(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
23 July 2015 (23.07.2015)

WIPO | PCT

(10) International Publication Number
WO 2015/108609 A1

(51) International Patent Classification:
*A61F 2/95* (2013.01)

(21) International Application Number:
PCT/US2014/063758

(22) International Filing Date:
3 November 2014 (03.11.2014)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
14/159,221 20 January 2014 (20.01.2014) US

(71) Applicant: **BRIGHTWATER MEDICAL, INC.** [US/US]; 1 Brockway Avenue, Peoria Heights, IL 61616 (US).

(72) Inventors: **SMOUSE, Harry, R.**; 1 Brockway Avenue, Peoria, IL 61616 (US). **WILLIAMS, Tim, H.**; 114 Heritage Village Way, Campbell, CA 95008 (US).

(74) Agent: **REIFMAN, Nicole, E.**; McDonnell Boehnen Hulbert & Berghoff LLP, 300 South Wacker Drive, Suite 3100, Chicago, IL 60606 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU,

*[Continued on next page]*

WO 2015/108609 A1

(54) Title: CONVERTIBLE NEPHROURETERAL CATHETER

(57) Abstract: A nephroureteral catheter is provided that comprises a detachable portion such that when the detachable portion is removed, the catheter converts into an internal stent. The catheter includes a tube with two retention features, a detachable portion, and an inner tube. The inner tube is removably insertable into both the tube and the detachable portion, and a wire extends through at least a portion of a lumen of the inner tube and through the tube, to keep the pieces attached. The wire may be removed to remove the inner tube and then the detachable portion from the tube. When the detachable portion is attached to the tube, the catheter is a nephroureteral catheter. When the detachable portion is removed from the tube, the catheter becomes a stent.

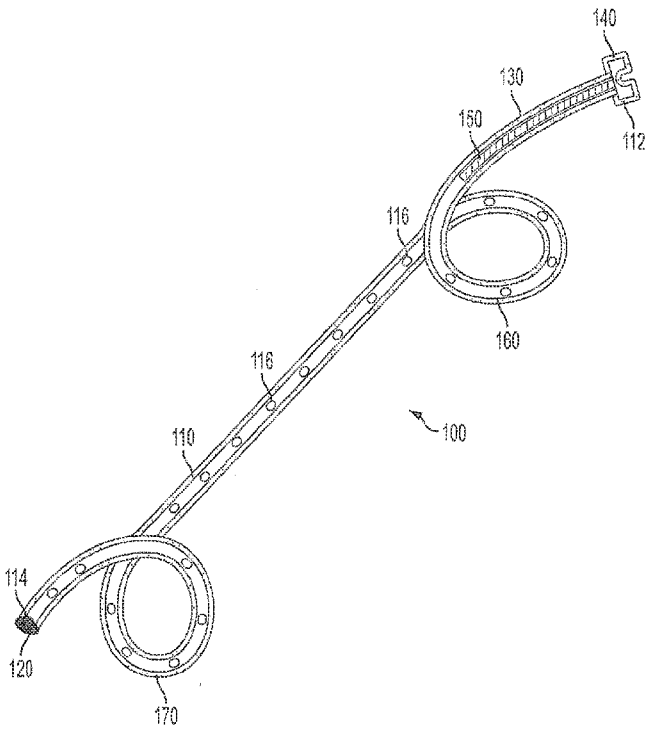


FIG. 1

LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

**Published**:

— *with international search report (Art. 21(3))*

# CONVERTIBLE NEPHROURETERAL CATHETER

## CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority to U.S. Patent Application No. 14/159,221, filed January 20, 2014, which is hereby incorporated by reference in its entirety.

## FIELD

The present invention relates generally to catheters. More particularly, the present invention relates to a nephroureteral catheter.

## BACKGROUND

Many patients experience the development of a stricture or blockage within the ureter of one or both kidneys. The ureter is the muscular tube that connects the kidney to the bladder. As urine is made by the kidney it drains into a central collecting system of the kidney and then travels though the ureter into the bladder. Patients can develop strictures, or blockages, of the ureter due to kidney stones, cancers, infections, trauma, and prior medical instrumentations. In rare instances, some children are born with blockages of one or both ureters. If untreated, the blockage will eventually lead to kidney failure.

Regardless the cause, the treatment for a blocked ureter is to relieve the blockage. Blockage removal is performed by inserting a long tube to connect the collecting system of the kidney to the bladder. This tube is called a stent and is placed through the ureter.

Stent insertion is typically performed by one of two methods. The stent may be inserted urologically. With this method, a scope is advanced through the urethra into the bladder. A wire is then inserted into the ureter in a retrograde fashion, using the scope to thread the wire. When the wire reaches the collecting system of the kidney, a plastic stent is inserted over the wire. The stent is a straight plastic tube that has a pigtail-shaped curl on each end. Once in place, the wire is removed and the scope is taken out of the bladder. One pigtail curl of the stent resides in the collecting system

of the kidney and the other resides in the bladder. The straight portion of the stent traverses the ureter. This is performed using direct visualization with the scope and also with fluoroscopic guidance. The stent usually stays in for a period of approximately three months, at which point the stent is then swapped out for a new stent by the urologist using a similar technique.

The second method for insertion is to insert the stent percutaneously. This method is typically performed in stages. The right or left flank of the patient is sterilely prepared depending upon which kidney is to be accessed (sometimes both are accessed to treat bilateral blockages). Intravenous sedation is used. A small bore needle is used to puncture the collecting system of the kidney and contrast is injected allowing the complete visualization of the entire collecting system. The central portion is initially punctured with a small needle, and then a larger needle is used to puncture a smaller but safer area of the collecting system. A guidewire is threaded into the collecting system of the kidney and a pigtail drain, or nephrostomy catheter, is placed, sutured to the back, and hooked up to a bag for external drainage. Once the urine has cleared from bleeding, the patient is brought back to the angiography table, placed prone, and a wire is inserted through the catheter into the kidney. The catheter is then removed. The wire is threaded through the ureter into the bladder (across the stricture) and a nephroureteral catheter is placed.

A nephroureteral catheter is a long plastic tube that goes from the outside of the patient into the kidney's collecting system, through the ureter, and into the bladder. The catheter allows drainage of urine into the bladder and externally into a bag. The catheter typically stays in the patient for 7-10 days, at which time the patient is brought back to the angiography table and a wire is threaded through this tube into the bladder. The tube is removed and an internal stent is placed using fluoroscopic guidance. This is the same type of stent that is placed by the urologist working through the bladder. This can be a complex and difficult procedure.

## SUMMARY

In accordance with the present invention, a nephroureteral catheter is provided that comprises a detachable portion such that when the detachable portion is removed, the catheter converts into an internal stent.

The catheter includes a tube having a circular cross section, a first end, a second end, a first retention feature near the first end, and a second retention feature near the second end. The catheter also comprises a detachable portion, wherein the detachable portion is in fluid communication with and is removably attachable to the tube at the second end, an inner tube comprising at least one lumen, wherein the inner tube is removably insertable into both the tube and the detachable portion, and a wire extending through at least a portion of a lumen of the at least one lumen of the inner tube. A portion of the wire is attached to the tube.

The convertible nephroureteral catheter eliminates the step of removing a nephroureteral catheter and placing a new internal stent into a patient. Because a step is eliminated, the convertible nephroureteral catheter saves time. Instead of a physician having to take steps such as sterile prep to place a new catheter inside a patient, the physician need only unlock the hub of the convertible nephroureteral catheter to detach the external portion of the catheter. Money is also saved since one less catheter will be required. In addition, other supplies such as wires, sheaths, and other equipment needed to place a typical internal catheter will be spared. The patient will only be subjected to minimal, if any, radiation from fluoroscopy.

The convertible nephroureteral catheter will also result in less patient discomfort, again due to minimal manipulation because less steps are required. With previous stent insertion procedures, local and IV sedation and nursing monitoring were required.

Patients will not require sedation for the process of removing the removable portion of the convertible nephroureteral catheter. The new procedure for transforming the convertible nephroureteral catheter may be performed at bedside.

The convertible nephroureteral catheter allows for the catheter insertion process to be a single

step instead of a multiple-step process. The ability to insert a catheter percutaneously with a single step might provide an advantage over urological insertion, as they will both now require only a single step for insertion, yet using the convertible nephroureteral catheter will not require the general anesthesia required by urological insertion.

## BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments are described herein with reference to the following drawings. Certain aspects of the drawings are depicted in a simplified way for reason of clarity. Not all alternatives and options are shown in the drawings and, therefore, the invention is not limited in scope to the content of the drawings. In the drawings:

Figure 1 depicts a nephroureteral catheter, in accordance with example embodiments;

Figure 2 depicts a detachable portion of the nephroureteral catheter of Figure 1, in accordance with example embodiments;

Figure 3 depicts a detachable portion of the nephroureteral catheter of Figure 1, in accordance with example embodiments;

Figure 4a depicts a detailed view of a removable attachment system, in accordance with example embodiments;

Figure 4b depicts a detailed view of a removable attachment system, in accordance with example embodiments;

Figures 5a-5b depict detailed views of a removable attachment system, in accordance with example embodiments;

Figure 6 depicts a detailed view of a removable attachment system, in accordance with example embodiments;

Figure 7 depicts a detailed view of a removable attachment system, in accordance with example embodiments; and

Figure 8 depicts a stent that remains after a detachable portion has been removed, in accordance with example embodiments.

## DETAILED DESCRIPTION

Figure 1 depicts a catheter 100, in accordance with example embodiments. Catheter 100 is provided for use as a nephroureteral catheter and is configured to be placed within a patient.

Catheter 100 allows for the drainage of urine into the bladder and externally into a bag. Catheter 100 includes a tube 110 having a circular cross section 120, a detachable portion 130, a locking mechanism 140, an inner tube 150, a first pigtail curl 160, a second pigtail curl 170, and a marker 190. Catheter 100 also includes a first end 112, a second end 114, and a plurality of holes 116. When detachable portion 130 is attached to the catheter, catheter 100 is a nephroureteral catheter. When detachable portion 130 is removed from the catheter, the catheter becomes a stent 200, as shown in Figure 8.

Tube 110 may be flexible. The tube 110 has a hollow interior or lumen to allow for fluids to flow through the tube. A plurality of holes 116 extend through tube 110 so that fluids may flow into or out of tube 110 through the holes. Tube 110 is of sufficient length so that it extends from the outside of the patient into the kidney, through the ureter and into the bladder.

First pigtail curl 160 and second pigtail curl 170 serve the purpose of retaining or keeping tube 110 in the proper position within the patient. First pigtail curl 160 is located near first end 112 and second pigtail curl 170 is near second end 114, so that first pigtail curl 160 lies within the collecting system of the kidney and second pigtail curl 170 lies within the bladder. Each curl serves as a retention feature and ensures tube 110 will not move out of the ureter, because each curl is too large to pass through the ureter. Second pigtail curl 170 enters the ureter in a straight position, but the material of tube 110 at the section of second pigtail curl room to bend, or once it has exited the ureter.

First pigtail curl 170 is such that it will bend into the curl position shown in Figure 1 after the tube has curl enters the kidney in the straight position as well, and may also bend into the curl position once in place. However, to help first pigtail curl bend to the proper position, a string 180

may be pulled through a hole of the plurality of holes 116, as shown in Figure 2, and the string may be manually pulled on both ends 182, 184 until first pigtail curl is set in place. Thereafter, string 180 may be manually removed by pulling one of ends 182, 184. String 180 may be a suture. Alternatively, string 180 may be a number of other materials.

Locking mechanism 140 may be a number of locking mechanisms currently used in the art. Locking mechanism closes off detachable portion 130 of tube 110, and may be manually opened and removed to access any of detachable portion 130, inner tube 150, or tube 110.

Detachable portion 130 may be made from the same material as tube 110. Detachable portion 130 may be flush with tube 110 at marker 190. Detachable portion 130 comprises a hollow section within which inner tube 150 may slide through. Inner tube may extend through a portion of tube 110, as shown in Figure 2. Inner tube 150 comprises a hollow interior to allow for fluid to flow through the interior of inner tube 150. Fluid is exchanged between tube 110 and inner tube 150 through the hollow interior of inner tube 150. Tube 110 also comprises at least a portion of a hollow section within which tube portion 150 may slide through. In some example embodiments, the hollow portions of both detachable portion 130 and tube 110 may be sized such that when inner tube portion 150 is inside the hollow portions of the detachable portion 130 and tube 110, there is a friction seal between the exterior surface of tube portion 150 and the walls of the hollow portions. However, tube portion 150 may be attached to tube 110 in a number of other ways. For example, in an alternative embodiment, inner tube 150 may comprise threads on its exterior surface that correspond to threads along the walls of the hollow interior of tube110, and thus to remove inner tube 150 from tube 110, inner tube 150 must be unscrewed from tube 110. In another alternative embodiment, detachable portion 130 may comprise a smaller circumference than tube 110 such that detachable portion 130 may also fit within the hollow portion of tube 110, for example 2 or 3 mm into tube 110. Thus when inner tube 150 is in place within both tube 110 and detachable portion 130, inner tube 150 pushes outward on detachable portion 130, which in turn presses on tube 110, resulting in a tighter fit. In

this embodiment, detachable portion 130 may still be manually removed from tube 110 after the removal of inner tube 150 from tube 110.

Detachable portion 130 may be manufactured as part of catheter 100. When attached to catheter 100 and in place inside a patient, detachable portion 130 extends from the center of the kidney to an exit in the back of the patient, ending with locking mechanism 140, which is located outside the patient's body.

In another example embodiment, an inner tube portion 250 and a wire 255 may extend through both detachable portion 230 and the tube 210, as shown in Figure 3. In this embodiment, inner tube portion 250 comprises a hollow interior or lumen 252 to allow for fluid to flow therethrough. Thus, fluid is exchanged between tube 210 and inner tube portion 250 through the hollow interior of inner tube portion 250. Tube 210 also comprises at least a portion of a hollow section within which tube portion 250 may slide through.

Detachable portion 230 may be manufactured as part of catheter 200. When attached to catheter 200 and in place inside a patient, detachable portion 230 extends from the center of the kidney to an exit in the back of the patient, ending with locking mechanism 240, which is located outside the patient's body.

Figure 4a shows a detailed view of the catheter 200 of Figure 3. Wire 255 is shown to extend through lumen 252 of inner tube 250. Wire 255 may extend from locking mechanism 240 in the distal direction through the entire length of lumen 252 of inner tube 250, in some example embodiments. In other example embodiments, however, wire 255 may only extend partially through lumen 252 of inner tube 250. Wire 255 may comprise a portion 256 that extends through and over the exterior of tube 210, at a region where tube 210 overlaps the inner tube 250, thereby affixing tube 210 and inner tube 250. The portion 256 may comprise a first angled section 257 that extends from within lumen 252 of inner tube 250, through the wall of tube 210 and an outer surface 202 of tube 210, a generally flattened section 258 that extends above outer surface 202 of tube 210, and a second

angled section 259 that extends from generally flattened section 258, through the wall of tube 210 back into lumen 252 of inner tube 250.

The wire 255 may be affixed to and then removed at the locking mechanism 240 to disconnect the distal section of inner tube 250 from tube 210, rendering the catheter 200 a stent, as will be described with further detail below. The locking mechanism may comprise a luer lock, for example. Other locking mechanisms may also be envisioned. Such a locking mechanism may be affixed via any of a number of bonding or fastening methods.

Wire 255 may comprise a material that has sufficient tensile strength to hold inner tube 250 and tube 210 together, such as a metallic composite material. Example metallic composite materials that may be used are stainless steel, Elgiloy, a nickel cobalt alloy (e.g., MP35N), or a nickel titanium alloy (e.g., Nitinol), for example.

To connect the detachable portion 230 to tube 210, wire 255 may be sent through inner tube 250, which may contain one or more lumens.

In an alternative embodiment shown in Figure 4b, instead of wire 255 traveling through the wall of tube 210 and extending beyond exterior 202 of tube 210 to affix the inner tube 250 within the tube 210, wire 255 may continue over a separate wire segment 254 which is normal to wire 255 and within lumen of tube 210. The separate wire segment 254 may be fused into the wall of tube 210 while providing a small area for passage of wire 255 and a large area for passage for inner tube 252. The wire 255 may continue its path over the separate wire segment 254, remaining entirely within the lumen of tube 210, and completing second angled section 259 to return into lumen 252 of inner tube 250.

Figures 5a-5b show detailed top and side views of a wire 350 within a tube 310, in accordance with an example embodiment. The tube 310 may take the same form as or may be similar in form to the tube 110 or 210 described with reference to Figures 1-4. A detachable portion 330 and an inner tube 350 are also shown, and may take the same form as or may be similar in form to the

detachable portion 130 or 230 and the inner tube 150 or 250 described with reference to Figures 1-4. In the embodiment shown in Figures 5a-5b, a wire 355, comprising a metal band, may be used to removably attach the detachable portion 330 to the tube 310. An engagement portion 356 of the wire 355 is shown to engage into an interior wall 305 of the catheter 300. The engagement portion 356 may comprise a bump, hill, or other pronounced surface extending above the surface of the remaining wire 355.

Figure 6 shows a detailed cross-sectional side view of a wire 450 within a catheter 400, in accordance with an example embodiment. The catheter 400 may take the same form as or may be similar in form to catheter 100 or 200 described with reference to Figures 1-4. A detachable portion 430 is also shown, and may take the same the detachable portion 130 or 230 described with reference to Figures 1-4.

An inner tube 450 may comprise two lumens, first lumen 451 and second lumen 452. First lumen 451 may comprise a wall to separate first lumen 451 from second lumen 452. A wire 455, which may take the form of either wire 255 or wire 355, may run through first lumen 451 and thus be isolated within lumen 451 so as not to interfere with second lumen 452. Second lumen 452 may serve as a wire guide or stent straightening lumen. The dual lumen feature of inner tube 450 permits the use of an isolated access pathway (second lumen 452) to be used for device tooling such as a wire guide or stent straightener without risk of disrupting wire 455 located within lumen 451. First lumen 451 provides a protective safeguard against dislodgement of wire 455 during implantation of the catheter within patient and during the corresponding exchange of catheter tooling during intervention. Fluid may be exchanged between catheter 400 and inner tube 450 via both first lumen 451 and second lumen 452.

Figure 7 shows a detailed cross-sectional side view of an example detachable portion 530 of a catheter 500, according to an example embodiment. The catheter 500 may take the same form as or may be similar in form to catheter 100 or 200 described with reference to Figures 1-4. The catheter

500 may comprise a tube 510, which may take the same form as or may be similar in form to tube 110 or 210 described with reference to Figures 1-4.

Detachable portion 530 may comprise a first tube portion 532, a second tube portion 534, and a transition 536 from the first tube portion 532 to the second tube portion 534. Transition 536 may take the form of a step and may comprise about a 90 degree transition. A lumen 533 may extend through both the first tube portion 532 and the second tube portion 534 as shown, and may comprise the same diameter through both portions. Transition 536 may mate with or abut an end 505 of catheter 500. Second tube portion 534 comprises a smaller diameter than the first tube portion 532, and is sized and shaped to fit within the lumen of the catheter 500. Such a design for detachable portion 530 renders having an additional inner tube, such as inner tubes 150 and 250, for example, unnecessary.

Figure 8 shows a perspective view of a stent 200 that remains after the detachable portion has been removed. Stent 200 comprises the same tube 110 as catheter 100, with first pigtail curl 160 and second pigtail curl 170 untouched within the body of the patient. Detachable portion 130, inner tube 150, and locking mechanism 140 have been removed. A new end 210 is at marker 190.

In operation, the right or left flank of the patient is sterilely prepared depending upon which kidney is to be accessed. Intravenous sedation is used. A small bore needle is used to puncture the collecting system of the kidney and contrast is injected allowing the complete visualization of the entire collecting system. The central portion is initially punctured with a small needle, and then a larger needle is used to puncture a smaller but safer area of the collecting system. A guidewire is threaded into the collecting system of the kidney and a pigtail drain, or nephrostomy catheter, is placed, sutured to the back, and hooked up to a bag for external drainage.

Once the urine has cleared from bleeding, the patient is brought back and a wire is inserted through the catheter into the kidney and the catheter is removed. The wire is threaded through the ureter into the bladder (across the stricture) and catheter 100 is placed. Pigtail curls 160, 170 are

curled to their proper position. The catheter typically stays in the patient for 7-10 days, at which time the patient is brought back.

At this point, if the physician desires to exchange the catheter 100 for a stent 200, the physician will unlock locking mechanism 140, and will remove the locking mechanism to access inner tube 150. The physician will then manually pull inner tube 150 through the hollow portion of tube 110 toward first end 112, until inner tube 150 has been pulled past marker 190 and is no longer within the hollow portion of tube 110.

In another example embodiment, wherein a wire is used, such as described with reference to Figures 3-7, the physician will first release the locking mechanism maintaining connection with a wire, such as wire 255, 355, 455, or 555. The wire may be released using a method such as unscrewing a cap, for example. In such an example embodiment, the unscrewed cap (which has been attached to the wire at the proximal luer hub) disengages the wire from the catheter (*e.g.*, catheters 310 and 400) by pulling the cap away from the hub and fully withdrawing the wire from the inner tube (*e.g.*, inner tubes 250, 350, 450). Once the wire has been removed, the detachable portion (*e.g.*, detachable portions 330 and 530) and the inner tube may now be fully withdrawn from the patient's body, converting the catheter into a stent (*e.g.*, stent 200).

Once inner tube 150 has been removed from tube 110, detachable portion 130 is no longer attached to tube 110 and both detachable portion 130 and inner tube 150 may be removed from the patient's body. Once detachable portion 130 and inner tube 150 are removed, catheter 100 becomes a stent 200, as shown in Figure 3. This is same type of stent that would typically be placed by the urologist working through the bladder. Stent 200 now comprises a new end 210 that is located at marker 190.

An example of when the convertible nephroureteral catheter may be used is a situation in which a patient has a blockage of the ureter and presents with hydronephrosis (dilation of the kidney's collecting system) and hydroureter (dilation of the ureter). The patient has a device inserted

through the flank, into the collecting system, and through the ureter into the bladder. The device will be left open to external drainage until the urine clears from infection or bleeding. When the urine has cleared, the external portion of the convertible nephroureteral catheter 100 will be detached, converting the catheter into an internal stent. From this point forward, the stent will drain urine directly from the kidney to the bladder. The internal stent will remain in place until it is ready to be removed or replaced.

Another example of use is when a patient recently passed a kidney stone and the ureter is temporarily inflamed and blocked. The convertible nephroureteral catheter is inserted in the same manner described above. In this situation, however, the catheter is in place temporarily until the inflammation improves; once this is confirmed, the entire catheter is removed by pulling it out of the flank with contrast injection under fluoroscopy. In this situation the detachable portion is not detached. However, the catheter may also be left in place as an internal stent, and the detachable portion removed, depending on the clinical need.

Another example of use is when a patient has leakage from the ureter due to trauma, instrumentation, stone removal, cancer, or another reason, and internal and external urine diversion is necessary. In this case, convertible nephroureteral catheter 100 is placed in the patient and urine is allowed to drain externally. When there is improvement in the leakage and the catheter is converted to an internal stent by removing detachable portion 130, internal urine diversion is allowed for a longer period of time. The stent 500 will be removed at a later date after the leak is resolved.

It will thus be seen that certain changes may be made in the above constructions without departing from the spirit and scope of the invention. It is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

WE CLAIM:

1. A catheter comprising:

A tube comprising a cylindrical wall, a first end, a second end, a first retention feature near the first end and a second retention feature near the second end;

a detachable portion, wherein the detachable portion is in fluid communication with and is removably attachable to the tube at the second end;

an inner tube comprising at least one lumen, wherein the inner tube is removably insertable into both the tube and the detachable portion; and

a wire extending through at least a portion of a lumen of the at least one lumen of the inner tube;

wherein a portion of the wire is attached to the tube.

2. The catheter of claim 1, wherein once the wire is removed, the inner tube and the detachable portion are removable to transform the catheter into an internal stent.

3. The catheter of claim 1, wherein the first retention feature and the second retention feature comprise a first curl and a second curl, respectively.

4. The catheter of claim 2, further comprising a plurality of holes extending through an outer surface of the tube.

5. The catheter of claim 1, further comprising a locking mechanism at a first end of the detachable portion, wherein the locking mechanism is configured to open and close, and wherein when closed, the locking mechanism prevents access to an interior of the detachable portion.

6. The catheter of claim 1, wherein the inner tube comprises two lumens.

7. The catheter of claim 1, wherein the wire is a flat wire comprising a raised portion, and wherein the raised portion affixes to an interior wall of the tube.

8. A nephroureteral catheter that converts into a stent, comprising:

a tube, wherein the tube comprises a lumen, a first end, a second end, a first retention feature near the first end, and a second retention feature near the second end;

a detachable portion, wherein the detachable portion is insertable into the tube and comprises a lumen that is in fluid communication with the lumen of the tube when inserted;

a wire extending through at least a portion of the detachable portion and the tube;

wherein once the wire is removed from the tube, the detachable portion is removable from the tube.

9. The nephroureteral catheter of claim 8, wherein the detachable portion is the portion of the tube that extends from the center of the kidney to the back of the patient.

10. The nephroureteral catheter of claim 8, wherein a first portion of the wire extends substantially parallel to the lumen, a second portion of the wire extends through the detachable portion and the tube, a third portion of the wire extends over an exterior surface of the tube, and a fourth portion of the wire extends back through the tube into the detachable portion.

11. The nephroureteral catheter of claim 8, wherein the tube comprises a plurality of holes each extending through the tube.

12. The catheter of claim 8, further comprising a locking mechanism that is at the first end and is located outside a patient's body when the catheter is placed inside the patient's body.

13. A method for converting a catheter into a stent comprising:

providing a catheter having a tube comprising a first end, a second end, a first retention feature near the first end and a second retention feature near the second end, and a detachable portion, wherein the detachable portion is in fluid communication with and is removably attachable to the tube at the second end; and

removing the detachable portion from the catheter to convert the catheter into an internal stent.

14. The method of claim 13, further comprising:

providing an inner tube that extends through at least a portion of both the tube and the detachable portion and comprises at least one lumen;

extending a wire through at least a portion of the at least one lumen of the inner tube; and

attaching a portion of the wire to the tube;

wherein removing the detachable portion comprises removing the wire and the inner tube from the tube.

15. The method of claim 13, further comprising:

providing a locking mechanism at a first end of the detachable portion, wherein the locking mechanism is configured to open and close; and

closing the locking mechanism to prevent access to an interior of the detachable portion.

16. The method of claim 13, further comprising:

positioning the catheter in a patient by creating an incision in the patient at a surgical site and inserting the catheter through the incision.

17. The method of claim 16, wherein the surgical site is a urethra of the patient to access one or more of a bladder, a ureter, and a kidney via a flank.

18. The method of claim 16, further comprising:

attaching the catheter to tubing exterior to the patient.

19. The method of claim 16, wherein removing the detachable portion comprises removing the detachable portion from the patient.

20. The method of claim 13, wherein the method is used to provide or monitor treatment for a disorder of the kidney or bladder.

21. A method for converting a medical device from a catheter to a stent, comprising:

providing a medical device in a first form as a catheter, wherein the catheter comprises a proximal portion extending outside a patient's body when inserted into the patient; and

transitioning the medical device from the first form to a second form by detaching the proximal portion and removing the proximal portion from the patient;

wherein in the second form the medical device comprises a stent.

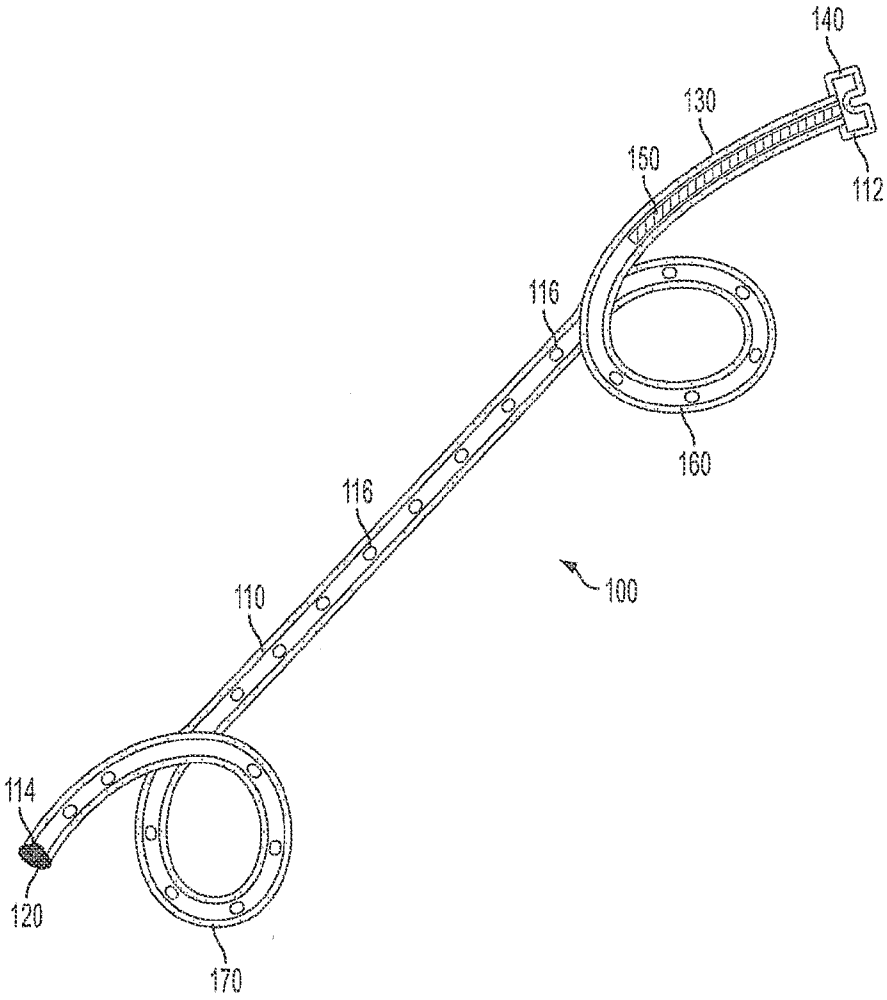


FIG. 1

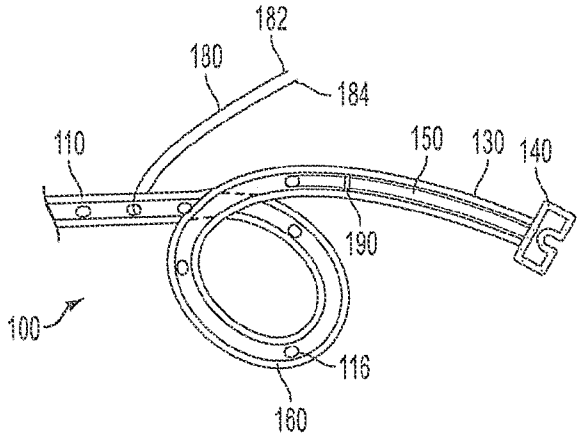


FIG. 2

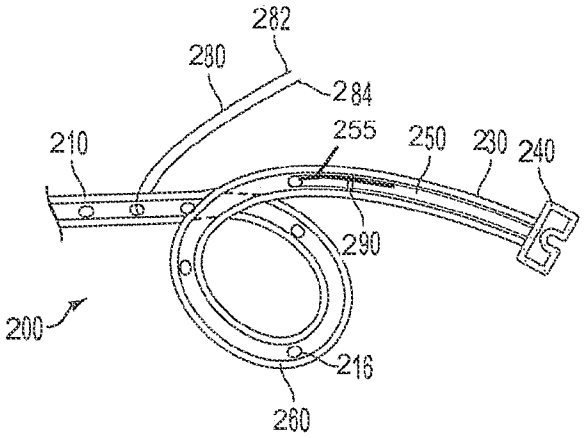


FIG. 3

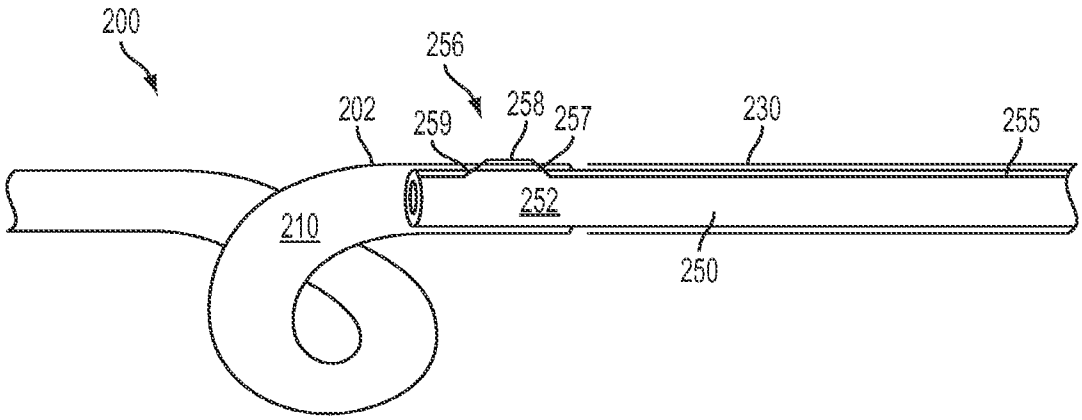


FIG. 4a

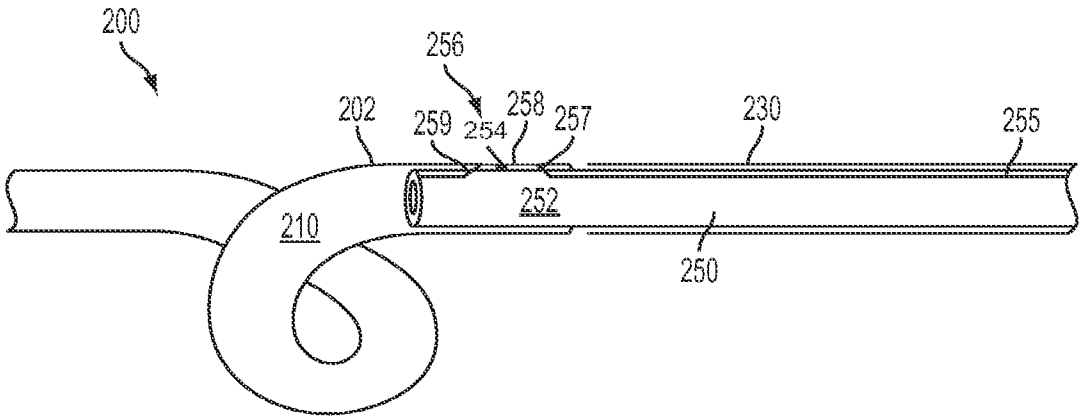


FIG. 4b

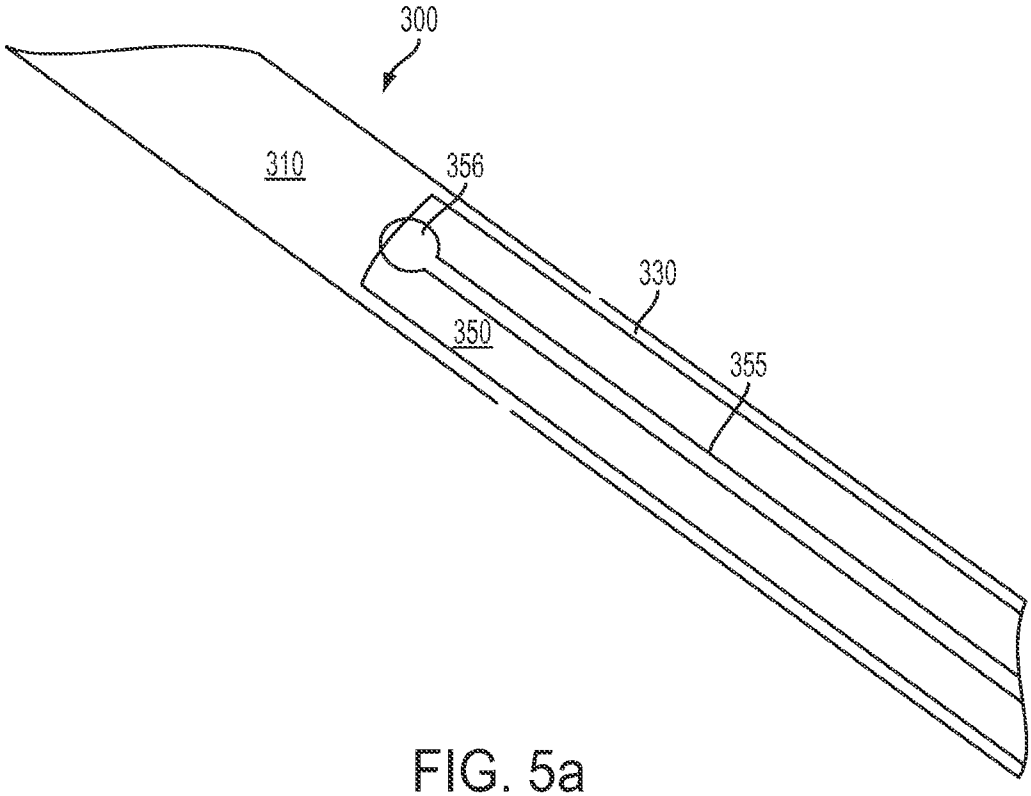


FIG. 5a

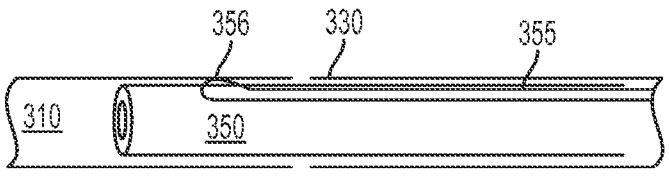


FIG. 5b

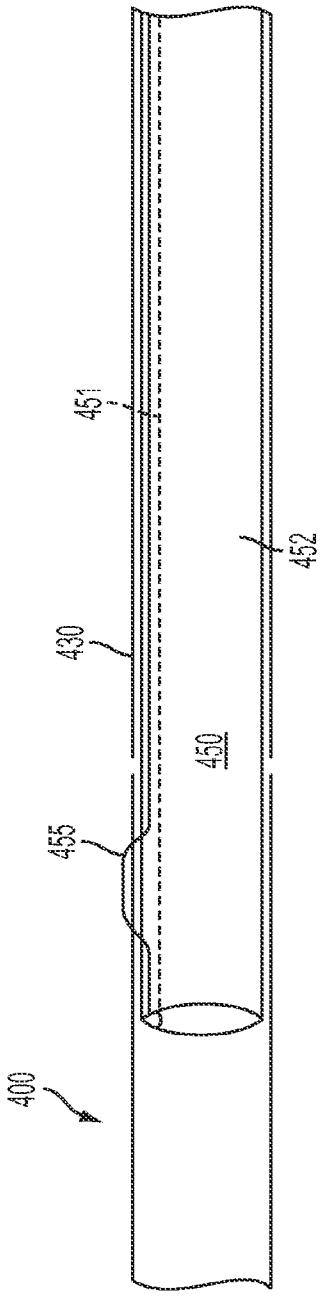


FIG. 6

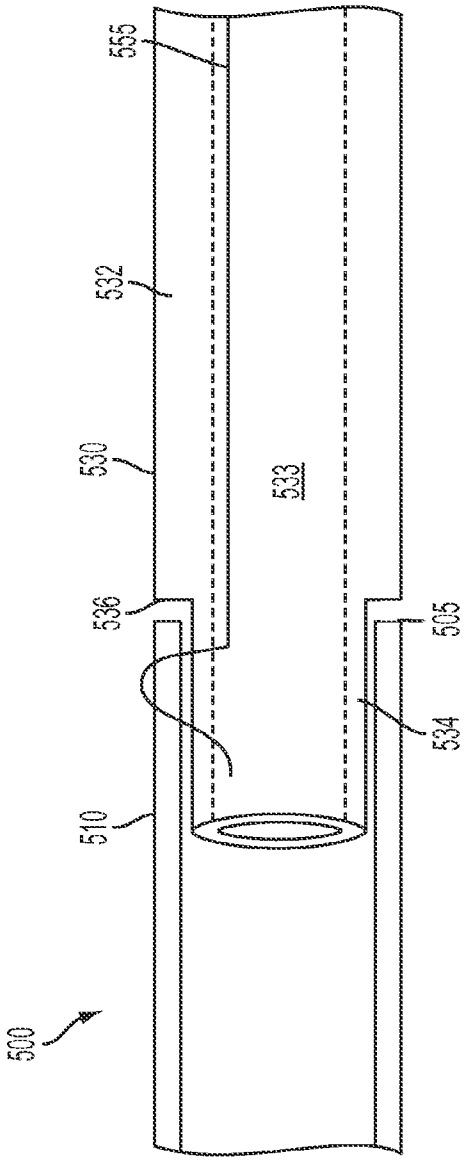


FIG. 7

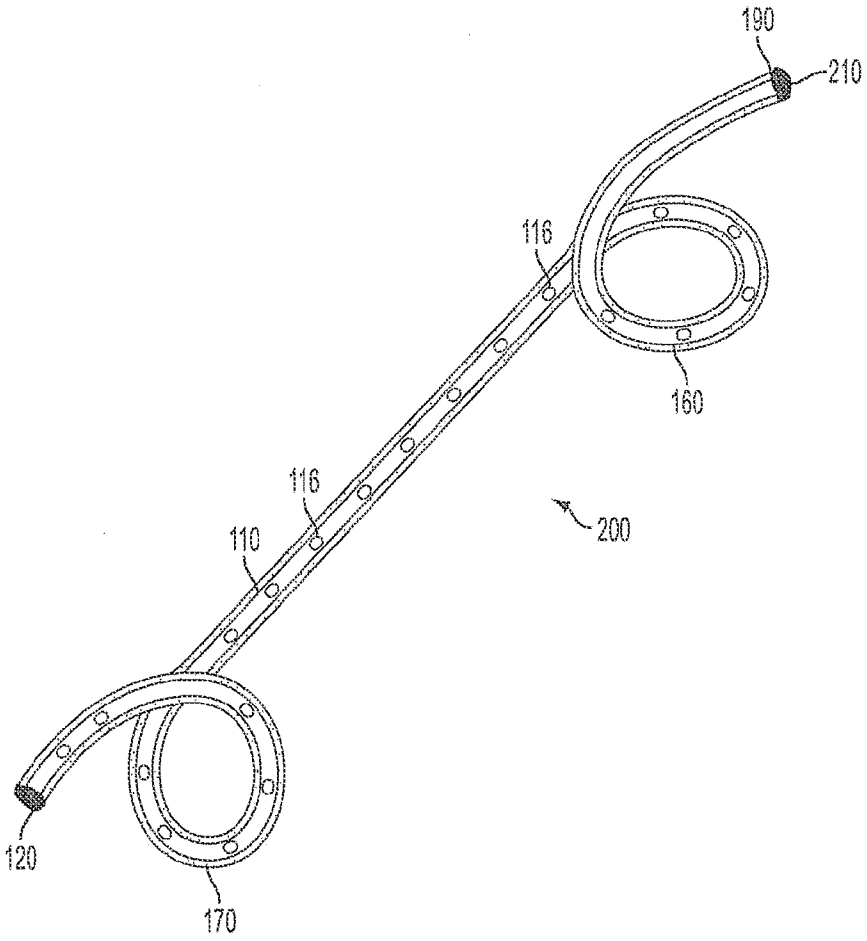


FIG. 8

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/063758

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/95 (2015.01)
CPC - A61F 2002/9505 (2015.01)
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(8) - A61F 2/00, 2/04, 2/82, 2/84, 2/95; A61M 25/00, 27/00 (2015.01)
CPC - A61F 2/00, 2/042, 2002/048, 2/82, 2/848, 2002/8483, 2002/8486, 2/95, 2002/9505; A61M 25/00, 25/0017, 2025/0031, 25/0041, 27/00, 2027/004, 27/008 (2015.01)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 604/8; 623/23.64, 23.65, 23.66, 23.67, 23.7 (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Orbit, Google Patents, Google Scholar
Search terms used: barb, retention, catheter, lumen, tube, kidney, ureteral, nephroureteral, convert, stent, detach

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 2010/0070047 A1 (SMOUSE) 18 March 2010 (18.03.2010) entire document | 13, 15-21 |
| Y | | 1-12, 14 |
| Y | US 2003/0191450 A1 (TEAGUE et al) 09 October 2003 (09.10.2003) entire document | 1-7 |
| Y | US 5,964,771 A (BEYAR et al) 12 October 1999 (12.10.1999) entire document | 8-12, 14 |

☐ Further documents are listed in the continuation of Box C. ☐

* 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 application or patent 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 February 2015 | 25 MAR 2015 |
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US, Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-3201 | Authorized officer:<br>Blaine R. Copenheaver<br>PCT Helpdesk: 571-272-4300<br>PCT OSP: 571-272-7774 |

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/063758

**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 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.:
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:

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 No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

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

See extra sheet.

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 additional fees, this Authority did not invite payment of additional fees.

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 and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☒ No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT**

International application No.
PCT/US2014/063758

CONTINUED FROM BOX NO. III:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-12, are drawn to a catheter.

Group II, claims 13-21, are drawn to a method for converting a catheter into a stent.

The inventions listed as Groups I - II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical features of Group I, a wire extending through at least a portion of a lumen of the inner tube and attached to the tube, are not present in Group II; and the special technical features of Group II, removing the detachable portion from the catheter to convert the catheter into an internal stent, are not present in Group I.

Groups I and II share the technical features of a catheter having a tube comprising a first end, a second end, a first retention feature near the first end and a second retention feature near the second end, and a detachable portion, wherein the detachable portion is in fluid communication with and is removably attachable to the tube at the second end. However, these shared technical features do not represent a contribution over the prior art. Specifically, US 6,569,150 B2 to Teague et al teaches a catheter (15) having a tube (12, 12A) comprising a first end (near 16 or 16A), a second end (near 18 or 18A), a first retention feature (34) near the first end (Fig. 5) and a second retention feature (32) near the second end (Fig. 5), and a detachable portion (13), wherein the detachable portion is in fluid communication with and is removably attachable to the tube (Fig. 2A) at the second end (col. 6, lines 37-50; Figs. 2A and 5).

Since none of the special technical features of the Group I - II inventions are found in more than one of the inventions, unity of invention is lacking.