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(54) **Title**: LEAD DELIVERY DEVICE AND METHOD

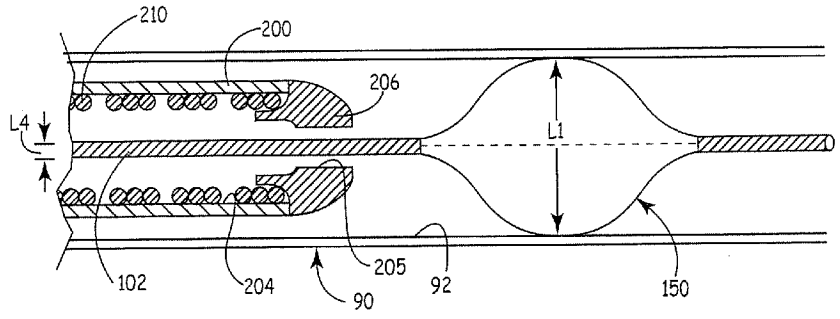


FIG. 14

(57) **Abstract**: A medical apparatus includes an electrically conductive lead for a medical device, the lead having an internal bore terminating at a distal lead opening, and a lead delivery device for delivering the distal end of the lead to a blood vessel during implantation of the lead. The lead delivery device includes a removably anchorable guidewire, and a fixator attached to a distal portion of the guidewire for anchoring the guidewire. The fixator is movable between a compact configuration and an expanded configuration. The fixator is capable of passing through the distal lead opening of the lead in the compact configuration. The fixator is capable of exerting a holding force in the range of about 0.89 to 4.45 N in the lumen of the blood vessel in the expanded configuration.

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# LEAD DELIVERY DEVICE AND METHOD

## INTRODUCTION

Various cardiac devices providing electrical stimulation, rhythm management, or resynchronization therapy to the heart include electrically conductive leads in contact with excitable heart or other body tissue.

The present teachings provide a device and method for delivering an electrically conductive lead to a target site for a use with a cardiac or other medical device.

## SUMMARY

The present teachings provide a medical apparatus that includes an electrically conductive lead for a medical device, the lead having an internal bore terminating at a distal lead opening, and a lead delivery device for delivering the distal end of the lead to a blood vessel during implantation of the lead. The lead delivery device includes a removably anchorable guidewire, and a fixator attached to a distal portion of the guidewire for anchoring the guidewire. The fixator is movable between a compact configuration and an expanded configuration. The fixator is capable of passing through the distal lead opening of the lead in the compact configuration. The fixator is capable of exerting a holding force in the range of about 0.89 to 4.45 N in the lumen of the blood vessel in the expanded configuration.

The present teachings also provide a medical method that includes inserting a distal end of cannulated catheter through cardiac tissue into a main cardiac vessel, attaching an expandable fixator to a distal portion of a guidewire, inserting the guidewire through the catheter, advancing the guidewire past the distal end of the catheter and into a target site in a lumen of a branching vessel, expanding the fixator into the target site, removably anchoring the fixator into the lumen with a holding force in the range of about 0.89 to 4.45 N, and removing the catheter. The method further includes advancing an electrically conductive lead of a medical device over the guidewire to the target site without moving the guidewire while tensioning the guidewire, and delivering the distal portion of the lead at the target site.

In another aspect, the present teachings provide a medical apparatus that includes a medical device for providing cardiac therapy, or cardiac sensing, or a combination thereof, an electrically conductive lead having proximal and distal ends, the proximal end couplable to the

medical device, the lead having an internal bore terminating at a distal opening at the distal end, and a lead delivery device for delivering the distal end of the lead to a blood vessel during implantation of the lead. The lead delivery device includes a removably anchorable guidewire, and a fixator attached to a distal portion of the guidewire, the fixator movable between a compact configuration and an expanded configuration. The fixator has a compact width less or equal to about 0.483 mm and is capable of passing through the distal lead opening of the lead in the compact configuration. The fixator has an expanded width up to about 5 mm, and is capable of exerting a holding force in the range of about 0.89 to 4.45 N in the lumen of the blood vessel in the expanded configuration.

Further areas of applicability of the present teachings will become apparent from the description provided hereinafter. It should be understood that the description and specific examples are intended for purposes of illustration only and are not intended to limit the scope of the present teachings.

## BRIEF DESCRIPTION OF THE DRAWINGS

The present teachings will become more fully understood from the detailed description and the accompanying drawings, wherein:

FIG. 1 is an environmental view of a lead delivery device according to the present teachings shown in a first aspect;

FIG. 1A is an environmental view of the lead delivery device of FIG. 1, shown in a second aspect;

FIG. 1B is an enlarged detail of the lead delivery device of FIG. 1B;

FIG. 2 is a perspective environmental view of the medical device with the lead implanted after the lead delivery device of FIG. 1B is removed;

FIG. 3 is a plan view of a lead delivery device having a fixator according to the present teachings, the lead delivery device shown with the fixator in an expanded configuration;

FIG. 3 is a plan view of a lead delivery device having a fixator according to the present teachings, the lead delivery device shown with the fixator in a compact configuration;

FIGS. 5-11 illustrate various fixators for a lead delivery device according to the present teachings;

FIG. 11A is a top view of the fixator of FIG. 11;

FIG. 12 is a side view of the fixator of FIG. 11, illustrating a deployment mechanism;

FIG. 13 is a sectional view of a lead delivery device according to the present teachings with a fixator in a compact configuration inside a lead;

FIG. 14 is the lead delivery device of FIG. 13, shown with the fixator in an expanded configuration outside the lead;

FIG. 15 is the lead delivery device of FIG. 13, shown with the fixator partially retracted inside the lead; and

FIG. 16 is an end view of a distal end of an electrical lead with an offset distal opening.

DESCRIPTION OF VARIOUS ASPECTS

The following description is merely exemplary in nature and is in no way intended to limit the present teachings, applications, or uses. The present teachings are applicable to any devices that require implantation of electrically conductive leads, including pacemakers, defibrillators or other medical devices providing rhythm management, resynchronization therapy or other cardiac therapy.

During left heart (LH) lead delivery methods for implanting cardiac therapy devices, cannulated catheters can be used to provide support and stiffness and allow trackability of the lead into the coronary sinus and more acute branching vessels. For example, in Cardiac Resynchronization Therapy (CRT), a special third lead that is implanted via the Coronary Sinus (CS) and positioned in a sub-selected cardiac vein to sense and/or pace the left ventricle in combination with atrial-synchronized, biventricular pacing using standard pacing technology. Following a sensed atrial contraction or atrial-paced event, both ventricles are stimulated to synchronize their contraction. The resulting ventricular resynchronization reduces mitral regurgitation and optimizes left ventricular filling, thereby improving cardiac function.

Guidewires can be used inside the Coronary Sinus and Great Cardiac Vein to gain access to acute side branches. A guidewire is placed into the targeted vessel and the lead is placed over the guidewire and through the catheter. Under existing methods, during lead delivery, a compressive force is maintained by a forward pressure on both the guidewire and

lead to allow the lead to travel distally in the branching veins at the target site. The lead itself is designed to provide stiffness and steerability characteristics for the purpose of placement into the vessels. After the LH lead has reached its desired location, the delivery catheters used during the procedure must be removed by slitting because the proximal end of the lead is larger in diameter that the bore of the catheter and the catheter cannot be removed over the lead. The slitting procedure requires a very specific skill set, provides multiple avenues for user error and places constraints on catheter design, construction and use.

In contrast to the existing method described above, the present teachings provide a lead delivery device method that does not require slitting the catheter. The lead delivery device includes a guidewire that can be temporarily anchored in a sub-selected acute coronary vein branch during lead delivery. Fixation can be provided by a fixator that expands from a compact configuration of very low profile fitting inside a lead to an expanded configuration having a dimension large enough to allow sufficient tension to be placed on the guidewire to enable lead delivery over the guidewire in a zip-line or rope-climbing manner, as described below. The guidewire with the fixator in the compact configuration can be guided through the catheter to the target site. The catheter can then be removed before the lead is advanced over the guidewire. After the lead is implanted, the fixator is returned to the compact configuration and removed together with the guidewire through the implanted lead without slitting.

An exemplary lead delivery device 100 according to the present teachings is illustrated during lead delivery of an electrically conductive lead 200 in FIGS. 1, 1A and 1B. An implanted lead 200 is shown in FIG. 2, after the lead delivery device 100 is removed. The lead 200 can be cannulated having an internal bore or lumen 204, a proximal portion 201, and a distal portion 202. The proximal portion 201 can be coupled with a connector pin 207 to a connector block of a cardiac or other medical device 300, with which the lead 200 is in electrical communication. A catheter 250 having a proximal end 252 and a distal end 254 can be used to insert the lead delivery device initially through heart tissue 80, as shown in FIG. 1.

The lead delivery device 100 can include a guidewire 102 entering a proximal end 252 of the catheter 250 and exiting through a distal end 254 of the catheter 250 as shown in FIG. 1. The guidewire 102 can be solid or cannulated with a bore 103, as shown in FIG. 12. The guidewire 102 can include a distal portion 104 terminating in a tip 106. The distal portion 104 can be flexible for ease in guiding the guidewire 102 through tortuous blood vessels to a target site 82, such as a branching vein branching off the coronary sinus or other main blood vessel.

The lead delivery device 100 can include a fixator 150 coupled to the guidewire 102. The fixator 150 can assume an expanded or deployed configuration for anchoring the guidewire 102 near a target site 82 during lead delivery and implantation, as shown in FIGS. 3, and 5-11, illustrating various fixator aspects. Referring to FIG. 1A, the catheter 250 can be removed by retracting the catheter 250 from heart tissue 80 after the lead delivery device is anchored at the target site 82. No slitting of the catheter 250 is required for removal of the catheter 250. After the catheter 250 is removed, the lead 200 can be guided over the guidewire 102 to the target site 82, as discussed further below.

The fixator 150 can be returned to a compact or undeployed configuration, such as the configuration illustrated in FIG. 4, for retracting and removing the guidewire 102 after lead delivery and implantation. The maximum dimension, diameter or width of the fixator 150 in the expanded configuration is denoted as L1 and in the contracted configuration as L2, as illustrated in FIGS. 3 and 4 for a fixator in the form of a balloon.

FIGS. 5-11 illustrate various fixators 150 in their expanded configuration showing the maximum dimension L1 for each fixator 150. The dimension L1 is selected to achieve a fixation force within a blood vessel of an amount that allows the guidewire 102 to be pulled in tension without being dislodged from the blood vessel while the lead is pushed over the guidewire 102, as discussed below. The fixation force F can be equal to or greater than about 2.24 N, or about 0.5 lbf for achieving sufficient fixation within the blood vessel wall. The fixation force F can generally be in the range of about 0.89 to 4.45 N (or 0.2 to 1.0 lbs), depending on various factors, including the geometry of the branching vessel. The deployed width or dimension L1 corresponding to this fixation force F can be 5 mm, while the undeployed width or dimension L2 can be maintained to equal to or less than about 0.019 inches, or about 0.483 mm, to allow easy passage through commercially available leads, such as those used with medical devices available from Medtronic, Inc., of Minneapolis, Minnesota.

Referring to FIGS. 13-15, the distal portion 202 of an electrical lead 200 is illustrated in connection with a guidewire 102 having a width L4 and a fixator 150 having an undeployed width L2. The lead 200 is conductive and can deliver therapy in the form of electric energy at the target site 82. In one aspect, the lead 200 can also sense and relay information about electrical activity from the heart tissue 80 or target site 82 back to the medical device 300. The lead 200 can have an internal bore or lumen 204, an internal coil or other conductive element 210 and a tip portion 206 that can be an electrode tip with or without a seal. The tip portion

206 can define a distal opening 205 with width L3. In one aspect, the tip portion 206 can include a seal with flexible flaps, not shown. The guidewire width L4 can be about 0.346 mm (or about 0.014 inches) for providing steerability, stiffness and sufficient support for lead delivery over the guidewire 102.

The compact width L2 of the fixator 150 can be equal to or less than the width L3 of the distal opening 205, such that the fixator 150 can be pushed through the distal opening 205 in the direction C, as shown in FIG. 13. In one aspect the distal opening 205 can be offset relative to a central longitudinal axis of the lead 200, as shown in FIG. 16. The fixator 150 can be deployed to the expanded configuration within the blood vessel 90 such that the expanded width L1 of the fixator 150 can press against the internal lumen 92 of the blood vessel 90 with a holding force F, as discussed above, for temporarily anchoring the guidewire 102 into the blood vessel 90, as shown in FIG. 14.

Various fixators 150 can be used to temporarily and removably anchor the guidewire 102 in the lumen 92 of a blood vessel 90. Referring to FIGS. 3 and 4, the fixator 150 can be a balloon having first and second ends 111, 113 attached to the guidewire 102. The balloon can be inflated, for example, with a gas or a fluid, including a gel or other liquid provided by a syringe through a valve 110 at a proximal end of the guidewire 102. In another aspect, a luer lock inflation port 120 can be coupled to the guidewire 102 for deploying the balloon. The balloon can be made from a polyblend material which is heated and stretched, placed around the guidewire 102 and bonded at first and second ends 111, 113 of the balloon onto the guidewire 102 with small amounts of cyanoacrylate adhesive, for example. A radio-opaque marker 108 in the form of a band can be placed adjacent the second (proximal) end 113 of the balloon for visualization during guided navigation. The radio-opaque marker 108 can also be in the form of a radio-opaque balloon coating or radio-opaque fluid filling the balloon. In another aspect, the balloon-type fixator 150 can include an etched fixation surface with etched surface fixation formations 154 in the form of bumps, rings, etc, as illustrated in FIGS. 5 and 7. In another aspect, the fixator 150 can be a balloon with spiral or helical or otherwise curved configuration for maintaining a percentage of blood flow through the blood vessel 90 and aiding fixation in tortuous anatomy.

Referring to FIGS. 9-12, the fixator 150 can also be in the form of a mechanical anchor with deployable straight wings 160, as shown in FIG. 9, or curved wings 160, as shown in FIG. 10, or a pinwheel-type fixator 150, as shown in FIGS. 11 and 11A. The mechanical anchor

150 can be deployed with a longitudinal actuator 170 in the form of a wire or string or other elongated member passing through the bore 103 of a cannulated guidewire 102. Referring to FIG. 12, for example, the anchor wings 160 can pivot about a pivot pin 124 connected to the actuator 170 and can be deployed to the expanded position in the direction of arrows E by pulling the actuator 170 in the direction of arrow D. In other aspects, the fixator 150 can be in the form of a superelastic wire, such as nitinol, and can be pre-shaped to expand to an anchorable configuration within the blood vessel 90.

In another aspect, fixators 150 including polymer lobes or superelastic or memory-shape wire can be used. Further, the dimensions of the fixator 150, including the expanded width L1 and the compact width L2 can be selected to match the range of most common vessel sizes. The expanded shape of the fixator 150 can be selected to increase the contact area with the blood vessel and or provide multiple contact surfaces for increasing holding force and stability, as shown in FIGS. 6, 8, and 10, for example. The expanded shape can have a symmetric profile, as shown in FIG. 9, for example, or a non-symmetric profile, as shown in FIG. 6, for example. In other aspects, the expanded shape can have an asymmetric profile for anchoring unidirectionally rather than bi-directionally.

As discussed above, deployment of the fixator 150 and anchoring can occur after the cannulation of the coronary sinus CS with the catheter 250 and after sub-selection of a side branch with the guidewire 102. Further, fixation of the guidewire 102 by the expandable fixator 150 can be maintained during lead delivery and terminated after the lead 200 is delivered to the target vessel at the target site 82. At the discretion of the operating physician, fixation and release can occur multiple times during the medical procedure. Damage to the lead 200 during fixation can be avoided because fixator expansion and fixation occurs outside the lead 200.

It should be appreciated, that according to the present teachings the lead delivery device 100 with either a balloon or mechanical fixator 150 is configured and designed to function as a wedge or anchoring device for temporarily anchoring the guidewire 102 during the implantation of the electrical lead 200.

Referring to FIGS. 1-2, and 13-15, the cannulated catheter 250 can be inserted through heart tissue 80 into a coronary sinus CS, cardiac great vein or other main vessel stopping short of a target site 82 that is located in a sub-selected acute branching vessel 90. The guidewire 102 with the fixator 150 in the undeployed compact configuration can be inserted through the

catheter 250, advanced past the distal end 254 of the catheter 250 through a main vessel to the target site 82 in the branching vessel 90, as shown in FIG. 1. The fixator 150 can then be deployed and become anchored in the lumen 92 of the branching vessel 90 with a holding force F, as discussed above. The catheter 250 can then be retracted and completely removed with no slitting procedure. The lead 200 can be guided over the anchored guidewire 102 until the distal portion 202 of the lead 200 reaches the target site 82, as shown in FIG. 1B. The lead 200 can be advanced by keeping the guidewire 102 in tension while pushing the lead 200 in the direction of the fixator 150. When the distal portion 202 of the lead 200 reaches the target site 82, the fixator 150 can be returned to its undeployed compact configuration and be retracted through the lumen 204 of the lead 200, as shown in FIG. 15. The lead 200 can remain installed in the target site 82, as shown in FIG. 2, or advanced more distally in the branching vessel 90 beyond the original target site 82 after the removal of the guidewire 102.

It will be appreciated that, in other aspects, the catheter 250 may be retained during the entire lead delivery procedure, such that the lead is inserted through the catheter 250 and over the guidewire 102, but in such cases slitting of the catheter 250 may not be avoided after lead implantation. In further aspects, the guidewire 102 and the lead 200 can be inserted through the catheter 250 in any order, i.e., guidewire 102 first, or lead 200 first or at the same time. In all aspects, however, the guidewire 102 can first be advanced to the target site 82 of a branching vessel 90 and the fixator 150 be deployed at the target site 82. Only then the distal portion 202 of the lead 200 is advanced to the target site 82 by pushing the lead 200 over the guidewire 102 toward the target site 82, while the guidewire 102 remains fixed. Specifically, the lead 200 can be advanced to the target site 82 in a climbing-like or zip line-like manner by pulling and tensioning the guidewire 102 while the guidewire 102 remains anchored with the deployed fixator 150 at the target site 82.

The foregoing discussion discloses and describes merely exemplary arrangements of the present teachings. Furthermore, the mixing and matching of features, elements and/or functions between various embodiments is expressly contemplated herein, so that one of ordinary skill in the art would appreciate from this disclosure that features, elements and/or functions of one embodiment may be incorporated into another embodiment as appropriate, unless described otherwise above. Moreover, many modifications may be made to adapt a particular situation or material to the teachings of the invention without departing from the essential scope thereof. One skilled in the art will readily recognize from such discussion, and from the accompanying

drawings and claims, that various changes, modifications and variations can be made therein without departing from the spirit and scope of the present teachings as defined in the following claims.

## CLAIMS

1. A medical apparatus comprising:

an electrically conductive lead for a medical device, the lead having an Internal bore terminating at a distal lead opening;

a lead delivery device for delivering the distal end of the lead to a blood vessel during implantation of the lead, the lead delivery device including:

a removably anchorable guidewire; and

a fixator attached to a distal portion of the guidewire for anchoring the guidewire, the fixator movable between a compact configuration and an expanded configuration, the fixator capable of passing through the distal lead opening of the lead in the compact configuration, and the fixator capable of exerting a holding force in the range of about 0.89 to 4.45 N in the lumen of the blood vessel in the expanded configuration.

2. The medical apparatus of claim 1, wherein the fixator includes a compact width of equal to or less than 0.483 mm in the compact configuration.

3. The medical apparatus of claim 2, wherein the fixator includes an expanded width up to about 5 mm in the expanded configuration.

4. The medical apparatus of claim 3, wherein the fixator includes an inflatable balloon having first and second ends attached to the guidewire.

5. The medical apparatus of claim 4, wherein the balloon includes etched surface fixation formations.

6. The medical apparatus of claim 4, wherein the balloon includes a helical or spiral configuration for following a tortuous path in the vessel.

7. The medical apparatus of claim 3, wherein the fixator includes a mechanical anchor having deployable parts.

8. The medical apparatus of claim 7, wherein the deployable parts include movable wings.

9. The medical apparatus of claim 7, wherein the fixator includes a pinwheel.

10. The medical apparatus of claim 3, wherein the guidewire has a width of about 0.356 mm.

11. A medical method comprising:

inserting a distal end of cannulated catheter through cardiac tissue into a main cardiac vessel;

attaching an expandable fixator to a distal portion of a guidewire;

inserting the guidewire through the catheter;

advancing the guidewire past the distal end of the catheter and into a target site in a lumen of a branching vessel;

expanding the fixator into the target site;

removably anchoring the fixator into the lumen with a holding force in the range of about 0.89 to 4.45 N;

removing the catheter;

advancing an electrically conductive lead of a medical device over the guidewire to the target site without moving the guidewire while tensioning the guidewire; and

delivering the distal portion of the lead at the target site.

12. The method of claim 11, further comprising:

contracting the fixator to a compact width;

releasing the fixator from the lumen of the branching vessel;

retracting the guidewire with the fixator through a distal opening of the lead; and removing the guidewire and fixator through the lumen of the lead.

13. The method of claim 12, wherein expanding the fixator comprises expanding the fixator to an expanded width of about 5 mm.

14. The method of claim 12, wherein contracting the fixator comprises contracting the fixator to a compact width equal to or less than about 0.483 mm.

15. The method of claim 11, wherein attaching an expandable fixator comprises attaching an inflatable balloon.

16. The method of claim 11, wherein attaching an expandable fixator comprises attaching an expandable mechanical anchor including movable parts.

17. The method of claim 12, wherein removing the catheter comprises removing the catheter without slitting the catheter.

18. The method of claim 12, wherein removing the catheter comprises removing the catheter prior to advancing the lead to the target site over the guidewire.

19. A medical apparatus comprising:

a medical device for providing cardiac therapy, or cardiac sensing, or a combination thereof;

an electrically conductive lead having proximal and distal ends, the proximal end couplable to the medical device, the lead having an internal bore terminating at a distal opening at the distal end;

a lead delivery device for delivering the distal end of the lead to a blood vessel during implantation of the lead, the lead delivery device including:

a removably anchorable guidewire; and

a fixator attached to a distal portion of the guidewire, the fixator movable between a compact configuration and an expanded configuration, the fixator having a compact width equal to or less than about 0.483 mm, the fixator capable of passing through the distal lead opening of the lead in the compact configuration, the fixator having an expanded width up to about 5 mm, the fixator capable of exerting a holding force in the range of about 0.89 to 4.45 N in the lumen of the blood vessel in the expanded configuration.

20. The medical device of claim 19, wherein the fixator includes an inflatable balloon.

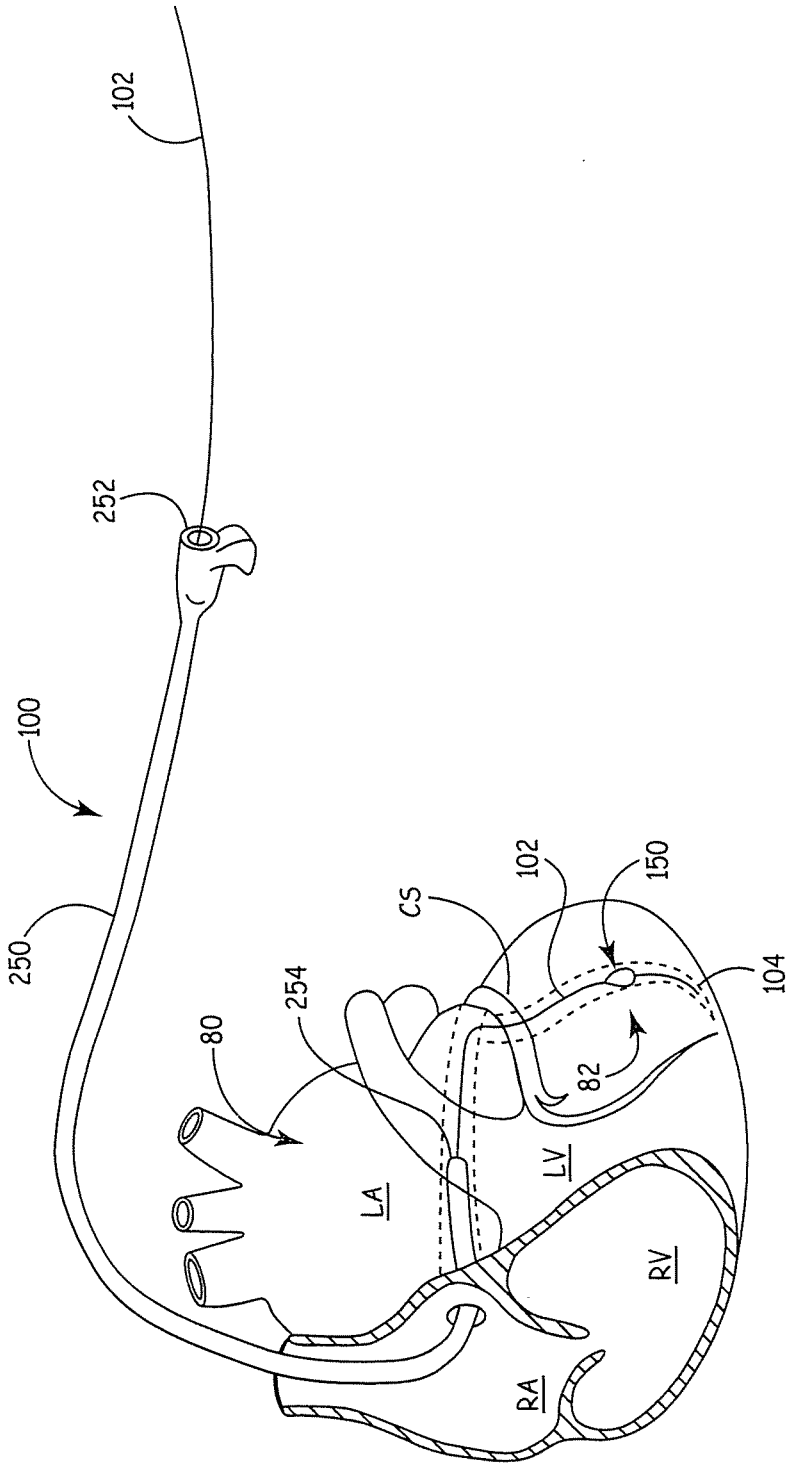
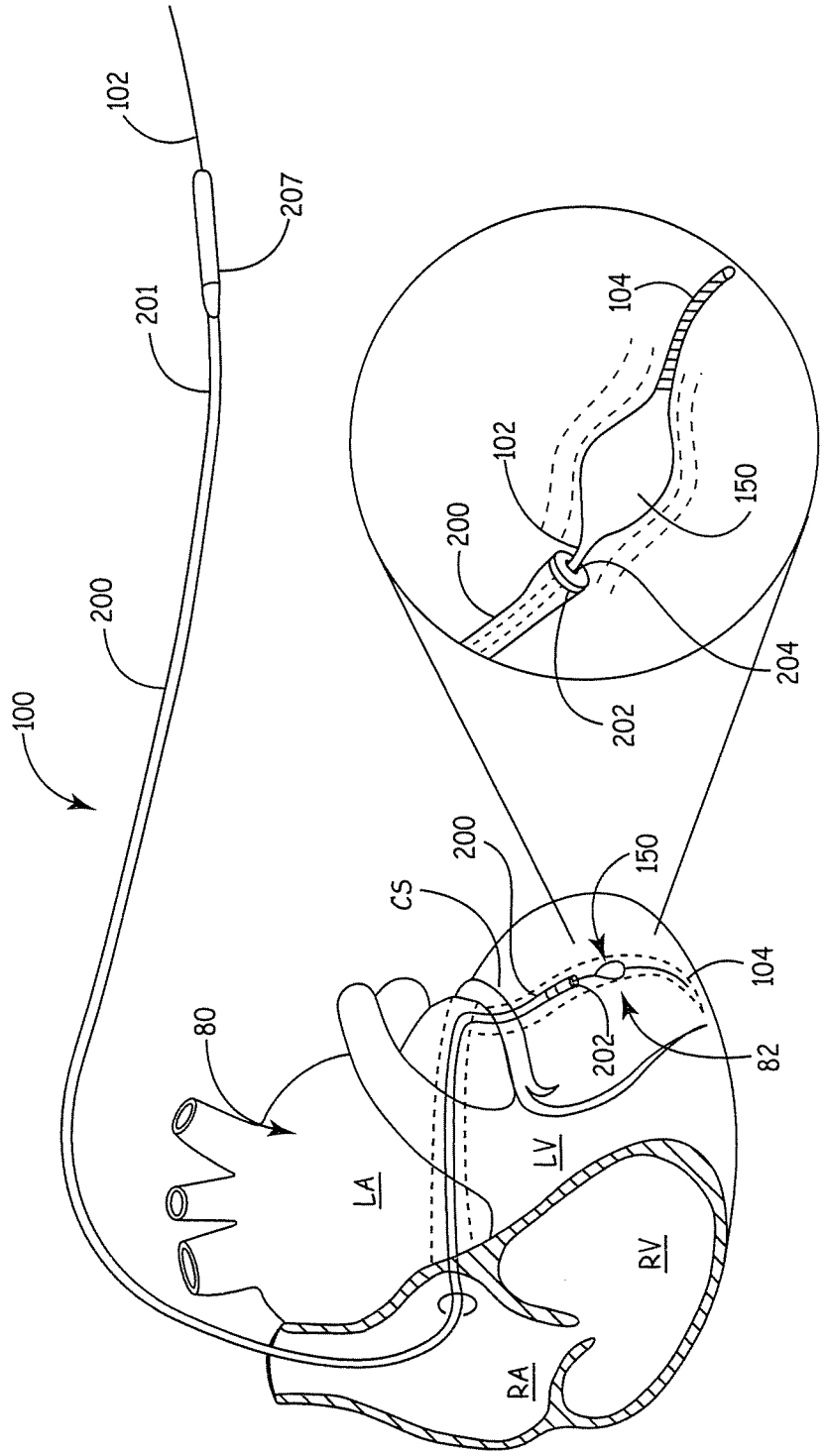



FIG. 1


102
207
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200
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104
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CS
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104
80
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LA
LV
RV
RA

FIG. 1A

FIG. 1B

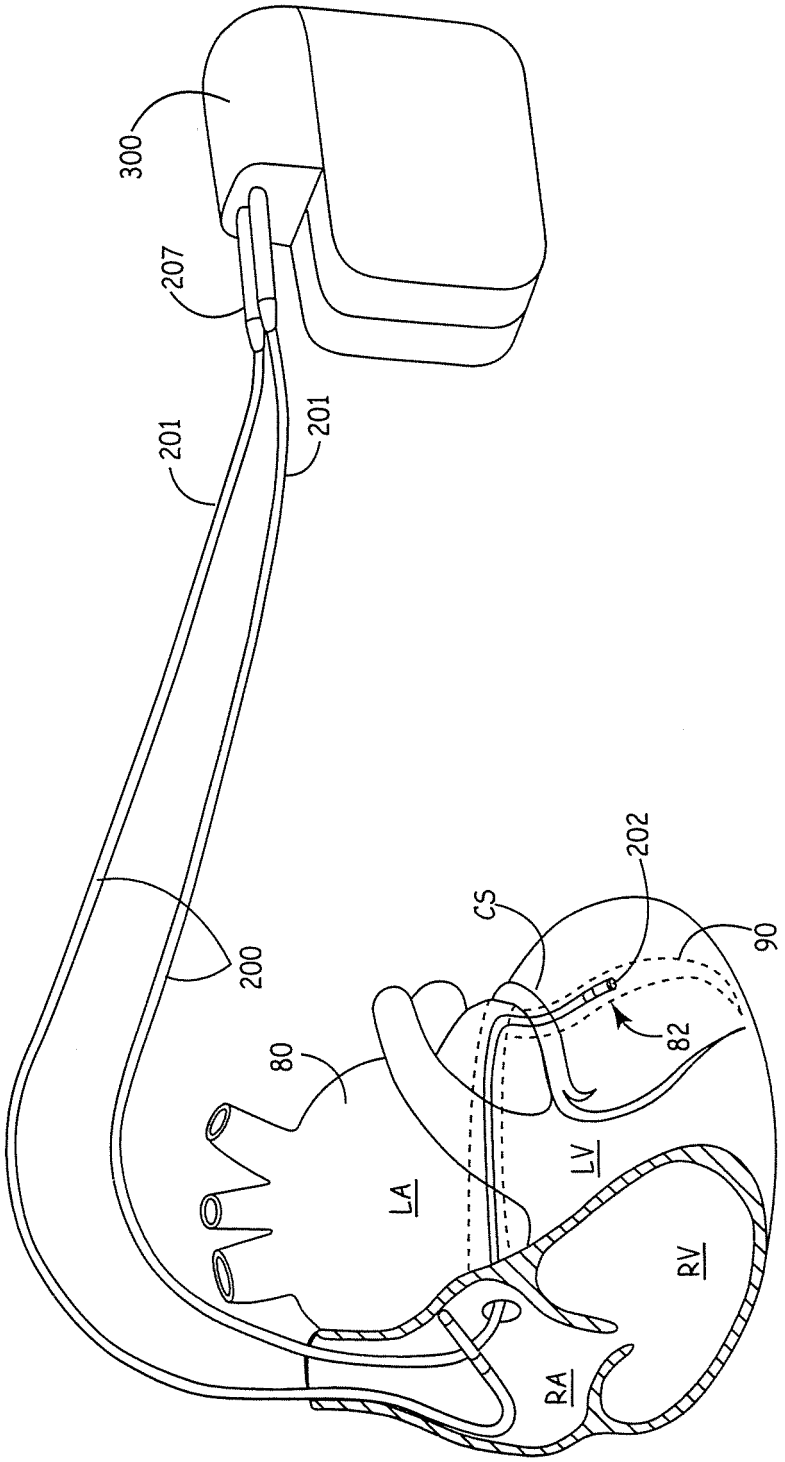


FIG. 2

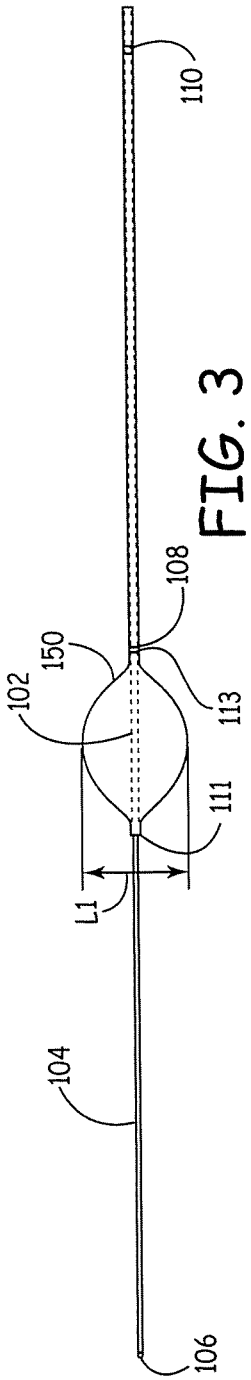


FIG. 3

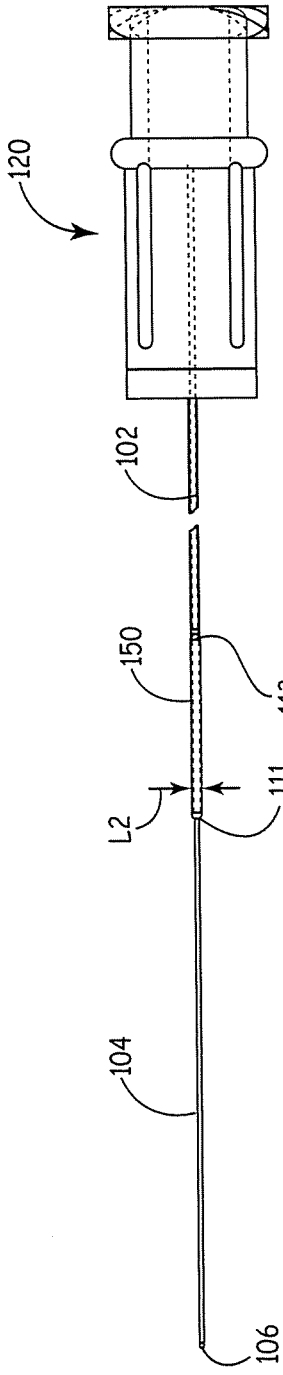


FIG. 4

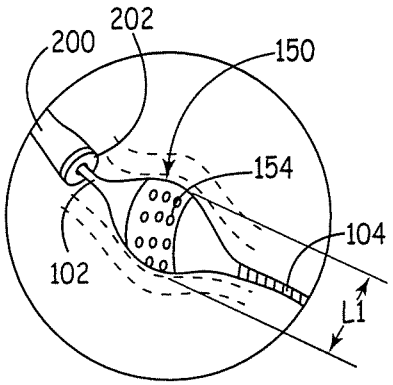


FIG. 5

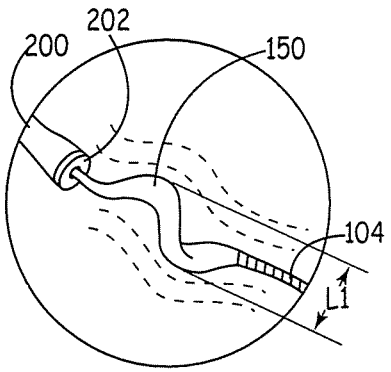


FIG. 6

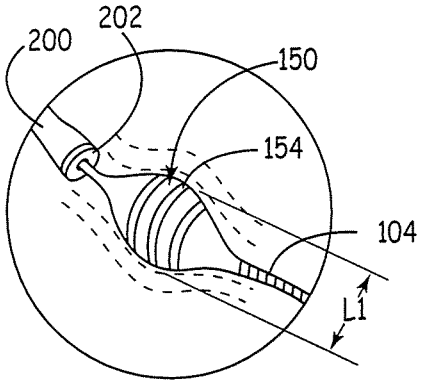


FIG. 7

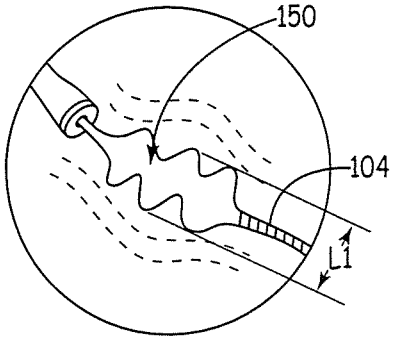


FIG. 8

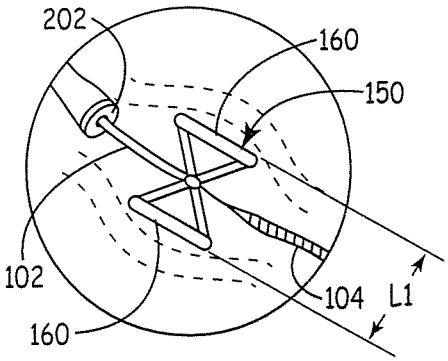


FIG. 9

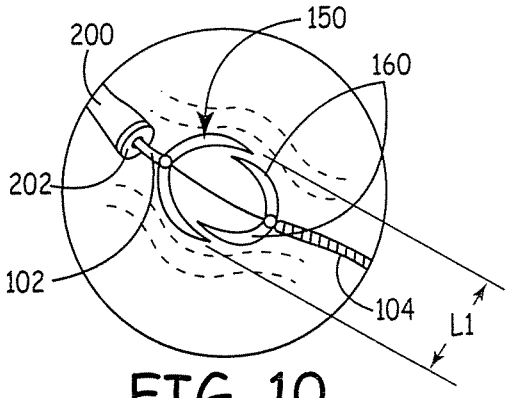


FIG. 10

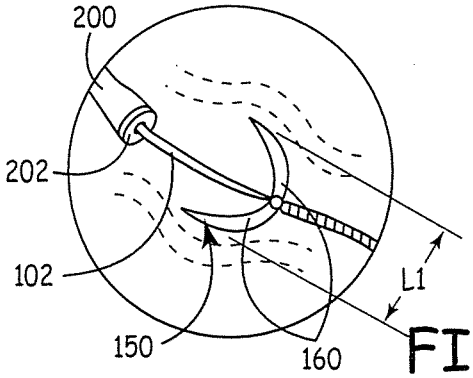


FIG. 11

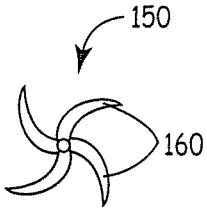


FIG. 11A

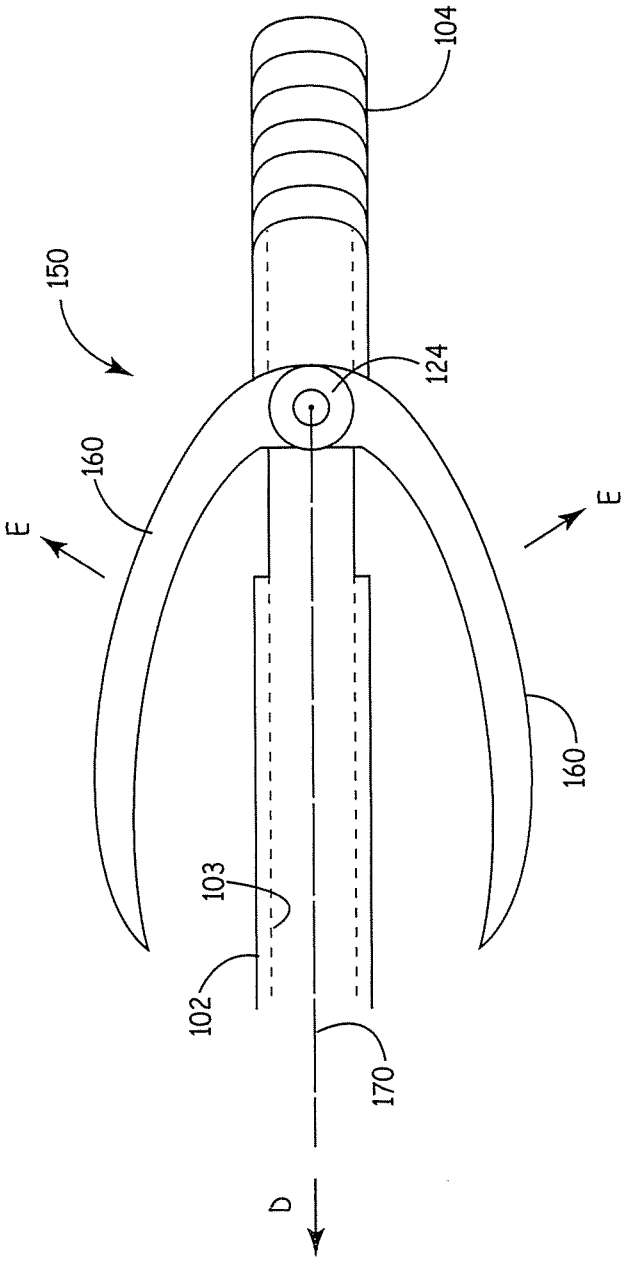


FIG. 12

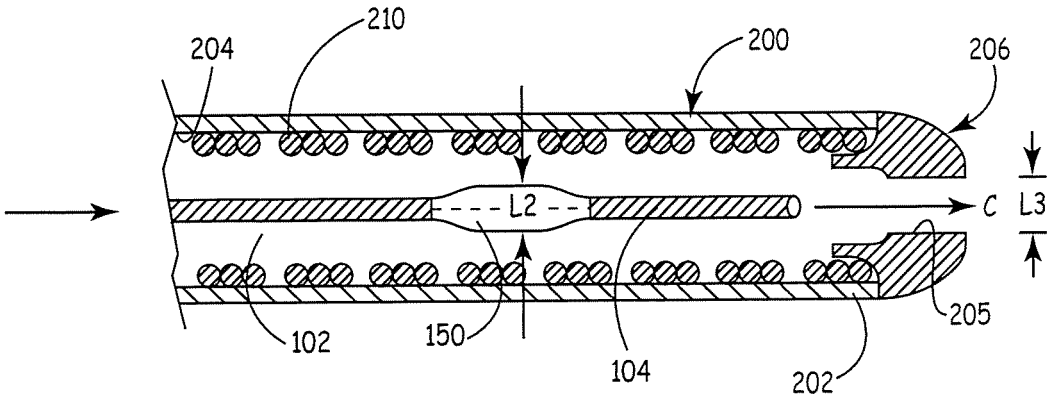


FIG. 13

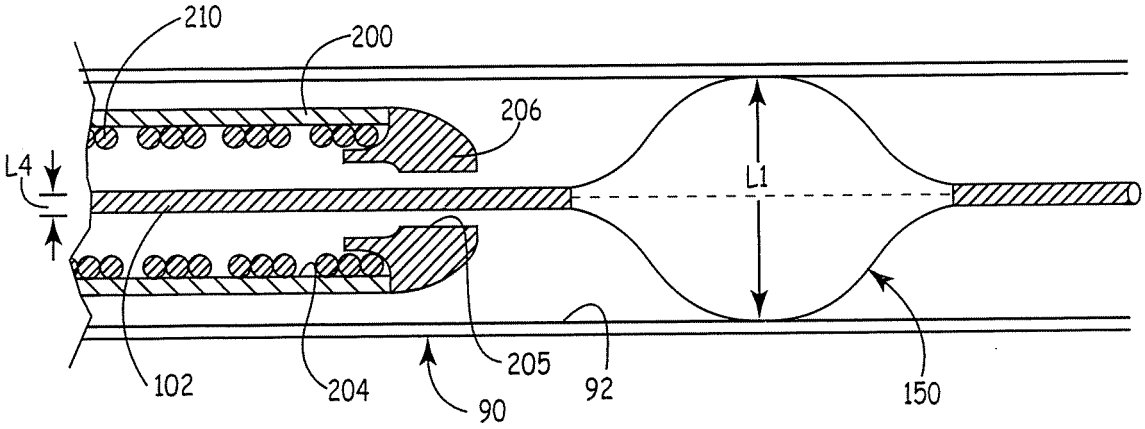


FIG. 14

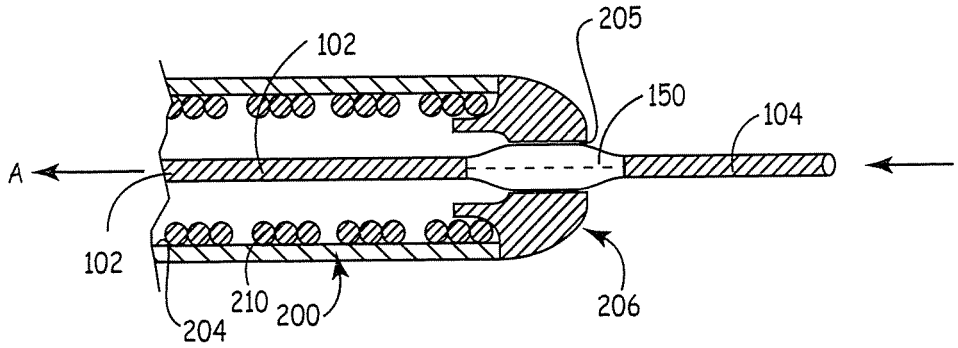


FIG. 15

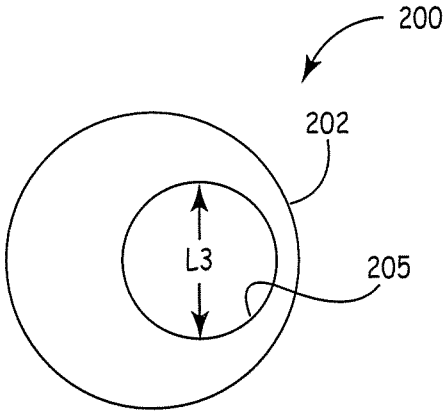


FIG. 16

# INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/048542

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/05

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)
A61N

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| Y | US 2002/147487 A1 (SUNDQUIST STEPHEN K [US] ET AL SUNDQUIST STEPHEN [US] ET AL) 10 October 2002 (2002-10-10) abstract; figures 1A,2-4,9-11,14A-B paragraphs [0002], [0003], [0014], [0015], [0048] - [0051], [0059], [0085] - [0090], [0094] - [0099] | 1-10,19, 20 |
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-/--

[X] 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 document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 16 September 2009 | 30/09/2009 |

| Name and mailing address of the ISA/ | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>Fax: (+31-70) 340-3016 | Molina Silvestre, A |

# INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/048542

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
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| Y | US 5 181 911 A (SHTURMAN LEONID [US])<br>26 January 1993 (1993-01-26)<br>abstract; figures 1,13<br>column 1, lines 5-9<br>column 2, lines 8-20<br>column 3, lines 4-29<br>column 5, lines 20-30 | 6 |
| A | US 2005/113862 A1 (BESSELINK PETRUS A [NL] ET AL) 26 May 2005 (2005-05-26)<br>the whole document | 1-10,19, 20 |
| A | WO 2005/053784 A (AETHERWORKS I INC [US]; ATKINSON ROBERT E [US]; KEITH PETER T [US]; BE) 16 June 2005 (2005-06-16)<br>the whole document | 1-10,19, 20 |
| A | US 2004/162599 A1 (KURTH PAUL A [US])<br>19 August 2004 (2004-08-19)<br>the whole document | 1-10,19, 20 |

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/048542

**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. [X] Claims Nos.: 11-18
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2009/048542

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
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