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(54) **MEDICAL ABLATION SYSTEM AND METHOD OF MAKING**

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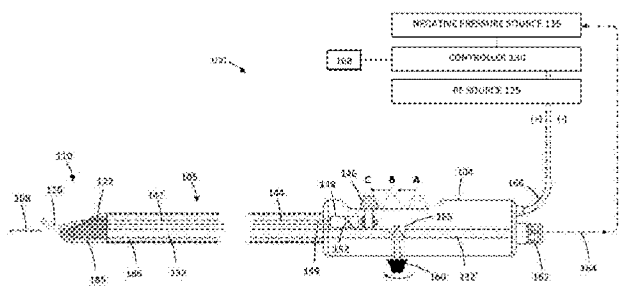
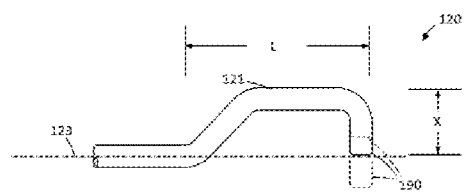
CPC .. *A61B 18/148* (2013.01); *A61B 2018/00202* (2013.01)

(57) **ABSTRACT**

An electrosurgical device comprises an elongated shaft having an axis with an interior channel extending along the axis to an opening in a distal end of the shaft. The channel is configured to be coupled to a negative pressure source, and an electrode with a conductive, usually hook-shaped, distal portion is coupled to the shaft and moveable between a first position in which a distal tip of the electrode is disposed proximate to a periphery of the opening of and a second position in which the distal electrode tip is exposed and spaced apart from the opening.





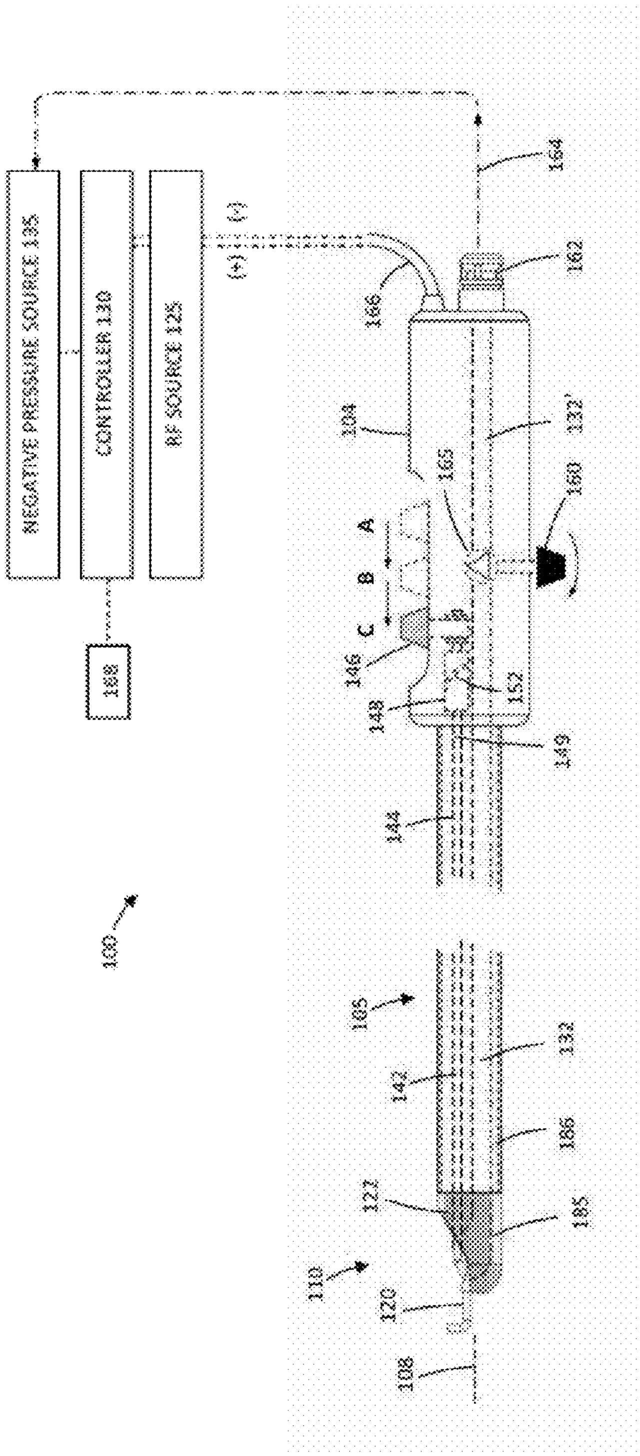

NEGATIVE PRESSURE SOURCE 135
CONTROLLER 130
RF SOURCE 125
168
164
162
166
(+)
(-)
104
132'
165
160
A
B
C
146
148
152
149
144
100
105
142
132
186
122
185
110
120
108

FIG. 1A

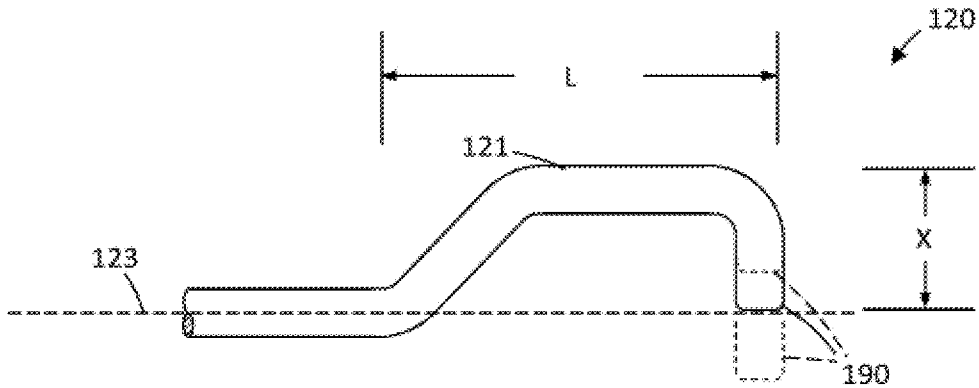


FIG. 1B

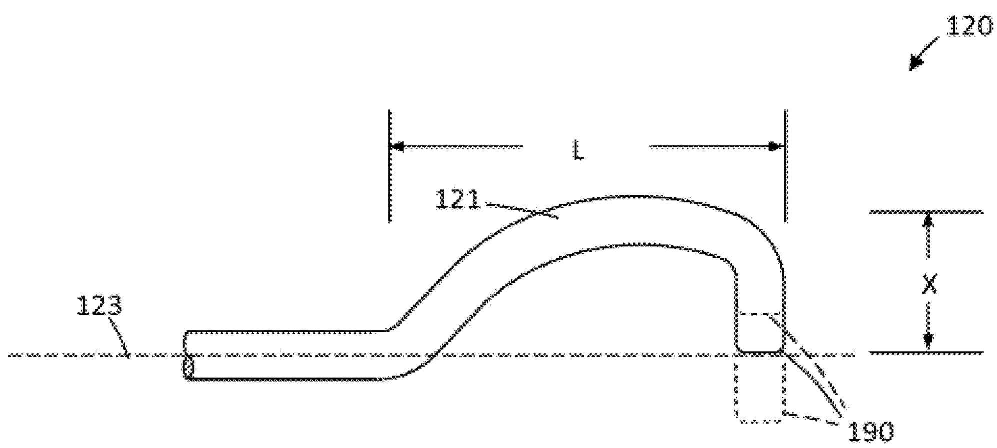


FIG. 1C

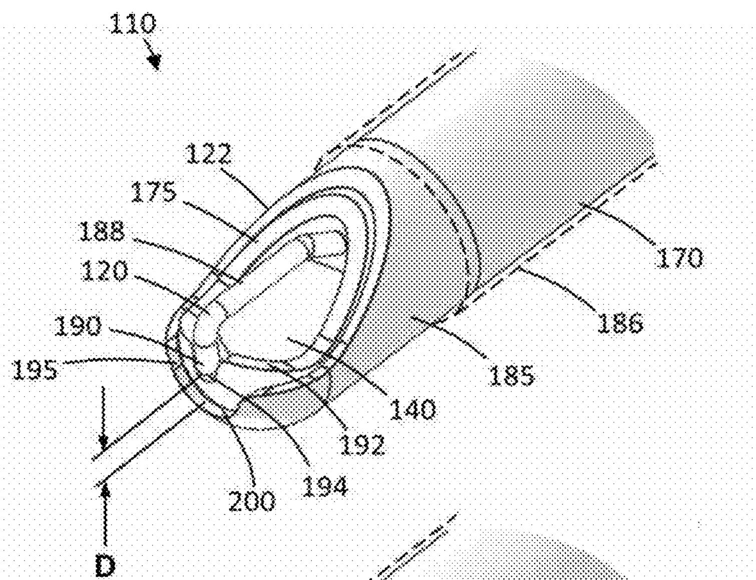


FIG. 2A

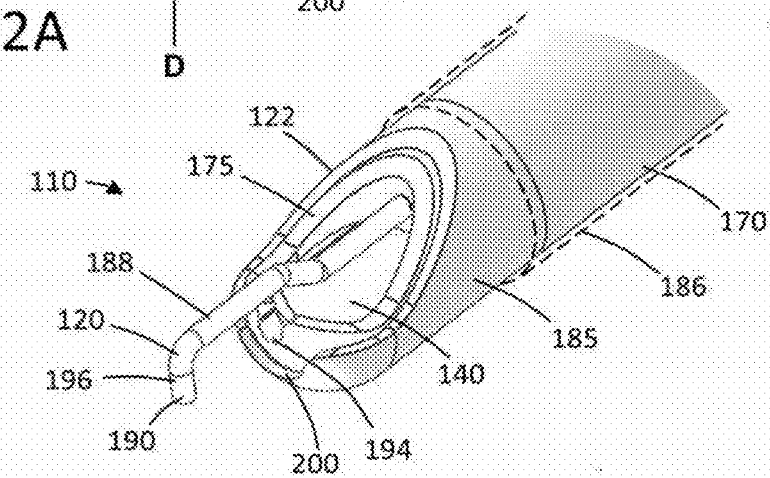


FIG. 2B

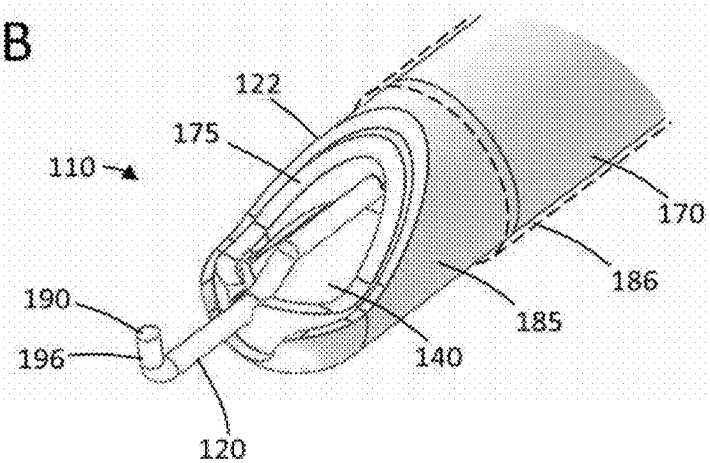


FIG. 2C

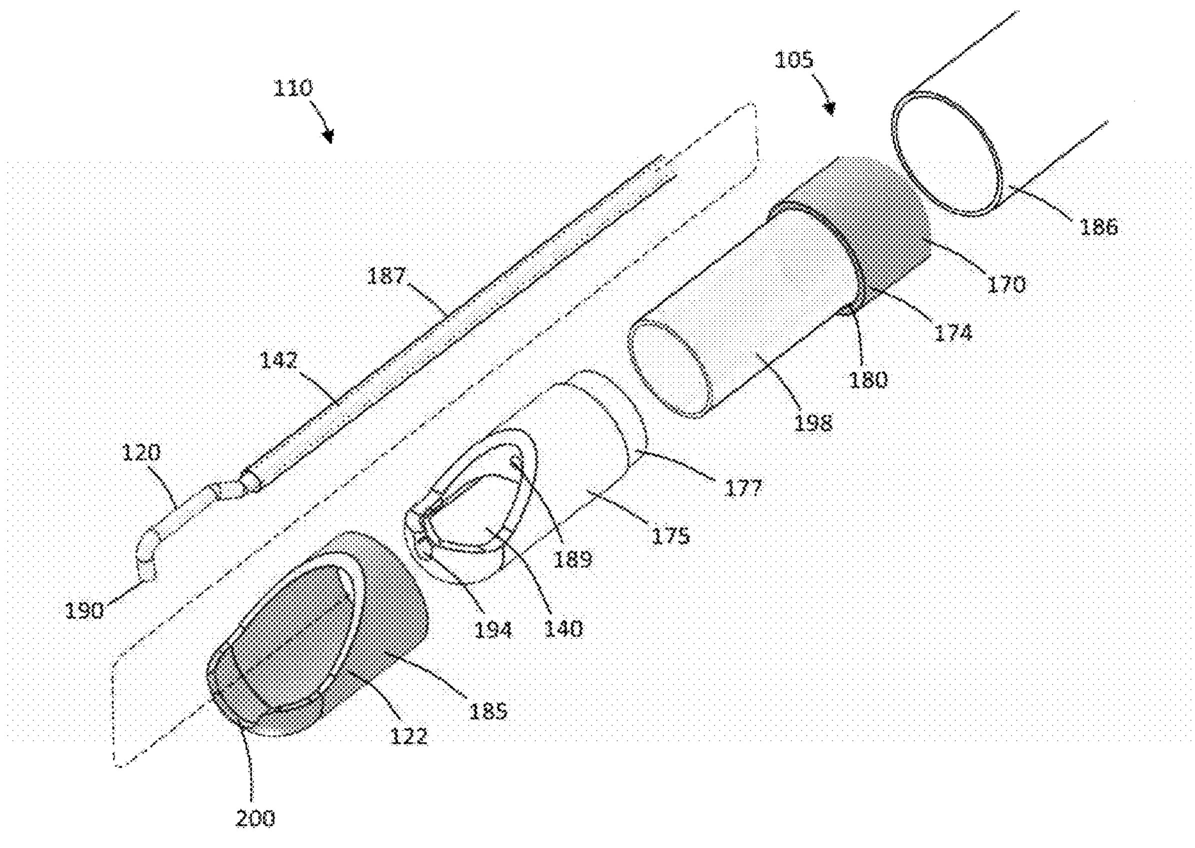

110
105
186
187
170
174
142
180
198
120
177
175
189
190
194
140
185
122
200

FIG. 3

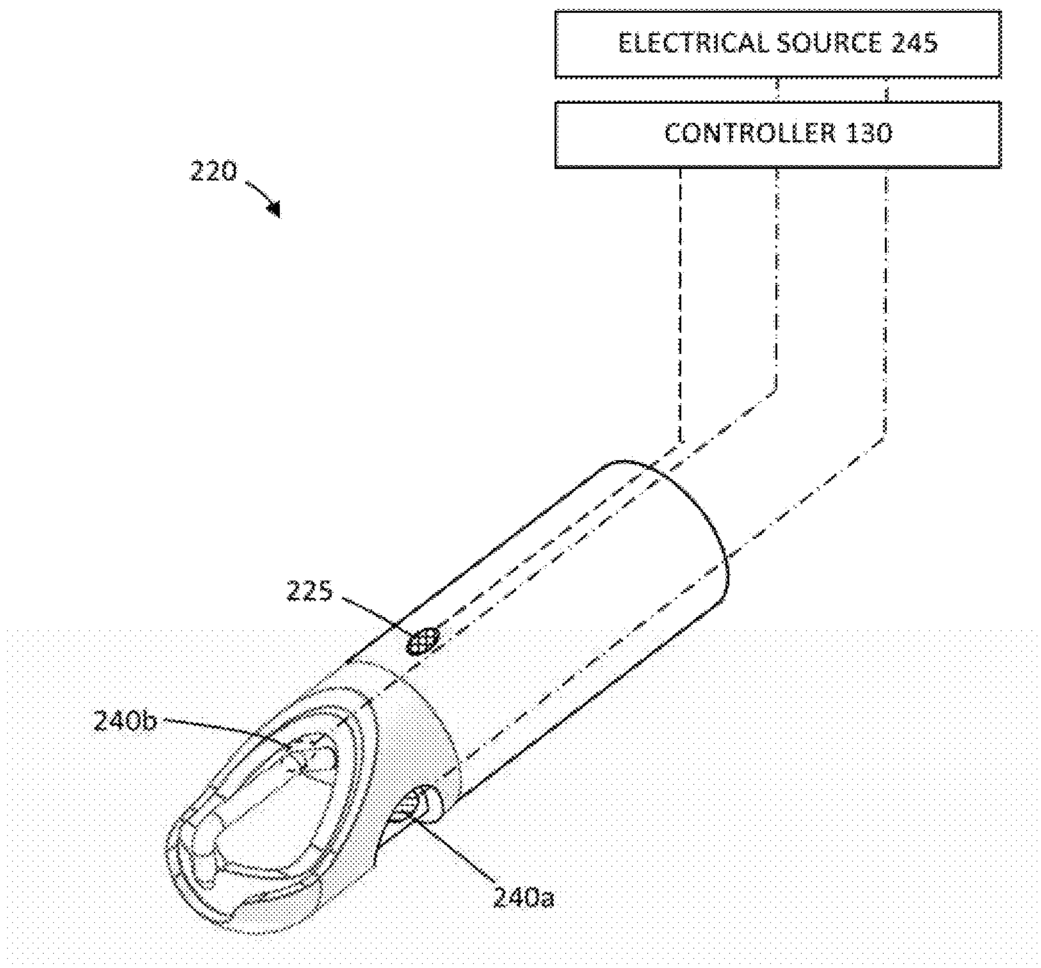


FIG. 4

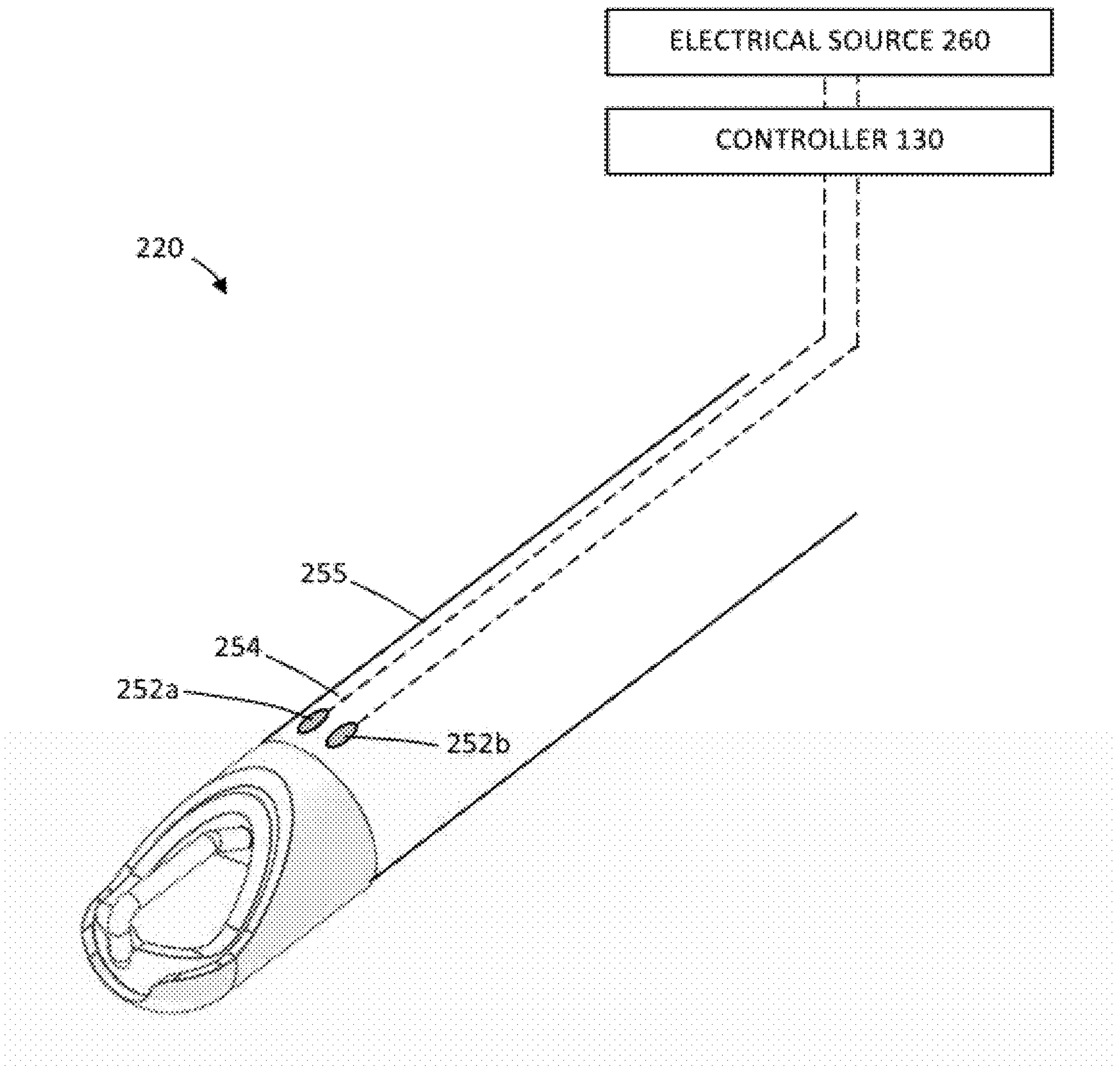


FIG. 5

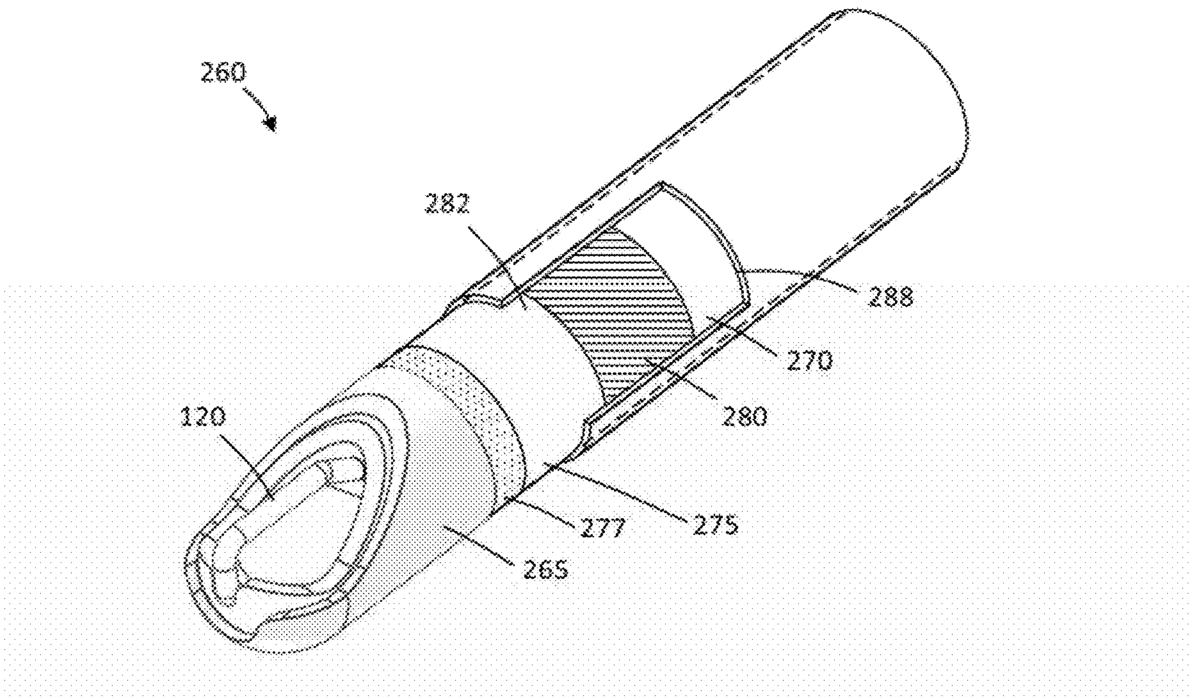

260
282
288
270
280
120
277
275
265

FIG. 6A

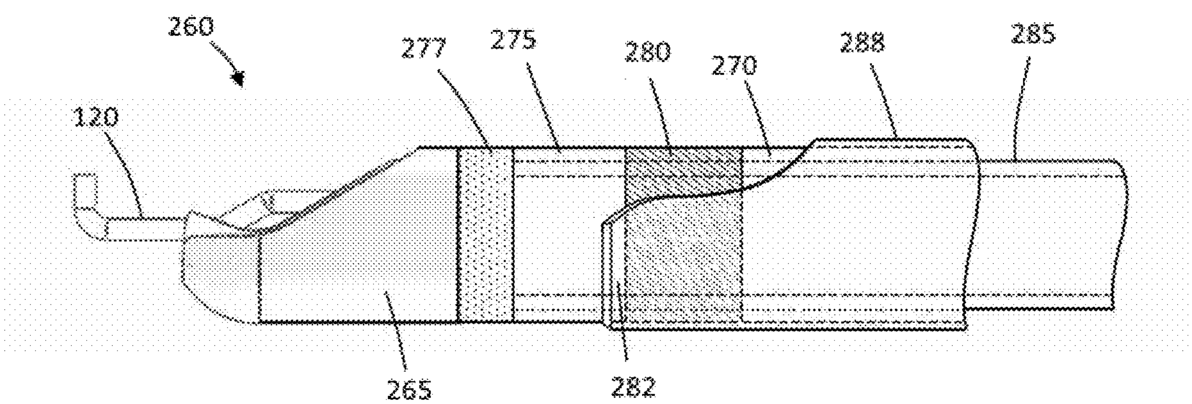

260
120
277
275
280
270
288
285
265
282

FIG. 6B

MEDICAL ABLATION SYSTEM AND METHOD OF MAKING

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. patent application Ser. No. 13/857,068 (Attorney Docket No. 37644-708.201), filed Apr. 4, 2013, now U.S. Pat. No. ______, the entire content of which is incorporated herein by reference.

FIELD OF THE INVENTION

[0002] This invention relates to medical instruments and systems for applying energy to tissue, and more particularly relates to an electrosurgical probe adapted for ablating, cutting and treating tissue in an endoscopic procedure.

BACKGROUND OF THE INVENTION

[0003] Various types of medical instruments utilizing radiofrequency (RF) energy, laser energy and the like have been developed for delivering thermal energy to tissue, for example to ablate tissue and to cut tissue. Arthroscopic and other endoscopic electrosurgical tools often comprise treatment electrodes of different configurations where the tools may optionally be combined with irrigation and/or aspiration tools for performing particular minimally invasive procedures. Often the nature of the electrode limits use of a particular tool, and tools must be exchanged during a procedure to perform different tasks. For these reasons, it would be desirable to provide new and different designs for electrosurgical tools that allow the tools to be re-configured during a procedure to perform different tasks. At least some of these objectives will be met by the inventions described below.

SUMMARY OF THE INVENTION

[0004] In a first aspect of the present invention, an electrosurgical device comprises an elongated shaft having an axis with an interior channel extending along the axis to an opening in a distal end of the shaft. The channel is configured to be coupled to a negative pressure source, and an electrode with a hook-shaped distal portion is coupled to the shaft and moveable between a first position in which a distal tip of the electrode is disposed at a periphery of the opening and a second position in which the distal tip extends distally beyond the opening. With the distal portion of the electrode in the first position, the tool is particularly useful for surface ablation of tissue such as cartilage. With the distal portion of the electrode in the second position, the tool is particularly useful for cutting tissue structures. In one application, the hook-shaped electrode can be used in a lateral release, which is an arthroscopic procedure for releasing tight capsular structures, e.g., the lateral retinaculum, on the outer or lateral aspect of the kneecap. Such a procedure is performed due to pain related to the kneecap being pulled over to the outer (lateral) side and not being able to move properly in a groove of the femur bone as the knee bends and straightens. In a second aspect of the present invention, an electrosurgical device comprises an elongated shaft extending along an axis with an interior channel extending to an opening with a periphery in a working end. The channel is adapted to be coupled to a negative pressure source. A moveable electrode having a conductive portion with a proximal end and a distal end is coupled to the shaft so that the distal end of the conductive portion is located proximate the periphery of the opening when the electrode is in a proximally retracted position and the distal end of the electrode extends distally beyond the periphery when the electrode is in a distally extended position. With the conductive portion of the electrode in the first position, the tool is particularly useful for surface ablation of tissue and cautery. With the conductive portion of the electrode in the second position, the tool is particularly useful for capturing and cutting tissue structures.

[0005] Usually, in both aspects, the electrode of the electrosurgical device is mounted to axially translate between the first and second positions. Optionally, the electrode is mounted to rotate about the axis between the first and second positions. In another variation, the electrode of the electrosurgical device of is mounted to axially translate and/or rotate about the axis between the first and second positions.

[0006] In specific embodiments, the electrosurgical device may further comprise a valve in the interior channel for controlling fluid flow therethrough. An exterior of the electrosurgical shaft may comprise a second electrode. The electrosurgical device may further comprise a rotator coupled to the electrode, where the rotator causes the electrode to rotate as it is being axially translated. The opening of the electrosurgical device may define a plane which is angled relative to the axis of the shaft, and the hook-shaped portion of the electrode may be turned so that a back of the hook portion extends outwardly above the plane when the electrode is in the first position. The electrosurgical device may still further comprise a temperature sensor and/or impedance sensing electrodes near a distal end of the shaft. Alternatively, or in addition to the sensors, the electrosurgical device may further comprise a temperature-responsive current limiting element in series with the electrode in order to inhibit or prevent overheating of distention fluid in a treatment site.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] FIG. **1**A is side view of an electrosurgical probe corresponding to the invention that includes an elongated shaft extending along an axis to a working end with a re-configurable electrode.

[0008] FIGS. **1**B and **1**C illustrate various embodiments of the re-configurable electrode of FIG. **1**.

[0009] FIG. **2**A is a perspective view of the working end of FIG. **1** with the moveable electrode in a first position.

[0010] FIG. **2**B is a perspective view of the working end of FIG. **1** with the moveable electrode in a second position.

[0011] FIG. **2**C is a perspective view of the working end of FIG. **1** with the moveable electrode in a third position.

[0012] FIG. **3** is an exploded view of the components of the working end of FIG. **1**.

[0013] FIG. **4** is a perspective view of a working end of an electrosurgical device similar to that of FIG. **1** with temperature sensor for measuring the temperature of distention fluid in a joint and a controller that can signal an LED to illuminate as a high temperature alert to the physician.

[0014] FIG. **5** is a perspective view of the working end of an electrosurgical device similar to that of FIG. **1** with a second electrode arrangement configured to measure impedance in distention fluid in a joint in order to determine the temperature of the fluid.

[0015] FIG. 6A is a cut-away perspective view of the working end of an ablation device similar to that of FIG. 1 with a PTCR (positive temperature coefficient of resistance) material in the return electrode assembly which can sense distention fluid temperature to de-activate the electrical path from the return electrode to the RF source.

[0016] FIG. 6B is another cut-away view of the working end of FIG. 7A showing an inner sleeve that carries the working end assembly.

DETAILED DESCRIPTION OF THE INVENTION

[0017] Referring now to the drawings and the reference numbers marked thereon, FIGS. 1A and 2A-2C illustrate one embodiment of electrosurgical probe 100 that includes handle portion 104 and elongated shaft 105 that extends about longitudinal axis 108. FIG. 1 is a schematic view of the probe in which the shaft 105 consists of an assembly further described below having a diameter ranging from about 3.0 mm to 6.0 mm and any suitable length for arthroscopy or another endoscopic procedure. The working end 110 carries an electrode arrangement including a moveable first polarity or active electrode 120 and a second polarity or return electrode 122 operatively coupled to an RF source 125 and controller 130. As can be seen in FIG. 1A, the shaft 105 has a fluid extraction channel 132 in communication with a negative pressure source 135 that can be a wall suction source in an operating room or a pump system in controller 130. In FIG. 2A, it can be seen that fluid channel 132 extends distally to an opening 140 in the working end 110 which is proximate the electrode 120.

[0018] In one embodiment in FIGS. 1A and 2A-2C, the first polarity electrode 120 has an elongated medial portion 142 that extends through a passageway 144 (or channel 132) in shaft 105 to an acutator mechanism 146 in the handle 104. The electrode 120 terminates in an electrically conductive portion free from insulation, with the conductive portion typically being hook-shaped as described in more detail below. In FIG. 1A, it can be seen that actuator 146 is adapted to slide from position A to position B to position C to thereby move the electrode 120 from the non-extended position of FIG. 2A to the extended position of FIG. 2B and then to the extended and rotated position of FIG. 2C. Any suitable actuator mechanism known in the art can be used to move the electrode 120 axially and rotationally, and in one variation shown in FIG. 1, a barrel 148 with a spiral groove 152 therein can translate linear motion of the actuator mechanism 146 to rotational motion. In another embodiment, the actuator 146 can be fixed to the proximal end 149 of electrode 120 and adapted to move both axially and rotationally to move the electrode 120 between the various positions shown in FIGS. 2A-2C. The moveable actuator 146 can be configured with detents that engages a portion of handle 104 to releaseably maintain the electrode 120 in one of the selected positions of FIGS. 2A-2C.

[0019] Referring again to FIG. 1A, a second actuator 160 in handle 104 is adapted to modulate outflows in fluid extraction channel 132. FIG. 1A shows the extraction channel portion 132' in handle 104 extends to a quick-connect 162 on handle 104 to which an outflow tubing 164 is coupled that extends to the negative pressure source 135. The actuator 160 can operate any type of suitable valve 165 to control the amount of outflow from a treatment site, such as a knee or shoulder. In such an arthroscopic procedure, the fluid inflows are provided through an independent inflow path which can be through a fluid channel in an endoscope or through another independent cannula accessing the treatment site.

[0020] Still referring to FIG. 1A, an electrical cable 166 extends from RF source 125 and controller 130 to the handle 104 with leads in the handle coupled to the first and second electrodes. The system can include a footswitch 168 operatively connected to controller 130 for ON-OFF actuation of RF energy to the electrode arrangement. In another variation, the switch for actuation of RF energy can be positioned in the probe handle 104. The RF source and controller can provide for various power setting as is known in the art, and can use any radiofrequency known in the art for creating a plasma about the electrode 120 for cutting tissue.

[0021] Referring to FIGS. 1B and 1C, the active electrode 120 which includes the conductive portion of the electrode extending distally from the medial portion 142 is typically hook-shaped and may have an a square or trapezoidal profile, as shown in FIG. 1B, or may have a curved or arcuate profile, as shown in FIG. 1C. The hook portion will typically have a length L in the range from 3 mm to 10 mm and a depth X in the range from 2 mm to 6 mm. The hook-shaped active electrode will also include a back or a spine region 121 that remains exposed over a plane defined by the opening 140 when the electrode is proximally retracted and a distal tip 190 of the electrode engages or lies proximate to the periphery or perimeter 192 surrounding the opening 140. The distal tip 190 may terminate at, above, or below a centerline 123 of the electrode, as shown in full line and broken lines in FIGS. 1B and 1C.

[0022] The exploded view of a portion of the probe of FIG. 3 illustrates the components and assembly of the working end 110. In one variation shown in FIG. 3, the shaft 105 includes an elongate metal sleeve 170 (e.g., stainless steel) that is coupled to handle 104 which provides structural strength to the shaft 105 and further serves an electrical conductor to function as, or connect to, the return electrode 122. The proximal end of sleeve 170 is fixed to handle 104 with an electrical connector (not shown) within the handle coupling the sleeve 170 to cable 166 and a pole of the RF source 125 (see FIG. 1).

[0023] In FIG. 3, it can be seen that the distal end 174 of sleeve 170 couples with non-conductive ceramic body 175, which can be zirconium oxide, aluminum oxide or a similar material. In one variation, a reduced diameter proximal end 177 of ceramic body 175 can mate with bore 180 in sleeve 170. FIG. 3 further shows a metal distal body or housing 185 that is configured to slide over ceramic body 175 and then is welded to the distal end 174 of sleeve 170 to thus provide the assembled working end of FIG. 2A-2C. The metal distal body or housing 185 then functions as second polarity electrode 122 as can be understood from FIG. 2A-2C. In one variation, a thin-wall dielectric material 186 such a heat shrink material (PFA, FEP or the like) covers the sleeve 170 proximally from the distal metal housing 185 to the handle 104.

[0024] In FIG. 3, it can be seen that first polarity electrode 120 and more particularly its medial portion 142 extends through a bore 189 in ceramic body 175. The elongated portion of electrode 120 is covered by a heat-shrink insulator 187 of a material such as FEP or PFA. The distal portion of electrode 120 is configured with bends or curvature to provide a hook-shaped electrode with an outermost electrode surface **188** that is approximately within an envelope defined by the cylindrical periphery of shaft **105** in the position of FIG. **2**A. This configuration permits the physician to paint the outermost surface **188** of electrode **120** across a tissue surface to perform an electrosurgical surface ablation of such tissue. Referring to FIGS. **2**A and **3**, the distal tip **190** of electrode **120** in the position shown in FIG. **2**A is configured to be disposed within or adjacent a periphery or perimeter **192** of opening **140** in the working end. More particularly, distal tip **190** in the position of FIG. **2**A is configured to rest in a notch **194** in ceramic body **175**. When the distal tip **190** is in the position of FIG. **2**A, the tip **190** is distance D of at least 0.010" (see FIG. **2**A) from the closest edge of window **195** of the metal body **185**. As can be seen in FIGS. **2**A-**2**C, the window edge **195** of metal body **185** is configured to have notch **200** that is larger than the notch **194** in ceramic body **175** to insure that the first and second electrodes, **120** and **122**, are not in close proximity in the electrode position shown in FIG. **2**A.

[0025] As can be seen in FIGS. **2**B and **2**C, the hook-shaped distal portion of electrode **120** can be extended axially and optionally rotationally to orient the distal tip **190** and terminal hook portion **196** for electrosurgical cutting of tissue as is known in the art using hook electrode tools. Thus, the electrode **120** is re-configurable to perform electrosurgical surface ablation treatments or electrosurgical cutting treatments. The electrode **120** can be a wire formed of tungsten, stainless steel or any other suitable material having a round, oval or polygonal cross section.

[0026] Referring again to FIG. **3**, in one variation, it can be seen that the bore **180** in sleeve **170** is lined with a thin-wall dielectric material **198** such a Teflon®, Nylon, PFA, FEP, polyethylene or the like which prevents the inner wall of sleeve **170** from functioning as an electrode. In another aspect of the invention, FIG. **4** illustrates a temperature sensing and signaling system that is carried within the working end **220** of a probe similar to that of FIGS. **1**-**3**. Temperature sensing of distention fluid in an arthroscopic procedure is important as the fluid can be heated during any electrosurgical ablation procedure. If the distention fluid is at an elevated temperature for an excessive time period, tissue throughout the joint can be damaged. In FIG. **4**, it can be seen a temperature sensor **225** is provided in a surface of the working end which can comprise any form of thermocouple, thermistor or other type of sensor. The sensor **225** is configured to send temperature signals to the controller **130** which can signal the operator of elevated temperature and/or terminate energy delivery from the RF source to the working end **220**. In one variation shown in FIG. **5**, the controller **130** can signal the physician of a high temperature signal from sensor **225** by illuminating LED lights **240***a* and **240***b* coupled to electrical source **245** on either side of the working end **220**. In such an embodiment, the controller **130** may have algorithms for blinking the LEDs at increasing rates that increase with temperature of the distention fluid. Any combination of visual, aural and tactile signals may be used to alert the physician of elevated temperatures in the distention fluid. In another embodiment (not shown), the temperature sensor **225** can actuate at least one light source in the controller that is coupled to optical fibers to carry light to light emitters in the working end. In another variation, a plurality of different wavelength light sources in the controller can send different wavelengths to the emitter(s) in the working end to indicate different temperatures of the distention fluid.

[0027] FIG. **5** illustrates another temperature sensing system that can be carried by the working end **220** as in FIG. **5**. In FIG. **5**, spaced apart first and second electrodes, **252***a* and **252***b* are provided in insulated surface **254** of the probe shaft **255**. The electrodes **252***a* and **252***b* are coupled to an electrical source **255** and controller **130** which is configured to measure an electrical parameter of the distention fluid, for example impedance or capacitance of a saline distention fluid. The measured electrical parameter then can be compared to known values of saline at various temperatures in a look-up table to determine fluid temperature. The calculated temperature then can actuate any visual, aural or tactile signal to alert the physician of elevated temperatures in the saline.

[0028] FIGS. **6**A-**6**B illustrate another system embodiment that integrates a temperature sensing mechanism with the return electrode to control energy delivery to tissue. As can be seen in FIG. **6**A, the working **260** of a probe is similar to that of FIGS. **1**-**3**. However, the distal metal housing **265** does not function as a return electrode. The metal housing **265** is not welded to elongated sleeve **270** which is electrically coupled to RF source **125** and controller **130**. Rather, an independent return electrode sleeve **275** with a short length is positioned proximally from the distal metal housing **265**. In one variation, an insulative ceramic collar **277** separates the distal metal housing **265** from the return electrode sleeve **275**. The temperature-sensing component of the working end **260** comprises a polymer PTCR (positive temperature coefficient of resistance) sleeve **280** forms an intermediate electrical connector between the return electrode sleeve **275** and sleeve **270** which is electrically coupled to RF source **125** (see FIG. **1**). The return electrode sleeve **275**, the PTCR sleeve **280** and sleeve **270** can be mounted over insulated support sleeve **285** shown in FIG. **6**B. The PTCR material of sleeve **280** allows conduction of RF current therethrough within a selected low temperature range, but can prevent current flow through the sleeve at a selected elevated temperature. As can be seen in FIGS. **6**A-**6**B, the proximal end **282** of the return electrode **275**, the PTCR sleeve **280** and the elongated sleeve **270** is covered with a thin-wall insulator **288** to thus prevent conductive saline contact with this portion of the probe. As can be understood in FIGS. **6**A-**6**B, the thin-wall insulator **288** allows heat transfer from the distention fluid through the insulator **288** to the PTCR sleeve **280** which then can cause the PTCR sleeve to become non-conductive to terminate current flow from the return electrode **275** to the RF source **125**. By this means, the PTCR mechanism can terminate RF energy delivery in response to elevated temperatures in the distention fluid. The PTCR material can be selected to have a any suitable switching temperature, for example any temperature between about 40° C. and 45° C. Suitable polymer PTCR materials can be fabricated by Bourns, Inc. 3910 Freedom Circle, Ste. 102, Santa Clara, Calif. 95954.

[0029] Although particular embodiments of the present invention have been described above in detail, it will be understood that this description is merely for purposes of illustration and the above description of the invention is not exhaustive. Specific features of the invention are shown in some drawings and not in others, and this is for convenience only and any feature may be combined with another in accordance with the invention. A number of variations and alternatives will be apparent to one having ordinary skills in the art. Such alternatives and variations are intended to be included within the scope of the claims. Particular features that are presented in dependent claims can be combined and fall within the scope of the invention. The invention also encompasses embodiments as if dependent claims were alternatively written in a multiple dependent claim format with reference to other independent claims.

What is claimed is:

1. An electrosurgical device, comprising:

an elongated shaft having a longitudinal axis with an interior channel extending along the axis to an opening in a distal surface of the shaft, said channel being configured to be coupled to a negative pressure source, wherein the distal surface is sloped relative to the longitudinal axis;

an electrode with a hook-shaped distal tip, said electrode being moveable between a first position in which the distal tip is positioned within the opening in the distal surface and a second position in which the distal tip is spaced distally from a distal-most edge of the opening, wherein the electrode is mounted to axially translate between the first and second positions; and

a rotator coupled to the electrode which causes the electrode to rotate as it is being axially translated.

2. The electrosurgical device of claim **1**, wherein the electrode is mounted to axially translate and/or rotate about the axis between the first and second positions.

3. The electrosurgical device of claim **1**, further comprising a valve in the interior channel for controlling fluid flow therethrough.

4. The electrosurgical device of claim **1**, wherein an exterior of the shaft comprises a second electrode.

5. The electrosurgical device of claim **1**, wherein a notch is formed in a periphery of the opening and the notch is configured to receive the hook-shaped distal tip of electrode when the electrode is in the first position.

6. The electrosurgical device of claim **1**, further comprising a temperature sensor near a distal end of the shaft.

7. The electrosurgical device of claim **1**, further comprising impedance sensing electrodes near a distal end of the shaft.

8. The electrosurgical device of claim **1**, further comprising a temperature-response current limiting element in series with the electrode.

9. An electrosurgical device, comprising:

an electrically non-conductive elongated shaft extending along a longitudinal axis;

an electrically conductive distal housing coupled to a distal end of the elongated shaft and having an opening in a distal surface thereof;

a moveable hook-shaped electrode having a conductive portion with a proximal end and a distal end, wherein the distal end of the conductive portion is disposed within the opening of the housing when the electrode is in a non-extended position and the distal end extends distally beyond the periphery when the electrode is in an extended position, wherein the electrode is mounted to axially translate between the first and second positions, wherein the hook portion the electrode is turned so that a back of the hook extends outwardly from the opening when the electrode is in the first position; and

a rotator coupled to the electrode which causes the electrode to rotate as it is being axially translated.

10. The electrosurgical device of claim **9**, wherein the electrode is mounted to rotate about the axis between the first and second positions.

11. The electrosurgical device of claim **9**, wherein the electrode is mounted to axially translate and/or rotate about the axis between the first and second positions.

12. The electrosurgical device of claim **9**, further comprising a valve in the interior channel for controlling fluid flow therethrough.

13. The electrosurgical device of claim **9**, wherein an exterior of the shaft comprises a second electrode.

14. The electrosurgical device of claim **9**, wherein a notch is formed in a periphery of the opening and the notch is configured to receive a distal tip of the hook-shaped of electrode when the electrode is in the first position and to receive a back portion of the electrode when the electrode is in its second position.

15. The electrosurgical device of claim **9**, further comprising a temperature sensor near a distal end of the shaft.

16. The electrosurgical device of claim **9**, further comprising impedance sensing electrodes near a distal end of the shaft.

17. The electrosurgical device of claim **9**, further comprising a temperature-response current limiting element in series with the electrode.

18. An electrosurgical device, comprising:

an elongated member having a central axis with an interior channel and a passage extending axially in the member, said interior channel extending to an opening in a distal surface of the member and being configured to be coupled to a negative pressure source, wherein the distal surface is sloped relative to the central axis;

an electrode having a shaft portion with a centerline and a distal spine portion with a length radially offset from said centerline, said distal spine portion extending across an axial length of the opening and said shaft portion rotatable within the passage to move the offset length of the spine portion in and out of the opening; and

a rotator coupled to the electrode shaft which causes the electrode to rotate.

19. The electrosurgical device of claim **18**, wherein the electrode shaft is mounted to axially translate in the passage.

20. The electrosurgical device of claim **18**, further comprising a actuator for controlling fluid flow through the interior channel.

21. The electrosurgical device of claim **18**, wherein an exterior of the shaft comprises a second electrode.

22. The electrosurgical device of claim **18**, wherein a notch is formed in a periphery of the opening and the notch is configured to receive a distal tip of the electrode.

23. The electrosurgical device of claim **18**, wherein the passage comprises a bore in the elongated member.

24. An electrosurgical device, comprising:

an elongated member having a central axis with an interior channel extending to an opening in a distal surface of the member and being configured to be coupled to a negative pressure source, wherein the distal surface is sloped relative to the central axis; and

an electrode having a shaft portion with a centerline and a distal spine portion with a length radially offset from said centerline, said shaft portion rotatable within the interior channel in the elongate member wherein the offset length of the spine portion can be moved laterally back and forth across the opening;

wherein the hook-shaped distal tip the electrode is configured to be turned so that a back of the hook-shaped distal tip extends laterally beyond the distal surface when the electrode is in the first position.

25. The electrosurgical device of claim **1**, wherein a notch is formed in a periphery of the opening and the notch is configured to receive a distal tip of the electrode and to allow the offset length of the spine portion to be moved laterally back and forth across the opening

* * * * *