(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
13 September 2007 (13.09.2007)

PCT

(10) International Publication Number
WO 2007/103239 A2

(51) International Patent Classification:
A61M 29/00 (2006.01)

(21) International Application Number:
PCT/US2007/005478

(22) International Filing Date: 2 March 2007 (02.03.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
11/367,607 2 March 2006 (02.03.2006) US

(71) Applicant *(for all designated States except US)*: **KMS DEVELOPMENT LLC** [US/US]; 7290 S.W. 42nd Street, Miami, FL 33155 (US).

(72) Inventors: **SMITH, Kevin**; 750 Arvida Parkway, Coral Gables, FL 33156 (US). **DEVILLE, Derek**; 5730 S.W. 34 Street, Miami, FL 33155 (US). **KLINE, Korey**; 7028 S.W. 65th Avenue, Miami, FL 33143 (US). **PALMER, Matthew**; 12790 S.W. 64th Court, Miami, FL 33156 (US).

(74) Agents: **GREENBERG, Laurence, A.** et al.; Lerner Greenberg Stemer LLP, P.O. Box 2480, Hollywood, FL 33022-2480 (US).

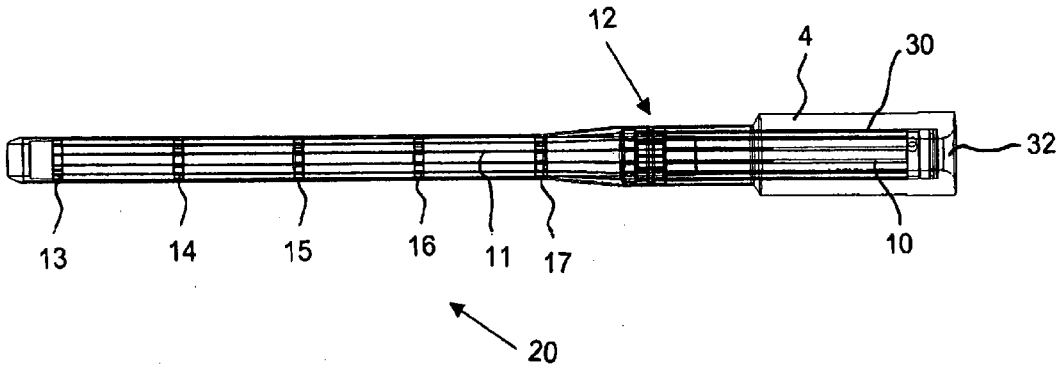
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: VARIABLY FLEXIBLE INSERTION DEVICE AND METHOD FOR VARIABLY FLEXING AN INSERTION DEVICE



(57) Abstract: A variably flexible insertion device (1) includes a hollow body (4, 6, 7, 30, 35, 36) having a proximal end (2) with an entrance (32) for receiving an instrument (38) and a distal end (3) with a tip (7) for protrusion of the instrument (38) . A device (5) transitions the hollow body (4, 6, 7, 30, 35, 36) between a relatively flexible condition and a relatively stiff condition. Tendons (11) within the hollow body (4, 6, 7, 30, 35, 36) maintain the hollow body (4, 6, 7, 30, 35, 36) in the relatively flexible and relatively stiff conditions. A method for variably flexing an insertion device for receiving an instrument includes providing a hollow body having inner and outer sleeves defining a space therebetween in which tendons are disposed. Suction is applied to create a vacuum in the space for frictionally locking the tendons in place between the sleeves in a relatively stiff condition of the hollow body. The vacuum is relieved to release the tendons in a relatively flexible condition of the hollow body.

WO 2007/103239 A2

Description

VARIABLY FLEXIBLE INSERTION DEVICE AND METHOD FOR VARIABLY FLEXING AN INSERTION DEVICE

Technical Field:

The invention relates to a variably flexible insertion device and to a method for variably flexing an insertion device. The insertion device may be used to insert an instrument, in particular a scope, such as an endoscope or a colonoscope, into a patient.

Background Art:

Various insertion devices for scopes are known in the art. For example, U.S. Patent No. 6,942,613 to Ewers et al. discloses a shape lockable apparatus and method, in which nestable elements of an overtube are linked by elastic tension wires connected to an actuator to selectively stiffen the overtube for advancing an instrument. Similarly, U.S. Patent No. 5,759,151 to Sturges uses a spine having cylindrical segments interconnected by a flexible cable. The cable is secured to a controller for selectively stiffening and relaxing the spine. The Ewers et al. and Sturges devices are complicated and have only elastic tension wires or a flexible cable to maintain stiffness.

U.S. Patent Nos. 6,984,203 and 6,800,056 to Tartaglia et al. teach a guide which advances in a distal portion of a steerable endoscope having a segmented body. Related U.S. Patent Nos. 6,468,203 and 6,610,007 to Belson et al. disclose a steerable endoscope with a body, a steering control for a distal portion of the body which selects a path within the patients body and a motion controller for a proximal end of the body which assumes the selected curve. A fiber optic imaging bundle or a video camera are disposed

in the body. The Tartaglia et al. and Belson et al. devices provide no mechanism for variably stiffening the guide.

U.S. Patent No. 5,337,733 to Bauerfeind et al. relates to a tubular inserting device with variable rigidity, in which a flexible insertion part has outer and inner walls defining an intermediate space therebetween. Application of a vacuum to the intermediate space causes the inner wall to lie against the outer wall to render the insertion part rigid. The Bauerfeind et al. device relies merely upon contact between the outer and inner walls for rigidity, with no additional stiffening aid.

ASGE Abstract 136 submitted in 1983 discloses a soft-plastic, split, stiffening overtube to be placed over a colonoscope at any point during the examination.

Disclosure of the Invention:

It is accordingly an object of the invention to provide a variably flexible insertion device and a method for variably flexing an insertion device, which overcome the hereinafore-mentioned disadvantages of the heretofore-known devices and methods of this general type and in which the device and method are simpler, have more varied uses and are more reliable than the prior art.

With the foregoing and other objects in view there is provided, in accordance with the invention, a variably flexible insertion device. The device comprises a hollow body having a proximal end with an entrance for receiving an instrument, such as a scope, and a distal end with a tip for protrusion of the instrument. A device is provided for transitioning the hollow body between a relatively flexible condition and a relatively stiff condition. Tendons are disposed within the hollow body for maintaining the hollow

body in the relatively flexible and relatively stiff conditions.

With the objects of the invention in view, there is also provided a method for variably flexing an insertion device for receiving an instrument. The method comprises providing a hollow body having inner and outer sleeves defining a space therebetween and providing tendons in the space. Suction is applied to create a vacuum in the space for frictionally locking the tendons in place between the inner and outer sleeves in a relatively stiff condition of the hollow body. The vacuum is relieved to release the tendons in a relatively flexible condition of the hollow body.

In accordance with another feature of the invention, the hollow body has an inner sleeve and an outer sleeve defining a space therebetween at least partly surrounding the tendons, and the transitioning device, such as a vacuum port communicating with said space, applies suction to the space for frictionally locking the tendons in place. Vertebrae may be disposed within the hollow body for guiding the tendons.

In accordance with a further feature of the invention, the hollow body has a handle and a flexible section with a given length. The tendons extend substantially entirely over said given length. The tendons float in said handle when said hollow body is in said relatively flexible condition, but are rigidly attached at said distal end. The tendons are not under tension both in said relatively flexible and in the relatively stiff conditions.

In accordance with an added feature of the invention, vertebrae are disposed within said hollow body for guiding said tendons. The vertebrae include a distal-most vertebra at which said tendons are attached.

In accordance with an additional feature of the invention, the hollow body may have a longitudinal slit formed therein for radially loading the hollow body onto the instrument. The slit may be sealed by a closure, such as a slide or press zipper used for plastic storage bags, permitting the device to be resealed after the hollow body has been loaded.

In accordance with yet another feature of the invention, the hollow body has a coil for maintaining a circular cross section. The coil may be a bookbinding-type coil to permit loading of the hollow body on the instrument. Such a bookbinding-type coil is known as a ring wire, double wire, double loop or twin loop binding.

In accordance with yet a further feature of the invention, the hollow body has a handle, a distal end cap to accommodate differently sized instruments, and a flexible portion having a predetermined length in a longitudinal direction between said handle and said distal end cap. The hollow body and said tendons extend entirely along said predetermined length.

In accordance with yet an added feature of the invention, locking pads encircle said tendons in a friction lock area transversely to said longitudinal direction for frictionally locking said tendons in place in addition to said friction locking by said inner and outer sleeves.

In accordance with a concomitant feature of the invention, the handle is an outer handle and the hollow body has an inner handle within said outer handle. The inner handle has channel grooves permitting movement of said tendons. The inner handle has a groove formed therein receiving an O-ring for sealing a space between said outer handle and said inner handle.

Therefore, according to the invention, both a transitioning device using a vacuum to cause contact between the inner and outer sleeves and tendons supporting the stiffening but being free of tension, are combined to enhance the reliability of the device. The capability of loading the hollow body onto the instrument at any time during a procedure also exists by virtue of the slit in the hollow body.

Other features which are considered as characteristic for the invention are set forth in the appended claims.

Although the invention is illustrated and described herein as embodied in a variably flexible insertion device and a method for variably flexing an insertion device, it is nevertheless not intended to be limited to the details shown, since various modifications and structural changes may be made therein without departing from the spirit of the invention and within the scope and range of equivalents of the claims.

The construction and method of operation of the invention, however, together with additional objects and advantages thereof will be best understood from the following description of specific embodiments when read in connection with the accompanying drawings.

Brief Description of the Drawings:

Fig. 1 is a diagrammatic, side-elevational view of a variably flexible insertion device according to the invention;

Fig. 2 is a view similar to Fig. 1 showing details of the interior of the insertion device of the invention;

Fig. 3 is an enlarged, fragmentary, perspective view showing inner and outer handles, locking pads and tendons of the insertion device of the invention;

Fig. 4 is a view similar to Fig. 3, showing the inner and outer handles and a friction surface and grooves for the tendons;

Fig. 5 is a perspective view of a portion of the insertion device of the invention, showing details of the inner and outer handles;

Fig. 6 is an enlarged, fragmentary, side-elevational view of a nose tip and tendons of the insertion device of the invention;

Fig. 7 is a fragmentary, perspective view of the nose tip showing details of the tendons and vertebrae;

Fig. 8 is a fragmentary, longitudinal-sectional view of the nose tip and vertebrae;

Fig. 9 is an enlarged, fragmentary, perspective view of the tendons over a friction zone;

Fig. 10 is a fragmentary, perspective view illustrating the tendons in transition and locking;

Fig. 11 is a fragmentary, perspective view showing the locking pads for the tendons;

Fig. 12 is a fragmentary, longitudinal-sectional view of the handle;

Fig. 13 is a fragmentary, longitudinal-sectional view of a handle locking area;

Fig. 14 is a cross-sectional view taken along a line XIV- XIV of Fig. 3, through the handle assembly during transition;

Fig. 15 is a cross-sectional view taken along a line XV-XV of Fig. 10, through the vertebrae with the tendons;

Fig. 16 is a cross-sectional view taken along a line XVI-XVI of Fig. 3, through the vertebrae with the tendons;

Fig. 17 is a fragmentary, side-elevational view of the device in a flexed condition, showing the nose tip, the vertebrae and the effect of bending on the tendons;

Fig. 18 is a view similar to Fig. 1, showing a slit hollow body with a zipper closure; and

Fig. 19 is a perspective view of a coil used with the embodiment of Fig. 18.

Best Mode for Carrying out the Invention:

Referring now to the figures of the drawings in detail and first, particularly, to Fig. 1 thereof, there is seen a variably flexible insertion device 1 according to the invention. The insertion device 1 has a hollow body with a proximal end 2 for manipulation by an operator and for receiving an instrument 32 such as an endoscope or colonoscope seen in Fig. 5. The insertion device 1 also has a distal end 3 for insertion into a patient and for protrusion of the instrument 32. An outer handle 4 of the hollow body for the operator is disposed at the proximal end 2. The handle 4 has a vacuum port 5 formed therein. An outer sleeve 6 of the hollow body is disposed between the outer handle 4 and a nose tip 7 of the hollow body at the distal end 3. The outer sleeve 6 provides a flexible section with a given length extending beyond the handle 4.

Fig. 2 shows that the outer handle 4 contains an inner handle 30 of the hollow body having channel grooves 10 which permit movement of tendons 11. The tendons 11 extend substantially entirely over the given length of the flexible section provided by the outer sleeve 6. The tendons 11 may have a rounded or flattened cross section or a flattened cross section twisted along its length. A friction lock area 12 is disposed within the outer sleeve 6 for locking the tendons 11 in a manner to be discussed below. Vertebrae 13-17 are distributed along a flexible area 20 which is approximately 30 inches long. Whereas the vertebrae 14-17 allow movement of the tendons 11, the first vertebra 13

closest to the distal end 3 is fixed to the tendons 11. Although six vertebrae are shown, it is understood that more or fewer vertebrae may be provided, for example eight vertebrae, depending on the length of the device 1. The number of tendons 11 is also variable, although twelve is used as an example.

As is seen in Fig. 3, a ring of locking pads 25 encircles the friction lock area 12. Each tendon 11 is assigned a respective locking pad 25, which is clearly shown in Fig. 16. The tendons 11 are disposed between the locking pads 25 and a friction surface 26 shown in Figs. 4 and 16. The friction surface 26 is part of the inner handle 30 having the grooves 10 in which the tendons 11 move.

Fig. 5 illustrates the outer handle 4 as well as the inner handle 30 with the channel grooves 10 for the tendons 11. The outer handle 4 is shown as being transparent in Fig. 5, so as to be able to illustrate an entrance 32 for the surgical instrument 38, such as an endoscope or colonoscope, a groove 33 for receiving an O-ring and the vacuum port 5.

Fig. 6 shows the region of the nose tip 7. The tendons 11 are fixed and welded to the first vertebra 13. Fig. 7 also shows the tendons 11 fixed to the first vertebra 13 as well as the second vertebra 14 under which the tendons are free to move in the channel grooves 10 formed in the inner handle 30.

The sectional view of Fig. 8 illustrates the outer sleeve 6, the nose tip 7, two tendons 11, as well as the tendons being welded to the first vertebra 13 and being freely movable in the second vertebra 14. An inner sleeve 35 of the hollow body is also shown in Fig. 8. Fig. 8 additionally shows an end cap 37 to be snapped-on at the

distal end to accommodate different sized instruments or scopes 38.

Fig. 9 shows how the tendons 11 are freely movable in the channel grooves 10 in the inner handle 30 and pass over the friction surface 26.

Fig. 10 also shows the friction locking pads 25, the inner handle 30 with the grooves 10 and the tendons 11 passing through the grooves 10 and under the fifth vertebra 17. The cross section of the vertebra 17 illustrated in Fig. 15 additionally shows a coil 36 of the hollow body disposed within and supporting the inner sleeve 35. The coil may be a wire which is TEFLON- or hydrophilic-coated to ease insertion of an endoscope or colonoscope. The stiffness or spring constant k of the coil 36 tends to maintain the device 1 in a straight condition. However, as will be explained in detail below, the device 1 does not remain straight when held horizontal in its flexible state. The coil 36 is used to maintain the round cross section of the device 1 while it is flexed.

The view of Fig. 11 shows the tendons 11 passing through the channel grooves 10 formed in the inner handle 30 and under the friction locking pads 25. The tendons 11 are freely movable in the channel grooves 10, except when pinched between the friction locking pads 25 and the friction surface 26 in the friction lock area 12.

The cross-sectional view of Fig. 12 shows an O-ring 31 disposed in the groove 33. Fig. 14 shows a space 34 between the outer handle 4 and the inner handle 30. The space 34 is sealed by the O-ring 31 and communicates with the vacuum port 5 for applying positive and negative pressure (vacuum) to the space.

Fig. 13 is a cross-sectional view illustrating details of the friction lock area 12. It may be seen that the

tendons 11 which pass below the vertebrae 16, 17 are pinched between the friction locking pads 25 and the friction surface 26 in the friction area 12.

According to another embodiment of the invention which is illustrated in Fig. 18, the hollow body 4, 6, 7, 30, 35, 36 has a longitudinal slit 39 formed therein for radially loading the hollow body onto the instrument 38. The slit has a closure 40, such as a slide or press zipper used for plastic storage bags, permitting the device to be resealed after the hollow body has been loaded. The coil in this case is a ring wire, double wire, double loop or twin loop binding 41 seen in Fig. 19, such as is used for notebooks.

The operation of the variably flexible insertion device 1 is best understood by making reference to Fig. 17 in conjunction with the above-described figures. After the device 1 is forced into a flexed condition against the stiffness or spring constant k of the coil 36 as seen in Fig. 17, for example upon traversing the rectosigmoid junction, and it is desired to maintain that flexed condition for guiding an endoscope, such as a colonoscope, vacuum is applied to the space 34 through the vacuum port 5. When suction is applied to create the vacuum, it causes the inner sleeve 35 and the outer sleeve 6 to firmly contact each other with the tendons 11 sandwiched and frictionally locked therebetween. Therefore, the vacuum port 5 acts as a device for transitioning the hollow body 4, 6, 7, 30, 35, 36 between the relatively flexible condition and the relatively stiff condition through the application of a vacuum. Most of the stiffness causing the device 1 to maintain its flexed condition is accomplished by this interaction of the inner and outer sleeves and the tendons. However, additional stiffness may optionally be accomplished by providing the friction locking pads 25 which contract and hold the tendons

11 against the friction surface 26 in the friction area 12. The device 1 therefore maintains its flexed condition. Fig. 17 shows that in the flexed condition, the tendons 11 at the outer periphery of the bend become shorter and the tendons 11 at the inner periphery of the bend become longer, since they are all fixed in place at the first vertebra 13.

The tendons or wires 11 are passive elements which are not in tension at any time. The tendons float within the hollow body when it is in the flexible condition, except at the distal end. The tendons are frictionally locked by the inner sleeve 35 and the outer sleeve 6 when the hollow body is in the stiff condition. However, in both the relatively flexible condition and the relatively stiff condition, the tendons have no active control imposed on them and are not pulled or constrained.

When it is desired to resume flexibility of the device 1, the vacuum in the space 34 is replaced by air at ambient or positive pressure. This causes the inner sleeve 35 and the outer sleeve 6 to release the tendons 11 and allows the stiffness or spring constant k of the coil 36 to place the device 1 into its normally flexible condition. If friction locking pads 25 are used, they also relax and expand, which in turn releases the tendons 11.

The device is intended to be used in a manner similar to prior art devices. Therefore, the device will be placed over the endoscope. The endoscope will then be inserted into the rectum. The device will then be pushed in its flexible condition, to follow the curvature of the scope. The device will then be stiffened, allowing the scope to be pushed forward with less pressure exerted on the colon of the patient. This procedure can be repeated until the scope reaches the cecum.

An alternative use of the device is to aid in small bowel endoscopy. The device is placed over the endoscope. The endoscope is inserted into the patient transorally, through the stomach and then partially into the small bowel. The device is then pushed in its flexible condition, to follow the curvature of the scope. The device is then stiffened, allowing the scope to be pushed forward without the scope looping in the stomach.

Another use of the device is for aiding in access to internal body parts, such as the gallbladder, through an opening of an internal body cavity, such as the stomach. The device is placed over the endoscope. The endoscope is inserted into the patient transorally, through the stomach and then up against the internal surface of the stomach. The device is then pushed in its flexible condition, to follow the curvature of the scope. The device is then stiffened, allowing the surgeon to create an opening in the stomach wall without the scope looping in the stomach. Once the opening is created, the device and the scope can be advanced outside the stomach. The device can then be stiffened to create a stable platform to perform surgical procedures outside of the stomach. The device could contain one or more features (i.e. balloons) for sealing the outer periphery of the device to the stomach wall to prevent gastric fluids from exiting the stomach.

According to the other embodiment of the invention, the device is capable of being loaded on the instrument or scope after the scope is inserted into the patient. In this embodiment, the slit down the length of the device allows it to be loaded on the scope so that the scope is inserted radially into the hollow body.

Claims

1. A variably flexible insertion device, comprising:

a hollow body having a proximal end with an entrance for receiving an instrument and a distal end with a tip for protrusion of the instrument;

a device for transitioning said hollow body between a relatively flexible condition and a relatively stiff condition; and

tendons disposed within said hollow body for maintaining said hollow body in said relatively flexible and relatively stiff conditions.

2. The device according to claim 1, wherein said hollow body has an inner sleeve and an outer sleeve defining a space therebetween at least partly surrounding said tendons, and said transitioning device applies suction to said space for frictionally locking said tendons in place.

3. The device according to claim 1, which further comprises vertebrae disposed within said hollow body for guiding said tendons.

4. The device according to claim 2, wherein said hollow body has a handle and a flexible section with a given length, and said tendons extend substantially entirely over said given length.

5. The device according to claim 4, wherein said tendons float in said handle when said hollow body is in said relatively flexible condition.

6. The device according to claim 1, wherein said hollow body has a handle, and said tendons are rigidly attached at said distal end and allowed to float at said handle.

7. The device according to claim 6, which further comprises vertebrae disposed within said hollow body for guiding said tendons, said tendons being attached to one of said vertebrae.

8. The device according to claim 1, wherein said vertebrae include a distal-most vertebra at which said tendons are attached.

9. The device according to claim 1, wherein said hollow body has a coil for maintaining a circular cross section.

10. The device according to claim 1, wherein said tendons are not in tension or compression when said hollow body is in said relatively stiff condition.

11. The device according to claim 2, wherein said hollow body has a handle, a distal end cap to accommodate differently sized instruments, and a flexible portion having a predetermined length in a longitudinal direction between said handle and said distal end cap, said hollow body and said tendons being extended entirely along said predetermined length.

12. The device according to claim 6, which further comprises locking pads encircling said tendons in a friction lock area transversely to said longitudinal direction for frictionally locking said tendons in place in addition to said friction locking by said inner and outer sleeves.

13. The device according to claim 2, which further comprises locking pads encircling said tendons in a friction lock area for frictionally locking said tendons in place in addition to said friction locking by said inner and outer sleeves.

14. The device according to claim 2, wherein said transitioning device is a vacuum port communicating with said space.

15. The device according to claim 4, wherein said handle is an outer handle, said hollow body has an inner handle within said outer handle, and said inner handle has channel grooves permitting movement of said tendons.

16. The device according to claim 15, wherein said inner handle has a groove formed therein receiving an O-ring for sealing a space between said outer handle and said inner handle.

17. The device according to claim 1, wherein the instrument is a scope.

18. The device according to claim 1, wherein said tendons are not under tension in both said relatively flexible and relatively stiff conditions.

19. A method for variably flexing an insertion device for receiving an instrument, the method comprising the following steps:

providing a hollow body having inner and outer sleeves defining a space therebetween;

providing tendons in the space;

applying suction to create a vacuum in the space for frictionally locking the tendons in place between the inner and outer sleeves in a relatively stiff condition of the hollow body; and

relieving the vacuum to release the tendons in a relatively flexible condition of the hollow body.

20. The method according to claim 19, wherein the hollow body has a handle and the tendons float in the handle when the hollow body is in the relatively flexible condition.

21. The method according to claim 19, which further comprises maintaining a circular cross section of the hollow body with a coil.

22. The method according to claim 19, wherein the tendons are not in tension or compression when the hollow body is in the relatively stiff condition.

23. The method according to claim 19, which further comprises encircling the tendons with locking pads in a friction lock area, and frictionally locking the tendons in

place with the locking pads in addition to the friction locking by the inner and outer sleeves.

24. The method according to claim 19, wherein the instrument is a scope.

25. The method according to claim 19, which further comprises maintaining the tendons in a non-tensioned state in both the relatively stiff and the relatively flexible conditions of the hollow body.

26. A variably flexible insertion device, comprising:

a hollow body having a proximal end with an entrance for receiving a proximal portion of an instrument and a distal end with a tip for protrusion of a distal portion of the instrument, and said hollow body having a longitudinal slit formed therein for radially loading said hollow body onto the instrument;

a device for transitioning said hollow body between a relatively flexible condition and a relatively stiff condition; and

tendons disposed within said hollow body for maintaining said hollow body in said relatively flexible and relatively stiff conditions.

27. The device according to claim 26, wherein said hollow body has an inner sleeve and an outer sleeve defining a space therebetween at least partly surrounding said tendons, and said transitioning device applies suction to said space for frictionally locking said tendons in place.

28. The device according to claim 26, wherein said tendons are not under tension in both said relatively flexible and relatively stiff conditions.

29. The device according to claim 26, wherein said slit has a closure permitting said slit to be resealed after said hollow body has been loaded.

30. The device according to claim 29, wherein said closure is a slide or press zipper.

31. The device according to claim 26, wherein said hollow body has a ring wire coil for maintaining a circular cross section and permitting said hollow body to be loaded.

32. A method for variably flexing an insertion device for receiving an instrument, the method comprising the following steps:

providing a hollow body having inner and outer sleeves defining a space therebetween, the hollow body having a longitudinal slit formed therein;

providing tendons in the space;

loading the hollow body radially onto the instrument through the slit;

applying suction to create a vacuum in the space for frictionally locking the tendons in place between the inner and outer sleeves in a relatively stiff condition of the hollow body; and

relieving the vacuum to release the tendons in a relatively flexible condition of the hollow body.

33. The method according to claim 32, which further comprises maintaining the tendons in a non-tensioned state in both the relatively stiff and the relatively flexible conditions of the hollow body.

34. The method according to claim 32, which further comprises resealing the slit with a closure after the hollow body has been loaded.

35. The method according to claim 34, wherein the closure is a slide or press zipper.

36. The method according to claim 32, which further comprises placing a ring wire coil in the hollow body for maintaining a circular cross section of the hollow body and permitting the hollow body to be loaded.

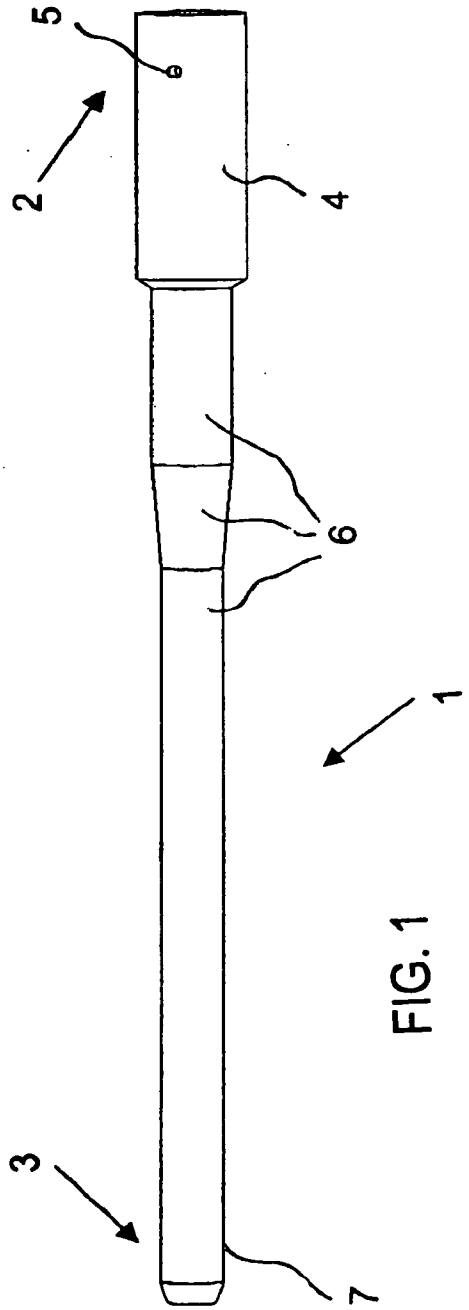


FIG. 1

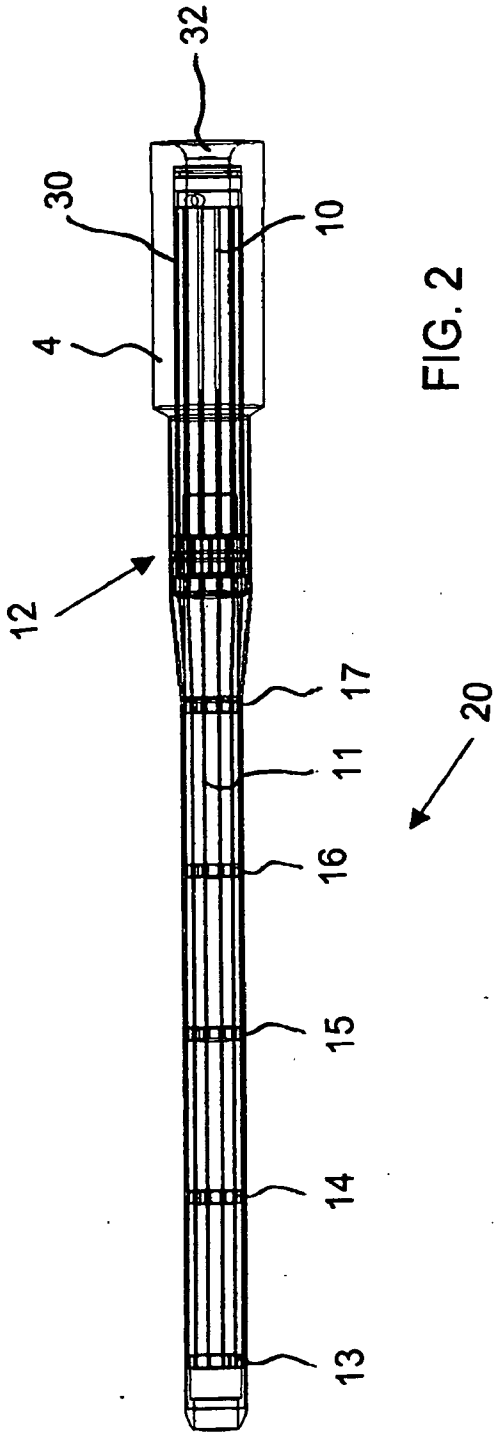


FIG. 2

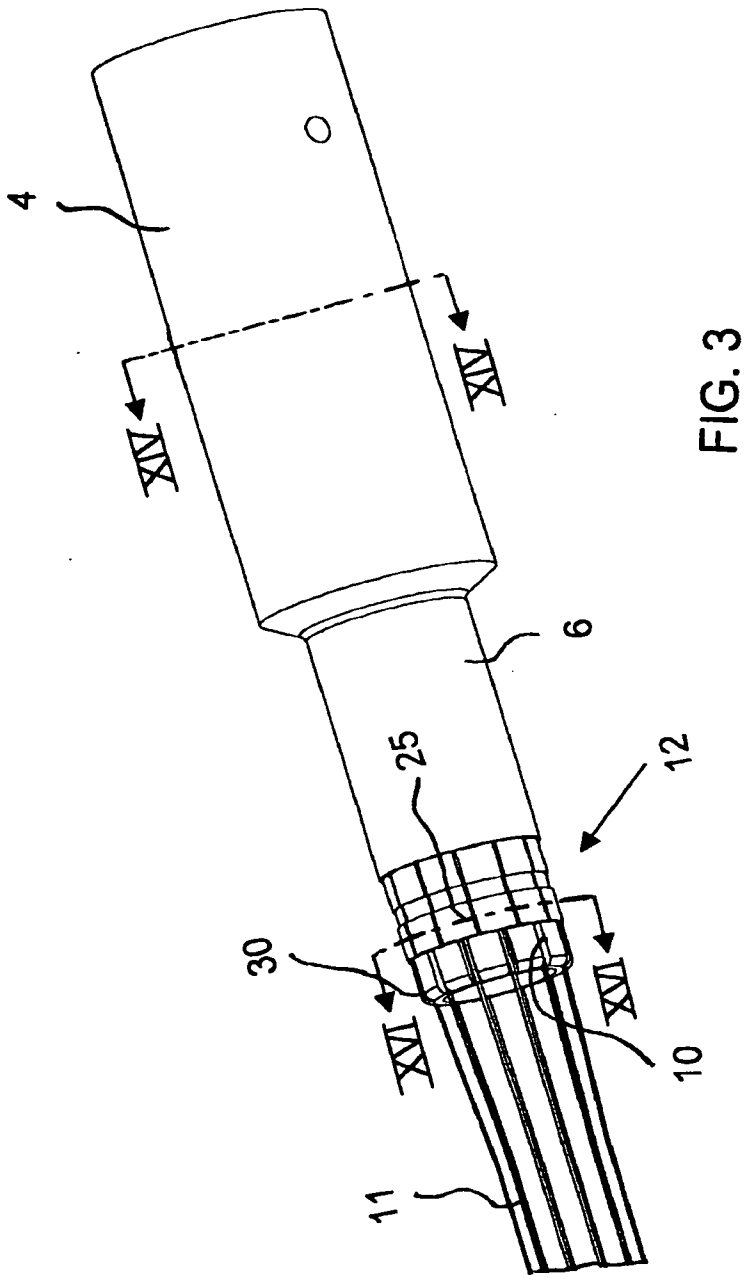


FIG. 3

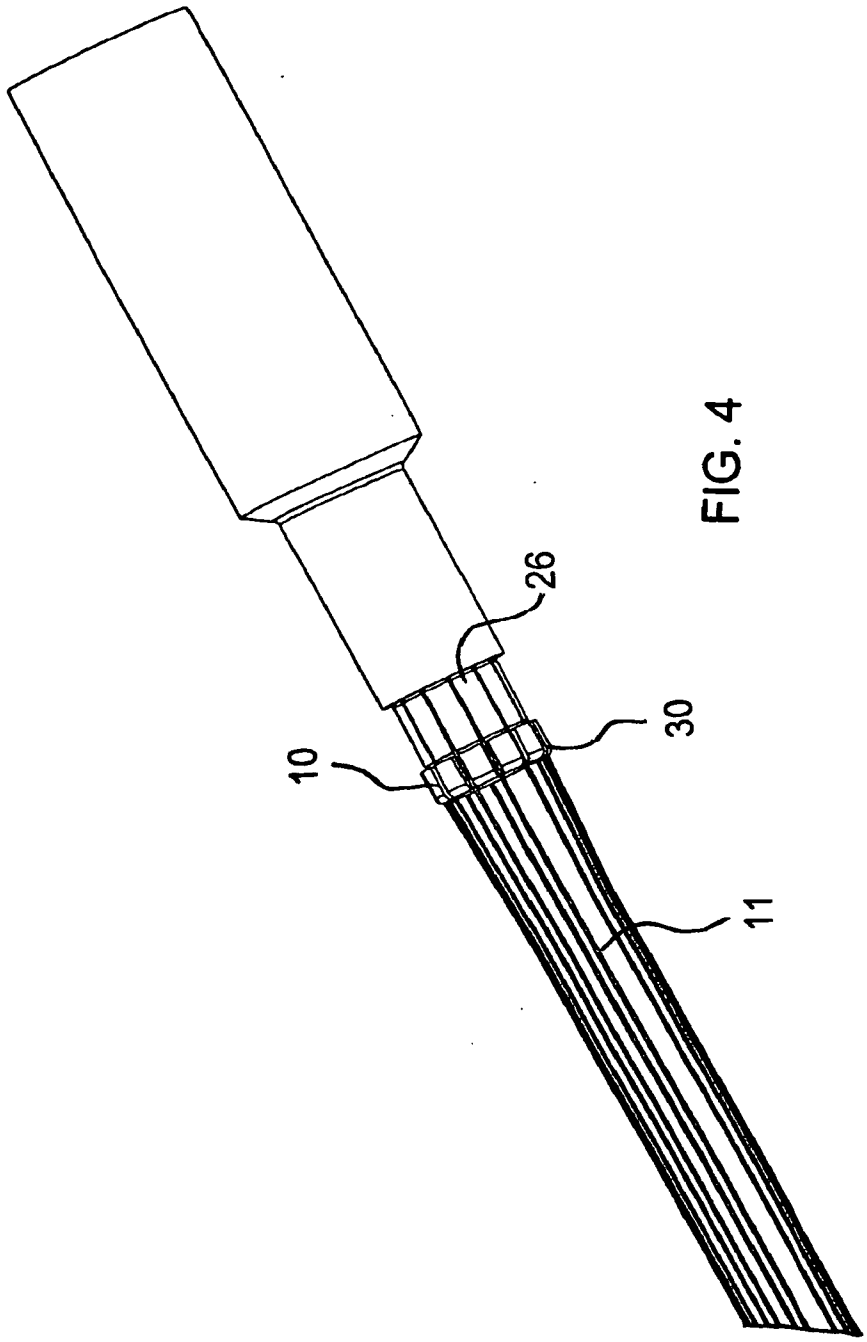


FIG. 4

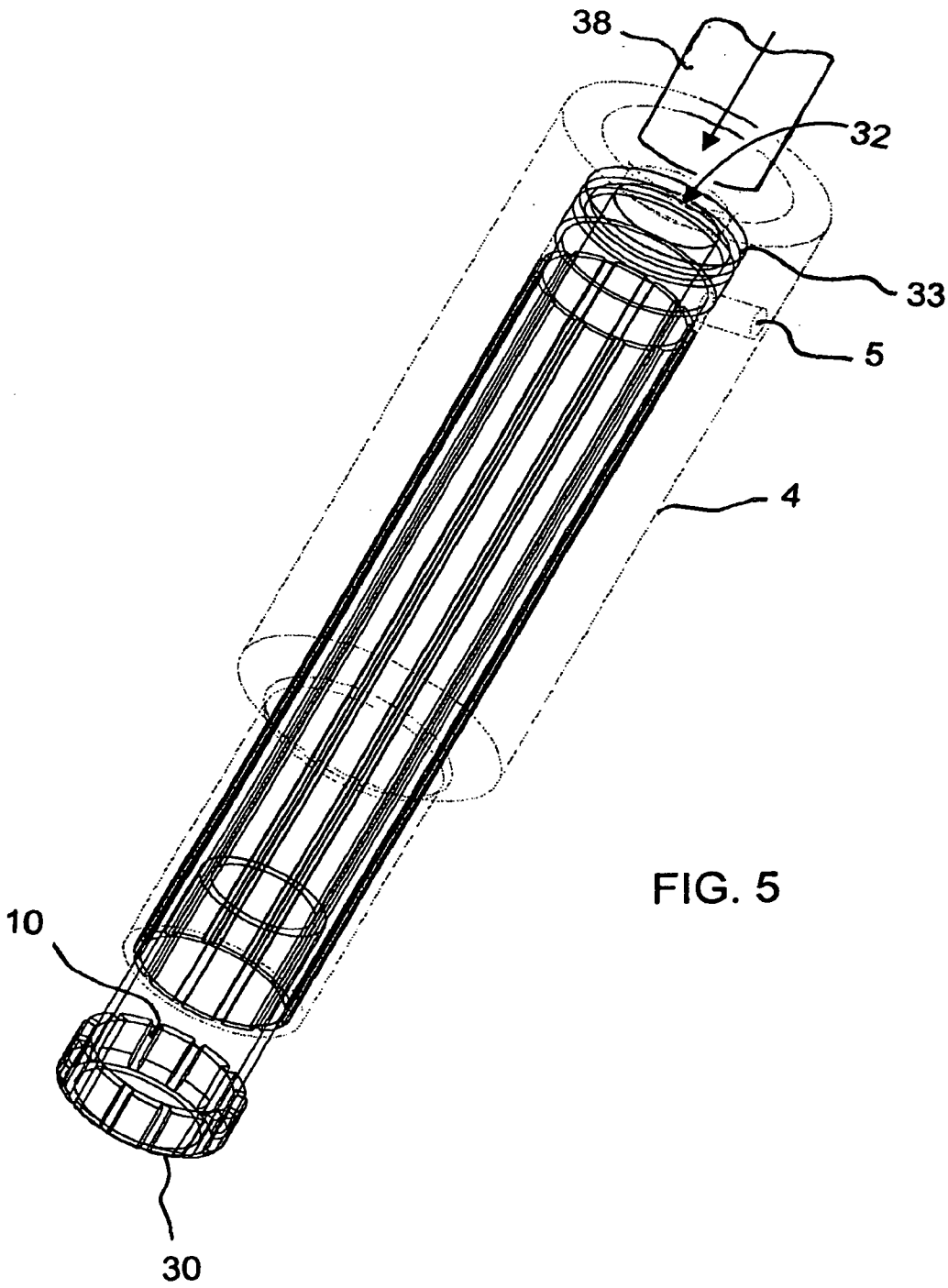


FIG. 5

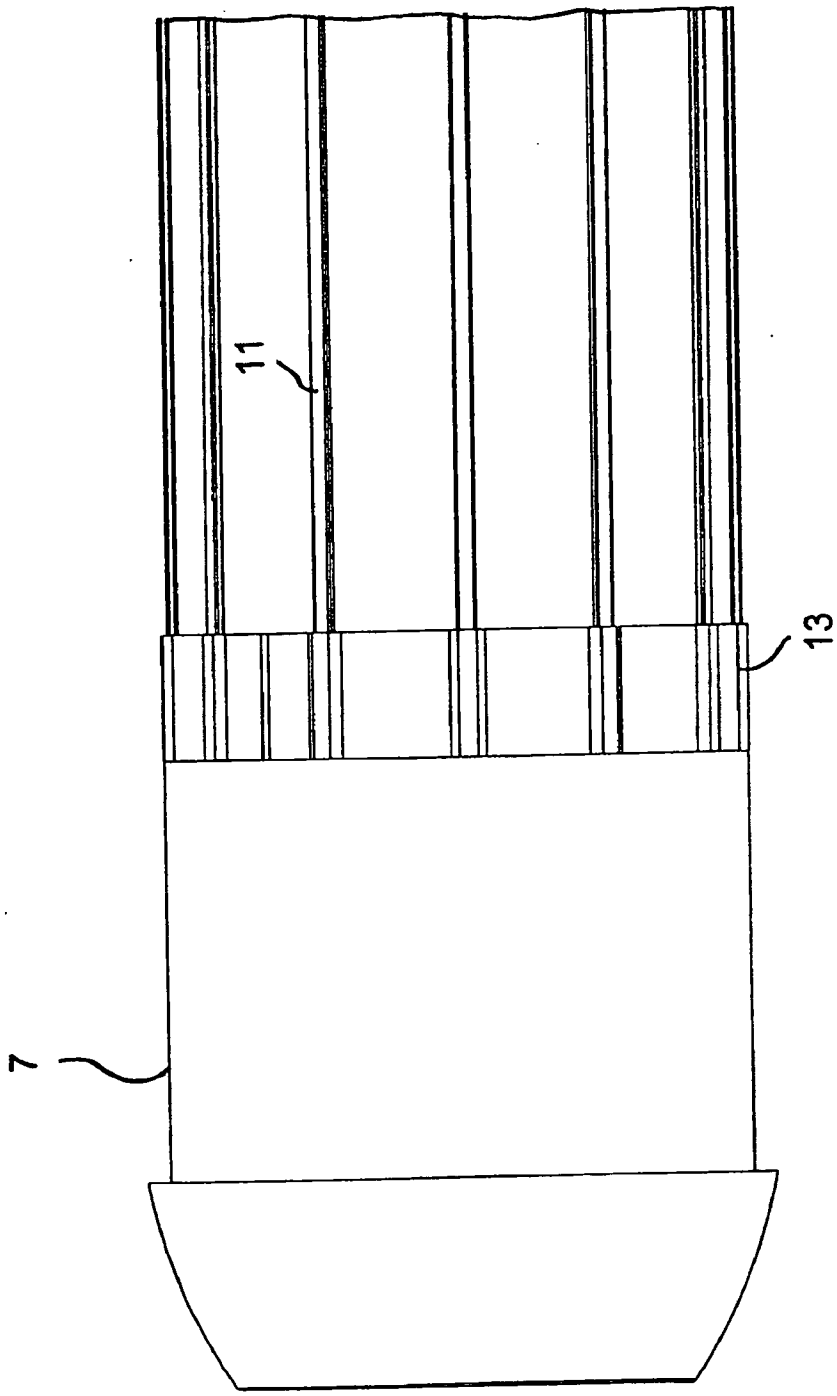


FIG. 6

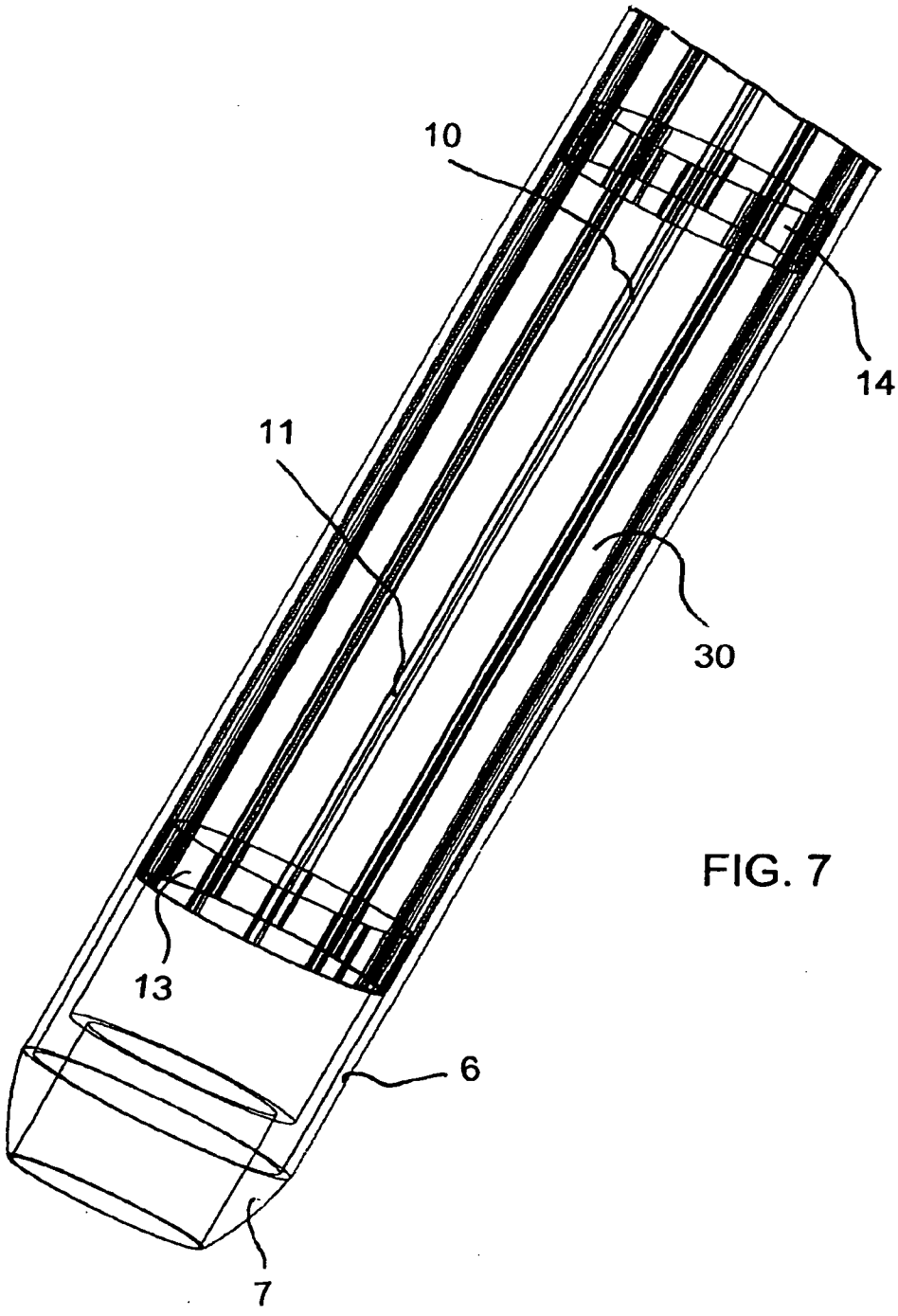


FIG. 7

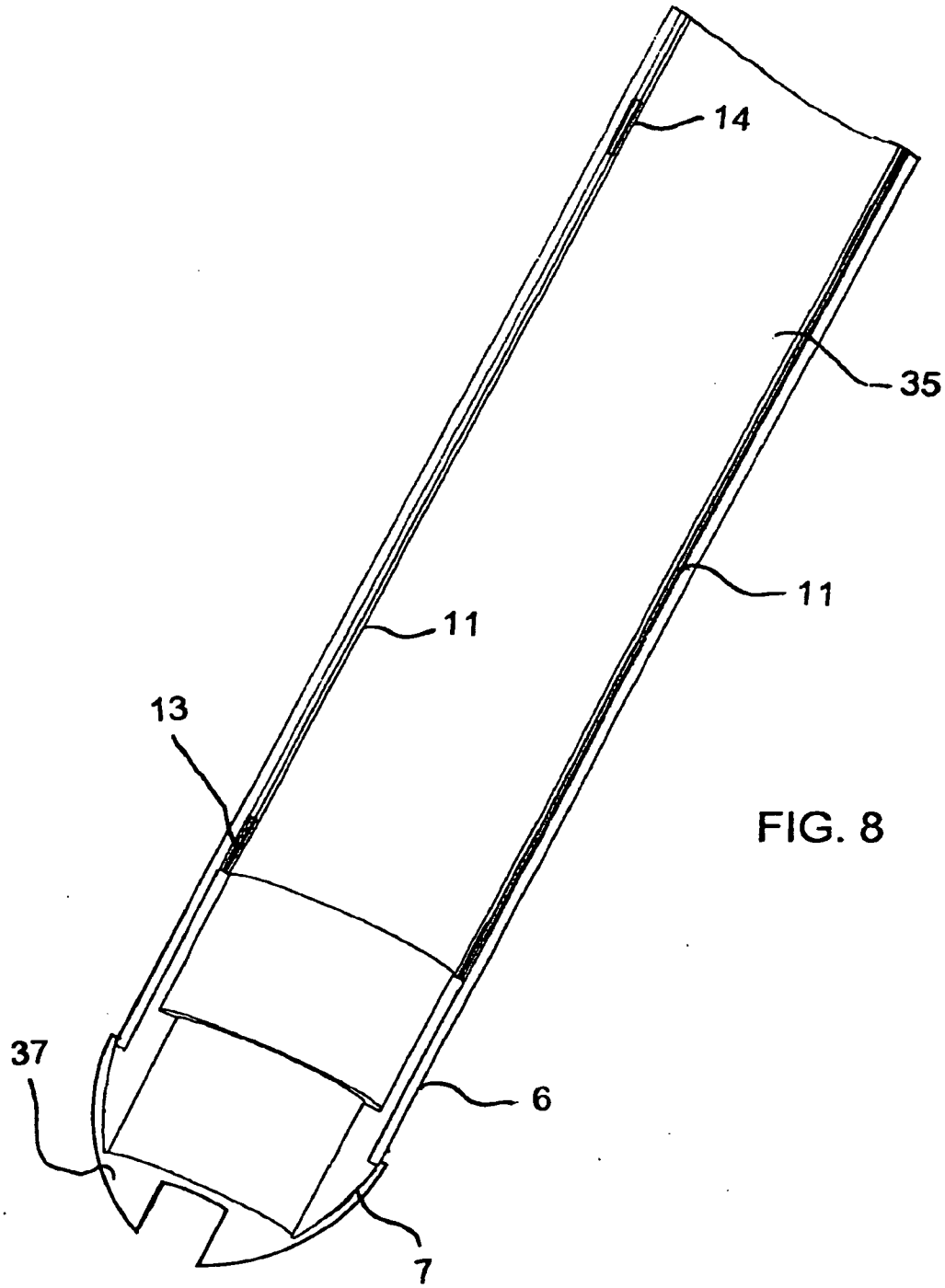


FIG. 8

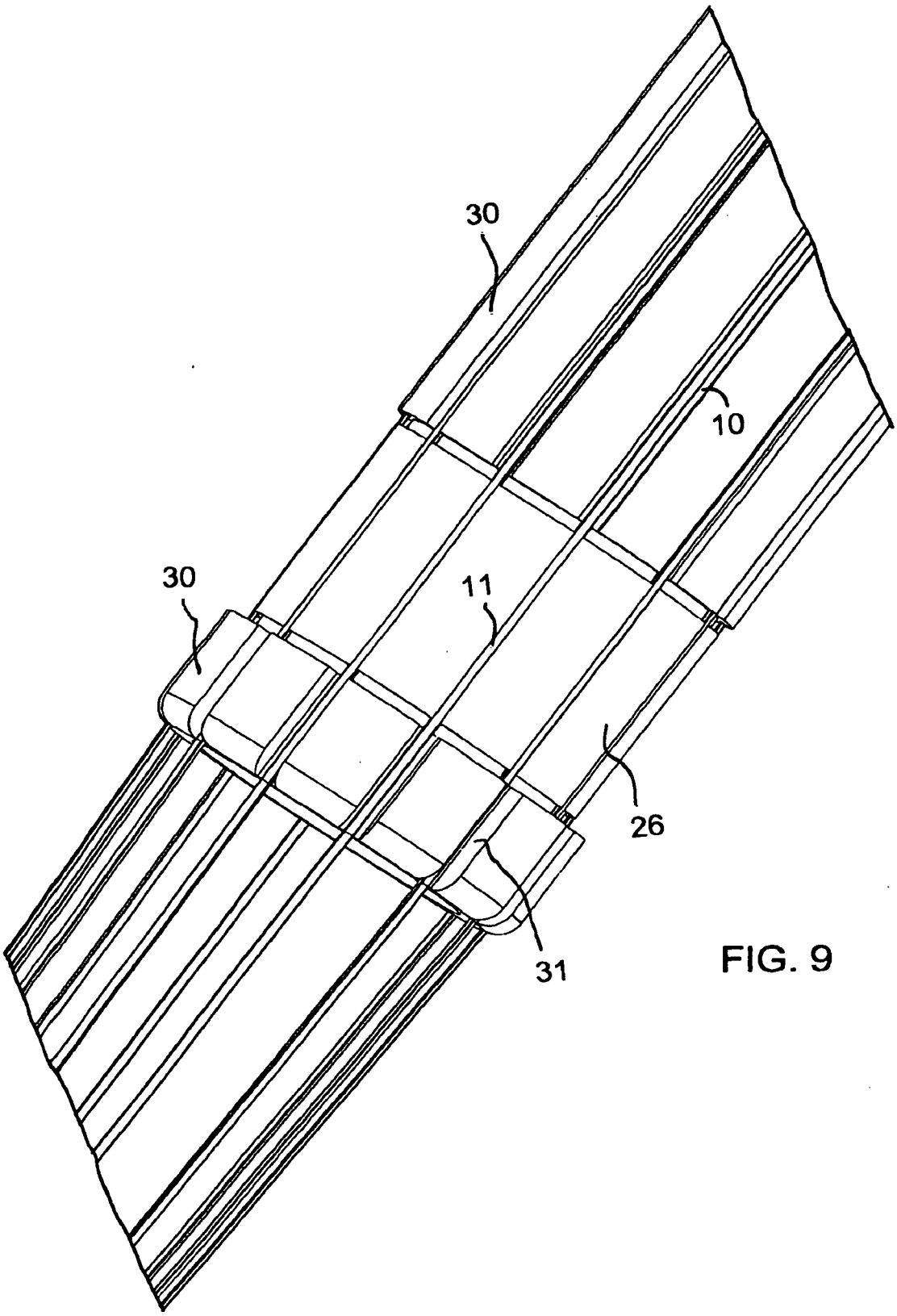


FIG. 9

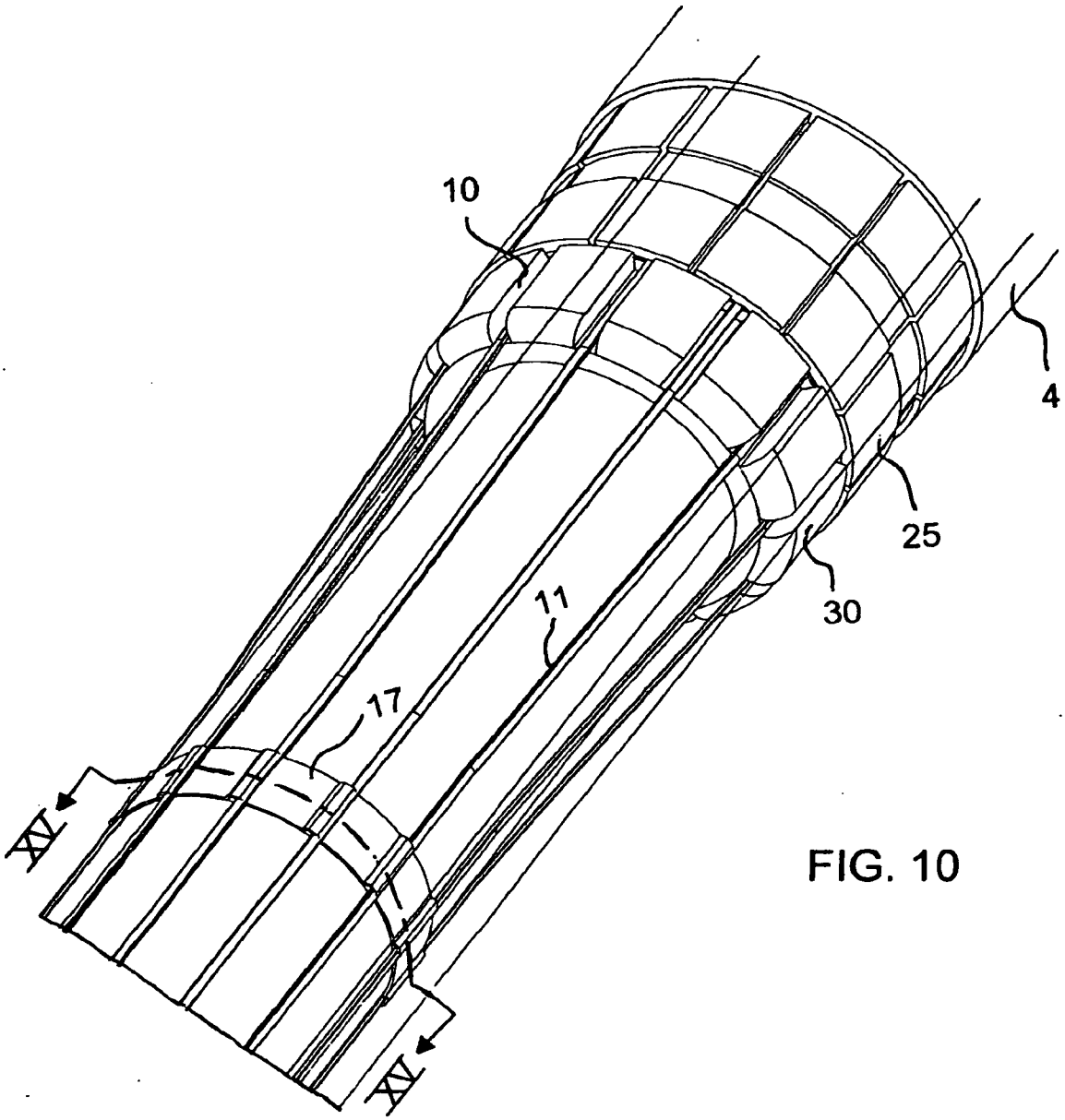


FIG. 10

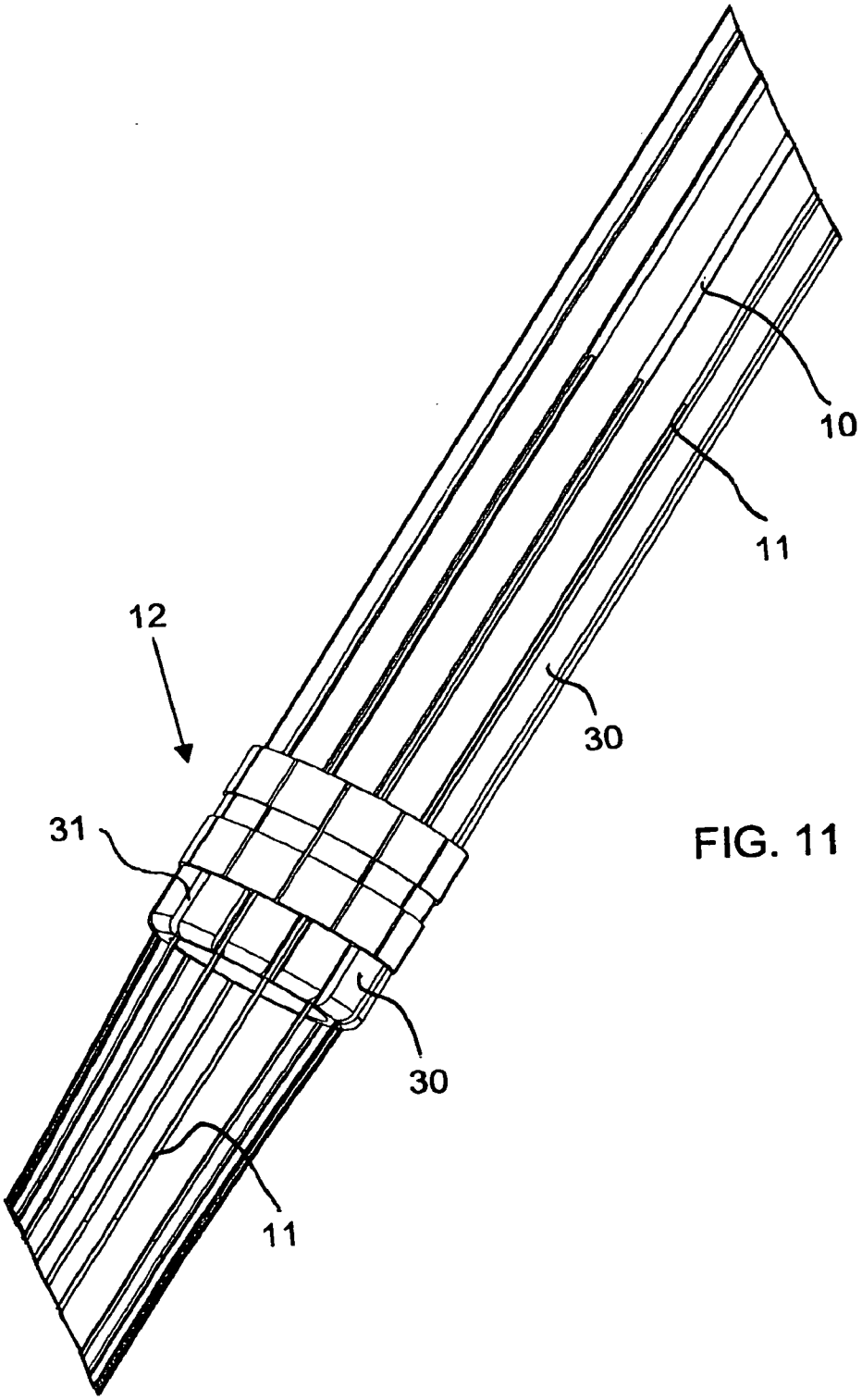


FIG. 11

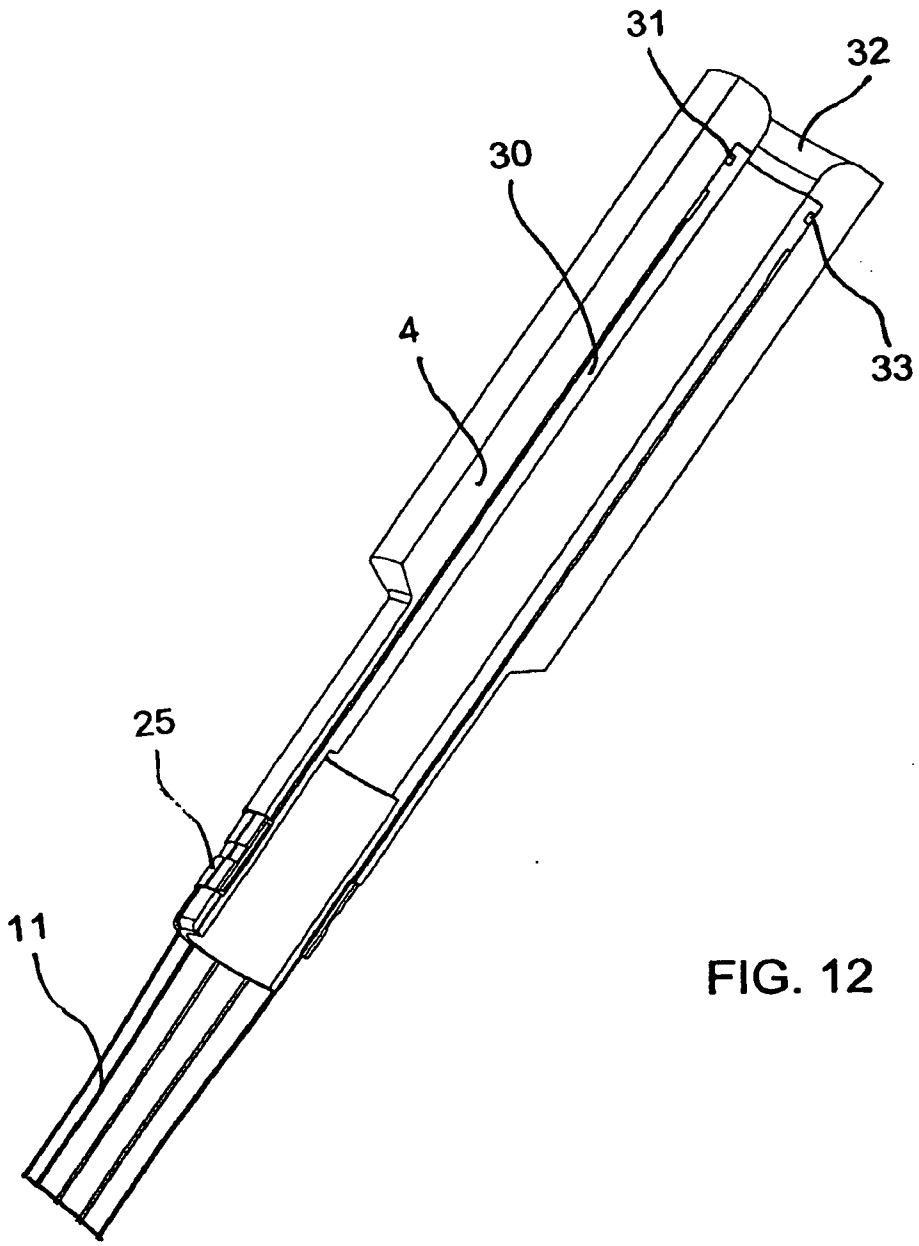


FIG. 12

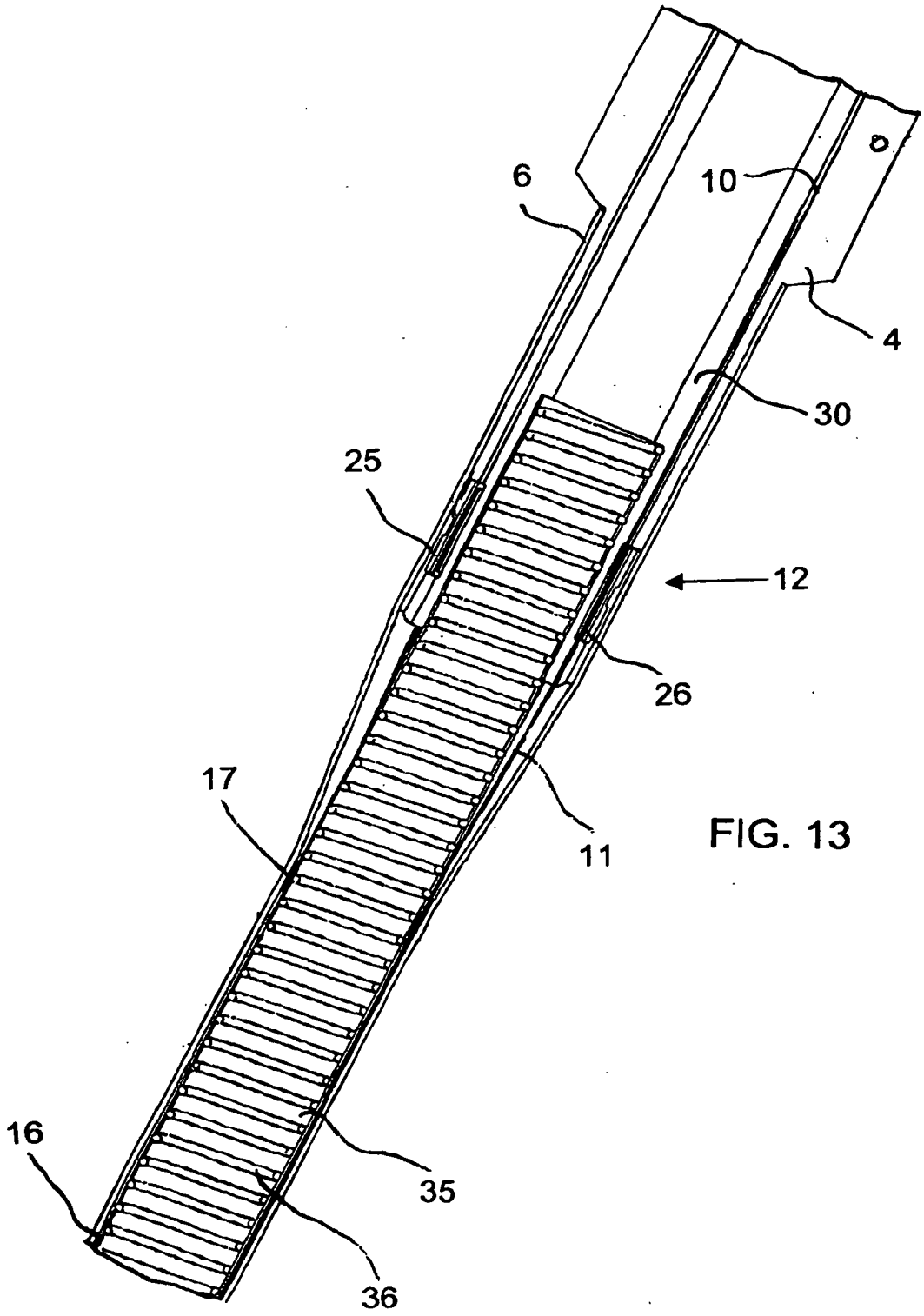


FIG. 13

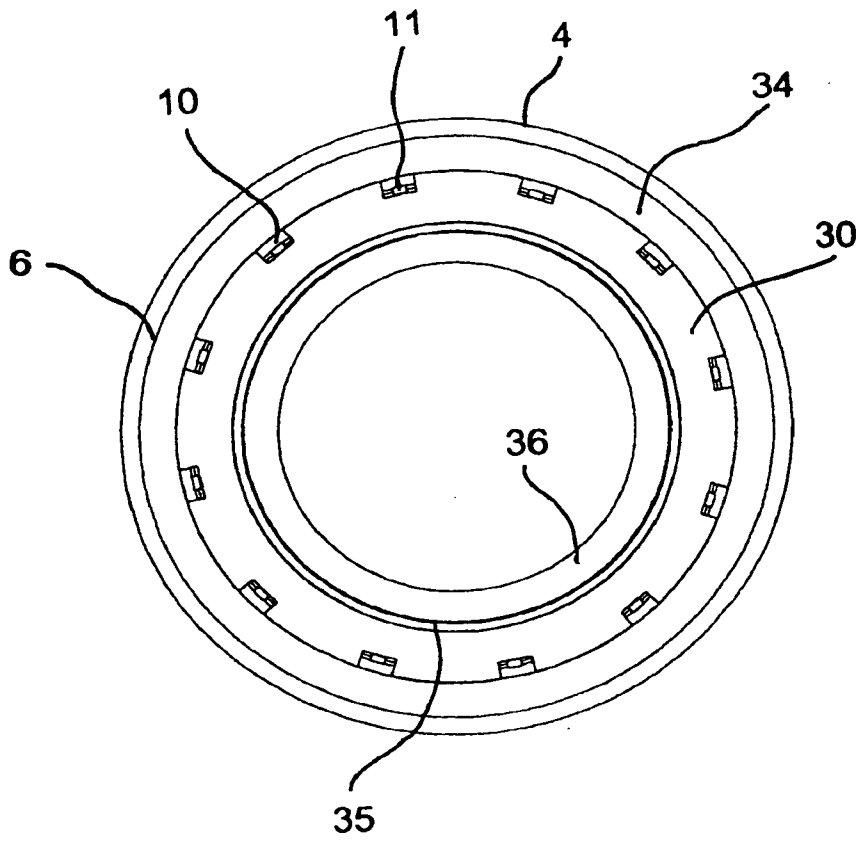


FIG. 14

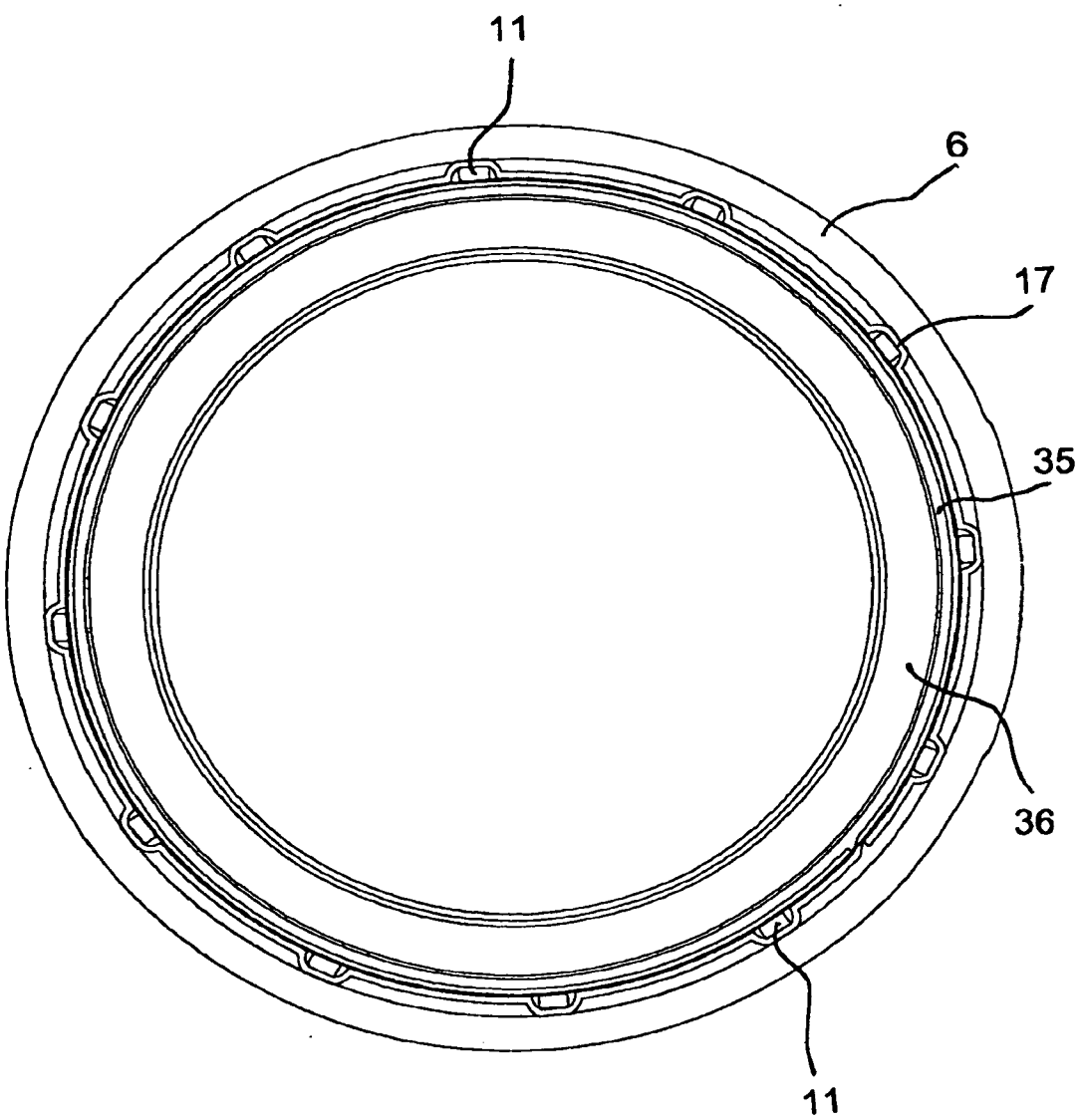


FIG. 15

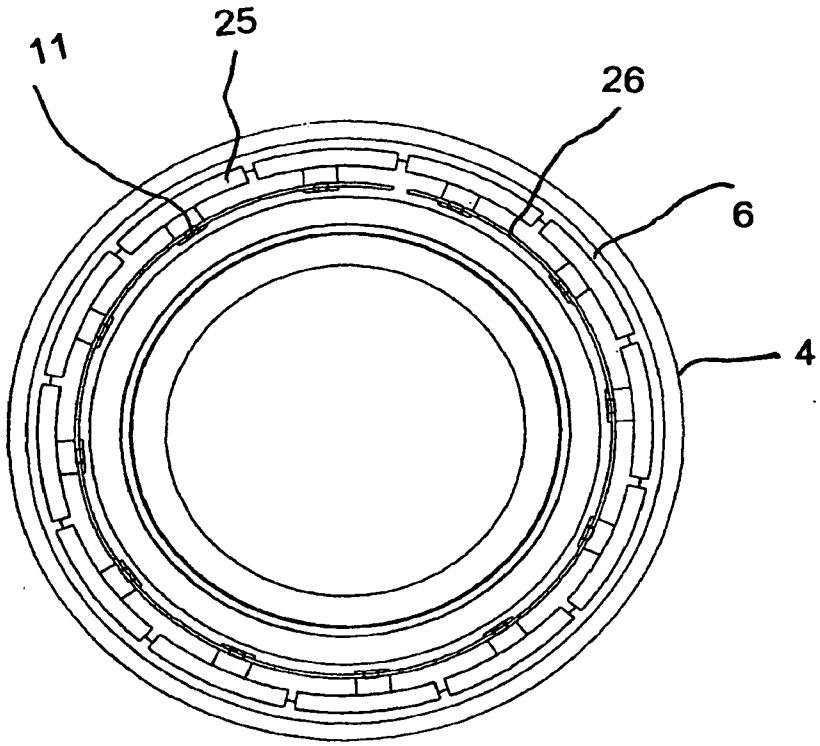


FIG. 16

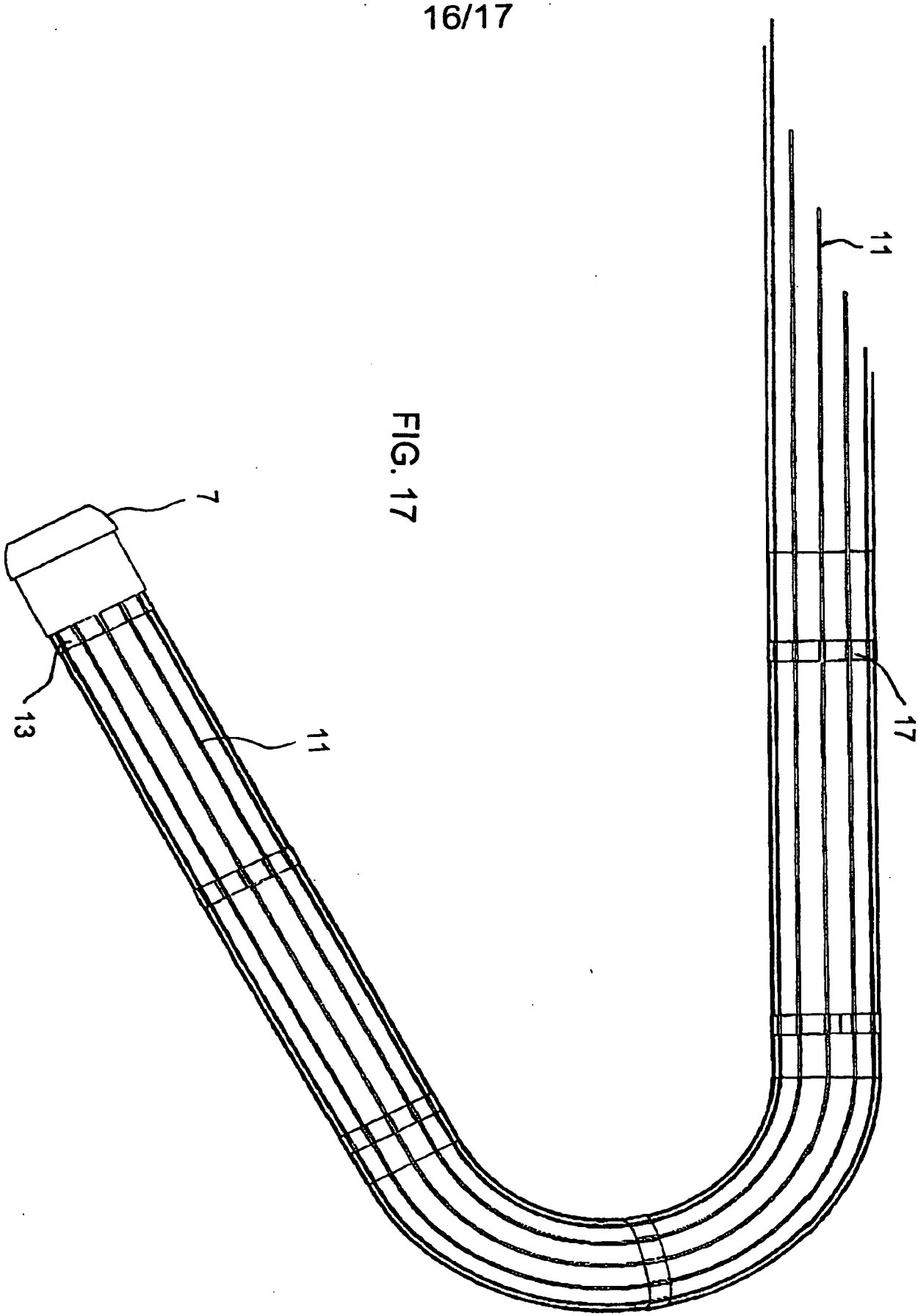


FIG. 17

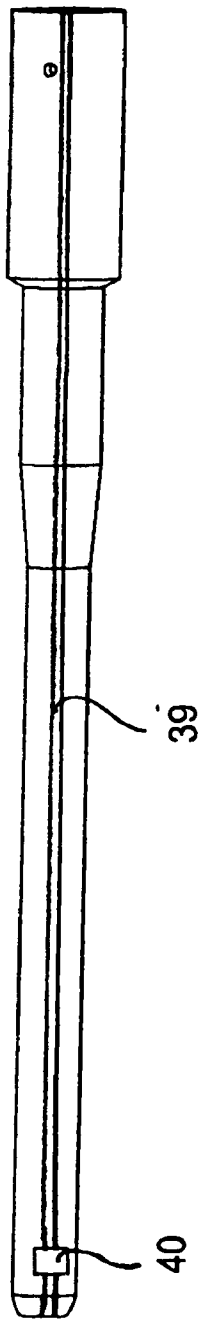


FIG. 18

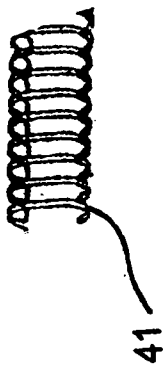


FIG. 19