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(71) Applicant (for all designated States except US): **UNIVERSITY OF VIRGINIA PATENT FOUNDATION** [US/US]; 250 West Main Street, Suite 300, Charlottesville, Virginia 22902 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **GILLIES, George T.** [US/US]; 202 Colthurst Drive, Charlottesville, Virginia 22901 (US). **POLLAK, Peter** [US/US]; 2304 Crestmont Avenue, Charlottesville, Virginia 22903 (US). **MAHAPATRA, Srijoy** [US/US]; 1963 Old Ballard Farm Lane, Charlottesville, Virginia 22901 (US).

(74) Agent: **DECKER, Robert J.**; 250 West Main Street, Suite 300, Charlottesville, Virginia 22902 (US).

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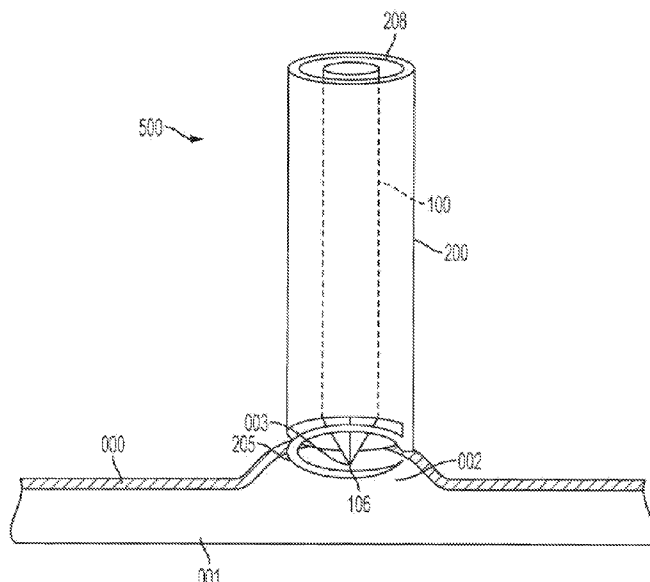


FIG. 6

(57) Abstract: System and method that is directed to medical treatments of organs having anatomical spaces, such as (but not limited to) the heart and the pericardial space. Specifically, an apparatus and method is provided for safely accessing anatomical spaces with surfaces to deliver medical devices or media into such spaces, or to remove fluids from such spaces. The methods and apparatus may include a first elongated member with a sharp tip used to penetrate the surface surrounding the anatomical space with a second elongated member with a helical tine used to engage the surface and lift the surface away from the underlying anatomical space. Once the first elongated member has incised the surface, it is removed, and the incision may be used as a point of entry for delivering media or medical devices into the anatomical space, or for carrying out further medical procedures.

## ACCESS TROCAR AND RELATED METHOD THEREOF

### RELATED APPLICATIONS

5           This application claims priority under 35 U.S.C. § 119(e) from U.S. Provisional Application Serial No. 61/174,763, filed May 1, 2009, entitled “Epicardial Access Trocar and Related Method Thereof,” the disclosure of which is incorporated by reference herein in its entirety.

10

### FIELD OF THE INVENTION

          The present invention generally relates to medical treatments of organs having anatomical spaces, such as (but not limited to) the heart and the pericardial space. Specifically, the present invention relates to an apparatus and method for safely accessing  
15           anatomical spaces with surfaces to deliver medical devices or media into such spaces, or to remove fluids from such spaces.

### BACKGROUND OF THE INVENTION

20           The heart muscle is surrounded by tissue known as the pericardial sac, which consists of several layers of tissue. The outermost of these layers is the fibrous pericardium. Inside the fibrous pericardium is the serous pericardium. The serous pericardium consists of three parts: the parietal pericardium, which is bonded to the inside of the fibrous pericardium; the innermost visceral pericardium; and a fluid-containing potential space between the parietal  
25           pericardium and the visceral pericardium called the pericardial space. Inside the visceral pericardium is the myocardium, the actual heart muscle itself.

          Epicardial procedures on the heart are growing in number, efficacy, and complexity. Currently, ablations for ventricular tachycardia and atrial fibrillation as well as intra-cardiac procedures for valve repair are done using approaches on the outside of the heart.  
30           Establishing epicardial access is often difficult and frequently requires the assistance of a surgeon. Similar difficulties exist in establishing access to other anatomical spaces with surfaces, such as the kidneys, the dura mater of the brain, blood vessels, and the peritoneum.

          Several conventional devices establish access to such anatomical spaces using vacuum or forceps. One problem with vacuum designs is that it is difficult to maintain the

vacuum seal on the pericardium required to create and uphold a bleb. Additionally, if the vacuum seal is broken, the tissue bleb may re-collapse away from the tip of the suction probe, thus interrupting the procedure. Vacuum suction is also likely to cause trauma and scarring to the pericardium. Moreover, vacuum designs are likely to clog on other bodily tissues

5 encountered before reaching the pericardium. Forceps designs also pose several problems. First, forceps designs provide an uncertain grasp on the pericardium. Second, forceps devices require such shallow approach angles that they often have difficulty grasping the pericardium. Moreover, such forceps devices require that large incisions be made in the subject in order to provide a large enough window to facilitate their use.

10 Conventional approach with penetration devices and access tubes do not grip the anatomical surface with uniform force, increasing the risk of tearing. Additionally, significant mechanical difficulties are encountered with fat and other tissue in the body before reaching the anatomical surface, as fat and tissue may become caught in the penetrating elements and restrict further movement.

15 There is therefore a need in the art for a safe, consistent, accurate, and easy to use percutaneous system to access the pericardial space. Similar needs arise in the context of accessing other anatomical spaces with surfaces as well.

## 20 SUMMARY OF THE INVENTION

By practicing the methods and apparatus of various embodiments of the present invention, the skilled practitioner can easily and safely access the underlying anatomical space. An aspect of an embodiment of the present invention provides, but not limited thereto, a first elongated member with a sharp tip used to penetrate the surface surrounding the anatomical space with a second elongated member with a helical tine used to engage the surface and lift the surface away from the underlying anatomical space. Once the first elongated member has incised the surface, it is removed, and the incision may be used as a point of entry for delivering media or medical devices into the anatomical space, or for carrying out further medical procedures.

30 An aspect of an embodiment of the present invention may be used to access any anatomical space with a surface. Anatomical spaces that may be accessed with various embodiments may include but are not limited to the pericardial space, the interior of the kidneys, the brain, blood vessels, the peritoneal cavity, the spinal cord, the intra-abdominal space, the intra-thoracic space or any space in the body bounded by a membrane or

membranous entity. Surfaces include but are not limited to the parietal pericardium, the renal capsule, the dura mater, blood vessel walls, the peritoneum, the dural lining of the spinal cord, the pleura, the seurosa, or any other membrane in the body. It should be appreciated that the various embodiments may be practiced not only upon human subjects but upon  
5 animal subjects as well.

Media may comprise a pharmaceutically active substance, cells, fluids, biological fluids, drugs, gene therapy vectors, irrigation fluids, growth factors, nuclear medicine agents, antibiotics, anti-viral agents, contrast agents, chemotherapies, or other diagnostic or therapeutic agents.

10 Medical devices may include but are not limited to sheath catheters, ablation catheters, guide wires, other catheters, visualization and recording devices, lumens, steering devices or systems, drug or cell delivery catheters, fiber endoscopes, suctioning devices, irrigation devices, electrode catheters, needles, optical fiber sensors, sources of illumination, vital signs sensors, pacing leads, cathode or other electrodes, fluid delivery or removal  
15 means, devices for delivering and unfurling or spreading surface patches or coverings onto the heart, biopsy devices, suture- or staple-placement devices, endoscopes, fiber-optic probes, temperature sensors, pH or other chemical sensors, feedback or regulation devices, batteries or other energy sources, cryoprobes, laser light delivery probes, artherectomy devices, angioplasty devices, surgical devices, and the like.

20 An advantage conferred by an aspect of an embodiment of the present invention is that the single point of contact made helical tine minimizes the resistance faced by the apparatus as it passes through other tissue such as fat and muscle in order to reach the surface of the anatomical space. Another advantage of using aspect of an embodiment of the present invention is a minimized risk of tearing the anatomical surface as it is lifted away from the  
25 anatomical space, since the helical tine provides a stable and uniform distribution of lift across the anatomical surface after it has engaged the surface. Thus, the teachings of the present invention overcome the limitations of the prior art devices by consistently, safely, and stably lifting the surface from the anatomical space in order to establish access to the anatomical space.

30 An aspect of an embodiment of the present invention provides methods and apparatus used to implement a novel approach for accessing anatomical spaces with surfaces safely, consistently, accurately, and with ease. An aspect of an embodiment of present the invention, the apparatus is advanced through the body to abut the parietal pericardium or other anatomical surface. The apparatus is then turned so that the helical tine of the second

elongated member penetrates and engages the surface and draws it in a proximal direction, thereby enlarging the anatomical space and pulling the surface onto the sharpened first elongated member, causing the first elongated member to incise the anatomical surface. Once the anatomical surface has been penetrated, the first elongated member is withdrawn in a proximal direction. After the first elongated member has been at least partially withdrawn, medical devices or media may be inserted through the incision into the anatomical space, with the second elongated member left in place in order to maintain the expansion of the anatomical space. In an aspect of an embodiment of this method, the medical devices or media are inserted into the anatomical space through the second elongated member while its helical tine remains engaged with the surface.

In an aspect of an embodiment of the present invention, the apparatus is advanced through the body to abut the parietal pericardium or other anatomical surface. The apparatus is then turned so that the helical tine of the second elongated member penetrates and engages the surface and draws it in a proximal direction, thereby enlarging the anatomical space and pulling the surface onto the sharpened first elongated member, causing the first elongated member to incise the anatomical surface. Once the anatomical surface has been penetrated, the first elongated member is withdrawn in a proximal direction. After the first elongated member has been withdrawn, a guide wire may be inserted through the incision into the anatomical space. Once the guide wire has been inserted into the anatomical space, the second elongated member is rotated so that its helical tine disengages from the surface. Once the second elongated member is no longer engaged with the surface, it is withdrawn in a proximal direction.

In an aspect of an embodiment of the present invention, the apparatus may be equipped with actuating means to control precisely the movement of the helical tine in order to improve the safety of access procedures and to stabilize the helical tine's grip on the surface.

An aspect of an embodiment of the present invention may comprise imaging components of the apparatus so that the practitioner may determine the position of the device within the subject's body. For example, the sharp end of the first elongated member may be adapted to be used with an imaging device. In a currently preferred embodiment, the sharp end is echogenic, meaning that it is adapted to scatter ultrasonic waves. By using an ultrasonic transducer in conjunction with an imaging device and in conjunction with the echogenic sharp end, the practitioner of the invention may precisely determine the position of the sharp end of the first elongated member within the body. In an embodiments, any

component of any embodiment of the apparatus may be adapted for use with ultrasound or with other medical imaging modalities, including but not limited to magnetic resonance imaging, computed tomography, fluoroscopy, or other radiological modalities.

An aspect of an embodiment of the present invention provides an apparatus for  
5 accessing a subject's anatomical space having a surface. The apparatus may comprise: a first elongated member comprising a proximal end and a distal end, wherein the distal end includes a sharp end or portion. The apparatus may comprise: a second elongated member comprising a proximal end and a distal end, wherein the distal end includes a helical tine. The helical tine is configured to: engage and penetrate the surface of the anatomical space,  
10 wherein when the second elongated member is turned the helical tine lifts the surface in a proximal direction. This lifting assists in advancing the surface in contact with the sharp end (or portion) to cause an incision of the surface by the sharp end (or portion).

An aspect of an embodiment of the present invention provides a method for accessing a subject's anatomical space having a surface. The method may comprise: providing a first  
15 elongated member having a proximal end and a distal end, wherein the distal end includes a sharp end or portion. The method may further comprise: providing a second elongated member having a proximal end and a distal end, wherein the distal end includes a helical tine. The method may further comprise: engaging the surface of the anatomical space with the helical tine. The method may further comprise: turning the helical tine to cause lifting of the  
20 surface in a proximal direction, whereby the lifting assists in advancing the surface in contact with the sharp end or portion to cause an incision of the surface by the sharp end or portion.

System and method that is directed to medical treatments of organs having anatomical spaces, such as (but not limited to) the heart and the pericardial space. Specifically, an apparatus and method is provided for safely accessing anatomical spaces with surfaces to  
25 deliver medical devices or media into such spaces, or to remove fluids from such spaces. The methods and apparatus may include a first elongated member with a sharp tip used to penetrate the surface surrounding the anatomical space with a second elongated member with a helical tine used to engage the surface and lift the surface away from the underlying anatomical space. Once the first elongated member has incised the surface, it is removed, and  
30 the incision may be used as a point of entry for delivering media or medical devices into the anatomical space, or for carrying out further medical procedures.

An aspect of an embodiment of the present invention may comprise sensing the pressure regimes of the subject's body so that the practitioner may accurately navigate the

device within the subject's body. An embodiment of this aspect may comprise an access needle configured to monitor pressures as the access needle is advanced through the body.

The invention itself, together with further objects and attendant advantages, will best be understood by reference to the following detailed description taken in conjunction with the accompanying drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings illustrate several aspects and embodiments of the present invention, and, together with the description herein, serve to explain the principles of the invention. The drawings are provided only for the purpose of illustrating select embodiments of the invention and are not to be construed as limiting the invention.

FIG. 1 depicts an embodiment of the first elongated member

FIG. 2 depicts an embodiment of the second elongated member.

FIG. 3 depicts the embodiment of the first elongated member of FIG. 1 and the embodiment of the second elongated member of FIG. 2 used in tandem, with the first elongated member housed inside the second elongated member.

FIG. 4 depicts the embodiment in FIG. 3 in use as it engages the anatomical surface.

FIG. 5 depicts the embodiment in FIG. 3 in use as it enlarges the anatomical space.

FIG. 6 depicts the embodiment in FIG. 3 in use as it penetrates the anatomical surface.

FIG. 7 depicts the first elongated member of an alternate embodiment.

FIG. 8 depicts the second elongated member of an alternate embodiment.

FIG. 9 depicts the embodiment of the first elongated member of FIG. 7 and the embodiment of the second elongated member of FIG. 8 used in tandem, with the second elongated member housed inside the first elongated member.

FIG. 10 depicts the embodiment in FIG. 9 in use as it engages the anatomical surface.

FIG. 11 depicts the embodiment in FIG. 9 in use as it enlarges the anatomical space.

FIG. 12 depicts the embodiment in FIG. 9 use as it penetrates the anatomical surface.

FIG. 13 is a top-down cross-section view of an embodiment of the means used to hold the first elongated member in a fixed position with respect to the second elongated member.

FIG. 14 depicts the embodiment of the invention in FIG. 3 used in conjunction with an access needle and pressure-sensing means.

FIG. 15 depicts an embodiment of the first elongated member of FIG. 1 adapted for use with an imaging system.

FIG. 16 depicts an embodiment of the invention incorporating an imaging system and the first elongated member depicted in FIG. 15.

FIG. 17 depicts an embodiment incorporating a third elongated member substantially enclosing the embodiment of FIG. 3.

5        FIG. 18 depicts an alternate embodiment of the third elongated member with an alternate embodiment of the helical tine of the second elongated member.

FIG. 19 depicts the embodiment in FIG. 17 with an optional skin bumper for stabilizing the device at the skin.

10        FIG. 20 depicts grooves in the second elongated member of the embodiment in FIG. 17.

FIG. 21 depicts the actuator system for use with the embodiment in FIG. 20.

FIG. 22 depicts the embodiment in FIG. 17 with an optional side port.

FIG. 23 depicts the withdrawal of the first elongated member once the anatomical space has been accessed using the embodiment in FIG. 3.

15        FIG. 24 depicts the embodiment of FIG. 23 wherein the second elongated member remains in place for use in introducing medical devices into the anatomical space.

FIG. 25 depicts the embodiment of FIG. 24 wherein a guide wire is introduced into the anatomical space.

20        FIG. 26 depicts the embodiment of FIG. 25 wherein second elongated member is disengaged from the surface and withdrawn after the guide wire has been introduced into the anatomical space.

## DESCRIPTION OF THE SPECIFIC EMBODIMENTS

25        FIG. 1 shows an embodiment of the first elongated member 100. This elongated member comprises a proximal end 101 and a distal end 102. Disposed at the distal end 102 is a sharp end 103 that may be configured so as to provide a sharp point 106. It should be appreciated that the sharp end may be a variety of sharp structures or points such as beveled structure, serrated structure, tapered structure, or cutting edge structure, etc. In an approach,  
30        the first elongated member 100 may be configured as a cylinder, rectangular, prism, tube, shaft or other geometric shape as desired or required, with a length of about 1 cm to about 40 cm or as desired or required, and a width of about 1mm to about 15mm or as desired or required. It should be appreciated that that other lengths, shapes, contours and cross-sections may be used. The first elongated member 100 may be hollow or solid. The sharp point 106

may be configured as any one of a variety of structures, including but not limited to beveled structure, serrated structure, tapered structure, or cutting edge structure. In an embodiment, the first elongated member **100** may be composed of surgical-grade stainless steel, such as 306 stainless steel. In other embodiments, the first elongated member **100** may be composed of materials selected to be compatible with various medical imaging modalities, including but not limited to ferrous metals and alloys; non-ferrous metals and alloys such as titanium, nitinol, or magnesium; or plastics.

FIG. **2** shows an embodiment of the second elongated member **200** of the invention. This elongated member comprises a proximal end **201** and a distal end **202**. Disposed at the distal end **202** is a helical tine **205** configured as a corkscrew or the like. The axis of the helical tine **205** may be angled with respect to the longitudinal axis defined by the second elongated member **200** at a range of varying degrees from 0 degrees to 90 degrees, and preferably between about 10 and about 35 degrees, or as desired or required, so that when turned it can engage the anatomical surface. The helical tine **205** may subtend about 30 degrees of arc to about 360 degrees of arc, or as desired or required. Running through the second elongated member **200** is at least one lumen **208**. In an embodiment, the second elongated member **200** is configured as a cylinder, rectangular, prism, tube, hollow shaft or other geometric shape as desired or required, with a length of about 1 cm to about 40 cm or as desired or required and a width of about 1 mm to about 15 mm or as desired or required. It should be appreciated that other lengths, shapes, contours and cross-sections may be used. In an embodiment, the second elongated member **200** may be composed of surgical-grade stainless steel, such as 306 stainless steel. In other embodiments, the second elongated member **200** may be composed of materials selected to be compatible with various medical imaging modalities, including but not limited to ferrous metals and alloys; non-ferrous metals and alloys such as titanium, nitinol, or magnesium; or plastics. In an embodiment, the shape of the lumen **208** is also adapted to house the first elongated member **100**.

FIG. **3** shows an embodiment of the apparatus **500** comprising the first elongated member **100** and the second elongated member **200**. The first elongated member is inserted through the lumen **208** of the second elongated member **200** and housed therein. In an embodiment, the two elongated members may be selectively held in a fixed position relative to each other. It should be appreciated that the means for the selective holding may be a variety of approaches. For example, FIG. **13** depicts an embodiment of this selective hold aspect comprising switchable spring-ball mechanism **209** comprising a non-deformable high friction ball attached to a spring disposed inside the lumen **208** of the second elongated

member **200**. The ball of the spring-ball mechanism **209** presses against the first elongated member **100** and holds it in place inside the lumen **208**. Moreover, for example, grooves, high-friction materials, or other structures disposed on either the first elongated member **100** or the second elongated member **200** may also be employed to hold or selectively hold the two elongated members in a fixed position with respect to each other.

FIGS. 4-6 depict the embodiment of the apparatus **500** in use. Once the apparatus is in place or adjacent to the surface **000** of the anatomical space **001**, as shown in Figure 4, the helical tine **205** can engage and penetrate the surface **000** when it rotated. As shown in FIG. 5, as the helical tine is rotated, the helical tine **205** draws (or advances) the surface **000** in a proximal direction, causing an expansion of the anatomical space **002**. As shown in FIG. 6, the helical tine may continue to be turned so as to cause the helical tine **205** to draw (or advance) the surface **000** onto the sharp point **106** (or sharp end **103**) of the first elongated member **100** so as to cause an incision **003** in the surface **000** by the sharp point **106**. It should be appreciated that in addition to the rotation of the helical tine **205**, the incision **003** by the sharp point **106** may be also be effected by 1) moving the first elongated member **100** in a distal direction, 2) moving the second elongated member **200** in a proximal direction, or 3) moving the first elongated member **100** in a distal direction and moving the second elongated member **200** in a proximal direction. It should be appreciated that any of the drawing (advancing) and moving (distally/proximally) may be accomplished simultaneously, sequentially or any combination thereof.

FIG. 7 depicts an embodiment of the first elongated member **110**. This elongated member comprises a proximal end **101** and a distal end **102**. Disposed at the distal end **102** is a sharp end **103** configured as a sharp rim **105**. Running through the alternate first elongated member **110** is a lumen **104**. In an approach, the first elongated member **110** may be configured as a cylinder, rectangular, prism, tube, hollow shaft or other geometric shape as desired or required, with a length of about 1cm to about 40cm or as desired or required and a width of about 1 mm to about 15 mm or as desired or required. It should be appreciated that that other lengths, shapes, contours, and cross-sections may be used. In an embodiment, the first elongated member **110** is composed of surgical-grade stainless steel, such as 306 stainless steel. In other embodiments, the first elongated member **110** may be composed of materials selected to be compatible with various medical imaging modalities, including but not limited to ferrous metals and alloys; non-ferrous metals and alloys such as titanium, nitinol, or magnesium; or plastics. In an embodiment, the lumen **104** of the first elongated member **110** may be adapted to house the second elongated member **210**, shown in FIG. 8. It

should be appreciated that the lumen **104** and the second elongated member **210** may be configured to accommodate other devices or structures. In an embodiment, the second elongated member **210** may be hollow or solid.

FIG. **8** shows an embodiment of the second elongated member **210** of the invention.

5 This elongated member comprises a proximal end **201** and a distal end **202**. Disposed at the distal end **202** is a helical tine **205** configured as a corkscrew or the like. The axis of helical tine **205** may be angled with respect to the longitudinal axis defined of the second elongated member **200** at a range of varying degrees from about 0 degrees to about 90 degrees, and preferably between 10 and 35 degrees, or as desired or required, so that when turned it can  
 10 engage the anatomical surface. The helical tine **205** may subtend about 30 degrees of arc to about 360 degrees of arc, or as desired or required. Running through the second elongated member **200** is at least one lumen **208**. In an embodiment, the second elongated member **200** is configured as a cylinder, cylinder, rectangular, prism, tube, hollow shaft or other geometric shape as desired or required, with a length of about 1 cm to about 40 cm or as desired or  
 15 required and a width of about 1 mm to about 15 mm or as desired or required. It should be appreciated that other lengths, shapes, contours, and cross-sections may be used. In an embodiment, the second elongated member **210** may be composed of surgical-grade stainless steel, such as 306 stainless steel. In other embodiments, the second elongated member **200** may be composed of materials selected to be compatible with various medical imaging  
 20 modalities, including but not limited to ferrous metals and alloys; non-ferrous metals and alloys such as titanium, nitinol, or magnesium; or plastics.

FIG. **9** shows an embodiment of the apparatus **500** comprising the first elongated member **110** and the second elongated member **210**. The second elongated member **210** is inserted through the lumen **104** of the first elongated member **110** and housed therein. In a  
 25 currently preferred embodiment, the two elongated members may be selectively held in a fixed position relative to each other.

FIGS. **10-12** depicts an embodiment of the apparatus **500** in use. Once the apparatus is in place or adjacent to the surface **000** of the anatomical space **001**, as shown in FIG. **10**, the helical tine **205** can engage and penetrate the surface **000** when it is rotated. As shown in  
 30 FIG **11**, as the helical tine **205** is rotated, the helical tine **205** draws (or advances) the surface **000** in a proximal direction, causing an expansion of the anatomical space **002**. As shown in FIG. **12**, the helical tine **205** may continue to be turned so as to cause the helical tine **205** to draw (or advance) the surface **000** onto the sharp rim **105** of the first elongated member so as to cause incisions **003** in the surface **000** by the sharp rim **105**. It should be appreciated that in

addition to the rotation of the helical tine **205**, the incision **003** by the sharp rim **105** may be also be effected by 1) moving the first elongated member **100** in a distal direction, 2) moving the second elongated member **200** in a proximal direction, or 3) moving the first elongated member **100** in a distal direction and moving the second elongated member **200** in a proximal direction. It should be appreciated that any of the drawing (advancing) and moving (distally/proximally) may be accomplished simultaneously, sequentially or any combination thereof.

FIG. **14** depicts an embodiment of the apparatus **500** used in conjunction with an embodiment of an access needle **400** (i.e., access device) disclosed in PCT International Application . Serial No. PCT/US2008/056643, filed March 12, 2008, (Pub. No. WO/2008/115745, published September 25, 2008), entitled "Access Needle Pressure Sensor Device and Method of Use," and its corresponding U.S. National Stage Application Serial No. 12/530,830, filed September 11, 2009; of which the disclosure are hereby incorporated by reference herein in their entirety. In an embodiment, the access needle **400** is advanced through the subject's skin **004** and thorax **005** until it is near the surface **000** of the anatomical space to be accessed. The apparatus **500** is first presented (as shown in the top portion of the drawing sheet) then advanced through the access needle **400** (as shown in the lower portion of the drawing sheet). The access needle **400** may optionally further comprise a pressure monitoring system **402** in communication with a side port **401** of the access needle **400**. The pressure monitoring system **402** may employ any number or type of pressure sensors, including sensors that are manometric, solid-state, optical, or otherwise sensitive to hydrostatic and hydrodynamic pressures. Moreover, other devices that the access device (access needle) may accommodate with the practice of this invention include, but not limited thereto, the following: ablation catheters, guidewires, pacing leads, pacing catheters, pacemakers, visualization and recording devices, drugs, and drug delivery devices, lumens, steering devices or systems, drug or cell delivery catheters, fiber endoscopes, suctioning devices, irrigation devices, electrode catheters, needles, optical fiber sensors, sources of illumination, vital signs sensors, and the like. These devices may be deployed for procedures in an integral body part or space.

FIGS. **15-16** depict an embodiment of the first elongated member **100** of the apparatus **500** adapted for use with a medical imaging modality. In an embodiment, the sharp end **103** of the first elongated member **100** comprises etchings **107** capable of scattering ultrasonic waves **404** generated by an ultrasonic transducer **403** connected to an imaging display **405** capable of displaying the combination apparatus' position under the skin **004**. However,

several modifications may be made upon this embodiment. Any part of any constituent of the apparatus **500** could be modified for use with the ultrasonic transducer **403** or for use with any other medical imaging modality, including but not limited to magnetic resonance imaging, computed tomography, fluoroscopy, or other radiological modalities.

FIG. **17** depicts an embodiment of an apparatus **500** comprising a third elongated member **300** comprising a proximal end **301**, a distal end **303**, and a middle portion **302**. In this embodiment, the third elongated member encloses the second elongated member **200** and the first elongated member **100**. Regarding the third elongated member **300**, it should be appreciated that the contours, shapes, lengths, and dimensions may be of any variety disclosed for the first and second elongated members, as well as desired or required. The third elongated member may be configured to accommodate a variety of devices or structures as desired or required. It should be appreciated that the third elongated member doesn't necessarily need to complete enclose the first and second elongated members.

FIG. **18** depicts an embodiment of the third elongated member **300**. This embodiment comprises two substantially parallel tracks **310** for holding the first elongated member **100** and the second elongated member **200**. The second elongated member has disposed at its distal end **202** the helical tine **215**, wherein the helical tine has a cross-section such that the sharp end **103** of the first elongated member **100** is inside the cross section of the helical tine **215**. Regarding the third elongated member **300**, it should be appreciated that the contours, shapes, lengths, and dimensions may be of any variety disclosed for the first and second elongated members, as well as desired or required. The third elongated member may be configured to accommodate a variety of devices or structures as desired or required. The tracks **310** may be composed of silicone rubber, silicon, rubber, plastic, polymer, cloth, metal, foam, or any type of composite material or substance. In an approach, the two tracks **310** may be joined by a central body component **313**. It should be appreciated that there may be less than two tracks or more than two tracks. Moreover, it should be appreciated that the first and second elongated members may be disposed inside one another as discussed in this disclosure, rather than side by side. Moreover, the side-by-side arrangement of the first and second elongated members may be implemented with the third elongated member as shown in FIG. **17**, whereby the first and second elongated members are enclosed or at least substantially enclosed by the third elongated member.

FIG. **19** depicts an embodiment of the apparatus **500** further comprising a skin bumper **304** attached to or in communication of the exterior of the middle portion **303** of the third elongated member **300**. This skin bumper **304** is used for stabilizing the combination

apparatus **500** on the skin of the subject. In an embodiment, the skin bumper **304** may be configured as a donut composed of silicone rubber, though other geometric configurations, contours, shapes, sizes and materials may be used. For example, the skin bumper may instead be composed of silicon, rubber, plastic, polymer, cloth, metal, foam, or any other type of composite material or substance.

FIG. **20** depicts an embodiment of the second elongated member **200** as a part of the apparatus **500**. In this embodiment, the second elongated member **200** further comprises a first middle portion **204** adjacent to the distal end **202**, and a second middle portion **203** adjacent to the proximal end **201**. The second middle portion **203** further comprises a helical groove **206** bored into the surface (or provided in some appropriate technique) of the second elongated member **200** that terminates in a V-shape as shown (or in a shape as desired or required). The first middle portion **204** further comprises an L-shaped groove **207** bored into the surface of the second elongated member **200**. The first elongated member **100** and second elongated member **200** are then placed inside the third elongated member **300**.

FIG. **21** depicts an embodiment of the apparatus **500** further comprising an actuator in a partially actuated state. In this embodiment, pressing down on the actuator button **309** causes an attached driver tab **306** passing through a longitudinal aperture **305** in the third elongated member **300** and engaged with the helical groove **206** to move in a distal direction, causing the interior first elongated member **100** and second elongated member **200** to advance in a distal direction while simultaneously causing the rotation of the second elongated member **200** and attached helical tine **205** as well as the compression of a spring **308**. When the actuator button **309** is fully depressed, the driver tab **306** moves into the V-shaped terminus of the helical groove **206**, holding the interior (i.e., first elongated member **100** and second elongated member **200**) in a fixed position. When the actuator button **309** is depressed again from this position, the driver tab **306** is withdrawn from the V-shaped terminus, and the spring **308** drives the driver tab **306** back up the helical groove **206**, causing the interior combination (i.e., first elongated member **100** and second elongated member **200**) to rotate in the opposite direction and driving it in a proximal direction. In an embodiment the actuator button **309** is connected to a rigid actuator spine **311** to the driver tab **306**. In an embodiment, the apparatus **500** also includes a restrictor tab **307** connected to the driver tab **306** by a compressible actuator spine **313**. The restrictor tab **307** is adapted to pass through the longitudinal aperture **305** and to engage the L-shaped groove **207**. This groove functions to stabilize the apparatus as it is actuated. It should be appreciated that a number of actuator

devices or systems may be utilized that are configured to longitudinally drive the helical tine in a proximal and/or distal direction.

FIG. 22 depicts an embodiment of the apparatus 500 wherein the third elongated member 300 further comprises a side port 312. The side port 312 may be used to infuse fluids into the anatomical space or to drain fluids from the anatomical space. The port may be utilized for egress and ingress. The port may be configured as more than one valve, two-way valve, channel, lumen or conduit, or the like.

FIGS. 23-26 depict various embodiments of different technique methods of the present invention. For instance, FIG. 23 illustrates that the first elongated member 100 is partially withdrawn from the system in a proximal direction, after the second elongated member 200 has been turned, the helical tine 205 has engaged and penetrated the surface 000, which as a result caused an expansion 002 of the anatomical space 001, and an incision 003 in the surface 000 by the sharp end. In an approach, the first elongated member 100 may be completely removed (but not necessarily) from the lumen 208 and a medical device 406 may be introduced through the lumen 208 before passing through the incision 003 and into the anatomical space 001, as shown in FIG. 24.

Although not shown, a medical device may be introduced into the incision while bypassing the first elongated member and/or second elongated member (and/or third elongated member). Moreover, the first elongated member may remain, may be removed or partially removed.

FIG. 25 illustrates an embodiment whereby a guide wire 407 is introduced through the lumen 208 before passing through the incision 003 and into the anatomical space 001. As shown in FIG. 26, once the guide wire 407 is inside the anatomical space 001, the second elongated member 200 may be rotated in the opposite direction of the initial rotation so that the helical tine 205 is disengaged from the surface 000. The second elongated member 200 is then withdrawn in a proximal direction.

Persons of ordinary skill in the art will understand and appreciate that a wide range of changes and modifications could be made to the embodiments described in detail above. As such, it is to be understood that the following claims, including all equivalents, are intended to define the scope of this invention.

It should be appreciated that any of the first, second and/or third elongated members may have one or more lumens there through. Such lumens may have a variety of cross-sections, diameter length, radius length, shape and contours. Moreover, the lumens may be multi-lumen or multi-channel.

It should be appreciated that as discussed herein, a subject may be a human or any animal. It should be appreciated that an animal may be a variety of any applicable type, including, but not limited thereto, mammal, veterinarian animal, livestock animal or pet type animal, etc. As an example, the animal may be a laboratory animal specifically selected to have certain characteristics similar to human (e.g. rat, dog, pig, monkey), etc. It should be appreciated that the subject may be any applicable human patient, for example.

It should be appreciated that various sizes, dimensions, contours, rigidity, shapes, flexibility and materials of any of the embodiments discussed throughout may be varied and utilized as desired or required.

It should be appreciated that elongated members (first, second, and third) and their related components discussed herein may take on all shapes along the entire continual geometric spectrum of manipulation of x, y and z planes to provide and meet the anatomical and structural demands and requirements. Size and shape of the elongated members (first, second, and third) during or prior to operation could also be manipulated by varying their compliance.

The devices, systems, compositions, computer program products, and methods of various embodiments of the invention disclosed herein may utilize aspects disclosed in the following references, applications, publications and patents and which are hereby incorporated by reference herein in their entirety:

U.S. Patent Application No. 12/760,837 entitled "Coaxial Catheter Systems for Transference of Medium," filed April 15, 2010. (00877-04).

U.S. Patent Application No. 11/191,676 entitled "Coaxial Catheter Systems for Transference of Medium," filed July 28, 2005. (00877-03), 2006-0025752 February 2, 2006.

International Patent Application No. PCT/US2005/026738 entitled "Coaxial Catheter Systems for Transference of Medium," filed July 28, 2005. (00877-02), WO06/15091 February 9, 2006.

U.S. Patent Application No. 12/625,153 entitled "Blood Flow Bypass Catheters and Methods for the Delivery of Medium to the Vasculature and Body Ducts," filed November 24, 2009. (01098-04).

U.S. Patent Application No. 11/884,421 entitled "Blood Flow Bypass Catheters and Methods for the Delivery of Medium to the Vasculature and Body Ducts," filed August 15, 2007. (01098-03), US2008/0262467 A1 October 23, 2008.

International Patent Application No. US2006/005876 entitled "Blood Flow Bypass

Catheters and Methods for the Delivery of Medium to the Vasculature and Body Ducts,” filed February 16, 2006. (01098-02), WO06089243 August 24, 2006.

U.S. Patent Application No. 12/532,233 entitled “Electrode Catheter for Ablation Purposes and Related Method Thereof,” filed September 21, 2009. (01380-03).

5 International Patent Application No. PCT/US2008/057626 entitled “Electrode Catheter for Ablation Purposes and Related Method Thereof,” filed March 20, 2008. (01380-02), WO 2008/118737 October 2, 2008.

U.S. Patent Application No. 12/530,938 entitled “Epicardial Ablation Catheter and Method of Use,” filed September 11, 2009. (01363-03).

10 International Patent Application No. PCT/US2008/056816 entitled “Epicardial Ablation Catheter and Method of Use,” filed March 13, 2008. (01363-02), WO 2008/112870 September 18, 2008.

U.S. Patent Application No. 12/530,830 entitled “Access Needle Pressure Sensor Device and Method of Use,” filed September 11, 2009. (01378-03), 2010/0094143 April 15,  
15 2010.

International Patent Application No. PCT/US2008/056643 entitled “Access Needle Pressure Sensor Device and Method of Use,” filed March 12, 2008. (01378-02), WO 2008/115745 September 25, 2008.

International Patent Application No. 12/304,801 entitled “Closure Device for Skull  
20 Plates and Related Method Thereof,” filed May 18, 2009. (01270-03), 2010/0042158 February 18, 2010.

International Patent Application No. PCT/US2007/014881 entitled “Closure Device for Skull Plates and Related Method Thereof,” filed June 26, 2007. (01270-02),  
WO20082595 January 3, 2008.

25 U.S. Patent Application No. 12/513,258 entitled “Means and Methods for Cytometric Therapies,” filed May 1, 2009. (01321-06).

International Patent Application No. PCT/US2007/023047 entitled “Means and Methods for Cytometric Therapies,” filed November 1, 2007. (01321-02), WO 2008/057370  
May 15, 2008.

30 U.S. Patent Application No. 12/375,139 entitled “System and Method for Intracranial Implantation of Therapeutic or Diagnostic Agents,” filed January 27, 2009. (01277-03),

2009-0192487 July 30, 2009.

International Patent Application No. PCT/US2007/016256 entitled "System and Method for Intracranial Implantation of Therapeutic or Diagnostic Agents," filed July 18, 2007. (01277-02), WO2008/013709 January 31, 2008.

5 International Patent Application No. PCT/US2008/082835 entitled "STEERABLE EPICARDIAL PACING CATHETER SYSTEM PLACED VIA THE SUBXIPHOID PROCESS," filed November 7, 2008. (01473-02), WO 2009/062061 May 14, 2009.

U.S. Patent Application No. 12/160,378 entitled "Multi-Port Catheter System with Medium Control and Measurement Systems for Therapy and Diagnosis Delivery," filed  
10 August 1, 2008. (01080-04), 2009-0048577 February 19, 2009.

International Patent Application No. PCT/US2007/000353 entitled "Multi-Port Catheter System with Medium Control and Measurement Systems for Therapy and Diagnosis Delivery," filed January 9, 2007. (01080-03), WO/2007/081842 July 19, 2007.

International Patent Application No. US2006/013621 entitled "Catheter Systems for  
15 Delivery of Agents and Related Method Thereof," filed April 12, 2006. (00982-03)WO06113267 October 26, 2006.

U.S. Patent Application No. 11/105,166 entitled "Catheter Systems for Delivery of Agents and Related Method Thereof," filed April 13, 2005. (00982-02), 2005/0245896  
November 3, 2005, 7,670,327 March 2, 2010.

20 U.S. Patent Application No. 10/985,340 entitled "Catheter Navigation Within an MR Imaging Device," filed November 10, 2004. (00681-04)0119556 June 2, 2005.

U.S. Patent Application No. 10/429,524 entitled "Catheter Navigation Within an MR Imaging Device," filed May 5, 2003. (00681-03), 030195412 October 16, 2003, 6,834,201  
December 21, 2004.

25 International Patent Application No. US02/02363 entitled "Catheter Navigation within an MR Imaging Device," filed January 28, 2002. (00681-02).

U.S. Patent Application No. 09/772,188 entitled "Catheter Navigation within an MR Imaging Device," filed January 29, 2001. (00681-01).

U.S. Patent Application No. 10/444,884 entitled "Cell Delivery Catheter and  
30 Method," filed May 23, 2003. (00827-03), 2003/0204171 October 30, 2003.

U.S. Patent Application No. 09/574,857 entitled "Cell Delivery Catheter and

Method,” filed May 19, 2000. (00827-02), 6,599,274 July 29, 2003.

U.S. Patent Application No. 09/548,110 entitled “Multi-Probe System,” filed April 12, 2000. (00578-01, 6,626,902 September 30, 2003.

International Patent Application No. US99/24253 entitled “MRI AND MAGNETIC  
5 STEREOTAXIS SURGICAL SYSTEM,” filed October 15, 1999. (00198-02), WO00/23000  
April 27, 2000.

U.S. Patent Application No. 09/174,189 entitled “Combined Magnetic Resonance  
Imaging and Magnetic Stereotaxis Surgical Apparatus and Processes,” filed October 16,  
1998. (00198-01), 6,298,259 October 2, 2001.

10 U.S. Patent Application No. US99/17880 entitled “MR-Visible Device for Magnetic  
Stereotaxis Neurological Interventions,” filed August 6, 1999. (00199-02), WO00/07652  
February 17, 2000.

U.S. Patent Application No. 09/131,031 entitled “MR-Visible Medical Device for  
Neurological Interventions Using Nonlinear Magnetic Stereotaxis and a Method Imaging,”  
15 filed August 7, 1998. (00199-01), 6,272,370 August 7, 2001.

U.S. Patent Application No. 09/114,414 entitled “Magnetic Stereotactic System for  
Treatment Delivery,” filed July 13, 1998. (00220-05), 6,216,030 April 10, 2001.

U.S. Patent Application No. 08/464,279 entitled “Magnetic Stereotactic System for  
Treatment Delivery,” filed June 5, 1995. (00220-04), 5,707,335 January 13, 1998.

20 U.S. Patent Application No. 08/096,214 entitled “Magnetic Stereotactic System for  
Treatment Delivery,” filed July 19, 1993. (00220-03), 5,779,694 July 14, 1998.

U.S. Patent Application No. 07/904,032 entitled “MAGNETIC STEREOTACTIC  
SYSTEM FOR TREATMENT DELIVERY,” filed June 25, 1992. (00220-02).

25 U.S. Patent Application No. 07/463,340 entitled “Magnetic Stereotactic System for  
Treatment Delivery,” filed January 10, 1990. (00220-01), 5,125,888 June 30, 1992.

1. U.S. Patent No. 6,423,051 B1 to Kaplan, et al., July 23, 2002, “Methods and  
Apparatus for Pericardial Access”.

2. U.S. Patent No. 6,156,009 to Grabek, J., December 5, 2000, “Apparatus for  
Accessing the Pericardial Space”.

30 3. U.S. Patent No. 6,592,552 B1 to Schmidt, C., July 15, 2003, “Direct Pericardial  
Access Device and Method”.

4. U.S. Patent No. 6,162,195 to Igo, et al., December 19, 2000, "Method and Apparatus for Accessing the Pericardial Space".

5. U.S. Patent Application Publication No. US2008/0108945 A1 to Kaplan, et al., May 8, 2008, "Methods and Apparatus for Pericardial Access".

5 6. U.S. Patent No. 7,309,328 B2 to Kaplan et al., December 18, 2007, "Methods and Apparatus for Pericardial Access."

In summary, while the present invention has been described with respect to specific embodiments, many modifications, variations, alterations, substitutions, and equivalents will be apparent to those skilled in the art. The present invention is not to be limited in scope by  
10 the specific embodiment described herein. Indeed, various modifications of the present invention, in addition to those described herein, will be apparent to those of skill in the art from the foregoing description and accompanying drawings. Accordingly, the invention is to be considered as limited only by the spirit and scope of the following claims, including all modifications and equivalents.

15 Still other embodiments will become readily apparent to those skilled in this art from reading the above-recited detailed description and drawings of certain exemplary embodiments. It should be understood that numerous variations, modifications, and additional embodiments are possible, and accordingly, all such variations, modifications, and embodiments are to be regarded as being within the spirit and scope of this application. For  
20 example, regardless of the content of any portion (e.g., title, field, background, summary, abstract, drawing figure, etc.) of this application, unless clearly specified to the contrary, there is no requirement for the inclusion in any claim herein or of any application claiming priority hereto of any particular described or illustrated activity or element, any particular sequence of such activities, or any particular interrelationship of such elements. Moreover,  
25 any activity can be repeated, any activity can be performed by multiple entities, and/or any element can be duplicated. Further, any activity or element can be excluded, the sequence of activities can vary, and/or the interrelationship of elements can vary. Unless clearly specified to the contrary, there is no requirement for any particular described or illustrated activity or element, any particular sequence or such activities, any particular size, speed, material,  
30 dimension or frequency, or any particularly interrelationship of such elements. Accordingly, the descriptions and drawings are to be regarded as illustrative in nature, and not as restrictive. Moreover, when any number or range is described herein, unless clearly stated otherwise, that number or range is approximate. When any range is described herein, unless clearly stated otherwise, that range includes all values therein and all sub ranges therein. Any

- information in any material (e.g., a United States/foreign patent, United States/foreign patent application, book, article, etc.) that has been incorporated by reference herein, is only incorporated by reference to the extent that no conflict exists between such information and the other statements and drawings set forth herein. In the event of such conflict, including a
- 5 conflict that would render invalid any claim herein or seeking priority hereto, then any such conflicting information in such incorporated by reference material is specifically not incorporated by reference herein.

**CLAIMS**

We claim:

1. An apparatus for accessing a subject's anatomical space having a surface, the apparatus comprising:

5 a first elongated member comprising a proximal end and a distal end, said distal end comprising a sharp end; and

a second elongated member comprising a proximal end and a distal end, said distal end comprising a helical tine, wherein said helical tine is adapted to:

engage and penetrate said surface, and wherein when said second elongated  
10 member is turned, said helical tine lifts said surface in a proximal direction, whereby the lifting assists in advancing said surface in contact with said sharp end to cause an incision of the surface by said sharp end.

2. The apparatus of claim 1, wherein said first elongated member comprises at least  
15 one lumen.

3. The apparatus of claim 2, wherein said second elongated member is inside said at least one lumen of said first elongated member.

20 4. The apparatus of claim 3, wherein sharp end of said first elongated member is configured as a sharp rim.

5. The apparatus of claim 3, wherein said second elongated member comprises at least one lumen.

25 6. The apparatus of claim 2, wherein said second elongated member is outside said at least one lumen of said first elongated member.

7. The apparatus of claim 6, wherein said second elongated member is at least one  
30 lumen, wherein said at least one lumen of side second elongated member is outside said lumen of said lumen of said first elongated member.

8. The apparatus of claim 6, wherein said sharp end of said first elongated member is configured as a point.

9. The apparatus of claim 6, wherein said end comprises at least one of the following; beveled structure, serrated structure, tapered structure, or cutting edge structure.

5           10. The apparatus of claim 1, wherein said second elongated member is outside said first elongated member.

10           11. The apparatus of claim 10, wherein said second elongated member comprises at least one lumen, wherein said at least one lumen of said second elongated member is outside said first elongated member.

            12. The apparatus of claim 10, wherein sharp end of said first elongated member is configured as a point.

15           13. The apparatus of claim 10, wherein said end comprises at least one of the following; beveled structure, serrated structure, tapered structure, or cutting edge structure.

            14. The apparatus of claim 1, wherein said second elongated member comprises at least one lumen.

20           15. The apparatus of claim 1, wherein said advancing of said surface in contact with said sharp end is caused by either:

- a) said lift of the surface;
- b) said lift of the surface and a movement of said first elongated member in distal
- 25   direction;
- c) said lift of the surface and a movement of said second elongated member in a proximal direction; or
- d) said lift of the surface, a movement of said first elongated member in a distal
- 30   direction and a movement of said second elongated member in a proximal direction.

            16. The apparatus of claim 1, wherein said helical tine is defined by a lateral cross-section, wherein said lateral cross-section of said helical tine has an area that defines the geometry of the surface being lifted to provide a surface contact.

17. The apparatus of claim 1, wherein said anatomical space comprises a pericardial space.

18. The apparatus of claim 17, wherein said surface is the parietal pericardium.

19. The apparatus of claim 1, wherein said anatomical space comprises a kidney, a brain, a blood vessel, a peritoneal cavity, a spinal cord, an intra-abdominal space, an intra-thoracic space or any space in the body bounded by a membrane or membranous entity.

20. The apparatus of claim 19, wherein said surface is a renal capsule, a dura mater, a blood vessel wall, a peritoneum, a dural lining of the spinal cord, a pleura, a seurosa, or any other membrane in the body.

21. The apparatus of claim 1, further comprising an access needle, said access needle adapted to be navigated and inserted into the anatomical space.

22. The apparatus of claim 21, wherein said first elongated member and said second elongated member are configured to be used in conjunction with said access needle.

23. The apparatus of claim 22, wherein said conjunction is an insertion through said access needle.

24. The apparatus of claim 1, further comprising a pressure sensing means to identify the different pressure-frequency regimes of the tissues through which said elongated members are being moved.

25. The apparatus of claim 1, wherein said apparatus is adapted to be visible on a medical imaging modality.

26. The apparatus of claim 25, wherein said medical imaging modality comprises at least one of magnetic resonance imaging, computed tomography, fluoroscopy, ultrasound, or other radiological modalities.

27. The apparatus of claim 25, wherein said medical imaging modality further comprises display means for displaying said sharp end's position or communication means for communicating said sharp end's position.

5           28. The apparatus of claim 1, further comprising switchable means for holding said first elongated member in a fixed position with respect to said second elongated member.

29. The apparatus of claim 1, further comprising:

10           a third elongated member comprising a distal end, a middle portion, and a proximal end, said third elongated member configured to retain said first elongated member and said second elongated member to a movement that is at least substantially longitudinal as defined by the proximal and distal directions..

30. The apparatus of claim 1, further comprising:

15           a third elongated member comprising a distal end, a middle portion, and a proximal end, said third elongated member that at least substantially encloses said first elongated member and said second elongated member.

20           31. The apparatus of claim 30, wherein said third elongated member further comprises a side port.

32. The apparatus of claim 31, wherein said side port is adjacent to said proximal end of said third elongated member.

25           33. The apparatus of claim 30, further comprising means for stabilizing said third elongated member on a subject's skin.

34. The apparatus of claim 30, further comprising a bumper disposed to said middle portion of said third elongated member.

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35. The apparatus of claim 34, wherein said bumper comprises at least one of the following: silicone rubber, silicon, rubber, plastic, polymer, cloth, metal, foam, or any type of composite material or substance.

36. The apparatus of claim 30, wherein said second elongated member further comprises a first middle portion adjacent to said distal end and a second middle portion adjacent to said proximal end.

5           37. The apparatus of claim 36, wherein said second middle portion of said second elongated member further comprises a helical groove.

38. The apparatus of claim 37, wherein said third elongated member further comprises a longitudinal aperture disposed therein.

10

39. The apparatus of claim 38, further comprising a driving mechanism comprising:  
a driver tab, said driver tab adapted to pass through said longitudinal aperture of said third elongated member and engage said helical groove of said second elongated member, wherein:

15           if said driver tab is moved distally then said tab drives said second elongated member in a distal direction;

            if said driver tab is moved proximally then said tab drives said second elongated member in a proximal direction.

20           40. The apparatus of claim 39, wherein said first middle portion further comprises an L-shaped groove

41. The apparatus of claim 40, further comprising a restricting tab adapted to pass through said longitudinal aperture and engage said L-shaped groove, thereby restricting said  
25           second elongated member regarding its distal longitudinal movement.

42. The apparatus of claim 1, further comprising actuator means for longitudinally driving said helical tine in a proximal and/or distal direction.

30           43. A method for accessing a subject's anatomical space having a surface, the method comprising:

            providing a first elongated member comprising a proximal end and a distal end, said distal end comprising a sharp end; and

providing a second elongated member comprising a proximal end and a distal end,  
said distal end comprising a helical tine  
engaging said surface with said helical tine;  
turning said helical tine to cause lifting of said surface in a proximal direction,  
5 whereby the lifting assists in advancing said surface in contact with said sharp end to cause  
an incision of the surface by said sharp end.

44. The method of claim 43, wherein said first elongated member comprises at least  
one lumen.

45. The method of claim 44, wherein said second elongated member is inside said at  
least one lumen of said first elongated member.

46. The method of claim 45, wherein sharp end of said first elongated member is  
15 configured as a sharp rim.

47. The method of claim 45, wherein said second elongated member comprises at  
least one lumen.

48. The method of claim 44, wherein said second elongated member is outside said at  
least one lumen of said first elongated member.

49. The method of claim 48, wherein said second elongated member is at least one  
lumen, wherein said at least one lumen of side second elongated member is outside said  
25 lumen of said lumen of said first elongated member.

50. The method of claim 48, wherein said sharp end of said first elongated member is  
configured as a point.

51. The method of claim 50, wherein said point comprises at least one of the  
following; beveled structure, serrated structure, tapered structure, or cutting edge structure.

52. The method of claim 43, wherein said second elongated member is outside said  
first elongated member.

53. The method of claim 52, wherein said second elongated member comprises at least one lumen, wherein said at least one lumen of said second elongated member is outside said first elongated member.

5

54. The method of claim 52, wherein sharp end of said first elongated member is configured as a point.

55. The method of claim 54, wherein said point comprises at least one of the following; beveled structure, serrated structure, tapered structure, or cutting edge structure.

10

56. The method of claim 43, wherein said second elongated member comprises at least one lumen.

57. The method of claim 44, wherein said advancing of said surface in contact with said sharp end is caused by either:

15

- a) said lift of the surface;
- b) said lift of the surface, and moving said first elongated member in distal direction;
- c) said lift of the surface, and moving said second elongated member in a proximal

20

direction; or

d) said lift of the surface, and moving said first elongated member in a distal direction and moving said second elongated member in a proximal direction.

25

58. The method of claim 43, wherein said helical tine is defined by a lateral cross-section, wherein said lateral cross-section of said helical tine has an area that defines the geometry of the surface being lifted to provide a surface contact.

59. The method of claim 43, wherein said anatomical space comprises a pericardial space.

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60. The method of claim 59, wherein said surface is the parietal pericardium.

61. The method of claim 43, wherein said anatomical space comprises a kidney, a brain, a blood vessel, a peritoneal cavity, a spinal cord, an intra-abdominal space, an intra-thoracic space, or any space in the body bounded by a membrane or membranous entity.

5           62. The method of claim 61, wherein said surface is a renal capsule, a dura mater, a blood vessel wall, a peritoneum, a dural lining of the spinal cord, a pleura, a seurosa, or any other membrane in the body..

10           63. The method of claim 1, further comprising inserting an access needle into the anatomical space.

64. The method of claim 63, further comprising inserting said first elongated member and said second elongated through said access needle for said engagement.

15           65. The method of claim 64, further comprising sensing the pressure of the tissues through which said elongated members are being moved. to identify the different pressure-frequency regimes of the tissues.

20           66. The method of claim 43, further comprising medically imaging at least a portion of said first elongated member and/or at least a portion of second elongated member

25           67. The method of claim 66, wherein said medical imaging is provided by at least one of the following systems: magnetic resonance imaging, computed tomography, fluoroscopy, ultrasound, or other radiological modalities.

68. The method of claim 67, wherein said imaging device further comprises display means for displaying said sharp end's position or communication means for communicating said sharp end's position.

30           69. The method of claim 43, further comprising selectively holding said first elongated member in a fixed position with respect to said second elongated member.

70. The apparatus of claim 43, further comprising: retaining said first elongated member and said second elongated member to a movement that is at least substantially longitudinal as defined by the proximal and distal directions.

5           71. The method of claim 70, wherein said retaining is provided by a third elongated member.

          72. The method of claim 43, further comprising:  
          at least substantially enclosing said first elongated member and said second elongated  
10   member.

          73. The method of claim 72, wherein said enclosing is provided by a third elongated member comprising a distal end, a middle portion, and a proximal end, said third elongated member.

15           74. The method of claim 72, wherein said third elongated member further comprises a side port.

          75. The method of claim 74, further comprising drawing fluids out of said anatomical  
20   space through said side port.

          76. The method of claim 74, further comprising infusing a media into said anatomical space through said side port.

25           77. The method of claim 74, further comprising infusing a media into said anatomical space through said side port and drawing fluids out of said anatomical space through said side port.

          78. The method of claim 72, further comprising stabilizing said third elongated  
30   member on a subject's skin.

          79. The method of claim 78, wherein said stabilizing is provided by a bumper disposed to said third elongated member.

80. The apparatus of claim 79, wherein said bumper comprises at least one of the following: silicone rubber, silicon, rubber, plastic, polymer, cloth, metal, foam, or any type of composite material or substance

5           81. The method of claim 43, further comprising controlling movement of said second elongated member in a distal direction and a proximal direction.

82. The method of claim 81, further comprising restricting said second elongated member regarding its distal longitudinal movement.

10

83. The method of claim 43, further comprising withdrawing said first elongated member in a proximal direction.

15           84. The method of claim 83, further comprising introducing a medical device into said anatomical space.

85. The method of claim 84, wherein said medical device is introduced into said anatomical space through, over or adjacent to said second elongated member.

20           86. The method of claim 84, wherein said medical device comprises an ablation catheter.

87. The method of claim 84, wherein said medical device comprises means for delivering a medium into said anatomical space.

25

88. The method of claim 87 wherein said medium comprises a pharmaceutically active substance, cells, fluids, biological fluids, drugs, gene therapy vectors, irrigation fluids, growth factors, nuclear medicine agents, antibiotics, anti-viral agents, contrast agents, chemotherapies, or other diagnostic or therapeutic agents.

30

89. The method of claim 84, wherein said medical device comprises a guide wire.

90. The method of claim 89, further comprising disengaging said helical tine from said surface.

91. The method of claim 90, further comprising withdrawing said second elongated member in a proximal direction.

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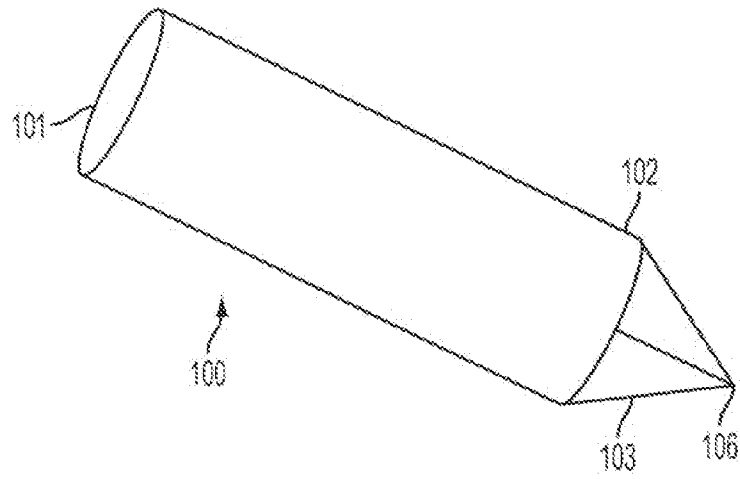


FIG. 1

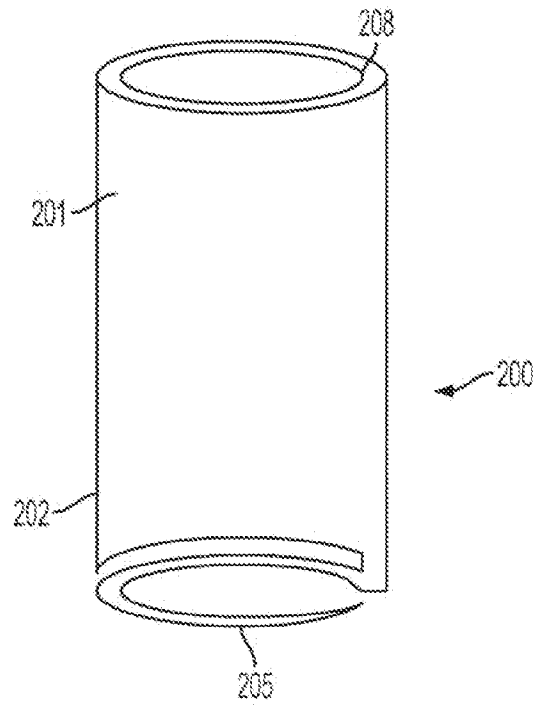


FIG. 2

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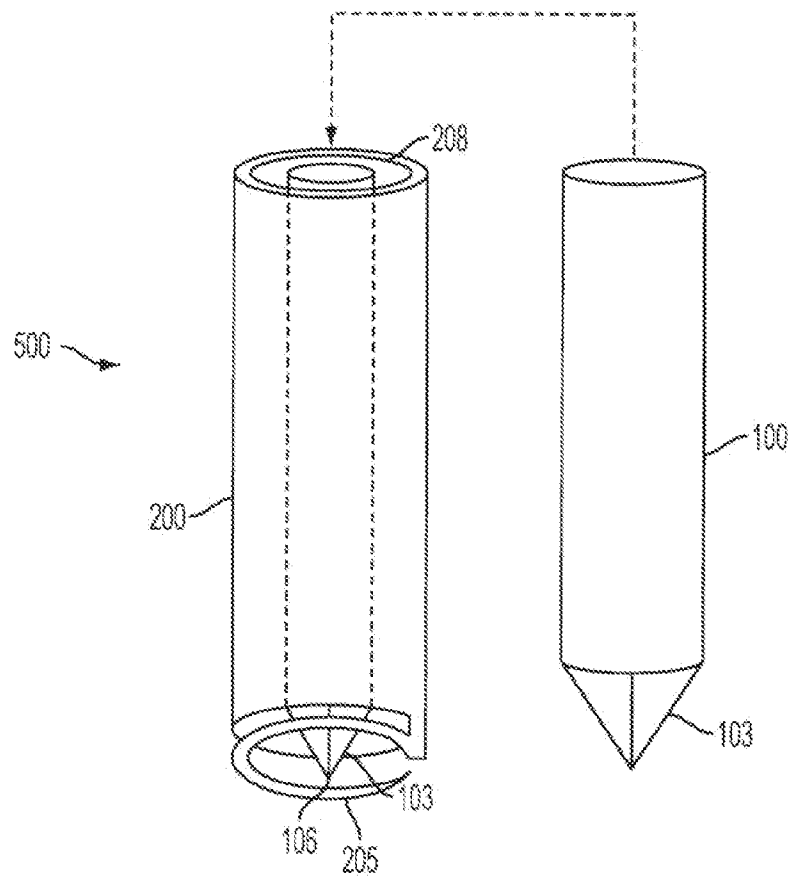


FIG. 3

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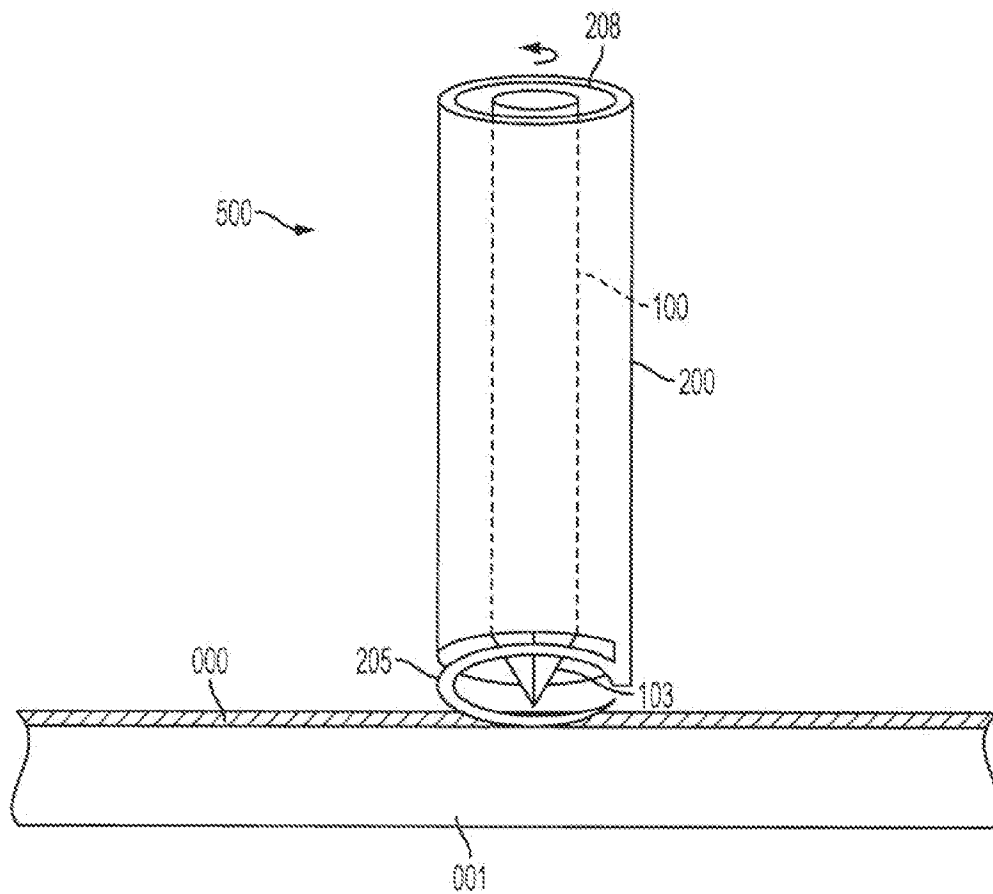


FIG. 4

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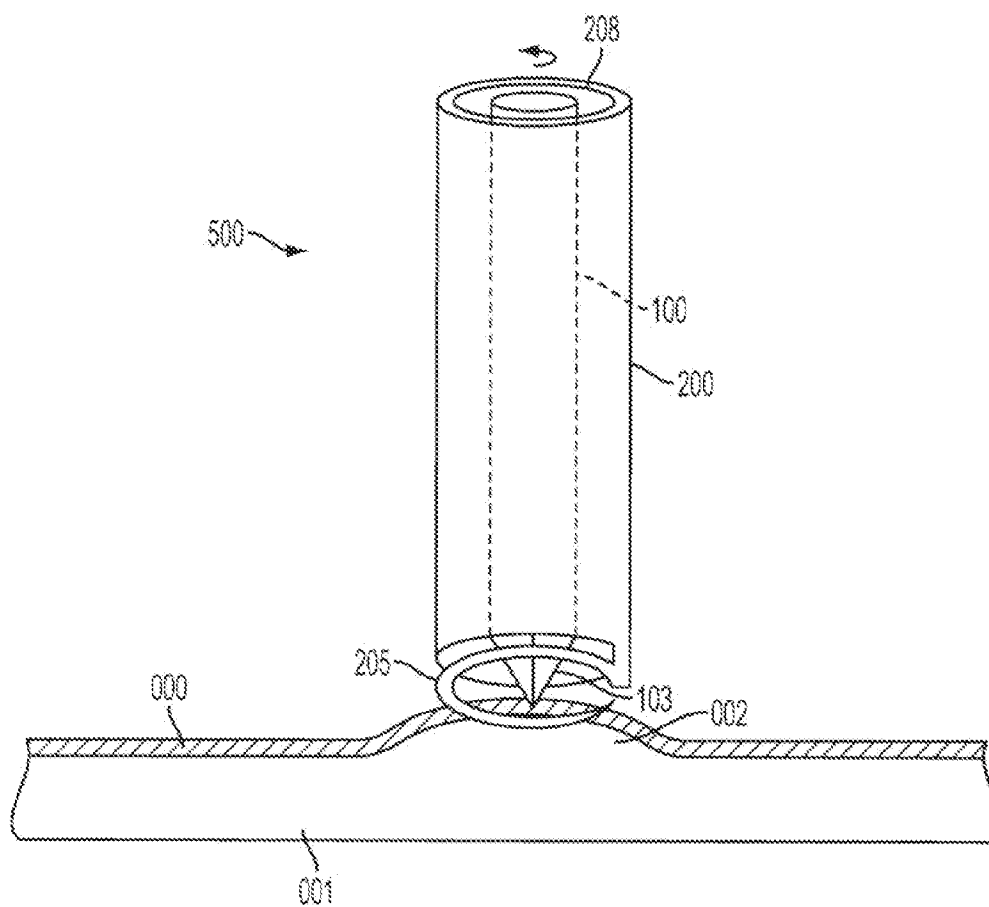


FIG. 5

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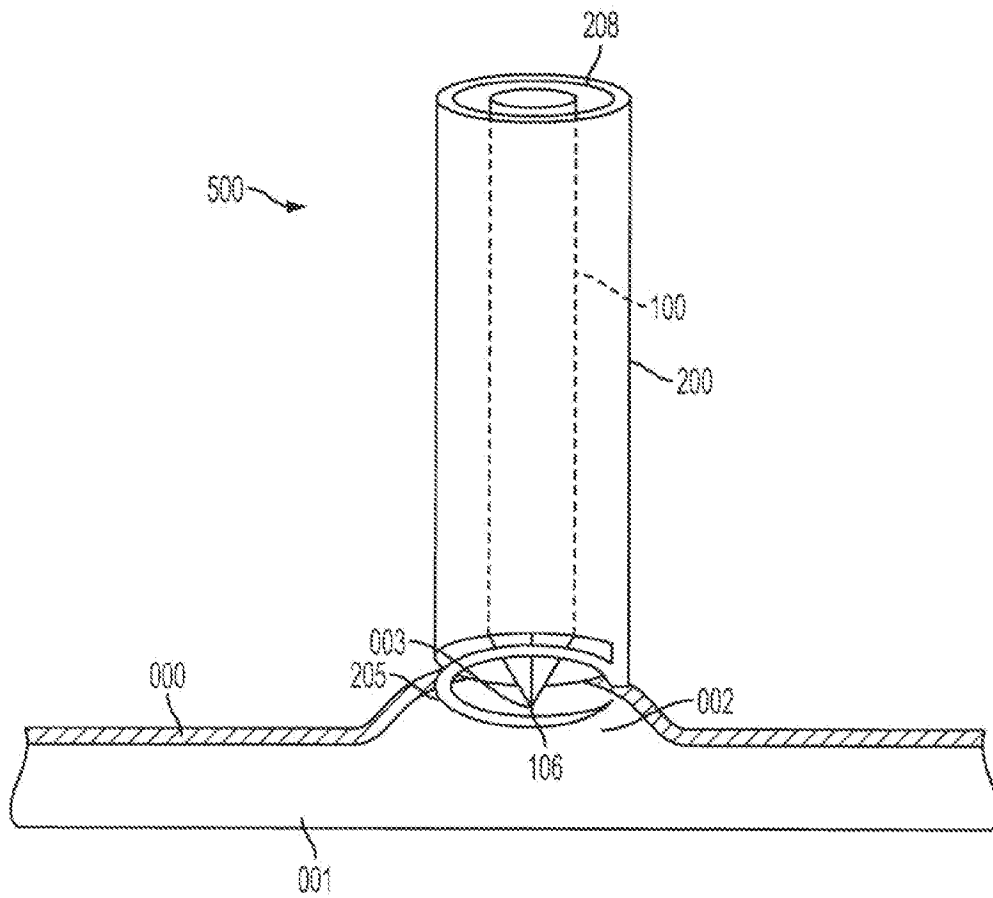


FIG. 6

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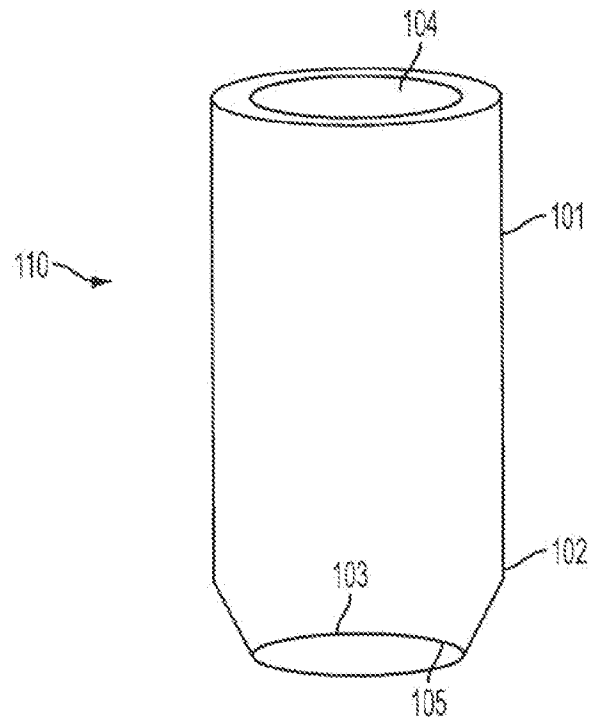


FIG. 7

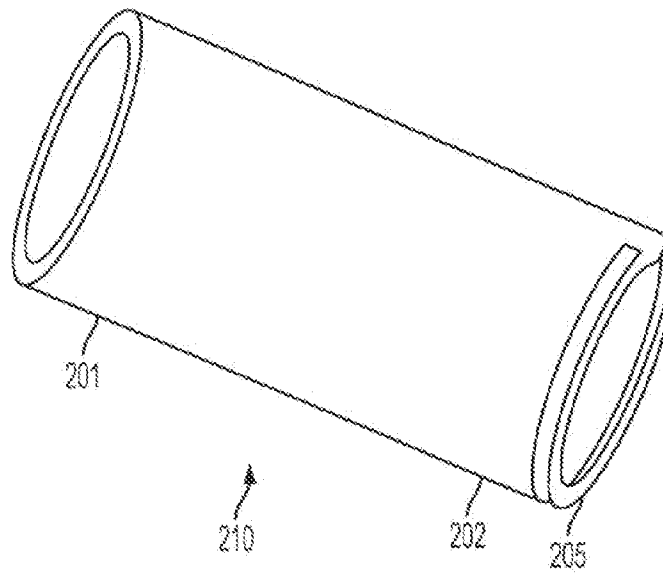


FIG. 8

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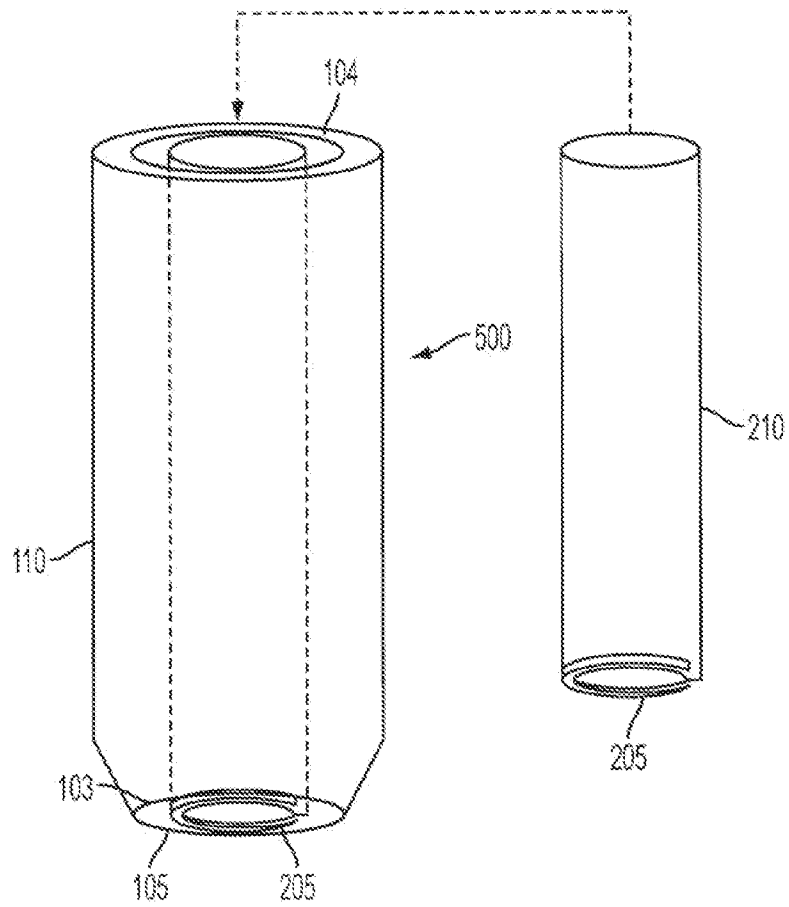


FIG.9

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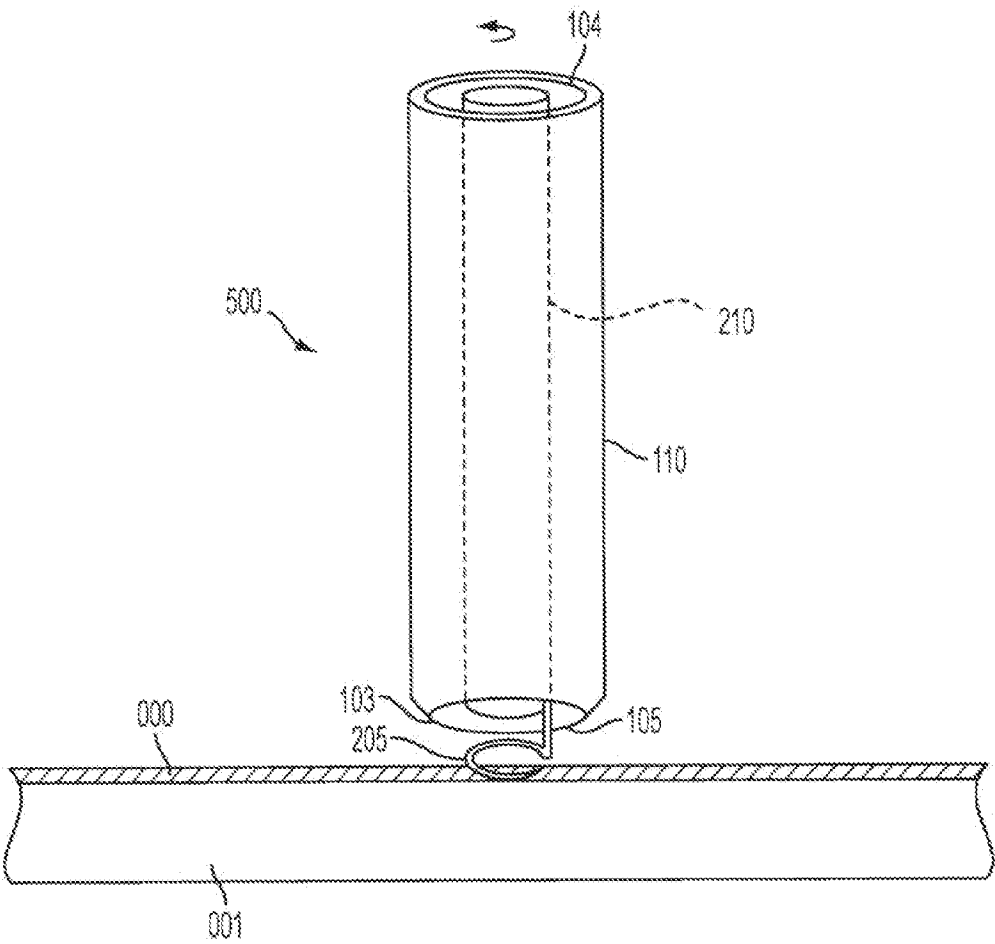


FIG. 10

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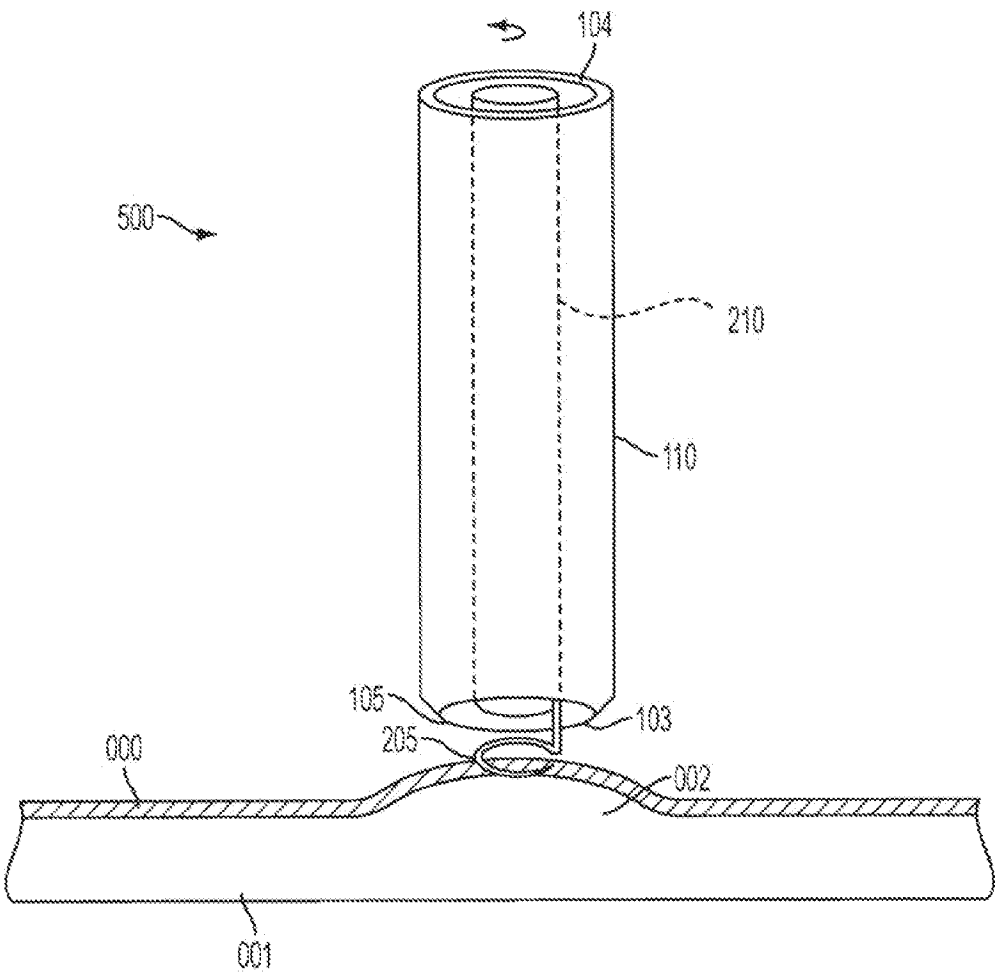


FIG. 11

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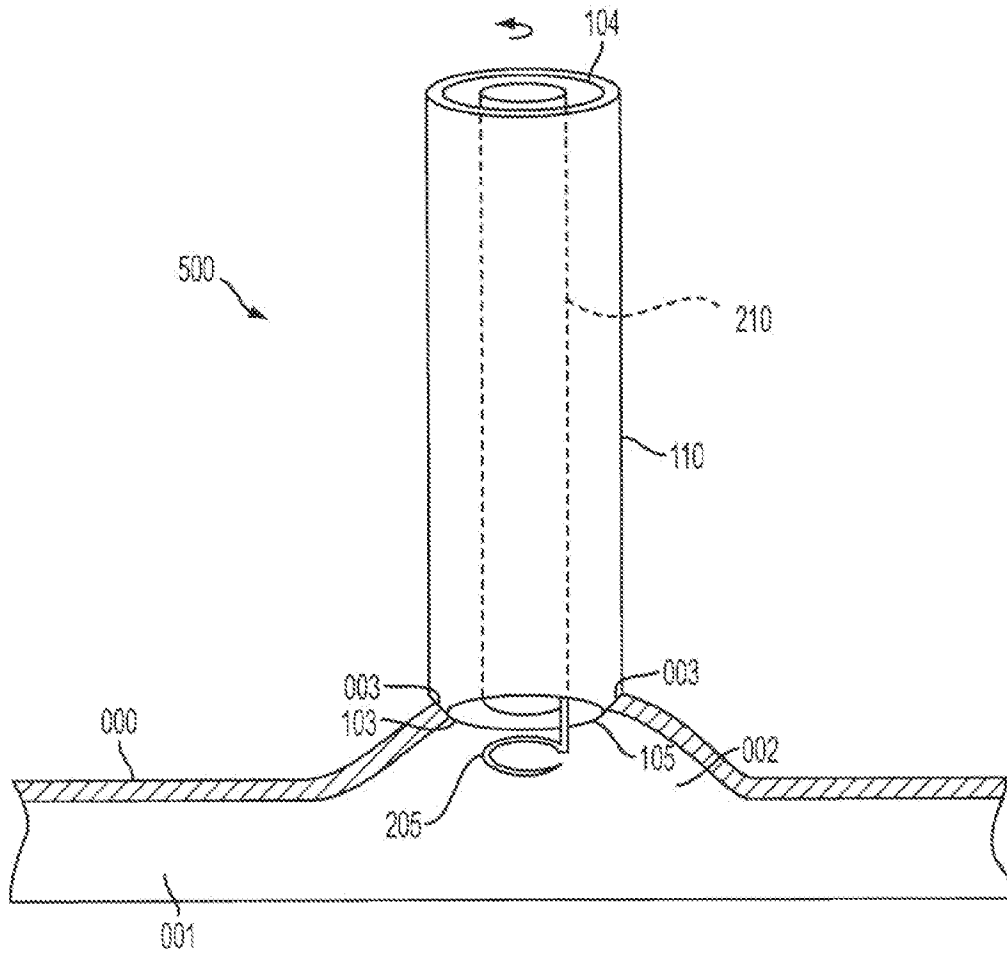


FIG. 12

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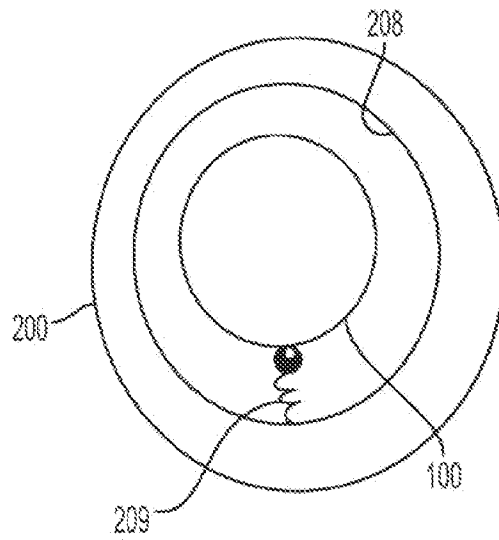


FIG. 13

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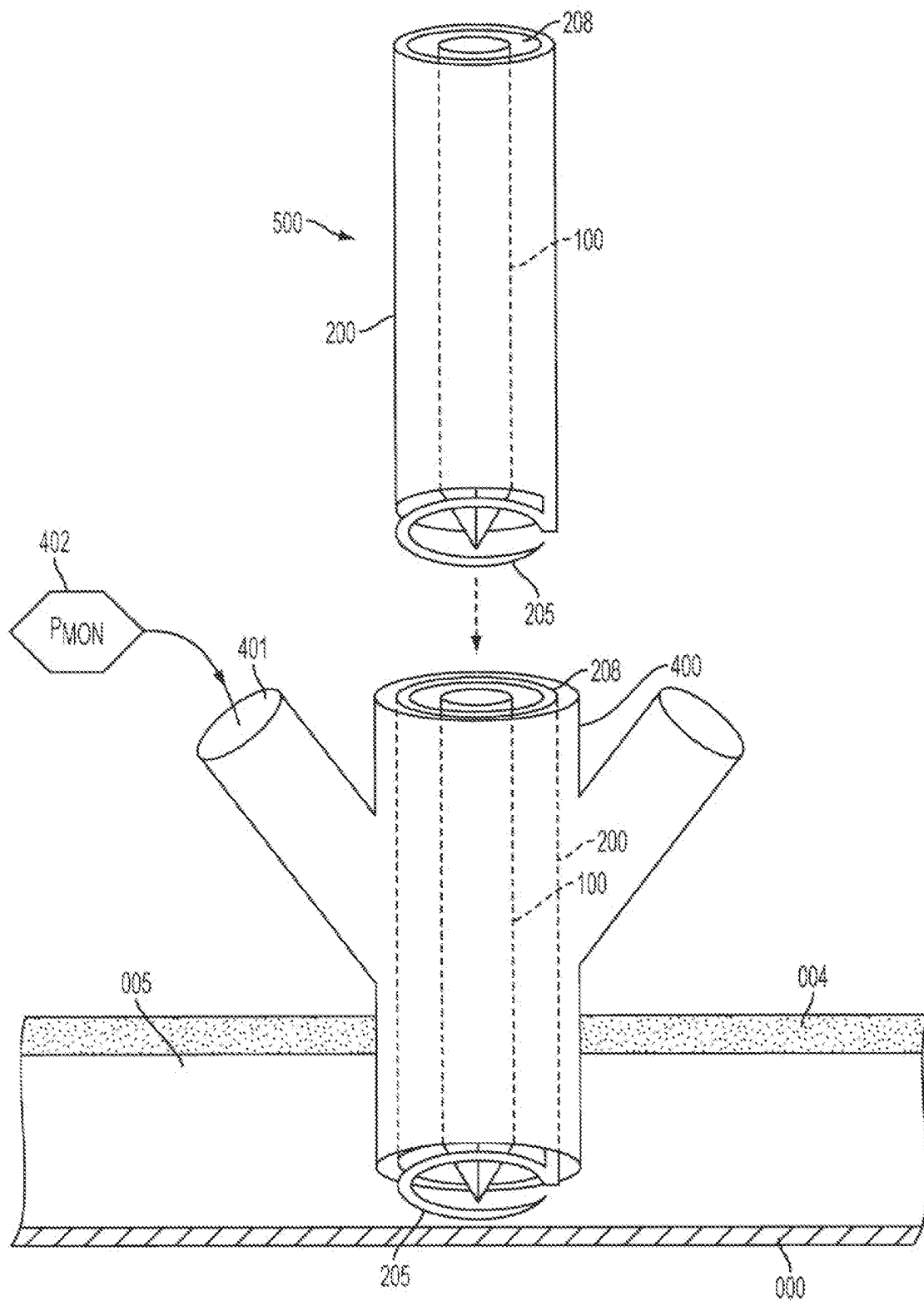


FIG. 14

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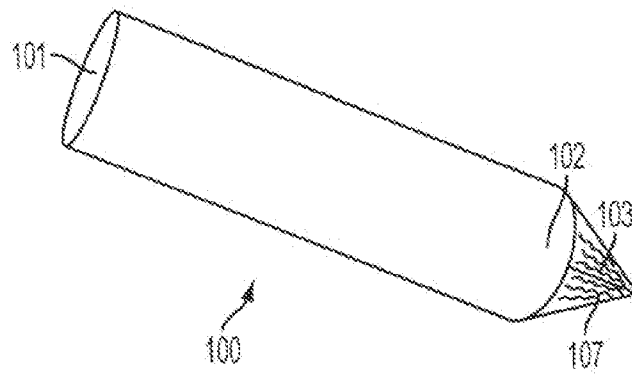


FIG. 15

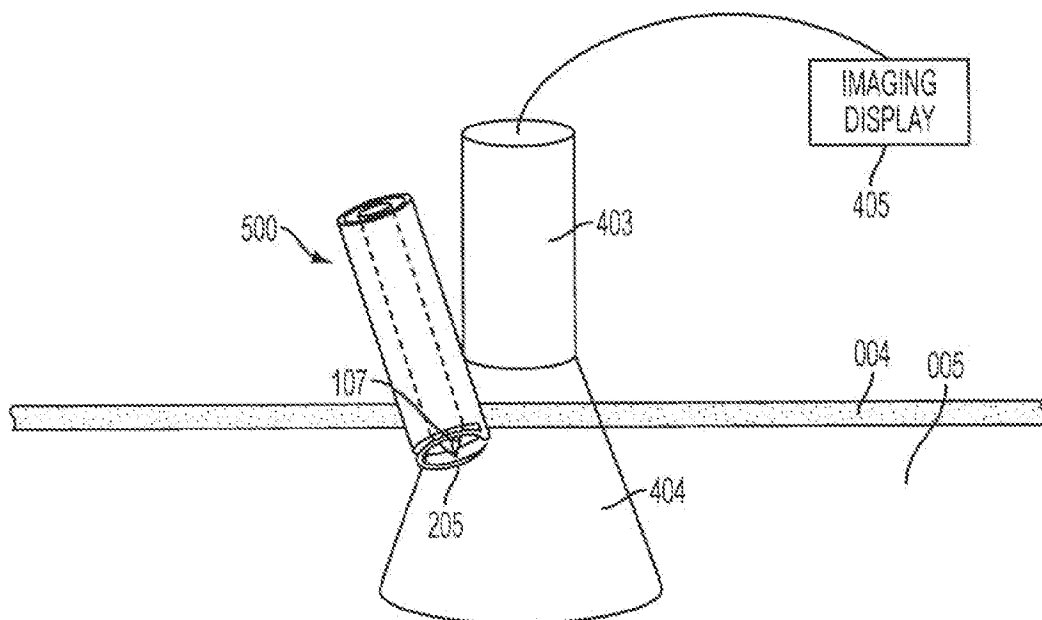


FIG. 16

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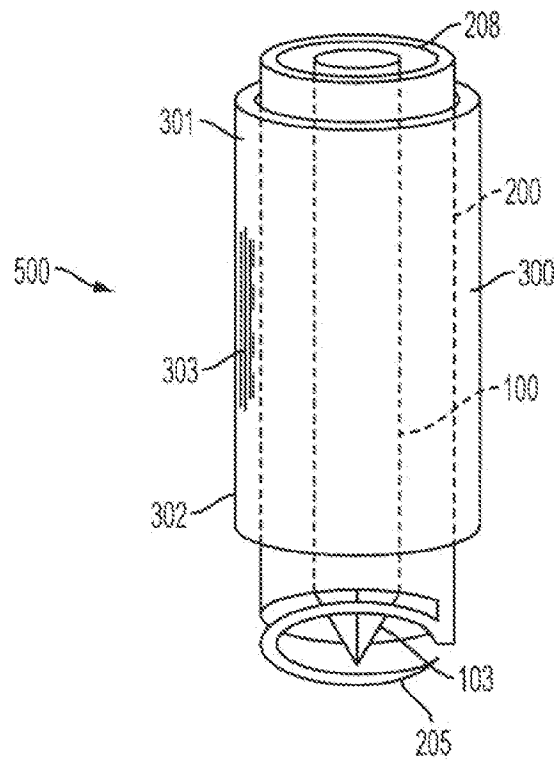


FIG. 17

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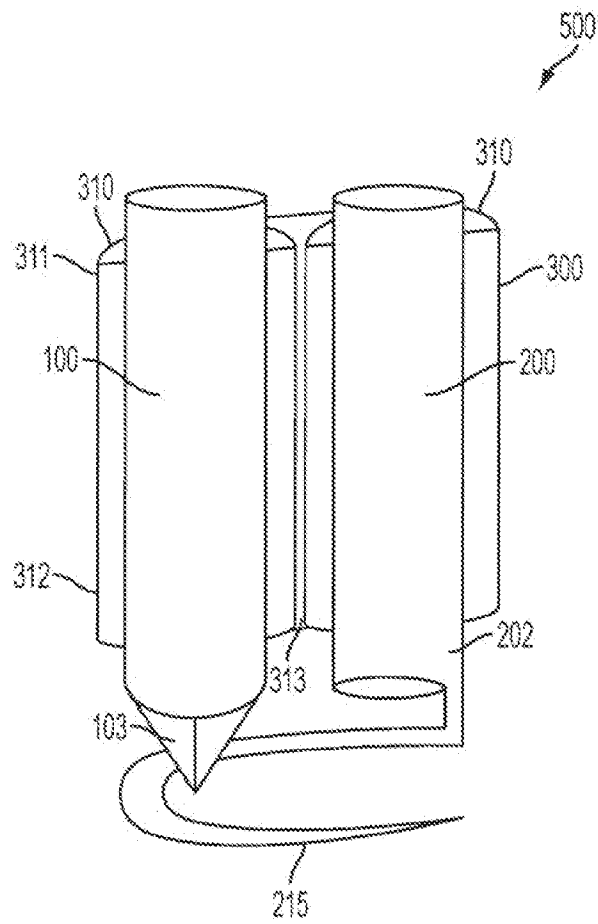


FIG. 18

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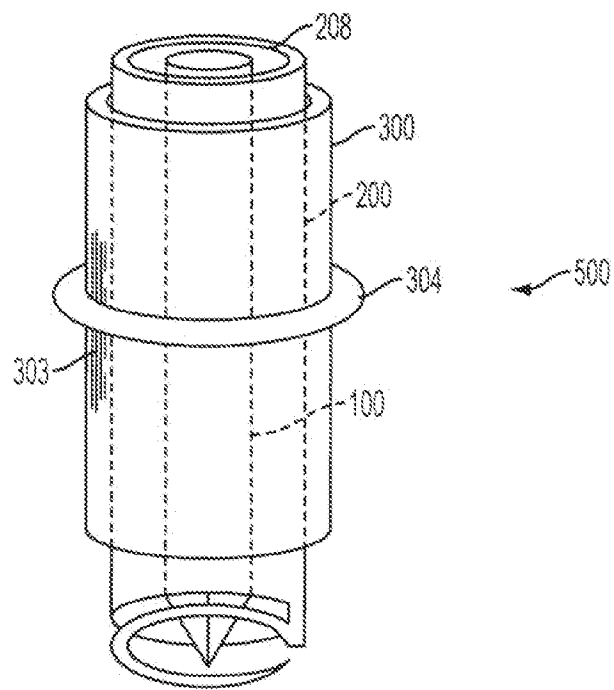


FIG. 19

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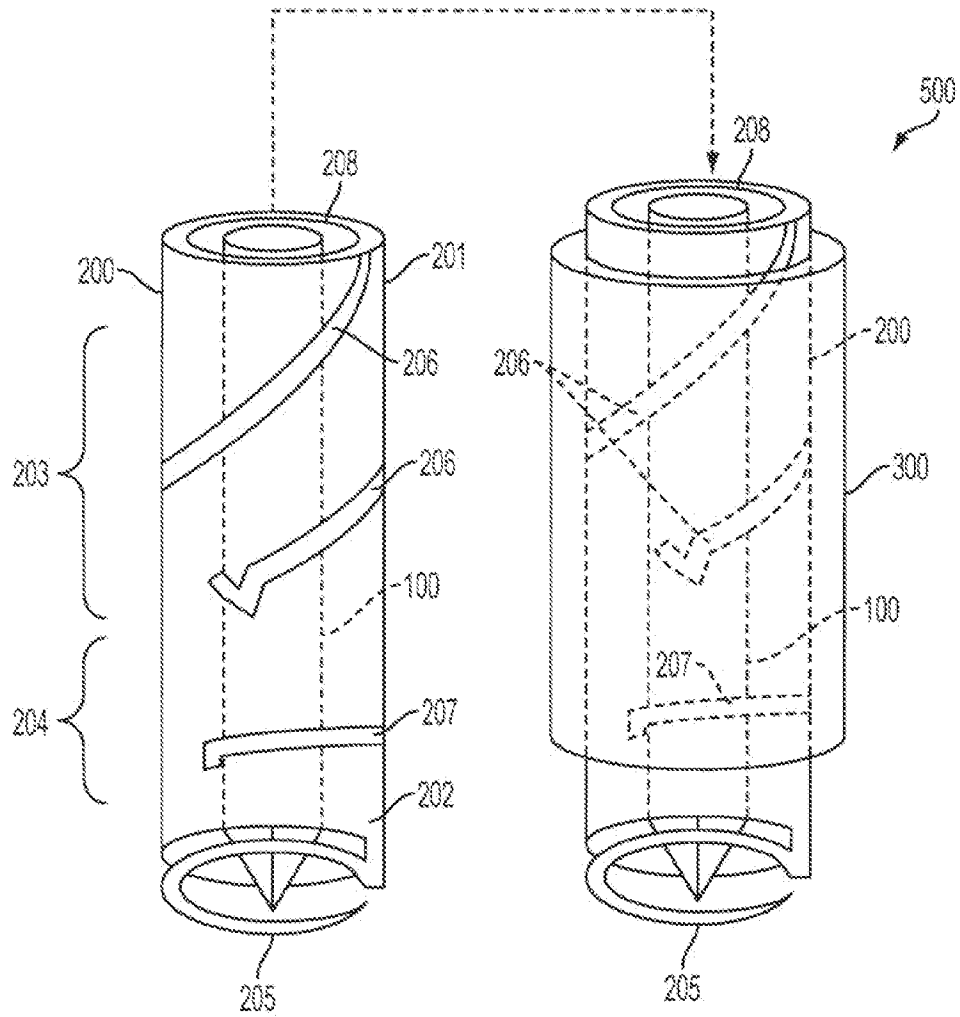


FIG. 20

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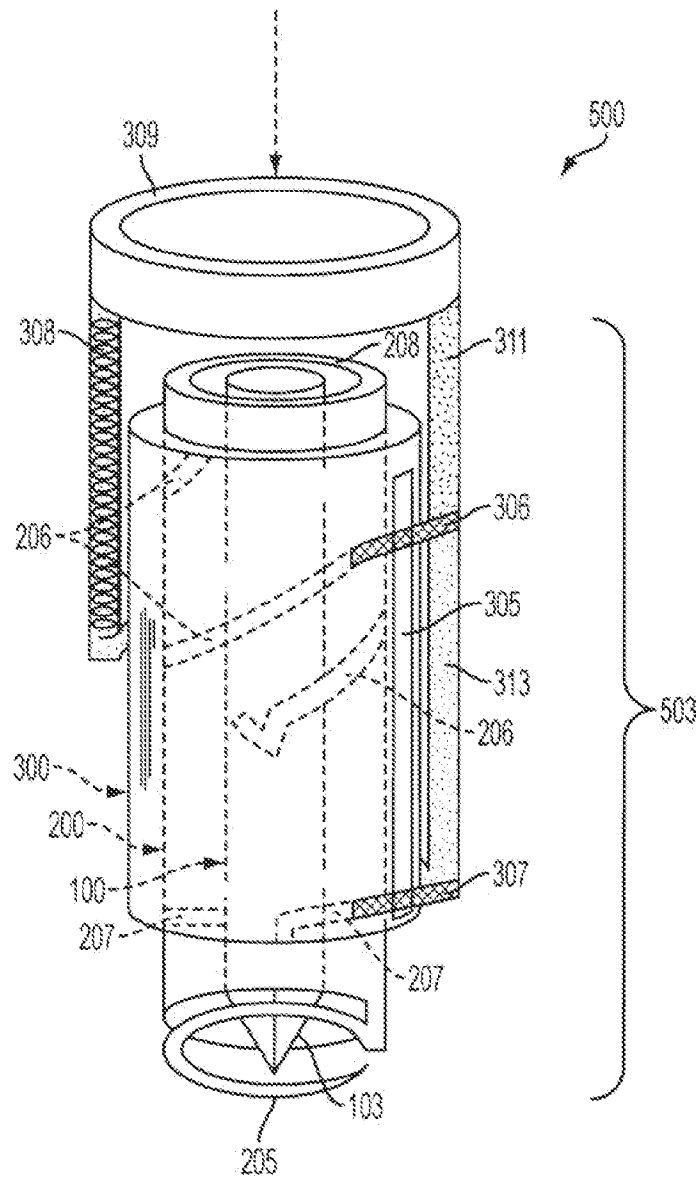


FIG. 21

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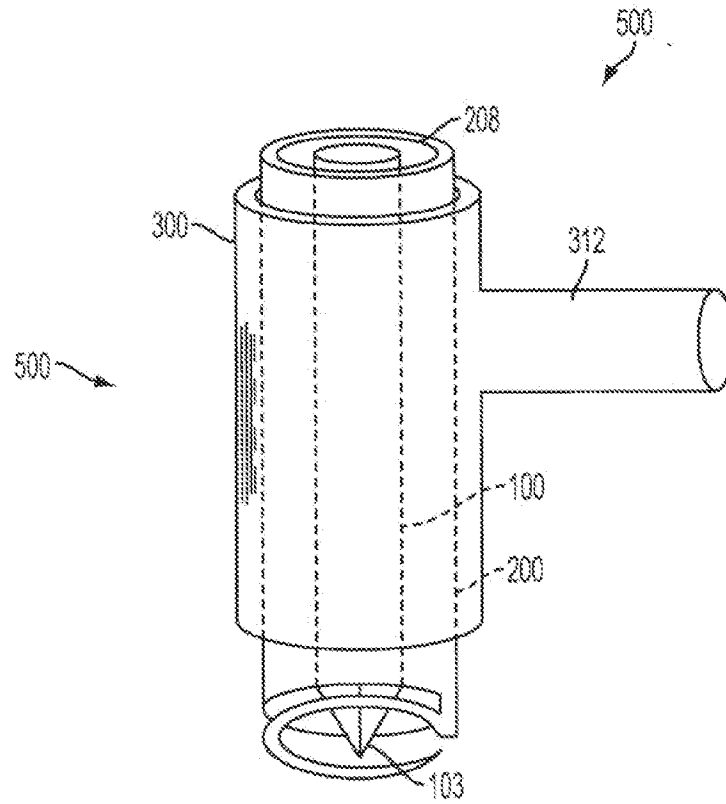


FIG. 22

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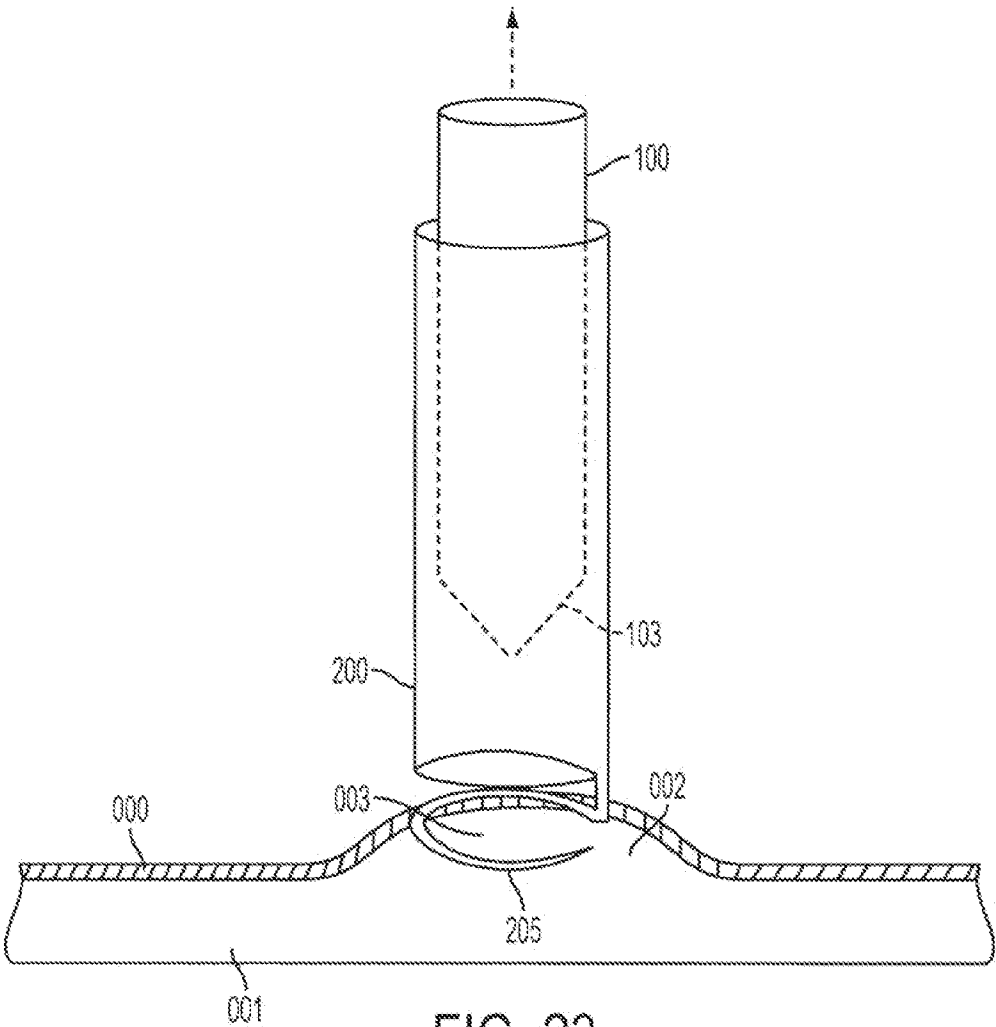


FIG. 23

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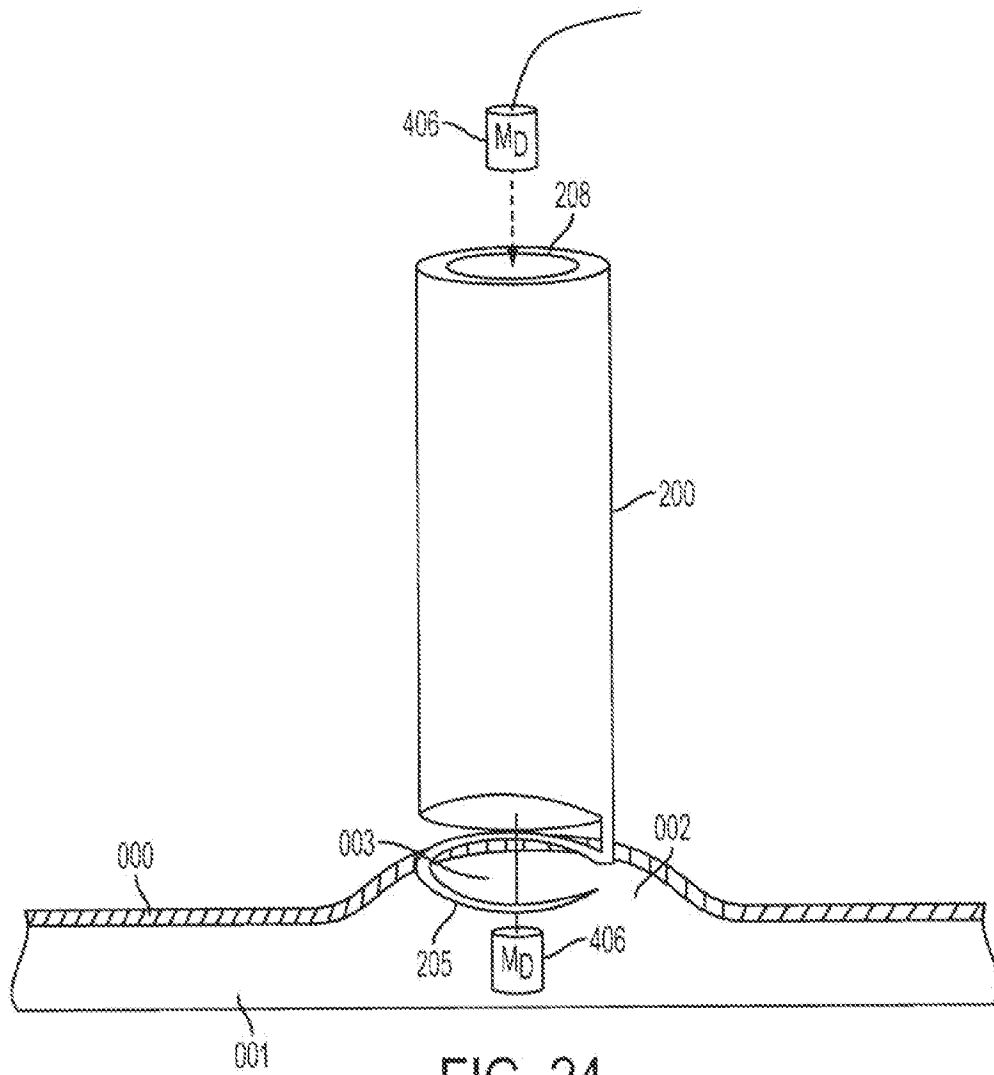


FIG. 24

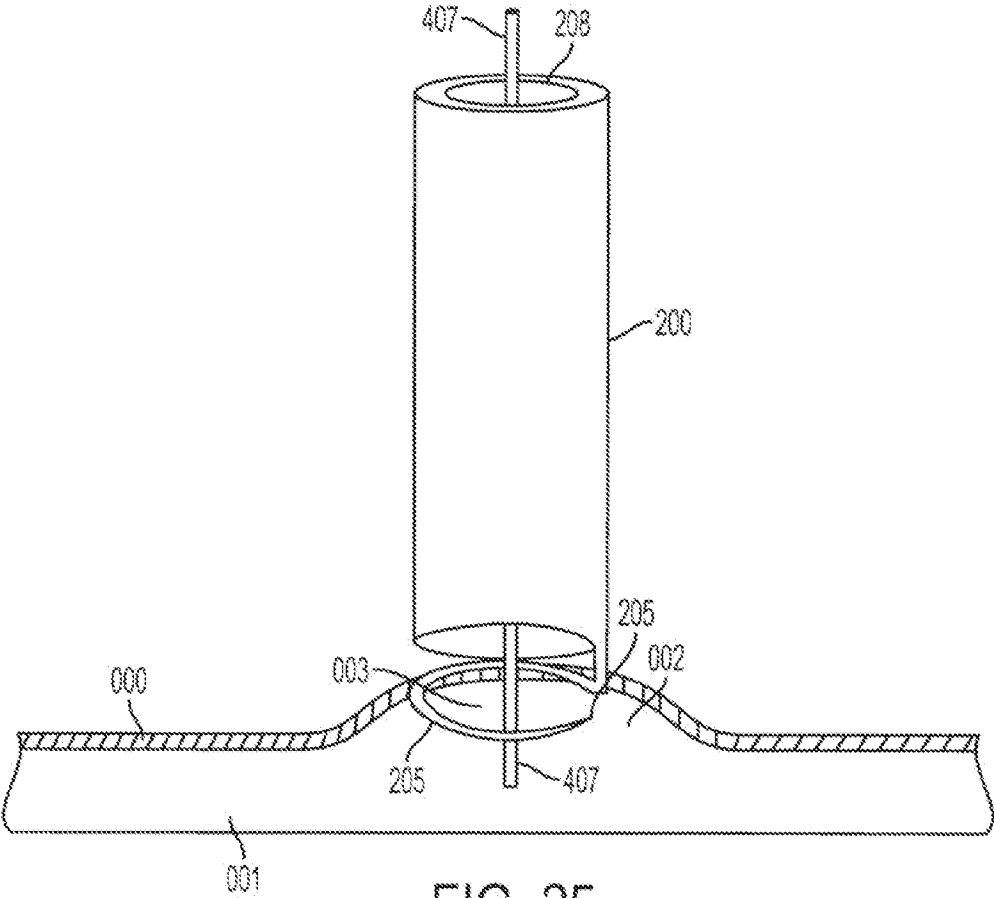


FIG. 25

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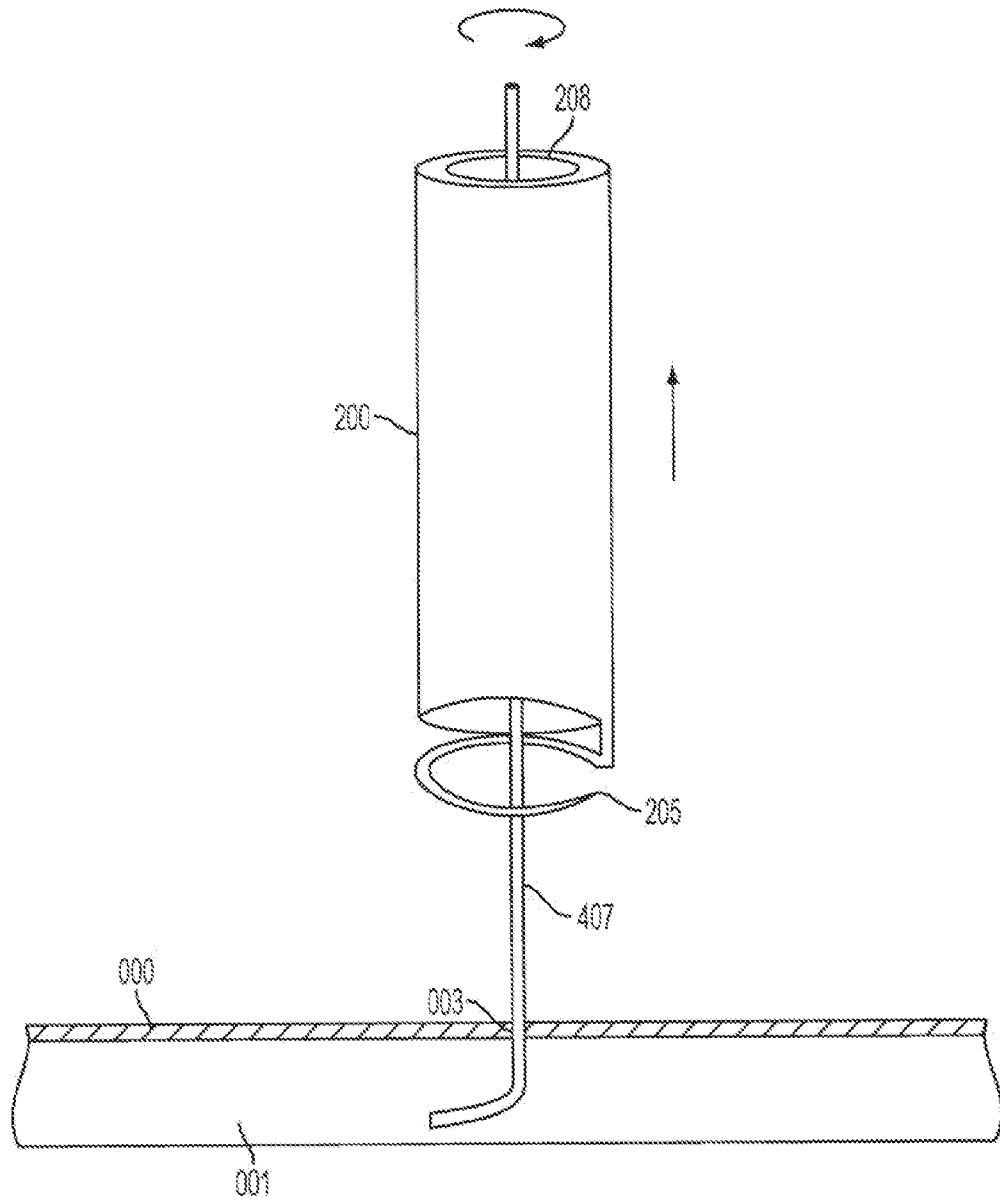


FIG. 26

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2010/033189

| <b>A. CLASSIFICATION OF SUBJECT MATTER</b><br>IPC(8) - A61M 25/06 (2010.01)<br>USPC - 604/506<br>According to International Patent Classification (IPC) or to both national classification and IPC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                    |                                                                                                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| <b>B. FIELDS SEARCHED</b><br>Minimum documentation searched (classification system followed by classification symbols)<br>IPC(8) - A61M 5/14, 25/06 (2010.01)<br>USPC - 604/115, 164.01, 164.13, 506<br>Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched<br>Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)<br>PatBase and Google Patents                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                    |                                                                                                     |
| <b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                    |                                                                                                     |
| Category*                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No.                                                                               |
| Y                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | US 6,423,051 B1 (KAPLAN et al) 23 July 2002 (23.07.2002) entire document           | 1-38, 42-91                                                                                         |
| Y                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | US 6,132,438 A (FLEISCHMAN et al) 17 October 2000 (17.10.2000) entire document     | 1-38, 42-91                                                                                         |
| Y                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | WO 2008/115745 A2 (MAHAPATRA et al) 25 September 2008 (25.09.2008) entire document | 21-27, 63-68                                                                                        |
| Y                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | US 6,162,195 A (IGO et al) 19 December 2000 (19.12.2000) entire document           | 28, 69                                                                                              |
| Y                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | US 6,890,295 B2 (MICHELS et al) 10 May 2005 (10.05.2005) entire document           | 29-38, 70-80                                                                                        |
| Y                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | US 5,354,283 A (BARK et al) 11 October 1994 (11.10.1994) entire document           | 33-35, 78-80                                                                                        |
| Y                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | US 4,240,433 A (BORDOW) 23 December 1980 (23.12.1980) entire document              | 36-38, 82                                                                                           |
| Y                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | US 5,538,504 A (LINDEN et al) 23 July 1996 (23.07.1996) entire document            | 38                                                                                                  |
| Y                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | US 7,179,249 B2 (STEWART et al) 20 February 2007 (20.02.2007) entire document      | 75-77                                                                                               |
| <input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                    |                                                                                                     |
| * Special categories of cited documents:<br>"A" document defining the general state of the art which is not considered to be of particular relevance<br>"E" earlier application or patent but published on or after the international filing date<br>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)<br>"O" document referring to an oral disclosure, use, exhibition or other means<br>"P" document published prior to the international filing date but later than the priority date claimed<br>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention<br>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone<br>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art<br>"&" document member of the same patent family |                                                                                    |                                                                                                     |
| Date of the actual completion of the international search<br>17 June 2010                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                    | Date of mailing of the international search report<br><b>02 JUL 2010</b>                            |
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US, Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-3201                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                    | Authorized officer:<br>Blaine R. Copenheaver<br>PCT Helpdesk: 571-272-4300<br>PCT OSP: 571-272-7774 |