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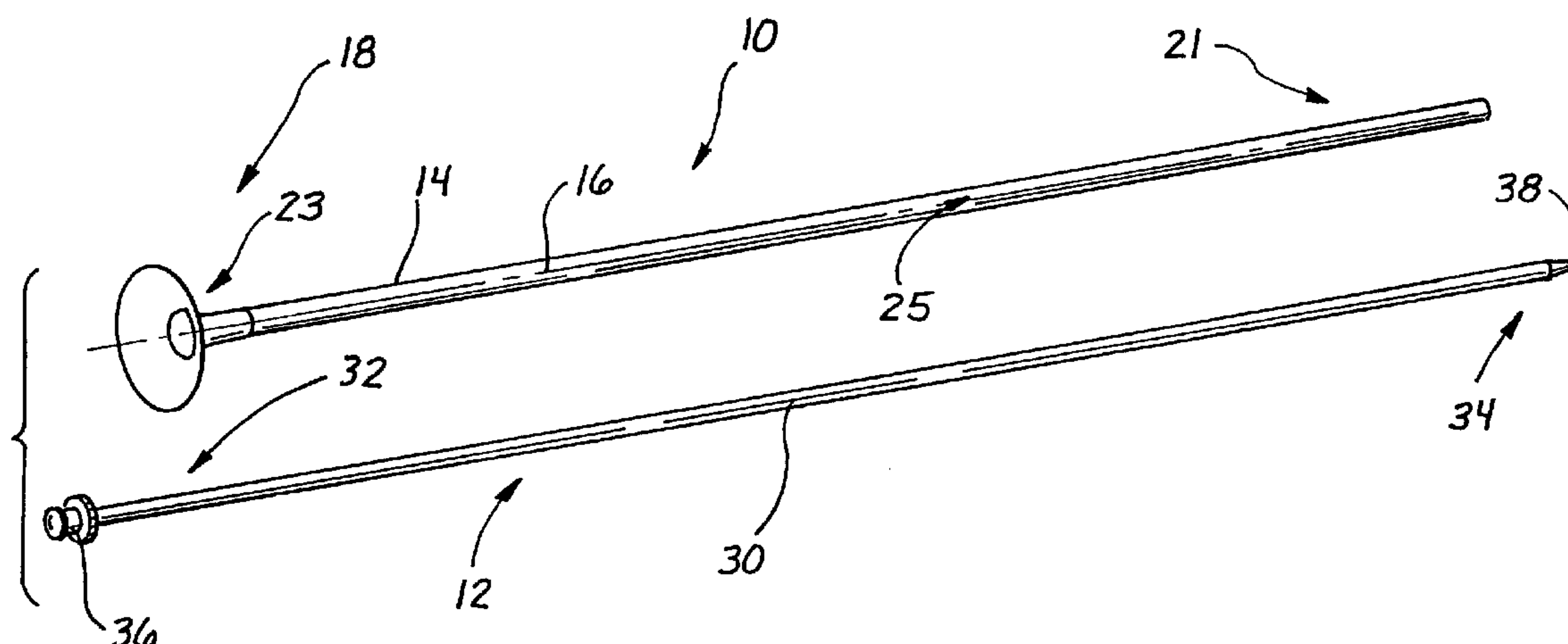
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(54) Title: URETERAL ACCESS SHEATH



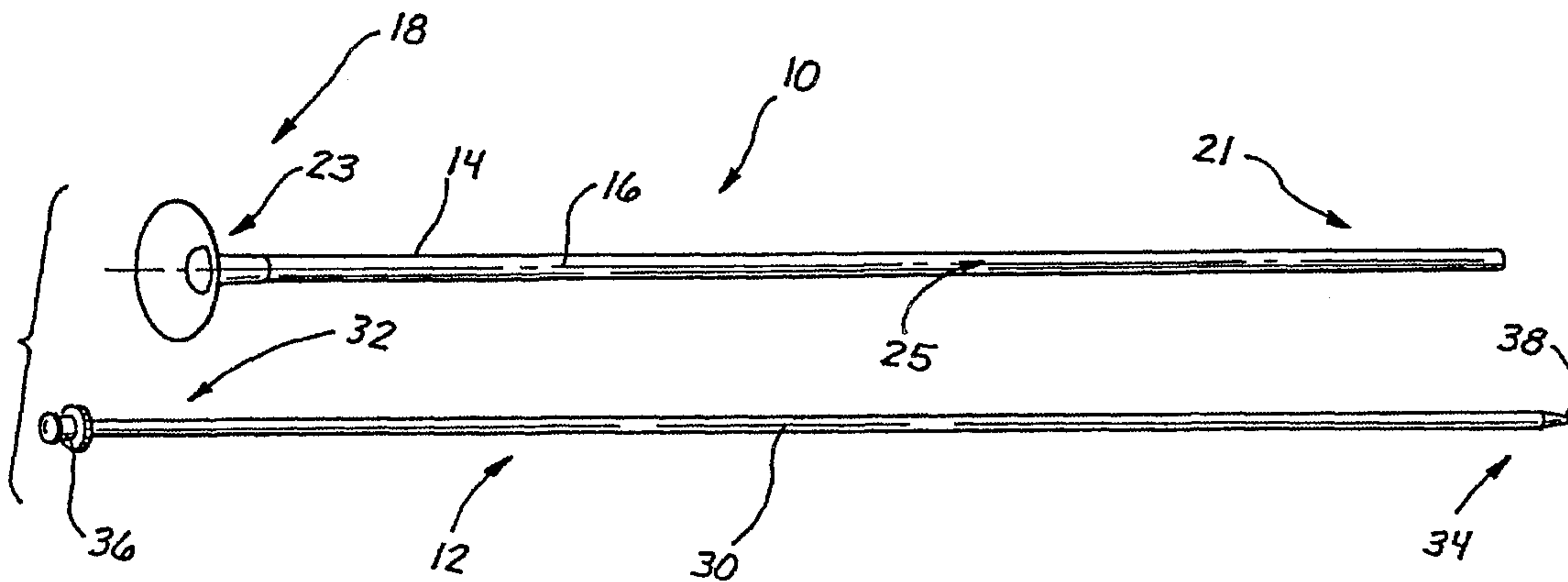
(57) **Abrégé/Abstract:**

A ureteral access sheath (10) adapted for insertion into a urethra includes an elongate tube (14) extending between a proximal end, and a distal end. A handle (23) assembly is disposed at the proximal end, and includes enlarged portions which inhibit migration of the sheath into the urethra. The enlarged portion is shaped like the bell of a horn with a concave, distally facing outer surface (41), and a convex, proximally facing inner surface. The inner surface functions as a funnel while the outer surface is sized, and configured to receive adjacent fingers of a user's hand held in its natural position. In an associated method, this shape of the handle assembly facilitates maintaining the sheath (10) in a stationary position during insertion, and removal of instrumentation. The handle assembly can be movable on the tube to facilitate variation of the sheath link in situ.

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(21) International Application Number: PCT/US00/11219 (22) International Filing Date: 26 April 2000 (26.04.00) (30) Priority Data: 09/303,485 30 April 1999 (30.04.99) US (71) Applicant: APPLIED MEDICAL RESOURCES CORPORATION [US/US]; 26051 Merit Circle, Suite 103, Laguna Hills, CA 92653 (US). (72) Inventors: DULAK, Gary, R.; 786 Alderwood, Newport Beach, CA 92660 (US). CLAYMAN, Ralph, V.; 14 Ridgemoor Drive, Clayton, MO 63105 (US). (74) Agent: MYERS, Richard, L.; 26051 Merit Circle, Suite 103, Laguna Hills, CA 92653 (US).		(81) Designated States: CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>

(54) Title: URETERAL ACCESS SHEATH**(57) Abstract**

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URETERAL ACCESS SHEATHBackground of the Invention

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Field of the Invention

This invention relates generally to guideways for endoluminal access and more specifically to surgical access devices adapted to introduce surgical instrumentation into body conduits.

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Discussion of the Prior Art

Surgical access devices of the prior art typically include a sheath having an outside diameter and an inside diameter. An obturator or dilator is inserted into the sheath to facilitate introduction of the sheath into the body conduit. Once the sheath is positioned, the
15 obturator is removed leaving a working channel for surgical instrumentation.

Particularly in the field of urology, the sheath has been provided in the form of an elongate tube having an axis extending between a proximal end and a distal end. The diameter of the tube is generally constant, except for a reduced diameter segment at the distal end. Although the obturator has had an enlarged structure at its proximal end, there has been no such
20 enlargement for the sheath. This has presented a problem as the sheath has tended to migrate distally and disappear beneath the urethral meatus. Representative of this art is the FLEXIBLE URETEROSCOPE SHEATH manufactured and sold by Cook Urological Incorporated.

Access devices particularly adapted for other body conduits have had enlargements at the proximal end, but these have not been specifically configured to prevent
25 migration or facilitate the introduction of instrumentation. Representative of this art are the "banana peel" sheaths which split axially for removal after catheter placement.

During the introduction and removal of dilators, obturators, and instrumentation into and out of a sheath, it is always desirable to facilitate maintenance of the sheath in a relatively stationary orientation. In the past, there has been no handle structure which was sized
30 and shaped to accommodate engagement by a user's hand disposed in its natural position with the palm facing the user. Nor has there been any progressive funnel structure which would facilitate the introduction of instrumentation into the working channel of the sheath.

Summary of the Invention

These deficiencies of the prior art have been eliminated with the present access device which includes a sheath having at its proximal end a handle specifically adapted to inhibit migration and facilitate use with instrumentation. The handle is formed as a radial enlargement having a distally-facing surface and a proximally-facing surface. The distally-facing surface has a generally concave configuration which provides a gradual enlargement inhibiting migration of the sheath into the ureter. The concave configuration is sized to receive adjacent fingers of a user's hand disposed in its natural position, in order to facilitate the stationary orientation of the sheath. The concave, distally-facing surface is continuous around the axis of the sheath so that the advantage of this concave configuration can be appreciated regardless of the radial orientation of the sheath.

The proximal-facing surface has a generally convex configuration providing for an increased funneling of an instrument as it is inserted into the working channel of the sheath. Both the distally-facing surface and the proximally-facing surface extend radially inwardly with progressively equal distal positions along the sheath. This provides the handle with the general shape of the bell of a horn. This configuration is not only ergonomically comfortable, but highly practical in addressing the problems of migration, as well as instrument insertion and removal.

The handle can be provided with characteristics permitting the handle to be moved to a preferred position along the tube of the sheath, and then to be fixed to the tube at that preferred location. This makes it possible to provide the sheath with any desired length, even after it has been inserted into the body conduit. A metal structure such as a spring, can be molded into the tube of the sheath to facilitate kink resistance.

The inner dilator can be provided with a Luerlock end, permitting attachment of a sidearm adaptor (not shown). This allows for installation of contrast during sheath placement without the need to remove the guidewire.

These and other features and advantages of the invention will become more apparent with a description of preferred embodiments and reference to the associated drawings.

Description of the Drawings

Fig. 1 is a perspective view illustrating a sheath of the present invention with an obturator or dilator adapted for use with the sheath;

Fig. 2 is a perspective view illustrating the obturator operatively disposed within the sheath;

Fig. 3 is an axial cross-section view taken along lines 3-3 of Fig. 2 and illustrating the obturator operatively disposed within a tube and "handle" of the sheath;

Fig. 4 is an enlarged radial cross-section view of the handle assembly illustrated in Fig. 3;

Fig. 5 is a side-elevation view of the sheath and obturator operatively disposed in the urethra and illustrating a preferred configuration for the handle assembly of the sheath;

Fig. 6 is a side-elevation view similar to Fig. 5 of a further embodiment of the handle assembly of the present invention;

Fig. 7 is a side-elevation view partially in phantom and exploded to illustrate components of another preferred embodiment of the handle assembly providing for sheath length adjustment;

Fig. 8 is a side-elevation view illustrating the components of Fig. 7 in an assembled configuration;

Fig. 9 is a radial cross-section view taken along lines 9-9 of Fig. 8;

Fig. 10 is a perspective, disassembled view of a further embodiment of a handle assembly permitting length adjustment;

Fig. 11 is a perspective, assembled view of the components illustrated in Fig. 10; and

Fig. 12 is a side-elevation view partially in fragment and illustrating a spring embodiment of the tube associated with the sheath of the present invention.

Description of Preferred Embodiments and Best Mode of the Invention

A ureteral access sheath is illustrated in Figure 1 and designated generally by the reference numeral 10. In Figure 1, the sheath 10 is illustrated in combination with a separate, but associated, dilator or obturator 12. The sheath 10 has the general configuration of an elongate tube 14 having an axis 16 which extends between a proximal end 18 and a distal end 21. A handle 23 is disposed at the proximal end 18 of the tube 14 and provides access into a working channel 25 of the tube 14.

The obturator 12 will typically have the configuration of an elongate rod 30 extending between a proximal end 32 and a distal end 34. A knob 36 is disposed at the proximal end 32 and a tapered tip 38 is formed at the distal end 34. The obturator 12 is adapted to be inserted into the working channel 25 of the sheath 10 with the knob 36 extending proximally of the sheath 10, and the distal end 34 extending distally of the sheath 10. This operative position of the obturator 12 within the sheath 10 is illustrated in the assembled view of Figure 2. An axial cross-section view of the assembled combination is illustrated in Figure 3 where the rod 30 of the obturator 12 is more clearly shown within the working channel 25 of the sheath 10.

If desired, the releasable lock (not shown) can be provided to removably attach the obturator 12 to the sheath 10. When locked in place, the obturator 12 and sheath 10 can then be passed as a single unit over the guidewire. This arrangement precludes inadvertent advancement of the sheath 10 in front of the obturator 12, which could greatly impede proper passage of the sheath and potentially the ureter.

The handle 23 associated with the sheath 10 is of particular interest to the invention and is illustrated in the enlarged, axial cross-section view of Figure 4. From this view it can be seen that the handle 23 has the general configuration of the bell of a horn. The handle 23 has a distally-facing surface 41 on the outside of the handle 23, and a proximally-facing surface 43 on the inside of the handle 23. Both of these surfaces 41 and 43 in the preferred embodiment are continuous and have a generally conical configuration. In the illustrated embodiment, the distally-facing surface 41 is generally concave, while the proximally-facing surface 43 is generally convex.

The handle 23 can be provided with two small holes 45, 46 for passage of sutures 47 and 48, respectively. Once the sheath is in place, the sutures 47, 48 can be clamped with hemostats (not shown) to the surgical drapes, thereby preventing distal migration of the sheath and loss of ureteral access. Once the obturator/sheath combination has been advanced to the desired position in the ureter, the obturator 12 can be unlocked from the sheath 10 and removed. In the manner discussed in greater detail below, these features offer particular advantages to the present invention.

One of the purposes of the proximally-facing surface 43 is to funnel the obturator 12 and other surgical instrumentation into the working channel 25 of the sheath 10. With the generally conical configuration, this proximally-facing surface functions as a funnel with a radius which decreases with progressive distal positions along the axis 16. Thus, as the instrumentation is moved distally, the proximally-facing surface 43 guides the instrument along a

decreasingly decreasing radius into the working channel 25 of the sheath 10. Providing the surface 43 with a generally convex configuration further facilitates this funneling feature of the invention. When the surface 43 is convex, its radius decreases at a decreasing rate with progressively equal distal positions along the axis 16.

5 The distally-facing surface 41 is intended to facilitate engagement of the sheath 10 by a user's hand held in its most natural state. In Figure 5, adjacent fingers 50 and 52 of the user's hands are illustrated schematically by the circles 50 and 52. In the natural state, the palm of the user's hands would be facing the user in the proximal direction, to the left in Figure 5. The sheath 10 is adapted to be operatively positioned between the fingers 50 and 52
10 with the handle 23 positioned so that the distally-facing surface 41 is in juxtaposition to the fingers 50 and 52. This fit is facilitated by forming the surface 41 with a size and configuration generally similar to the fingers 50 and 52, as illustrated in Figure 5. Thus, with the distally-facing surface 41 having a generally conical configuration, it has a radius which decreases with progressive distal positions along the axis 16. In an embodiment wherein the surface 41 is also
15 concave, the radius of the surface 41 decreases at a decreasing rate with progressively equal distal positions along the axis 16.

 In operation, as the surgical instrument, such as the obturator 12, is inserted into the handle 23, it produces a force F_1 (illustrated by arrow 54) in the distal direction. This force is opposed by the fingers 50 and 52, which engage the distally-facing surface 43 and apply
20 opposing forces F_2 and F_3 (represented by arrows 56 and 58). In this manner, the fingers 50 and 52 can maintain the sheath 10 generally stationary even when the obturator 12 is being inserted. It will also be noted that with the user's hand in the natural position, it tends to form a barrier which prevents any instrumentation from extending exteriorly beyond the handle 23 into contact with ureteral tissue 60.

25 Although the embodiment of Figure 5 is particularly adapted to facilitate insertion of a surgical instrument, such as the obturator 12, it will be appreciated that removal of the instrument also creates withdrawal forces on the sheath 10. A further embodiment of the handle which can easily accommodate not only insertion forces but also withdrawal forces, is illustrated in Figure 6. In this embodiment, a handle 61 is similar to the handle 23, except that the outer,
30 distally-facing surface 43 is curved distally outwardly to form a proximally-facing outer surface 63. In this case, the two surfaces 41 and 63 form a continuous surface which defines an annular recess sized and configured to receive the fingers 50 and 52.

In this embodiment, insertion of the instrument, such as the obturator 12, is resisted by the forces F_2 and F_3 applied by the fingers 50 and 52, respectively, to the distally-facing surface 43, as previously discussed with reference to Figure 5. In a similar manner, when the instrument such as the obturator 12 is withdrawn, it produces a force F_4 (illustrated by arrow 65) which must be resisted in order to maintain the sheath 10 stationary. This resistance is provided in the embodiment of Figure 6 by the pressure of the fingers 50, 52 against the proximally-facing outer surface 63. Thus, fingers 50, 52 provide opposing forces F_5 and F_6 designated by arrows 67, 70, respectively.

Figures 7-9 illustrated a further embodiment involving a handle, such as the handles 23 or 61, which is movable relative to the tube 14 of the sheath 10. This embodiment is particularly desirable as it permits the tube 14 to be cut in situ, at the operative site, to a preferred length. With a sheath of this type, only a single access device need be present at the operative site. Multiple sheaths having different lengths are not required to be present in order to have a sheath of the desired length. As illustrated in Figure 7, this embodiment of the sheath 10 includes the tube 14 which is slidingly engageable by a handle assembly 72 that includes a sleeve 74 and a funnel 76. The sleeve 74 is formed as a cylinder 77 having an interior bore 78 and external threads 81. An elastomeric element 83 is disposed within the bore 78 and is provided with an axial lumen 84 appropriately sized to receive the tube 14.

The funnel 76 is formed similar to the handle 23, but includes two concentric cylinders 85 and 87 which extend distally. The outer cylinder 85 is provided with interior threads 90, which are sized to receive the external threads 81 of the sleeve 74. The inner cylinder 87 of the funnel 76 is provided with an outer diameter less than the inner diameter of the bore 78. This inner cylinder 87 extends to a distal surface 92.

In operation, the funnel 76 is moved axially over the sleeve 74 and the internal threads 90 are screwed onto the external threads 81. Further rotation of the funnel 76 relative to the sleeve 74, causes the distal surface 92 of the inner cylinder 87 to axially compress the elastomeric element 83. This compression causes the element 83 to expand inwardly decreasing the diameter of its lumen 84 and thereby increasing the frictional engagement of the handle assembly 72 relative to the tube 14.

In order to provide the sheath 10 with a desired length, the tube 14 can be cut to a predetermined length, either before or after mounting the handle assembly 72 on the tube 14. Axial movement of the handle assembly 72 to a desired proximal location on the tube 14

provides the sheath 10 with the desired length. Operation of the handle 72 in the manner previously discussed will fix the assembly 72 on the tube 14 at this desired location.

In another embodiment illustrated in Figure 10, a movable handle assembly 96 includes a funnel 98 similar to the handle 23. It also includes a cylinder 99 which extends distally within portions 101 which have a reduced diameter. A separate finger clamp 102 includes a cylinder 104 which has a diameter which is dependent upon operation of finger tabs 103 and 105. When these tabs 103 and 105 are compressed, the cylinder 104 has a relatively large diameter. When the tabs 103 and 105 are not compressed, the cylinder 104 is biased toward a reduced diameter. This finger clamp 102 is intended to be operatively disposed over the thin portions 101 of the cylinder 99, as illustrated in Figure 11. In this operative position, the entire handle assembly 96 can be moved along the tube 14 by compressing the finger tabs 103 and 105 of the clamp 102. The tube 14 can then be cut, for example, with scissors 106, to any desired length. Compressing the finger tabs 103 and 105 will permit the handle assembly 96 to be moved to a distal position, as illustrated in Figure 11, where the tabs 103 and 105 can be released to compress the thin portions 101 and maintain the handle assembly 96 in a fixed relationship with the tube 14.

A further embodiment of the invention is illustrated in the side-view of Figure 11. In this embodiment, the tube 14 is formed with an inner plastic body 110, surrounded by a metal spring coil 112, which is further covered by an outer body 114. This particular embodiment of the tube 14 provides a high degree of kink resistance and can be used with any of the handle assemblies previously discussed. With this embodiment of the tube 14, the inner body 110 provides a smooth surface within the sheath 10, which facilitates passage of instrumentation. The spring coil 112 adds kink resistance to the tube 14, while the outer body 114 provides a suitable covering for the coils of the spring 112.

From the foregoing description of preferred embodiments, it will be apparent that many variations on the concept of this invention will be contemplated by those skilled in the art. For example, many different configurations of the tube 14 can be used with the various handle assemblies disclosed. Furthermore, the handle assemblies can be embodied in many different forms to provide at least one curved outer surface which is sized and configured to receive the fingers of a user's hand in a normal position. The fact that this desired outer shape can be combined with a funnel configuration at the proximal end of the sheath, will add further advantages to these various embodiments.

Although exemplary embodiments of the invention have been shown and described, many other changes, modifications, and substitutions will now be apparent to those of ordinary skill in the art, without necessarily departing from the spirit and scope of this invention as set forth in the following claims.

CLAIMS

1. A ureteral access sheath adapted for insertion into a urethra having a first diameter, comprising:

an elongate tube having a second diameter and a lumen extending between a proximal end and distal end;

5 a handle disposed at the proximal end of the tube;
portions of the handle extending radially outwardly of the tube to provide the handle with a third diameter greater than the first diameter of the body conduit; whereby, the handle portions inhibit distal migration of the proximal end of the tube into the urethra.

2. The access sheath recited in Claim 1 wherein the handle portions are defined by a first surface facing generally distally and a second surface facing generally proximally.

3. The access sheath recited in Claim 2 wherein the second surface forms a funnel leading into the lumen of the tube.

4. The access sheath recited in Claim 3 wherein the sheath is adapted for use by a person having a pair of adjacent fingers and wherein:
the first surface is continuous and is both sized and configured to receive the adjacent fingers of the user.

5. The access sheath recited in Claim 3 wherein the second surface is convex.

6. The access sheath recited in Claim 4 wherein the first surface is concave.

7. The access sheath recited in Claim 5 wherein the second surface extends decreasingly radially inwardly with progressive equal distal positions along the tube.

8. The access sheath recited in Claim 6 wherein the first surface extends decreasingly radially inwardly with progressive equal distal positions along the tube.

9. The access sheath recited in Claim 1 wherein the elongate tube includes a helical spring.

10. A method for inserting a medical instrument into a urethra, comprising the steps of:

providing a urethral access device having an elongate tube with a lumen extending along an axis between a proximal end and a distal end, and a handle at the proximal
5 end of the tube;

configuring the handle with a distally-facing surface and proximally-facing surface, the distally-facing surface being sized and configured to receive two adjacent fingers of a user's hand;

10 inserting the distal end of the tube into the urethra to an operating position in order to provide access for the medical device;

moving the medical device distally into the proximal end of the lumen of the tube and through the lumen of the tube into the urethra;

during the moving step creating a distal force on the urethral access sheath; and

15 applying a proximal force on the distally-facing surface of the handle to oppose the distal force and maintain the access sheath in the operative position.

11. The method recited in Claim 10 wherein the configuring step includes the step of forming the distally-facing surface with a concave configuration.

12. The method recited in Claim 11 wherein the configuring step further comprises the step of:

forming the proximally-facing surface with a convex configuration.

13. The method recited in Claim 10 further comprising the step of:
moving the handle distally axially along the tube beyond a
predetermined position;

removing a portion of the tube extending generally proximally of the
5 predetermined position;
moving this handle axially proximally to the predetermined position along the
tube; and

14. The method recited in Claim 14 further comprising the step of:
facilitating a generally fixed relationship between the handle and the tube at the
predetermined position.

15. A handle adapted for use with a surgical access device having the
configuration of an elongate tube with a working channel, comprising:
a distal section of the handle sized and configured to move on the tube of the
access device to a predetermined position along the tube;
5 a proximal section of the handle having a flared configuration and a surface
facing generally proximally, the surface extending radially inwardly with progressive distal
positions along the handle.

16. The handle recited in Claim 15 wherein the distal section includes:
engagement apparatus movable radially inwardly to facilitate a generally fixed
relationship between the tube and the handle when the handle is operatively disposed at the
predetermined position along the tube.

17. The handle recited in Claim 16 wherein the tube of the access device is
formed with a plurality of annular bumps disposed along the tube, and the engagement apparatus
of the handle includes:

a detent adapted to engage a predetermined one of the bumps at the predetermined
5 location.

18. The handle recited in Claim 16 wherein the engagement apparatus has a
first state facilitating movement of the handle along the tube and a second state facilitating the
generally fixed relationship between the handle and the tube at the predetermined position along
the tube.

19. The handle recited in Claim 18 wherein the engagement apparatus is biased to the second state.

20. The handle recited in Claim 18 wherein the engagement apparatus comprises:

an elastomeric washer disposed around the tube; and

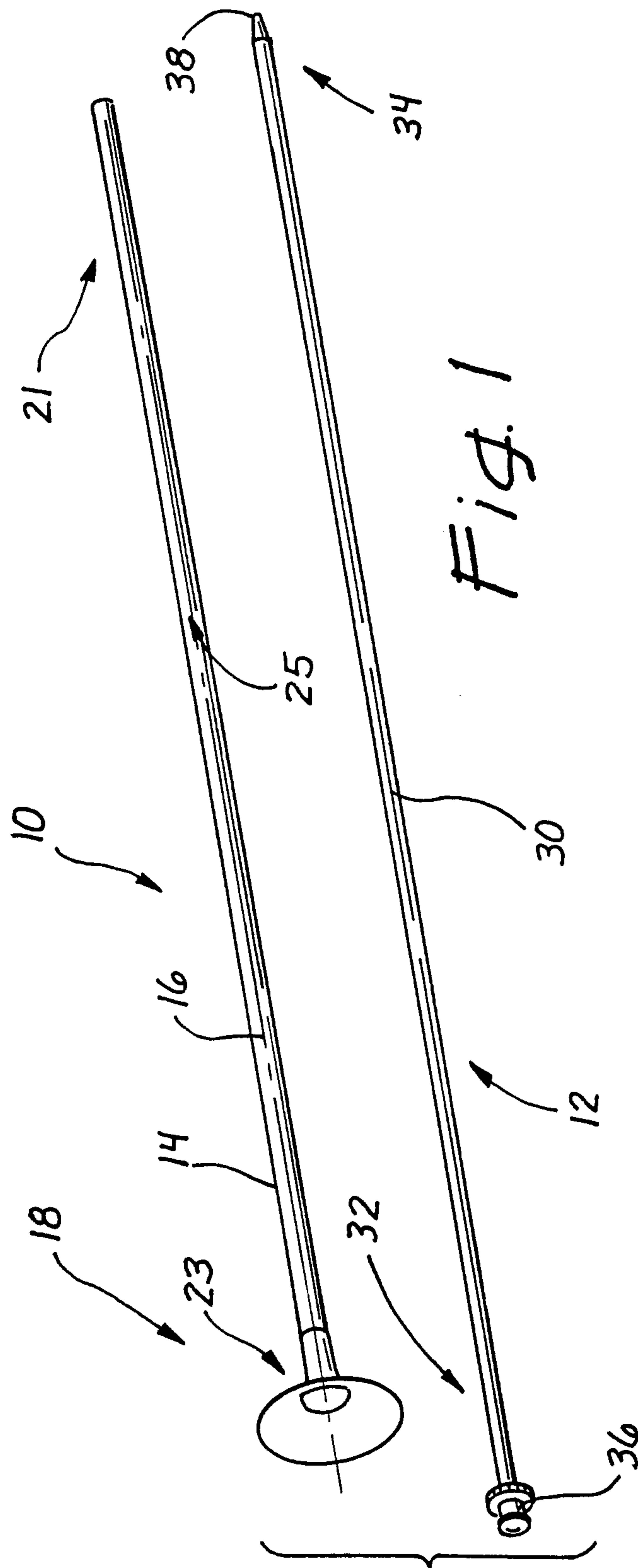
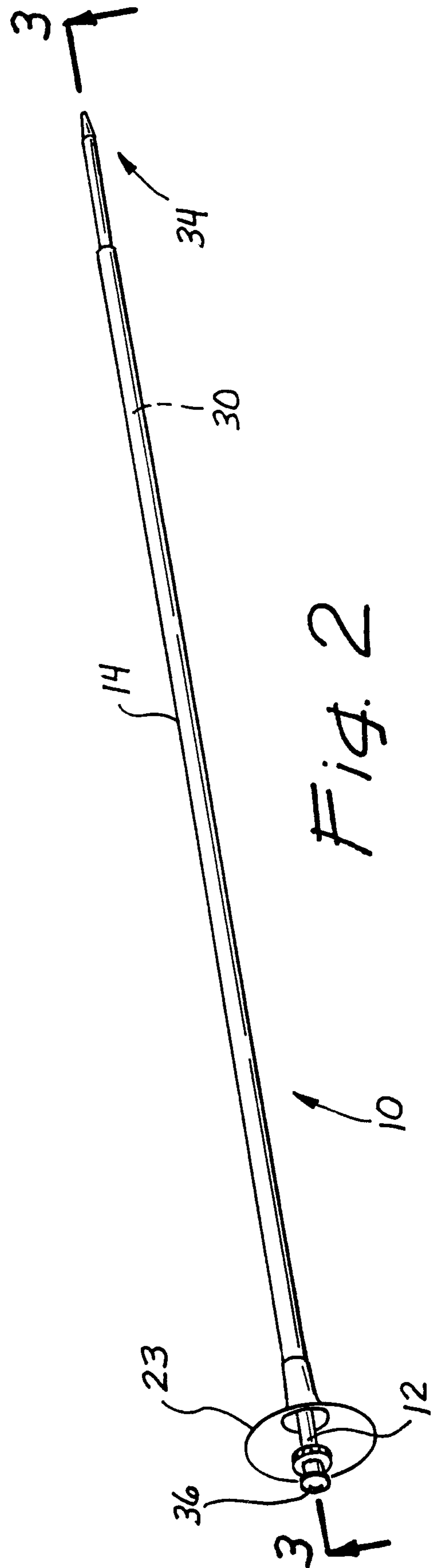
5 a nut operable to compress the washer against the tube to facilitate the fixed relationship between the handle and the tube at the predetermined position.

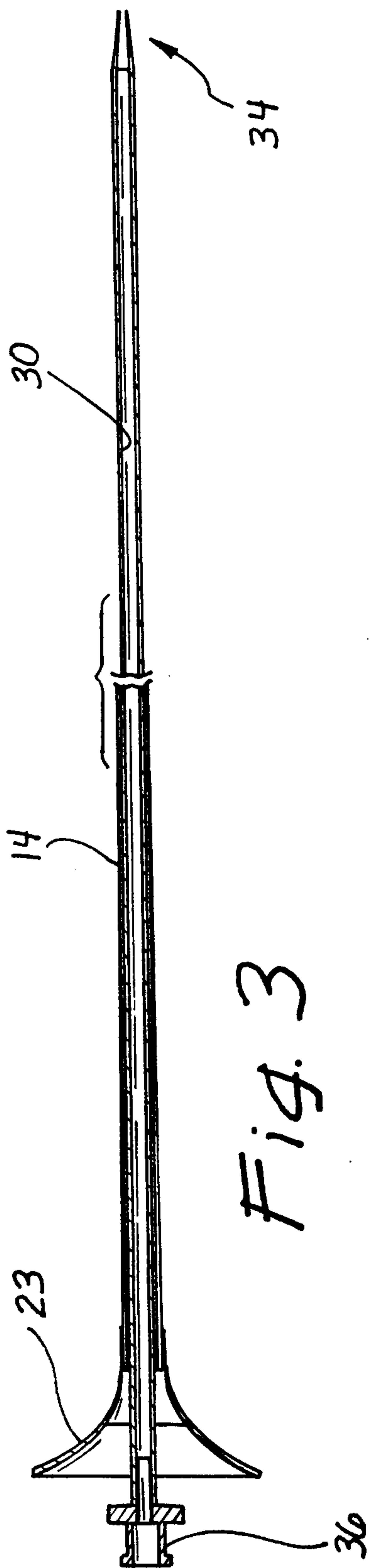
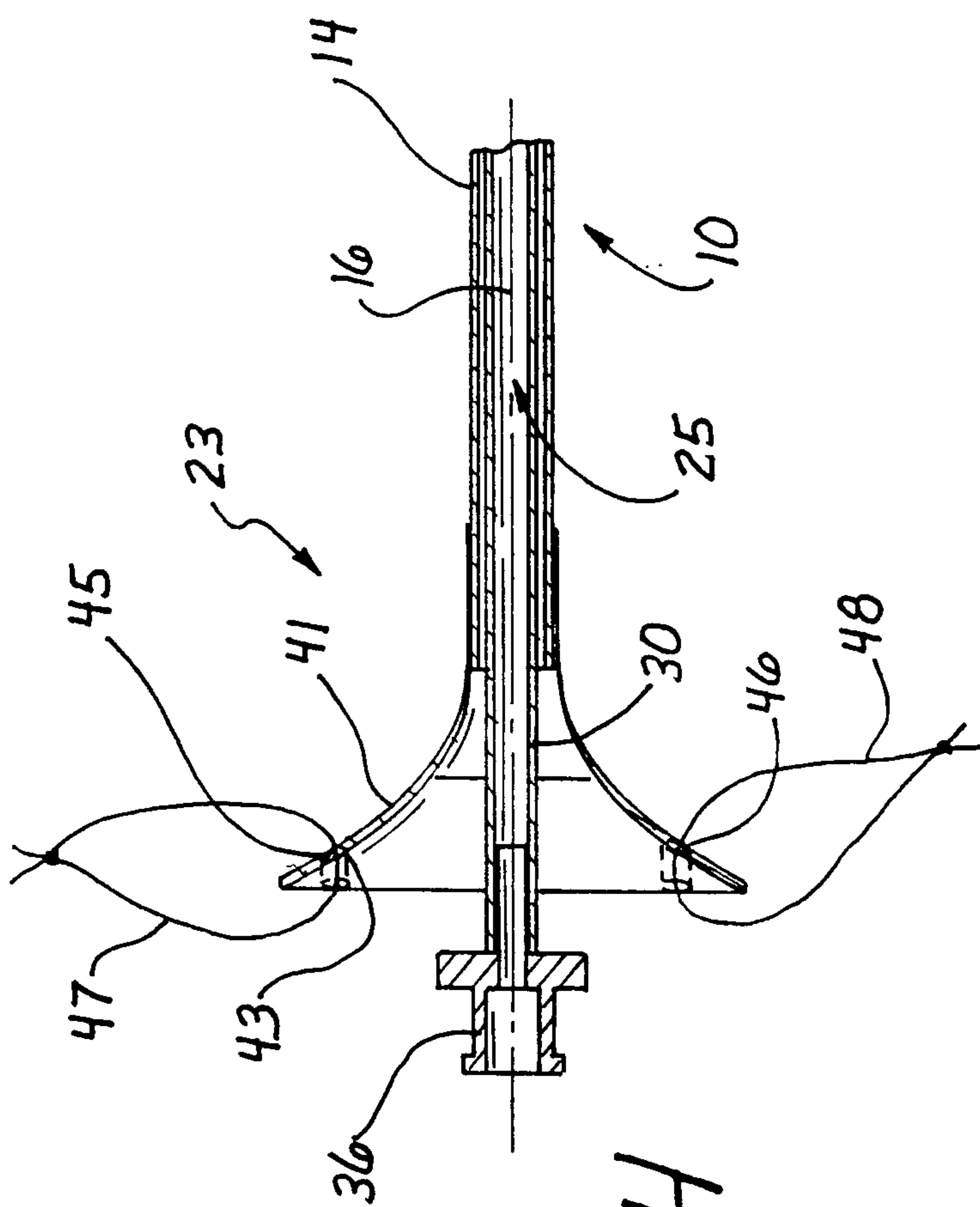
21. A method for providing a surgical access with a desirable length, comprising steps of:

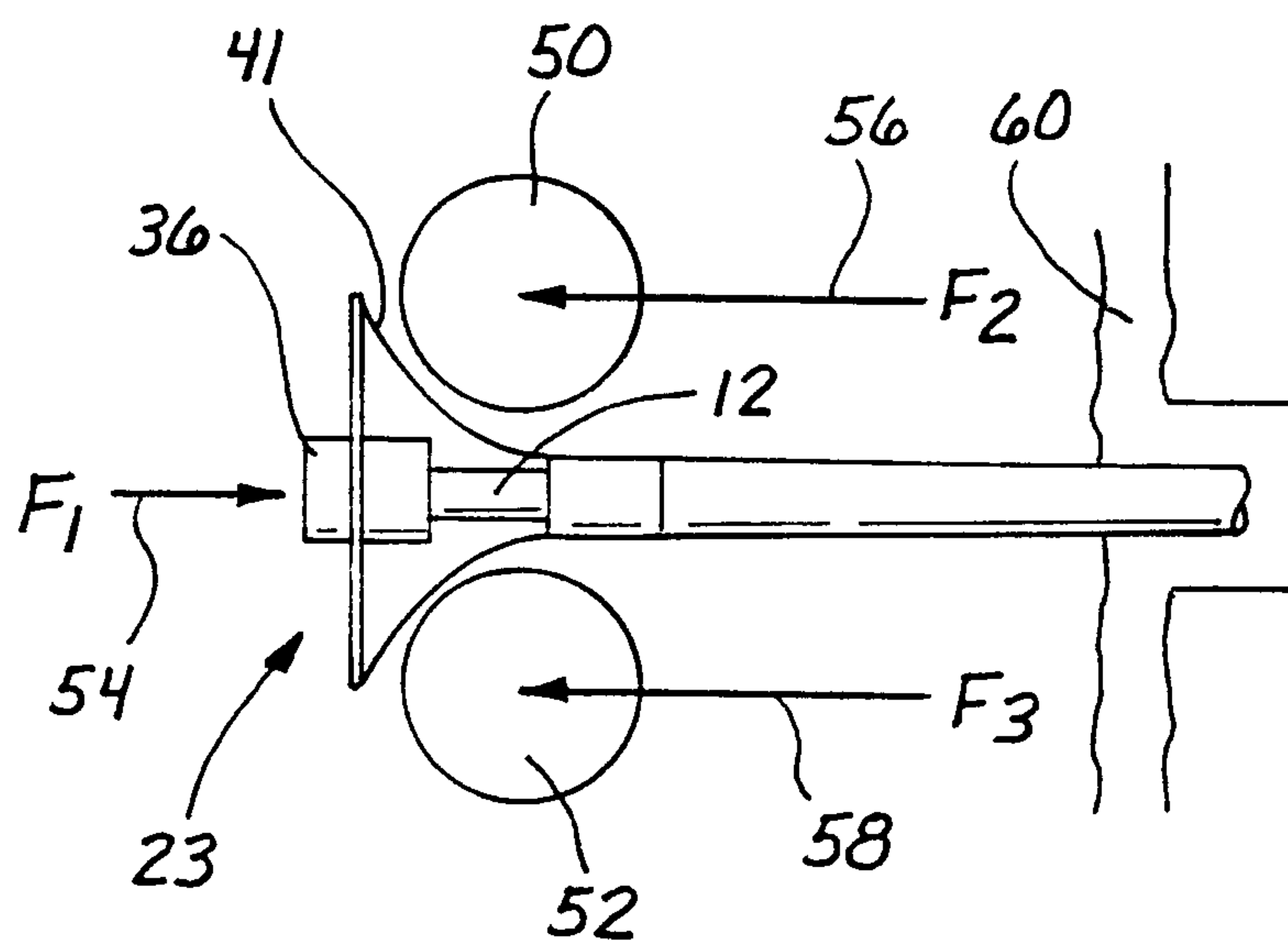
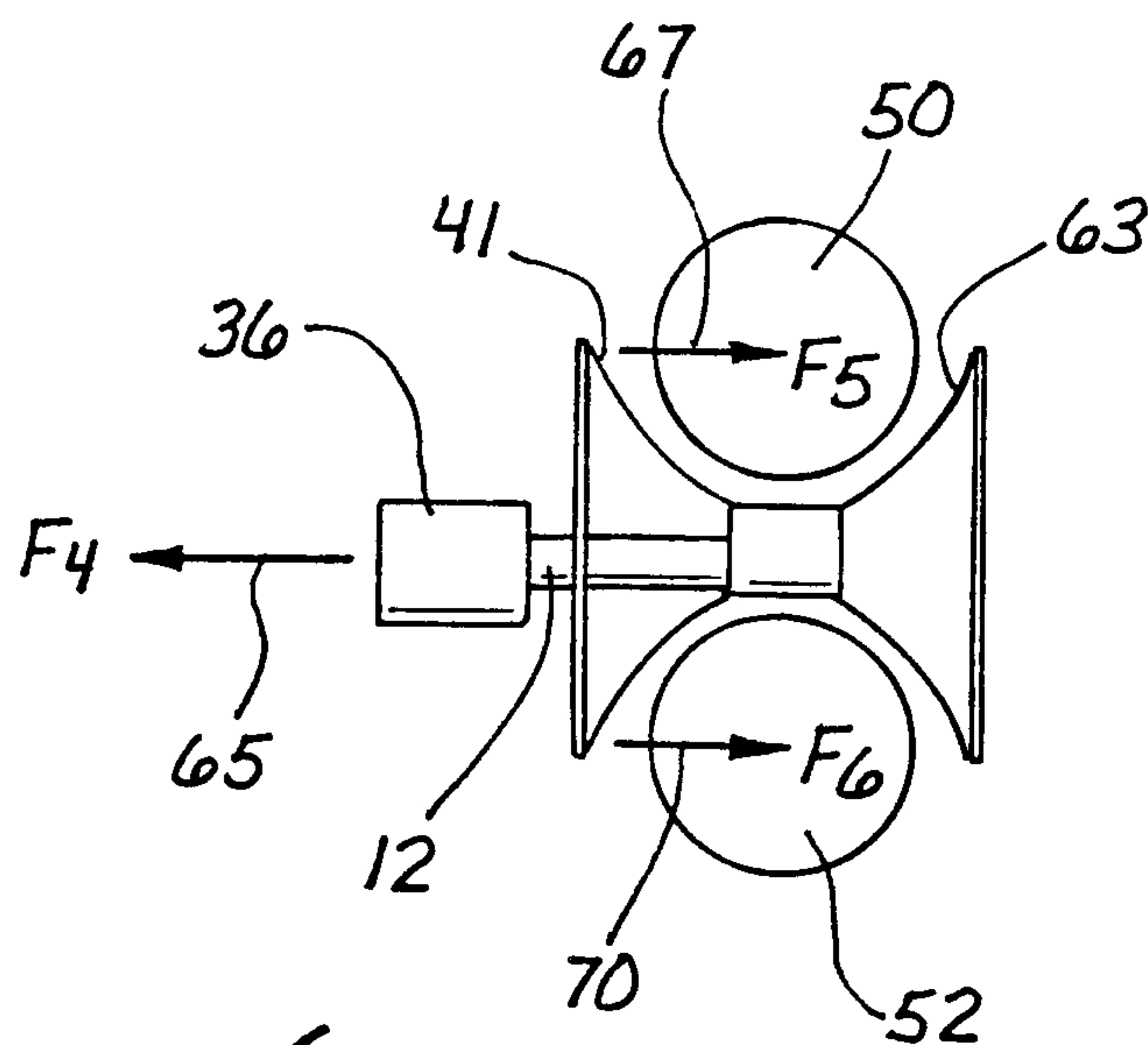
providing an elongate tube having a working channel and a handle assembly having an engagement apparatus adapted to fit over the tube, the handle having a movable
5 relationship with the tube when the engagement apparatus is in a first state and a fixed relationship with the tube when the engagement apparatus is in a second state;
placing the engagement apparatus in the first state;
removing a portion of the elongate tube to shorten the length of the tube generally to the desired length;
10 moving the handle to a predetermined location along the tube; and
placing the engagement apparatus in the second state to fix the handle to the tube at the predetermined location and provide the access device with the desired length.

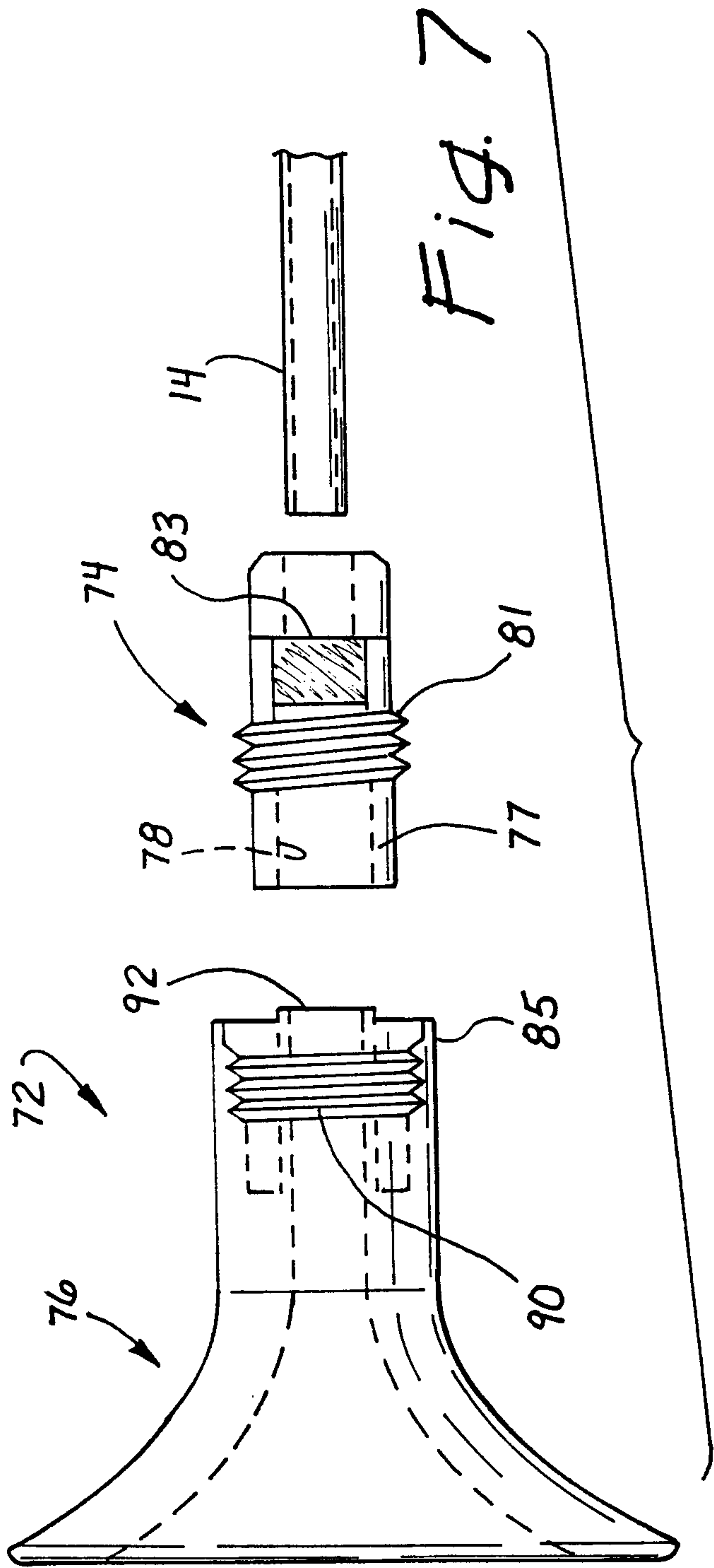
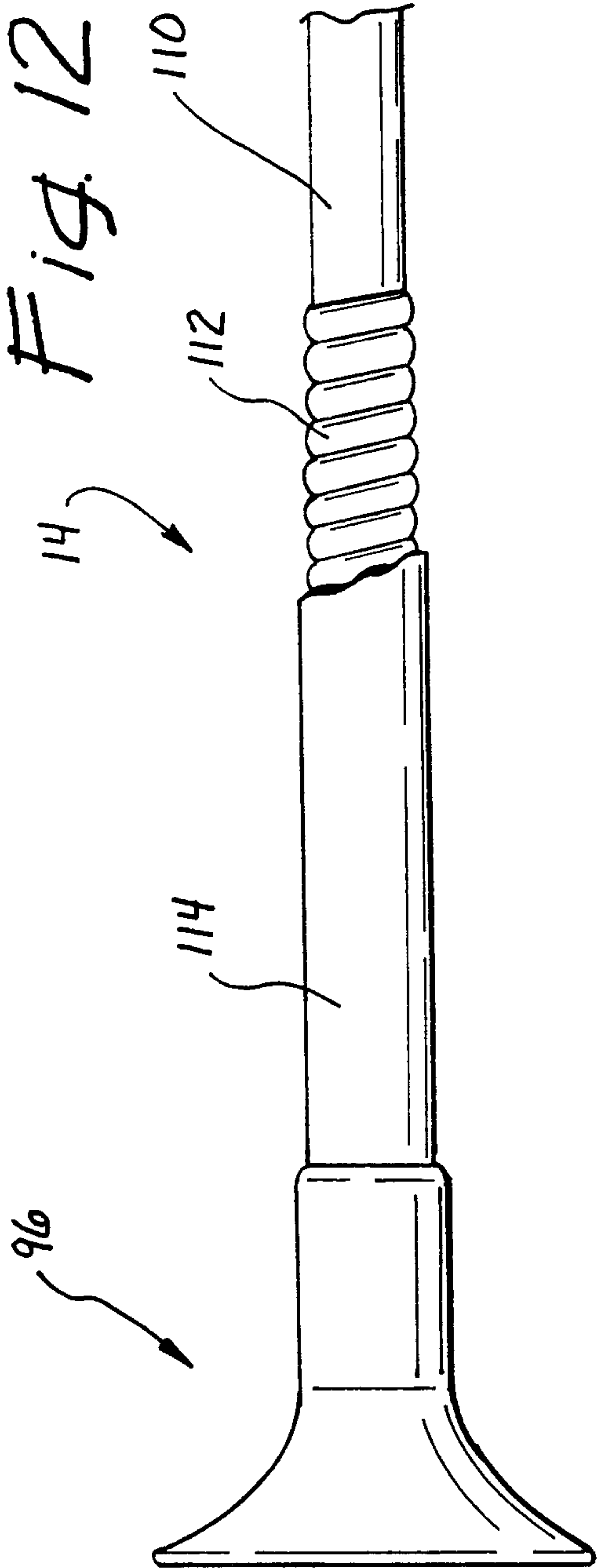
22. The method recited in Claim 21 wherein the second providing step includes the step of providing the engagement apparatus with an elastomeric washer sized and configured to fit around the tube; and

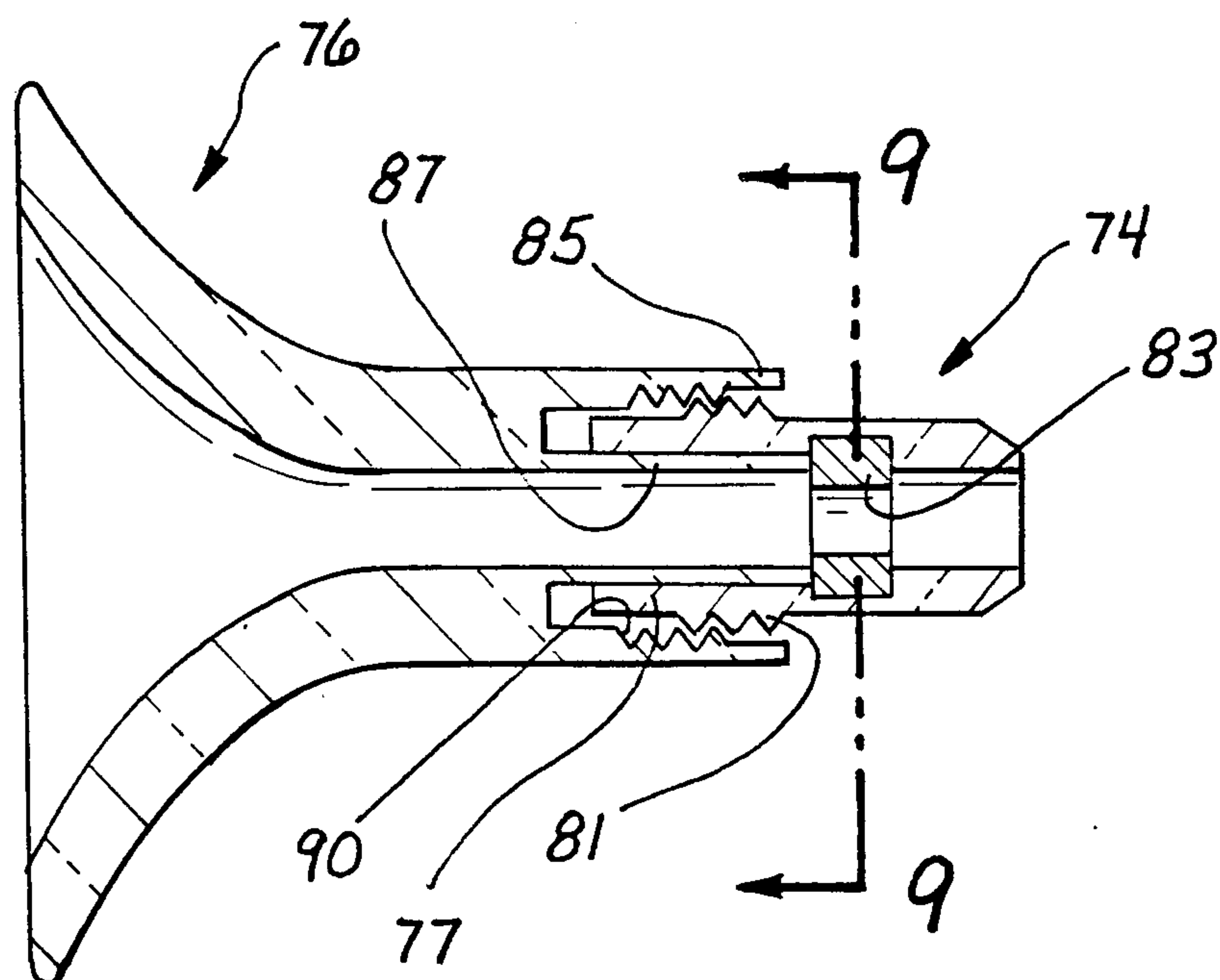
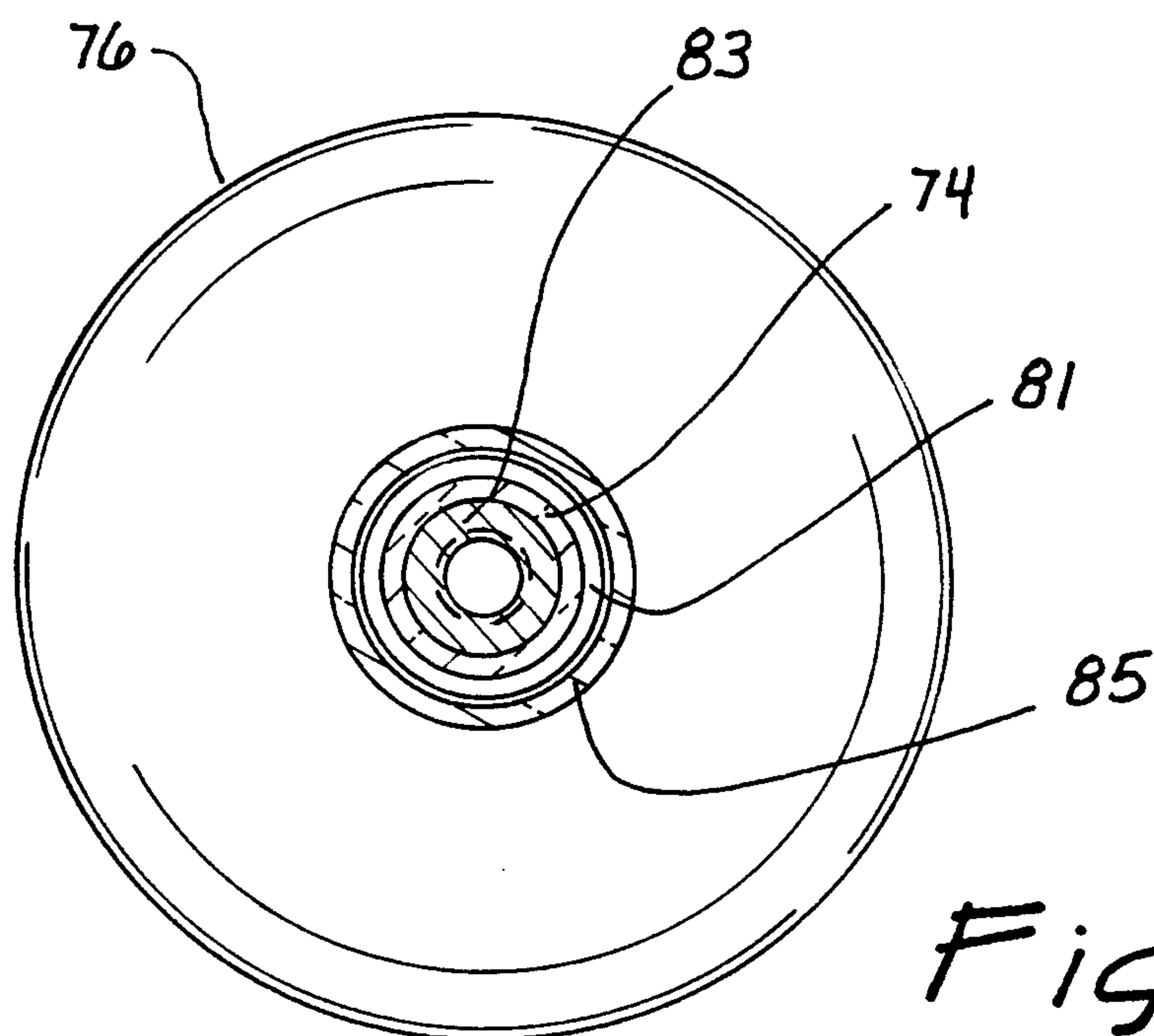
5 the second placing step includes the step of compressing the washer around the tube.





*Fig. 5**Fig. 6*



*Fig. 8**Fig. 9*

