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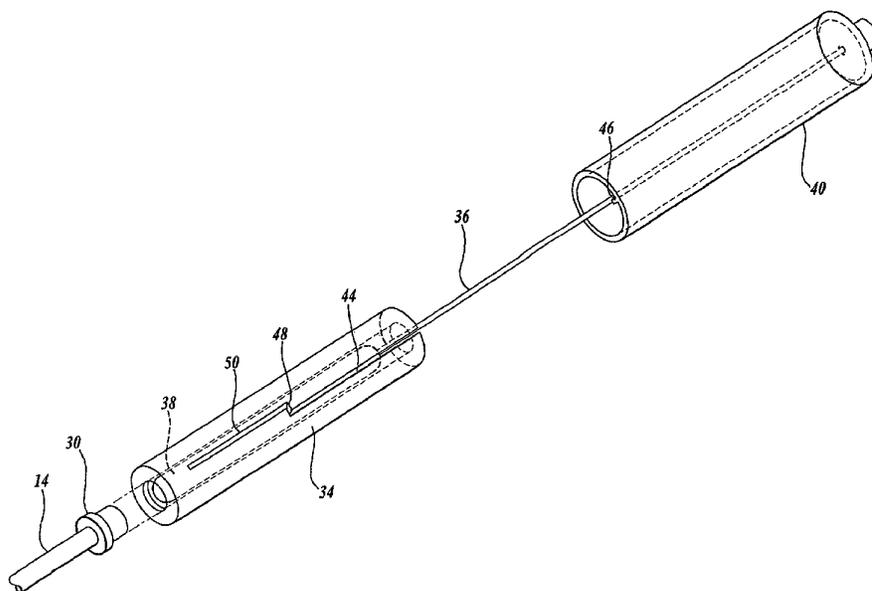
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[Continued on next page]

(54) Title: MEDICAL DEVICE DELIVERY SYSTEM



(57) Abstract: A system for selectively deploying a medical device includes a cartridge that is engageable with a proximal end of a delivery catheter that is routed to a desired location in a patient's body. An advancement mechanism is provided for advancing the medical device out of the cartridge and into the delivery catheter for deploying the medical device at the desired location in the patient's body.



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MEDICAL DEVICE DELIVERY SYSTEM

FIELD OF THE INVENTION

The present invention relates to a medical devices in general, and in particular to systems for delivering medical devices through a catheter.

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BACKGROUND OF THE INVENTION

In an effort to reduce patient trauma, shorten healing time, and reduce the risk of infection, many surgical procedures that previously required large incisions are now being performed using catheters and minimally invasive techniques. One area in which this is particularly true is in the field of vascular surgery. Medical devices such as ablation balloons or stents are often delivered to a desired location in a patient's body through a catheter that is inserted through a relatively small hole made in the patient's leg, neck or arm. The catheter is advanced through the vasculature to its intended destination and the medical device is then deployed from the catheter.

Some medical devices such as vascular stents are prepackaged in a delivery catheter for use by a physician. However, such pre-loaded catheters are not always easy to route to their intended destination. If a pre-loaded catheter is to be routed over a guidewire, there must be room for the guidewire to move past the medical device in a lumen of the catheter. Alternatively, a separate guidewire lumen must be provided. In either case the size of the catheter required is increased. In some cases, the pre-loaded catheter is advanced through a lumen of a guide catheter that has been previously placed at the intended destination. This approach requires that the guide catheter be made sufficiently large to accommodate the delivery catheter. However, to reduce patient complications, it is generally desirable to reduce the size of the catheters that are inserted into the patient.

Another problem that can occur during a minimally invasive surgical procedure is that the medical device becomes damaged prior to implantation. After the physician has placed a catheter in the desired location, the physician must insert the medical device into the end of the catheter that remains outside the patient. If the device is small and delicate, the physician may damage it while trying to fit it into the catheter and advance it to the desired location in the patient's body.

Finally, physicians generally want to be free to use the technique for placing a catheter that is best suited to the particular patient and the procedure to be performed. Physicians may not want to use the catheter in which a pre-loaded medical device is sold.

For example, the physician may want to use a guide wire, dilator or steering catheter to direct the guide catheter tip into position to then guide the medical device into position.

Given these problems, there is a need for a mechanism that allows a medical device to be delivered to a desired location within a patient's body in a way that does not dictate a physician's choice of particular routing technique or require an increased catheter size and that reduces the risk of damage to the device.

SUMMARY OF THE INVENTION

The invention provides a system for delivering a medical device to an intended destination in a patient's body. A distal tip of a delivery catheter is routed by a physician to its intended destination. The delivery catheter can be routed via a number of techniques and may be selected by the physician for the particular procedure to be performed. A cartridge having a pre-loaded medical device is engaged with a proximal end of the delivery catheter and an advancement mechanism moves the pre-loaded medical device out of the cartridge and into the delivery catheter. The delivery catheter and medical device are then moved relatively with respect to each other to deploy the medical device at the intended destination in the patient's body. The medical device can be pushed to the distal end of the catheter. The advancing mechanism can then fix the medical device position while the catheter is withdrawn to deploy the device.

Viewed from one aspect, the present invention provides a system for selectively advancing a medical device into a patient, comprising:

- a delivery catheter having a distal end that is inserted into a patient's body, a proximal end that remains outside the patient's body and one or more lumens that extend between the proximal and distal end;

- a cartridge that is engageable with the proximal end of the delivery catheter, the cartridge including a lumen that aligns with a lumen in the delivery catheter when the cartridge is engaged with the proximal end of the delivery catheter; the exterior of the cartridge comprising threads configured to engage with a nut;

- a medical device positioned within the lumen of the cartridge;

- a handle, wherein the handle and the cartridge are selectively engageable with the threads and the nut; and

- an advancing mechanism for advancing the medical device out of the cartridge and into a lumen of the delivery catheter.

Viewed from another aspect, the present invention provides a system for delivering a medical device to a desired location in a patient, comprising:

- a cartridge having a proximal end, a distal end and a cavity therein;

- a connector on the distal end of the cartridge for engaging a proximal end of a delivery catheter such that the cavity is aligned with a lumen in the delivery catheter;

- a compressed medical device preloaded within the cavity of the cartridge; and

- means for advancing the medical device from the cartridge and into the lumen of the delivery catheter.

Viewed from yet another aspect, the present invention provides a system for delivering a medical device to a desired location in a patient, comprising:

a cartridge having a proximal end, a distal end and a cavity therein;

a connector on the cartridge that engages a corresponding connector on a proximal end of a delivery catheter in order to align the cavity with a lumen of the delivery catheter;

a medical device collapsed within the cavity;

a push rod that engages a medical device and advances it into the lumen of the delivery catheter;

a handle secured to the push rod; and

means for selectively moving the handle and the cartridge including means for limiting the movement of the cartridge with respect to the handle.

Viewed from another aspect still, the present invention provides a method of deploying a medical device in a patient's body, comprising the steps of:

advancing a distal end of a delivery catheter to a desired location in a patient's body;

engaging a cartridge having a pre-loaded medical device therein to a proximal end of the delivery catheter; and

advancing the medical device out of the cartridge through a lumen of the delivery catheter to a distal end of the delivery catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing aspects and many of the attendant advantages of this invention will become more readily appreciated as the same become better understood by reference to the following detailed description, when taken in conjunction with the accompanying drawings, wherein:

FIGURE 1 illustrates a patient undergoing a minimally invasive procedure using a medical device delivery system in accordance with an embodiment of the present invention;

FIGURE 2 illustrates a medical device delivery system in accordance with one embodiment of the present invention;

FIGURE 3 illustrates another embodiment of a medical device delivery system in accordance with the present invention; and

FIGURE 4 illustrates one mechanism for releasably securing a medical device to a medical device delivery system.

FIGURE 5 illustrates a proximal end of a handle and an end cap in accordance with an embodiment of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

As indicated above, the present invention is a mechanism for delivering a medical device or implant to a desired location within a patient's body, that does not require a physician to use a particular type of delivery catheter, or technique for placing the catheter. Furthermore, the present invention reduces the chance that a medical device
5 will be damaged by the physician while inserting it into the catheter for delivery to its intended destination.

FIGURE 1 illustrates a patient 10 undergoing a minimally invasive surgical procedure that requires a medical device to be delivered to a desired location 12 within
10 the patient's body. To deliver the medical device, a physician routes a delivery catheter 14 through a small incision that is typically made in the patient's leg, neck or arm. The delivery catheter 14 is advanced through the vasculature until its distal end is positioned at or adjacent the desired location 12. Using the present invention, a physician is not limited to the type of delivery catheter that may be used or technique for routing it
15 to the desired location. For example, the physician may use a steerable catheter, a guide catheter, a dilator or a catheter that is routed over a guidewire. Once the physician has routed the delivery catheter 14 to its desired location 12, the physician is ready to deliver a medical device to the desired location.

In accordance with the present invention, the medical device delivery system
20 includes a cartridge 16 that can be engaged with a proximal end of the delivery catheter 14. The cartridge 16 holds a medical device within a lumen or cavity that is within the cartridge 16. The lumen in the cartridge that holds the medical device may have a constant diameter. Alternatively, the lumen may taper in either the proximal or distal direction.

25 With the cartridge 16 engaged with the delivery catheter 14, the medical device is aligned with a lumen of the delivery catheter 14. An advancement mechanism such as a push rod 18 is used by the physician to advance the medical device from within the cartridge 16 and through the delivery catheter 14 to its intended location. In one embodiment, the physician grasps a handle 20 at the proximal end of the push rod 18 and
30 moves it towards the cartridge 16 in order to push the medical device out of the cartridge 16 through a connector that joins the cartridge 16 to the delivery catheter 14. The medical device may then be pushed out the distal end of the delivery catheter 14 at the desired location 12, or the medical device can be unsheathed by retracting the

catheter. In some embodiments, the medical device is tethered to the advancement mechanism such that the medical device can be advanced from and retracted into the delivery catheter 14 if desired. In other embodiments, the medical device is not tethered such that once the medical device is advanced out of the distal end of the delivery catheter 14, it cannot be retrieved with the advancement mechanism.

FIGURE 2 illustrates one embodiment of a medical device delivery system in accordance with the present invention. A delivery catheter 14 has a connector 30 located at its proximal end that allows it to selectively engage a corresponding connector on the distal end of the cartridge 34 as described below. The connector 30 may be a luer fitting, a threaded connector, a quick release connector similar to those used on high pressure hoses, key and keyway or other device that allows the delivery catheter to become engaged with the distal end of the cartridge 34. The connector 30 has a lumen that aligns with a lumen or cavity in the cartridge 34 when the cartridge 34 is engaged with the connector 30. The delivery system also includes an advancement mechanism such as a push rod 36 that engages the medical device 38 within the cartridge 34. The proximal end of the push rod 36 is secured to a handle 40. The distal end of the push rod 36 is releasably connected to the medical device.

After engaging the distal end of the cartridge 34 and the proximal end of the delivery catheter 14, the physician pushes the handle 40 towards the cartridge 34 in order to move the medical device 38 out of the cartridge 34 and into a lumen of the delivery catheter 14. Further movement of the handle 40 with respect to the cartridge 34 advances the medical device 38 along the lumen of the delivery catheter 14 until it reaches the distal end of the delivery catheter 14. As will be appreciated, the distance that the medical device 38 can move depends upon the length of the push rod 36 compared to the length of the delivery catheter 14.

In some instances, it is desirable that the physician not be allowed to push the medical device 38 out the distal end of the catheter 14 without performing one or more required steps in a medical procedure. Therefore, mechanisms may be provided to limit the movement of the medical device in the delivery catheter until all required procedure steps have been completed. One such mechanism is shown in FIGURE 2.

Here, a slot 44 is cut within the cartridge 34. The slot 44 extends from the distal end of the cartridge along its length until it reaches a stop 48. The slot 44 receives a tab 46 formed on an inner circumference of a lumen in the handle 40. When the tab 46 is

aligned in the slot 44 of the cartridge, the cartridge 34 can be received into the lumen of the handle 40 until the tab 46 comes into contact with the stop 48. To further advance the handle over the cartridge, the handle 40 must be rotated with respect to the cartridge to move the slot around the circumference of the cartridge and align it with a second slot 50 that extends farther along the length of the cartridge. The stop 48 is positioned such that the medical device is at the correct position in the delivery catheter 14 for the physician to perform a desired procedure step. By providing one or more stops 48 and slots in the cartridge, the physician is less likely to fully advance the medical device within the delivery catheter 14 until all necessary steps in a procedure have been performed.

10 If the medical device 38 is coupled or tethered to the advancement mechanism, the medical device can be advanced or withdrawn in the delivery catheter 14 by moving the handle 40 towards or away from the cartridge 34.

FIGURE 3 illustrates another embodiment of a medical device delivery system in accordance with the present invention. As indicated above, a delivery catheter 14 has a connector 30 at its proximal end that allows the delivery catheter to be selectively engaged with a corresponding connector on a medical device delivery system. The medical device delivery system includes a cartridge 70 having a connector 72 at its distal end that engages the connector 30 in order to align a medical device 90 that is positioned within the cartridge 70 with a lumen of the delivery catheter 14.

20 On the outside of the cartridge 70 are a series of threads 72. A nut 74 on the cartridge can be rotated to advance the nut along the length of the threads 72. The nut 74 is designed to rotatably couple to a handle 80 that is secured to the proximal end of a push rod 85. In one embodiment, the distal end of the handle has a fitting 82 with a lip 84. When the handle 80 is engaged with the cartridge 70, leaves 76 on the nut 74 are forced over the lip 84 such that the nut 74 is rotatably coupled to the handle 80. The handle 80 has an interior lumen that is large enough to accommodate the cartridge. When the nut 74 is rotated, the cartridge 70 is drawn into the lumen of the handle 80. As the handle 80 is moved with respect to the cartridge 70, the push rod 85 pushes the medical device 90 in the delivery catheter 14. The pitch of the threads 72 can be varied as desired in order to change the amount of relative axial movement that occurs between the cartridge 70 and the handle 80 with each revolution of the nut 74. In one embodiment, a pitch of 1 revolution = 1/2 inch axial movement was found to provide sufficient control of the medical device without requiring the physician to make too many rotations of the

nut 74 in order to advance or retract it. Other thread pitches may include 1 revolution = 1/4, 3/8, 5/8 or 3/4 inch axial movement.

In use, the physician routes the delivery catheter 14 to the desired location in the patient's body using any desired routing technique. With the distal end of the cartridge 70
5 engaged with the connector 30 at the end of the delivery catheter 14, the handle 80 can be advanced such that the push rod 85 forces the medical device 90 into and along the length of the delivery catheter 14. The fitting 82 on the distal end of the handle 80 then engages the leaves 76 of the nut 74, whereupon rotation of the nut 74 draws the cartridge 70 into the handle portion 80 (or draws the handle over the cartridge depending on whether the
10 position of the handle or cartridge is fixed). Because the push rod 85 is fixed to the handle 80, rotating the nut 74 selectively moves the delivery catheter 14 with respect to the medical device 90 such that the medical device can be advanced or retracted from the distal end of the delivery catheter 14.

In order to prevent the physician from inadvertently advancing the medical device
15 too far out of the distal end of the delivery catheter 14, one or more mechanisms may be provided to limit movement of the medical device 90 with respect to the delivery catheter 14. In one embodiment of the invention, one or more safety keys 104 can be fitted over the threads 72 on the cartridge. The safety keys 104 prevent the nut 74 from moving past the key 104 until the physician pulls the key off the cartridge. Each key can
20 be color coded or contain printed reminders that instruct the physician to perform a desired procedure step prior to removal of the key. Once the key 104 is removed, the nut 74 can be advanced over the remainder of the cartridge 70 and thereby further advancing the medical device 90 out the distal end of the delivery catheter 14. Other safety mechanisms may include a source of friction on the threads 72 such that a
25 threshold torque is required to move the nut 74 over the high friction threads. High friction threads are placed at locations where certain procedural steps are required to be completed. The high friction can be created with an o-ring, surface treatment, a spring or the like.

In one embodiment of the invention, the proximal end of the handle 80 includes a
30 rotatable cap 110. The cap 110 is threaded such that upon rotation, a release wire is activated to disengage the medical device from the distal end of the push rod 85 and deploy it in the patient.

FIGURE 4 illustrates one embodiment of a mechanism for selectively releasing a medical device 90 from the distal end of the push rod 85 secured within the handle portion of the delivery system. In this embodiment, the medical device 90 includes an eyelet 122 through which a threaded loop 124 is passed. The threaded loop 124 is preferably made of a braided nylon or other high strength, low stretch material. A release wire 126 is also passed through the threaded loop 124 on the opposite side of the eyelet 122 such that the threaded loop 124 and the release wire 126 form a hitch over the eyelet 122. Upon retraction of the release wire 126, the threaded loop 124 is easily pulled out of the eyelet 122 and the medical device 90 can be disengaged from the push rod 85. In the embodiment shown, the push rod 85 is a hollow tube such that the thread that forms the threaded loop 124 and release wire 126 can be routed through a lumen of the push rod 85.

FIGURE 5 illustrates the end cap 110 at the proximal end of the handle 80. The end cap 110 is secured to the handle 80 by a set of threads 130 or other means. A button 132 at the proximal end of the end cap 110 is secured to the proximal end of the release wire 126 such that as the end cap 110 is rotated proximally on the threads 130, the release wire is also pulled proximally thereby releasing the medical device. The push rod 85 is secured to the handle 80 with a pair of set screws 140 in a bushing 142. The threads that form the loop 124 can also be tied off, soldered, crimped or threaded together at the bushing 142.

The push rod 85 is preferably formed of a hypotube at its proximal end and a wound coil at its distal end that are joined with a coupler. The wound coil provides sufficient flexibility so that the push rod 85 can be advanced on a tortuous path in the body. A polymer jacket may cover both the hypotube and the wound coil. Although a hypotube and wound coil make the preferred push rod, a polymer extruded tube or graphite shaft could also be used. Furthermore a solid rod could be used and the threads for the threaded loop and release wire routed adjacent the push rod.

Furthermore, the push rod could be a laser cut tubing with hydrophilic or Teflon® linings or coatings to provide sufficient lubricity of the push rod within the delivery catheter or an internal coating, for the threaded loop or release wire routed through the push rod.

In addition, each of these tubings may be reinforced with polymers, glass, ceramics, Teflon®, nylons, urethanes, polyethylenes, and polyolyfins, and combinations

thereof. The catheter may have a variable durometer jacket extending along its length such that the distal tip may be more or less stiff than the proximal end of the catheter. Hydrophilic liner coatings may be provided to provide sufficient lubricity.

5 The delivery catheter 14 can be routed to a desired position in the body with a guide wire made from either stainless steel, Nitinol, graded fiber or combinations thereof. Alternatively, a dilator catheter could be used to route the catheter into its intended location. Such a dilator can be wire enforced, braid enforced, with a variable durometer sections as with the delivery catheter itself. Finally, a steering catheter could be used to route the delivery catheter 14 to its intended location. Such a steering catheter could
10 include a one-way flex control, two-way flex control, and could be made of any materials used to manufacture the delivery catheter.

The medical device 90 may be a stent, vascular filter, time release drug delivery system or other device designed to be temporarily or permanently placed in a patient. In one actual embodiment of the invention, the medical device 120 is a suspension wire to
15 be placed in the coronary sinus and great cardiac vein in order to aid in the closure of a mitral valve in the heart. Such a suspension wire is disclosed in U.S. Patent Application Nos. 10/011,867, titled "Anchor and Pull Mitral Valve Device and Method" filed December 5, 2001, and 10/066,426, titled "Fixed Length Anchor and Pull Mitral Valve Device and Method" filed January 30, 2002, which are herein incorporated by reference.

20 As can be seen, the present invention provides a mechanism for routing a medical device to a catheter does not limit the particular selection of delivery catheter or the method of placing it at the desired location. Any type of delivery catheter can be used provided it can be engaged with the cartridge that holds the medical device. Furthermore, because the medical device is pre-loaded in the cartridge, there is less likelihood that the
25 medical device will become damaged as the physician inserts the medical device into the catheter.

While the preferred embodiment of the invention has been illustrated and described, it will be appreciated that various changes can be made therein without departing from the spirit and scope of the invention. Therefore the scope of the invention
30 is to be determined from the following claims and equivalents thereof.

The claims defining the invention are as follows:

1. A system for selectively advancing a medical device into a patient, comprising:
a delivery catheter having a distal end that is inserted into a patient's body, a proximal end that remains outside the patient's body and one or more lumens that extend between the proximal and distal end;
5 a cartridge that is engageable with the proximal end of the delivery catheter, the cartridge including a lumen that aligns with a lumen in the delivery catheter when the cartridge is engaged with the proximal end of the delivery catheter, the exterior of the cartridge comprising threads configured to engage with a nut;
a medical device positioned within the lumen of the cartridge;
10 a handle, wherein the handle and the cartridge are selectively engageable with the threads and the nut; and
an advancing mechanism for advancing the medical device out of the cartridge and into a lumen of the delivery catheter.

2. The system of Claim 1, wherein the advancing mechanism comprises a push rod that
15 engages the medical device.

3. The system of Claim 2, wherein the proximal end of the push rod is secured to a handle.

4. The system according to any one of the preceding claims, further comprising one or more devices for prohibiting the engagement of the handle and cartridge.

5. The system of Claim 4, wherein the one or more devices for prohibiting the engagement of
20 the handle and cartridge comprises a slot having at least one stop, and a tab that fits within the slot and engages the stop.

6. The system of Claim 4 or Claim 5, wherein the one or more devices for prohibiting the engagement of the handle and cartridge comprises a key that is engaged with one of the cartridge or handle to prevent relative motion between the handle and the cartridge.

7. A system for delivering a medical device to a desired location in a patient, comprising:
25 a cartridge having a proximal end, a distal end and a cavity therein;
a connector on the distal end of the cartridge for engaging a proximal end of a delivery catheter such that the cavity is aligned with a lumen in the delivery catheter;
a compressed medical device preloaded within the cavity of the cartridge; and
30 means for advancing the medical device from the cartridge and into the lumen of the delivery catheter.

8. A system for delivering a medical device to a desired location in a patient, comprising:
a cartridge having a proximal end, a distal end and a cavity therein;

a connector on the cartridge that engages a corresponding connector on a proximal end of a delivery catheter in order to align the cavity with a lumen of the delivery catheter; a medical device collapsed within the cavity;

a push rod that engages a medical device and advances it into the lumen of the delivery catheter; a handle secured to the push rod; and

means for selectively moving the handle and the cartridge including means for limiting the movement of the cartridge with respect to the handle.

9. The system of Claim 8, wherein the push rod comprises a hypotube at a proximal end, a coil at the distal end and a coupler that joins the hypotube and coil.

10. The system of Claim 9, further comprising a polymer jacket over the push rod.

11. The system according to any one of Claims 8 to 10, wherein the cavity in the cartridge is tapered.

12. The system of Claim 11, wherein the taper narrows distally in the cartridge.

13. The system of Claim 11, wherein the taper narrows proximally in the cartridge.

14. The system according to any one of Claims 8 to 13, wherein the medical device is compressed within the cartridge.

15. The system of Claim 14, wherein the medical device is a self expanding stent.

16. The system of Claim 14, wherein the medical device is a mitral valve suspension cable.

17. The system according to any one of the preceding claims, wherein the advancing mechanism, the cartridge and the delivery catheter are adapted to place the medical device at the distal end of the delivery catheter when the handle and cartridge are engaged.

18. The system according to any one of claims 1 to 7, wherein the advancing mechanism is adapted to move the medical device with respect to the delivery catheter.

19. The system of Claim 18, wherein the advancing mechanism is further adapted to withdraw the catheter proximally while holding the delivery catheter stationary to expel the medical device from the distal end of the catheter.

20. The system of Claim 18, wherein the advancing mechanism is further adapted to move the medical device distally out of the distal end of the catheter.

21. The system according to any one of claims 1 to 7, 19 and 20, further comprising an attachment mechanism comprising a tether for attaching the medical device to the advancing mechanism.

22. The system of Claim 21 further comprising a release mechanism for releasing the tether from the medical advice.

5 23. The system of Claim 22, wherein the attachment mechanism further comprises a hitch wire, the release mechanism comprising an actuator adapted to move the hitch wire with respect to the medical device.

24. The system according to any one of the preceding claims, wherein the medical device is adapted to be placed in the patient's coronary sinus or great cardiac vein.

10 25. The system according to any one of claims 1 to 23, wherein the medical device is adapted to aid in the closure of the patient's mitral valve.

26. A method of deploying a medical device in a patient's body, comprising the steps of:
advancing a distal end of a delivery catheter to a desired location in a patient's body;
engaging a cartridge having a pre-loaded medical device therein to a proximal end of the delivery
15 catheter; and
advancing the medical device out of the cartridge through a lumen of the delivery catheter to a distal end of the delivery catheter.

27. The method of claim 26, further comprising the step of:
moving the delivery catheter with respect to the medical device such that the medical device is
20 expelled from the distal end of the delivery catheter.

28. The method of claim 27, further comprising releasing a tether on the medical device so that it remains in the patient's body after removal of the delivery catheter.

29. The system of claim 1 wherein rotation of the nut selectively moves the delivery catheter with respect to the device.
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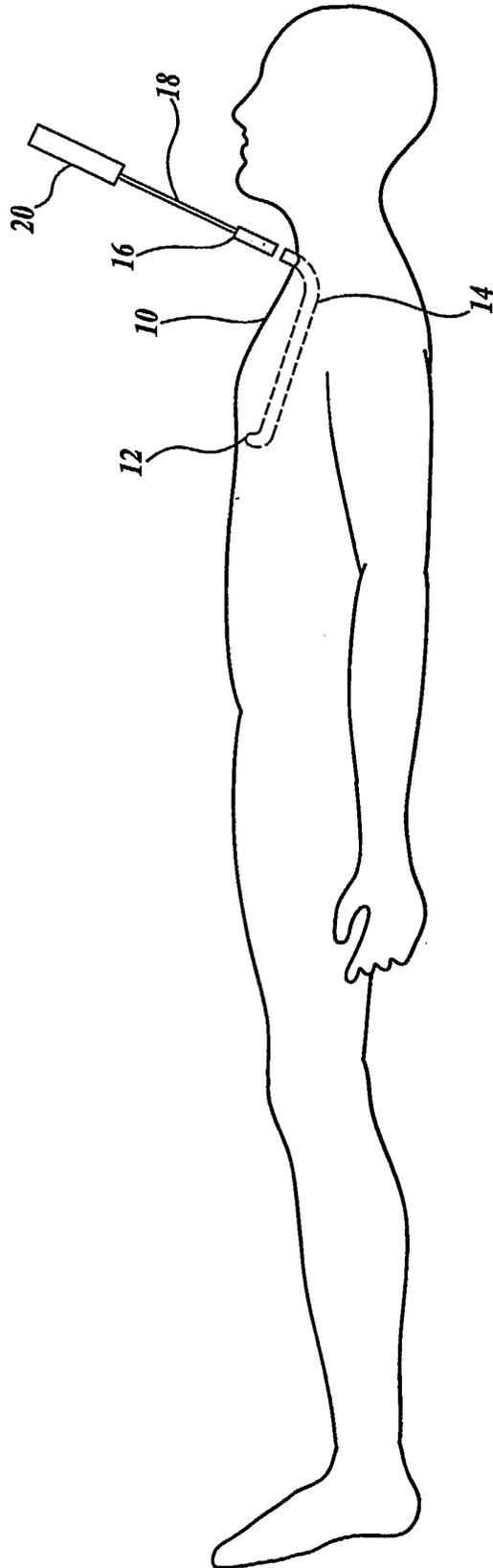


Fig. 1.

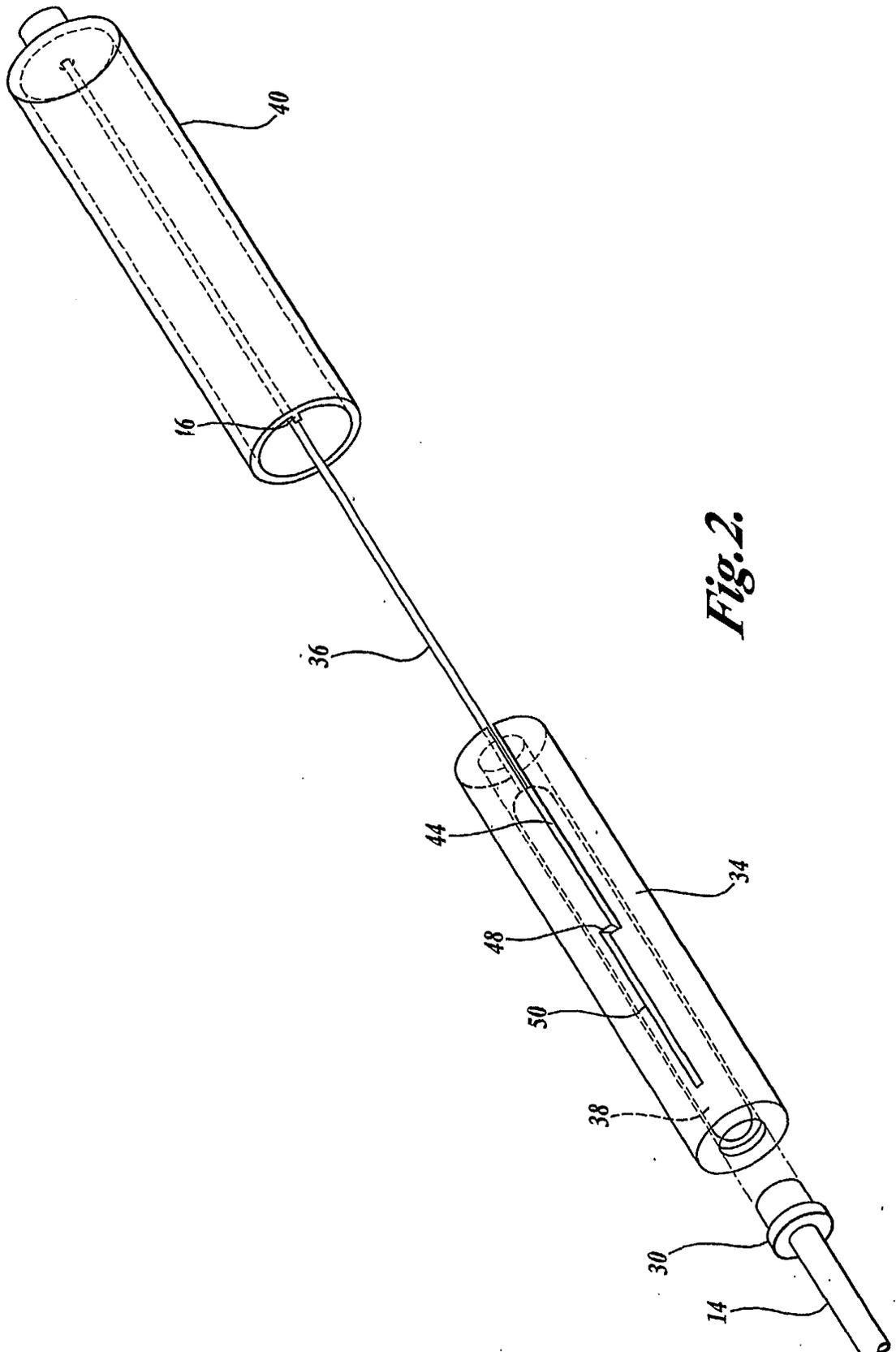


Fig. 2.

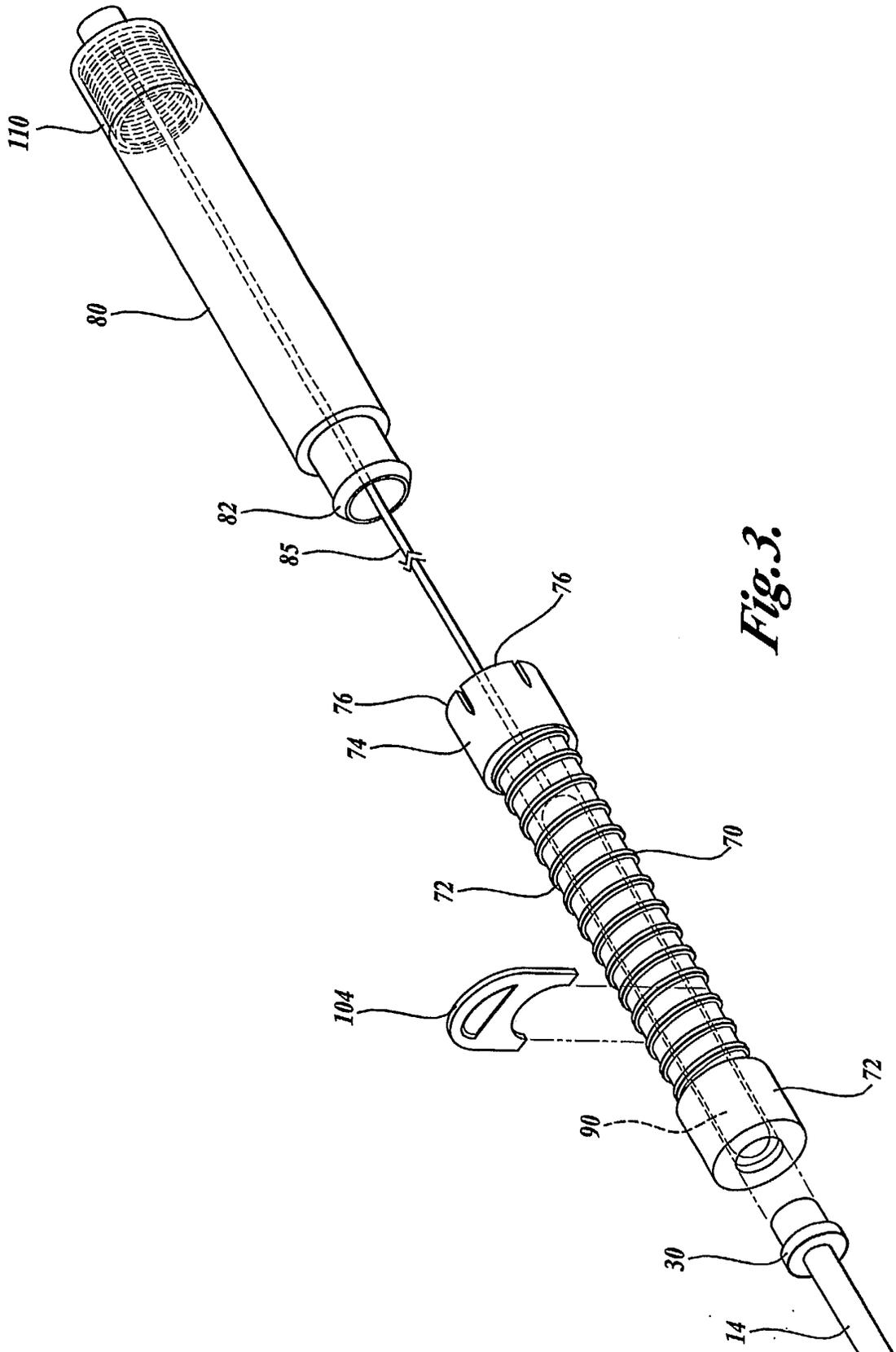


Fig. 3.

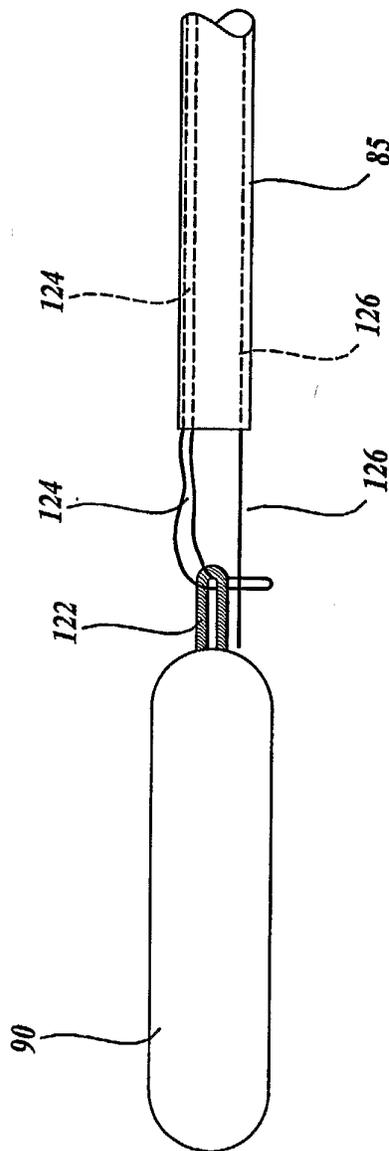


Fig. 4.

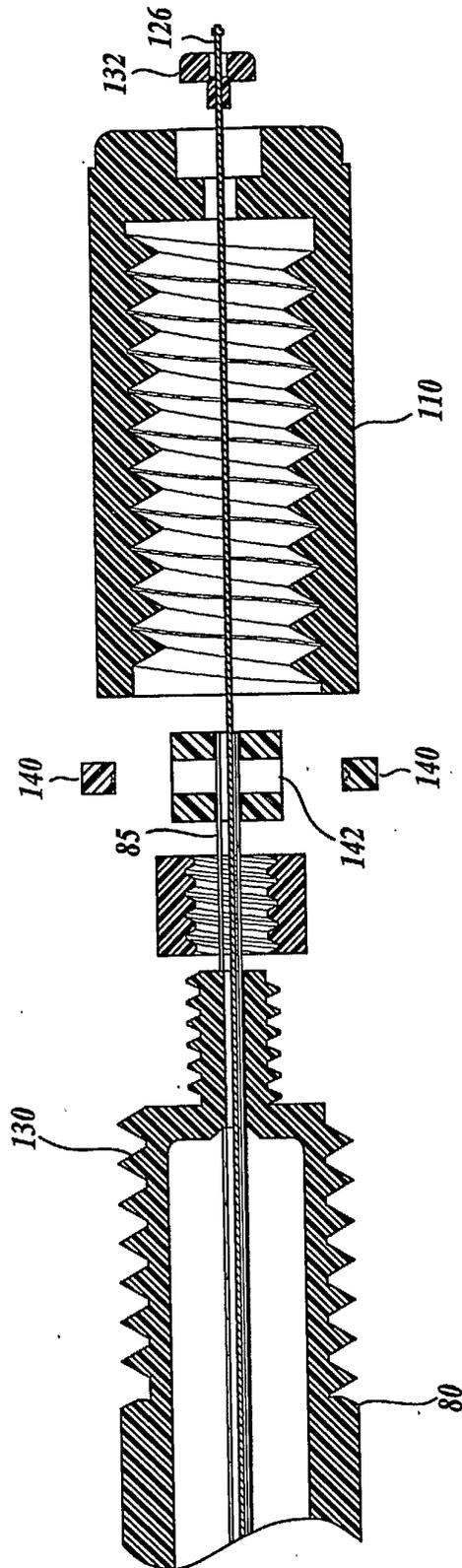


Fig. 5.