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(71) Applicant: SCIMED LIFE SYSTEMS, INC. [US/US]; One Scimed Place, Maple Grove, MN 55311-1566 (US).

(72) Inventor: GELLMAN, Barry, N.; 19 Pebblebrook Road, North Easton, MA 02356 (US).

(74) Agent: BIANCO, John, V.; Testa, Hurwitz & Thibeault, LLP, High Street Tower, 125 High Street, Boston, MA 02110 (US).

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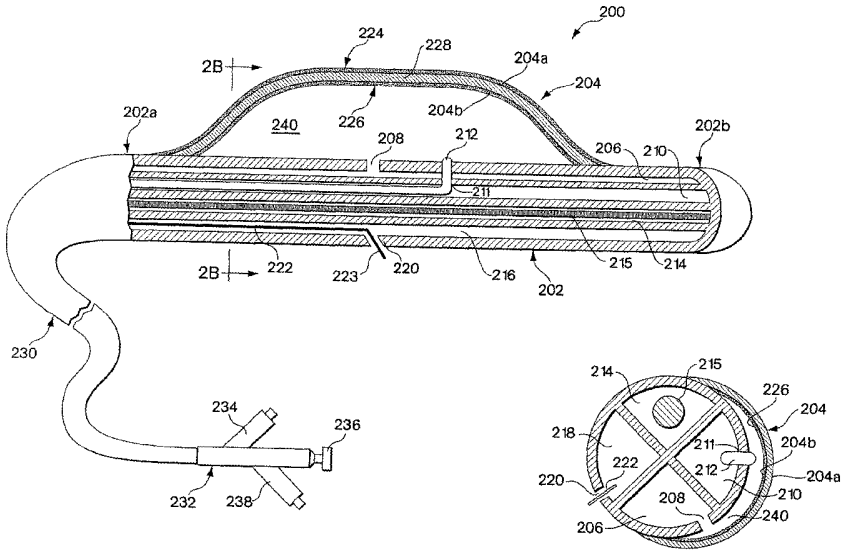
(54) Title: DILATION CATHETER ASSEMBLY AND RELATED METHODS



(57) Abstract: The invention, in one embodiment, is directed to a catheter assembly adapted to enable an operator to incise a human ureter from within, with reduced risk of damaging a crossing blood vessel. The dilation catheter includes an elongated body (202) and a dilatable bladder (204). The dilatable bladder (204) is adapted to dilate in a radially outward direction from the elongated body (202). A thermally responsive indicator incorporated with at least a portion of the dilation member exhibits a state change in response to a change in temperature. A temperature change indicates the existence of a nearby crossing vessel. In a surgical method, an operator repeatedly positions and inflates the dilatable bladder (204) in a human ureter proximal to a desired incision location to map the location of any crossing vessels. The operator then determines an inner wall incision location that avoids the detected crossing vessels.

WO 03/051449 A1

DILATION CATHETER ASSEMBLY AND RELATED METHODS

Field of the Invention

The invention relates generally to dilation catheters. More particularly, in one embodiment, the invention is directed to a dilation catheter assembly adapted for performing an endopylotomy.

Background of the Invention

An endopylotomy is performed to expand the size of a lumen of a patient's ureter to enable, for example, passage of stones and/or stone fragments through the lumen. Constriction of the ureter lumen may be caused at the uretero-pelvic junction (UPJ) from pressure created by crossing vessels, such as, the femoral artery and/or vein. Surgical intervention is often performed to relieve the ureteral pressure by cutting through the ureteral wall at a location opposite the crossing vessel(s) to relax the ureteral lumen. Once performed, a stent is placed within the lumen until ureteral healing occurs.

Figures 1A and 1B are conceptual background drawings showing a portion **100** of a human urinary tract being obstructed at the UPJ **102**. Referring to Figures 1A and 1B, in a human urinary tract **100**, the ureters **104** and **106** transport urine from the kidneys, one of which is shown at **108**, to the bladder **110**. The femoral artery **112** and femoral vein **114** cross the ureter **104** at the UPJ **102**.

As shown in Figure 1B, on occasion, the femoral artery **112** and/or the femoral vein **114** exert pressure on the ureter **104** and restrict urine flow through the ureter lumen **116**. Under normal circumstances, this may not cause discomfort. However, such obstruction may inhibit passage of a stone or stone fragment, such as the stone **118**, from the kidney **108** to the bladder **110**. As describe above, an endopylotomy can be performed to reduce the restriction in the

ureter lumen **116**. However, such a procedure is not without risk. For example, if a medical operator cuts the ureter lumen **116** on the inside wall portion **120** adjacent to the femoral artery **112** and vein **114**, the femoral artery **112** and/or vein **114** may be inadvertently ruptured. Such a condition may become life threatening.

Some conventional endopylotomy devices and methods attempt to avoid cutting into the femoral artery **112** and/or femoral vein **114** by employing fluoroscopy to identify the location **104** of the femoral artery **112** and vein **114** and cutting at a location **122** opposite to the location **104**. One disadvantage of this fluoroscopic approach is that it typically provides only two dimensional imaging. Another disadvantage is that appropriate fluoroscopy equipment is sometimes not readily available.

Summary of the Invention

Accordingly, an object of the invention is to provide an improved device and methodology for performing an endopylotomy with reduced risk of inadvertently cutting into the femoral artery **112** and/or femoral vein **114** of a patient.

The invention generally relates to dilation catheters. More particularly, in one embodiment, the invention is directed to a catheter assembly having an elongated body, a dilatable bladder and a thermally responsive indicator. The elongated body has first and second ends and an outer wall. The dilatable bladder is incorporated with the elongated body and adapted to dilate in a radially outward direction from the elongated body. The thermally responsive indicator is incorporated with at least a portion of the dilatable bladder and adapted to exhibit a state in response to detecting a change in temperature.

According to a further embodiment, the elongated body defines a first internal lumen extending from the first end to the second end of the elongated body, and the dilatable bladder is adapted to inflate in response to a positive fluid pressure in the first lumen. According to another feature, the dilatable bladder deflates in response to a negative fluid pressure in the first lumen.

In another embodiment, the dilatable bladder deflates in response to the positive fluid pressure being removed from the first lumen.

According to a further embodiment, the catheter assembly is adapted for insertion into a body of a mammal and the temperature change, and thus, the state change, is caused by a blood vessel being located proximally to the thermally responsive indicator. According to a further embodiment, the catheter assembly is adapted for insertion into a human ureter and the temperature change ,and thus, the state change, is caused by the thermally responsive indicator being located in close proximity to a blood vessel crossing the ureter at the utero-pelvic junction.

According to another embodiment, the catheter assembly is adapted to be deployed from a working lumen of an endoscope or like device. A fiber optic camera deployed in another lumen of the endoscope may be employed to observe any state changes.

In one embodiment, the dilatable bladder is substantially non-compliant. However, in other embodiments, the dilatable bladder is substantially compliant. In one embodiment, the dilatable bladder is formed separately from and then integrated with the elongated body. However, in other embodiments, a catheter body is treated to form a dilatable portion thereon. By way of example, in one embodiment, a portion of the elongated body is irradiated according to known methods to form the dilatable bladder.

According to one embodiment, the dilatable bladder radially circumscribes a longitudinal section of the elongated body. According to one feature of this embodiment, the dilatable bladder inflates radially outward from and circumscribes the longitudinal section of the elongated body in response to a positive fluid pressure from an inflation/deflation lumen in the elongated body. In an alternative embodiment, the dilatable bladder is disposed only around a portion of the section of the elongated body and thus, inflates radially outward from only the portion of the elongated body section.

In another alternative embodiment, the dilatable bladder includes at least two dilation chambers, which are independently dilatable via separate lumens in the elongated body. In one such embodiment, one chamber incorporates the thermally responsive detector and is employed to locate, for example, a crossing blood vessel. Whereas, the other chamber is used to deploy a surgical cutting wire located on its outer surface and adapted for incising a ureter.

According to one embodiment, the incorporated thermally responsive indicator is located on an outer surface of the dilatable bladder. In an alternative embodiment, the incorporated thermally responsive indicator is located on an inner surface of the dilatable bladder. In another alternative embodiment, the incorporated thermally responsive indicator includes a thermochromatic material and the thermochromatic material is dispersed in the material of the dilatable bladder. According to one embodiment, the thermochromatic material is incorporated over the entirety of the dilatable bladder. According to an alternative embodiment, the thermochromatic material is incorporated with only a portion of the dilatable bladder. In a further alternative embodiment, the thermochromatic material is incorporated at discrete locations of the dilatable bladder. As used with respect to the thermally responsive indicator "incorporated" includes, but is not limited to, coatings on an inner or outer surface or portion thereof of the dilatable bladder, dispersion within the material or a portion thereof of the dilatable bladder, and an independent material affixed over the dilatable bladder or a portion thereof.

In one preferred embodiment of the invention, the catheter assembly is adapted for insertion into a human ureter, and the thermally sensitive indicator changes state in response to the catheter assembly being positioned in the ureter at a location of a blood vessel crossing an external wall of the ureter. Such a crossing blood vessel sometimes occurs in at utero-pelvic junction. One use for detecting such a crossing vessel is to avoid damaging the crossing vessel during a ureteral surgical procedure, such as an endopylotomy.

According to one aspect of the invention, the catheter assembly includes a dedicated detector element adapted for detecting a thermally sensitive indicator state change and thus, the location of a crossing vessel. In one embodiment, the detector element is a fiber optic camera and the elongated body includes a detection lumen adapted for receiving the fiber optic camera to enable an operator to observe the state of the thermally sensitive indictor. In an embodiment wherein the thermally sensitive indicator is an thermochromatic material incorporated into a portion of the dilation element, using the fiber optic camera, an operator can observe a change in color of the portion of the dilation element in response to the dilation element encountering a crossing vessel.

In an alternative embodiment, the catheter assembly of the invention is deployed to a working channel of a conventional endoscope and rather than having a dedicated fiber optic camera, an operator views state changes through a non-dedicated fiber optic camera deployed through a viewing channel of the endoscope.

In a further embodiment, the catheter assembly of the invention includes a surgical cutting element. An operator uses the surgical cutting element to incise a portion of the ureter from within subsequent to establishing the position of any crossing blood vessel. In a typical endopylotomy procedure, the operator incises the ureter an inserts a stent to expand the inner diameter of the ureter to accommodate passage of, for example, kidney stones, or to relieve pressure caused, for example, by crossing blood vessels pushing against an outer wall of the ureter.

According to one feature, the surgical cutting element includes a wire located external to the elongated body and extends axially along the length of the dilation element. As the dilation element expands, the cutting wire extends radially outward to contact the inner wall of the ureter. When appropriately positioned, the operator can activate the cutting wire by, for example, passing a radio frequency current through the cutting wire. According to an alternative

embodiment, the cutting wire extends axially along the length of the elongated body on an opposite side of the elongated body from the dilation element. In this embodiment, when the catheter assembly is appropriately positioned, the operator can manually extend the cutting wire radially outward from the elongated body to contact the inner wall of the ureter prior to activating the cutting current.

In another alternative embodiment, the elongated body includes a cutting lumen that extends from the first end of the elongated body to the second end of the elongated body and includes a cutting aperture extending radially through an inner wall of the cutting lumen and the external wall of the elongated body. According to one feature, the cutting aperture is located on an opposite side of the elongated body from the dilation element. According to one methodology, the operator repeatedly positions and inflates the dilation element until observing a state change. Upon observing the state change, the operator extends the cutting element along the cutting lumen and though the cutting aperture to incise the ureter at a diametrically opposite location from the location of the detected state change and thus, detected crossing blood vessel. In this embodiment, any conventional cutting element can be employed, including for example, a cold knife, a radio frequency cutter, and a laser cutter.

In one embodiment, one end of the cutting wire is anchored inside of the cutting lumen at a location between the cutting aperture and the second end of the elongated body, and extends axially from that location, past the cutting aperture toward the first end of the elongated body. The first end of the elongated body is adapted to enable the operator to extend the cutting wire into the cutting lumen to cause a looped section of the cutting wire to radially protrude from the cutting aperture and contact the inner wall of the ureter.

In an alternative embodiment, the cutting wire is not anchored inside of the cutting lumen. Instead, the cutting wire is shaped such that when the end of the cutting wire encounters

the cutting aperture as the operator extends the cutting wire along the cutting lumen, the cutting wire tends to protrude axially from the cutting aperture to contact inner wall of the ureter.

According to a further embodiment of the invention, the operator flushes the dilatable bladder with a fluid of a particular temperature to initialize the state of the thermally responsive indicator. In one embodiment, the operator performs such flushing prior to inserting the catheter assembly. According to another embodiment, the operator performs such flushing subsequent to inserting the catheter assembly. In a further embodiment, the operator performs such flushing after each repositioning of the catheter assembly inside of the ureter.

The foregoing and other objects, aspects, features and advantages of the invention will become more apparent from the following description and from the claims.

Brief Description of the Drawings

The foregoing and other objects of the invention and the various features thereof may be more fully understood from the following illustrative description when read together with the accompanying drawings in which like reference designations generally refer to the same parts throughout the different views and in which the depicted components are not necessarily drawn to scale.

Figure 1A is a schematic view of a portion of a human urinary tract including the ureteral pelvic junction (UPJ);

Figure 1B is a cross-sectional view of the UPJ of Figure 1A taken along line 1B-1B;

Figure 2A is a longitudinal side view, partially in cross-section of dilatable catheter according to an illustrative embodiment of the invention;

Figure 2B is a radial, cross-sectional view of the dilatable catheter of Figure 2A taken along view 2B-2B;

Figure 3A is a longitudinal, cross-sectional view of a cutting element conduit of the dilatable catheter of Figure 2A containing a surgical cutting element in a retracted position according to an illustrative embodiment of the invention;

Figure 3B is a longitudinal, cross-sectional view of a cutting element conduit of the dilatable catheter of Figure 2A containing the surgical cutting element of Figure 3A in a deployed position according to an illustrative embodiment of the invention;

Figure 4A is a longitudinal, cross-sectional view of a cutting element conduit of the dilatable catheter of Figure 2A containing an alternative surgical cutting element in a retracted position according to an illustrative embodiment of the invention;

Figure 4B is a longitudinal, cross-sectional view of a cutting element conduit of the dilatable catheter of Figure 2A containing the surgical cutting element of Figure 4A in a deployed position according to an illustrative embodiment of the invention;

Figure 5 is a longitudinal cross-sectional view of a portion of the dilatable catheter of Figure 2A inserted into a patient's ureter according to an illustrative embodiment of the invention;

Figure 6 is a longitudinal cross-sectional view of a portion of a dilatable catheter according to an alternative illustrative embodiment of the invention and inserted into a patient's ureter by way of an endoscope or similar device;

Figure 7A is a longitudinal side view, partially in cross-section of dilatable catheter according to another alternative illustrative embodiment of the invention;

Figure 7B is a radial, cross-sectional view of the dilatable catheter of Figure 7A along view 7B-7B;

Figure 8 is a longitudinal, cross-sectional view of a portion of the dilatable catheter of Figure 7A inserted into a patient's ureter according to an illustrative embodiment of the invention; and

Figure 9 is a longitudinal, cross-sectional view of a portion of a dilatable catheter according to another alternative illustrative embodiment of the invention and inserted into a patient's ureter by way of an endoscope or similar device.

Illustrative Description

As described above in summary, the invention is generally related to dilation catheters. More particularly, in one in illustrative embodiment, the invention provides a dilation catheter assembly adapted for performing an endopylotomy procedure. As mentioned above, during an endopylotomy, a medical operator risks inadvertently damaging a femoral artery or vein that crosses a patient's ureter (collectively "crossing vessel"). According to the illustrative embodiment, the invention provides a mechanism for detecting the presence and location of such crossing vessels. Once located, the medical operator can choose an incision location that does not risk damage to the crossing vessel. As skilled artisans will appreciate, although the subject matter of the invention is discussed below with relation to the illustrative example of an endopylotomy and detecting a crossing vessel, the device and methods of the invention may be used to detect any feature that creates a thermal gradient between the feature and an internal temperature of an anatomical lumen.

Figure 2A depicts a side view, partially in cross-section of a dilation catheter assembly **200** according to an illustrative embodiment of the invention. Figure 2B shows a radial cross-sectional view of the catheter assembly **200** taken along view **2B-2B**. Referring to Figures 1A-2B, the dilation catheter assembly **200** is adapted for insertion into a body conduit, such as a human ureter. More particularly, the illustrative catheter assembly **200** is adapted for performing a surgical procedure from within a body conduit, such an endopylotomy from within a human ureter **104**. As depicted, the catheter assembly **200** includes an elongated body **202** having first and second axially spaced ends **202a** and **202b**, respectively. The catheter assembly **200** also

includes an dilatable bladder **204**, an inflation/deflation conduit **206**, a dedicated viewing conduit **210**, a guide wire conduit **214** and a cutting element conduit **216**.

In the illustrative embodiment, the dilatable bladder **204** is substantially non-compliant. However, in alternative embodiments, a compliant dilatable bladder **204** may be employed. A feature of the illustrative non-compliant, dilatable bladder **204** is that while it expands and contracts in a radial direction, substantially no expansion and contraction occurs in an axially direction. As shown in Figure 2B, the illustrative dilatable bladder **216** extends around only a portion of the circumference of elongated body **202**. The dilatable bladder **204** may be formed by any conventional approach, and may be formed either as an integral portion of or subsequently attached to the elongated body **202**.

According to the illustrative embodiment, the dilatable bladder **204** incorporates a thermally responsive material, which changes states in response to being brought into proximity of the heat generated by the crossing vessels **112** and **114**. According to a further illustrative embodiment, the thermally responsive material is a coating **224** of a thermochromatic material on an external surface **204a** of the dilatable bladder **204**. In an alternative illustrative embodiment, the thermally responsive material is a coating **226** of a thermochromatic material on an internal surface **204b** of the dilatable bladder **204**. In another alternative embodiment, the thermally responsive material is a thermochromatic material **228**, incorporated into the material forming the dilatable bladder **204**. One advantage of placing the thermochromatic material on the inner surface **204b** is that it reduces any risk of the thermochromatic material leaching into a patients bloodstream. It should be noted that while Figure 2A depicts all three possibilities for incorporating a thermally responsive material with the dilatable bladder **204**, Figure 2B only depicts the thermally responsive material disposed as a coating **226** on the inner surface **204b** of the dilatable bladder **204**. Although the illustrative embodiments of Figures 2A and 2B (and Figures 7A and 7B below) depict the thermally responsive material being disposed uniformly

either on the outer surface **204a**, inner surface **204a** or throughout the material of the dilatable bladder **204**, this need not be the case. Alternatively, the thermally responsive material may be coated or dispersed at only discrete portion(s) of the dilatable bladder **204**.

As skilled artisans will appreciate, any conventional method for incorporating a thermochromatic material, such as a thermochromatic liquid crystalline polymer, onto the surfaces **204a** or **204b** or into the material forming the dilatable bladder **204** may be employed with the present invention. By way of example, variations of the approaches disclosed by U.S. Patent No. 5,806,528 (*Magliochetti*), which describes a method for extruding a thermochromatic liquid crystalline polymer into a polymeric tube; U.S. Patent No. Re 32,743 (*Meyers et al.*), which describes an elastic, flexible temperature responsive film for an inflatable temperature detector; U.S. Patent No. 4,087,575 (*Bichara*), which describes stretchable, elastomeric films made from liquid crystal preparations; and/or U.S. Patent No. 6,245,135 (*Jaeger et al.*), which describes a phase change ink, the disclosures of all of which are hereby incorporated by reference, may be employed to incorporate a thermally responsive material with the dilatable bladder **204**, without departing from the scope of the invention.

The illustrative dilation catheter assembly **200** also includes a flexible extension **230**. The flexible extension **230** terminates in an adapter **232**. The adapter **232** includes an inflation/deflation valve **234**, a cutting element connection/control interface **236** and a fiber optic viewing port **238**.

The inflation/deflation conduit **206** extends from the second end **202b** axially through the elongated section **202** and the flexible extension **230** and terminates at the inflation/deflation valve **234**. The inflation/deflation conduit **206** includes a through aperture **208**, adapted to provide fluid communication with the dilatable bladder **204**. As described in further detail below with respect to Figures 5 and 6, according to the illustrative embodiment, upon insertion into a patient's body, prior to inflation for crossing vessel detection, a medical operator flushes the

dilatable bladder **204** via the inflation/deflation valve **234** and the inflation/deflation conduit **206**, with a relatively cold fluid to initialize the state of the thermally responsive material incorporated with the dilatable bladder **204**.

The dedicated viewing conduit **210** extends axially from the second end **202b** of the elongated body **202** through the flexible extension **230** and terminates at the fiber optic viewing port **238**. The fiber optic viewing port **238** is adapted for connection to conventional viewing devices. As shown most clearly in Figure 2B, the dedicated viewing conduit **210** includes an aperture **211** adapted for passing a conventional fiber optic viewing element **212** into an inner chamber **240** created by the dilatable bladder **204**. Illustratively, the aperture **211** creates a fluid tight seal with the viewing element **212** so as not to effect inflation or deflation of the dilatable bladder **204**.

The guide wire conduit **214** extends axially from the first end **202a** of the elongated body **202** to the second end **202b** of the elongated body **202** and is adapted to accommodate a conventional guide wire **215**. The guide wire **215** is adapted for providing structural stiffness to the elongated body **202** during insertion into a patient. In alternative embodiments, the guide wire conduit may continue through the flexible extension **230** to a port on the adapter **232**. In such an embodiment, the medical operator may insert and remove the guide wire **215** through the adapter **232** for increased operational flexibility.

The cutting element conduit **216** extends axially from the second end **202b** of the elongated body **202** through the flexible extension **230** and terminates at the cutting element connection/control interface **236**. The cutting element conduit **216** includes a cutting aperture **220**, which varies in size depending on the type of cutting element being employed. As discussed in further detail below with respect to Figure 5, the cutting aperture **220** is located substantially diametrically opposed to the portion of the dilatable bladder **204** that incorporates the thermally responsive material. According to the illustrative embodiment, any conventional

surgical cutter adapted for operation though a catheter conduit may be employed, without departing from the scope of the invention. By way of example, without limitation, the illustrative embodiment may employ a cold knife, laser, or radio frequency cutting element. Figures 2A and 2B depict one embodiment of a radio frequency cutting element **222** formed from tungsten metal. In alternative embodiments, the radio frequency cutting element **222** may be formed from stainless steel.

The cutting element connection/control interface **236** is adapted to enable a medical operator to extend and retract the cutting end **223** of the cutting element **222**. In the case of a laser cutting element **222**, the interface **236** is further adapted to couple power to a laser cutting end 223. In the case of a radio frequency cutting element **222**, the interface **236** is adapted to couple a radio frequency current to the cutting end **223**.

Figures 3A depicts a longitudinal, cross-sectional view of a portion of a cutting element **302**, according to one illustrative embodiment of the invention, in a retracted position within the cutting element conduit **216**. Figure 3B depicts a cross-sectional view of the cutting element **302** of Figure 3A in a deployed position according to an illustrative embodiment of the invention. In the embodiments of Figures 3A and 3B, the cutting element **302** includes a bend or curve **304** at a cutting end **306**. As shown in Figure 3B, upon a medical operator extending the cutting element **302** through the cutting element conduit **216**, the bent or curved cutting end **306** engages with and extends through the cutting aperture **220**. Upon the medical operator retracting the cutting element **302**, the cutting end **306** retracts back through the cutting aperture **220** and into the cutting element conduit **216**. According to the illustrative embodiment, the cutting element **302** is either a radio frequency or cold knife surgical cutter.

Figure 4A is a longitudinal, cross-sectional view of a portion of a cutting element **402**, according to another illustrative embodiment of the invention, in a retracted position within the cutting element conduit **216**. In the embodiment of Figure 4A, a first end **404** anchors to an

inner conduit wall **406** by way of a mount **408**. As shown in Figure 4B, in response to a medical operator extending the cutting element **402**, a portion of the cutting element **402** bows out of the cutting aperture **220** to form a loop cutting portion **410**. As in the embodiment of Figure 4, the illustrative cutting element **402** is either a radio frequency or cold knife surgical cutter.

Figure 5 depicts a longitudinal cross-sectional view **500** of a portion of the elongated body **202** of the dilation catheter assembly **200** of Figure 2A inserted into a patient's ureter **104** according to an illustrative embodiment of the invention. As shown, in this illustrative example, the crossing vessels **112** and **114** are pressing on the ureter wall **104** causing flow to be impeded through the ureter lumen **116**. According to the illustrative embodiment, subsequent to positioning the dilation catheter assembly **200** within the ureter lumen **116**, the medical operator flushes the inner chamber **240** of the dilatable bladder **204**, via the inflation/deflation lumen **206**, with cooled saline solution to initialize the state of the thermochromatic coating **226** to an initial state (e.g., color). Next, the medical operator inflates the bladder **204**, via the inflation/deflation lumen **206**, to bring the outer wall **204a** of the bladder **204** into contact with the inner wall portion **120**. In response to heat generated from blood flow through the crossing vessels **112** and **114**, the thermochromatic coating **226** changes state (e.g., changes color). The medical operator observes any such state change, for example, by way of the fiber optic camera **212**, discussed above with respect to Figures 2A and 2B.

No state change or a reduced state change in the thermochromatic coating **226** indicates that the bladder **204** has been inflated in a portion of the ureter lumen **116** other than where the vessels **112** and **114** cross. Should that be the case, the medical examiner deflates the bladder **204**, repositions the catheter assembly **200**, re-inflates the bladder **204** and looks for the appropriate state change. Optionally, the medical examiner repeats the flushing of the inner chamber **240** with cooled saline solution or the like to reinitialize the state of the thermochromatic coating **226**.

As mentioned above with respect to Figure 2A, the cutting aperture **220** is located substantially diametrically opposite to the portion of the balloon that incorporates the thermochromatic coating **226**. Thus, according to the illustrative embodiment, once the medial operator observes a state change indicating that the dilation catheter assembly **200** is positioned with the thermochromatic coating **226** proximate to the crossing vessels **112** and **114**, it is safe to begin incising the inner wall portion **122** of the ureter **104**, via the cutting aperture **220**, without risking damage to the crossing vessels **112** and **114**. As described above, the medical operator incises the wall portion **122** using any appropriate cutting device. In the illustrative embodiment of Figure 5, the catheter assembly **200** employs a surgical cutting device **402** of the type described with respect to Figure 4B. As skilled artisans will appreciate, subsequent to incising the wall portion **122** to widen the ureter lumen **116**, a stent may be inserted until healing has occurred.

Figure 6 depicts a longitudinal cross-sectional view **600** of a portion of an elongated body **202'** of an alternative embodiment of the dilation catheter assembly **200** of Figure 2A. In the illustrative embodiment of Figure 6, the dilation catheter assembly **200'** is deployed in a patient's ureter **104** through a working channel **606** of any conventional endoscope or like device **602**. In Figure 6, depicted elements having substantially equivalent counterparts in Figure 2A are indicated by the use of primed reference designations. One difference between the dilation catheter assemblies **200** and **200'** is that the dilation catheter assembly **200'** does not need a dedicated optical conduit, such as the conduit **206**. Instead, the inflatable/deflatable bladder **204'** is formed to be translucent enough for a medical operator to view any state changes of the thermochromatic coating **226'** by way of a conventional fiber optic camera **603** deployed through the lumen **604** of the endoscope **602**. Alternatively, as described above with respect to Figure 2A, the thermochromatic coating **226'** may located on the external surface **204a'** of the bladder **204'**, thus removing any need for the bladder **204'** to be translucent. As in the

embodiment of Figure 5, upon locating the crossing vessels **112** and **114**, the illustrative cutting element **402'** enables the medical operator to safely incise the wall portion **122**.

Figure 7A is a side view, partially in cross-section of an alternative embodiment **700** of the dilation catheter assembly **200** of Figure 2. Figure 7B is a radial, cross-sectional view of the dilation catheter assembly **700** along the view 7B-7B. Referring to Figures 1A, 1B, 7A and 7B, the dilation catheter assembly **700** is also adapted for performing a surgical procedure from within a body conduit, such an endopylotomy from within a human ureter **104**. As depicted, the catheter assembly **700** includes an elongated body **202** having first and second axially spaced ends **702a** and **702b**, respectively. The catheter assembly **700** also includes an dilatable bladder **704**, an inflation/deflation conduit **706**, a dedicated viewing conduit **710**, a guide wire conduit **714** and a cutting element conduit **716**.

In the illustrative embodiment, the dilatable bladder **704** is substantially non-compliant. However, in alternative embodiments, a compliant dilatable bladder **704** may be employed. A feature of the illustrative non-compliant, dilatable bladder **704** is that while it expands and contracts in a radial direction, substantially no expansion and contraction occurs in an axially direction. As shown in Figure 7B, unlike the catheter assembly **200** of Figures 2A and 2B, the dilatable bladder **704** extends around the entire circumference of at least a portion of the elongated body **702**. The dilatable bladder **704** may be formed by any conventional approach, and may be formed either as an integral portion of or subsequently integrated with the elongated body **702**.

As in the case of the dilatable bladder **204**, the dilatable bladder **704** incorporates a thermally responsive material, which changes states in response to being brought into proximity of the heat generated by the crossing vessels **112** and **114**. The illustrative thermally responsive material is depicted as a thermochromatic coating **726** on an internal surface **704b** of the dilatable bladder **704**. However, as described above with respect to Figures 2A and 2B, in

alternative illustrative embodiments, the thermally responsive material may be, for example, coated onto discrete locations of the inner surface 704b, discrete locations of or the entire external surface **704a** or may be incorporated into the material forming the dilatable bladder **704**, uniformly or at discrete locations.

The illustrative dilation catheter assembly **700** also includes a flexible extension **730**. The flexible extension **730** terminates in an adapter **732**. The adapter **732** includes an inflation/deflation valve **734**, a cutting element connection/control interface **736** and a fiber optic viewing port **738**.

The inflation/deflation conduit **706** extends from the second end **702b** axially through the elongated section **702** and the flexible extension **730** and terminates at the inflation/deflation valve **734**. The inflation/deflation conduit **706** includes a through aperture **708**, adapted to provide fluid communication with the dilatable bladder **704**. As described in further detail below with respect to Figures 10 and 11, according to the illustrative embodiment, upon insertion into a patient's body, prior to inflation for crossing vessel detection, a medical operator flushes the dilatable bladder **704** via the inflation/deflation valve **734** and the inflation/deflation conduit **706**, with a relatively cold fluid to initialize the state of the thermally responsive material incorporated with the dilatable bladder **704**.

The dedicated viewing conduit **710** extends axially from the second end **702b** of the elongated body **702** through the flexible extension **730** and terminates at the fiber optic viewing port **738**. The fiber optic viewing port **738** is adapted for connection to conventional viewing devices. As shown in Figures 7A and 7B, the dedicated viewing conduit **710** includes an aperture **711** adapted for passing a conventional fiber optic viewing element **712** into an inner chamber **740** created by the dilatable bladder **704**. Illustratively, the aperture **711** creates a fluid tight seal with the viewing element **712** so as not to effect inflation or deflation of the dilatable bladder **704**.

The guide wire conduit **714** extends axially from the first end **702a** of the elongated body **702** to the second end **702b** of the elongated body **702** and is adapted to accommodate a conventional guide wire **715**. The guide wire **715** is adapted for providing structural stiffness to the elongated body **702** during insertion into a patient. In alternative embodiments, the guide wire conduit **714** may continue through the flexible extension **730** to a port on the adapter **732**. In such an embodiment, the medical operator may insert and remove the guide wire **715** through the adapter **732** for selectively providing increased operational stiffness to the catheter assembly **700**.

The cutting element conduit **716** extends axially from the second end **702b** of the elongated body **702** through the flexible extension **730** and terminates at the cutting element connection/control interface **736**. The cutting element conduit **716** includes cutting apertures **720** and **721**, which vary in size depending on the type of cutting element being employed. The cutting element **742** extends through the cutting element conduit **716** from the second end **702b** of the elongated body **702**, out of the cutting aperture **721**, along an external surface portion **704c** of the dilatable bladder **704**, back into the cutting element conduit **716** by way of the cutting aperture **720**, and through the flexible extension **730** to the cutting element connection/control interface **736**. According to the illustrative embodiment of Figures 7A and 7B, any conventional surgical cutter adapted for operation though a catheter conduit may be employed, without departing from the scope of the invention.

As shown in Figure 7A, and as discussed in further detail below with respect to Figures 8 and 9, to reduce the risk of damaging the crossing vessels **112** and **114**, the external surface portion **704c** along which the cutting element **716** extends is substantially diametrically opposed from the inner and outer surface portions **704a** and **704b** where the thermally responsive material is disposed. However, according to alternative embodiments, the thermally responsive material

may be throughout the dilatable bladder **704**, with the location of the state change being detected by a fiber optic camera such as the camera **712**, discussed if further detail below.

According to one feature, the dilatable bladder **704** is inflated enough to bring the thermochromatic coating **726** into sufficient proximity with the inside wall portion **120** to cause a state change in response to detecting the femoral artery **112** or vein **114**, but not close enough to cause the cutting element **742** to incise adjacent tissue. Subsequent to locating the femoral artery **112** and vein **114** through one or more of inflation/deflation cycles described above with respect to Figure 2A, the medical operator can then inflate the dilatable bladder **704** sufficiently to enable the cutting element **742** to incise the inner wall portion **122**.

According to another feature, the cutting element connection/control interface **736** is adapted to enable the cutting element **742** to extend automatically in response to the dilatable bladder **704** expanding. According to a further feature, the connection/control interface **736** is adapted to enable a medical operator to retract the cutting element **742** as the dilatable bladder **704** contracts. According to an additional feature, the interface **736** is adapted to enable the medical operator to extend the cutting element **742** as the dilatable bladder **704** expands and/or to extend the cutting element **742** an additional amount after the dilatable bladder **704** is fully expanded. In the case of a powered cutting element **742**, the connection/control interface **736** is adapted to couple such power to the cutting element **742**.

Figure 8 depicts a longitudinal cross-sectional view **800** of a portion of the elongated body **702** of the dilation catheter assembly **700** of Figure 7A inserted into a patient's ureter **104** according to an illustrative embodiment of the invention. As in the case Figure 5, the crossing vessels **112** and **114** are pressing on the ureter wall **104** causing flow to be impeded through the ureter lumen **116**. According to the illustrative embodiment, subsequent to positioning the dilation catheter assembly **700** within the ureter lumen **116**, the medical operator flushes the inner chamber **740** of the dilatable bladder **704**, via the inflation/deflation lumen **706**, with

cooled saline solution to initialize the state of the thermochromatic coating **726** to an initial state (e.g., color). Next, the medical operator inflates the bladder **704**, via the inflation/deflation lumen **706**, to bring the outer wall **704a** of the bladder **704** into proximity with the inner wall portion **120**, but not close enough to cause the cutting element **742** to incise adjacent tissue. In response to heat generated from blood flow through the crossing vessels **112** and **114**, the thermochromatic coating **726** changes state (e.g., changes color). The medical operator observes any such state change, for example, by way of the fiber optic camera **712,** discussed above with respect to Figures 7A and 7B.

No state change or a reduced state change in the thermochromatic coating **726** indicates that the bladder **704** has been inflated in a portion of the ureter lumen **116** other than where the crossing vessels **112** and **114** contact the ureter **104**. Should that be the case, the medical examiner deflates the bladder **704**, repositions the catheter assembly **700**, re-inflates the bladder **704** and looks for the appropriate state change. Optionally, the medical examiner repeats the flushing of the inner chamber **740** with cooled saline solution or the like to reinitialize the state of the thermochromatic coating **726**.

As mentioned above with respect to Figure 7A, the cutting element **742** is located substantially diametrically opposite to the portion of the balloon that the camera **712** is viewing for a state change. Thus, according to the illustrative embodiment, once the medial operator observes the state change, indicating that the dilation catheter assembly **700** is positioned with the thermochromatic coating **726** proximate to the crossing vessels **112** and **114**, it is safe to begin incising the inner wall portion **122** of the ureter **104**, via the cutting element **742**, without risking damage to the crossing vessels **112** and **114**. As described above with respect to Figure 7A, the medical operator incises the wall portion **122** by extending the cutter element **742** either by further inflation of the bladder **704** or by way of the cutting element connection/control interface **736**.

Figure 9 depicts a longitudinal cross-sectional view **900** of a portion of an elongated body **702'** of an alternative embodiment of the dilation catheter assembly **700** of Figure 7A. In the illustrative embodiment of Figure 9, the dilation catheter assembly **900'** is deployed in a patient's ureter **104** through a working channel **906** of any conventional endoscope or like device **602**. In Figure 9, depicted elements having substantially equivalent counterparts in Figure 7A are indicated by the use of primed reference designations. One difference between the dilation catheter assemblies **700** and **700'** is that the dilation catheter assembly **700'** does not need a dedicated optical conduit, such as the conduit **706**. Instead, the inflatable/deflatable bladder **704'** is formed to be translucent enough for a medical operator to view any state changes of the thermochromatic coating **726'** by way of a conventional fiber optic camera **903** deployed through the lumen **904** of the endoscope **902**. Alternatively, as described above with respect to Figure 7A, the thermochromatic coating **726'** may located on the external surface **704a'** of the bladder **704'**, thus removing any need for the bladder **704'** to be translucent. As in the embodiment of Figure 8, upon locating the crossing vessels **112** and **114**, the illustrative cutting element **742'** enables the medical operator to safely incise the wall portion **122**.

The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. Accordingly, the above described embodiments are to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims, rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are intended to be embraced therein.

What is claimed is:

Claims

1. A catheter assembly comprising,

an elongated body having first and second ends and an outer wall,

a dilatable bladder incorporated with said elongated body, and adapted to dilate in a radially outward direction from said elongated body, and

a thermally responsive indicator incorporated with at least a portion of said dilatable bladder and adapted to exhibit a state in response to detecting a change in temperature.

2. The catheter assembly of claim 1, wherein said elongated body defines a first internal lumen extending from said first end to said second end, said dilatable bladder is in fluid communication with said first lumen, and inflates in response to a positive fluid pressure in said first lumen.

3. The catheter of claim 1, wherein said catheter is adapted for insertion into a body of a mammal and said change in temperature is caused by a said thermally responsive material being located in proximity of a blood vessel.

4. The catheter of claim 1, wherein said catheter is adapted for insertion into a human body and said change in temperature is caused by a proximity of a portion of said dilatable bladder to a blood vessel crossing a ureter.

5. The catheter assembly of claim 1, wherein a portion of said elongated body is adapted to form said dilatable bladder.

6. The catheter assembly of claim 1, wherein said dilatable bladder has an inner surface and said thermally responsive indicator is disposed on at least a portion of said inner surface.

7. The catheter assembly of claim 1, wherein said dilatable bladder has an outer surface and said thermally responsive indicator is disposed on at least a portion of said outer surface.

8. The catheter assembly of claim 1, wherein said thermally responsive indicator includes a thermochromatic material.

9. The catheter assembly of claim 1, wherein said dilatable bladder is formed from a first material and said thermochromatic material is disposed within said first material.

10. The catheter assembly of claim 1 further comprising a detector element adapted for detecting said state of said thermally sensitive material.

11. The catheter assembly of claim 10 further comprising a detector lumen extending between said first and second ends of said elongated body, and being adapted for receiving said detector element.

12. The catheter assembly of claim 10, wherein said detector element is a fiber optic camera adapted to enable an operator to view said state of said thermally responsive material.

13. The catheter assembly of claim 1 further comprising, a surgical cutter adapted to enable an operator to cut mammal flesh at a location other than a location of temperature change detected by said thermally responsive indicator.

14. The catheter assembly of claim 1, wherein said dilatable bladder extends around only first portion of a periphery of said elongated body and said catheter assembly further comprises a surgical cutter adapted to enable an operator to incise mammal flesh contacting a second portion of the periphery of said elongated body, said first portion and said second portion being non-overlapping.

15. The catheter assembly of claim 1 further comprising,

a cutting lumen extending from said first end to said second end of said elongated body, wherein said outer wall includes a cutting aperture into said cutting lumen, and

a surgical cutting wire anchored in said cutting lumen at a location between said cutting aperture and said second end of said elongated body, and extending axially from said location past said cutting aperture toward said first end of said elongated body, wherein said cutting lumen at said first end of said elongated body is adapted to enable an operator to extend said

surgical cutting wire to cause a looped portion of said surgical cutting wire to protrude radially through said cutting aperture.

16. The catheter assembly of claim 1 further comprising,

a cutting lumen extending from said first end to said second end of said elongated body, wherein said outer wall includes a cutting aperture into said cutting lumen, and

a surgical cutting element adapted to extend axially from said first end through said cutting lumen toward said cutting aperture, wherein said cutting lumen at said first end of said elongated body is adapted to enable an operator to extend and retract said surgical cutting element radially through said cutting aperture.

17. The catheter assembly of claim 1 further comprising, a surgical cutting wire extending external to said elongated body from a first location proximal to said first end of said elongated body to a second location proximal to said second end of said elongated body, said surgical cutting wire disposed in a fixed relationship to said second location and in a moveable relationship with said first location, said first location being adapted to enable an operator to extend and retract said surgical cutting element to adjust an amount of radial protrusion of said cutting element from said elongated body.

18. The catheter assembly of claim 1, wherein said dilatable bladder has an outer surface and said catheter assembly further comprises, a surgical cutting wire extending adjacent to said outer surface of said dilatable bladder from a first location proximal to said first end of said elongated body to a second location proximal to said second end of said elongated body, said surgical cutting wire disposed in a fixed relationship to said second location and in a moveable relationship to said first location.

19. The catheter assembly of claim 18, wherein said surgical cutting wire is adapted to extend in response to inflation of said dilatable bladder and retract in response to deflation of said dilatable bladder.

20. The catheter assembly of claim 1, where in said thermally responsive indicator is adapted to exhibit said state by changing color.

21. A method of detecting a location of a blood vessel comprising,

inserting a dilatable bladder into a body of a mammal, at least a portion of said dilatable bladder incorporating a thermally responsive indicator, said thermally responsive indicator being adapted to exhibit a state change in response to detecting a change in temperature, and

observing any said state change to detect said location of said blood vessel.

22. The method of claim 21 further comprising flushing said dilatable bladder with a fluid of a particular temperature to initialize said state of said thermally responsive indicator.

23. The method of claim 22 further comprising performing said flushing step subsequent to said inserting step.

24. The method of claim 21 further comprising inflating said dilatable bladder subsequent to said inserting step.

25. The method of claim 24 further comprising, in response to observing no said change of state,

deflating said dilatable bladder,

adjusting a position of said dilatable bladder inside of said mammal body,

re-inflating said dilatable bladder, and

observing any said change of state to detect said location of said blood vessel.

26. The method of claim 21, wherein said thermally responsive indicator is a thermochromatic material.

27. The method of claim 26, wherein said dilatable bladder has an outer surface and said thermochromatic material is incorporated into said outer surface.

28. The method of claim 26, wherein said dilatable bladder has an inner surface and said thermochromatic material is incorporated into said inner surface.

29. The method of claim 26, wherein said dilatable bladder is formed from a first material and said thermochromatic material is disposed within said first material.

30. A surgical method comprising,

providing a dilatable bladder having a thermally responsive indicator incorporated therewith, said thermally responsive indicator being adapted to exhibit a state in response to detecting a change in temperature,

inserting said dilatable bladder into a body of a mammal,

identifying a location of a blood vessel based at least in part on observing said state,

determining an incision location based at least in part on said identified location of said blood vessel.

31. The surgical method of claim 30 further comprising flushing said dilatable bladder with a fluid of a particular temperature to initialize said state of said thermally responsive indicator.

32. The surgical method of claim 31 further comprising performing said flushing step subsequent to said inserting step.

33. The surgical method of claim 30 further comprising inflating said dilatable bladder subsequent to said inserting step.

34. The surgical method of claim 33 further comprising, in response to observing no said change of state,

deflating said dilatable bladder,

adjusting a position of said dilatable bladder inside of said mammal body,

re-inflating said dilatable bladder, and

observing any said change of state to detect said location of said blood vessel.

35. The surgical method of claim 30, wherein said thermally responsive indicator is a thermochromatic material.

36. The surgical method of claim 35, wherein said dilatable bladder has an outer surface and said thermochromatic material is incorporated into said outer surface.

37. The surgical method of claim 35, wherein said dilatable bladder has an inner surface and said thermochromatic material is incorporated into said inner surface.

38. The surgical method of claim 35, wherein said dilatable bladder is formed from a first material and said thermochromatic material is incorporated into said first material.

39. The surgical method of claim 30, wherein said mammal is a human and said change in temperature is caused by a proximity of said thermally responsive indicator to a blood vessel crossing a ureter.

40. The surgical method of claim 30 further comprising inserting said dilatable bladder into a lumen inside of a said mammal body by way of an endoscopic device.

41. The surgical method of claim 30, wherein said dilatable bladder is substantially compliant.

42. The surgical method of claim 30, wherein said dilatable bladder is incorporated with an elongated body having a first internal lumen, and said method further comprises inflating said dilatable bladder by providing a positive fluid pressure in said first internal lumen.

43. The surgical method of claim 30 further comprising providing a detector element adapted for observing said state of said thermally sensitive material.

44. The surgical method of claim 43, wherein said dilatable bladder is incorporated with an elongated body having an internal lumen extending between said first and second ends of said elongated body, and said surgical method further comprises inserting said detector element through said internal lumen to perform said observing.

45. The surgical method of claim 44, wherein said detector element is a fiber optic camera adapted to enable an operator to perform said observing said state of said thermally responsive material.

46. The surgical method of claim 30 wherein said determining step comprises determining said incision location to be a location other than said location of said blood vessel.

47. The surgical method of claim 30, wherein said dilatable bladder is incorporated with an elongated body, and wherein said dilatable bladder extends around only a first portion of a periphery of said elongated body and said method further comprises radially extending a surgical cutter, adapted to incise mammal flesh, from second portion of said periphery of said elongated body, said first portion and said second portion being non-overlapping.

48. The surgical method of claim 30, wherein said dilatable bladder has an outer surface and is incorporated with an elongated body having first and second ends, and a surgical cutting wire extends adjacent to said outer surface of said dilatable bladder from a first location proximal to said first end of said elongated body to a second location proximal to said second end of said elongated body, said surgical cutting wire is disposed in a fixed relationship to said second location and in a moveable relationship to said first location, and said method further comprises, inflating said dilatable bladder to radially extend said surgical cutting wire from said elongated body.

49. A surgical method comprising,

positioning a dilatable bladder incorporating a thermochromatic material into a human ureter,

inflating said dilatable bladder to bring said thermochromatic material in proximity with a first location on an inner wall of said human ureter,

observing any change in state of said thermochromatic material,

in response to observing said change in state of said thermochromatic material,

incising said inner wall of said ureter at a second location different from said first location.

50. The surgical method of claim 49 further comprising, in response to observing no said change in state of said thermochromatic material,

deflating said dilatable bladder,

repositioning said dilatable bladder,

re-inflating said dilatable bladder to bring said thermochromatic material in proximity with another different from said first location on said inner wall of said human ureter,

further observing any change in state of said thermochromatic material,

in response to observing said change in state of said thermochromatic material,

incising said inner wall of said ureter at a location different from said other location.

51. The surgical method of claim 50 further comprising, repeating the steps of deflating, repositioning, re-inflating and further observing until a change in said state of said thermochromatic material is observed.

52. The surgical method of claim 49 further comprising, flushing said dilatable bladder with a fluid of a particular temperature to initialize said state of said thermochromatic material.

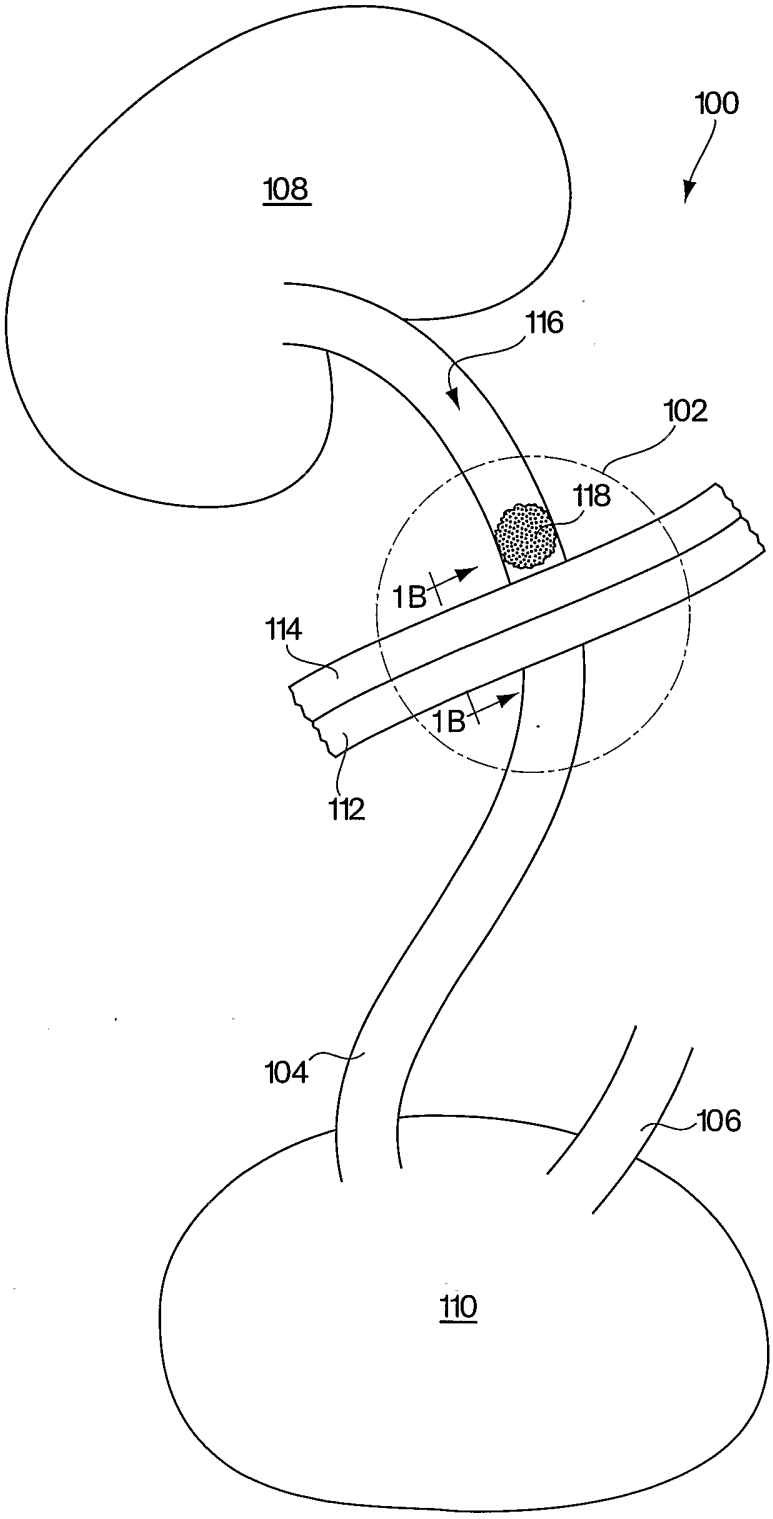

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Fig. 1A

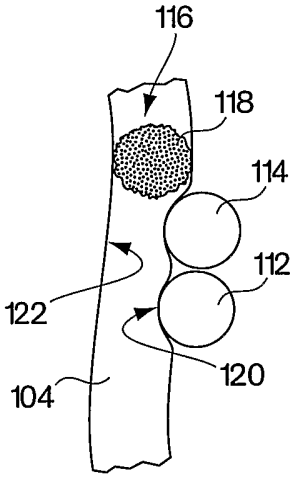
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Fig. 1B

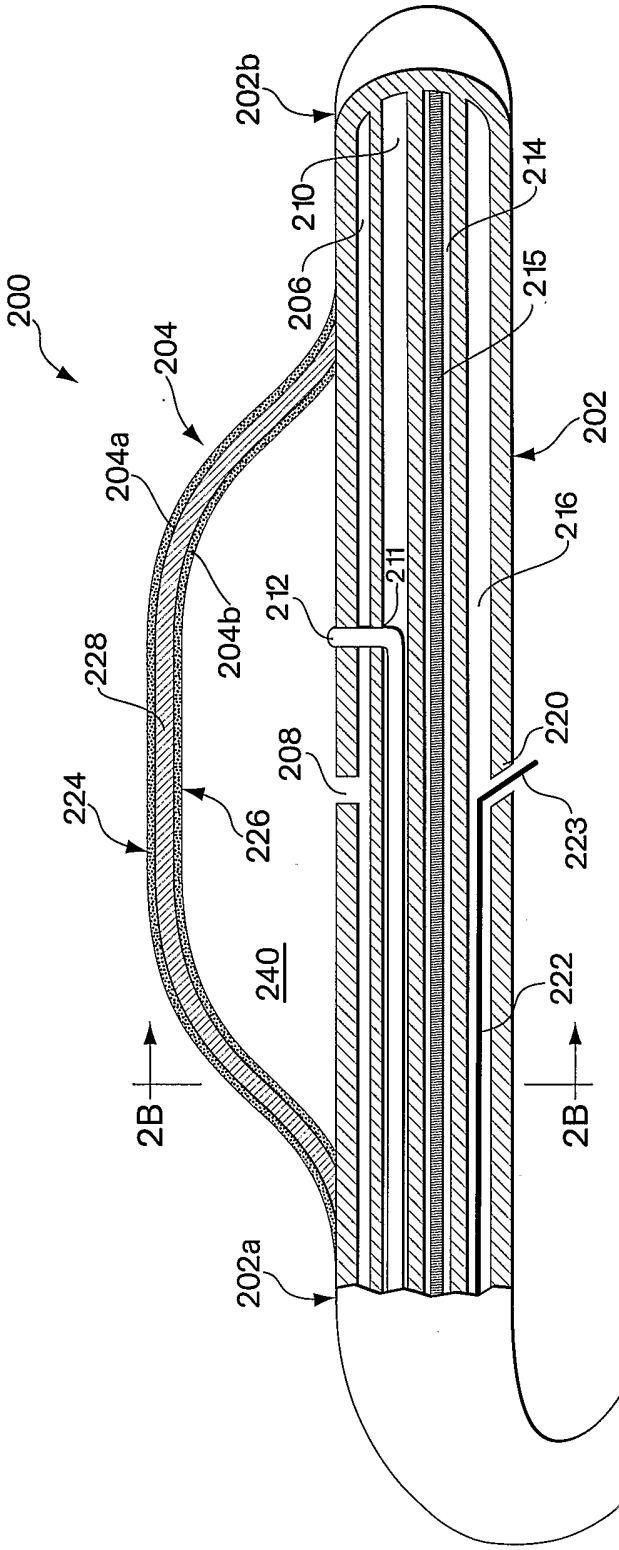
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Fig. 2A

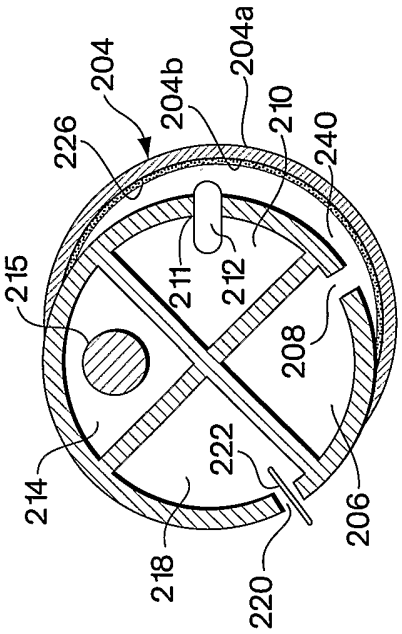
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Fig. 2B

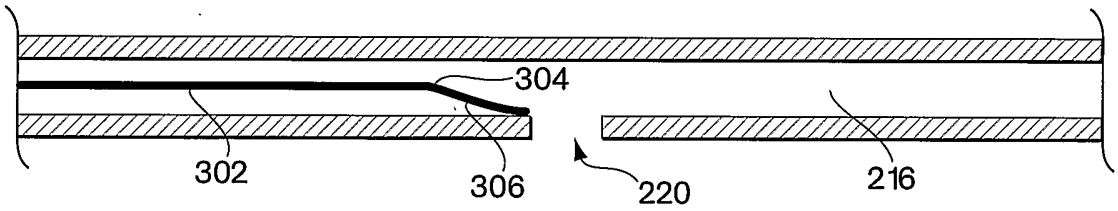

Fig. 3A

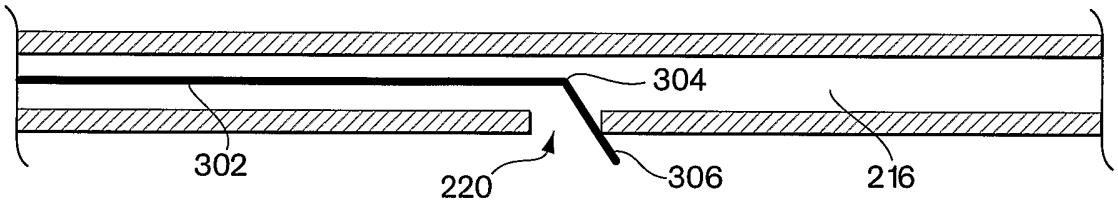

Fig. 3B

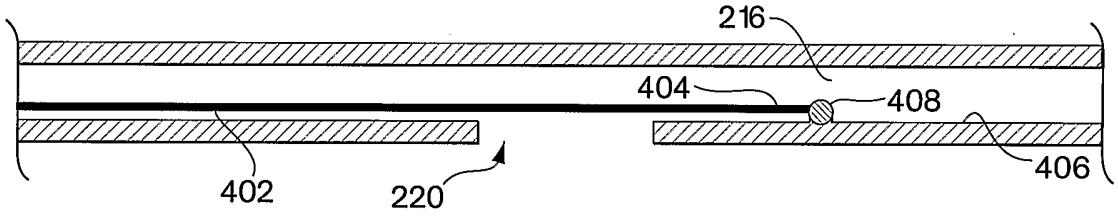

Fig. 4A

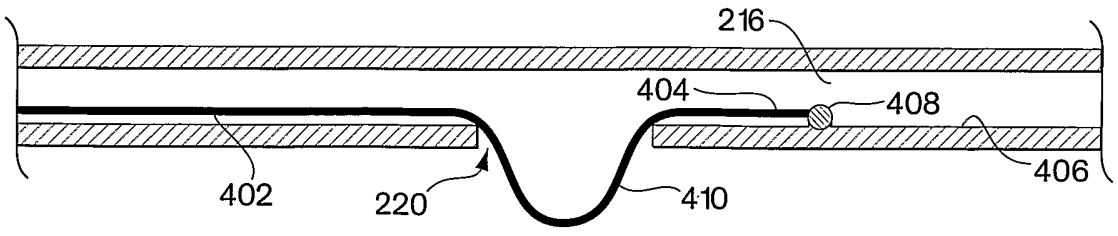

Fig. 4B

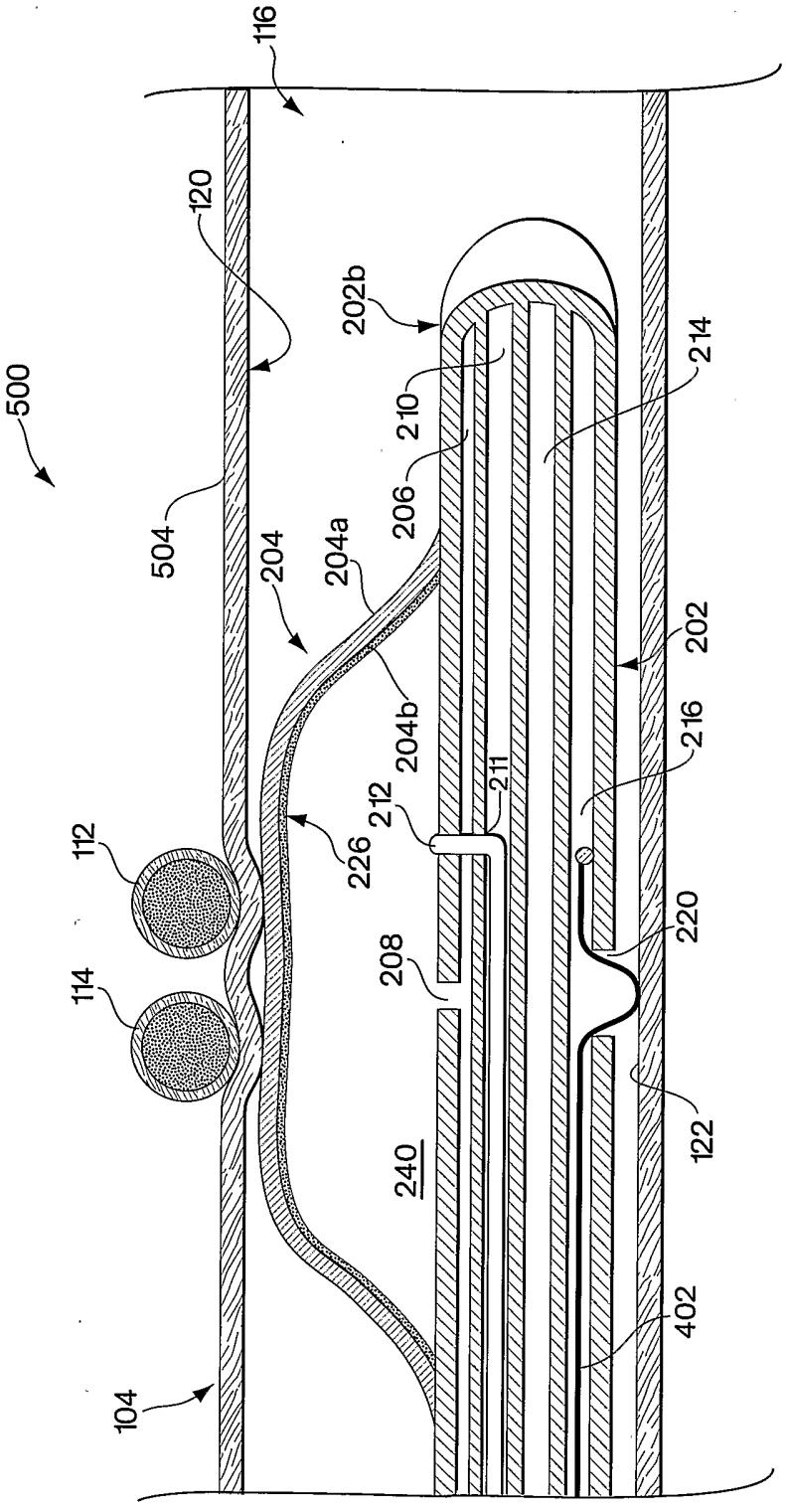
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Fig. 5

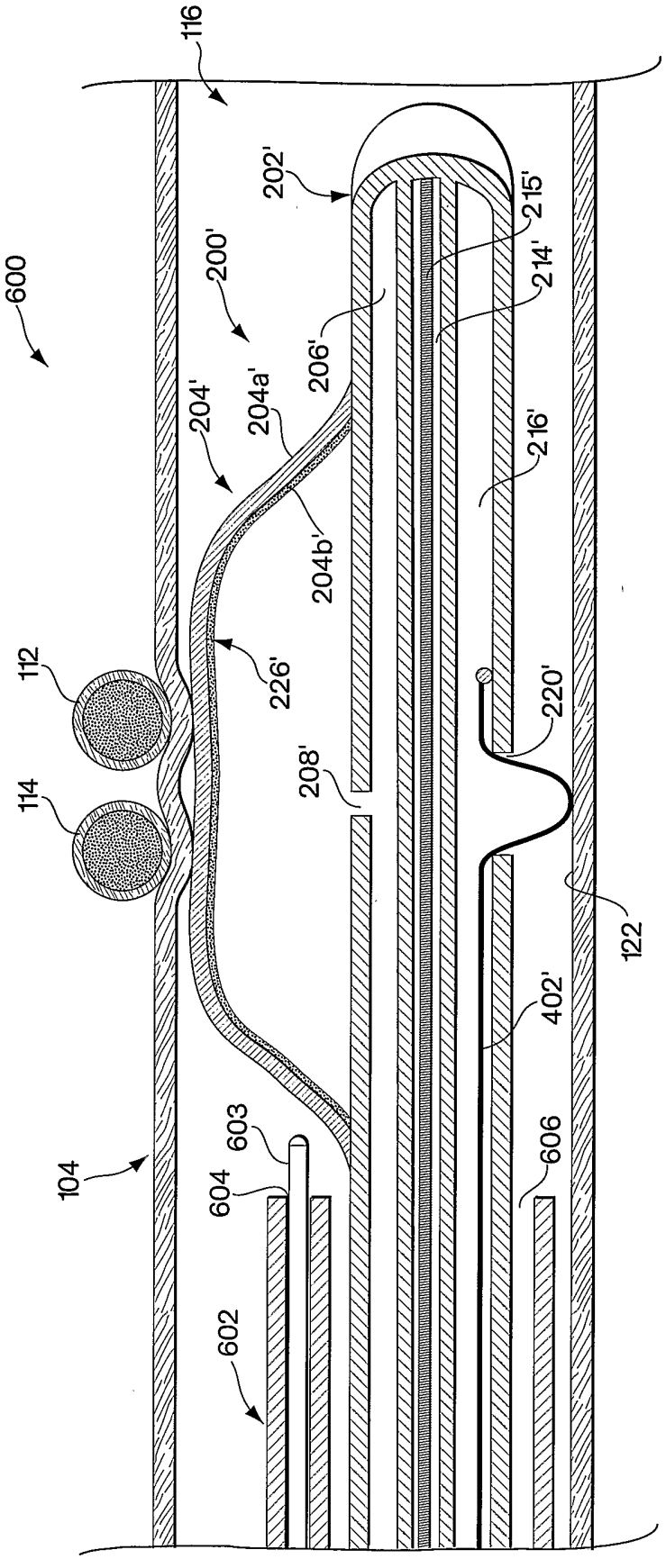
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Fig. 6

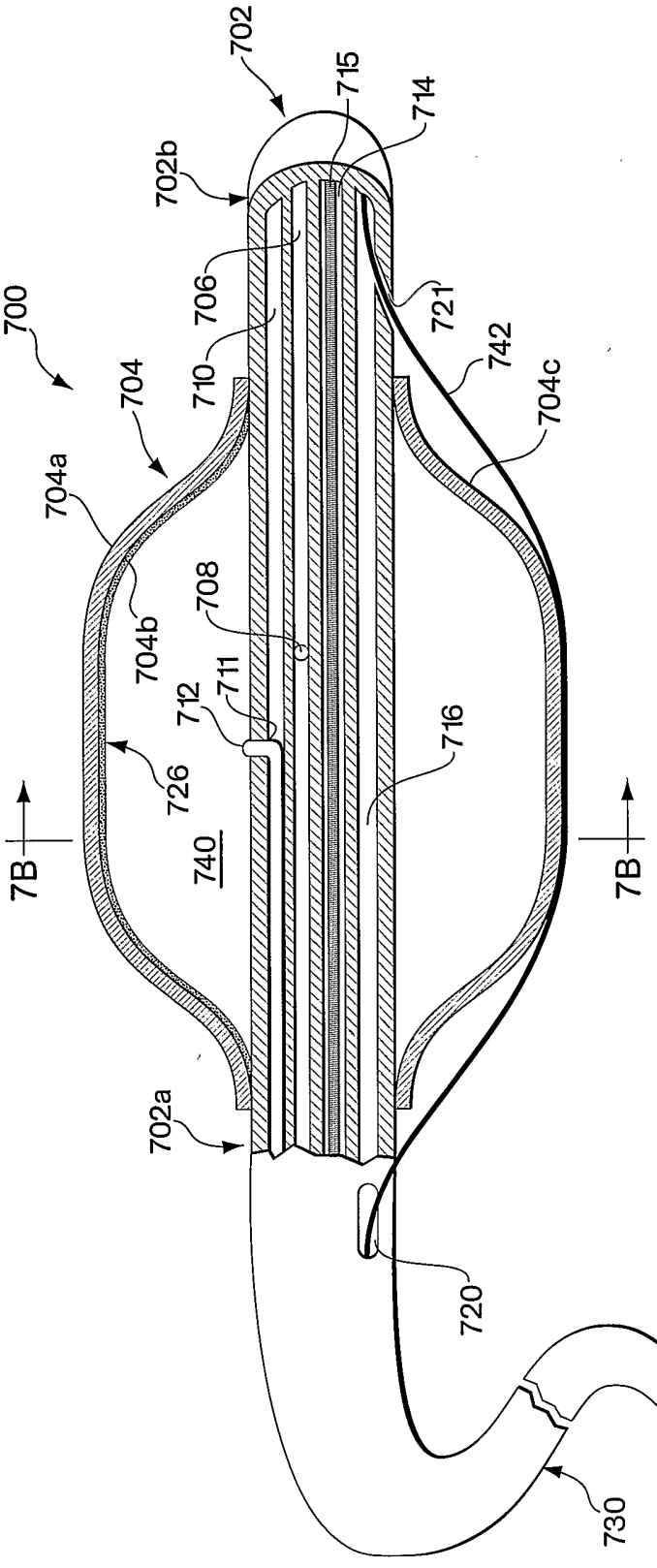
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Fig. 7A

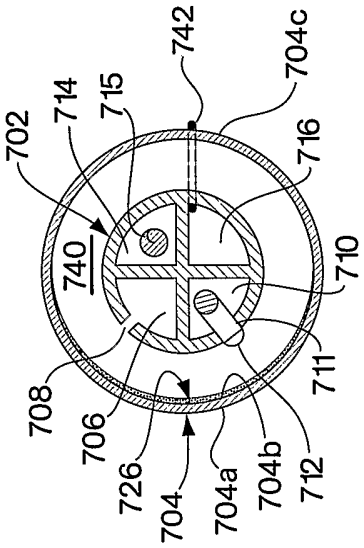
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Fig. 7B

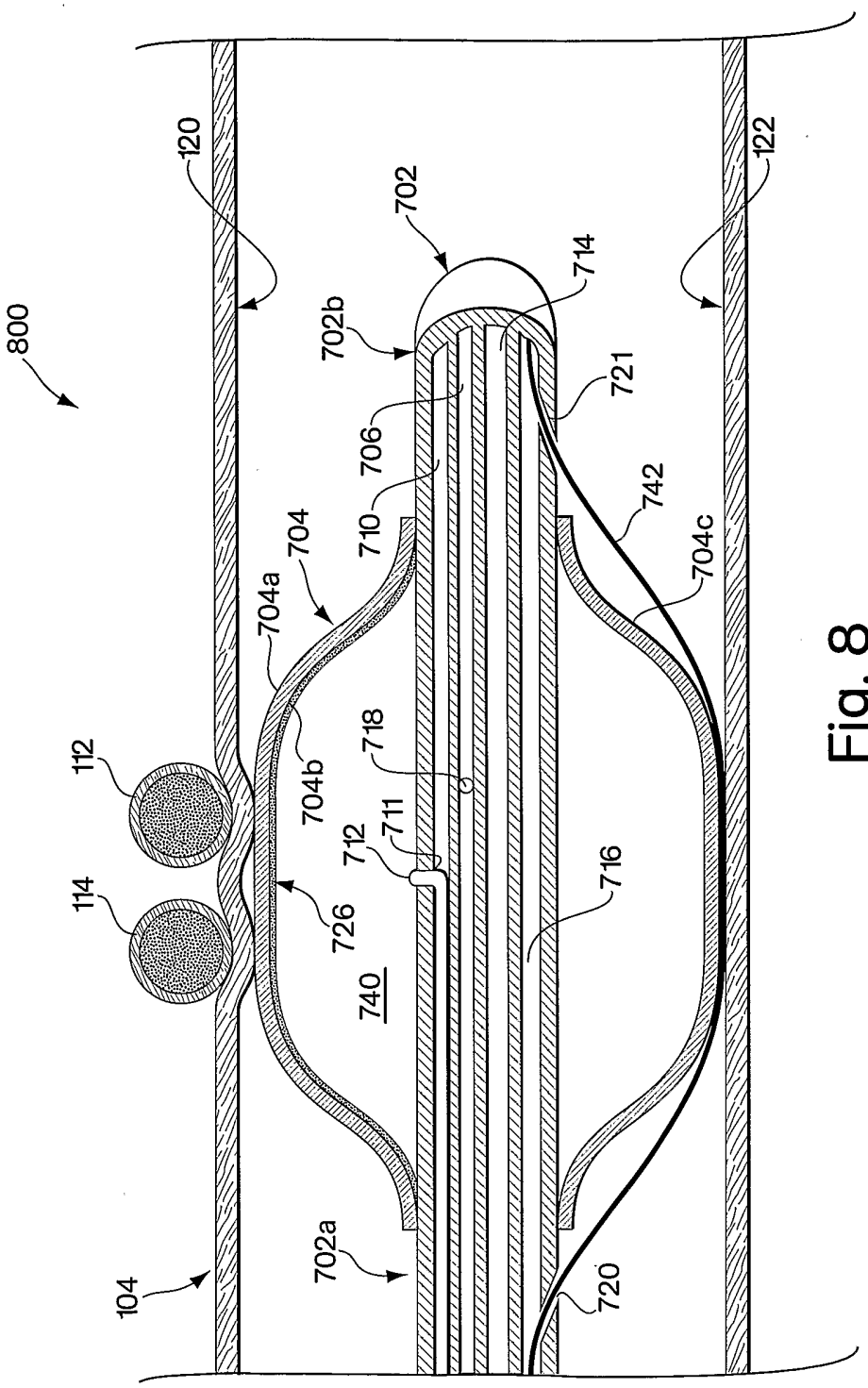
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Fig. 8

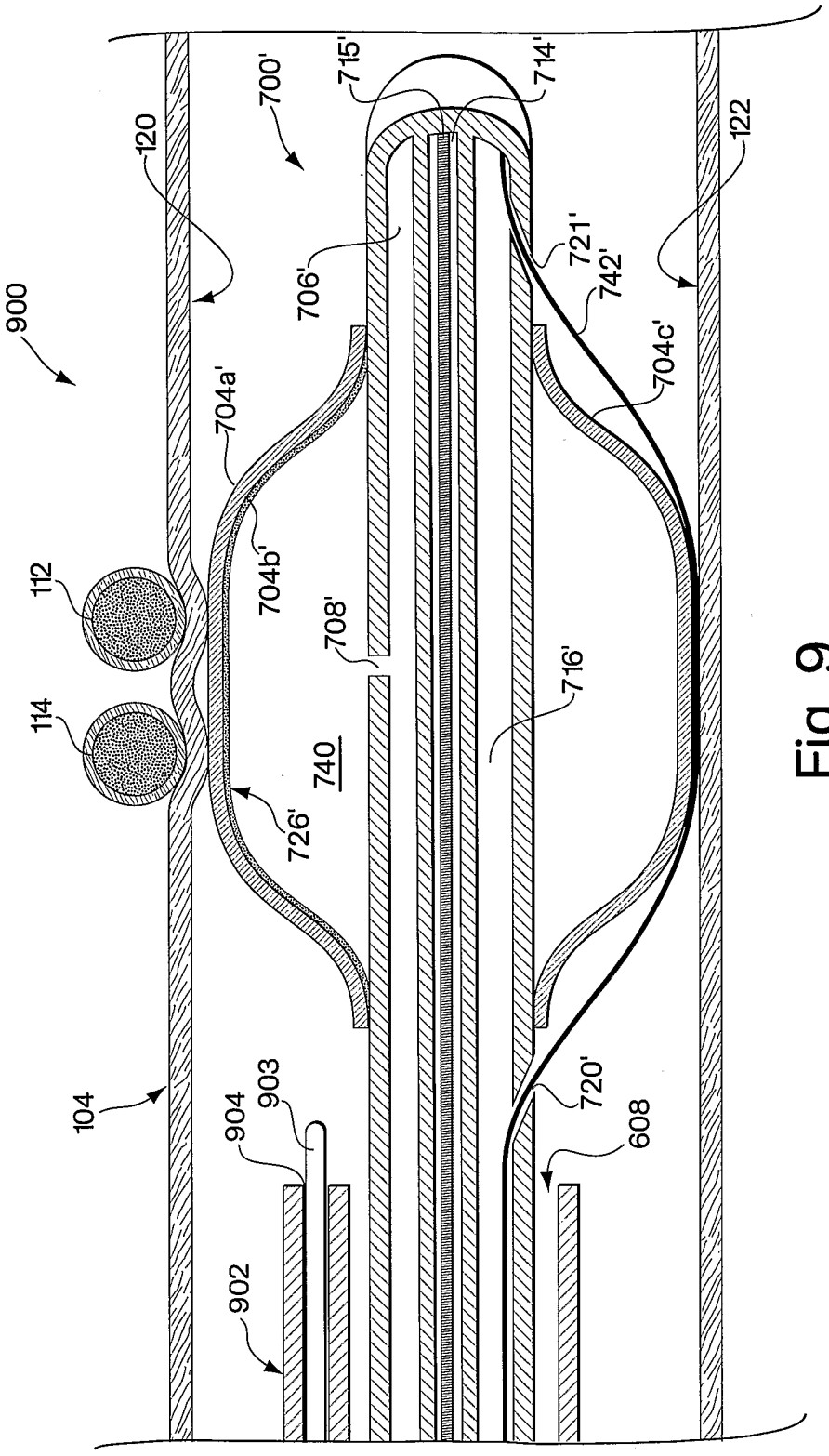
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Fig. 9

INTERNATIONAL SEARCH REPORT

Interna [redacted] l Application No
PCT/US 02/36321

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M29/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M A61L A61B G01K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 2001/047138 A1 (BERRADA MARWANE S ET AL) 29 November 2001 (2001-11-29) paragraphs '0034!-'0036!; figure 4 ---	1,2,4,5,7 3,8-20
X	US 5 498 261 A (STRUL BRUNO) 12 March 1996 (1996-03-12) column 4, line 25 - line 52; figures 1,2 ---	1,2,5,6
Y	US 5 806 528 A (MAGLIOCHETTI MICHAEL J) 15 September 1998 (1998-09-15) column 1, line 5 - line 8; figures 1-6 column 1, line 58 -column 2, line 21 column 3, line 46 - line 52 column 4, line 16 - line 26 --- -/--	3,8,9,20

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 March 2003	03/04/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Reinbold, S

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
Y	GB 2 308 652 A (BRITISH AEROSPACE ;BIOMEDICA LTD (GB)) 2 July 1997 (1997-07-02) page 3, paragraph 4 -page 4, paragraph 2; claim 6; figures 1,2 ---	10-12
Y	US 5 904 679 A (CLAYMAN RALPH V) 18 May 1999 (1999-05-18) column 3, line 37 - line 63; figures 1,2 column 5, line 23 - line 56 column 6, line 28 - line 33 column 6, line 57 - line 60 ---	13,18,19
Y	US 6 296 651 B1 (LARY BANNING GRAY ET AL) 2 October 2001 (2001-10-02) column 4, line 37 - line 65; figures 1-3 column 5, line 9 - line 17 ---	15,16
Y	US 5 554 163 A (SHTURMAN LEONID) 10 September 1996 (1996-09-10) column 1, line 5 - line 8; figures 1-5 column 6, line 47 - line 65 column 7, line 15 - line 36 ---	17
Y	US 5 413 557 A (SOLAR RONALD J) 9 May 1995 (1995-05-09) column 2, line 57 - line 60; figures 3,9-11 column 3, line 15 - line 21 column 5, line 1 - line 20 -----	14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 02/36321

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 21-52
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 21-52

The methods of claims 21-52 is carried out within a human body. The application does not meet the requirement of Article 52(4), because claims 21-52 are a method of treatment of the human.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 02/36321

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