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(54) Title: METHODS AND DEVICES FOR RECANALIZATION OF OCCLUDED BODY VESSELS USING A DOUBLE-SIDED GUIDEWIRE

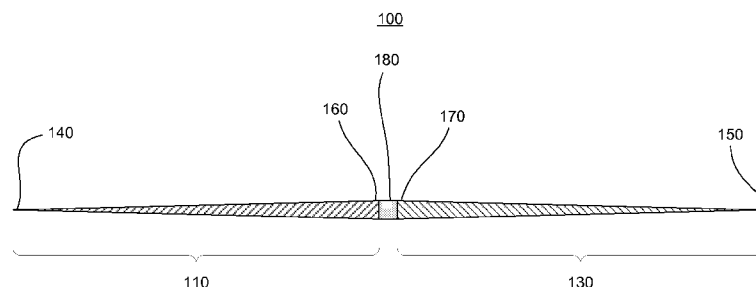


FIG. 2A

(57) Abstract: Devices and methods for recanalization of occluded body vessels using novel guidewires. A novel double-sided guidewire comprises a cross-section tapering from a more rigid middle section towards more flexible head sections. A first head of the guidewire is inserted into the occluded body vessel in a retrograde direction to traverse an occlusion. The guidewire is further advanced in the retrograde direction such that the first head and a portion of the middle section are retrieved from the body, thereby positioning the remainder of the guidewire traversing the occlusion in an antegrade direction and allowing for over the wire recanalization techniques in the antegrade direction.



**METHODS AND DEVICES FOR RECANALIZATION OF OCCLUDED BODY
VESSELS USING A DOUBLE-SIDED GUIDEWIRE**

FIELD OF THE INVENTION

[0001] The present embodiments relate generally to methods and devices for recanalizing occluded body vessels, and in particular to using a novel double-sided guidewire to penetrate an occlusion in a retrograde direction to allow for recanalization in an antegrade direction.

DESCRIPTION OF THE RELATED ART

[0002] Chronic total occlusion (CTO) is the complete blockage of a vessel and usually has serious consequences if not treated in a timely fashion. The blockage could be due to atheromatous plaque or old thrombus.

[0003] One of the common procedures for treating CTOs of the coronary arteries is percutaneous trans-luminal coronary angioplasty (PTCA). During a PTCA procedure, a small incision is, typically, made in the groin. A guiding catheter is introduced over a guidewire into the femoral artery and advanced to the occlusion. Frequently, with gentle maneuvering, the guidewire is able to cross the stenosis. Then, a balloon-tipped angioplasty catheter is advanced over the guidewire to the stenosis. The balloon is inflated, separating or fracturing the atheroma. Commonly, a stent is subsequently placed. Some of the common steps involved in the PTCA procedure are the simultaneous injection of a contrast agent in the contra-lateral vessel, getting backup force or stabilization for a guidewire (which could invoke additional personnel to handle the catheter), puncturing the plaque, drilling or rotating the guidewire to push it through the dense plaque, etc. Because of the stiff resistance sometimes offered by dense plaque, one could be forced to use rigid wires. Occasionally, the wires could puncture the vessel wall calling for remedial measures.

[0004] Percutaneous treatment of coronary chronic total occlusions remains one of the major challenges in interventional cardiology. Recent data have shown that successful

percutaneous recanalization of chronic coronary occlusions results in improved survival, as well as enhanced left ventricular function, reduction in angina, and improved exercise tolerance.

[0005] However, because of the perceived procedural complexity of angioplasty in CTOs, it still represents the most common reason for referral to bypass surgery, or for choosing medical treatment.

[0006] The most common percutaneous coronary intervention (PCI) failure mode for CTOs is the inability to successfully pass a guidewire across the lesion into the distal true lumen of the vessel. To date, there is no consensus on how best to treat CTOs after attempts with conventional guidewires have failed. Different strategies and specific devices for CTOs have been developed, including the subintimal tracking and reentry with side branch technique, parallel wire technique, IVUS guided technique, and retrograde approach. However, none of these alternate strategies have provided satisfactory results for the most challenging of the CTOs.

[0007] Therefore, it would be desirable to have alternate techniques and devices for simplifying the recanalization of CTOs while overcoming some of the shortcomings of current techniques. CTOs that are difficult and time consuming to recanalize would benefit from novel CTO recanalization approaches.

SUMMARY OF THE INVENTION

[0008] Disclosed are embodiments of devices and methods for recanalizing an occluded body vessel by using a novel double-sided guidewire.

[0009] In one embodiment, a device for recanalizing an occluded vessel comprises a first guidewire having a head and a tail; and a second guidewire having a head and a tail; wherein the tail of the first guidewire is configured to be coupled to the tail of the second guidewire; and wherein the first guidewire is configured to be advanced into the occluded vessel in a retrograde direction, and the head of the second guidewire is configured to be positioned in the occluded vessel in an antegrade direction.

[0010] In one aspect, a cross-sectional area of the guidewires increases from the head towards the tail.

[0011] In one aspect, the first or second guidewire comprises a core wire. The core wire may comprise a substantially flat cross-section. In one aspect, the device comprises a layer of structural polymer over the core wire. In one aspect, an outer surface of the first or second guidewire is coated with a hydrophilic coating for ease of navigation through tortuous passageways.

[0012] In one aspect, the device is separable into the first and second guidewires.

[0013] In one aspect, the first guidewire or the second guidewire is extendable.

[0014] In one aspect, the first guidewire and the second guidewire each have a fixed length.

[0015] In one embodiment, a method for positioning a guidewire in an occluded body vessel comprises advancing a first guidewire in the occluded body vessel in a retrograde direction, wherein the first guidewire comprises a head and a tail, and wherein the tail of the first guidewire is configured to be coupled to a tail of a second guidewire; penetrating an occlusion using the head of the first guidewire; advancing the first guidewire through the occlusion such that the first guidewire traverses the occlusion; coupling the tail of the first guidewire to the tail of the second guidewire; and advancing the coupled first and second guidewires through the

occluded body vessel in the retrograde direction until the first guidewire and the tail of the second guidewire are retrieved out of the occluded body vessel; thereby positioning the second guidewire such that it traverses the occlusion in an antegrade direction. The second guidewire comprises a head. The method may comprise extending the first and/or the second guidewire. The method may further comprise de-coupling the first guidewire from the second guidewire after the first guidewire and the tail of the second guidewire are retrieved out of the occluded body vessel.

[0016] In another embodiment, a method for positioning a guidewire in an occluded body vessel comprises advancing a guidewire in the occluded body vessel in a retrograde direction, wherein the guidewire comprises a first head, a middle section, and a second head, wherein a cross-sectional area of the guidewire decreases from the middle section towards the first and second heads; traversing an occlusion using the first head of the guidewire; and advancing the guidewire through the occluded body vessel in the retrograde direction until the first head and a portion of the middle section are retrieved out of the occluded body vessel; thereby positioning the guidewire such that it traverses the occlusion in an antegrade direction.

[0017] Other embodiments and variations are presented in the detailed description, as follows.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] The invention has other advantages and features which will be more readily apparent from the following detailed description of the invention and the appended claims, when taken in conjunction with the accompanying drawings, in which:

[0019] Figure 1 shows an occluded body vessel.

[0020] Figure 2A shows an embodiment of a double-sided guidewire device comprising a first guidewire coupled to a second guidewire tail-to-tail.

[0021] Figure 2B shows another embodiment of a double-sided guidewire device comprising a middle section that tapers towards two head sections.

[0022] Figure 3 is a flow diagram illustrating a method for recanalizing an occluded body vessel using a double-sided guidewire device.

[0023] Figures 4A-4G depict various stages of the recanalization procedure of Figure 3, according to an embodiment using a double-sided guidewire with a first and second guidewire coupled tail-to-tail.

DETAILED DESCRIPTION

[0024] Although the detailed description contains many specifics, these should not be construed as limiting the scope of the invention but merely as illustrating different examples and aspects of the invention. It should be appreciated that the scope of the invention includes other embodiments not discussed in detail herein. Various other modifications, changes and variations which will be apparent to those skilled in the art may be made in the arrangement, operation and details of the methods and devices of the present invention disclosed herein without departing from the spirit and scope of the invention as described here.

[0025] A schematic diagram of a portion of an occluded body vessel **BDL** is shown in Figure 1. The body vessel **BDL** could be any vessel or artery in which blood flows through the hollow tubular cavity. An occlusion **OCL** within the body vessel **BDL** may obstruct the blood flow and could have fatal consequences. Typically, treatment procedures may involve approaching the occlusion from an antegrade and/or a retrograde direction. The occlusion **OCL** comprises a distal cap **DC**, a proximal cap **PC**, and an occlusion body **BO** therebetween. In the combined, antegrade-retrograde approach, the distal cap **DC** is typically approached from a retrograde direction, whereas the proximal cap **PC** is typically approached from an antegrade direction. The occlusion **OCL** could be atheromatous plaque, old thrombus, or similar other deposit. One method of recanalizing the occlusion **OCL** is by using guidewire techniques, wherein a guidewire penetrates the occlusion **OCL** and a catheter recanalizes the vessel.

[0026] Depending on the type and the composition of the occlusion **OCL**, it may be difficult to successfully penetrate the occlusion **OCL** using standard guidewire techniques. In particular, the distal cap **DC** of the occlusion may be composed of dense, fibrous tissue with fibrocalcific regions. Generally, it may be necessary to use a guidewire of sufficient rigidity to successfully penetrate the distal cap **DC**. Also, it may generally be necessary to apply substantial force in order to penetrate the distal cap **DC** of the occlusion and recanalize the body vessel.

[0027] When traversing the occlusion in an antegrade direction, it has been a challenge to successfully penetrate and traverse the distal cap **DC** and enter the distal true lumen **DTL** without entering into subintimal space **SIS**. This is so because, combined with its fibrous composition, the distal cap **DC** of the occlusion often assumes a morphology that renders penetration difficult, as the guidewire is likely to be deflected away from the fibrous interior surface of the distal cap **DC** (see Figure 1). The difficulties in penetrating the distal cap **DC** of the occlusion often lead to the guidewire slipping away from the interior surface of the distal cap **DC** and entering into subintimal space **SIS**. The penetration of the subintimal space **SIS** may lead to the puncturing of the wall of the body vessel, which may cause bleeding as well as other undesirable side effects. Furthermore, by penetrating the subintimal space **SIS** instead of the distal cap **DC**, it is substantially more difficult for a catheter to advance into the distal true lumen **DTL** to complete the recanalization.

[0028] Embodiments of the present invention relate generally to devices, systems, and methods for simplifying the process of recanalization of an occluded body vessel. Specifically, one aspect of the present embodiments discloses devices and methods for positioning a guidewire within an occluded body vessel for recanalization without the need for an exchange. In one embodiment, a first guidewire may be coupled to a second guidewire is inserted into the occluded body vessel in a retrograde direction. The first guidewire may then penetrate the distal cap **DC** from the retrograde direction and advances through the occlusion. Thereafter, the first guidewire may be retrieved from the body vessel along with a portion of the second guidewire, leaving the second guidewire positioned within the occlusion in the antegrade direction. With the second guidewire positioned in the occlusion in an antegrade direction, over-the-wire recanalization techniques that are well known in the art may be performed to recanalize the body vessel. Furthermore, it is contemplated that the embodiments described herein may be applied analogously in the antegrade approach, wherein a first guidewire coupled to a second guidewire may be inserted into the occluded body vessel in an antegrade direction, and upon completion of

the procedure, the second guidewire may be positioned within the occlusion in the retrograde direction.

[0029] One embodiment of the double-sided guidewire device is shown in Figure 2A. The device **100** comprises a first guidewire **110** and a second guidewire **130**. The first guidewire **110** comprises a head **140** and a tail **160**. The second guidewire **130** comprises a head **150** and a tail **170**. The tail **160** of the first guidewire **110** is configured to be coupled with the tail **170** of the second guidewire **130** by a coupling means **180**.

[0030] In one embodiment, the coupling means **180** is configured to securely lock the first guidewire **110** and the second guidewire **130** to prevent separation during the guidewire placement procedure. Additionally and optionally, the coupling means **180** may be configured to provide quick and easy detachment of the two guidewires. In one embodiment, the coupling means **180** may comprise a male portion (not shown) disposed on the tail of either the first or the second guidewire, and a female portion (not shown) disposed on the tail of the other guidewire, wherein the male portion is configured to be inserted into the female portion. In one embodiment the male portion may be spring loaded to more securely attach inside the female portion. Alternatively, coupling may be achieved by other means of coupling, connecting, or extending guidewires such as the use of magnets or a screwing mechanism.

[0031] Additionally, as seen in Figure 2A, a cross-sectional area of the first guidewire **110** is configured to progressively increase from the head **140** towards the tail **160**. Similarly, a cross-sectional area of the second guidewire **130** is configured to progressively increase from the head **150** towards the tail **170**, such that the first and the second guidewires assume substantially tapered configurations. The tapered configuration may be advantageous in that the narrow head may be configured to effectively traverse through the vascular matrix and to penetrate the occlusion, whereas the larger tail is configured to allow a physician to manipulate the guidewire during the operation. Alternatively and optionally, a cross-sectional area of the first guidewire

110 and/or the second guidewire **130** may be configured to be substantially unchanged throughout the lengths of the guidewires.

[0032] It is noted that the flexibility of the first and the second guidewires may vary over their respective lengths. In one embodiment, the heads of the guidewires are substantially flexible, and the flexibility progressively decreases towards the tails.

[0033] Another embodiment of the present invention is shown in Figure 2B. Figure 2B shows a single guidewire embodiment, wherein a guidewire device **200** comprises a first head **210**, a middle section **220**, and a second head **230**. The cross-sectional area of the guidewire **200** may be minimal at the heads **210** and **230**, and may increase towards the middle section **220**, providing a tapered configuration similar to the embodiment shown in Figure 2A.

[0034] Figure 3 is a flow diagram illustrating the positioning of a guidewire device in an occluded body vessel, in accordance with one embodiment of the present invention and with reference to Figures 4A-4G. At step **310**, the head **140** of the first guidewire **110** is advanced through the occluded body vessel **BDL** in a retrograde direction (Figure 4A). Retrograde insertion may involve navigating the guidewire through narrow septal channels of the coronary vasculature, depending on the position of the occlusion.

[0035] At step **320**, the head **140** of the first guidewire **110** penetrates the distal cap **DC** of the occlusion (Figure 4B). At step **330**, the first guidewire **110** is advanced into and through the body **BO** of the occlusion (Figure 4C). At step **340**, the head **140** of the first guidewire **110** penetrates the proximal cap **PC** of the occlusion, and the first guidewire **110** is further advanced through the occlusion body **BO** until the head **140** emerges from the occlusion **OCL** (Figure 4D). At this point, the head **140** of the first guidewire **110** may have substantially fully traversed the occlusion **OCL** in a retrograde direction.

[0036] At step **350**, the first guidewire **110**, coupled with the second guidewire **130**, are advanced through the occluded body vessel **BDL** (Figure 4E). For this step, when the second

guidewire **130** is not already coupled with the first guidewire **110**, the physician couples the two guidewires (as described above) prior to performing step **350**. Retrograde advancement of the two coupled guidewires then proceeds until the first guidewire **110**, and a portion of the second guidewire **130**, are retrieved from the body of the patient (Figure 4F-4G).

[0037] At this point, the entire first guidewire **110**, and the tail **170** of the second guidewire **130**, are positioned outside of the patient's body, while the head **150** of the second guidewire **130** is positioned within the distal true lumen **DTL** of the occluded body vessel **BDL**, with a portion of the second guidewire **130** traversing the occlusion **OCL** in an antegrade direction. At step **360**, the tail **160** of the first guidewire and the tail **170** of the second guidewire may be decoupled by disengaging the coupling means. At step **370**, with the tail **170** of the second guidewire **130** positioned outside the patient and a portion of the second guidewire **130** traversing the occlusion, over the wire recanalization techniques that are well known in the art can be performed in an antegrade direction to recanalize the occluded body vessel **BDL**. In particular, the controlled antegrade and retrograde tracking (CART) techniques disclosed in the co-pending US Patent Application Serial Number 12/150,111, and the recanalization techniques combining the antegrade and retrograde approach with the use of radiofrequency energy as disclosed in PCT International Application Ser. No. PCT/US2008/077403, both by the same inventors and incorporated herein by reference, may be used in combination with the embodiments of the present invention. While the above steps have been illustrated with a guidewire device configured according to Figure 2A, it should be obvious that a similar process can be used with a guidewire device configured according to Figure 2B, or with other variants of such guidewire devices.

[0038] It is noted that the guidewires of the present embodiments may comprise core wires of different types and configurations for providing improved torque and easy maneuvering through body vessels. In one embodiment, such a core wire is configured to have a cross-section with an aspect ratio of approximately one. In another embodiment, the core wire is configured to

have a cross-section with an aspect ratio of less than one. In one embodiment, the core wire is configured to have a substantially flat cross-section. It is contemplated that the core wires may be stainless steel, Nitinol, Elgiloy, platinum, iridium, tantalum, titanium, cobalt, chromium, tungsten, combinations thereof, or other biologically compatible materials.

[0039] Optionally, it is noted that the guidewires of the present embodiments may comprise at least a layer of structural polymer over the core wire. Optionally, an outer surface of the first and/or the second guidewires are coated with hydrophilic coating for ease of navigation through tortuous passageways.

[0040] It is further contemplated that the guidewires may be configured to have a fixed length. In a double guidewire embodiment, such as that shown in Figure 2A, the first guidewire and the second guidewire are each configured to be about 180 cm in length. Optionally, the first and second guidewires may be of different lengths. In a single guidewire embodiment, such as that shown in Figure 2B, the guidewire device is configured to be about 300 cm from one head to the other head. Alternatively, the guidewires may be configured to be extendable.

[0041] While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.

WHAT IS CLAIMED IS:

1. A device for recanalizing an occluded vessel, comprising:
a first guidewire comprising a head and a tail; and
a second guidewire comprising a head and a tail, wherein the tail of the first guidewire is configured to be coupled to the tail of the second guidewire;
wherein the first guidewire is configured to be advanced into the occluded vessel in a retrograde direction, and the second guidewire is configured to be positioned in the occluded vessel in an antegrade direction.
2. The device of claim 1, wherein a cross-sectional area of the first guidewire increases from the head towards the tail of the first guidewire, and a cross-sectional area of the second guidewire increases from the head towards the tail of the second guidewire.
3. The device of claim 1, wherein the first or second guidewire comprises a core wire.
4. The device of claim 3, wherein the core wire comprises a substantially flat cross-section.
5. The device of claim 3, comprising a layer of structural polymer over the core wire.
6. The device of claim 1, wherein an outer surface of the first or second guidewire is coated with a hydrophilic coating.
7. The device of claim 1, wherein the device is separable into the first and second guidewires.
8. The device of claim 1, wherein the first guidewire or the second guidewire is extendable.
9. A method for positioning a guidewire in an occluded body vessel, comprising:

advancing a first guidewire in the occluded body vessel in a retrograde direction, wherein the first guidewire comprises a head and a tail, and wherein the tail of the first guidewire is configured to be coupled to a tail of a second guidewire;

penetrating an occlusion using the head of the first guidewire;

advancing the first guidewire through the occlusion such that the first guidewire traverses the occlusion;

coupling the tail of the first guidewire to the tail of the second guidewire; and

advancing the first and second guidewires through the occluded body vessel in the retrograde direction until the first guidewire and the tail of the second guidewire are retrieved out of the occluded body vessel.

10. The method of claim 9, further comprising positioning the second guidewire such that it traverses the occlusion in an antegrade direction.

11. The method of claim 9, wherein the second guidewire comprises a head.

12. The method of claim 11, wherein a cross-sectional area of the first guidewire increases from the head towards the tail of the first guidewire, and a cross-sectional area of the second guidewire increases from the head towards the tail of the second guidewire.

13. The method of claim 9, further comprising penetrating a distal cap of the occlusion in the retrograde direction using the head of the first guidewire.

14. The method of claim 9, further comprising de-coupling the first guidewire from the second guidewire after the first guidewire and the tail of the second guidewire are retrieved out of the occluded body vessel.

15. The method of claim 9, further comprising extending the first guidewire or the second guidewire.

16. A method for positioning a guidewire in an occluded body vessel, comprising:
- advancing a guidewire in the occluded body vessel in a retrograde direction, wherein the guidewire comprises a first head, a middle section, and a second head, wherein a cross-sectional area of the guidewire decreases from the middle section towards the first and second heads;
 - traversing an occlusion using the first head of the guidewire; and
 - advancing the guidewire through the occluded body vessel in the retrograde direction until the first head and a portion of the middle section are retrieved out of the occluded body vessel.

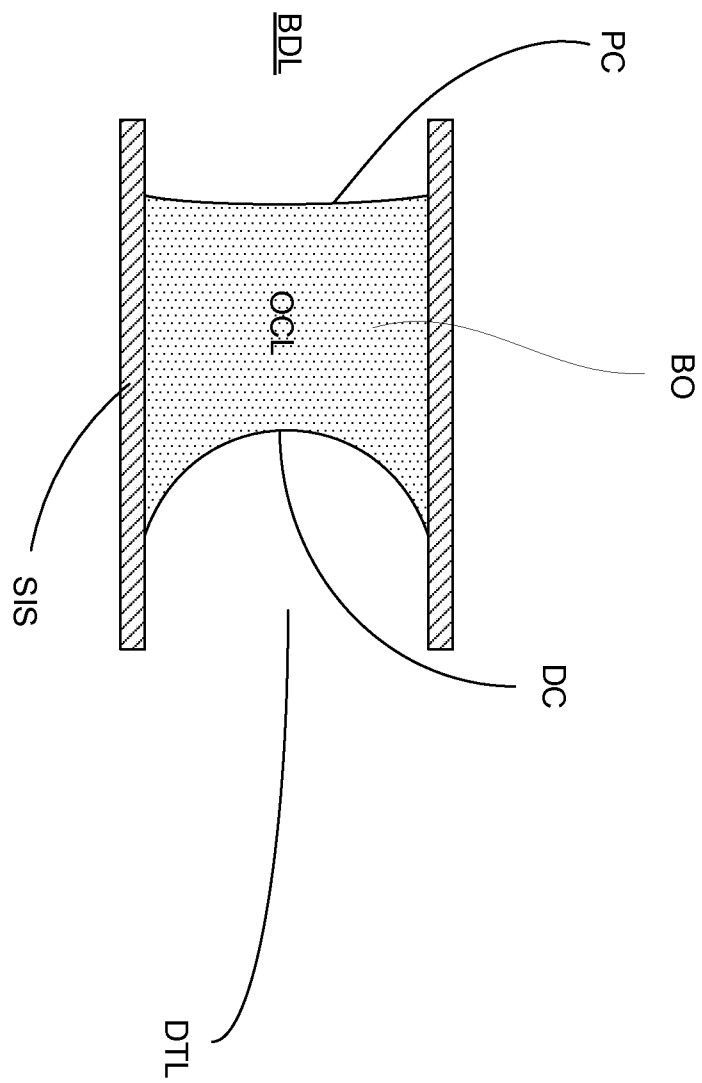


FIG. 1

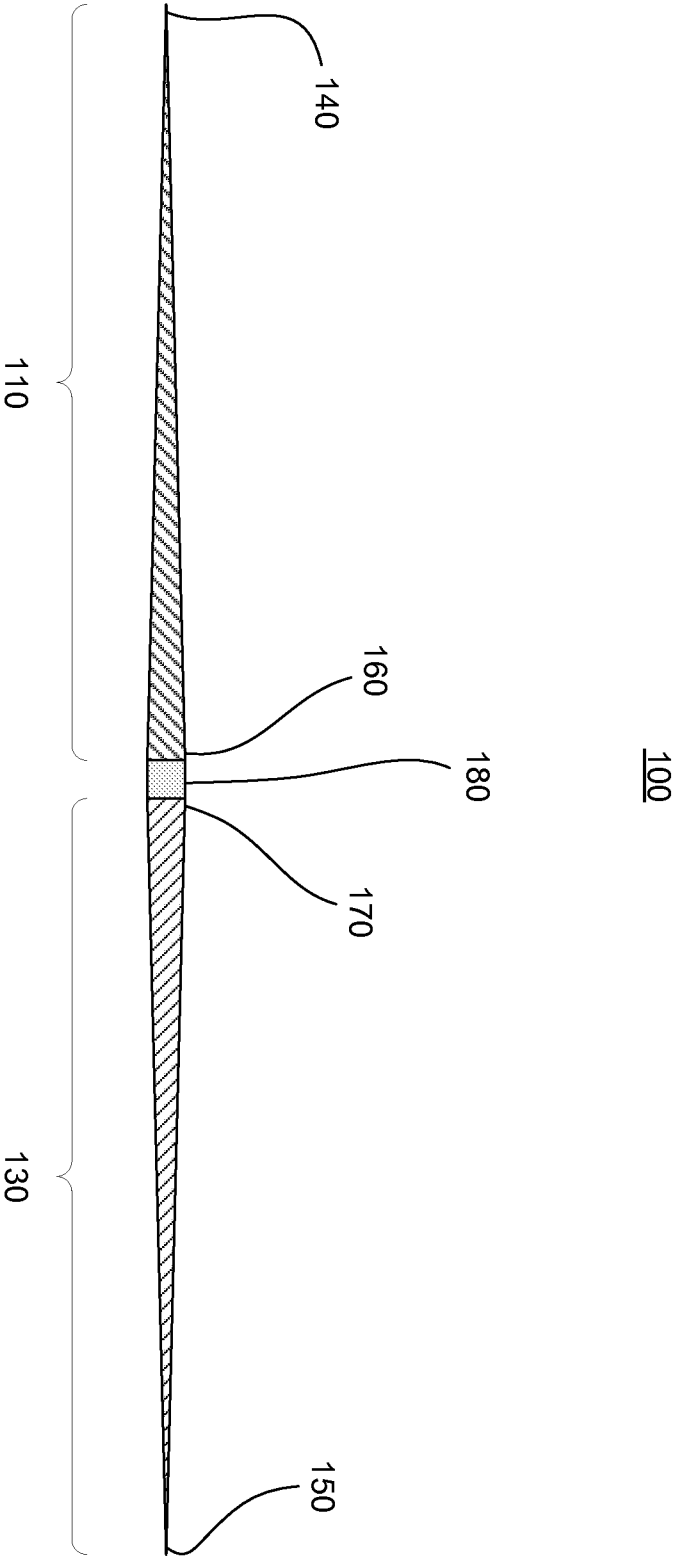


FIG. 2A

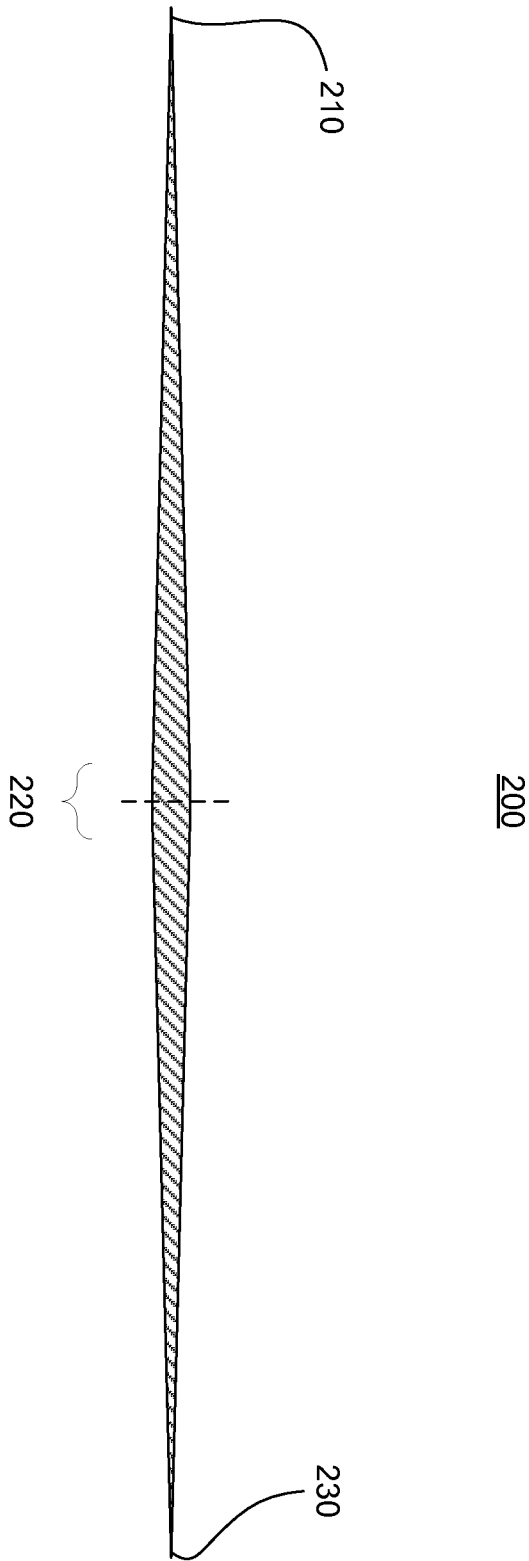
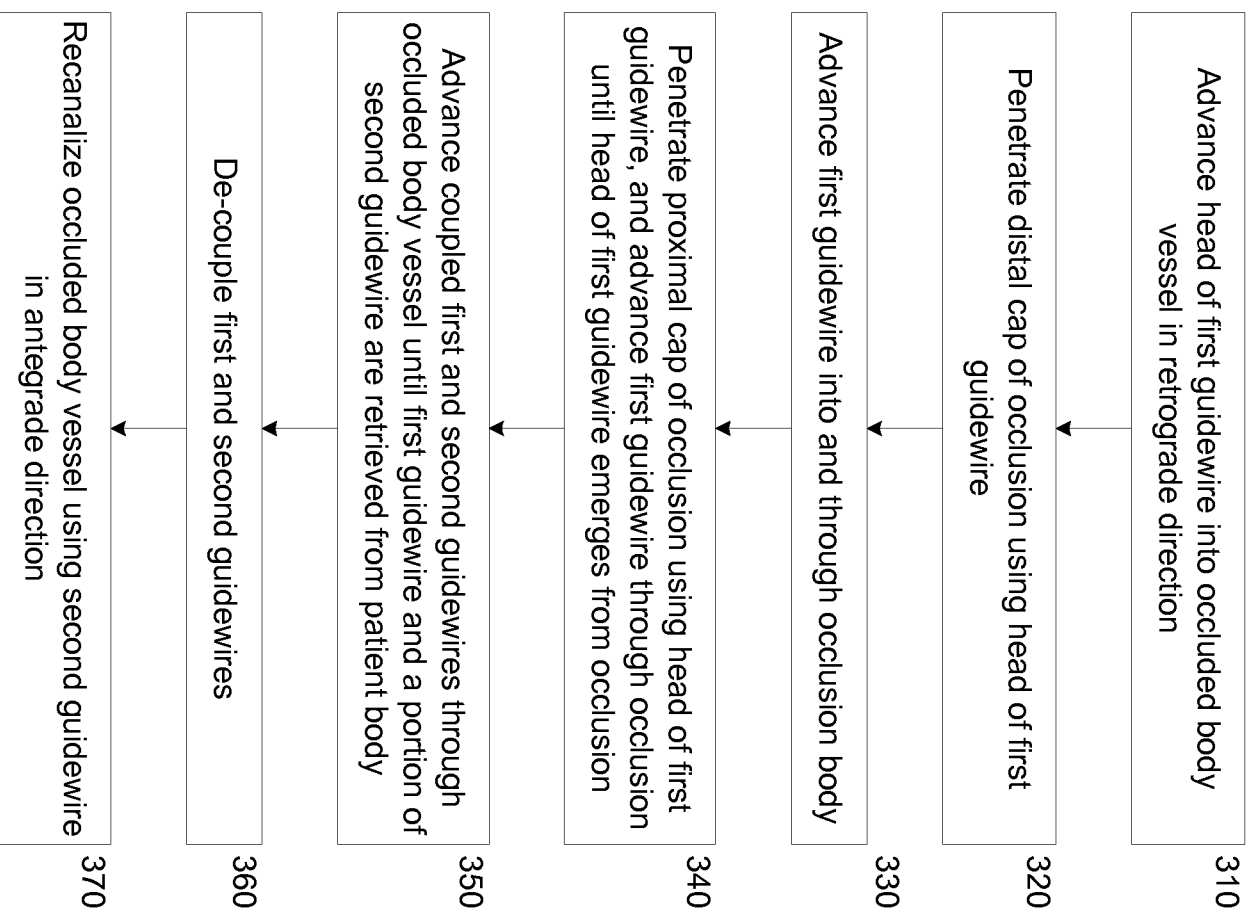
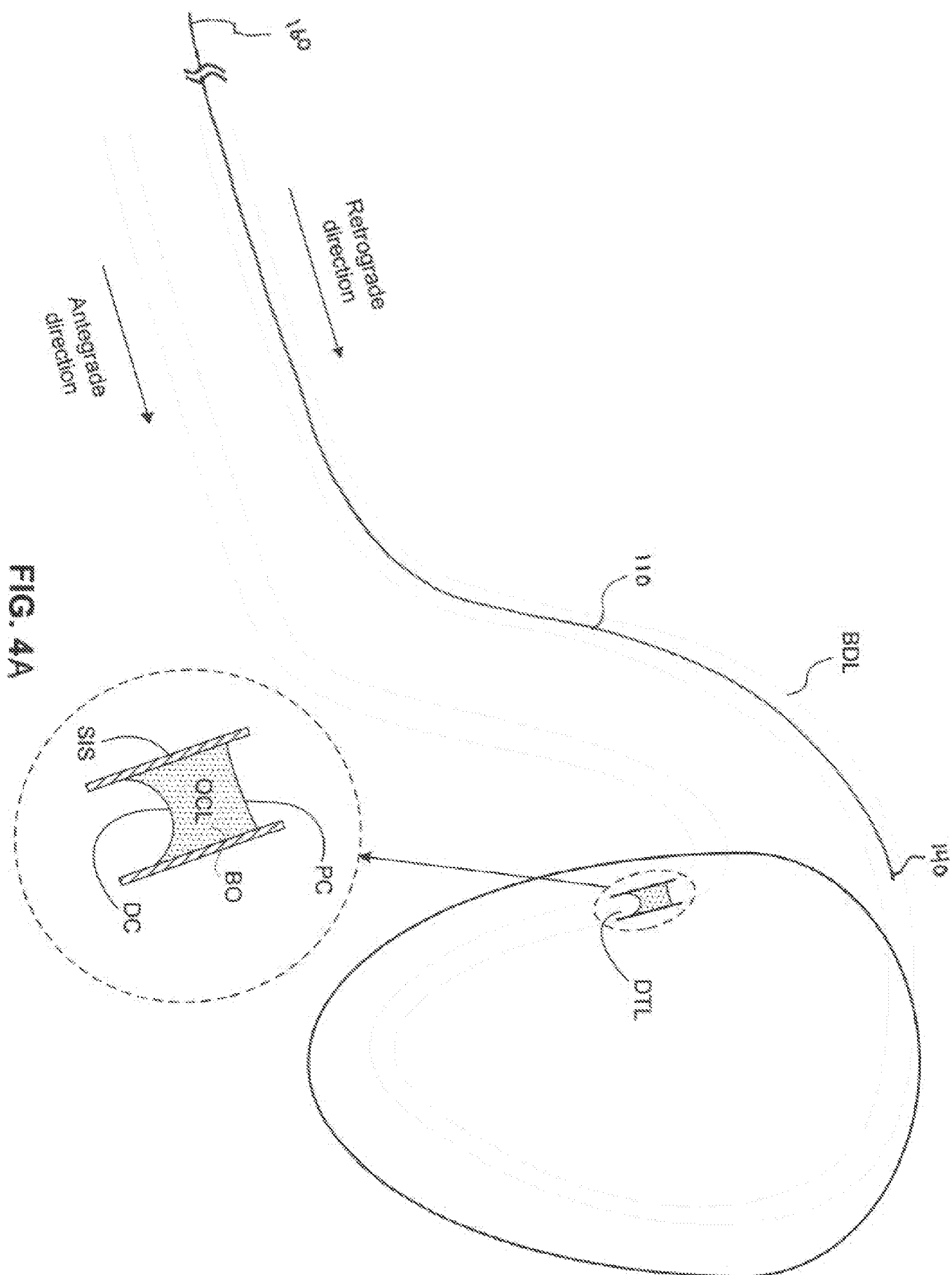
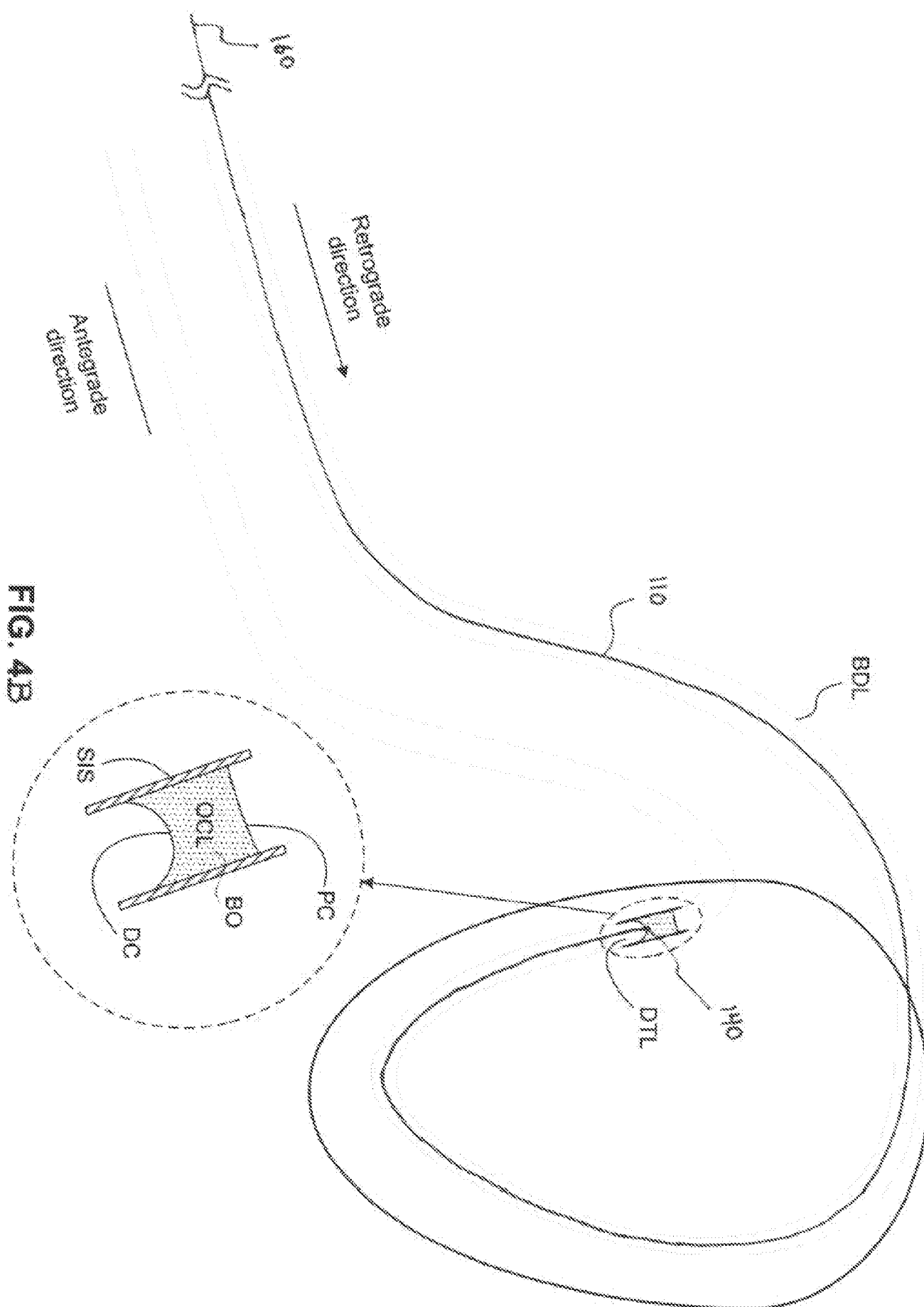
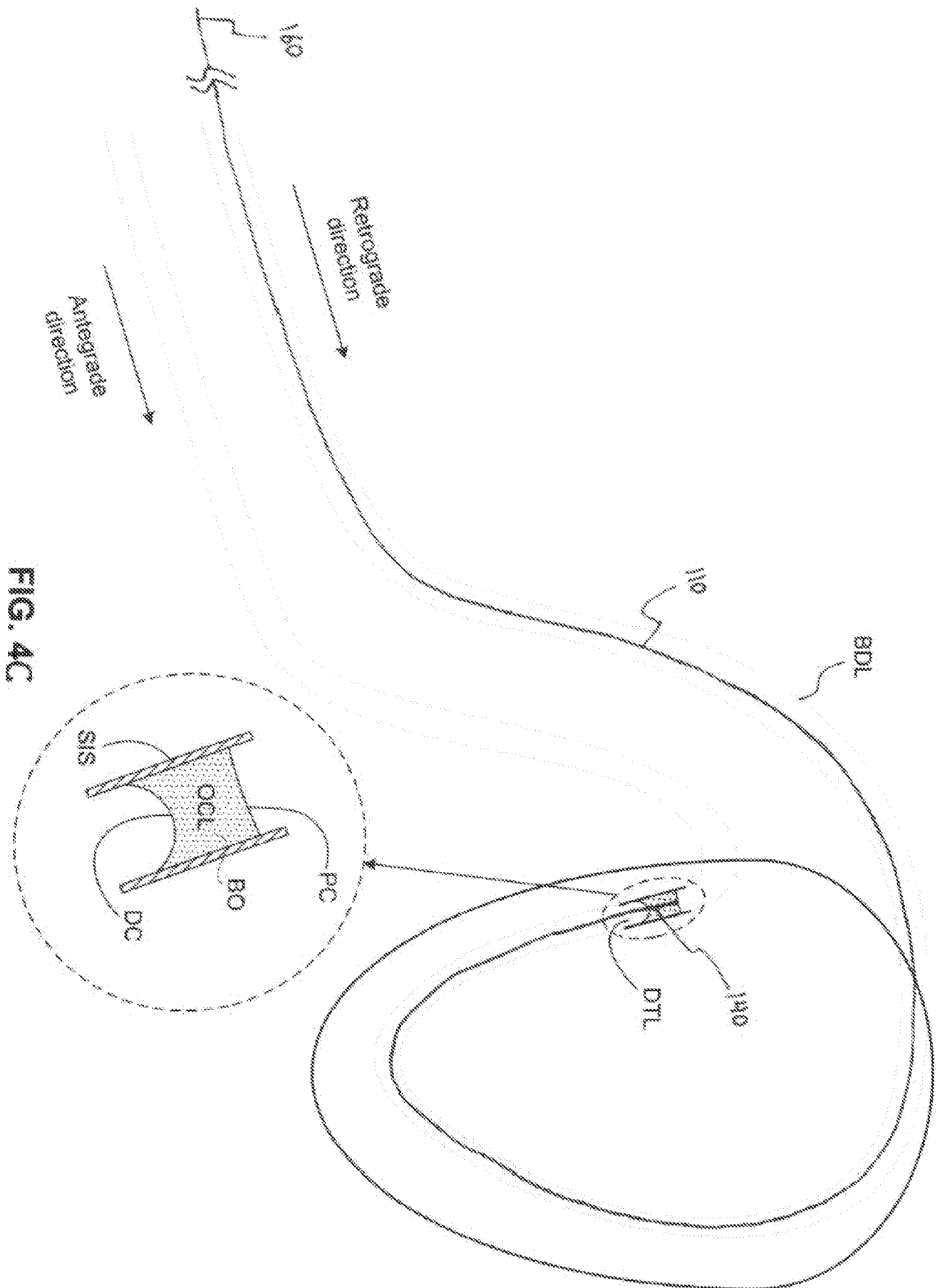


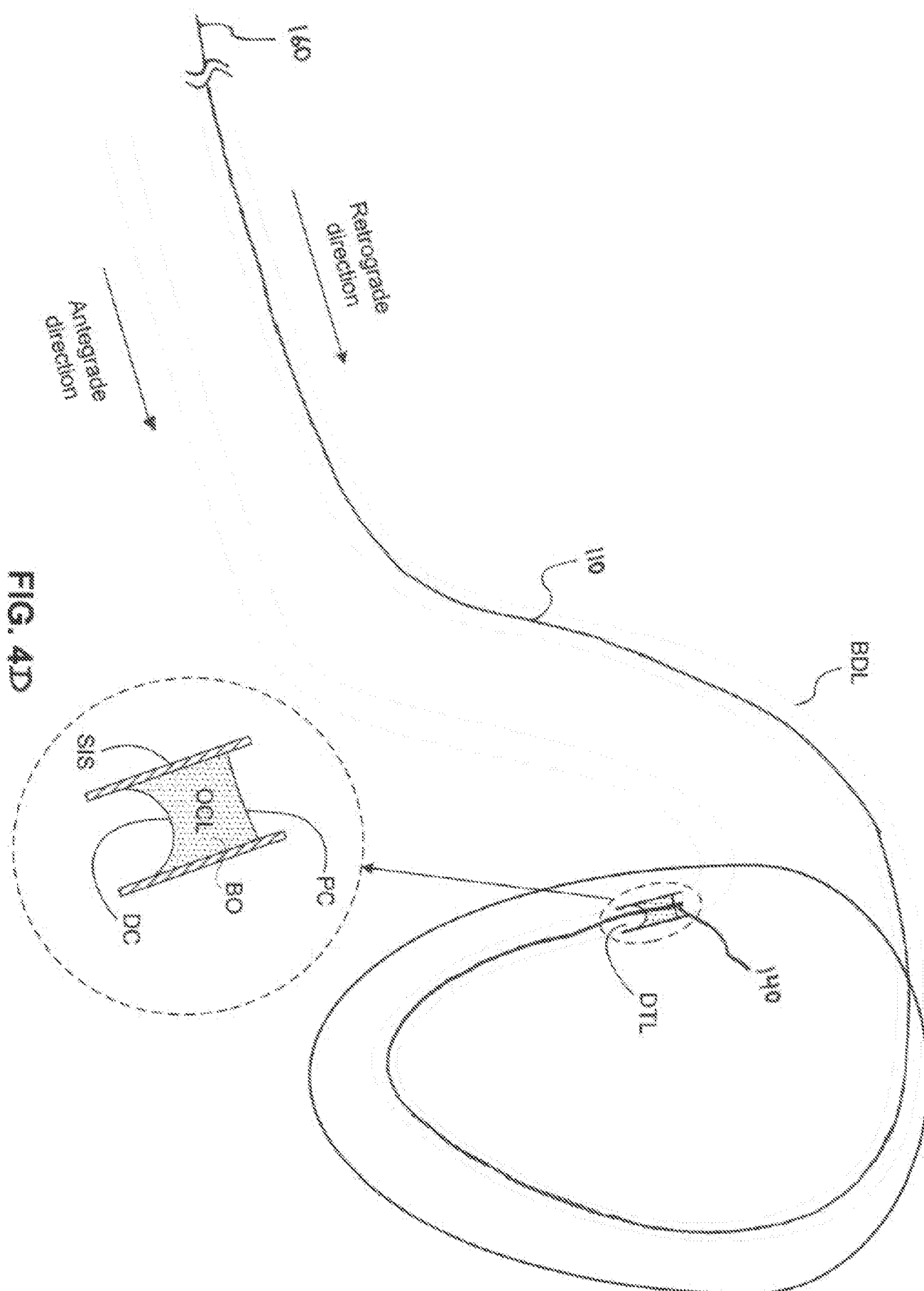
FIG. 2B

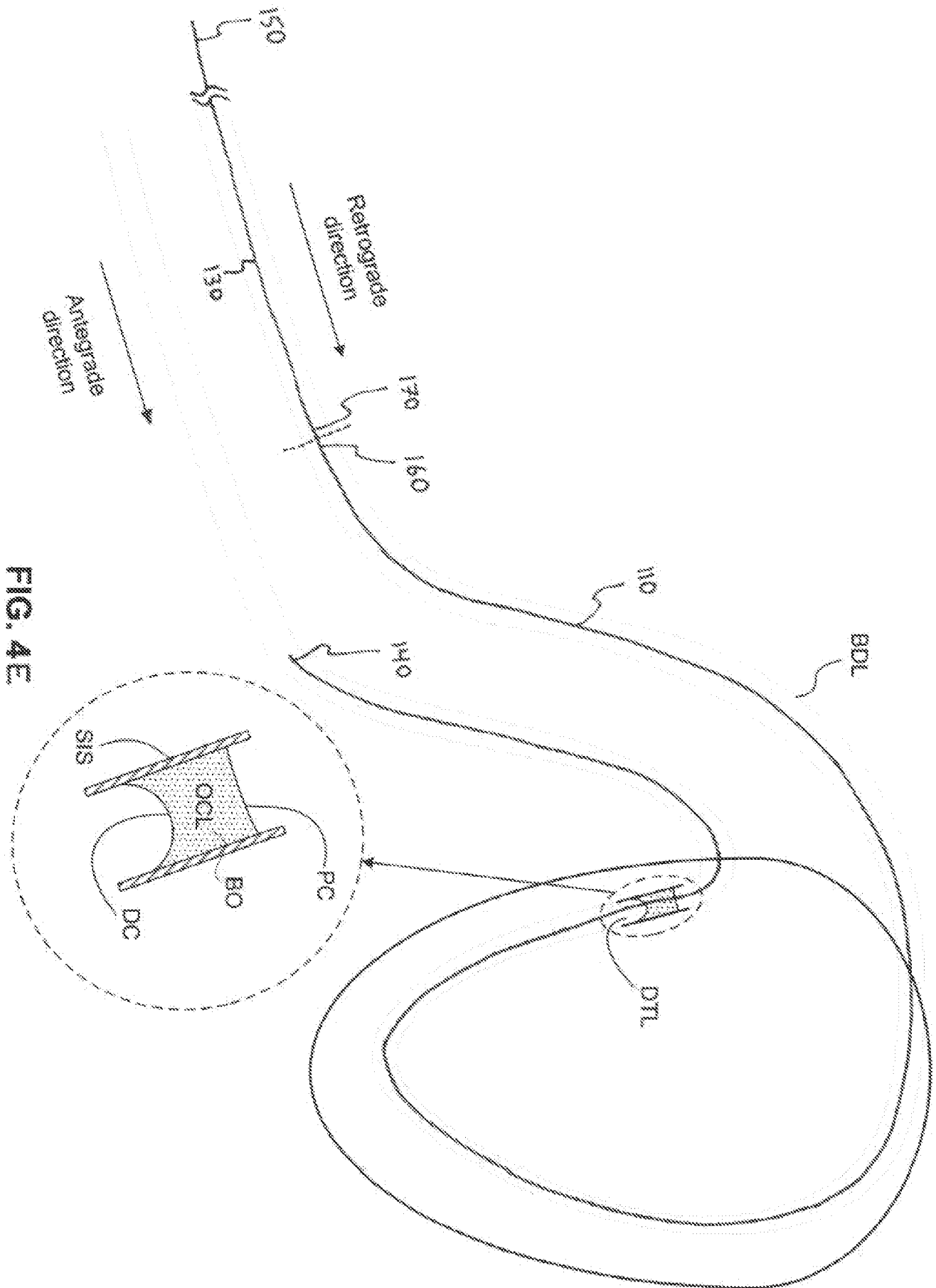
**FIG. 3**

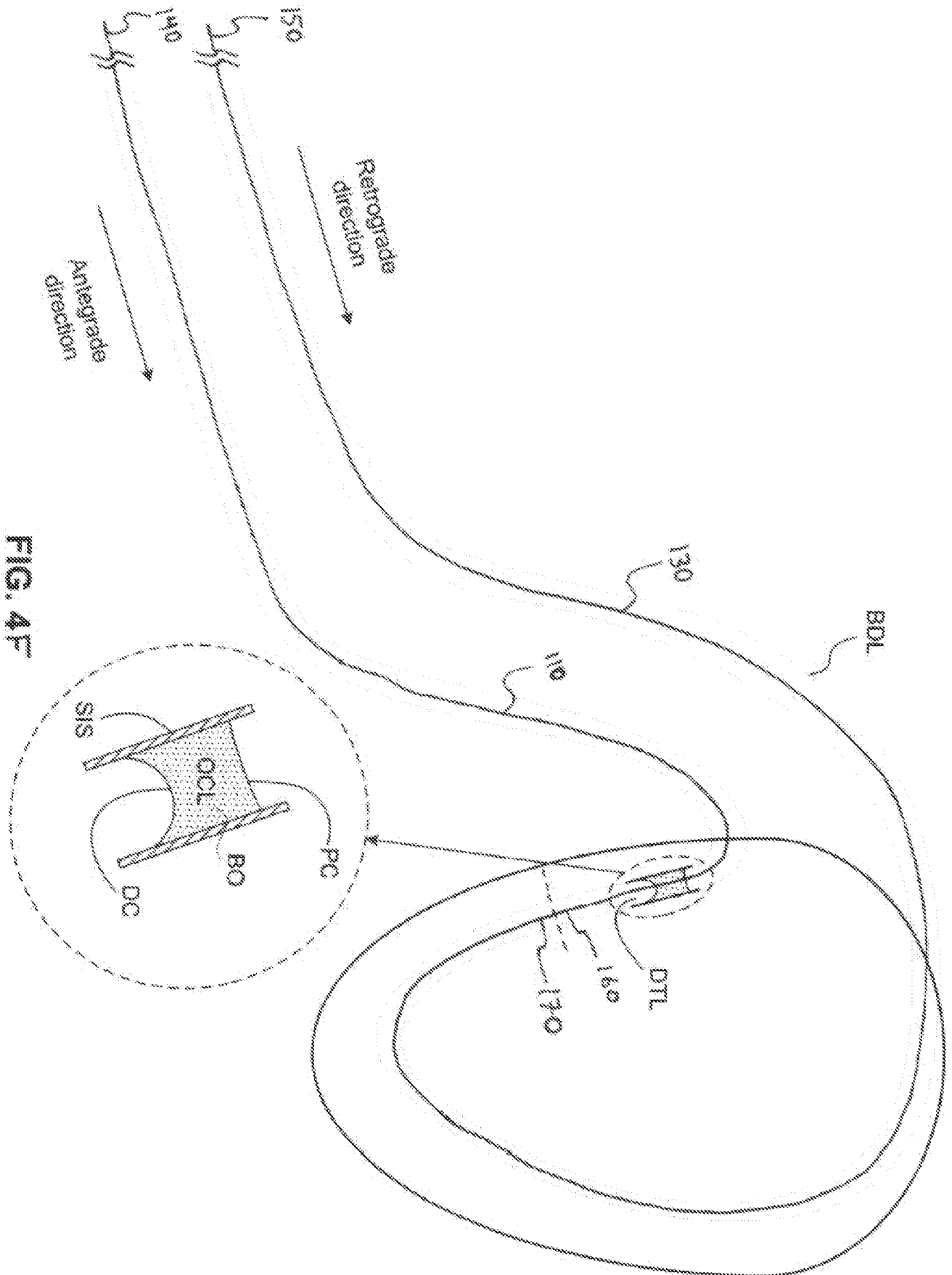












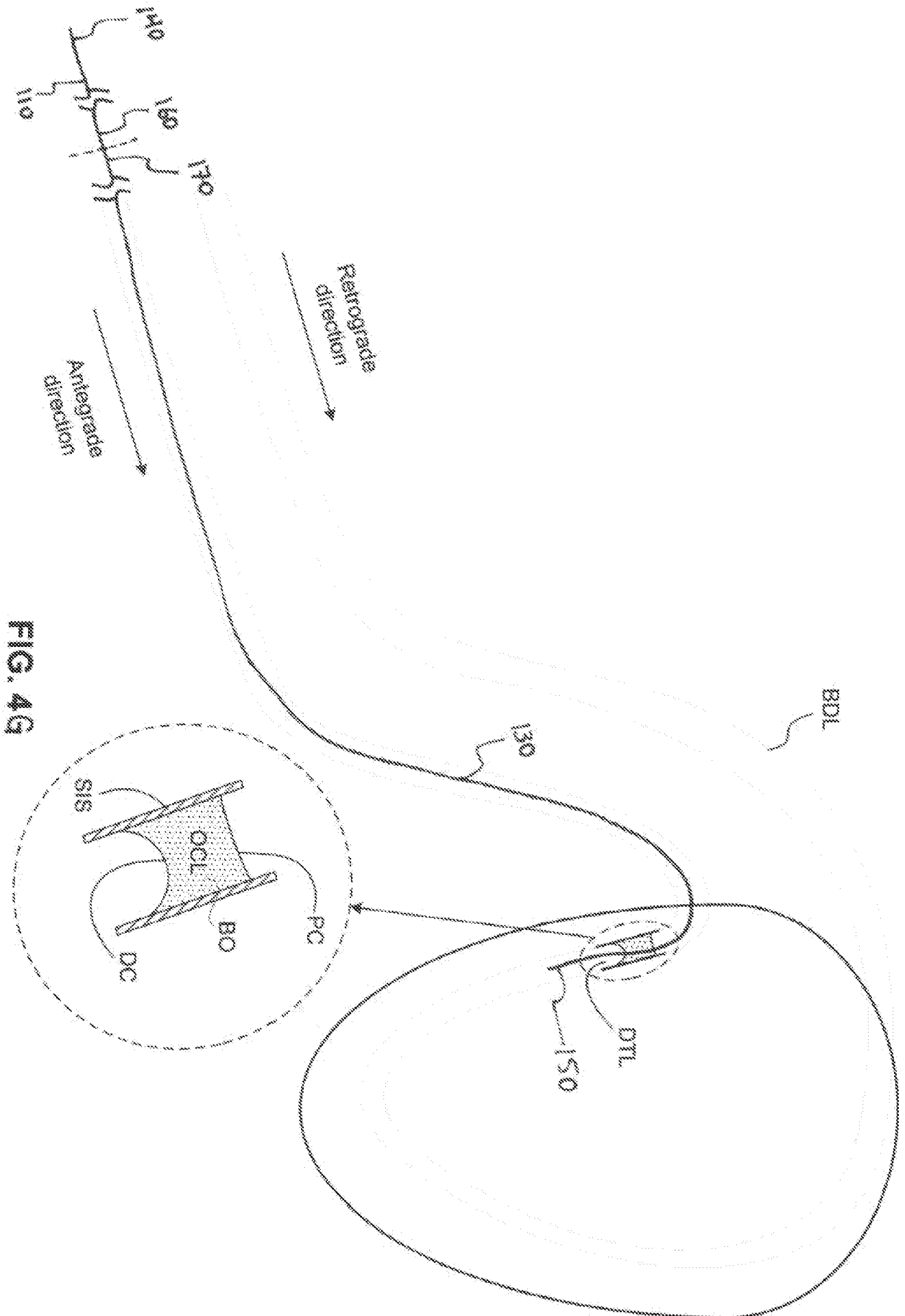


FIG. 4G