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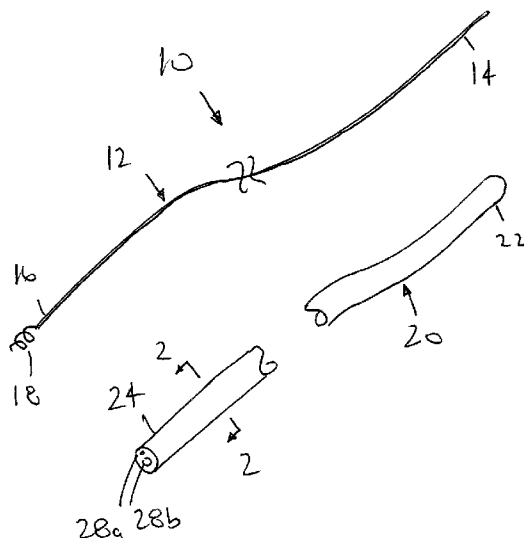
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(54) Title: APPARATUS AND METHODS FOR DELIVERING TRANSVENOUS LEADS



(57) Abstract: Apparatus and methods are provided for delivering a lead over a rail into a target body lumen, cavity, or other vessel, e.g., a coronary vein or a right ventricle within a patient's heart. For example, a distal end of an elongate guidewire or other rail may be introduced into the coronary venous system via the coronary sinus, advanced through the coronary venous system to a location beyond a target vessel, and secured at the location beyond the target vessel. A catheter or other elongate tubular member is advanced over the rail and manipulated to position an outlet of the tubular member adjacent to or otherwise aligned relative to the target vessel. A distal end of a lead is delivered through the tubular member and out the outlet into the target vessel. The catheter and rail are then removed, leaving the lead within the target vessel.

WO 2008/021997 A2

## APPARATUS AND METHODS FOR DELIVERING TRANSVENOUS LEADS

FIELD OF THE INVENTION

The present invention relates generally to apparatus and methods for delivering  
5 leads, and, more particularly, to apparatus and methods for delivering leads or other  
instruments using a delivery device movable over a guidewire or other rail.

BACKGROUND

It is known to place pacing leads in the area of the left ventricle via the coronary  
10 veins, e.g., for bi-ventricular pacing or resynchronization therapy. During such  
procedures, an electrical conductor (i.e., pacing lead) must be coupled to the left ventricle.  
In order to accomplish this in a minimally invasive fashion, the most common approach is  
by way of the coronary sinus and coronary venous system.

Such an approach can be difficult for a number of reasons. These include the  
15 inherent variability of venous anatomy, the multiplicity of turns that a device must take  
when tracking into the coronary sinus and/or its tributaries by way of subclavian or  
femoral vein approach, and the anatomical distortion that occurs secondary to diseases of  
the heart, as for example, heart failure or atrial fibrillation.

Furthermore, the design objectives of a lead system optimized for delivery often  
20 conflict with the design objectives of a system optimized to remain in stable position for  
long term pacing. For example, during delivery, a device is optimally lubricious and  
slides easily through the vasculature; however, once in place, the optimal device does not  
slide easily out of place, but remains in a stable position. As another example, during  
delivery, an optimal device has stiffness characteristics optimized to track around initial  
25 bends into the open chamber of the right atrium, into the lumen of the coronary sinus, and  
turn yet again into its tributaries. The optimal device during delivery should be pushable  
and hence have some degree of stiffness, whereas once in position the optimal device is  
generally flexible with high fatigue resistance. Furthermore, where the lead system  
specifically also includes a delivery component (e.g., sheath, guidewire, stylet, and the  
30 like) that is not left in the body, this component must be removed. Therefore, during  
introduction it is generally advantageous for his component to be stiffer and pushable,  
whereas during removal these properties may tend to dislodge the lead from it stable  
position.

- 2 -

Another problem associated with transvenous lead delivery is maintaining stable access into the coronary sinus and the coronary veins. Initial access of the coronary sinus may be difficult secondary to the presence of venous valve or tortuous or distorted anatomy. Once the coronary sinus has been accessed with a sheath or guidewire or other device, maintaining access is important and may be difficult during multiple exchanges of devices, for example a venography balloon catheter or pacing lead, or when attempting to move a pacing lead from one position to another position.

Accordingly, apparatus and methods for delivering leads would be useful.

10

### SUMMARY OF THE INVENTION

The present invention is directed generally to apparatus and methods for delivering leads and/or other instruments during a medical procedure. More particularly, the present invention is directed to apparatus and methods for delivering leads into one or more vessels, e.g., within a patient's coronary venous system.

15

Generally, transvenous leads or other instruments may be delivered using a rail, such as a guidewire, which may be secured at a location within the vasculature not entirely on the path to the final desired lead position. The rail may become a stable component of a delivery system that may remain in place during one or more stages of a procedure, for example, during a venogram, lead introduction, lead repositioning, and the like.

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The coronary venous system may provide a useful anatomical pathway with respect to lead delivery using such an approach. Generally, the anterior vein is not considered an ideal site for pacing given its anatomical location over the septum of the heart, while the posterior and posterolateral veins are considered to be superior locations for pacing. Therefore, a rail may be placed in the anterior vein to maintain stable access which the remaining delivery system may be designed to interface with this rail.

25

Using the rail, a device may be delivered that is adapted to track along the rail and also provide a path for delivering a lead or other instrument, although the path diverges from that of the rail at an appropriate point, e.g., at a location the point a posterior or posterolateral branch is encountered.

30

In accordance with one embodiment, a system is provided for delivering a pacing lead into a body lumen that includes an elongate rail including a proximal end, a distal end sized for introduction into a body lumen, and an anchor on the distal end for securing the distal end to tissue within a body lumen; and an elongate tubular member including a

- 3 -

proximal end, a distal end sized for introduction into a body lumen, and first and second lumens extending between the proximal and distal ends. The first lumen may be provided for receiving the rail therethrough such that the tubular member is advanceable over the rail, while the second lumen is sized for receiving a pacing lead therethrough. In addition,  
5 the system may include a pacing or other transvenous lead receivable within the second lumen.

In accordance with another embodiment, a method is provided for delivering an instrument within a branch body lumen or body cavity communicating with a main body lumen or body cavity. A distal end of an elongate rail may be introduced into the main  
10 body lumen, and advanced to a location beyond the branch body lumen. The distal end may be secured at the location beyond the branch body lumen, e.g., thereby providing a rail extending along the main body lumen. An elongate tubular member may be advanced over the rail, the elongate tubular member including an outlet communicating with an instrument lumen, and the outlet may be aligned with the branch body lumen. An  
15 instrument, e.g., a transvenous lead, may be introduced through the instrument lumen and out the outlet into the branch body lumen.

In accordance with still another embodiment, a method for delivering a lead into a target coronary vein within a patient's heart. A distal end of an elongate rail may be introduced into the coronary venous system via the coronary sinus, advanced through the  
20 coronary venous system to a location beyond a target coronary vein, and secured at the location beyond the target coronary vein. An elongate tubular member may be advanced over the rail and manipulated to position an outlet of the tubular member adjacent to or otherwise aligned relative to the target coronary vein. A distal end of a lead is delivered through the tubular member and out the outlet into the target coronary vein.

In accordance with yet another embodiment, a method is provided for delivering an instrument within a body cavity communicating with a main body lumen or body cavity. A distal end of an elongate rail may be introduced into the body cavity, e.g., the right ventricle, and advanced to a location beyond the body cavity, e.g., into the pulmonary artery or other body lumen of cavity. The distal end may be secured at the location  
25 beyond the body cavity, e.g., thereby providing a rail extending through the body cavity. An elongate tubular member may be advanced over the rail, the elongate tubular member including an outlet communicating with an instrument lumen, and the outlet may be aligned with the branch body lumen. An instrument, e.g., a transvenous lead, may be  
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- 4 -

introduced through the instrument lumen and out the outlet into the body cavity. The instrument may be secured within the body cavity, e.g., secured to tissue using a helical screw or other fixation device, or simply inserted with sufficient force to frictionally engage surrounding tissue.

5 Other aspects and features of the present invention will become apparent from consideration of the following description taken in conjunction with the accompanying drawings.

#### BRIEF DESCRIPTION OF THE DRAWINGS

10 FIG. 1 is a perspective view of a system for delivering a pacing lead or other instrument, including a guidewire and a delivery catheter.

FIG. 2 is a cross-section of the delivery catheter of FIG.1, taken along line 2-2.

FIG.3 is a schematic view of a heart showing the right atrium, coronary sinus, and anterior coronary vein.

15 FIGS. 4A-4D are details of a portion of the heart of FIG. 3, showing a method for delivering a lead into a target coronary vein using a delivery a device over a rail.

FIG. 5A is a side view of an embodiment of a delivery apparatus including a flexible sheath supported by a backbone for delivering a lead.

20 FIG. 5B is a detail of a patient's heart, showing a lead being delivered using the apparatus of FIG. 5A.

#### DETAILED DESCRIPTION

Turning to the drawings, FIG. 1 shows an exemplary embodiment of a system 10, including a guidewire or other elongate rail 12 and a catheter or other tubular member 20. 25 The system 10 may be used for delivering a lead, e.g., a pacing or other transvenous lead (not shown), or other instrument to a location within a body lumen, as described further below.

The guidewire 12 generally includes a proximal end 14, a distal end 16, and an anchor or other fixation device 18 on the distal end 16. The guidewire 12 may be formed 30 using known materials and methods, e.g., metal, such as stainless steel or Nitinol, plastics, or composite materials. For example, the guidewire 12 may be formed from a single strand of solid or hollow wire, multiple strands, and the like. The guidewire 12 has sufficient length to extend from a location outside a patient's body, e.g., from a

- 5 -

percutaneous entry site into the subclavian or femoral vein, to a target location where the distal end 16 is to be secured.

The anchor 18 may include any device capable of securing the distal end 16 to tissue or otherwise within a body lumen or body cavity, e.g., a helical coil, a barbed tip, hook, a balloon or other expandable device, and the like. The anchor 18 may be attached to the distal end 16 or integrally formed thereon. Alternatively, other elongate rails may be provided instead of guidewire 12, e.g., an elongate catheter, sheath, or other member (not shown), which is sized to be received in the catheter 20 and includes an anchor on its distal end.

With continued reference to FIG. 1 and additional reference to FIG. 2, the catheter 20 is an elongate tubular body including a proximal end 22, a distal end 24 sized for introduction into a body lumen, and one or more lumens 26 extending therebetween. As shown in FIG. 2, the catheter 20 includes a first lumen 26a for receiving the guidewire or other rail therethrough, and a second lumen 26b for receiving a lead or other instrument therethrough. As shown, the first lumen 26a may be smaller than the second lumen 26b. For example, the first lumen 26a may have a diameter between about 0.1 and one millimeter, while the second lumen 26b may have a diameter between about 0.3 and one hundred millimeters (0.3-100 mm), or between about 0.3 and twenty millimeters (0.3-20 mm).

One or more outlets 28 may be provided at the distal end 24 that communicate with respective lumens 26. As shown in FIG. 1, a first outlet 28a is provided that communicates with the first lumen 26a, and a second outlet 28b is provided that communicates with the second lumen 26b. As shown, the outlets 28 may be disposed adjacent one another disposed axially, i.e., oriented along a longitudinal axis of the catheter 20. Alternatively, the outlets 28 may be offset axially from one another and/or oriented laterally. For example, if it is desired to deliver an instrument laterally from the catheter 20, the second outlet may be disposed proximal to the first outlet, e.g., in a side wall of the catheter 20, rather on the distal tip. In such an alternative, the second lumen may include a ramp or other transition (not shown) for directing an instrument advanced through the second lumen out the lateral outlet.

As a further alternative to the catheter 20 shown in FIGS. 1 and 2, other delivery devices may be provided that may be directed over the guidewire 12 or other rail. For example, applications Serial Nos. 10/423,321, filed April 24, 2003, 10/958,034, filed

- 6 -

October 4, 2004, and 11/347,361, filed February 3, 2006 disclose expandable sheath apparatus that may be used to deliver a lead or other instrument. In such apparatus, one lumen may provide a guidewire lumen, e.g., a lumen within a stiffening member or backbone (not shown), and an expandable lumen defined at least partially by an expandable sheath may provide an instrument lumen (also not shown).

Turning to FIGS. 3 and 4A-4D, apparatus and systems as described herein may be used for delivering an instrument, e.g., a pacing or other transvenous lead 30, into a target vessel or other body lumen within a patient's body. For example, FIG. 3 shows a heart 90 that includes a right atrium 92, a coronary sinus 94 extending from the right atrium 92, and one or more coronary veins communicating with the coronary sinus 94 to define the coronary venous system of the heart. In FIG. 3, only the anterior vein 96 is shown in phantom for simplicity.

Turning to FIG. 4A, the guidewire 12 (or other rail) may be introduced into a patient's vasculature, e.g., from a percutaneous entry site into a subclavian or femoral vein, and advanced through the superior vena cava (not shown), the right atrium (also not shown), and into the coronary sinus 94 using known methods. Exemplary apparatus and methods for delivering a guidewire or other rail into the coronary sinus are disclosed in US Patent No. 6,979,290, issued December 27, 2005, and applications Serial Nos. 11/057,074, filed February 11, 2005, 11/062,074, filed February 17, 2005, and 11/379,562, filed April 20, 2006.

As shown in FIG. 4A, coronary vein 98 may be selected as a target location for placing a lead or other instrument. The guidewire 12 is advanced such that the distal end 16 is directed past the target coronary vein 98 and further into the coronary venous system, e.g., into the anterior vein 96. Turning to FIG. 4B, the distal end 16 of the guidewire 12 may be secured within the anterior vein 96 (or other desired location beyond the target coronary vein 98) using the anchor 18. For example, the guidewire 12 may be twisted or otherwise rotated about its longitudinal axis to thread a helical anchor into the wall and/or other tissue adjacent the anterior vein 96. Alternatively, if an expandable anchor is provided, the anchor may simply be expanded to frictionally engage the wall of the anterior vein 96, thereby preventing substantial movement of the distal end 16. In additional alternatives, the guidewire or other rail may be secured to tissue or other structures at other locations, e.g., within to the wall of a chamber of the heart, to tissue within the pericardial space or thoracic cavity, or other body cavity.

- 7 -

As explained elsewhere herein, the anterior vein 96 is generally not considered a good candidate for lead placement because of its location above the septum of the heart. Thus, positioning and securing the distal end 16 of the guidewire 12 within the anterior vein 96 may not interfere with accessing target veins between the coronary sinus 94 and the anterior vein 96, yet provide an anchor point. Thus, the guidewire 12 may then provide a substantially stable rail over which other devices, such as catheter 20, may be advanced.

Turning to FIGS. 4B and 4C, catheter 20 (or one or more other devices) may then be advanced over the guidewire 12 into the coronary venous system via the coronary sinus 94. For example, with additional reference to FIG. 1, a proximal end 14 of the guidewire 12 may be backloaded into the outlet 28a of the catheter 20, and advanced through the first lumen 26a. The distal end 24 of the catheter 20 may then be introduced into the patient's body at the entry site, and advanced over the guidewire 12 into the heart and coronary sinus 94, as shown in FIG. 4B.

As shown in FIG. 4C, the catheter 20 may be advanced until the distal end 24, in particular, the outlet 28b, is disposed adjacent to the target coronary vein 98. The guidewire allows the catheter 20 to be introduced over the rail and moved forward and/or back along the rail without fear of losing access to the coronary sinus because the rail is placed securely in the anterior vein 96. Optionally, external imaging, e.g., fluoroscopy, may be used to monitor and/or facilitate manipulation of the catheter 20.

In one embodiment, the target coronary vein 98 may include one of the posterior or posterolateral veins, which are often a desired site for lead placement. The outlet 28b of the catheter 20 may be positioned adjacent to the entry of the target coronary vein 98, and a lead 30 may be advanced through the catheter 20 and out the outlet 28b into the target coronary vein 98. As shown in FIG. 4D, the lead 30 may be advanced into the target coronary vein 98, e.g., until one or more electrodes 32 are disposed at a desired location, e.g., deep within the target coronary vein 98.

The lead 30 may be loaded directly into the proximal end 22 (not shown, see FIG. 1) of the catheter 20 and advanced through the second lumen 26b (also not shown, see FIG. 2), and out the outlet 28b. Alternatively, the lead 30 may be preloaded within the catheter 20 before the catheter 20 is introduced into the patient's body. In a further alternative, the lead 30 may be directed and/or advanced into the target coronary vein 98 using one or more additional devices. For example, before introducing the lead 30, an



- 8 -

additional guidewire (not shown) may be directed through the second lumen 28b of the catheter 20 and advanced out the outlet 28b and into the target coronary vein 98. The lead 30 may then be advanced over the additional guidewire, which may facilitate advancing the lead 30 deep within the target coronary vein 98. Alternatively, an expandable sheath apparatus, such as those disclosed in the applications identified above (not shown), may be introduced through the catheter 20 and into the target coronary vein 98, and the lead 30 may be directed through the expandable sheath.

If an initial target coronary vein is determined not to be therapeutically optimal, e.g., because of its location relative to the left ventricle or other anatomy to be stimulated, the lead 30 may be retracted from its position within the target coronary vein 98 without fear of losing access because of the rail that is in a stable position and not along the main path of lead delivery. For example, the lead 30 may be withdrawn into or removed entirely from the catheter 20, and the catheter 20 may be directed to another vessel extending from the path provided by the secured guidewire 12. Once a second target vessel is identified and accessed using the catheter 20, the lead 30 may be redeployed and advanced into the second target vessel.

Once the lead 30 is placed within a desired target vessel, the catheter 20 may be withdrawn from the venous system through the coronary sinus 94 and removed from the patient's body, leaving the lead within the target vessel. The guidewire 12 may also be removed, e.g., by unscrewing or otherwise disengaging the anchor 18, and withdrawing the guidewire 12 from the coronary venous system via the coronary sinus 94. The guidewire 121 may be removed before or after the catheter 20.

Additionally, other devices or agents may be delivered using the systems and method during the procedures described above or during other procedures. For example, contrast may be infused from the catheter 20, e.g., as the catheter 20 is moved along the guidewire 12 in order to visualize venous tributaries fluoroscopically. Thus, the catheter 20 may be manipulated along the path provided by the secured guidewire 12 to identify a target vessel for lead placement or other diagnosis and/or treatment.

In addition, the rail apparatus and methods described here may be used to identify initially a target vessel or other implantation site for a lead or other device. For example, an imaging or visualization device, such as a fiberoptic imaging catheter may be advanced over the guidewire 12 to visualize directly the path and identify a site for implantation or other treatment. Exemplary imaging catheters are disclosed in the references identified

above. Such an imaging catheter may be provided within a balloon or other clear surface through which imaging may occur, or the balloon may be eliminated. In addition, a rail, such as the guidewire 12, may be used to deliver a lead over the rail, e.g., using the apparatus and methods disclosed in application Serial No. 11/465,123, filed August 16, 5 2006, entitled, "Apparatus and Methods for Placing Leads Using Direct Visualization."

In addition to the concepts disclosed above, additional apparatus and methods may be provided for delivering leads into the coronary sinus or other body lumen. In the process of delivering leads it is advantageous to maximize pushing forces that are translated from pushing at the proximal end of the lead to the lead tip. One method of 10 translating pushing forces, e.g., for "floppy" or other flexible leads, is to use the elastic recoil of a lubricious delivery sheath, such as those disclosed in the references identified above. FIG. 5A shows an exemplary delivery sheath 50, including a substantially rigid or semi-rigid proximal segment 52 and a substantially flexible distal segment 54 that includes a tubular thin membrane 56 attached to a substantially rigid or semi-rigid backbone 58.

15 FIG. 5B shows a lead 30 being introduced through the apparatus 50. The apparatus 50 has been introduced into a patient's heart such that the distal segment 54 extends through the right atrium 92 into the coronary sinus 94, similar to previous embodiments described herein. As shown, a stenosis 95 exists within the coronary sinus 94, which may create resistance against easy advancement of a distal tip 32 of the lead 30. 20 As the lead 30 is advanced by pushing at its proximal end (not shown), the tip 32 encounters resistance and the thin membrane of the sheath 30 is stretched in direction C. If the proximal end of the lead 30 is held in place and not allowed to relax, the recoil of the membrane of the sheath 30 pushes against the lead 30 in a direction opposing direction C. Because the lead 30 is restrained from moving backward in direction A, the recoil force is 25 translated into direction B, e.g. toward the distal tip 32 of the lead 30, forcing the lead through and beyond the stenosis 95. The efficiency of this translation of force may be affected by the friction and elasticity properties of the membrane material.

To facilitate delivering leads, e.g., into a target coronary vein or other vessel, it may be desirable to include a lubricious interface between the lead and surrounding tissue 30 or devices. For example, a temporary lubricious interface may be provided between the lead being delivered and the vasculature to reduce friction and/or otherwise facilitate delivery. A temporary lubricious interface may be useful, because, once a lead is placed and secured, such a lubricious interface may be undesirable, since it may cause the lead to

slip or dislodge subsequent to placement. Thus, it may be desirable to remove or alter the lubricious interface following delivery in order to minimize the likelihood of acute or chronic dislodgement of the lead from a stable position.

Such a temporary lubricious interface may be accomplished by a number of ways. For example, the lead may be provided with a lubricious coating, for example a hydrophilic coating that is adapted to wear off over a predictable duration. Most hydrophilic coatings are intended to extend the life of the coating, rather than shorten the life. In the case of lead delivery, however, a limited working life of such a coating would be advantageous. In one case, the coating may be applied such that it wears off relatively quickly, largely by mechanical wear, e.g., under normal use conditions encountered during delivery. In another embodiment, a de-activating agent or energy may be introduced to change the properties of the coating, or even to make it have subsequently increased friction beyond that between the lead alone and the vasculature. A further embodiment might entail using an apparatus to speed mechanical wear of the coating.

Another option may entail introducing a lubricant into the vasculature or path of introduction of the lead that temporarily makes the path more lubricious. The lubricant may subsequently dissipate naturally, e.g., due to normal fluid flow, such that introduction of the lead is facilitated but once in place the final position is stable.

Still another option may entail disposing a lubricious interface along the lead during introduction and removing the interface following final placement of the lead. For example, a thin film, such as PTFE or other thin film with lubricious coating, or other lubricious material may be initially disposed along the lead. During introduction, the lubricious interface may facilitate delivering the lead easily through the vasculature, sheath or other component of the delivery pathway. Once the lead is in its final position, the thin film may then be removed, for example, by sliding back or by other methods, thereby exposing the surface of the lead to the surrounding vessel wall. Generally, the exposed lead surface may be less lubricious than the lubricious interface and therefore may facilitate stability of the lead in its final position.

Alternatively, a lubricious interface may be introduced into the vasculature or other body lumens before delivering a lead, such as the expandable sheath apparatus disclosed in the references identified above.

While the invention is susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein described in

detail. It should be understood, however, that the invention is not to be limited to the particular forms or methods disclosed, but to the contrary, the invention is to cover all modifications, equivalents and alternatives falling within the scope of the appended claims.

## WE CLAIM:

1. A system for delivering a pacing lead into a body lumen or cavity, comprising:

an elongate rail comprising a proximal end, a distal end sized for introduction into  
5 a body lumen, and an anchor on the distal end for securing the distal end within a body lumen or cavity; and

an elongate tubular member comprising a proximal end, a distal end sized for  
introduction into a body lumen, and first and second lumens extending between the  
proximal and distal ends, the first lumen for receiving the rail therethrough such that the  
10 tubular member is advanceable over the rail, the second lumen sized for receiving a pacing lead therethrough.

2. The system of claim 1, wherein the rail comprises a guidewire.

15 3. The system of claim 1, wherein the anchor comprises a helical screw tip.

4. The system of claim 1, wherein the first lumen has a cross-section smaller  
than the second lumen.

20 5. The system of claim 1, further comprising a pacing lead receivable within  
the second lumen.

6. The system of claim 1, further comprising an outlet port on the distal end of  
the tubular member communicating with the second lumen, the outlet port oriented  
25 laterally relative to a longitudinal axis of the tubular member.

7. The system of claim 1, further comprising a first outlet port on the distal  
end communicating with the first lumen, and a second outlet port on the distal end  
communicating with the second lumen, the second outlet port being located proximal to  
30 the first outlet port.

8. A method for delivering an instrument within a first body lumen or cavity  
communicating with a second body lumen or cavity, comprising:

- 13 -

introducing a distal end of an elongate rail into the first body lumen or cavity;  
advancing the distal end via the second body lumen or cavity to a location beyond  
the first body lumen or cavity;

securing the distal end at the location beyond the first body lumen or cavity;

5 introducing an elongate tubular member over the rail, the elongate tubular member  
comprising an outlet communicating with an instrument lumen;

aligning the outlet with the first body lumen or cavity; and

delivering an instrument through the instrument lumen and out the outlet into the  
first body lumen or cavity.

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9. The method of claim 8, wherein instrument comprises a lead.

10. The method of claim 8, wherein a distal end of the instrument is secured  
within the first body lumen or cavity.

15

11. The method of claim 8, wherein the first body lumen or cavity comprises a  
coronary vein within a heart.

12. The method of claim 11, wherein the second body lumen or cavity  
20 comprises a vessel communicating with the coronary sinus of the heart.

13. The method of claim 11, wherein the location beyond the first body lumen  
or cavity comprises a location within an anterior vein of the heart.

25 14. The method of claim 8, wherein the distal end of the rail comprises an  
anchor, the anchor securing the distal end at the location beyond the first body lumen or  
cavity.

15. The method of claim 8, wherein the rail comprises a guidewire.

30

16. The method of claim 8, further comprising removing the tubular member  
from the second body lumen or cavity while the instrument remains within the first body  
lumen or cavity.

17. The method of claim 16, further comprising removing the rail from the second body lumen or cavity.

5 18. The method of claim 8, wherein the first body lumen or cavity comprises a right ventricle of a heart.

19. The method of claim 18, wherein the second body lumen or cavity comprises a pulmonary artery communicating with the right ventricle.

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20. A method for delivering a pacing lead into a target coronary vein within a patient's heart, the heart comprising a coronary venous system communicating with a coronary sinus, the method comprising:

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introducing a distal end of an elongate rail into the coronary venous system via the coronary sinus;

advancing the distal end through the coronary venous system to a location beyond the target coronary vein;

securing the distal end at the location beyond the target coronary vein;

20

introducing an elongate tubular member over the rail, the elongate tubular member comprising an outlet communicating with an instrument lumen;

aligning the outlet with the target coronary vein; and

delivering a distal end of a lead through the instrument lumen and out the outlet into the target coronary vein.

25

21. The method of claim 20, further comprising removing the tubular member from the coronary venous system while the distal end of the lead remains within the target coronary vein.

30

22. The method of claim 21, further comprising removing the rail from the coronary venous system.

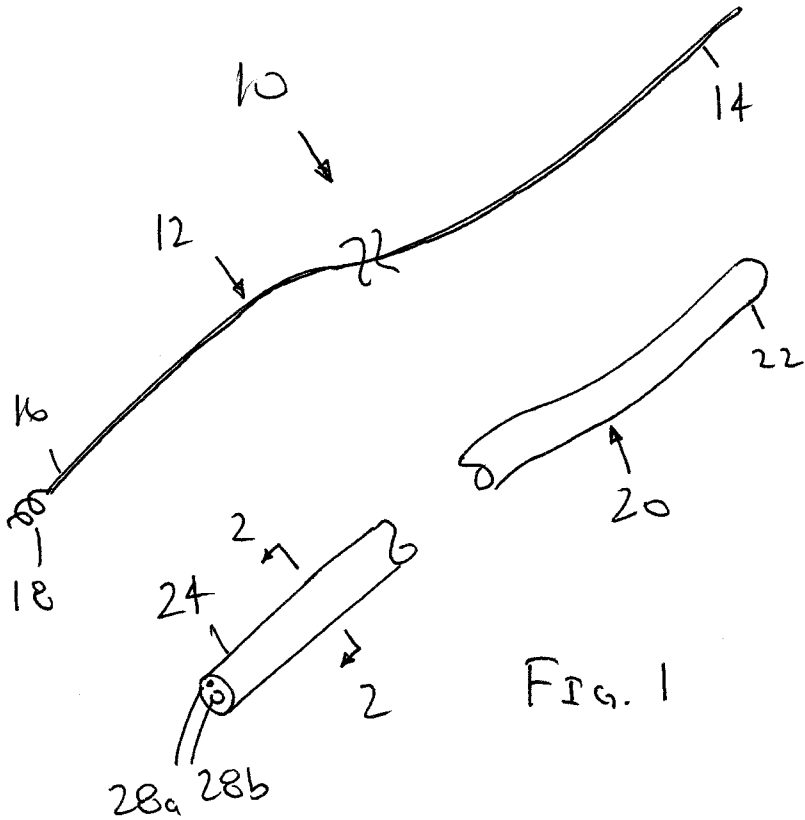


FIG. 1

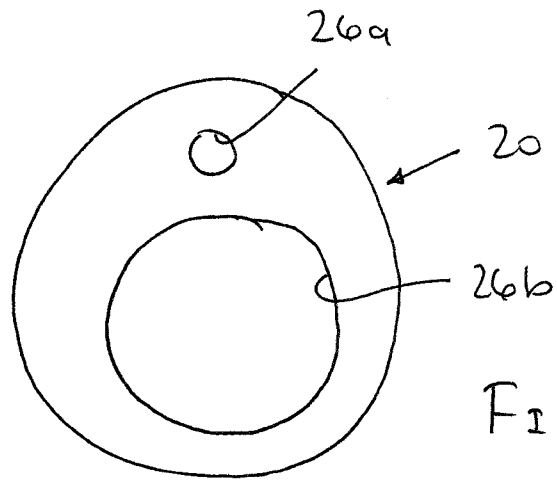


FIG. 2



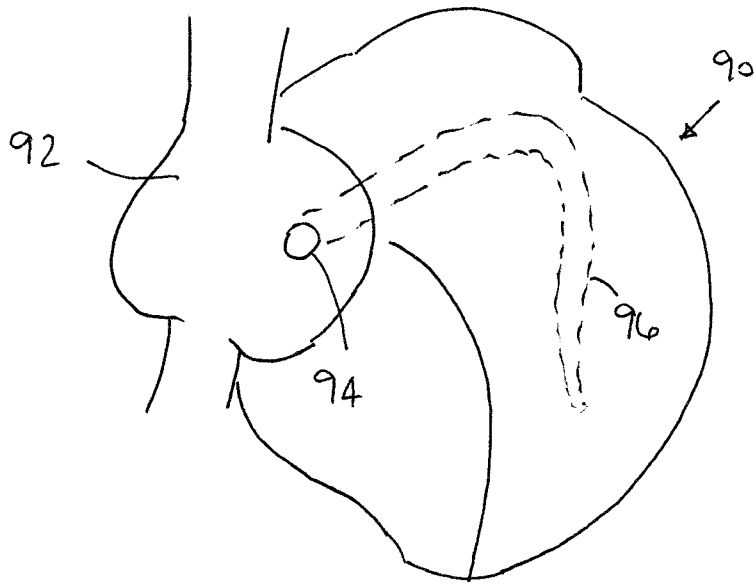


Fig. 3

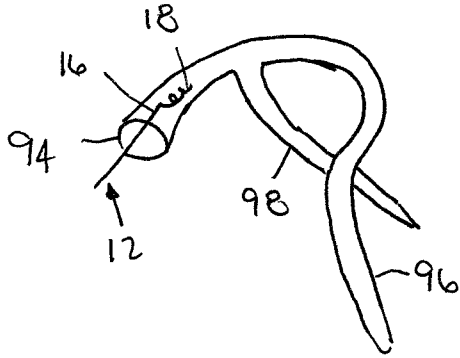


FIG. 4A

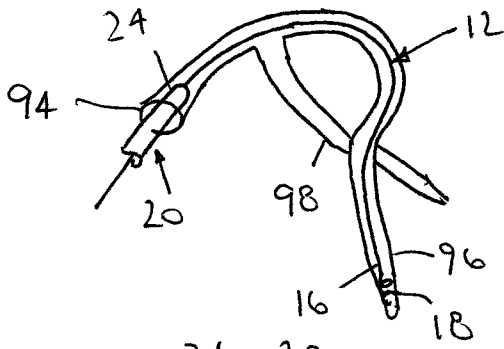


FIG. 4B

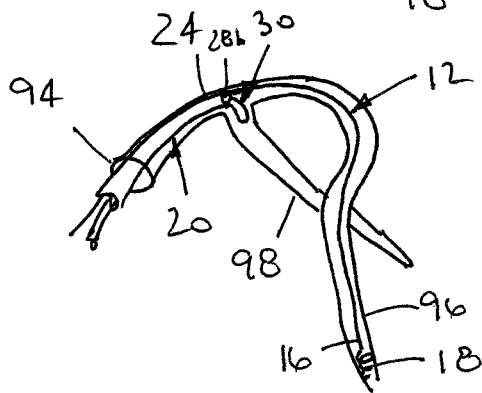


FIG. 4C

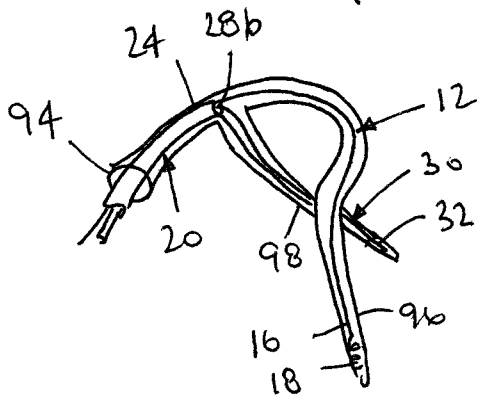


FIG. 4D

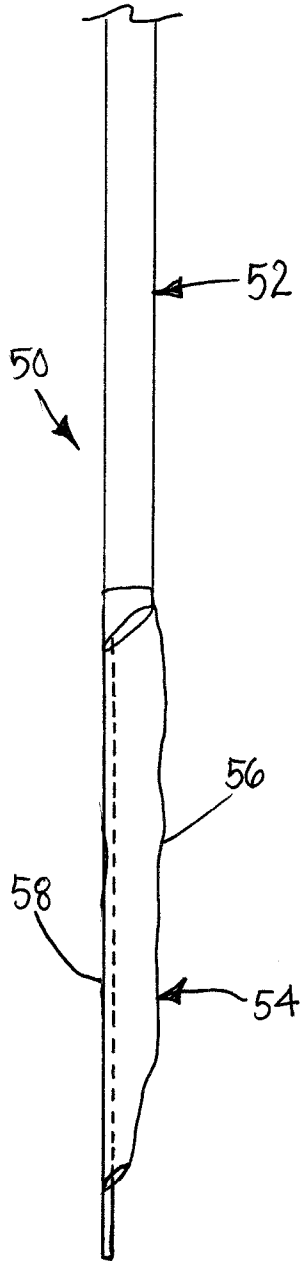


FIG. 5A

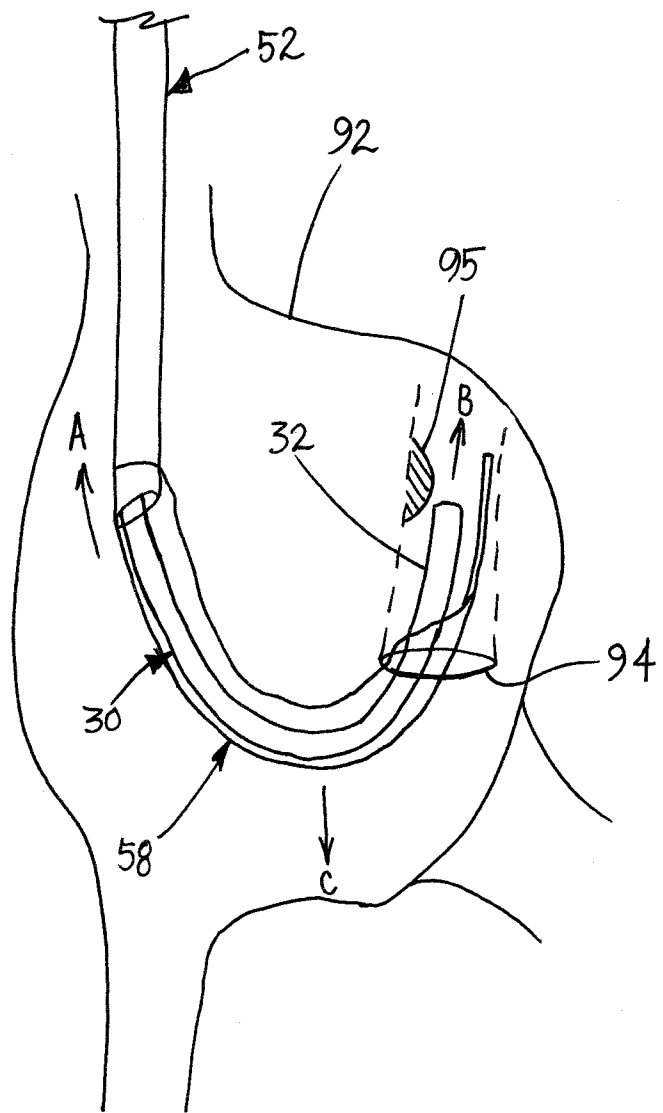


FIG. 5B