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(54) Title: ABLATION DEVICES AND METHODS

(57) Abstract: A device for treating atrial fibrillation that includes a shaft with at least one, and preferably two or more malleable probes extending from a distal end thereof. The probes are elongate and malleable such that the probes may be shaped as desired. A length of the probe emits energy, rather than just a tip of the probe, so the shape of the probe may be ablated into tissue in a single step.

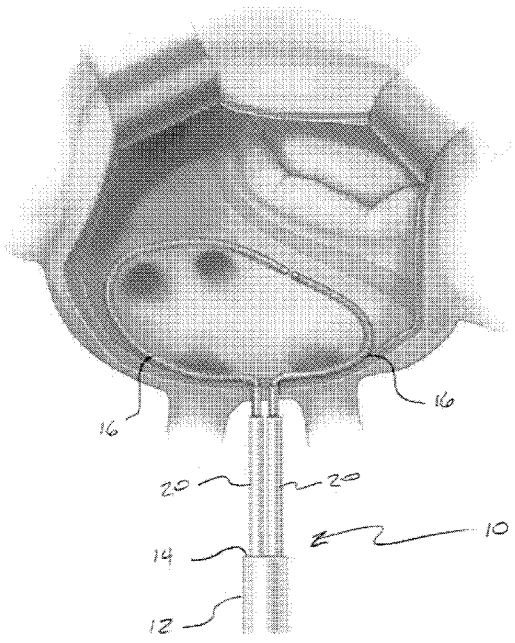


FIG. 1

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ABLATION DEVICES AND METHODS

RELATED APPLICATIONS

[0001] This application claims priority to and benefit of U.S. Provisional Application Serial No. 62/207,260 filed August 19, 2015 entitled *Devices And Methods For Treating Atrial Fibrillation*, which is hereby incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to devices and methods for the treatment of atrial fibrillation.

BACKGROUND OF THE INVENTION

[0003] Atrial fibrillation (AF) is a common and dangerous heart rhythm condition which frequently is initiated by errant electrical signals from the pulmonary veins which enter the left atrium (LA). These signals cause the heart muscles to transition out of the normal rhythm of the heartbeat. This results in an abnormal heart rhythm characterized by rapid and irregular beating. It is common in patients before open heart surgery.

[0004] A variety of surgical techniques and devices/technologies (unipolar and bipolar radiofrequency; cryoablation, microwave, high intensity focused ultrasound, laser) have been used to treat AF by ablating tissue at the time of open heart surgery. Of these, only bipolar radiofrequency is approved by the FDA for AF treatment at the time of surgery.

[0005] These techniques operate on the premise that scar tissue is a poor conductor of electricity. Thus, forming scar tissue in the heart muscle can effectively block unwanted electrical signals and, in some cases, reroute them to the ventricles.

[0006] The techniques typically involve the use of an energized probe that is introduced into the heart, either percutaneously or surgically. The tip of the probe is put into contact with a heart chamber and energized, thereby delivering to (or removing energy from in the case of cryoablation) the tissue to form scar tissue. The probe is then moved and the process repeated until a desired pattern is formed. This procedure can be tedious depending on the size of the desired pattern being created. The physician

must ensure that enough time is spent in each location to form an adequate scar without causing too much damage. Doing so requires that the cumulative heating or cooling effect on the probe be taken into account. Some devices include audible indications when a sufficient contact time has elapsed, but, ultimately the repetitive placing, energizing, holding and removing sequence leaves room for error.

[0007] It would thus be advantageous to provide a device for performing atrial fibrillation treatment more efficiently.

SUMMARY OF THE INVENTION

[0008] It is an aspect of the present invention to provide devices and methods for treating AF that are easier, safer and more efficacious than prior art AF treatment devices and methods.

[0009] One aspect of the invention provides an ablation device that includes a shaft having a distal end and at least two elongate flexible ablative probes extending from the distal end of the shaft. Each of the at least two elongate flexible probes has a length, and each of the at least two elongate flexible probes can deliver ablative energy along its length. Additionally, each of the at least two elongate flexible probes is malleable, allowing the length of the probe to be manipulated into a desired shape.

[0010] In one embodiment, the ablative device has at least two elongate flexible ablative probes extend from the shaft parallel to each other.

[0011] In another embodiment, the at least two elongate flexible ablative probes comprise at least three elongate flexible ablative probes.

[0012] In still another embodiment, the at least two elongate flexible ablative probes are manually malleable.

[0013] Alternatively, in another embodiment, the at least two elongate flexible ablative probes are capable of being shaped remotely.

[0014] Another embodiment provides an ablative device wherein each of the at least two elongate flexible probes can deliver cryo-ablative energy along its length.

[0015] In yet another embodiment each of the at least two elongate flexible probes can deliver energy along its length selected from the group including thermal, unipolar radiofrequency, bipolar radiofrequency, microwave, high intensity focused ultrasound, and laser.

[0016] The ablative device may include an adjustable sleeve surrounding the at least two elongate flexible probes and slidable thereon such that a portion of the length of the at least two elongate flexible probes that is exposed may be a adjusted.

[0017] Another aspect of the invention is a method for treating atrial fibrillation comprising: placing a device at a target area of the heart; shaping at least one elongate flexible probe such that a length thereof is shaped to match a desired ablation pattern; placing the at least one elongate flexible probe in contact with heart tissue to be treated; activating the at least one elongate flexible probe so the length thereof ablates the heart tissue to be treated.

[0018] This method may include repeating the shaping, placing and activating steps until a desired treatment is completed.

[0019] In one aspect, the step of placing a device at a target area of the heart includes placing a device such that a first elongate flexible probe is at a first target area inside the heart and a second elongate flexible probe is at a second target area outside the heart, substantially adjacent to the first target area.

[0020] In another aspect, the step of shaping at least one elongate flexible probe such that a length thereof is shaped to match a desired ablation pattern involves shaping at least two elongate flexible probes such that lengths thereof are shaped to match a desired ablation pattern.

[0021] In yet another aspect, the step of placing the at least one elongate flexible probe in contact with heart tissue to be treated includes placing the at least two elongate flexible probes in contact with heart tissue to be treated.

[0022] In another aspect, activating the at least one elongate flexible probe so the length thereof ablates the heart tissue to be treated includes activating the at least two elongate flexible probes so lengths thereof ablate the heart tissue to be treated.

[0023] Activating the at least one elongate flexible probe so the length thereof ablates the heart tissue to be treated may entail sending cryo-ablation fluid through a lumen of the at least one elongate flexible probe.

[0024] Alternatively, activating the at least one elongate flexible probe so the length thereof ablates the heart tissue to be treated could involve energizing the at least one elongate flexible probe so that energy is emitted therefrom.

[0025] In one aspect, the method also includes adjusting an exposed portion of the at least one elongate flexible probe by sliding an adjustable sleeve surrounding the at least one elongate flexible probe.

[0026] Another aspect of the invention provides an ablation device comprising: a shaft having a distal end, with at least two sleeves extending from the distal end. The sleeves are slidably associated with the shaft such that a portion of the sleeves extending past the distal end of the shaft may be adjusted. The device includes at least two elongate flexible ablative probes extending from the distal end of the shaft through the at least two sleeves. Each of the at least two elongate flexible probes can deliver ablative energy along its length. Adjusting the sleeves adjusts a portion of the probes that are not covered by the sleeves. Additionally, each of the at least two elongate flexible probes is malleable, allowing the length of the probe to be manipulated into a desired shape.

[0027] Additionally, each of the probes is shown as having a thin tubular shape. However, if different ablation shapes are needed for various applications, it is envisioned that a variety of probe shapes may be provided. Non-limiting examples of shapes include

round, flat (popsicle stick), square, or any other shape. Also, the length of the probes can be designed for a particular use. A typical length for common uses may be 8 to 12 cm, for example. Finally, one or more of the probes could be fully or partially covered with a balloon that separates the probe from flowing blood, or surrounding structures.

[0028] In one aspect, each of the probes has a length extending from the distal end of the shaft that is fixed relative to the shaft.

[0029] In another aspect, each of the probes is slidable within the shaft such that the probe length is adjustable.

BRIEF DESCRIPTION OF THE DRAWINGS

[0030] These and other aspects, features and advantages of which embodiments of the invention are capable of will be apparent and elucidated from the following description of embodiments of the present invention, reference being made to the accompanying drawings, in which

[0031] Fig. 1 is a perspective view of an embodiment of the invention being used in an exposed heart chamber showing a target site for performing AF treatment in accordance with the present invention;

[0032] Fig. 2 is a perspective view of an embodiment of the invention being used in an exposed heart chamber showing a target site for performing AF treatment in accordance with the present invention;

[0033] Fig. 3 is a perspective view of an embodiment of the invention including insulating balloons around the distal probes.

DESCRIPTION OF EMBODIMENTS

[0034] Specific embodiments of the invention will now be described with reference to the accompanying drawings. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete,

and will fully convey the scope of the invention to those skilled in the art. The terminology used in the detailed description of the embodiments illustrated in the accompanying drawings is not intended to be limiting of the invention. In the drawings, like numbers refer to like elements.

[0035] Referring first to Figure 1, there is shown a device 10 of the present invention. The device 10 generally includes a shaft 12 having a distal end 14. At least one, and preferably at least two, elongate flexible ablative probes 16 extend from the distal end 14 of the shaft 12.

[0036] Unlike most prior art ablation probes, which emit energy only from their distal tips, each of the elongate flexible probes 12 is able to emit energy along its length. Examples of the types of energy contemplated for delivery by the probes 12 include, but are not limited to, unipolar and bipolar radiofrequency; cryoablation, microwave, high intensity focused ultrasound, laser. It is to be understood that when referring to cryoablative energy herein, "emit energy" is to be interpreted as emiting cooling temperatures from the probes, even though technically energy is being taken away from the tissue, rather than emitted to the tissue. With this understanding, the term "emitting energy" is able to be applied to cryo-ablative energy without confusion.

[0037] The elongate flexible probes 12 are, in at least one embodiment, malleable, thereby allowing the length of the probe to be manipulated into a desired shape. Thus, the probes 12 extend from the distal end 14 of the shaft 12 in a parallel configuration but are able to be shaped independently of each other. As seen in Fig. 1, the two probes 16 are shaped to form a circle around the ostia of the pulmonary veins (am I using the correct terminology here?). This is known as a "box lesion" ablation pattern and is used to electrically isolate the posterior atrial wall and pulmonary veins from the rest of the LA. The present invention allows this to be accomplished with a single application of energy, rather than a tedious painting of the box using the ablative tip of a single probe.

[0038] Fig. 2 shows another application of the independently shapeable probes 16. In this case, one of the probes 16a is placed at a first target area inside the heart, such as the mitral annulus (LA isthmus lesion), for example, and a second elongate flexible probe 16b is placed at a second target area outside the heart, substantially adjacent to the first

target area, such as in this example, the outside atrium across the coronary sinus. In this manner, the heart wall is "sandwiched" between the two probes 16a and 16b. This may be advantageous in that the ablation line may be created more quickly and evenly, doing less damage to the surface tissue in an attempt to ablate the deeper tissue.

[0039] Other configurations are also contemplated. For example, additional probes 16 could extend from the shaft 12. It may be desired to have two sets of two shafts such that box lesions could be formed on an inside heart wall as well as an outside heart wall simultaneously.

[0040] It is also contemplated that the device of the present invention be adapted for use in other parts of the body. Non-limiting examples include the intestines, kidneys, liver, prostate, or tumor sites. Each place presents unique needs that would likely result in unique probe configurations.

[0041] It is also contemplated that the device 10 have a probe or probes 16 that are capable of being shaped remotely. Such an embodiment would be optimally suited for percutaneous ablation procedures.

[0042] Figs. 1 and 2 show that the device 10 further includes sleeves 20 extending from the distal end 14 of the shaft 12. The sleeves 20 are slidable relative to the shaft 10 and are usable by the user of the device to adjust the effective length of the probes 16 by extending the sleeve out of the shaft and along the probe 16, thereby changing a length of an exposed portion of the probe 16. The sleeves are made of an insulative material that protects tissue from energy emitted by a portion of the probe 16 that is covered by the sleeve 20.

[0043] In one embodiment the sleeve 20 may be a balloon that allows the probe 16 within the balloon to be positioned near an edge of the balloon so that energy may pass through the balloon into the tissue, but tissue or blood, etc. that is located adjacent a portion of the balloon that is spaced apart from the probe 16, is protected from the emitted energy.

[0044] Fig. 3 shows an embodiment of a device 10 that includes both a sleeve 20 and a balloon 30 surrounding one or more of the probes 16. The balloon 30 is fillable with a

fluid or gas and is usable to insulate selected surrounding tissue from the energy being emitted from the probe. The sleeve 20 may be adjusted and used to change the length of the inflated portion of the balloon as desired.

[0045] Although the invention has been described in terms of particular embodiments and applications, one of ordinary skill in the art, in light of this teaching, can generate additional embodiments and modifications without departing from the spirit of or exceeding the scope of the claimed invention. Accordingly, it is to be understood that the drawings and descriptions herein are proffered by way of example to facilitate comprehension of the invention and should not be construed to limit the scope thereof.

What is claimed is:

1. An ablation device comprising:

a shaft having a distal end; and,

at least two elongate flexible ablative probes extending from the distal end of the shaft;

wherein each of the at least two elongate flexible probes has a length;

wherein each of the at least two elongate flexible probes can deliver ablative energy along its length; and,

wherein each of the at least two elongate flexible probes is malleable, allowing the length of the probe to be manipulated into a desired shape.

2. The ablative device of claim 1 wherein the at least two elongate flexible ablative probes extend from the shaft parallel to each other.

3. The ablative device of claim 1 wherein the at least two elongate flexible ablative probes comprise at least three elongate flexible ablative probes.

4. The ablative device of claim 1 wherein the at least two elongate flexible ablative probes are manually malleable.

5. The ablative device of claim 1 wherein the at least two elongate flexible ablative probes are capable of being shaped remotely.

6. The ablative device of claim 1 wherein each of the at least two elongate flexible probes can deliver cryo-ablative energy along its length.

7. The ablative device of claim 1 wherein each of the at least two elongate flexible probes can deliver energy along its length selected from the group including thermal, unipolar radiofrequency, bipolar radiofrequency, microwave, high intensity focused ultrasound, and laser.

8. The ablative device of claim 1 further comprising an adjustable sleeve surrounding the at least two elongate flexible probes and slidable thereon such that a portion of the length of the at least two elongate flexible probes that is exposed may be adjusted.

9. A method for treating atrial fibrillation comprising:

placing a device at a target area of the heart;

shaping at least one elongate flexible probe such that a length thereof is shaped to match a desired ablation pattern;

placing the at least one elongate flexible probe in contact with heart tissue to be treated; and,

activating the at least one elongate flexible probe so said length thereof ablates the heart tissue to be treated.

10. The method of claim 9 further comprising repeating the shaping, placing and activating steps until a desired treatment is completed.

11. The method of claim 9 wherein placing a device at a target area of the heart comprises placing a device such that a first elongate flexible probe is at a first target area inside the heart and a second elongate flexible probe is at a second target area outside the heart, substantially adjacent to the first target area.

12. The method of claim 9 wherein the step of shaping at least one elongate flexible probe such that a length thereof is shaped to match a desired ablation pattern comprises shaping at least two elongate flexible probes such that lengths thereof are shaped to match a desired ablation pattern.

13. The method of claim 12 wherein the step of placing the at least one elongate flexible probe in contact with heart tissue to be treated comprises placing the at least two elongate flexible probes in contact with heart tissue to be treated.

14. The method of claim 12 wherein activating the at least one elongate flexible probe so said length thereof ablates the heart tissue to be treated comprises activating the at least two elongate flexible probes so lengths thereof ablate the heart tissue to be treated.

15. The method of claim 9 wherein activating the at least one elongate flexible probe so said length thereof ablates the heart tissue to be treated comprises sending cryo-ablation fluid through a lumen of the at least one elongate flexible probe.

16. The method of claim 9 wherein activating the at least one elongate flexible probe so said length thereof ablates the heart tissue to be treated comprises energizing the at least one elongate flexible probe so that energy is emitted therefrom.

17. The method of claim 9 further comprising adjusting an exposed portion of said at least one elongate flexible probe by sliding an adjustable sleeve surrounding said at least one elongate flexible probe.

18. An ablation device comprising:

a shaft having a distal end;

at least two sleeves extending from said distal end, said sleeves slidably associated therewith such that a portion of said sleeves extending past said distal end may be adjusted; and,

at least two elongate flexible ablative probes extending from the distal end of the shaft through said at least two sleeves;

wherein each of the at least two elongate flexible probes can deliver ablative energy along its length;

wherein adjusting said sleeves adjusts a portion of said probes not covered by said sleeves; and,

wherein each of the at least two elongate flexible probes is malleable, allowing the length of the probe to be manipulated into a desired shape.

19. The ablation device of claim 18 wherein at least one of the probes further comprises a fillable balloon surrounding at least part of the at least one probe, and usable to insulate selected surrounding tissue and fluid from energy being emitted from the probe.

20. The ablation device of claim 18 wherein each of said probes is slidable within said shaft such that said probe length is adjustable.

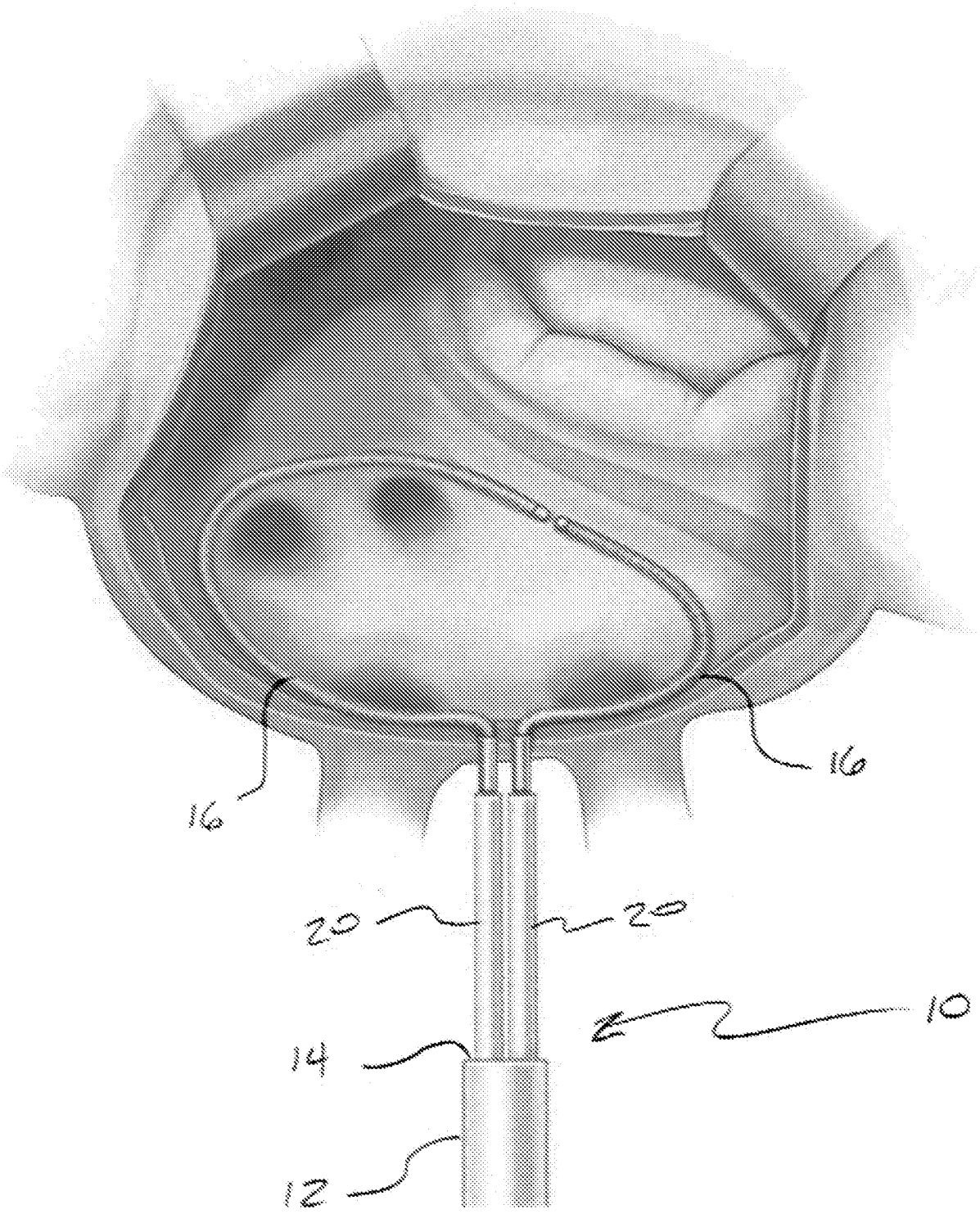


FIG. 1

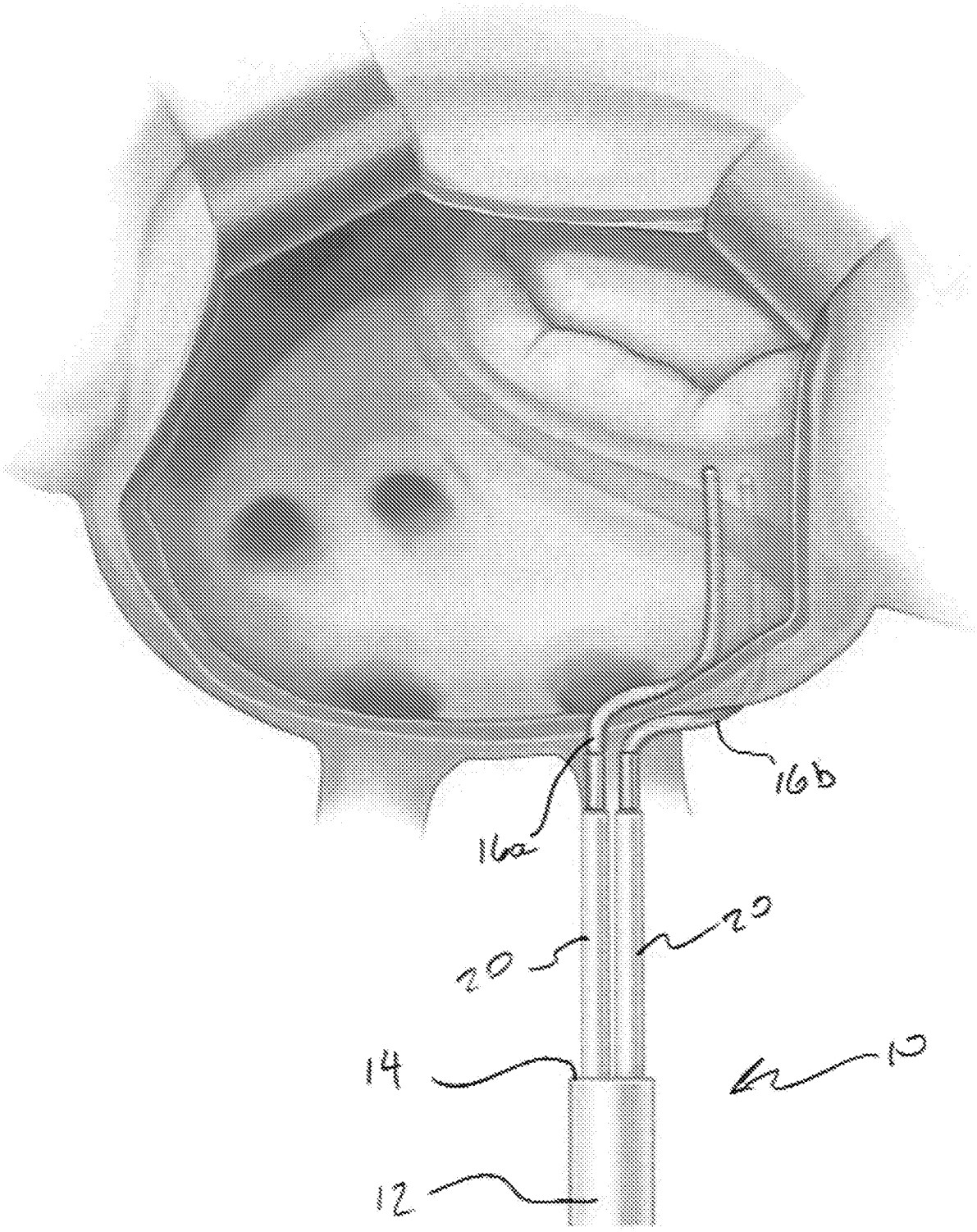


FIG. 2

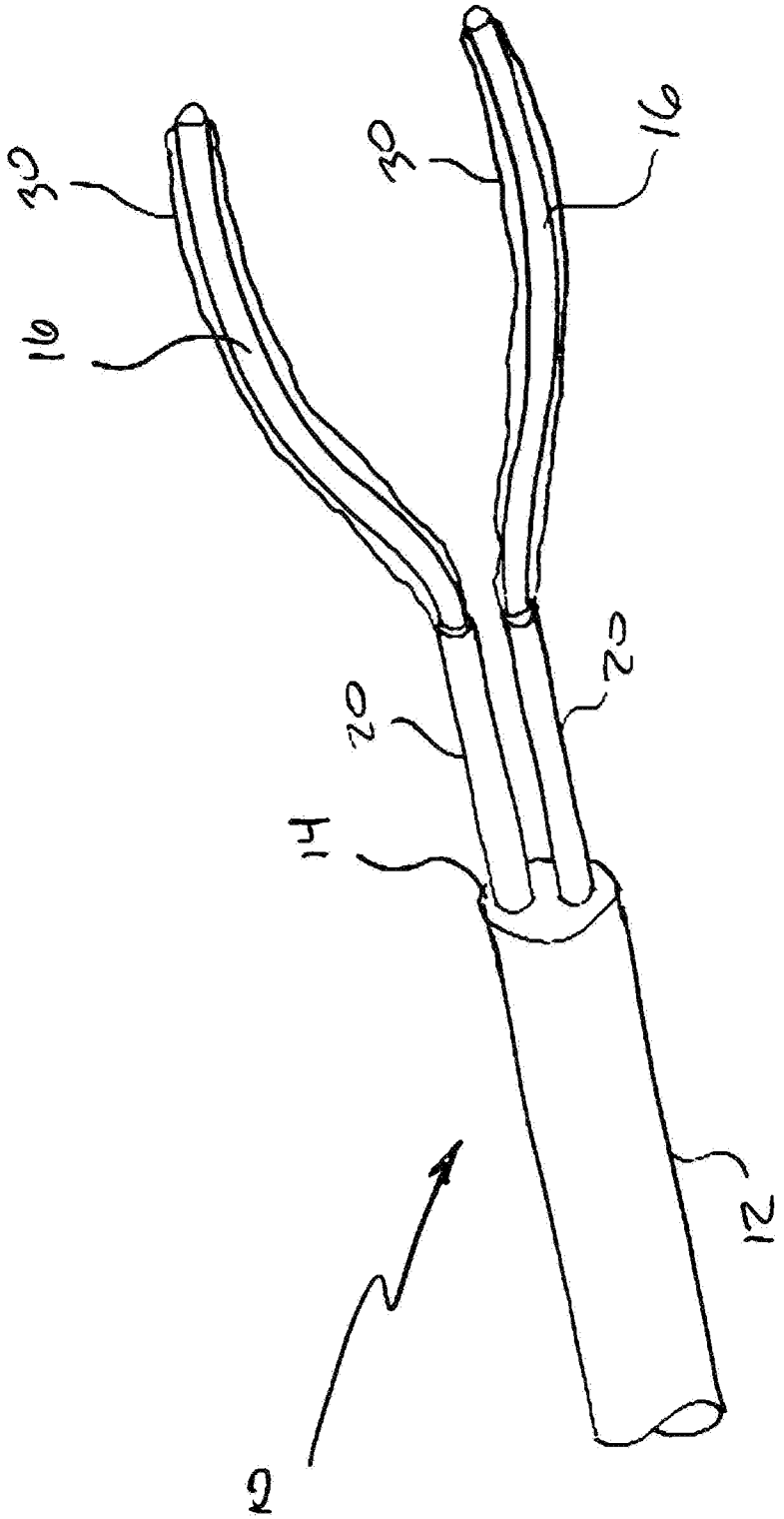


FIG. 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/47633

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 18/14 (2016.01)
CPC - A61B 2018/00369, 2018/00577, 2018/1465
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)
IPC(8) : A61B 18/14 (2016.01)
CPC : A61B 2018/00369, 2018/00577, 2018/1465

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC(8) : A61B 18/00, 18/02, 18/04, 18/08, 18/12, 18/20 (2016.01)
CPC: A61B 18/00, 18/02, 18/04, 18/08, 18/12, 18/14, 18/20, 2018/00351, 2018/00357, 2018/00363, 2018/1405, 2018/1467

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Patbase, Google Patent, Google, Scholar: dual, twin, double, two, second, three, triple, third, ablation, cryoblation, probe, element, prong, fork, arm, lead, flexible, malleable, bend, sleeve, sheath, cover, retract, extend, slide, translate, cardiac, heart, atrial, manual, remote, split, multiple, plural, forked

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2014/0214031 A1 (SWANSON) 31 July 2014 (31.07.2014) see especially para [0063], [0082], [0090], [0112], [0120], [0121], claim 8, fig 34	1, 4, 6-7, 9, 12-14, 16
X	US 2006/0184167 A1 (VASKA et al) 17 August 2006 (17.08.2006) see especially para [0010], [0011], [0014], [0157], [0158], [0160], [0162], [0164]-[0168], [0171], [0188], fig 1A, 2A-E, 5A-C, 12, 13	1, 3, 5-9, 11-20
X	US 2006/0015165 A1 (BERTOLERO et al) 19 January 2006 (19.01.2006) see especially para [0078], [0100], [0123], [0124], [0126], [0127], [0128], fig 7, 7A, 8	1-2, 5-7, 9-10, 12-14, 16
A	US 2015/0141785 A1 (HAYAM et al) 21 May 2015 (21.05.2015) see whole document	1-20
A	US 2011/0282344 A1 (WHAYNE et al) 17 November 2011 (17.11.2011) see whole document	1-20
A	US 2005/0033285 A1 (SWANSON et al) 10 February 2005 (10.02.2005) see whole document	1-20
A	US 2002/0111618 A1 (STEWART et al) 15 August 2002 (15.08.2002) see whole document	1-20
A	US 6,500,175 B1 (GOUGH et al) 31 December 2002 (31.12.2002) see whole document	1-20

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 October 2016	04 NOV 2016
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)