Innovation, Sciences et Développement économique Canada
Office de la Propriété Intellectuelle du Canada

Innovation, Science and Economic Development Canada
Canadian Intellectual Property Office

CA 3173440 A1 2021/11/18

(21) 3 173 440

(12) DEMANDE DE BREVET CANADIEN
CANADIAN PATENT APPLICATION

(13) A1

(86) Date de dépôt PCT/PCT Filing Date: 2021/05/06
(87) Date publication PCT/PCT Publication Date: 2021/11/18
(85) Entrée phase nationale/National Entry: 2022/09/26
(86) N° demande PCT/PCT Application No.: IB 2021/053876
(87) N° publication PCT/PCT Publication No.: 2021/229383
(30) Priorité/Priority: 2020/05/11 (US63/022,842)

(51) Cl.Int./Int.Cl. *A61B 17/00* (2006.01), *A61B 17/34* (2006.01), *A61B 18/00* (2006.01), *A61B 18/12* (2006.01), *A61B 18/14* (2006.01), *A61B 90/00* (2016.01)

(71) Demandeur/Applicant:
BOSTON SCIENTIFIC MEDICAL DEVICE LIMITED, IE

(72) Inventeurs/Inventors:
DICICCO, MATTHEW, CA;
DAVIES, GARETH, CA;
URBANSKI, JOHN PAUL, CA;
MORIYAMA, EDUARDO, CA;
RYAN, PATRICK, CA;
MOK, DANIEL WING FAI, CA; ...

(54) Titre : DISPOSITIF ELECTROCHIRURGICAL A ARRET AUTOMATIQUE
(54) Title: AN ELECTROSURGICAL DEVICE WITH AUTOMATIC SHUT-OFF

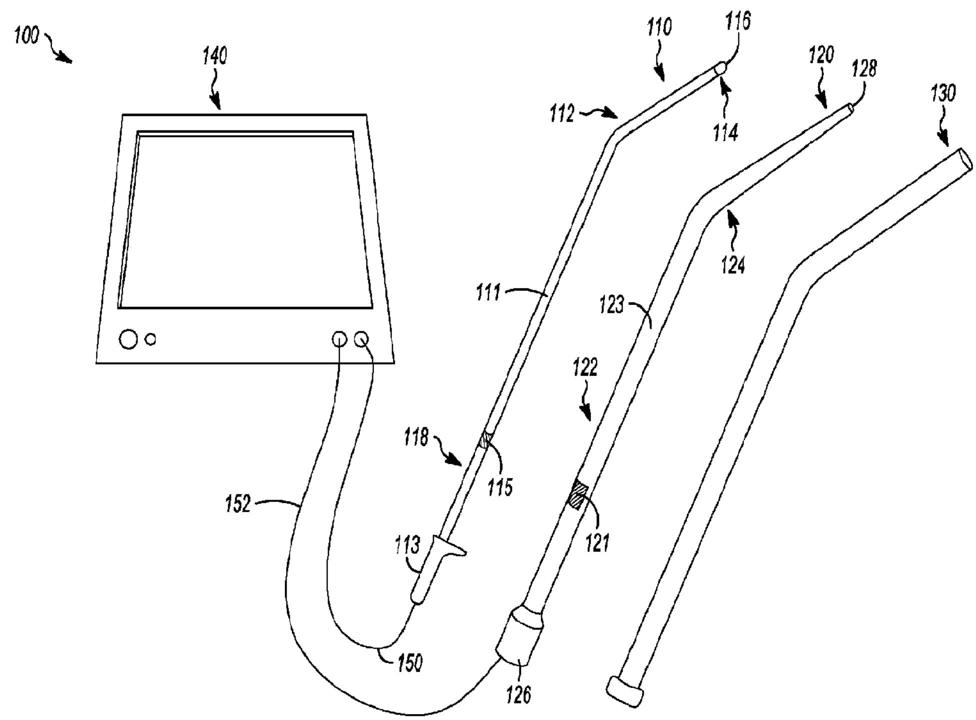

FIG. 1

(57) Abrégé/Abstract:
A method and apparatus are disclosed for creating a puncture in a tissue. The assembly includes a puncturing device having a distal tip configured to deliver energy to the tissue, creating the puncture. The puncturing device further includes a marker positioned along the puncturing device. The assembly further includes a dilator which has a lumen extending from a proximal portion to a distal portion and configured to receive the puncturing device. The dilator further comprises a sensor positioned along a length of the dilator. When the marker and the sensor are aligned, energy is delivered to the distal tip of the puncturing device.

(21) 3 173 440

(13) A1

(72) **Inventeurs(suite)/Inventors(continued)**: TYLER, BRANDON, CA

(74) **Agent**: BOSTON SCIENTIFIC MEDICAL DEVICE LIMITED

Date Submitted: 2022/09/26

CA App. No.: 3173440

Abstract:

A method and apparatus are disclosed for creating a puncture in a tissue. The assembly includes a puncturing device having a distal tip configured to deliver energy to the tissue, creating the puncture. The puncturing device further includes a marker positioned along the puncturing device. The assembly further includes a dilator which has a lumen extending from a proximal portion to a distal portion and configured to receive the puncturing device. The dilator further comprises a sensor positioned along a length of the dilator. When the marker and the sensor are aligned, energy is delivered to the distal tip of the puncturing device.

An Electrosurgical Device with Automatic Shut-Off

TECHNICAL FIELD

[0001] The disclosure relates to a surgical perforation device, configured to deliver energy to a tissue. More specifically, the invention relates to a device and method for creating a perforation in the atrial septum while using markers and sensors to control the delivery of energy.

BACKGROUND

[0002] Certain medical procedures require the use of a medical device that can create punctures or channels through tissues of the heart. Specifically, puncturing the septum of a heart creates a direct route to the left atrium where numerous cardiology procedures take place. One such device that gains access to the left atrium is a transseptal puncturing device which, in some devices, delivers radiofrequency energy from a generator into the tissue to create the perforation. The user positions the puncturing device at a target location on the fossa ovalis located on the septum of the heart and turns on the generator to begin delivering energy to the target location. The delivery of radiofrequency energy to a tissue results in vaporization of the intracellular fluid of the cells which are in contact with the energy delivery device. Ultimately, this results in a void, hole, or channel at the target tissue site.

[0003] Currently, the parameters around the delivery of energy involve the duration, as well as a pulsed or constant delivery of energy. Typically, the user will select the parameters, for example constant energy delivery for the duration of two seconds, prior to performing the puncture. The user activates the delivery via a push of a button on the generator or via a foot pedal. When the duration of energy delivery has been completed, the user will check, using various means (i.e., fluoroscopy, pressure readings, ultrasound, or contrast injections, etc.) to determine if the puncture was successful. If it was unsuccessful, the user will activate the energy delivery again. Once the duration is completed, the user will once again check to see if the puncture was successful. The user has the ability to turn off the delivery of energy before the duration is complete, using the button on the generator or the foot pedal, but there is still no way to confirm during the delivery of energy if the puncture was successful or not. This lack of knowledge around the success of the puncture during energy delivery may lead to inadvertent damage to surrounding tissues that are intended to be left unharmed during the procedure. For example, if the duration has been set for two seconds but the puncture has been completed in one second, the puncturing device is still delivering energy for additional time after entering the left atrium.

[0004] Inadvertent perforation of other tissues of the heart may result in general tissue damage within the left atrium, ancillary device damage (i.e., damage to pacemaker leads located in atrium) or potentially critical complications such as cardiac tamponade or inadvertent aortic perforation. A cardiac tamponade is a life-threatening complication of transseptal punctures which occurs when a perforation is created at the left atrial wall, left atrial roof, or left atrial appendage. This perforation of the atrial wall leads to an accumulation of fluid within the pericardial cavity around the heart. This buildup of fluid compresses the heart which in turn reduces the amount of blood able to enter the heart. An inadvertent aortic perforation is a rare life-threatening complication where the puncturing device enters and perforates the aorta which may require surgical repair.

[0005] Various minimally invasive procedures involve creating a puncture in a living tissue. One such procedure is performing a transseptal puncture which allows surgeons to gain access to the left side of the heart by creating a puncture from the right side of the heart through the septum. Recently, medical devices have been configured to perform the puncture by delivering energy, specifically radiofrequency energy, to the tissue. The delivery of radiofrequency energy to a tissue results in vaporization of the intracellular fluid of the cells which are in contact with the energy delivery device. This results in a perforation at the target tissue site. One of the complications which may arise during a transseptal puncture is the inadvertent puncturing of the left atrial wall or aorta. These potentially life-threatening complications may result in damage to surrounding tissue or ancillary devices, or perforation of the left atrial wall or aorta.

[0006] In light of these complications associated with inadvertent damage to surrounding tissues, there exists a need to provide a novel radiofrequency puncturing device wherein the delivery of radiofrequency energy is deactivated automatically after the puncture device has completed the puncture and entered the left atrium.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] In order that the invention may be readily understood, embodiments of the invention are illustrated by way of examples in the accompanying figures, in which:

[0008] Fig. 1 is an illustration of an exemplary system which may be used to puncture tissue.

[0009] Fig. 2a – 2e are illustrations of various marker bands which may be placed on the puncturing device.

[0010] Fig. 3a – 3b are illustrations of various detector placements on the dilator.

[0011] Fig. 3c is an illustration of the detector being placed on the puncturing device with a marker being placed on the dilator.

[0012] Fig 4a – 4c are illustrations of the puncturing device moving through the dilator, illustrating the alignment of the marker and detector.

[0013] Fig. 5a – 5c are illustrations of another embodiment wherein the dilator would deliver energy to the puncturing device via a conductive plate.

DETAILED DESCRIPTION

[0014] The problem of inadvertent puncturing of the left atrium is solved by providing an electrosurgical puncturing device with a mechanism to shut off the delivery of energy after the puncture of the septum has been completed.

[0015] In one broad aspect, embodiments of the present invention comprise an assembly to create a puncture in a tissue, comprising: a puncturing device comprising an elongate member having a distal tip configured to deliver energy to the tissue, creating the puncture. The puncturing device further comprises a marker positioned along the elongate member. A dilator wherein the dilator comprises a lumen extending from a proximal portion to a distal portion and configured to receive the puncturing device and further comprises a sensor positioned along a length of the dilator. When the marker and the sensor are aligned, energy is delivered to the distal tip of the puncturing device.

[0016] With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of certain embodiments of the present device only. Before explaining at least one embodiment of the device in detail, it is to be understood that the device is not limited in its application to the details of construction and the arrangement of the components set forth in the following description or illustrated in the drawings. The device is capable of other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

[0017] **Figure 1** illustrates an embodiment of a system **100** which may be used to gain access to the left atrium through a transseptal puncture. The system **100** comprises a puncturing device **110**, a dilator **120**, a sheath **130** and a generator **140**. The puncturing device **110** comprises an elongate member **111** having a distal region **112** that ends in a distal tip **114**. The distal tip **114** comprises an energy delivery device **116**, such as an electrode, that is configured to deliver energy to a tissue. The puncturing device **110** further comprises a proximal portion **118** that ends in a hub **113** which is connected to the generator **140** via a connector cable **150**. The generator **140** is capable of delivering energy to the puncturing device **110** which travels along the elongate member **111** from the hub **113** to the energy delivery device **116** at the distal tip **114**. The puncturing device **110** is preferably constructed from a conductive material, such as stainless steel or nitinol. The puncturing device **110** may be comprised of a solid, core wire, or a hollow tube, and may end in an atraumatic distal tip **114**. In order to ensure that the energy is delivered to the tissue by the energy delivery device **116**, the puncturing device **110** may be coated in any type of insulating material, such as PTFE (polytetrafluoroethylene), leaving the energy delivery device **116** exposed at the distal tip **114**. A marker **115** may be positioned anywhere along the length of the elongate member **111**, in either the proximal **118** or distal portion **112**. The marker **115** may be a colour band, bar code band, a band with a distinct surface roughness, or a band comprised of or doped with magnetic or conductive material.

[0018] The dilator **120** comprises an elongate member **123** with a proximal portion **122** and a distal portion **124**. The proximal portion **122** of the dilator ends in a hub **126**, while the distal portion **124** tapers down to an open distal tip **128**. A lumen (not shown) extends within the elongate member **123** between the hub **126** and the distal tip **128**. The lumen is sufficiently large enough such that the puncturing device **110** may be inserted into the hub **126** and move through the lumen. In use, the distal tip **114** of the puncturing device **110** extends past the distal tip **128** of the dilator **120**. The dilator **120** may be comprised of a harder material, such as high-density polyethylene (HDPE) or a softer material, for example polyurethane or polyether block amide. Embedded into the elongate member **123** body, in the proximal **122** or distal **124** region is a detector **121** which is able to detect the marker **115** positioned along the length of the elongate member **111** of the puncturing device **110**. The detector **121** may be a colour sensor, barcode reader, light intensity sensor, magnetic sensor, or a capacitance proximity sensor. The detector **121** can be hooked up to the generator **140** via a connector cable **152** that extends from the detector **121** and exits out of the hub **126** of the dilator **120**.

[0019] In use, when the puncturing device **110** is inserted into the dilator **120**, the alignment of the marker **115** and the detector **121** would send a signal to the generator **140** via the connector cable **152** of the dilator **120**, which in turn would enable the delivery of energy from the generator **140** to the puncturing device **110** via the connector cable **150**. If the marker **115** and detector **121** are not aligned, energy delivery is disabled.

[0020] An exemplary method involving the embodiment of the system **100** described above, involves the steps of delivering energy through the energy delivery device **116** to an atrial septum of a patient's heart, advancing the energy delivery device **116** through the puncture and automatically disabling the delivery of energy upon completion of puncture. The steps towards performing the transseptal puncture may include:

(i) gaining access to the vasculature through the groin to the femoral vein and advancing the assembly (i.e., puncturing device **110**, dilator **120** and sheath **130**) into the right atrium of the heart through the inferior vena cava. At this stage, the distal tip **114** of the puncturing device **110** is slightly protruding from the distal tip **128** of the dilator **120** and sheath **130**. The marker **115** of the puncturing device **110** would be aligned with the detector **121** of the dilator **120** which enables the delivery of energy.

(ii) The distal tip **114** of the puncturing device **110** is maneuvered to the target location, for example, the fossa ovalis on the atrial septum. When in position, the user activates energy delivery on the generator **140** which will send energy to the energy delivery device **116**. This energy may be in the high frequency range, such as radiofrequency energy.

(iii) Upon completion of the puncture, the puncturing device **110** is pushed through the puncture into the left atrium. At this point, the marker **115** of the puncturing device **110** and the detector **121** of the dilator **120** are no longer aligned, and the delivery of energy is disabled, automatically shutting off.

(iv) The dilator **120** and sheath **130** are then pushed through the puncture and access to the left atrium is achieved.

[0021] As previously described above, the marker **115** located on the puncturing device **110** may be any type of detectable band. **Figure 2a** illustrates an embodiment of the puncturing device **110** which has a marker **115** comprising a unique colour band. In this embodiment, the colour band may be applied as a spray coating directly to the elongate member **111** or as a heat shrink sleeve on top of the elongate member **111**. A coating of clear electrically insulative material **210** (i.e., such as a clear coat of polytetrafluorethylene (PTFE)) may be applied on top of elongate member **111**, either over just the colour band or the entire length of the elongate member **111**, to ensure that the marker 115 can be optically detected by the colour sensor detector **121** located on the dilator.

[0022] In an alternative embodiment, the marker **115** comprises a unique barcode or Radio Frequency Identification (RFID) code, as illustrated in **Figure 2b**. This may be applied as a heat shrinkable sleeve with a unique barcode on it or a heat shrinkable sleeve of a solid colour may be applied and using a laser, different lines may be ablated into the sleeve. For example, if a blue sleeve was applied to the elongate member **111**, the laser ablation would create white lines onto the sleeve. A clear coat of electrically insulating material **210** may be applied over the elongate member **111** where the marker **115** is located or over its entire length. This would ensure that the barcode is optically detected by the barcode reader on the dilator.

[0023] In some embodiments, the marker **115** comprises a band with a different surface roughness than the elongate member **111**. During manufacturing, the change in surface roughness may be directly applied to the elongate member **111** during the manufacturing process, as seen in **Figure 2c**. Alternatively, the marker **115** may be a band with different surface roughness may be placed over top of the elongate member **111**. The band may be swaged over the elongate member **111** or may be fit over top, either in tight or loose fit. Similarly, to the previous embodiments, a clear layer of electrically insulative material **210** may be applied over the elongate member **111**, over the marker **115** or the entire length of the member **111**, to allow for the detection of light intensity by the sensor in the dilator.

[0024] In another embodiment, the marker **115** on the puncturing device **110** is comprised of a magnetic material. The band may be comprised of a magnetic material, for example a band of any magnetic metal, or may be comprised of a non-metal band that is doped with magnetic material, such as metal doped plastic. For both the magnetic metal band or doped plastic, the marker **115** may be a mechanical fit that is swaged over the elongate member **111**, as illustrated in **Figure 2d(i)**, or the band may be fitted over the elongate member **111**, in a tight or loose fit around the shaft, as illustrated in **Figure 2d(ii)**. The elongate member **111** may have an electrically insulating layer **210** which covers its entire length and may act to confine the band in place. Alternatively, in embodiments that use a doped plastic band as a marker **115**, this may be applied as a heat shrinkable plastic tube doped with magnetic material which can be applied over top of the elongate member **111**.

[0025] In an alternative embodiment, the marker **115** on the puncturing device **110** is comprised of a conductive material. The marker **115** may be a band comprised fully of a conductive material or a non-metal material that has been doped with conductive material (i.e., a doped plastic band). In these embodiments, the band will need to be placed over top of the insulating layer **210** in order to ensure that it communicates with the detector in the dilator and does not interfere with the delivery of energy along the elongate member **111**. For both the conductive metal band or doped plastic band, the marker **115** may be a mechanical fit that is swaged over top the insulating layer **210**, as illustrated in **Figure 2e(i)**, or the band may be fitted over the insulating layer **210** in a tight fit to ensure that the band does not shift, as illustrated in **Figure 2e(ii)**. In an alternate embodiment, the marker **115** may be comprised of a heat shrinkable plastic tube that has been doped with conductive material which can be applied over top of the insulating material **210**.

[0026] In any of the previously described embodiments, the marker **115** may be placed anywhere along the proximal or distal portion of the puncturing device **110** as long as the placement of the marker **115** aligns with the detector **121** in the dilator in a position which would allow the delivery of energy when the puncturing device **110** is in the correct position within the dilator.

[0027] With reference to **Figure 3a**, the dilator **120** comprises a detector **121** which will be able to detect the marker **115** located on the puncturing device **110**. This detection may be used to enable and disable the delivery of energy from the generator to the distal tip of the puncturing device **110**. For example, when the marker **115** and the detector **121** are aligned, energy delivery is enabled; if the marker **115** and the detector **121** are not aligned, energy deliver is disabled. The position of the detector **121** may be anywhere along the dilator **120**. In one embodiment, the detector **121** is positioned on the elongate member **123** of the dilator **120**, in the proximal portion, as seen in **Figure 3a** or it may be positioned in the distal portion (not shown). This embodiment may be ideal as it allows for a tight fit between the detector **121** and marker **115** without the potential interference of blood or fluid. Alternatively, the detector **121** is positioned in the hub **126** of the dilator **120**, as illustrated in **Figure 3b**. The detector **121** is embedded into the wall of the dilator **120** and may comprise a colour sensor, barcode reader, light intensity sensor, magnetic sensor, or spring contacts that close connections in the presence of the conductive ring, for example.

[0028] In some embodiments, the detector **121** may be a colour sensor which would be able to detect the marker **115** band which is a unique colour. For example, the sensor would shine a white light onto the elongate member **111** and would then record the reflected light. The sensor may comprise a red, green, and blue colour filter which would be able to convert the amount of light to current. Additionally, the sensor may also comprise a converter to then convert the current into a voltage that may be sent to the generator. From there, the generator may have a switch, either implemented as hardware (such as a voltage-based switch) or software (such as a computer algorithm). This may then be used to enable or disable the delivery of energy to the puncturing device **110**.

[0029] In an alternative embodiment, the detector **121** may be a barcode reader or a barcode scanner which would be able to read the barcode information on the marker **115** of the puncturing device **110** and send the information to the generator. The scanner may shine a laser onto the barcode on the marker **115** which is reflected off the barcode into a photoelectric cell; light sections will reflect more light than the dark sections. The photoelectric cell may then generate a pattern of "on" or "off" pulses (i.e., "on" would be a light section, "off" would be a dark section). The barcode reader or scanner would then convert this information into a binary code which can be sent back to the generator. This may be used to enable or disable the delivery of energy to the puncturing device **110**.

[0030] In some embodiments, the detector **121** may be a light intensity sensor to detect the amount of light reflected from a surface. In this embodiment, the detector **121** would determine the amount of light reflected from the elongate member **111**, as well as the amount of light reflected from a marker **115** with a rough surface. For example, the detector **121** may be a photoelectric sensor comprising a light source and a receiving element. The light source may direct a beam of light onto the elongate member **111** which will be reflected back to the receiving element and converts it to either an analog (i.e., voltage) or digital (i.e., "on" or "off") output based on the amount of light reflected back. This output may then communicate with the generator to enable or disable energy delivery to the puncturing device **110**. This may be implemented as a hardware switch or a software algorithm.

[0031] In another embodiment, the marker **115** on the puncturing device **110** may comprise a magnetic band and while the detector **121,** to detect magnetic fields, would be placed in the dilator **120**. This type of sensor would detect the magnetic field present in the magnetic band of the device **110**. Generally, if there is a magnetic field, the sensor may output a binary signal which may be used to control the delivery of energy to the puncturing device **110**. For example, if a magnetic field is present (i.e., the marker **115** is aligned with the detector **121**) the sensor may output an "on" signal. In contrast, if no magnetic field is present, the sensor may output an "off" signal. These signals may be communicated back to the generator to control the delivery of energy.

[0032] In some embodiments, the marker **115** may comprise a metal band. The detector **121** in the dilator **120** may be in the form of a capacitance proximity sensor. This type of sensor world work similar to the magnetic sensor, detecting a metal (magnetic or non-magnetic) band along the puncture device **110**. When the marker **121** is not aligned with the detector **121**, the detector **121** will not sense the band. This would signal the generator to disable the delivery of energy to the puncturing device **110**. However, when the marker **115** is positioned such that it is detected by the capacitance proximity sensor, it will elicit a response from the generator to enable the delivery of energy to the puncturing device **110**. This may be implemented as a software algorithm, for example if there the marker **115** is detected, enable energy delivery; if not, disable energy delivery.

[0033] For the detector **121** to communicate with the generator, an insulative connector cable **152** will need to run from the detector **121** to the generator. This will signal the generator to enable the delivery of energy when the marker **115** and detector **121** are aligned or disable the delivery of energy when they are not aligned.

[0034] In an alternative embodiment, the puncturing device **110** comprises the detector **121** while the dilator **120** comprises the marker **115**. An example of this embodiment is illustrated in **Figure 3c**. Similarly, to the previously described embodiments, the marker **115** may comprise a colour band, bar code band, a band with a distinct surface roughness, or a band comprised of or doped with magnetic or conductive material, for example. These bands may be embedded into the dilator **121**. The detector **121** may be any sensor with the ability to detect the maker **115**, such as a colour sensor, barcode reader, light intensity sensor, magnetic sensor, or a capacitance proximity sensor. For some markers **115**, the material of the dilator may need to be comprised of a transparent material such that the optical detectors **121** would be able to detect when the marker **115** has been aligned. For example, the colour band and colour sensor, the barcode marker and barcode reader, as well as the marker with a surface roughness and light intensity sensor, use light transmission and receiving to detect and thus would need a transparent material. The marker **115** and detector **121** may be located anywhere along the length of the dilator **120** or puncturing device **110** (i.e., proximal or distal portions), if they are index to the proper locations for the automatic shut-off to function. For these embodiments, the connector cable **152** is insulated and runs along the length of the elongate member **111**, exiting out of the hub **113** of the puncturing device **110**. The connector cable **152** may be contained with the cable used to deliver energy to the puncturing device **110** so that the user would only need to plug in one cable to the generator rather than the two cables (i.e., one from the puncturing device **110** and one from the dilator **120**) of the previously described embodiments.

[0035] **Figure 4a – 4c** illustrate the puncturing device **110**, comprising a marker **115**, and the dilator **120**, comprising a detector **121**, as the puncturing device **110** moves along the length of the dilator **120**. **Figure 4a** illustrates the puncturing device **110** in a position where the energy delivery device **116** is still contained within the dilator **120**, prior to puncture. At this stage, the marker **115** and detector **121** are not aligned, and therefore energy is not able to be delivered to the energy delivery device **116**. Energy delivery is enabled when the marker **115** and detector **121** are aligned, this would occur when the energy delivery device **116** is slightly protruding from distal tip **128** of the dilator **121** (**Figure 4b**). When energy delivery is enabled, this may be signalled to the user via a sound or prompt on the generator. The user will then activate energy delivery to create a puncture in the tissue. Once the puncture is complete, the puncturing device **110** moves through the puncture, such that the energy delivery device **116** moves past the distal tip **128** of the dilator **121**. In turn, the marker **115** and the detector **121** are no longer aligned (**Figure 4c**). As a result, energy delivery to the puncturing device **110** will be disabled, automatically shutting off.

[0036] With reference now to **Figure 5a**, in an alternative embodiment, the dilator **120** is the device that delivers energy from the generator to the energy delivery device **116** at the distal tip **114** of the puncturing device **110**. The dilator **120** may be comprised of an electrically insulative material with a conductive plate **510** embedded into the sidewall of said dilator along the member **123**, such that the plate **510** may contact the puncturing device **110**. The dilator **120** may be comprised of a harder material, such as high-density polyethylene (HDPE) or a softer material, for example polyurethane or polyether block amide. The conductive plate **510** can deliver energy from the generator, via an insulated connecting cable **154**, which exits the dilator hub **126** and connects to the generator. The puncturing device **110** comprises a conductive band **520** which may be composed of a non-conductive material doped with conductive material or a band comprised entirely of conductive material. The band **520** may be fitted via a mechanical fit that is swaged over the elongate member **111**, or the band **520** may be fitted over the elongate member **111**. The elongate member **111** of the puncturing device **110** may be comprised of a conductive material, such as a conductive hypotube or shaft, with an insulative coating **210** covering the entire elongate member **111**, leaving the conductive band **520** exposed such that it is able to contact the conductive plate **510** of the dilator **120**, as illustrated in **Figure 5b**. The layer of insulation **210** may be one of many biocompatible dielectric materials, including, but not limited to, polytetrafluoroethylene (PTFE, Teflon®), parylene, polyimides, polyethylene, terephthalate (PET), polyether block amide (PEBAX®), and polyetheretherketone (PEEK™), or any combinations thereof. Alternatively, the elongate member may be manufactured such that it has a larger outer diameter in one section. This section would be exposed (i.e., not covered with insulative material) such that it is able to contact the conductive plate **510**. In some embodiments, the elongate member **111** may be comprised of a non-conductive material proximal **530** to the conductive band **520**, and a conductive material distal **540** of the conductive band **520** that has an insulative coating **210** over top (**Figure 5c**). In an alternative embodiment, the conductive band **520** may be part of the distal **540** elongate member **111**. For example, the outer diameter of the elongate member **111** may be larger such that it contacts the conductive plates **510**. The conductive band **520** is in electrical communication with the energy delivery device **116** of the puncturing device **110**. Energy delivery would only be enabled when the conductive plate **510** of the dilator **120** is in contact with the conductive band **520** of the puncturing device. When the energy delivery device **116** is slightly protruding from the distal tip **128** of the dilator **120**, the conductive band **520** and plate **510** will be in contact with one another. This would allow the energy to flow from the generator to the conductive plate **510** of the dilator **120**, and when in contact with the conductive band **520**, to the energy delivery device **116** of the puncturing device **110**. Upon completion of the puncture of tissue, the puncturing device **110** moves forward through the puncture and the contact between the conductive plate **510** and conductive band **520** is no longer present, disabling the delivery of energy.

[0037] Further Examples

1) An assembly to create a puncture in a tissue, comprising:
   A puncturing device comprising an elongate member having a distal tip configured to deliver energy to the tissue, creating the puncture;
   The puncturing device further comprises a marker positioned along the elongate member;
   A dilator wherein the dilator comprises a lumen extending from a proximal portion to a distal portion and configured to receive the puncturing device; and,
   The dilator further comprises a detector positioned along a length of the dilator;
   Whereby when the marker and the detector are aligned, energy is delivered to the distal tip of the puncturing device.
2) The assembly of example 1, wherein the marker is a colour band and the detector is a colour sensor.
3) The assembly of example 2, wherein the colour band comprises a spray coating.
4) The assembly of example 2, wherein the colour band comprises a sleeve of different colour positioned overtop the elongate member.
5) The assembly of any one of examples 3 or 4, wherein the elongate member comprises a coating of insulative material.
6) The assembly of example 5, wherein the coating of insulative material comprises a portion of clear coating positioned overtop the colour band.
7) The assembly of example 5, wherein the coating of insulative material comprises a clear coating extending the entire length of the elongate member.

8) The assembly of example 1, wherein the marker is a band with a barcode and the detector is a barcode reader.
9) The assembly of example 8, wherein the band comprises a sleeve positioned overtop the elongate member.
10) The assembly of example 9, wherein the sleeve comprises a unique barcode.
11) The assembly of example 9, wherein the sleeve is a solid color and an etching of lines is ablated onto the sleeve.
12) The assembly of any one of examples 9 to 11, wherein the elongate member comprises a coating of insulative material.
13) The assembly of example 12, wherein the coating of insulative material comprises a portion of clear coating positioned overtop of the band.
14) The assembly of example 12, wherein the coating of insulative material comprises a clear coating extending the entire length of the elongate member.
15) The assembly of example 1, wherein the marker is a band of a distinct surface roughness and the detector is a light intensity sensor.
16) The assembly of example 15, wherein the distinct surface roughness is applied directly to a surface of the elongate member.
17) The assembly of example 15, wherein the band is a separate piece, positioned overtop the elongate member.
18) The assembly of example 17, wherein the band is swaged over the elongate member.
19) The assembly of example 17, wherein the band is fit over top of the elongate member.
20) The assembly of any one of examples 16 to 19, wherein the elongate member comprises a coating of insulative material.
21) The assembly of example 20, wherein the coating of insulative material comprises a portion of clear coating positioned overtop of the band.
22) The assembly of example 20, wherein the coating of insulative material comprises a clear coating extending the entire length of the elongate member.

23) The assembly of example 1, wherein the marker is a magnetic band and the detector is a magnetic sensor.
24) The assembly of example 23, wherein the marker is positioned overtop the elongate member.
25) The assembly of example 23, wherein the marker is swaged over the elongate member.
26) The assembly of example 23, wherein the marker is comprised of a metal band.
27) The assembly of example 23, wherein the marker is comprised of a doped plastic band.
28) The assembly of any one of examples 24 to 27, wherein the elongate member comprises a coating of insulative material.
29) The assembly of example 27, wherein the doped plastic band comprises a heat shrinkable plastic tube doped with a magnetic material.
30) The assembly of a example 1, wherein the marker is a metal band and the detector is a capacitance proximity sensor.
31) The assembly of example 30, wherein the marker is positioned overtop of the elongate member.
32) The assembly of example 31, wherein the metal band is composed of a magnetic material.
33) The assembly of example 31, wherein the metal band is composed of a non-magnetic material.
34) The assembly of any one of examples 1 to 33, wherein the detector is embedded into a wall of the dilator.
35) An assembly to create a puncture in a tissue, comprising:

    A puncturing device comprising an elongate member having a distal tip configured to deliver energy to the tissue, creating the puncture;

    The puncturing device further comprises a detector positioned along the elongate member;

A dilator wherein the dilator comprises a lumen extending from a proximal portion to a distal portion and configured to receive the puncturing device; and,

The dilator further comprises a marker positioned along a length of the dilator;

Whereby when the marker and the detector are aligned, energy is delivered to the distal tip of the puncturing device.

36) The assembly of example 35, wherein the marker is a colour band and the detector is a colour sensor.

37) The assembly of example 35, wherein the marker is a band with a barcode and the detector is a barcode reader.

38) The assembly of example 35, wherein the marker is a band of distinct surface roughness and the detector is a light intensity sensor.

39) The assembly of any one of examples 35 to 37, wherein the dilator comprises a portion of transparent material where the marker is located.

40) The assembly of example 35, wherein the marker is a magnetic band and the detector is a magnetic sensor.

41) The assembly of example 35, wherein the marker is a metallic band and the detector is a capacitance proximity sensor.

42) An assembly to create a puncture in a tissue, comprising:

A puncturing device comprising an elongate member having a distal tip configured to deliver energy to the tissue, creating the puncture;

The puncturing device further comprising a conductive band;

A dilator, wherein the dilator comprises a lumen extending from a proximal portion to a distal portion configured to receive the puncturing device; and,

The dilator further comprises a conductive plate embedded into a side wall of the lumen;

Whereby when the conductive band of the puncturing device is proximate the conductive plate of the dilator, energy is delivered to the distal tip of the puncturing device.

43) The assembly of example 42, wherein the dilator is composed of an electrically insulative material.

44) The assembly of example 43, wherein the dilator is composed of one of or a combination of high-density polyethylene, polyurethane, or polyether block amide.

45) The assembly of example 42, wherein the dilator further comprises an insulative connection cable that runs from a proximal end of the dilator to the conductive plate.

46) The assembly of example 42, wherein the conductive band is comprised of a non-conductive material doped with a conductive material.

47) The assembly of example 42, wherein the conductive band is comprised entirely of a conductive material.

48) The assembly of any one of examples 46 or 47, wherein the conductive band may be swaged over the elongate member.

49) The assembly of any one of examples 46 or 47, wherein the conductive band is fitted over the elongate member.

50) The assembly of example 42, wherein the elongate member is comprised of a conductive material with an insulative coating extending over the entire length of the elongate member, and wherein the conductive band is positioned such that it is exposed from the insulative coating.

51) The assembly of example 50, wherein the conductive band is a portion of the elongate member that has an increased diameter such that it contacts the conductive plate of the dilator.

52) A method for creating a puncture in a septum of a heart using a puncture device with a marker positioned along a length of the puncture device and a dilator with a detector positioned along a length of the puncture device,

wherein alignment of the marker and the detector would enable energy delivery, the method comprising the steps of:

Introducing an assembly of the puncture device and the dilator into a right atrium of the heart, wherein the puncturing device is received within the dilator such that the marker and the detector are not aligned;

Locating a target location on the septum with a distal tip of the assembly;

Aligning the marker and the detector to enable energy delivery to a distal tip of the puncture device; and,

Advancing the puncture device such that the distal tip enters the left atrium, and whereby the marker and the detector are no longer align, disabling energy delivery.

[0038] It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination.

[0039] Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the broad scope of the appended claims. All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention.

We claim:

1) An assembly to create a puncture in a tissue, comprising:
   A puncturing device comprising an elongate member having a distal tip configured to deliver energy to the tissue, creating the puncture;
   The puncturing device further comprises a marker positioned along the elongate member;
   A dilator wherein the dilator comprises a lumen extending from a proximal portion to a distal portion and configured to receive the puncturing device; and,
   The dilator further comprises a detector positioned along a length of the dilator;
   Whereby when the marker and the detector are aligned, energy is delivered to the distal tip of the puncturing device.
2) The assembly of claim 1, wherein the marker is a colour band and the detector is a colour sensor.
3) The assembly of claim 2, wherein the colour band comprises a spray coating.
4) The assembly of claim 2, wherein the colour band comprises a sleeve of different colour positioned overtop the elongate member.
5) The assembly of any one of claims 3 or 4, wherein the elongate member comprises a coating of insulative material.
6) The assembly of claim 5, wherein the coating of insulative material comprises a portion of clear coating positioned overtop the colour band.
7) The assembly of claim 5, wherein the coating of insulative material comprises a clear coating extending the entire length of the elongate member.
8) The assembly of claim 1, wherein the marker is a band with a barcode and the detector is a barcode reader.
9) The assembly of claim 8, wherein the band comprises a sleeve positioned overtop the elongate member.
10) The assembly of claim 9, wherein the sleeve comprises a unique barcode.

11) The assembly of claim 9, wherein the sleeve is a solid color and an etching of lines is ablated onto the sleeve.

12) The assembly of any one of claims 9 to 11, wherein the elongate member comprises a coating of insulative material.

13) The assembly of claim 12, wherein the coating of insulative material comprises a portion of clear coating positioned overtop of the band.

14) The assembly of claim 12, wherein the coating of insulative material comprises a clear coating extending the entire length of the elongate member.

15) The assembly of claim 1, wherein the marker is a band of a distinct surface roughness and the detector is a light intensity sensor.

16) The assembly of claim 15, wherein the distinct surface roughness is applied directly to a surface of the elongate member.

17) The assembly of claim 15, wherein the band is a separate piece, positioned overtop the elongate member.

18) The assembly of claim 17, wherein the band is swaged over the elongate member.

19) The assembly of claim 17, wherein the band is fit over top of the elongate member.

20) The assembly of any one of claims 16 to 19, wherein the elongate member comprises a coating of insulative material.

21) The assembly of claim 20, wherein the coating of insulative material comprises a portion of clear coating positioned overtop of the band.

22) The assembly of claim 20, wherein the coating of insulative material comprises a clear coating extending the entire length of the elongate member.

23) The assembly of claim 1, wherein the marker is a magnetic band and the detector is a magnetic sensor.

24) The assembly of claim 23, wherein the marker is positioned overtop the elongate member.

25) The assembly of claim 23, wherein the marker is swaged over the elongate member.

26) The assembly of claim 23, wherein the marker is comprised of a metal band.

27) The assembly of claim 23, wherein the marker is comprised of a doped plastic band.

28) The assembly of any one of claims 24 to 27, wherein the elongate member comprises a coating of insulative material.

29) The assembly of claim 27, wherein the doped plastic band comprises a heat shrinkable plastic tube doped with a magnetic material.

30) The assembly of a claim 1, wherein the marker is a metal band and the detector is a capacitance proximity sensor.

31) The assembly of claim 30, wherein the marker is positioned overtop of the elongate member.

32) The assembly of claim 31, wherein the metal band is composed of a magnetic material.

33) The assembly of claim 31, wherein the metal band is composed of a non-magnetic material.

34) The assembly of any one of claims 1 to 33, wherein the detector is embedded into a wall of the dilator.

35) An assembly to create a puncture in a tissue, comprising:

A puncturing device comprising an elongate member having a distal tip configured to deliver energy to the tissue, creating the puncture;

The puncturing device further comprises a detector positioned along the elongate member;

A dilator wherein the dilator comprises a lumen extending from a proximal portion to a distal portion and configured to receive the puncturing device; and,

The dilator further comprises a marker positioned along a length of the dilator;

Whereby when the marker and the detector are aligned, energy is delivered to the distal tip of the puncturing device.

36) The assembly of claim 35, wherein the marker is a colour band and the detector is a colour sensor.

37) The assembly of claim 35, wherein the marker is a band with a barcode and the detector is a barcode reader.

38) The assembly of claim 35, wherein the marker is a band of distinct surface roughness and the detector is a light intensity sensor.

39) The assembly of any one of claims 35 to 37, wherein the dilator comprises a portion of transparent material where the marker is located.

40) The assembly of claim 35, wherein the marker is a magnetic band and the detector is a magnetic sensor.

41) The assembly of claim 35, wherein the marker is a metallic band and the detector is a capacitance proximity sensor.

42) An assembly to create a puncture in a tissue, comprising:

A puncturing device comprising an elongate member having a distal tip configured to deliver energy to the tissue, creating the puncture;

The puncturing device further comprising a conductive band;

A dilator, wherein the dilator comprises a lumen extending from a proximal portion to a distal portion configured to receive the puncturing device; and,

The dilator further comprises a conductive plate embedded into a side wall of the lumen;

Whereby when the conductive band of the puncturing device is proximate the conductive plate of the dilator, energy is delivered to the distal tip of the puncturing device.

43) The assembly of claim 42, wherein the dilator is composed of an electrically insulative material.

44) The assembly of claim 43, wherein the dilator is composed of one of or a combination of high-density polyethylene, polyurethane, or polyether block amide.

45) The assembly of claim 42, wherein the dilator further comprises an insulative connection cable that runs from a proximal end of the dilator to the conductive plate.

46) The assembly of claim 42, wherein the conductive band is comprised of a non-conductive material doped with a conductive material.

47) The assembly of claim 42, wherein the conductive band is comprised entirely of a conductive material.

48) The assembly of any one of claims 46 or 47, wherein the conductive band may be swaged over the elongate member.

49) The assembly of any one of claims 46 or 47, wherein the conductive band is fitted over the elongate member.

50) The assembly of claim 42, wherein the elongate member is comprised of a conductive material with an insulative coating extending over the entire length of the elongate member, and wherein the conductive band is positioned such that it is exposed from the insulative coating.

51) The assembly of claim 50, wherein the conductive band is a portion of the elongate member that has an increased diameter such that it contacts the conductive plate of the dilator.

52) A method for creating a puncture in a septum of a heart using a puncture device with a marker positioned along a length of the puncture device and a dilator with a detector positioned along a length of the puncture device, wherein alignment of the marker and the detector would enable energy delivery, the method comprising the steps of:

Introducing an assembly of the puncture device and the dilator into a right atrium of the heart, wherein the puncturing device is received within the dilator such that the marker and the detector are not aligned;

Locating a target location on the septum with a distal tip of the assembly;
Aligning the marker and the detector to enable energy delivery to a distal tip of the puncture device; and,
Advancing the puncture device such that the distal tip enters the left atrium, and whereby the marker and the detector are no longer align, disabling energy delivery.

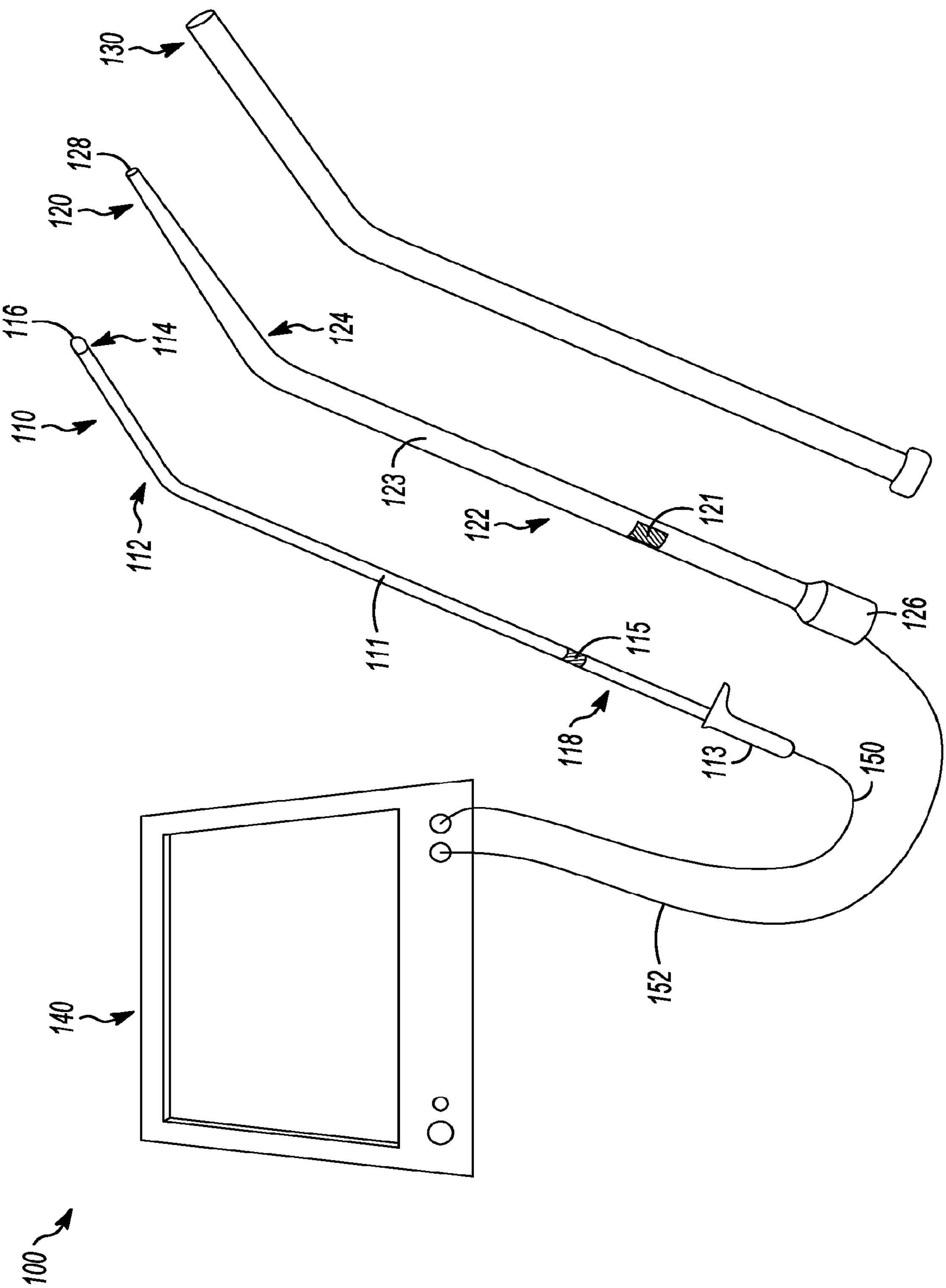
130
128
120
116
114
124
110
123
122
121
112
111
115
126
118
113
150
140
152
100

FIG. 1

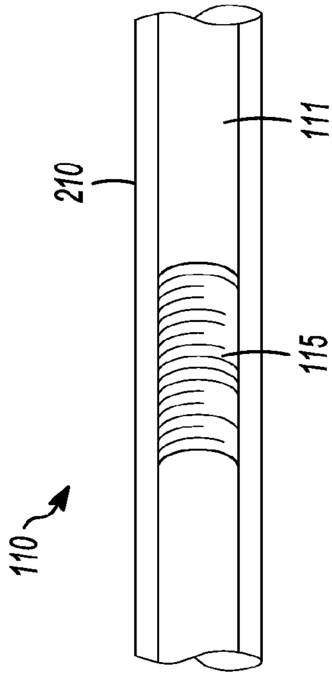

FIG. 2B

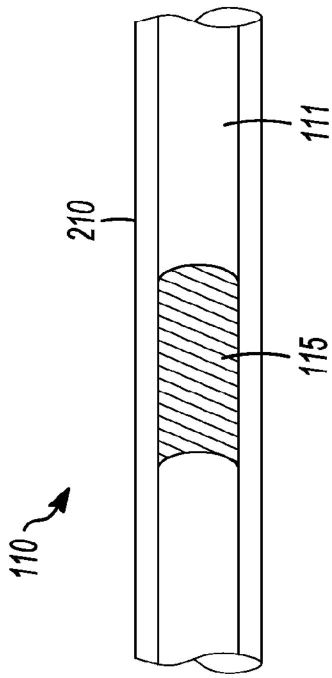

FIG. 2A

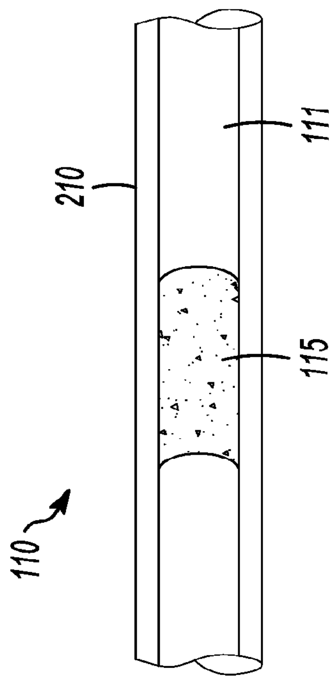

FIG. 2C

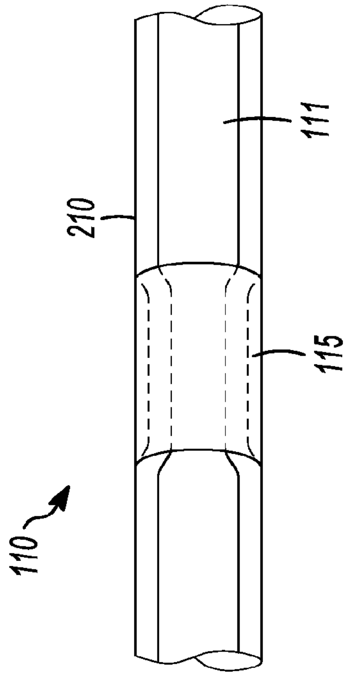

FIG. 2E(i)

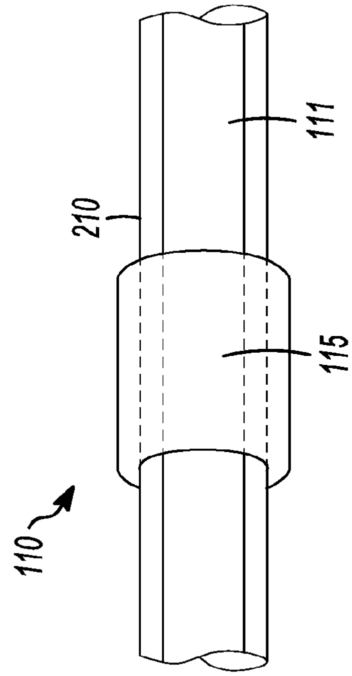

FIG. 2E(ii)

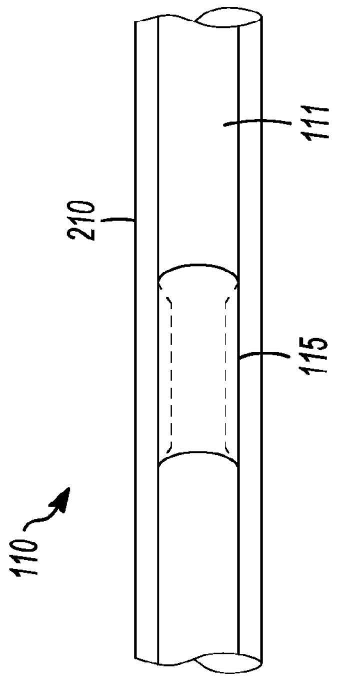

FIG. 2D(i)

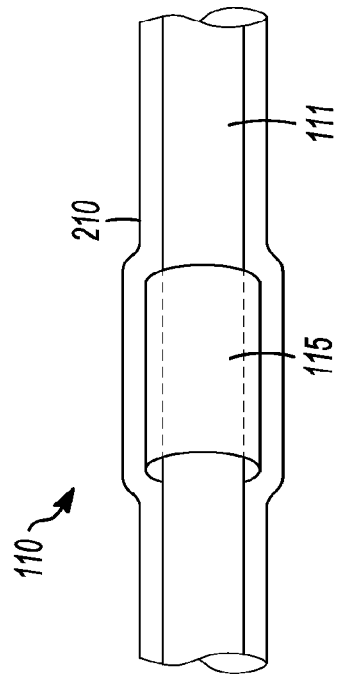

FIG. 2D(ii)

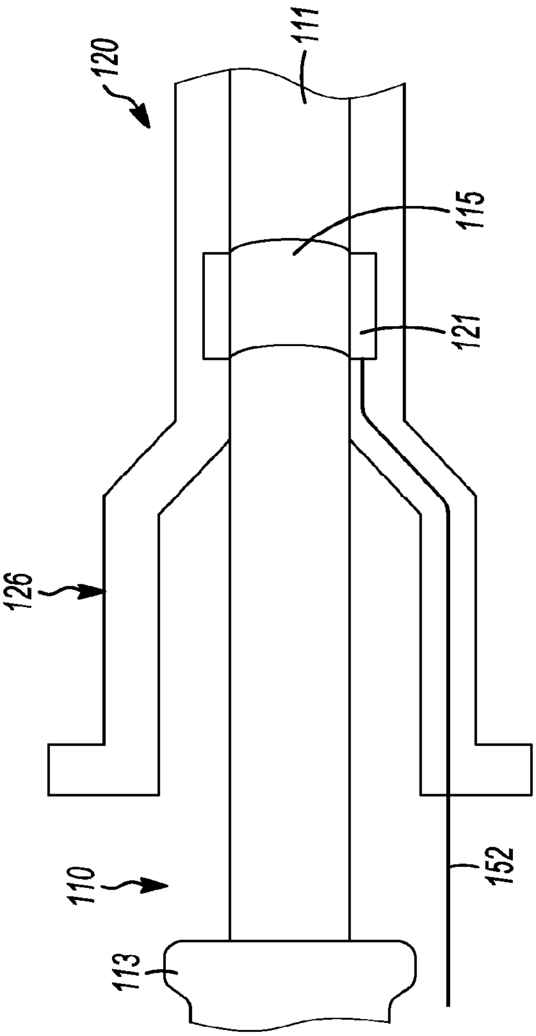

FIG. 3A

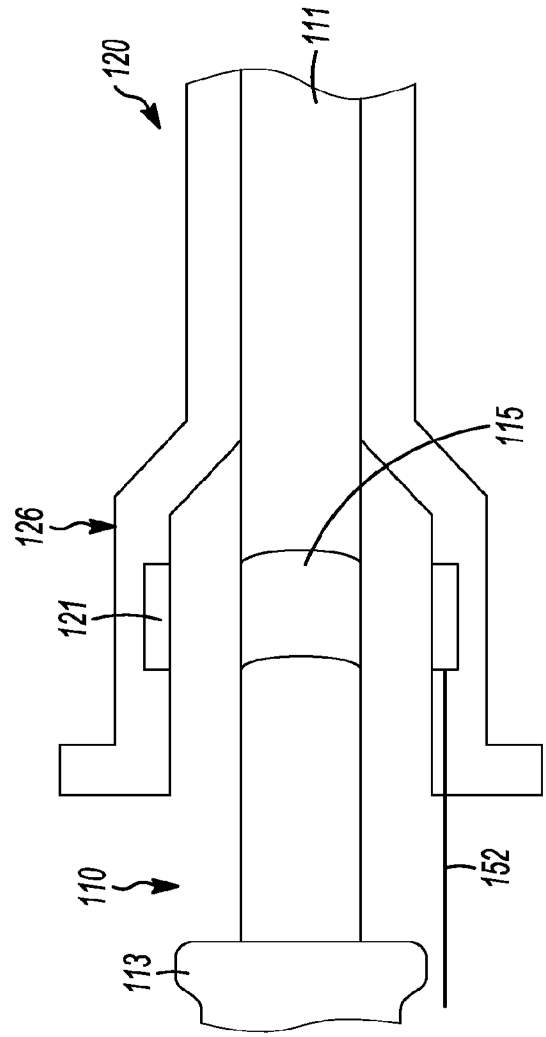

FIG. 3B

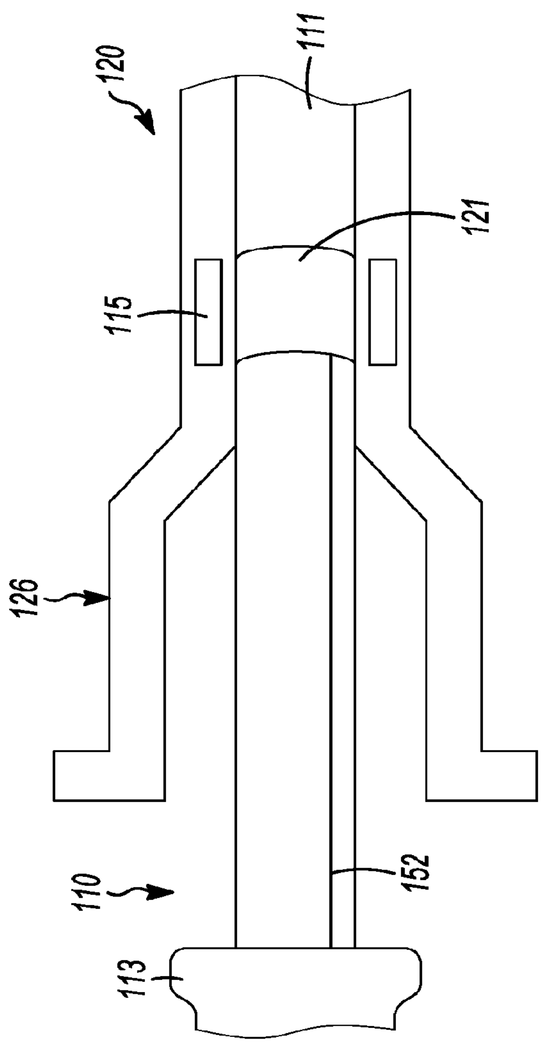

FIG. 3C

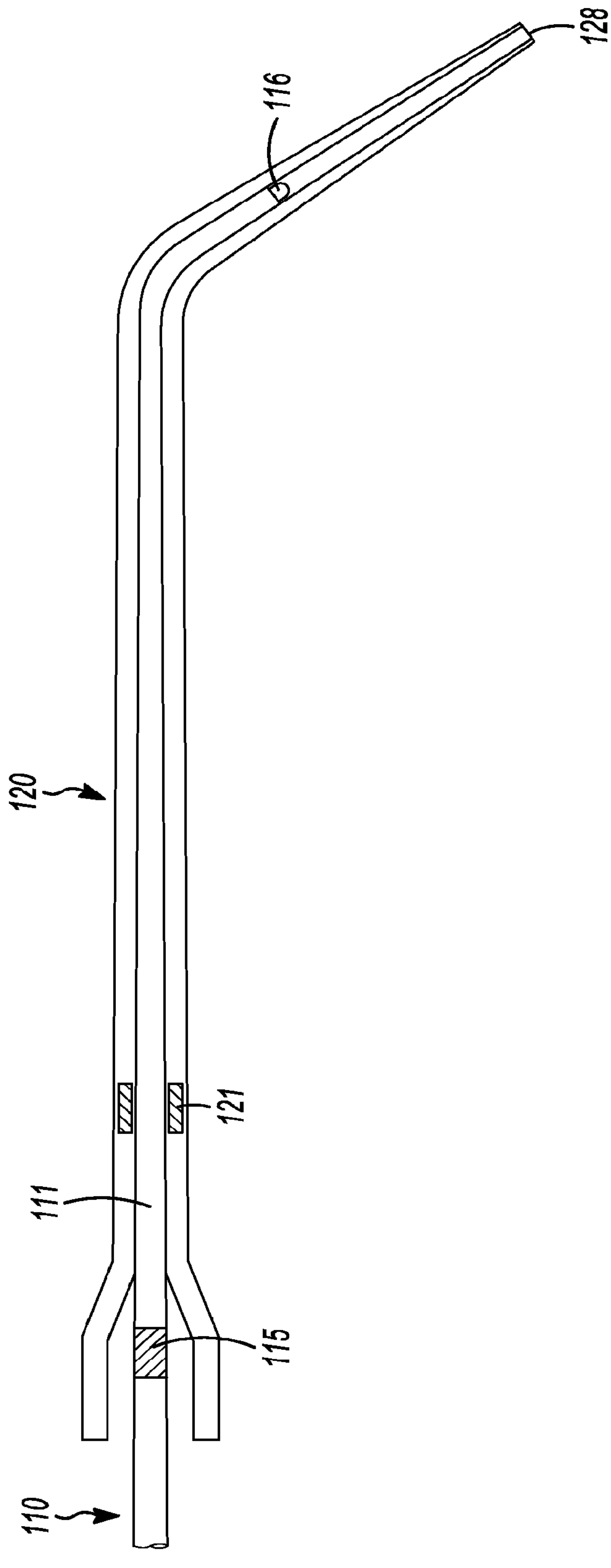

FIG. 4A

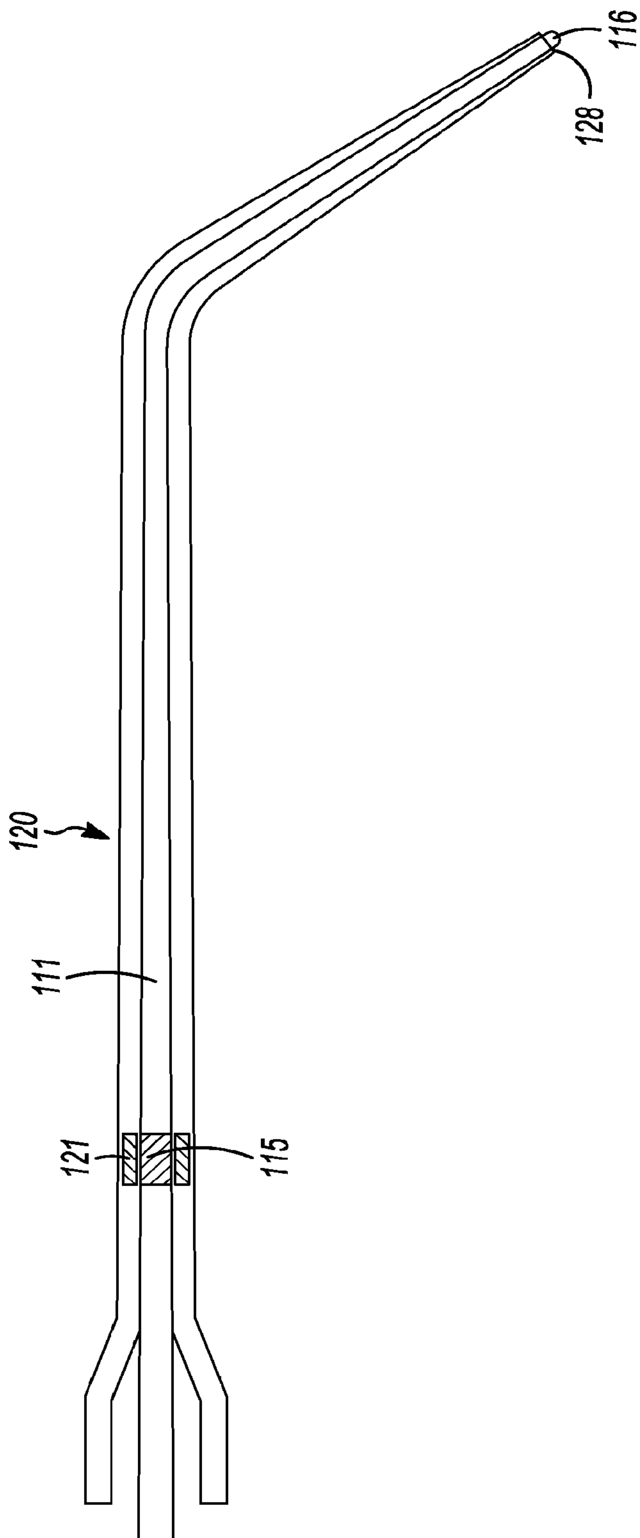

FIG. 4B

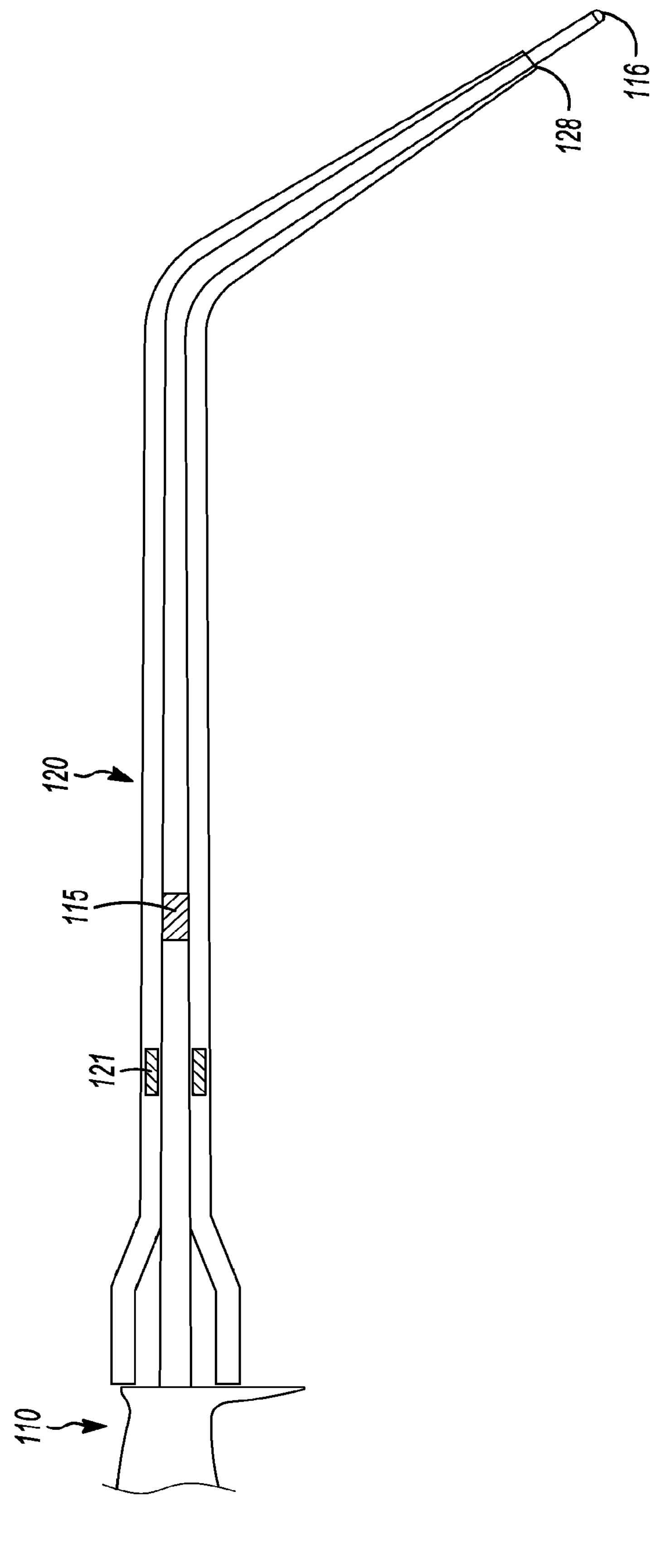

FIG. 4C

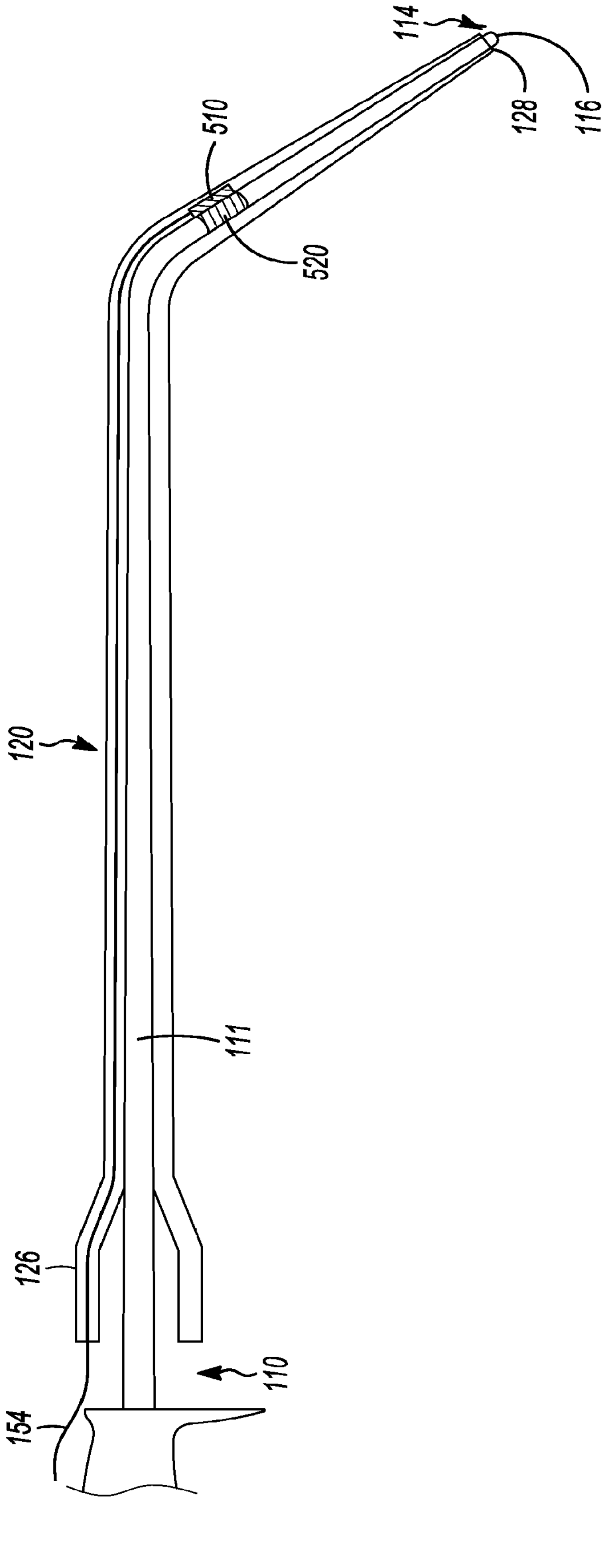

FIG. 5A

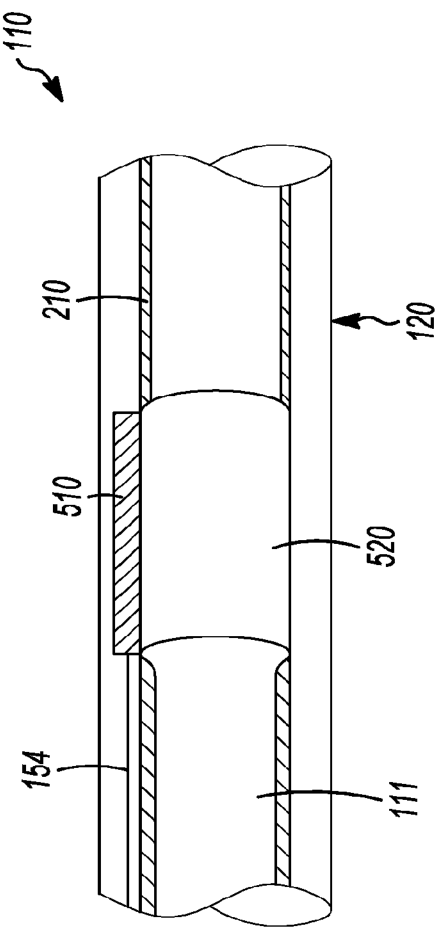

FIG. 5B

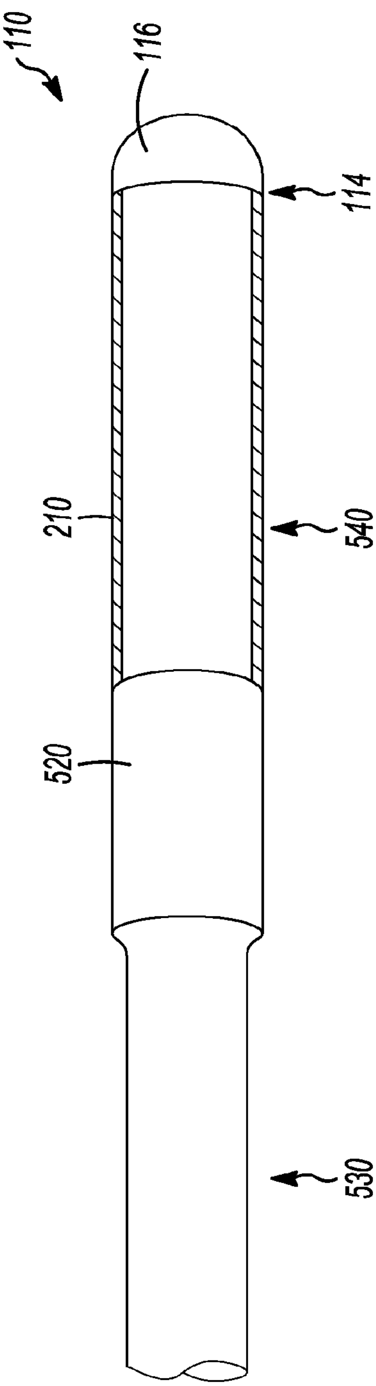

FIG. 5C

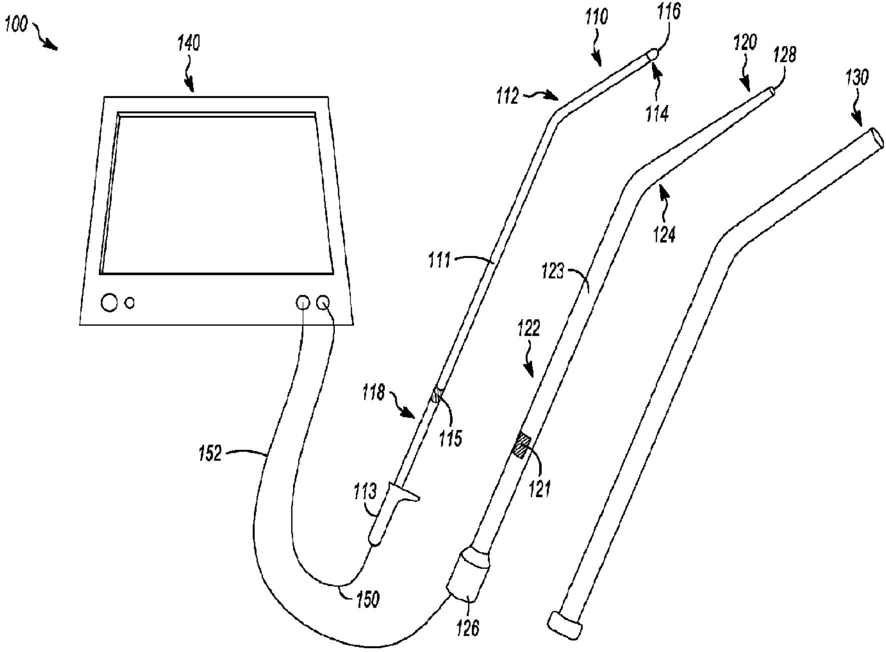
100
140
110
116
120
128
130
112
114
124
111
123
122
118
115
152
121
113
150
126

FIG. 1