

US 20060260617A1

(19) **United States**

(12) **Patent Application Publication**
Abolfathi et al.

(10) **Pub. No.: US 2006/0260617 A1**

(43) **Pub. Date: Nov. 23, 2006**

(54) **METHODS AND SYSTEMS FOR TRACHEAL ACCESS AND VENTILATION**

(60) Provisional application No. 60/777,973, filed on Feb. 28, 2006.

(75) Inventors: **Amir Abolfathi**, Woodside, CA (US);
Scott H. West, Livermore, CA (US);
Christopher Lolachi, Palo Verdes, CA (US);
Christopher Danek, San Carlos, CA (US)

Publication Classification

(51) **Int. Cl.**
A61M 16/00 (2006.01)

(52) **U.S. Cl.** **128/207.29**

Correspondence Address:

TOWNSEND AND TOWNSEND AND CREW, LLP

TWO EMBARCADERO CENTER
EIGHTH FLOOR

SAN FRANCISCO, CA 94111-3834 (US)

(73) Assignee: **APMed Solutions, Inc.**, Portola Valley, CA

(21) Appl. No.: **11/435,174**

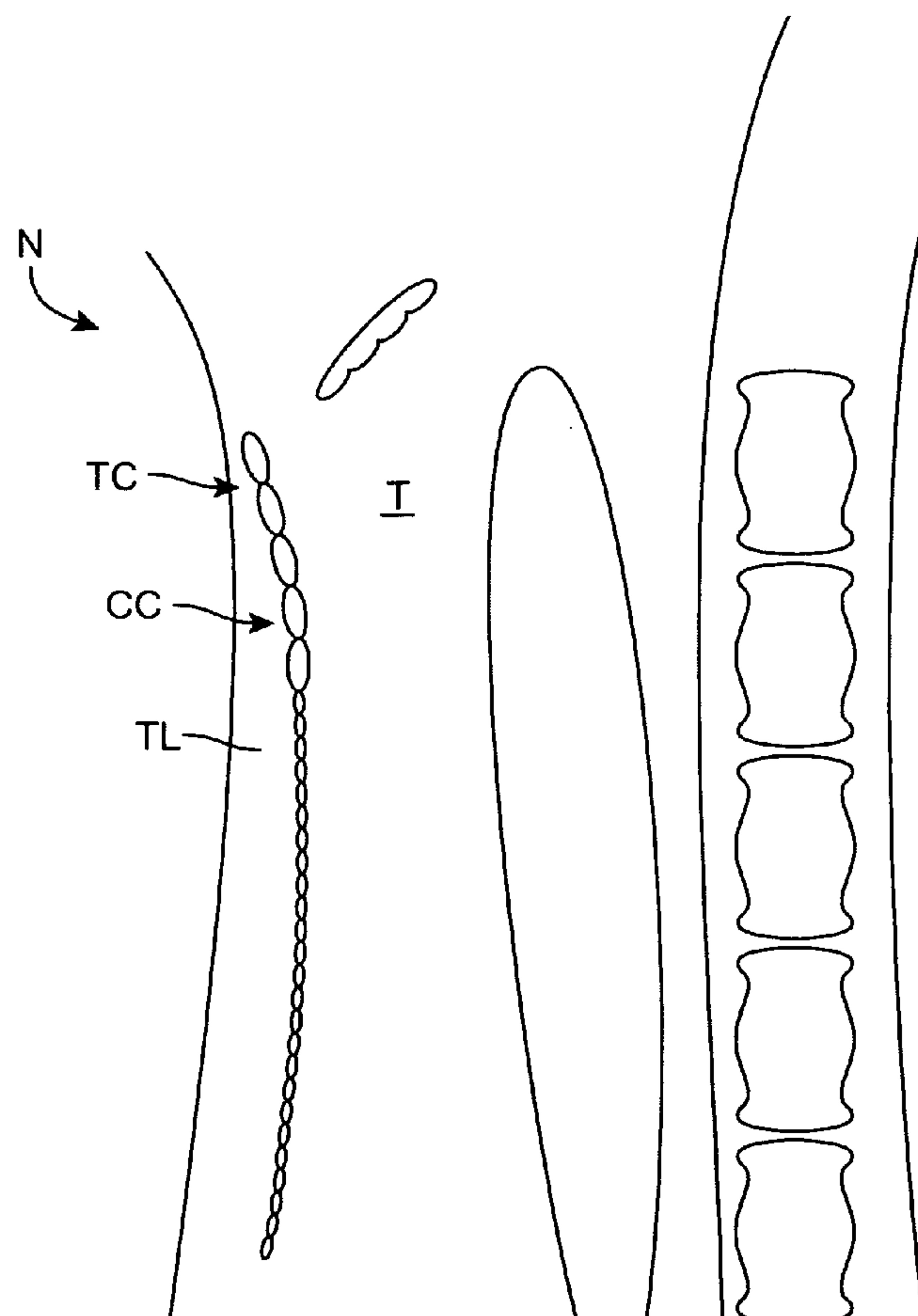
(22) Filed: **May 15, 2006**

Related U.S. Application Data

(63) Continuation-in-part of application No. 11/132,603, filed on May 18, 2005.

(57) **ABSTRACT**

A tracheostomy is performed using an access device and a separate ventilation device. The access device is introduced through a surgical opening in the tracheal wall and has an anchor which is expanded in situ to hold the access device in place. The ventilation device is introduced through a passage in the access device and has an expandable cuff which is oriented above the access point through the tracheal wall. A concavity in the expandable cuff collects body secretions, and other materials from the oral and nasal cavities and/or gastro-intestinal reflux into the trachea, and the collected secretions are removed by aspiration through a lumen provided in the ventilation device. A one-way valve may be provided in the expandable cuff in order to permit exhalation through the larynx to assist in speech.



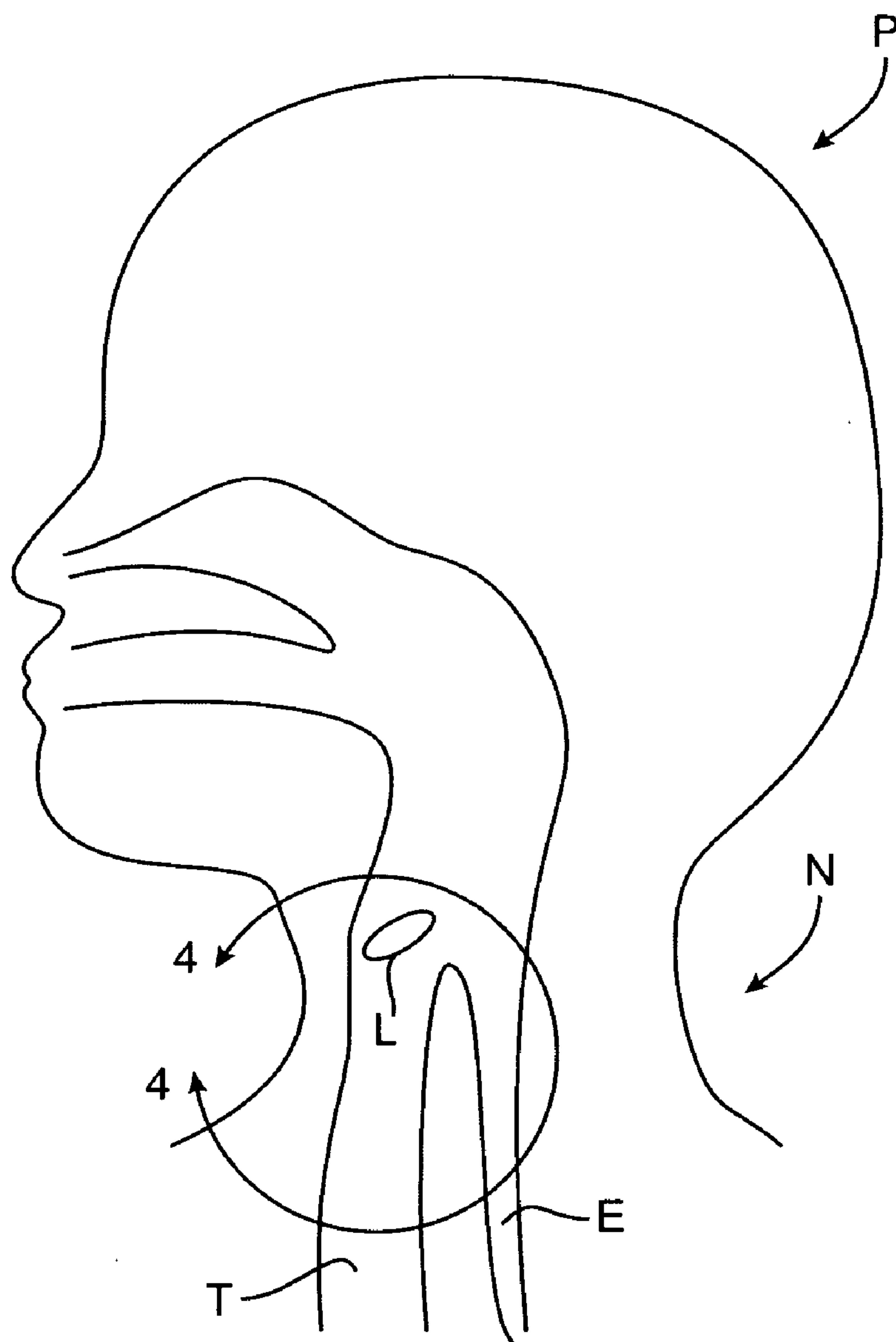


FIG. 1

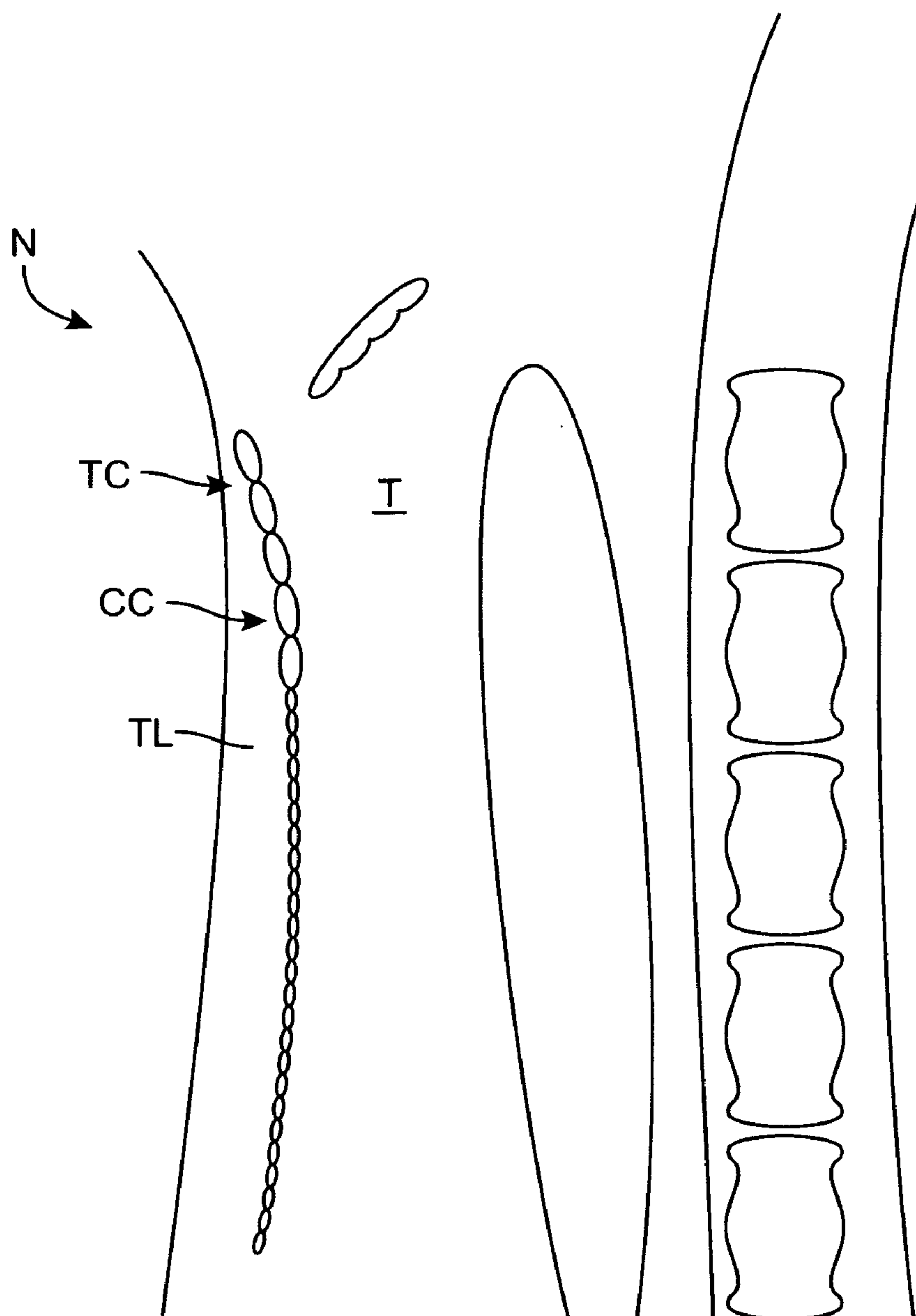


FIG. 4A

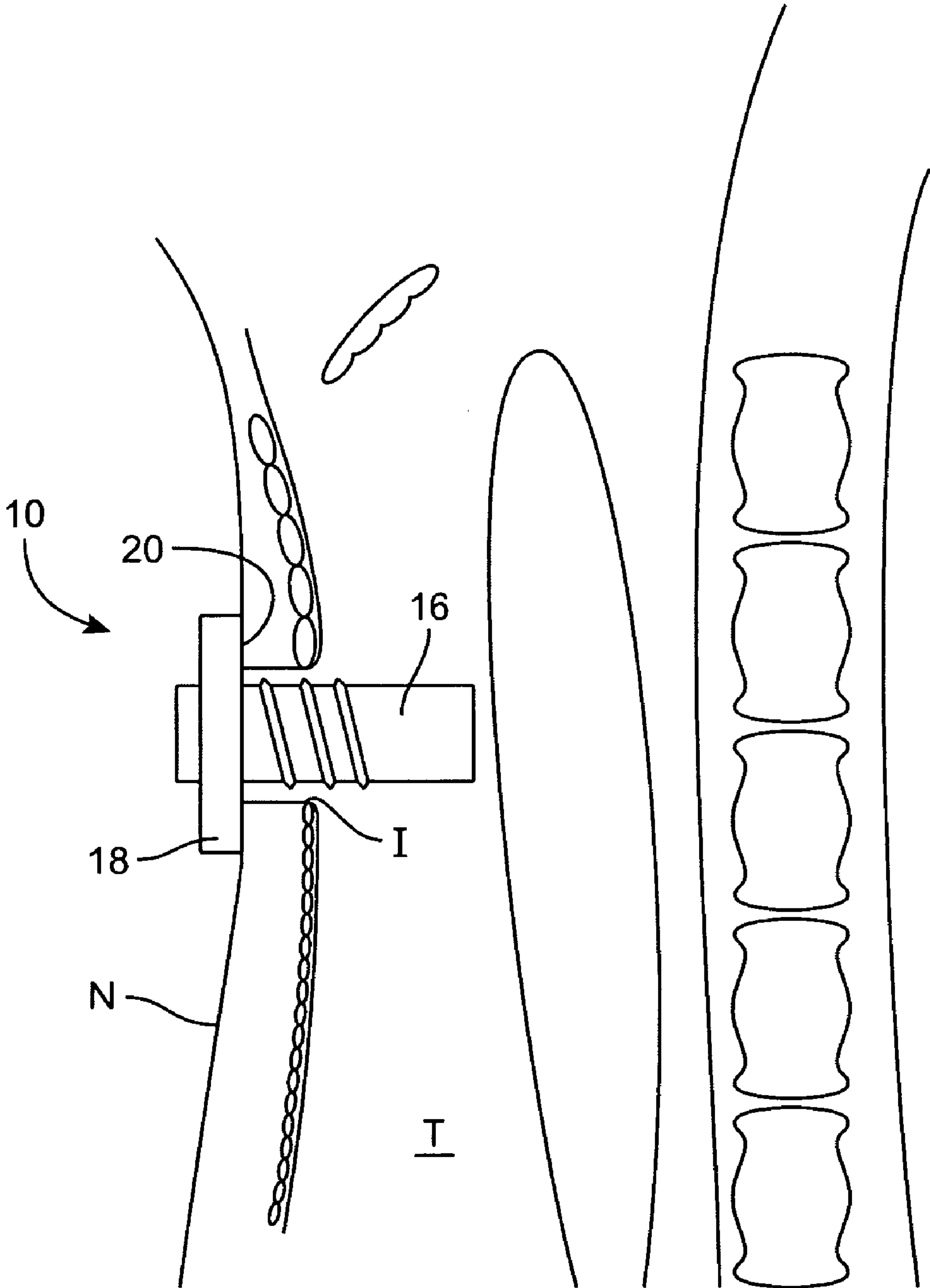


FIG. 4B

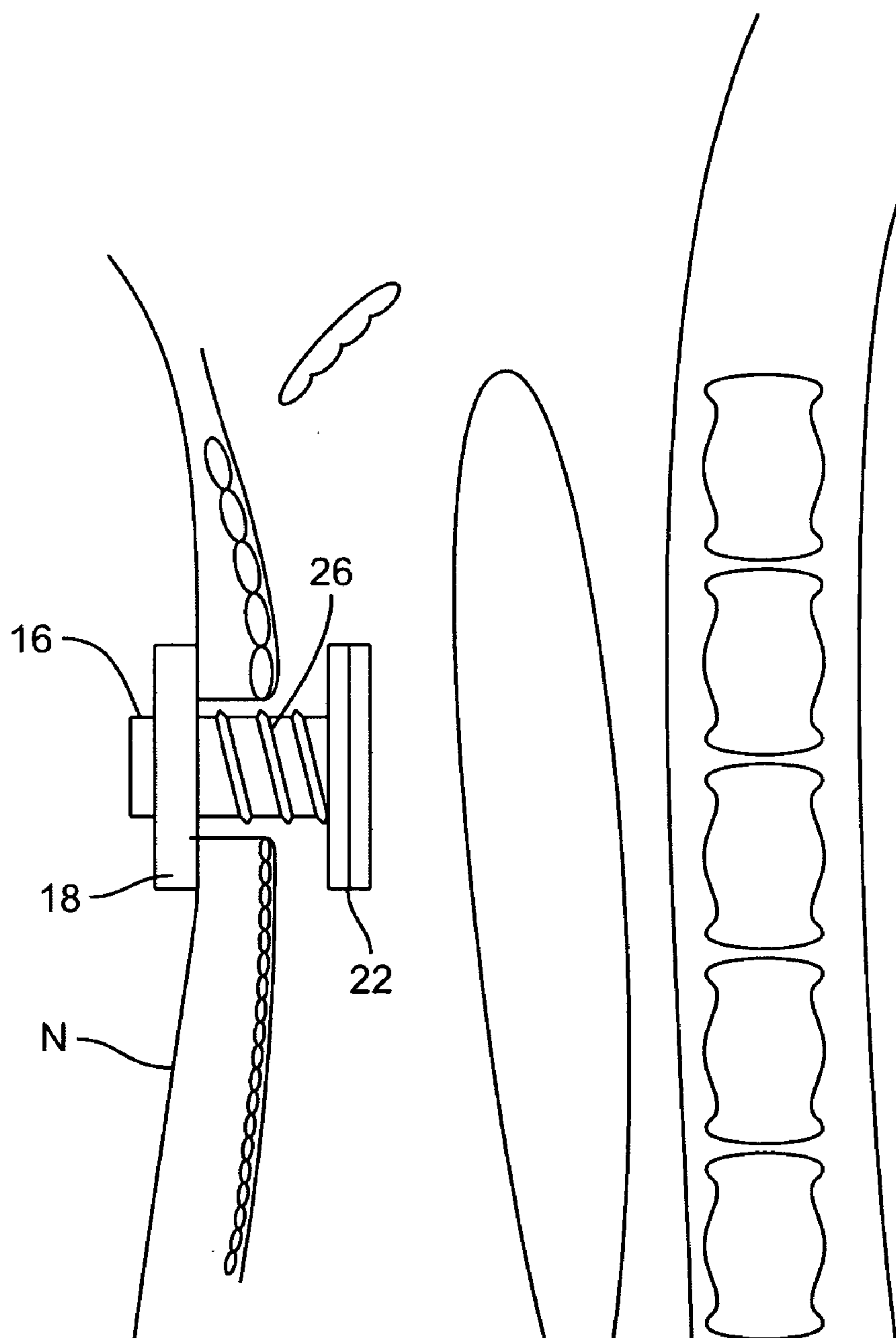


FIG. 4C

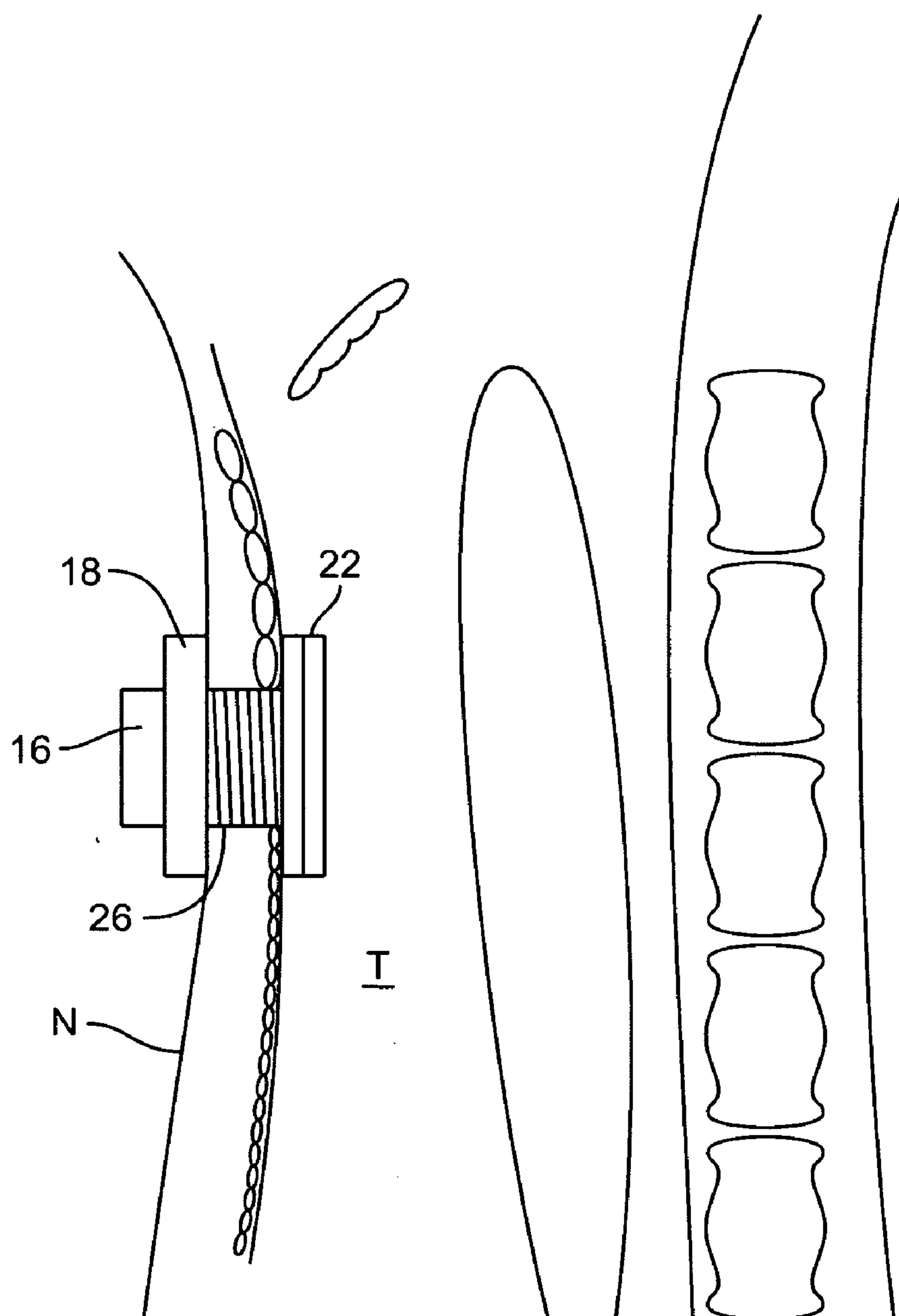


FIG. 4D

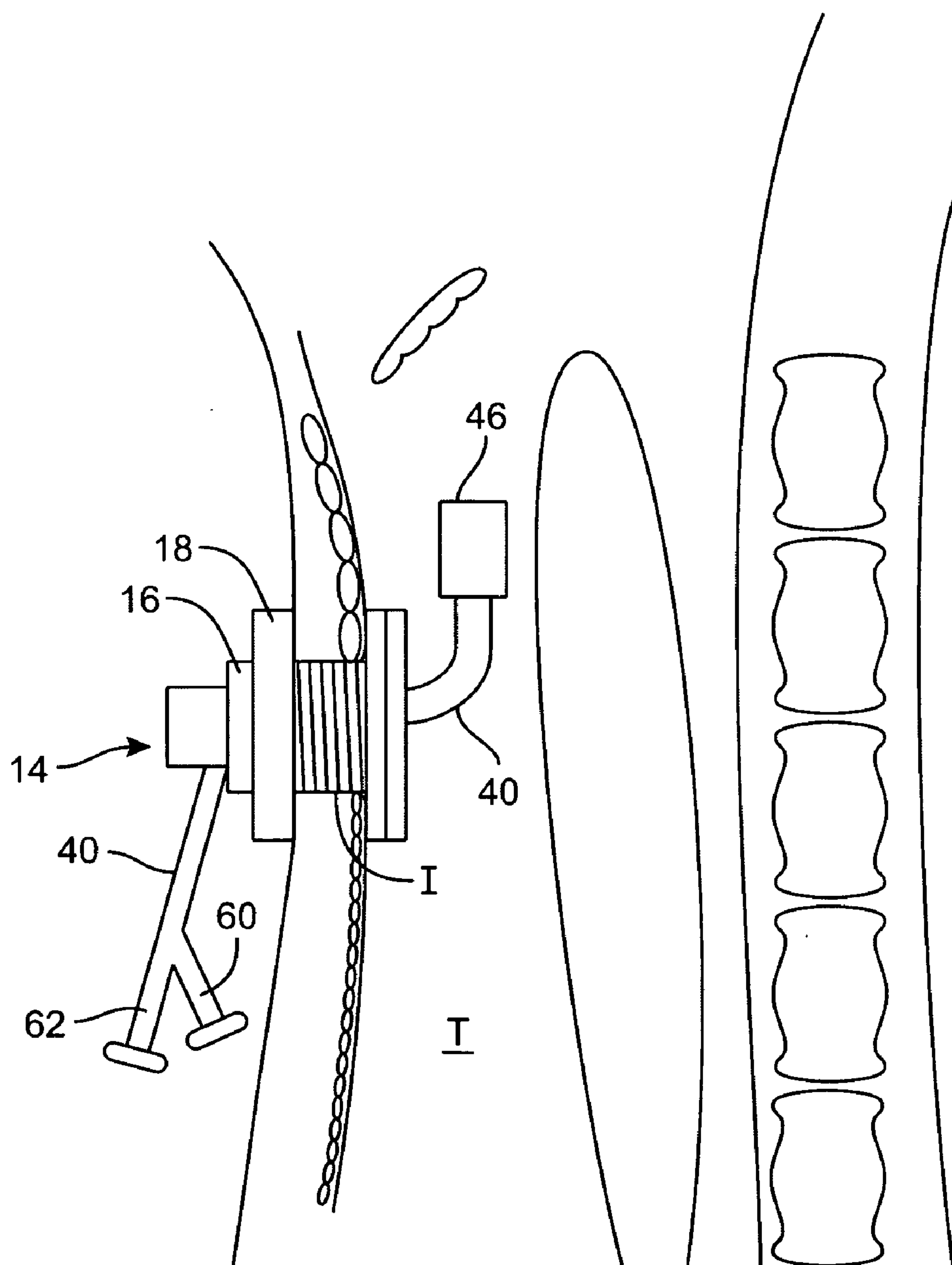


FIG. 4E

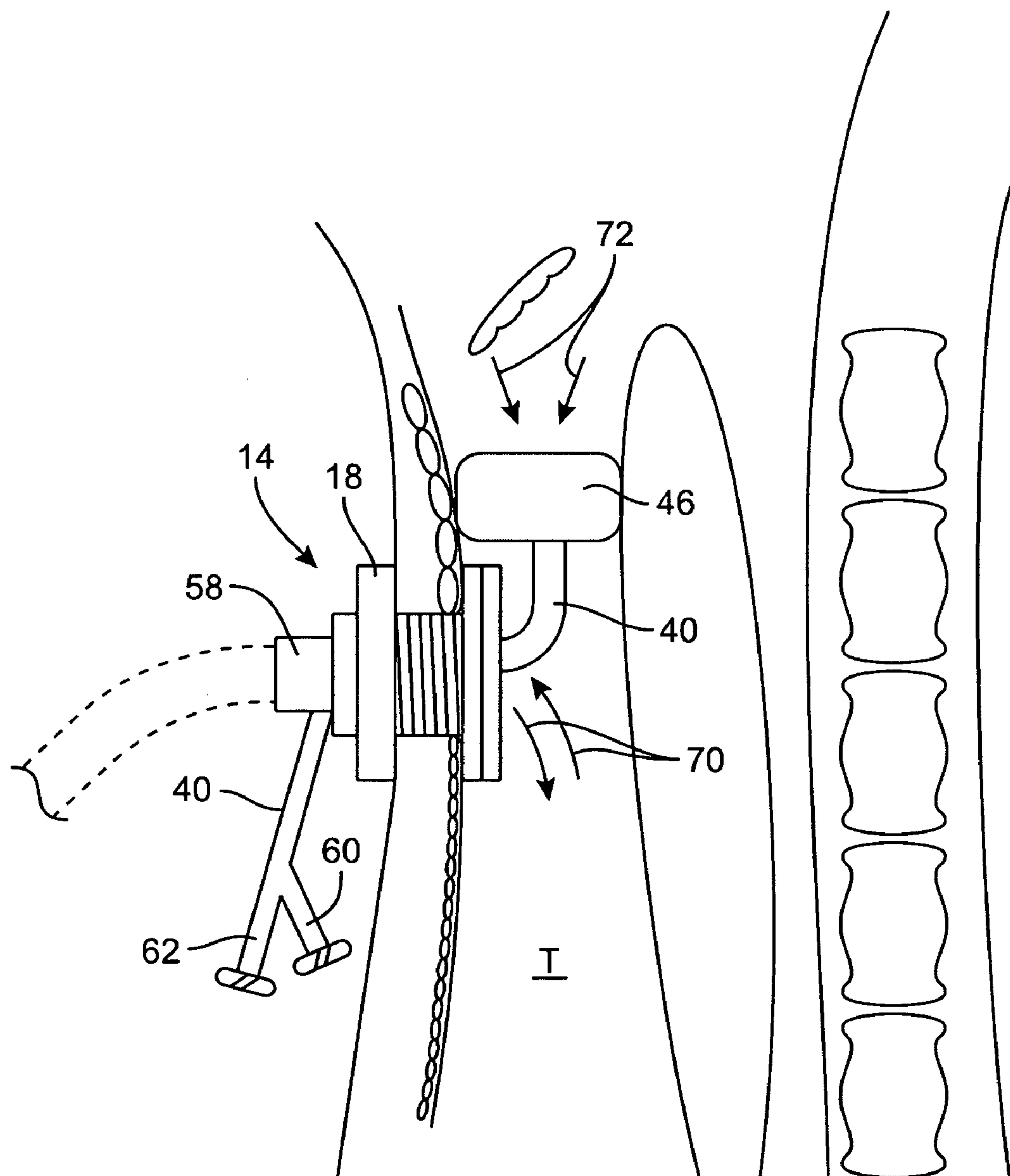
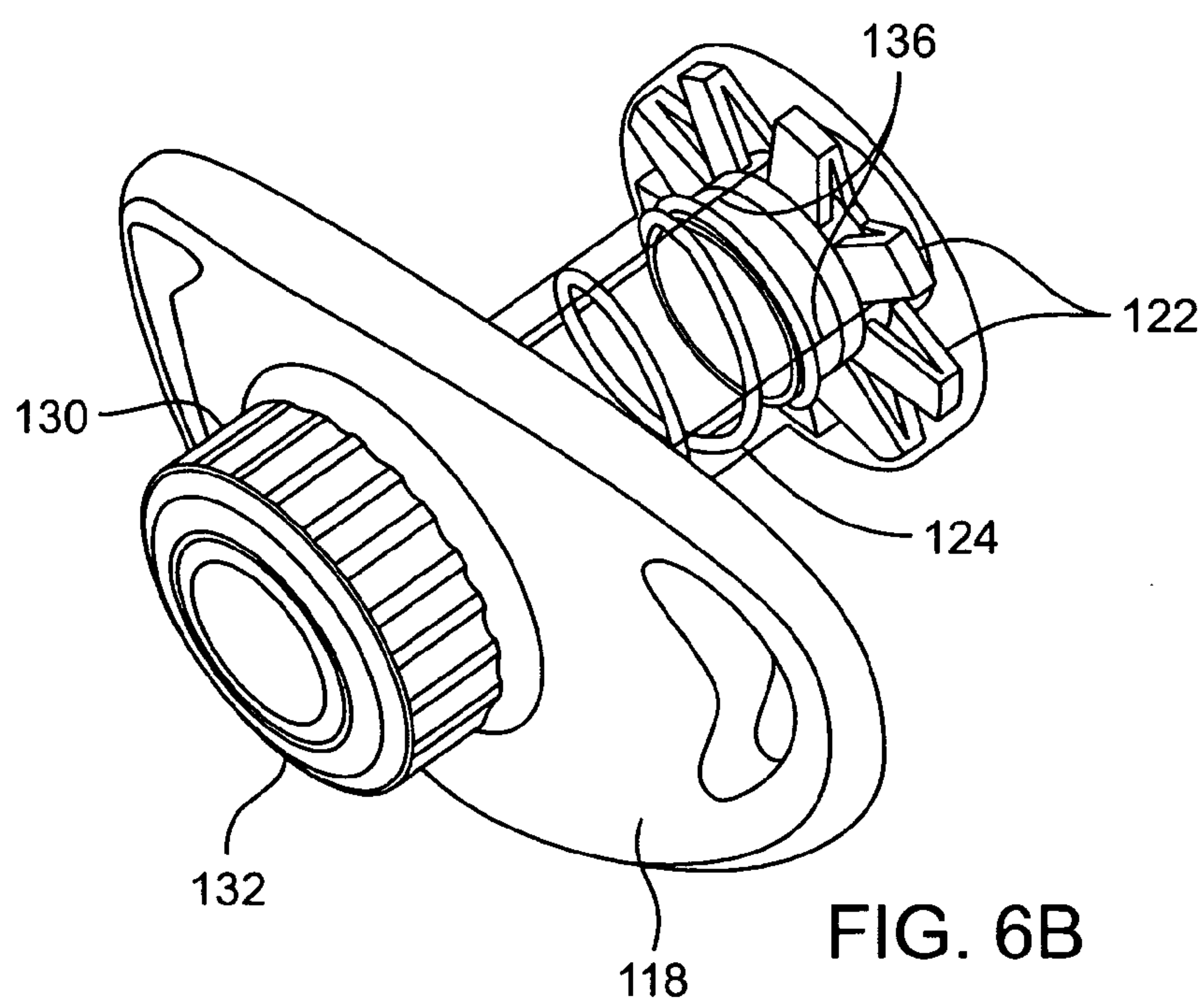
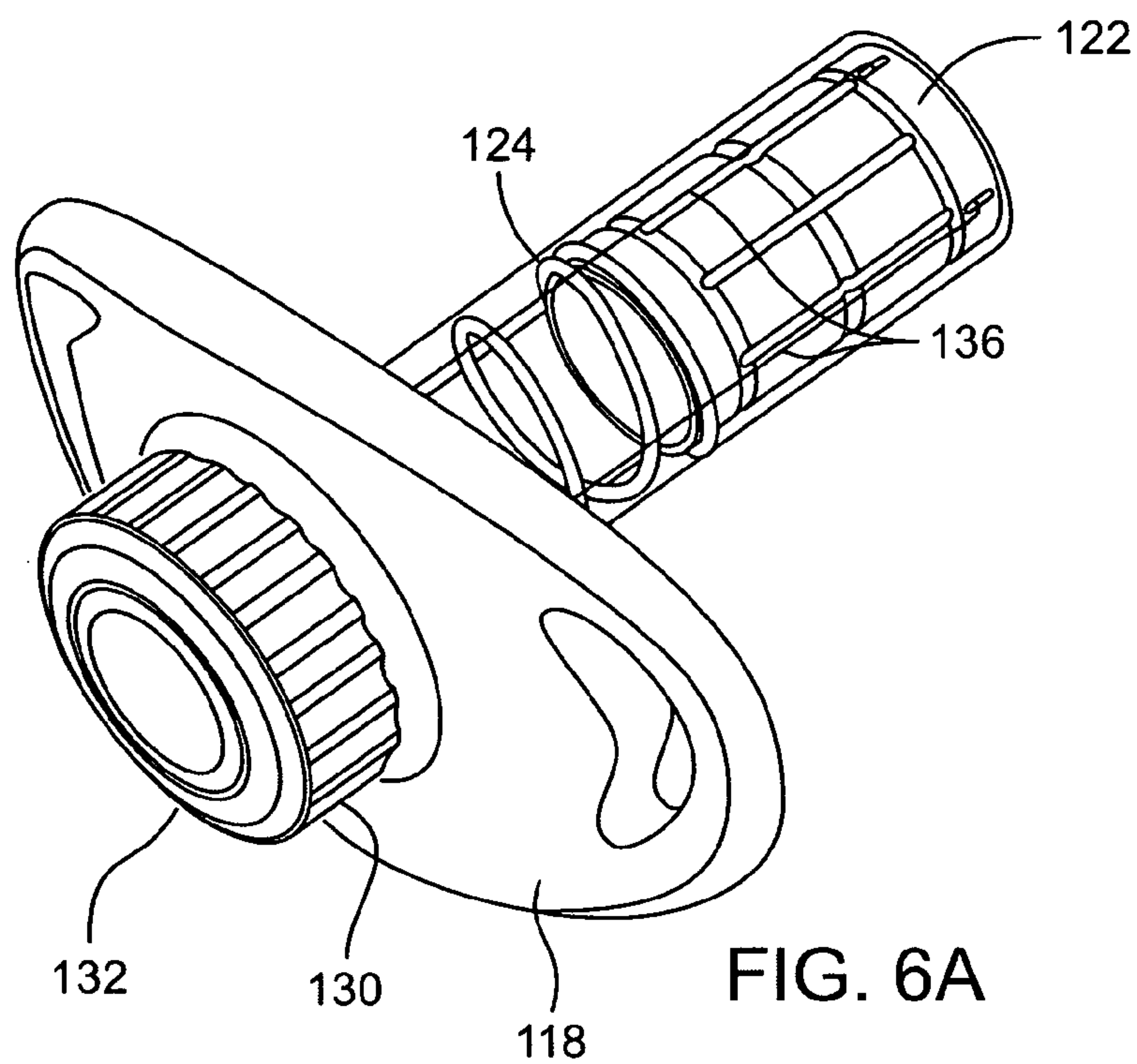


FIG. 4F



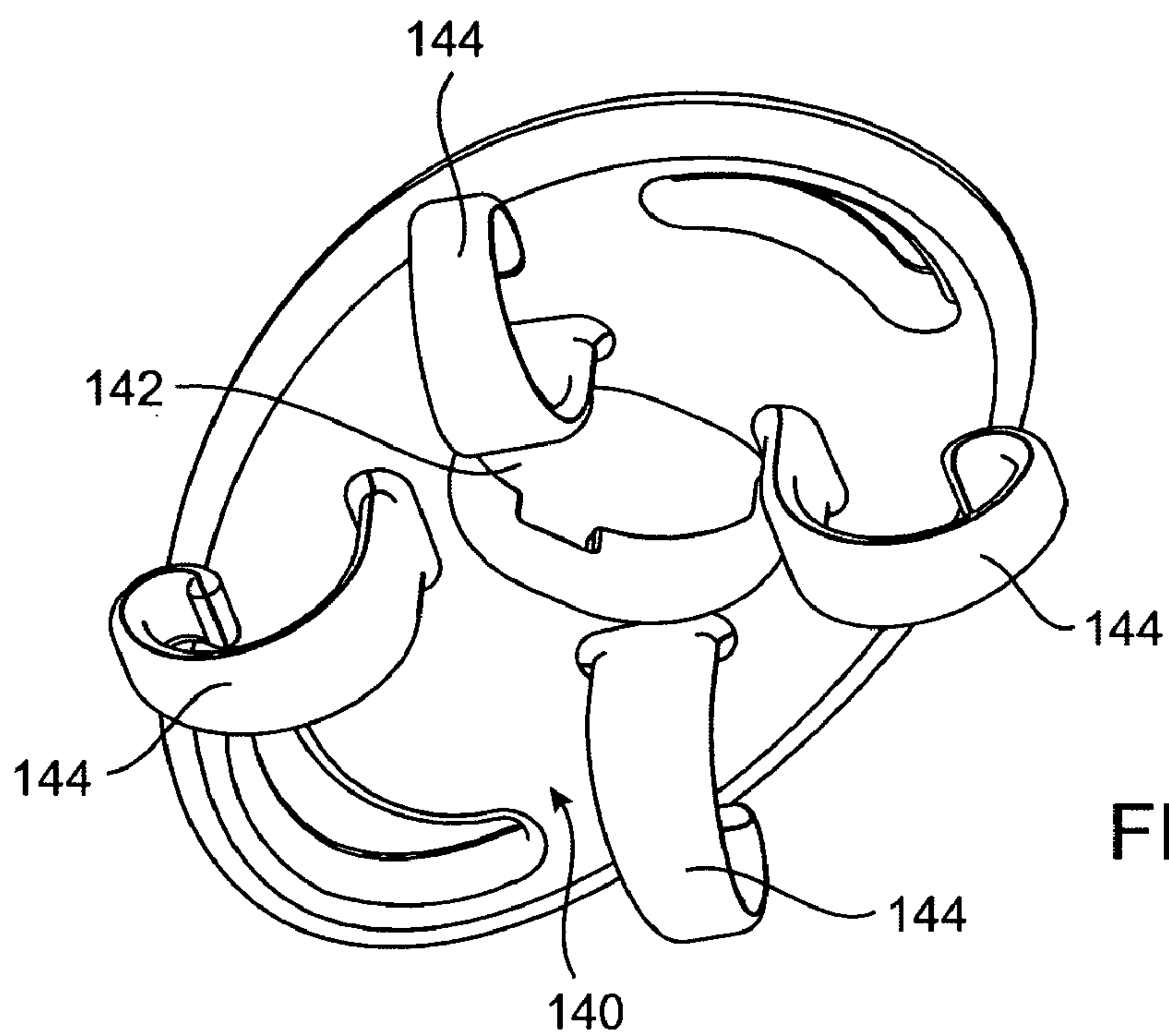


FIG. 7

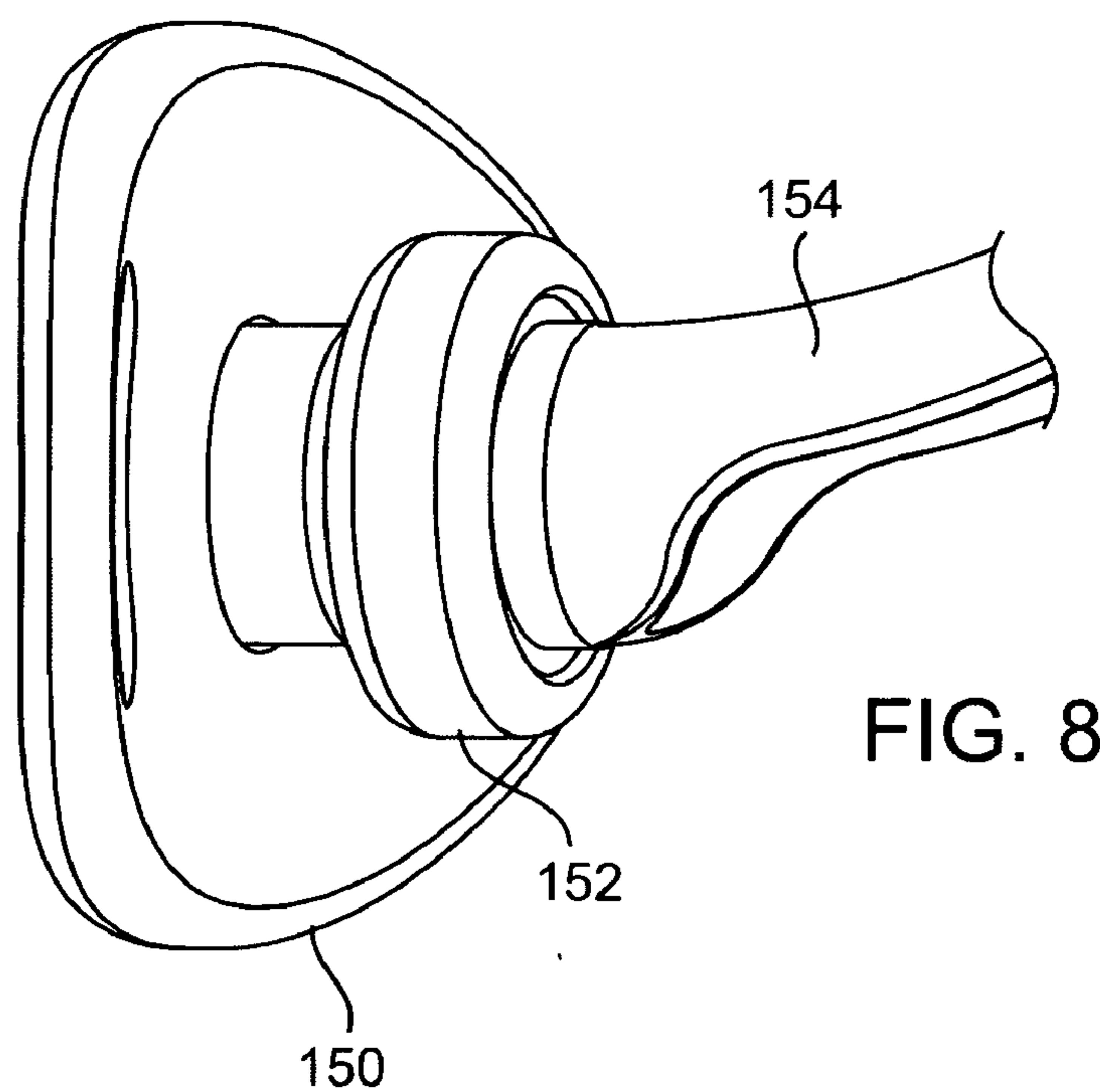


FIG. 8

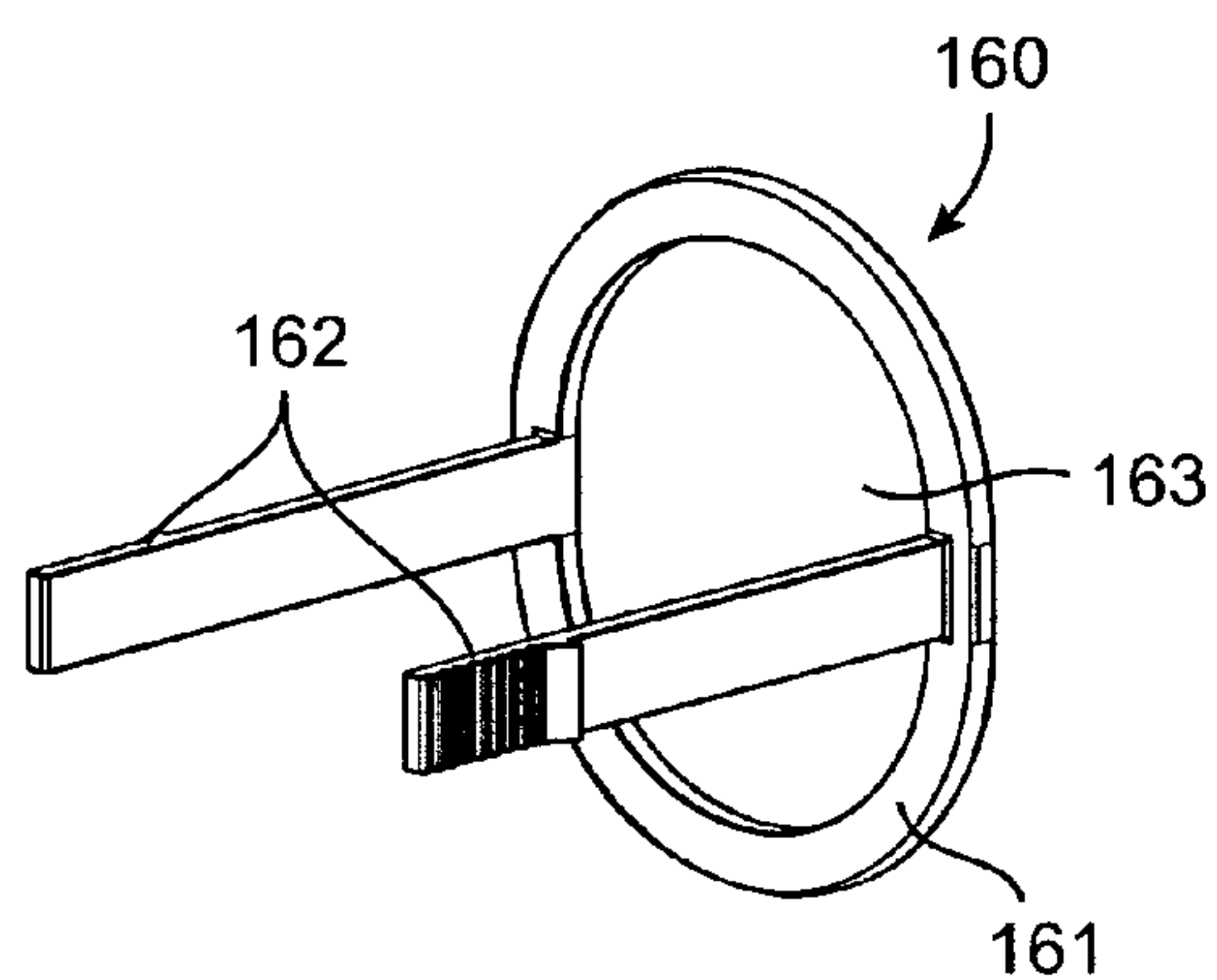


FIG. 9

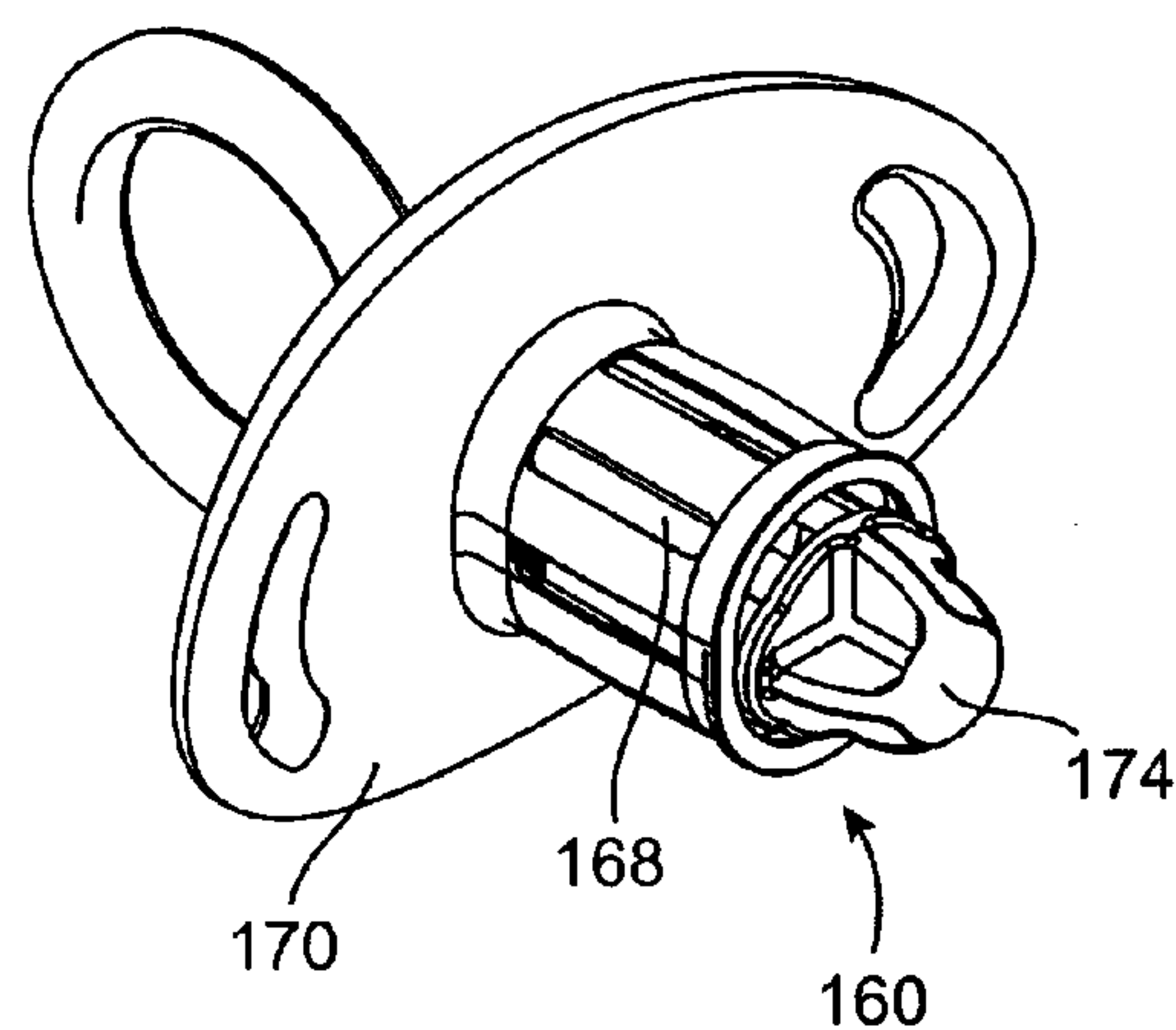


FIG. 10

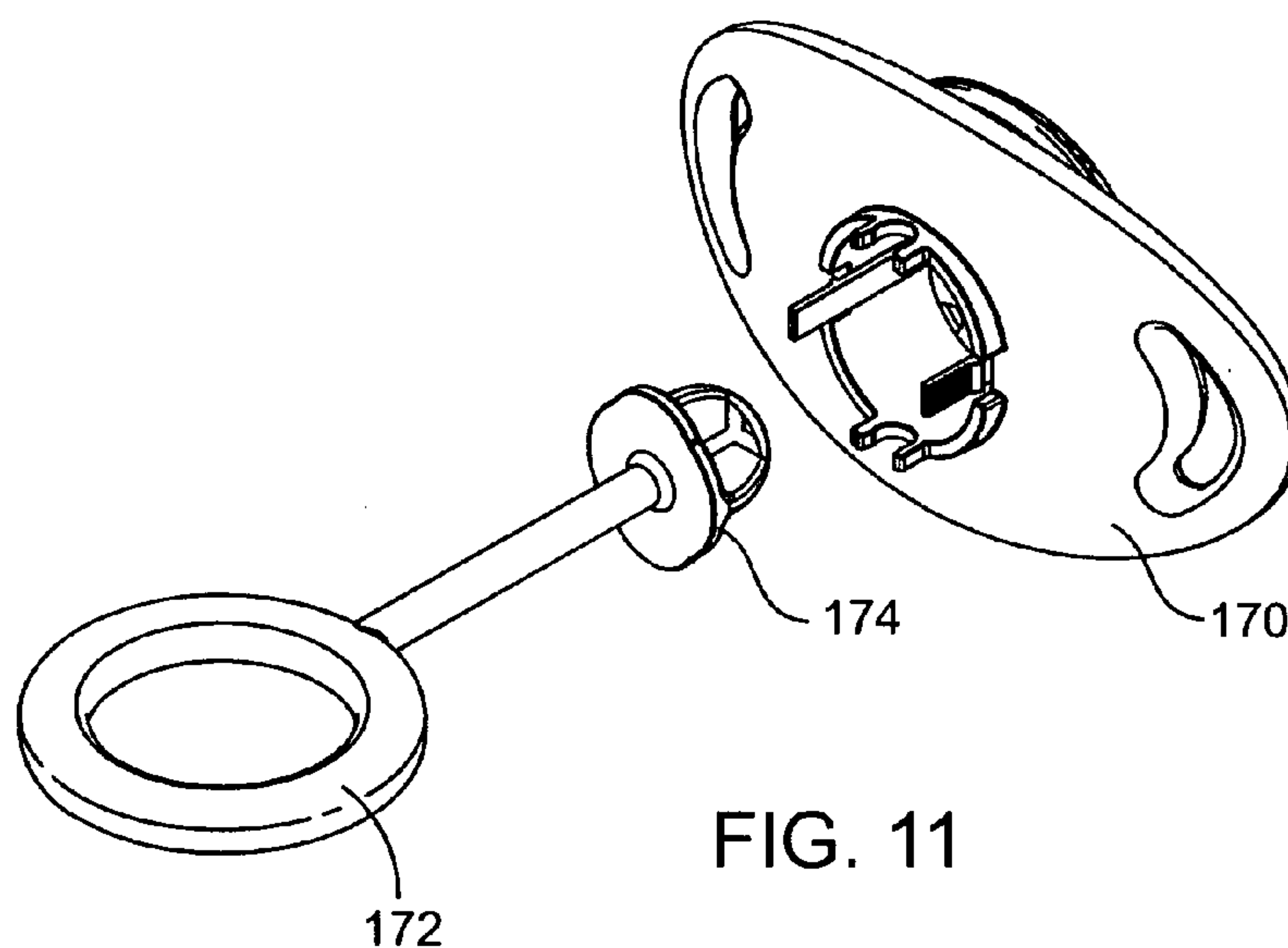


FIG. 11

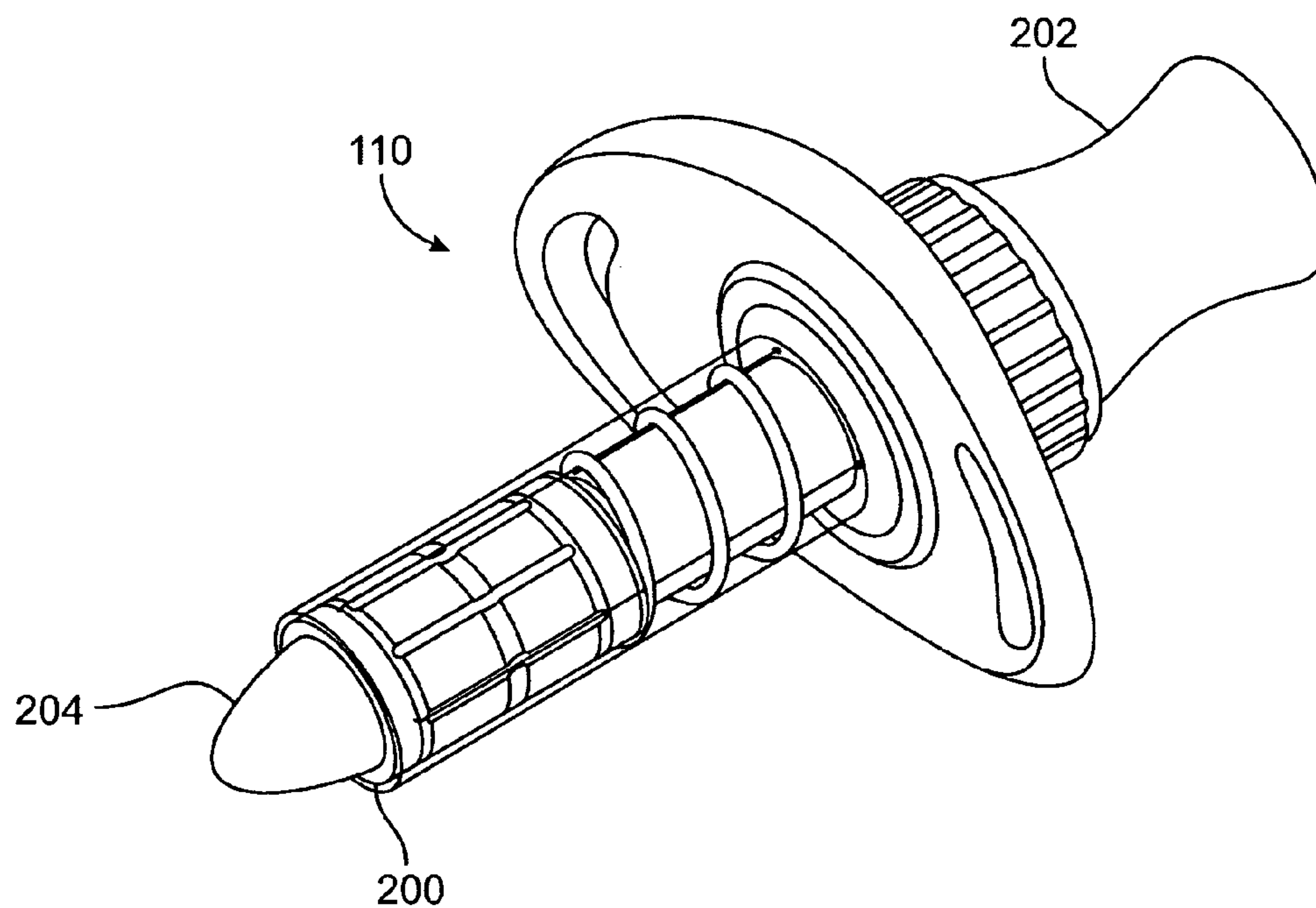


FIG. 12

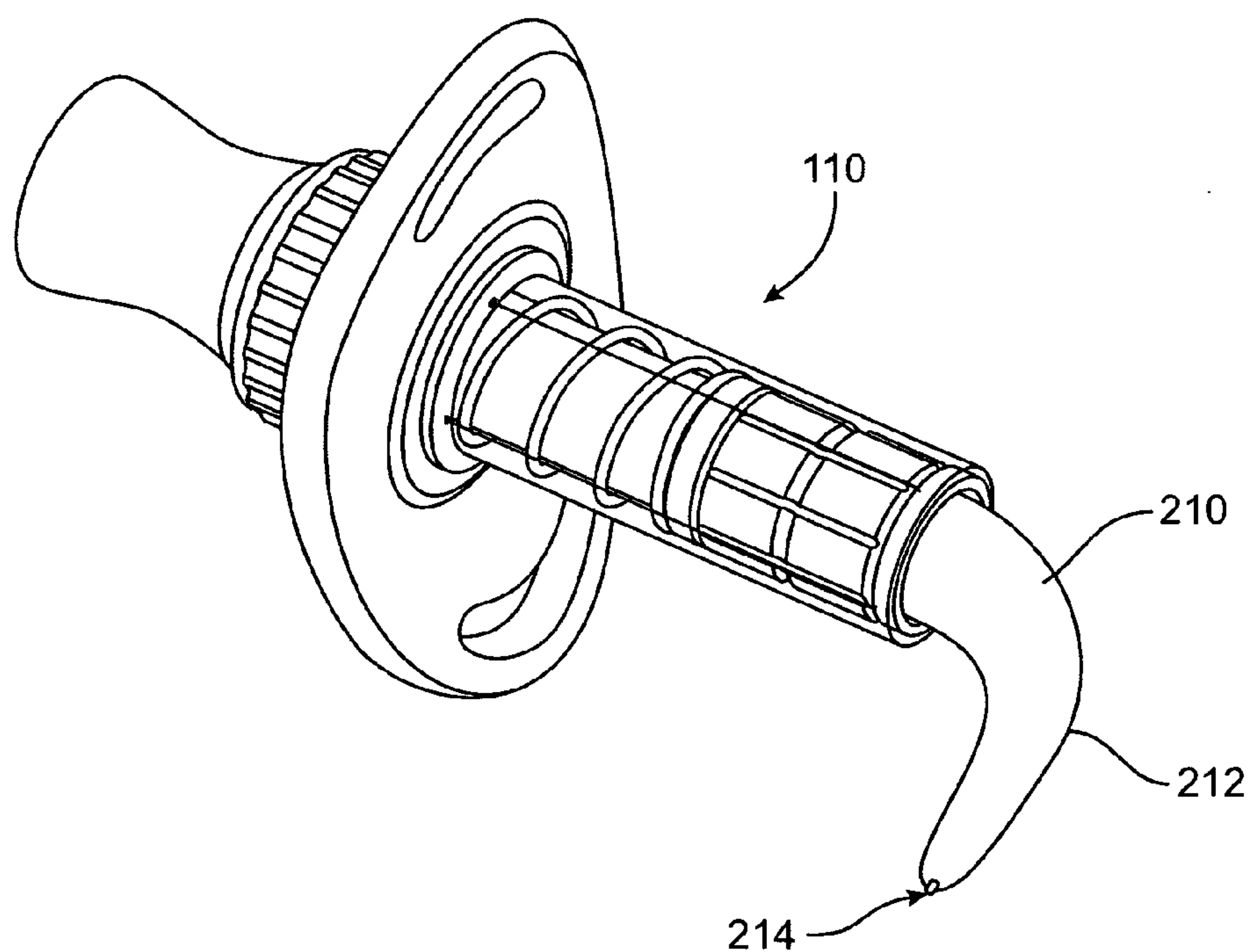


FIG. 13

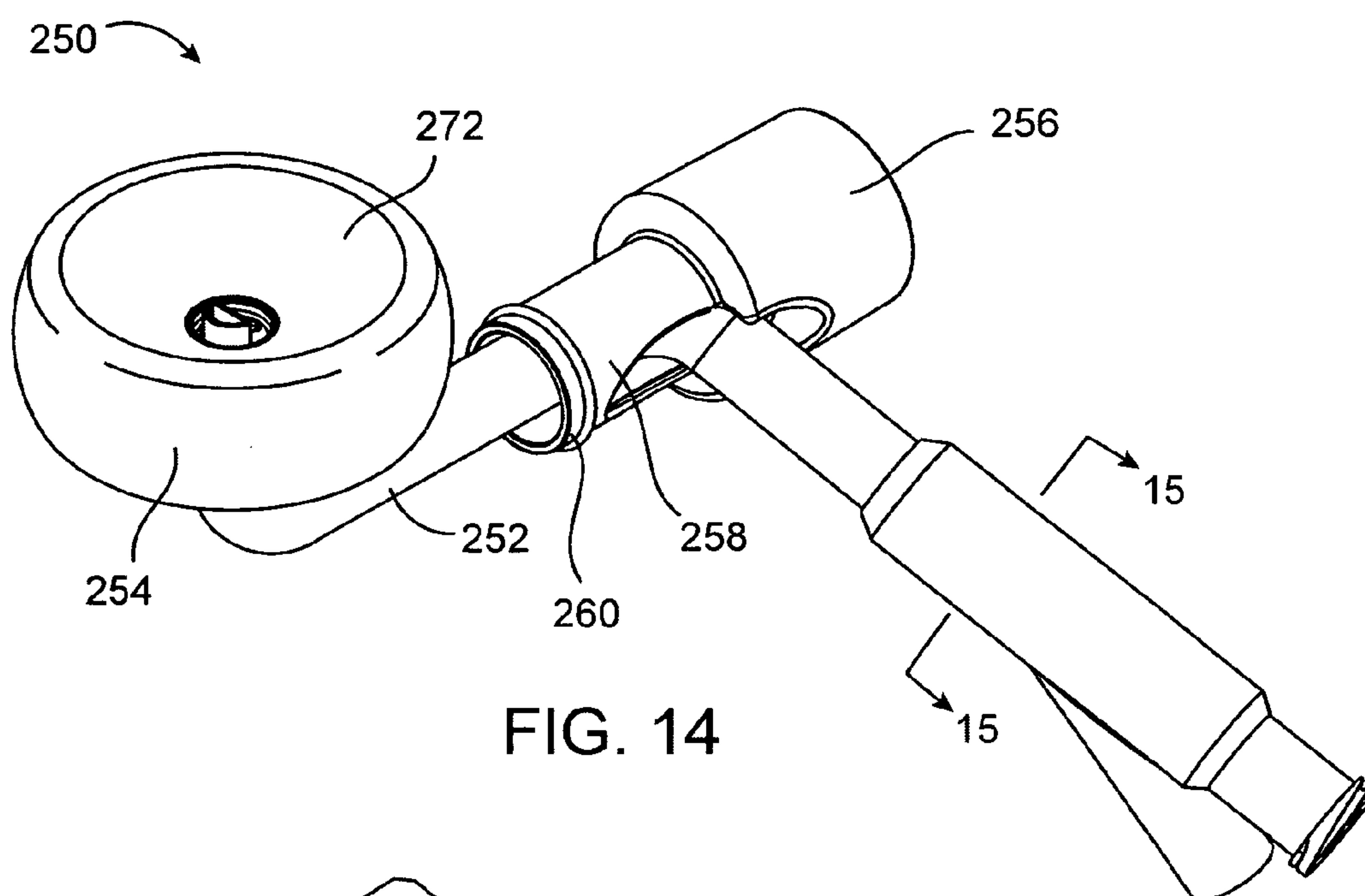


FIG. 14

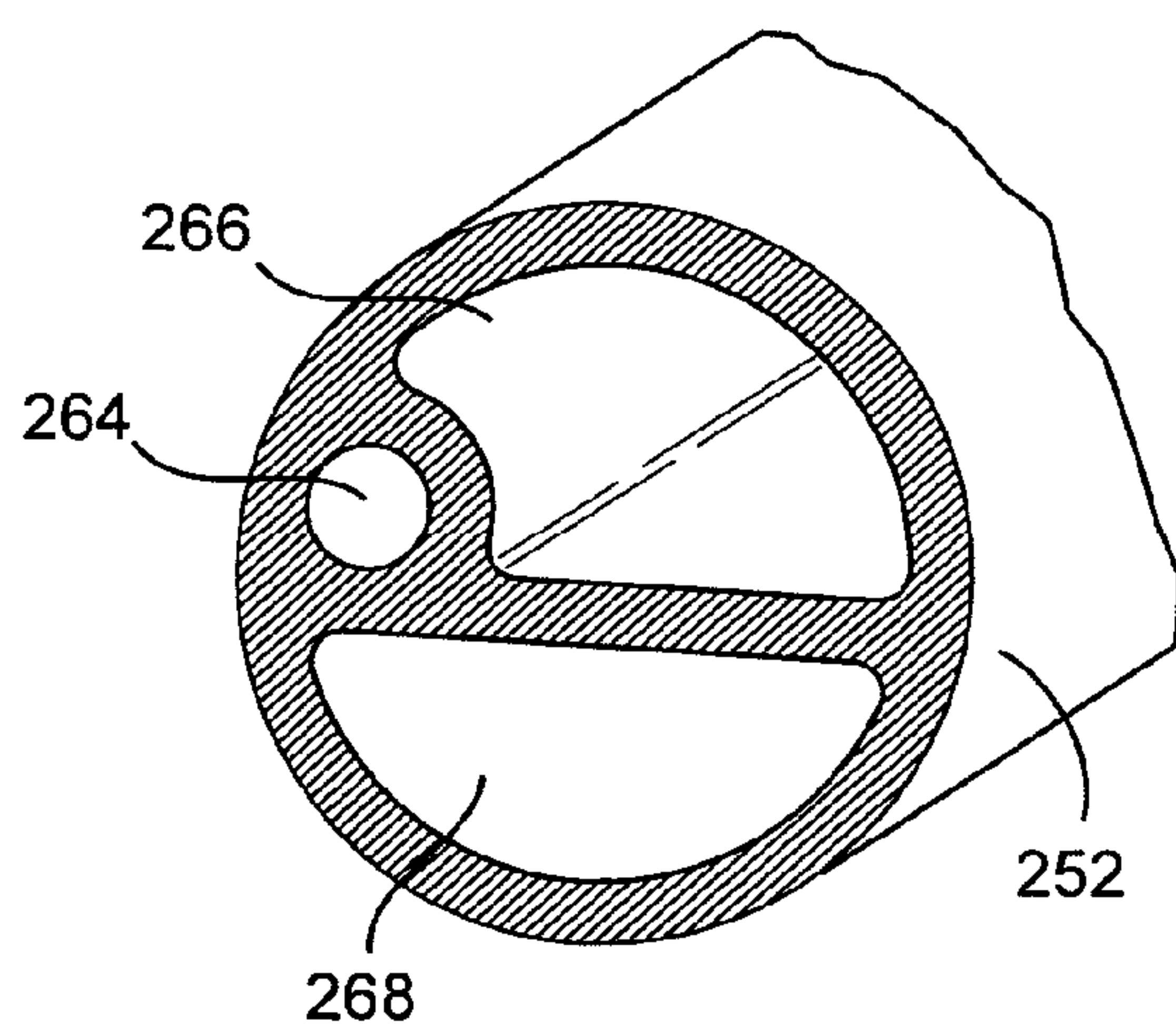


FIG. 15

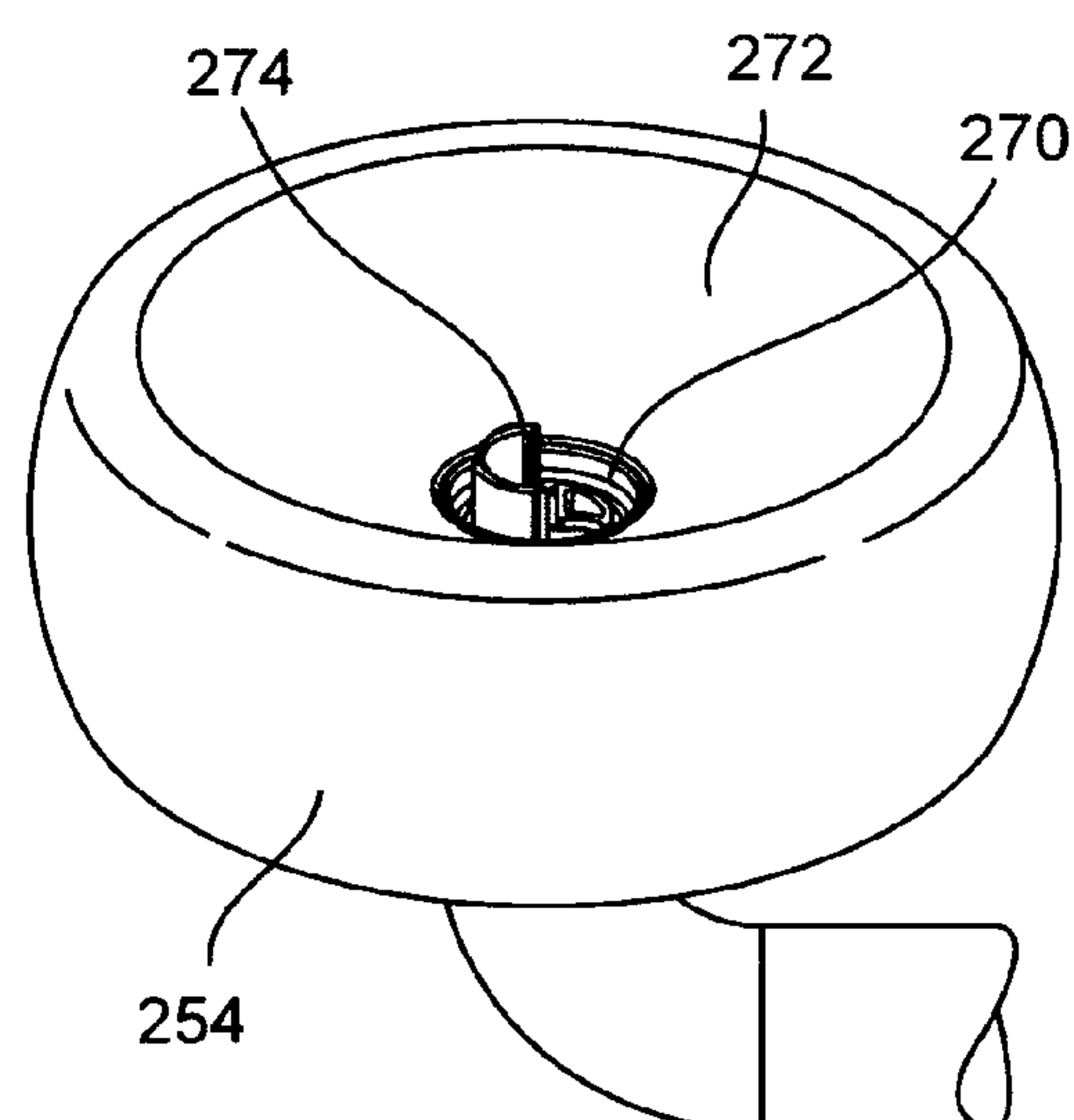


FIG. 16A

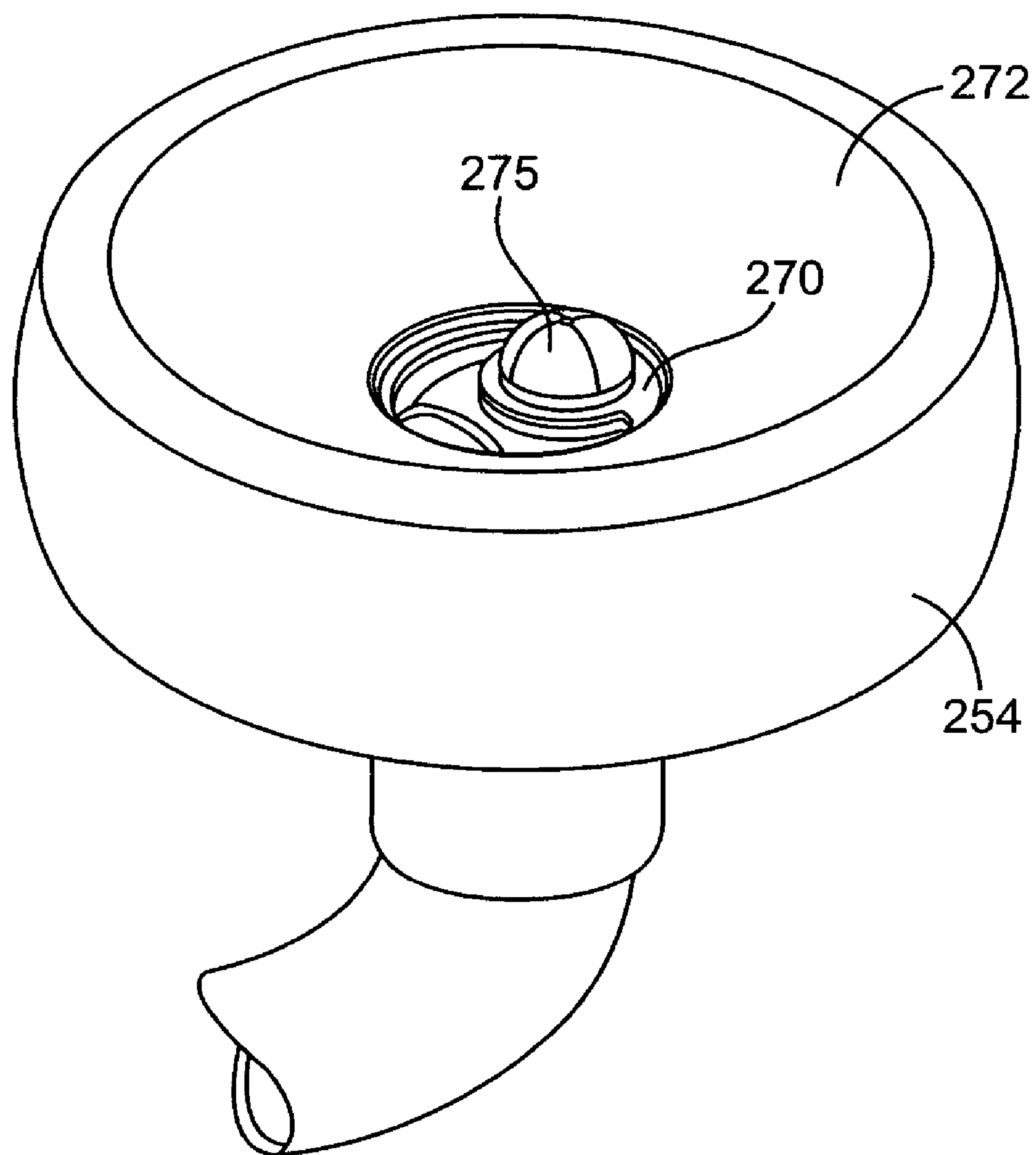


FIG. 16B

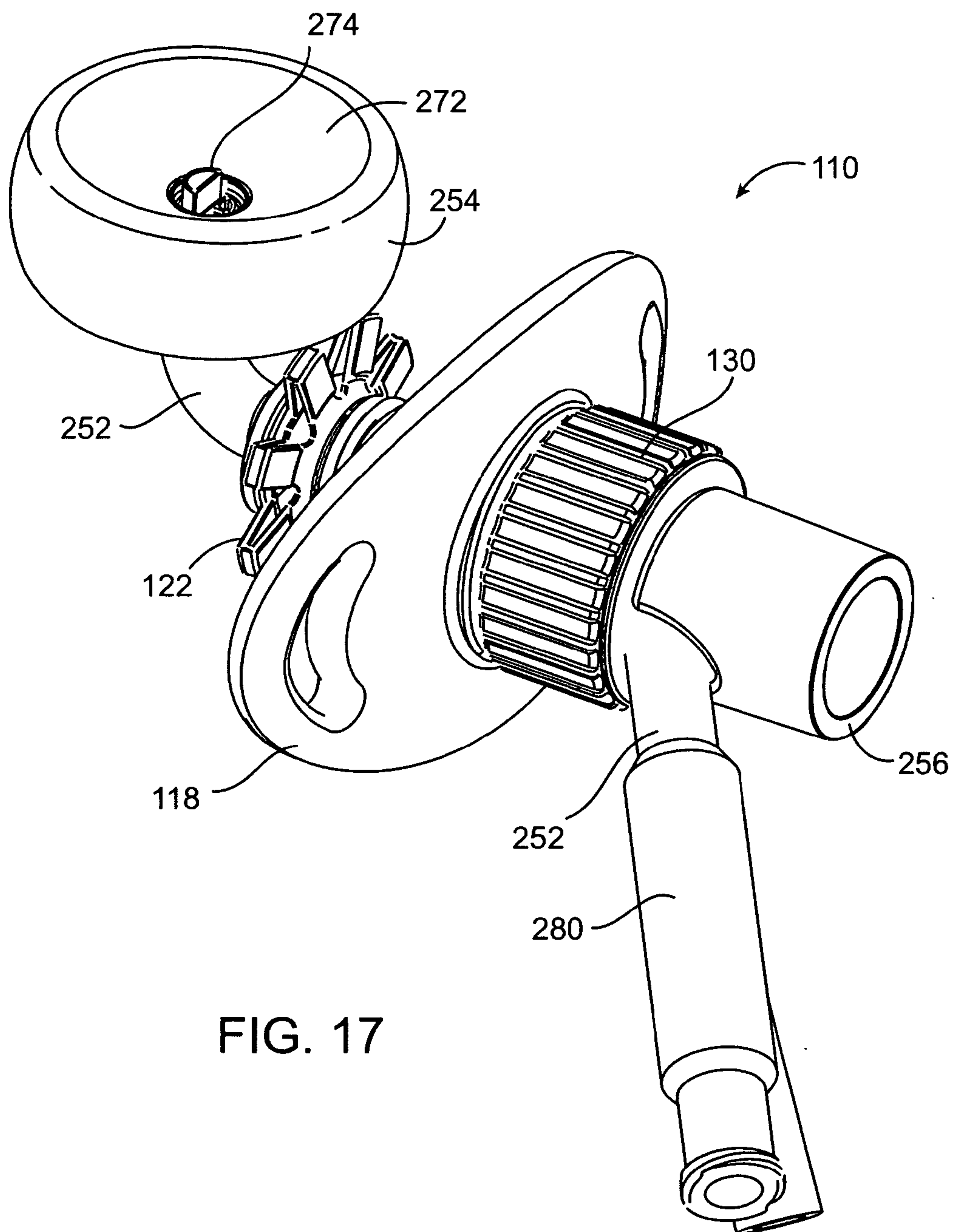
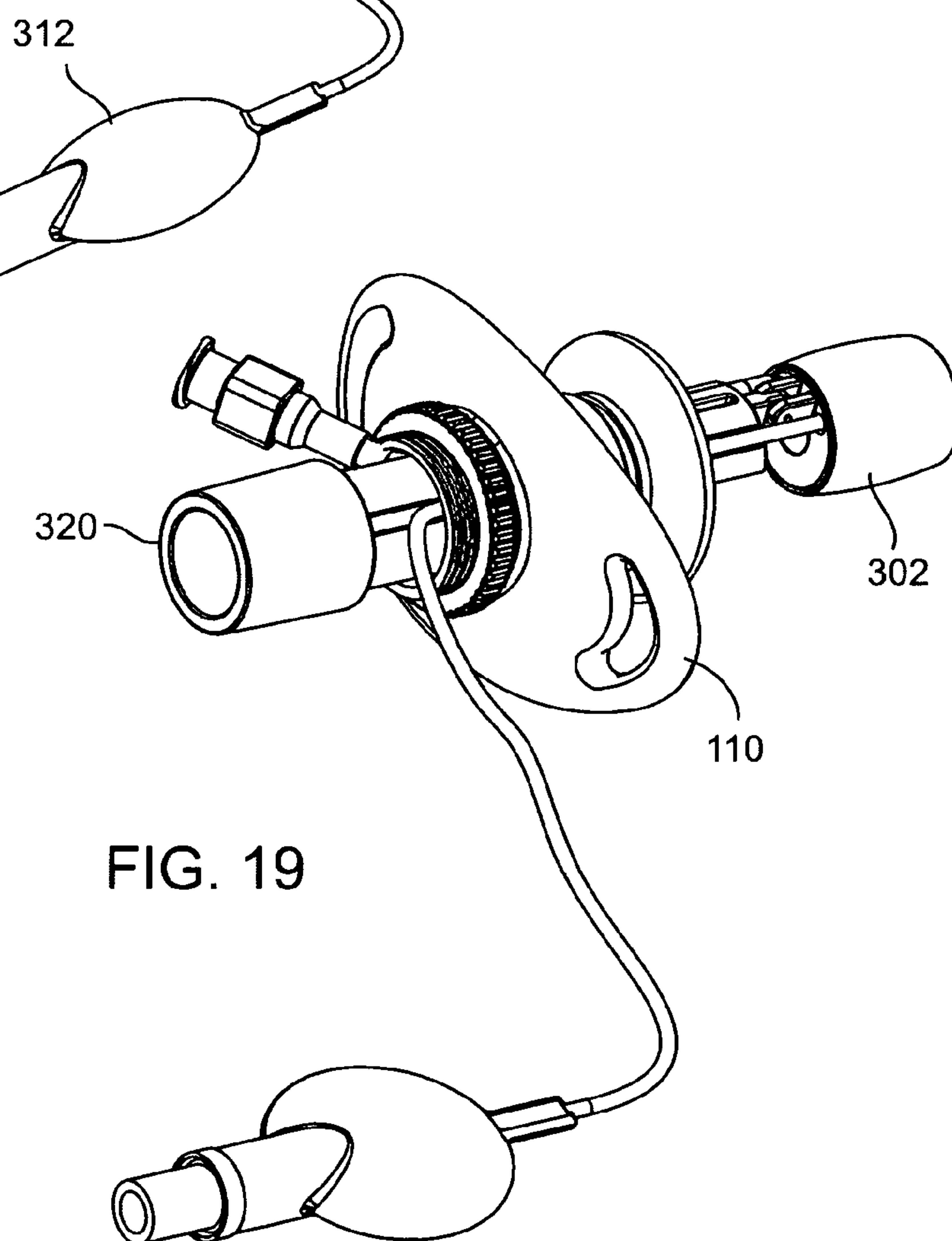
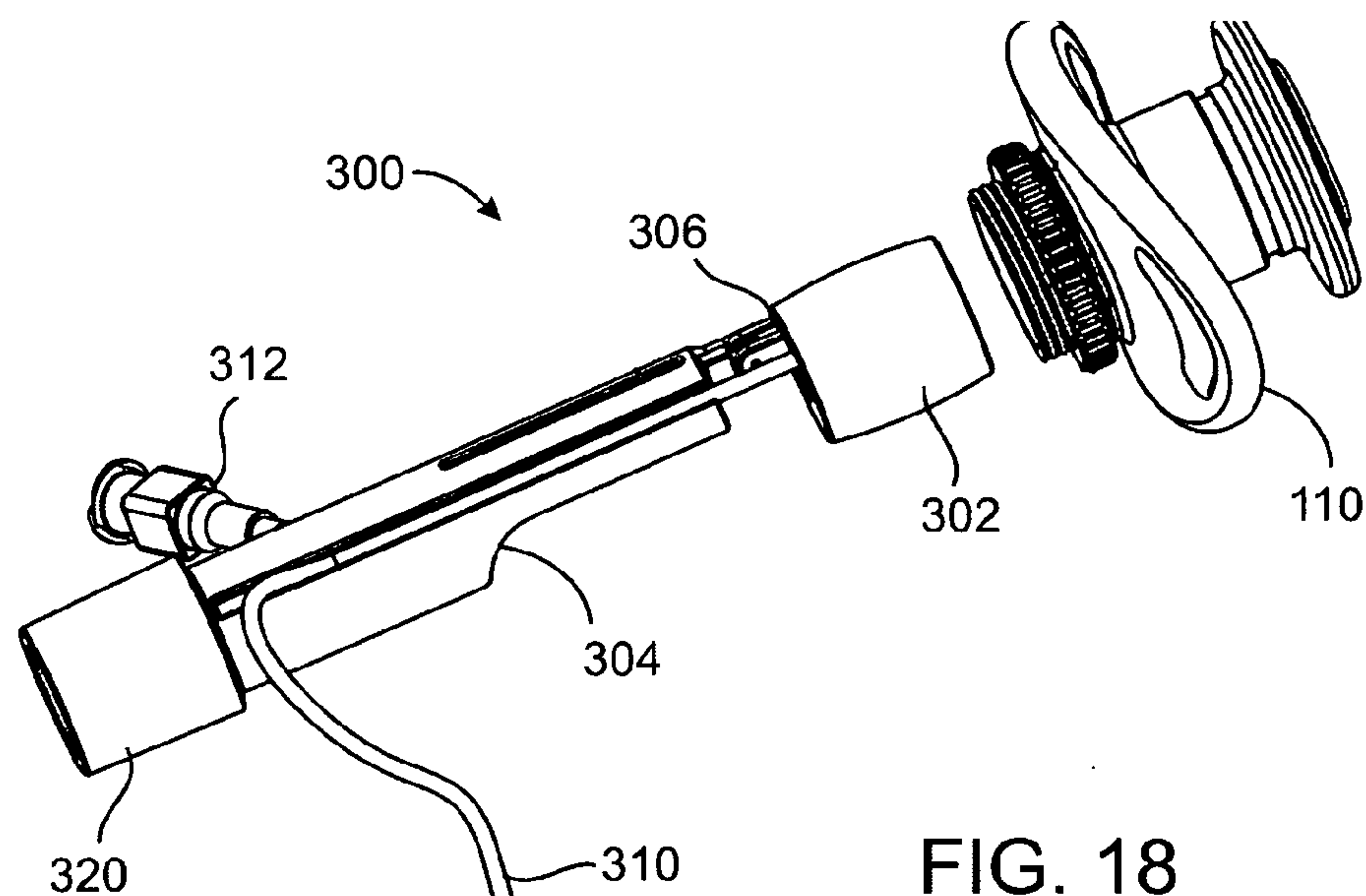


FIG. 17



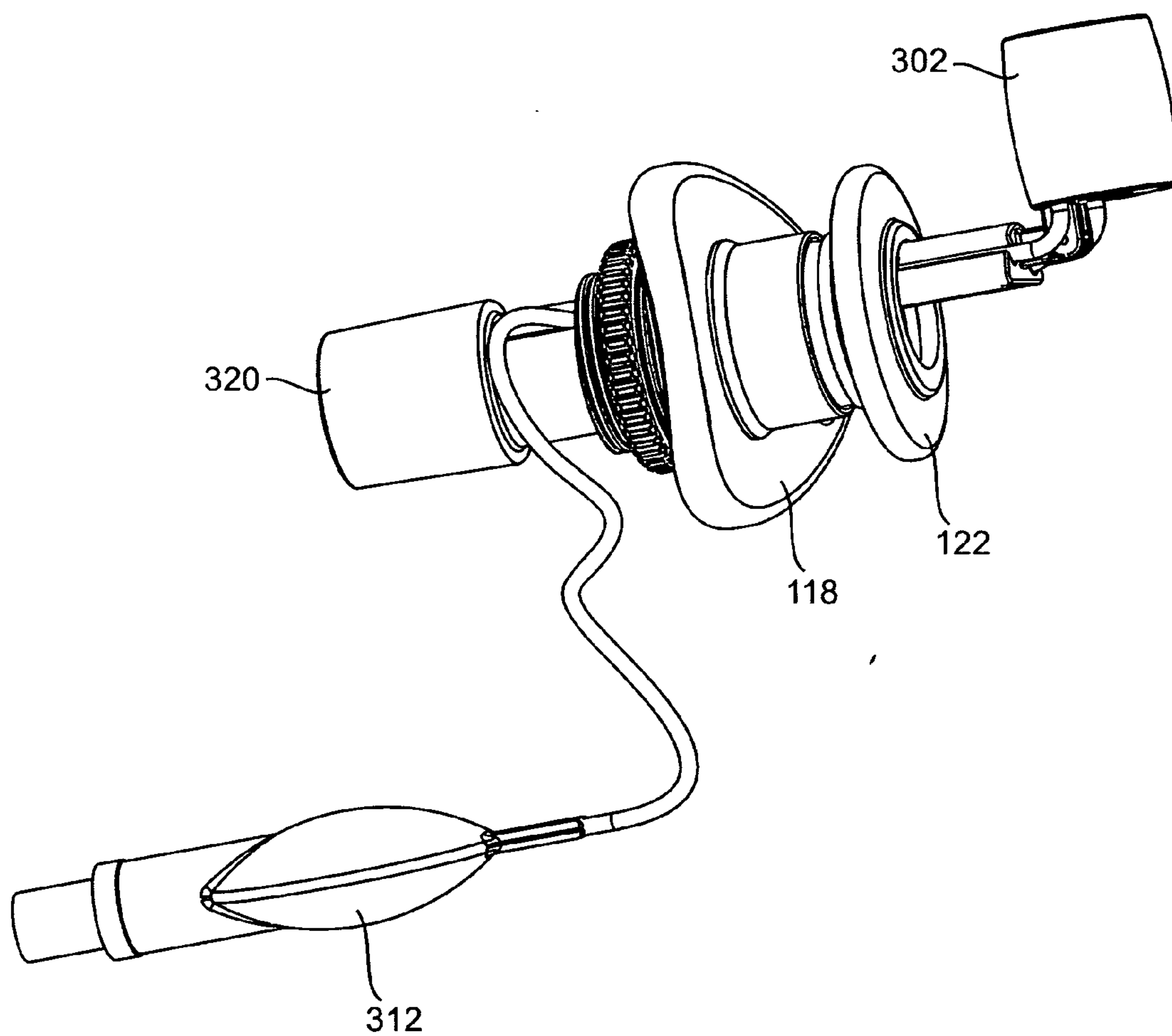


FIG. 20

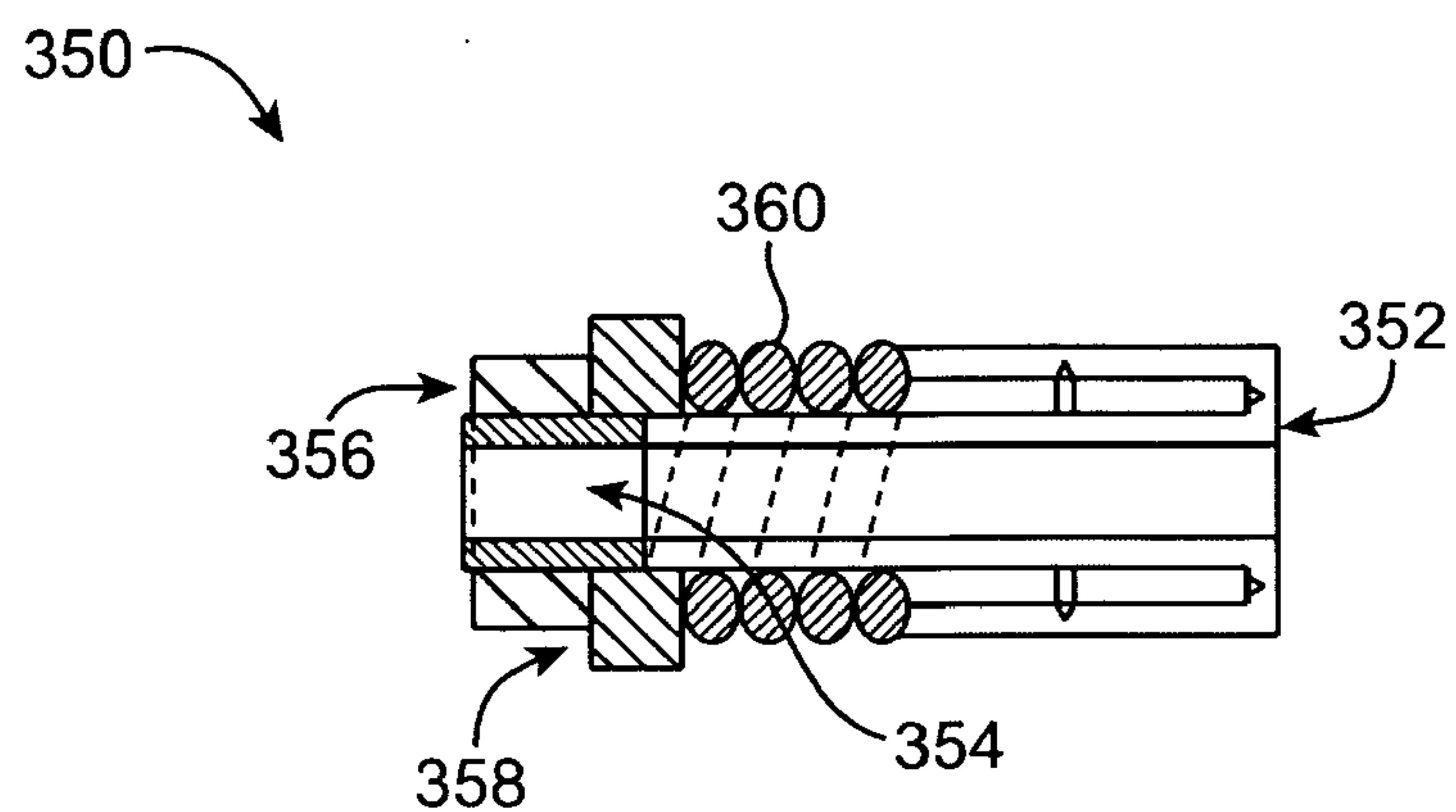


FIG. 21A

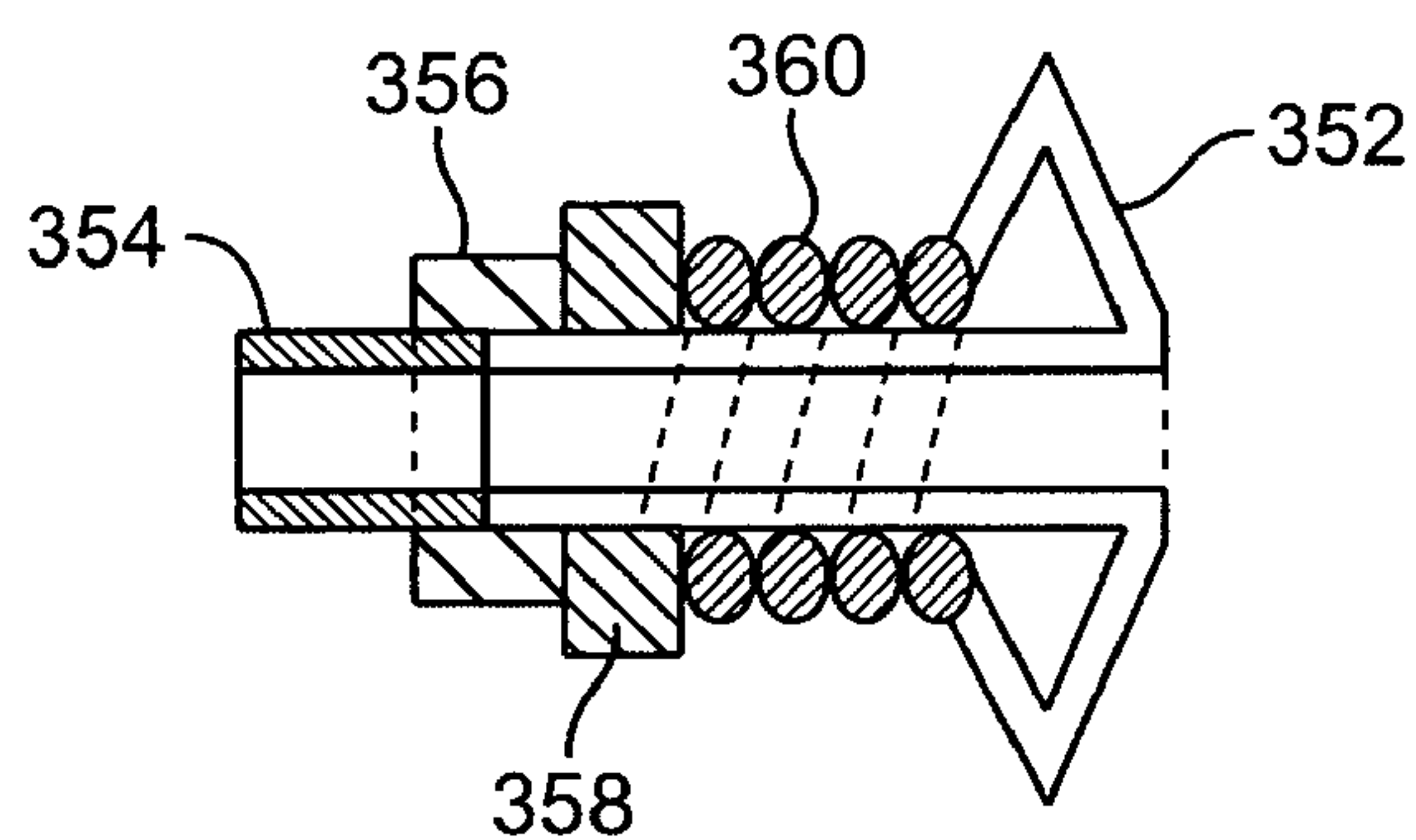


FIG. 21B

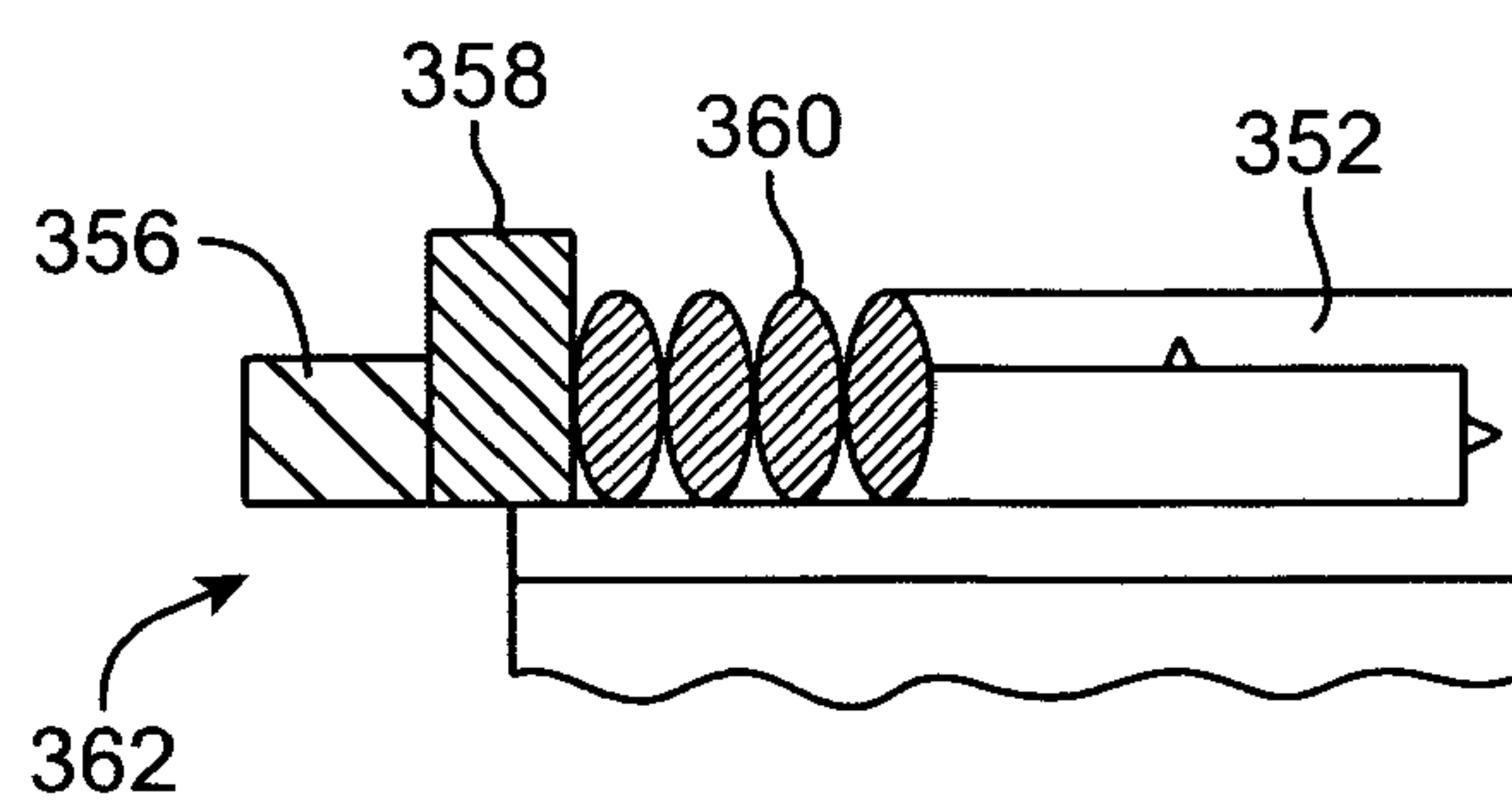


FIG. 22

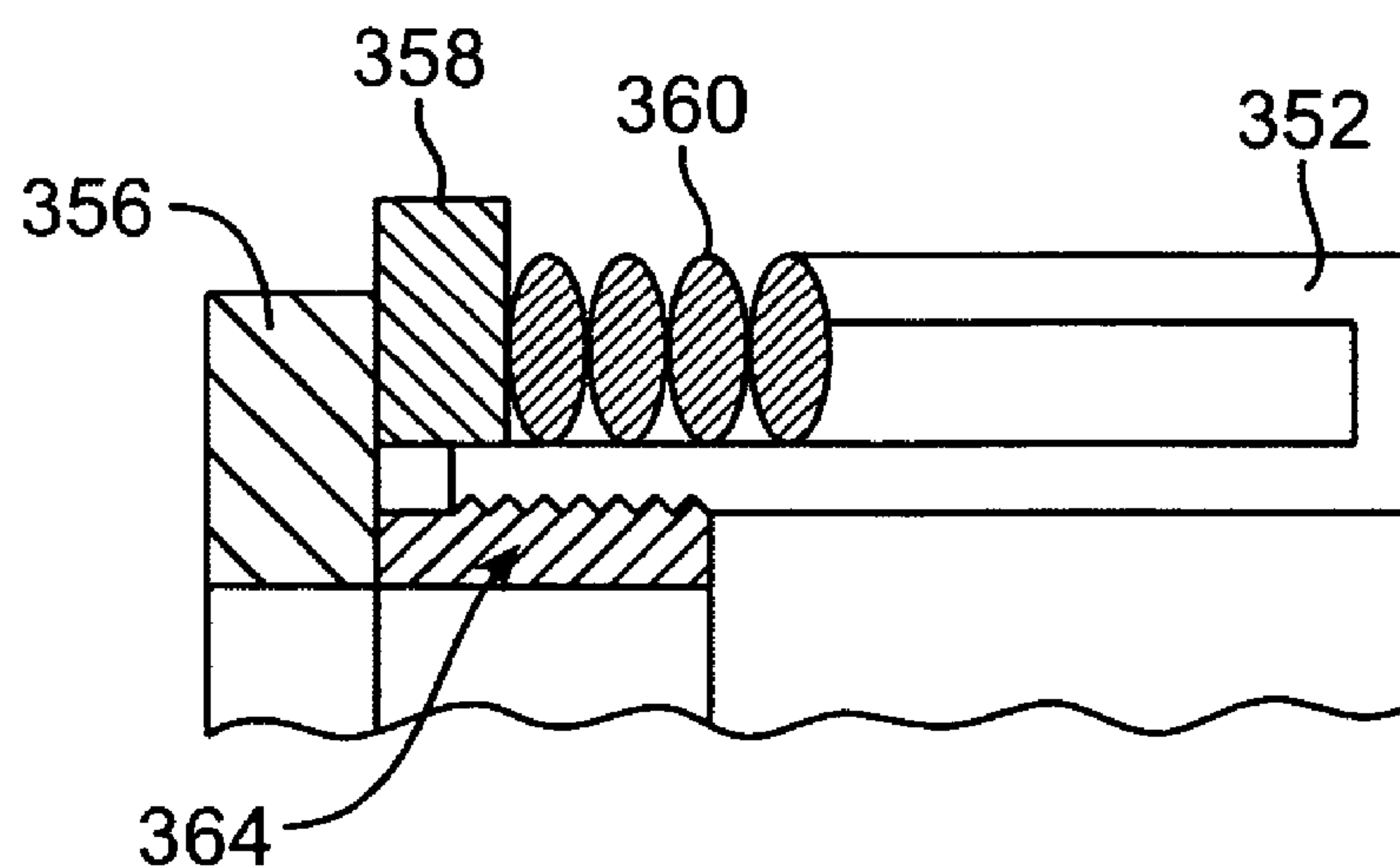


FIG. 23

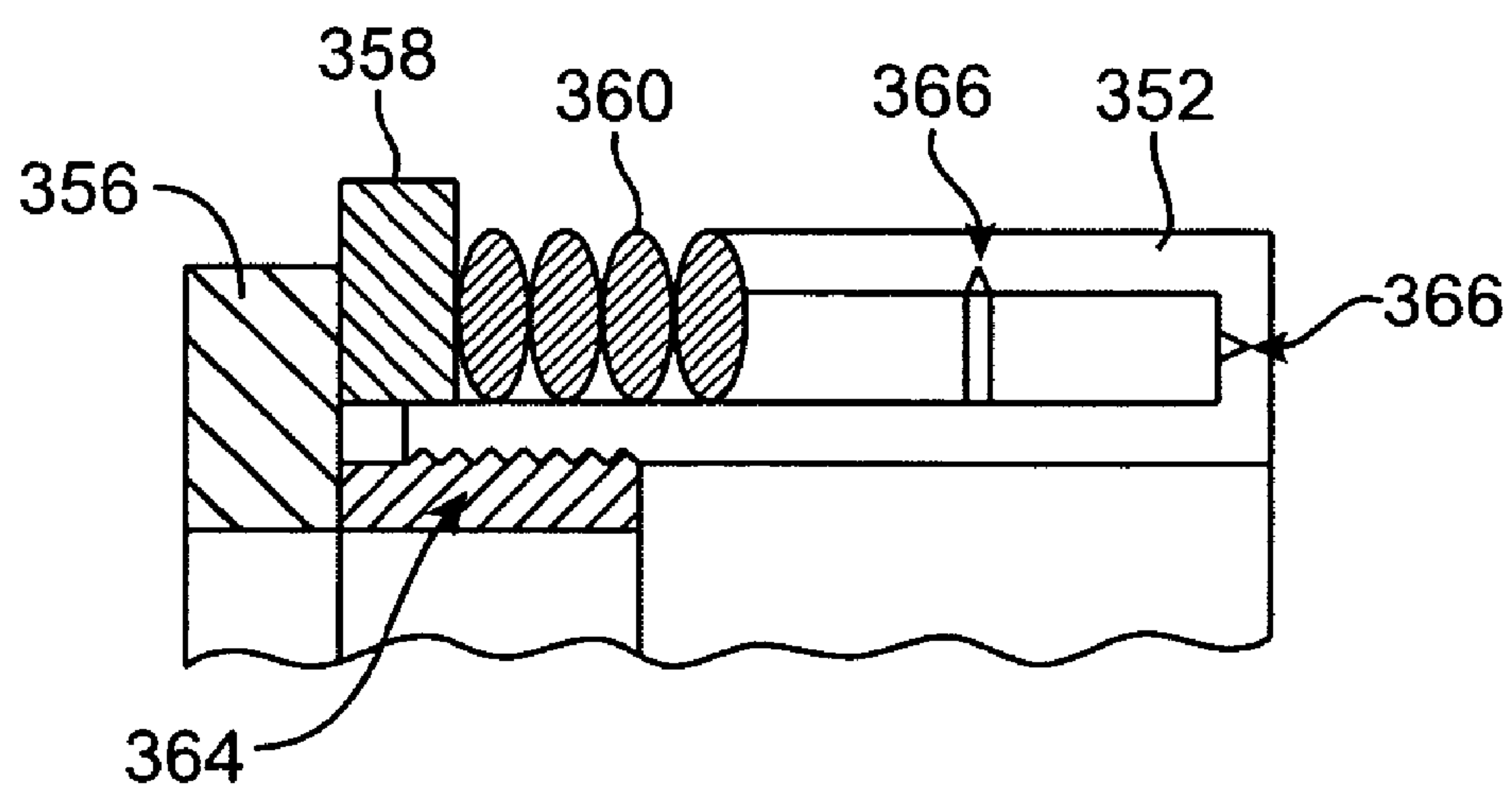
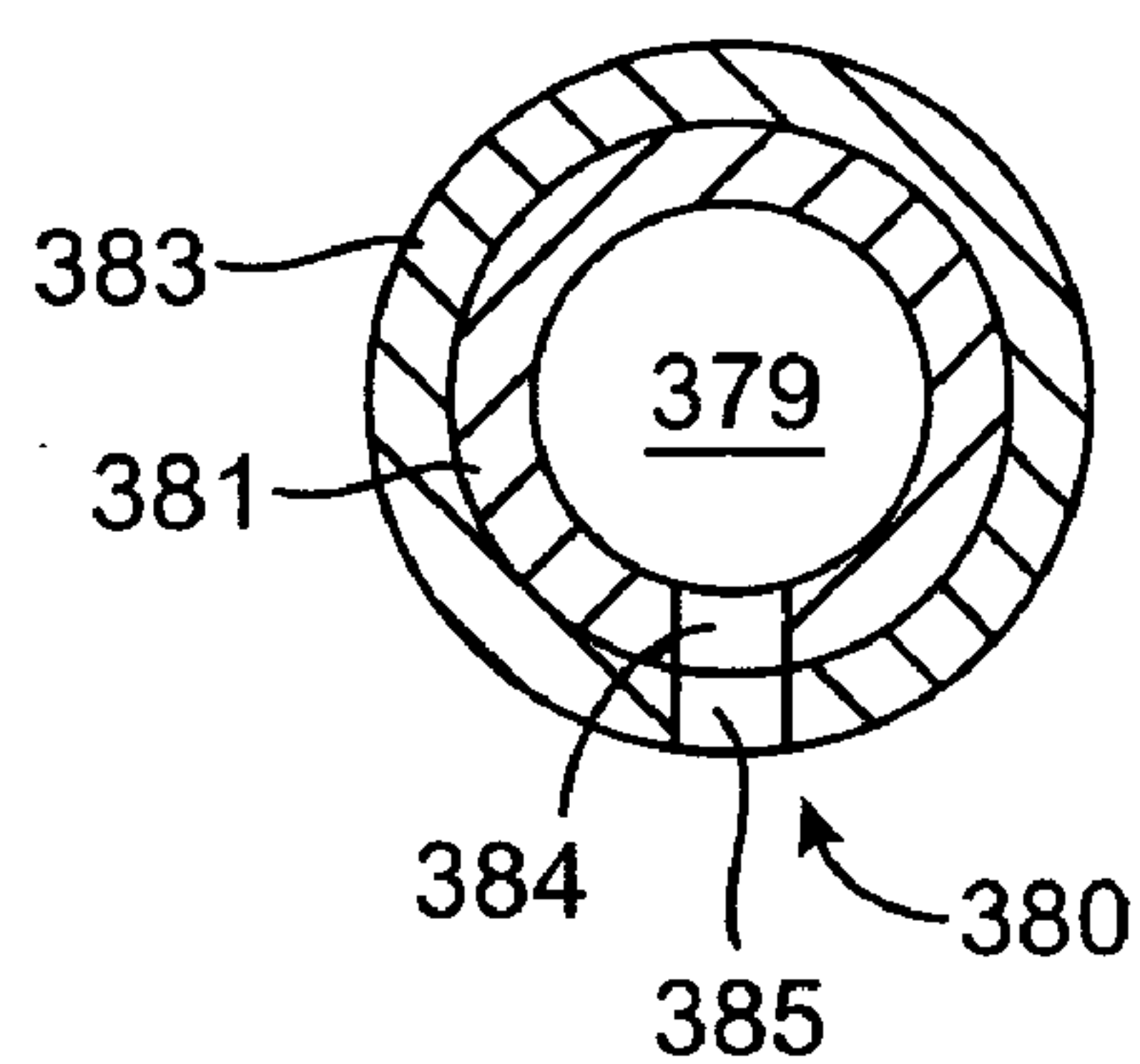
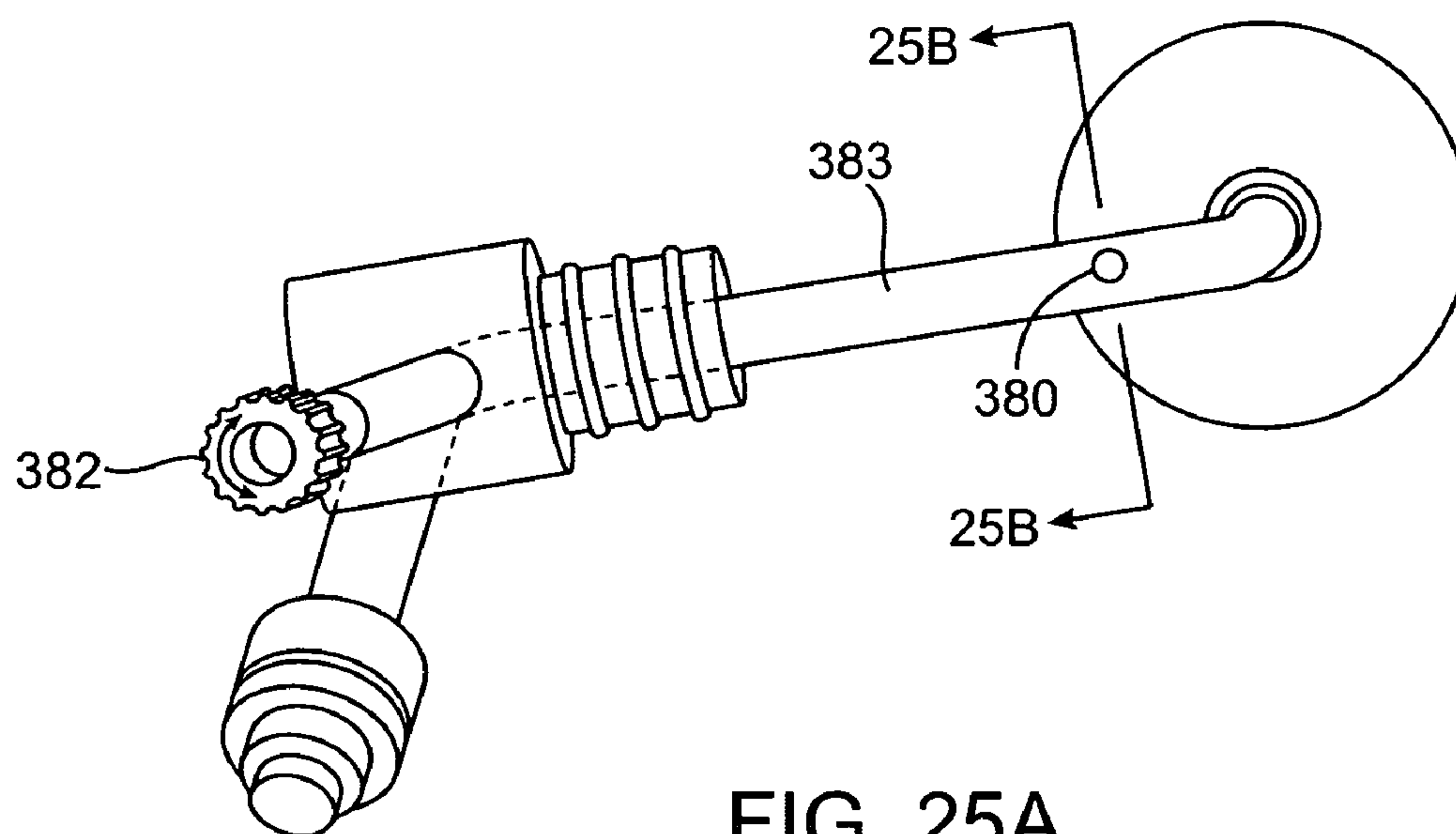


FIG. 24



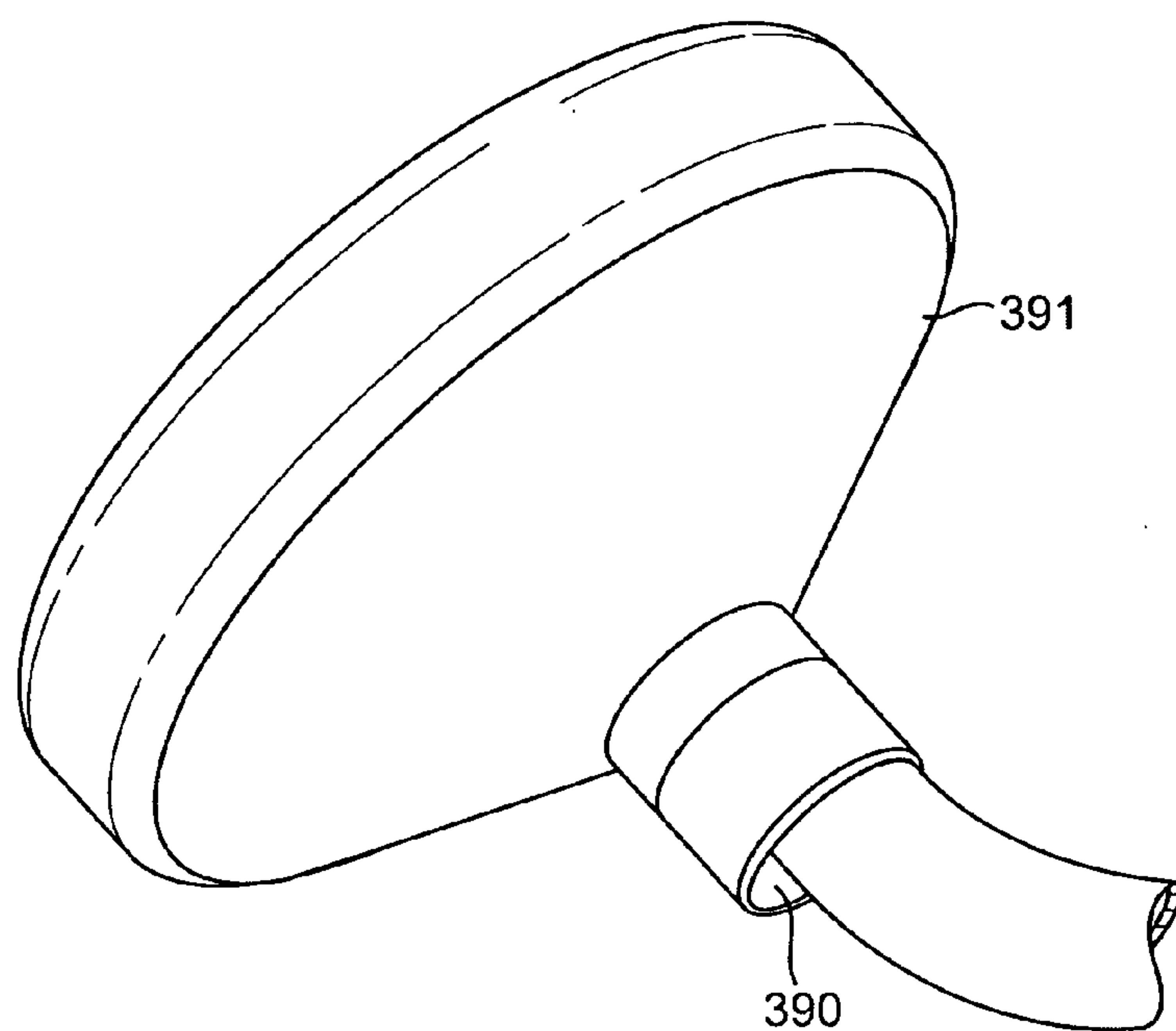


FIG. 26

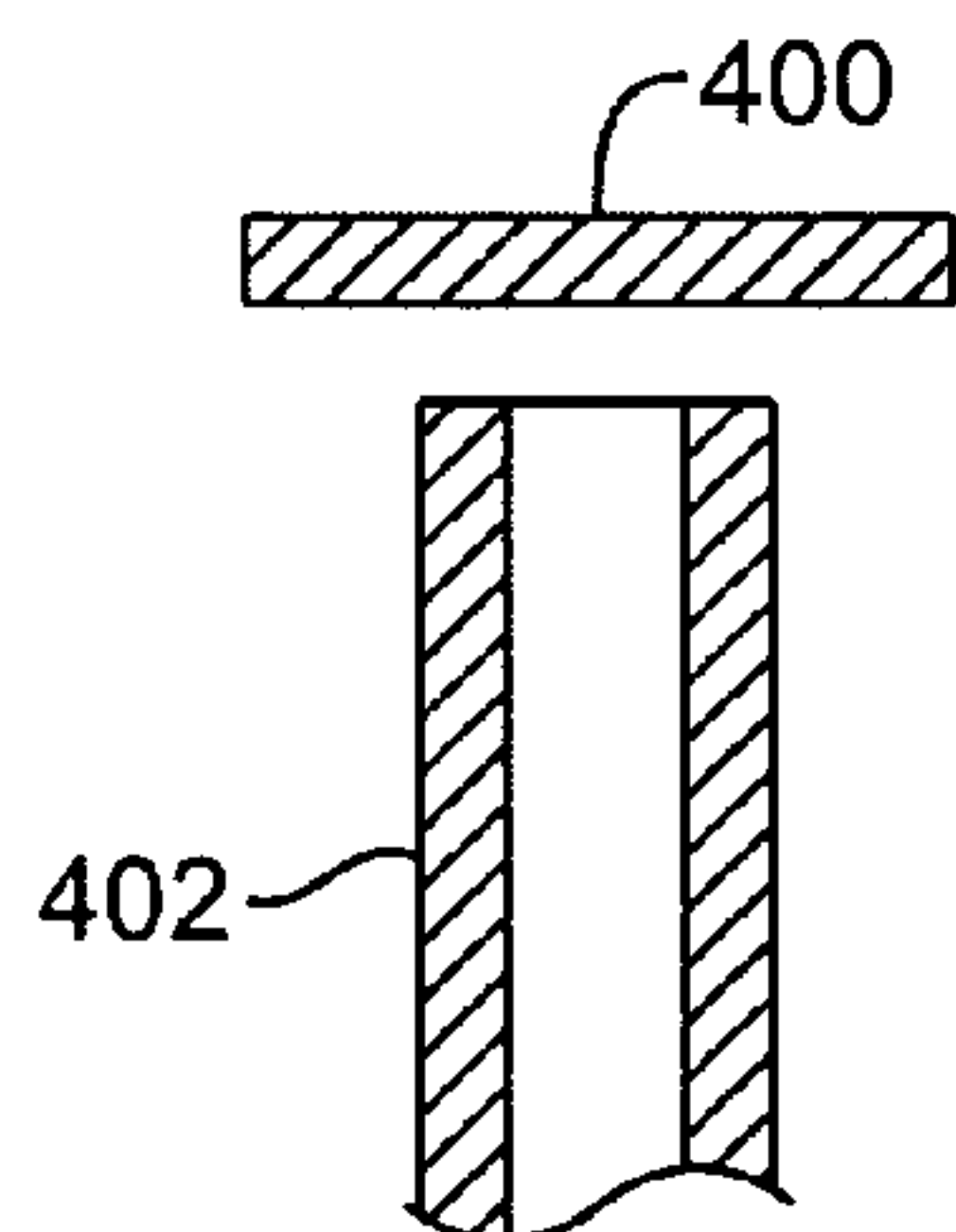


FIG. 27

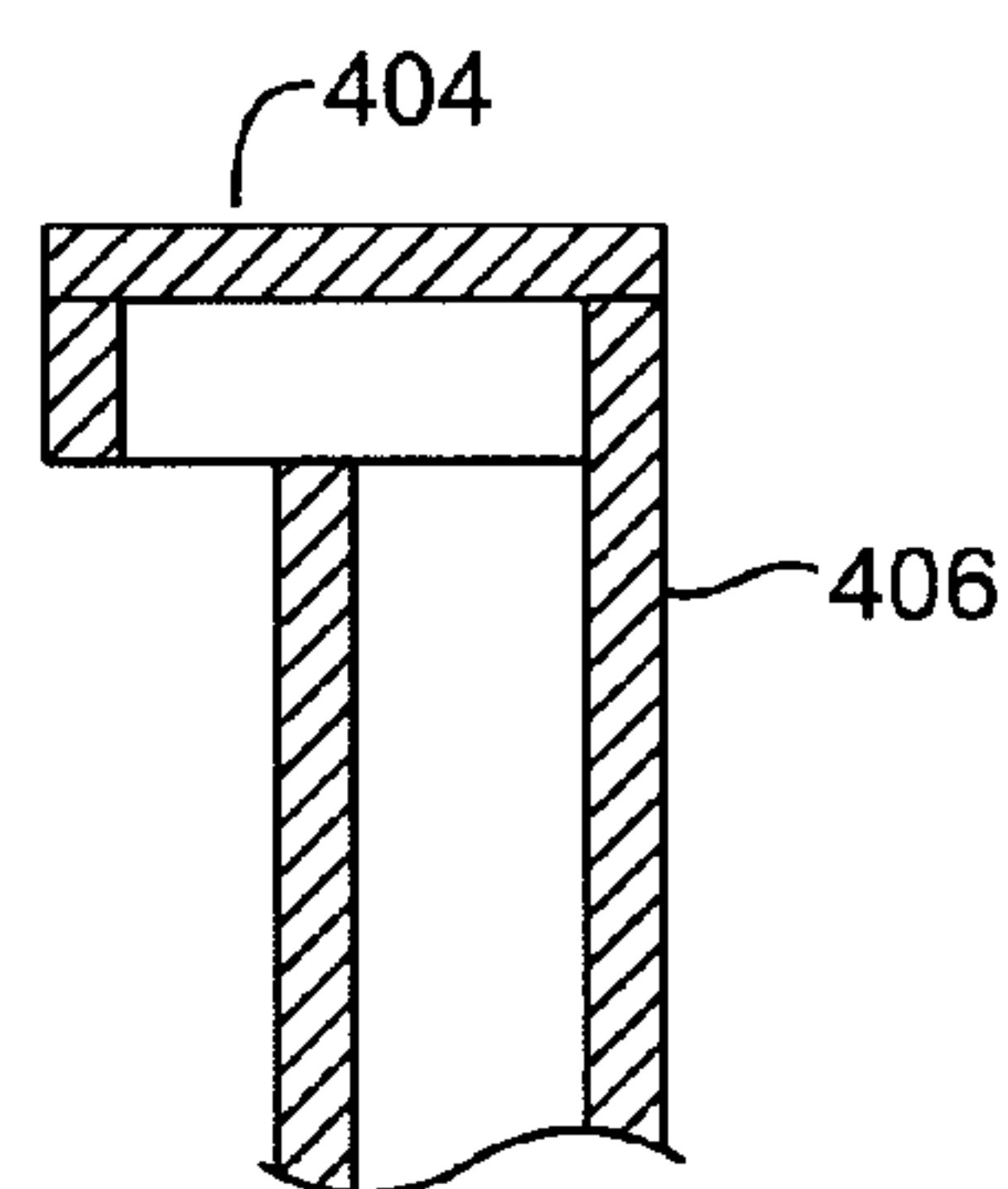


FIG. 28

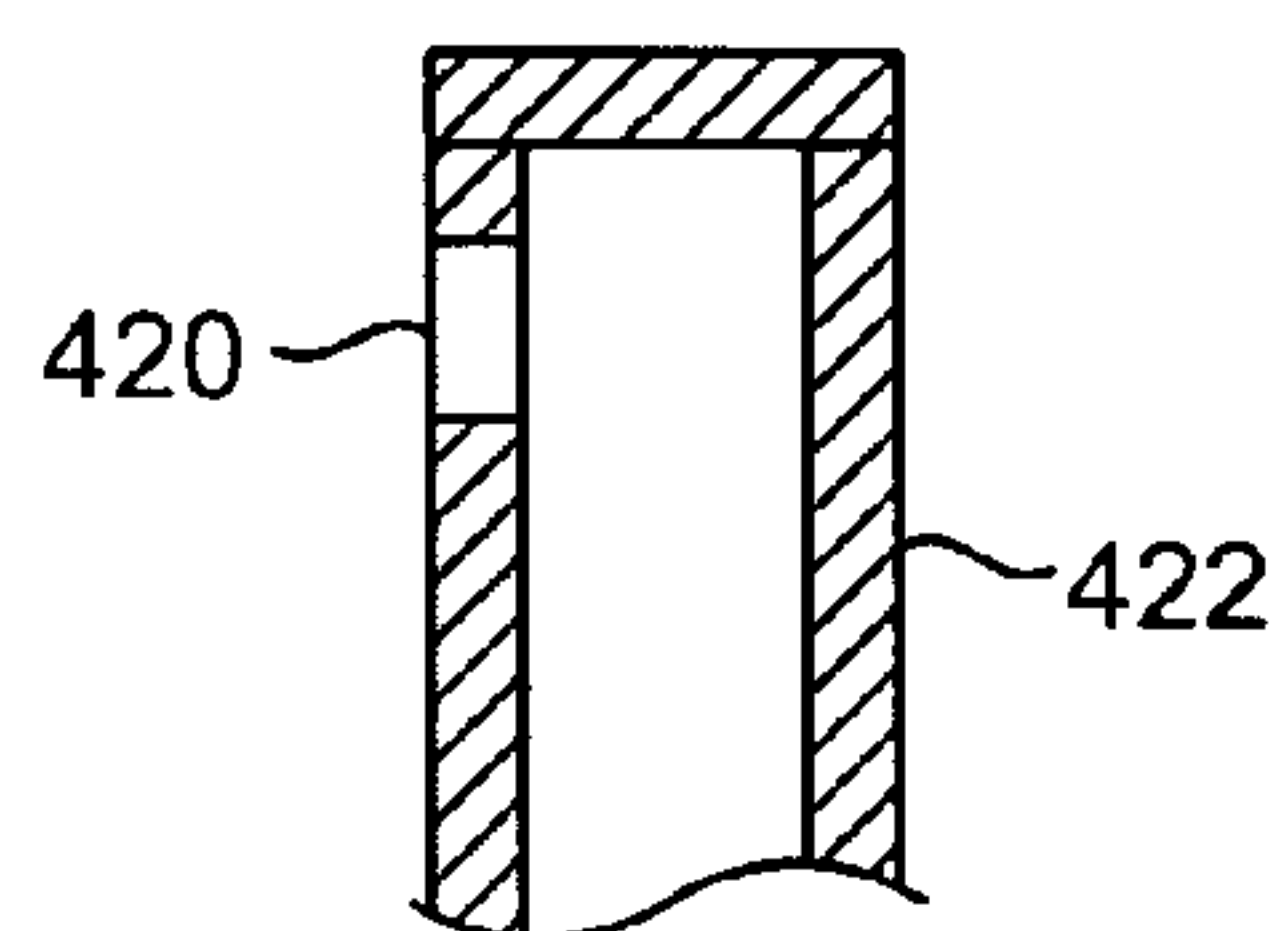


FIG. 29

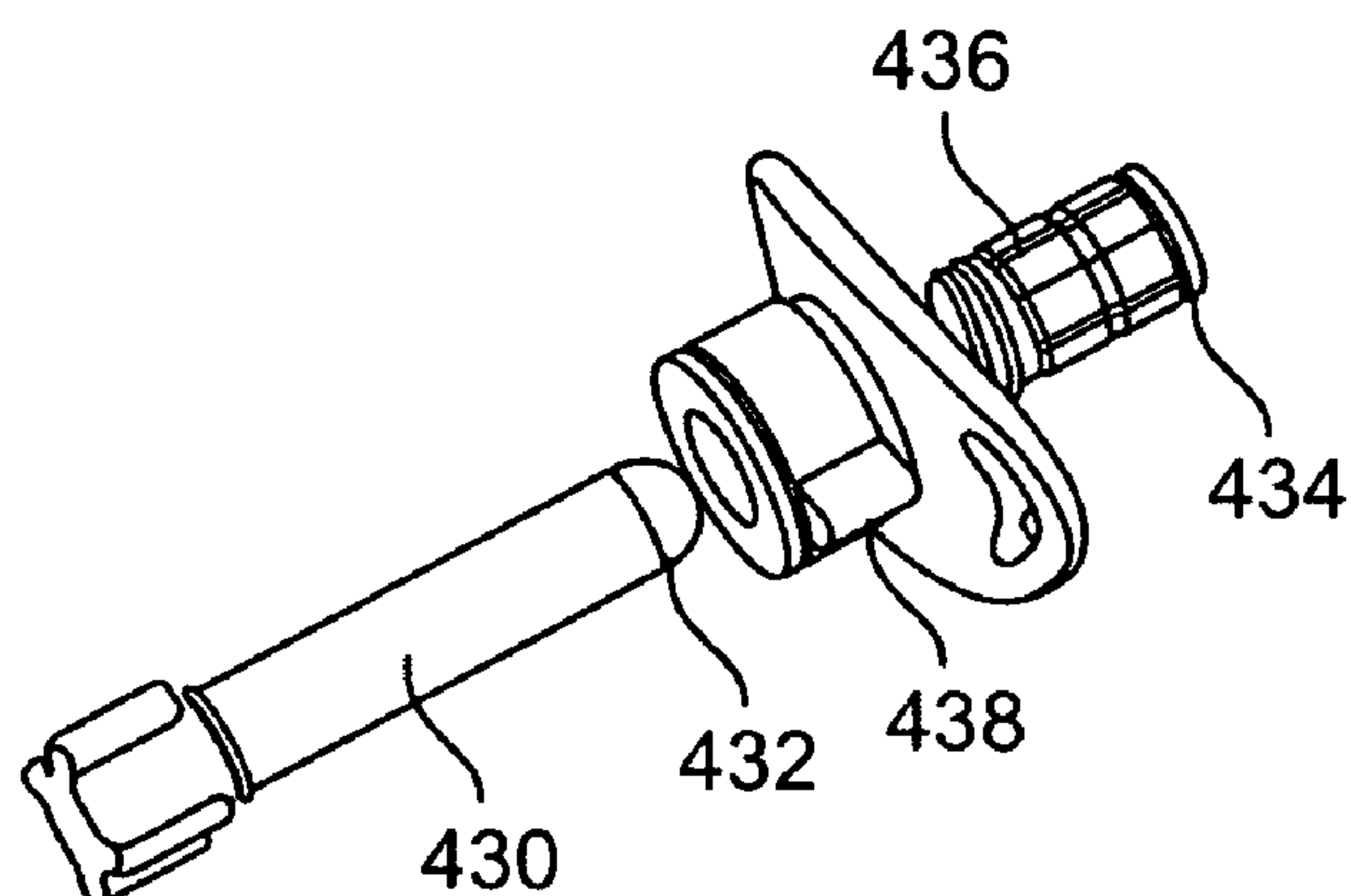


FIG. 30

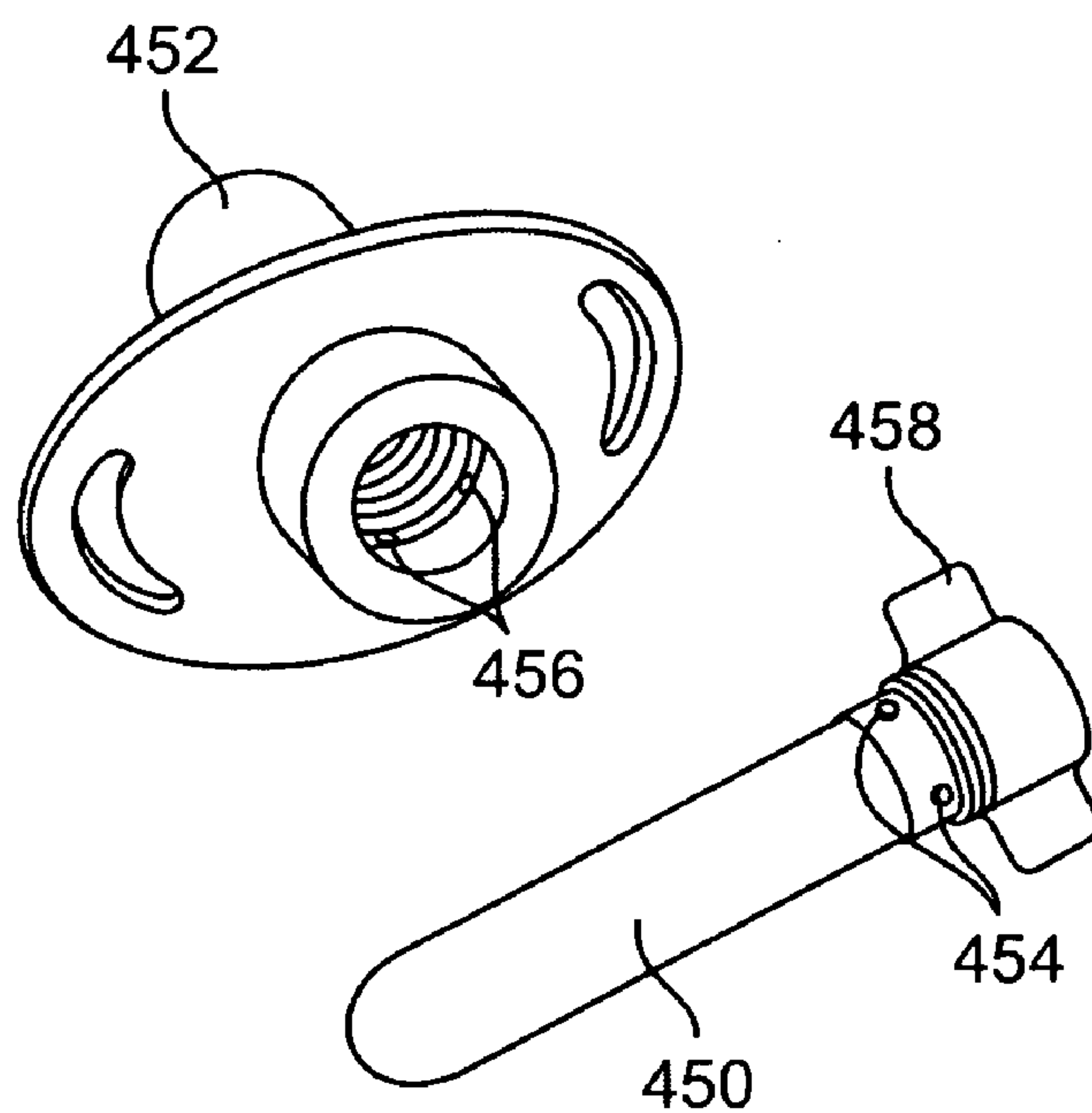


FIG. 31

METHODS AND SYSTEMS FOR TRACHEAL ACCESS AND VENTILATION

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] The present application is a non-provisional of U.S. Patent Application Ser. No. 60/777,973 (Attorney Docket No. 025808-000110US), filed Feb. 28, 2006, and is a continuation-in-part U.S. patent application Ser. No. 11/132,603 (Attorney Docket No. 025808-000100US), filed May 18, 2005, the full disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates generally to medical apparatus and methods. More particularly, the present application relates to apparatus, systems, and methods for airway management using a tracheostomy tube. The invention also relates to a transcutaneous access device useful for placing a tracheostomy device or other medical apparatus.

[0004] A tracheostomy is a surgical procedure to form an opening into a patient's trachea (windpipe) to provide a temporary or permanent path for ventilation. Usually, a tube is inserted through the opening to allow passage of air and optionally removal of secretions. Instead of breathing through the nose and the mouth, the patient will breathe directly through the "tracheal tube." Tracheostomies are often performed in the event of respiratory failure and/or upper airway blockage, and the tracheal tubes may be connected to mechanical ventilators when the patient is unable to breathe on his or her own.

[0005] Tracheal tubes may be simple tubes which are bent downward into the trachea to provide the lumen passageway for inhalation and exhalation. Often, however, the tracheal tube will have an inflatable cuff at its lower end in order to provide an airtight system for mechanical ventilation.

[0006] Of particular interest to the present invention, tracheal tubes with an inflatable cuff may collect body secretions and other materials from oral cavities, nasal cavities and/or gastro-intestinal reflux into the trachea, which may travel down the trachea from reaching the lungs. Often, these secretions and other materials collect or pool on top of the inflated cuff, thus requiring periodic removal. Even with the cuff inflated, due to movement of the tracheostomy tube and the collection of the materials on top, there could be slow and continuous of the secretions around the cuff. Whenever the cuff is deflated, the secretions remaining on top of the cuff will flow downward into the lung, leading to significant complications. For example, exposure of the lungs to such secretions can cause "aspiration pneumonia" and other pathological conditions, which can have serious consequences and which can prolong and complicate a hospitalization and or even lead to death.

[0007] In addition to collection of nasal and other secretions, presently designed tracheal tubes have a number of other shortcomings. For example, many tracheal tubes are difficult to introduce and deploy through penetrations made in the tracheal wall. It can be even more difficult to remove and exchange tracheal tubes for cleaning, repair, or other purposes. Additionally, the inflatable cuffs on at least most

trach tubes will be positioned below the tracheal penetration which can be disadvantageous in several respects. The device can be accidentally dislodged when attaching or removing other respiratory devices to the trach tube. In addition, the forces caused by airway irritation may cause the expulsion or dislodgment of the trach tube. Since these patients are dependent on mechanical ventilation, expulsion and dislodgment of the trach tube can cause significant morbidity. Furthermore, by placement of the cuff below the access site, the fluid collected above the cuff balloon can expose the tissue on the access site. Since these secretions are often rich in enzymes, it can lead to break down of the exposed tissue at the access site by the amylase of saliva. The degeneration of the exposed tissue by these enzymes is a well documented in clinical journals and is one of the leading causes of continuous enlargement of the access site for patients with chronic need for trach tube.

[0008] For these reasons, it would be desirable to provide improved tracheal tube designs and methods for their deployment and use. It would be particularly useful to provide tracheal tubes which allow for efficient and continuous removal of secretions without the need for separately accessing the tracheal tubes or removing any components of the tracheal tubes. It would be further desirable if the tracheal tubes were designed to permit easy introduction and removal of the tracheal tubes, thus permitting removal and exchange of tracheal tubes with minimum trauma to the patient. To that end, it would be desirable to provide access devices for penetrating the tracheal wall and providing an access port for insertion, removal, and replacement of the tracheal tube, particularly where the access device could be useful for other percutaneous access protocols. It would be still further desirable if the tracheal tubes were able to be firmly anchored in place within the tracheal penetration while causing minimal trauma and irritation to the patient. It is still further desirable that, with the tracheal tube in place, the penetration through the tracheal wall will be effectively sealed to prevent fluid and food aspiration into the lungs. Still further, it would be desirable to provide a tracheal tube which would facilitate patient speech while the tracheal tube is in place. At least some of these objectives will be met by the inventions described herein below.

[0009] 2. Description of the Background Art

[0010] U.S. Pat. No. 6,840,242 describes a tracheostomy aspiration suction tube for use with or without a tracheostomy cuff. Other tracheostomy tubes are described in U.S. Pat. Nos. 6,612,305; 6,575,944; 6,460,540; 5,957,978; 5,653,231; 5,392,775; 5,107,828; 5,056,515; 5,054,484; 4,979,505; 4,280,492; 4,278,081; and published U.S. application 2003/0037789. Certain endotracheal tubes are described in U.S. Pat. Nos. 6,843,250; 5,501,215; 5,311,864; 5,143,062; 5,067,497; 4,840,173; and 4,305,392.

BRIEF SUMMARY OF THE INVENTION

[0011] The present invention provides systems, devices, and methods for the improved deployment and maintenance of tracheal tubes for ventilating patients through tracheostomies. The systems of the present invention will usually comprise a percutaneous access device located in the tracheostomy and a separate ventilation tube which can be removably introduced through a passage provided by the access device. The access device is capable of being firmly

but atraumatically anchored in the tracheostomy opening, thus facilitating introduction, maintenance, removal, and replacement of the ventilation tube, with minimum patient trauma. Such facilitated replacement and removal of the ventilation tubes greatly improves the ability to clean, repair, and replace the ventilation tubes, which is a particular advantage for patients being ventilated over relatively lengthy periods.

[0012] The ventilation tubes themselves are also improved in a number of respects. For example, the endotracheal tubes are adapted to provide for efficient aspiration and removal of secretions and other materials released from the oral and nasal cavities or from gastro-intestinal reflux into the trachea. The secretions are collected on a structure which is positioned above the tracheal penetration and which may be continuously aspirated with either an active suction source or passively via gravitational force to remove secretions and other materials collecting on top of the cuff. The structure, typically in the form of a cup, is preferably valved in a way to facilitate passage of air from the lungs to the larynx in order to facilitate speech, and the cuff may be hinged to facilitate introduction and removal of the tube through the access device. In addition, a separate ventilation fitting may be provided to help seal the ventilation tube within the access device and to permit connection of the patient to a conventional ventilation system.

[0013] In a first specific aspect of the present invention, a percutaneous access device is provided which is useful for anchoring within a penetration in the patient's trachea. Although described with particularity for use in the trachea, it will be appreciated that the percutaneous access device may be used to provide other percutaneous access routes, including to the abdomen, thorax, intestines, and other body cavities and lumens. In particular, the access devices may be used in procedures including gastrostomies, colonoscopies, ileostomies, laparoscopies, vascular access, and the like.

[0014] Percutaneous access devices according to the present invention will usually comprise a base, a conduit having an access lumen, and an anchor. The base will have a posterior surface adapted to cover a percutaneous tissue penetration, and the conduit will be disposed through the base, typically being oriented at a generally perpendicular angle, and be adapted to pass through the tissue penetration. The anchor is located on a posterior portion of the conduit and is shiftable between an unexpanded deployment configuration and an expanded anchoring configuration. Usually, a compliant connector is provided between the base and the anchor to accommodate differences in the thickness of the tissue penetration. Conveniently, the compliant connector may comprise a coil spring, an accordion structure, or the like.

[0015] The anchor may comprise a variety of expandable mechanisms capable of being expanded in situ to effect anchoring of the base and conduit. For example, the anchor may comprise a mechanically expandable structure, such as a malecot, a deformable braid, deployable hooks, elongated coil, or the like. Alternatively, the anchor may comprise an inflatable structure, such as a toroidal balloon or other similar geometry. In all cases, the anchor will act to capture tissue circumscribing the tissue penetration between the base and an anterior surface of the anchor. The anterior surface of the anchor will often be tensioned or pressured against a

posterior surface of the tissue by the compliant connector as described in more detail below.

[0016] In a particular embodiment, the anchor comprises an anchor element which radially expands upon axial compression, typically being a malecot or an expandable braid. The anchor is secured to the base by a compliant mount, such as a coil spring, and a pulling assembly is connected between the anchor element and the base in order to both radially expand the anchor element and to pull the radially expanded anchor element against the posterior tissue surface. Often, the pulling assembly comprises a reel and one or more tethers between the reel and the anchor. Alternatively, the pulling assembly could comprise a pair of coaxial tubes for both opening the anchor and translating the anchor against the posterior tissue surface. In a still further embodiment, the pulling assembly may comprise a locking clip and a pull tool for capturing and pulling a posterior end of the anchor toward the base.

[0017] In a further aspect of the present invention, percutaneous access through skin is provided by first penetrating the skin to provide an access hole. A conduit is passed through the hole so that a posterior end of a base on the conduit covers the access hole. An anchor on the conduit is then expanded over a posterior surface of the skin to hold the conduit in place. Typically, the skin is in the neck, chest, or abdomen, most typically being in the neck in order to perform a tracheostomy. Penetrating typically comprises forming an incision or puncture, and the anchor may be expanded by mechanically expanding a structure, such as a malecot, deformable braid, or hooks, or by inflating an inflatable structure. Preferably, the methods further comprise adjusting the distance between the expanded anchor and the posterior surface of the base to accommodate the variable wall thickness. For example, adjusting may comprise tensioning a compliant member between the anchor and the base.

[0018] In a further aspect of the present invention, a tracheal ventilation device comprises a tube having a distal end, a proximal end, and an aspiration lumen therethrough. An expandable cuff is disposed at a distal end of the tube, and the cuff has an expandable periphery which can seal against an inner tracheal wall. The cuff further has an upper surface adapted to collect and pool nasal and other secretions, and the aspiration lumen of the tube is coupled to aspirate pooled secretions. A portion of the tube will be upwardly bent or bendable so that the cuff will be disposed above an axis of the tube when deployed in the trachea. In this way, the secretions pooling on the upper surface of the expandable cuff are maintained above the opening. This will prevent or minimize the exposure of these secretions rich in enzymes to the tissues surrounding the access site. As a result limited or no degeneration of the tissues is expected. By having the expandable cuff above the opening there is no risk of device dislodgment or expulsion caused by airway irritation since the exhalation port is positioned below the cuff. Furthermore, the design does not need external securing device such sutures or trach ties since the design allows for the flow of airway pressures in such manner to make the device more stable with patient coughing rather than expulsion that is seen in current trach tubes designs. Suction of the aspiration material in this design can be gravity dependent rather than the need for anti-gravity suctioning that is done with the current devices.

[0019] In yet another aspect of the present invention, a tracheal ventilation device may comprise a tube and an expandable cuff, as generally set forth above. The tracheal ventilation device will further comprise a one-way valve in the cuff to permit air from the lungs to pass upwardly into the larynx when the cuff is expanded in the trachea.

[0020] In still another aspect of the present invention, a tracheal ventilation device may comprise a tube and an expanded cuff, as just described. The ventilation device will further comprise a ventilation fitting having an end adapted to removably mount in the tracheal access device, a second end adapted to removably connect to a ventilator, and a passage therethrough to receive the ventilation tube. For each of these three tracheal ventilation devices, the ventilation tube will typically include at least a second lumen for ventilation, and will more usually include at least a third lumen for inflating an inflatable expandable cuff. The second lumen may be connected to a one-way valve in the cuff that permits airflow to the larynx (to facilitate speech), and the tube will typically be hinged to allow axial alignment of the tube during deployment and subsequent upward orientation of the cuff after entry of the tube into the trachea. The upper surface of the expandable cuff will typically have a concave region for collecting and pooling nasal and other secretions, typically being a conical concavity. The expandable cuff may be either inflatable or self-expanding.

[0021] In yet another aspect of the present invention, a tracheal ventilation system comprises a tracheal access device adapted to anchor in a hole in the trachea and provide an access passage therethrough and a tracheal ventilation device adapted to be removably secured in the tracheal access device. The tracheal access device preferably comprises a base, a conduit, and an anchor, as generally described above. The tracheal ventilation device typically comprises a tube and an expandable device, also as generally described above.

[0022] In still further aspects of the present invention, methods for providing tracheal ventilation comprise forming a percutaneous hole into a patient's trachea. A tracheal ventilation device is introduced through the hole, and a cuff on the ventilation device expanded to isolate the trachea below the cuff. The trachea below the cuff is otherwise unblocked to permit air exchange through the ventilation device, and nasal secretions which collect on an upper surface of the cuff may be aspirated. Usually, the cuff is expanded within the trachea at a position above the percutaneous hole, and the pooled secretions are collected in a concavity in the upper surface of the cuff. Usually, the secretions are aspirated from the concavity through a vertical passage through the expanded cuff, and in all cases, the tracheal ventilation device is preferably held in an access device which is anchored in the percutaneous hole.

[0023] In yet another aspect of the present invention, a method for providing tracheal ventilation comprises forming a percutaneous hole in a patient's trachea, anchoring an access device in the percutaneous hole, and removably introducing a tracheal ventilation device through an access passage of the access device. Usually, a cuff will be expanded on the tracheal ventilation device, preferably at a location in the trachea above the tracheal penetration. Usually, the trachea below the expanded cuff will remain otherwise unblocked to permit air exchange through the ven-

tilation device. The method will typically further comprise aspirating collected nasal and other secretions from a collection location on an upper surface of the cuff, and the cuff will be removably introduced through a ventilation fitting in the access passage of the access device.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] **FIG. 1** illustrates the relationship between the trachea and the esophagus in the neck of a patient.

[0025] **FIG. 2** is a schematic illustration of a system according to the present invention comprising an access device and a tracheal ventilation device.

[0026] **FIG. 3** is a schematic illustration of the system of **FIG. 2**, shown with the tracheal ventilation device in place within a passage of the access device.

[0027] **FIGS. 4A-4F** illustrate a method of the present invention for deploying the system of **FIGS. 2 and 3** in the neck of a patient.

[0028] **FIG. 5** illustrates a first specific embodiment of an access device constructed in accordance with the principles of the present invention.

[0029] **FIGS. 6A and 6B** illustrate the access device of **FIG. 5** shown with its anchor undeployed (**FIG. 6A**) and its anchor deployed (**FIG. 6B**).

[0030] **FIG. 7** illustrates a base of a second exemplary access device having a plurality of hooks utilized as the anchor.

[0031] **FIG. 8** illustrates a further alternative embodiment of the access device of the present invention illustrating an inflatable balloon as the anchor device.

[0032] **FIGS. 9-11** illustrate yet a further embodiment of the access device of the present invention illustrating use of a locking clip to deploy an anchor,

[0033] **FIG. 12** illustrates use of a straight obturator which can be used with the access device of the present application for deployment.

[0034] **FIG. 13** illustrates an obturator having a bent tip which can be used with a guidewire for introducing the access device of the present invention.

[0035] **FIG. 14** is a detailed illustration of a first embodiment of the tracheal ventilation device of the present invention.

[0036] **FIG. 15** is a cross-sectional view taken along line 15-15 of **FIG. 14**.

[0037] **FIGS. 16A and 16B** are enlarged views of the expandable cuff of the ventilation device of **FIG. 14** showing a duck bill valve and a cross-slit valve, respectively.

[0038] **FIG. 17** illustrates the ventilation device of **FIG. 14** present in the access device of **FIGS. 2 and 3**.

[0039] **FIGS. 18-20** illustrate a second embodiment of a ventilation device according to the present invention being deployed through an access device.

[0040] **FIGS. 21A, 21B and 22** illustrate alternate configurations of the basket expansion mechanisms of the present invention.

[0041] **FIGS. 23 and 24** illustrate still further basket expansion mechanisms.

[0042] **FIGS. 25A and 25B** illustrate an air bypass lumen having an internal valve.

[0043] **FIG. 26** illustrates an aspiration bypass lumen in the tracheal balloon assembly.

[0044] **FIGS. 27 and 28** show alternate baffle constructions to protect the air flow passage from secretions.

[0045] **FIG. 29** shows a side hole to prevent intrusion of secretions into the air flow passage.

[0046] **FIG. 30** shows an obturator structure for use with the basket.

[0047] **FIG. 31** shows an alternate obturator structure having a handle to effect deployment of the basket structure.

DETAILED DESCRIPTION OF THE INVENTION

[0048] The present invention is intended primarily to provide tracheal access to patients for ventilation, drug delivery, and other therapeutic purposes. To that end, the present invention relies on an access device which anchors in a surgical hole formed in the trachea to provide an access passage and a ventilation device which is removably deployable through the access passage. Although illustrated hereinafter for use in tracheal access protocols, the access device of the present invention is also useful for accessing other body lumens and cavities, such as the stomach, intestines, abdominal cavity, and the like, and for performing procedures such as laparoscopy, gastroscopy, feeding tube deployment, colostomies, ileostomies, and the like.

[0049] Referring now to **FIG. 1**, a neck region N of a patient P includes both the esophagus E for passing food and drink to the stomach and the trachea T for exchanging air with the lungs. The larynx L is located generally above the trachea, and incisions into the trachea to perform tracheostomies are generally made well below the larynx, as described in more detail below with reference to **FIGS. 4A-4F**.

[0050] Systems 10 according to the present invention generally comprise an access device 12 and a ventilation device 14. The access device comprises a conduit 16, which may be a single component or an assembly of a plurality of components, which is secured through a base 18 having a posterior surface 20 adapted to cover a percutaneous tissue penetration, such as a tracheal penetration of the type formed when performing a tracheostomy. An anchor structure 22 is disposed at or near a posterior end 24 of the conduit 16. The anchor structure is shiftable or deployable between a low-profile configuration (shown in full line in **FIG. 2**) and a radially expanded, deployed configuration (shown in broken line in **FIG. 2** and full line in **FIG. 3**). A spring 26 or other compliant member is provided between the anchor structure 22 and the base 18 in order to permit the anchor 22 to move axially relative to the base 20, as indicated by arrow 30 in **FIG. 2**. As illustrated in **FIG. 2**, the anchor structure 22 is a malecot having a plurality of individual arms 32 which will radially expand as the malecot is foreshortened, typically by a pulling assembly (not shown in **FIGS. 2 and 3**).

[0051] The ventilation device 14 comprises a tube 40 having a distal end 42 and a proximal end 44. An expandable

cuff 46 is mounted at or near the distal end 42 of the tube 40 and may be inflated from the low-profile configuration shown in full line to a radially expanded configuration shown in broken line in **FIG. 2**. In addition to inflatable structures, the expandable cuff 46 may also comprise self-expanding structures, such as a self-expanding cone formed from resilient polymer or other materials. A cavity 50 (shown in broken line in **FIG. 3**), is usually formed in an upper surface 52 of the expanded cuff 46 in order to collect nasal and other secretions after the cuff is deployed in the trachea. A valve structure 54 is disposed within the cavity 50 and typically serves two purposes. First, the valve will contain a port for aspirating the collected secretions through the tube 40, typically by connecting through a suction or vacuum connector 60 at or near the proximal end 44 of the tube. The valve structure 54 may also contain a second port to allow upward passage of exhaled air through the expanded cuff 46. Usually, the second port will comprise a one-way valve structure which will prevent entry of secretions or air from the upper airway past the expandable cuff 46. When the patient exhales with a sufficient pressure, however, air will flow through the second port past the patient's larynx to allow the patient to speak. When using an inflatable cuff 46, an inflation port 62 will usually be provided near the proximal end 44 of the tube 40. The tube 40 will thus usually be a multi-lumen extrusion to provide the necessary flow paths therethrough.

[0052] Referring now to **FIGS. 4A-4F**, deployment and use of the tracheal ventilation system 10 in the trachea of a patient will be described. As shown in **FIG. 4A**, the trachea T through the patient's neck region N is protected at its upper end by the thyroid cartilage TC and the cricoid cartilage CC at the upper end of the trachea. An incision to perform the tracheostomy is made in the region indicated at TR.

[0053] After a surgical incision is made in this region by conventional techniques, the conduit 16 of access device 10 may be inserted through the incision so that the posterior surface 20 of the base 18 is brought against the skin of the neck surrounding the incision, as shown in **FIG. 4B**. The anchor structure 22 is then radially expanded, as shown in **FIG. 4C**, and the expanded anchor drawn against the interior surface of the trachea T, as shown in **FIG. 4D**. Specific mechanisms for deploying the anchor 22, and for shortening the distance between the anchor and the base 18, will be described in detail with respect to certain specific embodiments hereinafter.

[0054] After the anchor is tightened against the inner wall of the trachea T, as shown in **FIG. 4D**, the ventilation device 14 may be introduced through the passageway defined through conduit 16, as shown in **FIG. 4E**. The ventilation device is introduced with the expandable cuff 46 in its unexpanded, low-profile configuration. The cuff 46 will be deployed upwardly in the trachea so that it is disposed above the incision I after the device 14 is in place. The cuff 46 may be expanded, typically by inflating through inflation port 62, as shown in **FIG. 4F**, and a ventilation device may be connected to the ventilation tube 58 as shown in broken line in **FIG. 4F**. Once in place, air may pass through the ventilation fitting 58, as shown by arrows 70, and the expanded cuff 46 will collect secretions passing into the trachea, as shown by arrows 72. The ventilation device 14 is held securely in place by the access device, but may be

conveniently removed, cleaned, and optionally replaced as required over time. When the ventilation device 14 is removed, however, the access device 10 will generally be left in place. By leaving the access device in place, the tracheal opening is protected and patient trauma significantly reduced. Additionally, reintroduction and/or exchange of the ventilation devices is simplified.

[0055] Referring now to **FIGS. 5, 6A, and 6B**, a detailed construction of the tracheal access system 110 will be described. The detailed system 110 comprises a base plate 118, a conduit 116, an anchor 122, and a coil spring 124. A flexible outer sheath 126 is provided to cover the anchor 122 and compression spring 124, as shown in more detail in **FIG. 6A**. A rotatable control ring 130 mounts on the forward end of the conduit 116, and is secured by a flange 132 and lock washer 134. Four tethers 136 are provided, and extend between a posterior end 140 of the anchor 122 and the control ring 130. The control ring may be rotated and may act as a reel in order to draw in the tethers in order to shorten and deploy the anchor, in the form of an expansible malecot, as best shown in **FIG. 6B**. After the malecot anchor 122 has been deployed, the control ring may be further rotated in order to draw the expanded anchor toward the base plate 118 in order to tighten the access device in the tissue opening through which it has been introduced.

[0056] While the anchor mechanism illustrated in **FIGS. 5, 6A, and 6B** will often be preferred, alternative anchor mechanisms for holding the base plate within the tissue opening may also be provided. For example, as shown in **FIG. 7**, a base plate 140 having an aperture 142 for receiving a conduit (not shown), may comprise deployable hook elements 144 for securing the plate over a tissue opening. For example, the hooks may be resilient and may be straightened prior to introduction through the tissue opening. Once in place, the hook constraint may be removed, allowing the hooks to curl back and deploy against the posterior side of the tissue. As shown in **FIG. 8**, a base 150 may be provided with an inflatable anchor 152 formed over a conduit 154. A lumen (not illustrated) may be provided in the conduit for inflating the balloon.

[0057] An alternative locking mechanism for a radially expansible malecot anchor is illustrated in **FIGS. 9-11**. A locking clip 160 (**FIG. 9**) comprises a pair of resilient fingers 162, each having a ratchet surface 164 near a distal end thereof. A locking clip 160 may be placed with the fingers 164 disposed within a radially expandable malecot 168 on the posterior surface of a base 170, as illustrated in **FIG. 10**. A pull tool 172 (**FIG. 11**) may be inserted through the malecot 168 so that a distal puller 174 can be engaged against the ring 161 of the locking clip 160. The ring has an oval opening 163 which permits entry of the oval puller 164 when properly aligned. By then rotating the puller 174 90°, the puller will engage the narrow diameter of the ring 161 to allow the malecot to be actually shortened and radially expanded. The malecot will be held in its radially expanded position by engagement of the ratchet surface 164 against the base 170, as best seen in **FIG. 11**.

[0058] Referring now to **FIGS. 12 and 13**, obturators may be used to facilitate introduction of the access devices through the stomal openings in the trachea or other body surfaces. For example, a straight obturator 200 may be placed through the central opening of the access device 110,

as shown in **FIG. 12**. Conveniently, a handle 202 will be provided on the proximal end of the obturator 200, and a blunt tip 204 will be provided on the distal end of the obturator. An obturator 210, as illustrated in **FIG. 13**, has a deflected distal tip 212 and a guidewire lumen therethrough 214. Thus, the obturator 210 can be used for introducing an access device 110 over a guidewire.

[0059] Referring now to **FIGS. 14-16A and 16B**, an exemplary ventilation device 250 comprises a tube 252, an inflatable cuff 254, and a ventilation fitting 256. The ventilation fitting has a distal end 258 adapted to fit in the central passage of an access device, such as the central lumen of device 110. An O ring 260 provides a hermetic seal when the fitting 256 is within the interior conduit 116. The tube 252 is typically a three-lumen extrusion, including a balloon inflation lumen 264, an aspiration lumen 266, and a ventilation lumen 268. The aspiration lumen is connected to an open port 270 disposed within the inflatable cuff 254, as best seen **FIG. 16A**. The open port 270 allows removal of secretions which collect within a concave depression or other concavity in an upper surface of the cuff 254. A second valve 274 is provided adjacent the aspiration port 270, and typically includes a duck bill or other one-way valve structure permitting air to flow from beneath the cuff 254 to above the cuff. In this way, the patient may exhale and permit to pass upward through the valve 274 to enter the region of the larynx to permit speech. In particular, by covering the ventilation fitting 256 (optionally having removed any ventilator device), the air will have no other place to go, thus will all pass through the valve 274 into the larynx. After the patient is done speaking, the ventilator may be uncovered and/or the ventilation device may be reconnected. Alternatively, the valve may be a cross-slit valve 275 as shown in **FIG. 16B**.

[0060] As shown in **FIG. 17**, the ventilator fitting 256 may be introduced through the center of the control ring 130 and the access device 110. A Y-connector at the proximal end of tube 252 provides for both aspiration (through aspiration lumen 266) and balloon inflation (through inflation lumen 264).

[0061] Referring now to **FIGS. 18-20**, an alternative ventilator device 300 for introduction through an access device 110 is illustrated. The ventilation device 300 includes an expandable cuff 302 which is connected to a tube 304 by a hinge structure 306. A cuff inflation tube 310 is connected to a hand pump 312 at one end and to the cuff 302 at the other end. An aspiration connection 312 is similarly connected through a flexible tube to a valve within the interior of the cuff 302 (not shown).

[0062] The expandable cuff 302 may be introduced through the central passage of the access device 110 while in axial alignment with the tube 304, as shown in **FIG. 18**. After the cuff 302 has been fully inserted through the access device 110, as shown in **FIG. 19**, the cuff may then be turned upwardly at a generally right angle as shown in **FIG. 20**. The cuff 302 may then be inflated using the pump 312. Ventilation fitting 320 remains available for patient breathing and optional connection to a ventilator.

[0063] The embodiments of the tracheal access port described above used strings to expand the tracheal access port. It would be desirable to provide other expansion mechanisms in order to enhance reliability of the access port

by minimizing the risk of string breakage and/or connecting joints. It would be further desirable to isolate the internal mechanical parts of the access port (e.g. spring, basket assembly) from contacting other devices or materials inserted or removed into the access port lumen. It would be still further desirable to require fewer mechanical parts resulting in better reliability of the system and reduction in manufacturing cost.

[0064] One embodiment of the access port **350** that could achieve at least some of these goals is illustrated schematically in **FIGS. 21A and 21B** and include a flexible basket which is attached at its distal end to a translating member **354**, which attaches to a rotating knob **356**. The basket could be a cylindrical element made from a polymer or metal, or it could comprise a plurality discrete column-type elements spaced around the circumference to evenly distribute the load. As shown in **FIGS. 21A and 21B**, the translating element **354** is axially retracted by rotating the knob **356** so that the translating member retracts relative to base **358**. The force transmitted by the translating member **354** is translated into an axial force with collapses the basket **352** as shown in **FIG. 21B**. The basket **352** is expanded by rotating the control knob in the opposite direction, putting tension on the basket and causing it to expand. Spring **360** will extend axially to accommodate different thickness of tissue as the basket is deployed.

[0065] Alternatively, the mechanism of **FIGS. 21A and 21B** may include a short string or tether **362** to retract the assembly in place of the translating member (**FIG. 22**). The string **362** may be attached at either the distal or proximal end of a translating, non-deforming portion of basket, and may translate linearly or wind about the port as it is retracted.

[0066] A threaded portion **364** of the control knob **356** may extend inwardly to telescope with an inner surface of the basket's **352** inner core as shown in **FIG. 23**. This requires additional diametric clearance but has the advantage of reducing the amount of the linear translation. Instead of jutting out from the anterior aspect of the port when the basket is expanded, the device can be made to stay within its original form factor between states (unexpanded and expanded). This is shown schematically by the overlapping rectangles in **FIG. 23**, between the sketches of the two device states.

[0067] The design described above may be further modified by attaching the translating, non-deforming element to the deforming portion of the basket using a hinge or pin arrangement **366** to assist the deflection of the basket. This may be optimized to lower deployment forces and to make the device more robust, as shown in **FIG. 24**.

[0068] It is desired to have an aspiration device that allows the patient to speak, while still preventing secretions and aspirated material from entering the lungs via the trachea. The following concepts may be used independently or in combination to achieve this desired results.

[0069] As shown in **FIGS. 25A and 25B**, an aspiration lumen **379** may be used to deliver air across the device to the vocal cords via a side hole **380** and a rotatable occlusion member **381**. The side hole **380** can be actuated on or off externally by an operator using knob **382** to rotate the flexible occlusion member **381** within outer tube **383** to open or close aligned ports **384** and **385**.

[0070] In the embodiment of **FIG. 26**, a lumen or channel **390** around the aspiration device, is disposed between the collection member (such as balloon **391**) and the trachea to allow for the passage of air across the device to the vocal cords. A robust seal may be provided by the design of the collection member and bypass lumen and the use of suitably compliant materials. The techniques for preventing fluid ingress into this bypass lumen include those disclosed below.

[0071] A baffle or cap **400** may protect of the airflow passage from entry of secretions, as shown schematically in **FIGS. 27A and 28**. The degree of baffling and shielding may be tailored by altering the shape and dimensions to suitably allow airflow while blocking secretions. **FIG. 28A** shows a section taken through fenestrations at top of a ventilation tube **402**. Support struts are not shown. Cap **400** may be flat, dome shaped, or conical, to better shed patient-aspirated materials and secretions. In **FIG. 28B**, a baffle entry **404** to ventilation tube **406** that supplies air to vocal cords. The baffle may completely or incompletely overlap entry to ventilation tube. Entry may be placed medially to further inhibit ingress of secretions, which can be transported along the tracheal wall by gravity and by the mucociliary elevator (these forces often may oppose one another, but that does not alter the effectiveness of this device). A semi-permeable filter material that allows gas to pass through but not fluid or solids; this may be accomplished with a relatively porous mesh given the viscous nature of secretions to be blocked.

[0072] One or more side hole(s) **420** in a ventilation tube **422** as shown in **FIG. 29** preferentially allow gas flow but do not easily admit secretions. Use of external air source of compressed air or gas via an external lumen that the patient can control can allow speech on demand, without needing an airflow path through the aspiration device. This approach does not lend itself as easily to that described above for complete freedom of speech without action on the part of the device or patient.

[0073] **FIG. 30** illustrates an obturator **430** having a ridge groove **432** to hold the basket component in place during insertion of the device into the trachea and preventing it from premature and unwanted partial deployment of the basket. The groove **432** engages a ridge **434** formed on an inner surface of the anchor **436**. Thus, the obturator can prevent the anchor from accidentally shortening while it is being introduced. The anchor is deployed once in place by rotating handle **438** to shorten the basket structure.

[0074] **FIG. 31** illustrates an obturator **450** useful for deployment of the basket **452**. By rotating the obturator, the basket is deployed via mating pins **454** disposed on the obturator which engage pins **456** housing assembly of the access port. Thus, rotation of handle **458** will in turn rotate and actuate the basket assembly as described above.

[0075] Other design modifications include using a ribbed ring made out of a polymeric or fabric material on the anterior side of the basket for sealing and protecting the stoma against enzymes present in normal secretions. Such ceiling has the benefit of preserving tissue over time. The control ring interfaces with limit stops on the base to control allowable deployment diameters of the basket during the deployment of the device. The obturator is made with fiducial marks to display tissue thickness or degree of

retraction of basket towards base to user. This is accomplished using a window in the base, which effectively translates the known relationship between deployment angles to retraction distance for the user. The markings may include length markings or symbols to depict the amount of retraction (such as using a triangle symbol to depict thickness or percent completed; the width of the bar at an interface between the obturator and base would serve as an indicator of distance in the same way a numbered scale would work). For laparoscopy and gastrostomy application, it might be desired to place a one-way valve in the center lumen of the access port to preserve sterility, minimize risk of infection, and/or prevent open communication between inside the body to the outside via the access port lumen. This can be achieved by placing and securing a slit valve at the center of the access port lumen.

[0076] The access port of the present invention can be delivered and implanted percutaneously by placing a hole through the obturator to allow for the passage of a conventional guidewire and introducer catheter combinations. The guide wire hole should be sized greater than 0.102 inches in diameter to allow the free fit of existing conventional devices which are up to 0.102" in diameter, but less than 0.127 inches in diameter to prevent entry of the depth stop on existing devices sized at approximately 0.127 inches in diameter. By adding this design feature to the APMed obturator, the APMed Access Port will be compatible with existing percutaneous tracheostomy kits such Blue Rhino (manufactured by Cook Medical). In addition, the hole through the obturator can be stepped between a first and second dimension (smaller diameter towards patient posterior) with the distance between chosen to provide the desired entry length of the introducer/guidewire, taking advantage of a depth stop on the existing percutaneous introducer catheters. The obturator distal tip may be chosen of a soft polymeric material with tapered and/or round tip to make it atraumatic for protecting the tissues of the trachea during insertion of the device. Excessive trauma, particularly if repeated during repeated insertions of devices over time, to the trachea can lead to long-term complications such as tracheomalacia (weakening of the cartilage supporting the trachea). Furthermore, instead of conventional dilators, a balloon or other radially expandable mechanical means could be used to expand the tissue to provide the opening necessary to deliver and deploy the access port. Instead of existing tapered tube dilator systems.

[0077] Still further design modifications include providing an anti-microbial or anti-bacterial coating or formulation within the aspiration catheter or access port for infection control. Examples of the agents which may be used include silver sulfadiazine and chlorhexidine. Alternatively or additionally, the materials of the catheter may be chosen to help prevent infection in addition to other design requirements (like mechanical performance, biocompatibility, sterilization compatibility, etc.). Preferred examples would include PTFE, polyurethanes, and the like. The material may also be suitable for sterilization by radiation (for ease of manufacture) or autoclave (for ease of resterilization by end-users). Suitable high-performance engineering thermoplastics such as PEEK, and silicones with radiation stabilizers, are example materials that withstand both types of sterilization. The tracheal access port may be adapted to allow delivery of aerosol drug using a nebulizing tube that is inserted directly into the trachea. If delivery deep into the lung is desired, the

nebulizing tube may be held by a balloon or support to center and align the aerosol pattern with the trachea enough to minimize impaction of aerosol on trachea walls. Alternatively, instilling the drug or saline (as liquid or aerosol) into the trachea can deliver the agent to the tracheobronchial tree by coating the walls of the airway; excess volume may be aspirated as desired. This may be done in combination with ventilation, or during normal breathing (and daily activities), as a replacement for nebulizers or metered dose inhalers. The activation may be patient, user, or automatically regulated. A means for securing a bronchial or tracheal catheter within the access port may be provided, with the catheter inserted into the tracheobronchial tree. This may be useful for lavage and suction of the airways, for example. The base or access port may have a place to snap a catheter line into place for example, by providing a rib with a C-shaped cross-section.

[0078] To limit trauma to the trachea by the access port, a force-limiting mechanism may be added to stop travel when force or torque limit is reached. Alternatively or additionally, compliant materials (such as a thermoplastic elastomer based foam) may be provided as a separate gasket or as a cushioning basket covering to protect the trachea from the flange formed by the deployed basket on the access port.

[0079] The aspiration catheter may be maintained in place in patients with impaired swallowing reflex (dysphagia) from temporary causes such as anesthesia until demonstration of return. This can be done by a swallow test using a dyed substance, and checking for it at the aspiration catheter. (Described by McCoy). Further, the device could be used in combination with a pH sensing element to detect aspiration of reflux materials or a pH controlled test medium administered orally. The ventilator adapter can be combined with gas sampling or sensing means to continuously or periodically monitor exhaled gases, for example for CO₂ level (for ventilation adjustment) or NO_x level (exhaled NO_x is a marker for lung inflammation).

[0080] The aspiration of pooled secretions could further include the method of breaking up larger aspirated materials with a catheter device (like an egg-beater) prior to aspiration. The aspiration port could also be used to aspirate saline instilled into the upper airways via separate catheter. In addition, this could be accompanied by a drug in solution or aerosolized, such as corticosteroids, to achieve therapeutic benefit such as reduction of inflammation.

[0081] As a new mechanical device for performing tracheostomy, the access port lends itself to novel training procedures. For example, computer simulation (virtual reality) with or without force-feedback inanimate models (see Immersion Technology for example in other fields) is a highly effective method of training users to perform this procedure. The method can effectively convey proper device placement, operation, and deployment without over-tightening the tissue between basket and base, without requiring the use of animal training or learning on human patients.

[0082] A curved tube or baffle can be provided, in addition to or attached to; a ventilator fitting that directs ventilator airflow along the axis of the trachea. This will further protect the tracheal wall by preventing ventilator airflow from being directed against the walls of the trachea, and reduce flow resistance by substantially eliminating the recirculation of flow caused by the jet of air impinging against the tracheal wall.

[0083] The tracheal access port may be sized to accommodate typical ventilation equipment as needed, by making the access port up to 12 mm diameter. For example, standard size endotracheal tubes (8 mm-10 mm in diameter). This would also allow simultaneous access by a bronchoscope and ventilation. Also, preferably size the access port to allow access by a bronchoscope (common sizes are 5 mm-6 mm in diameter, with smaller sizes readily available as well) for use in diagnostic or therapeutic procedures if necessary. This makes a preferred range of sizes between 6 mm and 12 mm diameter, with the larger sizes preferred as allowed by anatomy. This further suggests the provision of a family of port sizes (such as small, medium, and large), tailored to the individual patient and procedural requirements anticipated.

[0084] It is useful to provide devices and methods so that the patient or health care providers can clean the access port and aspiration catheter post implantation, either in-situ or by removing the device. This can be achieved by providing a device for cleaning the inside of the aspiration lumen and the collection surface on the upper surface of the device. This could be a brush with bristles or a swab device on a flexible member (such as a stylet) that allows the user to scrub the device back and forth. Furthermore, enzymatic detergents and anti-septic solutions for disinfection (hydrogen peroxide, iodine solutions, etc.), and/or anti-biotic solutions can also be incorporated as part of the maintenance kit for cleaning and disinfecting the system.

[0085] While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.

What is claimed is:

1. A percutaneous access device, said device comprising:
 - a base having a posterior surface adapted to cover a percutaneous tissue penetration.
 - a conduit having an access lumen disposed through the base and adapted to pass through the penetration; and
 - an anchor on a posterior portion of the conduit, said anchor shiftable between an expanded anchoring configuration and an unexpanded deployment configuration.
2. A percutaneous access device as in claim 1, further comprising a compliant connector between the base and the anchor to accommodate differences in thickness of the tissue penetration.
3. A percutaneous access device as in claim 2, wherein the compliant connector comprises a coil spring.
4. A percutaneous access device as in claim 1, wherein the anchor comprises a mechanically expandable structure.
5. A percutaneous access device as in claim 4, wherein the mechanically expandable structure comprises a malecot, a deformable braid, and hook.
6. A percutaneous access device as in claim 4, wherein the anchor comprises an inflatable structure.
7. A percutaneous access device as in claim 1, wherein the anchor comprises:
 - an anchor element which radially expands upon axial compression;

- a compliant mount securing the anchor element to the base; and

- a pulling assembly connected between the anchor element and the base to draw the anchor element toward the base and to both (1) axially compress the anchor element to cause radial expansion and (2) pull the radially expanded anchor element against a posterior tissue surface.

8. A percutaneous access device as in claim 7, wherein the anchor element a malecot or a deformable braid.

9. A percutaneous access device as in claim 7, wherein the compliant mount comprises a coil spring.

10. A percutaneous access device as in claim 7, wherein the pulling assembly comprises a reel on the base, and one or more tethers between the reel and anchor.

11. A percutaneous access device as in claim 7, wherein the pulling assembly comprises coaxial tubes.

12. A percutaneous access device as in claim 7, wherein the pulling assembly comprises a locking clip and a pull tool.

13. A method for providing percutaneous access through skin, said method comprising:

- penetrating the skin to provide an access hole;

- passing a conduit through the hole so that a posterior surface of a base on the conduit covers the access hole; and

- expanding an anchor on the conduit over a posterior surface of the skin.

14. A method as in claim 13, wherein the skin is in the neck, chest, or abdomen.

15. A method as in claim 13, wherein penetrating comprises forming an incision or puncture.

16. A method as in claim 13, wherein expanding the anchor comprises mechanically expanding a structure selected from the group consisting of a malecot, a deformable braid, and hooks.

17. A method as in claim 13, wherein expanding the anchor comprises inflating an inflatable structure on the conduit.

18. A method as in claim 17, wherein expanding the anchor comprises pulling on a pull member to axially compress and radially expand the anchor.

19. A method as in claim 18, wherein the pull member includes one or more tethers.

20. A method as in claim 18, wherein the pull member comprises a tube which is coaxial with the conduit.

21. A method as in claim 13, further comprising adjusting the distance between the expanded anchor and the posterior surface of the base to accommodate the thickness of the wall.

22. A method as in claim 21, wherein adjusting comprises compressing a compliant member between the expanded anchor and the base.

23. A method as in claim 22, wherein compressing comprises reeling tethers connected between the anchor and the base.

24. A tracheal ventilation device comprising:

- a tube having a distal end, a proximal end, and an aspiration lumen therethrough; and

- an expandable cuff at a distal end of the tube, said cuff having when expanded a periphery which seals against

a tracheal wall and an upper surface adapted to collect and pool nasal secretions, wherein the aspiration lumen is coupled to aspirate the pooled secretions;

wherein a portion of the tube is upwardly bent or bendable so that the cuff is above an axis of the tube when deployed in the trachea.

25. A tracheal ventilation device as in claim 24, wherein the tube has at least a second lumen for ventilation.

26. A tracheal ventilation device as in claim 25, wherein the tube has at least a third lumen for inflating an inflatable expandable cuff.

27. A tracheal ventilation device as in claim 26, wherein the second lumen is connected to a one-way valve on the cuff that permits air flow to the larynx.

28. A tracheal ventilation device as in claim 24, wherein the tube is hinged to allow axial alignment of the cuff during deployment and upward orientation of the cuff after entry to the trachea.

29. A tracheal ventilation device as in claim 24, wherein the upper surface of the expandable cuff has a concave region for collecting and pooling the nasal secretions.

30. A tracheal ventilation device as in claim 29, wherein the upper surface of the cuff has a conical concavity.

31. A tracheal ventilation device as in claim 24, wherein the expandable cuff is inflatable.

32. A tracheal ventilation device as in claim 24, wherein the expandable cuff is self-expanding.

33. A tracheal ventilation device comprising:

a tube having a distal end, a proximal end, and an aspiration lumen therethrough; and

an expandable cuff at a distal end of the tube, said cuff having when expanded a periphery which seals against a tracheal wall and an upper surface adapted to collect and pool nasal secretions, wherein the aspiration lumen is coupled to aspirate the pooled secretions;

a one-way valve in the cuff to permit air from the lungs to pass upwardly into the larynx when the cuff is expanded in the trachea.

34. A tracheal ventilation device as in claim 33, wherein the tube has at least a second lumen for ventilation.

35. A tracheal ventilation device as in claim 34, wherein the tube has at least a third lumen for inflating an inflatable expandable cuff.

36. A tracheal ventilation device as in claim 35, wherein the second lumen is connected to a one-way valve in the cuff that permits air flow to the larynx.

37. A tracheal ventilation device as in claim 33, wherein the tube is hinged to allow axial alignment of the cuff during deployment and upward orientation of the cuff after entry to the trachea.

38. A tracheal ventilation device as in claim 33, wherein the upper surface has a concave region for collecting and pooling the nasal secretions.

39. A tracheal ventilation device as in claim 38, wherein the upper surface of the cuff has a conical concavity.

40. A tracheal ventilation device as in claim 38, wherein the expandable cuff is self-expanding.

41. A tracheal ventilation device as in claim 33, wherein the expandable cuff is self-expanding.

42. A tracheal ventilation device comprising:

a tube having a distal end, a proximal end, and an aspiration lumen therethrough;

an expandable cuff at a distal end of the tube, said cuff having when expanded a periphery which seals against a tracheal wall and an upper surface adapted to collect and pool nasal secretions, wherein the aspiration lumen is coupled to aspirate the pooled secretions; and

a ventilator fitting having one end adapted to removably mount in a tracheal access device, a second end adapted to removably connect to a ventilator, and a passage therethrough to receive the tube.

43. A tracheal ventilation device as in claim 42, wherein the tube has at least a second lumen for ventilation.

44. A tracheal ventilation device as in claim 43, wherein the tube has at least a third lumen for inflating an inflatable expandable cuff.

45. A tracheal ventilation device as in claim 44, wherein the second lumen is connected to a one-way valve in the cuff that permits air flow to the larynx.

46. A tracheal ventilation device as in claim 42, wherein the tube is hinged to allow axial alignment of the cuff during deployment and upward orientation of the cuff after entry to the trachea.

47. A tracheal ventilation device as in claim 42, wherein the upper surface has a concave region for collecting and pooling the nasal secretions.

48. A tracheal device as in claim 47, wherein the upper surface of the cuff has a conical concavity.

49. A tracheal ventilation device as in claim 42, wherein the expandable cuff is inflatable.

50. A tracheal ventilation device as in claim 42, wherein the expandable cuff is self-expanding.

51. A tracheal ventilation system comprising:

a tracheal access device adapted to anchor in a hole in the trachea and provide an open access passage there-through; and

a tracheal ventilation device adapted to be removably secured in the tracheal access device.

52. A tracheal ventilation system as in claim 51, wherein the tracheal access device comprises:

a base having a posterior surface adapted to cover a tracheal penetration;

a conduit having an access lumen disposed through the base and adapted to pass through the penetration; and

an anchor on a posterior portion of the conduit, said anchor shiftable between an expanded anchoring configuration and an unexpanded deployment configuration.

53. A tracheal ventilation system as in claim 51, wherein the tracheal ventilation device comprises:

a tube having a distal end, a proximal end, and an aspiration lumen therethrough; and

an expandable cuff at a distal end of the tube, said cuff having when expanded a periphery which seals against a tracheal wall and an upper surface adapted to collect and pool nasal secretions, wherein the aspiration lumen is coupled to aspirate the pooled secretions.

54. A method for providing tracheal ventilation, said method comprising:

forming a percutaneous hole into a patient's trachea;

introducing a tracheal ventilation device through the hole;

expanding a cuff on the ventilation device to isolate the trachea below the cuff, wherein the trachea below the cuff is otherwise unblocked to permit air exchange through the ventilation device; and

aspirating collected nasal secretions from a collection location on an upper surface of the cuff.

55. A method as in claim 54, wherein the cuff is expanded within the trachea at a position above the percutaneous hole.

56. A method as in claim 55, wherein the nasal secretions pool in a concavity in the upper surface of the cuff from where they are aspirated.

57. A method as in claim 56, wherein the nasal secretions are aspirated through a vertical passage through the expanded cuff.

58. A method as in claim 54, further comprising anchoring an access device through the percutaneous hole, wherein the tracheal ventilation device is removably introduced through an access passage of the access device.

59. A method for providing tracheal ventilation, said method comprising:

forming a percutaneous hole into a patient's trachea;

anchoring an access device in the percutaneous hole; and

removably introducing a tracheal ventilation device through an access passage of the access device.

60. A method as in claim 59, further comprising expanding a cuff on the tracheal ventilation device.

61. A method as in claim 60, wherein the trachea below the cuff remains otherwise unblocked to permit air exchange through the ventilation device.

62. A method as in claim 61, further comprising aspirating nasal secretions from a collection location on an upper surface of the cuff.

63. A method as in claim 59, further comprising removably introducing a ventilation fitting in the access passage of the access device, wherein the tracheal ventilation device is positioned through.

* * * * *