Office de la Propriété Intellectuelle du Canada
Un organisme d'Industrie Canada

Canadian Intellectual Property Office
An agency of Industry Canada

CA 2350793 A1 2000/03/09

(21) 2 350 793

(12) DEMANDE DE BREVET CANADIEN
CANADIAN PATENT APPLICATION

(13) A1

(86) Date de dépôt PCT/PCT Filing Date: 1999/08/26
(87) Date publication PCT/PCT Publication Date: 2000/03/09
(85) Entrée phase nationale/National Entry: 2001/05/15
(86) N° demande PCT/PCT Application No.: US 99/19474
(87) N° publication PCT/PCT Publication No.: WO 00/12164
(30) Priorité/Priority: 1998/08/27 (09/141,225) US

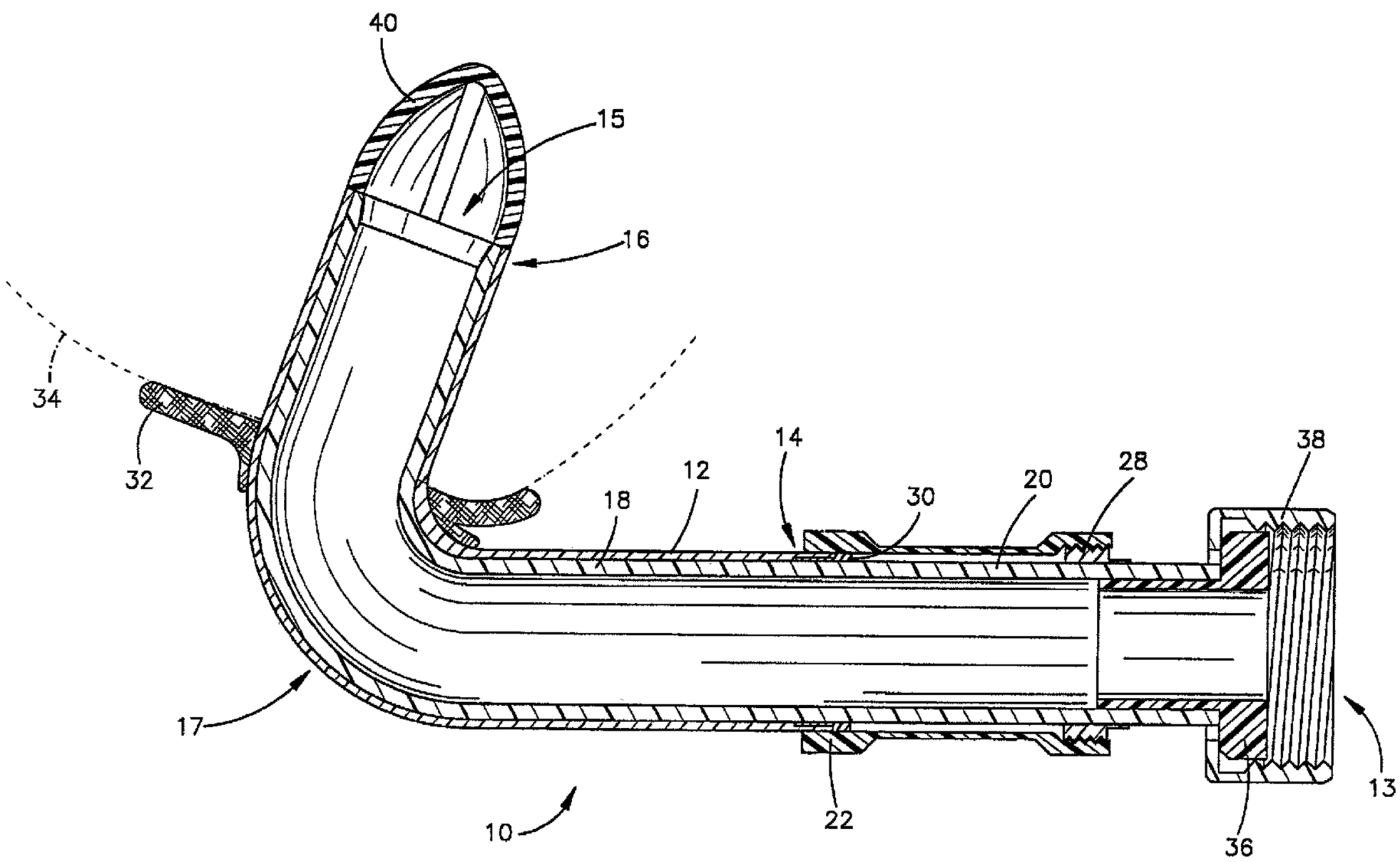
(51) Cl.Int.^{6}/Int.Cl.^{6} A61M 25/00

(71) Demandeur/Applicant:
THE CLEVELAND CLINIC FOUNDATION, US

(72) Inventeur/Inventor:
CHEN, JI-FENG, US

(74) Agent: SWABEY OGILVY RENAULT

(54) Titre : CANULE A ETRANGLEMENT RIGIDE
(54) Title: RIGID CLAMPABLE CANNULA



(57) Abrégé/Abstract:
A clamping cannula (10) comprises a generally rigid layer (12) having a first end (14), and a generally flexible tube (18) generally coaxial with the rigid layer. The flexible tube extends axially in a first direction beyond the first end. The cannula also has a generally rigid sleeve (22) movable between a cover position (Fig. 1), wherein the sleeve covers a first part of the flexible tube, and an uncovered position (Fig. 2), wherein the sleeve does not cover the first part of a flexible tube to enable clamping of the cannula.

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 25/00 — A1

(11) International Publication Number: **WO 00/12164**

(43) International Publication Date: 9 March 2000 (09.03.00)

(21) International Application Number: PCT/US99/19474

(22) International Filing Date: 26 August 1999 (26.08.99)

(30) Priority Data:
09/141,225 27 August 1998 (27.08.98) US

(71) Applicant *(for all designated States except US)*: THE CLEVELAND CLINIC FOUNDATION [US/US]; 9500 Euclid Avenue, Cleveland, OH 44195 (US).

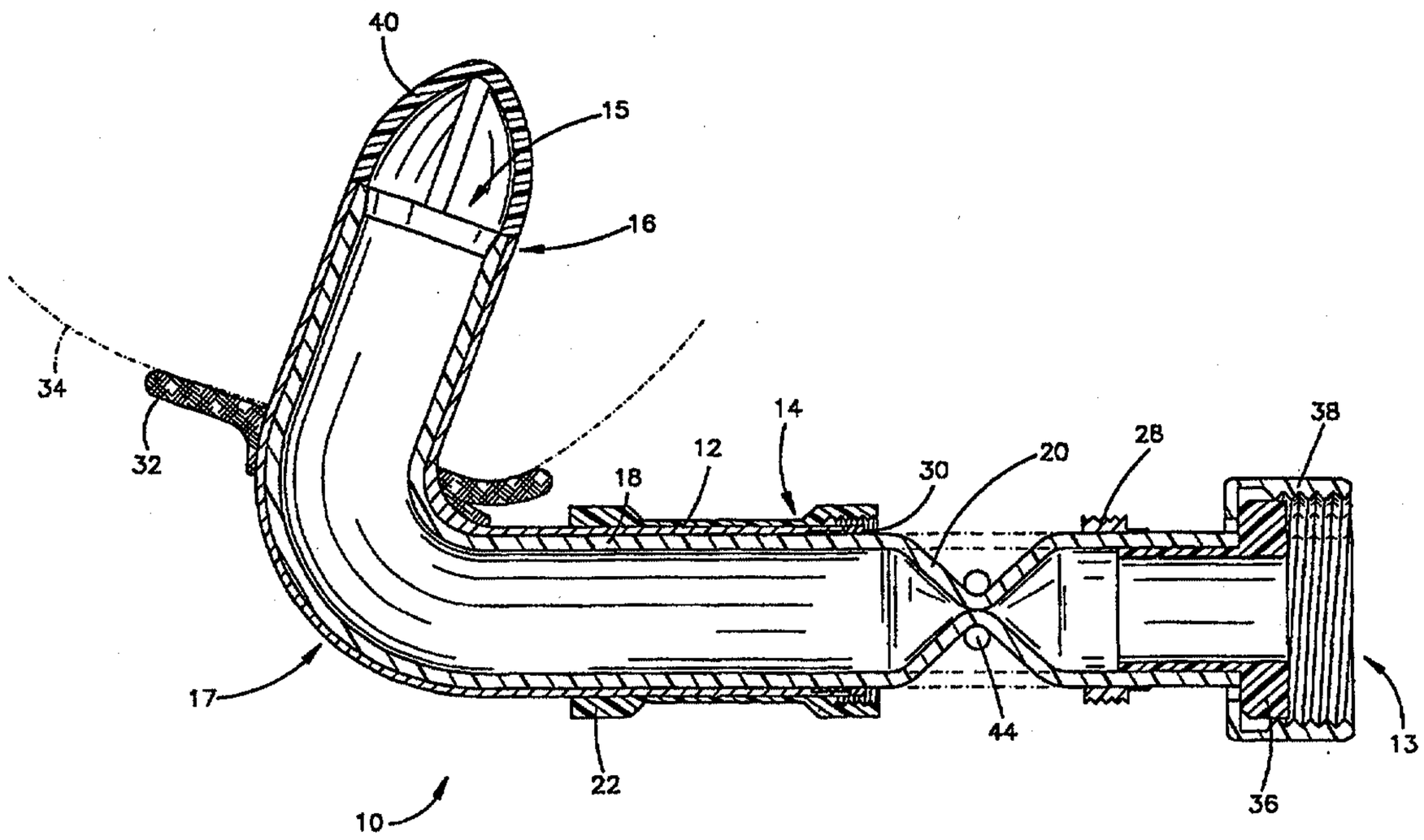
(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: CHEN, Ji–Feng [US/US]; 1217 Elbur Avenue, Lakewood, OH 44107 (US).

(74) Agents: LONGMUIR, Jeanne, E. et al.; Calfee, Halter & Griswold LLP, 1400 McDonald Investment Center, 800 Superior Avenue, Cleveland, OH 44114–2688 (US).

(81) Designated States: CA, JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: RIGID CLAMPABLE CANNULA



(57) Abstract

A clamping cannula (10) comprises a generally rigid layer (12) having a first end (14), and a generally flexible tube (18) generally coaxial with the rigid layer. The flexible tube extends axially in a first direction beyond the first end. The cannula also has a generally rigid sleeve (22) movable between a cover position (Fig. 1), wherein the sleeve covers a first part of the flexible tube, and an uncovered position (Fig. 2), wherein the sleeve does not cover the first part of a flexible tube to enable clamping of the cannula.

WO 00/12164 PCT/US99/19474

RIGID CLAMPABLE CANNULA

Field of the Invention

The present invention is directed to a blood flow cannula, and more particularly, to a generally rigid clampable blood flow cannula.

Background of the Invention

Cannulas of the type of the present invention are utilized in conjunction with ventricle assist devices to guide blood flow out of a person's heart and into the ventricle assist device. These ventricle assist devices are implanted into a patient's heart to assist in pumping blood to the body. One major disadvantage to prior art cannulas is that they require the use of a heart lung machine in order to be installed into a patient's heart so that the surgeon may work in a bloodless field. A second disadvantage is that the patient's heart must be immobilized and then restarted after surgery. In addition, additional anticoagulants must be used due to the usage of the heart lung machine. A third disadvantage to prior art cannulas is that they are generally designed to be rigid structures to avoid kinking and collapsing, and thus they cannot be clamped by a surgeon.

Accordingly, there exists a need for a cannula which avoids the need for use of a heart lung machine and heart immobilizing drugs during installation, kinking and inadvertent closure as well as avoiding but can be clamped and return to its original position when the clamp is removed.

Summary of the Invention

The present invention pertains to a generally rigid cannula which includes a clampable portion that can be clamped when it is desired to block the flow of blood therethrough. Because of this clamping feature, the present invention allows for the implantation of a ventricle assist device in conjunction with the cannula without the need to stop the patient's heart and install a heart lung machine. Upon removal of the clamp, the clampable portion returns to its original shape, thereby allowing the flow of blood to resume through the cannula. The present invention also avoids inadvertent kinking.

More particularly, the present invention is a clampable cannula comprising a generally rigid section having a first end and a generally flexible section generally coaxial with the rigid section. The flexible section extends axially in a first direction beyond the first end. The cannula also has a generally rigid sleeve moveable between a cover position, wherein the sleeve covers a first part of the flexible section, and an uncovered position, wherein the sleeve does not cover the first part of a flexible section, to enable clamping of the cannula. The sleeve ensures that the cannula remains protected from inadvertent closure.

Another aspect of the present invention provides a method for implanting a cannula and ventricle assist device into the heart of a patient, the method comprising the steps of clamping a flexible section of the cannula; installing an end of a cannula into the heart; connecting the ventricle assist device to the cannula; and unclamping the flexible section.

Other features and advantages of the present device will become apparent from the following detailed description, with reference to the accompanying drawings and claims, which form a part of the specification.

Brief Description of The Drawings

In the accompanying drawings, which are incorporated in and constitute a part of this specification, numerous embodiments of the device described are illustrated, and together with the general description above, and the description below, exemplify the device of the present application.

Fig. 1 is a side cross-sectional view of the cannula of the present invention shown with the sleeve in the cover position;

Fig. 2 is a side cross-sectional view of the cannula of Fig. 1, shown with the sleeve in the uncover position and being clamped with a clamp, with the unclamped shape of the cannula shown in hidden lines;

Fig. 3 is a side cross-sectional view of an alternate embodiment of the cannula of the present invention shown with the sleeve in the cover position;

Fig. 4 is a side cross-sectional view of the cannula of Fig. 3, shown with the sleeve in the uncover position and being clamped with a clamp;

Fig. 5 is a side cross-sectional view of the sleeve shown in Fig. 3 with the sleeve bent at an angle; and

Fig. 6 is a perspective view of the cannula shown with a ventricle assist device installed thereon.

Detailed Description of the Invention

Fig. 1 shows the cannula of the present invention, generally designated 10. The cannula 10 has an inflow end 15 and an outflow end 13. The cannula 10 comprises a generally rigid layer 12 having a first end 14 and a second end 16. The cannula 10 further comprises a generally flexible tube 18 generally coaxial with the rigid layer 12. In the illustrated embodiment the flexible tube 18 extends from the first end 14 of the rigid layer to the second end 16 of the rigid layer 12, and has an axially extending portion 20 extending beyond the first end 14. However, it is not essential that the flexible tube 18 extend back to the first end 16, merely as long as the tube 16 includes an axially extending portion 20. The flexible tube 18 may be bonded to the rigid layer 12 with a biocompatible, or blood compatible, adhesive. A cuff 32 is mounted toward the second end 16 of the rigid layer 12. The cuff provides a surface for attaching the cannula 10 to the heart wall, shown in phantom as 34. In a preferred embodiment, the cuff 32 is a fabric, such as polyester fabric, and the cuff may be sewn to the heart wall 34.

The flexible tube is preferably a flexible polymer, such as polyurethane. The flexible tube 18 is also preferably coated with a biocompatible urethane, and/or blood compatible urethane, on its inner surface (i.e. its blood-contacting surface). The blood compatible coating may be located on top of the biocompatible coating. In an alternate embodiment, the rigid layer 12 is somewhat flexible to be molded and bent to a desired configuration. The form shown in Figs. 1 and 2, which includes bend 17, shows merely one of many possible configuration of the cannula 10. The rigid layer 12 may be made of any suitable material, including titanium, titanium alloys, carbon fiber epoxy, and other materials. The rigid layer 12 is preferably made of a biocompatible material. Furthermore, the rigid layer 12 has a blood compatible coating on its blood contacting surfaces. The blood contacting surfaces of the rigid layer 12 are those portions within the heart wall 34; that is, forward of the cuff 32.

The cannula 10 further includes a generally rigid sleeve 22 that is coaxial with the rigid layer 12. The sleeve 22 is moveable between a cover position, as shown in Fig. 1, to an uncovered position shown in Fig. 2. The sleeve 22 is retained in the cover position by a fixation ring 28 having an external set of threads thereon. The sleeve 22 is preferably made from a titanium alloy, as is the fixation ring 28. The sleeve 22 has a set of cooperating threads which engage the fixation ring 28 to retain the sleeve 22 in the covered position. Nearly any manner of retaining means for retaining the sleeve 22 in the cover position may

be used without departing from the scope of the present invention. A finishing ring 30 may be located adjacent the first end 14 of the rigid layer 12 to provide a finished edge to the outside of the cannula 10.

As shown in figure 6, outlet fitting 36 is disposed in the axially extending end 20 to receive a threaded end of a tube 40 which delivers the blood to the ventricle assist device or blood pump 50. The ventricle assist device 50 may comprise a centrifugal pump or other pump which is known and readily apparent to those skilled in the art. The ventricle assist device further comprises an outlet tube 60 which is connected to the artery of a patient, and an electrical connector 70 for connection to a power source. The outlet fitting 36 (which is an inlet fitting in relation to the ventricle assist device) is preferably made of a titanium alloy. Clamp ring 38 retains the outlet fitting 36 in place, and is threaded to receive a corresponding threaded tube. The fixation ring 28 also clamps down on the outlet fitting 36 to provide a tight seal therebetween. A wire cage 40 is provided at the inflow end 15 of the cannula 10 to ensure the inflow end 15 remains in an open position, i.e., to prevent the ingress of tissue into the cannula due to the suction force of the ventricle assist device.

The clamping of the cannula 10 is as follows. As shown on Fig. 1, the sleeve 22 is in the cover position and covers the axially extending end 20 of the flexible tube 18. In this manner the cannula 10 is protected by the rigid layer 12 and the sleeve 22. Thus the cannula 10 avoids inadvertent closure due to pressure applied by internal organs, and also avoid kinking. When it is desired to clamp the cannula, the sleeve 22 is uncoupled from the fixation ring 28, and slid axially along the rigid layer 12 to the uncover position, as shown in Fig. 2. This leaves the axially extending end 20 of the flexible tube 18 exposed. A clamp 44, as shown in Fig. 2, may then be placed over the axially extending end 20 to block fluid flow through the cannula 10. When it is desired to allow flow to resume through the cannula 10, the clamp 44 is removed, and the tube 18 returns to its original form as shown in Fig. 1. The tube may return to its original shape by either the natural tendency of the tube, or the pressure of the blood in the cannula. The sleeve 22 may then be returned to the cover position and attached to the fixation ring 28. Various means may be used for moving the sleeve between the covered and uncovered position. For example, the sleeve 22 may be a split sleeve, thereby allowing it to be completely removed from the cannula 10.

It is to be further understood that several variations may be made without departing from the scope of the invention. For example, the sleeve 22 need not cover the entire axially extending end 20 of the flexible tube, but preferably covers substantially all of the end 20 when in the closed position to provide protection to the end 20 from kinking or closure.

Furthermore, when in the uncovered position, the sleeve 22 may still cover a portion of the axially extending end 20. It is only required that enough of the axially extending end 20 be uncovered so as to allow the clamp 44 to be placed thereon. Furthermore, in an alternate embodiment the flexible tube 18 does not extend to the second end 16 of the rigid layer 12, and extends only to the first end 14.

Additionally, the radial orientation of the rigid layer 12 and the flexible tube 18 may be reversed such that the flexible tube 18 is radially outward of the rigid layer 12. However, care must be taken to ensure that the inner surface of the cannula 10 remains as blood compatible as possible. It is also within the scope of the present invention to have a cannula having a generally rigid section and a generally flexible section. In this case, the rigid section and flexible section are not necessarily different layers, but may different materials, or the same material having a different stiffness or rigidity. For example, the rigid section may be made from generally the same material as the flexible section, but the rigid section of the cannula may be treated so as to have increased stiffness, or may have chemicals added to it to make it stiffer. Alternately, the flexible section may instead be treated in order to make it more flexible, or both sections may be treated. In another embodiment, the flexible section may consist of a flexible material, and the rigid section may be made of the same material, but have a wire mesh, wire strands, or other stiffeners incorporated in the material to add stiffness to the rigid section.

As a further variation, the clampable portion of the cannula 10 may be located in the middle of the cannula. In this embodiment the cannula 10 may have a rigid layer 12 having a discontinuity or area of weakness formed therein, and the flexible tube 18 spans the discontinuity or area of weakness. The flexible tube 18 may or may not extend the entire length of the cannula. The rigid layer 12 may thus has a first portion and a second portion separated by the discontinuity. In this embodiment the sleeve 22 is moveable from a covered position, wherein it covers the exposed flexible tube 18, to an uncovered position, where the flexible tube 18 is exposed and enabled to be clamped.

An alternate embodiment of the sleeve 22 of the present invention is shown in Figs. 3-5 as sleeve 22'. In this embodiment, the sleeve 22' has a telescopic shape and is comprised of two or more portions, for example portions 22'a, 22'b and 22'c are illustrated in the figures. The portions 22a,22b,22c are sized and configured such that they telescopically engage with a mating section. The telescopic shape allows the sleeve to be used with cannulas that have limited axial lengths. The telescoping shape allows the sleeve to move axially such that the three portions 22'a, 22'b, and 22'c radially overlap to expose part of the

flexible tube 18 for clamping (Fig. 4). Each telescopic portion preferably has an inner diameter sized to closely receive the flexible portion when in the closed position to eliminate gaps between the sleeve and the flexible tube 18. It is also desired to have relatively thick walls in the clampable portion of the cannula to increase the elasticity of the clampable portion. This is done to ensure that the clampable portion returns to its fully open shape when the clamp is removed, and also to ensure it remains in its fully open position when blood is flowing therethrough. In particular, it is desirable to avoid closure of the cannula due to pressure of adjacent internal organs, kinking, and closure due to differential pressure between the inside of the cannula and the surrounding environment. As shown in Fig. 5, the sleeve 22' has some flexibility to bend at an angle **A** to enable molding of the cannula in desired position. The flexible tube is shown in Figs 3 and 4 as including a plurality of grooves on its inner surface to increase the flexibility of the flexible tube 18.

The operation and installation of the cannula 10 may now be described as follows. Prior to installation of the cannula in a patient during open heart surgery, the sleeve 22 of the cannula 10 is moved from its covered position to the uncovered position in order to expose the flexible tube 18. A clamp 44 or other equivalent device is then used to clamp or close off the tube to prevent fluid flow therethough. The second end 16 of the cannula 10 may now be inserted into the ventricle of the patient's heart and the cuff 32 sewn to the adjacent heart tissue. It is important to note that use of the heart lung machine and heart immobilizing procedure is no longer needed due to the unique clamping feature of the invention, which prevents blood from flowing out of the first end of the cannula 10. Prior art cannulas do not provide for this unique clamping feature, so that a heart lung machine is necessary. The surgeon may then verify whether any blood leakage has occurred around the vicinity of the cuff 32 prior to installing the ventricle assist device.

Next, one end of an outflow cannula 60 is sutured to the artery of the patient, and then the other end is connected to the ventricle assist device. Once the ventricle assist device has been properly connected to the cannula and heart of the patient, the surgeon can release the clamp to ensure the device is operating properly and that no blood leakage has occurred. Once the clamp is removed, the sleeve 22 of the cannula 10 may be moved and secured into the closed position. Should the device need future maintenance, it is important to note that the clamping feature may be again utilized in order to replace the ventricle assist device without the need for the heart lung machine and the drug therapy.

The preferred form of the cannula has been described above. However, with the present disclosure in mind it is believed that obvious alterations to the preferred

embodiments, to achieve comparable features and advantages, will become apparent to those of ordinary skill in the art.

What is claimed is:

1. A clampable cannula comprising:

a generally rigid layer having a first end;

a generally flexible tube generally coaxial with said rigid layer, said flexible tube extending axially in a first direction beyond said first end; and

a generally rigid sleeve movable between a cover position wherein said sleeve covers a first part of said flexible tube and an uncovered position wherein said sleeve does not cover said first part of said flexible tube to enable clamping of said cannula.

2. The cannula of claim 1 wherein said flexible tube is located radially inwardly of said rigid layer.

3. The cannula of claim 2 wherein said flexible tube extends in a second direction from said first end, thereby extending inside said rigid layer.

4. The cannula of claim 3 wherein said flexible tube extends substantially the entire length of said cannula.

5. The cannula of claim 1 wherein said flexible tube is coupled to said rigid layer.

6. The cannula of claim 1 wherein said sleeve is axially slidable along said rigid layer.

7. The cannula of claim 1 further comprising retainer means for securing said sleeve in said cover position.

8. The cannula of claim 7 wherein said retainer means includes cooperating threads on said sleeve and on said flexible tube.

9. The cannula of claim 8 wherein said retainer means further includes a threaded fixation ring coaxially mounted on said flexible tube, said fixation ring being located so as to receive said threads on said sleeve when said sleeve is in said cover position.

10. The cannula of claim 1 wherein said sleeve is made from a titanium alloy.

11. The cannula of claim 1 wherein said rigid layer is moldable.

12. The cannula of claim 1 wherein said flexible tube is polyurethane.

13. The cannula of claim 12 wherein said flexible tube has a biocompatible surface.

14. The cannula of claim 12 wherein said flexible tube has a blood compatible inner surface.

15. The cannula of claim 1 wherein said rigid layer is a titanium alloy.

16. The cannula of claim 1 further comprising a sealing ring on said first end of said rigid layer.

17. The cannula of claim 16 wherein said sealing ring is made from a titanium alloy.

18. The cannula of claim 1 wherein said cannula has an inlet and outlet and wherein said cannula further includes an outlet fitting on said outlet.

19. The cannula of claim 18 further comprising a wire cage coupled to said inlet.

20. The cannula of claim 1 further comprising a flexible cuff adjacent said rigid layer for attaching said cannula to soft tissue.

21. The cannula of claim 20 wherein said sleeve is formed of two or more portions which telescopically engage each other.

22. The cannula of claim 1 wherein said rigid layer has a blood compatible coating on its outer surface.

23. A clampable cannula comprising:

a generally rigid outer layer;

a generally flexible tube generally coaxial with said rigid layer and radially inward of said outer layer, said flexible tube having an underlay portion overlapping with said rigid layer and an exposed portion extending axially beyond said rigid layer; and

a generally rigid sleeve comprised of two or more portions which telescopically engage with each other and cooperate such that the sleeve is movable between a cover position wherein said sleeve generally covers said exposed portion and an uncovered position wherein said sleeve generally does not cover said exposed portion.

24. A clampable cannula comprising:

a generally rigid section having a discontinuity; and

a generally flexible section spanning said discontinuity such that said cannula may be clamped at said generally flexible section.

25. The cannula of claim 24 further comprising a generally rigid sleeve movable from a cover position wherein said sleeve generally covers said flexible section to an uncover position wherein said sleeve generally does not cover said flexible section.

26. The cannula of claim 24 further comprising a sleeve movable from a cover position wherein said flexible section is protected from closure to an uncover position wherein said flexible section is able to be clamped.

27. The cannula of claim 25 wherein said sleeve is axially slidable along said rigid section.

28. The cannula of claim 25 further comprising means for retaining said sleeve in said cover position.

29. The cannula of claim 28 wherein said retaining means includes cooperating threads on said sleeve and on said rigid section.

30. A method for implanting a cannula and ventricle assist device to the heart of a patient, the method comprising the steps of :

moving a sleeve of the cannula into an uncovered position so that a flexible section of said cannula is exposed;

clamping the flexible section;

installing an end of a cannula into the heart;

connecting the ventricle assist device to the cannula; and

unclamping the flexible section.

31. A method for implanting a cannula and ventricle assist device to the heart of a patient, the method comprising the steps of :

clamping a flexible section of the cannula;

installing an end of a cannula into the heart;

connecting the ventricle assist device to the cannula; and

unclamping the flexible section.

32. The method of claim 31 further comprising the steps of moving the sleeve of the cannula into a covered position so that the flexible section of said cannula is covered.

33. A ventricle assist device comprising:

a cannula having a generally rigid outer layer; a generally flexible tube generally coaxial with said rigid layer and radially inward of said outer layer, said flexible tube having an underlay portion overlapping with said rigid layer and an exposed portion extending axially beyond said rigid layer;

a blood pump and means for supplying power to said pump.

34. The device of claim 33 wherein said cannula further comprises a generally rigid sleeve movable between a cover position wherein said sleeve generally covers said exposed portion and an uncovered position wherein said sleeve generally does not cover said exposed portion.

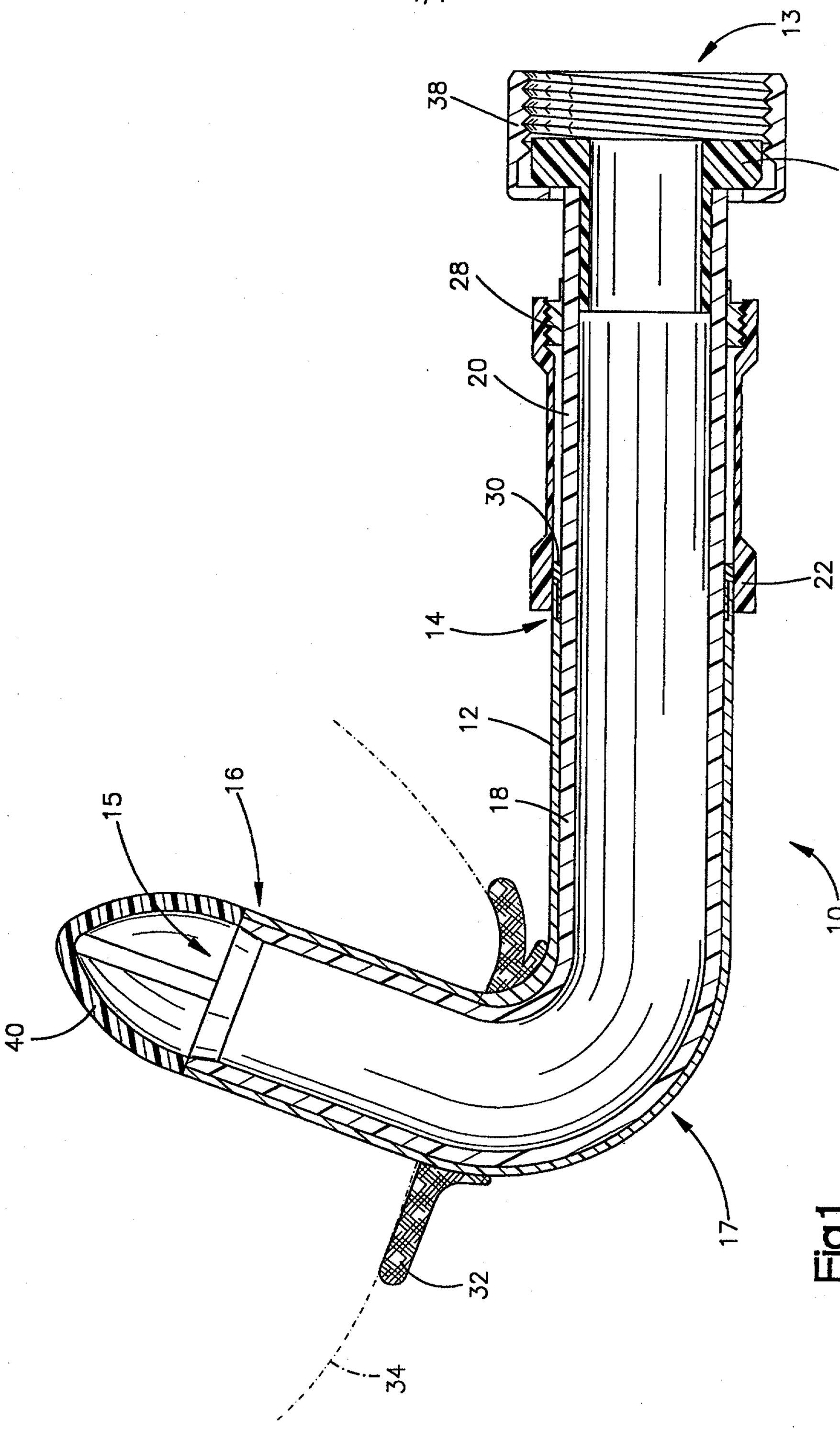


Fig.1

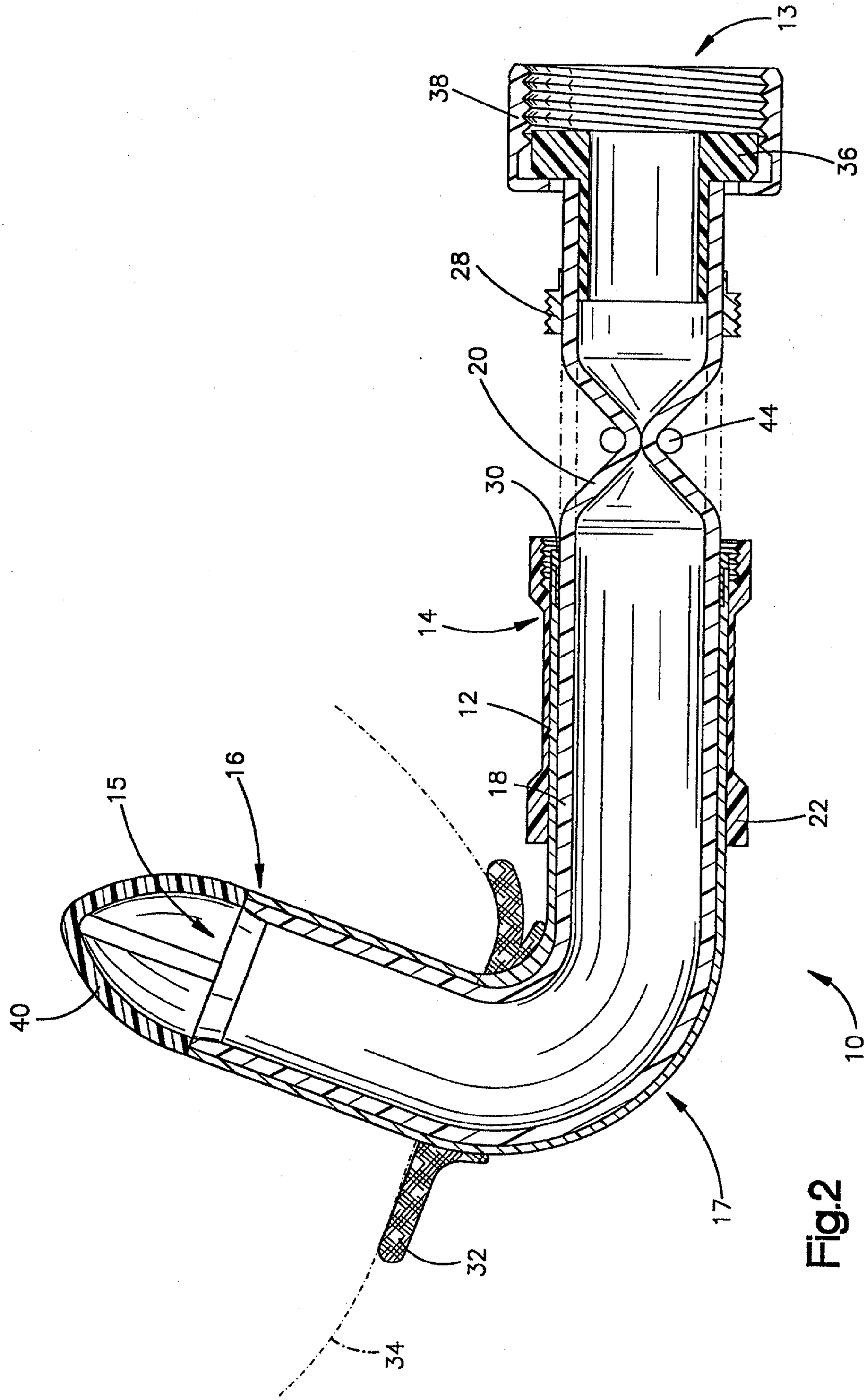


Fig.2

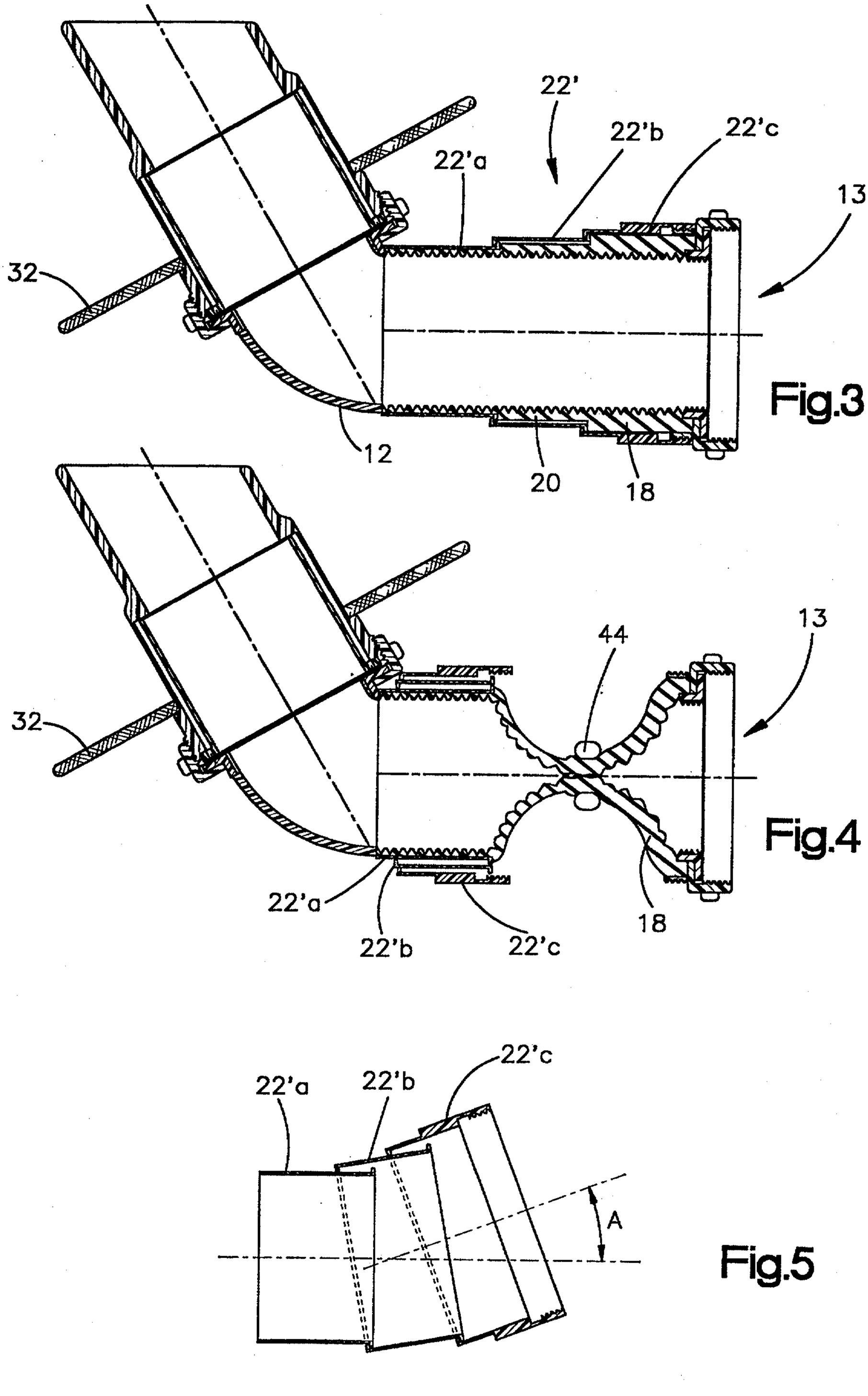


Fig.3

Fig.4

Fig.5

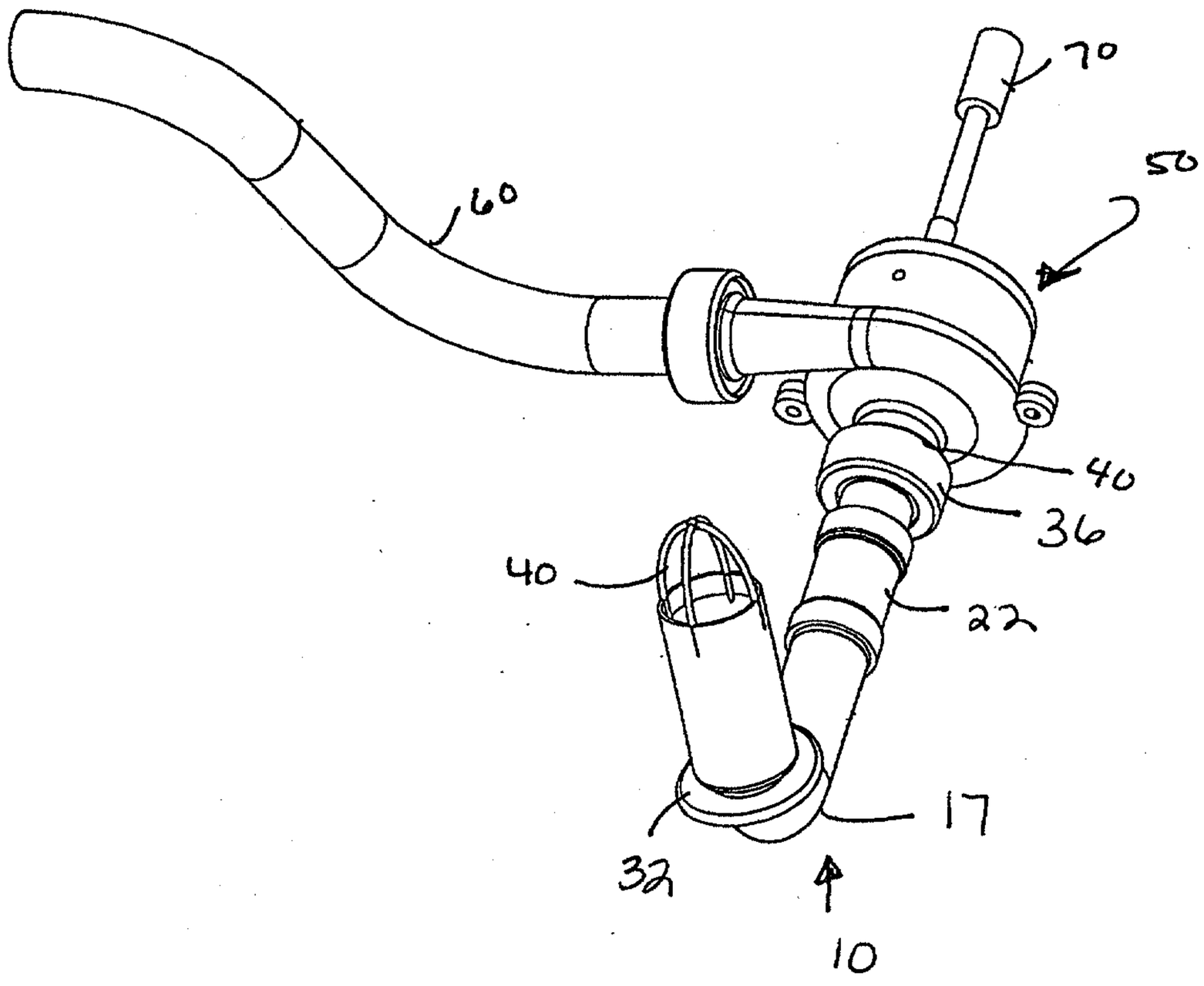
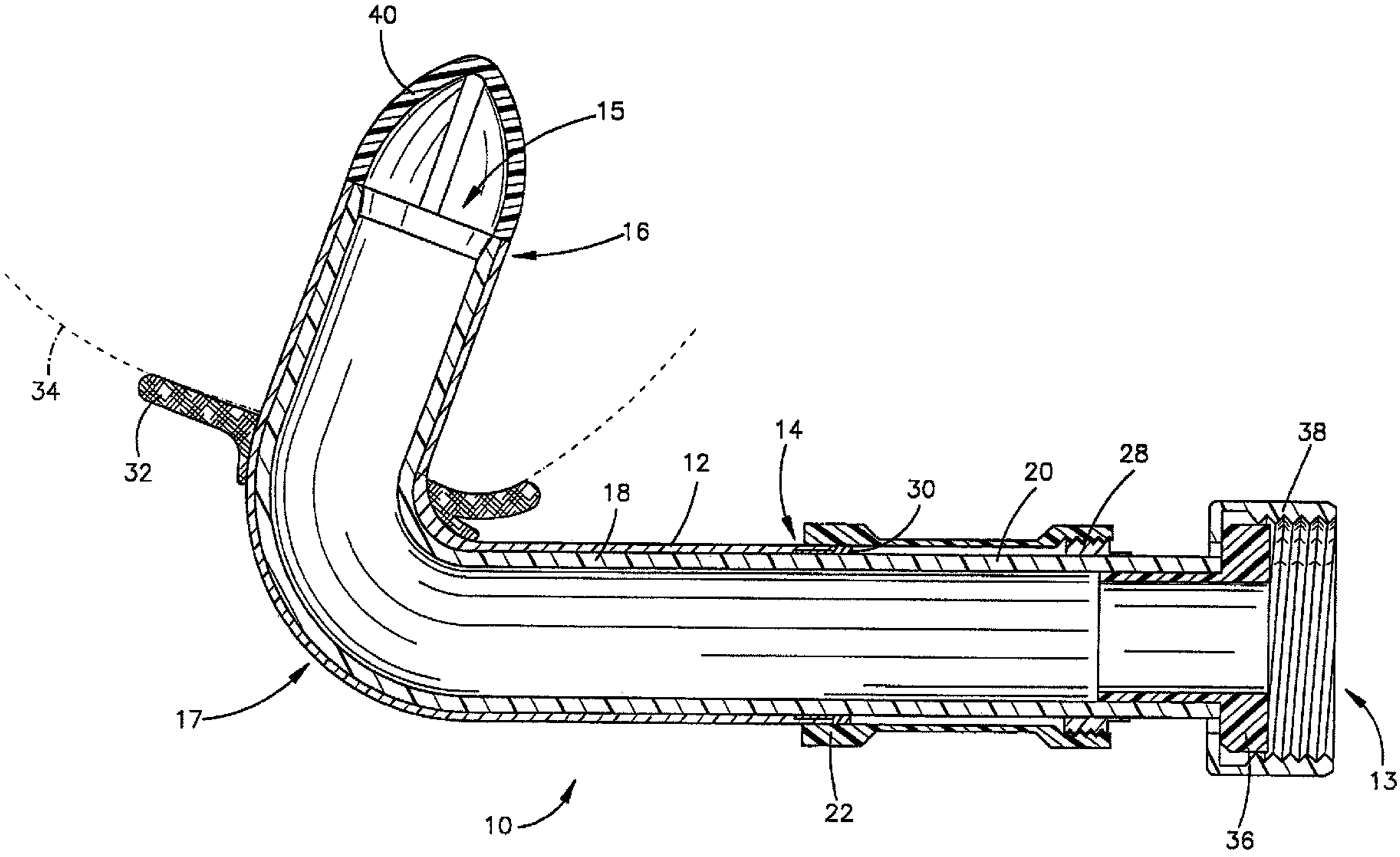


Figure 6


40
15
16
34
32
14
38
28
12
18
30
20
17
22
10
36
13