(19) World Intellectual Property Organization

International Bureau



US



(43) International Publication Date

17 April 2008 (17.04.2008)

- (51) International Patent Classification: A61N 1/02 (2006.01)
- (21) International Application Number:

PCT/US2007/080817

- (22) International Filing Date: 9 October 2007 (09.10.2007)
- (25) Filing Language:
- (26) Publication Language: English
- (30) Priority Data:

60/828,939 10 October 2006 (10.10.2006)

- (71) Applicant (for all designated States except US): ST. JUDE MEDICAL, ATRIAL FIBRILLATION DIVI-SION, INC. [US/US]; 6500 Wedgwood Road, Maple Grove, Minnesota 55311-3642 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): JUST, Dale E. [US/US]; 4005-19th Ave. S., Minneapolis, Minnesota 55407 (US). KAUPHUSMAN, James V. [US/US]; 11681 Norway Court, Champlin, Minnesota 55316-2623 (US). CHRISTIAN, Steven C. [US/US]: 695 Riviera Drive. New Brighton, MN 55112 (US).
- (74) Agent: HEIMBECHER, Reed R.; Legal Department, St. Jude Medical, AF Division, Inc., 14901 DeVeau Place, Minnetonka, Minnesota 55345-2126 (US).

(10) International Publication Number WO 2008/045877 A2

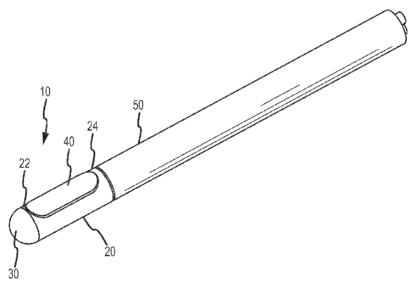
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM. ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

- as to the identity of the inventor (Rule 4.17(i))
- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))

[Continued on next page]

(54) Title: ELECTRODE TIP AND ABLATION SYSTEM



(57) Abstract: An electrode tip (10) for an ablation catheter (50) comprising an electrode carrier (20); a first electrode (30) provided at a distal portion (22) of the electrode carrier (20), the first electrode (30) adapted to direct energy in a forward longitudinal direction; and a second (e.g., side-firing) electrode (40) provided at a side portion of the electrode carrier (20), the second electrode (40) adapted to direct energy in a lateral direction. In an embodiment the first and second electrodes (30, 40) can be selectively activated. Other embodiments of electrode tips (10) that provide ablative elements that are directed laterally are also disclosed. Moreover, embodiments of several types of electrode tips (10), which may include positioning, orientation, irrigating, cooling, and deflecting features, whether provided individually or in various combinations, are also disclosed.



— as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

Published:

 without international search report and to be republished upon receipt of that report

ELECTRODE TIP AND ABLATION SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of United States Provisional Application No. 60/828,939, filed 10 October 2006, which is hereby incorporated by reference as though fully set forth herein.

BACKGROUND OF THE INVENTION

A. Field of the Invention

5

15

20

25

[0002] The present invention generally relates to electrode tips and ablation systems.

Aspects of the invention involve catheter-based ablation systems useful for ablating biological tissue, including the treatment of heart conditions.

B. Background Art

[0003] Catheters have been in use for medical procedures for a number of years. For example, one procedure, often referred to as "catheter ablation," utilizes a catheter to convey energy to a selected location within the human body. Another procedure oftentimes referred to as "mapping" utilizes a catheter with sensing electrodes to monitor various forms of electrical activity in the human body.

[0004] Moreover, catheters are increasingly used for medical procedures involving the human heart, including the treatment of certain types of ventricular arrhythmia and atrial arrhythmia. Such procedures commonly involve the ablation of tissue in the heart and are performed many times with an ablation catheter. Ablation catheters are commonly inserted in an artery or vein in the leg, neck, or arm of the patient and threaded, sometimes with the aid of a guidewire or introducer, through the vessels until the distal tip of the ablation catheter reaches a desired location for the ablation procedure. The ablation catheters commonly used to perform such procedures often electrically isolate or render the tissue non-contractile at particular points by physical contact of the tissue with an electrode of the ablation catheter and the application of energy.

[0005] In some conventional ablation procedures, the ablation catheter includes a single distal electrode secured to the tip of the ablation catheter to produce small lesions

wherever the tip contacts the tissue during energy application. To produce a linear lesion, the tip may be dragged slowly along the tissue during energy application. Increasingly, however, cardiac ablation procedures utilize multiple electrodes affixed to the catheter body to form multiple lesions.

[0006] One difficulty in obtaining an adequate ablation treatment using conventional ablation catheters is the constant movement of the heart, particularly when there is an erratic or irregular heart beat. Another difficulty in obtaining an adequate ablation treatment is caused by the inability of conventional catheters to obtain and retain sufficient contact with target tissue along or across various tissue surfaces.

10

15

20

25

30

5

BRIEF SUMMARY OF THE INVENTION

[0007] It is desirable to be able to provide a means for more selectively ablating tissue at a target site using minimally invasive approaches. It is further desirable provide good contact between the ablative element and the targeted tissue.

[0008] The present invention provides various embodiments of electrode tips for use in connection with an ablation catheter and ablation catheter systems. In an embodiment, an electrode tip is provided that comprises an electrode carrier; a first electrode provided at a distal portion of the electrode carrier, the first electrode adapted to direct energy in a forward longitudinal direction; and a second (e.g., side-firing) electrode provided at a side portion of the electrode carrier, the second electrode adapted to direct energy in a lateral direction. In an embodiment the first and second electrodes can be selectively activated.

[0009] Other embodiments of electrode tips that provide ablative elements that are directed laterally are also disclosed. Moreover, embodiments of several types of electrode tips, which may include positioning, orientation, irrigating, cooling, and deflecting features, whether provided individually or in various combinations, are also disclosed.

[0010] The foregoing and other aspects, features, details, utilities, and advantages of the present invention will be apparent from reading the following description and claims, and from reviewing the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

- [0011] FIG. 1 is a perspective view of an electrode tip in accordance with an embodiment of the invention.
- [0012] FIG. 2 is a top view of the electrode tip of FIG. 1.
- 5 [0013] FIG. 3 is a side view of the electrode tip of FIG. 1.

- [0014] FIG. 4 is a perspective view of an electrode tip in accordance with another embodiment of the present invention.
- [0015] FIG. 5 is a side view of the electrode tip shown in FIG. 4.
- [0016] FIG. 6 is a cross-sectional view of the electrode carrier included with the tip viewed along lines 6-6 in FIG. 5.
 - [0017] FIG. 7 is a perspective view of an electrode tip in accordance with an embodiment of the invention.
 - [0018] FIG. 8 is a partial cut-away view of the electrode tip of FIG. 7.
 - [0019] FIG. 9 is a perspective view of an electrode tip in accordance with an embodiment of the invention, showing portions of the tip in phantom.
 - **[0020]** FIG. 10 is cross-sectional representation of an electrode tip in accordance with an embodiment of the invention.
 - [0021] FIG. 11 is a cross-sectional view of the electrode tip of FIG. 10.
- [0022] FIG. 12 is a perspective view of an embodiment of an electrode carrier in accordance with an embodiment of the invention.
 - [0023] FIG. 13 is a perspective view of another embodiment of an electrode carrier in accordance with an embodiment of the invention.
 - [0024] FIG. 14 is a general representation and partial view illustration of a manner of assembling an electrode and an electrode carrier.
- 25 [0025] FIG. 15 is an end view of an assembled electrode and an electrode carrier.
 - [0026] FIG. 16 is a perspective view of an electrode tip in accordance with an embodiment of the invention.
 - [0027] FIG. 17 is a partial exposed view of an electrode tip as shown in FIG. 16.
 - [0028] FIG. 18 is a partial cut-away view of an electrode tip as shown in FIG. 16,
- viewed from the bottom and shown with the central electrode removed.

[0029] FIG. 19 is another partial cut-away view of an electrode tip as shown in FIG. 16, viewed from above and shown with a portion of the electrode carrier and the central electrode removed.

- [0030] FIG. 20 is another partial cut-away view of an electrode tip as shown in FIG.
- 5 16, viewed from the direction of an associated catheter.
 - [0031] FIG. 21 is partial cut-away view of an electrode tip according to an embodiment of the invention.
 - [0032] FIG. 22 is a side sectional view of an electrode tip according to an embodiment of the invention.
- 10 **[0033]** FIG. 23 is a side view of a graphical representation of an electrode tip according to an embodiment of the invention.
 - [0034] FIG. 24 is a perspective view of an electrode tip according to an embodiment of the invention.
- [0035] FIG. 25 is a side view of a graphical representation of an electrode tip according to an embodiment of the invention.
 - [0036] FIG. 26 is a top view of a portion of an electrode tip according to an embodiment of the invention.
 - [0037] FIG. 27 is a perspective view of an electrode tip according to an embodiment of the invention.
- 20 [0038] FIG. 28 is a front sectional view of an electrode tip of the type illustrated in FIG. 27.
 - [0039] FIG. 29 is a perspective view of an electrode tip according to an embodiment of the invention.
 - [0040] FIG. 30 is a rotated perspective view of the electrode tip illustrated in FIG.
- 25 29.
 - [0041] FIG. 31 is a side view of the electrode tip illustrated in FIG. 29.
 - [0042] FIG. 32 is a perspective view of an electrode tip according to an embodiment of the invention.
- [0043] FIG. 33 is a front view of an electrode tip according to an embodiment of the invention.
 - [0044] FIG. 34 is a rear perspective view of the electrode tip of FIG. 33.

[0045] FIG. 35 is a front perspective view of the electrode tip of FIG. 33, shown with a mechanical distention member in a deployed configuration.

- [0046] FIG. 36 is a front view of the electrode tip of FIG. 33, shown with a mechanical distention member in a deployed configuration.
- 5 [0047] FIG. 37 is a rear perspective view of the electrode tip of FIG. 33, shown with a mechanical distention member in a deployed configuration.
 - [0048] FIG. 38 is a perspective view of an electrode tip according to an embodiment of the invention, shown with a portion of the distal end in phantom.
- [0049] FIG. 39 is a perspective view of a portion of an electrode tip according to an embodiment of the invention.
 - [0050] FIG. 40 is a perspective view of an electrode tip according to an embodiment of the invention, shown with a portion of the distal end in phantom.
 - [0051] FIG. 41 is a perspective view of an electrode tip according to an embodiment of the invention, shown with a manifold and with a portion of the distal end in phantom and a portion of the associated tube in transparent form.

15

- [0052] FIG. 42 is a perspective view of a portion of an electrode tip according to an embodiment of the invention.
- [0053] FIG. 43A is representation of a focal point associated with multiple transducers.
- 20 **[0054]** FIG. 43B is representation of multiple focal points associated with multiple transducers.

DETAILED DESCRIPTION OF THE INVENTION

[0055] FIG. 1 illustrates an electrode tip 10 according to an embodiment of the invention. FIGS. 2 and 3 illustrate a top and side view of an electrode tip 10 of the type generally shown in FIG. 1. The illustrated electrode tip 10 includes an electrode carrier 20, including a distal portion 22 and a proximal portion 24; a first electrode 30; and a second electrode 40. As generally illustrated, electrode tip 10 may be adapted for connection to a portion of a catheter 50.

[0056] In an embodiment, the first electrode 30 is provided at the distal portion 22 of the electrode carrier 20. The first electrode 30 is adapted to direct energy in at least a forward longitudinal direction. For some embodiments, the exposed or potentially active portion of the first electrode 30 may be reduced, for example by providing an electrode with a different shape and/or covering a portion of the electrode with an insulated or isolative material that prevents transmission of energy into tissue not targeted for ablation. Consequently, depending upon the configuration of the first electrode, and the degree of non-insulated exposure, some portion of the energy conveyed by the first electrode 30 may also be directed in other than a forward longitudinal direction.

5

10

15

20

25

30

[0057] The second electrode 40 is provided at a side portion of the electrode carrier 20. The second electrode is adapted to direct energy in a side or lateral direction relative to the electrode carrier 20. As generally illustrated in FIGS. 1 and 2, the second electrode 40 may be generally oval and may extend outwardly, to some degree (for example as shown in FIG. 3) from the adjacent surface of the electrode carrier 20. However, the invention is not limited to such a configuration, and other configurations and positioning of the electrode carrier 20, including, without limitation, those illustrated in other embodiments disclosed herein are contemplated by the invention.

[0058] The first and/or second electrodes 30,40 may be configured to energize and ablate tissue, may additionally be a sensing electrode (for example, to provide a mapping function), and/or may include other functionality. Moreover, the first and/or second electrodes 30,40 may include one or more wires or lines that are provided or strung through a catheter to a proximal region of the catheter.

[0059] FIGS. 4-6 generally illustrate another embodiment of an electrode tip that also includes a first electrode 30 and a second electrode 40. In this embodiment, the electrode tip comprises a non-circular cross-section, which may take the form of an oval cross-section, such as shown in FIGS. 5 and 6. Further, for some embodiments, it may be desirable for the electrode tip 10 to include an orientation feature that can help indicate to a user that the tip 10 is appropriately directed toward a the targeted tissue. In addition to including a means for measuring impedance (including that discussed further in connection with other embodiments), the inventive concept may, instead of or in addition to, provide a portion of the electrode tip, particularly a portion near or adjacent

side electrode 40, with a geometry that, at least to some degree, is more stable and resistant to a "rolling" movement than an electrode carrier with a circular or curved outer surface and/or provides some mechanical or physical feedback (e.g., resistance to twisting or rotation) with respect to the positioning of the operative portion of the electrode tip 10 relative to a surface. For example, in the embodiment illustrated in FIGS. 4-6, the electrode carrier 20 includes a surface 26 with "flat" (i.e., flat or substantially flat) portions adjacent the second electrode 40 – for example at or about the distal and proximal portions 22, 24 illustrated in FIG. 4. Moreover, as generally illustrated in the cross section of the electrode carrier 20, the carrier may generally have a first dimension **X** and a second dimension **Y**. For some embodiments, second dimension **Y** will be at least 1.5 times dimension **X**. For other embodiment, dimension **Y** will be two or more times dimension **X**.

5

10

15

20

25

30

[0060] As generally illustrated in FIG. 4, the electrode tip may be connected to a catheter extension 60. The catheter extension 60 may be configured to provide a connective transition between electrode tip 10 and a distal portion of catheter 50. In alternative embodiments, electrode tip may include an extension portion that is formed integrally with a portion the electrode tip.

[0061] In an embodiment, the first and second electrodes can be selectively activated. For example, depending upon the circumstances, such as the area of target tissue intended to be subjected to ablation, the first electrode 30 may be "off" or inactive, while the second electrode 40 is "on" or active. For other circumstances, the first electrode may be "on" for distal end contact, while the second electrode 40 is "off." Such selective control may be provided via a remote (relative to the electrode tip) switch or control that may be associated with the energy or power source associated with each electrode. Moreover, there may be some circumstances in which it is desirable for both electrodes to be simultaneously active or inactive.

[0062] The energy associated with the first and/or second electrodes 30, 40 may be radio frequency (RF) energy provided via a catheter from one or more RF energy source or sources. However, the invention is not limited to such a source of energy, and other energy forms that permit the desired directional control associated with the electrodes may also be used. For example, without limitation, focused ultrasound, shielded

microwave, and other energy sources, particularly those with a directional aspect, may also be employed with embodiments of the invention.

[0063] FIG. 7 illustrates an electrode tip 10 according to another embodiment of the invention. The illustrated electrode tip 10 includes an electrode carrier 20, including a distal portion 22 and a proximal portion 24; and a side electrode 70, which functions similarly to the aforementioned second electrode 40. As generally illustrated, electrode tip 10 may be adapted for connection to a portion of a catheter 50 or various forms of catheter extensions. Optionally, and to the extent the overall width of the electrode tip can be configured for an intended application, a second similar side electrode (not shown) may be provided and positioned on the electrode tip, for example, about 180° from the illustrated side electrode 70. Further, as discussed in connection with prior multiple-electrode embodiments, the electrodes may be selectively activated.

5

10

15

20

25

30

[0064] As better illustrated in the cut-away view of the electrode tip 20 shown in FIG. 8, a portion 28 of the electrode carrier 20 may be adapted to be connected to a portion of catheter 50. For example, without limitation, a portion 52 of catheter 50 may surround and be firmly secured or connected to portion 28 of the electrode carrier 20.

[0065] The invention also contemplates the optional inclusion of a means for providing irrigation and/or cooling to at least a portion of the electrode tip 10. For example, as generally shown in FIGS. 8-11, electrode tip 20 may include one or more lines, passages and/or conduits 80, 82 for transmitting a fluid to and/or from the electrode tip 10. As shown, in an embodiment, the line, passage, and/or conduit that supplies a fluid (such as a cooling fluid, e.g., saline) may be provided about or in close proximity to the portion of the electrode tip 10 that performs the ablation, and, for some embodiments, an open tip portion 84 may be provided at or near the distal end of the electrode tip 10.

[0066] In an embodiment, the electrode tip (e.g., electrode carrier) may include an external porous membrane, and/or one or more external openings or orifices, to provide localized cooling to portions of the electrode tip in proximity to non-targeted surrounding areas or tissue. For example, a portion of the electrode carrier may be comprised of a material that permits controlled weeping. In an embodiment, a porous membrane may be provided that is comprised, at least in part, of a polymer (e.g., a

sintered expanded PTFE) that includes an open lattice construction. In yet another embodiment, the structure supporting the ablative element of the electrode tip may be comprised of a porous material to permit localized irrigation and/or cooling for nearby non-target tissue.

FIGS. 12 and 13 generally illustrate embodiments of the invention in which the electrode carrier 20 may be provided with a cut-out 21 through which an ablation electrode (e.g., electrode 70) may be exposed. FIGS. 12, 14, and 15 illustrate embodiments in which an electrode 70, which may include conduits or passages 80, 82, may be positioned and secured within an electrode carrier 20. For other embodiments, such as the type illustrated in FIG. 14, the electrode carrier 20 may be over-molded, or may be separately cast or otherwise formed.

[0068] Another embodiment of an electrode tip 10 is generally illustrated in FIG. 16. As generally shown, the electrode tip 20 may take on a "paddle"-like shape, and, if desired, may include more than one electrode. For example, in the illustrated embodiment, the electrode tip 20, includes a round, central electrode 90, and additionally includes a plurality of relatively smaller round EGM button electrodes 100.

15

20

25

30

[0069] FIGS. 17-20 illustrate additional views of an electrode tip 20 of the type shown in FIG. 16, as well as various sub-combinations thereof. Turning to FIG. 17, a side view of an electrode tip 20 is shown with a portion (see, e.g., element 102 in FIG. 20) of the electrode carrier 20 about the electrodes 90,100 removed. Depending upon the desired method of manufacturing, the removed portion 102 may be formed integrally with the remainder of the electrode carrier 20.

[0070] FIGS. 18 and 19 illustrate views of the electrode tip 20 shown with electrode 90 removed. As generally illustrated in this figure, the electrode 90 may additionally include an extension 110 and may further include one or more horizontal passages (e.g., 112, 114), which may be connected to cooling fluid passages (e.g., 80, 82) and/or one or more vertical passages (e.g., 116, 118). Such passages may, among other things, be configured to provide energy and/or cooling fluid to the electrode and/or in the vicinity of the intended ablation area. While various specifics, including specific configurations of components, have been disclosed, the invention is not so limited, and a wide number

of alternative configurations may be readily contemplated by those of skill in the art and are encompassed by the present invention as embodied in the claims.

[0071] Another aspect of the invention involves the sensing of contact with tissue and/or the orientation of the electrode tip 10. As generally illustrated in the embodiment shown in FIG. 21, the electrode tip 20 may include an electrode 70, and may additionally include another conductive formation 120, such as a ring or pad. The second conductive formation 120, which may be spaced a known longitudinal distance **D** from electrode 70, permits the measuring of a signal that is transmitted across the electrode 70 and conductive formation 120, which, in turn, can be used to determine contact with tissue and/or orientation of the electrode tip with respect to such tissue. FIG. 22 provides a side cross-sectional view of an electrode tip of the type generally illustrated in FIG. 21, and includes a form of cooling conduits or lines (e.g., lines 80, 82) to the tip.

5

10

15

20

25

30

[0072] FIG. 23 generally illustrates an embodiment of an electrode tip 20 with two conductive formations – comprising two conductive rings 120a, 120b. The conductive rings 120a, 120b may be longitudinally spaced apart at a known distance $\mathbf{D_1}$, may comprise a conductive material, and may be connected or coupled to leads 121a, 121b. In an embodiment, the spaced distance $\mathbf{D_1}$ may, for example and without limitation, be about 1 mm.

[0073] In an alternate embodiment, such as generally illustrated in FIG. 24, one or both conductive formations may comprise conductive pads 120c, 120b. FIG. 25 generally illustrates the connection of a first conductive formation 122 and a second conductive formation 124. First and second conductive formations 122, 124 may, respectively, be connected or coupled to separate leads 122a, 124a. In an embodiment, the diameter of the electrode tip, generally represented in FIG. 25 as D_2 , may be about 3 mm. However, the diameter of the electrode tip is typically only bounded by the diameters associated with the intended application and environment. Consequently, the electrode tip of the present invention may involve other sizes and configurations that are suitable for the intended environments and applications.

[0074] FIG. 26 illustrates a variation of an embodiment in which an electrode tip includes two rings 120a, 120b. As generally illustrated only a portion of the rings 120a, 120b are exposed. The remaining portions of the rings 120a, 120b may be coated or

otherwise covered, for example, by an electrical insulator or insulating material 130. With such a configuration, the conductive formations, in this instance, rings 120a, 120b, can be used to detect when the electrode tip is in a given conductive relationship. That is, among other things, the conductive formations can detect signals and provide feedback to a user that the electrode tip is in a given contact and orientation with targeted tissue. For example, an electrode tip having such a means for detecting can be rotated and, based upon the signal – which may be processed and displayed remotely (e.g., on a monitor or screen) - a user can ascertain if the ablation portion of the electrode tip is in operative contact or communication with an intended target.

5

10

15

20

25

30

[0075] With some embodiments, the electrode tip may optionally include a means for deflecting or distending adjacent tissue away from a portion of the electrode tip. FIGS. 27 and 28 illustrate an example of such a feature in the form of a balloon or bladder 140 that may be selectively filled (e.g., with a gas or fluid) and/or evacuated or collapsed. Depending upon the application and configuration, the associated balloon or bladder 140 may comprise a flexible, rigid, or semi-rigid material.

[0076] FIGS. 29-31 generally represent another embodiment of an electrode tip that includes a means for deflecting or distending. Among other things, the means for deflecting or distending may increase the distance of the electrical pathway to help protect adjacent tissue or structures from unintended damage due to the supply of energy or heat from the electrode tip. As generally shown, a side-firing electrode tip of the type previously shown and discussed in connection with FIGS. 16-20, may include a paddlelike carrier 20 and may include at least one balloon or bladder 140 that may surround or circumscribe the ablation region of the electrode tip (e.g., a central electrode 90 and a plurality of relatively smaller button electrodes 100). Depending upon the desired application and configuration, the balloon or bladder 140 may extend in a direction opposing the direction of ablation treatment from the electrode tip, which can help improve the contact or operative communication of the electrodes with an intended treatment site. As generally shown in FIG. 30, one or more supply openings or access ports 150 may be in internal communication with the balloon or bladder 140, and may provide for the controllable filling and/or evacuation of a gas or fluid from all or a portion of the balloon or bladder 140. Supply lines or conduits for such openings or

ports 150 can extend through an associated catheter 50 to one or more remote supply source and/or receiving unit.

[0077] FIG. 32 generally illustrates an electrode tip 10 according to another embodiment of the invention. As generally shown, electrode tip 10 may include an electrode 70 and an electrode carrier 20 having a distal portion 22 with a hemispherical portion, and a proximal portion 24. Electrode tip 10 may be connected to a portion of a catheter 50, and may further include a balloon or bladder 140 of the type previously disclosed.

5

10

15

20

25

[0078] For other embodiments, the means for deflecting or distending may comprise one or more small-diameter wires, plastic extensions, or other formations that can be deployed and reduced or retracted as necessary or desired. An example of such a configuration is disclosed in FIGS. 33-37. FIGS. 33 and 34 generally illustrate an electrode tip 10 in a non-deployed configuration, while FIGS. 35-37 generally illustrate the electrode tip 10 in a deployed configuration. As shown in the views of the illustrated embodiment, the electrode tip 10 may include an electrode carrier 20, an electrode 90, and a mechanical distention member 92. By way of example, without limitation, the electrode tip 10 may also optionally include one or more additional electrodes, such as a plurality of relatively smaller round button electrodes 100.

[0079] The mechanical distention member 92 may, for example, comprise one or more wires or leads 94 that may be secured at a position (see e.g., positions 96 shown in FIG. 36) on or about the electrode tip 10 such that portions of the wires or leads 94 may extend outwardly from the tip 10 to provide a means for separation from adjacent tissue or surfaces.

[0080] The foregoing means for deflecting or distending adjacent tissue or surfaces can, among other things, be configured to further separate ablation portions of the electrode tip from tissue or areas of the patient that are not intended to be treated; provide additional stability to the electrode tip relative to the area to be treated; and/or provide improved or additional contact force for the ablation portions of the electrode tip with respect to areas being treated (see, e.g., the surface generally designated as S_1).

30 **[0081]** Moreover, for some embodiments, including those previously described, the means for deflecting or distending adjacent tissue may be filled with a fluid or gas, and

may be additionally used to help cool adjacent tissue (e.g., tissue associated with the surface generally designated in FIG. 28 as S_2), which may reduce the likelihood of collateral damage to unintended tissue. In embodiments, the fluid or gas may comprise, without limitation, saline, sterile water, or air.

5

10

15

20

25

30

[0082] As previously noted, while various features and embodiments of the invention are generally discussed in connection with electrode tips employing radio frequency (RF) energy, the present invention is not limited to a single type of energy source. By way of example, without limitation, FIG. 38 generally illustrates an electrode tip that includes a transducer element 160, which may comprise one or more ultrasonic transducers. Typically, each transducer will have a line of focus (generally represented by lines 162). When a plurality of transducers are included in an electrode tip (i.e., with one or more transducer elements), the transducers may be positioned and configured so that their lines of focus will converge at a focal point 170. However, some embodiments, may include multiple focal points and, further, may include a focal region comprised of distributed foci.

[0083] FIG. 39 generally discloses an embodiment of a portion of an electrode tip 10 that includes a transducer element 160, an electrical access port 164, a coolant path 166 (which may follow the flow path indicated by the arrows), and one or more ports or openings 168 that are in communication with the coolant path and permit external release of a coolant about the transducer element 160 and possibly other portions of electrode tip 10. Further, in an embodiment, electrical access port 164 may, for example, provide access for electrical lines and may be potted closed. If desired, transducer element 160 may be bonded into electrode carrier 20. For some embodiments, the full active surface face of the transducer element may be exposed to a coolant, such as saline, which may be bled off through a plurality of ports or openings 168.

[0084] Additional embodiments of an electrode tip 10 are included in FIGS. 40-42. FIG. 40 generally illustrates an embodiment of an electrode tip 10 that includes a substantially flat transducer element 160. FIG. 41 generally illustrates an electrode tip 10 with a transducer element 160 according to an embodiment of the invention. The electrode tip 10 is shown including a plurality of openings 168 and a manifold 190. The electrode tip 10 is shown connected to a multi-lumen tube, which is shown with a

5

10

15

20

25

30

transparent outer surface to better illustrate several lumens 182 in communication with the electrode tip 10. FIG. 42 generally illustrates an electrode tip with an electrode element comprised of a plurality of transducers 200. As shown, the transducers 200 may be provided in the form of a curved linear array, which may, for example, be configured on a curved surface 202. FIG. 43A illustrates, in a non-limiting manner, how a plurality of transducers 200 may be configured such that their lines of focus will converge at a focal point or region 170. FIG. 43B represents an embodiment in which a plurality of transducers 200 are configured such that their lines of focus, the operation of activation/power which may be selectively controlled, provide a first focal point 170' at a first distance X, and a second focal point 170" at a second distance Y that is farther away from the transducer element. For example, as generally illustrated in FIG. 43A, a first intensity of power may be directed to the first focal point 170' by activating transducers 200b and 200d. It is possible for a second, higher intensity of power to be directed to the same first focal point 170' by additionally activating transducer 200c. A similar power/application control may be associated with focal point 170". Further, for other embodiments, additional focal points may be provided in connection with the configuration of the associated transducer element or elements. While various transducer-related embodiments are illustrated in FIGS. 38-42, it is important to note that various additional features discussed in connection with other embodiments may also be included with and/or incorporated into the transducer-related embodiments. example, without limitation, the transducer-related embodiments may also include similar means for cooling and/or means for deflecting or distending surrounding tissue.

[0085] As known to those of skill in the art, electrode tips in accordance with embodiments of the present invention may be configured to be connected to and have their positioning and orientations controlled by pull wires and/or other control means associated with various conventional catheters. The invention contemplates a catheter assembly with such electrode tips that is shapeable and/or steerable.

[0086] Although embodiments of this invention have been described above with a certain degree of particularity, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the spirit or scope of this invention. All directional references (e.g., upper, lower, upward, downward, left, right, leftward,

rightward, top, bottom, above, below, vertical, horizontal, clockwise, and counterclockwise) are only used for identification purposes to aid the reader's understanding of the present invention, and do not create limitations, particularly as to the position, orientation, or use of the invention. Joinder references (e.g., attached, coupled, connected, and the like) are to be construed broadly and may include intermediate members between a connection of elements and relative movement between elements. As such, joinder references do not necessarily infer that two elements are directly connected and in fixed relation to each other. It is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative only and not limiting. Changes in detail or structure may be made without departing from the spirit of the invention as defined in the appended claims.

5

CLAIMS

What is claimed is:

1. An electrode tip for an ablation catheter, comprising:

5 an electrode carrier:

15

- a first electrode provided at a distal portion of the electrode carrier, the first electrode adapted to direct energy in a forward longitudinal direction; and
- a second electrode provided at a side portion of the electrode carrier, the second electrode adapted to direct energy in a lateral direction;
- wherein the first and second electrodes can be selectively activated.
 - 2. The electrode tip of claim 1, wherein at least a portion of the first electrode is insulated or covered with a material to protect non-targeted external tissue or surfaces.
 - 3. The electrode tip of claim 1, wherein at least a portion of the second electrode is insulated or covered with a material to protect non-targeted external tissue or surfaces.
 - 4. The electrode tip of claim 1, wherein the first and second electrodes can be activated simultaneously.
 - 5. The electrode tip of claim 1, wherein the electrode tip includes a portion adapted for connection to a catheter.
- 6. The electrode tip of claim 1, wherein the electrode tip includes a portion that 20 is substantially cylindrical.
 - 7. The electrode tip of claim 1, wherein the electrode tip includes a portion having a substantially flat segment.
 - 8. The electrode tip of claim 1, wherein the electrode tip includes first and second conductive formations provided along a longitudinal axis that measure a signal transmitted across the electrode tip.

9. The electrode tip of claim 8, wherein the first conduction formation or the second conductive formation comprises the second electrode.

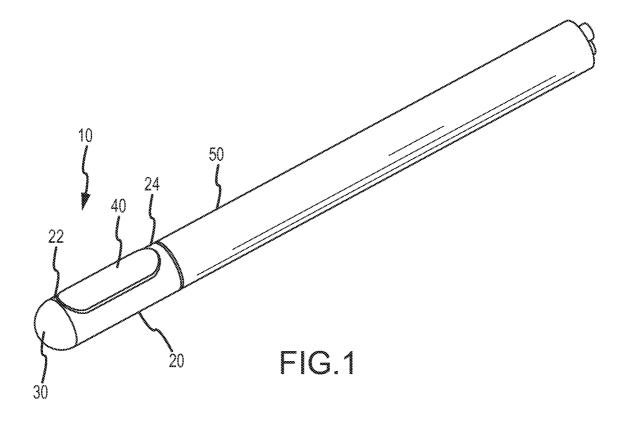
10. The electrode tip of claim 8, wherein the first and second conductive formations comprise two spaced conductive rings, two spaced conductive pads, or a ring and a pad.

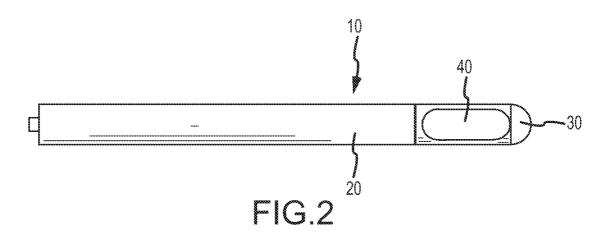
- 11. The electrode tip of claim 10, wherein the signal transmitted is used to determine contact with adjacent tissue, orientation of the electrode tip with respect to adjacent tissue, or contact with adjacent tissue and orientation of the electrode tip with respect to adjacent tissue.
- 10 12. The electrode tip of claim 1, including a means for providing cooling to external portions adjacent the first or second electrode.
 - 13. The electrode tip of claim 1, including a means for providing cooling to non-targeted external portions adjacent the electrode carrier.
- 14. The electrode tip of claim 1, including a closed-loop cooling system for cooling a portion of the tip portion.
 - 15. The electrode tip of claim 1, including a means for deflecting or distending adjacent tissue away from a portion of the electrode tip.
 - 16. The electrode tip of claim 15, wherein the means for deflecting or distending includes a balloon or ballast.
- 20 17. The electrode tip of claim 1, wherein the energy directed by the tip comprises radio frequency, ultrasound, or microwave energy.
 - 18. The electrode tip of claim 1, wherein the second electrode includes an ultrasound transducer that directs ultrasound energy in the lateral direction.
 - 19. An electrode tip for an ablation catheter, comprising:
- 25 an electrode carrier including a longitudinal axis;

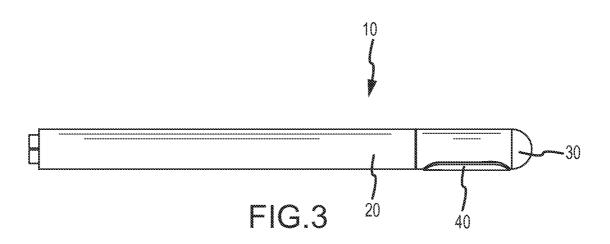
a side-firing electrode provided at a side portion of the electrode carrier, the sidefiring electrode adapted to direct energy in a lateral direction with respect to the longitudinal axis; and

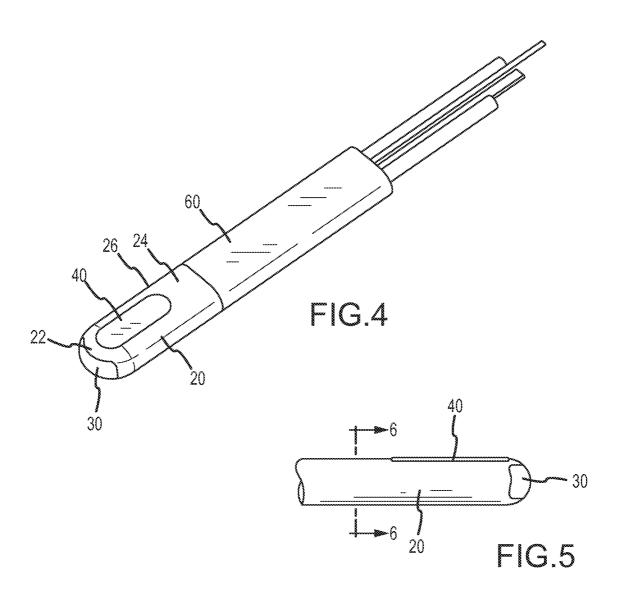
a means for positioning or orienting the electrode tip relative to an external target or surface.

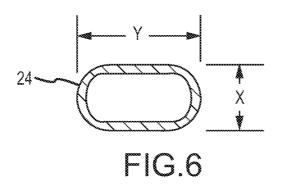
- 20. The electrode tip of claim 19, wherein the means for positioning or orienting the electrode tip comprises two conductive formations, or a means for deflecting or distending adjacent tissue away from a portion of the electrode tip.
- 21. The electrode tip of claim 19, including a means for providing cooling to external portions adjacent the side-firing electrode.
 - 22. The electrode tip of claim 19, including a means for providing cooling to non-targeted external portions adjacent the electrode carrier.

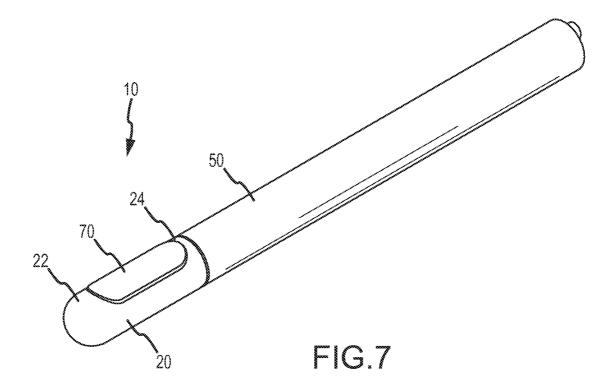












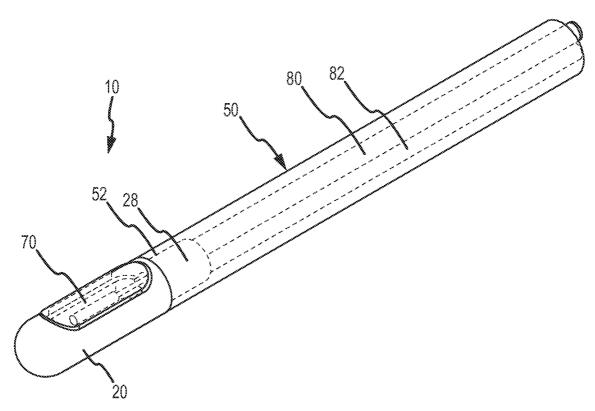


FIG.8

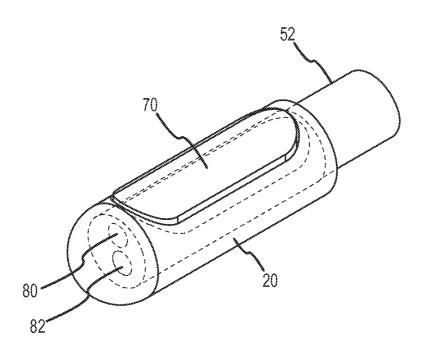
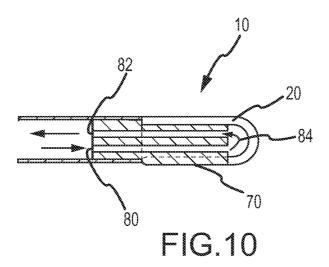


FIG.9



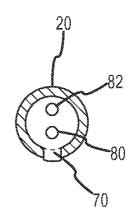


FIG.11

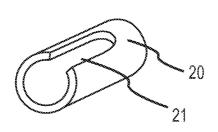


FIG.12

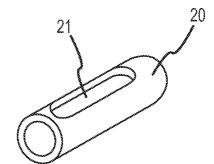


FIG.13

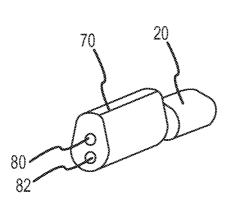


FIG.14

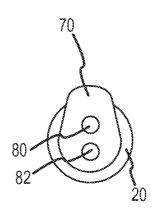
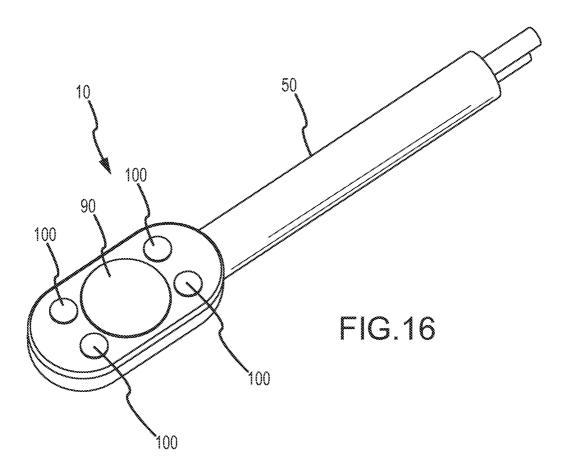


FIG.15



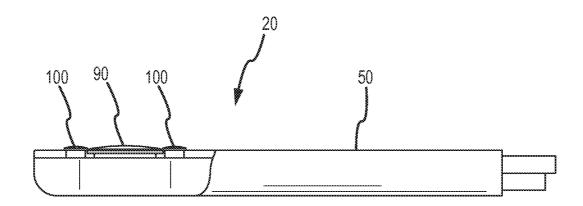
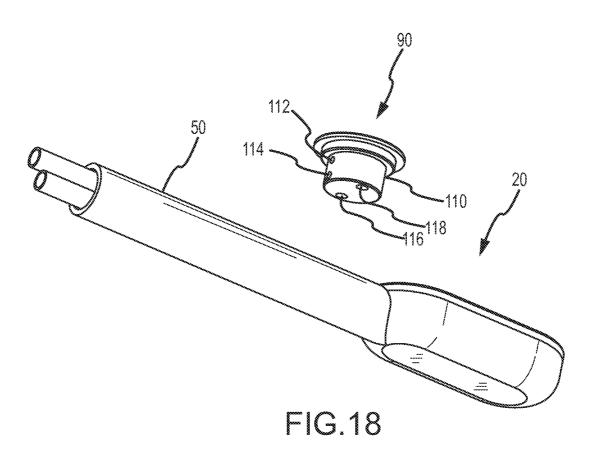
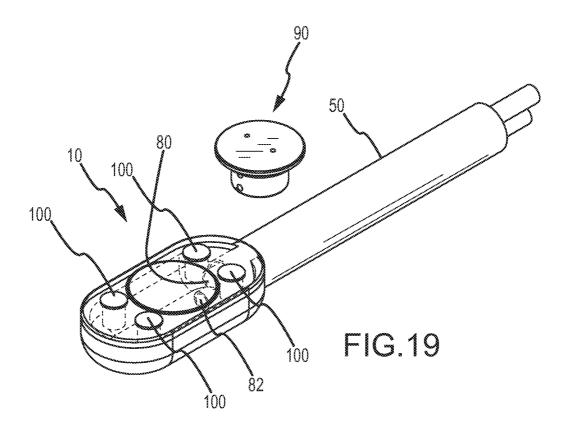


FIG.17





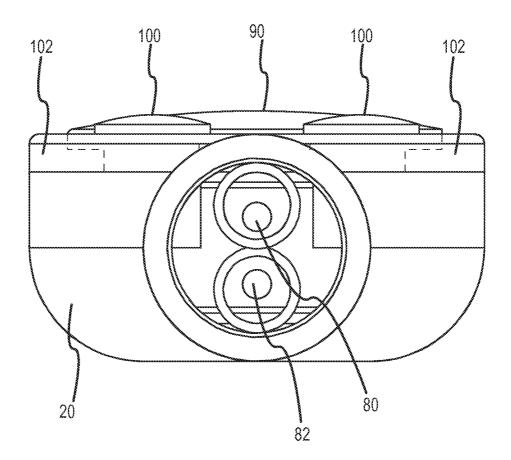
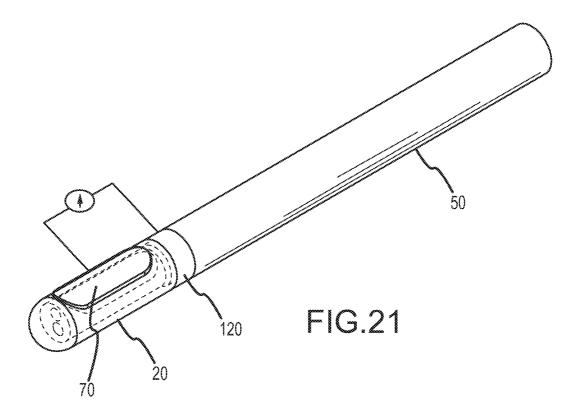


FIG.20



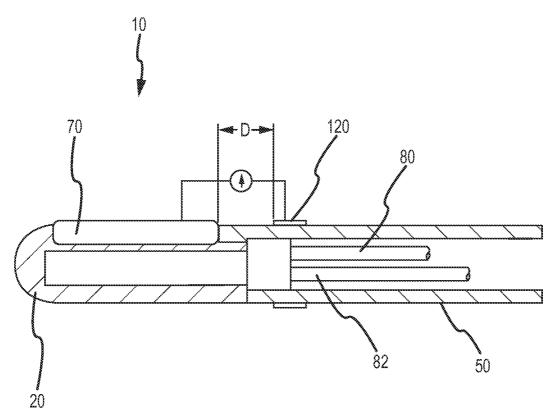
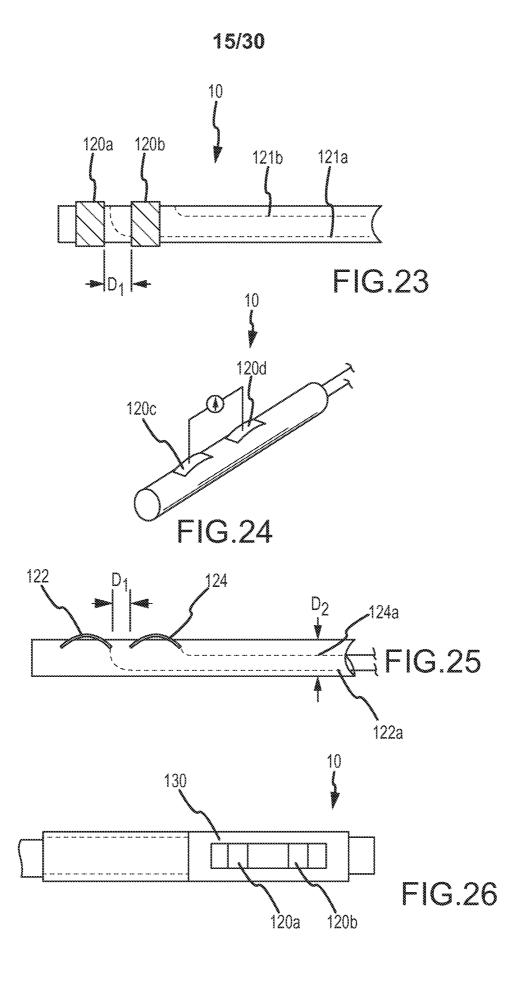
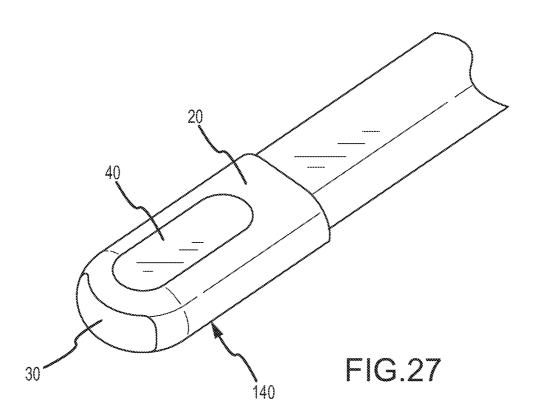
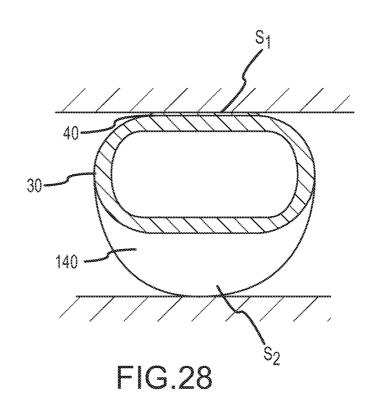


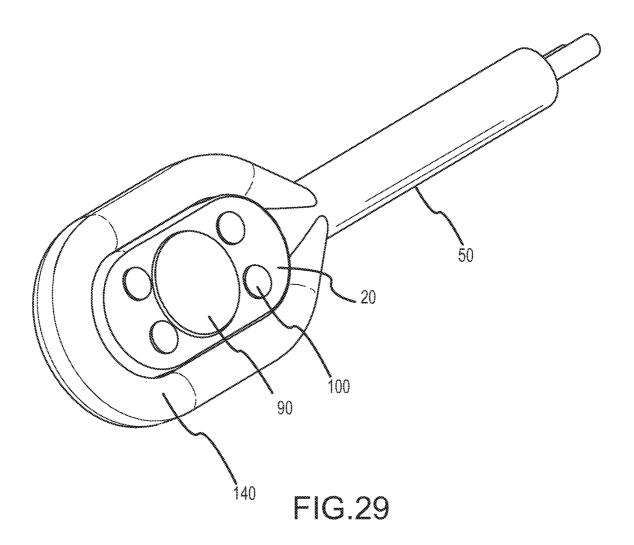
FIG.22



16/30







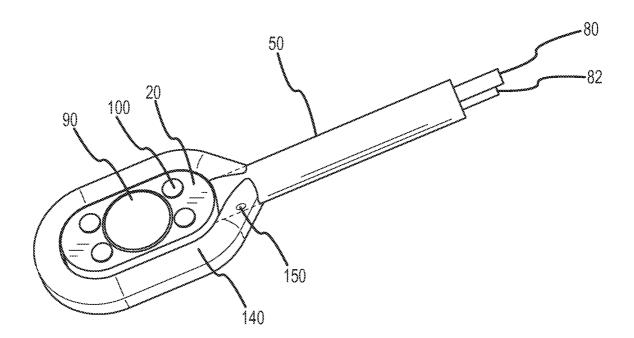


FIG.30

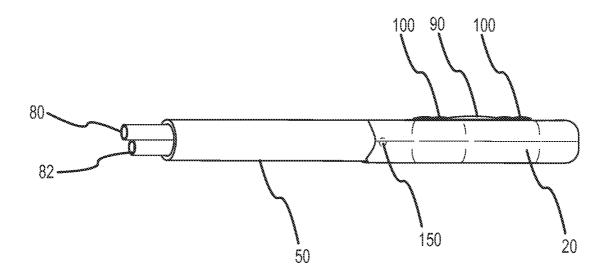


FIG.31

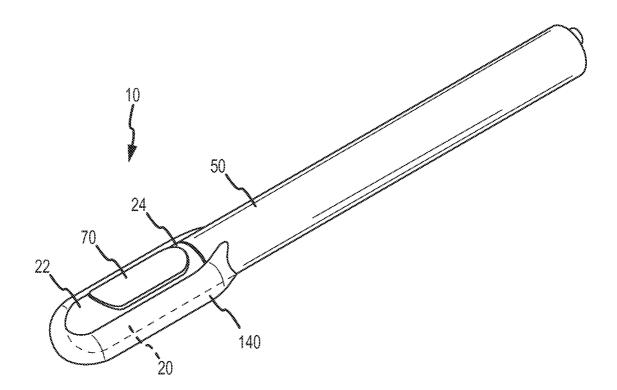


FIG.32

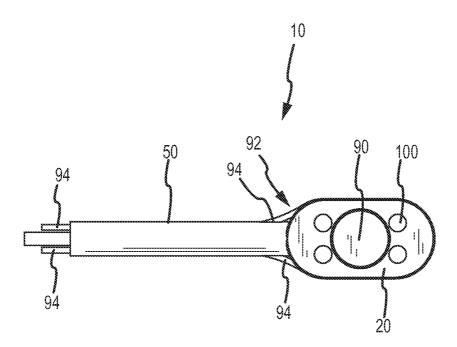


FIG.33

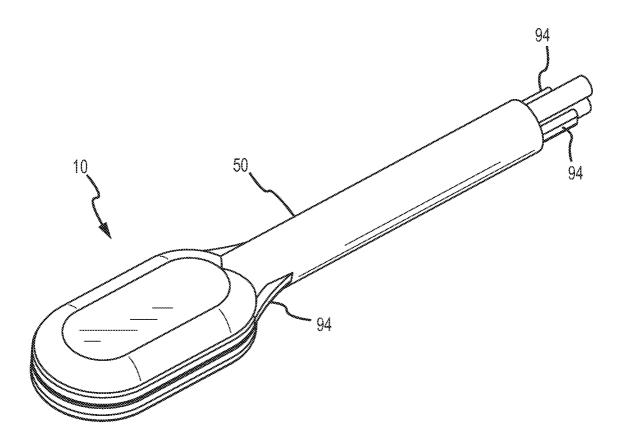


FIG.34

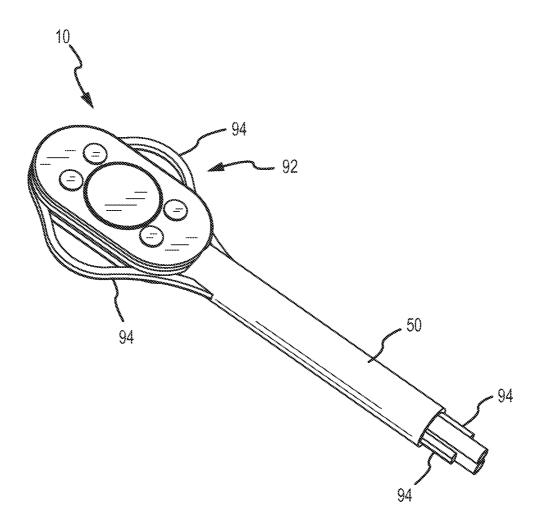


FIG.35

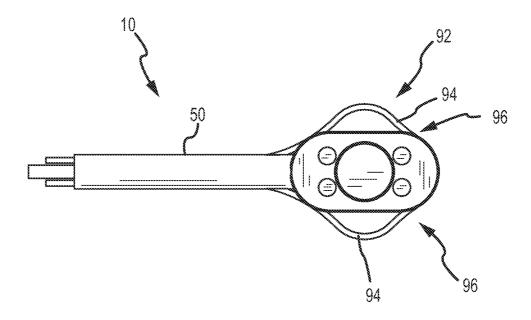


FIG.36

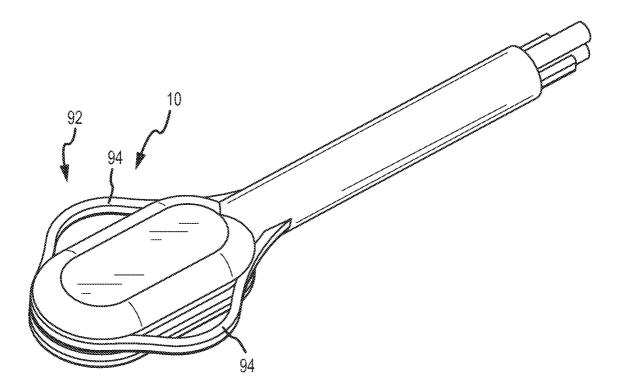


FIG.37

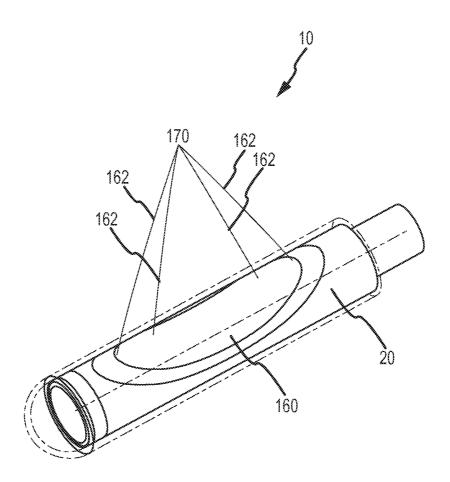


FIG.38

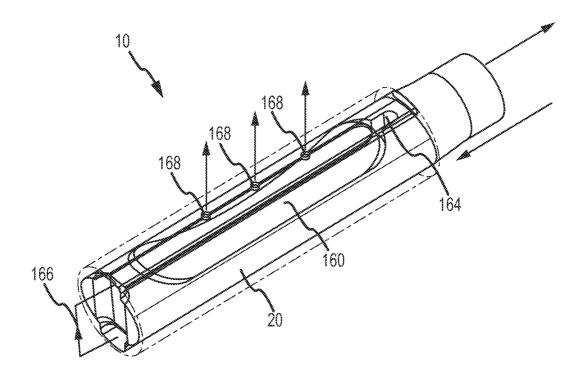


FIG.39

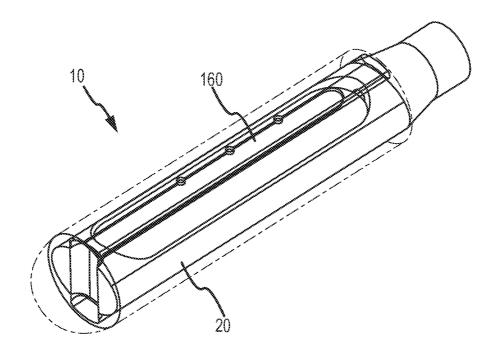


FIG.40

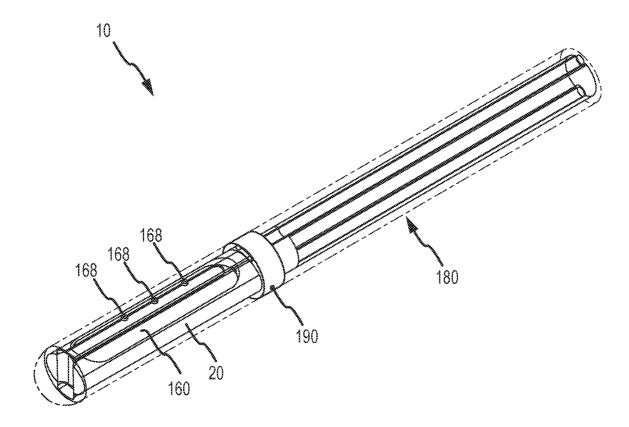


FIG.41

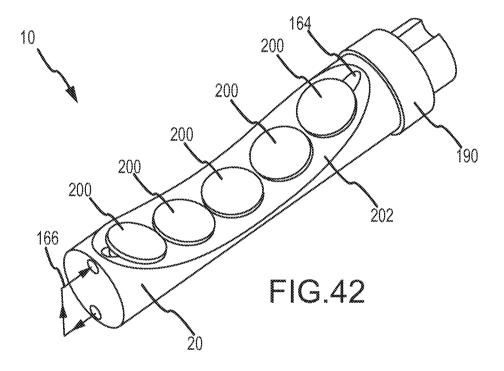




FIG.43A

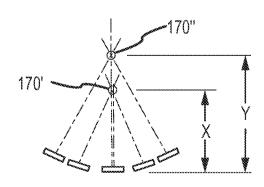


FIG.43B