

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
1 December 2005 (01.12.2005)

PCT

(10) International Publication Number
WO 2005/112573 A2

(51) International Patent Classification: **Not classified**

(21) International Application Number:
PCT/US2005/015893

(22) International Filing Date: 6 May 2005 (06.05.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/846,476 13 May 2004 (13.05.2004) US

(71) Applicant (for all designated States except US): **BOSTON SCIENTIFIC SCIMED, INC.** [US/US]; One Scimed Place, Maple Grove, Minnesota 55311-1566 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **RIOUX, Robert, F.** [US/US]; 5 Esther Lane, Ashland, Massachusetts 01721 (US). **DICARLO, Paul** [US/US]; 10 Starrett Avenue, Middleboro, Massachusetts 02346 (US).

(74) Agent: **BURSE, David, T.**; Bingham McCutchen LLP, Three Embarcadero Center, Suite 1800, San Francisco, California 94111-4067 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

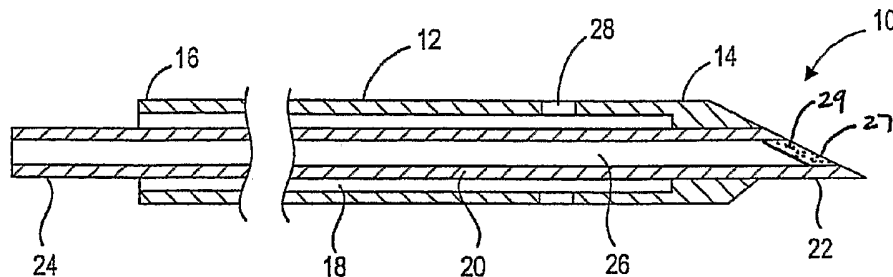
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, 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).

Published:

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

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: DEVICES FOR DELIVERING THERAPEUTIC OR DIAGNOSTIC AGENTS



(57) Abstract: An agent delivery device includes an inner tubular body having a proximal end, a sharpened distal end, a delivery lumen extending therebetween, and one or more outlet ports on the distal end communicating with the delivery lumen. The device also includes one or more seals sealing the one or more outlet ports, the one or more seals capable of being melted to allow a fluid to be delivered from the delivery lumen through the one or more outlet ports. The agent delivery device may further include a monopolar or bipolar electrode and/or a radio-opaque marker carried at the distal end of the device. The inner tubular body can be made from a conductive material to thereby allow the inner tubular body to function as an electrode.

DEVICES FOR DELIVERING THERAPEUTIC OR DIAGNOSTIC AGENTS

FIELD OF THE INVENTION

The field of the invention relates to medical devices, and, more particularly, to
5 apparatus for delivering therapeutic or diagnostic agents to a site within tissue.

BACKGROUND

Medical needles have been used to deliver therapeutic or diagnostic agents to a
target site within tissue for treatment or diagnostic purposes. Needles typically have a
10 tubular body for delivering an agent, and a sharp distal tip for puncturing skin and/or
other bodily tissues, thereby creating a needle tract through intervening tissues
between the skin and the target site. Before the tip of the needle reaches the target
site, i.e., while the needle is advanced through intervening tissue, there is a risk that
the agent may leak out of the distal tip of the needle and into the intervening tissue.
15 Since the agent may be sclerotic, necrotic, and/or toxic to living tissue, if the agent
leaks or spreads, it may damage the intervening tissue.

After an agent is delivered to the target site, the needle is typically withdrawn,
thereby leaving the created tract through the tissues that eventually closes up through
normal healing. However, before the tract is healed, the agent(s) delivered to the
20 target site may leak into the tract, possibly spreading the agent(s) to surrounding
tissue. As discussed previously, since the agent may be toxic to living tissue,
allowing the agent to spread may damage the surrounding tissue. For example, when
treating a prostate with Ethanol, significant amounts of the infused Ethanol may leak
through the needle tract, possibly damaging unintended tissue. Furthermore, when a
25 needle is used to deliver an agent to a tumor, tumor cells may be released into

surrounding tissue simply by perforating the tumor with the needle. For example, tumor cells may migrate into the needle tract and into surrounding healthy tissue through the needle tract. This phenomenon is known as "tract seeding."

5

SUMMARY OF THE INVENTION

The invention is directed to apparatus for delivering therapeutic or diagnostic agents to a target site within tissue.

In accordance with one embodiment of the invention, an apparatus is provided that may include an inner tubular body having a proximal end, a sharpened distal end, a delivery lumen extending therebetween, and one or more outlet ports on the distal end communicating with the delivery lumen. The apparatus may also include one or more seals sealing the one or more outlet ports. The seal may be melted to allow fluid to be delivered from the delivery lumen through the outlet port(s). In one embodiment, the seal may have a melting temperature of at least about fifty degrees Celsius (50 °C), and, preferably, at least about seventy degrees Celsius (70 °C). In another embodiment, the seal may have a melting temperature that is between about 70 °C and about 100 °C. In another embodiment, the seal may have a melting temperature that is close to a temperature at which tissue desiccation may occur.

Optionally, the apparatus may also include an outer tubular body having a proximal end, a distal end, an aspiration lumen extending therebetween, and one or more aspiration ports on the distal end communicating with the aspiration lumen. The inner tubular body may be slidably received in the outer tubular body such that the distal end of the inner tubular body may be advanced beyond the distal end of the outer tubular member. Optionally, one or more stops may be provided on one or both

of the inner and outer tubular bodies for limiting advancement and/or retraction of the inner tubular body relative to the outer tubular body.

Optionally, the apparatus may include a source of agent coupled to the proximal end of the inner tubular body such that the source of agent may

5 communicate with the delivery lumen, and/or a source of vacuum coupled to the proximal end of the outer tubular body such that the source of vacuum may communicate with the aspiration lumen. For example, the agent may be a cooling fluid, conductive fluid, therapeutic agent, or diagnostic agent.

In addition, the apparatus may include one or more of the following: an

10 electrode or a radio-opaque marker. For example, one or more electrodes may be provided on at least one of the distal end of the outer tubular body and the distal end of the inner tubular body. A source of electrical energy, e.g., a radio frequency ("RF") generator, may be coupled to the electrode(s). In addition or alternatively, a radio-opaque marker may be provided on at least one of the distal end of the outer

15 tubular body and the distal end of the inner tubular body, and preferably on both the inner and outer tubular bodies. In another embodiment, instead of carrying an electrode, the inner tubular member of the apparatus may be made from an electrically conductive material to allow the inner tubular member itself to function as an electrode.

20

BRIEF DESCRIPTION OF THE DRAWINGS

The drawings illustrate the design and utility of embodiments of the invention, in which similar elements are referred to by common reference numerals, and in which:

FIG. 1 is a cross-sectional side view of a first embodiment of an apparatus for delivering an agent into tissue, in accordance with the invention.

FIG. 2 is a cross-sectional side view of the apparatus of FIG. 1, showing an inner tubular body extending distally relative to an outer tubular body.

5 FIG. 3 is a cross-sectional side view of a variation of the apparatus of FIG. 1, showing the apparatus including an electrode carried at its distal end.

FIG. 4 is a cross-sectional detail of a variation of the apparatus of FIGS. 1 and 2, showing the inner tubular body having side ports.

FIG. 5 is a cross-sectional detail of a variation of the apparatus of FIGS. 1 and 10 2, showing the inner tubular body having a textured interior surface and a side port.

FIG. 6 is a cross-sectional side view of another embodiment of an apparatus, in accordance with the invention, including an inner tubular body fixed relative to an outer tubular body.

FIG. 7 is a cross-sectional side view of a variation of the apparatus of FIG. 6.

15 FIG. 8 is a cross sectional view of another embodiment of an agent delivery device.

FIG. 9A is a cross sectional view of an ablation probe that includes the agent delivery device of FIG. 8, showing the agent delivery device confined within a lumen of the ablation probe.

20 FIG. 9B is a cross sectional view of the ablation probe of FIG. 9A, showing at least a portion of the agent delivery device outside the lumen of the ablation probe.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

FIG. 1 shows an agent delivery device 10 constructed in accordance with an embodiment of the invention. The agent delivery device 10 includes an outer tubular

body 12 having a proximal end 16, a distal end 14, a lumen 18 extending between the proximal and distal ends 16, 14, and one or more suction or aspiration ports 28 located at or near the distal end 14 of the outer tubular body 12. The agent delivery device 10 also includes an inner tubular body 20, such as a needle, positioned

5 coaxially within the lumen 18 of the outer tubular body 12. The inner tubular body 20 has a distal end 22, a proximal end 24, a lumen 26 extending between the distal and the proximal ends 22 and 24, and an outlet port 27 at the distal end 22 that is in fluid communication with the lumen 26. The agent delivery device 10 also includes a seal 29 sealing the outlet port 27. The aspiration port 28 and the seal 29 are discussed in

10 further detail below.

The outer tubular body 12 may be made from a variety of materials, such as plastics, polymers, metals, alloys, graphite, and/or composites of such materials. In the illustrated embodiment, the distal end 14 of the outer tubular body 12 has a cross section that is thicker than the rest of the outer tubular body 12, thereby maintaining

15 the inner tubular body 20 substantially coaxially within the lumen 18 of the outer tubular body 12. The proximal end 16 of the outer tubular body 12 is configured to be coupled to a source of vacuum (not shown) that may generate a vacuum within the lumen 18, i.e., within the annular space between the outer tubular body 12 and the inner tubular body 20, that is substantially isolated from the lumen 26 of the inner

20 tubular body 20. Any source of vacuum, e.g., a syringe, a vacuum line, or a pump, may be used, as is generally well known in the art. The aspiration port 28 at or near the distal end 14 of the outer tubular body 12 communicates with the lumen 18 of the outer tubular body 12. When a vacuum is created within the lumen 18 of the outer tubular body 12, fluid or objects outside the outer tubular body 12 may be aspirated

25 into the lumen 18 through the aspiration port 28.

The source of vacuum may be coupled to the proximal end 16 of the outer tubular body 12 using any known manner, e.g., depending on the cross-sectional shape of the outer tubular body 12 and the configuration of the source of vacuum. For example, the proximal end 16 of the outer tubular body 12 may include a connector, 5 e.g., a male or female luer lock connector (not shown), that may substantially seal the lumen 18 at the proximal end of the outer tubular body 12 when connected to the source of vacuum. A section of tubing and the like that communicates with the source of vacuum may include a complementary connector that may engage the connector on the proximal end 16 of the outer tubular member 12. Alternatively, the proximal end 10 16 of the outer tubular member 12 may be closed, and a nipple or other side port may be provided on the outer tubular member 12 that communicates with the lumen 18. The manner in which the source of vacuum is coupled to the proximal end 16 is not critical to the invention.

In the illustrated embodiment, the distal end 22 of the inner tubular body 20 15 may have a tissue piercing tip and/or a low profile that may facilitate penetrating the inner tubular body 20 through skin or other bodily tissues. The proximal end 24 of the inner tubular body 20 is configured to be coupled to a source of fluid, such as a therapeutic and/or diagnostic agent, which may include genetic material and implantable cells for gene/cell therapy. For example, the proximal end 24 of the inner 20 tubular body 20 may include a connector (not shown) that may be coupled to a syringe, bottle, bag, or other container including the agent therein. Any of the materials discussed previously with reference to the outer tubular body 12 may also be suitable for construction of the inner tubular body 20. It should be understood by those skilled in the art that the flexibility or stiffness of the agent delivery device 10

may be varied by using different materials for the outer and/or inner tubular bodies 12, 20.

The inner tubular body 20 is preferably slidable axially relative to the outer tubular body 12. FIG. 2 shows the inner tubular body 20 advanced distally relative to the outer tubular body 12. The agent delivery device 10 may include one or more cooperating stops (not shown), e.g., secured to the proximal end 24 of the inner tubular body 20 and/or the outer tubular body 12 to prevent the inner tubular body 20 from being advanced beyond a predetermined distance relative to the outer tubular body 12.

10 In the illustrated embodiment, the seal 29 substantially covers the outlet port 27 such that material within the lumen 26 of the inner tubular body 20 cannot escape from the outlet port 27. During use, heat may be delivered to melt the seal 29, thereby allowing material within the lumen 26 of the inner tubular body 20 to be delivered through the outlet port 27. Towards this end, the seal 29 may be made from a material that may be melted when subjected to heat that is at least about fifty degrees Celsius (50 °C), and, preferably, at least about seventy degrees Celsius (70 °C). In another embodiment, the seal 29 can be made from a material having a melting point that is between about 70 °C and about 100 °C. Suitable materials may include wax (such as medical grade paraffin), gels that have reduced viscosity when heated, 20 polymers, and other suitable materials. Depending on the particular application, a desired melting point of the seal 29 may be achieved by varying a composition of the materials from which the seal 29 is made. The seal 29 may be a plug that may be inserted into the outlet port 27 during manufacturing, and/or before or after a fluid or other material is introduced into the lumen 26 of the inner tubular body 20. The seal 25 29 may be secured within the outlet port 27 by friction or a suitable adhesive.

Alternatively, the distal end 22 of the inner tubular body 20 may be dipped into a heated liquid or other solution to introduce the solution into the outlet port 27. The solution may be cooled and/or cured to solidify the solution, thereby forming the seal 29 in the outlet port 27. Other methods for creating the seal 29 and/or securing the seal 29 to the inner tubular body 20 may also be used.

As shown in FIG. 3, optionally, the agent delivery device 10 may include one or more electrodes 50 carried at the distal end 14 of the outer tubular body 12. In this case, the seal 29 may be positioned such that when the inner tubular body 20 extends distally from the distal end 14 of the outer tubular body 12 by a certain prescribed distance, the seal 29 may be adjacent to the electrode(s) 50. This configuration may provide a shorter path for the heat generated by the electrode 50 to reach the seal 29. Alternatively, if the inner tubular body 20 is made from a material that is conductive to heat, the seal 29 may be placed further away from the electrode(s) 50. In this case, heat generated by the electrode 50(s) may be conducted by the inner tubular body 20, and transmitted to the seal 29. In another embodiment, the electrode(s) 50 may be carried at the distal end 22 of the inner tubular body 20. Besides being used to melt the seal 29, the electrode(s) 50 may also be used to ablate tissue in a monopolar or bipolar manner, as is known in the art. In yet another embodiment, either or both of the outer tubular body 12 and the inner tubular body 20 may be made from an electrically conductive material, in which case, either or both of the outer and inner tubular bodies 12, 20 may be used to generate heat (e.g., in a bi-polar or monopolar arrangement) to melt the seal 29.

In the previously described embodiments, the outlet port 27 may be located at the distal tip of the inner tubular body 20. However, in alternative embodiments, the inner tubular body 20 may include one or more outlet ports 27 that are at other

locations of the inner tubular body 20. FIG. 4 shows a variation of the inner tubular body 20 having one or more outlet ports 54 located in the side wall(s) of the inner tubular body 20. The outlet port(s) 54 may be located at or near the distal end 22 of the inner tubular body 20 for delivering an agent therethrough. The outlet port(s) 54
5 may have different shapes other than the circular shape shown in the illustrated embodiment. For example, the delivery port(s) 54 may have an elliptical shape, rectangular shape, or other customized shape. In the illustrated embodiment, the outlet port(s) 54 may be sealed by a single seal 56. Alternatively, each of the outlet ports 54 may be sealed by a respective seal 56. The seal 56 may be secured to the
10 tubular body 20 by any of the methods described previously. Optionally, the tubular body 20 may include a sharp distal tip 58 for piercing tissue.

FIG. 5 shows a variation of an inner tubular body 20 that includes both an outlet port 27 at the distal tip of the inner tubular body 20, and one or more side outlet ports 54 located along a side wall of the inner tubular body 20. As discussed
15 previously, the outlet port 27 may be sealed by the seal 29, and the side outlet port(s) 54 may be sealed by the seal 56. Alternatively, a single seal may be used to seal both the outlet port 27 and the side outlet port(s) 54. In addition or alternatively, an interior surface 62 of a distal portion of the lumen 26 of the inner tubular body 20 may be textured (e.g., roughened), to retain tissue that may enter the distal portion of
20 the lumen 26 therein, e.g., while the agent is being delivered through the outlet port(s) 54.

In the previously described embodiments, the inner tubular body 20 may be slidable relative to the outer tubular body 12. However, the scope of the invention should not be so limited. For example, FIG. 6 shows an agent delivery device 100
25 including an outer tubular body 112 having a proximal end 116, a distal end 114, a

lumen 118 extending therebetween, and one or more suction ports 128 located at or near the distal end 114 of the outer tubular body 112. The agent delivery device 100 may also include an inner tubular body 120 positioned coaxially within the lumen 118 of the outer tubular body 112. The inner tubular body 120 has a distal end 122, a proximal end 124, a lumen 126 extending between the distal and the proximal ends 122 and 124, and an outlet port 127 at the distal end 122 that is in fluid communication with the lumen 126. The agent delivery device 100 may also include a seal 129 covering the outlet port 127.

The only difference between the embodiment shown in FIG. 6 and that shown in FIG. 1 is that the inner tubular body 120 is fixed relative to the outer tubular body 112. This may be accomplished using glue, solder, or other suitable adhesive between the outer and inner tubular bodies 112, 120, depending on the materials from which they are made. The outer and inner tubular bodies 112, 120 may also be constructed or formed as a single unit during manufacturing.

As shown in FIG. 6, the distal end 114 of the outer tubular body 112 may be secured to the inner tubular body 120 at a location proximal to the distal end 122 of the inner tubular body 112. Alternatively, as shown in FIG. 7, the distal end 114 of the outer tubular body 112 may be secured to the distal end 122 of the inner tubular body 112 so that the agent delivery device 100 has a substantially smooth and continuous exterior profile along a length of the agent delivery device 100.

In either of the embodiments shown in FIGS. 6 and 7, the agent delivery device 100 may include one or more electrodes 50, as discussed previously with reference to FIG. 3. Furthermore, the agent delivery device 100 may also include one or more side outlet ports and/or a textured interior surface at the distal end 122 of the inner tubular body 120, as discussed previously with reference to FIGS. 4 and 5.

In any of the embodiments discussed previously, the agent delivery device 10/100 may include one or more radio-opaque markers carried at the distal end of the agent delivery device 10/100, such as at the distal end 22/122 of the inner tubular body 20/120, and/or at the distal end 14/114 of the outer tubular body 12/112. The
5 radio-opaque marker(s) may assist monitoring the agent delivery device 10/100 as it is manipulated or positioned during a procedure, as is known in the art.

It should be noted that although the seal 29 (or 129) has been described with reference to the agent delivery device 10 (or 100), in alternative embodiments, the same or similar seal may also be incorporated into other types of medical devices
10 having fluid delivery capability. FIG. 8 shows another agent delivery device 300 that has tissue ablation capability. The agent delivery device 300 may include a tubular body 302 having a distal end 304, a proximal end 306, and a lumen 308 extending between the distal and proximal ends 304, 306. The tubular body 302 may have a curvilinear profile. Alternatively, the tubular body 302 may also have a rectilinear
15 profile or other shapes. The agent delivery device 300 may not include an outer tubular body, and therefore, may not include a fluid aspiration ability. However, in another embodiment, the agent delivery device 300 may also include an outer tubular body, as discussed previously. The agent delivery device 300 may also include a seal 310 disposed within the lumen 308 of the tubular body 302 to prevent material from
20 exiting through a distal opening 312. The construction and operation of the seal 310 may be similar to the embodiments discussed previously, e.g., to the seal 29 of FIG. 1. In the illustrated embodiment, the tubular body 302 may be made from a material that is electrically conductive, thereby allowing the tubular body 302 itself to function as an ablative electrode. Materials suitable for constructing the tubular body 302 may

include stainless steel, Nitinol, and/or other metals. The tubular electrode body 302 may operate in a bipolar, or monopolar arrangement.

As shown in FIGS. 9A and 9B, in one embodiment, the agent delivery device 300 may be an ablation electrode that is a part of an ablation probe 400. The ablation probe 400 may include a shaft 402 having a distal end 404, a proximal end 406, and a lumen 408 extending between the distal and proximal ends 404, 406. The ablation probe 400 may also include an elongate member 410 having distal and proximal ends 412, 414, a handle 416 on the proximal end 414, and a plurality of elongated electrodes 420. Each of the electrodes 420 may include the agent delivery device 300 of FIG. 8. As shown in FIG. 9A, each of the electrodes 420 may have a low profile when confined within the lumen 408 of the shaft 402. During use, the handle 416 may be used to advance the electrodes 420 relative to the shaft 410. When the electrodes 420 are at least partially outside the lumen 408 of the shaft 420, they may assume a relaxed and/or expanded configuration, such as that shown in FIG. 9B. Similar ablation probes have been described in U.S. Patent No. 5,855,576.

During use, the distal end 404 of the shaft 402 may be inserted into a patient, and advanced until it is adjacent target tissue, such as a tumor. The handle 416 may then be advanced relative to the shaft 402 to deploy the electrodes 420 (i.e., the tubular body 302) outside the distal end 404 of the shaft 402. The distal end 304 of the tubular body 302 may have a sharp distal tip allowing the distal end 304 to pierce into the target tissue, thereby creating a tract within the target tissue. Electrical energy may then be delivered to the tubular body 302 to ablate the target tissue. During ablation, the temperature of tissue adjacent the tubular body 302 may reach up to about ninety degrees Celsius (90 °C), at which point, the target tissue may begin to dessicate. This desiccation may create gas bubbles and/or increase impedance at

the tissue-electrode interface, the occurrence of which may prevent or reduce heat from being delivered by the electrodes 420 to the target tissue.

As the target tissue is being ablated, the temperature at the tubular body 302 may also rise, causing the seal 310 to heat up. In the illustrated embodiment, the seal
5 310 has a designed melting temperature that approximates the temperature above which tissue desiccation may occur. For example, the seal 310 may have a melting temperature that is higher than about fifty degrees Celsius (50 °C), and preferably, higher than about seventy degrees Celsius (70 °C). When the temperature of the seal 310 reaches its designed melting temperature, the seal 310 may melt, allowing a
10 material, such as cooling fluid, to be delivered from within the lumen 308 of the tubular member 302 to a space within the created tract, and more particularly, to the interface between the tubular member 302 and the target tissue.

Using cooling fluid in association with delivering electrical energy is known to force the electrode-tissue interface to lower temperature values. As a result, the
15 hottest tissue temperature region is shifted deeper into the tissue, which, in turn, shifts the boundary of the tissue rendered nonviable by ablation further away from the ablating tubular body 302. An electrode that is actively cooled may be used to transmit more ablation energy into the tissue, compared to the same electrode that is not actively cooled. The cooling fluid may be saline and/or other biocompatible
20 agent. Electrically conductive fluid (i.e., fluid that contains ions) may also be used. Using conductive fluid may further enhance transmission of radio frequency ("RF") energy between the tubular body 302 and another electrode, such as an adjacent electrode (as in the case for bipolar arrangement), or an indifferent electrode placed on a patient's skin (as in the case for monopolar arrangement). When a desired lesion

has been created by the ablating tubular body 302, the tubular body 302 is then removed from the target tissue and the patient.

For example, instead of carrying an electrode, the agent delivery device may carry other heat generating devices or mechanisms for delivering heat to the seal, e.g.,
5 electrically resistive elements, lasers or other fiber optic elements, and the like. Also, in alternative embodiments, the heat being used to melt the seal does not have to be generated by an electrode that is a part of the agent delivery device. Instead, the heat may be generated by an electrode or other heat generating mechanism that is located on another device, e.g., introduced in close proximity and/or in cooperation with the
10 agent delivery device. In this case, the agent delivery device may not include an electrode.

CLAIMS

1. An apparatus for delivering a therapeutic or diagnostic agent to a target site within tissue, comprising:

an inner tubular body comprising a proximal end, a sharpened distal end, a delivery lumen extending therebetween, and one or more outlet ports on the distal end communicating with the delivery lumen; and

one or more seals sealing the one or more outlet ports, the one or more seals capable of being melted to allow a fluid to be delivered from the delivery lumen through the one or more outlet ports.

10

2. The apparatus of claim 1, wherein the inner tubular body comprises only one outlet port.

3. The apparatus of claim 1, wherein the inner tubular body comprises a plurality of outlet ports.

15

4. The apparatus of any of claims 1 - 3, wherein the one or more seals have a melting point higher than a body temperature.

5. The apparatus of any of claims 1 - 4, wherein the one or more seals have a melting point of at least about fifty degrees Celsius (50 °C).

20

6. The apparatus of any of claims 1 - 5, further comprising a source of agent coupled to the proximal end of the inner tubular body such that the source of agent communicates with the delivery lumen.

5 7. The apparatus of any of claims 1 - 6, further comprising one or more electrodes carried on the distal end of the inner tubular body.

8. The apparatus of any of claims 1 - 7, wherein the one or more outlet ports comprise one or more openings in a side wall of the inner tubular body.

10

9. The apparatus of any of claims 1 - 8, wherein the distal end of the inner tubular body comprises an axial opening communicating with the delivery lumen, an interior surface of the inner tubular body being textured for retaining tissue that enters the axial opening.

15

10. The apparatus of claim 1, further comprising an outer tubular body having a proximal end, a distal end, an aspiration lumen extending therebetween, and one or more aspiration ports on the distal end communicating with the aspiration lumen, the inner tubular body slidably received in the outer tubular body such that the distal end of
20 the inner tubular body is advanceable beyond the distal end of the outer tubular member.

11. The apparatus of claim 10, further comprising a source of vacuum coupled to the proximal end of the outer tubular body such that the source of vacuum communicates with the aspiration lumen.

5 12. The apparatus of claims 10 or 11, further comprising one or more electrodes on the distal end of the outer tubular body.

13. The apparatus of any of claims 1 - 12, wherein the inner tubular body is made from an electrically conductive material.

10

14. An apparatus for delivering a therapeutic or diagnostic agent to a target site within tissue, comprising:

an elongate body comprising a proximal end, a distal end terminating in a tissue piercing distal tip, a delivery lumen extending from the proximal end to one or more

15 outlet ports adjacent the distal tip, one or more seals sealing the one or more outlet ports, and an aspiration lumen extending from the proximal end to one or more inlet ports on the distal end proximal to the one or more outlet ports;

a source of therapeutic or diagnostic agent communicating with the delivery lumen for delivering the agent through the delivery lumen to the one or more outlet ports;

20 and

a source of vacuum communicating with the aspiration lumen for aspirating material adjacent the one or more inlet ports into the aspiration lumen.

15. The apparatus of claim 14, wherein the one or more seals have a melting point higher than a body temperature.

16. The apparatus of claims 14 or 15, wherein the one or more seals have a
5 melting point of at least about fifty degrees Celsius (50 °C).

17. The apparatus of any of claims 14 - 16, further comprising one or more electrodes associated with the distal end.

10 18. The apparatus of claim 17, wherein the one or more electrodes are located proximal to the distal end of the elongate body.

19. The apparatus of claim 17, wherein the one or more electrodes are positioned at a distance from the seal such that heat generated by the one or more
15 electrodes can cause the seal to melt.

20. The apparatus of any of claims 14 -19, wherein the one or more outlet ports comprise one or more openings in a side wall at the distal end of the elongate body.

20 21. The apparatus of any of claims 14 - 20, wherein the distal tip comprises an axial opening communicating with the delivery lumen, an interior surface of the distal tip being textured for engaging tissue that enters the axial opening.

22. The apparatus of any of claims 14 - 21, wherein the distal tip is movable axially relative to the one or more inlet ports.

23. The apparatus of any of claims 14 - 22, wherein the aspiration lumen
5 comprises an annular lumen disposed concentrically around the delivery lumen.

1/4

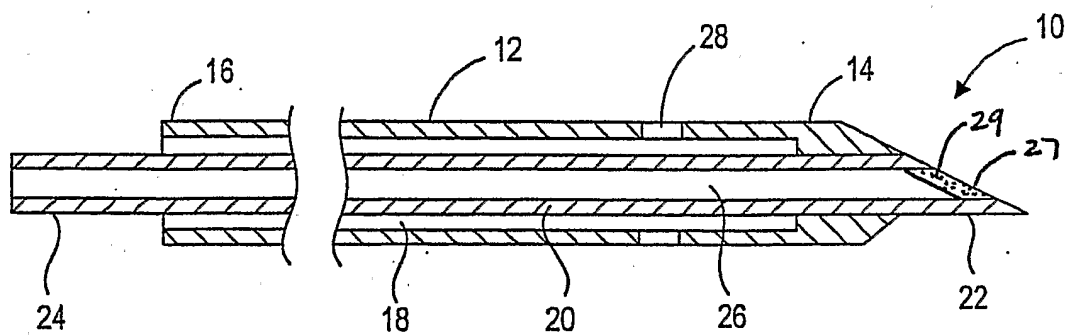


FIG. 1

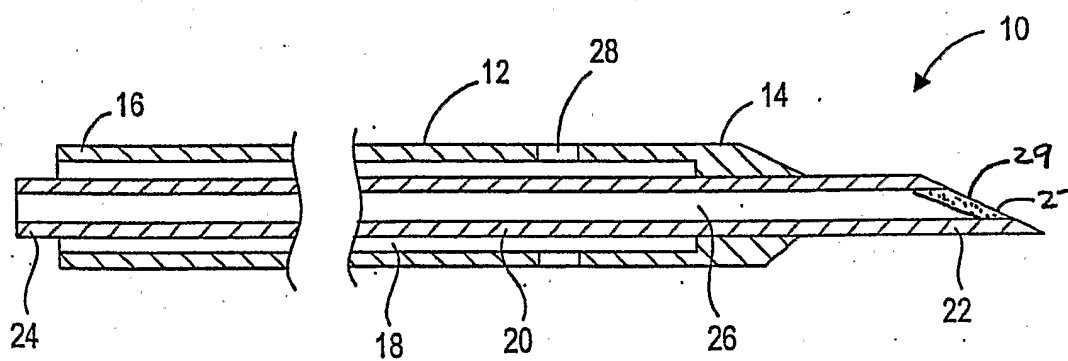


FIG. 2

2/4

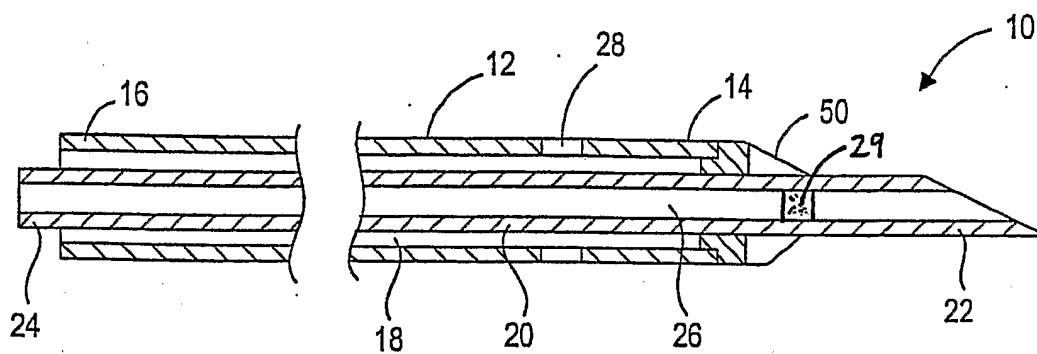


FIG. 3

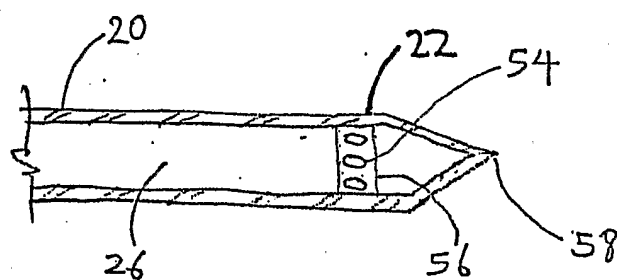
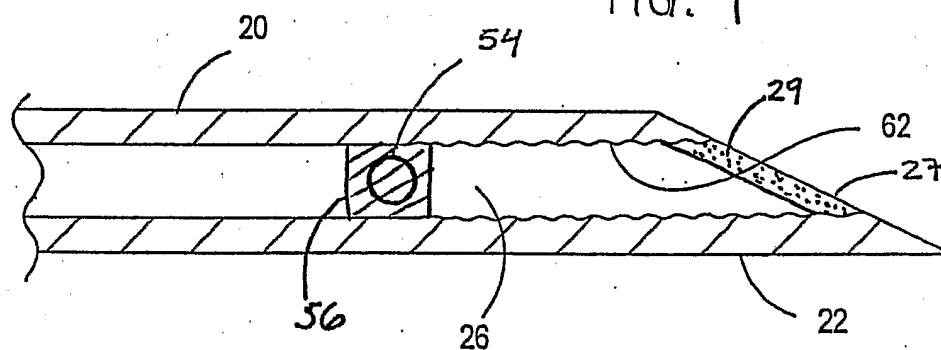


FIG. 4



3/4

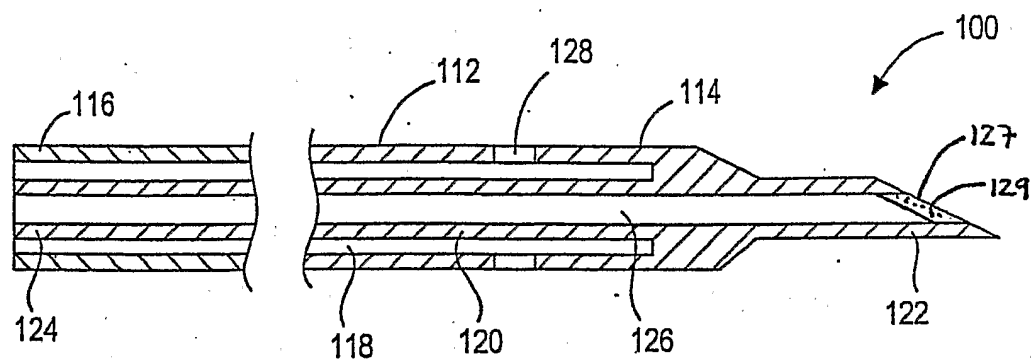


FIG. 6

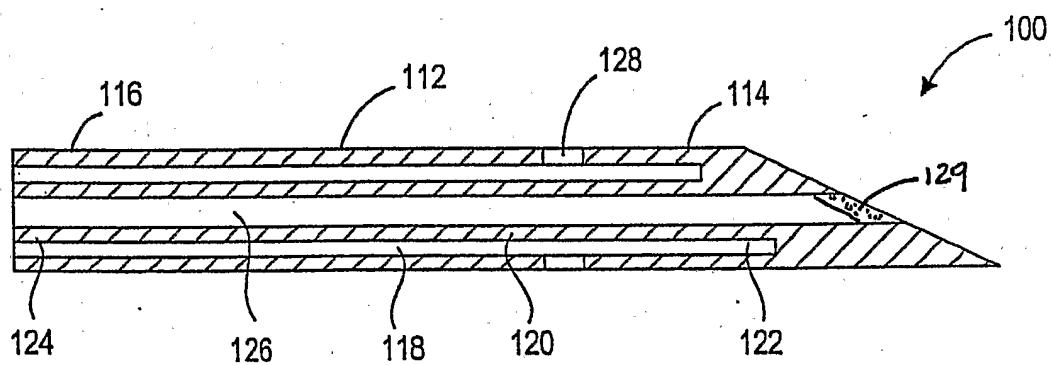


FIG. 7

4/4

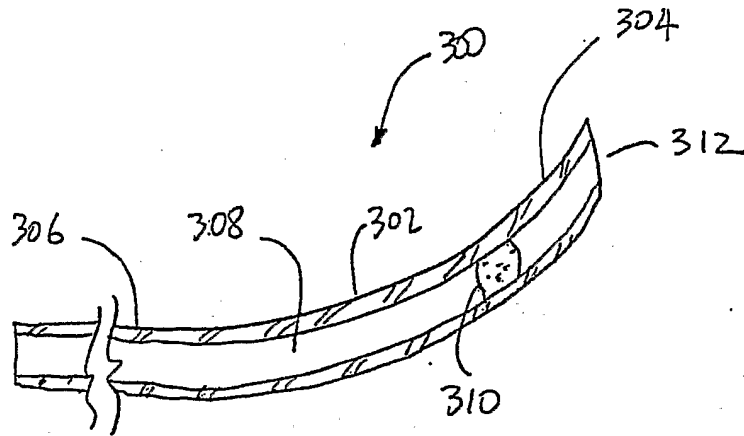


FIG. 8

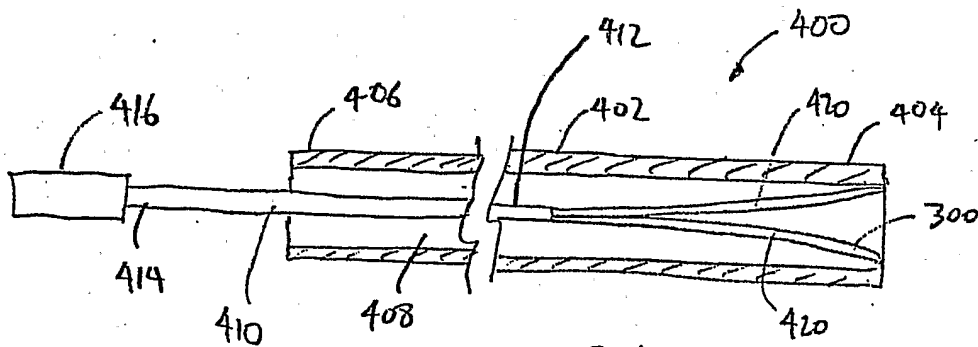


FIG. 9A

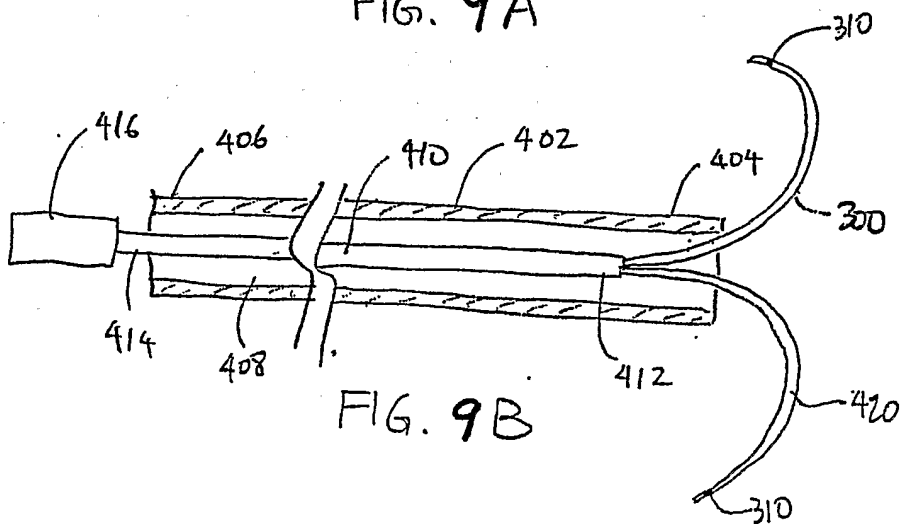


FIG. 9B