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(71) Demandeur/Applicant:
VIVANT MEDICAL, INC., US

(72) Inventeurs/Inventors:
TUROVSKIY, ROMAN, US;
KIM, STEVEN, US;
PRAKASH, MANI, US;
ROSSETTO, FRANCESCA, US

(74) Agent: MCFADDEN, FINCHAM

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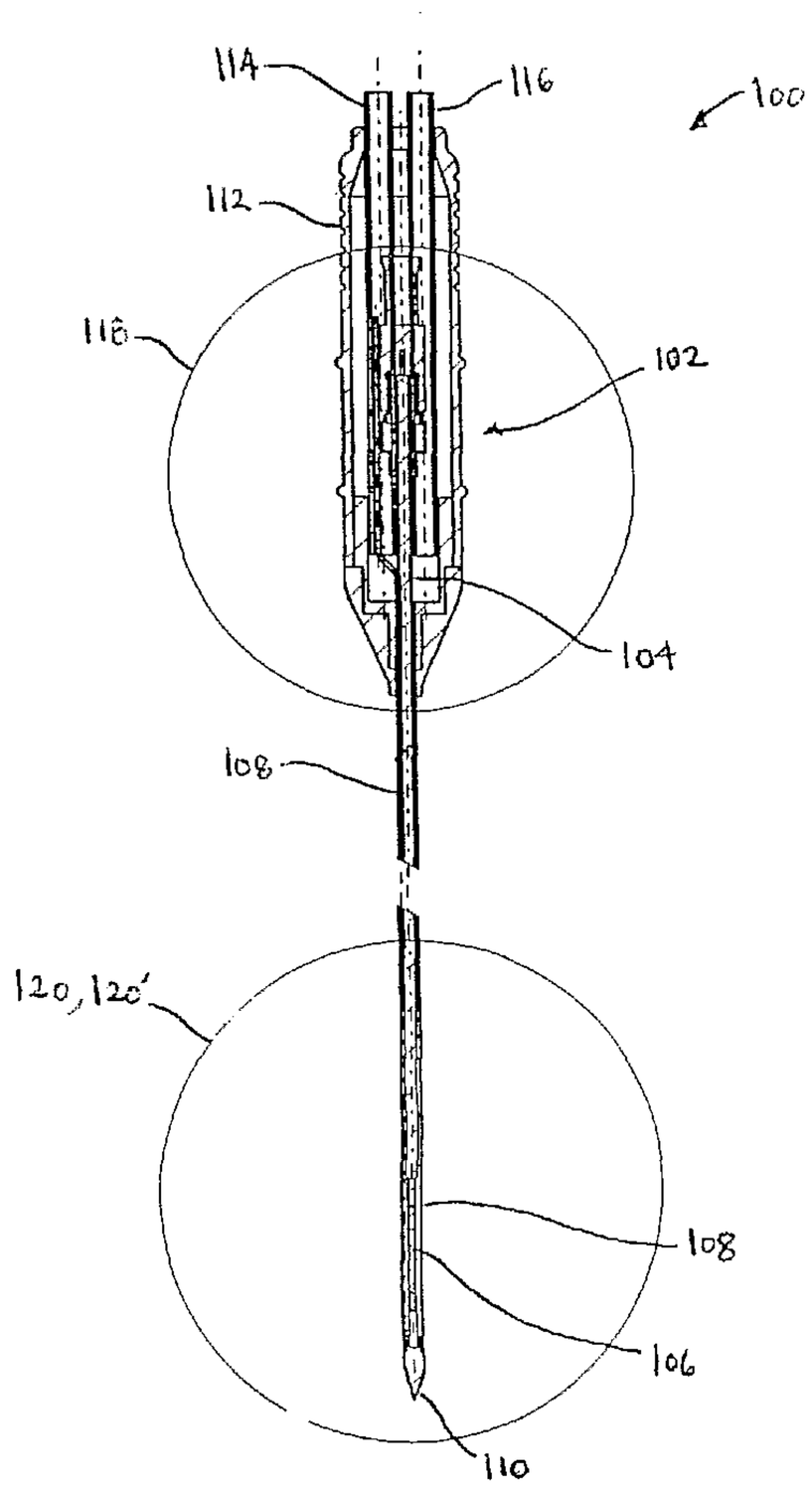

(57) Abrégé/Abstract:
Devices and methods for cooling microwave antennas are disclosed herein. The cooling systems (10) can be used with various types of microwave antennas. One variation generally comprises a handle portion with an elongate outer jacket extending from the

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(57) Abrégé(suite)/Abstract(continued):
handle portion. A microwave antenna is positioned within the handle and outer jacket such that cooling fluid pumped into the handle comes into contact directly along a portion of the length, or a majority of the length, or the entire length of the antenna to allow for direct convective cooling. Other variations include cooling sheaths which form defined cooling channels around a portion of the antenna. Yet another variation includes passively-cooled systems which utilize expandable balloons to urge tissue away from the surface of the microwave antenna as well as cooling sheaths which are cooled through endothermic chemical reactions. Furthermore, the microwave antennas themselves can have cooling lumens integrated directly therethrough.

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(71) Applicant *(for all designated States except US)*: **VIVANT MEDICAL, INC.** [US/US]; 1916-A Old Middlefield Way, Mountain View, CA 94043 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **TUROVSKIY, Roman** [US/US]; 240 N. Lake Merced Hills, San Francisco, CA 94132 (US). **KIM, Steven** [US/US]; 2029 Crist Drive, Los Altos, CA 94026 (US). **PRAKASH, Mani** [IN/US]; 576 Virginia Avenue, Campbell, CA 95008 (US). **ROSSETTO, Francesca** [IT/US]; 8 Locksley Avenue, Apt. 9B, San Francisco, CA 94122 (US).

(74) Agent: **TRACY, Kathleen**; Intellectual Property Manager, United States Surgical, 150 Glover Avenue, Norwalk, CT 06856 (US).

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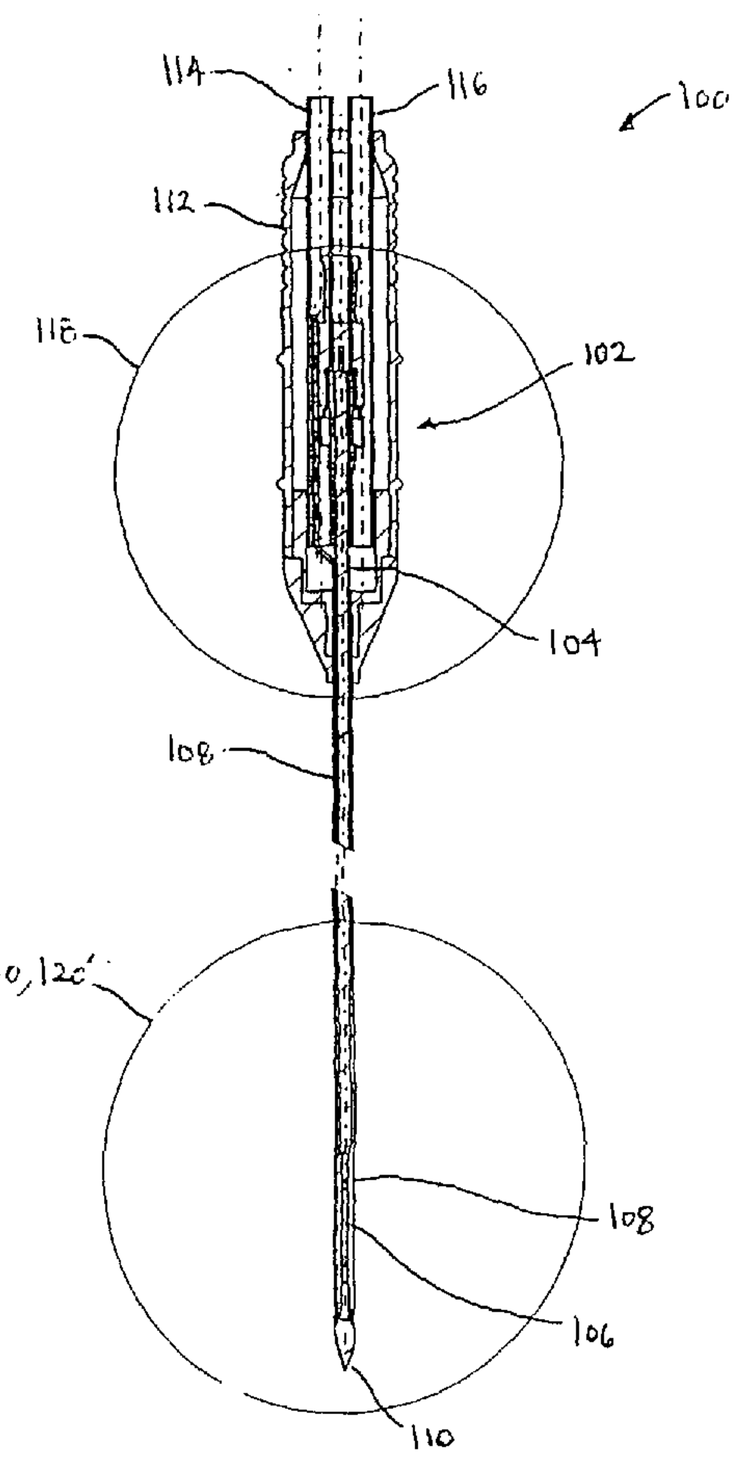
(54) Title: DEVICES AND METHODS FOR COOLING MICROWAVE ANTENNAS



(57) Abstract: Devices and methods for cooling microwave antennas are disclosed herein. The cooling systems (10) can be used with various types of microwave antennas. One variation generally comprises a handle portion with an elongate outer jacket extending from the handle portion. A microwave antenna is positioned within the handle and outer jacket such that cooling fluid pumped into the handle comes into contact directly along a portion of the length, or a majority of the length, or the entire length of the antenna to allow for direct convective cooling. Other variations include cooling sheaths which form defined cooling channels around a portion of the antenna. Yet another variation includes passively-cooled systems which utilize expandable balloons to urge tissue away from the surface of the microwave antenna as well as cooling sheaths which are cooled through endothermic chemical reactions. Furthermore, the microwave antennas themselves can have cooling lumens integrated directly therethrough.

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DEVICES AND METHODS FOR COOLING MICROWAVE ANTENNAS

FIELD OF THE INVENTION

[0001] The invention relates generally to microwave antennas which may be used in tissue ablation applications. More particularly, the invention relates to devices and methods for reducing or maintaining temperatures of microwave antennas used in such applications.

BACKGROUND OF THE INVENTION

[0002] In the treatment of diseases such as cancer, certain types of cancer cells have been found to denature at elevated temperatures which are slightly lower than temperatures normally injurious to healthy cells. These types of treatments, known generally as hyperthermia therapy, typically utilize electromagnetic radiation to heat diseased cells to temperatures above 41° C while maintaining adjacent healthy cells at lower temperatures where irreversible cell destruction will not occur. Other procedures utilizing electromagnetic radiation to heat tissue also include ablation and coagulation of the tissue. Such microwave ablation procedures, e.g., such as those performed for menorrhagia, are typically done to ablate and coagulate the targeted tissue to denature or kill it. Many procedures and types of devices utilizing electromagnetic radiation therapy are known in the art. Such microwave therapy is typically used in the treatment of tissue and organs such as the prostate, heart, kidney, lung, brain, and liver.

[0003] Presently, there are several types of microwave probes in use, e.g., monopole, dipole, and helical, which may be inserted into a patient for the treatment of tumors by heating the tissue for a period of time sufficient to cause cell death and necrosis in the tissue region of interest. Such microwave probes may be advanced into the patient, e.g., laparoscopically or percutaneously, and into or adjacent to the tumor to be treated. The probe is sometimes surrounded by a dielectric sleeve.

[0004] However, in transmitting the microwave energy into the tissue, the outer surface of the microwave antennas typically may heat up and unnecessarily necrose healthy tissue immediately adjacent the antenna outer surface. To prevent the charring of adjacent tissue, several different cooling methodologies are conventionally employed. For instance, some microwave antennas utilize balloons which are inflatable around selective portions of the antenna to cool the surrounding tissue. Thus, the complications associated with tissue damaged by the application of microwave radiation to the region is minimized. Typically, the cooling system and the tissue are maintained in contact to ensure adequate cooling of the tissue.

[0005] Other devices attempt to limit the heating of tissue adjacent the antenna by selectively blocking the propagation of the microwave field generated by the antenna. These cooling systems also protect surrounding healthy tissues by selectively absorbing microwave radiation and minimize thermal damage to the tissue by absorbing heat energy.

[0006] However, in order for microwave ablation to become a truly effective tool for the laparoscopic and/or percutaneous treatment of tumors, an effective microwave antenna should be implemented to efficiently transfer energy to the targeted tissue region while minimizing unnecessary tissue damage adjacent to the antenna outer surface. Moreover, the cooling aspects along the antenna should be controllable to allow for different regions of cooling as well as to allow for the coagulation of adjacent tissue along selected regions of the antenna, if desired.

BRIEF SUMMARY OF THE INVENTION

[0007] In minimally invasively treating diseased areas of tissue in a patient, trauma may be caused to the patient resulting in pain and other complications. One cause of trauma may result from excess tissue being unnecessarily ablated by the microwave antenna assembly. As the microwave antenna transmits microwave energy, the feedline or shaft of the antenna may increase in temperature and the contacting tissue may become charred or ablated unnecessarily. Moreover, charred tissue may decrease the effectiveness of the microwave antenna. The cooling systems, as described herein, may be used in conjunction with various types of microwave antennas, e.g., antennas having either a straight or looped radiating antenna portion, etc.

[0008] One variation of an antenna cooling system may generally comprise a cooling handle assembly with an elongate outer jacket extending from the handle assembly and terminating at a tip which may be tapered. A microwave antenna may be positioned within the handle assembly and the outer jacket. An inflow tubing may extend into the handle body and distally into at least a portion of the outer jacket. A corresponding outflow tubing may also extend from within handle body such that the distal ends of the inflow tubing and the outflow tubing are in fluid communication with one another. A fluid may be pumped into the handle body via a pump through the inflow tubing such that the fluid comes into contact directly along a portion of the length, or a majority of the length, or the entire length of the antenna to allow for direct convective cooling of the antenna shaft. The fluid may exit the handle body through the outflow tubing. Thus, the cooling assembly is effective in cooling the antenna through direct contact rather than cooling the tissue surrounding the antenna, although the surrounding tissue may also be indirectly cooled through conduction via the assembly.

[0009] The cooling fluid used may vary depending upon desired cooling rates and the desired tissue impedance matching properties. Various fluids may be used, e.g., liquids including, but not limited to, water, saline, Fluorinert®, liquid chlorodifluoromethane, etc. In other variations, gases (such as nitrous oxide, nitrogen, carbon dioxide, etc.) may also be utilized as the cooling fluid. In yet another variation, a combination of liquids and/or gases, as mentioned above, may be utilized as the cooling medium.

[0010] The distal end of the microwave antenna may be optionally secured within the cooling jacket through various methods. For instance, the antenna may remain either electrically or mechanically unconnected to the cooling assembly tip or the two may be optionally joined via a mechanical connection. In other variations, the antenna and tip may be mechanically and electrically connected, just electrically connected, or just mechanically connected. Various mechanical fastening methods which may be utilized to mechanically connect the antenna and the tip may include, e.g., adhesives, welding, soldering, clamping, crimping, etc.

[0011] Other cooling assembly variations may include an outer cooling jacket having an inlet tube externally located from the lumen of the outer jacket. The inlet tube may be a separate tube member attached to the surface of the outer jacket or it may be integrally formed with the outer jacket. Alternatively, an inlet lumen may be defined directly within the wall of the outer jacket. Yet another variation on antenna cooling assembly may include a cooling jacket modified to cover only the radiating portion of the microwave antenna. The cooling jacket may thus be configured to be shortened in length and may further omit a handle portion. Alternatively, another variation may have a cooling tube coiled around at least a portion of the shaft.

[0012] Another alternative for cooling a microwave antenna may comprise a passively cooled balloon assembly typically comprising a microwave antenna shaft or feedline with an inflatable balloon over a length of the shaft. The balloon member may be inflatable with a liquid or gas (or combination of both) and attached along the microwave antenna shaft through any variety of attachment methods, e.g., adhesives, crimping, etc. Alternatively, a separate inflatable balloon may simply be placed over the antenna shaft and reside unattached to the microwave antenna. In use, the microwave antenna may be advanced percutaneously or laparoscopically through the skin of a patient to position the antenna radiating portion within, near, or adjacent to a tumor. Once the radiating portion has been desirably positioned within the patient, the balloon may be inflated prior to or during microwave energy transmission through the antenna. The inflation of the balloon may dilate the tissue surrounding the shaft to urge the tissue out of contact with the shaft to prevent the tissue from overheating or becoming charred.

[0013] Alternative cooling methods and devices may also comprise passive cooling sheaths generally comprising a tubular cooling pack defining a lumen into which the shaft of the antenna may be positioned. Another variation may comprise a conformable cooling sheath having a proximal handle portion and a conformable portion which may be configured to spread over and cool the skin surface surrounding the area where the antenna shaft has been inserted.

[0014] Another alternative may comprise integrated cooling lumens defined through the length of the sheath. Optional barriers may be defined through the length of sheath to divide the interior lumen into at least two separate volumes. Within these lumens, a first defined volume may hold a first chemical or liquid (e.g., water, saline, etc.) and a second defined volume may hold a second chemical or liquid (ammonium chloride, sodium nitrate, or potassium chloride, etc.). When a cooling effect is desired, the sheath may be flexed slightly such that the barriers are broken or fractured within the sheath and allows for the mixing between the chemicals to result in an endothermic reaction. Another alternative may include a slidable sheath assembly comprising an inner tube, which defines a first volume for holding a first chemical or liquid, and a concentric outer tube, which defines a second volume for holding a second chemical or liquid. Alternative variations may have the cooling sheath or tube integrated with or within the microwave antenna shaft.

[0015] Cooling sheaths or jackets may be varied or tuned to match the requisite cooling for a given length of a microwave antenna. A typical microwave antenna may generally be divided into at least three different regions along the length of its shaft. For instance, a microwave antenna may be divided into a first region, second region, and third region. Accordingly, a multi-zone cooling assembly may be utilized to take advantage of optionally cooling multiple regions along the length of a microwave antenna.

[0016] Finally, yet another variation may include a microwave antenna in which the diameters of the inner conductor are modified so that proximal portions of the inner conductor functions as a heat sink to facilitate conductive cooling of the microwave antenna. This may be accomplished by creating an inner conductor having a larger proximal portion such that the proximal portion functions to draw and dissipate the heat at a faster rate.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] Fig. 1 shows an example of a microwave antenna assembly which may be utilized with the cooling systems described herein.

[0018] Figs. 2A and 2B show representative cross-sectional end and side views, respectively, of a microwave antenna assembly which may be utilized with the cooling systems described herein.

[0019] Fig. 3A shows a representative illustration of another variation of a microwave antenna assembly which may be utilized with the cooling systems described herein.

[0020] Fig. 3B shows a cross-sectional view of the antenna of Fig. 3A.

[0021] Figs. 4A and 4B show a cross-sectional side view and an end view, respectively, of one variation of an antenna cooling system.

[0022] Fig. 4C shows a detail view from Fig. 4A of the cooling system handle.

[0023] Figs 4D and 4E show detail views from Fig. 4A of alternative cooling configurations for the antenna.

[0024] Fig. 5A shows a representative cross-sectional view of the distal end of the antenna within a cooling system.

[0025] Figs. 5B to 5D show cross-sectional side views of alternative attachments between the antenna and cooling system tip.

[0026] Fig. 5E shows a cross-sectional side view illustrating one variation in which the cooling system tip may be energized.

[0027] Fig. 6 shows a representative side view of another variation of the cooling system which may have an externally positioned fluid tube.

[0028] Fig. 7 shows a representative side view of yet another variation of the cooling system which may have an integrated fluid lumen defined within a wall of the outer jacket.

[0029] Fig. 8 shows a side view of yet another variation of the cooling system having a separate mandrel for structural support.

[0030] Figs. 9A to 9C illustrate one variation in utilizing the device of Fig. 8.

[0031] Fig. 10 shows yet another variation of a cooling system configured to be placed over only the radiating portion of a microwave antenna.

[0032] Fig. 11 shows yet another variation of a cooling system comprising a tube which may be coiled over the microwave antenna.

[0033] Figs. 12A and 12B show side and cross-sectional views, respectively, of a loop antenna variation configured to cool the antenna.

[0034] Figs. 13A to 13C show end, cross-sectional side, and perspective views, respectively, of another variation of the system configured as a cooling sheath.

[0035] Fig. 14A shows a sheath in one variation used with a straight probe microwave antenna.

[0036] Fig. 14B shows the sheath in another variation used with a looped probe microwave antenna.

[0037] Fig. 14C shows the sheath in yet another variation used with a looped probe microwave antenna configured to cool the radiating looped antenna portion.

[0038] Fig. 15 shows a variation of a straight probe microwave antenna having a dilating balloon used to push surrounding tissue away from the antenna surface.

[0039] Fig. 16 shows another variation of a straight probe microwave antenna having multiple dilating balloons positioned along the length of the antenna.

[0040] Fig. 17 shows an exploded assembly view of another variation of the cooling system configured as a separate cooling sheath positionable over the microwave antenna shaft.

[0041] Fig. 18 shows a side view of yet another variation of a cooling sheath configured to conform at least partially to the tissue surface.

[0042] Figs. 19A and 19B show cross-sectional side and end views, respectively, of a cooling sheath.

[0043] Figs. 20A and 20B show cross-sectional side and end views, respectively, of another variation on the cooling sheath having a divider which may be breached to allow the intermixing of chemicals to create a cooling endothermic reaction.

[0044] Figs. 21A and 21B show cross-sectional side views of yet another variation on the cooling sheath in which slidable concentric tubes have openings which are alignable to allow for the intermixing of chemicals to create a cooling endothermic reaction.

[0045] Fig. 21C shows an end view of the cooling sheath of Fig. 21B where the openings are aligned.

[0046] Fig. 22A shows a perspective view of one example of a cooling sheath positioned over the microwave antenna.

[0047] Figs. 22B and 22C show perspective views of other variations of cooling sheaths having a number of fluid lumens defined between the sheath and antenna surface.

[0048] Fig. 22D shows a perspective view of another variation in which the dielectric between the inner and outer conductors may define a number of cooling lumens therethrough.

[0049] Fig. 23A shows a perspective view of a portion of a triaxial microwave antenna shaft.

[0050] Fig. 23B shows an example of cooling lumens which may be defined through the dielectric between the outer conductor and the choke layer.

[0051] Fig. 24 shows a side view of a straight microwave antenna probe delineating the various regions along the antenna shaft which may be in contact with various regions of tissue.

[0052] Fig. 25 shows yet another variation of a cooling system which may be configured to delineate multiple regions of varied cooling along the shaft of the microwave antenna.

[0053] Fig. 26A shows yet another variation in which a diameter of the coaxial cable may be non-uniform such that a larger cable may have improved power handling capabilities which facilitate a decrease in the generation of high temperatures.

[0054] Figs. 26B and 26C show cross-sectional side views of other transitional diameters for the inner conductor of Fig. 26A.

[0055] Fig. 27 shows a plot illustrating the temperature rise over time of an uncooled microwave antenna.

[0056] Fig. 28 shows a plot illustrating the decrease in microwave antenna temperature when the cooling system is activated.

DETAILED DESCRIPTION OF THE INVENTION

[0057] Various microwave antenna assemblies and cooling systems, as described herein, are less traumatic than devices currently available and as described in further detail below. Generally, in invasively treating diseased areas of tissue in a patient, trauma may be caused to the patient resulting in pain and other complications. One cause of trauma may result from excess tissue being unnecessarily ablated by the microwave antenna assembly. As the microwave antenna transmits microwave energy, the feedline or shaft of the antenna, as well as the radiation portion, may increase in temperature due to ohmic heating. Tissue in contact with a surface of the antenna may thus become charred or ablated unnecessarily. Aside from unnecessary trauma, charred tissue may decrease the effectiveness of the microwave antenna because of the changing impedance of the tissue as it dries out and becomes charred. The cooling systems, as described herein, may be used in conjunction with various types of microwave antennas.

[0058] Examples of various types of microwave antenna assemblies which may be used with the cooling systems herein shall now be described. For instance, Fig. 1 shows a representative diagram of a variation of a microwave antenna assembly **10** which may be used with a cooling system as described herein. The antenna assembly **10** is generally comprised of radiating portion **12** which may be connected by feedline **14** (or shaft) via cable **16** to connector **18**, which may further connect the assembly **10** to a power generating source **30**, e.g., a generator. Assembly **10**, as shown, is a dipole microwave antenna assembly, but other antenna assemblies, e.g., monopole or leaky wave antenna assemblies, may also be utilized. Distal portion **22** of radiating portion **12** preferably has a tapered end **26** which terminates at a tip **28** to

allow for insertion into tissue with minimal resistance. In those cases where the radiating portion **12** is inserted into a pre-existing opening, tip **28** may be rounded or flat.

[0059] Generally, the antenna assembly **10** in Fig. 1 shows a variation where a compressive load may be used to increase antenna strength. Proximal portion **24** is located proximally of distal portion **22**, and junction member **20** is preferably located between both portions such that a compressive force is applied by distal and proximal portions **22, 24** upon junction member **20**. Placing distal and proximal portions **22, 24** in a pre-stressed condition prior to insertion into tissue enables assembly **10** to maintain a stiffness that is sufficient to allow for unaided insertion into the tissue while maintaining a minimal antenna diameter, as described in detail below.

[0060] Feedline **14** may electrically connect antenna assembly **10** via cable **16** to generator **30** and usually comprises a coaxial cable made of a conductive metal which may be semi-rigid or flexible. Feedline **14** may also have a variable length from a proximal end of radiating portion **12** to a distal end of cable **16** ranging between about 1 to 15 inches. Most feedlines may be constructed of copper, gold, or other conductive metals with similar conductivity values, but feedline **14** is preferably made of stainless steel. The metals may also be plated with other materials, e.g., other conductive materials, to improve their properties, e.g., to improve conductivity or decrease energy loss, etc. A feedline **14**, such as one made of stainless steel, preferably has an impedance of about 50 Ω and to improve its conductivity, the stainless steel may be coated with a layer of a conductive material such as copper or gold. Although stainless steel may not offer the same conductivity as other metals, it does offer strength required to puncture tissue and/or skin.

[0061] Fig. 2A and 2B show an end view and a cross-sectional view, respectively, of a conventional dipole microwave antenna assembly **40** which may be utilized with the cooling systems described herein. As seen, antenna assembly **40** has a proximal end **42** which may be connected to a feedline **14** and terminates at distal end **44**. The radiating portion of antenna **40** comprises proximal radiating portion **46** and distal radiating portion **48**. Proximal radiating portion **46** may typically have an outer conductor **52** and an inner conductor **54**, each of which extends along a longitudinal axis. Between the outer and inner conductors **52, 54** is typically a dielectric material **56** which is also disposed longitudinally between the conductors **52, 54** to electrically separate them. A dielectric material may constitute any number of appropriate materials, including air. Distal portion **58** is also made from a conductive material, as discussed below. Proximal and distal radiating portions **46, 48** align at junction **50**, which is typically made of a dielectric material, e.g., adhesives, and are also supported by inner conductor **54** which runs

through junction opening **60** and at least partially through distal portion **58**. However, as discussed above, the construction of conventional antenna assembly **40** is structurally weak at junction **50**.

[0062] A further detailed discussion of microwave antennas which may be utilized herein may be found in U.S. Pat. App. Serial No. 10/052,848 entitled "High-Strength Microwave Antenna Assemblies" filed November 2, 2001 and U.S. Pat. App. Serial No. 10/272,058 entitled "High-Strength Microwave Antenna Assemblies And Methods Of Use" filed October 15, 2002, each of which is incorporated herein by reference in its entirety.

[0063] An alternative microwave antenna having a curved microwave antenna may also be utilized with the cooling systems described herein as shown in Fig. 3A. Microwave antenna assembly **70** may comprise at least one microwave antenna **72** electrically connected to generator **82**. Microwave antenna **72** preferably comprises shaft or feedline **74** with a distal end from which antenna or inner conductor **76** extends to define the ablation region **90**. The proximal end of feedline **74** preferably comprises coupler **78** which electrically couples the antenna **72** to generator **82** via power transmission cable **80**. The cable **80** is preferably a flexible cable which allows for the positioning of antenna **72** relative to a patient.

[0064] Feedline **74** is preferably a coaxial cable, as shown by the cross-section 3B-3B in Fig. 3B taken from Fig. 3A. The feedline **74**, similar to feedline **14** described above, may be formed of outer conductor **84** surrounding inner conductor **86**. Conductors **84, 86** may be made of a conductive metal which may be semi-rigid or flexible. Most feedlines **84**, as described above, may be constructed of metals such as stainless steel. Alternatively, metals such as copper, gold, or other conductive metals with similar conductivity values may also be utilized. A dielectric material **88** is preferably disposed between outer and inner conductors **84, 86**, respectively, to provide insulation therebetween and may be comprised of any appropriate variety of conventional dielectric materials.

[0065] Additional details regarding the curved loop microwave antenna configuration which may be utilized herein are further described in U.S. Pat. App. Serial No. 10/272,314 entitled "Microwave Antenna Having A Curved Configuration" filed October 15, 2002, which is incorporated herein by reference in its entirety.

[0066] Figs. 4A and 4B show a cross-sectional side view and an end view, respectively, of one variation of an antenna cooling system which may be utilized with any number of conventional microwave antennas or the microwave antennas described herein, particularly the straight probe configuration as shown in Figs. 1 and 2A-2B. Although this variation illustrates the cooling of a straight probe antenna, a curved or looped microwave antenna may also utilize

much of the same or similar principles, as further described below. Antenna cooling assembly **100** may generally comprise a cooling handle assembly **102** and an elongate outer jacket **108** extending from handle assembly **102**. Outer jacket **108** may extend and terminate at tip **110**, which may be tapered to a sharpened point to facilitate insertion into and manipulation within tissue, if necessary. Microwave antenna **104** may be positioned within handle assembly **102** such that the radiating portion **106** of antenna **104** extends distally into outer jacket **108** towards tip **110**. Inflow tubing **114** may extend into a proximal end of handle body **112** and distally into a portion of outer jacket **108**. Outflow tubing **116** may also extend from within handle body **112** such that the distal ends of inflow tubing **114** and outflow tubing **116** are in fluid communication with one another, as described in further detail below.

[0067] Fig. 4C shows handle assembly detail **118** from Fig. 4A. As shown, handle body **112** may be comprised of proximal handle hub **122**, which encloses a proximal end of antenna **104**, and distal handle hub **124**, which may extend distally into outer jacket **108**. Proximal handle hub **122** and distal handle hub **124** may each be configured to physically interfit with one another at hub interface **130** to preferably form a fluid tight seal. Accordingly, proximal handle hub **122** may be configured to be received and secured within a correspondingly configured distal handle hub **124**, seen in the figure as a male-female connection. Proximal and distal handle hubs **122**, **124** may each be formed from the same (or similar) or different materials. If hubs **122**, **124** are fabricated from the same material, a variety of non-conductive materials are preferably utilized, e.g., polymers, polyimides, plastics, etc. Alternatively, proximal handle hub **122** may be fabricated from a metal or alloy, e.g., stainless steel, platinum, nickel, nickel-titanium, etc., while distal handle hub **124** (or just the handle portion over the radiating portion of the microwave antenna) may be fabricated from one of the non-conductive materials previously mentioned.

[0068] The distal ends of inflow tubing **114** and outflow tubing **116** may be positioned within handle body **112** such that fluid may be pumped into handle body **112** via a pump (not shown) through inflow tubing **114**. Fluid entering handle body **112** may come into direct contact with at least a portion of the shaft of antenna **104** to allow for convective cooling of the antenna shaft to occur. The fluid may be allowed to exit handle body **112** via outflow tubing **116**. An additional inlet tube **126** may be positioned within antenna cooling assembly **100** to extend between handle body **112** and radiating portion **106** of antenna **104** and a corresponding outlet tube **128** may also extend between handle body **112** and radiating portion **106**. The proximal end of inlet tube **126** may be in fluid communication with inflow tubing **114** to allow the cooling fluid to flow distally within outer jacket **108** towards antenna radiation portion **106**. Alternatively, inlet tube **126** and outlet tube **128** may be omitted from cooling assembly **100** and

outer jacket **108** may remain in direct fluid communication with inflow tubing **114** and outflow tubing **116** such that fluid contacts the antenna **104** directly along a portion of the length, or a majority of the length, or the entire length of antenna **104**. Thus, the cooling assembly **100** is effective in cooling the antenna **104** directly rather than cooling the tissue surrounding the antenna **104**, although the surrounding tissue may also be conductively cooled via assembly **100**.

[0069] Fig. 4D and 4E shows outer jacket detail variations **120, 120'**, respectively, from Fig. 4A. Fig. 4D shows one variation where the distal end **132** of inlet tube **126** may extend distally through outer jacket **108**. The opening at distal end **132** may be positioned within outer jacket **108** near or at the distal end of outer jacket **108** such that distal end **132** opens to fluid channel **134**. The cooling fluid may enter fluid channel **134** and fill the volume surrounding at least a portion of the antenna **104**, and preferably surrounding at least the radiation portion **106**. As fluid enters fluid channel **134**, it may be withdrawn through a distal opening in outlet tube **128**, which is preferably located proximally of distal end **132** to allow for increased convective cooling between the cooling fluid and the antenna **104**. Alternatively, each of the distal ends of inlet tube **126** and outlet tube **128** may be aligned with one another. In either case, the cooling fluid may directly contact the outer surface of the antenna **104** and envelope the antenna **104** rather than being in conductive contact through some additional thermal interface. Allowing the direct fluid-to-antenna contact enables direct convective cooling to occur and may thereby facilitate the heat transfer from the antenna to the cooling fluid.

[0070] The cooling fluid may be pumped using positive pressure through inlet tube **126**; alternatively, negative pressure may also be used to draw the fluid out of the region through outlet tube **128**. Negative pressure through outlet tube **128** may be utilized either alone or in conjunction with positive pressure through inlet tube **126**. Alternatively, positive pressure through inlet tube **126** may be utilized either alone or in conjunction with negative pressure through outlet tube **128**. In pumping the cooling fluid through cooling assembly **100**, the cooling fluid may be passed through assembly **100** at a constant and uniform flow rate. In another variation, the flow may be intermittent such that a volume of cooling fluid may be pumped into fluid channel **134** and allowed to warm up by absorbing heat from the antenna. Once the temperature of the fluid reaches a predetermined level below temperatures where thermal damage to tissue occurs, e.g., about 43° to 45° C, the warmed fluid may be removed and displaced by additional cooling fluids. Temperature sensors (such as thermistors, thermocouples, etc.) may be incorporated within or upon the outer jacket **108** to sense the fluid and/or outer jacket **108** temperatures. The system may be configured to automatically pump additional cooling fluid into

cooling assembly **100** once the sensed temperature reaches the predetermined level or it may be configured to notify the user via, e.g., an audible or visual alarm.

[0071] The cooling fluid used may vary depending upon desired cooling rates and the desired tissue impedance matching properties. Preferably, biocompatible fluids having sufficient specific heat values for absorbing heat generated by microwave ablation antennas may be utilized, e.g., liquids including, but not limited to, water, saline, Fluorinert®, liquid chlorodifluoromethane, etc. In another variation, gases (such as nitrous oxide, nitrogen, carbon dioxide, etc.) may also be utilized as the cooling fluid. For instance, an aperture may be configured at the opening of distal end **132** to take advantage of the cooling effects from the Joule-Thompson effect, in which case a gas, e.g., nitrous oxide, may be passed through the aperture to expand and cool the enclosed antenna **104**. In yet another variation, a combination of liquids and/or gases, as mentioned above, may be utilized as the cooling medium.

[0072] Fig. 4E shows another variation in detail **120'** within outer jacket **108** which incorporates a barrier or gasket **138** to separate the radiating portion **142** of antenna **106** from a proximal portion of the antenna shaft. Barrier **138** may be, e.g., a polymeric or rubber material, configured to function as a gasket to maintain a fluid tight seal around the shaft of the antenna **106**. Fluid channel **140** may be defined within outer jacket **108** distally of barrier **138** within which radiating portion **142** may be positioned. A fluid, such as any one of the fluids mentioned above, may be maintained statically within fluid channel **140** to absorb heat generated by radiating portion **142**. Alternatively, channel **140** may be filled with a fluid, high-temperature chemical, e.g., epoxy, for better impedance matching with the antenna **106**. A separate fluid channel may be defined proximally of barrier **138** surrounding the remaining shaft portion of the antenna. An inlet tube **136** may be positioned within this proximal channel to allow for the exchange of cooling fluids therewithin in a manner as described above such that the fluid is allowed to directly contact the antenna shaft surface.

[0073] The distal end of the microwave antenna may optionally be secured within the cooling jacket through a variety of methods. Fig. 5A shows an illustrative cross-sectional view of cooling assembly distal end **150** which shows microwave antenna **154** positioned within outer jacket **152**. Although antenna **154** may remain either electrically or mechanically unconnected to cooling assembly tip **156**, the two may optionally be joined via a connection **158**. Fig. 5B shows one variation of connecting antenna **154** to tip **156** in which they may be mechanically and electrically connected. Tip **156** may be fabricated from a metal or alloy, e.g., stainless steel, and define a contact channel at its proximal end for receiving antenna **160**, which may also be metallic. Antenna end **160** may be secured into an electrically conductive connection **162** with

tip **156** through various mechanical fastening methods, e.g., adhesives, welding, soldering, clamping, crimping, press-fit, etc., such that connection **162** is a mechanical joint sufficiently strong enough to resist failure when deployed into tissue while also providing for an electrical connection.

[0074] Fig. 5C shows another variation where antenna **164** may be mechanically connected to but electrically insulated from tip **156**. Antenna **164**, or at least the portion of antenna **164** in contact with tip **156**, may have an insulative layer **166** over its outer surface. Thus, tip **156** may remain electrically insulated from antenna **164** yet retain the structural connection therebetween, as described above. In yet another alternative, Fig. 5D shows a connection in which antenna **154** may be electrically connected to tip **156** via a wire or cable **168**. Such a connection may be used to provide for electrical communication between antenna **154** and tip **156** but does not provide for structural support between the two.

[0075] In the case where antenna **164** is structurally attached to tip **156** yet electrically insulated, as shown in Fig. 5C, Fig. 5E shows a variation where electrical communication with tip **156** may be maintained with an externally located power source **161** to provide power for energizing tip **156**. Energized tip assembly **151** shows antenna **164** structurally connected to tip **156** with insulative layer **166** positioned therebetween. Antenna **164** is shown positioned within outer jacket **153**. Rather than having a direct electrical connection between wire **159** and tip **156**, wire **159** may be connected to choke **155** such that power source **161** is electrically connected to tip **156** through choke **155**, in an alternative variation. In yet another variation, power source **161** may instead be electrically connected to tip **156** via outer conductor **157** through wire **159**. In the variations where wire **159** is connected to either choke **155** or outer conductor **157**, an electrical connection between antenna **164** and tip **156** is present.

[0076] Rather than utilizing separate inlet and outlet tubes, other variations may also be utilized. Fig. 6 shows a side view of another cooling assembly variation **170**. In this variation, outer jacket **172** may have an inlet tube **176** externally located from the lumen of outer jacket **172**. Tube **176** may be fabricated from the same or similar material as outer jacket **172**, as described above, or it may be made from a material different from outer jacket **172**, provided that it is preferably non-electrically conductive. Tube **176** may be a completely separate tube member attached to the surface of outer jacket **172**. Alternatively, tube **176** may be integrally formed with outer jacket **172**. In either case, cooling fluid may be pumped through tube **176** to flow distally along outer jacket **172**, as shown by the arrows, until it passes through opening **180**, which may allow for the fluid communication between tube **176** and outlet channel **178** defined through the interior of outer jacket **172**. Opening **180** may be defined between tube **176** and

outlet channel **178** at a predetermined location along outer jacket **172** proximal to tip **174**. The location of opening **180** may depend upon the desired cooling effects and the desired location along the antenna over which the cooling fluid may flow. In another variation, the cooling fluid may be pumped into cooling jacket **172** through outlet channel **178** and the discharged fluid may be returned through tube **176**.

[0077] Fig. 7 shows a side view of another cooling assembly variation **190**. Outer jacket **192** may be seen with tip **194** at its terminal end. In this variation, however, inlet lumen **196** may be defined directly within the wall of outer jacket **192**. Inlet lumen **196** may terminate at opening **200** which may be in fluid communication with outlet channel **198**, within which a microwave antenna may be situated. Although opening **200** is shown terminating at the distal end of outer jacket **192**, opening **200** may be defined at some predetermined location along outer jacket **192** proximal to tip **194** between inlet lumen **196** and outlet channel **198**. Furthermore, outer jacket **192** may be fabricated out of any one of the materials as described above.

[0078] A combination introducer and cooling sheath is shown in the side view of assembly **210** in Fig. 8. Cooling introducer assembly **210** may comprise a polymeric tubing **212** having tubing hub **214** located at the proximal end of tubing **212**. Tip **216**, which may be tapered to facilitate assembly **210** introduction into tissue, may be located at the distal end of tubing **212**. A removable elongate mandrel **218** may be inserted within tubing **212** to provide structural support and column strength to tubing **212** during insertion of assembly **210** into tissue. Mandrel **218** may be fabricated from various materials having sufficient strength to withstand bending moments generated by tubing **212** during tissue insertion, e.g., stainless steel, and may be configured to slidably fit within lumen **220**.

[0079] Figs. 9A to 9C show one example of how assembly **210** may be used as an introducer and cooling jacket for the ablative treatment of tissue. Tubing **212**, with mandrel **218** positioned within, may be inserted into the tissue of a patient **230** until a distal portion of tubing **212** is positioned adjacent to or within a diseased region of tissue, e.g., tumor **232**, as shown in Fig. 9A. Once tubing **212** has been desirably positioned, inner mandrel **218** may be removed from tubing **212** while maintaining the position and orientation of tubing **212** within patient **230**, as shown in Fig. 9B. Microwave antenna **236** may then be inserted within lumen **220** of tubing **212** and advanced distally therewithin such that radiating portion **238** of antenna **236** is positioned within the distal portion of tubing **212** which is adjacent to or within tumor **232**. The proximal end of antenna **236** may have cooling hub **234** connected thereto and cable **240** extending proximally for connection to a microwave and/or RF power supply (not shown).

[0080] The length of antenna **236** may be configured to fit within tubing **212** such that tubing hub **214** and cooling hub **234** may come into contact with one another and locked together, as shown in Fig. 9C. One or both hubs **214, 234** may be configured to releasably lock together through any method of mechanical attachment. For example, hubs **214, 234** may be threaded to screw onto one another, or hubs **214, 234** may be configured to be secured via an interference fit, or any other mechanical fastening method known in the art may be utilized. Furthermore, a gasket may be provided to fit in-between hubs **214, 234** to provide for a fluid-tight seal therebetween. Cooling hub **234** may be fluidly connected to a pump via inlet tube **242** and outlet tube **244**. Once hubs **214, 234** have been secured together, cooling fluid may be introduced through inlet tube **242** and through hub **234** such that the fluid enters into lumen **220** to envelope and contact antenna **236** to cool antenna **236**, if desired. The fluid may be removed from lumen **220** via outlet tube **244**, which may also be in fluid communication with lumen **220** via hub **234**. Once the procedure has been completed, the entire assembly may be removed from the tissue.

[0081] Yet another variation on antenna cooling assembly **250** may be seen in the side view in Fig. 10. In assembly **250**, cooling jacket **256** may be modified to cover only the radiating portion **254** of the microwave antenna. Cooling jacket **256** may thus be configured to be shortened in length from, e.g., cooling jacket **108** described above, and may further omit a handle portion to form cooling channel **262** around radiating portion **254**. Inlet tube **258** and outlet tube **260** may be incorporated with jacket **256** to provide the cooling fluid flow within cooling jacket **256**. The remainder of antenna shaft **252** may remain uncovered by cooling jacket **256**.

[0082] Fig. 11 shows another variation in cooling assembly **270** in which antenna shaft **272** may have cooling tube **276** coiled around at least a portion of shaft **272**. Cooling tube **276** may have cooling fluid flowing therethrough via inlet tube **278** and outlet tube **280** connected to a pump. In the variation shown, tube **276** is coiled around a portion of antenna shaft **272** up to radiating portion **274**. In an alternative variation, tube **276** may also be coiled around radiating portion **274**, in which case tube **276**, or the portion of tube **276** covering radiating portion **274**, is preferably fabricated from a polymeric or plastic material. Furthermore, tube **276** may be coiled only over radiating portion **274**. An optional covering or sheath, preferably made from a polymeric material, e.g., PTFE, Pebax®, etc., may be formed or fitted over the coiled tube **276** (or a portion of the coiled tube **276**) to provide a lubricious surface for assembly **270** for insertion into tissue.

[0083] Another variation on the cooling assembly is shown in Figs. 12A and 12B, which show side and cross-sectional views, respectively, of a loop antenna variation **290** configured to

cool the antenna. This variation is shown for a microwave antenna having a looped antenna, but the principles are applicable to straight antenna probes, as will be described in further detail below. In assembly variation **290**, antenna shaft **292** may have fluid outer tube **294** positioned within antenna shaft **292** and fluid inner tube **296** coaxially positioned within outer tube **294**. The assembly of tubes **294**, **296** may form inner conductor assembly **298** and each tube may extend through the length of antenna shaft **292** and beyond to form the curved antenna portion. The distal end of fluid inner tube **296** may terminate proximally of the distal end of fluid outer tube **294**, which is preferably enclosed at its terminal end. The distal end of fluid inner tube **296** may also define an opening to allow for fluid communication between tubes **294**, **296**.

[0084] Fluid inner tube **296** may define an inflow lumen **300**, as shown in Fig. 12B, and fluid outer tube **294** may define an outflow lumen **302** in the space between tubes **294**, **296**. Thus, cooling fluid may be circulated through the inner conductor **298** itself to cool the antenna during microwave energy transmission. Tubes **294**, **296** may be formed from an electrically conductive material suitable for microwave transmission, e.g., stainless steel, platinum, gold, nickel, etc., or stainless steel plated with an electrically conductive material having a lower electrical resistivity than the stainless steel.

[0085] Aside from utilizing direct contact between the cooling fluid and the microwave antenna, other variations may employ cooling sheaths, such as the variation shown in Figs. 13A to 13C, which show end, cross-sectional side, and perspective views, respectively, of cooling sheath assembly **310**. Sheath assembly **310** may generally comprise main tubular member **312** which defines an antenna lumen **316** therethrough. Tubular member **312** may be fabricated of a polymeric or plastic material, as described above, and preferably defines a diameter sufficient to accommodate the shaft of a microwave antenna positioned within antenna lumen **316**. Furthermore, tubular member **312** may be at least partially formed of a metallic material (preferably proximal to the radiating portion), or member **312** may be formed of a ceramic material. Tubular member **312** is preferably wide enough to allow for direct contact or close contact against an outer surface of the microwave antenna when the antenna is positioned within to facilitate the heat transfer. The tubular member **312** may also be formed of a material, e.g., heat-shrink polymers, which allow for tubular member **312** to conform to an outer surface of the microwave antenna to ensure close thermal contact. Alternatively, a thermally conductive and conformable material, such as a gel or fluid, may be poured or placed within the space, if present, between antenna lumen **316** and the inner wall of tubular member **312** to ensure consistent thermal contact between the two.

[0086] A coaxially positioned fluid tube **314**, as seen in Fig. 13A, may be positioned around tubular member **312** and define fluid channel **322**, as seen in the cross-sectional view of Fig. 13B. Fluid tube **314** may be formed as a common channel such that fluid contained therewithin envelopes or encompasses the outer surface of tubular member **312**. Fluid tube **314** may also be varied in length to surround a majority of tubular member **312** or just a portion of it depending upon the desired cooling effects. Inlet tube **318** may be positioned within fluid channel **322** such that the distal end of inlet tube **318** is positioned near or at the distal end of fluid tube **314** while the distal end of outlet tube **320** may be positioned near or at the proximal end of fluid tube **314** to facilitate the heat transfer. Fluid tube **314** may be integrally fabricated with tubular member **312**; however, fluid tube **314** may also be made of a material different from tubular member **312** and attached through one of any mechanical fastening methods. The distal end of fluid tube **314** and the distal end of tubular member **312** may be joined together; and the proximal end of fluid tube **314** may be attached, connected, or integrally formed with either the proximal end of tubular member **312** or at a predetermined location along an outer surface distal of the proximal end of tubular member **312**. Thus, fluid channel **322** may be formed as a common circumferential fluid channel. If cooling sheath assembly **310** is positioned over only the shaft portion of a microwave antenna, assembly **310** may be made from a metallic material such as stainless steel. Alternatively, if assembly **310** is also configured to be positioned over the radiating portion of an antenna, the entire assembly **310**, or at least the portion of the assembly **310** covering the antenna, is preferably made from a polymeric or plastic material, as described above. The distal end of assembly **310** may be formed into a tapered or atraumatic end **324** to prevent damage to surrounding tissue when assembly **310** is inserted into a patient.

[0087] Fig. 14A shows a side view of a cooling sheath assembly in one variation **330** used with a straight probe microwave antenna. As shown in this variation, assembly **330** may comprise cooling sheath **332** for placement over a length of antenna shaft **344**. The radiating portion **342** is uncovered in this variation, although alternative sheath designs may be employed to entirely cover the radiating portion **342** as well. Assembly **330** may also comprise hub **334**, through which inlet tube **338** and outlet tube **340** may be in fluid communication with sheath **332** to allow for circulation of the cooling fluid. An optional adjustable securing member, e.g., tightening knob **336**, may be provided on hub **334**, or directly on sheath **332**, to prevent sheath **332** from moving relative to antenna shaft **344** by tightening knob **334** in a direction of the arrow shown. Knob **336** may be untightened as well to allow for removal or adjustment of sheath **332** over the antenna. Tightening knob **336** is shown as a rotatable securing mechanism, e.g., a

tightening screw, however, other tightening methods as known in the art may be employed for securing sheath **332** to antenna shaft **344**.

[0088] Fig. 14B shows a side view of the cooling sheath assembly of Fig. 14A in another variation **350** in which sheath **332** may be placed over the shaft **356** of a microwave antenna having a looped radiating portion **354**. In variation **350**, sheath **332** may be positioned over shaft **356** such that the portion of shaft **356** up to its distal end **352** is covered. Radiating portion **354** may remain uncovered in this variation. Fig. 14C shows the cooling sheath assembly in yet another variation **360** used with a looped microwave antenna configured to cool the radiating looped antenna portion. In this variation, sheath **332** may be used with a looped microwave antenna having an inner conductor configured to have cooling lumens integrated within, as shown and described for Figs. 12A and 12B above. Alternatively, and as shown in Fig. 14C, a separate cooling balloon or sheath **362** may be formed to surround the radiating portion **354**.

[0089] Balloon or sheath **362** is described in further detail in U.S. Pat. App. Serial No. 10/272,314, which has been incorporated herein above. Generally, balloon or sheath **362** may be disposed over the curved radiating portion **354** of the microwave antenna. Balloon or sheath **362** may be in a deflated state during the deployment of the antenna through sheath **332** and/or within the tissue, but once the curved antenna **354** has been desirably positioned, balloon **362** may be filled with the cooling fluid, e.g., chilled saline, water, etc., until it has sufficiently inflated. The size of balloon **362** may be varied according to the desired radiative effects (for impedance matching purposes), the length of radiating portion **354**, as well as the type of tissue which the antenna is inserted within. Furthermore, the cooling fluid may be maintained statically within balloon **362** or it may be circulated in a manner as described above.

[0090] Another alternative for cooling a microwave antenna and/or preventing unnecessary tissue damage by a heated antenna feedline or shaft is seen in Fig. 15. The variation shown is a passively cooled balloon assembly **370** which may typically comprise microwave antenna shaft or feedline **372** with an inflatable balloon **374** positioned over a length of shaft **372**. Fig. 15 shows balloon **374** in an inflated configuration over the microwave antenna. A balloon member **374**, which may be inflatable with a liquid or gas (or combination of both) such as saline, water, air, nitrogen, etc., may be attached along microwave antenna shaft **372** at proximal attachment region **376** and distal attachment region **378** through any variety of attachment methods, e.g., adhesives, crimping, etc. Alternatively, a separate inflatable balloon may simply be placed over antenna shaft **372** and reside unattached to the microwave antenna. Balloon **374** may reside along shaft **372** to cover the portion of the shaft **372** which may come into contact with tissue when inserted into a patient. Distal attachment region **378** may be positioned

proximally of antenna radiating portion **380** such that the entire radiating portion **380** is not covered by balloon **374**. Alternatively, distal attachment region **378** may be positioned near or at the distal tip of the antenna so that a portion, or a majority of radiating portion **380**, is at least partially covered by balloon **374**.

[0091] In use, the microwave antenna may be advanced percutaneously or laparoscopically through the skin **382** of a patient to position antenna radiating portion **380** near or adjacent to tumor **384**. Balloon **374** is preferably in a deflated configuration during the insertion through the skin **382**, although balloon **374** may alternatively be inflated prior to or during insertion through skin **382**, depending upon the circumstances. Once radiating portion **380** has been desirably positioned within the patient, balloon **374** may be inflated via an inlet tube prior to or during microwave energy transmission through the antenna. The inflation of balloon **374** may dilate the tissue **386** surrounding the shaft **372** and urge the tissue **386** out of contact with shaft **372**. The radiating portion **380** may remain in direct contact with tumor **384** to effect microwave ablation treatment. Having balloon **374** move tissue **386** away from direct contact with antenna shaft **372** helps to prevent the tissue **386** from overheating or becoming ablated.

[0092] An alternative multi-balloon assembly **390** is shown in the side view of Fig. 16. The microwave antenna assembly **390** may be divided into several, i.e., two or more, regions along its shaft. For instance, first antenna region **392**, second antenna region **394**, and third antenna region **396** may each have a respective first balloon **400**, second balloon **402**, and third balloon **404** over each region such that each balloon **400, 402, 404** is adjacent to one another along the shaft outer surface. Each balloon **400, 402, 404** may be attached to the microwave antenna distal of connector hub **414** at first, second, third, and fourth attachment regions **406, 408, 410, 412**, respectively, through one of any attachment methods as described above. A balloon may be positioned over radiating portion **398** or radiating portion **398** may be left exposed, as shown in the figure. The number of balloons in this example are merely illustrative and fewer or greater number of balloons may be utilized depending upon the desired configuration and cooling results. Moreover, each balloon **400, 402, 404** may be in fluid communication with one another in series such that all the balloons **400, 402, 404** may be inflated simultaneously. Alternatively, each balloon **400, 402, 404** may be individually inflatable such that a single balloon, or a combination of balloons, may be inflated while the other balloons may remain un-inflated, depending upon the desired cooling results. Moreover, each balloon may be inflatable with a liquid or gas (or combination of both) such as saline, water, air, nitrogen, etc., as described above. Furthermore, although a straight microwave antenna probe is

shown in the figures, this is intended to be illustrative; alternatively, a microwave antenna having a curved radiating portion may also be utilized.

[0093] Aside from the use of inflatable balloons, alternative cooling methods and devices may comprise passive cooling sheaths, as shown in the exploded assembly **420** of Fig. 17. Assembly **420** may comprise a microwave antenna **422** having a radiating portion **424**; in this example, a curved radiating portion **424**. A tubular cooling pack **426** may define a lumen **428** into which the shaft of antenna **422** may be positioned. Both antenna **422** and cooling pack **426** may be positioned within a handle lumen **434** defined within handle **430**. An optional insulation layer **432**, e.g., foam, rubber, etc., may be disposed upon the inner surface of handle lumen **434** between cooling pack **426** and handle **430**. Cooling pack **426** may simply be a plastic or polymeric tubular container of chilled or frozen water or saline, or another fluid which is preferably biocompatible, which may be cooled prior to use with the microwave antenna. Alternatively, cooling pack **426** may contain gels or chemicals which may be mixed (e.g., a mixture of water, urea, and ammonium chloride; alternatively, a mixture of potassium chloride or sodium nitrate and water, etc.) such that an endothermic reaction results and cooling of the antenna **422** may be achieved. Moreover, cooling pack **426** may be configured to come into intimate contact with the shaft of antenna **422** to ensure good thermal contact. Handle **430** may be molded from various materials, e.g., polymers, plastics, etc., and it may configured as a simple tubular handle. Alternatively, it may be ergonomically molded to allow for better handling by the user. The handle lumen **434** is preferably just wide enough to allow for the insertion of cooling pack **426** so that thermal contact between the two may occur. The cooling assembly **420** may be assembled prior to use with the antenna **422** such that the entire assembly is inserted into the tissue altogether; alternatively, it may be assembled within the tissue during tissue ablation.

[0094] Another variation may be seen in the side view of conformable cooling sheath assembly **440** in Fig. 18. The antenna shaft or feedline **442** of a microwave antenna may be inserted through a handle lumen **450** defined through conformable cooling sheath **440**. Cooling sheath **440** may comprise a proximal handle portion **444** and a conformable portion **446** which may be configured to spread over and cool the skin surface **452** surrounding the area where the antenna shaft **442** has been inserted. Proximal handle portion **444** may be comprised of a polymeric or plastic material which may be adapted to maintain its configuration while conformable portion **446** may be comprised of a polymeric material adapted to spread out and conform against skin surface **452** over contact surface **448**. Conformable sheath assembly **440** may be filled with any one of the liquids, gases, and/or chemical mixtures as described above.

[0095] Alternative cooling sheaths are further shown in Figs. 20A to 21C. A cross-sectional side and end view of cooling sheath **460** is shown in Figs. 19A and 19B, respectively, for comparison purposes. As shown, a simple cooling sheath **460**, as described above, may define antenna lumen **462** therethrough. Figs. 20A and 20B show cross-sectional side and end views of cooling sheath **470**. Antenna lumen **474** may be defined through the length of sheath **470**. Barriers **472** may be defined through the length of sheath **470** to divide the interior lumen into at least two separate volumes. A first defined volume **476** may hold a first chemical or liquid (e.g., water, saline, etc.) and second defined volume **478** may hold a second chemical or liquid (ammonium chloride, sodium nitrate, or potassium chloride, etc.). When a cooling effect is desired, sheath **470** may be flexed slightly such that barriers **472** may be broken or fractured within sheath **470** to allow for the mixing between the chemicals from first volume **476** and second volume **478** to result in an endothermic reaction.

[0096] Another alternative may be seen in the cross-sectional side views of Figs. 21A and 21B and the end view of Fig. 21C of slidable sheath assembly **480**. As shown in Fig. 21A, sheath assembly **480** may comprise an inner tube **484**, which defines a first volume **492** for holding a first chemical or liquid, and a concentric outer tube **482**, which defines a second volume **494** for holding a second chemical or liquid. The composition of the first chemical and/or second chemical contained in their respective volumes may include any of the chemicals and/or liquids mentioned above. Outer tube **482** may define a plurality of openings **488** over its inner surface and inner tube **484** may also define a plurality of openings **490** over its outer surface. Openings **488**, **490** may be defined in each of their respective tubes such that when inner tube **484** and outer tube **482** are in a first misaligned configuration relative to one another, their respective openings are blocked, as shown in Fig. 21A. However, inner tube **484** and outer tube **482** may be moved longitudinally and/or rotationally relative to one another into a second aligned configuration such that openings **488**, **490** may be aligned with one another and allow for the mixing of the respective chemicals to produce a cooling effect within antenna lumen **486**, as shown in Figs. 21B and 21C. These variations are intended to be illustrative and any variations on the number of openings or the manner in which openings may be aligned to allow for the mixture of various chemicals or liquids are intended to be within the scope of the invention.

[0097] Alternative variations in which the cooling sheath or tube may be integrated with or within the microwave antenna shaft are shown in the following Figs. 22A to 22D. Fig. 22A shows a perspective view of a portion of a microwave antenna shaft assembly **500** in which outer tubing **508** may be formed as an integral part of the microwave antenna. The antenna is shown as comprising, in part, outer conductor **502** coaxially surrounding inner conductor **504** with

dielectric **506** disposed therebetween. Outer tubing **508**, which may be comprised of a metallic, e.g., stainless steel, or polymeric material, as described above, may surround the length, or at least a partial length of the microwave antenna. Outer tubing **508** may define a cooling lumen **510** between the outer conductor **502** through which a cooling fluid may be pumped through or simply filled.

[0098] Fig. 22B shows another cooling tube variation **520** in which outer tubing **522** may surround the microwave antenna, as in assembly **500** of Fig. 22A. Tubing **522**, however, may include a barrier or divider **524** which separates the cooling lumen into at least a first lumen **526** and a second lumen **528**, which may act as inlet and outlet lumens, respectively, for a cooling fluid to be flowed through. Divider **524** may be formed of the same or similar material as outer conductor **502** and/or outer tubing **522**. Fig. 22C shows yet another variation **530** in which outer tube **532** may comprise a number of longitudinally formed dividers **534**, **536**, **538**, **540**, and **542** to create a number of corresponding cooling lumens **544**, **546**, **548**, **550**, and **552** in the space between outer conductor **502** and outer tubing **532**. The cooling lumens may be utilized as inlet lumens or outlet lumens or various combinations thereof depending upon the desired cooling results. The number of dividers and cooling lumens is intended merely to be illustrative of the various combinations and numbers of cooling lumens which may be formed.

[0099] Fig. 22D shows yet another variation **560** in which cooling lumens may be formed within the space between inner conductor **502** and outer conductor **504**, where a dielectric material is typically located. In this variation, longitudinally defined dividers **564**, **566**, **568**, **570**, and **572** may be formed of an electrically non-conductive material, e.g., polymers, to divide the space into a number of corresponding cooling lumens **574**, **576**, **578**, **580**, and **582**. An optional cooling tube **562** may be utilized and positioned over outer conductor **502**. As above, the cooling lumens may be utilized as inlet lumens or outlet lumens or various combinations thereof depending upon the desired cooling results. Moreover, the number of dividers and cooling lumens is intended merely to be illustrative and not limiting in scope.

[0100] In certain variations of the microwave antenna, an electrical choke may be utilized to improve the energy focus of an antenna assembly. The electrical choke and its use is described in further detail in U.S. Pat. App. Serial Nos. 10/052,848 and 10/272,058, which have been incorporated herein by reference above. Generally, the choke may be disposed on the antenna proximally of the radiating section. The choke is preferably placed over a dielectric material which may be disposed over the antenna. The choke is preferably a conductive layer and may be further covered by a tubing or coating. A cross-sectional view of a triaxial antenna **590** may be seen in Fig. 23A having inner conductor **592** and outer conductor **594** with dielectric

596 disposed therebetween. The choke layer **598** may be seen formed over outer conductor **594** with dielectric **600** disposed between the two layers. Fig. 23B shows a cooling choke variation **610** in which a number of longitudinally defined dividers **612**, **614**, **616**, **618**, and **620** may form a number of corresponding cooling lumens **622**, **624**, **626**, **628**, and **630**. The dividers may be formed of an electrically non-conductive material, e.g., polymers, and the cooling lumens may be utilized as inlet lumens or outlet lumens or various combinations thereof depending upon the desired cooling results.

[0101] Cooling sheaths or jackets, as described above, may be varied or tuned to match the requisite cooling for a given length of a microwave antenna. A typical microwave antenna may generally be divided into at least three different regions along the length of its shaft. For instance, in Fig. 24, a side view of microwave antenna **640** may be seen divided into a first region **642**, second region **644**, and third region **646**. First region **642** may generally comprise the radiating antenna or the region of active heating during microwave ablation. It may be desirable to cool this region **642** to maintain optimal energy delivery by preventing the surrounding tissue from charring, which in turn may change the effective wavelength. Second region **644** is generally the portion of antenna **640** which is in contact with the tissue surrounding a tumor or lesion to be ablated. This region **644** typically becomes hot from ohmic heating and some conductive heating from first region **642**. It may be desirable to allow second region **644** to heat up in certain tissue regions where coagulation of the insertion tract may be desirable. However, it may also be desirable to cool this region **644** in other applications to protect surrounding sensitive tissue structures from heat damage. Finally, third region **646** is generally the portion of antenna **640** which comes into contact with the skin of a patient. This region **646** typically heats up because of ohmic heating and it is generally desirable to keep this region cool when used in percutaneous or laparoscopic procedures to prevent heat damage to the skin surface. In other procedures, such as in applications where lesions are located deep within the tissue, it may be desirable to allow region **646** to become heated to allow for the coagulation of the insertion tract.

[0102] Accordingly, a multi-zone cooling assembly **650**, such as the variation shown in Fig. 25, may be utilized to take advantage of optionally cooling multiple regions along the length of a microwave antenna. Cooling jacket **652** may surround the length of microwave antenna **660** and define a smooth outer surface for insertion into tissue. The interior of cooling jacket **652** may define a distal first cooling region **654**, second cooling region **656**, and a proximal third cooling region **658**. These cooling regions **654**, **656**, **658** may correspond to and envelope the various regions of antenna **660**, e.g., first region **662** may be positioned within first cooling

region **654**, second region **664** may be positioned within second cooling region **656**, and third region **666** may be positioned within third cooling region **658**. Each of the cooling regions **654**, **656**, **658** may be divided from one another when antenna **660** is positioned within cooling jacket **652** via, e.g., electrically insulative gaskets such as rubber or polymers, to prevent fluid communication between the adjacent cooling regions. For instance, first divider **680** may separate first and second cooling regions **654**, **656**; second divider **682** may separate second and third cooling regions **656**, **658**; and third divider **684** may separate third cooling region **658** from the remainder of cooling jacket **652**.

[0103] Each individual cooling region may thus be maintained at a different cooling rate than from an adjacent cooling region, depending upon the desired cooling profile. To maintain the differential cooling regions, any of the various cooling methods described herein may be utilized; in particular, each cooling region may utilize its own fluid inlet and outlet tubes. For instance, as shown in the figure, first cooling region **654** may have a first inlet tube **668** and first outlet tube **670**; second cooling region **656** may have a second inlet tube **672** and second outlet tube **674**; and third cooling region **658** may have a third inlet tube **676** and third outlet tube **678**. Each pair of inlet and outlet tubes may be connected to separate pumps or they may be connected to a common pump with individually controlled valves for maintaining each cooling region at a different flow rate, if desired. The number of cooling regions is merely illustrative in this example and is not intended to be limiting.

[0104] Fig. 26A shows yet another variation in which the diameters of the inner conductor may be modified so that proximal portions of the inner conductor functions as a heat sink to facilitate conductive cooling of the microwave antenna. Multi-diameter cable assembly **690** may comprise an inner conductor assembly **692** having a proximal portion **694** with a first diameter and a distal portion **696** with a second diameter smaller than the first diameter. The two portions **694**, **696** may be joined via a tapered portion **698**. The inner conductor assembly **692** may be surrounded by outer conductor **700**, which may also similarly taper from a first portion having a diameter, e.g., 0.141 inches, down into a second portion having a diameter, e.g., 0.070 inches, smaller that the first portion to facilitate insertion into tissue. This dual-diameter inner conductor assembly may not only increase the pushability of the antenna portion into the tissue, but may also allow proximal portion **694** to function as a heat sink and to help conduct heat away proximally from the radiating portion. Moreover, having a larger cable helps to improve the power handling capabilities which in turn helps to facilitate a decrease in the generation of high temperatures which may be harmful to healthy tissue. The tapered portion **698** may be created, e.g., by soldering the two portions **694**, **696** together.

[0105] Figs. 26B and 26C show cross-sectional side views of optional transitional diameters which may be utilized for the inner conductors. As shown in Fig. 26B, first portion **102** may have a standard diameter of, e.g., 0.141 inches, while second distal portion **704** may transition down to a portion having a diameter of, e.g., 0.070 inches. Fig. 26C shows another example where first portion **102** may transition down to a second distal portion **706** having a diameter of, e.g., 0.085 inches. Other variations may utilize other diameters and these examples are shown for illustrative purposes only.

[0106] An example of the cooling capacity of some of the cooling variations described above is shown in the corresponding plots in Figs. 27 and 28. Fig. 27 shows a plot **710** over time of the heating which may occur in a microwave antenna which is uncooled. The temperature measurements were taken along a middle portion of a microwave antenna having a diameter of about 0.047 inches. At 60W of power, the measured temperature reaches approximately 100° C in less than 9 seconds. Fig. 28 shows an example in plot **720** of the cooling capacity of the same microwave antenna utilizing a cooling sheath as shown in Figs. 13A to 13C, as described above. With the power initially off, temperature measurements were taken on the surface of the cooling sheath above the same location where measurements were taken on the microwave antenna. Slope **722** indicates antenna heating at 60W of power with no cooling fluid being pumped through the sheath. Slope **724** indicates where the cooling fluid is being circulated through the sheath. Measurements indicated that the temperature of the antenna returned to normal levels within 6-8 seconds from when the cooling fluid was circulated. Cooling fluid was then shut off and a temperature rise **726** may be seen again. Slope **728** indicates again where the fluid is restarted to circulate within the sheath.

[0107] This invention has been described and specific examples of the invention have been portrayed. The use of those specifics is not intended to limit the invention in any way. It is also contemplated that combinations of features between various examples disclosed above may be utilized with one another in other variations. Additionally, to the extent there are variations of the invention with are within the spirit of the disclosure and yet are equivalent to the inventions found in the claims, it is our intent that this patent will cover those variations as well.

CLAIMS

We claim:

1. A cooling system for use with a microwave antenna, comprising:

a cooling jacket adapted to at least partially surround a microwave antenna,

wherein the cooling jacket is further adapted to retain a cooling fluid therein such that at least a portion of the microwave antenna is in fluid contact with the cooling fluid.

2. The system of claim 1 further comprising at least one inlet lumen and at least one outlet lumen each in fluid communication with the cooling jacket for circulating the cooling fluid therethrough.

3. The system of claim 2 wherein a distal end of the inlet lumen is positioned near or at a distal end of the microwave antenna.

4. The system of claim 2 wherein a distal end of the outlet lumen is positioned proximally of the microwave antenna distal end.

5. The system of claim 2 wherein the inlet lumen is defined along an outer surface of the cooling jacket.

6. The system of claim 2 wherein the inlet lumen is defined within a wall of the cooling jacket.

7. The system of claim 1 further comprising a tip at a distal end of the cooling jacket.

8. The system of claim 7 wherein the tip is tapered.

9. The system of claim 7 further comprising a power generator in electrical communication with the tip.

10. The system of claim 7 wherein a distal end of the microwave antenna is securable to a proximal portion of the tip.

11. The system of claim 10 wherein the tip is adapted to be in electrical communication with the distal end of the microwave antenna.

12. The system of claim 1 further comprising a handle assembly for attachment to a proximal end of the cooling jacket.

13. The system of claim 12 wherein the handle assembly defines at least one lumen therethrough which is in fluid communication with the cooling jacket.

14. The system of claim 1 further comprising a pump for circulating the cooling fluid through the cooling jacket.

15. The system of claim 1 wherein the cooling fluid comprises a liquid, gas, or combination thereof.

16. The system of claim 15 wherein the liquid comprises water or saline.

17. The system of claim 15 wherein the gas is selected from the group consisting of nitrous oxide, nitrogen, and carbon dioxide.

18. The system of claim 1 further comprising a temperature sensor for sensing a temperature of the system.

19. The system of claim 1 further comprising an introducer which is insertable into the cooling jacket.

20. The system of claim 1 wherein the cooling jacket is configured in length to match a radiating portion of the microwave antenna.

21. The system of claim 1 wherein the cooling jacket defines at least a first and a second region adjacent to and separate from one another, the first region being adapted to retain the cooling fluid from a first source in fluid contact with a first portion of the microwave antenna, and the second region being adapted to retain cooling fluid from a second source in fluid contact with a second portion of the microwave antenna.

22. The system of claim 21 wherein the cooling fluid from the first source is maintained at a first temperature and the cooling fluid from the second source is maintained at a second temperature.

23. The system of claim 21 wherein the cooling jacket defines a plurality of additional regions adjacent to and separate from one another.

24. The system of claim 1 wherein the cooling jacket defines at least a first and a second region adjacent to and separate from one another, the first region being adapted to retain the cooling fluid from a first source in fluid contact with a first portion of the microwave antenna, and the second region being adapted to retain cooling fluid from the first source in fluid contact with a second portion of the microwave antenna.

25. A method of cooling a microwave antenna, comprising:

providing a cooling jacket adapted to surround a microwave antenna at least partially along a length of the microwave antenna; and

flowing a cooling fluid through the cooling jacket such that the fluid is retained within the cooling jacket and directly contacts at least a portion of the microwave antenna.

26. The method of claim 25 further comprising advancing the cooling jacket with the microwave antenna into a tissue region to be treated prior to flowing the cooling fluid through the cooling jacket.

27. The method of claim 25 further comprising flowing the cooling fluid through the cooling jacket prior to advancing the cooling jacket with the microwave antenna into a tissue region to be treated.

28. The method of claim 25 further comprising flowing the cooling fluid through the cooling jacket while advancing the cooling jacket with the microwave antenna into a tissue region to be treated.

29. The method of claim 26 wherein advancing the cooling jacket comprises energizing a tip positioned at a distal end of the cooling jacket to cut through tissue.

30. The method of claim 25 further comprising energizing the microwave antenna prior to flowing the cooling fluid through the cooling jacket.

31. The method of claim 25 further comprising energizing the microwave antenna while flowing the cooling fluid through the cooling jacket.

32. The method of claim 25 wherein flowing the cooling fluid comprises pumping the cooling fluid through the cooling jacket.

33. The method of claim 25 wherein flowing the cooling fluid comprises passing the fluid through an inlet lumen into the cooling jacket.

34. The method of claim 33 wherein passing the fluid through the inlet lumen comprises passing the fluid through the inlet lumen defined along an outer surface of the cooling jacket.

35. The method of claim 33 wherein passing the fluid through the inlet lumen comprises passing the fluid through the inlet lumen defined within a wall of the cooling jacket.

36. The method of claim 33 further comprising passing the fluid through an outlet lumen out of the cooling jacket.

37. The method of claim 25 wherein the fluid is statically retained within the cooling jacket.

38. The method of claim 25 wherein flowing the cooling fluid comprises flowing the fluid at a uniform flow rate.

39. The method of claim 25 wherein flowing the cooling fluid comprises flowing the fluid at an intermittent flow rate.

40. The method of claim 25 wherein the fluid directly contacts a radiating portion of the microwave antenna.

41. The method of claim 25 wherein the fluid directly contacts a shaft portion of the microwave antenna.

42. The method of claim 25 further comprising sensing a temperature of the microwave antenna.

43. The method of claim 42 further comprising initiating an alarm upon the temperature reaching a predetermined level.

44. The method of claim 25 further comprising flowing the cooling fluid through a second portion of the cooling jacket such that the fluid is retained within the second portion and directly contacts at least a second portion of the microwave antenna.

45. The method of claim 25 further comprising removing the microwave antenna from a tissue region.

46. A cooling sheath system for use with a microwave antenna, comprising:

a first tubular member defining an antenna lumen therethrough, the first tubular member being adapted to at least partially surround the microwave antenna;

a second tubular member positioned about a length of the first tubular member; and

a fluid channel defined between the first tubular member and the second tubular member,

wherein the fluid channel is adapted to retain a cooling fluid therein and envelope at least a portion of the antenna lumen.

47. The system of claim 46 further comprising at least one inlet lumen in fluid communication with the fluid channel.

48. The system of claim 47 wherein a distal end of the inlet lumen is positioned near or at a distal end of the fluid channel.

49. The system of claim 47 further comprising at least one outlet lumen in fluid communication with the fluid channel.

50. The system of claim 49 wherein a distal end of the outlet lumen is positioned near or at a proximal end of the fluid channel.

51. The system of claim 46 wherein the second tubular member is coaxially positioned about the length of the first tubular member.

52. The system of claim 46 wherein a distal end of the first tubular member and a distal end of the second tubular member are attached together.

53. The system of claim 46 wherein a proximal end of the second tubular member is attached along an outer surface of the first tubular member.

54. The system of claim 46 wherein the antenna lumen is adapted to conform to a shape of the microwave antenna.

55. The system of claim 46 wherein the fluid channel is concentrically defined between the first tubular member and the second tubular member.

56. The system of claim 46 further comprising a pump in fluid communication with the fluid channel.

57. The system of claim 46 wherein the first tubular member and the second tubular member are integrally fabricated together.

58. The system of claim 46 wherein the first tubular member and the second tubular member are comprised of a metallic material.

59. The system of claim 46 wherein the first tubular member and the second tubular member are comprised of a polymeric material.

60. The system of claim 46 wherein the first tubular member and the second tubular member are comprised of a ceramic material.

61. The system of claim 46 further comprising a hub connected to a proximal portion of the system.

62. The system of claim 61 further comprising an adjustable securing member positioned on the hub which is adapted to inhibit movement of at least the first tubular member relative to the microwave antenna.

63. The system of claim 46 wherein the antenna lumen is adapted to surround a shaft portion of the microwave antenna.

64. A method of cooling a microwave antenna, comprising:

providing a cooling sheath adapted to surround a microwave antenna at least partially along a length of the microwave antenna; and

flowing a cooling fluid through the cooling sheath such that the fluid is retained within a fluid channel defined between an outer jacket and an antenna lumen positioned within the outer jacket, wherein the fluid channel envelopes at least a portion of the length of the antenna lumen.

65. The method of claim 64 further comprising advancing the cooling sheath with the microwave antenna into a tissue region to be treated prior to flowing the cooling fluid.

66. The method of claim 64 further comprising energizing the microwave antenna prior to flowing the cooling fluid through the cooling sheath.

67. The method of claim 64 further comprising energizing the microwave antenna while flowing the cooling fluid through the cooling sheath.

68. The method of claim 64 wherein the fluid is retained within a concentrically-defined fluid channel.

69. The method of claim 64 wherein flowing the cooling fluid comprises pumping the cooling fluid through the cooling sheath.

70. The method of claim 64 wherein flowing the cooling fluid comprises passing the fluid through an inlet lumen into the cooling sheath.

71. The method of claim 70 further comprising passing the fluid through an outlet lumen out of the cooling sheath.

72. The method of claim 64 wherein the fluid is statically retained within the cooling sheath.

73. The method of claim 64 wherein flowing the cooling fluid comprises flowing the fluid at a uniform flow rate.

74. The method of claim 64 wherein flowing the cooling fluid comprises flowing the fluid at an intermittent flow rate.

75. The method of claim 64 further comprising conforming the cooling sheath to an outer surface of the microwave antenna prior to flowing the cooling fluid.

76. The method of claim 64 further comprising securing the cooling sheath to the microwave antenna to inhibit movement of the cooling sheath relative to the microwave antenna prior to flowing the cooling fluid.

77. The method of claim 64 further comprising removing the microwave antenna from a tissue region.

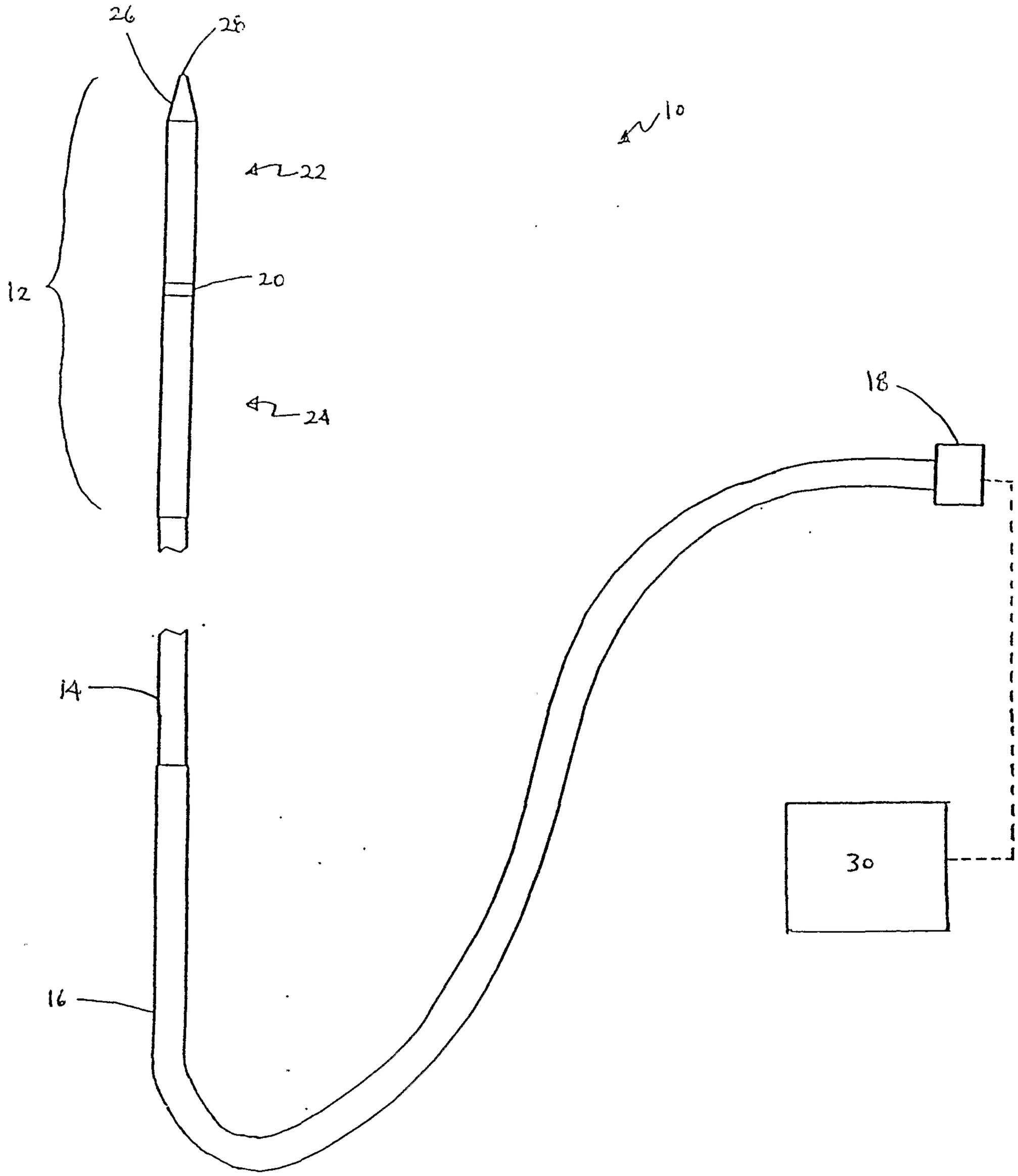


FIG. 1

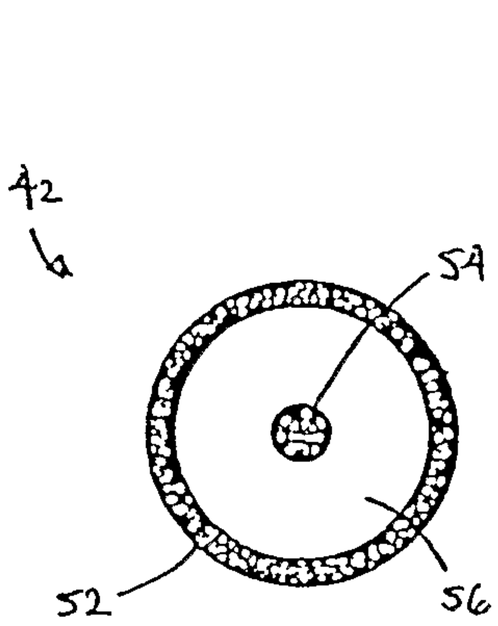


FIG. 2A

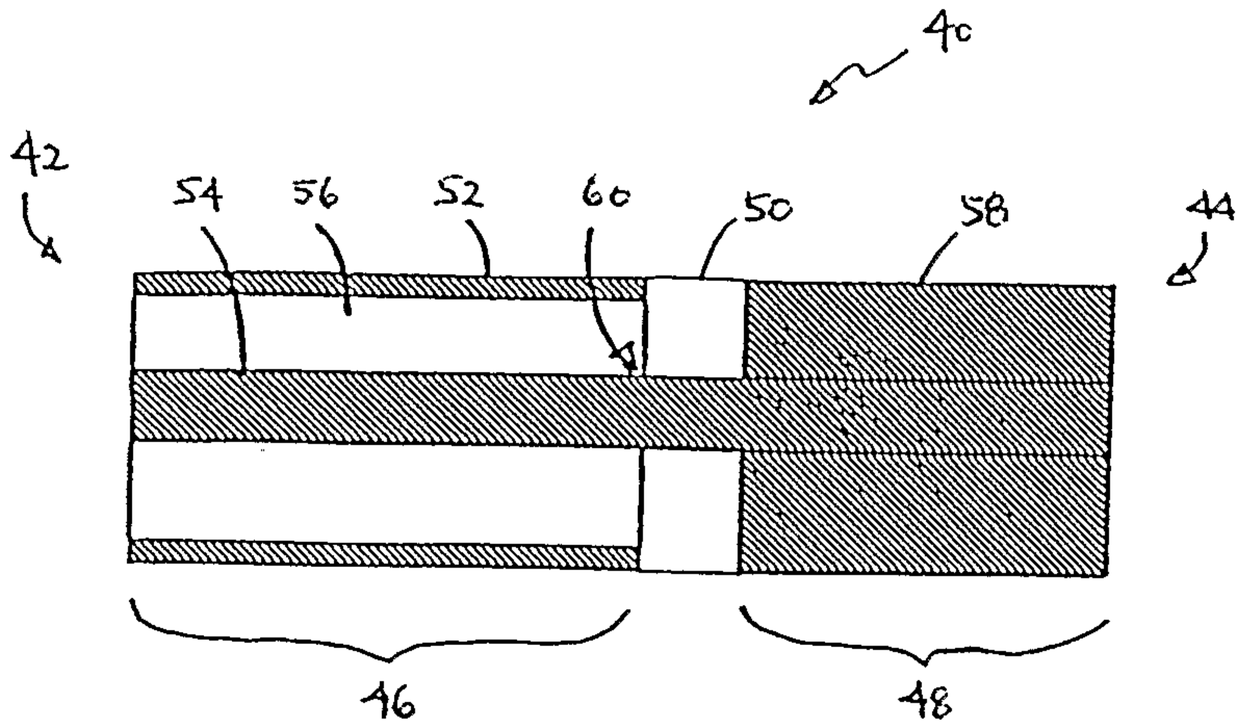


FIG. 2B

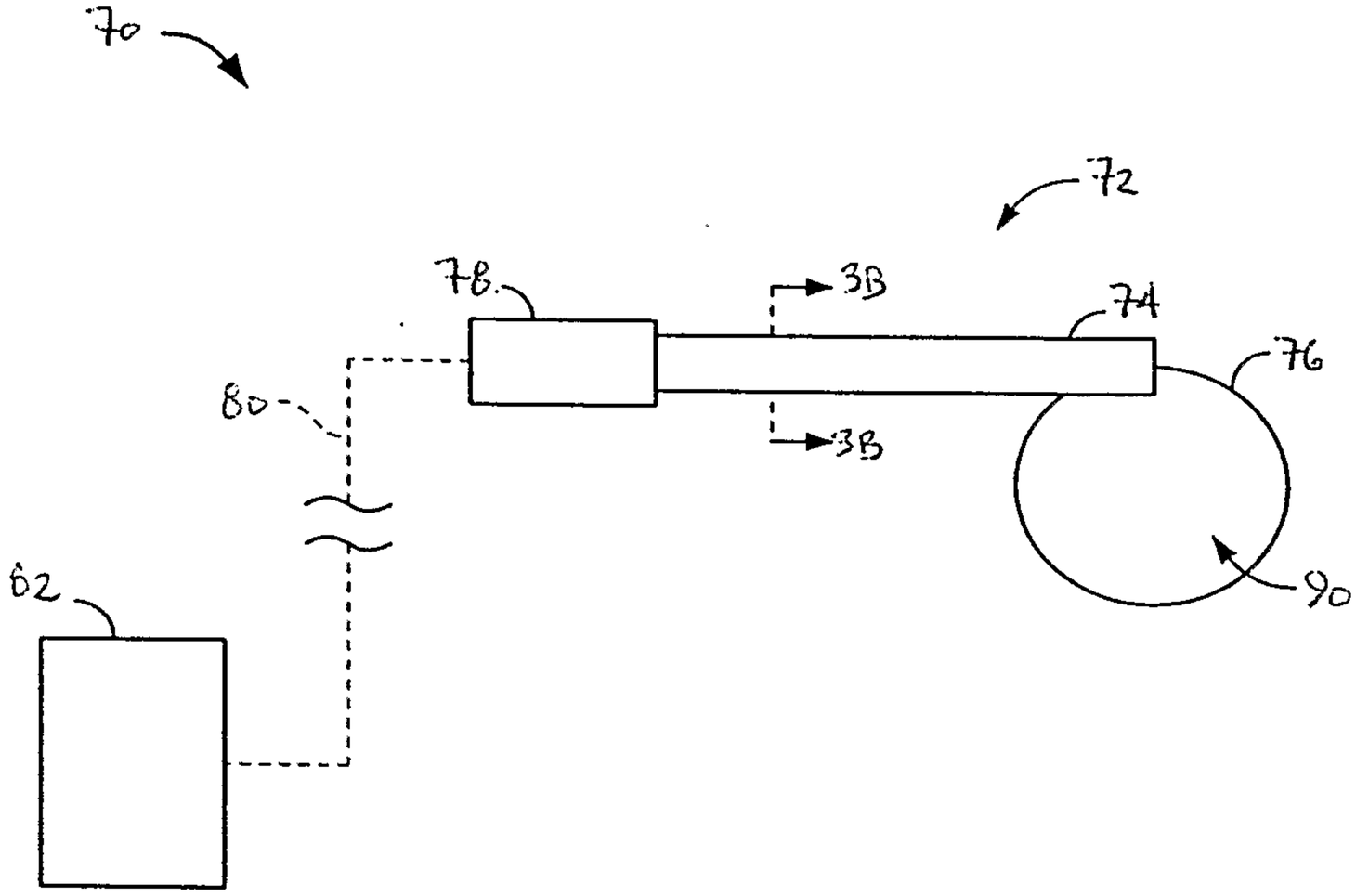


FIG. 3A

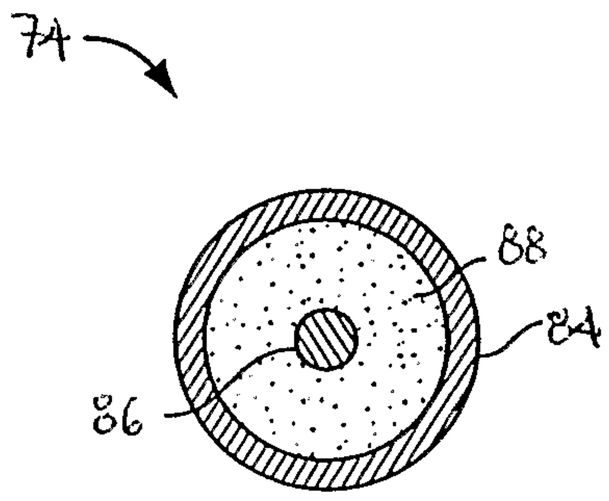


FIG. 3B

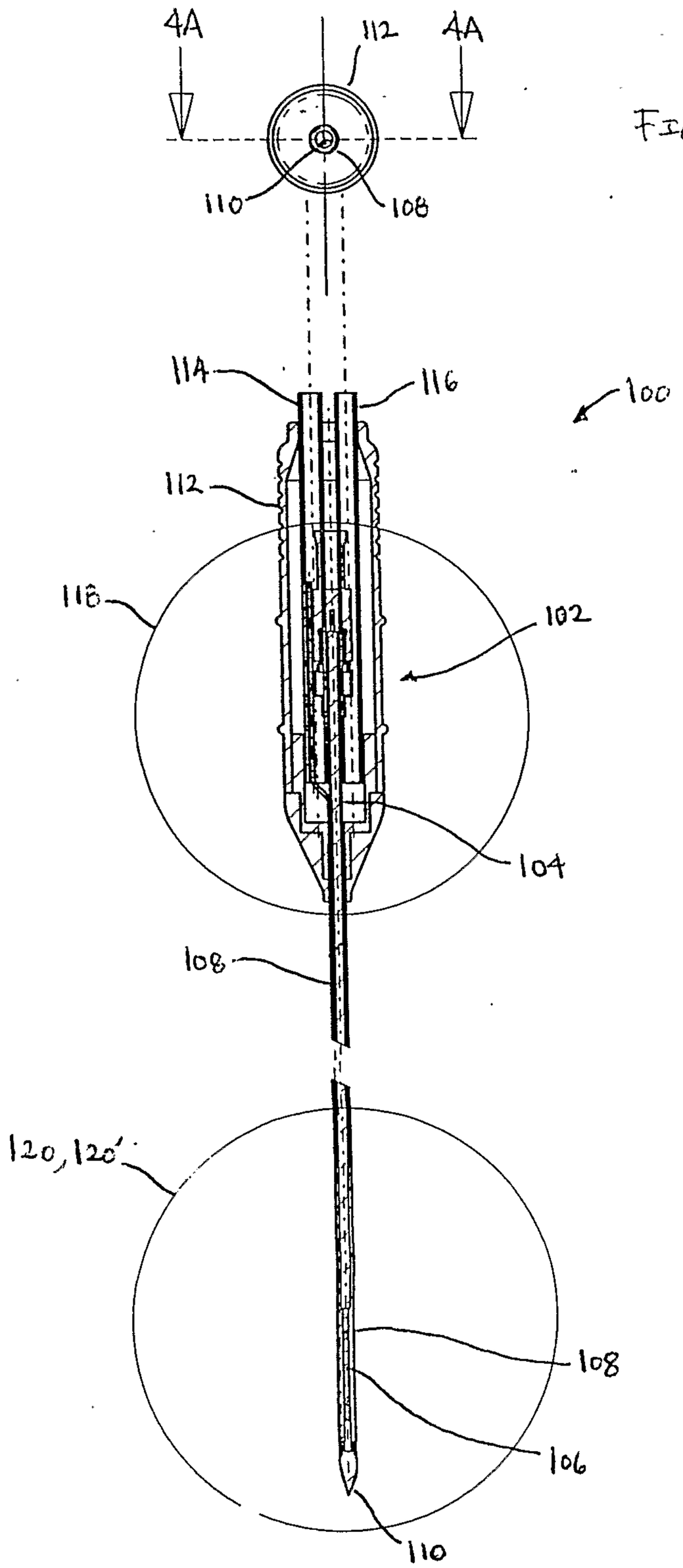

4A
112
4A
110
108
114
116
100
112
118
102
104
108
120, 120'
108
106
110

FIG. 4B

FIG. 4A

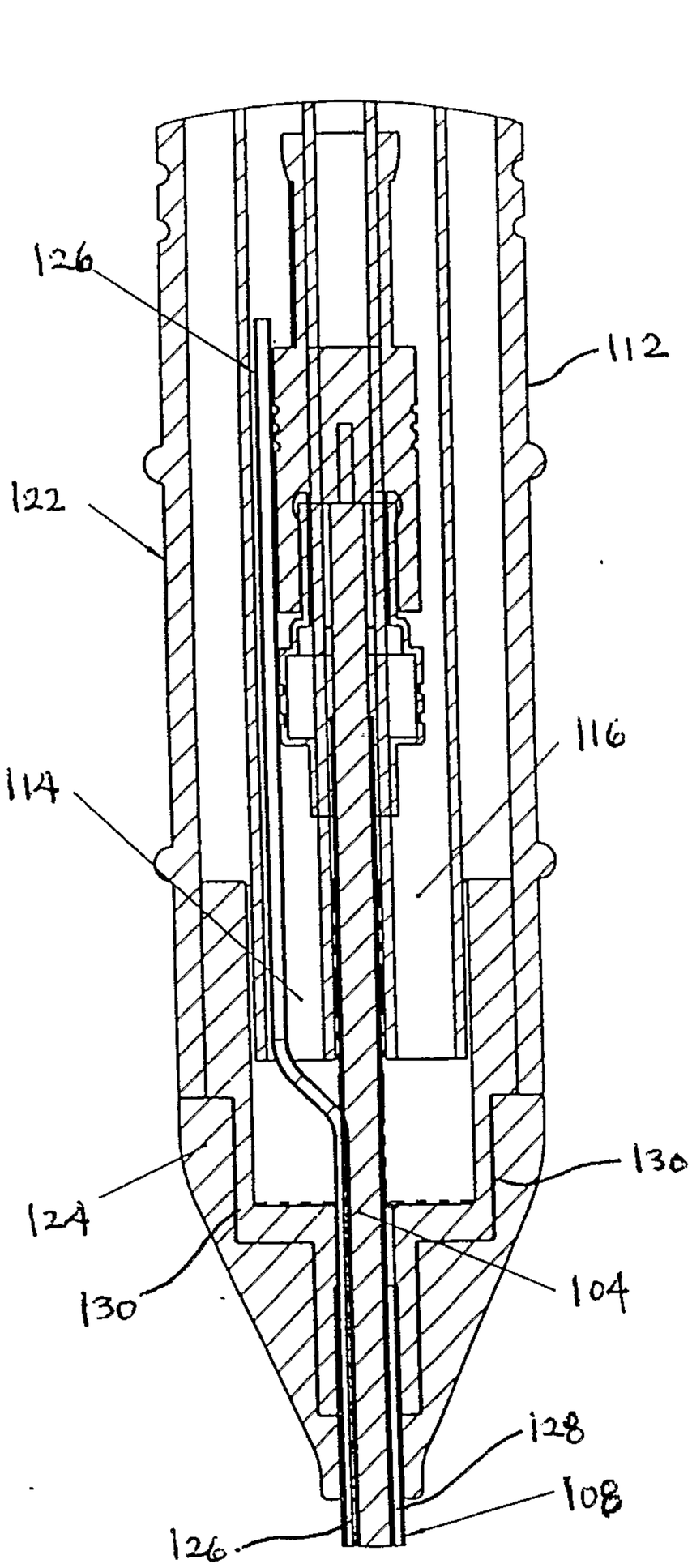


FIG. 4C

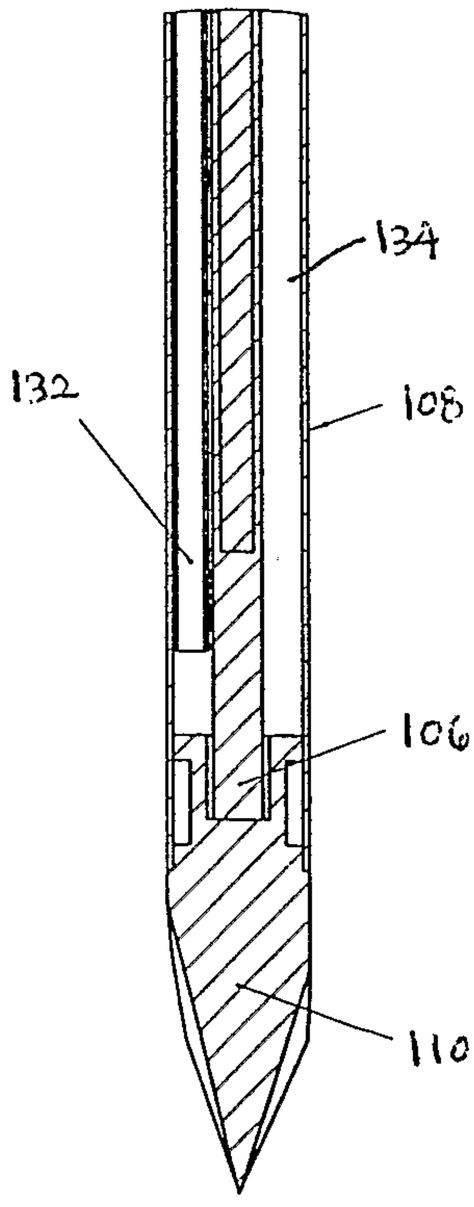


FIG. 4D

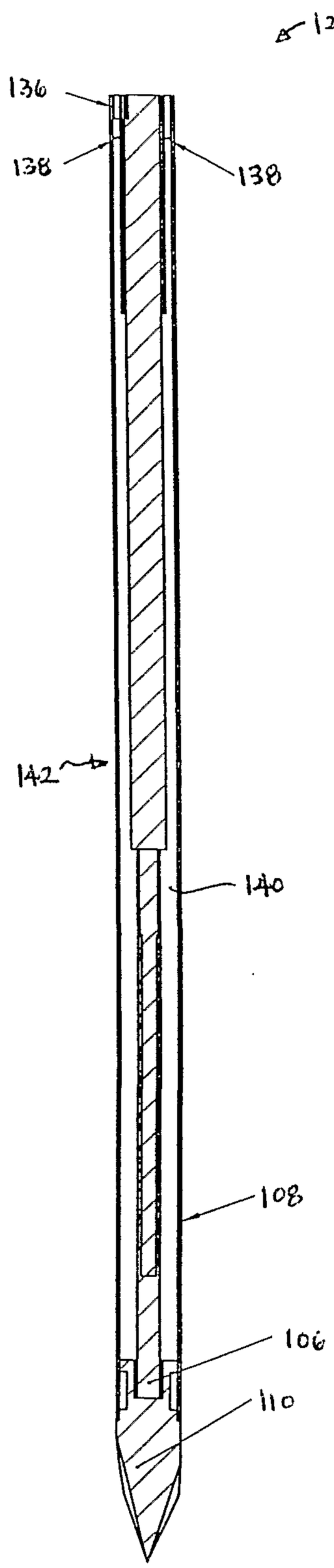


FIG. 4E

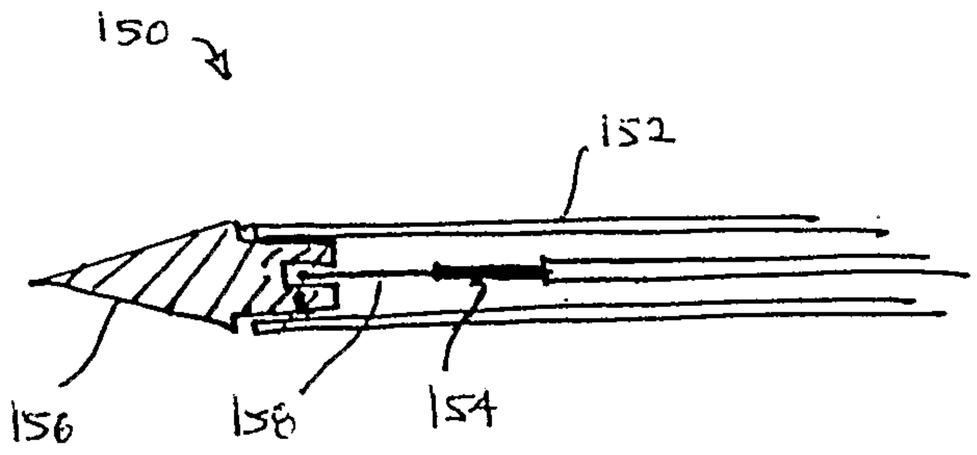


FIG. 5A

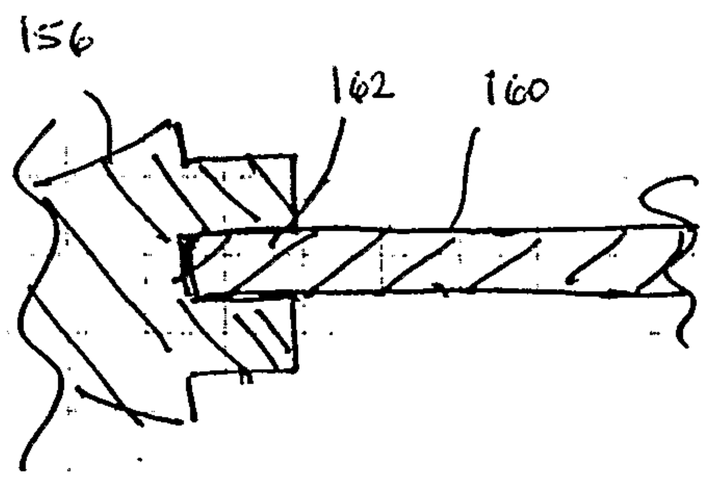


FIG. 5B

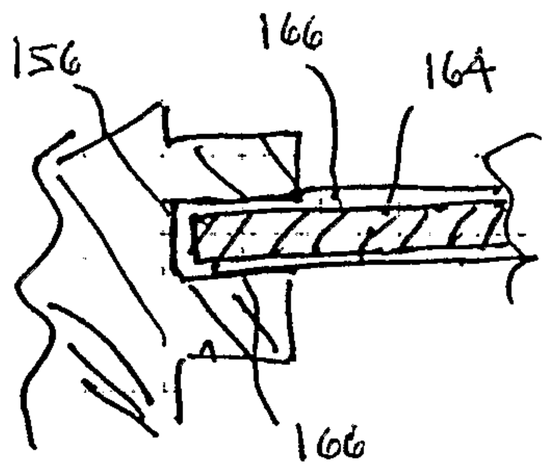


FIG. 5C

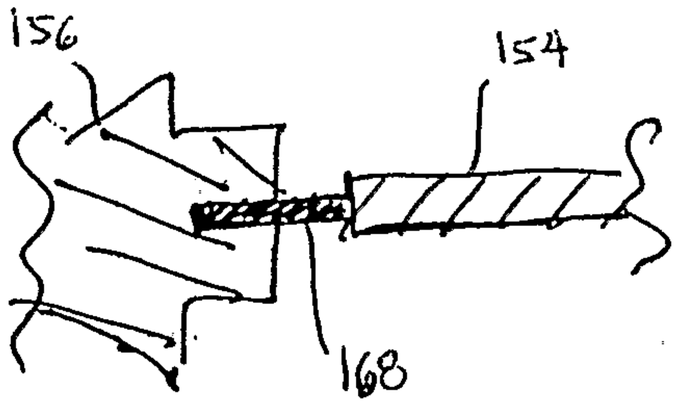


FIG. 5D

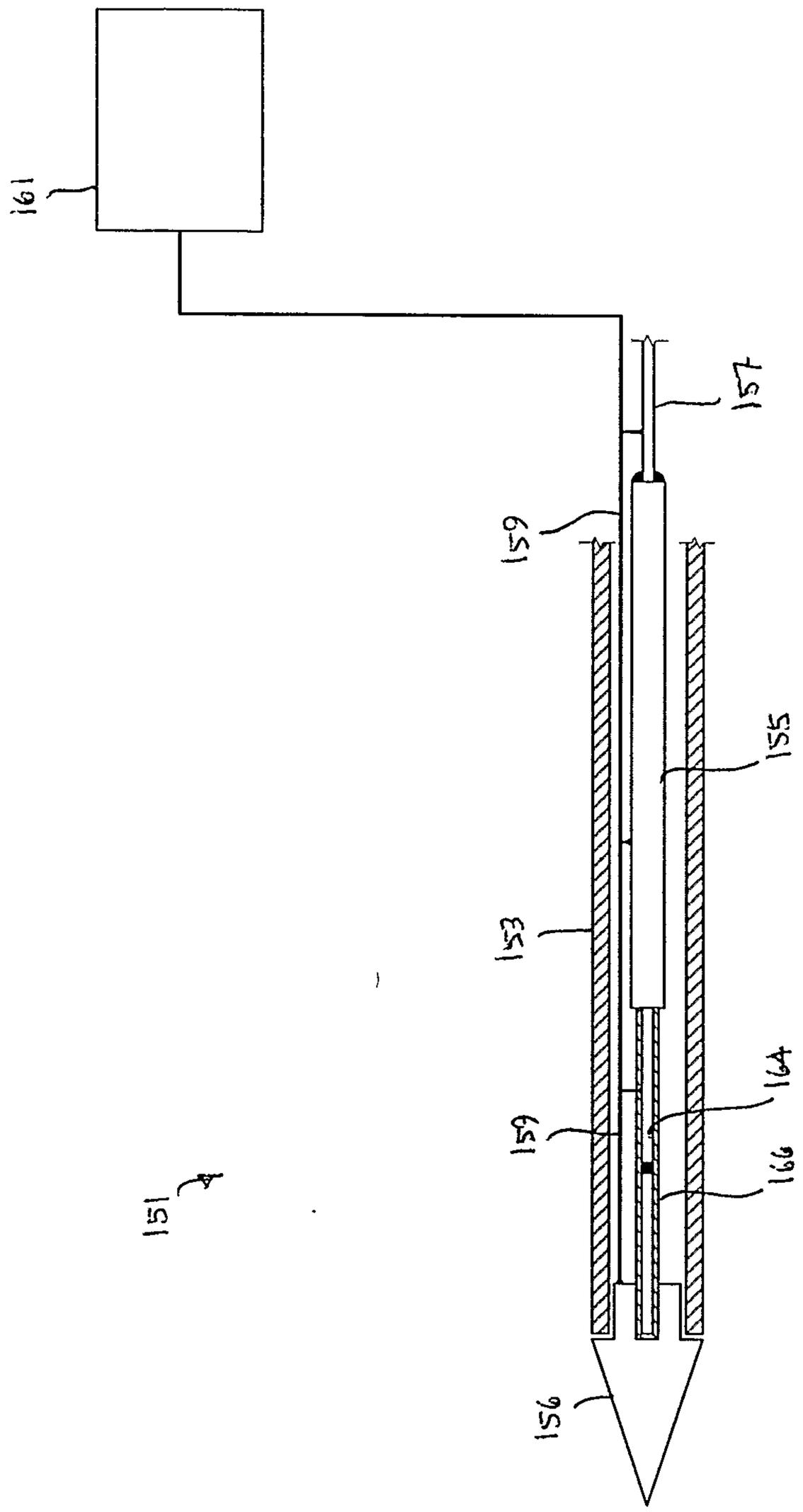


FIG. 5E

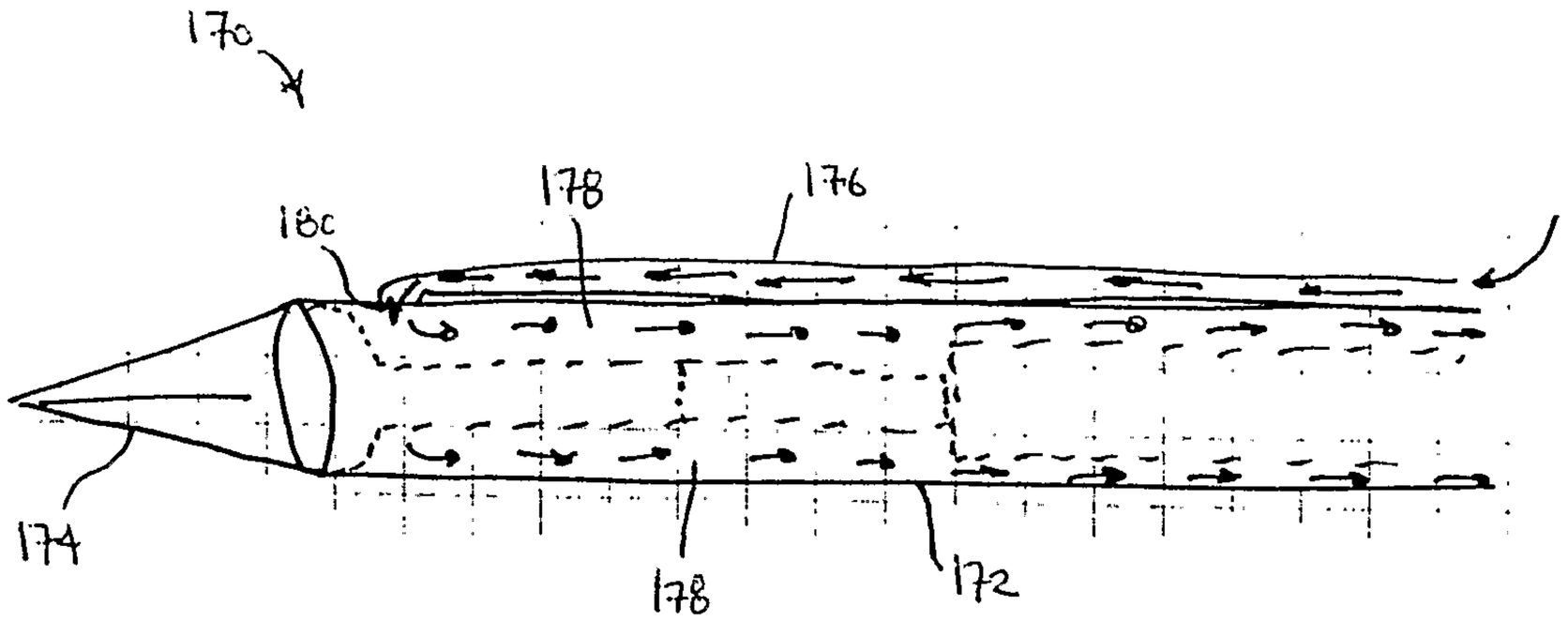


FIG. 6

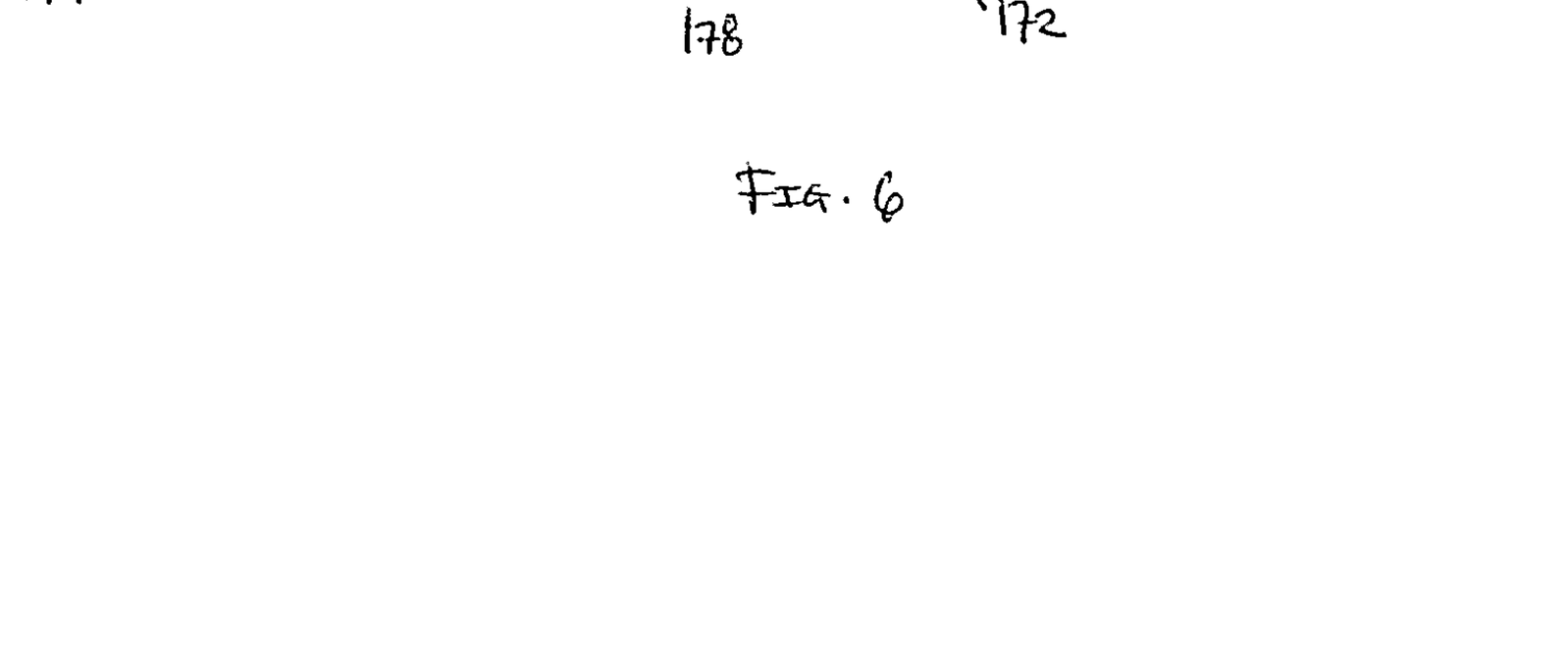


FIG. 7

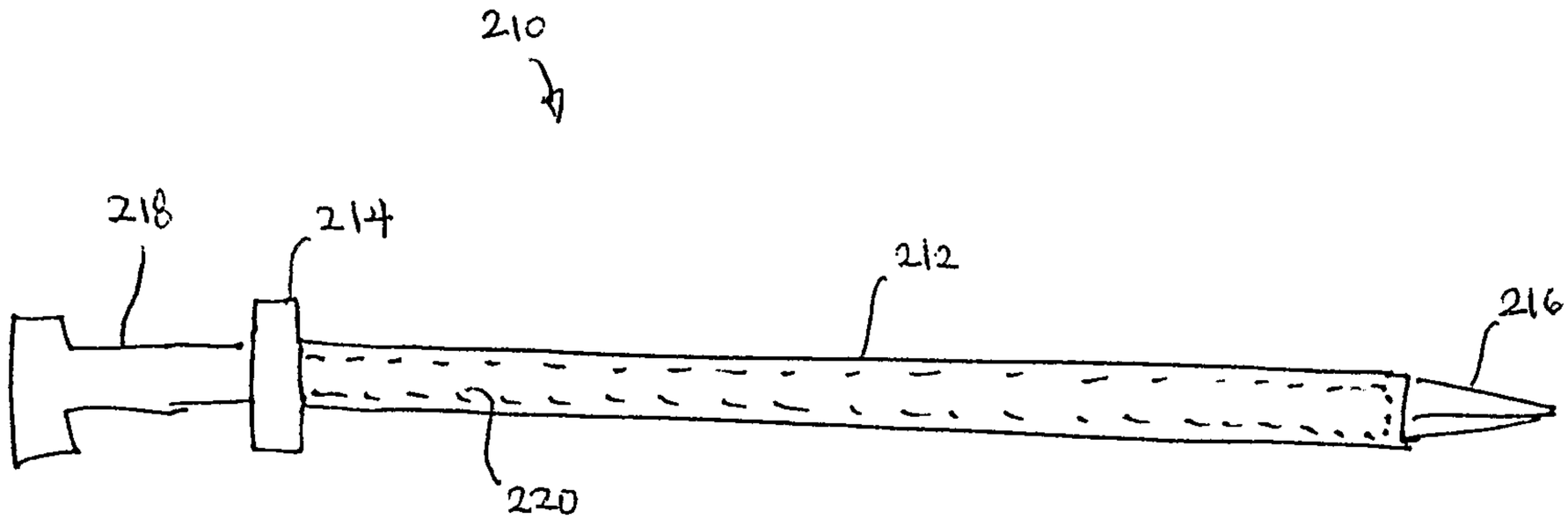


FIG. 8

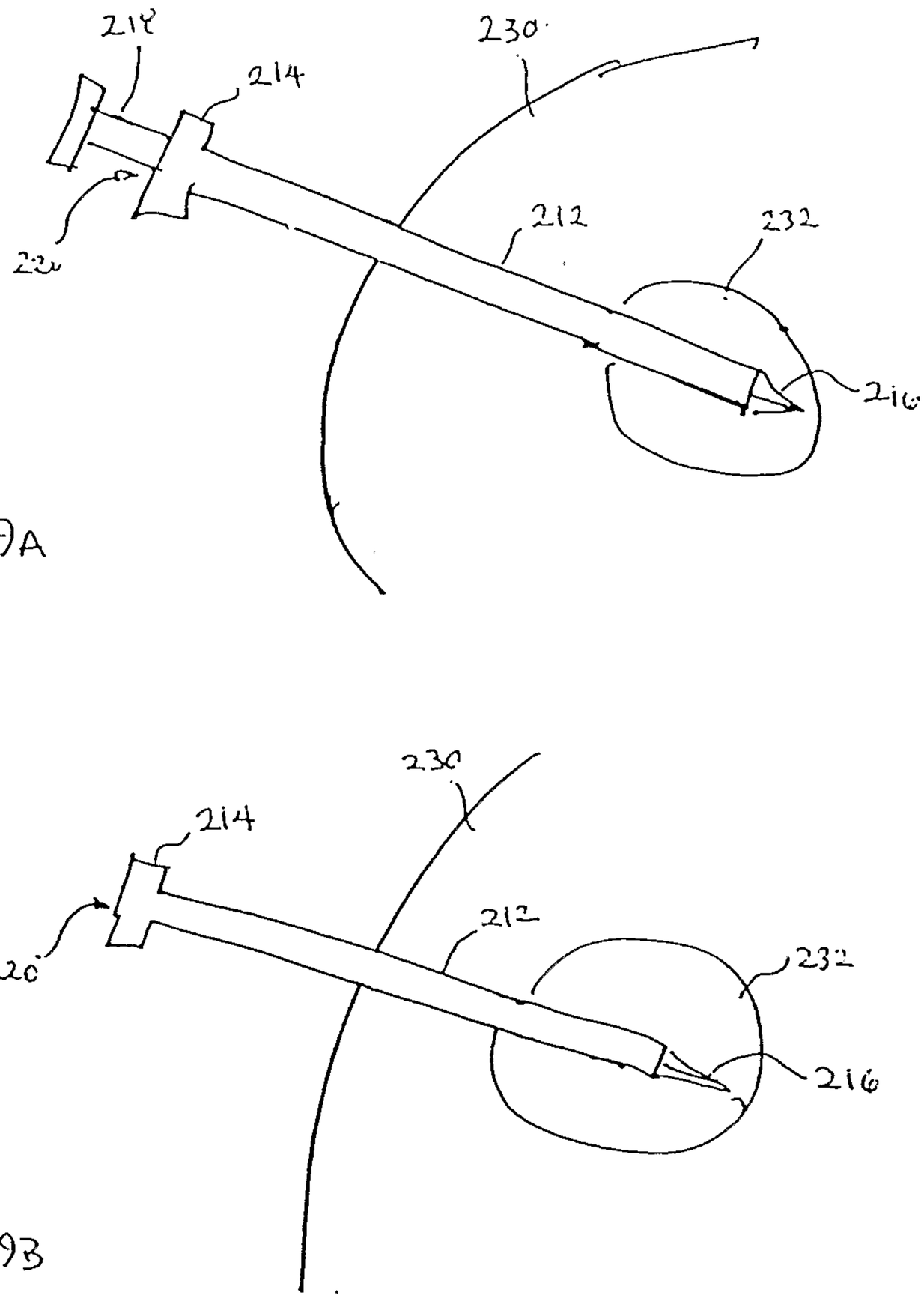


FIG. 9A

FIG. 9B

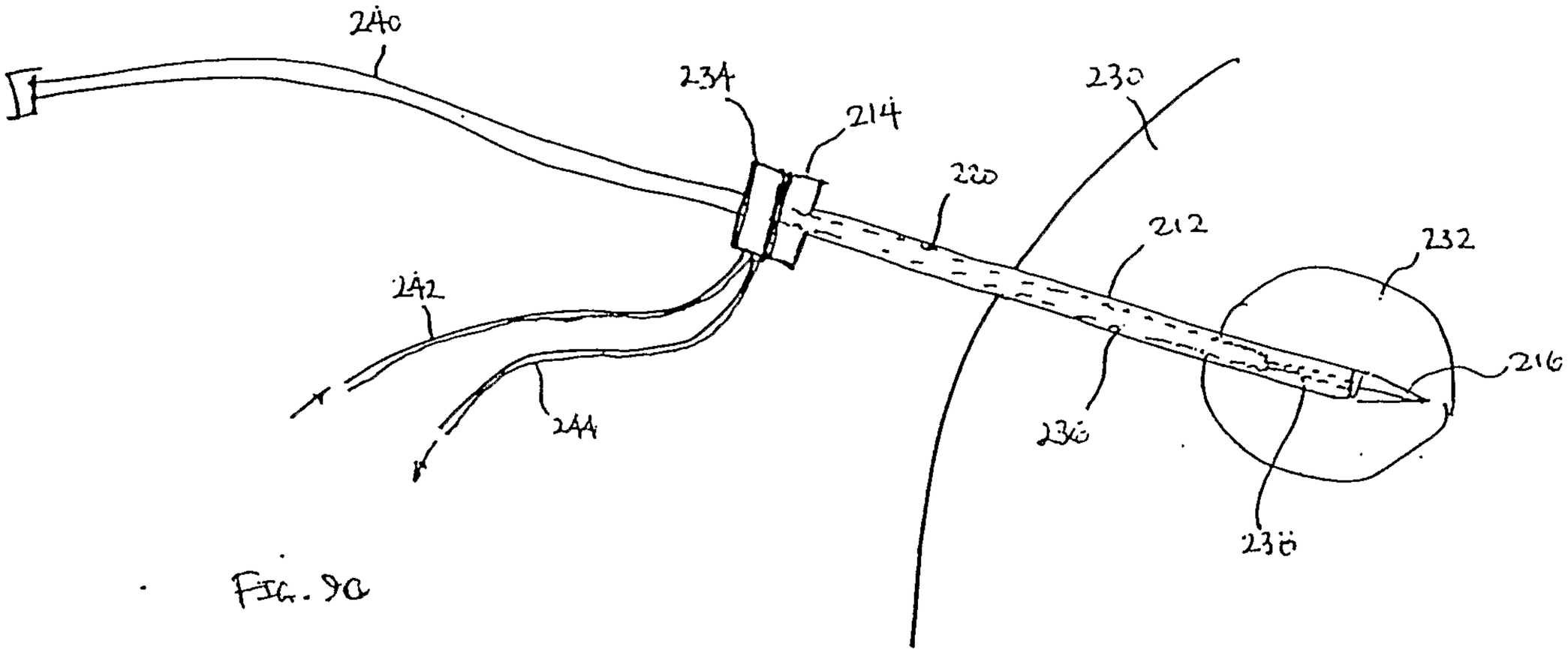


FIG. 9C

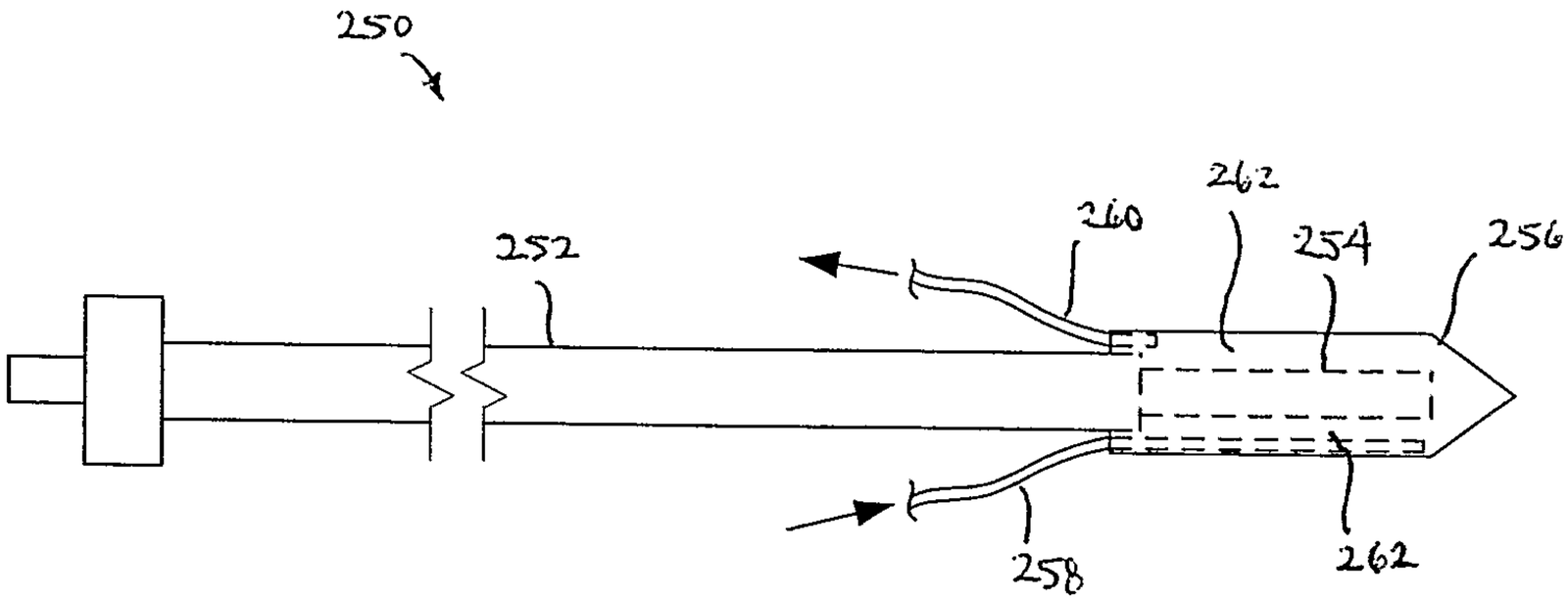


FIG. 10

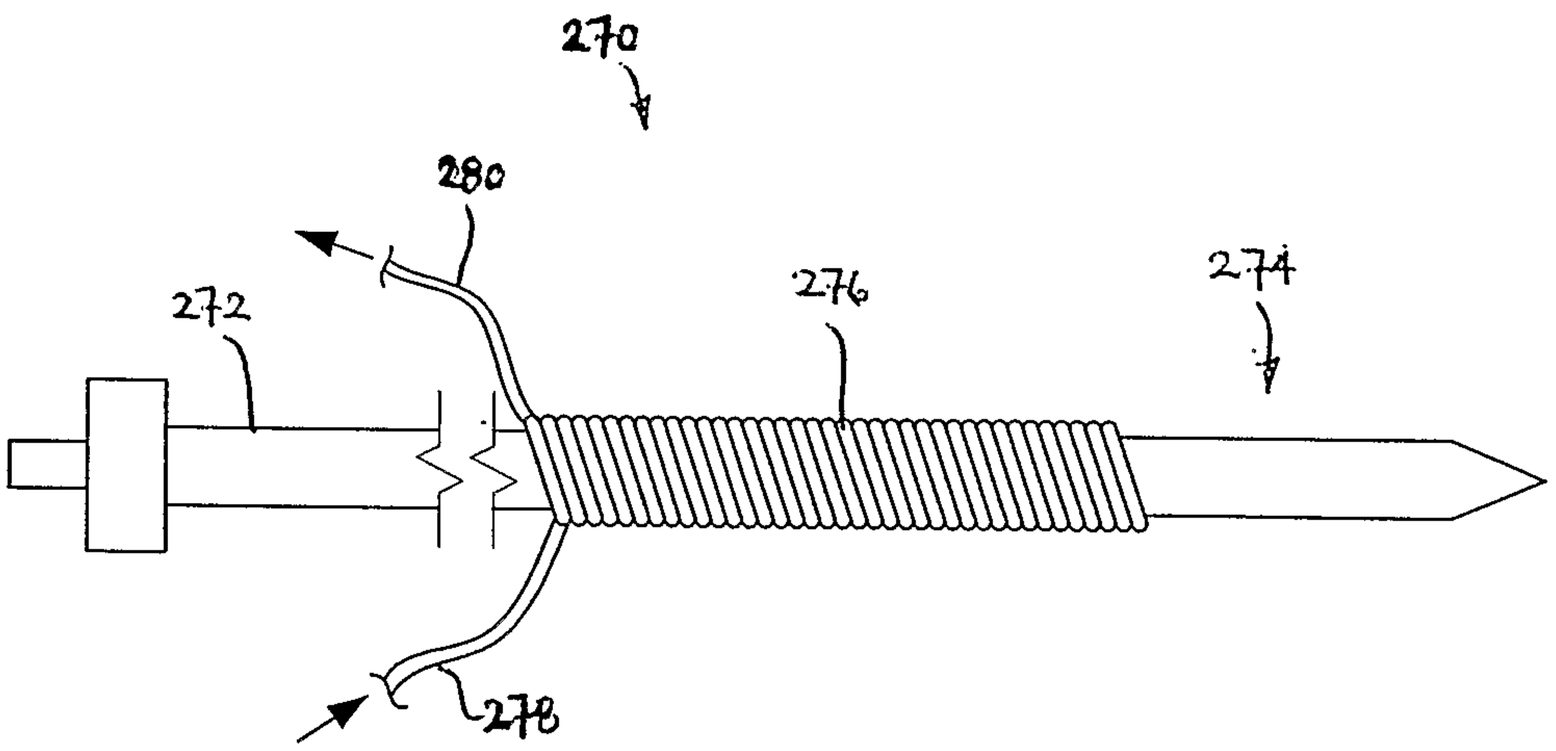


FIG. 11

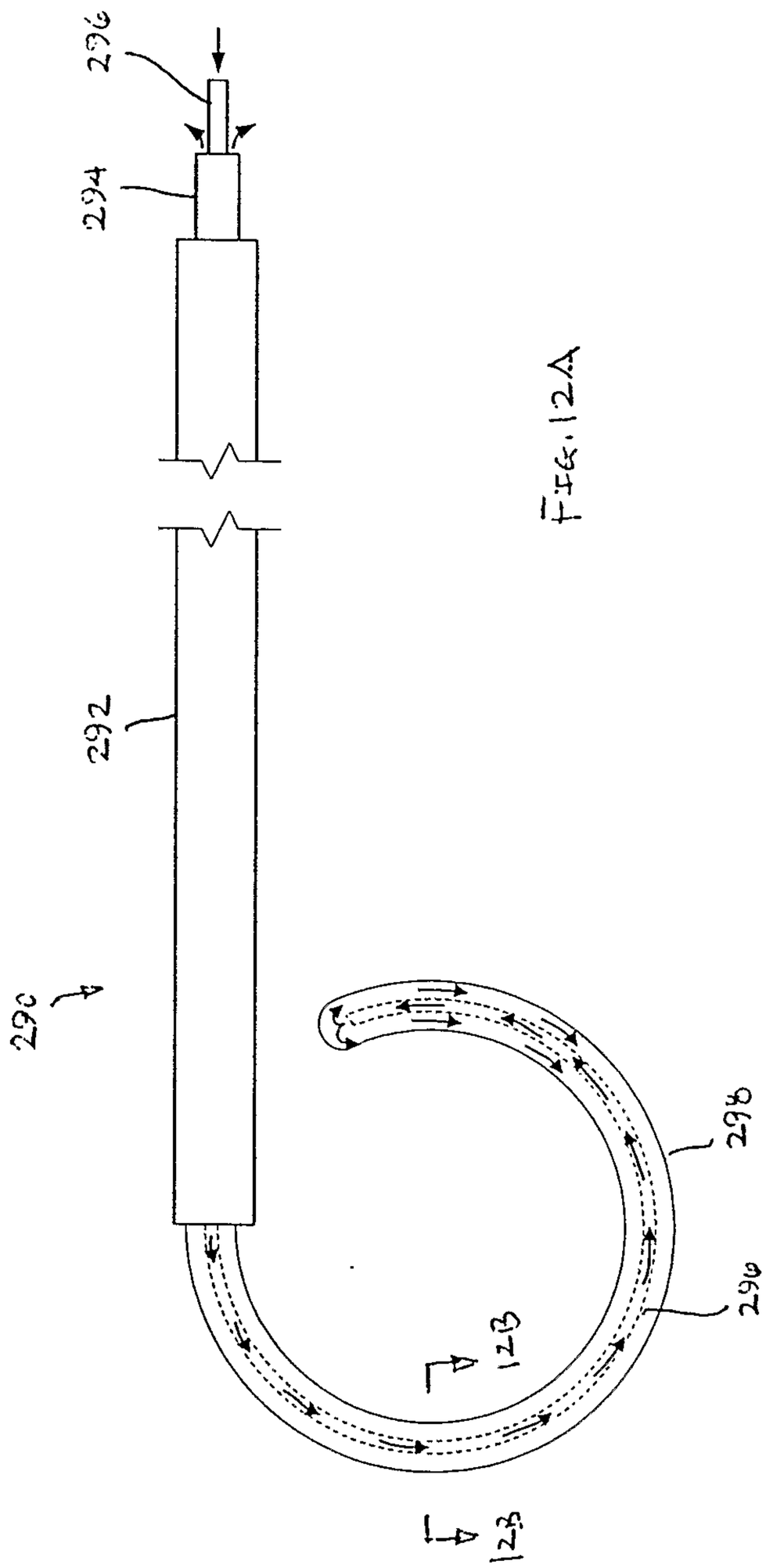


FIG. 12A

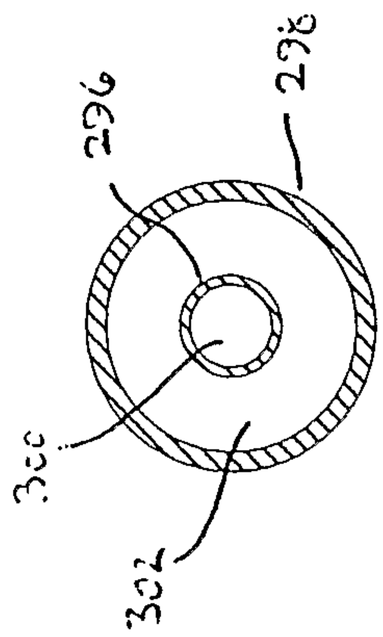


FIG. 12B

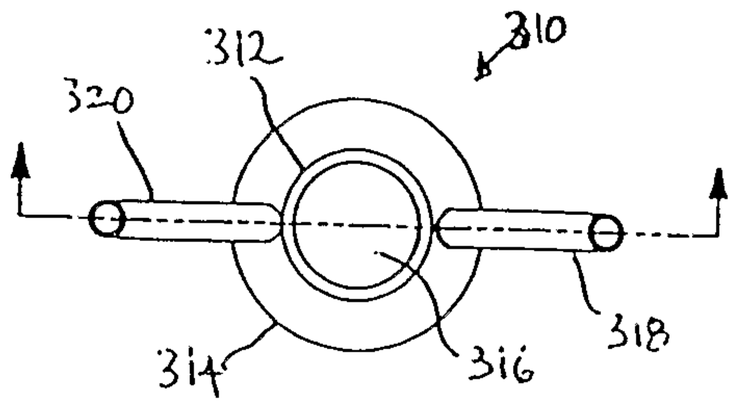
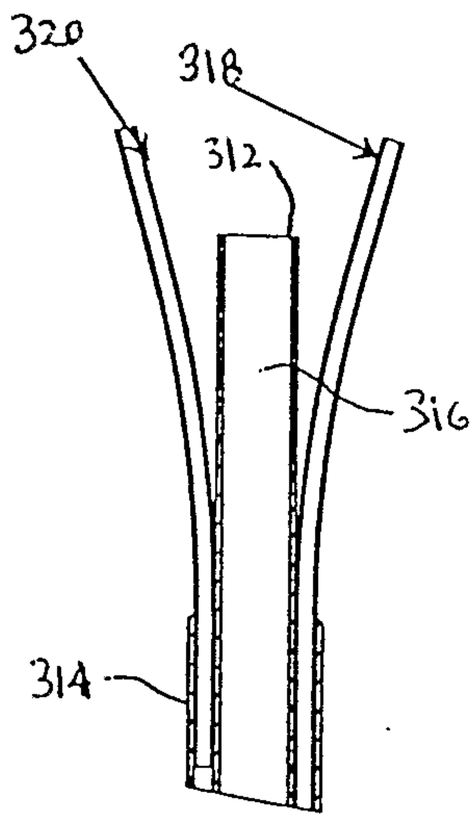


FIG. 13A



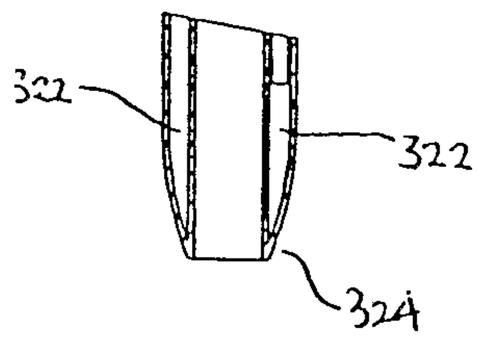


FIG. 13B

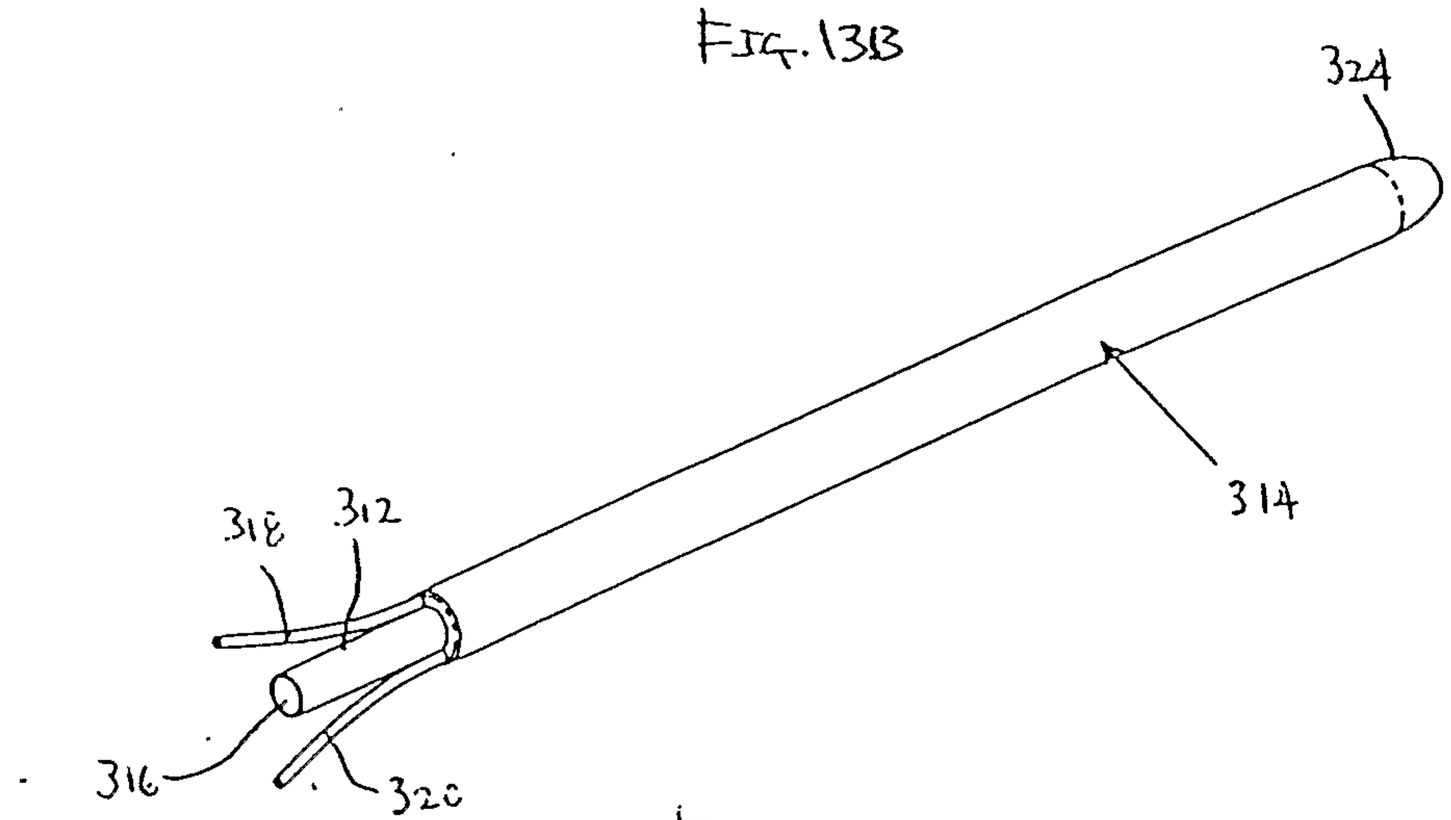


FIG. 13C

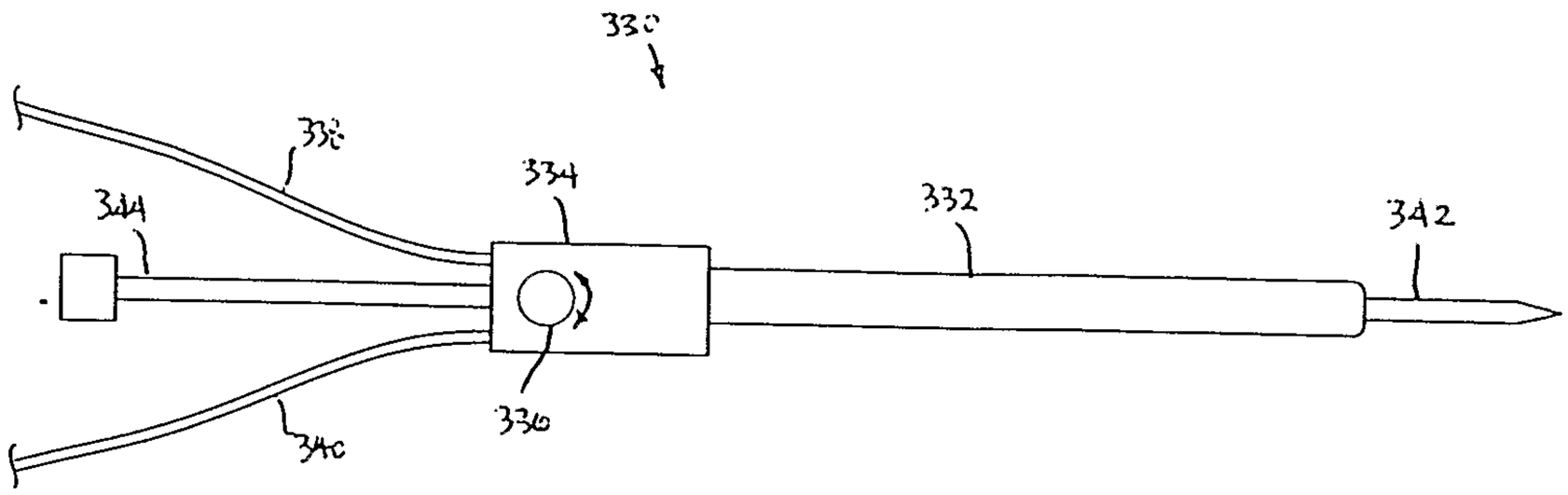


FIG. 14A

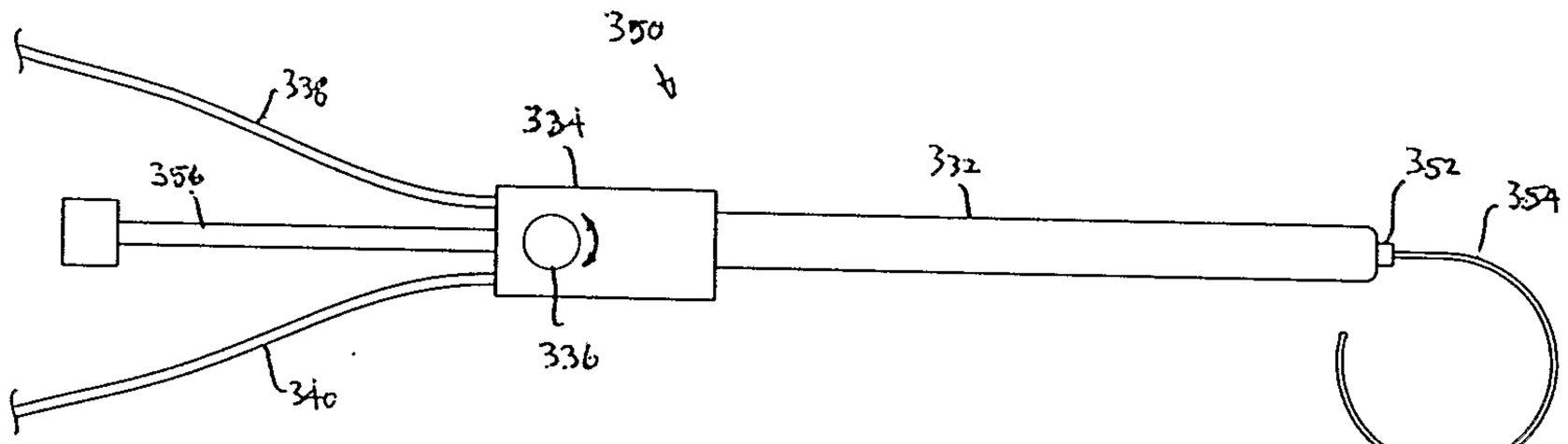


FIG. 14B

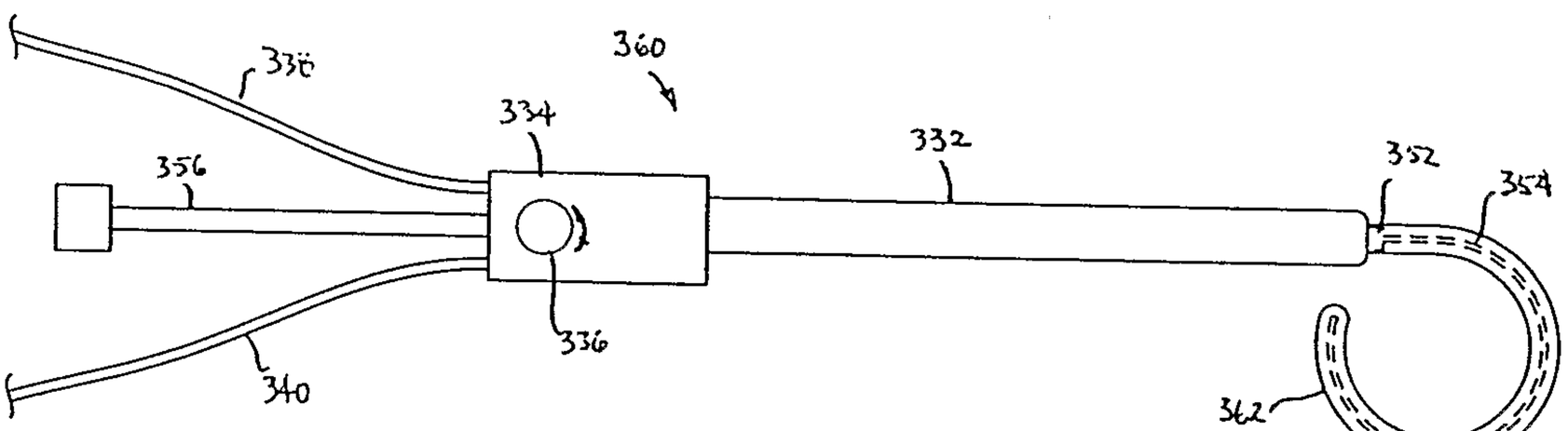


FIG. 14C

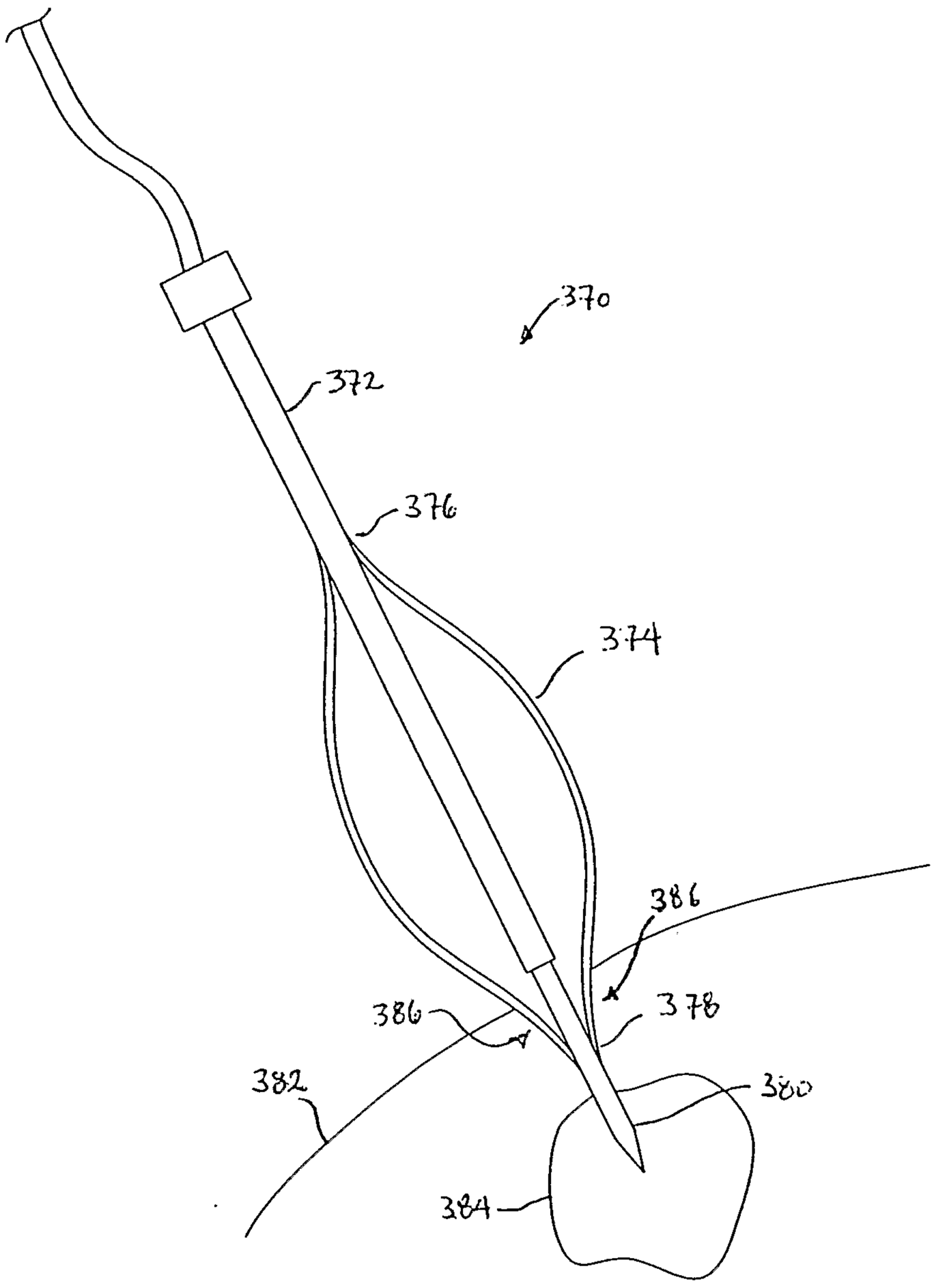


FIG. 15

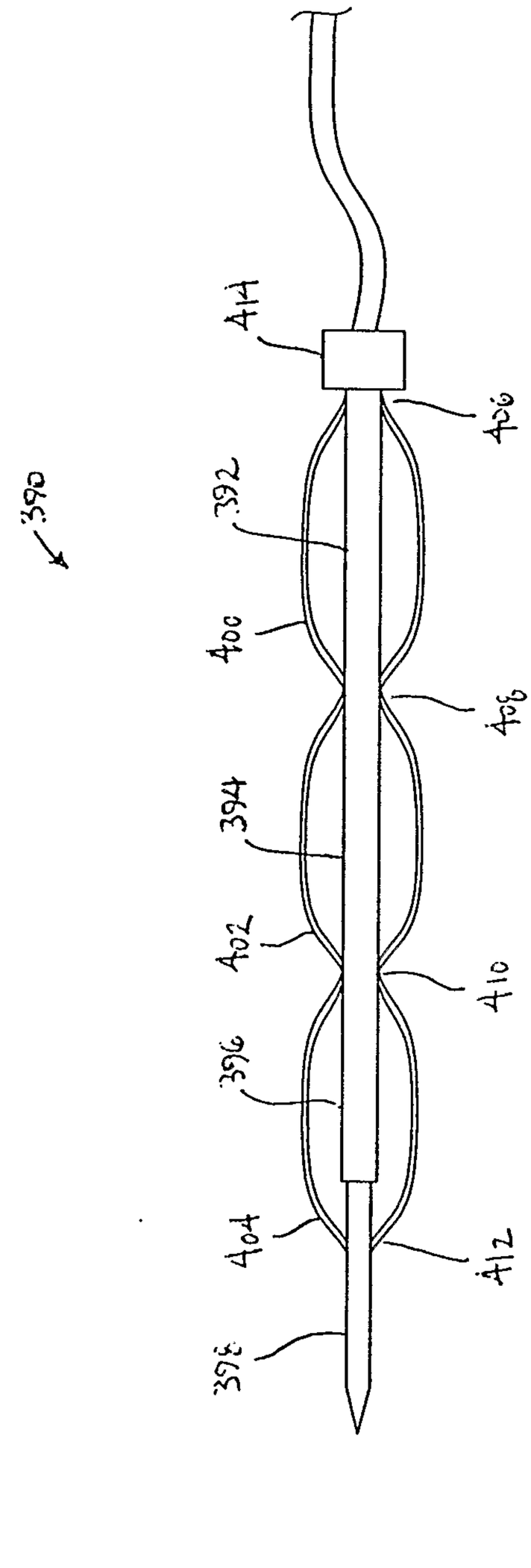


Fig. 16

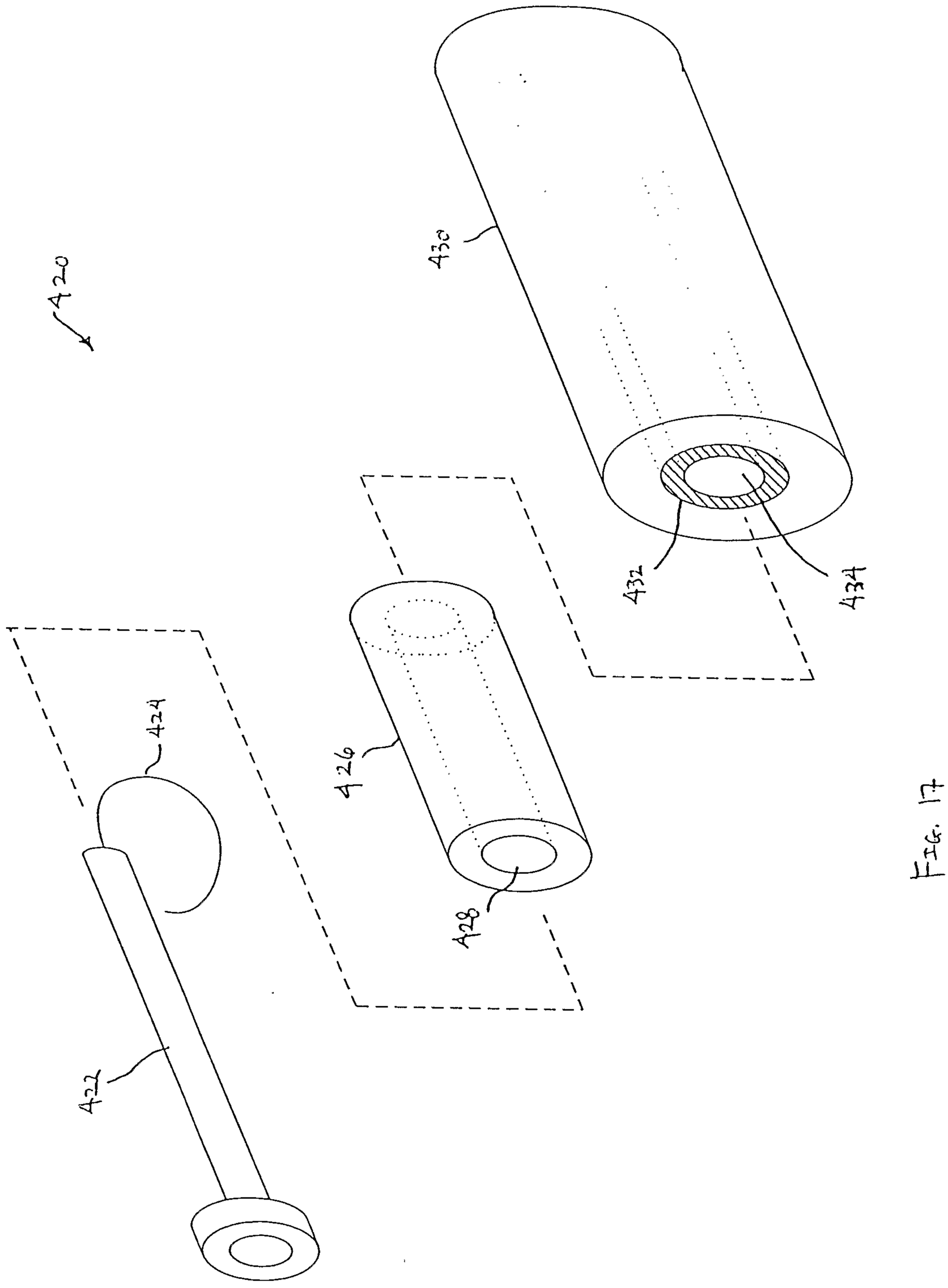


FIG. 17

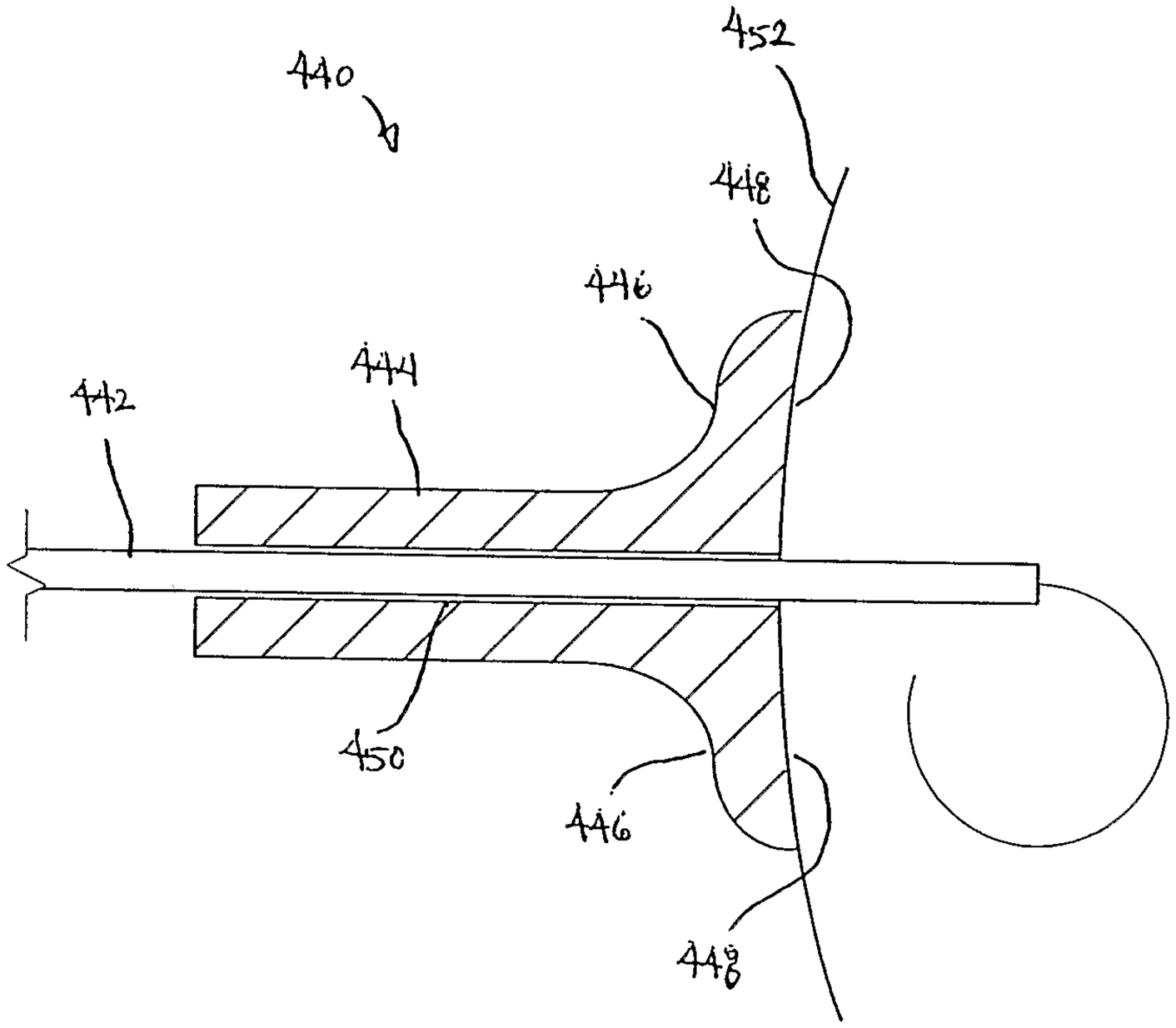


FIG. 16

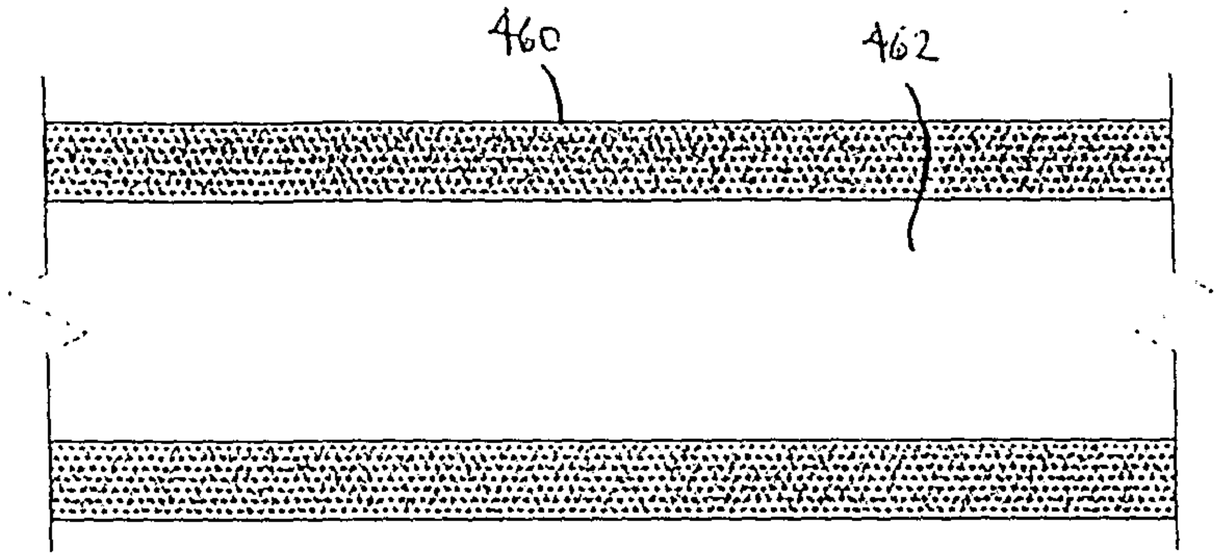


FIG. 19A

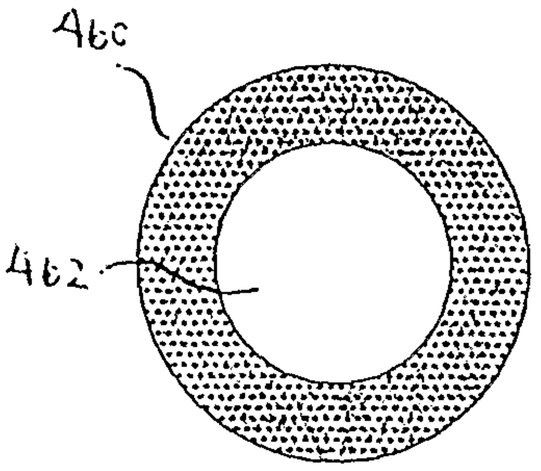


FIG. 19B

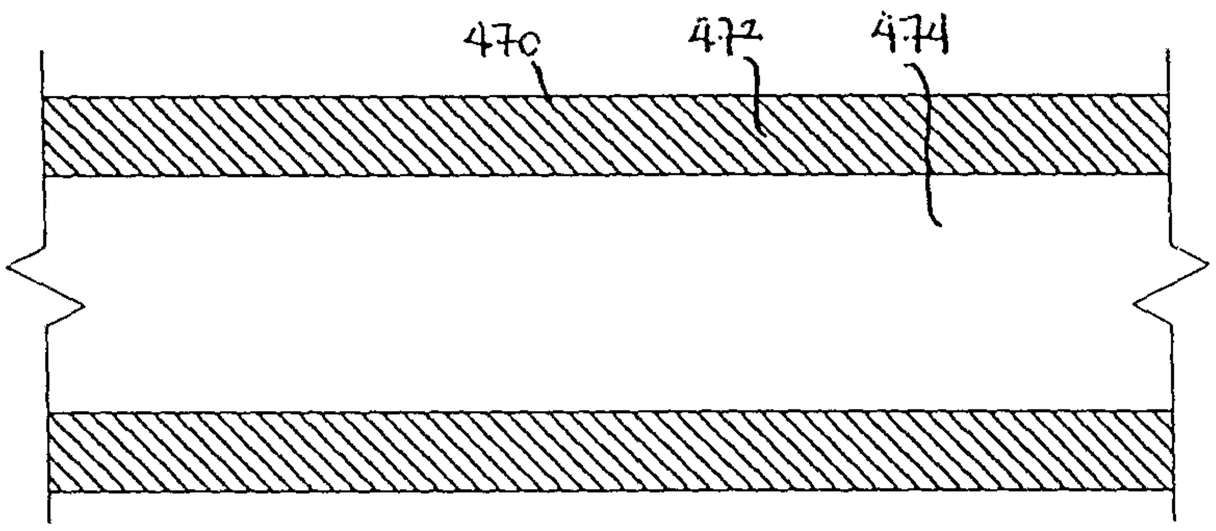


FIG. 20A

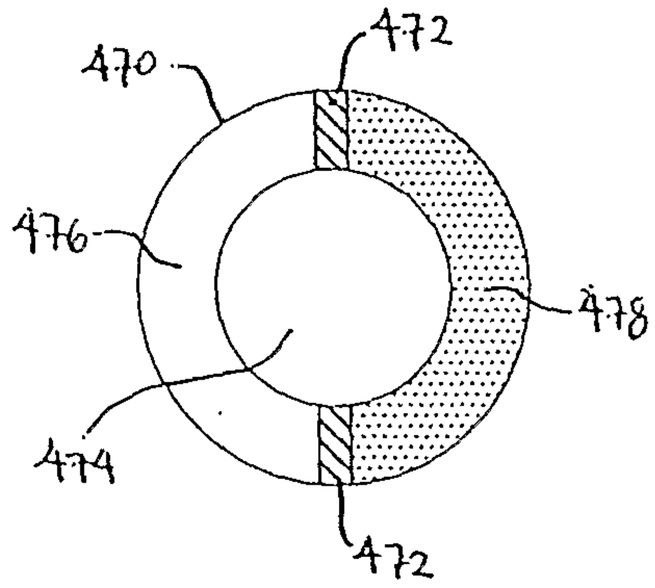


FIG. 20B

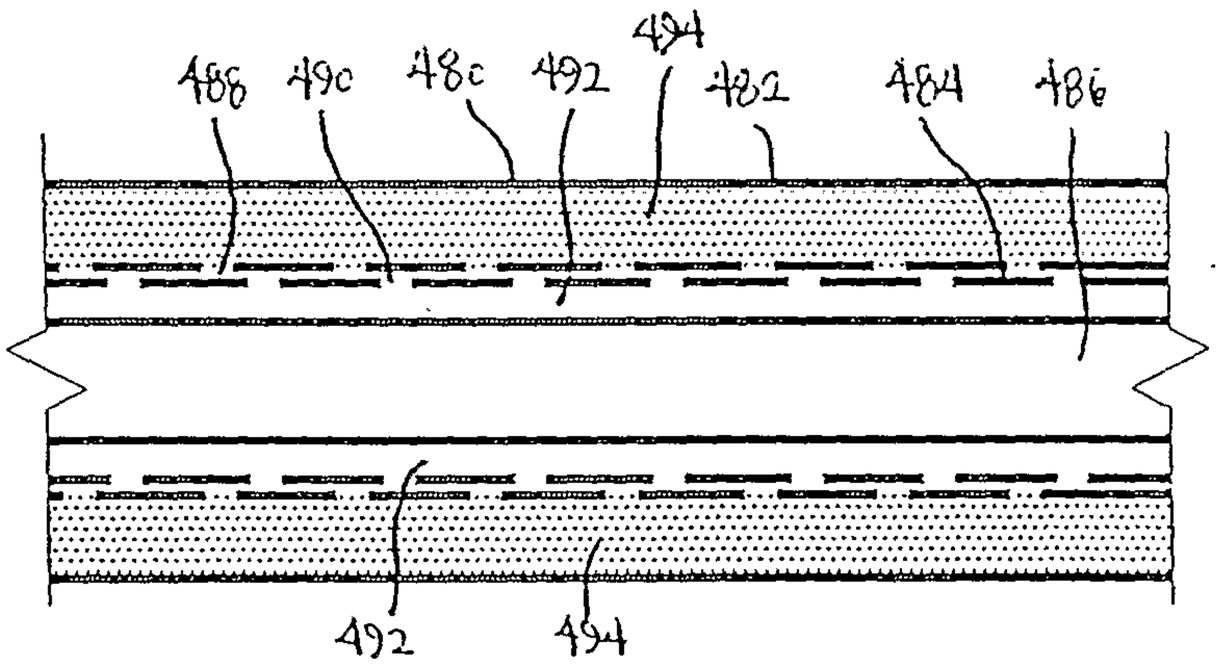


FIG. 21A

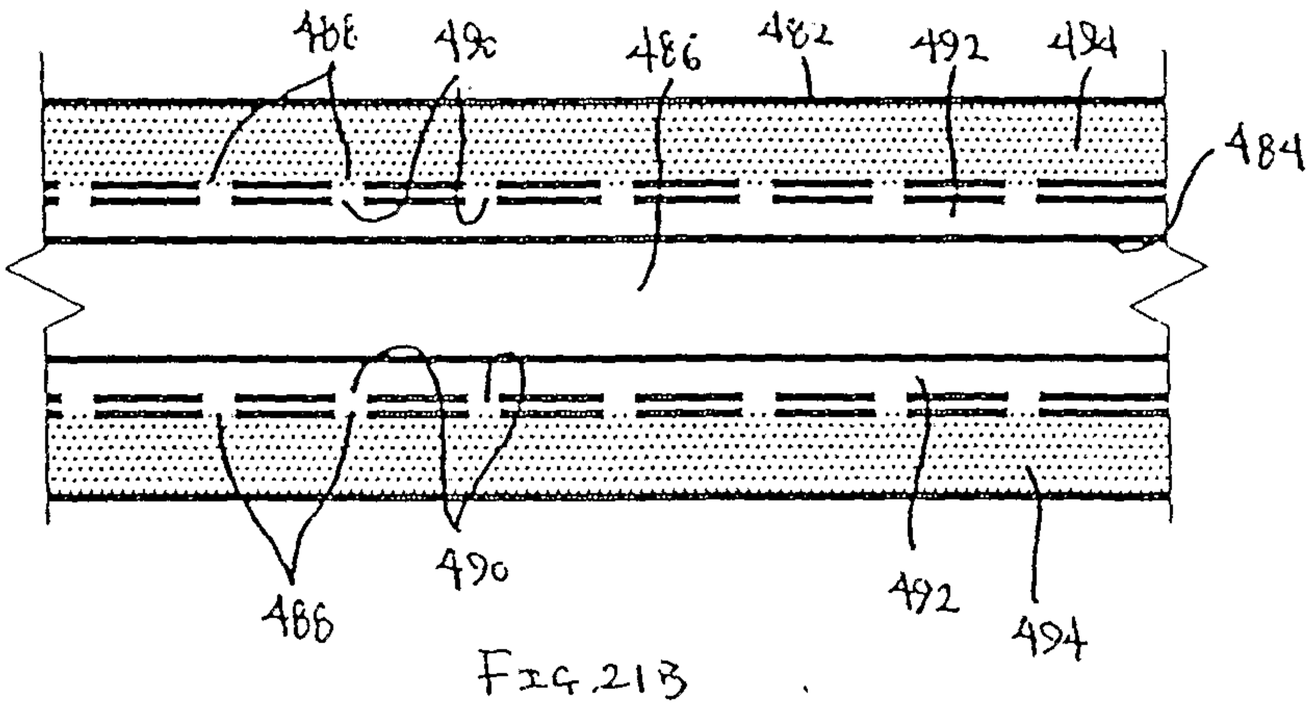


FIG. 21B

FIG. 21C

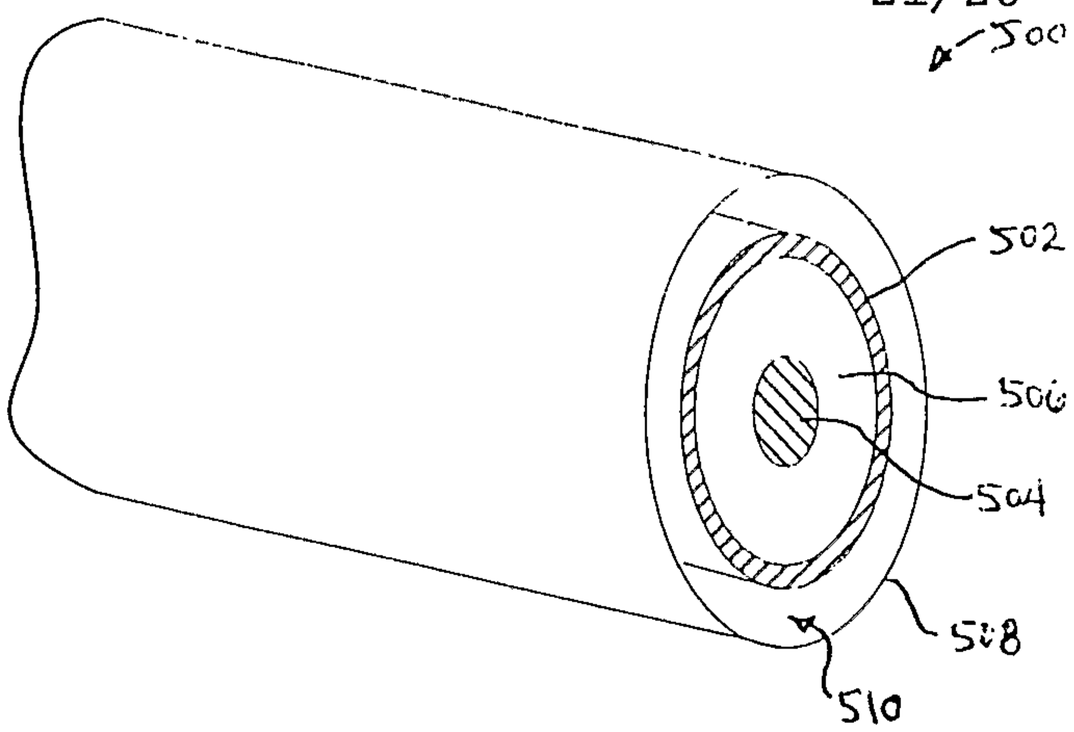


FIG. 22A

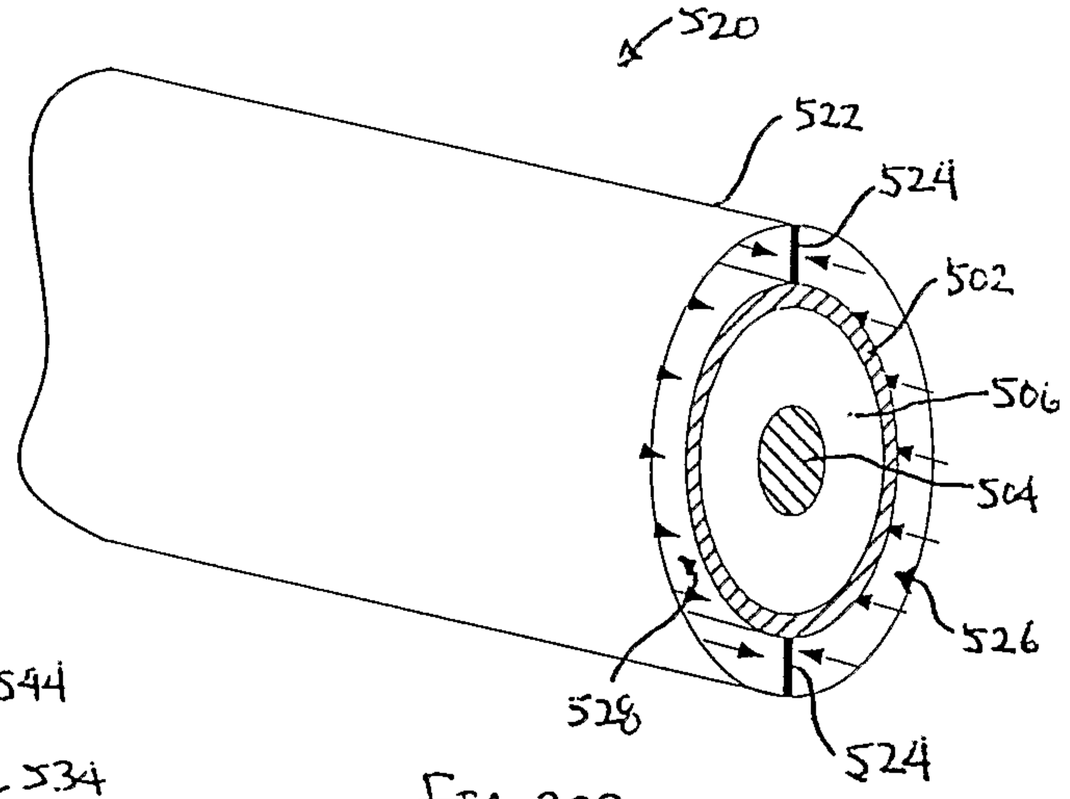


FIG. 22B

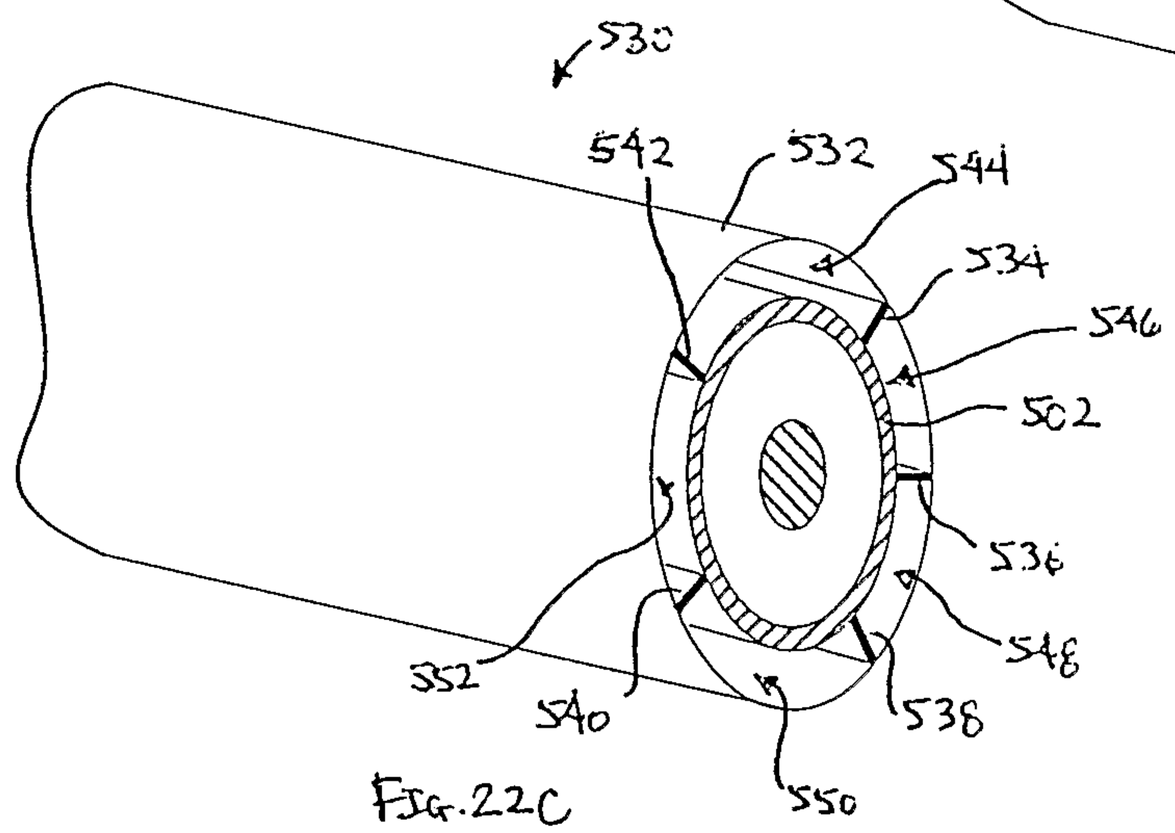


FIG. 22C

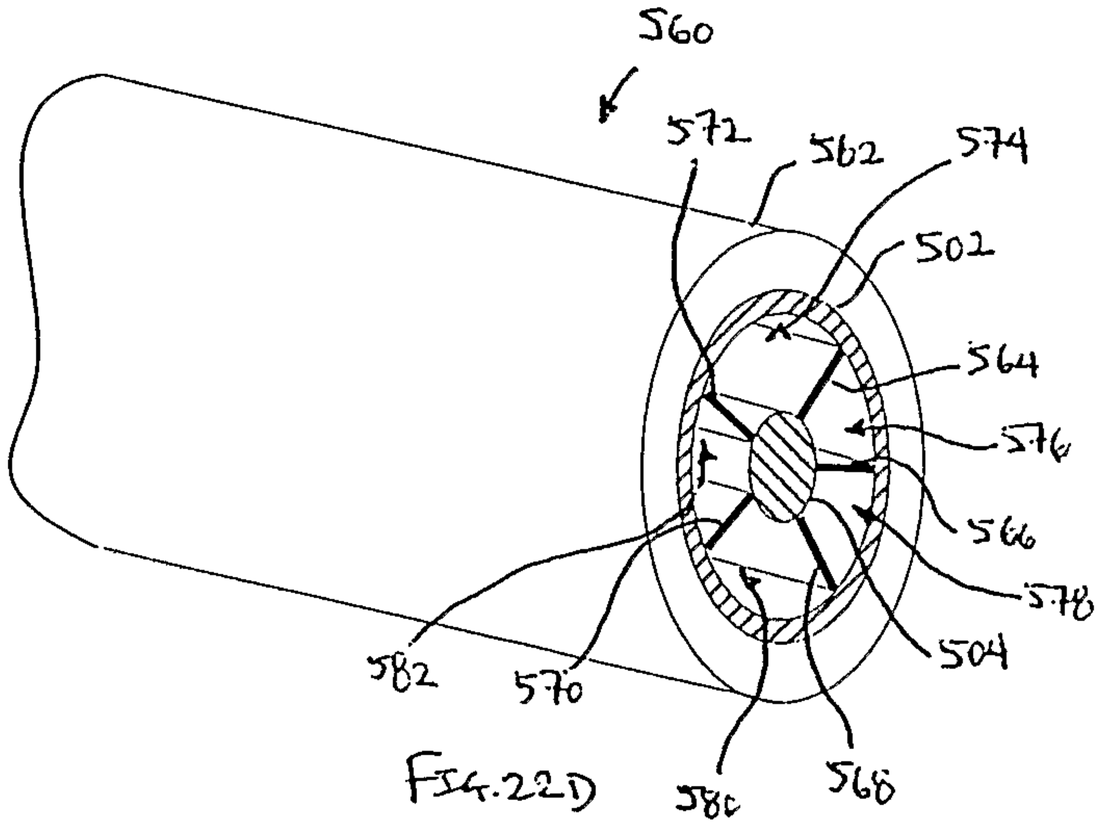


FIG. 22D

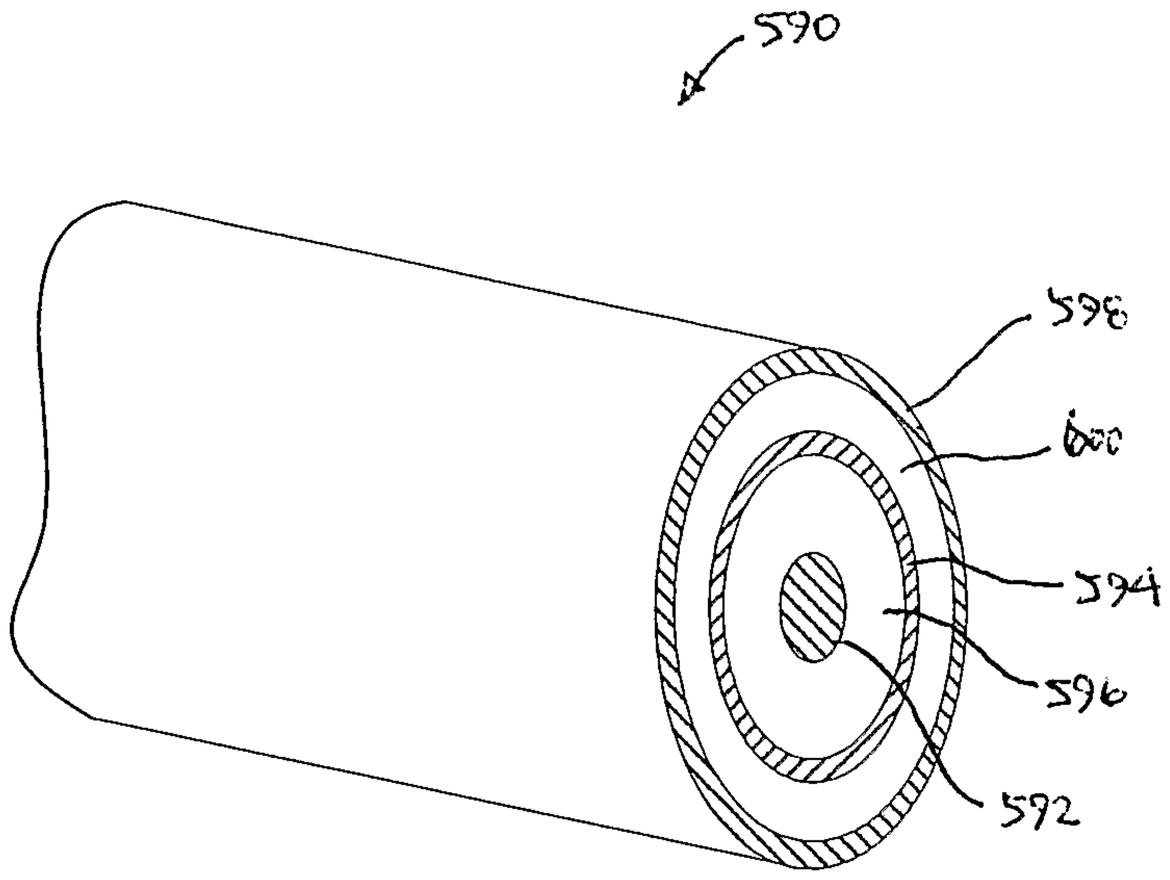


FIG. 23A

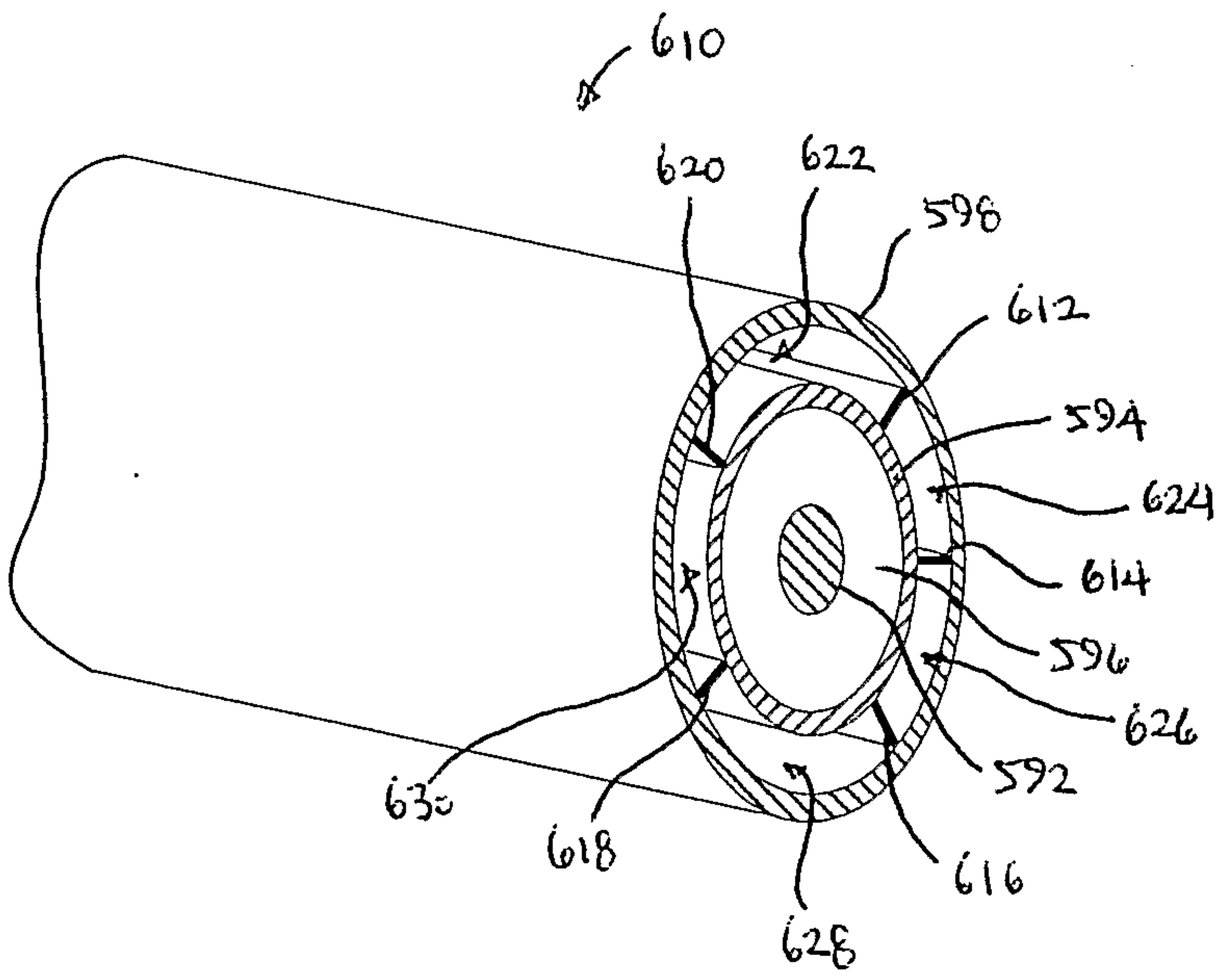


FIG. 23B

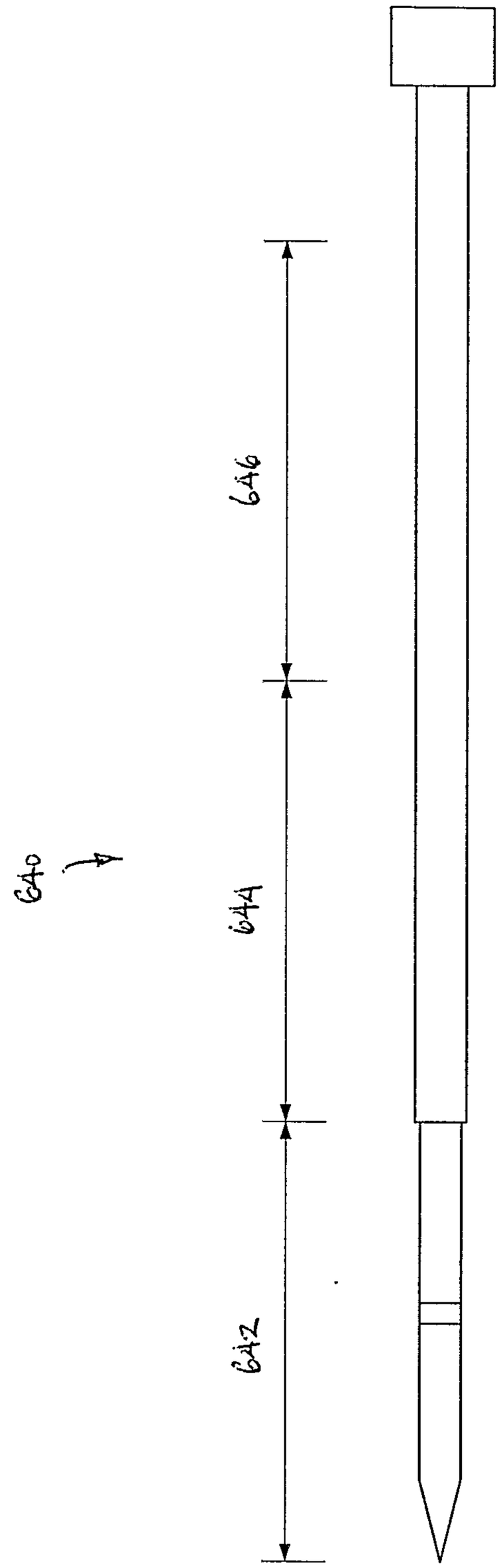


FIG. 24

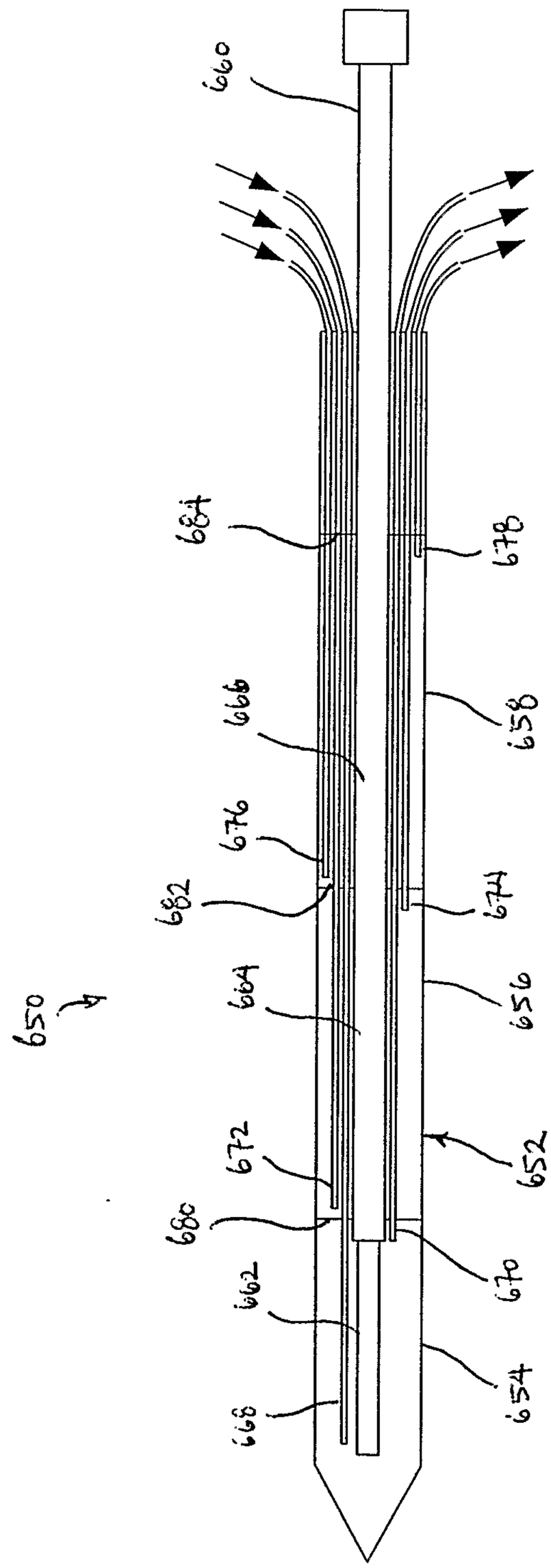

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FIG. 25

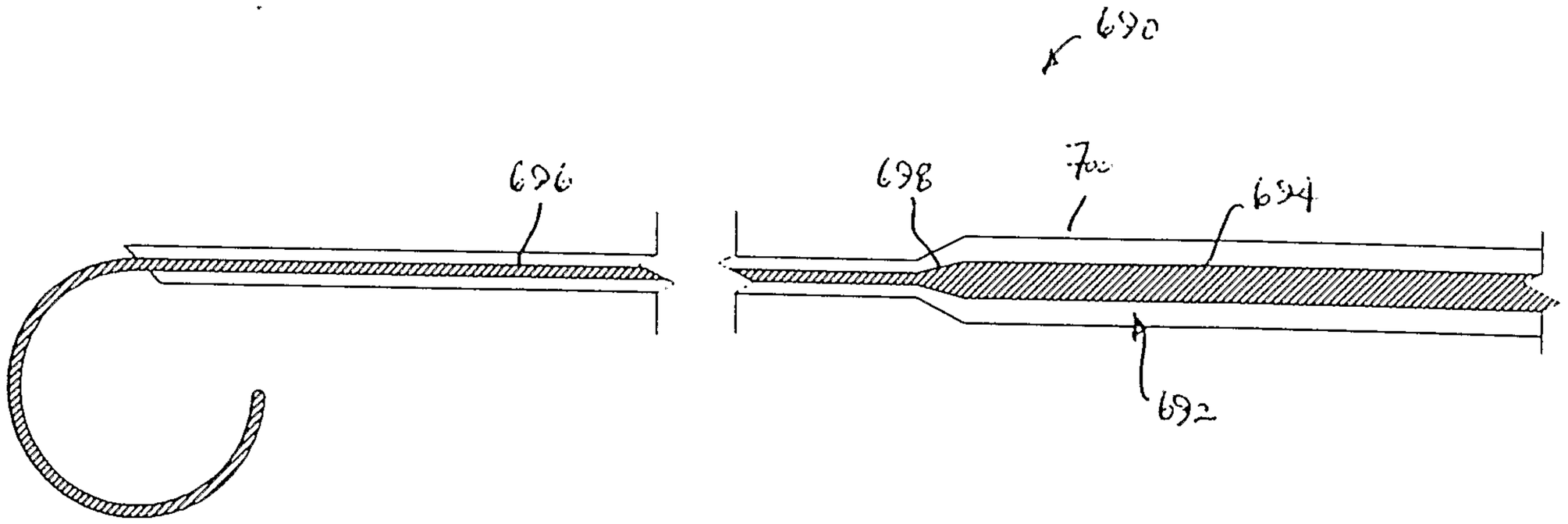


FIG. 26A

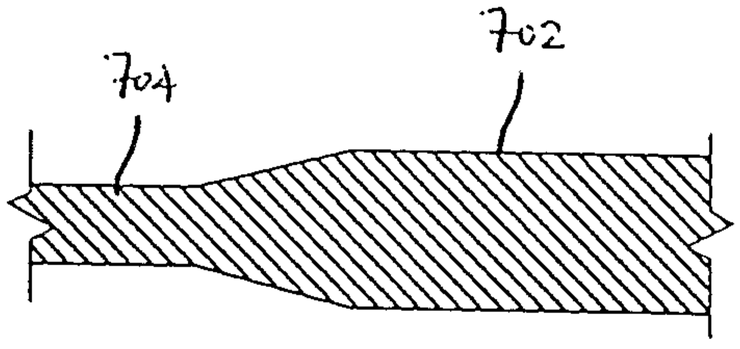


FIG. 26B

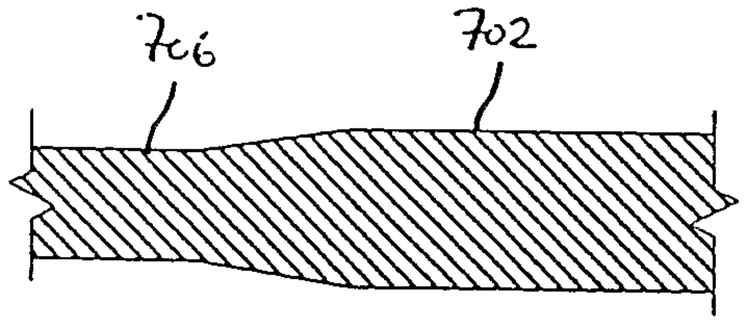
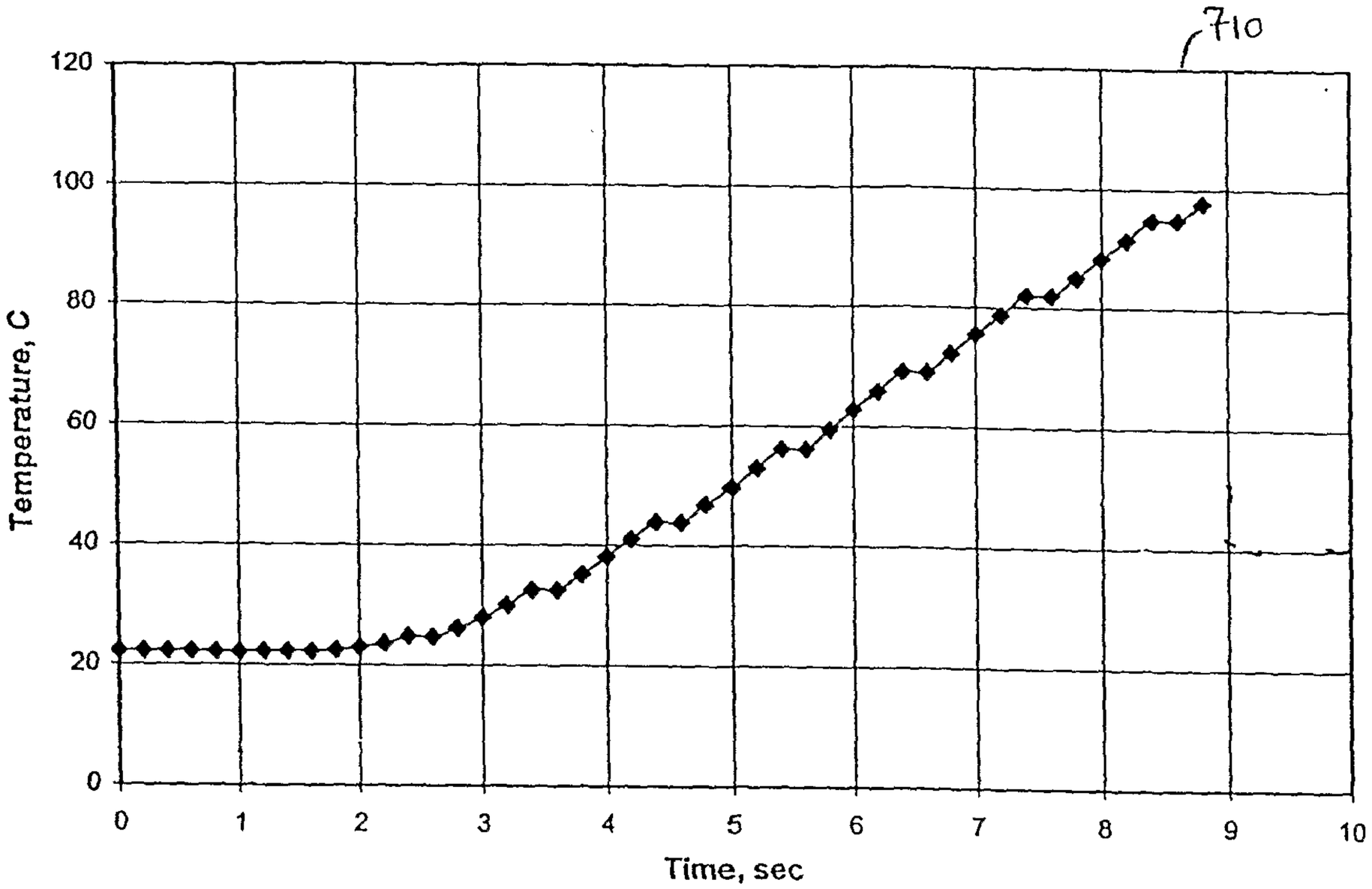


FIG. 26C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20
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Temperature, C
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2
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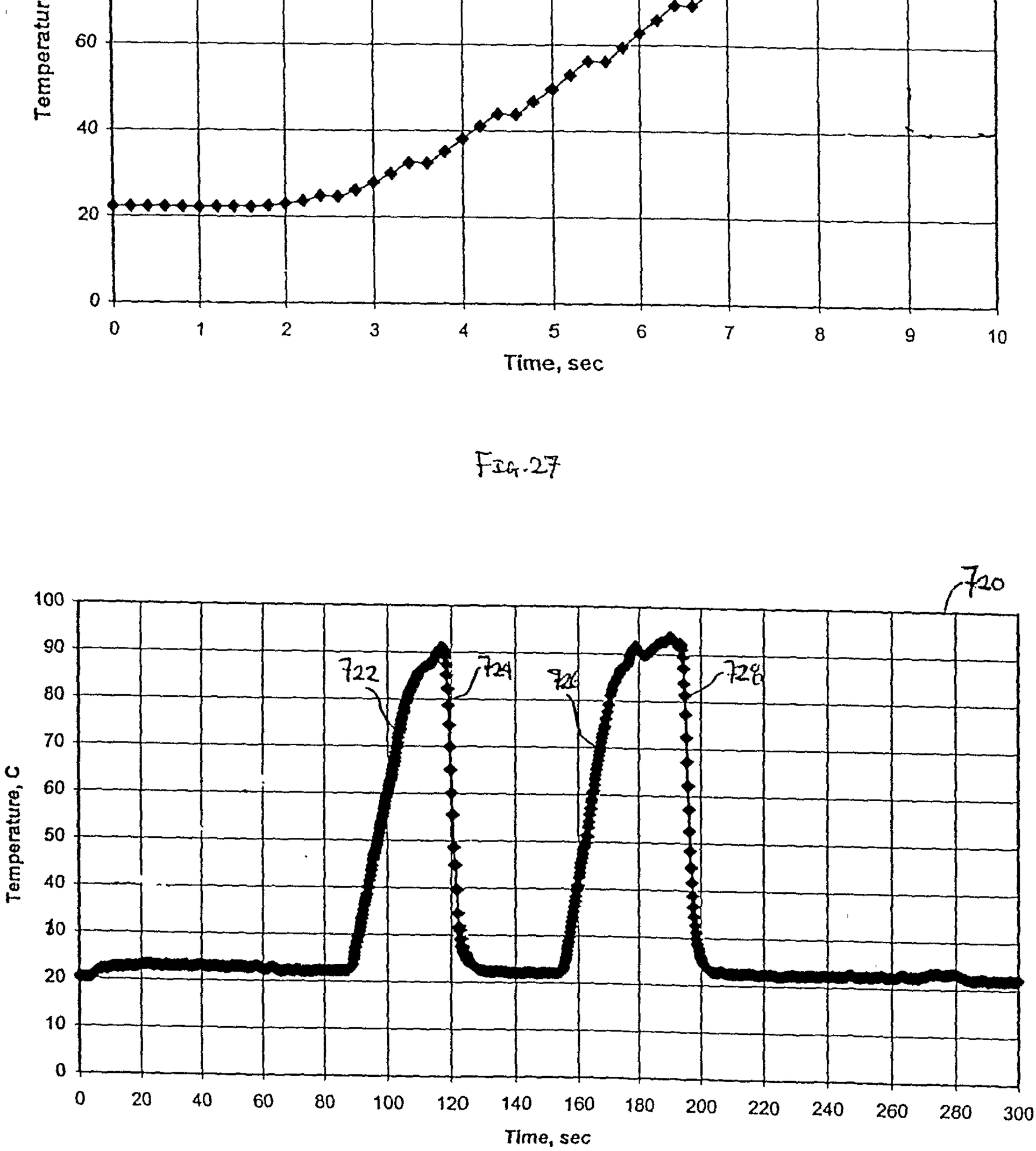
9
10
Time, sec

FIG. 27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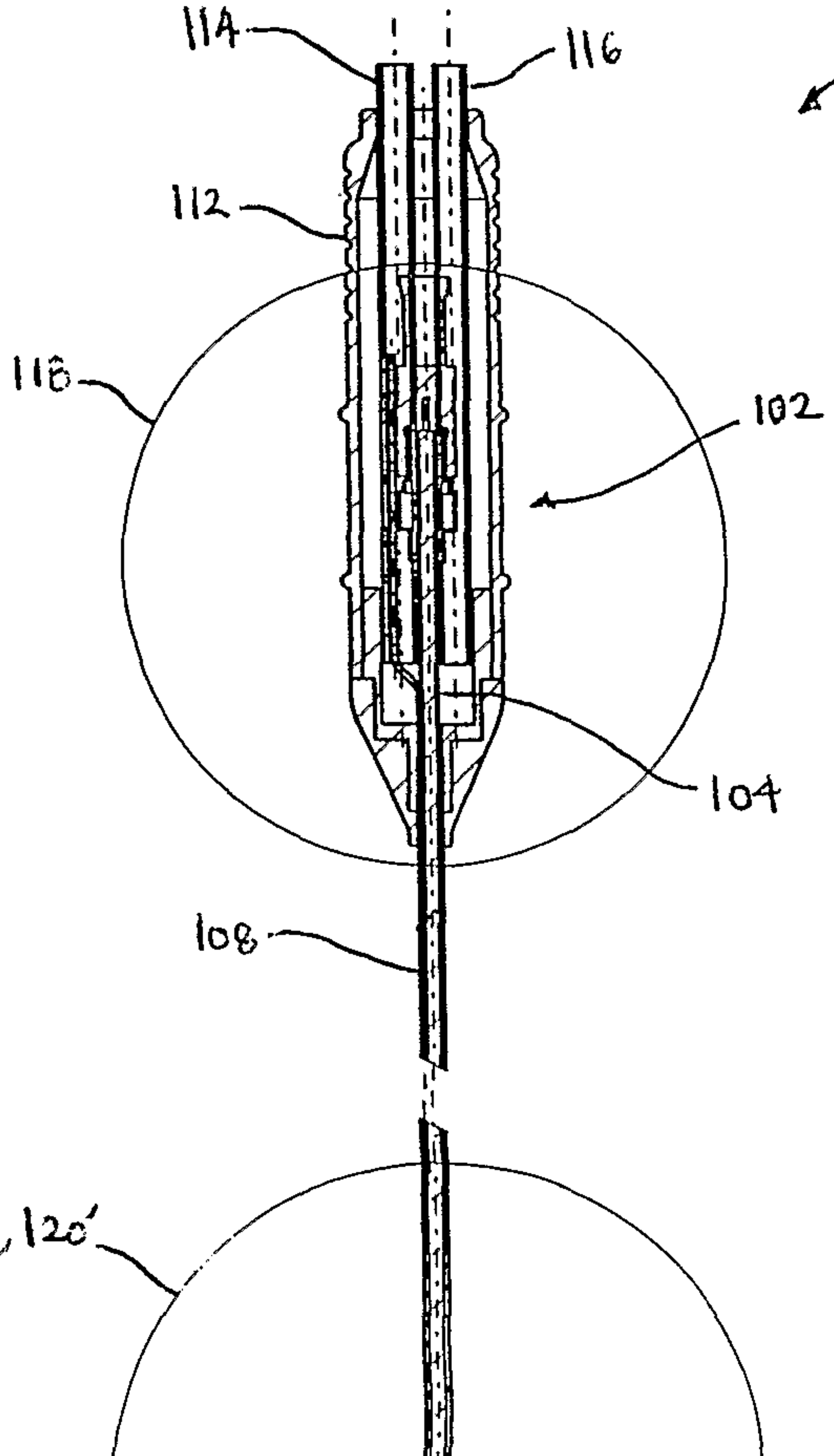
Time, sec

FIG. 28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