Lead delivery apparatus includes an electrically conductive lead for an implantable medical device, a delivery shaft for delivering the lead to a target site, a fixator and a pulley structure. A flexible member is coupled to the delivery shaft and the lead and engages the pulley structure such that pulling a first portion of the flexible member moves the lead to the target site.
LEAD DELIVERY DEVICE AND METHOD

INTRODUCTION

Various cardiac devices providing electrical stimulation, rhythm management, or resynchronization therapy to the heart include implantable electrically conductive leads in contact with excitable heart or other body tissue. The present teachings provide a device and method for delivering an implantable electrically conductive lead to a target site for a use with a cardiac device.

SUMMARY

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

In a further aspect, the present teachings provide a medical apparatus comprising a guidewire and a fixator catheter. The fixator catheter comprises a tubular body with a distal portion and a proximal portion. The fixator catheter further comprises a distal opening, a fixator secured to the distal portion, and a body opening arranged between the fixator and the proximal portion. The guidewire is passed through the body opening and the distal opening of the fixator catheter. The fixator is movable between a compact configuration and an expanded configuration.

In yet another aspect, the present teachings provide a medical method comprising passing a guidewire through a fixator catheter. The fixator catheter comprises a tubular body with a distal portion and a proximal portion. The fixator catheter further comprises a distal opening, a fixator secured to the distal portion, and a body opening arranged between the fixator and the proximal portion. The guidewire is passed through the body opening and the distal opening of the fixator catheter. The method further comprises navigating the guidewire and fixator catheter to a desired site. At the desired site, the fixator is expanded to an expanded configuration in order to releasably secure the fixator catheter. An
implantable electrically conductive lead of a cardiac device is advanced over the guidewire to the desired site while the fixator is deployed.

In various embodiments, the present teachings provide a lead delivery apparatus comprising an electrically conductive lead for an implantable medical device, a delivery shaft for delivering the lead to a target site, a fixator and a pulley structure. A flexible member is coupled to the delivery shaft and the lead and engages the pulley structure such that pulling a first portion of the flexible member moves the lead to the target site.

In various embodiments, the present teachings provide a method of delivering a medical lead to an anatomic target site. The method includes providing a delivery shaft and a fixator attached to a distal portion of the delivery shaft. The method also includes passing a flexible member having first and second ends through a longitudinal passage of the delivery shaft in a first orientation, around a pulley structure and out of the delivery shaft in a second direction substantially opposite to the first orientation such that a first end of the flexible member remains outside the deliver shaft. The method also includes inserting the lead delivery shaft loaded with the flexible member on a distal portion of the delivery shaft through cardiac tissue, fixating the fixator to a target site in a blood vessel, and coupling a lead over a portion of the flexible member associated with the second direction. Pulling the first end of the flexible member away from the proximal end of the delivery shaft in a first direction, advances the lead toward the target site in a second direction substantially opposite to the first direction.

In various embodiments, the present teachings provide a method of delivering a medical lead to an anatomic target site. The method includes inserting a guidewire to cardiac target site, and providing a catheter with a fixator and a flexible member having first and second ends and coupled to a pulley structure. The method includes positioning the catheter over the guidewire and fixating the catheter at the target site with the fixator. The method also includes coupling a medical lead to the flexible member, pulling the first end of flexible member in a first direction away from the target site, and advancing the lead to the target site. The guidewire and the catheter are removed.
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 various embodiments of the present teachings;

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 cardiac 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. 4 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;
FIG. 16 is an end view of a distal end of an electrical lead with an offset distal opening;

FIG. 17 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;

FIG. 18 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. 19 is an environmental view of a lead delivery device according to various embodiments of the present teachings;

FIG. 20 is an environmental view of a lead delivery device according to various embodiments of the present teachings;

FIG. 21 is an environmental view of a lead delivery device according to various embodiments of the present teachings;

FIG. 22 is an environmental view of a lead delivery device according to various embodiments of the present teachings;

FIG. 23 is a diagrammatic view of a lead delivery device having a pulley-like structure according to various embodiments of the present teachings;

FIG. 23A is a diagrammatic view of a lead delivery device having a pulley-like structure according to various embodiments of the present teachings;

FIG. 24 is an environmental view of a lead delivery device according to various embodiments of the present teachings;

FIG. 25 is an environmental view of a lead delivery device according to various embodiments of the present teachings;

FIG. 26 is an environmental view of a lead delivery device according to various embodiments of the present teachings;

FIG. 27 is an environmental view of a lead delivery device according to various embodiments of the present teachings;

FIG. 28 is a detail of an environmental view of a lead delivery device according to various embodiments of the present teachings;

FIG. 29 is a sectional view of a lead with an internal attachment device for a lead delivery device according to various embodiments of the present teachings;
FIG. 30 is an environmental view of a lead delivery device according to various embodiments of the present teachings;

FIG. 31 is an environmental view of a lead delivery device according to various embodiments of the present teachings; and

FIG. 32 is an environmental view of a lead delivery device according to various embodiments of the present teachings.

DESCRIPTION OF VARIOUS EMBODIMENTS

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 cardiac 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 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 than 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,
IA and IB. 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 device 290, 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. 1, 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 lbs, 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 cardiac device 290. 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 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.

Referring now to FIG. 17, a lead delivery device 300 according to some embodiments of the present disclosure is illustrated. Lead delivery device 300 comprises a guidewire 302 and fixator catheter 304. Guidewire 302 may comprise a solid wire (as illustrated) or be cannulated, and includes proximal portion 344 and distal portion 342. The fixator catheter 304 is a cannulated catheter comprising a tubular body 310 with a distal portion 320 and proximal portion 340. A fixator 312 is secured on the distal end 320 of fixator catheter 304. In FIGS. 17-22, fixator 312 comprises an inflatable balloon, although any other form of fixator may be utilized, as described above.

Guidewire 302 passes through fixator catheter 304 such that the guidewire 302 is encased within the tubular body 310 in at least a portion of the distal portion 320 of the fixator catheter 304. In the illustrated embodiments, this is accomplished by passing the distal portion 342 of the guidewire 302 through the body opening 316 of fixator catheter 304 such that it extends through the distal opening 314. In this manner, the guidewire 302 and fixator catheter 304 are in communication at their distal portions 342, 320, while being separate at their proximal portions 344, 340.

Referring now to FIG. 18, lead delivery device 300 is shown in the condition where fixator 312 is expanded. In the illustration, fixator 312 comprises an inflatable balloon that may be expanded by a gas or fluid, as described more fully above. In some embodiments, the tubular body 310 of the fixator catheter
includes a lumen (not shown) that is in communication with the inflatable balloon 312 and proximal end 340. By providing a pressurized gas or fluid to the balloon 312, the fixator 312 is expanded to the expanded configuration. In the expanded configuration, the pressure inside balloon 312 will exert a force on a compressible or collapsible portion 313 of tubular body 310. In the illustrated embodiment, the compressible portion 313 is a portion of the lumen of the fixator catheter within the inflatable balloon, however, the compressible portion 313 may comprise a lumen of the balloon itself or other arrangement. The force exerted by inflatable balloon 312 on portion 313 of tubular body 310 will cause that portion 313 to compress guidewire 302 such that guidewire 302 is secured to fixator catheter 304. Portion 313 may be formed by providing a thinner wall in portion 313 than is utilized in the remainder of tubular body 310. Alternatively, portion 313 may be formed of a different material than that used to form the rest of tubular body 310, or any other alternative structure may be utilized (such as, adding a constrictive device or other securing mechanism). While the illustration in FIG. 18 shows an inflatable balloon 312 and a compressible or contract portion 313 of tubular body 310 to secure the guidewire 302 to fixator catheter 304, alternative structures and fixators may be substituted such that the guidewire 302 and fixator catheter 304 are secured together in the expanded configuration, while remaining independently movable in the compact configuration.

Referring now to FIGS. 19-22, a method for using lead delivery device 300 to implant an implantable electrically conductive lead 360 within a blood vessel 350 is illustrated. Similar to FIG. 1, FIGS. 19-20 show the lead delivery device 300 utilized to implant implantable electrically conductive lead 360 within the coronary sinus CS of heart tissue 80. A delivery catheter 250 having a proximal end 252 and distal end 254 may be utilized to assist in the delivery of guidewire 302 and fixator catheter 304 to a target or desired site 82. The fixator catheter 304, with guidewire 302 passed therein, is inserted through catheter 250 and navigated to a position within the desired site 82. Upon delivery to desired site 82, fixator catheter 304 deploys its fixator 312 to secure guidewire 302 and fixator catheter 304 within blood vessel 350. In the expanded configuration, fixator 312 exerts a force, as described above, upon the wall of blood vessel 350 sufficient to anchor
both the guidewire 302 and fixator catheter 304 in the desired site 82 while
delivery catheter 250 is removed and/or implantable electrically conductive lead
360 is delivered to desired site 82, e.g., via guidewire 302.

In the illustrations of FIGS. 19 and 20, delivery catheter 250 is shown as
being present within the heart tissue 80 during delivery of lead 360. As shown in
FIG. 19, in the expanded configuration fixator 312 compresses or collapses portion
313 of fixator catheter 304 such that guidewire 302 is fixedly secured within
fixator catheter 304, as described more fully above. Alternatively, as shown in
FIG. 20, guidewire 302 may be removed from fixator catheter 304 before fixator
312 is expanded. Fixator 312 may then be expanded to fixedly secure guidewire
302 between fixator 312 and the wall of blood vessel 350. Once guidewire 302 is
fixedly secured within blood vessel 350, implantable electrically conductive lead
360 may be delivered to desired site 82 by, e.g., traveling over guidewire 302.
With the guidewire 302 secured, the risk of the lead 360 being delivered
incorrectly, i.e., outside of desired site 82, due to unintentional movement of
guidewire 302 is reduced.

Once lead 360 is delivered to the desired site 82, the fixator 312 may be
contracted to a compact configuration (as shown in FIG. 17, for example) and both
guidewire 302 and fixator catheter 304 may be removed from desired site 82 and
heart tissue 80. In some embodiments, fixator 312 may be utilized to secure lead
360 against blood vessel wall 350 while guidewire 302 is removed (see, e.g., FIG.
22). In this manner, it can be ensured that there is no unanticipated movement of
lead 360 from desired site 82 while guidewire 302 is removed from the patient's
body.

Referring now to FIGS. 21 and 22, a method of finely adjusting the position
of guidewire 302 and lead 360 is illustrated. FIG. 21 shows fixator 312 in the
expanded condition wherein guidewire 302 is secured between fixator 312 and the
wall of blood vessel 350. This is accomplished, for example, by delivering lead
delivery device 300 to the desired site 82 and then removing guidewire 302 from
distal opening 314 and body opening 316 of fixator catheter 304. The guidewire
302 may be pulled out of communication with fixator catheter 304 by pushing on
fixator catheter 304 until the distal portion 342 of guidewire 302 is pulled out of
and exits body opening 316. Then, guidewire 302 may be pushed past the distal portion 320 of fixator catheter 304, as illustrated. Fixator 312 may be expanded to secure guidewire 302 against the wall of blood vessel 350 and implantable electrically conductive lead 360 can then be navigated to desired site 82 by, for example, traveling over guidewire 302 through opening 364.

The position of implantable electrically conductive lead 360 and guidewire 302 may be finely adjusted with the selective use of fixator catheter 304. Fixator 312 may be expanded to secure guidewire 302 (as shown in FIG. 21) such that the position of lead 360 may be adjusted. Alternatively, as shown in FIG. 22, fixator catheter 304 may be moved such that fixator 312 is immediately adjacent the body of lead 360. Fixator 312 may then be expanded to secure lead 360 within blood vessel 350. With lead 360 secured, the position of guidewire 302 may be adjusted without the possibility of moving lead 360. In this manner, a user may alternate between securing the guidewire 302 or lead 360 at a certain position, while adjusting unsecured lead 360 or guidewire 302, respectively, and thus more accurately and simply adjust the positioning of lead 360 within desired site 82.

Referring to FIGS. 23-32, a lead delivery device 400 and associated methods are illustrated according to various exemplary embodiments. The lead delivery device 400 can employ a method similar to pulley or flagpole principle to advance the lead using a pulley or pulley-like structure.

An exemplary embodiment of the lead delivery device 400 is illustrated in FIGS. 23 and 23A largely diagrammatically. The lead delivery device 400 can include a delivery shaft 402 having an inner passage or lumen 420, a fixator/fixation device 404 for temporary fixation during lead delivery and an electrically conductive medical lead 406 for an implantable medical device 290 (shown in FIG 2). The medical lead 406 can have first and second ends 424, 426. The lead delivery device 400 can include a pulley structure 408 and an elongated flexible member 410, such as a string, rope or cable, having a first portion 412 and a second portion 414. The flexible member 410 can pass through the inner passage 420, change direction over or around the pulley structure 408 and pass through a lumen 422 of the lead 406, such that the flexible member 410 takes a U-shape by a U-turn at the pulley structure 408, as shown in FIG. 23. Pulling the first portion
412 of the flexible member 410 in the direction A moves the lead 406 in the direction B. A retainer, such as a knot, a button-like plate, a ball or a rod or other attachment device 416 can be at least temporarily coupled to the flexible member 410 and used as a stop to keep the lead 406 coupled onto the flexible member 410 as the flexible member 410 is pulled in the direction A away from heart tissue 80 to force the lead 406 to follow along the path of the flexible member 410.

Alternatively, as shown in FIG. 23A, the flexible member 410 can remain outside the delivery shaft 402 and outside the lead 406. The flexible member 410 can be coupled to the delivery shaft 402 with one or more external retainer elements 417, such as, for example, resilient rings, loose adhesive tape, easily breakable spot adhesive, or other devices that allow movement of the flexible member 410 relative to the delivery shaft 402, while maintaining coupling with the delivery shaft 402. Similarly, the flexible member 410 can be coupled to the lead 406 with one or more external retainer elements 417, or with one or more retainers 419 positioned adjacent to the distal end 424 of the lead 406. The retainer 419 can be an attachment made by a dissolvable adhesive or by various other means, as discussed below. In various embodiments, the attachment can be made by electrical or thermal fusing. In various embodiments, the retainer 419 can include an electrical fuse such that passing a specified electrical current through the flexible member 410 can cause the electrical fuse to blow/break and release the flexible member 410 from the lead 406. A delivery shaft 402 and lead 406 of smaller diameter can be used when the flexible member 410 remains outside the delivery shaft 402 and the lead 406. It will be appreciated that the flexible member 410 need not extend along the entire length of the lead 406. The flexible member 410 can terminate, for example, at the location of the retainer 419, or the retainer 417, if used.

In various embodiments, the delivery shaft 402 can be made of a biocompatible material, such as, for example, a metallic or polymeric or other material. The delivery shaft 402 can also be a tubular catheter 402a or a tubular guidewire 402b or a solid guidewire 402c or other anchoring wire, as is discussed below in connection with FIGS. 24, 25 and 30-32. The lead 406 can travel along a path substantially parallel and adjacent to the shaft 402, either outside the passage
420 of the shaft 402, as illustrated in FIG. 23, or within the shaft passage 420. The flexible member 410 can be metal, polymer, string, plastic, hybrid of materials or can be made of different materials along the length of the flexible member 410.

The pulley structure 408 can be a pulley of appropriate size, such as a micro-machined pulley, or a 180-degree corner or U-turn in the delivery shaft 402 or outside the deliver shaft 402. In some embodiments, the pulley structure 408 can be formed by passing the flexible member 410 through first blood vessel 90 and exiting through a second blood vessel 90 forming a U-turn loop. Various exemplary embodiments are discussed below.

The fixator 404 can be an inflatable balloon, an expandable anchor, a distal portion of a catheter or guidewire that can be wedged in a small blood vessel because of its size, surface texture, friction, shape, properties, etc. The fixator 404 can also be selected from various fixators described herein above, such as fixators 150 or 312.

In various embodiments, the lead delivery device 400 can include a shaft 402 in the form of a flexible deformable catheter 402a, such as the fixator catheter 402a illustrated in FIG. 24. The catheter 402a or shaft 402 can be a hollow tubular member and can include a distal end 430 and a proximal end 432. In FIG. 24 the lead delivery device 400 is utilized to guide the lead 406 through the coronary sinus osteum 84 of heart tissue 80. The distal end 430 of the catheter 402a can be deformed to a U-shape within the blood vessel 90 and can function both as a fixator 404 and as a pulley structure 408 for delivering the lead 406, as is also illustrated in FIG. 27. Pulling the first portion 412 of the flexible member 410 in the direction A moves the lead 406 along the flexible member 410 in the direction B substantially parallel to the catheter 402a through coronary sinus osteum 84 until the first end 424 of the lead 406 reaches the target site 82. The flexible member 410 can then be removed by pulling at portion 414 in the opposite direction of arrow B. The catheter 402a can be removed by pulling the proximal end 432 away from the patient in the direction of arrow A.

In various embodiments, the lead delivery device 400 can include a shaft 402 in the form of a flexible deformable guidewire 402b, as illustrated in FIG. 25. The guidewire 402b can be a hollow tubular member, generally of smaller
diameter than the catheter 402a. In FIG. 25, the fixator 404 is illustrated as an expandable member, such as a balloon. The flexible member 410 can pass through the lumen of the guidewire 402b and form a U-turn at pulley structure 408, which can be any one of the pulley structures discussed above, including an opening in the fixator 404. In various embodiments, the guidewire 402b itself can function as both the delivery shaft 402 and the flexible member 410 with the fixator 404 removably attached to the unitary guidewire/flexible member, such that it remains at the target site 82 when the guidewire/flexible member is removed.

With continued reference to FIG. 25, pulling the first portion 412 of the flexible member 410 in the direction A moves the lead 406 along the flexible member 406 in the direction B substantially parallel to the guidewire 402b through coronary sinus osteum 84 until the first end 424 of the lead 406 reaches the target site 82. The flexible member 410 can then be removed by pulling at portion 414 in the opposite direction of arrow B. The guidewire 402b can be removed by pulling the proximal end 432 away from the heart tissue 80 in the direction of arrow A. In various embodiments, the lead delivery device 400 can include a shaft 402 having a distal portion 405 with stiffness and width configured to form a fixator 404 by frictional attachment to the blood vessel 90, as illustrated in FIG. 26. In the illustrative embodiment of FIG. 26, the pulley structure 408 is a hole through which the flexible member 410 exits the delivery shaft 402, makes a U-turn and passes through the lumen of the lead 406.

In various embodiments, a portion 410a of the flexible member 410 can include a coiled portion 410a coiled around a portion of the delivery shaft 402 between the distal end 424 of the lead 406 and a distal end 430 of the shaft 402, as illustrated in FIG. 28. The coiled portion 410a can keep the lead 406 close to the delivery shaft 402 as the lead 406 is moved along the shaft 402. The coiled portion 410a moves in translation with the lead 406 and unravels as the flexible member enters the passage 420 of the delivery shaft 402 at the distal end 430 of the delivery shaft 402 where the flexible member 410 forms the pulley structure 408 by a U-turn.

In various embodiments, the various retainers 416, 417, 419 described above can be coupled to the flexible member 410 outside the lead 406, as shown in
the exemplary illustrations of FIGS. 23-25. In various embodiments, the retainer 416 can be coupled to the flexible member 410 within the lumen 422 of the lead 406, as illustrated in FIG. 29. The retainer 416 can be, for example, a knot in the flexible member 410, a metallic or polymer device, a wedge, an inflatable device, a deformable device, or an expandable basket. The retainer 416 can be temporarily shapeable or can be made of a memory-shaped device. The retainer 416 can also be a threaded screw or a device held in the lumen 422 of the lead by compression fit. The retainers 416, 419 can be attached to flexible member 410 and/or the lead 406 by electrical connection, by adhesive, by thermal connection (heating or freezing). The retainers 416, 419 can be detached and disconnected by softening an adhesive, by dissolving, by electrically breaking a fuse embedded in the retainer as described above in connection with retainer 419, by mechanical force to overcome the attachment force, such as by breaking the flexible member 410 or a portion of the lead 406, or by deforming, deflating, or breaking the retainer 416. A section of reduced width or a section weakened with a notch or other frangible feature 440 may be provided at selected location. In various alternative embodiments, the retainer 416 can be removed by pulling the flexible member 410 in a direction opposite to the direction B, as shown in FIGS. 24 and 25.

In various embodiments, the fixator 404 can be attached to a distal portion of the guidewire 402b or the catheter 402a as illustrated in various embodiments of FIGS. 30-32 (dimensions not in scale).

Referring to FIG. 30, for example, the guidewire 402b can include a fixator 404 attached to the distal portion 452 of the guidewire 402b for anchoring into the lumen 92 of a blood vessel 90. The guidewire 402b can include a guidewire lumen 442 with a side opening 454 that forms the pulley structure 408. The flexible member 410 can pass though the guidewire lumen 442, out of the side opening 454 and around the pulley structure 408 and extend between the guidewire 402b and the lumen 92 of the blood vessel 90. In various embodiments, the guidewire 402b can be pre-loaded with the flexible member 410. Once the guidewire 402b is positioned and fixated in the blood vessel 90, the lead 406 can be attached to the flexible member 410. Pulling the flexible member 410 in the direction A advances the lead 406 in the direction B.
Referring to FIG. 31, the fixator 404 can be attached to the catheter 402a. The catheter 402a can include a first lumen 446 with a side opening 456 that forms the pulley structure 408. The flexible member 410 can pass though the first lumen 446, out of the side opening 456 and around the pulley structure 408 and extend between the catheter 402a and the lumen 92 of the blood vessel 90. A relatively small diameter hollow or solid guidewire 402c can pass through a second lumen 448 through the fixator 404 for guiding the catheter 402a. Once the catheter 402a is positioned and fixated in the blood vessel 90, the lead 406 can be attached to the flexible member 410. Pulling the flexible member 410 in the direction A advances the lead 406 in the direction B.

Referring to FIG. 32, the fixator 404 can be attached to the catheter 402a. The catheter 402a can include a lumen 450 having a side opening 456 that forms the pulley structure 408. The lumen 450 can include a first or proximal lumen portion 451 and a second or distal lumen portion 453. The second lumen portion 453 can pass through the fixator 404. The flexible member 410 can pass though the first lumen portion 451, out of the side opening 456 and around the pulley structure 408 and can extend between the catheter 402a and the lumen 92 of the blood vessel 90. A small diameter hollow or solid cross-section guidewire 402c can extend through the first lumen portion 451 and the second lumen portion 453 for guiding the catheter 402a. The guidewire 402c can be first positioned in the blood vessel 90 and the catheter 402a pre-loaded with the flexible member can be positioned over the guidewire 402c. Pulling the flexible member 410 in the direction A advances the lead 406 in the direction B. Alternatively, the guidewire 402c can pass through the side opening 456 only though the second lumen portion 453, as shown in phantom line.

The various embodiments described above in connection with FIGS. 23-32 facilitate the implantation of a lead 406 using a pulley structure 408 and allow the physician to deliver the lead 406 to a target site by a pulling action rather than pushing. Because pulling a thin elongated member through a curved lumen can avoid buckling, kinking or other convolutions that may occur when pushing is used instead, a lead delivery device 400 using a pulley structure can utilize smaller
diameters or reduced stiffness for the lead as well as the catheters and/or guidewires.

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

What is claimed is:

1. A lead delivery apparatus comprising:
   an electrically conductive lead for an implantable medical device;
   a delivery shaft for delivering the lead to a target site;
   a fixator coupled to a distal portion of the delivery shaft;
   a pulley structure; and
   a flexible member having first and second portions, the flexible member
   coupled to the delivery shaft and the lead, the flexible member engaging the pulley
   structure such that pulling the first portion moves the lead to the target site.

2. The lead delivery device of claim 1, wherein the flexible member passes
   through a longitudinal passage of the delivery shaft in a first direction, changes
   direction at the pulley structure and passes through a longitudinal passage of the
   lead on a second direction substantially opposite to the first direction.

3. The lead delivery device of claim 1, wherein the flexible member is
   coupled to the delivery shaft outside the delivery shaft along a first direction,
   changes direction at the pulley structure and is coupled to the lead outside the lead
   along a second direction substantially opposite to the first direction.

4. The lead delivery device of claim 1, wherein the pulley structure comprises
   a side opening at the distal portion of the delivery shaft, the side opening
   communicating with the longitudinal passage of the delivery shaft.

5. The lead delivery device of claim 4, wherein the delivery shaft comprises a
   fixator catheter.

6. The lead delivery device of claim 4, wherein the delivery shaft comprises a
   guidewire.
7. The lead delivery device of claim 4, wherein the fixator comprises an expandable fixator.

8. The lead delivery device of claim 4, wherein the fixator comprises an inflatable balloon.

9. The lead delivery device of claim 4, wherein the distal portion of the delivery shaft has stiffness and dimensions for frictional attachment to the target site.

10. The lead delivery device of claim 1, wherein a distal portion of the delivery shaft deforms to a U-shape, the U-shape forming a fixator and a pulley structure at the target site.

11. The lead delivery device of claim 1, wherein a portion of the flexible member is coiled around a distal portion of the delivery shaft.

12. The lead delivery device of claim 4, further comprising a guidewire passing from outside the delivery shaft into and through a longitudinal inner passage of the fixator.

13. The lead delivery device of claim 4, further comprising a guidewire passing through the longitudinal passage of the delivery shaft and through a longitudinal inner passage of the fixator.

14. The lead delivery device of claim 1, further comprising retainer means for retaining the flexible member on the lead.

15. The lead delivery device of claim 14, wherein the retainer means includes a retainer external to the lead.

16. The lead delivery device of claim 14, wherein the retainer means includes a retainer internal to the lead.
FIG. 16
INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/036280

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/05 A61M25/01 A61M25/09 A61M25/10
ADD. A61B17/22

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 A61M

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, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Further documents are listed in the continuation of Box C

See patent family annex

Date of the actual completion of the international search
19 August 2010

Date of mailing of the international search report
27/08/2010

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