Title: STENT RETENTION ELEMENT AND RELATED METHODS

Abstract: In one embodiment, the invention is directed to a stent retention element (200) having an elastic member adapted to be incorporated with a first end (306) of an elongate stent and to coil toward a second end (304) of the elongate stent to anchor the elongate stent at an anatomical site. According to one feature, the stent retention element expands and compresses to effectively lengthen and shorten, respectively, the stent to accommodate ureter lengthening and shortening.
STENT RETENTION ELEMENT AND RELATED METHODS

Technical Field

[0001] This invention generally relates to stents. More particularly, in one embodiment, the
invention is directed to a stent retention element.

Background of the Invention

[0002] A stent is a medical device adapted for propping open an obstructed passage
within the body, such as a blocked ureter. In general, ureteral blockage is a medical condition
requiring treatment. A ureteral blockage can occur for a number of reasons, including the
passage of a kidney stone and/or other material into the ureter where it becomes entrapped.
Also, a tumor growing against the outer wall of the ureter can force compression or constriction
of the ureter. A tumor on the internal ureteral wall can also cause blockage of the ureter.

Ureteral stents are often used to correct such problems. A ureteral stent may be placed inside the
ureter on a temporary basis to allow proper drainage of fluids from the kidney to the urinary
bladder. One end of a typical ureteral stent is placed in the kidney and the other end is placed in
the urinary bladder. The end positioned in the kidney is typically configured to retain the stent
within the renal pelvis and to prevent the downward migration of the stent into the ureter. The
bladder end of the stent is typically configured to prevent upward migration of the stent towards
the kidney.

[0003] Figure 1 is a conceptual background drawing showing a portion of the human
urinary tract. Referring to Figure 1, in a human urinary tract 100, the ureters 102 and 104
transport urine from the kidneys 106 and 108 to the urinary bladder 110. The trigone region 112
of the urinary bladder 110 is located between the urethral opening 114 and the two ureteral
orifices 116 and 118. The pain associated with an in-dwelling ureteral stent is attributable in-
part to contact between the stent and the urinary bladder mucosa 120 in the trigone region 112.
The trigone region 112 is believed to be particularly innervated and sensitive to the presence of
any foreign bodies such as the bladder end of a ureteral stent.

[0004] The placement of conventional ureteral stents generally requires a measurement
by the physician to ascertain the length of, for example, the ureter 102. Typically, conventional
stents include an elongate body at least long enough to traverse the distance in the ureter 102
between the kidney 106 and the urinary bladder 110. Conventional stents also typically include
some type of anchor at one or both of the kidney 106 and urinary bladder 116 ends. Such anchors generally consist of a coil formed perpendicular to a stent axis and integrated with one or both of the kidney 106 and urinary bladder 110 ends of the stent. These coils secure the stent to prevent it from migrating in the ureter 102, either upward toward the kidney 106 or downward toward the urinary bladder 110.

[0005] One drawback of such conventional stents, is that typically, they need to be of sufficient length to allow for some relative movement between the kidney 106 and the urinary bladder 110, due to, for example, patient movement or peristaltic action, without becoming dislodged. However, such increased stent length can cause the stent to protrude far enough into the kidney 106 and/or the urinary bladder 110 to cause kidney 106 and urinary bladder 110 irritation. The trigone region 112 of the urinary bladder 110 is especially susceptible to such irritation. To further complicate matters, stents having insufficient length may dislodge and migrate in the ureter 102, either toward the kidney 106 or toward the urinary bladder 110.

Summary of the Invention

[0006] Accordingly, an anchoring approach is needed that reduces patient irritation and that does not lend itself to migration. The invention addresses this and other objects.

[0007] In one embodiment, the invention is directed to a stent retention element adapted for incorporation onto a first end of an elongate stent, and having an elastic member adapted to coil toward a second end of the elongate stent. In another embodiment, the stent retention element includes an elongate section adapted to extend axially from the first end of the elongate stent. According to another embodiment, the elastic member is adapted to coil toward the second end of the elongate stent at distances around the elongate section of the stent retention element. In an alternative embodiment, the elastic member is adapted to coil toward the second end of the elongate stent at distances around a first section of the elongate stent.

[0008] According to one embodiment, the distances at which the elastic member is adapted to coil are substantially constant to form the elastic member as a substantially cylindrical helix having a plurality of coils with substantially equal diameters. According to an alternative embodiment, the distances at which the elastic member is adapted to coil varies to form the elastic member as a conical spiral having a plurality of coils, each of the plurality of coils having an associated diameter, and the associated diameter increasing as the coils extend toward the second end of the elongate stent.

[0009] According to one embodiment, the elastic member is adapted for anchoring the first end of the elongate stent in a human urinary bladder. According to an alternative
embodiment, the elastic member is adapted for anchoring the first end of the elongate stent in a human kidney. According to one feature, the elastic member is formed to compress from a steady state in response to an axial force directed from the second end of the elongate stent toward the first end of the elongate stent. In one aspect, compression of the elastic member effectively retracts a portion of the elongate section of the stent retention element and/or a portion of the elongate stent into the kidney or urinary bladder to accommodate ureter shortening. According to another feature, the elastic member is formed to return to an uncompressed steady state in response to removal of the axial force, thus re-extending the previously retracted portion of the elongate section of the stent retention element or elongate stent back into the ureter.

[0010] According to a further feature, the elastic member is formed to expand from a steady state in response to an axial force directed from the first end of the elongate stent toward the second end of the elongate stent to effectively extend a portion of the elongate stent and/or a portion of the elongate section of the stent retention element further into the ureter to accommodate ureter lengthening. According to another feature, the elastic member is formed to return to an unextended steady state in response to removal of the axial force, thus retracting the previously extended portion of the elongate section of the stent retention element or elongate stent back out of the ureter. In one embodiment, the elastic member is formed to provide a compressive stroke of at least about 5 cm.

[0011] According to another feature of the invention, those of the plurality of coils that have a relatively smaller diameter are adapted to pass through each of the plurality of coils having a relatively larger diameter in response to an axial force directed from the first end toward the second end of the elongate stent. According to another feature, the elastic member is adapted to return to an initial steady state in response to removal of the axial force.

[0012] In one embodiment, the elastic member is formed to be hollow and defines a retention element lumen. According to an alternative embodiment, the retention element is formed to be substantially solid. According to one feature, the elastic member is adapted to uncoil in response to a catheter body being extended over the retention element and/or a guide wire being inserted into the retention element lumen. According to another feature, the elastic member is formed from a super elastic material.

[0013] In another embodiment, the invention is directed to a stent having an elongate body and a first retention element. The elongate body has first and second ends and defines an internal lumen extending there between. It also has a length at least sufficient to extend through
an anatomical lumen of a patient from a first anatomical site to a second anatomical site. In one embodiment, the first retention element is adapted for anchoring the stent at the first anatomical site and includes a first elastic member coiling toward the second end of the elongate body. According to a further embodiment, the first elastic member coils toward the second end of the elongate body at first distances around a first section of the elongate body. In an alternative embodiment, the first retention element includes a first elongate section extending axially from the first end of the elongate body. According to a feature of this embodiment, the first elastic member coils toward the second end of the elongate body at first distances around the first elongate section of the first retention element.

According to a further embodiment, the stent also includes a second retention element adapted for anchoring the stent at the second anatomical site. According to one embodiment, the second retention element includes a second elastic member coiling toward the first end of the elongate body. According to a further embodiment, the second elastic member coils toward the first end of the elongate body at second distances around a second section of the elongate body. In an alternative embodiment, the second retention element includes a second elongate section extending axially from the second end of the elongate body. According to a feature of this embodiment, the second elastic member coils toward the first end of the elongate body at second distances around the second elongate section of the second retention element.

According to one embodiment, the first and second distances at which the first and second elastic members coil is substantially constant to form the elastic members as substantially cylindrical helixes having a plurality of coils with substantially equal diameters. According to an alternative embodiment, the first and second distances at which the elastic members coil varies to form the elastic members as a conical spiral having a plurality of coils, each of the plurality of coils having an associated diameter that increases as the first elastic member coils toward the second end of the elongate body and the second elastic member coils toward the first end of the elongate body.

According one embodiment, the anatomical lumen is a ureter, the first anatomical site is a kidney and the second anatomical site is a urinary bladder. According to a further embodiment, the first retention element is adapted for insertion into the kidney and the second retention element is adapted for insertion into the urinary bladder.

According to one feature, at least one of the first and second retention elements is adapted to compress to retract a portion of the first or second sections of the elongate body or a portion of the elongate section of the first or second retention elements from the ureter to
accommodate ureter shortening. According to another feature, at least that retention element is adapted to decompress, thereby re-extending the retracted portion of the elongate body or retention element back into the ureter to accommodate re-lengthening. According to an additional feature, at least one of the first and second retention elements is adapted to expand, thereby extending a portion of the first or second sections of the elongate body or a portion of the elongate section of the first or second retention elements into the ureter to accommodate ureter lengthening.

[0018] According to another embodiment, the invention is directed to a method of placing a stent in a patient. The method includes the step of providing a stent having: an elongate body having first and second ends and defining an internal lumen extending there between, and having a length sufficient to extend through an anatomical lumen of a patient from a first anatomical site to a second anatomical site; and a retention element axially extending from the first end toward the second end of the elongate body while coiling at a first distance around a first section of the elongate body. The method further includes, inserting the stent into the anatomical lumen of the patient; and positioning the stent in the patient with the first retention element at the first anatomical site.

[0019] According to one embodiment, the first anatomical site is a urinary bladder and the positioning step includes, positioning the retention element substantially within the urinary bladder to anchor the first end of the elongate body to the urinary bladder. According to another embodiment, the first anatomical site is a kidney and the positioning step includes, positioning the retention element substantially within the kidney to anchor the first end of the elongate body to the kidney.

[0020] According to a further embodiment, the invention is directed to a method of removing a stent from a patient. The stent includes an elongate body with first and second ends and defining an internal lumen extending there between, and extending through an anatomical lumen of a patient from a first anatomical site to a second anatomical site. The stent also includes a retention element incorporated with the first end of the elongate body and coiling toward the second end of the elongate body to anchor the first end of the elongate body at the first anatomical site. The method includes the steps of releasing the retention element from the first anatomical site and removing the stent from the anatomical lumen of the patient. According to one embodiment of this method, the first anatomical site is a urinary bladder and the releasing step includes releasing the retention element from the urinary bladder. According to another
embodiment of this method, the first anatomical site is a kidney and the releasing step includes releasing the retention element from the kidney.

**Brief Description of the Drawings**

[0021] The foregoing and other objects of the invention and the various features thereof may be more fully understood from the following description when read together with the accompanying drawings in which like-reference designations generally refer to the same parts throughout the different views and in which the depicted components are not necessarily drawn to scale.

[0022] Figure 1 is a conceptual background diagram depicting a human urinary tract;

[0023] Figure 2A is a perspective, side view of a stent retention element according to an illustrative embodiment of the invention;

[0024] Figure 2B is a cross-sectional view, taken along view AA’, depicting a substantially solid stent retention element according to an illustrative embodiment of the invention;

[0025] Figure 2C is a cross-sectional view, taken along view AA’, depicting a substantially hollow stent retention element according to an alternative illustrative embodiment of the invention;

[0026] Figure 3A is a conceptual diagram depicting a stent employing the retention element of Figure 2A to anchor one end of the stent in a patient’s urinary bladder according to an illustrative embodiment of the invention;

[0027] Figure 3B is a conceptual diagram depicting a stent employing the retention element of Figure 2A to anchor one end of the stent in a patient’s kidney according to an illustrative embodiment of the invention;

[0028] Figure 3C is a conceptual diagram depicting a stent employing the retention element of Figure 2A to anchor a first end of the stent in a patient’s urinary bladder and a second end of the stent in a patient’s kidney according to an illustrative embodiment of the invention;

[0029] Figure 4A is a side view of the stent retention element of Figure 2A in a partially expanded state according to an illustrative embodiment of the invention;

[0030] Figure 4B is a side view of the stent retention element of Figure 2A in a partially compressed state according to an illustrative embodiment of the invention;

[0031] Figure 5A is a side view, partially in cross-section, of the stent retention element of Figure 2A uncoiled within a catheter lumen prior to insertion or subsequent to retraction according to an illustrative embodiment of the invention;
[0032] Figure 5B is a side view, partially in cross-section, of the stent retention element of Figure 2A coiling in response to being extended out of the catheter lumen of Figure 5A according to an illustrative embodiment of the invention; and

[0033] Figure 5C is a side view, partially in cross-section, of the stent retention element of Figure 2A uncoiling as it retracts into a catheter lumen during removal according to an illustrative embodiment of the invention.

Description of an Illustrative Embodiment

[0034] As described above in summary, the invention relates generally to stents. More particularly, in one embodiment, the invention is directed to a stent retention element. In further embodiments, the invention is directed to a ureteral stent having a retention element adapted to accommodate both ureter lengthening and shortening, while reducing patient discomfort and inhibiting stent migration.

[0035] Figure 2A is a side perspective view of a retention element 200 according to an illustrative embodiment of the invention. The retention element 200 includes an elastic member 206 and optionally, an elongate section 203. The elastic member 206 includes a plurality of coils 206a-206d coiling at a distance around a substantially central axis 207 from a first end 202 of the elastic member 206 to a second end 204 of the elastic member 206. Illustratively, the coils 206a-206d are formed, at least in part, from an elastic or super elastic material having shape retention features to enable the retention element 200 to return to a coiled shape after being substantially straightened during transitory stages of insertion and removal, and after being expanded or compressed while inside a patient. The shape retention features also enable various patient comfort aspects discussed in more detail below with respect to Figures 3A-3C.

[0036] Appropriate shape retention materials for the coils 206a-206d includes, for example, alloys of In—Ti, Fe—Mn, Ni—Ti, Ag—Cd, Au—Cd, Au—Cu, Cu—Al—Ni, Cu—Au—Zn, Cu—Zn—Al, Cu—Zn—Sn, Cu—Zn—Xe, Fe2Be, Fe2Pt, Ni—Ti—V, Fe—Ni—Ti—Co, and Cu—Sn, along with any other shape retaining materials. According to one illustrative embodiment, the super elastic material is a nickel and titanium alloy, known by the tradename Nitinol®, available from Memry Corp. of Brookfield, CT and SMA, Inc. of San Jose, CA. The ratio of nickel and titanium in Nitinol® can vary. In one preferred embodiment, the material of the retention element 200 has a nickel-to-titanium ratio of about 50% to about 56% nickel by weight.

[0037] Referring briefly to Figure 3A, the elastic member 206 is adapted to coil from a first end 306 of a stent 302 toward a second end 304 of the stent 302 at distances around a first
section 308 of the stent 302. As shown in Figure 2A, optionally, the retention element 200 includes an elongate section 203 adapted to extend axially from a stent end 304 or 306. In such an embodiment, the elastic member 206 is adapted to coil toward the second end 304 of the stent 302 at distances around the elongate section 203 of the retention element 200.

[0038] In one embodiment, the distances at which the elastic member 206 is adapted to coil about the stent section 308 or the elongate section 203 of the retention element 200 are substantially constant to form the elastic member 206 as a substantially cylindrical helix having a plurality of coils 206a-206d with substantially equal diameters.

[0039] However, according to the illustrative embodiment of Figure 2A the distances at which the coils 206a-206d coil around the stent section 308 or the elongate section 203 varies to form the elastic member 206 as a conical spiral having a plurality of coils 206a-206d, each having an associated diameter, and the associated diameter increasing from a minimum diameter 208 for coil 206a to a maximum diameter 210 for coil 206d as the retention element extends toward the second end 304 of the stent 302.

[0040] Figure 2B is a cross-sectional view of the coil 206d taken along view AA'. As depicted in Figure 2B, according to the illustrative embodiment, the coils 206a-206d are formed to be substantially solid. In the embodiment of Figure 2B, each coil 206a-206d is formed to have a substantially ellipsoidal cross-section AA'. More particularly, in the illustrative embodiment, each coil 206a-206d has a substantially circular cross-section AA', with an outside diameter 214 between about 0.052 inches and 0.13 inches. However according to alternative embodiments, other cross-sectional shapes may be employed.

[0041] Figure 2C is a cross-sectional view of the coil 206d taken along view AA' according to an alternative illustrative embodiment. In the alternative embodiment of Figure 2C, the coils 206a-206d are formed as a hollow tube having an inner wall 216 and an outer wall 220. In the illustrative embodiment of Figure 2C, coil 206d has an outside diameter 212 between about 0.5 inches and about 1.0 inches and a wall thickness 222 of at least about 0.005 inches to about 0.030 inches. In the embodiment of Figure 2C, the inner wall 216 defines an internal lumen 218 within which a guide wire may be inserted to straighten the coils 206a-206d during intermediate stages of insertion and removal. Although the illustrative embodiments of Figures 2B and 2C depict the retention element 200 as being formed from a material having a substantially uniformly shaped cross-section throughout, in other embodiments, such cross-sectional shape may vary. By way of example, a cross-section taken at end 202 may be less than or greater than a cross-section taken at end 204.
In the following descriptions of Figures 3A-3C, the use of a “prime” or “double prime” symbol indicates correspondence between elements of Figure 2A and like numbered elements of Figures 3A-3C.

Figure 3A is a conceptual diagram 300 depicting a retention element 200', of the type shown in Figure 2A, incorporated onto the bladder end 306 of a stent 302, placed inside the human urinary tract 100. The retention element 200' has an end 202' attached to the bladder end 306 of the stent 302. The section 308 of the stent 302 extends into the bladder 110 substantially along the axis 207'. As attached to the stent 302, the retention element 200' is located in the urinary bladder 110 and extends from the bladder end 306 of the stent 302 toward the kidney end 304 of the stent 302 while the coils 206a’-206d’ coil at a distance around the stent section 308.

The retention element 200' may be attached to the bladder end 306 by any appropriate means. Alternatively, the retention element 200' may be formed integrally with the bladder end 306. As mentioned above, in other alternative embodiments, the elongate section 203 may substitute for section 308 and be formed as part of the retention element 200' as opposed to part of the stent 302.

According to one illustrative embodiment, the stent 302 is sized to be an appropriate length to extend through the ureter 102 between the kidney 106 and the urinary bladder 110 during a nominal at-rest patient state. As mentioned above with respect to Figure 2A and as described in further detail below with respect to Figures 4A and 4B, in response to the ureter 102 lengthening from the nominal state for any reason, the coils 206a’-206d’ compress to allow enough of section 308 to extend into the ureter 102 to accommodate the ureter 102 lengthening. Subsequently, in response to ureter 102 shortening, the coils 206a’-206d’ decompress to retract enough of the stent section 308 back into the urinary bladder 110 to accommodate the shortening.

According to another illustrative embodiment, the stent 302 is sized to have a length too short to span the distance through the ureter 102 from the kidney 106 to the urinary bladder 110, to cause the coils 206a’-206d’ to remain somewhat compressed upon insertion into the urinary bladder 110. In such a state, the coils 206a’-206d’ are able to accommodate both ureter 102 shortening and ureter 102 lengthening. By way of example, if the coils 206a’-206d’ are formed to have a compressive stroke of at least about 5cm, and the stent is sized such that upon insertion the coils 206a’-206d’ are compressed to about 2.5cm of such stroke, the stent retention element 200' is able to accommodate about a 2.5cm of ureter 102 lengthening or
shortening. According to other illustrative embodiments, the coils 206a'-206d' may employ other compressive strokes without deviating from the scope of the invention.

Figure 3B is a conceptual diagram 301 depicting a retention element 200", of the type shown in Figure 2A, attached to the kidney end 304 of the stent 302, placed inside the human urinary tract 100. The retention element 200" is substantially identical to the retention element 200'. However, according to the illustrative embodiment, the retention elements 200" and 200' may be sized to accommodate the size of the anatomical site at which the retention element (200', 200") operates. The retention element 200" has an end 202" attached to the kidney end 304 of the stent 302. The section 310 of the stent 302 extends into the kidney 106 substantially along the axis 207". Thus, as attached to the stent 302, the retention element 200" extends from the kidney end 304 of the stent 302 toward the bladder end 306 of the stent 302 while the coils 206a"-206d" coil at a distance around the section 310.

As in the case of the retention element 200' of Figure 3A, the retention element 200" may be attached or formed to the kidney end 304 of the stent 302 by any appropriate means. Also, as in the case of section 308, the section 310 may be formed as either part of the stent 302 or part of the retention element 200".

In one illustrative embodiment, the stent 302 is sized to be an appropriate length to extend through the ureter 102 between the urinary bladder 110 and the kidney 106 during a nominal at-rest patient state. As mentioned above with respect to Figure 2A and as described in further detail below with respect to Figures 4A and 4B, in response to the ureter 102 lengthening from the nominal state for any reason, the coils 206a"-206d" compress to allow enough of the section 310 to extend into the ureter 102 to accommodate the lengthening. Subsequently, in response to ureter 102 shortening, the coils 206a"-206d" decompress to retract enough of the section 310 back into the kidney 106 to accommodate the shortening.

As in the example of Figure 3A, the stent 302 may be sized to have a length too short to span the distance through the ureter 102 from the urinary bladder 110 to the kidney 106 to cause the coils 206a"-206d" to remain somewhat compressed upon insertion into the kidney 106. In such a state, the coils 206a"-206d" are able to compress and/or decompress to accommodate both ureter 102 shortening and ureter 102 lengthening in a similar fashion to the coils 206a'-206d' described above with respect to Figure 3A.

Figure 3C is a conceptual diagram 303 depicting a stent 302 having a retention element 200', of the type shown in Figure 2A, attached to the bladder end 306 and a retention element 200", of the type shown in Figure 2A, attached to the kidney end 304, placed inside the
human urinary tract 100. The retention elements 200', and 200'' operate substantially as described above with respect to Figures 3A and 3B. However, with the urinary bladder end 306 and the kidney end 304 employing retention elements 200' and 200'', respectively, additional benefits are realized.

[0052] By way of example, as described above, the stent 302 may be sized to extend through the ureter 102 between the urinary bladder 110 and the kidney 106 during a nominal at-rest patient state. With both retention elements 200' and 200'' being utilized, in response to the ureter 102 lengthening from the nominal state for any reason, both sets of coils 206a'-206d' and 206a''-206d'' are available for compression to allow both sections 308 and 310 of the stent 302 to extend into the ureter 102 to accommodate for the lengthening. Similarly, in response to ureter 102 shortening, both sets of coils 206a'-206d' and 206a''-206d'' are available for decompression to retract enough of sections 308 and 310 back into the urinary bladder 110 and the kidney 106, respectively, to accommodate the shortening. Thus, use of both retention elements 200' and 200'' increases the amount of ureter 102 lengthening and shortening for which the stent 102 can compensate.

[0053] An additional benefit is also realized when the stent 302 is sized to have a length too short to span the distance through the ureter 102 between the urinary bladder 110 and the kidney 106. By way of example, if each set of coils 206a'-206d' and 206a''-206d'' are formed to have a compressive stroke of about 5cm, and the stent is sized such that upon insertion both sets of coils 206a'-206d' and 206a''-206d'' are compressed to about 2.5cm, the stent retention elements 200' and 200'' combined can accommodate up to a 5cm ureter 102 lengthening or shortening, twice as much as with the single retention element embodiments of Figures 3A and 3B.

[0054] In one embodiment, the stent 302 has drain holes. In other embodiments, the stent retention element 200 has drain holes along one or more coils 206a-206d. In some embodiments, the elongate section 203 of the stent retention element 200 contains drain holes. In some embodiments, the drain holes have a diameter of 0.030 inches. In other embodiments, the drain holes have a diameter between 0.010 inches and 0.050 inches.

[0055] Figure 4A is a side view of the stent retention element 200 of Figure 2A in a partially expanded state according to an illustrative embodiment of the invention. Figure 4B is a side view of the stent retention element 200 of Figure 2A in a partially compressed state according to an illustrative embodiment of the invention. As illustrated in Figure 4A, the retention element 200 is adapted to expand along the axis 207 to effectively shorten the stent.
302, while maintaining an anchored position, to accommodate ureter 302 lengthening during patient activity. As illustrated in Figure 4B, the retention element 200 is also adapted to compress along the axis 207 to effectively lengthen the stent 102, in response to ureter 102 shortening during patient activity. In this way, the retention element 200 maintains the stent 302 in an anchored position while accommodating ureter 102 lengthening and shortening to reduce kidney 106 and/or bladder 110 irritation.

[0056] The cylindrical or conical spiral configuration of the coils 206a-206d of the retention element 200 performs substantially as a spring and permits compression motion. The effective spring force to compress the retention element 200 will be a function of the material Modulus of Elasticity selected, wall thickness, or diameter. According to the illustrative embodiment, the retention element 200 is capable of maximum compression and maximum decompression, as well as all intermediate positions in-between, including that of a neutral, or relaxed, state.

[0057] Figure 5A is a side view, partially in cross-section, of the stent retention element 200 of Figure 2A uncoiled within a catheter-type lumen 504 according to an illustrative embodiment of the invention. As shown during insertion, a medical operator inserts the retention element 200 through a catheter-type lumen 504, which substantially straightens coils 206a-206d. In one illustrative embodiment, a guide wire 508 is inserted into a lumen 506 of the stent 302 to push the retention element 200 through the catheter-type lumen 504 and into position. In other illustrative embodiments, other devices may be used to push the retention element 200 through the catheter-type lumen 504 and into position.

[0058] Figure 5B is a side view, partially in cross-section, of the stent retention element 200 of Figure 2A coiling in response to being extended out of the catheter-type lumen 504 according to an illustrative embodiment of the invention. As shown, due to its shape retention features, the retention element 200 returns to its coiled configuration as it emerges from the lumen 504.

[0059] Figure 5C is a side view, partially in cross-section, of the stent retention element 200 of Figure 2A uncoiling as it is retracted into a catheter-type lumen 510 during removal from a patient, according to an illustrative embodiment of the invention.

[0060] According to the illustrative embodiment of the invention, a medical operator inserts a catheter-type lumen 512 over the stent 302 and applies an axial load 514 to the retention element end 202. In response, the stent retention element 200 progressively uncoils, such that those of the plurality of coils 206a-206d having a relatively smaller diameter pass through each
of the plurality of coils 206a-206d having a relatively larger diameter. Although the retention element 200 is forced to uncoil into the lumen 512, the shape retention features of the retention element 200 enable the retention element 200 to return to its neutral, or relaxed, coiled state upon removal of the axial load 514 and release from the lumen 512. It should be noted that in the optional embodiment of Figure 2A, with the elongate section 203, a similar removal process may be followed.

The insertion and removal process depicted in Figures 5A through 5C function comparably whether the retention element 200' is placed in the urinary bladder 110, or the retention element 200'' is placed in the kidney 106, or both.

Variations, modifications, and other implementations of what is described herein will occur to those of ordinary skill in the art without departing from the spirit and the scope of the invention. This invention is not limited to the preceding illustrative description.

What is claimed is:
1. A stent comprising,
   an elongate body having first and second ends and defining an internal lumen extending
   there between, and having a length at least sufficient to extend through an anatomical lumen of a
   patient from a first anatomical site to a second anatomical site, and
   a first retention element incorporated with the first end of the elongate body and
   including a first elastic member coiling toward the second end of the elongate body at first
distances around a first section of the elongate body and adapted to anchor the stent at the first
anatomical site.
2. The stent of claim 1, wherein the first retention element includes a first elongate section
   extending axially from the first end of the elongate body and the first elastic member coils
   toward the second end of the elongate body at first distances around the first elongate section of
   the first retention element.
3. The stent of claim 1 further comprising,
   a second retention element incorporated with the second end of the elongate body and
   including a second elastic member coiling toward the first end of the elongate body and adapted
to anchor the stent at the second anatomical site.
4. The stent of claim 3, wherein the second elastic member coils toward the first end of the
   elongate body at second distances around a second section of the elongate body.
5. The stent of claim 3, wherein the second retention element includes a second elongate
   section extending axially from the second end of the elongate body and the second elastic
   member coils toward the first end of the elongate body at second distances around the second
   elongate section of the second retention element.
6. The stent of claim 1, wherein the first elastic member is adapted to compress in response
   to an axial force directed from the second end toward the first end of the elongate body, the
   compression retracting a portion of the elongate body from the ureter to accommodate ureter
   shortening.
7. The stent of claim 6, wherein the first retention element is adapted to return to an
   uncompressed steady state in response to removal of the axial force to re-expand the portion of
   the elongate body back into the ureter to accommodate ureter re-lengthening.
8. The stent of claim 1, wherein the first retention element is adapted to expand in response
   to an axial force directed from the first end toward the second end of the elongate body to extend
a portion of at least one of the elongate body and the first retention element into the ureter to accommodate ureter lengthening.

9. The stent of claim 8, wherein the first retention element is adapted to return to an unexpanded state in response to removal of the axial force to retract the portion of the elongate body or retention element from the ureter to accommodate ureter re-shortening.

10. The stent of claim 1, wherein the first distances are substantially constant to form the first retention element as a substantially cylindrical helix having a plurality of coils having substantially equal diameters.

11. The stent of claim 1, wherein the first distances are substantially constant to form the first retention element as a substantially cylindrical helix having a plurality of coils having substantially equal diameters.

12. The stent of claim 1, wherein the first distances vary to form the first retention element as a conical spiral having a plurality of coils, each having an associated diameter, the associated diameter increasing as the plurality of coils extends from the first end toward the second end of the elongate body.

13. The stent of claim 1, wherein the first distances vary to form the first retention element as a conical spiral having a plurality of coils, each having an associated diameter, the associated diameter increasing as the plurality of coils extends from the first end toward the second end of the elongate body.

14. The stent of claim 12, wherein those of the plurality of coils having a relatively smaller diameter are adapted to pass through those of the plurality of coils having a relatively larger diameter in response to an axial force on the first retention element directed from the first end toward the second end of the elongate body.

15. The stent of claim 13, wherein those of the plurality of coils having a relatively smaller diameter are adapted to pass through those of the plurality of coils having a relatively larger diameter in response to an axial force on the first retention element directed from the first end toward the second end of the elongate body.

16. The stent of claim 1, wherein the first retention element defines an internal retention element lumen.

17. The stent of claim 16, wherein the first retention element is adapted to uncoil in response to inserting a guide wire into the internal retention element lumen.
18. A stent retention element comprising, an elastic member adapted to be incorporated with
a first end of an elongate stent and to coil toward a second end of the elongate stent to anchor the
elongate stent at an anatomical site.

19. The stent retention element of claim 18, wherein the elastic member is adapted to coil
toward the second end of the elongate stent at first distances around a first section of the elongate
stent.

20. The stent retention element of claim 19, wherein the retention element includes an
elongate section adapted to extend axially from the first end of the elongate body, and the elastic
member is adapted to coil toward the second end of the elongate stent at first distances around
the elongate section of the stent retention element.

21. The stent retention element of claim 19, wherein the first distances are substantially
constant to form the elastic member as a substantially cylindrical helix having a plurality of coils
with substantially equal diameters.

22. The stent retention element of claim 20, wherein the first distances are substantially
constant to form the elastic member as a substantially cylindrical helix having a plurality of coils
with substantially equal diameters.

23. The stent retention element of claim 19, wherein the first distances vary to form the
elastic member as a conical spiral having a plurality of coils, each of the plurality of coils having
an associated diameter, and the associated diameter increasing as the plurality of coils extend
toward the second end of the elongate stent.

24. The stent retention element of claim 20, wherein the first distances vary to form the
elastic member as a conical spiral having a plurality of coils, each of the plurality of coils having
an associated diameter, and the associated diameter increasing as the plurality of coils extend
toward the second end of the elongate stent.

25. The stent retention element of claim 23, wherein those of the plurality of coils having a
relatively smaller diameter are adapted to pass through each of the plurality of coils having a
relatively larger diameter in response to an axial force directed from the first end toward the
second end of the elongate stent.

26. The stent retention element of claim 24, wherein those of the plurality of coils having a
relatively smaller diameter are adapted to pass through each of the plurality of coils having a
relatively larger diameter in response to an axial force directed from the first end toward the
second end of the elongate stent.
27. The stent retention element of claim 18, wherein the elastic member defines a retention element lumen.
Figure 4B
**INTERNATIONAL SEARCH REPORT**

**A. CLASSIFICATION OF SUBJECT MATTER**

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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)

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

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

**EPO-Internal**

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

<table>
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<td>EP 0 806 189 A (VARIOMED AG) 12 November 1997 (1997-11-12) column 5, line 12 - line 34; figure 1</td>
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<td>US 4 531 933 A (WOLOSKY IRWIN S ET AL) 30 July 1985 (1985-07-30) figures 1,6 column 2, line 59 - line 66 column 3, line 16 - line 35</td>
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Further documents are listed in the continuation of box C.

* Special categories of cited documents:
  * A: document defining the general state of the art which is not considered to be of particular relevance
  * E: earlier document published on or after the international filing date
  * L: document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
  * O: document referring to an oral disclosure, use, exhibition or other means
  * P: document published prior to the international filing date but later than the priority date claimed
  * T: later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
  * X: document of particular relevance; the claimed invention cannot be considered without the document; it is not obvious that the document was not known at the filing date of the priority claim
  * Y: document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is taken alone
  * Z: document member of the same patent family

Date of the actual completion of the international search 6 June 2003

Date of mailing of the international search report 27/06/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5318 Patentlaan 2 NL - 2280 HV Rijswijk

Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016

Authorized officer

Franz, V
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</table>
INTERNATIONAL SEARCH REPORT

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

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

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

2. □ Claims Nos.: 6–9, 14, 17–27
   because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
   see FURTHER INFORMATION sheet PCT/ISA/210

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

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

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

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

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

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

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

Remark on Protest

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

□ No protest accompanied the payment of additional search fees.

Form PCT/ISA210 (continuation of first sheet (1)) (July 1998)
Continuation of Box I.2

Claims Nos.: 6-9, 14, 17-27

Present claims 6-9, 14, and 17 relate to an apparatus defined by reference to a desirable characteristic or property, namely being "adapted" to expand, to compress or to return to a former state. The claims cover all apparatus having this characteristic or property, whereas the application provides support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT for only a very limited number of such apparatus. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). An attempt is made to define the apparatus by reference to a result to be achieved. Again, this lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible.

In view of the wording of independent claims 1 and 18 and the claims 19-27 depending thereupon presently on file, it Is difficult, if not impossible, to determine the matter for which protection is sought. Thus, the present application fails to comply with the clarity and conciseness requirements of Article 6 PCT (see also Rule 6.1(a) PCT) to such an extent that a meaningful search is impossible.

Consequently, the search has been carried out for those parts of the claims which appear to be clear, supported and disclosed, namely those parts claimed in claims 1-5, 10-13, 15, and 16.

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