A delivery introducer provides access or anchoring to the right atrial septal wall. It is comprised of a flexible proximal segment lying through the superior vena cava into the right atrium. The proximal segment has a straight prebiased portion and a proximal end point. A flexible curved segment is prebiased to assume a curved shape. The proximal segment and at least part of the curved segment lie in a common plane. A portion of the curved segment lies against the right atrial free wall opposite the right atrial septal wall. A flexible distal segment extends from the right atrial free wall to the intra-atrial septum. The flexible distal segment is prebiased to extend out of the common plane. The combination of these segments causes the distal tip to be securely pressed against the intra-atrial septal wall, which is necessary for effective pacemaker anchoring.
A METHOD AND APPARATUS FOR ATRIAL WALL ACCESS AND ANCHORING FOR PACEMAKER LEADS

Related Applications

[001] The present application is related to U.S. Provisional Patent Application, serial no. 60/618,834, filed on Oct. 12, 2004, which is incorporated herein by reference and to which priority is claimed pursuant to 35 USC 119.

Background of the Invention

Field of the Invention

[002] The invention relates to the field of pacemaker leads and in particular to a method and apparatus for atrial septal wall access or anchoring.

Description of the Prior Art

[003] Right intra-atrial pacing is required as the electrophysiological treatment for some cardiac conditions, namely implanting a pacemaker into the right atrium 58 of heart 56 as shown in Fig. 8 and propagating the pacing pulse through the intra-atrial septum 66 to the left atrium 60 through a cardiac bundle, called the Bachman fiber bundle accessible at septum 66. However, unless the pacemaker lead (not shown) is correctly placed in the right atrium 58, depending on electrophysiological cardiac pathways, it may be possible in some cases to
propagate the contraction into the right and left ventricles 62, 64 slightly before an effective contraction can be induced in the left atrium 60 with the result that a left atrium contraction occurs, which is attempting, at least in part, to pump blood into a contracting left ventricle 64 and hence through a closed or closing left mitral valve 68. Such misalignment is clearly unintended and disadvantageous.

[004] It is often difficult with conventional introducers to correctly access atrial septum 66. Typically a pacemaker introducer 10 is led on a guidewire into right atrium 58. A dilator (not shown) maintains introducer 10 in a substantially straight shape or at least in a smoothly curved shape. Once in place, the dilator is removed and introducer 10 is then free to assume any prebiased shape that may have been provided for it. A pacemaker lead (not shown) or other vascular instrument of device can then be delivered through introducer 10 to the accessed cardiac location.

**Brief Summary of the Invention**

[005] The illustrated embodiment of the invention is a delivery introducer for right atrial septal wall access or anchoring comprising a flexible proximal segment lying through the superior vena cava into the right atrium. The proximal segment has a straight prebiased portion and a proximal end point. A flexible curved segment is prebiased to assume a curved shape and extends from the proximal end point of the proximal segment. The proximal segment and at least part of the curved segment lie in a common plane. A portion of the curved
segment lies against the right atrial free wall opposite the right atrial septal wall. A flexible distal segment extends from the right atrial free wall to the intra-atrial septum. The curved segment terminates in a distal end point. The flexible distal segment extends from the distal end point of the curved segment. The flexible distal segment is prebiased to extend out of the common plane. The combination of these segments causes the distal tip to be securely pressed against the intra-atrial septal wall, which is necessary for effective pacemaker anchoring.

[006] In one embodiment the distal end point of the curved segment is defined to lie in the common plane, but a curved portion of the distal segment continues from the end point of the curved portion and is inclined out of the common plane and continues into a straight portion of the distal segment which is also inclined out of the common plane.

[007] In another embodiment the straight distal portion of the distal segment lies in a plane generally parallel to the proximal segment, i.e. within 30° or less of exact parallelism.

[008] The proximal segment has a length preferably of approximately 3.9 to 47.3 inches (10 to 120 cm). The length will be determined according to whether a superior or inferior approach to the vena cava is chosen.

[009] The curved segment is prebiased to have a circular curve with a diameter of approximately 0.5 to 3 inches or preferably approximately 1.1 inch.

[010] The horizontal distance from the maximal extent of the curved segment to the distal end has a size of approximately 1.25 to 6 inches or
preferably approximately 1.58 inches or 1.6 ± 0.05 inch.

[011] The distal segment is inclined by approximately 5° to 50° with respect to the common plane or preferably 22° ± 0.5° with respect to the common plane.

[012] The horizontal distance from the distal end to a point of the curved segment where it begins to lift out of the common plane is approximately 0.75 to 3 inches or preferably 1.31 ± 0.05 inches.

[013] The angle between the projection of distal segment onto a plane perpendicular to the common plane and the common plane itself is approximately 45° to 140° or preferably 90° ± 0.5°.

[014] A distal portion of the circular curved segment also extends out of the common plane.

[015] The distal portion of the distal segment is prebiased to be substantially straight.

[016] The illustrated embodiment of the invention is also a method of making and using the above described embodiments of the introducer. The processing steps for creating biases in the material of the introducer and the material itself of the introducer are conventional and hence need not be further detailed. The kinds of steps and materials included are intended to include all such steps and materials now known or later devised.

[017] While the apparatus and method has or will be described for the sake of grammatical fluidity with functional explanations, it is to be expressly understood that the claims, unless expressly formulated under 35 USC 112, are
not to be construed as necessarily limited in any way by the construction of "means" or "steps" limitations, but are to be accorded the full scope of the meaning and equivalents of the definition provided by the claims under the judicial doctrine of equivalents, and in the case where the claims are expressly formulated under 35 USC 112 are to be accorded full statutory equivalents under 35 USC 112. The invention can be better visualized by turning now to the following drawings wherein like elements are referenced by like numerals.

**Brief Description of the Drawings**

[018] Fig. 1 is a perspective view of the introducer of the invention.

[019] Fig. 2 is a side elevational view of the introducer of Fig. 1.

[020] Fig. 3 is an end plan view of the introducer of Figs. 1 and 2.

[021] Fig. 4 is a top plan view of the introducer of Figs. 1 – 3.

[022] Fig. 5 is a rotated version of the view of Fig. 4 of the introducer showing certain dimensional parameters.

[023] Fig. 6 is a side elevational view of Fig. 2 of the introducer showing certain dimensional parameters.

[024] Fig. 7 is an end elevational view of Fig. 3 of the introducer showing certain dimensional parameters.

[025] Fig. 8 is an illustration of the heart illustrating the anatomy in which the introducer of Figs. 1 – 7 is employed.

[026] The invention and its various embodiments can now be better understood by turning to the following detailed description of the preferred
embodiments which are presented as illustrated examples of the invention defined in the claims. It is expressly understood that the invention as defined by the claims may be broader than the illustrated embodiments described below.

**Detailed Description of the Preferred Embodiments**

[027] One or more distal radiopaque markers (not shown) are provided on introducer 10 to allow convenient fluoroscopic visualization of introducer 10 in heart 56. It has been determined according to the invention that the appropriate position in the right atrium can be more securely and reliably accessed if the pacemaker implanting introducer is appropriately curved or biased. Fig. 1 is a perspective view of the shaped or biased introducer 10 of the invention as seen from the dihedral direction, namely \( e_x + e_y + e_z \) where \( e_x \) etc. are the unit vectors in the direction of the coordinate axes if introducer 10 had its proximal segment 12 laid along the x axis. From the view of Fig. 1 introducer 10 is comprised of a proximal straight segment 12 which leads to a bend or curved segment 14 and a distal segment 16. Introducer 10 is of course flexible and the depiction of the figures represent what would be seen if introducer 10 were laid flatly on a flat surface or table. In use introducer 10 assume other shapes as determined by the shape of the vascular system, guidewire, introducer or other elements in which introducer 10 is disposed.

[028] Fig. 2 illustrates a view of introducer 10 as seen looking down the z axis and shows distal segment 16 as a distal portion of introducer 10 extending out of the common plane in which curved segment 14 and proximal segment 12
lie as would be seen if introducer 10 were laid flatly on a flat surface or table. Distal segment 16 is illustrated here as a prebiased portion of introducer 10, which extends in the x-y plane as a straight inclined length.

[029] Fig. 3 illustrates a view of introducer 10 as seen looking down the x axis and shows distal segment 16 as a length extending upwardly toward the viewer out of the common x-z plane in which curved segment 14 and proximal segment 12 lie as would be seen if introducer 10 were laid flatly on a flat surface or table. The proximal segment 12 is seen end on and in the figure appears only in an end section. A distal portion of curved segment 14 is also shown as lifted out of the common x-z plane and extending to a straight segment 20. Thus, it can be understood that distal segment 16 is comprised of an elbow or curved segment 18 and a straight segment 20, or that curved segment 18 is part of curved segment 14 with the remainder of out-of-plane distal segment 16 comprised of straight segment 20.

[030] Fig. 4 illustrates a view of introducer 10 as seen down the y axis and shows distal segment 16 as a straight length extending back along the x axis parallel to proximal segment 12 as would be seen if introducer 10 were laid flatly on a flat surface or table. In the illustrated embodiment curved segment 14 is shown as symmetrical but with the corresponding curved segment 22 lies entirely in the common plane defined by the x-z axes and segment 18 thus appears somewhat foreshortened although it is in fact symmetrical with curved segment 22.

[031] Fig. 5 corresponds to the view of Fig. 4 and shows that in the
illustrated embodiment as seen in the x-z projection, dimension 24 from the distal end of distal segment 16 to the leftmost extend of curved segment 14 as seen in Fig. 5, namely the horizontal distance from the maximal extent of the curved segment 14 to the distal end 26, has a size of approximately 1.25 to 6 inches, with a preferred embodiment at approximately 1.58 inches or 1.6 ± 0.05 inch. The shape of curved segment 14 is a simple circle with a diameter of approximately 0.5 to 3 inches with a preferred embodiment of approximately 1.11 inches or 1.1± 0.05 inch. This diameter size can be varied to accommodate different heart anatomies.

[032] Fig. 6 corresponds to Fig. 2 rotated by 180 degrees in plane and shows that in the illustrated embodiment as seen in the x-y projection, distal segment 16 is inclined by approximately 5° to 50° with a preferred embodiment of approximately 22° ± 0.5° with respect to the common x-z plane as would be seen if introducer 10 were laid flatly on a flat surface or table. This angle can be varied to accommodate different heart anatomies, and hence should be understood as obtaining any value as may be needed for the heart anatomy in question. The distance 28 in the x-z plane from the distal end 26 of distal segment 16 to proximal end of curved segment 18 where it begins to lift out of the common x-z plane is approximately 0.75 to 3 inches with a preferred embodiment of approximately 1.31 ± 0.05 inches. Again this projected distance 28 can be varied to accommodate different heart anatomies.

[033] Fig. 7 corresponds to Fig. 3 and shows that the angle as would be seen if introducer 10 were laid flatly on a flat surface or table between distal
segment 16 and curved segment 14 as seen in the z-y plane, or equivalently the angle between the projection of distal segment 16 onto a plane perpendicular to the common plane and the common plane itself is approximately 45° to 140° with a preferred embodiment of approximately 90° ± 0.5°. Again this angle can be varied to accommodate different heart anatomies.

To be clear, it is understood that each of the disclosed dimensions and angles given here are examples which can be varied to accommodate different anatomies, such as an infant, juvenile and different sized adult hearts, but that the general or average adult size is that given as the preferred embodiment. A pacemaker lead then implanted through introducer 10 can be readily placed at the approximate location on the intra-atrial septum 66 to avoid the missynchronization of cardiopulsing discussed above. For example, a pacemaker lead is introduced through curved introducer 10 and anchoring or screwed into place in intra-atrial septum 66. Placement of the pacemaker lead is tested using a test pulse and a determination is made if the desired intra-atrial pacing has occurred through the Bachman bundle. If not, the pacemaker is freed or screwed out and redelivered to the intra-atrial septum 66 with introducer 10 to a new position that is believed may be a more efficacious placement. The process is repeated until the desired placement is achieved.

Many alterations and modifications may be made by those having ordinary skill in the art without departing from the spirit and scope of the invention. Therefore, it must be understood that the illustrated embodiment has been set forth only for the purposes of example and that it should not be taken as
limiting the invention as defined by the following invention and its various embodiments.

[036] Therefore, it must be understood that the illustrated embodiment has been set forth only for the purposes of example and that it should not be taken as limiting the invention as defined by the following claims. For example, notwithstanding the fact that the elements of a claim are set forth below in a certain combination, it must be expressly understood that the invention includes other combinations of fewer, more or different elements, which are disclosed in above even when not initially claimed in such combinations. A teaching that two elements are combined in a claimed combination is further to be understood as also allowing for a claimed combination in which the two elements are not combined with each other, but may be used alone or combined in other combinations. The excision of any disclosed element of the invention is explicitly contemplated as within the scope of the invention.

[037] The words used in this specification to describe the invention and its various embodiments are to be understood not only in the sense of their commonly defined meanings, but to include by special definition in this specification structure, material or acts beyond the scope of the commonly defined meanings. Thus if an element can be understood in the context of this specification as including more than one meaning, then its use in a claim must be understood as being generic to all possible meanings supported by the specification and by the word itself.
The definitions of the words or elements of the following claims are, therefore, defined in this specification to include not only the combination of elements which are literally set forth, but all equivalent structure, material or acts for performing substantially the same function in substantially the same way to obtain substantially the same result. In this sense it is therefore contemplated that an equivalent substitution of two or more elements may be made for any one of the elements in the claims below or that a single element may be substituted for two or more elements in a claim. Although elements may be described above as acting in certain combinations and even initially claimed as such, it is to be expressly understood that one or more elements from a claimed combination can in some cases be excised from the combination and that the claimed combination may be directed to a subcombination or variation of a subcombination.

Insubstantial changes from the claimed subject matter as viewed by a person with ordinary skill in the art, now known or later devised, are expressly contemplated as being equivalently within the scope of the claims. Therefore, obvious substitutions now or later known to one with ordinary skill in the art are defined to be within the scope of the defined elements. The claims are thus to be understood to include what is specifically illustrated and described above, what is conceptionally equivalent, what can be obviously substituted and also what essentially incorporates the essential idea of the invention.
We claim:

1. A delivery introducer for right atrial septal wall access or anchoring comprising:
   a flexible proximal segment lying through the superior vena cava into the right atrium having a straight prebiased portion and having a proximal end point;
   a flexible curved segment prebiased to assume a curved shape extending from the proximal end point of the proximal segment, the proximal segment and at least part of the curved segment lying in a common plane, a portion of the curved segment lying against the right atrial free wall opposite the right atrial septal wall; and
   a flexible distal segment extending from the right atrial free wall to the intra-atrial septum, the curved segment terminating in a distal end point, the flexible distal segment extending from the distal end point of the curved segment, the flexible distal segment prebiased to extend out of the common plane, such that the distal tip is securely pressed against the intra-atrial septal wall.

2. The introducer of claim 1 where the distal end point of the curved segment is defined to lie in the common plane, but a curved portion of the distal segment continuing from the end point of the curved portion being inclined out of the common plane and continuing into a straight portion of the distal segment which is also inclined out of the common plane.
3. The introducer of claim 1 where the curved segment is prebiased to have a circular curve with a diameter of approximately 0.5 to 3 inches.

4. The introducer of claim 1 where the curved segment is prebiased to have a circular curve with a diameter of approximately 1.1 inch.

5. The introducer of claim 1 where the horizontal distance from the maximal extent of the curved segment to the distal end has a size of approximately 1.25 to 6 inches.

6. The introducer of claim 1 where the horizontal distance from the maximal extent of the curved segment to the distal end has a size of approximately 1.58 inches.

7. The introducer of claim 1 where the horizontal distance from the maximal extent of the curved segment to the distal end has a size of 1.6 ± 0.05 inch.

8. The introducer of claim 1 where the distal segment is inclined by approximately 5° to 50° with respect to the common plane.

9. The introducer of claim 1 where the distal segment is inclined by 22° ± 0.5° with respect to the common plane.

10. The introducer of claim 1 where the horizontal distance from the distal end
to a point of the curved segment where it begins to lift out of the common plane is approximately 0.75 to 3 inches.

11. The introducer of claim 1 where the horizontal distance from the distal end to a point of the curved segment where it begins to lift out of the common plane is 1.31 ± 0.05 inches.

12. The introducer of claim 1 where the angle between the projection of distal segment onto a plane perpendicular to the common plane and the common plane itself is approximately 45° to 140°.

13. The introducer of claim 1 where the angle between the projection of distal segment onto a plane perpendicular to the common plane and the common plane itself is 90° ± 0.5°.

14. The introducer of claim 1 where a distal portion of the circular curved segment also extends out of the common plane.

15. The introducer of claim 1 where a distal portion of the distal segment is prebiased to be substantially straight.

16. A delivery introducer for right atrial septal wall access or anchoring comprising:
a flexible proximal segment lying through the superior vena cava into the right atrium having a straight prebiased portion and having a proximal end point; a flexible curved segment prebiased to assume a curved shape extending from the proximal end point of the proximal segment, the proximal segment and at least part of the curved segment lying in a common plane, a portion of the curved segment lying against the right atrial free wall opposite the right atrial septal wall; and a flexible distal segment extending from the right atrial free wall to the intra-atrial septum, the curved segment terminating in a distal end point, the flexible distal segment extending from the distal end point of the curved segment, the flexible distal segment prebiased to extend out of the common plane, such that the distal tip is securely pressed against the intra-atrial septal wall, a straight distal portion of the distal segment lying in a plane generally parallel to the proximal segment.

17. The introducer of claim 16 where the distal end point of the curved segment is defined to lie in the common plane, but a curved portion of the distal segment continuing from the end point of the curved portion being inclined out of the common plane and continuing into the straight distal portion of the distal segment which is also inclined out of the common plane.
**INTERNATIONAL SEARCH REPORT**

A. **CLASSIFICATION OF SUBJECT MATTER**
   IPC(S): A61M 25/00 (2006.01)
   USPC: 604/532
   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.: 604/532, 523-531, 264

   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**

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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<tbody>
<tr>
<td>A</td>
<td>US 5799350 A (Ferlek-Petric et al.) 01 September 1998 Note: Please review the entire patent.</td>
<td>1-17</td>
</tr>
<tr>
<td>A</td>
<td>US 5505698 A (Booth et al.) 09 April 1996 Note: Please review the entire patent.</td>
<td>1-17</td>
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☐ 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
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Date of the actual completion of the international search: 20 February 2006 (20.02.2006)

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