

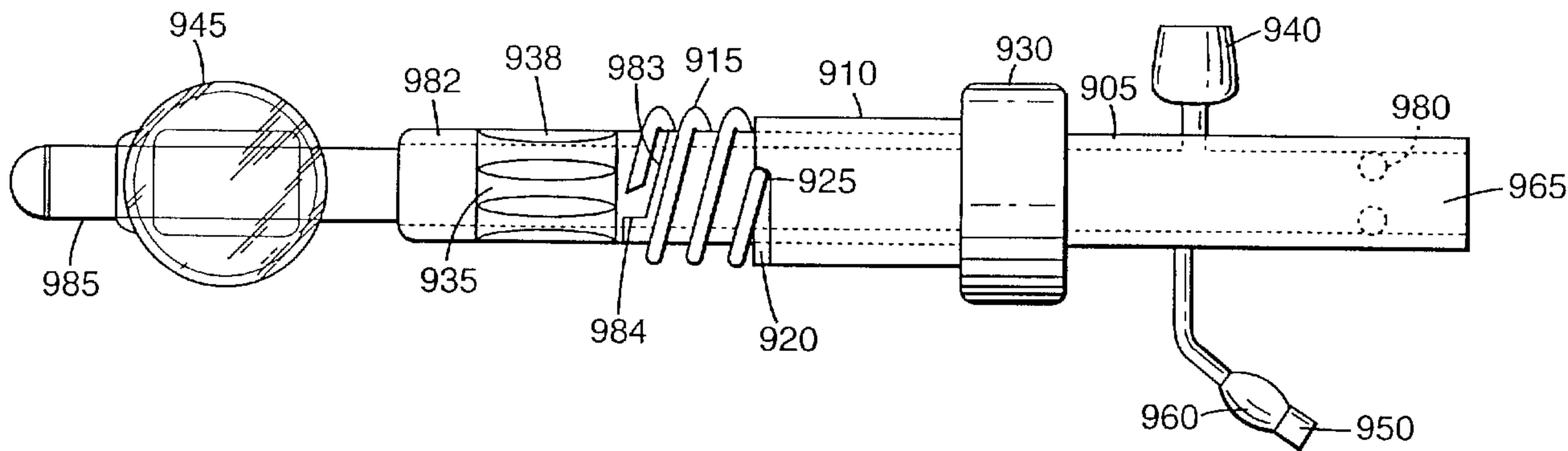


(86) Date de dépôt PCT/PCT Filing Date: 2001/03/26
 (87) Date publication PCT/PCT Publication Date: 2001/10/04
 (85) Entrée phase nationale/National Entry: 2002/09/23
 (86) N° demande PCT/PCT Application No.: US 2001/009571
 (87) N° publication PCT/PCT Publication No.: 2001/072238
 (30) Priorités/Priorities: 2000/03/24 (60/191,932) US;
 2000/07/14 (09/616,411) US

(51) Cl.Int.⁷/Int.Cl.⁷ A61B 17/064, A61B 17/068
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(54) Titre : DISPOSITIFS ET METHODES PERMETTANT DE TRAITER ENTRE AUTRES L'INCONTINENCE URINAIRE D'EFFORT

(54) Title: DEVICES AND METHODS FOR TREATING E.G. URINARY STRESS INCONTINENCE



(57) Abrégé/Abstract:

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

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
4 October 2001 (04.10.2001)

PCT

(10) International Publication Number
WO 01/72238 A3

(51) International Patent Classification⁷: **A61B 17/064**,
17/068

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(21) International Application Number: PCT/US01/09571

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(22) International Filing Date: 26 March 2001 (26.03.2001)

(25) Filing Language: English

(81) Designated States (*national*): CA, JP, KR.

(26) Publication Language: English

(84) Designated States (*regional*): European patent (AT, BE,
CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC,
NL, PT, SE, TR).

(30) Priority Data:

60/191,932 24 March 2000 (24.03.2000) US
09/616,411 14 July 2000 (14.07.2000) US

Published:

— with international search report

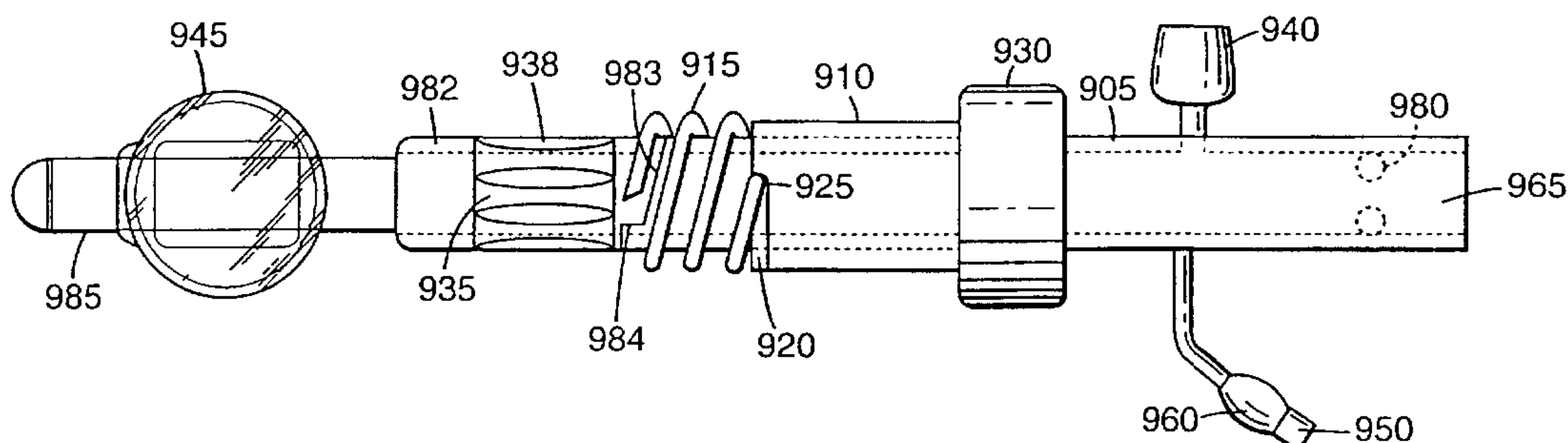
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(88) Date of publication of the international search report:
31 January 2002

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

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WO 01/72238 A3

**DEVICES AND METHODS FOR TREATING
E.G. URINARY STRESS INCONTINENCE**

5 **CROSS-REFERENCE TO RELATED APPLICATIONS**

The present application is a Continuation-In-Part of U.S. Application No. 09/309,617, filed May 11, 1999, which application claims priority under 35 U.S.C. § 119(e) to U.S. Application No. 60/085,054, filed May 11, 1998. Further, the present application claims priority under 35 U.S.C. § 119(e) to U.S. Application No. 60/191,932, filed March 24, 2000. All of the above-identified applications are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. **Field of the Invention**

15 The invention relates to devices and methods for treating urinary incontinence. More specifically, the invention relates to surgical devices and methods for eliminating or reducing urinary stress incontinence, particularly (though not exclusively) in minimally invasive surgical settings.

2. **Description of Related Art**

20 Urinary incontinence involves the involuntary passage of urine. A wide range of disorders and conditions can cause urinary incontinence, including injuries to the pelvic region, pregnancy/childbirth, infection, and degenerative changes associated with aging. In a healthy patient, on the other hand, urine

remains in the bladder until the patient voluntarily causes it to flow through the urethra and out of the body.

Currently, an estimated 13 million Americans suffer some form of incontinence. As many as 85% of them are women, and indeed it is believed that
5 as many as one in four women aged 30-59 has experienced at least one episode of urinary incontinence. Naturally, incontinence causes not only physical discomfort and inconvenience but also has emotional and psychological consequences as well.

Five forms of incontinence are generally recognized. Stress
10 incontinence, an important focus of the present invention, often occurs when the pelvic muscles have deteriorated or been damaged. Coughing, sneezing, laughing, and other activities that put pressure on the abdomen and bladder may cause leakage. Stress incontinence is discussed further below. With another type of incontinence, known as urge incontinence, nerve passages between the bladder
15 and brain are damaged. This damage causes sudden, seemingly uncontrollable bladder contractions that then cause leakage of urine. With overflow incontinence, the bladder's capacity is exceeded by the quantity of urine produced. Reflex incontinence, in which the patient generally is unaware of the need to urinate, can result from a leak in the bladder, urethra, or ureter, or an abnormal
20 opening in the bladder. Finally, incontinence can be caused by certain surgical procedures involving e.g. the urethra or bladder neck. A single patient can have multiple forms of incontinence.

Stress incontinence often is caused by weakened muscles in the pelvic floor, as referenced earlier. Without adequate pelvic support, the bladder and proximal end of the urethra tend to sag, the bladder neck dilates, the proximal urethra widens, and the urethra as a whole shortens. Normal flow resistance from the bladder neck and the urethral sphincter decreases, causing leakage upon increase in intra-abdominal pressure that might be due to coughing, for example. Figure 1 roughly illustrates three anatomical configurations with respect to pelvic floor 2: normal anatomy 4, descended bladder/urethra 6, and widened bladder neck/shortened urethra 8. Figure 1 is adapted from Mundy, A.R., ed., Urodynamics - Principles, Practice and Application, 1984, p. 229. The Urodynamics text is incorporated by reference herein in its entirety.

Recent research suggests that incontinence requires multiple anatomic defects, not just one, and that the mere position of the urethra does not predict urinary incontinence. At least four anatomic factors are believed involved, namely, urethral length; support of the bladder neck and urethra by the pubo-urethral, urethropelvic, vesicopelvic and cardinal ligaments; changes in the bladder neck and urethra during times of stress; and coaptation of the urethra. The two most important factors in female urinary incontinence, recent research suggests, are hypermobility of the bladder neck and defective support of the midurethra. Note the discussion of this topic in "Anatomy of female continence redefined by photographs, imaging techniques," Urology Times of Canada, April, 1996, which is incorporated herein by reference.

Many varieties of general surgical procedures are used to treat stress incontinence. Most, if not all, such procedures involve open/endoscopic surgery and are significantly invasive, requiring general anesthesia and hospitalization. Such procedures are peri-urethral, i.e. they are performed from
5 outside the urethra. Suspension procedures, for example, use sutures to lift the urethra and bladder neck to their normal positions. Sling procedures use synthetic material or tissue, often anchored to bone, to do the same. In some cases, an implantable artificial sphincter is used to restore the compressive action needed to stop the flow of urine.

10 Various invasive surgical procedures are described in the Urodynamics text referenced above. Additional discussion is found in Campbell's Urology, 5th ed., 1986, which is incorporated by reference herein. Additional methods and devices for treatment of incontinence are disclosed in, among others, U.S. Patents Nos. 5,647,836, 5,611,515, 5,520,606, 5,417,226,
15 5,256,133, 5,234,409, 5,007,894, 4,857,041, 4,686,962, 4,139,006, 4,019,499, and 3,661,155, all of which are incorporated herein by reference.

As referenced above, most, if not all, known surgical procedures and devices for treating stress incontinence successfully are significantly invasive, complicated, or both. Significant trauma to the pelvic region can result.
20 Additionally, although stress incontinence primarily affects females and thus the majority of known surgical procedures are directed at female patients, a significant number of males suffer stress incontinence as well. A need has

arisen, therefore, to treat both female and male stress incontinence with minimal complexity and minimal invasiveness. Embodiments of the invention address complexity, invasiveness, and other problems.

5

SUMMARY OF THE INVENTION

Embodiments of the invention provide a permanent implanted support for e.g. the urethral neck of the bladder, generally preventing urinary leakage caused by transmission of intra-abdominal pressure pulse waves. The support is implanted in a straightforward manner without the significant complexity and invasiveness associated with known surgical techniques. Pelvic trauma is dramatically reduced. Embodiments of the invention can be used in treatment of stress incontinence, and other types of incontinence, in both males and females.

10

Other embodiments and aspects of the invention will be apparent from the following detailed description.

15

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the invention will be described with reference to the figures, in which like reference numerals denote like elements and in which:

20

Figure 1 illustrates three anatomical configurations of the bladder and urethra;

Figure 2 is an exploded perspective view of an incontinence treatment device according to an embodiment of the invention;

Figures 3-6 are cross-sectional views showing supportive interaction with a staple, according to embodiments of the invention;

5 Figure 7 shows an incontinence treatment device in a substantially assembled condition, according to an embodiment of the invention;

Figure 8 shows the incontinence treatment device of Figure 7 with the cover removed;

10 Figure 9 shows an incontinence treatment device with a deployed balloon, according to an embodiment of the invention;

Figure 10 shows a balloon and endoscope port according to an embodiment of the invention;

Figure 11 shows an incontinence treatment device inserted into the urethra and bladder, according to an embodiment of the invention;

15 Figure 12 shows an implanted staple with healed-over tissue, according to an embodiment of the invention;

Figure 13 shows a more detailed view of an inserted incontinence treatment device according to an embodiment of the invention;

20 Figure 14 shows an incontinence treatment device according to an alternative embodiment of the invention;

Figure 15 is a detail view of the device shown in Figure 14;

Figure 16 shows an incontinence treatment device with indrawn tissue, according to an embodiment of the invention;

Figures 17-20 show an incontinence treatment device as it is inserted into a sagging bladder/urethra, according to embodiments of the invention;

Figure 21 shows an alternative staple, according to an embodiment of the invention;

Figure 22 is a cross-sectional view of an incontinence treatment device according to an alternative embodiment;

Figure 23 is a cross-sectional view of a staple ring and a staple mounted on an insertion device, according to an embodiment of the invention;

Figure 24 is a cross-sectional view of a staple insertion/actuator mechanism, according to an embodiment of the invention;

Figure 25 shows a staple ring retainer/release mechanism according to an embodiment of the invention;

Figure 26 shows a mounting device, according to an embodiment of the invention;

Figure 27 shows a vacuum retainer mechanism, according to an embodiment of the invention;

Figure 28 shows a balloon and catheter assembly, according to an embodiment of the invention;

Figure 29 is a side view of an incontinence treatment device according to an alternative embodiment of the invention;

Figure 30 is a perspective view of the Figure 29 device;

Figure 31 is a perspective view of a staple, according to an
5 embodiment of the invention;

Figure 31A is a top view of a support for the staple of Figure 31;

Figure 32 is a side view of an upper portion of the Figure 29
device;

Figure 33 is a perspective view of the Figure 32 device;

10 Figure 34 is a side view similar to Figure 32, but with portions of the staple disposed behind the staple ring, according to an embodiment of the invention;

Figure 35 is a perspective view of the Figure 34 device;

15 Figure 36 is a partial exploded view of a staple insertion/actuator mechanism, according to an embodiment of the invention;

Figure 37 is a perspective view showing an incontinence treatment device with relatively extended staple-ring engaging tips, according to an embodiment of the invention;

20 Figures 38-41 are lower perspective views of incontinence treatment devices, according to alternative embodiments of the invention;

Figure 42 is a top perspective view of a thumbwheel mechanism, according to an embodiment of the invention;

Figure 43 is a bottom perspective view of the Figure 42 thumbwheel;

Figure 44 is a top perspective view of a handle outer shell, according to an embodiment of the invention;

5 Figure 45 is a top view of the Figure 44 shell;

Figure 46 is a bottom perspective view of the Figure 44 shell;

Figure 47 is an exploded view showing a ring retainer assembly according to an embodiment of the invention;

10 Figure 48 shows an incontinence treatment device according to an embodiment of the invention;

Figure 49 shows a viewing device useable with the Figure 48 embodiment;

Figure 50 is an end view of a staple useable with incontinence treatment devices and methods according to embodiments of the invention; and

15 Figure 51-56 are photographs showing an incontinence treatment device according to embodiments of the invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

20 Embodiments of the invention relate to devices and methods for treating incontinence, primarily urinary stress incontinence (USI). Although many if not most known surgical procedures and devices for treating USI are intended for the female population, embodiments of the invention are applicable equally to

both females and males. Therefore, references in this application to female anatomy or treatment should be interpreted as applying equally to males, as well. Further, although embodiments of the invention are particularly well-suited for minimally invasive surgery, conventional surgical techniques also can be used, and this application should be interpreted accordingly. Other types of incontinence, e.g. surgically induced incontinence, also can be treated in certain circumstances. As will become clear, embodiments of the invention treat USI in a relatively uncomplicated, minimally invasive, and cost-effective manner not believed known or contemplated by the prior art.

Figure 2 shows an exploded view of incontinence treatment device 10 according to an embodiment of the invention. Device 10 includes staple holder 20, having elongated shaft 30 terminating in handle 35. At the end of shaft 30 opposite handle 35 is staple mount 40 with retractable, tapered support portions or wings 50. Staple 60, having an annulus 65 with descending teeth or needles 70 as will be described, is secured to staple mount 40 during initial placement of device 10. Staple 60, as with all the staples described and/or illustrated in this application, preferably is formed of a biocompatible material.

According to embodiments of the invention, the outermost portions of retractable wings 50 each include a protrusion, such as a pin, extending therefrom. Figures 3-4 illustrate two of these embodiments. In Figure 3, staple 60 is provided with a substantially U-shaped groove 61 extending around the interior circumference of annulus 65. Of course, substantially V-shaped or other-shaped

grooves are also contemplated, as is a groove extending around the exterior circumference of annulus 65. Multiple grooves in a single staple are also contemplated, with correspondingly shaped engaging wing structure. In Figure 4, staple 60' is provided with a plurality of downwardly directed holes 62 through annulus 65, for example, through which corresponding downwardly directed pins 63 extend. Radially extending pins and holes are also contemplated. When wings 50 are in an extended position, the ends or pins of the wings engage the groove or holes of annulus 65 to secure staple 60 on staple mount 40. Other mating configurations are contemplated as well. In Figure 5, for example, each wing 50 has groove 64 extending therethrough to accommodate corresponding portions 66 of staple 60", which portions can be raised or ridged.

Wings 50 preferably are spring-biased to an extended position, according to embodiments of the invention, for engaging and holding staple 60. Wings 50 can be retracted by a screw mechanism, extending through staple holder 20 and emerging near handle 35 for manipulation by the surgeon. Alternatively, wings 40 can be extended and retracted by telescoping and clasp mechanism 68, similar to that found on conventional umbrellas, as shown, for example, in Figure 6. Although Figure 6 shows the mating configuration of Figure 5, use with alternative mating configurations is also contemplated.

Returning to Figure 2, device 10 also includes vacuum support 80, having a plurality of vacuum apertures 90. Vacuum support 80 is substantially hollow and is constructed to receive and accommodate staple holder 20. At the

lower end of vacuum support 80, O-ring vacuum seal 95 provides a fluid-tight seal and allows handle 35 of holder 20 to extend therethrough. Vacuum port 100 is provided to draw a vacuum through support 80 and vacuum apertures 90.

Figures 7-8 show device 10 in a substantially assembled condition.

5 Figure 7 shows cover 120, for shielding and preventing contamination of e.g. staple holder 20 and vacuum support 80 during insertion into the patient, and maintaining these and other elements in a sterile environment. Cover 120 also acts as a safety cover during insertion, to prevent injury to the patient due to staple 60 or other portions of device 10. Cover 120 is simply removed from the
10 remainder of device 10, putting device 10 in a "ready" condition, by pulling it off over the mechanisms, etc. at the lower end of device 10.

Figure 8 is substantially similar to Figure 7 but eliminates cover 120 and shows additional features in the ready condition. Attached to and extending into staple holder 20 is pressure port 130, for a purpose to be described.

15 Further, endoscope port 140 extends into staple holder 20 for accommodating an endoscope to view the interior of the urethra or bladder. Staple holder 20 is positioned substantially concentrically within vacuum support 80. Staple holder 20 includes retainer mechanism 141 with outwardly biased retaining legs 142 having staple-engaging portions 143. After implantation of staple 60 in a manner
20 to be described, retaining legs 142 are urged inwardly, by e.g. an outer tube, a position out of contact with staple 60, such that staple holder 20 and associated elements can be removed.

Balloon or blocking member 150 is housed within staple holder 20 of device 10. Balloon 150 is operably connected to pressure port 130, and according to one example is one-piece with it. As balloon 150 is inflated via pressure port 130, balloon 150 moves from its housed position to the deployed position shown in Figure 9. Flexible guide 153, made of e.g. plastic, folds out during balloon deployment and substantially prevents balloon 150 from going under staple 60.

As best shown in Figure 10, balloon 150 also can be in a one-piece configuration with endoscope port 140. Balloon 150 is substantially transparent, according to this embodiment. Endoscope 155 is inserted through port 140 for viewing e.g. the bladder through balloon 150. Direct visualization can help the surgeon ensure proper positioning and engagement of balloon 150 with the bladder walls, as described below.

A method of use according to one embodiment of the invention will now be described, beginning with Figures 11-12. First, device 10 is inserted into urethra 160 of the patient to bladder 170. When fully inserted, as shown in Figure 11, staple holder 40 and staple 60 have passed substantially all the way through bladder neck 175, as shown. The other end of device 10 extends substantially beyond urethral opening 180 for manipulation by the surgeon, as do vacuum port 110, pressure port 130, endoscope port 140, and the screw or other actuation mechanism for retractable wings 50.

Once inserted, pressure is applied through pressure port 130 to inflate balloon 150, causing it to extend from its housed position to the deployed position shown in e.g. Figure 11. Balloon 150 is ultimately used to create a seal between bladder 170 and urethra 160, substantially preventing urine from passing
5 out of bladder 170.

Once balloon 150 is inflated, a vacuum is pulled through vacuum port 110 and apertures 90 of vacuum support 80. The created vacuum condition in urethra 160 pulls balloon 150 toward urethra 160 to effect the above-described seal and pulls the sides of urethra 160 into a substantially tight relationship against
10 vacuum support 80. According to one embodiment, apertures 90 of vacuum support 80 are large enough to sustain a vacuum in urethra 160, but small enough that significant portions of the walls of urethra 160 are not drawn into support 80. Endoscope 145 can be used to ensure that a proper seal has occurred between the balloon and the walls of bladder 170.

15 According to an alternative embodiment, balloon 150 and its associated apparatus is not used. Bladder 170 is allowed to collapse during application of the vacuum; the effect of the vacuum on the bladder neck and/or urethra is similar to that which occurs when balloon 170 is used.

Drawing the vacuum through support 80 causes bladder neck 175
20 and the immediately adjacent portion of urethra 160 to assume a shape akin to the substantially normal anatomical shape shown in Figure 1. To aid this process, the anterior wall of the vagina can be lifted, e.g. manually or with a trans-vaginal

balloon, while the vacuum is applied. These maneuvers elevate urethra 160 and help narrow the urethral neck/bladder neck region 175. Once neck region 175 has assumed a desired shape, staple 60 is implanted in the neck region to maintain that shape, as described below. Of course, device 10 can be constructed to cause neck region 175 to assume any of a number of desired shapes, depending on e.g. the size of the patient, the surgical procedure or surgical environment, etc. For example, the size of the desired shape, the depth thereof, and other characteristics of the shape can be manipulated according to e.g. the surgeon's preference.

Device 10 is positioned such that needles 70 of staple 60 are adjacent neck region 175. To implant the staple, the surgeon then pulls handle 35 such that staple 60 moves towards the urethral opening. Traction on handle 35 pulls staple 60 into the interior tissue of neck 175, below the first layer of tissue, to hold neck 175 in the substantially normal shape caused by the vacuum.

Then, wings 50 are retracted inwardly and disengage and release staple 60. The vacuum applied through port 110 is released, and balloon 150 is deflated. Device 10 then is withdrawn from the urethra. Staple 60 is left behind to form a permanent, implanted support for neck 175.

Ultimately, as shown in Figure 12, tissue 190 heals over and covers staple 60, making it "invisible" to interior regions of the bladder and urethra. These regions thus are free of foreign bodies, substantially reducing the likelihood of stones or lesions. Additionally, implantation of staple 60 in the manner

described occurs substantially without killing the muscle, tissue or nerves of the urethra, all of which are important to normal urinary tract function.

According to preferred embodiments, annulus 65 of staple 60 is of low profile and forms a substantially complete circle. Staple 60 can also be
5 elliptically shaped or formed in a partial-ring or arc shape. Staple 60 can include different numbers of needles 70, and these needles and/or staple 60 itself can be of various diameters, widths and thicknesses. The structural characteristics of staple
60 can be selected based on e.g. the anatomy of the patient, the anatomical location where the staple is placed, the degree of support desired, etc. According
10 to preferred embodiments, staple 60 is comprised of inert metal, plastic or other biocompatible material suitable for implantation in the body and non-corrosive in urine and other fluids. It may also be elastic, to a degree, to allow for some expansion of the neck region 175 while still maintaining structural stability and support. Needles 70 can be formed of a memory metal to form a curve within the
15 penetrated tissue, and to reduce the likelihood that staple 60 will work itself out over time.

Balloon 150 preferably is formed of an elastic, biocompatible material capable of sustaining relatively high pressures. Balloon 150 may be reinforced with internal or external ribbing to provide increased strength and/or
20 support. Balloon 150 can include two dissimilar materials to aid in sealing the junction between bladder 170 and urethra 160. For example, balloon 150 can have a thicker top portion and a thinner bottom portion. As pressure within

balloon 150 increases, the thinner bottom portion expands to a greater extent than the thicker top portion, aiding the sealing process. Similarly, the top portion of balloon 150 can have additional rib portions relative to the bottom portion to provide greater structural stability and again to encourage the bottom portion to seal off the bladder at the urethral opening.

A more detailed view of the distal end of device 10, with notations indicating applicable process steps, is shown in Figure 13.

Figures 14-21 illustrate other staple embodiments and associated insertion devices according to embodiments of the invention. In Figure 14, insertion device 200 includes vacuum port 205 for drawing a vacuum through interior vacuum chamber 210. Balloon 250, extending substantially down the center of device 200, is substantially similar to that described with respect to previous embodiments. Staple 260 preferably is of a different construction, however, and includes one or more base portions 261, needles 263, and one or more receiving portions 265. Note especially Figure 15, showing a cross-section of staple 260 alone.

Inflating and deploying balloon 250 in the manner of previous embodiments, and then drawing a vacuum through vacuum chamber 210, causes portion 267 of the urethral wall, e.g. in the bladder neck region, to be drawn into the recess defined between base portion 261 and receiving portion 265. In this configuration, the bladder neck and surrounding area are restored to a

substantially normal anatomical configuration, or at least to a configuration sufficient to prevent leakage when intra-abdominal pressure pulses occur.

Once the desired, vacuum-induced anatomical configuration is achieved, the surgeon applies pressure to handle 270 in the direction of arrow 280, causing push rod 285 to contact base portion 261 and urge needles 263 through tissue portion 267 and into receiving portion 265. Vacuum seal 287 is provided between push rod 285 and base portion 261. Back pressure against receiving portion 265 can be provided by a ledge or other member fixedly attached to structure surrounding balloon 250 (in its withdrawn position), in a manner akin to portions 143 in Figures 8-9 and 13.

A variety of structural features are contemplated to keep needles 263 retained within receiving member 265. Receiving member 265 can cause needles 263 to curve as they enter and penetrate, e.g. by including one or more internal, curved, substantially impenetrable portions. Needles 263 curve along the substantially impenetrable material as they enter, much in the manner of a conventional paper stapler. Alternatively, or additionally, needles 263 can be formed of a memory-type metal, the memory causing the needles to curve so as to prevent removal from receiving member 265.

Once needles 263 have been secured in receiving member 265, the vacuum is released, balloon 250 is deflated, and device 200 is withdrawn from the urethra. Staple 260 remains, holding the bladder neck (or other anatomical region) in the desired configuration. Other features of these embodiments are

substantially as shown and described with respect to previous embodiments. For example, staple 260 can be ring-shaped, elliptical, arc-shaped, of different dimensions, etc., and, as described with respect to Figures 48-56, below, generally coil-, spiral- or helix-shaped.

5 The Figure 16 embodiment is somewhat similar to the embodiment of Figure 14, but a preferably lightweight, strong retractable plastic portion 275 in the form of an inverted umbrella is used to provide the vacuum seal between the bladder and the urethra. Also shown in Figure 16 is a central open lumen 290 for an endoscope to be inserted through the center of the device, for visually
10 confirming that the plastic portion is positioned properly to form the desired seal. Lumen 290 is for pulling a vacuum in the direction of arrows 292, in the manner described earlier. Tissue and muscle 267 are drawn inwardly by the vacuum, as shown.

 Figures 17-20 generally show the anatomical correction achievable
15 according to embodiments of the invention. As shown, sagging bladder 370 and neck region 375 of Figure 17 receive insertion device 300 in Figure 18. Vacuum is applied and a more normal anatomical configuration is induced in Figure 19, as described previously. Finally, the staple is closed, as in Figure 20, to maintain the desired anatomical configuration achieved by vacuum.

20 Figure 21 shows an additional staple embodiment. Staple 360 includes needles 363, of greater relative length than the needles of previous embodiments, for penetration through a relatively large tissue region 367 between

annular staple supports 361, 365. This arrangement supports a greater length of the urethra while still allowing the sphincter to act naturally, as with previous embodiments. Other features of this embodiment are substantially as described with previous embodiments.

5 Figures 22-28 show cross-sections of a preferred embodiment of the invention that uses many of the apparatus and method principles described above. Figure 22 is a cross-sectional view of device 400 in a substantially assembled condition, and Figures 23-28 show and highlight individual components of device 400.

10 Device 400 implants a two-part stapling mechanism comprising locking member or staple ring 410 and staple 420, shown in e.g. Figure 23. Depending needles 423 of staple 420 each preferably include a tapered-surface tip or barb 425 for engaging behind and clipping over staple ring 410. According to one embodiment, needles 423 are substantially flexible with respect to the base
15 portion of staple 420 and snap into locking engagement with staple ring 410. This structure provides firm securement of the staple in the bladder neck. Further, device 400 causes staple 420 to slide along an inner supporting tube, as will be described, for better control and to avoid "rocking," i.e. insertion at an undesirable angle. Before implantation, staple ring 410 rests on bead 428.

20 Figure 24 shows staple insertion/actuator mechanism 430, to which handle 435 (Figure 22) is attached at its proximal end. Mechanism 430 includes leg member 440 and pedestal portion 445, on which staple 420 rests. When the

surgeon or other medical professional moves handle 435 farther into the urethra, leg member 440 and pedestal 445 push staple 420 along an inner supporting tube towards staple ring 410. Eventually, barbs 425 pierce the pulled-in tissue, as described with respect to previous embodiments, and snap behind staple ring 410
5 for a secure engagement.

Figure 25 illustrates staple ring retainer/release mechanism 450, attached to handle 455 (Figure 22) at its proximal end. Mechanism 450 includes outwardly biased retaining legs 460 with staple-ring engaging tips 470. Tips 470 include ramped portions 473, which extend outwardly through slots or other track
10 structure in a surrounding tube, described with respect to e.g. Figure 26, below. Once the stapling device is implanted, the medical professional urges release mechanism 450 farther into the urethra. This causes ramped portions 473 of tips 470 to ride within the tracks in the outer tube, which in turn urges retaining legs 460 inwardly. Once tips 470 are urged inwardly far enough to clear staple ring
15 410, and the balloon is deflated, the entire mechanism 450 can be withdrawn from the urethra through the center of staple ring 410.

Figure 26 illustrates mounting device 480, secured at its proximal end to device support 485 (Figure 22). Mounting device 480 includes tube 490 with recessed portion 495 for accommodating the pulled-in tissue. Device 480
20 also includes a distal wall portion with slots or tracks 475, through which ramped portions 473 of tips 470 protrude.

Figure 27 shows vacuum retainer mechanism 500, which defines vacuum apertures 510 for drawing a vacuum through vacuum port 515 (Figure 22), substantially in the manner described earlier.

Finally, Figure 28 shows balloon and catheter assembly 520.

5 Catheter 530 preferably extends down the center of device 400, and is coupled with endoscope port 535 (Figure 22) to accommodate an endoscope, as described earlier. Balloon 540 is illustrated in its undeployed position, and is coupled with pressure port 550 for inflation and deployment, in a manner substantially as described previously.

10 Device 400 optionally can be fit into a handle mechanism made of plastic or other suitable material. The handle preferably has slots to accommodate e.g. handle 435 of insertion/actuator mechanism 430, handle 455 of staple ring retainer mechanism 450, device support 550, etc. The handle can be disposable or constructed for reuse, as desired.

15 Figures 29-41 show handles and associated structure according to additional embodiments of the invention, incorporating many of the previously described features in a more refined form. Many of the concepts embodied in Figures 29-41 have already been described; to simplify the disclosure, many such concepts will not be repeated. For example, the various balloon/inflatable
20 members described above will not be described again here.

As shown in Figures 29-30, the illustrated incontinence treatment device 600 includes base handle 605, which preferably is one-piece with or

otherwise attached to substantially cylindrical, upwardly extending member 610. Member 610, in turn, preferably is one-piece with or otherwise attached to ring retainer 620. Ring retainer 620 defines recessed portion 630, for accommodating tissue and/or muscle pulled therein by a vacuum source in a manner described
5 previously. Further details of retainer 620 are provided below.

Figures 29-30 also illustrate staple-release handle 650, disposed above base handle 605 in this embodiment. Staple-release handle 650 preferably is one-piece with or attached to substantially cylindrical, upwardly extending member 660 (not visible in Figures 29-30, but shown in e.g. Figures 36-37),
10 which preferably surrounds member 610. Disposed above staple-release handle 650 is staple-advance handle 670, which is one-piece with or rigidly attached to substantially cylindrical, upwardly extending member 680. Member 680 preferably surrounds member 660. Finally, Figure 29 illustrates base or support 485, which is one-piece with or rigidly attached to vacuum retainer mechanism
15 500. Mechanism 500 includes vacuum apertures 510 and has already been described.

Figure 31 illustrates staple 420, which has been described previously. Also visible in Figure 31 are detents 685. According to one embodiment, shown in Figure 31A, upwardly extending member 680 includes a
20 plurality of radially inwardly extending pins 687. Pins 687 fit within detents 685 of staple 420, to provide support for staple 420 relative to member 680. Detents 685 also allow rotational indexing, so that staple 420 can be prealigned before a

treatment procedure begins. Member 680 can be rotated, e.g. via handle 670 or otherwise, until needles 423 are properly aligned with respect to ring retainer 620, which will now be described in more detail.

As shown in Figure 32, ring retainer 620 includes a plurality of
5 sprung legs 690. The illustrated embodiment includes six such legs 690, but of course a greater or lesser number of legs, for example three legs, is also contemplated. Providing fewer legs tends to allow more room for the balloon or other structure disposed within device 600. Each leg 690 preferably includes one or more slanted surfaces 700, 720. Such surfaces preferably engage structure
10 external to mechanism 620, to drive legs 690 inwardly after staple 420 has been brought through the tissue/muscle in gap 630 and into contact with staple ring 410. This contact occurs as the medical professional moves staple-release handle 650. Moving legs 690 inwardly withdraws legs 690 from staple ring 410 and removes legs 690 from supporting contact with staple ring 410 at groove 710,
15 once it is desired to withdraw treatment device 600 from the bladder/urethra.

As best shown in Figure 37, ring retainer 620 also defines recesses 730 at the uppermost portion of upwardly extending member, for accommodating depending needles 423 of staple 420. Recesses 730 preferably are disposed directly beneath gaps 740 between legs 690 of retainer 620, such that needles 423
20 slide from recesses 730, across gap 630 and into gaps 740. This configuration assures accurate and even positioning of needles 423 behind staple ring 410. As

referenced previously, handle 670 can be turned to rotationally index staple 420 for correct positioning.

In use, ring retainer 620 is first disposed as shown in Figure 32-33.

The staple is mounted on pins 687 and rotationally aligned with respect to
5 retainer 620. The device is inserted into the patient in the manner described
previously. Vacuum is applied and the tissue/muscle is drawn into gap 630, also
as described previously. Staple 420 then is urged across gap 630, by movement of
staple-advance handle 670, through the tissue and into contact with staple ring
410. As shown, barbs 425 each include a tapered surface for engaging and sliding
10 relative to ring 410, and depending needles 423 of staple 420 then lock into place
behind ring 410. The configuration of Figures 34-35 thus is achieved.

Figure 38 shows a streamlined version of the lower end of device
600. Figure 39 shows the undersides of handles 605, 650 and 670. Ridges 680
provide a better gripping surface for the surgeon or other medical professional.
15 Figure 39 also illustrates aperture 690, through which extend e.g. the catheter and
endoscope described previously, along with other instruments that might be
desirable for a particular procedure, such as a camera, electrocautery, endoscopic
suture device, etc.

Turning to Figure 40, the lower end of device 600 includes vacuum
20 port 760 with associated vacuum line 770, as shown. Vacuum port 760 preferably
is one-piece with and molded as a part of base 485. Sealing ring 775 provides a

vacuum seal between the upper portion 777 of the hub of base 485, and the remainder of base 485.

Locking mechanism 800 will now be described with reference to Figures 41-47. Locking mechanism 800 includes thumbwheel 810 with ridged surface 815, rod support 820, and upwardly extending locking rods 830, shown in Figure 47. Locking rods 830 extend upwardly from apertures 840 in supports 820, and into and through corresponding apertures in handle 670. Rods 830 include detents 850 at their upper ends, for engaging and locking into apertures 860 (Figures 45-46) in base 485. Locking rods 830 extend on opposite sides of handle 650. Thus, handles 605, 650 and 670, as well as base 485, are all held in a substantially fixed angular orientation with respect to each other. Handles 650, 670 preferably are allowed to slide along locking rods 830. Thumbwheel 810 is placed over and tightened down with respect to base 485, holding all of the component parts substantially in place with respect to each other.

Referring to Figures 48-56, incontinence treatment device 900 includes many of the features and advantages described with respect to the previous embodiments. To simplify the description, not every feature and advantage will be repeated verbatim here. Those of ordinary skill will appreciate that the previous descriptions of e.g. inflation balloons, corresponding inflation mechanisms, vacuum devices, viewing devices, methods of use, materials and other features of previously described embodiments are equally applicable here.

Incontinence treatment device 900 includes first generally cylindrical member 905 and second generally cylindrical member 910 disposed generally concentrically over first member 905. A coil-shaped staple 915 is also disposed generally concentrically over first member 905, as shown. Second member 910 defines recess or cutout portion 920 for contacting engagement end 925 of staple 915. As can be immediately appreciated, rotating second member 910, e.g. when a surgeon or other user of device 900 turns raised portion 930 of member 910, causes staple 915 to rotate by a corresponding amount in the same direction. Sharp, tissue-penetrating tip 935 of staple 915 thus penetrates and is driven into the desired anatomical tissue, which is held in place e.g. by vacuum, as described earlier. As staple 915 advances longitudinally into the desired anatomical tissue, member 910 advances longitudinally with it, maintaining the driving contact between them.

Embodiments of the invention provide a significant advantage, in that no complicated locking or retaining mechanism is needed to hold staple 915 in place with respect to member 910 during the rotation/implantation process. Correspondingly, after staple 915 has been implanted, member 910 can be disengaged from staple 915 simply by withdrawing device 900; no special release mechanisms or other devices are needed to disengage the one from the other.

Figure 49 illustrates "left hand" configurations of recess 920 and staple 915, in that member 910 is rotated to the left (as viewed from a distal end of device 900) to advance staple 915. Those of ordinary skill will appreciate that

embodiments of the invention equally contemplate "right hand" configurations as well. If desired, recess 920 of member 910 can be substantially rectangular or otherwise shaped such that both "left hand" and "right hand" staples 915 can be used.

5 Device 900 further includes vacuum apertures or slots 938 disposed through first member 905 and fluidly coupled to a vacuum source, such as a syringe or vacuum pump, for example, through vacuum port 940. As with previous embodiments, member 905 can include an inwardly curved shape in the region of apertures 938, according to the shape desired for the surrounding
10 anatomical tissue. Other aspects of the vacuum application process will be appreciated from previously described embodiments.

Device 900 further includes inflation balloon 945, also generally in accordance with previous embodiments. Inflation balloon 945 is fluidly coupled with inflation port 950, which in turn is coupled with an inflation source (such as
15 syringe 955, Figure 52, a pump, or the like). To better enable an operator of device 900 to judge the degree to which balloon 945 is inflated, device 900 further includes pilot balloon 960, disposed at port 950 or another location for easy visibility.

First member 905 defines hollow interior 965 for receiving
20 viewing device 970, shown in e.g. Figure 49. Viewing device 970 is a 4 mm cystoscope, according to one embodiment, but cystoscopes of other sizes, and other viewing devices (including but not limited to endoscopes, as described

previously), can be used. Viewing device 970 preferably includes light source 975, e.g. a fiber optic light source. O-ring 980 provides a seal between viewing device 970 and first member 905. As will be apparent, viewing device 970 is constructed such that the operator of device 900 can view a region at a distal end of the first generally cylindrical member, before, during and/or after a staple-insertion procedure. Accordingly, member 905, at least in the region of tip 982 thereof, is preferably composed of clear or generally transparent material.

Tip 982 can include a generally helical trough 983 to prevent undesired lateral or other movement into the adjoining tissue. At the end of trough 983, tip 982 can include stop 984, which contacts engagement member 925 at the end of its normal course of travel in trough 983, to prevent over-insertion of staple 915. Of course, stop 984 is an optional feature, as is trough 983.

In the embodiment illustrated in Figure 48, first member 900 also includes an extended portion 985, which can be one-piece with member 900 or separately joined to it. Extended portion 985 supports inflation balloon 945 in a desired position with respect to the bladder, bladder neck, urethra or other anatomical structure to which staple 915 is being applied. Portion 985 can be formed of a flexible and/or rubbery material, according to one embodiment, for easier insertion and to reduce the possibility of trauma to the urethra, bladder or other tissue.

Figure 50 is an end view of staple 915, according to one embodiment. The main body of staple 915 is generally in the form of a coil or

spiral, as previously described. Tip 935 is disposed at one end of main body 990, and engagement portion 925 at the other, as shown. Engagement portion 925 is constructed to engage second cylindrical member 910, e.g. at recess 920, and to engage first cylindrical member 905 along optional trough 983. Engagement
5 portion 925 also can be grasped for removal of staple 915, should removal be desired. Staple 915 can be removed simply and easily, merely by reversing its path of rotation into the tissue.

Staple 915 has a generally circular shape defining a circumferential path 995 when viewed from an end of staple 915, e.g. in the manner of Figure 50.
10 As can be seen, engagement portion 925 is generally disposed along circumferential path 995. This configuration is in contrast to certain prior art staples, in which a corresponding portion extends all the way, or substantially all the way, to and/or through the central axis of the staple instead of being generally along the circumferential path defined herein. In addition, the staple can be
15 placed such that in tissue structures with a lumen, e.g. the urethra, bladder neck, or a blood vessel, the staple can be in the wall of the lumen structure and covered by tissue. By keeping engagement portion 925 generally along path 995, instead of having it extend all the way to the center, embodiments of the invention allow room for accommodation of delivery apparatus, a viewing device, a balloon
20 and/or other structure, in the manner previously described. In addition, fluids, e.g. bodily fluids, are able to pass in the lumen defined by the staple.

As can be seen from e.g. Figure 50, engagement portion 925 extends no more than about 33 percent into the interior of staple 915 along a diameter thereof, preferably no more than about 25%, more preferably no more than about 15%, and even more preferably no more than about 10% into the interior along the diameter.

According to other embodiments, engagement portion 925 can be disposed entirely within circumferential path 995. Although this disposition might tend to require more precise positioning for positive engagement with first member 910, it reduces even further the degree to which an interior portion of staple 915 might tend to be obstructed.

Staple 915 generally defines a helix extending along a helical path, engagement portion 925 forming an end of the helix without generally deviating from the helical path. Staple 915 can be formed from a generally stiff wire formed into a helical shape, according to one embodiment, and a cross section of the wire can generally flatten out toward engagement portion 925 of staple 915, for better tissue penetration. Alternatively, the entire staple can be of flattened cross-sectional shape, e.g. in the form of a rectangular cross-section, to provide better flexibility and deformability as may be desired in particular surgical situations.

According to one embodiment of staple 915, visible in e.g. Figure 48, engagement portion 925 is extended in the longitudinal direction, relative to

the remainder of the staple, for better engagement with staple advancing device /
second member 910.

Device 900 can optionally include a hood, disposed over at least tip
935 of staple 915, for protection during insertion of the apparatus into the patient.

5 The hood prevents tip 935 from "catching" on, penetrating, or otherwise
undesirably contacting anatomical tissue before staple 915 has been properly
positioned by device 900. The hood also prevents uncoiling, unwinding or other
undesirable extension or deformation of staple 915 during insertion. In one
embodiment, the hood is bivalved and withdrawn from the patient once the device
10 is in place, e.g. in the manner of a bivalved speculum, prior to deployment of the
staple.

Additionally, a collar can be placed over the knurled end 930 of
staple advancing member 910. The collar constrains staple advancing member
910 so that it cannot move axially with respect to the remainder of device 900,
15 during initial insertion. The collar then may be removed for deployment of the
staple.

According to embodiments of the invention, staple 915 can be
internally hollow or include a hollowed out interior area. Medication thus can be
placed within the staple, e.g. epithelial growth inhibitor, sclerosing agent, and/or
20 antibiotic, for administration immediately upon implantation and/or over an
extended period of time thereafter. Openings can be disposed at one or both ends
of the staple, with one or more plugs in place as needed. Additionally, or

alternatively, staple 915 can be used for delivery of e.g. absorbable suture material, with such material remaining in place as the staple is backed out of the tissue. Accordingly, initially the suture would be disposed within the staple, with at least one end protruding from the staple. Once the staple has been introduced, at least the protruding end is grasped and the staple removed, leaving the suture in place. The ends of the suture then would be tied off.

Once anatomical tissue has been held in place for a certain length of time, e.g. six weeks or more, staple 915, suture or other holding material may no longer be needed to keep the tissue in the desired configuration. Accordingly, staple 915 itself can be absorbable, as well as any suture material that is used along with it. Additionally, staple 915 can include a textured exterior, and/or a surface coating, to induce scarring and thus promote retention of the desired shape. Staple 915 then can be absorbed, or removed physically, if desired.

In operation, cystoscope or other viewing device 970 is placed within treatment device 900, specifically within hollow interior 965 of first member 905. Device 900 then is placed into the urethra of the patient, so that inflation balloon 945 is within the bladder. Inflation balloon 945 then is inflated, e.g. with syringe 955, and device 900 is pulled back so that balloon 945 contacts the bladder neck. The operator of device 900 thus is able to more accurately move staple 915 to the correct location within the urethra or bladder neck.

A vacuum then is applied to vacuum apertures or slots 938 through vacuum port 940, and consequently the tissue of the urethra is pulled into slots or

apertures 938, i.e. into a desired configuration, with the aid of cystoscopic or other visualization. Staple advancing member 910 then is rotated to implant staple 915, again under cystoscopic or other visualization. Once implanted, the vacuum is released and balloon 945 is deflated. Device 900 then is completely and easily
5 removed from the patient, leaving staple 915 implanted.

Embodiments of the invention described with respect to Figures 48-56 provide a number of advantages. The amount of staple material left exposed to the interior of the urethra or bladder neck is significantly reduced. The staple may be placed submucosally, with only a small portion of the staple
10 exposed, to facilitate extraction. According to one embodiment, only the end of engagement portion 925 is exposed once implantation is complete. This feature tends to reduce the possibility of stone formation, infection, and other adverse effects.

With all of the embodiments, the urethra and bladder neck region
15 are supported in a substantially normal anatomic configuration, allowing the sphincter to act normally without the downward and radial forces of the bladder fluid on it. Permanent correction of e.g. USI is achieved, using minimally invasive techniques and with minimal or no necrosis of the tissue.

While the invention has been described with respect to particular
20 embodiments, the description herein is intended to be illustrative and not limiting. For example, although specific reference has been made to the urethra and bladder, embodiments of the invention can be used to repair or sustain other

anatomical structures, such as the rectum, anal canal, liver or other organs.

Embodiments for use in male patients can be of greater length than those for use in female patients; dimensions can generally be chosen in accordance with particular anatomies. Further, the procedures described herein can be performed

5 without creating a vacuum, wherein the restoration of the urethra/bladder neck is accomplished with physical maneuvering. As will be apparent to those of ordinary skill, the structures and other concepts disclosed with respect to one embodiment or figure can be applied, and in many cases are intended to be applied, in combination with those of other embodiments or figures. Various

10 other modifications and changes will be apparent to those of ordinary skill.

WHAT IS CLAIMED IS:

1. An implantable surgical staple, comprising:
 - a main body generally in the form of a coil, the main body having a
5 sharp, tissue-penetrating tip at one end thereof and an engagement portion at an
opposite end thereof;
wherein the engagement portion is constructed to engage a staple
advancing device for longitudinal and rotational advancement of the staple into an
implanted configuration;
 - 10 further wherein the staple has a generally circular shape defining a
circumferential path when viewed from an end of the staple, the engagement
portion being generally disposed along the circumferential path;
further wherein the staple is composed of a biocompatible material.
- 15 2. The staple of claim 1, wherein the engagement portion is disposed entirely
within the circumferential path.
3. The staple of claim 1, wherein the staple generally defines a helix
extending along a helical path, the engagement portion forming an end of the
20 helix without generally deviating from the helical path.

4. The staple of claim 1, wherein the staple is formed from a generally stiff wire formed into a helical shape.
5. The staple of claim 4, wherein a cross section of the wire generally flattens out toward the engagement portion of the staple.
6. The staple of claim 1, wherein the engagement portion is extended in the longitudinal direction, relative to the remainder of the staple, for better engagement with the staple advancing device.
7. A surgical treatment device, comprising:
an implantable surgical staple having a main body generally in the form of a coil, the main body having a sharp, tissue-penetrating tip at one end thereof and an engagement portion at an opposite end thereof, the engagement portion being constructed to engage a staple advancing device for longitudinal and rotational advancement of the staple into an implanted configuration, wherein the staple has a generally circular shape defining a circumferential path when viewed from an end of the staple, the engagement portion being generally disposed along the circumferential path, the staple being composed of a biocompatible material;
delivery structure for supporting the surgical staple and delivering the surgical staple to a desired anatomical site of a patient;

movement structure, operatively coupled with the delivery structure, for moving anatomical tissue into position for engagement by the staple; and

a staple advancing device for rotationally and longitudinally advancing the staple through the anatomical tissue to hold the anatomical tissue in a desired
5 configuration.

8. The surgical treatment device of claim 7, wherein the staple advancing device comprises a cylindrical body disposed generally parallel to the staple, rotation of the cylindrical body causing rotation of the staple through the
10 anatomical tissue.

9. The surgical treatment device of claim 8, wherein the amount and direction of rotation of the cylindrical body causes rotation of the staple in a like amount and direction.

15 10. The surgical treatment device of claim 8, wherein the cylindrical body defines a recessed portion, the recessed portion engaging the engagement end of the staple for driving the staple through the anatomical tissue.

20 11. The surgical treatment device of claim 8, wherein the cylindrical body defines a generally hollow interior, the surgical treatment device further comprising viewing apparatus disposed within the hollow interior, the viewing

apparatus allowing an operator of the surgical treatment device to view
implantation of the staple in the anatomical tissue.

12. The surgical treatment device of claim 11, wherein the viewing apparatus
5 comprises a cystoscope.

13. The surgical treatment device of claim 11, wherein the viewing apparatus
extends within the coil of the staple.

10 14. The surgical treatment device of claim 8, further comprising a raised
portion attached to the cylindrical body, rotational engagement of the raised
portion by the fingers of an operator of the surgical treatment device causing
rotation of the cylindrical body and implantation of the staple.

15 15. The surgical treatment device of claim 7, further comprising a hood
disposed over the staple, the hood covering the sharp, tissue-penetrating tip of the
staple during initial insertion of the surgical treatment device into a patient.

16. A surgical treatment device, comprising:
20 delivery structure for supporting a coil-shaped surgical staple and
delivering the coil-shaped surgical staple to a desired anatomical site of a patient;

movement structure, operatively coupled with the delivery structure, for moving anatomical tissue into position with respect to the coil-shaped surgical staple; and

5 a staple advancing device for rotating the coil-shaped surgical staple into the anatomical tissue to hold the anatomical tissue in a desired configuration.

17. The surgical treatment device of claim 16, wherein the movement structure comprises a vacuum device for drawing desired tissue into a new anatomical position.

10

18. The surgical treatment device of claim 17, wherein the vacuum device comprises a syringe.

19. The surgical treatment device of claim 17, wherein the vacuum device
15 comprises a vacuum pump.

20. The surgical treatment device of claim 17, wherein the movement structure comprises a blocking device, operatively coupled with the vacuum device, for preventing the vacuum device from applying vacuum to a portion of
20 the anatomy of the patient.

21. The surgical treatment device of claim 20, wherein the blocking device comprises an inflatable mechanism.
22. The surgical treatment device of claim 21, wherein the inflatable
5 mechanism is a first inflatable mechanism, the surgical treatment device further comprising a pilot inflatable mechanism, operably coupled with the first inflatable mechanism, for indicating inflation of the first inflatable mechanism.
23. The surgical treatment device of claim 20, wherein the blocking device
10 comprises a balloon constructed for insertion into the bladder of the patient, further wherein the anatomical tissue is at least a portion of the bladder neck and/or urethra.
24. The surgical treatment device of claim 16, wherein the movement
15 structure is physically connected to the delivery structure.
25. The surgical treatment device of claim 16, being constructed for use in minimally invasive surgical procedures.
- 20 26. The surgical treatment device of claim 16, wherein the delivery structure and advancing device together comprise a plurality of concentrically disposed generally cylindrical members.

27. The surgical treatment device of claim 26, wherein at least one of the cylindrical members extends through the coil-shaped surgical staple along its axis.

5 28. The surgical treatment device of claim 26, wherein the delivery structure and staple advancing device are constructed for removal from the patient by simple withdrawal from the patient, said withdrawal from the patient automatically causing disengagement of the staple advancing mechanism from the coil-shaped surgical staple.

10

29. The surgical treatment device of claim 17, wherein the vacuum device comprises a generally cylindrical member defining vacuum apertures.

15

30. The surgical treatment device of claim 17, where the vacuum device is generally concentrically disposed with respect to the advancing device.

31. A method of treating urinary incontinence in a patient, the method comprising:

20 inserting a surgical treatment device into at least the urethra of the patient;
applying a vacuum with the surgical treatment device to draw at least a urethra portion and/or bladder neck portion of the patient into a desired configuration;

delivering a coil-shaped surgical staple to the patient with the device, the
staple holding the desired configuration; and
withdrawing the device from the patient.

5 32. The method of claim 31, further comprising:

inserting a balloon into the bladder of the patient;

inflating the balloon;

blocking application of vacuum to at least the bladder with the balloon;

deflating the balloon; and

10 withdrawing the balloon from the patient.

33. Urinary incontinence treatment apparatus, comprising:

means for applying a vacuum to draw at least a urethra portion and/or

bladder neck portion of a patient into a desired configuration;

15 means for delivering a coil-shaped surgical staple to the patient, the staple
holding the desired configuration; and

means for withdrawing the means for delivering from the patient such that
the coil-shaped surgical staple remains within the patient.

20 34. The apparatus of claim 33, further comprising:

means for blocking application of vacuum to at least the bladder; and

means for withdrawing the means for blocking from the patient.

35. The apparatus of claim 33, further comprising means for viewing implantation of the coil-shaped surgical staple, the means for viewing being operably coupled to the means for delivering.

5

36. Apparatus for implanting a staple into a patient, the staple generally defining a spiral shape, the apparatus comprising:

a first generally cylindrical member, the staple being disposed generally concentrically over the first cylindrical member;

10 a second generally cylindrical member disposed generally concentrically over the first cylindrical member, rotation of the second cylindrical member by an operator of the apparatus causing rotation of the staple into anatomical tissue of the patient.

15 37. The apparatus of claim 36, wherein the second generally cylindrical member comprises a cutout portion for engaging and driving the staple.

38. The apparatus of claim 36, wherein rotation of the second generally cylindrical member away from the staple releases the staple from engagement
20 with the second generally cylindrical member such that the apparatus can be withdrawn from the patient.

39. The apparatus of claim 36, further comprising at least one vacuum aperture extending through the first generally cylindrical member, the at least one vacuum aperture being constructed and disposed to apply vacuum pressure to anatomical tissue of the patient where the staple is to be delivered.

5

40. The apparatus of claim 39, further comprising a vacuum source fluidly coupled with the at least one vacuum aperture, the vacuum source being disposed at a proximal end of the first generally cylindrical member, the vacuum source applying vacuum through the first generally cylindrical member to the at least one vacuum aperture, the at least one vacuum aperture being disposed at a distal end of the first generally cylindrical member.

10

41. The apparatus of claim 39, further comprising an inflatable balloon operably coupled with the vacuum aperture.

15

42. The apparatus of claim 36, further comprising a hood disposed over the staple during insertion of the apparatus into the patient.

43. The apparatus of claim 36, further comprising a viewing device received within the first generally cylindrical member, the viewing device being constructed to view a region at a distal end of the first generally cylindrical member during a staple-insertion procedure.

20

44. Apparatus for implanting a staple into a patient, the apparatus comprising:
structure for delivering the staple to a desired anatomical site and
implanting the staple at the site; and
- 5 structure, operably coupled with the structure for delivering and
implanting, for supporting an optical viewing device within a body of the staple
during implantation.
45. The apparatus of claim 44, wherein the structure for delivering and
- 10 implanting is constructed to deliver and implant a staple having a shape in the
form of a coil.

Fig. 1
PRIOR ART

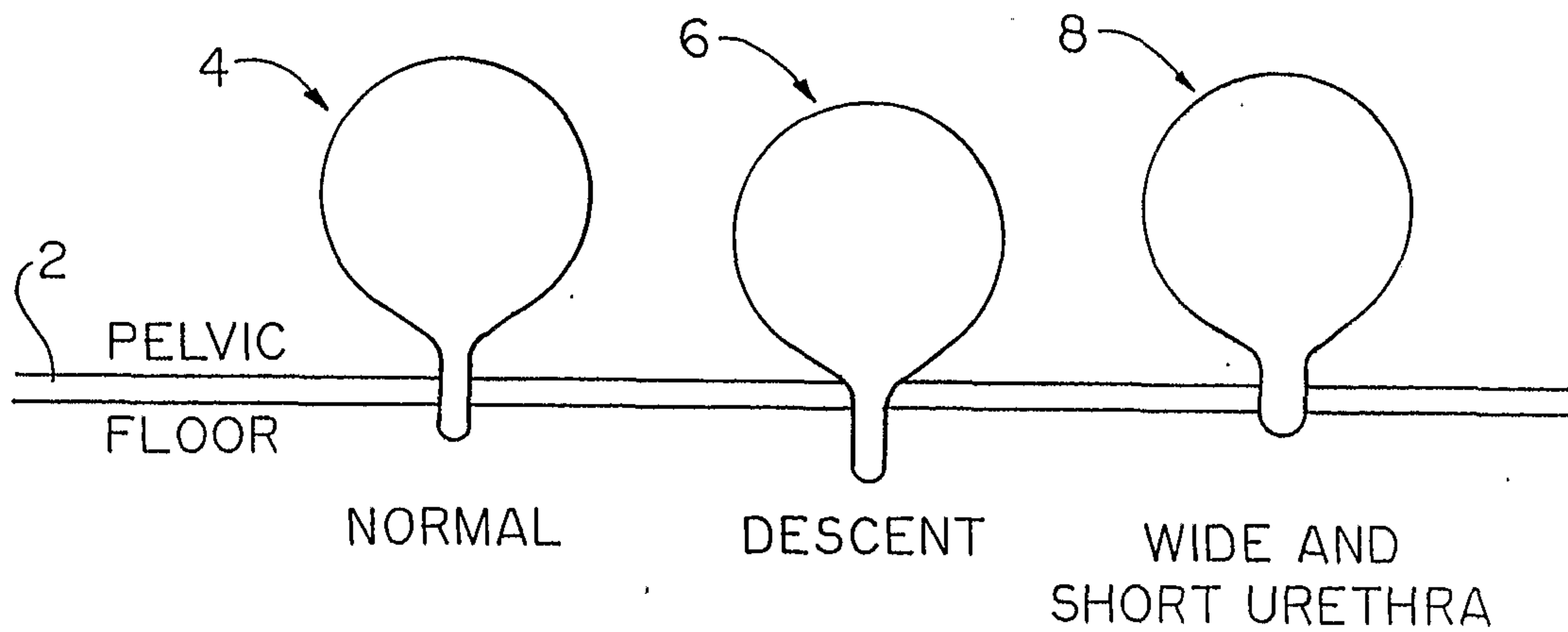


Fig. 2

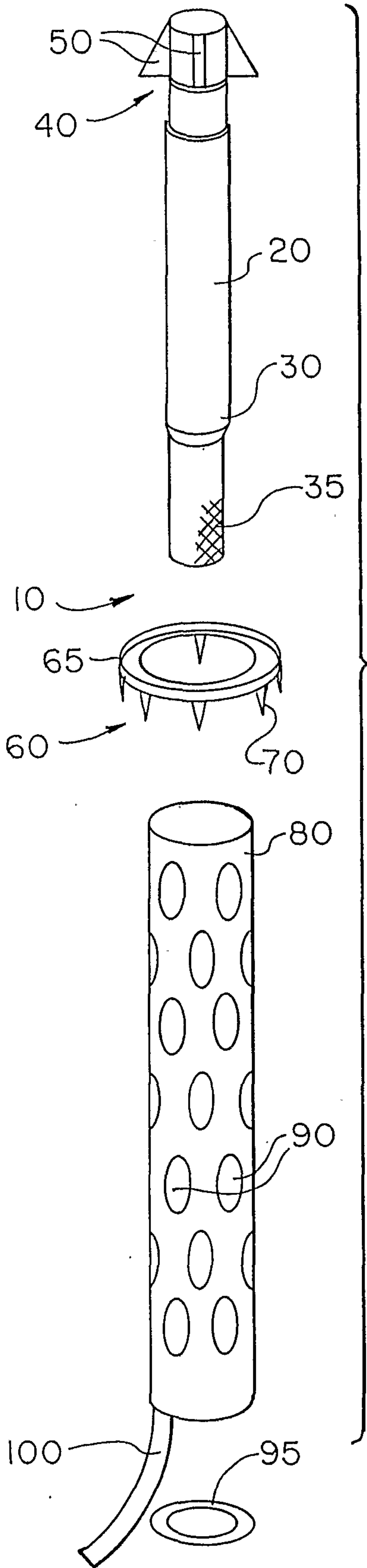


Fig. 3

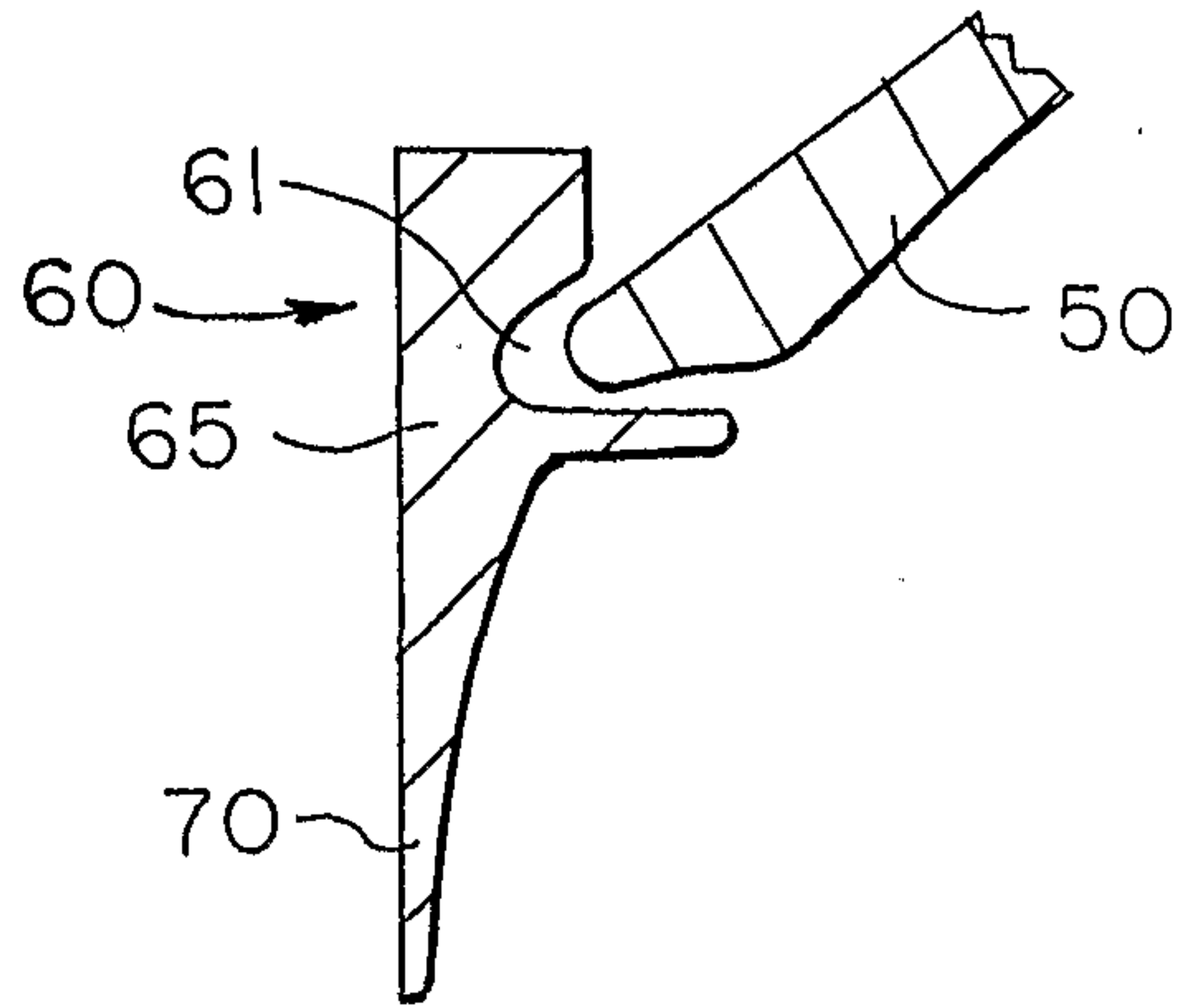


Fig. 4

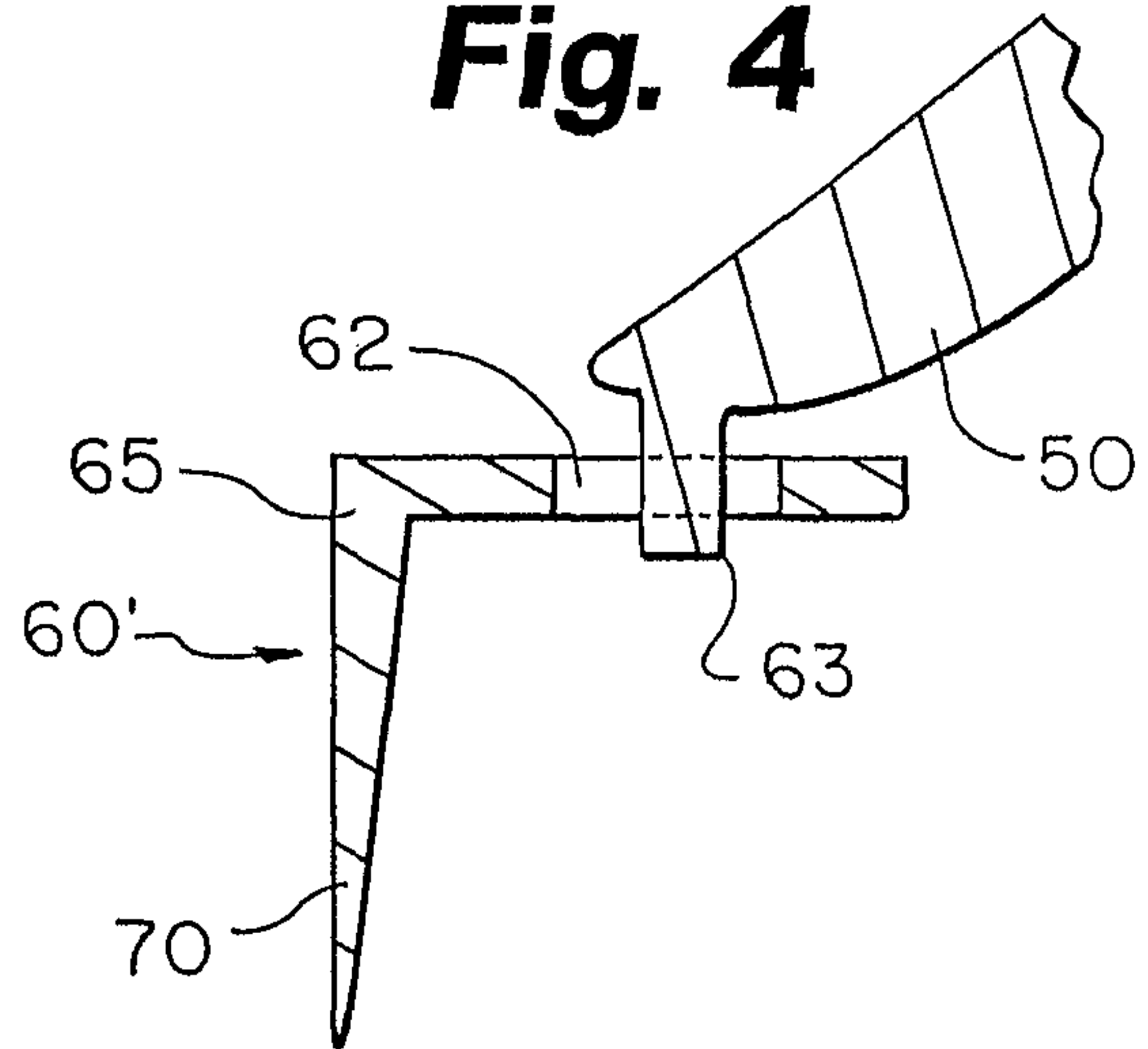


Fig. 5

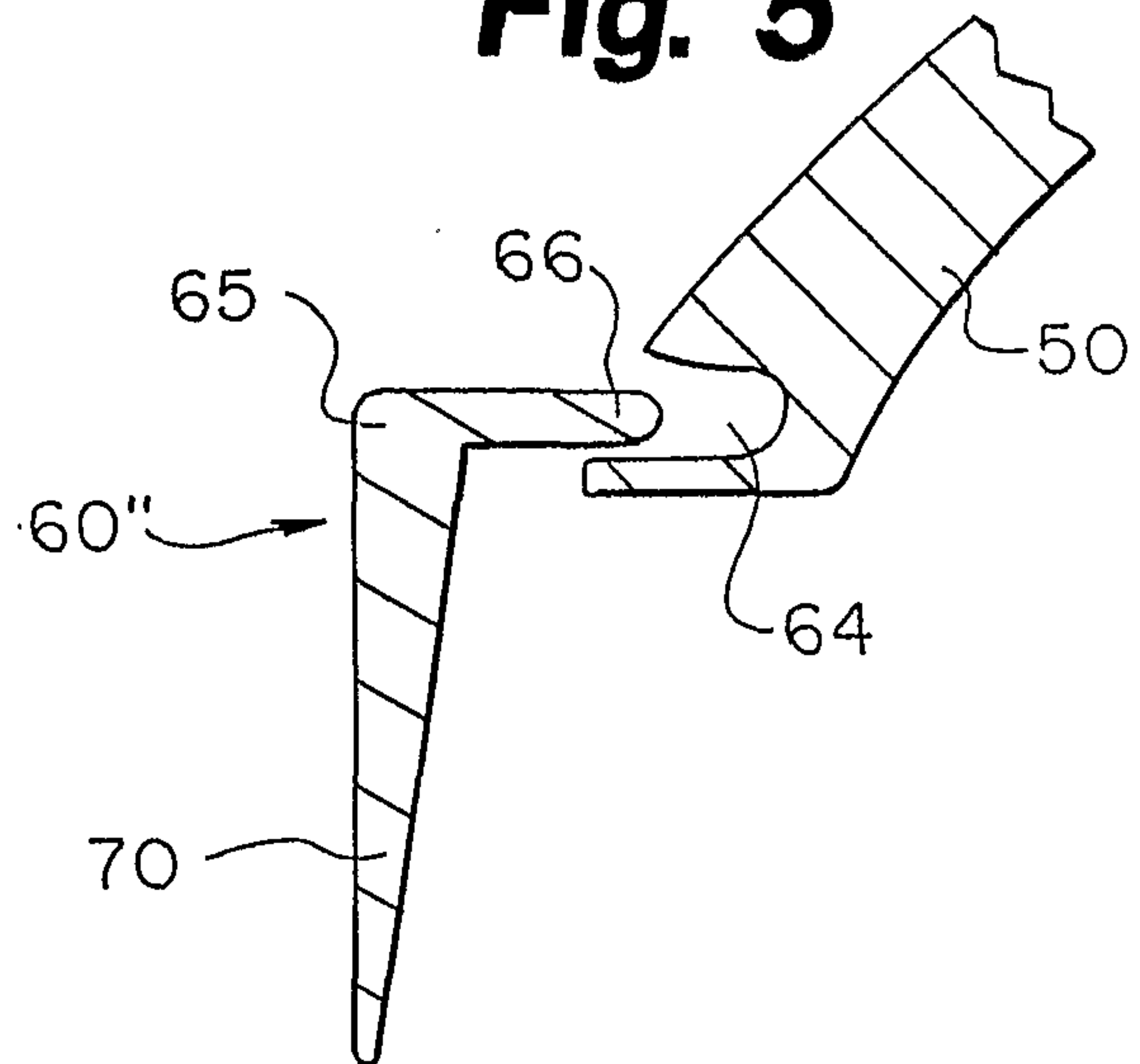


Fig. 6

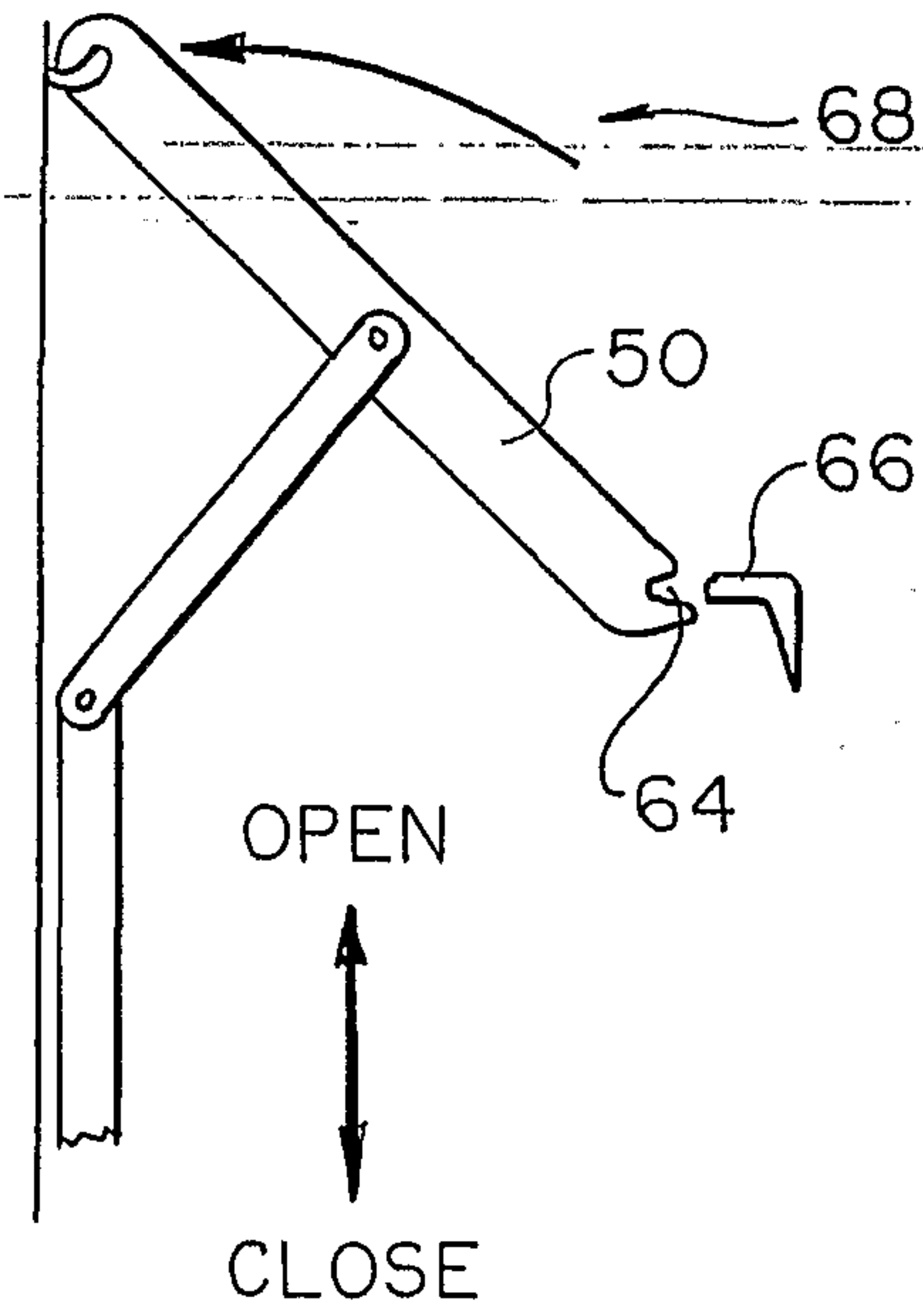


Fig. 7

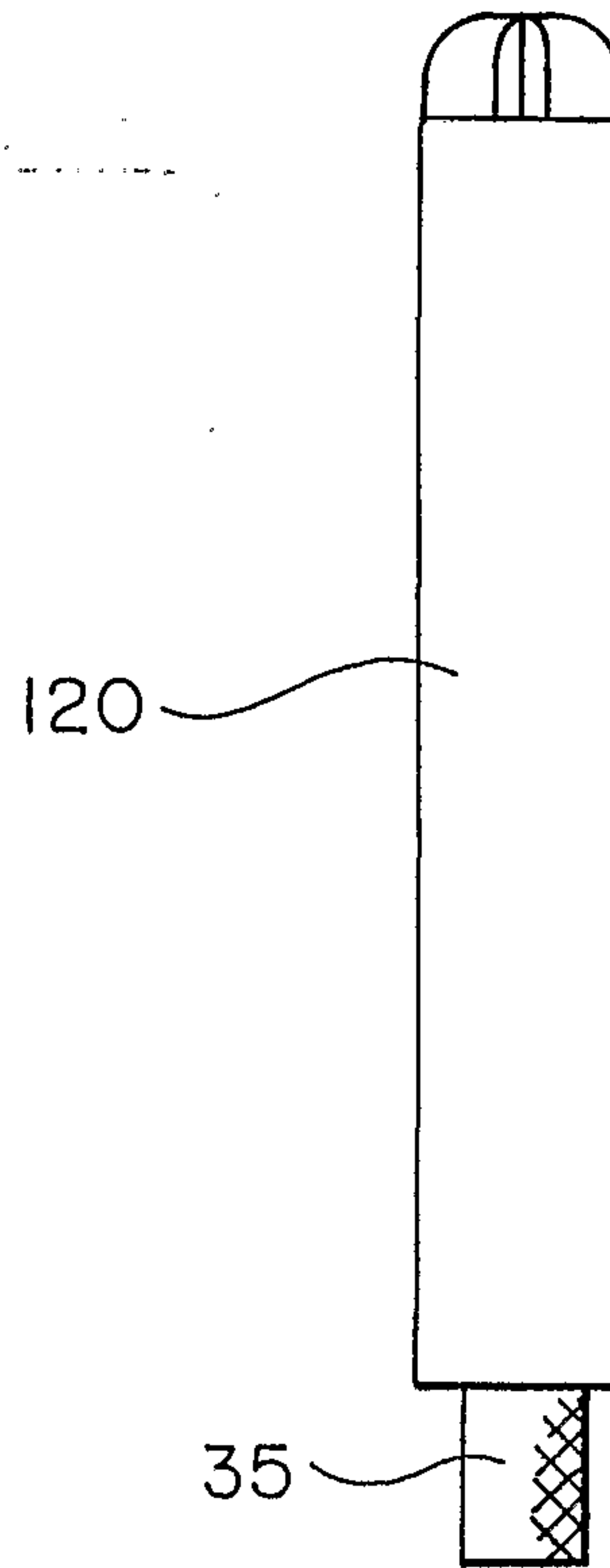


Fig. 8

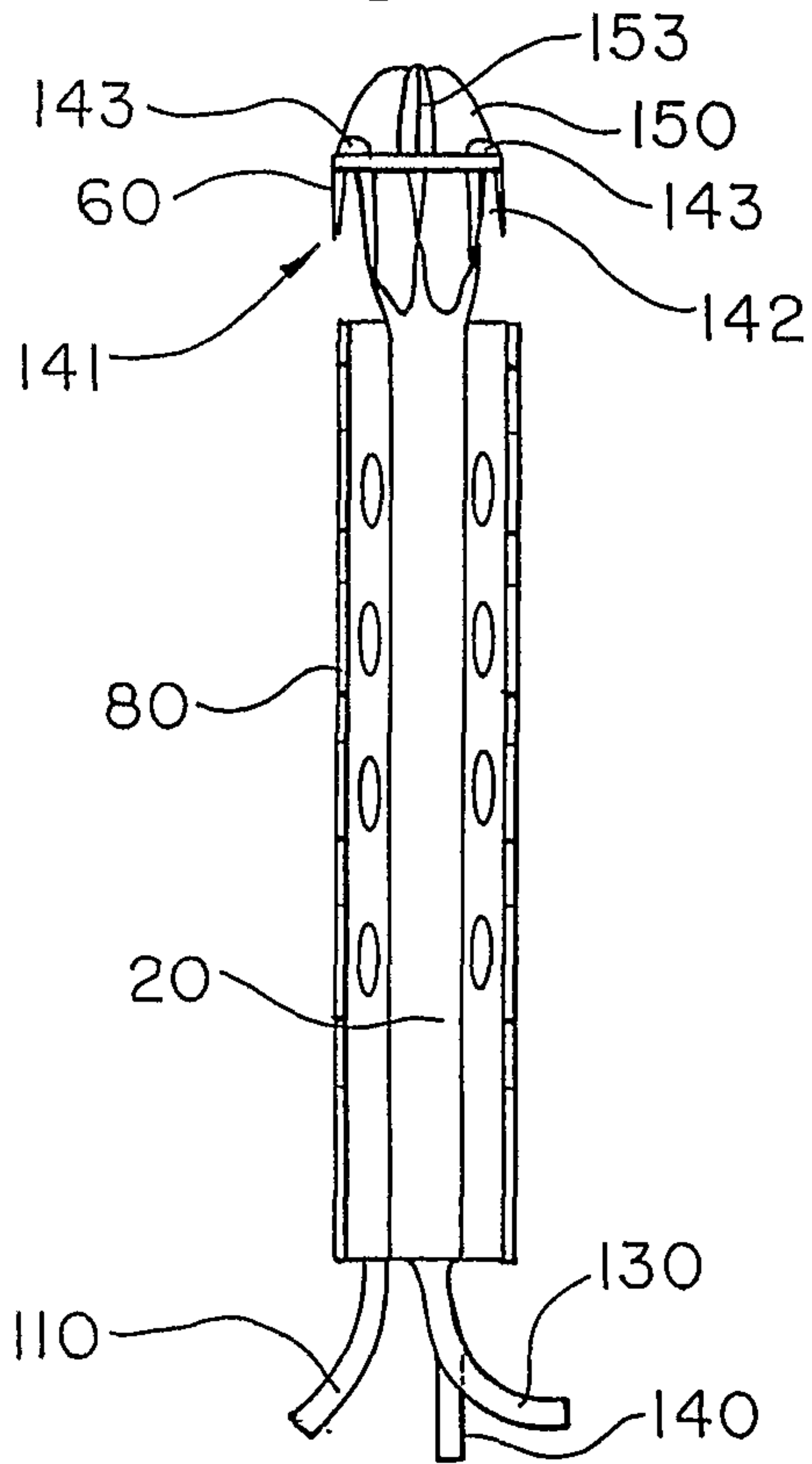
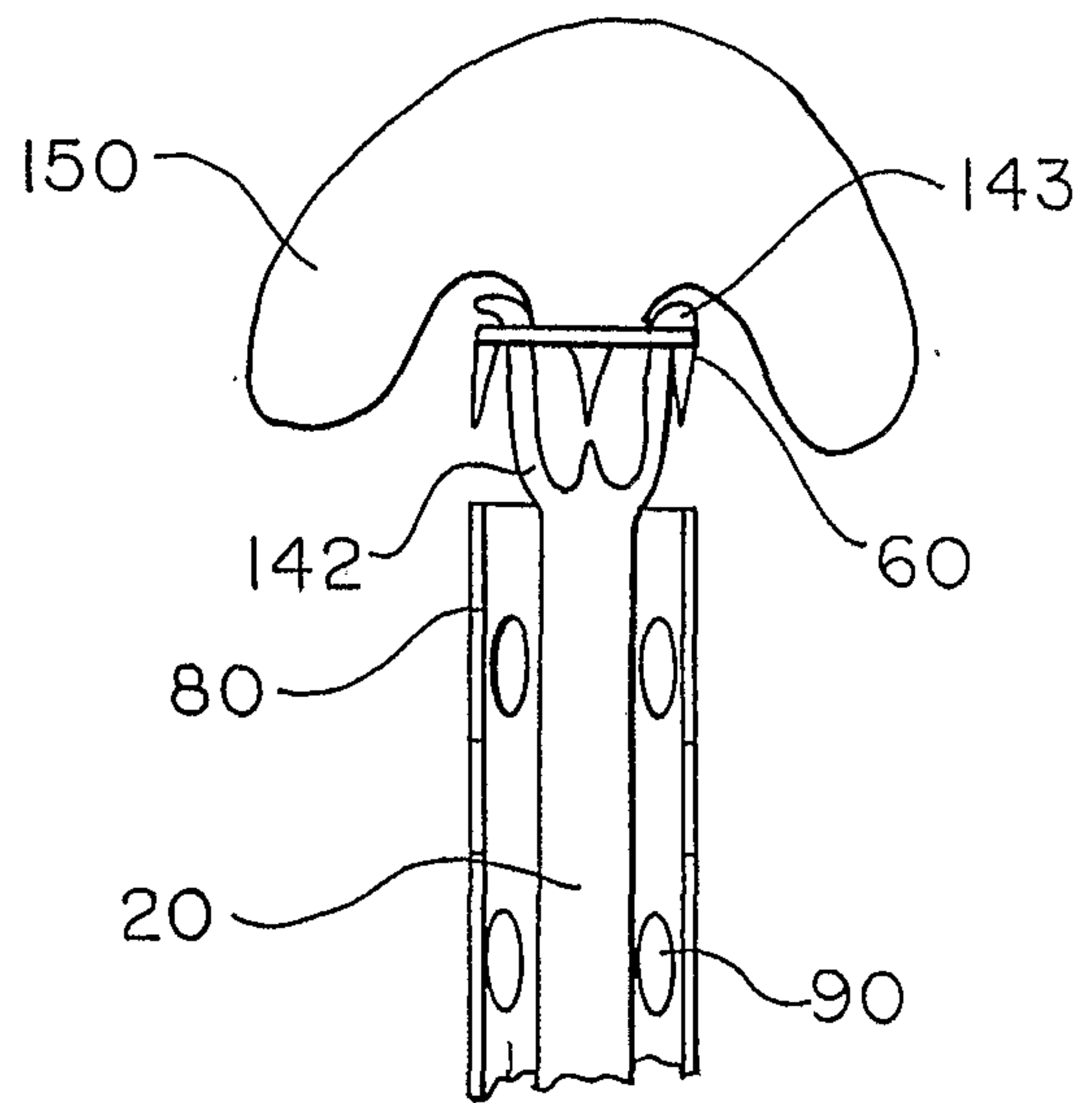


Fig. 9



4/28

Fig. 10

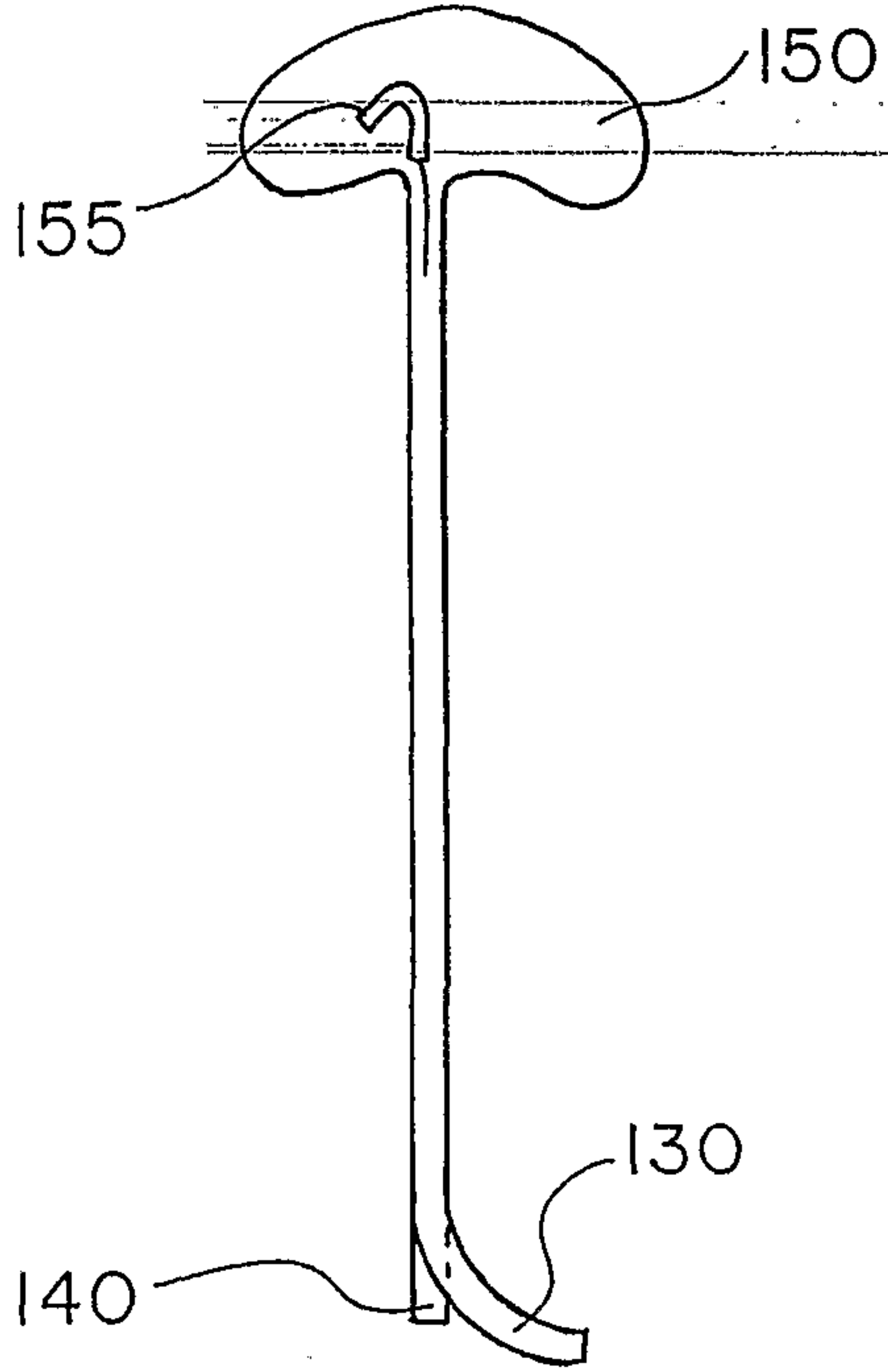


Fig. 11

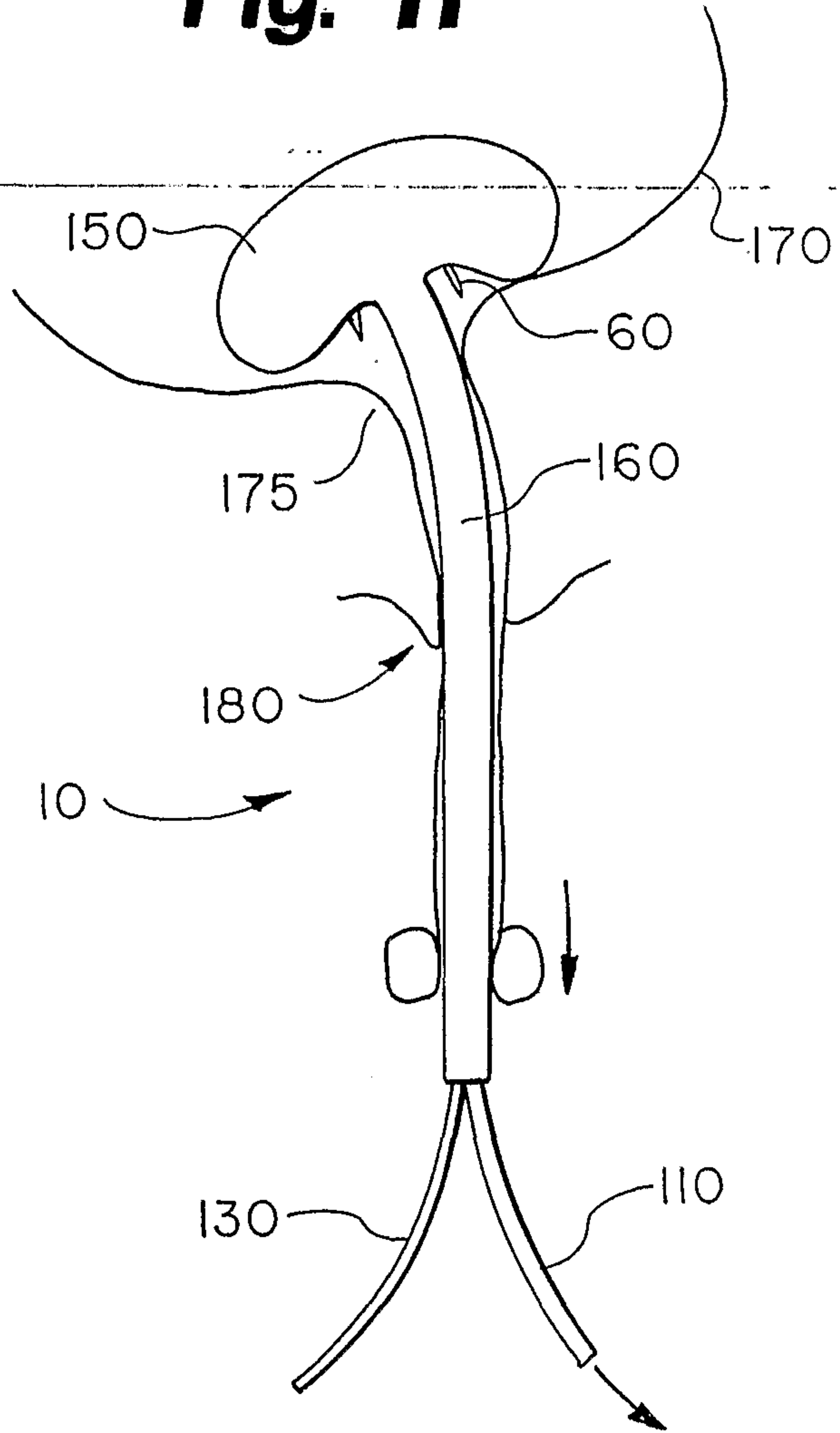


Fig. 12

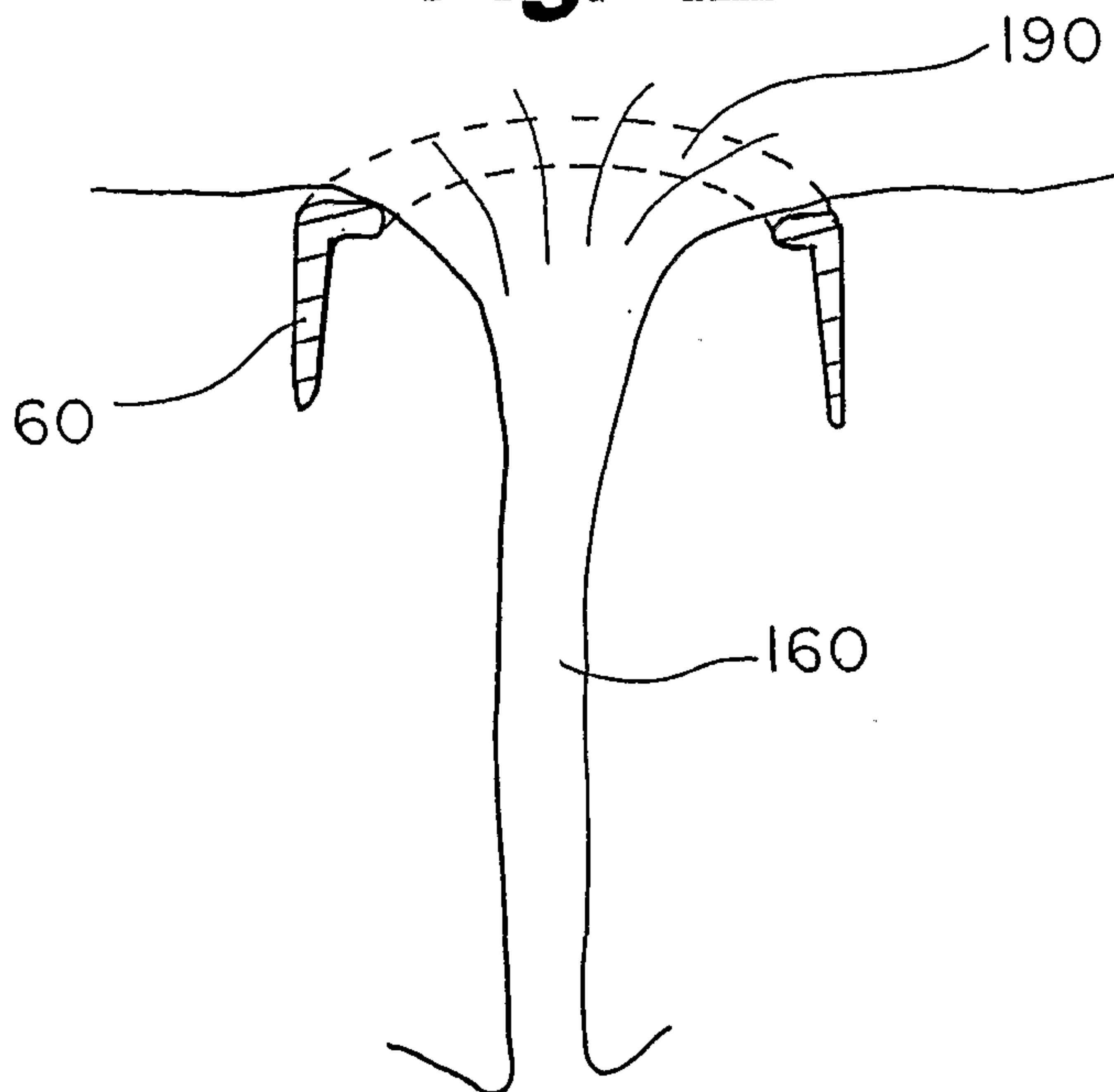


Fig. 13

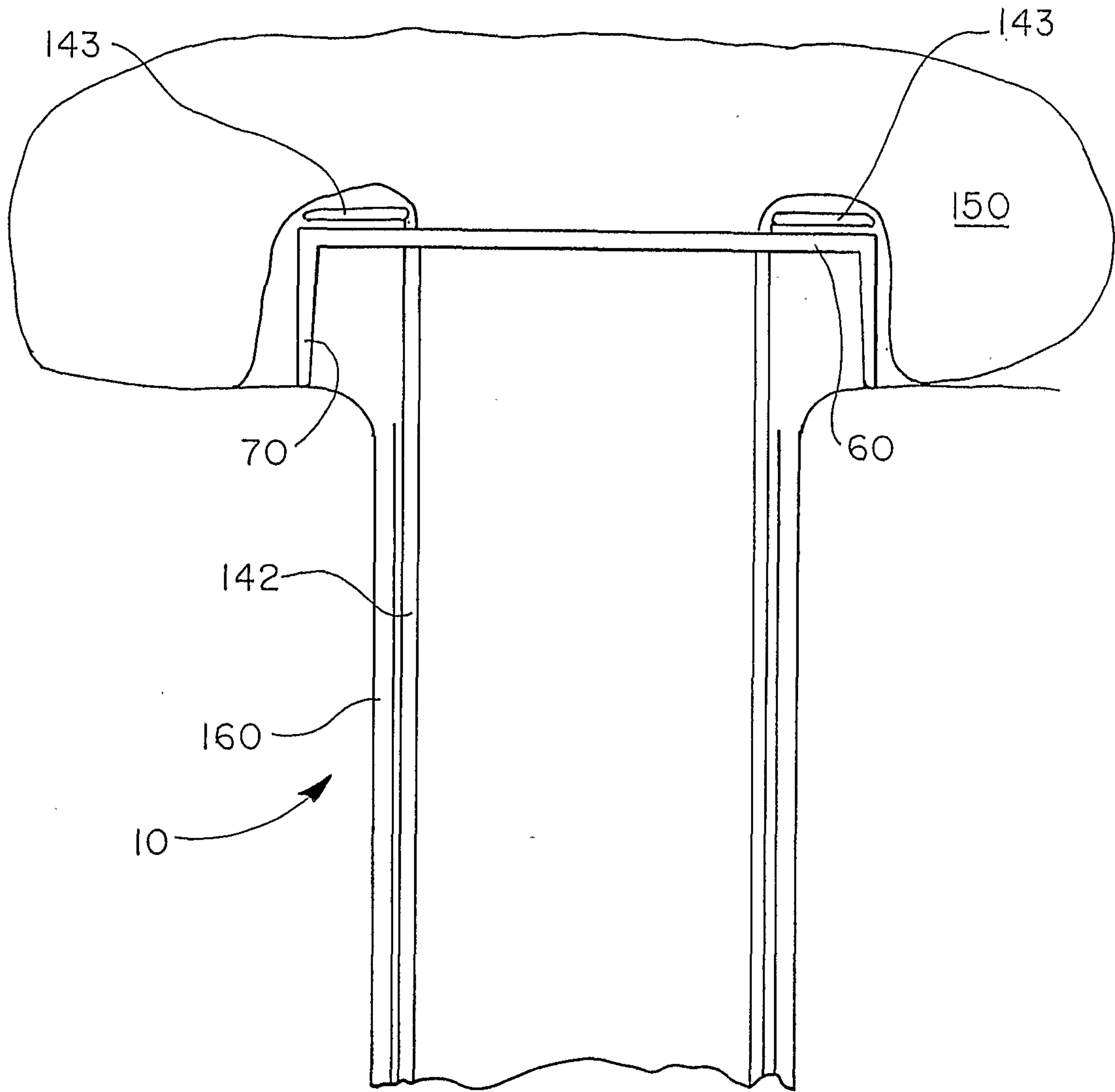


Fig. 14

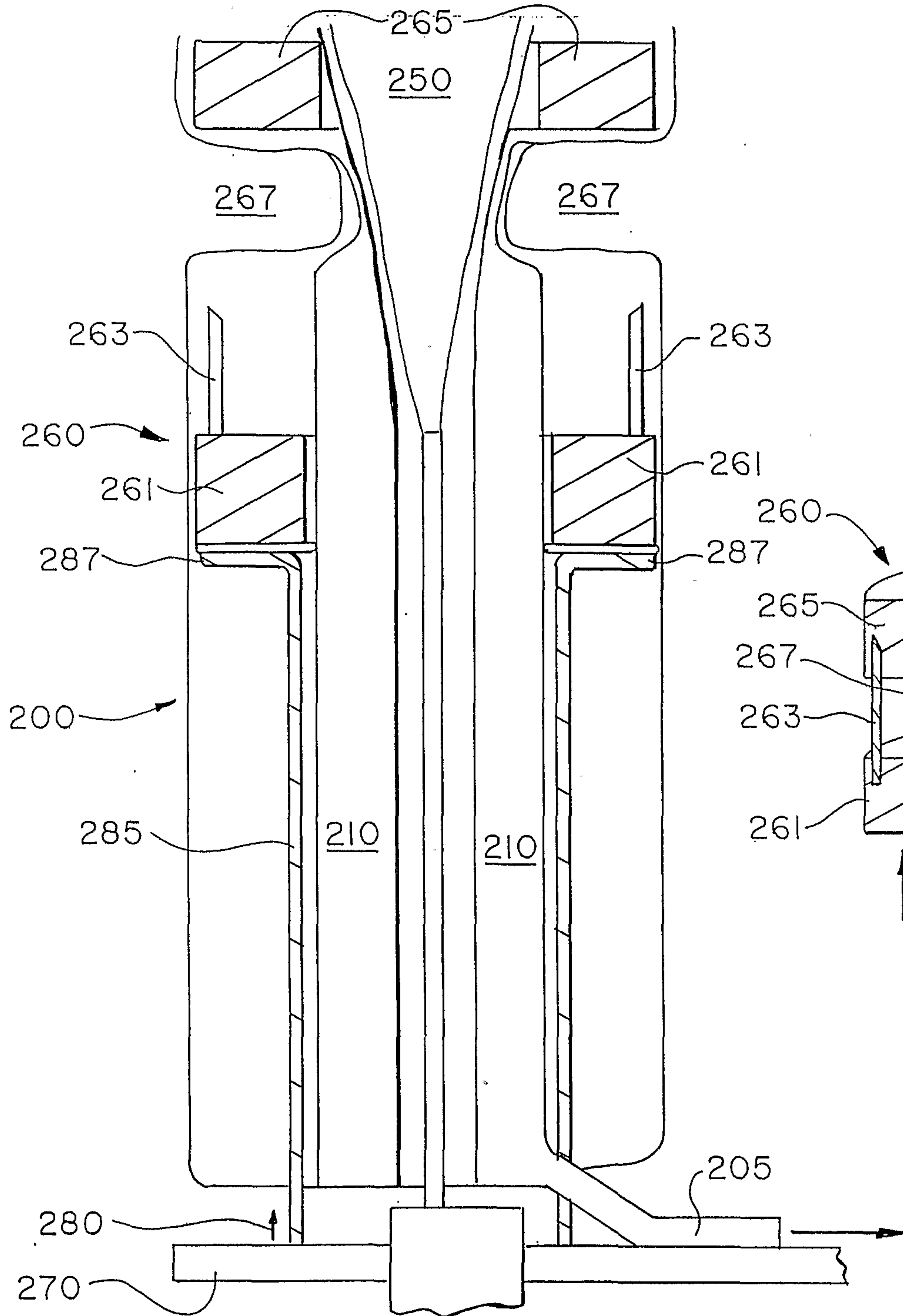


Fig. 15

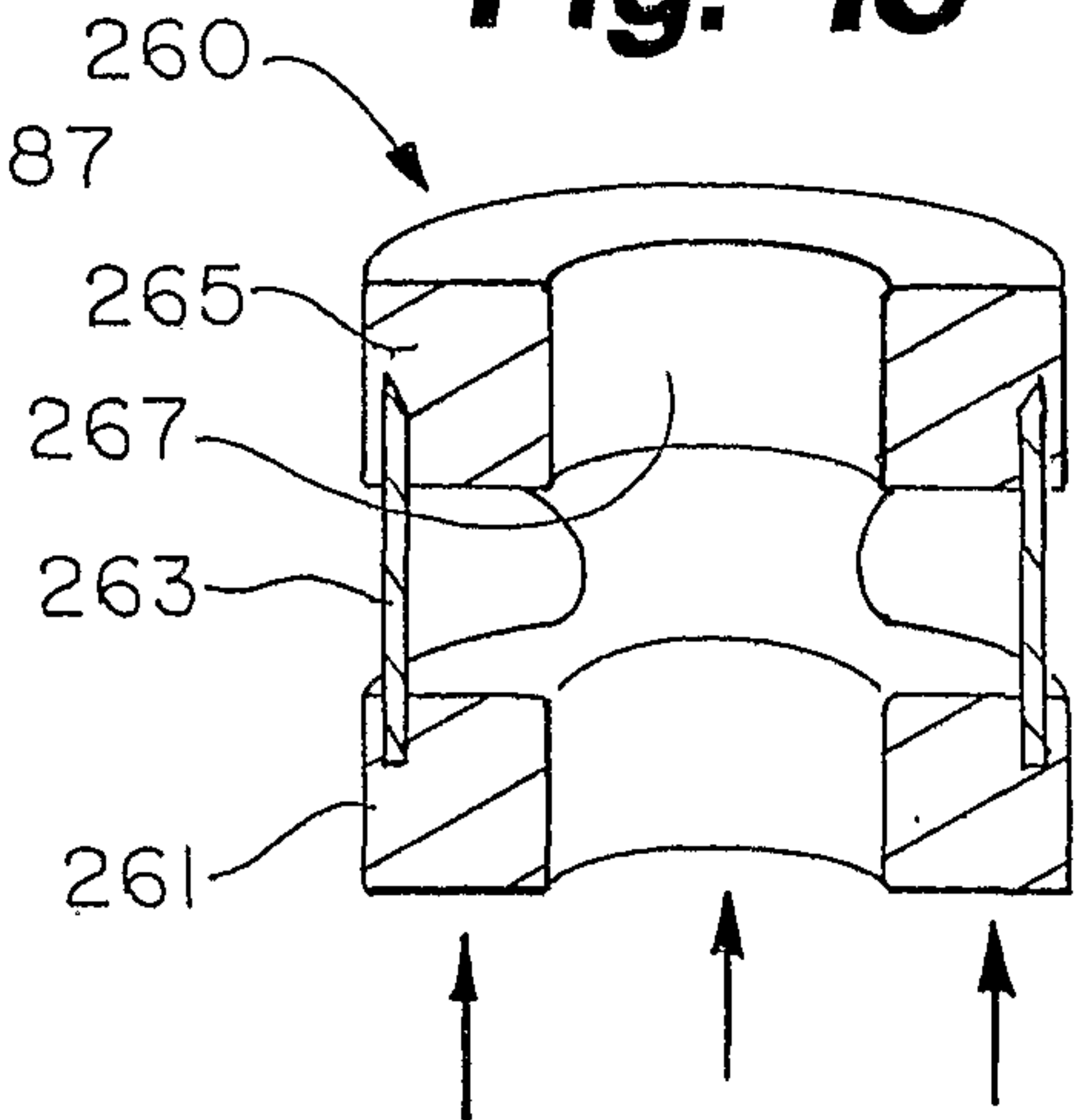
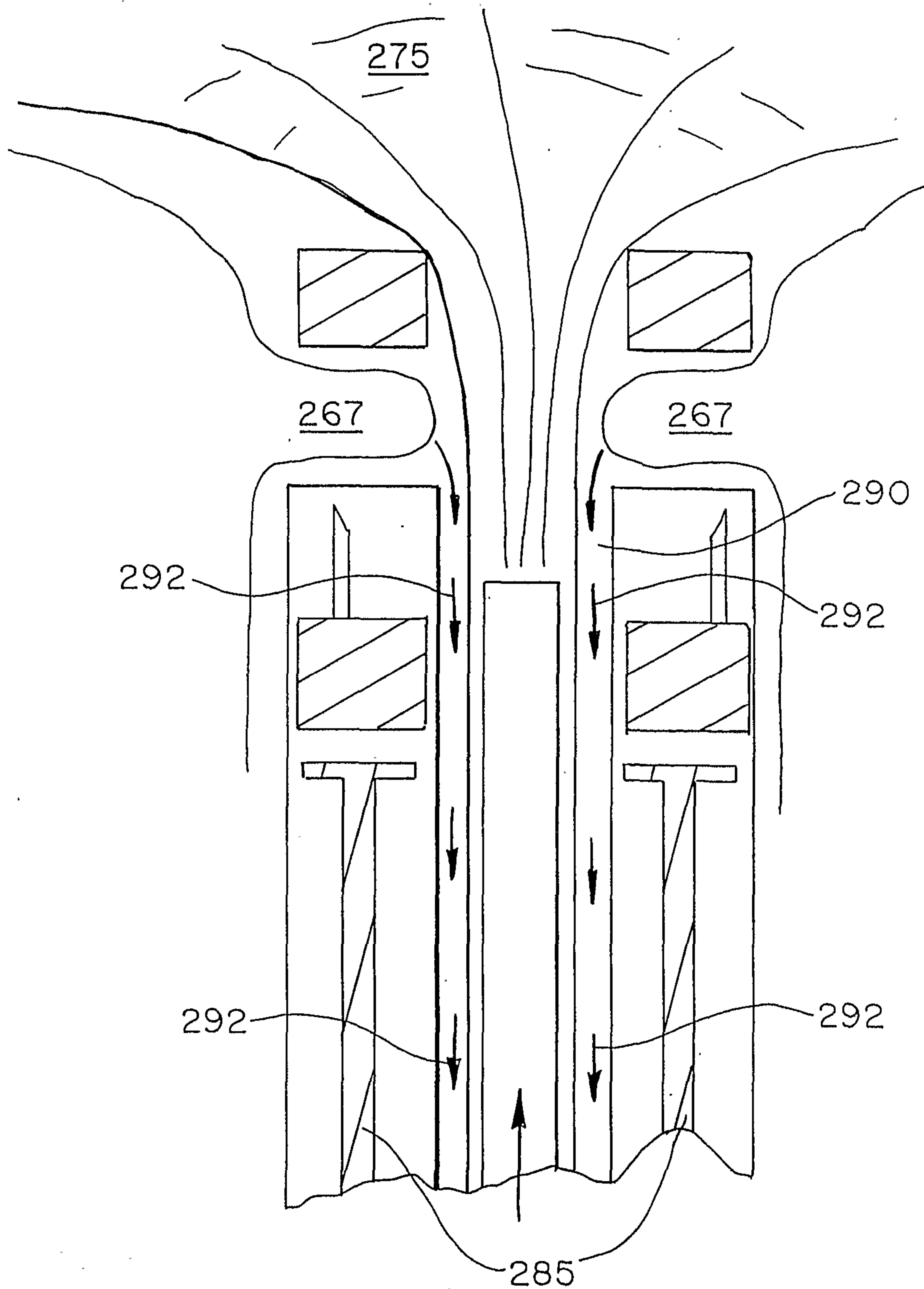
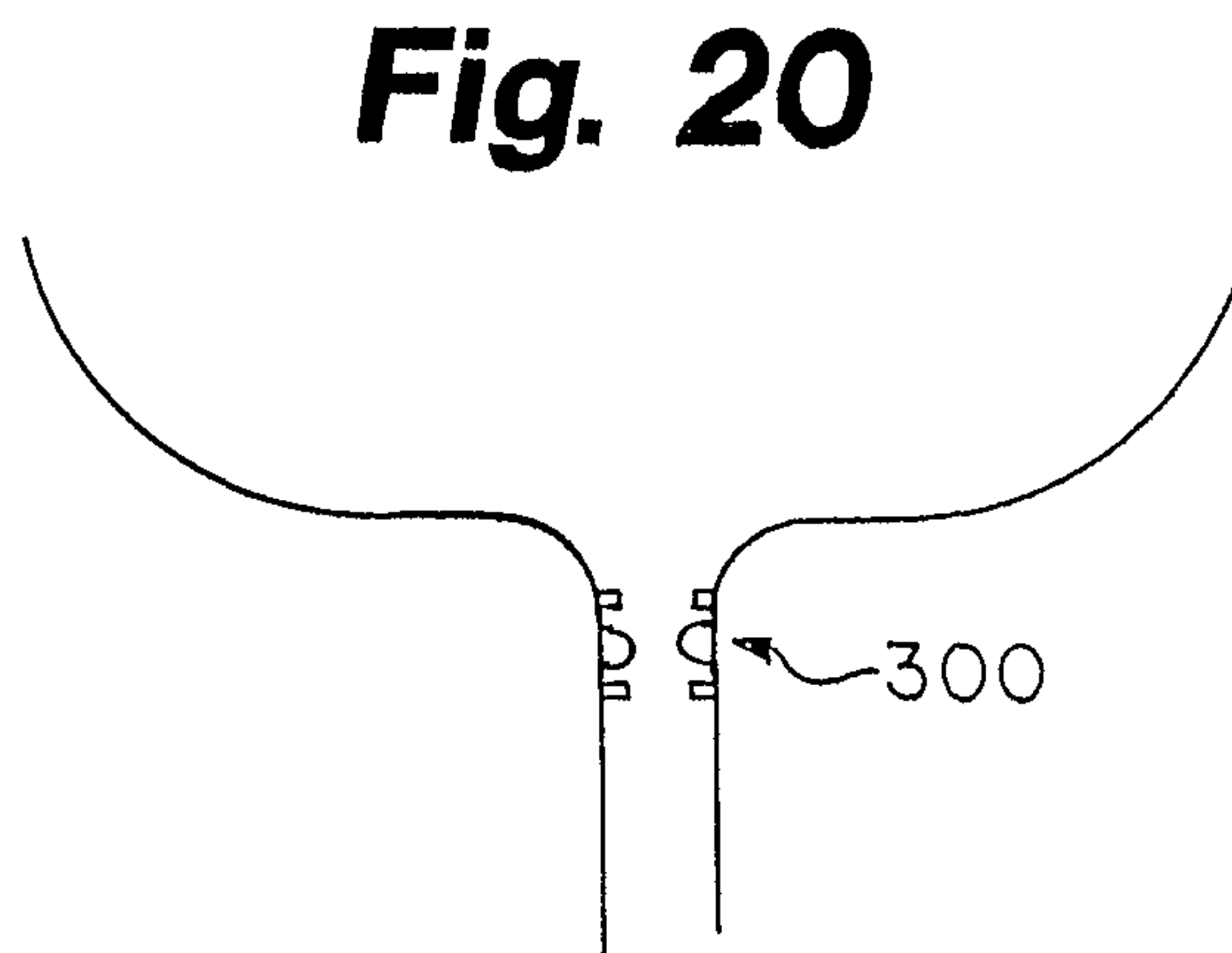
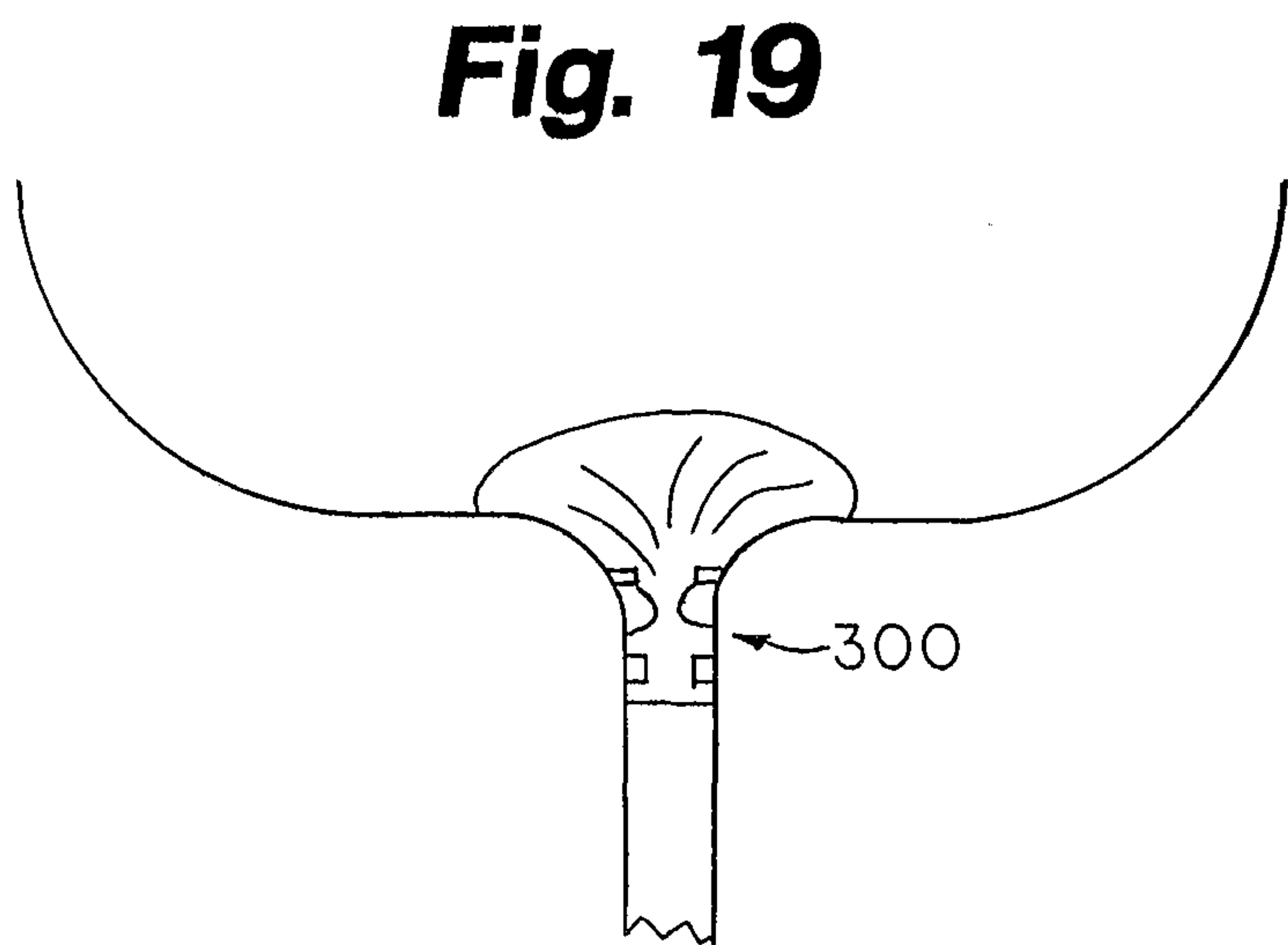
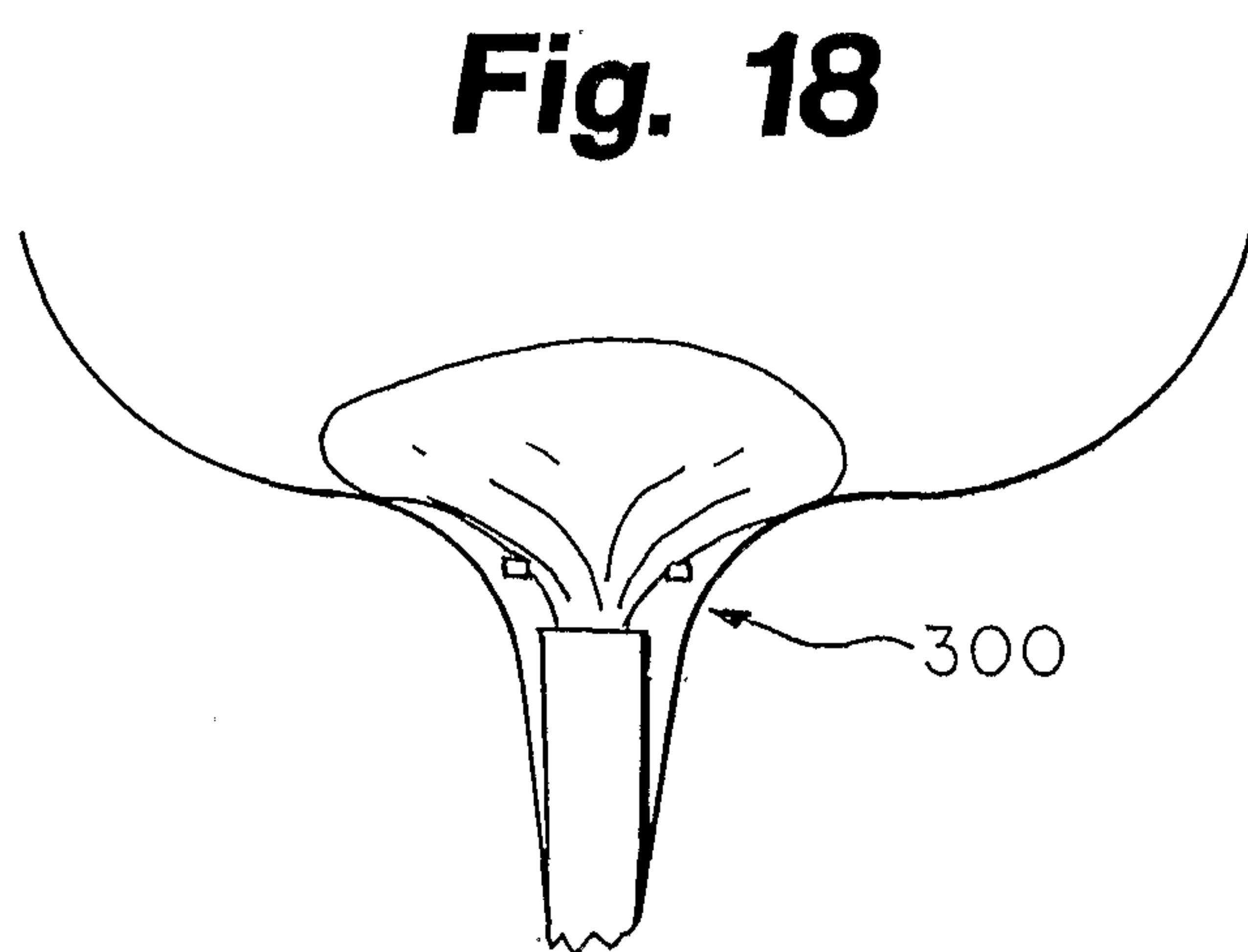
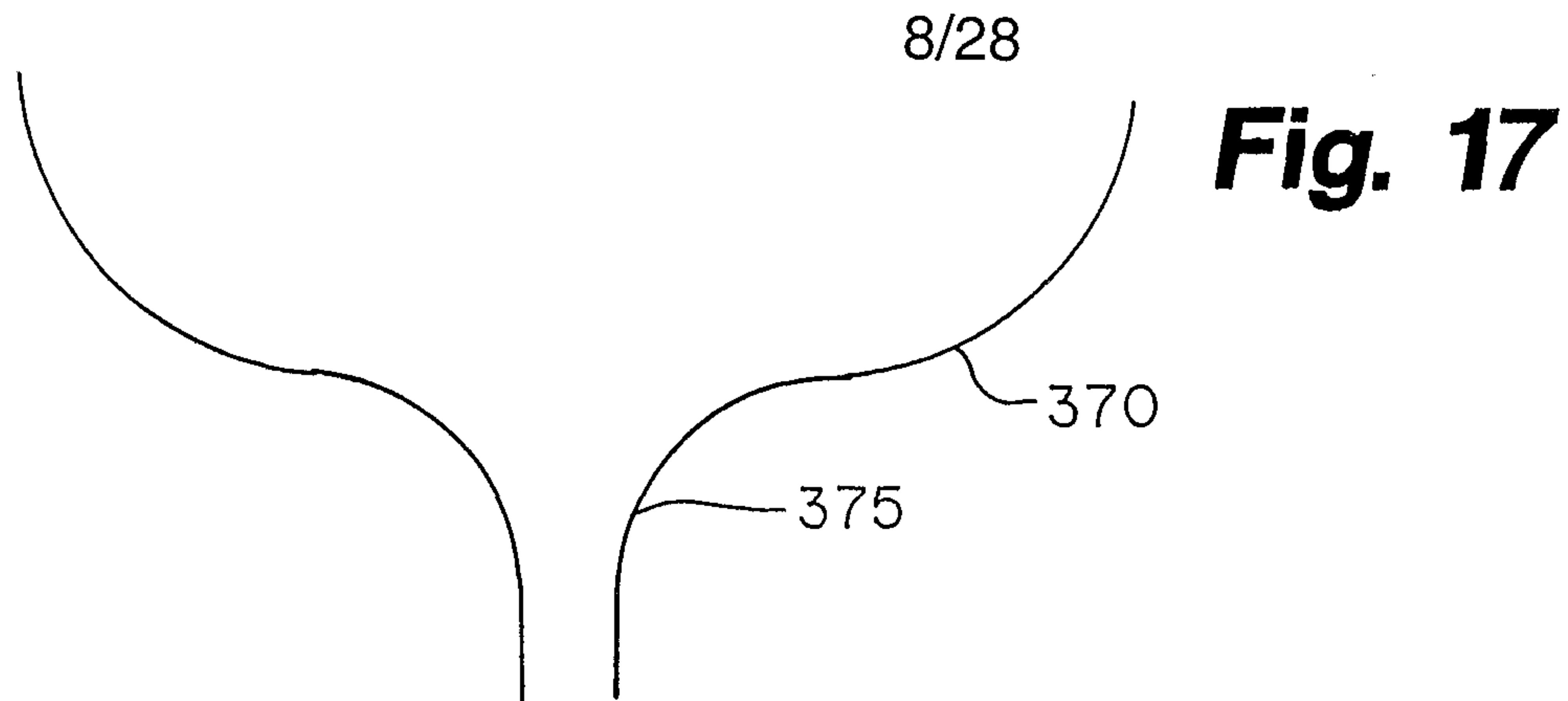


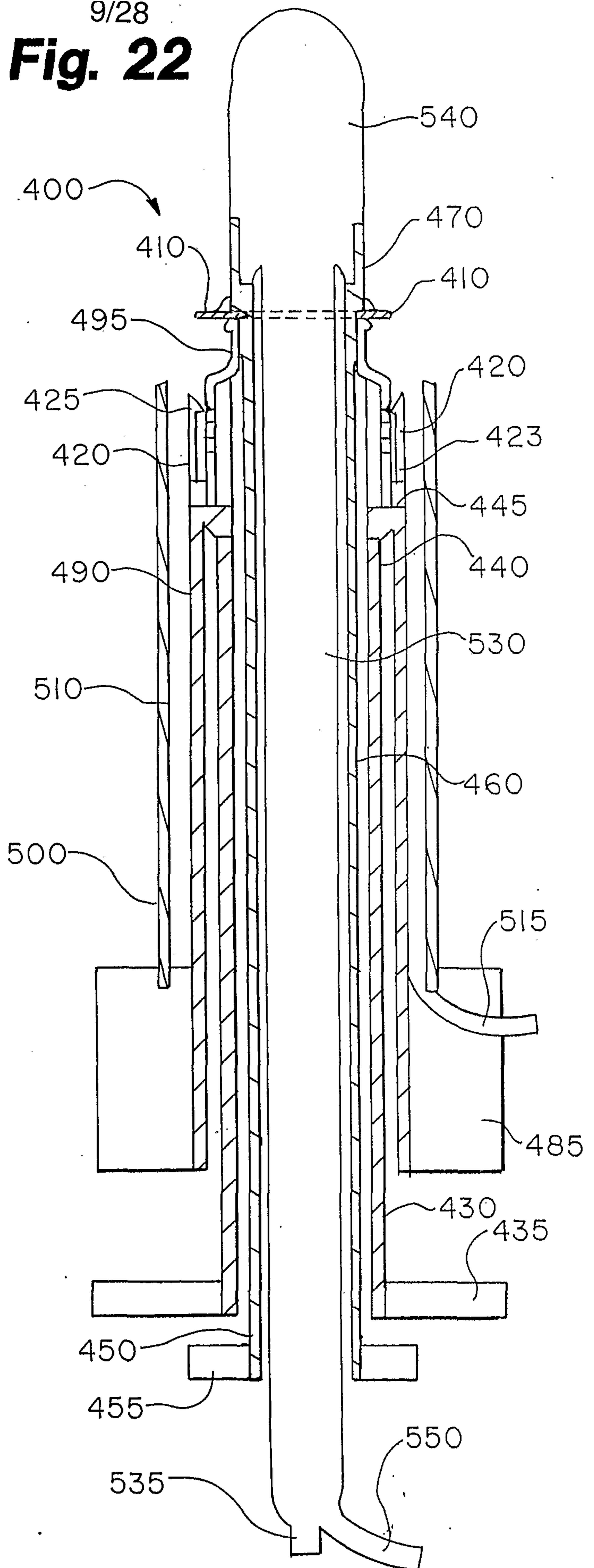
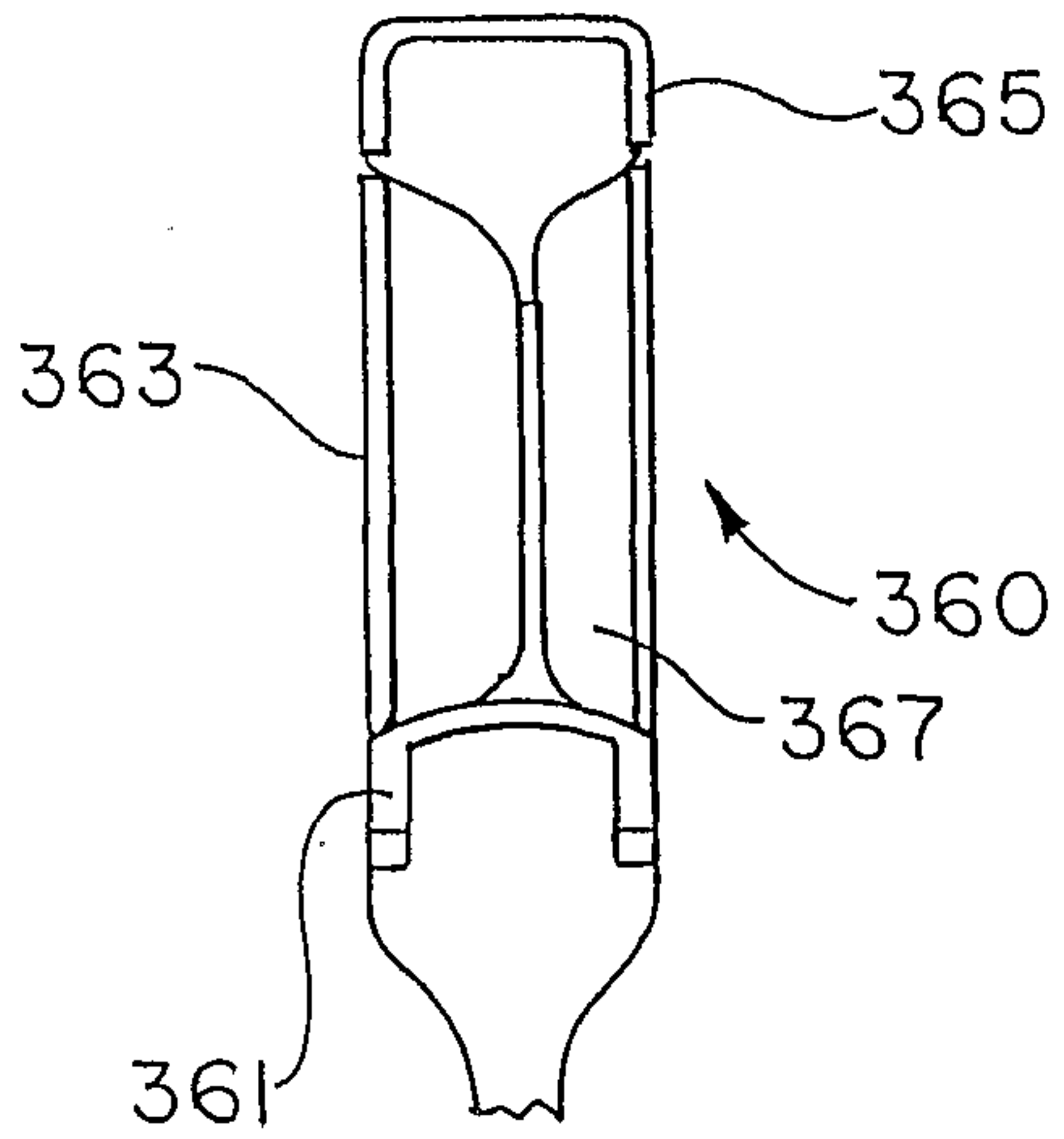
Fig. 16





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Fig. 22

Fig. 21



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Fig. 23

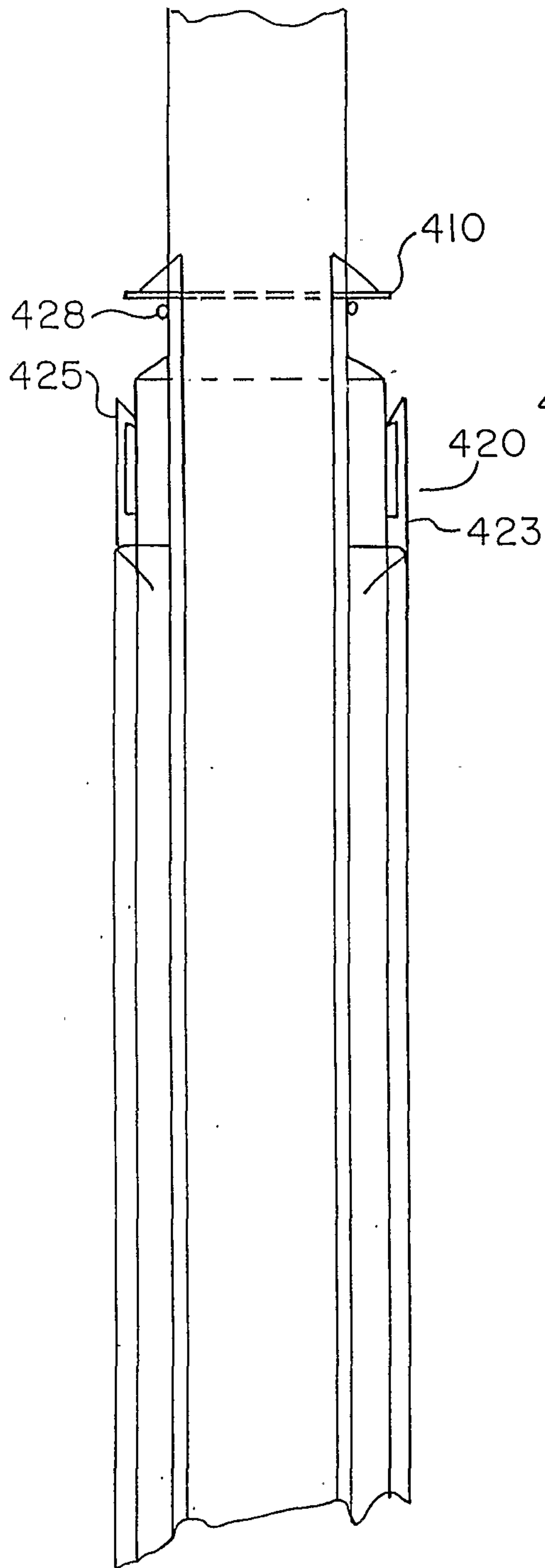
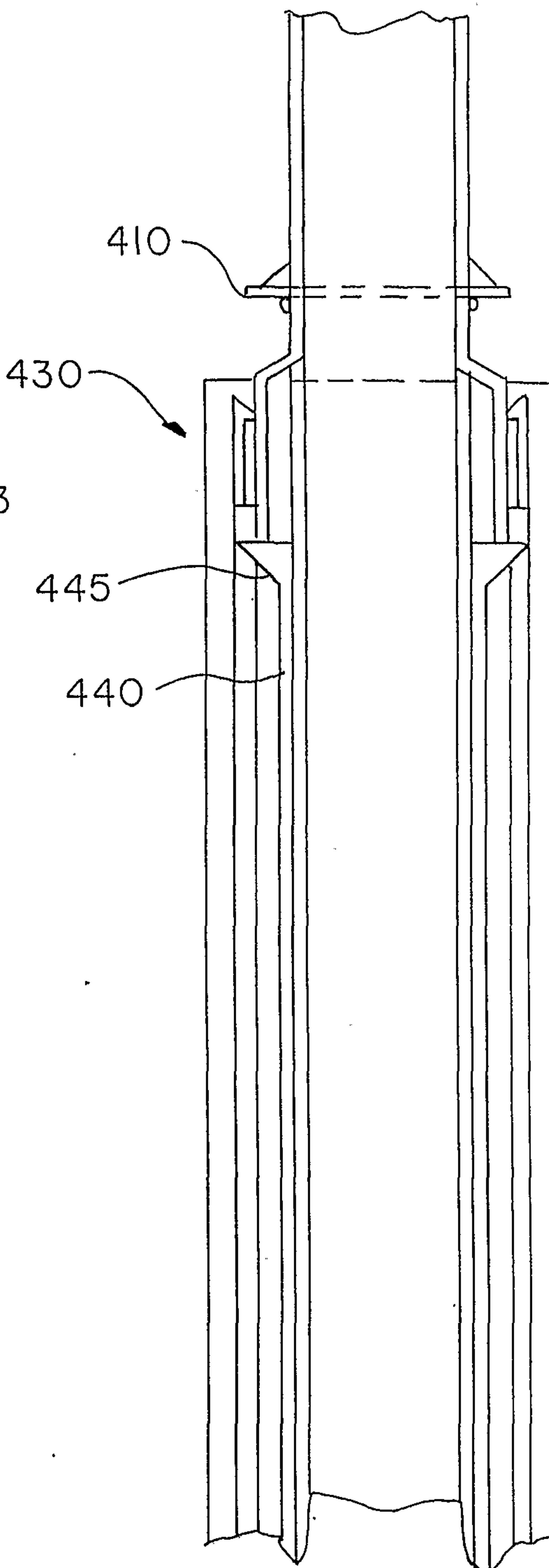


Fig. 24



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Fig. 25

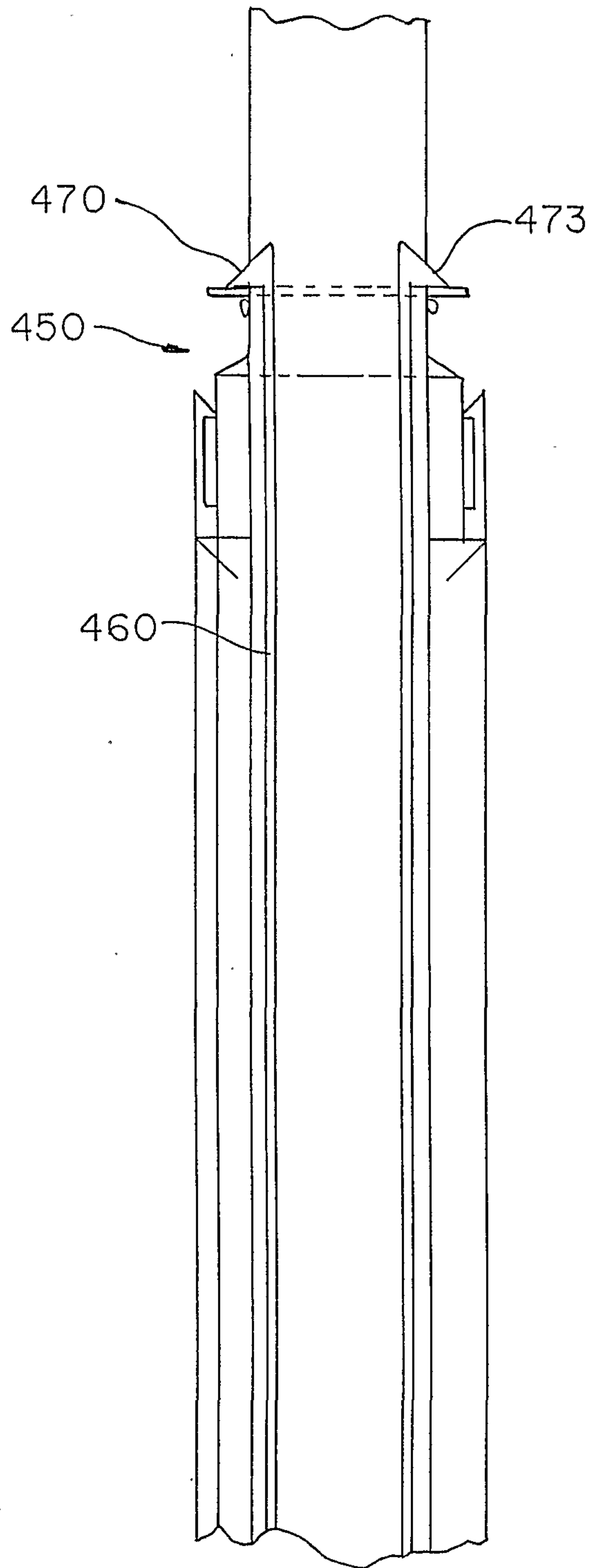


Fig. 26

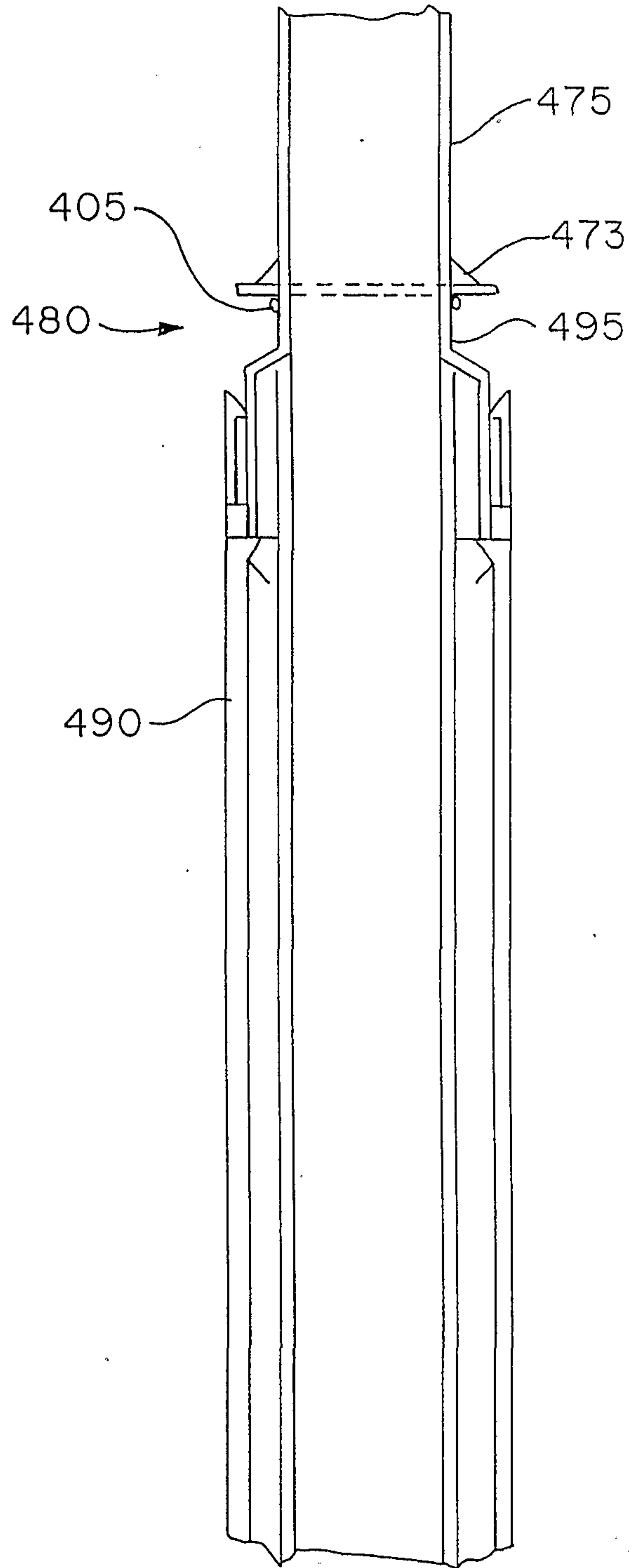


Fig. 27

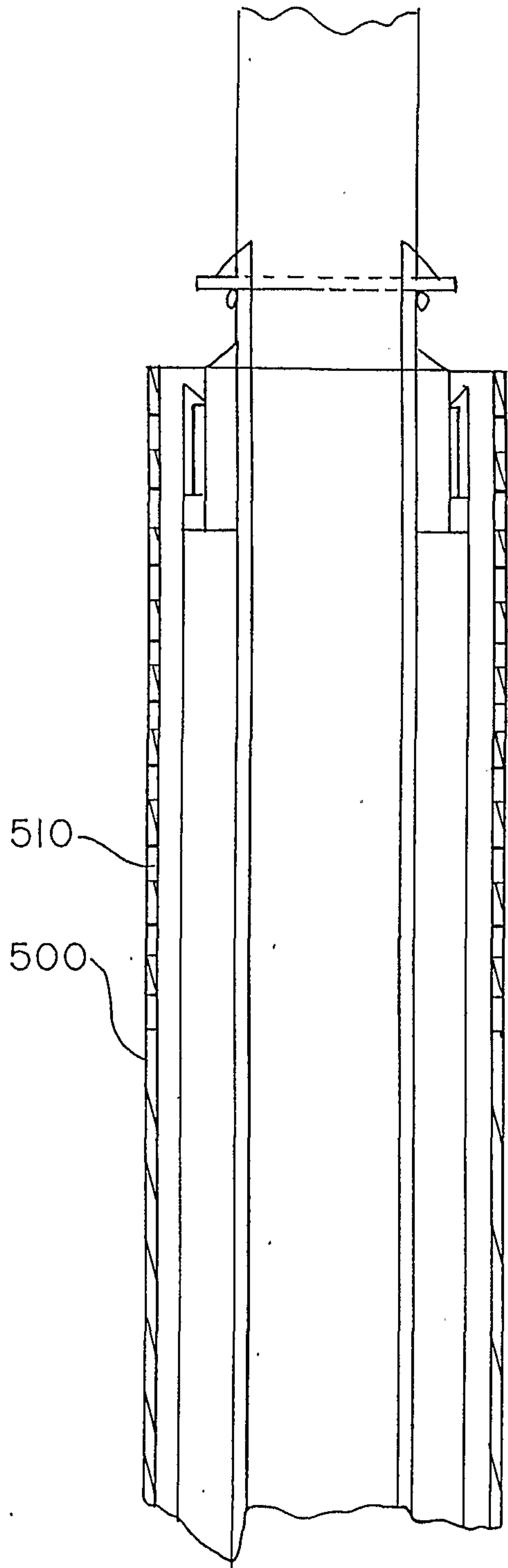


Fig. 28

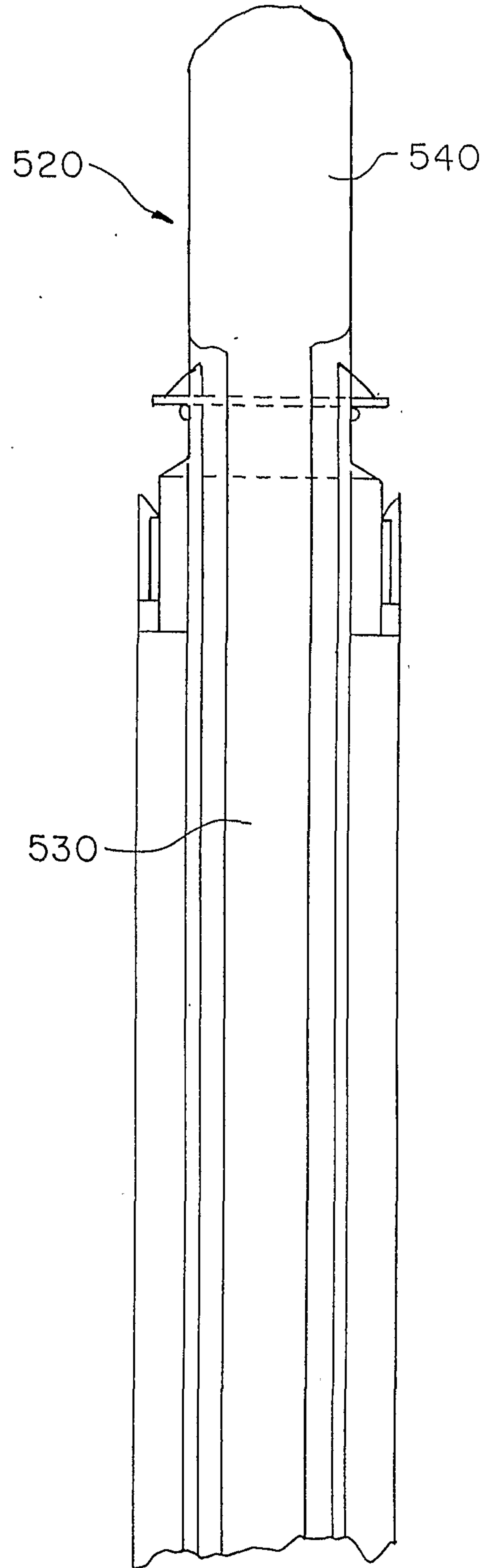


Fig. 29

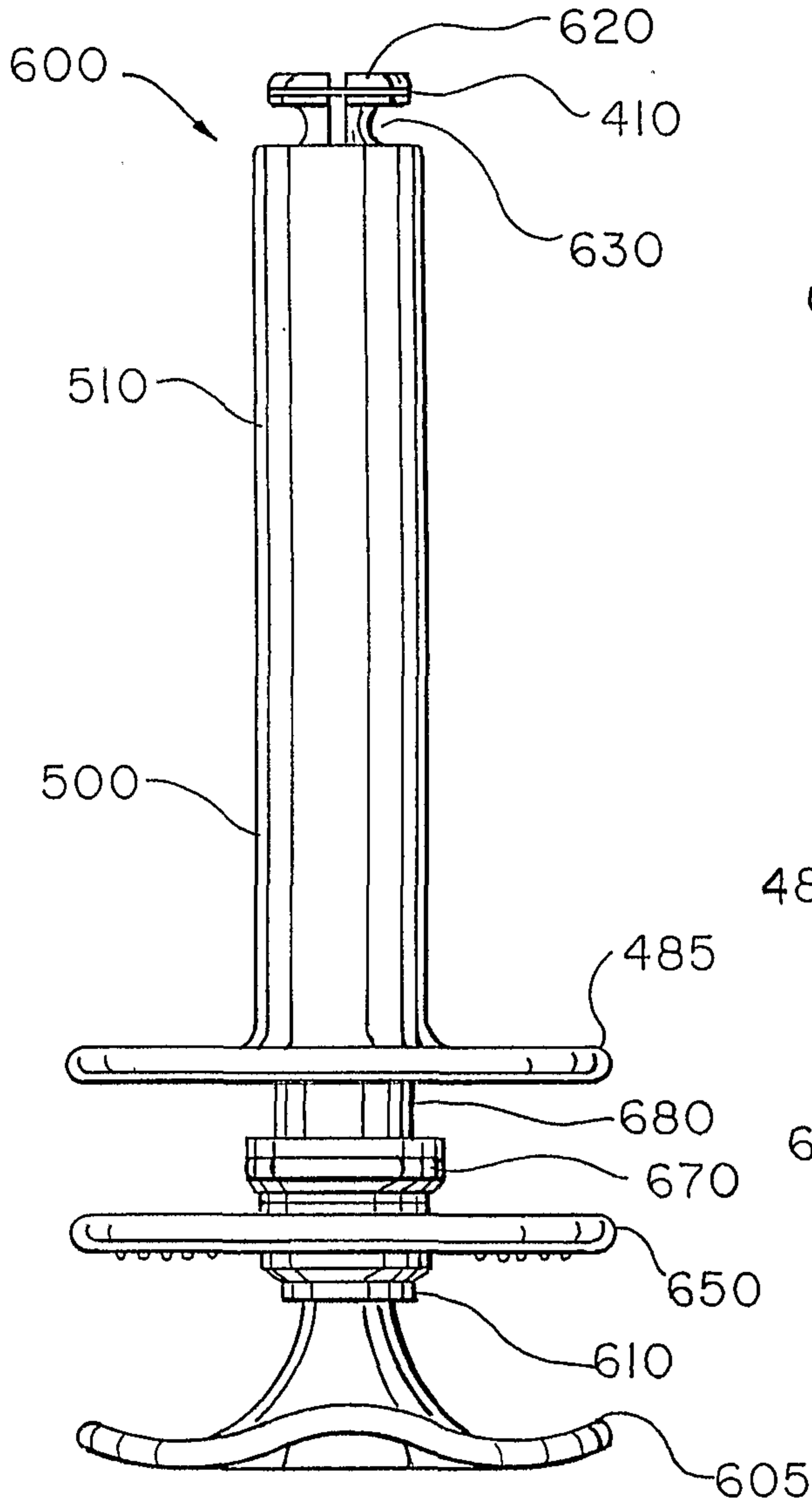
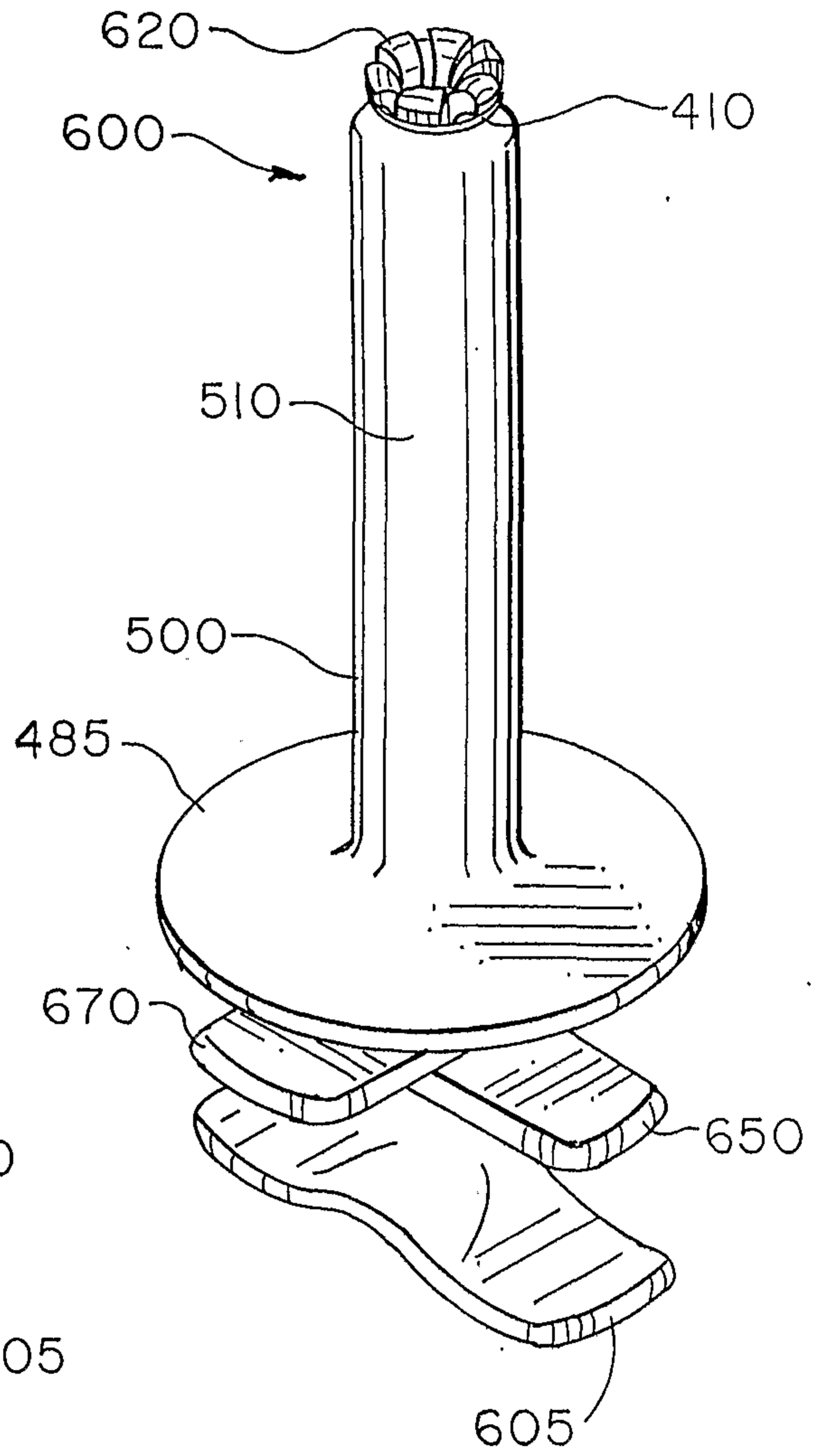


Fig. 30



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Fig. 31

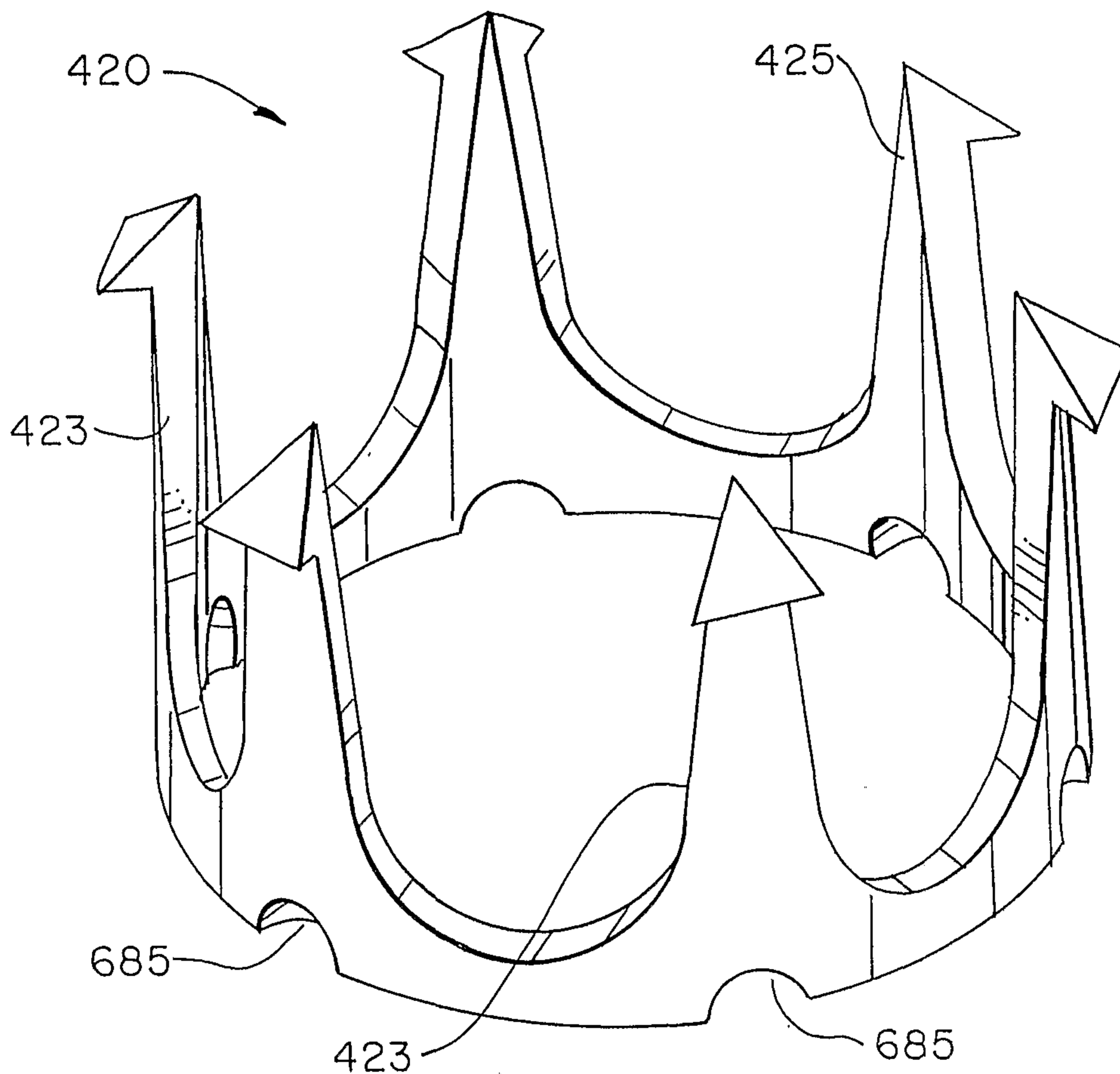


Fig. 31A

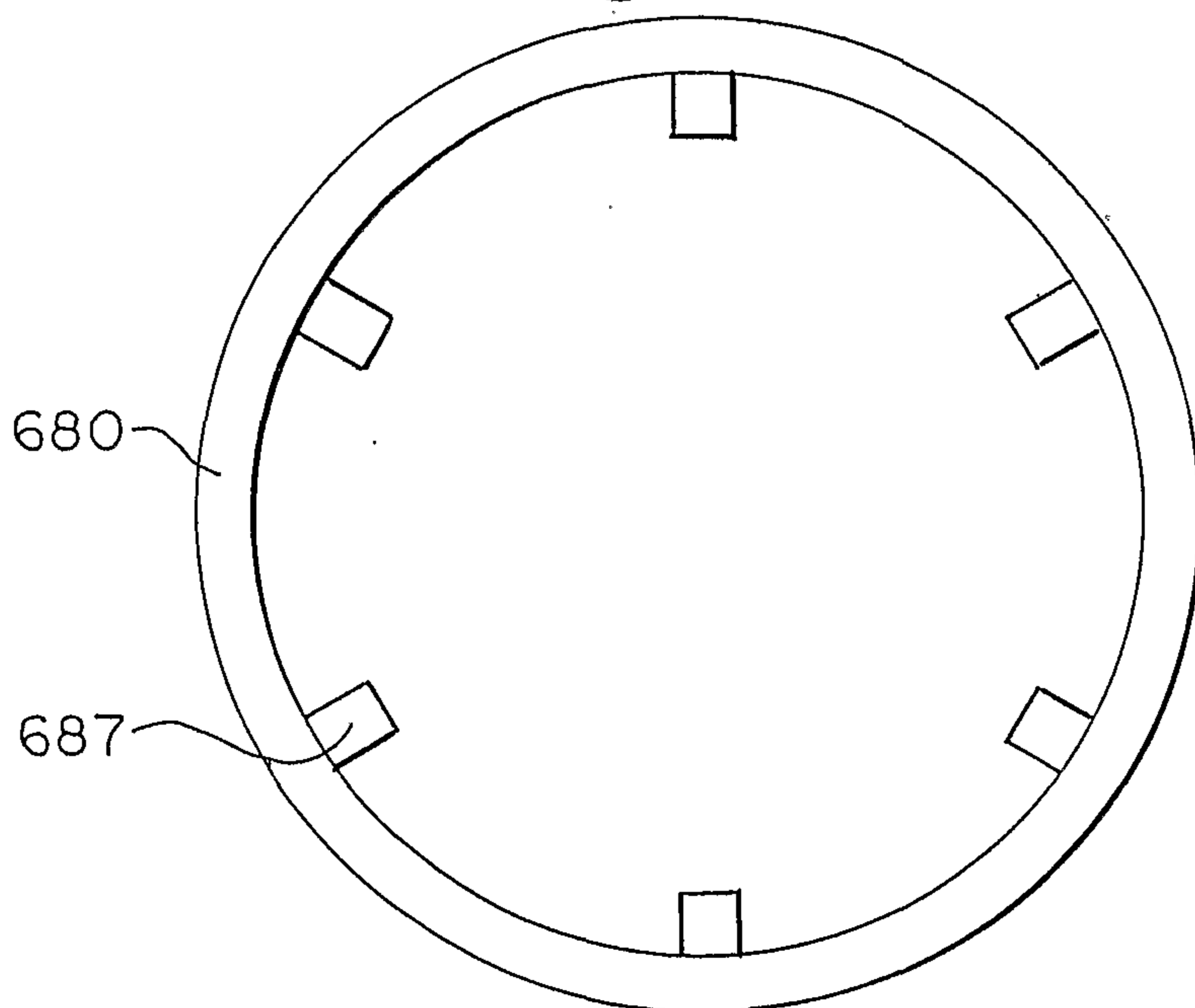


Fig. 32

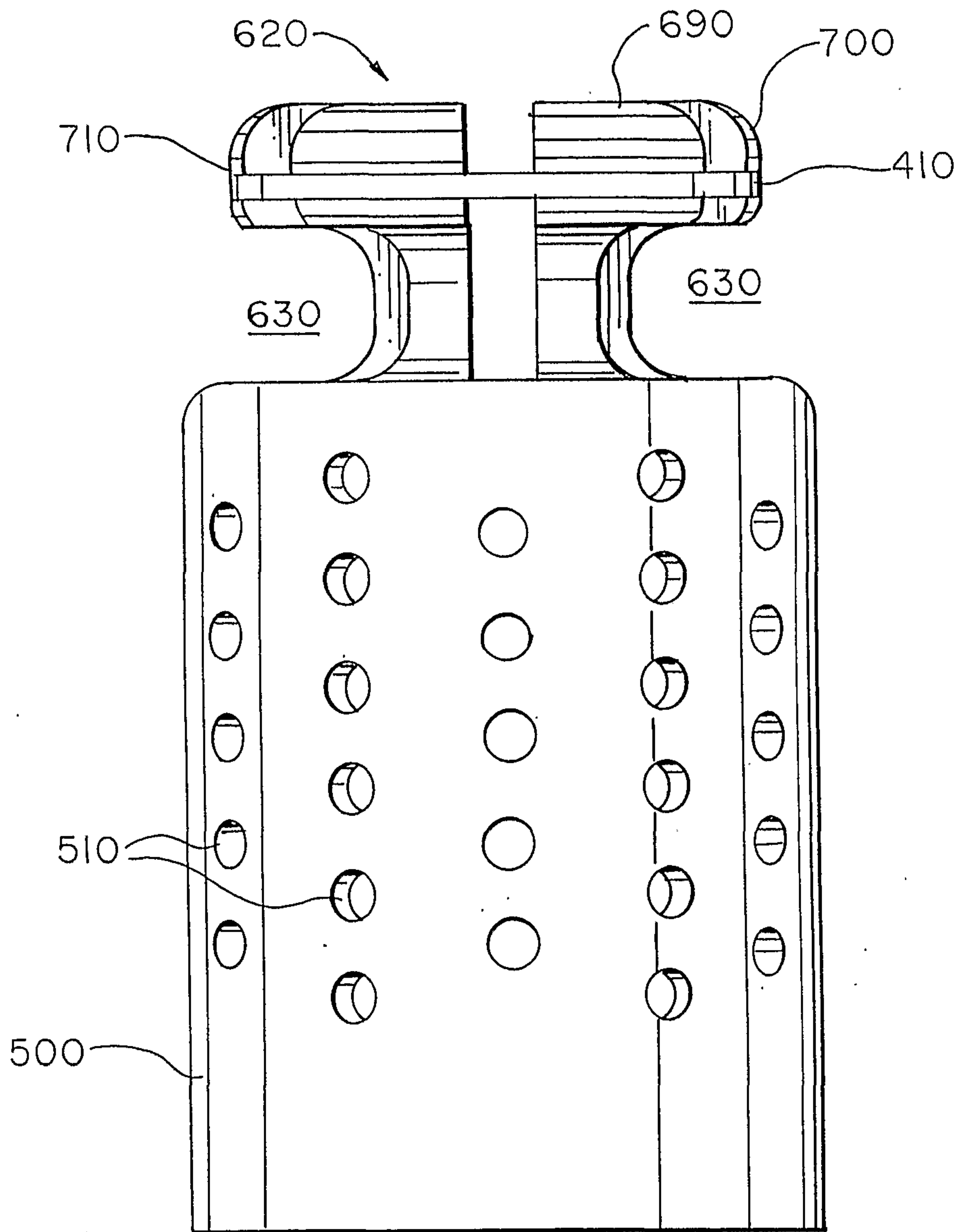


Fig. 33

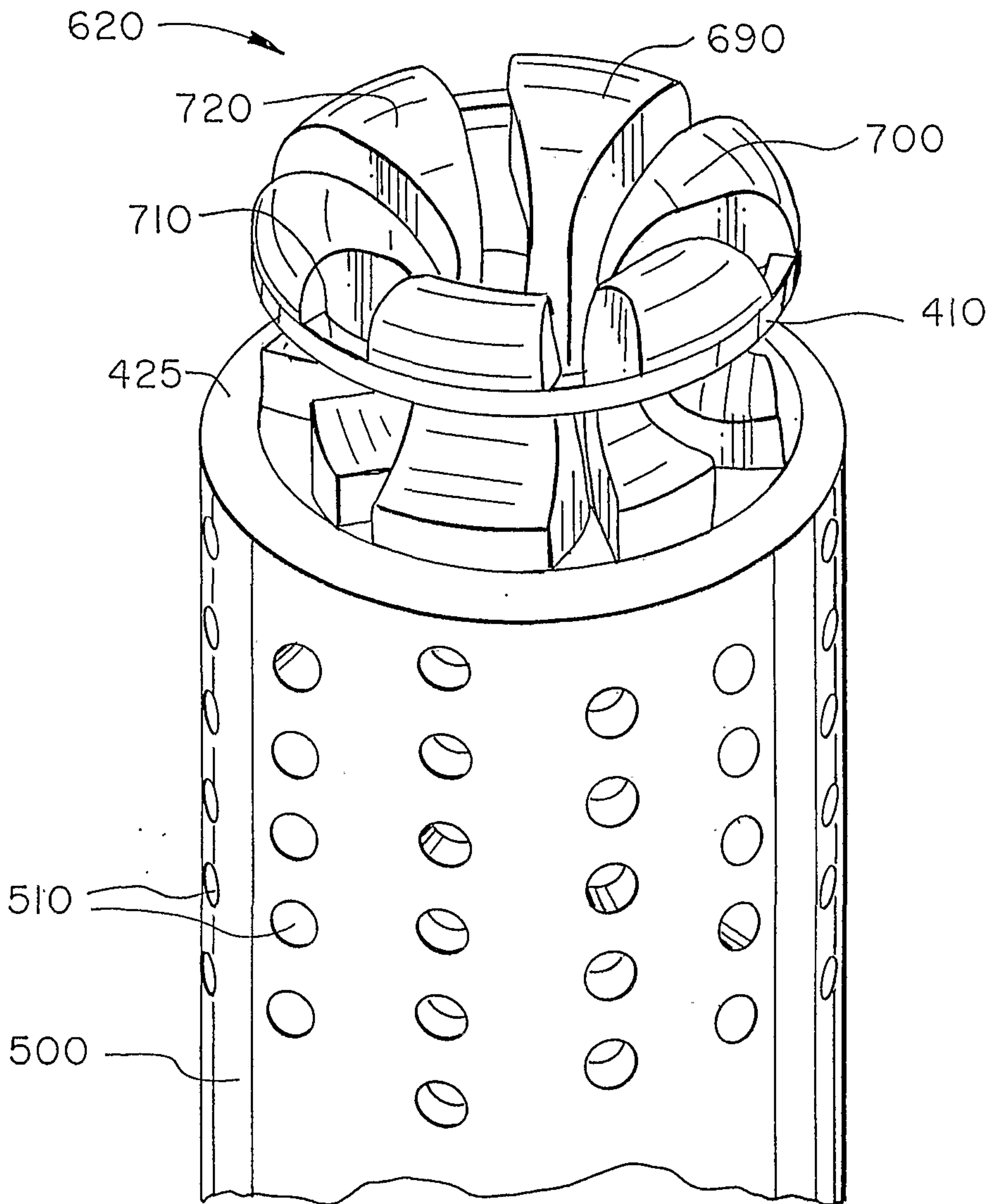


Fig. 34

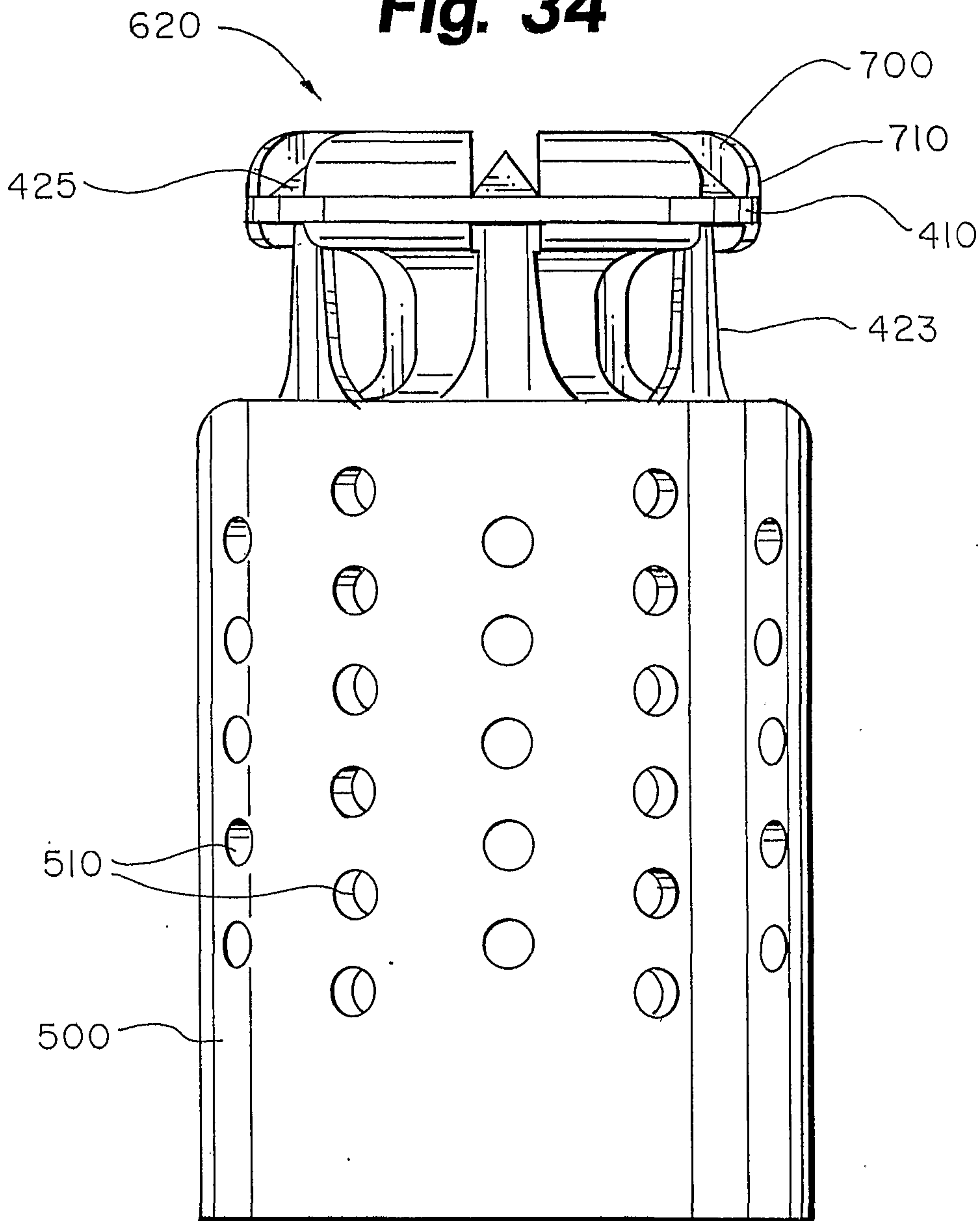


Fig. 35

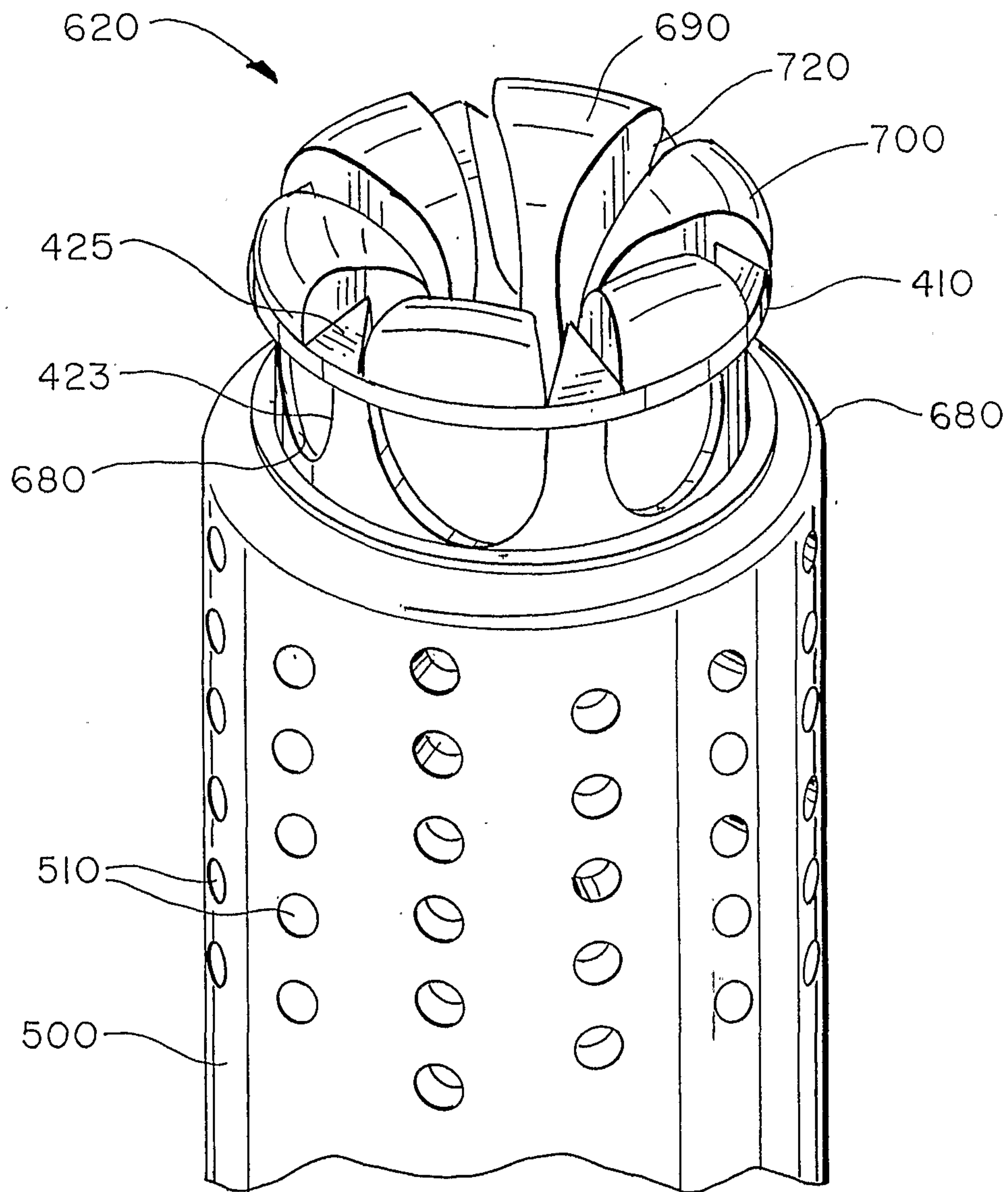


Fig. 36

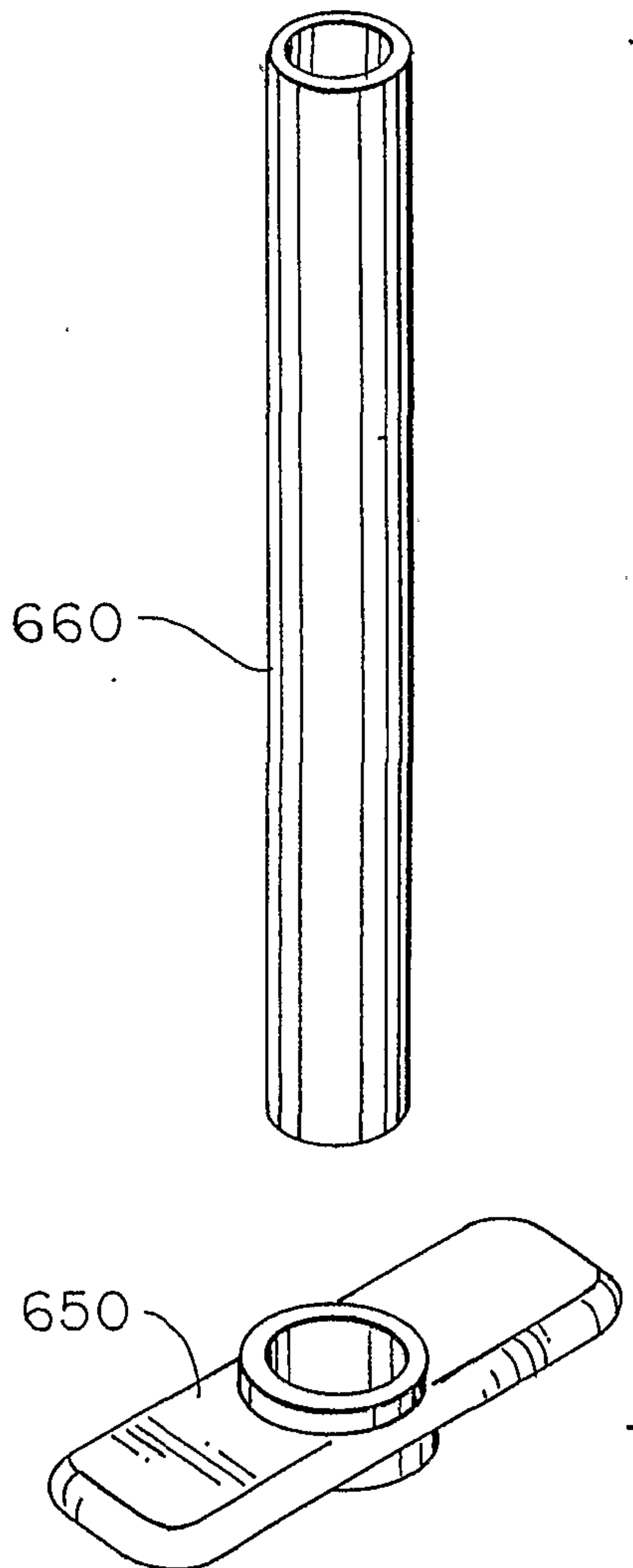


Fig. 37

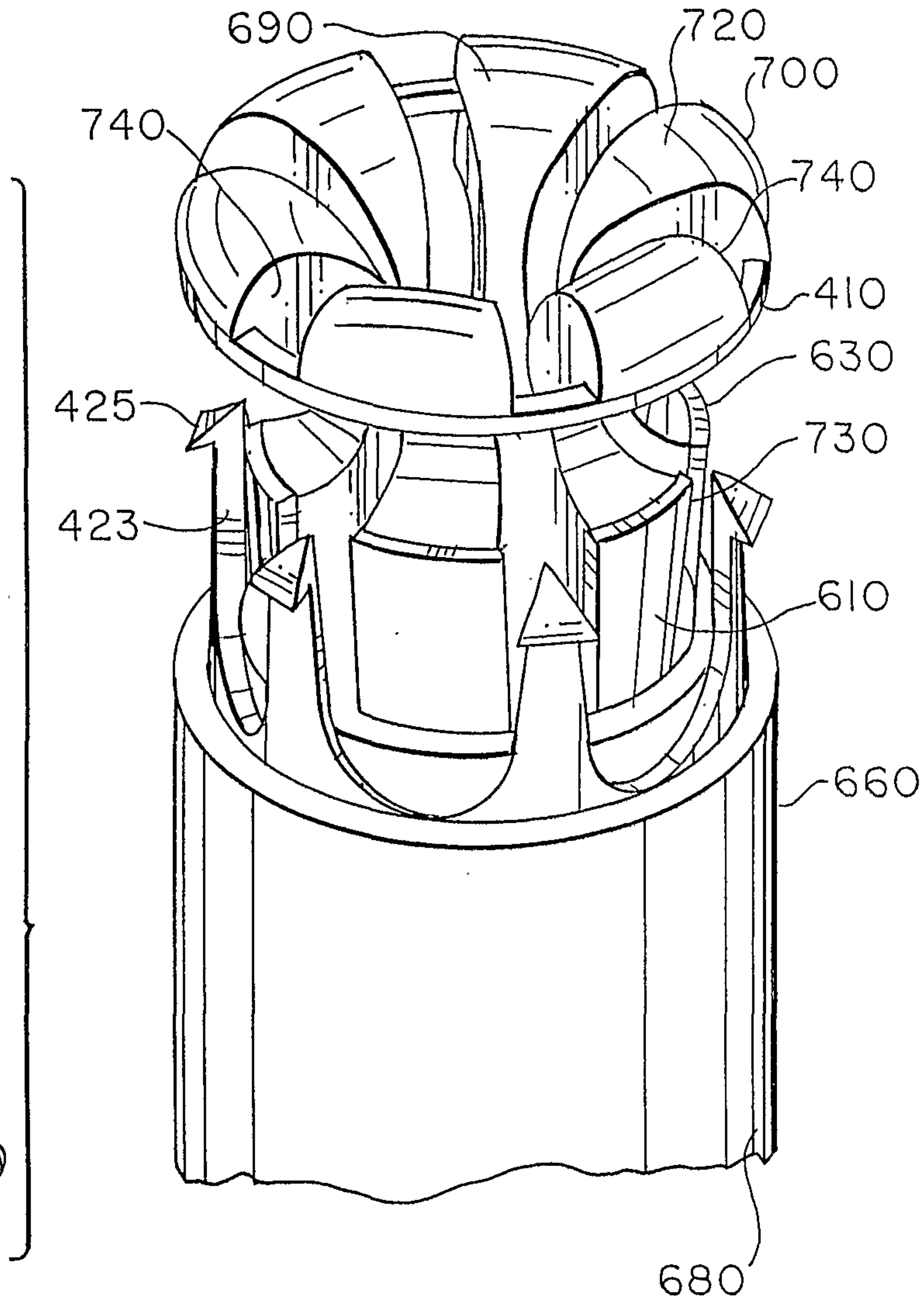


Fig. 38

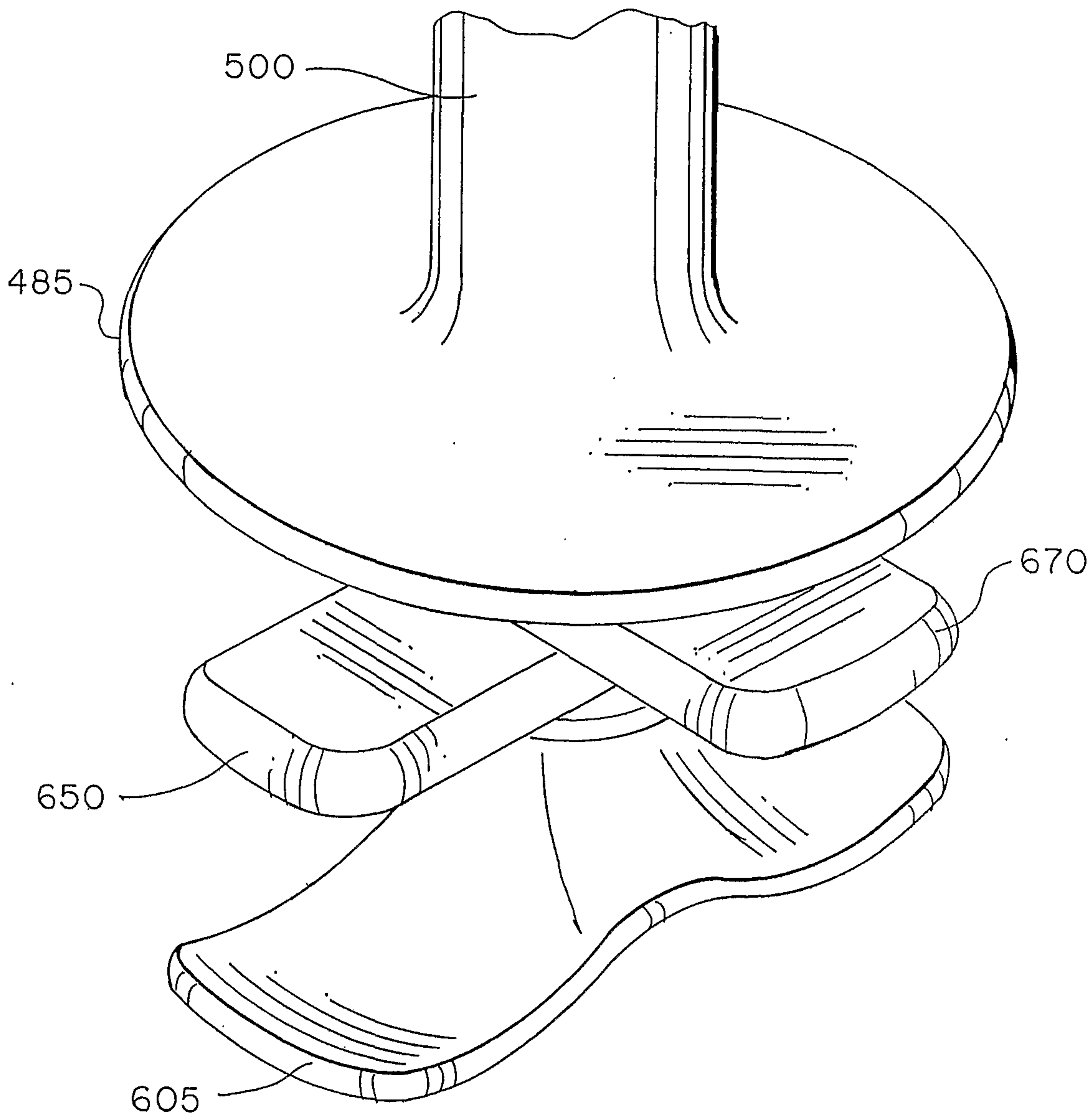


Fig. 39

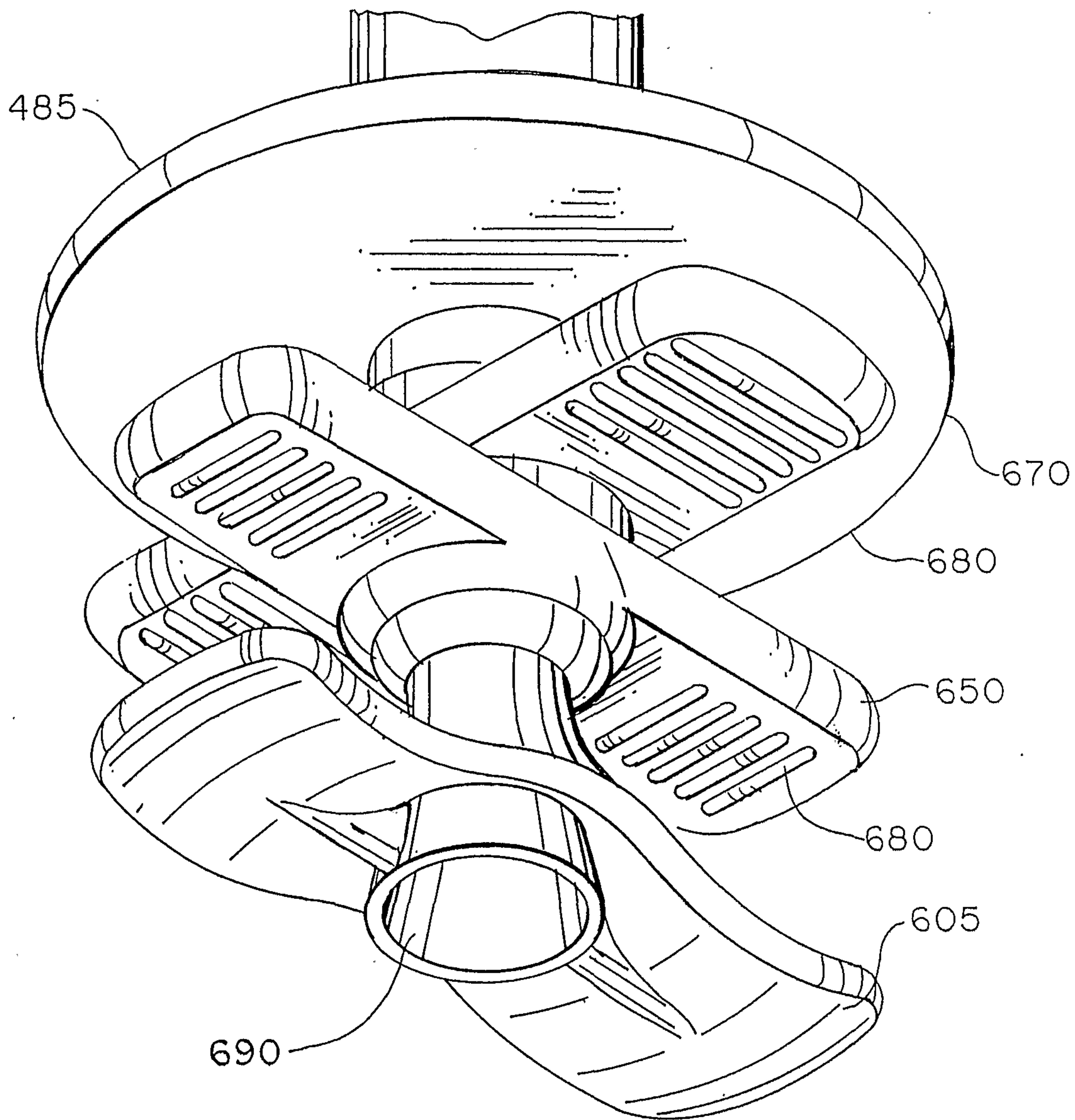
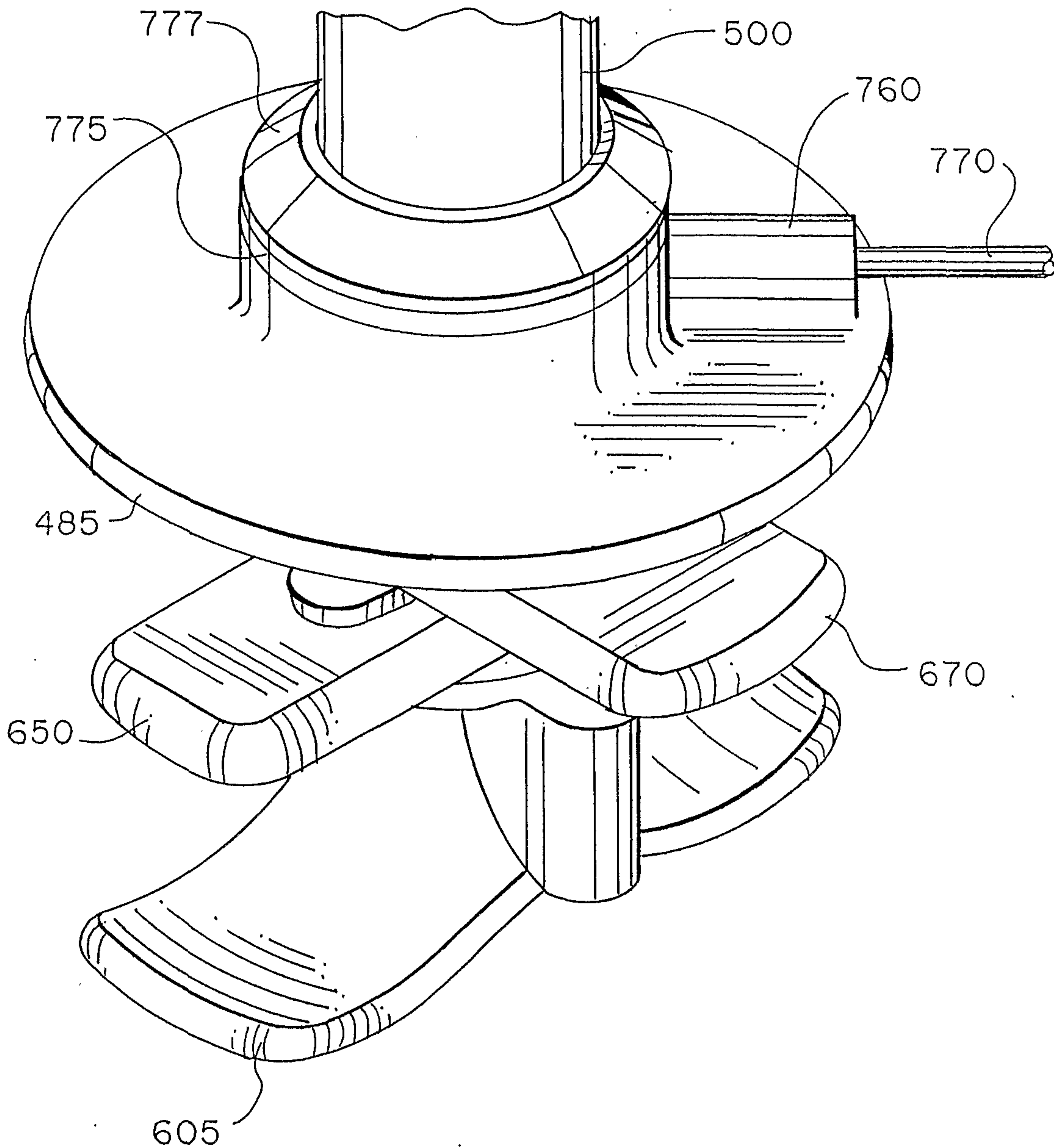


Fig. 40



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Fig. 41

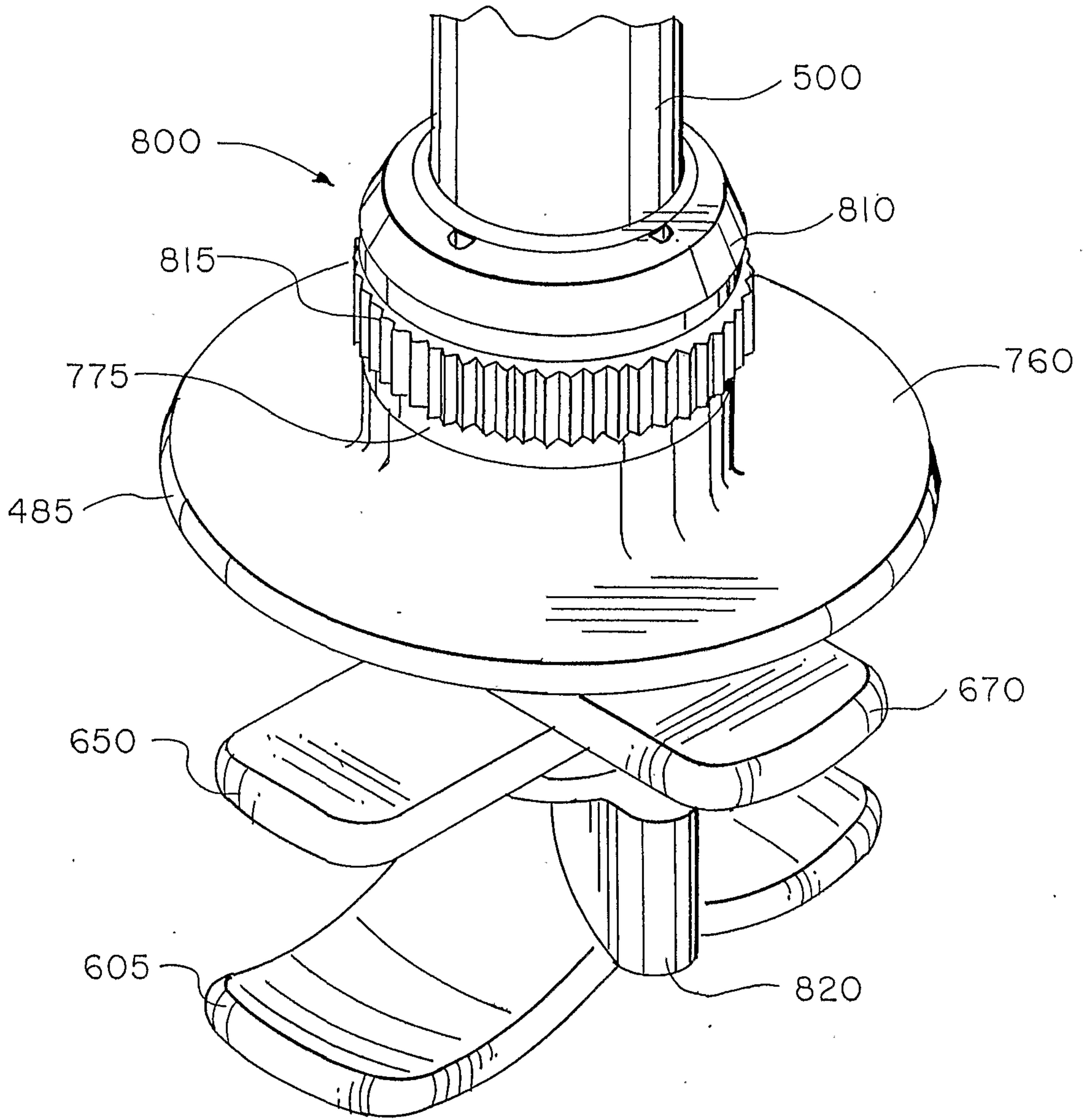


Fig. 42

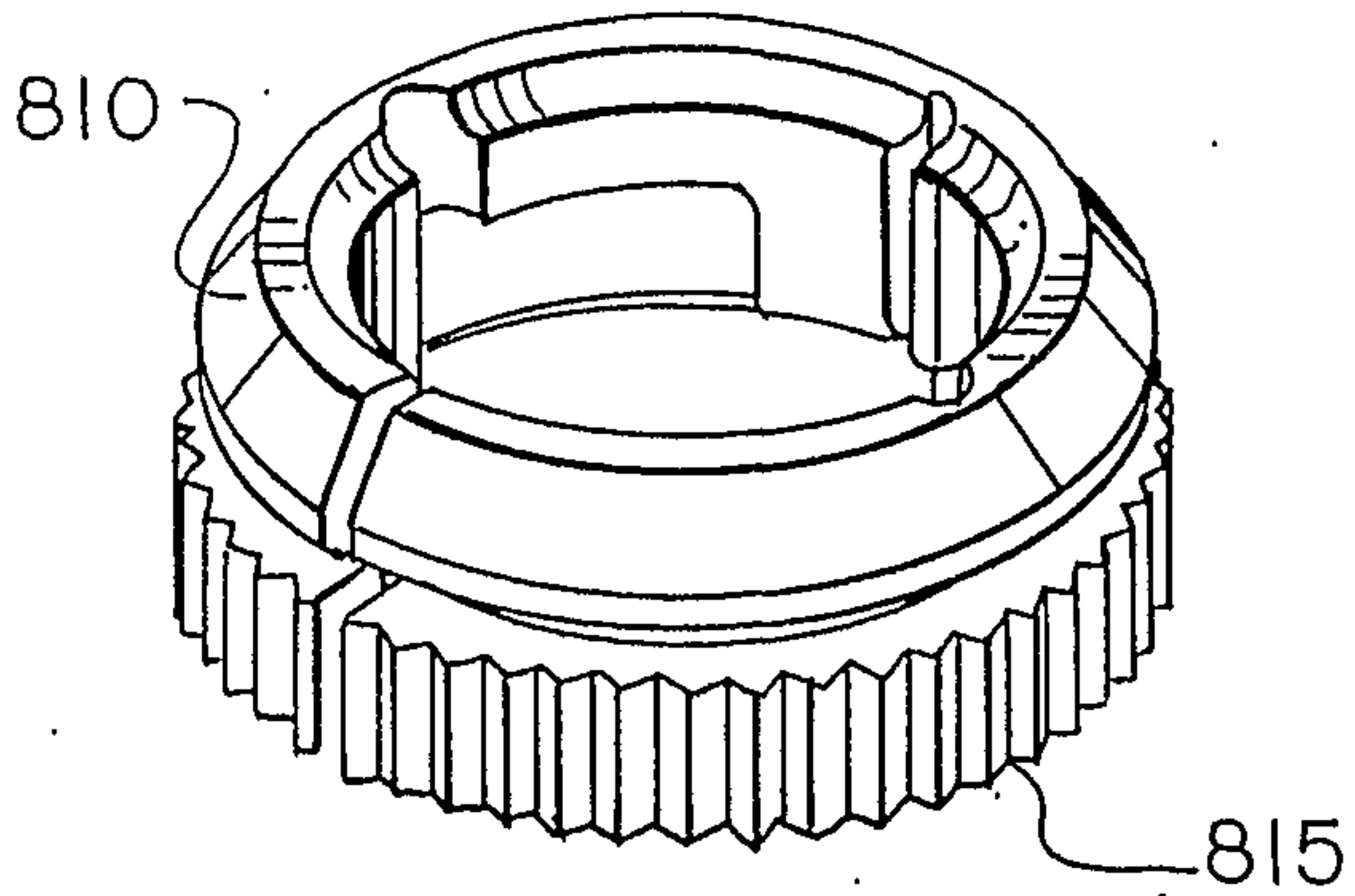


Fig. 43

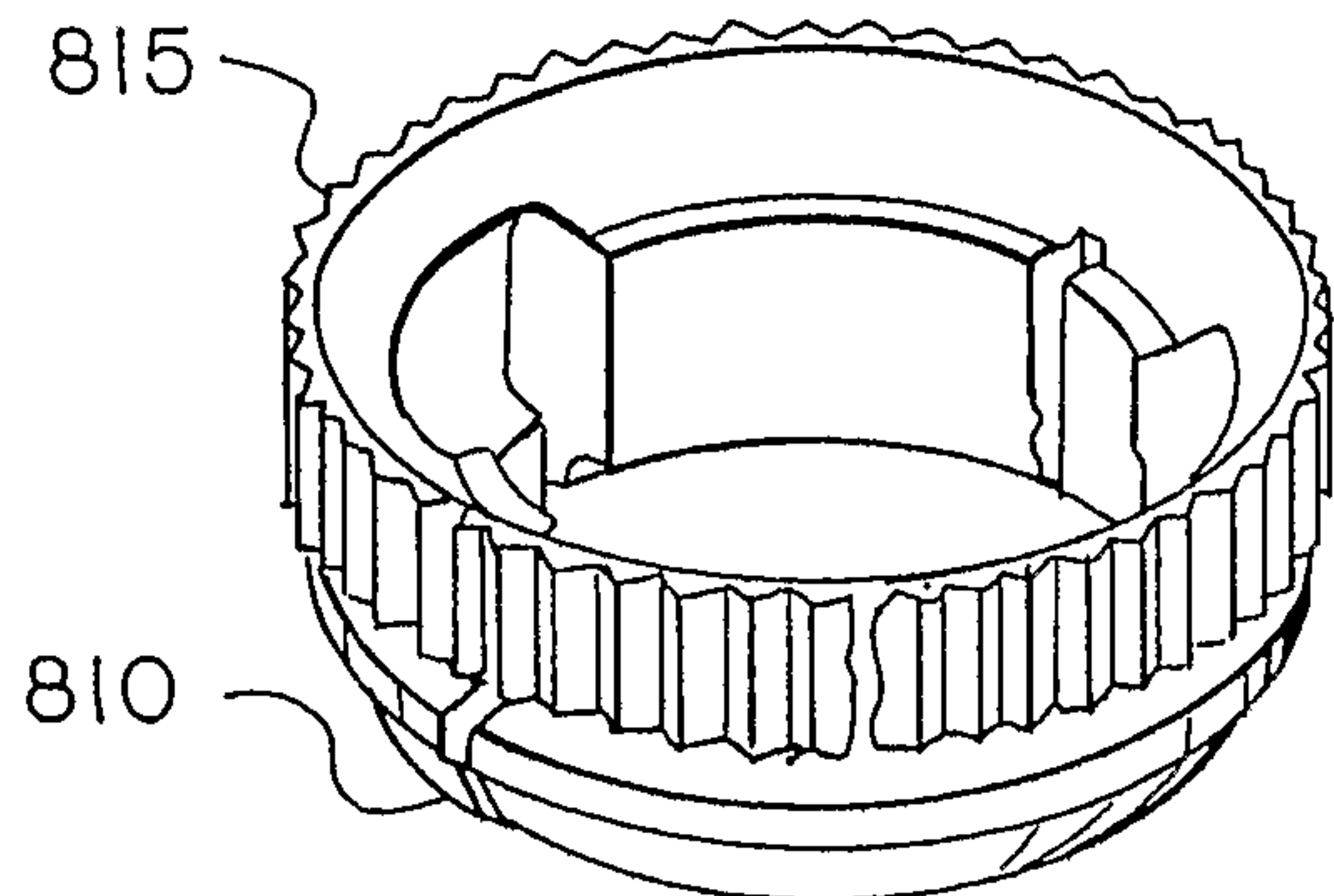


Fig. 44

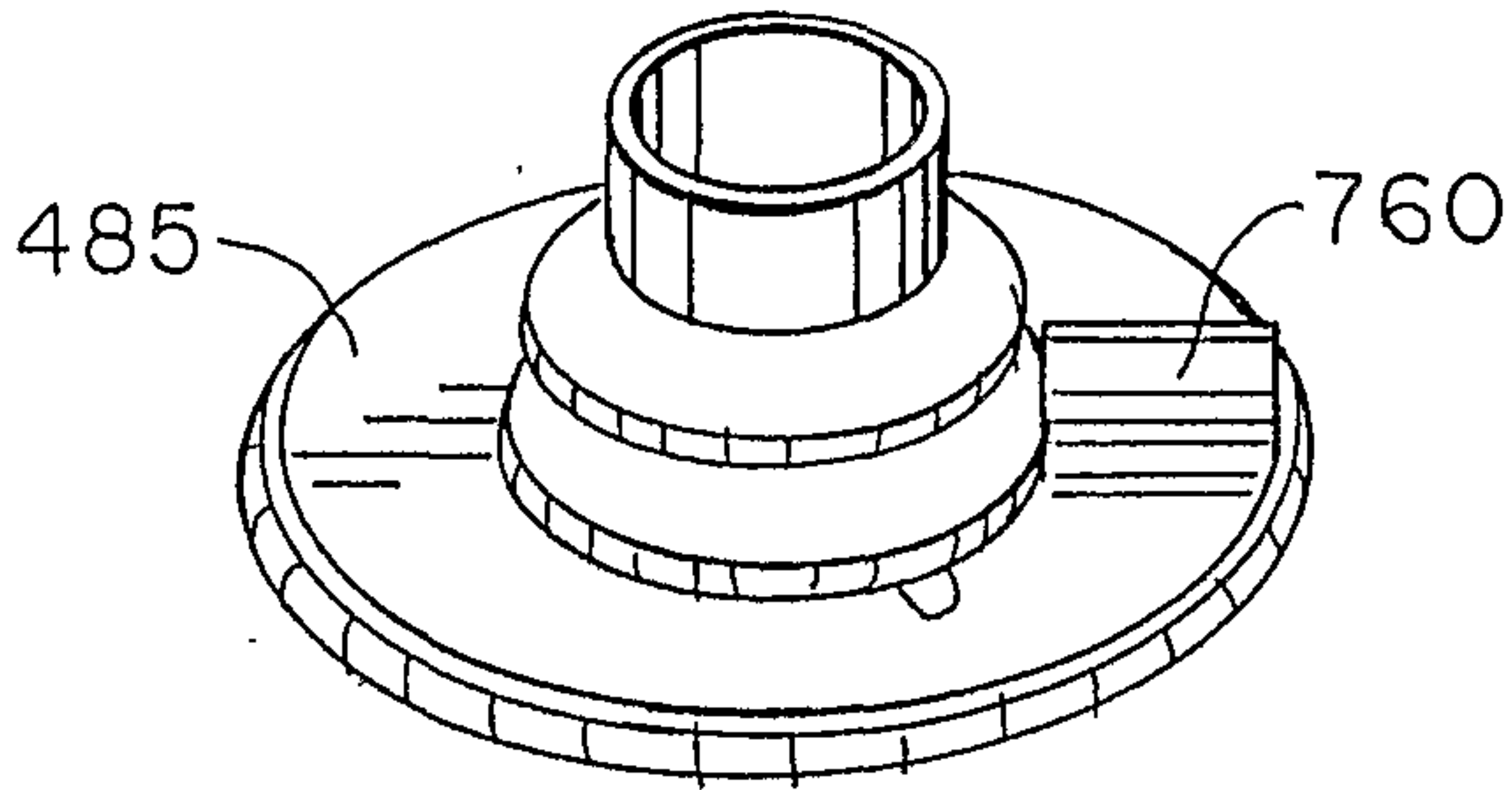


Fig. 45

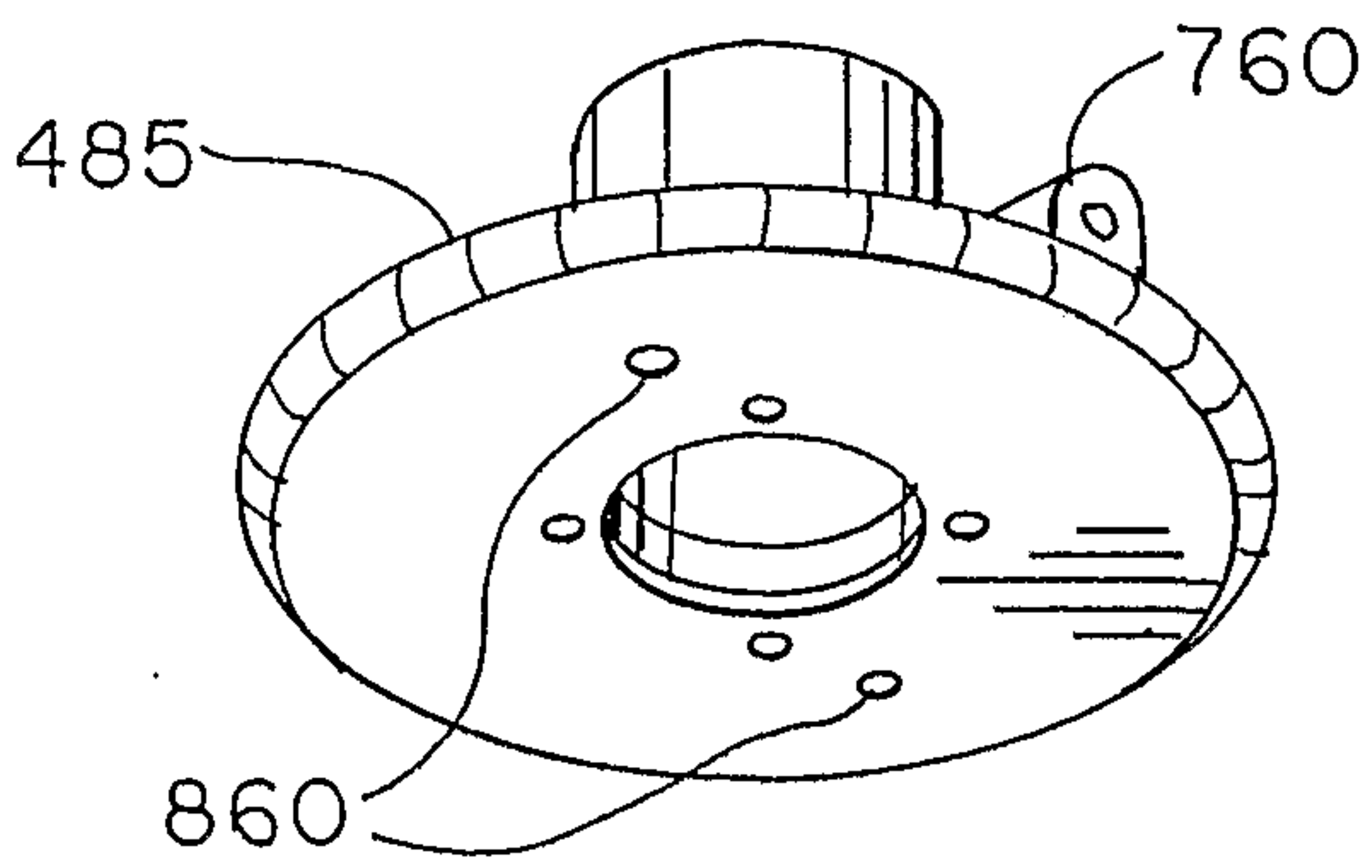


Fig. 46

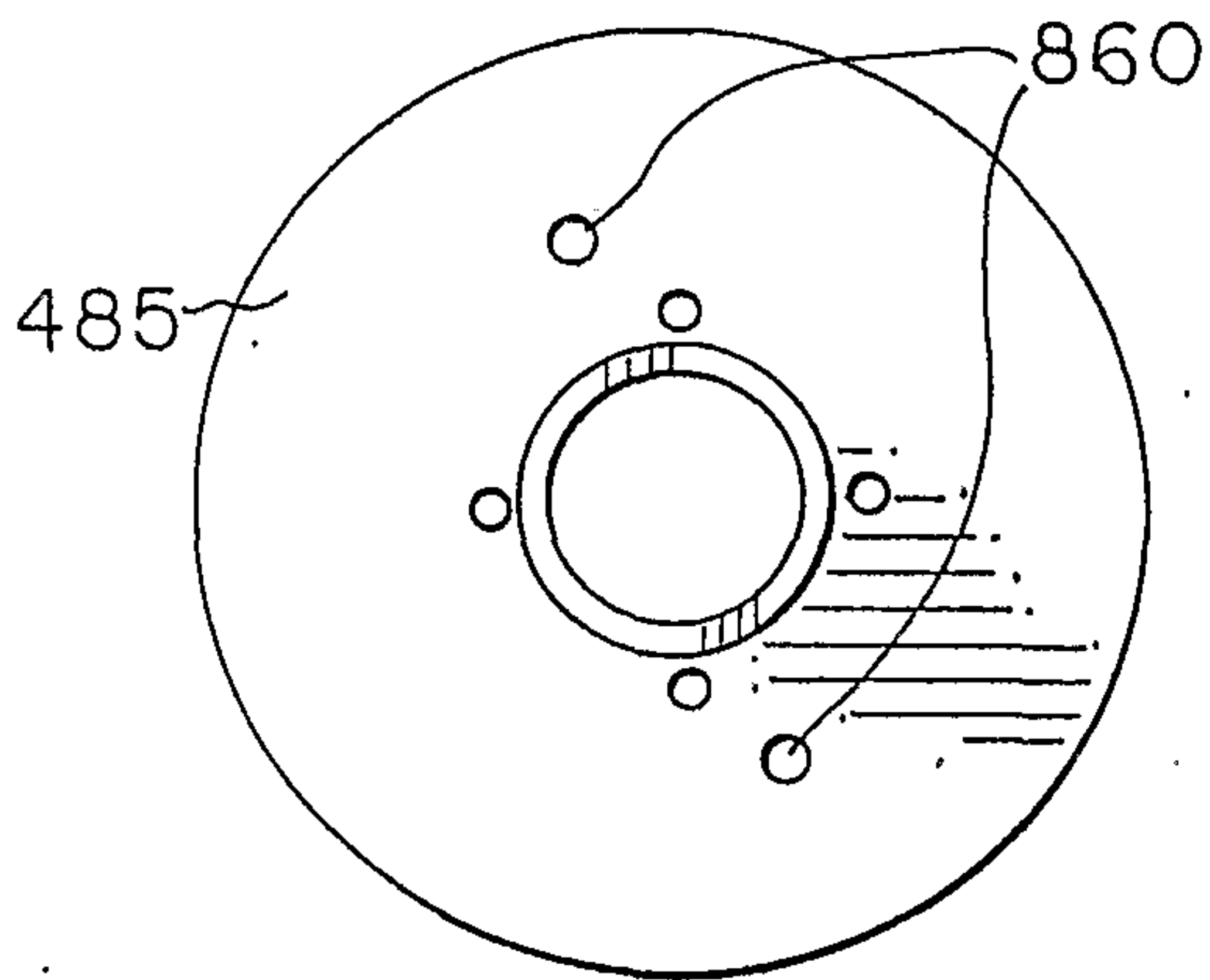
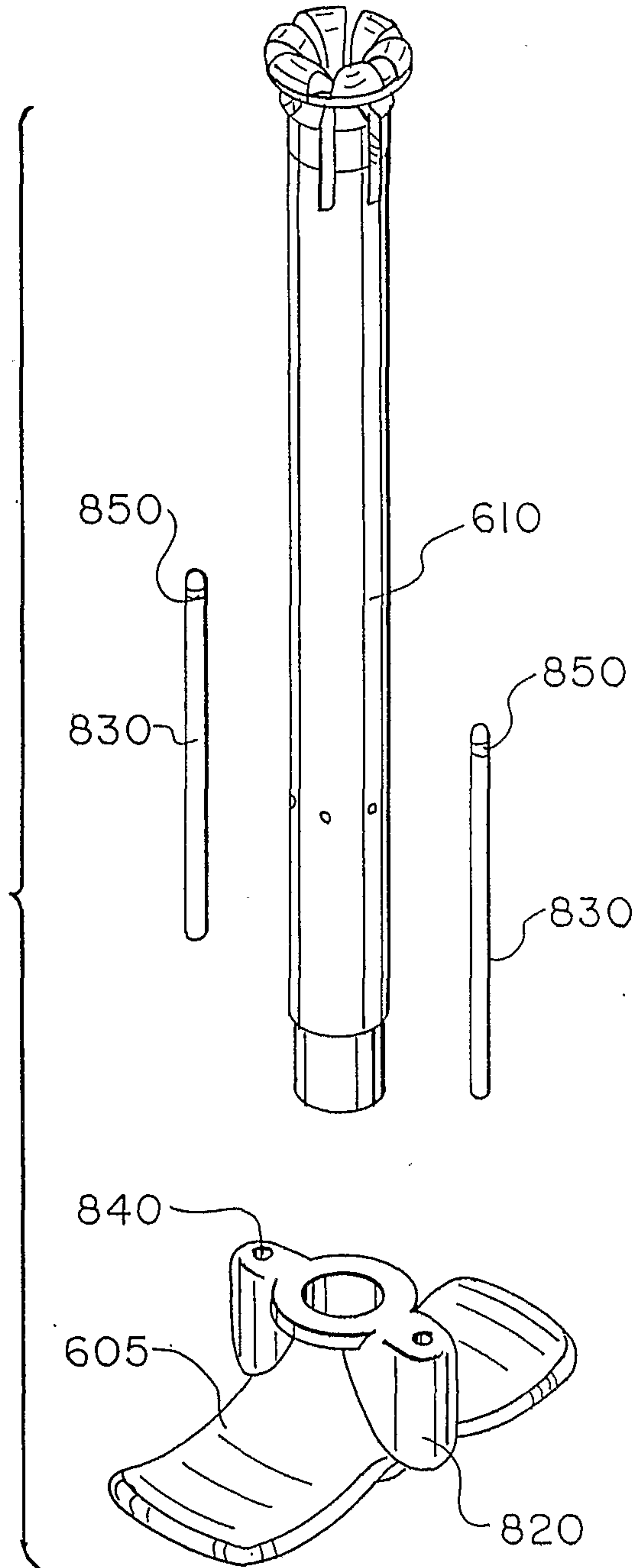


Fig. 47



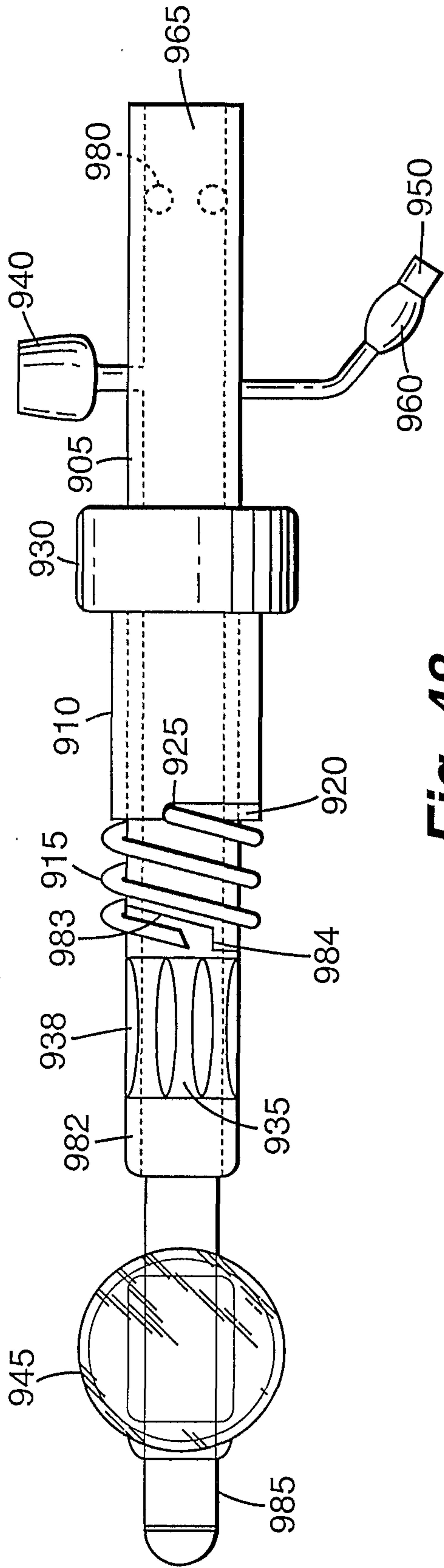


Fig. 48

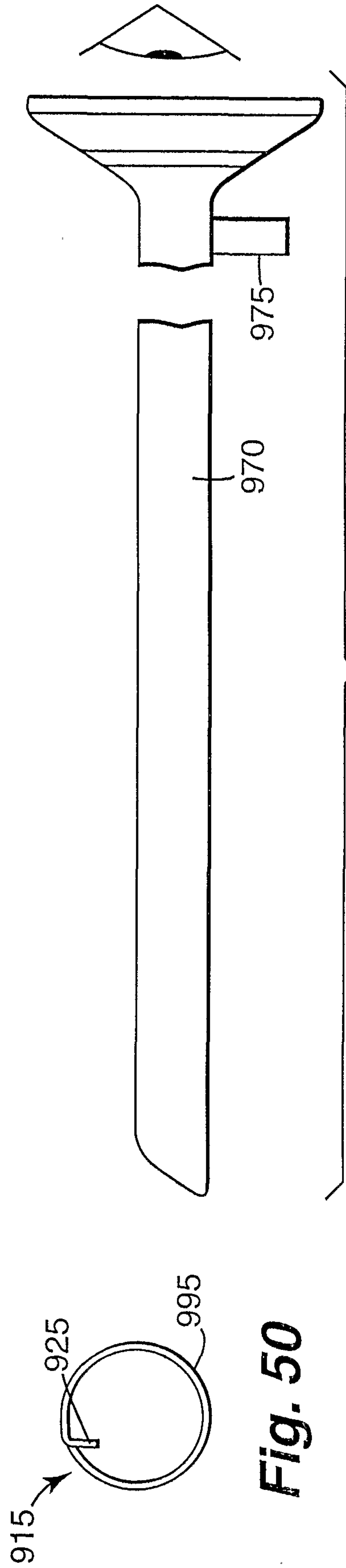


Fig. 49

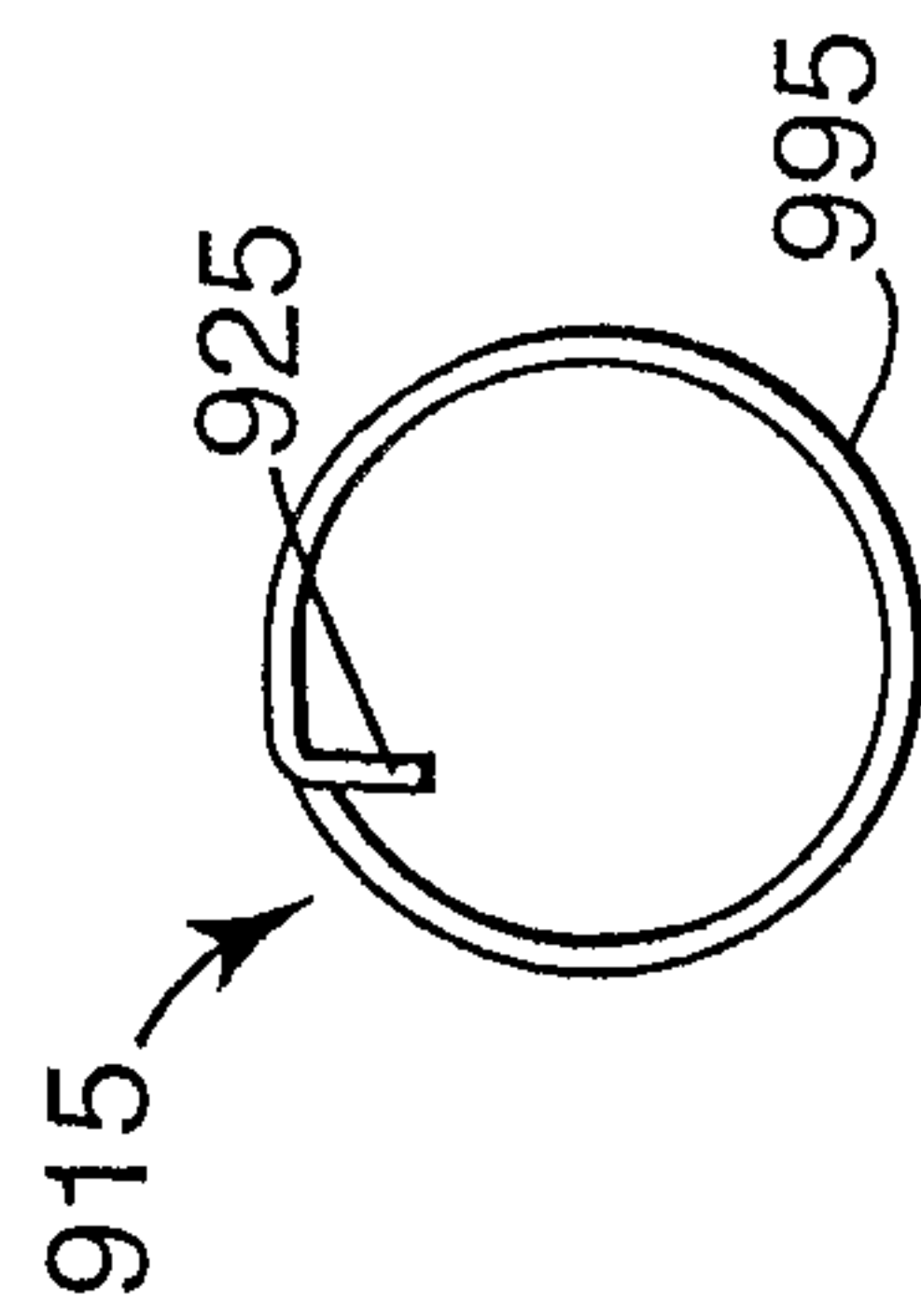


Fig. 50

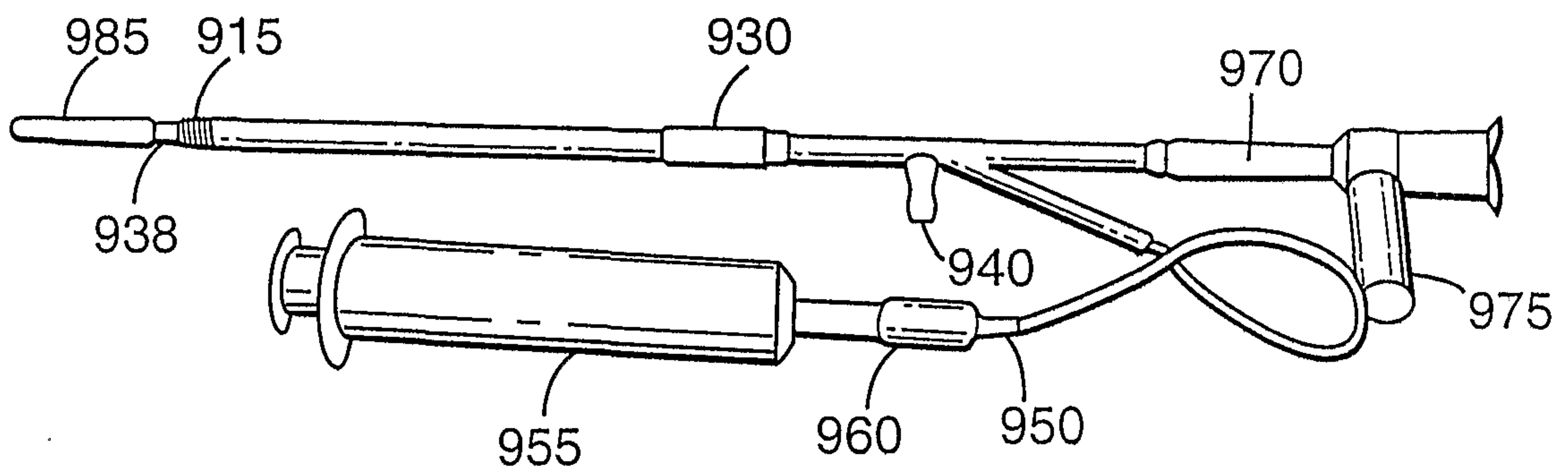


Fig. 51

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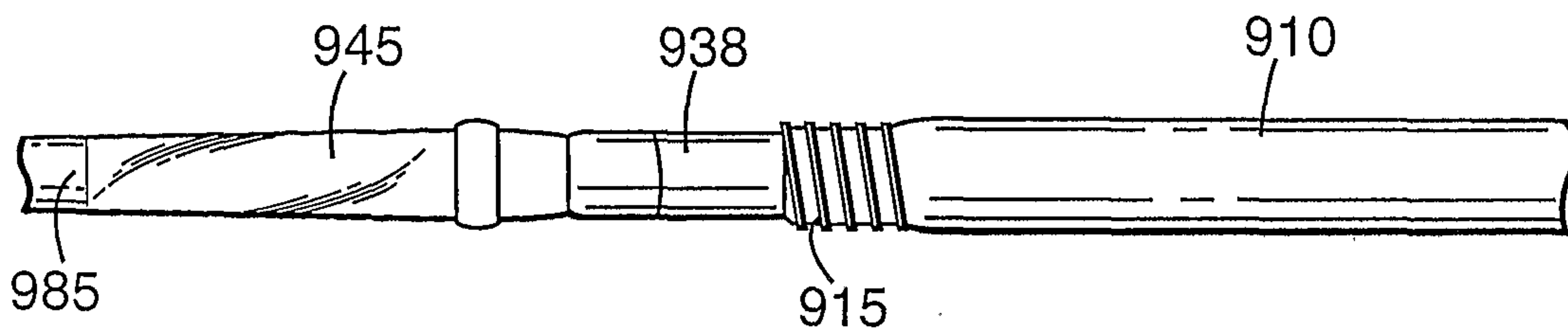


Fig. 52

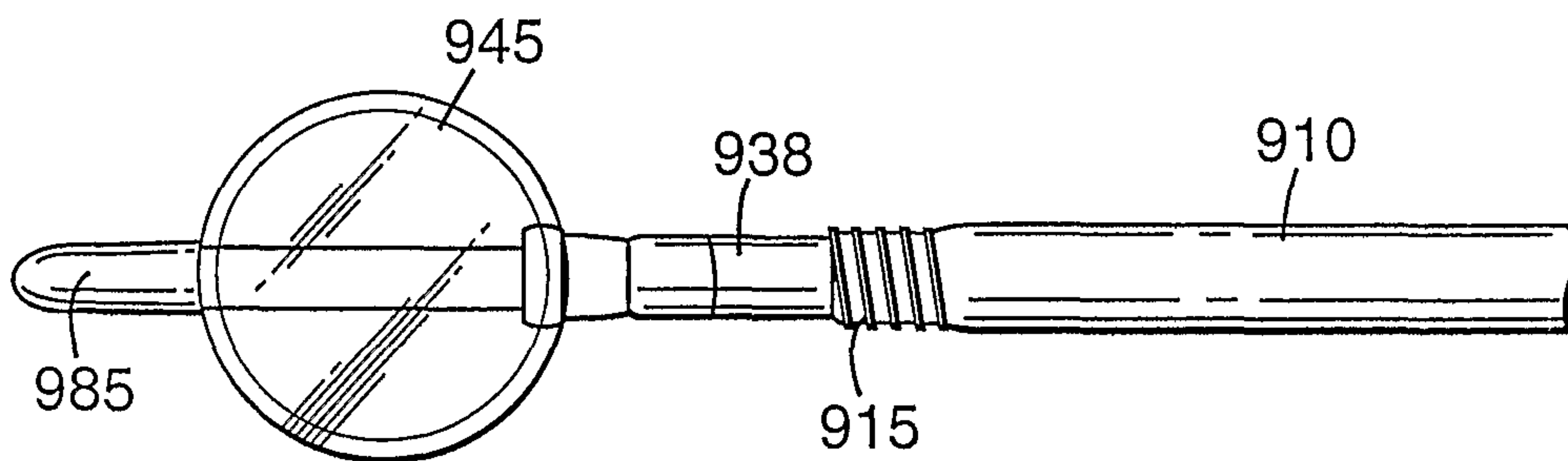


Fig. 53

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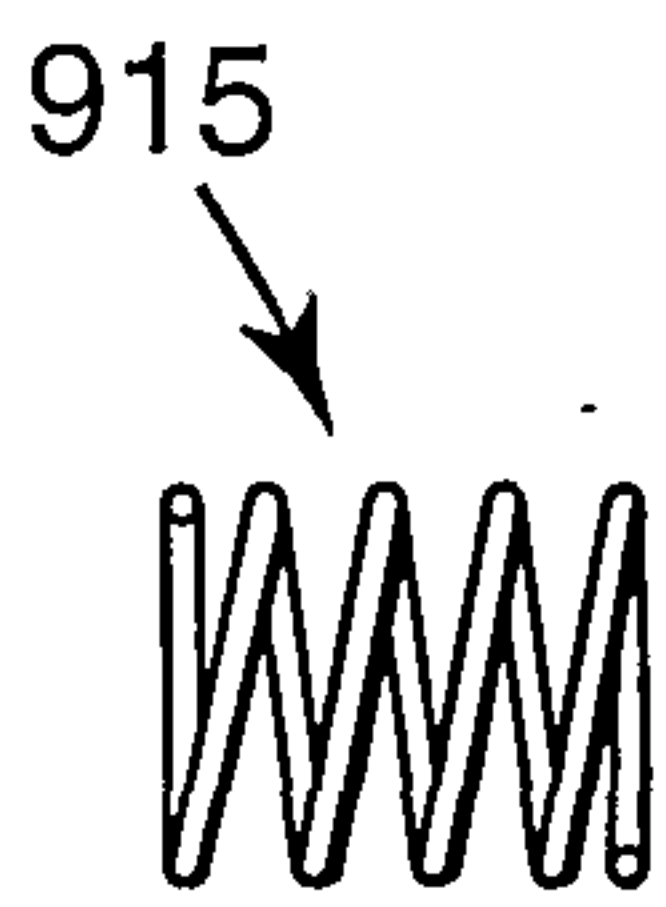


Fig. 54

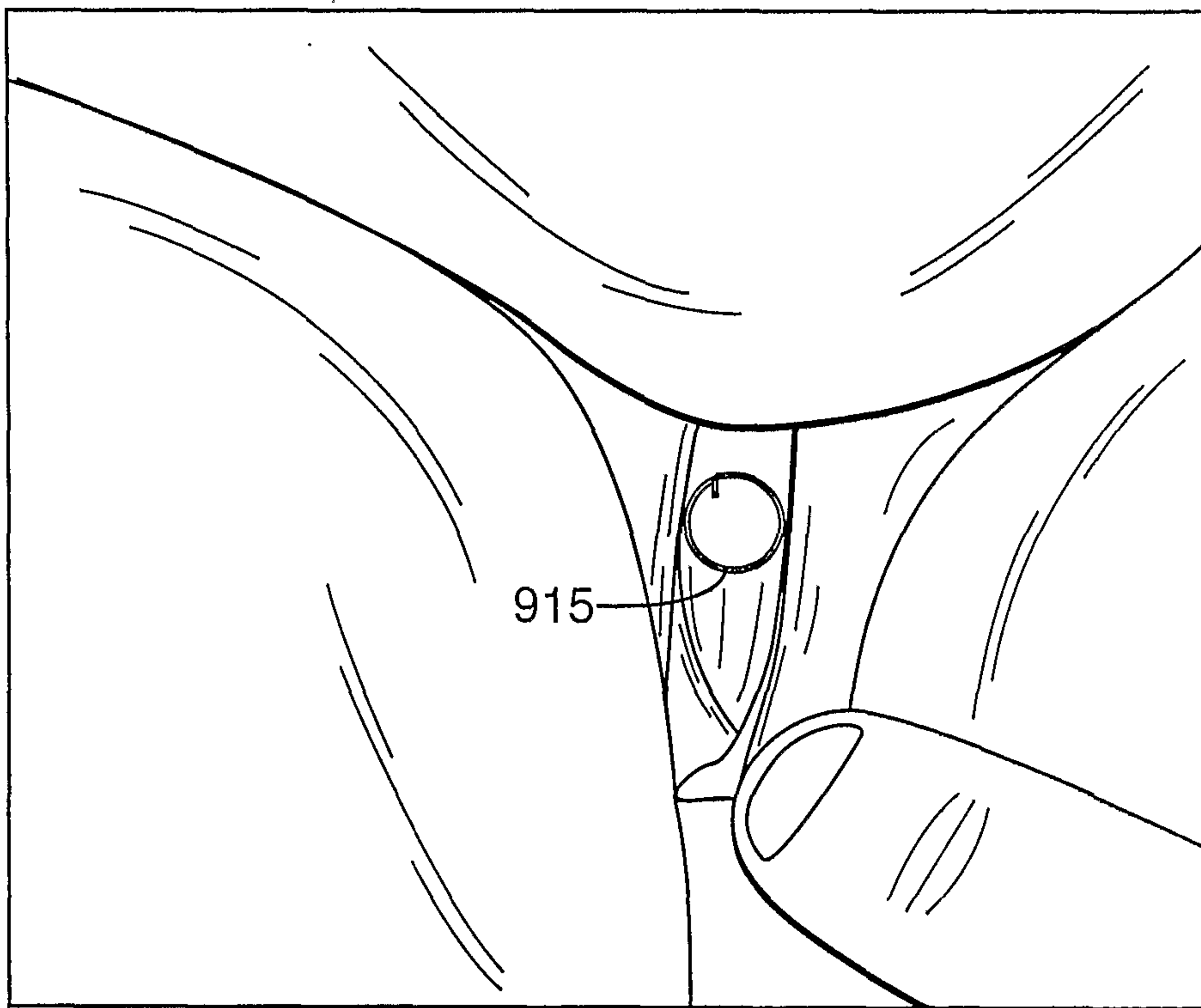


Fig. 55

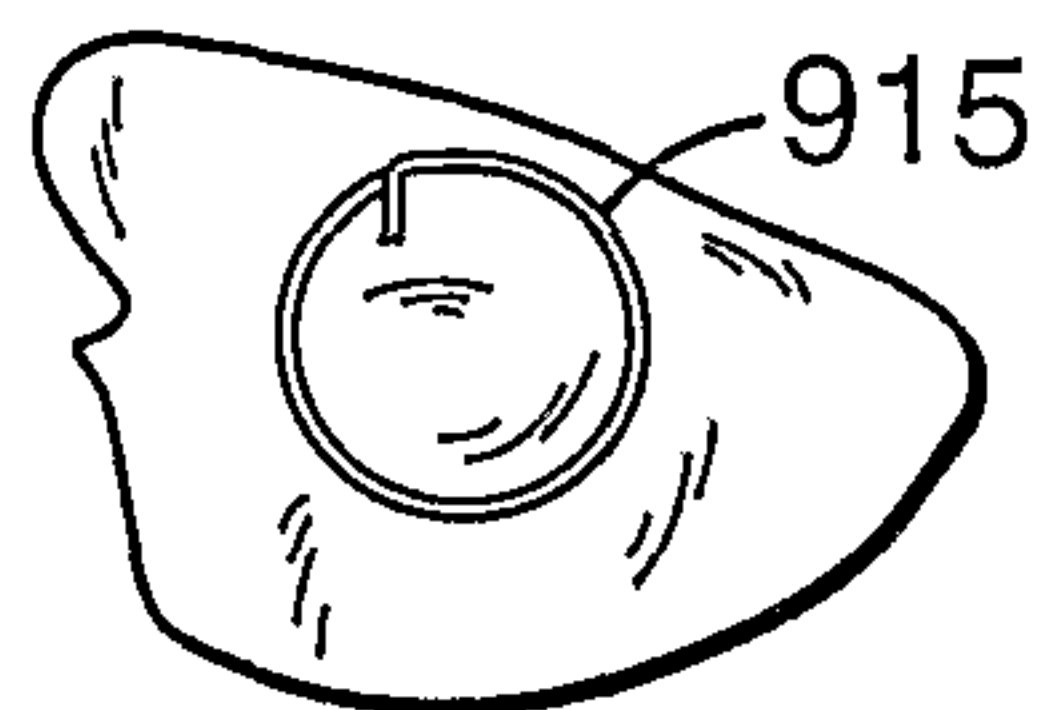


Fig. 56

