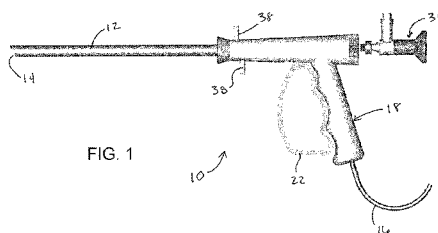




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- (81) **Designated States** (*unless otherwise indicated, for every
kind of national protection available*): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY,
BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM,
DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
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MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM,
PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC,
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DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU,
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(54) **Title:** DISPOSABLE ELECTROSURGICAL PROBE AND KIT AND METHOD OF USING



(57) **Abstract:** Disposable electrosurgical probes for treating tissue, and surgical procedures that make use of such probes. Such a probe (10) includes a working element (18), an elongate sheath (12) secured to the working element (18), and a core member (24) within the sheath (12). At least one active electrode (20) and conductor (21) are disposed in a first (32) of a plurality of internal longitudinal channels (26, 32, 36) within the core member (24). The electrode (20) is adapted to extend from a distal end (14) of the sheath (12) and configured to perform cutting, coagulation, or ablation of tissue with radio frequency current. The probe (10) further includes a fluid passage (36) defined by at least a second (36) of the internal longitudinal channels (26, 32, 36) within the core member (24). At least the working element (18), the sheath (12), and the core member (24) are formed of a disposable material.

DISPOSABLE ELECTROSURGICAL PROBE AND KIT AND METHOD OF USING

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 62/000,262, filed May 19, 2014, the contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] The present invention relates to electrosurgical probes for treating damaged, diseased or enlarged tissue, and to surgical procedures that make use of such probes.

[0003] Electrosurgical effects can be accomplished by applying a highly damped radio frequency (RF) current to tissue through an electrode in the form of an active (+) electrode (tip) of an electrosurgical (electrocautery) probe, from which the RF current flows to a ground (–) electrode. RF electrosurgical probes (RF probes), such as those commonly used in urological and hysteroscopic procedures, are said to be monopolar or bipolar or said to have a monopolar or bipolar operating mode, depending on their electrode configuration. RF probes operating in a monopolar mode utilize a single (active) electrode (tip) and rely on external grounding of a patient (e.g., a ground electrode in the form of a patient plate) to cause current flow from the active electrode to tissue of the patient. RF probes operating in a bipolar mode have two electrodes, typically designated as active and return electrodes, and current flow is localized between these electrodes. As it passes through tissue from the active electrode to the ground or return electrode, the RF current resects (cuts), coagulates and/or ablates (desiccates) the tissue, depending on the type of probe

and the RF power and wave length combinations used. RF electrosurgical probes are typically placed through a resectoscope (used in urological procedures), hysteroscope (used in gynecological procedures) or other device, which is often equipped with a telescope so that the active electrode of the probe is in direct view of the surgeon at all times. Irrigating solutions are commonly used as a distention medium and a coolant for the active electrodes of RF probes during electrosurgical procedures.

[0004] Resectoscopes and hysteroscopes (hereinafter referred to as electrosurgical probes) have been used for decades to diagnose and treat medical conditions in the human bladder and the uterus, respectively. Electrosurgical resection refers to procedures by which damaged, diseased or enlarged tissue is removed with an electrosurgical probe. A nonlimiting example is transurethral resection of the prostate (TURP), in which prostate tissue is removed by means of an active electrode (for example, a cutting loop) passed through the urethra by means of a resectoscope. This procedure has served as the historical treatment of benign prostate hypertrophy (BPH)), commonly known as “enlarged prostate,” and prostatitis. Bladder tumors and cysts in men and women are also treated by electrosurgical resection. Electrosurgical ablation refers to procedures by which an electrosurgical probe is used to ablate (dessicate) tissue, which eventually sloughs off instead of being immediately removed on contact with the electrode. A nonlimiting example of an electrosurgical ablation procedure is endometrial ablation to treat endometriosis in women, in which tissue is removed by means of roller that serves as the active electrode. Another example is transurethral ablation of the prostate (TUAP), in which prostate tissue is ablated by means of an electrocautery probe passed over a stylet/obturator or guide wire, through the prostatic urethra.

[0005] In addition to its electrode, an electrosurgical probe typically includes a

working element equipped with a power cord for connection to an RF electrosurgical current generator, and a sheath that extends from the working element and through which one or more conductors are routed to deliver RF current to the electrode protruding from a distal end of the sheath. The probe is also typically equipped with a telescope and/or light source disposed in one or more internal channels within the sheath to allow direct vision during placement and use of the probe. The electrode and its conductor(s) may be capable of reciprocal movement within the sheath through the operation of an actuation lever of the working element. The sheath may also define an internal flow channel to enable an irrigation fluid to be delivered for immersion cooling of the electrode. The RF generator, light source, and telescope are capital equipment and available in a typical surgical suite. While electrosurgical probe electrodes are disposable and therefore do not require sterilization after use, the remaining components of a electrosurgical probe, including the working element, sheath and telescope, are typically formed of stainless steels or another durable metallic material and durable heat-resistant plastics that enable these components to be reused following re-sterilization, for example, using an autoclave and/or ethylene oxide gas. As such, electrosurgical probes typically have high initial purchase costs. The distal end of the sheath is often equipped with a plastic tip that becomes damaged over time, in some cases after a single use, as a result of the high RF current levels, necessitating that the sheath undergo an expensive and time-consuming repair. Also due to the RF currents, metal components of an electrosurgical probe require electrical insulation to protect the surgeon from receiving shocks and burns during use of the probe. Even so, surgeons are commonly required to wear two pairs of latex gloves as a safety precaution.

[0006] Sterilization can be a complicated process, particularly in view of the internal channels within the sheath that accommodate a light source, telescope, and/or cooling flow stopcocks and channels. Furthermore, components of reusable

electrosurgical probes are conventionally individually reprocessed, sterilized, and packaged, and then kept in drawers, cabinets, and carts accessible to the surgical team. If any of the components are unavailable or the wrong size, the procedure cannot go forward. Generally, hospitals have additional electrosurgical probes on hand in case one fails during surgery. However, at times when case loads are high, a physician may be forced to either wait for another unit to be sterilized or cancel the surgery.

[0007] Since the late 1980's, the use of disposable (sterile, one-time use) surgical instruments and devices has dramatically increased in the United States. This trend of cycling from reusable to disposable surgical instruments and devices is taking place now in countries around the world as their economies grow, as is the awareness of the risks and costs associated with hospital-acquired infections, especially those in the operating room. This trend is driven by numerous factors, such as sterility assurance, quality/performance, reducing cross contamination, and cost factors (cost control, convenience, and patient charges).

BRIEF DESCRIPTION OF THE INVENTION

[0008] The present invention provides electrosurgical probes for treating damaged, diseased or enlarged tissue, and to surgical procedures that make use of such probes.

[0009] According to one aspect of the invention, a disposable electrosurgical probe includes a working element, an elongate sheath secured to the working element, and a core member within the sheath. The core member has a plurality of internal longitudinal channels, and at least one active electrode and conductor are disposed in a first of the internal longitudinal channels. The conductor is

adapted to carry a radio frequency current to and from the electrode, and the electrode is reciprocable within the sheath, adapted to extend from a distal end of the sheath, and configured to perform cutting, coagulation, or ablation of tissue when the radio frequency current flows to the electrode. The disposable electrosurgical probe further includes means associated within the working element for reciprocating the electrode relative to the sheath, and a fluid passage defined by at least a second of the internal longitudinal channels of the core member. At least the working element, the sheath, and the core member are formed of a disposable material.

[0010] According to another aspect of the invention, a method of using the disposable electrosurgical probe to perform a medical procedure includes placing the electrode of the disposable electrosurgical probe within a patient, performing an electrosurgical procedure on the patient using the disposable electrosurgical probe, and disposing of the working element, the sheath, and the core member after performing the procedure.

[0011] A technical effect of the invention is that the disposable electrosurgical probe can be offered as a kit, in which the working element, sheath, core member, and one or more electrodes are all disposable components of the kit.

[0012] Other aspects and advantages of this invention will be better appreciated from the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] FIG. 1 is a side view representing an electrosurgical probe in accordance with a nonlimiting embodiment of this invention.

[0014] FIG. 2 represents an electrode protruding from a distal end of a sheath of the electrosurgical probe of FIG. 1 as a result of operating a handle of the working element.

[0015] FIG. 3 represents a partial cutaway view of the distal end of the sheath of FIG. 2, showing the electrode protruding therefrom and revealing an electrode connection and irrigation tube within the sheath.

[0016] FIG. 4 is a perspective view of the probe of FIG. 1, showing a partial cutaway of the distal end of the sheath.

[0017] FIG. 5 represents a detailed view of the distal end of the sheath of FIG. 4.

DETAILED DESCRIPTION OF THE INVENTION

[0018] FIGS. 1 through 5 depict an electrosurgical probe 10 in accordance with a nonlimiting embodiment of the present invention. The drawings depict the probe 10 as a resectoscope, though other electrosurgical probes capable of use in a wide variety of procedures are also within the scope of the invention. The probe 10 is represented as including a sheath 12 through which conductors can be routed to one or more electrodes disposed at a distal end 14 of the sheath 12. The conductors carry a current, preferably an RF current, generated by an electrosurgical generator (not shown) that is connected to the probe 10 via a power cord 16 extending from a working element 18 of the probe 10. The probe 10 can be a monopolar or bipolar RF electrosurgical probe. FIGS. 1 through 5 depict a single electrode 20 configured as a cutting loop (wire), though other electrode configurations are possible and within the scope of this invention, for example, such

well-known types as ball tip, disk, roller tip, barrel, cone, point, knife, flat band, coagulating, and punctate electrodes. As a cutting loop, the electrode 20 is represented as electrically connected to one or more insulated conductors 21 to define an active (+) pole of the RF circuit.

[0019] The electrode 20 and its conductors 21 are preferably capable of reciprocal movement within the sheath 12, as evidenced by the retracted and extended positions of the electrode 20 depicted in FIGS. 1 and 2, respectively. Movement of the electrode 20 and conductors 21 relative to the sheath 12 can be effected through the operation of an actuation lever 22 of the working element 18. The electrode 20 and its conductors 21 are disposed in an internal longitudinal channel 26 defined within a core member 24 that is coaxially disposed within an internal passage 25 defined by the sheath 12, such that the core member 24 is completely surrounded by the sheath 12. The electrode 20 and its conductors 21 may be reciprocally disposed in the internal channel 26, or the core member 24 may be reciprocally disposed within the passage 25 of the sheath 12. As evident from FIGS. 4 and 5, the core member 24 has a circular-shaped outer circumference defined by a tubular outer wall 28 of the member 24, and an internal web 30 that defines the internal channel 26 as well as a second internal longitudinal channel 32 in which a telescope 34 is represented as being received to allow direct vision during placement and use of the probe 10. The internal channels 26 and 32 preferably have circular cross-sections and the core member 24 is represented as having a plane of symmetry through the channels 26 and 32, with the result that the channels 26 and 32 are between two internal longitudinal channels 36 (one of which is visible in FIGS. 4 and 5) that are defined by the remainder of the circular interior cross-section of the core member 24 surrounded by the outer wall 28. As a result of the circular cross-sectional shapes of the outer wall 28 and channels 26 and 32 and the symmetrical shape of the core member 24, the channels 36 are

substantially identical mirror-images of each other and have fan-shaped cross-sections. Either or both of the channels 36 can serve as an irrigation tube that enables an irrigation fluid to be delivered to the electrode 20, for example, to perform immersion cooling of the electrode 20. Alternatively, a separate tube could be located within either or both channels 36 through which an irrigation fluid could flow through the sheath 12. In either case, at least one of the channels 36 is adapted to be fluidically coupled to a fluid source, for example, via one or more irrigation ports 38 located on the working element 18. As a result of the channels 36 being disposed on opposite sides of the channel 26 containing the electrode 20, the channels 36 are able to direct irrigation fluid to opposite sides of the electrode 20, thereby enveloping the electrode 20 and promoting the desired effect of the irrigation fluid in close proximity to the electrode 20.

[0020] Whereas the telescope 34, RF generator, and other such components including light sources are capital equipment of the probe 10, a preferred aspect of the invention is that the sheath 12, working element 18, electrode 20, and core member 24 are intended to be disposable after a single use, and therefore do not require sterilization after use and are not required to be formed of a stainless steel or other durable metallic material that would enable these components to be sterilized and reused. For example, the sheath 12, working element 18, and core member 24 can be formed of polymeric materials, including but not limited to plastics of the types commonly used for disposable surgical components, for example, plastics manufactured in an FDA/ISO Certified Facility with FDA marketing clearance. As such, the term “disposable” is used and defined herein to mean an article that is not adapted to be cleaned, sterilized, and reused for a medical procedure performed on a patient. If the sheath 12, working element 18, and core member 24 are formed of electrically dielectric polymeric materials, the conductors 21 of the electrode 20 may be routed through the sheath 12 without requiring

electrical insulation. Optionally, the distal end 14 of the sheath 12, including that portion of the sheath 12 that protrudes over the opening of the sheath passage 25, may be formed of or coated with a material that offers a greater degree of erosion and heat resistance to the high RF current levels, a notable but nonlimiting example of which is a phenol-formaldehyde resin such as Bakelite. Though also intended to be disposable, preferred materials for the electrode 20 include tungsten and stainless steels, though other materials could be used.

[0021] To facilitate use of the probe 10, the sheath 12, working element 18, electrode 20, core member 24, and telescope 34 of the probe 10 are preferably separable, allowing the electrode 20 to be removed from the core member 24, allowing the core member 24 to be removed from the sheath 12, and allowing the sheath 12, core member 24 and telescope 34 to be separated from the working element 18. The conductors 21 for the electrode 20 can be permanently fixed within the core member 24 or within the working element 18, in which case the electrode 20 can preferably be electrically coupled and decoupled from the conductors 21 and/or the conductors 21 can preferably be electrically coupled and decoupled from the working element 18 with suitable quick-connect features.

[0022] In view of the above, with the possible exception of the telescope 34, all of the components of the probe 10 depicted in FIGS. 1 through 5 are intended to be disposable. Due to being disposable, the electrosurgical probe 10 can reduce if not eliminate the handling, sterilization, packaging, and testing of and risk of damage to individual reusable components of probes that are currently used in electrosurgical procedures at surgery centers and hospitals. The risk of injury and/or contamination to the personnel involved with this process can be virtually eliminated with the disposable electrosurgical probe 10. The electrosurgical probe 10 is not required to be re-sterilized after use, as is conventional with reusable

electrosurgical probes, though it should be understood that each individual disposable electrosurgical probe 10 would be pre-sterilized prior to use to ensure safety. Maintenance, wear due to use, and cross-contamination are also avoided with the disposable electrosurgical probe 10. Furthermore, it is foreseeable that the disposable electrosurgical probe 10 may be readily adapted or adaptable to particular brands of generators and telescopes.

[0023] The electrosurgical probe 10 and its components shown in FIGS. 1 through 5, as well as other optional components and materials, can be packaged together to form what will be referred to as a "disposable electrosurgical kit" or simply a "kit." The convenience and ability to access one kit with all the necessary components in a ready-to-use sterile package reduce the time and frustration that can be encountered when attempting to ensure that an electrosurgical probe and its components are available and ready to perform an electrosurgical procedure. Other major advantages include the ability to customize an individual kit, for example, to provide electrodes of various configurations within a single kit. In addition, the kit can offer different types of tubing connections to provide secure attachment to a scope, including but not limited to a stopcock, tubing with stopcock, and/or a luer connector.

[0024] The disposable electrosurgical kit has the ability to save money, reduce procedure time, reduce the risk of hospital-acquired infections by patients, and reduce the risk of injury or infections to hospital personnel and physicians. The functionality of the disposable electrosurgical probe 10 and kit relative to conventional reusable electrosurgical probes is not affected by its disposable nature, as RF generators, light sources, and telescopes usable with the probe 10 can be the same as those commercially available and commonly used at surgery centers and hospitals. As such, physicians may maintain the power and optical

equipment they are familiar with.

[0025] While the invention has been described in terms of specific embodiments, it is apparent that other forms could be adopted by one skilled in the art. For example, the physical configuration of the disposable electrosurgical probe 10 could differ from that shown, a disposable telescope could be used, and materials and processes other than those noted could be used. Therefore, the scope of the invention is to be limited only by the following claims.

CLAIMS:

1. A disposable electrosurgical probe (10) comprising:
 - a working element (18);
 - an elongate sheath (12) secured to the working element (18);
 - a core member (24) within the sheath (12), the core member (24) having a plurality of internal longitudinal channels (26,32,36);
 - at least one active electrode (20) and conductor (21) disposed in a first (26) of the internal longitudinal channels (26,32,36) of the core member (24), the conductor (21) being adapted to carry a radio frequency current to and from the electrode (20), the electrode (20) being reciprocable within the sheath (12), adapted to extend from a distal end (14) of the sheath (12), and configured to perform cutting, coagulation, or ablation of tissue when the radio frequency current flows to the electrode (20);
 - means (16) associated within the working element (18) for reciprocating the electrode (20) relative to the sheath (12); and
 - a fluid passage (36) defined by at least a second (36) of the internal longitudinal channels (26,32,36) of the core member (24);
 - wherein at least the working element (18), the sheath (12), and the core member (24) are formed of a disposable material.
2. The disposable electrosurgical probe (10) of claim 1, wherein the working element (18), the sheath (12), and the core member (24) are formed of FDA/ISO certified plastics.
3. The disposable electrosurgical probe (10) of claim 1 or 2, further comprising a telescope (34) disposed in another (32) of the internal longitudinal channels (26,32,36) of the core member (24).

4. The disposable electrosurgical probe (10) of claim 3, wherein the telescope (34) is disposable.

5. The disposable electrosurgical probe (10) of any one of claims 1 to 4, wherein the core member (24) comprises an internal web (30) that defines the plurality of internal longitudinal channels (26,32,36).

6. The disposable electrosurgical probe (10) of claim 5, wherein the core member (24) has a plane of symmetry through the first internal longitudinal channel (26) thereof and the first internal longitudinal channel (26) is between and separates the fluid passage (36) defined by the second internal longitudinal channel (36) from a second fluid passage (36) defined by a third (36) of the internal longitudinal channels (26,32,36) within the core member (24).

7. The disposable electrosurgical probe (10) of claim 6, further comprising a fourth (32) of the internal longitudinal channels (26,32,36) defined by the internal web (30) within the core member (24), the plane of symmetry of the core member (24) being through the fourth internal longitudinal channel (36).

8. The disposable electrosurgical probe (10) of claim 7, wherein the core member (24) has a circular interior cross-section, the first and fourth internal longitudinal channels (26,32) each have a circular cross-section, and the fluid passage (36) defined by the second internal longitudinal channel (36) and the second fluid passage (36) are defined by a remainder of the circular interior cross-section of the core member (24).

9. The disposable electrosurgical probe (10) of any one of claims 1 to 8, wherein the sheath (12), the working element (18), the electrode (20), and the core

member (24) are separable from each other.

10. The disposable electrosurgical probe (10) of any one of claims 1 to 9, wherein the electrode (20) is removable from the core member (24).

11. The disposable electrosurgical probe (10) of any one of claims 1 to 10, wherein the core member (24) is removable from the sheath (12).

12. The disposable electrosurgical probe (10) of any one of claims 1 to 11, wherein the sheath (12) and the core member (24) are separable from the working element (18).

13. The disposable electrosurgical probe (10) of claim 1, further comprising a second fluid passage (36) defined by a third (36) of the internal longitudinal channels (26,32,36) of the core member (24).

14. The disposable electrosurgical probe (10) of claim 13, wherein the first internal longitudinal channel (26) of the core member (24) separates the second fluid passage (36) from the fluid passage (36) defined by the second internal longitudinal channel (36) of the core member (24).

15. The disposable electrosurgical probe (10) of claim 13 or 14, wherein the second fluid passage (36) is a mirror-image of the fluid passage (36) defined by the second internal longitudinal channel (36) of the core member (24).

16. The disposable electrosurgical probe (10) of any one of claims 13 to 15, wherein the fluid passage (36) defined by the second internal longitudinal channel (36) and the second fluid passage (36) are each fan-shaped.

17. The disposable electrosurgical probe (10) of any one of claims 1 to 16, wherein the disposable electrosurgical probe (10) is a disposable kit and the working element (18), the sheath (12), the core member (24), and the electrode (20) are components of the disposable kit.

18. A method of using the disposable electrosurgical probe (10) of any one of claims 1 to 17 to perform a medical procedure, the method comprising:

placing the electrode (20) of the disposable electrosurgical probe (10) within a patient;

performing an electrosurgical procedure on the patient using the disposable electrosurgical probe (10); and

disposing of the working element (18), the sheath (12), and the core member (24) after performing the electrosurgical procedure.

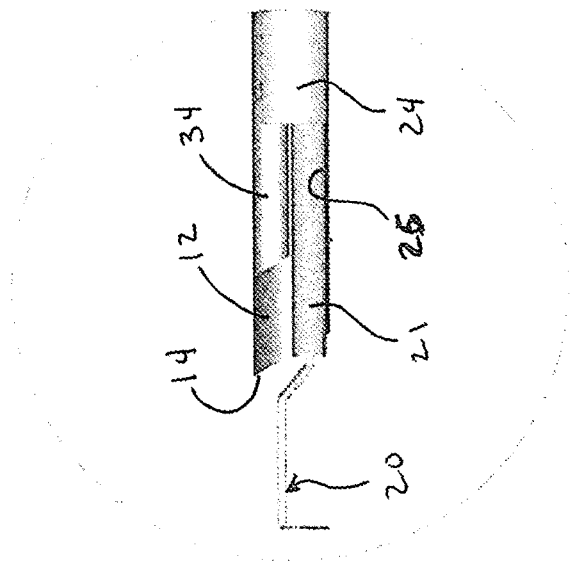
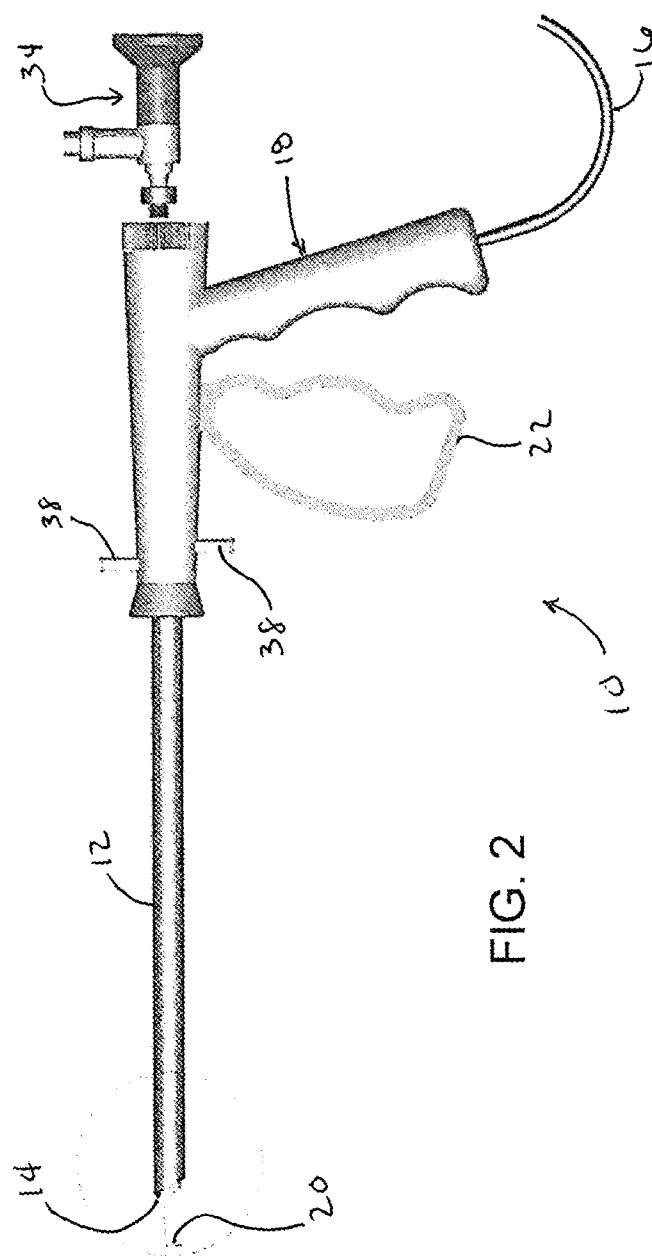
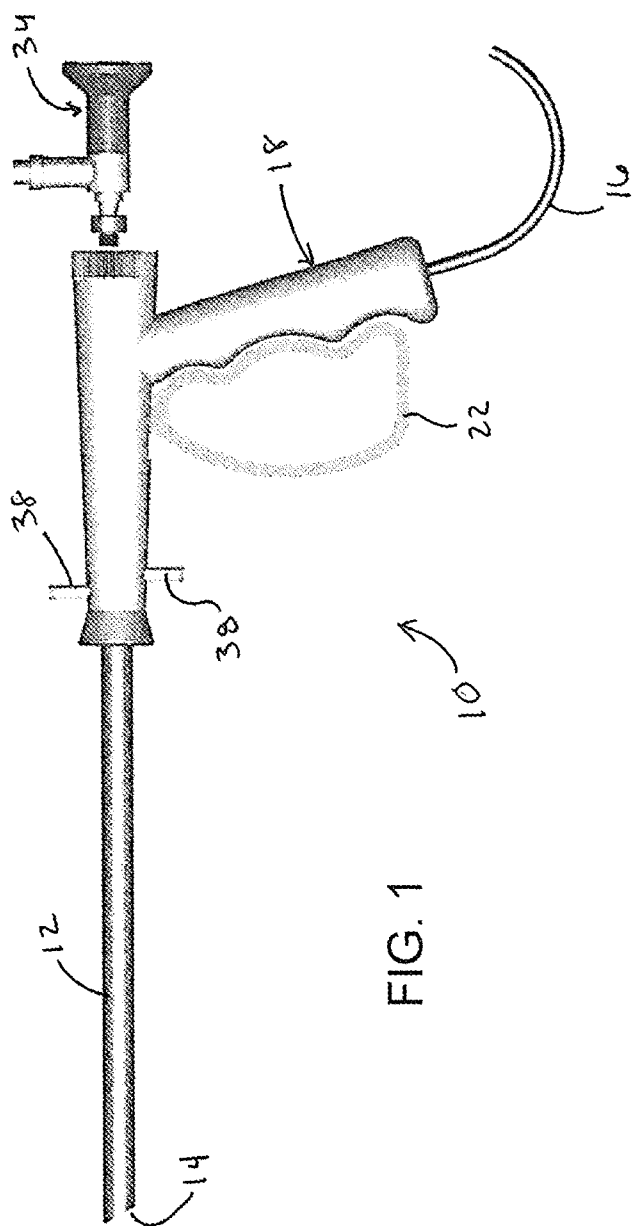
19. A medical procedure comprising:

placing within a patient an electrode (20) of a disposable electrosurgical probe (10) that comprises a working element (18) and an elongate sheath (12) from which the electrode (20) protrudes;

performing a single electrosurgical procedure on the patient using the electrode (20) of the disposable electrosurgical probe (10); and then

disposing of the working element (18), the sheath (12), and the electrode (20) after performing the electrosurgical procedure.

20. The method of claim 19, wherein the electrosurgical procedure is a urological or hysteroscopic procedure.



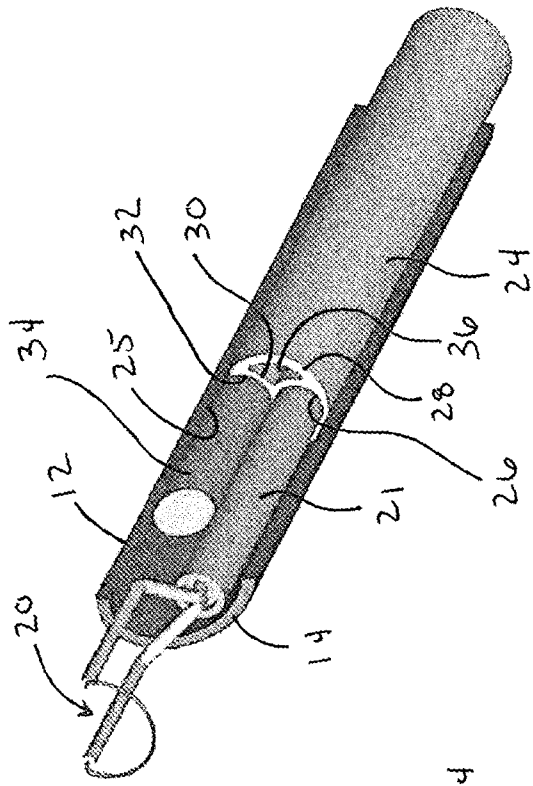


FIG. 5

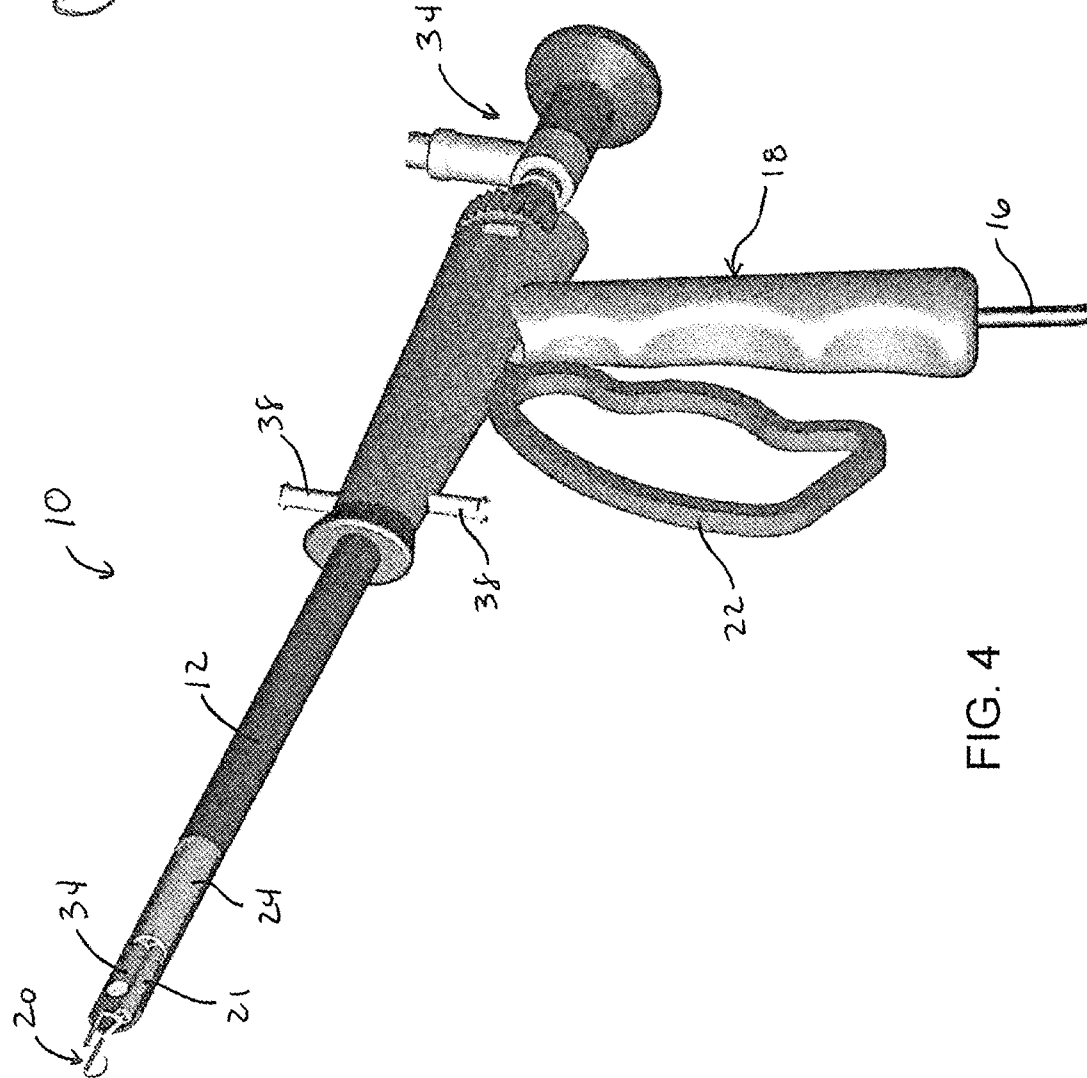


FIG. 4

A. CLASSIFICATION OF SUBJECT MATTER**A61B 18/14(2006.01)i**

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B 18/14; A61N 1/05; A61B 17/39; A61B 18/18

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

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

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

eKOMPASS(KIPO internal) & Keywords: disposable, electrosurgical probe, multi-channels, electrode, reciprocating, cooling fluid, telescope

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6106521 A (BLEWTT et al.) 22 August 2000 See column 2, line 45-column 3, line 2; column 2, line 59-column 7, line 45; claims 1-17; and figures 1-17.	1-4, 13-15
A	US 2011-0208184 A1 (BRANNAN, JOSEPH D.) 25 August 2011 See paragraphs [0009]-[0043]; claims 1-20; and figures 1-4.	1-4, 13-15
A	US 5348554 A (IMRAN et al.) 20 September 1994 See column 2, line 38-column 14, line 21; claims 1-11; and figures 1-13.	1-4, 13-15
A	US 2014-0081256 A1 (ELECTROMEDICAL ASSOCIATES LLC) 20 March 2014 See paragraphs [0017]-[0086]; claims 1-18; and figures 1-25.	1-4, 13-15
A	US 2004-0260280 A1 (SARTOR, JOE DON) 23 December 2004 See paragraphs [0010]-[0037]; claims 1-17; and figures 1A-5.	1-4, 13-15



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

25 August 2015 (25.08.2015)

Date of mailing of the international search report

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Name and mailing address of the ISA/KR

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Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 18-20
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 18- 20 pertain to methods for treatment of the human body by surgery, and thus relate to a subject matter which the International Searching Authority is not required to search, under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv).
2. ☒ Claims Nos.: 6-8
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
Claims 6-8 refer to any one of unsearchable claims which do not comply with PCT Rule 6.4(a).
3. ☒ Claims Nos.: 5, 9-12, 16-18
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of any additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

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