(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
1 June 2006 (01.06.2006)

PCT

(10) International Publication Number
WO 2006/058253 A1

(51) International Patent Classification:
A61B 18/18 (2006.01)

(21) International Application Number:
PCT/US2005/042815

(22) International Filing Date:
23 November 2005 (23.11.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/997,713 24 November 2004 (24.11.2004) US
11/107,190 15 April 2005 (15.04.2005) US

(71) Applicant *(for all designated States except US)*: **ABLATION FRONTIERS, INC.** [US/US]; 5838 Avenida Encinas, Suite 118, Carlsbad, California 92008 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **HAKAN, Oral** [TR/US]; 1754 Hgih Pointe Lane, Ann Arbor, Michigan 48108 (US). **WERNETH, Randell** [US/US]; 10228 Lone Dove Street, San Diego, California 92127 (US). **CASTELLANO, Thomas** [US/US]; 39960 Sweetbrier Circle, Temecula, California 92591 (US). **KUNIS, Christopher** [US/US]; 26228 Crescendo Dr., San Diego, California 92026 (US). **CURRIE, Gary** [US/US]; 2582 Havencrest Drive, Fallbrook, California 92028 (US).

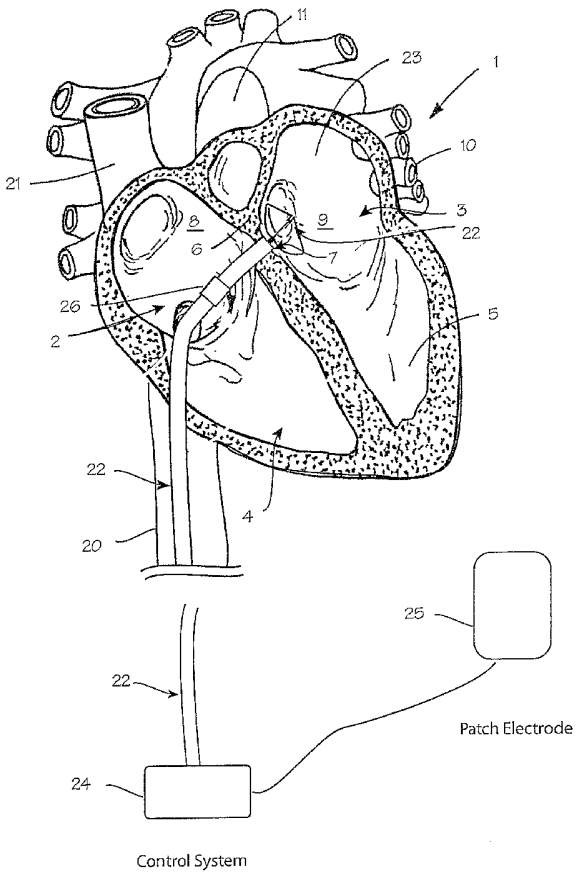
(74) Agent: **WIEZOREK, Mark**; C/O MAYER & WILLIAMS, PC, 251 North Avenue West, 2nd Floor, Westfield, New Jersey 07090 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH,

[Continued on next page]

(54) Title: ATRIAL ABLATION CATHETER



(57) Abstract: An atrial ablation catheter with an electrode array particularly adapted to locate and ablate foci of arrhythmia which are required for sustained atrial fibrillation is provided. The array is easily deployed and retracted from the catheter, and presents a proximally oriented electrode array that can be pulled against the septal wall of the left atrium to engage the septal wall.

WO 2006/058253 A1

GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

PCT

WIPO PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 8002/5 PCT	**FOR FURTHER ACTION** see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US05/42815	International filing date (*day/month/year*) 23 November 2005 (23.11.2005)	(Earliest) Priority Date (*day/month/year*) 24 November 2004 (24.11.2004)
Applicant ABLATION FRONTIERS, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the Report**
   a. With regard to the **language**, the international search was carried out on the basis of:
      ☒ the international application in the language in which it was filed.
      ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.
2. ☒ **Certain claims were found unsearchable** (See Box No. II)
3. ☐ **Unity of invention is lacking** (See Box No. III)
4. With regard to the **title**,
   ☐ the text is approved as submitted by the applicant.

ATRIAL ABLATION CATHETER

5. With regard to the **abstract**,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
6. With regard to the **drawings**,
   a. the figure of the **drawings** to be published with the abstract is Figure No. 1
      ☒ as suggested by the applicant.
      ☐ as selected by this Authority, because the applicant failed to suggest a figure.
      ☐ as selected by this Authority, because this figure better characterizes the invention.
   b. ☐ none of the figures is to be published with the abstract.

ATRIAL ABLATION CATHETER

This application is a continuation-in-part of U.S. Patent Application 10/997,713 filed November 24, 2004.

Field of the Inventions

The inventions described below relate the field of atrial ablation.

Background of the Inventions

Atrial fibrillation is a form of arrhythmia, or irregular heartbeat, in which the atria (the two small upper chambers of the heart) quiver instead of beating effectively. While there are a number of variations of atrial fibrillation with different causes, they all involve irregularities in the transmission of electrical impulses through the heart. As a result of abnormalities in the heart's electrical impulses, the heart is not able to pump the blood out properly, and it may pool and clot. If a blood clot moves to an artery in the brain, AF can lead to stroke. AF is also associated with increased risks of congestive heart failure and cardiomyopathy. These risks warrant medical attention for patients with AF even if the symptoms are mild. Atrial fibrillation is the most common sustained heart rhythm disorder and increases the risk for heart disease and stroke, both leading causes of death in the United States. Over 2 million adults in the United States have been diagnosed with atrial fibrillation.

Various ablation techniques have been proposed to treat atrial fibrillation, including the Cox-Maze procedure, linear ablation of various regions of the atrium, and circumferential pulmonary vein ablation. Each of these techniques has its various drawbacks. The Cox-Maze procedure and linear ablation procedures are tedious and time-consuming, taking up to several hours to accomplish endocardially. Circumferential ablation is proving to lead to rapid stenosis and occlusion of the pulmonary veins, and of course is not applicable to treatment of the septal wall of the left atrium. The catheter mounted electrode arrays described in our co-pending patent application Kunis, et al., Atrial Ablation Catheter and Method of Use, U.S. App. 10/997,172 filed November 24, 2004 provide for more efficient and effective treatment of atrial fibrillation. The treatment of the septal wall is facilitated with the devices and methods described below, which permit septal wall treatment from a percutaneous venous access route without the need to maneuver a distally facing electrode array in apposition to the septal wall.

Summary

The devices and methods described below provide for a simplified approach to the treatment of atrial fibrillation with substantially improved efficacy and outcomes in patients with paroxysmal or persistent atrial fibrillation, especially for those arrhythmia originating from, or sustained by, arrhythmogenic foci located on the septal wall of the left atrium. An endocardial catheter with an electrode array particularly adapted to locate and ablate foci of arrhythmia which are required for sustained atrial fibrillation is provided. The array is easily deployed and retracted from the catheter, and presents a proximally oriented electrode array

that can be pulled against the septal wall of the left atrium to engage the septal wall. A control system comprising an ECG analyzer and a RF power supply operates to analyze electrical signals obtained from the electrode array, determine if an arrhythmogenic focus is present in the area covered by the array, and supply RF power to appropriate electrodes to ablate the focus.

Brief Description of the Drawings

Figure 1 illustrates the treatment to be accomplished with the devices and methods described below.

Figure 2 illustrates an atrial sensing and ablation catheter with an expandable electrode array constrained within an outer catheter tube.

Figure 3 is an enlarged view of the distal portion of the catheter of Figure 2.

Figure 4 is a cross-section of the distal portion of the catheter of Figure 2.

Figure 5 illustrates the atrial sensing and ablation catheter of Figure 2 with the electrode array in its expanded configuration.

Figure 6 and 6a is an enlarged view of the electrode array in its expanded configuration.

Figure 6b illustrates the meaning of the terminology which precisely defines the electrode array of Figures 5 and 6

Figure 7 is an end view of the electrode array in its expanded configuration.

Figure 7a is an end view of the electrode array, with an asymmetric arrangement of electrodes, in its expanded configuration.

Figures 8 and 9 illustrate the mechanism of recapture of the electrode array of the atrial ablation catheter.

Figure 10 and 10a illustrates an alternate geometry of the septal wall array.

Figure 10b illustrates the meaning of the terminology which precisely defines the electrode array of Figures 10 and 10a.

Figures 11, 12 and 13 illustrate additional alternative geometries of the array.

Figure 14 and 15 illustrate the method of using the device of to treat the septal wall of the left atrium.

Detailed Description of the Inventions

Figure 1 illustrates the treatment to be accomplished with the devices and methods described below. Figure 1 shows a cutaway view of the human heart **1**, showing the major structures of the heart including the right atrium **2**, the left atrium **3**, the right ventricle **4**, and the left ventricle **5**. The atrial septum **6** separates the left and right atria. The fossa ovalis **7** is a small depression in the atrial septum which is easily punctured and easily heals. The percutaneous venous approach through the right atrium and the fossa ovalis is the preferred access pathway to the left atrium. In a patient suffering from atrial fibrillation, aberrant electrically conductive tissue may be found in the atrial walls **8** and **9**, including the septal wall surrounding the fossa ovalis, as well as in the pulmonary veins **10** and pulmonary arteries **11**. These areas of aberrant

electrically conductive tissue, referred to as arrhythmogenic foci, drivers or rotors, cause or sustain atrial fibrillation. Ablation of these areas is an effective treatment for atrial fibrillation. Though circumferential ablation of the pulmonary veins cures the arrhythmia which originates in the pulmonary veins, it often results in rapid stenosis of the pulmonary veins. Ablation of foci, rotors or drivers on atrial walls, however, may prevent the propagation of any aberrant electrical activity that originates in the pulmonary veins, originates in other regions of the atrial wall, or originates on the septal wall itself.

To accomplish ablation of the septal wall of the left atrium, a catheter is inserted into the atrium, preferably through the inferior vena cava **20**, as shown in the illustration, or through the superior vena cava **21**, into the right atrium and then into left atrium. When passing into the left atrium, as illustrated, the catheter penetrates the fossa ovalis (a trans-septal puncture will facilitate the crossing). The catheter **22** carries a distal electrode array **23** into the atrium, and this electrode array is adapted to be pulled into contact with the section of the atrial wall surrounding the fossa ovalis. The electrode array is electrically connected to circuitry in a control system **24** which is operable to analyze electrical signals detected by the electrodes and pass RF current through the electrodes and heart tissue to ablate the tissue. A surface electrode **25** is mounted on the patient's body (typically on the back) to permit use of the electrodes in monopolar modes. A return electrode **26** may also be provided on the catheter 22, proximal to the electrode array. Using the catheter, an electrophysiologist will map regions of the septal wall of the left atrium and apply energy through the catheter to ablate any arrhythmogenic foci which are identified in the mapping

procedure. The procedure may be repeated as necessary on the septal wall, rotating the array if necessary, to ablate all detected foci.

Figure 2 illustrates an atrial sensing and ablation catheter 22 with an expandable electrode array. The catheter comprises a handle **30** with a steering control knob **31**, electrical connector **32** and side-arm connector **33**. The electrical connector is used to connect the catheter to the control box. An outer catheter tube **34** is slidably mounted on the inner catheter tube **35**, and they may be releasably secured to each other by sliding the proximal portion of the outer catheter sheath strain relief **36** over the cylindrical detent **37** which is fixed to the handle. The side arm connector is used as a flushing port, to allow the flushing of debris and blood from the space between the inner and outer catheter tubes. The electrode array 23 is fixed to the inner catheter tube 35, and is restrained within the distal portion of the outer catheter tube 34.

Figure 3 is an enlarged view of the distal portion of the catheter of Figure 2. The electrode array 23 comprises a number of resiliently biased arms **39** which each carry a number of electrodes **40**. An array of three arms, each of which carry four electrodes, is suitable for use in the atria. The arms each comprise a wire (preferably a flat wire) with a distal section **41**, a proximal section **42** and an intervening bend section **43**. The electrodes are placed on the proximal sections. The proximal end of each arm is fixed to the inner catheter tube 35. The distal end of each arm is fixed to the floating tube (or pin) **44**. This floating tube is retained within the inner catheter tube, but is free to slide longitudinally within the inner catheter tube. The necessary electrical wires **45** and **46**

which connect the electrodes to the control system run from each electrode proximally along the arm (and through any intervening electrodes), and enter the lumen of the floating tube 44 and then run proximally through the inner catheter tube and into the catheter handle. (Additional wires for temperature sensing thermistor or thermocouples may be included.) The wires are looped within the handle to provide the distension necessary for the resilient deployment of the electrode array as illustrated in Figure 5. A steering pull wire 47 is secured to the distal end of the inner catheter tube. The pull wire runs proximally to the steering control knob in the proximal handle, and is operably connected to the control knob so that rotation of the control knob pulls the pull wire to effectuate steering of the distal end of the device. The outer catheter tube is sufficiently flexible so that it is steered by deflection of the inner catheter tube. The materials used for each component are selected to provide the suitable flexibility, column strength and steerability. The outer catheter tube 34 may comprises nylon, polyester or other suitable polymer, and the inner catheter tube 35 comprises a stainless steel coil covered in shrink tubing to provide tensile strength. The electrode arms 39 comprise flat nitinol wires. The floating tube 44 comprises a stainless steel coil. The floating tube may be disposed over the inner catheter if accommodations are made for proximal fixation of the proximal arm segments to the inner catheter, such as placing the fixation points proximally on the inner catheter or providing slots on the proximal portion of the floating tube. The electrode wires may be disposed on or in the wall of the inner catheter, rather than passing through the lumen of the inner catheter as shown in the Figures.

Figure 4 is a cross-section of the proximal portion of the catheter of Figure 2. At this cross section, an electrode 40 is

mounted on each arm 39. These electrodes will be located on the proximally facing portion of the deployed array as shown in Figures 5 and 6. The electrodes are tubes of triangular cross section, with tissue contacting faces directed radially outwardly from the catheter. The electrode wires 45, which are connected to the inside electrodes, run through the outer electrodes on their route to the floating tube. The electrode wires 46 are fixed to the inner wall of the outer electrode. As shown in this view, the electrodes are collapsed upon the floating tube 44, and due to the triangular shape they are securely packed within the outer catheter tube 34. The floating tube 44 also houses the various electrode wires 45 and 46.

Figures 5 and 6 illustrate the atrial sensing and ablation catheter of Figure 2 with the electrode array in its expanded configuration. The outer catheter tube 34 has been withdrawn proximally over the catheter inner tube, allowing the array arms 39 to expand to create array elements defining a substantially cordate or hastate proximal outline. The term cordate is used as it is in botany to describe a leaf with a base (where the leaf attaches to the stem) which is heart-shaped, having rounded lobes at the base which arch proximally away from the tip and then curve distally toward the tip of the leaf, as shown in Figure 6b. The term hastate is also adopted from botany, and refers to proximally tending lobes with slightly curved proximal outlines and sharply bending tips, also as shown in Figure 6b. In the array shown in Figure 5 and 6, the base of the array (the proximal portion analogous to the base of a leaf) is heart-shaped, having rounded lobes at the base which arch proximally away from the base and then curve outward and distally toward the tip of the array. Each proximal arm segment resiliently bends radially outwardly from the proximal connection with the inner catheter tube, bending sharply in the proximal direction

before arching outwardly and distally, while each distal arm segment bends radially inwardly from the bend portion toward the longitudinally axis of the catheter.

The electrode array includes a number electrodes 40 mounted on the proximal section 42 of each array arm, and the distal section 41 need not have any electrodes disposed on it, as is shown. The overall shape of each arm is elongate on an axis perpendicular to the long axis of the catheter, having a radial length R which is several times the axial length A.

The resilient expansion of the electrode array pushes the floating tube 44 proximally into the inner catheter tube. When the outer catheter tube is pushed distally over the electrode array, the distal electrode arms will be forced distally, as the proximal segments are compressed inwardly starting from the proximal end, to first splay the distal segments toward and through a perpendicular relationship with the floating tube such that the joint between the arms and the floating tube is distal to the bend point, while drawing the floating tube distally within the inner catheter tube.

Figure 7 is a proximal end view of the electrode array in its expanded configuration. In this view, the three-arm array is fully expanded resiliently. The array provides four electrodes on each of three arms evenly distributed about the floating tube 44. The electrode wires 45 and 46 (shown in Figure 3) extend inwardly from the electrodes and run proximally down the floating tube. The arms are each separated from the adjacent arms by about 120°. The array, when deployed and flattened as shown, is preferably about 15 to 30 mm in diameter (to the outer extent of the arm), with each distal arm segment 41 being about 7.5 to 15 mm long. The diameter of the electrode group (from the center to the outer extent of the electrodes) is

preferably about 2 to 30 mm. The wire width is preferable about 0.26 mm, and the distal face of the electrodes is preferably about 1 to 2 mm wide and 2 to 3 mm long (the illustrated electrodes are 2 mm wide and 1.6 mm wide). The electrode array can comprise any number of arms, and each arm can carry any number of electrodes, though the three arm array, with dimensions described above, is well suited for the septal wall ablation therapy. Figure 7a is an end view of the electrode array, with an asymmetric arrangement of electrodes, in its expanded configuration. In this embodiment, each electrode is 2 mm long, and is fixed to the array arm with a 2 mm gap between adjacent electrodes. The inner electrode of the first set of electrodes 40a is placed at a distance of 2 mm (indicated by item d1) from the inner catheter tube 35 and each of the additional electrodes are placed with 2 mm gaps between each electrode, while the inner electrode of the second set of electrodes 40b is placed at a distance of 4 mm (indicated by item d2) from the inner catheter tube 35 and each of the additional electrodes are placed with 2 mm gaps between each electrode, and the inner electrode of the third set of electrodes 40c is placed at a distance of 6 mm (indicated by item d3) from the inner catheter tube 35 and each of the additional electrodes are placed with 2 mm gaps between each electrode. With the electrodes arranged in this asymmetric pattern on each of the otherwise symmetrical array arms, rotation of the array after ablation in one position will be less likely to result in seating the electrodes directly on a previously ablated section of the septal wall.

Figures 8 and 9 illustrate the mechanism of recapture of the electrode array. When the outer catheter tube 34 is pushed distally over the inner catheter tube 35 and the electrode array, the distal electrode arms 41 will be forced distally, as

the proximal segments 42 are compressed inwardly starting from the proximal end, as shown in Figure 8. This initially splays the distal segments toward a perpendicular relationship with the floating tube as shown in Figure 8. As the outer catheter tube is translated further distally, such that the joint between the arms and the floating tube is distal to the bend point, the distal arm segments become further splayed, such that they are distal to the proximal arms segments. Because the distal arm segments are fixed to the floating tube, their movement distally draws the floating tube distally within the inner catheter tube. The array is completely captured when the outer catheter tube is translated fully forward to resume the position shown in Figures 2 and 3. As can be seen from the illustration, the bend sections provide a means for rotatably joining the distal arm segment to the proximal arm segment, and other suitable mechanisms, such as hinges, may be used instead.

Figures 10 and 10a illustrate an alternate geometry of the septal wall array. The outer catheter tube 34 has been withdrawn proximally over the catheter inner tube, allowing the array arms 39 to expand to create array elements defining a substantially sagittate proximal outline. We use the term sagittate as that term is used in botany, where it describes a leaf with a base (where the leaf attaches to the stem) which is arrow-shaped (the back end of the arrow), having sharply triangular lobes with generally straight sides at the base which bend proximally away from the tip and then sharply turn distally toward the tip of the leaf, as shown in Figure 10b. Here, the array arms have sharply triangular lobes at the base which bend proximally away from the catheter and then sharply turn distally toward the tip of the array. Each proximal arm segment resiliently bends radially outwardly from the proximal connection with the inner catheter tube, bending sharply in the

proximal direction, while each distal arm segment bends radially inwardly from the bend portion toward the longitudinally axis of the catheter. The floating tube 44 of Figure 6 need not be used, as in this example the array distal arm segments are joined at their extreme distal ends to floating pins **51** which comprise proximally running segments that enter the inner catheter tube to provide the floating attachment of the distal arm segments to the catheter body. (Thus both floating pin or arm extensions, or the floating tube, and other suitable means, may be used to fix the distal end of the electrode arms in a radially central area while leaving the distal ends of the electrode arms freely translatable along the catheter longitudinal axis.) The electrode array can be restrained within the outer catheter tube, released and recaptured by sliding the outer catheter proximally or distally.

Figures 11, 12 and 13 illustrate additional alternative geometries of the array. In each device, the overall shape of the array arms may be as shown in any of the previous figures, but the array is asymmetrical or oblique. In Figure 11, the array consists of a single arm 39, while in Figure 12 the array comprises two arms disposed at a slight angle to each other, so that the array is radially asymmetrical. In Figure 13, the array comprises an array arms 39 and 39a which are of substantial different sized, resulting in an oblique arrangement. Again, the term oblique is borrowed from botany, where it refers to leaves with lopsided proximal lobes, very similar to the lopsided proximal outlines of the array arms in Figure 13. These arrays may be used where the anatomy of a particular patient's atrium demands, as where the fossa ovalis is positioned very near an upper or lower wall which would prevent full deployment of a symmetrical array.

Figure 14 and 15 illustrate the method of using the device of Figures 6 or 10. Figure 14 shows the heart 1 fro the left side, showing the left atrium 3, the left ventricle 5, pulmonary veins 10, pulmonary artery 11. The left atrium is shown in a cutaway view, in which the atrial septum 6 and its left atrial surface **53** and the fossa ovalis 7 are shown. To treat arrhythmogenic foci, drivers or rotors on the septal wall near the fossa ovalis, the distal end of the catheter of Figure Figures 6 or 10 is inserted through the fossa ovalis (via the transeptal approach from the right atrium). Thereafter, the outer catheter is withdrawn, so that the electrode array arms 39 resiliently expand to the configuration in which the proximal arm segments are substantially parallel or slightly reflexed relative to the long axis of the catheter. As shown in Figure 15, to engage the septal wall, the electrode array is pulled proximally into contact with the septal wall, by pulling proximally on the catheter inner tube 35. As shown, the array will deform, forcing the distal arm segments 41 to splay distally, drawing the floating posts or pins 51 distally in response to the deformation of the array, while at the same time resiliently biasing the proximal arm segments 42 and the electrodes 40 against the septal wall 53 of the left atrium.

After contact has been established between the atrium wall and the electrode array, the operator will analyze electrical signals detected by the electrodes to determine if the array has been placed over an arrhythmogenic focus. If it has, the operator may energize any of the electrodes, as appropriate, to ablate the focus. Bipolar RF energy may be applied between pairs of the electrodes, or monopolar energy may be applied to any of the electrodes (grounded to the surface electrode or a return electrode located proximally on the catheter body). The array may moved off the septal wall, rotated slightly, and

reseated against the septal wall to test and treat the entire area surrounding the fossa ovalis with just a few array arms (alternatively, the array may be provided with many arms, such that the electrode density it sufficient to find an ablate all significant foci within its footprint). Linear lesions may be created using the electrodes along a single proximal arm, operating the electrodes in bipolar mode, and other therapeutic lesions may be created using electrodes pairs established between the electrodes of one arm and the electrodes of another arm, operating such pairs in bipolar mode, or operating electrodes in conjunction with return electrodes in a monopolar mode.

While the preferred embodiments of the devices and methods have been described in reference to the environment in which they were developed, they are merely illustrative of the principles of the inventions. Other embodiments and configurations may be devised without departing from the spirit of the inventions and the scope of the appended claims.

We claim:

1. An ablation catheter comprising:

a catheter having a distal end adapted for insertion into the left atrium of a patient;

an electrode array comprising at least one resilient arm, each arm having a proximal arm segment and a distal arm segment extending distally from an outer end of the proximal arm toward the center line of the catheter; and

a plurality of electrodes disposed on each of the proximal arm segments of the array;

wherein the proximal arms are arcuate, and extend outwardly and proximally and then curve distally from their attachment point to catheter.

2. An ablation catheter of claim 1 wherein the proximal arm segments are curved in a cordate arc.

3. An ablation catheter of claim 1 wherein the proximal arm segment is curved in a hastate arc.

4. An ablation catheter of claim 1 wherein the proximal arm segment and distal arm segment define a sagittate lobe.

5. An ablation catheter of claim 1 wherein each distal arm segment is characterize by a proximal end and a distal end; further comprising

a proximally extending pin fixed at the distal end of the distal arm and extending into the catheter, said pin being longitudinally slidable relative to the catheter:

6. An ablation catheter of claim 1 further comprising:

a plurality of resilient arms on the array, wherein each of the plurality of arms is substantially the same size and shape, and the resilient arms are uniformly distributed radially about the axis of the catheter.

7. An ablation catheter of claim 1 further comprising:

a plurality of resilient arms on the array, wherein at least one of the plurality of resilient arms is substantially different in size or shape than other arms in the array.

8. An ablation catheter of claim 1 further comprising:

a plurality of resilient arms on the array unevenly distributed such that several arms are concentrated in a small radial section about the axis of the catheter, and a significant radial section is vacant.

9. An ablation catheter comprising:

an outer catheter tube;

an inner catheter tube slidably disposed within the outer catheter tube, said inner catheter tube having a distal end adapted for insertion into a vessel of the body;

an electrode array comprising a plurality of resilient arms, each arm having a proximal arm segment fixed to the inner catheter tube and a distal arm segment extending distally from an outer end of the proximal arm;

a plurality of electrodes disposed on each of the proximal arm segments of the array;

means for fixing the distal end of the electrode arms in a radially central area while leaving the distal ends of the electrode arms freely translatable along the catheter longitudinal axis

wherein the proximal arm segments are curved in cordate arc.

10. An ablation catheter comprising:

an outer catheter tube;

an inner catheter tube slidably disposed within the outer catheter tube, said inner catheter tube having a distal end adapted for insertion into a vessel of the body;

an electrode array comprising a plurality of resilient arms, each arm having a proximal arm segment fixed to the inner catheter tube and a distal arm segment having proximally tending extension extending proximally from the distal end of the distal arm segment, said extension being longitudinally translatable within the inner catheter tube, whereby the electrode array may be compressed by longitudinal translation of the outer catheter tube relative to the inner catheter tube, and the proximally tending extension longitudinally translates relative to the inner tube to accommodate longitudinal movement of the distal end of the resilient arms in response to compression of the electrode array;

an electrode array comprising a plurality of resilient arms, each arm having a proximal arm segment fixed to the inner catheter tube and a distal arm segment extending distally from an outer end of the proximal arm;

a plurality of electrodes disposed on each of the proximal arm segments of the array;

means for fixing the distal end of the electrode arms in a radially central area while leaving the distal ends of the electrode arms freely translatable along the catheter longitudinal axis

11. The ablation catheter of claim 10, wherein:

the floating tube is disposed at least partially within the distal end of the inner catheter tube.

12. The ablation catheter of claim 10, wherein:

the electrode array is resiliently movable from a small diameter configuration to a large diameter configuration, and in the large diameter configuration each proximal arm segment resiliently bends radially outwardly from the inner catheter tube, and each distal arm segment bends radially inwardly toward the longitudinal axis of the catheter from a bend point connecting the proximal arm segment to the distal arm segment, creating an acute angle between each distal arm segment and its associated proximal arm segment.

13. The ablation catheter of claim 10, wherein:

the electrode array is resiliently movable from a small diameter configuration and a large diameter configuration, and in the large diameter configuration each proximal arm segment resiliently bends radially outwardly from the inner catheter tube, and each distal arm segment bends radially inwardly and proximally toward the longitudinal axis of the catheter from a bend point

connecting the proximal arm segment to the distal arm segment.

14. The ablation catheter of claim 10, wherein:

the electrode array is resiliently movable from a small diameter configuration and a large diameter configuration, and in the large diameter configuration each proximal arm segment resiliently bends radially outwardly from the inner catheter tube, and each distal arm segment bends radially inwardly and proximally toward the longitudinal axis of the catheter from a bend point connecting the proximal arm segment to the distal arm segment, and said electrode arms are further deformable upon pressing the array against a surface to position the distal arm segments into a substantially planar arrangement.

15. The ablation catheter of claim 14 in the small diameter configuration, the distal arm segments are restrained within a segment of the outer catheter tube which is distal to the proximal arm segments, and extend distally from the bend point.

16. The ablation catheter of claim 14 wherein, in the small diameter configuration, the distal arm segments are folded inwardly so as to be disposed proximate the proximal arm segments and extend proximally from the bend point.

Fig. 1

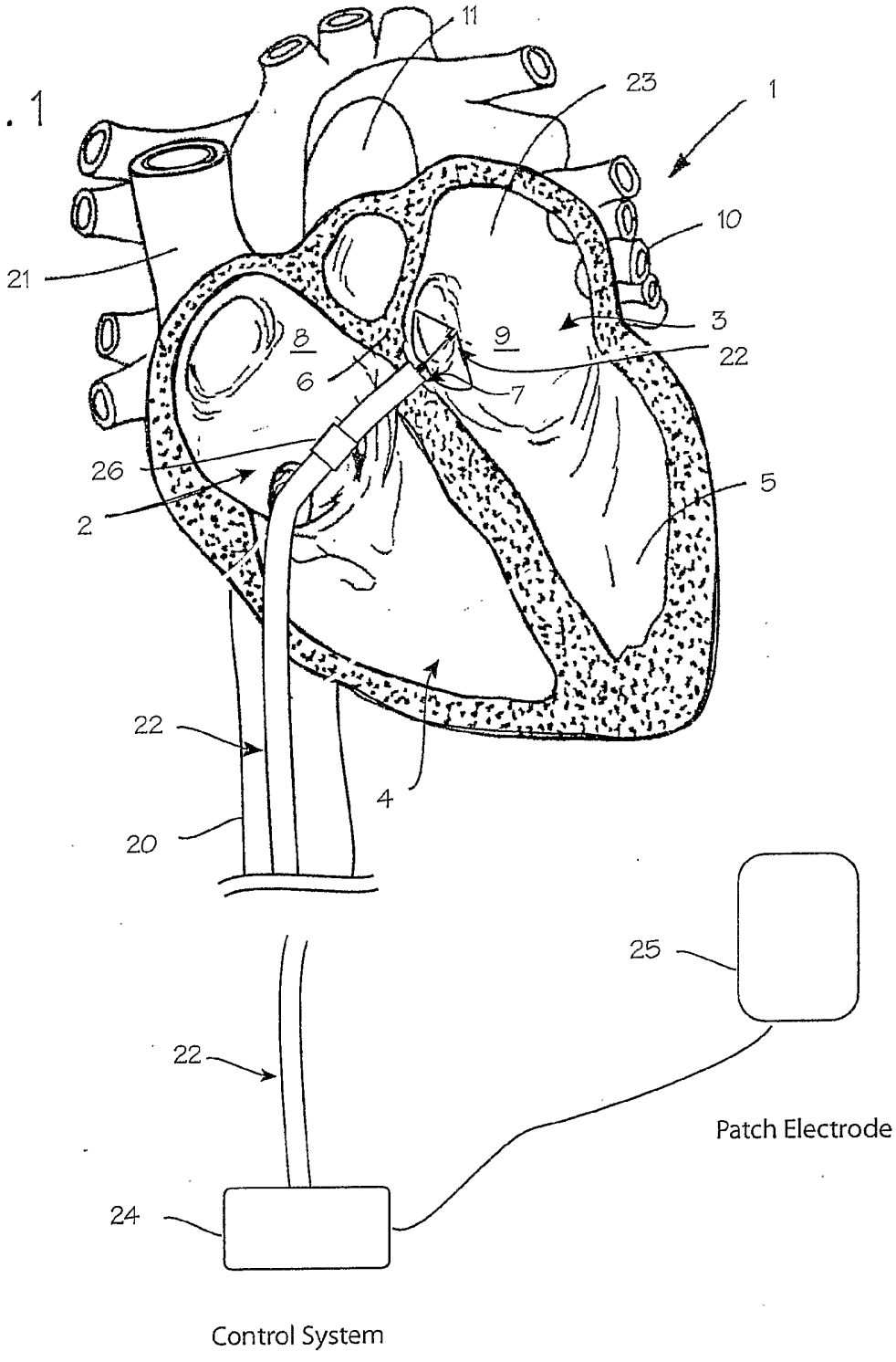

11
23
1
10
21
3
8
9
22
6
7
26
5
2
22
4
20
25
22
Patch Electrode
24
Control System

Fig. 2

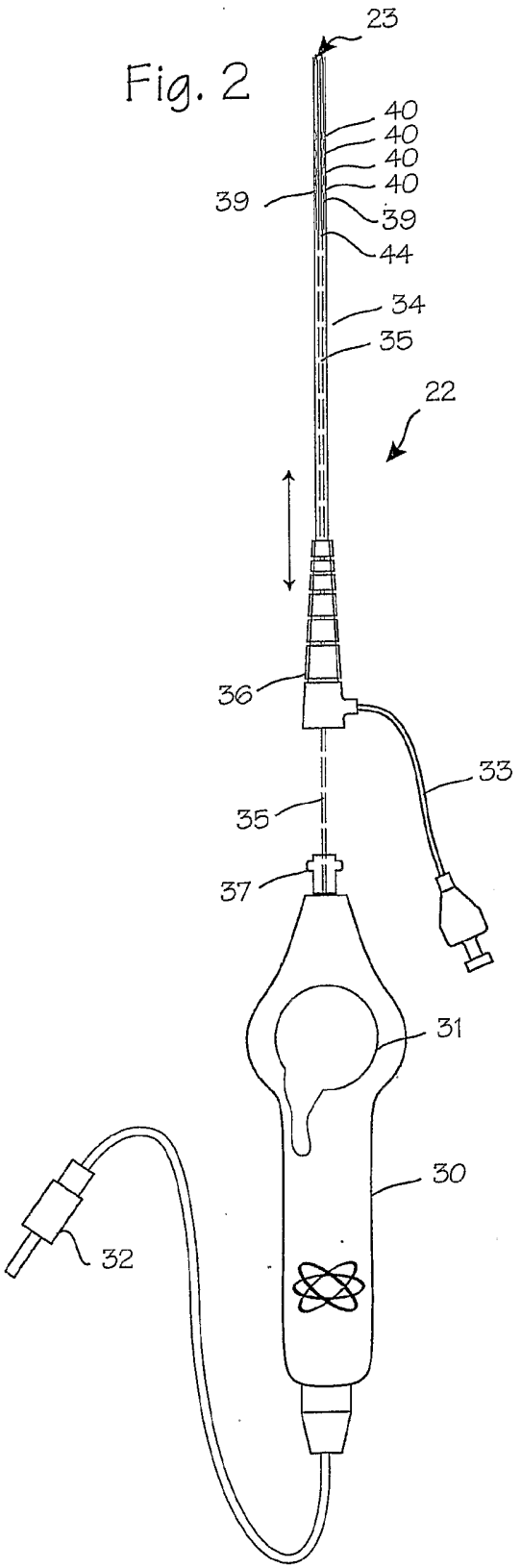


Fig. 3

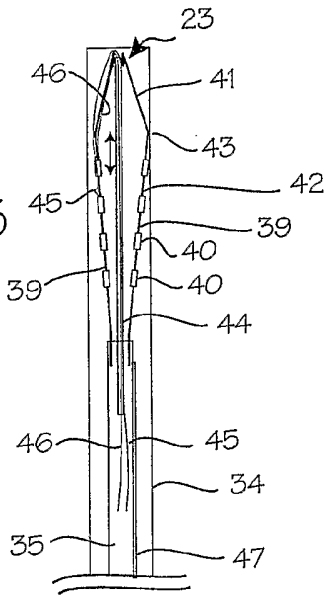


Fig. 4

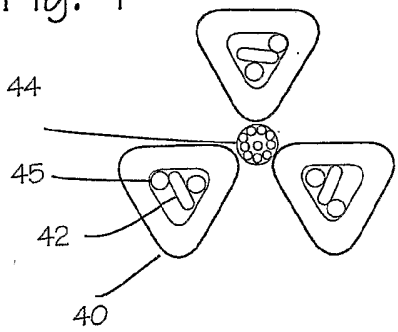
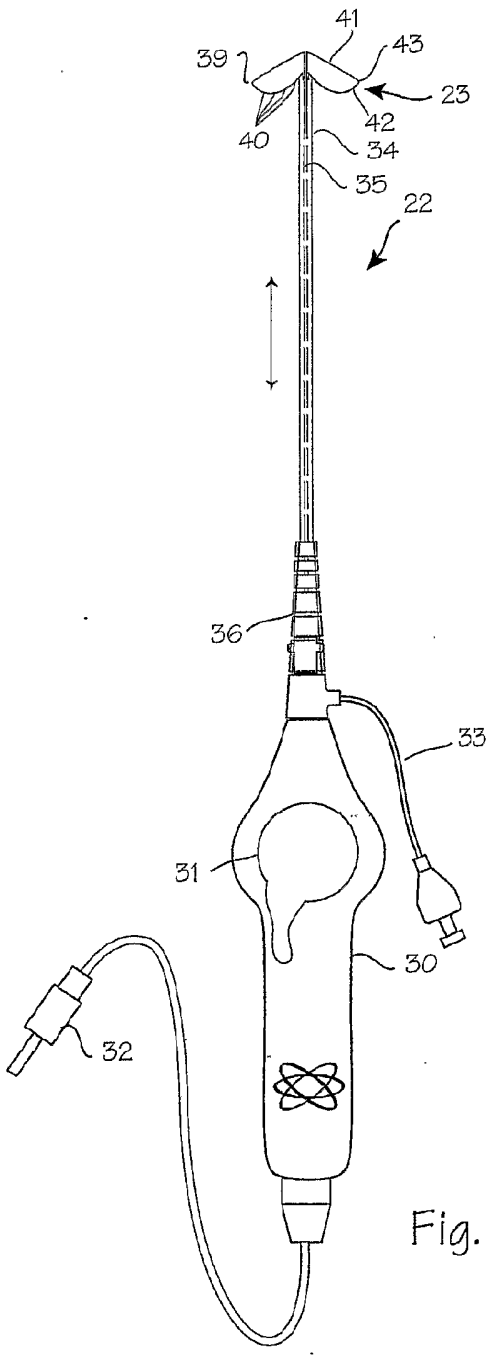


Fig. 5



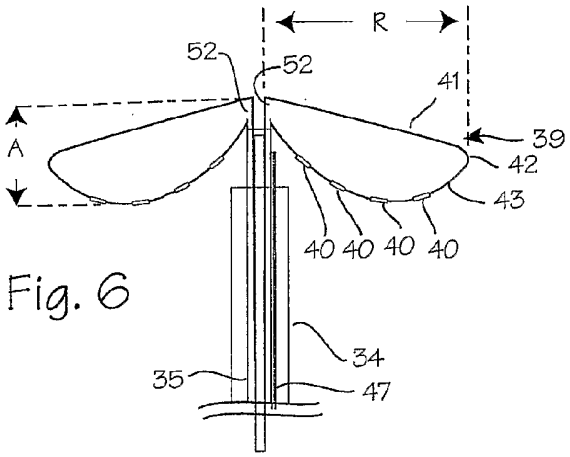


Fig. 6

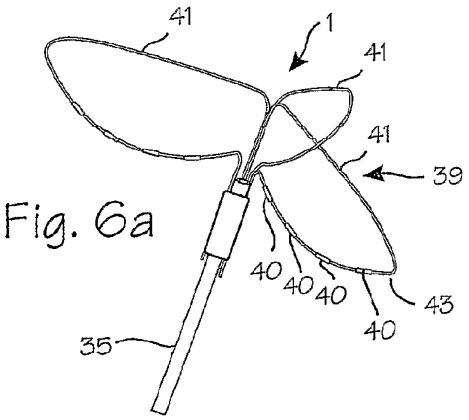


Fig. 6a

Fig. 6b

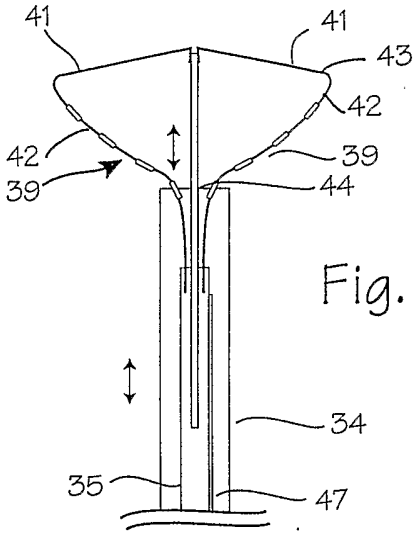


Fig. 8

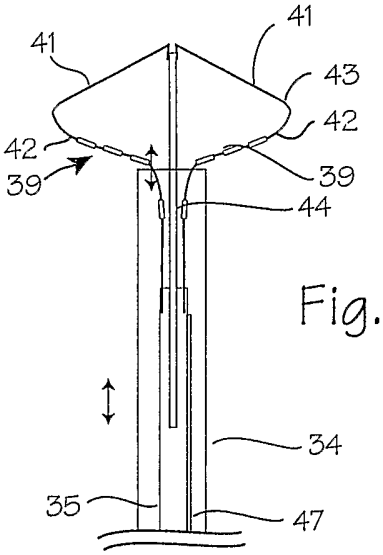


Fig. 9

Fig. 7

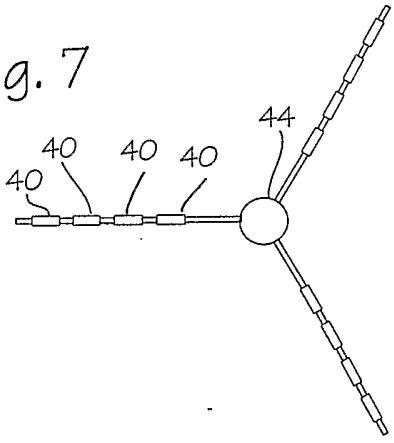


Fig. 7a

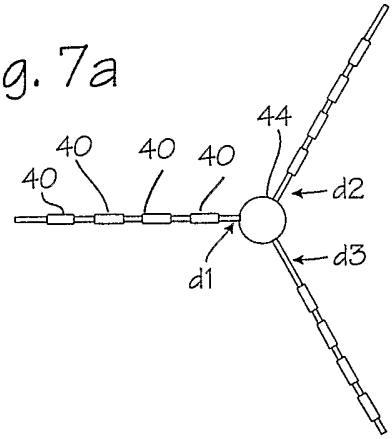


Fig. 10

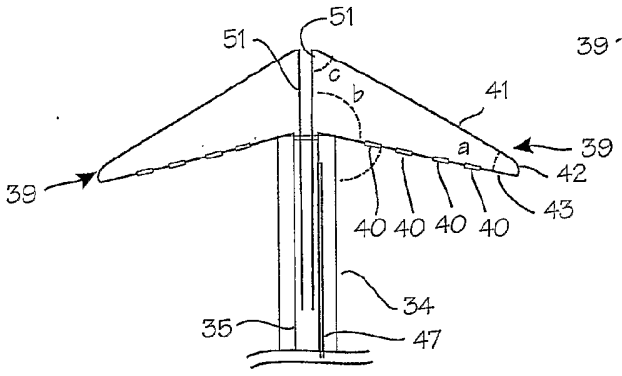


Fig. 10a

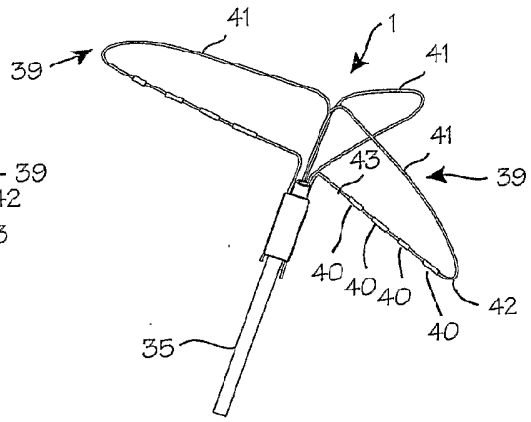
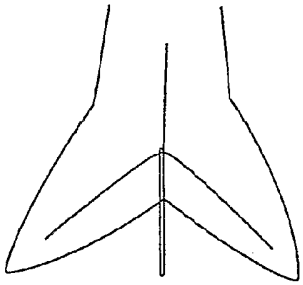


Fig. 10b



SAGITTATE

Fig. 11

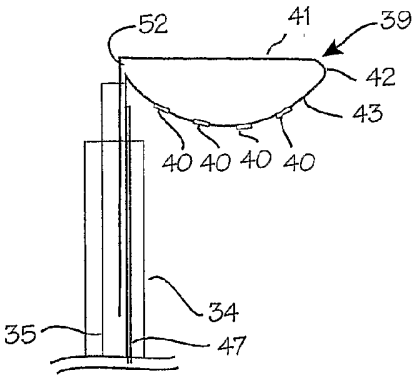


Fig. 12

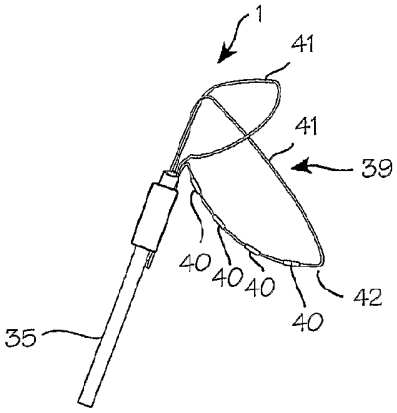


Fig. 13

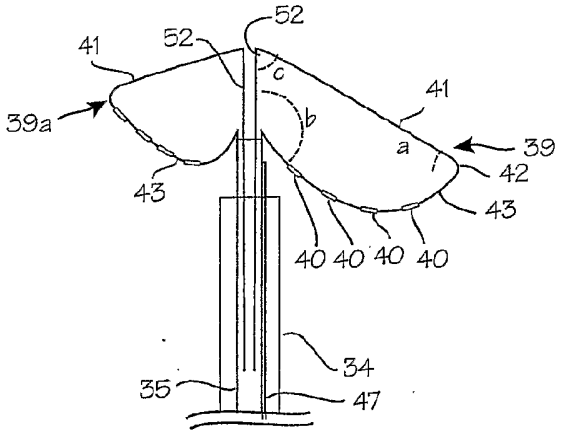


Fig. 14

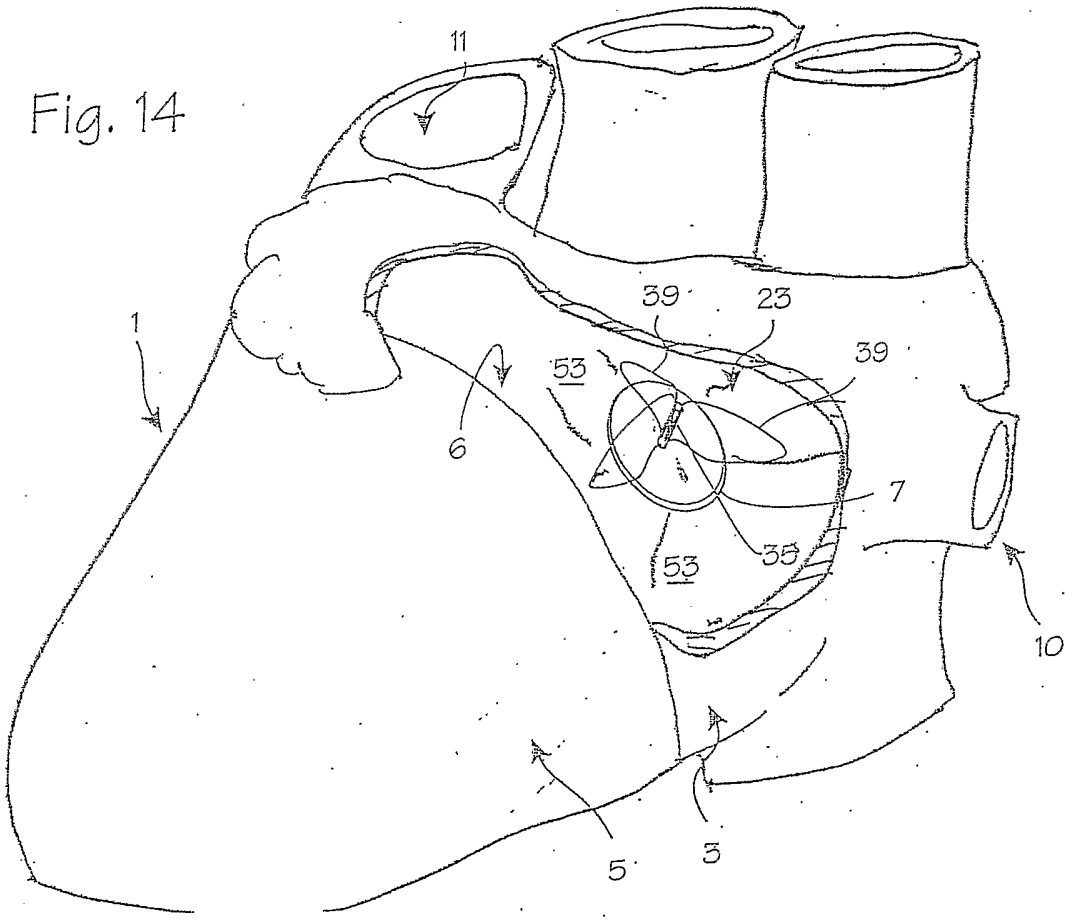
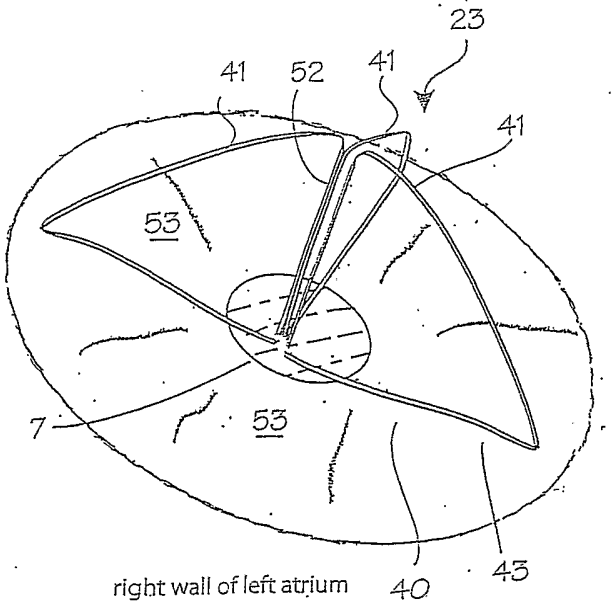

11
1
39
23
39
53
6
7
53
35
10
5
3

Fig. 15


23
41
52
41
41
53
7
53
right wall of left atrium
40
43

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/42815

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) **A61B 18/18**(2006.01)
A61N 1/00(2006.01)

USPC: 606/41;607/122
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)
U.S. : 606/41, 45-50; 607/101, 102, 115, 116, 122

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,782,899 A (IMRAN) 21 July 1998, whole document	1,5,6,9 --- 1-4,7,8
Y	US 5,968,040 A (SWANSON et al) 19 October 1999, whole document	2-4,7,8
A	US 5,904,680 A (KORDIS et al) 18 May 1999, whole document	1-9
A	US 6,544,262 B2 (FLEISCHMAN) 08 April 2003, whole document	1-9

☐ 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 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
28 March 2006 (28.03.2006)

Date of mailing of the international search report
20 APR 2006

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (571) 273-3201

Authorized officer
For Linda Dvorak
Virginia Libby
Telephone No. (703) 308-0858

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/42815

Box II Observations where certain claims were found unsearchable 1. because they relate to subject matter not required to be searched by this Authority, namely:

Continuation of Box II Reason 2:

Claim 10 recites two entirely different sets of limitations for "an electrode array" and it is impossible to determine the scope of the claim and which recitation should be considered. It is noted that the description does not disclose the use of two different electrode arrays, and it does not appear applicant could have claimed "a first electrode array" and "a second electrode array". Rather, it appears as though two different descriptions of the electrode array, which were meant for two separate claims, were mistakenly included in the same claim.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/42815

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.:
because they relate to subject matter not required to be searched by this Authority, namely:
Please See Continuation Sheet

2. ☒ Claims Nos.: 10-16
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:
Please See Continuation Sheet

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 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.