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(54) **DEVICE FOR INTRA-CARDIAC AND INTRA-VASCULAR SURGICAL PROCEDURE HAVING AN ENDOLUMINAL ULTRASOUND PROBE**

VORRICHTUNG FÜR INTRAKARDIALEN UND INTRAVASKULÄREN CHIRURGISCHEN EINGRIFF
MIT EINER ENDOLUMINALEN ULTRASCHALLSONDE

DISPOSITIF POUR PROCÉDURE CHIRURGICALE INTRA-CARDIAQUE ET INTRA-VASCULAIRE
AYANT UNE SONDE À ULTRASONDS ENDOLUMINALE

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Description

Technical field

[0001] The present disclosure relates to a device for intra-cardiac and intra-vascular surgical procedure with beating heart, for catheter based and complex surgical procedures on beating heart and blood filled vessels. The device comprises an endoluminal ultrasound probe having a working channel for catheter based devices and specially designed surgical instruments, that can be introduced in the patient major peripheral arteries and veins as vascular port sites, in which the probe distal component is flexible and can be controlled in a wide range of positions to guide and point an ultrasonic transducer and the working channel in anatomic vascular and cardiac structures.

Background Art

[0002] For intra-cardiac and vascular surgical intervention the heart or vessel must be blood free bypassing the blood thru cardiopulmonary bypass machine for conventional open heart surgery or by cross clamping the vessel for conventional vascular surgery.

[0003] The conventional heart and vascular surgery is considerably invasive and is associated with significant morbidity and mortality risk despite the state of the art in such surgical treatments.

[0004] The natural history of most heart and vascular diseases is related to degenerative progression, aging and increasing weakness of the anatomical structures. This intrinsic systemic fragility is inherent to all systems and organs adding exceedingly high intervention risk to the conventional surgical intervention that may state as prohibitive.

[0005] To prevent the high surgical risk a wide range of minimal invasive intra-cardiac and vascular intervention treatments are known and available but most of these therapeutics options are limited to catheter delivered stent prostheses and devices previously collapsed to an insertion diameter and introduced into a peripheral vessel distant from the diseased vessel or heart structure to treat. These minimal invasive catheter based procedures are performed remotely by indirect vision usually in the hemodynamic laboratory or hybrid operation room using real-time image fluoroscopy or alternatively image echography for guidance and deployment of the stents and devices. The precision for placement and deployment of these devices and stents is paramount, therefore, an accurate dynamic real-time image is mandatory. In addition, in the current state of the art, the real-time image from fluoroscopy is two-dimensional and when assisted with computer tomography or echography for three dimension image the real-time image with direct structure interaction capacity is lost.

[0006] Nevertheless these minimally invasive procedures are still very limited in the range of diseases already

treated by conventional surgery. Accordingly, for patients that must have a heart or vascular surgical correction but are excessively fragile for conventional surgery and there is no minimally invasive solution available, the disease goes untreated. Consequently, in the field of cardiovascular treatment there is continuous interest and demand for significant development in the field of complex surgical treatment by minimally invasive approaches with reduced procedural risk and improved recovery status. Furthermore, any significant improvement to treat cardiovascular diseases in less complex settings like hemodynamic laboratories and operating rooms to perform complex cardiovascular treatments is warranted.

[0007] Document US2010280316A1 describes an improved catheter is which may include a deflectable member located at a distal end of a catheter body. The deflectable member may comprise an ultrasound transducer array. The deflectable member may be interconnected to the catheter body by a live hinge. The catheter may include a lumen extending from a proximal end of the catheter body to the distal end. The lumen may be used to deliver an interventional device to a point distal to the distal end of the catheter body. The deflectable member may be selectively deflectable in a pivot-like manner through an arc of at least 90 degrees. In embodiments where the deflectable member includes an ultrasound transducer array, the ultrasound transducer array may be operable to image both when aligned with the catheter body and when pivoted relative to the catheter body.

[0008] Document US2010280316A1 discloses multiple embodiments of a device for intra-cardiac and intra-vascular surgical procedure said embodiments, when considered individually or together, comprising a surgical endoluminal ultrasound probe, said probe comprising: a flexible tube having a longitudinal hollow which defines a working channel for receiving and guiding transcatheter devices or instruments for the surgical procedure, a deflectable distal end which may be seen as a hatch, and a three-dimension ultrasonic transducer, wherein the flexible tube has a working channel outlet on the distal end of the flexible tube, wherein the deflectable distal end is coupled to the distal end of the flexible tube by a hinge for opening and closing the working channel outlet, wherein the ultrasonic transducer is placed at said hatch door.

[0009] Document US2010280316A1 does not disclose a hatch door hinged to rotate about an axis parallel to the longitudinal axis of the flexible tube, in particular the hatch door being hinged to rotate 180° between closed and open positions.

[0010] Document US2010145306A1 discloses a catheter device comprising a proboscis shaft and a proboscis disposed within the proboscis shaft. In certain embodiments, the catheter device further comprises an elongate tubular member, wherein the proboscis shaft is disposed within the elongate tubular member. In certain embodiments, the catheter device comprises a tissue surface engagement structure, which has a first configuration and

a second configuration. In the second configuration, the tissue surface engagement structure presents a larger transverse profile in comparison to the first configuration. The tissue surface engagement structure may have any of various designs, including an expandable assembly and a hinged assembly. In certain embodiments, a deformable cushion is positioned at the distal end of the proboscis shaft. The deformable cushion comprises a pocket that is filled with a reshapeable material. In certain embodiments, the proboscis shaft comprises a longitudinally compressible portion.

[0011] Document US2014222043A1 discloses an atherectomy catheter provided for excising and imaging material in a body lumen. In one embodiment, the catheter comprises a catheter body, a cutting blade, and an imaging device. A cutting blade is mounted on a catheter body and configured to move between a first position and a second position relative to an aperture or cutting window. When the cutting blade is in the second position, a blade substantially closes the aperture on the catheter body. An imaging device which is mounted on or otherwise coupled to the cutting blade is configured to be in an imaging position when the cutting blade substantially closes the aperture or cutter window. This allows the imaging device to survey material within the cutting zone of the atherectomy catheter. By allowing the imaging device to view materials within this cutting zone, material may be imaged and then removed from the body lumen without having to reposition the catheter between each step.

[0012] Document US2014378772A1 relates to medical devices (e.g., organ ports such as transapical heart ports) and methods and materials for implanting and using such medical devices. For example, organ ports and entry devices that can be used to implant an organ port are provided. Document US2014378772A1 discloses a system for implanting an organ port into a mammal, wherein said system comprises: (a) an entry device comprising a body and a blade attached to said body, and (b) an organ port comprising a housing having a first end and a second end, wherein said housing defines a channel extending between said first end and said second end, wherein said first end is configured to be inserted into an organ of said mammal, wherein said channel is configured to provide repeated access to the interior of said organ through said channel, wherein said first end comprises a securing portion configured to secure said first end to an interior region of said organ, and wherein said second end comprises a securing portion configured to secure said second end to an exterior region of said organ, and wherein said entry device is configured to be withdrawn through said channel.

[0013] Documents US2010145306A1, US2014378772A1 and US2014222043A1 do not disclose a hatch door which is coupled to a distal end of a catheter device flexible tube by a hinge for opening and closing the working channel outlet, wherein the ultrasonic transducer is placed at said hatch door, wherein the hatch

door is hinged to rotate about an axis parallel to the longitudinal axis of the flexible tube, in particular the hatch door being hinged to rotate 180° between closed and open positions.

[0014] Accordingly a need exists in the art to allow a trained clinician to perform complex heart and vascular intervention and surgery in a minimally invasive approach and less complex setting.

[0015] These facts are disclosed in order to illustrate the technical problem addressed by the present disclosure.

General Description

[0016] The invention is defined by a device for intracardiac and intra-vascular surgical procedure comprising a surgical endoluminal ultrasound probe, as defined in claim 1. The disclosed embodiments falling outside the scope of claim 1 do not form part of the invention and are merely provided as reference examples. A minimally invasive device for intervention inside the heart and major vessels for catheter based and complex surgical procedures on beating heart and blood filled vessels is disclosed. This device allows a real-time three dimension echography image of the vessels, heart chambers and valves for diagnose and intervention throughout a working channel for catheter based devices and specially designed surgical instruments. The disclosed device has a probe component that can be introduced in the patient major peripheral arteries and veins as vascular port sites in one or more ports depending on the complexity of the procedure. The probe distal component is flexible and can be controlled in a wide range of positions to guide and point the ultrasonic transducer and the working channel in small anatomic vascular and cardiac structures.

[0017] The disclosure relates to a device that comprises the capability for real-time three dimension image acquisition for diagnostic, intervention and surgical procedures inside the heart and major vascular vessels through a minimally invasive approach and with beating heart.

[0018] Embodiments hereof are directed to a device to access the heart chambers and major vessels in a physiologic blood filled beating heart clinical setup by direct three dimension reconstruction vision through a minimally invasive technique for interventional and surgical procedures.

[0019] In an embodiment the device comprises two main components, the processor and display unit and the endoluminal probe. The processor and display unit comprises a console unit with a computer module to process the data from the three dimension ultrasonic transducer and a display element to exhibit the real-time three dimension high-resolution images from the ultrasonic transducer. The endoluminal probe has a flexible mechanically controlled cylindrical arm to fit the natural individual vessel and heart anatomy and a hollow hemodynamic valve sealed working channel. The endoluminal and endocardiac images are acquired by a miniaturized

three dimension ultrasonic transducer placed at the tip of the endoluminal probe to allow real-time dynamic visualization of the anatomical endovascular or endocardiac structure. The distal component of the probe is flexible and can be controlled in a wide range of positions to guide and point the ultrasonic transducer and the working channel inside the small anatomic vascular and cardiac structures. The interventional and surgical endovascular and endocardiac manipulation are achieved throughout the hollow hemodynamic valve sealed working channel using the variety of currently available and forthcoming transcatheter devices and specially designed surgical appliances and instruments for cylindrical small caliber working channels. The endoluminal probe is designed for introduction in a major peripheral vessel as vascular access port through a vascular introducer placed by transcatheter or minimal surgical cut down approach. The peripheral vessels eligible to access with this device may be an artery or a vein suitable to access the anatomical location of the structure to treat. Depending on the complexity of the intended procedure two or more endoluminal probes introduced throughout additional arterial or venous access ports may be required and used at the same time. The more common arteries and veins to access with this device are the femoral vessels, the axillary vessels, the carotid and jugular vessels, although other more central or peripheral vessels may be used. Since the image acquisition of this device is echography based, the use image fluoroscopy and endovascular contrast is unnecessary, avoiding the radiation exposure, the toxicity of the endovascular contrast and the need for complex settings like hemodynamic laboratory or hybrid operation room. The direct real time three dimension reconstruction vision of this device combined with the direct handling feedback feeling from the structures to treat through the working channel allow to this device a enhanced capability to operate on complex anatomical structures similar to the conventional open surgical field. In addition, the controlled and extraordinary wide flexibility of the distal sensing and interface component of the endoluminal probe allows precise intervention capability that can further be enhanced by the combination of the real time three and two dimension image data collected by the three dimension ultrasonic transducer for more accurate definition of depth, transmuralty and limits of the anatomical structures. Likewise, the three dimension ultrasonic transducer additionally allows real time Doppler ultrasound image for diagnostic and procedural end result evaluation. Furthermore, this device may allow a fully percutaneous alternative for previously exclusive surgical option procedures and depending on the complexity of the procedure intended this device can be operated throughout the entire procedure by a skilled clinician without specific or extensive surgical training.

[0020] The design of the device enables a significantly larger working channel opening diameter in relation to the outer diameter of the probe. The larger working channel is of utmost importance for the variety of procedures

possible with the currently available and forthcoming transcatheter devices and specially designed surgical appliances and instruments for cylindrical small caliber working channels. The larger working channel is also essential for precise tactile feedback from the transcatheter devices and specially designed surgical appliances and instruments when interacting with the vascular and cardiac structures. In particular, a decentralized position of the working channel in relation to the outer ring of the probe is designed to maximize the working channel diameter with the greatest flexibility and tension resistance, in particular in an articulated portion of the flexible mechanically-controlled cylindrical probe.

[0021] It is disclosed an embodiment of a device for intra-cardiac and intra-vascular surgical procedure comprising a surgical endoluminal ultrasound probe, said probe comprising:

a flexible tube having a longitudinal hollow which defines a working channel for receiving and guiding transcatheter devices or instruments for the surgical procedure,
a hatch door, and
a three-dimension ultrasonic transducer,
wherein the flexible tube has a working channel outlet on the distal end of the flexible tube,
wherein the hatch door is coupled to the distal end of the flexible tube by a hinge for opening and closing the working channel outlet, wherein the ultrasonic transducer is placed at said hatch door.

[0022] It is also disclosed an embodiment of a device for intra-cardiac and intra-vascular surgical procedure comprising a surgical endoluminal ultrasound probe, said probe comprising:

a flexible tube having a longitudinal hollow which defines a working channel for receiving and guiding transcatheter devices or instruments for the surgical procedure, and
a three-dimension ultrasonic transducer,
wherein the flexible tube has a working channel outlet on the distal end of the flexible tube defining a ring-shaped surface,
wherein the working channel longitudinal axis is off-centred in respect of the flexible tube longitudinal axis, thus defining two sections of said ring-shaped surface, a wider section and a narrower section,
wherein the ultrasonic transducer is placed or coupled to the wider section of the ring-shaped surface.

[0023] The invention comprises a hatch door for opening and closing the working channel outlet, the hatch door being coupled to said wider section by a hinge, wherein the ultrasonic transducer is placed at said hatch door.

[0024] According to the invention, the hatch door is hinged to rotate about an axis parallel to the longitudinal axis of the flexible tube, in particular the hatch door is

hinged to rotate 180° between closed and open positions.

[0025] In an embodiment, the ultrasonic transducer is placed at the forward-facing part of the hatch door.

[0026] As a reference example, the hatch door is hinged to rotate about an axis perpendicular to the longitudinal axis of the flexible tube, in particular the hatch door is hinged to rotate between 90° and 180° in respect of the longitudinal axis of the flexible tube between closed and open positions.

[0027] In an embodiment, the ultrasonic transducer is placed at the part of the hatch door that is forward-facing when the hatch door is open.

[0028] A reference example comprises a secondary ultrasonic transducer in addition to said ultrasonic transducer herewith main ultrasonic transducer, wherein the secondary ultrasonic transducer is placed at the part of the hatch door that is forward-facing when the hatch door is closed.

[0029] As a reference example, the secondary ultrasonic transducer has a lower definition than the main ultrasonic transducer.

[0030] In an embodiment, the flexible tube has the working channel outlet on the distal end of the flexible tube thus defining a ring-shaped surface, wherein the working channel longitudinal axis is off-centred in respect of the flexible tube longitudinal axis, thus defining two sections of said ring-shaped surface, a wider section and a narrower section, wherein the hatch door is placed or coupled to the distal end of the flexible tube at said wider section of the ring-shaped surface.

[0031] In an embodiment, the longitudinal hollow is cylindrical.

[0032] In an embodiment, the flexible tube is cylindrical.

[0033] In an embodiment, the ring-shaped surface is annular and bounded by two non-concentric circles defined respectively by the flexible tube and the longitudinal hollow.

[0034] In an embodiment said probe comprises an embedded motor cable for opening or closing the hinge of the hatch door, in particular wherein the embedded motor cable is a rotation motor cable.

[0035] An embodiment comprises a wheel gear mechanism for rotational coupling between the rotation motor cable and the hatch door.

[0036] It is also disclosed an embodiment of a device for intra-cardiac and intra-vascular surgical procedure comprising a surgical probe, said probe comprising a flexible tube having a longitudinal hollow which defines a working channel for receiving and guiding transcatheter devices or instruments for the surgical procedure, wherein the flexible tube has a working channel outlet on the distal end of the flexible tube defining a ring-shaped surface, and the distal part of the flexible tube comprises a sequential arrangement of a plurality of ring-shaped units along the flexible tube, wherein each unit comprises a ball-joint and is coupled with the adjoining unit or units by said ball-joint.

[0037] In an embodiment, the proximal part of the flexible tube is a flexible tube coupled to the most proximal of said units having less flexibility than the sequential arrangement of a plurality of ring-shaped units of the distal part.

[0038] In an embodiment, the proximal part of the flexible tube is a polymeric flexible tube coupled to the most proximal of said units.

[0039] In an embodiment, the proximal part of the flexible tube is a sequential arrangement of interlocked slidably disposed units, in particular having a lower flexibility than the sequential arrangement of a plurality of ring-shaped units of the distal part of the flexible tube.

[0040] In an embodiment, the unit has one or more openings for tunneled passage of embedded motor or electrical cables.

[0041] An embodiment comprises one or more embedded motor cables embedded in said openings for axially orienting the distal end of the flexible tube, wherein the embedded motor cable is attached at one of the cable ends to one of said units, in particular wherein the embedded motor cable is attached at one of the cable ends to the most distal unit.

[0042] In an embodiment, one of the motor cables is a push-pull motor cable having the tunnelled passage opening and attachment placed in the ring-shaped unit opposite the ball-joint placement, in particular the tunnelled passage being ribbon-shaped.

[0043] In an embodiment, the tunnelled passage is an arcuate ribbon-shaped tunnelled passage.

[0044] In an embodiment, one of the motor cables is a push-pull motor cable having the tunnelled passage opening and attachment placed in the ring-shaped unit laterally in respect of the ball-joint placement, in particular the push-pull motor cable having a circular section.

[0045] In an embodiment, two of the motor cables are push-pull motor cables having the tunneled passage openings and attachments placed in the ring-shaped unit laterally in respect of the ball-joint placement and opposite in respect of the other cable opening and attachment, in particular the two push-pull motor cables having a circular section.

[0046] In an embodiment, the ring-shaped unit has a tapering decreasing thickness in the direction away from the ball-joint.

[0047] In an embodiment, the ball-joint of each unit is placed at said wider section of the ring-shaped surface.

[0048] In an embodiment, the flexible tube has a working channel inlet on the proximal end of the flexible tube.

[0049] An embodiment comprises a handle for the flexible tube on the proximal end of the flexible tube, wherein the working channel inlet is comprised in said handle.

[0050] An embodiment of the handle comprises one or more motors for actuating the motor cables, an electronic circuit for controlling said motors and one or more user controls for inputting control of said electronic circuit.

[0051] An embodiment comprises a computer for processing data from the ultrasonic transducer and a dis-

play for displaying real-time three-dimension images from the ultrasonic transducer.

[0052] An embodiment of the handle comprises the terminating connections of the motor and electric cables of the flexible tube.

[0053] An embodiment of the handle comprises a valve at the working channel inlet for minimizing blood leaks.

[0054] An embodiment of the handle comprises an air removal outlet.

[0055] An embodiment of the comprises an electronic circuit and user controls for inputting control of said electronic circuit, wherein said electronic circuit is for controlling image parameters of the ultrasonic transducer placed at the distal end of the flexible tube and/or for controlling the flexibility of the distal end of the flexible tube.

[0056] Ring-shaped surface means a surface that is a flattened ring or loop, wherein the ring may be circular, oval, stadium-shaped, or even other shapes regular or irregular.

[0057] Annular surface means a surface bounded by two non-intersecting circles, concentric or non-concentric (i.e. the width of the surface is not constant).

[0058] The hatch door is a door that closes the working channel outlet in such a way to minimise intra-cardiac or intra-vascular damage. When closed, it may, or may not, enclose the outlet working channel in a fluid-tight way.

[0059] Forward-facing in respect of the endoluminal probe means towards the region where the intervention is to be carried out, i.e. in the direction beyond the distal end of the flexible tube.

[0060] A rotation motor cable is a cable able to transmit motion by its own rotation. The rotation motor cable may have an outer sheathing, which preferably does not rotate. A rotation motor cable is preferably circular. A push-pull motor cable is a cable able to transmit motion by its pulling.

[0061] A pull motor cable may have an outer sheathing, which preferably does not pull. A push-pull motor cable may have a circular section or be ribbon-shaped. A push-pull motor cable may also be able to transmit motion by its pushing. Also, the outer sheathing preferably does not push.

[0062] A section is any of the more or less distinct parts into which something is or may be divided or from which it is made up. In particular, wherein the working channel longitudinal axis is off-centred in respect of the flexible tube longitudinal axis, thus defining two sections of said ring-shaped surface, a wider section and a narrower section, these sections are the two parts of the ring-shaped surface into which the ring-shaped surface may be divided, one having a wider section than the other.

Brief Description of the Drawings

[0063] The following figures provide preferred embodiments for illustrating the description and should not be seen as limiting the scope of disclosure. Drawings are

not necessarily to scale.

Figure 1 is a schematic illustration of an embodiment of the device and its components.

Figure 2 is a schematic illustration of a side view of an embodiment of the endoluminal probe and its components.

Figure 3 is a schematic illustration of a top view of an embodiment of the operating control element and its components.

Figure 4 is a schematic illustration of embodiments of the probe sensing and interface element and its components. Figures 4.5 - 4.8 are provided as reference examples.

Figure 5-6 is a schematic illustration to represent the degree of orientation of the distal segment of an embodiment of the endoluminal probe in the horizontal and vertical axis.

Figure 7 is a schematic illustration of an embodiment of the flexibility unit.

Figure 8 is a schematic illustration of an embodiment of device in four potential intervention and surgical clinical scenarios.

Figure 9 is a schematic illustration of an embodiment of device in which the flexible tube has a working channel outlet on the distal end of the flexible tube thus defining a ring-shaped surface, wherein the working channel longitudinal axis is off-centred in respect of the flexible tube longitudinal axis, thus defining two sections of said ring-shaped surface, a wider section (134) and a narrower section (135), for example wherein the hatch door can be placed or coupled at said wider section of the ring-shaped surface of the distal end of the flexible tube.

Detailed Description

[0064] Specific embodiments of the present disclosure are now described with reference to the figures, wherein like reference numbers indicate identical or functionally similar elements.

[0065] Although the description of embodiments hereof is in the context of minimally invasive interventional and surgical procedures in the heart and major vessels, the disclosure may be adapted to be used for other concurrent vascular and cardiac diagnostic and therapeutic procedures where it is deemed useful.

[0066] The terms "Doppler", "transcatheter aortic valve", "transcatheter mitral valve", "neocordae", "edge-to-edge stitch", "endoprosthesis stent", "sandwich technique", "rapid pacing stimulation", "extracorporeal mem-

brane oxygenator (ECMO)" and "mini-extracorporeal circulation (MECC)" are used in the following description concerning medical devices, surgical techniques, interventional techniques, methods and apparatus according to the published literature and are used as exemplary references.

[0067] Examples of materials that may be used in the components of the described device are those that may be normally used to improve the performance of the various components according to the state of the art of the available materials.

[0068] Embodiments hereof are related to a device to access the heart chambers and major vessels in a physiologic blood filled beating heart clinical setup by direct three dimensional reconstruction vision through minimally invasive technique for interventional and surgical procedures. All the figures are schematic not to scale illustrations of the described device as the materials, shape and relative size of all components and diagrams may vary accordingly to the desired functionality.

[0069] FIG. 1 is a schematic illustration of the endoluminal probe **100**, the connecting cable **104**, the processor unit **102**, the display unit **103** and the support portable module **101**. The connecting cable **104** connects the endoluminal probe **100** with the processor unit **102** for data transmission and power supply. The processor unit **102** is connected with the display unit **103** to display image and other data obtained by the endoluminal probe **100**. The components **100**, **101**, **102**, **103** and **104** may vary in size, shape and length according to the integrated constituent components specifications like cabling materials, computer processors, transducer configuration or any other included components. The device described is intended for use in hospital environment, however, as it is self sufficient regarding image acquisition and anatomical structure intervention, its use in a hemodynamic laboratory or an operating room is not mandatory. The processor unit **102** can be connected with more simultaneous endoluminal probes **100** if needed for the intended procedure. The display unit **103** can be repeated in other display monitors placed in different locations in the room regarding the operator position. Furthermore, the display unit **103** can display the real-time three dimension, the two dimension and the Doppler images acquired from the endoluminal probe **100** and any other data collected from other monitoring systems as required.

[0070] FIG. 2 is a schematic illustration of a side view of the endoluminal probe **100** and its components, specifically the operating control element **105**, the flexible cylindrical extension element **106** and the probe sensing and interface element **107** in accordance with an embodiment hereof. The operating control element **105** is designed for one hand operation to control the position of the flexible cylindrical extension element **106** and the probe sensing and interface element **107** in the desired anatomical vascular or cardiac structure. The flexible cylindrical extension element **106** is designed to be introduced into a peripheral major artery or vein throughout

a vascular introducer and be manually advanced until the desired anatomical vascular or cardiac structure. The progression and regression in the vascular and cardiac structure of the flexible cylindrical extension element **106** and the probe sensing and interface element **107** is obtained by pushing and pulling of the endoluminal probe **100** throughout the vascular introducer. The direct vascular and cardiac structure interaction is possible with the other hand operation through the working channel that crosses the operating control element **105** until the distal opening in the probe sensing and interface element **107**.

[0071] The operating control element **105** additionally incorporates the electrical motors and cables to operate the fine guiding of the flexible cylindrical extension element **106** and the probe sensing and interface element **107**. The complete length of the flexible cylindrical element **106** and the connecting cable **104** is reduced by the dashed lines to comprise a comprehensive visualization of the endoluminal probe **100** components.

[0072] FIG. 3 is a schematic illustration of a top view of operating control element **105**, with the representation of the working channel access inlet **108** and the air removal outlet **109**. At the top of the operating control element **105** is the keyboard control buttons **110** for the image settings and the flexible cylindrical element **106** fine guiding orientation. The keyboard control buttons **110** may vary in configuration and position in the operating control element **105** according with the best operation function and ergonomic handling. The working channel access inlet **108** may have a different position in the operating control element **105** to improve the other hand handling. The air removal outlet **109** is needed to guarantee a complete blood filled and air free valve sealed working channel. The working channel access inlet **108** has a valve apparatus to minimize the blood leak and lost during the introduction and removal of the devices, appliances and instruments needed for the intended procedure. The working channel of the endoluminal probe **100** is a cylindrical pathway that starts in the working channel access inlet **108**, crosses the operating control element **105** and continues thru the flexible cylindrical extension element **106** until the probe sensing and interface element **107** where it ends and opens. The dash point dash lines represent the explained pathway of the cylindrical working channel from the working channel access inlet **108** until the probe sensing and interface element **107**. The complete length of the flexible cylindrical element **106** and the connecting cable **104** is reduced by the dashed lines to comprise a comprehensive visualization of the endoluminal probe **100** components.

[0073] FIG. 4 is a schematic illustration of the probe sensing and interface element **111** according to various embodiments.

[0074] FIG. 4.1 represents a sectional view of the probe sensing and interface element **111** in the progression mode. FIG. 4.2 represents a sectional view of the probe sensing and interface element **111** in the Intervention

mode. **FIG. 4.3** represents a frontal view of the probe sensing and interface element **111** in both progression and intervention modes. **FIG. 4.4** represents a frontal and top view of the probe sensing and interface element **111** rotating mechanism. **FIG. 4.5** represents a sectional view of a reference example hatch design for the probe sensing and interface element **111** in the progression mode. **FIG. 4.6** represents a sectional view of a reference example hatch design for the sensing and interface element **111** in the Intervention mode. **FIG. 4.7** represents a sectional view of a reference example design for the probe sensing and interface element **111** maintaining the same configuration in both progression and intervention modes. **FIG. 4.8** represents a frontal view of a reference example design for the probe sensing and interface element **111**.

[0075] The probe sensing and interface element **111** is composed by two components, the sensing element **112** and the probe working channel outlet **113** as represented in FIG. 4.1 to FIG. 4.4. The sensing element **112** in the probe sensing and interface element **111** integrates a miniaturized high definition three dimension ultrasonic transducer **114**. The miniaturized high definition three dimension ultrasonic transducer **114** may be assembled in a Capacitive Micromachined Ultrasonic Transducer (CMUT) on complementary metal-oxide-semiconductor (CMOS) similar to the CMUT-on-CMOS chip described in the document "Compact, energy-efficient ultrasound imaging probes using cmut arrays with integrated electronics" (US 20130128702 A1) but with different arrangement of the array transmit and receive elements placed in a matrix fashion instead of a dual-ring fashion, with more transmit and receive elements for improved image definition, and an improved working channel design. The components design of the sensing element **112** may vary from the design represented in the figures without departing from the scope of the disclosure hereof.

[0076] **FIG. 4.1** is a schematic illustration of a sectional view of the large caliber probe sensing and interface element **111** in the progression mode. During progression of the probe in the vascular introducer and vascular structure, the sensing element **112** is rotated downwards the probe working channel outlet **113** with the three dimension ultrasonic transducer **114** facing forward to sense and guide the progression of the endoluminal probe throughout the vessel until the desired anatomical location. In the progression mode the three dimension ultrasonic transducer **114** is rotated downwards to the working channel outlet **114** to preserve the same diameter as the flexible cylindrical element **106** during the progression of the probe until the anatomical endovascular or endocardiac structure to treat.

[0077] **FIG. 4.2** is a schematic illustration of a sectional view of the probe sensing and interface element **111** in the Intervention mode. When the probe sensing and interface element **111** reaches the desired anatomical location to intervene, the sensing element **113** is rotated upwards 180° around a longitudinal axis of the probe to

open the working channel outlet **113**. In the Intervention mode the three dimension ultrasonic transducer **114** is positioned in an upper position for better angle to point the three dimension ultrasonic transducer **114** forward in the same direction as the working channel outlet **113** to allow the anterior sensing and visualization of the working channel outlet **113** working field in the anatomical endovascular or endocardiac structure. Advantageously, the transducer being displaced laterally in respect of the line of sight improves the viewing angle, reduces ultrasonic 'shadows' and spurious reflections.

[0078] **FIG. 4.3** is a schematic illustration of a frontal view of the probe sensing and interface element **111** in the progression mode **4.3a** and intervention modes **4.3b**. The probe sensing element **112** covers the working channel outlet **113** in the progression mode **4.3a** and rotates upwards to expose the working channel outlet **113** in the intervention mode **4.3b**. In particular, the rotation is 180° which maximises the view perspective and reduces ultrasound shadows or interferences. The endoluminal probe **100** may be assembled with smaller calibers applied to the flexible cylindrical extension element **106** and the probe sensing and interface element **107** but with the same structure configuration of all the remaining elements of endoluminal probe **100** in all its components although some components may have different shape, size and integrated components fitting the increasing miniaturization. Smaller caliber endoluminal probe **100** may be used for simple diagnostic and intervention procedures with smaller diameter access vascular port or as additional vascular port manipulation for more complex procedures combining two or more endoluminal probes **100** with either smaller or larger caliber endoluminal probes **100** with different arterial and venous vascular ports depending on the complexity of the procedure and the anatomical structures to treat.

[0079] **FIG. 4.4** is a schematic illustration of a frontal and top view of the probe sensing and interface element **111** rotating mechanism for the three dimension ultrasonic transducer **114** to open the working channel outlet **113**. The 180° rotation is operated by a gear wheel mechanism **115** activated by a rotatable cable. In the top view the electrical communication cable **116** for the three dimension ultrasonic transducer **114** is represented. The proportion of the probe working channel diameter in relation to the endoluminal probe **100** total diameter may vary but is designed to maximize the working channel diameter according to the present disclosure.

[0080] **FIG. 4.5** is a schematic illustration of a sectional view of a reference example hatch design for the probe sensing and interface element **111** in the progression mode. During progression of the probe in the vascular introducer and vascular structure, the sensing element **112** is rotated inwards to the probe working channel outlet **113** with a (possibly lower definition) three dimension ultrasonic transducer **117** facing forward to sense and guide the progression of the endoluminal probe throughout the vessel until the desired anatomical location. In

the progression mode the (possibly higher definition) three dimension ultrasonic transducer **114** is rotated inwards to the working channel outlet **113** to protect the higher definition transducer interface and to preserve the same diameter as the flexible cylindrical element **106** during the progression of the probe until the anatomical endovascular or endocardiac structure to treat.

[0081] FIG 4.6 is a schematic illustration of a sectional view of a reference example design for the probe sensing and interface element **111** in the Intervention mode. When the probe sensing and interface element **111** reaches the desired anatomical location to intervene, the sensing element **112** is rotated upwards around a transversal axis of the probe to open the working channel outlet **113**. In the Intervention mode the low definition three dimension ultrasonic transducer **117** is facing upward and/or backwards and may be used for additional guidance and the higher definition three dimension ultrasonic transducer **114** is positioned frontward pointing the higher definition three dimension ultrasonic transducer **114** in the same direction as the working channel outlet **113** to allow the anterior sensing and visualization of the working channel outlet **113** working field in the anatomical endovascular or endocardiac structure where the intervention is to be carried out. Preferably, the rotation is more than 90° such that the higher definition transducer **114** rotates into the region where the intervention is to be carried out. Preferably, the rotation is less than 180° such that lower definition transducer **117** faces sideways in order to obtain a lateral view.

[0082] FIG 4.7 is a schematic illustration of a sectional view of a reference example design for the probe sensing and interface element **111**. The reference example design may be used for smaller caliber probe sensing and interface element **111** with smaller caliber flexible cylindrical extension element **106** and the probe sensing and interface element **107** but with the same structure configuration in all the remaining elements of endoluminal probe **100** in all its components except for the component **112** and **117** that may have different shape, size and integrated components. The smaller caliber probe sensing and interface element **111** can be used for simple diagnostic and intervention procedures with smaller diameter access vascular port or for additional vascular port manipulation for more complex procedures combining two or more endoluminal probes **100** with either small caliber or large caliber probe sensing and interface element **111** with different arterial and venous vascular ports depending on the complexity of the procedure and the anatomical structures to treat. The sensing element **112** in the smaller caliber probe sensing and interface element **111** maintains the same position in relation to the probe working channel outlet **113** in both progression and intervention modes. The smaller caliber probe sensing and interface element **111** integrate only a lower definition three dimension ultrasonic transducer **117**.

[0083] FIG 4.8 is a schematic illustration of a frontal view of the of a reference example design for a smaller

caliber probe sensing and interface element **111** with the lower definition three dimension ultrasonic transducer **117** and the working channel outlet **113**. The proportion of the probe working channel diameter in relation to the smaller caliber probe sensing and interface element **111** total diameter may vary. In this a reference example, the working channel is located in the endoluminal probe asymmetrically in respect of the longitudinal axis.

[0084] FIG. 5 is a schematic illustration of the superior view of the distal segment of the flexible cylindrical extension element **106** and the probe sensing and interface element **107** to further illustrate the degree of orientation in the horizontal axis allowed by the sequential arrangement of a series of flexibility units **118** in accordance with an embodiment hereof. The degree of horizontal axis orientation of the cylindrical extension element **106** and the probe sensing and interface element **107** may vary and be limited by the specific flexibility characteristics of the currently available and forthcoming transcatheter devices and specially designed surgical appliances and instruments for cylindrical small caliber working channels catheter based devices and surgical instruments. The orientation fine movement of the distal segment of the flexible cylindrical extension element **106** and the probe sensing and interface element **107** is cable operated and powered by electrical motors housed in the operating control element **105** and controlled with the keyboard control buttons **110**.

[0085] FIG. 6 is a schematic illustration of the lateral view of the distal segment of the flexible cylindrical extension element **106** and the probe sensing and interface element **107** to further illustrate the degree of orientation in the vertical axis allowed by the sequential arrangement of a series of flexibility units **118** in accordance with an embodiment hereof. The degree of vertical axis orientation of the cylindrical extension element **106** and the probe sensing and interface element **107** may vary and be limited by the specific flexibility characteristics of the currently available and forthcoming transcatheter devices and specially designed surgical appliances and instruments for cylindrical small caliber working channels catheter based devices and surgical instruments. The orientation fine movement of the distal segment of the flexible cylindrical extension element **106** and the probe sensing and interface element **107** is cable operated and powered by electrical motors housed in the operating control element **105** and controlled with the keyboard control buttons **110**.

[0086] FIG. 7 is a schematic illustration of flexibility unit **118** in the frontal view **118a**, in the superior view **118b** and in the lateral view **118c**. The flexibility unit **118** is composed by a flexibility unit joint **119** that articulates with the next flexibility unit **118**. In particular, the articulating joint is a ball joint.

[0087] In particular, the flexibility unit is ring-shaped, shaped as a hollow cylinder segment normal to the cylinder axis, i.e. a transversal hollow cylinder slice or a hollow disc, with the joint **119** being placed in one of the

lateral parts of the ring in a face towards the next flexibility unit. The hollow of consecutive units defines a space. This space is the working channel **123**. The working channel **123** is in a decentralized position in relation to the outer ring of the flexibility unit. This way, larger openings and joint elements may be placed in one of the lateral parts of the ring, maximizing the useful diameter of the working channel **123**.

[0088] Further in particular, the ring may have a tapering thickness towards the end opposite the location of the joint **119**, such that the flexibility of the sequential arrangement of a series of connected flexibility units is increased.

[0089] The flexibility unit **118** has communication openings **120** to allow the tunnelled passage of the cable needed for the gear wheel mechanism **115** for mechanical rotation of the sensing element **112** in the probe sensing and interface element **111**. The communication openings **120** additionally allow the tunnelled passage of the communication cable **116** needed for power supply and data transmission between the sensing element **112** through flexible cylindrical extension element **106** until the operating control element **105** and the processor unit **102**. The flexibility unit **118** furthermore has two horizontal axis orientation openings **121** and one vertical axis orientation opening **122** to allow the tunneled passage of the cables needed for the mechanical horizontal and vertical axis orientation of the sensing and interface element **111**. The vertical and horizontal axis openings **121** and **122** are not represented in the superior view **118b** and in the lateral view **118c**.

[0090] The design of the flexibility unit **118** has a large working channel opening **123** that maximizes the working channel **123** diameter in relation to the outer diameter of the flexibility unit **118**. The large working channel **123** is of utmost importance for the variety of procedures possible with the currently available and forthcoming transcatheter devices and specially designed surgical appliances and instruments for cylindrical small caliber working channels. The large working channel **123** is also essential for precise tactile feedback from the transcatheter devices and specially designed surgical appliances and instruments when interacting with the vascular and cardiac structures. The decentralized position of the working channel **123** in relation to the outer ring of the flexibility unit **118** is designed to maximize the working channel diameter with the greatest flexibility and tension resistance supported in the ampler portion where the flexibility unit joint **119** articulates.

[0091] In the frontal view illustration **118a** the flexible outer coating sheath **124** and inner coating sheath **125** are represented. The flexible outer coating sheath **124** and inner coating sheath **125** materials may be polymeric membrane based, nevertheless the coating sheath materials may vary according to the state of the art materials for better flexibility, durability, sterilization compatibility and endovascular introduction and use. All the constituents of the flexibility unit **118** may vary in shape, materials

and methods of fabrication and can be used as would be apparent to one of skill in the art in accordance with various embodiments of the present disclosure. The flexibility unit **118** material may be metallic (for example steel, aluminum or titanium alloys) or a hard polymeric material.

[0092] FIG. 8 is a schematic illustration of the endoluminal probe **100** in four potential clinical intervention and surgical scenarios. The potential clinical intervention and surgical scenarios represented in FIG. 8 are merely exemplary in nature and is not intended to limit the disclosure or the application and uses of the disclosure. According to the complexity of the procedure, the use of one or more endoluminal probes **100** thru additional arterial or venous vascular ports with another large caliber probe sensing and interface element **111** or a small caliber probe sensing and interface element **112** may be required. FIG. 8.1 - the endoluminal probe **100** is introduced thru the femoral artery until the ascending aorta to preform a deployment of a transcatheter aortic valve **126**. The endoluminal probe **100** allow a safe and accurate deployment of the transcatheter aortic valve **126** regarding the coronary ostium and the aortic valve annulus and the degree and location of the calcification in the native aortic valve. FIG. 8.2 - the endoluminal probe **100** is introduced thru the femoral vein until the right atrium and thru the interatrial septum by transeptal puncture to the left atrium to preform a complex mitral valve repair with the implantation of transcatheter mitral ring **127**, a transcatheter neocordae **128** and a leaflet transcatheter edge-to-edge stitch **129**. The approach represented in FIG. 8.2 can also be used for deployment of a transcatheter mitral valve. To reduce the transcatheter mitral valve deployment system diameter the mitral valve ring may be previously secured with a transcatheter mitral ring **126** using the endoluminal probe **100** followed by the deployment of a smaller caliber transcatheter mitral valve. FIG. 8.3 - the endoluminal probe **100** is introduced thru the femoral vein until the right atrium and thru the interatrial septum by transeptal puncture to the left atrium to preform the ablation pathways **130** in the left and right atriums to treat for atrial fibrillation using under direct three dimension reconstruction vision an ablation catheter **131**. The orientation flexibility and the three dimension real-time image permitted by the endoluminal probe **100** allow a comprehensive left and right atrium ablation pathway. The endoluminal probe **100** additionally allows the continuous ablation transmural evaluation required for successful atrial fibrillation treatment with the simultaneous two dimension echography images. FIG. 8.4 - the endoluminal probe **100** is introduced thru the femoral artery thru the true lumen until the ascending aorta to identify the tear from an ascending aorta dissection and place by direct reconstruction three dimensional real-time vision a sealing endoprosthesis stent **132** to occlude and correct the dissection. The endoluminal probe **100** allows a secure size and location identification of the aortic intima tear and the location of the true and false lumen to clearly identify the proper site to deploy the sealing en-

doprosthesis stent **132**. To treat the ascending aorta dissection as represented in FIG. 8.4 the placement of smaller endoprosthesis stents **133** in the true lumen guided under by direct reconstruction real-time vision with the endoluminal probe **100** may be needed for posterior expansion using the sandwich technic after the main sealing endoprosthesis stent **132** deployment to assure the perfusion of the aortic arch arteries. The procedure described in FIG. 8.4 using the endoluminal probe **100** can similarly be reproduced to treat other acute aortic syndromes and ascending aorta and aortic arch aneurisms. With the increasing complexity of the procedure, a less contracting heart may be desirable for a more secure structure manipulation and this can be obtained with transitory rapid pacing stimulation. If a standstill heart is required for longer periods of time, additionally or alternatively to the rapid pacing, the temporary use of an extracorporeal membrane oxygenator (ECMO) or a mini-extracorporeal circulation (MECC) thru the available arterial and venous ports may be necessary.

[0093] FIG. 9 is a schematic illustration of a cross section of an embodiment of the endoluminal probe **100** to identify the location of the wider **134** and narrower **135** sections

[0094] It is disclosed an embodiment of the device for intra-vascular and intra-cardiac access for image acquisition and surgical intervention comprising an endoluminal probe that connects with a processor and display unit, wherein the endoluminal probe has a probe component designed to be introduced in a peripheral vascular artery or vein to access the endovascular and endocardiac structures. The probe component has a distal mechanically controlled flexibility to maneuver and direct the distal portion of the probe inside the endovascular and endocardiac structures. The probe component has an elongated cylindrical lumen or working channel having a distal end and a proximal end. The probe distal component has a vision module comprising three dimension high-resolution ultrasonic transducer for image acquisition.

[0095] It is also disclosed an embodiment of the device wherein the endoluminal probe comprise: a plurality of flexibility units disks spaced along the distal portion of the probe length.

[0096] A method, non-forming part of the claimed invention, of operating the embodiments of the disclosed device in a endovascular or endocardiac structure filled with blood and with beating heart may comprise: Inserting a enclosed lumen through a single vascular port, wherein the lumen or working channel comprises a distal portion and a proximal portion; Obtaining a visual image of the environment surrounding the distal portion of the lumen during and after insertion; Opening the distal portion of the lumen to expose the vision module and working channel outlet; Rotating the vision module along the longitudinal axis of the lumen and vertically from the distal portion of the lumen.

[0097] The term "comprising" whenever used in this document is intended to indicate the presence of stated

features, integers, steps, components, but not to preclude the presence or addition of one or more other features, integers, steps, components or groups thereof.

[0098] The disclosure should not be seen in any way restricted to the embodiments described and a person with ordinary skill in the art will foresee many possibilities to modifications thereof. The above described embodiments are combinable. The following claims further set out particular embodiments of the disclosure.

Claims

1. Device for intra-cardiac and intra-vascular surgical procedure comprising a surgical endoluminal ultrasound probe (100), said probe comprising:

a flexible tube (106) having a longitudinal hollow which defines a working channel (113, 123) for receiving and guiding transcatheter devices or instruments for the surgical procedure, a hatch door (112), and a three-dimension ultrasonic transducer (114),

wherein the flexible tube (106) has a working channel outlet on the distal end (111) of the flexible tube,

wherein the hatch door is coupled to the distal end of the flexible tube by a hinge for opening and closing the working channel outlet, wherein the ultrasonic transducer is placed at said hatch door,

wherein the hatch door is hinged to rotate about an axis parallel to the longitudinal axis of the flexible tube, in particular the hatch door is hinged to rotate 180° between closed and open positions.

2. Device according to the previous claim wherein the ultrasonic transducer (114) is placed at the forward-facing part of the hatch door (112).

3. Device according to any previous claim, wherein the flexible tube has the working channel (113, 123) outlet on the distal end of the flexible tube thus defining a ring-shaped surface, wherein the working channel longitudinal axis is off-centred in respect of the flexible tube longitudinal axis, thus defining two sections of said ring-shaped surface, a wider section (134) and a narrower section (135), wherein the hatch door (112) is placed or coupled to the distal end of the flexible tube at said wider section of the ring-shaped surface.

4. Device according to any previous claim wherein the longitudinal hollow is cylindrical, wherein the flexible tube is cylindrical, and wherein the ring-shaped surface is annular and bounded by two non-concentric circles defined respectively by the flexible tube and

the longitudinal hollow (113, 123).

5. Device according to any previous claim wherein said probe comprises an embedded motor cable for opening or closing the hinge of the hatch door (112), and comprising a wheel gear mechanism (115) for rotational coupling between the rotation motor cable and the hatch door. 5
6. Device according to any previous claim wherein the distal part of the flexible tube comprises a sequential arrangement of a plurality of ring-shaped units (118) along the flexible tube, wherein the unit comprises a ball-joint (119) and is coupled with the adjoining unit or units by said ball-joint. 10
7. Device according to the previous claim wherein the unit (118) has one or more openings (120, 121, 122) for tunnelled passage of embedded motor or electrical cables, comprising one or more embedded motor cables embedded in said openings (121, 122) for axially orienting the distal end of the flexible tube, wherein the embedded motor cable is attached at one of the cable ends to one of said units, in particular wherein the embedded motor cable is attached at one of the cable ends to the most distal unit. 20
8. Device according to the previous claim wherein one of the motor cables is a push-pull motor cable (121) having the tunnelled passage opening and attachment placed in the ring-shaped unit laterally in respect of the ball-joint placement, in particular the push-pull motor cable having a circular section. 25
9. Device according to the claim 7 wherein two of the motor cables are push-pull motor cables (121) having the tunnelled passage openings and attachments placed in the ring-shaped unit laterally in respect of the ball-joint placement and opposite in respect of the other cable opening and attachment, in particular the two push-pull motor cables having a circular section. 30
10. Device according to any claim 6 - 9 wherein the proximal part of the flexible tube is a flexible tube coupled to the most proximal of said units having less flexibility than the sequential arrangement of a plurality of ring-shaped units (118) of the distal part. 35
11. Device according to any claim 6 - 10 wherein the ring-shaped unit (119) has a tapering decreasing thickness in the direction away from the ball-joint. 40
12. Device according to claim 3 and any claim 6 - 11 wherein the ball-joint of each unit (119) is placed at said wider section of the ring-shaped surface. 45
13. Device according to any previous claim wherein the 50

flexible tube (106) has a working channel inlet (108) on the proximal end of the flexible tube, the device further comprising a handle (100) for the flexible tube on the proximal end of the flexible tube, wherein the working channel inlet is comprised in said handle, wherein the handle comprises one or more motors for actuating the motor cables, an electronic circuit for controlling said motors and one or more user controls for inputting control of said electronic circuit.

14. Device according to any previous claim comprising a handle (100) on the proximal end of the flexible tube, wherein said handle comprises an electronic circuit and user controls (105, 110) for inputting control of said electronic circuit, said electronic circuit for controlling image parameters of the ultrasonic transducer placed at the distal end of the flexible tube and/or for controlling the flexibility of the distal end of the flexible tube. 55
15. Device according to any of the previous claims comprising a computer (102) for processing data from the ultrasonic transducer and a display (103) for displaying real-time three-dimension images from the ultrasonic transducer.

Patentansprüche

1. Vorrichtung für einen intrakardialen und intravaskulären chirurgischen Eingriff, umfassend eine chirurgische endoluminale Ultraschallsonde (100), wobei die genannte Sonde umfasst:

einen flexiblen Schlauch (106) mit einem längs gerichteten Hohlraum, der einen Arbeitskanal (113, 123) zur Aufnahme und Führung von Transkathetervorrichtungen oder -instrumenten für den chirurgischen Eingriff bildet, einer Klappe (112) und einen dreidimensionalen Ultraschallwandler (114), wobei der flexible Schlauch (106) am distalen Ende (111) des flexiblen Schlauchs einen Arbeitskanalauslass aufweist, wobei die Klappe über ein Scharnier zum Öffnen und Schließen des Arbeitskanalauslasses mit dem distalen Ende des flexiblen Schlauchs gekoppelt ist, wobei sich der Ultraschallwandler an der genannten Klappe befindet, wobei die Klappe so aufgehängt ist, dass sie sich um eine parallel zur Längsachse des flexiblen Schlauchs verlaufende Achse drehen lässt und die Klappe insbesondere so aufgehängt ist, dass sie sich um 180 ° zwischen einer geschlossenen und geöffneten Position drehen lässt. 55
2. Vorrichtung nach dem vorherigen Anspruch, wobei der Ultraschallwandler (114) an dem nach vorne ge-

richteten Teil der Klappe (112) angebracht ist.

3. Vorrichtung nach einem der vorherigen Ansprüche, wobei sich der Auslass des Arbeitskanals (113, 123) am distalen Ende des flexiblen Schlauchs befindet, wodurch eine ringförmige Oberfläche gebildet wird, wobei die Längsachse des Arbeitskanals in Bezug auf die Längsachse des flexiblen Schlauchs exzentrisch ist und so auf der genannten ringförmigen Oberfläche zwei Abschnitte bildet, einen breiteren Abschnitt (134) und einen schmaleren Abschnitt (135), wobei sich die Klappe (112) an dem distalen Ende des flexiblen Schlauchs an dem genannten breiteren Abschnitt der ringförmigen Oberfläche befindet oder mit diesem gekoppelt ist. 5
4. Vorrichtung nach einem der vorherigen Ansprüche, wobei der längs gerichtete Hohlraum zylindrisch ist, wobei der flexible Schlauch zylindrisch ist, und wobei die ringförmige Oberfläche ringförmig ist und durch zwei nicht-konzentrische Kreise begrenzt wird, die jeweils durch den flexiblen Schlauch und den längs gerichteten Hohlraum (113, 123) gebildet werden. 10
5. Vorrichtung nach einem der vorherigen Ansprüche, wobei die genannte Sonde ein eingebettetes Motorkabel zum Öffnen oder Schließen des Scharniers der Klappe (112) umfasst, und einen Mechanismus mit Getrieberad (115) für den drehbaren Anschluss des sich drehenden Motorkabels und der Klappe umfasst. 15
6. Vorrichtung nach einem der vorherigen Ansprüche, wobei der distale Teil des flexiblen Schlauchs eine aufeinander folgende Anordnung mehrerer ringförmiger Einheiten (118) entlang des flexiblen Schlauchs umfasst, wobei die Einheit ein Kugelgelenk (119) umfasst und über das genannte Kugelgelenk mit der oder den benachbarten Einheiten gekoppelt ist. 20
7. Vorrichtung nach dem vorherigen Anspruch, wobei die Einheit (118) eine oder mehrere Öffnungen (120, 121, 122) für den getunnelten Durchgang von eingebetteten Motor- oder Elektrokabeln aufweist, umfassend ein oder mehrere in die genannten Öffnungen (121, 122) eingebettete Motorkabel zur axialen Ausrichtung des distalen Endes des flexiblen Schlauchs, wobei das eingebettete Motorkabel an einem der Kabelenden an einer der genannten Einheiten befestigt ist, wobei insbesondere das eingebettete Motorkabel an einem der Kabelenden mit der am distalsten Einheit befestigt ist. 25
8. Vorrichtung nach dem vorherigen Anspruch, wobei eines der Motorkabel ein Zug-Druck-Motorkabel (Push-Pull) (121) ist, bei dem die Öffnung des getunnelten Durchgangs und die Befestigung in der 30

ringförmigen Einheit seitlich zu der Platzierung des Kugelgelenks angeordnet sind, insbesondere das Zug-Druck-Motorkabel (Push-Pull) mit einem kreisförmigen Abschnitt.

9. Vorrichtung nach Anspruch 7, wobei zwei der Motorkabel Zug-Druck-Motorkabel (Push-Pull) (121) sind, bei denen die Öffnung des getunnelten Durchgangs und die Befestigungen in der ringförmigen Einheit seitlich zu der Platzierung des Kugelgelenks und gegenüber der anderen Kabelöffnung und Befestigung angebracht sind, insbesondere die zwei Zug-Druck-Motorkabel (Push-Pull) mit einem kreisförmigen Abschnitt. 35
10. Vorrichtung nach einem der Ansprüche 6 - 9, wobei der proximale Teil des flexiblen Schlauchs ein flexibler Schlauch ist, der mit der am proximalsten der genannten Einheiten gekoppelt ist und weniger Flexibilität aufweist als die sequentielle Anordnung der verschiedenen ringförmigen Einheiten (118) des distalen Teils. 40
11. Vorrichtung nach einem der Ansprüche 6 - 10, wobei sich die ringförmige Einheit (119) in Richtung vom Kugelgelenk weg eine sich verjüngende Dicke aufweist. 45
12. Vorrichtung nach Anspruch 3 und einem der Ansprüche 6 - 11, wobei das Kugelgelenk jeder Einheit (119) an dem genannten breiteren Abschnitt der ringförmigen Oberfläche angeordnet ist. 50
13. Vorrichtung nach einem der vorherigen Ansprüche, wobei der flexible Schlauch (106) am proximalen Ende des flexiblen Schlauchs einen Arbeitskanaleinlass (108) aufweist, wobei die Vorrichtung ferner einen Griff (100) für den flexiblen Schlauch am proximalen Ende des flexiblen Schlauchs umfasst, wobei der Einlass des Arbeitskanals in den Griff integriert ist, wobei der Griff einen oder mehrere Motoren zum Betätigen der Motorkabel, eine elektronische Schaltung zum Steuern der genannten Motoren und eine oder mehrere Bedienelemente zum Steuern der elektronischen Schaltung durch den Benutzer umfasst. 55
14. Vorrichtung nach einem der vorherigen Ansprüche, umfassend einen Griff (100) am proximalen Ende des flexiblen Schlauchs, wobei der genannte Griff eine elektronische Schaltung und Bedienelemente für den Benutzer (105, 110) zur Steuerung der genannten elektronischen Schaltung umfasst, die genannte elektronische Schaltung zur Steuerung der Bildparameter des am distalen Ende des flexiblen Schlauchs angebrachten Ultraschallwandlers und/oder zum Steuern der Flexibilität des distalen Endes des flexiblen Schlauchs dient.

15. Vorrichtung nach einem der vorherigen Ansprüche, umfassend einen Computer (102) zum Verarbeiten der Daten des Ultraschallwandlers und eine Anzeige (103) zur Darstellung dreidimensionaler Bilder in Echtzeit aus dem Ultraschallwandler.

Revendications

1. Dispositif pour procédure chirurgicale intra-cardiaque et intra-vasculaire ayant une sonde à ultrasons endoluminale (100), ladite sonde comprenant :

un tube flexible (106) ayant un creux longitudinal qui définit un canal de travail (113, 123) pour recevoir et guider des dispositifs ou instruments à transcathéter pour le procédé chirurgical, une trappe (112), et un transducteur ultrasonique tridimensionnel (114), dans lequel le tube flexible (106) a une sortie de canal de travail sur l'extrémité distale (111) du tube flexible, dans lequel la trappe est accouplée à l'extrémité distale du tube flexible par une charnière pour ouvrir et fermer la sortie du canal de travail, dans laquelle le transducteur ultrasonique est placé sur ladite trappe, dans lequel la trappe est articulée de façon à pivoter sur un axe parallèle à l'axe longitudinal du tube flexible, en particulier la trappe est articulée pour pivoter à 180° entre les positions ouverte et fermée.

2. Dispositif selon la revendication précédente dans lequel le transducteur ultrasonique (114) est placé sur le côté de la trappe (112) orienté vers l'avant.

3. Dispositif selon l'une quelconque des revendications précédentes, dans lequel la sortie du canal de travail (113, 123) du tube flexible est sur l'extrémité distale du tube flexible, définissant ainsi une surface en forme d'anneau, dans laquelle l'axe longitudinal du canal de travail est décentré par rapport à l'axe longitudinal du tube flexible, définissant ainsi deux sections de ladite surface en forme d'anneau, une section plus large (134) et une section plus étroite (135), dans laquelle la trappe (112) est placée ou accouplée à l'extrémité distale du tube flexible au niveau de ladite section plus large de la surface en forme d'anneau.

4. Dispositif selon l'une quelconque des revendications précédentes dans lequel le creux longitudinal est cylindrique, dans lequel le tube flexible est cylindrique, et dans lequel la surface en forme d'anneau est annulaire et liée par deux cercles non concentriques définis respectivement par le tube flexible et le creux longitudinal (113, 123).

5. Dispositif selon l'une quelconque des revendications précédentes dans lequel ladite sonde comprend un câble moteur incorporé pour ouvrir ou fermer la charnière de la trappe (112), et comprenant un mécanisme de roue dentée (115) pour l'accouplement rotatif entre le câble moteur de rotation et la trappe.

6. Dispositif selon l'une quelconque des revendications précédentes dans lequel la partie distale du tube flexible comprend un arrangement séquentiel d'une pluralité d'unités en forme d'anneau (118) au long du tube flexible, dans lequel l'unité comprend un joint à rotule (119) et est accouplée à l'unité ou unités adjacente(s) par ledit joint à rotule.

7. Dispositif selon la revendication précédente dans lequel l'unité (118) a une ou plusieurs ouvertures (120, 121, 122) pour le passage en tunnel des câbles moteurs ou électriques incorporés, comprenant un ou plusieurs câbles moteurs incorporés, incorporés dans lesdites ouvertures (121, 122) pour orienter axialement l'extrémité distale du tube flexible, dans lequel le câble moteur incorporé est attaché de l'une des extrémités de câble à l'une desdites unités, en particulier dans lequel le câble moteur incorporé est attaché de l'une des extrémités de câble à l'unité la plus distale.

8. Dispositif selon la revendication précédente dans lequel l'un des câbles moteurs est un câble moteur de pression-traction (121) dont l'ouverture du passage en tunnel et l'attachement sont placés dans l'unité en forme d'anneau latéralement par rapport au placement du joint à rotule, le câble moteur de pression-traction ayant en particulier une section circulaire.

9. Dispositif selon la revendication 7 dans lequel deux des câbles moteurs sont des câbles moteurs de pression-traction (121) dont les ouvertures du passage en tunnel et des attachements sont placés dans l'unité en forme d'anneau latéralement par rapport au placement du joint à rotule et opposées par rapport à l'autre ouverture et attachement de câble, les deux câbles moteurs de pression-traction ayant en particulier une section circulaire.

10. Dispositif selon l'une quelconque des revendications 6 - 9 dans lequel la partie proximale du tube flexible est un tube flexible accouplé à la plus proche de ces unités ayant moins de flexibilité que l'arrangement séquentiel d'une pluralité d'unités en forme d'anneau (118) de la partie distale.

11. Dispositif selon l'une quelconque des revendications 6 - 10 dans lequel l'unité en forme d'anneau (119) a une épaisseur en pointe qui se réduit dans la direction opposée au joint à rotule.

12. Dispositif selon la revendication 3 et l'une quelconque des revendications 6 - 11 dans lequel le joint à rotule de chaque unité (119) est placé sur ladite section plus large de la surface en forme d'anneau. 5
13. Dispositif selon l'une quelconque des revendications précédentes dans lequel le tube flexible (106) a une entrée de canal de travail (108) sur l'extrémité proximale du tube flexible, le dispositif comprenant également une poignée (100) pour le tube flexible sur l'extrémité proximale du tube flexible, dans lequel l'entrée du canal de travail est comprise dans ladite poignée, dans lequel la poignée comprend un ou plusieurs moteurs pour actionner les câbles moteurs, un circuit électronique pour contrôler lesdits moteurs et une ou plusieurs commandes d'utilisateur pour le contrôle d'entrée dudit circuit électronique. 10 15
14. Dispositif selon l'une quelconque des revendications précédentes comprenant une poignée (100) sur l'extrémité proximale du tube flexible, dans lequel ladite poignée comprend un circuit électronique et des commandes d'utilisateur (105, 110) pour le contrôle d'entrée dudit circuit électronique, 20 25
ledit circuit électronique pour contrôler des paramètres d'image du transducteur ultrasonique placé sur l'extrémité distale du tube flexible et/ou pour contrôler la flexibilité de l'extrémité distale du tube flexible. 30
15. Dispositif selon l'une quelconque des revendications précédentes comprenant un ordinateur (102) pour le traitement de données venant du transducteur ultrasonique et un écran (103) pour afficher des images tridimensionnelles en temps réel à partir du transducteur ultrasonique. 35

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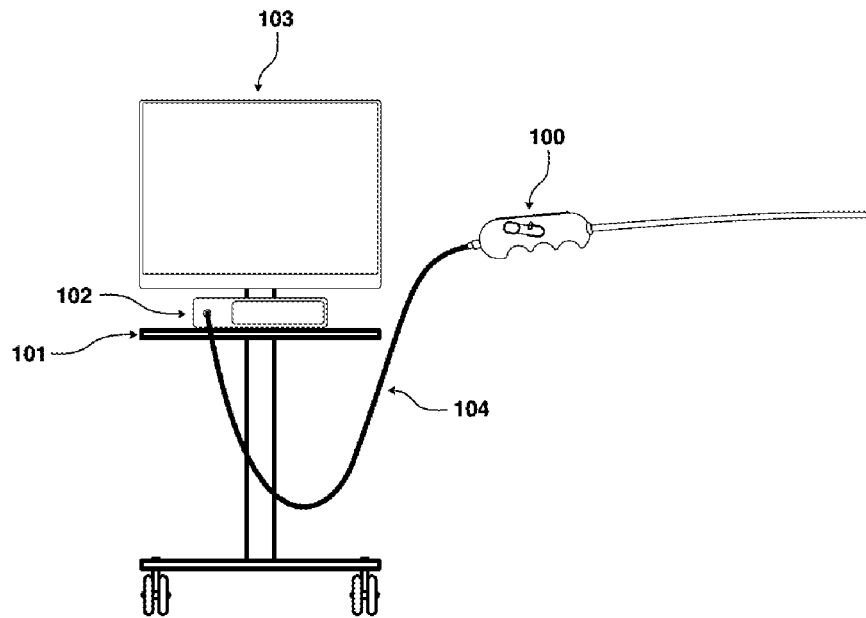


Fig. 1

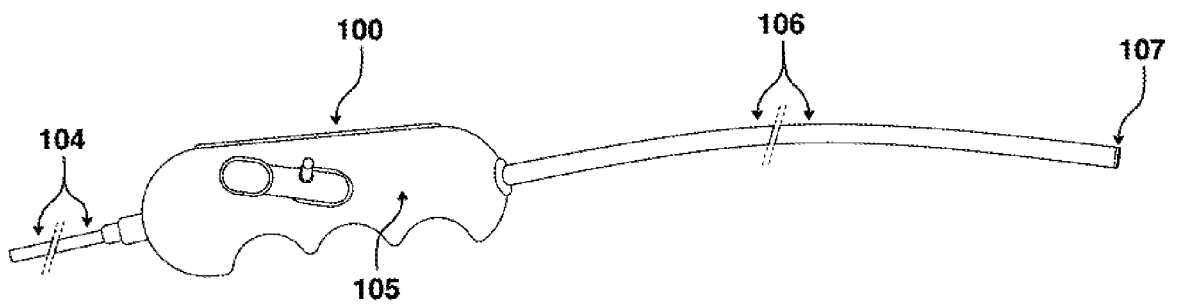


Fig. 2

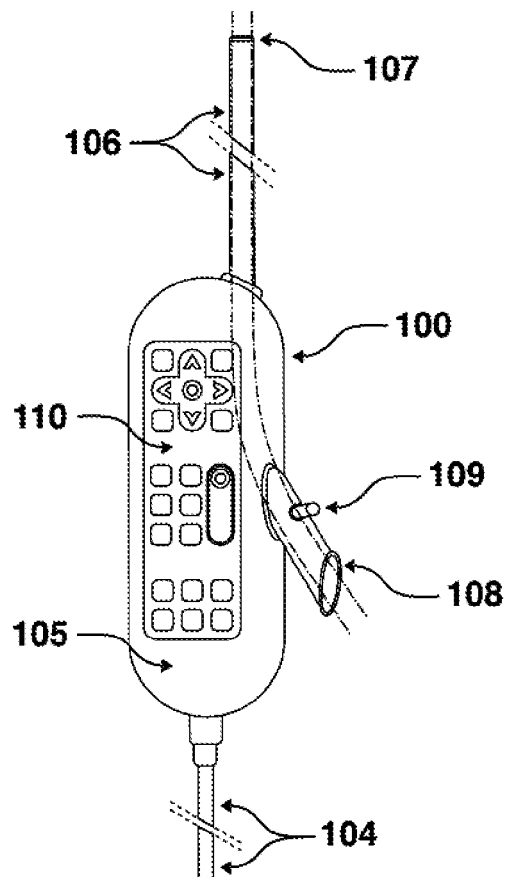


Fig. 3

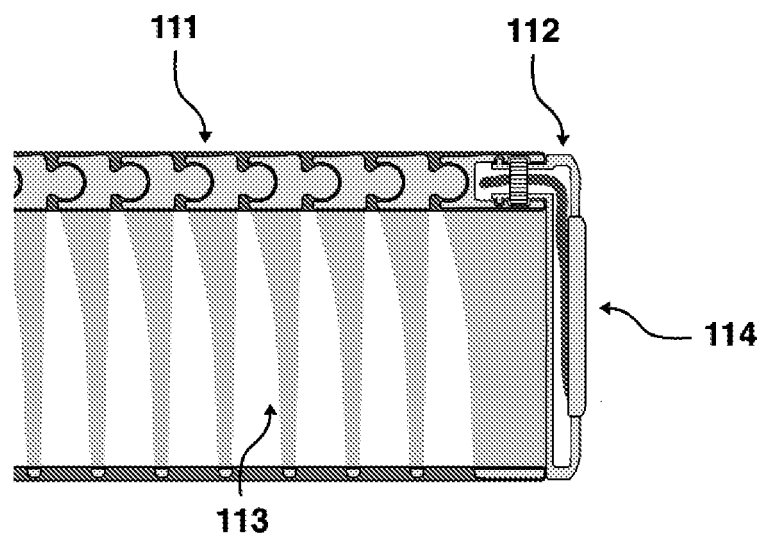


Fig. 4.1

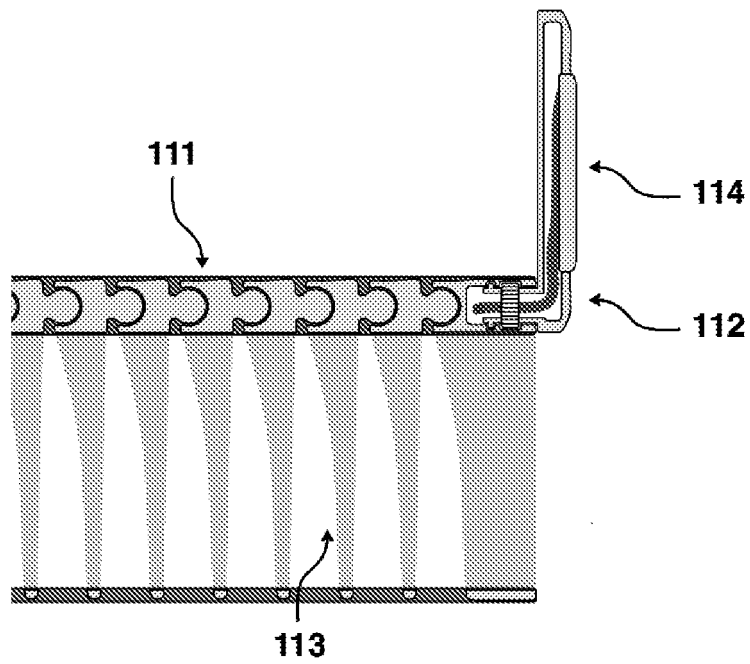


Fig. 4.2

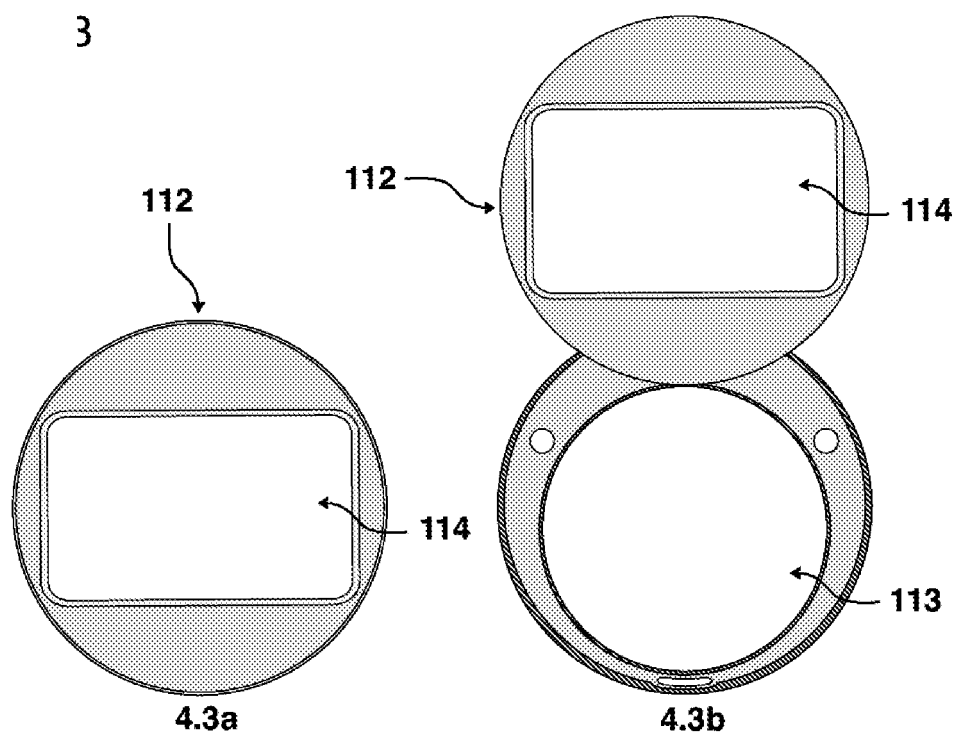


Fig. 4.3

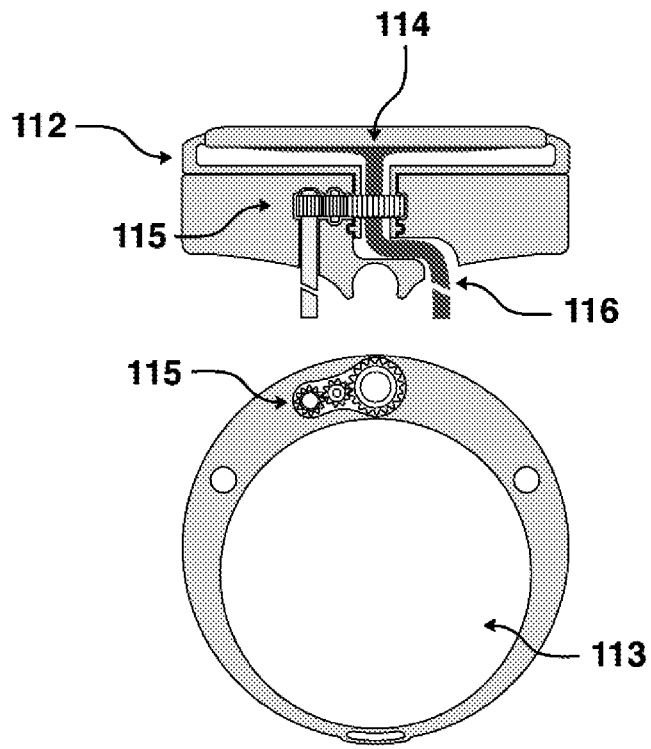


Fig. 4.4

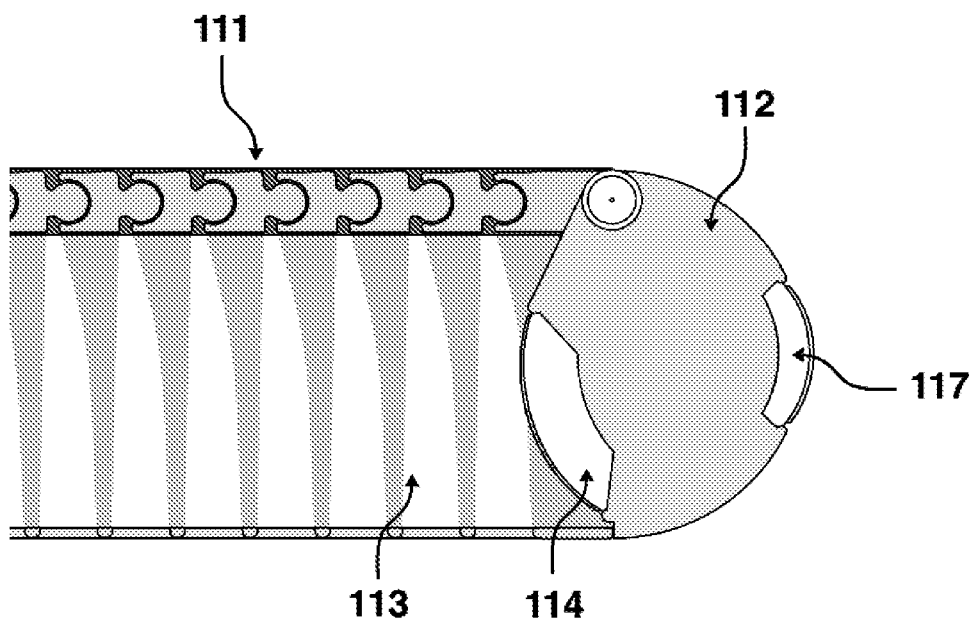


Fig. 4.5

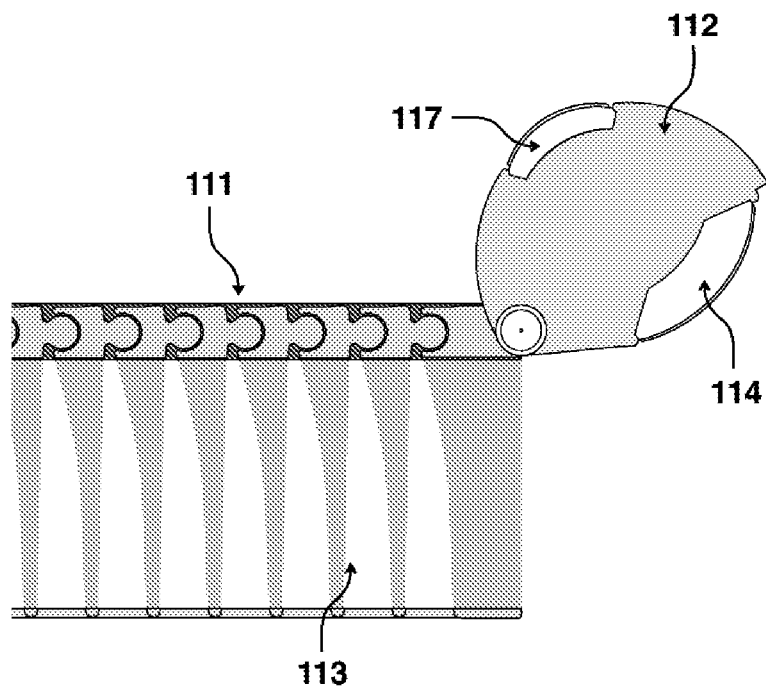


Fig. 4.6

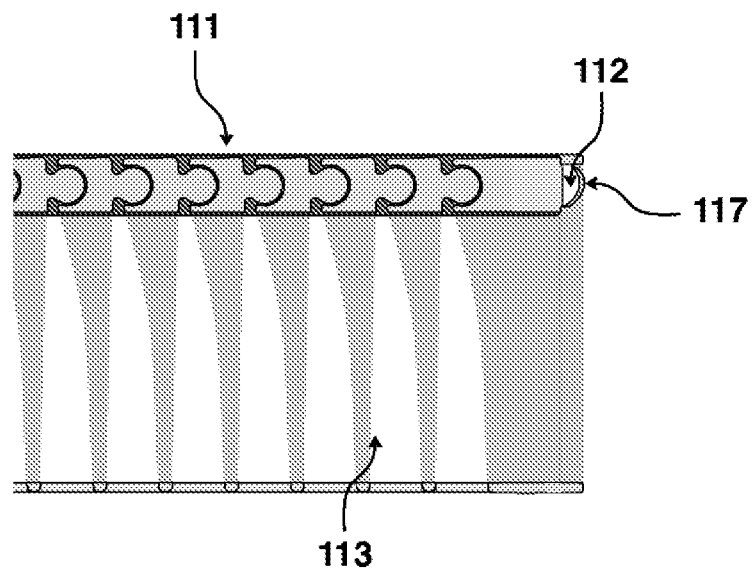


Fig. 4.7

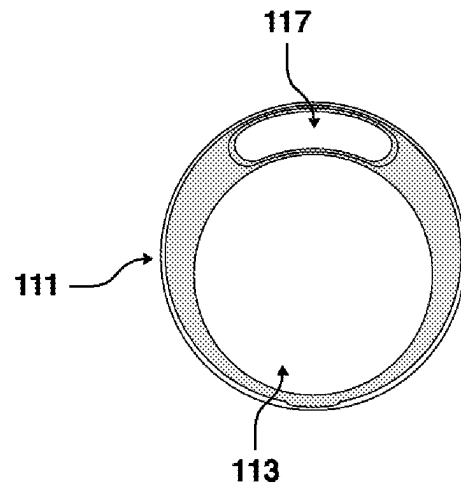


Fig. 4.8

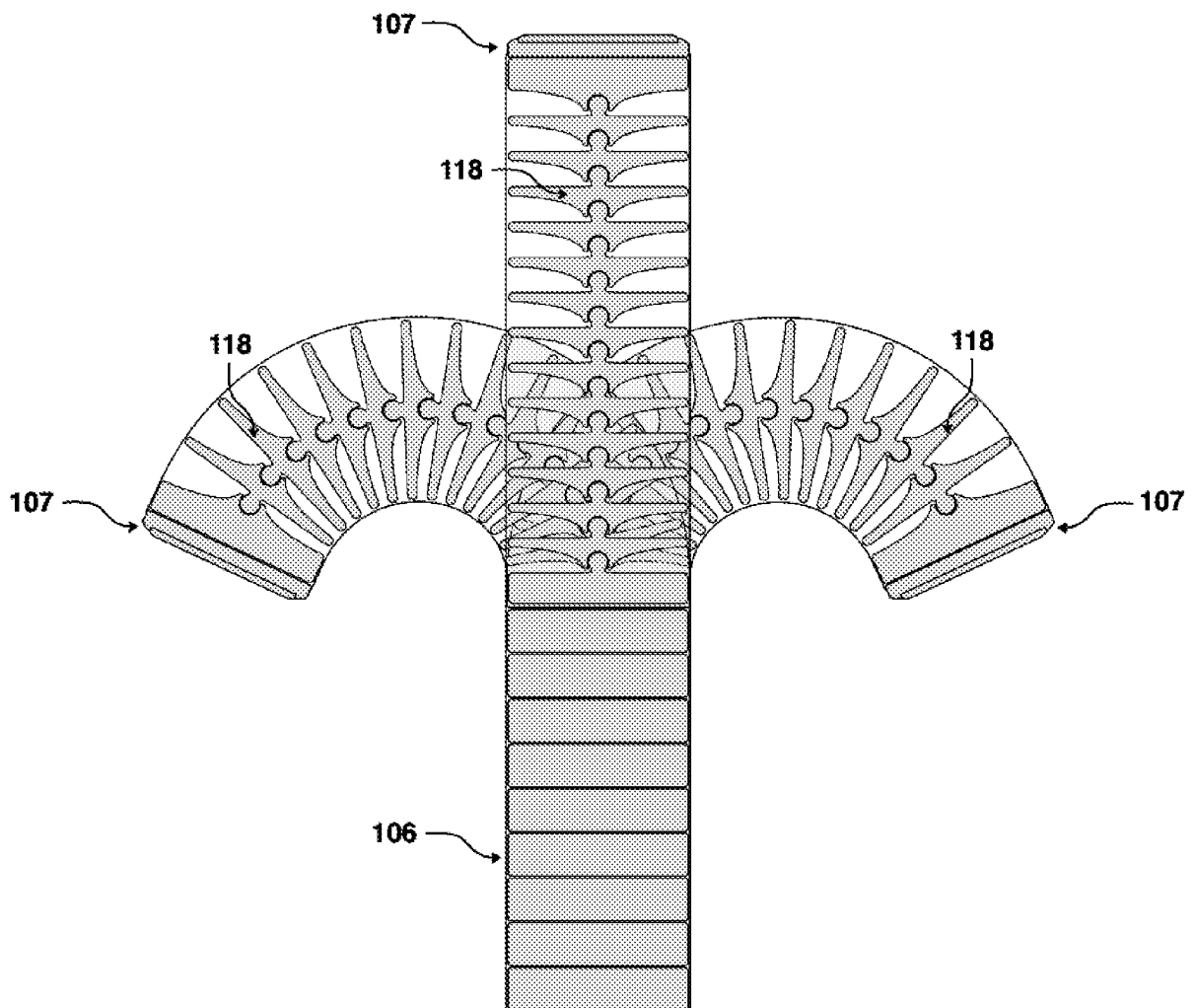


Fig. 5

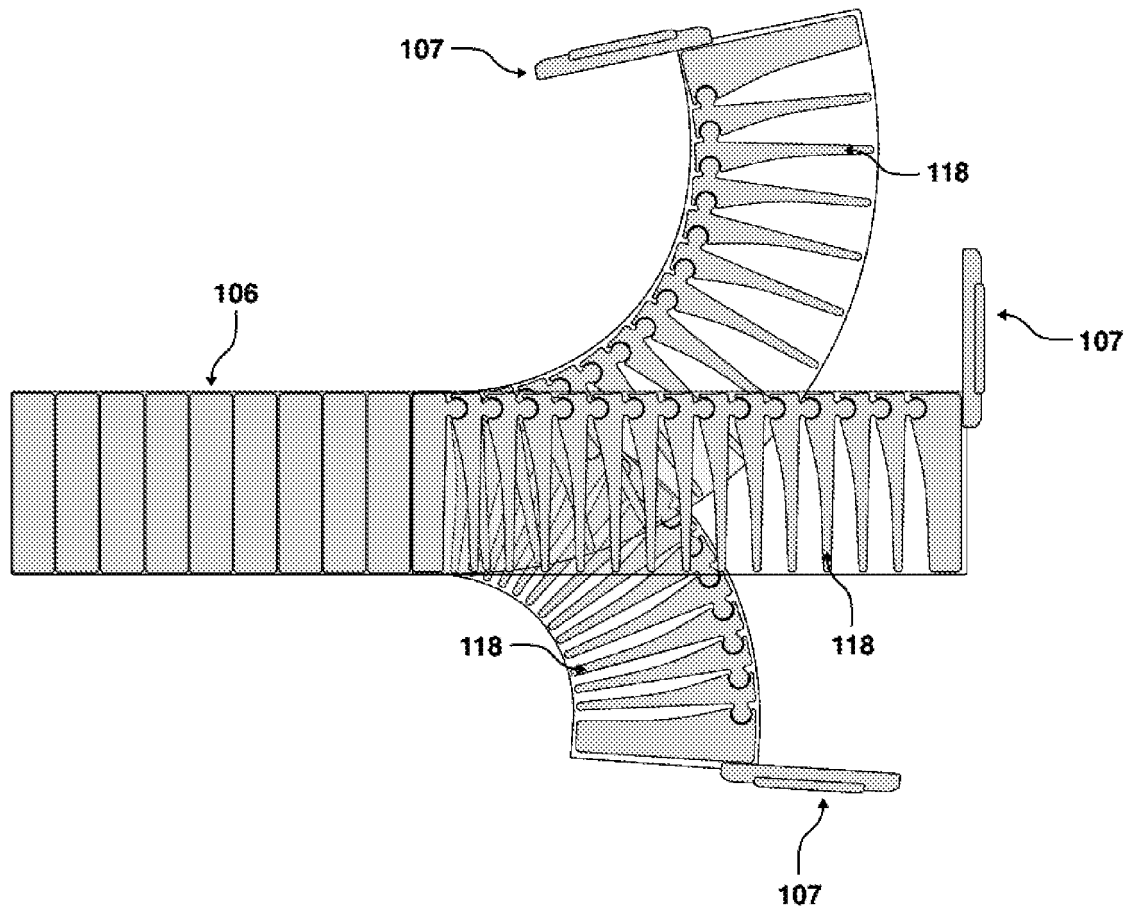


Fig. 6

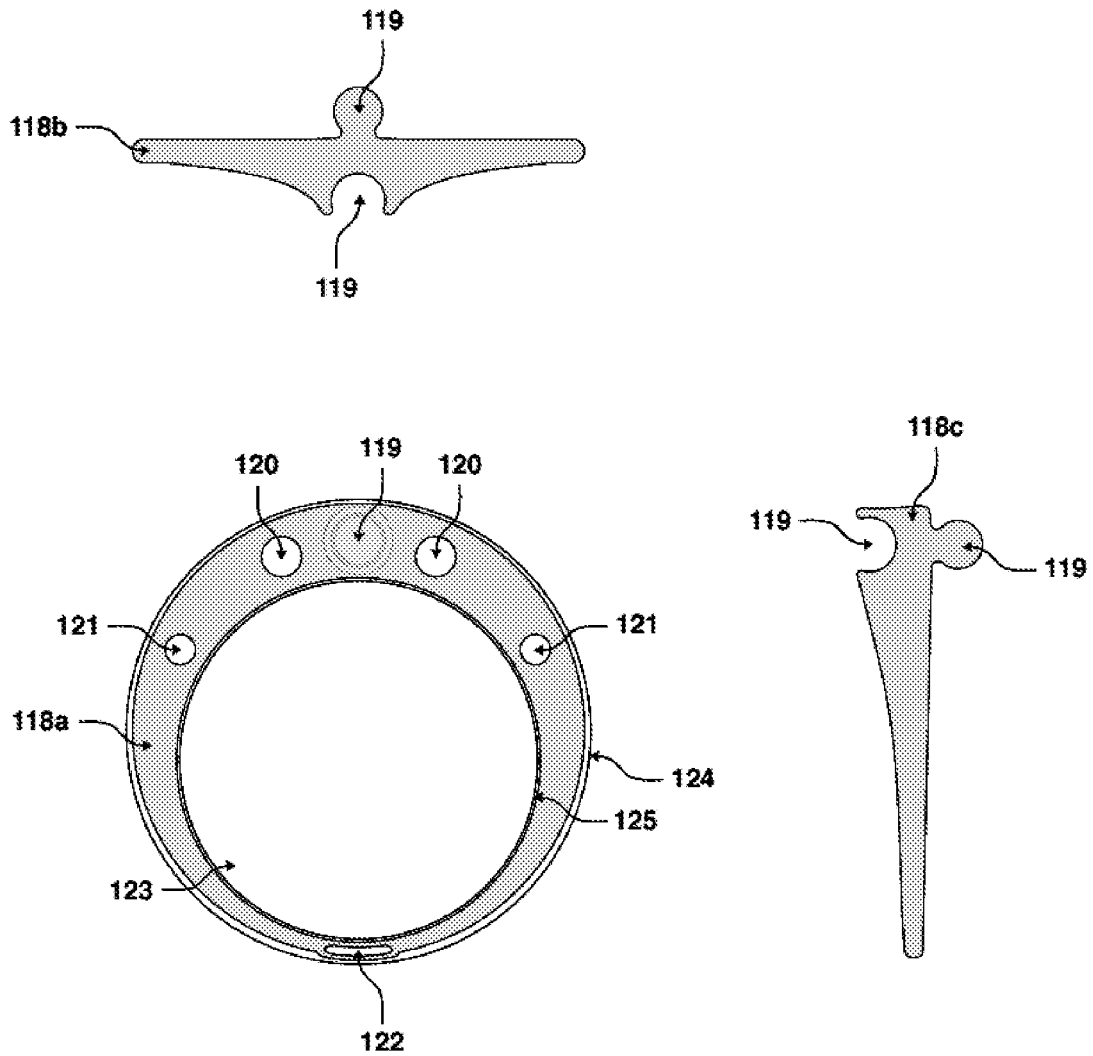


Fig. 7

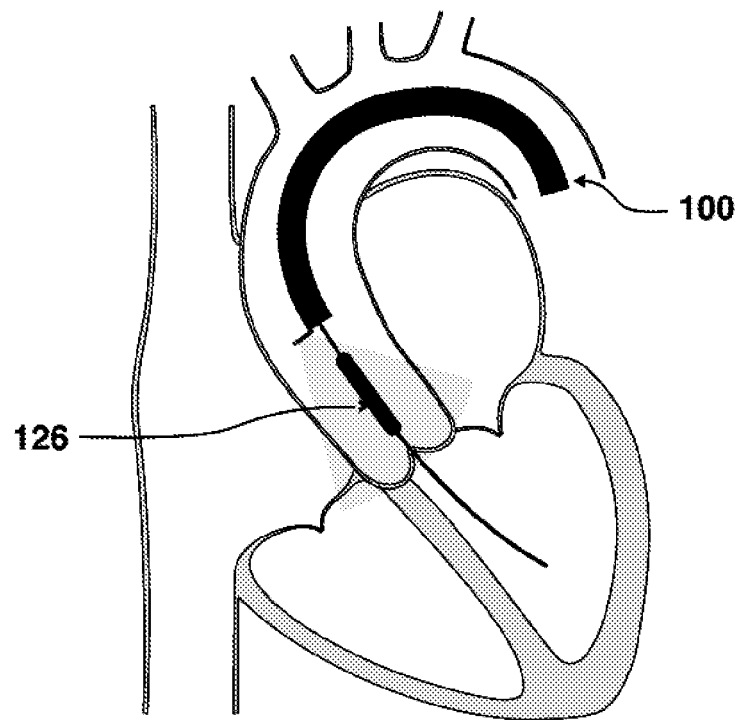


Fig. 8.1

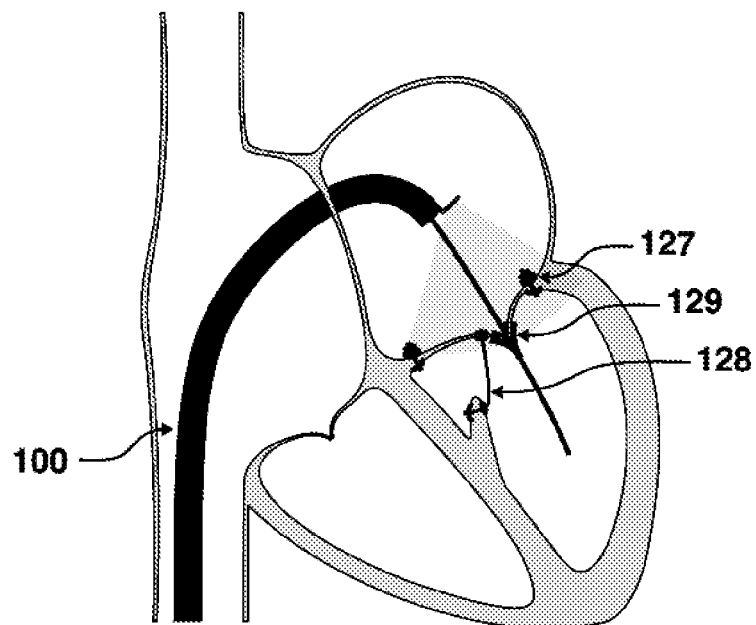


Fig. 8.2

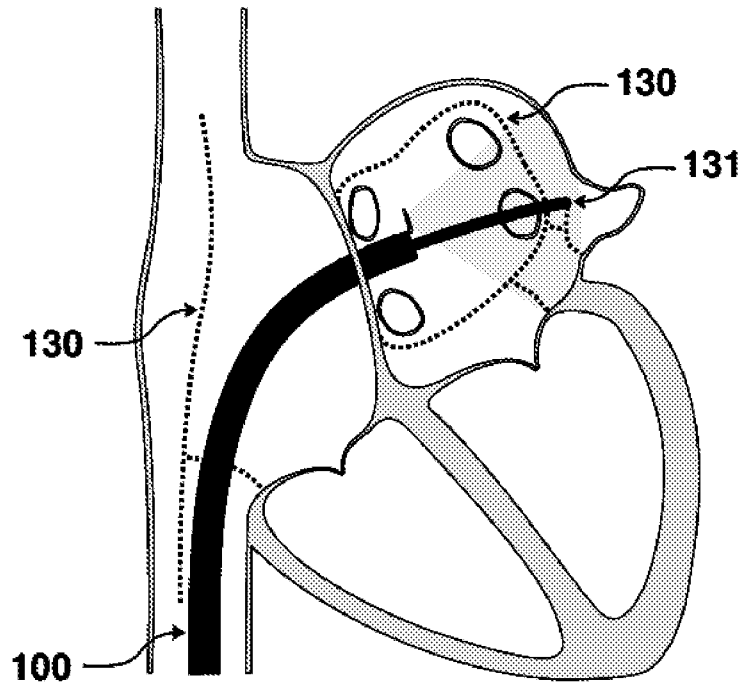


Fig. 8.3

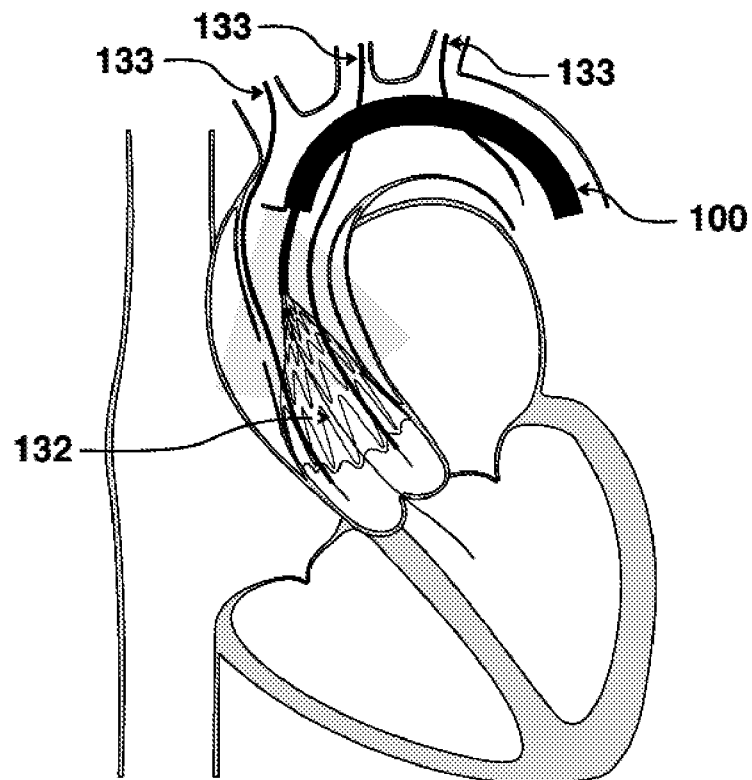


Fig. 8.4

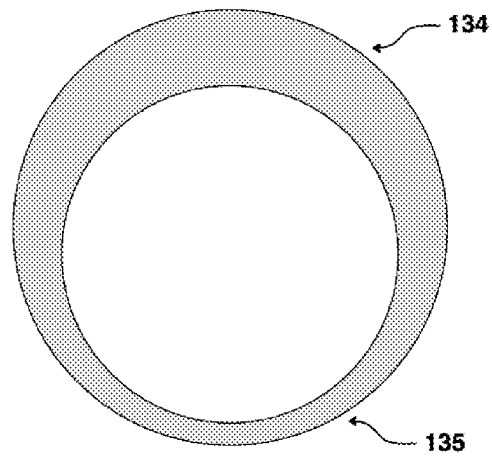


Fig. 9

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	用于心腔内和血管内外科手术的装置，具有腔内超声探头		
公开(公告)号	EP3282976B1	公开(公告)日	2019-05-15
申请号	EP2016723161	申请日	2016-04-13
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当前申请(专利权)人(译)	TEIXEIRA多斯桑托斯PAULO JORGE NELSON		
[标]发明人	TEIXEIRA DOS SANTOS PAULO NELSON JORGE		
发明人	TEIXEIRA DOS SANTOS PAULO, NELSON JORGE		
IPC分类号	A61B17/34 A61B8/12 A61B1/00 A61B90/00		
CPC分类号	A61B8/12 A61B17/3421 A61B17/3478 A61B90/37 A61B2017/00243 A61B2017/00292 A61B2017/00314 A61B2017/00323 A61B2017/00783 A61B2090/3782 A61B2090/3784 A61B1/00006 A61B1/015 A61B8/00 A61B17/00234 A61B1/00133 A61B1/00137 A61B1/0052 A61B1/0055 A61B1/008 A61B1/018 A61B1/3137 A61B8/445 A61B8/4494 A61B8/466 A61B8/467 A61B8/52 A61B2017/0034		
优先权	2015108357 2015-04-13 PT 2015108996 2015-11-30 PT		
其他公开文献	EP3282976A1		
外部链接	Espacenet		

摘要(译)

用于心腔内和血管内外科手术的装置，包括腔内超声导管探针，其包括柔性管，用于接收和引导导管装置或用于外科手术的器械的工作通道，以及三维超声换能器，其中柔性管在远端上具有工作通道出口，该工作通道出口限定环形表面，其中工作通道纵向轴线相对于柔性管纵向轴线偏心，从而限定所述环形表面的较宽部分和较窄部分。，其中超声换能器放置或耦合到较宽部分。一个实施例包括用于打开和关闭出口的舱门，舱门通过铰链连接到所述较宽部分，其中超声换能器放置在所述舱门处，并且舱门铰接以围绕平行于所述舱门的轴线旋转。柔性管的纵轴。

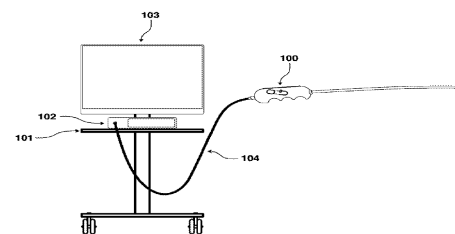


Fig. 1

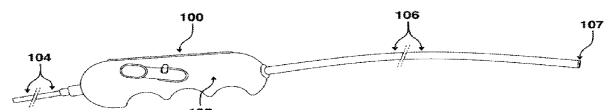


Fig. 2