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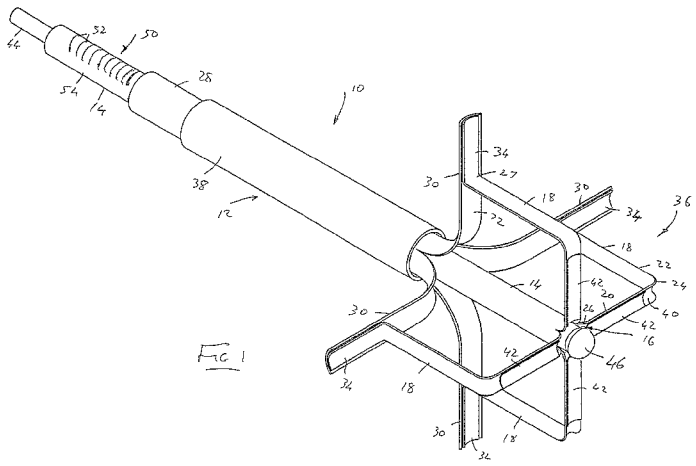
(54) Title: A CATHETER



(57) Abstract: A catheter sheath (12) includes a tubular member (14), a distal region of the tubular member defining a plurality of discrete elements (18), the discrete elements (18) being displaceable between a first, inoperative position in which the discrete elements (18) extend substantially parallel to a longitudinal axis of the tubular member (14) and a second, operative position in which at least a portion (20) of each of the discrete elements (18) projects outwardly transverse to the longitudinal axis of the tubular member (14). At least one electrode (42) carried at least by the portion (20) of the at least one of the discrete elements (18), the at least one electrode (42) being exposed when the discrete elements (18) are in their second position. A sleeve (38) is mounted about the tubular member (14). A bracing structure (22, 30, 34) is interposed between a distal part of the sleeve (38) and the portions (20) of the discrete elements (18) to brace the portions (20) of the discrete elements (18) in their operative position.

WO 2010/000020 A1

"A catheter"

Cross-Reference to Related Applications

The present application claims priority from United States of America Provisional Patent Application No 61/077,037 filed on 30 June 2008, the contents of which are incorporated herein by reference.

Field

This invention relates generally to the field of catheters and, more particularly, to a catheter sheath for a catheter assembly and to a catheter assembly including the catheter sheath.

Background

In the field of heat treatment of tissue, it is desirable if the device heating the tissue is in contact only with the tissue being treated and not surrounding tissue or bodily fluids. This minimises the power required to heat the tissue and also minimises unnecessary damage to other tissue, structures or fluid.

In addition, it is often necessary to overcome tissue irregularities at a site in a patient's body being heat treated. An example where a site in a patient's body is subjected to heat treatment is in the treatment of heart arrhythmias where tissue is ablated in an effort to cure the arrhythmia. The tissue is ablated to create a lesion to block the electrical impulses causing the arrhythmia. To ensure that a lesion of adequate depth is formed, it is desirable that the ablating electrode make good contact with the tissue. Other examples of the use of heat treatment at a site in a patient's body include treatment of Parkinson's disease, tumour ablation, endometriosis and pain management.

Still further, in the treatment of a heart arrhythmia, it may be necessary to ablate over a reasonably wide area in an attempt to cure the arrhythmia. It is therefore desirable to be able to obtain such larger ablated areas with minimum manipulation of the catheter when in position at the site to be treated.

Summary

In a first aspect, there is provided a catheter sheath which includes

a tubular member, a distal region of the tubular member defining a plurality of discrete elements, the discrete elements being displaceable between a first, inoperative position in which the discrete elements extend substantially parallel to a longitudinal axis of the tubular member and a second, operative position in which at least a portion

of each of the discrete elements projects outwardly transverse to the longitudinal axis of the tubular member;

at least one electrode carried at least by the portion of the at least one of the discrete elements, the at least one electrode being exposed when the discrete elements are in their second position;

a sleeve mounted about the tubular member, and

a bracing structure interposed between a distal part of the sleeve and the portions of the discrete elements to brace the portions of the discrete elements in their operative position.

The bracing structure may be a collapsible structure and may be erected into its operative, bracing configuration when the portions of the discrete elements are in their operative position.

Preferably, the bracing structure is defined partially by distal parts, or leaves, of the sleeve and partially by additional portions of the discrete elements.

In a second aspect, there is provided a catheter sheath which includes

a tubular member, a distal region of the tubular member defining a plurality of discrete elements, the discrete elements being displaceable between a first, inoperative position in which the discrete elements extend substantially parallel to a longitudinal axis of the tubular member and a second, operative position in which a first portion of each of the discrete elements projects outwardly transverse to the longitudinal axis of the tubular member;

a sleeve mounted about the tubular member, a distal part of the sleeve defining a plurality of leaves and each discrete element of the tubular member being attached to one of the leaves of the sleeve, the sleeve and the tubular member being displaceable axially with respect to each other for effecting displacement of the discrete elements between their first and second positions and, when the discrete elements of the tubular member are in their second position, a second portion of each discrete element, outwardly of the first portion, extends towards a proximal end of the tubular member; and

at least one electrode carried by at least the first portion of at least one of the discrete elements with the at least one electrode being exposed when the discrete elements are in their second position.

When the discrete elements of the tubular member are in their operative position, the discrete elements and the leaves of the sleeve may define a substantially box-frame shaped structure at a distal end of the tubular member.

Preferably, the first portion of each discrete element carries at least one electrode. The at least one electrode may be arranged on an operatively inner surface of its associated discrete element so that, when the discrete elements are in their first position, the electrodes are contained within the interior of the tubular member.

Each discrete element may be attached to its associated leaf by a pad portion which is secured to the leaf. The pad portions splay outwardly when the discrete elements are in their second position and define bracing points to enhance tissue-electrode contact, in use. Further, the second portion of each discrete element may extend between the pad portion and the first portion and may act as a strut for enhancing contact of the at least one electrode with tissue at a site in a patient's body.

Bending zones may be defined at a junction between each discrete element and the tubular member and at a junction between the first portion and the second portion of each discrete element so that each discrete element has at least two articulations, or joints. It will be appreciated that the joints may be integrally formed with the portions of the discrete element to provide the bending zones. Instead the joints may be discrete elements such as hinges, zones of weakness, score lines, or the like.

According to a third aspect of the invention, there is provided a catheter assembly which includes

a catheter sheath as described above; and

a support member arranged within a lumen of the tubular member.

The catheter assembly may include an operating member for displacing the discrete elements of the catheter sheath from the second position to the first position. The operating member may be a tube displaceably arranged about the sleeve. The tube may be displaced distally to effect "closing" or collapsing of the catheter sheath.

The catheter assembly may include an end electrode carried on a distal end of the support member. In an embodiment, the support member may be displaceably arranged relative to the tubular member so that, when the discrete elements are in their second position, the end electrode is brought into a position in which it lies approximately in a plane in which the first portions of the discrete elements lie.

Brief Description of Drawings

Fig. 1 shows a three dimensional view of a distal part of an embodiment of a catheter assembly in an open, operative configuration;

Fig. 2 shows a sectional side view of the distal part of the catheter assembly in its operative configuration; and

Fig. 3 shows a sectional side view of the distal part of the catheter assembly in a closed, inoperative configuration.

Detailed Description of Exemplary Embodiment

In the drawings, reference numeral 10 generally designates an embodiment of a catheter assembly. The catheter assembly 10 comprises an embodiment of a catheter sheath 12. The catheter sheath 12 includes an inner, tubular member 14 defining a lumen 16. A plurality of discrete elements, or limbs, 18 are defined at a distal end of the tubular member 14. Each limb 18 is an articulated limb having a first portion 20 connected to a second, outer portion 22 via a bending zone 24. A proximal end of each limb 18 is connected to a distal end of the tubular member via a further bending zone 26.

The catheter sheath 12 further includes a sleeve 28 mounted about the tubular member 14. The sleeve 28 is axially, displaceably arranged relative to the tubular member 14. A distal end of the sleeve 28 defines a plurality of discrete leaves 30. There are the same number of leaves 30 as there are limbs 18 of the tubular member 14. Each limb 18 of the tubular member 14 is connected to an operatively inner surface 32 of its associated leaf 30 of the sleeve 28.

For this purpose, each limb 18 terminates in a pad or foot portion 34 which is secured to the surface 32 of its associated leaf 30. A further bending zone 27 is defined between a distal end of the portion 22 and the pad portion 34 of each limb 18. The arrangement is such that the pad portions 34 provide bracing for a substantially box-frame shaped structure 36 formed at the end of the tubular member 14, as will be described in greater detail below, in use.

The catheter assembly 10 includes an operating member in the form of a tube 38. The tube 38 is axially displaceable relative to the sleeve 28 and is used for collapsing the structure 36 after use.

In the illustrated embodiment, an operatively inner surface 40 of each portion 20 of each limb 18 carries an elongate electrode 42. It will, however, be appreciated that, in other embodiments, each portion 20 could carry a different shaped electrode, a series of spaced electrodes or be free of electrodes, as the case may be.

The catheter assembly 10 further includes a support member 44 arranged within the lumen 16 of the tubular member 14. A distal end of the support member 44 carries an end electrode 46 which, when the structure 36 is in its operative position, as illustrated in Figs. 1 and 2 of the drawings, lies approximately in the same plane as the electrodes 42 on the limbs 18 of the tubular member 14.

In an embodiment, the support member 44 is fixed within the tubular member 14 and, when the structure 36 is in its collapsed, inoperative position, the structure 36 surrounds the electrode 46 of the support member 44 as shown in Fig. 3 of the drawings. In another embodiment (not illustrated), the support member 44 is displaceably arranged relative to the tubular member 14 so that, when the structure 36 is in its collapsed configuration, the end electrode 46 is arranged distally of the structure 36. When the structure 36 is erected into its operative configuration, as illustrated in Figs. 1 and 2 of the drawings, the support member 44 is displaced proximally with respect to the structure 36 to bring the end electrode 36 into a position in which it lies approximately in the same plane as a plane in which the electrodes 42 of the tubular member 14 lie. A suitable device for effecting relative displacement between the catheter sheath 12 and the support structure 44 is described in the Applicant's European Patent No. 1902746 filed 18 September 2008 and entitled "Catheter Actuator".

It is also to be noted that, in the illustrated embodiment, the end electrode 46 is a button-shaped electrode. It will, however, be appreciated that, instead, the end electrode 46 could be a needle electrode to facilitate percutaneous therapy at a site in a patient's body.

To facilitate deflection of a distal end of the catheter sheath 12, at least one of the tubular member 14 and the sleeve 28 defines a deflection zone 50. In this embodiment, the tubular member 14 is illustrated as defining the deflection zone 50. The deflection zone 50 comprises a plurality of longitudinal spaced slots formed in the tubular member 14, for example, by laser cutting. The slots 52 extend approximately two thirds to three quarters of the way about the periphery of the tubular member 14 to leave a longitudinally extending spine zone 54 about which the tubular member 14 can be deflected for effecting steering of the distal end of the catheter sheath 12.

Further, it will be appreciated that each electrode 42, 46 has conductors (not shown) associated with it. The conductors for the electrodes 42 may be arranged within the lumen 16 of the tubular member 14 or, instead, may be embedded within a sidewall of the tubular member 14 as taught in the applicant's International Patent Application No. PCT/AU0 1/0 1339 dated 19 October 2001 entitled "An electrical lead". The conductors for the end electrode 46 may be contained within a lumen (not shown) of the support member 44. It will be appreciated that each electrode 42, 46 has four conductors associated with it being a pair of conductors for the delivery of RF energy and a Constantin/copper wire pair for sensing temperature of the electrode 42, 46 and tissue in the region of the electrode 42, 46.

The tubular member 14, the sleeve 28 and the tube 38 are all of a suitable synthetic plastics material which is biocompatible. For example, the tubular member 14 is of a polyetheretherketone (PEEK) material as is the sleeve 28. The tube 38 is also of a suitable synthetic plastics material such as a polyether block amide material such as Pebax®.

In use, the catheter assembly 10 is intended particularly for use in the treatment of heart arrhythmias and, more particularly, atrial fibrillation in a patient's heart. Atrial fibrillation is treated by ablation therapy and the electrodes 42 and 46 are used for the delivery of RF energy to tissue with which the electrodes 42, 46 are in contact to effect ablation of the tissue and to interrupt electrical pathways giving rise to the atrial fibrillation. Thus, in use, with the end structure 36 in a collapsed configuration, as shown in Fig. 3 of the drawings, the catheter assembly 10 is inserted through the patient's vasculature to enable the catheter assembly 10 to be steered to the desired site in the patient's heart.

When the catheter 10 is inserted into the patient's heart, the catheter 10 is inserted through the right atrium and punctures the septum of the heart through the fossa ovalis in the septum. The tube 38 is urged proximally relative to the rest of the tubular members, thus exposing the structure 36. The structure 36 then expands into its erected, operative configuration to enable ablation therapy to be effected. For this purpose, the leaves 30 may include biasing members (not shown), such as leaf springs of a suitable resiliently flexible material arranged within each leaf 30 or on an outer surface of each leaf 30, which urge the leaves 30 into their operative configuration and result in the structure 36 being formed.

At the desired site, the sleeve 28 is pulled proximally with respect to the tubular member 14. This causes the structure 36 to be expanded into its operative configuration. More particularly, each first portion 20 of the limbs 18 bends radially outwardly, with respect to a longitudinal axis of the catheter assembly 10, to extend substantially transversely relative to the longitudinal axis, the first portion bending about the bending zone 26.

The portions 22 of the limbs 18 face towards the proximal end of the catheter assembly 10 and serve as struts for supporting the portions 20 of the limbs 18 in their operative outwardly extending configuration.

The bending zones 24, 26 and 27 of each limb 18 are integrally formed with the limb 18 and need not be in the form of hinges, any discrete structure, any other zone of weakness, or the like. The bending zones 24, 26 and 27 provide articulations for articulation of the portion 20 of each limb 18 relative to the portion 22, articulation of

the portion 20 relative to the distal end of the tubular member 14 and articulation between the portion 22 and the pad portion 34, respectively. It will be appreciated that, although not essential, by having some form of zone of weakness in the region of the bending zones 24, 26 and 27, bending of the limbs 18 into their operative configuration is facilitated.

If the end electrode 46 had been arranged distally of the structure 36 when the structure 36 was in its collapsed configuration, the support member 44 is drawn proximally with respect to the structure 36 to bring the electrode 46 into register with the electrodes 42 of the structure 36.

Selected electrodes 42, 46 are then used for effecting ablation therapy at the site in the patient's body. The electrodes 42, being elongate, allow long, shallow lesions to be formed.

In addition, due to the strut-like arrangement of the end structure 36, improved electrode-tissue contact occurs between the electrodes 42 and the tissue at the site in the patient's heart because a greater, distally directed force can be exerted on the structure 36 than would be the case if distal ends of the portions 20 were unsupported. It will be appreciated that, by having improved tissue-electrode contact, improved lesion formation is facilitated.

Once the ablation therapy has been completed, the sleeve 28 is urged distally with respect to the tubular member 14. This causes the structure 36 to collapse to the position shown in Fig. 3 of the drawings. When the structure 36 is in its collapsed configuration, the leaves 30 of the sleeve 28 extend distally, parallel to the longitudinal axis of the catheter assembly 10. Similarly, the limbs 18 of the tubular member 14 also extend distally, parallel to the longitudinal axis. After collapsing of the structure 36, the tube 38 is urged distally to cover the collapsed structure 36 which facilitates withdrawal of the catheter assembly 10 from the patient's heart.

It is a particular advantage of the described embodiments that a compact catheter assembly 10 is provided which, when in its operative configuration, facilitates the formation of long lesions at a site in a patient's body. The arrangement of the structure 36 further facilitates tissue-electrode contact thereby improving lesion formation. It will also be appreciated that, while the lesions formed using the electrodes 42 are longer, they are also shallower. Shallower lesions result in less trauma but more effective treatment of heart arrhythmias. It is also a particular advantage that, by having longer electrodes 42, fewer ablating procedures need to be carried out in the treatment of arrhythmogenic foci. This simplifies the clinician's task.

It also allows more rapid treatment to be effected thereby reducing trauma to the patient and reduced convalescing time.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the embodiments as described without departing from the broadly described scope. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

CLAIMS:

1. A catheter sheath which includes

a tubular member, a distal region of the tubular member defining a plurality of discrete elements, the discrete elements being displaceable between a first, inoperative position in which the discrete elements extend substantially parallel to a longitudinal axis of the tubular member and a second, operative position in which at least a portion of each of the discrete elements projects outwardly transverse to the longitudinal axis of the tubular member;

at least one electrode carried at least by the portion of the at least one of the discrete elements, the at least one electrode being exposed when the discrete elements are in their second position;

a sleeve mounted about the tubular member, and

a bracing structure interposed between a distal part of the sleeve and the portions of the discrete elements to brace the portions of the discrete elements in their operative position.

2. The catheter sheath of claim 1 in which the bracing structure is a collapsible structure and is erected into its operative, bracing configuration when the portions of the discrete elements are in their operative position.

3. The catheter sheath of claim 1 or claim 2 in which the bracing structure is defined partially by distal parts of the sleeve and partially by additional portions of the discrete elements.

4. A catheter sheath which includes

a tubular member, a distal region of the tubular member defining a plurality of discrete elements, the discrete elements being displaceable between a first, inoperative position in which the discrete elements extend substantially parallel to a longitudinal axis of the tubular member and a second, operative position in which a first portion of each of the discrete elements projects outwardly transverse to the longitudinal axis of the tubular member;

a sleeve mounted about the tubular member, a distal part of the sleeve defining a plurality of leaves and each discrete element of the tubular member being attached to one of the leaves of the sleeve, the sleeve and the tubular member being displaceable axially with respect to each other for effecting displacement of the discrete elements between their first and second positions and, when the discrete elements of the tubular

member are in their second position, a second portion of each discrete element, outwardly of the first portion, extends towards a proximal end of the tubular member; and

at least one electrode carried by at least the first portion of at least one of the discrete elements with the at least one electrode being exposed when the discrete elements are in their second position.

5. The catheter sheath of claim 4 in which, when the discrete elements of the tubular member are in their operative position, the discrete elements and the leaves of the sleeve define a substantially box-frame shaped structure at a distal end of the tubular member.

6. The catheter sheath of claim 4 or claim 5 in which the first portion of each discrete element carries at least one electrode.

7. The catheter sheath of claim 6 in which the at least one electrode is arranged on an operatively inner surface of its associated discrete element so that, when the discrete elements are in their first position, the electrodes are contained within the interior of the tubular member.

8. The catheter sheath of any one of claims 4 to 7 in which each discrete element is attached to its associated leaf by a pad portion which is secured to the leaf.

9. The catheter sheath of claim 8 in which the second portion of each discrete element extends between the pad portion and the first portion and acts as a strut for enhancing contact of the at least one electrode with tissue at a site in a patient's body.

10. The catheter sheath of any one of claims 4 to 9 in which bending zones are defined at a junction between each discrete element and the tubular member and at a junction between the first portion and the second portion of each discrete element so that each discrete element has at least two articulations.

11. A catheter assembly which includes

a catheter sheath as claimed in any one of the preceding claims; and

a support member arranged within a lumen of the tubular member.

12. The catheter assembly of claim 11 which includes an operating member for displacing the discrete elements of the catheter sheath from their second position to their first position.

13. The catheter assembly of claim 12 in which the operating member is a tube displaceably arranged about the sleeve of the catheter sheath.

14. The catheter assembly of any one of claims 11 to 13 which includes an end electrode carried on a distal end of the support member.

15. The catheter assembly of claim 14 in which the support member is displaceably arranged relative to the tubular member so that, when the discrete elements are in their second position, the end electrode is brought into a position in which it lies approximately in a plane in which the first portions of the discrete elements lie.

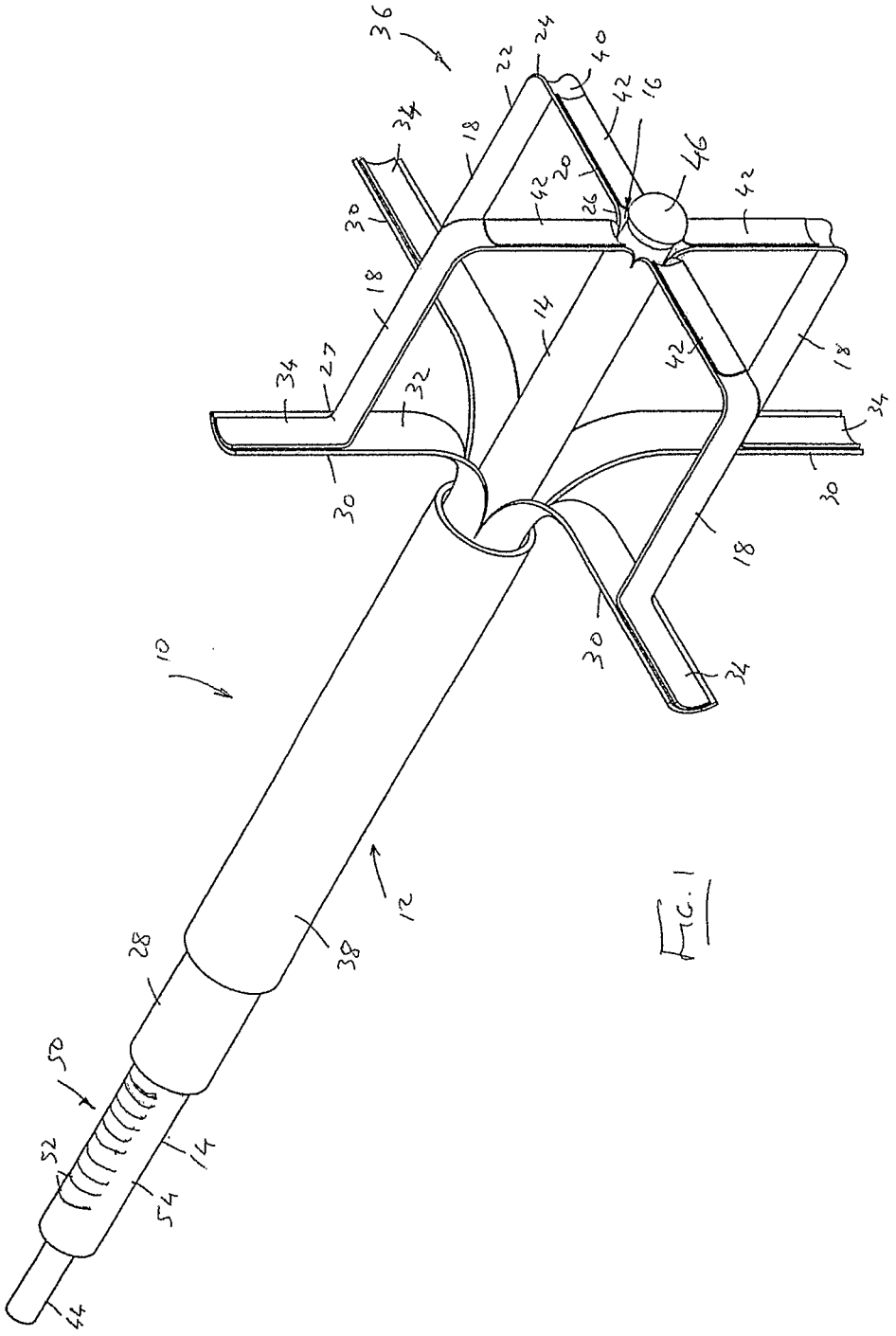


FIG. 1

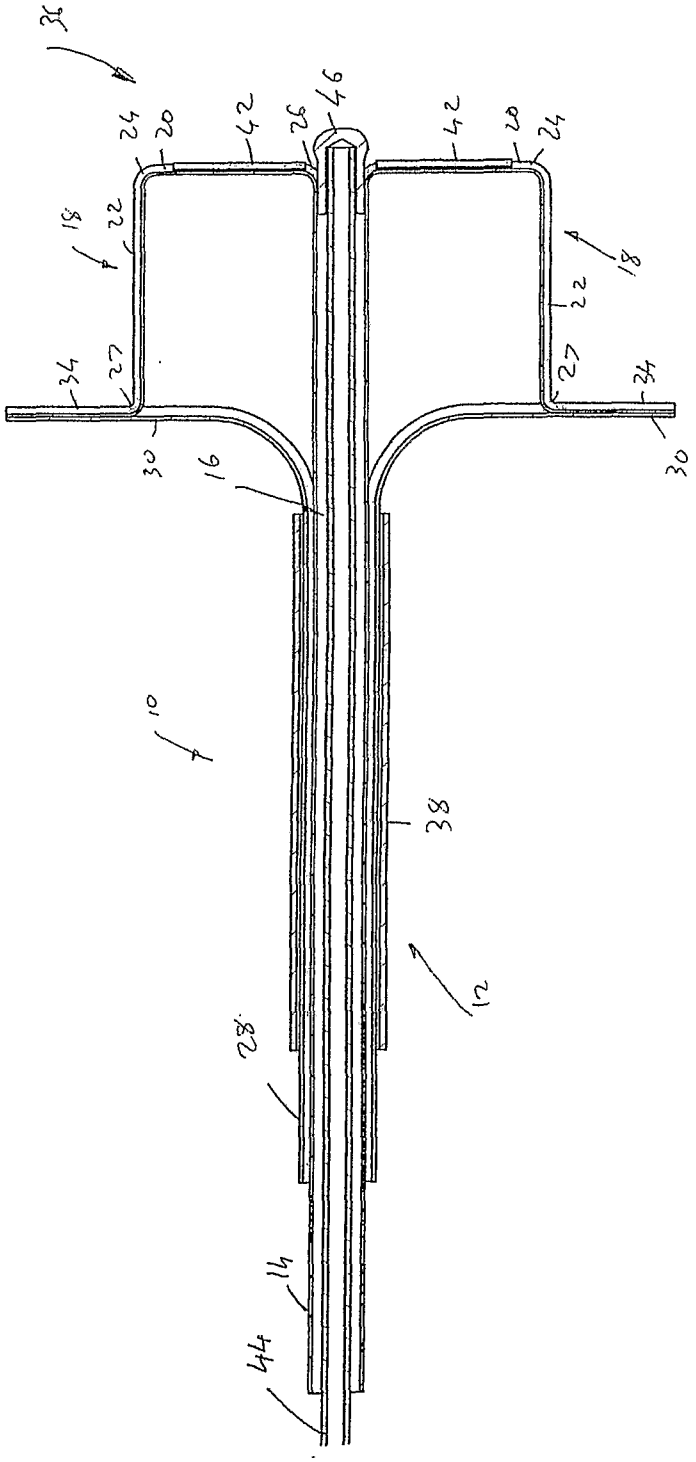

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FIG. 2

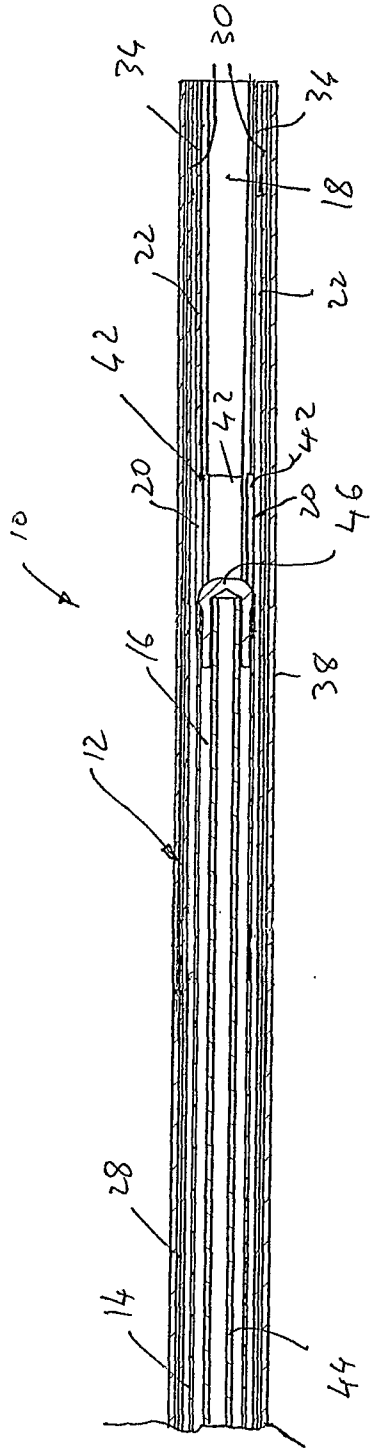

FIG. 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2009/000839

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61M 25/01 (2006.01) *A61M 25/088* (2006.01)

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)

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPODOC AND WPI, KEYWORDS: CATHETER?, ELECTRODE?, EXPAND+, COLLAPS+. FOLD+, OPEN+, CLOSE+, CONTRACT+, PIVOT+, BRAC+, SCAFFOLD+, STRUT?, FRAM+, TRANSVERSE, ORTHOGONAL, ETC.
ESP@CENET, KEYWORDS: CATHETER, ELECTRODE, EXPAND

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
X Y	WO 1996/034652 A1 (HEART RHYTHM TECHNOLOGIES, INC.) 07 Nov 1996 See, in particular, figures 1 to 5; page 9, lines 4 to 20; page 15, lines 19 to 22	1-6, 8-15 7
Y	US 5782239 A (WEBSTER, JR.) 21 Jul 1998 See, in particular, abstract; figure 16	7

D Further documents are listed in the continuation of Box C

X 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 patenl 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 dale 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 (he document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

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Date of the actual completion of the international search	Date of mailing of the international search report
02 September 2009	7 SEP 2009

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU2009/000839

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
WO	1996/034652	US	5681280				
US	5782239	CA	2220071	EP	0879016	JP	6205837
		US	541 1025	US	5628313	US	5772590
		WO	1996/034559				

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001 .

END OF ANNEX