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(54) Title: IMPROVED BANDING DEVICE FOR TREATING HEMMORRHOIDS AND RELOADING DEVICE

(57) Abstract: The application provides for an elastic band application ligation device. The following medical device medical device features an embowed inner tube, having a wall and a flat tip, a pusher which is complementarily shaped to said inner tube; and a receiving port, which is configured to removably attach to a device capable of generating suction. Preferably, this device capable of generating suction will be a disposable luer lock syringe.

“IMPROVED BANDING DEVICE FOR TREATING HEMMORRHOIDS AND
RELOADING DEVICE”

5

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Claim of Priority

This application claims priority of the U.S. utility application number 15/049,498 filed on February 22, 2016 and U.S. provisional patent application number 62/118,777 filed on February 20, 2015, the contents of both of which are fully incorporated herein by reference.

15

FIELD OF THE EMBODIMENTS

The invention and its embodiments relate to medical devices, namely an elastic band ligator. In particular, the present invention and its embodiments relate to an improved elastic band ligator for use in the treatment of hemorrhoids.

20

BACKGROUND OF THE EMBODIMENTS

Hemorrhoids are one of the most common issues in America today. Studies indicate that by the age of 50, 50% of Americans have been diagnosed with hemorrhoids. Hemorrhoids are clusters of swollen blood vessels that begin to swell into the alimentary canal of humans. At first hemorrhoids can easily go undetected, but if left alone can turn into the source of serious pain. Worse, if left unattended for a long enough period of time, hemorrhoids will begin to prolapse. That is, untreated hemorrhoids will descend through the alimentary canal and extend through

one's anus. Additionally, there exist "external" hemorrhoids which form not inside the alimentary canal, but around one's anus.

There are a number of different methods to treat and/or remove hemorrhoids, however, one such method, ligation, has gained popularity. Over the years, ligation is the act of closing off
5 the blood vessels in the swollen hemorrhoid tissue. Over time, due to the lack of blood flow, the ligated hemorrhoid will eventually wither and fall off, painlessly. Ligation has been performed as early as 460 BC, however since then a number of apparatuses and methods have been developed to perform this task. That said, the prior art leaves a number of areas to be improved upon. For example, the devices taught by the prior art are notoriously difficult to operate with gloves on
10 which is a prerequisite to ligating hemorrhoids. Further, the devices of the prior art are incapable of ligating hemorrhoids placed in the more remote areas of the alimentary canal.

Thus, there is a need for an elastic band ligation device that is easy to operate while wearing medical gloves, that also provides the ability to ligate the hard-to-reach places in a patient's alimentary canal. The present invention and its embodiments meet and exceed these
15 objectives.

Review of related technology:

U.S. Patent 5,741,273 pertains to an elastic band ligation device for that treatment of hemorrhoids. The device permits a doctor to band hemorrhoidal tissue without the help of an assistant and does not have to be attached to an aspirator. The device has the capability of
20 suctioning tissue into a tubular member before banding. The device also has a plastic inner tubular member retains a stretched elastic band over a front end of an inner tubular member which extends for a sufficient length for insertion into the rectum of a patient. A plunger in the tubular member may be slid backwards to draw a suction in the tubular member to draw tissue in

through the front end. A plastic outer pusher sleeve fits over the tubular member and is adapted to push the elastic band off the front end of the tubular member to capture the hemorrhoidal tissue drawn into the tubular member.

U.S. Patent Publication 2014/0121679 pertains to an elastic band ligation device for
5 treating hemorrhoids and treatment method are provided. The device includes an inner tubular member for retaining an elastic band over the front end and the entire device is insertable into the rectum of a patient. The device is equipped with a plunger which generates suction for drawing hemorrhoidal tissue into the inner tubular member through the front end. A plastic outer tubular
10 pusher sleeve has an arced configuration corresponding to the arcuate inner tubular member to provide a limited friction fit over the inner tubular member. The pusher sleeve is equipped with a thumb pusher to allow the outer tubular pusher sleeve to be pushed towards the front end of the inner tubular member and release the elastic band from the front end of the inner tubular member to engage hemorrhoidal tissue extending through the opening in the inner tubular member.

Various devices are known in the art. However, their structure and means of operation
15 are substantially different from the present invention. Such devices fail to provide a device that can be easily operated through medical gloves and that provide a tool that can be used on a wider array of hemorrhoidal tissue. Further, the prior art teaches devices that are difficult to release suction with, provide for a poor fit within a patients rectum, and are so large that significant discomfort is caused in a patient being treated. At least one embodiment of this invention is
20 presented in the drawings below and will be described in more detail herein.

SUMMARY OF THE EMBODIMENTS

The present invention provides for a medical device, comprising: an inner tube, having a wall and a flat tip, wherein said flat tip is comprised of an edge that is perpendicular to the walls of said inner tube; a pusher, complementarily shaped to said inner tube; and a receiving port, 5 wherein said receiving port is configured to removably attach to a device capable of generating suction. Preferably, this device capable of generating suction is a luer lock syringe, and preferably said inner tube is embowed. In one embodiment, said pusher is permanently affixed to said inner tube and comes equipped with a plurality of protrusions. In some embodiments, the present invention is equipped with a reloader comprising: a conical frustum, an indentation, an a 10 cylinder with at least one recessed flange.

In a preferred embodiment, the present invention is an elastic band ligation device, comprising: a curved inner tube, having a distal end, a proximate end, and a primary recessed flange located at said distal end; a pusher, wherein: said pusher is complementarily shaped to said curved inner tube, said pusher has a limited friction fit with the curved inner tube, said 15 pusher is equipped with at least one protruding portion, and said pusher is equipped with a secondary recessed flange; and a receiving member, having an outer chamber, a receiving port located within said outer chamber, and a rear flange attached to said outer chamber, wherein said receiving port is configured to removably attach to a device capable of generating suction. In a preferred embodiment said pusher is capable of being extended at least 1 millimeter beyond the 20 distal end of the inner rigid member.

In yet another embodiment, the present invention consists of a kit, comprising: a medical device, comprising: an inner tube, having a wall and a flat tip, wherein said flat tip is comprised of an edge that is perpendicular to the walls of said inner tube; a pusher, complementarily shaped

to said inner tube; and a receiving port, wherein said receiving port is configured to removably couple to a device capable of generating suction; at least one elastic band; and a reloader, comprising: a bottom lip, a conical frustum section, a recessed flange, and a fitted opening, wherein said fitted opening is configured to receive the distal end of the curved inner tube.

5 Additionally, the present invention may be comprised of an inner tube, having a wall and a flat tip, wherein said flat tip is comprised of an edge that is perpendicular to the walls of said inner tube; a pusher, complementarily shaped to said inner tube; and a receiving port, wherein said receiving port is configured to removably attach to a syringe, preferably a luer lock syringe. In a preferred embodiment, this inner tube is embowed to allow for greater access to a patient's
10 alimentary canal.

 In yet another preferred embodiment, the inner tube and receiving port of the present invention are a single, unitary piece. This is intended to allow for the simplification of the manufacture of the present invention. In many embodiments, said pusher is engaged via a limited friction fit with the inner tube. This pusher may be equipped with a plurality of protrusions as
15 well. In yet another preferred embodiment, the pusher is sized to extend at least one millimeter beyond the tip of the inner tube when extended.

 The present invention also contemplates an elastic band reloader that works in conjunction with the medical device of the present invention. In a preferred embodiment, this reloader is comprised of a recessed flange, intended to be preloaded with an elastic band, a
20 conical frustum section to allow for easy loading of the elastic band onto the medical device, and an indentation sized to receive the tip of the medical device of the present invention.

 In general, the present invention succeeds in conferring the following, and other not mentioned, benefits and objectives.

The present invention has the benefit of the primary elastic band being preloaded on the device. This has the benefit of removing the difficult step found in the prior art, where an elastic band had to be manually loaded onto the ligator; something that is difficult while wearing medical gloves. Further, the embowed nature of the inner tube of the present invention allows for both easier insertion by the operator, and provides for increased comfort for the patient. Moreover, the inner tube of the present invention is significantly smaller than similar components found in the prior art, and said inner tube is equipped with a rounded flat tip, both of which provide for further increased comfort in a patient. Additionally, in a preferred embodiment, the present invention is entirely preassembled, providing for a sturdier product than that was is taught by the prior art.

It is an object of the present invention to provide a means for treating hemorrhoids.

It is an object of the present invention to provide a medical device.

It is an object of the present invention to provide an improved medical device for ligating hemorrhoids.

It is an object of the present invention to provide a medical device that is inexpensive and easy to use.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a front view of an embodiment of the present invention, wherein the present invention is removably attached to a standard luer lock syringe.

Fig. 2 is a front view of an embodiment of the invention, highlighting the removable nature of the present invention.

Fig. 3 is a perspective view of an embodiment of the invention.

Fig. 4 is a perspective view of an embodiment of the present invention, wherein the medical device of the present invention is interfacing with the reloader of the present invention.

Fig. 5 is a top view of an embodiment of the present invention, illustrating the reloading mechanism.

5 **Fig. 6** is an illustration of the present invention in use is provided.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The preferred embodiments of the present invention will now be described with reference to the drawings. Identical elements in the various figures are identified with the same reference
10 numerals.

Reference will now be made in detail to each embodiment of the present invention. Such embodiments are provided by way of explanation of the present invention, which is not intended to be limited thereto. In fact, those of ordinary skill in the art may appreciate upon reading the present specification and viewing the present drawings that various modifications and variations
15 can be made thereto.

Referring to Fig. 1, a front view of an embodiment of the present invention is provided, wherein the present invention is removably attached to a standard luer lock syringe. Here, medical device 100 is shown. It is comprised of inner tube 101, which may be permanently affixed to pusher 106. Inner tube 101 is equipped with primary recessed flange 105. Primary
20 recessed flange 105 is intended to, when loaded, house at least one elastic band (not pictured). In a preferred embodiment, to account for a failed deployment of an elastic band from the primary recessed flange 105, the present invention is equipped with secondary recessed flange 107. Secondary recessed flange may be equipped with an elastic band such that it can be easily slid

down pusher 106 onto primary recessed flange 105. This mechanism provides the additional benefit that it may be done easily while wearing medical gloves; something that is essential when hemorrhoid ligation is performed. In a preferred embodiment, medical device 100 is equipped with rear flange 102. This makes handling the present invention easier. Another feature of this particular embodiment is flat tip 111. Flat tip 111 allows for the consistent deployment of any elastic bands from primary recessed flange 105. The inclusion of flat tip 111 is particularly important when inner tube 101 is embowed. This is because the embowment of inner tube 101 allows for medical device 100 to reach previously unreachable areas of a patient's alimentary canal. In a preferred embodiment, medical device 100 operates by interfacing with a device that is capable of generating suction 115. Preferably, device capable of generating suction 115 is a luer lock syringe. Note that pusher 106 will engage with clicking stop point 118 such that it was informed the operator of the present invention that pusher 106 is in a position that provides for immediate deployment of at least one elastic band 117 (see Figs. 4 or 6). This is achieved by allowing pusher 106 to engage in a limited friction fit with inner tube 101. This feature has the benefit of preventing misfires, as well as allowing the operator to be certain of medical device's 100 position before deploying at least one elastic band 117. In an alternative embodiment, pusher 106 is equipped with bumps to allow for a tactile feel, increasing the dexterity in which medical device 100 may be operated with.

In one embodiment, once medical device 100 has interfaced with device capable of generating suction 115, it is equipped with an elastic band. Note that at least one elastic band may be comprised of latex, or a non-latex material. Medical device 100 is subsequently inserted into a patient's anus into the patient's alimentary canal. It should be noted that medical device 100 is suitable for treating external hemorrhoids, however, this description of use is for treatment

of internal hemorrhoids. Once inserted into the patients alimentary canal, flat tip 111 is placed in close proximity to said hemorrhoid and device capable of generating suction 115 will generate suction, resulting in said hemorrhoid being drawn into inner tube 101. Once the hemorrhoid has been drawn into inner tube 101, pusher 106 is engaged and pushed beyond flat tip 111. This motion results in the loaded elastic band being wrapped around the base of said hemorrhoid. This placement of the elastic band will result in the hemorrhoid eventually falling off.

Referring to Fig. 2, a front view of an embodiment of the invention is shown, highlighting the removable nature of the present invention. Specifically, viewing port 112 and receiving port 103 are highlighted. Receiving port 103 is the aspect of the invention that interfaces with device capable of generating suction 115. When interfaced, these two components create a seal sufficient to support a vacuum capable of drawing a hemorrhoid within inner tube 101. Viewing port 112 is a feature of the present invention so that a user attempting to interface receiving port 103 with device that is capable of generating suction 115 may have a visual aid. Outer chamber 116 exists to help preserve the seal between receiving port 103 and device capable of generating suction 115. However, without the inclusion of viewing port 112, outer chamber 116 would inhibit the ease of interfacing between receiving port 103 and device capable of generating suction 115. This increases the efficiency of use of the present invention. Also present in this figure are flat tip 111, primary recessed flange 105, inner tube 101, pusher 106, protrusions 114.

To use an alternative embodiment of the present invention, first device capable of generating suction 115, here a luer lock syringe, is screwed into receiving port 103. This provides for a seal between receiving port 103 and the luer lock syringe, allowing a vacuum to be generated near flat tip 111. Next, elastic band reloader 108 is accessed. If an elastic band is not

present in cylinder with at least one recessed flange 109, an elastic band should be placed there. Then, elastic band reloader is used to load an elastic band onto primary recessed flange 105. Then, the luer lock syringe is engaged to draw the hemorrhoid inside of inner tube 101. From there, pusher 106 is used to slide the elastic band over the hemorrhoid.

5 Fig. 3 shows a perspective view of an embodiment of the invention. Fig. 3 highlights the relationship between inner tube 101 and pusher 106. Specifically, Fig. 3 shows that in a preferred embodiment, pusher 106 is shaped such that it creates a limited friction fit with inner tube 101. Protrusions 114 are also shown in Fig. 3. Protrusions 114 serve the purpose of providing a plurality of surfaces for a user to engage pusher 106 with. This is particularly beneficial in
10 embodiments where inner tube 101 is embowed due to the fact that when in use, medical device 100 will likely be rotated after being inserted into a patient's alimentary canal. The embowment of inner tube 101 is also beneficial because it allows for a better fit around the patient's hemorrhoid, increasing the likelihood of success of the elastic band ligation. Having a plurality of protrusions will enable a user of medical device 100 to track the movement of the embowed
15 inner tube 101, as well as provide ample surfaces to engage pusher 106 with. It should be noted that in a preferred embodiment, the position of protrusions 114 should not obstruct viewing port 112, and should not scrape against outer chamber 116.

Referring to Fig. 4, a perspective view of an embodiment of the present invention is provided, wherein the medical device of the present invention is interfacing with the reloader of
20 the present invention. Medical device 100 interfaces with elastic band reloader 108 by having flat tip 111 inserted into indentation 113. It is not imperative that any kind of seal be maintained at this junction, merely that the fit is tight enough that at least one elastic band 117 may be easily loaded onto primary recessed flange 105 (not shown) by sliding down conical frustum 110. The

elasticity of at least one elastic band 117 will hold at least one elastic band 117 to inner tube 101 (not shown) when loaded. In a preferred embodiment, at least one elastic band 117 is preloaded onto cylinder with at least one recessed flange 109. In another preferred embodiment, elastic band loader 108 is shaped such that it may be used to load elastic bands onto secondary recessed
5 flange 107. There, pusher 106 would interface with indentation 113, again forming a seal such that at least one elastic band 117 may slide down conical frustum 110, as well as pusher 106 down to secondary recessed flange 107 (not shown). Also of note here is the relationship between receiving port 103 and viewing port 112. In one embodiment, viewing port 112 is sized such that the entirety of receiving port 103 is visible through viewing port 112.

10 In a preferred embodiment, secondary recessed flange 107 and elastic band reloader 108 are preloaded with elastic bands. In an alternative embodiment, secondary recessed flange 107 and primary recessed flange 105 are both preloaded with elastic bands. Preferably, these bands will be located on secondary recessed flange 107 and cylinder with at least one recessed flange 109. There, flat tip 111 is inserted into indentation 113. This creates a substantially flush surface
15 between conical frustum 110 and inner tube 101, providing for an easy means to load the elastic band onto primary recessed flange 105.

Regarding Fig. 5, a top view of an embodiment of the present invention is shown, illustrating the reloading mechanism. Here, the fact that more than one of the at least one elastic band 117 may be loaded onto cylinder with at least one recessed flange 109, and that primary
20 recessed flange 105 is also capable of receiving more than one of the at least one elastic band 117. In an alternative embodiment, secondary recessed flange 107 is also capable of receiving more than one of the at least one elastic band 117.

Referring to Fig. 6, an illustration of the present invention in use is provided. The process illustrated here involves placing flat tip 111 in close proximity to a hemorrhoid to be treated. Device capable of generating suction 115 then generates suction, drawing the hemorrhoid within inner tube 101. Pusher 106 is subsequently engaged resulting in at least one elastic band 117 being wrapped around said hemorrhoid. The suction is then turned off and medical device 100 is removed from the patient. This view illustrates the benefit of protrusions 114, as it gives a number of different surfaces to begin the deployment of at least one elastic band 117.

The appended claims are to be considered as incorporated into the above description.

Throughout this specification, reference to any advantages, promises, objects or the like should not be regarded as cumulative, composite and/or collective and should be regarded as preferable or desirable rather than stated as a warranty.

Throughout this specification, unless otherwise indicated, "comprise," "comprises," and "comprising," (and variants thereof) or related terms such as "includes" (and variants thereof)," are used inclusively rather than exclusively, so that a stated integer or group of integers may include one or more other non-stated integers or groups of integers.

When introducing elements of the present disclosure or the embodiment(s) thereof, the articles "a", "an," and "the" are intended to mean that there are one or more of the elements. Similarly, the adjective "another," when used to introduce an element, is intended to mean one or more elements. The terms "including" and "having" are intended to be inclusive such that there may be additional elements other than the listed elements.

While the disclosure refers to exemplary embodiments, it will be understood by those skilled in the art that various changes may be made and equivalents may be substituted for elements thereof without departing from the scope of the disclosure. In addition, many modifications will be appreciated by those skilled in the art to adapt a particular instrument, situation or material to the teachings of the disclosure without departing from the spirit thereof. Therefore, it is intended that the disclosure not be limited to the particular embodiments disclosed.

CLAIMS

1. A medical device, comprising:
 - an inner tube, having a wall, and a flat tip, wherein said flat tip is comprised of an edge that is perpendicular to the wall of said inner tube;
 - a pusher having a recessed flange disposed thereon, the pusher being complementarily shaped to, and slidably engaged with, said inner tube, wherein a stop point of the pusher is configured to engage in a stop point of said inner tube;
 - a receiving member having an outer chamber, at least one viewing port, and a receiving port, wherein said at least one viewing port is disposed in a sidewall of said outer chamber; and
 - a syringe configured to be removably coupled to the receiving port, wherein the syringe is configured to generate suction.

2. The medical device of claim 1, wherein said syringe is a luer lock syringe.

3. The medical device of claim 1 or claim 2, wherein said inner tube is embowed.

4. The medical device of any one of the preceding claims, wherein said inner tube and said receiving port are comprised of a solitary construction.

5. The medical device of any one of the preceding claims, wherein said pusher is permanently affixed to said inner tube.

6. The medical device of any one of the preceding claims, wherein said pusher is equipped with a plurality of protrusions.

7. The medical device of any one of the preceding claims, further comprising an elastic band reloader.

8. The medical device of claim 7, wherein said elastic band reloader further comprises an indentation, shaped to receive said flat tip.

9. The medical device of claim 7 or claim 8, said elastic band reloader further comprising a conical frustum.

10. The medical device of any one of the preceding claims, said inner tube further comprising a rear flange.

11. The medical device of any one of the preceding claims, wherein said pusher is capable of extending at least 1 millimeter beyond said flat tip of the inner tube.

12. The medical device of claim 7, further comprising at least one elastic band wherein said elastic band reloader is equipped with a third recessed flange, and wherein said at least one elastic band is preloaded on the third recessed flange of the elastic band reloader.

13. The medical device of any one of the preceding claims, wherein the pusher further comprises a secondary recessed flange.

14. The medical device of any one of the preceding claims, wherein the inner tube further comprises a primary recessed flange.

15. A kit, comprising:

a medical device, comprising:

a curved inner tube, having a wall and a flat tip, wherein said flat tip is comprised of an edge that is perpendicular to the wall of said curved inner tube;

a pusher having a recessed flange disposed thereon, the pusher being complementarily shaped to said curved inner tube, said pusher configured to engage a stop point of said curved inner tube; and

a receiving member having a circular outer chamber, at least one viewing port, a receiving port located within said circular outer chamber, and a rear flange extending perpendicularly from said circular outer chamber, wherein said receiving port is configured to removably couple to a device capable of generating suction, and wherein said at least one viewing port is disposed in a sidewall of said circular outer chamber;

at least one elastic band; and

a reloader, comprising:

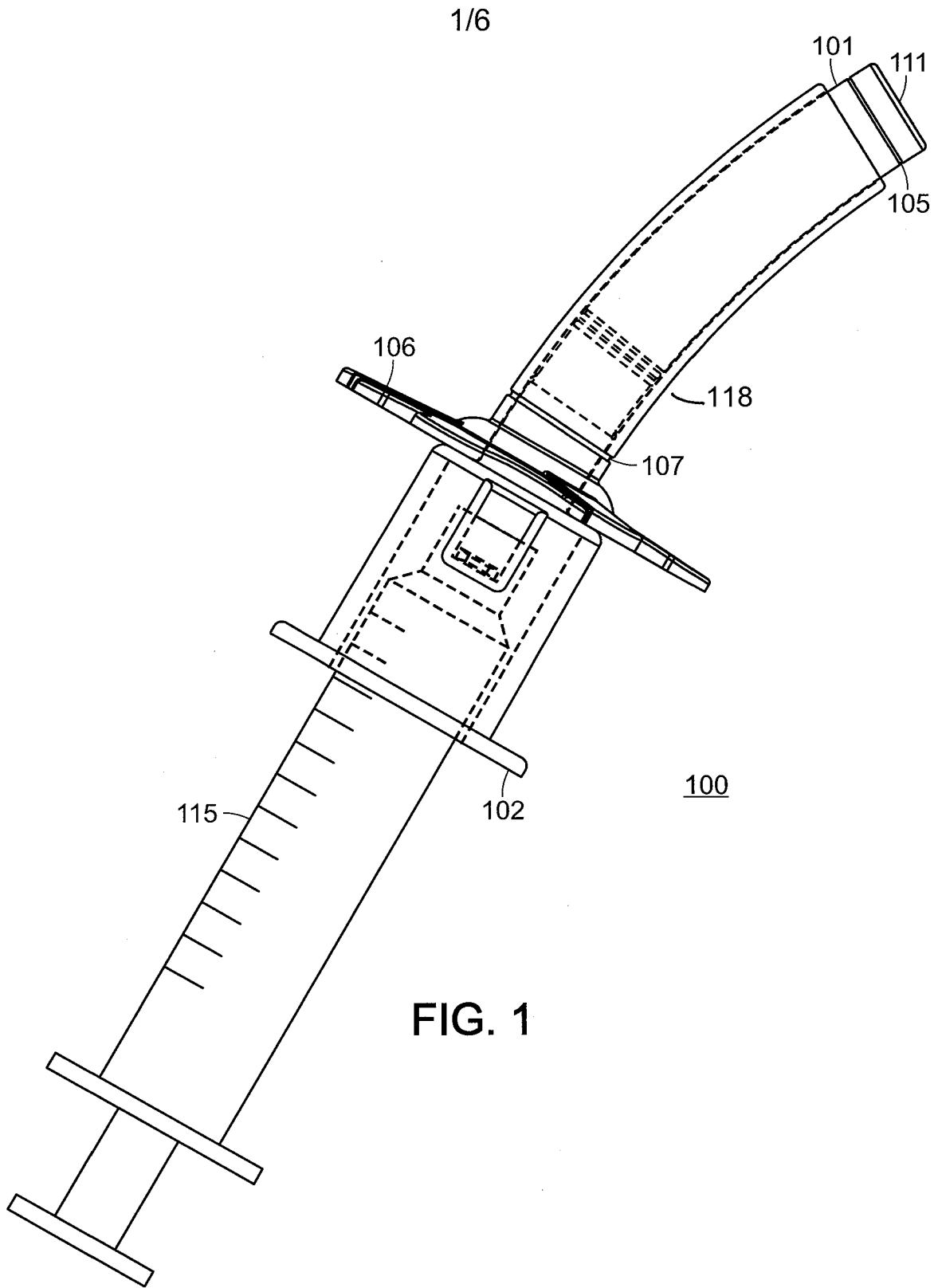
a bottom lip;

a conical frustum section;

a recessed flange, and

a fitted opening, wherein said fitted opening is configured to receive the distal end of the curved inner tube.

16. The medical device of any one of the preceding claims, said inner tube further comprising a clicking stop point capable of engaging in a limited friction fit with said pusher.



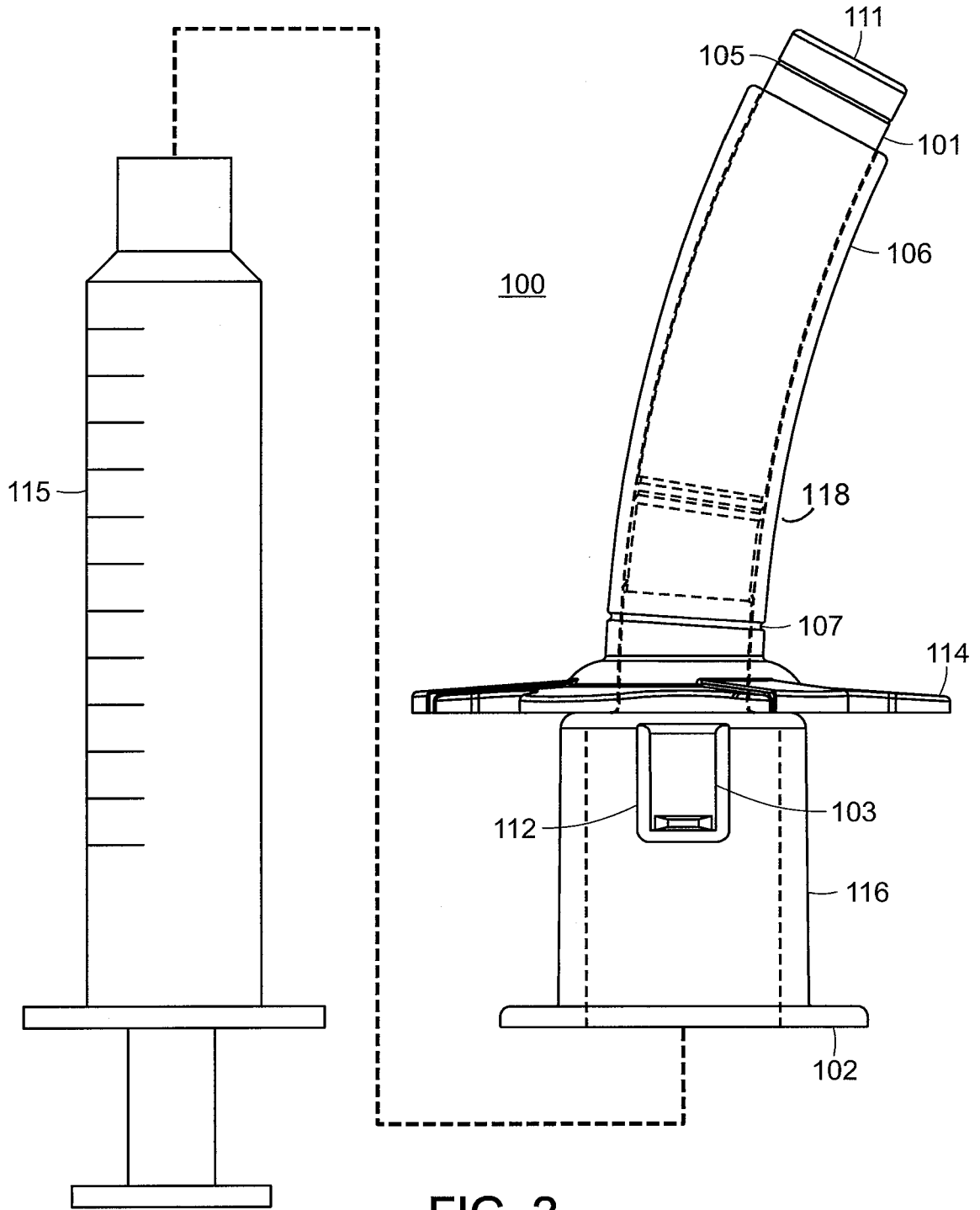


FIG. 2

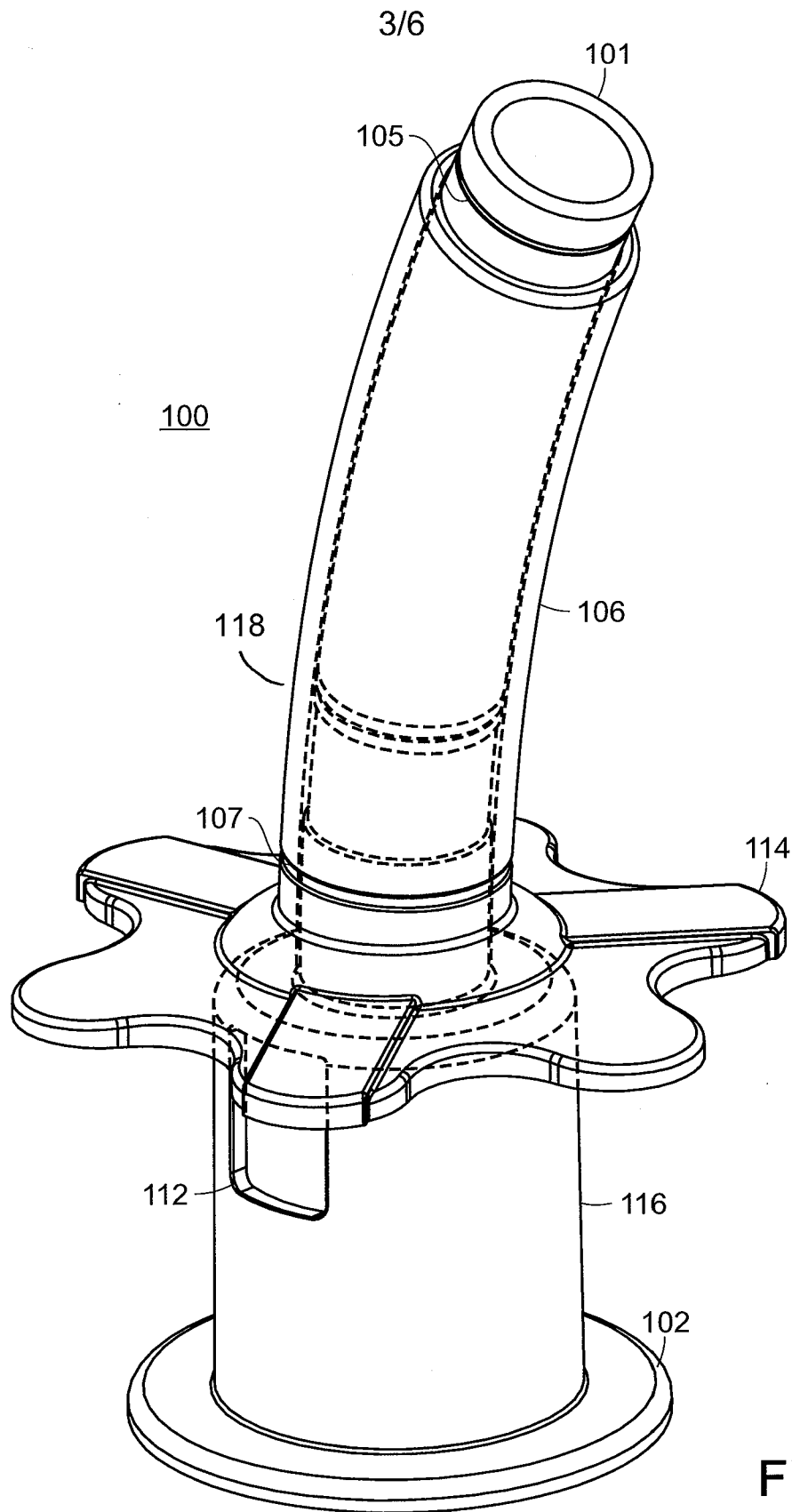


FIG. 3

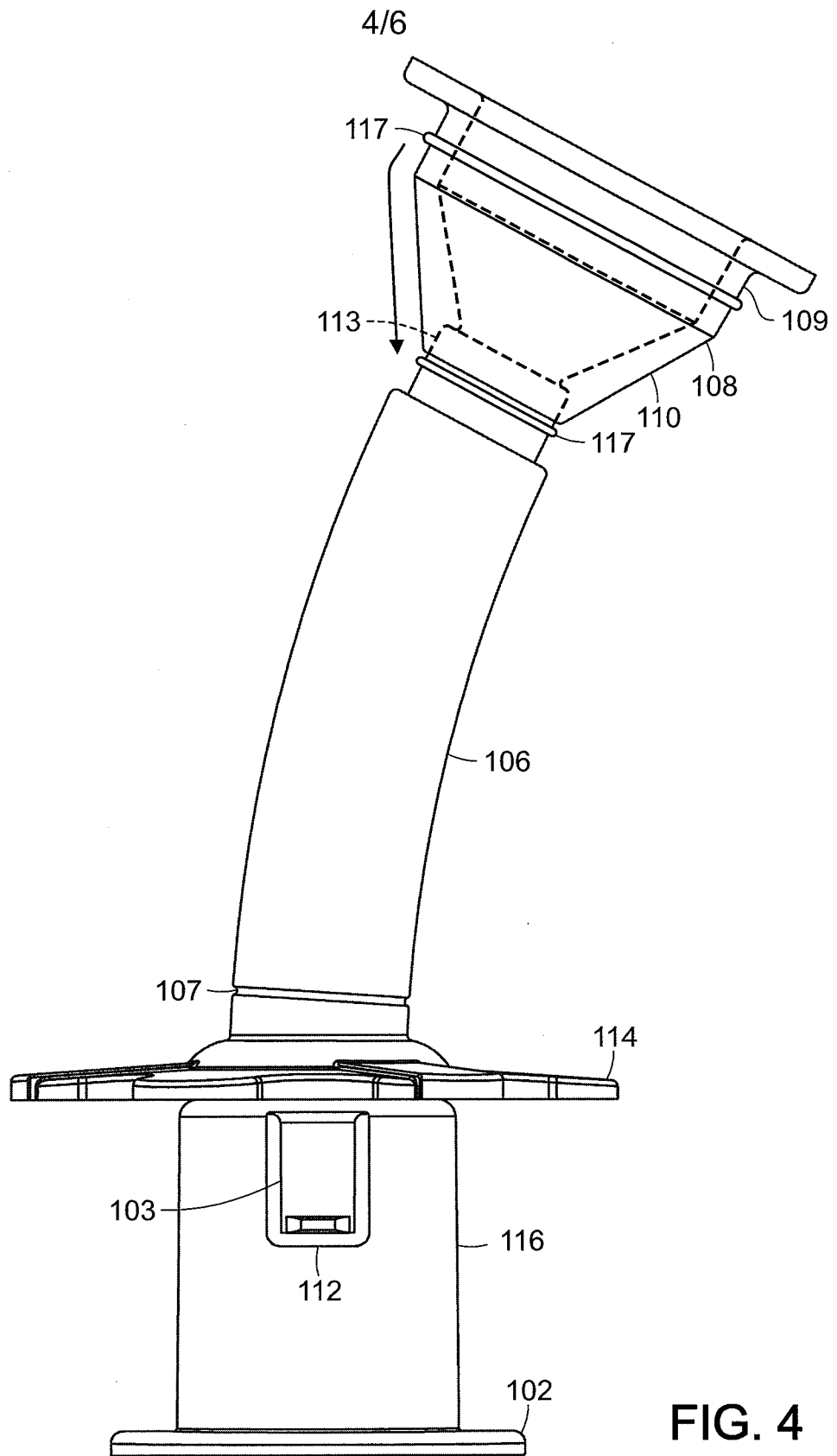


FIG. 4

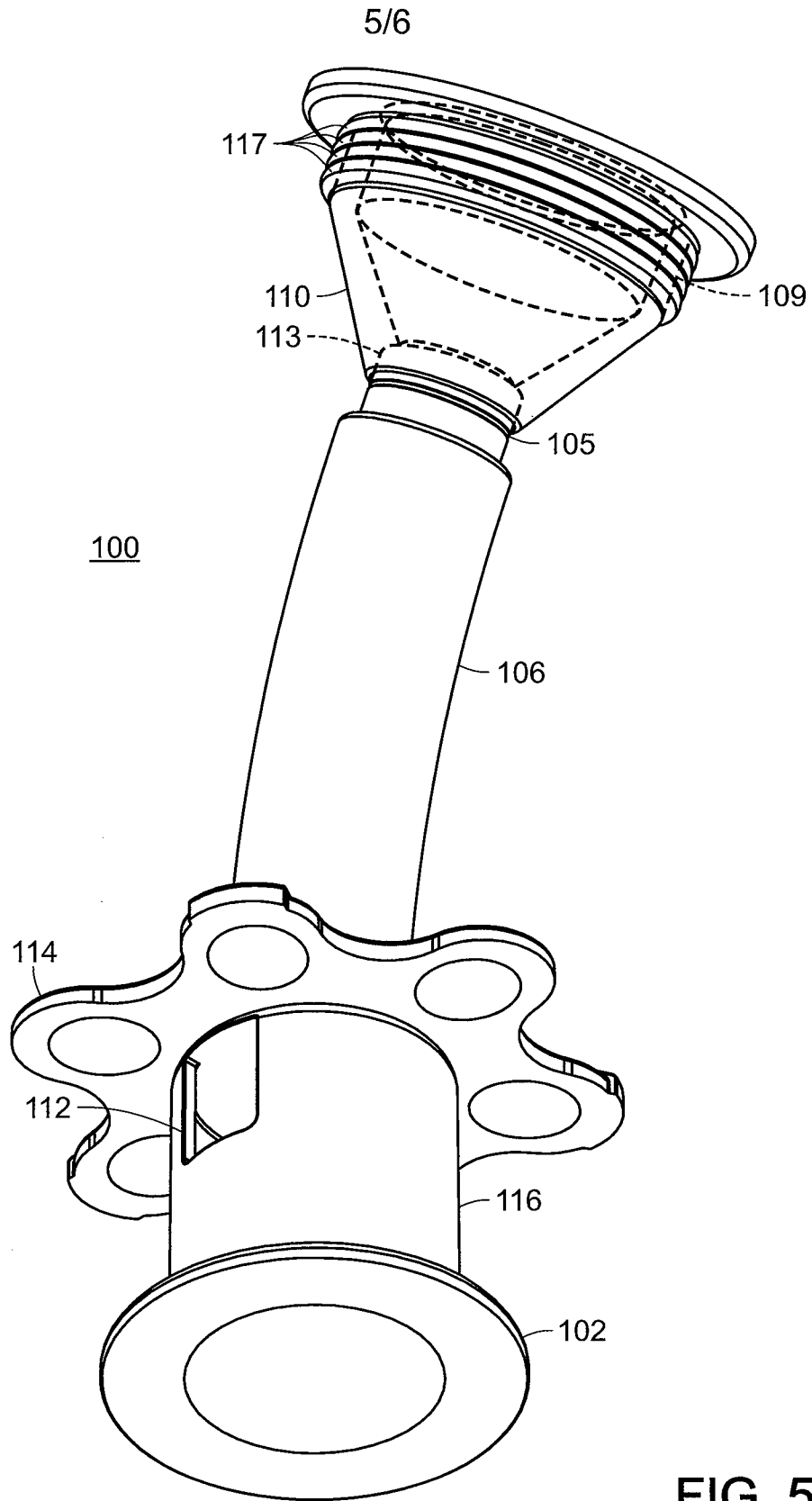


FIG. 5

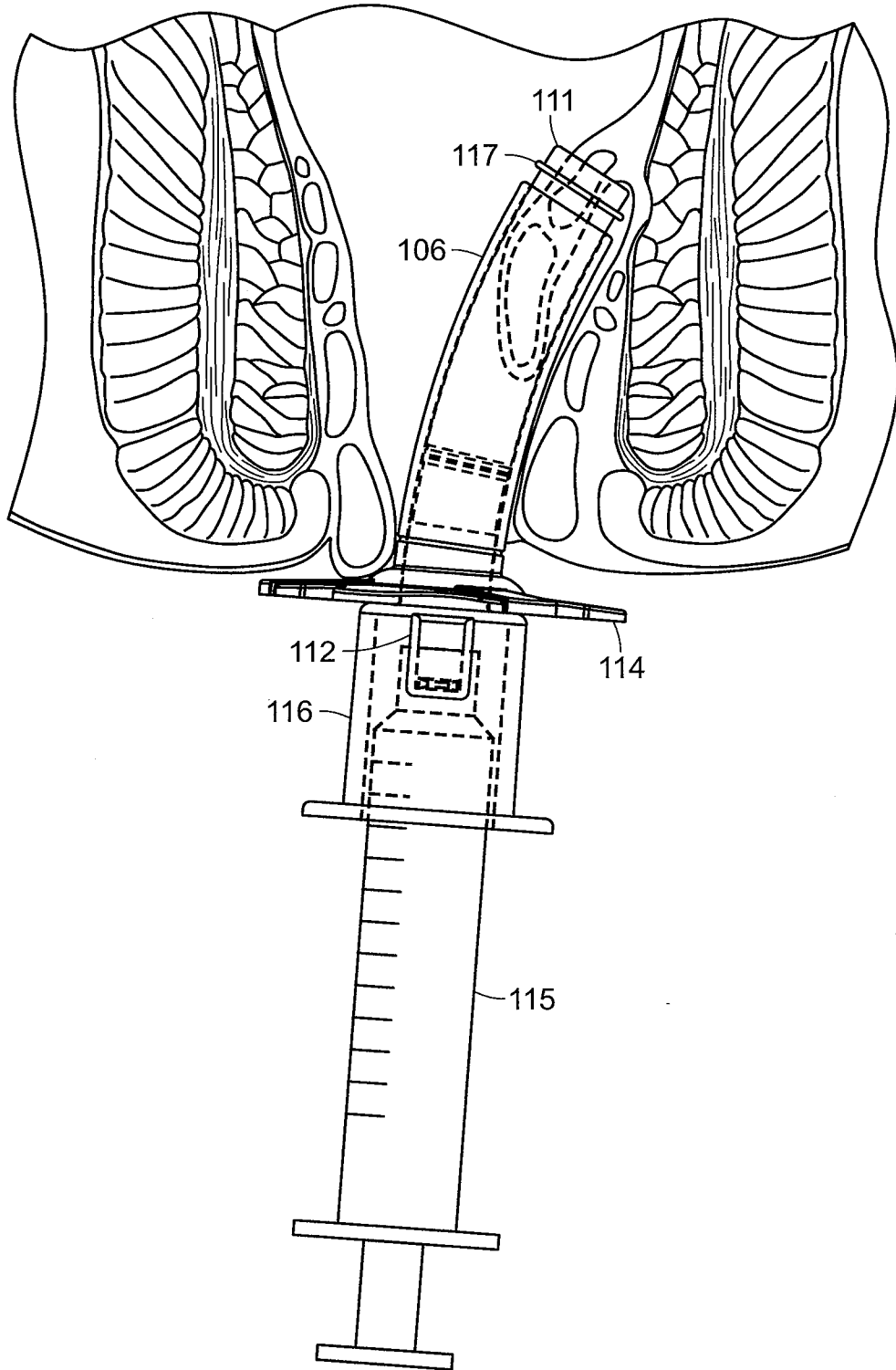


FIG. 6