



- (51) International Patent Classification:
A61F 2/04 (2013.01)
- (21) International Application Number:
PCT/US2016/044780
- (22) International Filing Date:
29 July 2016 (29.07.2016)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
62/198,452 29 July 2015 (29.07.2015) US
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- (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, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK,

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(54) Title: TRANSFORMABLE URETERAL STENT

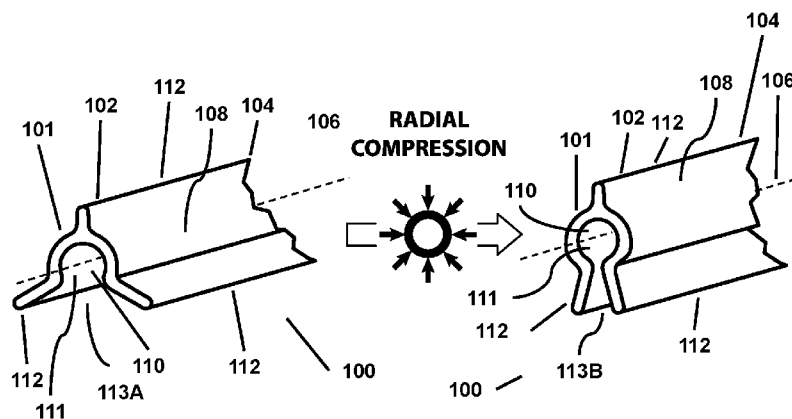


FIG. 1

(57) Abstract: A transformable stent having an elongated body comprising a proximal end, a distal end, a longitudinal axis, an outer surface, and an inner surface. The inner surface defining a transformable bore extending along the longitudinal axis from the proximal end to the distal end. The transformable bore having a default orientation and a second orientation. The default orientation comprises an open bore defining a longitudinally open channel. The second orientation comprises a closed bore defining a longitudinally closed channel. The transformable stent can optionally include at least two fins that project radially away from the outer surface of the body.

WO 2017/019974 A1



SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, **Published:**

GW, KM, ML, MR, NE, SN, TD, TG).

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

TRANSFORMABLE URETERAL STENT

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims benefit of U.S. Provisional Application No. 62/198,452, filed July 29, 2015, which is hereby incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] This disclosure relates to a medical device, and more particularly to a ureteral stent.

BACKGROUND

[0003] Nephrolithiasis is a medical condition better known as kidney stones. This obstruction in the ureter causes patients to experience varied degrees of pain as the stones and stone fragments pass through as peristalsis attempts to move the stones out of the body. Patients can also experience hematuria, nausea, vomiting, dysuria, and urgency. Kidney stone removal is achieved via ureteroscopy or ureteroscopy with lithotripsy, depending on the size of the stones. However, both of these procedures can be damaging to the ureter, resulting in ureteral strictures that may limit urine flow, ultimately causing hydronephrosis. Left untreated, hydronephrosis can result in permanent kidney damage. As such, ureteral stents are placed in the ureter after kidney stone removal, in order to facilitate urine flow as well as the passage of any remaining stones, thereby limiting development of hydronephrosis. Albeit successful in keeping the ureter unobstructed, current stents often result in stent-associated pain and discomfort, as well as poor outcomes.

[0004] There are several relevant clinical findings that motivated pursuing this medical device. The three main theories of why pain occurs are retrograde flow, the presence of the stent in the ureter, and the anchors. Studies show that urine flows more readily around the stent wall than through the bore of the stent itself. In fact, at some pressure differentials, there is a negative flow rate in the bore, suggesting that reflux is occurring, which is one of the main theories of why pain occurs. Furthermore, the normal physiology of the ureter is an important consideration. The ureteral inner wall has infoldings that are present during rest, and this shape changes to become more dilated during a peristaltic wave. Thus, placing a circular static tube in the lumen of the ureter results in the malposition of these folds, adding to the discomfort felt by patients. Finally, the presence of

the stent anchors (generally pigtail curls at both ends) can cause irritation in the renal pelvis and bladder, leading to pain or discomfort.

SUMMARY

[0005] Provided are transformable ureteral stents that purposefully adapt to a dynamic ureteral environment.

[0006] In an example embodiment, a transformable stent may include an elongated body comprising a proximal end, a distal end, a longitudinal axis, an outer surface, and an inner surface. The inner surface defines a transformable bore that may extend along the longitudinal axis from the proximal end to the distal end. The transformable bore may include a default orientation and a second orientation. The default orientation may include an open bore defining a longitudinally open channel. The second orientation may include a closed bore defining a longitudinally closed channel. The transformable bore may be moveable from the default orientation to the second orientation upon radial compression forces being applied to the outer surface. In some embodiments a transformable stent may include at least two fins projecting radially away from the outer surface of the body.

[0007] The details of one or more embodiments of the disclosure are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the disclosure will be apparent from the description, drawings, and from the claims.

DESCRIPTION OF DRAWINGS

[0008] To facilitate an understanding of and for the purpose of illustrating the present disclosure, exemplary features and implementations are disclosed in the accompanying drawings, it being understood, however, that the present disclosure is not limited to the precise arrangements and instrumentalities shown, and wherein similar reference characters denote similar elements throughout the several views, and wherein:

[0009] FIG. 1 is a dimetric view of an example “wishbone”-style transformable stent in accordance with the present disclosure, wherein the image on the left represents the uncompressed status of the stent and the image on the right represents the compressed state;

[0010] FIG. 2 is a front-view of an another example “wishbone”-style transformable stent in accordance with the present disclosure;

[0011] FIG. 3 is a front-view of a another example “wishbone”-style transformable stent in accordance with the present disclosure;

[0012] FIG. 4 is a dimetric view of an example “omega”-style transformable stent in accordance with the present disclosure, wherein the image on the left represents the uncompressed status of the stent and the image on the right represents the compressed state;

[0013] FIG. 5 is a dimetric view of an example “hinge”-style transformable stent in accordance with the present disclosure, wherein the image on the left represents the uncompressed status of the stent and the image on the right represents the compressed state;

[0014] FIG. 6 is a dimetric view of an example “spline”-style transformable stent in accordance with the present disclosure, wherein the image on the left represents the uncompressed status of the stent and the image on the right represents the compressed state;

[0015] FIG. 7 is a dimetric view of an example “arrow”-style transformable stent in accordance with the present disclosure, wherein the image on the left represents the uncompressed status of the stent and the image on the right represents the compressed state.

DETAILED DESCRIPTION

[0016] The following is a description of several illustrations of a transformable ureteral stent that purposefully adapts to a dynamic ureteral environment. By transforming and purposefully adapting to the dynamic ureteral environment, the natural peristalsis of the ureter in natural physiological urine movement from the kidney to the bladder can be better accommodated, and in certain ways mimicked by the transformable stent.

[0017] Certain terminology is used herein for convenience only and is not to be taken as a limitation on the present invention. In the drawings, the same reference numbers are employed for designating the same elements throughout the several figures. A number of examples are provided, nevertheless, it will be understood that various modifications can be made without departing from the spirit and scope of the disclosure herein. As used in the specification, and in the appended claims, the singular forms “a,” “an,” “the” include plural referents unless the context clearly dictates otherwise. The terms “comprising,” “such as,” and variations thereof as used herein are used synonymously with the term “including” and variations thereof and are open, non-limiting terms. Although the terms “comprising” and “including” have been used herein to describe various embodiments, the terms “consisting

essentially of” and “consisting of” can be used in place of “comprising” and “including” to provide for more specific embodiments of the invention and are also disclosed.

[0018] The present invention now will be described more fully hereinafter with reference to specific embodiments of the invention. Indeed, the invention can be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will satisfy applicable legal requirements.

[0019] FIG. 1 shows an example of a transformable stent 100 in accordance with the present disclosure having a “wishbone”-style design. The transformable stent 100 can include an elongated body 101 comprising a proximal end 102, a distal end 104, a longitudinal axis 106, an outer surface 108, and an inner surface 110. The inner surface 110 can define a transformable bore 111 that extends along the longitudinal axis 106 from the proximal end 102 to the distal end 104. The distance between the distal end 102 and the proximal end 104 can be, for example, 20-30cm. The transformable stent 100 itself can have a mid-fin diameter between about 4.8-8Fr.

[0020] Optionally, the transformable stent 100 can include at least two fins 112 projecting radially away from the outer surface 108 of the body which allow for the transformable stent 100 to seat itself into the natural inner geometry of an undilated ureter. An undilated ureter exhibits fingerlings and crevices, therefore the fins 112 of the transformable stent 100 can fit into these natural crevices.

[0021] The transformable bore 111 of the transformable stent 100 can be movable from a default orientation 113A to a predictable second orientation 113B upon radial compression forces being applied to the outer surface 108. If the transformable stent 100 includes fins 112, the fins 112 can help stabilize the transformable bore 111 and facilitate the ability to direct the shape of the transformable bore 111 from the default orientation 113A into the second orientation 113B. The default orientation 113A can comprise an open bore defining a longitudinally open channel and the second orientation 113B can comprise a closed bore defining a longitudinally closed channel, both which allow for urine to flow from the kidney to the bladder. When a radially compressive force acts upon the outer surface 108 of the body, the fins 112 approach each other thereby closing off the transformable bore 111.

[0022] The radial compression forces can be provided by the normal and pathologic ureteral as well as proximal tissue physiology. The default orientation 113A and the second orientation 113B support urine flow not only through the transformable bore 111 but also

around the outer surface 108 of the body 101. As shown in FIGs. 1-7, when the transformable bore 111 is the second orientation 113B, in certain embodiments the transformable stent 100 is not contiguously closed but rather is non-contiguously closed. In certain embodiments, when the transformable bore 111 is the second orientation 113B, the transformable stent 100 is contiguously closed.

[0023] In certain embodiments, the transformable bore 111 of the transformable stent 100 can be movable from a default orientation 113A to a predictable third orientation (not shown) upon radial compression forces being applied to the outer surface 108. The third orientation can comprise, for example, a partially closed bore defining a longitudinally partially closed channel. Similar to the first and second orientation, the third orientation allows for urine to flow from the kidney to the bladder.

[0024] The inner surface 110 of body 101 has a diameter which can be reduced upon the transformable bore 111 moving from the default orientation 113A to the second orientation 113B. Optionally, the diameter is reducible up to the point above where urine flow through the transformable bore 111 would be compromised. For example, the diameter could be reduced to that of a pediatric stent (approximately 3Fr), which could still support drainage comparable to that of a 4.7Fr stent. In some examples, the diameter can be reduced by about 40% upon the transformable bore 111 moving from the default orientation 113A to the second orientation 113B. For example, the reduced internal bore diameter can be about 1mm.

[0025] The transformable stent 100 can be formed from a flexible material such as silicon, rubber, or plastic. In certain exemplary embodiments, the fins 112 and body 101 comprise a flexible material that, based on the Shore hardness scale, is medium soft to medium hard, or medium hard to hard. For example, the fins 112 and body 101 can have a durometer between about 40-70A or about 85-90A, or more, for example 90-100A. Durometer ranges include 30-100A, 40-90A, 50-85A, 70-100A, and 80-95A. In other exemplary embodiments, the fins 112 comprise a flexible material that is soft to medium soft and the body 101 comprises a flexible material that is medium hard to hard based on the Shore hardness scale. For example, the fins 112 can have a durometer between about 15-40A and the body 101 can have a durometer between about 80-90A.

[0026] The durometers described above allow for the stent 100 to be strong enough to avoid collapsing from the ureteral forces imparted on the stent 100 while being soft enough to prevent large amounts of irritation of the ureteral tissue. This results in greater comfort for the patient while allowing the transformable stent 100 to function as it is

intended. It also allows for the ureterovesical junction (UVJ) present between the ureter and bladder to continue functioning normally. The transformable stent 100 can be deformed and flattened through the ureteral opening in the bladder allowing the valves to close when voiding the bladder, thus decreasing reflux into the ureter and kidney. The durometers of the transformable stent 100 can also help prevent adverse tissue effects in the renal pelvis of the kidney and bladder from currently marketed ureteral stent anchors. A softer set of anchors still function to prevent implant migration but also reduce patient discomfort from anchors protruding into surrounding tissues.

[0027] FIG. 2 shows another example of a transformable stent 200 in accordance with the present disclosure, the transformable stent 200 having a “wishbone”-style and the dimensions identified below which would allow that the transformable stent 200 to be capable fitting through a standard cystoscope or ureteroscope. The transformable stent 200 is similar to the transformable stent 100 having depicted in FIG. 1, like reference symbols are used to indicate like elements. The difference between the transformable stent 200 and the transformable stent 100 are disclosed below.

[0028] In some exemplary embodiments, the transformable stent 200 is comprised of three fins 212 that are aligned every 120 degrees. Each of the fins 212 can include a rounded tip 220 having a diameter that ranges from, for example, about .001 to .011 inches. The distance from the tips 220 to the longitudinal axis 206 can range from, for example, about .038 to .043 inches. Additionally, each of the fins 212 can have a first straight side 235 and a second straight side 240 which can comprise, for example, substantially straight edges. Each of the first straight side 235 and the second straight side 240 of each of the fins 212 can be the same or different. The transformable stent 200 can include as part of the at least two fins 212, a top fin 245 and two bottom fins 250. The first straight side 235 and second straight side 240 of top fin 245 can have a length that ranges from, for example, about .011 to .021 inches. The bottom fins 250 can have a first straight side 235 and a second straight side 240 of different lengths. The length of first straight side 235 can range from, for example, about .015 to .025 inches, and the length of the second straight side 240 can range from, for example, about .011 to .021 inches.

[0029] The inner surface 210 of the body 201 can have a diameter that ranges from, for example, about .019 to .029 inches. The outer surface 208 of the body 201 can have a diameter that ranges from, for example, about .031 to .041 inches. The transformable stent 200 can also have fillets 225 on edges that range from, for example, about .001 to .011 inches

in radius. Accordingly, the transformable stent 200 can fit within roughly a 2mm diameter (.079 inch) circle 260.

[0030] FIG. 3 shows another example of a transformable stent 300 in accordance with the present disclosure, the transformable stent 300 having a “wishbone”-style and the dimensions identified below which would allow that the transformable stent to be capable of fitting through a standard cystoscope. The transformable stent 300 is similar to the transformable stent 200 having depicted in FIG. 2, like references symbols are used to indicate like elements. The difference between the transformable stent 300 and the transformable stent 200 are disclosed below.

[0031] Each of the fins 312 can have a rounded tip 320 having a diameter that ranges from, for example, about .007 to .017 inches. The distance from the tips 220 to the longitudinal axis 306 can range from, for example, about .036 to .042 inches. The inner surface 310 can have a diameter that ranges from, for example, about .025 to .035 inches. The outer surface 308 can have a diameter that ranges from, for example, about .048 to .058 inches. The transformable stent 300 can also have fillets on edges 325 that range from, for example, about .005 to .017 inches in radius. The transformable stent 300 can include as part of the at least two fins 312, a top fin 345 and two bottom fins 350, however different from transformable stent 200, the top fin 340 does not have substantially straight edges and bottom fins 350 only has a first straight side 335. The first straight side of the bottom fin can have a length that ranges from, for example, about .004 to .014 inches. Accordingly, the transformable stent 300 can fit within roughly a 2mm diameter (.079 inch) circle 360.

[0032] FIG. 4 shows an example of a transformable stent 400 in accordance with the present disclosure, the transformable stent 400 having an “omega”-style design. The transformable stent 400 is similar to the transformable stent 100 having the “wishbone”-style depicted in FIG. 1, except the transformable stent 400 includes two fins 412, like references symbols are used to indicate like elements. When the transformable stent 400 is radially compressed, the fins 412 rotate towards each other, thereby moving the orientation of the transformable bore 411 from a default position 413A to a second position 413B. The roundedness of the outer surface 408 allows the radial forces that act upon it to disperse across its surface, leading to a minimal level bore deformation.

[0033] Referring to FIGs. 1-3, in certain embodiments, other suitable dimensions may be used. For example, in certain embodiments, the distance between the outer wall 108, 208, 308, 408, and the inner wall 110, 210, 310, and 410, may be relatively increased to provide improved “pushability.”

[0034] FIG. 5 shows an example of a transformable stent 500 in accordance with the present disclosure, the transformable stent 500 having a “hinge”-style design. The transformable stent 500 is similar to that of the transformable stent 400 having the “omega”-style design depicted in FIG. 4, like references symbols are used to indicate like elements. The difference between the transformable stent 500 and the transformable stent 400 are disclosed below.

[0035] The transformable stent 500 exhibits two main features. One being a series of split transformable bores 511 which are features of the two fins 512. When a radially compressive force acts upon the transformable stent 500, the fins 512 rotate about the junction 565 of the fins 512 towards each other, thereby moving the orientation of the transformable bores 511 from a default position 513A to a second position 513B.

[0036] FIG. 6 shows an example of a transformable stent 600 in accordance with the present disclosure, the transformable stent 600 having a “spline”-style design. The transformable stent 600 is similar to that of the “hinge”-style design depicted in FIG. 5, like references symbols are used to indicate like elements. The difference between the transformable stent 600 and the transformable stent 500 are disclosed below.

[0037] The transformable stent 600 can have an elongated body 601 that is constructed to have a spline feature 670 arranged in an s-shape that extends from the proximal end 602 to the distal end 604. When a radially compressive forces deforms the transformable stent 600, the ends 672 and 674 of the spline curl upon themselves, forming a transformable bore 611 in a second orientation 613B. Note that an s-shape is not necessarily required by the mechanism of this transformable stent 600 where the ends 672 and 674 curl towards themselves for the appropriate function.

[0038] FIG. 7 shows an example of a transformable stent 700 in accordance with the present disclosure, the transformable stent 700 having an “arrow”-style design. The transformable stent 700 is similar to that of the “hinge”-style design depicted in FIG. 5, like references symbols are used to indicate like elements. The difference between the transformable stent 700 and the transformable stent 500 are disclosed below.

[0039] The transformable stent 700 includes three fins 712 of which two are side fins 776 and one of which is a bottom fin 750. The side fins 776 can be a perpendicular to the bottom fin 750 and all of the fins 712 meet at the same point 765. The inner corners of the fins 712 feature two transformable bores 711. When radially compressed, the side fins 776 rotate towards the bottom fin 750, thereby moving the orientation of the transformable bores 711 from a default position 713A to a second position 713B having an arrow shape.

The bottom fin 750 can remain stationary which helps situate the transformable stent 700 in the undilated ureteral geometry.

[0040] In certain embodiments the transformable stents can have the traditional pigtail curls on the proximal and distal ends for helping to anchor the transformable stents. The size and shape of these curls can be as needed and understood in the art. In certain embodiments, the curls can have a lower-profile/size. This can be produced, for example, by a lower stent durometer that yields increased amount of friction.

[0041] Various suitable coatings, can be placed on the transformable stent. In certain embodiments, the entirety of the stent is coated, effectively coating both the “inside” and “outside” of the stents in the closed bore orientation.

[0042] Beneficial outcomes of using the disclosed transformable stents include improved peristalsis of ureter which can be measured in animal models, improved vital signs in animal models, and improved urine flow in animal models.

[0043] In operation, the transformable stents provided herein can be utilized on patients by urologists after performing ureteroscopy or ureteroscopy with lithotripsy. After kidney stone removal, a patient’s ureter is often inflamed from the procedure. In order to facilitate the passage of urine and any remaining kidney stones, the device can be placed into a patient’s ureter after the procedure, using, for example, a guidewire and stent positioner. Once in place, the device can be deployed by, for example, removing the sheath that encompasses it. Successful deployment can result in the transformable stent anchoring in the kidney and bladder so as to limit migration. In certain embodiments, using a contiguously closed bore has the effect of restricting the transformable stent from transaxially coming off of the guidewire. In certain embodiments, the transformable stent can be designed to have a relaxed configuration, in which the shape of the transformable bore is designed to be more closed allowing for the stent to ‘hug’ the guidewire more closely. A relaxed configuration can include, for example, a decreased gap angle between two lever fins or a decreased gap distance with constant gap angle.

[0044] In certain configurations, the transformable stent can be similar to Cook’s Resonance Metallic Ureteral Stent deployed via sleeve, where the sleeve/transformable stent combination is then deployed over a guidewire and the sleeve being removed after deployment.

[0045] Additionally, in certain configurations, a guidewire with increased thickness relative to a typical guidewire can be used.

[0046] Removal of the transformable stent is encouraged to be completed by an urologist; however, a patient can also remove the transformable stent on their own. Stent removal can be facilitated by, for example, a wire that is attached to the distal end of the transformable stent. The transformable stent can be placed and removed slowly so as to not injure or cause significant discomfort to the patient.

[0047] Transformable stents in accordance with the present disclosure can be intended for single use applications. As such, prior to use, it is encouraged that the transformable stents be properly stored in their original packaging, in order to assure sterility before use.

[0048] A number of embodiments of the invention have been described. Nevertheless, it will be understood that various modifications may be made without departing from the spirit and scope of the invention. Accordingly, other embodiments are within the scope of the following claims.

[0049] Disclosed are materials, systems, devices, compositions, and components that can be used for, can be used in conjunction with, can be used in preparation for, or are products of the disclosed methods, systems and devices. These and other components are disclosed herein, and it is understood that when combinations, subsets, interactions, groups, etc. of these components are disclosed that while specific reference of each various individual and collective combinations and permutations of these components may not be explicitly disclosed, each is specifically contemplated and described herein.

WHAT IS CLAIMED IS:

1. A transformable ureteral stent that purposefully adapts to a dynamic ureteral environment, the ureteral stent comprising:
 - an elongated body comprising a proximal end, a distal end, a longitudinal axis, an outer surface, and an inner surface, wherein the inner surface defines a transformable bore that extends along the longitudinal axis from the proximal end to the distal end; and
 - at least two fins projecting radially away from the outer surface of the body; wherein the transformable bore comprises:
 - (a) a default orientation comprising an open bore defining a longitudinally open channel; and
 - (b) a second orientation comprising a closed bore defining a longitudinally closed channel, wherein the transformable bore is moveable from the default orientation to the second orientation upon radial compression forces being applied to the outer surface.
2. The transformable ureteral stent of claim 1, wherein the inner surface of the body has a diameter which is reduced upon the transformable bore moving from the default orientation to the second orientation, wherein the diameter is reducible up to the point above where urine flow through the transformable bore would be compromised.
3. The transformable ureteral stent of claim 2, wherein the diameter is reduced by 40% upon the transformable bore moving from the default orientation to the second orientation.
4. The transformable ureteral stent of claim 1, wherein the at least two fins comprise a flexible material that is soft to medium soft based on the Shore hardness scale, and wherein the body comprises a flexible material that is medium hard to hard based on the Shore hardness scale.
5. The transformable ureteral stent of claim 4, wherein the at least two fins have a durometer between about 15-40A and the body has a durometer between about 80-90A.
6. The transformable ureteral stent of claim 1, wherein the at least two fins and the body comprises a flexible material that is medium soft to medium hard based on the Shore hardness scale.
7. The transformable ureteral stent of claim 6, wherein the at least two fins and the body have a durometer between about 40-70A.

8. The transformable ureteral stent of claim 1, wherein the at least two fins and the body comprises a flexible material that is medium hard to hard based on the Shore hardness scale.

9. The transformable ureteral stent of claim 8, wherein the at least two fins and the body have a durometer between about 85-90A.

10. The transformable ureteral stent of claim 2, wherein the default orientation and the second orientation support urine flow around the outer surface of the stent in addition to through the transformable bore.

11. The transformable ureteral stent of claim 1, wherein the at least two fins extend longitudinally from the proximal end to the distal end.

12. The transformable ureteral stent of claim 1, wherein the outer surface of the body has a diameter of about .036 inches.

13. The transformable ureteral stent of claim 9, wherein the inner surface of the body has a diameter of about .024 inches.

14. The transformable ureteral stent of claim 10, wherein each of the at least two fins has a tip that is about 0.040 inches from the longitudinal axis.

15. The transformable ureteral stent of claim 1, wherein the radial compression forces are provided by a normal and pathologic ureteral and proximal tissue physiology.

16. The transformable ureteral stent of claim 1, wherein the number of fins is two.

17. The transformable ureteral stent of claim 1, wherein the number of fins is three.

18. A transformable ureteral stent that purposefully adapts to a dynamic ureteral environment, the ureteral stent comprising:

an elongated body comprising a proximal end, a distal end, a longitudinal axis, an outer surface, and an inner surface, wherein the inner surface defines a transformable bore that extends along the longitudinal axis from the proximal end to the distal end; wherein the transformable bore comprises:

- (a) a default orientation comprising an open bore defining a longitudinally open channel; and
- (b) a second orientation comprising a closed bore defining a longitudinally closed channel, wherein the transformable bore is moveable from the default orientation to the second orientation upon radial compression forces being

applied to the outer surface of the body, wherein the inner surface of the body has a diameter which is reduced upon the transformable bore moving from the default orientation to the second orientation, wherein the diameter is reducible up to the point above where urine flow through the transformable bore would be compromised.

19. The transformable ureteral stent of claim 18, wherein the diameter is reduced by 40% upon the transformable bore moving from the default orientation to the second orientation.

20. The transformable ureteral stent of claim 18, wherein the body comprises a flexible material that is medium hard to hard based on the Shore hardness scale.

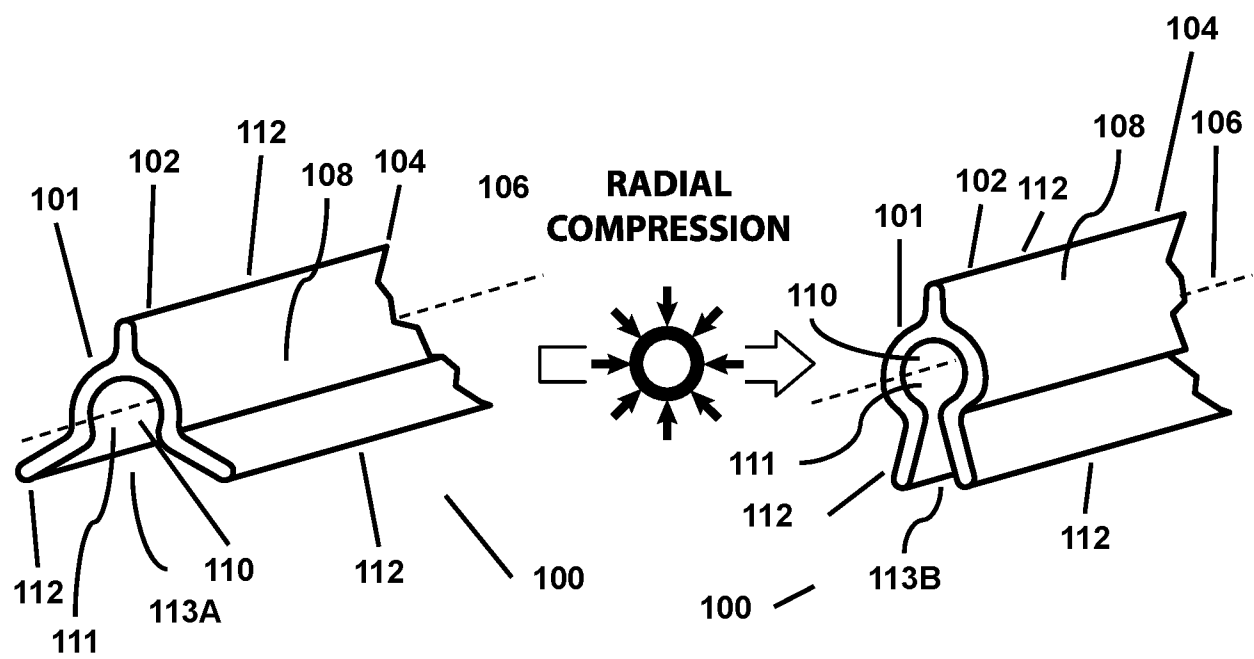
21. The transformable ureteral stent of claim 20, wherein the body has a durometer between about 80-90A.

22. The transformable ureteral stent of claim 21, wherein the body has a durometer between about 85-90A.

23. The transformable ureteral stent of claim 18, wherein the body comprises a flexible material that is medium soft to medium hard based on the Shore hardness scale.

24. The transformable ureteral stent of claim 23, wherein body has a durometer between about 40-70A.

25. The transformable ureteral stent of claim 18, wherein the default orientation and the second orientation support urine flow around the outer surface of the stent in addition to through the transformable bore.



2/7

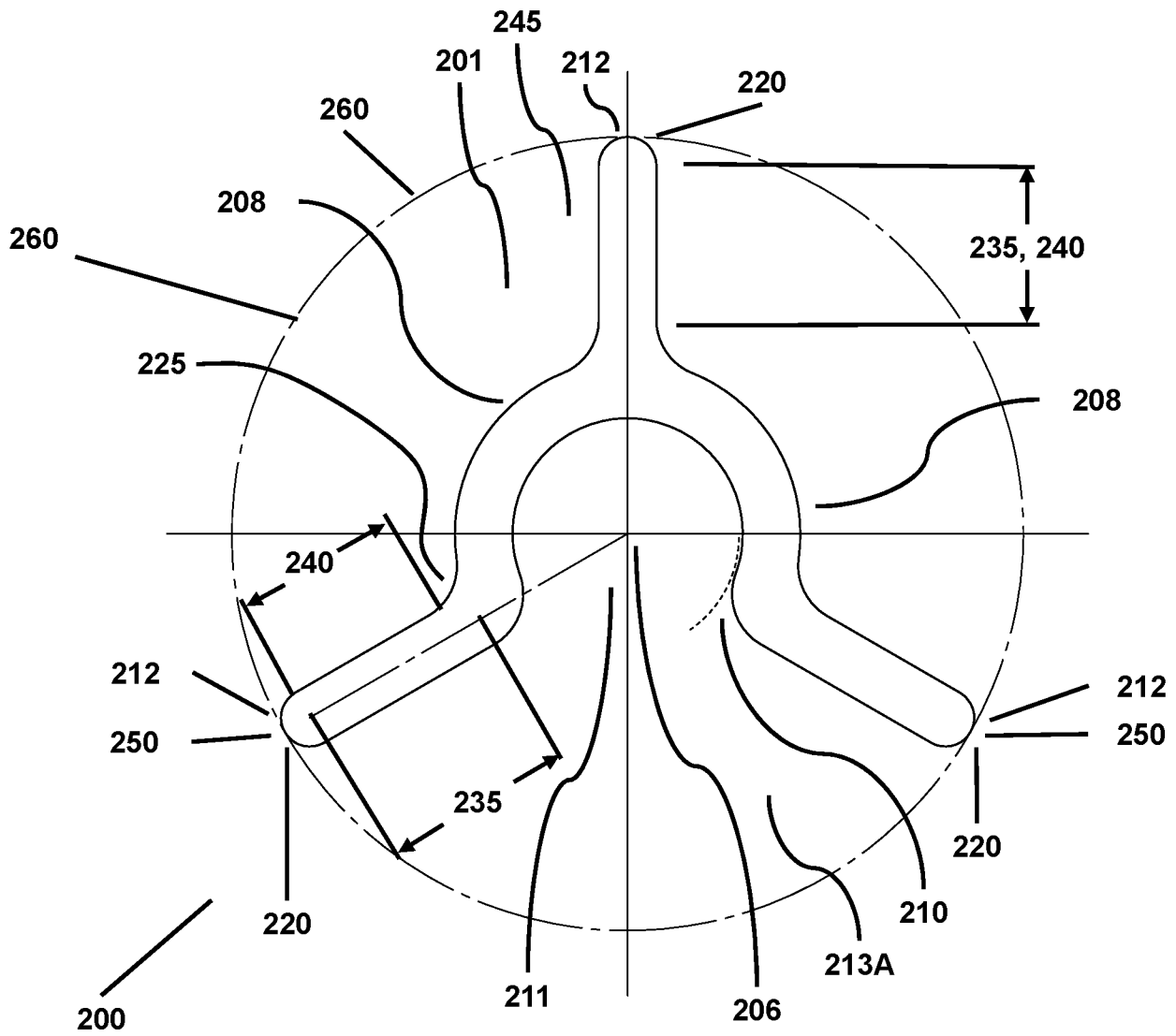


FIG. 2

3/7

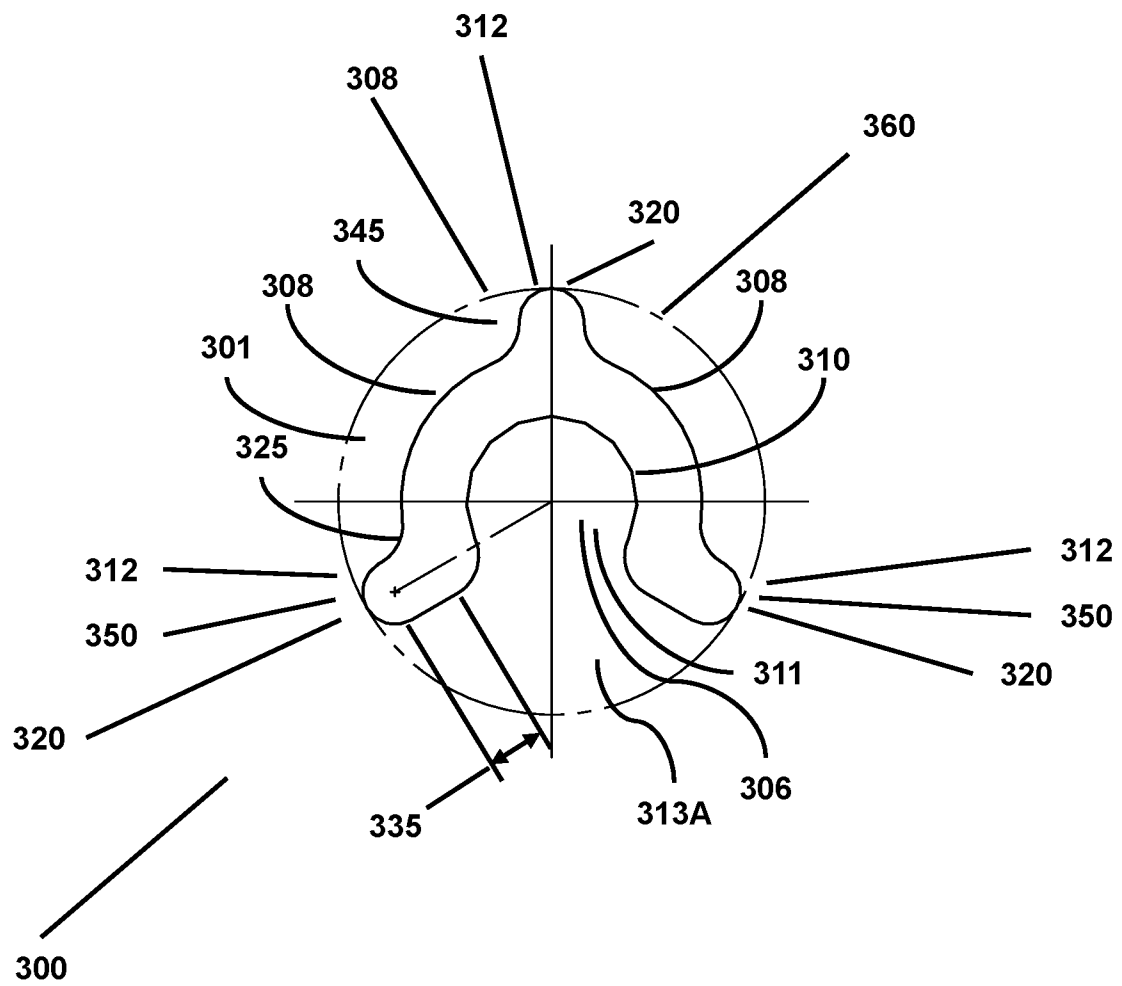


FIG. 3

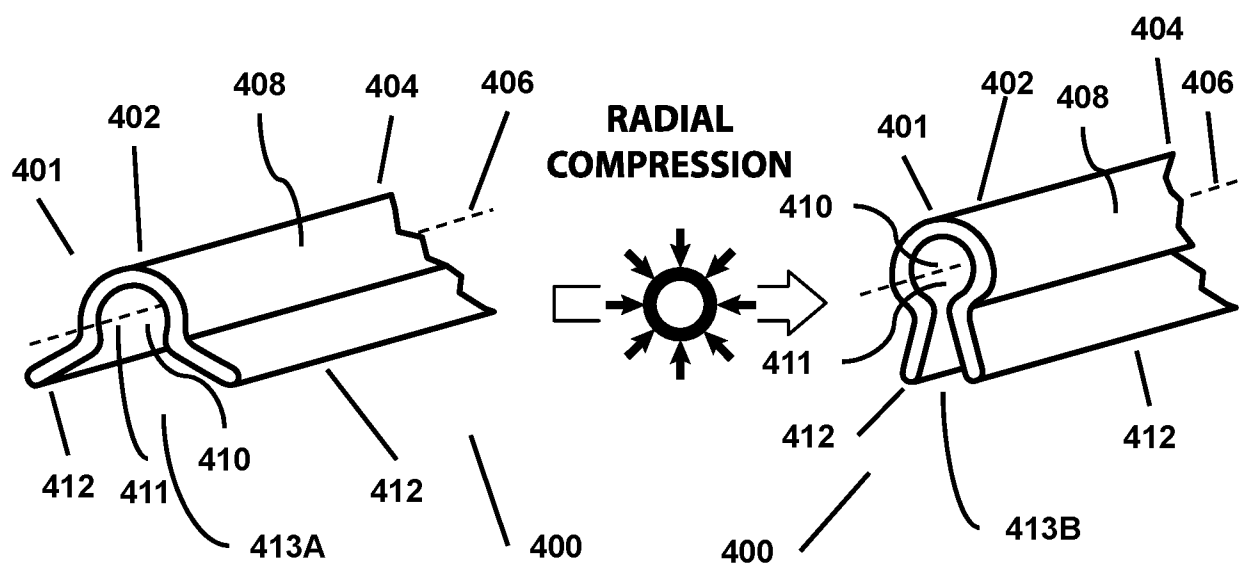


FIG. 4

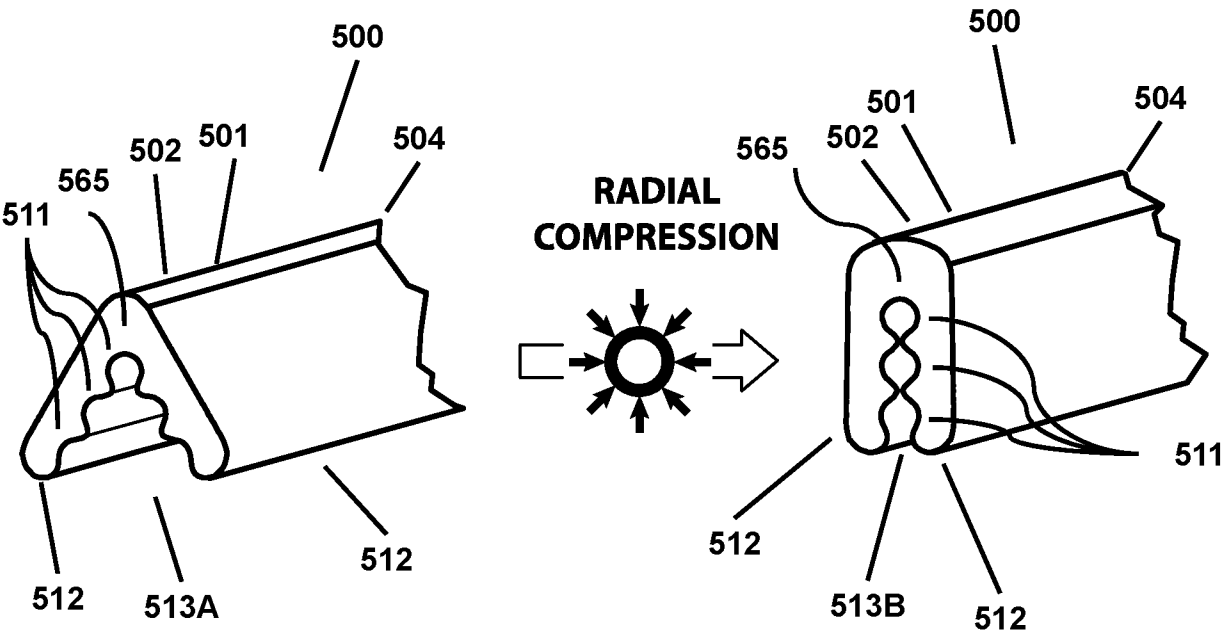


FIG. 5

6/7

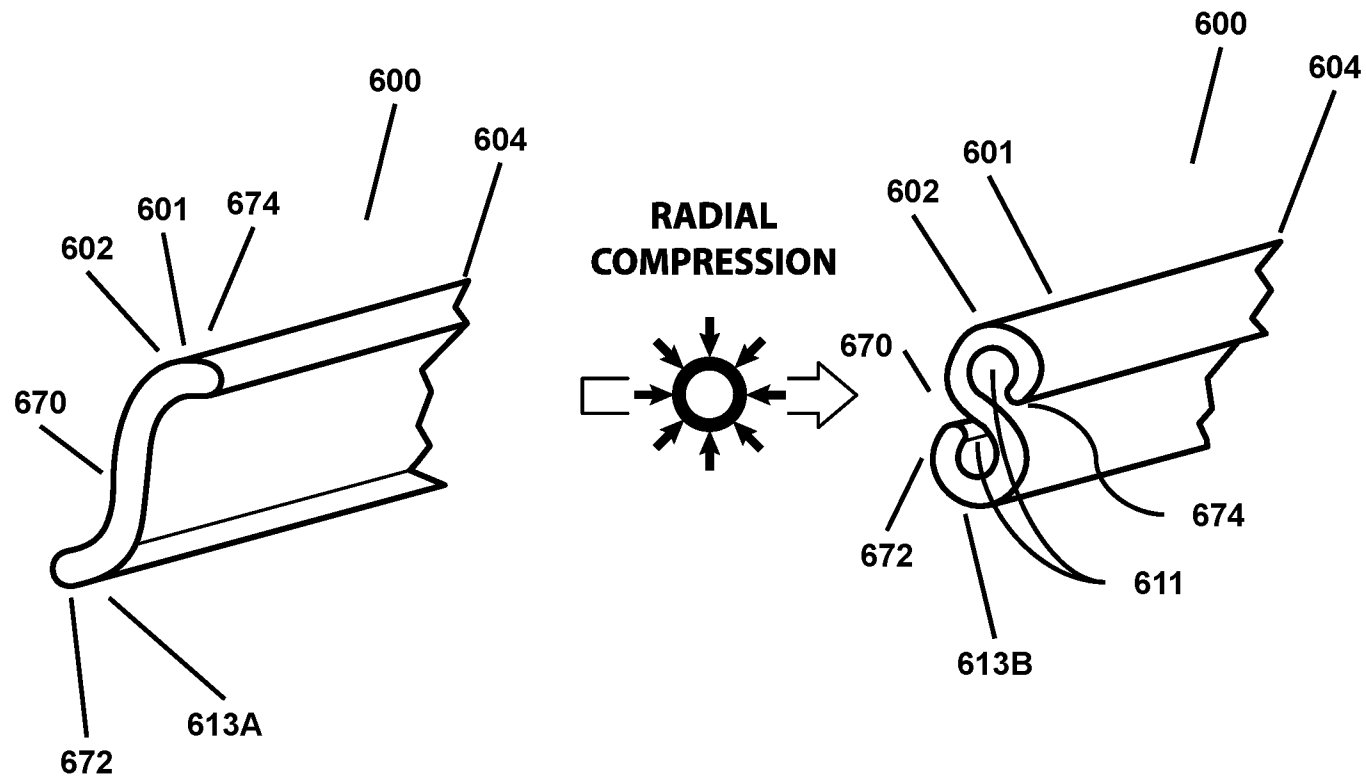


FIG. 6

7/7

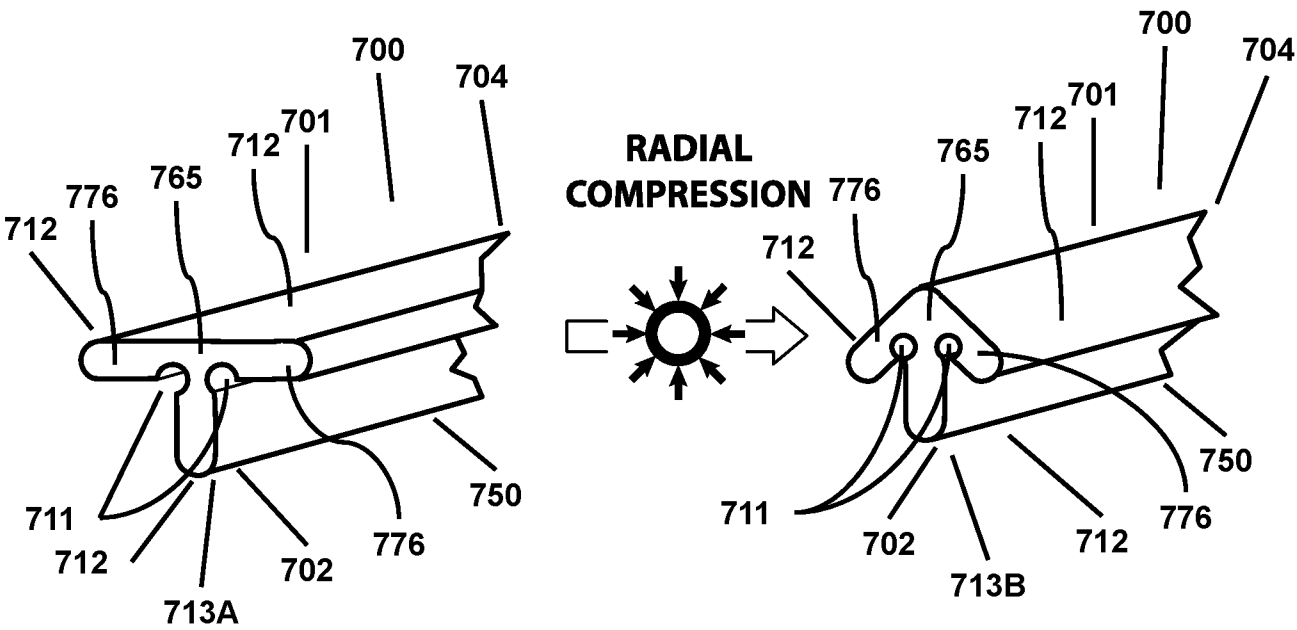


FIG. 7

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 16/44780

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 2/04 (2016.01)

CPC - A61F 2002/048, A61F 2/04, A61F 2002/825, A61F 2/844, A61F 2/92, A61F 2/82

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 2/04 (2016.01)

CPC - A61F 2002/048, A61F 2/04, A61F 2002/825, A61F 2/844, A61F 2/92, A61F 2/82

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched (UPC) 623/23.7, 623/1.1, 23.64-23.7; (CPC) A61F 2/04-2/07, A61F 2/82-2/95
(Search term limited; see below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PubWest (PGPB, USPT, EPAB, JPAB); Google; PatBase (All);

Search Terms: Ureter*, stent, chang*, dynamic*, adjust*, vary*, shape*, size*, geometry*, configuration*, soft*, pliab*, auto*, self*, shore, durometer, wing*, arm*, finger*, projection*, extension*, longitudinal*, rib*, hard*, flex*, compress*, collaps*, shrink*, squeeze*, natural, bod

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/0183853 A1 (MITCHELL et al.) 04 December 2002 (04.12.2002) Entire document, especially Abstract, para[0008]- para[0009], para[0025], para[0039]- para[0043] and FIGS. 2, 4, 10.	18-19, 25
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Y		20-24
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A		1-17
Y	US 2015/0134073 A1 (TANG et al.) 14 May 2015 (14.05.2015) Entire document, especially Abstract, para[0043].	20-24
A	US 2011/0230950 A1 (KNAPP) 22 September 2011 (22.09.2011) Entire document, especially Abstract, para[0071]- para[0073] and FIGS. 19-20.	1-17
A	US 2008/0288082 A1 (DEAL) 20 November 2008 (20.11.2008) Entire document, especially Abstract, para[0043] and FIG. 3.	1-17
A	US 2004/0143209 A1 (LIU et al.) 22 July 2004 (22.07.2004) Entire document, especially Abstract, para[0008]- para[0009].	1-17
A	US 5,662,713 A (ANDERSEN et al.) 02 September 1997 (02.09.1997) Entire document, especially Abstract, col 7, ln 16-40.	1-17
A	US 2003/0153970 A1 (RAO et al.) 14 August 2003 (14.08.2003) Entire document.	1-17
A	US 5,989,207 A (HUGHES) 23 November 1999 (23.11.1999) Entire document.	1-17
A	US 3,938,529 A (GIBBONS) 17 February 1876 (17.02.1876) Entire document.	1-17

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

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

Date of the actual completion of the international search

22 September 2016

Date of mailing of the international search report

20 OCT 2016

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
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