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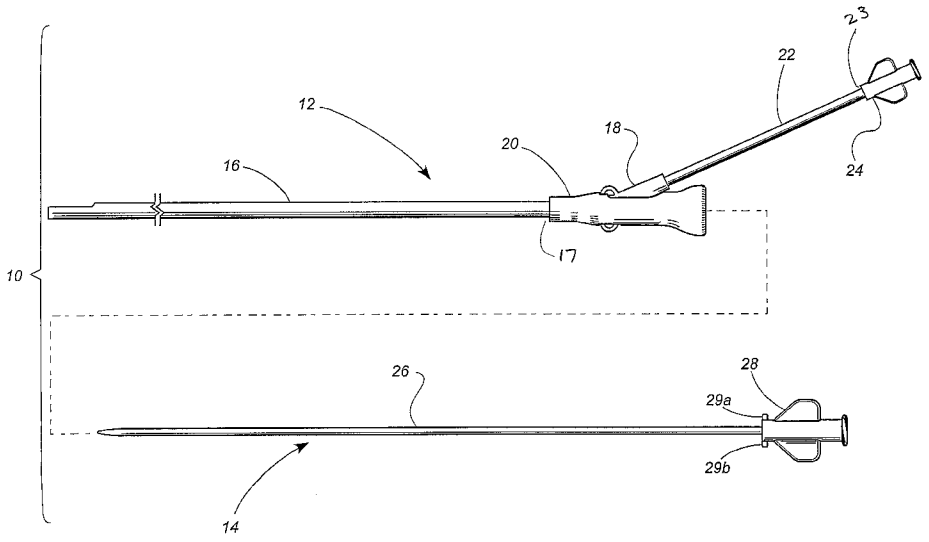
(54) Title: URETERAL ACCESS SHEATH



(57) **Abstract:** A ureteral access sheath comprises a sheath assembly having a main lumen and one or more secondary lumens. The sheath assembly can be configured with medical devices in both lumens, for example, a ureteroscope in the main working channel, and a guidewire, stone basket, grasper, laser fiber, or other surgical instrument in the secondary working channel. Or the sheath assembly can be configured with a medical device in one channel and the other lumen coupled to an irrigation means, such that irrigation of the surgical field can be efficiently accomplished even though the main working channel is substantially completely occupied by, e.g., a ureteroscope. Or the sheath assembly can be configured for irrigation through one lumen and aspiration through the other lumen, thereby creating a turbulent flow which washes the surgical field to facilitate removal of particles and debris.

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"URETERAL ACCESS SHEATH"

TECHNICAL FIELD

The present invention relates generally to surgical devices and relates more specifically to a ureteral access sheath for creating an access channel from the external meatus to a location within the ureter of a patient.

BACKGROUND OF THE INVENTION

It is known to use a ureteral access sheath for creating an access channel from the external meatus to a location within the ureter of a patient to perform surgical procedures within the ureter and/or kidney. With an established channel to the ureter, a surgeon is able to insert and to withdraw a ureteroscope or other instrument more rapidly and with limited trauma to a patient's urinary system.

A typical prior art ureteral access sheath includes two subassemblies: a dilator and a sheath. The dilator is placed within the sheath, and the dilator and sheath combination is advanced through the urethra, through the bladder, and to the ureter. The dilator is then withdrawn, leaving the sheath in place. A ureteroscope is then advanced through the sheath to access the ureter.

A problem with known prior art ureteroscopic procedures concerns the need to irrigate the target site. Irrigation is critical during

most ureteroscopic procedures. Since the inability to view the surgical area could have devastating effects, a procedure will not be continued until adequate viewing is achieved. Typically, irrigation fluid is supplied through the working channel of the ureteroscope. Because other instruments (*i.e.,* a stone basket, grasper, laser fiber, *etc.*) also occupy the working channel, the flow rate of the irrigation fluid is reduced in proportion to be diameter of the instrument being used. Thus it would be desirable to provide a surgical environment in which the flow rate of irrigation fluid is not restricted by the presence of instruments within the working channel of the ureteroscope.

An additional problem with known prior art ureteral access sheaths concerns the need for guidewires in conjunction with the placement of the sheath. To use a typical prior art ureteral access sheath, the physician performs the following steps:

1. A cystoscope is inserted into the patient's urethra and advanced into the bladder, where the ureteral orifices are identified.
2. Using the cystoscope, a guidewire is inserted into the ureteral orifice.
3. Using fluoroscopy, the proximal end of the guidewire is inserted through the ureter and into the kidney.
4. With the guidewire carefully held in place, the cystoscope is removed over the guidewire.
5. The dilator is placed within the sheath.
6. The distal end of the ureteral access sheath is now back-loaded onto the proximal end of the guidewire and advanced over the guidewire and into the ureter. Advancement and position of the ureteral access sheath is usually verified with fluoroscopy.
7. The dilator is removed from the sheath.

Now the sheath is in place to provide a working channel from outside the patient to the ureter. However, on occasion a surgical procedure may inadvertently puncture or lacerate the ureter. Normally, a secondary "safety wire" has been placed for access, in the event the access sheath needs to be adjusted or otherwise removed.

The safety wire is normally placed alongside the sheath. Placement of the secondary safety wire requires a number of additional steps:

8. The safety wire is inserted into the lumen of the sheath and advanced into the kidney.
9. With both the original guidewire and the safety wire held in place, the sheath is removed.
10. The dilator is placed into the sheath.
11. The sheath is back-loaded onto the initial guidewire as explained before and advanced into the ureter.
12. The dilator is removed from the sheath.

At this juncture, the sheath is in place, the original guidewire is disposed within the sheath, and the safety wire runs along the outside of the sheath. However, because the original guidewire occupies the same channel of the sheath into which the ureteroscope will be inserted, the original guidewire must now be removed before a surgical procedure can be commenced. Hence,

13. The guidewire is removed from the sheath.

As can be seen, the requirement for a safety wire located outside the working channel of the sheath adds a number of steps and additional time and complexity to the procedure of positioning the sheath. In addition, the presence of the safety wire within the ureter alongside the sheath increases the possibility of lacerating the ureter.

In addition, some surgical procedures require the removal from the ureter of objects that are larger than the lumen of the sheath. In such instances, the objects are grasped against the distal end of the sheath, and the sheath must be completely withdrawn from the patient to extract the object. The sheath may be repositioned by once again placing the dilator into the sheath and advancing the sheath over the safety wire. However, there is now no safety wire running alongside the sheath. To position another safety wire alongside the sheath, the sequence of steps previously set forth must be repeated.

Thus there is a need for a ureteral access sheath which minimizes the number of steps required to position the sheath.

There is a further need for an improved ureteral access sheath which facilitates the placement of a safety wire.

SUMMARY OF THE INVENTION

Stated generally, the present invention comprises a ureteral access sheath which addresses the described shortcomings of prior art ureteral access sheaths such as those described above. Like the prior art devices, the proposed ureteral access sheath comprises two separate components: a sheath and a dilator. However, the proposed sheath differs from known prior art devices in that it comprises multiple lumens—a main working channel and one or more secondary lumens. A secondary lumen integral with the ureteral access sheath can be used to irrigate the surgical field. Thus it is not necessary to rely upon the working channel of the ureteroscope, typically occupied by a surgical device, for irrigation. Additionally, the secondary lumen can be used to accommodate a safety wire. The guidewire is received within the main working channel of the ureteral access sheath. The safety wire can be introduced through the secondary lumen, while the main guidewire is removed from the working channel to, for instance, accommodate the ureteroscope. The safety wire can simply remain in place via the secondary lumen. Alternatively the safety wire can remain outside the sheath in a manner analogous to existing practices.

According to one embodiment, the sheath comprises two lumens: the working channel and a secondary lumen for accommodating the safety wire or providing an irrigation channel (or both). According to a second embodiment, the sheath comprises at least three lumens: the working channel, a first secondary lumen for use as an irrigation channel, and a second secondary lumen for accommodating the safety wire.

To use the proposed ureteral access sheath, the guidewire is positioned, and the dilator is loaded into the sheath as set forth in steps 1–5 above. The guidewire is likewise threaded through the working channel of the sheath. Once the sheath has been advanced over the guidewire and into position, the safety wire may be threaded through the secondary lumen. The main guidewire can be removed

for use of instruments through the working channel, with the safety wire providing the ability to reposition the sheath.

Objects, features, and advantages of the present invention will become apparent upon reading the following specification, when taken in conjunction with the drawings and the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described with reference to the following drawings, wherein:

FIG. 1 is an exploded view of a ureteral access sheath according to a first disclosed embodiment.

FIG. 2 is a side view of a hub of the ureteral access sheath of FIG. 1.

FIG. 3 is a front view of the hub of FIG. 2.

FIG. 4 is a rear view of the hub of FIG. 2.

FIG. 5 is a side cutaway view of the hub of FIG. 2.

FIG. 6 is a side view of an elastomeric cover of the ureteral access sheath of FIG. 1.

FIG. 7 is a top view of the elastomeric cover of FIG. 6.

FIG. 8 is a side cutaway view of the elastomeric cover of FIG. 6.

FIG. 9 is a front view of the elastomeric cover of FIG. 6.

FIG. 10 is a rear view of the elastomeric cover of FIG. 6.

FIG. 11 is an isometric view of the elastomeric cover of FIG. 6.

FIG. 12 is an isometric view of the sheath tubing of the ureteral access sheath of FIG. 1.

FIG. 13 is a side cutaway view of the sheath tubing of FIG. 12.

FIG. 14 is an end view of the sheath tubing of FIG. 12.

FIG. 15 is a side cutaway view illustrating the assembly of the sheath tubing of Fig. 12 through the elastomeric cover of FIG. 6 and into the hub of FIG. 2.

FIG. 16 is a side cutaway view of the hub of FIG. 2 mounted onto the end of the sheath tubing of FIG. 12.

FIG. 17 is a side cutaway view of the assembly of FIG. 16 with the elastomeric cover of Fig. 6 fitted over the hub of Fig. 2.

FIG. 18 is a side cutaway view of the assembly of FIG. 17 with a leader tube coupled to the hub of Fig. 2.

FIG. 19 is a side view of the assembly of FIG. 18.

FIG. 20 is an end view of the assembly of FIG. 18.

FIG. 21 is a side cutaway view of the ureteral access sheath of FIG. 1 with a guidewire extending through the main channel of the sheath.

FIG. 22 is a side cutaway view of the ureteral access sheath of FIG. 21 with the first guidewire extending through the main channel of the sheath and a safety guidewire extending through the secondary channel of the sheath.

FIG. 23 is a side cutaway view of the ureteral access sheath of FIG. 22 with the first guidewire and dilator withdrawn from the main channel of the sheath and the safety guidewire remaining in place within the secondary channel of the sheath

FIG. 24 is a side cutaway view of the ureteral access sheath of FIG. 23 with an endoscope sheath positioned within the main lumen of the ureteral access sheath.

FIG. 25 is a side cutaway view of the ureteral access sheath of FIG. 1 with the dilator removed and with an endoscope sheath positioned within the main lumen of the ureteral access sheath and an irrigation syringe coupled to the secondary lumen of the sheath.

FIG. 26 is a side cutaway view of the ureteral access sheath of FIG. 1 with the dilator removed and with an aspiration syringe coupled to the main lumen of the ureteral access sheath and an irrigation syringe coupled to the secondary lumen of the sheath.

FIG. 27 is an end view of a sheath tubing for use with the hub of FIG. 28.

FIG. 28 is a side cutaway view of a hub of an alternate embodiment of a ureteral access sheath.

FIG. 29 is a side cutaway view of an alternate embodiment of eight ureteral access sheath comprising the hub of FIG. 28 and the sheath tubing of FIG. 27.

DETAILED DESCRIPTION OF THE DISCLOSED EMBODIMENT

Referring now to the drawings, in which like numerals indicate like elements throughout the several views, FIG. 1 depicts a ureteral access sheath according to a disclosed embodiment of the present invention. The ureteral access sheath **10** comprises a sheath assembly **12** and a dilator assembly **14**, which fits within the sheath assembly **12** when the ureteral access sheath **10** is being positioned within a patient.

The sheath assembly **12** includes an elongated sheath tubing **16** having a distal end **17** and a proximal end coupled to a hub **18**. The hub **18** is partially encased within an elastomeric cover **20**. A leader tube **22** is also coupled to the hub **18**. A female luer fitting **24** is mounted to the proximal end **23** of the leader tube **22**.

The dilator assembly **14** comprises a dilator tubing **26** having a dilator luer **28** attached to the proximal end of the tubing. A pair of locking tabs **29a, b** are formed or otherwise provided at a distal portion of the luer **28**.

FIG. 1 is intended to provide only a general overview of the ureteral access sheath **10** of the present invention. Each of the components of the sheath assembly **12** will be more fully described with respect to additional drawing figures.

Referring now to FIG. 2, the hub **18** comprises a generally cylindrical main body portion **30** having a proximal end **32** and a distal end **34**. A fitting **36** branches off from the main body portion **30**. As will be explained in more detail below, the fitting **36** provides access to an auxiliary or secondary lumen of the sheath tubing **16**. A pair of rings **38, 40** extend from the upper and lower edges of the main body portion **30** adjacent the distal end **34**. The rings **38, 40** provide a means by which sutures can be attached to the hub **18** to secure the sheath assembly **12** to a surgical drape. A pair of mutually opposed locking slots **41a, b** are formed or otherwise provided adjacent to the proximal end **32** of the hub **18**. The function of the locking slots **41a, b** is to cooperate with the locking tabs **29a, b** on

the luer **28** of the sheath assembly **12** to permit the luer **28** to lock to the hub **18**.

The interior structure of the hub **18** is illustrated in FIGS. 3–5. An oblong opening **42** is formed in the proximal end **32** of the hub **18**. Within the oblong opening **42**, a bowl-shaped funnel portion **44** feeds into tapered section **46**. The tapered section **46** in turn feeds into a second tapered section **48**, which narrows into a short cylindrical bore **50**. In the disclosed embodiment, the tapered section **46** is preferably configured to mate with the luer tip of a conventional Toomey syringe, for reasons that will be explained below.

At the distal end **34** of the hub **18**, an ovate opening **52** is vertically elongated and is wider and its lower end than its upper end. An oblong front chamber **54** communicates with a cylindrical bore **56**. The cylindrical bore **56** coaxially joins the smaller cylindrical portion **50**. A step **58** is formed where the larger cylindrical bore **56** meets the smaller cylindrical portion **50**.

Referring now to the fitting **36** at the upper end of the hub **18**, an opening **60** is formed in the end of the fitting. Within the opening **60** is a cylindrical bore **62**. The cylindrical bore **62** coaxially joins a smaller cylindrical bore **64**, creating a step **66** where the bores **62**, **64** join. The opposite end of the smaller cylindrical bore **64** opens into the chamber **54** in the distal end **34** of the hub **18**.

Referring now to FIGS. 6–11, the elastomeric cover **20** has a proximal end **70** and a distal end **72**. The proximal end **70** includes a vertically elongated opening **74** surrounded by an inwardly extending peripheral flange **76**. The vertically elongated opening **74** corresponds in size and shape to the oblong opening **42** in the proximal end **32** of the hub **18**. Similarly, a vertically elongated opening **78** in the distal end **72** of the elastomeric cover **20** generally corresponds in size and shape to the ovoid opening **52** in the distal end of the hub **18**.

An elongated opening **80** is formed in the upper surface of the elastomeric cover **20**. The opening **80** is rounded at its proximal and distal ends. The distal end of the opening **80** is in communication with a notch **82**. A short elongated opening **84** is formed in the lower surface of the elastomeric cover **20**.

FIGS. 12–14 illustrate the sheath tubing **16** of the sheath assembly **12**. The sheath tubing **16** comprises a substantially circular tube **90** having a distal end **92** and a proximal end **94**. The tube **90** defines a main lumen **96**. In a preferred embodiment the main lumen **96** is substantially circular in cross-section. A U-shaped housing **98** sits atop the tube **90** and defines a secondary lumen **100** disposed above the main lumen **90**. The housing **98** terminates at distal and proximal locations **102, 104** respectively, that are spaced inward from the ends of the tube **90**. Thus the secondary lumen **100** terminates at locations which are axially displaced inward from the ends of the main lumen **96**.

As illustrated in FIGS. 12–14, the disclosed embodiment comprises a tube **90** that is substantially circular in cross-section, a main lumen **96** that is substantially circular in cross-section, and a secondary lumen **100** that is substantially crescent-shaped in cross-section. However, it will be understood that the invention is not limited to these shapes, and that tubes, main lumens, and secondary lumens of other cross-sectional configurations may be employed as may be expeditious for particular surgical applications or convenient or for manufacturing purposes.

Assembly of the ureteral access sheath **10** will now be explained with reference to FIGS. 15–18. Referring first to FIG. 15, the proximal end **94** of the sheath tubing **16** is inserted through the opening **78** in the distal end **72** of the elastomeric cover **20** and all the way through the cover **20** until the proximal end of the sheath tubing **16** protrudes from the opening **74** in the proximal end **70** of the cover **20**. The hub **18** is aligned with the sheath tubing **16** as shown in FIG. 15. Then, as depicted in FIG. 16, the hub **18** is advanced onto the sheath tubing **16**. The proximal end **94** of the sheath tubing **16** enters the opening **52** at the distal end **34** of the hub **18**. As the hub **18** is advanced further, the proximal end **94** of the tube **90** passes through the front chamber **54** of the hub **18** and enters the cylindrical bore **56**. When the hub **18** has been fully advanced, the proximal end **94** of the tube **90** abuts the stop **58** at the rearward end of the cylindrical bore **56**, as shown in FIG. 16.

Next, as illustrated in FIG. 17, the elastomeric cover **20** is drawn rearward over the hub **18**. The distal end **34** of the hub **18** passes into the opening **74** in the proximal end **70** of the elastomeric cover **20**. The elastomeric cover **20** is drawn rearward until the ring **38** on the upper surface of the hub resides within the notch **82** in the upper surface of the elastomeric cover **20**, and the ring **40** on the lower surface of the hub resides within the short elongated opening **84** in the lower surface of the elastomeric cover. The fitting **36** extends through the elongated opening **80** in the upper surface of the elastomeric cover **20**. When the hub **18** has been fully received into the elastomeric cover **20**, the elastomeric cover snugly fits to the contours of the outer surface of the hub, as shown in FIG. 17.

Referring now to FIG. 18, the leader tube **22** has been inserted into the hub **18**. The end of the leader tube **22** is inserted into the opening **60** of the fitting **36** at the upper end of the hub **18**. The end of the leader tube is advanced through the cylindrical bore **62** until it confronts the stop **66**. The lumen **110** of the leader tube is in fluid communication with the secondary lumen **100** of the sheath tubing **16** by way of the smaller cylindrical bore **64** and the upper portion of the chamber **54** of the hub **18**. The main lumen **96** of the sheath tubing **16** is in fluid communication with the opening **42** in the proximal end **32** of the hub **18** by way of the bore **50**, second tapered section **48**, tapered section **46**, and funnel portion **44**.

FIG. 19 is a side view of the assembly of FIG. 18. The hub **18** is encased by the elastomeric cover **20**. The leader tube **22** extends from the fitting **32** of the hub **18**. The sheath tubing **16** extends from the distal end of the hub **18**.

FIG. 20 is a rear view of the assembly of FIG. 18. Once again, the hub **18** is encased by the elastomeric cover **20**, and the leader tube **22** extends from the fitting **36** of the hub **18**. The flange **76** of the elastomeric cover **20** conceals the rear edge (element **32** in FIG. 4) of the hub **18**. The funnel portion **44** and the tapered portion **48** of the hub **18** are visible. The main lumen **96** of the sheath tubing is also visible.

Use of the ureteral access sheath **10** to provide a working channel will now be explained with reference to FIGS. 21–23. Steps 1–4 are conventional and hence are not shown in the drawings.

1. A cystoscope is inserted into the patient's urethra and advanced into the bladder, where the ureteral orifices are identified.
2. Using the cystoscope, a guidewire **120** is inserted into the ureteral orifice.
3. Using fluoroscopy, the guidewire **120** is advanced through the ureter and into the kidney.
4. With the guidewire **120** carefully held in place, the cystoscope is removed over the guidewire.
5. Referring now to FIG. 21, the dilator assembly **14** is placed within the main lumen of the sheath assembly **12**. The dilator assembly **14** is inserted into the sheath assembly **12** with the locking tab 29a of the dilator luer **28** oriented vertically. Then, when the dilator luer **28** is seated within the hub **18** of the sheath assembly **12**, the dilator luer **28** is rotated 90° clockwise, and the locking tabs **29a, b** on the dilator luer engage the locking slots **41a, b** at the proximal end **32** of the hub **18** to lock the dilator assembly **14** to the sheath assembly **12**.
6. With further reference to FIG. 21, the proximal end **180** of the guidewire **120** is inserted into the distal end **121** of the dilator tubing **26**. The guidewire **120** is advanced through the dilator tubing **26** and exits through the proximal end **25** of the dilator luer **28**.
7. The sheath assembly **12** with dilator assembly **14** in place is advanced over the guidewire **120** and into the ureter. Advancement and position of the ureteral access sheath is usually verified with fluoroscopy.
8. Referring now to FIG. 22, with the sheath assembly **12** in position with its distal end **123** within the ureter, the distal end **181** of a safety guidewire **122** is fed into the opening in the proximal end **27** of the luer fitting **24**. The

safety guidewire **122** is advanced through the lumen **110** of the leader tube **22** and into the small cylindrical bore **64**, from where it enters the chamber **54** of the hub **18**. The distal end **27** of the safety wire **122** then enters the secondary lumen **100** at the proximal end **104** of the housing **98** and traverses the length of the secondary lumen, exiting at the distal end **102** of the housing **98**.

9. With the safety guidewire **122** thus positioned, the dilator assembly **14** and main guidewire **120** are removed from the sheath assembly **12**, as shown in FIG. 23.

Once the sheath assembly is in place to provide a working channel, a surgical procedure can commence. For example, a ureteroscope **125** has its distal end **126** introduced into the proximal end of the main lumen **96** of the sheath assembly **12**, as shown in FIG. 24. The ureteroscope **125** is advanced through the sheath assembly **12** to the target site until the distal end **126** of the ureteroscope resides adjacent the target site. A surgical instrument, such as a grasper for crushing and removing calculi, is inserted through the working channel of the ureteroscope **125** and used in the conventional manner. When it becomes necessary to irrigate the surgical field, an irrigation means is coupled to the female luer fitting **24** at the end of the leader tube **22**, and an irrigation fluid is infused through the secondary lumen **100**. The irrigation means can comprise, for example, a syringe, a bag of saline solution hung from an IV pole, an irrigation system including rollers for pressurized expulsion of saline solution from a bag, or the like. To facilitate coupling an irrigation means to the secondary lumen **100** while the safety guidewire **122** is still in place, a Y-fitting can be coupled to the female luer **24**, the safety guidewire fed through one of the branches of the Y-fitting, and the irrigation means coupled to the other branch of the Y-fitting. Because the safety guidewire **122** occupies only a small portion of the cross section of the secondary lumen **100**, irrigation can be effected through the same secondary lumen occupied by the guidewire.

FIG. 25 shows an alternate configuration wherein the sheath assembly **12** is used to accommodate an endoscope **125** in the main

working channel **96** and an irrigation means such as a syringe **130** is coupled to the secondary lumen **100**. Even with the working channel of the ureteroscope **125** almost completely occupied by a surgical instrument, and even with the main working channel **96** of the sheath assembly **12** almost completely occupied by the ureteroscope **125**, the surgical field can still be irrigated efficiently by infusing the irrigation fluid through the secondary lumen **100**.

FIG. 26 shows yet another alternate configuration wherein the sheath assembly **12** is used to accommodate an aspiration means such as a Toomey syringe **140** coupled to the main working channel **96**, and an irrigation means such as a syringe **130** coupled to the secondary lumen **100**. With this configuration, simultaneous irrigation and aspiration can be accomplished, which can create a turbulent effect in the operative field that is useful for removing particles and debris.

The ureteral access sheath **12** of the disclosed embodiment thus provides a number of advantages over known prior art ureteral access sheaths. Because of the dual lumens **96**, **100**, the sheath assembly **12** can be configured as follows:

Device–Device. Both lumens can be occupied by medical devices. While the main working channel will most often be occupied by a ureteroscope, the secondary channel can be occupied by a safety guidewire, a laser fiber, a stone basket, a grasper, or any other medical device suitable to the procedure being performed. In the case of placing a safety guidewire in the secondary lumen, the sheath assembly **12** can be rapidly repositioned without the need for multiple backloads.

Device–Irrigation. The main working channel can be occupied by a ureteroscope, and the secondary working channel can be coupled to a source of irrigation such as a syringe, irrigation bag, irrigation system, or the like. Thus even when the main working channel of the ureteroscope is almost completely occupied by a surgical instrument, the surgical field can be irrigated efficiently by infusing the irrigation fluid through the secondary lumen.

Device–Device/Irrigation. The main working channel can be occupied by an instrument such as a ureteroscope **125**. A Y-fitting can be attached to the female luer **24** of the leader tube **22**. The safety guidewire **122** can be fed through the opening in one branch of the Y-fitting, and an irrigation means can be coupled to the other branch of the Y-fitting so that irrigation can be achieved while the safety guidewire is still in place within the secondary lumen **100**.

Irrigation–Irrigation. The main working channel can be coupled to an aspiration means such as a Toomey syringe by locking the luer of the syringe into the tapered section **46** of the hub **18**, and the secondary channel can be coupled to a source of irrigation such as a syringe, irrigation bag, irrigation system, or the like. Thus it is possible to irrigate the operative field through the secondary channel while aspirating the field through the main channel, setting up a turbulent flow in the operative field which is helpful in removing particles and debris.

FIG. 27 illustrates an alternate embodiment of a sheath tubing **16'**. The sheath tubing **16'** includes a first U-shaped housing **98A** on top of the tube **90** and a second U-shaped housing **98B** on the side of the tube opposite the first housing **98A**. Two secondary lumens **100A**, **100B** are thus formed on opposite sides of the main lumen **96**.

FIG. 28 illustrates an alternate embodiment of a hub **18'** for use with the sheath tubing **16'** of FIG. 27. The hub **18'** differs from the hub **18** previously described in that it has two fittings **32A**, **32B**. In addition, the opening **52'** at the forward end of the hub **18'** is reconfigured to accommodate the sheath tubing **16'** with two U-shaped housings **98A.**, **98B**.

FIG. 29 depicts an alternate embodiment of a sheath assembly **12'** that comprises a sheath tubing **16'**, a hub **18'**, and two leader tubes **22A**, **22B**. Each of the two leader tubes **22A**, **22B**. is in fluid communication with a separate one of the two secondary lumens **100A.**, **100B**. In the case of the sheath tubing **16'** having two secondary lumens **100A.**, **100B**, the irrigation fluid is introduced through a secondary lumen different from the secondary lumen occupied by the guidewire. Or, a guidewire can occupy one channel

while a grasper, laser fiber, or stone basket is used in the other secondary channel. As yet another option, a surgical instrument such as a grasper, stone basket, laser fiber, or the like can be used in one secondary channel while the other secondary channel is being used for irrigation. As still another option, one secondary channel can be hooked up to an irrigation means while the other secondary channel is hooked up to an aspiration means. In this manner simultaneous irrigation and aspiration to create a turbulent wash in the surgical field can be performed without removing a surgical instrument such as a ureteroscope from the main working channel.

Finally, it will be understood that the preferred embodiment has been disclosed by way of example, and that other modifications may occur to those skilled in the art without departing from the scope and spirit of the appended claims.

CLAIMS

What is claimed is:

1. A medical device comprising:
a sheath having proximal and distal ends, a main lumen extending longitudinally of said sheath, and a secondary lumen extending longitudinally of said sheath alongside said main lumen;
a ureteroscope having a shaft positioned within said main lumen of said sheath; and
a guidewire positioned within said secondary lumen of said sheath and extending from a first location proximate the distal end of said sheath to a location exterior of the proximal end of said sheath.

2. The medical device of Claim 1,
wherein said ureteroscope comprises a working channel, and
wherein said medical device further comprises a surgical instrument disposed within said working channel of said ureteroscope.

3. The medical device of Claim 1,
wherein said secondary lumen has a fitting at a proximal end thereof for connecting to a syringe for infusing an irrigation medium through said secondary lumen.

4. A method for placing a ureteral access sheath to create a working channel between the outside of a patient's body and a ureter of the patient, comprising the steps of:
inserting the forward end of an endoscope into the patient's urethra and advancing said forward end of said endoscope into the bladder;
identifying the ureteral orifices through said endoscope;

using said endoscope, inserting a forward end of a guidewire through a channel of said endoscope and into the ureteral orifice;

advancing said forward end of said guidewire through said ureter and into a kidney;

with said guidewire held in place, removing said endoscope over said guidewire;

placing a dilator within a main lumen of a sheath assembly;

inserting a rearward end of said guidewire into a forward end of a secondary lumen of said sheath tubing and out a rearward end of said secondary lumen;

advancing said sheath assembly and dilator over said guidewire and into said ureter; and

removing said dilator from said sheath assembly.

5. The method of Claim 4 comprising the additional step, subsequent to said step of advancing said sheath assembly and dilator over said guidewire and into said ureter, of leaving said guidewire in place within said secondary lumen to serve as a safety wire.

6. The method of Claim 4, comprising the additional step, subsequent to said step of removing said dilator from said sheath assembly, of introducing a surgical instrument through said main lumen of said sheath assembly.

7. The method of Claim 4, comprising the additional step, subsequent to said step of advancing said sheath assembly and dilator over said guidewire and into said ureter, of infusing a fluid through a rearward end of said secondary lumen and out said forward end of said secondary lumen so as to irrigate a surgical field proximate said forward end of said secondary lumen.

8. The method of Claim 7, wherein said step of infusing a fluid through a rearward end of said secondary lumen comprises the steps of coupling a fluid-containing syringe to a connection means in fluid communication with said rearward end of said secondary lumen, and actuating said syringe to infuse said fluid into said rearward end of said secondary lumen.

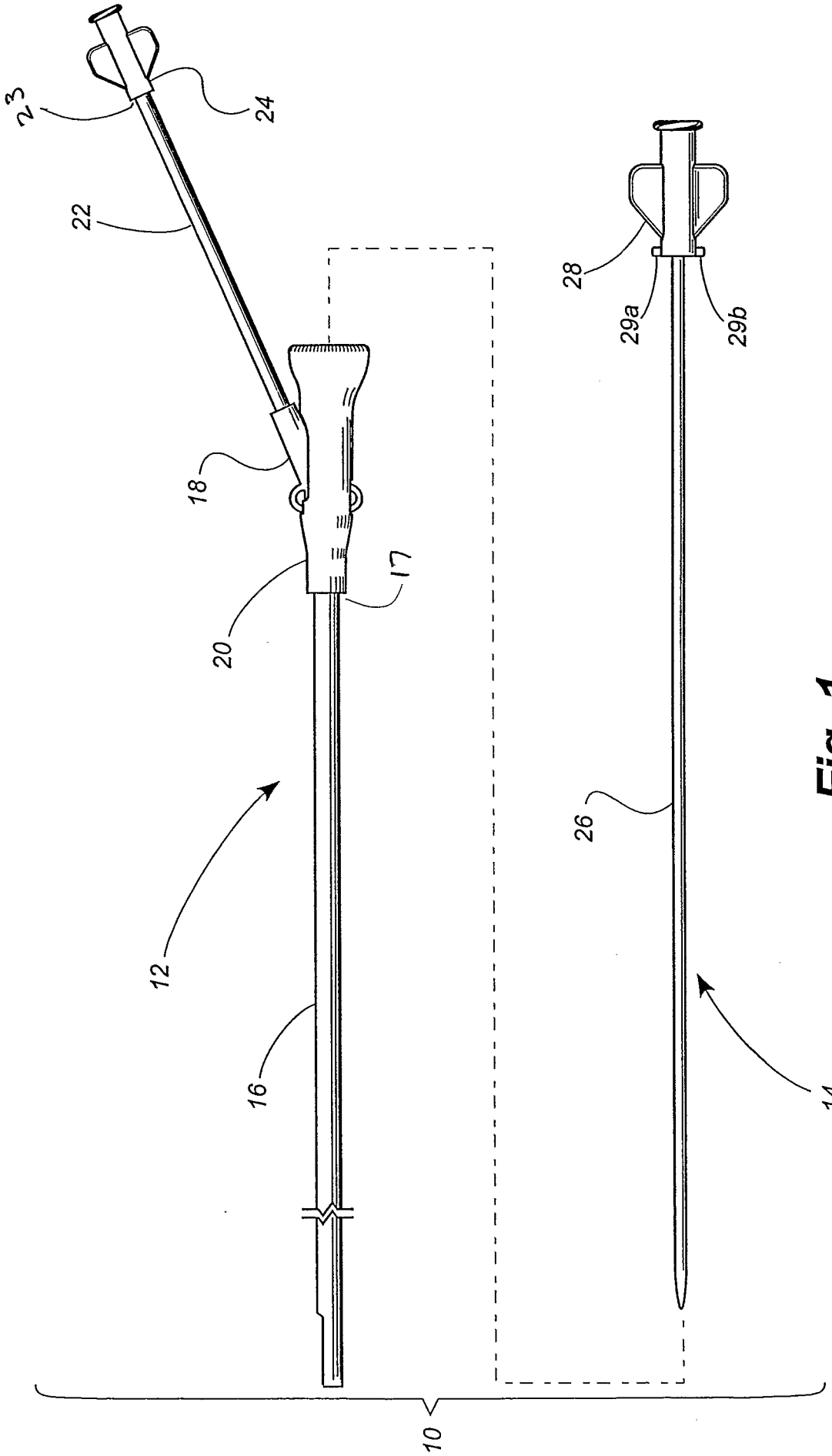


Fig. 1

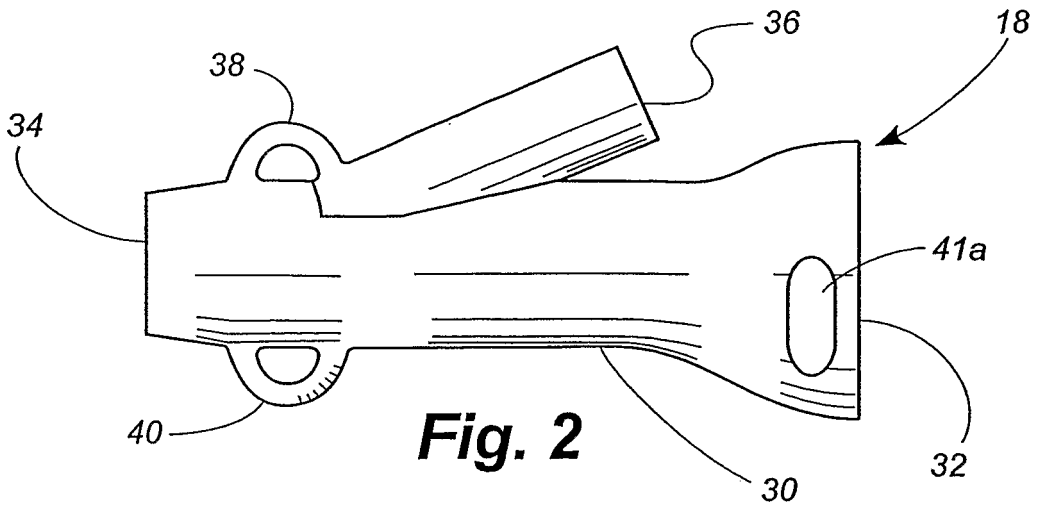


Fig. 2

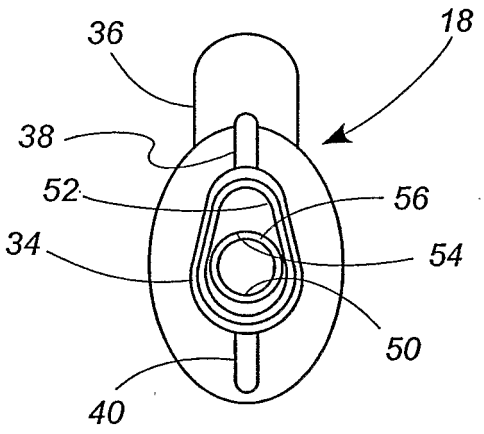
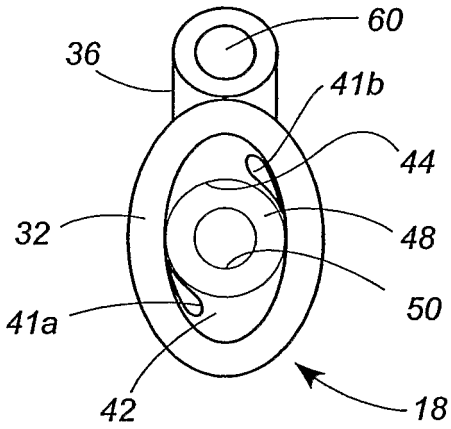


Fig. 3



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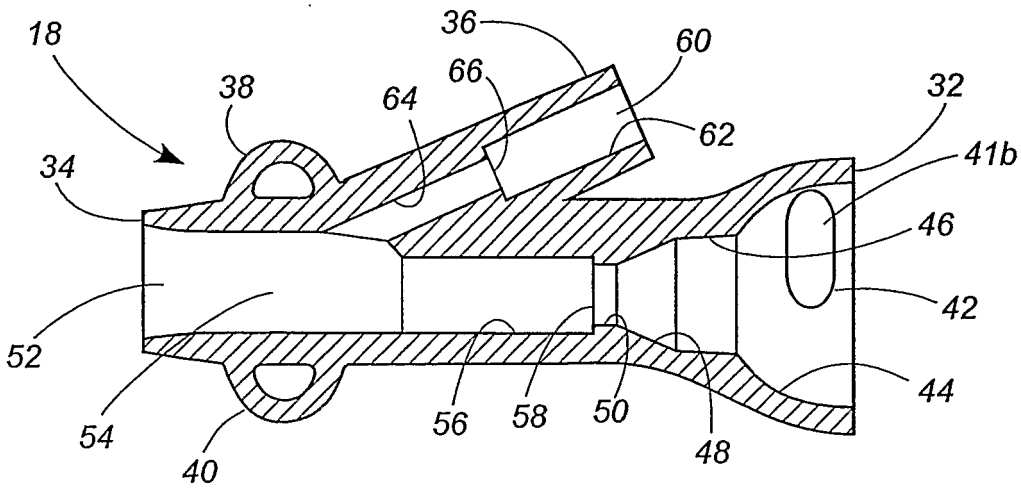
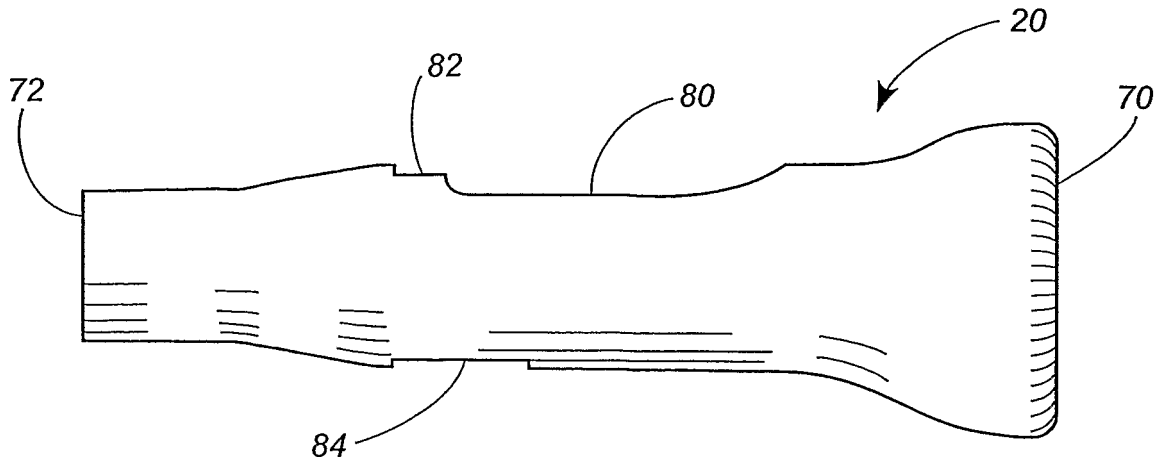


Fig. 5



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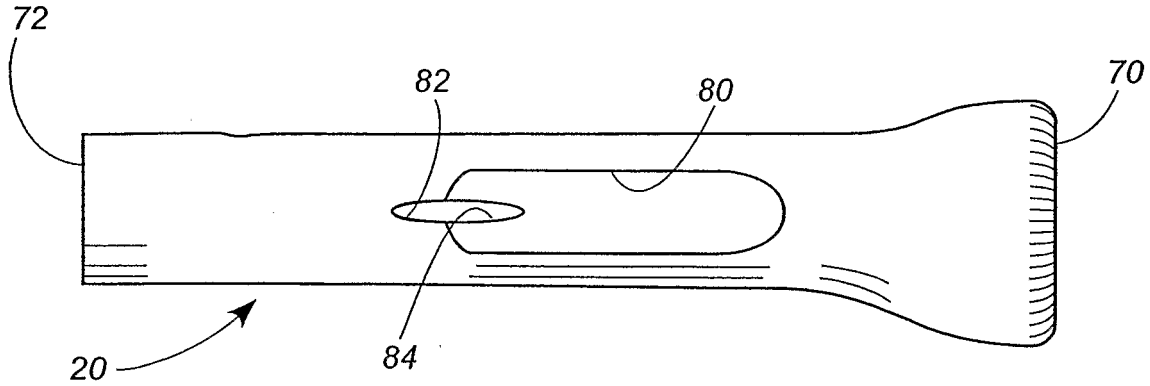

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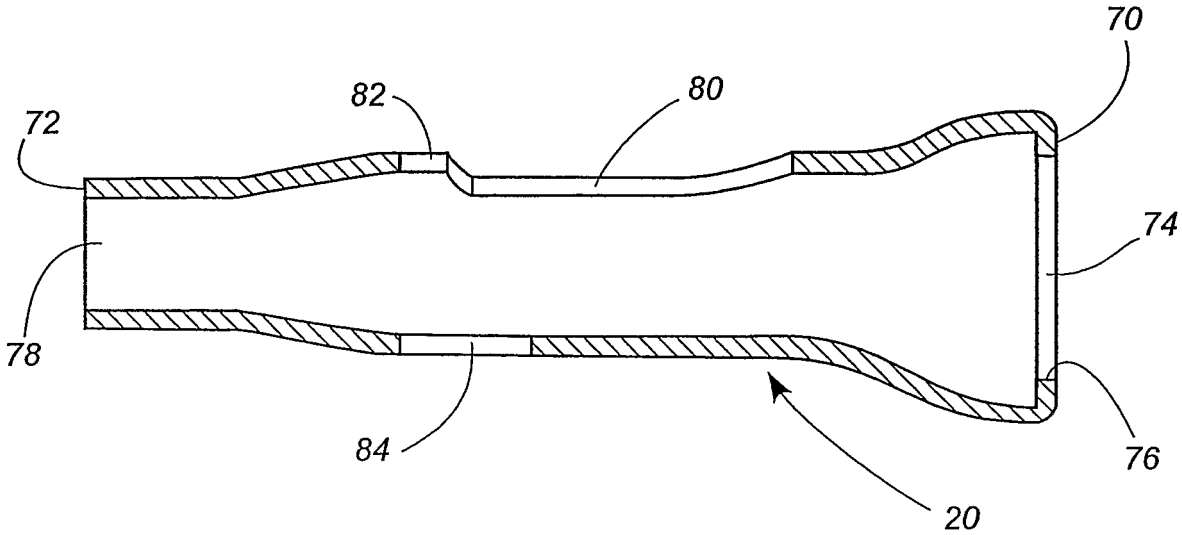

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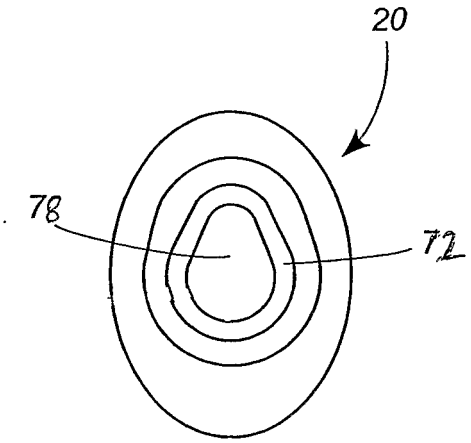

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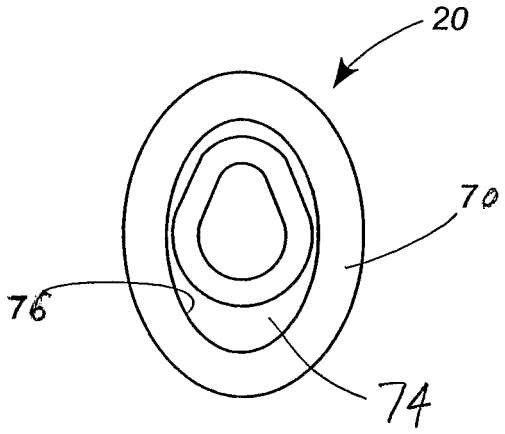


Fig. 10

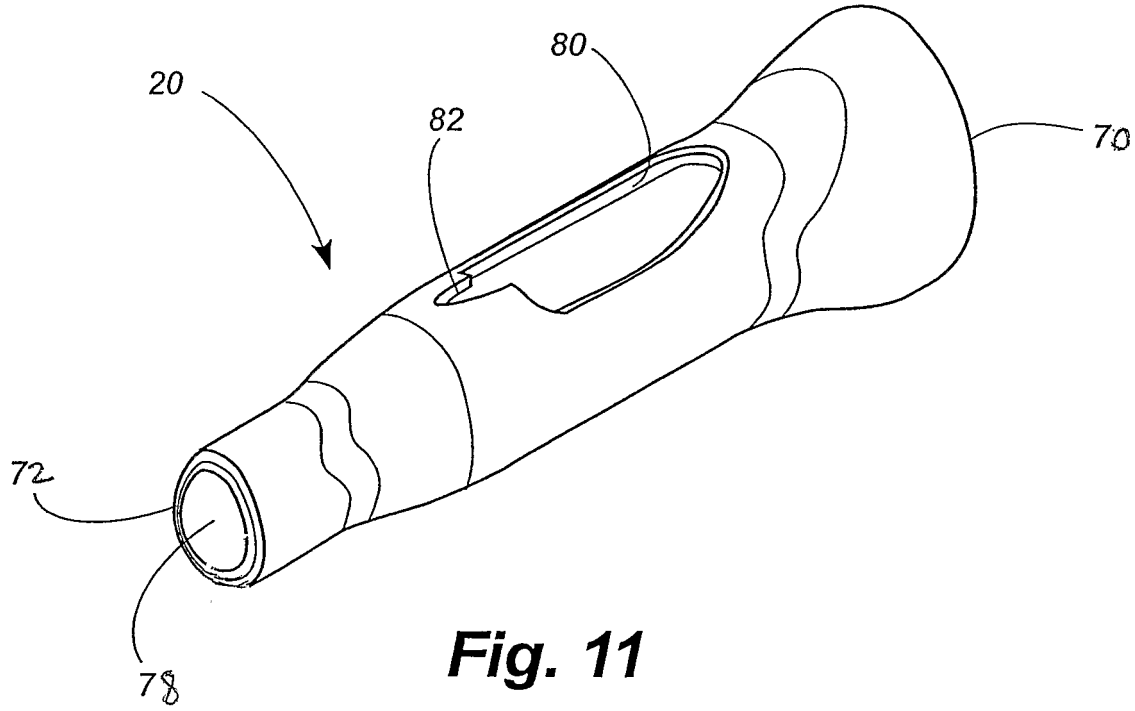


Fig. 11

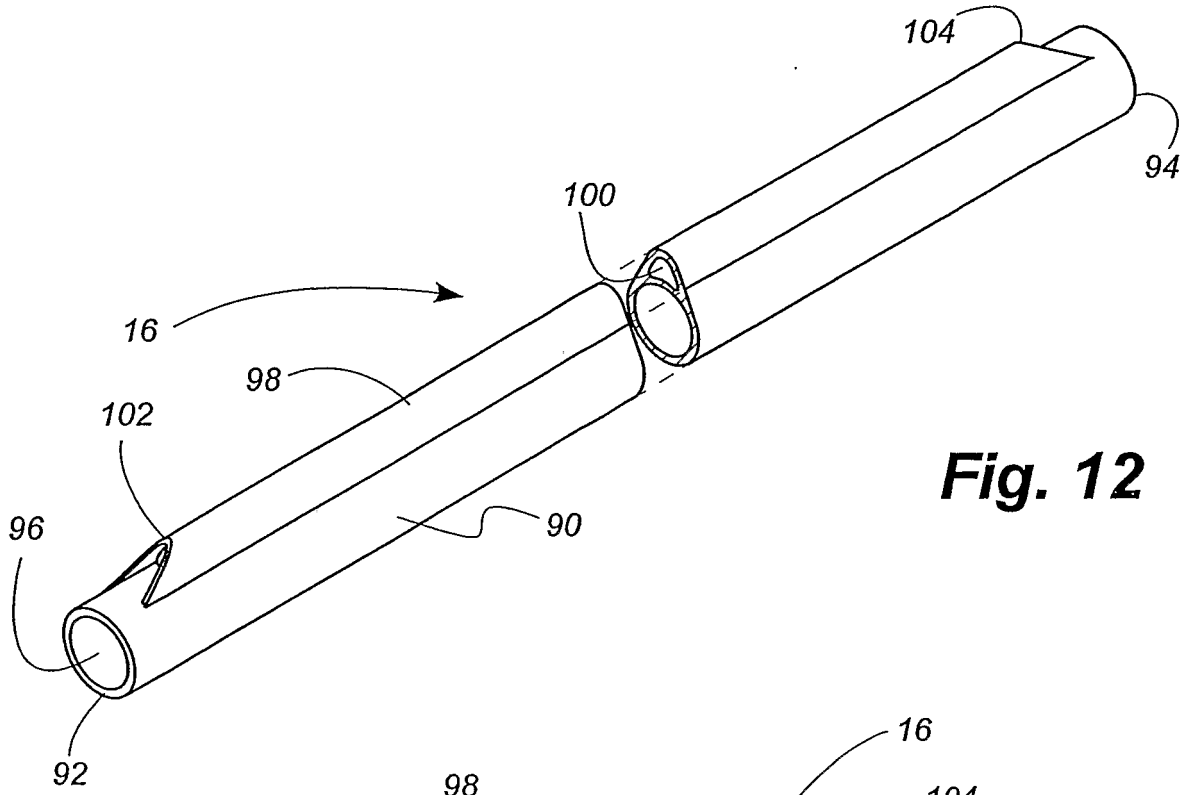


Fig. 12

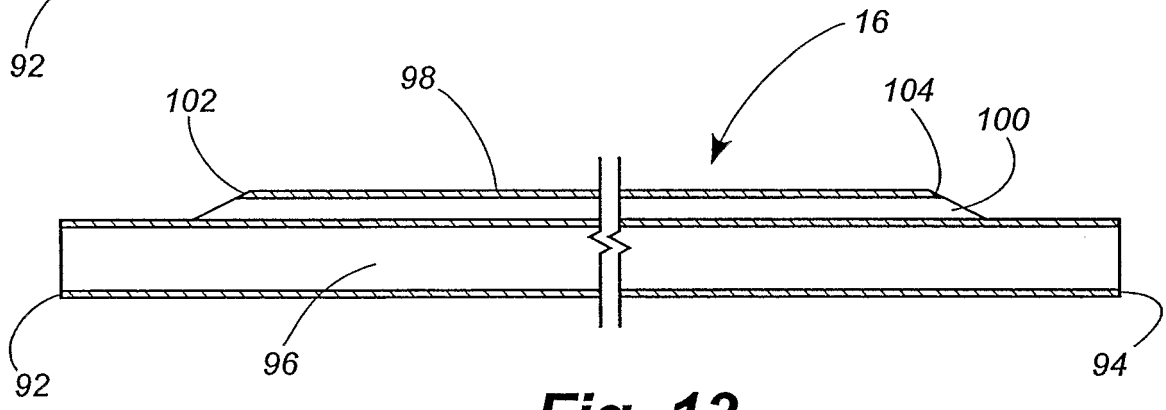
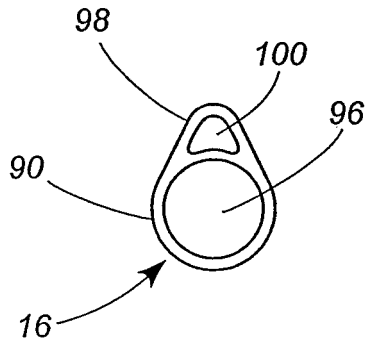


Fig. 13



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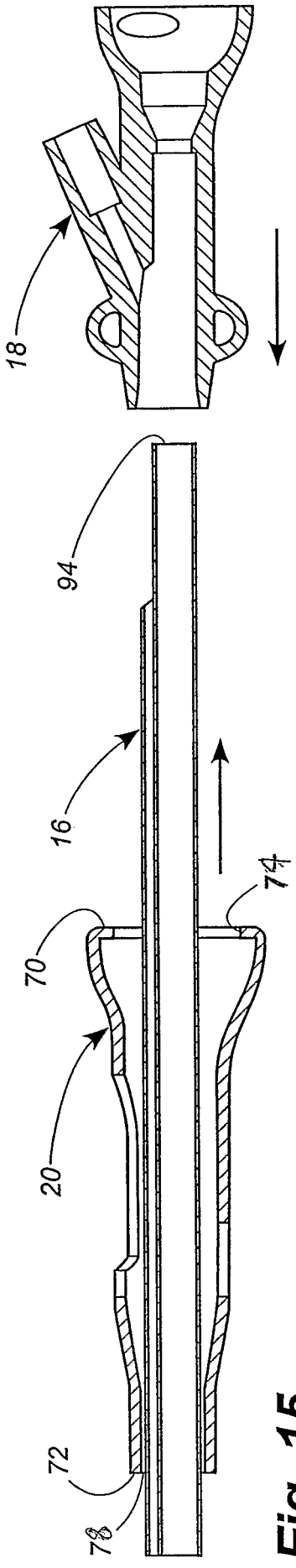

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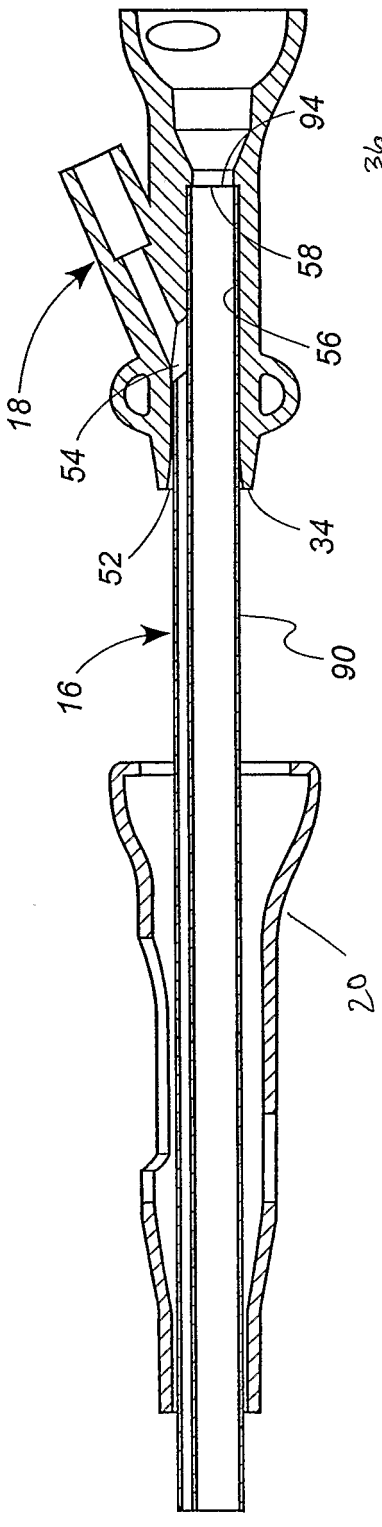

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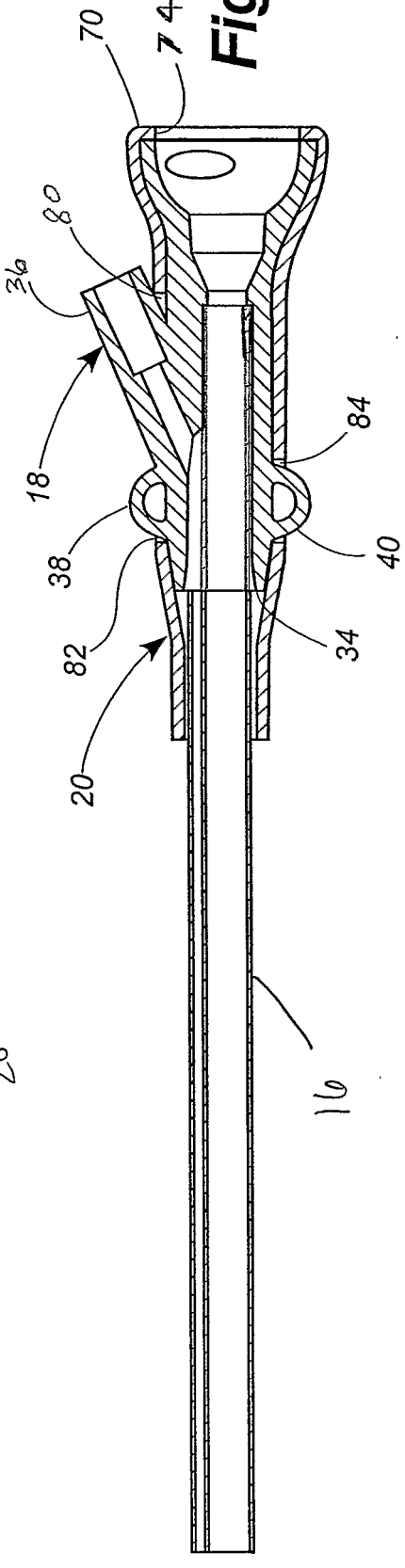


Fig. 17

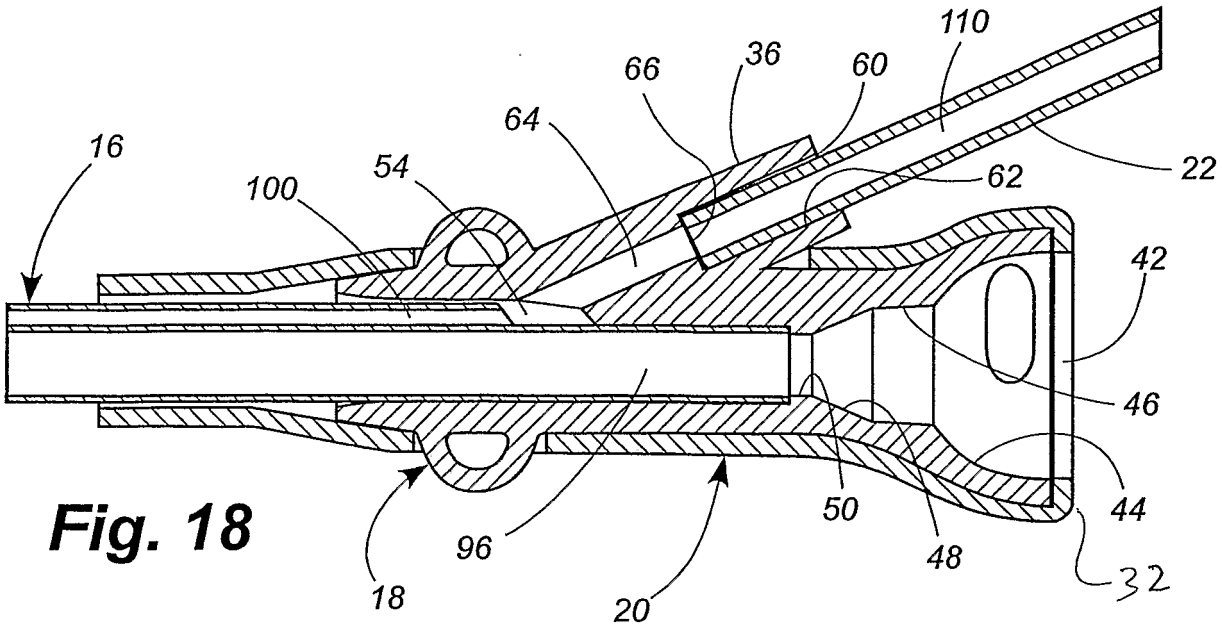
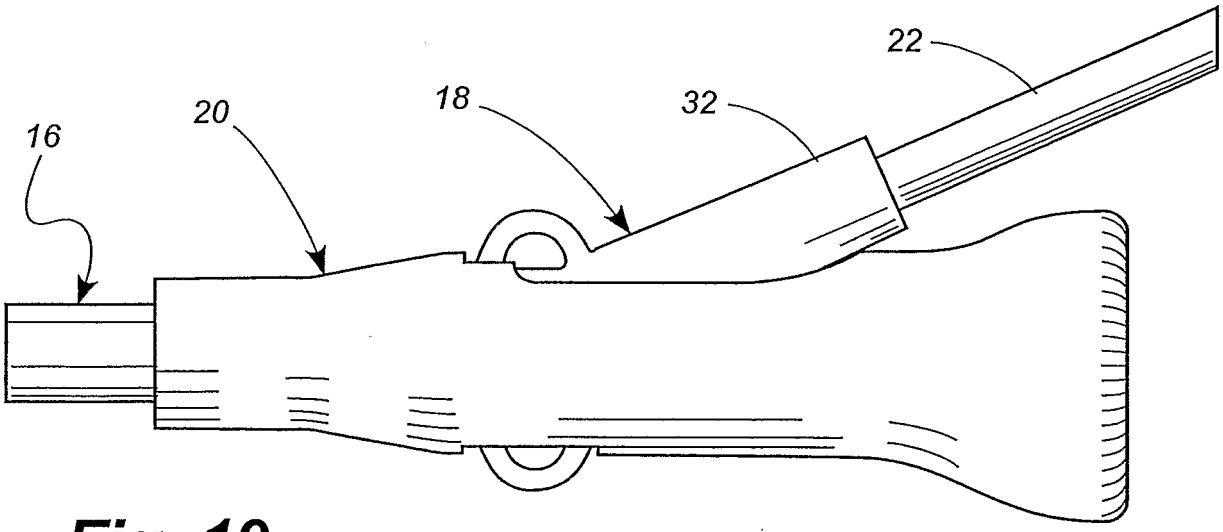


Fig. 18



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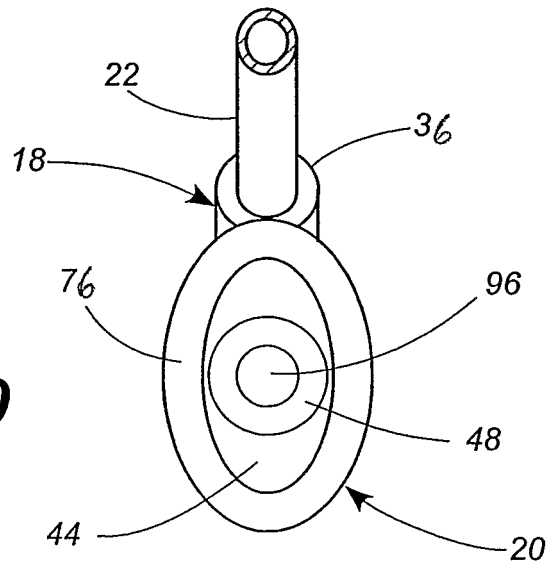

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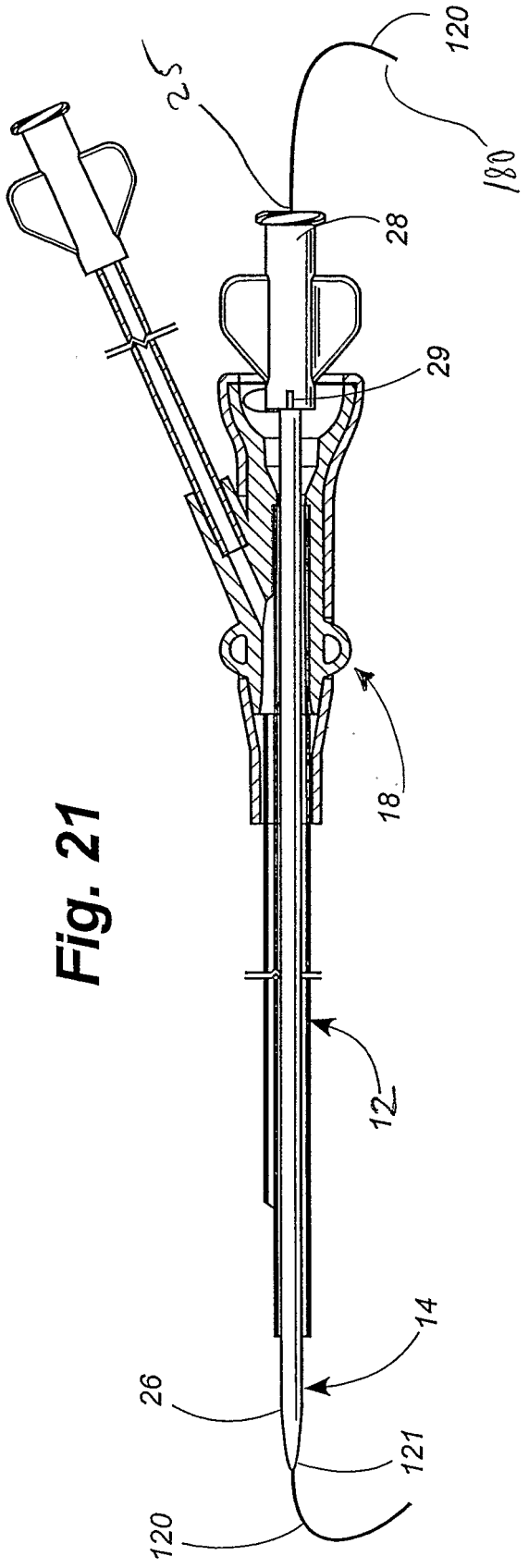

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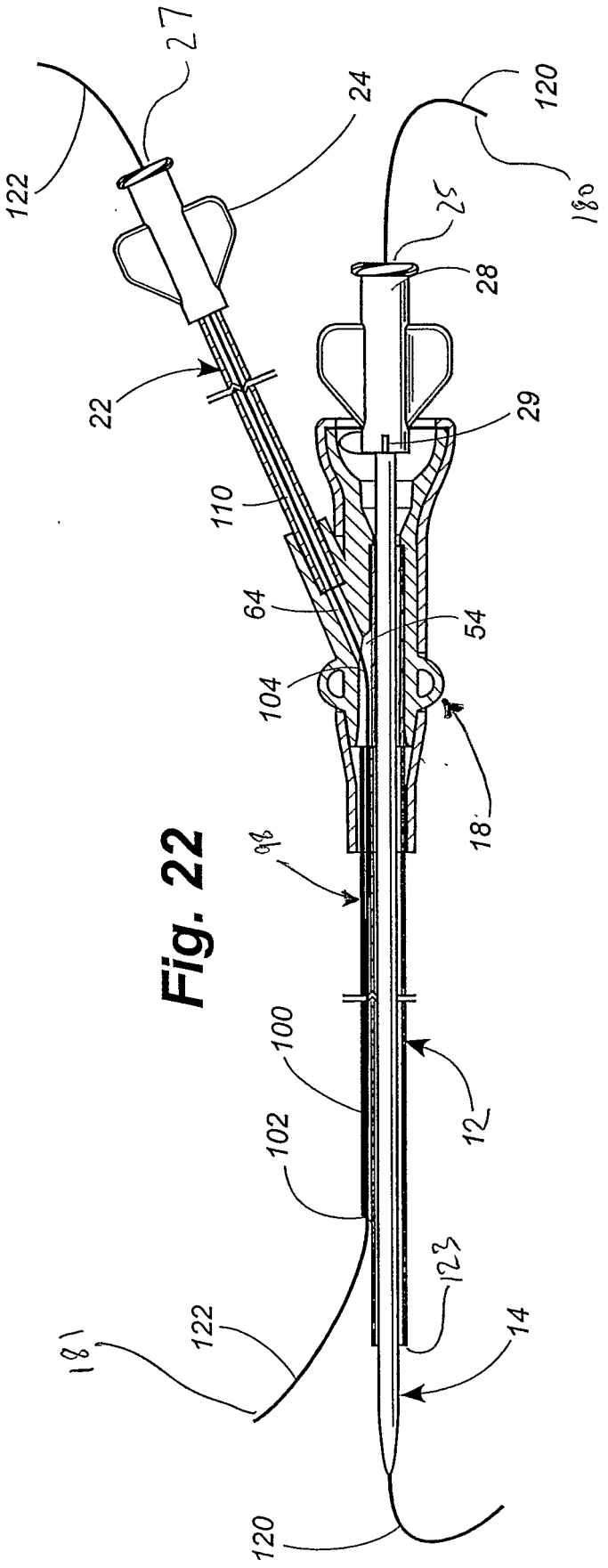
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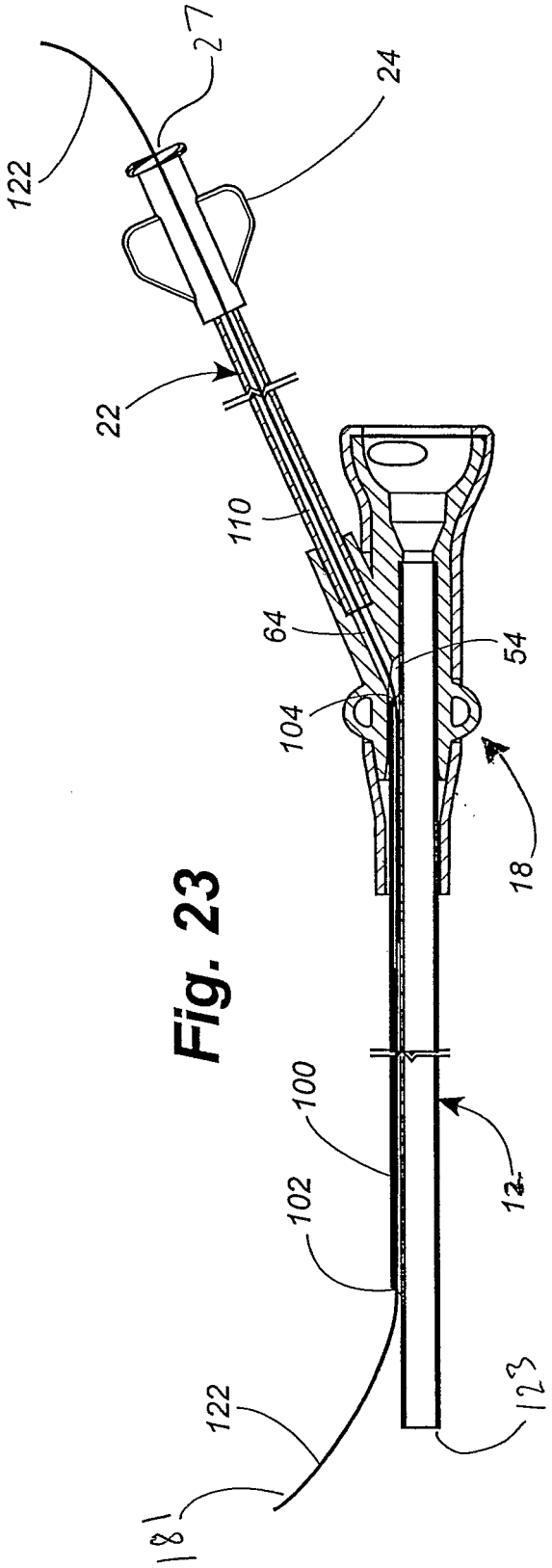
Fig. 22



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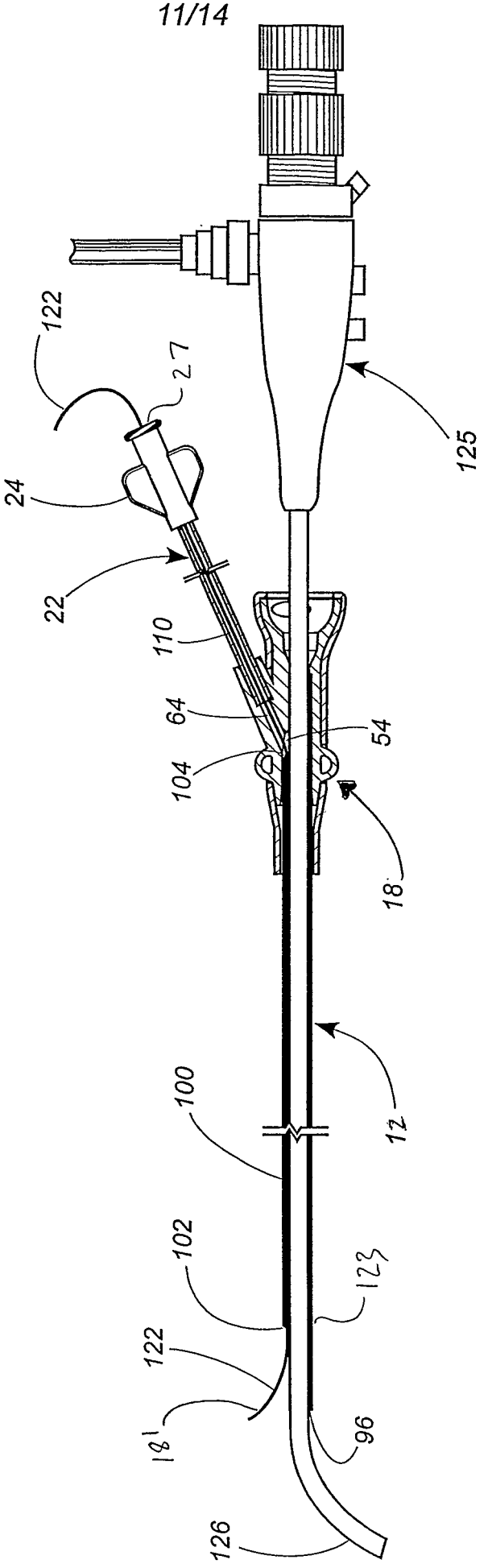
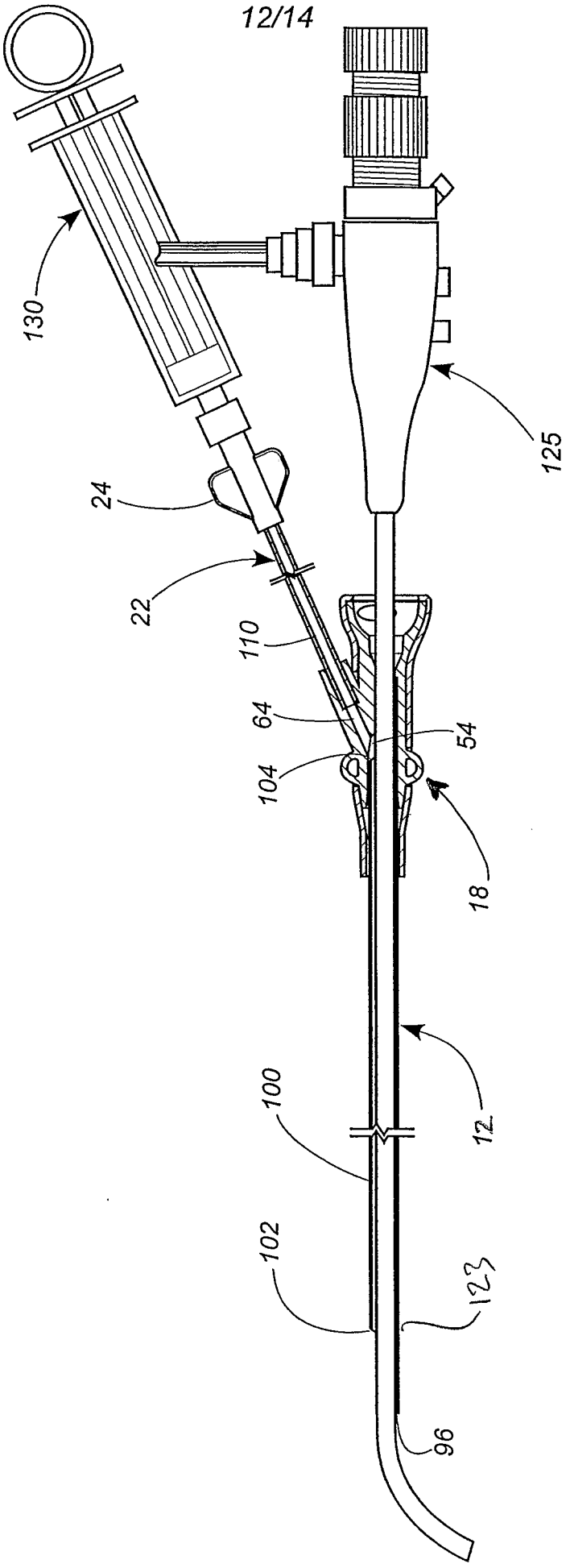


Fig. 24



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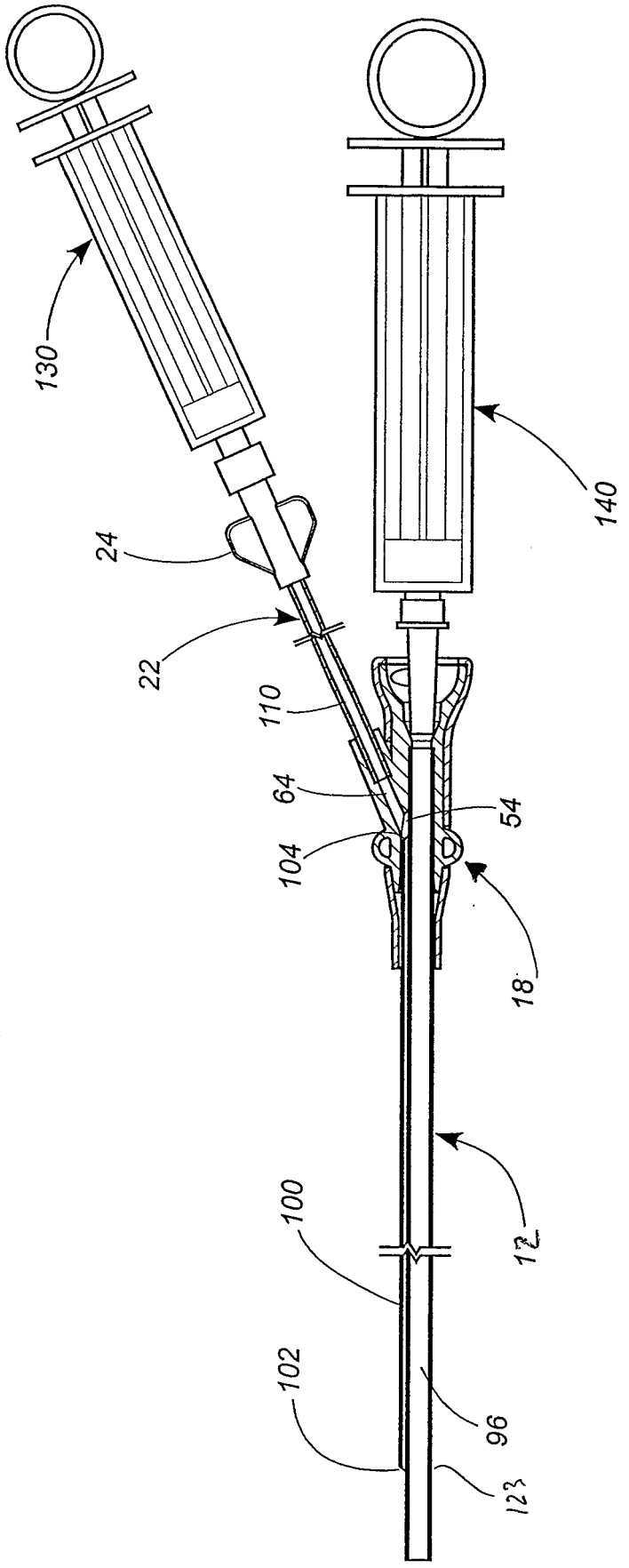

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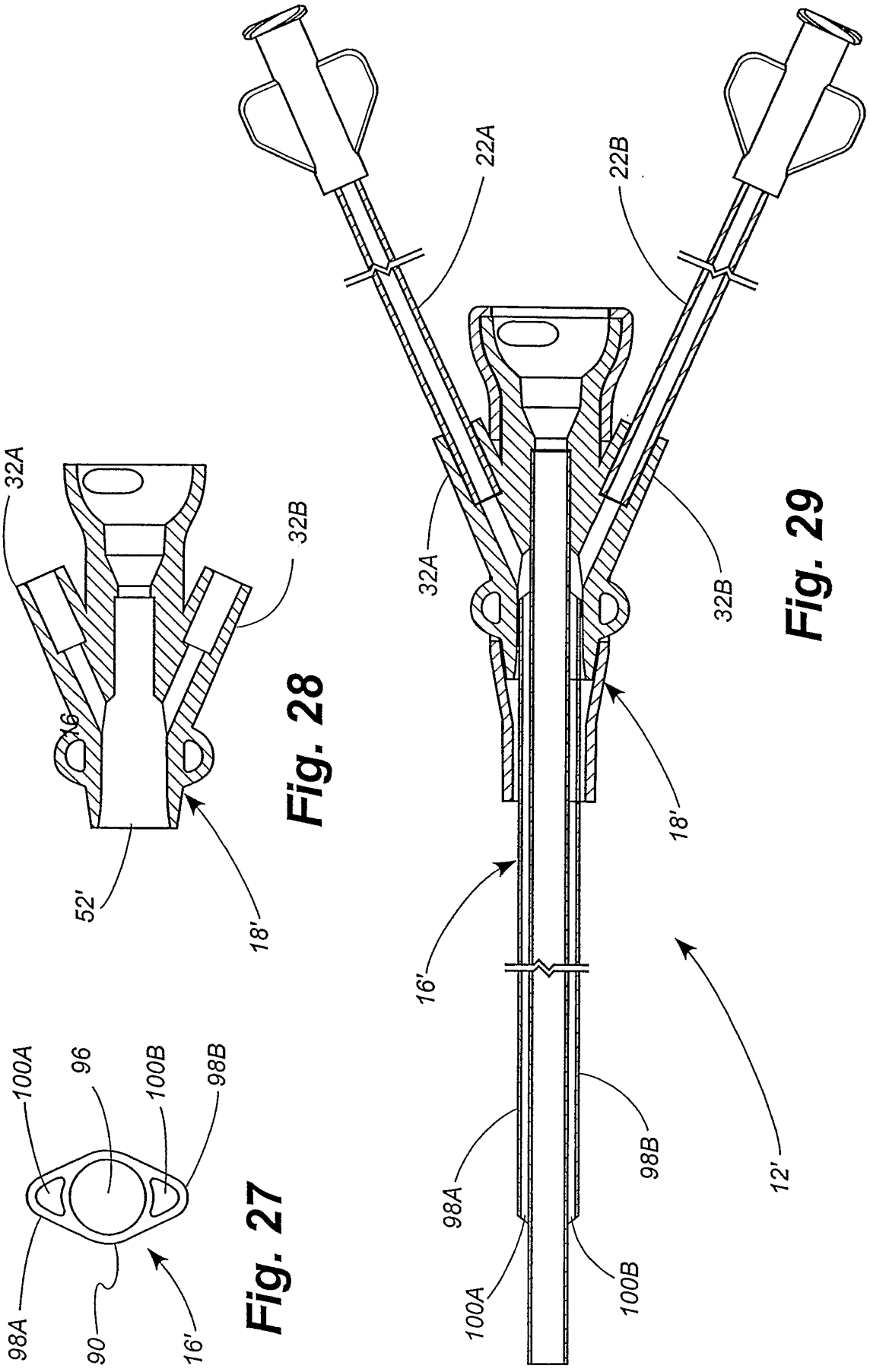

Fig. 29

Fig. 28

Fig. 27

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/010821

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B1/307

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61M

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2002/188175 A1 (TREMAGLIO ANTHONY R ET AL) 12 December 2002 (2002-12-12) column 1, line 4 - line 8 column 2, line 17 - line 25 column 2, line 47 - line 59 column 3, line 65 - column 4, line 8 column 7, line 47 - line 52 column 8, line 42 - column 9, line 3 figures 9A,10A,10B claims 23,27-29	1-3
Y	EP 0 515 119 A (SCIMED LIFE SYSTEMS INC) 25 November 1992 (1992-11-25) page 2, line 35 - line 42 page 3, line 22 - line 28 page 3, line 52 - line 54 page 4, line 5 - line 23 figure 1	1

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
1 September 2004	08/09/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Quentric, F-X

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/010821

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6 440 123 B1 (ENGEL KONRAD) 27 August 2002 (2002-08-27) column 2, line 66 - column 3, line 2 figure 5	2
Y	US 4 741 326 A (SAVITT ROBERT L ET AL) 3 May 1988 (1988-05-03) column 1, line 60 - line 63 column 3, line 63 - line 67	3
Y,P	US 2003/114732 A1 (SCHNEIDERMAN GARY ET AL) 19 June 2003 (2003-06-19) paragraphs '0008!, '0018!, '0046! figure 2A	1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/010821

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

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

1. [X] Claims Nos.: 4-8
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

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

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

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

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

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

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

Remark on Protest

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

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US2004/010821

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2002188175 A1	12-12-2002	US 6447473 B1	10-09-2002
		US 6254061 B1	03-07-2001
		AU 4806600 A	17-11-2000
		WO 0066194 A2	09-11-2000
EP 0515119 A	25-11-1992	US 5158551 A	27-10-1992
		US 5219335 A	15-06-1993
		CA 2068450 A1	24-11-1992
		DE 69212387 D1	29-08-1996
		DE 69212387 T2	20-02-1997
		EP 0515119 A1	25-11-1992
		JP 3202062 B2	27-08-2001
		JP 5154204 A	22-06-1993
		US 6309379 B1	30-10-2001
		US 6066100 A	23-05-2000
		US 6022319 A	08-02-2000
US 6440123 B1	27-08-2002	DE 19715698 A1	22-10-1998
		DE 59808641 D1	10-07-2003
		WO 9846146 A1	22-10-1998
		EP 0975268 A1	02-02-2000
		US 2002165558 A1	07-11-2002
US 4741326 A	03-05-1988	NONE	
US 2003114732 A1	19-06-2003	WO 03051183 A2	26-06-2003

专利名称(译)	输尿管通路护套		
公开(公告)号	EP1615542A1	公开(公告)日	2006-01-18
申请号	EP2004759272	申请日	2004-04-08
申请(专利权)人(译)	C.R. BARD，INC.		
当前申请(专利权)人(译)	C.R. BARD，INC.		
[标]发明人	KNAPP TRACEY E		
发明人	KNAPP, TRACEY, E.		
IPC分类号	A61B1/307		
CPC分类号	A61B17/0218 A61B1/307 A61B1/32 A61B2017/0225 A61M25/0032 A61M25/0097 A61M25/01 A61M25/0662 A61M25/09 A61M29/02 A61M2025/0037 A61M2025/0177		
优先权	10/409527 2003-04-08 US		
外部链接	Espacenet		

摘要(译)

输尿管进入护套包括护套组件，护套组件具有主腔和一个或多个次腔。护套组件可以配置有两个腔中的医疗装置，例如主工作通道中的输尿管镜，以及辅助工作通道中的导丝，石篮，抓紧器，激光纤维或其他手术器械。或者，护套组件可以在一个通道中配置有医疗装置，并且另一个腔连接到灌溉装置，使得即使主工作通道基本上完全被例如一个占据，也可以有效地完成外科手术区的冲洗。输尿管镜。或者，护套组件可以构造成用于通过一个腔进行冲洗并且通过另一个腔进行抽吸，从而产生湍流，该湍流清洗手术区域以便于去除颗粒和碎屑。