alliage à mémoire de forme présente un état d'activation et un état de désactivation; et où l'élément mobile, le bout distal de la fibre optique et le réflecteur se déplacent dans une première direction par rapport à l'élément oblong et au premier et au deuxième ancrages par activation du premier actionneur à alliage à mémoire de forme.

32. Appareil selon la revendication 31, où le composant déformable comprend un deuxième actionneur à alliage à mémoire de forme,
où le deuxième actionneur présente un état d'activation et un état de désactivation; et
où par activation du deuxième actionneur à alliage à mémoire de forme consécutive à la désactivation du premier actionneur à alliage à mémoire de forme, l'élément mobile, le bout distal de la fibre optique et le réflecteur se déplacent par rapport à l'élément oblong et au premier et au deuxième ancrages dans une deuxième direction opposée à la première direction de déplacement.

33. Appareil selon la revendication 31, où le composant déformable est élastique ou superélastique, et présente un état de relâchement et un état de déformation;

où le composant déformable est dans un état de relâchement quand le premier actionneur à alliage à mémoire de forme est désactivé;
où le déplacement de l'élément mobile, du bout distal de la fibre optique et du réflecteur dans la première direction par activation du premier actionneur à alliage à mémoire de forme déforme le composant déformable élastique ou superélastique; et
où après la désactivation du premier actionneur à alliage à mémoire de forme, le composant déformable élastique ou superélastique retourne sensiblement vers l'état de relâchement, l'élément mobile, le bout distal de la fibre optique et le réflecteur se déplaçant dans une deuxième direction de déplacement opposée à la première direction de déplacement.

34. Appareil selon l'une des revendications 1 à 33, où la première et la deuxième directions de déplacement, ou le mouvement cyclique, sont à rotation autour de l'axe longitudinal de l'élément oblong, ou sensiblement parallèles à l'axe longitudinal de l'élément oblong.

35. Appareil selon la revendication 34, où la première et la deuxième directions de déplacement, ou le mouvement cyclique, sont à rotation autour de l'axe longitudinal de l'élément oblong.

36. Appareil selon la revendication 34, où la première et la deuxième directions de déplacement, ou le mouvement cyclique, sont sensiblement parallèles à l'axe longitudinal de l'élément oblong.

37. Appareil selon la revendication 34, où le mouvement rotatif est compris entre environ 1 et environ 400 degrés, et le mouvement longitudinal entre environ 1 mm et environ 20 mm.

38. Appareil selon la revendication 37, où l'angle est compris entre environ 80° et environ 110°.

39. Appareil selon l'une des revendications 1 à 38, où l'élément oblong est un guide fil.

40. Appareil selon l'une des revendications 1 à 39, où le diamètre de l'extrémité distale de l'élément oblong n'est pas supérieur à environ 0,1524 cm (0,060 pouces).

FIG. 1

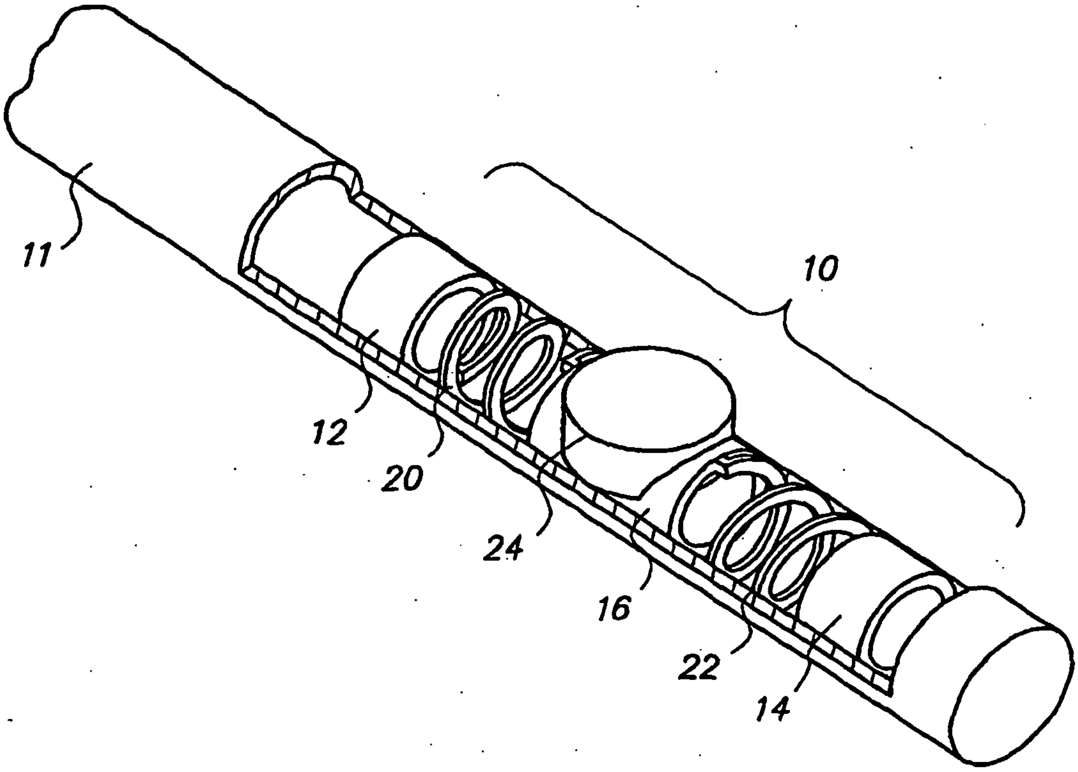


FIG. 2A

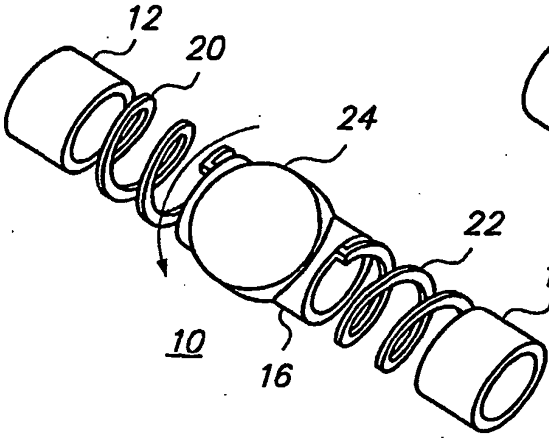


FIG. 2B

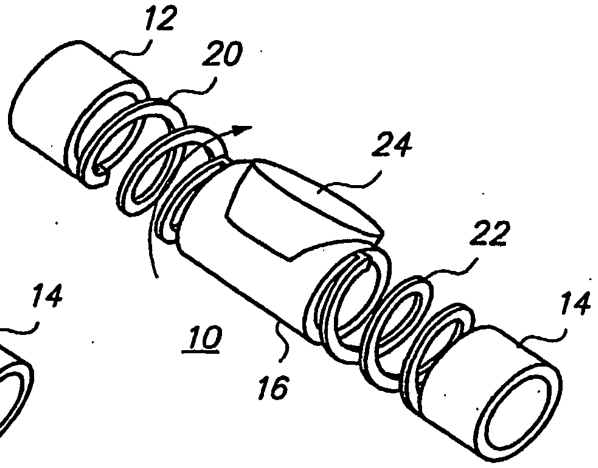


FIG. 2C

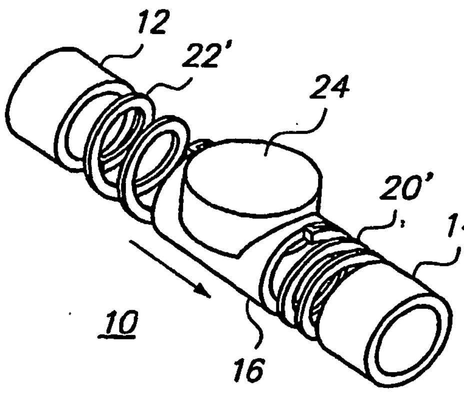


FIG. 2D

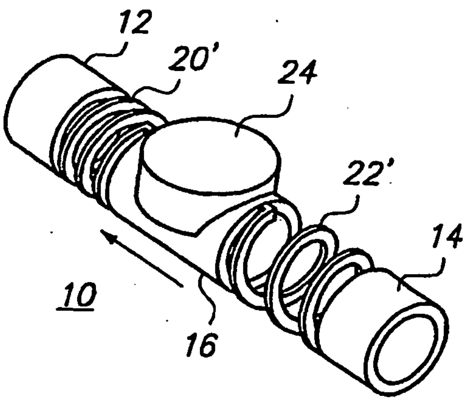


FIG. 3

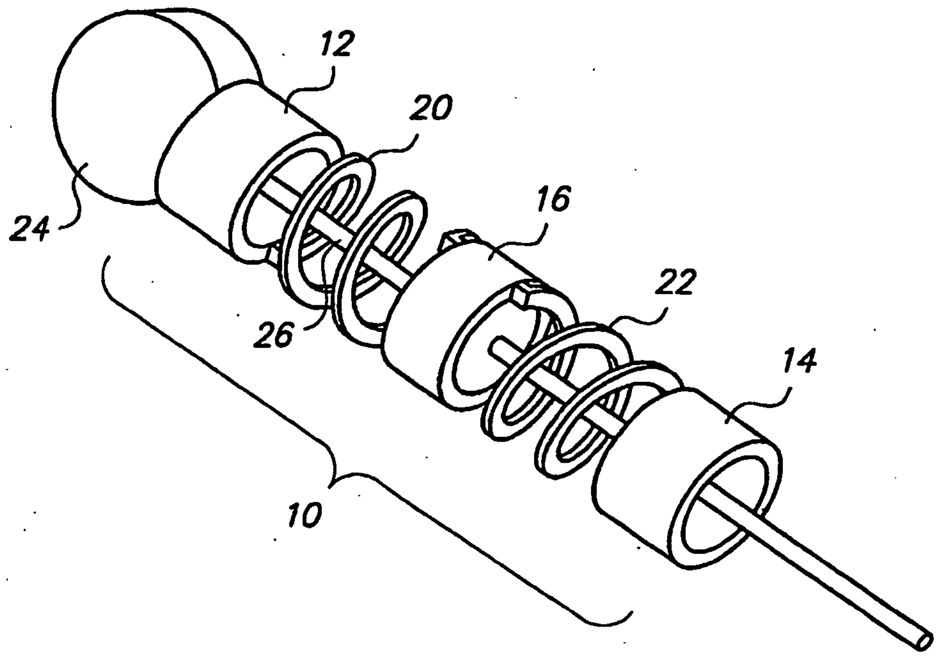


FIG. 4

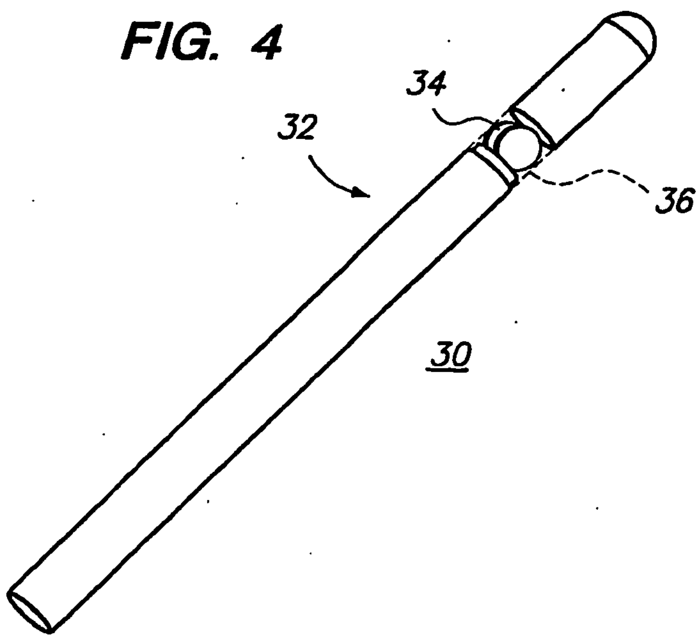


FIG. 5

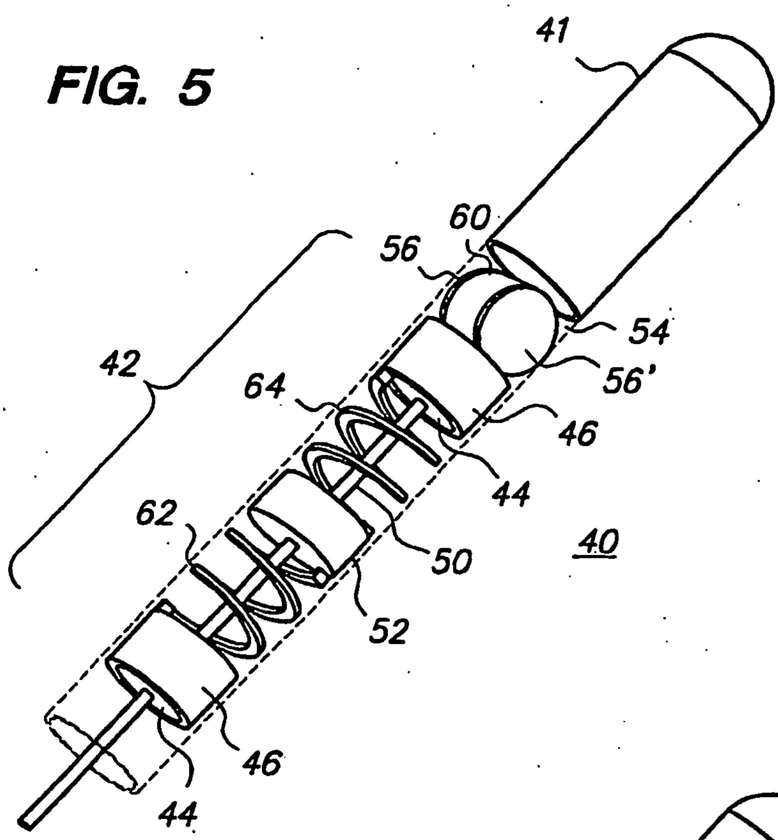


FIG. 6

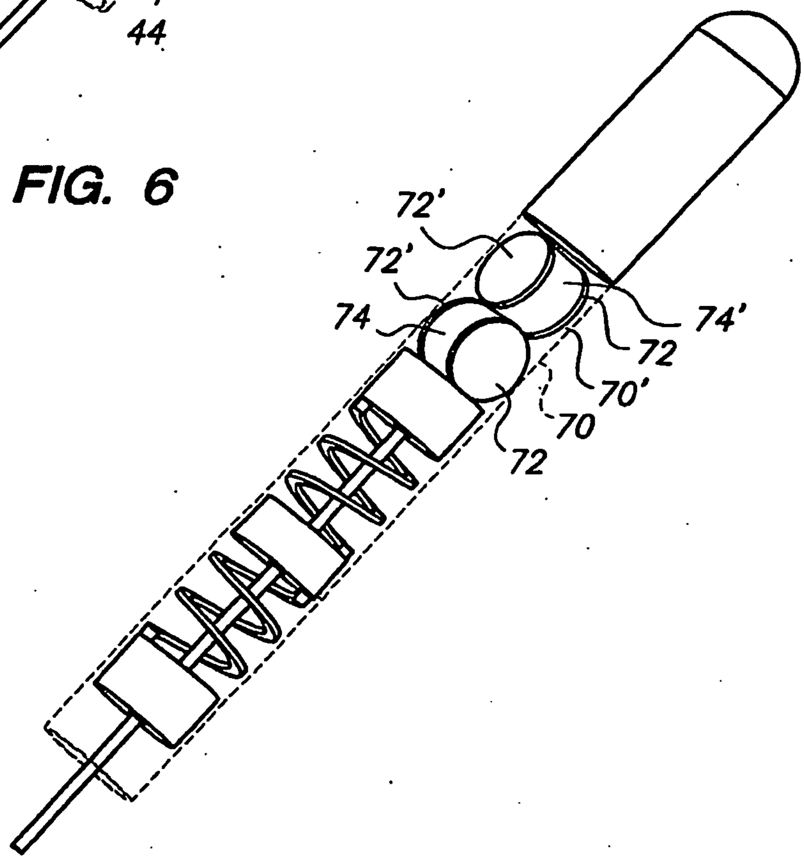


FIG. 7

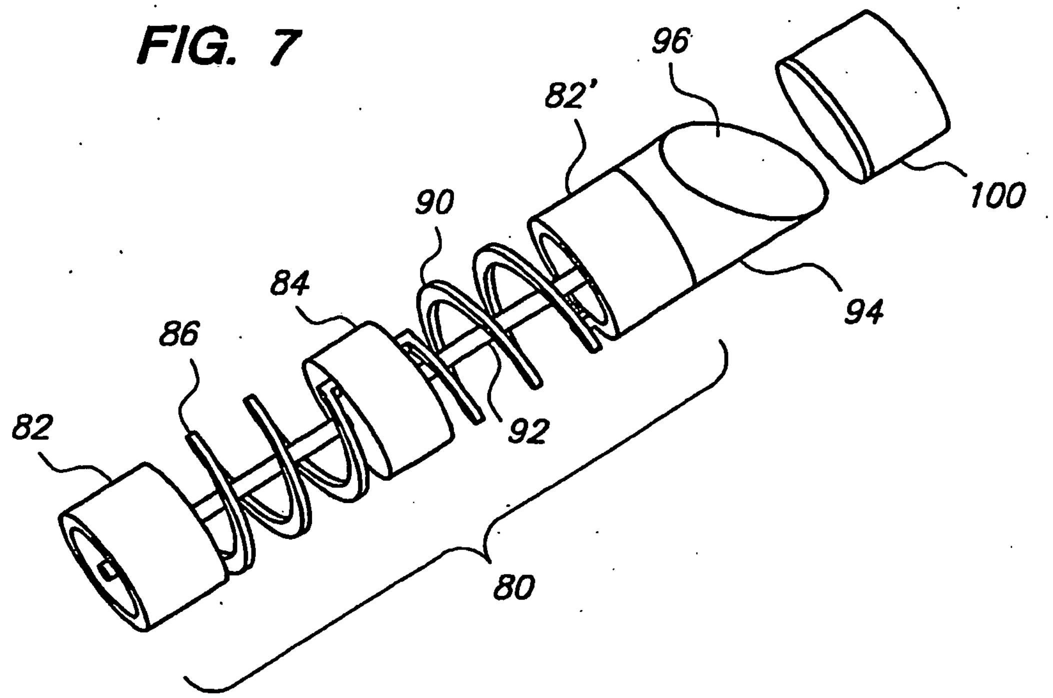


FIG. 8

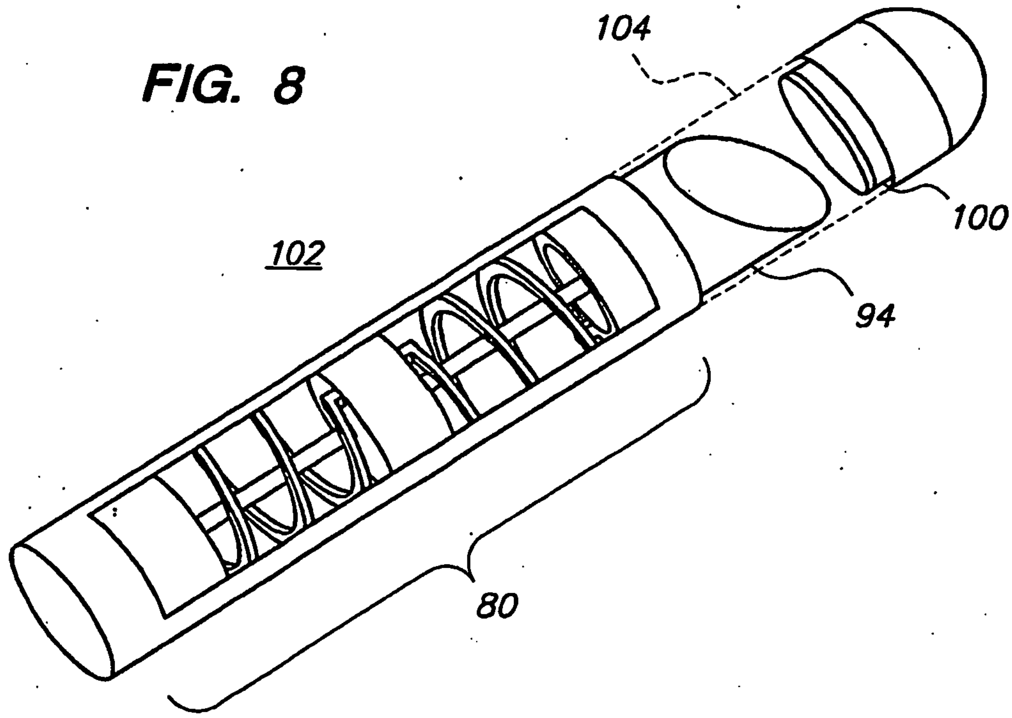


FIG. 9

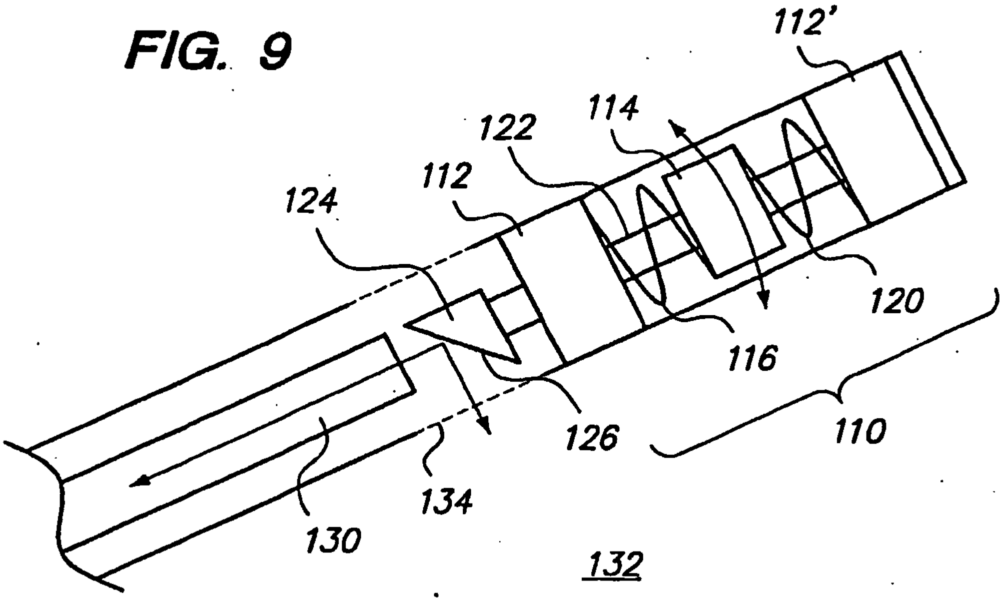

112'
114
122
112
124
120
116
126
110
134
130
132

FIG. 10

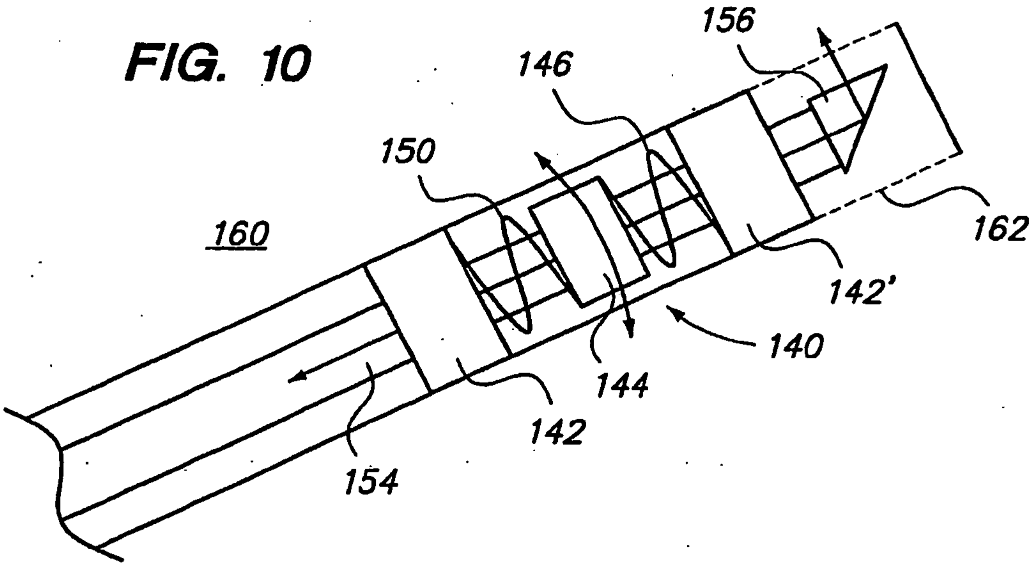

156
146
150
160
162
142'
140
144
142
154

FIG. 11

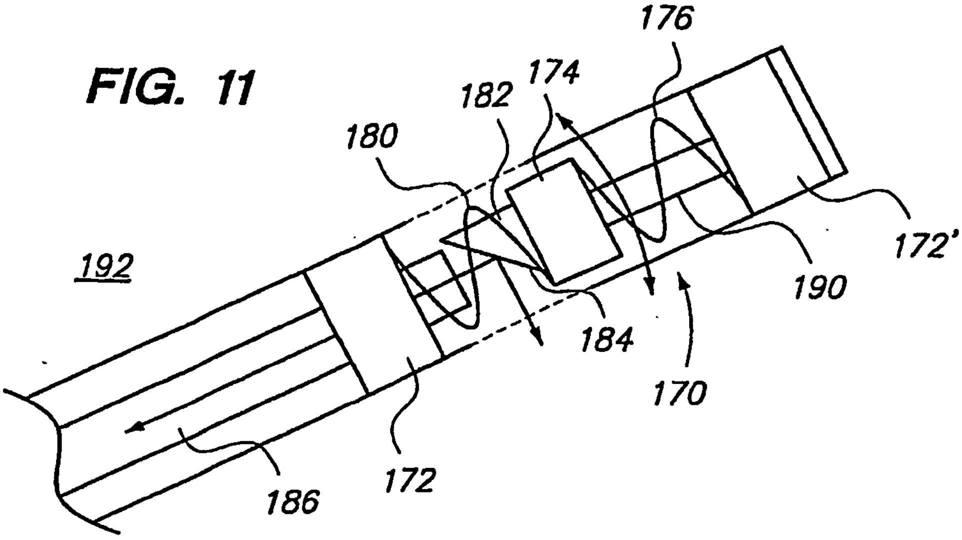


FIG. 12A

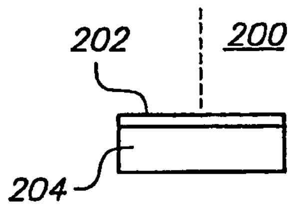


FIG. 12B

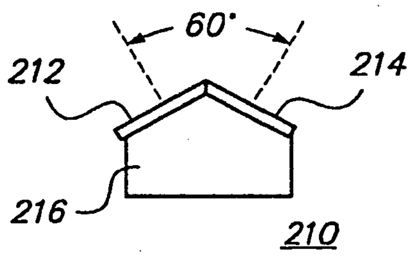


FIG. 12C

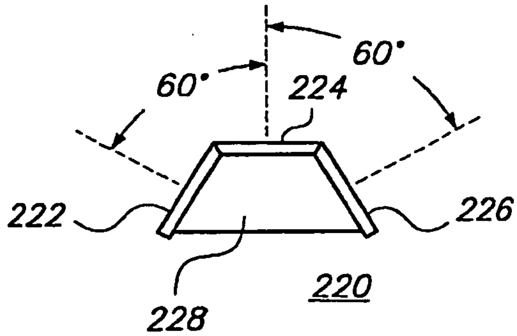


FIG. 12D

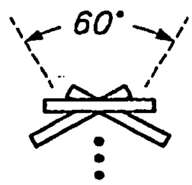


FIG. 12E

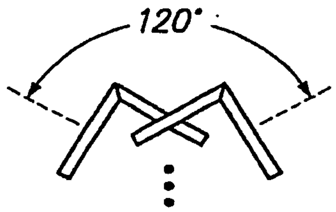


FIG. 12F

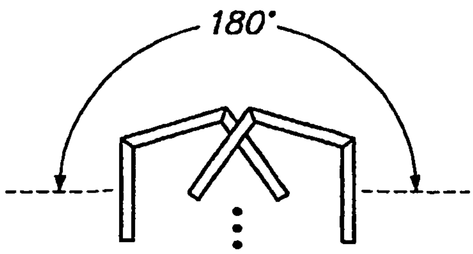


FIG. 13A

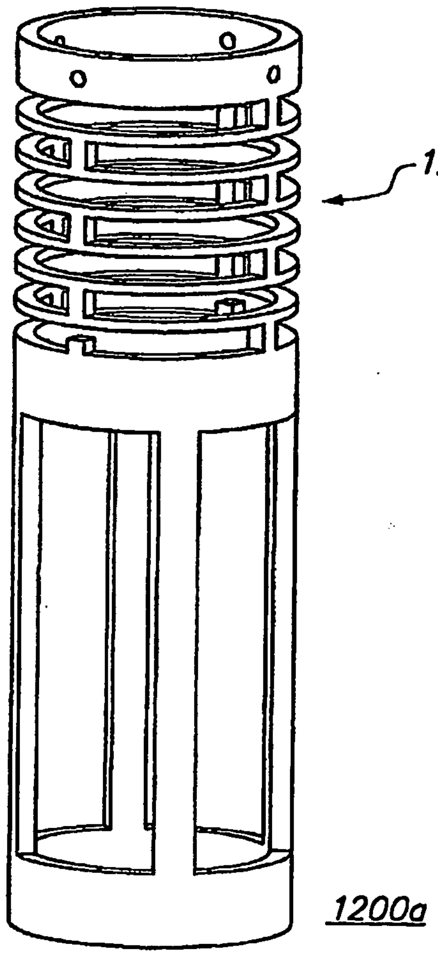


FIG. 13B

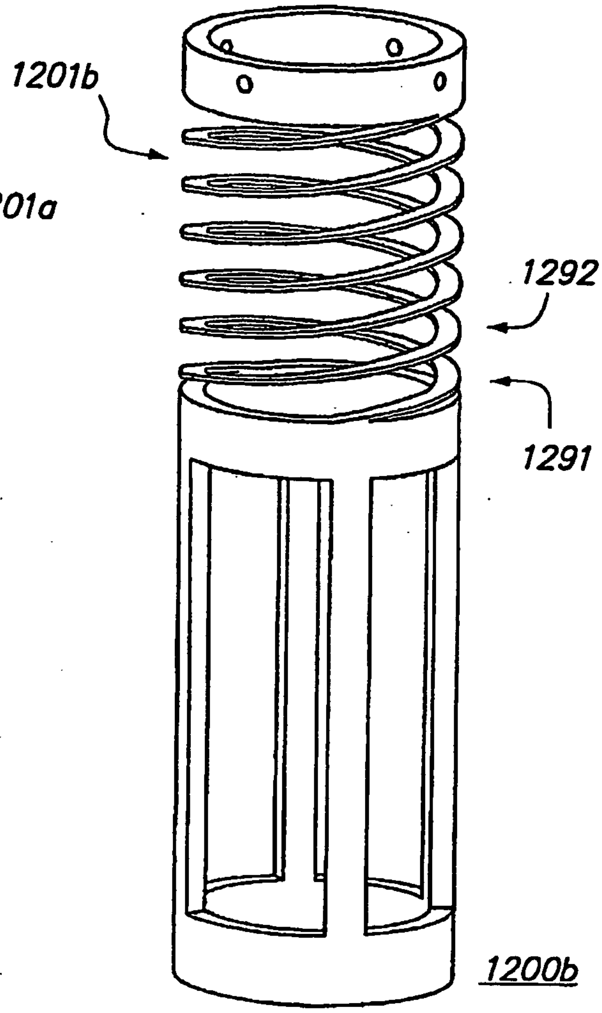
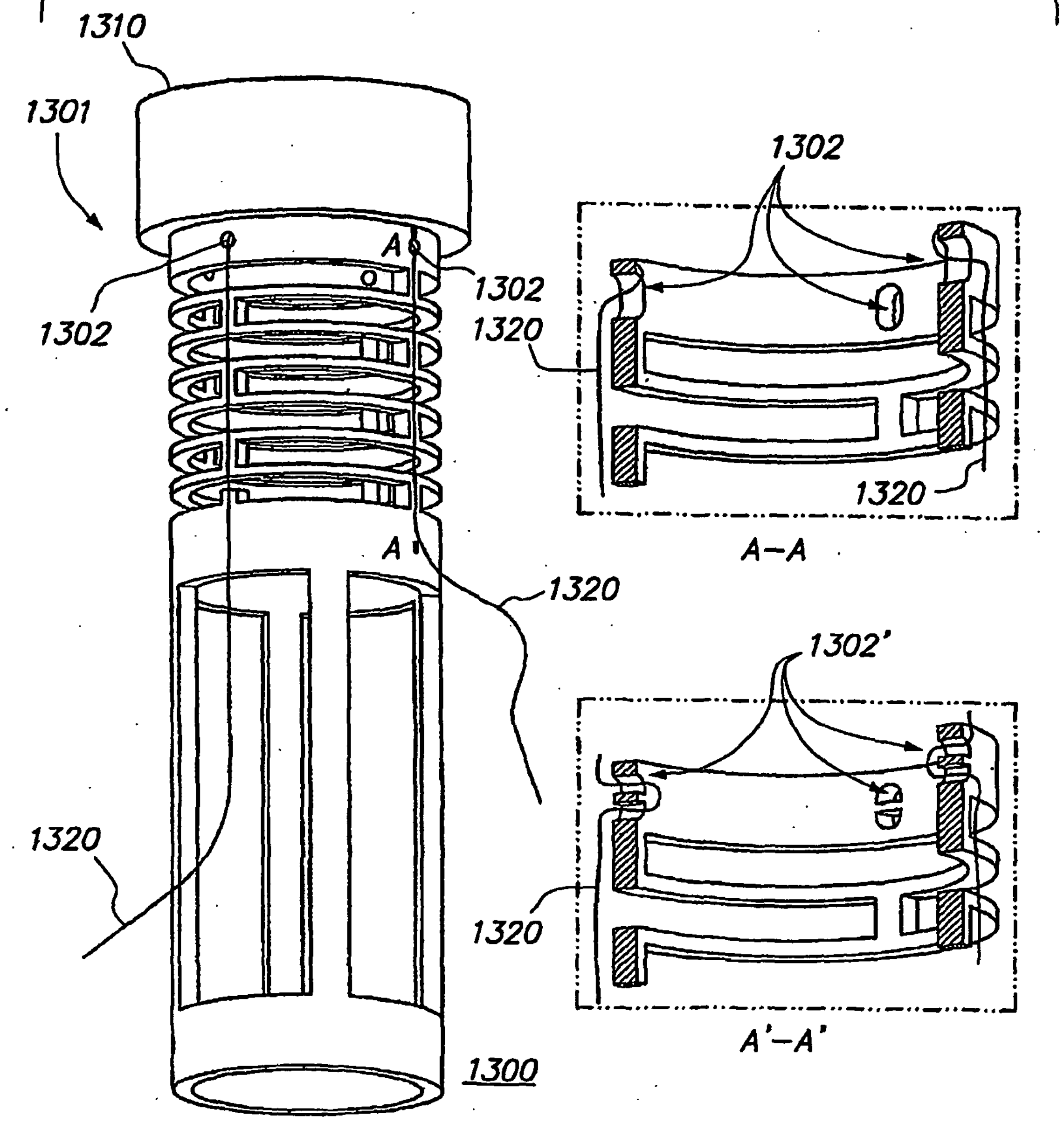


FIG. 14


1310
1301
1302
A
1302
1320
A'
1320
1320
1300
1302
1320
1320
A–A
1302'
1320
A'–A'

REFERENCES CITED IN THE DESCRIPTION

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当前申请(专利权)人(译)	火山CORPORATION		
[标]发明人	PARK BYONG HO RUDY STEPHEN		
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CPC分类号	A61B5/0066 A61B5/02007 A61B8/12 A61B8/145 A61B8/445 A61B8/4461 A61B8/4483 A61B2090/3614 A61B2090/3784 A61M25/0138 A61M25/0158 F03G7/065 F16C2202/28 G01S7/52079 G01S15/8943 G10K11/004		
代理机构(译)	法思博事务所		
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其他公开文献	EP1902331A2		
外部链接	Espacenet		

摘要(译)

本发明涉及一种基于形状记忆合金（SMA）致动器机构的新型血管内成像装置，该致动器机构嵌入细长构件（例如导丝或导管）内。本发明利用新颖的SMA机制通过为超声换能器或光学相干断层扫描（OCT）元件提供移动来提供侧视成像。这种新颖的SMA致动器机构可以容易地以微尺度制造，提供优于现有成像装置的优点，因为它提供了使装置的整体尺寸小型化的能力，同时使用多个换能器晶体使超声装置的视野最大化。还公开了使用它们的方法。

FIG. 1