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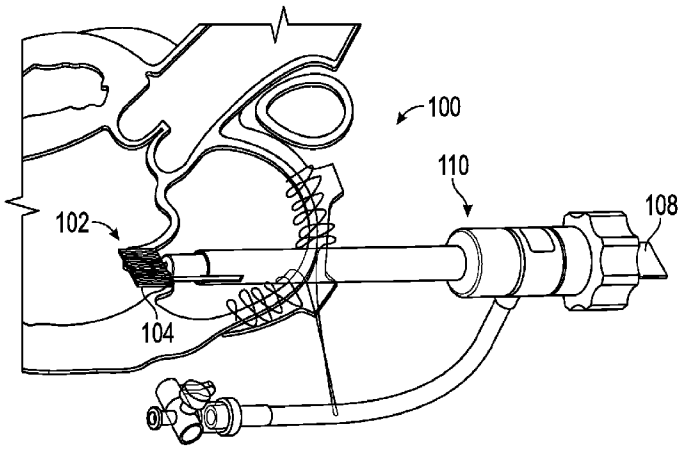

FIG. 1A

(57) Abstract: Disclosed herein are coaptation measurement devices and methods that enable measurement of coaptation forces between tissues.

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COAPTATION MEASUREMENT DEVICE AND METHODS OF USE THEREOF

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to U.S. Patent Application No. 62/796,269, filed January 24, 2019, the entire content of which is incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention relates generally to measuring, quantifying, and displaying the coaptation or closure force between at least two tissues in a patient.

BACKGROUND

[0003] Mitral regurgitation (MR) is a failure of the sealing function of mitral valve (MV) leaflets. MR occurs in roughly 2% of the US population and its incidence increases with age. Primary lesions are the most frequent mechanism of MR. In this etiology, MV repair (MVr) under cardiac arrest is the gold-standard treatment. The goal of MVr is to restore a proper contact between the two mitral leaflets (so called coaptation phenomena) in order to ensure the sealing function and to decrease global valvular stress.

[0004] Currently, there are limited methods for intraoperative (e.g. on an empty and stopped heart) assessment of the quality of the MVr. One current technique includes inflating the left ventricle with saline liquid (a “saline test”) to mimic ventricular systole resulting in the closing of the mitral leaflets. The saline test is also used to subjectively and globally assess coaptation function. Another test includes “painting” the appearing surface of mitral leaflets (atrial surface) during the saline test. Thus, when the ventricular content is subsequently sucked, the coaptation surface is the only valvular part appearing without ink. This “ink test” provides an approximate assessment of the height of coaptation. However, both of these tests are subjective and approximate and therefore rely on the expertise of the surgeon. Therefore, MVr success rates and outcomes mainly rely on surgical expertise and the consequences of MVr failure strongly impact survival.

[0005] Currently, the only definitive assessment of MVr is obtained after closure of the heart cavities and after withdrawal of the cardiopulmonary bypass. An intraoperative transesophageal echocardiography is systematically performed to assess the MVr results (e.g., the quality of the valvular sealing function and morphological description of leaflet morphology). Echocardiography allows a two-dimensional morphological assessment of the coaptation in the cut plane of ultrasound but it is unable to show the global render of the coaptation surface, as well as the coaptation forces. In the case of obvious immediate failure of MVr, additional repair techniques could be performed but sometimes the valve needs to be replaced. Additionally, even with a good intraoperative echocardiographic result, early failure of MVr can happen.

[0006] Accordingly, there is a need for a device allowing real-time MVr intraoperative objective assessment to increase repair rate and repair success rate.

BRIEF SUMMARY

[0007] The disclosure provides for systems and methods for measuring a coaptation force of a heart valve in a patient. The system may include a coaptation measurement device, a deployment apparatus for deploying and retrieving the coaptation measurement device within the heart valve, and/or a computing system for generating a two-dimensional (2D) map of the coaptation force.

[0008] The coaptation measurement device may have a sensor body with an array of sensors on a flexible substrate configured to measure a plurality of pressures along a contact surface between two leaflets of the heart valve. The plurality of pressures provides a measurement of the coaptation force of the two leaflets.

[0009] The deployment apparatus may include an internal body and an external sheath. The internal body may have a first body portion and a second body portion, where a portion of the coaptation measurement device is configured to be placed between the first body portion and the second body portion. The external sheath may have two slots on the distal end of the external sheath. In an aspect, the external sheath is configured to rotatably surround at least a portion of the internal body.

[0010] Further provided herein is a method of measuring a coaptation force of two tissues in a patient. In an aspect, the method may include inserting a coaptation

measurement device between the two tissues and measuring, with the array of sensors, a plurality of pressures along a contact surface between the two tissues, such that the plurality of pressures provides a measurement of the coaptation force of the two tissues.

[0011] Also provided herein is a method of deploying a coaptation measurement device within a deployment apparatus. In an aspect, the method may include loading at least a portion of the coaptation measurement device into the deployment apparatus, so that the sensor body extends from a distal end of the deployment apparatus, placing a portion of the coaptation measurement device into a patient, and placing the sensor body of the coaptation measurement device along a contact surface between two tissues to be measured for coaptation.

[0012] The disclosure further provides a method of removing a deployment apparatus from a patient. In an aspect, the method includes removing a sensor body of a coaptation measurement device from between two tissues to be measured for coaptation. In an aspect, the method further includes pulling, towards a proximal end of the deployment apparatus, a portion of the coaptation measurement device between a first body portion and a second body portion of an internal body of the deployment apparatus. In another aspect, the method further includes pushing, towards a distal end of the deployment apparatus, an external sheath surrounding the internal body, aligning two slots of the external sheath with the sensor body of the coaptation measurement device so that the sensor body is within the two slots, and rotating the internal body such that the sensor body is rolled within the external sheath.

[0013] Additional aspects and features are set forth in part in the description that follows, and will become apparent to those skilled in the art upon examination of the specification or may be learned by the practice of the disclosed subject matter. A further understanding of the nature and advantages of the disclosure may be realized by reference to the remaining portions of the specification and the drawings, which forms a part of this disclosure.

DESCRIPTION OF THE DRAWINGS

[0014] The description will be more fully understood with reference to the following figures, which are presented as variations of the disclosure and should not be construed as a complete recitation of the scope of the disclosure, wherein:

[0015] FIG. 1A shows the coaptation measurement system within a heart in one embodiment.

[0016] FIG. 1B shows the coaptation measurement system within a heart and connected to the computing system with an acquisition system in one embodiment.

[0017] FIG. 2A shows the coaptation measurement device in one embodiment.

[0018] FIG. 2B shows the coaptation measurement device in one embodiment.

[0019] FIG. 2C shows the coaptation measurement device in one embodiment.

[0020] FIG. 2D shows a portion of the coaptation measurement device in one embodiment.

[0021] FIG. 2E shows a portion of the coaptation measurement device in one embodiment.

[0022] FIG. 3 shows a sample 2D map from the coaptation measurement device in one embodiment.

[0023] FIG. 4A shows a perspective view of the internal body in one embodiment.

[0024] FIG. 4B shows a perspective view of a body portion of the internal body in one embodiment.

[0025] FIG. 4C shows a body portion of the internal body in one embodiment.

[0026] FIG. 5A shows an exploded view of both body portions of the internal body with the coaptation measurement device between the body portions in one embodiment.

[0027] FIG. 5B shows the internal body with the coaptation measurement device between the body portions in one embodiment.

[0028] FIG. 6 shows a body portion of the internal body with magnets and wire in one embodiment.

[0029] FIG. 7A shows the external sheath in one embodiment.

[0030] FIG. 7B shows the external sheath in one embodiment.

[0031] FIG. 8A shows the external sheath surrounding the internal body with the coaptation measurement device in one embodiment.

[0032] FIG. 8B shows the external sheath surrounding the internal body with the coaptation measurement device in one embodiment.

[0033] FIG. 9A shows the coaptation measurement system in the mitral valve.

[0034] FIG. 9B shows the proximal end of the coaptation measurement device being pulled proximally to remove the sensor from the mitral valve.

[0035] FIG. 9C shows the proximal end of the external sheath being pushed distally.

[0036] FIG. 9D shows the internal body being rotated and the sensor body being rolled within the external sheath.

[0037] FIG. 10 shows a method of inserting and removing the coaptation measurement system in one embodiment.

[0038] FIG. 11 shows an example computing system.

DETAILED DESCRIPTION

[0039] The coaptation measurement device and method of use will be understood, both as to its structure and operation, from the accompanying drawings, taken in conjunction with the accompanying description. It is noted that, for purposes of illustrative clarity, certain elements in various drawings may not be drawn to scale. Several variations of the device are presented herein. It should be understood that various components, parts, and features of the different variations may be combined together and/or interchanged with one another, all of which are within the scope of the present application, even though not all variations and particular variations are shown in the drawings. It should also be understood that the mixing and matching of features, elements, and/or functions between various variations is expressly contemplated herein so that one of ordinary skill in the art would appreciate from this disclosure that the features, elements, and/or functions of one variation may be incorporated into another variation as appropriate, unless described otherwise.

[0040] For purposes of this description, “distal” refers to the end extending into a body and “proximal” refers to the end extending out of the body.

[0041] For purposes of this description, "connected to" includes two components being directly connected or indirectly connected with intervening components.

[0042] For purposes of this description, "coaptation" includes the closing or drawing together of separated tissue. Coaptation may occur in a wound, fracture, or in a functioning tissue such as valves in the heart. In a physiologic state during the systole the two mitral leaflets encounter each other in a meeting zone (the coaptation phenomena) ensuring proper sealing. Proper coaptation prevents blood regurgitation from left ventricle to the left atrium. In tri-leaflet valves (aortic and tricuspid valve), the sealing of the valve is ensured by the proper configuration of all leaflets. However, in the tri-leaflet valves, the coaptation still occurs between two leaflets aside from the very center of the valve where the coaptation may occur between the three leaflets.

[0043] A "coaptation force" includes the pressure or closure force between the two tissues when the tissues are closed together. For example, the coaptation force may be measured along the contact surface between the two tissues.

[0044] For the purposes of this description, "contact surface" includes a two-dimensional surface between two tissues created when the two tissues are in contact with each other. The contact surface may have a length and a width. Since the shape of the mitral valve is complex and not flat, in some examples the contact surface may take a 3D shape.

[0045] Disclosed herein is a coaptation measurement system and methods of use thereof that enables the measurement of coaptation or closure forces along an entire contact surface between at least two tissues. In an example, the coaptation measurement system may include a coaptation measurement device and a deployment apparatus. In some examples, the coaptation measurement system further includes a computing system. In addition, the coaptation measurement device enables measurement of the coaptation force *in vivo* and allows real-time assessment of the success of surgical repair to at least one of the tissues. In a non-limiting example, the tissue may be valvular tissue within the heart. The coaptation measurement system also facilitates the two-dimensional (2D), three-dimensional (3D) mapping, or four-dimensional (4D) mapping of the coaptation force for precise identification and visualization of the coaptation forces along the contact surface between the tissues.

[0046] The coaptation measurement system **100** is used to objectively measure the coaptation force between two tissues in a patient's body. For example, the two tissues may be within the patient's heart. Non-limiting examples of tissues include valvular tissues such as leaflets of a mitral valve, an aortic valve, or tricuspid valve. The coaptation measurement system **100** may be used intraoperatively to provide an objective measurement of the coaptation force between the two tissues after repair to at least one tissue. For example, prior methods of assessing mitral valve repair were subjective or only provided high level information regarding inadequate coaptation. These assessment levels are not quantitative and do not provide localized information as to where a correction may need to occur. The objective measurement of the coaptation force provides detailed intraoperative information to the surgeon to determine whether the repair was sufficient, whether further adjustments are needed prior to completion of the surgery, and where the repair insufficiencies are located.

[0047] **FIG. 1A** depicts a coaptation measurement system **100** in one embodiment. In various embodiments, the coaptation measurement system **100** includes a coaptation measurement device **102** and a deployment apparatus **110**. **FIG. 1B** depicts a coaptation measurement system **100** in another embodiment, which includes a coaptation measurement device **102**, a deployment apparatus **110**, and a computing system **200**. It will be appreciated that the coaptation measurement system **100** and/or coaptation measurement device **102** overcomes one or more of the above-listed problems commonly associated with conventional means for observing and evaluating valve closure.

[0048] As seen in **FIG. 1A**, the coaptation measurement system **100** includes the coaptation measurement device **102** within the deployment apparatus **110** for insertion and removal of the coaptation measurement device from between two tissues in the body of a patient. In some examples, the coaptation measurement system **100** may be inserted into the heart of the patient. In various examples, the coaptation measurement system **100** may be inserted into a heart that is under cardiopulmonary bypass. In another embodiment, the coaptation measurement system **100** may be inserted into the heart through percutaneous surgery, without cardiopulmonary bypass. In some examples, the heart is currently undergoing or has recently undergone surgery to repair

at least one tissue in the heart. For example, **FIG. 1A** shows the coaptation measurement system **100** placed between atrioventricular valves in the heart during surgery post surgical repair of at least one of the atrioventricular valves, after closure of the atrium. In this example, the coaptation measurement device **102** is placed between the leaflets of the mitral valve and the heart is sutured around the deployment apparatus **110**. The various aspects of the coaptation measurement system **100**, including the coaptation measurement device **102** and the deployment apparatus **110**, are waterproof and biocompatible for use in surgery, such as open heart surgery.

I. Coaptation Measurement Device

[0049] Referring again to **FIG. 1A**, the coaptation measurement system **100** may include a coaptation measurement device **102** for measuring a coaptation force of two tissues in a patient. As seen in **FIG. 1A** and **FIGS. 2A-2E**, the coaptation measurement device **102** may include a sensor body **104**, an intermediate portion **106**, and a sensor output portion **108**.

[0050] The sensor body **104** may include a flexible substrate **107** and an array of sensors **105** on the flexible substrate configured to measure a plurality of pressures along a contact surface between the two tissues. The plurality of pressures may then provide a measurement of the coaptation force of the two tissues.

[0051] The sensor body **104** has a size capable of being placed within a valve of a patient. For example, the sensor body **104** may have a width **W1** of about 15 mm to about 35 mm. In an embodiment, the sensor body has a width of at least about 15 mm. In an embodiment, the sensor body has a width of at least about 20 mm. In an embodiment, the sensor body has a width of at least about 25 mm. In an embodiment, the sensor body has a width of less than about 30 mm. In one embodiment, the sensor body **104** has a width **W1** of about 20 mm. In another embodiment, the sensor body **104** has a width **W1** of about 22 mm. The sensor body **104** may have a length **L1** of about 5 mm to about to about 25 mm. In an embodiment, the sensor body has a length of at least about 5 mm. In an embodiment, the sensor body has a length of at least about 10 mm. In an embodiment, the sensor body has a length of at least about 15 mm. In an embodiment, the sensor body has a length of at least about 20 mm. In an embodiment,

the sensor body has a length of less than about 25 mm. In one embodiment, the sensor body **104** has a length **L1** of about 8.5 mm. In another embodiment, the sensor body **104** has a length **L1** of about 23 mm. The sensor body **104** may have a thickness such that it does not significantly impede with the closure of the two tissues. In an embodiment, the sensor body **104** may have a thickness of 125 µm or less. For example, the sensor body **104** may have a thickness of about 5 µm to about 125 µm.

[0052] The sensor body **104** includes a flexible substrate **107**. The flexible substrate **107** provides support for the array of sensors **105** arranged on the surface of the flexible substrate **107**. In general, the dimensions of the sensor body correlate to the dimensions of the flexible substrate. The flexible substrate may be made of a material that is thin enough to be placed between two tissues and flexible enough such that it is capable of being rolled.

[0053] The sensor body **102** includes an array of sensors **105** arranged on the surface of the flexible substrate **107**. In an embodiment the array of sensors is an array of pressure sensors. Non-limiting examples of pressure sensors include resistive, piezoresistive, capacitive, electromagnetic, piezoelectric, optical, or potentiometric pressure sensors. The array of sensors is configured to detect a minimum pressure of 2gF. In an embodiment, the array of sensors measures forces, such as pressure of at least about 2 gF. In an embodiment, the array of sensors measures pressures of less than about 5 gF. In an embodiment, the array of sensors measures pressures of less than about 10 gF.

[0054] The array of sensors may be arranged on the flexible substrate in at least 1, at least 2, at least 3, at least 4, or at least 5 rows across the width of the sensor body. In various embodiments, the array of sensors **105** may include at least 5 sensors, at least 8 sensors, at least 10 sensors, at least 15 sensors, at least 20 sensors, at least 25 sensors, at least 28 sensors, at least 30 sensors, at least 40 sensors, or at least 50 sensors. In one embodiment, as seen in **FIG. 2B**, the array of sensors may include at least 10 sensors arranged in 1 row across the width of the sensor body. In another embodiment, as seen in **FIG. 2C**, the array of sensors may include at least 30 sensors arranged in 3 rows across the width of the sensor body.

[0055] Each sensor in the array of sensors **105** may have a length **L2** of about 0.5 mm to about to about 10 mm. In an embodiment, each sensor may have a length of at least about 0.5 mm. In an embodiment, each sensor may have a length of at least about 1 mm. In an embodiment, each sensor may have a length of at least about 2 mm. In an embodiment, each sensor may have a length of at least about 4 mm. In an embodiment, each sensor may have a length of at least about 5 mm. In an embodiment, each sensor may have a length of at least about 8 mm. In an embodiment, each sensor may have a length of less than about 5 mm. In one embodiment, each sensor of the array of sensors **105** has a length **L2** of about 5 mm. Each sensor in the array of sensors **105** may have a width **W2** of about 0.5 mm to about 3 mm. In an embodiment, each sensor may have a width of at least about 0.5 mm. In an embodiment, each sensor may have a width of at least about 1 mm. In an embodiment, each sensor may have a width of at least about 2 mm. In an embodiment, each sensor may have a width of less than about 3 mm. In one embodiment, each sensor of the array of sensors **105** has a width **W2** of less than about 1 mm. In some examples,

[0056] The coaptation measurement device **102** may further include an intermediate portion **106** for transmitting the signals received by the array of sensors **105** to a sensor output portion **108**. In some embodiments, the intermediate portion **106** may extend a length **L3** from the proximal end of the sensor body **102** to the sensor output portion **108**. In some embodiments, the intermediate portion may have a length at least as long as the internal body and/or the external sheath described herein below. In other embodiments, the coaptation measurement device **102** may not include an intermediate portion. In some embodiments, the intermediate portion **106** has a length **L3** of about 100 mm to about 200 mm. In an embodiment, the intermediate portion has a length of at least about 100 mm. In an embodiment, the intermediate portion **106** has a length of at least about 150 mm. In an embodiment, the intermediate portion has a length of at least about 175 mm. In an embodiment, the intermediate portion has a length of less than about 200 mm. In one embodiment, the intermediate portion **106** has a length **L3** of about 152 mm. In another embodiment, the intermediate portion has a length of about 153 mm. In an embodiment, the intermediate portion **106** may have a thickness of 125

μm or less. For example, the intermediate portion **106** may have a thickness of about 5 μm to about 125 μm.

[0057] The coaptation measurement device **102** may further include a sensor output portion **108** for outputting the signals received by the array of sensors **105**. The sensor output portion **108** may connect to a computing system through any means capable of receiving an electrical signal. In an embodiment, the sensor output portion may connect to the computing system through a printed circuit board with a zero insertion force (ZIF) connector. In other aspects, the sensor output portion may include a wireless transceiver to transmit the signals wirelessly to the computing system. For example, the sensor output portion may include a Bluetooth transceiver.

II. Computing System

[0058] As seen in **FIG. 1B**, the coaptation measurement system **100** may further include a computing system. **FIG. 11** shows an example of computing system **200** in which the components of the system are in communication with each other using connection **205**. Connection **205** can be a physical connection via a bus, or a direct connection into processor **210**, such as in a chipset or system-on-chip architecture. Connection **205** can also be a virtual connection, networked connection, or logical connection.

[0059] In some examples, one or more of the described system components represents many such components each performing some or all of the function for which the component is described. In some examples, the components can be physical or virtual devices.

[0060] Example computing system 400 includes at least one processing unit (CPU or processor) **210** and connection **205** that couples various system components including system memory **215**, read only memory (ROM) **220** or random access memory (RAM) **225** to processor **210**. Computing system **200** can include a cache of high-speed memory **212** connected directly with, in close proximity to, or integrated as part of processor **210**.

[0061] Processor **210** can include any general purpose processor and a hardware service or software service, such as an acquisition system **232** and data post-

processing system **234** stored in storage device **230**, configured to control processor **210** as well as a special-purpose processor where software instructions are incorporated into the actual processor design. Processor **210** may essentially be a completely self-contained computing system, containing multiple cores or processors, a bus, memory controller, cache, etc. A multi-core processor may be symmetric or asymmetric.

[0062] To enable user interaction, computing system **200** includes an input device **245**, which can represent any number of input mechanisms, such as a touch-sensitive screen for gesture or graphical input, keyboard, mouse, or input from the sensor output portion **108**. The input device **245** may be wired or wireless. Computing system **200** can also include output device **235**, which can be one or more of a number of output mechanisms known to those of skill in the art. For example, the output device **235** may be a display. In some instances, multimodal systems can enable a user to provide multiple types of input/output to communicate with computing system **200**. There is no restriction on operating on any particular hardware arrangement and therefore the basic features here may easily be substituted for improved hardware or firmware arrangements as they are developed.

[0063] Storage device **230** can be a non-volatile memory device and can be a hard disk or other types of computer readable media which can store data that are accessible by a computer, such as magnetic cassettes, flash memory cards, solid state memory devices, digital versatile disks, cartridges, battery backed random access memories (RAMs), read only memory (ROM), and/or some combination of these devices.

[0064] The storage device **230** can include software services, servers, services, etc., that when the code that defines such software is executed by the processor **210**, it causes the system to perform a function. In some examples, a hardware service that performs a particular function can include the software component stored in a computer-readable medium in connection with the necessary hardware components, such as processor **210**, connection **205**, output device **235**, etc., to carry out the function. In some examples, the storage device **230** includes an acquisition system **232** and a data post-processing system **234**.

[0065] The acquisition system **232** may include instructions to cause the processor **210** to receive the plurality of pressures from the array of sensors **105**. The acquisition system may have an acquisition speed of at least 16Hz. In an embodiment, the acquisition system may have an acquisition speed of at least 18Hz. In an embodiment, the acquisition system may have an acquisition speed of at least 20Hz.

[0066] The data post processing system **234** may include instructions to cause the processor **210** to process the pressures acquired from the acquisition system **232**. The data post-processing system **434** may further generate a mapping of the coaptation force along the contact surface between the two tissues. In one embodiment, the data post-processing system may generate a 2D map of the coaptation force. In some examples, a 3D contact surface may be used to generate a 3D mapping of the coaptation. In other examples a "continuous, real time" dimension may be integrated with the 3D mapping to generate a 4D mapping of the coaptation.

[0067] The generated mapping of the coaptation force from the data post-processing system **234** may be output to the output device **235**, such as a display. **FIG. 3** is an example display of a 2D mapping generated from the acquisition system and the data post-processing system. The visual display may be used by the physician to easily identify where the pressure at a point or area on the contact surface may be problematic. For example, the mapping allows the physician to assess the entire contact surface, allowing identification of abnormal coaptation or zones of coaptation. In some aspects, the physician may correct an aspect of the surgical repair based on the information in the visual display. In some embodiments, the visual display may be a table, a graph, or a two-dimensional (2D) map of the plurality of pressures measured from the array of sensors. In various embodiments, the 2D map may be color coded to indicate pressure values.

III. Deployment Apparatus

[0068] The coaptation measurement system **100** may further include a deployment apparatus **110** for deploying and retrieving the coaptation measurement device **102** between two tissues in a patient. In various embodiments, the deployment apparatus

110 may include an internal body **112** and an external sheath **120** that surrounds the internal body **112**.

[0069] The internal body **112** has a proximal end and a distal end. In various embodiments, the internal body **112** may include a first body portion and a second body portion, each **111**, which are combined to form the internal body **112**. A portion of the coaptation measurement device **102** is configured to be placed between the first body portion and the second body portion of the internal body, as seen in **FIGS. 1A, 1B, 5A, 5B, 6B, 8A, and 8B**.

[0070] The internal body **112** may have a cylindrical shape. The first body portion and the second body portion **111** may have a half cylindrical shape. In an embodiment, a cylindrical mandrin, catheter, or cannula may be split in half to form the first body portion and the second body portion. The first and second body portions may be hollow or solid.

[0071] The first body portion and the second body portion **111** may be connected together after the intermediate portion **106** has been placed between the two body portions. The first and second body portions **111** may be connected through any means capable of securing the two portions together. In an embodiment, the first body portion and the second body portion **111** are connected using at least one magnet **118**. In an embodiment, each of the body portions includes at least two magnets **118**, as seen in **FIG. 6**. In other embodiments, each of the body portions may include at least three magnets **118**. In various embodiments, each of the body portions may include a magnet near the distal end, middle, and/or proximal end of the body portion. For example, each body portion may include two magnets at the proximal end of the body portion. In an embodiment, the magnets **118** are positioned on each side of the intermediate portion **106** such that, for example, there are no interferences by the magnets **118** with the sensors **105** or sensor body **104**. The magnets **118** on the body portions align such that the magnets secure the connection between the body portions to form the internal body **112**. In some examples, the magnets are of a strength such that the coaptation measurement device can be pulled between the first body portion and the second body portion while maintaining the connection between the first body portion and the second body portion. For example, when the coaptation measurement device is ready to be removed from the patient, the physician may pull on the intermediate portion or the

sensor output portion to withdraw the sensor body partially or completely between the distal end of the internal body. In other embodiments, the first and second body portions **111** may be connected through a clasp or connector at the distal end of the body portions.

[0072] In some embodiments, the first body portion and the second body portion **111** may be connected through a handle **114** of the internal body 112. The handle **114** may include two ring portions that may be connected together to form the handle **114** of the internal body **112**. In an embodiment, the first ring portion and the second ring portion surround the internal body **112** and secure the first and second body portions **111**. In another embodiment, the first ring portion and second ring portion are integral to the first and second body portions, as seen in **FIGS. 4A-4C**. The each ring portion of the handle **114** may include at least one protrusion on a first ring portion and at least one recession for receiving the at least one protrusion on a second ring portion, in one embodiment. In other embodiments, the first and second ring portions may be connected through at least one magnet. For example, each ring portion may include two magnets **118**, as seen in **FIG. 6**. The handle **114** may provide for a location to hold and/or move the internal body **112**. For example, the handle **114** may have a diameter greater than the rest of the internal body **112**. In some examples, the handle **114** may have recessions or indentations for easily gripping the handle **114**.

[0073] The internal body **112** is made of a flexible material such that it may be navigable through a surgical opening in the heart. For example, the internal body **112** may be conformable for placement inside the heart cavity. The internal body **112** may further include a shape memory mechanism **119**. In an embodiment, the shape memory mechanism **119** is a wire extending from the proximal end to the distal end of at least one body portion **111** of the internal body **112**, as seen in **FIG. 6**. For example, the wire may be a rigid but conformable wire. In some embodiments, the internal body **112** is Doppler opaque to allow visualization of the internal body **112** and the deployment apparatus **110** during insertion and removal of the coaptation measurement device **102**.

[0074] In some embodiments, the distal end of the internal body **112** is narrower than the proximal end of the internal body. For example, the internal body **112** may include a taper **113** to the distal part **115** of the internal body. As seen in **FIG. 4C**, each of the first

and second body portions **111** may include the taper **113** to the narrower distal part **115**.

[0075] In various embodiments, the internal body **112** may have a diameter of about 2 mm to about 15 mm. In an embodiment, the internal body may have a diameter of at least about 2 mm. In an embodiment, the internal body may have a diameter of at least about 3 mm. In an embodiment, the internal body may have a diameter of at least about 5 mm. In an embodiment, the internal body may have a diameter of at least about 7 mm. In an embodiment, the internal body may have a diameter of at least about 10 mm. In an embodiment, the internal body may have a diameter of less than about 15 mm. In one embodiment, the internal body may have a diameter of about 3.3 mm. In another embodiment, the internal body may have a diameter of about 6.9 mm. The internal body **112** may have a length that is at least as long as the intermediate portion **106**. In various embodiments, the internal body may have a length of about 100 mm to about 200 mm. In an embodiment, the internal body may have a length of at least 100 mm. In an embodiment, the internal body may have a length of at least 140 mm. In an embodiment, the internal body may have a length of less than 200 mm. In one embodiment, the internal body may have a length of about 142.5 mm. In another embodiment, the internal body may have a length of about 140 mm.

[0076] The deployment apparatus further includes an external sheath **120** configured to be rotatable and surround at least a portion of the internal body **112**. The external sheath **120** has a proximal end and a distal end.

[0077] As seen in **FIGS. 7A and 7B**, the external sheath **120** may include two slots **122** on the distal end of the external sheath **120**. In use, the sensor body **104** may fully extend past the distal end of the external sheath **120**, the sensor body **104** may pass through the two slots **122**, or the sensor body **104** may be rolled up within the external sheath **120**.

[0078] The two slots **122** may have a length at least as long as the length of a sensor body **104** of the coaptation measurement device **102**. Accordingly, the sensor body **104** may be fully received through the slots **112** and rolled up into the external sheath **120**. In another embodiment, the two slots **122** may have a length less than the length of the sensor body **104**. In various embodiments, the two slots **122** have a length of about 5

mm to about to about 25 mm. In an embodiment, the two slots have a length of at least about 5 mm. In an embodiment, the two slots have a length of at least about 10 mm. In an embodiment, the two slots have a length of at least about 15 mm. In an embodiment, the two slots have a length of at least about 20 mm. In an embodiment, the two slots have a length of less than about 25 mm.

[0079] The external sheath may further include a lateral tube **124** fluidly connected to the inside of the external sheath for rinsing or flushing the external sheath.

[0080] The external sheath is flexible and takes the shape of the internal body. The external sheath may also be Doppler opaque, allowing for navigation of the deployment apparatus under echographical view.

[0081] The external sheath **120** has a cylindrical shape. The external sheath may have an internal diameter that generally conforms to the external diameter of the internal body **112**. In various embodiments, the external sheath **120** may have a diameter of about 2 mm to about 15 mm. In an embodiment, the external sheath may have a diameter of at least about 2 mm. In an embodiment, the external sheath may have a diameter of at least about 3 mm. In an embodiment, the external sheath may have a diameter of at least about 5 mm. In an embodiment, the external sheath may have a diameter of at least about 7 mm. In an embodiment, the external sheath may have a diameter of at least about 10 mm. In an embodiment, the external sheath may have a diameter of less than about 15 mm. In one embodiment, the external sheath may have an inner diameter of about 3.3 mm. In another embodiment, the external sheath may have an inner diameter of about 6.9 mm. In various embodiments, the external sheath may have a French size of at least 10 F. In an embodiment, the external sheath may be at least 11 F. In an embodiment, the external sheath may be at least 12 F. In an embodiment, the external sheath may be at least 13 F. In an embodiment, the external sheath may be at least 14 F. The external sheath **120** may have a length that is at least as long as the internal body **112**. In various embodiments, the external sheath may have a length of about 100 mm to about 200 mm. In an embodiment, the external sheath may have a length of at least 100 mm. In an embodiment, the external sheath may have a length of at least 140 mm. In an embodiment, the internal body may have a length of less than 200 mm.

IV. Methods of Use

[0082] Further provided herein are methods of using the coaptation measurement system **100**, including methods of measuring a coaptation force, methods of deploying the coaptation measurement device, and methods of removing the coaptation measurement device.

[0083] **FIG. 10** provides an overview of a method of using the coaptation measurement device in a heart. For example, the method may include opening the heart, installing the sensor between valvular tissues, temporarily closing the heart, measuring the coaptation force, removing the device, and fully closing the heart.

[0084] The method of measuring a coaptation force of two tissues in a patient may include inserting the coaptation measurement device between the two tissues and measuring, with the array of sensors, a plurality of pressures along a contact surface between the two tissues. The plurality of pressures then provides a measurement of the coaptation force of the two tissues.

[0085] The method may further include inserting the coaptation measurement device after the patient has had at least one of the two tissues repaired. The two tissues may be valvular tissues in the heart, such as leaflets of a mitral valve, leaflets of an aortic valve, or leaflets of a tricuspid valve. In some examples, the coaptation measurement device may be inserted between two leaflets of the mitral valve before, during, and after a mitral valve repair. In another example, at least one leaflet of the mitral valve may be repaired and the coaptation measurement device measures the coaptation force between the mitral valve leaflets after repair. In yet another example, the coaptation measurement device may be inserted between two leaflets of another valve (e.g., tricuspid, aortic valve, etc.). The coaptation measurement device may measure the plurality of pressures in vivo. The coaptation measurement device may measure the plurality of pressures in a beating heart. In some embodiments, the heart may be on cardiopulmonary bypass while measuring the coaptation force. In other embodiments, the heart may be filled with blood while measuring the coaptation force. In other embodiments, the coaptation measurement device measures the plurality of pressures ex vivo.

[0086] The method may further include generating a visual display of the coaptation force. In an embodiment, the method may include generating a two-dimensional map of the coaptation force along the contact surface between the two tissues from the plurality of pressures.

[0087] The coaptation measurement device is sensitive enough to detect a wide range of pressures along the contact surface. The method may further include measuring down to a minimum pressure of 2 gF. This sensitivity may allow for a more complete understanding of the coaptation force and any repairs to the tissues.

[0088] The coaptation measurement system may also capture the plurality of pressures, and therefore the coaptation force, in real time. The acquisition system of the computing system may have an acquisition speed of at least 16 Hz. In various embodiments, the coaptation measurement device measures the plurality of pressures at least as fast as the rate of the beating heart.

[0089] Further provided herein is a method of deploying the coaptation measurement device within the deployment apparatus. In an embodiment, the method may include loading at least a portion of the coaptation measurement device in the deployment apparatus such that the sensor body extends from a distal end of the deployment apparatus. The method further includes placing a portion of the coaptation measurement device into a patient and placing the sensor body of the coaptation measurement device along a contact surface between two tissues to be measured for coaptation.

[0090] In various aspects, the patient may be in open surgery when the coaptation measurement device is placed within the patient. For example, the patient may be in open heart surgery. In some examples, the surgery may be needed to repair a valve in the heart. In an embodiment, the coaptation measurement device may be placed through an incision in the patient's heart. The coaptation measurement device may be placed at the beginning of surgery to understand lesions in the tissue, during repair of a valve, or after repair of a valve. The method may further include suturing the patient around the placed coaptation measurement device. In some embodiments, the heart may be under bypass as the coaptation measurement device is placed and as the

plurality of pressures are measured. In an embodiment, the coaptation measurement device measures the plurality of pressures in a beating heart.

[0091] The method further includes generating a visual display, such as a two-dimensional map of the coaptation force along the contact surface between the two tissues from the plurality of pressures. The coaptation force may be compared to a predetermined value and the computing system may notify the physician if the repair to the tissue is insufficient.

[0092] The method may further include retracting the coaptation measurement device within the deployment apparatus after completion of measuring the coaptation force. **FIGS. 9A-9D** generally show one example of retracting the coaptation measurement device. The figures are not drawn to scale and are shown for illustrative purposes only. The method of retracting and removing the deployment apparatus from the patient may include removing the sensor body of a coaptation measurement device from between two tissues (**FIG. 9A**). The method may then include pulling, towards a proximal end of the deployment apparatus, a portion of the coaptation measurement device so that at least a portion of the sensor body is between the first and second body portions of the internal body (**FIG. 9B**). For example, the physician may pull on the intermediate portion or the sensor output portion to withdraw the sensor body partially or completely between the distal end of the internal body (for example, between the distal ends of the first and second body portions of the internal body) to provide a rigid axis of rotation. The method further includes pushing, towards a distal end of the deployment apparatus, the external sheath to align the two slots with the sensor body such that the sensor body is within the two slots of the external sheath (**FIG. 9C**). Alternatively, the method may include pulling internal body into the external sheath such that the sensor body is within the two slots of the external sheath. The method may then include rotating the internal body such that the sensor body is rolled around the internal body within the external sheath (**FIG. 9D**). The method may further include removing the deployment apparatus from the patient.

[0093] In another example, the sensor body of the coaptation measurement device may be removed from between two tissues and then further removed from the patient's

body without retraction of the sensor body between the first and second body portions of the internal body and/or without rolling the sensor body within the external sheath.

[0094] The particular variations disclosed above are illustrative only, as the variations may be modified and practiced in different but equivalent manners apparent to those skilled in the art having the benefit of the teachings herein. It is therefore evident that the particular variations disclosed above may be altered or modified, and all such variations are considered within the scope and spirit of the application. Accordingly, the protection sought herein is as set forth in the description. Although the present variations are shown above, they are not limited to just these variations, but are amenable to various changes and modifications without departing from the spirit thereof. Additionally, a number of well-known processes and elements have not been described in order to avoid unnecessarily obscuring the present invention. Accordingly, the above description should not be taken as limiting the scope of the invention.

[0095] Those skilled in the art will appreciate that the presently disclosed variations teach by way of example and not by limitation. Therefore, the matter contained in the above description or shown in the accompanying drawings should be interpreted as illustrative and not in a limiting sense. The following claims are intended to cover all generic and specific features described herein, as well as all statements of the scope of the present method and system, which, as a matter of language, might be said to fall therebetween.

CLAIMS

What is claimed is:

1. A system for measuring a coaptation force of a heart valve in a patient comprising:

a coaptation measurement device comprising:

a sensor body comprising:

a flexible substrate; and

an array of sensors on the flexible substrate configured to measure a plurality of pressures along a contact surface between two leaflets of the heart valve,

wherein the plurality of pressures provides a measurement of the coaptation force of the two leaflets; and

a deployment apparatus for deploying and retrieving the coaptation measurement device within the heart valve, the deployment apparatus comprising:

an internal body having a proximal end and a distal end, the internal body comprising a first body portion and a second body portion, wherein a portion of the coaptation measurement device is configured to be placed between the first body portion and the second body portion; and

an external sheath having a proximal end and a distal end, the external sheath comprising two slots on the distal end of the external sheath,

wherein the external sheath is configured to rotatably surround at least a portion of the internal body.

2. The system of claim 1 further comprising a computing system connected to the coaptation measurement device, wherein the computing system comprises at least one non-transitory computer readable medium storing instructions which when executed by at least one processor, cause the at least one processor to receive and process the plurality of pressures.

3. The system of claim 2, wherein the computing system comprises an acquisition system for receiving the plurality of pressures and a data post-processing system for processing the plurality of pressures.

4. The system of claim 3, wherein the acquisition system has an acquisition speed of at least 16Hz.

5. The system of claim 3, wherein the data post-processing system is configured to generate a mapping of the coaptation force along the contact surface between the two tissues from the plurality of pressures.

6. The system of claim 5, wherein the computing system further comprises a display operable to display the mapping generated by the data post-processing system.

7. The system of claim 5, wherein the mapping is a two-dimensional map.

8. The system of claim 1, wherein the sensor body has a width of about 15 mm to about 30 mm and a length of about 5 mm to about to about 25 mm.

9. The system of claim 1, wherein the sensor body has a thickness of 125 μm or less.

10. The system of claim 1, wherein the array of sensors comprises at least 3 rows of sensors.

11. The system of claim 1, wherein the first body portion and the second body portion have a half cylindrical shape.

12. The system of claim 1, wherein the external sheath has a cylindrical shape.

13. The system of claim 1, wherein the first body portion and the second body portion are connected using at least one magnet.

14. The system of claim 1, wherein the two slots have a length of about 5 mm to about to about 25 mm.

15. The system of claim 1, wherein the external sheath further comprises a lateral tube for rinsing.

16. The system of claim 1, wherein the internal body is flexible and further a wire extending from the proximal end to the distal end of the internal body.

17. The system of claim 1, wherein the external sheath is flexible and takes the shape of the internal body.

18. A device for measuring a coaptation force of two tissues in a patient comprising:

a sensor body comprising:

a flexible substrate; and

an array of sensors on the flexible substrate configured to measure a plurality of pressures along a contact surface between the two tissues,

wherein the plurality of pressures provides a measurement of the coaptation force of the two tissues.

19. The device of claim 18, wherein the two tissues are within the patient's heart.

20. The device of claim 19, wherein the two tissues are valvular tissues.

21. The device of claim 20, wherein the two tissues are leaflets of a mitral valve.

22. The device of claim 20, wherein the two tissues are leaflets of an aortic valve or tricuspid valve.

23. The device of claim 18, wherein the sensor body has a size capable of being placed within a valve of a patient.

24. The device of claim 18, wherein the sensor body has a width of about 15 mm to about 30 mm.

25. The device of claim 18, wherein the sensor body has a length of about 5 mm to about to about 25 mm.

26. The device of claim 18, wherein the sensor body has a thickness of 125 μm or less.

27. The device of claim 18, wherein the array of sensors is configured to detect a minimum pressure of 2gF.

28. The device of claim 18, wherein the array of sensors comprises at least 1 row of sensors.

29. The device of claim 18, wherein the array of sensors comprises at least 3 rows of sensors.

30. A method of measuring a coaptation force of two tissues in a patient comprising:

inserting a coaptation measurement device between the two tissues, the coaptation measurement device comprising:

a sensor body comprising:

a flexible substrate; and

an array of sensors on the flexible substrate; and

measuring, with the array of sensors, a plurality of pressures along a contact surface between the two tissues,

wherein the plurality of pressures provides a measurement of the coaptation force of the two tissues.

31. The method of claim 30 further comprising inserting the coaptation measurement device before the patient has had at least one of the two tissues repaired.

32. The method of claim 30 further comprising inserting the coaptation measurement device while the patient is having at least one of the two tissues repaired.

33. The method of claim 30 further comprising inserting the coaptation measurement device after the patient has had at least one of the two tissues repaired.

34. The method of claim 20, wherein the coaptation measurement device measures the plurality of pressures *in vivo*.

35. The method of claim 20, wherein the coaptation measurement device measures the plurality of pressures *ex vivo*.

36. The method of claim 20, wherein the two tissues are valvular tissues in the heart and the coaptation measurement device measures the plurality of pressures in a beating heart.

37. The method of claim 20 further comprising generating a two-dimensional map of the coaptation force between the two tissues from the plurality of pressures.

38. The method of claim 37 further comprising comparing elements of the two-dimensional map to determine the efficacy of the coaptation.

39. The method of claim 30, wherein the two tissues are leaflets of a mitral valve.

40. The method of claim 30, wherein the two tissues are leaflets of an aortic valve or tricuspid valve.

41. The method of claim 30, wherein the sensor body has a size capable of being placed within a valve of a patient.

42. The method of claim 30, wherein the array of sensors is configured to detect a minimum pressure of 2gF.

43. A deployment apparatus for deploying and retrieving a coaptation measurement device between two tissues in a patient, the deployment apparatus comprising:

an internal body having a proximal end and a distal end, the internal body comprising a first body portion and a second body portion, wherein a portion of the coaptation measurement device is configured to be placed between the first body portion and the second body portion; and

an external sheath having a proximal end and a distal end, the external sheath comprising two slots on the distal end of the external sheath,

wherein the external sheath is configured to rotatably surround at least a portion of the internal body.

44. The deployment apparatus of claim 43, wherein the first body portion and the second body portion have a half cylindrical shape.

45. The deployment apparatus of claim 43, wherein the external sheath has a cylindrical shape.

46. The deployment apparatus of claim 43, wherein the first body portion and the second body portion are connected using at least one magnet.

47. The deployment apparatus of claim 43, wherein the first body portion and the second body portion are connected through a handle comprising a first ring portion a second ring portion, wherein the first ring portion and the second ring portion connect to form the handle of the internal body.

48. The deployment apparatus of claim 43, wherein the two slots have a length at least as long as the length of a sensor body of the coaptation measurement device.

49. The deployment apparatus of claim 43, wherein the two slots have a length of about 5 mm to about to about 25 mm.

50. The deployment apparatus of claim 43, wherein the external sheath further comprises a lateral tube for rinsing.

51. The deployment apparatus of claim 43, wherein the external sheath is Doppler opaque, allowing for navigation of the deployment apparatus under echographical view.

52. The deployment apparatus of claim 43, wherein the internal body is Doppler opaque.

53. The deployment apparatus of claim 43, wherein the internal body further comprises threading on the proximal end of the internal body.

54. The deployment apparatus of claim 43, wherein the distal end of the internal body is narrower than the proximal end of the internal body.

55. The deployment apparatus of claim 43, wherein the internal body is flexible and further comprises a shape memory mechanism.

56. The deployment apparatus of claim 55, wherein the shape memory mechanism is a wire extending from the proximal end to the distal end of the internal body.

57. The deployment apparatus of claim 43, wherein the external sheath is flexible and takes the shape of the internal body.

58. A method of deploying a coaptation measurement device within a deployment apparatus comprising:

loading at least a portion of the coaptation measurement device comprising a sensor body into the deployment apparatus, wherein the sensor body extends from a distal end of the deployment apparatus;

placing a portion of the coaptation measurement device into a patient; and

placing the sensor body of the coaptation measurement device along a contact surface between two tissues to be measured for coaptation.

59. The method of claim 58 further comprising suturing the patient around the placed coaptation measurement device.

60. The method of claim 58 further comprising measuring a plurality of pressures along the contact surface between the two tissues, wherein the plurality of pressures provides a measurement of the coaptation force of the two tissues.

61. The method of claim 60, wherein the coaptation measurement device measures the plurality of pressures *in vivo*.

62. The method of claim 60, wherein the coaptation measurement device measures the plurality of pressures *ex vivo*.

63. The method of claim 60, wherein the two tissues are valvular tissues in the heart and the coaptation measurement device measures the plurality of pressures in a beating heart.

64. The method of claim 60 further comprising generating a two-dimensional map of the coaptation force along the contact surface between the two tissues from the plurality of pressures.

65. The method of claim 60 further comprising retracting the coaptation measurement device within the deployment apparatus after completion of measuring the coaptation force.

66. A method of removing a deployment apparatus from a patient comprising:

removing a sensor body of a coaptation measurement device from between two tissues to be measured for coaptation;

pulling, towards a proximal end of the deployment apparatus, a portion of the coaptation measurement device between a first body portion and a second body portion of an internal body of the deployment apparatus;

pushing, towards a distal end of the deployment apparatus, an external sheath comprising two slots on its distal end, wherein the external sheath surrounds the internal body;

aligning the two slots with the sensor body of the coaptation measurement device wherein the sensor body is within the two slots; and

rotating the internal body such that the sensor body is rolled within the external sheath.

67. The method of claim 66 further comprising pulling the internal sheath, wherein the sensor body is completely within the external sheath.

68. The method of claim 66 further comprising removing the deployment apparatus from the patient.

69. A coaptation measurement system comprising the coaptation measurement device of claim 18 and the deployment apparatus of claim 43.

70. The system of claim 69 further comprising a computing system connected to the coaptation measurement device, wherein the computing system comprises at least one non-transitory computer readable medium storing instructions which when executed by at least one processor, cause the at least one processor to receive and process the plurality of pressures.

71. The system of claim 70, wherein the computing system comprises an acquisition system for receiving the plurality of pressures and a data post-processing system for processing the plurality of pressures.

72. The system of claim 71, wherein the acquisition system has an acquisition speed of at least 16Hz.

73. The system of claim 71, wherein the data post-processing system is configured to generate a mapping of the coaptation force along the contact surface between the two tissues from the plurality of pressures.

74. The system of claim 73, wherein the computing system further comprises a display operable to display the mapping generated by the data post-processing system.

75. The system of claim 73, wherein the mapping is a two-dimensional map.

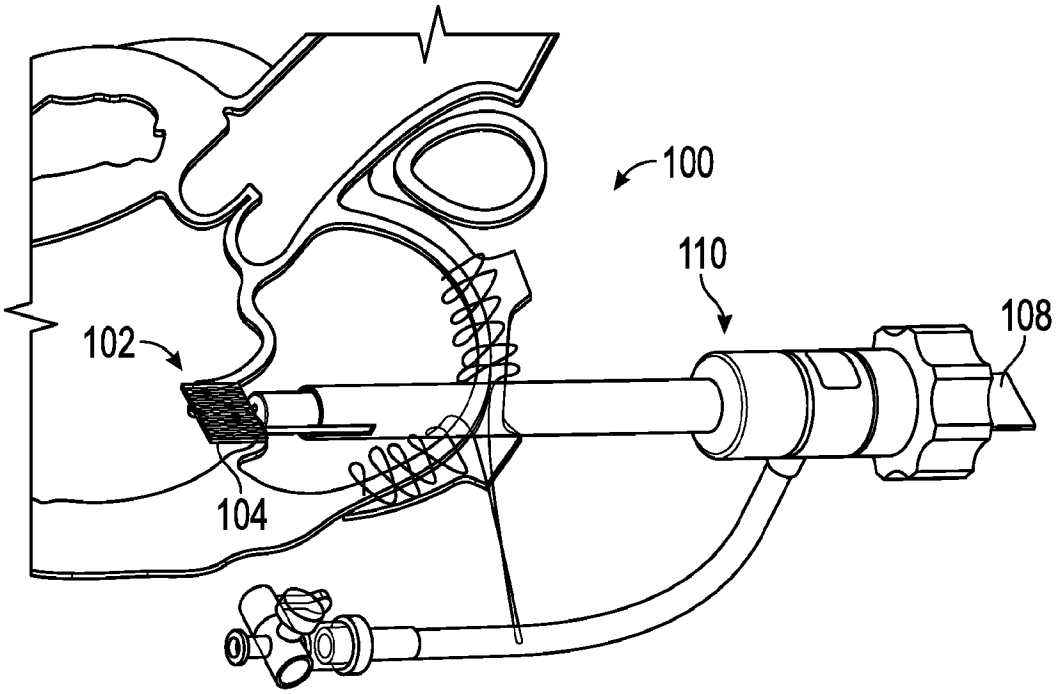

FIG. 1A

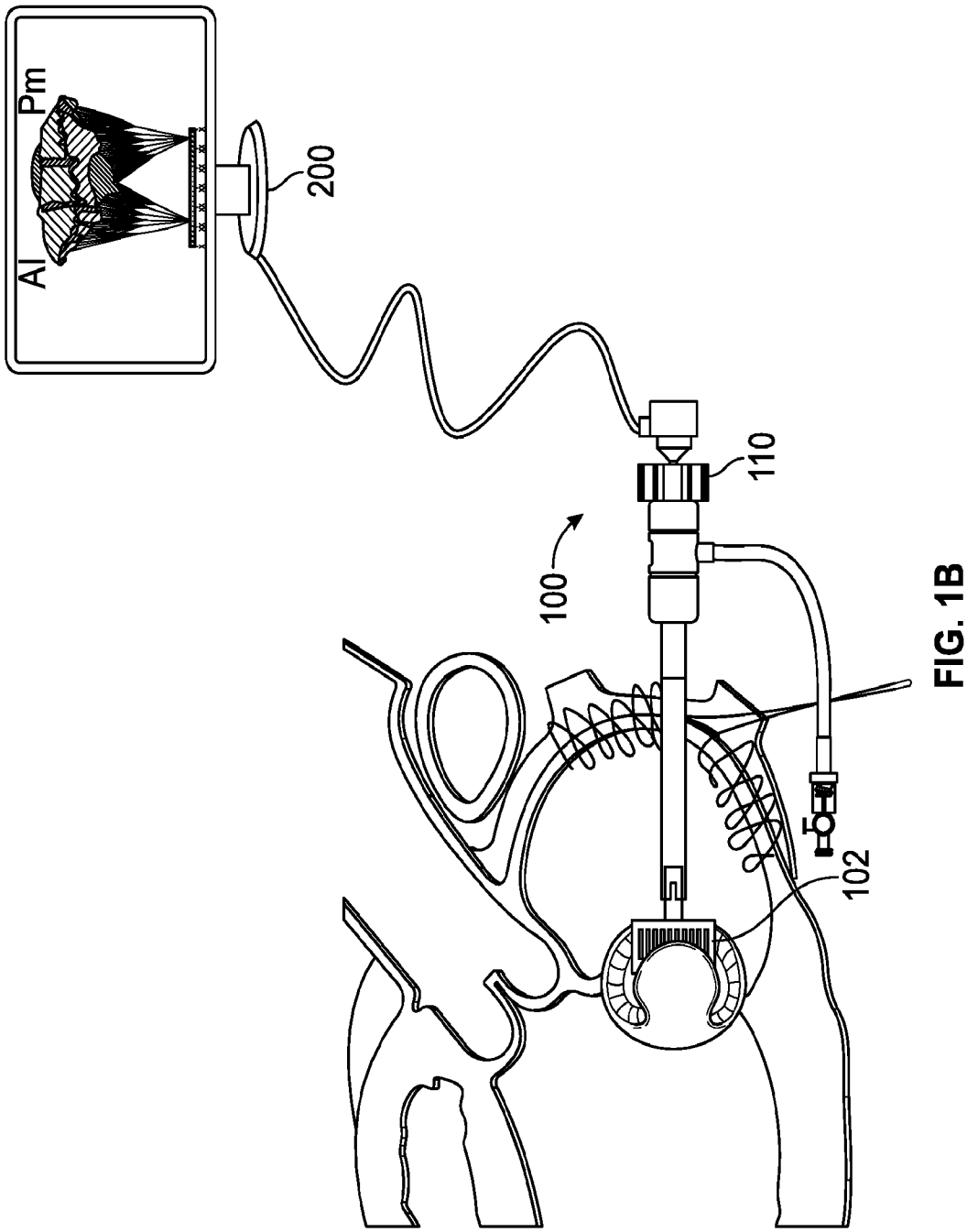

FIG. 1B

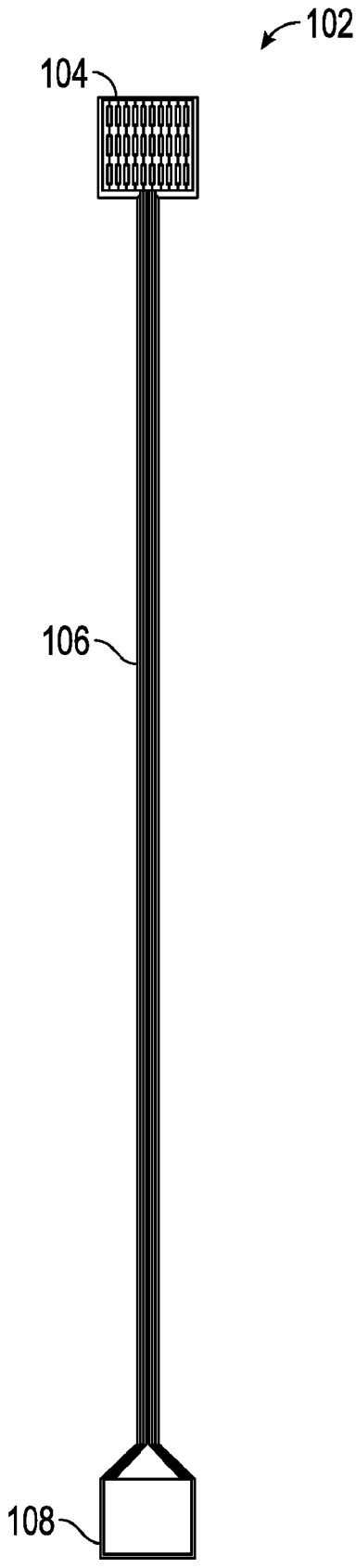

FIG. 2A

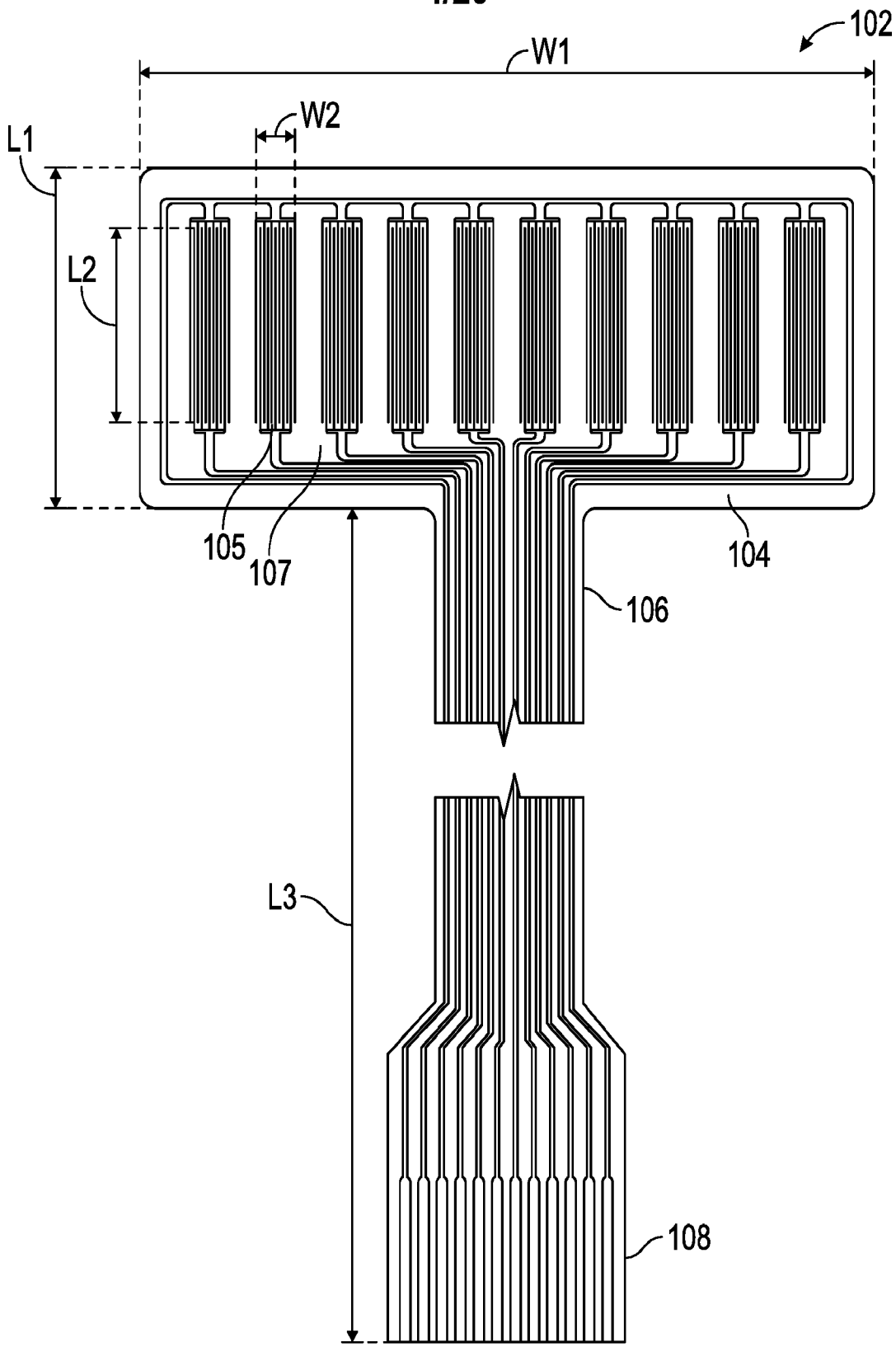

FIG. 2B

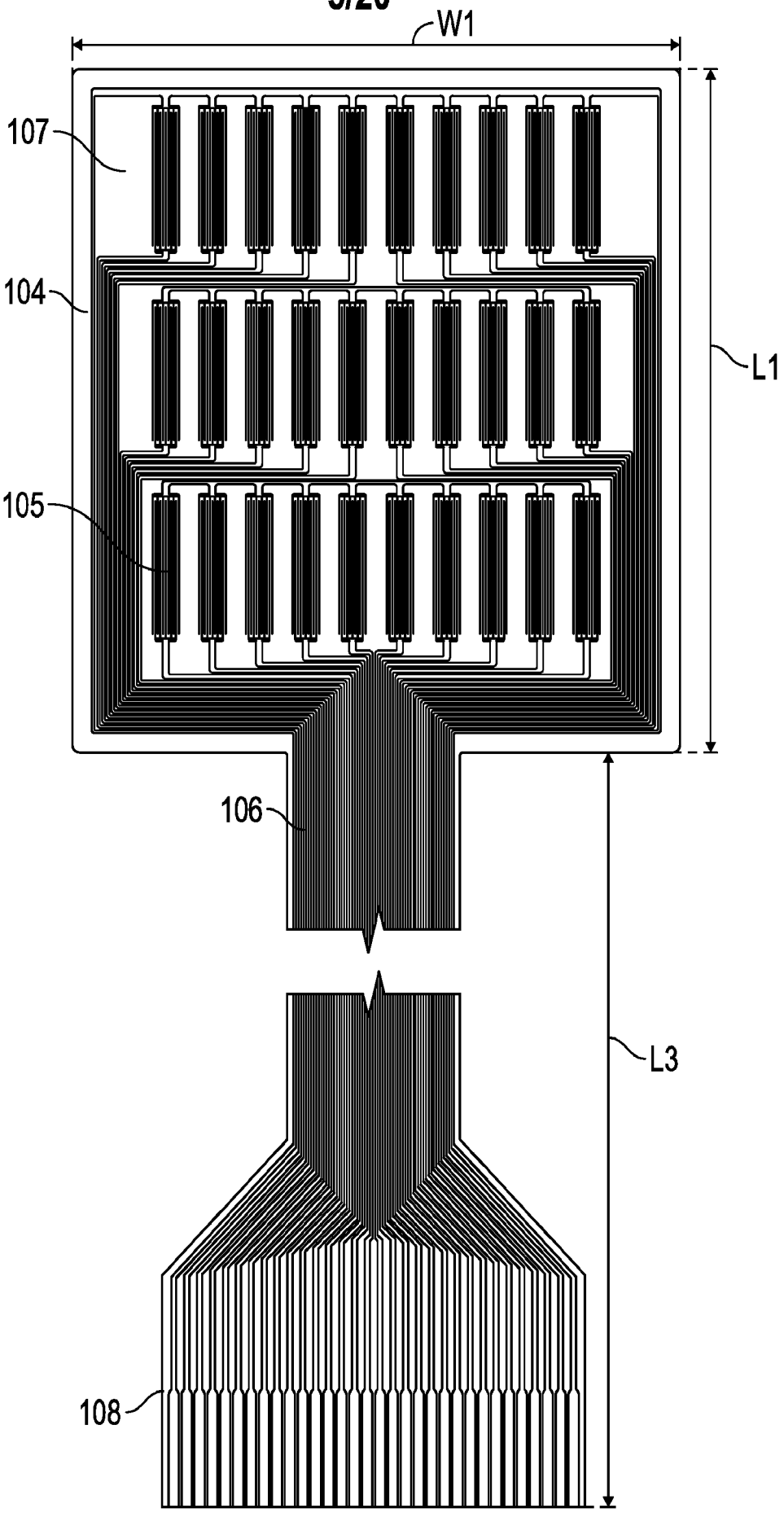

FIG. 2C

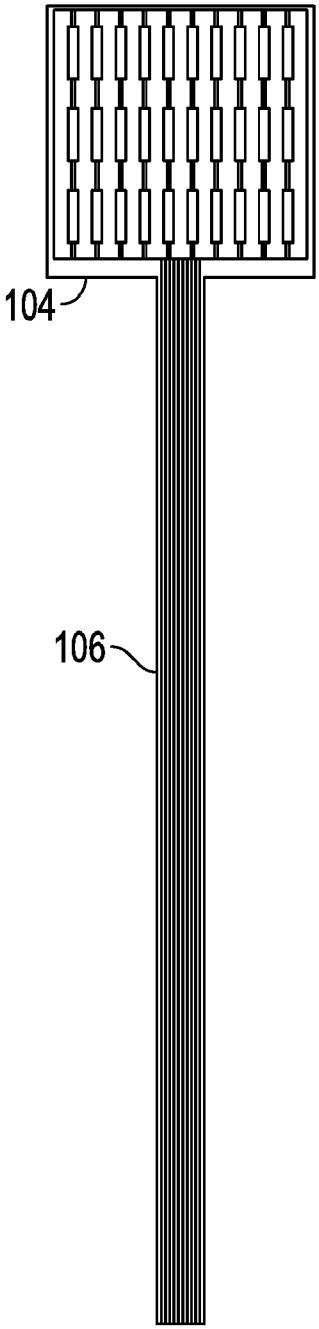

FIG. 2D

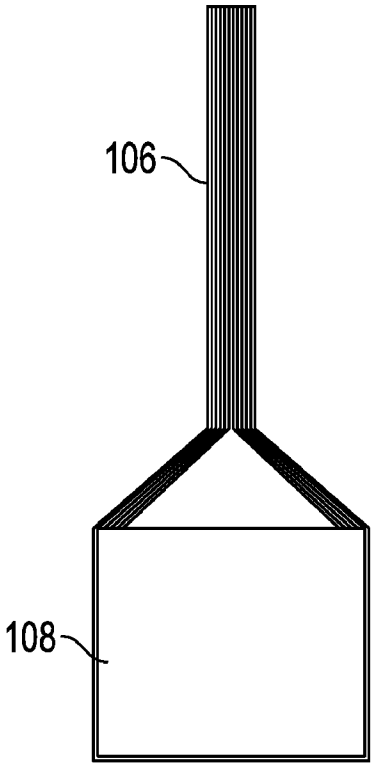

FIG. 2E

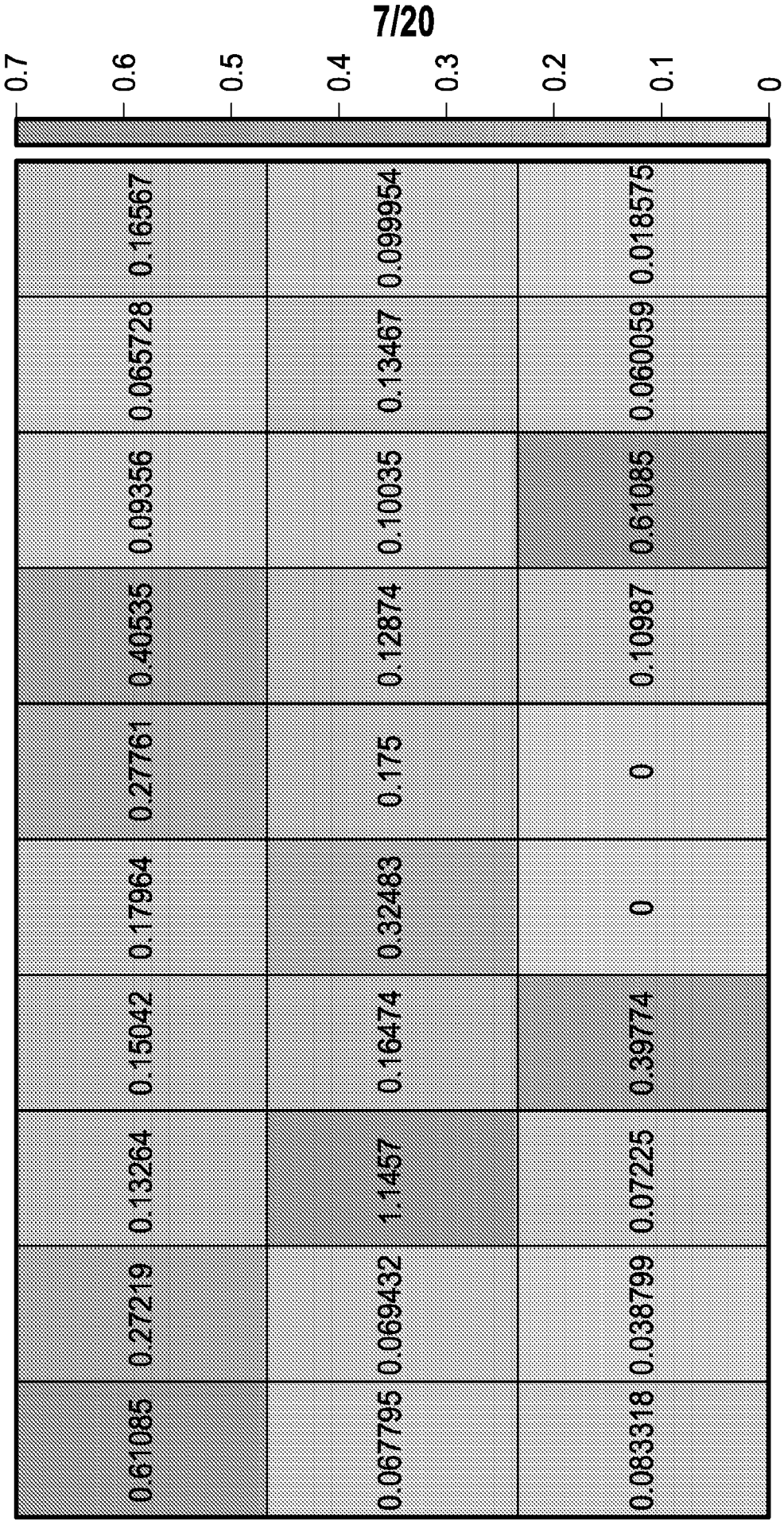
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
0.61085 0.27219 0.13264 0.15042 0.17964 0.27761 0.40535 0.09356 0.065728 0.16567
0.067795 0.069432 1.1457 0.16474 0.32483 0.175 0.12874 0.10035 0.13467 0.099954
0.083318 0.038799 0.07225 0.39774 0 0 0.10987 0.61085 0.060059 0.018575

FIG. 3

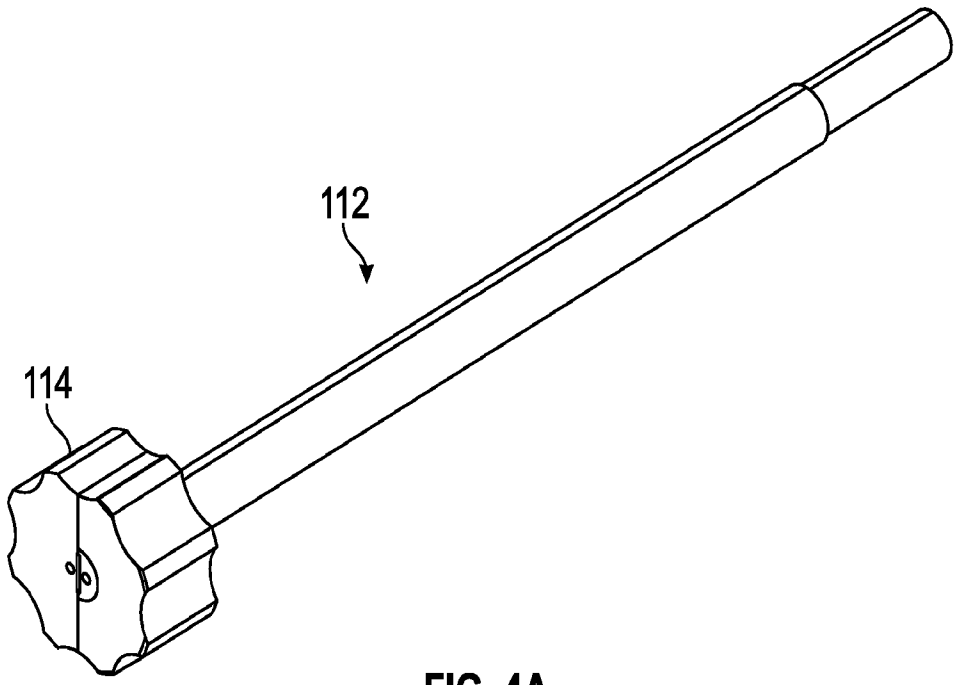

FIG. 4A

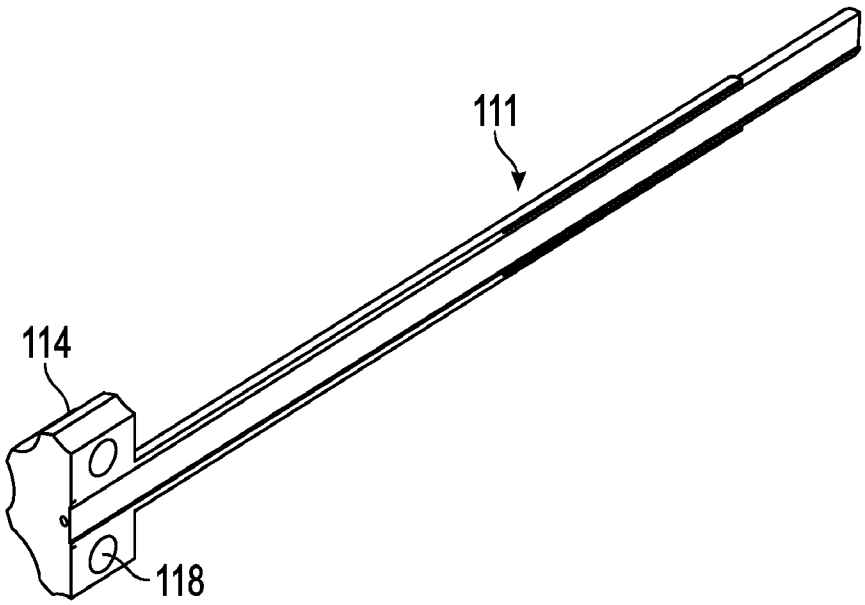

FIG. 4B

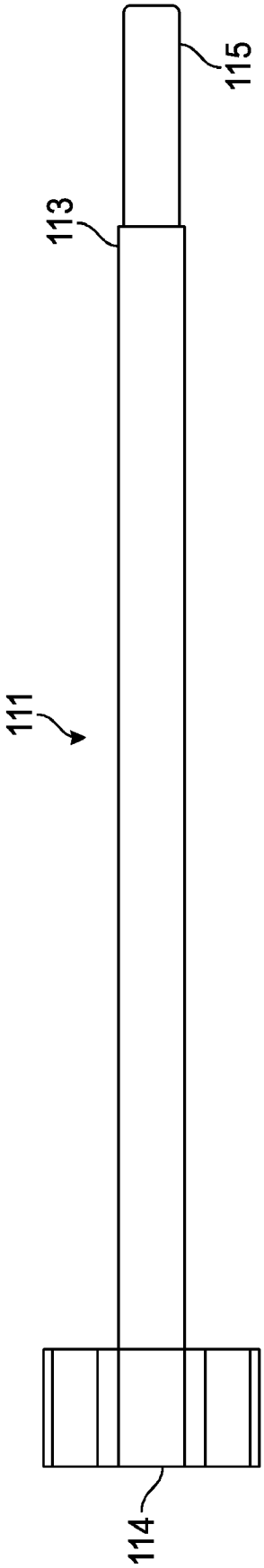

FIG. 4C

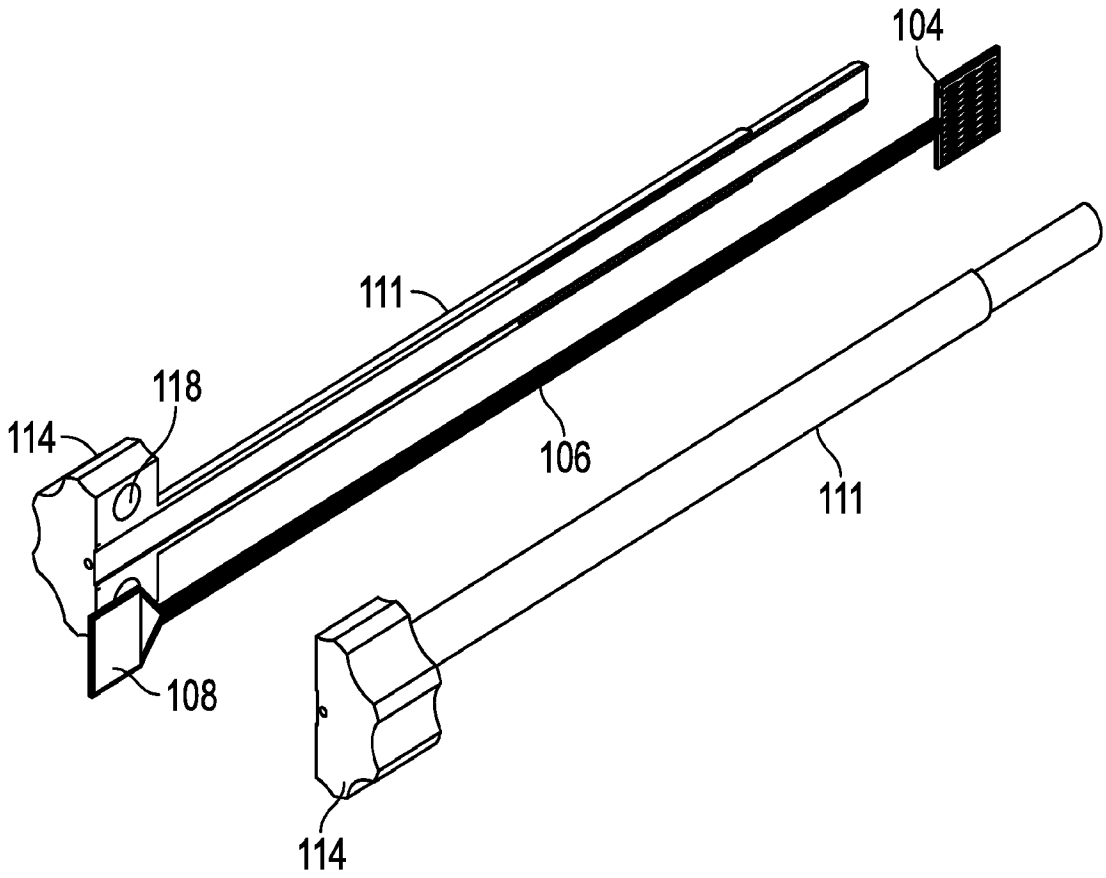

FIG. 5A

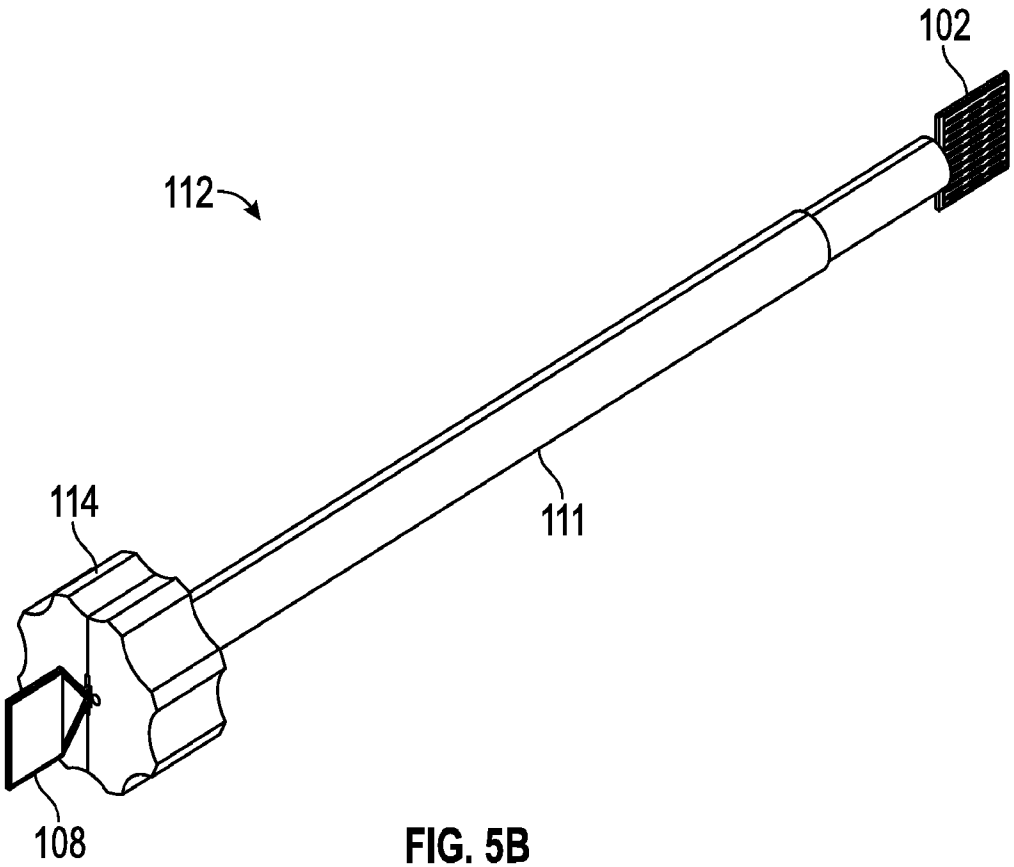

FIG. 5B

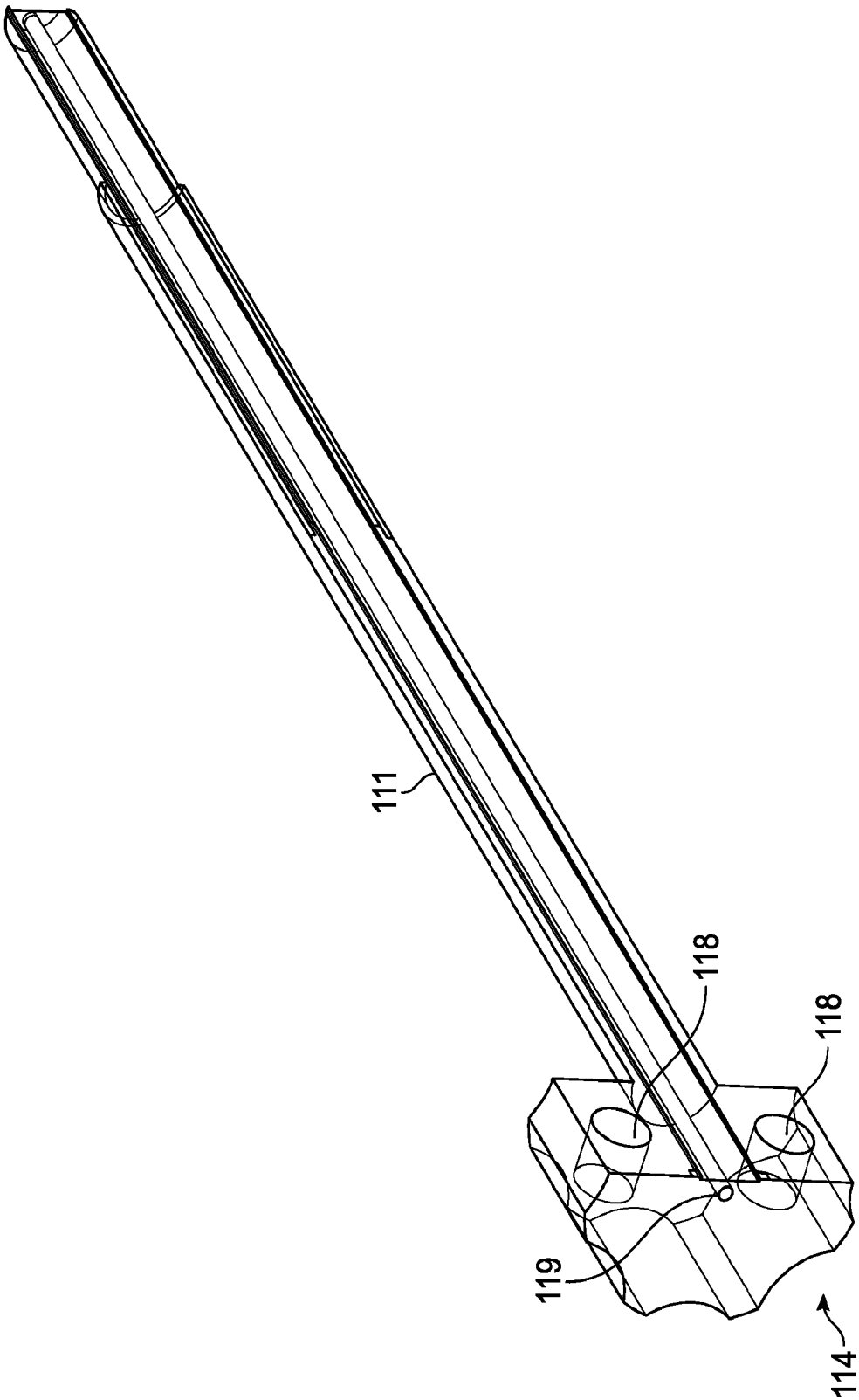

FIG. 6

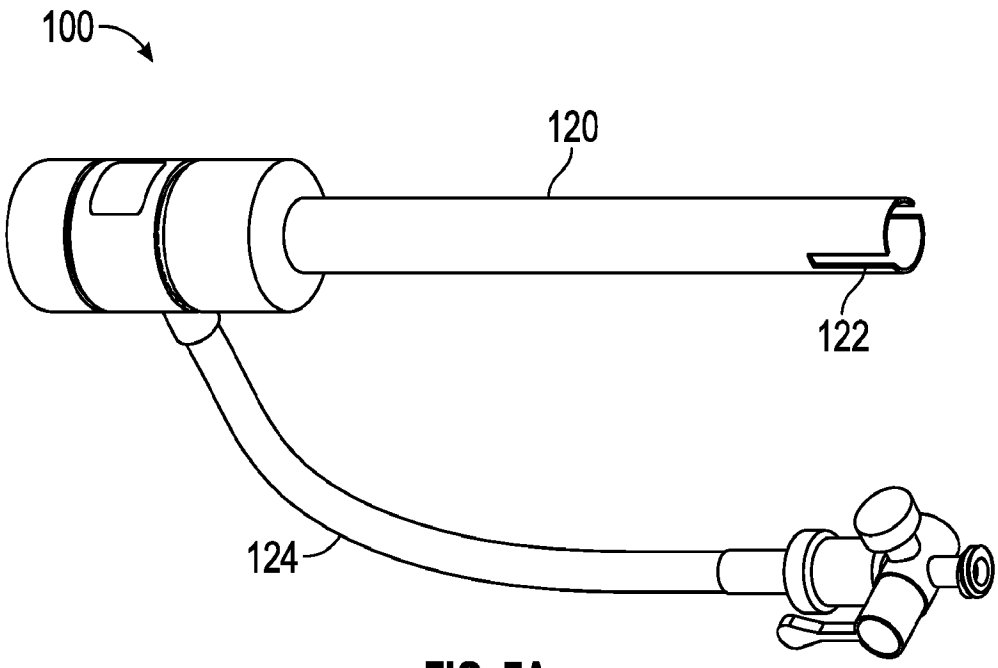

FIG. 7A

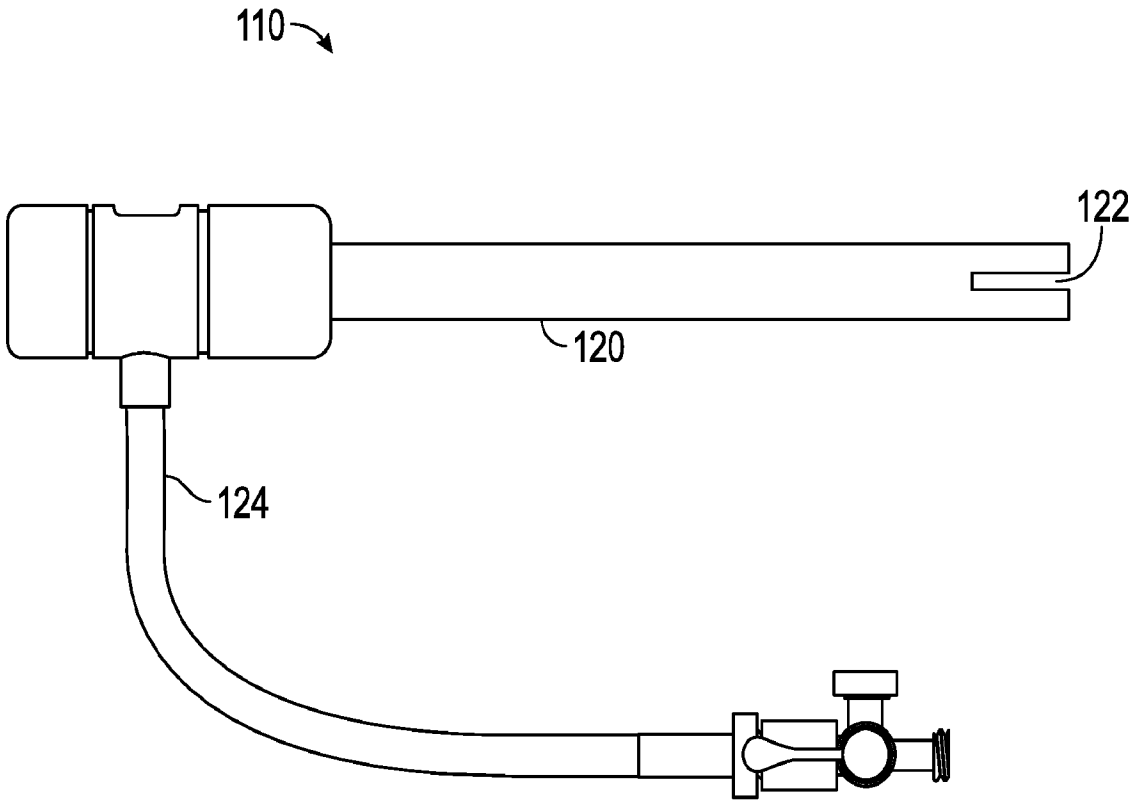

FIG. 7B

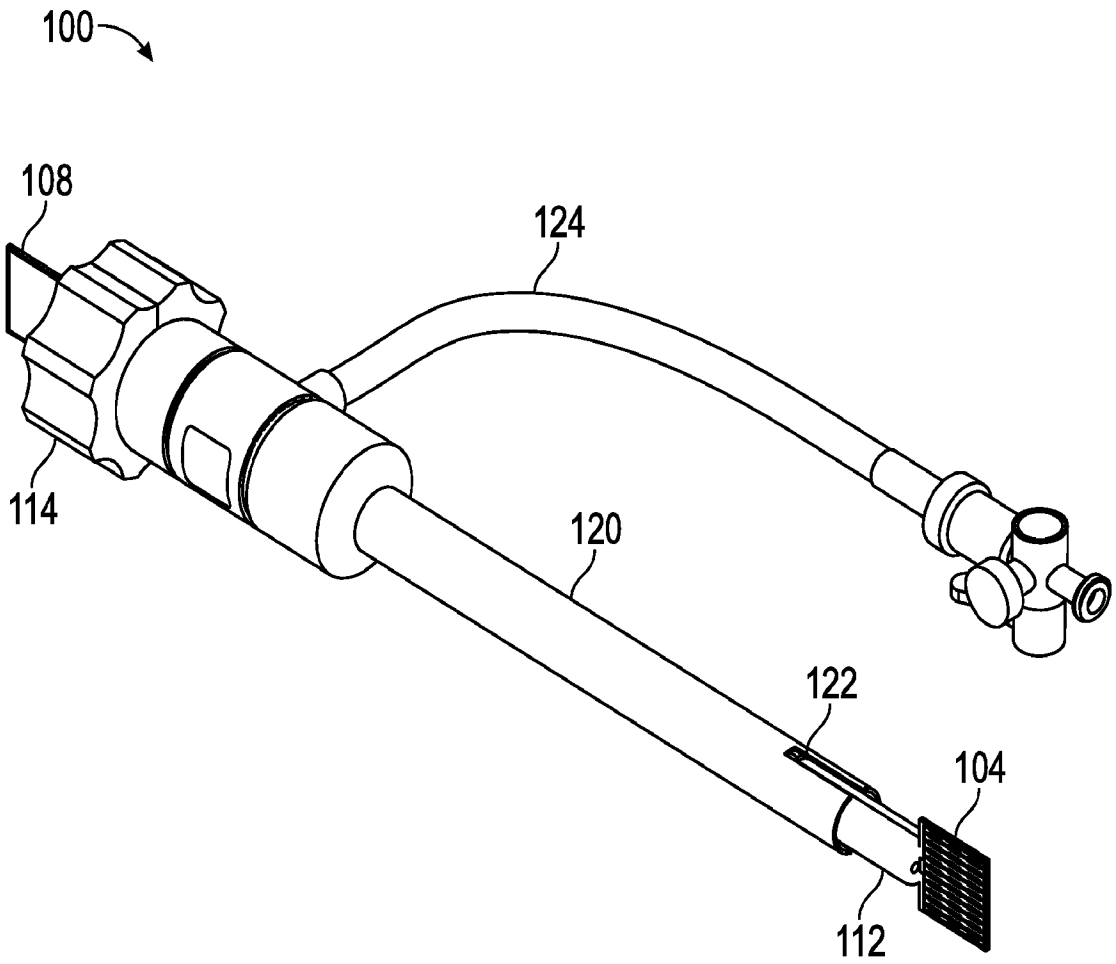

FIG. 8A

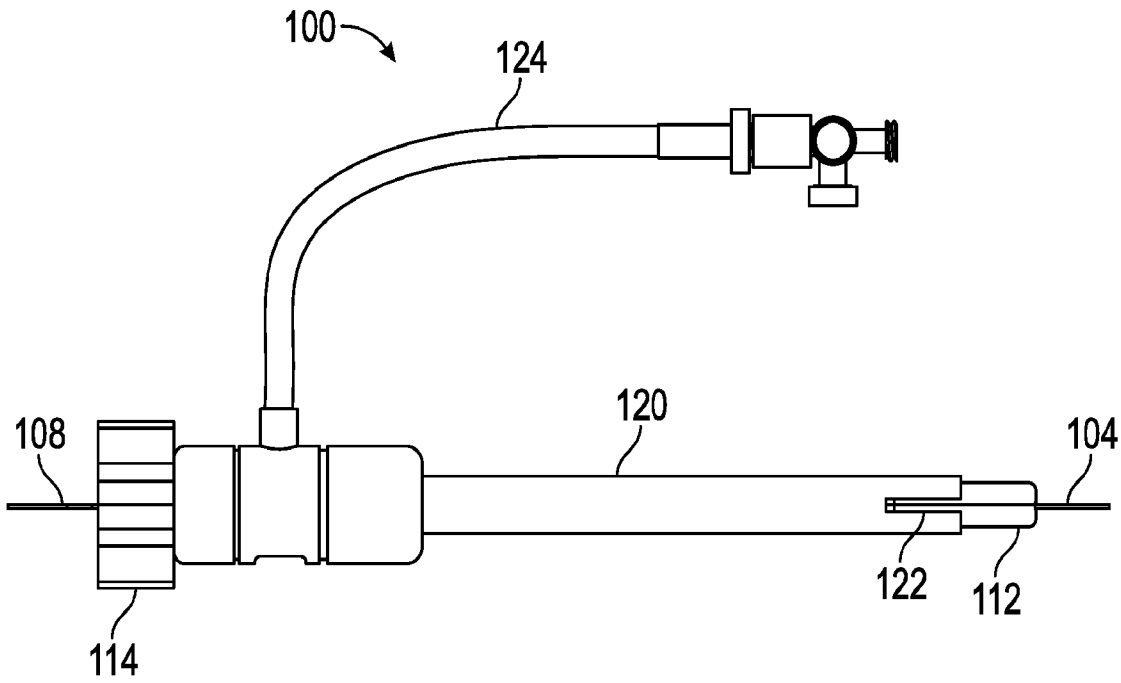

FIG. 8B

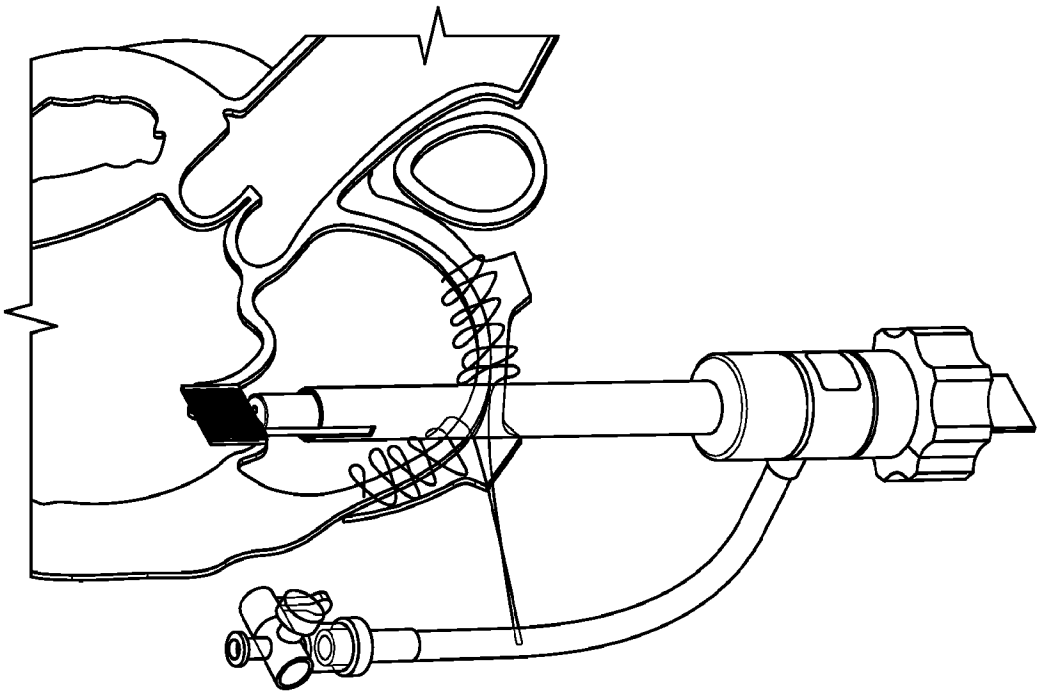

FIG. 9A

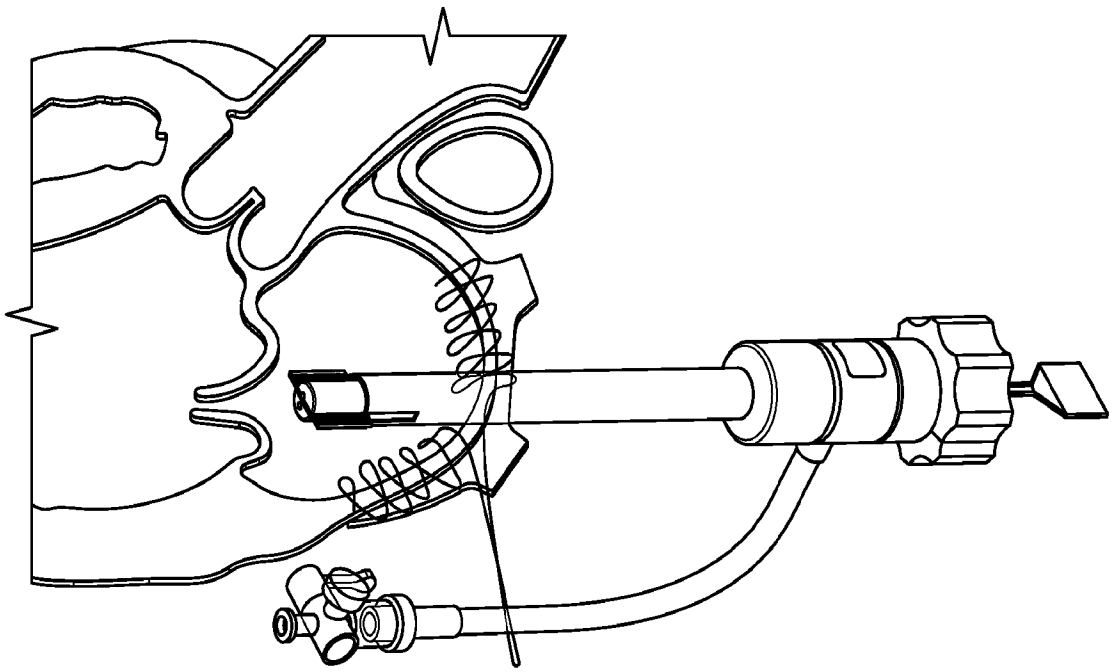

FIG. 9B

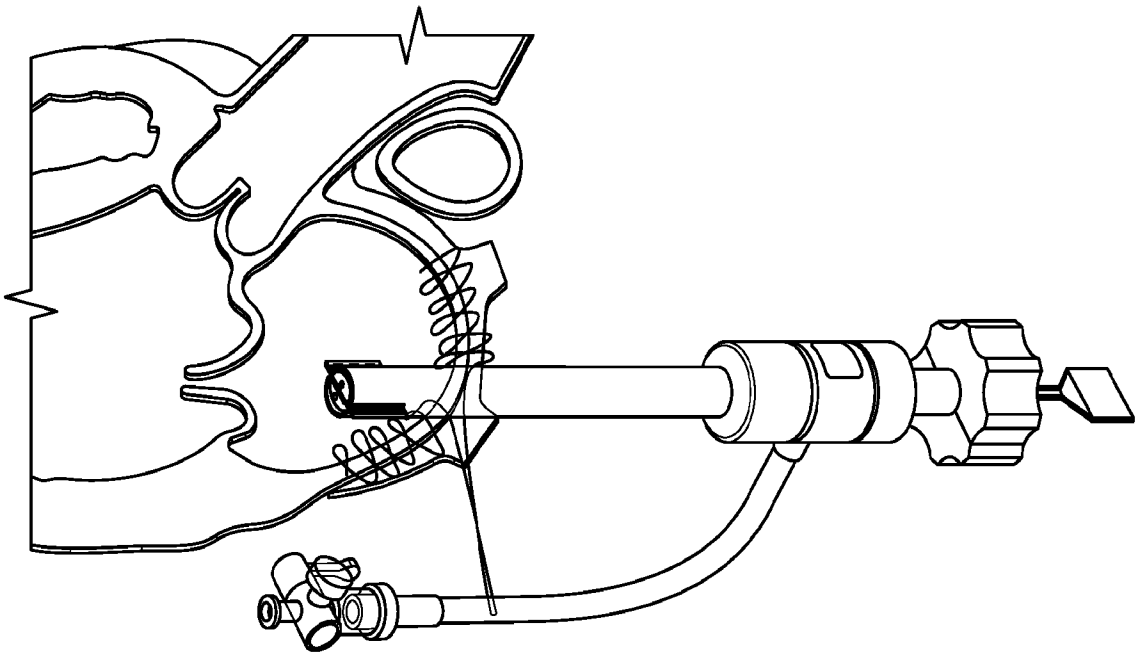

FIG. 9C

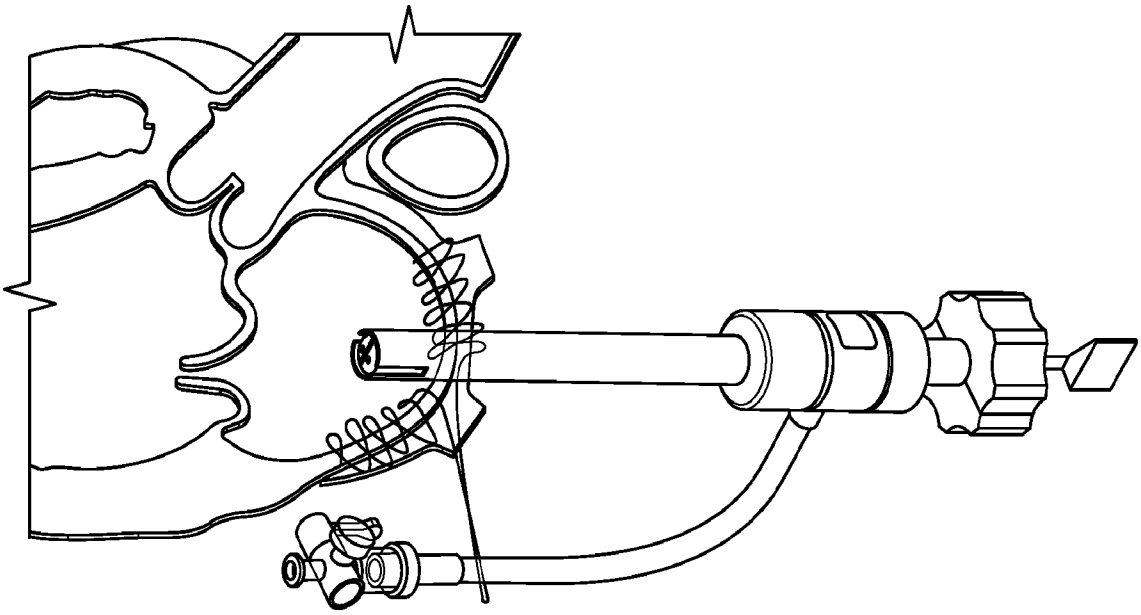

FIG. 9D

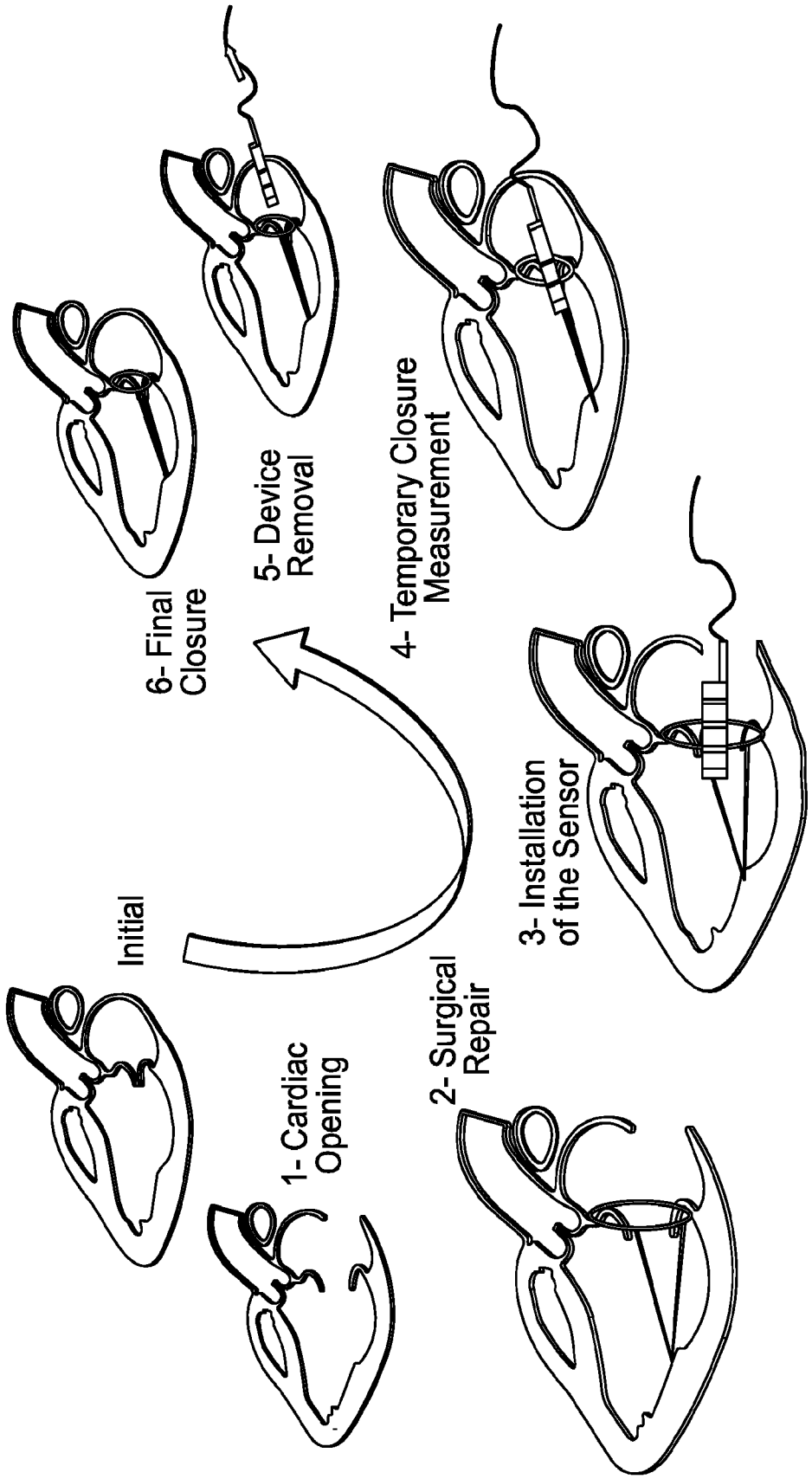
Initial
1- Cardiac Opening
2- Surgical Repair
3- Installation of the Sensor
4- Temporary Closure Measurement
5- Device Removal
6- Final Closure

FIG. 10

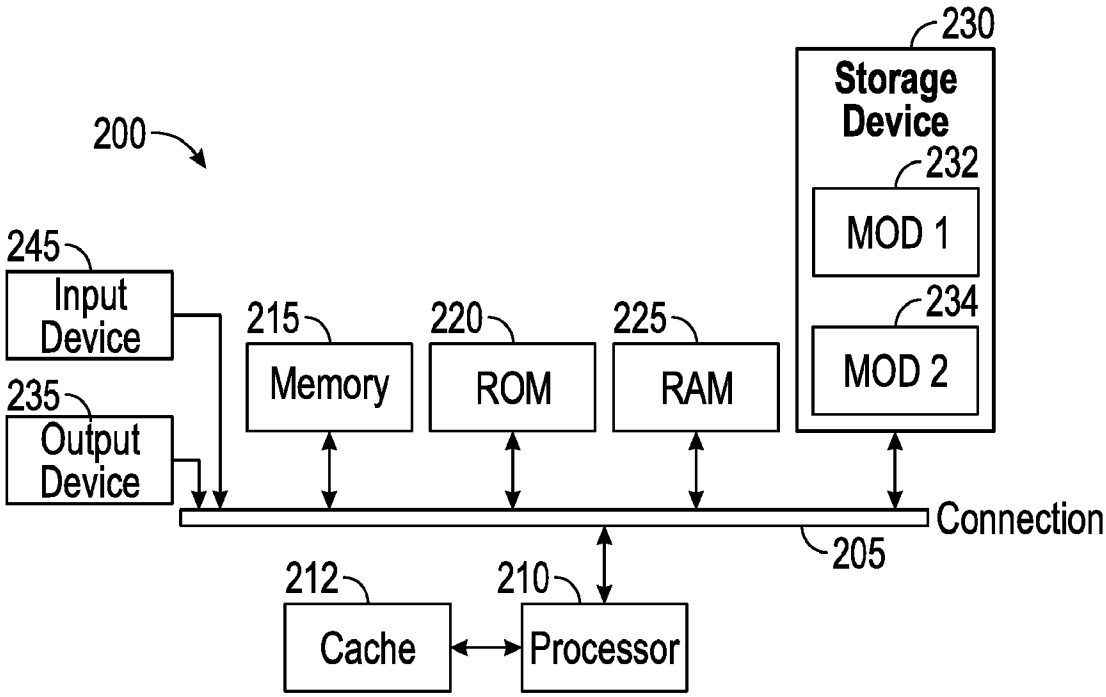
200
230
Storage Device
232
MOD 1
234
MOD 2
245
Input Device
235
Output Device
215
Memory
220
ROM
225
RAM
Connection
205
212
Cache
210
Processor

FIG. 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US20/14950

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61B 5/02, 5/021, 5/0215, 5/03; G01L 5/00 (2020.01)

CPC - A61B 5/02, 5/02028, 5/021, 5/0215, 5/03, 5/68, 5/6846, 5/6847, 5/6852, 5/6867, 5/6869, 5/6885; G01L 5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2018/0360533 A1 (ST. JUDE MEDICAL, CARDIOLOGY DIVISION, INC.) 20 December 2018; figures 17A-B; paragraphs [0121]-[0125]	18-25, 28-29 ---------- 26-27
X, P	WO 2019/075477 A2 (CHILDREN'S MEDICAL CENTER CORPORATION) 18 April 2019; figures 2D,3C; pages 8, 11	18-24, 28-34, 36, 39-41
Y	WO 2018/150314 A1 (ST. JUDE MEDICAL INTERNATIONAL HOLDING S.À R.L) 23 August 2018; figure 5B; paragraphs [0075],[0080]	26-27
A	US 2014/0012367 A1 (ST. JUDE MEDICAL, CARDIOLOGY DIVISION, INC.) 09 January 2014; entire document	1-17, 30-42, 66-75
A	US 2005/0085903 A1 (LAU, J) 21 April 2005; entire document	1-17, 30-75
A	US 2015/0196210 A1 (MEDTRONIC VASCULAR GALWAY) 16 July 2015; entire document	43-65

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
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"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)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"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
"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
"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
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 March 2020 (22.03.2020)	08 APR 2020
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas Telephone No. PCT Helpdesk: 571-272-4300