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(54) **METHODS FOR IMPLANTING A GASTRIC RESTRICTION DEVICE**

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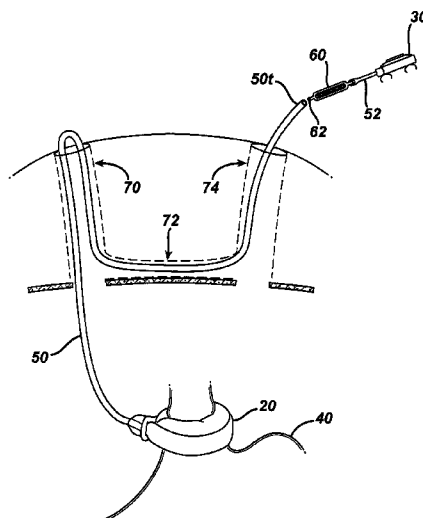
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(57) **ABSTRACT**

Various exemplary methods are disclosed for implanting a restriction device for forming a restriction in a patient. The methods can be used with a variety of restriction devices, but in an exemplary embodiment the methods are used for implanting a gastric restriction device.

21 Claims, 17 Drawing Sheets



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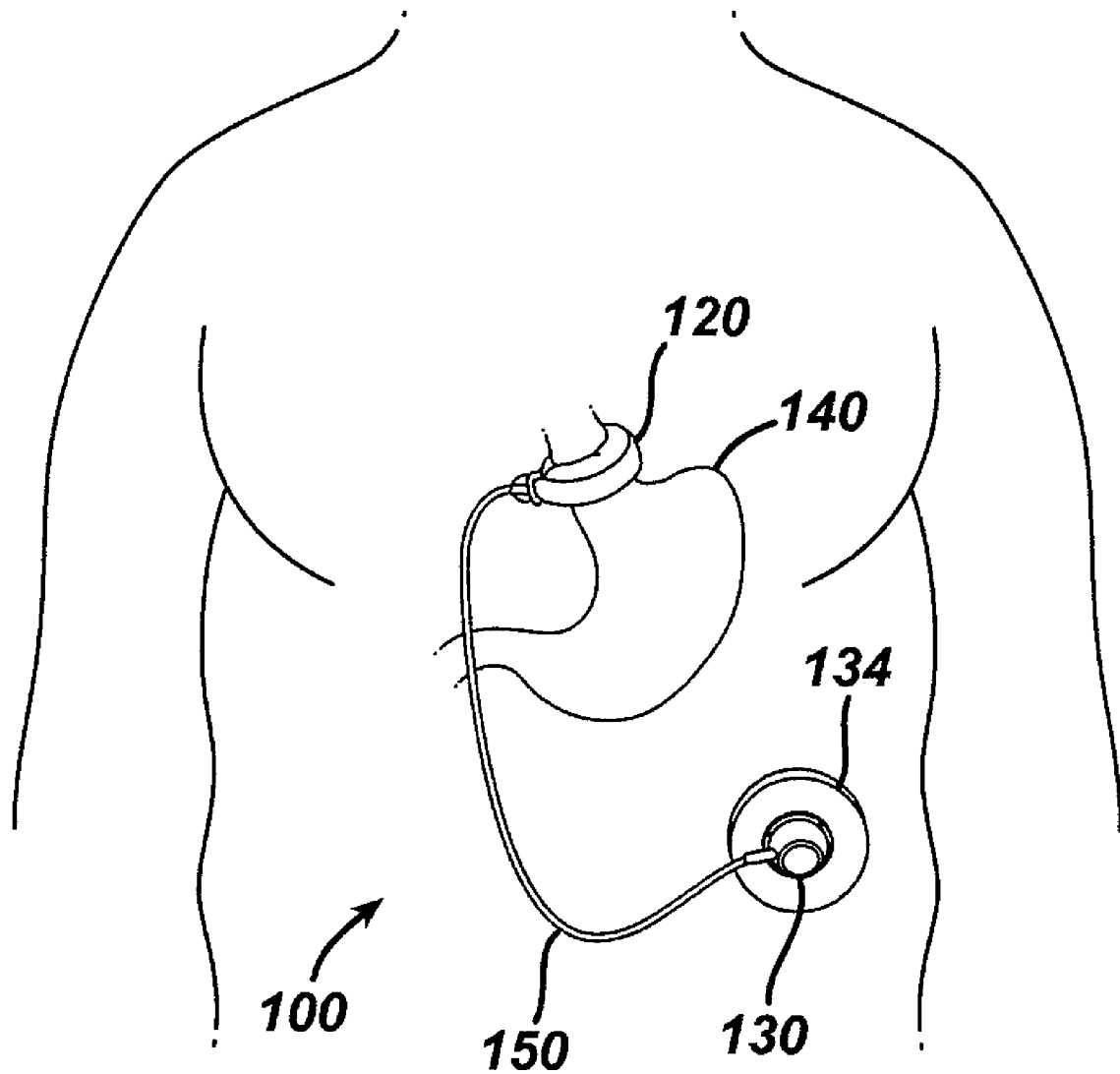
FIG. 1A PRIOR ART

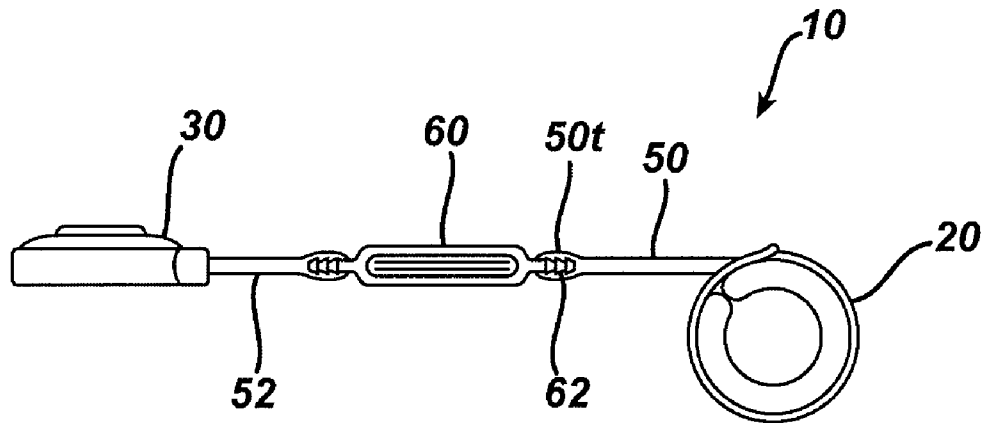
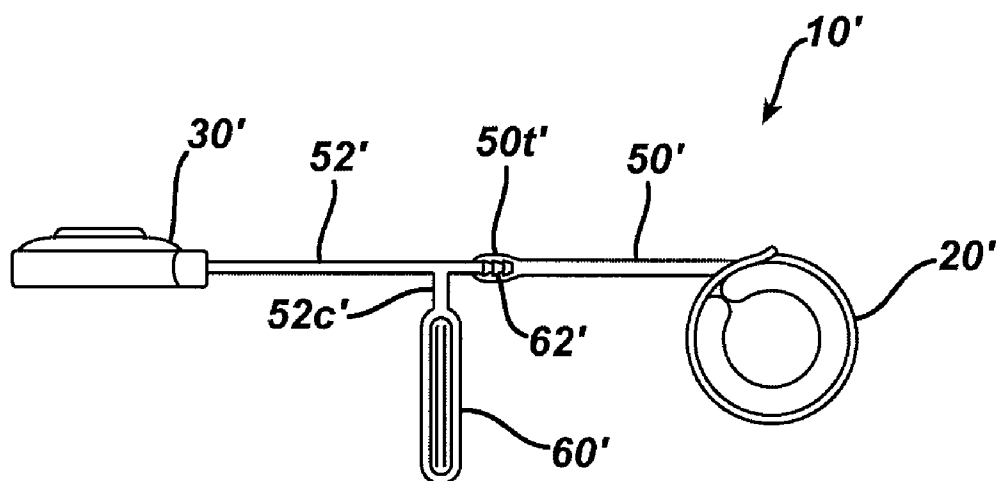
FIG. 1B PRIOR ART**FIG. 1C** PRIOR ART

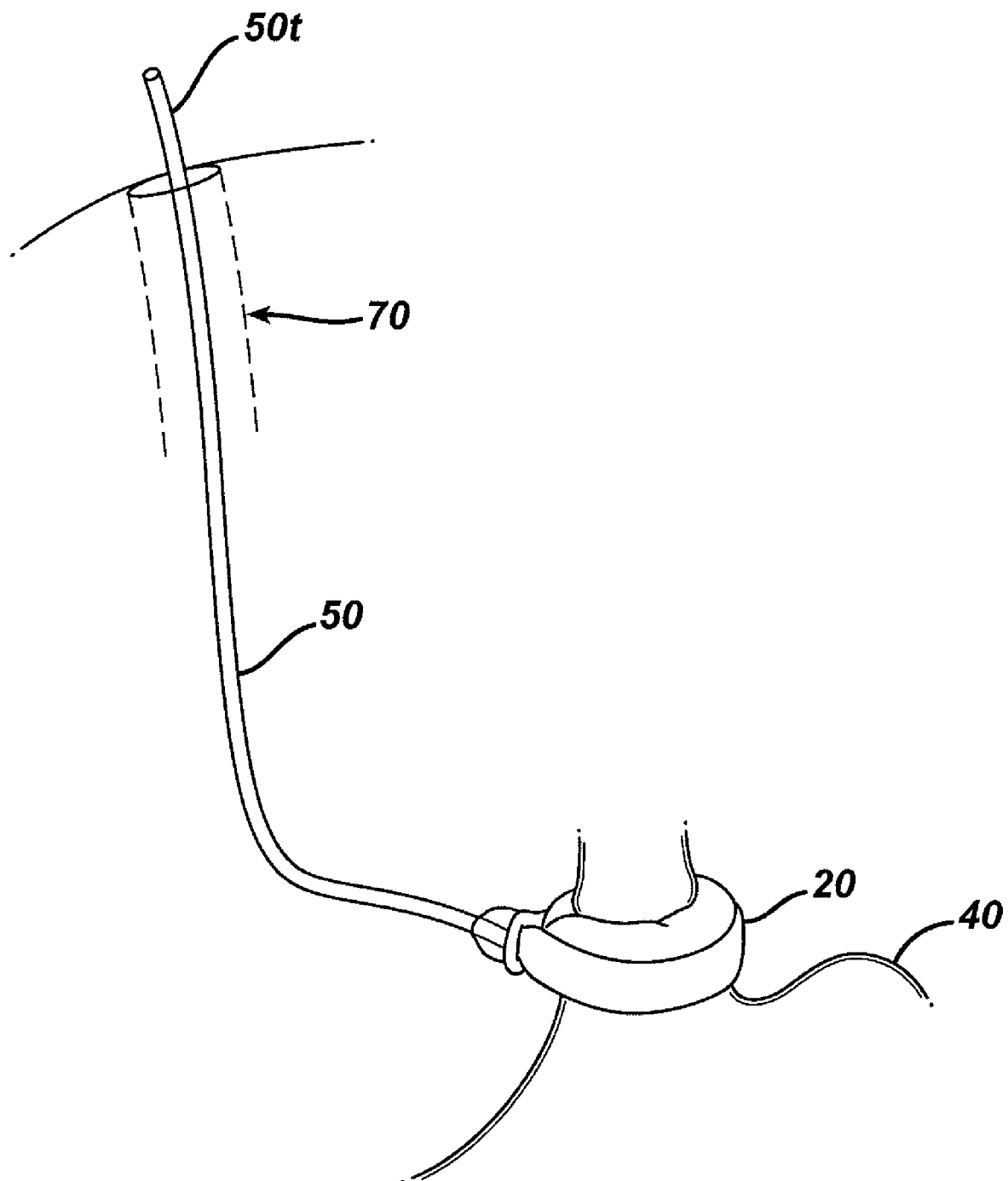
FIG. 2

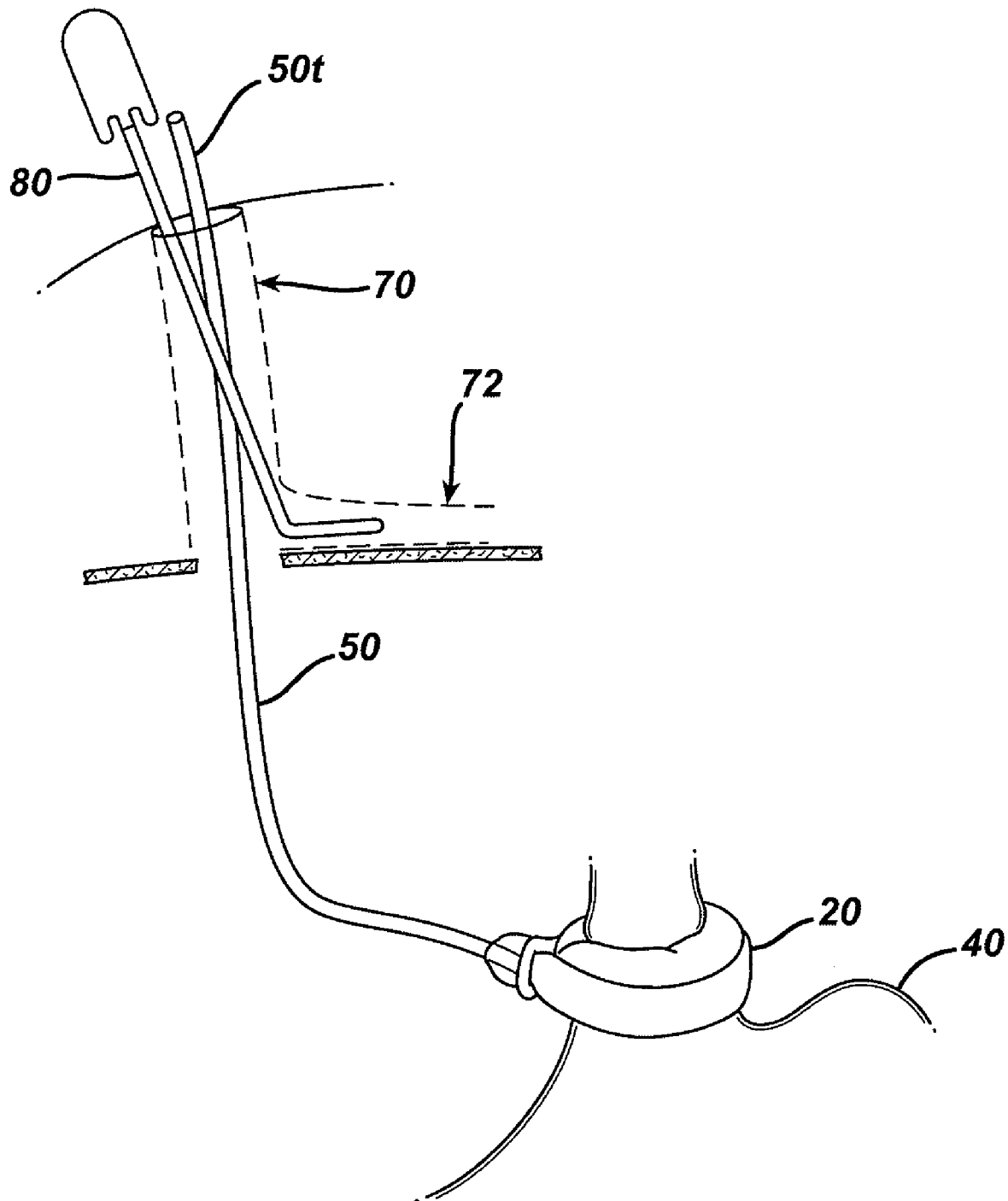
FIG. 3A

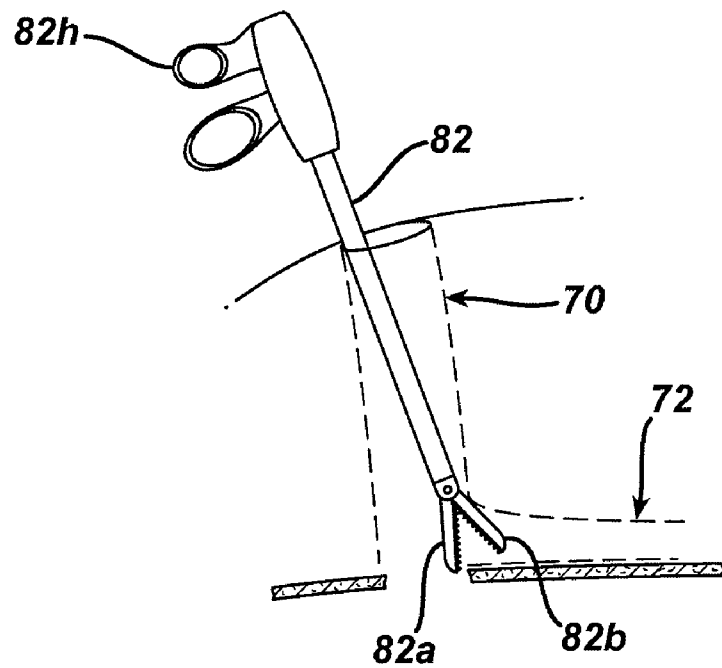
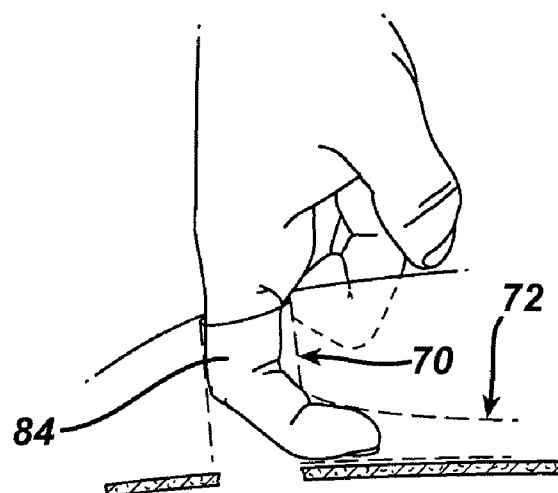
FIG. 3B**FIG. 3C**

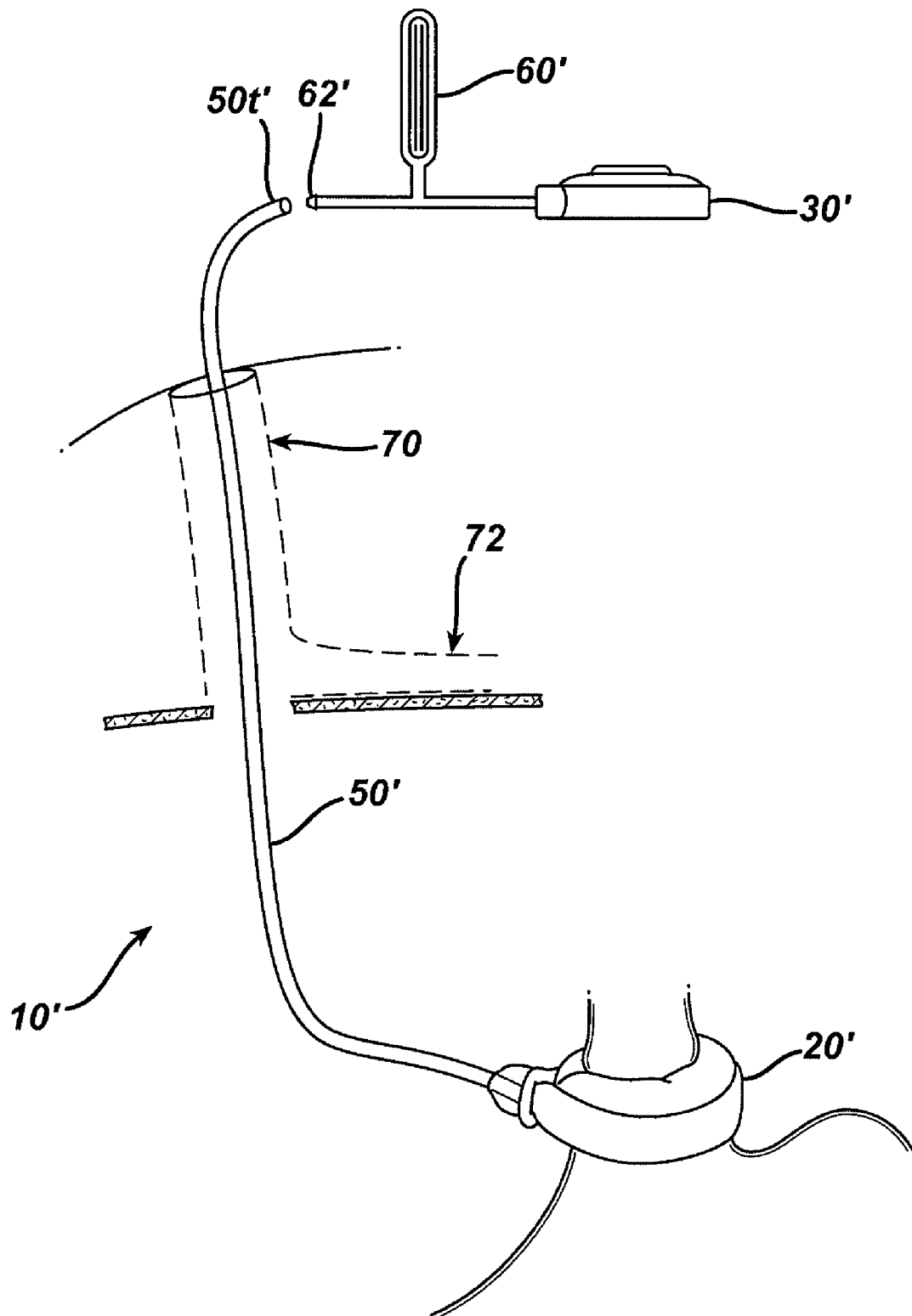
FIG. 4

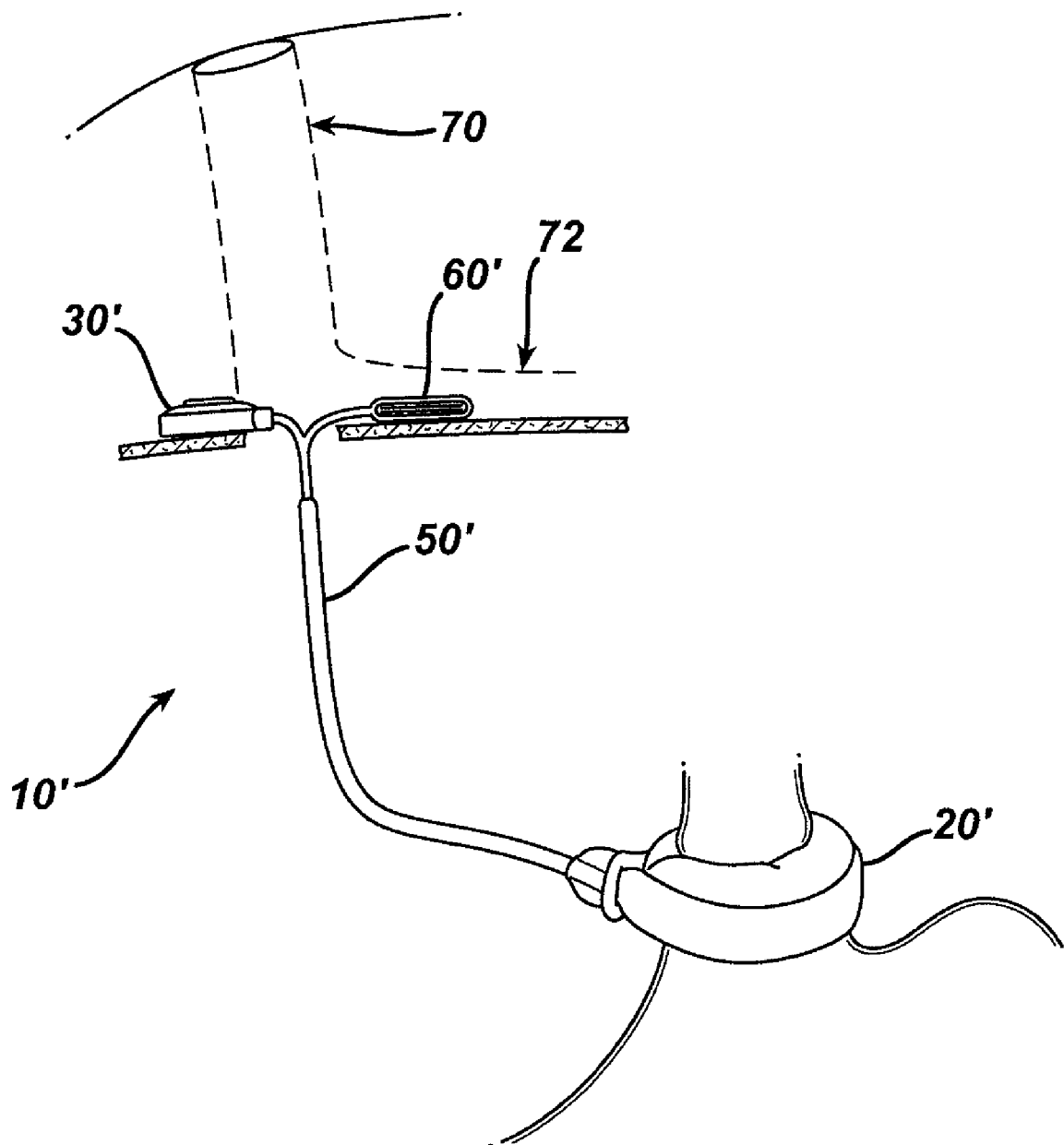
FIG. 5

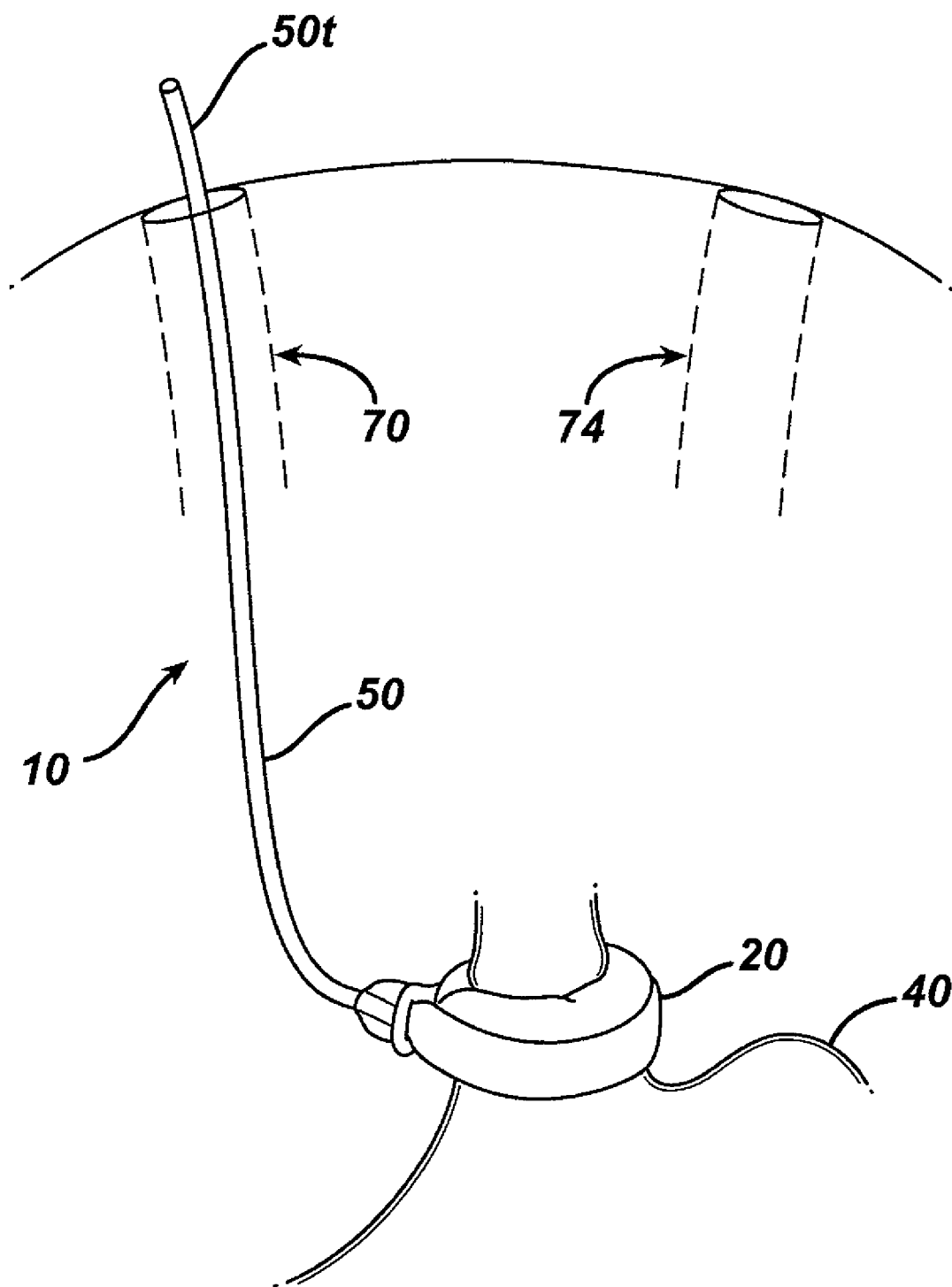
FIG. 6

FIG. 7A

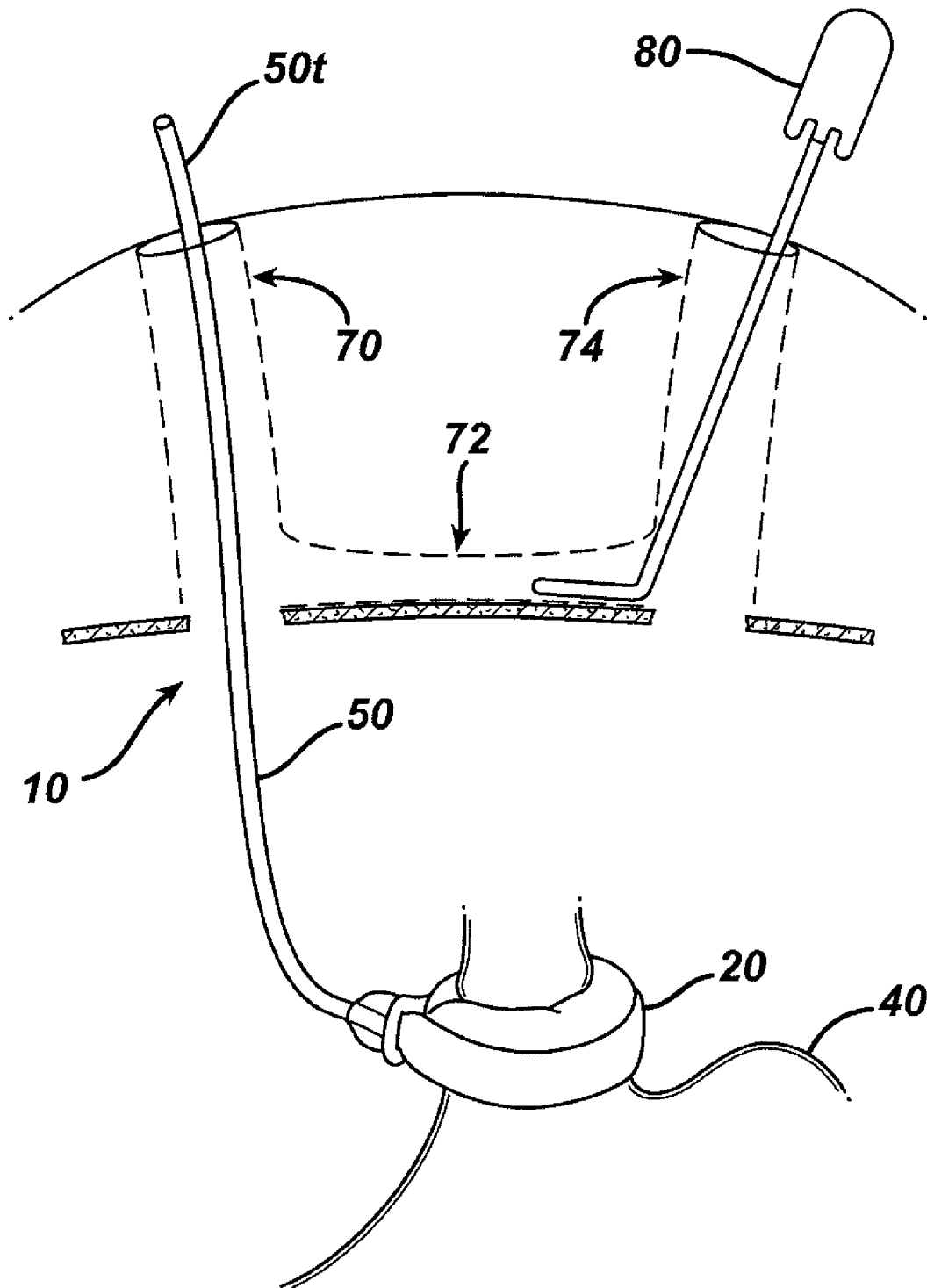


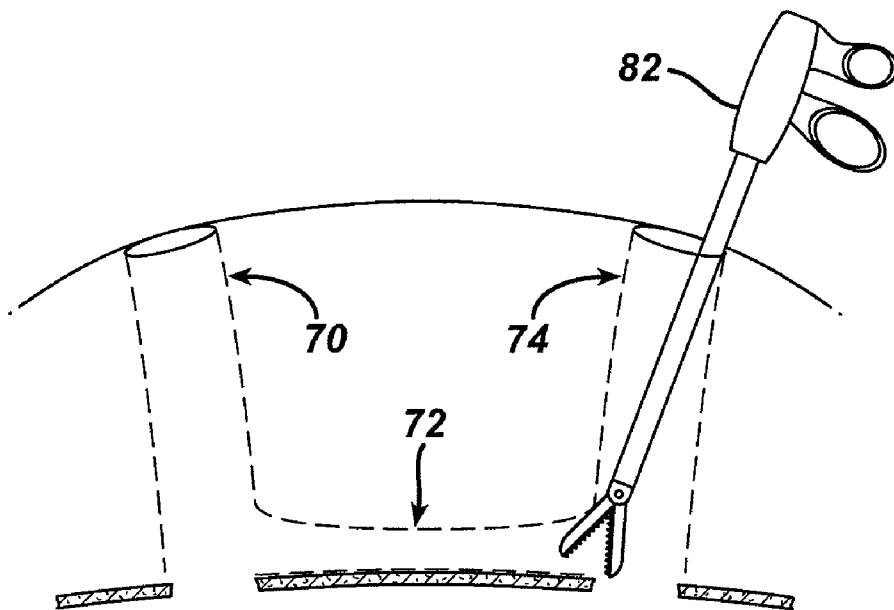
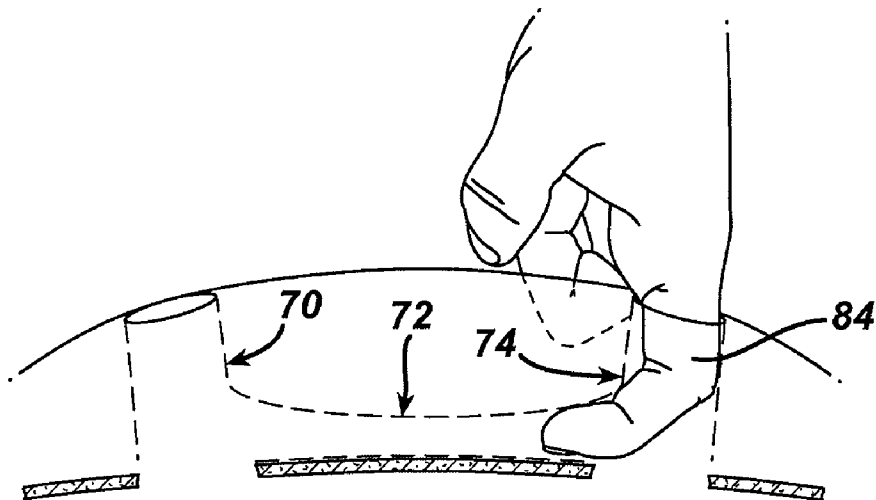
FIG. 7B**FIG. 7C**

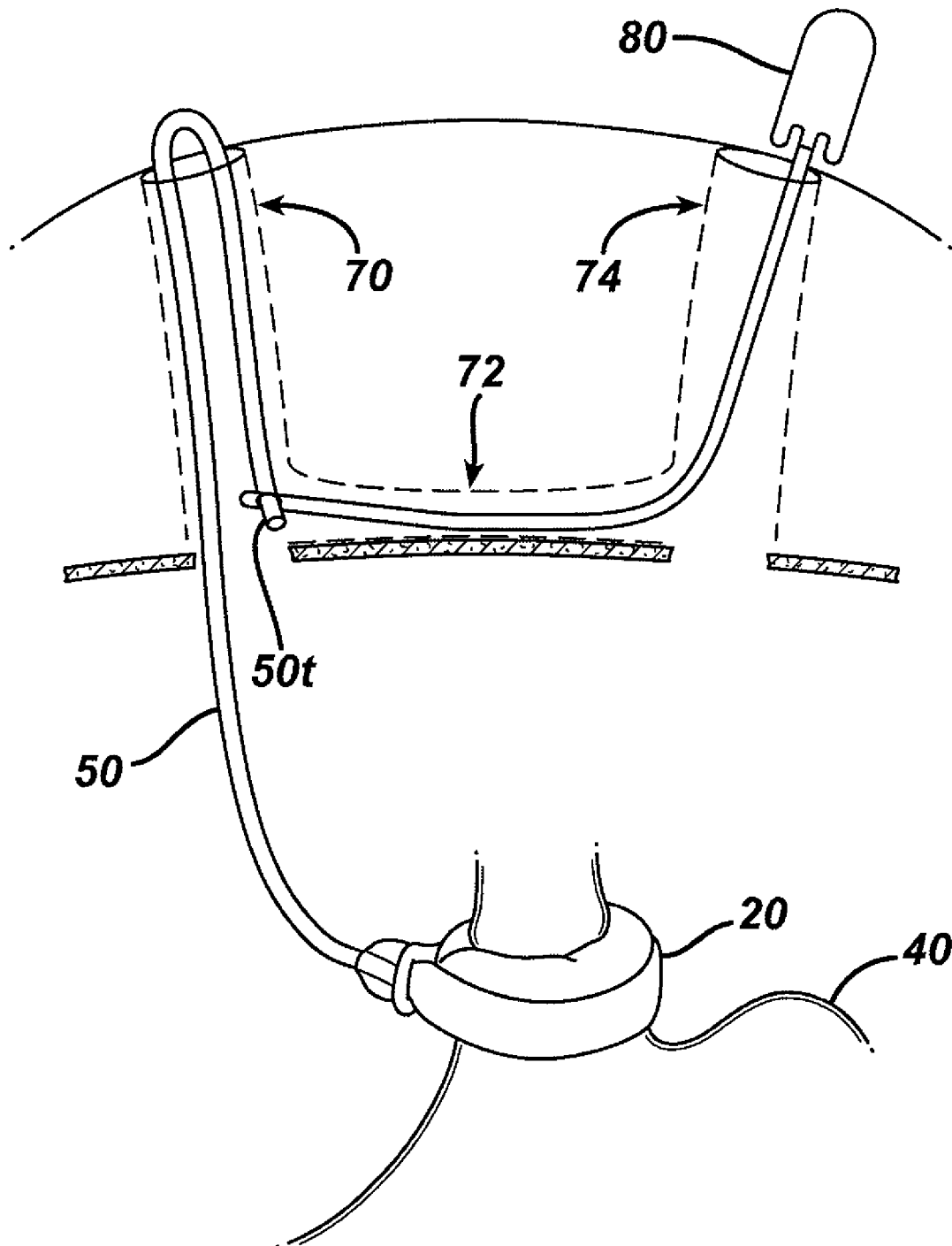
FIG. 8A

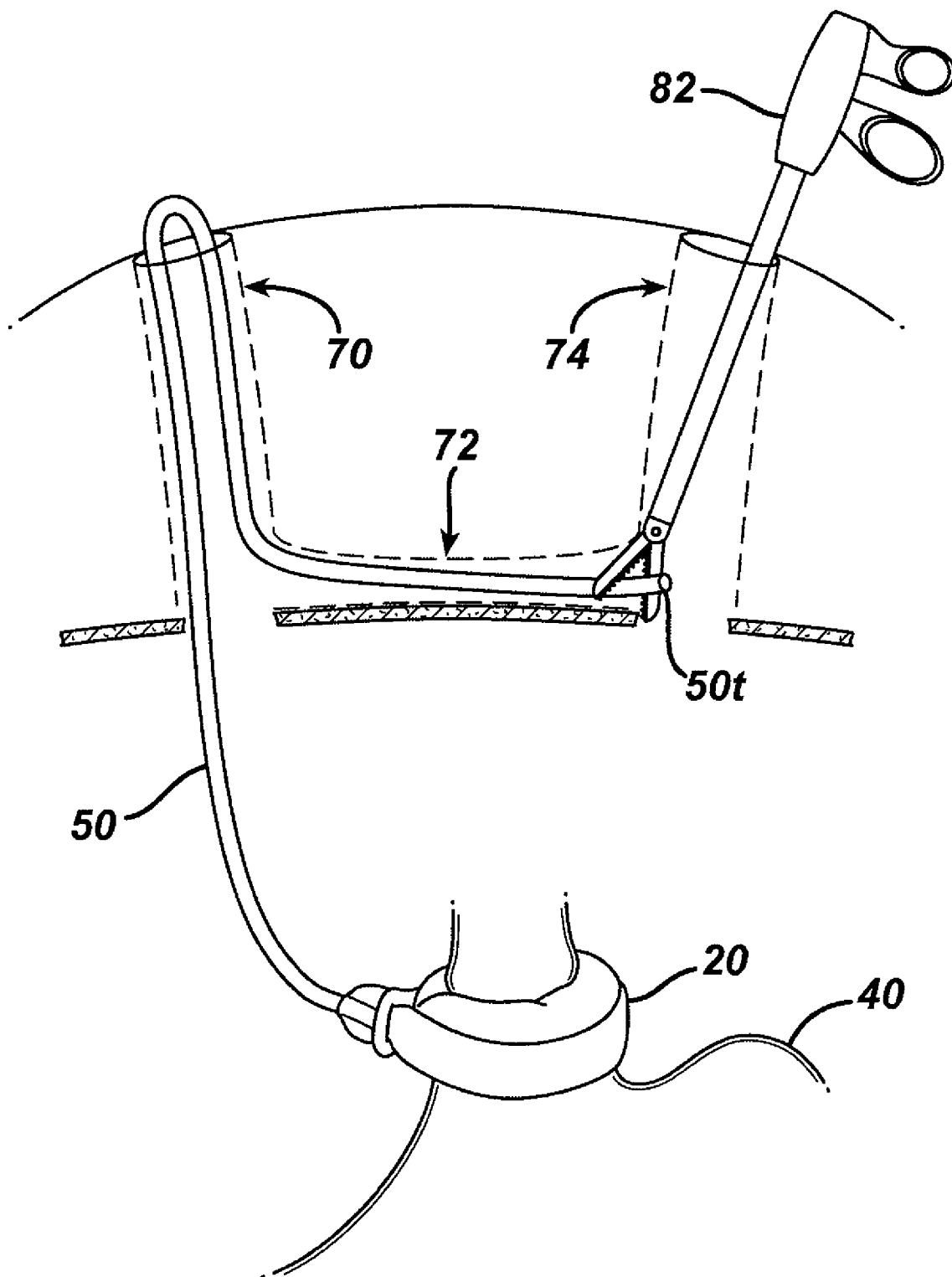
FIG. 8B

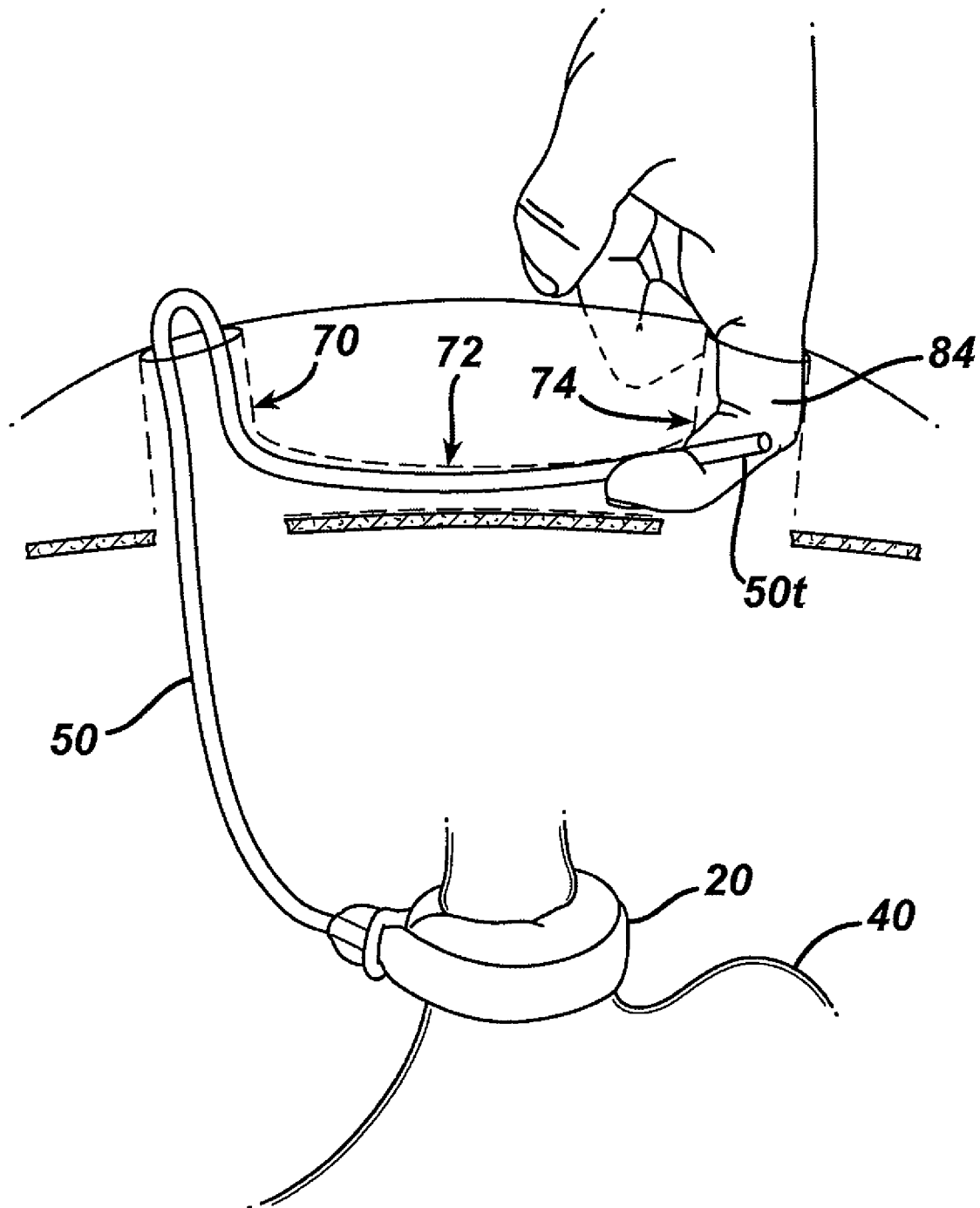
FIG. 8C

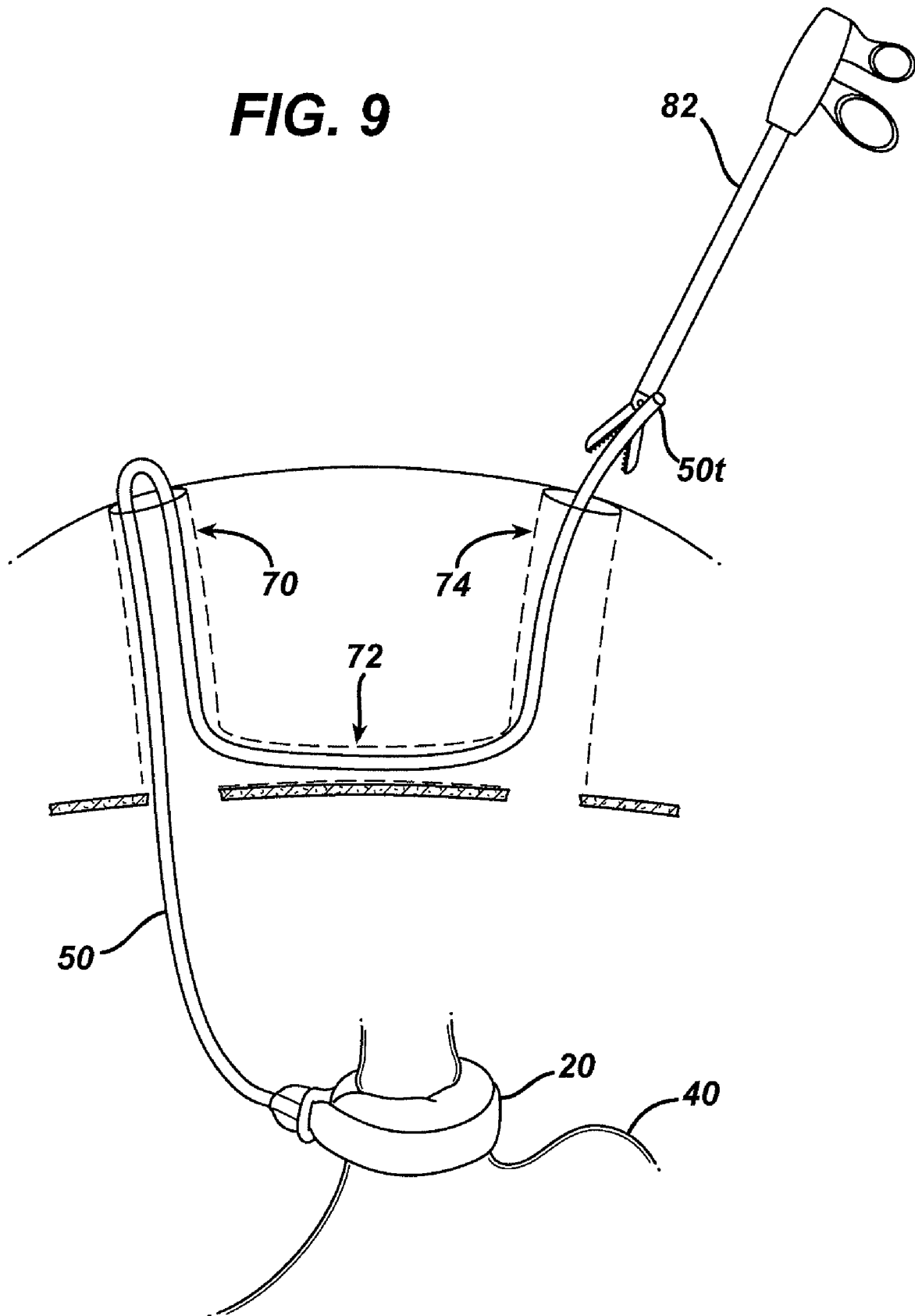
FIG. 9

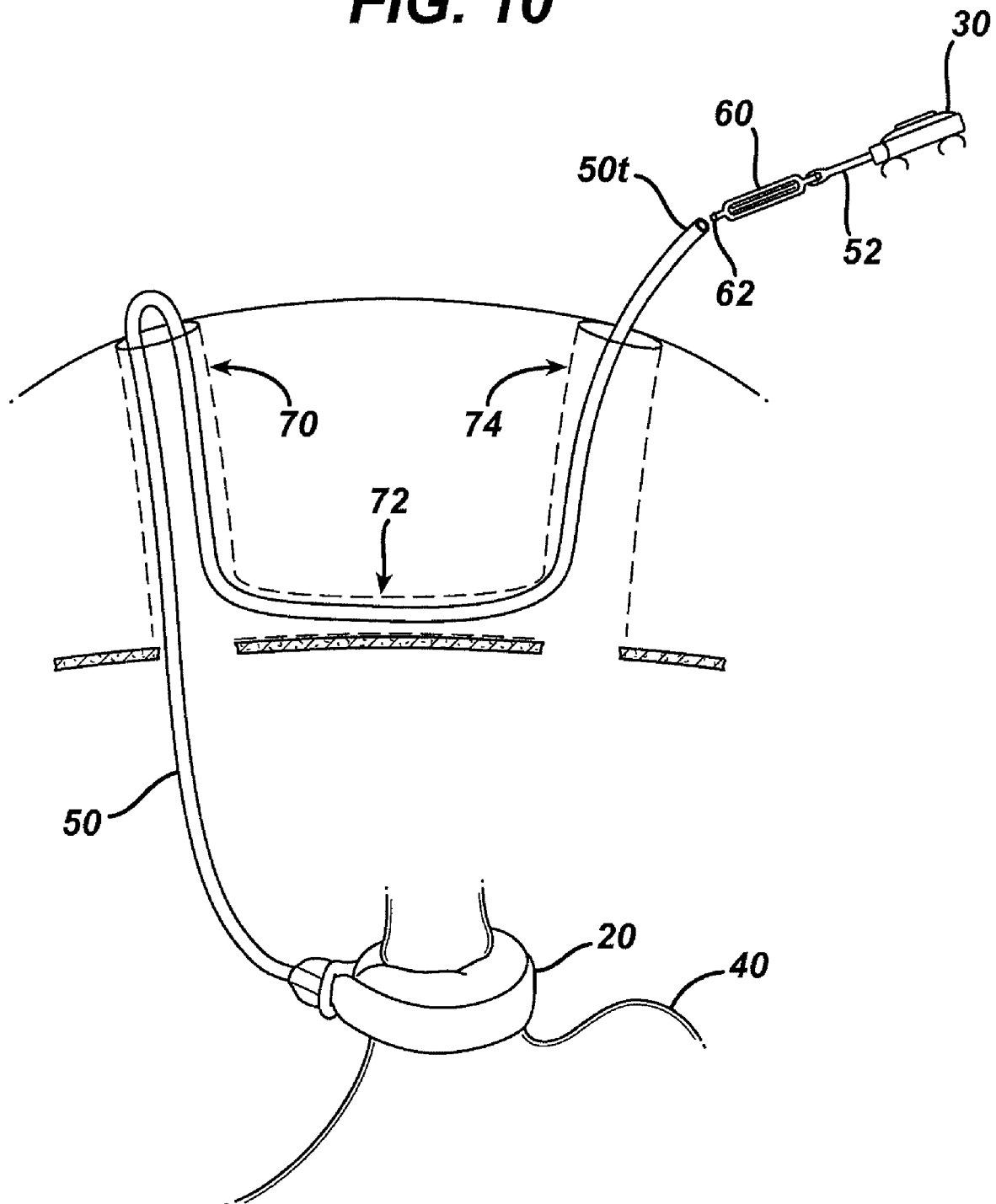
FIG. 10

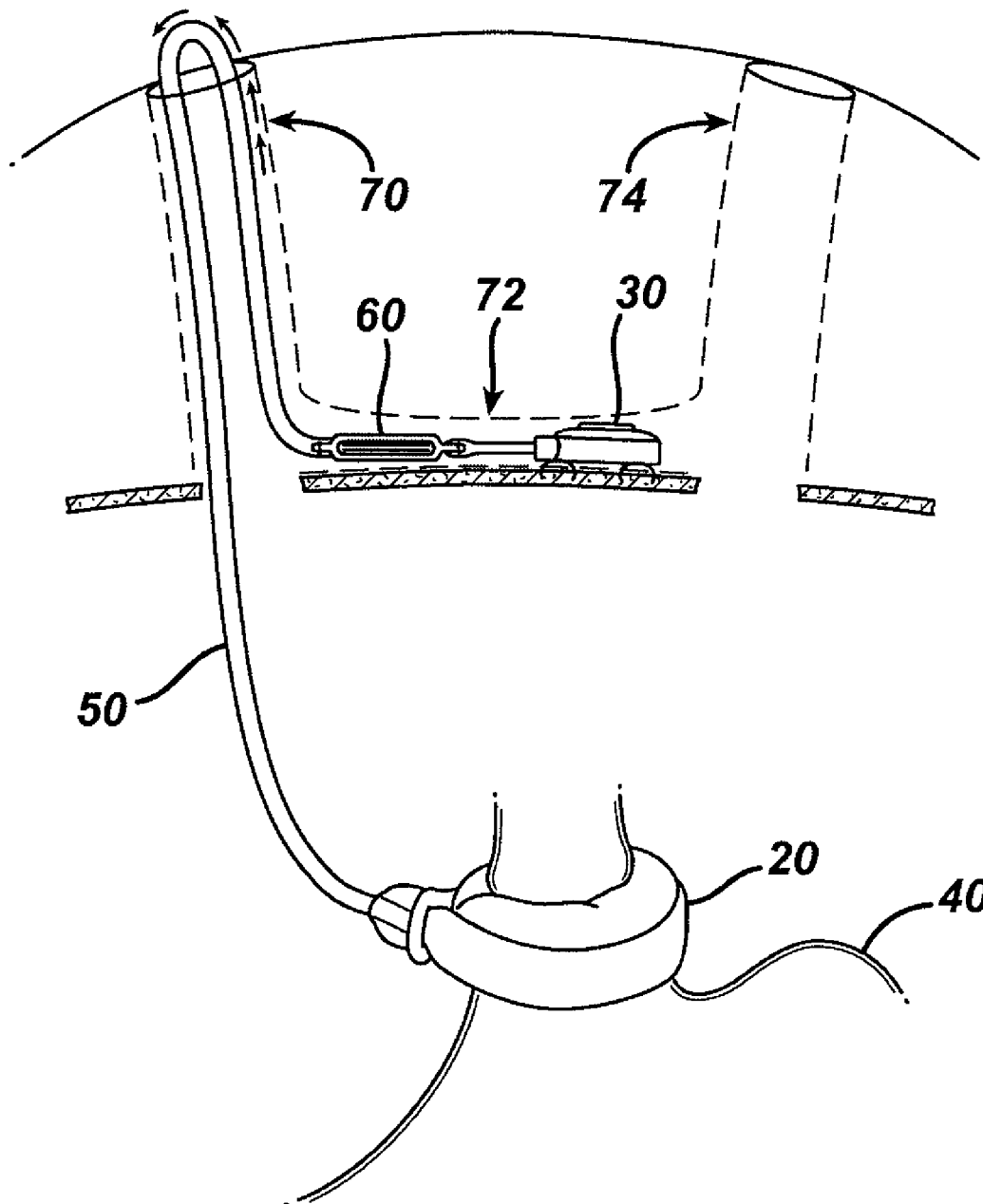
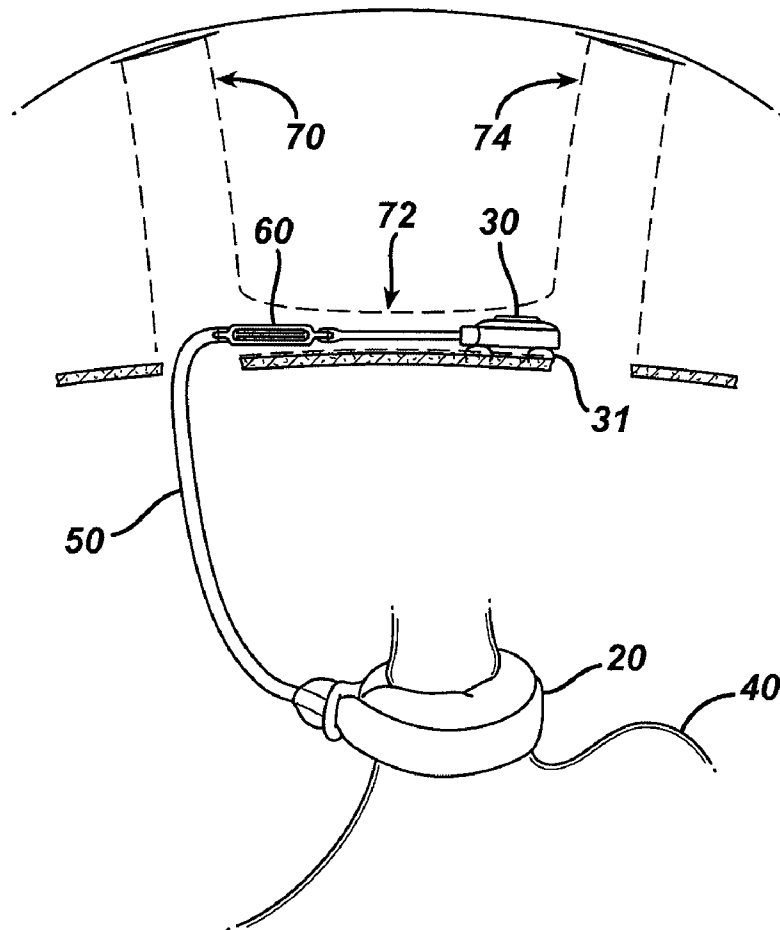
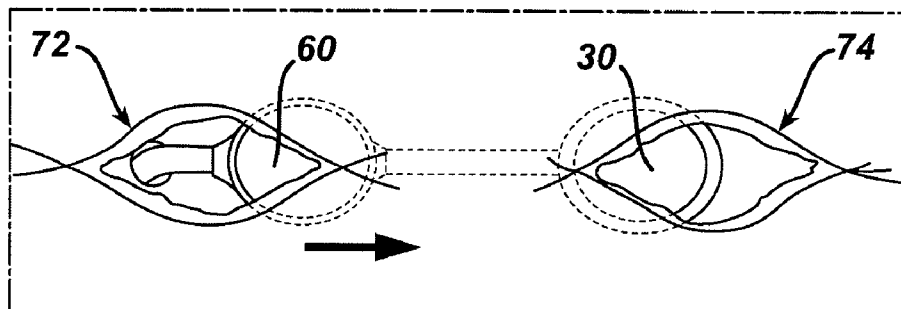
FIG. 11

FIG. 12A**FIG. 12B**

1

METHODS FOR IMPLANTING A GASTRIC RESTRICTION DEVICE

FIELD OF THE INVENTION

The present invention relates to surgical methods, and in particular to methods for implanting a restriction device.

BACKGROUND OF THE INVENTION

Obesity is becoming a growing concern, particularly in the United States, as the number of obese people continues to increase, and more is learned about the negative health effects of obesity. Morbid obesity, in which a person is 100 pounds or more over ideal body weight, in particular poses significant risks for severe health problems. Accordingly, a great deal of attention is being focused on treating obese patients. One method of treating morbid obesity has been to place a restriction device, such as an elongated band, about the upper portion of the stomach. Gastric bands have typically comprised a fluid-filled elastomeric balloon with fixed endpoints that encircle the stomach just inferior to the esophageal-gastric junction to form a small gastric pouch above the band and a reduced stoma opening in the stomach. When fluid is infused into the balloon, the band expands against the stomach creating a food intake restriction or stoma in the stomach. To decrease this restriction, fluid is removed from the band. The effect of the band is to reduce the available stomach volume and thus the amount of food that can be consumed before becoming "full."

Food restriction devices have also comprised mechanically adjusted bands that similarly encircle the upper portion of the stomach. These bands include any number of resilient materials or gearing devices, as well as drive members, for adjusting the bands. Additionally, gastric bands have been developed that include both hydraulic and mechanical drive elements. An example of such an adjustable gastric band is disclosed in U.S. Pat. No. 6,067,991, entitled "Mechanical Food Intake Restriction Device" which issued on May 30, 2000, and is incorporated herein by reference. It is also known to restrict the available food volume in the stomach cavity by implanting an inflatable elastomeric balloon within the stomach cavity itself. The balloon is filled with a fluid to expand against the stomach walls and, thereby, decrease the available food volume within the stomach.

With the advent of various restriction devices, there is a need for improved methods for implanting such devices. Accordingly, novel methods are provided for implanting a gastric restriction device.

SUMMARY OF THE INVENTION

Various exemplary methods are provided for implanting a restriction device. In one embodiment, a method for implanting a restriction system is provided and includes forming a pathway through a skin incision, coupling a catheter exiting through the skin incision to a housing such that the housing is coupled, via the catheter, to a restriction device implanted to form a restriction, forming a tunnel extending from the pathway, and positioning the housing within the tunnel. In an exemplary embodiment, the tunnel extends transverse to a longitudinal axis of the pathway, and the pathway extends from a skin incision and into a body cavity. The method can also include advancing the restriction device through the pathway and into the body cavity.

The tunnel can be formed using various techniques. For example, the tunnel can be a finger tunnel. In other embodi-

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ments, an elongate member can be inserted into the pathway and manipulated to form a tunnel extending from the pathway. The location of the tunnel can also vary, but in an exemplary embodiment the tunnel is formed adjacent to a fascia layer.

The housing can have various configurations, and in one embodiment the device can include a first housing that is coupled to a second housing. The method can further include positioning the second housing adjacent to the pathway. The restriction device can also include a sensor that measures at least one physiological parameter. In one embodiment, the sensor can be a pressure sensor. The sensor can be disposed anywhere within the system, including within one or more of the housings. Depending on the particular configuration of the device, in other embodiments the housing can be in fluid communication with the restriction device.

In another embodiment, the pathway can be a primary pathway and the tunnel can extend from the primary pathway to a secondary pathway. The method can include advancing the catheter from one of the primary pathway and the secondary pathway, through the tunnel, to the other one of the primary pathway and the secondary pathway. The catheter can be coupled to the housing prior to or after advancing the catheter. In another embodiment, positioning the housing within the tunnel can include retracting the catheter into the tunnel to pull the housing through one of the primary pathway and the secondary pathway and into the tunnel.

In another embodiment, a method for implanting a restriction system is provided and includes advancing a restriction device through a pathway extending from a skin incision into a body cavity. A catheter coupled to the restriction device can optionally extend through the pathway and exit the skin incision, or it can be fully disposed within the body cavity. The method can also include forming a single connection between a catheter coupled to the restriction device and one of a first housing and a second housing. The first and second housings can be coupled to one another by a connector extending therebetween. The method can also include implanting the first and second housings in tissue.

In one embodiment, the first housing can be implanted in a tunnel extending from the pathway and adjacent to a fascia layer, and the second housing can be implanted in the pathway at an offset location. In another embodiment, the pathway can be a first pathway, and the tunnel can extend from the first pathway to a second pathway. Implanting the first and second housings can include retracting the catheter into the tunnel. In an exemplary embodiment, the catheter is advanced from the first pathway to the second pathway prior to forming a single connection between the catheter and one of the first and second housings.

In other aspects, a method of implanting a restriction system is provided and includes advancing a restriction device through a primary pathway extending from a skin incision to a body cavity to position the restriction device around an organ to be restricted, forming a tunnel between the primary pathway and a secondary pathway, advancing the trailing end of a catheter coupled to the restriction device through the tunnel, coupling the trailing end of the catheter to a housing, and implanting the housing in tissue. In one embodiment, the trailing end of the catheter can exit from the skin incision when the restriction device is advanced through the primary pathway.

In an exemplary embodiment, advancing the trailing end of the catheter through the tunnel can include advancing the trailing end of the catheter through the primary pathway, across the tunnel, and through the secondary pathway such that the trailing end of the catheter exits the secondary pathway.

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way. Implanting the housing can include retracting the catheter to position the housing within the tunnel, and implanting the housing in the tunnel. The catheter can be retracted by, for example, pulling on a portion of the catheter extending from the primary pathway. In an exemplary embodiment, the housing is a sensor housing that is coupled to a fill port, and the method can include implanting the fill port in tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be more fully understood from the following detailed description taken in conjunction with the accompanying drawings, in which:

FIG. 1A is a front view illustration of a prior art gastric restriction device implanted in a patient to form a restriction in the patient's stomach;

FIG. 1B is a side view of another embodiment of a prior art gastric restriction device having an injection port coupled to a sensor housing in an in-line configuration;

FIG. 1C is a side view of another embodiment of a prior art gastric restriction device having an injection port coupled to a sensor housing in a T-configuration;

FIG. 2 is a side view illustration showing a first pathway extending from a skin incision to a body cavity containing a gastric band implanted to form a restriction in a stomach, showing a catheter coupled to the gastric band exiting from the first pathway;

FIG. 3A is a side view illustration showing an elongate device being used to form a tunnel extending from the first pathway of FIG. 2;

FIG. 3B is a side view illustration showing graspers being used to form a tunnel extending from the first pathway of FIG. 2;

FIG. 3C is a side view illustration showing a finger being used to form a tunnel extending from the first pathway of FIG. 2;

FIG. 4 is a side view illustration showing the sensor housing and injection port of FIG. 1C being coupled to a catheter exiting from the first pathway;

FIG. 5 is a side view illustration showing the sensor housing and injection port of FIG. 4 implanted within the tunnel and first pathway;

FIG. 6 is a side view illustration showing a second pathway being formed at a distance apart from a first pathway having a catheter extending therefrom and coupled to a gastric band;

FIG. 7A is a side view illustration of the first and second pathways of FIG. 6, showing a tunnel being formed between the pathways using an elongate device;

FIG. 7B is a side view illustration of the first and second pathways of FIG. 6, showing a tunnel being formed between the pathways using graspers;

FIG. 7C is a side view illustration of the first and second pathways of FIG. 6, showing a tunnel being formed between the pathways using a finger;

FIG. 8A is a side view illustration of the first and second pathways and the tunnel of FIGS. 7A-7C, showing an elongate device being used to grasp the catheter extending through the first pathway;

FIG. 8B is a side view illustration of the first and second pathways and the tunnel of FIGS. 7A-7C, showing graspers being used to grasp the catheter extending through the first pathway;

FIG. 8C is a side view illustration of the first and second pathways and the tunnel of FIGS. 7A-7C, showing a finger being used to grasp the catheter extending through the first pathway;

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FIG. 9 is a side view illustration showing the graspers of FIG. 8B after pulling the catheter through the tunnel and out of the second pathway;

FIG. 10 is a side view illustration showing a terminal end of the catheter of FIG. 9 being coupled to a sensor housing which is coupled to an injection port;

FIG. 11 is a side view illustration showing the catheter of FIG. 10 retracted into the tunnel to position the sensor housing and injection port within the tunnel;

FIG. 12A is a side view of the sensor housing and injection port of FIG. 11 implanted in the tunnel, showing the sensor housing anchored to tissue; and

FIG. 12B is a top view of the sensor housing and injection port of FIG. 12A implanted in the tunnel.

DETAILED DESCRIPTION OF THE INVENTION

Certain exemplary embodiments will now be described to provide an overall understanding of the principles of the structure, function, manufacture, and use of the devices and methods disclosed herein. One or more examples of these embodiments are illustrated in the accompanying drawings. Those of ordinary skill in the art will understand that the devices and methods specifically described herein and illustrated in the accompanying drawings are non-limiting exemplary embodiments and that the scope of the present invention is defined solely by the claims. The features illustrated or described in connection with one exemplary embodiment may be combined with the features of other embodiments. Such modifications and variations are intended to be included within the scope of the present invention.

The present invention generally discloses various exemplary methods for implanting a restriction device for forming a restriction in a patient. The methods can be used with a variety of restriction devices, but in an exemplary embodiment the methods are used for implanting a gastric restriction device. While various types of gastric restriction devices are known, including electrical, mechanical, and/or fluid-based devices, for reference purposes the methods disclosed herein are discussed in connection various embodiments of a gastric restriction device disclosed in commonly-owned U.S. Publication No. 2006/0211913 of Dlugos et al. (hereinafter "Dlugos") filed on Mar. 7, 2006 and entitled "Non-Invasive Pressure Measurement In A fluid Adjustable Restrictive Device," which is hereby incorporated by reference in its entirety. A person skilled in the art will appreciate that the method is not intended to be limited to use with any particular device.

FIG. 1A illustrates one embodiment of an implantable restriction device, as disclosed in Dlugos. As shown, the implantable restriction device 100 generally includes an adjustable gastric band 120 that is configured to be positioned around the upper portion of a patient's stomach 140, and an injection port 130 that is fluidly coupled to the adjustable gastric band 120, e.g., via a catheter 150. A person skilled in the art will appreciate that the catheter can be a single, unitary member, or it can be formed from multiple components joined together. The injection port 130 is adapted to allow fluid to be introduced into and removed from the gastric band 20 to thereby adjust the size of the band 120, and thus the pressure applied to the stomach. The injection port 130 can thus be implanted at a location within the body that is accessible through the tissue. Typically, injection ports are positioned in the lateral subcostal region of the patient's abdomen under the skin and layers of fatty tissue. Surgeons also typically implant injection ports on the sternum of the patient.

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The illustrated device **100** also includes a pressure reading device **134** for reading the pressure of the fluid within the closed fluid circuit of the device **100**. While Dlugos discloses a pressure reading device **134**, the device could be any sensing device for sensing various parameters. The sensing device can also have various configurations and it can be coupled to or positioned anywhere in the gastric restriction device **100**. In the illustrated embodiment, the pressure reading device **134** is coupled to the injection port **130**. In another embodiment, as shown in FIG. 1B, Dlugos discloses a device **10** having a separate sensor housing **60** that is disposed in-line with the gastric band **20** and the injection port **30**. In particular, a first catheter portion **50a** is coupled between the sensor housing **60** and the gastric band **20** and a second catheter portion **50b** is coupled between the injection port **30** and the sensor housing **60**. In another embodiment, the gastric restriction device can have a Y-configuration or T-shaped configuration. As shown in FIG. 1C, Dlugos discloses a device **10'** having include a catheter **52'** with a T-shaped intersection **52c'** with terminal ends that mate to the injection port **30'** and the sensor housing **60'**. While not disclosed by Dlugos, the third terminal end can mate, e.g., via connector **62'**, to the terminal end **50'** of the catheter **50'** extending from the gastric band **20'**. A person skilled in the art will appreciate that the gastric restriction device can have a variety of other configurations, and the sensor, if provided, can be implanted anywhere within the system, including within the injection port. Moreover, the system also may not have an injection port, but instead may have a single housing containing a sensor or contain other apparatus. Various configurations are possible, and any known restriction system or device can be used with the methods of the present invention.

In order to implant a restriction device, such as the gastric devices disclosed by Dlugos, a first pathway is typically formed through the stomach wall to provide access to the abdominal cavity. This can be achieved using various techniques known in the art, but in one exemplary embodiment a small skin incision is formed and a trocar is inserted through the skin incision until the tip of the trocar penetrates into the abdominal cavity. The trocar will thus form a primary or first pathway into the abdomen. This pathway can be used to introduce a gastric band. While only one pathway is shown, additional pathways are often created to provide access for various other devices, such as an endoscope for viewing the surgical site. Various techniques are known in the art for implanting a gastric band to form a restriction around the upper portion of a patient's stomach. By way of non-limiting example, U.S. Pat. No. 6,102,922 filed on Jun. 29, 1998 and entitled "Surgical Method and Device for Reducing Food Intake of a Patient," and U.S. Pat. No. 4,592,339 filed on Jun. 12, 1985 and entitled "Gastric Banding Device," which are hereby incorporated by reference in their entireties, disclose various methods for implanting a gastric band. FIG. 2 illustrates a first pathway **70** extending through a skin surface and into an abdominal cavity, showing the gastric restriction device **10** of FIG. 1B having the gastric band **20** positioned to form a restriction around an upper portion of a stomach **40**, and showing the catheter **50** extending from the gastric band **20** and through the pathway such that the terminal end **50t** of the catheter **50** exits the skin incision and remains external to the patient's body. While not shown, in other embodiments the catheter **50**, including the terminal end **50t**, can be fully disposed within the body cavity.

Once the gastric band **20** is implanted, the terminal end **50t** of the catheter **50** can be connected to one or more housings and the housing(s) can be implanted in tissue. In an exemplary embodiment, only a single connection needs to be made

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between the terminal end **50t** of the catheter **50** and the housing(s). For example, where the restriction device **10** includes two or more housings, the housings can be pre-connected to one another during manufacturing and packaged together as a single sterile package. The terminal end **50t** of the catheter **50** extending from the gastric band **20** can thus be connected to a connector. Thus, with the device **10** of FIG. 1B, for example, the sensor housing **60** and injection port **30** can be pre-connected to one another during manufacturing, and the terminal end **50t** of the catheter can be connected to a connector **62** formed on the sensor housing **60** during the surgical procedure. Similarly, with the device **10'** of FIG. 1C, the sensor housing **60'** and injection port **30'** can be pre-connected to one another during manufacturing and package together as a single sterile package. The terminal end **50t'** of the catheter **50'** extending from the gastric band **20'** can be connected to a connector **62'** formed on the catheter **52'** that couples the sensor housing **60'** and the injection port **30'**. As previously noted, while the two housings are referred to as a "sensor housing" and an "injection port," the housings can contain various components for performing various functions, and the device can include any number of housings.

With the terminal end of the catheter connected to one or more housings, the housings can be implanted in tissue. The particular implant location can vary depending on the configuration of the device. For example, where the device includes an injection port, the port is preferably implanted just beneath the tissue surface to allow a needle or other device to be penetrated through tissue and into the injection port to add or remove fluid from the gastric restriction device. Where the device includes a sensor housing, the sensor housing is also preferably implanted in tissue at a location that is accessible to allow for wireless communication with the sensor, thus allowing data and/or energy to be transmitted between an external device and the sensor. In certain exemplary embodiments, the port and/or sensor housing are implanted on the fascia layer beneath up to 10 cm to 15 cm of subcutaneous abdominal fat.

The particular method for implanting the housing(s) can vary depending on the configuration of the device. FIGS. 3A-5 illustrate one exemplary embodiment of a method for implanting a restriction device having a T- or Y-configuration, such as the restriction device **10'** of FIG. 1C. FIGS. 6-12B illustrate another exemplary embodiment of a method for implanting a device having at least one housing that is in-line with the gastric band, such as the device **10** of FIG. 1A. Again, a person skilled in the art will appreciate that the particular configuration can vary, and that the various methods disclosed herein can be used with any restriction device. Moreover, the various steps can be performed in any order.

As shown in FIGS. 3A-3C, in an exemplary embodiment at least one tunnel **72** is formed extending from the first pathway **70**. The particular direction and orientation of the tunnel **72** can vary, however as shown the tunnel **72** extends laterally outward from the first pathway **70** in a direction transverse to a longitudinal axis of the first pathway **70**. As a result, the tunnel **72** extends across the fascia layer, thus allowing at least one housing to be implanted and/or anchored to the fascia. A person skilled in the art will appreciate that the tunnel **72** can be formed at any particular point in time during the procedure, including prior to or after connecting the terminal end of the catheter to the housing(s). Moreover, where a trocar or other device is used to gain access to the abdominal cavity, the trocar or other device can remain within the first pathway **70** or it can be removed during tunnel formation. Several additional tunnels can also be formed, and the particular quantity can vary depending on the configuration of the device.

Various techniques can be used to form the tunnel 72. In one embodiment, as shown in FIG. 3A, the tunnel is formed using a device having an elongate shaft with a flexible and/or bent distal end, such as the Goldfinger™ device 80 available from Ethicon Endo-Surgery and used as a surgical dissector and suture retrieval device. U.S. Publication No. 2007/0185519 of Hassler et al. filed on Feb. 7, 2006 and entitled “Articulating Surgical Instrument,” which is hereby incorporated by reference in its entirety, discloses one exemplary embodiment of such a device. The device 80 can be inserted through the pathway 70 and manipulated to separate the tissue and form a tunnel 72 extending transverse or laterally from the first pathway 70. The length or depth of the tunnel can vary, but preferably the tunnel has a size sufficient to receive at least a portion of a housing therein. The size can thus vary depending on the particular configuration of the housing.

In another embodiment, as shown in FIG. 3B, the tunnel 72 can be formed using a tissue-grasping and/or cutting device. FIG. 3B illustrates graspers 82 having opposed jaws 82a, 82b formed on the distal end thereof and configured to grasp tissue. The device 82 can be inserted through the first pathway 70, and a handle 82h on the device 82 can be manipulated to open and close the jaws 82a, 82b, thus allowing the jaws 82a, 82b to grasp and move and/or remove tissue to form the tunnel 72.

In yet another embodiment, as shown in FIG. 3C, the tunnel 72 can be formed using one's finger. In particular, the surgeon or other surgical staff can insert their finger 84 into the first pathway 70 and manipulate the finger to form the tunnel 72. A person skilled in the art will appreciate that a variety of other tools and techniques can be used to form a tunnel 72 extending from the first pathway 70. For example, in other embodiments the tunnel 72 can be formed internally from devices disposed within the body cavity.

Once the tunnel 72 is formed, one or more housings coupled to the gastric restriction device can be implanted in the tunnel 72. FIG. 4 illustrates the connector 62' on device 10' of FIG. 1C about to be connected to the terminal end 50t' of the catheter 50', and FIG. 5 illustrates the sensor housing 60' and the injection port 30' implanted. The housings can be implanted by inserting the sensor housing 60', either manually or using an insertion tool, through the pathway 70 and into the tunnel 72. In an exemplary embodiment, the sensor housing 60' is fully disposed within the tunnel 72 and is positioned to rest on the fascia. The sensor housing 60' can optionally be anchored to the fascia using, for example, sutures or other tissue engaging mechanisms, or it can merely rest on the fascia within the tunnel 72. The injection port 30' can also be inserted through the first pathway 70, either manually or using an insertion tool, such as a port applier as disclosed in U.S. Publication No. 2006/0293626 of Byrum et al. filed on Jun. 24, 2005 and entitled “” and U.S. Publication No. 2006/0293627 of Byrum et al. and entitled “Applier For Safety With Implantable Medical Device,” which are hereby incorporated by reference in their entireties. The sensor housing 60' and/or the injection port 30' could also be pulled into the pathway by retracting the catheter 50, e.g., by pulling on a portion of the catheter 50 disposed within the body cavity. The particular implant location of the injection port 30' can also vary, but in an exemplary embodiment the injection port 30' is positioned in the first pathway, preferably just offset from the first pathway 70 at least partially within tissue surrounding the first pathway 70. The injection port 30' can likewise be anchored to tissue using various anchoring techniques, such as sutures or other tissue engaging mechanisms. U.S. Publication No. 2005/0277899 of Conlon et al. filed on Jun. 1, 2004 and entitled “Method Of Implanting A Fluid

Injection Port,” which are hereby incorporated by reference in their entireties, disclose various embodiments of an injection port having tissue-engaging anchors formed on a distal surface thereof. A person skilled in the art will appreciate that various anchoring mechanisms can optionally be used, and the particular anchoring mechanism can depend on the particular configuration of the housing(s). With the sensor housing 60' and the injection port 30' implanted in tissue, the catheter 50' can extend from the housings to the gastric band 20'. The first pathway 70 can thus be closed, leaving the gastric restriction device 10' fully implanted.

While not shown, in another embodiment, rather than having the catheter 50 extend through the first pathway 70 and exit the skin incision, the catheter 50 could be fully disposed within the body cavity and a device inserted into the body cavity (e.g., the abdominal cavity) can be used to form an incision (e.g., through the peritoneum) and a second pathway extending into the tunnel 72. The second pathway does not necessarily need to extend out through a skin incision, it could be a fully internal pathway. The tunnel 72 will thus extend between the first pathway and the second pathway. The terminal end 50t' of the catheter 50 can be inserted into the second pathway and grasped and pulled across the tunnel 72 and then removed through the first pathway 70 to allow the terminal end 50t' of the catheter 50 to be mated to the housing(s). Once mated, the catheter 50 can be retracted to pull the housing(s) into the tunnel 72.

As indicated above, FIGS. 6-12B illustrate another exemplary embodiment of a method for implanting a device having at least one housing that is in-line with the gastric band, such as the device 10 of FIG. 1B. In this embodiment, a second pathway 74 is formed through a stomach wall, and it can extend to the fascia or all the way into the abdominal cavity. While not shown, the second pathway 74 can alternatively extend from the body cavity to the fascia, as explained above, to form an internal pathway. The second pathway 74 can be formed using various techniques, as previously explained with respect to the first pathway 70, and it can include an access device, such as a trocar, disposed therein and defining a working channel. In an exemplary embodiment, the second pathway 74 is positioned a distance apart from the first pathway 70. The distance can vary, but in certain exemplary embodiments the distance is in the range of about 10 cm to 20 cm.

Once the second pathway 74 is formed, a tunnel 72 can be formed between the first and second pathways 70, 74. As explained above, the particular direction and orientation of the tunnel 72 can vary, however as shown the tunnel 72 extends laterally between the first and second pathways 70, 74 in a direction transverse to a longitudinal axis of the pathways 70, 74. As a result, the tunnel 72 extends across the fascia layer, thus allowing at least one housing to be implanted and/or anchored to the fascia. The tunnel 72 can also be formed using various techniques, including those explained above with respect to FIGS. 3A-3C. Where the tunnel 72 extends between two pathways 70, 74, the tools and/or one's finger, can be inserted through one or both of the pathways 70, 74 to form a tunnel 72 extending between the two pathways 70, 74. FIGS. 7A illustrates the Goldfinger™ device inserted through the second pathway 74, FIG. 7B illustrates the graspers 82 inserted through the second pathway 74, and FIG. 7C illustrates a finger 84 inserted through the second pathway 74 for forming the tunnel 72. Again, a person skilled in the art will appreciate that various other techniques can be used to form a tunnel 72 extending between the first and second pathways 70, 74.

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Once the tunnel 72 is formed, in one embodiment the terminal end 50t of the catheter 50 can be advanced back into the first pathway 70 and pulled across the tunnel 72 and out of the second pathway 74 to exit through the skin incision. Various devices can be used to grasp and pull the terminal end 50t of the catheter 50 through the tunnel 72 and out of the second pathway 74. FIG. 8A illustrates the Goldfinger™ device 80 extending through the second pathway 74 and the tunnel 72, to grasp the terminal end 50t of the catheter 50 and thus pull it through the tunnel 72. FIG. 8B similarly illustrates the graspers 82 extending through the second pathway 74 and the tunnel 72 to grasp the terminal end 50t of the catheter 50, and FIG. 8C similarly illustrates a finger 84 extending through the second pathway 74 and the tunnel 72 to grasp the terminal end 50t of the catheter 50. Again, various other techniques can be used to advance and/or pull the terminal end 50t of the catheter 50 through the tunnel 72 and out of the second pathway 74. With the terminal end 50t of the catheter 50 extending from the second pathway 74, as shown in FIG. 9 which illustrates the graspers 82 engaging the terminal end 50t of the catheter, the terminal end 50t can be connected to one or more housings. As shown in FIG. 10, the terminal end 50t is about to be mated to the connector 62 on the sensor housing 60, which in turn is coupled to the injection port 30 via the connector 52. The sensor housing 60 and injection port 30 are thus in communication with the gastric band 20. Where the device 10 is a fluid-based device, the sensor housing 60 and injection port 30 are in fluid communication with the gastric band 20 when coupled, thus allowing the sensor housing 60 to measure, for example, the fluid pressure within the device 10, and allowing fluid to be introduced and/or removed through the injection port 30.

Once connected, the catheter 50 can be retracted, for example, by pulling on the portion of the catheter 50 extending from the first pathway 70 and out through the skin incision, and/or by pulling on a portion of the catheter 50 disposed within the body cavity. This will pull the sensor housing 60 and injection port 30 into the second pathway 74 and into the tunnel 72, as shown in FIG. 11. Both housings can be fully disposed within the tunnel 72, or one or both housings can be positioned within or just adjacent to the pathways 70, 74. For example, as shown in FIG. 12A, the injection port 30 can be implanted within the second pathway 74 at a location offset from the longitudinal axis, i.e., in surrounding tissue or just at an entrance of the tunnel 72, and the sensor housing 60 can be implanted within the first pathway 70 at a location offset from the longitudinal axis, i.e., in surrounding tissue or just at an entrance of the tunnel 72. Such positioning can allow the injection port 30 and/or the sensor housing 60 to be anchored to tissue. By way of non-limiting example, FIG. 12A illustrates tissue-engaging members 31 on a distal surface of the injection port 30 engaging the fascia to retain the injection port 30 in a substantially fixed position. As previously explained, various other anchoring techniques can be used, if desired. While not shown, the sensor housing 60 can also optionally be anchored to tissue. FIG. 12B illustrates a top view of the device of FIG. 12A, showing the injection port 30 positioned adjacent to the second pathway 74 and the sensor housing 60 positioned adjacent to the first pathway 72.

In other embodiments, the terminal end 50t of the catheter 50 can be connected to one or more housings prior to being inserted through the first pathway 70 and advanced through the tunnel 72 to extend from the second pathway 74. For example, the terminal end 50t could be connected to a first housing, and the first housing, with the catheter attached thereto, could be inserted through the first pathway 70, across the tunnel 72, and through the second pathway 74 to exit the

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skin incision. One or more additional housings could then be coupled to the first housing and the catheter could be retracted to pull the additional housing(s) into the second pathway 74 and optionally into the tunnel 72. Alternatively, all housings could be coupled to the catheter prior to inserting the catheter through the first pathway 70 and into the tunnel 72. A person skilled in the art will appreciate that various techniques could be used, and the particular technique may depend on the particular configuration of the catheter.

One skilled in the art will appreciate further features and advantages of the invention based on the above-described embodiments. Accordingly, the invention is not to be limited by what has been particularly shown and described, except as indicated by the appended claims. All publications and references cited herein are expressly incorporated herein by reference in their entirety.

What is claimed is:

1. A method for implanting a restriction system, comprising:
 - forming a primary pathway through a skin incision;
 - coupling a catheter exiting through the skin incision to a housing such that the housing is coupled, via the catheter, to a restriction device implanted to form a restriction;
 - forming a tunnel extending from the primary pathway to a secondary pathway;
 - positioning the housing within the tunnel;
 - advancing the catheter from one of the primary pathway and the secondary pathway, through the tunnel, to the other one of the primary pathway and the secondary pathway; and
 - coupling the catheter to the housing after advancing the catheter.
2. The method of claim 1, wherein the tunnel extends transverse to a longitudinal axis of the pathway.
3. The method of claim 1, wherein forming the tunnel comprises forming a finger tunnel.
4. The method of claim 1, wherein forming the tunnel comprises inserting an elongate member into the pathway and manipulating the elongate member to form a tunnel extending from the pathway.
5. The method of claim 1, wherein the tunnel is formed adjacent to a fascia layer.
6. The method of claim 1, wherein the housing comprises a first housing that is coupled to a second housing, and wherein the method further comprises positioning the second housing adjacent to the pathway.
7. The method of claim 1, wherein positioning the housing within the tunnel comprises retracting the catheter into the tunnel to pull the housing through one of the primary pathway and the secondary pathway and into the tunnel.
8. The method of claim 1, wherein the pathway extends from a skin incision and into a body cavity and the method further comprises advancing the restriction device through the pathway and into the body cavity.
9. The method of claim 1, wherein the housing is in fluid communication with the restriction device.
10. The method of claim 1, wherein the restriction device includes a sensor that measures at least one physiological parameter.
11. The method of claim 10, wherein the sensor comprises a pressure sensor.
12. A method for implanting a restriction system, comprising:
 - advancing a restriction device through a pathway extending from a skin incision into a body cavity;

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forming a single connection between a catheter coupled to the restriction device and one of a first housing and a second housing, the first and second housings being coupled to one another by a connector extending therebetween; and

implanting the first and second housings in tissue, the first housing being implanted in a tunnel extending from the pathway and adjacent to a fascia layer, and the second housing being implanted in the pathway at an offset location.

13. The method of claim 12, wherein, when the restriction device is advanced through the pathway and into a body cavity, the catheter extends through the pathway and exits the skin incision.

14. The method of claim 12, wherein the pathway comprises a first pathway, and wherein the tunnel extends from the first pathway to a second pathway, and implanting the first and second housings comprises retracting the catheter into the tunnel.

15. The method of claim 14, wherein the catheter is advanced from the first pathway to the second pathway prior to forming a single connection between the catheter and one of the first and second housings.

16. The method of claim 12, wherein the tunnel is formed by advancing a finger through tissue adjacent to the pathway.

17. The method of claim 12, wherein the tunnel is formed by inserting an elongate member into the pathway and manipulating the elongate member to extend transverse to a longitudinal axis of the pathway.

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18. A method of implanting a restriction system, comprising:

advancing a restriction device through a primary pathway extending from a skin incision to a body cavity to position the restriction device around an organ to be restricted;

forming a tunnel between the primary pathway and a secondary pathway;

advancing the trailing end of a catheter coupled to the restriction device through the primary pathway, across the tunnel, and through the secondary pathway such that the trailing end of the catheter exits the secondary pathway;

coupling the trailing end of the catheter to a housing; and implanting the housing in tissue;

wherein the trailing end of the catheter exits from the skin incision when the restriction device is advanced through the primary pathway.

19. The method of claim 18, wherein implanting the housing comprises retracting the catheter to position the housing within the tunnel, and implanting the housing in the tunnel.

20. The method of claim 19, wherein the catheter is retracted by pulling on a portion of the catheter extending from the primary pathway.

21. The method of claim 18, wherein the housing comprises a sensor housing that is coupled to a fill port, and wherein the method further comprises implanting the fill port in tissue.

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