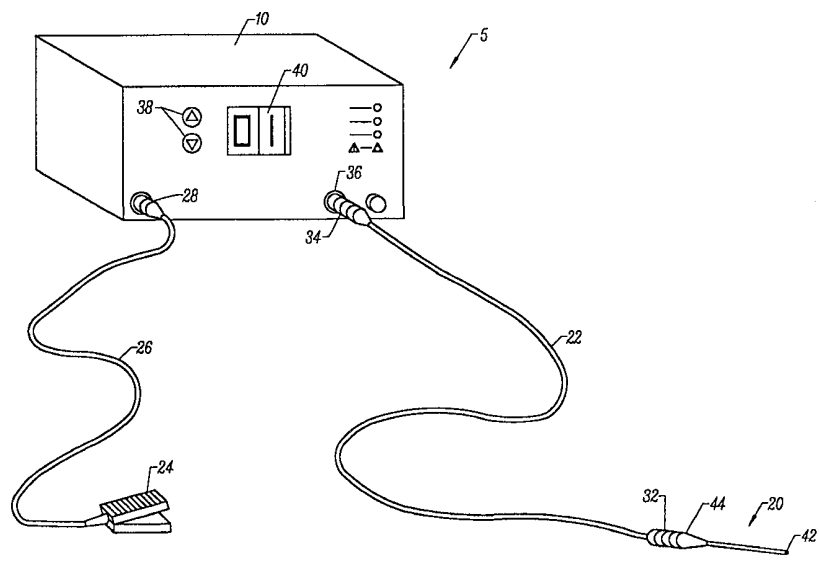




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(54) Title: SYSTEMS AND METHODS FOR ELECTROSURGICAL TISSUE CONTRACTION



(57) Abstract

Systems and methods are provided for performing electrosurgical interventions, such as selectively contracting soft collagen tissue and other body structures, while limiting thermal damage or molecular dissociation of such tissue and limiting the thermal damage to tissue adjacent to and underlying the treatment site. The systems and methods of the present invention are particularly useful for surgical procedures in electrically conducting environments, such as arthroscopic procedures in the joints, e.g., shoulder, knee, hip, hand, foot, elbow or the like. The present invention is also useful in relatively dry environments, such as treating and shaping the cornea, and dermatological procedures involving surface tissue contraction of tissue underlying the surface of the skin for tissue rejuvenation, wrinkle removal and the like.

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BACKGROUND OF THE INVENTION

The present invention relates generally to the field of electrosurgery and, more particularly, to surgical devices and methods which employ high frequency voltage to contract soft tissue structures, such as collagen connective tissue.

Collagen connective tissue can be found in many places in the human body, such as the soft tissue surrounding joints, the tissue of the cornea, the epidermal and dermal layers of the skin and the like. Collagen fibers shrink or contract when subjected to elevated temperatures, causing the caliber of the collagen fibers to increase without substantially changing the structural integrity of the connective tissue. This molecular response to temperature elevation has made contraction of collagen tissue important in many applications, such as the shrinkage of collagen tissue in the shoulder capsule or knee joint, or the collagen soft tissue in the skin in wrinkle removal procedures.

Collagen tissue is particularly important in the stability of peripheral joints, such as the shoulder, knee, hip, or the like. Peripheral joints generally comprise a covering of hyaline cartilage surrounded by a soft tissue joint capsule that maintains the constant contact of the cartilage surfaces on the ends of bones. This joint capsule also maintains the synovial fluid that provides nutrition and lubrication of the joint surfaces. Instability of peripheral joints is a significant cause of disability and functional limitation in active patients. When a joint becomes unstable, for example, its soft tissue allows for excessive motion of the joint surfaces relative to each other, and in directions not normally permitted by the ligaments or capsule. Typically, the more motion a joint demonstrates, the more inherently loose the soft tissue is surrounding the joint. If the instability is severe and recurrent, functional incapacity and arthritis may result.

Recent surgical attempts to treat joint instability have focused on tightening the soft tissue restraints that have become loose in the joints. These procedures are typically performed through open surgical approaches that often require hospitalization and prolonged rehabilitation programs. Endoscopic techniques generally cause less blood loss, have a lower risk of infection, and faster postoperative recovery times. However, arthroscopic procedures are more technically demanding than open surgical procedures because it is often difficult to access the loose tissue within the joints with endoscopic instruments.

Laser energy has been employed to effect tissue heating for contracting

collagen fibers in soft tissue. For example, infrared laser energy has been used on the cornea to induce collagen shrinkage for shape modification of the cornea (laser thermokeratoplasty). In these techniques, the collagen is typically irradiated with laser coherent energy in a wavelength range of about 1.8 to about 2.55 microns to elevate the collagen temperature to about 23°C above normal body temperature to achieve collagen shrinkage.

Electrosurgery techniques have also been used to contract the collagen fibers in soft tissue. These techniques typically involve the application of radiofrequency (RF) energy to soft collagen tissue to contract and restrict the tissue elasticity. U.S. Patent No. 5,458,596 to Lax, for example, describes a monopolar electrosurgical device for contracting soft tissue in which RF voltage is applied to an electrode terminal positioned near the target tissue. The electric current is caused to flow through the tissue to induce contraction of the collagen fibers. The transfer of the RF current can be through direct contact between the active electrode and the tissue, or through a thin layer of electrically conducting fluid, such as saline or gel.

Current electrosurgical devices and procedures such as the one described in Lax, however, suffer from a number of disadvantages. For example, monopolar devices generally direct electric current along a defined path from the exposed or active electrode through the patient's body to the return electrode, which is externally attached to a suitable location on the patient. This creates the potential danger that the electric current will flow through undefined paths in the patient's body, thereby increasing the risk of unwanted electrical stimulation to portions of the patient's body. In addition, the direct transfer of RF current through the target tissue tends to increase the thermal damage caused to the target tissue, and it may induce thermal damage or necrosis of body structures underlying and/or surrounding the target tissue.

For these and other reasons, improved systems and methods are desired for the electrosurgical contraction of collagen tissue.

SUMMARY OF THE INVENTION

The present invention provides systems and methods for selectively applying electrical energy to structures within or on the surface of a patient's body. The systems and methods allow the surgical team to perform electrosurgical interventions, such as selectively contracting soft collagen tissue and other body structures, while limiting thermal damage or molecular dissociation of such tissue and limiting the thermal damage to tissue adjacent to and underlying the treatment site. The systems and methods of the present invention are particularly useful for surgical procedures in electrically conducting environments, such as arthroscopic procedures in the joints, e.g., shoulder, knee, hip, hand, foot, elbow or the like. The present invention is also useful in relatively dry environments, such as treating and shaping the cornea, and dermatological procedures involving surface tissue contraction of tissue underlying the surface of the skin for tissue rejuvenation, wrinkle removal and the like.

In one aspect of the present invention, a method for contracting soft collagen tissue involves positioning one or more active electrode(s) adjacent to the target site in the presence of electrically conductive fluid, and positioning one or more dispersive return electrode(s) within the electrically conductive fluid to generate a current flow path between the active and return electrodes. A sufficient high frequency voltage difference is applied between the active and return electrodes to induce contraction or shrinkage of the collagen fibers in the target tissue. The target tissue is heated to a temperature sufficient to substantially irreversibly contract the collagen fibers, which generally requires a tissue temperature in the range of about 45°C to 90°C, usually about 60°C to 70°C.

In one aspect of the invention, the electrosurgical probe is designed to enhance the depth of current penetration into the tissue at a voltage sufficiently low to minimize or completely avoid vaporization, necrosis or ablation of the tissue surface. In one embodiment, the return electrode comprises an annular electrode on the shaft spaced axially from the active electrode about 5 to 50 mm, preferably about 10 to 30 mm. The return electrode will generally have a larger exposed surface area than the active electrode to minimize or eliminate high current densities at the return electrode surface. Applicant has found that the depth of current penetration into the tissue may be increased (with a given voltage) when the return electrode is spaced further away from the active electrode on the shaft. Deeper current penetration allows a deeper, more uniform heating of the tissue (and thus more effective tissue contraction) without increasing the temperature of the

surface tissue to a level that would result in irreversible damage, such as vaporization, necrosis or ablation to the tissue surface. Specifically, applicant has found that, at the voltages described herein (e.g., about 20 to 100 volts rms), the techniques of the present invention will allow sufficient current penetration into the tissue to contract collagen fibers at about 2.0 to 4.0 mm deep without causing tissue necrosis at the tissue surface.

According to the present invention, the dispersive return electrode is positioned relative to the active electrode such that the instrument effectively functions as a virtual unipolar system in which the return electrode has substantially no effect on the electric fields surrounding the active electrode (similar to a true monopolar system with a dispersive return pad). In this configuration, there is a lower impedance contact between the return electrode and the electrically conducting fluid surrounding return electrode. As the conductive volume becomes large, there is very little potential difference around the return electrode so that the tissue surrounding the return electrode substantially behaves as a virtual return electrode. There is, therefore, almost no thermal heating around the return electrode. This configuration allows for deeper current penetration into the tissue, resulting in increased thermal heating and tissue contraction. In addition, this configuration still maintains the advantages of bipolar modalities; namely that the current path is substantially restricted to the region treated. Thus, if the treated region is the shoulder capsule, the current will remain in this area, and will not flow through the heart or other sensitive organs, which minimizes the risk of arrhythmias.

In a specific application of the invention, a method is provided for contracting or shrinking the collagen fibers within a joint capsular tissue, such as the shoulder, knee, hip, hand, foot, elbow or the like, to eliminate capsular redundancy or to otherwise tighten the ligamentous complex. In this method, an active electrode is percutaneously introduced through a portal in the joint and positioned adjacent to the joint capsular tissue. The cavity surrounding the joint is immersed in electrically conducting fluid, such as isotonic saline, and a return electrode is positioned within the electrically conducting fluid. A high frequency voltage difference is applied between the electrode terminal and the return electrode to induce contraction of the collagen fibers within the joint capsular tissue. In the representative embodiment, the active and return electrodes are both located on an electrosurgical probe, and the return electrode is configured (i.e., sized and spaced relative to the active electrode) to allow the electric current to fully penetrate the joint capsule, while maintaining the temperature of the surface tissue below

the threshold of cell vaporization or 100°C. Typically, the joint capsule has a thickness in the range of about 2.0 to 4.0 mm. Accordingly, the return electrode is configured to allow the electric current to penetrate about 2.0 to 4.0 mm of tissue, at a voltage level (e.g., about 40 to 90 volts rms) that is below the threshold for tissue vaporization at the tissue surface.

The active electrode may comprise an array of active electrodes or a single active electrode at the distal end portion of an electrosurgical probe. The return electrode is positioned in contact with the electrically conducting fluid to provide a current flow path from the electrode terminal(s), through the electrically conducting fluid, to the return electrode. The electrically conducting fluid may be delivered to the target site before or during the surgical procedure. In relatively dry environments, for example, the fluid is delivered along a fluid path past the electrode terminal and the return electrode to the target site to generate the current flow path between the return electrode and the electrode terminal. In other procedures, such as arthroscopic procedures, the electrically conductive fluid is delivered into the arthroscopic cavity to immerse the target site in the fluid. The return electrode is then positioned within the cavity either by introducing the surgical instrument into the cavity or introducing a separate instrument. In an exemplary embodiment, a supplementary lumen is incorporated into the electrosurgical probe to direct a jet of electrically conductive fluid past the electrode(s) to effect a more defined zone of heating on the target tissue surface.

In one embodiment, the active electrode comprises a dome-shaped member having a plurality of holes mounted to an electrically insulating support member on the distal end portion of the instrument shaft. The instrument further comprises one or more electrical connectors extending through the instrument shaft, and at least partially through the holes in the dome-shaped active electrode to electrically couple the active electrode to a high frequency power supply. The connectors each have distal ends that are slightly larger than the holes in active electrode so that these distal ends also serve to help fix the active electrode to the electrode support member. The dome-shaped active electrode has a substantially irregular surface with a plurality of holes or distal connector ends protruding therefrom. These irregularities (i.e., holes and protrusions) create multiple edges on the surface of electrode that increase the current densities around electrode. This increased current density enables the probe 400 to provide increased thermal penetration of RF energy for the same level of voltage to improve the contraction of collagen tissue. Thus,

the present invention allows improved tissue contraction with relatively low power levels, and in a bipolar modality that minimizes current flow beyond the target site into the patient's body.

5 In another aspect of the invention, a system includes an electrosurgical probe with a shaft, an active electrode near the distal end of the shaft, and a dispersive return electrode spaced axially from the active electrode. In this embodiment, the system further includes a second return electrode on the shaft between the dispersive return electrode and the active electrode, and a switch or equivalent device for switching between the two return electrodes. In this manner, the physician may determine the depth of
10 current penetration desired, and vary this depth without changing the voltage level. In some cases, for example, it may be desirable to minimize current penetration into the tissue and thus the physician will deactivate the dispersive return electrode and apply voltage between the active and second return electrodes. Of course, the invention may include more than two return electrodes.

15 The system may optionally include a temperature controller coupled to one or more temperature sensors at or near the distal end of the probe. The controller adjusts the output voltage of the power supply in response to a temperature set point and the measured temperature value. The temperature sensor may be, for example, a thermocouple, located in the insulating support that measures a temperature at the distal
20 end of the probe. In this embodiment, the temperature set point will preferably be one that corresponds to a tissue temperature that results in the contraction of the collagen tissue, i.e., about 60°C to 70°C. Alternatively, the temperature sensor may directly measure the tissue temperature (e.g., infrared sensor). This embodiment is advantageous in situations when the surgeon is moving the probe transversely across the tissue.

25 In another aspect of the invention, an electrosurgical system comprises a high frequency power supply and a surgical instrument capable of both bipolar and monopolar electrosurgical techniques without having to disconnect the instrument from the power supply. In this embodiment, a switch is included in the system to switch the return terminal on the power supply between a dispersive return pad coupled to the surgical
30 instrument (monopolar mode) and a return electrode on the surgical instrument spaced proximally from the active electrode (bipolar mode).

In yet another aspect of the invention, a monopolar electrosurgical system is described for collagen shrinkage. This system includes a high frequency power supply, a

surgical instrument having one or more electrode terminal(s) and a dispersive pad return electrode coupled to the surgical instrument. In the preferred embodiment, the dispersive pad is directly coupled to the handle of the surgical instrument, and the active and return terminals of the power supply are, in turn, both coupled to the handle of the surgical instrument. Thus, the surgical instrument and the dispersive pad are both disposable components of the system.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

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BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of an electrosurgical system incorporating a power supply and an electrosurgical probe for tissue contraction and vessel hemostasis according to the present invention;

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Fig. 2 is a side view of the electrosurgical probe of Fig. 1;

Fig. 3 is a cross sectional view of the electrosurgical probe of Fig. 1;

Fig. 4 is an exploded view of a proximal portion of the electrosurgical probe;

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Fig. 5 is an end view of the probe illustrating an array of electrode terminals embedded within a support;

Fig. 6 is a sectional view of the distal portion of an electrosurgical probe according to the present invention;

Fig. 7 is an end view of the probe of Fig. 6;

25

Figs. 8A-8D are end views of alternative configurations for the probe of Fig. 6;

Fig. 9 is a view of the distal portion of the electrosurgical probe of Fig. 6, illustrating use of the probe for contraction of collagen fibers in an electrically conducting environment;

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Fig. 10 is a graph illustrating the electrical impedance of tissue and isotonic saline with operating frequency;

Figs. 11 and 12 are sectional views illustrating another electrosurgical probe and method for contraction of collagen tissue according to the present invention;

Fig. 13 illustrates another method of contracting tissue with heating fluid

according to the present invention;

Fig. 14 illustrates another electrosurgical probe with a single active electrode lead;

5 Figs. 15 and 16 are sectional and end views, respectively, of another electrosurgical probe having a single tubular-shaped electrode;

Figs. 17 and 18 are sectional and end views, respectively, of another electrosurgical probe having a solid cylindrical electrode;

Figs. 19 and 20 illustrate another embodiment wherein the electrosurgical probe includes a fluid lumen for delivering electrically conductive fluid to the target site;

10 Fig. 21 illustrates a surgical kit for shrinking the collagen fibers of the joint capsular tissue according to the present invention;

Fig. 22 is a perspective view of another embodiment of the electrosurgical probe of the present invention;

Figs. 23 and 24 are cross-sectional and end views of the probe of Fig. 22;

15 Fig. 25 illustrates a monopolar embodiment of the electrosurgical system of the present invention;

Fig. 26 illustrates an alternative embodiment of an electrosurgical probe having a return electrode spaced further away from the active electrode(s);

20 Fig. 27 illustrates an embodiment of an electrosurgical probe having two return electrodes;

Fig. 28 illustrates an embodiment of an electrosurgical probe having a dome-shaped active electrode;

Fig. 29 is an enlarged view of the electrode assembly of the probe of Fig. 28;

25 Fig. 30 is an enlarged view of the dome-shaped active electrode;

Fig. 31 is an enlarged view of an electrically insulating support member for the dome-shaped active electrode of Fig. 30;

Fig. 32 schematically illustrates one embodiment of a power supply according to the present invention; and

30 Fig. 33 illustrates an electrosurgical system incorporating a plurality of active electrodes and associated current limiting elements.

DESCRIPTION OF SPECIFIC EMBODIMENTS

The present invention provides systems and methods for selectively applying electrical energy to a target location within or on a patient's body, such as solid tissue or the like, particularly including procedures where the tissue site is flooded or submerged with an electrically conducting fluid, such as arthroscopic surgery of the knee, shoulder, ankle, hip, elbow, hand or foot. In addition, tissues which may be treated by the system and method of the present invention include collagenous tissue within the eye, epidermal and dermal tissues underlying the surface of the skin, tissue within the esophagus or lower sphincter, tissue within the patient's mouth, such as the uvula, soft palate or tongue, or the like. When applied to a joint, the invention provides shrinkage of the joint capsule and consequent contraction of the volume and interior circumference of the joint capsular to provide joint stability. For convenience, the remaining disclosure will be directed specifically to the contraction of collagen fibers within a joint during an arthroscopic procedure, but it will be appreciated that the system and method can be applied equally well to procedures involving other tissues of the body, as well as to other procedures including open surgery, laparoscopic surgery, thoracoscopic surgery, and other endoscopic surgical procedures.

The present invention applies high frequency (RF) electrical energy in an electrically conducting fluid environment to shrink or contract collagen connective tissue, such as the collagen capsular tissue within a joint, or the collagen tissue within the epidermal and dermal layers of the skin. The RF energy heats the tissue directly or, indirectly by heating the fluid environment, to elevate the tissue temperature from normal body temperatures (e.g., 37°C) to temperatures in the range of 55°C to 85°C, preferably in the range from 60°C to 70°C. Thermal shrinkage of collagen fibers occurs within a small temperature range which, for mammalian collagen is in the range from 60°C to 70°C (Deak, G., et al., "The Thermal Shrinkage Process of Collagen Fibres as Revealed by Polarization Optical Analysis of Topooptical Staining Reactions," *Acta Morphologica Acad. Sci. of Hungary*, Vol. 15(2), pp 195-208, 1967). Previously reported research has attributed thermal shrinkage of collagen to the cleaving of the internal stabilizing cross-linkages within the collagen matrix (Deak, *ibid*). It has also been reported that when the collagen temperature is increased above 70°C, the collagen matrix begins to relax again and the shrinkage effect is reversed resulting in no net shrinkage (Allain, J. C., et al., "Isometric Tensions Developed During the Hydrothermal Swelling of Rat Skin," *Connective Tissue Research*, Vol. 7, pp 127-133, 1980). Consequently, the controlled

heating of tissue to a precise depth is critical to the achievement of therapeutic collagen shrinkage.

The preferred depth of heating to effect the shrinkage of collagen in the heated region (i.e., the depth to which the tissue is elevated to temperatures between 60°C to 70°C) generally depends on (1) the thickness of the tissue, (2) the location of nearby structures (e.g., nerves) that should not be exposed to damaging temperatures, (3) the depth of collagen shrinkage or thermal heating desired in the surgical application; and/or (3) the location of the collagen tissue layer within which therapeutic shrinkage is to be effected. The depth of heating is usually in the range from 0 to 3.5 mm. In the case of joint capsular tissue, the depth of heating is preferably in the range from 0.2 mm to 2.0 mm. In the case of collagen underlying the surface of the skin, the depth of heating is preferably in the range from 0.1 mm to 0.5 mm.

The present invention may use a single active electrode or an electrode array distributed over a contact surface of a probe. The electrode array usually includes a plurality of independently current-limited and/or power-controlled electrode terminals to apply electrical energy selectively to the target tissue and/or the immediate conductive fluid environment, while limiting the unwanted application of electrical energy to the surrounding tissue and environment resulting from power dissipation into surrounding electrically conductive fluids, such as normal saline. The electrode terminals may be independently current-limited by isolating the terminals from each other and connecting each terminal to a separate power source that is isolated from the other electrode terminals. Alternatively, the electrode terminals may be connected to each other at either the proximal or distal ends of the probe to form a single wire that couples to one or more power sources.

The electrosurgical instrument will comprise a shaft having a proximal end and a distal end and one or more electrical connector(s) therebetween for coupling one or more active electrode(s) to a high frequency power supply. The shaft may assume a wide variety of configurations, with the primary purpose being to mechanically support the active electrode(s) and permit the treating physician to manipulate the active electrode(s) from a proximal end of the shaft. Usually, the shaft will be a narrow-diameter rod or tube, more usually having dimensions which permit it to be introduced into a body cavity, such as the mouth or the abdominal cavity, through an associated trocar or cannula in a minimally invasive procedure, such as arthroscopic, laparoscopic, thoracoscopic, and other

endoscopic procedures. Thus, the shaft will typically have a length of at least 5cm for oral procedures and at least 10 cm, more typically being 20 cm, or longer for endoscopic procedures. The shaft will typically have a diameter of at least 0.5 mm and frequently in the range from 1 to 10 mm. Of course, for dermatological procedures on the outer skin, the shaft may have any suitable length and diameter that would facilitate handling by the surgeon.

The shaft may be rigid or flexible, with flexible shafts optionally being combined with a generally rigid external tube for mechanical support. Flexible shafts may be combined with pull wires, shape memory actuators, and other known mechanisms for effecting selective deflection of the distal end of the shaft to facilitate positioning of the active electrode(s). The shaft will usually include one or more wires or other conductive elements running axially therethrough to permit connection of the active electrode(s) to a connector at the proximal end of the shaft. Specific shaft designs will be described in detail in connection with the figures hereinafter.

The active electrode(s) are preferably supported within or by an inorganic insulating support positioned near the distal end of the instrument shaft. The return electrode may be located on the instrument shaft, on another instrument or on the external surface of the patient (i.e., a dispersive pad). The close proximity of nerves and other sensitive tissue in the joints, however, makes a bipolar design more preferable because this minimizes the current flow through healthy tissue, surrounding nerves and the patient's heart. Accordingly, the return electrode is preferably either integrated with the instrument body, or another instrument located in close proximity to the distal end of the instrument. The proximal end of the instrument will include the appropriate electrical connections for coupling the return electrode(s) and the active electrode(s) to a high frequency power supply, such as an electrosurgical generator.

The current flow path between the active electrodes and the return electrode(s) may be generated by submerging the tissue site in an electrical conducting fluid (e.g., within a viscous fluid, such as an electrically conductive gel) or by directing an electrically conducting fluid along a fluid path to the target site (i.e., a liquid, such as isotonic saline, or a gas, such as argon). The conductive gel may also be delivered to the target site to achieve a slower more controlled delivery rate of conductive fluid. In addition, the viscous nature of the gel may allow the surgeon to more easily contain the gel around the target site (e.g., rather than attempting to contain isotonic saline).

Alternatively, the electrode assembly (i.e., active and return electrodes) may be dipped into a conductive fluid prior to its introduction to the target site. A more complete description of an exemplary method of directing electrically conducting fluid between the active and return electrodes is described in U.S. Patent No. 5,697,281, previously
5 incorporated herein by reference. Alternatively, the body's natural conductive fluids, such as blood, may be sufficient to establish a conductive path between the return electrode(s) and the active electrode(s). However, conductive fluid that is introduced to the patient is generally preferred over blood because blood will tend to coagulate at certain temperatures. Advantageously, a liquid electrically conductive fluid (e.g., isotonic saline)
10 may be used to concurrently "bathe" the target tissue surface to provide an additional means for removing any tissue, and to cool the region of the target tissue ablated in the previous moment.

In some embodiments of the present invention, the return electrode is large enough, and spaced far enough away from the tissue site on the instrument shaft, that the
15 instrument effectively functions as a virtual unipolar system in which the return electrode has substantially no effect on the electric fields surrounding the active electrode (similar to a true monopolar system with a dispersive return pad). In this configuration, there is a lower impedance contact between the return electrode and the electrically conducting fluid surrounding return electrode. As the conductive volume becomes large, there is very little
20 potential difference around the return electrode so that the tissue surrounding return electrode substantially behaves as a virtual return electrode. There is, therefore, almost no thermal heating around the return electrode. In an isotropic environment, the electrical field around the active electrode is spherical, and the voltage potential decreases sharply with distance. This configuration allows for deeper current penetration into the tissue,
25 resulting in increased thermal heating and tissue contraction. In addition, this configuration still maintains the advantages of bipolar modalities; namely that the current path is substantially restricted to the region treated. Thus, if the treated region is the shoulder capsule, the current will remain in this area, and will not flow through the heart or other sensitive organs, which minimizes the risk of arrhythmias.

30 The power supply may include a fluid interlock for interrupting power to the active electrode(s) when there is insufficient conductive fluid around the active electrode(s). This ensures that the instrument will not be activated when conductive fluid is not present, minimizing the tissue damage that may otherwise occur. A more complete

description of such a fluid interlock can be found in commonly assigned, co-pending U.S. Application No. 09/058,336, filed April 10, 1998 (attorney Docket No. CB-4), the complete disclosure of which is incorporated herein by reference.

5 In one configuration, each individual active electrode in the electrode array is electrically insulated from all other active electrodes in the array within said instrument and is connected to a power source which is isolated from each of the other active electrodes in the array or to circuitry which limits or interrupts current flow to the active electrode when low resistivity material (*e.g.*, blood or electrically conductive saline irrigant) causes a lower impedance path between the return electrode and the individual
10 active electrode. The isolated power sources for each individual active electrode may be separate power supply circuits having internal impedance characteristics which limit power to the associated active electrode when a low impedance return path is encountered. By way of example, the isolated power source may be a user selectable constant current source. In this embodiment, lower impedance paths will automatically result in lower
15 resistive heating levels since the heating is proportional to the square of the operating current times the impedance. Alternatively, a single power source may be connected to each of the active electrodes through independently actuatable switches, or by independent current limiting elements, such as inductors, capacitors, resistors and/or combinations thereof. The current limiting elements may be provided in the instrument, connectors,
20 cable, controller or along the conductive path from the controller to the distal tip of the instrument. Alternatively, the resistance and/or capacitance may occur on the surface of the active electrode(s) due to oxide layers which form selected active electrodes (*e.g.*, titanium or a resistive coating on the surface of metal, such as platinum)

The tip region of the instrument may comprise many independent active
25 electrodes designed to deliver electrical energy in the vicinity of the tip. The selective application of electrical energy to the conductive fluid is achieved by connecting each individual active electrode and the return electrode to a power source having independently controlled or current limited channels. The return electrode may be a tubular member of conductive material proximal to the electrode array at the tip which also serves as a
30 conduit for the supply of the electrically conducting fluid between the active and return electrodes. The application of high frequency voltage between the return electrode and the electrode array results in the generation of high electric field intensities at the distal tips of the active electrodes with conduction of high frequency current from each individual active

electrode to the return electrode. The current flow from each individual active electrode to the return electrode is controlled by either active or passive means, or a combination thereof, to deliver electrical energy to the surrounding conductive fluid while minimizing energy delivery to surrounding (non-target) tissue.

5 The application of a high frequency voltage between the return electrode and the electrode array for appropriate time intervals effects heating of the conductive fluid and contraction of the target tissue. The tissue volume over which energy is dissipated (*i.e.*, a high current density exists) may be precisely controlled, for example, by the use of a multiplicity of small active electrodes whose effective diameters or principal dimensions
10 range from about 5 mm to 0.01 mm, preferably from about 2 mm to 0.05 mm, and more preferably from about 1 mm to 0.1 mm. Electrode areas for both circular and non-circular terminals will have a contact area (per active electrode) below 25 mm², preferably being in the range from 0.0001 mm² to 1 mm², and more preferably from 0.005 mm² to .5 mm². The circumscribed area of the electrode array is in the range from 0.25 mm² to 75 mm²,
15 preferably from 0.5 mm² to 40 mm², and will usually include at least two isolated active electrodes, more usually at least four active electrodes, preferably at least six active electrodes, and often 50 or more active electrodes, disposed over the distal contact surfaces on the shaft. The use of small diameter active electrodes increases the electric field intensity and reduces the extent or depth of tissue heating as a consequence of the
20 divergence of current flux lines which emanate from the exposed surface of each active electrode.

The electrically conducting fluid should have a threshold conductivity to provide a suitable conductive path between the return electrode and the active electrode(s). The electrical conductivity of the fluid (in units of milliSiemens per centimeter or mS/cm)
25 will usually be greater than 0.2 mS/cm, preferably will be greater than 2 mS/cm and more preferably greater than 10 mS/cm. In an exemplary embodiment, the electrically conductive fluid is isotonic saline, which has a conductivity of about 17 mS/cm. For some embodiments, a saline solution with higher levels of sodium chloride than conventional saline (which is on the order of about .9% sodium chloride) e.g., on the order of greater
30 than 1% or between about 3% and 20%, may be desirable. Alternatively, the invention may be used with different types of conductive fluids that have a higher or lower conductivity than isotonic saline. For example, the present invention may be used with elements other than sodium, such as potassium, magnesium, calcium and other metals near

the left end of the periodic chart. In addition, other electronegative elements may be used in place of chlorine, such as fluorine.

The voltage applied between the return electrode and the electrode array will be at high or radio frequency, typically between about 5 kHz and 20 MHz, usually being between about 30 kHz and 2.5 MHz, preferably being between about 100 kHz and 500 kHz, and, in some embodiments, between about 100 kHz and 200 kHz. The RMS (root mean square) voltage applied will usually be in the range from about 5 volts to 1000 volts, preferably being in the range from about 10 volts to 500 volts, and more preferably being in the range from about 20 volts to about 90 volts, and often in the range of about 40 to 70 volts depending on the active electrode size and the operating frequency. These frequencies and voltages will result in peak-to-peak voltages and current that are sufficient to heat the electrically conductive fluid to temperatures sufficient to induce contraction of collagen tissue. Typically, the peak-to-peak voltage will be in the range of 10 to 2000 volts and preferably in the range of 20 to 500 volts and more preferably in the range of about 40 to 450 volts (again, depending on the electrode size and the operating frequency).

An important aspect of the present invention is the discovery that the output voltage frequency of the generator can be selected to control the depth of tissue heating. The electrical impedance of tissue is known to decrease with increasing frequency due to the electrical properties of cell membranes which surround electrically conductive cellular fluid. As shown, the electrical impedance of tissue to current at a frequency of 100 kHz is on the order of four times larger than at a frequency of 450 to 500 kHz. As a result of the higher tissue impedance, the current flux lines tend to penetrate less deeply resulting in a smaller depth of tissue heating. This principle of operation of the present invention can be used to advantage in applications where the depth of tissue heating is to be maintained small (e.g., 0.2 to 0.5 mm). In some embodiments, the operating frequency is between about 100 and 200 kHz for applications requiring shallow depths of collagen shrinkage (e.g., less than 1.5 mm). Conversely, in situations where much larger depths of collagen shrinkage are to be effected, a higher output voltage frequency may be used. By way of example, to achieve therapeutic collagen shrinkage to a depth of 1.5 to 3.0 mm, a higher operating frequency may be used (e.g., 500 kHz). Alternatively, the diameter of the active electrodes and/or the spacing between the outer perimeter of the active electrodes and the electrode support member, W_3 (see Fig. 7) may be selected to increase the depth of current penetration. By way of example, increasing the distance W_3 will increase the depth

of heating, L_4 (see Fig. 9) for a given operating frequency.

As discussed above, the voltage is usually delivered in a series of voltage pulses or alternating current of time varying voltage amplitude with a sufficiently high frequency (e.g., on the order of 5 kHz to 20 MHz) such that the voltage is effectively applied continuously (as compared with e.g., lasers claiming small depths of necrosis, which are generally pulsed about 10 to 20 Hz). In addition, the duty cycle (i.e., cumulative time in any one-second interval that energy is applied) is on the order of about 50% for the present invention, as compared with pulsed lasers which typically have a duty cycle of about 0.0001%.

The preferred power source of the present invention delivers a high frequency current selectable to generate average power levels ranging from several milliwatts to tens of watts per electrode, depending on the volume of target tissue being heated, and/or the maximum allowed temperature selected for the instrument tip. The power source allows the user to select the voltage level according to the specific requirements of a particular arthroscopic surgery, dermatological procedure, ophthalmic procedures, open surgery or other endoscopic surgery procedure.

The power source may be current limited or otherwise controlled so that undesired heating of the target tissue or surrounding (non-target) tissue does not occur. In a presently preferred embodiment of the present invention, current limiting inductors are placed in series with each independent active electrode, where the inductance of the inductor is in the range of 10uH to 50,000uH, depending on the electrical properties of the target tissue, the desired tissue heating rate and the operating frequency. Alternatively, capacitor-inductor (LC) circuit structures may be employed, as described previously in co-pending PCT application No. PCT/US94/05168, the complete disclosure of which is incorporated herein by reference. Additionally, current limiting resistors may be selected. Preferably, these resistors will have a large positive temperature coefficient of resistance so that, as the current level begins to rise for any individual active electrode in contact with a low resistance medium (e.g., saline irrigant), the resistance of the current limiting resistor increases significantly, thereby minimizing the power delivery from said active electrode into the low resistance medium (e.g., saline irrigant).

As an alternative to such passive circuit structures, regulated current flow to each active electrode may be provided by a multi-channel power supply. A substantially constant current level for each individual active electrode within a range which will limit

power delivery through a low resistance path, *e.g.*, isotonic saline irrigant, and would be selected by the user to achieve the desired rate of tissue heating. Such a multi-channel power supply thus provides a substantially constant current source with selectable current level in series with each active electrode, wherein all electrodes will operate at or below
5 the same, user selectable maximum current level. Current flow to all active electrodes could be periodically sensed and stopped if the temperature measured at the surface of the electrode array exceeds user selected limits. Particular control system designs for implementing this strategy are well within the skill of the art.

Yet another alternative involves the use of one or several power supplies
10 which allow one or several active electrodes to be simultaneously energized and which include active control means for limiting current levels below a preselected maximum level. In this arrangement, only one or several active electrodes would be simultaneously energized for a brief period. Switching means would allow the next one or several active electrodes to be energized for a brief period. By sequentially energizing one or several
15 active electrodes, the interaction between adjacent active electrodes can be minimized (for the case of energizing several active electrodes positioned at the maximum possible spacing within the overall envelope of the electrode array) or eliminated (for the case of energizing only a single electrode at any one time). As before, a resistance measurement means may be employed for each active electrode prior to the application of power wherein a
20 (measured) low resistance (below some preselected level) will prevent that active electrode from being energized during a given cycle. By way of example, the sequential powering and control scheme of the present invention would function in a manner similar to an automobile distributor. In this example, an electrical contact rotates past terminals connected to each spark plug. In this example, each spark plug corresponds to the exposed
25 surface of each of the active electrodes. In addition, the present invention includes the means to measure the resistance of the medium in contact with each active electrode and cause voltage to be applied only if the resistance exceeds a preselected level. A more complete description of suitable mechanisms for limiting current to individual active electrodes can be found in PCT International Application, U.S. National Phase Serial No.
30 PCT/US94/05168, filed on May 10, 1994 (Attorney Docket 16238-000440), the complete disclosure of which has previously been incorporated herein by reference.

It should be clearly understood that the invention is not limited to electrically isolated active electrodes, or even to a plurality of active electrodes. For

example, the array of active electrodes may be connected to a single lead that extends through the instrument shaft to a power source of high frequency current. Alternatively, the instrument may incorporate a single electrode that extends directly through the instrument shaft or is connected to a single lead that extends to the power source.

5 The active electrode(s) are formed over a tissue treatment surface on the shaft of the electrosurgical instrument. The return electrode surface will be recessed relative to the distal end of the instrument and may be recessed within a fluid conduit provided for the introduction of electrically conducting fluid to the site of the target tissue and active electrode(s). In the exemplary embodiment, the shaft will be cylindrical over
10 most of its length, with the tissue treatment surface being formed at the distal end of the shaft. In the case of endoscopic applications, the tissue treatment surface may be recessed since it helps to protect and shield the active electrodes on the surface while they are being introduced, particularly while being introduced through the working channel of a trocar channel or a viewing scope.

15 The area of the tissue treatment surface can vary widely, and the tissue treatment surface can assume a variety of geometries, with particular areas and geometries being selected for specific applications. Active electrode surfaces can have areas in the range from 0.25 mm² to 75 mm², usually being from about 0.5 mm² to 40 mm². The geometries can be planar, concave, convex, hemispherical, conical, linear "in-line" array
20 or virtually any other regular or irregular shape. Most commonly, the active electrode(s) or active electrode(s) will be formed at the distal tip of the electrosurgical instrument shaft, frequently being planar, disk-shaped, or hemispherical surfaces for use in reshaping procedures or being linear arrays for use in cutting. Alternatively or additionally, the active electrode(s) may be formed on lateral surfaces of the electrosurgical instrument shaft
25 (*e.g.*, in the manner of a spatula), facilitating access to certain body structures in endoscopic procedures.

Referring now to Fig. 1, an exemplary electrosurgical system 5 for contraction of collagen tissue will now be described in detail. As shown, electrosurgical system 5 generally includes an electrosurgical probe 20 connected to a power supply 10 for
30 providing high frequency voltage to one or more active electrodes (not shown in Fig. 1) on probe 20. Probe 20 includes a connector housing 44 at its proximal end, which can be removably connected to a probe receptacle 32 of a probe cable 22. The proximal portion of cable 22 has a connector 34 to couple probe 20 to power supply 10. Power supply 10

has an operator controllable voltage level adjustment 38 to change the applied voltage level, which is observable at a voltage level display 40. Power supply 10 also includes a foot pedal 24 and a cable 26 which is removably coupled to a receptacle 30 with a cable connector 28. The foot pedal 24 may also include a second pedal (not shown) for remotely
5 adjusting the energy level applied to electrode terminals 104. The specific design of a power supply which may be used with the electrosurgical probe of the present invention is described in parent application PCT US 94/051168, the full disclosure of which has previously been incorporated herein by reference.

Referring now to Figs. 32 and 33, a representative high frequency power
10 supply for use according to the principles of the present invention will now be described. The high frequency power supply of the present invention is configured to apply a high frequency voltage of about 10 to 500 volts RMS between one or more active electrode(s) and one or more return electrode(s). In the exemplary embodiment, the power supply applies about 70-350 volts RMS in the ablation mode and about 20 to 90 volts in a
15 subablation or contraction mode, preferably about 45 to 70 volts in the subablation mode (these values will, of course, vary depending on the probe configuration attached to the power supply and the desired mode of operation).

The preferred power source of the present invention delivers a high frequency current selectable to generate average power levels ranging from several
20 milliwatts to tens of watts per electrode, depending on the volume of target tissue being heated, and/or the maximum allowed temperature selected for the probe tip. The power source allows the user to select the voltage level according to the specific requirements of a particular procedure, e.g., arthroscopic surgery, dermatological procedure, ophthalmic procedures, open surgery or other endoscopic surgery procedure.

As shown in Fig. 32, the power supply generally comprises a radio
25 frequency (RF) power oscillator 100 having output connections for coupling via a power output signal 102 to the load impedance, which is represented by the electrode assembly when the electrosurgical probe is in use. In the representative embodiment, the RF oscillator operates at about 100 kHz. The RF oscillator is not limited to this frequency and
30 may operate at frequencies of about 300kHz to 600kHz. In particular, for cardiac applications, the RF oscillator will preferably operate in the range of about 400 kHz to about 600 kHz. The RF oscillator will generally supply a square wave signal with a crest factor of about 1 to 2. Of course, this signal may be a sine wave signal or other suitable

wave signal depending on the application and other factors, such as the voltage applied, the number and geometry of the electrodes, etc. The power output signal 102 is designed to incur minimal voltage decrease (i.e., sag) under load. This improves the applied voltage to the active electrodes and the return electrode, which improves the rate of volumetric
5 removal (ablation) of tissue.

Power is supplied to the oscillator 100 by a switching power supply 104 coupled between the power line and the RF oscillator rather than a conventional transformer. The switching power supply 140 allows the generator to achieve high peak power output without the large size and weight of a bulky transformer. The architecture of
10 the switching power supply also has been designed to reduce electromagnetic noise such that U.S. and foreign EMI requirements are met. This architecture comprises a zero voltage switching or crossing, which causes the transistors to turn ON and OFF when the voltage is zero. Therefore, the electromagnetic noise produced by the transistors switching is vastly reduced. In an exemplary embodiment, the switching power supply 104 operates
15 at about 100 kHz.

A controller 106 coupled to the operator controls 105 (i.e., foot pedals and voltage selector) and display 116, is connected to a control input of the switching power supply 104 for adjusting the generator output power by supply voltage variation. The controller 106 may be a microprocessor or an integrated circuit. The power supply may
20 also include one or more current sensors 112 for detecting the output current. The power supply is preferably housed within a metal casing which provides a durable enclosure for the electrical components therein. In addition, the metal casing reduces the electromagnetic noise generated within the power supply because the grounded metal casing functions as a "Faraday shield", thereby shielding the environment from internal
25 sources of electromagnetic noise.

The power supply generally comprises a main or mother board containing generic electrical components required for many different surgical procedures (e.g., arthroscopy, urology, general surgery, dermatology, neurosurgery, etc.), and a daughter board containing application specific current-limiting circuitry (e.g., inductors, resistors,
30 capacitors and the like). The daughter board is coupled to the mother board by a detachable multi-pin connector to allow convenient conversion of the power supply to, e.g., applications requiring a different current limiting circuit design. For arthroscopy, for example, the daughter board preferably comprises a plurality of inductors of about 200 to

400 microhenries, usually about 300 microhenries, for each of the channels supplying current to the electrode terminals 102 (see Fig. 2).

Alternatively, in one embodiment, current limiting inductors are placed in series with each independent electrode terminal, where the inductance of the inductor is in the range of 10uH to 50,000uH, depending on the electrical properties of the target tissue, the desired tissue heating rate and the operating frequency. Alternatively, capacitor-inductor (LC) circuit structures may be employed, as described previously in co-pending PCT application No. PCT/US94/05168, the complete disclosure of which is incorporated herein by reference. Additionally, current limiting resistors may be selected. Preferably, these resistors will have a large positive temperature coefficient of resistance so that, as the current level begins to rise for any individual electrode terminal in contact with a low resistance medium (e.g., saline irrigant or conductive gel), the resistance of the current limiting resistor increases significantly, thereby minimizing the power delivery from said electrode terminal into the low resistance medium (e.g., saline irrigant or conductive gel). Power output signal may also be coupled to a plurality of current limiting elements 96, which are preferably located on the daughter board since the current limiting elements may vary depending on the application.

Figs. 2-5 illustrate an exemplary electrosurgical probe 20 constructed according to the principles of the present invention. As shown in Fig. 2, probe 20 generally includes an elongated shaft 100 which may be flexible or rigid, a handle 204 coupled to the proximal end of shaft 100 and an electrode support member 102 coupled to the distal end of shaft 100. Shaft 100 preferably comprises an electrically conducting material, usually metal, which is selected from the group consisting of tungsten, stainless steel alloys, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and nickel or its alloys. Shaft 100 includes an electrically insulating jacket 108, which is typically formed as one or more electrically insulating sheaths or coatings, such as polytetrafluoroethylene, polyimide, and the like. The provision of the electrically insulating jacket over the shaft prevents direct electrical contact between these metal elements and any adjacent body structure or the surgeon. Such direct electrical contact between a body structure (e.g., tendon) and an exposed electrode could result in unwanted heating and necrosis of the structure at the point of contact causing necrosis.

Handle 204 typically comprises a plastic material that is easily molded into a suitable shape for handling by the surgeon. As shown in Fig. 3, handle 204 defines an

inner cavity 208 that houses the electrical connections 250 (discussed below), and provides a suitable interface for connection to an electrical connecting cable 22 (see Fig. 1).

Electrode support member 102 extends from the distal end of shaft 100 (usually about 1 to 20 mm), and provides support for a plurality of electrically isolated active electrodes 104 (hereinafter referred to as electrode terminals 104; see Fig. 5).

As shown in Fig. 2, the distal portion of shaft 100 is preferably bent to improve access to the operative site of the tissue being treated (e.g., contracted).

Electrode support member 102 has a substantially planar tissue treatment surface 212 that is usually at an angle of about 10 to 90 degrees relative to the longitudinal axis of shaft 100, preferably about 30 to 60 degrees and more preferably about 45 degrees. In alternative embodiments, the distal portion of shaft 100 comprises a flexible material which can be deflected relative to the longitudinal axis of the shaft. Such deflection may be selectively induced by mechanical tension of a pull wire, for example, or by a shape memory wire that expands or contracts by externally applied temperature changes. A more complete description of this embodiment can be found in PCT International Application, U.S. National Phase Serial No. PCT/US94/05168, filed on May 10, 1994 (Attorney Docket 16238-000440), the complete disclosure of which has previously been incorporated herein by reference.

The bend in the distal portion of shaft 100 is particularly advantageous in arthroscopic treatment of joint capsular tissue as it allows the surgeon to reach the target tissue within the joint as the shaft 100 extends through a cannula or portal. Of course, it will be recognized that the shaft may have different angles depending on the procedure. For example, a shaft having a 90° bend angle may be particularly useful for accessing tissue located in the back portion of a joint compartment and a shaft having a 10° to 30° bend angle may be useful for accessing gingiva near or in the front portion of the joint compartment.

Referring to Fig. 5, the electrically isolated electrode terminals 104 are spaced apart over tissue treatment surface 212 of electrode support member 102. The tissue treatment surface and individual electrode terminals 104 will usually have dimensions within the ranges set forth above. In the representative embodiment, the tissue treatment surface 212 has an oval cross-sectional shape with a length L in the range of 1 mm to 20 mm and a width W in the range from 0.3 mm to 7 mm. The oval cross-sectional shape accommodates the bend in the distal portion of shaft 202. The individual electrode

terminals 104 are preferably substantially flush with tissue treatment surface 212.

Applicant has found that this configuration minimizes any sharp electrode edges and/or corners that would promote excessively high electric field intensities and associated current densities when a high frequency voltage is applied to the electrode terminals.

5 It should be noted that the electrode terminals 104 may protrude slightly outward from surface 212, typically by a distance from 0 mm to 2 mm, or the terminals may be recessed from this surface. For example, the electrode terminals 104 may be recessed by a distance from 0.01 mm to 1 mm, preferably 0.01 mm to 0.2 mm. In one embodiment of the invention, the electrode terminals are axially adjustable relative to the
10 tissue treatment surface so that the surgeon can adjust the distance between the surface and the electrode terminals.

In the embodiment shown in Figs. 2-5, probe 20 includes a return electrode 112 for completing the current path between electrode terminals 104 and a high frequency power supply 10 (see Fig. 1). As shown, return electrode 112 preferably comprises an
15 annular exposed region of shaft 102 slightly proximal to tissue treatment surface 212 of electrode support member 102, typically about 0.5 to 10 mm and more preferably about 1 to 10 mm. Return electrode 112 is coupled to a connector 258 that extends to the proximal end of probe 10, where it is suitably connected to power supply 10 (Fig. 1).

As shown in Fig. 2, return electrode 112 is not directly connected to
20 electrode terminals 104. To complete this current path so that electrode terminals 104 are electrically connected to return electrode 112, electrically conducting fluid (e.g., isotonic saline) is caused to flow therebetween. In the representative embodiment, the electrically conducting fluid is delivered from a fluid delivery element (not shown) that is separate from probe 20. In arthroscopic surgery, for example, the body cavity will be flooded with
25 isotonic saline and the probe 20 will be introduced into this flooded cavity. Electrically conducting fluid will be continually resupplied to maintain the conduction path between return electrode 112 and electrode terminals 104.

In alternative embodiments, the fluid path may be formed in probe 20 by, for example, an inner lumen or an annular gap (not shown) between the return electrode
30 and a tubular support member within shaft 100. This annular gap may be formed near the perimeter of the shaft 100 such that the electrically conducting fluid tends to flow radially inward towards the target site, or it may be formed towards the center of shaft 100 so that the fluid flows radially outward. In both of these embodiments, a fluid source (e.g., a bag

of fluid elevated above the surgical site or having a pumping device), is coupled to probe 20 via a fluid supply tube (not shown) that may or may not have a controllable valve. A more complete description of an electrosurgical probe incorporating one or more fluid lumen(s) can be found in commonly assigned, co-pending application Serial No.

5 08/485,219, filed on June 7, 1995 (Attorney Docket 16238-0006000), the complete disclosure of which has previously been incorporated herein by reference.

Fig. 4 illustrates the electrical connections 250 within handle 204 for coupling electrode terminals 104 and return electrode 112 to the power supply 10. As shown, a plurality of wires 252 extend through shaft 100 to couple terminals 104 to a
10 plurality of pins 254, which are plugged into a connector block 256 for coupling to a connecting cable 22 (Fig. 1). Similarly, return electrode 112 is coupled to connector block 256 via a wire 258 and a plug 260.

According to the present invention, the probe 20 further includes a voltage reduction element or a voltage reduction circuit for reducing the voltage applied between
15 the electrode terminals 104 and the return electrode 112. The voltage reduction element serves to reduce the voltage applied by the power supply so that the voltage between the electrode terminals and the return electrode is low enough to avoid excessive power dissipation into the electrically conducting medium and/or ablation of the soft tissue at the target site. The voltage reduction element primarily allows the electrosurgical probe 20 to
20 be compatible with other ArthroCare generators that are adapted to apply higher voltages for ablation or vaporization of tissue. Usually, the voltage reduction element will serve to reduce a voltage of about 100 to 135 volts rms (which is a setting of 1 on the ArthroCare Model 970 and 980 (i.e., 2000) Generators) to about 45 to 60 volts rms, which is a suitable voltage for contraction of tissue without ablation (i.e., molecular dissociation) of
25 the tissue.

In the representative embodiment, the voltage reduction element is a dropping capacitor 262 which has first leg 264 coupled to the return electrode wire 258 and a second leg 266 coupled to connector block 256. The capacitor usually has a capacitance of about 2700 to 4000 pF and preferably about 2900 to 3200 pF. Of course,
30 the capacitor may be located in other places within the system, such as in, or distributed along the length of, the cable, the generator, the connector, etc. In addition, it will be recognized that other voltage reduction elements, such as diodes, transistors, inductors, resistors, capacitors or combinations thereof, may be used in conjunction with the present

invention. For example, the probe 20 may include a coded resistor (not shown) that is constructed to lower the voltage applied between return electrode 112 and electrode terminals 104 to a suitable level for contraction of tissue. In addition, electrical circuits may be employed for this purpose.

5 Alternatively or additionally, the cable 22 that couples the power supply 10 to the probe 20 may be used as a voltage reduction element. The cable has an inherent capacitance that can be used to reduce the power supply voltage if the cable is placed into the electrical circuit between the power supply, the electrode terminals and the return electrode. In this embodiment, the cable 22 may be used alone, or in combination with
10 one of the voltage reduction elements discussed above, e.g., a capacitor.

Further, it should be noted that the present invention can be used with a power supply that is adapted to apply a voltage within the selected range for contraction of tissue. In this embodiment, a voltage reduction element or circuitry would not be desired.

15 Referring to Figs. 6 and 7, one embodiment of the distal or working end 42 of electrosurgical probe 200 will now be described. As shown, the probe includes a shaft 100 with two or more electrode terminals 104 whose distal ends are secured in an electrode support member 102. Electrode support member 102 may be secured to cannula 118 by adhesive 110. As shown in Fig. 7, the distal surfaces 136 of active electrodes 104 are in
20 the same plane as the distal surface 138 of electrode support member 102. Applicant has found that this configuration minimizes any sharp electrode edges and/or corners that would promote high electric field intensities and associated current densities when a high frequency voltage is applied to the electrode terminals. The surfaces of electrode terminals 104 proximal to electrode support member 102 are covered with electrically insulating
25 layer 106. Each electrode terminal 104 is secured in electrode support member 102 using adhesive 110. The cannula 118 is covered with electrically insulating sleeve 108 except over length, L_5 at the distal end of cannula 118. The exposed length, L_5 of cannula 128 serves as return electrode 112 to provide an electrical pathway between the electrode terminals 104 and return electrode 112.

30 The electrode terminals 104 may be constructed using round, square, rectangular or other shaped conductive metals. By way of example, the electrode terminal materials may be selected from the group including stainless steel, tungsten and its alloys, molybdenum and its alloys, titanium and its alloys, nickel-based alloys, as well as platinum

and its alloys. Electrode support member 102 is preferably a ceramic, glass or glass/ceramic composition (e.g., aluminum oxide, titanium nitride). Alternatively, electrode support member 102 may include the use of high-temperature biocompatible plastics such as polyether-ether-keytone (PEEK) manufactured by Vitrex International Products, Inc. or polysulfone manufactured by GE Plastics. The adhesive 110 may, by way of example, be an epoxy (e.g., Master Bond EP42HT) or a silicone-based adhesive. The cannula 118 may be selected from the group including stainless steel, copper-based alloys, titanium or its alloys, and nickel-based alloys. Electrically insulating sleeve 108 may be a coating (e.g., nylon) or heat shrinkable plastic (e.g., fluropolymer or polyester). The electrically insulating layer 106 may be a polyimide or Teflon coating or may be a polyethylene covering.

In the first embodiment and referring to Fig. 7, a total of 7 circular active electrodes or electrode terminals 104 are shown in a symmetrical pattern having an active electrode diameter, D_1 in the range from 0.05 mm to 1.5 mm, more preferably in the range from 0.1 mm to 0.75 mm. The interelectrode spacings, W_1 and W_2 are preferably in the range from 0.1 mm to 1.5 mm and more preferably in the range from 0.2 mm to 0.75 mm. The distance between the outer perimeter of the electrode terminal 104 and the perimeter of the electrode support member, W_3 is preferably in the range from 0.1 mm to 1.5 mm and more preferably in the range from 0.2 mm to 0.75 mm. The overall diameter, D_2 of the working end 42 of probe 20 is preferably in the range from 0.5 mm to 10 mm and more preferably in the range from 1.0 mm to 5 mm. As discussed above, the shape of the active electrodes may be round (as shown in Fig. 7), square, triangular, hexagonal, rectangular, tubular, flat strip and the like and may be arranged in a circularly symmetric pattern as shown in Fig. 7 or may, by way of example, be arranged in a rectangular pattern, square pattern, or strip pattern as shown in Figs. 8A through 8D.

Referring to Figs. 6 and 7, the thickness of the cannula 118 is preferably in the range from 0.08 mm to 1.0 mm and more preferably in the range from 0.1 mm to 0.4 mm. As stated previously, the material for the cannula 118 may be advantageously selected from a group of electrically conductive metals so that the cannula functions as both a structural support member for the array of electrode terminals 104 as well as a return electrode 112. The cannula 118 is connected to an electrical lead wire at its proximal end within connector housing 44 (not shown) and continues via probe cable 22 to generator 10 to provide electrical continuity between one output pole of high frequency

generator 10 and said return electrode 112. The thickness of the electrically insulating sleeve 108 is preferably in the range from 0.01 mm to 0.5 mm and more preferably in the range from 0.02 mm to 0.2 mm. The thickness of the electrically insulating layer 106 on the proximal portions of the electrode terminals 104 is preferably in the range from 0.01
5 mm to 0.5 mm and more preferably in the range from 0.02 mm to 0.2 mm.

Referring now to Fig. 6, the length of the return electrode, L_5 is preferably in the range from 1 mm to 30 mm and more preferably in the range from 2 mm to 20 mm.

The spacing between the most distal portion of the return electrode 112 and the plane of the distal surface 138 of the electrode support member, L_1 is preferably in the range from
10 0.5 mm to 30 mm and more preferably in the range from 1 mm to 20 mm.

Figs. 8A-8D illustrate alternative embodiments of the end of the electrosurgical probe. As shown, the distal surface 102 of the probe may have a substantially square or rectangular shape. Figs. 8C and 8D illustrate embodiments with linear or band shaped electrodes 104. Typically, the probe is moved laterally in the
15 direction of arrows 142 perpendicular to the longitudinal axis of the linear electrodes 104.

This embodiment provides a substantially uniform application of thermal energy over a relative larger area, and is particularly advantageous in treatment of external body surfaces, such as wrinkle removal procedures.

Referring now to Fig. 9, the working end 42 of probe 20 is shown in
20 contact with or in close proximity to a target tissue 120. In particular, electrode terminals 104 are in contact or in close proximity with tissue 120. The volume which surrounds the working end 42 of probe 20 is filled with an electrically conductive fluid 122 which may, by way of example, be isotonic saline or other biocompatible, electrically conductive irrigant solution. When a voltage is applied between the electrode terminals 104 and the
25 return electrode 112, electrical current flows between the electrode terminals 104 and the return electrode 112 along current flux lines 124. The current flux lines 124 flow a short distance, L_4 , into the surface of tissue 120 and through the electrically conductive fluid 122 in the region above the surface of the tissue to complete the electrical path between the electrode terminals 124 and the return electrode 112. As a consequence of the electrical
30 impedance of the tissue and the proper selection of the applied voltage and current, heating of the tissue 120 occurs in a region 126 (shaded) below the surface of the tissue 120,

Another embodiment of the present invention is illustrated in Fig. 11 and 12. This embodiment is similar previous embodiments except that distal surface 136 of the

electrode terminals 104 extends beyond the plane of the distal surface 138 of the electrode support member 102 by an extension length, L_2 . This extension length, L_2 , is preferably in the range from 0.05 mm to 2 mm and more preferably is in the range from 0.1 mm to 0.5 mm. All other dimensions and materials of construction are similar to those defined for the first embodiment described above. As shown in Fig. 12, the distal surfaces 136 of the electrode terminals 104 are in close proximity with or in direct contact with the surface of tissue 120.

The volume which surrounds the working end of probe 20 is filled with an electrically conductive fluid 122 which may, by way of example, be isotonic saline or other biocompatible, electrically conductive irrigant solution. When a voltage difference is applied between the electrode terminals 104 and the return electrode 112, electrical current flows between the electrode terminals 104 and the return electrode 112 along current flux lines 124. The current flux lines 124 flow a short distance, L_4 into the surface of tissue 120 and through the electrically conductive fluid 122 in the region above the surface of the tissue to complete the electrical path between the electrode terminals 104 and the return electrode 112. As a consequence of the electrical impedance of the tissue and the proper selection of the applied voltage and current, heating of the tissue 120 occurs in a region 126 below the surface of the tissue 120, said heating elevating the temperature of the tissue from normal body temperature (e.g. 37°C) to a temperature in the range 55°C to 85°C, preferably in the range from 60°C to 70°C.

Referring now to Fig. 13, an alternative method of contracting collagen soft tissue according to the present invention will now be described. As shown, one or more electrode terminals 104 on the distal end of an electrosurgical instrument 100 are positioned adjacent to the target tissue 120. In this method, electrically conducting fluid is delivered to the target site to submerge the target tissue 120 and the distal portion of instrument 100 in the fluid. As discussed above, the fluid may be delivered through instrument 100, or by a separate delivery instrument. When a voltage difference is applied between the electrode terminals 104 and the return electrode 112, electrical current flows between the electrode terminals 104 and the return electrode 112 through the conductive fluid, as shown by current flux lines 124. The current flux lines 124 heat the electrically conductive fluid. Since the electrode terminals are spaced from the tissue 120 (preferably about 0.5 to 10 mm), the current flux lines 124 flow only in the electrically conductive fluid such that little or no current flows in the adjacent tissue 120. By virtue of

the current flow through the electrically conductive fluid 122 in the region above the surface of the tissue, heated fluid is caused to flow away from the working end 42 towards the target tissue 120 along heated fluid path 128. Alternatively, the fluid may be delivered past the electrode terminals 104 in a jet of fluid that is delivered onto the target tissue to effect a more define zone of heating. The heated fluid elevates the temperature of the tissue from normal body temperatures (e.g., 37°C) to temperatures in the range from 55°C to 85°C, preferably in the range from 60°C to 70°C.

Still yet another embodiment of the present invention is illustrated in Fig. 14. This embodiment is similar to previous embodiments except that the electrode terminals 104 are joined to a single electrode terminal lead 140 through a low resistance bond 114. By way of example, low resistance bond 114 may be effective through the use of solder, braze, weld, electrically conductive adhesive, and/or crimping active electrode wires 104 within a deformable metal sleeve (not shown). In the configuration shown in Fig. 14, all active electrode leads are maintained at the same potential independent of the current flowing between a particular electrode terminal 104 and the return electrode. This configuration offers the simplicity of requiring only two leads between the generator 10 and the working end 42 of probe 20, viz., one lead for the electrode terminals 104 and one lead for the return electrode.

Referring again to Fig. 7, an advantage of a symmetrical array of electrode terminals 10 is that the loci of current flux lines 124 in tissue 120 is independent of the direction of the translational movement of the electrode array over the surface of the target tissue 120. In contrast, the electrode terminal array 104 in Fig. 8C requires that the translational movement be normal to the major axis of the electrode terminal 104 as illustrated by the preferred translation vector 142.

In the embodiment illustrated in Figs. 6 and 7, each active electrode 104 can be independently controlled by generator 10 by active or passive current and/or voltage controlling means as fully described in co-pending of PCT International Application, U.S. National Phase Serial No. PCT/US94/05168, and U.S. Patent Application Nos. 08/562,332 and 08/485,219, the complete disclosures of which have previously been incorporated herein by reference for all purposes. As described in the referenced co-pending patent applications, the independent control of current and/or voltage applied to each individual electrode terminal 104 provides the benefit of minimizing unwanted heating of either (1) surrounding fluids (e.g., isotonic saline) or (2) non-target tissue

(having distinguishably different electrically properties) when the working end 42 is being translated into and out of contact or close proximity with the target tissue (e.g., joint capsular tissue).

Still yet another embodiment of the present invention is illustrated in Figs. 5 15 and 16. In this embodiment, a single tubular-shaped electrode 104 replaces the array of electrode terminals. Other than the configuration and number of electrode terminal(s), all other dimensions and materials of construction remain the same as those described herein above for the first embodiment. The tubular electrode terminal 104 may conventionally be constructed using metal tubing formed by conventional tube drawing (e.g., welded and 10 drawn or seamless drawn) processes. The inside diameter, D_3 of the tubular electrode is preferably in the range from 0.3 mm to 5 mm and the thickness of the tubing, W_4 is preferably in the range from 0.05 mm to 1 mm and more preferably in the range from 0.1 mm to 0.6 mm.

The distance between the outer perimeter of the electrode terminals 104 and 15 the perimeter of the electrode support member, W_3 is preferably in the range from 0.1 mm to 1.5 mm and more preferably in the range from 0.2 mm to 0.75 mm. As discussed above with respect to Fig. 14, this embodiment provides the advantage of requiring only one lead between the electrode terminal 104 at the working end 42 of probe 20 and the generator 10. As before, current flows between electrode terminal 104 and return 20 electrode 112 through the adjacent target tissue 120 and the intervening electrically conductive fluid in the manner described above. Still yet another embodiment of the present invention is shown in Figs. 17 and 18. This embodiment is similar to that illustrated in Figs. 15 and 16 except that the single tubular electrode terminal 104 is replaced with a solid cylindrical electrode whose diameter, D_4 is preferably in the range 25 from 0.3 mm to 10 mm. This embodiment offers similar advantages to that described above with respect to the embodiment shown in Figs. 15 and 16. All other dimensions and materials of construction are similar to those specified with respect to the embodiment shown in Figs. 6 and 7.

Yet another embodiment of the present invention is illustrated in Figs. 19 30 and 20. This embodiment is the same as the first embodiment described in Figs. 6 and 7 except that a supply channel for the electrically conductive fluid is provided to allow the working end 42 of probe 20 to be used in applications where the volume surrounding the working end 42 of the probe 20 and tissue 120 is not filled with an electrically conductive

liquid (e.g., an irrigant fluid compartment surrounding the knee or shoulder joint). As a consequence, the embodiment shown in Fig. 19 can be used on tissue surfaces that are otherwise dry (e.g., the surface of the skin).

As shown in Figs. 19 and 20, electrically conductive fluid 122 is supplied through an annular space formed between cannula 118 and outer sleeve 116. Outer sleeve 116 may be an electrically insulating material (e.g., polyimide or polyethylene tubing), or a metallic tubular member covered by an electrically insulating sleeve 108 as described above. The electrically conductive fluid is caused to move along flow path 132 and exit the annular flow space at annular orifice 134. As shown in Fig. 19, the application of a voltage difference between the electrode terminal or electrodes 104 and the return electrode 112 causes current flow through the tissue 120 in region 126 and along the stream of electrically conductive fluid 122 to complete the electrical circuit. All other dimensions and materials of construction are the same as defined for the preceding embodiments. This embodiment is particularly useful for therapeutic contraction of collagen underlying the surface of the skin.

Referring now to Fig. 21, a surgical kit 300 for shrinking the collagen fibers of the joint capsular tissue according to the invention will now be described. As shown, surgical kit 300 includes a package 302 for housing a surgical instrument 304, and an instructions for use 306 of instrument 304. Package 302 may comprise any suitable package, such as a box, carton, wrapping, etc. In the exemplary embodiment, kit 300 further includes a sterile wrapping 320 for packaging and storing instrument 304. Instrument 304 includes a shaft 310 having at least one electrode terminal 312 at its distal end, and at least one connector (not shown) extending from electrode terminal 312 to the proximal end of shaft 310. The instrument 304 is generally disposable after a single procedure. Instrument 304 may or may not include a return electrode 316.

The instructions for use 306 generally includes the steps of adjusting a voltage level of a high frequency power supply (not shown) to effect a contraction of the collagen within the soft tissue at the target site, connecting the surgical instrument 304 to the high frequency power supply, positioning the electrode terminal 312 within electrically conductive fluid at or near the soft tissue at the target site, and activating the power supply to induce contraction of the collagen tissue. The voltage level is usually about 30 to 70 volts rms and preferably about 40 to 60 volts rms for surgical instruments having electrode diameters or principal dimensions of about 0.3 to about 0.4 mm and operating frequencies

of about 100 to 200 kHz. In the preferred embodiment, the positioning step includes introducing at least a distal portion of the instrument 304 through a portal into a joint.

The instructions for use 306 further includes the instruction of maintaining the instrument 304 in motion during application of RF current to achieve the maximum effect on the target tissue. The amount of thermal energy imparted by the electrode terminals to the tissue (and consequently the temperature of the tissue) will also depend on the time in which the electrodes are held in contact with or in close proximity to the tissue.

With the operating frequency and electrode configuration of the present invention, the surgeon should generally move the instrument transversely across the tissue at a relatively slow rate (e.g., usually about 0.1 to 5.0 cm/sec and preferably about 0.2 to 3 cm/sec) in order to ensure that the tissue is heated to a temperature within the target range of 60°C to 70°C, without applying too much thermal energy to the tissue.

Other modifications and variations can be made to disclose embodiments without departing from the subject invention as defined in the following claims. For example, it should be noted that the invention is not limited to an electrode array comprising a plurality of electrode terminals. The invention could utilize a plurality of return electrodes, e.g., in a bipolar array or the like. In addition, depending on other conditions, such as the peak-to-peak voltage, electrode diameter, etc., a single electrode terminal may be sufficient to form a heated plume of fluid that induces the contraction of collagen tissue.

Further, the electrode array may include both active and return electrodes. In this embodiment, the active and return electrodes are both located on a distal tissue treatment surface adjacent to each other. The active and return electrode may be located in active/return electrode pairs, or one or more return electrodes may be located on the distal tip together with a plurality of electrically isolated electrode terminals. The proximal return electrode may or may not be employed in these embodiments. For example, if it is desired to maintain the current flux lines around the distal tip of the probe, the proximal return electrode will not be desired.

Figs. 22-24 illustrate an alternative embodiment of an electrosurgical probe 400 according to the present invention. As shown in Fig. 22, probe 400 is similar to the previously described probes, having a shaft 402 with a proximal handle 404, an electrically insulating member 406 on the distal end portion of the shaft 402, and a return electrode 408 spaced proximally from insulating member 406. In this embodiment, probe 400

includes an electrode terminal in the shape of a planar disc 410 attached to the distal surface of the insulating member 406. The planar disc 410 functions as a single active electrode that distributed electrical energy substantially uniformly to the tissue.

As shown in Fig. 23, disc 410 may be attached to insulating member 406 in a variety of manners, such as adhesives or the like. In the exemplary embodiment, disc 410 is attached with adhesives 411 as described above, and with the electrical connectors coupling the disc 410 to the power supply (not shown). As shown in Fig. 22, disc 410 includes a plurality of holes 412 for receiving one or more electrical connectors 414 extending through probe shaft 402. The connectors 414 extend through a portion of the disc 410, preferably to the distal surface thereof without extending beyond the planar surface of disc 410. Connectors 414 are welded to disc 410 to enhance the bond between disc and insulating member 406.

Applicant has found another advantage with the exemplary embodiment shown in Fig. 22. The provision of multiple holes 412 in the planar disc 410 appears to create multiple edges in the disc that increases the current density around disc 410. This increased current density enables the probe 400 to provide increased thermal penetration of RF energy for the same level of voltage to improve the contraction of collagen tissue. Thus, the present invention allows improved tissue contraction with relatively low power levels, and in a bipolar modality that minimizes current flow beyond the target site into the patient's body. In the representative embodiment shown in Fig. 24, disc 410 will include a plurality of holes 412, i.e. about 5 to 30. Although disc 410 has a circular configuration in Fig. 24, it should be understood that other configurations are possible, such as oval, square, rectangular, etc. In this embodiment, a plurality of electrical connectors or electrode terminals 414 extend into some, but not all, of the holes 412. Preferably, these terminals 414 extend into the peripheral holes 414, as shown in Fig. 24. This arrangement tends to increase the current densities near the periphery of disc 410. Applicant has found through experiment that increasing the current densities near the periphery of disc 410 tends to increase the current penetration into the tissue and, thus, increase the visual shrinkage effect for a given voltage level.

Fig. 25 illustrates yet another embodiment of an electrosurgical system 440 incorporating a dispersive return pad 450 attached to the electrosurgical probe 400. In this embodiment, the invention works in a monopolar modality in which a high frequency voltage difference is applied between the active electrode, disc 410, and the dispersive

return pad 450. In the exemplary embodiment, the pad 450 and the probe 400 are coupled together, and are both disposable, single-use items. The pad 450 includes an electrical connector 452 that extends into handle 404 of probe 400 for direct connection to the power supply. Of course, the invention would also be operable with a standard return pad that connects directly to the power supply. In this embodiment, the power supply 460 will include a switch, e.g., a foot pedal 462, for switching between the monopolar and bipolar modes. In the bipolar mode, the return path on the power supply is coupled to return electrode 408 (see Fig. 22), as described above. In the monopolar mode, the return path on the power supply is coupled to connector 452 of pad 450 and return electrode 408 is decoupled from the electrical circuit. This allows the surgeon to switch between bipolar and monopolar contraction modes during, or prior to, the surgical procedure. In some cases, it may be desirable to operate in the monopolar mode to provide deeper current penetration and, thus, a greater visual shrinkage effect for the surgeon. In other cases, the bipolar modality may be preferable to limit the current penetration to the tissue.

In one configuration, the dispersive return pad 450 is adapted for coupling to an external surface of the patient in a region substantially close to the target region. For example, during capsular shrinkage of the shoulder joint, the dispersive return pad is designed and constructed for placement in or around the patient's shoulder. This design limits the current path through the patient's body to the shoulder area, which minimizes the damage that may be generated by unwanted current paths in the patient's body. The return pad is also designed to minimize the current densities at the pad, to thereby minimize patient skin burns in the region where the pad is attached.

Fig. 26 illustrates another embodiment of an electrosurgical probe 400 comprising a shaft 402 with a handle 404 attached to its proximal end, and an electrically insulating electrode support member 406 at the distal end of the shaft 402. Probe 400 further includes a shrink wrapped insulating sleeve 403 over shaft 402, and exposed portion of shaft 402 that functions as the return electrode 408. In the representative embodiment, probe 400 comprises a single active electrode 410 coupled to the distal end of support member 406. As shown, return electrode 408 is spaced a further distance from active electrode 410 than in the embodiments described above. In this embodiment, the return electrode 408 is spaced a distance of about 2.0 to 100 mm, preferably about 5 to 50 mm and more preferably about 10 to 30 mm, from active electrode 410. In addition, return electrode 408 has a larger exposed surface area than in previous embodiments,

having a length in the range of about 2.0 to 40 mm, preferably about 5 to 20 mm. Accordingly, electric current passing from active electrode 410 to return electrode 408 will follow a current flow path (not shown) that is further away from shaft 402 and active electrode 410 than in the previous embodiments. In some applications, this current flow path results in a deeper current penetration into the surrounding tissue with the same voltage level, and thus increased thermal heating and increased depth of tissue contraction. As discussed above, this increased thermal heating may have advantages in some applications of collagen shrinkage.

In one application, the present invention is used for shrinkage of the shoulder joint capsule to provide joint stability. In this application, it is typically desired to achieve a tissue temperature in the range of about 55°C to 70°C to a depth of about 0.5 to 5 mm, usually about 1 to 2 mm. The voltage required for this thermal heating will partly depend on the electrode configurations, the frequency of the voltage, the conductivity of the tissue and the area immediately surrounding the electrodes, the time period in which the voltage is applied and the depth of tissue contraction desired. With the electrode configuration described in Fig. 26, the voltage level for thermal heating will usually be in the range of about 20 to 300 volts rms, preferably about 20 to 100 volts rms. The peak-to-peak voltages for thermal heating with a square wave form having a crest factor of about 2 are typically in the range of about 40 to 600 volts peak-to-peak, preferably about 40 to 200 volts peak-to-peak. The higher the voltage is within this range, the less time required. If the voltage is too high, however, the surface tissue may be vaporized, debulked or ablated, which is undesirable.

In alternative embodiments, the electrosurgical system used in conjunction with probe 400 may include a dispersive return electrode 450 (see Fig. 25) for switching between bipolar and monopolar modes. In this embodiment, the system will switch between a bipolar, where the dispersive pad 450 is deactivated and voltage is applied between active and return electrodes 410, 408, and a monopolar mode, where the return electrode 408 is deactivated and voltage is applied between the dispersive pad 450 and the active electrode 410. In the bipolar mode, the electric current will not penetrate as deeply into the tissue as in the monopolar mode, resulting in less thermal heating and less tissue contraction.

Fig. 27 illustrates an alternative embodiment of an electrosurgical probe 400 having a return electrode 408 configured similar to previous embodiments, and a second

return electrode 430 spaced distally from return electrode 408. In this embodiment, the system can be toggled between at least two modes: (1) a first mode where return electrode 430 is deactivated and voltage is applied between active electrode 410 and return electrode 408; and (2) a second mode where return electrode 408 is deactivated and voltage is applied between active electrode 410 and return electrode 430. In the first mode, the return electrode 408 has less exposed surface area than return electrode 430, and is closer to active electrode 410. Accordingly, the electric current will not penetrate the tissue as deeply in the first mode as in the second mode. This allows the surgeon to select the current penetration and thus the depth and strength of thermal heating, either before or during the procedure.

In the representative configuration, return electrode 408 is spaced about 0.2 to 20 mm, preferably about 1 to 5 mm from active electrode 410, and has an exposed length of about 0.5 to 10 mm, preferably about 2 to 5 mm. This configuration, with the voltage levels described above, will typically result in current penetration in the range of about 0.2 to 1.0 mm into the tissue. Return electrode 430 is spaced about 2.0 to 100 mm, preferably about 5 to 50 mm and more preferably about 20 to 30 mm, from active electrode 410, and has an exposed length in the range of about 2.0 to 40 mm, preferably about 5 to 20 mm. This configuration, with the voltage levels described above, will typically result in current penetration of about 0.5 to 5.0, usually about 2 to 4 mm into the tissue. Of course, a wide variety of embodiments are possible, including those with more than two return electrodes spaced along shaft 402, or various degrees of spacing and exposed length to vary the depth of current penetration.

Figs. 28-31 illustrate an exemplary embodiment having a dome-shaped active electrode 410 and a return electrode 408 with spacing and exposed lengths similar to the embodiment in Fig. 26. In this embodiment, active electrode 410 comprises a hollow, dome-shaped screen 440 having a plurality of openings 442 of varying diameters, typically in the range of about 0.01 to 0.1 mm. As shown in Figs. 29 and 31, probe 400 includes a cylindrical electrode support member 460 having a main body 462 with a diameter substantially equal to the diameter of shaft 402, and front and rear extensions 464, 466, respectively, with a slightly diameters than main body 462. Front extension 464 functions as a hub for mounting active electrode 410 onto support member 460, and rear extension functions as a hub for mounting support member 460 to shaft 402. In the preferred configuration, support member 460 includes a plurality of holes 468 for receiving

electrical connectors (not shown). The electrical connectors couple active electrode 410 to power supply 28. As shown in Fig. 29, the electrical connectors have distal ends 470 that are slightly larger than openings 442 in active electrode 410 to both electrically couple active electrode 410 to power supply 28, and to help fix electrode 410 to electrode support
5 460.

Dome-shaped active electrode 410 has a substantially irregular surface with a plurality of holes or distal connector ends 470 protruding therefrom. These irregularities (i.e., holes and protrusions) create multiple edges on the surface of electrode 410 that increase the current densities around electrode 410. This increased current density enables
10 the probe 400 to provide increased thermal penetration of RF energy for the same level of voltage to improve the contraction of collagen tissue. Thus, the present invention allows improved tissue contraction with relatively low power levels, and in a bipolar modality that minimizes current flow beyond the target site into the patient's body. In addition, the dome-shape of electrode 410 allows the surgeon to access target areas with less
15 manipulation of the probe 400, which is advantageous in arthroscopy procedures.

WHAT IS CLAIMED IS:

1. An apparatus for applying high frequency electrical energy to a tissue structure at a target site on a patient comprising:
- 5 an electrosurgical instrument having a shaft with a proximal end portion and a distal end portion;
- an active electrode on the distal end portion of the shaft;
- a dispersive return electrode on the shaft spaced proximally from the active electrode, the return electrode being sized relative to the active electrode and spaced from
- 10 the active electrode a sufficient distance such that, when the active and return electrodes are submersed in electrically conductive fluid and a high frequency voltage difference is applied between the active and return electrodes, the electric fields immediately surrounding the active electrode and the tissue structure are substantially unaffected by the presence of the return electrode;
- 15 an electrically insulating member between the active and return electrodes;
- and
- one or more connectors coupled to the active and return electrodes for connecting the electrodes to a high frequency power source.
2. The apparatus of claim 1 wherein the return electrode comprises an annular electrode on the shaft and has an exposed length in the range of about 5 to 20 mm.
3. The apparatus of claim 1 wherein the return electrode is spaced a distance of about 5 to 50 mm from the active electrode.
- 25 4. The apparatus of claim 1 wherein the return electrode is spaced a distance of about 10 to 30 mm from the active electrode.
5. The apparatus of claim 1 wherein the active electrode comprises a plurality of electrode terminals at the distal end of the shaft.
- 30 6. The apparatus of claim 1 wherein the active electrode comprises a single electrode having a hemispherical surface.

7. The system of claim 1 wherein the voltage is selected to heat the tissue to a temperature sufficient to cause contraction of the collagen fibers within the tissue.

5

8. The system of claim 7 wherein the voltage is selected to heat the collagen fibers to a temperature of about 45°C to 70°C.

9. The system of claim 1 further comprising a second return electrode positioned on the shaft between the dispersive return electrode and the active electrode, a connector for coupling the second return electrode to the high frequency power source, and a switch for switching between the second return electrode and the dispersive return electrode.

10. The system of claim 1 wherein the active electrode comprises a screen having a plurality of openings.

11. The system of claim 1 wherein the active electrode comprises a disc having a substantially planar distal surface, wherein the disc has at least two holes, the instrument further comprising at least two connectors extending through the shaft and at least partially through the holes in the disc to electrically couple the disc to a high frequency power supply.

12. The system of 1 wherein the active electrode comprises a dome-shaped member having at least two holes, the instrument further comprising at least two connectors extending through the shaft and at least partially through the holes in the domed-shaped member to electrically couple the active electrode to a high frequency power supply.

13. An electrosurgical system for applying electrical energy to tissue at a target site on or within a patient's body comprising:

an electrosurgical probe having a shaft with proximal and distal ends, an active electrode at or near the distal end, and a return electrode spaced from the active

electrode;

a dispersive return pad having an electrical connector attached directly to the electrosurgical probe; and

5 a high frequency electrosurgical power supply having an active terminal coupled to the active electrode and a return terminal, wherein the probe includes an electrical connection for coupling either the return electrode or the dispersive return pad to the return terminal of the power supply.

10 14. The system of claim 13 further comprising a switch for alternatively coupling and decoupling the dispersive return pad and the return electrode to the return terminal on the power supply.

15 15. The system of claim 13 wherein the power supply is configured to apply a high frequency voltage difference between the active and return electrodes in the presence of electrically conductive fluid, the voltage difference being sufficient to contract collagen fibers in the tissue adjacent the active electrode.

20 16. A method for applying electrical energy to tissue at a target site comprising:
positioning an active electrode adjacent to a tissue structure at the target site in the presence of electrically conductive fluid;
positioning a dispersive return electrode within the electrically conductive fluid and spaced from the active electrode;
25 applying a high frequency voltage difference between the active and return electrode to modify the tissue structure; and
locating the dispersive return electrode relative to the active electrode and the tissue structure such that the electric fields between the active electrode and the tissue structure are substantially unaffected by the presence of the return electrode.

30 17. The method of claim 16 wherein the return electrode comprises an annular electrode on the instrument shaft and has an exposed length in the range of about 1 to 20 mm.

18. The method of claim 16 wherein the return electrode is located such that the active electrode is positioned between the return electrode and the tissue structure and the return electrode is spaced a distance of about 10 to 30 mm from the active electrode.

5

19. The method of claim 16 wherein the voltage is selected to heat the tissue structure to a temperature sufficient to cause contraction of the collagen fibers within the tissue.

10

20. The method of claim 16 wherein the voltage is selected to heat the collagen fibers to a temperature of about 45°C to 70°C.

21. The method of claim 16 wherein the voltage is selected to ablate the tissue structure.

15

22. The method of claim 16 wherein the return electrode is positioned to confine the electric currents within the general body area of the target site.

20

23. The method of claim 16 further comprising positioning a second return electrode within the electrically conductive fluid, and applying a high frequency voltage difference between the second return electrode and the active electrode, wherein the return electrodes and the active electrode are all located on a shaft of an electrosurgical instrument.

25

24. The method of claim 23 wherein the return electrodes are axially spaced from each other and the active electrode.

30

25. The method of claim 23 further comprising:
applying a high frequency voltage difference between the active electrode and the dispersive return electrode such that electric currents flow from the active electrode, through a portion of the tissue structure and the electrically conductive fluid, to the dispersive return electrode; and

applying a high frequency voltage difference between the active electrode a

second return electrode positioned between the dispersive return electrode and the active electrode such that electric currents flow from the active electrode, through a portion of the tissue structure and the electrically conductive fluid, to the second return electrode, wherein the electric currents flow deeper into the tissue structure when flowing between
5 the dispersive return electrode and the active electrode than when flowing between the second return electrode and the active electrode.

26. A method for shrinking collagen tissue within a joint capsule comprising:

10 submersing collagen tissue within a joint capsule in electrically conductive fluid;

positioning an active electrode through a portal into the joint adjacent to a tissue structure;

15 contacting the electrically conductive fluid with a dispersive return electrode having greater than an exposed surface area of the active electrode and being spaced at least 10 mm from the active electrode; and

applying a sufficient high frequency voltage difference between the active and return electrodes to shrink collagen tissue within the tissue structure.

20 27. The method of claim 26 further comprising restricting current flow to the region of the joint capsule.

28. A system for contracting collagen tissue at a target site on or within a patient's body comprising:

25 an electrosurgical instrument having a shaft with a proximal end portion, a distal end portion and an active electrode on the distal end portion of the shaft;

a dispersive return electrode on the shaft spaced proximally from the active electrode, wherein the return electrode has an exposed surface area larger than the exposed surface area of the active electrode, and the return electrode is axially spaced at least about
30 10 mm from the active electrode; and

a high frequency power supply coupled to the active and return electrodes for applying a high frequency voltage difference therebetween sufficient to contract collagen tissue.

29. A method for contracting collagen tissue at a target site on or within a patient's body comprising:

5 positioning an active electrode adjacent to or in contact with a tissue structure at target site in the presence of electrically conductive fluid;

positioning one or more return electrodes within the electrically conductive fluid;

10 applying a high frequency voltage difference between the active and return electrodes such that a high frequency current flows from the active electrodes through the tissue structure at the target site and, through the electrically conductive fluid to the return electrodes; and

15 spacing the return electrode from the active electrodes such that a sufficient high frequency current flows into the tissue structure to induce contraction of collagen fibers at least about 1.0 mm beyond the surface of the tissue structure without causing molecular dissociation of tissue cells at the surface of the tissue structure.

30. The method of claim 29 further comprising spacing the return electrode from the active electrode such that a sufficient high frequency current flows into the tissue structure to induce contraction of collagen fibers at least about 1.5 mm beyond the surface of the tissue structure without causing molecular dissociation of tissue cells at the surface of the tissue structure.

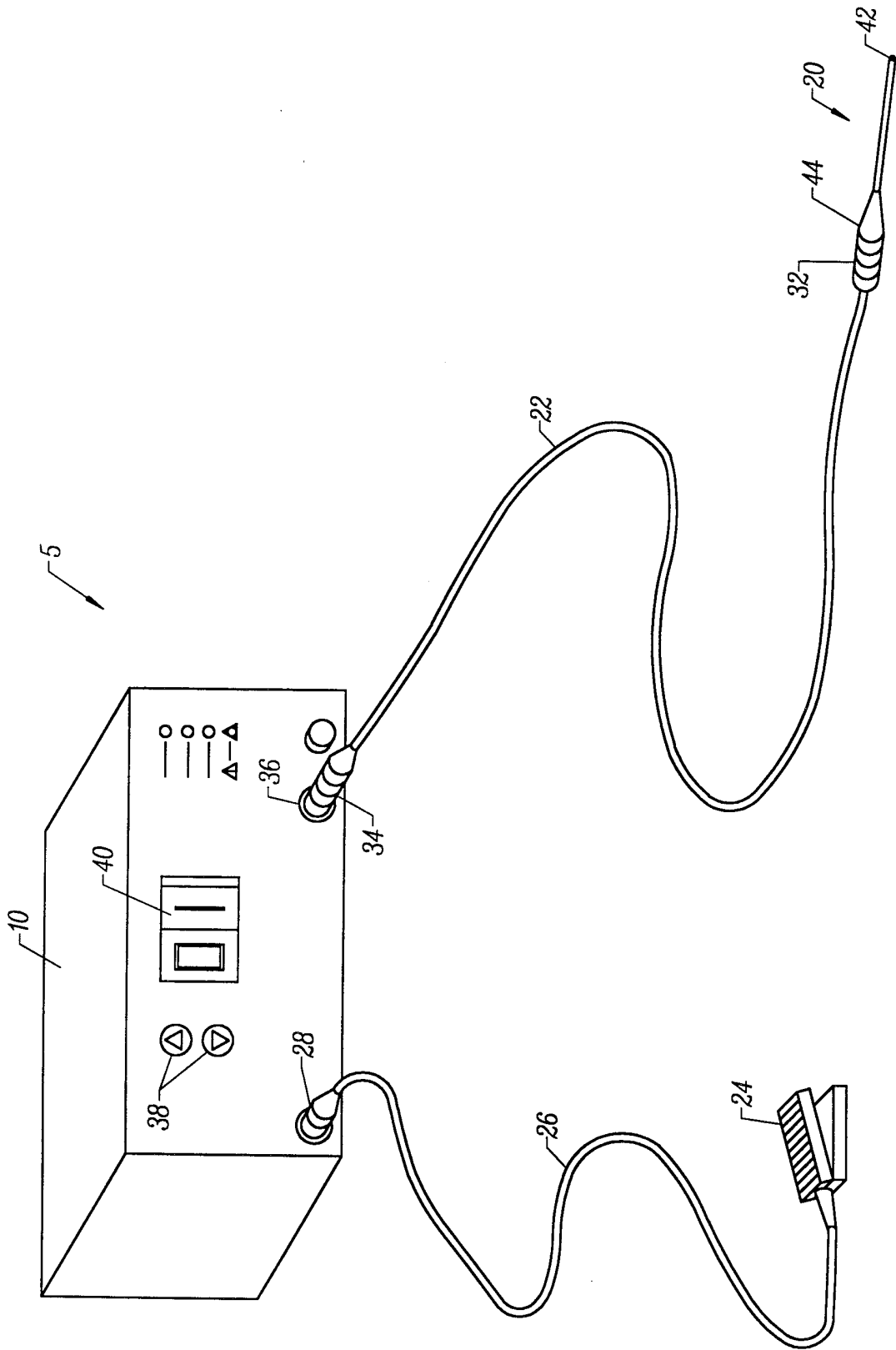


FIG. 1

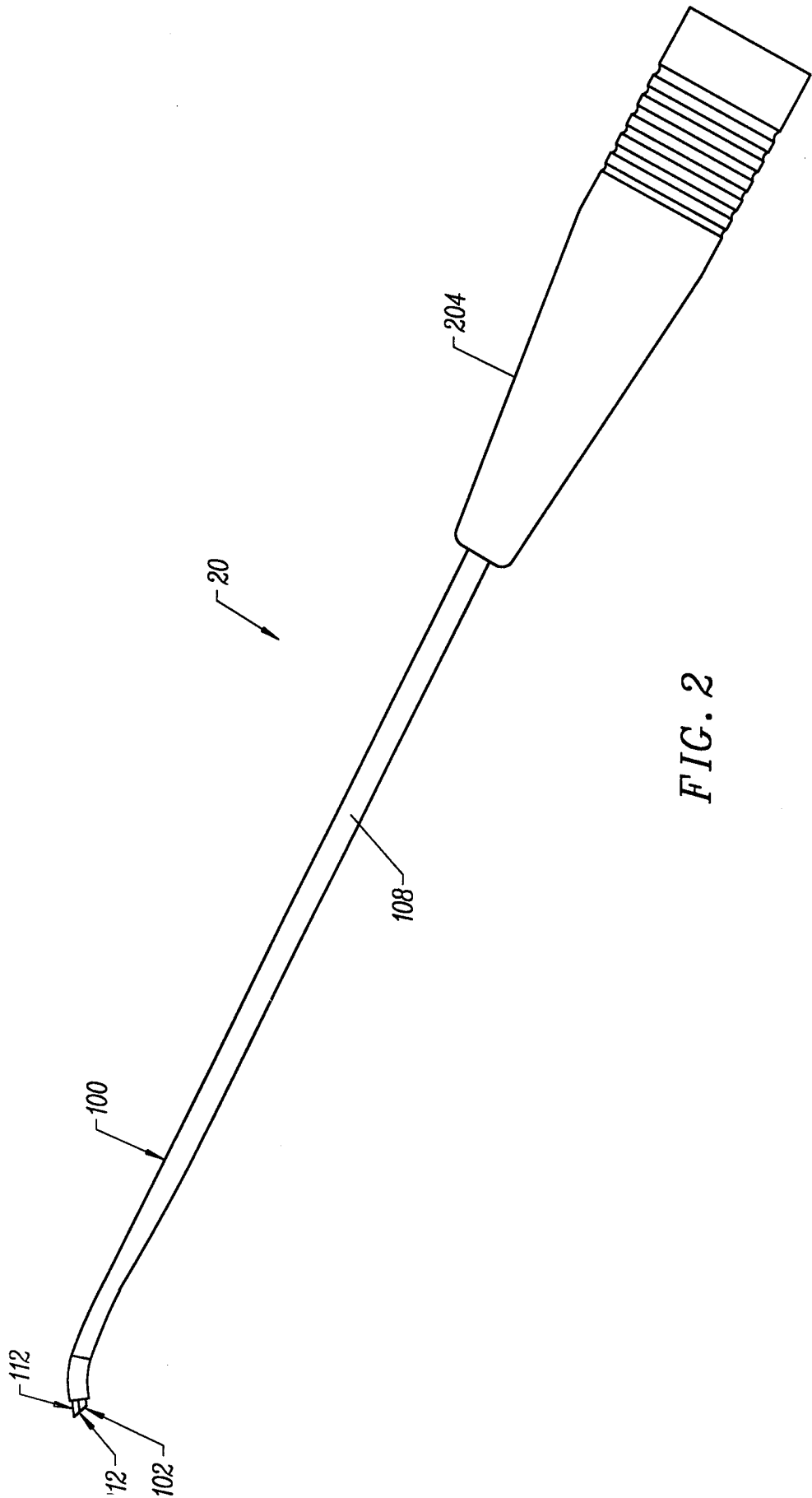


FIG. 2

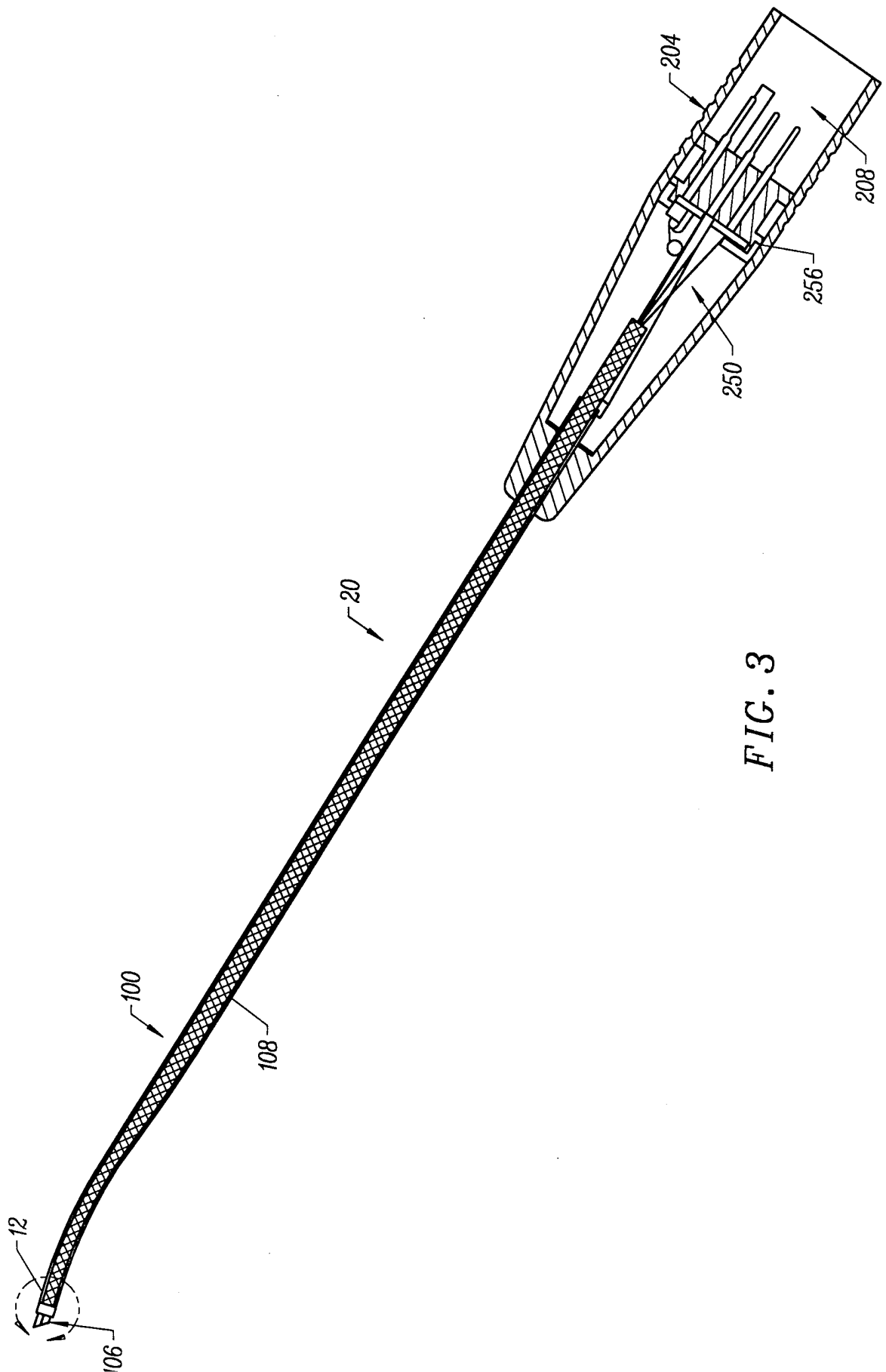


FIG. 3

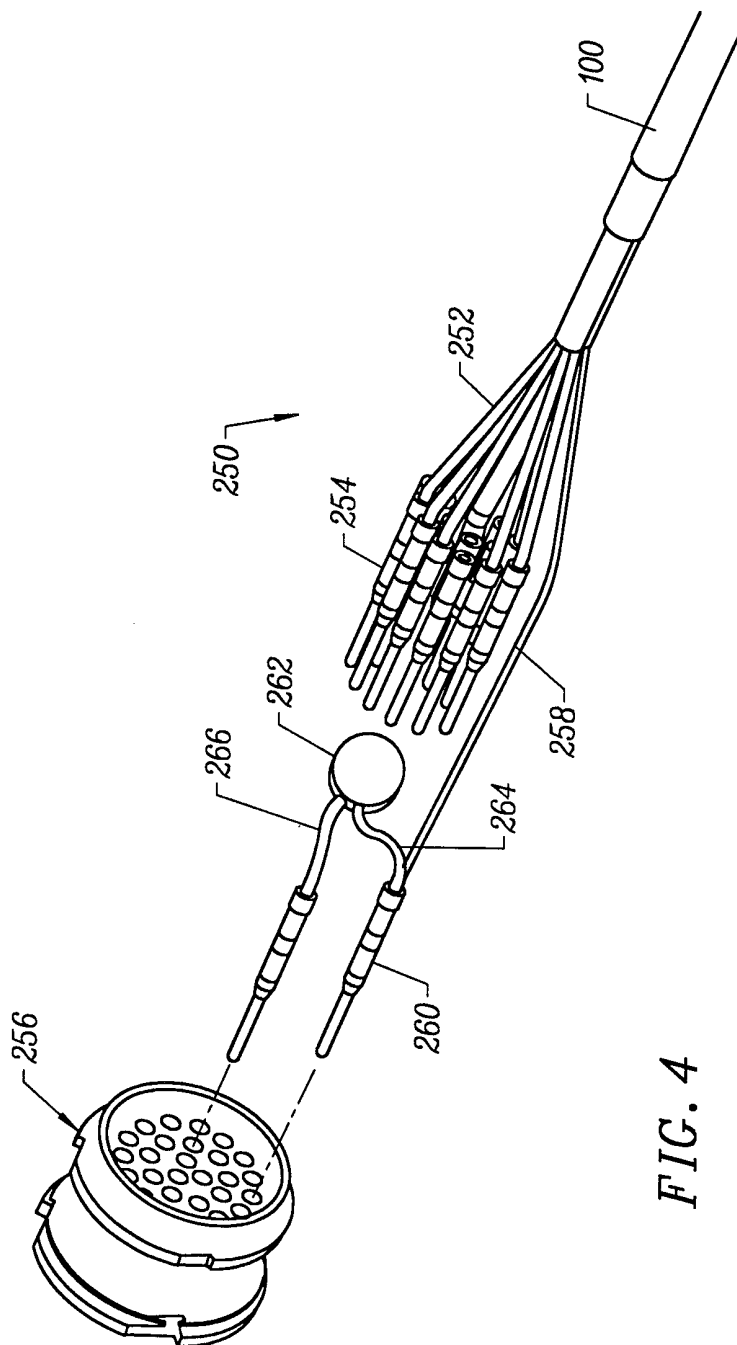


FIG. 4

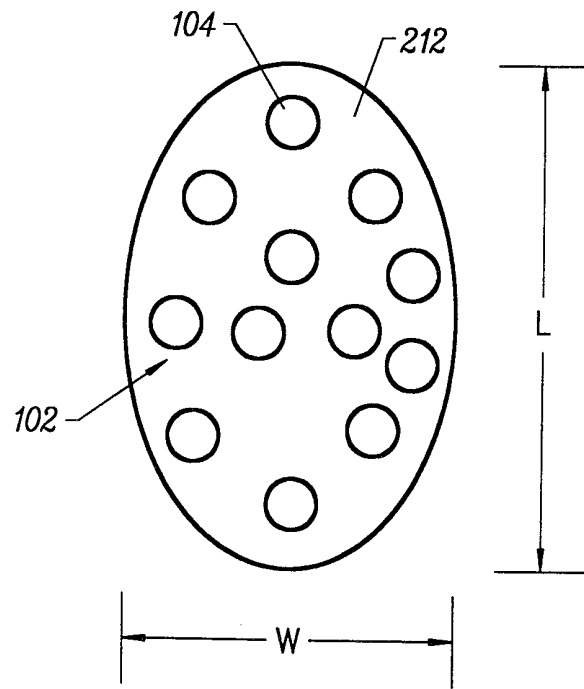


FIG. 5

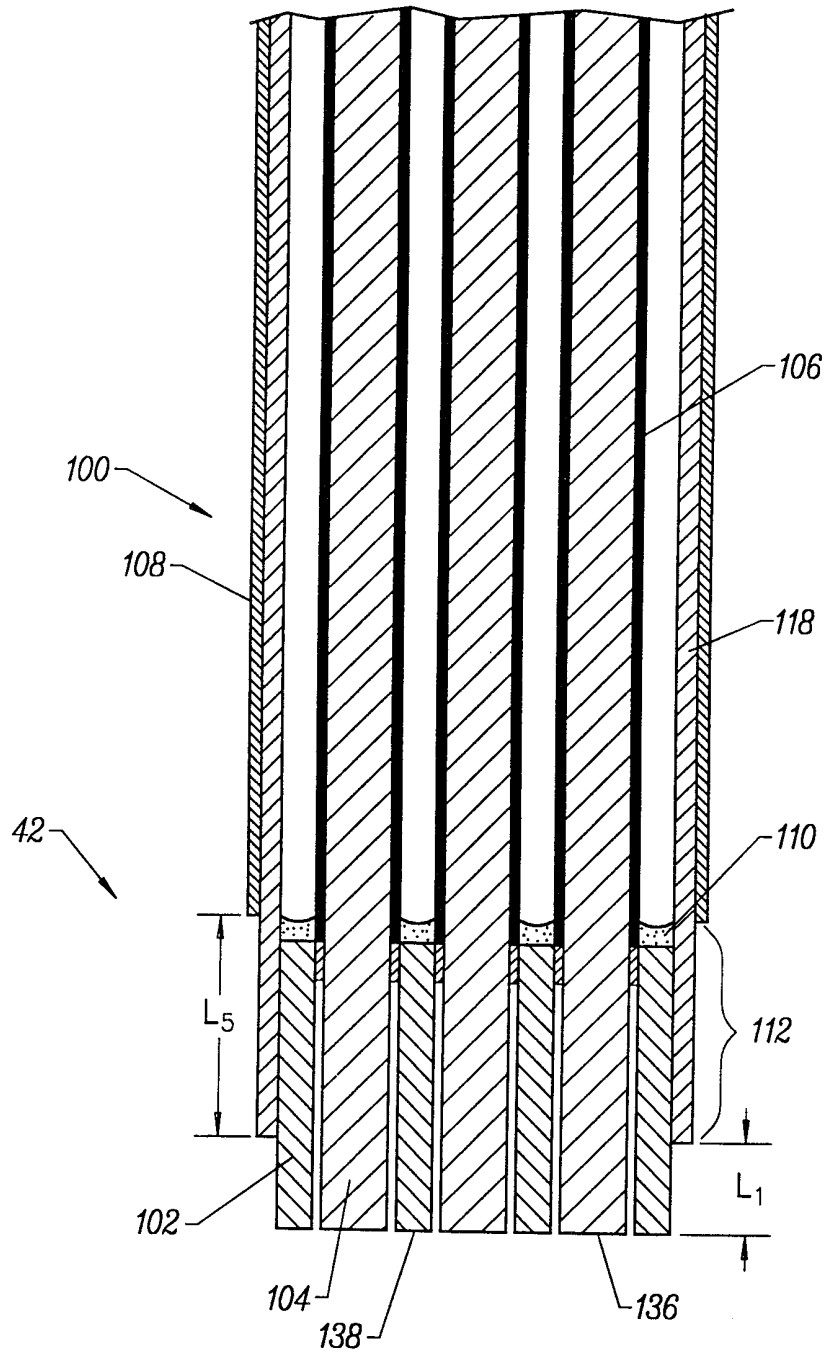


FIG. 6

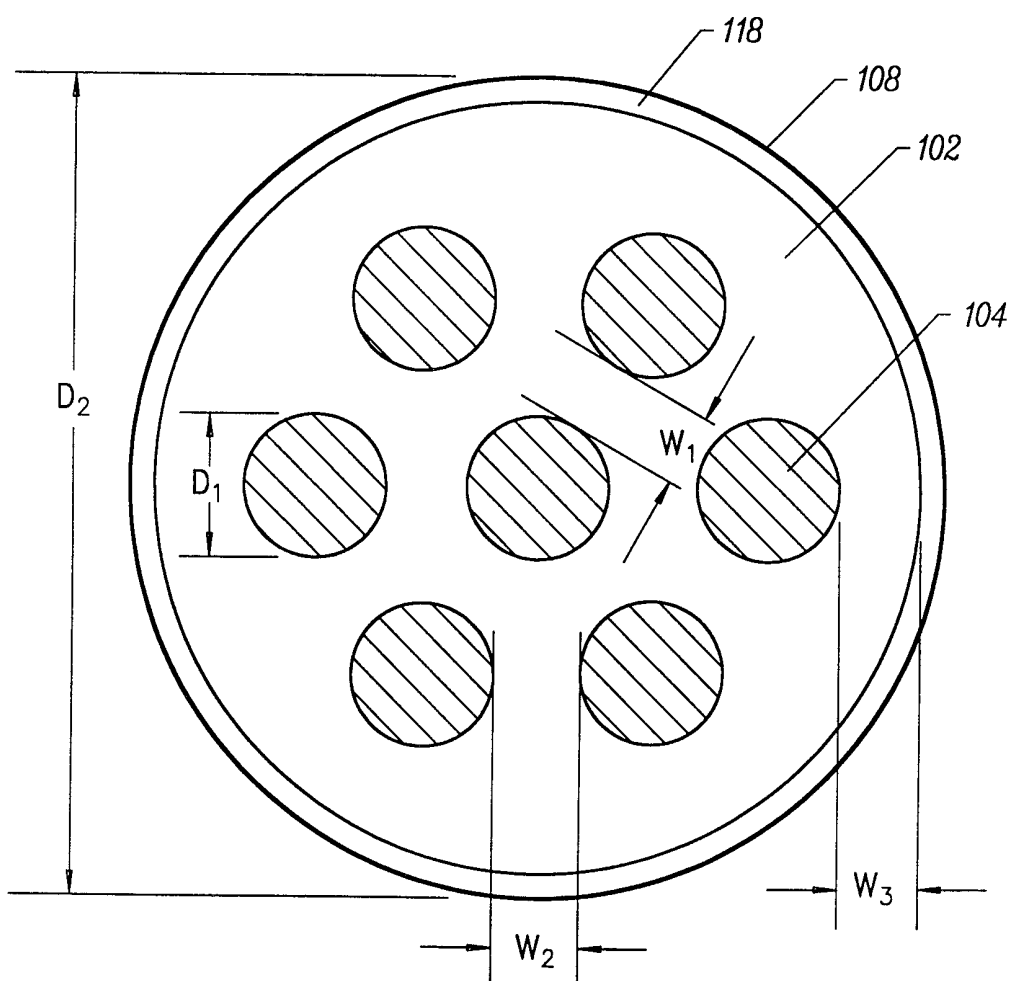


FIG. 7

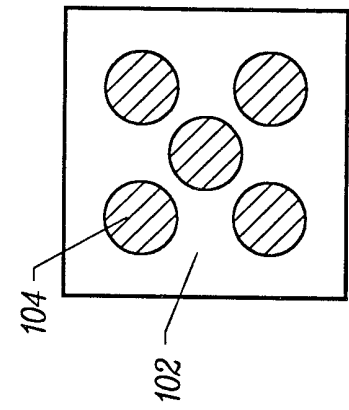


FIG. 8B

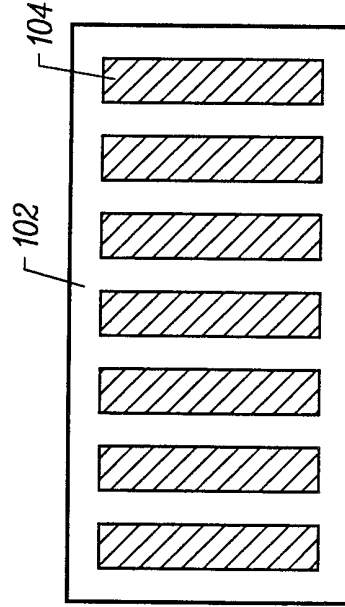


FIG. 8D

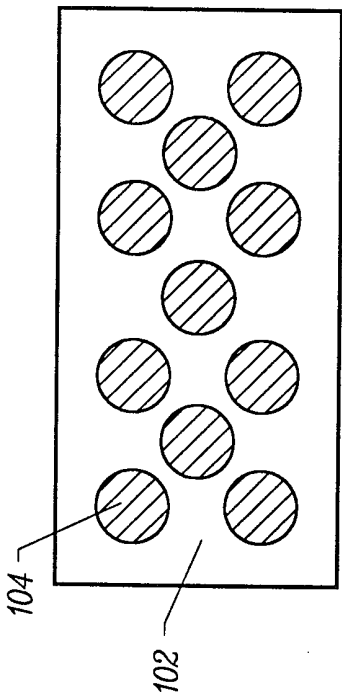


FIG. 8A

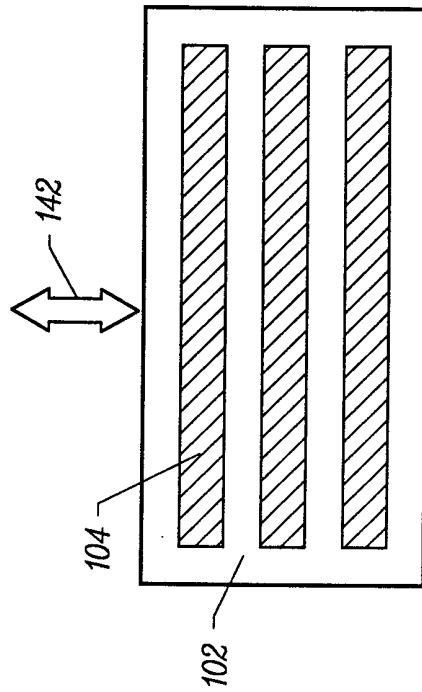


FIG. 8C

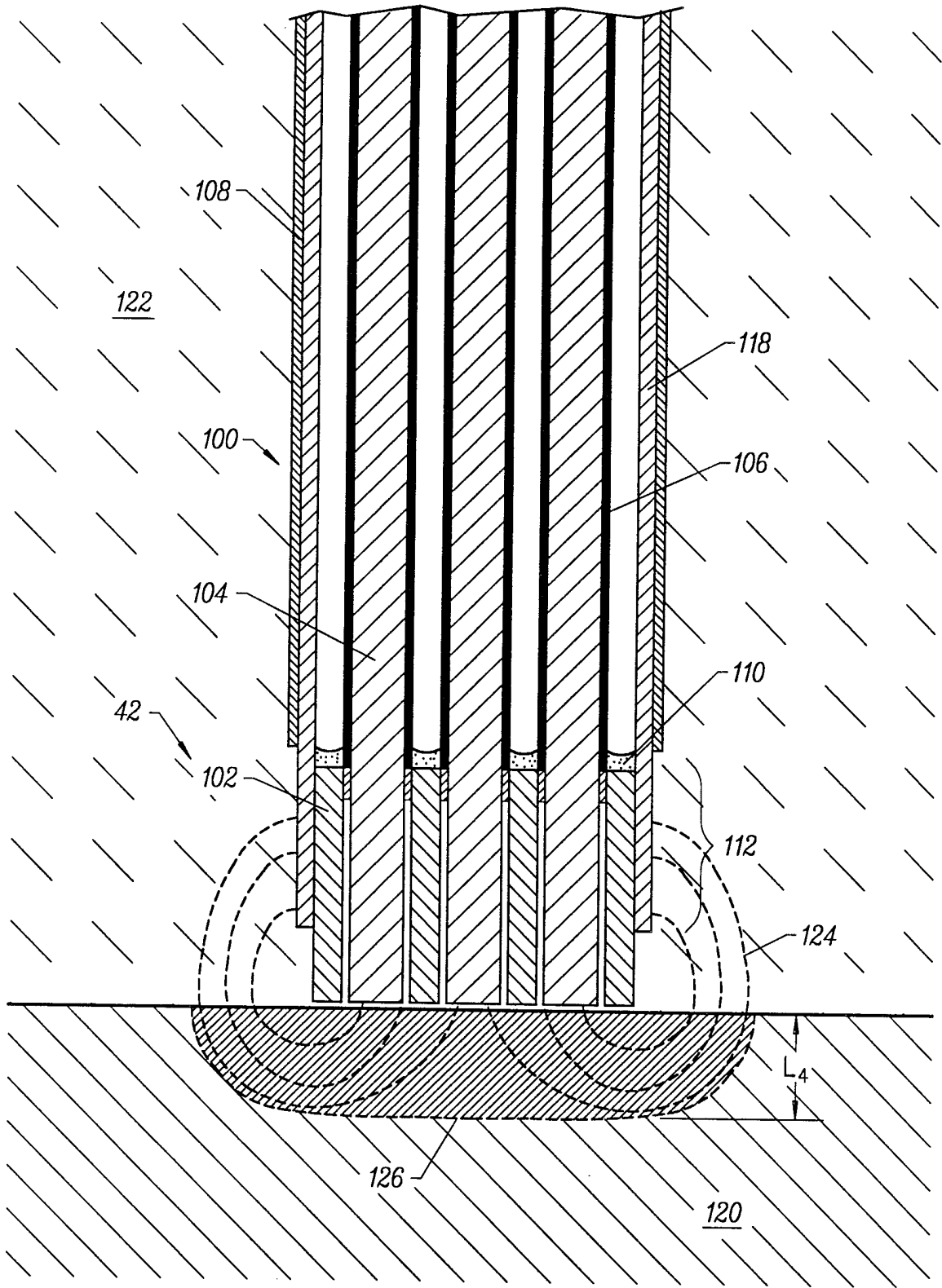


FIG. 9

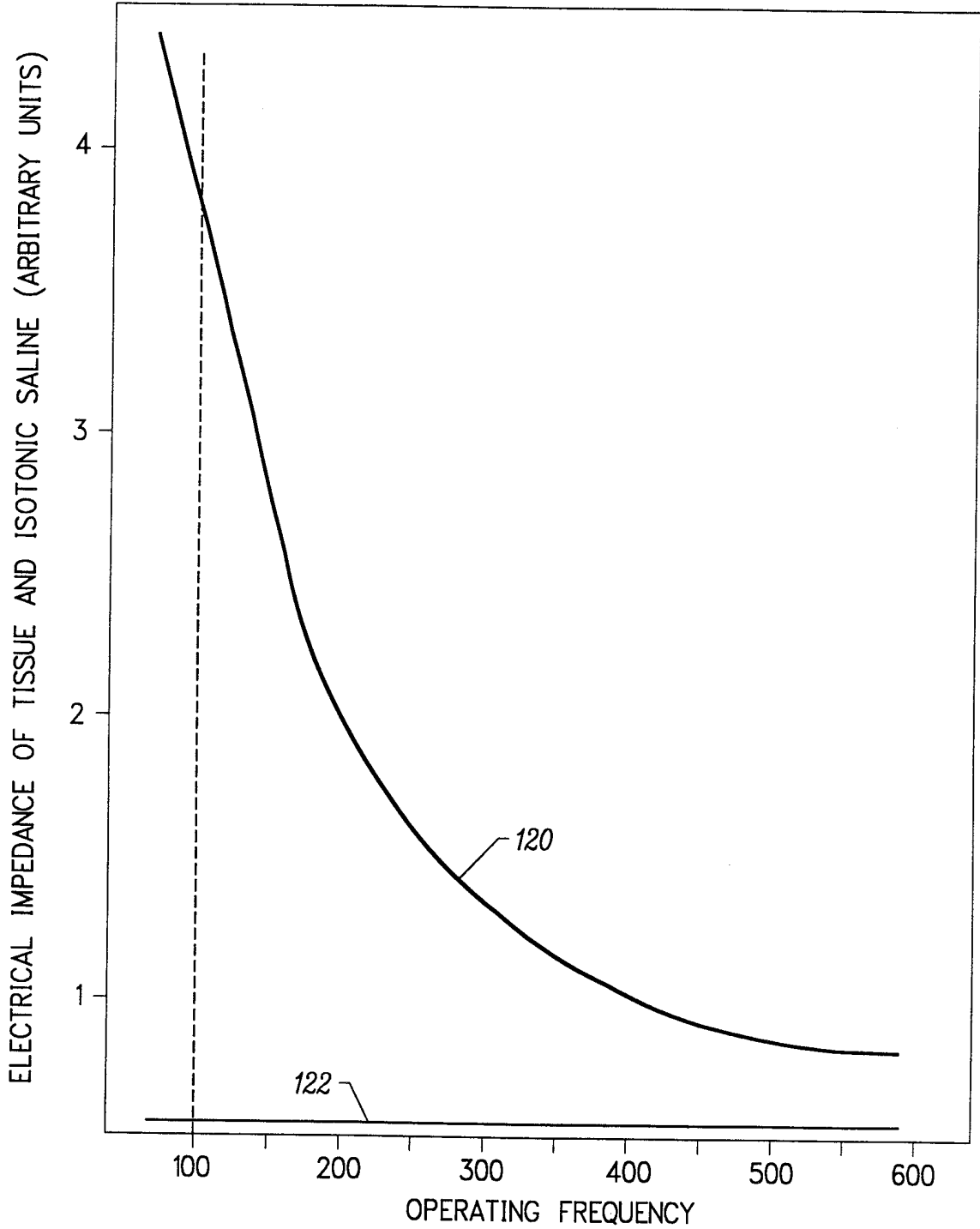


FIG. 10

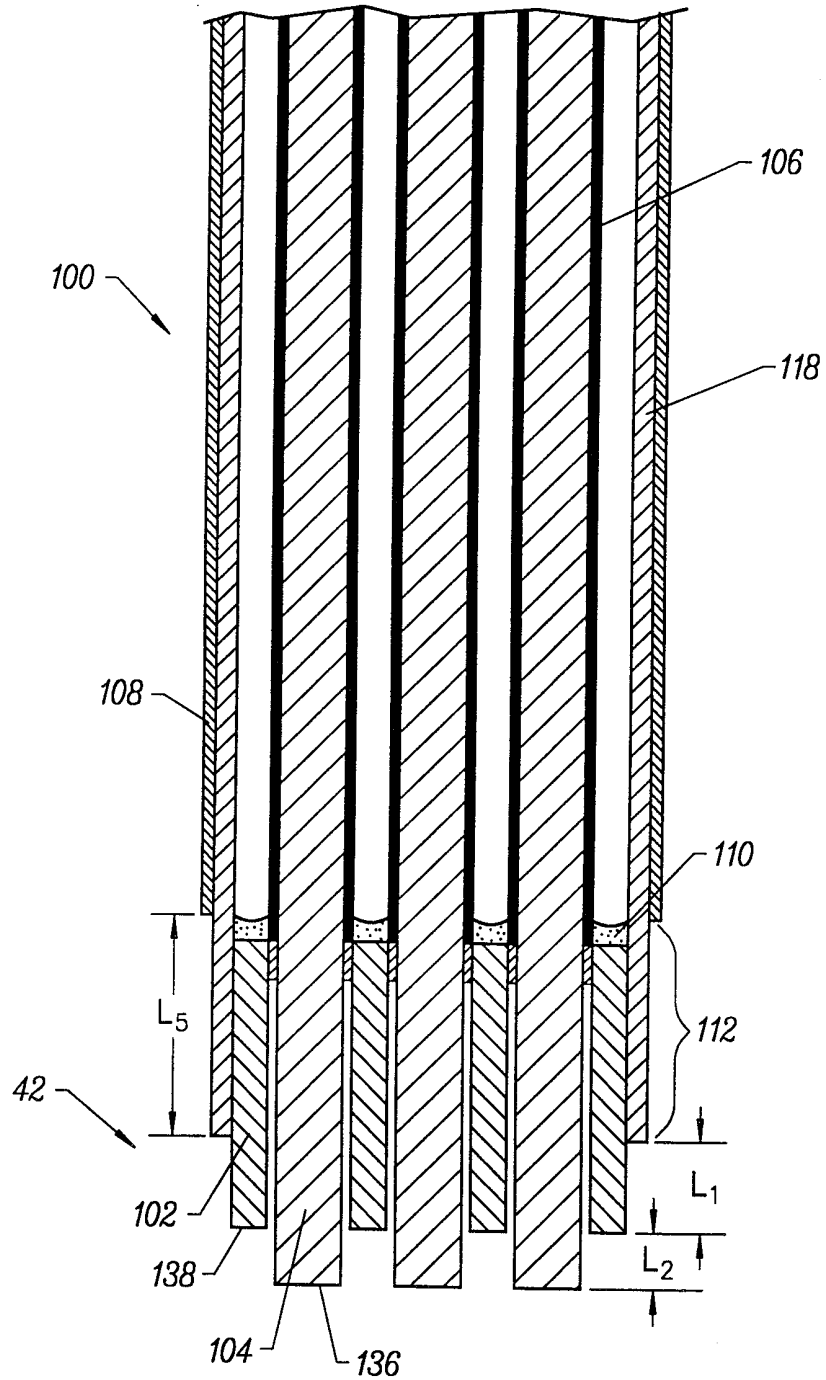


FIG. 11

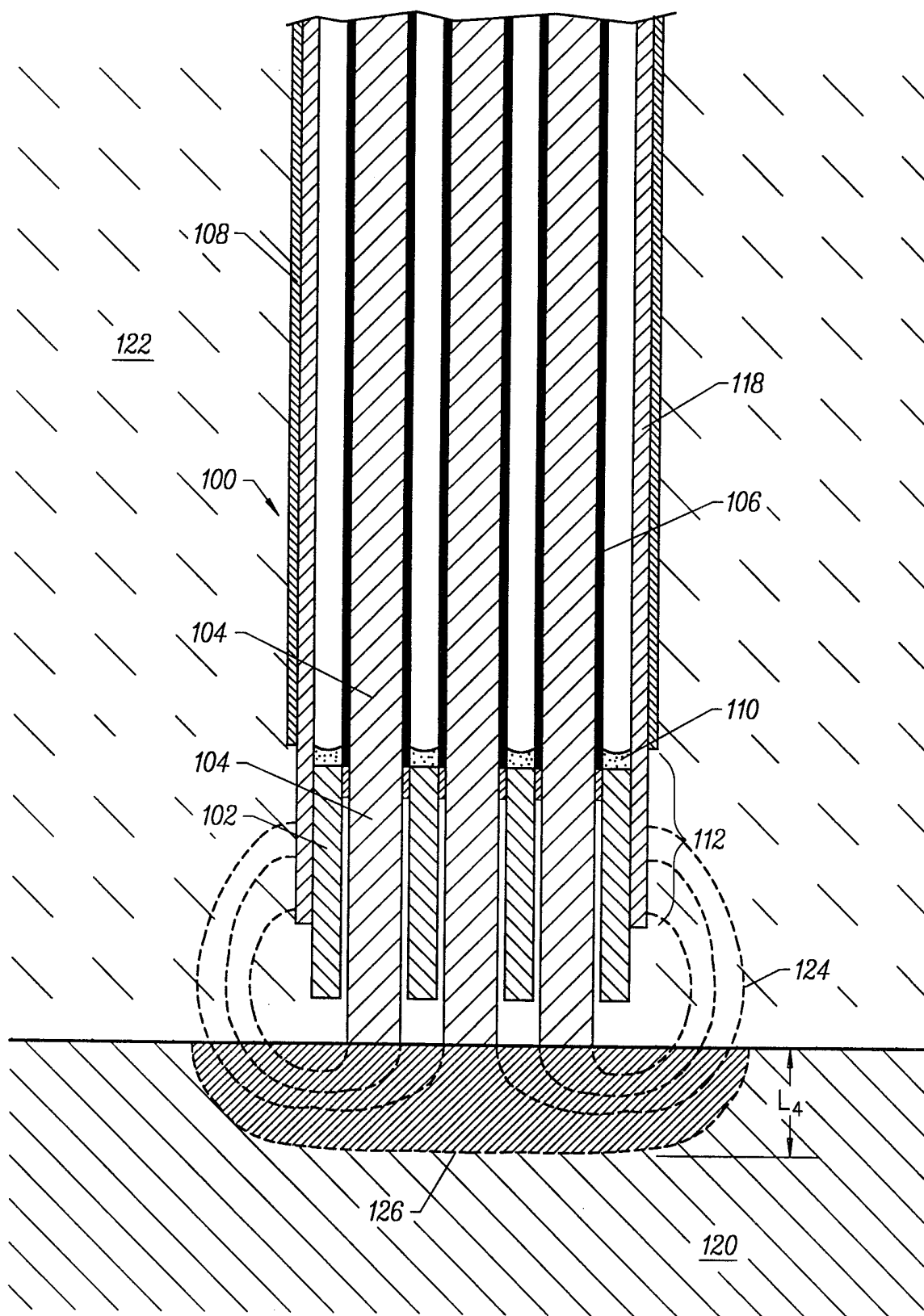


FIG. 12

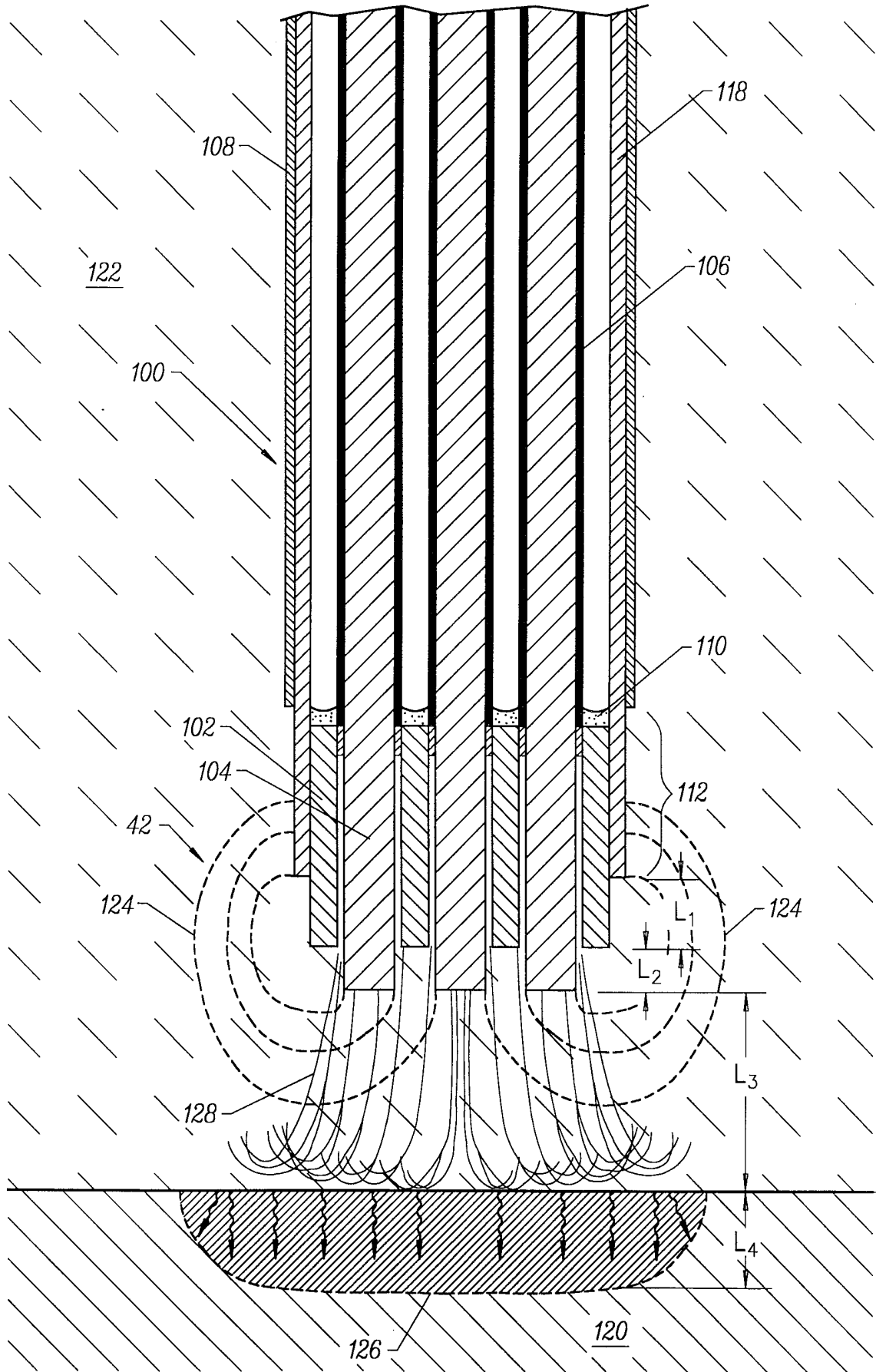


FIG. 13

SUBSTITUTE SHEET (RULE 26)

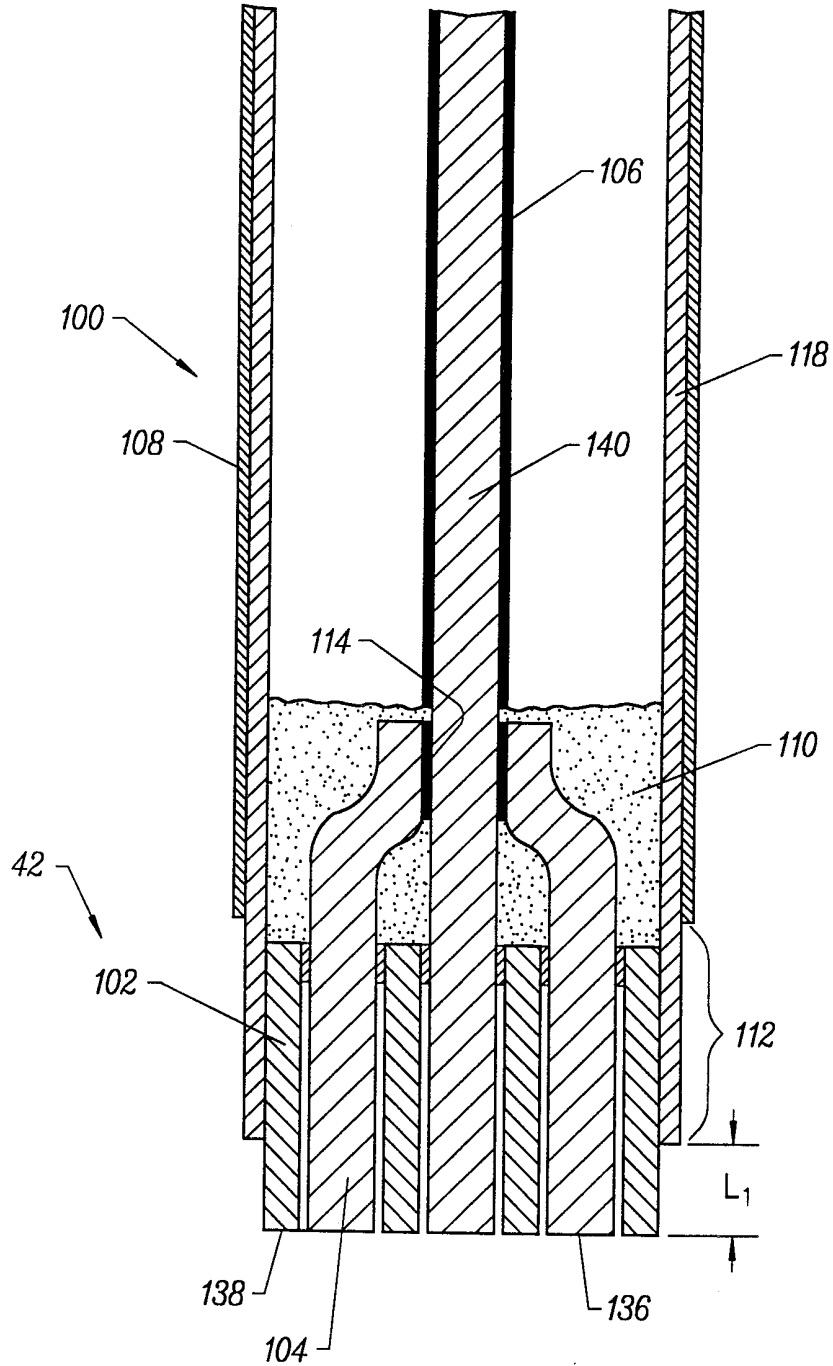


FIG. 14

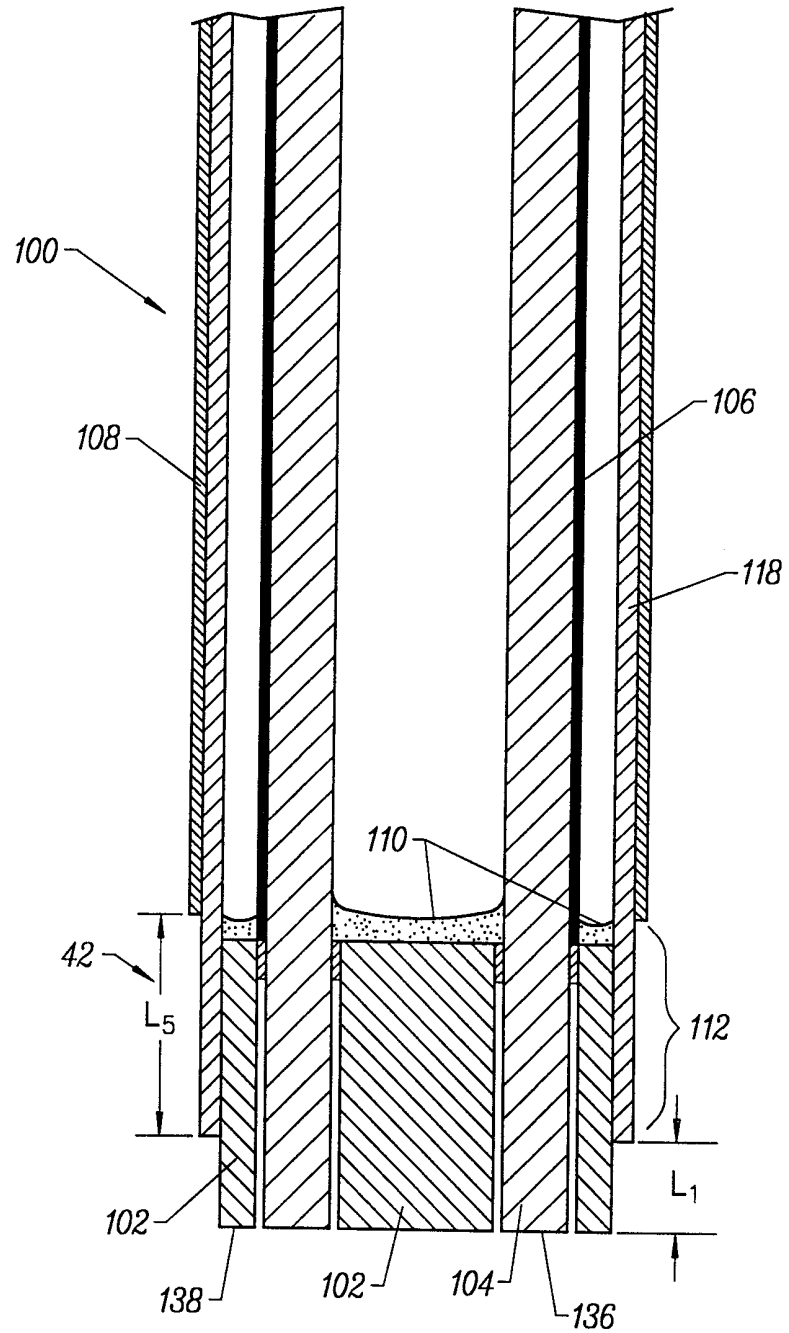


FIG. 15

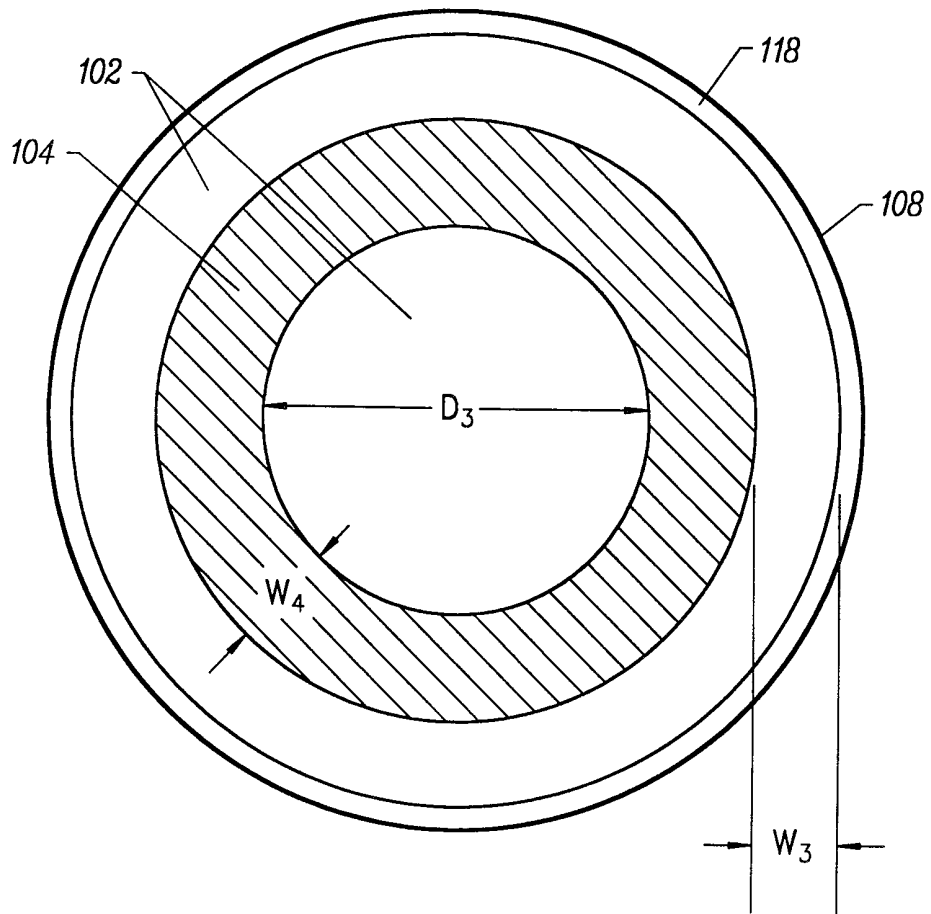


FIG. 16

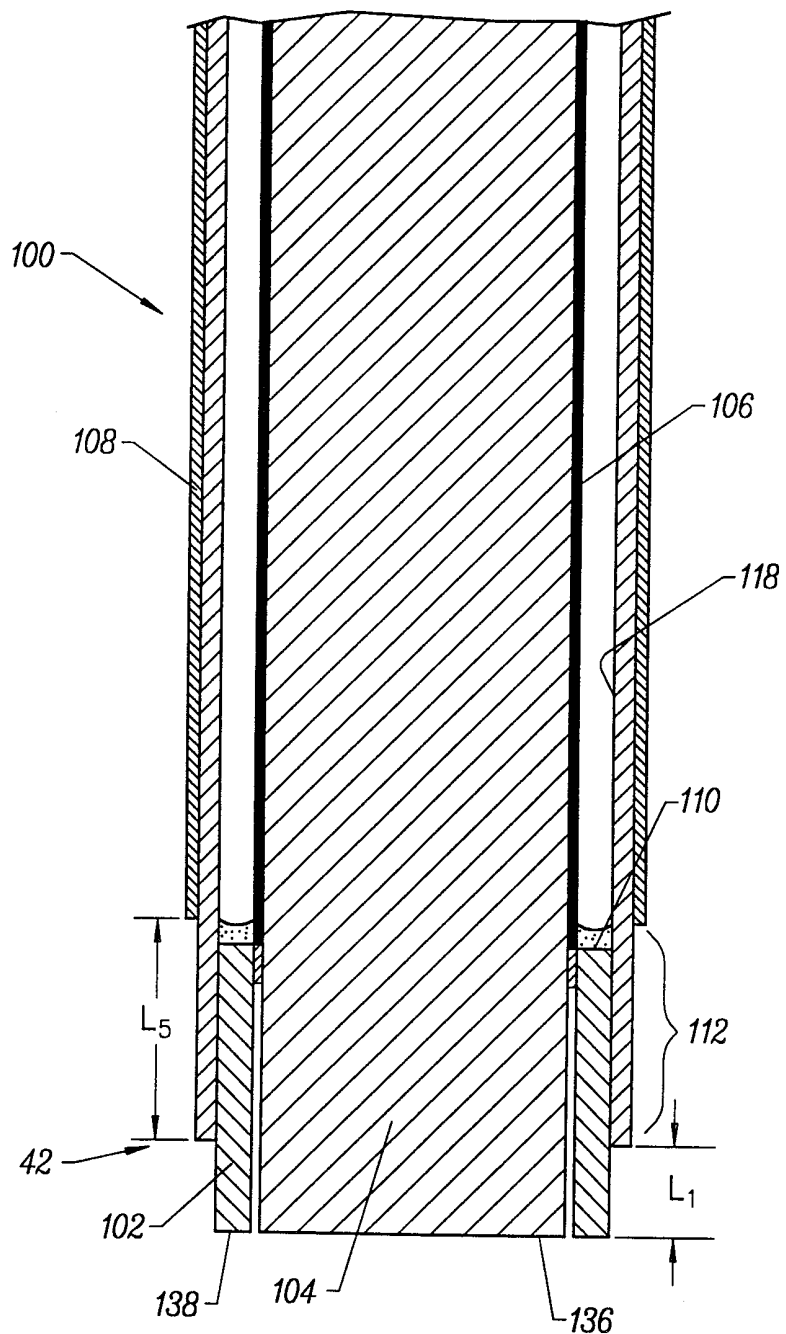


FIG. 17

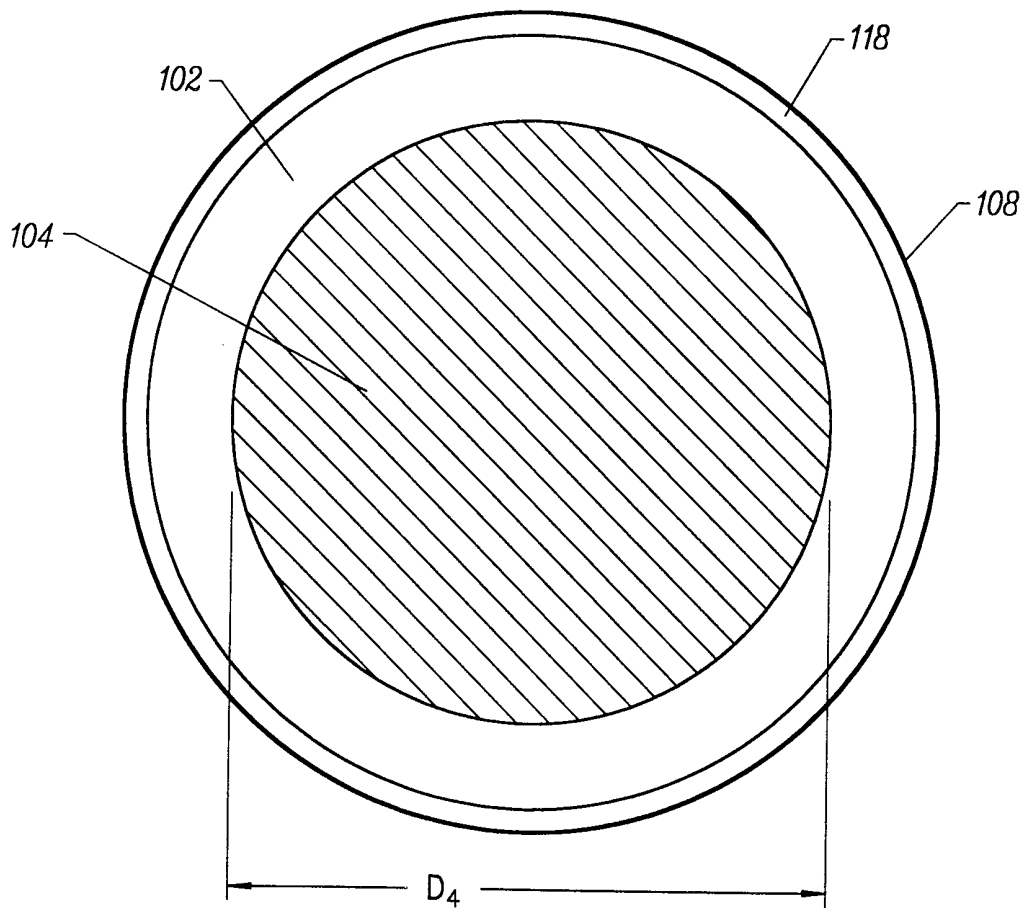


FIG. 18

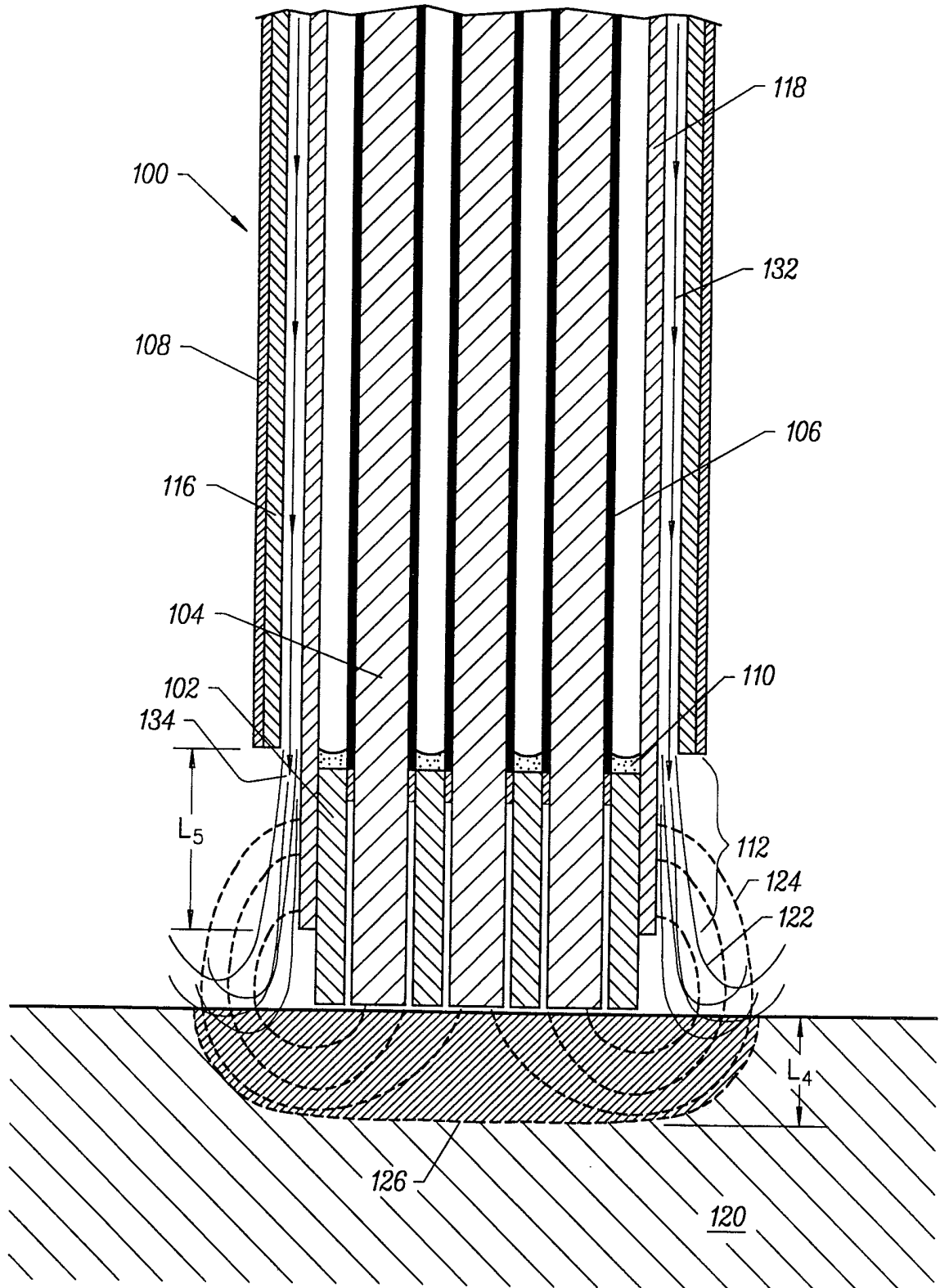


FIG. 19

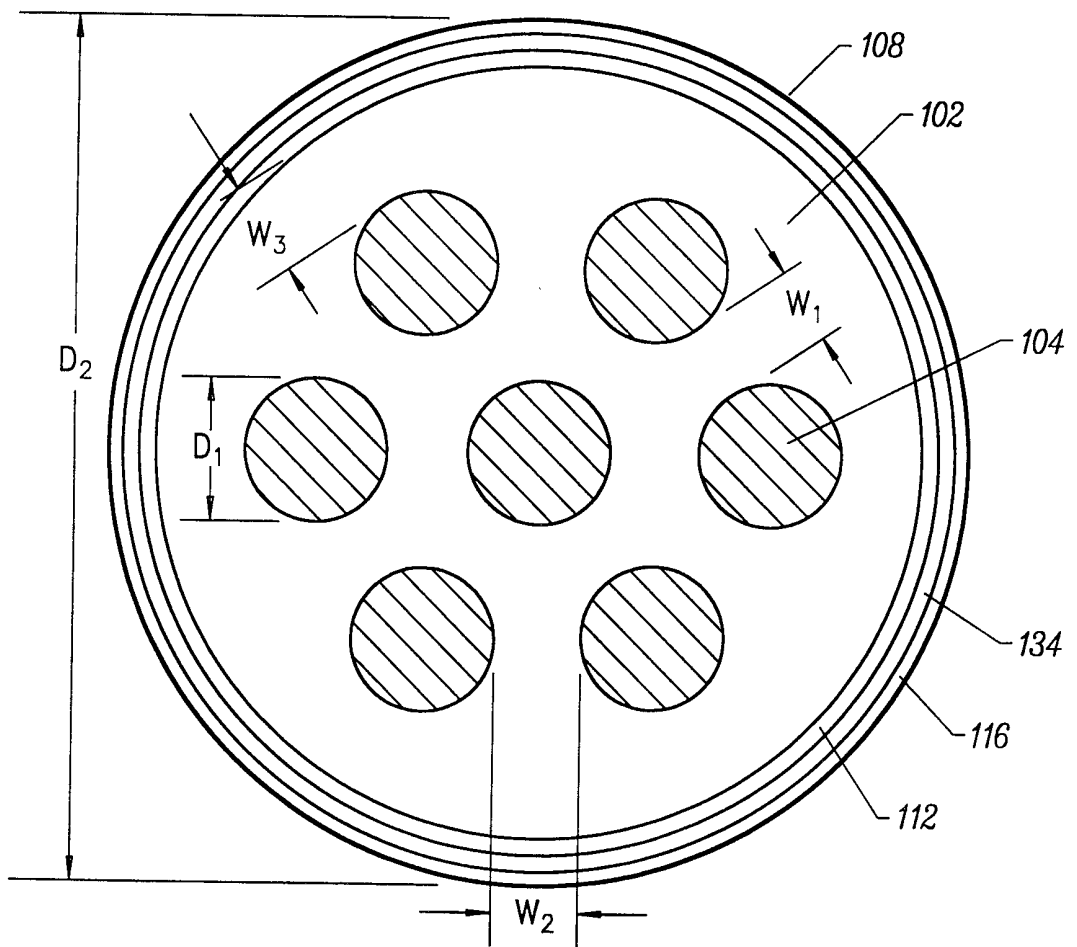


FIG. 20

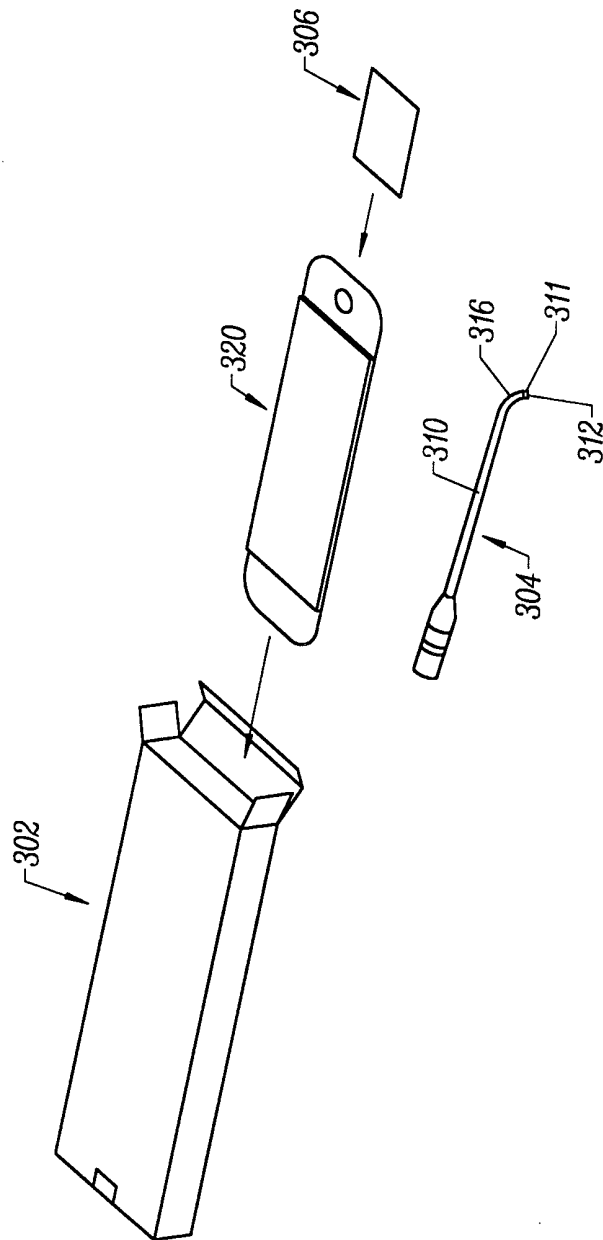


FIG. 21

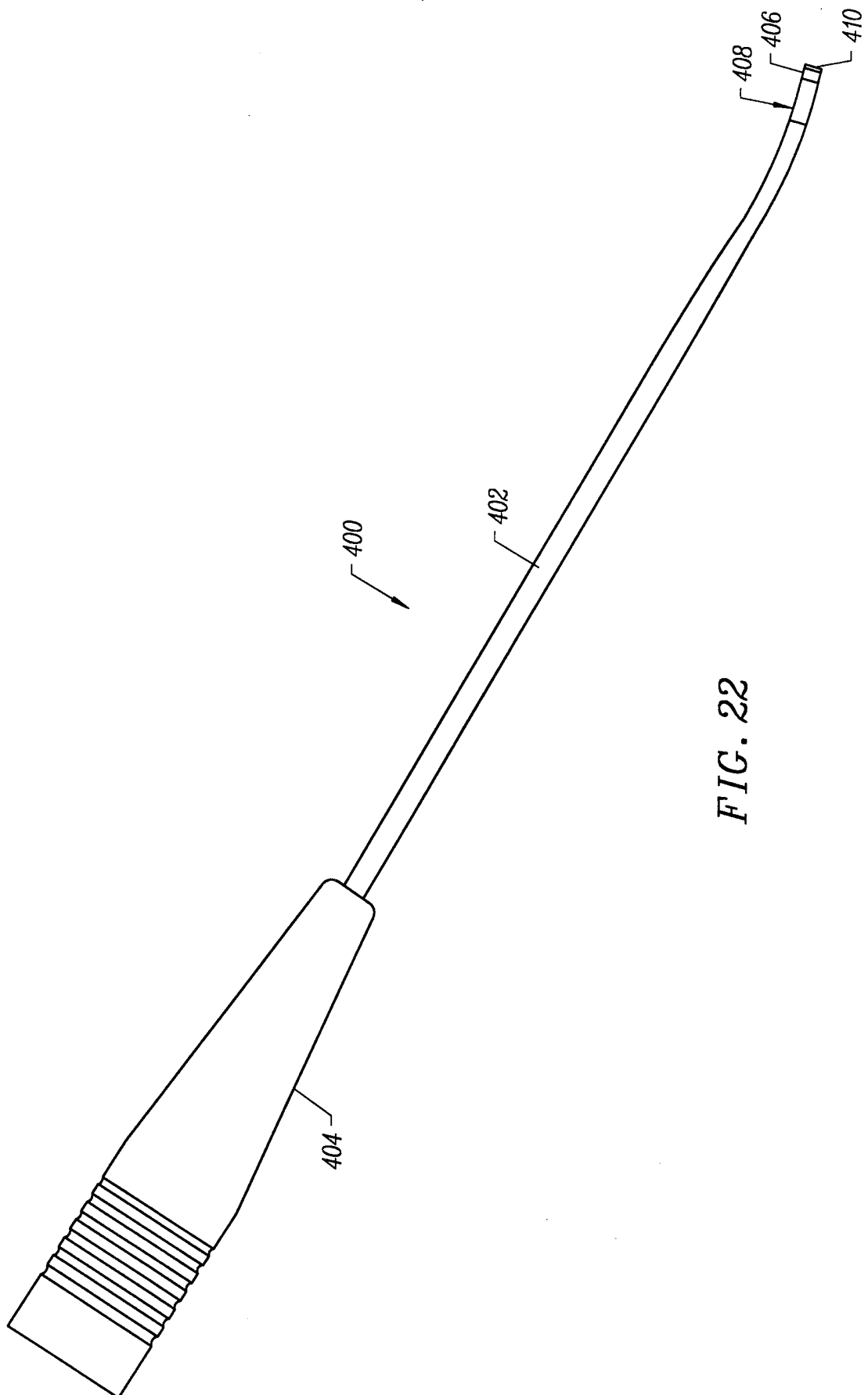


FIG. 22

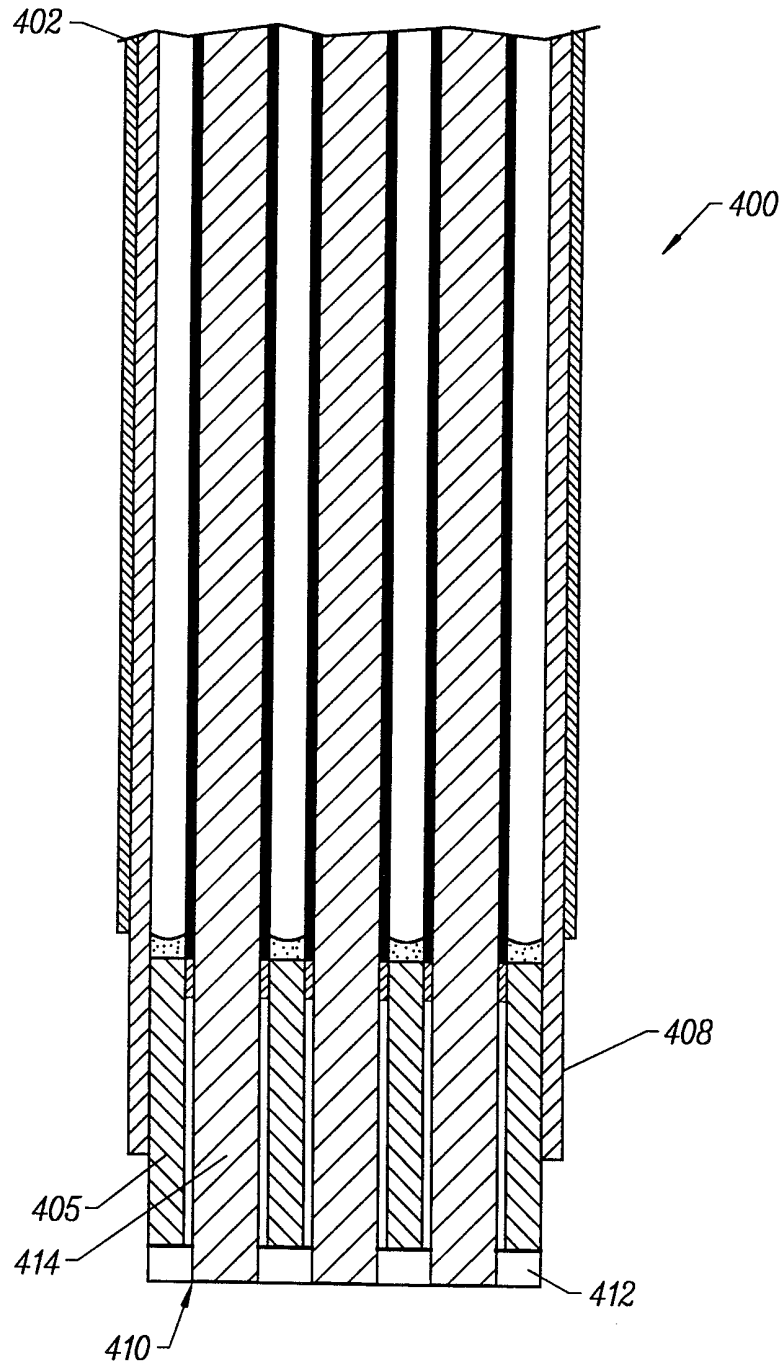


FIG. 23

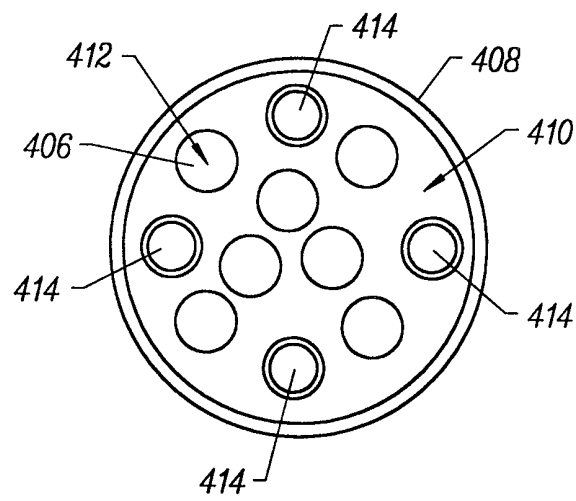


FIG. 24

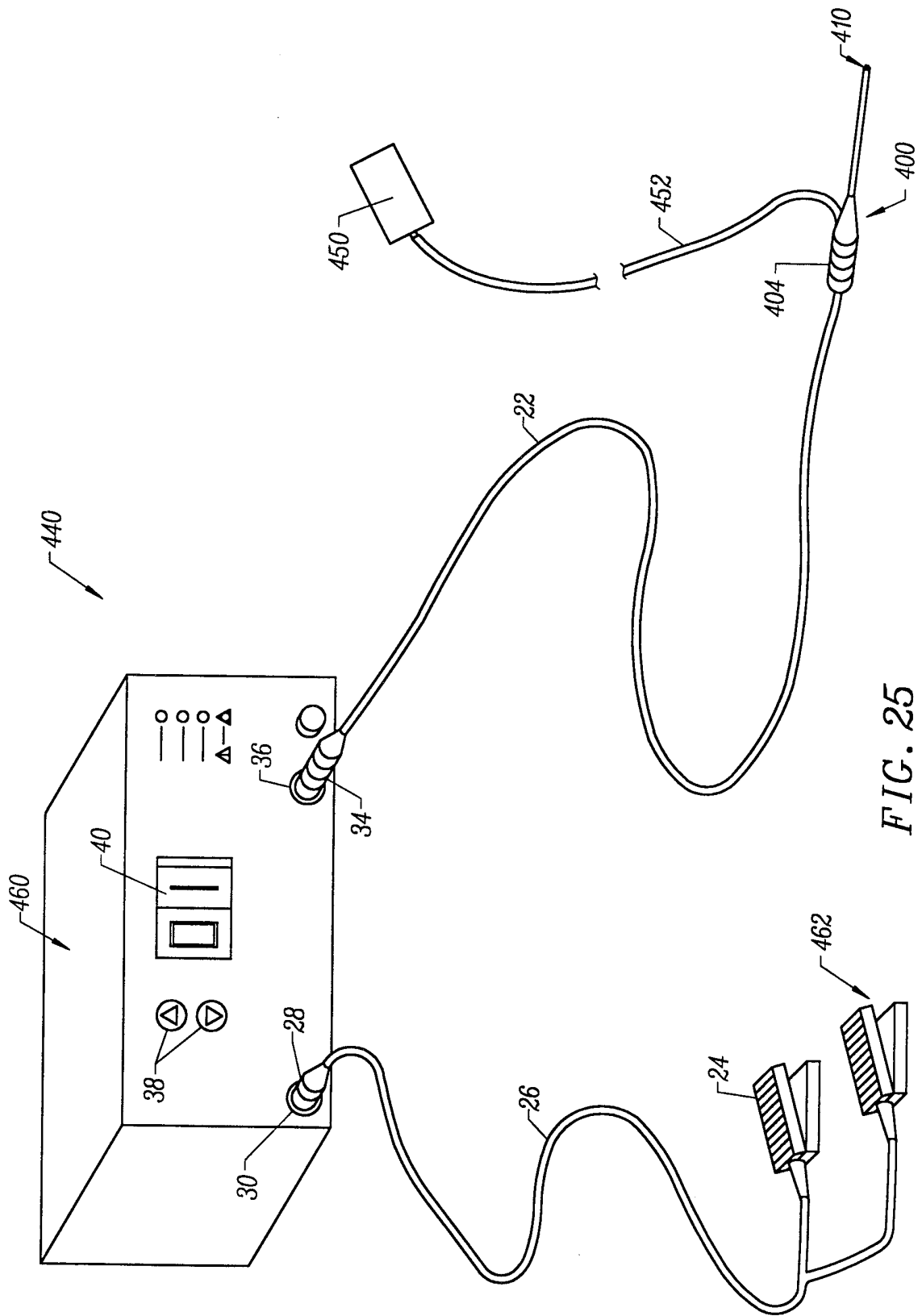


FIG. 25

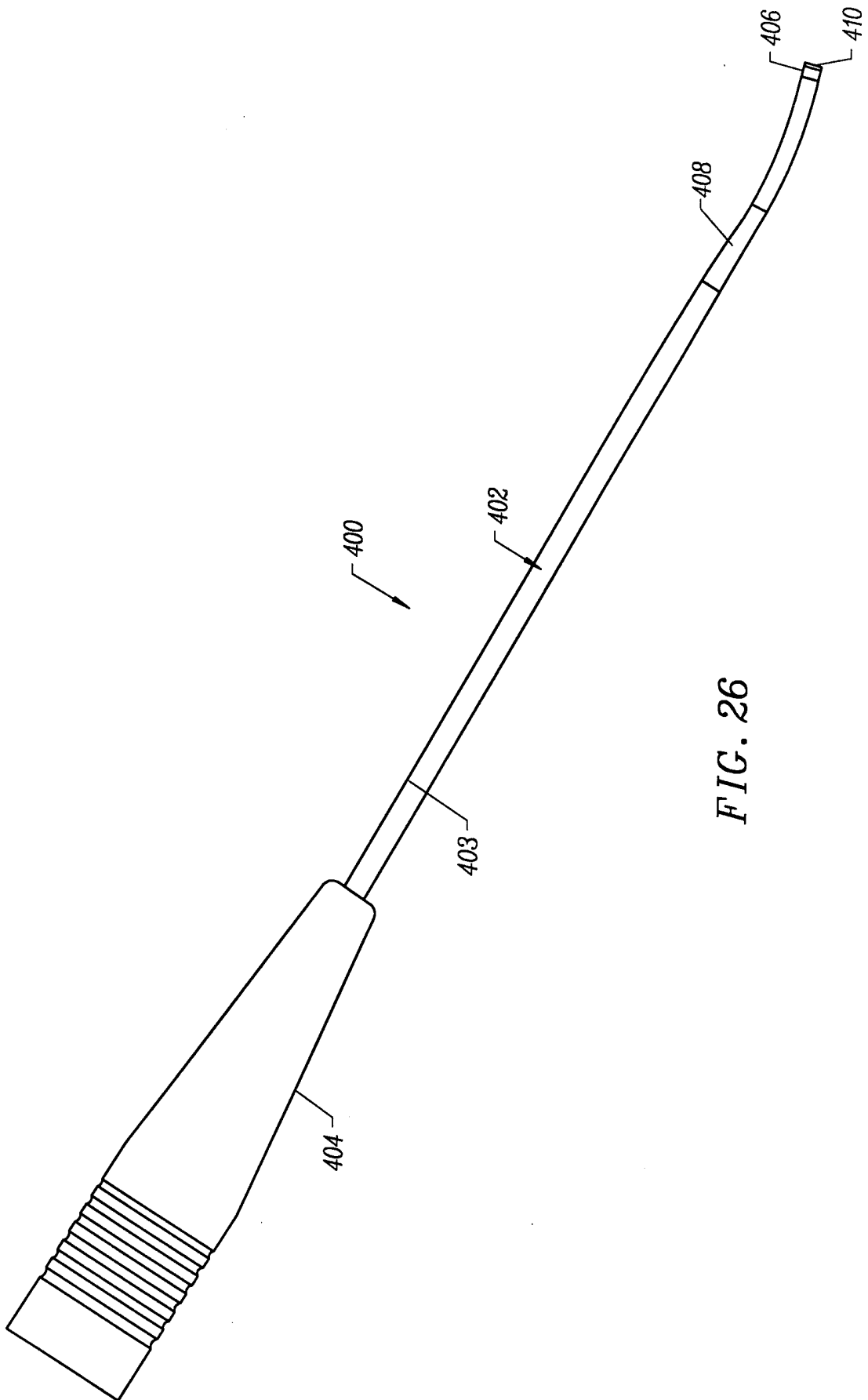


FIG. 26

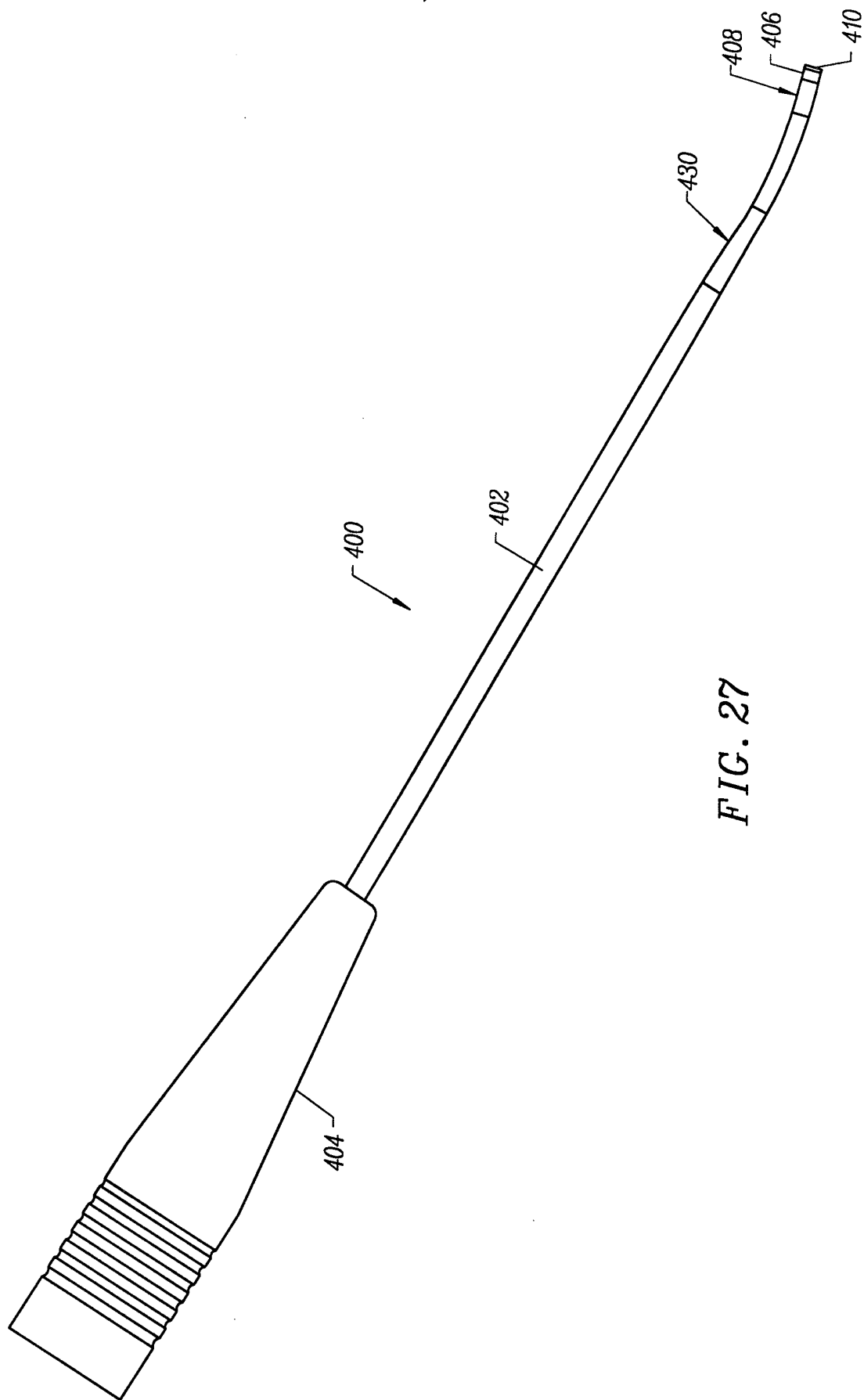


FIG. 27

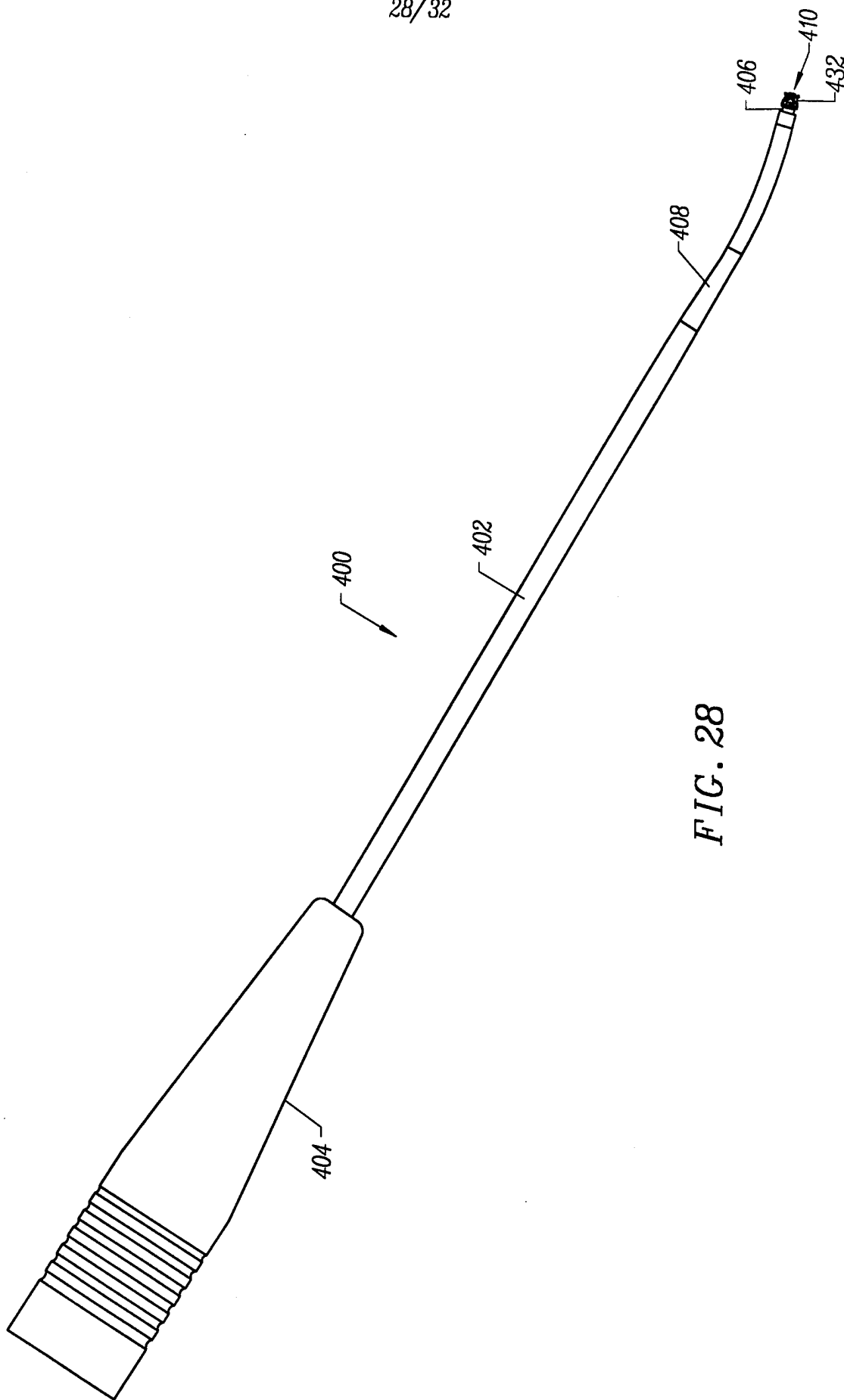


FIG. 28

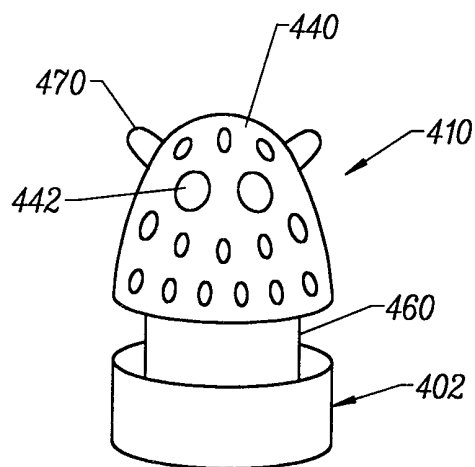


FIG. 29

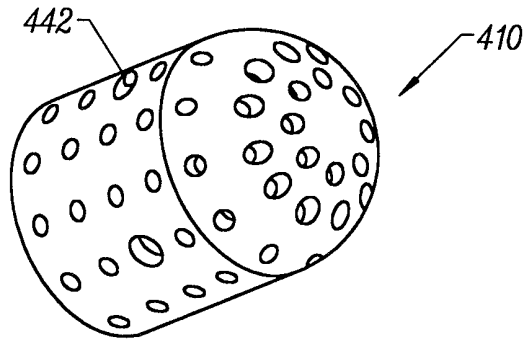


FIG. 30

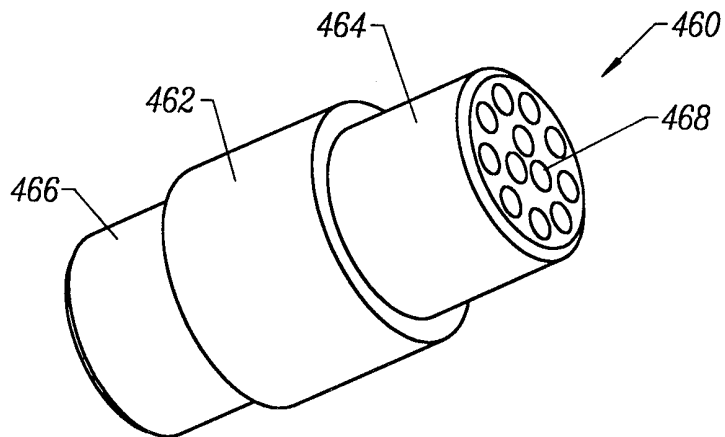


FIG. 31

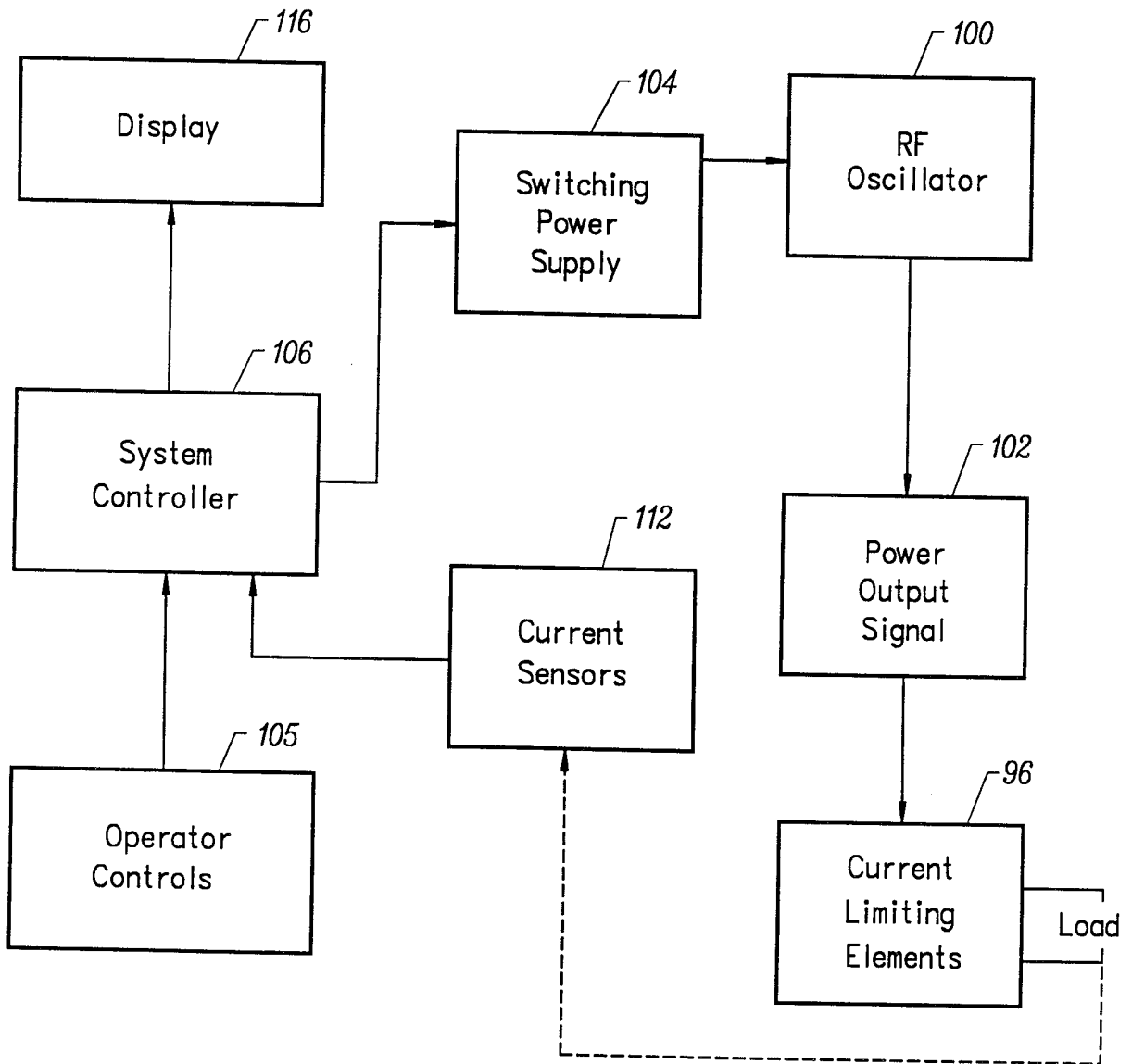


FIG. 32

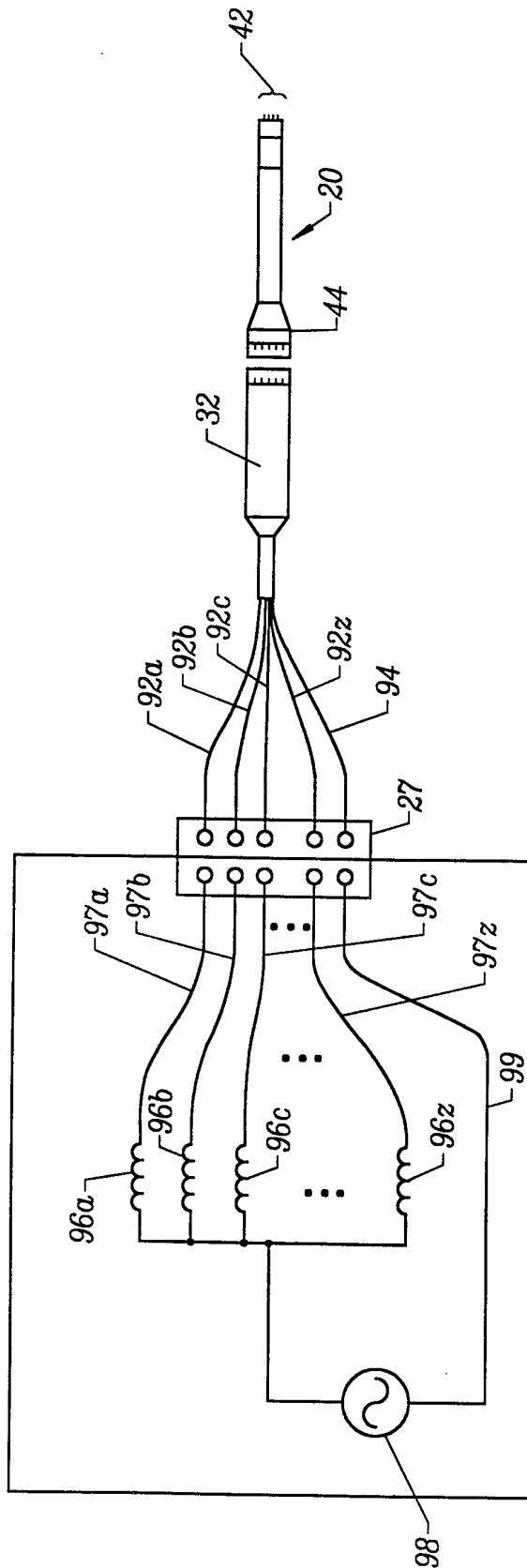


FIG. 33

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/07718

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 17/20
US CL :604/22

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/22; 606/27, 41; 607/96/99

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,832,048 A (COHEN) 23 May 1989, entire patent.	1-30
Y	US 4,682,596 A (BALES et al.) 28 July 1987, entire patent.	1-30
Y	WO 97/00646 A (GOBLE) 09 January 1997, entire patent.	1-30

Further documents are listed in the continuation of Box C. See patent family annex.

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

Date of the actual completion of the international search

14 AUGUST 2000

Date of mailing of the international search report

05 SEP 2000

Name and mailing address of the ISA/US
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Box PCT
Washington, D.C. 20231

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