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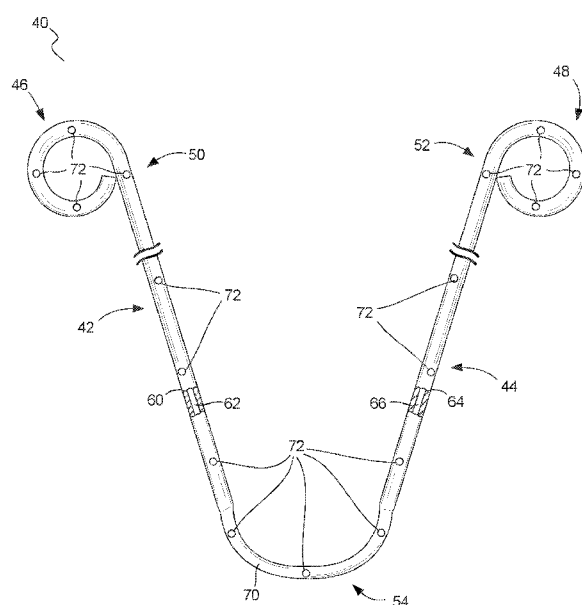


**FIG. 2**

(57) Abstract: The embodiments disclosed herein relate to a ureteral stent having two stent bodies and a tether. The stent can minimize or prevent migration of the device out of the bladder of the patient while also reducing patient discomfort associated with such stents.

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## URETERAL STENT AND RELATED METHODS

### Cross-Reference to Related Application(s)

**[001]** This application claims priority to U.S. Provisional Application 62/382,833, filed September 2, 2016 and entitled "Ureteral Stent and Related Methods," which is hereby incorporated herein by reference in its entirety.

### Field of the Invention

**[002]** The various embodiments herein relate to an improved stent, including, for example, a ureteral stent.

### Background of the Invention

**[003]** For a patient with an obstructed ureter, a ureteral stent is used to aid in transfer of urine from one of the patient's kidneys to the patient's bladder through the obstructed ureter. As best shown in FIG. 1B, the ureters 20, 22 connect the kidneys 24, 26, respectively, to the bladder 28 for the drainage of urine from the kidneys 24, 26 to the bladder 28. Ureter obstruction can occur as a result of one or more kidney stones, stricture, tumors, or scarring from various causes, including infection, surgery, or radiation. While aiding with the flow of urine to the bladder, the stent should also function to stay in the desired position within the ureter and not migrate out of or further into the kidney or the bladder. "Stent migration" is a phenomenon in which the end of the stent positioned in the bladder or kidney moves or "migrates" into and/or through the ureter, thereby resulting in the failure of the stent to provide the desired urinary diversion from the kidney to the bladder.

**[004]** As shown in FIG. 1A, one typical design of a known ureteral stent 10 that is configured to aid flow while maintaining its position has a hollow tubular stent body 12 with having spirals or loops 14, 16 at both ends. The stent body 12 can also be solid (have no lumen therein). The first self-contained loop (also referred to as a "first loop," "first coil," "renal loop," or "renal coil") 14 is coupled to or integral with one end of the body 12, and the second self-contained loop (also referred to as a "second loop," "second coil," "bladder loop," or "bladder coil") 16 is coupled to or integral with the other end. Other structures/configurations other than loops are also used in various known stents.

**[005]** In use, as shown in FIG. 1B, when the stent 10 is successfully implanted into the patient, the renal loop 14 is positioned in the kidney 26 or renal pelvis, the body 12 is positioned in and through the ureter 22, and the bladder loop 16 is positioned in the bladder 28. The loops 14, 16 (or other types of configurations/structures) function to retain the stent 10 in its desired position, with the first loop 14 being retained in the kidney 26 and the second loop 16 being retained in the bladder 28. The loops 14, 16 are formed as a result of both ends of the stent 10 deviating from a substantially linear or tubular shape and instead forming structures that reduce the risk of migration of the stent 10. It is understood that while the stent 10 is positioned in the left ureter 22 as shown, it can also be positioned in the right ureter 20 in the same fashion as described herein. A stent can be required for a period ranging from a day to several months.

**[006]** In this type of stent 10, the urine flows through the lumen (not shown) of the tubular stent body 12 such that the wall of the body 12 prevents obstructions from blocking the flow. Alternatively, the urine can flow around or external to the tubular stent body 12. Thus, the body 12 in these various types of stents 10 can have a small or large lumen diameter (typically ranging from about 3.7 French up to about 10 French).

**[007]** One disadvantage of this type of stent is patient discomfort. Typically, the above stent type causes pain or discomfort due to the bladder loop irritating, scratching, puncturing, or poking the bladder lining. While the loop prevents or reduces the incidence of stent migration, the loop can cause debilitating pain.

**[008]** Another typical design of a ureteral stent has a highly flexible strands or loops at the bladder end of the stent (replacing the standard loop described above) that reduce the size of the stent in the bladder end to reduce patient discomfort. More specifically, this type of stent has a renal end that is substantially similar to the renal end of the stent type described above, but at some (usually significant) distance from the renal end, the flexible strands or loops are coupled thereto or integrated therein - typically at about the iliac vessels of the patient when the stent is properly positioned in the patient.

**[009]** One disadvantage of this type of stent is that stents of multiple sizes are required and then a physician must select the stent size to use based on approximations of the patient's physiology. Further, despite the reduced size of the strands or loops, significant patient discomfort is still a common problem, and there is little evidence that these alternative stent designs reduce stent discomfort. In these designs, the common feature is the presence of a bulky bladder component that causes bladder pain.

**[010]** While multiple designs have been tested, no stent configuration to date has been able to successfully overcome both the migration problem and the patient discomfort associated with the various structures/configurations (such as the loop or highly flexible strands/loops described above) used to prevent the migration.

**[011]** There is a need in the art for an improved ureteral stent and related systems and methods.

### **Brief Summary of the Invention**

**[012]** Discussed herein are various devices and methods for promoting flow of urine through the ureter to the bladder of a patient.

**[013]** In Example 1, a ureteral stent comprises a first tubular stent body comprising a first lumen, a first retention structure extending from a distal end of the first tubular stent body, a second tubular stent body comprising a second lumen, a second retention structure extending from a distal end of the second tubular stent body, and a connection member comprising a first end extending from a proximal end of the first tubular stent body, and a second end extending from a proximal end of the second tubular stent body.

**[014]** Example 2 relates to the ureteral stent according to Example 1, wherein the first tubular stent body, the second tubular stent body, and the connection member form a unitary component.

**[015]** Example 3 relates to the ureteral stent according to Example 1, wherein the first end of the connection member is coupled to the proximal end of the first tubular stent body and the second end of the connection member is coupled to the proximal end of the second tubular stent body.

**[016]** Example 4 relates to the ureteral stent according to Example 3, wherein the connection member comprises a cord, a string, a monofilament, or a braided material.

**[017]** Example 5 relates to the ureteral stent according to Example 1, wherein the connection member comprises a first portion comprising the first end extending from the proximal end of the first tubular stent body, and a second portion comprising the second end extending from the proximal end of the second tubular stent body, wherein the first and second portions are magnetically coupleable.

**[018]** Example 6 relates to the ureteral stent according to Example 1, wherein the connection member is configured to prevent distal migration of the first and second tubular stent bodies.

**[019]** Example 7 relates to the ureteral stent according to Example 1, further comprising openings defined in the first tubular stent body and the second tubular stent body.

**[020]** Example 8 relates to the ureteral stent according to Example 7, wherein the openings provide fluidical access to the first and second lumens.

**[021]** In Example 9, a ureteral stent comprises a first tubular stent body comprising a first lumen, a first retention structure extending from a distal end of the first tubular stent body, a connection member comprising a first end extending from a proximal end of the first tubular stent body, a second tubular stent body comprising a second lumen, and a second retention structure extending from a distal end of the second tubular stent body. A second end of the connection member extends from a proximal end of the second tubular stent body. Further, the first tubular stent body is disposable within a first ureter, the first retention structure is disposable within a first kidney, at least a portion of the connection member is disposable within a bladder, the second tubular stent body is disposable within a second ureter, and the second retention structure is disposable within a second kidney.

**[022]** Example 10 relates to the ureteral stent according to Example 9, wherein the connection member is a unitary component.

**[023]** Example 11 relates to the ureteral stent according to Example 10, wherein the connection member comprises a lumen.

**[024]** Example 12 relates to the ureteral stent according to Example 9, wherein the first end of the connection member is coupled to the proximal end of the first tubular stent body and the second end of the connection member is coupled to the proximal end of the second tubular stent body.

**[025]** Example 13 relates to the ureteral stent according to Example 12, wherein the connection member comprises a cord, a string, a monofilament, or a braided material.

**[026]** Example 14 relates to the ureteral stent according to Example 9, wherein the connection member comprises a first portion comprising the first end coupled to the proximal end of the first tubular stent body and a second portion comprising the second end coupled to the proximal end of the second tubular stent body, wherein the first and second portions are magnetically coupleable.

**[027]** Example 15 relates to the ureteral stent according to Example 9, wherein the connection member comprises a first portion and a second portion. The first portion comprises the first end coupled to the proximal end of the first tubular stent body, and a first magnet coupled to the first

portion. The second portion comprises the second end coupled to the proximal end of the second tubular stent body, and a second magnet coupled to the second portion, wherein the second magnet is magnetically coupled with the first magnet.

**[028]** Example 16 relates to the ureteral stent according to Example 9, wherein the connection member is configured to prevent distal migration of the first and second tubular stent bodies.

**[029]** In Example 17, a method of promoting flow of urine to a bladder comprises inserting a first guidewire into a first kidney via a first ureter, inserting a second guidewire into a second kidney via a second ureter, and urging a first tubular stent body distally on the first guidewire until a first retention structure extending from a distal end of the first tubular stent body is disposed in the first kidney. The first tubular stent body comprises a first lumen. The method further comprises urging a second tubular stent body distally on the second guidewire until a second retention structure extending from a distal end of the second tubular stent body is disposed in the second kidney. The second tubular stent body comprises a second lumen. At least a portion of a connection member is disposable within the bladder when the first retention structure is disposed in the first kidney and the second retention structure is disposed in the second kidney, and the connection member comprises a first end coupled to a proximal end of the first tubular stent body and a second end coupled to a proximal end of the second tubular stent body.

**[030]** Example 18 relates to the method according to Example 17, further comprising magnetically coupling a first portion of the connection member to a second portion of the connection member in the bladder.

**[031]** Example 19 relates to the method according to Example 17, further comprising urging the connection member proximally out of the bladder to remove the connection member, the first tubular stent body, and the second tubular stent body from the patient.

**[032]** Example 20 relates to the method according to Example 17, wherein the connection member prevents distal migration of the first and second tubular stent bodies.

**[033]** While multiple embodiments are disclosed, still other embodiments of the present invention will become apparent to those skilled in the art from the following detailed description, which shows and describes illustrative embodiments of the invention. As will be realized, the invention is capable of modifications in various obvious aspects, all without departing from the spirit and scope of the present invention. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not restrictive.

#### **Brief Description of the Drawings**

**[034]** FIG. 1A is a perspective view of a known ureteral stent.

**[035]** FIG. 1B is a cross-sectional schematic view of the known ureteral stent of FIG. 1A implanted in the ureter of a patient.

**[036]** FIG. 2 is a front view of a ureteral stent, according to one embodiment.

**[037]** FIG. 3 is a front view of a tether of a ureteral stent, according to one embodiment.

**[038]** FIG. 4 is a cross-sectional schematic view of the ureteral stent of FIG. 2 implanted in a patient, according to one embodiment.

### Detailed Description

**[039]** The various embodiments disclosed herein relate to a ureteral stent that minimizes or prevents migration of the stent body out of the bladder (and into the ureter) while also reducing or eliminating the discomfort resulting from known ureteral stents.

**[040]** FIG. 2 depicts a ureteral stent 40, according to one embodiment. The stent 40 has a first tubular stent body (or “right stent body”) 42 and a second tubular stent body (or “left stent body”) 44. The right stent body 42 has a first retention structure (or “right retention structure”) 46 extending from or at the distal end 50 of the body 42, while the left stent body 44 has a second retention structure (or “left retention structure”) 48 extending from or at the distal end 52 of the body 44. In addition, the stent 40 has a connection member (also referred to herein as a “tether” or “third retention structure”) 54 coupled to, extending from, or integral with the proximal ends of the right and left stent bodies 42, 44.

**[041]** In the instant Application, the ends of the stent bodies (such as stent bodies 42, 44) that are positioned in the kidneys will be referred to as the “distal” ends of those bodies because those ends are the ends that are typically first inserted into the patient. However, it is understood that others may refer to the ends positioned in the kidneys as “proximal” ends. The terms used herein are not intended to be limiting, but instead are intended to identify the various components of the various embodiments herein in a fashion that allows for the various components to be easily identified in relation to each other.

**[042]** In accordance with one implementation, the right stent body 42 is a tubular body 42 having a tubular wall 60 that defines a lumen 62. Similarly, the left stent body 44 is a tubular body 44 having a tubular wall 64 that defines a lumen 66. In one implementation, the outer diameter of the tubular bodies 42, 44 can range from 3 to 10 French. Further, certain embodiments of the bodies 42, 44 have a length ranging from about 10 to 32 cm. According to certain embodiments, the bodies 42, 44 can be made of one or more thermoplastic materials (such as, for example, polyurethanes), one or more thermoset elastomers (such as, for example, silicone), one or more hydrogels, one or more metal alloys, one or more biodegradable materials, or one or more other polymers (such as, for example, polyisobutylene, polylactic acid, polyglycolic acid, polystyrene, and/or polymethylmethacrylate). In one implementation, regardless of the material selected, it is radiopaque so that the material can be visualized within the patient's body using imaging technology. Alternatively, it is understood that the right and left stent bodies 42, 44 can have the structure and/or features of any ureteral tube with a lumen in any known ureteral stent.

**[043]** In the specific exemplary embodiment discussed above and depicted in FIG. 2, the right and left retention structures 46, 48 are renal coils 46, 48 having known renal coil structures. According to one implementation, each of the coils 46, 48 can have a curl diameter ranging from about 2 to 5 cm. According to certain embodiments, the coils 46, 48 can be made of the same or similar materials as those described above with respect to the bodies (such as bodies 42, 44). In one implementation, regardless of the material selected, it is radiopaque so that the material can be visualized within the patient's body using imaging technology. Alternatively, it is understood that the right and left retention

structures 46, 48 can be any known retention structure having any known structure and/or features that is positioned in a kidney to aid in retention of a ureteral stent in its desired implanted position.

**[044]** The stent 40, according to one implementation, has multiple openings 72 defined in the stent 40 as shown in FIG. 2. For example, the right and left stent bodies 42, 44 have openings 72 defined in the tubular walls 60, 64 such that the openings 72 are in fluidic communication with the lumens 62, 66 therein. According to one embodiment, the openings 72 allow fluid to pass into and out of the lumens 62, 66 of the right and left stent bodies 42, 44.

**[045]** According to certain implementations, the tether 54 as shown is a tubular component 54 having a lumen 70 defined therein. In one embodiment, the tether 54 has a similar or smaller diameter in comparison to the right and left stent bodies 42, 44. That is, the tether 54 has a diameter ranging from about 3 French to about 10 French. In further implementations, the tether 54 is softer and/or more flexible or pliable than the right and left stent bodies 42, 44. Alternatively, the tether 54 has no lumen. In a further alternative, the tether 54 is a cord or string. The tether 54 can be made of the same or similar materials as those described above with respect to the bodies (such as bodies 42, 44) and the coils (such as coils 46, 48). Further, the tether 54 can also be made of a monofilament or braided material such as silk or nylon. In one implementation, regardless of the material selected, it can be radiopaque so that the material can be visualized within the patient's body using imaging technology. Alternatively, the tether 54 is not radiopaque.

**[046]** In accordance with some implementations, the tether 54 is a separate component that is coupled at a first end to the proximal end of the right stent body 42 and at a second end to the proximal end of the left stent body 44. Alternatively, the tether 54 is integral with the right and left stent bodies 42, 44 such that the right stent body 42, the tether 54, and the left stent body 44 are a single unitary component.

**[047]** According to other embodiments as best shown in FIG. 3, the tether 54 is made up of two components: a first portion 80 having a first magnetic component 86 at a second end 84 of the portion 80 and a second portion 90 having a second magnetic component 96 at a second end 94 of the portion 90. The first and second magnetic components 86, 96 are configured to be coupleable with each other. The first portion 80 is coupled at the first end 82 to the proximal end of the right stent body 42, while the second portion 90 is coupled at the first end 92 to the proximal end of the left stent body 44. Alternatively, the first portion 80 is integral with the right stent body 42 such that the right stent body 42 and the first portion 80 are a single unitary component, and the second portion 90 is integral with the left stent body 44 such that the left stent body 44 and the second portion 90 are a single unitary component.

**[048]** As best shown in FIG. 4, in use according to one embodiment, the stent 40 can be positioned in the patient as depicted to aid the flow of urine from one or both of the kidneys 100, 102 to the bladder 104. More specifically, the right and left retention structures 46, 48 are positioned in the right and left kidneys 100, 102, respectively, and the right and left stent bodies 42, 44 are positioned in the right and left ureters 106, 108, respectively. Further, the tether 54 is positioned in the bladder 104.

**[049]** It is understood that the right and left retention structures 46, 48 are typically positioned entirely within the kidneys 100, 102 to help retain the stent 40 in its desired position. However, it is

further understood that portions of the structures 46, 48 coupled to or integral with the stent bodies 42, 44 may extend out of the kidneys 100, 102 and into the ureters 106, 108. In addition, it is understood that, in other embodiments, portions of the stent bodies 42, 44 that are coupled to or integral with the retention structures 46, 48 may extend from the ureters 106, 108 into the kidneys 100, 102. Similarly, it is understood that portions of the stent bodies 42, 44 that are coupled to or integral with the tether 54 may extend into the bladder 104 through the ureteral orifices 110, 112, and that, in other implementations, portions of the tether 54 that are coupled to or integral with the stent bodies 42, 44 may extend into the right and left ureters 106, 108 through the ureteral orifices 110, 112.

**[050]** The various stent embodiments disclosed or contemplated herein, including, for example, stent 40, reduce the patient discomfort prevalent in known ureteral stents while also preventing migration of the stent 40 out of the bladder. These two benefits are accomplished via the use of the two ureteral stent bodies 42, 44 that are coupled together by the tether 54 in the bladder 104, thereby eliminating the need for a standard bladder coil positioned in the bladder as described above in the Background. The elimination of the bladder coil reduces the incidence of injury to the bladder lining or the bladder that is typically caused by such a coil, thereby reducing the pain associated with such injury. In addition, the tether 54 prevents migration without the associated pain of known stents by coupling together the two stent bodies 42, 44, which are retained in their desired positions by the retention members 46, 48 in the kidneys 100, 102.

**[051]** One method of implanting the stent 40, according to one embodiment, includes the following steps. First, two guidewires (not shown) are positioned into the right and left kidneys 100, 102 through the right and left ureters 106, 108 via the urethra and the bladder such that one guidewire is positioned in one kidney 100 and the other guidewire is positioned in the other kidney 102. Once the guidewires are positioned into the kidneys 100, 102, the distal ends of the stent bodies 42, 44 - including the right and left retention structures 46, 48 - are simultaneously loaded onto (or otherwise positioned over) the proximal ends of the two guidewires. As the stent bodies 42, 44 are advanced distally over the guidewires, the proximal ends of the guidewires (not shown) extend out of two sideholes (not shown) defined in the tether 54 that allow for the stent bodies 42, 44 and tether 54 to be advanced. Once the bodies 42, 44 and tether 54 have been advanced to the point that the guidewires (not shown) extend out of the sideholes (not shown), one or two known pusher devices (not shown) can be positioned on and advanced distally over the guidewires (not shown) behind the stent bodies 42, 44 and tether 54 such that the advancement of the pusher device (not shown) urges the stent bodies 42, 44 and tether 54 distally. The stent bodies 42, 44 are advanced distally until the right and left retention structures 46, 48 are positioned in the kidneys as desired. X-ray, ultrasound, or some other imaging technology can be used to determine that the right and left retention structures 46, 48 are positioned as desired. Once the right and left retention structures 46, 48 - and thus the stent bodies 42, 44 and tether 54 - are positioned correctly, the guidewires (not shown) can be removed, leaving the stent 40 in place.

**[052]** In an alternative method in which the stent 40 has two stent bodies 42, 44 that can be removably coupled together at the tether 54 via magnets (such as magnets 86, 96 as discussed

above), the two bodies 42, 44 can be advanced separately over the two guidewires (not shown) and positioned as desired. Once the retention structures 46, 48 and the stent bodies 42, 44 are positioned correctly, the magnets (such as magnets 86, 96, for example) on the proximal end of the bodies 42, 44 are coupled together in the bladder 104.

**[053]** In accordance with one embodiment, the stent 40 can be removed using a small removal tether (not shown). That is, the stent 40 can have a removal tether (not shown) coupled to the tether 54 such that the removal tether (not shown) extends away from the stent 40 (and in some embodiments extends out of the urethra) and can be grasped or captured and then a proximal force can be applied to the removal tether to remove the stent 40 from the patient.

**[054]** Alternatively, the stent 40 can be removed by using a tool of some kind. The tool can be inserted into the bladder and grasp the tether 54 of the stent and then be urged proximally to remove the stent 40.

**[055]** Although the present invention has been described with reference to preferred embodiments, persons skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

### Claims

What is claimed is:

1. A ureteral stent, comprising:
  - (a) a first tubular stent body comprising a first lumen;
  - (b) a first retention structure extending from a distal end of the first tubular stent body;
  - (c) a second tubular stent body comprising a second lumen;
  - (d) a second retention structure extending from a distal end of the second tubular stent body; and
  - (e) a connection member comprising:
    - (i) a first end extending from a proximal end of the first tubular stent body; and
    - (ii) a second end extending from a proximal end of the second tubular stent body.
2. The ureteral stent of claim 1, wherein the first tubular stent body, the second tubular stent body, and the connection member form a unitary component.
3. The ureteral stent of claim 1, wherein the first end of the connection member is coupled to the proximal end of the first tubular stent body and the second end of the connection member is coupled to the proximal end of the second tubular stent body.
4. The ureteral stent of claim 3, wherein the connection member comprises a cord, a string, a monofilament, or a braided material.
5. The ureteral stent of claim 1, wherein the connection member comprises:
  - (a) a first portion comprising the first end extending from the proximal end of the first tubular stent body;
  - (b) a second portion comprising the second end extending from the proximal end of the second tubular stent body,wherein the first and second portions are magnetically coupleable.
6. The ureteral stent of claim 1, wherein the connection member is configured to prevent distal migration of the first and second tubular stent bodies.

7. The ureteral stent of claim 1, further comprising openings defined in the first tubular stent body and the second tubular stent body.

8. The ureteral stent of claim 7, wherein the openings provide fluidical access to the first and second lumens.

9. A ureteral stent, comprising:

- (a) a first tubular stent body comprising a first lumen, wherein the first tubular stent body is disposable within a first ureter;
- (b) a first retention structure extending from a distal end of the first tubular stent body, wherein the first retention structure is disposable within a first kidney;
- (c) a connection member comprising a first end extending from a proximal end of the first tubular stent body, wherein at least a portion of the connection member is disposable within a bladder;
- (d) a second tubular stent body comprising a second lumen, wherein the second tubular stent body is disposable within a second ureter, wherein a second end of the connection member extends from a proximal end of the second tubular stent body; and
- (e) a second retention structure extending from a distal end of the second tubular stent body, wherein the second retention structure is disposable within a second kidney.

10. The ureteral stent of claim 9, wherein the connection member is a unitary component.

11. The ureteral stent of claim 10, wherein the connection member comprises a lumen.

12. The ureteral stent of claim 9, wherein the first end of the connection member is coupled to the proximal end of the first tubular stent body and the second end of the connection member is coupled to the proximal end of the second tubular stent body.

13. The ureteral stent of claim 12, wherein the connection member comprises a cord, a string, a monofilament, or a braided material.

14. The ureteral stent of claim 9, wherein the connection member comprises:

- (a) a first portion comprising the first end coupled to the proximal end of the first tubular stent body;

- (b) a second portion comprising the second end couple to the proximal end of the second tubular stent body,  
wherein the first and second portions are magnetically coupleable.
15. The ureteral stent of claim 9, wherein the connection member comprises:
- (a) a first portion comprising:
    - (i) the first end coupled to the proximal end of the first tubular stent body;  
and
    - (ii) a first magnet coupled to the first portion;
  - (b) a second portion comprising:
    - (i) the second end coupled to the proximal end of the second tubular stent body; and
    - (ii) a second magnet coupled to the second portion, wherein the second magnet is magnetically coupled with the first magnet.
16. The ureteral stent of claim 9, wherein the connection member is configured to prevent distal migration of the first and second tubular stent bodies.
17. A method of promoting flow of urine to a bladder of a patient, the method comprising:  
inserting a first guidewire into a first kidney via a first ureter;  
inserting a second guidewire into a second kidney via a second ureter;  
urging a first tubular stent body distally on the first guidewire until a first retention structure extending from a distal end of the first tubular stent body is disposed in the first kidney, wherein the first tubular stent body comprises a first lumen; and  
urging a second tubular stent body distally on the second guidewire until a second retention structure extending from a distal end of the second tubular stent body is disposed in the second kidney, wherein the second tubular stent body comprises a second lumen,  
wherein at least a portion of a connection member is disposable within the bladder when the first retention structure is disposed in the first kidney and the second retention structure is disposed in the second kidney, wherein the connection member comprises a first end extending from a proximal end of the first tubular stent body and a second end extending from a proximal end of the second tubular stent body.

18. The method of claim 17, further comprising magnetically coupling a first portion of the connection member to a second portion of the connection member in the bladder.

19. The method of claim 17, further comprising urging the connection member proximally out of the bladder to remove the connection member, the first tubular stent body, and the second tubular stent body from the patient.

20. The method of claim 17, wherein the connection member prevents distal migration of the first and second tubular stent bodies.

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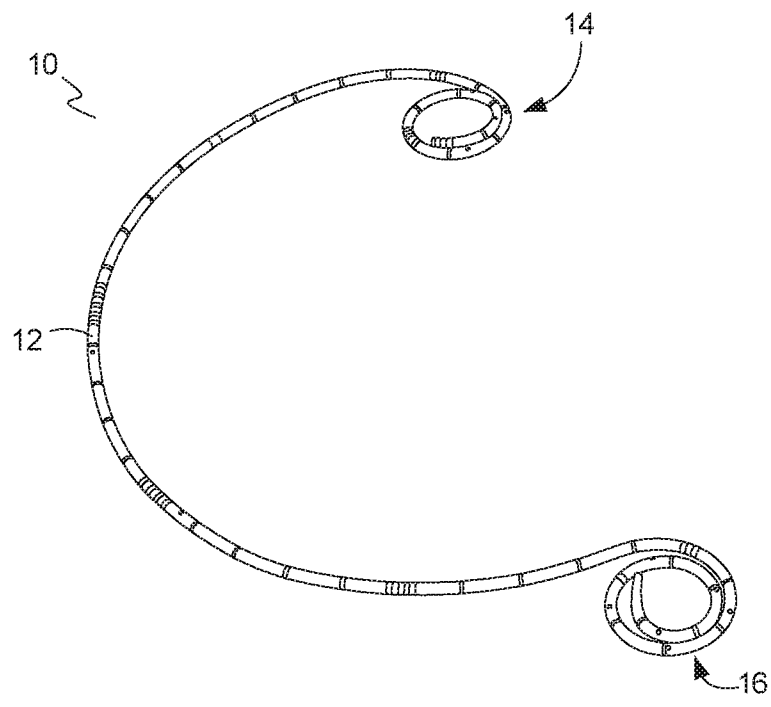


**FIG. 1A**  
(PRIOR ART)

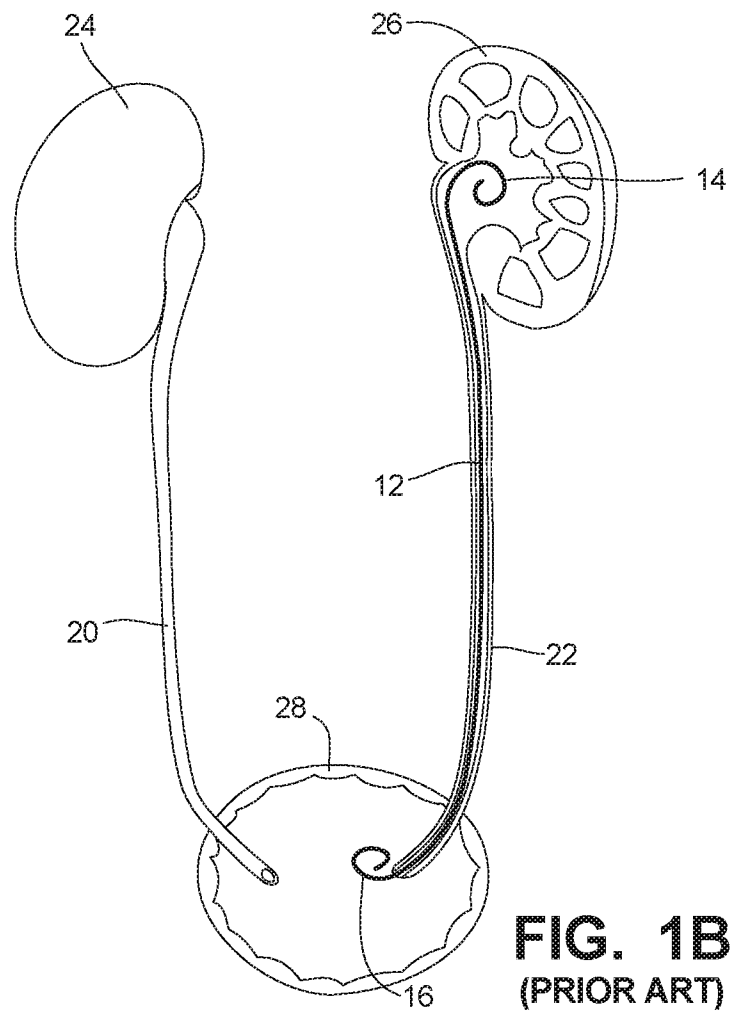


**FIG. 1B**  
(PRIOR ART)

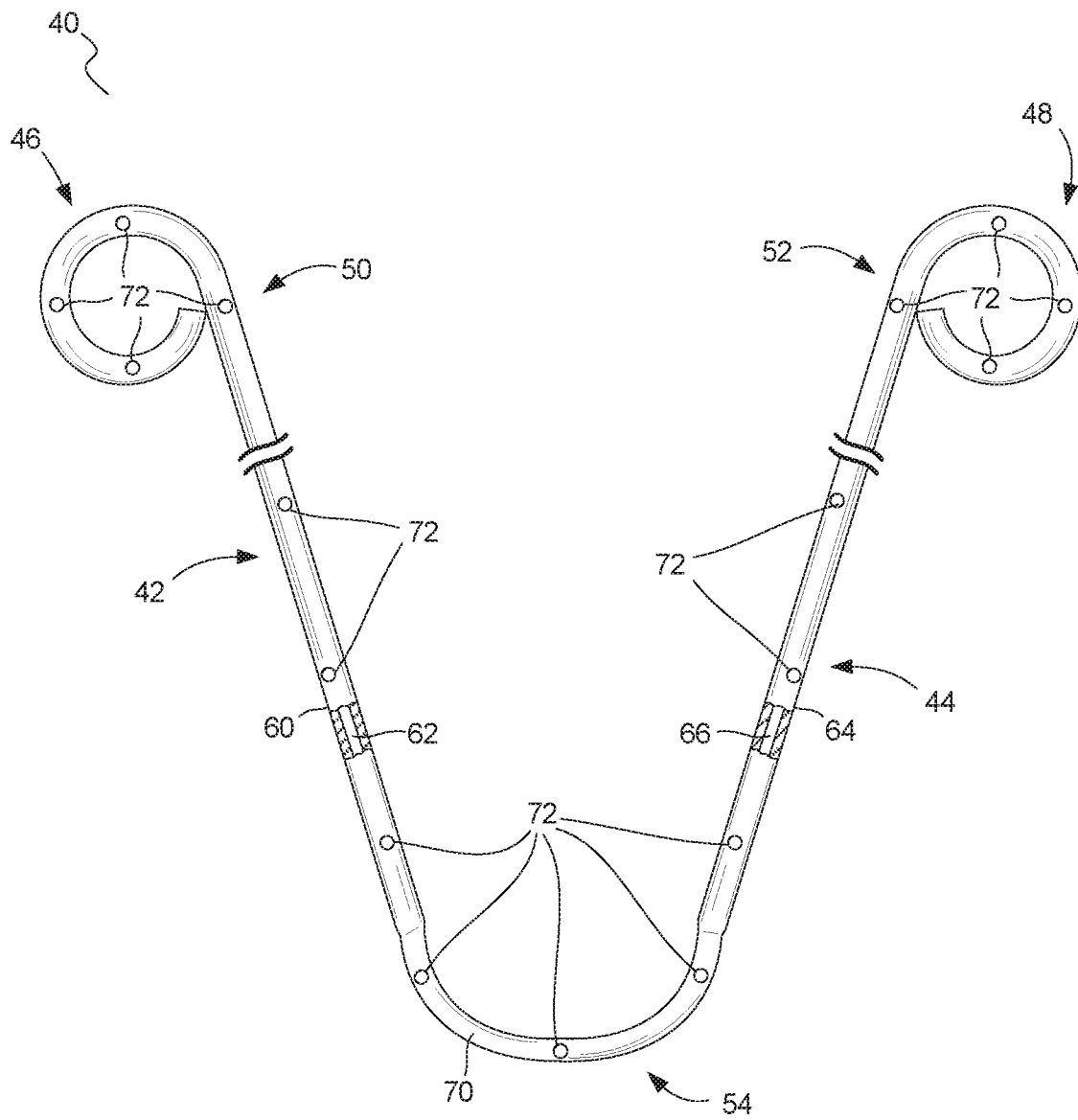


**FIG. 2**

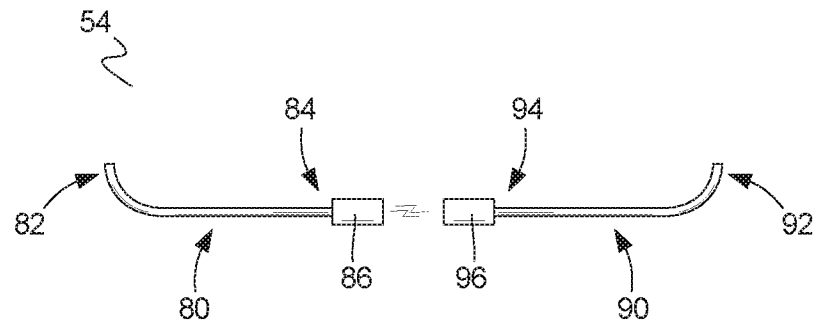


FIG. 3

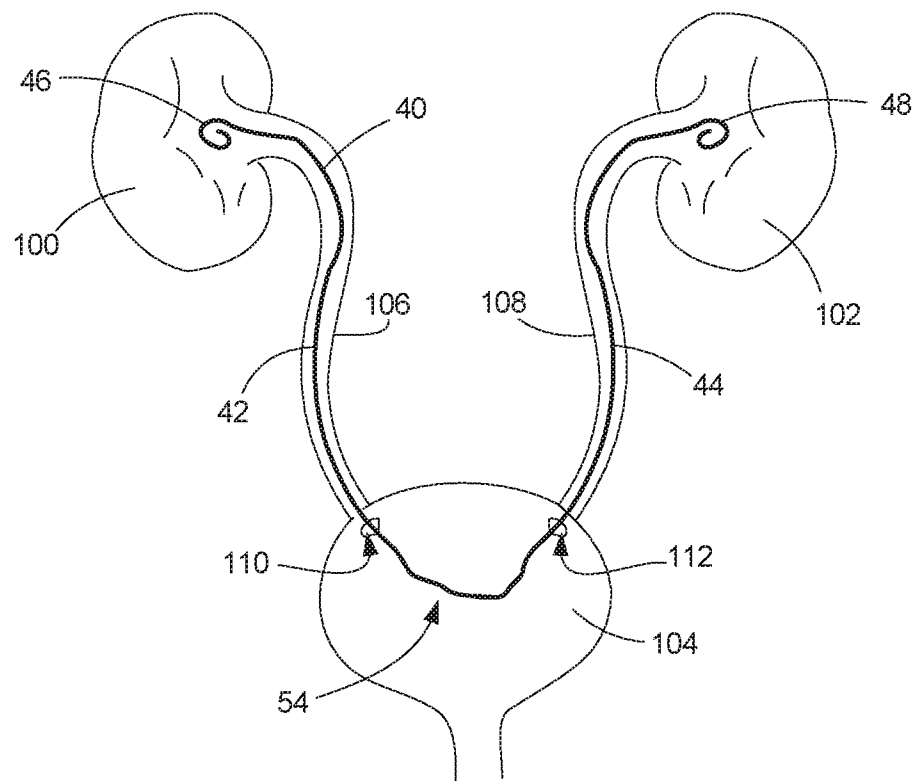


FIG. 4

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 17/49883

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 2/04; A61M 5/00 (2017.01)

CPC - A61F 2/94; A61M 27/002; A61M 27/006; A61M 27/008

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)

See Search History Document

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

See Search History Document

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

See Search History Document

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages                                    | Relevant to claim No. |
|-----------|-----------------------------------------------------------------------------------------------------------------------|-----------------------|
| X         | US 2002/0138154 A1 (LI et al) 26 September 2002 (26.09.2002) fig 1a, para [0030]                                      | 1-3, 6, 9-12, 16      |
| Y         |                                                                                                                       | 4, 13                 |
| X         | US 4,790,810 A (PUGH JR. et al) 13 December 1988 (13.12.1988) fig 1, col 2, ln 60-68, col 3, ln 8-22, col 3, ln 44-48 | 1, 7-8                |
| Y         | US 6,395,021 B1 (HART et al) 28 May 2002 (28.05.2002) fig 41, 42, col 11, ln 57 to col 12, ln 15                      | 4, 13                 |
| A         | US 2012/0157833 A1 (BERENT et al) 21 June 2012 (21.06.2012) entire document                                           | 1-4, 6-13, 16         |
| A         | US 2014/0135941 A1 (SMOUSE et al) 15 May 2014 (15.05.2014) entire document                                            | 1-4, 6-13, 16         |
| A         | US 4,790,809 A (KUNTZ) 13 December 1988 (13.12.1988) entire document                                                  | 1-4, 6-13, 16         |

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

\* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&amp;" document member of the same patent family

Date of the actual completion of the international search

12 December 2017

Date of mailing of the international search report

08 JAN 2018

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents  
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-8300

Authorized officer:

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PCT Helpdesk: 571-272-4300  
PCT OSP: 571-272-7774

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 17/49883

## Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
  
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

This International Searching Authority found multiple inventions in this international application, as follows:  
This application contains the following species of the generic invention which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid

Group I: Claims 1-4, 6-13, 16 directed to a ureteral stent having a cord/string/monofilament/braided connection member.

Group II: Claims 1-3, 5-12, 14-16 directed to a ureteral stent having a magnetic connection member.

Group III: Claims 17-20 directed to method of promoting flow of urine to a bladder of a patient.

**\*\*Claims 1-3, 6-12, 16 are generic to groups I-II.\*\***

----Continued on Supplemental Page----

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:  
1-4, 6-13, 16

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☒ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

Continuation of Box III: Observations where unity of invention is lacking

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

#### SPECIAL TECHNICAL FEATURES

The special technical feature of each species (Groups I-II) is provided in the group descriptions above. None of these special technical features are common to the other species, nor do they correspond to a special technical feature in the other species.

Group III includes the special technical feature of method of promoting flow of urine to a bladder of a patient, the method comprising: inserting a first guidewire into a first kidney via a first ureter; inserting a second guidewire into a second kidney via a second ureter; urging a first tubular stent body distally on the first guidewire until a first retention structure extending from a distal end of the first tubular stent body is disposed in the first kidney, wherein the first tubular stent body comprises a first lumen; and urging a second tubular stent body distally on the second guidewire until a second retention structure extending from a distal end of the second tubular stent body is disposed in the second kidney, wherein the second tubular stent body comprises a second lumen, wherein at least a portion of a connection member is disposable within the bladder when the first retention structure is disposed in the first kidney and the second retention structure is disposed in the second kidney, wherein the connection member comprises a first end extending from a proximal end of the first tubular stent body and a second end extending from a proximal end of the second tubular stent body, not required by Groups I-II.

#### COMMON TECHNICAL FEATURES

Groups I-III share the technical features of claim 1 and 9. Groups I-II are species of generic independent claims 1 and 9. Groups I-III are related as an apparatus (Groups I-II) and methods for producing the apparatus (Group III). The apparatus is known in prior art as shown in US 2002/0138154 A1 to Li, et al. (hereinafter 'Li').

Regarding claim 1, Li discloses a ureteral stent, comprising:

- (a) a first tubular stent body (portion of 100 from left 102 to connecting portion 104) comprising a first lumen (fig 1a, para [0030]);
- (b) a first retention structure (curl) extending from a distal end (upper end) of the first tubular stent body (fig 1a, para [0030]);
- (c) a second tubular stent body (portion of 110 from right 102 to connecting portion 104) comprising a second lumen (fig 1a, para [0030]);
- (d) a second retention structure (curl) extending from a distal end of the second tubular stent body (fig 1a, para [0030]);
- and (e) a connection member (104) comprising:
  - (i) a first end (portion of 104 adjacent left 102) extending from a proximal end (lower portion of left 102 nearest connecting portion 104) of the first tubular stent body (fig 1a, para [0030]);
  - and (ii) a second end (portion of 104 adjacent right 102) extending from a proximal end (lower portion of right 102 nearest connecting portion 104) of the second tubular stent body (fig 1a, para [0030]).

Regarding claim 9, Li discloses a ureteral stent, comprising:

- (a) a first tubular stent body (portion of 100 from left 102 to connecting portion 104) comprising a first lumen (fig 1a, para [0030]), wherein the first tubular stent body is disposable within a first ureter (intended use, see para [0030]);
- (b) a first retention structure (curl) extending from a distal end (upper end) of the first tubular stent body (fig 1a, para [0030]), wherein the first retention structure is disposable within a first kidney (intended use, see para [0030]);
- (c) a connection member (104) comprising a first end (portion of 104 adjacent left 102) extending from a proximal end (lower portion of left 102 nearest connecting portion 104) of the first tubular stent body (fig 1a, para [0030]), wherein at least a portion of the connection member is disposable within a bladder (intended use, see para [0030]);
- (d) a second tubular stent body (portion of 110 from right 102 to connecting portion 104) comprising a second lumen (fig 1a, para [0030]), wherein the second tubular stent body is disposable within a second ureter (intended use, see para [0030]), wherein a second end (portion of 104 adjacent right 102) extending from a proximal end (lower portion of right 102 nearest connecting portion 104) of the second tubular stent body (fig 1a, para [0030]); and
- (e) a second retention structure (curl) extending from a distal end of the second tubular stent body (fig 1a, para [0030]), wherein the second retention structure is disposable within a second kidney (intended use, see para [0030]).

As the common features were known in the art at the time of the invention, they cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-III lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.