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(54) **TRANSSEPTAL LEFT ATRIAL ACCESS AND SEPTAL CLOSURE**

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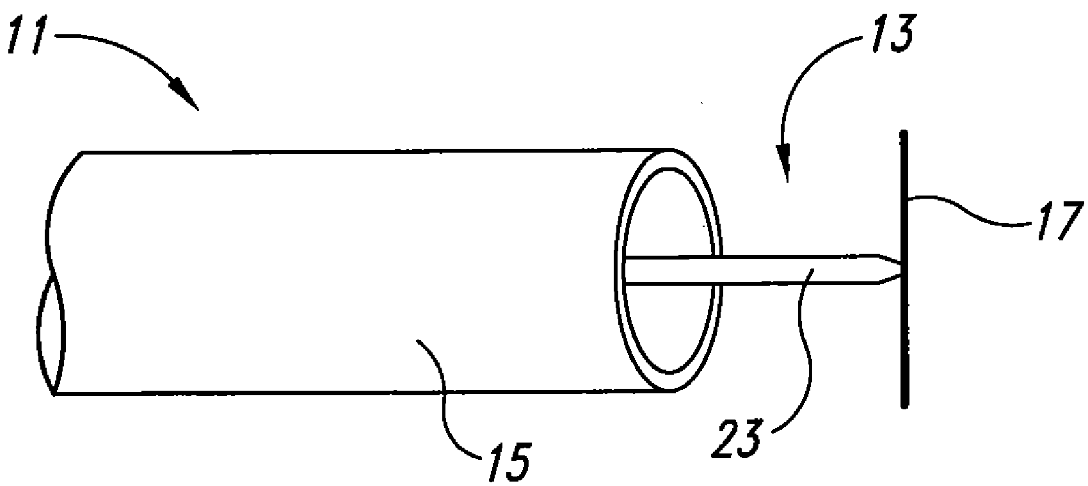
(57) **ABSTRACT**

Methods, systems, and devices for transseptal access into the left atrium of a heart. In one embodiment an apparatus for transseptal left atrial access comprised of a catheter adapted for insertion into a vessel and one or more RF devices adapted to be extendable from the distal end of said catheter and configured for the penetration or sealing of septal tissue.



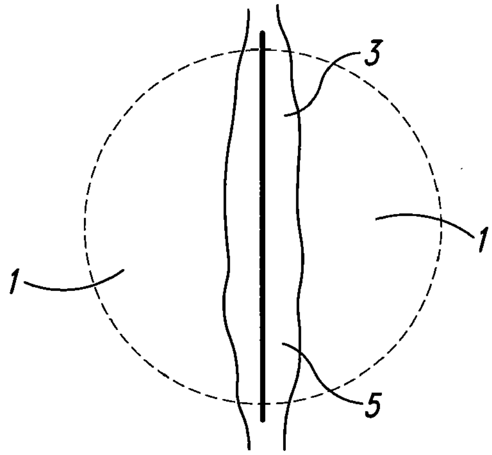


Fig. 1A

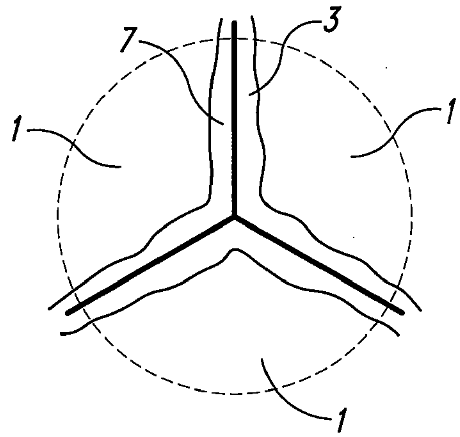


Fig. 1B

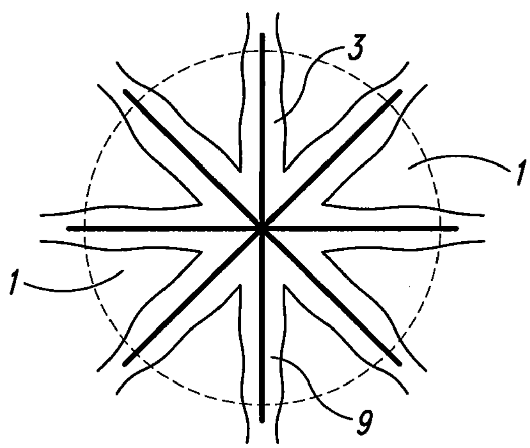


Fig. 1C

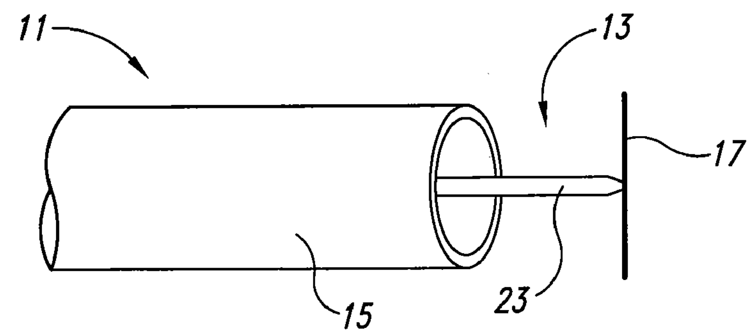


Fig. 2

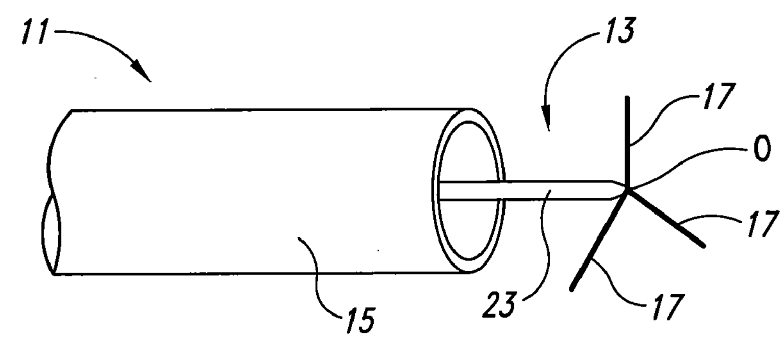


Fig. 3

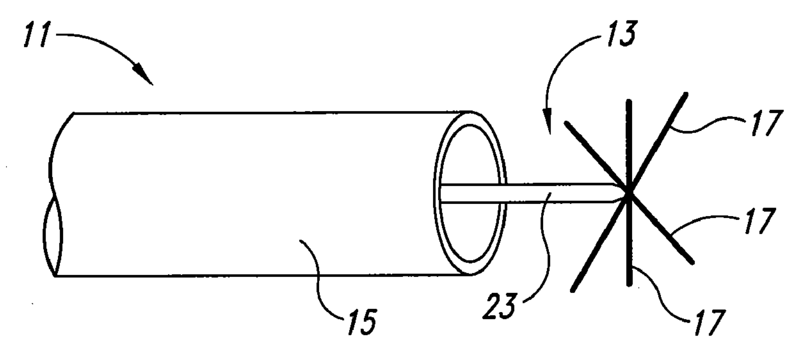


Fig. 4

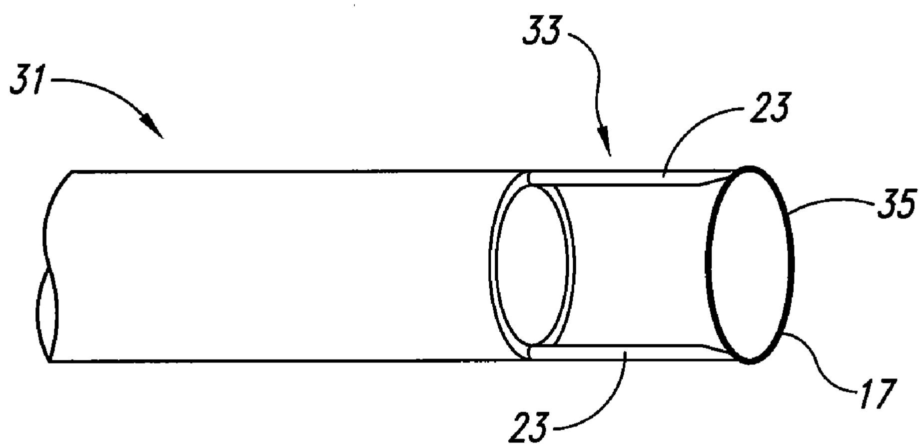


Fig. 5

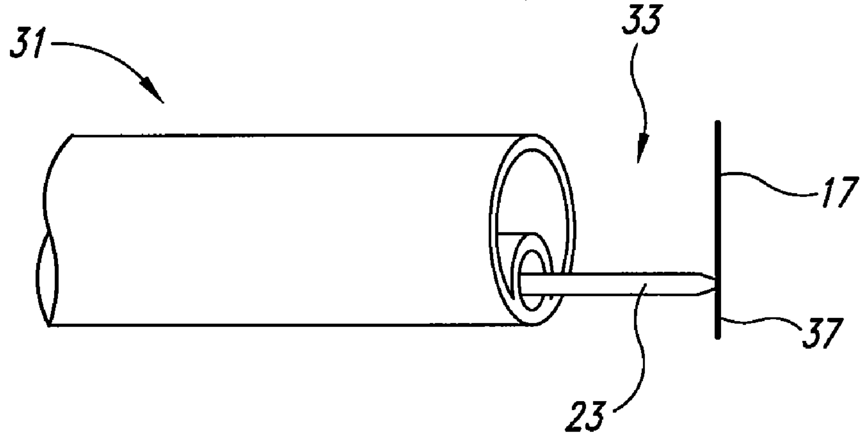


Fig. 6

TRANSSEPTAL LEFT ATRIAL ACCESS AND SEPTAL CLOSURE

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FIELD OF THE INVENTION

[0002] The present invention relates generally to the medical arts and specifically to transseptal methods, devices, and systems for accessing the left atrium of a patient's heart and for sealing closed an opening in the septum and/or for sealing septal tissue together.

BACKGROUND OF THE INVENTION

[0003] With recent advances in the cardiovascular arts, there's a renewed interest in finding safe and uncomplicated methods for accessing the left atrium of a patient's heart. Currently, a retrograde transaortal technique is most often and involves advancing a catheter through the aorta, into the left ventricle, accessing the left atrium from the left ventricle. However, this path into the left atrium is tortuous. A simple and more attractive alternative is accessing the left atrium directly from the right atrium by crossing the interatrial septum ("septum") that divides the two atrial chambers of the heart. The right atrium can be easily accessed and crossing the septum is the only requirement to entering the left atrium.

[0004] The left atrium can be accessed by puncturing across the septum of the heart at the fossa ovalis membrane, typically the thinnest part of the septum, with a needle-like device such as a Brockenbough needle. While this technique has been widely known since the **1950**'s, it has not been used largely because the technique has not proven reliable or secure. Misalignment or the incorrect orientation of the needle against the septum, for example, may have severe consequences for the patient, including perforation of the left atrium of the heart or perforation of a patient's aorta. Inadvertent perforations of the inferior vena cava and the coronary sinus have also been reported as a possible complication of this technique. Therefore, rapid, precise and controlled methods and devices for crossing the interatrial septum are needed. The present invention meets these, as well as other, needs.

SUMMARY OF THE INVENTION

[0005] Broadly, the invention is directed at methods and radiofrequency (RF) devices for crossing an interatrial septum and sealing an opening in it closed.

[0006] In yet another aspect of the invention, methods, RF systems and devices for sealing septal tissue are provided.

[0007] In yet another aspect of the invention, methods, RF systems, and devices for sealing closed an naturally occurring opening in a heart is a provided.

[0008] These, as well as other additional embodiments and features of the invention, will appear in the following description in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] FIGS. **1**A-**1**C are schematics illustrating the types of opening and closure patterns that can be created in the interatrial septum in accordance with the present invention.

[0010] FIGS. **2**-**4** illustrate various embodiments of RF penetrating probes in accordance with the present invention.

[0011] FIGS. **5**-**6** illustrate various embodiments of RF sealing probes in accordance with the present invention.

DESCRIPTION OF THE EMBODIMENTS

[0012] Broadly, methods, systems and RF devices for crossing the septum **1** and creating openings **3** of a specified size and pattern are provided. Methods, systems and RF devices for closing these openings **3** and joining septal tissue are also provided. Openings **3** in a wide variety of patterns and sizes can be created in the septum **1** in accordance with the present invention, including but not limited to: single slits **5** (FIG. **1**A), radial slits **7** (FIG. **1**B) and a plurality of bisecting slits **9** (FIG. **1**C) as illustrated in FIGS. **1**A-**1**C. The specific shape or pattern of the opening **3** is determined by the configuration of the wire(s) or electrodes(s) located on the distal end of an RF penetrating device or catheter as described herein. FIG. **1** further illustrates yet another aspect of the invention involving the use of an adaptively shaped RF sealing device or catheter to close the various types of openings **3**. The dotted lines in FIG. **1** depict the shapes of various RF sealing devices or catheters that can be preferentially used to close septal openings **3** and join septal tissues **1** flaps together.

[0013] Turing now to the other figures, FIGS. **2**, **3** and **4** illustrates various embodiments of RF penetrating devices **11**. The various RF penetrating devices **11** are comprised of an RF penetrating probe **13** located at a distal end **15**. The RF penetrating probe **13** is comprised of one or more wires **17** arranged in a particular shape. In a preferred embodiment, the RF penetrating probes **13** are made of shape memory wires **17** (such as Nitinol) to ensure the correct formation of the desired shape when the RF penetrating probe **13** is exposed inside the right atrium. The correct shape and orientation of the RF penetrating probe **13** and wires **17** against the septum **1** will determine the pattern of the opening **3** created in the septum **1** by the RF penetrating probe **13**. When energized, the wires **17** or electrodes will supply sufficient RF energy to affect tissue penetration upon contact in the pattern dictated by the arrangement of the RF probe **13**.

[0014] Each wire **17** of an RF penetrating probe **13** can be configured as a wire electrode, or in yet another implementation, each wire may be comprised of one or more spaced RF electrodes located within insulated shape memory wires. The electrodes of an RF penetrating probe **11** can be configured to operate as monopolar or bipolar electrodes delivering sufficient RF current to electrosurgically penetrate septal tissue **1** on contact. As will be readily appreciated by one skilled in the art, various strategies can be implemented to prevent sticking of tissues to the RF penetrating probes **13**, wires **17** or electrodes described herein. In one possible implementation, various fluids or gels (either cooling and/or electrically conductive) may be used to prevent sticking of tissues during the penetration procedure. Yet another possible implementation may include a fluid (cooling or conductive) eluted from one or more ports located on a guide catheter. Alternatively, a fluid, coating or gel can be used on the RF probes **13**, wires **17**, or electrodes themselves to prevent tissue adhesion to the devices. In addition, one or more feedback sensors may be incorporated the present invention, preferably located adjacent to the RF penetration probes **13** to prevent unintended injury. The one or more feedback sensors can be configured to measure tissue impedances, temperatures, etc. as a means of preventing or controlling tissue heating, overheating or excessive tissue adhesion caused by heat generation.

[**0015**] FIG. **2** illustrates one embodiment of an RF penetration probe **13** for creating a slit-like opening **5** in the septum **1** of a patient's heart. As shown, the RF probe **13** comprises a relatively straight RF wire **17**. RF wire **17** is attached to a connection member **23**, which secures it to the distal end **15** of the RF penetration catheter **11**. A described above, RF wire **17** can be configured as a wire electrode or can be comprised of a electrode located preferably in the middle of wires **17** wherein the ends of wire are insulated as illustrated. The size of the RF wire **17** or the electrode will depend on the desired size of the septal opening **3**; if a longer slit **5** is desired a larger RF wires **17** or electrode may be employed. Though not illustrated, RF wire **17** is operationally connected by lead wires, or other like means, to an RF generator or energy source (not shown).

[**0016**] FIG. **3** illustrates yet another embodiment of an RF penetration probe **13**. In this embodiment, RF penetration probe **13** is comprised of a plurality of wires **17** radiating from center point **0**. The wires **17** of the RF penetration probe **13**, which are preferably straight, are secured to connection member at center point **0**. This RF penetration probe **13** illustrated in FIG. may be used to create the type of opening **7** depicted in FIG. **1**B.

[**0017**] FIG. **4** illustrates yet another embodiment of the present invention wherein RF penetration probe **13** comprise a plurality of bisecting RF wires **17** that can be used to affect an opening **9** of the type illustrated in FIG. **1**C. Each wire **17** in these embodiments may be configured as a wire electrode **17** or portions of the wire may be insulated **21**.

[**0018**] Turing to FIGS. **5** and **6**, yet another aspect of the invention, is provided. In this aspect, various RF tissue sealing devices or catheters **31** comprising a distally located RF sealing probe **33**, are illustrated. The RF sealing probe **33** is comprised of one or more wires **17** arranged in a predetermined shape. Similar to the RF penetrating devices **11**, the RF tissue sealing devices **31** can be configured as separate catheter device insertable into a guide catheter, or alternatively, can adapted to extend from the distal end of a guide catheter by use of a manipulator. For example, movement of a manipulator may control extension or retraction of both an RF penetrating device **11** and an RF sealing device **31** from the distal end of a guide catheter. To affect closure, RF wires **17**, or electrodes of a RF sealing device **31**, are configured to be operable at less intense modalities than the electrodes of an RF penetrating device **11** or probe **13**. Specifically, the RF sealing probes **33** and the electrodes comprised therein are configured to heat, melt or coagulate tissues coming in contact with it. In addition, as provided in the art, heating of tissues at less intense parameters will trigger a healing response in the RF heated tissues, which will contribute and further promote closure of an opening and promote sealing of septal tissues.

[**0019**] Like the RF penetration probes **13**, the RF sealing probes **33** of the present invention can be configured in a variety of shapes and sizes depending on the opening **3** to be closed. As illustrated in FIG., RF sealing probe **33** may be a circular wire **35** or a straight wire **37**. Circular or straight type wires **35**, **37** can be used to seal an opening **3** having several different patterns; for example, a circularly shaped RF sealing probe **35** can be used to seal a radial **7** or slit type **5** opening as illustrated in FIG. **1**.

[**0020**] The various devices of the invention can be used similarly. The RF devices (including the tissue penetrating **11**, **13** and sealing devices, catheters, probes **31**, **33**) can be delivered as a component of a catheter assembly system. The catheter assembly can comprise: a conventional guide or sheath catheter that can be introduced over a guidewire (not shown), an RF penetrating device **11** and/or an RF sealing device **31**. First, the catheter assembly can be introduced into the right atrium from a number of access points using well known catheterization techniques. For example, to gain access to a patient's vasculature and the right atrium of the heart, commercially available introducers can be inserted into a vessel such as into the femoral vein or artery. The introducer can be of a variety of sizes, 4-14 French. The guide catheter should be readily insertable into an introducer and extend from the access point to the septum; this will require use of a guide catheter about 80-120 cm long and about 4-14 French. The guide catheter can be manufactured in accordance with a variety of known techniques, including as an extrusion of an appropriate material, such as high density polyethylenes (HDPE), polytetrafluoroethylenes, nylons, polyether-block amides, polyurethanes, polyimides, polyolefin copolyester and the like. However, other catheter materials well known in the catheter art, as well as various braiding techniques, may be employed depending on the desired catheter performance characteristics. In one embodiment, the guide catheter can be manufactured to be self-positioning to a desired location on a septum **3**. For example, the guide catheter can be adapted so its distal tip preferentially locates to pre-determined position (such as at the fossa ovalis or above it), in which case the appropriate braiding technique can be used to affect preferential positioning of the distal tip of the catheter. Other component of the catheter assembly, in addition to a guide catheter, can include one or more of the following: an RF penetrating device **11**, an RF sealing device **31**, a guidewire, imaging components and the like. These components can be configured to be inserted into and extend out of the distal end of a guide catheter. Alternatively, these components, such as the RF devices **11**, **31** can be configured to be extendable from the distal tip of guide catheter via a manipulator or other like means located at a proximal end of the guide catheter. In addition, these devices **11**, **31** can be configured to extend only to predetermined distances from the distal end of a guide catheter to ensure accurate penetration of the interatrial septum **1**.

[**0021**] An RF penetrating device or catheter **5** can then be advanced into the guide catheter **43** and an RF penetrating probe **13** extended from its distal end. The RF penetration probe **43** should be placed into contact against the septum **1**, and the electrodes energized to affect penetration. Pressure exerted on the proximal end of the RF penetration device or catheter **11** can used to ensure contact of septal tissue and the RF penetration probe **13**. Other possible implementations include configuring the guide catheter to include a vacuum or suction port to help immobilize septal tissue against the RF penetration probe **13** during septal penetration.

[**0022**] Once a desired opening **3** has been created, the RF penetrating device or catheter **11** can be withdrawn from the guide catheter and replaced with other diagnostic or therapeutic devices or catheters. Once the left atrium has been sufficiently accessed and the other devices and catheters withdrawn, the closing or sealing procedure can be initiated using the RF sealing device or catheter **31** of the present invention. To affect closure or sealing of an atrial opening **3**, a RF sealing probe **33** should be delivered into the right atrium and the RF wire or electrodes **17** energized. As previously described, activation of the RF sealing probe **33** will cause tissue and collagen melting, as well as coagulation, around the tissue flaps **1** of a septal opening **3**. In addition, a heat-induced healing process, including scar formation and cell proliferation, will further contribute to of the septal closure and adhesion of the septal tissues.

[**0023**] As will be readily appreciated by one skilled in the art, the RF sealing devices and catheters **31** may be configured and used not only to seal actively created openings **3** but also those that occur naturally (ASDs, PFOs, floppy or aneurismal septums or PFOs). In one method of treatment, the distal end of an RF treatment catheter can be delivered adjacent an aneurismal or floppy PFO and RF energy applied to tighten the loose or septal tissue.

[**0024**] While this invention has been described in terms of specific embodiments, other embodiments will become apparent to those skilled in the art. Accordingly, the scope of the present invention is not intended to be limited by the specific embodiments disclosed herein, but rather, by the full scope of the claims.

1-29. (canceled)

30. A method for treating a patient, comprising:

introducing a catheter into a patient's right atrium;

forming an opening in septal tissue between the patient's right atrium and the patient's left atrium;

passing at least one of a diagnostic device and a therapeutic device through the opening;

performing at least one of a diagnostic process and a therapeutic process in the left atrium with the at least one device; and

removing the at least one device through the opening.

31. The method of claim 30, further comprising sealing the opening.

32. The method of claim 31, wherein sealing the opening includes sealing the opening from the right atrium.

33. The method of claim 31, wherein sealing the opening includes sealing the opening with RF energy.

34. The method of claim 30, further comprising sealing a PFO.

35. The method of claim 30, further comprising tightening loose septal tissue.

36. The method of claim 30, wherein forming an opening includes forming an opening with RF energy.

37. The method of claim 36, wherein forming an opening includes forming an opening with a monopolar RF electrode.

38. The method of claim 30, wherein forming an opening includes forming an opening with a bipolar RF electrode.

39. The method of claim 30, wherein forming an opening includes forming at least one slit.

40. The method of claim 39, wherein forming at least one slit includes forming a single slit.

41. The method of claim 30, wherein forming at least one slit includes forming multiple slits.

42. The method of claim 30, further comprising immobilizing the septal tissue while forming an opening in the septal tissue.

43. The method of claim 30, further comprising sensing a characteristic of the septal tissue.

44. The method of claim 43, wherein sensing a characteristic of the septal tissue includes sensing a tissue impedance.

45. The method of claim 43, wherein sensing a characteristic of the septal tissue includes sensing a tissue temperature.

46. The method of claim 30, further comprising eluting at least one of a cooling fluid and an electrically conductive fluid from the catheter.

47. A device for treating a patient comprising:

an intravenous catheter configured to be introduced into a patient's right atrium, the catheter having a distal portion and a proximal portion;

a tissue penetrating device carried by the catheter, the tissue penetrating device including an RF electrode deployable from the distal portion of the catheter and configured to make an opening in septal tissue between the patient's right atrium and left atrium;

an RF energy source coupled to the tissue penetrating device at the proximal portion of the catheter; and

at least one of a diagnostic device and a therapeutic device carried by the catheter and deployable from the distal portion through the opening made by the tissue penetrating device and into the left atrium.

48. The device of claim 47, wherein the RF electrode is shaped to make a slit in the septal tissue.

49. The device of claim 47, further comprising a tissue sealing member carried by the catheter.

50. The device of claim 47, wherein the electrode includes a monopolar electrode.

51. The device of claim 47, wherein the electrode includes a bipolar electrode.

52. The device of claim 47, further comprising a tissue sensor carried by the catheter.

* * * * *