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## DESCRIPTION

### RELATED APPLICATIONS

[0001] This application claims priority to United States provisional patent application 61/649,102 filed 18 May 2012.

### TECHNICAL FIELD

[0002] This invention relates to the field of stent placement, where the stent may be used to keep open body channels. In particular, the invention relates to a stent placement pusher apparatus.

### BACKGROUND

[0003] Stents are used to keep open body channels. For example, ureteral stents may provide drainage of urine from the kidneys to the bladder. Similarly, biliary stents may provide drainage of the bile ducts between the liver and gallbladder and between the gallbladder and small intestine. A stent is a flexible, tubular structure that is made from relatively inert materials (for example, silicon, teflon™, polyethylene, polyurethane, stainless steel, or nickel-titanium alloy). Often a stent may be perforated to provide small drainage holes along its length. Stents may also be shaped to define "hooks" at either end. For example, such hooks may prevent migration of a ureteral stent from the kidney toward the bladder or from the bladder upwards. A shortened ureteral stent has only one hook at the distal or kidney end of the stent. Often, shortened stents are used to reduce irritation caused by the presence of a stent within the lower ureter and within the bladder. With a shortened stent, the stent resides in the ureter, remote from the bladder and the ureteral orifice (i.e. the junction of the ureter and the bladder).

[0004] Indwelling stents periodically need to be removed or periodically replaced. Conventional stent removal procedures may be complex and may be painful, sometimes requiring general anesthesia.

[0005] A thin thread may be attached to a shortened stent to extend into the bladder to assist with the removal of the stent. However, such a shortened stent (with thread) requires endoscopic visualization of the threads so that they may be grasped, and the stent may be withdrawn.

[0006] Although this is a relatively simple procedure, it requires specialized instruments used by a urologist in a sterile setting. Nevertheless, general anesthesia may also be required.

[0007] An alternative stent removal method is described in WO 99/58083, which employs the use of a tethered bead at the proximal or bladder end of the stent that may be removed with the aid of magnet tipped catheter.

[0008] WO 2011/086175 A1 discloses a tool comprising a longitudinal rod member adapted for manipulating a solid object in a cavity of a human or animal body.

### SUMMARY

[0009] The pusher apparatus or pusher attachment apparatus attached to a pusher described herein allow for the insertion of a shortened stent (the stent having a bead suspended by a tether) into a patient's ureter **90** without the need for a positioning line to withdraw the bead from the ureter **90** during positioning of the stent. Using the modified pusher apparatus described herein or pusher attachment apparatus attached to a pusher, the bead does not need to be pushed past the ureteral orifice **85** and into the ureter **90**, but remains within the pusher receptacle **17** and can stay within the bladder. Accordingly, the pusher apparatus described herein may reduce irritation to the patient's ureter and simplify the insertion, when used with a shortened stent with a tethered bead.

[0010] In accordance with one embodiment, there is provided an apparatus for the insertion of a shortened stent, said stent having a bead suspended by a tether, wherein, the pusher includes: (a) a hollow tube having a distal end and a proximal end; and (b) an opening defined in the peripheral wall of the pusher near the distal end, which reaches the inner hollow portion of the

pusher and may be sized to allow for the positioning of the bead into the opening and at least partially within the receptacle defined by the opening.

**[0011]** According to a first aspect of the invention, there is provided a pusher apparatus as defined in claim 1.

**[0012]** In accordance with another embodiment, there is provided a pusher apparatus, for the insertion of a shortened stent, said stent having a bead suspended by a tether, wherein, the pusher includes:

1. (a) a hollow tube having a distal end and a proximal end; and (b) an opening defined in the peripheral wall of the pusher near the distal end, which extends into the inner hollow portion of the pusher and may be sized to allow for the positioning of the bead into the opening and at least partially within the receptacle defined by the opening.

**[0013]** In accordance with another embodiment, there is provided a pusher apparatus, for the insertion of a shortened stent, said stent having a bead suspended by a tether, wherein, the pusher includes:

1. (a) a hollow tube having a distal end and a proximal end; and (b) an opening defined in the peripheral wall of the pusher near the distal end, which reaches the inner hollow portion of the pusher and may be sized to allow for the positioning of the bead through the opening and within the receptacle defined by the opening.

**[0014]** In accordance with another embodiment, there is provided a pusher apparatus, for the insertion of a shortened stent, said stent having a bead suspended by a tether, wherein, the pusher includes:

1. (a) a hollow tube having a distal end and a proximal end; and (b) an opening defined in the peripheral wall of the pusher near the distal end, which reaches the inner hollow portion of the pusher and may be sized to allow for the positioning of the bead through the opening and within the pusher.

**[0015]** In accordance with another embodiment, there is provided a pusher apparatus, including: (a) a hollow tube with a distal end and a proximal end; and (b) an opening defined in the peripheral wall of the pusher near the distal end, which reaches the inner hollow portion of the pusher and may be sized to allow for positioning of a tethered bead into the opening and at least partially within the pusher.

**[0016]** In accordance with another embodiment, there is provided a pusher attachment apparatus, including: (a) a hollow tube having a distal end and a proximal end; (b) a connector at the proximal end of the hollow tube for attachment to a pusher having a lumen, whereby the lumen of the pusher may be contiguous with the lumen of the hollow tube; and (c) an opening defined in the peripheral wall of the hollow tube, which extends to the inner hollow portion of the hollow tube and may be sized to allow for positioning of a tethered bead into the opening and at least partially within the receptacle defined by the opening.

**[0017]** In accordance with another embodiment, there is provided a pusher attachment apparatus, including: (a) a hollow tube having a distal end and a proximal end; (b) a connector at the proximal end of the hollow tube for attachment to a pusher having a lumen, whereby the lumen of the pusher may be contiguous with the lumen of the hollow tube; and (c) an opening defined in the peripheral wall of the hollow tube, which reaches the inner hollow portion of the hollow tube and may be sized to allow for positioning of a tethered bead into the opening and at least partially within the pusher attachment apparatus.

**[0018]** In accordance with another embodiment, there is provided a commercial package including: (a) a guide wire over which a stent may be pushed; (b) a stent assembly for keeping open body channels and having a tethered bead for stent retrieval, the stent and bead being adapted to be pushed over the guide wire; (c) a pusher attachment, as described herein, adapted to be pushed over the guide wire to advance the stent relative to the guide wire and to accept the tethered bead within the opening; and (d) a pusher tube adapted to be pushed over the guide wire for advancing the stent relative to the guide wire.

**[0019]** In accordance with another embodiment, there is provided a commercial package comprising: (a) a guide wire over which a stent may be pushed; (b) a stent assembly for keeping open body channels and having a tethered bead for stent retrieval, the stent and bead being adapted to be pushed over the guide wire; and (c) a pusher apparatus, as described herein, adapted to be pushed over the guide wire to advance the stent relative to the guide wire and to accept the tethered bead into the opening.

**[0020]** The guide wire, the stent assembly, the pusher attachment, and the pusher tube may be for use in delivering the stent assembly to a human ureter. The guide wire, the stent assembly, and the pusher apparatus may be for use in delivering the stent assembly to a human ureter.

**[0021]** The outer diameter of the hollow tube may be less than the diameter of the bead, provided that the pusher apparatus with a bead positioned within the receptacle is able to pass through the lumen of a cytoscope. The outer diameter of the hollow tube may be approximately the diameter of the bead. The outer diameter of the hollow tube may be greater than the diameter of the bead.

**[0022]** Alternatively, the outer diameter of the hollow tube may be greater than the diameter of the bead plus the cross-sectional area of the peripheral wall of the pusher opposite the opening. The outer diameter of the hollow tube may be less than the diameter of the bead plus the cross-sectional area of the peripheral wall of the pusher opposite the opening, provided that the pusher apparatus with a bead positioned within the receptacle is able to pass through the lumen of a cytoscope. The outer diameter of the hollow tube may be approximately the diameter of the bead plus the cross-sectional area of the peripheral wall of the pusher opposite the opening.

**[0023]** The opening may be greater than 180° of the circumference of the pusher. The opening may be greater than 185° of the circumference of the pusher. The opening may be greater than 190° of the circumference of the pusher. The opening may be greater than 195° of the circumference of the pusher. The opening may be greater than 200° of the circumference of the pusher. The opening may be greater than 205° of the circumference of the pusher. The opening may be greater than 210° of the circumference of the pusher. The opening may be greater than 215° of the circumference of the pusher. The opening may be greater than 220° of the circumference of the pusher. The opening may be greater than 225° of the circumference of the pusher. The opening may be greater than 230° of the circumference of the pusher. The opening may be greater than 235° of the circumference of the pusher. The opening may be greater than 240° of the circumference of the pusher. The opening may be greater than 250° of the circumference of the pusher. The opening may be greater than 255° of the circumference of the pusher. The opening may be greater than 260° of the circumference of the pusher. The opening may be greater than 265° of the circumference of the pusher. The opening may be greater than 270° of the circumference of the pusher. The opening may be greater than 280° of the circumference of the pusher. The opening may be greater than 285° of the circumference of the pusher. The opening may be greater than 290° of the circumference of the pusher. The opening may be greater than 295° of the circumference of the pusher. The opening may be greater than 300° of the circumference of the pusher. The opening may be greater than 305° of the circumference of the pusher. The opening may be greater than 310° of the circumference of the pusher. The opening may be greater than 315° of the circumference of the pusher. The opening may be greater than 320° of the circumference of the pusher. The opening may be greater than 325° of the circumference of the pusher. The opening may be greater than 330° of the circumference of the pusher. The opening may be greater than 335° of the circumference of the pusher. The opening may be greater than 340° of the circumference of the pusher. The opening may be greater than 345° of the circumference of the pusher. The opening may be greater than 350° of the circumference of the pusher. The opening may be greater than 355° of the circumference of the pusher.

**[0024]** The area adjacent the opening may be reinforced to maintain structural integrity of the pusher tube. The reinforcement may be by the addition of a material that is less flexible than the pusher. The reinforcement may be by the use of a material that is less flexible than the pusher tube adjacent the opening.

**[0025]** The minimum distance between the distal end of the pusher and the opening may be about 3 cm. The minimum distance between the distal end of the pusher and the opening may be about 2.5 cm. The minimum distance between the distal end of the pusher and the opening may be about 5.0 cm. The minimum distance between the distal end of the pusher and the opening may be about 4.9 cm. The minimum distance between the distal end of the pusher and the opening may be about 4.8 cm. The minimum distance between the distal end of the pusher and the opening may be about 4.7 cm. The minimum distance between the distal end of the pusher and the opening may be about 4.6 cm. The minimum distance between the distal end of the pusher and the opening may be about 4.5 cm. The minimum distance between the distal end of the pusher and the opening may be about 4.4 cm. The minimum distance between the distal end of the pusher and the opening may be about 4.3 cm. The minimum distance between the distal end of the pusher and the opening may be about 4.2 cm. The minimum distance between the distal end of the pusher and the opening may be about 4.1 cm. The minimum distance between the distal end of the pusher and the opening may be about 4.0 cm. The minimum distance between the distal end of the pusher and the opening may be about 3.9 cm. The minimum distance between the distal end of the pusher and the opening may be about 3.8 cm. The minimum distance between the distal end of the pusher and the opening may be about 3.7 cm. The minimum distance between the distal end of the pusher and the opening may be about 3.6 cm. The minimum distance between the distal end of the pusher and the opening may be about 3.5 cm. The minimum distance between the distal end of the pusher and the opening may be about 3.4 cm. The

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**[0027]** The minimum distance between the distal end of the pusher attachment and the opening may be about 2.7 cm. The minimum distance between the distal end of the pusher attachment and the opening may be about 2.6 cm. The minimum distance between the distal end of the pusher attachment and the opening may be about 2.4 cm. The minimum distance between the distal end of the pusher attachment and the opening may be about 2.3 cm. The minimum distance between the distal end of the pusher attachment and the opening may be about 2.2 cm. The minimum distance between the distal end of the pusher attachment and the opening may be about 2.1 cm. The minimum distance between the distal end of the pusher attachment and the opening may be about 2.0 cm. The minimum distance between the distal end of the pusher attachment and the opening may be about 1.9 cm. The minimum distance between the distal end of the pusher attachment and the opening may be between about 4 cm and 10 cm. The minimum distance between the distal end of the pusher attachment and the opening may be between about 5 cm and 8 cm.

The minimum distance between the distal end of the pusher attachment and the opening may be between about 5 cm and 10 cm.  
 The minimum distance between the distal end of the pusher attachment and the opening may be between about 5 cm and 9 cm.  
 The minimum distance between the distal end of the pusher attachment and the opening may be between about 5 cm and 7 cm.  
 The minimum distance between the distal end of the pusher attachment and the opening may be between about 5 cm and 6 cm.  
 The minimum distance between the distal end of the pusher attachment and the opening may be between about 4 cm and 10 cm.  
 The minimum distance between the distal end of the pusher attachment and the opening may be between about 4 cm and 9 cm.  
 The minimum distance between the distal end of the pusher attachment and the opening may be between about 4 cm and 8 cm.  
 The minimum distance between the distal end of the pusher attachment and the opening may be between about 4 cm and 7 cm.  
 The minimum distance between the distal end of the pusher attachment and the opening may be between about 4 cm and 6 cm.  
 The minimum distance between the distal end of the pusher attachment and the opening may be between about 3 cm and 12 cm.  
 The minimum distance between the distal end of the pusher attachment and the opening may be between about 3 cm and 11 cm.  
 The minimum distance between the distal end of the pusher attachment and the opening may be between about 3 cm and 10 cm.  
 The minimum distance between the distal end of the pusher attachment and the opening may be between about 3 cm and 9 cm.  
 The minimum distance between the distal end of the pusher attachment and the opening may be between about 3 cm and 8 cm.

**[0028]** The pusher apparatus described herein allows for the insertion of a shortened stent (the stent having a bead suspended by a tether) into a patient's ureter **90** without the need for a positioning line to withdraw the bead from the ureter **90** during positioning of the stent. Using the modified pusher apparatus described herein, the bead does not need to be pushed past the ureteral orifice **85** and into the ureter **90**, but remains within the pusher receptacle **17** and can stay within the bladder. Accordingly, the pusher apparatus described herein may reduce irritation to the patient's ureter and simplify the insertion, when a shortened stent with a tethered bead is used.

**[0029]** In accordance with one embodiment, there is provided an apparatus for the insertion of a shortened stent, said stent having a bead suspended by a tether, wherein, the pusher includes: (a) a hollow tube having a distal end and a proximal end; and (b) an opening defined in the peripheral wall of the pusher near the distal end, which reaches the inner hollow portion of the pusher and may be sized to allow for the positioning of the bead through the opening and within the receptacle defined by the opening.

**[0030]** In accordance with another embodiment, there is provided a pusher apparatus, for the insertion of a shortened stent, said stent having a bead suspended by a tether, wherein, the pusher includes:

1. (a) a hollow tube having a distal end and a proximal end; and (b) an opening defined in the peripheral wall of the pusher near the distal end, which reaches the inner hollow portion of the pusher and may be sized to allow for the positioning of the bead through the opening and within the receptacle defined by the opening.

**[0031]** In accordance with another embodiment, there is provided a pusher apparatus, for the insertion of a shortened stent, said stent having a bead suspended by a tether, wherein, the pusher includes:

1. (a) a hollow tube having a distal end and a proximal end; and (b) an opening defined in the peripheral wall of the pusher near the distal end, which reaches the inner hollow portion of the pusher and may be sized to allow for the positioning of the bead through the opening and within the pusher.

**[0032]** In accordance with another embodiment, there is provided a pusher apparatus, including: (a) a hollow tube with a distal end and a proximal end; and (b) an opening defined in the peripheral wall of the pusher near the distal end, which reaches the inner hollow portion of the pusher and may be sized to allow for positioning of a tethered bead through the opening and within the pusher.

**[0033]** According to a second aspect of the invention, there is provided a pusher attachment apparatus as defined in claim 8.

**[0034]** In accordance with another embodiment, there is provided a pusher attachment apparatus, including: (a) a hollow tube having a distal end and a proximal end; (b) a connector at the proximal end of the hollow tube for attachment to a pusher having a lumen, whereby the lumen of the pusher may be contiguous with the lumen of the hollow tube; and (c) an opening defined in the peripheral wall of the hollow tube, which reaches the inner hollow portion of the hollow tube and may be sized to allow for positioning of a tethered bead through the opening and within the receptacle defined by the opening.

**[0035]** In accordance with another embodiment, there is provided a pusher attachment apparatus, including: (a) a hollow tube having a distal end and a proximal end; (b) a connector at the proximal end of the hollow tube for attachment to a pusher having a lumen, whereby the lumen of the pusher may be contiguous with the lumen of the hollow tube; and (c) an opening defined in the peripheral wall of the hollow tube, which reaches the inner hollow portion of the hollow tube and may be sized to allow for positioning of a tethered bead through the opening and within the pusher attachment apparatus.

**[0036]** According to a third aspect of the invention, there is provided a commercial package as defined in claim 15.

**[0037]** In accordance with another embodiment, there is provided a commercial package including: (a) a guide wire over which a stent may be pushed; (b) a stent assembly for keeping a body channel open and having a tethered bead for stent retrieval, the stent and bead being adapted to be pushed over the guide wire; (c) a pusher attachment, as described herein, adapted to be pushed over the guide wire to advance the stent relative to the guide wire and to accept the tethered bead within the opening; and (d) a pusher tube adapted to be pushed over the guide wire for advancing the stent relative to the guide wire.

**[0038]** In accordance with another embodiment, there is provided a commercial package including: (a) a guide wire over which a stent may be pushed; (b) a stent assembly for keeping a body channel open and having a tethered bead for stent retrieval, the stent and bead being adapted to be pushed over the guide wire; and (c) a pusher apparatus, as described herein, adapted to be pushed over the guide wire to advance the stent relative to the guide wire and to accept the tethered bead within the opening.

**[0039]** In accordance with another embodiment, there is provided a commercial package including (a) a stent assembly for keeping a body channel open and having a tethered bead for stent retrieval, the stent and bead being adapted to be pushed over a guide wire; (b) a pusher attachment as described herein adapted to be pushed over the guide wire to advance the stent relative to the guide wire and to accept the tethered bead within the opening, wherein the tethered bead is retained within the opening by an holder until a guide wire is inserted; and (c) a pusher tube adapted to be pushed over the guide wire for advancing the stent relative to the guide wire.

**[0040]** In accordance with another embodiment, there is provided a commercial package including (a) a stent assembly for keeping a body channel open and having a tethered bead for stent retrieval, the stent and bead being adapted to be pushed over a guide wire; and (b) a pusher apparatus as described herein adapted to be pushed over the guide wire to advance the stent relative to the guide wire and to accept the tethered bead within the opening, wherein the tethered bead is retained within the opening by an holder until a guide wire is inserted.

**[0041]** In accordance with another embodiment, there is provided a commercial package including (a) a stent assembly for keeping a body channel open and having a tethered bead for stent retrieval, the stent and bead being adapted to be pushed over a guide wire; (b) a pusher attachment as described herein adapted to be pushed over the guide wire to advance the stent relative to the guide wire and to accept the tethered bead within the opening, wherein the tethered bead is retained within the opening by an external holder until a guide wire is inserted; and (c) a pusher tube adapted to be pushed over the guide wire for advancing the stent relative to the guide wire.

**[0042]** In accordance with another embodiment, there is provided a commercial package including (a) a stent assembly for keeping a body channel open and having a tethered bead for stent retrieval, the stent and bead being adapted to be pushed over a guide wire; and (b) a pusher apparatus as described herein adapted to be pushed over the guide wire to advance the stent relative to the guide wire and to accept the tethered bead within the opening, wherein the tethered bead is retained within the opening by an external holder until a guide wire is inserted.

**[0043]** In accordance with another embodiment, there is provided a commercial package including (a) a stent assembly for keeping a body channel open and having a tethered bead for stent retrieval, the stent and bead being adapted to be pushed over a guide wire; (b) a pusher attachment as described herein adapted to be pushed over the guide wire to advance the stent relative to the guide wire and to accept the tethered bead within the opening, wherein the tethered bead is retained within the opening by an internal holder until a guide wire is inserted; and (c) a pusher tube adapted to be pushed over the guide wire for advancing the stent relative to the guide wire.

**[0044]** In accordance with another embodiment, there is provided a commercial package including (a) a stent assembly for keeping a body channel open and having a tethered bead for stent retrieval, the stent and bead being adapted to be pushed over a guide wire; and (b) a pusher apparatus as described herein adapted to be pushed over the guide wire to advance the stent relative to the guide wire and to accept the tethered bead within the opening, wherein the tethered bead is retained within the opening by an internal holder until a guide wire is inserted.

**[0045]** The holder may internal or external or a combination of both. The holder may be a wrapper. The holder may be a mandrel.

**[0046]** The outer diameter of the hollow tube may be less than the diameter of the bead, provided that the pusher apparatus with a bead positioned within the receptacle is able to pass through the lumen of a cytoscope. The outer diameter of the hollow tube may be approximately the diameter of the bead. The outer diameter of the hollow tube may be greater than the diameter of the bead.

**[0047]** Alternatively, the outer diameter of the hollow tube may be greater than the diameter of the bead plus the cross-sectional area of the peripheral wall of the pusher opposite the opening. The outer diameter of the hollow tube may be less than the diameter of the bead plus the cross-sectional area of the peripheral wall of the pusher opposite the opening, provided that the pusher apparatus with a bead positioned within the receptacle is able to pass through the lumen of a cytoscope. The outer diameter of the hollow tube may be approximately the diameter of the bead plus the cross-sectional area of the peripheral wall of the pusher opposite the opening.

**[0048]** The opening may be greater than 180° of the circumference of the pusher. The opening may be greater than 185° of the circumference of the pusher. The opening may be greater than 190° of the circumference of the pusher. The opening may be greater than 195° of the circumference of the pusher. The opening may be greater than 200° of the circumference of the pusher. The opening may be greater than 205° of the circumference of the pusher. The opening may be greater than 210° of the circumference of the pusher. The opening may be greater than 215° of the circumference of the pusher. The opening may be greater than 220° of the circumference of the pusher. The opening may be greater than 225° of the circumference of the pusher. The opening may be greater than 230° of the circumference of the pusher. The opening may be greater than 235° of the circumference of the pusher. The opening may be greater than 240° of the circumference of the pusher. The opening may be greater than 250° of the circumference of the pusher. The opening may be greater than 255° of the circumference of the pusher. The opening may be greater than 260° of the circumference of the pusher. The opening may be greater than 265° of the circumference of the pusher. The opening may be greater than 270° of the circumference of the pusher. The opening may be greater than 280° of the circumference of the pusher. The opening may be greater than 285° of the circumference of the pusher. The opening may be greater than 290° of the circumference of the pusher. The opening may be greater than 295° of the circumference of the pusher. The opening may be greater than 300° of the circumference of the pusher. The opening may be greater than 305° of the circumference of the pusher. The opening may be greater than 310° of the circumference of the pusher. The opening may be greater than 315° of the circumference of the pusher. The opening may be greater than 320° of the circumference of the pusher. The opening may be greater than 325° of the circumference of the pusher. The opening may be greater than 330° of the circumference of the pusher. The opening may be greater than 335° of the circumference of the pusher. The opening may be greater than 340° of the circumference of the pusher. The opening may be greater than 345° of the circumference of the pusher. The opening may be greater than 350° of the circumference of the pusher. The opening may be greater than 355° of the circumference of the pusher.

**[0049]** The area adjacent the opening may be reinforced to maintain structural integrity of the pusher tube. The reinforcement may be by the addition of a material that is less flexible than the pusher. The reinforcement may be by the use of a material that is less flexible than the pusher tube adjacent the opening.

**[0050]** The minimum distance between the distal end of the pusher and the opening may be about 3 cm. The minimum distance between the distal end of the pusher and the opening may be about 2.5 cm. The minimum distance between the distal end of the pusher and the opening may be about 5.0 cm. The minimum distance between the distal end of the pusher and the opening may be about 4.9 cm. The minimum distance between the distal end of the pusher and the opening may be about 4.8 cm. The minimum distance between the distal end of the pusher and the opening may be about 4.7 cm. The minimum distance between the distal end of the pusher and the opening may be about 4.6 cm. The minimum distance between the distal end of the pusher and the opening may be about 4.5 cm. The minimum distance between the distal end of the pusher and the opening may be about 4.4 cm. The minimum distance between the distal end of the pusher and the opening may be about 4.3 cm. The minimum distance between the distal end of the pusher and the opening may be about 4.2 cm. The minimum distance between the distal end of the pusher and the opening may be about 4.1 cm. The minimum distance between the distal end of the pusher and the opening may be about 4.0 cm. The minimum distance between the distal end of the pusher and the opening may be about 3.9 cm. The minimum distance between the distal end of the pusher and the opening may be about 3.8 cm. The minimum distance between the distal end of the pusher and the opening may be about 3.7 cm. The minimum distance between the distal end of the pusher and the opening may be about 3.6 cm. The minimum distance between the distal end of the pusher and the opening may be about 3.5 cm. The minimum distance between the distal end of the pusher and the opening may be about 3.4 cm. The minimum distance between the distal end of the pusher and the opening may be about 3.3 cm. The minimum distance between

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The minimum distance between the distal end of the pusher attachment and the opening may be between about 5 cm and 7 cm.  
 The minimum distance between the distal end of the pusher attachment and the opening may be between about 5 cm and 6 cm.  
 The minimum distance between the distal end of the pusher attachment and the opening may be between about 4 cm and 10 cm.  
 The minimum distance between the distal end of the pusher attachment and the opening may be between about 4 cm and 9 cm.  
 The minimum distance between the distal end of the pusher attachment and the opening may be between about 4 cm and 8 cm.  
 The minimum distance between the distal end of the pusher attachment and the opening may be between about 4 cm and 7 cm.  
 The minimum distance between the distal end of the pusher attachment and the opening may be between about 4 cm and 6 cm.  
 The minimum distance between the distal end of the pusher attachment and the opening may be between about 3 cm and 12 cm.  
 The minimum distance between the distal end of the pusher attachment and the opening may be between about 3 cm and 11 cm.  
 The minimum distance between the distal end of the pusher attachment and the opening may be between about 3 cm and 10 cm.  
 The minimum distance between the distal end of the pusher attachment and the opening may be between about 3 cm and 9 cm.  
 The minimum distance between the distal end of the pusher attachment and the opening may be between about 3 cm and 8 cm.  
 The minimum distance between the distal end of the pusher attachment and the opening may be between about 2 cm and 10 cm.

**[0052]** The tether connecting the bead and the stent, may be made available in variable diameters. Particularly, in the event that drainage would be useful. For example, occasionally, after the ureter has been traversed with an instrument it may be traumatized causing edema and obstruction of the urinary flow. When there is swelling in the intramural (bladder portion) of the ureter, drainage of the ureter may assist with reducing the swelling. Generally, a stent will allow for drainage of the ureter, but in some instances the swelling may be such that the stent alone is not sufficient to provide drainage, in particular, where a shortened stent is used. In such circumstances the tether may also assist with drainage of the ureter. A larger diameter tether or possibly even a flat tether may help with drainage. Alternatively, tether with other non-circular cross-sections may be appropriate in the circumstances.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

**[0053]** In drawings which illustrate embodiments of the invention:

Figure 1 is a side view of a modified pusher apparatus according to a first embodiment;

Figure 2 is a side view of a modified pusher apparatus according to a second embodiment, wherein the area adjacent the opening is reinforced;

Figure 3 is a side view of a pusher attachment apparatus according to an embodiment adjacent to an unmodified pusher;

Figure 4 is a partial cross-sectional view of the modified pusher apparatus of Figure 1, adjacent to a stent assembly having a tether and a bead, all threaded over a guide wire, wherein the bead is positioned within the opening of the modified pusher apparatus;

Figure 5 is a cross-sectional view of the modified pusher apparatus of Figure 1, positioned within a cytoscope, threaded over a guide wire, with a bead positioned within the opening of the modified pusher apparatus;

Figure 6 illustrates a shortened stent positioned within the ureter and a tethered bead suspended in the bladder;

Figure 7 illustrates a shortened stent positioned within the ureter and a prior art tethered bead suspended in the bladder; and

Figure 8 illustrates a shortened stent positioned within the ureter and a smaller tethered bead than in Figure 6, suspended in the bladder.

#### **DETAILED DESCRIPTION**

**[0054]** As used herein a "bead" is meant to include any ferromagnetic member. Ferromagnetic as used herein is meant to include materials which may comprised of iron, nickel, chromium, or cobalt or combinations thereof and various alloys, such that the bead is attracted to a magnet. For example, a bead may be made from ferromagnetic stainless steel. Furthermore, beads are preferably biocompatible. For example, a stainless steel bead may be coated with a smooth layer of polymer, for example, polytetrafluoroethylene. A "biocompatible" bead or a bead coated with a biocompatible coating, may prevent the reaction of the bead with urine or bile, or other bodily fluids in which the bead may be placed. Furthermore, the bead may itself be a magnet.

Beads as described herein are generally biocompatible, rounded, perforated, and ferromagnetic. For example, a bead may be made from a rare earth magnet or a stainless steel having magnetic properties.

**[0055]** A pusher is essentially a hollow tube, which may be made in a variety of diameters and having a range of wall thicknesses, and may be selected to ensure compatibility for use with a given stent. A pusher may be made from high durometer (stiff), biocompatible, polymers and polymer blends (for example, polyurethane, high density polyethylene, nylon, etc. and blends thereof), as known in the art.

**[0056]** A holder as used herein, is meant to include any member that is capable of retaining a bead within an opening of a modified pusher apparatus or a pusher attachment, to facilitate the insertion of a guide wire through the bead, while the bead is within the opening of the modified pusher apparatus or the pusher attachment. The holder may be removed after insertion of a guide wire or may remain associated with the modified pusher apparatus or the pusher attachment, but be in a release position so that when the guide wire is removed during stent insertion, the bead may be released from the modified pusher apparatus or the pusher attachment. A commercial package containing such a holder, may facilitate loading of a selected guide wire, for insertion into the apparatus. A holder may be internal or external or a combination thereof. Furthermore, a holder may, for example, take the form of a removable wrapper, a clip, a mandrel, a wedge, an adhesive surface modification etc. An adhesive surface modification, may be prepared such that the adhesive dissolves when *in situ* (for example, in urine, at body temperature, etc.). Such a system allows for the selection of the best guide wire to suit the patient or the personal preferences of the user. For example, guide wires may be chosen for their frictional properties (for example, a hydrophilic coating may provide for less friction) or their 'pushability'.

**[0057]** A mandrel, as used herein, may be a wire that resides within the modified pusher apparatus or a pusher attachment, to hold the bead within the opening of the modified pusher apparatus or the pusher attachment until the guide wire is inserted. The mandrel may be sized to fit within the bead with the guide wire or such that it is pushed out of the bead as the guide wire is inserted. A wrapper, as used herein, may be any type of protective covering that is capable of retaining a bead within the opening of a modified pusher apparatus or a pusher attachment, to facilitate the insertion of a guide wire through the bead. Such a wrapper may be removed once the guide wire is inserted through the bead.

**[0058]** Referring to Figure 1, a modified pusher apparatus according to a first embodiment is shown generally at **10**. The inner hollow portion or lumen of the pusher is shown at **14** and the distal end of the modified pusher apparatus is shown at **19**. The modified pusher apparatus has a receptacle **17**, which is defined by an opening **15**. The lumen of the pusher may receive a guide wire (not shown in Figure 1) and the receptacle **17** is sized and positioned near the distal end of the pusher **19** to receive a tethered bead attached to the proximal end of the stent (the bead and stent are not shown in Figure 1).

**[0059]** Referring to Figure 2, a modified pusher apparatus according to a second embodiment is shown generally at **10**. Similar to Figure 1, the inner hollow portion or lumen of the pusher is shown at **14** and the distal end of the modified pusher apparatus is shown at **19**. The modified pusher apparatus has a receptacle **17**, which is defined by an opening **15**. The lumen of the pusher may receive a guide wire (not shown in Figure 2) and the receptacle **17** is sized and positioned near the distal end of the pusher **19** to receive a tethered bead attached to the proximal end of the stent (the bead and stent are not shown in Figure 2). However, the modified pusher of Figure 2 has a reinforced area **20** adjacent the opening to maintain the structural integrity of the pusher tube despite the opening **15** in the wall of the pusher tube. The reinforced area **20** may be made of a different material than the remainder of the pusher or the reinforced area **20** may have added material that is the same as or different than the remainder of the pusher. Furthermore, the reinforced area **20** may be made of a material that is less flexible than the remainder of the pusher or the reinforced area **20** may have added material that is less flexible than the remainder of the pusher. The reinforcement applied in the reinforced area **20** adjacent the opening and the size of the area to be reinforced **20** may depend on a number of factors, which may include the size of the opening **15**, the shape of the opening **15**, the properties of the material from which the remainder of the pusher is made, the properties of the material adjacent the opening **15**, the properties of the material defining the borders of the receptacle **17**, and the use in which the pusher is to be implemented. In view of the above a person of skill in the art would be well aware of the reinforcement that may be applied to maintain the structural integrity of the pusher. The reinforced area, for example, may be made from stainless steel or another alloy.

**[0060]** Referring to Figure 3, a pusher attachment apparatus according to an embodiment is generally shown at **100**. The inner hollow portion or lumen of the pusher attachment apparatus is shown at **140**, the inner hollow portion or lumen of the pusher is shown at **141**, and the distal end of the pusher apparatus is shown at **190**. The pusher attachment apparatus has a receptacle **17**, which is defined by an opening **15**. The lumen of the pusher may receive a guide wire (not shown in Figure 3) and the receptacle **17** is sized and positioned to receive a tethered bead attached to the proximal end of the stent (the bead and stent are not shown in Figure 3). The pusher attachment apparatus may be designed, to be attached to any standard pusher apparatus to allow for the positioning of a bead, which is tethered to a stent, within the receptacle **17**.

[0061] Referring to Figure 4, a modified pusher apparatus according to a first embodiment is shown in a partial cross-section generally at **10**, adjacent a partial cross-section of a shortened stent **30**. The stent **30** is positioned along a guide wire **50** at the distal end **19** of the modified pusher **10**, whereby the distal end **19** of the modified pusher **10** is adjacent to the proximal end **39** of the stent **30**. The guide wire **50** is shown, from proximal to distal (left to right), passing through the inner hollow portion or lumen **14** of the modified pusher apparatus **10**, passing through the bore or perforation in the bead **40**, through the remainder of the lumen **14** of the modified pusher apparatus **10**, and passing through the inner hollow portion or lumen **34** of the stent **30**. The modified pusher apparatus has a receptacle **17**, which is defined by an opening **15**. The bead **40** is shown positioned near the distal end of the pusher **19**, within the receptacle **17** and with the guide wire passing through the bore within the bead. A tether **60** is shown looping around the exterior of the stent and passing through a stent perforation **36**, passing through the inner hollow portion or lumen **34** of the stent **30** to the proximal end of the stent **39**, then along the outer surface of the modified pusher apparatus **10**, to the bead **40** and through the tether opening **43** of the bead, wherein the tether opening as shown is generally extend through the bead perpendicular to the long axis of the bead. As shown in Figure 4, only one side of the tether loop is shown between the bead and the stent lumen.

[0062] Referring to Figure 5, a modified pusher apparatus according to a first embodiment is shown in a partial cross-section generally at **10**, positioned within the lumen **74** of a cystoscope **70**. The bead **40** is shown in cross-section positioned within the receptacle **17** adjacent the distal end **19** of the modified pusher **10**, whereby the distal end **19** of the modified pusher **10** is adjacent to the distal end **79** of the cystoscope **70**. Also shown, is the bead tether opening **43**, but the tether is not shown. The guide wire **50** is shown, from proximal to distal (bottom left to top right), passing through the inner hollow portion or lumen **14** of the modified pusher apparatus and through the lumen of the cystoscope **74**, passing through the bore or perforation in the bead **40**, through the remainder of the lumen **14** of the modified pusher apparatus **10**, and passing through the inner hollow portion or lumen **34** of the stent **30**.

[0063] Referring to Figures 6, 7, and 8, shortened stents are shown positioned within the ureter **90**, following insertion with the insertion apparatus removed (i.e. cystoscope, pusher and guidewire). The stent assembly, which includes the shortened perforated stent **30**, tether **60**, and bead **40** are shown in Figures 6, 7, and 8 with three different bead designs. The bead design in Figure 7 is reproduced from the PCT application PCT/CA99/00405. The positioning of the stent assembly is such that the proximal end of the stent **39** is positioned within the ureter **90** and away from the ureteral orifice **85** and whereby the bead **40** is suspended in the bladder **80** by the tether **60**, which passes through the bead tether opening **43**. Figure 7 also shows a passage for a positioning line **45** within the bead (positioning line not shown). Figure 6 shows a larger bead design relative to Figure 8. Nevertheless, the shorter bead designs of Figures 6 and 8 may permit better rotation on the tether, as compared to the bead of Figure 7, which may assist in release of the tethered bead from the pusher apparatus or pusher attachment (not shown in Figures 6-8). Referring to Figures 4-8, the bead tether opening **43** as shown is generally at a midpoint in the bead **40** to allow the bead to lie perpendicular to the ureteric orifice **85** and prevent migration up the ureter **90**.

[0064] The operation of the modified pusher apparatus for the insertion of a shortened stent **30** into a ureter **90** may be described as follows:

a cystoscope **70** is inserted into the bladder, and a guide wire **50** is passed up the cystoscope lumen **74** to the bladder and up the ureter into a kidney;

a shortened stent **30** is threaded onto the guide wire **50**, without threading the bead **40**, followed by the modified pusher apparatus **10** until the guide wire approaches the receptacle **17**,

the bead **40** tethered to the stent **30** is positioned within the receptacle **17** such that the guide wire **50** may pass through the bead and towards the proximal end of the pusher (alternatively, the stent **30**, pusher **10**, bead **40** and guidewire **50** may be preassembled to allow for insertion as a unit);

the shortened stent **30** followed by the modified pusher apparatus **10**, with the bead **40** positioned within the receptacle **17** and held in place by the guide wire, are advanced up the guide wire **50** and through the cystoscope **70** into the bladder **80**;

the shortened stent **30** and the modified pusher apparatus **10** are further advanced up the ureter so that the hook or pigtail (not shown) on the distal end of the stent is positioned within the kidney and the proximal end of the stent **39** is positioned within the ureter **90** as shown in Figures 6-8;

the cystoscope **70**, which is situated in the bladder **80**, is used to visually confirm (fluoroscopic confirmation) the correct positioning of the stent **30** based on the position of the modified pusher apparatus **10** relative to the ureteral orifice **85** (such a fluoroscopic confirmation may be simplified, where the pusher has markings or gradations so that the operator can gauge the depth of the

stent within the ureter);

the modified pusher apparatus **10** is held in position adjacent the proximal end of the stent **39**, while the guide wire **50** is removed so that the shortened stent **30** does not slide down the ureter **90** (from distal to proximal) as the guide wire is withdrawn from the ureter; and

the modified pusher apparatus **10** is withdrawn into the cystoscope and removed together with the cystoscope **70** (to avoid damaging the urethra with the receptacle **17**).

[0065] Removal of the stent **30** may be accomplished by a non-surgical procedure that does not even require endoscopy. As described in an earlier patent application (WO99/58083) a retrieval catheter (not shown), which comprises a conventional catheter that is modified to mount a magnet at the distal tip of the catheter. The magnet may also be covered with a biocompatible coating and/or may be rounded to prevent injury to the patient. The magnet-tipped end of the retrieval catheter is inserted, through the urethra and into the bladder, where the catheter tip magnetically engages the suspended bead **40**. As the catheter is withdrawn the bead **40** and tether-connected stent **30** are pulled from the ureter and explanted from the patient.

[0066] As the retrieval catheter approaches the bead **40**, the magnetic flux acting on the bead **40** should be sufficient to cause the bead to rotate relative to the tether from its normal, suspended position, so that one of the ends of the bead **40** rotates on the tether to contact the tip of the retrieval catheter. Accordingly, the bead will be oriented generally coaxially with the end of the retrieval catheter. If this orientation is not attained in the bladder, as the retrieval catheter and bead enter the urethra passage, the urethra will likely cause the axial alignment of the bead **40** with the retrieval catheter, which is desired for comfortable removal of the bead through the urethra. It will be appreciated that this rotation of the bead will be assured where the bead is magnetized, and one of its ends has a polarity opposite that of the magnet on the retrieval catheter.

[0067] Alternatively, the bead **40** could be a magnet and the retrieval catheter tipped with ferromagnetic material or another magnet. Although a rare-earth magnet is preferred, other types, including electromagnets could be employed with the retrieval catheter. In addition, the bead may be of a more ball shape Figures 6 and 8, rather than the elongated bead of figure 7.

[0068] Although various embodiments of the invention are disclosed herein, many adaptations and modifications may be made within the scope of the invention in accordance with the common general knowledge of those skilled in this art. Such modifications include the substitution of known equivalents for any aspect of the invention in order to achieve the same result in substantially the same way. Numeric ranges are inclusive of the numbers defining the range. The word "comprising" is used herein as an open-ended term, substantially equivalent to the phrase "including, but not limited to", and the word "comprises" has a corresponding meaning. As used herein, the singular forms "a", "an" and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a thing" includes more than one such thing. Citation of references herein is not an admission that such references are prior art to an embodiment of the present invention. The invention includes all embodiments and variations substantially as hereinbefore described and with reference to the examples and drawings.

## REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

### Patent documents cited in the description

- [US61649102B](#) [0001]
- [WO9958083A](#) [0007] [0065]
- [WO2011086175A1](#) [0008]
- [CA9900405W](#) [0063]

**PATENTKRAV**

1. Skubbeindretning (10) til indsætning af en afkortet stent (30), under anvendelse af en føringstråd (50), hvilken stent har en perle (40) ophængt i en strop (60), hvor skubbe-  
5 indretningen omfatter:
  - (a) et hult rør (14) med en distal ende (19) og en proximal ende indrettet til at blive skubbet over føringstråden; og
  - (b) en åbning (15) defineret i den perifere væg i skubbeindretningen nær den distale ende, som strækker sig ind i den indre hule del af skubbeindretningen og er dimensioneret til at tillade positioneringen af perlen i åbningen og i det mindste delvis i  
10 modtageåbningen (17) defineret ved åbningen.
2. Skubbeindretning ifølge krav 1, hvor den udvendige diameter af det hule rør er;
  - a) mindre end diameteren af perlen;
  - 15 b) større end diameteren af perlen; eller
  - c) omtrent lig med diameteren af perlen.
3. Skubbeindretning ifølge krav 2, når denne er som angivet i afsnit a), hvor skubbeindretningen med en perle placeret i modtageåbningen er i stand til at passere igennem  
20 lysningen i et cystoskop (74).
4. Skubbeindretning ifølge ethvert af kravene 1-3, hvor åbningen er større end 180° af omkredsen af skubbeindretningen.
- 25 5. Skubbeindretning ifølge ethvert af kravene 1-4, hvor området i tilstødning til åbningen er forstærket for at opretholde den strukturelle integritet af skubberøret.
6. Skubbeindretning ifølge krav 5, hvor forstærkningen er tilvejebragt ved tilføjelse af et materiale, som er:
  - 30 a) mindre fleksibelt end skubbeindretningen;
  - b) mere fleksibel end skubbeindretningen; eller
  - c) har samme fleksibilitet som skubbeindretningen.
7. Skubbeindretning ifølge ethvert af kravene 1-6, hvor den minimale afstand imellem  
35 den distale ende af skubbeindretningen og åbningen er:
  - a) omkring 3 cm;

- b) omkring 2 cm;
- c) imellem omkring 4 cm og 10 cm;
- d) imellem omkring 5 cm og 8 cm;
- e) imellem omkring 5 cm og 7 cm; eller
- 5 f) imellem omkring 5 cm og 6 cm.

8. Skubberforbindelsesapparat (100), som er indrettet til at blive skubbet over en føringstråd, omfattende:

- (a) et hult rør (140) med en distal ende (190) og en proximal ende;
- 10 (b) en forbindelsesindretning ved den proximale ende af det hule rør til forbindelse med en skubbeindretning med en lysning, idet, under brug, lysningen i skubbeindretningen er en fortsættelse af lysningen i det hule rør; og
- (c) en åbning (15) defineret i den perifere væg i det hule rør, som strækker sig til den indvendige hule del af det hule rør, og som er dimensioneret til at tillade positioneringen af en tøjret perle i åbningen og i det mindste delvis i modtageåbningen
- 15 (17) defineret ved åbningen.

9. Skubberforbindelsesapparat ifølge krav 8, hvor den udvendige diameter af det hule rør er:

- 20 a) større end diameteren af perlen;
- b) mindre end diameteren af perlen; eller
- c) omtrent lig med diameteren af perlen.

10. Skubberforbindelsesapparat ifølge krav 8 eller 9, hvor åbningen er større end  $180^\circ$

25 af omkredsen af det hule rør.

11. Skubberforbindelsesapparat ifølge ethvert af kravene 8-10, hvor området i tilstødning til åbningen er forstærket for at opretholde den strukturelle integritet af det hule rør.

30

12. Skubberforbindelsesapparat ifølge krav 11, hvor forstærkningen er tilvejebragt ved tilføjelsen af et materiale, som er:

- a) mindre fleksibelt end skubbeindretningen;
- b) mere fleksibelt end skubbeindretningen; eller
- 35 c) omtrent med samme fleksibilitet som skubbeindretningens materiale.

13. Skubberforbindelsesapparat ifølge ethvert af kravene 8-12, hvor området i tilstødning til åbningen er mere stift end skubbermaterialet for opretholdelse af strukturel integritet af det hule rør.

5 14. Skubberforbindelsesapparat ifølge ethvert af kravene 8-13, hvor den minimale afstand imellem den distale ende af det hule rør og åbningen er:

- a) omkring 3 cm;
- b) omkring 2 cm;
- c) imellem omkring 4 cm og 10 cm;
- 10 d) imellem omkring 5 cm og 8 cm;
- e) imellem omkring 5 cm og 7 cm; eller
- f) imellem omkring 5 cm og 6 cm.

15. Kommerciel pakke omfattende en skubbeindretning ifølge ethvert af kravene 1-7, hvor den kommercielle pakke yderligere omfatter:

- (a) en føringstråd over hvilken en stent kan skubbes;
- (b) en stentkonstruktion til at holde en kropskanal åben og som har en tøjret perle for stentfjernelse, idet stenten og perlen er indrettede til at blive skubbet over føringstråden; og hvor
- 20 (c) skubbeindretningen er indrettet til at blive skubbet over føringstråden for at fremføre stenten i forhold til føringstråden og til at optage den tøjrede perle i åbningen.

16. Kommerciel pakke ifølge krav 15, hvor føringstråden, stentarrangementet og skubbeindretningen er til anvendelse ved indføring af stentarrangementet i et humant ureter  
25 (90).

17. Kommerciel pakke ifølge krav 15 eller 16, som yderligere omfatter en holder, hvor den tøjrede perle er fastholdt i åbningen af holderen, indtil en føringstråd er indsat.

30 18. Kommerciel pakke ifølge krav 17, hvor holderen er:

- a) en bøsning; eller
- b) en dorn.

DRAWINGS

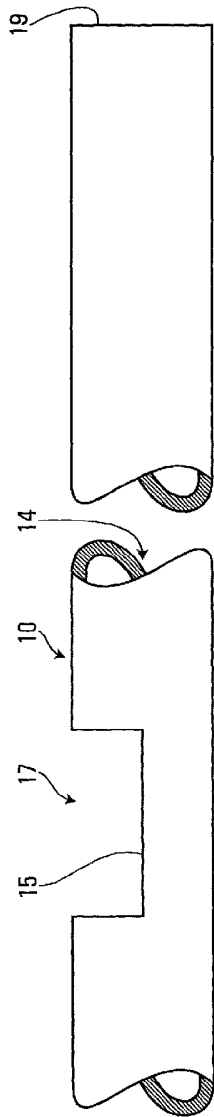


FIG. 1

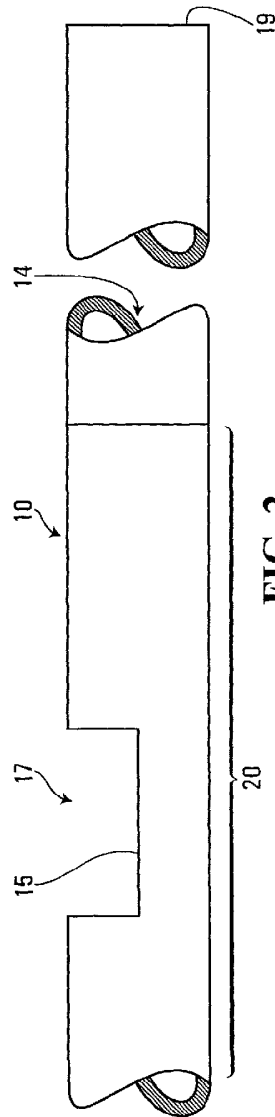


FIG. 2

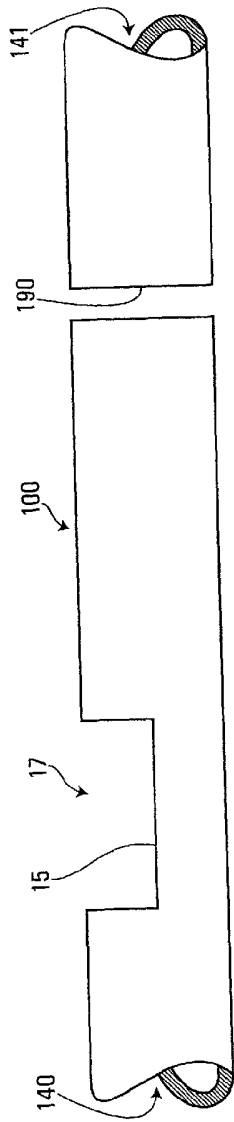


FIG. 3

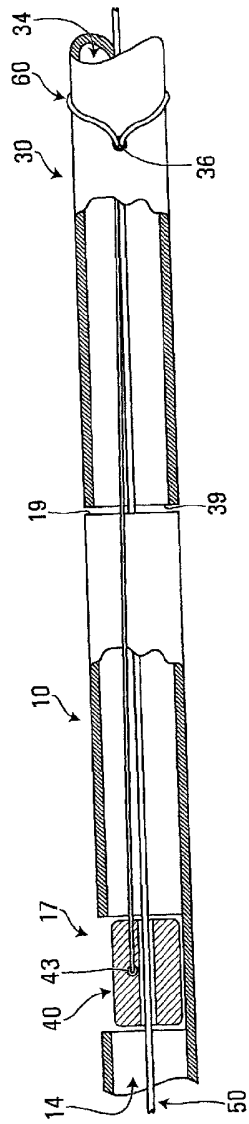


FIG. 4

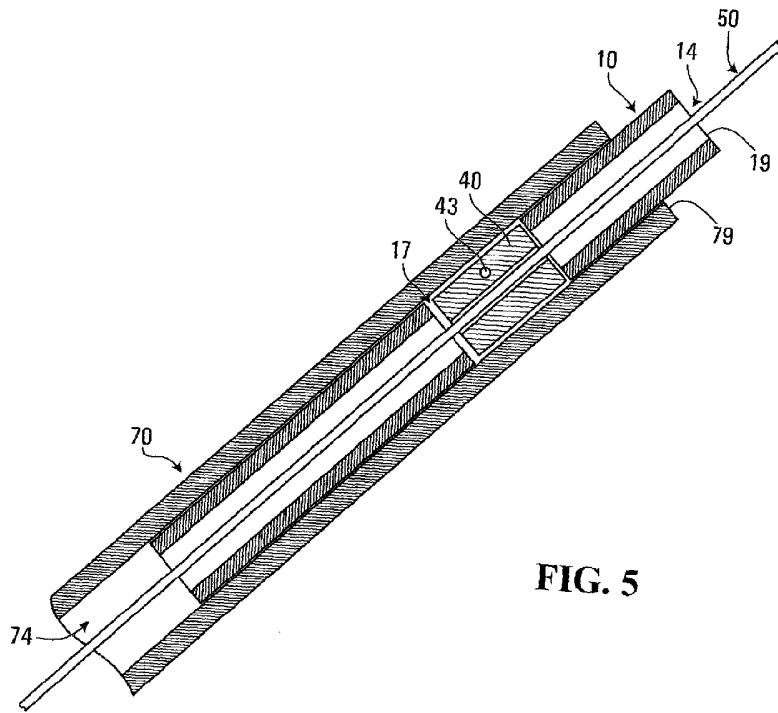
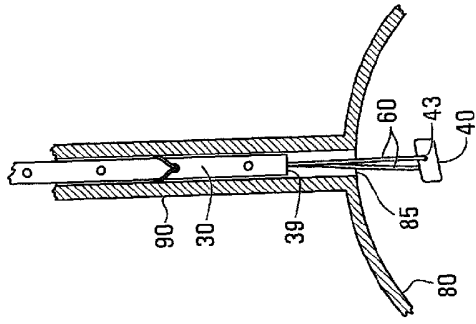
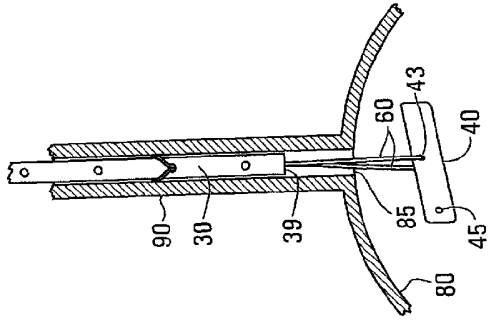


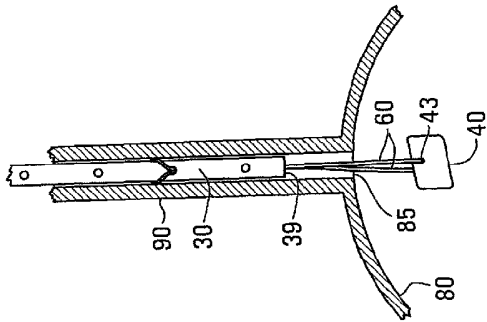
FIG. 5



**FIG. 8**



**FIG. 7**  
Prior Art



**FIG. 6**