US 20040056751A1

(19) **United States**
(12) **Patent Application Publication** (10) **Pub. No.: US 2004/0056751 A1**
Park et al. (43) **Pub. Date: Mar. 25, 2004**

(54) **TUBULAR COMPLIANT MECHANISMS FOR ULTRASONIC IMAGING SYSTEMS AND INTRAVASCULAR INTERVENTIONAL DEVICES**

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(21) Appl. No.: **10/667,230**

(22) Filed: **Sep. 18, 2003**

Related U.S. Application Data

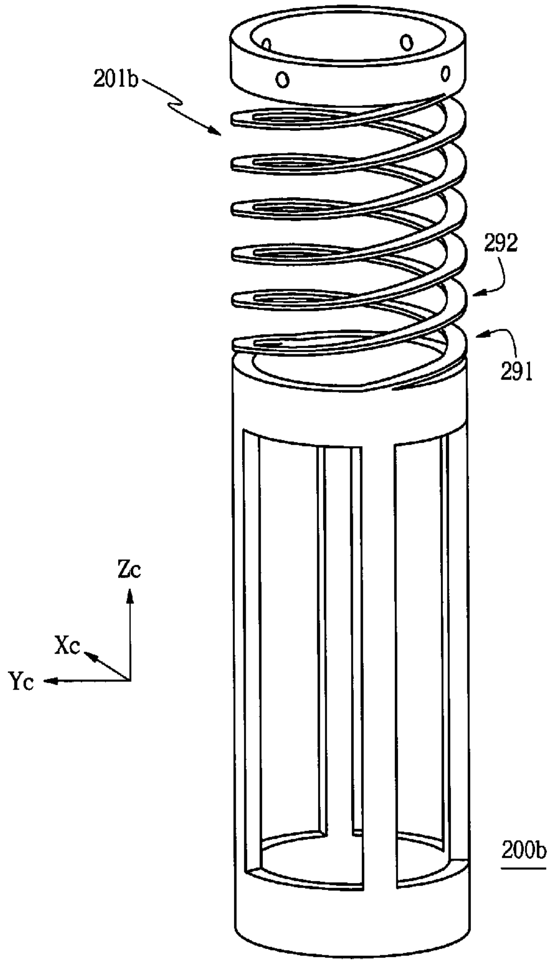
(60) Provisional application No. 60/411,924, filed on Sep. 18, 2002.

Publication Classification

(51) Int. Cl.^{7} **H01H 61/06**; H01H 71/18
(52) U.S. Cl. **337/139**

(57) **ABSTRACT**

A micromanipulator comprising a tubular structure and a structural compliance mechanism that are formed from a tube made of an elastic and/or superelastic material. Fabricated with laser machining and has no mechanical joints, the micromanipulator can be manipulated in various motions and degree-of-freedoms without permanent deformation. Shape Memory Alloys (SMAs) in one embodiment are implemented as main actuators of the micromanipulator. The micromanipulator can be implemented with multiple SMAs to manipulate the mechanism with multiple degree-of-freedom. In another implementation, multiple segments of the mechanisms are formed and arranged in various configurations, including a "double-helix"-like configuration, for enabling intricate motions of the micromanipulator. The micromanipulator is useful for intravascular interventional applications and particularly ultrasonic imaging when coupled with an ultrasound transducer.



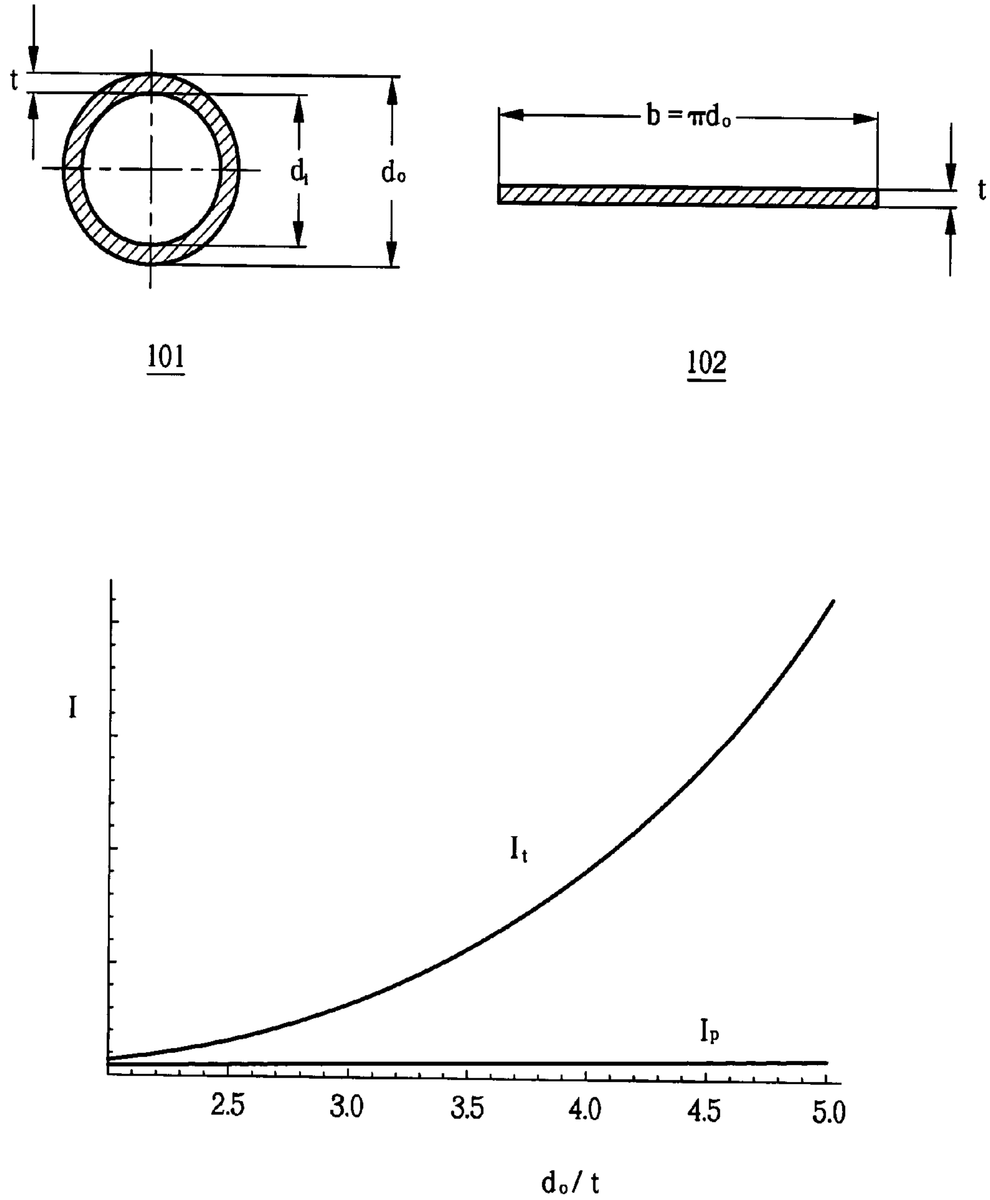


FIG. 1

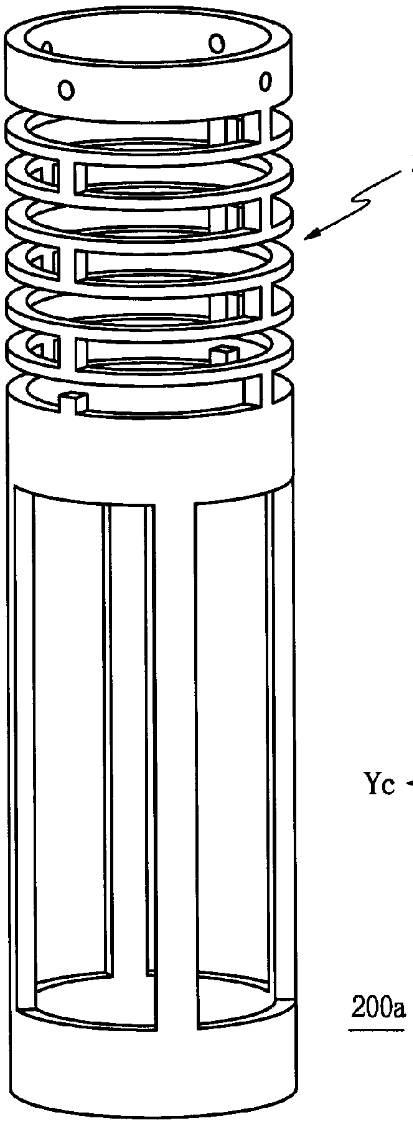
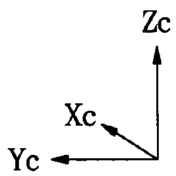


FIG. 2a



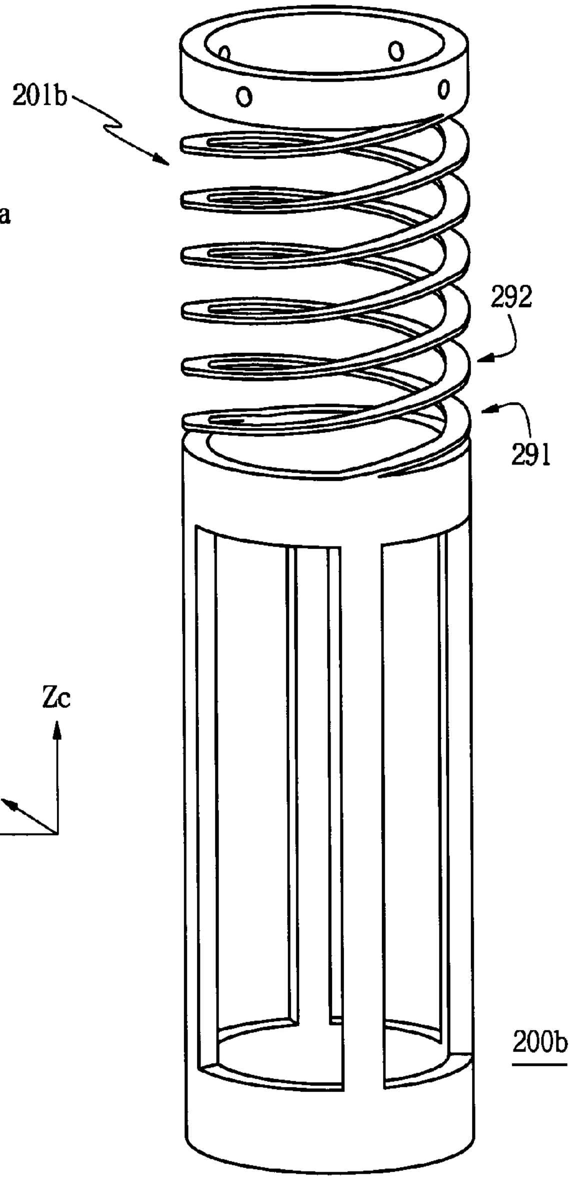


FIG. 2b

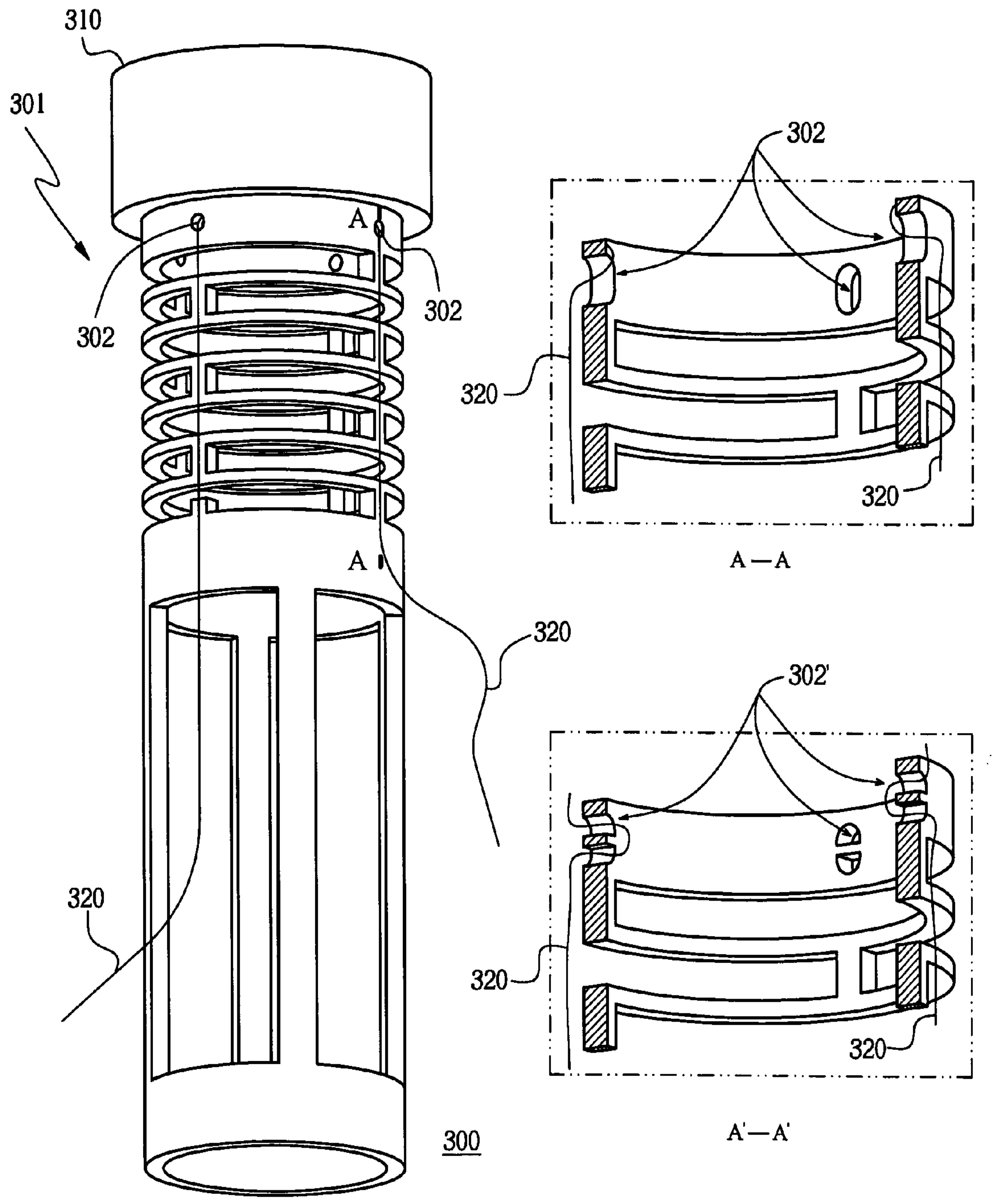


FIG. 3

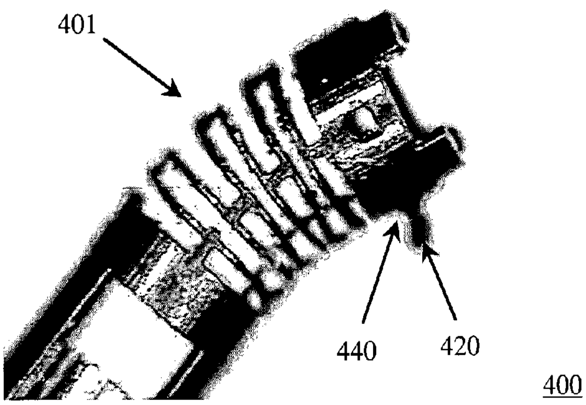


FIG. 4

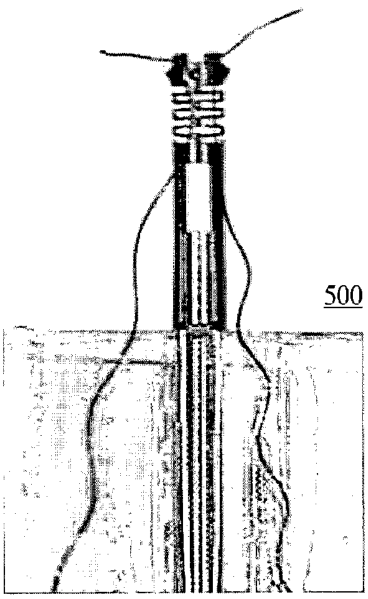


FIG. 5A

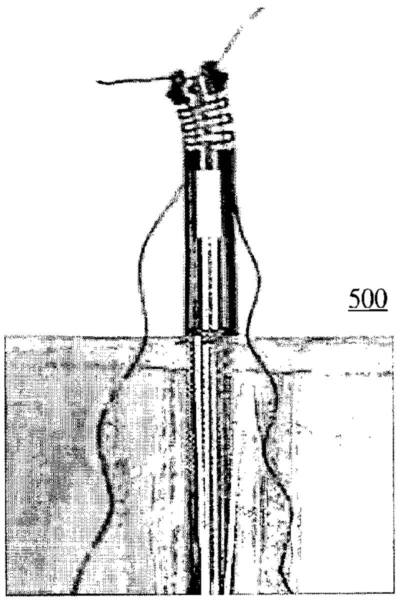


FIG. 5B

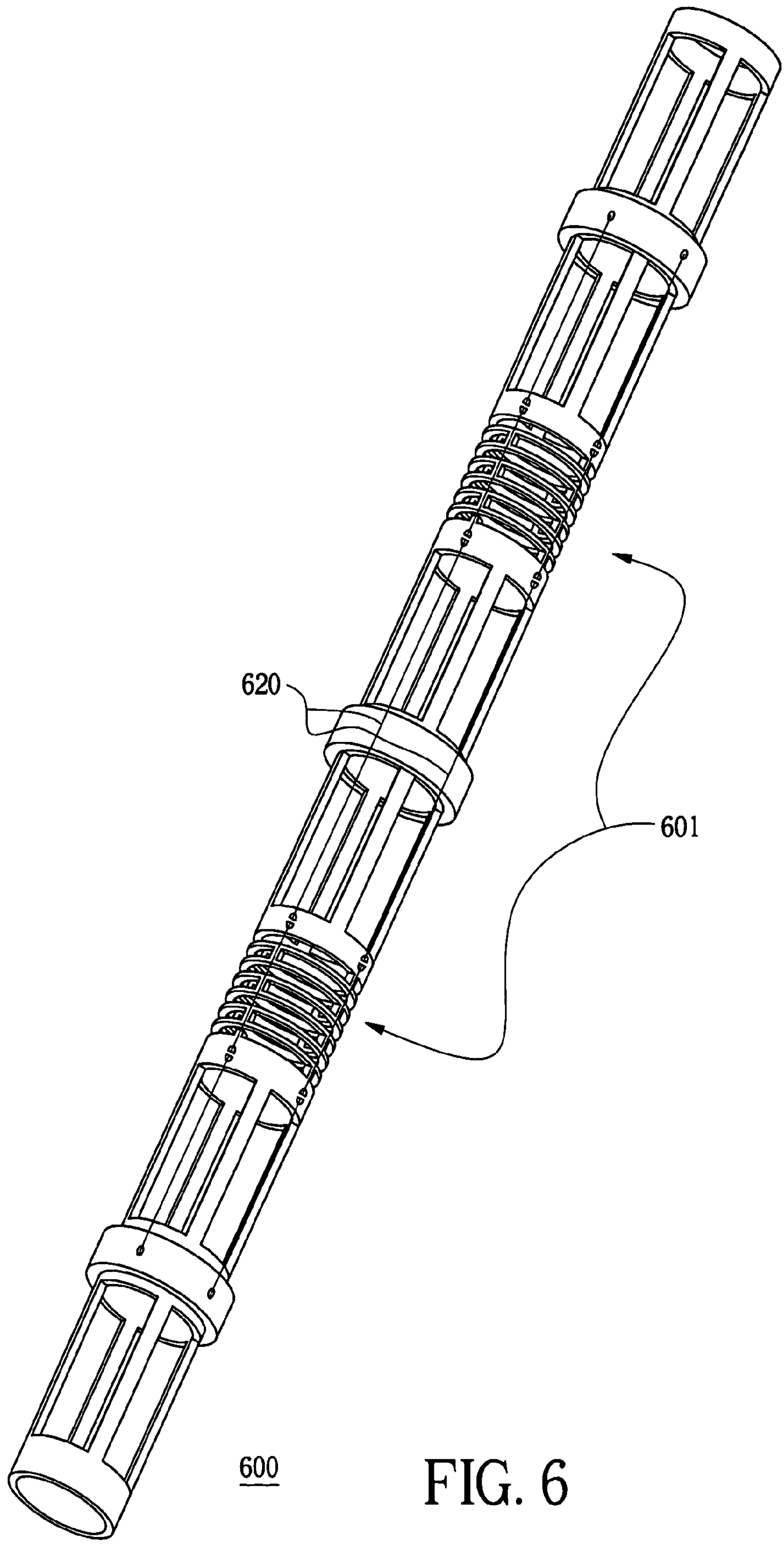


FIG. 6

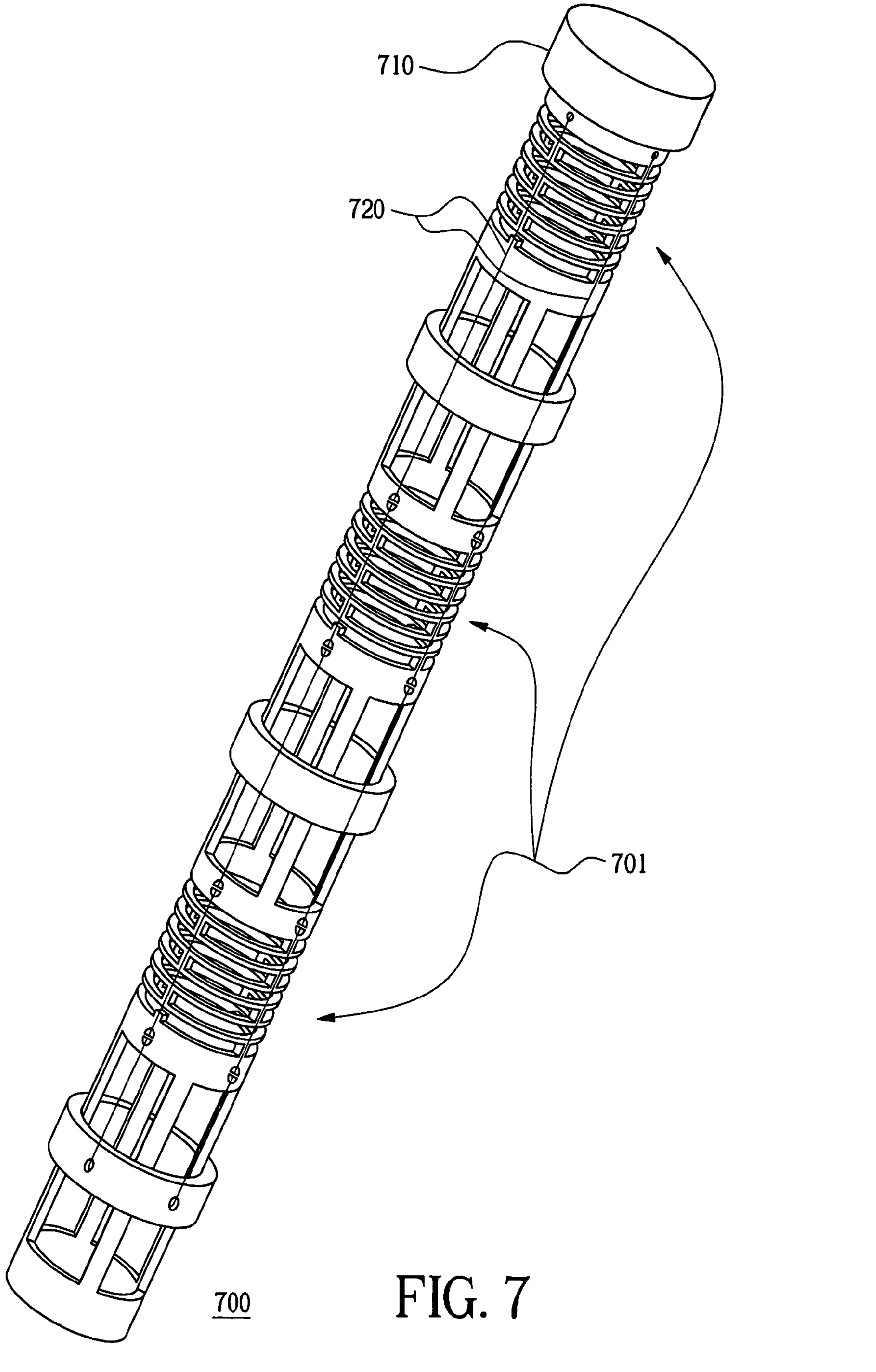


FIG. 7

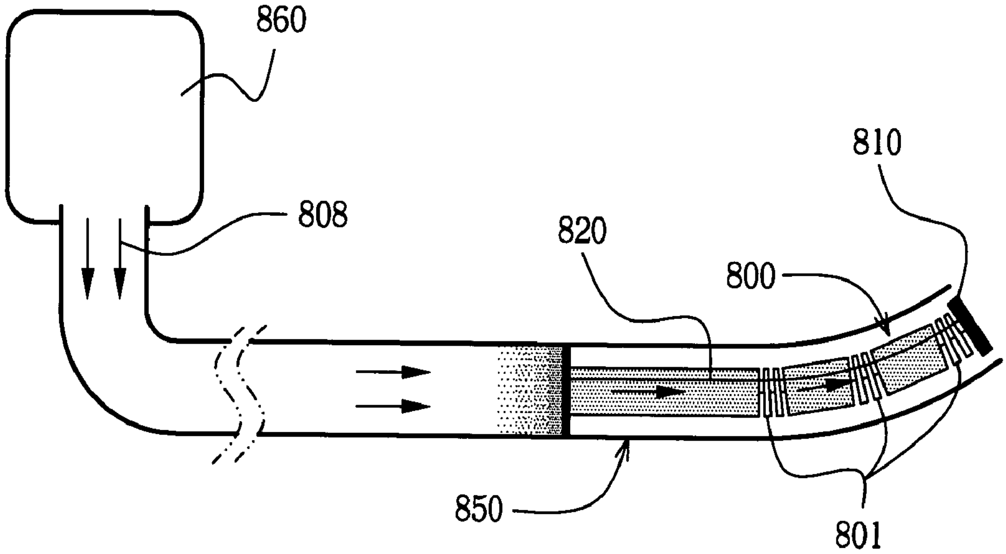


FIG. 8

900

FIG. 9

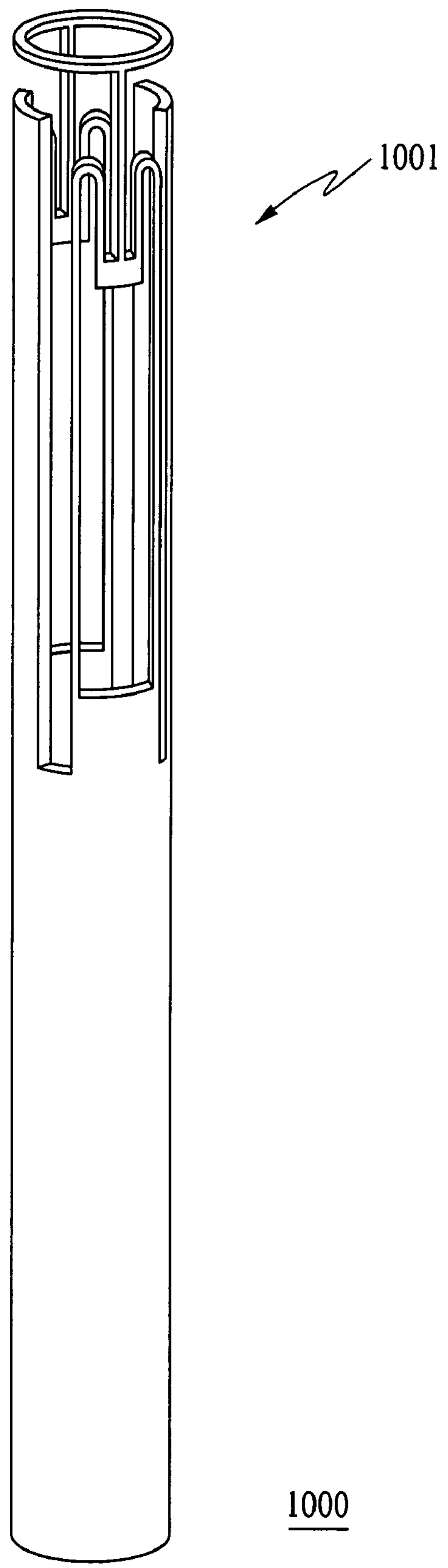


FIG. 10

TUBULAR COMPLIANT MECHANISMS FOR ULTRASONIC IMAGING SYSTEMS AND INTRAVASCULAR INTERVENTIONAL DEVICES

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of a provisional patent application No. 60/411,924, filed Sep. 18, 2002, the entire content and appendices of which are hereby incorporated by reference.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates generally to micromanipulators useful for ultrasonic imaging systems and tools, and, more particularly, to a micromanipulator having a tubular structure and at least one compliant mechanism formed from a single tube made of an elastic and/or superelastic material, the micromanipulator enabling treating diseases in a minimally invasive fashion and particularly useful for intravascular intervention applications and the like.

[0004] 2. Description of the Related Art

[0005] Currently, heart disease such as heart attack and stroke is the number one killer in the United States. One out of four men and women would experience this disease during his/her lifetime. In this category, the coronary artery disease is the most serious and often requires an emergency operation to save lives. The main cause of the 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 (balloon-expandable wire mesh implants), 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 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.

[0006] In order to resolve these issues, an ultrasonic transducer has been implemented in the endovascular intervention to visualize the inside of the blood vessels. To date, however, the ultrasonic transducer is only able to see side images of the blood vessels by rotating the transducers in parallel to the blood vessels. Thus, known ultrasonic transducers have a fundamental limitation in their uses in endovascular/intravascular applications. What is needed is a micromanipulator capable of maneuvering the ultrasonic transducer and generating a scanning motion so that front images of the blood vessels in various angles can be captured.

SUMMARY OF THE INVENTION

[0007] The present invention addresses this need in the art by disclosing a new micromanipulator useful for ultrasonic imaging, intravascular intervention, and the like. The micromanipulator enables its user to visualize and inspect inside blood vessels in essentially all directions and to treat any abnormalities identified in a minimally invasive manner.

[0008] According to an aspect of the present invention, an elastic or superelastic material is utilized as a structural material for the new micromanipulator. Elasticity or superelasticity is therefore a key design parameter for compliant mechanisms of the 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.

[0009] In some embodiments, Shape Memory Alloys (SMAs) are implemented as main actuators for the micromanipulator. The compliant mechanism is actuated with SMA contraction as well as rotation motion to maximize output displacement. By activating the SMAs, it is possible to achieve ±30° angular deflections. It is anticipated that the compliant mechanism can be designed to accommodate two other SMAs in an orthogonal direction, in which case, the compliant mechanism can be manipulated with two degree-of-freedom, which would provide the micromanipulator with full 3-D scanning motions.

[0010] According to an aspect of the invention, 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 30 μm. The outer diameter of the tube is about 800 μm and the wall thickness is about 75 μm. Actual feature size is about 25 μm, 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.

[0011] Micromanipulators of the present invention with novel features such as structural compliance, elasticity/superelasticity, tubular structure, etc. are particularly useful in the fields of intravascular ultrasound (WUS) imaging and intravascular intervention.

[0012] Still further objects and advantages of the present invention will become apparent to one of ordinary skill in the art upon reading and understanding the drawings and detailed description of the preferred embodiments disclosed herein. As it will be appreciated by one of ordinary skill in the art, various changes, substitutions, and alternations can be made without departing from the principles and the scope of the present invention. As such, the drawings disclosed herein are for purposes of illustrating embodiments of the present invention and are not to be construed as limiting the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] **FIG. 1** compares the second moment of inertia between a plate form and a tubular structure.

[0014] FIGS. **2**A-**2**B show two tubular structures each with a built-in compliant mechanism in different design configuration.

[0015] **FIG. 3** schematically shows an ultrasound transducer coupled to a micromanipulator having the compliant structure of **FIG. 2**A and two SMA actuators configured to actuate the compliant mechanism thereof.

[0016] **FIG. 4** is a photograph showing an exemplary compliant structure of **FIG. 2A** having no mechanical joints and made of a nitinol tube with a built-in compliant mechanism.

[0017] FIGS. **5A-5B** are photographs showing a micromanipulator having the compliant structure of **FIG. 4** and two SMA actuators configured to actuate the compliant mechanism thereof.

[0018] **FIG. 6** schematically shows an implementation of **FIG. 2A** useful for a catheter steering system. The tubular compliant structure has multiple segments of compliant mechanisms each individually controllable via SMA actuators assembled therewith.

[0019] **FIG. 7** schematically shows an implementation of **FIG. 6** coupled with an ultrasound transducer.

[0020] **FIG. 8** schematically shows an exemplary intravascular imaging device embodying the implementation of **FIG. 7**, the imaging device integrated with a cooling system.

[0021] **FIG. 9** is a photograph showing another exemplary compliant structure under loading in a bulging-out configuration.

[0022] **FIG. 10** schematically shows a tubular structure with a built-in compliant mechanism that enables the bulging-out configuration of **FIG. 9**.

DETAILED DESCRIPTION

[0023] To address the fracture toughness and stress issue, a superelastic material such as nitinol is utilized as a structural material for the micromanipulator of the present invention. Thus, superelasticity is implemented as a key design parameter for compliant mechanisms disclosed herein. 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 back to its original shape. However, an elastic material such as stainless steel can also be utilized as a structural material for compliant mechanisms if the fracture and stress issue can be appropriately addressed with elasticity as a design parameter.

[0024] To shape a nitinol structure, there are two fabrication processes currently commercially available: chemical etching and laser machining. 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, El. Considering the structural rigidity, a tube shape **101** is more attractive than a plate form **102** as demonstrated in **FIG. 1**, where

$$I_P = \frac{bt^3}{12} = \frac{\pi d_o t^3}{12} \tag{1}$$

$$I_t = \frac{\pi(d_o^4 - d_i^4)}{64} = \frac{\pi(d_o^4 - (d_o - 2t)^4)}{64} \tag{2}$$

[0025] I_t and I_p respectively represents the second moment of inertia of a tube and a plate. The lengths of the plate and the tube are assumed to be the same for correct comparisons in equations (1) and (2).

[0026] **FIG. 1** shows that there is an exponential difference in structural rigidity as d_o/t increases, which is a reasonable estimation for the compliant mechanism. Thus, the tube was selected as a basic form of structure for the compliant mechanisms. **FIG. 2A** illustrates an exemplary tubular structure **200***a* with a built-in compliant mechanism **201***a*. **FIG. 2B** illustrates another exemplary tubular structure **200***b* with a built-in compliant mechanism **201***b* in a helical configuration having helix **291** and helix **292** 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.

[0027] As illustrated in **FIG. 2**B, compliant mechanisms can be in a "double helix" configuration. It is desirable with the present 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.

[0028] 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.

[0029] According to the present invention, 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 0.5 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.

[0030] **FIG. 3** schematically shows, according to an aspect of the invention, a micromanipulator **300** tightly coupled with an ultrasound transducer **310** for image scanning. Micromanipulator **300**, 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. As discussed before, most of the research efforts on ultrasonic imaging system for intravascular intervention utilized ultrasonic transducers to inspect sidewall images inside blood vessels. These transducers are turned inside at high speed to capture the inner images, which do not provide any information about the front images. As one skilled in the art would appreciate, it would be extremely helpful if cardiologists can see the cross-section (front images) of the blood vessels in front of the device used to remove the stenosis. To catch the front images in various angles needed to create the images in front of the device, a micromanipulator is required to maneuver the transducer and generate a scanning motion.

[0031] The micromanipulator **300** enables the ultrasound transducer **310** to be directly coupled to the compliant mechanisms **301**. In this fashion, the rotational center of the transducer **310** for the scanning motion is substantially closer to the rotational axis of the mechanisms **301**. This novel configuration can produce images with much better resolutions than known devices. In an embodiment, SMAs (Shape Memory Alloys) are implemented as main actuators **320** for the micromanipulator **300**. To allow the SMAs **320** be attached thereto, the micromanipulator **300** might have one or more attachment points or built-in micro structures such as welding-enabling structures **302** as shown in a cross-sectional view A-A and clamping-enabling structures **302**' as shown in another cross-sectional view A'-A'. In some embodiments, the SMAs **320** are attached to the compliant apparatus via the one or more attachment points or welding-enabling structure **302** using a laser having a laser beam size of about 200 μm or less. In some embodiments, the SMAs **320** are fastened to the compliant apparatus via the built-in clamping-enabling structures **302**'.

[0032] The compliant mechanisms **301** are actuated with SMA **320** 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 here.

[0033] The amount of continuous power applied to all of the actuators is 1W or less, with a peak power of 10W or less. It will be appreciated that the micromanipulator of the present invention can have at least two actuator. Additional actuators can be utilized, subject to the ability to manufacture, cost, size, and like.

[0034] According to an aspect of the invention, a Nd:YAG laser was implemented in fabricating compliant structures out of nitinol tubes. The laser has a wavelength of 1.06 μm and an average power of 75W. The cutting depth of the laser is about 125 μm. Nd:YAG lasers as well as other lasers suitable for the laser machining are known in the art and thus are not further described herein. Referring to **FIG. 4, a** compliant structure **400** was successfully fabricated out of a nitinol tube using laser machining. The outer diameter of the nitinol tube is about 800 μm and the wall thickness is about 75 μm. The compliant structure **400** can be characterized as a tubular nitinol structure with a built-in compliant mechanism **401** and loading points **440**. The compliant structure **400** shown in **FIG. 4** is actuated with a SMA actuator **420** via one of the loading points **440**. It is also useful to pattern the compliant structures with holding structures (not shown) for temporarily holding the SMA actuator during assembly and to decrease stress upon the SMA actuator at the attachment point in the final device. In this embodiment, the compliant structure **400** has features about 30 μm in size. In practice, actual feature size is mostly limited by the size of the laser beam, which was about 25 μm in this example. It will be apparent to one skilled in the art that, by reducing the beam size, the resolution of the laser machining can be enhanced.

[0035] The size of the various elements of micromanipulators of the present invention can be customized depending on applications. For example, if it is desired to insert a micromanipulator into the inner diameter of another device, the diameter of the micromanipulator is selected so that the micromanipulator can fit in the inner diameter of that device. In a more specific example, for a coronary artery, it is desired to have a micromanipulator with a diameter of 2 mm or less. For larger vessels, the diameter of micromanipulator can be 4 mm or less.

[0036] The tubular nitinol compliant structure **400** was tested under cyclic loading. Specifically, SMA actuators generated a cyclic motion of the compliant structure **400** at 10 Hz under water. The compliant structure **400** successfully endured the mechanical loading test while it was actuated. No mechanical failure was noticed up to 20,000 cycles.

[0037] FIGS. **5A-5B** show a micromanipulator **500** having a compliant structure as shown in **FIG. 4** and two main actuators in the form of SMA wires successfully assembled therewith. In various embodiments, the actuators of micromanipulator **500** provide angular deflection of at least ±20°. In the embodiments illustrated in FIGS. **5A-5B** the actuators are activated, resulting in ±40° angular deflections. The micromanipulator **500** can be assembled with two other actuators in an orthogonal direction. The micromanipulator **500** so assembled will be able to manipulate the compliant mechanism with two degree-of-freedom, which would provide full 3-D scanning motions. 3-D scanning motions can be achieved by utilizing an actuator for one direction of deflection, and then a second actuator for the second direction of deflection. It will be appreciated that the second direction of deflection can be achieved by rotation movement, for example by way of illustration, and without limitation, in a helical type of scan.

[0038] In addition to being particularly useful in ultrasound intravascular interventional devices, systems, and applications, the present invention can also be useful in catheter steering related applications including but not limited to any vessels in the body, such as those in neurology, biliary vessles, the fallopian tubes, coronary vessels (including peripheral vessels), and the like. It will be appreciated that the present invention can also be utilized for industrial applications as mentioned above. In a conventional catheter steering system, it is difficult to steer a small catheter inside human blood vessels, especially in small artery. However, by implementing a compliant structure with multiple segments of compliant mechanisms in various configurations and individually controlling each segment, it is possible to generate intricate motions and steer the catheter in any direction, even in a tiny area. For example, a catheter steering system implementing a micromanipulator **600** according to the present invention may include multiple segments of compliant mechanisms **601** actuated with SMAs **620**, as shown in **FIG. 6**. These tubular compliant mechanisms are arranged in various configurations for intricate motions of the micromanipulator. Such catheter steering system is particularly useful for intravascular applications including imaging and therapy.

[**0039**] **FIG. 7** shows a micromanipulator **700** with an ultrasound transducer **710** directly coupled thereto at one end of the micromanipulator **700** for forward imaging. The micromanipulator **700** has multiple segments of compliant mechanisms **701** actuated with SMAs **720**. Multiple segments of compliant mechanisms **701** are useful for vessels with different curvatures. For example, one section of a vessel may require a larger curvature than another area. Therefore, multiple segments of compliant mechanisms **701** make it easier to traverse through a vessel with different curvatures. A user of the system controls individual segment's compliant mechanism via a user interface of an external electronic circuitry, e.g., a computer (not shown).

[**0040**] When SMAs are implemented as main actuators for the micromanipulator, the performance (e.g., bandwidth and endurance) of the manipulator and devices associated therewith, e.g., an imaging or therapeutic device, can be substantially enhanced by regulating the temperature of the SMAs. Regulation of the temperature can be controlled by any suitable cooling system (e.g., peristaltic pump and IV pump). **FIG. 8** shows a micromanipulator **800** having multiple segments of compliant mechanisms **801** actuated by SMAs **820**. The micromanipulator **800** is coupled to an ultrasound transducer **810** and steered by SMA actuators **820**. A plastic tube, catheter **850**, encapsulates the micromanipulator **800**, SMAs **820**, transducer **810**, etc. A cooling system **860**, comprising a pumping means and cooling fluid, provides a constant fluid flow **808** to the micromanipulator **800** to prevent the SMAs **820** from overheating during normal operation. Here, the cooling fluid can be any biocompatible solution such as water or saline.

[**0041**] Another application includes utilizing the novel design disclosed herein for angioplasty. Currently, depending on the size of arteries that need to be cleared, surgeons use different sizes of balloons during operation. This means that they would have to change balloon sizes several times and each balloon must be taken out of the body for another balloon to be inserted in. As one skilled in the art would appreciate, the exchange of balloons is a necessary but undesirable procedure. Implementing the compliant mechanisms disclosed herein, it is possible to cover certain ranges of balloon sizes with one single device, as exemplified in **FIG. 9**. **FIG. 9** shows an actual compliant structure **900** under loading in a bulging-out configuration. **FIG. 10** schematically shows a tubular structure **1000** with a built-in compliant mechanism **1001** that enables the bulging-out configuration of **FIG. 9**. It will be apparent to one skilled in the art that the compliant mechanisms disclosed herein have more capabilities in terms of pressure and deployment control than prior art surgical balloons. Moreover, with the present invention, the need to exchange balloons during operation can be substantially reduced or eliminated, thereby simplifying and possibly shorting the angioplasty procedure, making it easier on the surgeons and safer for the patients. The advantages of the present invention are innumerable.

[**0042**] To date, we are not aware of any methods for manufacturing compliant mechanisms out of a nitinol tube for intravascular intervention. Similarly, we are not aware of anyone implementing laser machining as a main fabrication tool for constructing compliant mechanisms. The present invention advantageously utilizes structural compliance, elasticity/superelasticity, and strain energy as a restoring force. Compliant structures and micromanipulators based on these features (structural compliance, elasticity/superelasticity, tubular structure, etc.) as disclosed herein are believed to be unprecedented. The present invention is useful in many fields, e.g., a micromanipulator implemented with an ultrasound transducer such as one shown in **FIG. 3** would be useful in intravascular ultrasound (IVUS) applications and particularly in forward imaging systems. A micromanipulator implemented with multiple segments of compliant mechanisms would be useful in steering a catheter in any direction, even in a tiny area. In various embodiments, the present invention can utilize a variety of different interventions for treatment, including but not limited to laser, rotor blader, RF, mechanical, stiff guide wire, microwave, ultrasound, chemical, and the like.

[**0043**] A micromanipulator implemented with a bulging-out configuration as shown in FIGS. **9-10** would be useful in angioplasty and other types of operations where exchanging different sizes of balloons and the like is necessary but undesirable. The micromanipulator of the present invention is made of a monolithic material, e.g., a nitinol tube with a reversible structural behavior, with a built-in compliant mechanism. Since there are no mechanical joints, the micromanipulator can be very small and can facilitate surgical operations in a minimally invasive fashion.

[**0044**] Although the present invention and its advantages have been described in detail, it should be understood that the present invention is not limited to or defined by what is shown or described herein. Known methods, systems, or components may be discussed without giving details, so to avoid obscuring the principles of the invention. As it will be appreciated by one of ordinary skill in the art, various changes, substitutions, and alternations could be made or otherwise implemented without departing from the principles of the present invention. As such, the drawings are for purposes of illustrating a preferred embodiment(s) of the present invention and are not to be construed as limiting the present invention. Accordingly, the scope of the invention should be determined by the following claims and their legal equivalents.

We claim:

1. A compliant apparatus comprising:

a tubular structure formed from a tube made of a material having a reversible structural behavior, and at least one compliant mechanism also formed from the tube as part of the tubular structure; wherein

the compliant apparatus has no mechanical joints; and wherein

the compliant apparatus is capable of being controlled to maneuver reversibly in various motions and degree-of-freedoms without permanent deformation.

2. The compliant apparatus of claim 1, wherein the cross-section of the tube is characterized as circular, oval, rectangular, square, straight, curvy, angular, or irregular.

3. The compliant apparatus of claim 1, wherein the reversible structural behavior is characterized as elastic or superelastic.

4. The compliant apparatus of claim 1, wherein the material is selected from the group consisting of an elastic alloy including stainless steel and titanium alloy, and a superelastic alloy including nitinol, Cu—Al—Ni, Cu—Al, Cu—Zn—Al, Ti—V and Ti—Nb alloy.

5. The compliant apparatus of claim 1, wherein the compliant mechanism stores strain energy and utilizes the stored energy as a bias force for shape recovery.

6. The compliant apparatus of claim 1, wherein the compliant mechanism is capable of being actuated by at least one actuators.

7. The compliant apparatus of claim 6, wherein the at least one actuators are made of Shape Memory Alloys (SMAs) and wherein the SMAs are based on shape memory effects including contraction, rotation, and a combination thereof.

8. The compliant apparatus of claim 7, wherein the SMAs are configured for manipulating the compliant apparatus and the compliant mechanism.

9. The compliant apparatus of claim 6, wherein the at least one actuators are characterized as piezoelectric or electro-active polymer actuators.

10. The compliant apparatus of claim 6, wherein the at least one actuators are characterized as wires connected to an external apparatus and actuated remotely via the external apparatus.

11. The compliant apparatus of claim 6, wherein the at least one actuators are characterized as Shape Memory Alloy wires or Shape Memory Alloy springs.

12. A method of fabricating the compliant apparatus of claim 1, comprising:

forming the compliant mechanism and the tubular structure out of a tube with laser machining.

13. The method of claim 12, wherein

the laser machining having a laser beam size of about 50 μm or less.

14. The compliant apparatus of claim 1, further comprising at least one built-in micro structure selected from the group consisting of a welding-enabling structure and a clamping-enabling structure.

15. A method of joining the compliant apparatus of claim 14 with at least one actuators, comprising the step of:

attaching the at least one actuators to the compliant apparatus via the at least one built-in micro structure.

16. The method of claim 15, wherein the at least one built-in micro structure is the welding-enabling structure, the method further comprising the step of:

welding the at least one actuators to the welding-enabling structure using a laser.

17. The method of claim 16, wherein

the laser having a laser beam size of about 200 μm or less.

18. An ultrasonic imaging system useful for intravascular ultrasound forward imaging applications, the ultrasonic imaging system comprising:

a compliant apparatus having no mechanical joints and capable of being manipulated in various motions and degree-of-freedoms without permanent deformation, the compliant apparatus comprising:

a tubular structure formed from a tube made of a material having a reversible structural behavior; and

at least one compliant mechanism integrally formed from the tube;

an ultrasound transducer coupled to the compliant apparatus; and

at least one actuators attached to the compliant apparatus for manipulating the compliant apparatus and the at least one compliant mechanism.

19. The ultrasonic imaging system of claim 18, wherein the reversible structural behavior is characterized as elastic or superelastic.

20. The ultrasonic imaging system of claim 18, wherein the material is selected from the group consisting of an elastic alloy including stainless steel and titanium alloy, and a superelastic alloy including nitinol, Cu—Al—Ni, Cu—Al, Cu—Zn—Al, Ti—V and Ti—Nb alloy.

21. The ultrasonic imaging system of claim 18, wherein the at least one actuators are made of Shape Memory Alloys (SMAs) and wherein the SMAs are based on shape memory effects including contraction, rotation, and a combination thereof to maximize output displacement of the at least one compliant mechanism.

22. The ultrasonic imaging system of claim 18, wherein the at least one actuators are characterized as piezoelectric or electro-active polymer actuators.

23. The ultrasonic imaging system of claim 18, wherein the at least one actuators are characterized as wires connected to an external apparatus and actuated remotely via the external apparatus.

24. The ultrasonic imaging system of claim 18, further comprising:

two additional actuators configured to actuate the compliant apparatus in an orthogonal direction, enabling the compliant apparatus to provide the ultrasound transducer with full three dimensional scanning motions.

25. The ultrasonic imaging system of claim 24, wherein the at least one actuators and the two additional actuators are characterized as SMA wires or SMA springs.

26. A micromanipulator useful for intravascular applications including imaging and

therapy, the micromanipulator comprising:

a tubular elastic or superelastic element having no mechanical joints and formed from a tube made of a material having a reversible structural behavior; and

at least one actuators for manipulating the tubular elastic or superelastic element.

27. The micromanipulator of claim 26, wherein the at least one actuators are selected from the group consisting of

Shape Memory Alloy (SMA) actuators, piezoelectric actuators, and electro-active polymer actuators.

28. The micromanipulator of claim 27, wherein the at least one actuators are characterized as wires connected to an external apparatus and actuated remotely via the external apparatus.

29. A system useful for intravascular applications including imaging and therapy, the system comprising:

a micromanipulator having no mechanical joints and characterized as a tubular structure made of an elastic or superelastic material; and

a plurality of compliant mechanisms forming an integral part of the micromanipulator, having various configurations, and positioned in various locations of the micromanipulator for enabling intricate motions of the micromanipulator; and

at least one actuators coupled to the plurality of compliant mechanisms for effecting the intricate motions of the micromanipulator.

30. The system of claim 29, wherein the at least one actuators are selected from the group consisting of Shape Memory Alloy (SMA) actuators, piezoelectric actuators, and electro-active polymer actuators.

31. The system of claim 29, wherein the at least one actuators are characterized as wires connected to an external apparatus and actuated remotely via the external apparatus.

32. The system of claim 29, further comprising:

two additional actuators configured to actuate the compliant apparatus in an orthogonal direction, enabling the micromanipulator with full three dimensional steering motions.

33. The system of claim 29, wherein the at least one actuators and the two additional actuators are characterized as SMA wires or SMA springs.

34. The system of claim 29, wherein

each compliant mechanism is individually controllable via the at least one actuators.

35. The system of claim 29, wherein

the at least one actuators are controlled by a remote electronic circuitry via a user interface.

36. The system of claim 29, wherein

the micromanipulator and the plurality of compliant mechanisms are assembled together subsequent to being respectively formed.

37. The system of claim 29, further comprising:

an ultrasound transducer coupled to the micromanipulator.

38. The system of claim 29, further comprising:

a cooling system coupled to the micromanipulator for regulating temperature thereof.

39. The system of claim 38, wherein

the cooling system comprises a pumping means and biocompatible cooling fluid; and wherein

the pumping means provides a constant flow of the cooling fluid to the micromanipulator to prevent the at least one actuators from overheating.

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专利名称(译)	用于超声成像系统和血管内介入装置的管状顺应机构		
公开(公告)号	[US20040056751A1](US20040056751A1)	公开(公告)日	2004-03-25
申请号	US10/667230	申请日	2003-09-18
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IPC分类号	A61B8/12 A61M25/01 H01H61/06 H01H71/18		
CPC分类号	A61B1/0008 A61B8/12 A61M2025/0058 A61M25/0158 A61M25/0105		
优先权	60/411924 2002-09-18 US		
其他公开文献	US7115092		
外部链接	Espacenet USPTO		

摘要(译)

一种显微操纵器，包括管状结构和结构顺应机构，其由弹性和/或超弹性材料制成的管形成。采用激光加工制造且无机械接头，微操纵器可以各种运动和自由度进行操作，不会发生永久变形。在一个实施例中，形状记忆合金（SMA）被实现为微操纵器的主致动器。微操纵器可以用多个SMA实现，以操纵具有多个自由度的机构。在另一种实施方式中，机构的多个区段以各种配置形成和布置，包括“双螺旋”状配置，用于实现微操纵器的复杂运动。当与超声换能器耦合时，微操纵器可用于血管内介入应用，尤其是超声成像。