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(54) Title: ANTI-REFLUX URETERAL STENTS AND METHODS

(57) Abstract: An anti-reflux ureteral stent includes an elongated member with a distal end having a first retention structure and a proximal end having a second retention structure. A lumen extends between the distal and proximal ends. The elongated member may include a valve near the proximal end and distal to the second retention structure. The valve may include one or more slits or windows tending to render the elongated member collapsible. The valve may include one or more protrusions to partially occlude the lumen. A protrusion, if present, may be shaped as a helical thread. The second retention structure may be shaped as a barb to engage a ureteral orifice in a bladder.

ANTI-REFLUX URETERAL STENTS AND METHODS

Technical Field

[0001] This invention generally relates to medical devices for drainage of fluids, and more specifically to anti-reflux medical devices for drainage of fluids.

Background Information

[0002] Drainage devices or stents may be used to treat or avoid obstructions in fluid passageways due to ureteral tumors that disrupt the flow of urine from the kidneys to the bladder. They also may be used to strengthen a compromised vessel such as a ureteral wall. Ureteral stents typically are tubular in shape, terminating in two opposing ends: a kidney distal end and a bladder proximal end. One or both of the ends may be curved in a pigtail or J-shape to prevent the migration of the stent due, for example, to physiological movements.

Summary of the Invention

[0003] Stents may cause or contribute to significant patient discomfort. One problem associated with ureteral stents is bladder pain attributed to stent contact with the trigone area of the bladder, particularly when the stent extends through the ureteral orifice and into the bladder. The region known as the trigone or trigonum is a triangular-shaped region located on the floor of the urinary bladder between the opening of the urethra in front and the two ureters at the sides. The trigone is believed to be particularly innervated and sensitive to the presence of any foreign bodies such as stent members. Another problem associated with ureteral stents is flank pain caused by urine reflux that occurs when urine travels from the bladder to the kidneys in response to retrograde pressure. Retrograde pressure occurs in the bladder when attempting to void the bladder of urine, and may transmit urine or other fluids up the stent to the kidney. The rigidity of even relatively soft ureteral stents may also irritate the intramural tunnel (the lower 1-2 cm of the ureter prior to its entry into the bladder). In the absence of a stent, the intramural tunnel closes during voiding of the bladder; the presence of a stent may interfere with this closure, irritating the intramural tunnel and permitting urine reflux.

[0004] The present invention concerns a ureteral stent designed to reduce patient discomfort generally caused by stents contacting the trigone or by urine flowing up the stent toward the kidney. Thus, increased comfort may be gained by reducing the size of the retention structure at the bladder (proximal) end of the stent. Patient discomfort can be minimized by reducing the amount of contact with the trigone. Valves and other structures can minimize flank pain by interrupting urine backflow up the stent toward the kidney without preventing drainage of urine from the kidney to the bladder. Modifying that portion of the stent residing in the intramural tunnel to render that portion deformable or collapsible can ease closure of the intramural tunnel during voiding of the bladder, reducing intramural tunnel irritation and urine reflux. In all aspects of the following invention descriptions, all members have a distal retention end structure, the purpose of which is to prevent downward migration of the stent from kidney to bladder and maintain the proximal retention structure to be as close to the ureteral orifice as possible.

[0005] In one aspect, the invention relates to a ureteral stent including an elongated member having a distal end with a first retention structure and a proximal end with a second retention structure. A lumen extends between the proximal and distal ends of the elongated member. The elongated member includes a valve positioned near the proximal end, but distal to the proximal retention structure. The valve is preferably between about one centimeter to about four centimeters (more preferably at about two centimeters) from the proximal retention structure. The distance of the valve from the proximal retention structure is measured from that portion of the proximal retention structure that, in use, contacts the ureteral orifice and restrains further movement of the elongated member towards the kidney; the distance is therefore the distance from the valve to the ureteral orifice when the stent is in use. Where applicable, the middle of the valve (*e.g.* the middle of a slit, window, *etc.*) is considered to be the position of the valve for measuring purposes. The elongated member should be long enough such that when the stent is in a human ureter, the distal end may reside in a kidney and the proximal end in the bladder. The elongated member preferably has a plurality of openings permitting fluid access to the lumen.

[0006] The valve may include a slit or a window in a wall of the elongated member. The slit or window may be at least one centimeter long. The valve may include a plurality of slits or windows. For example, the valve may include two windows, or three parallel slits.

[0007] The valve may also include a flap extending from a wall of the elongated member. For example, the valve may include at least two flaps extending proximally from the wall and positioned such that the flaps are in contact with one another, closing the valve, when fluid pressure from the proximal (bladder) end is greater than the pressure from the distal (kidney) end. When fluid pressure from the distal end exceeds the pressure from the proximal end, the flaps separate, opening the valve.

[0008] The proximal retention structure may include a hydrophilic polymer that expands upon hydration and may be shaped, for example, as a cylinder. The hydrophilic polymer may be, for example, polyurethane, nylon, polycarbonate, poly(ethylene oxide), polyvinyl pyrrolidone, polyvinyl alcohol, poly(ethylene glycol), polyacrylamide, poly(hydroxyethylacrylate), or copolymers thereof.

[0009] In another embodiment, the invention relates to a ureteral stent including an elongated member having a distal end with a first retention structure, a proximal end with a second retention structure, and an inner surface defining a lumen between the distal and proximal ends. One or more protrusions extend from the inner surface into the lumen to partially occlude the lumen. The one or more protrusions are shaped and positioned to introduce turbulence into urine flow from the proximal end during voiding of the bladder when the distal end is in a kidney and the proximal end in a bladder, reducing urine reflux. The one or more protrusions permit urine flow from the kidney to the bladder at other times. The one or more protrusions may be rigid, and preferably reduce the hydraulic radius by a factor of at least two, three, or four.

[0010] In yet another embodiment, the invention relates to a ureteral stent including an elongated member having a distal end with a first retention structure, a proximal end with a second retention structure, and an inner surface defining a lumen between the distal and proximal ends. A portion of the inner surface between the distal and proximal ends includes a helical thread having a height extending into the lumen. The height of a proximal portion of the thread may exceed the height of a distal portion of the thread. Preferably, the lumen has a substantially circular cross-section and the height of a proximal portion of the thread is greater than the radius of the lumen. The helical thread may include a proximally-facing wall forming a 90 degree angle with the inner surface; the angle may be sharp-edged or round-edged. In a preferred embodiment, a proximally-facing wall and a second wall of the helical thread form a sharp-edged angle no greater than about 90 degrees. The helical thread may include a distally-facing wall forming an angle of no more than 90 degrees with the inner surface.

[0011] In another aspect, the invention relates to a method of promoting ureteral urine flow. The method includes the steps of providing a ureteral stent and introducing it into a ureter. The stent has a distal end with a retention structure and a proximal end with a barb. The stent is introduced into the ureter such that the distal end of the stent is in a kidney and the proximal end is in the bladder. The barb engages the ureteral orifice of the ureter to prevent distal migration of the ureteral stent out of the bladder.

[0012] In another embodiment, the invention relates to a method of promoting ureteral urine flow without undue bladder irritation. The method includes the steps of providing a ureteral stent and introducing it into a ureter. The stent has a distal end with a first retention structure and a proximal end with a second retention structure. The stent is introduced such that the distal end of the stent is in a kidney and the proximal end in the bladder. The proximal end of the ureteral stent extends less than two centimeters into the bladder.

[0013] In yet another embodiment, the invention relates to a method of promoting ureteral urine flow while minimizing intramural tunnel irritation. The method includes the steps of providing a ureteral stent and introducing it into a ureter. The stent has a compressible portion between a distal end with a first retention structure and a proximal end with a second retention structure. The proximal end may be positioned in a bladder, and the distal end may be positioned in a kidney. The stent is preferably positioned in a patient such that the compressible portion is in an intramural tunnel, permitting compression of the stent by the intramural tunnel during voiding of the bladder.

[0014] In still another embodiment, the invention includes a method for promoting ureteral urine flow from a kidney to a bladder. The method includes the steps of providing a ureteral stent and introducing it into a ureter. The ureteral stent includes an elongated member having a distal end with a first retention structure and a proximal end with a second retention structure. The elongated member also has an inner surface defining a lumen between the distal and proximal ends. The inner surface has one or more protrusions that extend into and partially occlude the lumen. The one or more protrusions disrupt urine flow from the bladder during voiding of the bladder, thereby reducing reflux, while permitting urine flow from the kidney to the bladder at other times. The stent is preferably positioned in a patient with the distal end in a kidney and the proximal end in the bladder.

[0015] In a preferred embodiment, the invention includes a method of promoting ureteral urine flow from a kidney to a bladder. The method includes the steps of providing a ureteral stent and introducing it into a ureter. The stent includes an elongated member having a distal end with a first retention structure and a proximal end with a second retention structure. The elongated member also has an inner surface defining a lumen between the distal and proximal ends. A portion of the inner surface includes a helical thread having a height extending into the lumen. A height of a proximal portion of the thread is greater than the height of a distal portion of the thread. The stent may be positioned with the distal end in a kidney, and may be positioned with a proximal end in the bladder. The stent is preferably positioned such that the height of the thread is greater in a portion of the thread toward the proximal end of the stent, discouraging urine reflux from the bladder to the kidney and permitting urine drainage from the kidney to the bladder.

[0016] The foregoing and other aspects, embodiments, features, and advantages of the invention will become apparent from the following description, figures, and claims.

Brief Description of the Drawings

[0017] The drawings are not necessarily to scale, emphasis instead generally being placed upon illustrating the principles of the invention.

[0018] **FIG. 1A** depicts an exemplary embodiment of a ureteral stent of the invention with a slit valve in the elongated member and a pigtail at the proximal end; **FIG. 1B** depicts the proximal portion of another exemplary embodiment with a plurality of slits in the elongated member and a barb at the proximal end.

[0019] **FIGS. 2A-2D** depict exemplary ureteral stents with window valves.

[0020] **FIG. 3** depicts a pair of the ureteral stents of **FIG. 2A** implanted in a pair of mammalian ureters.

[0021] **FIG. 4** depicts an exemplay ureteral stent with a slit valve in a tapered portion of the stent.

[0022] **FIGS. 5A-B** depict exemplary ureteral stents with flap valves. **FIG. 5A** depicts a stent with an internal flap valve and with a pigtail as a proximal retention structure; **FIG. 5B** depicts a proximal portion of a stent with large windows and a flap valve.

[0023] **FIG. 6** depicts protrusions in a ureteral stent lumen.

[0024] **FIG. 7** depicts a helical thread protruding into a ureteral stent lumen.

[0025] **FIGS. 8A-8E** depict ureteral stents having an expandable retention structure at the proximal end.

Description

[0026] This invention generally concerns a ureteral stent that significantly reduces discomfort to a patient when positioned within a patient's ureter. The devices and methods of the present invention increase patient comfort by minimizing the degree of contact of the device with the trigone region, by providing a deformable or collapsible stent portion in the intramural tunnel, and/or by reducing or eliminating reflux of liquid to the kidneys from the bladder.

[0027] Referring to **FIG. 1A**, ureteral stent **10** includes elongated member **12** having distal end **14** with first retention structure **16**, depicted as a first pigtail. Elongated member **12** also includes proximal end **18** with second retention structure **20**, depicted as a second pigtail.

preferably about two centimeters long. As shown in **FIG. 1B**, valve **22** may alternatively include a plurality (*e.g.* three or more) of parallel slits **24**. Valve **22** is preferably positioned at a distance from second retention structure **20** by about zero (juxtaposition) to about four centimeters.

[0031] Referring to **FIGS. 2A-D**, valve **22** may instead include a deformable wall with one or more (*e.g.* two) windows **28** traversing the wall of elongated hollow member **12**. The window or windows **28** are preferably at least one centimeter long and are more preferably about two centimeters long. proximal end **18** of elongated member **12** may include a second retention structure. The retention structure may include one or more barbs **20'** (**FIGS. 2A, 2B, 2D**); a structure **20"** having an outer dimension W, perpendicular to the longitudinal axis of elongated member **12**, that is greater than the outer diameter of the elongated member **12** (**FIG. 2C**, shown with rounded edges), or a pigtail as in **FIG. 1A**. Furthermore, elongated hollow member **12** may be twisted about its longitudinal axis in the vicinity of valve **22** as shown in **FIG. 2D**, facilitating fluid flow through the window or windows **28** and potentially reducing the effective diameter of that portion of elongated hollow member **12**.

[0032] A second retention structure **20** may be formed by skiving elongated member **12** to form a barb **20'** (**FIGS. 2A, 2B, 2D**), or by molding a barb from, for example, a silicone flap. A barb, if present, is preferably no more than about 4 mm long.

[0033] In use, ureteral stent **10** is inserted into a mammalian ureter **30** such that distal end **14** of elongated member **12** is in a kidney **32** and proximal end **18** is in bladder **34**, as shown in **FIG. 3**. Ureteral stent **10** may be inserted with the aid of a guidewire and a pusher through the urethra (not shown) and bladder **34** to the final position in ureter **30**. In some embodiments, first retention structure **16** and second retention structure **20** are formed from a material that reforms its structure after having its shape distorted. This property of the material allows first retention structure **16** and second retention structure **20** to be collapsed or straightened during insertion of the stent into the body, yet allowing the structures to reform into their original shapes after placement of ureteral stent **10** in ureter **30**. The guidewire or a cannula may be used to temporarily straighten the retention structure during insertion and placement of ureteral stent **10**. Ureteral stent **10** may also be inserted into position by use of an endoscope, a ureteroscope, or a cytoscope, for example.

[0034] If proximal end **18** includes a second retention structure **20** shaped as a barb **20'** (**FIGS. 2A, 2B, 2D**), the barb preferably engages ureteral orifice **36** to prevent ureteral stent **10** from migrating distally out of bladder **34**. A cannula, sleeve, or cytoscope is preferably used to cover the barb during insertion of ureteral stent **10** into the patient. Desirably, as shown in **FIG. 3**, this configuration minimizes the amount of material from the ureteral stent **10** that resides in bladder **34** as compared to, for example, the amount of material from the first retention structure **16** shown residing in kidney **32**. Thus, the potential for irritation to the trigone region **38** of bladder **34** is reduced. Valve **22** is preferably placed within intramural tunnel **40** of ureter **30**. In embodiments where valve **22** includes window or windows **28**, as shown in **FIG. 3**, or a slit or other modification reducing the resistance to kinking of the wall of that portion of elongated member **12**, intramural tunnel **40** closes around the outer surface of the valve, activating it by collapsing its wall such that opposite walls contact one another and obstruct the lumen, preventing urine reflux during voiding of bladder **34**. Thus, the positioning of valve **22** within intramural tunnel **40** minimizes irritation to intramural tunnel **40**, reducing patient discomfort. To further reduce irritation to intramural tunnel **40**, the portion of elongated member **12** intended for placement in intramural tunnel **40** may also be tapered (*e.g.* to a size of about 5 French) as shown in **FIG. 4**.

[0035] As shown in **FIGS. 5A-5B**, valve **22** may include at least one flap **42** (*e.g.* a pair of flaps **42**, as shown) extending inward from an internal wall of elongated member **12** to better reduce urine reflux. The flap (or flaps) **42** contact a wall of elongated member **12** (and/or each other) to resist fluid flow from the bladder. The flap or flaps **42** nevertheless open to permit fluid drainage from the kidney.

[0036] Urine reflux may also be minimized a valve that includes one or more protrusions **44** as shown in **FIG. 6**. Protrusion(s) **44** extend from the inner surface of elongated member **12** into the lumen, partially occluding the lumen. Protrusion(s) **44** introduce turbulence into urine flow toward kidney **32** during voiding of bladder **34**. Urine in bladder **34** is at a relatively high pressure during voiding, and would travel at relatively high speed toward a kidney through an open ureteral stent, in the absence of a valve, protrusion, or other mechanism to retard the urine reflux. Protrusion(s) **44** in ureteral stent **10** act as one or more "speed bumps" to absorb or deflect the energy or velocity of high pressure urine, slowing and (thereby) reducing urine reflux. Generally, protrusion(s) **44** increase(s) turbulence in refluxing urine, dissipating the energy of the urine flow. Protrusion(s) **44**, which are preferably rigid, nevertheless do not preclude the normal flow of urine from the kidney to the bladder. Thus, in embodiments where a protrusion **44** spans the lumen of elongated member **12**, one or more gaps or pores in protrusion **44** permit passage of urine therethrough. Protrusion(s) **44** reduce(s) the hydraulic radius of a portion of elongated member **12**. Preferably, the protrusions are positioned and shaped to reduce the hydraulic radius by at least a factor of two, and more preferably by at least a factor of four. A discussion of factors determining the hydraulic radius of a channel and the effects of various types of protrusions on hydraulic radius may be found in Chapter 4 of Lindeburg, P.E., Engineer In Training Review Manual, Professional Publications: San Carlos, CA (1982), herein incorporated by reference.

[0037] Ureteral stent **10** may include a protrusion **44'** shaped as a helical thread like an Archimedes' screw as shown in **FIG. 7**. Protrusion **44'** need not extend throughout the length of ureteral stent **10**; indeed, protrusion **44'** is preferably limited to only a portion (*e.g.* a 1-3 cm portion) of ureteral stent **10**. Preferably, the height of the thread/protrusion is varied along its length such that a portion of protrusion **44'** closer to proximal end **18** of elongated member **12** has a height into the lumen that is greater than the height of a more distal portion of the protrusion **44'**. In an embodiment where the lumen has a substantially circular cross-section, the height of a proximal portion of protrusion **44'** is preferably greater than a radius of the lumen. Thus, fluid passing through the lumen necessarily follows the helical threads, because no line-of-sight fluid path is available. Generally, the sides of the protrusion form right and/or obtuse angles with the inner surface of the elongated member; the angles may be sharp or rounded. In one embodiment, a proximal surface **45** of protrusion **44'** forms a right angle with the inner surface of elongated member **12**. In another embodiment, a distal surface **47** of protrusion **44'** forms an obtuse angle α with the inner surface of the elongated member **12**.

[0038] Ureteral stent **10** with protrusion(s) **44** or **44'** may be formed, for example, by injection molding the protrusion(s) or by lamination over an insert. The protrusion(s) may be formed of a metal or a polymer.

[0039] In preferred embodiments shown in **FIGS. 8A-8E**, second retention structure **20** includes a hydrophilic swellable polymer that expands upon hydration. Thus, as shown in **FIGS. 8A** and **8C**, prior to hydration, second retention structure **20** may be as small as 5 to 9 French, ensuring that ureteral stent **10** can be delivered using standard stent delivery equipment (*e.g.* cytoscopes). Upon insertion of ureteral stent **10** into a ureter **30** (**FIGS. 8B**, **8D**, and **8E**), exposure of the hydrophilic polymer to moisture from urine causes significant hydration of the hydrophilic polymer, leading to expansion of second retention structure **20**. Second retention structure **20** thus becomes larger than the opening of ureteral orifice **36**. Thus, upon expansion of second retention structure **20**, proximal end **18** of ureteral stent **10** is necessarily retained within bladder **34**. Generally, expansion is substantially complete within about 1-2 hours. Expansion of second retention structure **20** also dramatically softens it from, for example, about

65D to about 35-40A. This softening should reduce irritation to trigone region **38** of bladder **34** (**FIG. 8E**), and facilitates stent extraction, as the material easily deforms through the urethra upon removal.

[0040] Despite the post-hydration expansion of second retention structure **20** in the preferred ureteral stent **10** shown in **FIGS. 8A-8E**, second retention structure **20** remains smaller in mass and surface area than a conventional stent bladder coil. Second retention structure **20** may be shaped as a cylinder, for example, or in any other shape, so long as, after expansion, second retention structure **20** is larger than the opening of ureteral orifice **36** in a dimension permitting retention of second retention structure **20** at ureteral orifice **36**.

[0041] A hydrophilic swellable polymer, if present, may be any polymer capable of sufficient expansion upon hydration, such as, reticulated or crosslinked polymers derived from any of polyurethane, nylon, polycarbonate, poly(ethylene oxide), polyvinyl pyrrolidone, polyvinyl alcohol, poly(ethylene glycol), polyacrylamide, poly(hydroxyethylacrylate), and copolymers thereof. Generally, hydration expands the swellable polymer by at least a factor of 1.2. Preferably, outer diameter of the hydrophilic polymer expands at least a factor of 1.5 upon hydration; more preferably, the outer diameter expands by at least a factor of 2.0 upon hydration. Thus, for example, the outer diameter of second retention structure **20** may be about 0.08 inches prior to hydration, and about 0.16 inches or more after hydration. Useful hydrophilic polymers and their application in ureteral stents can be found, for example, in U.S. Patent Nos. 5,599,291; and 5,964,744, both of which are herein incorporated by reference in their entirety.

[0042] An expandable second retention structure **20** may be joined to the remainder of ureteral stent **10** through a plurality (*e.g.*, 2-8) of connectors **46**, as shown in **FIGS. 8A, 8B**, and **8E**. In this embodiment, ureteral stent **10** transitions from a cylindrical extrusion to a series of solid-core polymer connectors **46** about 5 cm from the ureteral orifice. The cylindrical extrusion typically has an outer diameter of 5-8 French and an inner diameter of 0.04"-0.08"; the connectors **46** typically have outer diameters of about 0.01"-0.04." Connectors **46** may be attached to the remainder of ureteral stent **10** by a thermal attachment/ lamination process, in which case connectors **46** should be thermally compatible with the hydrophilic polymer of second retention structure **20**, and more preferably is formed of the same base polymer. Alternatively, connectors **46** may be formed by excising or otherwise removing material from a portion of a cylindrical extrusion, or may be incorporated into ureteral stent **10** using coextrusion techniques.

[0043] As shown in **FIG. 8E**, connectors **46** provide a collapsible proximal ureter/ intramural tunnel section to reduce intramural tunnel irritation when compared to a conventional cylindrical stent portion. Because the intramural tunnel compresses about connectors **46** during voiding of bladder **34**, urine reflux is diminished by the reduction in the "free-volume" available in the distal ureter.

[0044] Alternatively, second retention structure **20** may be attached directly to the remainder of ureteral stent **10** as shown in **FIGS. 8C-8D**, through thermal attachment procedures, for example. Even in the absence of connectors **46**, second retention structure **20** is free to expand and function as intended in this alternative embodiment, preventing upward stent migration toward kidney **32** and providing a relatively soft portion in bladder **34** to reduce irritation to trigone region **38.**

[0045] Elements of the ureteral stents of the present invention may be attached to each other by any of a variety of methods including, for example, the use of adhesives, heat welding, mechanical fasteners, and/or by inserting one component into the internal diameter of another. For example, two elements may be formed, one with a female end and one with a male end with teeth stamped therein, so that when the male end is inserted into the female end, it is locked or snap-fit into position with the teeth. Retention structures, such as pigtails, hooks, barbs, and/or lips, may be made of memory-shaped material so that the structures may be temporarily straightened for insertion along a guidewire and thereafter returned to their "normal" shapes.

[0046] Having thus described certain embodiments of the present invention, various alterations, modifications, and improvements will be apparent to those of ordinary skill. Such alterations, modifications, and improvements are intended to be within the spirit and scope of the invention. Accordingly, the foregoing description of illustrative embodiments of the invention is not intended to be limiting.

What is claimed is:

Claims

1. A ureteral stent comprising:

an elongated member having a distal end comprising a first retention structure and a proximal end comprising a second retention structure and defining a lumen extending therebetween,

the elongated member comprising a valve distal to the second retention structure.

2. The ureteral stent of claim 1, wherein the valve comprises a slit defined by a wall of the elongated member.

3. The ureteral stent of claim 2, wherein the slit is a longitudinal slit.

4. The ureteral stent of claim 1, wherein the valve comprises at least three parallel slits defined by a wall of the elongated member.

5. The ureteral stent of claim 1, wherein the valve comprises a window defined by a wall of the elongated member.

6. The ureteral stent of claim 5, wherein the valve comprises two windows defined by a wall of the elongated member.

7. The ureteral stent of claim 1, wherein the valve comprises a flap extending from a wall of the elongated member.

8. The ureteral stent of claim 7, wherein the valve comprises at least two flaps extending from a wall of the elongated member and positioned such that the flaps are in contact with each other when fluid pressure from the proximal end exceeds fluid pressure from the distal end, closing the valve, and are separated when fluid pressure from the distal end exceeds fluid pressure from the proximal end, opening the valve.

9. The ureteral stent of claim 1, wherein the second retention structure comprises a barb.

10. The ureteral stent of claim 1, wherein the second retention structure comprises a hydrophilic polymer that expands upon hydration.

11. The ureteral stent of claim 10, wherein the hydrophilic polymer is selected from the group consisting of polyurethane, nylon, polycarbonate, polyethylene, poly(ethylene oxide),

polyvinyl pyrrolidone, polyvinyl alcohol, poly(ethylene glycol), polyacrylamide, poly(hydroxyethylacrylate), and copolymers thereof.

12. The ureteral stent of claim 1, wherein the valve is disposed at a distance between about one centimeter to about four centimeters from the second retention structure.

13. The ureteral stent of claim 1, wherein the elongated member has a length sufficient to permit the distal end to reside in a kidney and the proximal end to reside in a bladder while the ureteral stent is in a human ureter.

14. The ureteral stent of claim 1, wherein the elongated member further defines a plurality of openings permitting fluid access to the lumen.

15. A ureteral stent comprising:

an elongated member having a distal end comprising a first retention structure and a proximal end comprising a second retention structure, the elongated member having an inner surface defining a lumen between the distal end and the proximal end; and

one or more protrusions extending from the inner surface into the lumen to partially occlude the lumen, wherein the one or more protrusions are shaped and positioned to introduce turbulence into urine flow from the proximal end during voiding of a bladder when the distal end is disposed in a kidney and the proximal end is disposed in the bladder.

16. The ureteral stent of claim 15, wherein the one or more protrusions reduce the hydraulic radius by at least a factor of two.

17. A ureteral stent comprising:

an elongated member having a distal end comprising a first retention structure and a proximal end comprising a second retention structure, the elongated member having an inner surface defining a lumen between the distal end and the proximal end,

wherein a portion of the inner surface between the distal end and the proximal end comprises a helical thread having a height extending into the lumen.

18. The ureteral stent of claim 17, wherein the height of a proximal portion of the helical thread is greater than the height of a distal portion of the helical thread.

19. The ureteral stent of claim 18, wherein the lumen has a substantially circular cross-section, and wherein the height of the proximal portion of the helical thread is greater than a radius of the lumen.

20. The ureteral stent of claim 17, wherein the helical thread comprises a proximally-facing wall forming a 90 degree angle with the inner surface.

21. The ureteral stent of claim 17, wherein a proximally-facing wall of the helical thread and a second wall of the helical thread form a sharp-edged angle no greater than about 90 degrees.

22. The ureteral stent of claim 17, wherein the helical thread comprises a distally-facing wall forming an angle of more than 90 degrees with the inner surface.

23. A method of promoting ureteral urine flow, the method comprising the steps of:

providing a ureteral stent having a distal end comprising a retention structure and a proximal end comprising a barb; and

introducing the ureteral stent into a ureter having a ureteral orifice in a bladder such that the distal end of the ureteral stent is in a kidney and the proximal end is in the bladder, the barb of the proximal end engaging the ureteral orifice of the ureter to prevent distal migration of the ureteral stent out of the bladder.

24. A method of promoting ureteral urine flow without undue bladder irritation, the method comprising the steps of:

providing a ureteral stent having a distal end comprising a first retention structure and a proximal end comprising a second retention structure; and

introducing the ureteral stent into a ureter such that the distal end of the ureteral stent is in a kidney and the proximal end of the ureteral stent is in a bladder, wherein the proximal end of the ureteral stent extends less than two centimeters into the bladder.

25. A method of promoting ureteral urine flow without undue intramural tunnel irritation, the method comprising the steps of:

providing a ureteral stent having a distal end comprising a first retention structure, a proximal end comprising a second retention structure, and a compressible portion therebetween; and

introducing the ureteral stent into a ureter.

26. The method of claim 25, wherein the ureteral stent is positioned in the ureter such that the compressible portion is in an intramural tunnel, permitting compression of the stent by the intramural tunnel.

27. A method of promoting ureteral urine flow from a kidney to a bladder, the method comprising the steps of:

providing a ureteral stent comprising an elongated member having a distal end comprising a first retention structure and a proximal end comprising a second retention structure, the elongated member having an inner surface defining a lumen between the distal end and the proximal end, the inner surface comprising one or more protrusions extending into and partially occluding the lumen;

introducing the ureteral stent into a ureter; and

disrupting urine flow from the bladder to the kidney during voiding of the bladder through partial occlusion of the lumen, thereby reducing reflux.

28. A method of promoting ureteral urine flow from a kidney to a bladder, the method comprising the steps of:

providing a ureteral stent comprising an elongated member having a distal end comprising a first retention structure and a proximal end comprising a second retention structure, the elongated member having an inner surface defining a lumen between the distal end and the proximal end, a portion of the inner surface comprising a helical thread having a height extending into the lumen, and wherein the height of a proximal portion of the helical thread is greater than the height of a distal portion of the helical thread;

introducing the ureteral stent into a ureter; and

positioning the helical thread to reduce urine flow from the bladder to the kidney during voiding of the bladder, thereby reducing reflux.

29. The method of claim 28, wherein the ureteral stent is positioned such that the height of the helical thread is greater in a portion of the thread toward the bladder, thereby discouraging reflux of urine from the bladder to the kidney and permitting drainage of urine from the kidney to the bladder.

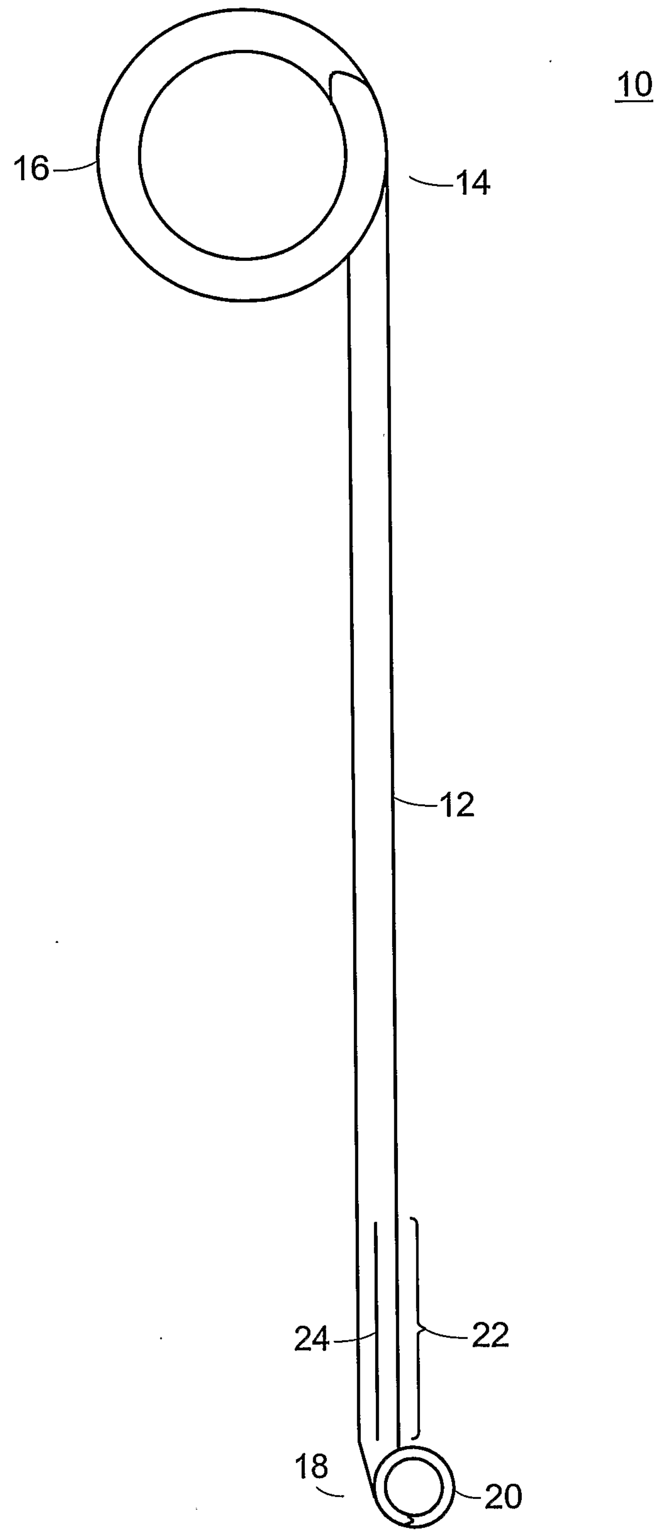

FIG. 1A

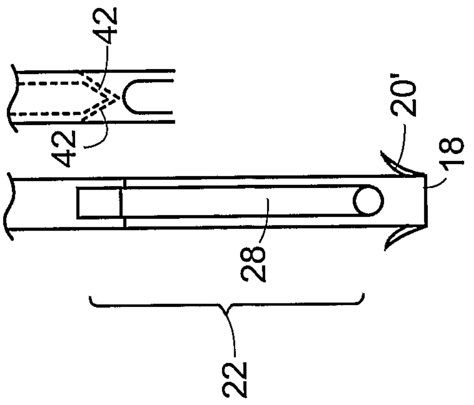

FIG. 5B

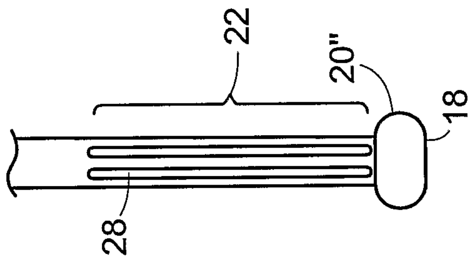

FIG. 2C

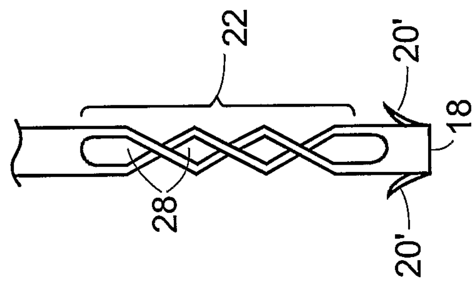

FIG. 2D

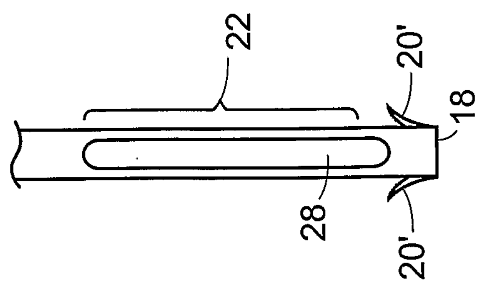

FIG. 2B

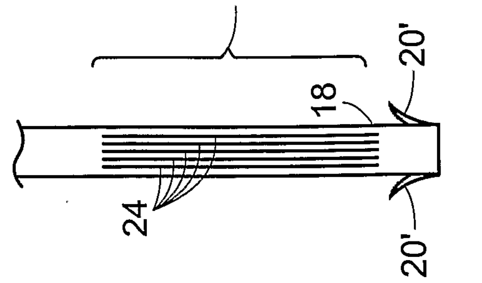

FIG. 1B

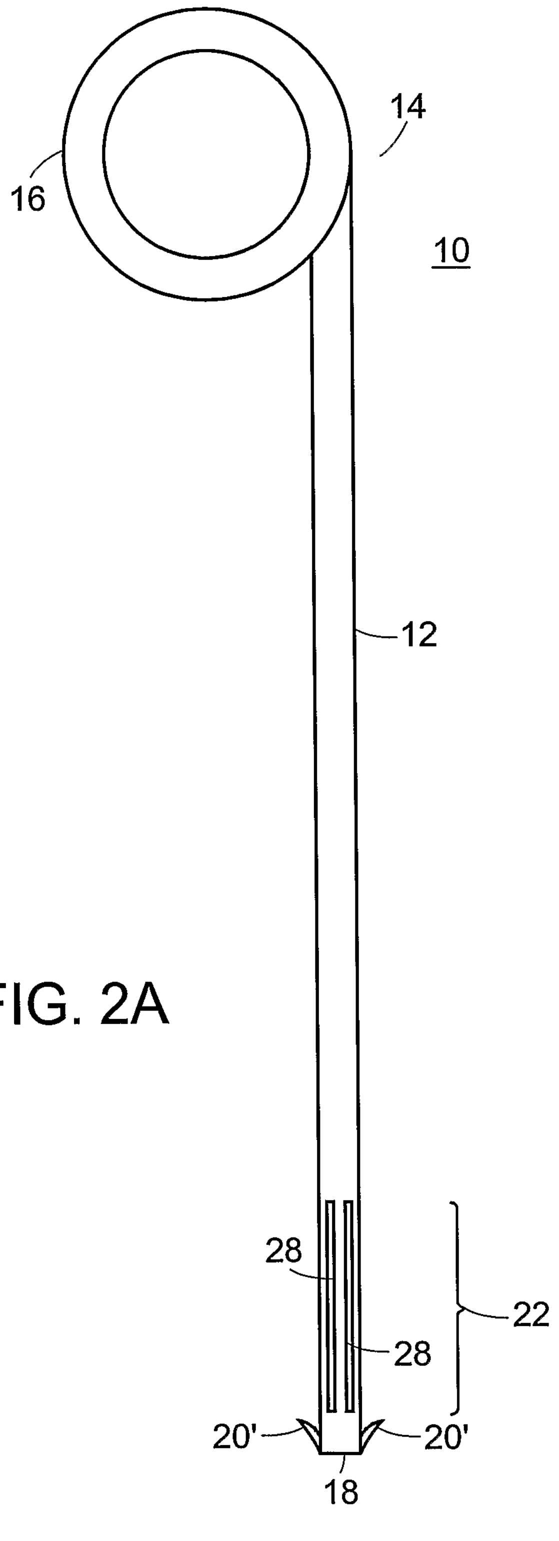

FIG. 2A

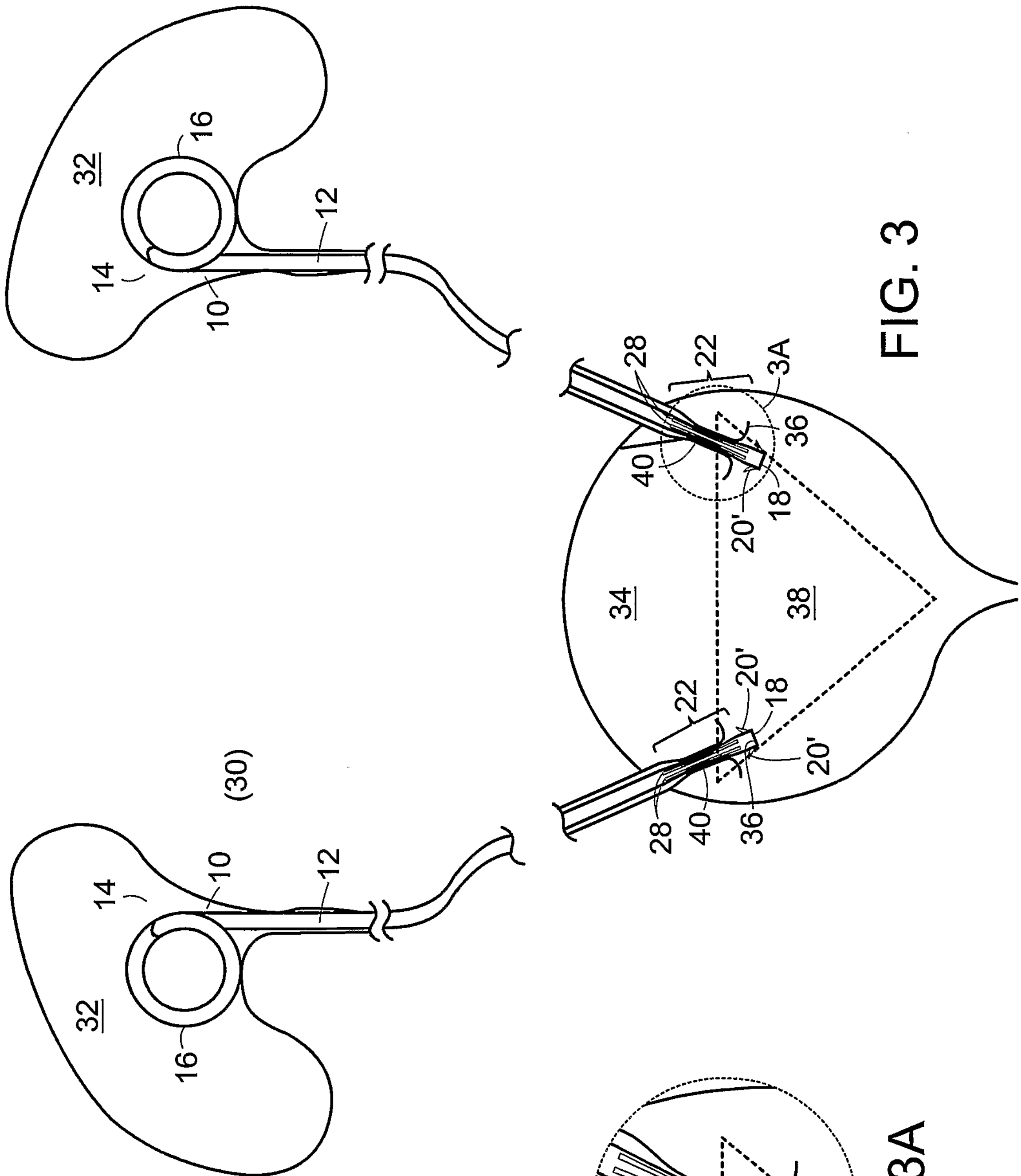

FIG. 3

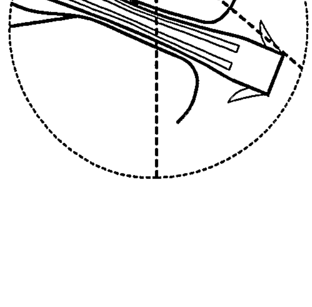

FIG. 3A

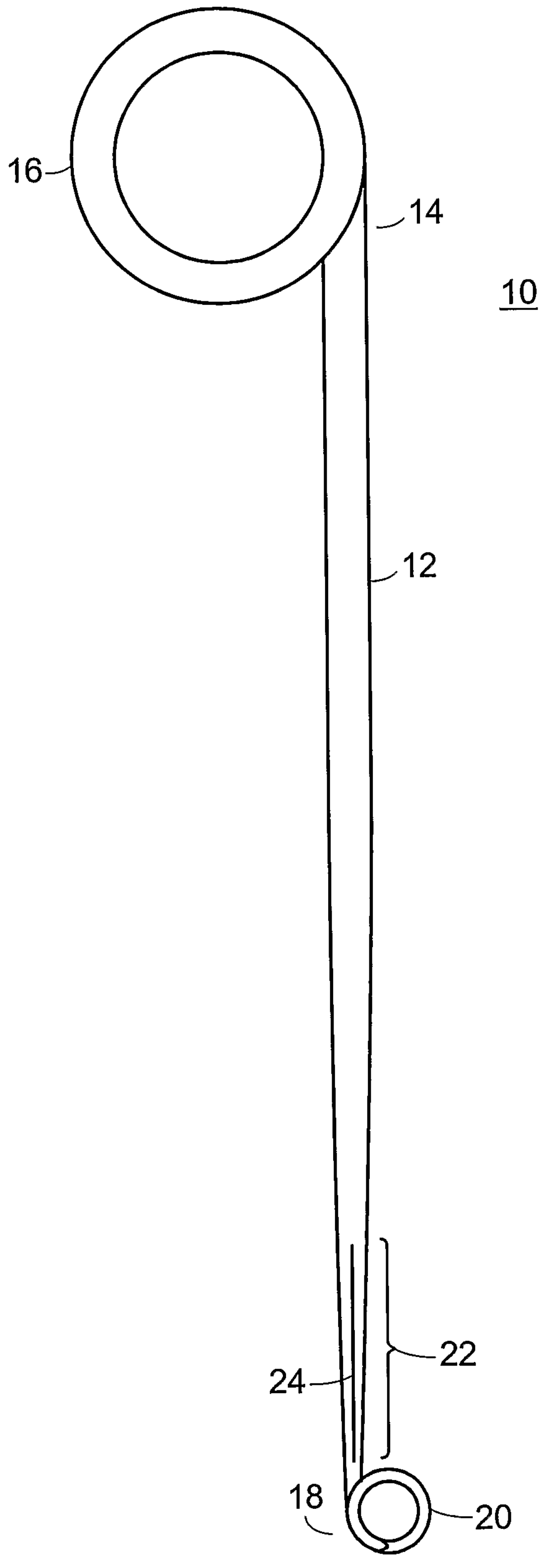

FIG. 4

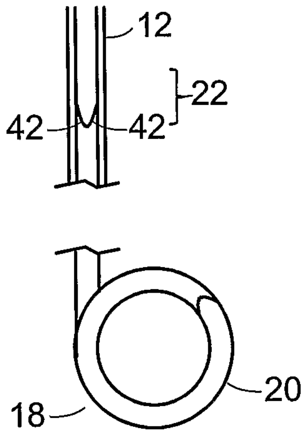

FIG. 5A

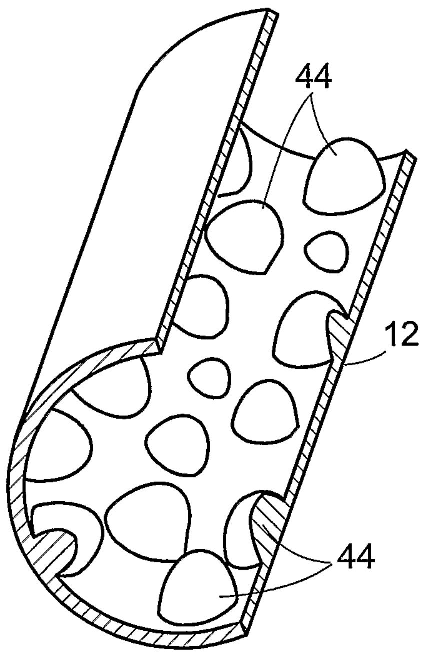

FIG. 6

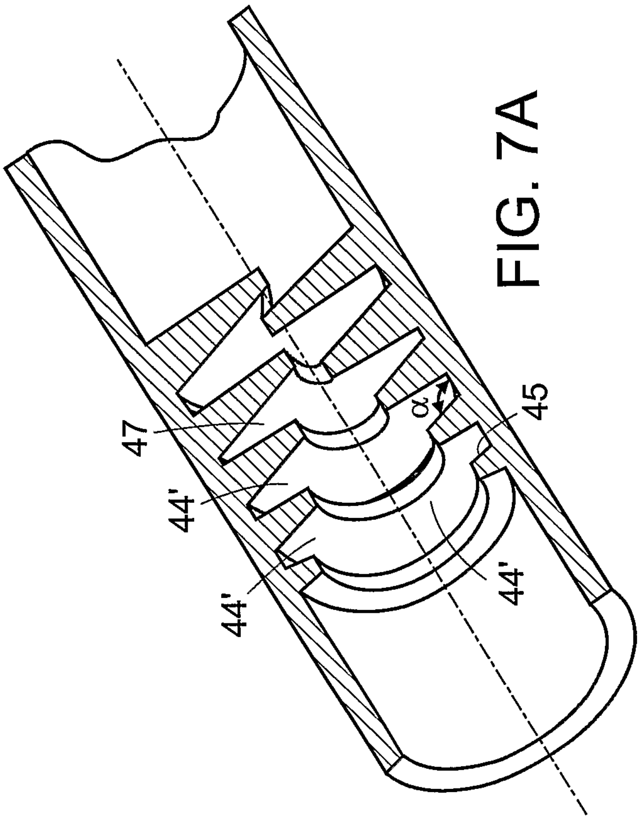

FIG. 7A

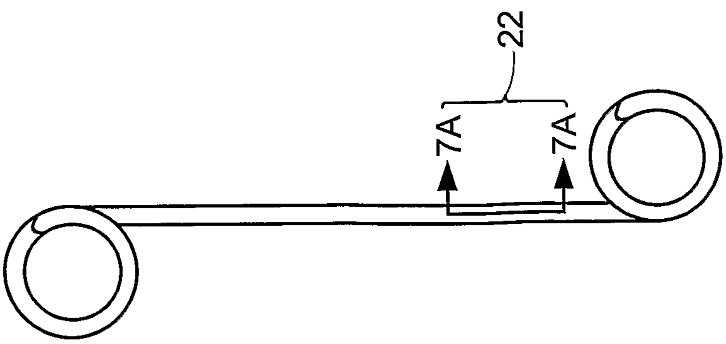

FIG. 7

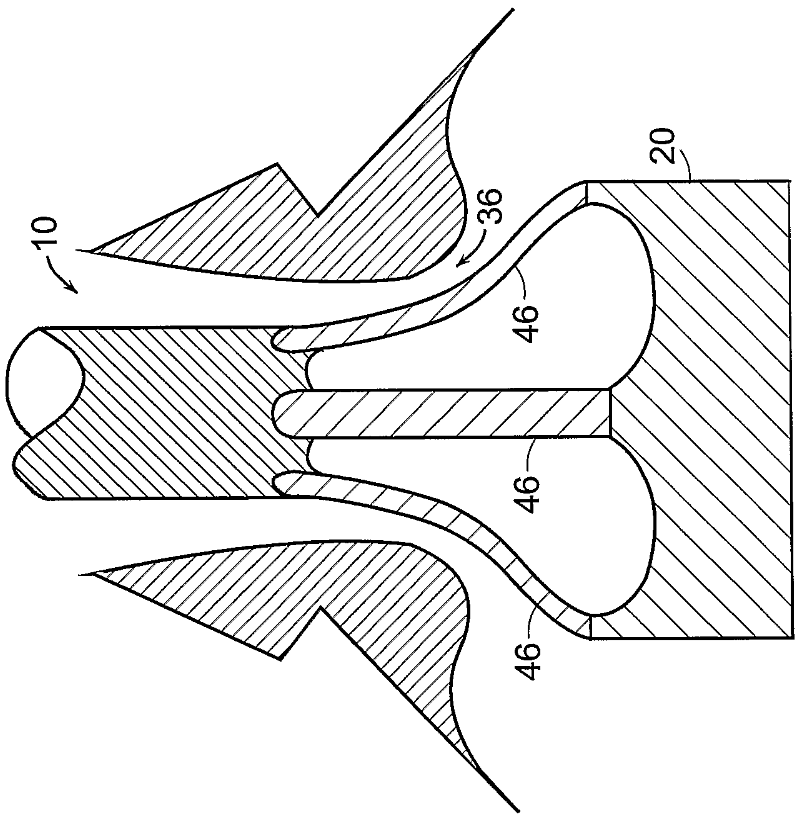

FIG. 8B

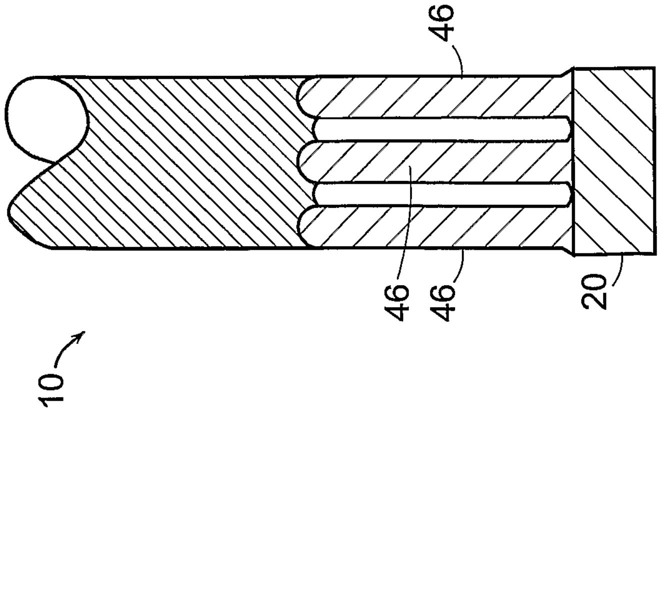

FIG. 8A

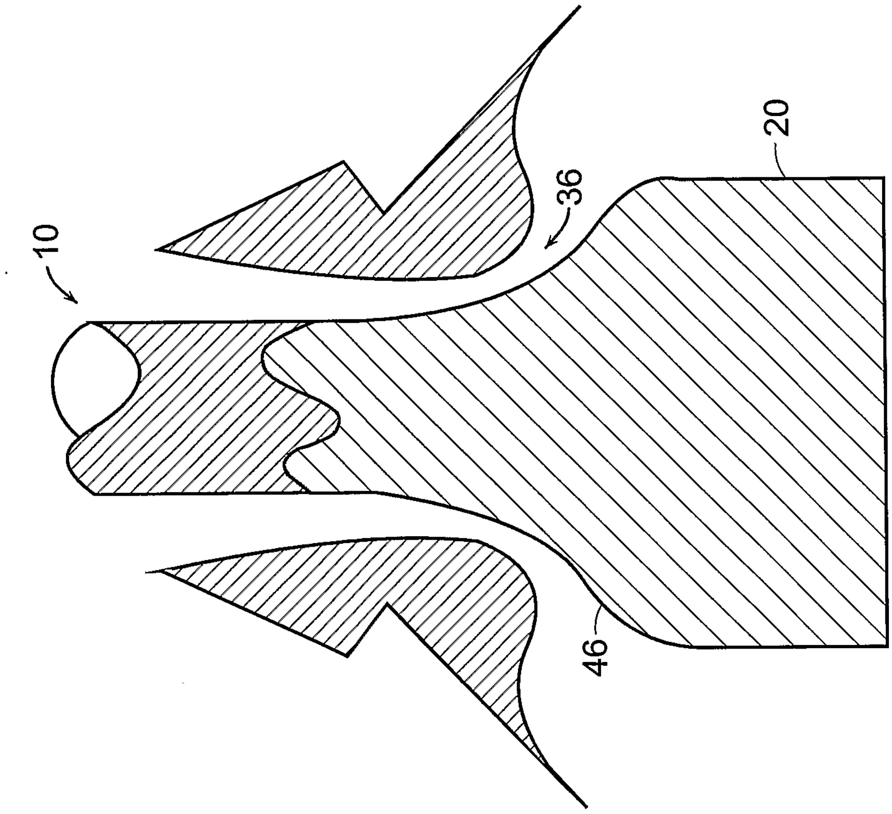

FIG. 8D

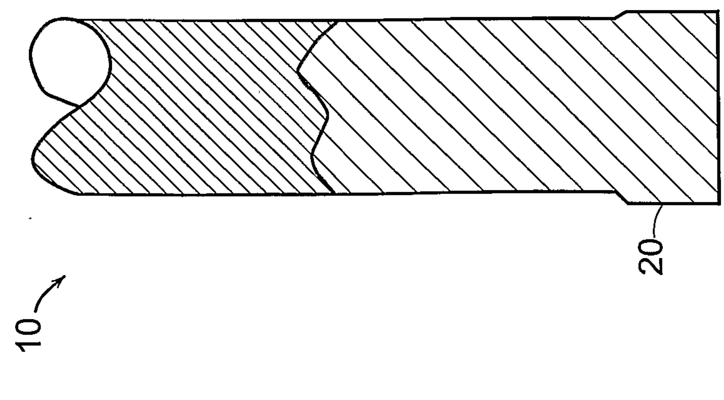

FIG. 8C

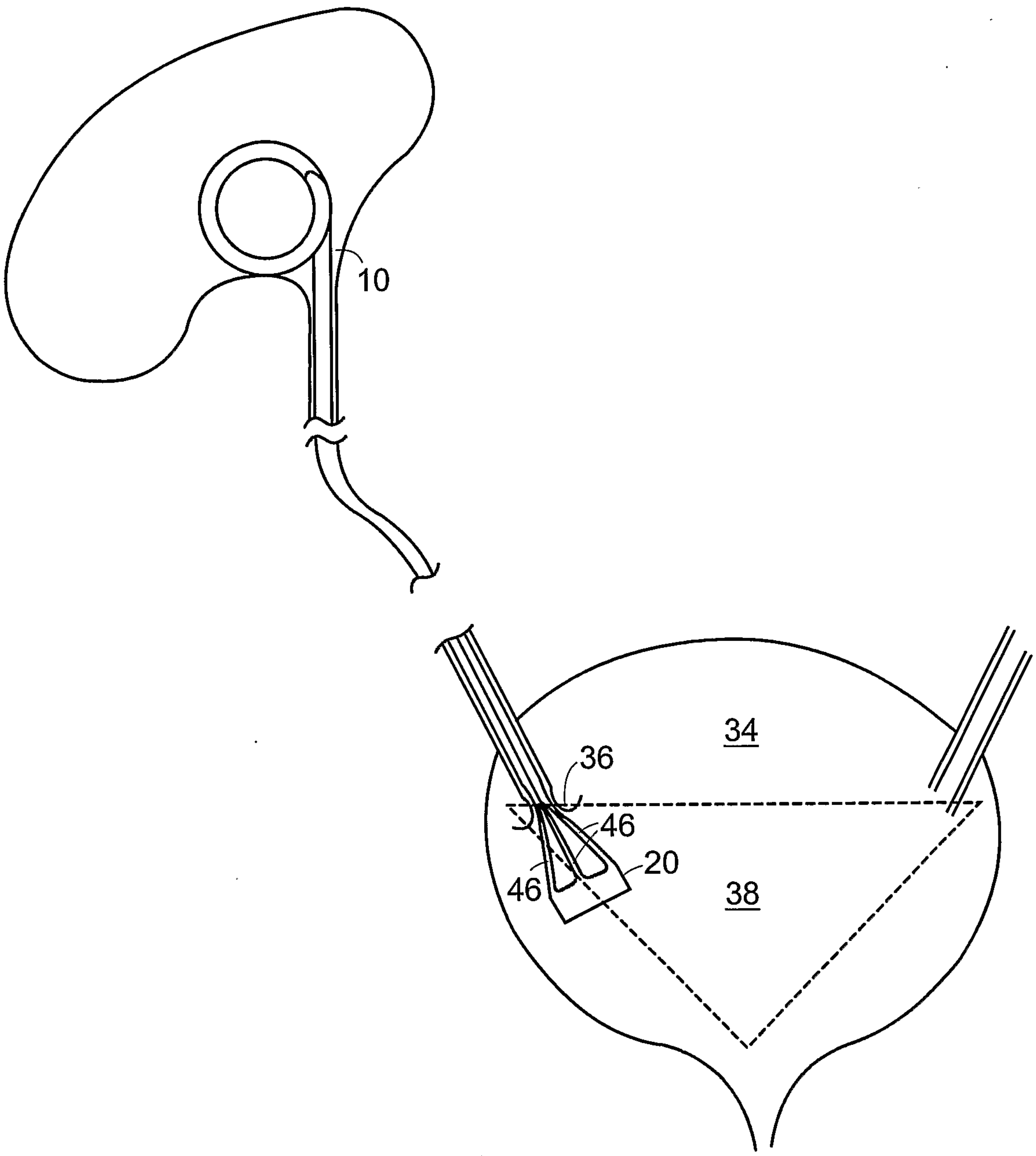

FIG. 8E