



(51) International Patent Classification:

A61B 18/14 (2006.01) *A61B 34/20* (2016.01)
A61B 5/06 (2006.01) *A61M 25/01* (2006.01)
A61B 18/04 (2006.01) *A61M 25/095* (2006.01)

(21) International Application Number:

PCT/US2021/045666

(22) International Filing Date:

12 August 2021 (12.08.2021)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

63/107,968 30 October 2020 (30.10.2020) US

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(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN,

HR, HU, ID, IL, IN, IR, IS, IT, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: ELECTROMAGNETIC SENSING FOR USE WITH ABLATION TREATMENT

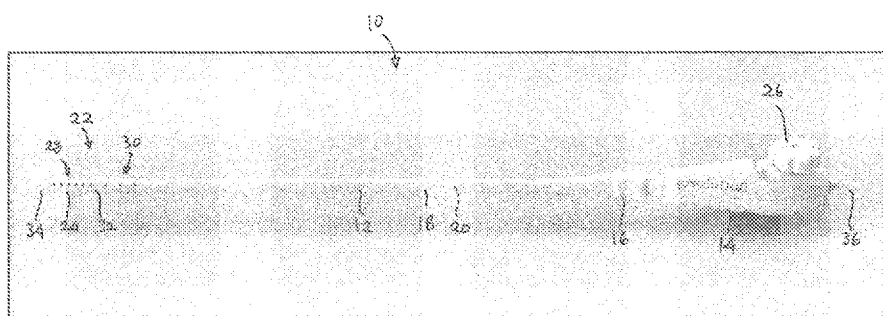


FIG. 1

(57) **Abstract:** Electromagnetic sensing for use with ablation treatment devices are described. Generally, an elongate body may be configured for introduction into an esophageal lumen and a distal portion may be pivotably coupled to the elongate body such that actuation of the distal portion reconfigures the distal portion within a plane relative to the elongate body. The elongate body may define one or more openings along the distal portion and which are in fluid communication with a fluid port. A sensor may also be positioned near or at a distal end of the distal portion where the sensor is configured to communicate with an electromagnetic navigational system to determine a distance to an ablation catheter.



ELECTROMAGNETIC SENSING FOR USE WITH ABLATION TREATMENT

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority to U.S. Prov. 63/107,968 filed
5 October 30, 2020, which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates generally to treatment devices having sensing
capabilities. In particular, the present invention is related to instruments which can be
10 tracked via electromagnetic sensing mechanisms.

BACKGROUND OF THE INVENTION

[0003] Atrial fibrillation affects more than 33 million people worldwide with
millions each year being diagnosed. A common treatment option for atrial fibrillation is
15 catheter ablation where a physician uses various modalities of energy delivered from a
catheter to ablate cells within the heart intended to restore normal heart rhythm.

[0004] When performing catheter ablation, collateral damage can occur to adjacent
organs and cells not intended for ablation. Catheter ablation for atrial fibrillation and other
arrhythmias occurs inside the left atrium and other regions of the heart or vascular system.
20 The posterior wall of the left atrium and other regions of the heart or vascular system may
be in close vicinity and often in direct contact with the esophagus. When ablating the
posterior wall of the left atrium or other regions of the heart or vascular system it is not
uncommon for energy to pass beyond the heart wall or the vascular system and reach the
esophagus and cause thermal damage to the esophageal cells.

[0005] Physicians performing catheter ablation on patients with atrial fibrillation or
other arrhythmias use a variety of diagnostic and ablation catheters to diagnose, map, and
ablate areas inside the heart. These catheters can be tracked using current electromagnetic
(EM) systems. In simple terms, these EM systems comprise an electromagnetic field
generator (to create the sensing field), sensors that can be picked up within the field,
30 fiducial markers to create reference points, and software that communicates the locations of
the sensors. The sensors are placed on the catheters thereby providing location information

to the physician.

[0006] A rare, but potentially deadly complication of catheter ablation is thermal injury from the ablation energy radiating out and causing injury to the esophagus.

Physicians try to mitigate the issue through monitoring of the temperature inside the
5 esophagus, or with use of devices designed to deviate the esophagus. Some deflection
devices that utilize suction along with deflection have shown promise.

[0007] Accordingly, there is a need for a system which would enable the user to
safely move the esophagus as well as know its location in relation to the ablation catheter
in order to safely perform catheter ablation, for example within the left atrium or other
10 regions of the heart or vascular system.

BRIEF SUMMARY OF THE INVENTION

[0008] Devices and methods are described for the prevention of thermal damage to
the esophagus during an ablation treatment, e.g., within the heart or vascular system.

15 Generally, communication between an ablation catheter inside the left atrium or other
regions of the heart or vascular system and an esophageal instrument may provide an
indication that ablation energy from the ablation catheter may be too close to the
esophageal tissue.

[0009] A first instrument such as an endoscopic instrument may be configured to
20 provide for detection of its location within the body and a second instrument such as an
ablation catheter may also be configured to provide for detection of its location within the
body. An ablation catheter may be advanced intravascularly inside the left atrium or other
regions of the heart or vascular system, and the endoscopic device may be advanced per-
orally inside the esophagus of the patient and into proximity of the ablation catheter. A
25 navigation software system may be used to determine the locations of each device relative
to one another and provide this information to the user.

[0010] One example of a navigation and mapping system which may be used with
the systems described here may include a three-dimensional system such as but not limited
to CARTO® System (Biosense Webster, Inc., Irvine, CA) which can be used to provide the
30 user with real-time information of the location of instruments within the body, such as the
heart or vascular system. The CARTO® System utilizes an electromagnetic field
generated outside of the patient body that communicates with one or more sensors typically
placed near the tip of the device which is inserted into the patient body. The sensors

communicate their location within the electromagnetic field and the software displays their location often within an anatomical computer rendering of the organ.

[0011] One example of an instrument may incorporate a sensor into an endoscopic instrument having an elongate body which is advanceable into the patient body per-orally through the mouth or through the nose and at least partially into the esophagus. A handle assembly may incorporate an actuator such as a knob or lever which may be articulated by the user to reconfigure a distal portion of the body in a number of different configurations. The handle assembly may also incorporate at least one port through which a lumen may extend through the handle assembly and through the body to fluidly communicate with one or more openings defined along the distal portion. The elongate body may be further comprised of a sheath which extends over an underlying structure attached to the handle assembly and which provides structural support to the body such that the body may be advanced into the and through the esophagus or other body lumen.

[0012] The sensor positioned near or at the distal end of the elongate body may incorporate at least a single sensor although any number of additional sensors may be incorporated along the body. A second instrument, e.g., ablation catheter, which may be used in a corresponding manner with the instrument may also incorporate at least a single sensor near or at its distal tip. Any number of additional instruments may also be used in combination with instrument and each additional instrument may incorporate at least a single sensor as well to be used in a corresponding manner with the instrument.

[0013] During use, the elongate body may be advanced per-orally into the esophagus such that the distal member is positioned within the esophagus adjacent to the left atrium, or other regions of the heart or vascular system of the patient. The suction force may be optionally actuated such that the esophageal tissue surrounding the distal and proximal openings may be adhered to the outer surface of the distal portion of the elongate body.

[0014] The relative distance between the tip of the ablation catheter and sensor located on the elongate body may be determined and monitored by the controller prior to and/or during an ablation treatment. With a threshold distance between the ablation catheter and sensor predetermined, e.g., 5 mm to 10 mm, or any selected distance as determined by the user, the ablation catheter may be used to deliver ablation energy for tissue treatment. In the event that the ablation catheter and sensor are moved too close to one another within the threshold distance, an indication may be provided by a controller to the user that the ablation catheter may be too close to the esophageal tissue such that the

ablation energy from within the left atrium or other regions of the heart or vascular system may be conducted through the tissue and inadvertently damage the adjacent esophageal tissue.

5 **[0015]** In the event that the ablation catheter and esophageal tissue are determined to be too close to one another, the controller may be programmed to provide the alert to the user and/or optionally automatically stop the ablation catheter to prevent any esophageal tissue damage. The user may also actuate the knob or lever on the handle assembly to reconfigure the distal portion to rotate in order to reposition a portion of the esophagus away from the exterior of the heart or vascular system such that a larger gap is formed
10 between the two. The distal portion may be actuated while the surrounding esophageal tissue is adhered to the outer surface of the elongate body via a suction force or with the suction force turned off although having the esophageal tissue adhered to the distal portion when deflected can help ensure that the gap is formed between the esophagus and heart tissue or vascular system.

15 **[0016]** While the distal portion may be actuated manually by the user, the distal portion in other variations may be actuated automatically by the controller upon detecting that the ablation catheter and elongate body are too close to one another. In yet another variation, other sensors such as a temperature sensor may be optionally incorporated along the elongate body and used to monitor for a temperature rise due to the ablation energy
20 from the ablation catheter. If the monitored temperature detected by the temperature sensor rises above a predetermined threshold limit, the controller may provide an indication or alert to the user. Additionally and/or alternatively, the controller may also be programmed to either stop the ablation energy, actuate the distal portion to deflect the esophageal tissue away, or both.

25 **[0017]** Generally, one variation of a tissue treatment apparatus may generally comprise an elongate body configured for introduction into an esophageal lumen and a handle assembly coupled to the elongate body and having a fluid port in communication with a lumen defined through the elongate body. A distal portion may be pivotably coupled to the elongate body such that actuation of the distal portion reconfigures the distal
30 portion within a plane relative to the elongate body, wherein the elongate body defines one or more openings along the distal portion and which are in fluid communication with the fluid port. A sensor may also be positioned near or at a distal end of the distal portion, wherein the sensor is configured to communicate with an electromagnetic navigational system.

[0018] One example of a method of treating a tissue region within a heart or vascular system of a patient body may generally comprise positioning an elongate body having a first sensor positioned near or at a distal end of a distal portion within an esophageal lumen in proximity to the heart or vascular system of the patient body and positioning an ablation catheter having a second sensor positioned near or at a distal end of the ablation catheter within a left atrium or other regions of the heart or vascular system in proximity to the esophageal lumen. A distance between the first sensor within the esophageal lumen relative and the second sensor may also be monitored within the left atrium or other regions of the heart or vascular system and the ablation catheter may be actuated to deliver ablation energy to a tissue surface within the left atrium or other regions of the heart or vascular system while monitoring the position. Additionally, the distal portion of the elongate body may be reconfigured to deflect a region of the esophageal lumen away from the left atrium or other regions of the heart or vascular system when the distance is below a threshold distance.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] FIG. 1 shows a side view of one variation of an endoscopic device which provides for electromagnetic tracking as well as deflection of esophageal tissue when actuated.

[0020] FIG. 2 shows a perspective assembly view of the endoscopic device with a sheath removed from the underlying elongate body.

[0021] FIG. 3A shows a detail side view of a distal portion of the elongate body with the sheath removed to illustrate a deflection mechanism incorporating a pivoting structure.

[0022] FIG. 3B shows a detail side view of a distal portion of the sheath to illustrate an alternative location for positioning of the sensor.

[0023] FIGS. 4A and 4B show schematic views of one variation of how the electromagnetic sensor within the device may be used for positional tracking.

[0024] FIG. 4C shows a side view of another variation of the endoscopic device having multiple positioning sensors incorporated.

[0025] FIG. 5A shows a partial cross-sectional side view of a heart and esophagus to illustrate their relative positioning within the patient body.

[0026] FIG. 5B shows a partial front view from within the left atrium of a heart to

illustrate the relative positioning of the esophageal device positioned within the esophagus and in proximity to the heart and an ablation catheter positioned within the left atrium or other regions of the heart or vascular system for an ablation procedure.

[0027] FIG. 5C shows an example of the esophageal device and ablation catheter in communication with a controller and with the navigational system.

[0028] FIGS. 6A and 6B show an example of how the distal portion of the esophageal device may be actuated to defect the esophageal tissue away from the external surface of the heart or vascular system.

10 DETAILED DESCRIPTION OF THE INVENTION

[0029] A first instrument such as an endoscopic device may be configured to provide for detection of its location within the body and a second instrument such as an ablation catheter may also be configured to provide for detection of its location within the body. For instance, an ablation catheter may be advanced intravascularly inside the left atrium or other regions of the heart or vascular system such as the pulmonary vessels, then the endoscopic device may be advanced per orally inside the esophagus of the patient and into proximity of the ablation catheter. A navigation software system could be used to determine the locations of each device relative to one another and may provide this information to the user such as a physician. In one variation, the user may want the ablation catheter to be a certain distance away from the endoscopic device positioned within the esophagus. In the event that the two instruments are located too close to one another within a desirable threshold, the system may provide an indication such as an alert or warning that the two instruments are located too close to one another. In the event that the ablation catheter is used to deliver energy to the tissues within the left atrium, the system may also provide an alert or warning to the user prior to delivering the energy if the two instruments are within a specified distance to one another.

[0030] One example of a navigation and mapping system which may be used with the systems described here may include a three-dimensional system such as CARTO® System (Biosense Webster, Inc., Irvine, CA) which can be used to provide the user with real-time information of the location of instruments within the body, such as the heart or the vascular system. The CARTO® System utilizes an electromagnetic field generated outside of the patient body that communicate with one or more sensors typically placed near the tip of the device which is inserted into the patient body. The sensors communicate

their location within the electromagnetic field and the software displays their location often within an anatomical rendering of the organ.

[0031] One example of an instrument **10** which may incorporate such a sensor is shown in the side view of FIG. 1 which illustrates an endoscopic instrument **10** having an elongate body **12** which is advanceable into the patient body per-orally through the mouth and at least partially into the esophagus. The elongate body **12** may have a length which ranges from, e.g., 15 to 75 cm, extending from a handle assembly **14** which may remain outside the patient body. The handle assembly **14** may incorporate an actuator such as a knob or lever **26** which may be articulated by the user to reconfigure a distal portion **22** of the body **12** in a number of different configurations. The handle assembly **14** may also incorporate at least one port **36** through which a lumen may extend through the handle assembly **14** and through the body **12** to fluidly communicate with one or more openings **28, 30** defined along the distal portion **22**.

[0032] The elongate body **12** may be further comprised of a sheath **18** which extends over an underlying structure **20** attached to the handle assembly **14** and which provides structural support to the body **12** such that the body **12** may be advanced into the and through the esophagus or other body lumen without buckling or kinking along its length. A proximal end of the sheath **18** may include a connector **16** for removable attachment to the handle assembly **14** so that the sheath **18** may be coupled and de-coupled from the handle. The distal portion of the sheath **18** may define the openings **28, 30** which allow for fluid communication between the internal lumen and the external surface of the sheath **18**. The underlying structure **20** may further incorporate a hinge or pivoting mechanism **32** which allows for the displacement or actuation of a distal member **24** relative to the remainder of the body **12**. The distal member **24** may also incorporate a sensor **34** which allows for the detection of the instrument **10** when positioned within the body lumen.

[0033] FIG. 2 illustrates a perspective assembly view of the sheath **18** de-coupled from the handle assembly **14** and removed entirely from the underlying structure **20** for illustration purposes. The sheath **18** may be fabricated from any number of biocompatible materials which retain their flexibility such as silicone, polyvinylchloride (PVC), polyethersulfone (PES), polyethylene (PE), polycarbonate (PC), polyetheretherketone (PEEK), polypropylene (PP), polysulfone (PS), polyurethane (PU), etc. Furthermore, while remaining coupled at its proximal end to the handle assembly **14** via the connector **16**, the sheath **18** may remain unattached along its length to the underlying structure **20** or

it may be coupled at one or more various points along its length, particularly along its distal portion.

[0034] The fluid port **36** is shown extending from the handle assembly **14** and one or more lumens may be defined along the length of the structure **20** to extend along its length and into fluid communication with the distal portion **22** of the structure **20** and body **12**. A vacuum force may be drawn through the fluid port **36**, e.g., via a pump (not shown), such that a negative fluid pressure is drawn through the distal portion **22** of the structure **20**. This negative fluid pressure may draw any tissue in proximity or in contact against the outer surface of the openings **28, 30**.

[0035] FIG. 3A shows a side view of the distal portion **22** with the sheath **18** removed for illustrative purposes. The structure **20** may be comprised of a number of elongate plates or ribbon members which are layered to provide structural strength such that the structure **20** is relatively rigid within a rotational plane **PL** but which allows for some flexibility in the plane transverse to the rotational plane **PL**. The distal member **24** may be seen extending distally from the hinge or pivoting mechanism **32** and the sensor **34** may be seen positioned within or in proximity to the distal end of the device. The hinge or pivoting mechanism **32** may be configured to enable the distal member **24** to rotate about the hinge or pivoting mechanism **32** when the actuator **26** upon the handle assembly **14** is manipulated such that the distal member **24** rotates within the rotational plane **PL**. The rotation of the distal member **24** may be limited to rotate within a predetermined range within the plane **PL**, e.g., ± 30 degrees, ± 45 degrees, ± 90 degrees, or any other angle lesser than or greater than 90 degrees, as practicable.

[0036] When the sheath **18** is positioned over the structure **20**, the distal openings **28** along the sheath **18** may correspondingly be positioned along the distal member **24** distal to the hinge or pivoting mechanism **32** while the proximal openings **30** along the sheath **18** may correspondingly be positioned along the structure **18** proximal to the hinge or pivoting mechanism **32**. The distal openings **28** may be positioned in a pattern which is relatively more dense than a pattern of the proximal openings **30** such that the tissue in proximity to the distal openings **28** may be more securely adhered to the distal openings **24** when a suction force is drawn through the openings **28, 30**.

[0037] Another variation is shown in the detail side view of FIG. 3B where the sensor **34** may be positioned within the sheath **18** itself rather than along the distal member **24**. In this variation, the sensor **34** may be located along the sheath **18** such as the distal tip with one or more lumens defined through the length of the sheath **18** for connection to the

sensor **34**. Optionally, lumens through the sheath **18** may also be provided for fluidly coupling to the fluid openings defined along the sheath **18**.

[0038] It is intended that the instrument **10** may incorporate any of the different embodiments described herein in various combinations. For example, the instrument **10** may incorporate a sheath **18** having the sensor located along the distal member **24** or along the sheath **18** itself. Additionally, such a combination may incorporate lumens along the structure **20** or along the sheath **18** or both. These examples are not intended to be limiting of the various possible combinations.

[0039] Turning now the sensor **34** positioned near or at the distal end of the elongate body **12**, the instrument **10** may incorporate at least a single sensor **34** although any number of additional sensors may be incorporated along the body **12**. A second instrument, e.g., ablation catheter, which may be used in a corresponding manner with the instrument **10** may also incorporate at least a single sensor near or at its distal tip, as described in further detail below. Any number of additional instruments may also be used in combination with instrument **10** and each additional instrument may incorporate at least a single sensor as well to be used in a corresponding manner with the instrument **10**.

[0040] Regardless of the number of additional instruments utilized, the instrument **10** may utilize the sensor **34** near or at the tip of the instrument **10** which may be detected by the navigational system positioned externally of the patient body. The navigational system may generally incorporate multiple coils in proximity to or in contact with the external surface of the patient body. In one variation, as shown schematically in FIG. 4A, the system may use a first coil **40** which emits a first electromagnetic field **42**, a second coil **44** positioned at a distance from the first coil **40** and which emits a second electromagnetic field **46**, and a third coil **48** positioned at a distance from the first coil **40** and the second coil **44** and which emits a third electromagnetic field **50**. Each of the coils **40**, **44**, **48** may be used to detect not only the sensor **34** in the instrument **10** but also any other sensors in other instruments used in combination with the instrument **10**. FIG. 4B illustrates an example of how the navigational system may be used to detect the position of the sensor **34** and hence the instrument **10** in space relative to the coils **40**, **44**, **48** as well as relative motion of the instrument **10** (e.g., up-down, back-forward, left-right, roll, yaw, pitch) in space as illustrated by schematic **52**.

[0041] With the instrument **10** inserted into and positioned within the esophagus of the patient, a single sensor **34** at the distal tip may be used. Although in other variations, as shown in FIG. 4C, the elongate body **12** may incorporate multiple sensors **34'**, **34''**, **34'''**

along the body **12**. A fewer number or greater number of sensors may be used depending upon the desired application. With the use of multiple sensors, the elongate body **12** may be used to assess the positional relationship of the instrument **10** relative to the esophagus as well as the positional relationship of the ablation catheter relative to the instrument **10**

5 and esophagus without require a constant movement of the instrument **10** within the esophagus as the ablation instrument is moved within the adjacent body lumen such as the heart or vascular system. This may also enable the system to determine the outer edges of the esophagus, e.g., to create a three-dimensional model of the esophagus. In this manner, the instrument **10** may be positioned once within the esophagus while the corresponding
10 ablation catheter may be moved freely while the relative positioning can be tracked through the multiple sensors.

[0042] FIG. 5A illustrates a partial cross-sectional side view (along a sagittal plane of the patient body) of the elongate body **12** advanced within the esophagus **ES** such that the sensor **34** and distal portion **22** are positioned within the esophagus **ES** at a location
15 directly adjacent to where the left atrium **LA** of the heart or other regions of the heart or vascular system is in proximity or in direct contact against the exterior surface of the esophagus **ES**. The left ventricle **LV** and right ventricle **RV** of the heart are indicated for reference as well as the aortic arch **AA**, descending aorta **DA**, and trachea **TR** of the patient body. FIG. 5B illustrates a partial cross-sectional view from within the patient heart (along
20 a coronal plane of the patient body) of the second instrument such as an ablation catheter **60** having a location sensor **62** positioned along the ablation catheter **60** near or at the distal tip. The ablation catheter **60** may be seen as having been advanced intravascularly into the left atrium **LA** of the heart (or can be positioned in other chambers of the heart or in the vascular system), with the esophagus **ES** positioned posteriorly of the left atrium **LA**. The
25 elongate body **12** of the instrument **10** is shown as having been positioned within the esophagus **ES** in proximity to the left atrium **LA** while the tip of the ablation catheter **60** is positioned in proximity to the ostia of the pulmonary veins / vascular system (LSPV, LIPV, RSPV, RIPV) for treatment such as tissue ablation.

[0043] FIG. 5C illustrates an example of how the one or more sensors, such as
30 sensor **34**, along the elongate body **12** may be in wired or wireless communication **66** with a controller **64** while the sensor **62** located along the ablation catheter **60** may also be in wired or wireless communication **68** with the controller **64**. The detection coils **40**, **44**, **48** positioned in proximity to the patient body may be in communication with the controller **64** as well and used to determine the position of the elongate body **12** and ablation catheter **60**

relative to one another. As the controller **64** may determine the relative distance between the distal portion **22** of the elongate body **12** and the ablation catheter **60**, the controller **64** may also be programmed to provide an indication or alert to the user when the two instruments are within a predetermined distance from one another, e.g., 5 mm to 10 mm, or any selected distance as determined by the user. The distance determination may be performed with or without the use of another imaging modality such as fluoroscopy (which may be omitted altogether) during a treatment procedure.

[0044] FIGS. 6A and 6B illustrate another example of how the instrument **10** may be used in an ablation procedure. FIG. 6A shows a partial cross-sectional side view (along a sagittal plane of the patient body) where the ablation catheter **60** has been intravascularly advanced into the left atrium **LA** (or other regions of the heart or vascular system) of the patient with the sensor **62** and ablation tip positioned in proximity or in contact against the interior of the left atrial tissue (or other regions of the heart or vascular system) for ablation treatment, e.g., for creating a conduction block. The elongate body **12** is shown as having been advanced per-orally into the esophagus **ES** such that the distal member **24** is positioned within the esophagus **ES** adjacent to the left atrium **LA** (or other regions of the heart or vascular system) of the patient. The suction force may be optionally actuated such that the esophageal tissue surrounding the distal and proximal openings **28**, **30** may be adhered to the outer surface of the distal portion **24** of the elongate body **12**.

[0045] The relative distance between the tip of the ablation catheter **60** and sensor **34** located on the elongate body **12** may be determined and monitored by the controller **64** prior to and/or during an ablation treatment. With a threshold distance between the ablation catheter **60** and sensor **34** predetermined, e.g., 5 mm to 10 mm, or any selected distance as determined by the user, the ablation catheter **60** may be used to deliver ablation energy for tissue treatment. In the event that the ablation catheter **60** and sensor **34** are moved too close to one another within the threshold distance, an indication may be provided by the controller **64** to the user that the ablation catheter **60** may be too close to the esophageal tissue such that the ablation energy from within the left atrium **LA**, or other regions of the heart or vascular system, may be conducted through the tissue and inadvertently damage the adjacent esophageal tissue.

[0046] In the event that the ablation catheter **60** and esophageal tissue are determined to be too close to one another, the controller **64** may be programmed to provide the alert to the user and/or optionally automatically stop the ablation catheter **60** to prevent any esophageal tissue damage. The user may also actuate the knob or lever **26** on the

handle assembly **14** to reconfigure the distal portion **24** to rotate within the plane **PL** relative to the remainder of the elongate body **12** in order to reposition a portion of the esophagus **ES** away from the exterior of the heart or vascular system such that a gap **70** is formed between the two, as shown in FIG. 6B. The distal portion **24** may be actuated while the surrounding esophageal tissue is adhered to the outer surface of the elongate body **12** via the suction force or with the suction force turned off although having the esophageal tissue adhered to the distal portion **24** when deflected can help ensure that the gap **70** is formed between the esophagus **ES** and heart tissue or vascular system.

[0047] While the distal portion **24** may be actuated manually by the user, the distal portion **24** in other variations may be actuated automatically by the controller **64** upon detecting that the ablation catheter **60** and elongate body **12** are too close to one another. In yet another variation, other sensors such as a temperature sensor **72** may be optionally incorporated along the elongate body **12** and used to monitor for a temperature rise due to the ablation energy from the ablation catheter **60**. If the monitored temperature detected by the temperature sensor **72** rises above a predetermined threshold limit, the controller **64** may provide an indication or alert to the user. Additionally and/or alternatively, the controller **64** may also be programmed to either stop the ablation energy, actuate the distal portion **24** to deflect the esophageal tissue away, or both.

[0048] Another example of how the device may be used relates to treatments applied to a lung or lungs of the patient rather than the heart. Radiation energy may be applied to the lungs, for example, in treating tumors or lesions for lung cancer. The instrument **10** (or any of its variations described) may be positioned within the esophagus and used to deflect portions of the esophagus. By moving the esophagus out of the radiation port, collateral radiation damage to the esophagus may be reduced and may also allow for the delivery of a higher dose of radiation than would otherwise be possible if the esophageal tissue were present.

[0049] The applications of the disclosed invention discussed above are not limited to the embodiments described, but may include any number of other applications and uses. Modification of the above-described methods and devices for carrying out the invention, and variations of aspects of the invention that are obvious to those of skill in the arts are intended to be within the scope of this disclosure. Moreover, various combinations of aspects between examples are also contemplated and are considered to be within the scope of this disclosure as well.

CLAIMS

What is claimed is:

1. A tissue treatment apparatus, comprising:
an elongate body configured for introduction into an esophageal lumen;
5 a handle assembly coupled to the elongate body and having a fluid port in communication with a lumen defined through the elongate body;
a distal portion pivotably coupled to the elongate body such that actuation of the distal portion reconfigures the distal portion within a plane relative to the elongate body, wherein the elongate body defines one or more openings along the distal portion and which
10 are in fluid communication with the fluid port; and
a sensor positioned near or at a distal end of the elongate body, wherein the sensor is configured to communicate with an electromagnetic navigational system.
2. The apparatus of claim 1 wherein the elongate body further comprises a sheath
15 connectable to the handle assembly.
3. The apparatus of claim 1 wherein the elongate body is configured to provide structural support within the plane.
- 20 4. The apparatus of claim 1 further comprising a controller in communication with the sensor and the electromagnetic navigational system.
5. The apparatus of claim 4 further comprising an ablation catheter having a sensor positioned near or at a distal end of the catheter, wherein the sensor is in communication
25 with the controller.
6. The apparatus of claim 5 wherein the controller is programmed to determine a relative distance between the sensor of the distal portion and the sensor of the ablation catheter.
30
7. The apparatus of claim 6 wherein the controller is further programmed to provide an indication or alert when the relative distance is within a predetermined threshold

distance.

8. The apparatus of claim 7 wherein the controller is further programmed to halt an energy delivery from the ablation catheter when the relative distance is within the
5 predetermined threshold distance.

9. The apparatus of claim 7 wherein the controller is further programmed to reconfigure a position of the distal portion when the relative distance is within the predetermined threshold distance.
10

10. The apparatus of claim 1 wherein the sensor is positioned along distal portion.

11. The apparatus of claim 1 wherein the sensor is positioned along a sheath connectable to the handle assembly.
15

12. The apparatus of claim 1 further comprising the electromagnetic navigational system.

13. A method of treating a tissue region within a heart or vascular system of a
20 patient body, comprising:

positioning an elongate body having a first sensor positioned near or at a distal end of a distal portion within an esophageal lumen in proximity to the heart of the patient body;

positioning an ablation catheter having a second sensor positioned near or at a distal end of the ablation catheter within a left atrium or other regions of the heart or vascular
25 system in proximity to the esophageal lumen;

monitoring a distance between the first sensor within the esophageal lumen relative and the second sensor within the left atrium or other regions of the heart or vascular system;

actuating the ablation catheter to deliver ablation energy to a tissue surface within
30 the left atrium or other regions of the heart or vascular system while monitoring the position; and

reconfiguring the distal portion of the elongate body to deflect a region of the esophageal lumen away from the left atrium or other regions of the heart or vascular system when the distance is below a threshold distance.

14. The method of claim 13 wherein positioning the elongate body comprises advancing the elongate body into the esophageal lumen.

5 15. The method of claim 13 wherein positioning the ablation catheter comprises intravascularly advancing the ablation catheter into the left atrium or other regions of the heart or vascular system.

10 16. The method of claim 13 wherein monitoring the distance comprises determining the distance via an electromagnetic navigational system in communication with the first sensor and the second sensor.

15 17. The method of claim 13 further comprising monitoring a temperature within the esophageal lumen via a temperature sensor.

20 18. The method of claim 13 wherein reconfiguring the distal portion further comprises drawing a suction force through the distal portion of the elongate body such that the region of the esophageal lumen is adhered to an outer surface of the distal portion of the elongate body.

25 19. The method of claim 13 wherein reconfiguring the distal portion comprises actuating a lever or knob on a handle assembly.

30 20. The method of claim 13 further comprising halting the ablation energy from the ablation catheter when the distance is below the threshold distance.

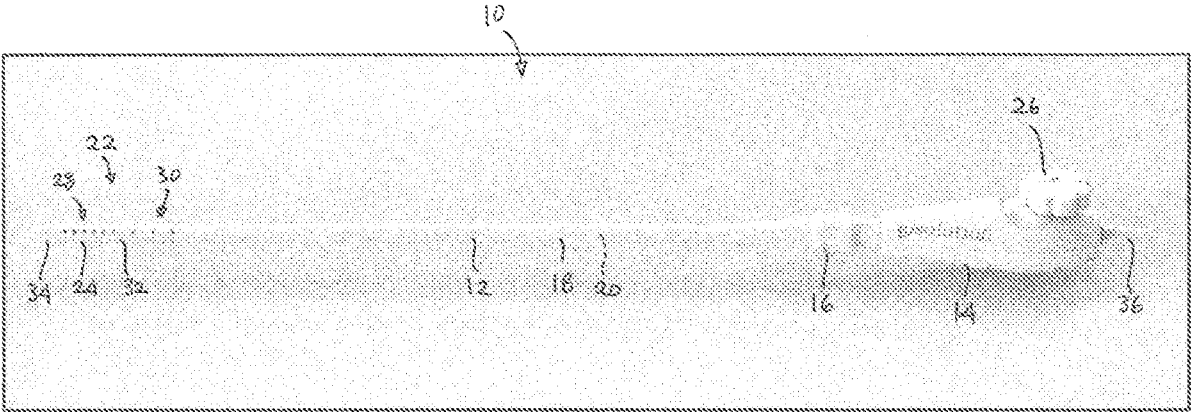


FIG. 1

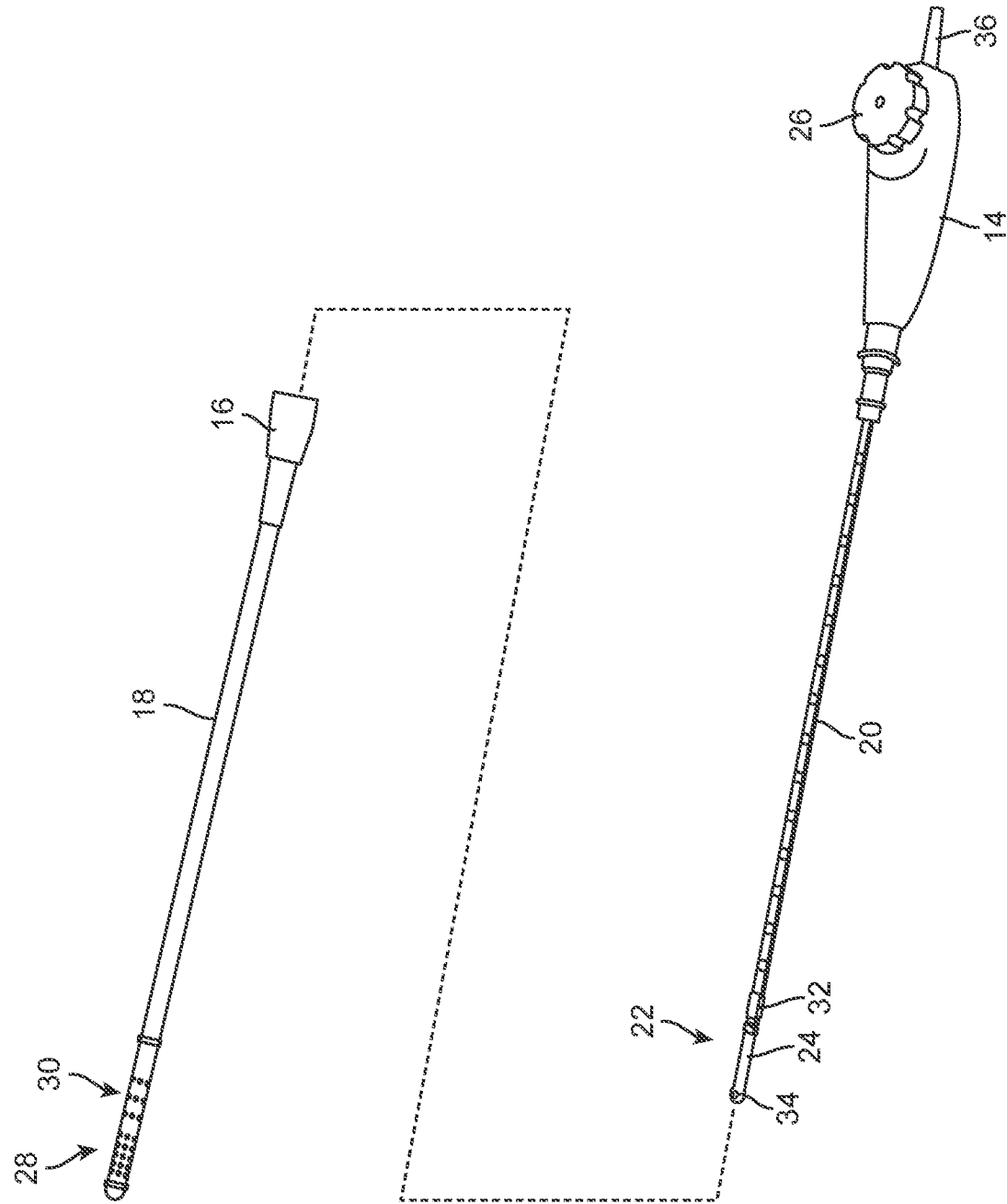


FIG. 2

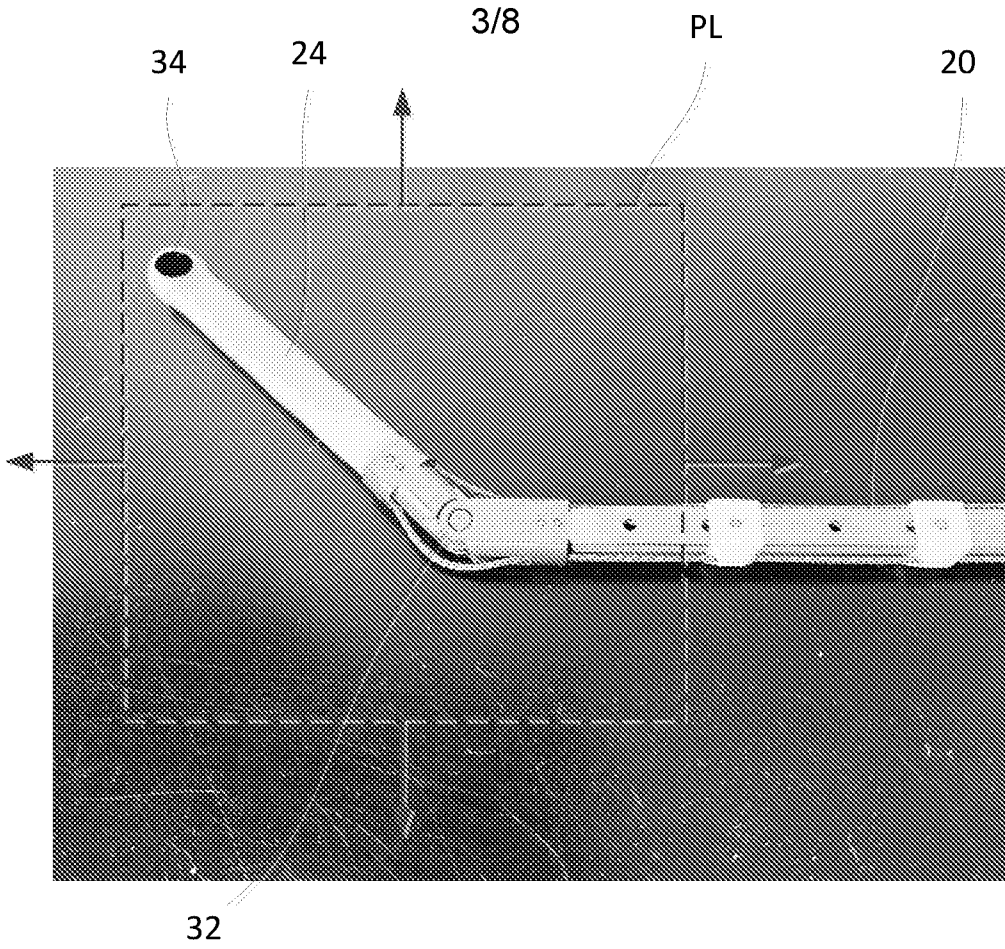


FIG. 3A

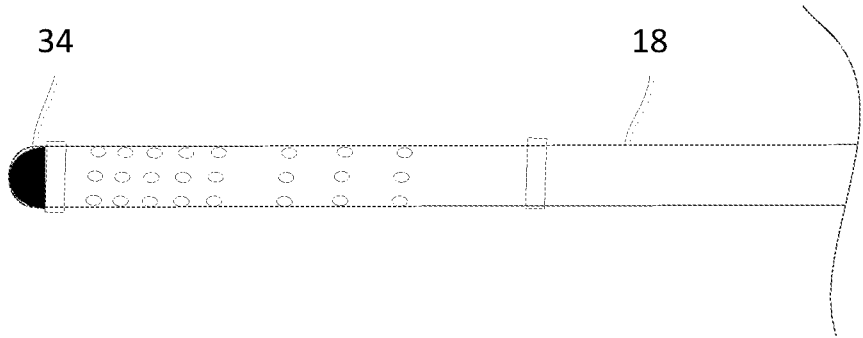


FIG. 3B

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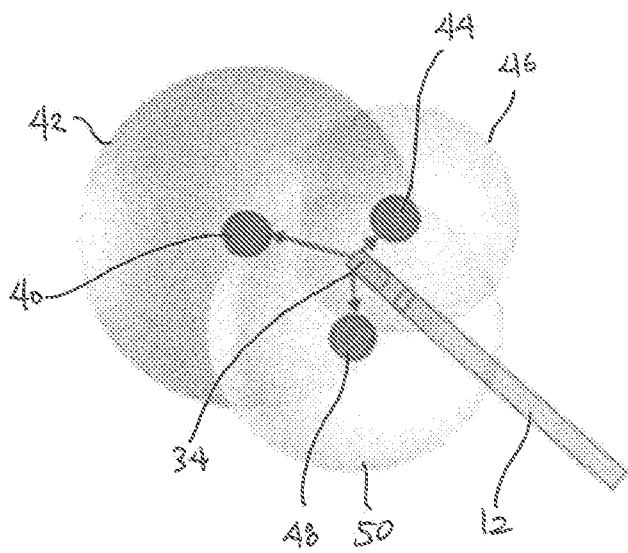


FIG. 4A

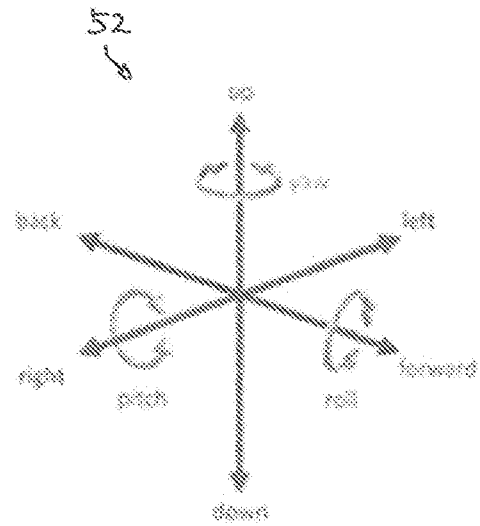


FIG. 4B

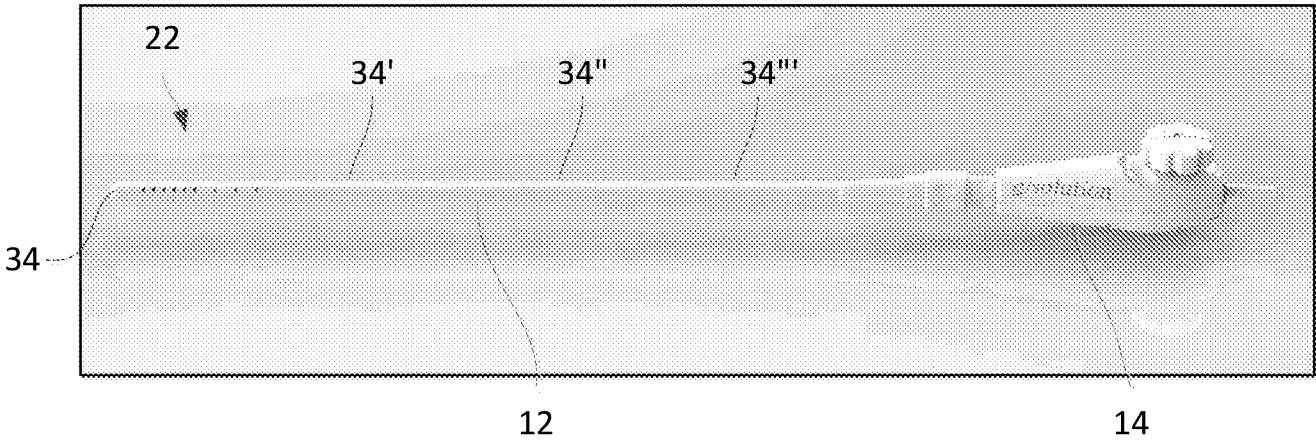


FIG. 4C

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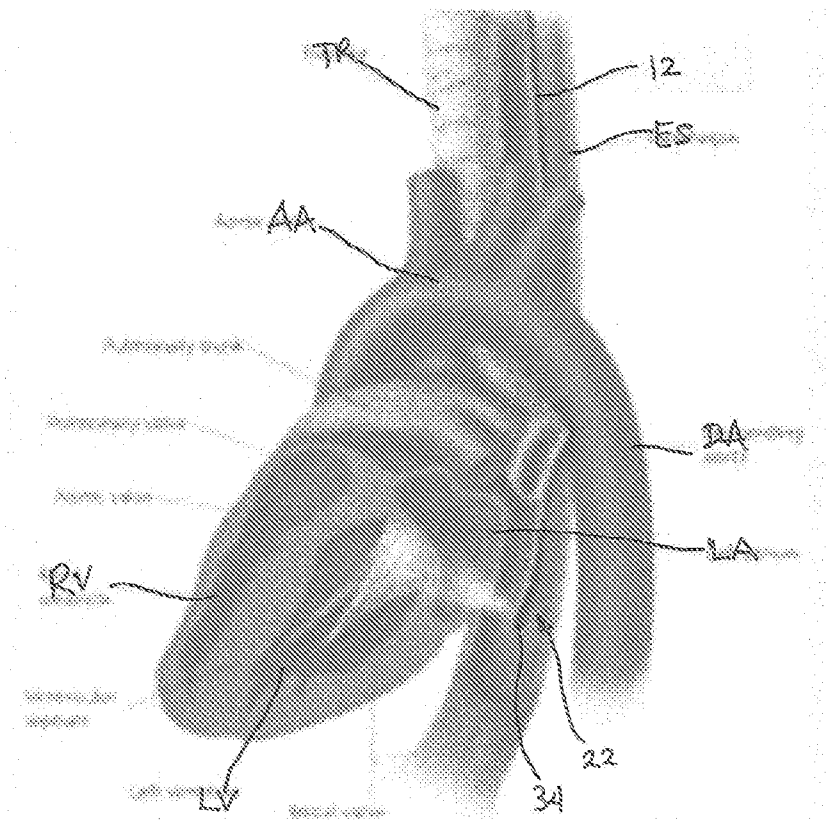


FIG. 5A

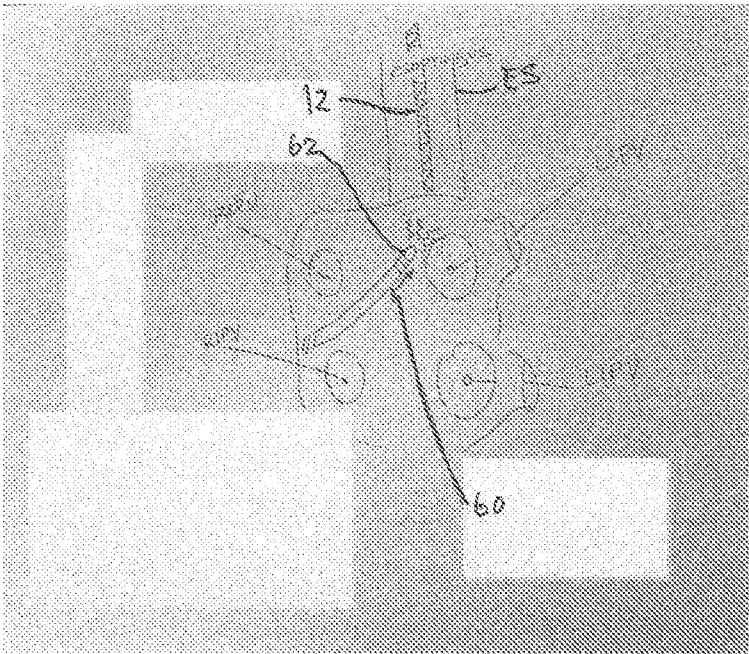


FIG. 5B

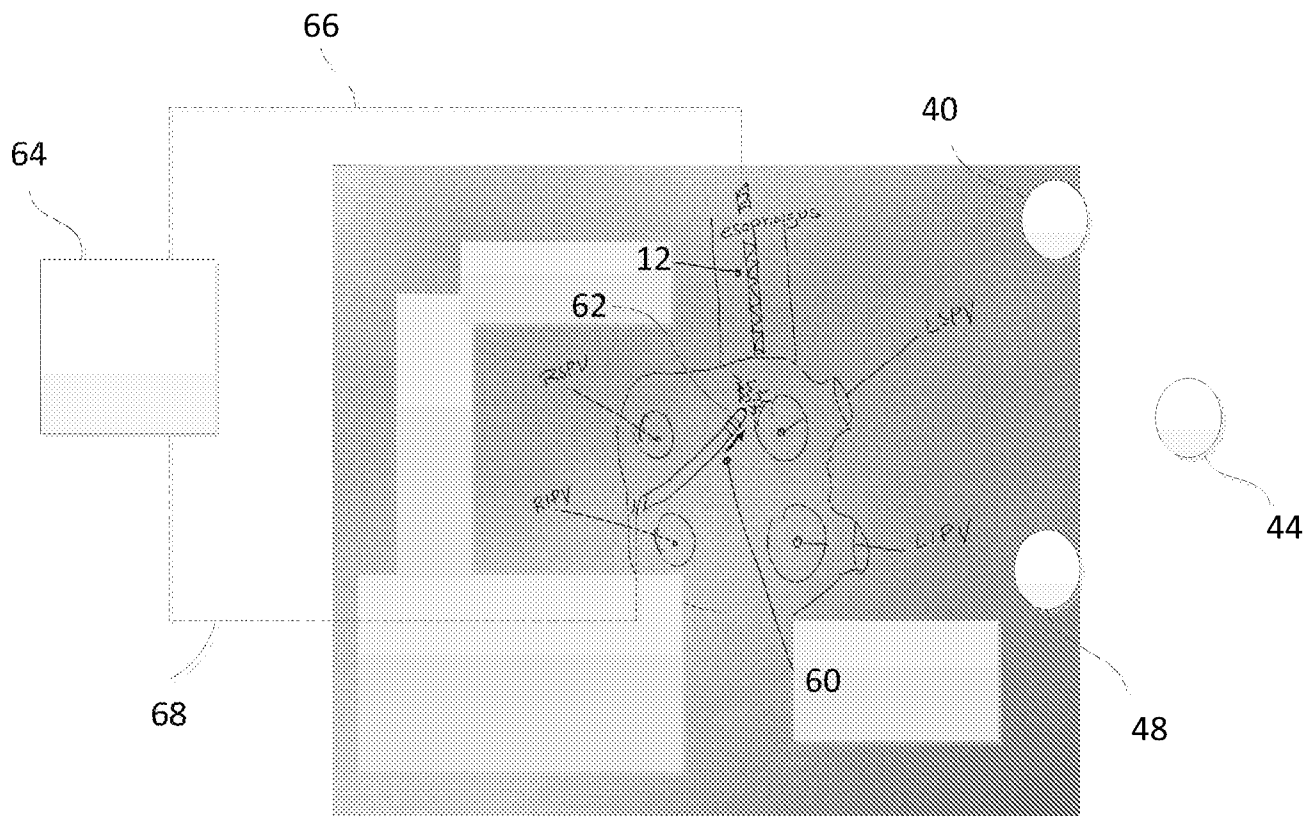


FIG. 5C

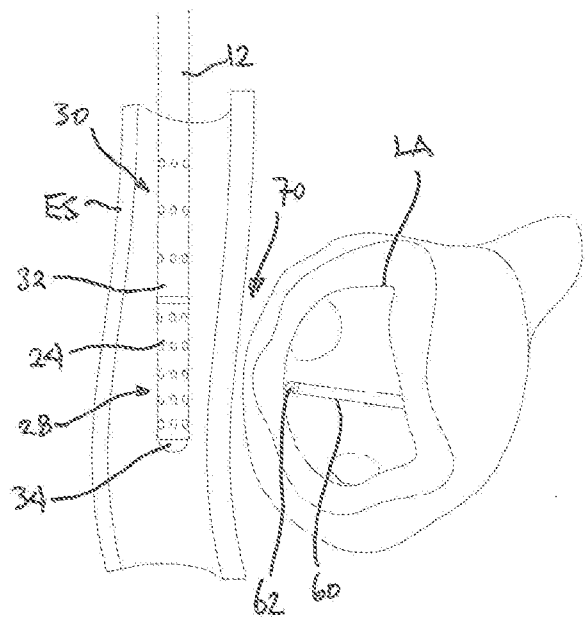


FIG. 6A

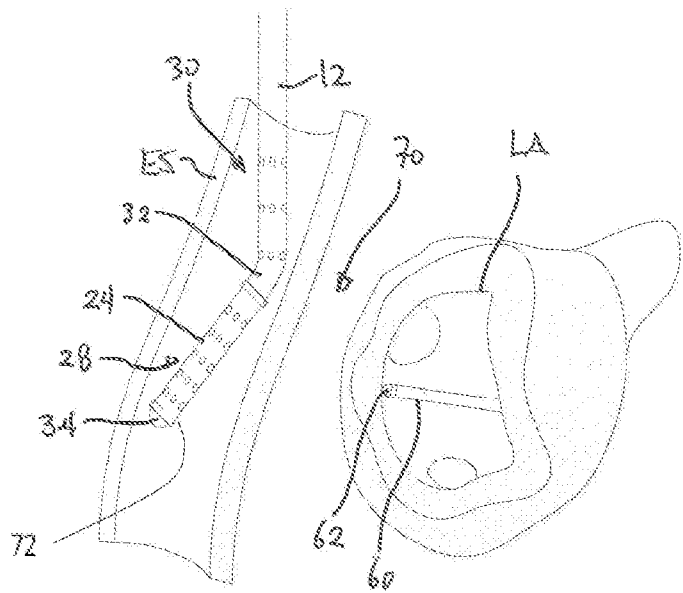


FIG. 6B

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2021/045666

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 18/14; A61B 5/06; A61B 18/04; A61B 34/20; A61M 25/01; A61M 25/095 (2021.01)

CPC - A61B 18/14; A61B 5/06; A61B 18/04; A61B 34/20; A61M 25/01 (2021.08)

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.
Y	US 2007/0106287 A1 (O'SULLIVAN) 10 May 2007 (10.05.2007) entire document	1, 3-8, 10, 12
Y	US 2019/0269834 A1 (OHIO STATE INNOVATION FOUNDATION) 05 September 2019 (05.09.2019) entire document	1, 3-8, 10, 12
Y	US 2019/0150753 A1 (ST JUDE MEDICAL CARDIOLOGY DIVISION INC) 23 May 2019 (23.05.2019) entire document	8
A	US 2006/0106375 A1 (WERNETH et al) 18 May 2006 (18.05.2006) entire document	1-20
A	US 2019/0125210 A1 (BIOSENSE WEBSTER (ISRAEL) LTD) 02 May 2019 (02.05.2019) entire document	1-20
A	US 5,170,803 A (HEWSON et al) 15 December 1992 (15.12.1992) entire document	1-20
A	US 2008/0033415 A1 (RIEKER et al) 07 February 2008 (07.02.2008) entire document	1-20

☐ 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

24 October 2021

Date of mailing of the international search report

NOV 30 2021

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