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(54) **Title:** DYNAMIC LENGTH URETERAL STENT FOR IMPROVED PATIENT COMFORT

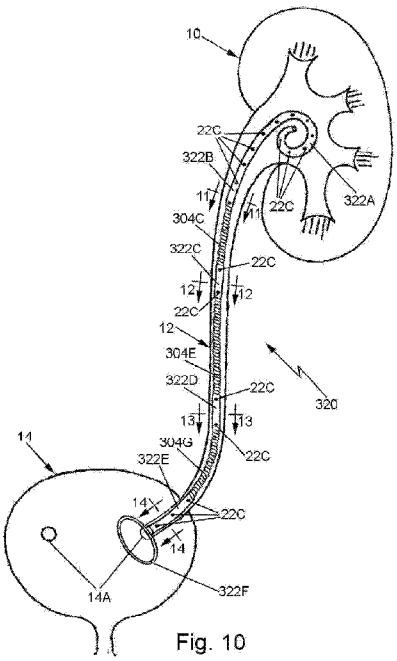


Fig. 10

(57) **Abstract:** A ureteral stent having a proximal section, a distal section and an intermediate section is disclosed. The proximal section is configured for disposition within a kidney and includes a tubular portion in communication with the interior of the kidney. The distal section is configured for disposition within the bladder and includes a portion to anchor the distal section therein. The intermediate section is connected between the proximal section and the distal section and has a passageway extending therethrough in fluid communication with the tubular portion of the proximal section. The intermediate section is configured to elongate dynamically to accommodate ureteral length changes in automatic response to changes in spacing between the kidney and the bladder.

DYNAMIC LENGTH URETERAL STENT FOR IMPROVED PATIENT COMFORT

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not Applicable

CROSS-REFERENCE TO RELATED APPLICATIONS

This PCT application claims priority under 35 U.S.C. §119(e) of United States Provisional Patent Application Serial Nos. 62/490,684 filed on April 27, 2017, entitled DYNAMIC LENGTH URETERAL STENT FOR IMPROVED PATIENT COMFORT, the disclosure of which is incorporated by reference herein.

SUBMITTED ON A COMPACT DISK

"Not Applicable"

FIELD OF THE INVENTION

This invention relates generally to stents and particularly to ureteral stents.

BACKGROUND OF THE INVENTION

The ureters are the anatomic conduit for urine from the kidneys to the bladder. Obstruction of a ureter can occur from disease in the ureteral lumen such as a tumor, or a kidney stone that has migrated into the ureter, or from disease processes that cause compression or other narrowing of the lumen, such as an external mass or inflammatory stricture. Ureteral stents are medical devices designed to relieve all such obstructions to urine flow and maintain a conduit in the ureteral lumen that is adequate for urine flow from the kidney to the bladder in the presence of an actual or potential obstruction. Ureteral stents have been in common use for decades with excellent clinical results in this primary role. However, in general, ureteral stents are poorly tolerated by the patient because they also are irritating to the various sensory nerves in the bladder. Typically, the patient trades relief of the kidney pain caused by the ureteral obstruction for the immediate and persistent feelings of irritation and urinary urgency caused by the segment of the stent in the bladder.

There are no sensory nerves in the lining of the kidney or the ureter, and kidney pain is caused only by active stretching of the kidney capsule when there is obstruction to urine drainage. But, the bladder wall and mucosal lining has abundant sensory nerves, especially on the trigone area where the ureters enter the bladder.

The segment of a typical urinary stent that is in the bladder, that may be in constant or intermittent contact with the sensitive bladder mucosal lining, is generally accepted as the main cause of patient symptoms from a ureteral stent. A lesser cause of stent discomfort is the pain that can occur by stretching of the kidney capsule from urinary reflux during voiding. The intravesical hydraulic pressure caused by bladder contraction during normal voiding is around 50-60 centimeters of water pressure. The kidney capsule starts to stretch and transmit pain signals when the pressure in the renal pelvis acutely rises above about 15 centimeters of water pressure. This is not typically a major cause of patient discomfort or complaint because of the short duration of voiding and the delay of pressure buildup in the renal pelvis caused by the inherent resistance to rapid retrograde urine flow of the long narrow ureter and stent combination.

It should be pointed out at this juncture that the words "proximal" and "distal", which are used in this application, are relative terms used in different ways in different patents. However, to establish a convention for purposes of the disclosure and discussion herein, the kidney region shall be referred to as being "proximal," the bladder region as being "distal" and the intervening or intermediate ureteral segment as being "middle."

All commercially available ureteral stents have three regions or segments: 1) a proximal segment that has a spring-like, pre-formed, memory shape that curls up inside the urine collecting system of the kidney, predominantly the renal pelvis, that serves to retain the stent in the kidney and prevent distal migration (i.e., to keep it from falling out); (2) an elongate middle segment (typically a straight hollow tube with multiple perforations) that traverses the ureter between the kidney and bladder that provides the urine a conduit to bypass any obstruction in the ureter; and (3) a distal, bladder (intravesical) segment that completes the conduit, has a pre-formed, memory shape that keeps the stent from migrating proximally and that provides an end that is visible on simple cystoscopy to facilitate removal. The most common ureteral stents are a hollow tube with multiple apertures or holes through the wall along its entire length intended to enhance urine drainage through and around it. Stents typically are made with a low friction, highly flexible biocompatible plastic that has a sufficient shape memory resilience to form the retaining coils in the ends. Fig. 2 shows a common prior art ureteral stent in place.

Multiple attempts have been made by the medical device industry to mitigate the bladder irritation problem of ureteral stents. See for example, U.S. Patent Nos.: 6,764,519; 6,849,069; 6,656,146; 6,945,950; 6,991,614; 7,316,663; 7,678,154; 8,088,170; 8,246,689 and 8,852,289. In fact, stent manufacturers have attempted to address the bladder irritation problem in various ways, such as by varying the materials (e.g. softer, more lubricious plastics, wicking materials, etc.) and producing designs to alter the shape and reduce the volume of material in the bladder segment (e.g., tail stents, anchoring features to eliminate as much as possible the bladder component and the like). However, to date none have attained that goal. One reason may be that the prior art has not adequately recognized the effect of renal motion.

While renal motion has been considered in stent design, it has been underappreciated in regards to the comfort problem. In particular, more than simple contact with the bladder surface, the discomfort caused by ureteral stents is due principally to the combination of stent motion in the bladder and the unavoidable dynamic mucosal contact of the intravesical segment of the stent. This motion is caused by the movement of the kidneys with respiration that effectively lengthens and then shortens the straight line ureteral length (i.e., the distance between the renal pelvis and the relatively fixed position of the ureteral orifice during each respiratory cycle). The trigone and ureteral orifices are fixed anatomically in the pelvis by blood vessels and nerves. On the other hand, the kidneys are highly mobile. With every breath, the kidneys are moving several centimeters up and down in the retroperitoneum. They move as much as six centimeters or more with a deep breath relative to the essentially fixed position of the ureteral orifice at the base of the bladder. In healthy individuals, all distance changes between the ureteral orifice and kidney are managed by the lengthening and shortening of the very flexible, somewhat redundant and elastic ureter. This includes straightening and recurving of curved regions and true ureteral tissue elasticity.

There is no ureteral stent yet produced that is designed to mimic these normal anatomic characteristics of ureteral function. The middle segment of all current stents is just a straight tube with no significant elasticity or intentional capacity to match active anatomic ureteral curvature or length changes. All existing ureteral stents are simply designed to coil or uncoil on the ends, or slide up or down

in the ureter to manage the distance changes between the bladder and kidney that occur with every breath. The fact that the proximal (renal end) of the stent is essentially fixed within the kidney by the size of the coil relative to the size of the renal pelvis (in most patients) means that any changes in the straight line distance to the ureteral orifice are mechanically reconciled by motion of the stent in the bladder. This physiologic kidney movement is the major reason for stent discomfort, because it causes the bladder portion of the stent to be constantly rubbing and/or poking the trigone or other sensitive area of the bladder wall and mucosa.

Evidence that stent motion in the bladder from normal physiologic kidney movement is the major reason for stent discomfort includes the following. (1) It is well known from performing millions of cystoscopies under local anesthesia or no anesthesia, that the bladder mucosa and bladder wall in general are exquisitely sensitive to active touch from any cystoscopic instrument. (2) Also, it is well known from a past era when bladder stones were common, that when the patient was physically at rest the stones were typically asymptomatic, but, when the patient was active, being jostled, or voiding, they caused discomfort. It was movement of the stones in the bladder, or bladder movement around the stones with voiding that caused symptoms, rather than just their static presence. So, movement of the bladder segment of the stent has to play a similar role in the discomfort problem, much more so than just the presence of a stationary object. (3) Finally, stent discomfort may be elicited in a patient by deep breathing as opposed to holding their breath or very shallow breathing. Also relevant is what may be termed the "tachyphylaxis of touch". One can take any sensitive area of your body and touch it with your most sensitive fingertip. If you then hold everything motionless, within 10 seconds or less you cannot detect, either with your fingertip or the area being touched, that there is anything in contact (being touched). Movement or other sensory irritation such as heat or cold is required for detection. These observations make up the key principle of the thesis for a new approach to what can be referred to as a "comfort" stent, i.e., a ureteral stent constructed in accordance with this invention.

As discussed above, the bladder mucosa and bladder wall in general are exquisitely sensitive to touch. So, constant or frequent intermittent movement of the bladder segment of the stent is much more irritating to a patient than just the presence of a stationary object. With the kidneys moving several centimeters up and

down in the retroperitoneum during normal respiration and the inelasticity of current ureteral stents, choosing an ideal size (length) stent for any patient is somewhat difficult, and it causes most urologists to err toward the long side for size in order to avoid any risk of retrograde migration. This increases the amount of stent mass and movement in the bladder, further aggravating the discomfort problem.

The present invention is designed to resolve the physiologic discrepancies of existing stents with the normal ureter toward a better stent design with two essential goals, but also with highly beneficial and unique secondary goals.

The first essential goal is to eliminate, as much as possible, any movement of the stent segment that is present within the bladder caused by respiratory or other anatomic movement of the kidneys. This means that all the distance changes with kidney movement must be taken up, absorbed or otherwise reconciled in the middle (preferably) or kidney, segments of the stent.

The second essential goal is to choose a segment shape and size at the distal/bladder end that will minimize the mucosal contact, prevent retrograde migration and make it easy to achieve a relatively motionless positioning of the stent at the ureteral orifice.

Currently, all prior art ureteral stents cause a cessation of normal ureteral peristalsis after being in place for a few days. Why this occurs is poorly understood, but it is believed to be a detrimental, if unavoidable, side effect. Also, when treating renal stones with lithotripsy, it is always most desirable to avoid placing a ureteral stent if possible because the stent itself can prevent the passage of stone debris.

Thus, there is a need for an improved ureteral stent to solve the patient comfort problem and other problems that currently are associated with all ureteral stents because of non-physiologic movement and the bladder component. Such a stent must provide adequate urinary drainage, but eliminate, or at least greatly reduce, bladder irritation. The subject invention addresses that need by providing a stent which is configured to address renal motion by dynamically changing length in response to renal motion. Moreover, the stents of this invention more closely mimic the normal ureter functionally, thereby providing potentially advantageous additional goals such as the preservation of normal ureteral peristalsis, and improvement in the passage of stone debris. Further still, the stents of this invention

may solve additional functional and physiologic problems associated with conventional ureteral stents.

All references cited herein are incorporated herein by reference in their entireties.

SUMMARY OF THE INVENTION

In accordance with one aspect of the invention there is provided a ureteral stent for a living being. The ureteral stent comprises a proximal section, a distal section and a middle or intermediate section. The proximal section is configured for disposition within the kidney of the living being and includes a tubular portion having a first, e.g., central, passageway extending therethrough and at least one aperture in fluid communication with the interior of the kidney and the first passageway. The distal section is configured for disposition within the bladder of the living being and includes a portion configured for engaging a portion of the bladder to anchor the distal section in place. The intermediate section is tubular and connected between the proximal section and the distal section. The intermediate section has a second, e.g., central, passageway extending therethrough that is in fluid communication with the first passageway. The intermediate section is configured for location within a ureter of the being is also configured to elongate dynamically to accommodate ureteral length changes in automatic response to changes in spacing between the kidney and the bladder of the living being.

In accordance with one preferred aspect of this invention, the proximal and intermediate sections are configured to generate a retrograde tension force to limit, as much as possible, the motion of the distal section and to hold the distal section against the ureteral orifice.

In accordance with another preferred aspect of this invention the distal end section is configured to prevent retrograde migration and minimize mucosal contact.

In accordance with another preferred aspect of this invention the tubular intermediate section is configured to dynamically expand and contract in diameter to assist in maintaining normal ureteral peristalsis and/or passage of kidney stone debris therethrough.

In accordance with another preferred aspect of this invention the intermediate section comprises a plurality of undulations.

In accordance with another preferred aspect of this invention the intermediate section comprises a plurality of coils.

In accordance with another preferred aspect of this invention the plurality of coils of the intermediate section together define the second passageway.

In accordance with another preferred aspect of this invention the plurality of coils comprise portions of a continuous wire, with the continuous wire including a portion extending along the tubular portion of the proximal section, and a portion extending along the distal section.

In accordance with another preferred aspect of this invention the distal section comprises a generally planar ring.

In accordance with another preferred aspect of this invention the intermediate section includes a distally located open end having a central longitudinal axis and wherein the distal end section comprises a planar ring connected to the distally located open end.

In accordance with another preferred aspect of this invention the plane of the generally planar ring is oriented approximately perpendicularly to the central longitudinal axis.

In accordance with another preferred aspect of this invention the plane of the generally planar ring is oriented approximately parallel to the central longitudinal axis.

In accordance with another preferred aspect of this invention the generally planar ring is formed of a shape memory material.

In accordance with another preferred aspect of this invention the proximal section comprises a planar spiral.

In accordance with another aspect of this invention the proximal section comprises a plurality of coils.

Another aspect of this invention is an anchor for a ureteral stent having a proximal section and an intermediate section. The proximal section is configured for disposition within the kidney of a living being and includes a tubular portion having at least one aperture therein in communication with the interior of the kidney. The intermediate section is generally tubular and configured for disposition within the ureter of the living being. The intermediate section is in fluid communication with the proximal section and terminates at an open end. The anchor is configured for

disposition within the bladder of the being to prevent retrograde migration of the stent and to minimize mucosal contact. The anchor comprises a ring and a plurality of filaments. The ring is formed of a shape memory material. Each of the filaments is connected to the intermediate section adjacent the open end and is also connected to a respective portion of the ring.

In accordance with another aspect of this invention the open end of the tubular intermediate section includes a central longitudinal axis and the ring forming the anchor is generally planar, with the plane thereof extending generally perpendicularly to the central longitudinal axis of the tubular intermediate section.

Still another aspect of this invention is an anchor for a ureteral stent having a proximal section and an intermediate section. The proximal section is configured for disposition within the kidney of a living being and includes a tubular portion having at least one aperture therein in communication with the interior of the kidney. The intermediate section is tubular and configured for disposition within the ureter of the living being. The intermediate section is in fluid communication with the proximal section and terminates at an open end having a central longitudinal axis. The anchor is configured for disposition within the bladder of the being to prevent retrograde migration of the stent and to minimize mucosal contact. The anchor comprises a ring or other shape formed of a shape memory material. The ring is generally planar, with the plane thereof being generally parallel to the central longitudinal axis of the intermediate section.

In accordance with another aspect of this invention the ring is directly connected to the open end of the intermediate section.

In accordance with another aspect of this invention the ring is indirectly connected to the open end of the intermediate section by plural filaments.

DESCRIPTION OF THE DRAWING

Fig. 1 is an illustration of one exemplary embodiment of a ureteral stent constructed in accordance with this invention shown in place in the body of a living human being;

Fig. 2 is an illustration similar to Fig. 1, but showing a conventional prior art ureteral stent in place in the body of a living human being;

Fig. 3 is an isometric view, slightly enlarged, of the exemplary stent shown in Fig. 1;

Fig. 4 is an isometric view similar to Fig. 3, but showing an alternative exemplary embodiment of a ureteral stent constructed in accordance with this invention;

Fig. 5 is an isometric view similar to Fig. 3, but showing still another alternative exemplary embodiment of a ureteral stent constructed in accordance with this invention;

Fig. 6 is an enlarged sectional view taken along line 6 – 6 of Fig. 5;

Fig. 7 is an enlarged isometric view of the portion of the ureteral stent shown within the broken line circle designated by the reference number 7 in Fig. 5;

Fig. 8 is an isometric view similar to Fig.7 but showing an alternative embodiment of the ureteral stent shown in Fig. 5;

Fig. 9 is an enlarged isometric view of an alternative proximal segment or section of a ureteral stent constructed in accordance with this invention;

Fig. 10 is an isometric view similar to Fig. 3, but showing yet another alternative exemplary embodiment of a ureteral stent constructed in accordance with this invention;

Fig. 11 is an enlarged sectional view taken along line 11 – 11 of Fig. 10;

Fig. 12 is an enlarged sectional view taken along line 12 – 12 of Fig. 10;

Fig. 13 is an enlarged sectional view taken along line 13 – 13 of Fig. 10;

Fig. 14 is an enlarged sectional view taken along line 14 – 11 of Fig. 10; and

Fig. 15 is an isometric view of a wire with coiled segments which forms a precursor in the making of the alternative embodiment of the ureteral stent shown in Fig. 10.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the various figures of the drawing wherein like reference characters refer to like parts, there is shown at 20 in Fig. 1 one exemplary embodiment of a ureteral stent constructed in accordance with this invention. Other exemplary embodiments of ureteral stents are shown in other figures and will be discussed later. Suffice it for now to state that all of the ureteral stents of this invention include three segments or sections, namely, a proximal section configured to be located in the kidney 10, an intermediate or middle section configured to be located in the ureter 12, and a distal section configured to be located in the bladder 14. In this regard, the ureteral stents of this invention are similar to prior art ureteral

stents. However, unlike prior art ureteral stents the stents of this invention make use of a middle, ureteral segment or section which serves as both the spring tensioning and length adjustment components. Moreover, the ureteral stents of this invention have simple anchoring segments at both end sections, as will be described in detail later.

Prior to describing the ureteral stents of this invention a brief discussion of a typical prior art ureteral stent is in order. To that end, as can be seen in Fig. 2, one such prior art ureteral stent 2 is shown. That stent basically comprises a proximal (kidney) section 4, a middle (ureteral) section 6, and a distal (bladder) section 8. The sections 4, 6 and 8 are preferably formed as an integral unit of any suitable flexible, biocompatible material. The proximal or kidney section in the form of a planar, spiral tubular coil having a central passageway (not shown) extending at least partially through it from a point adjacent its free end to the point at which it merges with the ureteral section 6. The coiled section is configured to be located within the kidney 10 and anchored therein by virtue of the spring-like nature of the coil. The coil section 4 includes a plurality of apertures 4A in communication with the central passageway of the coil section into which urine or other body fluids from the kidney can flow. The ureteral section 6 is an elongated tubular member which when in place extends through the ureter from the coil section 4 through the ureteral orifice 14A where it merges with the distal (bladder) section 8. The tubular ureteral section 6 is generally the same outside diameter as the coil section 4 and has a central passageway (not shown) extending through its entire length from the point at which it merges with the kidney section to the point where it merges with the distal (bladder) section 8. The inner diameter of the central passageway of the ureteral section 6 is the same as the inner diameter of the central passageway of the kidney section 4 and is in fluid communication therewith so that fluid flowing into the passageway from the kidney section can pass down the central passageway in the ureteral section. Moreover, like the kidney section the ureteral section 6 includes a plurality of apertures 6A along the length thereof and which are in fluid communication with the central passageway of the ureteral section and the interior of the ureter 12. The distal or bladder section 8 in the form of a spiral tubular coil having a central passageway (not shown) extending at least partially through it from a point adjacent its open free end to the point at which it merges with the ureteral

section 6. The coiled section 8 is configured to be located within the bladder 14 and anchored therein by virtue of the spring-like nature of the coil. The coil section 8 includes a plurality of apertures 8A in communication with the central passageway of the coil section through which urine or other body fluids from the kidney can flow for egress into the bladder. If desired the coil section 8 may include retrieval filaments 8B which extend out of the bladder to be used to effect the removal of the stent.

While the ureteral stents of this invention share several features of prior art ureteral stents, like that shown in Fig. 2, the stents of this invention differ in several significant respects. In this regard, all of the ureteral stents of this invention are designed in accordance with two critical goals, which are not achieved by prior art ureteral stents. The first goal is to eliminate, as much as possible, any movement of the stent segment that is present within the bladder during respiration. This means that all the stent length changes with kidney movement must be taken up, absorbed or otherwise reconciled in the middle (ureteral) segment or proximal (kidney) segment of the stent. The second goal is to choose a shape at the distal/bladder end that will minimize the mucosal contact, prevent retrograde migration and make it easy to achieve a relatively motionless positioning of the stent at or immediately adjacent to the ureteral orifice.

To achieve the first goal requires a region in the stent, proximal to the bladder segment that will expand and contract in length. Length change of at least 5 cm or greater, for an adult patient, must be accommodated with minimal changes in any internal tension force in the stent. Also, required is a relatively constant, small, tension force in the proximal direction on the distal, intravesical (bladder) segment of the stent. Some force in this direction must be present continuously to keep this bladder segment seated, as motionless as possible and essentially fixed (minimum relative motion) in position at or near to the ureteral orifice. It is estimated that a physiologically safe and adequate range of force that will achieve these goals is approximately 0.000 to 0.02 Newton, with a more desirable range being 0.0001 – 0.01 Newton, and with the most desirable range being 0.0005 – 0.003 Newton. This constant "pulling" force must be generated by one or both of the upper two segments of the stent, while the kidney segment serves as the "anchor" to provide the counterforce.

Turning now to Figs. 1 and 3, it can be seen that the exemplary embodiment of the ureteral stent 20 shown therein basically comprises an integral unit which is made up in sequence of a proximal (kidney) section 22, a middle (ureteral) section 24, and a distal (bladder) section 26. The proximal section is in the form of a planar spiral tubular coil 22A constructed like the distal coiled section of many prior art ureteral stents, e.g., coiled section 4 of Fig. 2. Thus, the kidney section 22 is formed of a flexible material defining a thin sidewall through which a central passageway (not shown) extends. That passageway extends at least partially through the kidney section from a point adjacent its free end 22A to the point 22B at which it merges with the ureteral section 24. The coiled section 22 is configured to be located within the kidney 10 and anchored therein by virtue of the spring-like nature of the coil. The coil 22 includes a plurality of apertures 22C in communication with the central passageway of the coil section into which urine or other body fluids from the kidney can flow.

The middle or ureteral section 24 is an elongated tubular member of generally the same outside diameter as the kidney section 22 and has a central passageway (not shown) extending through its entire length from the point 22B at which it merges with the kidney section 22 to its distally located free end 24A. The free end 24A is open. The inner diameter of the central passageway of the ureteral section 24 is the same as the inner diameter of the central passageway of the kidney section 22 and is in fluid communication therewith so that fluid flowing into the passageway from the kidney section can pass down the central passageway in the ureteral section 24. Moreover, the ureteral section includes a plurality of apertures 24C along the length thereof and which are in fluid communication with the central passageway of the ureteral section and the interior of the ureter 12. Unlike prior art ureter sections, the middle ureter section 24 of the ureteral stent 20 is in the form of a tension inducing "memory" spring in an undulating (e.g., sinusoidal) shape that is made up of a plurality of serially located undulations 24D. The plural undulations 24D coupled with the fact that the material making up the ureter section 24 is flexible and resilient enables the ureter section to automatically expand and contract in length in response to movement between the kidney and the bladder. The length of the undulations in this segment will be determined by their shape and dimensions necessary to achieve the desired in-situ length changes with respiration, while

maintaining a relatively constant tension force as described above. The space in the ureter created by this region of the stent in any cross-sectional view will vary depending on how the stent is being stretched and anatomical factors. Correctly sized for initial length, this configuration will fit comfortably within the body of the ureter and fully absorb any length changes required by respiratory movement of the kidney. The highly elastic and mobile ureter will readily adapt to such internal shapes, and the pulling force that results from the tension spring "memory" on the ends of the stent will remain fairly constant as long as the undulations are not straightened completely, i.e., some degree of undulation remain. It should be noted that the when the ureteral stent 20 is placed over a guidewire for insertion, the straightened stent may be around 6 cm, or more, longer than the measured ureteral length of the stent at rest. Proper sizing for a patient will take this into account.

As best seen in Fig. 3 a short length 24E of the ureter section contiguous with the open free end 24A is generally linear, i.e., doesn't include any undulations 24D. That portion 24E of the ureter section has a longitudinally extending central axis A and is configured to be located within the ureter adjacent ureteral orifice 14 when the ureteral stent 20 is in place.

The distal or bladder segment 26, which serves as the intravesical segment of the ureteral stent 20 is best seen in Fig. 3 and basically comprises a ring 26A and plural, e.g., four, strings or filaments 26B. The strings may be somewhat similar to that of the Polaris Loop™ stent sold by Boston Scientific Corporation and shown in U.S. 8,845,752. To that end, one could take the same termination of the stent body at the distal end of the Polaris Loop™ stent but fuse a generally planar ring 26A to the distal portions of the loops to achieve a four string symmetrical connection to the collapsible ring. This achieves a parachute effect under tension such that the four strings 26B will maintain a relatively open passage for urine through the ureterovesical junction while being less obstructing of the orifice and intramural ureter in the case of stone passage. The planar ring 26A is configured so that its plane is generally perpendicular to the longitudinal central axis A of the distal end portion of the middle (ureteral) section 24. Moreover, the ring 26A is sized to strongly resist retrograde migration, provide an excellent handle for stent removal and absolutely minimize mucosal contact. To achieve this, it is estimated that the ring should be approximately 15 mm diameter or larger, (e.g. 12 to 25 mm

diameter). The ring may be formed of a shape memory metal, e.g., Nitinol, and may be coated with plastic if desired. Also, there is potential for the natural anti-reflux mechanism to remain functional with this configuration. Moreover, while the ring is secured to the free end 34A of the ureteral section 24 by four strings 24B, that is merely exemplary. Accordingly, any number of strings can be used providing the arrangement produces a parachute effect wherein the ring is open and located within the bladder, with the strings 24B extending through the ureteral orifice 14A such that they become more parallel to each other and connect to the open free end 24B of the ureteral section 24.

It should be pointed out at this juncture that while the use of the ring-like bladder segment 26 as just described is preferable, it is contemplated that other bladder segment construction can be utilized if desired and appropriate. For example, a suitable prior art bladder segment can be used in the ureteral stent 20 in lieu of the bladder segment 26. One such type of suitable bladder segment is found in a stent which is sometimes referred to as a "vortex" stent, wherein the bladder segment is in the form a flexible ring and an associated funnel shaped enlargement to serve as the retention shape. Vortex stents are shown in previously identified U.S. Patent Nos.: 6,764,519; 7,316,663; 8,088,170; and 8,852,289. Moreover, anti-reflux flap valves may be used as described in those patents if this type of bladder segment shape is chosen.

Turning now to Fig. 4 there is shown another exemplary embodiment of a ureteral stent 120 constructed in accordance with this invention. The ureteral stent 120 is identical to the ureteral stent 20, except for the middle (ureteral) section. Thus, in the interest of brevity the components of the ureteral stent 120 which are common to the ureteral stent 20 will be given the same reference numbers and the details of their construction and operation will not be reiterated. To that end, it can be seen the ureteral stent 120 basically comprises a proximal (kidney) segment or section 22, a middle (ureteral) segment or section 124, and a distal (bladder) segment or section 26. The middle (ureteral) section 124 is an elongated tubular member of generally the same outside diameter as the kidney section 22 and has a central passageway (not shown) extending through its entire length from the point 22B at which it merges with the kidney section 22 to its distally located free end 24A. The free end 24A is open. The inner diameter of the central passageway of the

ureteral section 124 is the same as the inner diameter of the central passageway of the kidney section 22 and is in fluid communication therewith so that fluid flowing into the passageway from the kidney section can pass down the central passageway in the ureteral section 24. Moreover, the ureteral section includes a plurality of apertures 24C along the length thereof and which are in fluid communication with the central passageway of the ureteral section and the interior of the ureter 12.

Like the ureter section 24 of the ureteral stent 20, the ureter section 124 of the ureter stent 120 is in the form of a tension inducing "memory" spring. In this case the memory spring is in the form of a helical coil that is made up of a plurality of serially located helices or coils 124D. The plurality of coils 124D coupled with the fact that the material making up the ureter section 124 is flexible and resilient enables the ureter section to automatically expand and contract in length in response to movement between the kidney and the bladder. The length of the coils in this segment will be determined by their shape and dimensions necessary to achieve the desired in-situ length changes with respiration, while maintaining a relatively constant tension force as described above. The space in the ureter created by this region of the stent in any cross-sectional view will vary depending on how the stent is being stretched and anatomical factors. Correctly sized for initial length, this design will fit comfortably within the body of the ureter and fully absorb any length changes required by respiratory movement of the kidney. The highly elastic and mobile ureter will readily adapt to such internal shapes, and the pulling force that results from the tension spring "memory" on the ends of the stent will remain fairly constant as long as the coils are not straightened completely, i.e., some degree of curvature remain. It should be noted that when the ureteral stent 120 is placed over a guidewire for insertion, the straightened stent may be around 6 cm, or more, longer than the measured ureteral length of the stent at rest. Proper sizing for a patient will take this into account.

Turning now to Fig. 5 there is shown another and more preferred exemplary embodiment of a ureteral stent 220 constructed in accordance with this invention. The ureteral stent 120 is identical to the ureteral stent 20, except for the middle (ureteral) section and the distal (bladder) section. Thus, in the interest of brevity the components of the ureteral stent 220 which are common to the ureteral stent 20 will be given the same reference numbers and the details of their construction and

operation will not be reiterated. To that end, it can be seen the ureteral stent 220 is an integral unit that basically comprises in sequence a thin-walled tubular proximal (kidney) segment or section 22, a middle (ureteral) segment or section 224, and a distal (bladder) segment or section 126. The middle (ureteral) section 224 is an elongated member of generally the same outside diameter as the kidney section 22. In the exemplary embodiment shown the ureteral section 224 is an integral unit composed of plural elongated tubular sections 224A, 224B and 224C and plural tightly wound helical coil sections 224D and 224E. Each of the coil sections 224D and 224E is wound very closely into a, more or less, fully collapsed tension spring shape when at rest. Each of the tubular sections 224A, 224B and 22C is an elongated tubular member having a central passageway (not shown) extending therethrough. Each tubular section 224A, 224B and 224C includes a plurality of apertures 24C in fluid communication with the central passageway of the section and the interior of the ureter. The proximal end of the tubular section 224A is connected to and merges with the distal end of the kidney section 22 so that their central passageways are in fluid communication with each other. The tightly wound coil section 224D is in the form of a solid bodied helical coil that is connected between the distal end of the tubular section 224A and the proximal end of the tubular section 224B. The tightly wound coil section 224D is of approximately the same outside diameter as the tubular sections 224A and 224B and includes a central passageway 230 (Fig. 6) extending therethrough which is in fluid communication with the central passageways of the tubular sections 224A and 224B. The tightly wound coil section 224E is constructed like the tightly wound coil section 224D and is connected between the distal end of the tubular section 224B and the proximal end of the tubular section 224C. Thus, the tubular section 224B forms what may be referred to as a "node" of the middle (ureteral) section 224. The node section 224B is somewhat resistant to longitudinal expansion and contraction for reasons to be described later. The tightly would coil section 224E is of approximately the same outside diameter as the tubular sections 224B and 224C and includes a central passageway 230 (Fig. 6) extending therethrough which is in fluid communication with the central passageways of the tubular sections 224B and 224C. The distal end of the tubular section 224C is open at 224F and has a central longitudinally extending axis A.

The distal (bladder) section 126 of the ureteral stent 220 is shown in Figs. 5 and 7. 7 is in the form of collapsible, planar ring 126A, or other shape as may be preferred such as an oval, D-shape or rectangle, that is directly fixedly secured (e.g., fused, welded, etc.) to the free (open) end 224F of the tubular section 224C. The ring can be of any suitable size, e.g., approximately 15 mm diameter, but other sizes and shapes are also contemplated. The cross sectional area of the ring material(s) is preferably circular and of a diameter of approximately 1 – 2 mm. If desired the shape of the ring may be oval or some other shape such that its outer periphery is curved perpendicular the plane of the ring. Moreover, the ring may be coated with plastic or uncoated. As best seen in Fig. 7, the plane of the ring 126A is oriented such that its diameter is aligned approximately with the centerline axis of the tubular section 224C whereupon the plane of the ring 126A is parallel to the central axis A. Therefore, the tension force generated by the dynamic stretching of the stent 220 with kidney movement and with correct sizing of the initial stent length in the patient (such that there is some stretching of the stent from its resting state when the kidney is as close as it can be anatomically from the ureteral orifice physiologically in that patient) is sufficient to hold an arc-like portion 126B of the ring 126A consistently against the ureteral orifice within the bladder 14. The span of the arc-like portion 126B and the stiffness of the ring 126A are intended to be sufficient to prevent retrograde migration of the ureteral stent 220. This design eliminates the need for any strings (though a short string or strings may be used in this same configuration, if desired), and may further minimize material and material movement in the bladder.

In Fig. 8 there is shown an alternative embodiment 326 of the distal (bladder) section 126 shown in Fig. 7. The distal section 326 is identical in construction to the distal section 126 except for the manner in which it is secured to the open distal end 224F of the tubular section 224C. In the interest of brevity the components of the distal section 326 which are common to the distal section 126 will be given the same reference numbers and the details of their construction and operation will not be reiterated. To that end, as can be seen in Fig. 8 the ring 126A is secured to the free (open) end 224F of the tubular section 224C by a pair of short flexible filament sections 326A.

It should be noted at this juncture that the distal section 126 of the ureteral stent 220 need not make use of the ring-like structure shown in Figs. 5 and 7. Instead, the distal section of the ureteral stent 220 may be constructed similarly to the distal section 26 of the ureteral stents 20 and 120 described heretofore. In fact, the distal section of the ureteral stent 220 can be constructed like that of conventional "vortex" ureteral stents, such as those disclosed above.

As will be appreciated by those skilled in the art, since the solid bodied tightly wound coil sections 224D and 224E are wound very closely into a, more or less, fully collapsed tension spring shape when at rest, the ureteral stent 220 forms a closed tubular shape prior to insertion in a patient, with inner lumen diameter and outer diameter dimensions essentially the same as the tubular body of the stent segments 22 and 126 to which it is connected. Thus, this tightly wound tension spring section effectively forms a hollow tube with an outside and inside diameter comparable to a normal straight tubular stent. Initial stent length will be chosen for any patient so that when inserted and in proper position in-situ in a patient, one or more of the spring sections 224D and 224E will be at least partially expanded to achieve a tension force within the desired range required for ideal stent function, and adequate additional length accommodation will be in reserve to handle all kidney movement while maintaining tension force in the desired range. While the exemplary embodiment shown in Fig. 5 makes use of three tubular sections 224A, 224B and 224C and two tightly wound coil sections 224D and 224E, that arrangement is merely exemplary of various arrangements that can be made so that the ureteral section includes at least one tubular section and at least one tightly wound coil section.

Irrespective of the number of tubular and tightly wound coil sections used, the ureteral stent should perform the required length changes within the tension force range desired, as well as provide excellent urinary drainage when the overall stent length is correctly sized for a given patient. Advantages of the stent 220, when compared to the embodiments of Figs. 3 and 4, include its more conventional look, the spacing and multiplicity of spring sections allow it to handle great anatomic variation, and perhaps, greater length changes may be accommodated with relatively minimal "delta" in the tension force. Disadvantages may include some increased complexity and cost of manufacturing. The spring sections could be made of a

nickel titanium, shape memory, alloy, coated or not, or other spring material of plastic or reinforced plastic composite materials. They may be attached seamlessly to the tubular sections of the stent monolithically via a molding process or via adhesives and/or mechanical methods.

Alternatively, and perhaps simplest of all, the entire stent 220 may be constructed as a continuous wire, tightly coiled in the kidney and ureteral segments and then formed into a closed loop at the bladder end segment. That alternative embodiment of a ureteral stent is shown in Fig. 10 and designated by the reference number 320. The stent 320 is similar in construction and virtually identical in operation to the ureteral stent 220, but with a few structural differences. In particular, the stent 320 is fabricated or formed from a continuous wire 302, which is shown in Fig. 15. The continuous wire thus forms a precursor for the stent 320. The construction of the stent 320, its wire precursor 302 and the manner of making the stent will be described in detail shortly. Suffice it for now to state that the stent 320, like the stent 220, has the appearance of a fairly typical prior art ureteral stent when at rest ex-situ. Thus, it allows all standard handling techniques for insertion and removal to be used and should provide excellent urinary drainage because it has the overall proven tubular characteristics and shape of most common prior art stents. However, unlike prior art ureteral stents, the stent 320, like other stents of this invention, makes use of a middle, ureteral segment to provide and control both the spring tensioning and length adjustment features. Moreover, the stent 320 has simple anchoring segments at both the proximal and distal end sections.

Turning now to Fig. 15, it can be seen that the wire precursor 302 of the stent 320 is in the form of a continuous, integral wire, which includes in sequence from the proximal end a spiral coil section 304A, a generally linear section 304B, a tightly helically coiled section 304C, another generally linear section 304D, another a tightly helically coiled section 304E, another generally linear section 304F, another tightly helically coiled section 304G, generally linear section 304H, and an oval closed loop section 304I. The wire sections 304A and 304B make up the proximal (kidney) section of the stent 320. The sections 304C, 322C, 304E, 322D, 304E, 322D, 304G, and 322E make up the middle segment 324 of the stent 320. The section 304I makes up the distal (bladder) section of the stent 320.

The wire precursor 302 used to make the stent 320 is preferably made of a metal alloy that has excellent longevity functioning as a tension spring. One such alloy that may be used in this capacity is a nickel titanium type, one example being Nitinol. It may also be possible to use a spring steel or other safe and biocompatible material. Each of the tightly coiled helical sections 304C, 304E and 304G is similar in construction to the sections 224D and 224E of the stent 220. Thus, each section 304C, 304E and 304G includes a central passageway extending through the section.

The spiral coil section 304A has a standard memory curled shape at the proximal (kidney) end. The wire at spiral coil section 304A and its contiguous linear section 304B are overmolded by a flexible plastic polymer, e.g., silicone, to form respective thin-walled tubular sections 322A and 322B similar to the corresponding sections of the stent 220. The section 322A thus includes a sidewall surrounding a central passageway in which the wire making up the spiral coil section 304A is embedded, whereupon the coil section 304A extends longitudinally through the section 322A. Like the sidewall of the section 22B of the stent 220, the sidewall of the section 322A also includes a plurality of apertures 22C extending through it and in fluid communication with the central passageway. The proximal or free end of the section 322A is open.

It should be pointed out at this juncture that the memory curled shape of the section 322A may be achieved in a number of ways other than making use of the memory of the wire section 304A of the precursor wire 302. For example, the plastic overmolding material making up section 322A can provide the shape memory by itself or in combination with shape memory of the wire section 304A.

Since the generally linear wire section 304B is overmolded with the plastic polymer as mentioned above to form a generally linear tubular section 322B, the wire section 304A is thus embedded in that section and extends longitudinally through that section. Moreover, the sidewall of the section 322B is of the same outside diameter as the sidewall of the section 322A and also includes a central passageway extending therethrough. That central passageway is shown in Fig. 11, is designated by the reference number 306 and is in fluid communication with the central passageway in the section 322A. The sidewall of the section 322A also includes a plurality of apertures 22C extending through it in fluid communication with the central passageway 306.

The generally linear section 304D of the precursor wire 302 is overmolded similarly to section 304B to form a generally tubular "node" section 322C, which like the node section described earlier is essentially resistant to longitudinal expansion and contraction. The sidewall of the node section 322C is of the same outside diameter as the sidewall of the section 322B and also includes a central passageway 306 (Fig. 12). The generally linear section 304F of the precursor wire 302 is overmolded similarly to section 304B to form another generally tubular node section 322D, which is also essentially resistant to longitudinal expansion and contraction. The sidewall of the section 322D is of the same outside diameter as the sidewall of the node section 322C and also includes a central passageway 306 (Fig. 13).

The generally linear section 304H of the precursor wire 302 is overmolded similarly to section 304B to form another generally tubular section 322E. The sidewall of the section 322E is of the same outside diameter as the sidewall of the node sections 322C and 322D and also includes a central passageway 306 (Fig. 14).

Like the middle section of the stent 220, the middle section 324 of the stent 320 takes full advantage of the tension spring capacity and elasticity of the wire coils is a straight (at rest), spiral, hollow, tube-like region for the full length in the middle segment. It is this segment that will determine the length /size chosen for a particular patient. There must be sufficient length expansion capacity in this segment to achieve the dynamic length changes from kidney movement within the designed tension force parameters. This middle section will likely benefit from the inclusion of the intermittent short lengths of adherent polymer overcoating or overmolding that forms the nodes 322C and 322D. As described above, these nodes are essentially resistant to expansion/contraction. As such they will likely add some stability to the stent for improving uniformity of movement along the length of the middle segment or section, e.g., they may tend to equalize the dynamic expansion and contraction of the coil portions of the middle segment or section. Moreover, the use of the nodes may also facilitate ease of handling.

It should be noted at this juncture that the subject invention contemplates modification of the middle section 324 of the stent 320 so that instead of being made using a precursor wire having sections 304C, 304D, 304E, 304F and 304G, the stent will be made of a precursor wire including the proximal sections 304A and 304B

and the distal section 304H and 034I, but with a single intermediate or middle coil section interposed between the proximal and distal sections. Such a single middle coil section would be constructed like any of the coil sections 304C, 304E and 304G, but would be of a length equal to the combined lengths of those coil sections and the linear wire sections 304D and 304F. Moreover, that intermediate coil section would make use of a plastic polymer that is overcoated or overmolded onto two spaced-apart portions of the middle coil sections corresponding to the length and location of the linear sections 304D and 304F of the precursor wire 302. That arrangement will effectively produce two nodes similar to the nodes 322C and 322D since the overmolding will prevent longitudinal elastic expansion and contraction of the wire coils at the nodes. Thus, the overmolded sections in this alternative embodiment of the stent 320, should serve to equalize the dynamic expansion and contraction of the portions of the intermediate coil section which are not overmolded, thereby enhancing the dynamic operation of that alternative stent in the same manner as the nodes 322C and 322D of the stent 320 function.

It should be pointed out at this juncture, that while the embodiment 320 makes use of two nodes that is merely exemplary. As such, the middle or intermediate section of the stent may make use of as many nodes, as desired for the particular application. In fact, the middle section of the stent need not include any node, but may be expandable and contractible along its entire length.

As best seen in Fig. 10 the bladder segment of the stent 320 is in the form of a closed loop 322F. In the exemplary embodiment shown it is in the form of an oval, but can be of other shapes, if desired. In any case it is preferably a closed loop formed from the same precursor wire 302. In particular the distal end of the precursor wire 302 is looped back to form the loop segment 304I and is secured thereto by a weld or other securement means. The looped wire section 304I is overmolded with the same plastic as that used to form the segments 322A, 322B, 322C, 322D, and 322E to result in a coated closed loop or ring segment 322F.

The oval loop/ring segment is preferably oriented to have the long side of the oval loop against the ureteral orifice and have the short side aligned with the longitudinal axis A of the stent. Moreover, the closed loop or ring 322F is sized and oriented to resist retrograde migration, provide an excellent handle for stent removal and absolutely minimize mucosal contact. To achieve this, it is estimated that the

long axis of the ring should be approximately 15 mm. The short axis may be approximately 10 mm. The overmolding of the wire loop 304I with the plastic polymer should improve comfort and other functional characteristics.

When sized correctly and in-situ, the middle, ureteral segment 324 ideally will always will be slightly expanded and inducing a light, relatively constant tension on the proximal and distal end segments as previously described. The length(s) and windings per centimeter of the expanding and contracting elastic spiral coil regions in the middle segment will determine what is required to achieve the desired length changes with kidney movement while maintaining a relatively constant tension force as described above. Moreover, and quite significantly the dynamic longitudinal expansion/contraction features of the middle segments of the stents of this invention (particularly, the stents 220 and 320 and others like them), will also exhibit some expansion and contraction of the outside diameter of the coiled sections of the middle segment in addition to the dynamic longitudinal expansion and contraction of middle segment. The dynamic expansion and contraction of the outside diameter of the coiled sections should have a significant beneficial effect in addition to providing increased comfort. In particular, the dynamic expansion and contraction of the outside diameter of the middle segment of the stents should provide some assistance or enhancement of the normal peristaltic function of the ureter, something prior art stents are incapable of achieving since they remain of constant diameter in use.

As should be appreciated by those skilled in the art, the cross-sectional area of the ureter created by this region of the stent in any cross-sectional view may vary slightly depending on how the stent is being stretched. For example, if the initial circumference of the stent is say 6.5 French (6.5 mm), then at 50% of theoretical maximum stretch (e.g., ~6 cm out of a maximum of 12 cm possible stretch) the theoretical stent circumference may decrease to ~5 mm (5 French). But, in general, by choosing a sufficiently small diameter wire and a sufficient number of coil windings per centimeter of length in this region at rest, the functional diameter changes with expansion and contraction of this middle segment should never be so great as to compromise urinary drainage.

The stents of this invention can be inserted and removed by employing guidewires, pushers and extraction methods that are well known in urology practice.

Also, a small magnet could be placed on the distal side of the bladder ring to facilitate magnetic removal techniques. The surgeon will choose a length based on the shortest physiologic length measured between the uretero-pelvic junction of the renal pelvis and ureteral orifice. The simple ring/oval shape of the segment in the bladder will minimize mucosal contact and eliminate any sharp ends, yet be readily compressed as needed to pass through a cystoscope for insertion/removal.

Turning now to Fig. 9 there is shown an alternative proximal (renal) section 422 which can be used in any of the ureteral stents of this invention. In particular, as can be seen the proximal (renal) section 422 includes plural helical coils 422A, 422B and 422C and a loop section 422D which extends into the central opening of those coils. The coils and the loop section cooperate to manage both the length and force requirements. However, one potential problem with such an arrangement is that there is a risk of "knotting", where the end of the stent section curls inside itself and forms a knot making the stent difficult, if not impossible, to remove by standard techniques. Also, while the size (volume) of the renal pelvis and collecting system in the kidney can vary dramatically, since it is more commonly quite small, often there would not be sufficient space for this type of multi-coil/loop anchor to operate properly. Therefore, it is preferred that the ureteral stent have a simple curled shape, e.g., like sections 22, and just serve as an anchor for the kidney end of the stent. Then the tension or "pulling" force, the force maintenance requirements and the desired length changes are managed in the middle, ureteral segment of the stent.

As should become apparent to those skilled in the art from the foregoing discussion, that while mechanically it is possible to achieve a reliable functioning stent with these characteristics using multicomponent screw-like mechanisms involving torsion springs and the like, or tension or compression springs and telescoping elements, such arrangements are most likely to fail or be problematic in the areas of insertion, removal and/or longevity in the urinary milieu. Also, material elasticity alone or in combination with these mechanisms, while theoretically possible, seems less likely to offer ideal solutions because of the delicate and limited range of force needed with relatively large changes in length. Fortunately, the ureteral stents of the subject invention do not present these problems and should allow all standard handling techniques for insertion and removal to be used. Moreover, the ureteral stents of this invention should clearly provide excellent

urinary drainage. They use the middle, ureteral segment of the stent itself as both the spring tensioning and length adjustment components and have simple anchoring segments at both end segments. In particular, the stents of this invention make use of a middle segment that remains or has the skeletal structure of a continuous tube, but functions as a tension inducing "memory" spring formed by plural undulations, helical coils, or other spring-like shapes for a chosen length of this ureteral segment. The length of the memory spring in the middle segment will be determined by the shape and dimensions of the coils, undulations or the like necessary to achieve the desired in-situ length changes with respiration while maintaining a relatively constant tension force as described above. The space in the ureter created by this region of the stent in any cross-sectional view will vary depending on how the stent is being stretched and anatomical factors. Correctly sized for initial length, the stents of this invention will fit comfortably within the body of the ureter and fully absorb any length changes required by respiratory movement of the kidney. The highly elastic and mobile ureter will readily adapt to such internal shapes, and the pulling force that results from the tension spring "memory" on the ends of the stent will remain fairly constant as long as some helical, sinusoidal, or coil spring shape remains. When placed over a guidewire for insertion, in some embodiments the straightened stent may be around 6 cm, or more, longer than the measured ureteral length of the stent at rest. Proper sizing for a patient will take this into account.

General characteristics of the ureteral stents of this invention include the precepts that resistance to uncoiling in the proximal, kidney segment of the stent will be greater than the force typically generated by the springs or the coils in the ureteral segment when sized correctly for a given patient. And, the resistance to collapse and retrograde movement of the ring or other memory shaped anchor at the distal, bladder segment of the stent, optimally, will be greater than the resistance to uncoiling at the proximal, kidney end.

Stent construction and materials are expected to be those currently applied in the marketplace or proven to be biocompatible for human implantation or in the urinary milieu, including all materials and methods described in the prior art stent patents. Any metal component(s) may be encased or otherwise coated with plastic. The durometer of any plastic used may vary along the length of the stent to achieve the desired flexibility, elasticity and other functional characteristics. Lubricious

coatings may be used and coatings or additives to the construction materials such as antibiotics or antiseptics to delay infection and chemical agents to reduce crystallization of urine may be used.

It is believed that the stents of the subject invention should not be inferior in any respect to ureteral stents already in use for providing a urine conduit and excellent functional drainage. A point for consideration that might be raised is what effect a helical coil, like the embodiment of Fig. 4, in the body of the ureter could have over time. Clearly, it may have a bending and/or dilating effect along the course of the ureter both immediately and over time. It should be stated that the normal ureter is both highly flexible and elastic, so one can expect normal ureter to contour somewhat closely to the shape of the stent. Abnormal sections of ureter may be fixed and rigid and will control the shape of the stent in the area of ureter where that abnormality is present. If there is a portion of the ureter that is dilated, then the helical shape of the stent will move freely within it. Thus, there should be little or no concern that the helical coils of the ureteral segment of the stent could cause erosion or otherwise harm the ureter to any greater degree than a standard "straight" ureteral stent. In any case, if a coiled middle section stent, like that of Fig. 4, is considered problematic then the coil springs of Figs. 5 and 10 bypass these considerations. Hence at present the embodiment of the ureteral stents 220 and 320 as shown in Figs. 5 and 10, respectively, are the most preferred for that reason and the other reasons stated previously. That said the subject invention contemplates various changes and modifications to the stents 220 and 320 and to the other stents disclosed and described herein.

Without further elaboration the foregoing will so fully illustrate my invention that others may, by applying current or future knowledge, adopt the same for use under various conditions of service.

CLAIMS

I claim:

1. A ureteral stent comprising;

a) a proximal section configured for disposition within the kidney of a living being, said proximal section including a tubular portion having at least one aperture therein in fluid communication with the interior of the kidney;

b) a distal section configured for disposition within the bladder of the living being, said distal section including a portion configured for engaging a portion of the bladder to anchor said distal section in place; and

c) a tubular intermediate section connected between said proximal section and said distal section, said tubular intermediate section having a central passageway extending therethrough, said central passageway being in fluid communication with said tubular portion of said proximal section, said tubular intermediate section being configured for location within a ureter of the being to elongate dynamically to accommodate ureteral length changes in automatic response to changes in spacing between the kidney and the bladder of the living being.

2. The ureteral stent of Claim 1 wherein said proximal and intermediate sections are configured to generate a retrograde tension force to hold said distal section in a stable position adjacent to or against the ureteral orifice.

3. The ureteral stent of Claim 1 wherein said distal section is configured to prevent retrograde migration and minimize mucosal contact.

4. The ureteral stent of Claim 1 wherein said tubular intermediate section is configured to dynamically expand and contract in diameter to assist in peristaltic action of the ureter.

5. The ureteral stent of Claim 1 wherein said intermediate section comprises a plurality of undulations.

6. The ureteral stent of Claim 1 wherein said intermediate section comprises a plurality of coils.

7. The ureteral stent of Claim 6 wherein each of said plurality of coils together define a central passageway, said central passageway of said plurality of coils being in fluid communication with said central passageway of said tubular intermediate section.

8. The ureteral stent of Claim 7 wherein said plurality of coils comprise portions of a continuous wire, said continuous wire including a portion extending along said tubular portion of said proximal section, and a portion forming said distal section.

9. The ureteral stent of Claim 8 wherein said distal section comprises a generally planar ring.

10. The ureteral stent of Claim 1 wherein said tubular intermediate section includes a distally located open end having a central longitudinal axis and wherein said distal section comprises a generally planar ring connected to said distally located open end.

11. The ureteral stent of Claim 10 wherein the plane of said generally planar ring is oriented approximately perpendicularly to said central longitudinal axis.

12. The ureteral stent of Claim 10 wherein the plane of said generally planar ring is oriented approximately parallel to said central longitudinal axis

13. The ureteral stent of Claim 10 wherein said ring is formed of a shape memory material.

14. The ureteral stent of Claim 1 wherein said proximal section comprises a planar spiral.

15. The ureteral stent of Claim 1 wherein said proximal section comprises a plurality of coils.

16. An anchor for a ureter stent having a proximal section and an intermediate section, the proximal section being configured for disposition within the kidney of a living being and including a tubular portion having at least one aperture therein in communication with the interior of the kidney, the intermediate section being tubular and configured for disposition within the ureter of the living being, the intermediate section being in fluid communication with the proximal section and terminating at an open end, said anchor being configured for disposition within the bladder of the being to prevent retrograde migration of the stent and minimize mucosal contact, said anchor comprising;

a) a ring formed of a shape memory material,

b) a plurality of filaments, each of said filaments being connected to the intermediate section adjacent the open end and also being connected to a respective portion of said ring.

17. The anchor of Claim 16 wherein the open end of the tubular intermediate section includes a central longitudinal axis and wherein said ring is generally planar, with the plane thereof extending generally perpendicularly to the central longitudinal axis of the tubular intermediate section.

18. An anchor for a ureter stent having a proximal section and an intermediate section, the proximal section being configured for disposition within the kidney of a living being and including a tubular portion having at least one aperture therein in communication with the interior of the kidney, the intermediate section being tubular and configured for disposition within the ureter of the living being, the intermediate section being in fluid communication with the proximal section and terminating at an open end having a central longitudinal axis, said anchor being configured for disposition within the bladder of the being to prevent retrograde migration of the stent and to minimize mucosal contact, said anchor comprising a ring or other shape formed of a shape memory material, said ring or other shape being generally planar, with the plane thereof being generally parallel to the central longitudinal axis of the intermediate section.

19. The anchor of Claim 18 wherein said ring is directly connected to the open end of the intermediate section.

20. The anchor of Claim 18 wherein said ring is indirectly connected to the open end of the intermediate section by plural filaments.

Fig. 1

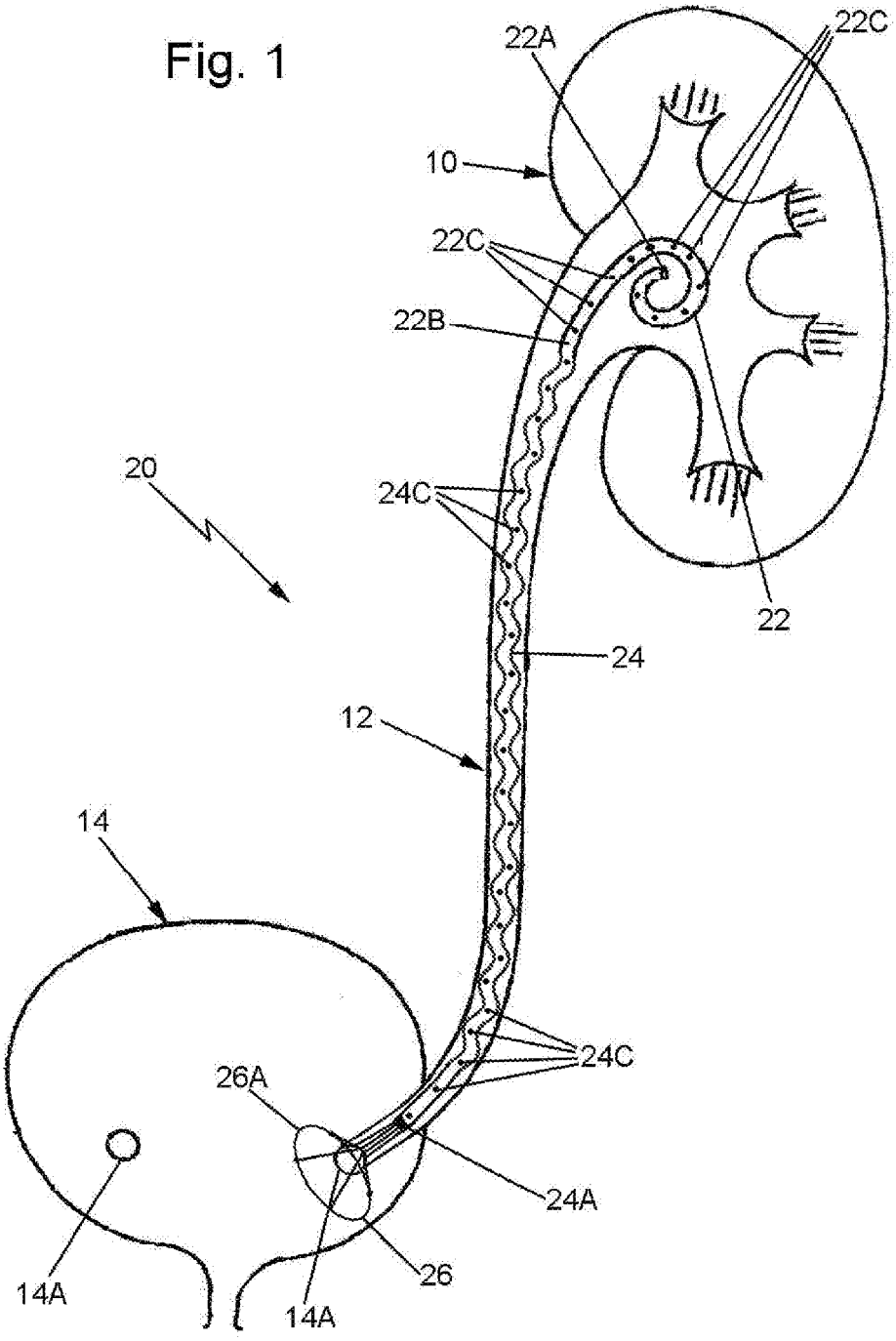
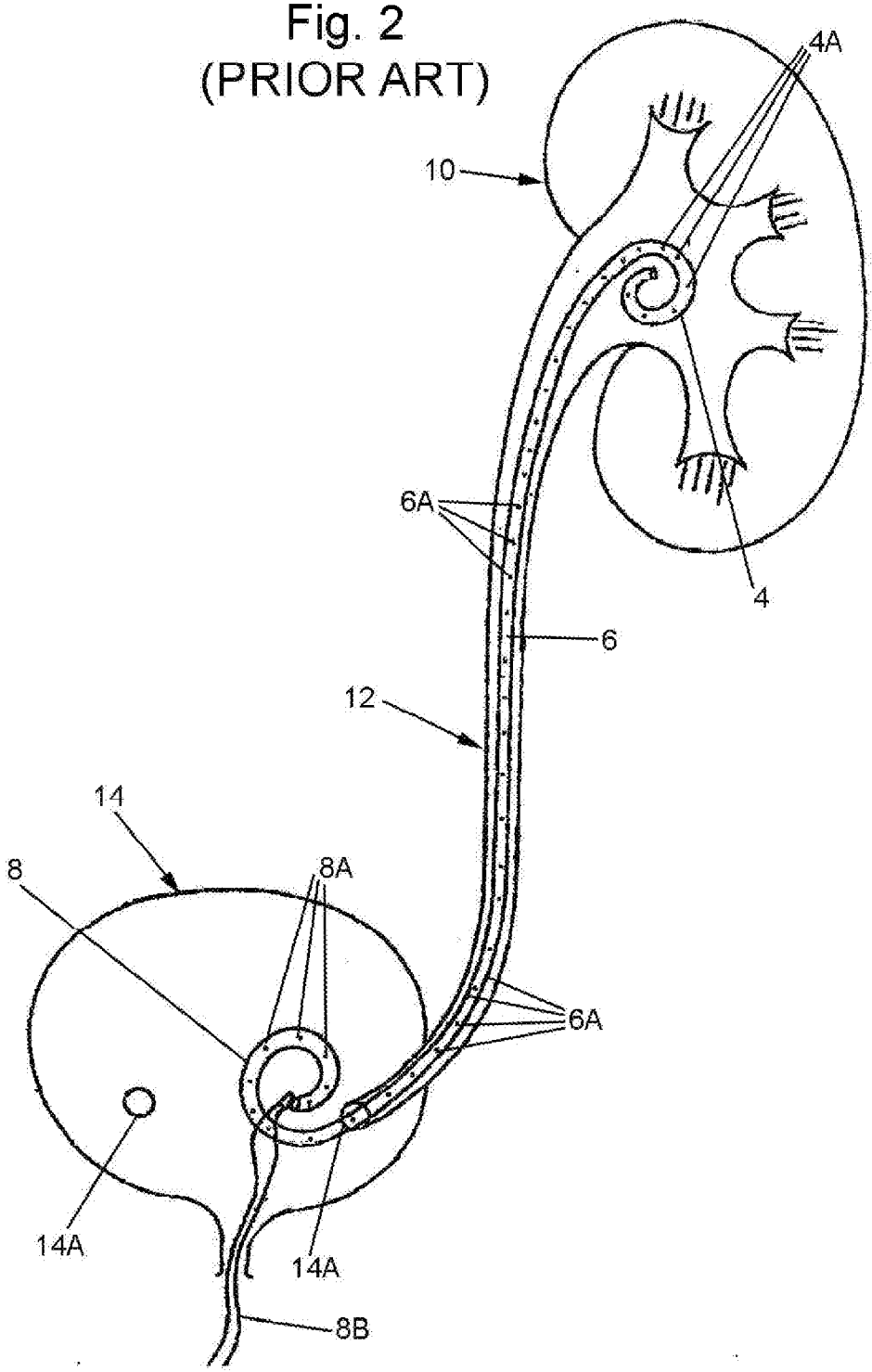


Fig. 2
(PRIOR ART)



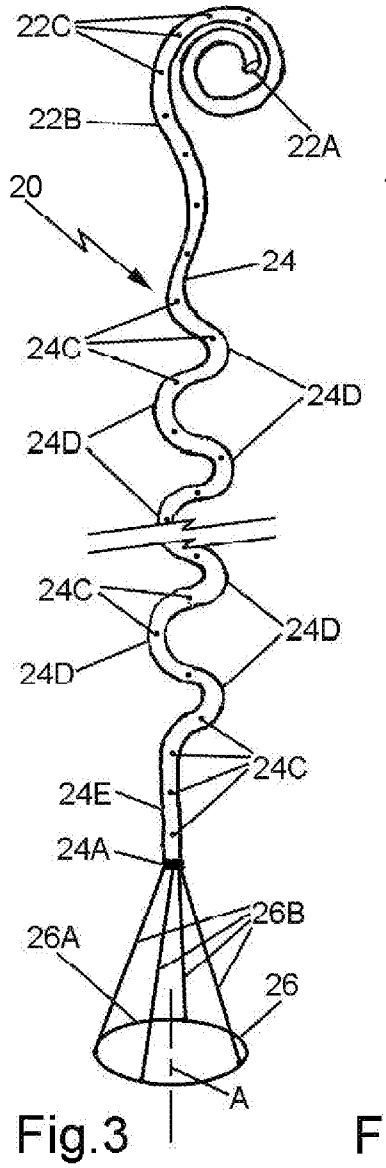


Fig.3

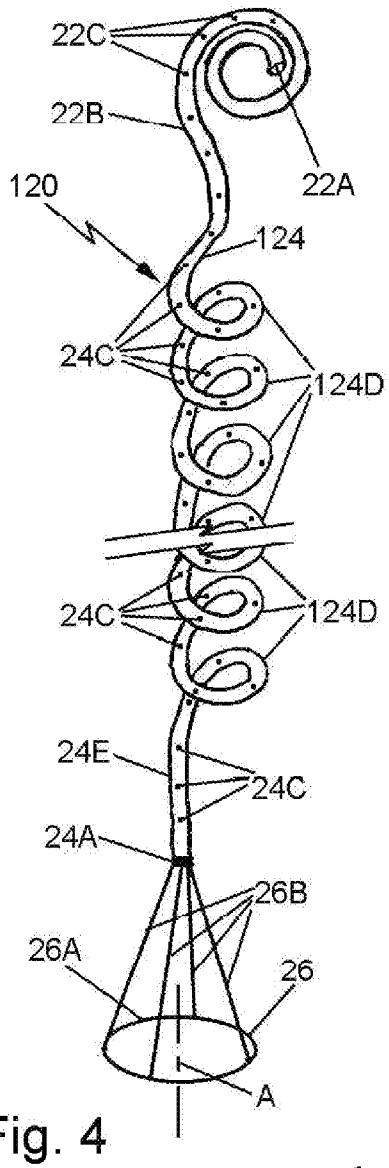


Fig. 4

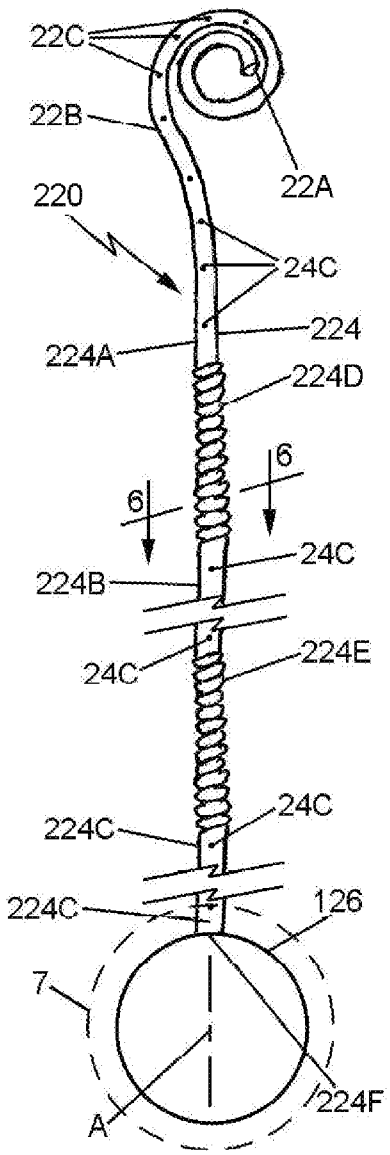


Fig. 5

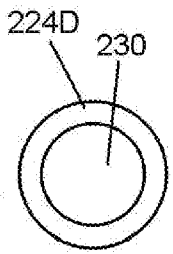


Fig. 6

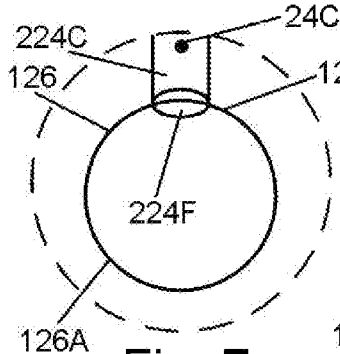


Fig. 7

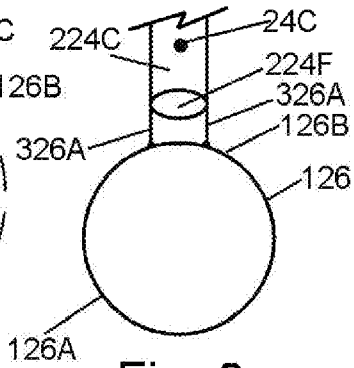


Fig. 8

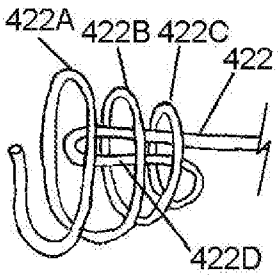


Fig. 9

Fig. 11

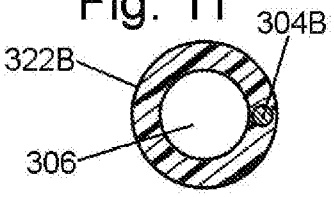


Fig. 12

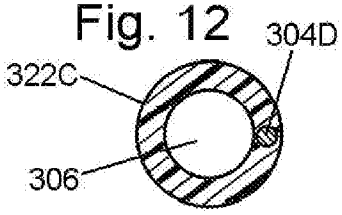


Fig. 13

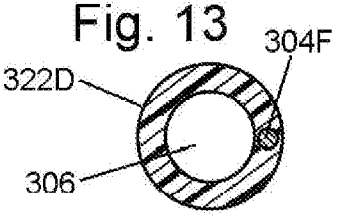


Fig. 14

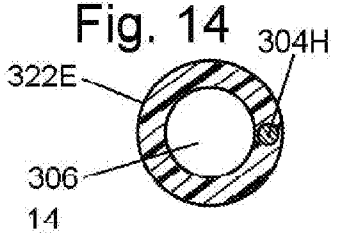


Fig. 10

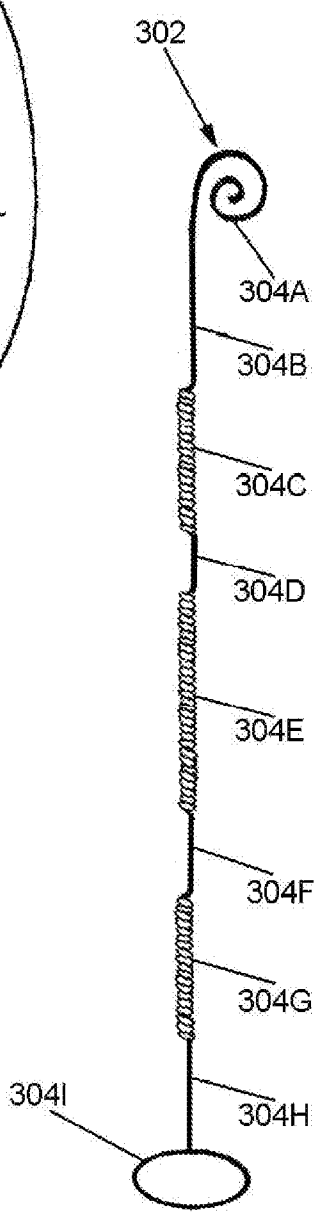


Fig. 15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/017586

A. CLASSIFICATION OF SUBJECT MATTER

A61M 27/00(2006.01)i, A61F 2/82(2006.01)i, A61F 2/04(2006.01)i

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)
A61M 27/00; A61F 002/04; A61M 5/00; A61F 2/04; A61F 2/82

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: ureteral stent, anchor, length change, coil, ring

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004-0087886 A1 (GELLMAN, B. N.) 06 May 2004 See claims 1-24; paragraphs [0014]-[0040]; figures 3A-5C.	1-8,14,15
Y		9-13
X	US 2005-0246038 A1 (O`KEEFE, C. R. et al.) 03 November 2005 See claims 40-47; paragraphs [0032]-[0041]; figures 1A-5A.	18,19
Y		9-13,16,17,20
Y	US 2005-0149201 A1 (MCWEENEY, J. O. et al.) 07 July 2005 See claims 1-5; paragraph [0042].	16,17,20
A	US 2004-0143209 A1 (LIU, C. M. et al.) 22 July 2004 See the whole document.	1-20
A	US 2012-0053700 A1 (RICKNER, T. W.) 01 March 2012 See the whole document.	1-20

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

☒ See patent family annex.

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"O" document referring to an oral disclosure, use, exhibition or other means
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"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
31 May 2018 (31.05.2018)	**31 May 2018 (31.05.2018)**

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2018/017586

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