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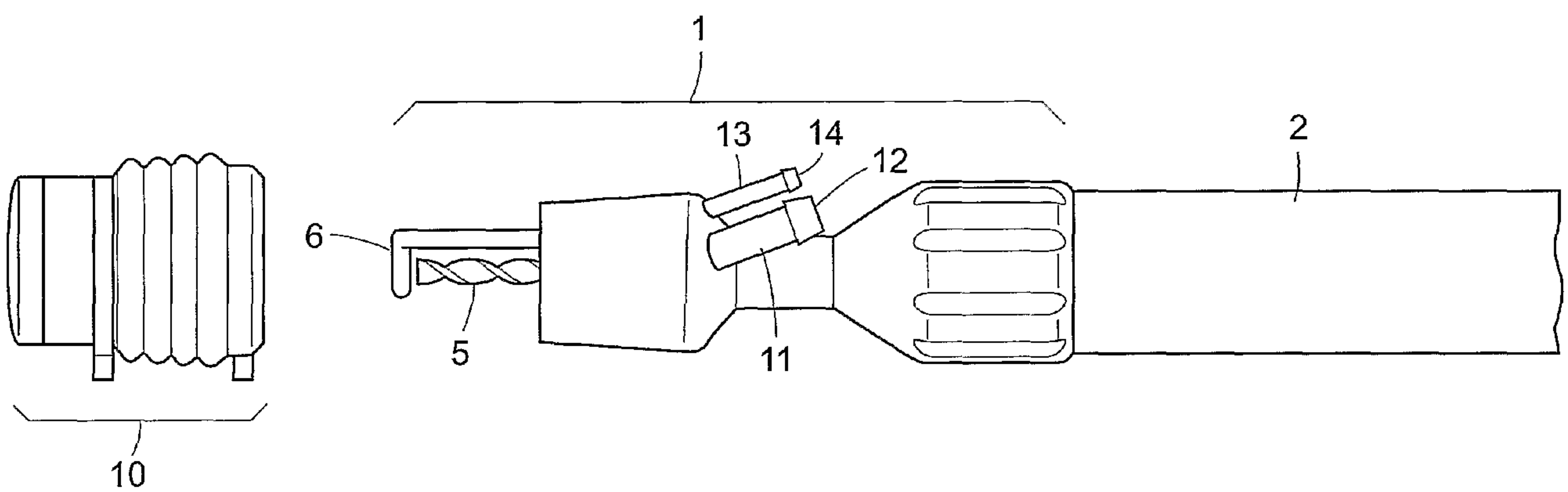
(54) Title: AUTOLOGOUS BONE HARVEST DURING OSTEOTOMY AND BONE DRILLING PROCEDURES



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An apparatus and method for collecting particulate bone from the operating site during an osteotomy or bone drilling procedure so that it can be used subsequently to augment the bone fusion process. A bone cutting or drilling tool is provided with a module for collecting particulate bone simultaneously with cutting or drilling the bone. The collected particulate bone is transferred continuously to a sterile containment module and maintained under sterile conditions until it is prepared for re-use in the patient.

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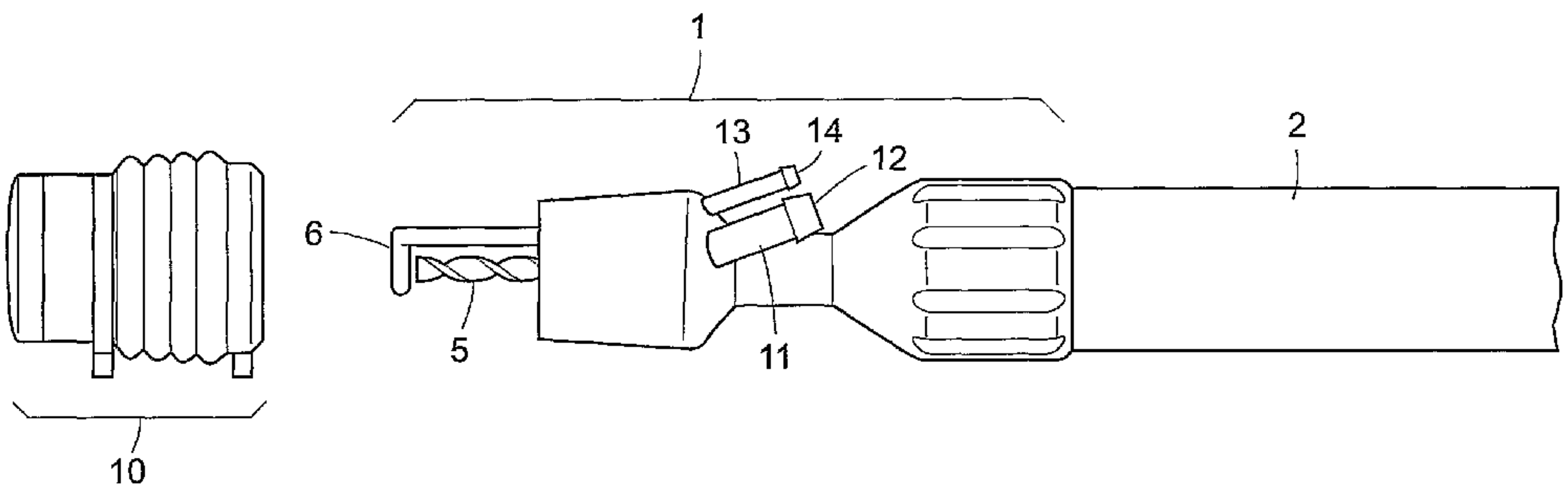

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AUTOLOGOUS BONE HARVEST DURING OSTEOTOMY AND BONE DRILLING PROCEDURES

BACKGROUND OF THE INVENTION

The present application claims priority from U.S. Application No. 11/409,816 filed April 24, 2006, the disclosure of which is incorporated herein by reference.

Field of the Invention

The present invention has to do with apparatus and methods for performing osteotomies and drilling holes in bones. More specifically, the invention relates to apparatus and methods for harvesting bone from the operating site during the osteotomy or bone drilling procedure so that it can be used to augment the bone fusion process.

The Related Art

Osteotomies are routinely performed for surgical access or to divide (and reposition) a bone for the correction of a skeletal deformity. Holes may be drilled in bones for various reasons to accommodate screws, pins and various other implantable devices and materials or to take a bone sample for analysis.

One of the more common examples of an osteotomy for surgical access is a craniotomy. In this procedure, the surgeon removes a significant portion of the patient's skull (termed a craniotomy flap, a cranial flap, a skull flap or bone flap) for access to the brain. The removed section of the skull is set aside in a sterile field and at the end of surgery, it is returned to its original position and affixed to the native skull, typically with plates and screws. The intent of the surgeon is to restore the patient's skull to its original contour and to provide physical protection for the brain. The ideal outcome would be complete fusion of the craniotomy flap to the native skull, leaving no long term bony deficit or weakness. In addition, many surgeons would prefer there to be minimal foreign bodies remaining and no imaging artifacts postoperatively. Unfortunately this is difficult to accomplish with the current surgical techniques.

The surgical instrument used to cut the craniotomy (a craniotome) utilizes a rotating cutter approximately 2mm in diameter. The bone that is removed by this instrument is lost during surgery and as a result, when the cranial flap is returned to its original position, there is a gap around the entire periphery which corresponds to the diameter of the cutter. This gap creates a number of problems. The most obvious deficiency is that bone-to-bone contact, essential for achieving bony fusion, is impossible around the periphery of the cranial flap. This continuous gap (or kerf) creates a surgical "dead space" which is never desirable, it also allows soft tissue (the scalp and dura) to intrude into this space and inhibit bony healing. The step-off between the skull and cranial flap also may result in a cosmetic deformity for the patient. To combat these problems, surgeons use one or more strategies which have their own shortcomings. For example, the surgeon may choose to bias the cranial flap toward one side of the craniotomy. This produces bone-to-bone contact in a local area but increases the gap elsewhere around the periphery.

The surgeon may also elect to fill the gap between the skull and skull flap with a material which will encourage bony fusion. These fill materials can be autologous, allograft, or artificial. Autologous bone grafts are harvested directly from the patient and are the "gold standard," since they are inherently biocompatible, osteoconductive, osteoinductive, and osteogenic. Harvesting autologous bone is currently carried out by taking bone from a part of the patient's body other than the surgical site. This results in additional surgical time and the additional (surgical) harvest has its own attendant risk of complications such as donor site pain and morbidity. Allografts, derived from donor (cadaver) tissues, are only osteoconductive, and they involve considerable cost, pose the risk of disease transmission and are objectionable to certain religious groups. Artificial materials such as alloplastic bone cement are another alternative. These bone cements are almost always used in conjunction with plates and screws. The drawbacks to this approach include substantial additional cost, risk of infection and no certainty that the bone cement will ever remodel into actual bone.

While this problem is illustrated with a craniotomy example, it occurs whenever an osteotomy is created strictly for surgical access and the bones must be returned to their original positions in order to prevent a postoperative deformity or a functional problem. In the skull alone, this problem exists in skull base surgery, craniofacial tumor surgery and mandibular osteotomies for oncologic resection. At the conclusion of all these procedures, the surgical goal is to restore the original bony anatomy. This precludes achieving bone-to-bone contact of the severed ends since they must remain separated by the width of the blade (or cutter) used for the osteotomy.

Perforations (or holes) are routinely created in bones for surgical access and other reasons. These perforations may be performed for biopsy purposes, to create access for minimally invasive surgery or as the prelude to an osteotomy. An example of the latter is the burr hole that is initially created in the skull which allows the craniotome to be inserted for completion of the craniotomy. In these cases, it is desirable to close the perforation, preferably in a manner which restores the bone to its original condition. Additionally, holes are routinely drilled into bone as a step in preparation for orthopaedic screw or pin insertion. Most of these cases would also benefit from the availability of autologous bone graft.

When osteotomies are used to divide a bone so that it may be repositioned to correct a surgical deformity, a different problem exists. In many cases, bone graft material is needed to fill the gaps created as the bones are repositioned and severed bony ends move relative to each other. This is obviously the case where a gap is intentionally created, such as an osteotomy to elevate a collapsed tibial plateau. It also may occur when the intent of the osteotomy is to decrease the bone volume. In these surgeries it is not uncommon for the contours of the bony ends to be slightly mismatched and in these cases the surgeon may elect to augment the fusion with additional bone graft material. As previously discussed, allograft bone, autogenous bone or alloplastic materials may all be used in such situations, each with their related problems.

In all these procedures where an osteotomy (or perforation) is necessary, a common problem exists: bone is removed by the osteotomy or drilling instrument and at the conclusion of surgery, additional bone is required to complete the reconstruction.

The current surgical practice is to manually irrigate the bone as it is cut and also to manually suction off the resulting solids and liquids into the operating room's non-sterile vacuum system. These activities are performed concurrently by other operating room personnel while the surgeon operates the osteotomy instrument. Some of the shortcomings of these practices are detailed in the following text which is excerpted from the USC Neurosurgery website. (http://uscneurosurgery.com/infonet/ecrani/instruments.htm).

Irrigation

> With even optimal illumination and magnification and organization of his field, the surgeon is still incapacitated by obscuring blood, cloudy irrigation fluid, or other debris. Efficient intracranial surgery requires

keeping the operative field clear of physical and visual obstacles by diligent irrigation, attentive aspiration, and meticulous hemostasis.

Irrigation and aspiration are complimentary aspects of surgical field maintenance. The irrigating-aspirating assistant must concentrate on following the movements of the surgeon's hands visually and with irrigant and suction. Areas of surgical interest are most safely addressed at the time of maximal cleanliness; immediately after they have been washed clean and aspirated dry.

Irrigant should be squirted onto the field under enough pressure to displace blood, but if the bulb is squeezed too hard and fluid issues under too much pressure, fluid from the bulb will be reflected back against the stream because it cannot dissipate fast enough, with the consequence that a splashing of mixed blood-irrigant fluid ends up in the surgeon's face and widely scattered across the field. Better control of the stream from the irrigation fluid bulb is achieved by manipulating it with the dominant hand.

The primarily aqueous solution used for surgical irrigation not only dilutes the blood but pushes it ahead of the irrigant stream. This washing force is greatest at the tip of a irrigation bulb where the irrigant fluid pressure is maximal.

Suction

Blood accumulates with irrigation fluid in dependent portions of the field as it escapes and is washed from lacerated vessels. The bloody fluid then interferes with the working of the electrocautery devices used to stop further bleeding from the openings in the vessels. To this is added the problem of blood's opacity, so that even in small quantities as even a thin layer, it obscures the surgical field.

Suction is a maintenance activity, keeping the operative field clear of debris, blood, or smoke that can obstruct visualization. Whenever possible the suction attachment should be held in the non-dominant hand.

Surgical field suction instrumentation attaches to the same suction canisters which provide suction for anesthesia. Distally non-sterile, proximally sterile tubing connects the suction device to the distal end of

> the metal suction handle and tip. The proximal end of the metal sucker connects to the suction tubing.

The importance and difficulty of performing simultaneous irrigation and suction in concert with the surgeon's movements are detailed above. Later in the text they discuss the importance of irrigation when cutting the bone:

> Bone is perforated and/or cut in the course of any intracranial trauma surgery. Irrigation accomplishes two purposes in the setting of drilling bone. First, it cools down the bone. This is important in terms of the mechanics of bone cutting. The bits cut more effectively through cooler bone and in the absence of bone dust that can clog its rotations.

These comments are directed toward neurosurgical craniotomies but the same principles apply to all osteotomies and perforations. Proper irrigation not only improves the efficiency of the cutting instrument, it also prevents thermal necrosis of the bone which can later retard the healing process. This principle takes on even greater importance when one intends to collect the bone particles generated during the cutting process and reuse them in surgery. Irrigation has traditionally been conducted using a liquid. But according to the present invention we can irrigate with a liquid or compressed gas source or a combination of liquid and a compressed gas source. The compressed gas can be chilled if required and also can be intermixed with a fluid (e.g., saline).

Up until now, a reliable and essentially free source of autogenous bone has been overlooked by the surgical community. Manufacturers of surgical cutting instruments have incorporated irrigation on some instruments but none have ever proposed taking the concept one step further – collecting the bone particulate in a sterile fashion for later use in the bony reconstructive phase of the surgery.

We have now developed apparatus and methods for sterilely collecting and containing the particulate bone created during osteotomy and bone drilling procedures. The apparatus and methods also enable more controlled irrigation of the bone as it is cut or drilled and a reduction in the amount of patient bone that is scattered or aerosolized during surgery.

The terms particulate bone, bone particulate and bone particles are used interchangeably in this patent and all are intended to have the same meaning.

SUMMARY OF THE INVENTION

A collection module is provided on the cutting end, also referred to herein as the distal end, of a bone cutting tool to prevent the scatter and loss of particulate bone created at the operating site during an osteotomy or bone drilling procedure. The collection module suctions off the bone particulate as well as irrigant, blood and other body fluids and reduces contamination of the surgical field from the cutting operation. The module can be partially or completely disposable.

The collection module contains a suction port which evacuates the particulate bone from the cutting operation. A sterile containment module is provided downstream for collecting the particulate bone and separating it from irrigant and body fluids suctioned off from the surgical field.

An irrigation system is incorporated in some cutting tools and when it is not, it can be incorporated in the collection module to provide a reliable and effective source of irrigation to the cutting area. The irrigant prevents thermal necrosis, prevents the formation of bone dust, improves cutting efficiency and improves visibility within the surgical field. As previously disclosed, the irrigation system in our invention can disperse fluids, gasses or a combination of the two.

The sterile bone particles which are harvested according to the invention are used to augment the reconstructive portion of the surgery. The particulate bone can be used "as is" or mixed with any number of readily available additives such as, but not limited to:

a. Patient's blood;
b. Patient's platelet rich plasma (PRP);
c. Bone morphogenic proteins;
d. Other bone growth factors; and
e. Antibiotics.

BRIEF DESCRIPTION OF THE DRAWINGS

The drawing figures are provided for purposes of illustrating the elements of the invention and are not intended to be drawn to scale.

FIG. 1 is an expanded perspective view of a bone cutting tool (a craniotome) of the invention which has been provided with integral irrigation and suction systems. A collection module of the invention is illustrated to the left before attachment to the tool. The craniotome is attached to a handpiece which in turn is attached to a pneumatic line or an electric power source.

FIG. 2 is a perspective view of the craniotome of FIG. 1 with the collection module and the pneumatic line attached.

FIG. 3 is an elevation view of the craniotome of FIG. 2.

FIG. 3A is a view of the left end of FIG. 3.

FIG. 4 is a section view of FIG. 3A taken at section line 4-4 of FIG. 3A and illustrating a portion of the suction system.

FIG. 4A is a section of FIG. 3A taken at section line 3-3 of FIG. 3A and illustrating a portion of the irrigation system.

FIG. 5 is an elevation view of a collection module of the invention.

FIG. 6 is a distal end view of the collection module of FIG. 5.

FIG. 7 is a section view of the collection module of FIGS. 5 and 6.

FIG. 8 is an expanded elevation view of a standard prior art craniotome and a collection module of the invention. This embodiment of a collection module is for use with standard craniotomes and is illustrated to the left before attachment to the tool.

FIG. 9 is an elevation view of the craniotome of FIG. 8 with the collection module and the pneumatic line attached.

FIG. 9A is a view of the left end of FIG. 9.

FIG. 10 is a section view of FIG. 9A taken at section line 10-10 of FIG. 9.

FIG. 11 is an elevation view of the collection module of FIGS. 8-10.

FIG. 12 is a distal end view of FIG. 11.

FIG. 13 is a section view of the collection module of FIGS. 11 and 12 taken at section line 13-13 of FIG. 12.

FIG. 14 is an illustration of an apparatus of the invention in operation during a cranial osteotomy.

FIG. 15 is a perspective view of a drill guide of the invention which can suction and collect bone particulate during a bone drilling procedure.

FIG. 16 is a bottom view of FIG. 15.

FIGS. 17 and 18 are partial section views of FIG. 16. FIG. 17 is taken at section line 17-17 of FIG. 16 and FIG. 18 is taken at section line 18-18 of FIG. 16.

FIG. 19 is a perspective view of the guide of FIG. 15 illustrating the relationship of the guide to a drill and a bone plate.

FIG. 20 is a partial section of FIG. 19 taken at section line 20-20 of FIG. 19.

FIG. 21 is a perspective view of another embodiment of a bone particulate collection system for use with a drill.

FIG. 22 is a distal end view of FIG. 21.

FIG. 23 is a section view of FIG. 22 taken at section line 23-23 of FIG. 22.

FIG. 24 is an elevation view of a transparent embodiment of the FIG. 21 collection module affixed to a drill.

FIG. 25 is an enlarged section view of a portion of FIG. 24.

FIG. 26 illustrates a sterile containment module of the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 1 is an expanded perspective view of a bone cutting tool of the invention having integral irrigation and suction systems. The tool is a craniotome which is used to cut an opening in the skull for brain surgery. The craniotome **1** is attached to a handpiece **2** which in turn is attached to a pneumatic line **3** (see Figs. 2-4) or an electric power source. Cutting burr **5** is actuated by a foot switch (not shown) and the foot plate **6** is used to guide the tool along the inside of the skull in order to prevent penetration of the dura. A suction tube **11** is provided with a barbed fitting **12** and an irrigation tube **13** has a barbed fitting **14**. Collection module **10** is illustrated before it is attached to craniotome **1**.

FIG. 2 is a perspective view of FIG. 1 with the collection module **10** of the invention attached to the craniotome. A flexible bellows **15** is shown in this embodiment with a shield **16** and an elastomeric seal **17** at the distal end. The shield **16** normally will be comprised of a relatively stiff, clear plastic tube.

FIG. 3 is an elevation view of FIG. 2 and FIG. 4 is a section view of FIG. 3.

FIG. 4 illustrates suction tube **11** which has an open mouth **23** at its distal end around cutting burr **5**. FIG. 4A is a different section view of FIG. 3 which illustrates irrigation tube **13** of the irrigation system.

FIG. 5 illustrates the collection module **10** in an elevation view and FIG. 6 illustrates the distal end of the collection module **10**. FIG. 7 is a section view of the collection module **10**.

FIG. 8 illustrates in expanded elevation another embodiment of the invention. Collection module **110** is made for use with a standard prior art craniotome **101**. FIG. 9 is an elevation view of craniotome **101** with collection module **110** affixed thereto. The collection module **110** comprises a suction tube **111** having a barbed fitting **112**, an irrigation tube **113** having a barbed fitting **114**, a flexible bellows **115** and a clear tubular shield **116**. An optional indicator tab **119** is also illustrated. The craniotome has a foot plate **106** and a cutting burr **105**.

FIG. 10 is a section view of FIG. 9 illustrating the relationship of the elements of collection module **110** to the craniotome **101**. In particular, the suction tube **111** connects to a suction channel **121** and the irrigation tube **113** connects to an irrigation channel **123**.

FIG. 11 is an elevation view of the collection module **110** by itself. The collection module **110** provides the irrigation and suction capability needed to carry out the objectives of the invention when a standard craniotome having no irrigation or suction capability is employed. (Some commercially available craniotomes have irrigation capability in which case the embodiment of FIG. 11 described herein can be made with suction capability but without irrigation capability as will be apparent to those skilled in the art.) This embodiment does not employ a seal of the type illustrated as element **17** in FIGS. 1-7. In FIG. 12, the distal end of the module is illustrated with an opening **118** for a cutting burr and foot plate. An irrigation port **133** is also provided. Referring to the section view FIG. 13, the irrigation port **133** and the irrigation channel **123** are illustrated as well as the suction channel **121** and a suction port **131**.

FIG. 14 illustrates the operation of the distal (cutting) end of the embodiment of the invention illustrated in FIGS. 1-7. The craniotome **1** has a cutting burr **5** (and burr shaft **5a**) and an integral foot plate **6**. Unlike current instruments, however, the improved craniotome of the invention has many advantageous features. In this embodiment, the craniotome also incorporates internal passages for suction and irrigation. Each of these terminates proximally in a barbed fitting. The collection module **10** comprises an elastomeric bellows **15**, a clear tubular shield **16** and an elastomeric seal **17**. The collection module can constitute a preassembled, sterile, disposable item, although other configurations are certainly possible.

The collection module **10** is adapted to the distal end of the craniotome **1** (as shown in FIGS. 2-4). Module **10** mates with the outer diameter of the craniotome **1** and is sealingly engaged therewith. The two are aligned in the correct orientation to set the slot **18** in the seal **17** in-line with the footplate **6**. Optional indicator tabs **19** (in the direction that the instrument will cut, **arrow 20**) can be used to facilitate correct orientation. The bellows **15** is constructed from an elastomer, allowing it to flex so that the distal portion of the collection module **10** can follow the irregularities of the skull **30** without excessive resistance. On the other end of the bellows is an internal lip seal **22** which prevents debris from being forced into the radial space between the craniotome

1 and the bellows **15**. It should be noted that the cutting burr, or the drill bit or saw blade in other tools, may or may not extend beyond the distal end of the module when the tool is not in use. This is because the collection module is sufficiently flexible to allow such burr, bit or blade to extend beyond the distal end of the module when the tool is in use.

The shield **16** is a relatively stiff, clear tubular section that forms the radial wall of the collection module **10**. Attached to the distal end of the shield **16** is the elastomeric seal **17**. Ideally this would be a relatively clear material as well to aid in visualizing the cut. The seal **17** has an optionally, outwardly domed flexible end with a slot **18** to better contain and suction the bone particulate. The domed shape limits the contact area with the bone to reduce resistance. As the surgeon operates the craniotome, he applies both sideways force to cut as well as upward force to keep the tip of the footplate **6** in contact with the underside of the skull. This allows the footplate to ride between the dura **4** (the outer covering of the brain **104**) and the inner table of the skull **30**. Ahead of the cutting burr **5** is solid skull **30** and trailing the cutting burr is the kerf **31**. The rotation of the cutting burr **5** and its helical flutes help to draw much of the bone particulate **32** upwards into a collection chamber **24** of the collection module. A funnel shaped depression or mouth **23** at the junction of the suction tube **11** and the distal face of the craniotome guides these bone fragments into the suction tube **11** and draws in by vacuum additional bone particles, irrigant and bodily fluids. The suction tube **11** is connected to a sterile vacuum tube **40**. A barbed fitting **12** is provided for this connection. The sterile vacuum tube **40** is connected downstream to a containment module **60** as will be discussed later. (See FIG. 26.) Suction is applied to tube **40** and the result is that all material aspirated into the collection module **10** (bone fragments, irrigant, blood, tissue, etc.) is evacuated in the direction of arrow **41**. The irrigation system is not illustrated because it is behind the suction system in this drawing. But the irrigation system is illustrated and discussed above in connection with FIGS. 1, 2 and 4A. Irrigant supply can be most easily provided from a pressurized IV bag of saline or from a hand syringe, peristaltic pump, sterile compressed gas source, or other common means. When the irrigant is a combination of gas and liquid an additional channel can be provided in either the craniotome of the invention (see FIGS. 1-4 and 14) or the collection module, for the purpose of introducing a second irrigation means. This additional channel could communicate with the liquid channel to serve as a mixing device as will be apparent to those having skill in the art based on the disclosures herein.

FIG. 15 is a perspective view of a drill guide of the invention which can suction and collect bone particulate in a sterile environment during a bone drilling procedure. The guide **201** comprises a handle **202** and a collection module **210**. Sterile vacuum tube **241** connects to suction tube **211** and irrigant supply tube **243** connects to irrigation tube **213** during operation of the guide. Opening **218** accommodates a drill bit **205** (see FIGS. 19 and 20) and irrigation and suctioning take place generally through the same opening. A bottom view of guide **201** is illustrated in FIG. 16.

FIGS. 17 and 18 are section views of collection module **210** taken through line A - A and line B - B, respectively, of FIG. 16. The FIG. 17 section illustrates a barbed fitting **212** at the end of suction tube **211** and the connection of tube **211** with suction chamber **221**. Irrigation channel **223** and irrigation ports **233** are illustrated. The FIG. 18 section illustrates another part of suction chamber **221**. The FIG. 18 section also illustrates the barbed fitting **214** at the end of irrigation tube **213** and the connection of tube **213** with irrigation channel **223**.

A perspective view illustrating the relationship of the guide with a drill **203**, drill bit **205** and a bone plate **206** is illustrated in FIG. 19. FIG. 20 is a partial section of FIG. 19 illustrating the relationship of drill bit **205** to the suction chamber **221**, irrigation channel **223** and irrigation ports **233**. During drilling, bone particulate is carried upward by the drill bit **205** and by suction. Suction vacuum tube **241** is connected to suction tube **211** and the particulate bone is carried by vacuum to a sterile containment module **60** (see FIG. 26). The operating area is irrigated by irrigant exiting irrigation ports **233**.

FIG. 21 is a perspective view of another embodiment of a bone particulate collection system for use with a drill. Collection module **310** is comprised of an outer telescoping section **301** and an inner telescoping section **302**. A spring **304** is biased between section **301** and distal end section **303**. When drilling, inner telescoping section **302** telescopes into outer telescoping section **301** and when the drilling is complete spring **304** returns section **302** to its original position (as illustrated). Sterile vacuum tube **341** and irrigant supply tube **343** are also illustrated.

FIG. 22 is a distal end view of the collection module **310** also illustrating opening **318** which accommodates a drill bit **305** (see FIGS. 24 and 25) and irrigation and suctioning take place through the same opening.

FIG. 23 is a section view of collection module **310** illustrating a collection chamber **321** and irrigation duct **323** in relation to opening **318**.

FIG. 24 is an elevation view of a transparent embodiment of collection module **310** affixed to drill **303** having a drill bit **305**. An enlarged section view of a portion of FIG. 24 is provided in FIG. 25. Arrow **320** illustrates the direction of the telescoping movement of section **302** into section **301** when the drill bit is drilled into a bone. Spring **304** causes section **302** to return to the position illustrated when drilling is completed. Sterile vacuum tube **341** is in suctioning communication with suction chamber **321** and irrigant supply tube **343** is in irrigating communication with irrigation duct **323**. The suctioning and irrigating operations function in the same manner as the other embodiments of the invention discussed above.

FIGS. 1-25 depict just a few possible configurations of a cutting or drilling and collection apparatus of the invention which would be consistent with the method of the invention. The principles of the invention can easily be adapted to other osteotomy instruments (e.g. an oscillating saw, a rotary saw or a reciprocating saw) to achieve the same results.

According to the method of the invention, a surgeon can simultaneously cut or drill bone and irrigate and suction with essentially no additional effort. Eliminated is the splatter of the irrigant and cutting debris and also the need for an assistant to precisely coordinate with the movements of the surgeon as he or she irrigates and suctions. These benefits however, are secondary to the main purpose of the apparatus and method of the invention, namely, the ability to collect the sterile bone particulate generated by the osteotomy or drilling process for use in the reconstructive portion of the procedure.

FIG. 26 illustrates an embodiment of a sterile containment module **60** for the separation of the bone particles **32** from liquids **33**, the liquids comprising irrigant and body fluids. Unlike traditional hospital suction systems, this is a sterile system so that the bone particles collected can be reused in the reconstructive portion of surgery.

The aspirate from the containment chamber is conveyed though the sterile vacuum tube **40** to the containment module **60**. The aspirate consists of bone particles, irrigant, small amounts of tissue, blood and other body fluids. The containment module comprises three sterile parts: the canister **61**, the collection cup **62** and the cover **63**. Of course, other embodiments are certainly possible and would be apparent to those skilled in the art based upon the disclosures herein. It is envisioned that all three items would be provided as a sterile unit for single use. All could be produced (molded) from a clear polymer for visualizing the contents. The suction tube **40** connects to a fitting **64** molded into the cover. A second fitting **65** is then connected to the hospital suction system in a sterile fashion through tube **66**. The suction travels in the direction of the arrows **67**. When the aspirate enters the canister **61**, a deflector **68** forces the flow downward and gravity then separates the contents (solid and liquid) from the air flow. The solids and liquids fall into the cup **62** and settle to the bottom where perforations **69** allow the liquid to drain into the bottom of the canister **61**. Optionally the cup may be fitted with a filter to better trap the smaller bone particles. At the conclusion of the osteotomy or drilling procedure, the bone particles in the cup can be left to drain until needed, at which point the cover **63** is removed and the cup **62** is extracted with its sterile contents. As mentioned previously, the bone particles can then be used "as is" or mixed with other biological additives for use in the reconstructive portion of the procedure.

In today's operating room environment, the contents of the canister **61** described above are simply suctioned into the non-sterile hospital system and discarded. A valuable and much-needed commodity, (autologous) bone graft, is simply wasted and later replaced with autograft harvested from a second site, allograft or with alloplastic materials.

WHAT IS CLAIMED IS:

1. Apparatus for collecting particulate bone for use in combination with a bone cutting or drilling tool during an osteotomy or bone drilling procedure, the bone cutting or drilling tool having a distal end with a bone cutting or drilling element, comprising

a collection module adaptable to the distal end, the module comprising an open distal end and a suction port opening into the distal end.

2. The apparatus of claim 1 further comprising an irrigation port opening into the distal end.

3. The apparatus of claim 1 wherein the collection module is flexible.

4. The apparatus of claim 1 wherein the bone cutting or drilling element extends beyond the distal end of said module.

5. The apparatus of claim 1 further comprising a means of containing the particulate bone.

6. The apparatus of claim 1 wherein the collection module is disposable.

7. Apparatus for cutting or drilling bone and collecting particulate bone during an osteotomy or a bone drilling procedure comprising

a bone cutting or drilling tool having a distal end comprising a bone cutting or drilling element,

a collection module adapted to the distal end, the module comprising a suction port opening into the open distal end.

8. The apparatus of claim 7 wherein the module further comprises an irrigation port opening into the distal end.

9. The apparatus of claim 7 wherein the collection module is flexible.

10. The apparatus of claim 7 wherein the bone cutting or drilling element extends distally from said module through an open distal end of said module.

11. The apparatus of claim 7 wherein the bone cutting or drilling tool further comprises an irrigation port opening into the distal end.

12. Apparatus for cutting or drilling bone and collecting particulate bone during an osteotomy or bone drilling procedure comprising

a bone cutting or drilling tool having a distal end comprising a bone cutting or drilling element and a suction port

a collection module adapted to the distal end, said module being sealingly engaged with the tool at the proximal end of the module and having an opening at the distal end of the module wherein the bone cutting or drilling element can extend distally through the opening and beyond the distal end of the module, and the suction port is in suctioning communication with the opening.

13. The apparatus of claim 12 wherein the bone cutting or drilling tool further comprises an irrigation port opening into the distal end and the irrigation port is in irrigating communication with the opening.

14. The apparatus of claim 12 wherein the collection module is flexible.

15. The apparatus of claim 12 wherein the collection module is disposable.

16. A method of assembling an apparatus for cutting or drilling bone and collecting particulate bone during an osteotomy procedure or bone drilling comprising affixing to the distal end of a bone cutting or drilling tool, the distal end comprising a bone cutting or drilling element, a collection module having an open distal end, the bone cutting element capable of extending distally through said open distal end, the module or the tool comprising a suction port in suctioning communication with said open distal end.

17. The method of claim 16 wherein the module or the tool further comprise an irrigation port opening into said open distal end and in irrigating communication with said open distal end.

18. A method of collecting particulate bone created at the operating site during an osteotomy or bone drilling procedure comprising cutting or drilling the bone with a bone cutting or drilling tool having a distal end, the distal end comprising a bone cutting or drilling element and a collection module, the bone cutting element extending distally from an open distal end of the collection module during cutting, the module or tool comprising a suction port opening into the open distal end, and suctioning the particulate bone from the operating site into the collection module.

19. The method of claim 18, wherein the module or tool further comprises an irrigation system having an irrigation port opening into the distal end, further comprising irrigating the operating site during the osteotomy or bone drilling procedure.

FIG. 1

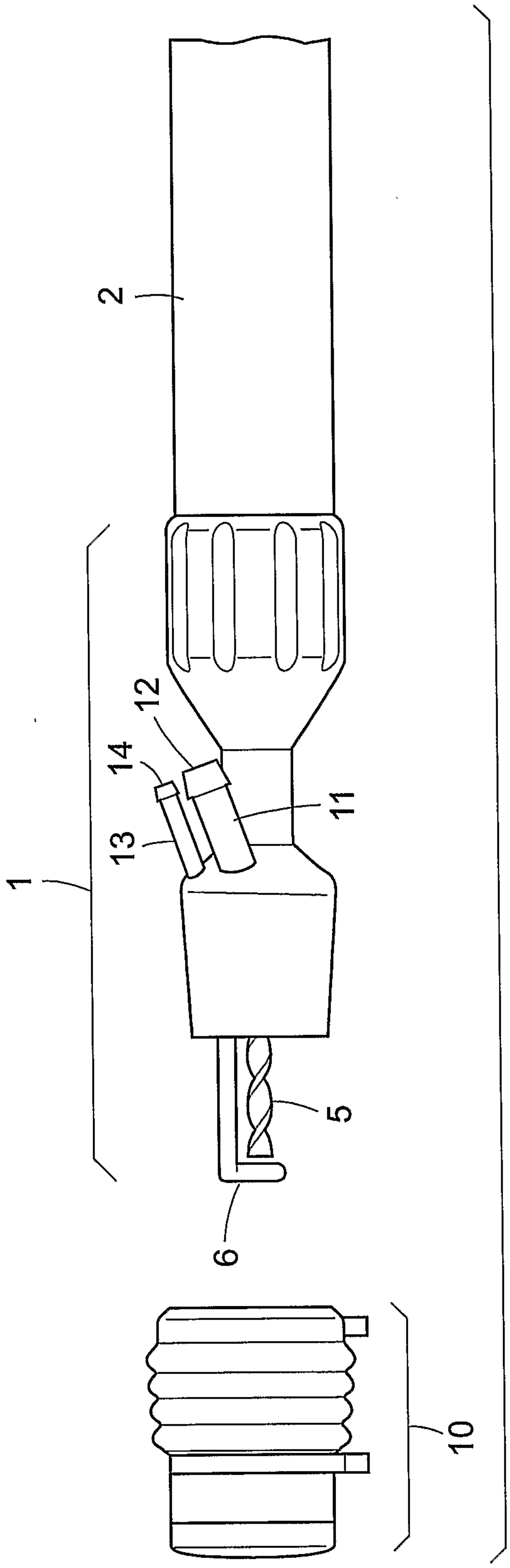

FIG. 2

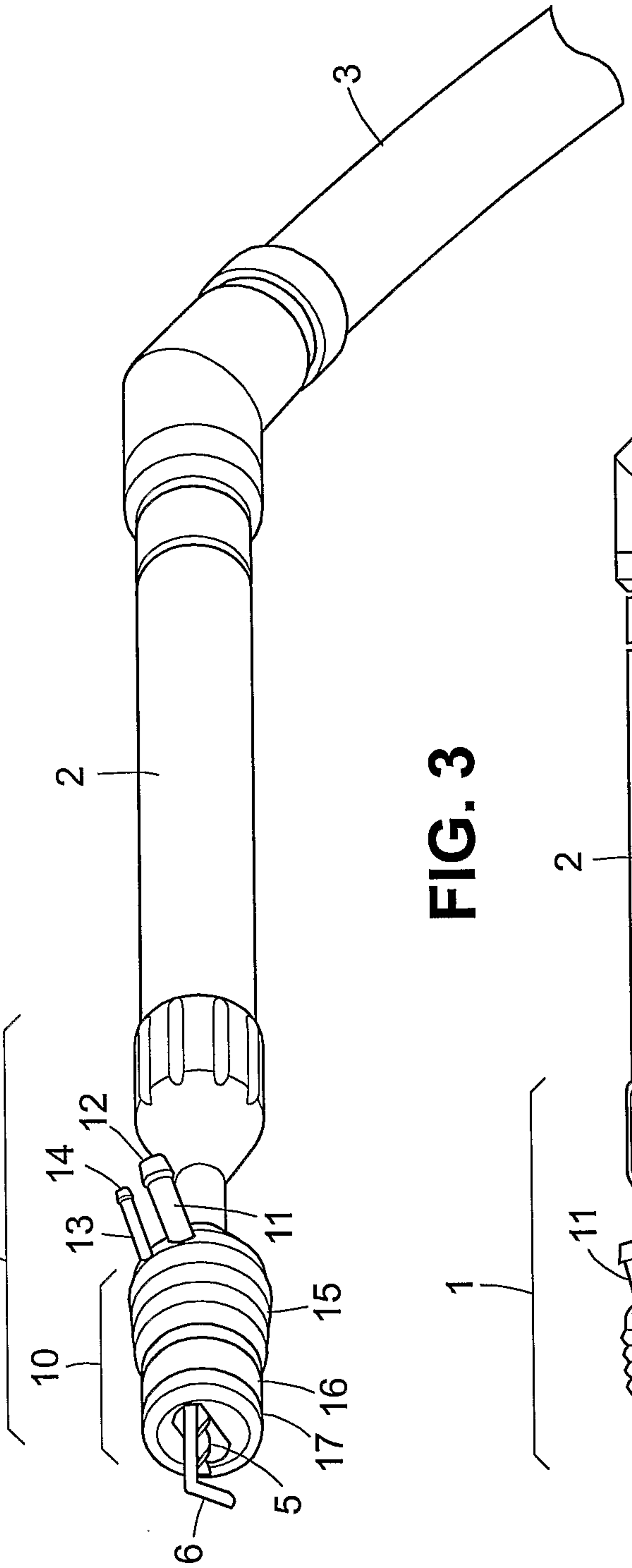

FIG. 3

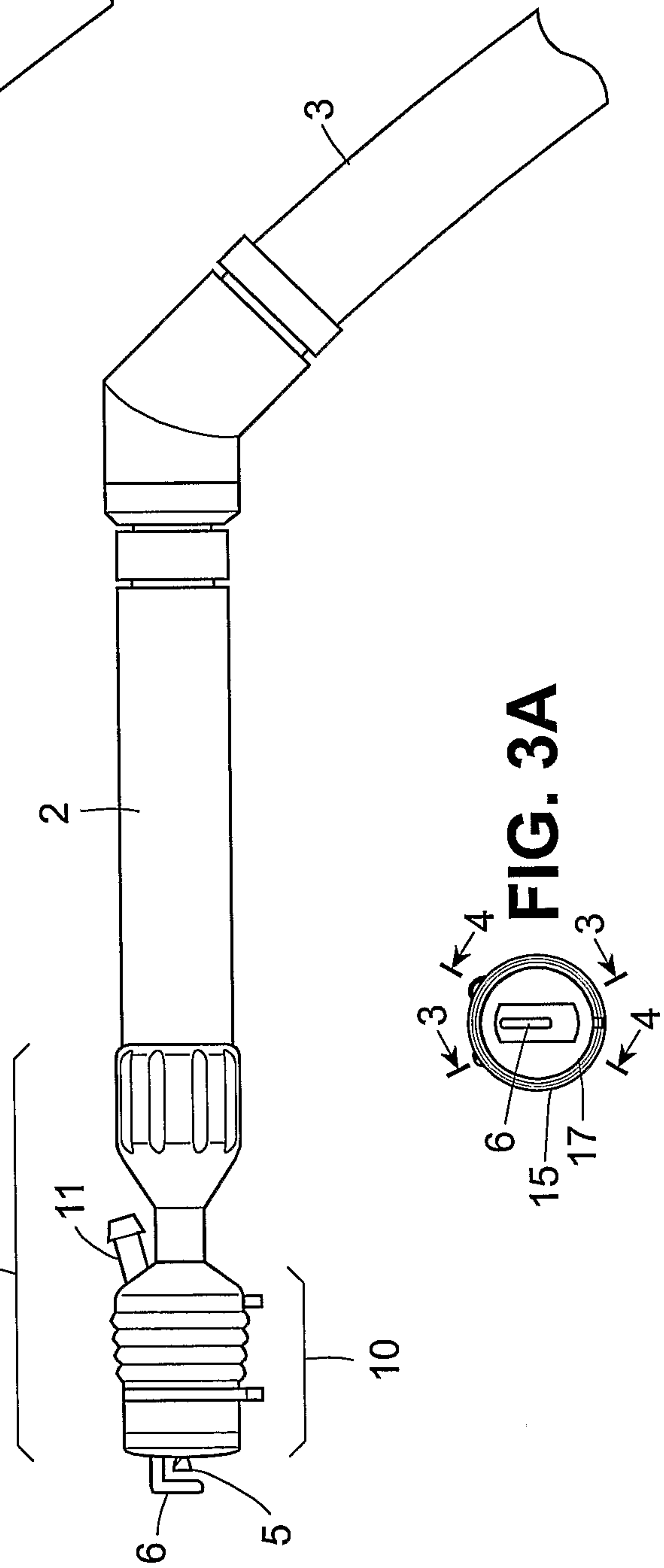

FIG. 3A

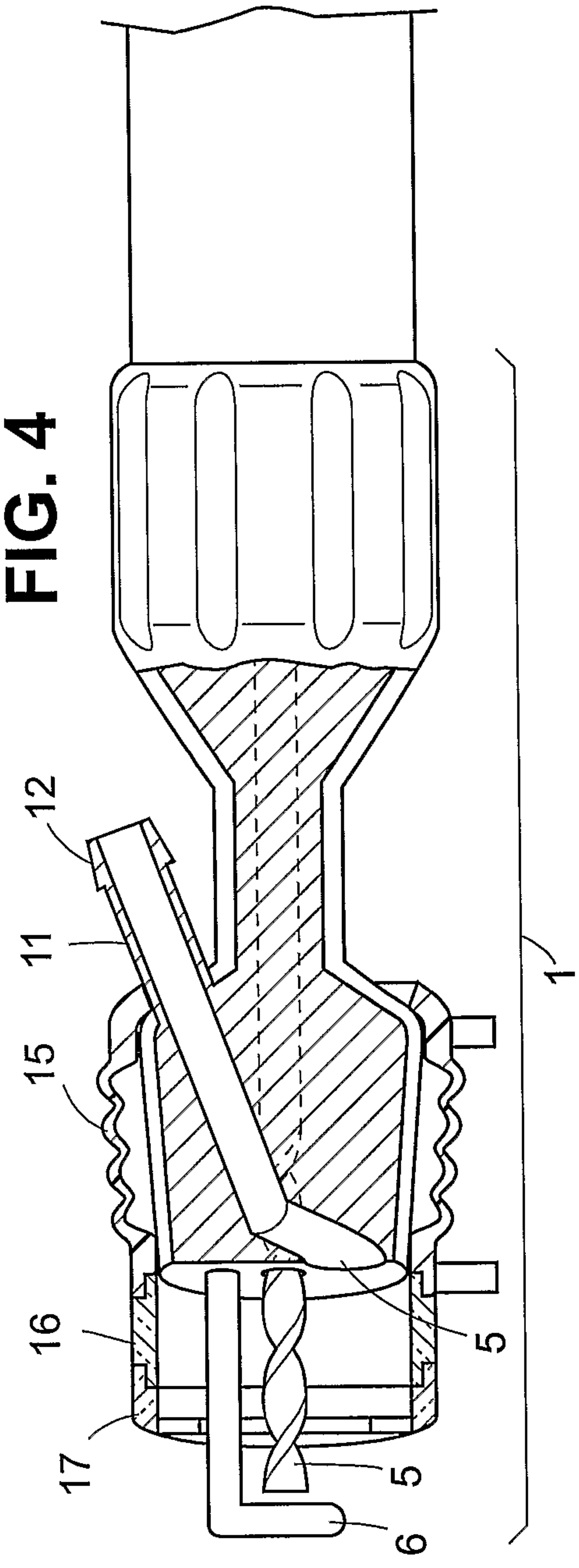

FIG. 4

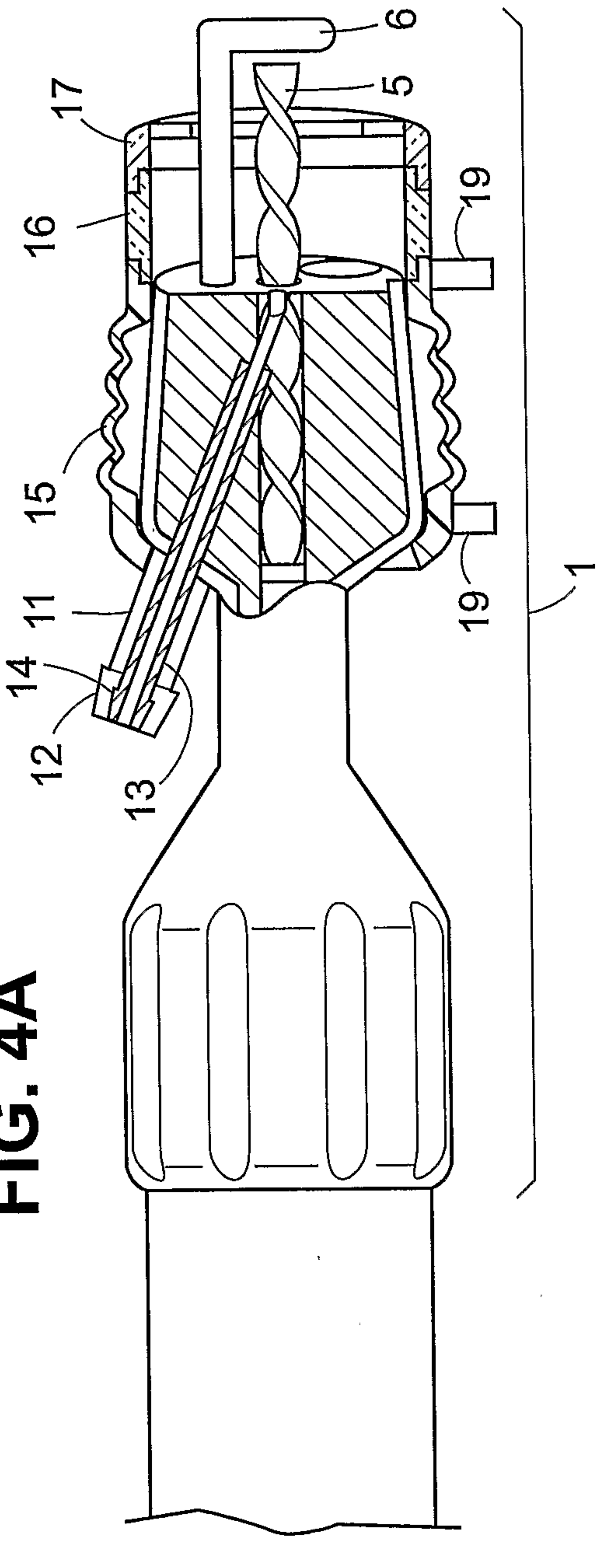

FIG. 4A

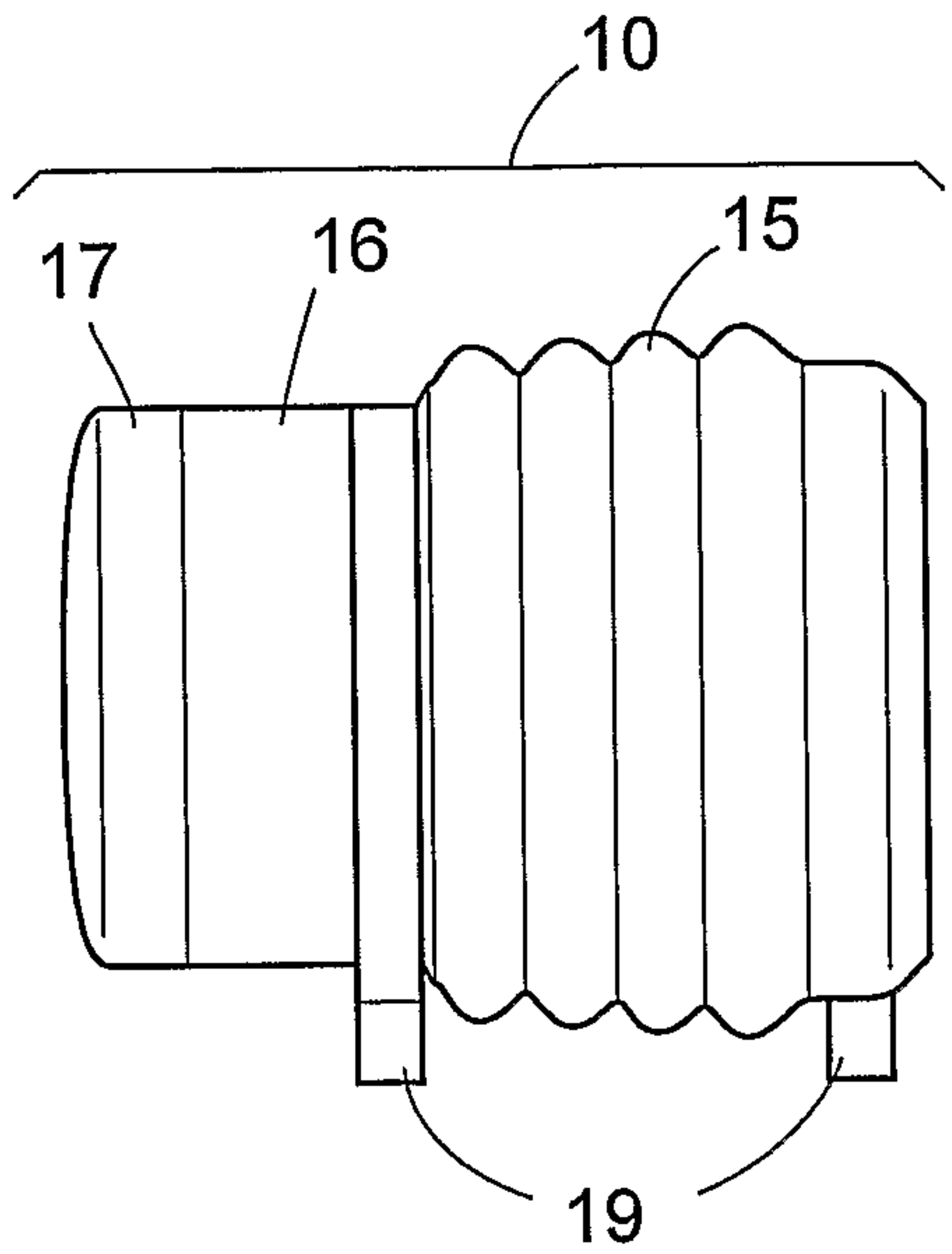

FIG. 5

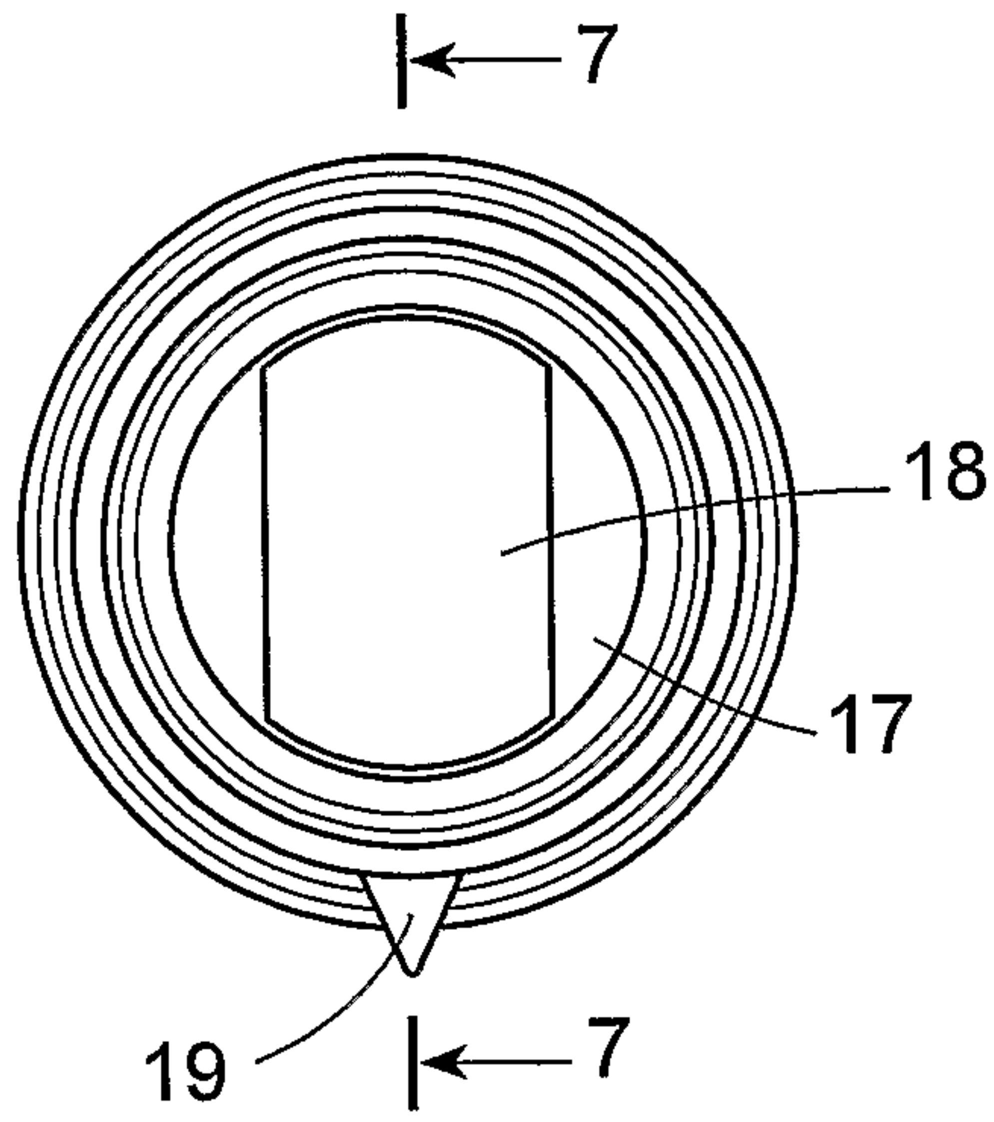

FIG. 6

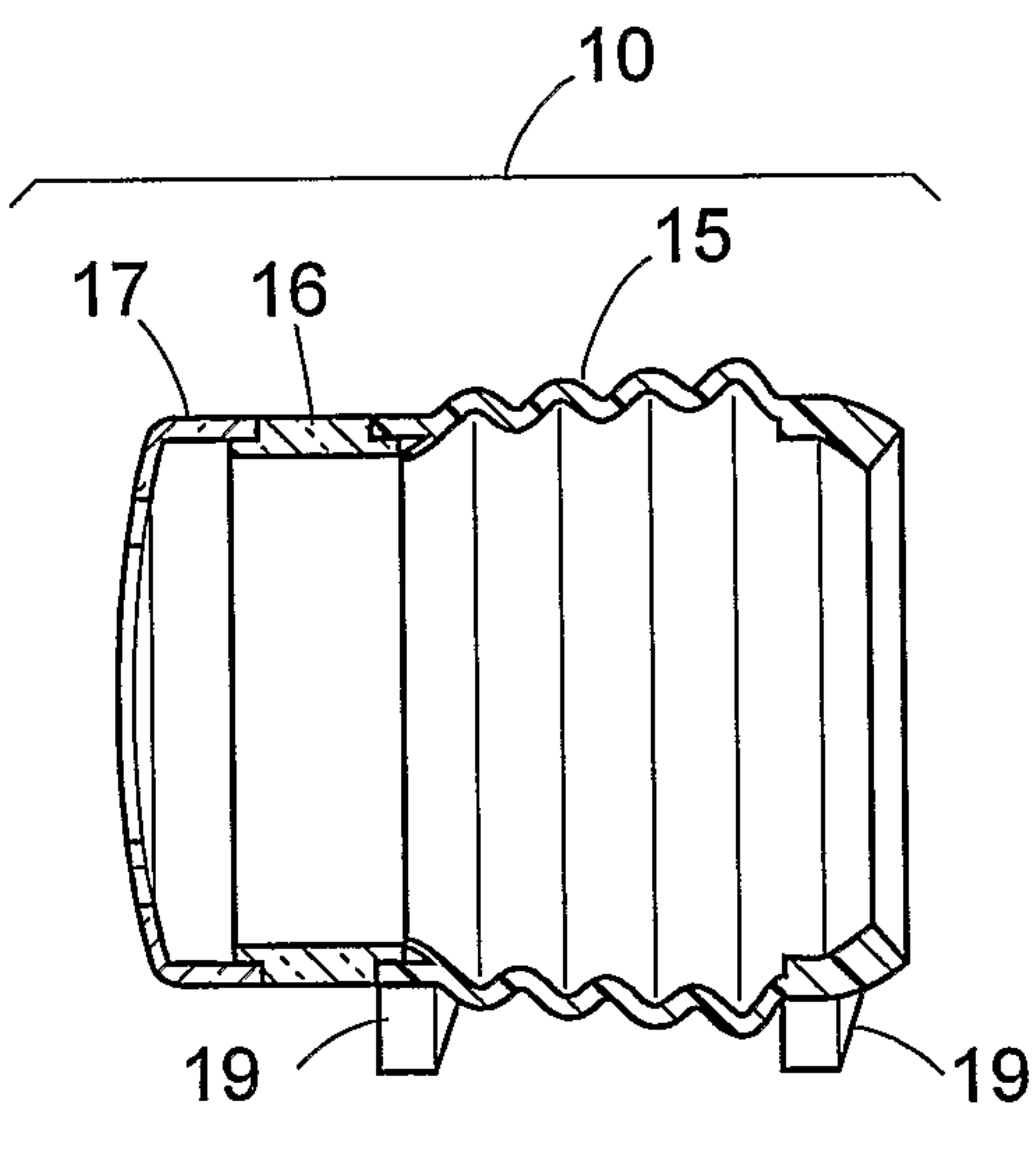

FIG. 7

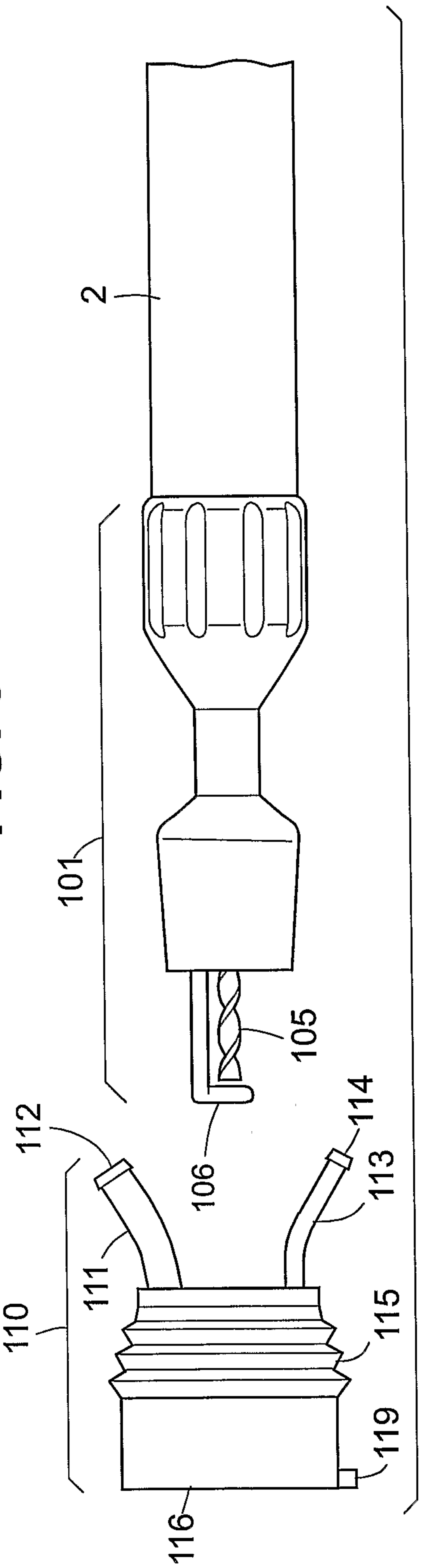
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FIG. 8

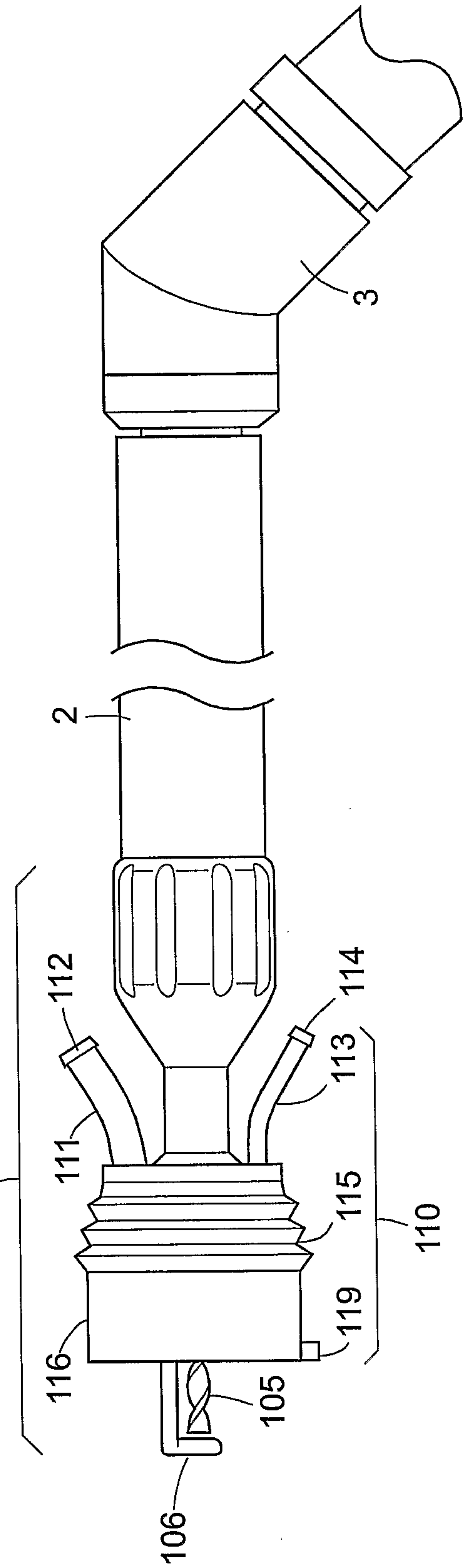
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FIG. 9

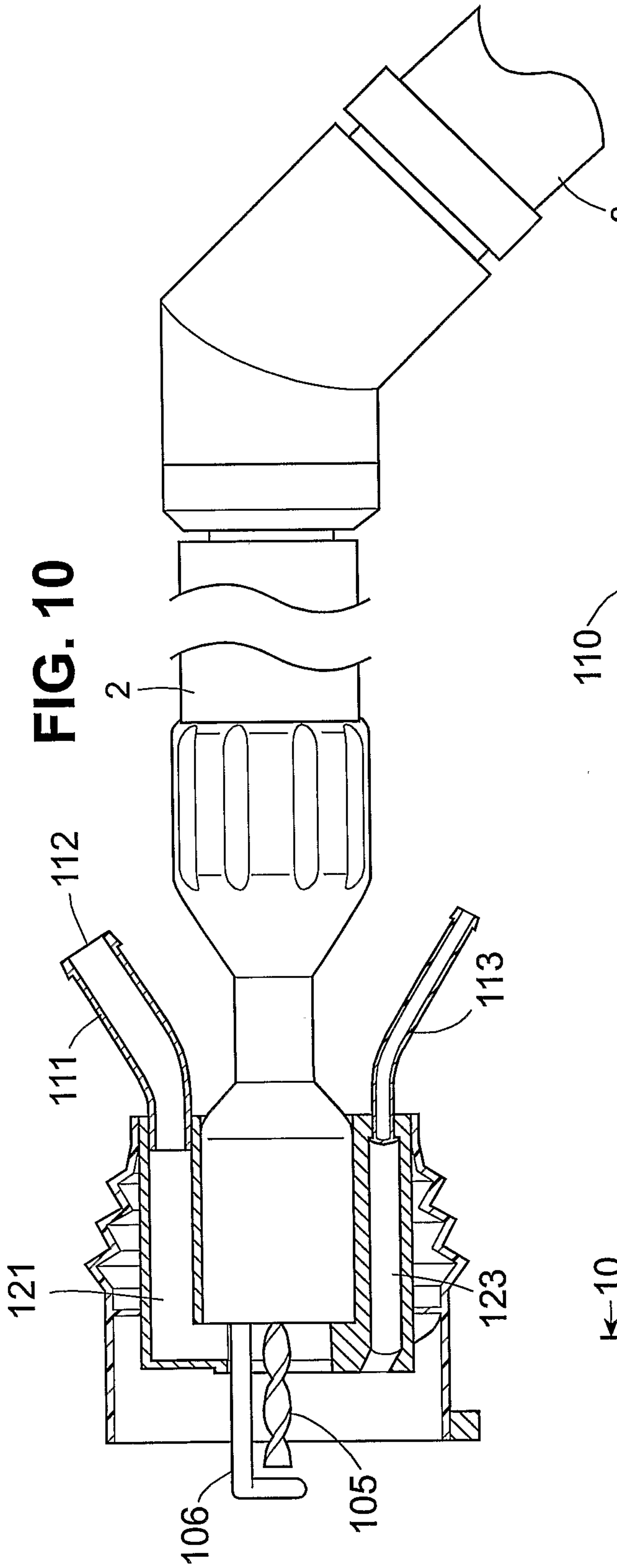


FIG. 10

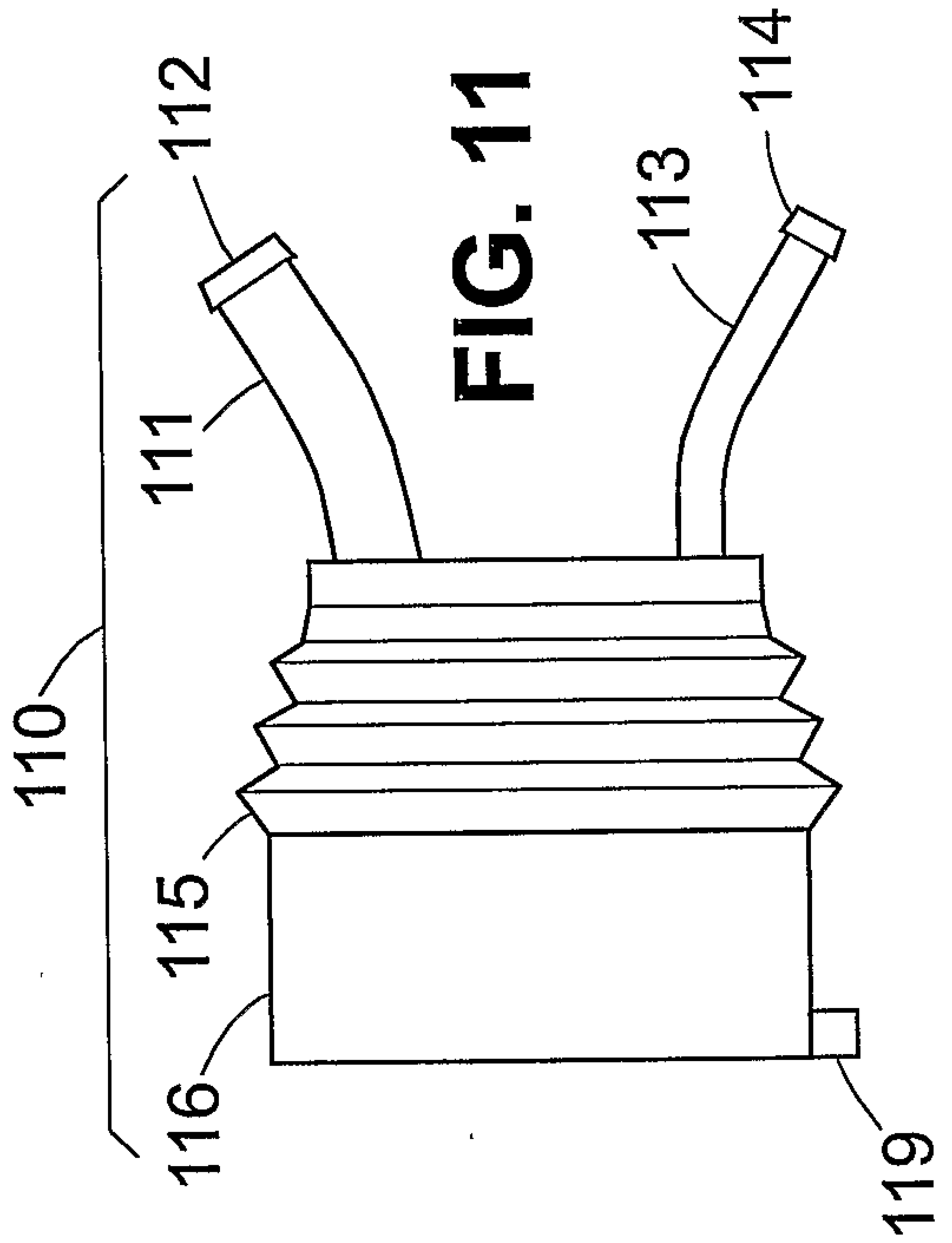


FIG. 11

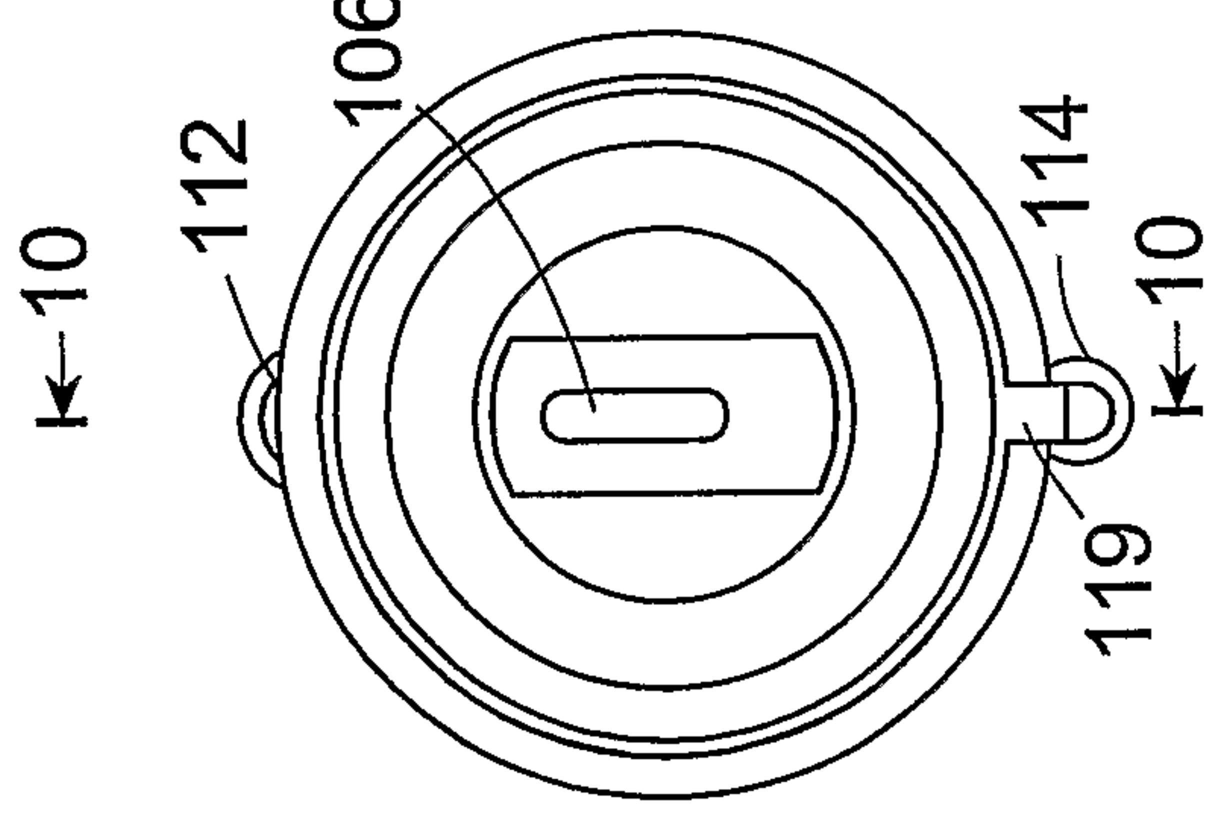


FIG. 9A

FIG. 12

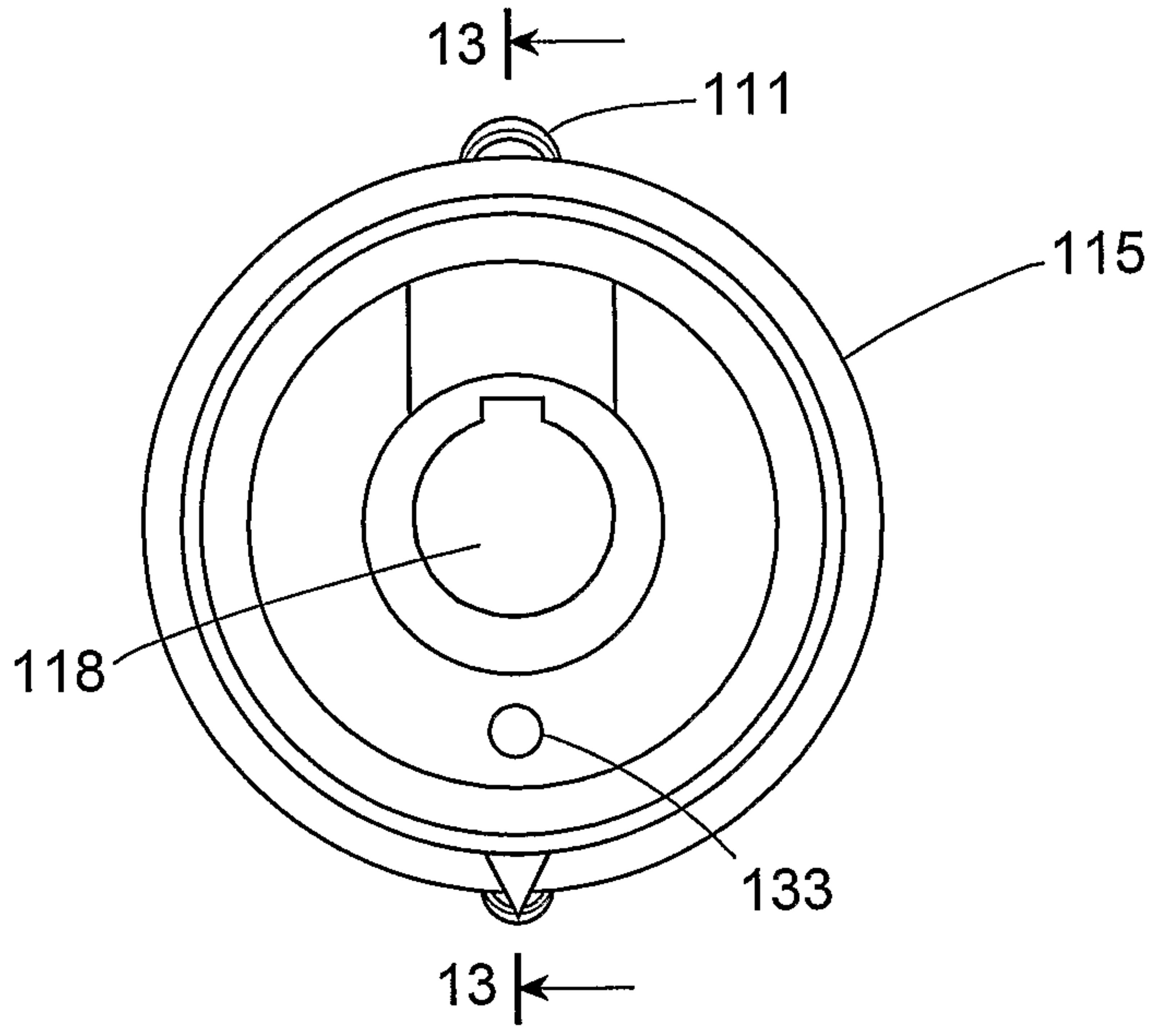


FIG. 13

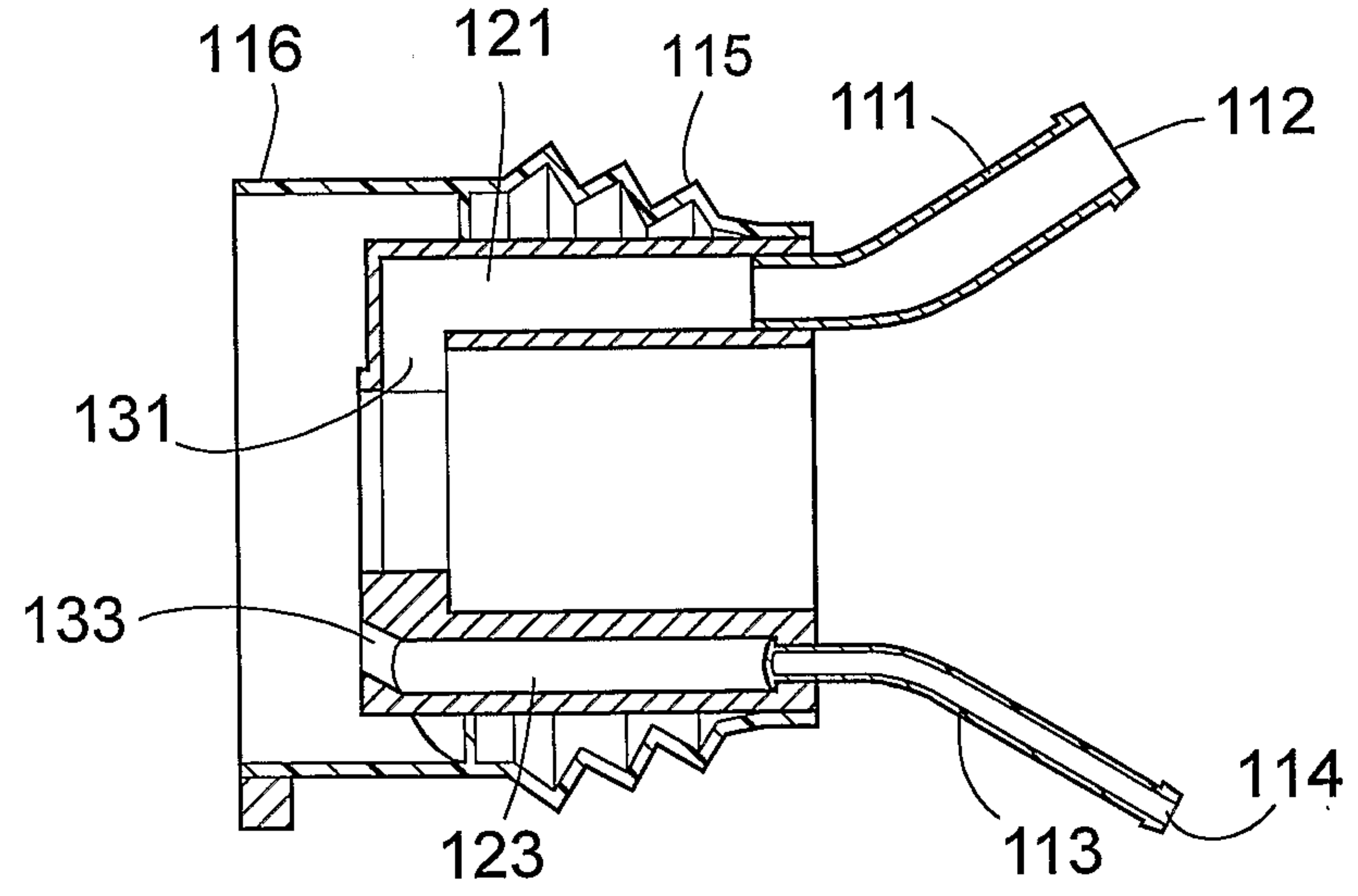
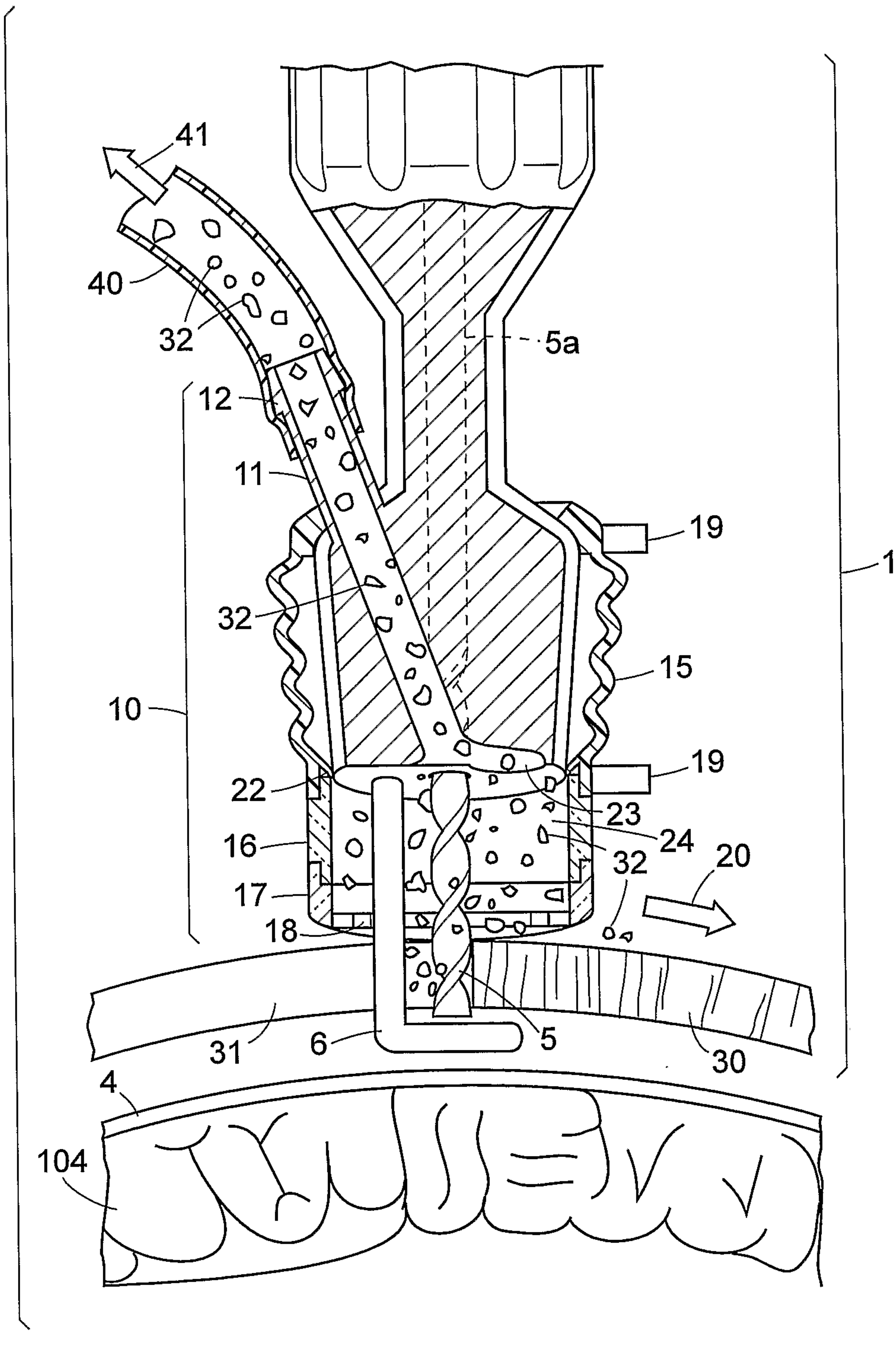


FIG. 14



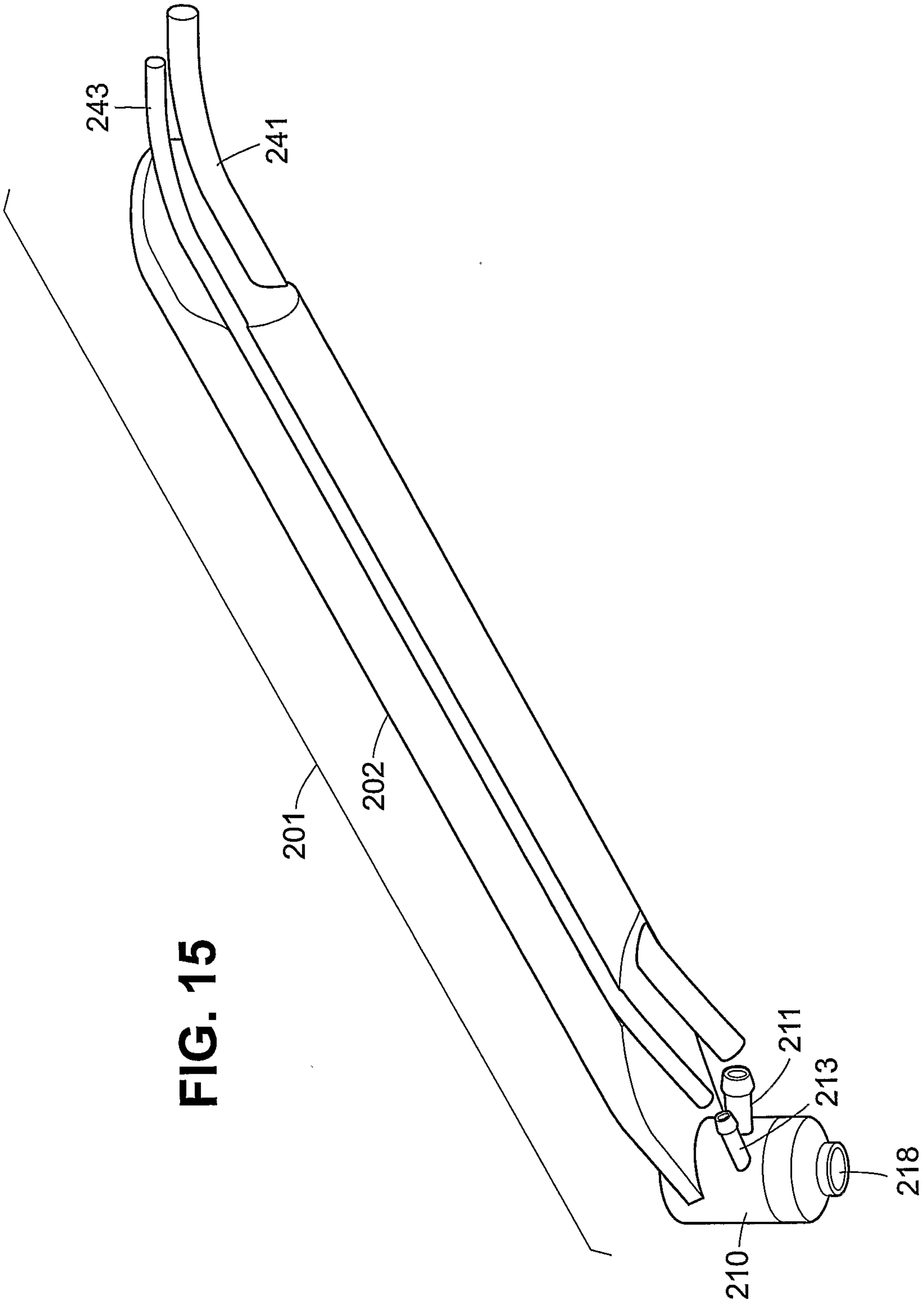


FIG. 15

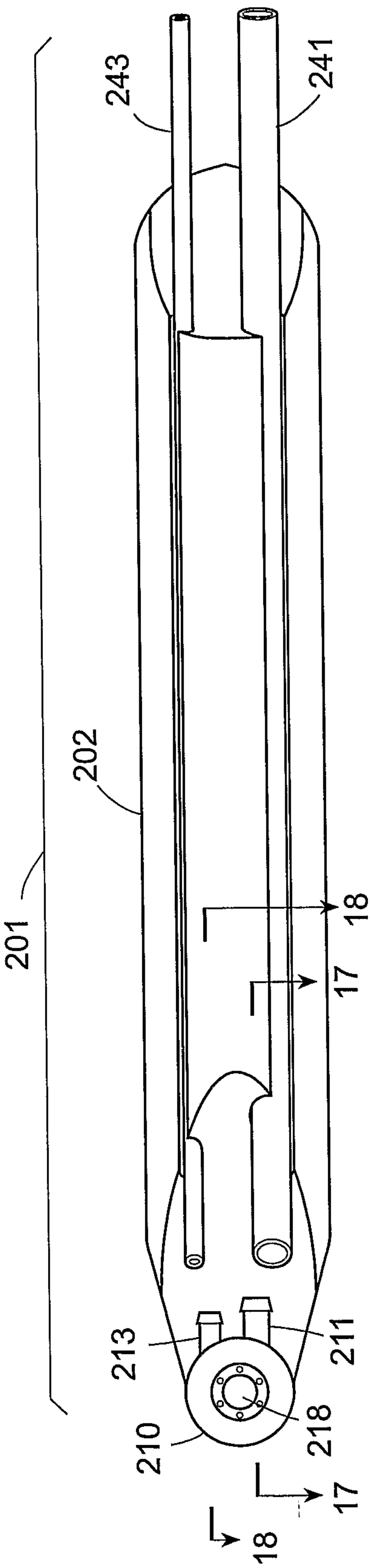


FIG. 16

FIG. 17

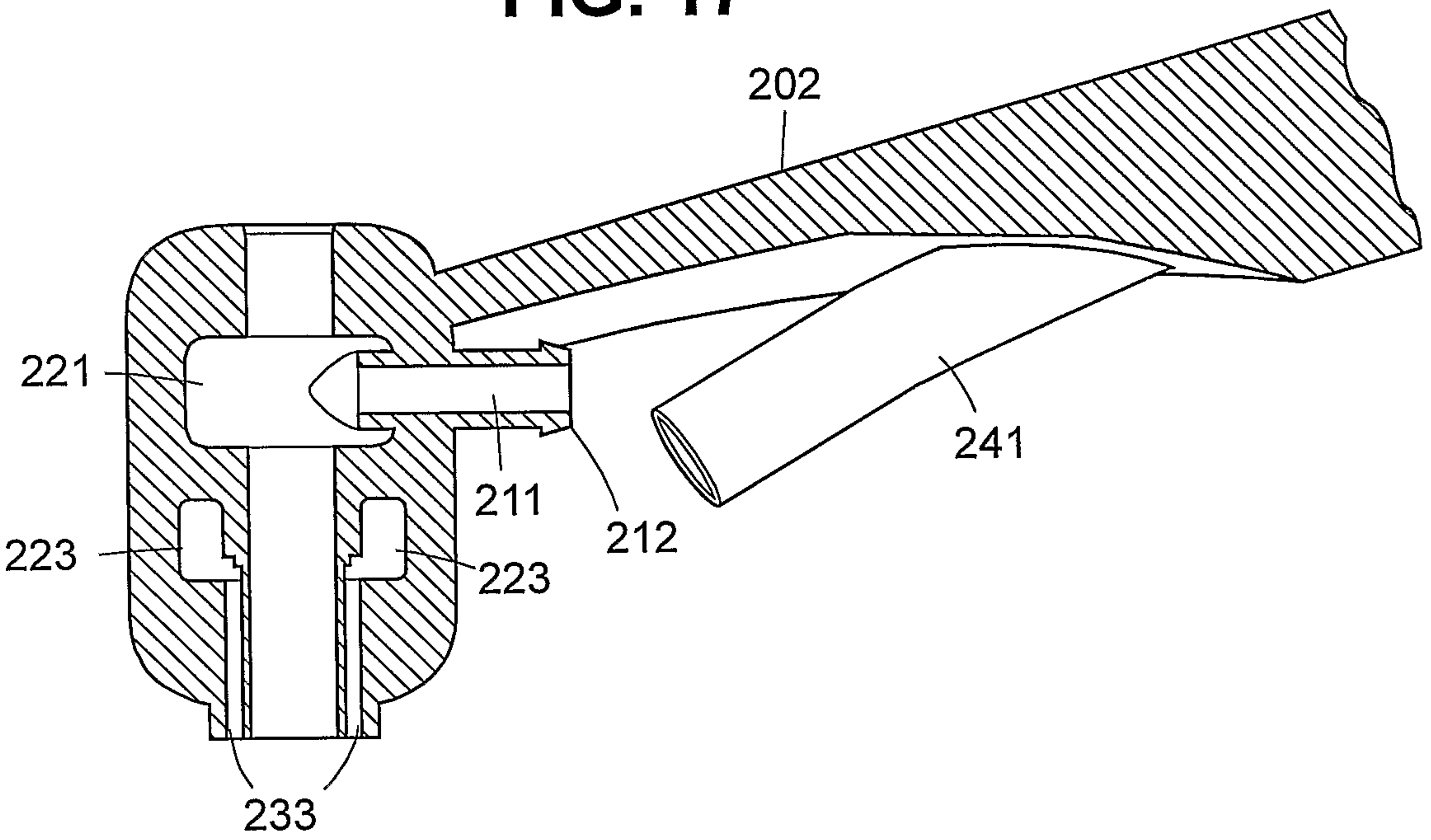
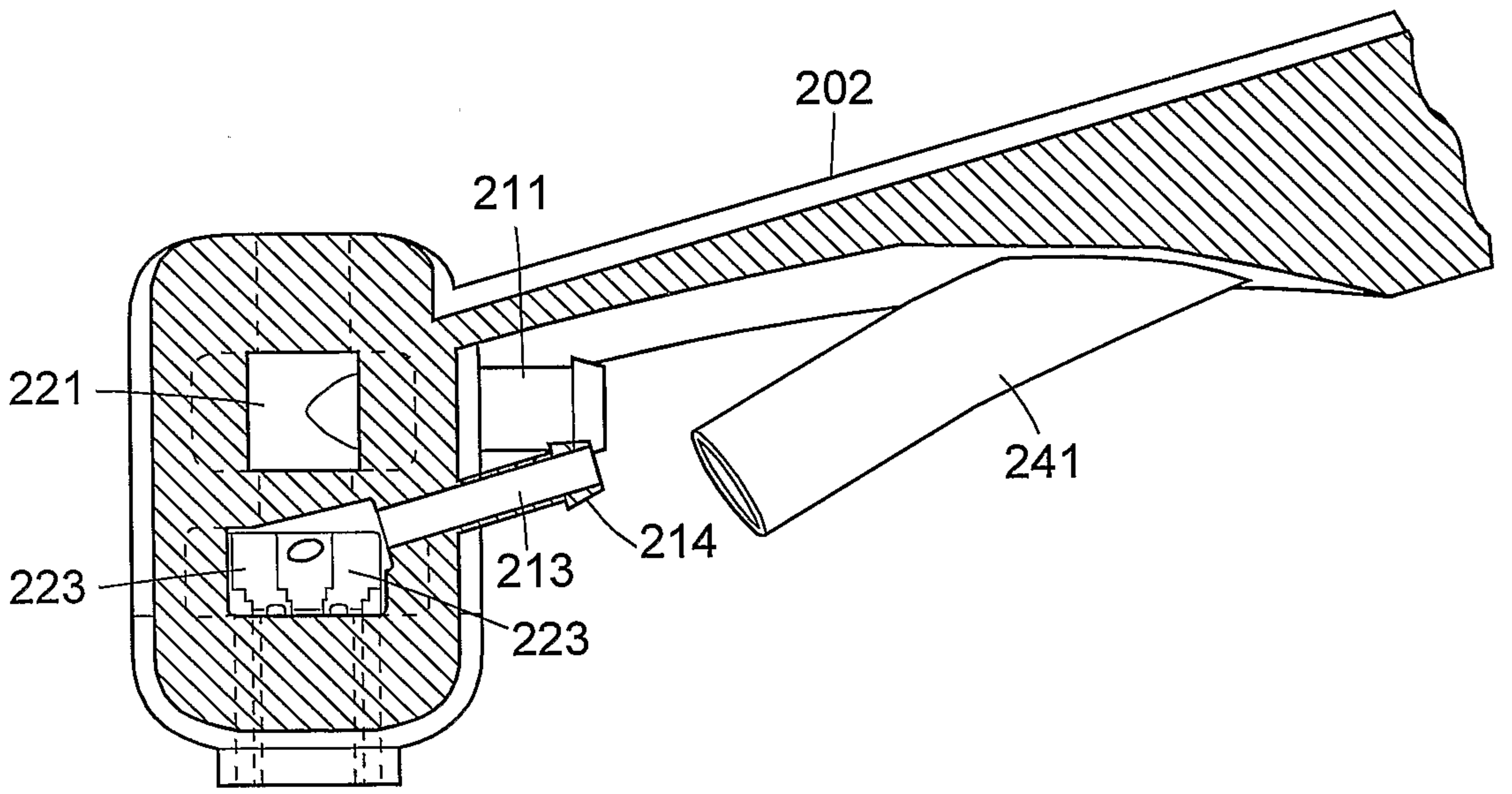


FIG. 18



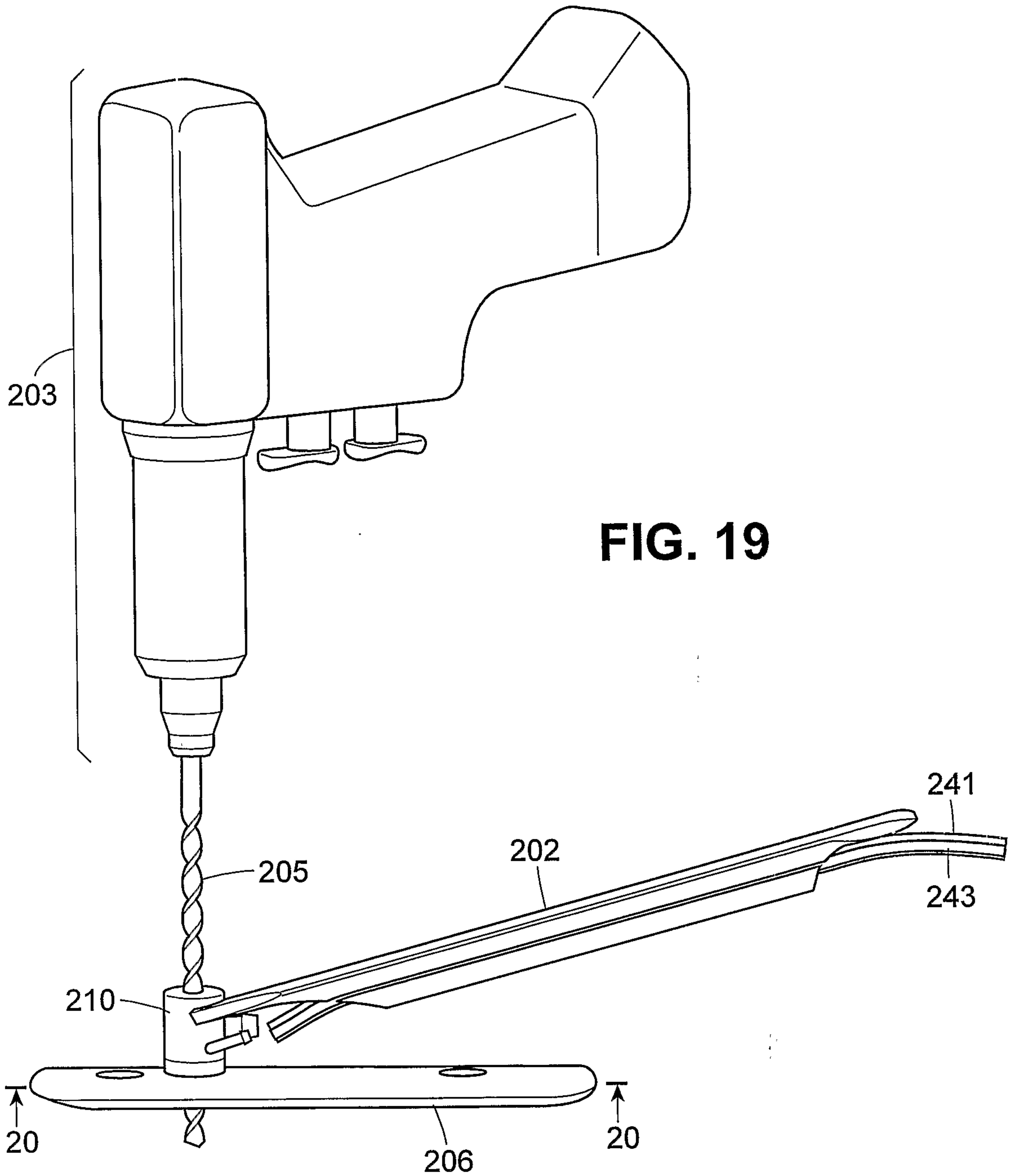


FIG. 19

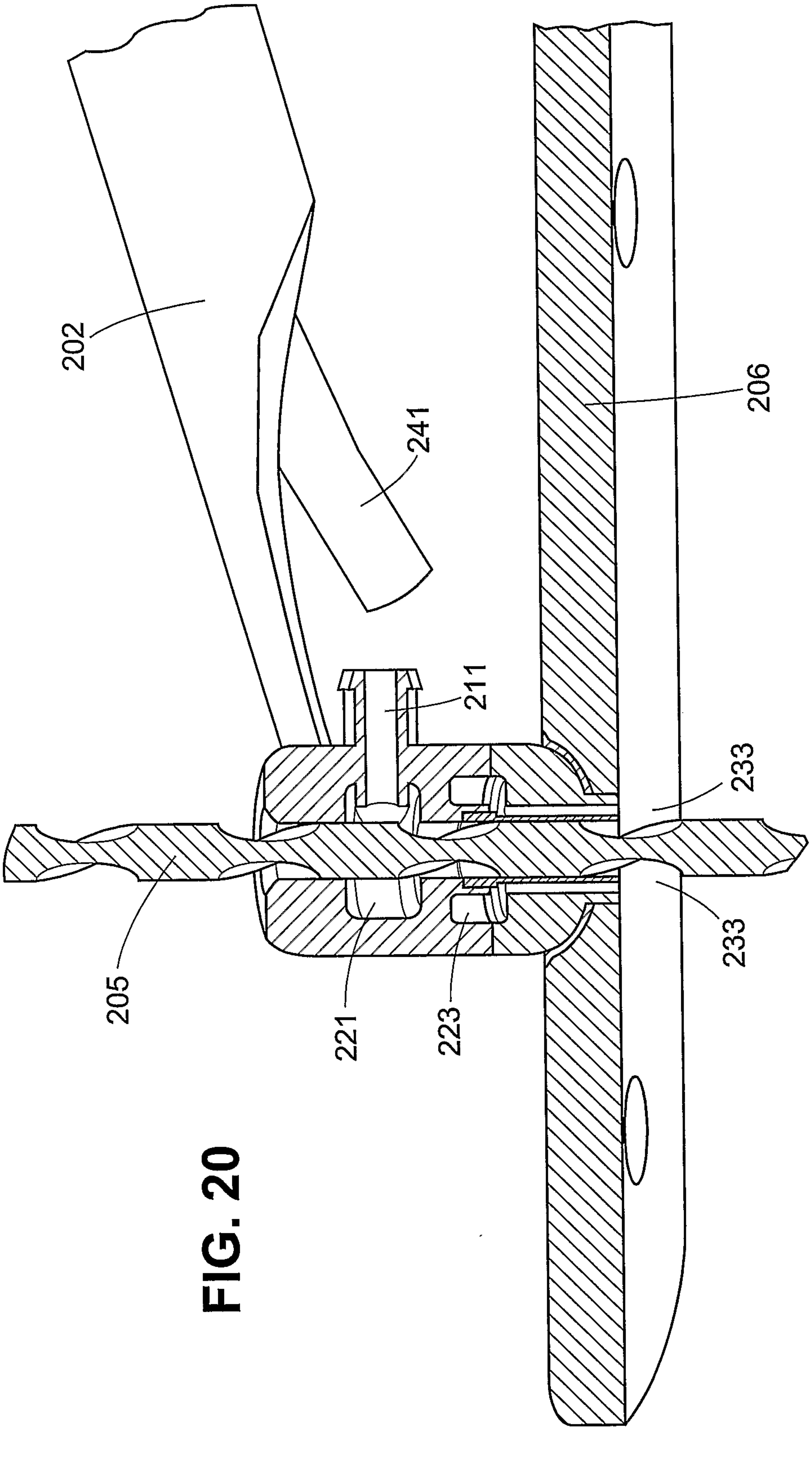


FIG. 20

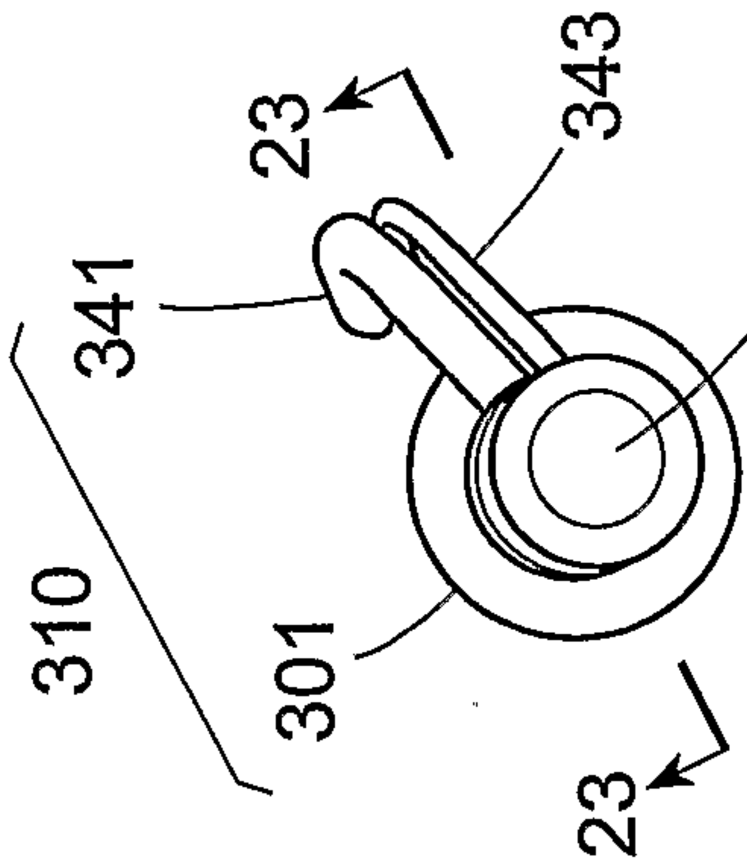


FIG. 22

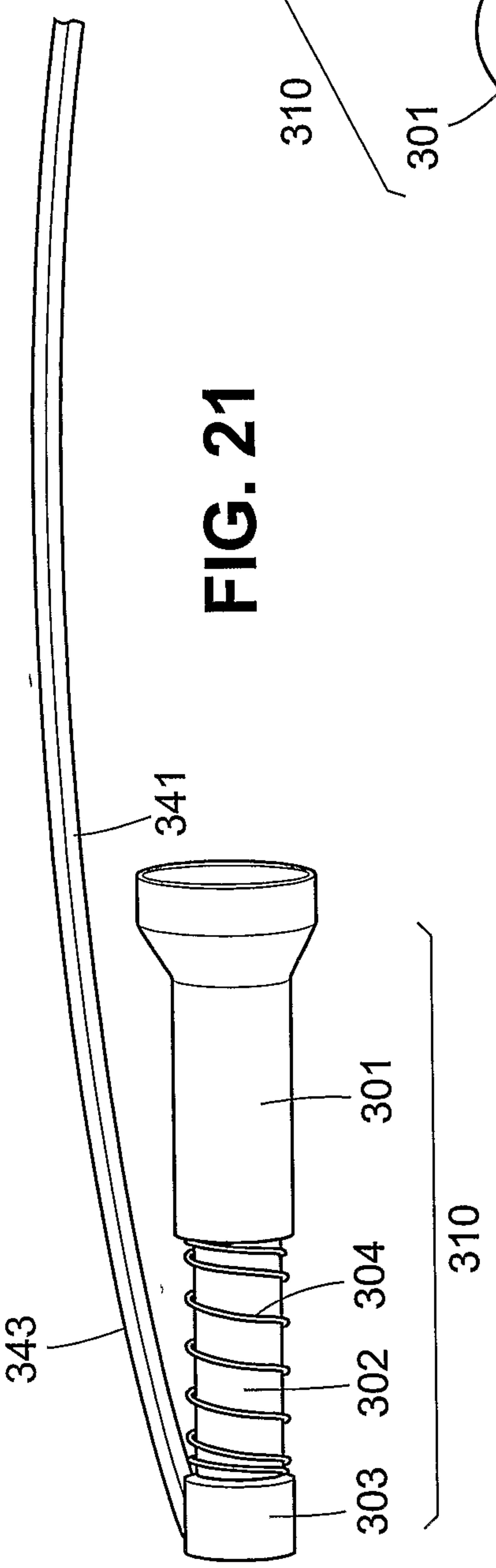


FIG. 21

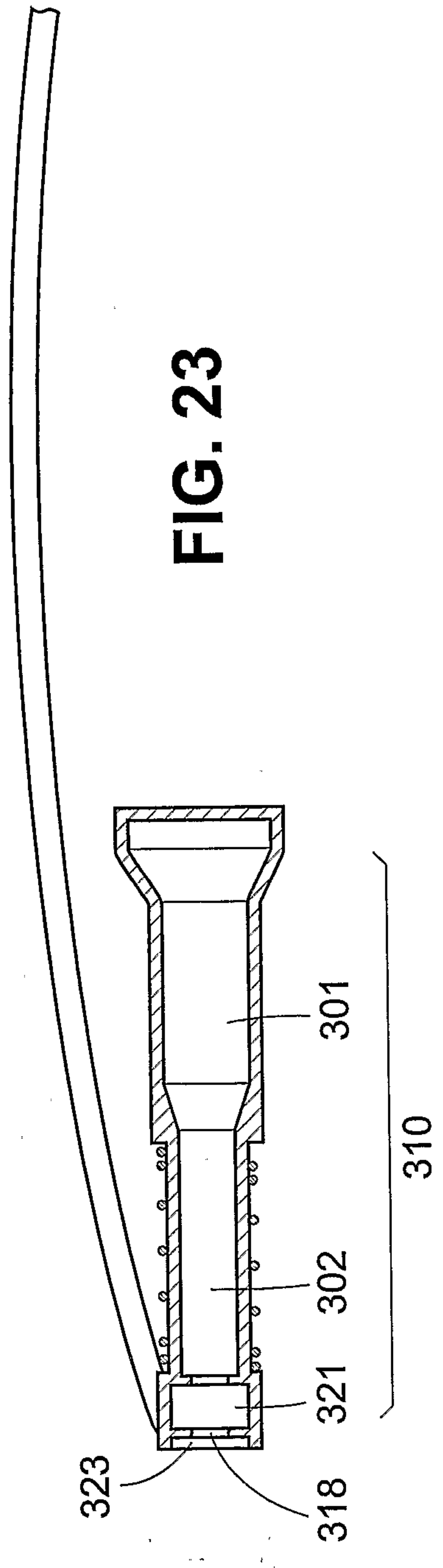


FIG. 23

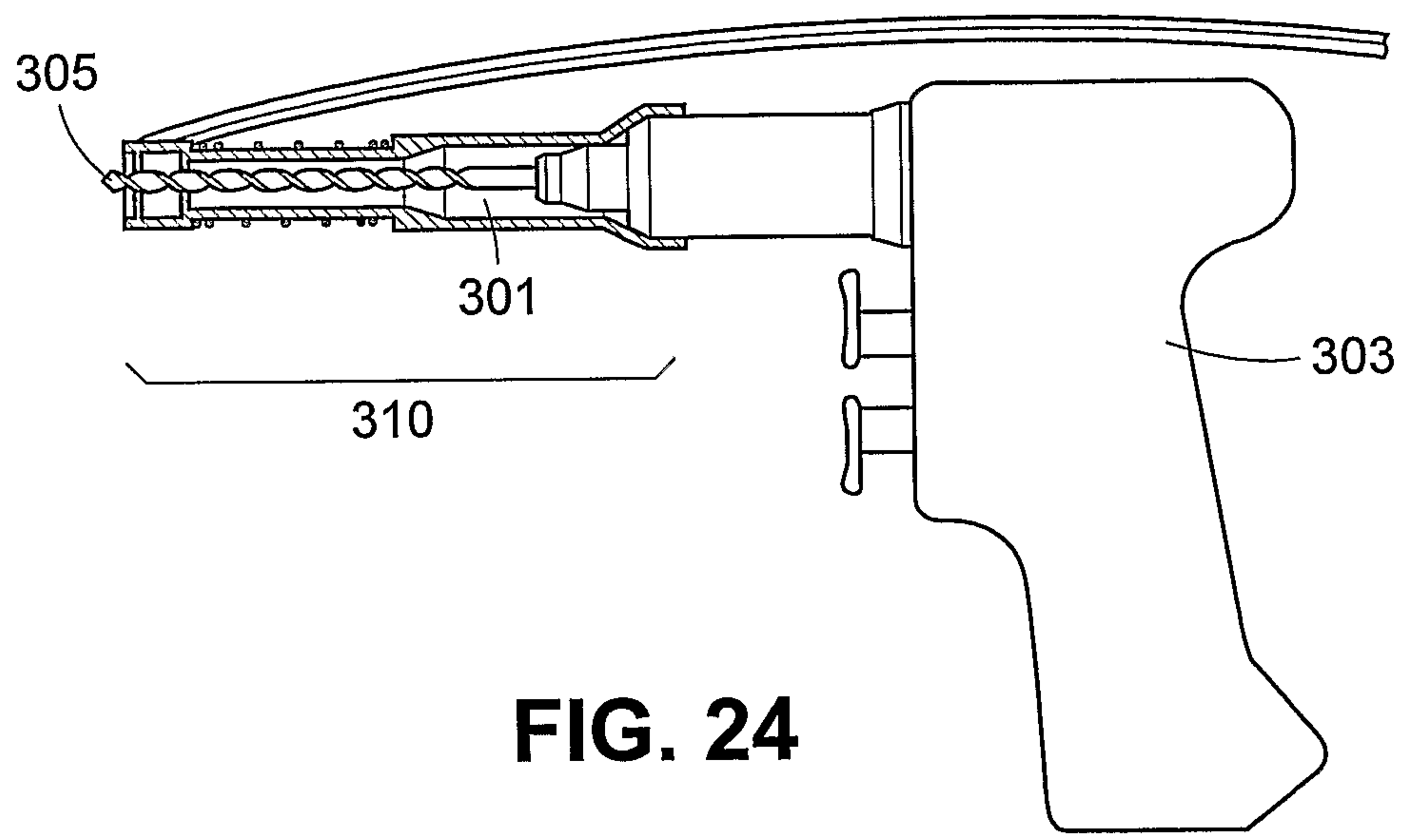


FIG. 24

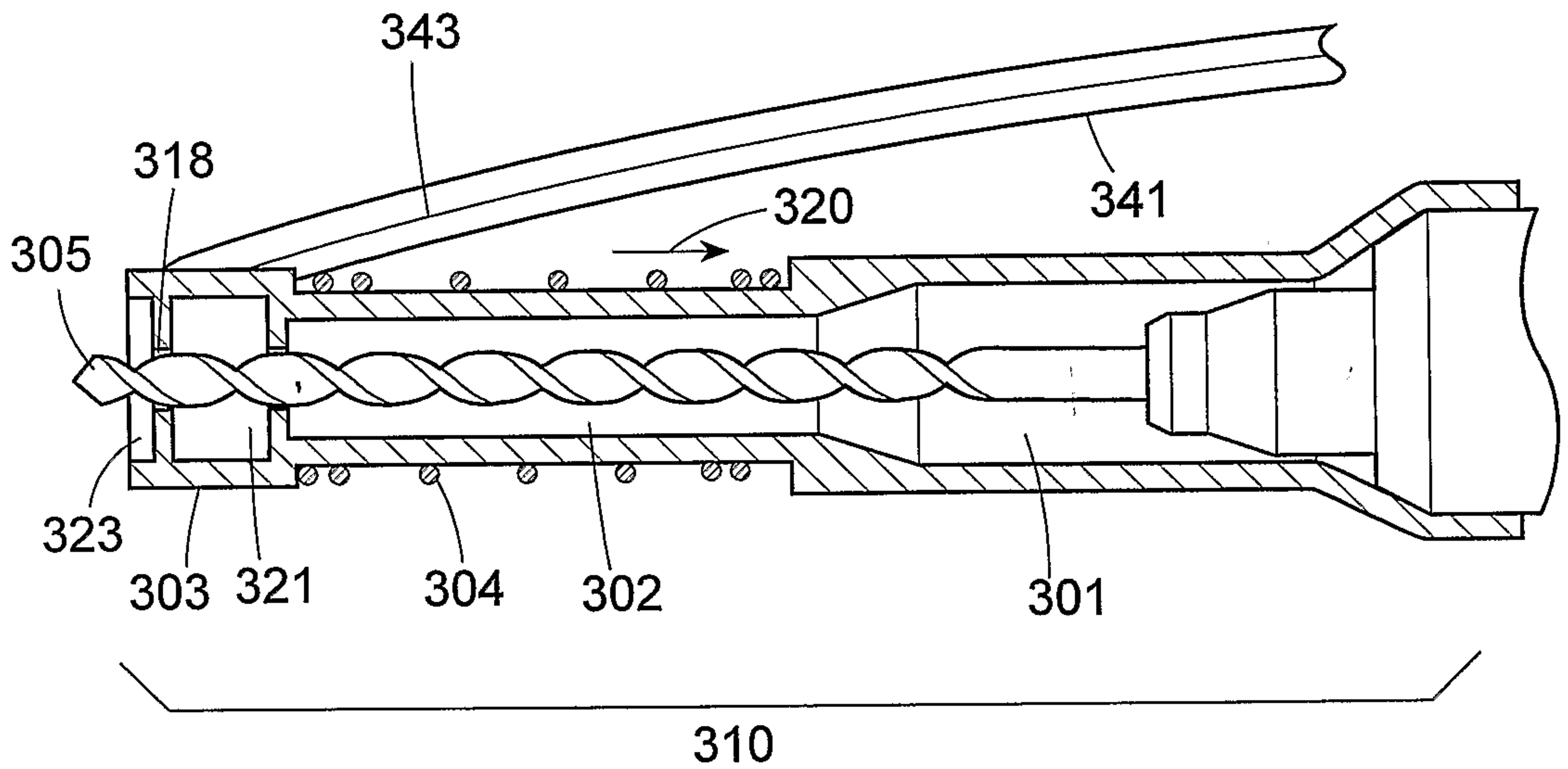
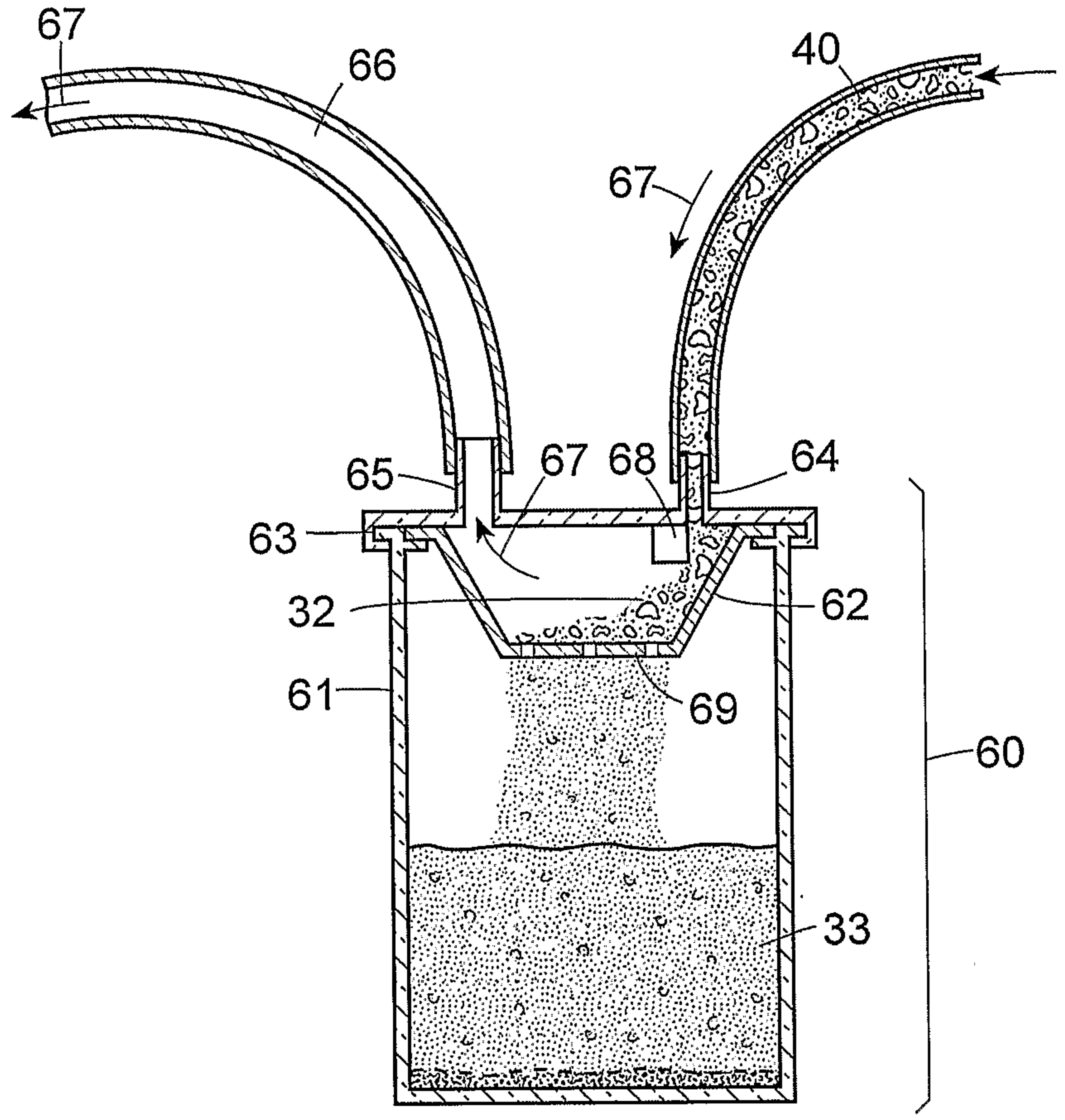


FIG. 25

FIG. 26

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