

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
13 May 2004 (13.05.2004)

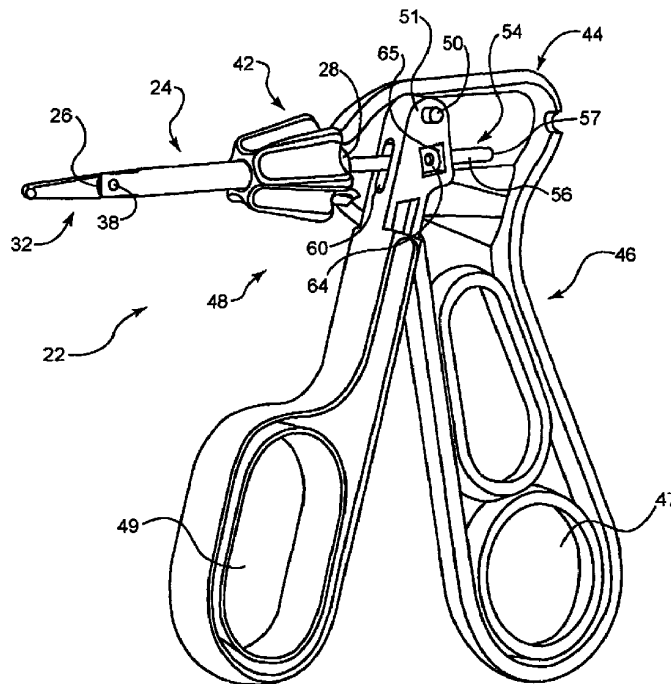
PCT

(10) International Publication Number
WO 2004/039416 A2

- (51) International Patent Classification⁷: **A61L**
- (21) International Application Number: PCT/US2003/034306
- (22) International Filing Date: 28 October 2003 (28.10.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/422,190 29 October 2002 (29.10.2002) US
- (71) Applicant (for all designated States except US): **TIS-SUELINK MEDICAL, INC.** [US/US]; Suite 400, One Washington Center, Dover, NH 03820 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **MCCLURKEN, Michael, E.** [US/US]; 26 Deer Meadow Road, Durham, NH 03824 (US). **GREELEY, Roger, D.** [US/US]; 95 Burkitt Street, Portsmouth, NH 03801 (US). **BERRY, John, W.** [US/US]; 1018 Saddleback Way, Bel Air, MD 21014 (US).
- (74) Agent: **BRUESS, Steven, C.**; Merchant & Gould P.C., P.O. Box 2903, Minneapolis, MN 55402-0903 (US).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:**
— without international search report and to be republished upon receipt of that report

[Continued on next page]

(54) Title: FLUID-ASSISTED ELECTROSURGICAL SCISSORS AND METHODS



(57) Abstract: An electrosurgical scissors comprising an end effector comprising a first blade member and a second blade member, the first blade member and the second blade member pivotally connected; an electrical connector configured to couple the scissors to a power source; and a fluid passage in fluid communication with at least one fluid outlet.

WO 2004/039416 A2



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

FLUID-ASSISTED ELECTROSURGICAL SCISSORS AND METHODS

This application is being filed on 28 October 2003 as a PCT International Patent application in the name of TissueLink Medical, Inc. (a U.S. national corporation), applicant for the designation of all countries except the US, and Michael E. McClurken, Roger D. Greeley, and John W. Berry (all US citizens), applicants for the designation of the US only.

Field

This invention relates generally to the field of medical devices, systems and methods for use upon a body during surgery. More particularly, the invention relates to electrosurgical devices, systems and methods for use upon tissues of a human body during surgery, particularly open surgery and minimally invasive surgery such as laparoscopic surgery.

Background

As is well known in electrosurgery, with a monopolar device configuration, electrical power is delivered from a power source to an active terminal provided with the device. The electrical energy from the device then is passed through the patient generally to a large surface, electrically dispersive ground pad, often referred to as the return terminal, located on the back or other suitable anatomical location of the patient, and then back to the power source. Conversely, bipolar devices include both the active and return electrodes on the device. Electrical current flows from the active electrode generally through localized tissue and then to the return electrode and back to the power source.

One often cited advantage of bipolar devices as compared to monopolar devices is the elimination of electrical current flowing through the patient to a ground pad. However, devices such as bipolar scissors tend to be fairly complex in attempting to electrically isolate the active electrical terminal (pole) from the other return electrical terminal (pole). Furthermore, as disclosed in U.S. Patent No. 5,658,281 in the name of Heard entitled "Bipolar Electrosurgical Scissors and Method Of Manufacture", one of the advantages of monopolar electrosurgical tools is that the surgeon can apply electrosurgical current whenever the conductive portion of the tool is in electrical contact with the patient. Thus, a surgeon may operate with monopolar electrosurgical tools from many different angles. In contrast, bipolar tools suffer from the drawback that the surgeon must carefully position the tool to ensure that both electrical poles are in electrical contact with the patient in order to

apply electrosurgical current. This may limit the range of motion and the angle from which the surgeon can effectively use the bipolar tool.

However, with dry tip electrosurgical devices, both monopolar and bipolar, the temperature of tissue being treated may rise significantly higher than 100 °C, possibly resulting in tissue desiccation, tissue sticking to the electrodes, tissue perforation, char formation and smoke generation.

One attempt with monopolar scissors, in order to restrict the electric current flow through the patient, has been to decrease the size of the active electrode to only a portion of the confronting (shearing) surfaces. In this manner, the chance that a surgeon may inadvertently conduct current into and burn surrounding tissue is also reduced. One such solution, as disclosed in U.S. Patent No. 5,827,281 in the name of Levin entitled "Insulated Surgical Scissors," is to entirely cover the pair of opposing cutting blades with an electrically and thermally insulative material except along corresponding segments of the confronting surfaces. Thus, this '281 patent does not recognize any benefit to providing electrically active surfaces on the pair of opposing cutting blades other than certain segments of the confronting surfaces and aims to prevent such. However, the need for this insulative material also increases the complexity of the scissors.

However, the teachings of the 5,827,281 patent are somewhat in contrast to the 5,658,281 patent. The 5,658,281 patent discloses that it would be desirable to allow surgeons to use the exterior surfaces of the scissors to coagulate tissue. However, the 5,658,281 patent does not address how to reduce the burning of surrounding tissue addressed by the 5,827,281 patent, nor any other concerns of tissue desiccation, tissue sticking to the electrodes, coagulum build-up on the electrodes, tissue perforation, char formation and smoke generation which may occur with use of dry electrosurgical devices.

In light of the above, it is an object of the invention to provide devices, systems and methods which overcome the limitations of the art.

Summary of the Invention

According to the present invention, radio frequency electrical power from a device is coupled to tissue through a coupling of fluid, also provided from the device, to inhibit such undesirable effects of tissue desiccation, sticking to the device, coagulum build-up on the device, tissue perforation, char formation and smoke generation. Specifically with regards to inhibiting tissue desiccation, one key factor is to inhibit the tissue temperature from exceeding 100 °C where the intracellular water may boil away, leaving the tissue extremely dry and much less electrically conductive.

According to one embodiment, electrosurgical scissors are provided comprising an end effector comprising a first blade member and a second blade member with the first blade member and the second blade member pivotally connected, an electrical connector configured to couple the scissors to a power source; and a fluid passage in fluid communication with at least one fluid outlet.

Brief Description Of The Drawings

To better understand and appreciate the invention, refer to the following detailed description in connection with the accompanying drawings, hand and computer generated:

FIG. 1 is a schematic side view of an exemplary device as part of a system according to the present invention;

FIG. 2 is a schematic isometric view of the device shown in FIG. 1 with a portion of the handle removed;

FIG. 3 is a schematic side view of the device shown in FIG. 2 with power cable and fluid line connected to the device;

FIG. 4 is a schematic, close-up, exploded isometric view of a distal portion of the device shown in FIG. 3;

FIG. 5 is another schematic, close-up, exploded isometric view of a distal portion of the device shown in FIG. 3;

FIG. 6 is a schematic, cross-sectional side view of the device shown in FIG. 2 with the blade members removed;

FIG. 7 is a schematic, close-up, cross-sectional side view of a distal portion of the device shown in FIG. 6;

FIG. 8 is a schematic, close-up, top view of a distal portion of the device shown in FIG. 2 in the presence of tissue;

FIG. 9 is a schematic, close-up, top view of a distal portion of an alternative embodiment of the device of FIG. 2;

FIG. 10 is a schematic, close-up, isometric view of a distal portion of another alternative embodiment of the device of FIG. 2;

FIG. 11 is a schematic, close-up, cross-sectional view taken along line 11-11 of FIG.10 with tissue located between the blade members; and

FIG. 12 is an isometric view of a cannula which may be used with the device of the present invention.

Detailed Description

Throughout the present description, like reference numerals and letters indicate corresponding structure throughout the several views, and such

corresponding structure need not be separately discussed. Furthermore, any particular feature(s) of a particular exemplary embodiment may be equally applied to any other exemplary embodiment(s) of this specification as suitable. In other words, features between the various exemplary embodiments described herein are
5 interchangeable as suitable, and not exclusive. Also, from the specification, it should be clear that any use of the terms “distal” and “proximal” are made in reference to the user of the device, and not the patient.

An exemplary electrosurgical device according to the present invention will now be described in detail. The electrosurgical device may be used with the system
10 of the invention to be described herein. However, it should be understood that the description of the combination is for purposes of illustrating the system of the invention only. Consequently, it should be understood that the electrosurgical device of the present invention can be used alone, or in conjunction with, the system of the invention. Conversely, it should be equally understood that the system of the
15 present invention can be used with a wide variety of devices.

The electrosurgical devices disclosed herein may be configured for both open and laparoscopic surgery. For laparoscopic surgery, the devices are preferably configured to fit through either a 5 mm or 10 mm trocar cannula. When used in
20 conjunction with a cannula, the devices disclosed herein eliminate the need to switch instruments from the cannula for the purposes of coagulating and cutting tissue.

An exemplary electrosurgical device of the present invention, which may be used in conjunction with one or more aspects of the system of the present invention, is shown at reference character **22** in FIG. 1. As shown, device **22** preferably
25 comprises electrosurgical scissors, and more particularly laparoscopic electrosurgical scissors. When device **22** comprises laparoscopic electrosurgical scissors, preferably device **22** is configured to extend through a working channel of a trocar cannula.

Device **22** is designed and configured to coagulate and seal tissue from the flow of bodily fluids and/or air by shrinking the tissue (particularly collagen in the
30 tissue and particularly vessels) and cut tissue. More specifically, device **22** can be painted over a raw, oozing surface of tissue to seal the tissue against bleeding, or focused on individual large vessels, such as to seal a bleeding vessel which has been cut or to occlude a vessel prior to its being cut.

As shown in FIG. 1, the system of the invention includes both a fluid source
35 **78** and a power source **76** coupled to device **22** as discussed in greater detail below. As shown, fluid source **78** comprises an I.V. bag. The power source **76** shown in FIG. 1 preferably comprises a generator which provides alternating current, radio-frequency electrical energy at various rates (i.e. power). As to the frequency of the

RF electrical energy, it is preferably provided within a frequency band (i.e. a continuous range of frequencies extending between two limiting frequencies) in the range between and including about 9 kHz (kilohertz) to 300 GHz (gigahertz). More preferably, the RF energy is provided within a frequency band in the range between and including about 50 kHz (kilohertz) to 50 MHz (megahertz). Even more preferably, the RF energy is provided within a frequency band in the range between and including about 200 kHz (kilohertz) to 2 MHz (megahertz). Most preferably, RF energy is provided within a frequency band in the range between and including about 400 kHz (kilohertz) to 600 kHz (kilohertz). The power from the power source 76 to device 22 is preferably turned on and off via a footswitch 77 or other easily operated switch connected to the power source 76.

As best shown in FIGS. 2 and 3, device 22 preferably includes an intermediate portion comprising an elongated, hollow, electrically insulated, rigid shaft 24 having a distal end 26, a proximal end 28 and a central lumen 30 (shown in FIG. 7). While shown greatly shortened as indicated by the break lines, the length of shaft 24 is preferably in the range between and including about 5 inches to 15 inches.

As best shown in FIG. 4, for strength purposes, shaft 24 preferably comprises an inner, cylindrical metal tube 27, such as stainless steel, with the outer layer 29 of insulating material applied thereon, such as a polymer, ceramic or glass material. Where the outer layer 29 comprises a polymer, preferably the outer layer is provided in the form of a shrink wrap sleeve which may be heated and thereafter shrunk directly onto the metal tube 27 in a manner known in the art. In other embodiments, cylindrical tube 27 may comprise an electrically insulating material itself, such as a polymer, ceramic or glass material, thus eliminating the need for outer layer 29.

Also as shown in FIGS. 2 and 3, device 22 also preferably includes an end effector 32. As best shown in FIGS. 4 and 5, end effector 32 comprises two cooperating, relatively moveable blade members 34, 36. Blade members 34, 36 extend distally from and are pivotally coupled adjacent the distal end 26 of the shaft 24 such that they hinge about a pivot 38 provided, for example, by a separate metal pin, extending through a fixed pivot hole 40 of shaft 24 and aligning holes 35, 37 in the blade members 34, 36.

Returning to FIGS. 2 and 3, device 22 also preferably includes a collar 42 for rotating the entire shaft 24 and end effector 32 relative to a proximal handle 44 comprising an electrically insulated first handle member 46 and an electrically insulated second handle member 48, which are coupled adjacent the proximal end 28 of shaft 24. As shown in FIGS. 2 and 3, a mirrored half of the first handle member

46, which is preferably formed from two separately formed mating pieces, has been removed to expose the inner workings of the handle 44. The first and second handle members 46, 48 are preferably made electrically insulating by virtue of being molded of an electrically insulating polymer material.

5 First handle member 46 is preferably coupled to the proximal end 28 of the shaft 24 by means a circular flange lip 43 of the shaft 24 contained within a mating and interlocking circular recess 45 formed in the first handle member 46, while the second handle member 48 is pivotally coupled to the first handle member 46 about a pivot 50 provided, for example, by a pin. The second handle member 48 is
10 indirectly coupled to the blade members 34, 36 through a push/pull rod assembly 52 extending through the lumen 30 of the elongated shaft 24 so that axial reciprocal movement of the push/pull rod assembly 52 relative to shaft 24 opens and closes the blade members 34, 36. In this manner, shaft 24 functions as a guide barrel for the rod 54 of the push/pull rod assembly 52.

15 As best shown in FIGS. 2 and 6, a proximal portion 56 of a rod 54 extends through a longitudinally orientated (i.e. extending proximally and distally with respect to device 22) slotted receptacle 60 extending through a head portion 51 of second handle member 48. Returning to FIG. 3, rod 54 is preferably coupled to second handle member 48 such that the position of rod 54 relative to the position of
20 the second handle member 48 may be adjustably fixed thereto (e.g. to accommodate manufacturing). As shown, rod 54 is coupled to the second handle member 48 by a mechanical fastener 62 comprising here, for example, a set screw. However, rather than threading the screw into a threaded hole in handle 48 and into contact with the rod 54, preferably the set screw 62 is threaded into the side wall of metal sleeve 64.
25 In this manner the strength of the threaded connection is substantially increased with less likelihood of stripping threads. Screw 62 is preferably treaded through the side wall of sleeve 64 such that the distal end surface of the set screw 62 engages and locks against a side surface of the rod 54 intersecting the threaded hole in the sleeve 64.

30 As shown in FIGS. 2 and 3, once sleeve 64 is fixed to rod 54, the sleeve 64 is than coupled to handle 48 by being located in a fastener or sleeve interlocking receptacle 65. As receptacle 65 moves proximally and distally with the movement of handle 48, the surfaces of the receptacle accordingly act on the opposing surfaces of the sleeve 64 to move the sleeve 64 and fixed rod 54 in unison with the handle 48.

35 In addition, rod 54 is also preferably pivotally coupled to the second handle member 48 about a pivot connection, provided here, for example, by the sleeve 64 and receptacle 65 interaction. As shown in FIGS. 3 and 6, certain surfaces 69 of

receptacle 65 are spaced from interacting surfaces 67 of the sleeve 64 to allot for limited pivotal movement between sleeve 64 and receptacle 65.

Continuing with FIG. 3, the grasping first handle member 46 also provides a pistol grip configuration while second handle member 48 provides a trigger or lever configuration. Also as shown, first handle member 46 is provided with a thumb
5 loop 47 while second handle member 48 is provided with a finger loop 49 for easier grasping and manipulation of device 22. With the configuration shown, as the first and second handle members 46, 48 are moved towards one another, rod 54 is moved proximally to close the blade members 34, 36 relative to one another. Conversely,
10 when the first and second handle members 46, 48 are moved apart from one another, rod 54 is moved distally to open the blade members 34, 36 relative to one another.

As shown in FIGS. 1 and 3, device 22 is preferably connected to a power source 76 (shown in FIG. 1) via proximal portion 56 of rod 54. As shown, to provide power to device 22, an electrical connection to a power source 76 is
15 preferably provided with a cable 68. As shown in FIG. 3, cable 68 comprises an insulated wire 70, comprising a wire conductor 72, and a plug 74 (shown in FIG. 1). With regards to the electrical connection, rod 54 is coupled to one end of cable 68 by a soldered connection 66 while the other end of the cable 68 is coupled to power source 76 with plug 74 inserted into a plug receptacle of the power source 76.

20 With the above configuration, device 22 may be electrically energized for coagulating and cutting tissue to be discussed in greater detail herein. As constructed, electrical power provided to rod 54 from power source 76, which may be referred to as the active terminal, will also flow to blade members 34, 36 by virtue of their mechanical and metallic coupling to the rod 54, as well as tube 27 of
25 shaft 24. Thus, the device 22 comprises a monopolar configuration, i.e., electrical power is delivered from the power source 76 via a single conductor 72 to each of the blade members 34, 36 (each comprising a metal such as titanium or stainless steel), with both blade members consequently being at substantially the same voltage or electrical potential. The return for the electrical energy from device 22 is through
30 the patient (not shown) generally to a large surface, electrically dispersive ground pad 79 (shown in FIG. 1), often referred to as the return or indifferent terminal, located on the patient, typically on the back or other suitable anatomical location, and then back to the power source 76, as is well-known in the art.

Continuing with FIGS. 1 and 3, device 22 is preferably connected to a fluid
35 source 78 (shown in FIG. 1) also via proximal portion 56 of rod 54. As shown, to provide fluid 84 to device 22, a fluid connection to a fluid source 78 is preferably provided with an input fluid line 80. As shown in FIG. 3, input fluid line 80 comprises a flexible fluid line made from a polymeric material, such as

polyvinylchloride (PVC) or polyolefin (e.g. polypropylene, polyethylene) and has a fluid passage **82** (lumen). With regards to the fluid connection, rod **54** is coupled to one end of fluid line **80** by interference fitting the lumen **82** of the input fluid line **80** over the proximal end **57** and outside diameter of rod **54** to provide a press fit seal
5 there between. Additionally an adhesive may be disposed there between to strengthen the seal. The other end of input fluid line **80** may be directly connected to fluid source **78**.

Fluid source **78** preferably provides an electrically conductive fluid **84**, which preferably is a saline solution and, more preferably sterile, physiologic saline.
10 It should be understood that where description herein references the use of saline as the fluid **84**, other electrically conductive fluids can be used in accordance with the invention.

For example, in addition to the conductive fluid comprising physiologic saline (also known as "normal" saline, isotonic saline or 0.9 weight-volume
15 percentage sodium chloride (NaCl) solution), the conductive fluid may comprise hypertonic saline solution, hypotonic saline solution, Ringers solution, lactated Ringer's solution, Locke-Ringer's solution, or any other electrolyte solution. In other words, a solution that conducts electricity via an electrolyte, a substance (salt, acid or base) that dissociates into electrically charged ions when dissolved in a
20 solvent, such as water, resulting solution comprising an ionic conductor.

In certain embodiments as discussed herein, hypertonic saline, saturated with NaCl to a concentration of about 15% (weight-volume percentage), may be preferred to physiologic saline to reduce the electrical resistivity of the saline from about 50 ohm-cm at 0.9% to about 5 ohm-cm at 15%. This ten-fold reduction in
25 electrical resistivity of the conductive fluid will enhance the reduction in heating (both resistance heating and conduction heating) of tissue and the conductive fluid itself as shown herein.

While a conductive fluid is preferred, as will become more apparent with further reading of this specification, the fluid **84** may also comprise an electrically
30 non-conductive fluid. The use of a non-conductive fluid is less preferred to that of a conductive fluid as the non-conductive fluid does not conduct electricity. However, the use of a non-conductive fluid still provides certain advantages over the use of a dry electrode including, for example, reduced occurrence of tissue sticking to the blade members **34**, **36**, cooling of tissue and/or the blade members **34**, **36**, and
35 removal of any coagula, if existent, from the blade members **34**, **36** and/or the tissue treatment site. Therefore, it is also within the scope of the invention to include the use of a non-conducting fluid, such as, for example, deionized water. Other non-conductive fluids include 5% w/v dextrose injection USP and 10% w/v dextrose

injection USP (i.e. sterile solutions of 5g and 10g dextrose hydrous in 100ml water, respectively); 1.5% w/v glycine irrigation USP (i.e. sterile solution of 1.5 g glycine in 100ml water); 5% w/v, 10% w/v, 15% w/v and 20% w/v mannitol injection USP (i.e. sterile solution of 5g, 10g, 15g and 20g mannitol in 100ml water, respectively);
5 3% sorbitol irrigation USP (i.e. sterile solution of 3g sorbitol in 100 ml water);
0.54% sorbitol/2.75% mannitol irrigation USP (i.e. sterile solution of 0.54g sorbitol and 2.75g mannitol in 100 ml water); and sterile water for irrigation USP.

Once the input fluid line 80 is coupled to rod 54, the fluid passage 82 provided by fluid line 80 is now fluidly coupled to fluid passage 55, here provided
10 by the bore or lumen, of rod 54 (shown in FIGS. 6 and 7). In this manner fluid 84 from fluid source 78 may flow towards the distal end of device 22.

As best shown in FIGS. 4 and 7, the distal end 59 of rod 54 is preferably coupled to a connector member 86. More specifically, as shown in FIG. 7, a distal portion 58 of rod 54 is interference fit (pressed) into rod connector portion
15 comprising a circular receptacle portion 88. Alternatively, the outer side wall of distal portion 58 of rod 54 may be provided with external threads configured to mate with internal threads contained on the inner side wall of receptacle portion 88.

Continuing with FIGS. 4 and 7, a circular portion 90 of connector member 86 is configured to have an outer diameter slightly smaller (e.g. about 0.001 inches to 0.040 inches) than the inner diameter of tube 27. In this manner, outer circular surface 92 of connector member 86 may easily slide along inner surface 31 of tube 27 with the reciprocal movement of rod 54 while, at the same time, receptacle portion 88 of connector member 86 is able to position the distal portion 58 of rod 54 towards the center of tube 27. In order to inhibit the back flow of fluid 84 (which
25 has been provided from device 22 to a tissue treatment site or by virtue of the orientation of device 22 with the distal end positioned above the proximal end) into lumen 30, preferably the outer diameter of the circular portion 90 fits with the inner surface 31 of tube 27 to substantially seal the lumen 30 of tube 27 and handle 44 against the back flow of fluid 84 therein. In order to increase the seal, a separate seal member 94 (shown in FIG. 4) may be placed between surfaces 92 and 31, such as a flexible O-ring gasket. Alternatively, the O-ring gasket may be located near
30 between a proximal portion 56 of rod 54 and a proximal portion of shaft 24.

As best shown in FIG. 5, located distally from receptacle portion 88, connector member 86 comprises a blade member connector portion 96, which has a
35 substantially planar tongue extending distally relative to the circular receptacle portion 88, and which is sandwiched between and spaces apart the proximal portions 98, 100 of blade members 34, 36 respectively. As shown, flat interior surfaces 102,

104 of blade members 34, 36, which face one another, overlie opposing flat surfaces 106, 108 of blade member connector portion 96.

Continuing with FIG. 5, blade member connector portion 96 includes opposing pins 110, 112 extending laterally from opposing surfaces 106, 108. Pins 110, 112 are configured to fit within and travel along the slotted recesses 114, 116 in surfaces 102, 104 of blade members 34, 36 to open and close blade members 34, 36 relative to each other. More specifically, as pins 110, 112 move proximally while in recesses 114, 116 (due to proximal movement of rod 54), blade members 34, 36 rotate in opposing directions relative to each other around pivot 38 and close relative to one another. Conversely, as pins 110, 112, move distally while in recesses 114, 116 (due to distal movement of rod 54), blade members 34, 36, which still rotate in opposing directions relative to each other, now rotate in opposing directions to their closing directions around pivot 38, to open relative to one another. As shown, in order to facilitate the opening and closing movement of blade members 34, 36, the orientation of recesses 114, 116 is such that they are orientated in opposing directions relative to one another.

In order to expel fluid 84 which has flowed distally in lumen 55 of rod 54 from device 22, the connector member 86 is preferably provided with one or more apertures in fluid communication with lumen 55, the apertures providing a fluid outlet for fluid 84. As best shown in FIG. 7, the bottom wall of receptacle portion 88 includes an aperture 118 there through to provide a fluid outlet 120 for fluid 84. As shown in FIG. 7, fluid outlet 120 is located proximal to the distal end 26 of shaft 24 such that it is remote from the tissue interacting portions of blade members 34, 36. Stated another way, fluid outlet 120 is recessed and protected within the distal end 26 of shaft 24 which provides a location substantially inaccessible to direct contact or occlusion with tissue. While only a single fluid outlet 120 is shown, it should be understood that additional fluid outlets (with varying locations) may be similarly incorporated to the extent necessary.

As shown in FIG. 8, during use of device 22 for coagulating tissue, a fluid coupling 122, preferably comprising a discrete localized web, provides a film of fluid 84 between the surface 126 of the tissue 124 and blade members 34, 36. When a user of device 22 places the blade members 34, 36 at a tissue treatment site and moves the blade members 34, 36 across the surface 126 of the tissue 124, fluid 84 is simultaneously expelled from fluid outlet 120 around and onto the proximal portions 98, 100 and to the distal portions 128, 130 of blade members 34, 36 and thereafter onto the surface 126 of tissue 124 via fluid coupling 122. The fluid 84 flows from the distal end of connector 86 towards the distal portions 128, 130 and ends 140, 142 of blade members 34, 36 due to the force of gravity, and the orientation of the device

22, which is almost always with the distal end downward. Surface tension forces tend to keep the fluid 84 from dripping off the blade members 34, 36 before the fluid 84 reaches the distal ends 140, 142 of blade members 34, 36 and the contact with tissue 124.

5 Fluid 84 lubricates the surface 126 of the tissue 124 and facilitates the movement of blade members 34, 36 across the surface 126 of the tissue 124 and, in the instance of an electrically conductive fluid, provides an electrical coupling between the device 22 and the tissue 124. During movement of the blade members 34, 36, the user of device 22 typically slides the blade members 34, 36 across the
10 surface 126 of the tissue 124 back and forth with a painting motion while using the fluid 84 as, among other things, a lubricating coating. Preferably the thickness of the fluid coupling 122 between the blade members 34, 36 and the surface 126 of the tissue 124 is in the range between and including about 0.05 mm to 2.5 mm. More preferably, the fluid coupling 122 between the blade members 34, 36 and the surface
15 126 of the tissue 124 is in the range between and including about 0.1 mm to 1.0 mm.

Preferably tissue coagulation is performed with blade member exterior side surfaces 137, 139 of blade members 34, 36 which oppose blade member interior side shearing surfaces 136, 138, respectively. As shown in FIG. 8, in order to better facilitate sliding of device 22 on the surface 126 of tissue 124, preferably the distal
20 portions 128, 130 of blade members 34, 36 proximally adjacent distal ends 140, 142 may each comprise opposing bulbous portions, here having preferably smooth (i.e. devoid of edges), semi-circular surfaces 150, 152 (preferably of about 180 degrees and having a surface finish in the range between and including about 16-64 microinches RMS (Root Mean Square)) provided by enlarged semi-circular regions.
25 Consequently, when blade members 34, 36 are closed together, the two opposing semi-circular regions may provide a spherical distal end tip for device 22. In this manner, the distal end surface area of device 22 is increased to provide an appropriate power density for coagulating tissue with a painting motion. For example, for a power level of 50 watts, which is a typical upper limit for most
30 laparoscopic procedures, a spherical cross-sectional dimension, here diameter, in the range of between and including about 2 to 2.5 millimeters has been found to work best. If the power can be as high as 100 watts, then the dimension should be larger, in the range of between and including about 3 to 4 millimeters. If the power is smaller, for instance 25 watts, then the dimension should be smaller, in the range
35 between and including about 1.25 to 1.75 millimeters. Furthermore, in order to further facilitate tissue coagulation, preferably the distal portions 128, 130 of blade members 34, 36 are arcuate to provide a convex surface 139 of blade member 36 which may be more easily positioned against tissue and slide there along.

When electric current is applied to blade members **34, 36**, heating of the tissue **124** occurs by means of electrical resistance heating. In other words, increasing the temperature of the tissue **124** as a result of electric current flow through the tissue, with the associated electrical energy being converted into thermal energy (i.e. heat) via accelerated movement of ions as a function of the tissue's electrical resistance. Resistance heating provides direct, instantaneous heating inside tissue **124** due to the current flow through tissue **124**.

Device **22** is particularly useful to a surgeon who wishes to coagulate and seal tissue, including vessels such as blood vessels, prior to tissue **124** being cut with blade members **34, 36**. More specifically, as blade members **34, 36** are moved along the surface **126** of tissue **124**, tissue **124** there beneath is coagulated. As known in the art, when exposed to heat, the collagen of the blood vessels will shrink, thus decreasing the diameter and associated lumen of the vessel. Certain vessels, depending on size and proximity to surface **126** of tissue **124** will become completely occluded (e.g. vessels up to about 1 mm in diameter and 1-5 mm deep), while vessels greater than 1 mm may become only partially occluded and need additional treatment with another device, such as a clip applicator, or with suture ligation. Some vessels, such as those 1 mm diameter or less, may not be initially sealed because they are too deep in the tissue, but these may be occluded as the device **22** is used to coag and cut deeper into the tissue.

Once surface **126** of tissue **124** is adequately treated with device **22**, at least one of the distal ends **140, 142** of blade members **34, 36** may be used to pierce and perforate tissue **124**, such as through the capsule of a liver. Preferably, the depth of the perforation is no deeper than the depth of tissue treatment provided by the surface coagulation to avoid possible puncturing of an untreated vessel. After making the first perforation in tissue **124**, a second perforation laterally spaced from the first perforation may be made, also into treated tissue **124**. Thereafter, the portion of tissue **124** between the first and second perforations may be located between shearing edges **132, 134** and shearing surfaces **136, 138** and thereafter cut when blade members **34, 36** are closed together. In alternative embodiments, both perforations may be made simultaneously with distal ends **140, 142** of blade members **34, 36**. In still other embodiments, only one perforation made may be made. In this manner one blade member **34** may be located in the perforation while the distal end **142** of the other blade member **36** is laterally spaced and pressed against the surface **126** of tissue **124** to cut the tissue **124** when blade members **34, 36** are closed together. In still other embodiments, no perforations of tissue **124** may be required prior to cutting as where tissue **124** may be manipulated and located

between the shearing edges 132, 134 and shearing surfaces 136, 138 of open blade members 34, 36 without the need for the perforations.

It should be noted that, as shown, preferably distal ends 140, 142 of blade members 34, 36 are blunt. In other words distal ends 140, 142 of blade members 34, 36 preferably do not comprise a distal end point. The distal ends 140, 142 of blade members 34, 36 preferably are not pointed so that the distal ends 140, 142 of blade members 34, 36 will slide along the tissue surface 126 while the blade members 34, 36 are moved along the tissue surface 126 with a back and forth painting motion, and while tissue coagulation is performed with blade member exterior side surfaces 137, 139 of blade members 34, 36.

In the instance of parenchyma tissue, such as for liver, the distal end 140, 142 of one or both of blade members 34, 36 may be used to simultaneously blunt dissect and coagulate tissue without first perforating the tissue 124. As the surface 126 of tissue 124 is coagulated under and around the at least one of the blade members 34, 36, the blade member may then be used to blunt dissect into the coagulated parenchyma, with the distal ends 140, 142. As the device 22 enters an elongated crevice in the surface 126 of the tissue 124 formed by the blunt dissection, shearing edges 132, 134 of blade members 34, 36 may be used to further blunt dissect the coagulated parenchyma on the sidewalls of the crevice, or blunt dissect and coagulate simultaneously. Blunt dissection of the coagulated parenchyma is performed by continuous abrading or splitting apart of the parenchyma with the substantially the same back and forth motion as coagulation of the surface 126 of the tissue 124. However, with blunt dissection, the surgeon typically applies more force to the tissue. In various embodiments, once the parenchyma is coagulated, blunt dissection may be performed with or without the radio frequency power (i.e. on or off) and/or with or without the presence of fluid 84.

In yet another technique, blade members 34, 36 may be used for wedge dissection. In other words, while blade members 34, 36 are in the closed position and without tissue 124 there between, they are wedged into tissue 124, preferably between adjacent tissue planes. Thereafter, the blade members 34, 36 may be slowly opened and, due to the separation forces placed on the tissue 124 at the distal ends 140, 142 of the blade members 34, 36, the tissue will dissect.

The above techniques can also be used on other parenchymal organs such as the pancreas, the kidney, and the lung. In addition, it may also be useful on muscle tissue and subcutaneous fat. Its use can also extend to benign tumors, cysts or other tissue masses found in the urological or gynecological areas. It would also enable the removal of highly vascularized tumors such as hemangiomas.

The use of the disclosed devices can result in significantly lower blood loss during surgical procedures such as liver resections. Typical blood loss for a right hepatectomy can be in the range of 500 – 1,000 cubic centimeters. Use of the devices disclosed herein to perform pre-transection coagulation of the liver can result in blood loss in the range of 50 – 300 cubic centimeters. Such a reduction in blood loss can reduce or eliminate the need for blood transfusions, and thus the cost and negative clinical consequences associated with blood transfusions, such as prolonged hospitalization and a greater likelihood of cancer recurrence. Use of the device can also provide improved sealing of bile ducts, and reduce the incidence of post-operative bile leakage, which is considered a major surgical complication.

In addition to liver resections, device **22** may be particularly useful to a surgeon performing a laparoscopic cholecystectomy (abbr. “lap chole”) for the case of, for instance, either acute cholecystitis or an intrahepatic gallbladder in that the device provides multi-functional uses. More particularly, device **22** is useful to the surgeon for coagulation and dissection of an inflamed serosal layer of tissue between the liver and gallbladder, which may include tough, fibrous, highly vascular connecting tissue between the organs.

The power provided from the surgical device **22** is generally in the range between and including about 20 watts to 150 watts, and more preferably in the range between and including about 50 watts to 100 watts. The fluid provided from the surgical device **22** is generally in the range between and including about 1 cubic centimeter per minute to 100 cubic centimeters per minute, and more preferably in the range between and including about 5 cubic centimeter per minute to 25 cubic centimeters per minute. For a more complete discussion of an exemplary power to fluid flow rate relationship see U.S. Publication No. 2002/0062123 in the name of McClurken entitled “Fluid-Assisted Medical Devices, Fluid Delivery Systems And Controllers For Such Devices, And Methods” published May 23, 2002.

In order to minimize the sticking of tissue, particularly coagulum, to blade members **34**, **36**, but yet adequately heat the tissue for treatment, preferably the temperature of the tissue should remain in the range between and including about 75 °C to 120 °C. As known in the art, tissue containing Type I collagen (e.g., walls of blood vessels, bronchi, bile ducts, etc.) shrinks when exposed to about 85 °C for an exposure time of 0.01 seconds, or when exposed to about 65 °C for an exposure time of 15 minutes. An exemplary target temperature/time for tissue shrinkage is about 75 °C with an exposure time of about 1 second. More generally, the power provided to the tissue should be sufficient to shrink collagen in the range between and including about 1 second to 10 seconds after RF activation. An exemplary method of controlling the tissue temperature below 120 °C is to remove excess heat

generated in the tissue by means of fluid **84**, particularly by boiling the fluid coupling **122**. Where fluid **84** comprises saline, the fluid **84** boils at approximately 100 °C to remove heat from the tissue and inhibit the tissue temperature from exceeding 100 °C. For a more detailed discussion, see U.S. Publication No. 5 2002/0062123 in the name of McClurken as identified above.

Thus far the device **22** has been described relative to use with scissors with curved blade members **34**, **36**. In still other embodiments, as shown in FIG. **9**, the device of the present invention may comprise straight blade members **34**, **36**.

In yet another embodiment as shown in FIG. **10**, only blade members **36** of 10 electrosurgical device **22** has a bulbous portion **154**, thus providing an asymmetric tip. Also different from previous embodiments, as shown the exterior side surfaces **137**, **139** of blade members **34**, **36** include a covering **156** of electrically insulating material, such as a polymer, ceramic or glass, except for the surface **152** of bulbous portion **154**. An exemplary polymer comprises fluorine and, more particularly, 15 polytetrafluoroethylene. In this manner, electrical current from blade members **34**, **36** may be concentrated into tissue through bulbous portion **154**. From the above description it should be understood that in other embodiments, covering **152** may also be used when neither of blade members **34**, **36** include a bulbous portion **154**.

While exterior bulbous portion **154** is configured to coagulate tissue, blade 20 members **34**, **36** are also used to coagulate and cut tissue, and particularly seal vessels **158**, such as blood vessels, as shown in FIG. **11**. When blade members **34**, **36** are electrified and provide RF power to tissue including a blood vessel **158**, the collagen in the tissue and forming the wall **160** begins to shrink as discussed above. As the vessel **158** continues to shrink, the lumen **162** goes from being partially 25 occluded to being completely occluded.

Due to tissue irregularities, the surface **164** of the vessel **158** to be treated may be uneven or undulated with microscopic peaks and valleys. Consequently, with conventional scissors, the area of direct electrical coupling of the vessel **158** to the scissors can be limited to the isolated peaks in the tissue surface **164**. In this 30 situation, upon the application of RF power to vessel **158**, the electrical coupling of only the tissue peaks to the scissors may result in corresponding increase in current density through the electrically coupled peaks which has the ability to desiccate and char the vessel **158** at these isolated locations. In other locations, the electric current in the form of a spark may jump a gap created between a valley in the surface **164** of 35 the vessel **158** and the scissors and burn, or even perforate, the vessel **158**.

Also with conventional scissors, there may be a decrease in the electrical coupling between the surface **164** of vessel **158** and scissor surfaces upon tissue shrinkage and/or desiccation during treatment. As tissue shrinks and/or desiccates

during treatment, the surface 164 of vessel 158 may lose contact with the scissors, which, similar to above, decreases the area of electrical coupling therebetween and correspondingly increases the current density and associated heat at the locations which remain electrically coupled. This difficulty is further exacerbated if the tissue is undulated as described above.

To offset a decrease in electrical coupling between the scissors and vessel 158 as the vessel shrinks, the user of conventional scissors may be required to further close or push the scissors into increased contact with the vessel 158. However, with the increased force placed on the vessel 158, there may be increased risk of inadvertently severing the vessel with a shearing edges 132, 134 of the scissors before the vessel is completely occluded.

As shown in FIG. 11, in addition to direct electrical coupling of the surface 164 of vessel 158 to the tissue abutting surfaces 144, 146 of blade members 34, 36, the surface 164 of vessel 158 is indirectly coupled to the shearing surfaces 136, 138 of blade members through fluid coupling 148 comprising an electrically conductive fluid 84. Furthermore, fluid coupling 148 couples the tissue abutting surfaces 144, 146 of blade members 34, 36 at locations where there may be a gap 166 and no direct contact between the surface 164 of vessel 158 to the tissue abutting surfaces 144, 146 of blade members 34, 36.

The fluid coupling 148, preferably comprising saline, inhibits the desiccation, tissue sticking to the shearing surfaces 136, 138 and tissue abutting surfaces 144, 146 of blade members 34, 36, tissue perforation, char formation, smoke generation and sparking encountered with conventional scissors. When an electrically conductive fluid 84 such as saline is used, the fluid cools the tissue while at the same time better dispersing the electrical current into the tissue more uniformly to inhibit heating of the tissue to where desiccation, charring, smoking, sticking and burning occur.

In addition to fluid coupling 148 offsetting (reducing) increases in current densities associated with undulated tissue, or tissue otherwise poorly coupled to the device, fluid coupling 148 also offsets increases in current densities due to so called "edge effects" often associated with sharp edges of electrodes. For example, the sharpness of shearing edges 132, 134 of device 22 may give rise to an increase in current density into tissue adjacent thereto. In providing fluid coupling 148 adjacent each side of shearing edges 132, 134, the increase in current density will be offset by the presence of fluid coupling 148 which spreads the electrical current transmission into the tissue over a larger surface area.

As previously disclosed, the electrosurgical devices 22 disclosed herein may be used in conjunction with a cannula as illustrated in FIG. 12 at reference character

10, during laparoscopic surgery such as, for example, a laparoscopic
cholecystectomy. Cannula 10 comprises a proximal portion 12 separated from a
distal portion 14 by an elongated rigid shaft portion 16. Proximal portion 12 of
cannula 10 preferably comprises a head portion 18 connected to rigid shaft portion
5 16, preferably by threaded engagement. Most importantly, cannula 10 has a
working channel 20 which extends through head portion 18 and shaft portion 16
from proximal portion 12 to distal portion 14 of cannula 10. In one particular
embodiment, during insertion into cannula 10, the electrosurgical devices disclosed
herein configured to enter the proximal end of working channel 20, move along the
10 channel 20 distally, and then be extended from the distal end of the working channel
20. In the same embodiment, during retraction from cannula 10, electrosurgical
devices disclosed herein are configured to enter the distal end of working channel
20, move along the channel 20 proximally, and then be removed from the proximal
end of working channel 20.

15 For purposes of the appended claims, the term "tissue" includes, but is not
limited to, organs (e.g. liver, lung, spleen, gallbladder), highly vascular tissues (e.g.
liver, spleen), soft tissues, hard tissues and tissue masses (e.g. tumors).

While a preferred embodiment of the present invention has been described, it
should be understood that various changes, adaptations and modifications can be
20 made therein without departing from the spirit of the invention and the scope of the
appended claims. The scope of the invention should, therefore, be determined not
with reference to the above description, but instead should be determined with
reference to the appended claims along with their full scope of equivalents.

For example, while the above description of the coupling and operation
25 between rod 54 and first and second handle members 46, 48 has been presented in
detail, it should be understood not to constitute a limitation of the invention and that
a variety of mechanisms may be employed. Similarly to the coupling and operation
between rod 54 and first and second handle members 46, 48, the coupling of blade
members 34, 36 to the distal end portion 58 of rod 54 for controlling or effecting the
30 relative movement of blade members 34, 36 at the distal end of device 22 may be
performed by a variety of mechanisms known in the art and the specific structures
disclosed should be understood not to constitute a limitation of the invention.

Furthermore, it should be understood that the appended claims do not
necessarily comprise the broadest scope of the invention which the Applicant is
35 entitled to claim, or the only manner(s) in which the invention may be claimed, or
that all recited features are necessary.

We claim:

1. An electrosurgical scissors comprising:
an end effector (32) comprising a first blade member (34) and a second blade
5 member (36), the first blade member (34) and the second blade member (36)
pivotally connected;
a fluid passage (82) in fluid communication with at least one fluid outlet
(120);
at least one of the first blade member (34) and the second blade member (36)
10 electrically coupled to an electrical connector (68), the electrical connector (68)
configured to electrically couple the scissors to a radio frequency power source;
the first blade member (34) having a first blade member exterior surface
(137) and the second blade member (36) having a second blade member exterior
surface (139), at least one of the exterior surfaces configured to slide along tissue
15 while the exterior surface is coupled adjacent the tissue with a fluid expelled from
the fluid outlet and radio frequency power is provided to the tissue from the scissors;
and
whereby the tissue may be sealed from at least one of a flow of bodily fluid
and air.
20
2. The electrosurgical scissors of claim 1 wherein the electrosurgical scissors
further comprise monopolar electrosurgical scissors.
3. The electrosurgical scissors of claim 1 wherein the electrosurgical scissors
25 further comprise laparoscopic electrosurgical scissors.
4. The electrosurgical scissors of claim 1 wherein:
the first blade member comprises a first blade member distal portion;
the second blade member comprises a second blade member distal portion;
30 and
at least one of the distal portions further comprises a bulbous portion.
5. The electrosurgical scissors of claim 1 wherein at least one of the first blade
member exterior surface and the second blade member exterior surface at least
35 partially comprises an electrically insulative material.

6. The electrosurgical scissors of claim 1 wherein:
the first blade member further comprises a first blade member shearing surface;
the second blade member further comprises a second blade member shearing surface;
5 the first blade member shearing surface and the second blade member shearing surface face one another;
the first blade member exterior surface is located generally opposite the first blade member shearing surface; and
10 the second blade member exterior surface is located generally opposite the second blade member shearing surface.
7. The electrosurgical scissors of claim 1 further comprising:
an elongated shaft;
15 a lumen located within the confines of the shaft; and
the lumen providing a portion of the fluid passage.
8. The electrosurgical scissors of claim 1 further comprising:
an elongated hollow shaft; and
20 the at least one fluid outlet is located within the confines of the shaft.
9. The electrosurgical scissors of claim 1 further comprising:
a push rod;
a lumen located within the confines of the push rod; and
25 the lumen providing a portion of the fluid passage.
10. The electrosurgical scissors of claim 1 wherein the fluid passage passes through a connector member which couples the blade members to a push rod.
- 30 11. The electrosurgical scissors of claim 1, wherein the at least one fluid outlet is provided by a connector member which couples the blade member and a push rod.
12. The electrosurgical scissors of claim 1 wherein the at least one fluid outlet is positioned to provide the fluid expelled from the fluid outlet to the end effector.
35
13. The electrosurgical scissors of claim 1 wherein the fluid outlet is obstructed to direct contact by tissue by the blade members.

14. The electrosurgical scissors of claim 1 wherein the fluid outlet is provided at a location substantially inaccessible to direct contact with tissue.
15. The electrosurgical scissors of claim 1 wherein the blade members are
5 configured to pass through a cannula for laparoscopic surgery.
16. The electrosurgical scissors of claim 1 wherein at least one of the first and second blade members is curved.
- 10 17. The electrosurgical scissors of claim 1 wherein the at least one of the exterior surface is further configured such that the fluid expelled from the fluid outlet forms a localized fluid coupling between a surface of the tissue and the exterior surface when the exterior surface is located adjacent the tissue surface.
- 15 18. A method for treating tissue comprising:
providing tissue having a tissue surface;
providing radio frequency power at a power level;
providing a fluid at a fluid flow rate;
providing electrosurgical scissors configured to provide the radio frequency
20 power and the fluid to tissue;
providing the fluid to the tissue at the tissue surface;
forming a fluid coupling with the fluid which couples the tissue and the electrosurgical scissors;
providing the radio frequency power to the tissue;
25 sealing the tissue against at least one of a flow of bodily fluid and air from the tissue; and
cutting the sealed tissue with the electrosurgical scissors.

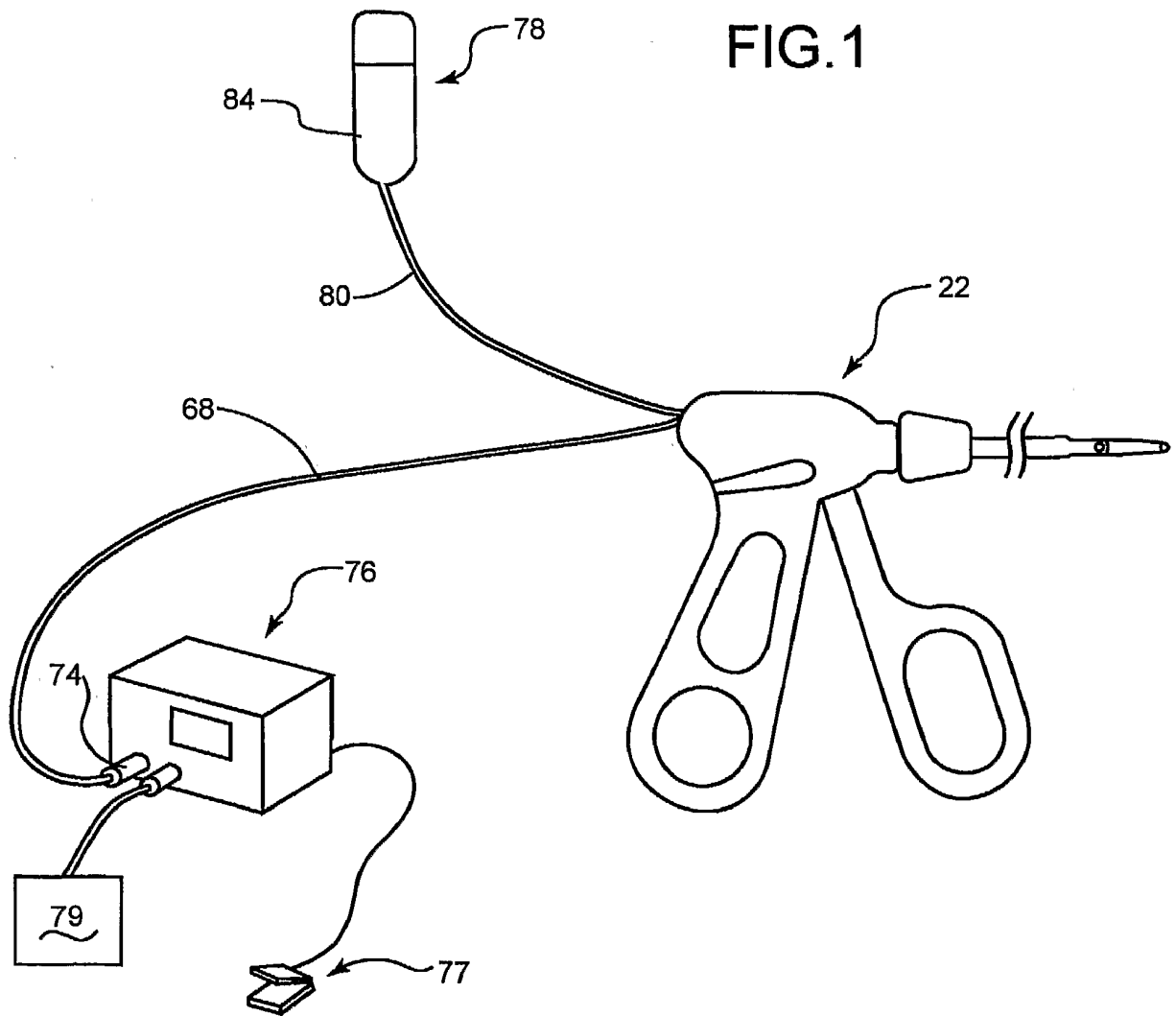


FIG.2

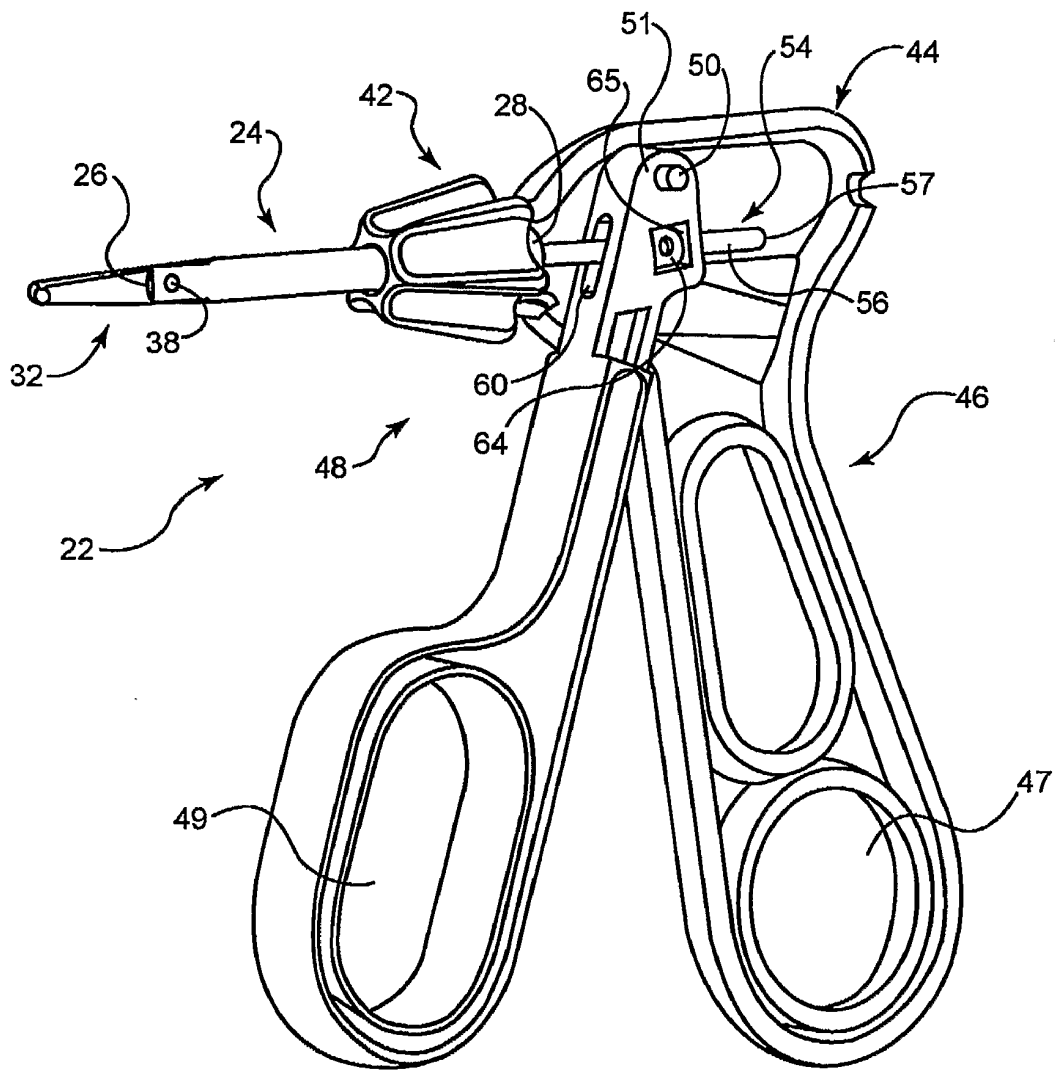


FIG.3

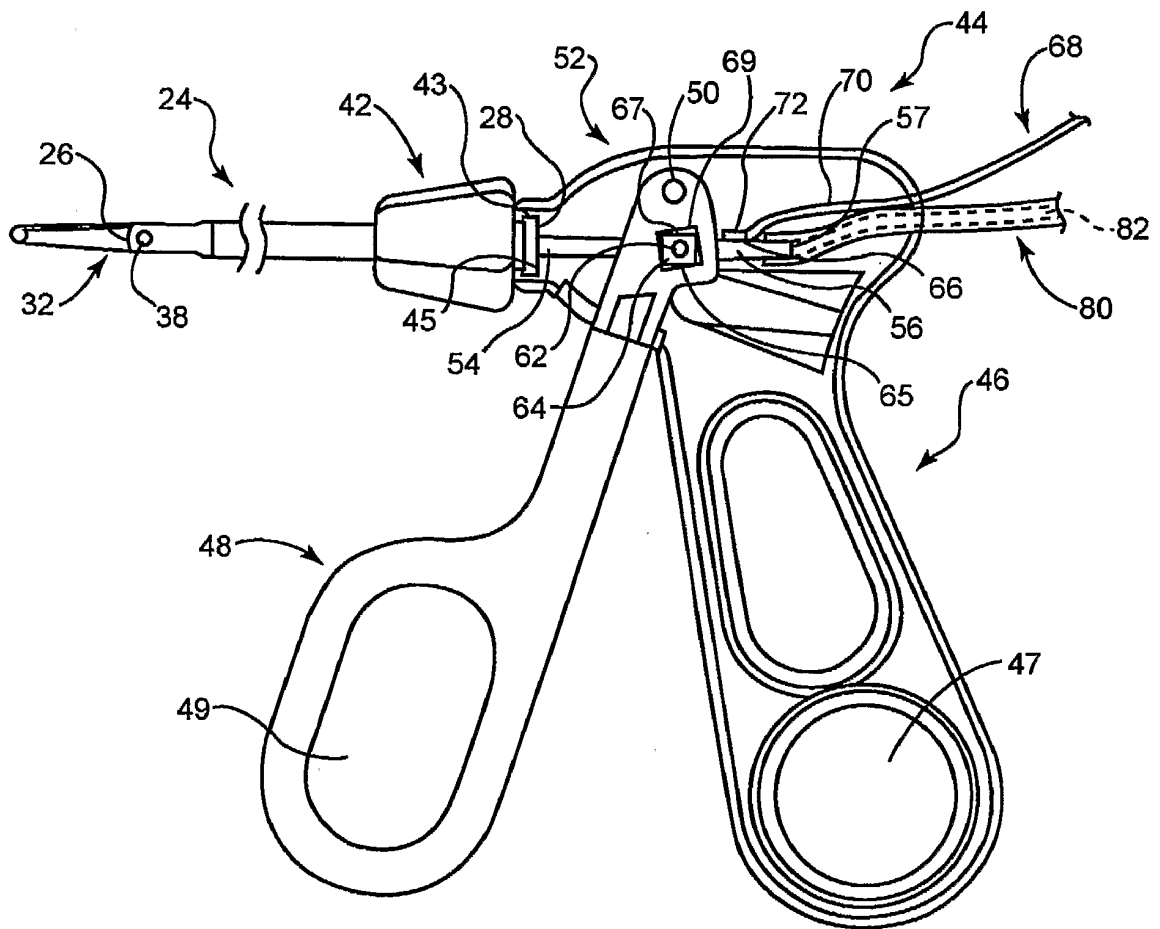


FIG.4

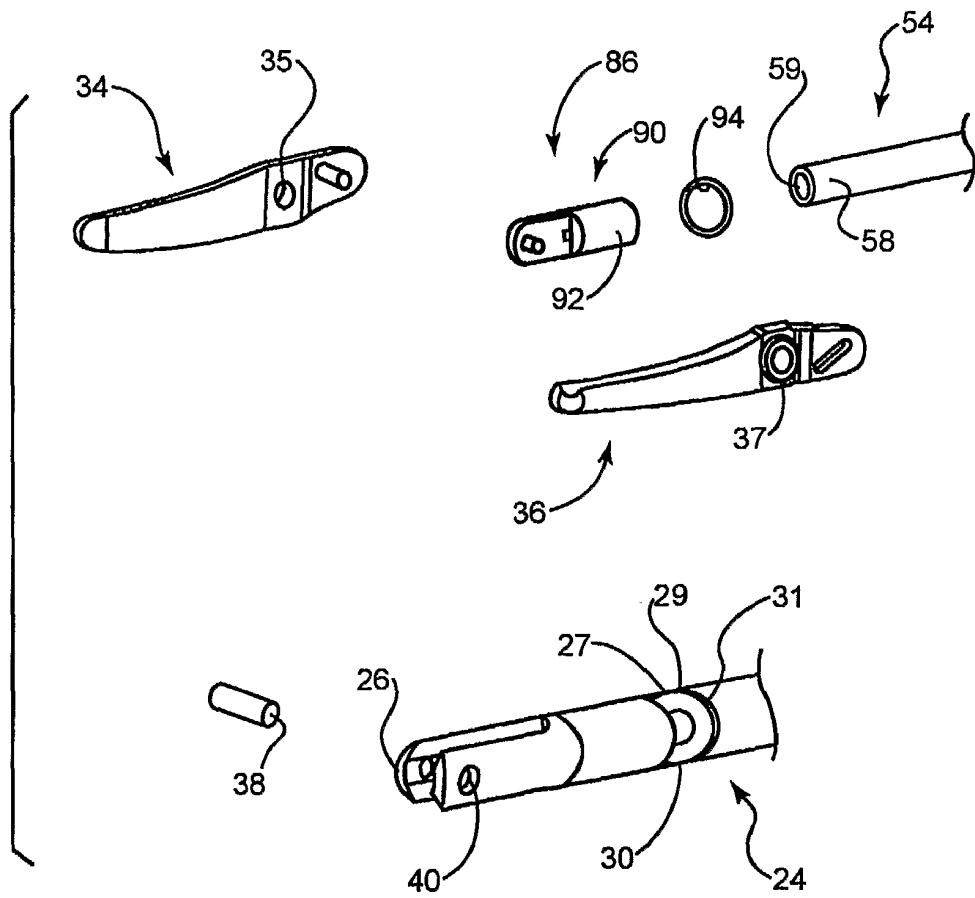


FIG. 5

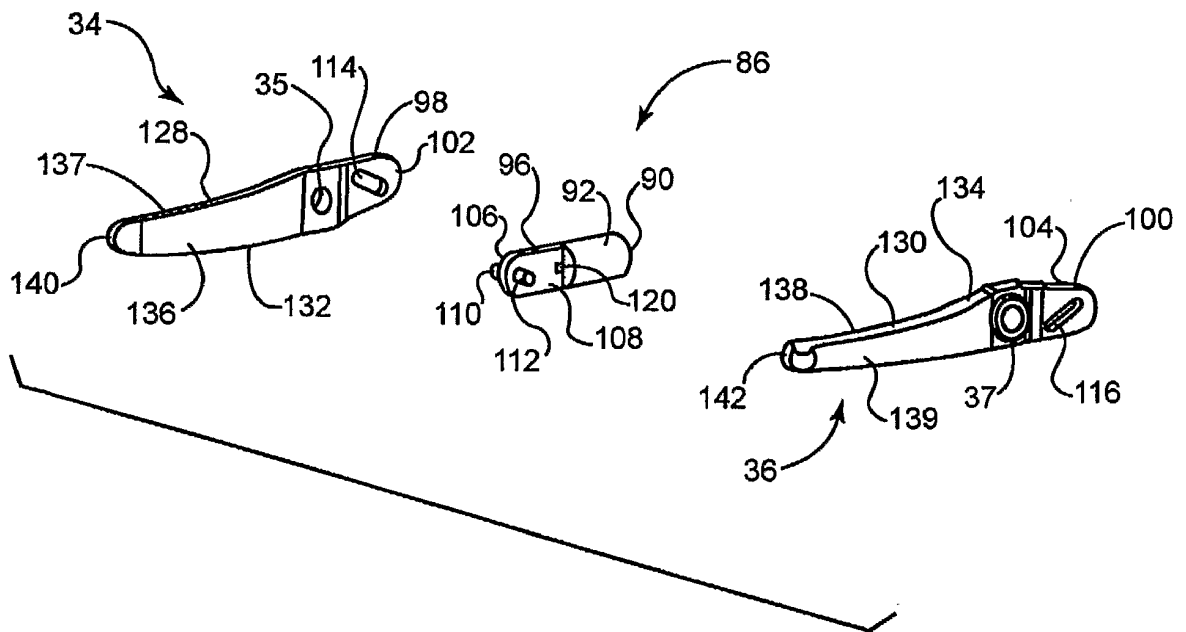


FIG.6

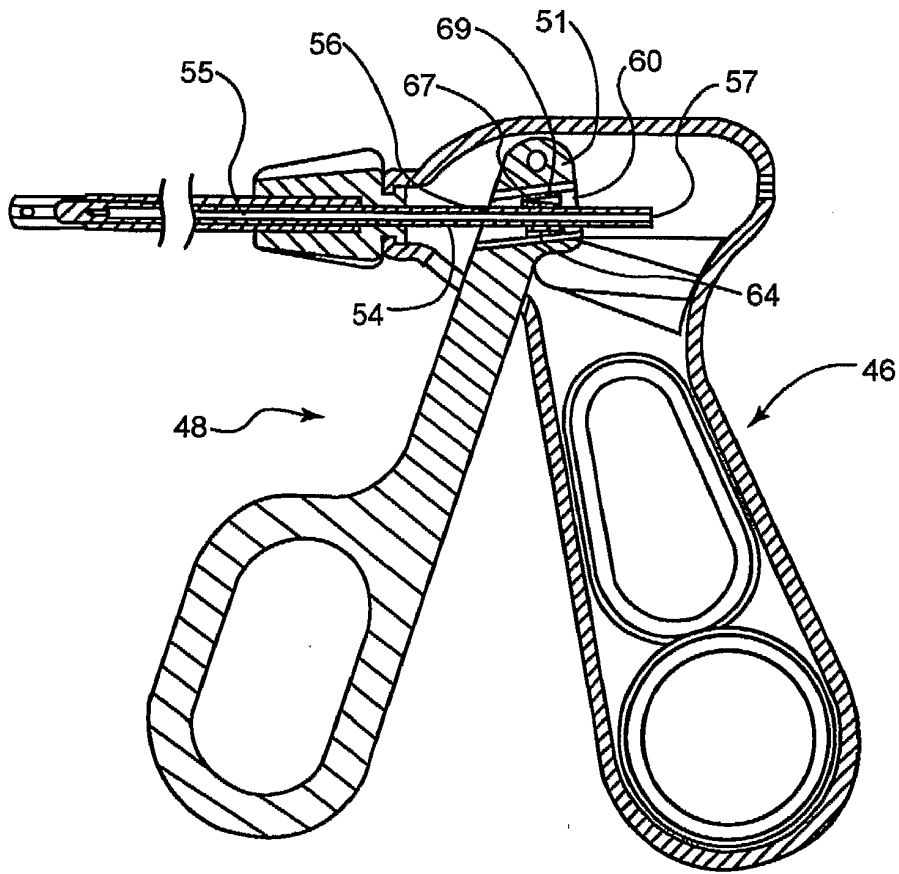


FIG. 7

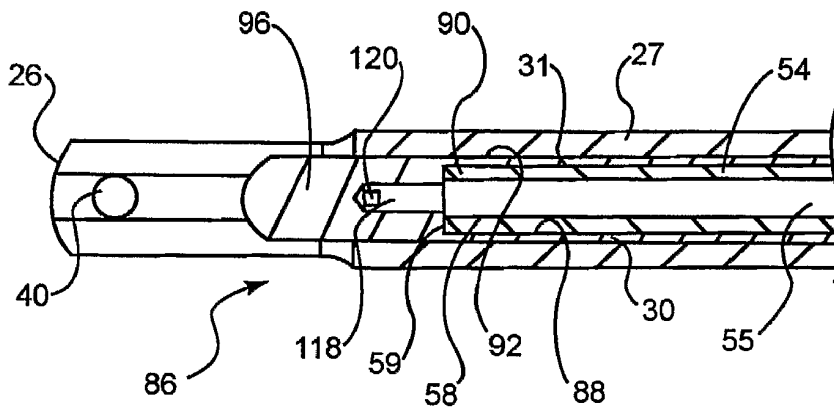


FIG. 8

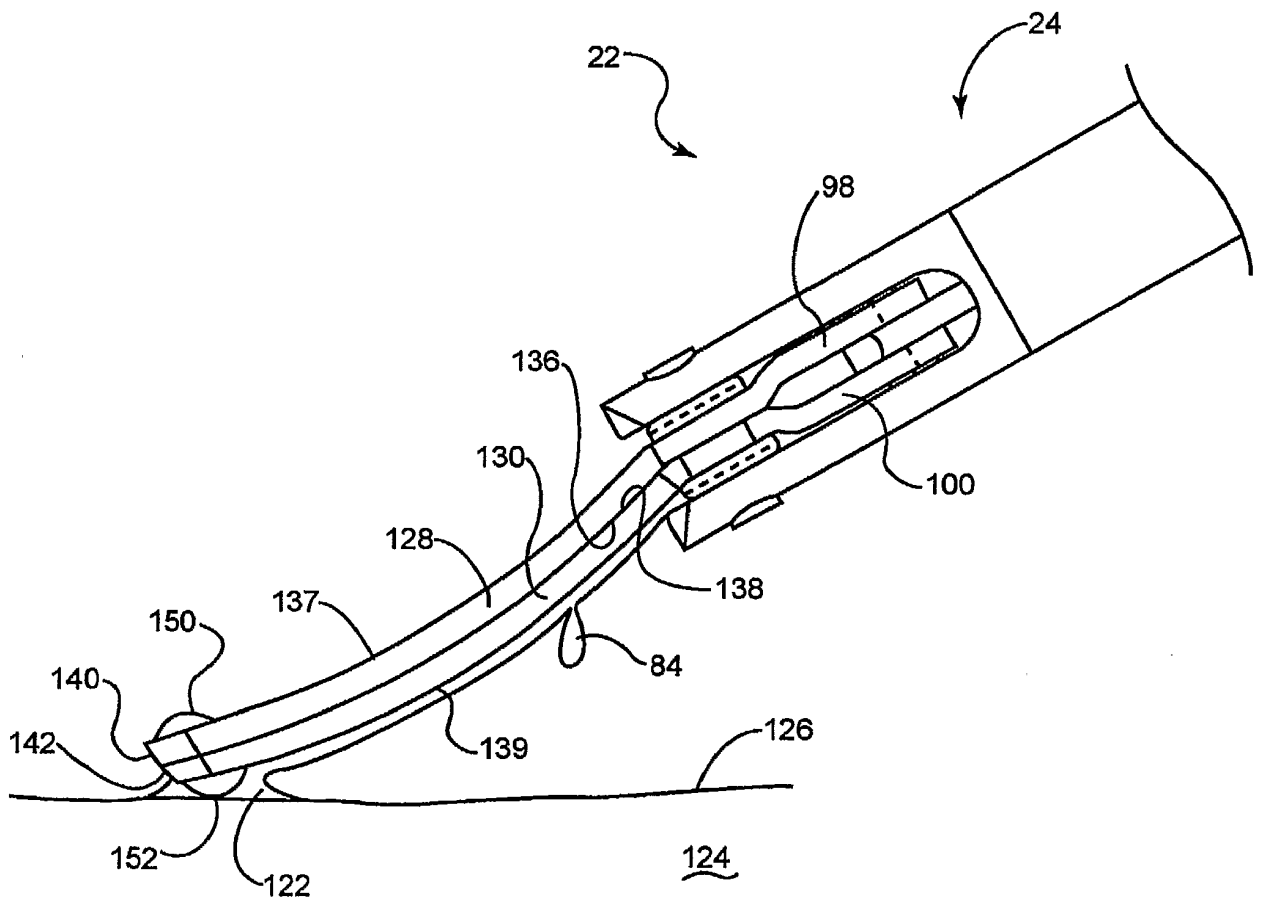


FIG.9

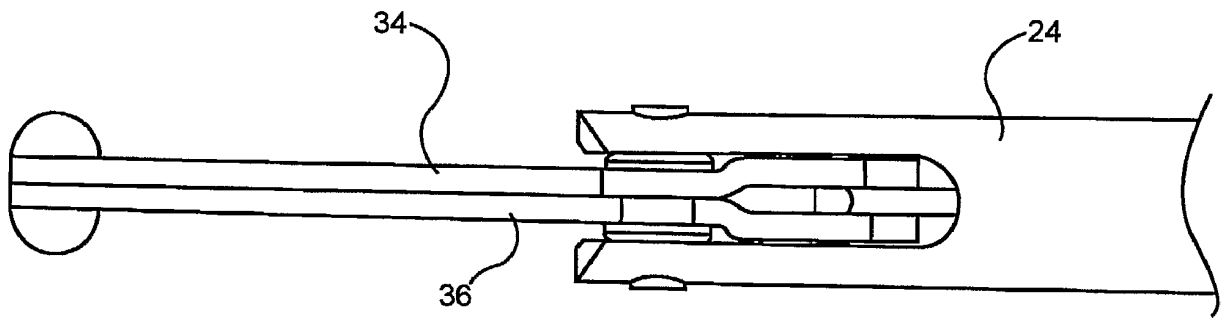


FIG. 10

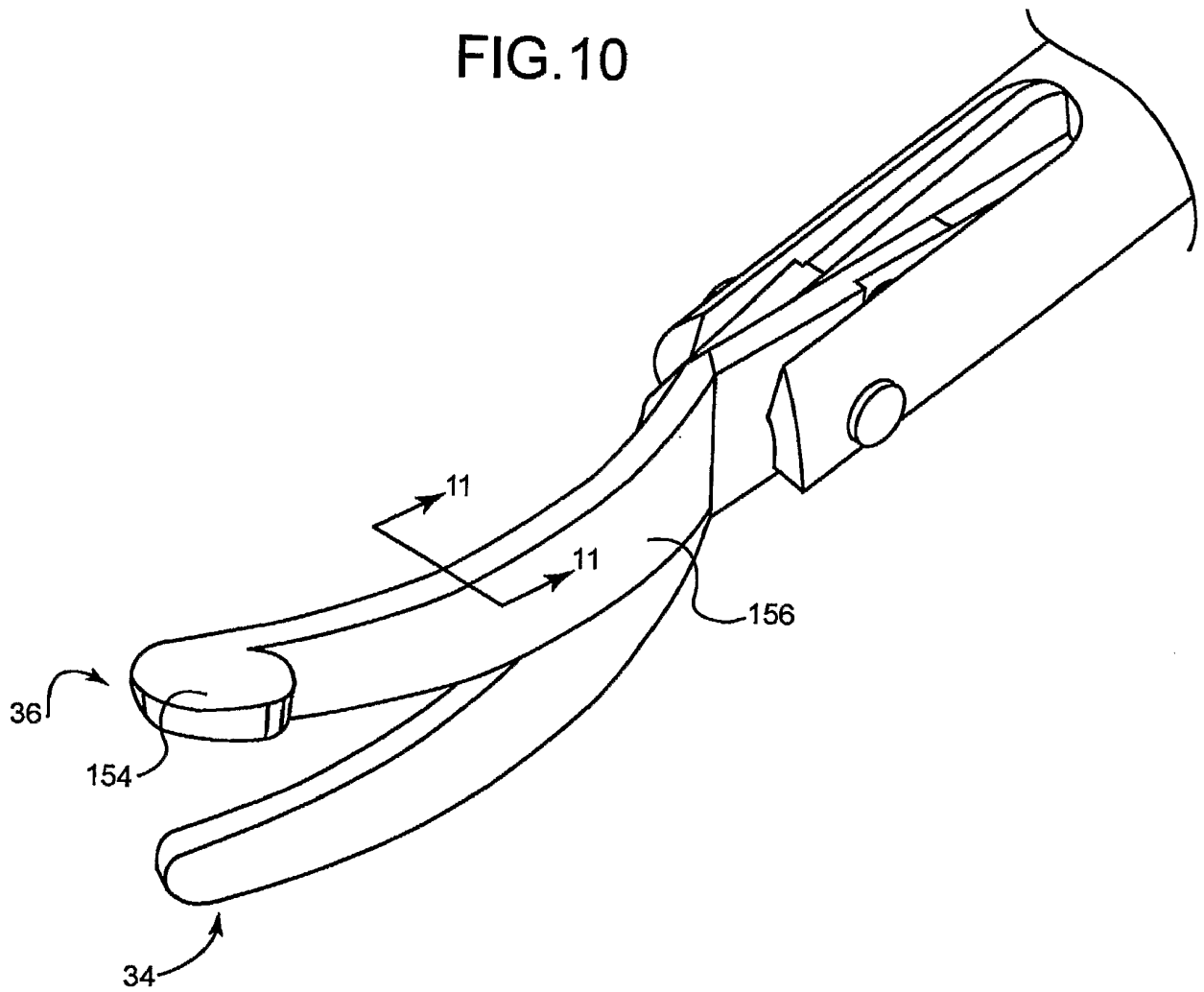


FIG. 11

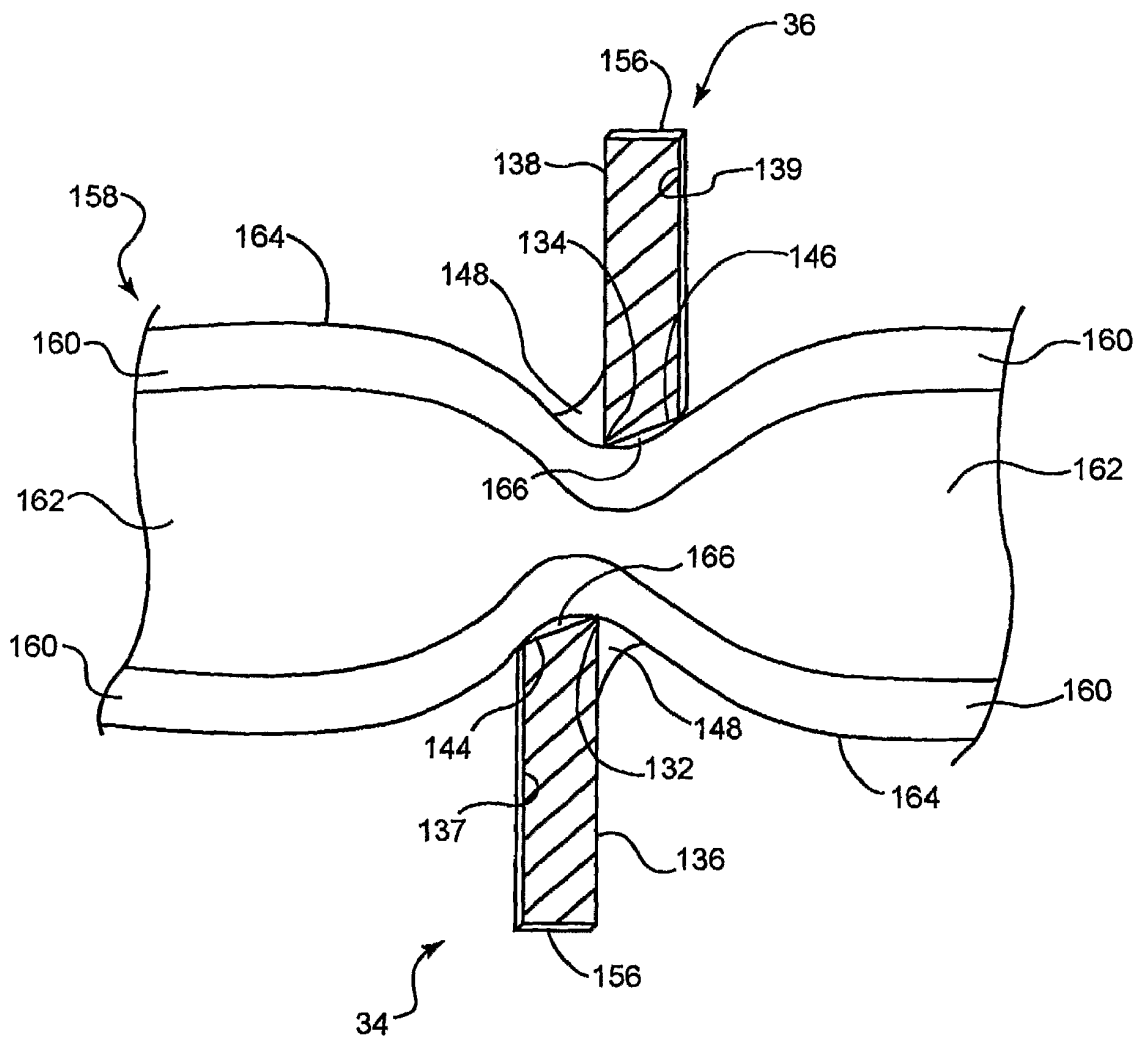
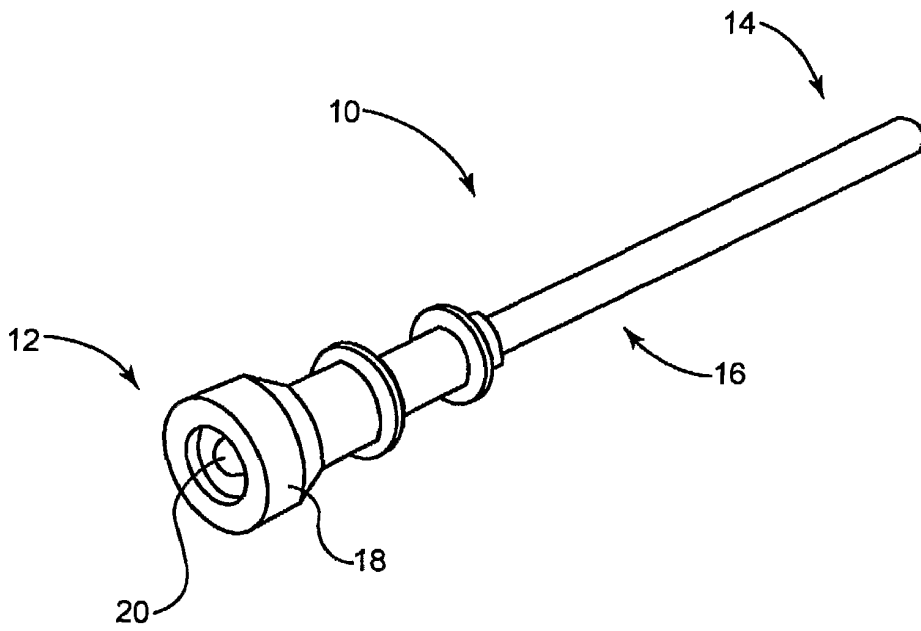


FIG. 12



专利名称(译)	流体辅助电外科剪刀和方法		
公开(公告)号	EP1572020A4	公开(公告)日	2006-05-03
申请号	EP2003781437	申请日	2003-10-28
[标]申请(专利权)人(译)	TISSUELINK医疗		
申请(专利权)人(译)	TISSUELINK MEDICAL , INC.		
当前申请(专利权)人(译)	TISSUELINK MEDICAL , INC.		
[标]发明人	MCCLURKEN MICHAEL E GREELEY ROGER D BERRY JOHN W		
发明人	MCCLURKEN, MICHAEL, E. GREELEY, ROGER, D. BERRY, JOHN, W.		
IPC分类号	A61B18/18 A61B17/28 A61B17/32 A61B18/14 A61L A61M1/00		
CPC分类号	A61B18/1445 A61B17/3201 A61B2017/2936 A61B2017/2945 A61B2018/1432 A61B2018/146 A61B2218/002		
代理机构(译)	法思博事务所		
优先权	60/422190 2002-10-29 US		
其他公开文献	EP1572020A2		
外部链接	Espacenet		

摘要(译)

一种电外科剪刀 (22) , 包括末端执行器 (32) , 所述末端执行器包括第一刀片构件和第二刀片构件 (34,36) , 所述第一刀片构件和所述第二刀片构件可枢转地连接;电连接器 (74) , 用于将剪刀连接到电源 (76) ; 流体通道 (82) 与至少一个流体出口 (120) 流体连通。

