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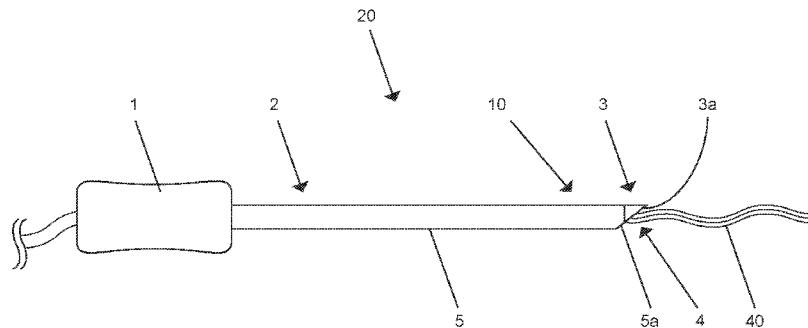


Fig. 1

(57) Abstract: A method and apparatus are disclosed for providing forward fluid delivery through an energy delivery device, while avoiding coring when energy is delivered to the energy delivery device. The device has a distal face defining an opening, with the distal face including at least one electrically exposed portion and at least one electrically insulated portion. An embodiment of the energy delivery device includes an elongate member defining a lumen structured to receive a fluid and a distal face defining an aperture in communication with the lumen, the distal face including an electrically exposed conductive portion and an electrically insulated portion, where the electrically exposed conductive portion is configured such that energy delivered by the electrically exposed conductive portion, while the energy delivery device is advanced into a tissue, punctures the tissue without the tissue substantially occluding the lumen and without creating embolic particles.

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Electrosurgical device having a distal aperture

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. provisional application No. 61/787,617, filed March 15, 5 2013, which is hereby incorporated by reference in its entirety.

TECHNICAL FIELD

[0002] The disclosure relates to methods and devices usable to deliver energy within the body of a patient. More specifically, the present invention is concerned with an electrosurgical perforation apparatus.

SUMMARY

10 [0003] Disclosed herein are embodiments of an energy delivery device providing forward fluid delivery, while avoiding coring, the device comprising a distal face defining an opening, the distal face including at least one electrically exposed portion and at least one electrically insulated portion.

15 [0004] In one broad aspect, embodiments of the present invention include an energy delivery device comprising: an elongate member defining a lumen for receiving a fluid, a distal face of the elongate member defining an aperture in communication with the lumen, the distal face including at least one electrically exposed conductive portion and at least one electrically insulated portion, the distal face being thereby configured to avoid creation of emboli upon delivery of energy via the electrically exposed conductive portion.

20 [0005] As a feature of this aspect, some embodiments include the elongate member comprising an electrically conductive tubular member at least partially covered by electrically insulating material. Other embodiments include the elongate member comprising a non-conductive material.

25 [0006] In a further broad aspect, embodiments of the present invention include a method of puncturing tissue comprising the steps of: (a) delivering energy through a first portion of a distal face of an energy delivery device to tissue at a target site to create a puncture through the tissue, while preventing delivery of energy from a second portion of the distal face; and (b) advancing the energy delivery device through the tissue by pushing aside a flap of tissue defined by the puncture.

[0007] Another broad aspect of the invention is for an energy delivery device comprising: an electrically conductive tubular member at least partially covered by electrically insulating material, the

tubular member defining a lumen for receiving a fluid, a distal face of the tubular member defining an aperture in communication with the lumen, and the distal face including at least one electrically exposed conductive portion and at least one electrically insulated portion, whereby energy delivered to a tissue via the at least one electrically exposed conductive portion results in a puncture having a shape substantially corresponding to a shape of the electrically conductive portion of the distal face.

[0008] In another broad aspect, embodiments of the invention are for an energy delivery device comprising: an elongate member defining a lumen for receiving a fluid, a beveled distal face of the elongate member defining an aperture in communication with the lumen and the beveled distal face including at least one electrically exposed conductive portion and at least one electrically insulated portion.

[0009] In yet another broad aspect embodiments of the invention are for an energy delivery device comprising: an elongate member defining a lumen for receiving a fluid; and a distal face defining an aperture in communication with the lumen, the distal face including at least one electrically exposed conductive portion and at least one electrically insulated portion; the distal face being configured to puncture through a tissue at a target site upon delivery of energy via the electrically exposed conductive portion substantially without coring tissue from the target site.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] In order that the invention may be readily understood, embodiments of the invention are illustrated by way of examples in the accompanying drawings, in which:

[0011] Fig. 1 is an illustration of an embodiment of a device including a handle and shaft;

[0012] Fig. 2 is an illustration of an electrically conductive tubular member with an angled front face;

[0013] Figs. 3a-c are illustrations of an embodiment of a device with an electrically conductive tubular member and insulation;

[0014] Fig. 4 is an illustration of an alternative embodiment in which an electrically conductive tubular member is comprised of proximal and distal components;

[0015] Figs. 5a to 5c are illustrations of another alternative embodiment in which an electrically conductive tubular member receives a non-conductive insert and insulation;

[0016] Fig. 6 is an illustration of an embodiment of a device with a non-conductive elongate member;

[0017] Figs. 7a and 7b are illustrations of an embodiment of a method of puncturing tissue within a heart;

[0018] Fig. 8 is an embodiment of a handle; and

[0019] Fig. 9a and 9b illustrates examples of embedded markers.

DETAILED DESCRIPTION

[0020] Devices used for puncturing tissue, for example transseptal tissue of a patient's heart, are typically either mechanical or electrosurgical in nature. Some electrosurgical devices incorporate side-ports and do not have a forward facing lumen aperture, and consequently lack the ability, for example, to effectively inject fluid or monitor fluid pressure when confined inside of a close-fitting dilator lumen. In addition, while it is possible in some cases for a guide-wire to be passed through or to be received by a side-port, in general, devices lacking a forward facing aperture do not facilitate the use of a guide-wire with the device. In contrast, devices with a forward facing aperture typically are more effective in injecting fluid, monitoring pressure, and facilitate usage of a guide-wire.

[0021] A conventional Brockenbrough transseptal needle with a sharp beveled tip has a forward facing aperture that may be used for injecting fluid or monitoring pressure. However, conventional transseptal needles typically utilize mechanical force to puncture tissue, which is not effective at puncturing tissue under certain circumstances. To meet the challenge of puncturing through a tissue that does not facilitate being mechanically punctured, physicians have proposed using an electrocautery generator or the like to electrify the mechanical needle and to thereby produce an ad hoc electrosurgical device with a forward facing aperture. One drawback to electrifying a Brockenbrough needle is the risk of tissue coring. A core (or plug) of tissue is typically cut from surrounding tissue upon delivery of energy and is subsequently captured in the lumen of the electrosurgical device upon advancement of the needle through tissue. The tissue core may be released from the lumen by flushing, potentially leading to emboli and increasing the risk of a stroke or some other ischemic event. Furthermore, a non-insulated and electrified Brockenbrough needle bears an additional increased risk of burns to the patient and physician.

[0022] This disclosure includes different embodiments of a device that has a forward facing lumen aperture to provide for pressure monitoring, forward fluid delivery, being used with a guide-wire, and that is configured to reduce the risks of tissue coring and emboli formation.

[0023] In particular, the described embodiments are configured such that an electrode used for puncturing tissue does not completely encircle or enclose a forward facing lumen aperture, thereby avoiding having a ring-shaped electrode that may possibly core tissue. Ring-shaped electrodes are typically circular, but non-circular ringed electrodes (e.g. square-shaped, elliptical-shaped) are also possible. For explanatory purposes, this disclosure generally describes ring-shaped electrodes as being circular. Furthermore, while this disclosure describes electrosurgical devices that are generally circular in cross-

section, the concepts and claims of this disclosure also apply to non-circular devices. Some embodiments comprise a device having a metallic tube that is operable to deliver energy in which a portion of the tube's distal (forward facing) face or surface is insulated to thereby interrupt the creation of a ring-shaped electrode such that the electrode only partially encircles the forward facing lumen aperture (or front opening). In some embodiments, the distal surface of the electrode (the cutting surface) is situated to be substantially lateral to the front opening, such that the electrode does not encircle the front opening. In typical embodiments, the outer perimeter of the electrode defines a portion, but not all, of the outer perimeter of the distal face of the disclosed energy device, whereby the device creates a puncture corresponding with a portion (but not all) of the outer perimeter of the distal face with the puncture defining a flap of tissue which the beveled distal face pushes aside when the device is advanced. In some embodiments, the distal surface of the electrode defines a shape selected from the group consisting of generally C-shaped shapes and generally semicircular shapes.

[0024] Thus, the present inventors have conceived and reduced to practice a needle for puncturing tissue, such as an atrial septum of a heart, where the needle allows for forward fluid delivery for staining the septum and has less risk of coring tissue relative to an electrified Brockenbrough needle. The device comprises a distal face defining an opening with the distal face including an electrically exposed portion and an electrically insulated portion extending radially from the opening to the periphery of the distal face. Typical embodiments can be advanced over a guide-wire to a treatment site.

[0025] With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of certain embodiments of the present invention only. Before explaining embodiments of the invention in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of the components set forth in the following description or illustrated in the drawings. The invention is capable of other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

[0026] Fig. 1 is an illustration of an embodiment of a device including a handle and shaft. Fig. 1 includes energy delivery device 20 which is comprised of elongate member 2, electrically insulating material 5 and distal portion 10. The handle 1 is mechanically coupled to the proximal end of the elongate member 2. Elongate member 2 defines a lumen (Fig. 4). Distal portion 10 includes electrode 3 and distal face 4 (further described herein below) which defines an aperture. The embodiment is operable to direct a fluid forward, as represented by fluid flow lines 40, and facilitates being used with a guide-wire.

[0027] In some embodiments, elongate member 2 has a length of about 30 cm to about 100 cm to facilitate the puncture of a septum of a heart. In some embodiments, the elongate member has an outer diameter of about 0.40 mm to about 1.5 mm to minimize hemodynamic stability, for example, by ensuring that the perforation will not cause hemodynamic instability once energy delivery device 20 is removed. In 5 some embodiments, the energy delivery device 20 is a stiff elongate needle.

[0028] Some embodiments of energy delivery device 20 include an elongate member 2 having flexural rigidity of at least about 0.016 Nm², for example a flexural rigidity of about 0.017 Nm², to provide tactile feedback for a user of the device.

[0029] Some embodiments of the device have markers for highlighting the location of important 10 landmarks on energy delivery device 20. Such landmarks may include the location where the elongated member 2 begins to curve, the location of the electrode 3, or the location of the proximal edge a beveled distal face. In some embodiments the marker is radiopaque. Fig. 9a and 9b illustrates examples of markers 6 embedded in the sidewall of elongate member 2. Fig. 9a is an example of an embodiment in which a marker 6 is embedded in the inside surface of the sidewall of elongate member 2 whereby fluid can flow 15 through lumen 9 without being obstructed and the outer diameter of elongate member 2 is not increased. Marker 6 can be embedded in the inside sidewall using different techniques, such as overmoulding. Fig. 9b is an example of an embodiment in which a marker 6 is embedded in the outside sidewall of elongate member 2 whereby fluid can flow through lumen 9 without being obstructed and the outer diameter of elongate member 2 is not increased. Imaging marker 6 can be different shapes including, but not limited to, 20 a ring-shaped hollow band or a coil. Alternative embodiments include imaging markers that are disc-shaped, rectangular, and elongate, that define other geometric shapes, or that define symbols.

[0030] For the embodiments of Figs. 9a and 9b, elongate member 2 can be comprised of one or more layers/components of plastic, other polymers, metal, or other materials. The marker is embedded in a 25 sidewall which may be either all metal or substantially (mostly) metal. For example, the marker receiving sidewall can be covered with a relatively thin layer of polymer, such as the sidewall of Fig. 9b being covered with a layer of electrical insulation. As all metals are radiopaque to some degree, a radiopaque marker should be more radiopaque than the metal tube to function properly. In general, for any embodiment of the device having a radiopaque marker, the radiopaque marker may be comprised of a material that is more radiopaque than whatever material elongate member 2 is comprised of. In Figs. 9a and 9b, the distal end of lumen 9 is open. Embodiments of Figs. 9a and 9b having a metal shaft can 30 optionally have a layer of electrically insulating material 5 (not shown in Fig. 9).

[0031] While the embodiment of Fig. 1 has a generally straight elongate member 2, in alternative embodiments, the elongate member comprises a curved section. In some examples, the curved section has a

curve length of from about 10 to about 25 cm and traverses from about 20° to about 40° of a circle. In some other examples, the curved section has a curve length of from about 4 to about 7 cm and traverses from about 70 degrees to about 110 degrees of a circle.

[0032] Fig. 8 illustrates an exemplary handle 1. Handle 1 comprises connector 502 for receiving an electrical plug or other electrical connector, and fluid port 505 for receiving a second connector, for example, a luer lock. Electrical energy may be delivered from an energy source, through a connector 502 and, typically, a wire (not shown in the drawing) located within handle 1. The electrical energy is then conveyed to the elongate member 2 and electrode 3.

[0033] In the embodiment of Fig. 8, the handle 1 includes a relatively large graspable surface having ridges 512 so that tactile feedback can be transmitted relatively efficiently, for example by transmitting vibrations.

[0034] The embodiment of Fig. 8 further comprises an orientation indicator 510 located on one side of the handle, in particular, on the side of the part of the handle housing fluid port 505. Orientation indicator 510 indicates the direction of the curve of the curved section of elongate member 2. The direction of the curve is also indicated by flange 514. In alternative embodiments, orientation indicators comprise inks, etching, or other materials that enhance visualization or tactile sensation.

[0035] In some embodiments, a tubing is operatively coupled at one end thereof to a source of fluid (not shown in drawing), for example a syringe, pump, intravenous fluid bag, etc., and the other end of the tubing is operatively coupled with a connector to fluid port 505 (of handle 1) which is in fluid communication with lumen 9 of elongate member 2 via a conduit in the handle (not shown), whereby the tubing and lumen 9 are in fluid communication with one another, thus allowing for a flow of fluid between an external device and lumen 9.

[0036] In some embodiments, aperture 7 and the lumen 9 (Figs. 4) together provide a pressure transmitting lumen which is coupled to the external tubing by a connector, and the tubing is in fluid communication with a pressure sensing device, for example a pressure transducer.

[0037] Referring now to Figure 2, Fig. 2 is an illustration of an embodiment of an electrosurgical device initially lacking electrical insulation over its distal face. The device includes an electrically conductive tubular member 12 with an angled or beveled front face (distal face 4). As previously described, the distal (or front) surface of a device configured as illustrated in Fig. 2 may function as a ring-shaped electrode when advanced through tissue while delivering electrical energy, thereby coring out a plug of tissue having a circumference defined by aperture 7. Configuring a portion of the distal surface to be non-conductive may reduce or eliminate the risk of coring tissue, as described further hereinbelow.

[0038] Figs. 3a to 3c illustrate the distal portion of an embodiment of an energy delivery device 20 having an electrically conductive tubular member. Energy delivery device 20 comprises an elongate member 2 which defines a lumen 9 for receiving a fluid and a distal face 4 which defines an aperture 7 in communication with the lumen. The fluid within the lumen may be injected, withdrawn, or may remain substantially stationary. The electrically conductive tubular member is at least partially covered by electrically insulating material 5 with a distal portion of the electrically conductive tubular member uncovered (i.e. electrically exposed) to define electrode 3. In some embodiments, the electrically conductive tubular member is comprised of stainless steel.

[0039] In the embodiment of Fig. 3, distal face 4 is beveled and is comprised of an electrically exposed conductive portion 3a and an electrically insulated portion 5a. The electrically exposed conductive portion 3a is comprised of the distal surface of electrode 3 which, in this embodiment, is generally C-shaped when viewing the distal face head-on. The electrically exposed conductive portion 3a does not completely encircle, circumscribe or enclose aperture 7 but rather partially surrounds the aperture. A distal portion of the distal face 4 comprises a distal surface of electrode 3 (i.e. the beveled face is not truncated).

[0040] The proximal portion of distal face 4 is comprised of electrically insulated portion 5a. Electrically insulated portion 5a extends radially from a wall of the aperture 7 to a periphery 45 of distal face 4 (i.e. extending from the center outwardly or from the circumference inwardly). In some embodiments, the electrically insulated portion of distal face 4 is comprised of polymer insulation, which may be a heat shrink, a spray coating, or a material selectively coated by vapor deposition. In some alternative embodiments, electrically insulated portion 5a comprises a ceramic. In some embodiments, the distal face of the electrically conductive tubular member has a step recess wherein a layer of insulation is received to thereby provide for a planar distal face 4 (i.e. to avoid having a stepped surface).

[0041] The electrically exposed conductive portion 3a is configured such that, when the energy delivery device is advanced into a tissue, energy delivered by the electrically exposed conductive portion 3a punctures the tissue without the tissue substantially occluding lumen 9. In particular, it is the leading surface of electrode 3 that defines the cutting surface of the electrode (i.e. electrically exposed conductive portion 3a) which actually cuts into tissue when the energy delivery device is advanced while delivering energy. Electrically exposed conductive portion 3a does not completely encircle the forward facing lumen aperture 7, thereby avoiding having a ring-shaped (i.e. closed-loop, when viewed head-on) electrode that could core tissue. Electrically insulated portion 5a interrupts the distal surface of electrically conductive tubular member 12 to prevent the formation of a ring-shaped electrode such that the cutting surface of the electrode only partially encircles aperture 7. The outer perimeter of the distal surface of electrode 3 defines a portion (but not all) of the perimeter of distal face 4, whereby the device creates a puncture corresponding

with a portion (but not all) of the perimeter of the distal face, such that the puncture defines a flap of tissue which the beveled distal face pushes aside as the device is advanced.

[0042] The embodiment of energy delivery device 20 of Fig. 3 includes a distal tip 46 which is substantially rounded or atraumatic, as it is not necessary to have a sharp tip on the device for puncturing.

5 The rounded tip reduces the risk of accidental tissue puncture and skiving of supporting dilators. In other words, the distal portion of the distal face is substantially rounded. In some alternative embodiments, the tip of the device is sharp. Furthermore, the planar surface of distal face 4 is substantially atraumatic.

[0043] Fig. 4 illustrates another embodiment of an energy delivery device 20 having an electrically conductive tubular member. The embodiment of Fig. 4 includes the electrically conductive tubular member being comprised of two parts, a proximal electrically conductive tubular member 12a, and a distal electrically conductive tubular member 12b which fits into the proximal tubular member. The two tubular members are joined together in any suitable manner, for example welding, soldering, friction fitting, or the use of adhesives.

[0044] This embodiment also includes electrically insulating material 5 extending to the end of the outer surface of distal electrically conductive tubular member 12b to help minimize electrical leakage. Electrically insulating material 5 extends to cover a portion on the distal end surface of electrically conductive tubular member 12b to define electrically insulated portion 5a of distal face 4 (seen in the bottom of the drawing). In some alternative embodiments, electrically insulated portion 5a is comprised of a different material than the insulating material 5 which covers the sidewalls of electrically conductive tubular members 12a and 12b.

[0045] Similar to the embodiment of Fig. 3, the embodiment of Fig. 4 has an electrically exposed conductive portion 3a which is generally C-shaped. The embodiment of Fig. 4 functions in substantially the same manner as the embodiment of Fig. 3. Details of a similar tube-in-tube configuration are disclosed in co-pending application U.S. application Ser. No. 13/468,939, filed May 10, 2012, incorporated herein by reference in its entirety.

[0046] Figs. 5a to 5c illustrate another embodiment of energy delivery device 20 with an electrically conductive tubular member. The energy delivery device of Fig 5 includes a recess cut away from the end of electrically conductive tubular member 12 for receiving non-conductive insert 44. Typically, non-conductive insert 44 is a polymer. In some embodiments, non-conductive insert 44 is a stiff plastic, and in some particular embodiments is re-flowed FEP (Fluorinated ethylene propylene). Fig. 5c, which is a rotated side-view, illustrates the device with electrically insulating material 5 partially cut away and shows how electrically conductive tubular member 12 receives non-conductive insert 44.

[0047] Fig. 5b is a cut-away side-view illustrating that electrode 3 extends from electrically conductive tubular member 12. The side-view of Fig. 5a and Fig. 5b show that electrode 3 is an electrically exposed portion of tubular member 12 i.e. the electrode is continuous with conductive tubular member 12 and is not covered by electrically insulating material 5.

5 **[0048]** The end view of Fig. 5a shows the non-conductive insert 44 located between a layer of electrically insulating material 5 and electrode 3. Figs. 5b and 5c show that non-conductive insert 44 fits into the recess in electrically conductive tubular member 12, and that insulating material 5 encloses both conductive insert 44 and electrically conductive tubular member 12.

10 **[0049]** As seen in the Fig. 5a end-view, the electrically insulated portion 5a of distal face 4 is comprised of the end surfaces of both electrically insulating material 5 and non-conductive insert 44. Electrically exposed conductive portion 3a is comprised of the distal surface of electrode 3. The end views of Fig. 5 show that electrically exposed conductive portion 3a is substantially semi-circular in shape and that electrically insulated portion 5a extends radially from aperture 7 to the periphery 45 of the distal face 4. Electrically exposed conductive portion 3a does not fully or partially encircle aperture 7, but instead is 15 lateral to aperture 7, and consequently does not form a ring-shaped electrode capable of coring out tissue.

[0050] Fig. 6 illustrates an embodiment of energy delivery device 20 having a non-conductive elongate member 2. Electrode 3 is attached to the end of the elongate member. Typically, a non-conductive elongate member 2 is comprised of polymer.

20 **[0051]** The embodiment of Fig. 6 has a beveled distal face 4. The electrically exposed conductive portion 3a of distal face 4 comprises a distal surface of electrode 3 and is generally crescent-shaped. Wire 11 is connected to electrode 3 for delivering energy thereto. In typical embodiments, wire 11 is contained in a lumen of appropriate size. Alternatively, wire 11 is embedded in a wall of the non-conductive elongate member 2.

25 **[0052]** In the illustrated embodiment, the electrically insulated portion 5a is located at a proximal portion of distal face 4 and is comprised of the distal surface of the non-conductive elongate member 2. When the embodiment of Fig. 6 is viewed from the end, electrically insulated portion 5a encircles aperture 7, and electrically exposed conductive portion 3a does not encircle the aperture, but instead is lateral to the aperture, and consequently does not form a ring-shaped electrode capable of coring tissue.

30 **[0053]** Figs. 7a and 7b illustrate an embodiment of a method of puncturing tissue. The method comprises the steps of (a) delivering energy through electrically exposed conductive portion 3a of energy delivery device 20 to tissue 41 at a target site for creating a puncture substantially corresponding to a distal

surface of the electrically exposed conductive portion; and (b) dilating the puncture primarily by advancing an angled distal surface of the energy delivery device, without coring the tissue. In some embodiments the step of delivering energy comprises creating a flap in the tissue and the step of dilating is completed without further delivery of energy. In some embodiments, the target site is a tissue within a heart, and in 5 some particular embodiments the tissue is an atrial septum 32. Typically, the method uses a sheath, such as, for example, sheath 30 of Fig. 7a.

[0054] An alternative embodiment of a method of puncturing tissue comprises the steps of (a) delivering energy through a first portion of a distal face of an energy delivery device to tissue at a target site to create a puncture through the tissue, while preventing delivery of energy from a second portion of 10 the distal face; and (b) advancing the energy delivery device through the tissue by pushing aside a flap of tissue defined by the puncture. The step of delivering energy comprises creating a slit in the tissue.

[0055] Dilating the puncture typically includes displacing the tissue. In some embodiments dilation includes wedging apart and thereby outwardly compressing surrounding portions of the tissue.

[0056] Some embodiments of the method include using a medical imaging modality to guide the energy 15 delivery device 20 to the target site. Some embodiments comprise measuring pressure for positioning energy delivery device at the target site. In some embodiments, the method includes using a radiopaque marker 6 for positioning energy delivery device 20. Some embodiments include advancing the energy delivery device to the target site over a guide-wire.

[0057] In some embodiments, the method includes advancing energy delivery device 20 to the target 20 site through a dilator 28; positioning energy delivery device 20 such that electrically exposed conductive portion 3a is aligned with or protruding slightly from a distal end of the dilator 28; and delivering fluid through an aperture (e.g. Fig. 3) at a distal end of energy delivery device 20 to stain the tissue. The fluid is typically delivered longitudinally forward through the energy delivery device. Some embodiments further comprise a step of withdrawing a fluid via an open distal face of the energy delivery device.

[0058] In some embodiments, the distal surface of the electrically exposed conductive portion 3a is generally C-shaped and step (b) includes creating a generally C-shaped puncture. In some other 25 embodiments, the distal surface of the electrically exposed conductive portion is generally crescent-shaped and step (b) includes creating a generally crescent-shaped puncture.

[0059] In some embodiments of the broad aspect, the aperture 7 and the lumen 9 together comprise a 30 pressure transmitting lumen, and the method further comprises measuring a fluid pressure of the pressure transmitting lumen using a pressure sensing mechanism.

[0060] In an RF perforation or puncturing procedure, unlike RF ablation, energy is applied to rapidly increase tissue temperature to the extent that the intracellular fluid becomes converted to steam, inducing cell lysis as a result of elevated pressure within the cell. Upon the occurrence of cell lysis and rupture, a void is created, allowing the tip of the catheter to penetrate the tissue. In order to achieve this effect, RF 5 perforation devices must apply a high voltage to the tissue region over a short period of time. Also, the tip of the device being used should be relatively small, in order to increase the impedance of the device. This is in contrast to RF ablation, whereby a larger-tipped device is utilized to deliver a low impedance and high power signal to the region involved. Furthermore, as opposed to RF perforation, which creates a void in the tissue through which the device may be advanced, the objective of RF ablation is to create a large, non- 10 penetrating lesion in the tissue, in order to disrupt electrical conduction. Thus, for the purposes of the present invention, perforation is defined as the creation of a void within a material.

[0061] Embodiments of the present invention are operable to create such punctures or voids without substantially removing a plug or core of material from the tissue at the target site, since the puncture resulting from devices as described hereinabove are typically slit-like, C-shaped, or similar configurations 15 corresponding to the shape(s) of the electrically exposed and conductive portion of the distal face.

[0062] Energy delivery device 20 may be used in conjunction with a source of radiofrequency energy suitable for perforating material within a patient's body. The source of energy may be a radiofrequency (RF) electrical generator, operable in the range of about 100 kHz to about 1000 kHz, and designed to generate a high voltage over a short period of time. More specifically, in some embodiments, the voltage 20 generated by the generator increases from about 0 V (peak-to-peak) to greater than about 75 V (peak-to-peak) in less than about 0.6 seconds. The maximum voltage generated by generator may be between about 180V peak-to-peak and about 3000V peak-to-peak. The waveform generated may vary, and may include, for example, a sine-wave, a rectangular-wave, or a pulsed rectangular wave, amongst others. During delivery of radiofrequency energy, the impedance load may increase due to tissue lesioning near the target- 25 site, or the formation of a vapor layer following cell rupture, for example. The generator may be operable to continue to increase the voltage, even as the impedance load increases. For example, energy may be delivered to a tissue within a body at a voltage that rapidly increases from about 0 V (RMS) to about 220 V (RMS) for a period of between about 0.5 seconds and about 5 seconds.

[0063] Without being limited to a particular theory of operation, it is believed that under particular 30 circumstances, for example as mentioned hereinabove, dielectric breakdown and arcing may occur upon the delivery of radiofrequency energy, whereby polar molecules may be pulled apart. The combination of these factors may result in the creation of an insulative vapor layer around the electrode, therein resulting in an increase in impedance, for example the impedance may increase to greater than 4000 Ω . In some

embodiments, despite this high impedance, the voltage continues to increase. Further increasing the voltage increases the intensity of fulguration, which may be desirable as it allows for an increased perforation rate and puncture creation. An example of an appropriate generator for this application is the BMC RF Perforation Generator (model number RFP-100A, Baylis Medical Company, Montreal, Canada). This 5 generator delivers continuous RF energy at about 460 kHz.

[0064] A grounding pad or dispersive electrode may be electrically coupled to the generator for contacting or attaching to the body of the patient to provide a return path for the RF energy when the generator is operated in a monopolar mode.

[0065] Additional details regarding the device and method may be found in U.S. application Ser. No. 10 13/468,939, filed May 10, 2012, U.S. application Ser. No. 11/905,447, filed Oct. 1, 2007 (now issued as U.S. patent 8,192,425), U.S. application Ser. No. 13/113,326, filed May 23, 2007, U.S. application Ser. No. 11/265,304, filed Nov. 3, 2005 (now U.S. patent 7,947,040), U.S. application Ser. No. 10/666,301, filed Sep. 19, 2003 (now issued as U.S. patent 7,048,733), U.S. application Ser. No. 10/760,479, filed Jan. 21, 2004 (now issued as U.S. patent 7,270,662), U.S. application Ser. No. 10/666,288, filed Sep. 19, 2003, 15 U.S. application Ser. No. 10/347,366, filed Jan. 21, 2003 (now issued as U.S. patent 7,112,197), U.S. provisional application Ser. No. 60/522,753, filed Nov. 3, 2004, and provisional applications Ser. No. 60/884,285, filed Jan. 10, 2007, 60/827,452, filed Sep. 29, 2006, Ser. No. 61/653967, filed May 31, 2012, and Ser. No. 61/681,512, filed Aug. 9, 2012. The contents of all above-named applications and patents are incorporated herein by reference in their entirety.

20 **[0066]** Thus, the problem of puncturing tissue without coring, while providing forward fluid delivery, is solved by an energy delivery device having a distal face defining an opening, with the distal face including at least one electrically exposed portion and at least one electrically insulated portion.

Example 1:

[0067] Embodiments having the configuration of Fig. 3 were tested and found to puncture tissue 25 substantially without coring. Electrified Brockenbrough needles were also tested, and found to core tissue when puncturing. The testing revealed that Fig. 3 embodiments cut C-shaped punctures that correspond to the shape of the electrode when viewed from the end, resulting in a flap of skin that is displaced sideways by the proximal portion of distal face 4 when energy delivery device 20 is advanced, whereby the C-shaped puncture is dilated.

30 **[0068]** The embodiments of the invention described above are intended to be exemplary only. The scope of the invention is therefore intended to be limited solely by the scope of the appended claims.

[0069] It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination.

5 **[0070]** Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the broad scope of the appended claims. All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent
10 as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention.

CLAIMS

1. An energy delivery device comprising:

an elongate member defining a lumen for receiving a fluid,

a distal face of the elongate member defining an aperture in communication with the lumen,

5 the distal face including at least one electrically exposed conductive portion and at least one electrically insulated portion,

the distal face being thereby configured to avoid creation of emboli upon delivery of energy via the electrically exposed conductive portion.

2. The energy delivery device of claim 1, wherein the electrically exposed conductive portion partially surrounds the aperture.

10 3. The energy delivery device of claim 2, wherein the electrically insulated portion extends radially from a wall of the aperture to a periphery of the distal face.

4. The energy delivery device of any one of claims 1-3, wherein the elongate member comprises an electrically conductive tubular member at least partially covered by electrically insulating material.

15 5. The energy delivery device of claim 3, wherein the electrically insulated portion of the distal face comprises a material selected from the group consisting of polymer insulation and ceramic.

6. The energy delivery device of claim 4, wherein the distal face is beveled.

7. The energy delivery device of claim 6, wherein a proximal portion of the distal face is insulated.

20 8. The energy delivery device of claim 7, wherein a distal portion of the distal face is electrically exposed to at least partially define an electrode.

9. The energy delivery device of claim 8, wherein the distal portion of the distal face is substantially rounded.

10. The energy delivery device of claim 8, wherein a distal surface of the electrode defines a shape selected from the group consisting of generally C-shaped shapes and generally semicircular shapes.

25 11. The energy delivery device of claim 4, wherein the tubular member comprises stainless steel.

12. The energy delivery device of any one of claims 1-3, wherein the elongate member comprises a non-conductive material.

13. The energy delivery device of claim 12, wherein the distal face is beveled.

14. The energy delivery device of claim 12, wherein the electrically exposed conductive portion comprises a distal surface of an electrode located at a distal portion of the distal face.

15. The energy delivery device of claim 14, wherein the distal surface of the electrode is generally crescent-shaped.

16. The energy delivery device of claim 14, further comprising a wire electrically coupled to the electrode, the wire being operable to convey energy to the electrode.

17. The energy delivery device of claim 16, wherein the wire is embedded in a sidewall of the elongate member.

18. The energy delivery device of claim 14, wherein the electrically insulated portion comprises a polymer located at a proximal portion of the distal face.

19. A method of puncturing tissue comprising:

15 (a) delivering energy through a first portion of a distal face of an energy delivery device to tissue at a target site to create a puncture through the tissue, while preventing delivery of energy from a second portion of the distal face; and

(b) advancing the energy delivery device through the tissue by pushing aside a flap of tissue defined by the puncture.

20 20. The method of claim 19, wherein the step of delivering energy comprises creating a slit in the tissue.

21. The method of claim 19, further comprising using a medical imaging modality to guide the energy delivery device to the target site.

22. The method of claim 19, further comprising:

advancing the energy delivery device to the target site through a dilator;

25 positioning the energy delivery device such that the first portion is aligned with or protruding slightly from a distal end of the dilator; and

delivering fluid through an aperture at a distal end of the energy delivery device to stain the tissue.

23. The method of claim 19, further comprising measuring pressure using an aperture defined in a distal face of the energy delivery device.

24. The method of claim 19, wherein the target site is within a heart.

25. The method of claim 24, wherein the tissue is an atrial septum.

5 26. The method of claim 19, wherein step (b) includes creating a generally C-shaped puncture.

27. The method of claim 19, wherein step (b) includes creating a generally crescent-shaped puncture.

28. The method of claim 19, further comprising a step of delivering a fluid through an aperture defined by the distal face of the energy delivery device.

10 29. The method of claim 19, further comprising a step of withdrawing a fluid through an aperture defined by the distal face of the energy delivery device.

30. The method of claim 19, further comprising advancing the energy delivery device to the target site over a guide-wire.

31. An energy delivery device comprising:

an electrically conductive tubular member at least partially covered by electrically insulating material, the 15 tubular member defining a lumen for receiving a fluid,

a distal face of the tubular member defining an aperture in communication with the lumen, and

the distal face including at least one electrically exposed conductive portion and at least one electrically insulated portion,

20 whereby energy delivered to a tissue via the at least one electrically exposed conductive portion results in a puncture having a shape substantially corresponding to a shape of the electrically conductive portion of the distal face.

32. An energy delivery device comprising:

an elongate member defining a lumen for receiving a fluid,

a beveled distal face of the elongate member defining an aperture in communication with the lumen and

25 the beveled distal face including at least one electrically exposed conductive portion and at least one electrically insulated portion.

33. An energy delivery device comprising:

an elongate member defining a lumen for receiving a fluid,

a distal face defining an aperture in communication with the lumen,

the distal face including at least one electrically exposed conductive portion and at least one electrically insulated portion; and

the distal face being configured to puncture through a tissue at a target site upon delivery of energy via the electrically exposed conductive portion substantially without coring tissue from the target site.

34. The energy delivery device of claim 33, wherein the elongate member has a cut away portion proximal of the distal face and wherein the cut away portion of the elongate member includes electrically insulating material for insulating a proximal portion of the distal face.

35. The energy delivery device of any one of claims 31, 32, or 33, wherein the electrically exposed conductive portion partially surrounds the aperture.

36. The energy delivery device of any one of claims 31, 32, or 33, wherein the electrically insulated portion extends radially from a wall of the aperture to a periphery of the distal face.

37. The energy delivery device of claim 1, wherein the elongate member has a length of about 30 cm to about 100 cm to facilitate a puncture of a septum of a heart.

38. The energy delivery device of claim 1, wherein the elongate member has an outer diameter of about 0.40 mm to about 1.5 mm to minimize hemodynamic stability upon puncturing tissue.

39. The energy delivery device of claim 1, wherein the elongate member has a flexural rigidity of at least about 0.016 Nm².

40. The energy delivery device of claim 39, wherein the elongate member has a flexural rigidity of about 0.017 Nm².

41. The energy delivery device of claim 8, further comprising a radiopaque marker for marking a location of the electrode.

42. The energy delivery device of claim 41, wherein the marker is embedded in a sidewall of the elongate member.

43. The energy delivery device of claim 1, wherein the elongate member comprises a curved section.

44. The energy delivery device of claim 43, wherein the curved section has a curve length of from about 10 to about 25 cm and traverses from about 20° to about 40° of a circle.

45. The energy delivery device of claim 43, wherein the curved section has a curve length of from about 4 to about 7 cm and traverses from about 70 degrees to about 110 degrees of a circle.

5 45. The energy delivery device of claim 31, wherein the electrically exposed conductive portion partially circumscribes the aperture.

46. The energy delivery device of claim 1, further comprising a handle coupled to a proximal end of the elongate member.

10 47. The energy delivery device of claim 46, wherein the handle comprises an electrical connector operable to be coupled to an electrosurgical generator.

48. The energy delivery device of claim 46, wherein the handle comprises a fluid port for allowing for fluid communication between the lumen and a source of fluid.

49. The energy delivery device of claim 46, wherein the handle comprises at least one orientation indicator for indicating a direction of a curve of a curved section of the elongate member.

15 50. The energy delivery device of claim 47, wherein the elongate member comprises an electrically conductive tubular member at least partially covered by electrically insulating material, the handle further comprising a wire for transmitting the electrical energy from the electrical connector to the elongate member.

20 48. The energy delivery device of claim 46, wherein the handle comprises a plurality of ridges for transmitting tactile feedback.

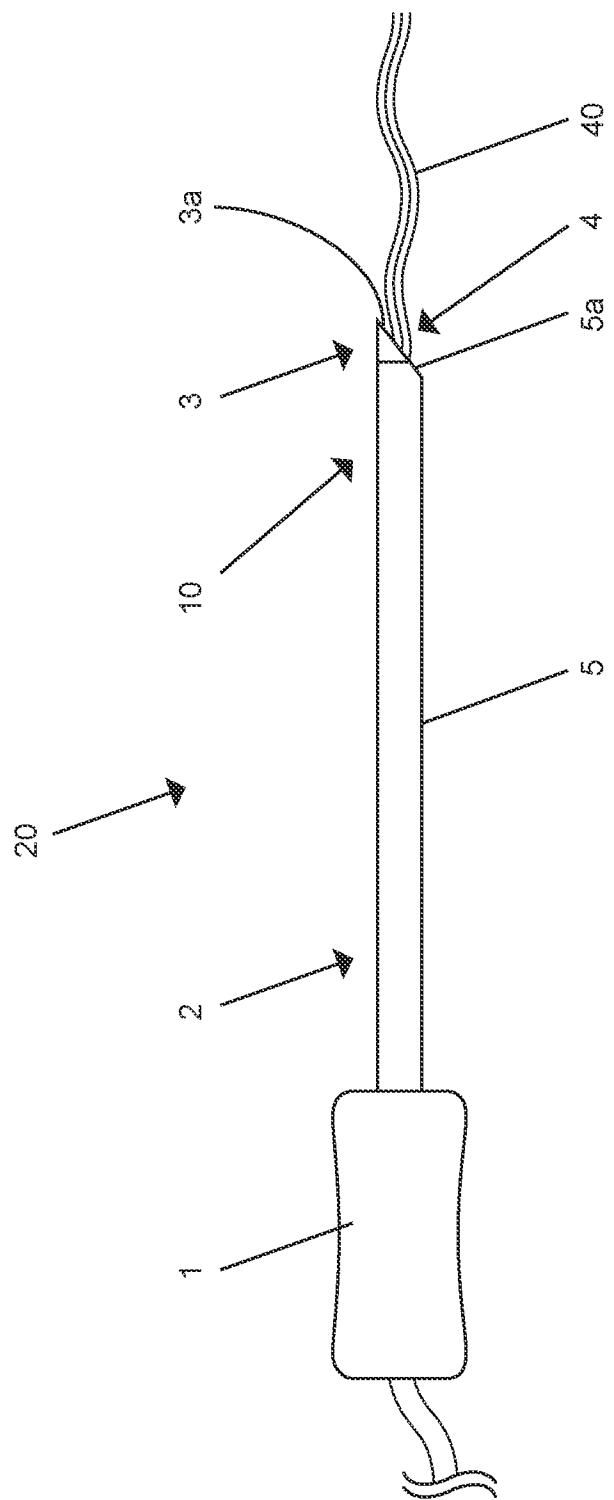


Fig. 1

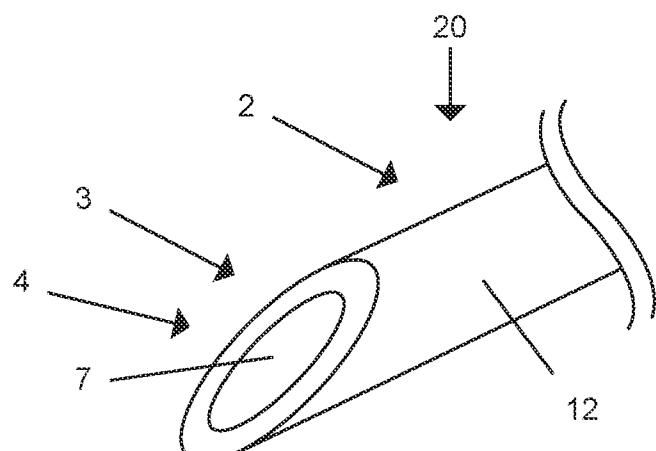


Fig. 2

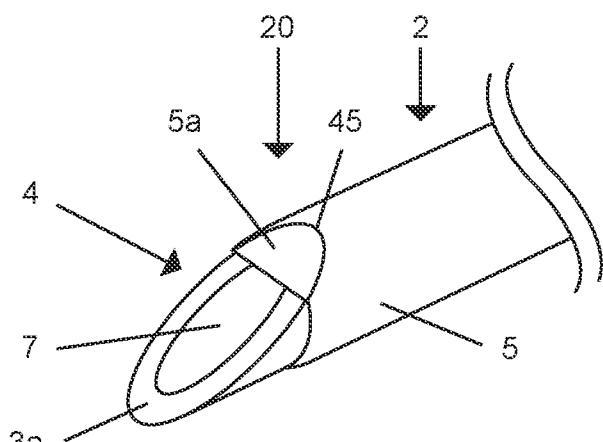


Fig. 3a

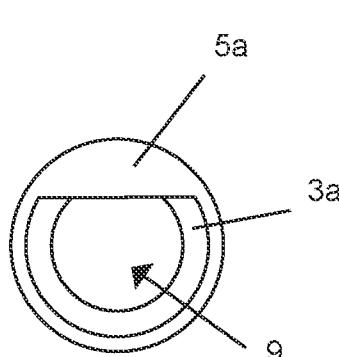


Fig. 3b

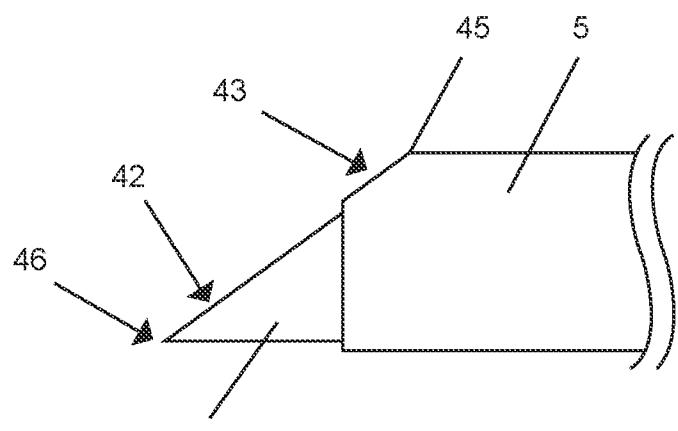


Fig. 3c

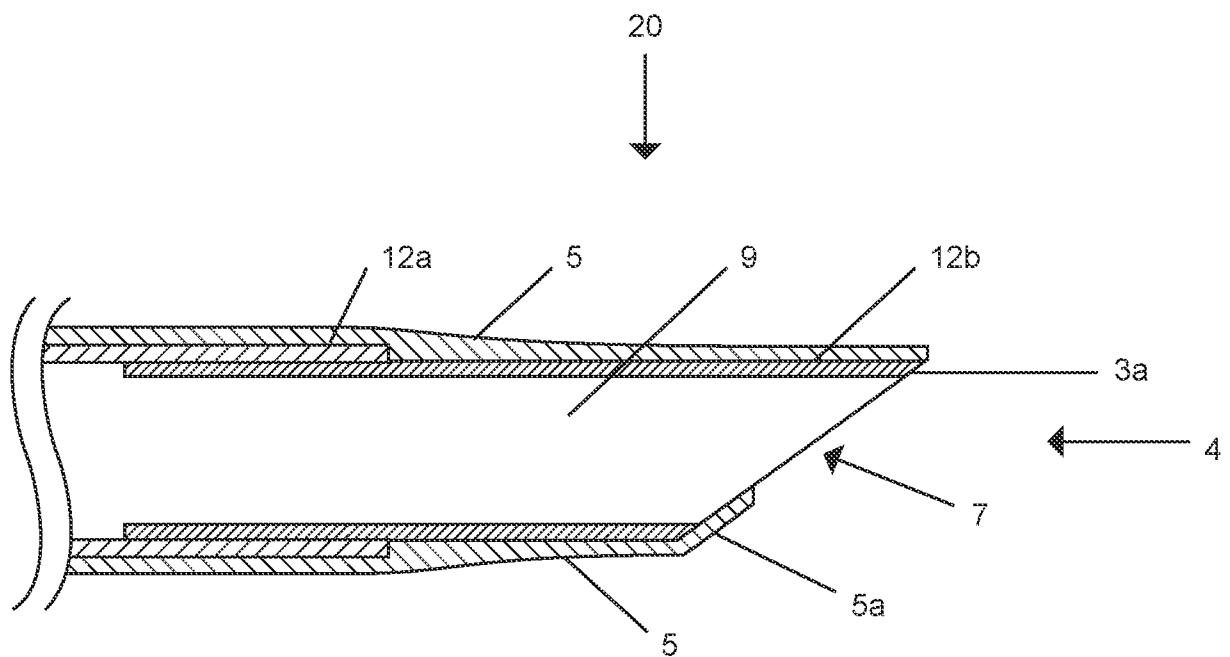


Fig. 4

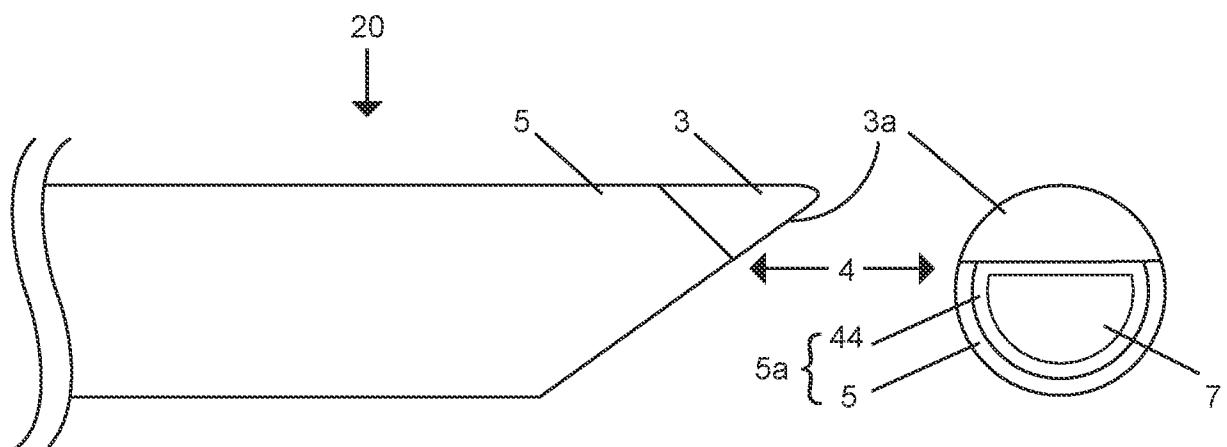


Fig. 5a

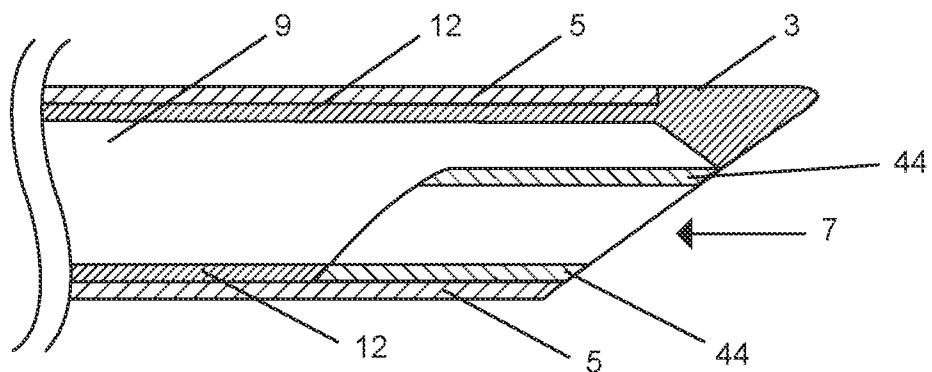


Fig. 5b

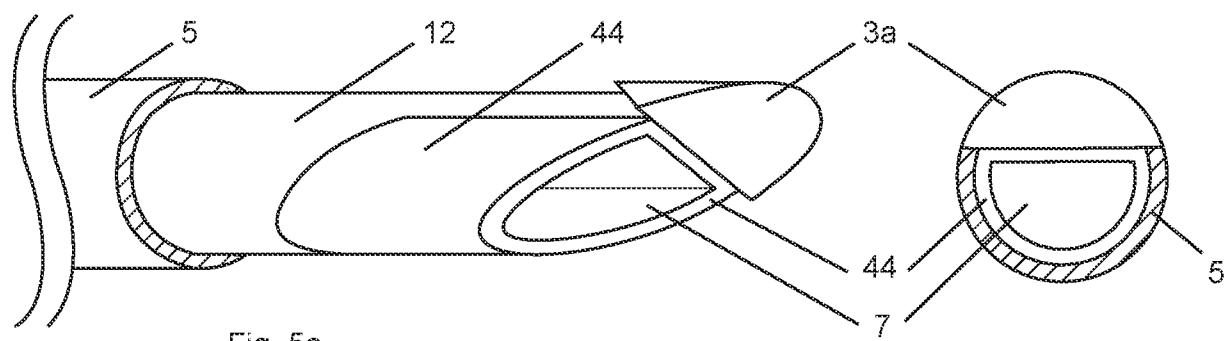


Fig. 5c

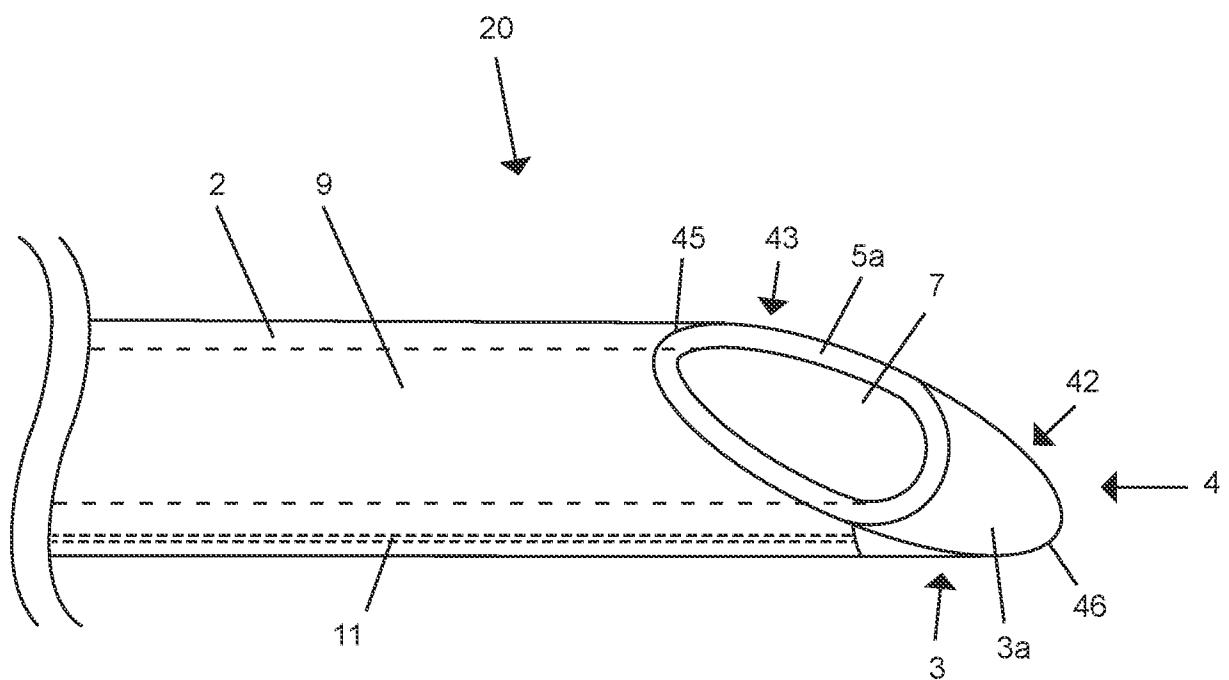


Fig. 6

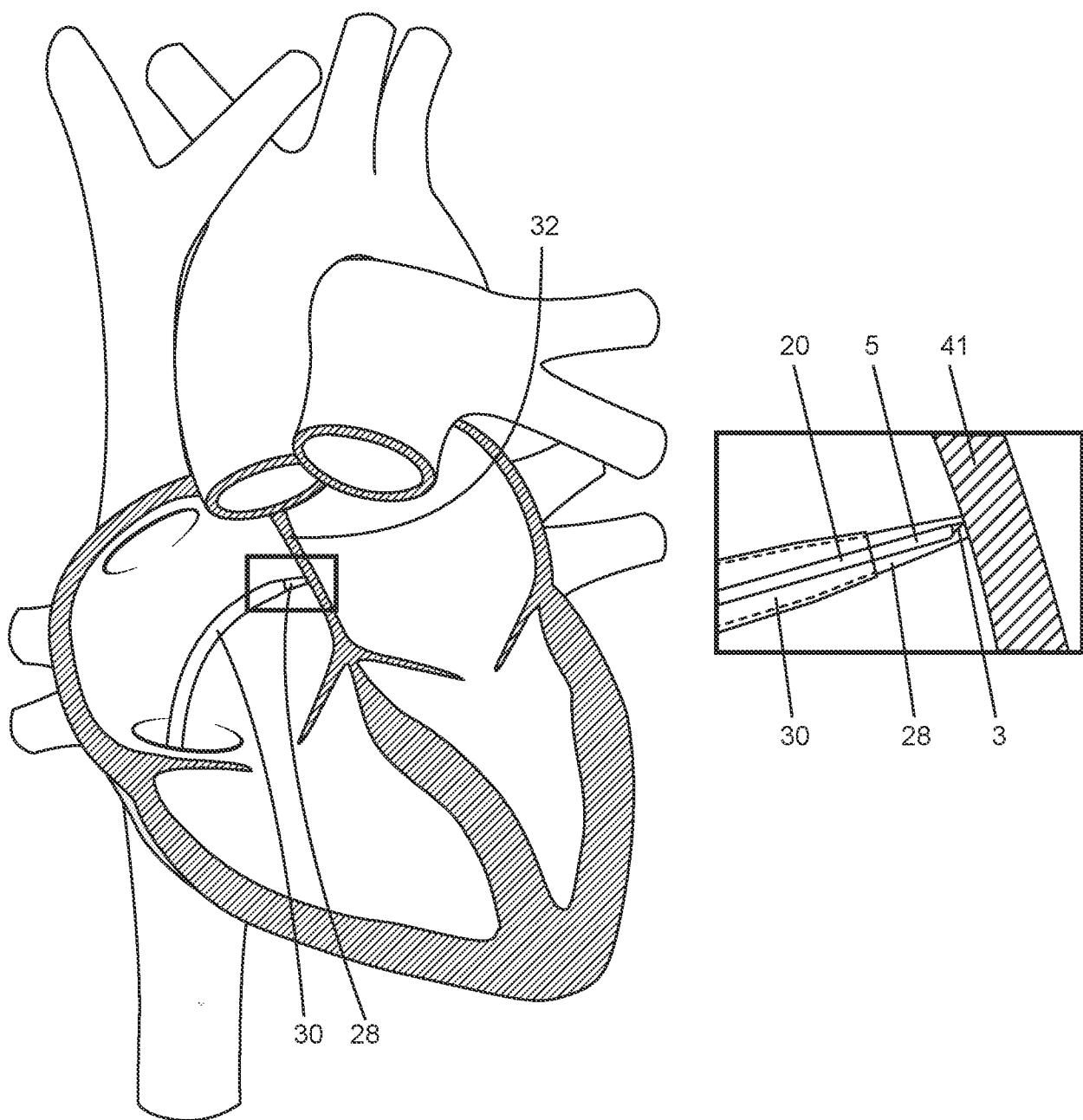


Fig. 7A

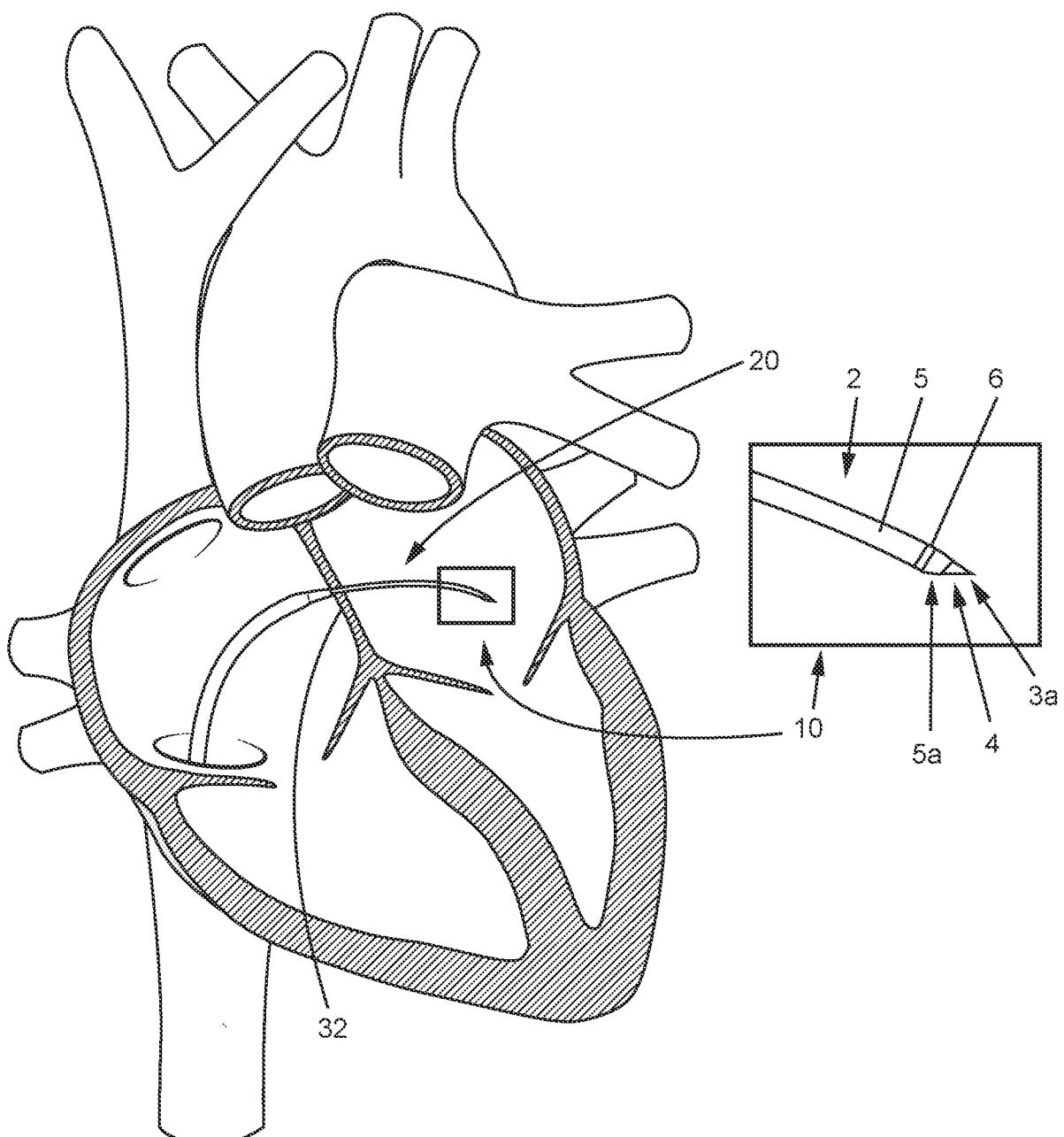
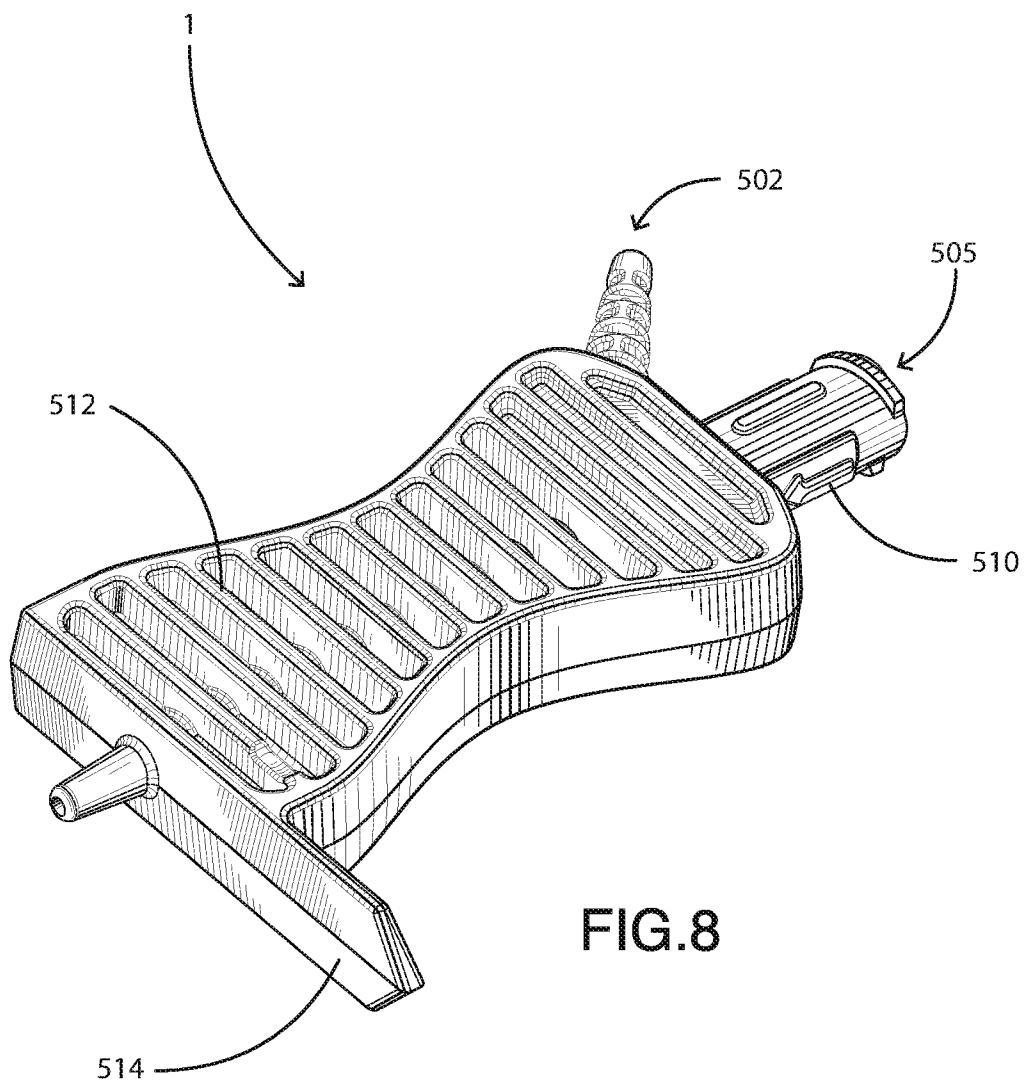
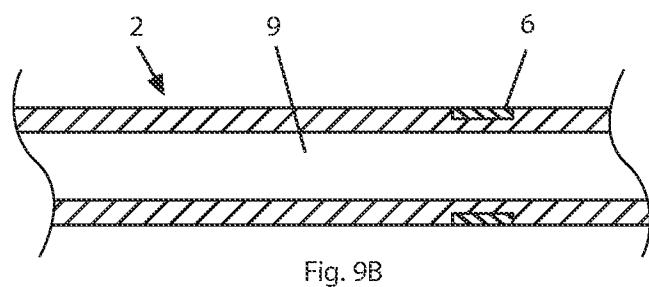
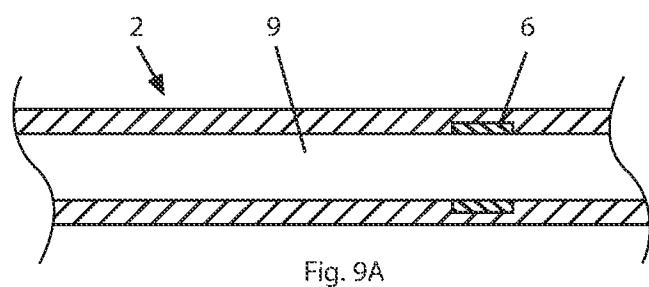


Fig. 7B





INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2014/059641

A. CLASSIFICATION OF SUBJECT MATTER

A61B 18/18(2006.01)i, A61M 37/00(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 18/18; A61B 18/14; A61B 17/3205; A61F 2/06; A61M 37/00

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: puncture, tissue, conductive portion, insulate portion, electrode, C-shaped shape

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005-0065507 A1 (HARTLEY et al.) 24 March 2005 See paragraphs [0007]–[0016], [0030]–[0049]; claims 1–39; and figures 1–11.	1, 2, 12–18, 32, 33, 35, 37–40, 43–45, 46–48, 48(1), 49
A		3–11, 31, 34, 36, 41, 42, 45(1), 50
A	US 2006-0178666 A1 (COSMAN et al.) 10 August 2006 See paragraphs [0052]–[0127]; claims 1–32; and figures 1A–18.	1–18, 31–45, 45(1), 46–48, 48(1), 49, 50
A	US 2012-0271334 A1 (PLESS et al.) 25 October 2012 See paragraphs [0116]–[0224]; claims 14–19; and figures 1A–73.	1–18, 31–45, 45(1), 46–48, 48(1), 49, 50
A	US 2013-0046305 A1 (DAVIES, GARETH) 21 February 2013 See paragraphs [0018]–[0107]; and figures 1A–8C.	1–18, 31–45, 45(1), 46–48, 48(1), 49, 50
A	US 2007-0005053 A1 (DANDO, JEREMY D.) 04 January 2007 See paragraphs [0037]–[0066]; claims 1–24; and figures 1–17.	1–18, 31–45, 45(1), 46–48, 48(1), 49, 50

 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
27 June 2014 (27.06.2014)

Date of mailing of the international search report

27 June 2014 (27.06.2014)

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2014/059641**C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>US 2009-0264977 A1 (BRUSZEWSKI et al.) 22 October 2009 See paragraphs [0032]-[0071]; claims 1-20; and figures 1-7F.</p> <p>*Note: For the claims 45(1) and 48(1), the claims were renumbered by this authority because the claims 45 and 48 are found twice respectively.</p>	1-18, 31-45, 45(1), , 46-48, 48(1), 49, 50

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2014/059641**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.: 19-30
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 19-30 pertain to a method for treatment of the human body by surgery and thus relate to a subject matter which this ISA is not required, under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv), to search.
2. Claims Nos.:
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:
3. Claims Nos.:
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.

PCT/IB2014/059641

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2005-0065507 A1	24/03/2005	EP 1587438 A2 EP 2401978 A1 US 2004-0143261 A1 US 2004-0143262 A1 US 2005-0159738 A1 US 2006-0142756 A1 US 2007-0066975 A1 US 2007-0123964 A1 US 2007-0185522 A1 US 2011-0118735 A1 US 7048733 B2 US 7112197 B2 US 7270662 B2 US 7828796 B2 US 7947040 B2 US 8092450 B2 WO 2004-064657 A2 WO 2004-064657 A3 WO 2007-090075 A2 WO 2007-090075 A3	26/10/2005 04/01/2012 22/07/2004 22/07/2004 21/07/2005 29/06/2006 22/03/2007 31/05/2007 09/08/2007 19/05/2011 23/05/2006 26/09/2006 18/09/2007 09/11/2010 24/05/2011 10/01/2012 05/08/2004 11/11/2004 09/08/2007 21/12/2007
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/IB2014/059641

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		WO 2007-018751 A2 WO 2007-018751 A3	15/02/2007 07/06/2007
US 2009-0264977 A1	22/10/2009	US 8292885 B2	23/10/2012