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(54) DEVICE AND METHOD TO EXPAND TREATMENT ARRAY

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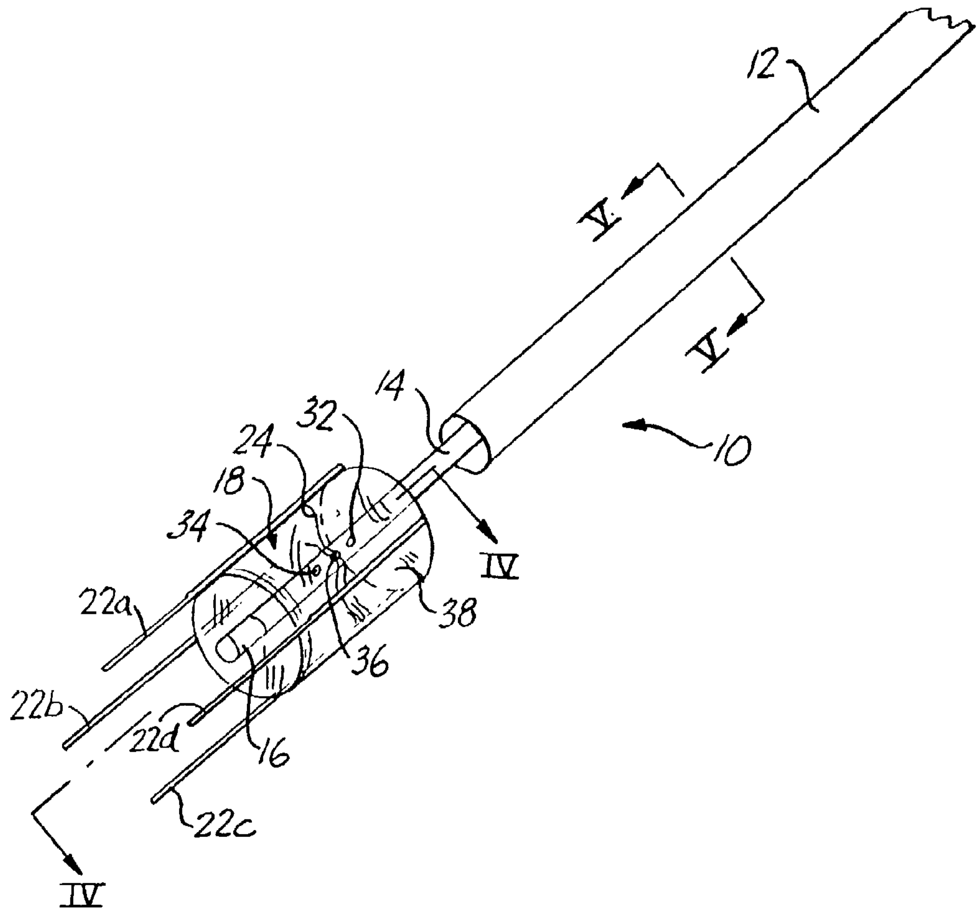
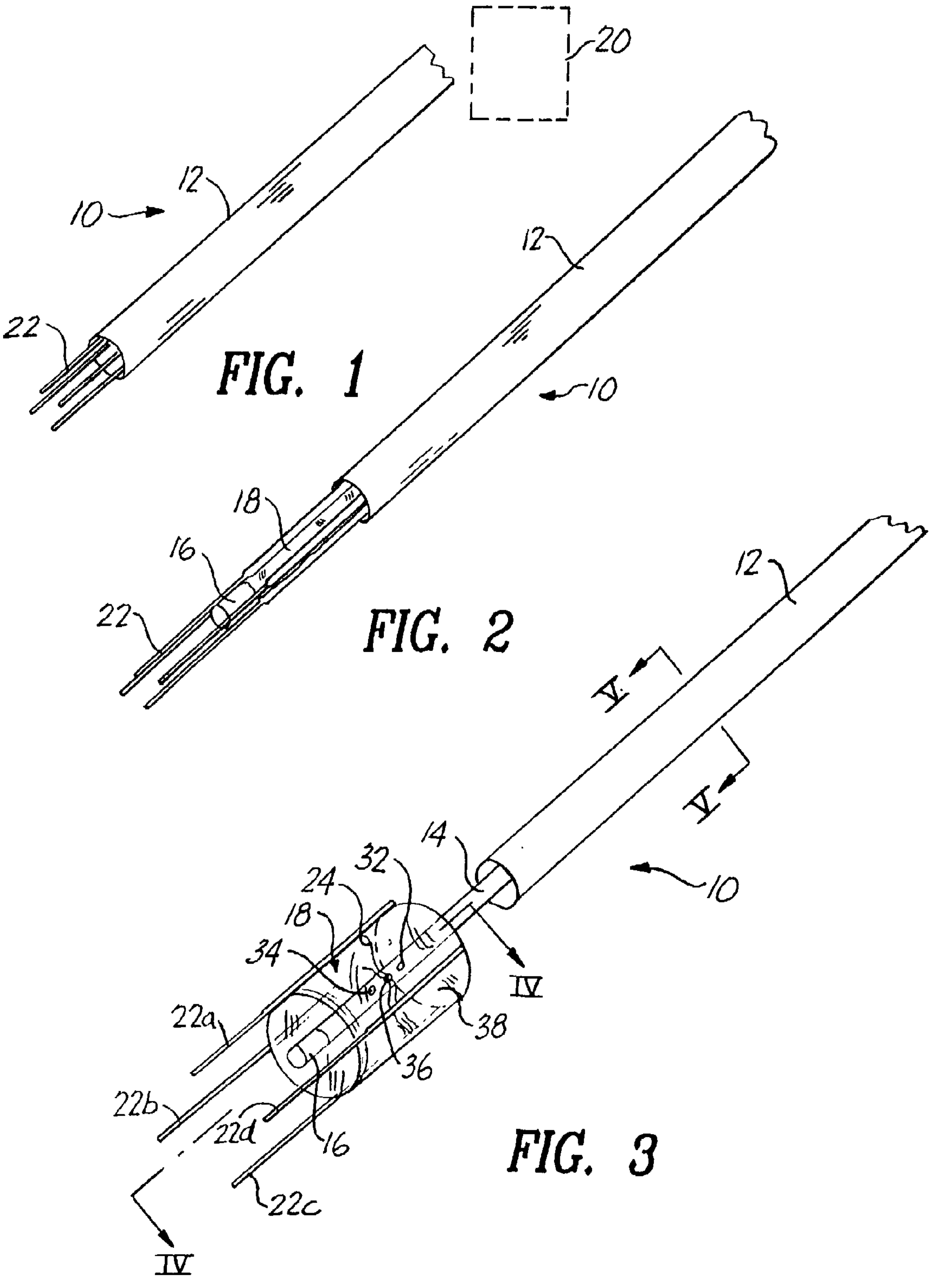
(57) ABSTRACT

A medical device is provided and includes an elongated tube that has a longitudinal axis and an expandable member attached to the tube. The expandable member is expandable from a collapsed configuration to an expanded configuration. A plurality of electrodes is attached to the expandable member. The electrodes are used to emit energy. Each of the electrodes is arranged generally coaxially relative to the tube when the expandable member is in its collapsed and expanded configurations.




20
12
10
22
FIG. 1
12
10
18
16
22
FIG. 2
12
V
V
14
32
24
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34
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IV
22a
38
36
22b
22d
16
22c
IV

FIG. 3

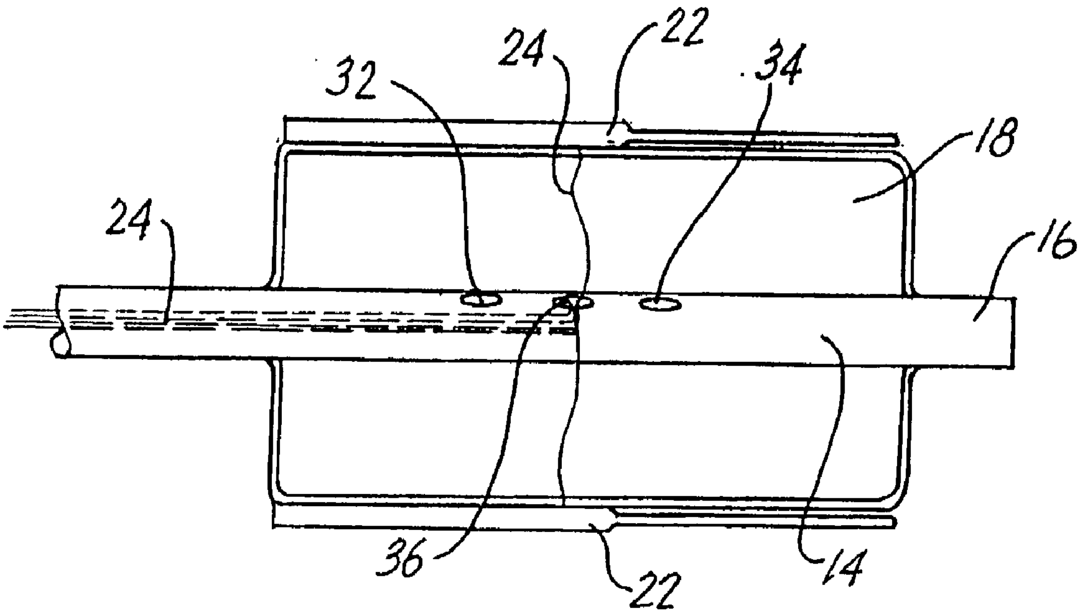

FIG. 4

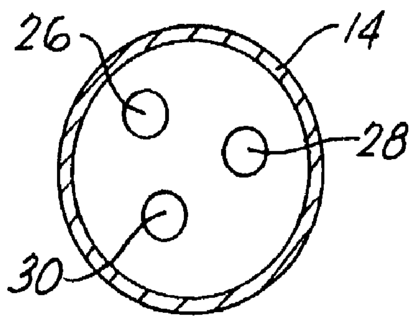

FIG. 5

DEVICE AND METHOD TO EXPAND TREATMENT ARRAY

FIELD OF THE INVENTION

[0001] The present invention relates to an RF (radio frequency) device for use in the performance of RF thermal treatment of tissue, and more particularly, to an RF device adapted for use during a laparoscopic or percutaneous procedure.

BACKGROUND OF THE INVENTION

[0002] During an RF procedure, a probe is placed into a target tissue for treating malignant and nonmalignant conditions. The probe is typically provided with an array of electrodes so that RF energy can be supplied to the target tissue.

[0003] Various RF devices have been employed to treat a large volume of tissue with a single applicator in a single procedure. One such device employs an array of wire electrodes that deploys and assumes an inverted umbrella shape after reaching the target tissue. When deployed, the inverted umbrella shape of the electrode array may be altered by tissue mechanical resistance or calcifications such that the electrode array exhibits a non-uniform pattern of thermal treatment. Such a non-uniform pattern is undesirable because tissue effects will be affected by the changing distance between adjacent electrodes that diverge or converge.

[0004] An alternative approach involves the use of an array of electrodes that have a large diameter. Such an approach is also undesirable because the large electrode array cannot be inserted through the body unless an open surgery is performed. Further, the large electrode array cannot be accommodated through a laparoscopic trocar that has a small diameter of 5 to 10 mm.

[0005] Accordingly, there is a need for an improved RF device having electrodes that deploy in a uniform and parallel manner along the length of the electrodes and that can be accommodated in a laparoscopic trocar having a small diameter.

SUMMARY OF THE INVENTION

[0006] In accordance with the present invention, there is provided a medical device used for thermal treatment of tissue. The medical device includes an elongated tube that has a longitudinal axis and an expandable member attached to the tube. The expandable member is expandable from a collapsed configuration to an expanded configuration. A plurality of energy-emitting electrodes is attached to the expandable member. Each of the electrodes is arranged generally coaxially relative to the tube when the expandable member is in its collapsed and expanded configurations.

[0007] A method is also disclosed for performing thermal treatment of tissue using the medical device. Initially, the tube is placed near the tissue area with the expandable member in its collapsed configuration. In this step, the electrodes are in close proximity to each other and all of the electrodes are arranged generally co-axially relative to the tube. Then, the expandable member is expanded so that it assumes its expanded configuration. In this step, the electrodes are spaced apart from each other and all of the electrodes are arranged generally coaxially relative to the tube.

[0008] Other features and aspects of the present invention will become more fully apparent from the following detailed description of the exemplary embodiment, the appended claims and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] For a more complete understanding of the present invention, reference is made to the following detailed description of the exemplary embodiment considered in conjunction with the accompanying drawings, in which:

[0010] **FIG. 1** is a front, perspective view of an RF device constructed in accordance with the present invention, which shows a multi-lumen tube in a retracted position;

[0011] **FIG. 2** is a view similar to the view shown in **FIG. 1**, except that the multi-lumen tube is between its retracted and extended positions, and which shows a balloon member in its collapsed configuration;

[0012] **FIG. 3** is a view similar to the view shown in **FIG. 1**, except that the multi-lumen tube is in its extended position and the balloon member is in its expanded configuration;

[0013] **FIG. 4** is a cross-sectional view, taken along section lines IV-IV and looking in the direction of the arrows, of the RF device of **FIG. 3**; and

[0014] **FIG. 5** is a cross-sectional view, taken along section lines V-V and looking in the direction of the arrows, of the RF device of **FIG. 3**.

DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENT

[0015] **FIG. 1** shows an RF device **10** used for thermal treatment of tissue. The RF device **10** can be applied through 5-10 mm or larger laparoscopic trocar. Alternatively, the RF device **10** can be applied percutaneously to the affected tissue area.

[0016] With reference to FIGS. **1** to **3**, the RF device **10** includes an outer sheath **12** which is linearly shaped and an elongated multi-lumen tube **14** sized and shaped to be coaxially received within the outer sheath **12**. The multi-lumen tube **14** has a longitudinal axis and is also linearly shaped. The multi-lumen tube **14** is also sized and shaped to move relative to the outer sheath **12** by conventional methods such as by laparoscopic surgical tools (e.g., graspers, forceps, retractors) sliding through a plastic or metal trocar. As shown in **FIG. 2**, the multi-lumen tube **14** has a distal end **16** that can extend from the outer sheath **12**. More particularly, the multi-lumen tube **14** is movable between a retracted position (see **FIG. 1**), in which the multi-lumen tube **14** retracts into the outer sheath **12**, and an extended position (see **FIG. 3**), in which the multi-lumen tube **14** extends from the outer sheath **12**. Alternatively, the outer sheath **12** can be sized and shaped to move relative to the multi-lumen tube **14**.

[0017] Referring to **FIG. 3**, the RF device **10** further includes a balloon member **18** attached to the multi-lumen tube **14**. The tube **14** extends completely through the balloon member **18**. More particularly, the balloon member **18** is positioned along an intermediate length of the tube **14**. For reasons to be discussed hereinafter, the balloon member **18** is sized and shaped to inflate into a fully expanded configuration as shown in **FIG. 3** and to deflate into a fully collapsed configuration as shown in **FIG. 2**. Further, when the multi-lumen tube **14** is in its retracted position, the balloon member **18** is in its collapsed configuration and compressed within the outer sheath **12** so as to facilitate insertion into a trocar for delivery to the affected tissue area. When the multi-lumen tube **14** is in its extended position, the balloon member **18** is released from the outer sheath **12** such that it can move between its expanded configuration and collapsed configuration.

[**0018**] The RF device **10** is powered by an RF energy source, such as a conventional electrosurgical generator **20** (shown in phantom in **FIG. 1**). The operating frequency ranges from 300 to 1,000 kHz. As illustrated in **FIG. 3**, the RF device **10** includes a plurality of generally linearly shaped electrode needles **22** for delivering RF energy. The electrode diameters are between 0.25 and 1.0 mm, preferably 0.5 mm. The tips may be beveled, as a hypodermic needle, or other sharp tip. The polarity of the electrode needles **22** can be regulated such that each of the electrode needles **22** can be activated in various arrangements to be used as an active or return electrode. For example, two adjacent electrode needles **22***a*, **22***b* may be active and the remaining two electrode needles **22***c*, **22***d* may be return. Alternatively, adjacent electrode needles **22***a*, **22***b* may be active and return, making an alternating pattern. Alternatively, all electrode needles **22***a*, **22***b*, **22***c*, and **22***d* may be active and the return is a ground pad on the patient (not shown). Each of the electrode needles **22** is attached to the outer surface of the balloon member **18** by conventional attaching means, such as a solvent-based glue. It will be understood that although four electrode needles **22** are shown in **FIG. 3**, the number of electrode needles **22** can vary. The electrosurgical generator **20** is electrically connected to the electrode needles **22** and provides monopolar or bipolar energy to them in order to thermally treat tissue. With reference to **FIG. 4, a** plurality of wire leads **24** extends through the multi-lumen tube **14** and is electrically connected to the electrosurgical generator **20** and to the electrode needles **22**. As shown in **FIG. 4**, each of the electrode needles **22** is attached to one of the wire leads **24**.

[**0019**] When the balloon member **18** is in its collapsed configuration, the electrode needles **22** are in a compressed position, in which the electrode needles **22** are proximate to the multi-lumen tube **14** as shown in **FIG. 2** so as to facilitate insertion within the outer sheath **22**. Further, as the balloon member **18** inflates to its expanded configuration, the electrode needles **22** move to a deployed configuration, in which the electrode needles **22** move radially outward relative to the multi-lumen tube **14** such that each of the electrode needles **22** extends in a substantially parallel relationship relative to the other electrode needles **22** as shown in **FIG. 3**. The balloon member **18** expands to a diameter of between 10 and 50 mm, preferably 20 mm if four electrode needles **22***a*, **22***b*, **22***c*, **22***d* are provided and 30 mm if six electrode needles are provided. After extending, each of the electrode needles **22** is substantially spaced from the other electrode needles **22**. Because RF energy is applied to the affected tissue area interstitially, having substantial spacing between the electrode needles **22** facilitates the spread of RF energy deposition, thereby treating a large volume of tissue. The electrode needles **22** are arranged generally coaxially relative to the tube when the balloon member **18** is in its collapsed configuration and its expanded configuration.

[**0020**] With reference to **FIG. 5**, the multi-lumen tube **14** includes a passageway **26** for receiving air or liquid, either of which can be used to inflate the balloon member **18** (see **FIG. 3**) to its fully expanded configuration (see **FIG. 3**). This could be simply done with a syringe. A passageway **28** is also provided for receiving a vacuum to evacuate the air or liquid from the balloon member **18**, thereby causing it to deflate and assume its fully collapsed configuration as shown in **FIG. 2**. This could also be done with a syringe. Alternatively, the multi-lumen tube **14** can employ a single passageway (not shown) that can receive air, fluid, and vacuum, rather than having the two separate passageways **26**, **28**. Further, a passageway **30** is sized and shaped to allow the wire leads **24** (see **FIG. 4**) to pass therethrough.

[**0021**] Referring to **FIG. 3**, the multi-lumen tube **14** includes a vent **32** for receiving air/liquid from the passageway **26** (see **FIG. 5**), a vent **34** for receiving vacuum from the passageway **28** (see **FIG. 5**), and a plurality of wire vents **36**, each of which is sized and shaped to allow one of the wire leads **24** to pass therethrough and connect to one of the electrode needles **22**. The vents **32**, **34** and the wire vents **36** are located underneath the balloon member **18**.

[**0022**] When inflated as shown in **FIG. 3**, the balloon member **18** has a substantially cylindrically-shaped configuration and includes an interior chamber **38** filled with air or liquid. The balloon member **18** can be made from a material which is selected from a group including silicone, latex, urethane, and other flexible polymers.

[**0023**] In operation, a conventional laparoscopic trocar (not shown) is initially placed through the skin. The RF device **10** is then applied through the laparoscopic trocar such that the RF device **10** enters the open body cavity. Note that in the foregoing step, the multi-lumen tube **14** is in its retracted position (see **FIG. 1**).

[**0024**] As shown in **FIG. 2**, the multi-lumen tube **14** is then extended from the outer sheath **12**. Turning now to **FIG. 3**, the balloon member **18** is fully inflated with air or liquid so as to assume its expanded configuration. As the balloon member **18** inflates, the electrode needles **22** move toward their deployed configuration. The array of electrode needles **22** is now placed into the target tissue. Voltage is then supplied to the electrode needles **22** such that RF energy is emitted therefrom to the tissues surrounding each of the electrode needles **22**. After a predetermined time period between 5 and 50 minutes, preferably 15 minutes, the power to the electrode needles **22** is terminated. Next, the RF device **10** is removed from the target tissue and then from the body cavity by initially deflating the balloon member **18** into its collapsed configuration such that the electrode needles **22** assume their compressed configuration, and then retracting the multi-lumen tube **14** into the outer sheath **12**. Lastly, the device is removed from the body through the trocar.

[**0025**] As is evident from the description above, the present invention provides numerous advantages. For instance, because each of the electrode needles **22** extends in a substantially parallel relationship relative to the other electrode needles **22** as shown in **FIG. 3**, the heating and electric fields will be homogenous along the length of the electrode needles **22**. Only the desired penetration depth is used since the electrode needles **22** can be inserted into tissue between 5 and 50 mm, preferably 30 mm. Further, the RF device **10** provides a more predictable heating than that of competitive devices. The RF device **10** can thermally treat malignant or benign pathologies without requiring surgery.

[**0026**] It should be noted that the RF device **10** can have numerous modifications and variations. For instance, the RF device **10** can be either disposable or non-disposable. The RF device **10** can have laparoscopic applications and can be used to treat various sites such as the liver, the lung, and fibroids on or in the wall of the uterus. Also, the RF device **10** can have percutaneous applications and can be used to treat various sites such as the breast and the prostate. The RF device **10** can employ other means, rather than the balloon member **18**, to deploy the electrode needles **22**. For example, the RF device **10** can employ mechanical means to space the electrode needles **22**. The electrode needles **22** can be insulated in sections to regulate the conductive portion and the heating field. In such aspects, RF current will flow only through the needle portion that is not covered by insulation. The RF device **10** can employ alternative energy sources such as laser fibers, ultrasound PZT based cylinders, chemical, microwave antennas, and/or a cryogenic device. The foregoing energy sources can include either catheters or needles. All such variations and modifications are intended to be included within the scope of the invention as defined in the appended claims.

What is claimed is:

1. A medical device used for thermal treatment of tissue, comprising an elongated tube having a longitudinal axis; an expandable member attached to said elongated tube, said expandable member being expandable from a collapsed configuration to an expanded configuration; and a plurality of energy-emitting electrodes attached to said expandable member such that each of said electrodes is arranged generally coaxially relative to said tube when said expandable member is in its said collapsed and expanded configurations.

2. The medical device of claim 1, further comprising a sheath sized and shaped so as to receive said tube and said expandable member when said expandable member is in its said collapsed configuration.

3. The medical device of claim 2, wherein each of said electrodes moves radially outward from said tube as said expandable member moves from its said collapsed configuration to its said expanded configuration.

4. The medical device of claim 3, wherein said electrodes are in close proximity to each other when said expandable member is in its said collapsed configuration and wherein said electrodes are spaced apart from each other when said expandable member is in its said expanded configuration.

5. The medical device of claim 4, wherein said tube extends completely through said expandable member, whereby said expandable member is positioned along an intermediate length of said tube.

6. The medical device of claim 5, wherein each of said electrodes has a generally linear shape.

7. The medical device of claim 6, wherein said tube is movable between a retracted position, in which said tube retracts into said sheath, and an extended position, in which said tube extends axially outward from said sheath.

8. The medical device of claim 7, wherein said tube includes a plurality of channels, at least one of said channels being sized and shaped so as to allow a fluid to pass therethrough.

9. The medical device of claim 8, wherein said expandable member is expandable to its said expanded configuration when a fluid is passed through said at least one of said channels.

10. The medical device of claim 9, wherein said expandable member is collapsible to its said collapsed configuration when a vacuum is supplied to said expandable member through at least another of said channels.

11. The medical device of claim 10, further comprising a plurality of wire leads connected to said electrodes.

12. The medical device of claim 11, wherein at least another of said channels is sized and shaped to allow said wire leads to pass therethrough.

13. The medical device of claim 12, wherein said expandable member is a balloon member.

14. The medical device of claim 13, wherein said electrodes emit RF energy.

15. The medical device of claim 14, wherein said balloon member is substantially cylindrically-shaped when it is in its said expanded configuration.

16. The medical device of claim 15, wherein said electrodes surround said tube when said balloon member is in its expanded configuration.

17. The medical device of claim 16, wherein said expandable member is attached to said tube by a solvent-based glue.

18. A method for performing thermal treatment of tissue using a medical device which includes a tube, an expandable member attached to the tube and expandable from a collapsed configuration to an expanded configuration, and a plurality of electrodes attached to the expandable member, said method comprising the steps of:

(a) inserting the medical device within a tissue area with the expandable member in its collapsed configuration, in which the electrodes are in close proximity to each other and in which all of the electrodes are arranged generally coaxially relative to the tube; and

(b) expanding the expandable member so that it assumes its expanded configuration, in which the electrodes are spaced apart from each other and, in which all of the electrodes are arranged generally coaxially relative to the tube.

19. The method of claim 18, wherein the method is used in a laparoscopic application.

20. The method of claim 19, wherein the method is used in a percutaneous application.

* * * * *

专利名称(译)	扩展治疗阵列的装置和方法		
公开(公告)号	US20040002747A1	公开(公告)日	2004-01-01
申请号	US10/186389	申请日	2002-06-28
[标]申请(专利权)人(译)	ETHICON. INC		
申请(专利权)人(译)	ETHICON INC.		
当前申请(专利权)人(译)	ETHICON INC.		
[标]发明人	RYAN THOMAS P SINTON ALEXANDER J		
发明人	RYAN, THOMAS P. SINTON, ALEXANDER J.		
IPC分类号	A61B18/14 A61F2/00		
CPC分类号	A61B18/1477 A61B18/1482 A61B2018/143 A61B2018/0022 A61B2018/00214		
外部链接	Espacenet USPTO		

摘要(译)

提供了一种医疗装置，其包括细长管，该细长管具有纵向轴线和附接到管的可扩张构件。可扩张构件可从收缩构型扩张到扩张构型。多个电极附接到可扩张构件。电极用于发射能量。当可扩张构件处于其收缩和扩张构型时，每个电极通常相对于管同轴地布置。