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United States Patent [19]

Thapliyal et al.

[11] **Patent Number: 6,109,268**

[45] **Date of Patent: Aug. 29, 2000**

[54] **SYSTEMS AND METHODS FOR ELECTROSURGICAL ENDOSCOPIC SINUS SURGERY**

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[21] Appl. No.: **08/990,374**

[22] Filed: **Dec. 15, 1997**

Related U.S. Application Data

[63] Continuation-in-part of application No. 08/485,219, Jun. 7, 1995, Pat. No. 5,697,281.

[51] **Int. Cl.**[7] **A61B 18/18**

[52] **U.S. Cl.** **128/898**; 606/41; 607/101

[58] **Field of Search** 606/41, 42, 45–50; 607/100–105; 128/898; 604/21, 22, 114

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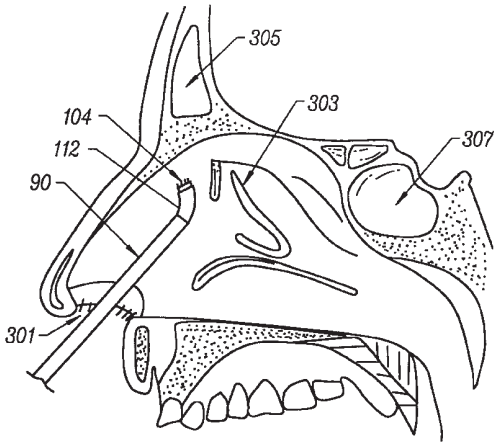
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[57] **ABSTRACT**

The present invention provides systems and methods for selectively applying electrical energy to a target location within the head and neck of a patient's body, particularly including tissue in the ear, nose and throat. The present invention applies high frequency (RF) electrical energy to one or more electrode terminals in the presence of electrically conductive fluid to remove and/or modify the structure of tissue structures. Depending on the specific procedure, the present invention may be used to: (1) volumetrically remove tissue (i.e., ablate or effect molecular dissociation of the tissue structure); (2) shrink or contract collagen connective tissue; and/or (3) coagulate severed blood vessels. For example, the present invention may be useful for ablation and hemostasis of tissue in sinus surgery (e.g., chronic sinusitis or the removal of turbinates, polypectomies), collagen shrinkage, ablation and/or hemostasis in procedures for treating snoring and obstructive sleep apnea (e.g., soft palate, such as the uvula, or tongue/pharynx stiffening, and midline glossectomies), for gross tissue removal, such as tonsillectomies, adenoidectomies, tracheal stenosis and vocal cord polyps and lesions, or for the resection or ablation of facial tumors or tumor with the mouth and pharynx, such as glossectomies, laryngectomies, acoustic neuroma procedures and nasal ablation procedures.

26 Claims, 16 Drawing Sheets



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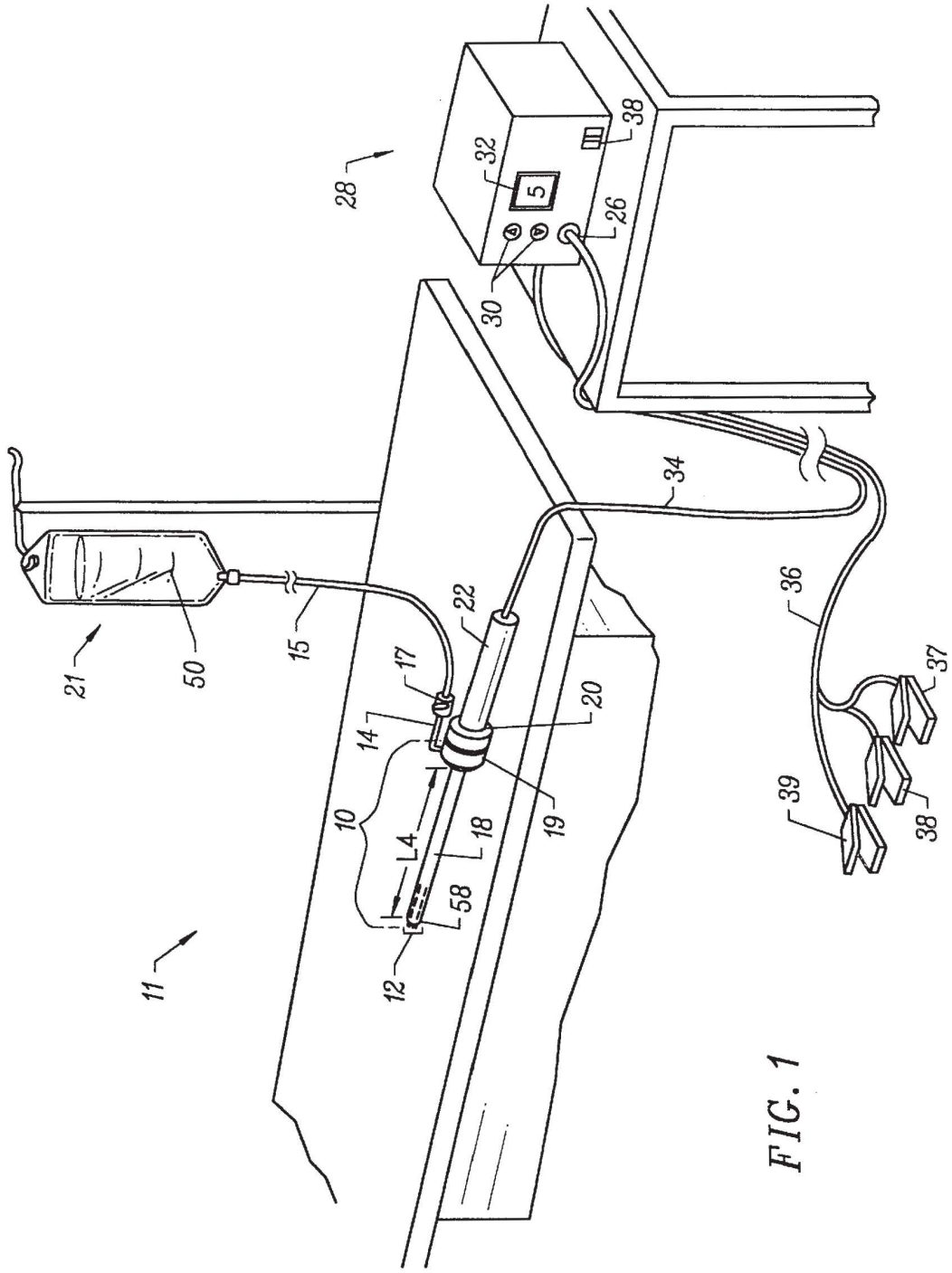


FIG. 1

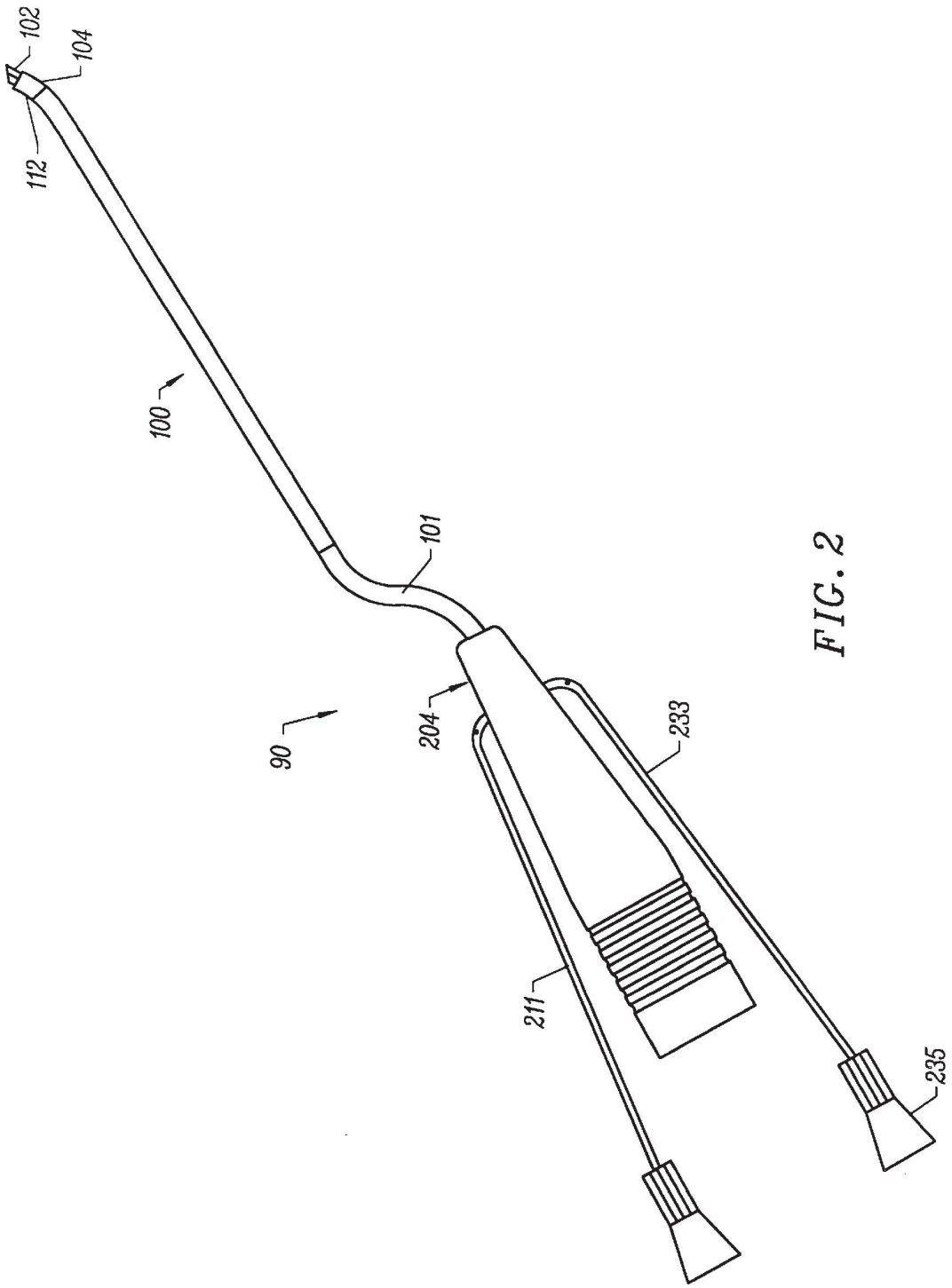


FIG. 2

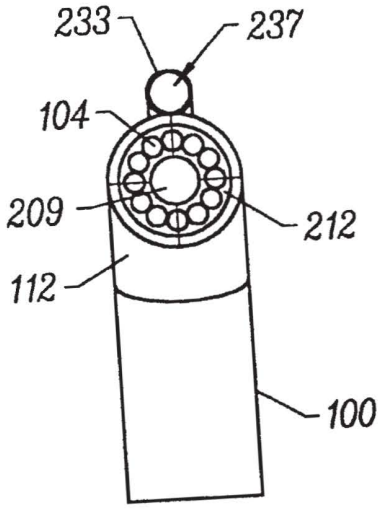


FIG. 3

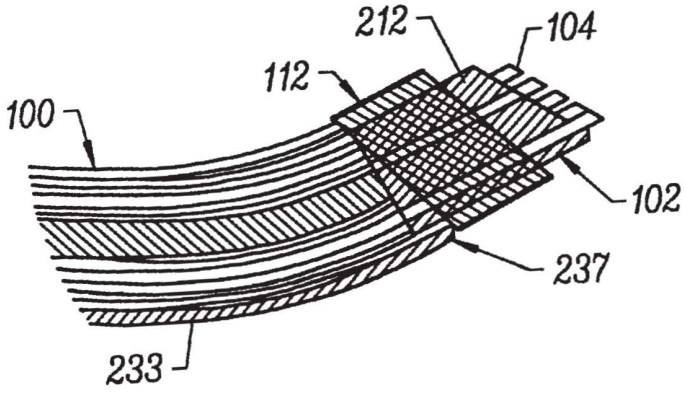


FIG. 4

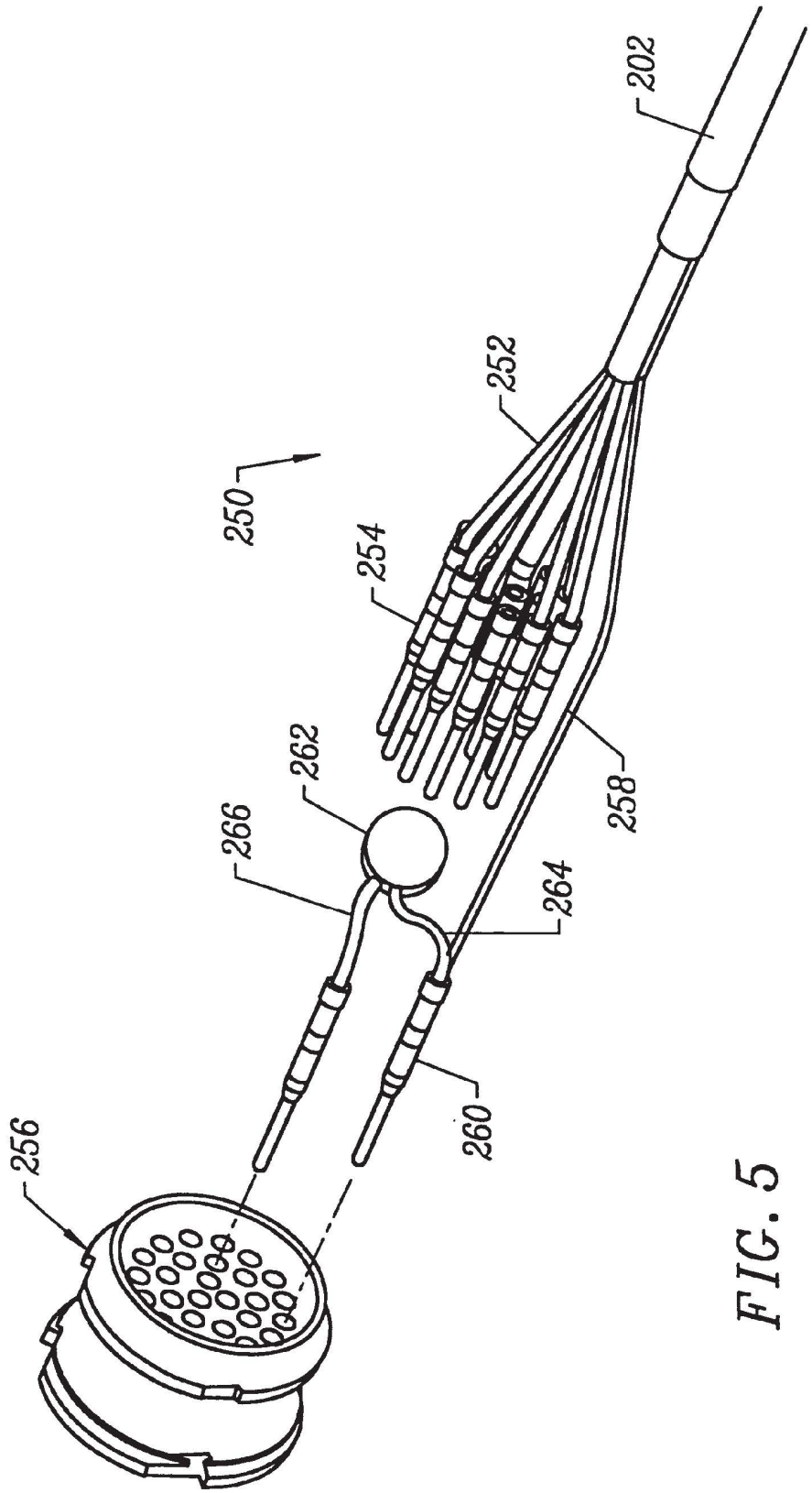


FIG. 5

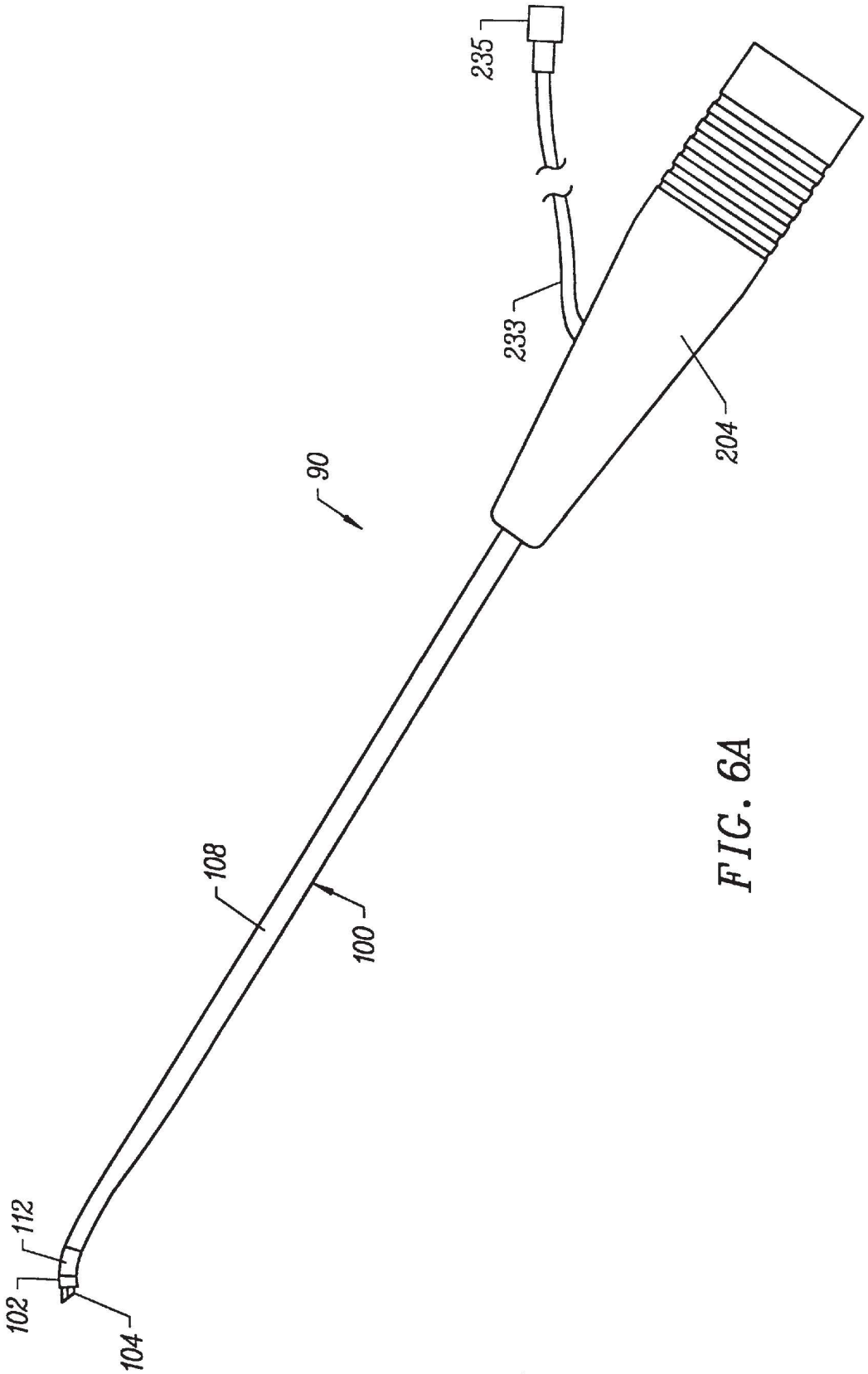


FIG. 6A

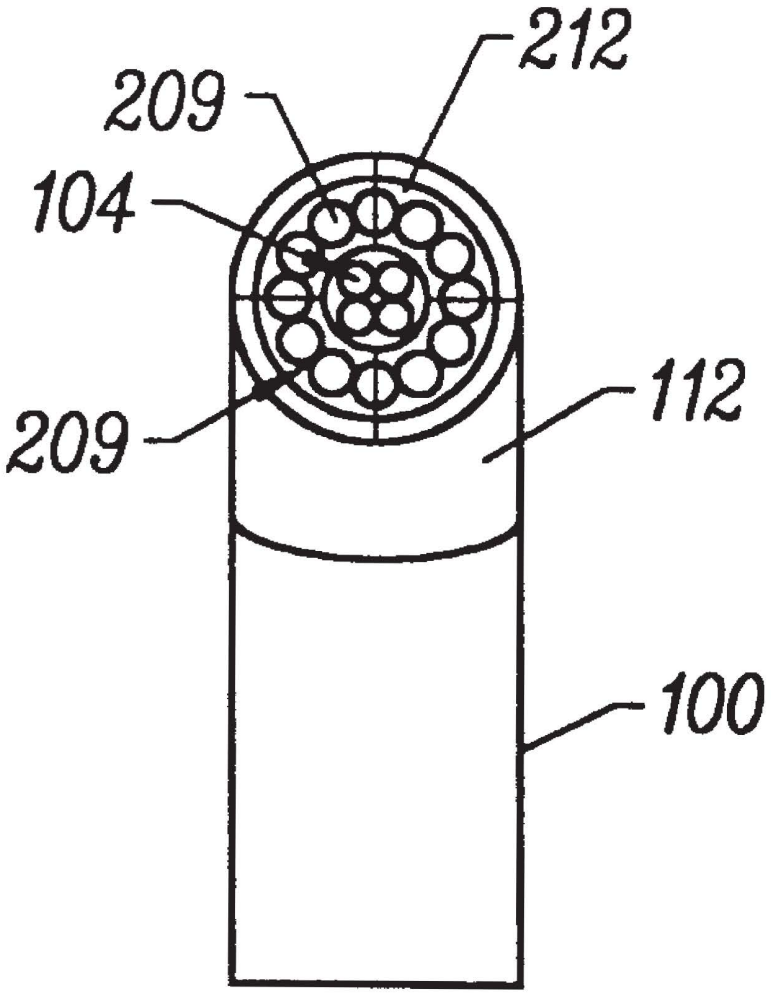


FIG. 6B

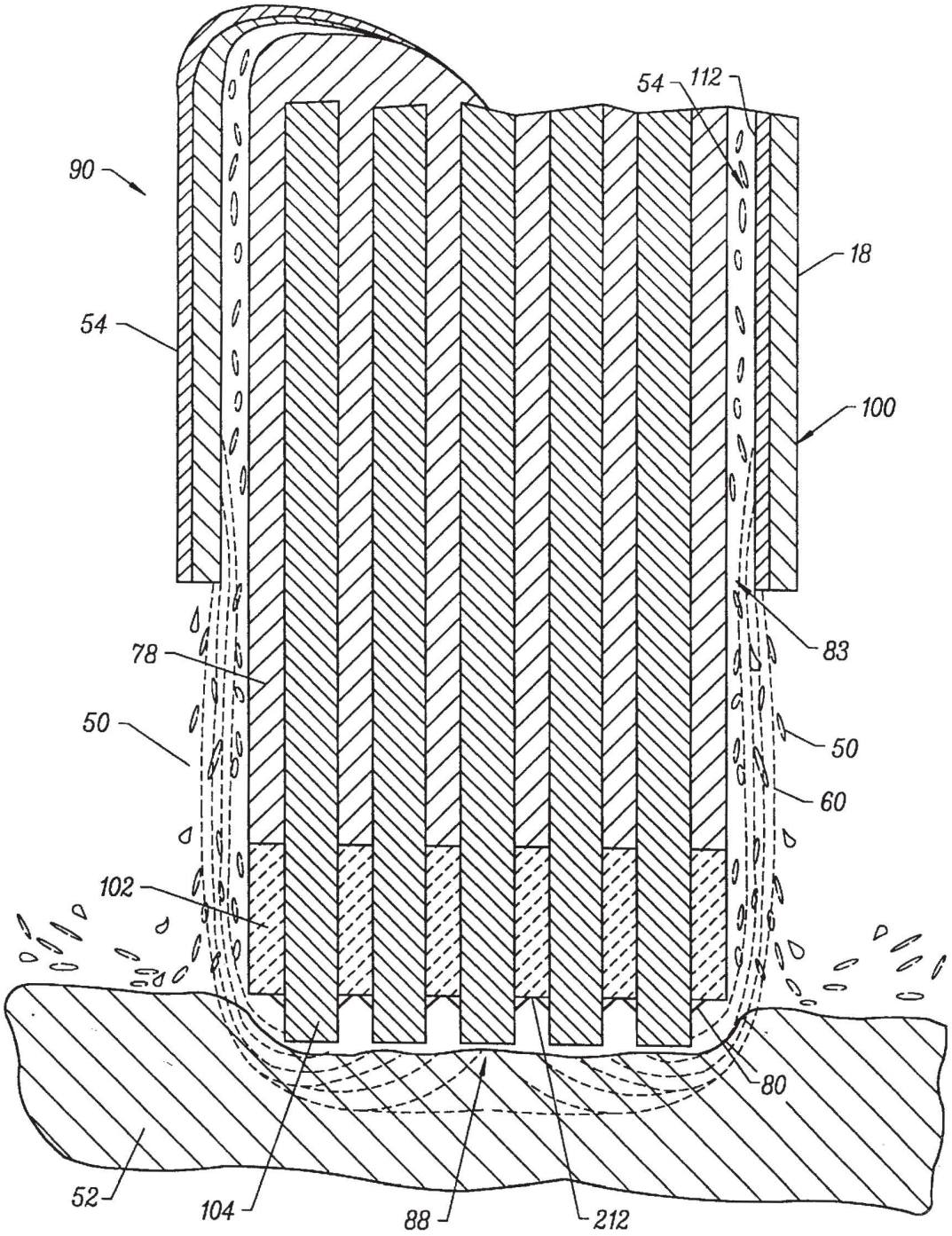


FIG. 7A

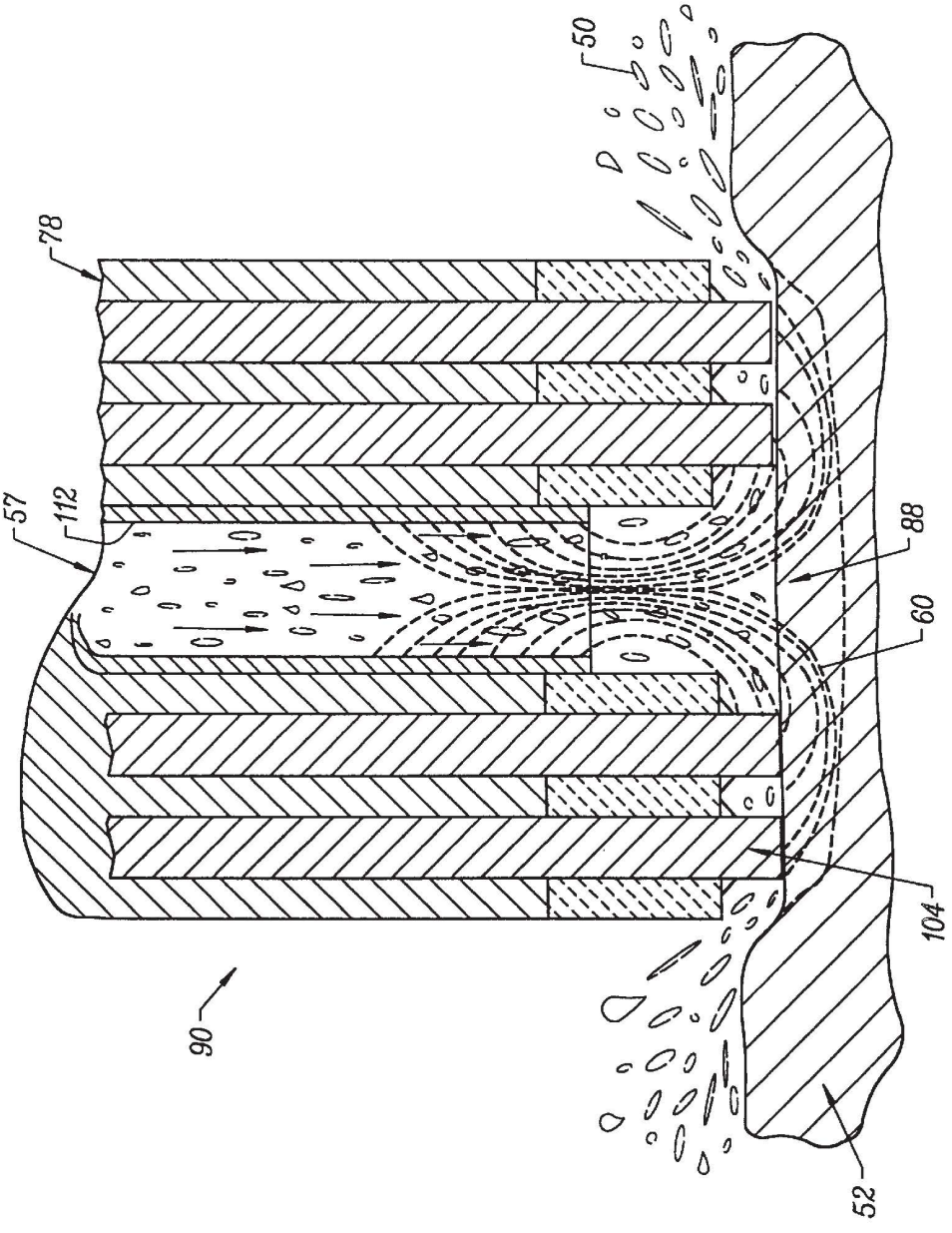


FIG. 7B

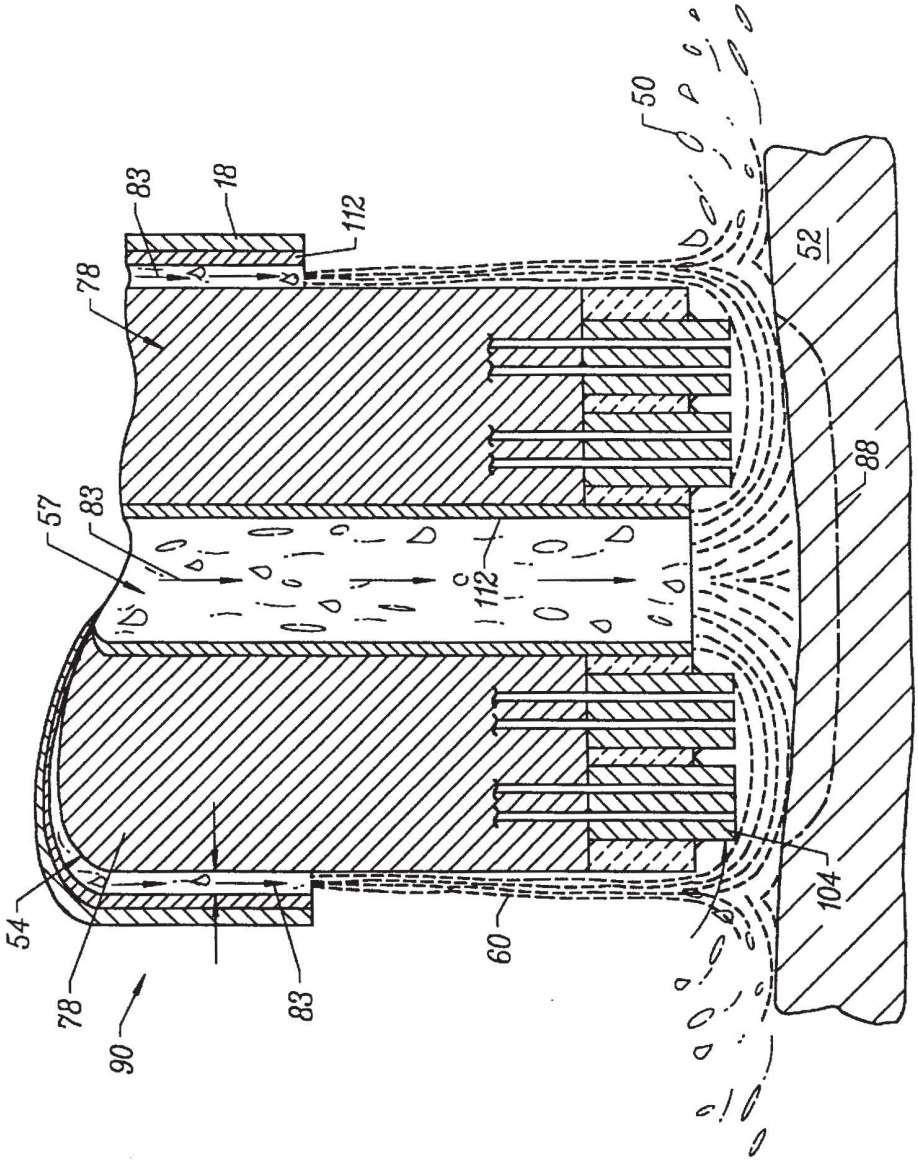


FIG. 7C

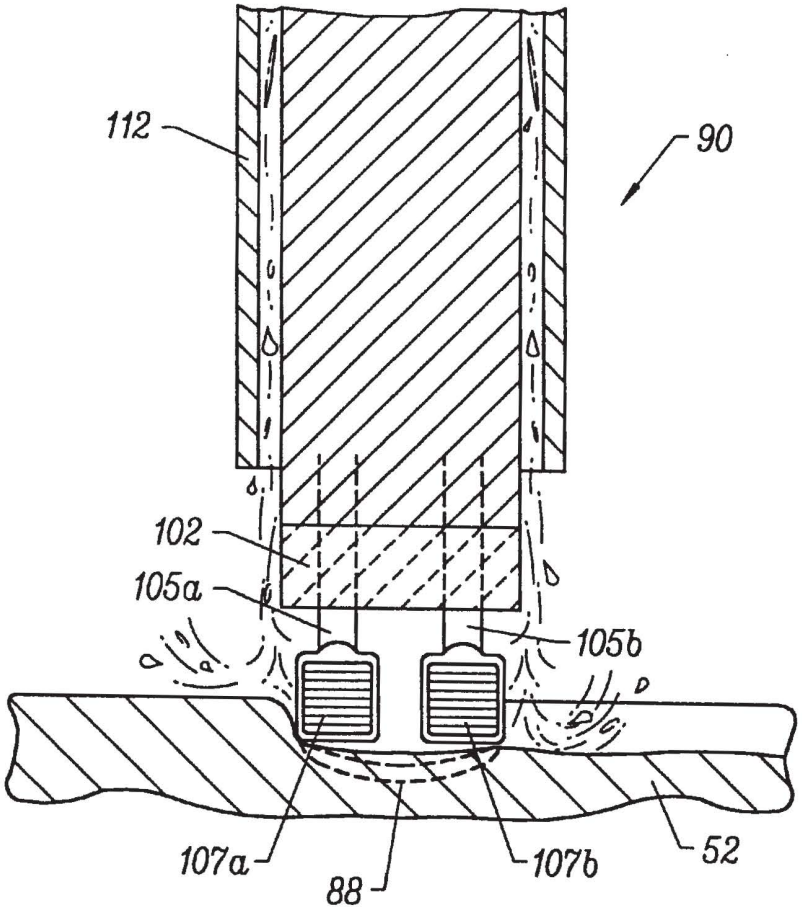


FIG. 8A

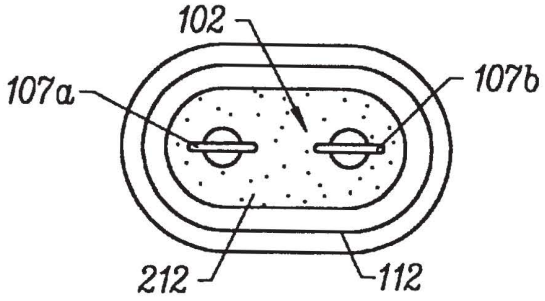


FIG. 8B

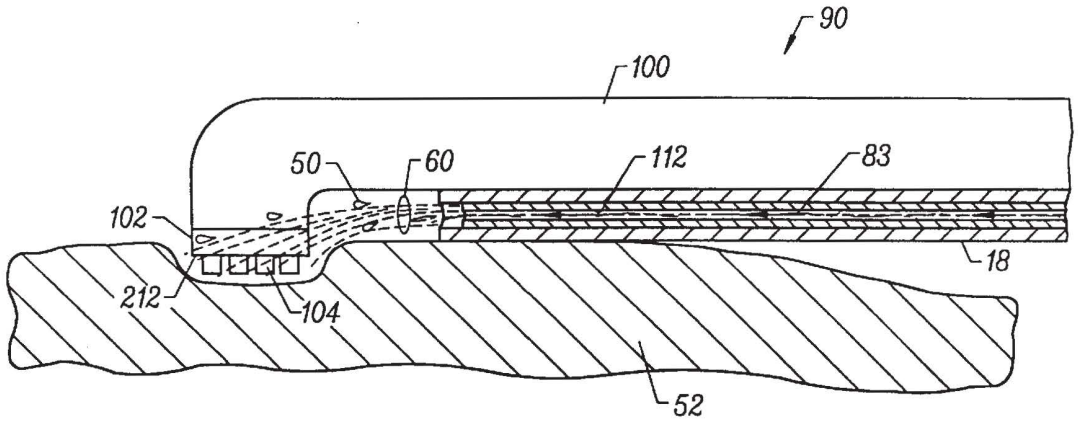

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FIG. 9

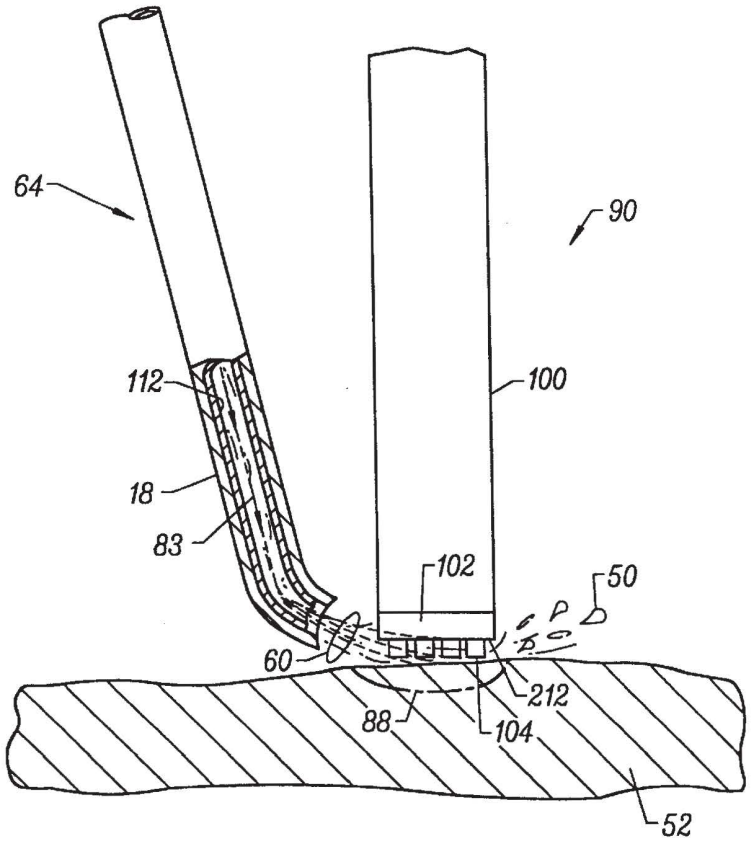

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FIG. 10

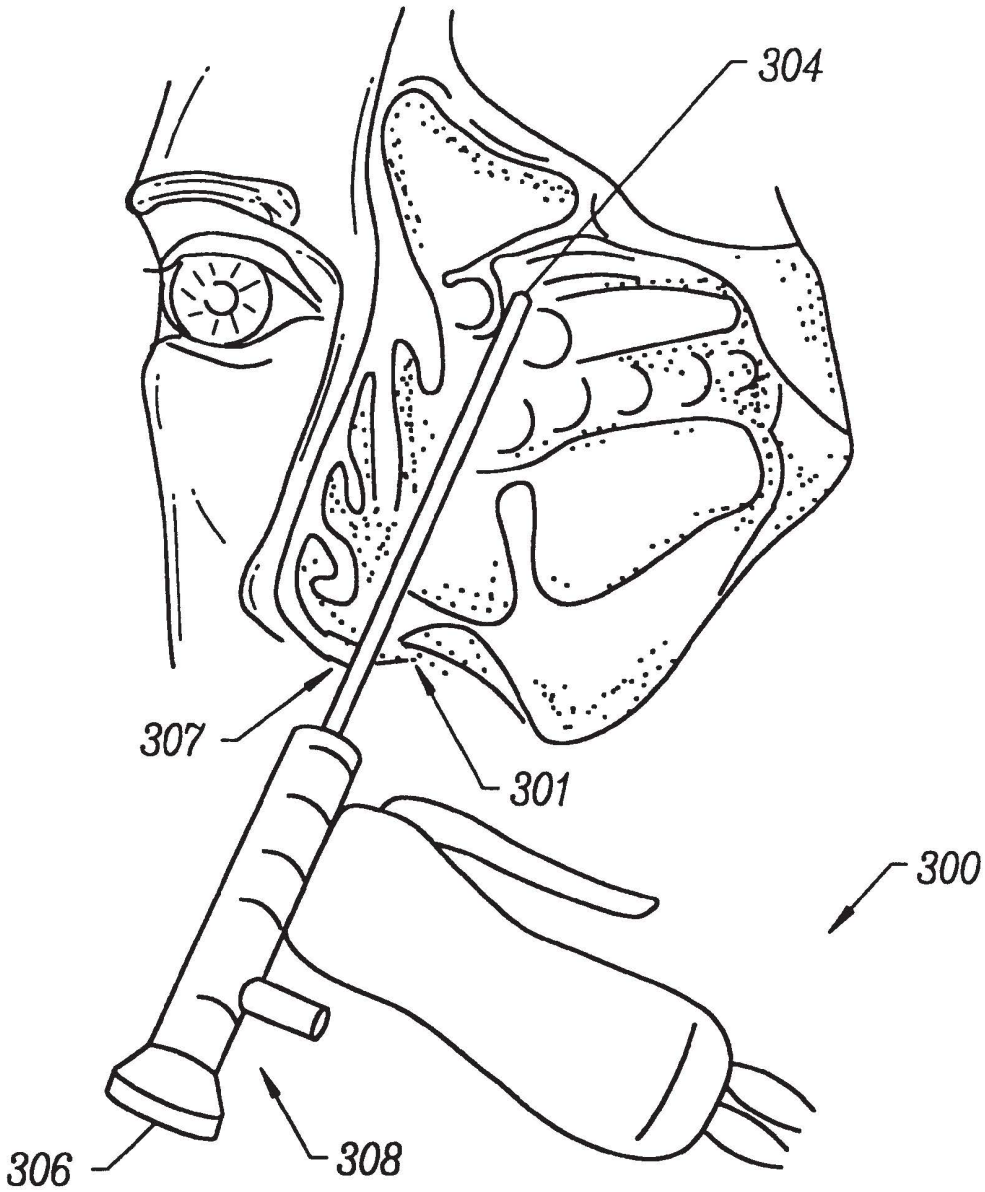


FIG. 11

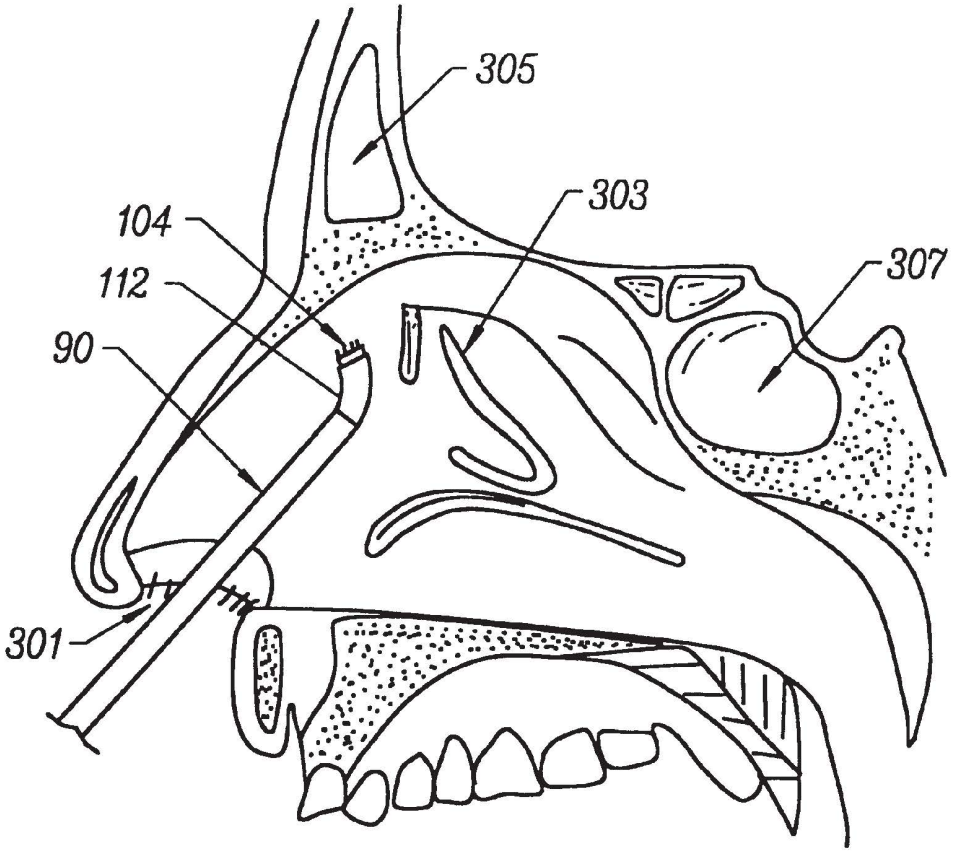


FIG. 12

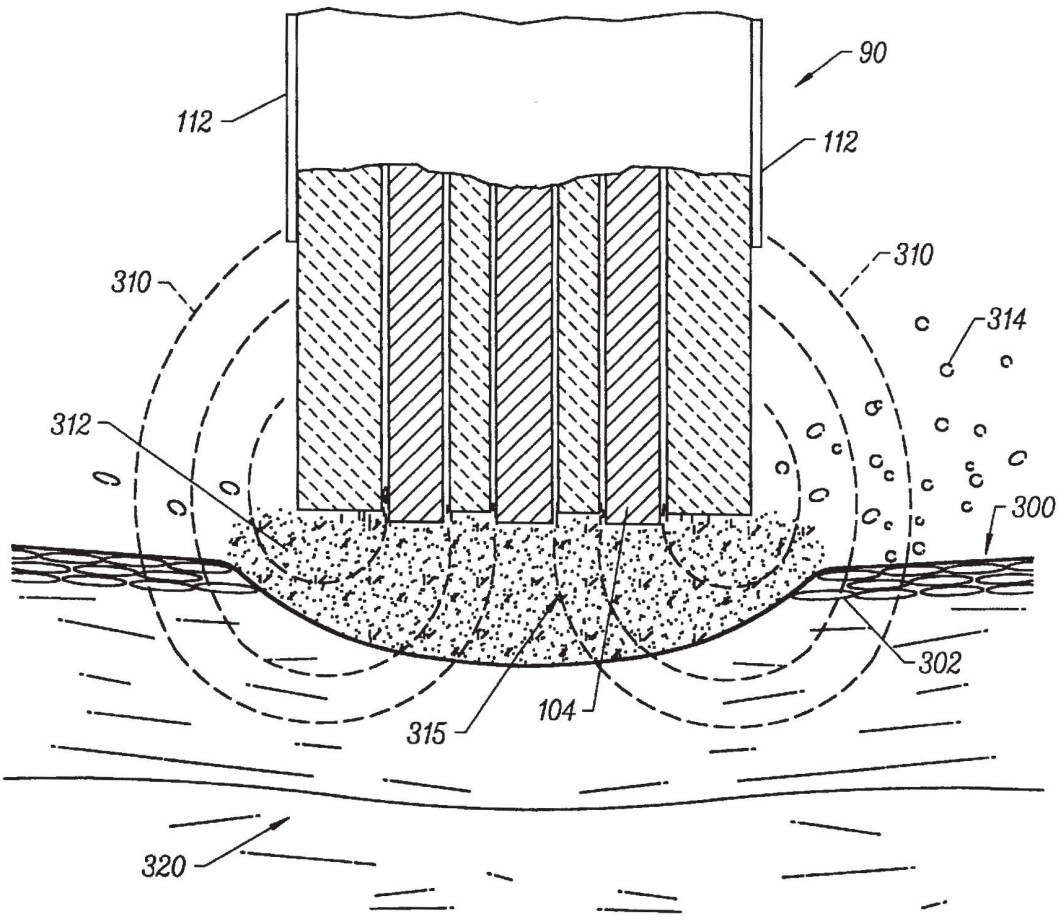


FIG. 13A

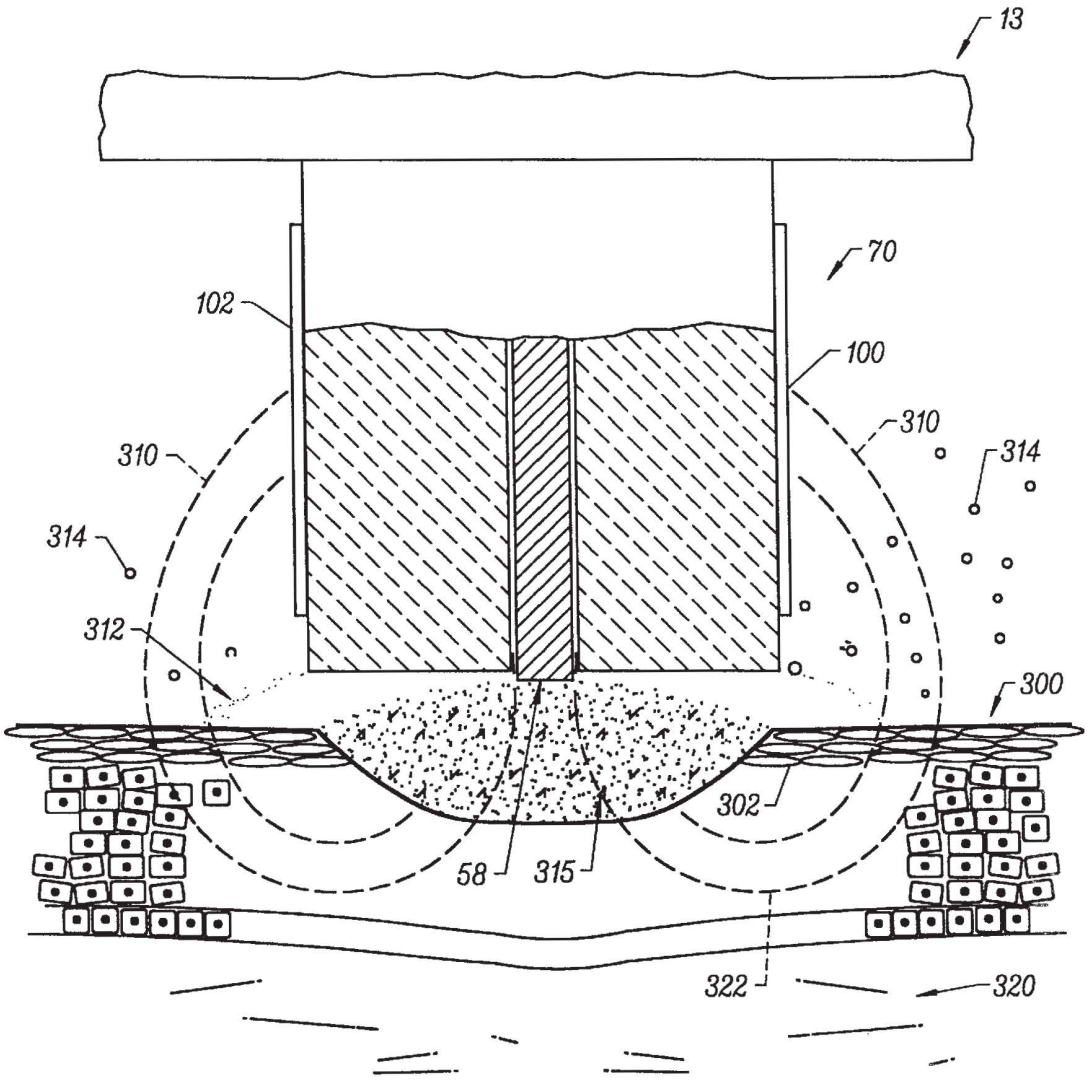


FIG. 13B

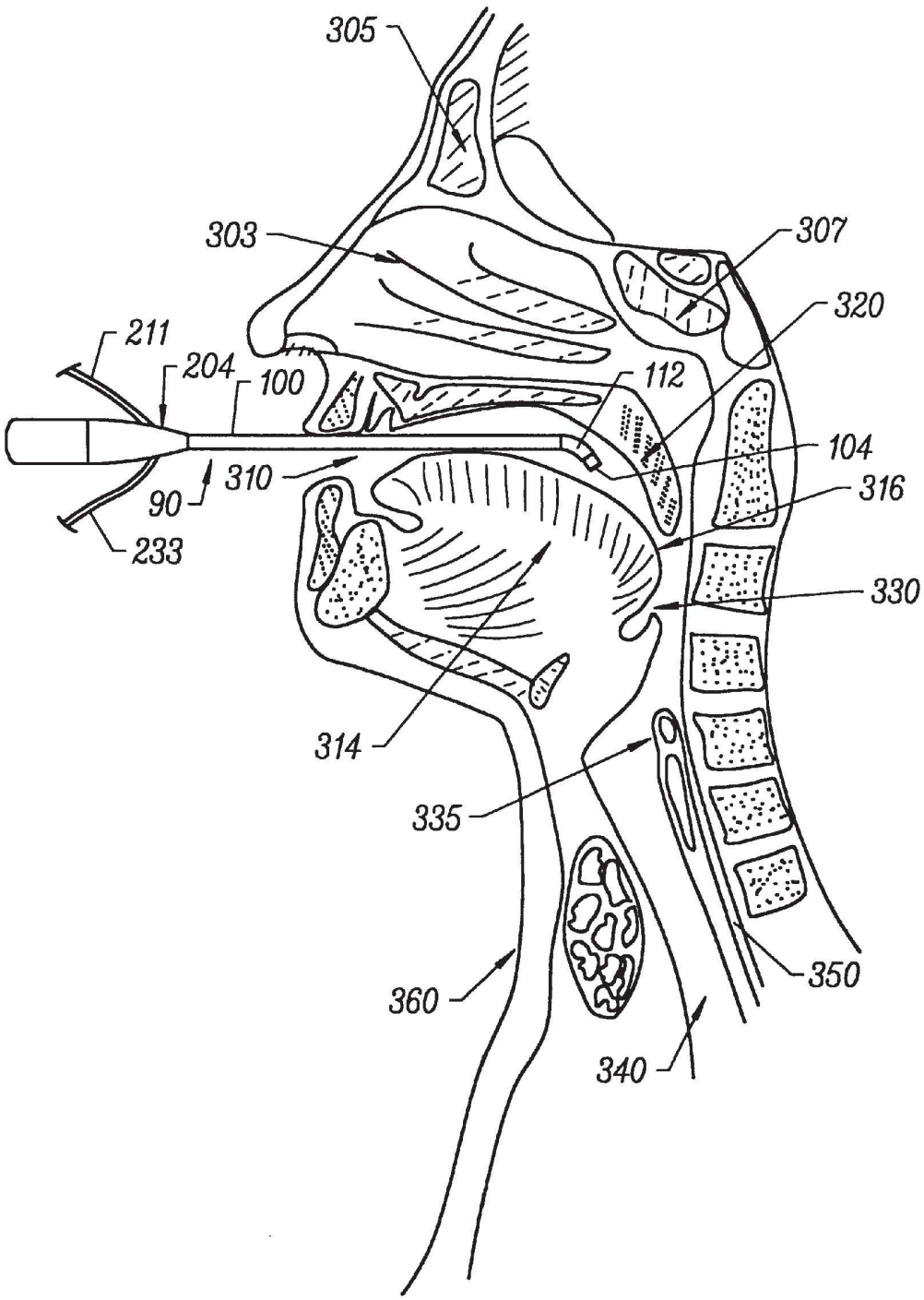

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FIG. 14

SYSTEMS AND METHODS FOR ELECTROSURGICAL ENDOSCOPIC SINUS SURGERY

RELATED APPLICATIONS

The present invention is a continuation-in-part of U.S. patent application Ser. No. 08/485,219, filed on Jun. 7, 1995 now U.S. Pat. No. 5,697,287, the complete disclosure of which is incorporated herein by reference for all purposes.

The present invention is related to commonly assigned co-pending Provisional patent applications entitled "Systems and Methods for Electrosurgical Tissue Resection and Ablation", Application No. 60/062,996 and "Systems and Methods for Electrosurgical Tissue and Fluid Coagulation", Application No. 60/062,997, filed on Oct. 23, 1997, non-provisional U.S. patent applications entitled "Systems and Methods for Electrosurgical Dermatological Treatment", application No. 08/977,845 filed on Nov. 25, 1997, entitled 'SYSTEMS AND METHODS FOR ELECTROSURGICAL TISSUE CONTRACTION", application No. 08/942,580 filed on Oct. 2, 1997, U.S. application Ser. No. 08/753,227, filed on Nov. 22, 1996, now U.S. Pat. No. 5,873,855, U.S. application Ser. No. 08/687,792, filed on Jul. 18, 1996, now U.S. Pat. No. 5,843,019, and PCT International Application, U.S. National Phase Ser. No. PCT/US94/05168, filed on May 10, 1994, now U.S. Pat. No. 5,697,909, which was a continuation-in-part of application Ser. No. 08/059,681, filed on May 10, 1993, which was a continuation-in-part of application Ser. No. 07/958,977, filed on Oct. 9, 1992, now U.S. Pat. No. 5,366,443, which was a continuation-in-part of application Ser. No. 07/817,575, filed on Jan. 7, 1992, the complete disclosures of which are incorporated herein by reference for all purposes. The present invention is also related to commonly assigned U.S. Pat. No. 5,683,366, filed Nov. 22, 1995, the complete disclosure of which is incorporated herein by reference for all purposes.

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 electrical energy to treat tissue in regions of the head and neck, such as the ear, nose and throat. The present invention is particularly suited for sinus surgery and the treatment of obstructive sleep disorders.

Sinuses are the air-filled cavities insides the facial bones that open into the nasal cavities. Sinusitis is the inflammation of the mucous membranes of one or more of the paranasal sinus cavities. Sinusitis is often associated with a viral or bacterial upper respiratory infection that spreads to the sinuses. When the sinus opening becomes blocked, the cavities fill, producing deep pain and pressure. Postnasal or nasal drainage, nasal congestion with pressure, headaches, sinus infections and nasal polyps are most commonly associated with chronic sinusitis.

Treatment of mild sinusitis typically involves antibiotics, decongestants and analgesics, and is designed to prevent further complications. For more severe or chronic sinusitis, surgery is often necessary to return the nose and sinuses to normal function, particularly with patients who have undergone years of allergy treatment and still suffer from sinus blockage, or patients born with small sinuses and nasal passages. Recent developments in the field of endoscopic surgical techniques and medical devices have provided skilled physicians with instrumentation and methods to perform complicated paranasal sinus surgical procedures.

Improved visualization of the nasal cavity and the paranasal sinuses, for example, has now made these anatomical areas more accessible to the endoscopic surgeon. As a result, functional endoscopic sinus surgery (FESS) has become the technique of choice in the surgical approach to sinus disease.

Another nasal symptom, runny noses (e.g., allergic rhinitis or vasomotor rhinitis), is typically caused by small shelf-like structures in the nose called turbinates. Turbinates are responsible for warming and humidifying the air passing through the nose into the lungs. When the air contains an irritant, the turbinates react to the airborne particles by swelling and pouring mucus, as if the body were trying to block and cleanse the breathing passage. For temporary relief of swollen turbinates, decongestant nasal sprays and pills are often prescribed. These measures, however, have limited effectiveness, and the long term use of such nasal sprays typically makes the problem worse. Moreover, decongestant pills may cause high blood pressure, increase the heart rate and, for some people, cause sleeplessness.

In the past several years, powered instrumentation, such as microdebrider devices and lasers, has been used to remove polyps or other swollen tissue in functional endoscopic sinus surgery. Microdebriders are disposable motorized cutters having a rotating shaft with a serrated distal tip for cutting and resecting tissue. The handle of the microdebrider is typically hollow, and it accommodates a small vacuum, which serves to aspirate debris. In this procedure, the distal tip of the shaft is endoscopically delivered through a nasal passage into the sinus cavity of a patient, and an endoscope is similarly delivered through the same or the opposite nasal passage to view the surgical site. An external motor rotates the shaft and the serrated tip, allowing the tip to cut the polyps or other tissue responsible for the sinus blockage. Once the critical blockage is cleared, aeration and drainage are reestablished and the sinuses heal and return to their normal function.

While microdebriders have been promising, these devices suffer from a number of disadvantages. For one thing, the tissue in the nasal and sinus cavities is extremely vascular, and the microdebrider severs blood vessels within this tissue, usually causing profuse bleeding that obstructs the surgeon's view of the target site. Controlling this bleeding can be difficult since the vacuuming action tends to promote hemorrhaging from blood vessels disrupted during the procedure. In addition, the microdebrider often must be removed from the nose periodically to cauterize severed blood vessels, which lengthens the procedure. Moreover, the serrated edges and other fine crevices of the microdebrider can easily become clogged with debris, which requires the surgeon to remove and clean the microdebrider during the surgery, further increasing the length of the procedure. More serious concerns, however, are that the microdebrider is not precise, and it is often difficult, during the procedure, to differentiate between the target sinus tissue, and other structures within the nose, such as cartilage, bone or cranial. Thus, the surgeon must be extremely careful to minimize damage to the cartilage and bone within the nose, and to avoid damaging nerves, such as the optic nerve.

Lasers were initially considered ideal for sinus surgery because lasers ablate or vaporize tissue with heat, which also acts to cauterize and seal the small blood vessels in the tissue. Unfortunately, lasers are both expensive and somewhat tedious to use in these procedures. Another disadvantage with lasers is the difficulty in judging the depth of tissue ablation. Since the surgeon generally points and shoots the laser without contacting the tissue, he or she does not receive any tactile feedback to judge how deeply the laser is cutting.

Because healthy tissue, cartilage, bone and/or cranial nerves often lie within close proximity of the sinus tissue, it is essential to maintain a minimum depth of tissue damage, which cannot always be ensured with a laser.

Sleep-apnea syndrome is a medical condition characterized by daytime hypersomnolence, intellectual deterioration, cardiac arrhythmias, snoring and thrashing during sleep. This syndrome is classically divided into two types. One type, termed "central sleep apnea syndrome", is characterized by repeated loss of respiratory effort. The second type, termed obstructive sleep apnea syndrome, is characterized by repeated apneic episodes during sleep resulting from obstruction of the patient's upper airway or that portion of the patient's respiratory tract which is cephalad to, and does not include, the larynx.

Treatment for sleep apnea has included various medical, surgical and physical measures. Medical measures include the use of medications and the avoidance of central nervous system depressants, such as sedatives or alcohol. These measures are sometimes helpful, but rarely completely effective. Surgical interventions have included uvuolopalatopharyngoplasty, tonsillectomy, surgery to correct severe retrognathia and tracheostomy. While these procedures are effective, the risk of surgery in these patients is often prohibitive, and the procedures are unacceptable to the patient. Physical measures have included weight loss, nasopharygeal airways, nasal CPAP and various tongue retaining devices used nocturnally. These measures are cumbersome, uncomfortable and difficult to use for prolonged periods of time.

Recently, RF energy has been used to selectively ablate portions of the tongue to treat air passage disorders, such as sleep apnea. This procedure, which was developed by Somnus Medical Technologies of Sunnyvale, California, involves the use of a monopolar electrode that directs RF current into the target tissue to desiccate or destroy tissue in the tongue. Of course, such monopolar devices suffer from the disadvantage 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, since the defined path through the patient's body has a relatively high impedance (because of the large distance or resistivity of the patient's body), large voltage differences must typically be applied between the return and active electrodes in order to generate a current suitable for ablation or cutting of the target tissue. This current, however, may inadvertently flow along body paths having less impedance than the defined electrical path, which will substantially increase the current flowing through these paths, possibly causing damage to or destroying surrounding tissue or neighboring peripheral nerves.

SUMMARY OF THE INVENTION

The present invention provides systems, apparatus and methods for selectively applying electrical energy to structures in the head and neck of a patient's body, such as tissue within the ear, nose and throat. The systems and methods of the present invention are particularly useful for ablation and hemostasis of tissue in sinus surgery (e.g., chronic sinusitis and/or removal of polypectomies) and collagen shrinkage, ablation and/or hemostasis in procedures for treating snoring and obstructive sleep apnea (e.g., soft palate or tongue/pharynx stiffening, and midline glossectomies).

The method of the present invention comprises positioning an electrosurgical probe adjacent the target tissue so that one or more electrode terminal(s) are brought into at least partial contact or close proximity with the target site. Electrically conducting fluid, such as isotonic saline, is directed to the target site to generate a current flow path between the electrode terminal(s) and one or more return electrode(s). High frequency voltage is then applied between the electrode terminal(s) and the return electrode(s) through the current flow path created by the electrically conducting fluid. Depending on the procedure, the probe may then be translated, reciprocated or otherwise manipulated to cut, remove, ablate, contract, coagulate, vaporize, desiccate or otherwise modify the tissue structure at the target site. This method is particularly effective in a naturally dry environment (i.e., the tissue is not submerged in fluid), such as nasal or oral surgery, because the electrically conducting fluid provides a suitable current flow path from the electrode terminal(s) to the return electrode(s).

In one aspect of the invention, a method is provided for removing tissue in the nasal cavity or a paranasal sinus of a patient to remove a blockage, such as swollen nasal tissue, mucus membranes, turbinates, polyps, neoplasms, cartilage (e.g., the nasal septum) or the like. In this method, one or more electrode terminal(s) are delivered into the nasal cavity, either endoscopically through one of the nasal passages or directly in an open procedure. An electrically conductive fluid, such as isotonic saline, is delivered to the target site within or around the nasal cavity to substantially surround the electrode terminal(s) with the fluid. Alternatively, a more viscous fluid, such as an electrically conductive gel, may be applied to the target site such that the electrode terminal(s) are submerged within the gel during the procedure. In both embodiments, high frequency voltage is applied between the electrode terminal(s) and one or more return electrode(s) to remove at least a portion of the tissue. The high frequency voltage is preferably selected to effect a controlled depth of hemostasis of severed blood vessels within the tissue, which greatly improves the surgeon's view of the surgical site.

In a specific configuration, the nasal tissue is removed by molecular dissociation or disintegration processes. In these embodiments, the high frequency voltage applied to the electrode terminal(s) is sufficient to vaporize an electrically conductive fluid (e.g., gel or saline) between the electrode terminal(s) and the tissue. Within the vaporized fluid, a ionized plasma is formed and charged particles (e.g., electrons) are accelerated towards the tissue to cause the molecular breakdown or disintegration of several cell layers of the tissue. This molecular dissociation is accompanied by the volumetric removal of the tissue. The short range of the accelerated charged particles within the plasma layer confines the molecular dissociation process to the surface layer to minimize damage, and necrosis to the underlying tissue. This process can be precisely controlled to effect the volumetric removal of tissue as thin as 10 to 150 microns with minimal heating of, or damage to, surrounding or underlying tissue structures. A more complete description of this phenomena is described in commonly assigned U.S. Pat. No. 5,683,366, the complete disclosure of which is incorporated herein by reference.

The present invention offers a number of advantages over current microdebrider and laser techniques for endoscopic sinus surgery. The ability to precisely control the volumetric removal of tissue results in a field of tissue ablation or removal that is very defined, consistent and predictable. The shallow depth of tissue heating also helps to minimize or completely eliminate damage to healthy tissue structures, cartilage, bone and/or cranial nerves that are often adjacent the target sinus tissue. In addition, small blood vessels

within the nose are simultaneously cauterized and sealed as the tissue is removed to continuously maintain hemostasis during the procedure. This increases the surgeon's field of view, and shortens the length of the procedure. Moreover, since the present invention allows for the use of electrically conductive fluid (contrary to prior art bipolar and monopolar electrosurgery techniques), isotonic saline may be used during the procedure. Saline is the preferred medium for irrigation because it has the same concentration as the body's fluids and, therefore, is not absorbed into the body as much as other fluids.

In one embodiment, a small tissue segment or hole is removed from the region near or in the turbinates within the nose to shrink the turbinates and prevent swelling, due to the formation of scar tissue as the wound heals. According to the present invention, one or more electrode terminals are positioned adjacent the target tissue near the turbinates, and fluid is delivered or applied to the target tissue as described above. As high frequency energy is applied to the electrode terminal(s) and the return electrode(s), the electrode terminals are advanced into the space vacated by the removed tissue to form a small hole or channel in the turbinate tissue. This hole or holes, typically less than 3 mm diameter, preferably less than 1 mm in diameter, help to shrink the turbinates and prevent swelling. In an exemplary embodiment, an incision is performed (i.e., with a separate instrument, or with the electrosurgical probe of the present invention), so that the mucosa can be lifted before ablating the underlying tissue. This helps to preserve the mucosa and its important function to the nose. Alternatively, the holes may be made directly through mucosa, which should not adversely affect mucosal transport given the small size of the holes formed by the present invention. A more complete description of electrosurgical methods for forming holes or channels in tissue can be found in U.S. Pat. No. 5,683,366, previously incorporated herein by reference.

In another aspect of the invention, a method includes positioning one or more electrode terminal(s) in close proximity to a target site within the head or neck of a patient, such as the nasal cavity or in the patient's throat. High frequency voltage is applied to the electrode terminal(s) to elevate the temperature of collagen fibers within the tissue at the target site from body temperature (about 37° C.) to a tissue temperature in the range of about 45° C. to 90° C., usually about 60° C. to 70° C., to substantially irreversibly contract these collagen fibers. In a preferred embodiment, an electrically conducting fluid is provided between the electrode terminal(s) and one or more return electrode(s) positioned proximal to the electrode terminal(s) to provide a current flow path from the electrode terminal(s) away from the tissue to the return electrode (s). The current flow path may be generated by directing an electrically conducting fluid along a fluid path past the return electrode and to the target site, or by locating a viscous electrically conducting fluid, such as a gel, at the target site, and submersing the electrode terminal(s) and the return electrode(s) within the conductive gel. The collagen fibers may be heated either by passing the electric current through the tissue to a selected depth before the current returns to the return electrode(s) and/or by heating the electrically conducting fluid and generating a jet or plume of heated fluid, which is directed towards the target tissue. In the latter embodiment, the electric current may not pass into the tissue at all. In both embodiments, the heated fluid and/or the electric current elevates the temperature of the collagen sufficiently to cause hydrothermal shrinkage of the collagen fibers.

The contraction of collagen tissue is particularly useful in procedures for treating obstructive sleep disorders, such as snoring or sleep apnea. In these procedures, one or more electrode terminal(s) are introduced into the patient's mouth, and positioned adjacent the target tissue, selected portions of the tongue, tonsils, soft palate tissues (e.g., the uvula), hard tissue and mucosal tissue. An endoscope or other type of viewing device, may also be introduced, or partially introduced, into the mouth to allow the surgeon to view the procedure (the viewing device may be integral with, or separate from, the electrosurgical probe). Electrically conductive fluid is applied as described above, and high frequency voltage is applied to the electrode terminal(s) and one or more return electrode(s) to, for example, ablate or shrink sections of the uvula without causing unwanted tissue damage under and around the selected sections of tissue.

Apparatus according to the present invention generally include an electrosurgical probe or handpiece having a shaft with proximal and distal ends, one or more electrode terminal(s) at the distal end and one or more connectors coupling the electrode terminal(s) to a source of high frequency electrical energy. For endoscopic sinus surgery, the shaft will have at least a distal end portion sized for delivery through one of the patient's nasal passages. For treating swollen turbinates, the distal end portion of the shaft will usually have a diameter of less than 3 mm, preferably less than 1 mm, to facilitate the formation of small hole(s) or channel(s) within the swollen turbinate tissue. The shaft may additionally include a lens at the distal end coupled to a proximal eye piece for endoscopically viewing the target tissue. Alternatively, the endoscope may be a separate instrument that is introduced through the same or a different opening as the electrosurgical probe.

The apparatus will preferably further include a fluid delivery element for delivering electrically conducting fluid to the electrode terminal(s) and the target site. The fluid delivery element may be located on the probe, e.g., a fluid lumen or tube, or it may be part of a separate instrument. Alternatively, an electrically conducting gel or spray, such as a saline electrolyte or other conductive gel, may be applied the target site. In this embodiment, the apparatus may not have a fluid delivery element. In both embodiments, the electrically conducting fluid will preferably generate a current flow path between the electrode terminal(s) and one or more return electrode(s). In an exemplary embodiment, the return electrode is located on the probe and spaced a sufficient distance from the electrode terminal(s) to substantially avoid or minimize current shorting therebetween and to shield the return electrode from tissue at the target site.

In a specific configuration, the electrosurgical probe will include an electrically insulating electrode support member having a tissue treatment surface at the distal end of the probe. One or more electrode terminal(s) are coupled to, or integral with, the electrode support member such that the electrode terminal(s) are spaced from the return electrode. In one embodiment, the probe includes an electrode array having a plurality of electrically isolated electrode terminals embedded into the electrode support member such that the electrode terminals extend about 0.2 mm to about 10 mm distally from the tissue treatment surface of the electrode support member. In this embodiment, the probe will further include one or more lumens for delivering electrically conductive fluid to one or more openings around the tissue treatment surface of the electrode support member. In an exemplary embodiment, the lumen will extend through a fluid tube exterior to the probe shaft that ends proximal to the return electrode.

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 end of the probe. In this embodiment, the temperature set point will preferably be one that corresponds to a tissue temperature that results, for example, 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).

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 ablation, resection, incision, contraction and for vessel hemostasis according to the present invention;

FIG. **2** is a side view of an electrosurgical probe according to the present invention;

FIG. **3** is an end view of the probe of FIG. **2**

FIG. **4** is a cross sectional view of the electrosurgical probe of FIG. **1**;

FIG. **5** is an exploded view of a proximal portion of the electrosurgical probe;

FIGS. **6**A and **6**B are perspective and end views, respectively, of an alternative electrosurgical probe incorporating an inner fluid lumen;

FIGS. **7**A–**7**C are cross-sectional views of the distal portions of three different embodiments of an electrosurgical probe according to the present invention;

FIGS. **8**A and **8**B are cross-sectional and end views, respectively, of yet another electrosurgical probe incorporating flattened electrode terminals;

FIG. **9** illustrates an electrosurgical probe with a 90° distal bend and a lateral fluid lumen;

FIG. **10** illustrates an electrosurgical system with a separate fluid delivery instrument according to the present invention;

FIG. **11** illustrates an endoscopic sinus surgery procedure, wherein an endoscope is delivered through a nasal passage to view a surgical site within the nasal cavity of the patient;

FIG. **12** illustrates an endoscopic sinus surgery procedure with one of the probes described above according to the present invention;

FIGS. **13**A and **13**B illustrate a detailed view of the sinus surgery procedure, illustrating ablation of tissue according to the present invention; and

FIG. **14** illustrates a procedure for treating obstructive sleep disorders, such as sleep apnea, according to the present invention.

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, particularly including tissue in head and neck, such as the ear, mouth, pharynx, larynx, esophagus, nasal cavity and sinuses. These procedures may be performed through the mouth or nose using speculae or gags, or using endoscopic techniques, such as functional endoscopic sinus surgery (FESS). These procedures may include the removal of swollen tissue, chronically-diseased inflamed and hypertrophic mucus linings, polyps and/or neoplasms from the various anatomical sinuses of the skull, the turbinates and nasal passages, in the tonsil, adenoid, epi-glottic and supra-glottic regions, and salivary glands, submucus resection of the nasal septum, excision of diseased tissue and the like. In other procedures, the present invention may be useful for collagen shrinkage, ablation and/or hemostasis in procedures for treating snoring and obstructive sleep apnea (e.g., soft palate, such as the uvula, or tongue/pharynx stiffening, and midline glossectomies), for gross tissue removal, such as tonsillectomies, adenoidectomies, tracheal stenosis and vocal cord polyps and lesions, or for the resection or ablation of facial tumors or tumors within the mouth and pharynx, such as glossectomies, laryngectomies, acoustic neuroma procedures and nasal ablation procedures. In addition, the present invention is useful for procedures within the ear, such as stapedotomies, tympanostomies or the like.

The present invention may also be useful for cosmetic and plastic surgery procedures in the head and neck. For example, the present invention is particularly useful for ablation and sculpting of cartilage tissue, such as the cartilage within the nose that is sculpted during rhinoplasty procedures. The present invention may also be employed for skin tissue removal and/or collagen shrinkage in the epidermis or dermis tissue in the head and neck, e.g., the removal of pigmentations, vascular lesions (e.g., leg veins), scars, tattoos, etc., and for other surgical procedures on the skin, such as tissue rejuvenation, cosmetic eye procedures (blepharoplasties), wrinkle removal, tightening muscles for facelifts or browlifts, hair removal and/or transplant procedures, etc.

In the present invention, high frequency (RF) electrical energy is applied to one or more electrode terminals in the presence of electrically conductive fluid to remove and/or modify the structure of tissue structures. Depending on the specific procedure, the present invention may be used to: (1) volumetrically remove tissue or cartilage (i.e., ablate or effect molecular dissociation of the tissue structure); (2) cut or resect tissue; (3) shrink or contract collagen connective tissue; and/or (4) coagulate severed blood vessels.

In some procedures, e.g., soft palate or tongue/pharynx stiffening, it is desired to shrink or contract collagen connective tissue at the target site. In these procedures, the RF energy heats the tissue directly by virtue of the electrical current flow therethrough, and/or indirectly through the exposure of the tissue to fluid heated by RF energy, to elevate the tissue temperature from normal body temperatures (e.g., 37° C.) to temperatures in the range of 45° C. to 90° C., preferably in the range from about 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). Collagen fibers typically undergo thermal shrinkage in the range of 60° C. to about 70° C. 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. A more detailed description of collagen shrinkage

can be found in U.S. patent application Ser. No. application No. 08/942,580, filed on Oct. 2, 1997, entitled 'SYSTEMS AND METHODS FOR ELECTROSURGICAL TISSUE CONTRACTION" (Attorney Docket No. 16238-001300).

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, 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 collagen within the soft palate or uvula, the depth of heating is preferably in the range from about 0.5 to about 3.5 mm.

In another method of the present invention, the tissue structures are volumetrically removed or ablated. In this procedure, a high frequency voltage difference is applied between one or more electrode terminal(s) and one or more return electrode(s) to develop high electric field intensities in the vicinity of the target tissue site. The high electric field intensities lead to electric field induced molecular breakdown of target tissue through molecular dissociation (rather than thermal evaporation or carbonization). Applicant believes that the tissue structure is volumetrically removed through molecular disintegration of larger organic molecules into smaller molecules and/or atoms, such as hydrogen, oxides of carbon, hydrocarbons and nitrogen compounds. This molecular disintegration completely removes the tissue structure, as opposed to dehydrating the tissue material by the removal of liquid within the cells of the tissue, as is typically the case with electrosurgical desiccation and vaporization.

The high electric field intensities may be generated by applying a high frequency voltage that is sufficient to vaporize an electrically conducting fluid over at least a portion of the electrode terminal(s) in the region between the distal tip of the electrode terminal(s) and the target tissue. The electrically conductive fluid may be a gas or liquid, such as isotonic saline, delivered to the target site, or a viscous fluid, such as a gel, that is located at the target site. In the latter embodiment, the electrode terminal(s) are submersed in the electrically conductive gel during the surgical procedure. Since the vapor layer or vaporized region has a relatively high electrical impedance, it increases the voltage differential between the electrode terminal tip and the tissue and causes ionization within the vapor layer due to the presence of an ionizable species (e.g., sodium when isotonic saline is the electrically conducting fluid). This ionization, under optimal conditions, induces the discharge of energetic electrons and photons from the vapor layer and to the surface of the target tissue. This energy may be in the form of energetic photons (e.g., ultraviolet radiation), energetic particles (e.g., electrons) or a combination thereof. A more detailed description of this cold ablation phenomena, termed Coblation™, can be found in commonly assigned U.S. Pat. No. 5,683,366 the complete disclosure of which is incorporated herein by reference.

The present invention applies high frequency (RF) electrical energy in an electrically conducting fluid environment to remove (i.e., resect, cut or ablate) or contract a tissue structure, and to seal transected vessels within the region of the target tissue. The present invention is particularly useful for sealing larger arterial vessels, e.g., on the order of 1 mm or greater. In some embodiments, a high frequency power supply is provided having an ablation mode, wherein a first voltage is applied to an electrode terminal sufficient to effect molecular dissociation or disintegration of the tissue, and a coagulation mode, wherein a second, lower voltage is applied to an electrode terminal (either the same or a different electrode) sufficient to achieve hemostasis of severed vessels within the tissue. In other embodiments, an electrosurgical probe is provided having one or more coagulation electrode(s) configured for sealing a severed vessel, such as an arterial vessel, and one or more electrode terminals configured for either contracting the collagen fibers within the tissue or removing (ablating) the tissue, e.g., by applying sufficient energy to the tissue to effect molecular dissociation. In the latter embodiments, the coagulation electrode(s) may be configured such that a single voltage can be applied to coagulate with the coagulation electrode(s), and to ablate or contract with the electrode terminal(s). In other embodiments, the power supply is combined with the coagulation probe such that the coagulation electrode is used when the power supply is in the coagulation mode (low voltage), and the electrode terminal(s) are used when the power supply is in the ablation mode (higher voltage).

In the method of the present invention, one or more electrode terminals are brought into close proximity to tissue at a target site, and the power supply is activated in the ablation mode such that sufficient voltage is applied between the electrode terminals and the return electrode to volumetrically remove the tissue through molecular dissociation, as described below. During this process, vessels within the tissue will be severed. Smaller vessels will be automatically sealed with the system and method of the present invention. Larger vessels, and those with a higher flow rate, such as arterial vessels, may not be automatically sealed in the ablation mode. In these cases, the severed vessels may be sealed by activating a control (e.g., a foot pedal) to reduce the voltage of the power supply into the coagulation mode. In this mode, the electrode terminals may be pressed against the severed vessel to provide sealing and/or coagulation of the vessel. Alternatively, a coagulation electrode located on the same or a different probe may be pressed against the severed vessel. Once the vessel is adequately sealed, the surgeon activates a control (e.g., another foot pedal) to increase the voltage of the power supply back into the ablation mode.

The present invention is particularly useful for removing or ablating tissue around nerves, such as spinal or cranial nerves, e.g., the olfactory nerve on either side of the nasal cavity, the optic nerve within the optic and cranial canals, the palatine nerve within the nasal cavity, soft palate, uvula and tonsil, etc. One of the significant drawbacks with the prior art microdebriders and lasers is that these devices do not differentiate between the target tissue and the surrounding nerves or bone. Therefore, the surgeon must be extremely careful during these procedures to avoid damage to the bone or nerves within and around the nasal cavity. In the present invention, the Coblation™ process for removing tissue results in extremely small depths of collateral tissue damage as discussed above. This allows the surgeon to remove tissue close to a nerve without causing collateral damage to the nerve fibers.

In addition to the generally precise nature of the novel mechanisms of the present invention, applicant has discovered an additional method of ensuring that adjacent nerves are not damaged during tissue removal. According to the present invention, systems and methods are provided for distinguishing between the fatty tissue immediately surrounding nerve fibers and the normal tissue that is to be removed during the procedure. Nerves usually comprise a connective tissue sheath, or endoneurium, enclosing the

bundles of nerve fibers to protect these nerve fibers. This protective tissue sheath typically comprises a fatty tissue (e.g., adipose tissue) having substantially different electrical properties than the normal target tissue, such as the turbinates, polyps, mucus tissue or the like, that are, for example, removed from the nose during sinus procedures. The system of the present invention measures the electrical properties of the tissue at the tip of the probe with one or more electrode terminal(s). These electrical properties may include electrical conductivity at one, several or a range of frequencies (e.g., in the range from 1 kHz to 100 MHz), dielectric constant, capacitance or combinations of these. In this embodiment, an audible signal may be produced when the sensing electrode(s) at the tip of the probe detects the fatty tissue surrounding a nerve, or direct feedback control can be provided to only supply power to the electrode terminal(s) either individually or to the complete array of electrodes, if and when the tissue encountered at the tip or working end of the probe is normal tissue based on the measured electrical properties.

In one embodiment, the current limiting elements (discussed in detail above) are configured such that the electrode terminals will shut down or turn off when the electrical impedance reaches a threshold level. When this threshold level is set to the impedance of the fatty tissue surrounding nerves, the electrode terminals will shut off whenever they come in contact with, or in close proximity to, nerves. Meanwhile, the other electrode terminals, which are in contact with or in close proximity to nasal tissue, will continue to conduct electric current to the return electrode. This selective ablation or removal of lower impedance tissue in combination with the Coblation™ mechanism of the present invention allows the surgeon to precisely remove tissue around nerves or bone.

In addition to the above, applicant has discovered that the Coblation™ mechanism of the present invention can be manipulated to ablate or remove certain tissue structures, while having little effect on other tissue structures. As discussed above, the present invention uses a technique of vaporizing electrically conductive fluid to form a plasma layer or pocket around the electrode terminal(s), and then inducing the discharge of energy from this plasma or vapor layer to break the molecular bonds of the tissue structure. Based on initial experiments, applicants believe that the free electrons within the ionized vapor layer are accelerated in the high electric fields near the electrode tip(s). When the density of the vapor layer (or within a bubble formed in the electrically conducting liquid) becomes sufficiently low (i.e., less than approximately 10^{20} atoms/cm^3 for aqueous solutions), the electron mean free path increases to enable subsequently injected electrons to cause impact ionization within these regions of low density (i.e., vapor layers or bubbles). Energy evolved by the energetic electrons (e.g., 4 to 5 eV) can subsequently bombard a molecule and break its bonds, dissociating a molecule into free radicals, which then combine into final gaseous or liquid species.

The energy evolved by the energetic electrons may be varied by adjusting a variety of factors, such as: the number of electrode terminals; electrode size and spacing; electrode surface area; asperities and sharp edges on the electrode surfaces; electrode materials; applied voltage and power; current limiting means, such as inductors; electrical conductivity of the fluid in contact with the electrodes; density of the fluid; and other factors. Accordingly, these factors can be manipulated to control the energy level of the excited electrons. Since different tissue structures have different molecular bonds, the present invention can be configured to break the molecular bonds of certain tissue, while having too low an energy to break the molecular bonds of other tissue. For example, fatty tissue, (e.g., adipose) tissue has double bonds that require a substantially higher energy level than 4 to 5 eV to break. Accordingly, the present invention in its current configuration generally does not ablate or remove such fatty tissue. Of course, factors may be changed such that these double bonds can be broken (e.g., increasing voltage or changing the electrode configuration to increase the current density at the electrode tips).

The electrosurgical probe will comprise a shaft or a handpiece having a proximal end and a distal end which supports one or more electrode terminal(s). The shaft or handpiece may assume a wide variety of configurations, with the primary purpose being to mechanically support the active electrode and permit the treating physician to manipulate the electrode from a proximal end of the shaft. 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 electrode array. The shaft will usually include a plurality of wires or other conductive elements running axially therethrough to permit connection of the electrode array to a connector at the proximal end of the shaft.

For procedures within the nose, the shaft will have a suitable diameter and length to allow the surgeon to reach the target site (e.g., a blockage in the nasal cavity or one of the sinuses) by delivering the probe shaft through one of the nasal passages or another opening (e.g., an opening in the eye or through an opening surgically creating during the procedure). Thus, the shaft will usually have a length in the range of about 5–25 cm, and a diameter in the range of about 0.5 to 5 mm. For procedures requiring the formation of a small hole or channel in tissue, such as treating swollen turbinates, the shaft diameter will usually be less than 3 mm, preferably less than about 1 mm. Likewise, for procedures in the ear, the shaft should have a length in the range of about 3 to 20 cm, and a diameter of about 0.3 to 5 mm. For procedures in the mouth or upper throat, the shaft will have any suitable length and diameter that would facilitate handling by the surgeon. For procedures in the lower throat, such as laryngectomies, the shaft will be suitably designed to access the larynx. For example, the shaft may be flexible, or have a distal bend to accommodate the bend in the patient's throat. In this regard, the shaft may be a rigid shaft having a specifically designed bend to correspond with the geometry of the mouth and throat, or it may have a flexible distal end, or it may be part of a catheter. In any of these embodiments, the shaft may also be introduced through rigid or flexible endoscopes. Specific shaft designs will be described in detail in connection with the figures hereinafter.

The current flow path between the electrode terminal(s) 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). This latter method is particularly effective in a dry environment (i.e., the tissue is not submerged in fluid) because the electrically conducting fluid provides a suitable current flow path from the electrode terminal to the return electrode. A more complete description of an exemplary method of directing electrically conducting fluid between the active and return electrodes is described in

parent application Ser. No. 08/485,219, filed Jun. 7, 1995 (docket no. 16238-000600), previously incorporated herein by reference.

In some procedures, it may also be necessary to retrieve or aspirate the electrically conductive fluid after it has been directed to the target site. For example, in procedures in the nose, mouth or throat, it may be desirable to aspirate the fluid so that it does not flow down the patient's throat. In addition, it may be desirable to aspirate small pieces of tissue that are not completely disintegrated by the high frequency energy, or other fluids at the target site, such as blood, mucus, the gaseous products of ablation, etc. Accordingly, the system of the present invention will usually include a suction lumen in the probe, or on another instrument, for aspirating fluids from the target site.

The present invention may use a single active electrode terminal or an electrode array distributed over a contact surface of a probe. In the latter embodiment, 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 while limiting the unwanted application of electrical energy to the surrounding tissue and environment resulting from power dissipation into surrounding electrically conductive liquids, such as blood, normal saline, electrically conductive gel and the like. 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 a power source.

In one configuration, each individual electrode terminal in the electrode array is electrically insulated from all other electrode terminals in the array within said probe and is connected to a power source which is isolated from each of the other electrode terminals in the array or to circuitry which limits or interrupts current flow to the electrode terminal when low resistivity material (e.g., blood, electrically conductive saline irrigant or electrically conductive gel) causes a lower impedance path between the return electrode and the individual electrode terminal. The isolated power sources for each individual electrode terminal may be separate power supply circuits having internal impedance characteristics which limit power to the associated electrode terminal 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 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 electrode terminals 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 probe, connectors, cable, controller or along the conductive path from the controller to the distal tip of the probe. Alternatively, the resistance and/or capacitance may occur on the surface of the active electrode terminal(s) due to oxide layers which form selected electrode terminals (e.g., titanium or a resistive coating on the surface of metal, such as platinum).

The tip region of the probe may comprise many independent electrode terminals 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 electrode terminal and the return electrode to a power source having independently controlled or current limited channels. The return electrode(s) may comprise a single tubular member of conductive material proximal to the electrode array at the tip which also serves as a conduit for the supply of the electrically conducting fluid between the active and return electrodes. Alternatively, the probe may comprise an array of return electrodes at the distal tip of the probe (together with the active electrodes) to maintain the electric current at the tip. The application of high frequency voltage between the return electrode(s) and the electrode array results in the generation of high electric field intensities at the distal tips of the electrode terminals with conduction of high frequency current from each individual electrode terminal to the return electrode. The current flow from each individual electrode terminal to the return electrode(s) 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.

The application of a high frequency voltage between the return electrode(s) and the electrode terminal(s) for appropriate time intervals effects cutting, removing, ablating, shaping, contracting or otherwise modifying 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 electrode terminals whose effective diameters or principal dimensions 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 electrode terminal) below 25 mm^2, preferably being in the range from 0.0001 mm^2 to 1 mm^2, and more preferably from 0.005 mm^2 to 0.5 mm^2. The circumscribed area of the electrode array is in the range from 0.25 mm^2 to 75 mm^2, preferably from 0.5 mm^2 to 40 mm^2, and will usually include at least two isolated electrode terminals, preferably at least five electrode terminals, often greater than 10 electrode terminals and even 50 or more electrode terminals, disposed over the distal contact surfaces on the shaft. The use of small diameter electrode terminals increases the electric field intensity and reduces the extent or depth of tissue heating as a consequence of the divergence of current flux lines which emanate from the exposed surface of each electrode terminal.

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 mm^2 to 75 mm^2, usually being from about 0.5 mm^2 to 40 mm^2. The geometries can be planar, concave, convex, hemispherical, conical, linear "in-line" array or virtually any other regular or irregular shape. Most commonly, the active electrode(s) or electrode terminal(s) will be formed at the distal tip of the electrosurgical probe 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 probe shaft (e.g., in the manner of a spatula), facilitating access to certain body structures in endoscopic procedures.

In the representative embodiments, the electrode terminals comprise substantially rigid wires protruding outward from the tissue treatment surface of the electrode support member. Usually, the wires will extend about 0.1 to 4.0 mm, preferably about 0.2 to 1 mm, from the distal surface of the

support member. In the exemplary embodiments, the electrosurgical probe includes between about two to fifty electrically isolated electrode terminals, and preferably between about three to twenty electrode terminals.

The electrically conducting fluid should have a threshold conductivity to provide a suitable conductive path between the return electrode(s) and the electrode terminal(s). The electrical conductivity of the fluid (in units of milliSiemans per centimeter or mS/cm) 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.

In some embodiments, the electrode support and the fluid outlet may be recessed from an outer surface of the probe or handpiece to confine the electrically conductive fluid to the region immediately surrounding the electrode support. In addition, the shaft may be shaped so as to form a cavity around the electrode support and the fluid outlet. This helps to assure that the electrically conductive fluid will remain in contact with the electrode terminal(s) and the return electrode(s) to maintain the conductive path therebetween. In addition, this will help to maintain a vapor or plasma layer between the electrode terminal(s) and the tissue at the treatment site throughout the procedure, which reduces the thermal damage that might otherwise occur if the vapor layer were extinguished due to a lack of conductive fluid. Provision of the electrically conductive fluid around the target site also helps to maintain the tissue temperature at desired levels.

The voltage applied between the return electrode(s) 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 50 kHz and 500 kHz, more preferably less than 350 kHz, and most preferably 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 depending on the electrode terminal size, the operating frequency and the operation mode of the particular procedure or desired effect on the tissue (i.e., contraction, coagulation or ablation). Typically, the peak-to-peak voltage will be in the range of 10 to 2000 volts, preferably in the range of 20 to 1200 volts and more preferably in the range of about 40 to 800 volts (again, depending on the electrode size, the operating frequency and the operation mode).

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 probe tip. The power source allows the user to select the voltage level according to the specific requirements of a particular FESS procedure, arthroscopic surgery, dermatological procedure, ophthalmic procedures, open surgery or other endoscopic surgery procedure. A description of a suitable power source can be found in "SYSTEMS AND METHODS FOR ELECTROSURGICAL TISSUE AND FLUID COAGULATION", Application No. 60/062,997, filed on Oct. 23, 1997 (Attorney Docket No. 16238-007400), the complete disclosure of which has been incorporated herein by reference.

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 electrode terminal, where the inductance of the inductor is in the range of 10 uH to 50,000 uH, 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 copending 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).

It should be clearly understood that the invention is not limited to electrically isolated electrode terminals, or even to a plurality of electrode terminals. For example, the array of active electrode terminals may be connected to a single lead that extends through the probe shaft to a power source of high frequency current. Alternatively, the probe may incorporate a single electrode that extends directly through the probe shaft or is connected to a single lead that extends to the power source. The active electrode may have a ball shape (e.g., for tissue vaporization and desiccation), a twizzle shape (for vaporization and needle-like cutting), a spring shape (for rapid tissue debulking and desiccation), a twisted metal shape, an annular or solid tube shape or the like. Alternatively, the electrode may comprise a plurality of filaments, a rigid or flexible brush electrode (for debulking a tumor, such as a fibroid, bladder tumor or a prostate adenoma), a side-effect brush electrode on a lateral surface of the shaft, a coiled electrode or the like. In one embodiment, the probe comprises a single active electrode terminal that extends from an insulating member, e.g., ceramic, at the distal end of the probe. The insulating member is preferably a tubular structure that separates the active electrode terminal from a tubular or annular return electrode positioned proximal to the insulating member and the active electrode.

Referring to FIG. **1**, an exemplary electrosurgical system **11** for treatment of tissue in the head and neck will now be described in detail. Electrosurgical system **11** generally comprises an electrosurgical handpiece or probe **10** connected to a power supply **28** for providing high frequency voltage to a target site and a fluid source **21** for supplying electrically conducting fluid **50** to probe **10**. In addition, electrosurgical system **11** may include an endoscope (not shown) with a fiber optic head light for viewing the surgical site, particularly in sinus procedures or procedures in the ear or the back of the mouth. The endoscope may be integral with probe **10**, or it may be part of a separate instrument. The

system **11** may also include a vacuum source (not shown) for coupling to a suction lumen or tube **205** (see FIG. **2**) in the probe **10** for aspirating the target site.

As shown, probe **10** generally includes a proximal handle **19** and an elongate shaft **18** having an array **12** of electrode terminals **58** at its distal end. A connecting cable **34** has a connector **26** for electrically coupling the electrode terminals **58** to power supply **28**. The electrode terminals **58** are electrically isolated from each other and each of the terminals **58** is connected to an active or passive control network within power supply **28** by means of a plurality of individually insulated conductors (not shown). A fluid supply tube **15** is connected to a fluid tube **14** of probe **10** for supplying electrically conducting fluid **50** to the target site.

Power supply **28** has an operator controllable voltage level adjustment **30** to change the applied voltage level, which is observable at a voltage level display **32**. Power supply **28** also includes first, second and third foot pedals **37**, **38**, **39** and a cable **36** which is removably coupled to power supply **28**. The foot pedals **37**, **38**, **39** allow the surgeon to remotely adjust the energy level applied to electrode terminals **58**. In an exemplary embodiment, first foot pedal **37** is used to place the power supply into the "ablation" mode and second foot pedal **38** places power supply **28** into the "coagulation" mode. The third foot pedal **39** allows the user to adjust the voltage level within the "ablation" mode. In the ablation mode, a sufficient voltage is applied to the electrode terminals to establish the requisite conditions for molecular dissociation of the tissue (i.e., vaporizing a portion of the electrically conductive fluid, ionizing charged particles within the vapor layer and accelerating these charged particles against the tissue). As discussed above, the requisite voltage level for ablation will vary depending on the number, size, shape and spacing of the electrodes, the distance in which the electrodes extend from the support member, etc. Once the surgeon places the power supply in the "ablation" mode, voltage level adjustment **30** or third foot pedal **39** may be used to adjust the voltage level to adjust the degree or aggressiveness of the ablation.

Of course, it will be recognized that the voltage and modality of the power supply may be controlled by other input devices. However, applicant has found that foot pedals are convenient methods of controlling the power supply while manipulating the probe during a surgical procedure.

In the coagulation mode, the power supply **28** applies a low enough voltage to the electrode terminals (or the coagulation electrode) to avoid vaporization of the electrically conductive fluid and subsequent molecular dissociation of the tissue. The surgeon may automatically toggle the power supply between the ablation and coagulation modes by alternatively stepping on foot pedals **37**, **38**, respectively. This allows the surgeon to quickly move between coagulation and ablation in situ, without having to remove his/her concentration from the surgical field or without having to request an assistant to switch the power supply. By way of example, as the surgeon is sculpting soft tissue in the ablation mode, the probe typically will simultaneously seal and/or coagulation small severed vessels within the tissue. However, larger vessels, or vessels with high fluid pressures (e.g., arterial vessels) may not be sealed in the ablation mode. Accordingly, the surgeon can simply step on foot pedal **38**, automatically lowering the voltage level below the threshold level for ablation, and apply sufficient pressure onto the severed vessel for a sufficient period of time to seal and/or coagulate the vessel. After this is completed, the surgeon may quickly move back into the ablation mode by stepping on foot pedal **37**. A specific design of a suitable power supply for use with the present invention can be found in provisional patent application entitled "SYSTEMS AND METHODS FOR ELECTROSURGICAL TISSUE AND FLUID COAGULATION", Application No. 60/062,997, filed Oct. 23, 1997 (attorney docket no. 16238-007400), previously incorporated herein by reference.

FIGS. **2–5** illustrate an exemplary electrosurgical probe **90** constructed according to the principles of the present invention. As shown in FIG. **2**, probe **90** 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 includes a bend **101** that allows the distal section of shaft **100** to be offset from the proximal section and handle **204**. This offset facilitates procedures that require an endoscope, such as FESS, because the endoscope can, for example, be introduced through the same nasal passage as the shaft **100** without interference between handle **204** and the eyepiece of the endoscope (see FIG. **11**). Shaft **100** preferably comprises a plastic material that is easily molded into the shape shown in FIG. **1**.

In an alternative embodiment (see FIG. **6**A), shaft **100** comprises an electrically conducting material, usually metal, which is selected from the group comprising tungsten, stainless steel alloys, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and nickel or its alloys. In this embodiment, 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. Handle **204** defines an inner cavity (not shown) that houses the electrical connections **250** (FIG. **5**), 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 electrode terminals **104** (see FIGS. **3** and **4**). As shown in FIG. **2**, a fluid tube **233** extends through an opening in handle **204**, and includes a connector **235** for connection to a fluid supply source, for supplying electrically conductive fluid to the target site. Depending on the configuration of the distal surface of shaft **100**, fluid tube **233** may extend through a single lumen (not shown) in shaft **100**, or it may be coupled to a plurality of lumens (also not shown) that extend through shaft **100** to a plurality of openings at its distal end. In the representative embodiment, fluid tube **233** extends along the exterior of shaft **100** to a point just proximal of return electrode **112** (see FIG. **4**). In this embodiment, the fluid is directed through an opening **237** past return electrode **112** to the electrode terminals **104**. Probe **90** may also include a valve **17** (FIG. **1**) or equivalent structure for controlling the flow rate of the electrically conducting fluid to the target site.

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. Electrode support member **102** has a substantially planar tissue treatment surface **212** (FIGS. **5**A

and 5B) 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 Ser. 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 the treatment of sinus tissue as it allows the surgeon to reach the target tissue within the nose as the shaft **100** extends through the nasal passage. 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 the mouth and a shaft having a 10° to 30° bend angle may be useful for accessing tissue near or in the front portion of the mouth or nose

In the embodiment shown in FIGS. **2–5**, probe **90** includes a return electrode **112** for completing the current path between electrode terminals **104** and a high frequency power supply **28** (see FIG. **1**). As shown, return electrode **112** preferably comprises an annular conductive band coupled to the distal end of shaft **100** 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 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 through fluid tube **233** to opening **237**, as described above. Alternatively, the fluid may be delivered by a fluid delivery element (not shown) that is separate from probe **90**. In arthroscopic surgery, for example, the body cavity will be flooded with isotonic saline and the probe **90** 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 **90** by, for example, an inner lumen or an annular gap between the return electrode and a tubular support member within shaft **100** (see FIG. **6**). 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 **90** 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 parent application Ser. No. 08/485,219, filed on Jun. 7, 1995 (Attorney Docket 16238-0006000), the complete disclosure of which has previously been incorporated herein by reference.

Referring to FIG. **3**, 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 in the range of 1 mm to 20 mm and a width in the range from 0.3 mm to 7 mm. The oval cross-sectional shape accommodates the bend in the distal portion of shaft **100**. The individual electrode terminals **104** preferably extend outward from tissue treatment surface **212** by a distance of about 0.1 to 4 mm, usually about 0.2 to 2 mm. Applicant has found that this configuration increases the high electric field intensities and associated current densities around electrode terminals **104** to facilitate the ablation of tissue as described in detail above.

In the embodiment of FIGS. **2–5**, the probe includes a single, larger opening **209** in the center of tissue treatment surface **212**, and a plurality of electrode terminals (e.g., about 3–15) around the perimeter of surface **212** (see FIG. **3**). Alternatively, the probe may include a single, annular, or partially annular, electrode terminal at the perimeter of the tissue treatment surface. The central opening **209** is coupled to a suction lumen (not shown) within shaft **100** and a suction tube **211** (FIG. **2**) for aspirating tissue, fluids and/or gases from the target site. In this embodiment, the electrically conductive fluid generally flows radially inward past electrode terminals **104** and then back through the opening **209**. Aspirating the electrically conductive fluid during surgery allows the surgeon to see the target site, and it prevents the fluid from flowing into the patient's body, e.g., through the sinus passages, down the patient's throat or into the ear canal.

Of course, it will be recognized that the distal tip of probe may have a variety of different configurations. For example, the probe may include a plurality of openings **209** around the outer perimeter of tissue treatment surface **212** (see FIG. **6**B). In this embodiment, the electrode terminals **104** extend from the center of tissue treatment surface **212** radially inward from openings **209**. The openings are suitably coupled to fluid tube **233** for delivering electrically conductive fluid to the target site, and suction tube **211** for aspirating the fluid after it has completed the conductive path between the return electrode **112** and the electrode terminals **104**.

FIG. **5** illustrates the electrical connections **250** within handle **204** for coupling electrode terminals **104** and return electrode **112** to the power supply **28**. As shown, a plurality of wires **252** extend through shaft **100** to couple terminals **104** to a 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 **90** further includes an identification element that is characteristic of the particular electrode assembly so that the same power supply **28** can be used for different electrosurgical operations. In one embodiment, for example, the probe **90** includes a voltage reduction element or a voltage reduction circuit for reducing the voltage applied between 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 **90** to be compatible with other ArthroCare generators that are adapted to apply higher voltages for ablation or vaporization of tissue. For contraction of tissue, for example, 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 (e.g., molecular dissociation) of the tissue.

Of course, for some procedures, such as endoscopic sinus surgery, the probe will typically not require a voltage reduction element. Alternatively, the probe may include a voltage increasing element or circuit, if desired.

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**. Of course, 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 **90** 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.

Alternatively or additionally, the cable **22** that couples the power supply **10** to the probe **90** 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 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 treatment of tissue. In this embodiment, a voltage reduction element or circuitry may not be desired.

FIGS. **7A–7C** schematically illustrate the distal portion of three different embodiments of probe **90** according to the present invention. As shown in **7A**, electrode terminals **104** are anchored in a support marix **102** of suitable insulating material (e.g., ceramic or glass material, such as alumina, zirconia and the like) which could be formed at the time of manufacture in a flat, hemispherical or other shape according to the requirements of a particular procedure. The preferred support matrix material is alumina, available from Kyocera Industrial Ceramics Corporation, Elkgrove, Ill., because of its high thermal conductivity, good electrically insulative properties, high flexural modulus, resistance to carbon tracking, biocompatibility, and high melting point. The support matrix **102** is adhesively joined to a tubular support member **78** that extends most or all of the distance between matrix **102** and the proximal end of probe **90**. Tubular member **78** preferably comprises an electrically insulating material, such as an epoxy or silicone-based material.

In a preferred construction technique, electrode terminals **104** extend through pre-formed openings in the support matrix **102** so that they protrude above tissue treatment surface **212** by the desired distance. The electrodes are then bonded to the tissue treatment surface **212** of support matrix **102**, typically by an inorganic sealing material **80**. Sealing material **80** is selected to provide effective electrical insulation, and good adhesion to both the alumina matrix **102** and the platinum or titanium electrode terminals. Sealing material **80** additionally should have a compatible thermal expansion coefficient and a melting point well below that of platinum or titanium and alumina or zirconia, typically being a glass or glass ceramic.

In the embodiment shown in FIG. **7A**, return electrode **112** comprises an annular member positioned around the exterior of shaft **100** of probe **90**. Return electrode **90** may fully or partially circumscribe tubular support member **78** to form an annular gap **54** therebetween for flow of electrically conducting liquid **50** therethrough, as discussed below. Gap **54** preferably has a width in the range of 0.25 mm to 4 mm. Alternatively, probe may include a plurality of longitudinal ribs between support member **78** and return electrode **112** to form a plurality of fluid lumens extending along the perimeter of shaft **100**. In this embodiment, the plurality of lumens will extend to a plurality of openings.

Return electrode **112** is disposed within an electrically insulative jacket **18**, which is typically formed as one or more electrically insulative sheaths or coatings, such as polytetrafluoroethylene, polyamide, and the like. The provision of the electrically insulative jacket **18** over return electrode **112** prevents direct electrical contact between return electrode **56** and any adjacent body structure. Such direct electrical contact between a body structure (e.g., tendon) and an exposed electrode member **112** could result in unwanted heating and necrosis of the structure at the point of contact causing necrosis.

As shown in FIG. **7A**, return electrode **112** is not directly connected to electrode terminals **104**. To complete this current path so that terminals **104** are electrically connected to return electrode **112**, electrically conducting liquid **50** (e.g., isotonic saline) is caused to flow along fluid path(s) **83**. Fluid path **83** is formed by annular gap **54** between outer return electrode **112** and tubular support member. The electrically conducting liquid **50** flowing through fluid path **83** provides a pathway for electrical current flow between electrode terminals **104** and return electrode **112**, as illustrated by the current flux lines **60** in FIG. **6A**. When a voltage difference is applied between electrode terminals **104** and return electrode **112**, high electric field intensities will be generated at the distal tips of terminals **104** with current flow from terminals **104** through the target tissue to the return electrode, the high electric field intensities causing ablation of tissue **52** in zone **88**.

FIG. **7B** illustrates another alternative embodiment of electrosurgical probe **90** which has a return electrode **112** positioned within tubular member **78**. Return electrode **112** is preferably a tubular member defining an inner lumen **57** for allowing electrically conducting liquid **50** (e.g., isotonic saline) to flow therethrough in electrical contact with return electrode **112**. In this embodiment, a voltage difference is applied between electrode terminals **104** and return electrode **112** resulting in electrical current flow through the electrically conducting liquid **50** as shown by current flux lines **60** (FIG. **3**). As a result of the applied voltage difference and concomitant high electric field intensities at the tips of electrode terminals **104**, tissue **52** becomes ablated or transected in zone **88**.

FIG. **7C** illustrates another embodiment of probe **90** that is a combination of the embodiments in FIGS. **7A** and **7B**. As shown, this probe includes both an inner lumen **57** and

an outer gap or plurality of outer lumens **54** for flow of electrically conductive fluid. In this embodiment, the return electrode **112** may be positioned within tubular member **78** as in FIG. **7**B, outside of tubular member **78** as in FIG. **7**A, or in both locations.

FIG. **9** illustrates another embodiment of probe **90** where the distal portion of shaft **100** is bent so that electrode terminals extend transversely to the shaft. Preferably, the distal portion of shaft **100** is perpendicular to the rest of the shaft so that tissue treatment surface **212** is generally parallel to the shaft axis. In this embodiment, return electrode **112** is mounted to the outer surface of shaft **100** and is covered with an electrically insulating jacket **18**. The electrically conducting fluid **50** flows along flow path **83** through return electrode **112** and exits the distal end of electrode **112** at a point proximal of tissue treatment surface **212**. The fluid is directed exterior of shaft to surface **212** to create a return current path from electrode terminals **104**, through the fluid **50**, to return electrode **12**, as shown by current flux lines **60**.

FIG. **10** illustrates another embodiment of the invention where electrosurgical system **11** further includes a liquid supply instrument **64** for supplying electrically conducting fluid **50** between electrode terminals **104** and return electrode **112**. Liquid supply instrument **64** comprises an inner tubular member or return electrode **112** surrounded by an electrically insulating jacket **18**. Return electrode **112** defines an inner passage **83** for flow of fluid **50**. As shown in FIG. **8**, the distal portion of instrument **64** is preferably bent so that liquid **50** is discharged at an angle with respect to instrument **64**. This allows the surgical team to position liquid supply instrument **64** adjacent tissue treatment surface **212** with the proximal portion of supply instrument **64** oriented at a similar angle to probe **90**.

The present invention is not limited to an electrode array disposed on a relatively planar surface at the distal tip of probe **90**, as described above. Referring to FIGS. **8**A and **8**B, an alternative probe **90** includes a pair of electrodes **105***a*, **105***b* mounted to the distal end of shaft **100**. Electrodes **105***a*, **105***b* are electrically connected to power supply as described above and preferably have tips **107***a*, **107***b* with a screwdriver shape. The screwdriver shape provides a greater amount of "edges" to electrodes **105***a*, **105***b*, to increase the electric field intensity and current density at the edges and thereby improve the cutting ability as well as the ability to limit bleeding from the incised tissue (i.e., hemostasis).

FIGS. **11–13** illustrate a method for treating nasal or sinus blockages, e.g., chronic sinusitis, according to the present invention. In these procedures, the polyps, turbinates or other sinus tissue may be ablated or reduced (e.g., by tissue contraction) to clear the blockage and/or enlarge the sinus cavity to reestablish normal sinus function. For example, in chronic rhinitis, which is a collective term for chronic irritation or inflammation of the nasal mucosa with hypertrophy of the nasal mucosa, the inferior turbinate may be reduced by ablation or contraction. Alternatively, a turbinectomy or mucotomy may be performed by removing a strip of tissue from the lower edge of the inferior turbinate to reduce the volume of the turbinate. For treating nasal polypi, which comprises benign pedicled or sessile masses of nasal or sinus mucosa caused by inflammation, the nasal polypi may be contracted or shrunk, or ablated by the method of the present invention. For treating severe sinusitis, a frontal sinus operation may be performed to introduce the electrosurgical probe to the site of blockage. The present invention may also be used to treat diseases of the septum, e.g., ablating or resecting portions of the septum for removal, straightening or reimplantation of the septum.

The present invention is particularly useful in functional endoscopic sinus surgery (FESS) in the treatment of sinus disease. In contrast to prior art microdebriders, the electrosurgical probe of the present invention effects hemostasis of severed blood vessels, and allows the surgeon to precisely remove tissue with minimal or no damage to surrounding tissue, bone, cartilage or nerves. By way of example and not limitation, the present invention may be used for the following procedures: (1) uncinectomy or medial displacement or removal of portions of the middle turbinate; (2) maxillary, sphenoid or ethmoid sinusotomies or enlargement of the natural ostium of the maxillary, sphenoid, or ethmoid sinuses, respectively; (3) frontal recess dissections, in which polypoid or granulation tissue are removed; (4) polypectomies, wherein polypoid tissue is removed in the case of severe nasal polyposis; (5) concha bullosa resections or the thinning of polypoid middle turbinate; (6) septoplasty; and the like.

FIGS. **11–13** schematically illustrate an endoscopic sinus surgery (FESS) procedure according to the present invention. As shown in FIG. **11**, an endoscope **300** is first introduced through one of the nasal passages **301** to allow the surgeon to view the target site, e.g., the sinus cavities. As shown, the endoscope **300** will usually comprise a thin metal tube **302** with a lens (not shown) at the distal end **304**, and an eyepiece **306** at the proximal end **308**. As shown in FIG. **2**, the probe shaft **100** (not shown in FIG. **11**) has a bend **101** to facilitate use of both the endoscope and the probe **90** in the same nasal passage (i.e., the handles of the two instruments do not interfere with each other in this embodiment). Alternatively, the endoscope may be introduced transorally through the inferior soft palate to view the nasopharynx. Suitable nasal endoscopes for use with the present invention are described in U.S. Pat. Nos. 4,517,962, 4,844,052, 4,881,523 and 5,167,220, the complete disclosures of which are incorporated herein by reference for all purposes.

Alternatively, the endoscope **300** may include a sheath (not shown) having an inner lumen for receiving the electrosurgical probe shaft **100**. In this embodiment, the shaft **100** will extend through the inner lumen to a distal opening in the endoscope. The shaft will include suitable proximal controls for manipulation of its distal end during the surgical procedure.

As shown in FIG. **12**, the distal end of probe **90** is introduced through nasal passage **301** into the nasal cavity **303** (endoscope **300** is not shown in FIG. **12**). Depending on the location of the blockage, the electrode terminals **104** will be positioned adjacent the blockage in the nasal cavity **303**, or in one of the paranasal sinuses **305**, **307**. Note that only the frontal sinus **305** and the sphenoidal sinus **307** are shown in FIG. **12**, but the procedure is also applicable to the ethmoidal and maxillary sinuses. Once the surgeon has reached the point of major blockage, electrically conductive fluid is delivered through tube **233** and opening **237** to the tissue (see FIG. **2**). The fluid flows past the return electrode **112** to the electrode terminals **104** at the distal end of the shaft. The rate of fluid flow is controlled with valve **17** (FIG. **1**) such that the zone between the tissue and electrode support **102** is constantly immersed in the fluid. The power supply **28** is then turned on and adjusted such that a high frequency voltage difference is applied between electrode terminals **104** and return electrode **112**. The electrically conductive fluid provides the conduction path (see current flux lines) between electrode terminals **104** and the return electrode **112**.

FIGS. **13**A and **13**B illustrate the removal of sinus tissue in more detail As shown, the high frequency voltage is

sufficient to convert the electrically conductive fluid (not shown) between the target tissue **302** and electrode terminal (s)**104** into an ionized vapor layer **312** or plasma. As a result of the applied voltage difference between electrode terminal (s) **104** and the target tissue **302** (i.e., the voltage gradient across the plasma layer **312**), charged particles **315** in the plasma (viz., electrons) are accelerated towards the tissue. At sufficiently high voltage differences, these charged particles **315** gain sufficient energy to cause dissociation of the molecular bonds within tissue structures. This molecular dissociation is accompanied by the volumetric removal (i.e., ablative sublimation) of tissue and the production of low molecular weight gases **314**, such as oxygen, nitrogen, carbon dioxide, hydrogen and methane. The short range of the accelerated charged particles **315** within the tissue confines the molecular dissociation process to the surface layer to minimize damage and necrosis to the underlying tissue **320**.

During the process, the gases **314** will be aspirated through opening **209** and suction tube **211** to a vacuum source. In addition, excess electrically conductive fluid, and other fluids (e.g., blood) will be aspirated from the target site **300** to facilitate the surgeon's view. During ablation of the tissue, the residual heat generated by the current flux lines (typically less than 150° C.), will usually be sufficient to coagulate any severed blood vessels at the site. If not, the surgeon may switch the power supply **28** into the coagulation mode by lowering the voltage to a level below the threshold for fluid vaporization, as discussed above. This simultaneous hemostasis results in less bleeding and facilitates the surgeon's ability to perform the procedure. Once the blockage has been removed, aeration and drainage are reestablished to allow the sinuses to heal and return to their normal function.

Another advantage of the present invention is the ability to precisely ablate layers of sinus tissue without causing necrosis or thermal damage to the underlying and surrounding tissues, nerves (e.g., the optic nerve) or bone. In addition, the voltage can be controlled so that the energy directed to the target site is insufficient to ablate bone or adipose tissue (which generally has a higher impedance than the target sinus tissue). In this manner, the surgeon can literally clean the tissue off the bone, without ablating or otherwise effecting significant damage to the bone.

Methods for treating air passage disorders according to the present invention will now be described. In these embodiments, an electrosurgical probe such as one described above can be used to ablate targeted masses including, but not limited to, the tongue, tonsils, turbinates, soft palate tissues (e.g., the uvula), hard tissue and mucosal tissue. In one embodiment, selected portions of the tongue **314** are removed to treat sleep apnea. In this method, the distal end of an electrosurgical probe **90** is introduced into the patient's mouth **310**, as shown in FIG. **14**. An endoscope (not shown), or other type of viewing device, may also be introduced, or partially introduced, into the mouth **310** to allow the surgeon to view the procedure (the viewing device may be integral with, or separate from, the electrosurgical probe). The electrode terminals **104** are positioned adjacent to or against the back surface **316** of the tongue **314**, and electrically conductive fluid is delivered to the target site, as described above. The power supply **28** is then activated to remove selected portions of the back of the tongue **314**, as described above, without damaging sensitive structures, such as nerves, and the bottom portion of the tongue **314**.

In another embodiment, the electrosurgical probe of the present invention can be used to ablate and/or contract soft palate tissue to treat snoring disorders. In particular, the probe is used to ablate or shrink sections of the uvula **320** without causing unwanted tissue damage under and around the selected sections of tissue. For tissue contraction, a sufficient voltage difference is applied between the electrode terminals **104** and the return electrode **112** to elevate the uvula tissue temperature from normal body temperatures (e.g., 37° C.) to temperatures in the range of 45° C. to 90° C., preferably in the range from 60° C. to 70° C. This temperature elevation causes contraction of the collagen connective fibers within the uvula tissue.

In one method of tissue contraction according to the present invention, an electrically conductive fluid is delivered to the target site as described above, and heated to a sufficient temperature to induce contraction or shrinkage of the collagen fibers in the target tissue. The electrically conducting fluid 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. The fluid is heated by applying high frequency electrical energy to the electrode terminal(s) in contact with the electrically conducting fluid. The current emanating from the electrode terminal(s) **104** heats the fluid and generates a jet or plume of heated fluid, which is directed towards the target tissue. The heated fluid elevates the temperature of the collagen sufficiently to cause hydrothermal shrinkage of the collagen fibers. The return electrode **112** draws the electric current away from the tissue site to limit the depth of penetration of the current into the tissue, thereby inhibiting molecular dissociation and breakdown of the collagen tissue and minimizing or completely avoiding damage to surrounding and underlying tissue structures beyond the target tissue site. In an exemplary embodiment, the electrode terminal(s) **104** are held away from the tissue a sufficient distance such that the RF current does not pass into the tissue at all, but rather passes through the electrically conducting fluid back to the return electrode. In this embodiment, the primary mechanism for imparting energy to the tissue is the heated fluid, rather than the electric current.

In an alternative embodiment, the electrode terminal(s) **104** are brought into contact with, or close proximity to, the target tissue so that the electric current passes directly into the tissue to a selected depth. In this embodiment, the return electrode draws the electric current away from the tissue site to limit its depth of penetration into the tissue. Applicant has discovered that the depth of current penetration also can be varied with the electrosurgical system of the present invention by changing the frequency of the voltage applied to the electrode terminal and the return electrode. This is because 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. At lower frequencies (e.g., less than 350 kHz), the higher tissue impedance, the presence of the return electrode and the electrode terminal configuration of the present invention (discussed in detail below) cause the current flux lines to penetrate less deeply resulting in a smaller depth of tissue heating. In an exemplary embodiment, an operating frequency of about 100 to 200 kHz is applied to the electrode terminal(s) to obtain shallow depths of collagen shrinkage (e.g., usually less than 1.5 mm and preferably less than 0.5 mm).

In another aspect of the invention, the size (e.g., diameter or principal dimension) of the electrode terminals employed for treating the tissue are selected according to the intended depth of tissue treatment. As described previously in

copending patent application PCT International Application, U.S. National Phase Ser. No. PCT/US94/05168, the depth of current penetration into tissue increases with increasing dimensions of an individual active electrode (assuming other factors remain constant, such as the frequency of the electric current, the return electrode configuration, etc.). The depth of current penetration (which refers to the depth at which the current density is sufficient to effect a change in the tissue, such as collagen shrinkage, irreversible necrosis, etc.) is on the order of the active electrode diameter for the bipolar configuration of the present invention and operating at a frequency of about 100 kHz to about 200 kHz. Accordingly, for applications requiring a smaller depth of current penetration, one or more electrode terminals of smaller dimensions would be selected. Conversely, for applications requiring a greater depth of current penetration, one or more electrode terminals of larger dimensions would be selected.

In addition to the above procedures, the system and method of the present invention may be used for treating a variety of disorders in the mouth **310**, pharynx **330**, larynx **335**, hypopharynx, trachea **340**, esophagus **350** and the neck **360**. For example, tonsillar hyperplasis or other tonsil disorders may be treated with a tonsillectomy by partially ablating the lymphoepithelial tissue. This procedure is usually carried out under intubation anesthesia with the head extended. An incision is made in the anterior faucial pillar, and the connective tissue layer between the tonsillar parenchyma and the pharyngeal constrictor muscles is demonstrated. The incision may be made with conventional scalpels, or with the electrosurgical probe of the present invention. The tonsil is then freed by ablating through the upper pole to the base of the tongue, preserving the faucial pillars. The probe ablates the tissue, while providing simultaneous hemostasis of severed blood vessels in the region. Similarly, adenoid hyperplasis, or nasal obstruction leading to mouth breathing difficulty, can be treated in an adenoidectomy by separating (e.g., resecting or ablating) the adenoid from the base of the nasopharynx.

Other pharyngeal disorders can be treated according to the present invention. For example, hypopharyngeal diverticulum involves small pouches that form within the esophagus immediately above the esophageal opening. The sac of the pouch may be removed endoscopically according to the present invention by introducing a rigid esophagoscope, and isolating the sac of the pouch. The cricopharyngeus muscle is then divided, and the pouch is ablated according to the present invention. Tumors within the mouth and pharynx, such as hemangionmas, lymphangiomas, papillomas, lingual thyroid tumors, or malignant tumors, may also be removed according to the present invention.

Other procedures of the present invention include removal of vocal cord polyps and lesions and partial or total laryngectomies. In the latter procedure, the entire larynx is removed from the base of the tongue to the trachea, if necessary with removal of parts of the tongue, the pharynx, the trachea and the thyroid gland.

Tracheal stenosis may also be treated according to the present invention. Acute and chronic stenoses within the wall of the trachea may cause coughing, cyanosis and choking.

The system and method of the present invention may also be useful to efficaciously ablate (i.e., disintegrate) cancer cells and tissue containing cancer cells, such as cancer on the surface of the epidermis, eye, colon, bladder, cervix, uterus and the like. The present invention's ability to completely disintegrate the target tissue can be advantageous in this application because simply vaporizing and fragmenting cancerous tissue may lead to spreading of viable cancer cells (i.e., seeding) to other portions of the patient's body or to the surgical team in close proximity to the target tissue. In addition, the cancerous tissue can be removed to a precise depth while minimizing necrosis of the underlying 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 contract collagen tissue, ablate tissue, or the like.

In addition, the active and return electrodes may both be located on a distal tissue treatment surface adjacent to each other. The active and return electrodes 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.

What is claimed is:

1. A method for treating tissue at a target site in a cavity within a patient's nose comprising:

introducing an electrode terminal through an opening in the patient's head such that the electrode terminal is positioned adjacent to the tissue within the cavity;

delivering electrically conductive fluid into the cavity and past the return electrode to substantially surround the electrode terminal with the electrically conductive fluid and to generate a current flow path between the return electrode and the electrode terminal; and

applying high frequency voltage between the electrode terminal and a return electrode, the high frequency voltage being sufficient to remove at least a portion of the tissue immediately while the voltage difference is being applied between the electrode terminal and the return electrode.

2. The method of claim **1** wherein the tissue comprises a blockage within the nasal cavity or a paranasal sinus of the patient.

3. The method of claim **2** wherein the blockage is selected from the group comprising swollen tissue, turbinates, polyps, neoplasms and swollen mucus membranes lining an inner surface of the nasal cavity.

4. The method of claim **1** wherein the tissue comprises cartilage within the nose.

5. The method of claim **1** wherein the high frequency voltage is sufficient to effect hemostasis of severed blood vessels within the tissue during the removal step.

6. The method of claim **1** wherein the electrode terminal comprises a single, active electrode at the distal end of a shaft.

7. The method of claim **1** wherein the electrode terminal comprises a plurality of electrically isolated electrode terminals at the distal end of a shaft.

8. The method of claim **1** further comprising aspirating fluid from the target site during the removal step.

9. The method of claim **1** wherein the opening in the patient's head comprises one of the patient's nasal passages.

10. The method of claim **1** further comprising viewing the target site with an endoscope delivering through one of the patient's nasal passages.

11. The method of claim 10 wherein the electrode terminal and the endoscope are delivered through the same nasal passage.

12. The method of claim 7 further comprising independently controlling current flow from at least two of the electrode terminals based on impedance between the electrode terminal and a return electrode.

13. The method of claim 1 further comprising applying sufficient voltage to the electrode terminal in the presence of the electrically conducting fluid to vaporize at least a portion of the fluid between the electrode terminal and the tissue at the target site.

14. The method of claim 13 further comprising accelerating charged particles from the vaporized fluid to the tissue to cause dissociation of the molecular bonds within the tissue structures.

15. The method of claim 1 further comprising axially translating the electrode terminal towards the tissue to generate a hole within the tissue.

16. The method of claim 15 wherein the hole has a diameter less than about 2 mm.

17. The method of claim 15 wherein the hole has a diameter less than about 1 mm.

18. The method of claim 1 wherein the cavity is a sinus cavity, the method further comprising removing tissue around the natural ostium of the sinus cavity to enlarge the sinus cavity and increase aeration of the sinus.

19. A method for endoscopic sinus surgery comprising:

introducing an endoscope into a patient's nasal cavity to view a tissue structure;

introducing an electrode terminal into the nasal cavity adjacent to the tissue structure;

applying an electrically conductive gel between the tissue structure and the electrode terminal; and

applying a high frequency voltage difference between the electrode terminal and a return electrode, the voltage difference being sufficient to modify a portion of the tissue structure.

20. A method for endoscopic sinus surgery comprising:

introducing an endoscope into a patient's nasal cavity to view a tissue structure;

introducing an electrode terminal into the nasal cavity adjacent to the tissue structure;

applying electrically conductive fluid between the tissue structure and the electrode terminal; and

applying a high frequency voltage difference between the electrode terminal and a return electrode, the voltage difference being sufficient to remove a portion of the tissue structure immediately while the voltage difference is being applied between the electrode terminal and the return electrode.

21. The method of claim 20 wherein the voltage difference is sufficient to effect molecular dissociation of the tissue structure.

22. The method of claim 20 wherein the voltage difference is sufficient to cauterize and seal transected blood vessels as said portion of the tissue structure is removed.

23. The method of claim 20 wherein the electrically conductive fluid is a liquid that is delivered to the tissue structure by a fluid delivery element.

24. The method of claim 20 further comprising generating an electrically conductive path from the electrode terminal to the return electrode through the electrically conductive fluid.

25. The method of claim 20 wherein the electrode terminal is introduced through a nasal passage.

26. The method of claim 20 further comprising:

positioning the electrode terminal in contact with, or close proximity to, the tissue structure in the presence of the electrically conductive fluid; and

spacing the return electrode away from the tissue structure within the electrically conductive fluid such that the return electrode is not in contact with the tissue structure.

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