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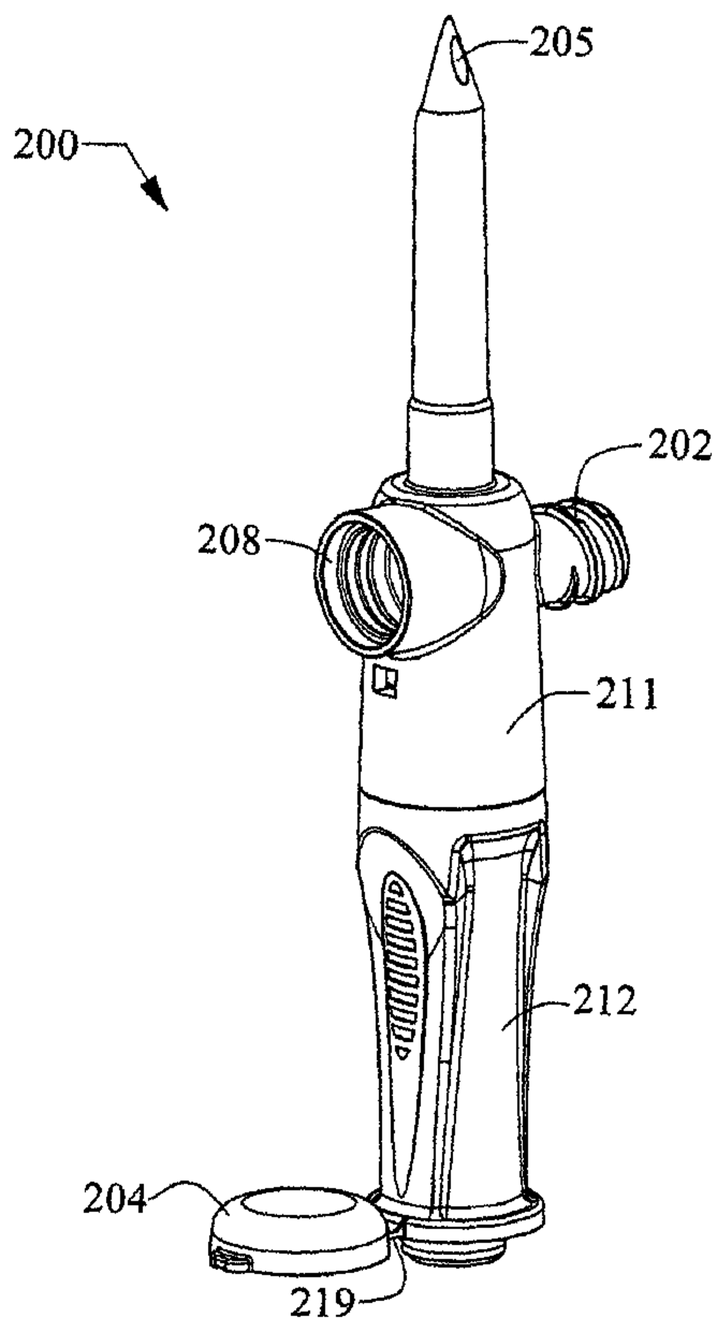
(54) **Titre : DISPOSITIF D'ACCES VENTILE POUR INFUSIONS**
(54) **Title: VENTED INFUSION ACCESS DEVICE**



(57) **Abrégé/Abstract:**
Device for accessing a toxic material, comprising a vented infusion access device for connection to an infusion container. The access device comprises a multi-lumen spike for connecting to the infusion container, connector means for accessing the infusion container, and venting means. The device is provided with a one-way check valve for safely providing and/or accessing toxic material of the infusion container while preventing or eliminating exposure to toxic material during access.

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[Continued on next page]

(54) Title: VENTED INFUSION ACCESS DEVICE

(57) Abstract: Device for accessing a toxic material, comprising a vented infusion access device for connection to an infusion container. The access device comprises a multi-lumen spike for connecting to the infusion container, connector means for accessing the infusion container, and venting means. The device is provided with a one-way check valve for safely providing and/or accessing toxic material of the infusion container while preventing or eliminating exposure to toxic material during access.

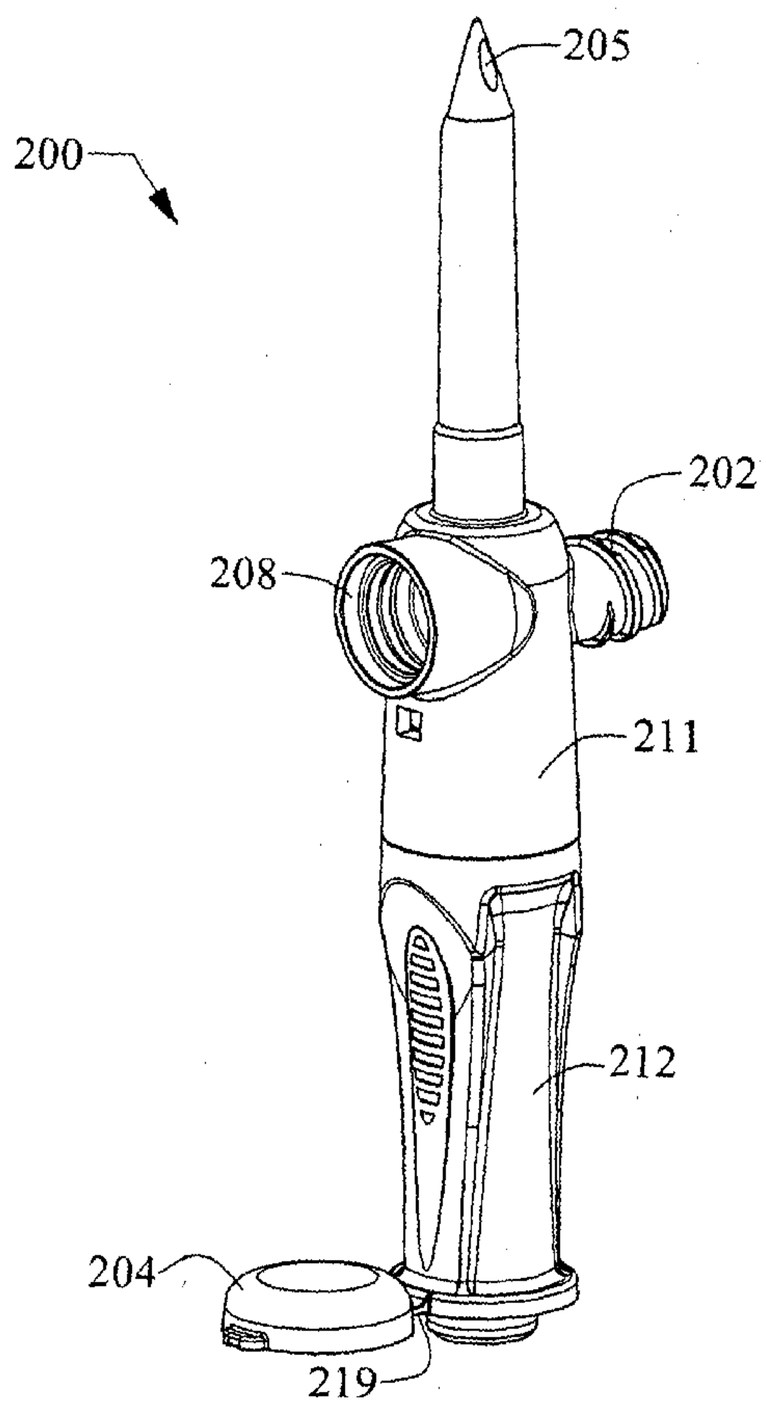

FIG 4

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VENTED INFUSION ACCESS DEVICE

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to a device for accessing an infusion container, which may contain a toxic material, comprising a vented infusion access device for connection to the infusion container. The device is provided with a spike for connection with the infusion container, the spike comprising at least two lumens for accessing, delivering a fluid, and venting.

Within the medical industry, medical personnel may be required to handle cytotoxic drugs, sometimes on a daily basis. A class of cytotoxic drugs is cytostatic chemotherapy agents. It is generally believed that cytostatics and some antibiotics may cause health problems if inhaled or exposed to the skin. Exposure or inhalation may be through leakage, aerosolization, or vaporization into the working environment during handling of the cytostatics.

When administering a drug via an infusion set, it is a common practice to use a spike to access the contents of the infusion container. In many cases, when the spike pierces the septum of the infusion container, fluid leaks before the spike fully creates a seal. With most infusion containers, this may cause slippery floors and if the contents are toxic, a serious health risk to the practitioner. To address this issue, a ported spike is commonly utilized to access the toxic solution in an infusion container so that the toxic drug may be added to the infusion contents through the access port in the spike. However, the prevention of health care provider to toxic material during access of infusion containers is not adequately addressed.

SUMMARY OF THE INVENTION

In an embodiment, a vented infusion access device is provided. The device comprises a housing having an open distal end and a forward end, the projecting forward open

end terminating as a spike, the spike capable of accessing an infusion container. An access lumen, a delivery lumen, and a vent lumen are located within the spike and each of the lumens provides an opening in proximity to the terminus of the spike. A connector means is positioned on the housing, the connector means and the access lumen provide a first fluid path. The delivery lumen and the open distal end provide a second fluid path. A check valve is positioned on the housing; the check valve and the vent lumen provide a third fluid path. The first fluid path, the second fluid path, and the third fluid path are each isolated from each other.

In another embodiment, a method of delivering toxic material to and/or accessing toxic material from an infusion container is also provided. The method comprises providing a toxic material to be delivered to or accessed from an infusion container and providing a vented infusion access device. The infusion access device comprises a housing having an open distal end and a forward end, the forward end terminating as a spike, the spike capable of accessing an infusion container. An access lumen, a delivery lumen, and a vent lumen, are located within the spike, each of the lumens providing an opening in proximity to the terminus of the spike. A connector means is positioned on the housing, the connector means and the access lumen provide a first fluid path. The delivery lumen and the open distal end provide a second fluid path. A check valve is positioned on the housing, the check valve and the vent lumen provide a third fluid path, where the first fluid path, the second fluid path, and the third fluid path are each isolated from each other. Penetrating the infusion container with the spike provides that the openings of the lumens be within the infusion container. Delivering the toxic material to and/or accessing the toxic material from the infusion container with the access lumen and/or the delivery lumen are provided.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of an infusion access device embodiment of the invention.

FIG. 2 is another perspective view of the infusion access device embodiment of FIG. 1.

FIG. 3 is a cross-sectional view of the infusion access device embodiment of FIG. 1.

FIG. 4 is a perspective view of an infusion access device embodiment of the invention.

FIG. 5 is a cross-sectional view of the infusion access device embodiment of FIG. 4.

FIG. 6 is a perspective view of an infusion access device embodiment of the invention.

FIG. 7 is a cross-sectional view of the infusion access device embodiment of FIG. 6.

FIG. 8 is another cross-sectional view of the infusion access device embodiment of FIG. 6.

FIG. 9 is a perspective view of the infusion access device embodiment of FIG. 6 with an attached needle-free female valve and check valve vent.

DETAILED DESCRIPTION

A vented infusion access device is provided for connection and accessing the contents of an infusion container, the access device preventing or eliminating exposure of the drug with the environment.

The vented infusion access device herein disclosed provides a solution for infusion bags and bottles intended for delivering hazardous drug. The vented infusion access device is first inserted into the infusion container prior to adding the drug, for example, in concentrated form, providing for the safe handling of the hazardous drug. While some fluid may leak out of the infusion container when the infusion container septum is pierced, the infusion fluid without the drug present is generally non-toxic. Hazardous drugs may then be added to the infusion bag or bottle through the needle-

free valve of the vented infusion access device while preventing or eliminating exposure to the hazardous drug.

After the toxic drug is mixed into the infusion container, a second device, such as an I.V. administration set (infusion kit), may be inserted into the distal end of the housing of the vented infusion access device. Before the second device pierces the membrane inside the vented infusion access device's housing, an annular sealing ring at the entrance of the vented infusion access device distal end provides sealing engagement of the second device. Thus, when the vented infusion access device handle membrane is pierced, hazardous fluid remains contained inside the housing of the vented infusion access device.

In one embodiment, the vented infusion access device includes a spike comprising two lumens, a delivery lumen for flow to the patient and an access lumen for adding drug to the infusion container as well as venting for providing higher flow out of the infusion container (particularly in the case of a non-collapsible infusion bottle). The access lumen may be in fluid communication with a hydrophobic filter membrane and check valve assembly to allow for the replacement of drug with air inside the infusion container as the drug is delivered to the patient. The two lumens provide for two isolated fluid flow paths within the device.

In another embodiment, the vented infusion access device includes a spike comprising three lumens. The lumens include a delivery lumen for flow to the patient, an access lumen for adding drug to the infusion container, and a vent lumen with inline check valve and optional filter. The vent lumen separates the hydrophobic filter/check valve port from the connector means/access lumen fluid path in order to ensure that any spike in pressure generated by injecting drug into the access lumen through the female needle-free valve port is not directly felt by the valve/filter, possibly causing the hydrophobic filter and check valve to become over-pressured and leak. The three lumens provide for three isolated fluid flow paths within the device.

The term "fluid" as used herein, refers to gas, liquid or a combination of gas and liquid.

The term "infusion container" refers to a fluid container such as an I.V. bag, I.V. bottle, blood bag, and the like. "Infusion container" includes containers for intrathecal administration of fluid.

The term "infusion connector" refers to a device for accessing an infusion container and includes, for example, spikes, blunt cannula, male luers, and female luers.

A vented infusion access device is provided which comprises a housing. The housing may be of plastic construction or may be fabricated out of one or more materials designed to withstand chemical attack from substances, such as cytotoxic drugs and other hazardous materials. Materials include for example, thermoplastics, engineering thermoplastics, filled or unfilled, and composites. Thermoplastics include materials such as acrylonitrile butadiene styrene (ABS), polybutylene terephthalate (PBT), polyethylene terephthalate (PET) polyethylenenaphthalate (PEN), high impact polystyrene (HIPS), cyclic olefinic copolymers (COC's) and polycarbonate (PC) The housing incorporates a vented and unidirectional flow port via a hydrophobic filter media and check-valve assembly. The vent only allows filtered air into the system to replace drug removed from the infusion container, which may result in a higher flow rate. This is particularly useful when using infusion bottles as opposed to bags.

The housing of the device includes a forward end, which terminates as a spike. The spike may be integral to the housing and provide for an opening for communicating with the drug container. The spike may include at least two lumens both of which may be open proximal to the distal end of the spike and function independently of each other. The openings in the lumens may be at the distal end of the spike, the side of the spike or one lumen opening may be at the distal end of the spike and another lumen opening may be on the side of the spike. The relative positions of the openings of the lumens proximal to the distal end of the spike may be the same or different. The spike may be constructed of plastic, metal or composite material. The spike may be designed such that it easily pierces the closure of the infusion container. The open end of the spike may be pointed and/or beveled for facile insertion into a closure or other access member of an infusion container.

The lumens of the spike provide for multiple fluid paths. At least one of the fluid paths provides for one-way communication with the atmosphere. One-way fluid communication may be achieved by any means capable of restricting fluid flow, such as a check valve. The fluid path may be in communication with a check valve disposed in cooperating relation with one of the lumens for providing one-way flow of air into the device and infusion container while preventing escape of hazardous material.

The check valves preferably have a low cracking pressure so as to prevent or eliminate pressure to build up during use of the device. The cracking pressure preferably is less than 2 psi, less than 1 psi, or less than 0.5 psi. The check valve may also have a low reverse leakage characteristic to prevent hazardous media from being released into the environment. Check valves include, for example, "duck bill" type or "umbrella" type. Various other types of check valves may be used, for example "top hat", "double duck bill", "umbrella", "flat disc", etc. The use of a check valve filter may significantly improve the flow rate through the vented infusion access device, for example, when used with glass infusion bottles. Without a vent, air must be pulled into the bottle to displace the fluid through the same lumen that the fluid is exiting. This causes a significant decrease in flow rate and increases the time needed to deliver the drug to a patient. By way of example, the 3 lumen design herein disclosed, utilizes a vent lumen that is separated from the injection port and its flow path, decreasing the possibility of the hydrophobic filter/check valve assembly being over pressured upon injection of the drug into the bag.

The communication between the fluid path and the check valve may be filtered to avoid contamination of the contents of the drug container. In this arrangement, the contents of infusion container may be accessed and/or withdrawn under uncontaminated atmospheric pressure conditions. A filter may be disposed in cooperating relation with the check valve. The filters may be sized commensurate with the overall size of the device or its components. The filter may be of a disk-type or any other size sized to fit cooperatively with a check valve. The disk filter may have a hydrophobic surface on one side or on both sides of the disk. The filter may

contain a small pore size, such as 1.0, 0.5, 0.4, 0.3, 0.2, or 0.1 micron, however, larger or smaller pore sizes may be used. The venting filter may include the hydrophobic surface in communication with a fluid path of the spike and surrounding areas to prevent wetting of the filter media, assuring adequate ability to equalize pressure during use of the device. Multiple filters may be used. The selection of filter type and size may be readily determined to provide adequate surface area and to effectively vent the device quickly under normal use.

The housing includes connector means for accessing the infusion container via at least one of the fluid paths of the spike. The connector means may provide two-way communication with the fluid paths and lumens of the spike. While in sealable communication with an infusion container, the connector means provides for introduction or withdrawal of fluid using a syringe or other device from the infusion container. The fluid communication between the connector means and the fluid paths or lumens may be filtered. The connector means may include a check valve to only allow one-way introduction of fluids into the infusion container. The connector means may be mounted on the housing to provide a sealed septum or similarly constructed valve capable of receiving a device for introduction of fluid to the infusion container. The device for introduction may be a needle, a spike, a blunt cannula, a male luer connector, or similar device. The connector means may comprise a septum containing connector penetrable by needles, cannula, blunt needles or spikes, for example. By way of example, connector means include a needle-free adapter, a pre-slit septum, or a penetrable septum. The needle-free adapter may be a female luer-activated two-way adapter or male luer adapter. The needle-free adapter may be secured to the housing. Various needle-free adapters as are known in the art are adaptable to the vented infusion access device housing, such as CLAVE®, SMARTSITE®, POSIFLOW®, BIONECTOR®, and CLEARLINK® and others.

The needle-free adapters in combination with the infusion access device herein described provides for accessing the infusion container for introduction and/or withdrawal of fluid through the closure of the infusion container. Hence, elimination or reduction of exposure to hazardous material incident to access and/or withdrawal as the needle-free adapter self-seals is reduced or eliminated and further provides for needle-free manipulation. The connector means preferably is compatible with most

syringes and other male luer devices that are readily available. Female needle-free valves may be directly integrated into the housing, potentially eliminating a component and simplifying manufacturing.

The housing may consist of a handle. The handle may include ergonomic features for facilitating a secure grip by the user. The housing may be one-piece or of multi-piece construction. Means for assembling the housing may be provided, such as mating snap-fit features or interference elements.

The housing may include a pre-access seal, such as an internal annular ring at the distal end. The pre-access seal may provide for an interference fit with a mating infusion connector.

The housing may include a membrane. The membrane may be positioned between the open distal end and the forward end of the housing. The membrane may provide prevention or elimination of leaks prior to a secondary device, such as an infusion spike, piercing the membrane.

The housing may include an integrated cap positioned at the distal end of the housing. The cap may prevent or eliminate touch contamination at the housing distal end and/or keep it covered until, for example, an infusion set may be mated with the housing distal end. With the use of the pre-access seal at the housing distal end together with a living hinged cover, the likelihood of toxic fluid in the system being leaked to the environment is reduced or eliminated. In conjunction with the check valve filter and a female needle-free valve connected to the female luer port of the device herein disclosed, toxic fluids escaping into the environment is reduced or eliminated.

Referring now to the drawings, various illustrative embodiments will be described. FIG. 1 depicts an embodiment of the device herein disclosed consisting of an access lumen 101 for flow out of the infusion container (e.g., bag or bottle) and a connector means (e.g., female port) 102 on the housing 111 that provides for the addition of drug into the infusion container by way of delivery lumen 105. The handle 112 has textured

grip areas 103 and a cap 104 connected to the housing via living hinge 119 so as to eliminate or prevent touch contamination before use. The handle may be securely attached to the housing with internal ramp features 114. Cap 104 reversibly bends at living hinge 119 connected to handle 212.

FIG. 2 depicts another view of the aforementioned embodiment, showing the delivery lumen 105 for injecting drugs from the needle-free valve (not shown) through the spike into an infusion container. Cap 104 may contain vents 113 for sterilization.

FIG. 3 depicts a cross section of the aforementioned embodiment, showing delivery lumen 105 and access lumen 101 flow paths, respectively. Penetrable membrane 106 is positioned inside the housing between the distal end and forward end of the housing. Tapered area 107 provides for sealably receiving a secondary penetrable device. Annular interference 110 creates a seal between handle 112 and the housing 111. Annular area 115 may provide means for securely attaching handle 112 to housing 111. An adhesive or other securing agent may be used at annular interference 110 to provide a securing means.

FIG. 4 depicts vented infusion access device 200. Venting port 208 is provided in fluid communication with access lumen 205. Connector means 202, in fluid communication with access lumen 205, may be used to add drug to the infusion container.

FIG. 5 depicts a section view of the device 200 wherein channel 209 provides fluid communication between both the connection means 202 and the venting port 208. Penetrable membrane 206 is positioned inside the housing between the distal end and forward end of the housing. Annular interference 210 creates a seal between handle 212 and the housing 211. Annular area 215 may provide means for securely attaching handle 212 to housing 211. Access lumen 205 and connector means 202 define a first fluid path. Delivery lumen 201 and penetrable membrane 206 define a second fluid path. The first fluid path and the second fluid path are isolated from each other.

FIGS. 6 through 8 depict vented infusion access device 300. Delivery lumen 301 provides for drug delivery to the patient, access lumen 305 for adding drug to the infusion container, and vent lumen 316 for venting. Hydrophobic filter 325 and check valve 320 are positioned in vent port 308.

Access lumen 305 and connector means 302 define a first fluid path. Delivery lumen 301 and penetrable membrane 306 define a second fluid path. Vent lumen 316 and vent port 308, including check valve 320, define a third fluid path. The first fluid path, the second fluid path, and the third fluid path are isolated from each other.

Retaining feature 315 on the handle and the retaining ramps 314 on the housing provide for assembly. Cap 304 reversibly bends at living hinge 319 connected to handle 312. Internal taper 317 of the cap pops onto housing distal end taper 318 of handle 312, securing the cap.

FIG. 9 depicts device 300 with a hydrophobic filter/check valve assembly 320a integral with housing 311 and a needle-free female valve 321 connected to connector means 302.

When administrating via infusion with the vented infusion access device as herein disclosed, the vented infusion access device is first connected normally to an infusion container such as a bag or bottle containing an infusion fluid. Upon access by an infusion connector via the open distal end of housing and penetration of the membrane, the fluid path defined by the penetrable membrane and the delivery lumen thereafter fills with the infusion fluid. An injector (not shown) with a corresponding mating means, which may be loaded with a drug to be administrated to the infusion container, is connected to the connector means. The injector is provided access to the contents of the infusion container with adequate venting by the check valve. Thereafter the injector may be withdrawn with little or no exposure to the contents of the infusion container. The infusion can now be started after mixing the contents of the infusion container and connection with the distal end of the vented infusion access device using, for example, an infusion kit.

The vented infusion access device described above will normally be supplied in assembled form or as a kit, and may be sterile. The term "vented infusion access device" as used herein is intended to include within its scope the elements thereof in partially or fully disassembled form. The vented infusion access device or kit may contain a needle-free adapter which may be separate, secured to or permanently affixed to the connector means as desired.

As used herein, "comprising," "including," "containing," "characterized by," and grammatical equivalents thereof are inclusive or open-ended terms that do not exclude additional, unrecited elements or method steps. "Comprising" is to be interpreted as including the more restrictive terms "consisting of" and "consisting essentially of." As used herein, "consisting of" and grammatical equivalents thereof exclude any element, step, or ingredient not specified in the claim.

As used herein, "consisting essentially of" and grammatical equivalents thereof limit the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristic or characteristics of the claimed invention.

The scope of the claims should not be limited by the preferred embodiments set forth in the examples, but should be given the broadest interpretation consistent with the description as a whole.

What is Claimed is:

1. A vented infusion access device (300) comprising;

a housing (311) having an open distal end and a forward end, the forward end terminating as a spike, the spike capable of accessing an infusion container;

an access lumen (305), a delivery lumen (301), and a vent lumen (316), each of said lumens located within the spike, each of said lumens (305, 301, 316) providing an isolated opening in proximity to the terminus of the spike;

a connector means (302) positioned on the housing, the connector means (302) and the access lumen (305) providing a first fluid path for delivery of toxic drugs into a container;

a second fluid path comprising the delivery lumen (301) and the open distal end for delivery of a mixed solution for intravenous injection; and

a check valve (320) positioned on the housing (311), the check valve (320) and the vent lumen (316) providing a third fluid path,

wherein the first fluid path, the second fluid path, and the third fluid path are each isolated from each other.

2. The device of claim 1, further comprising a penetrable membrane (306) positioned in the housing (311) between the open distal end and the forward end of the housing.

3. The device of claim 1, wherein the connector means (302) is a septum containing connector.

4. The device of claim 1, wherein the connector means is a needle-free valve connector.

5. The device of claim 1, wherein the open distal end is adapted to receive an infusion connector.

6. The device of claim 1, wherein the check valve (320) further comprises a hydrophobic filter (325).

7. The device of claim 1, further comprising a cap (304) connected at the open distal end, the cap reversibly covering the open distal end.

8. The device of claim 7, wherein the cap (304) is connected at the open distal end.

9. The device of claim 1, further comprising a seal (306) at the distal end of the housing (311) for sealably receiving an infusion connector.

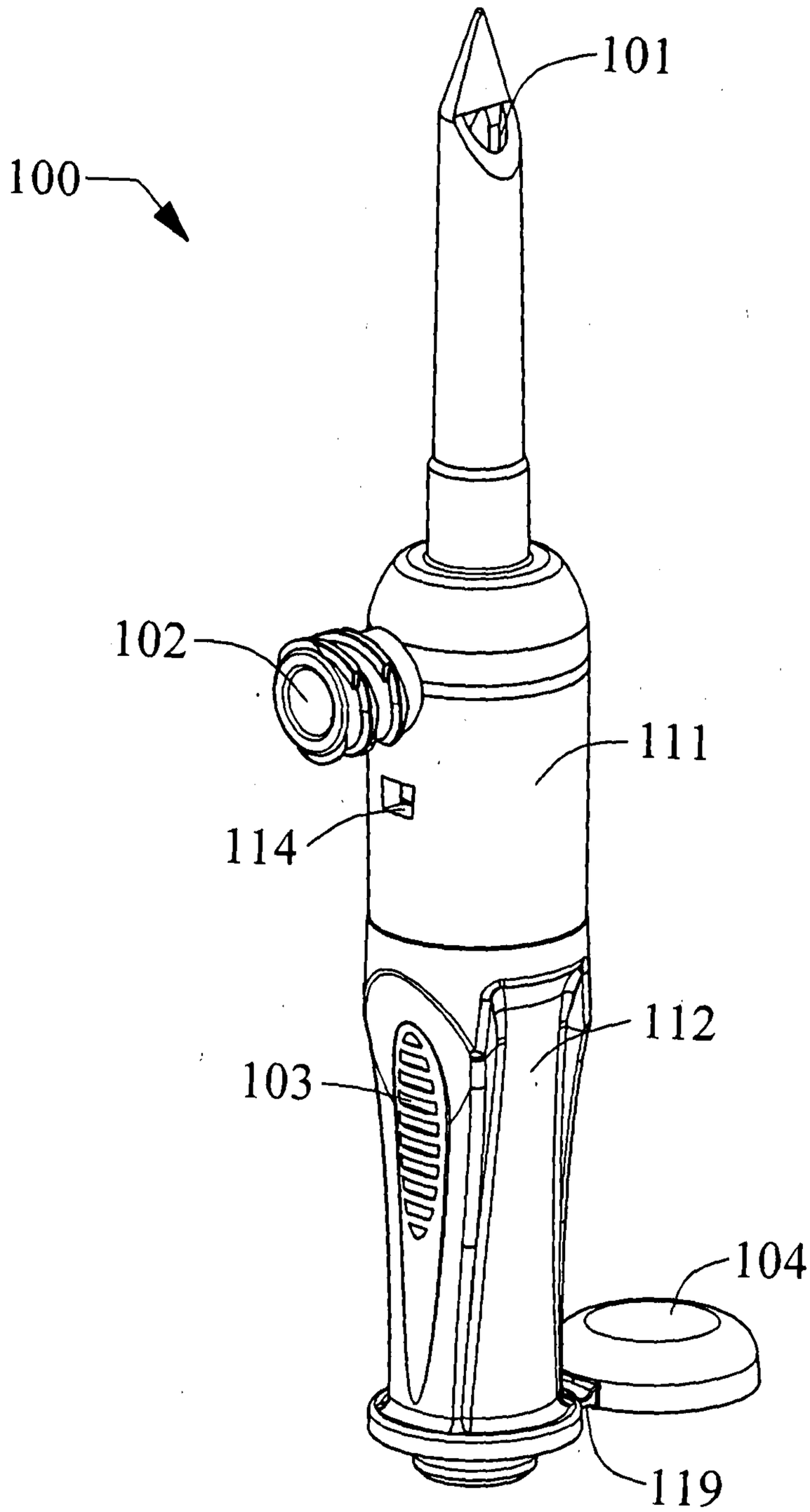


FIG 1

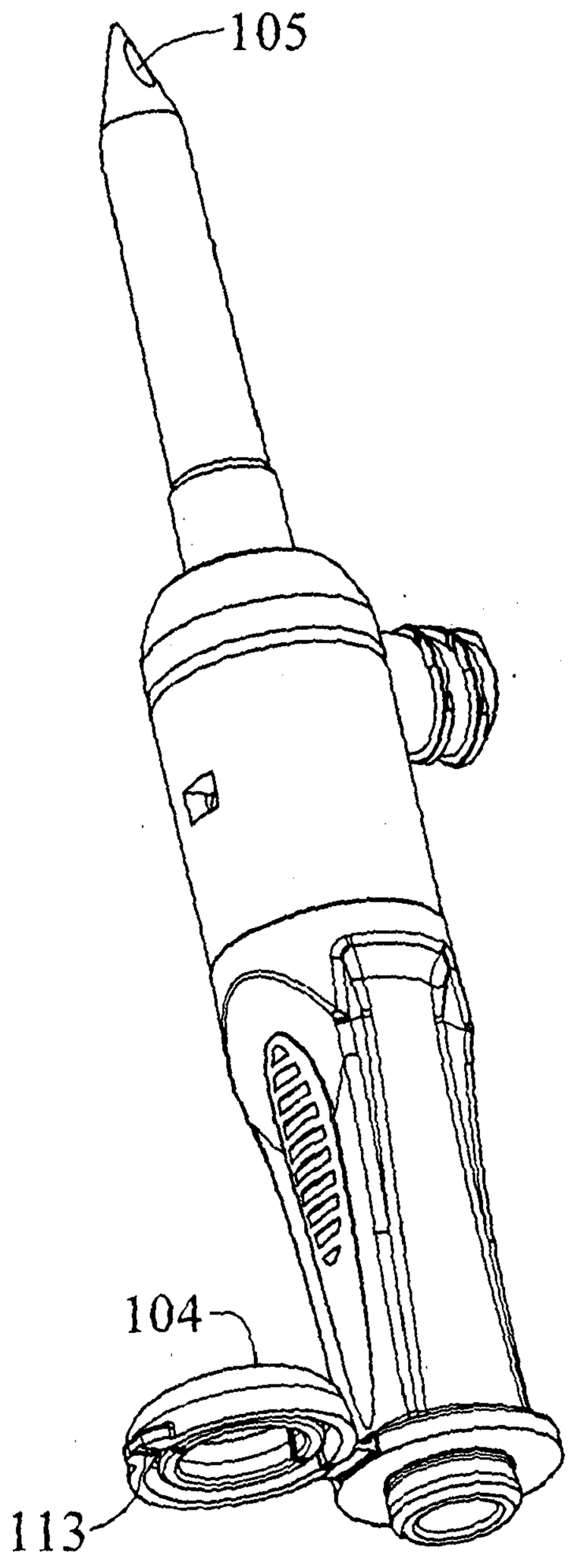


FIG 2

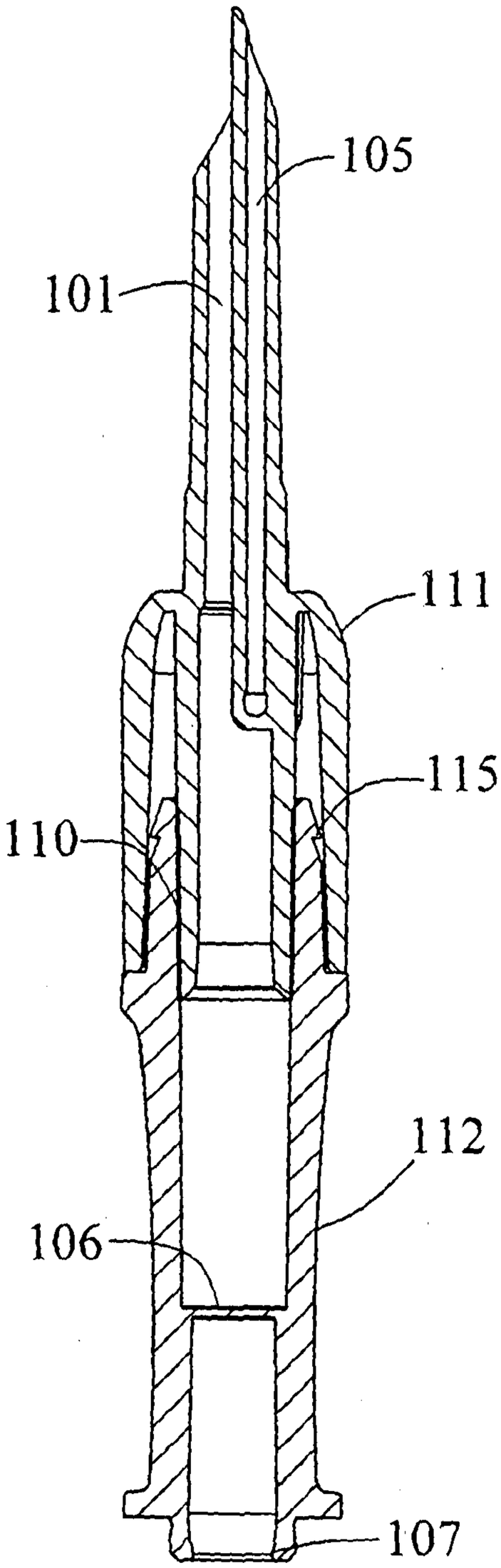


FIG 3

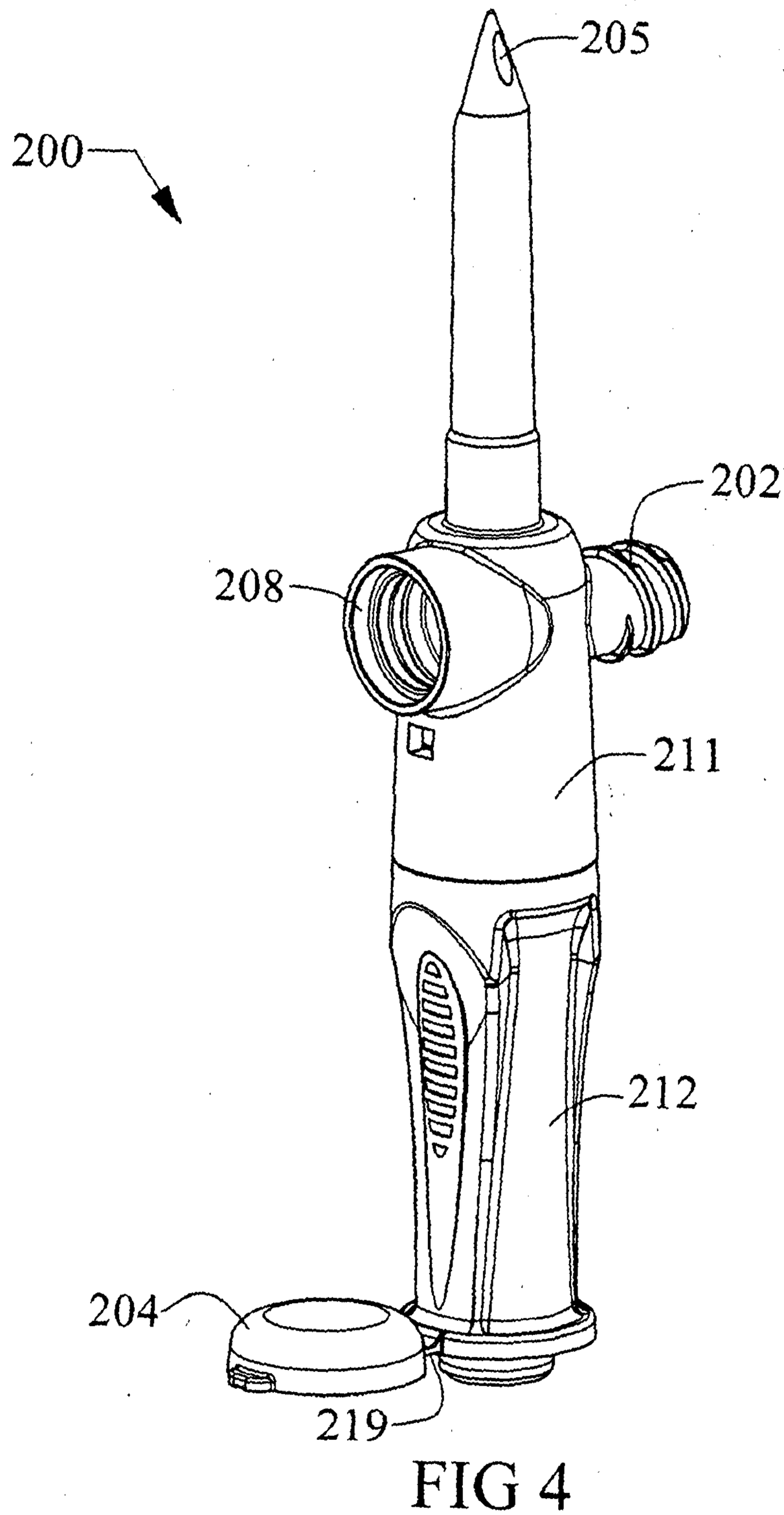


FIG 4

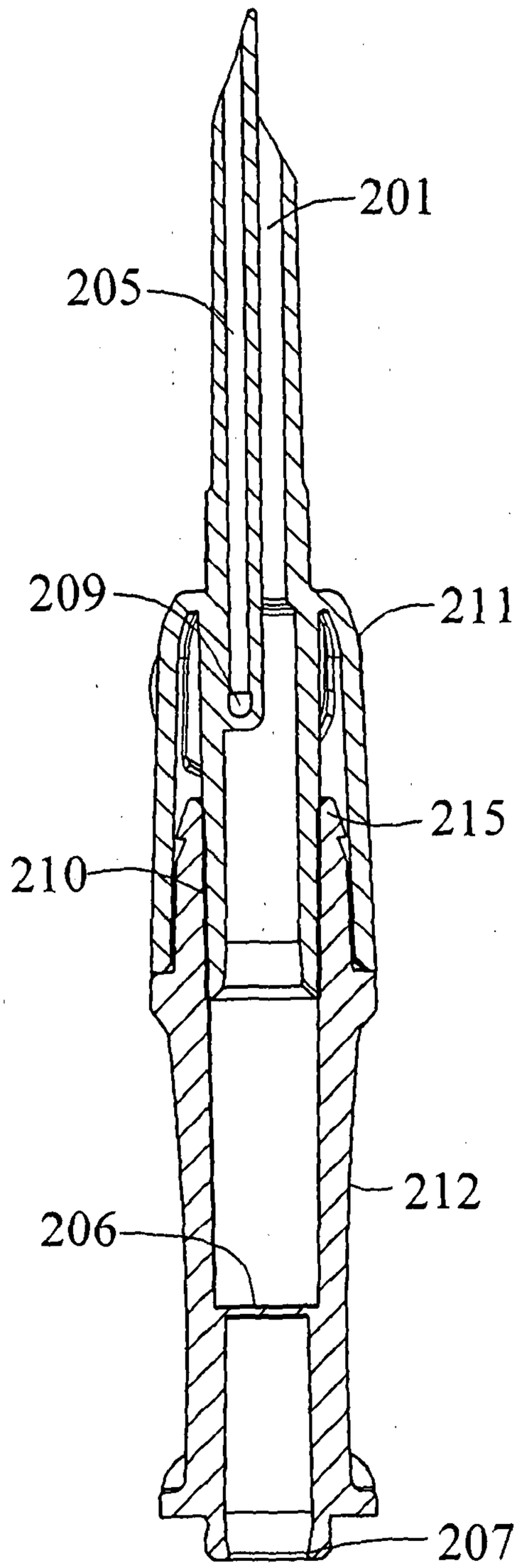


FIG 5

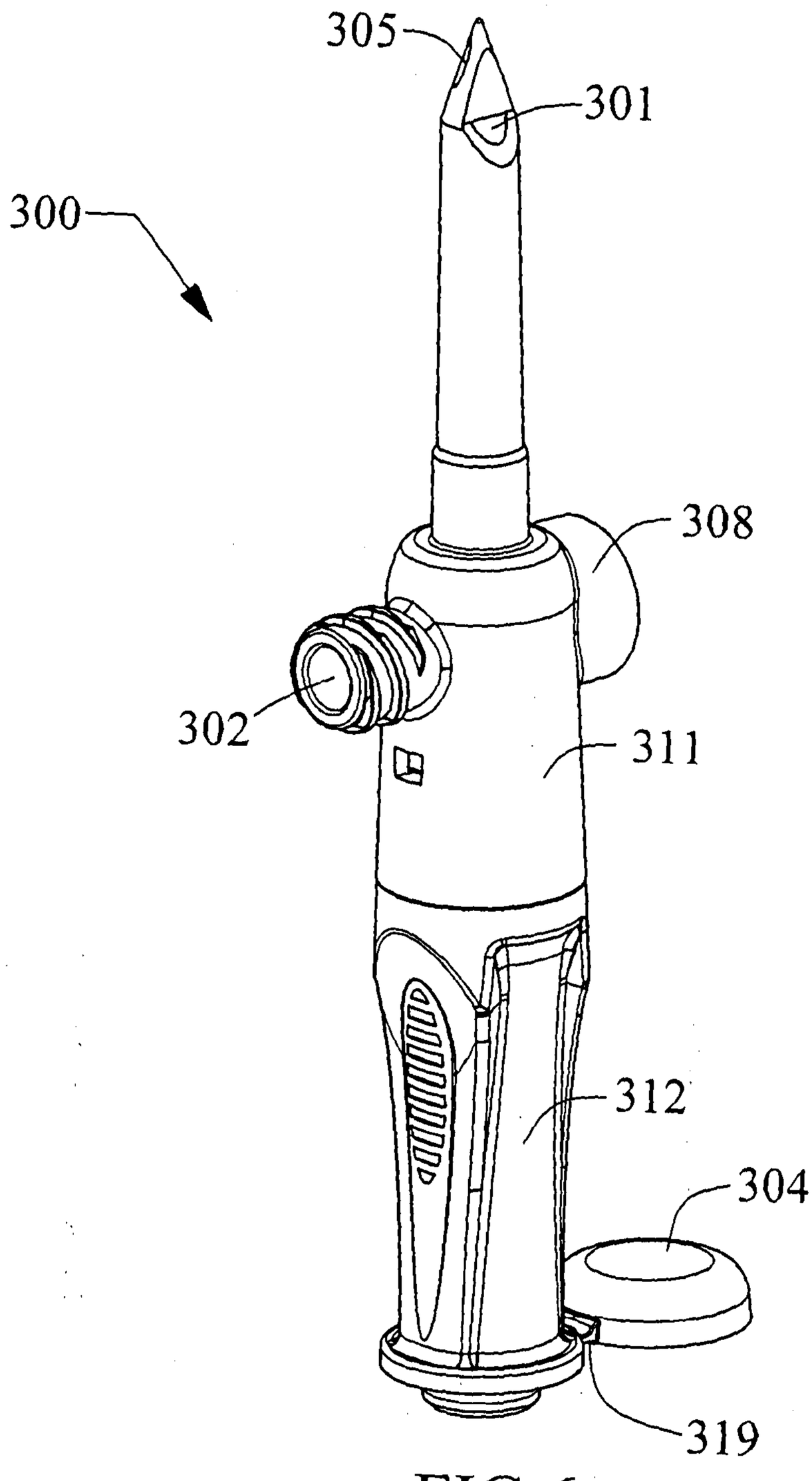


FIG 6

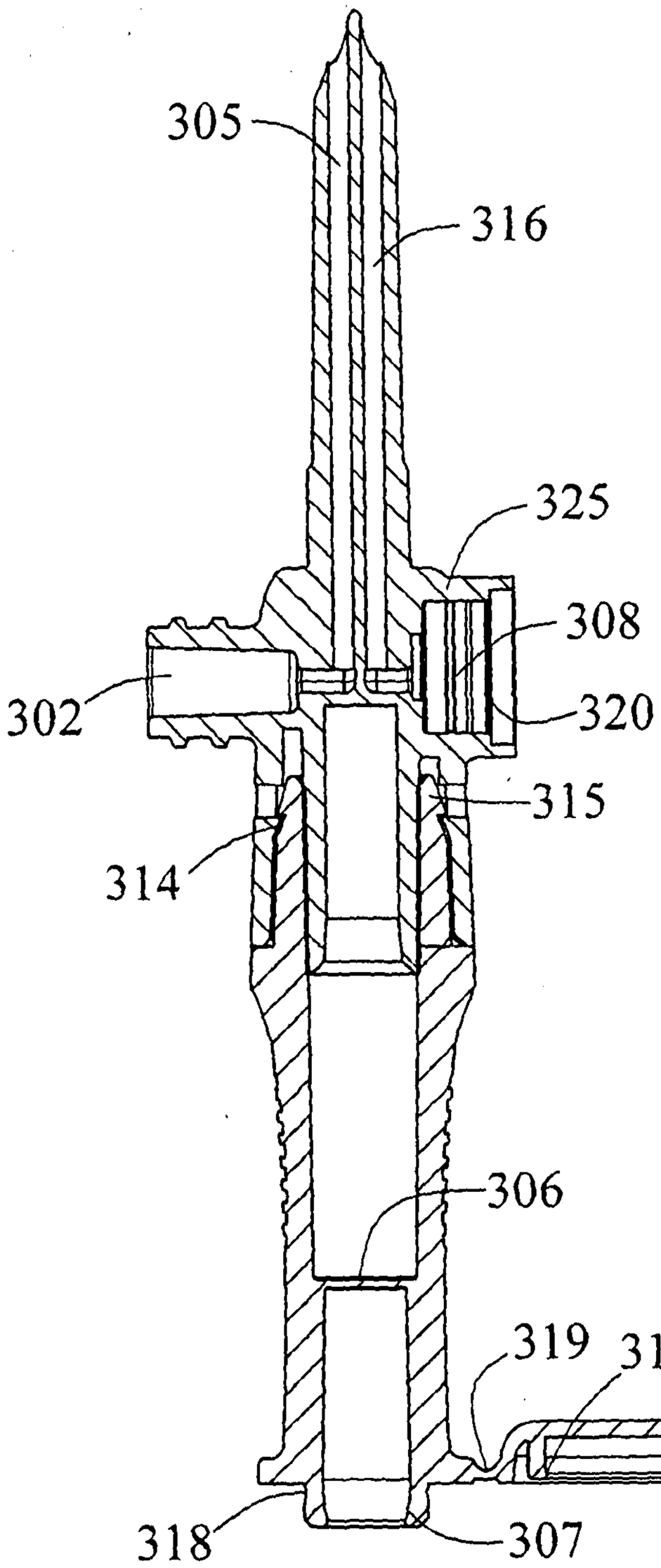


FIG 7

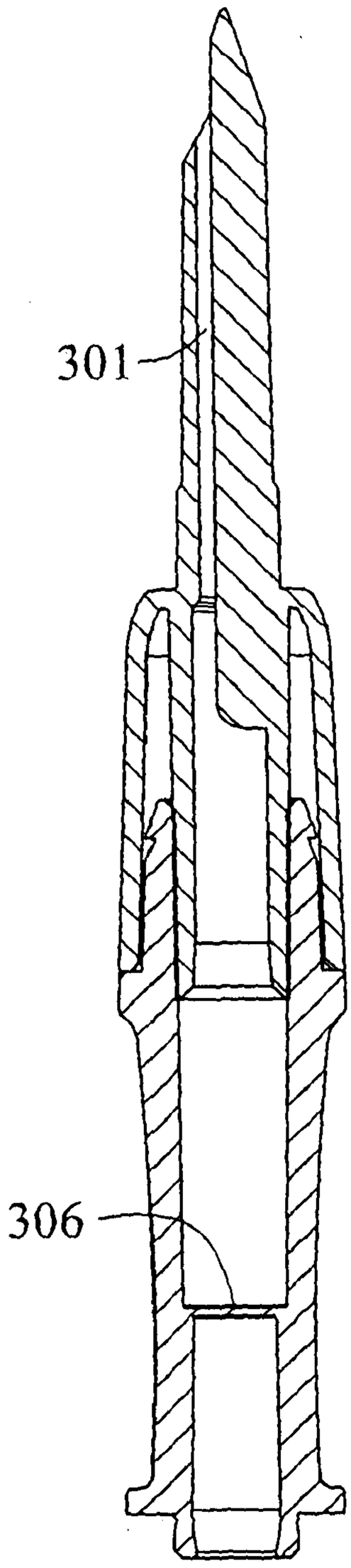


FIG 8

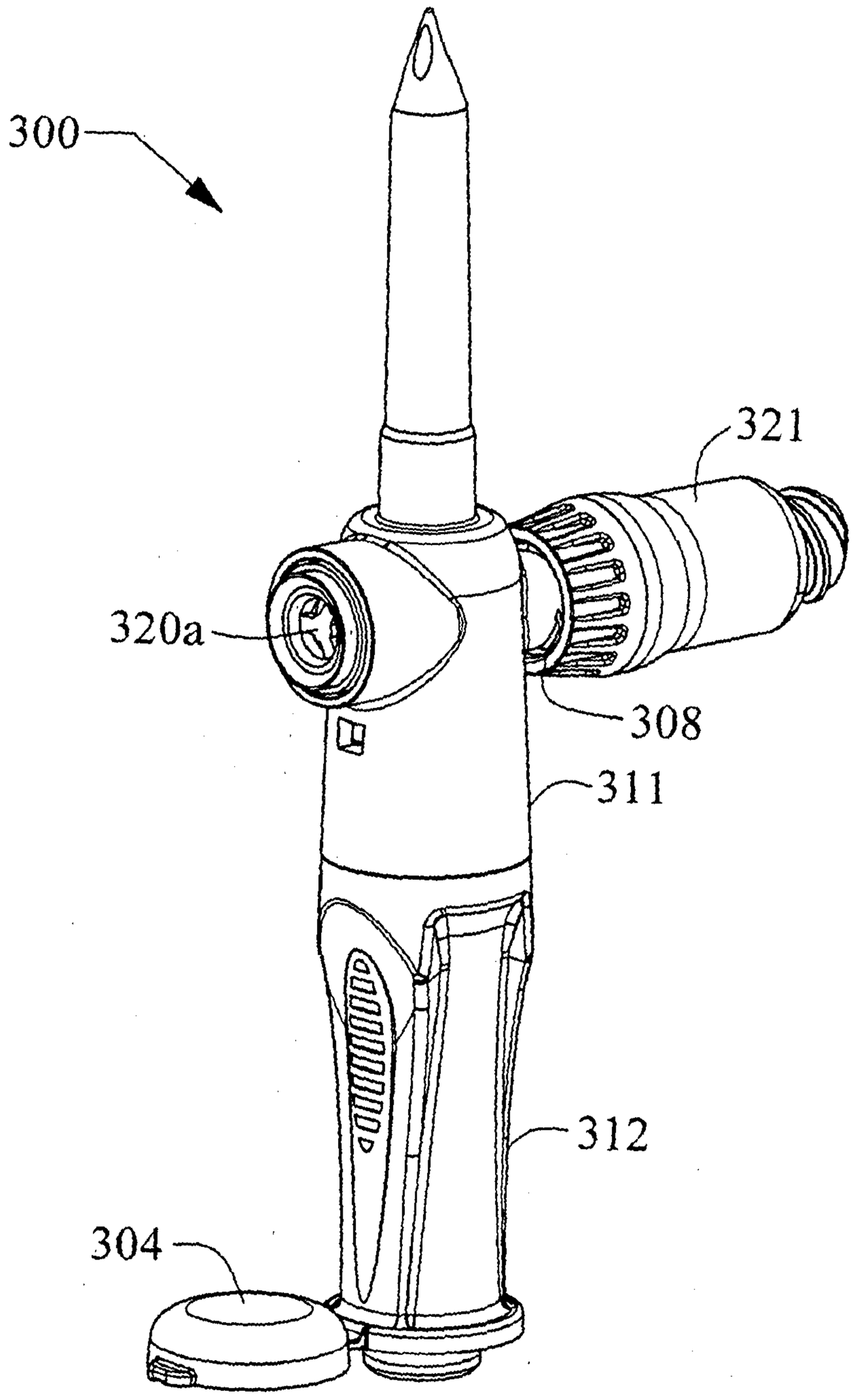
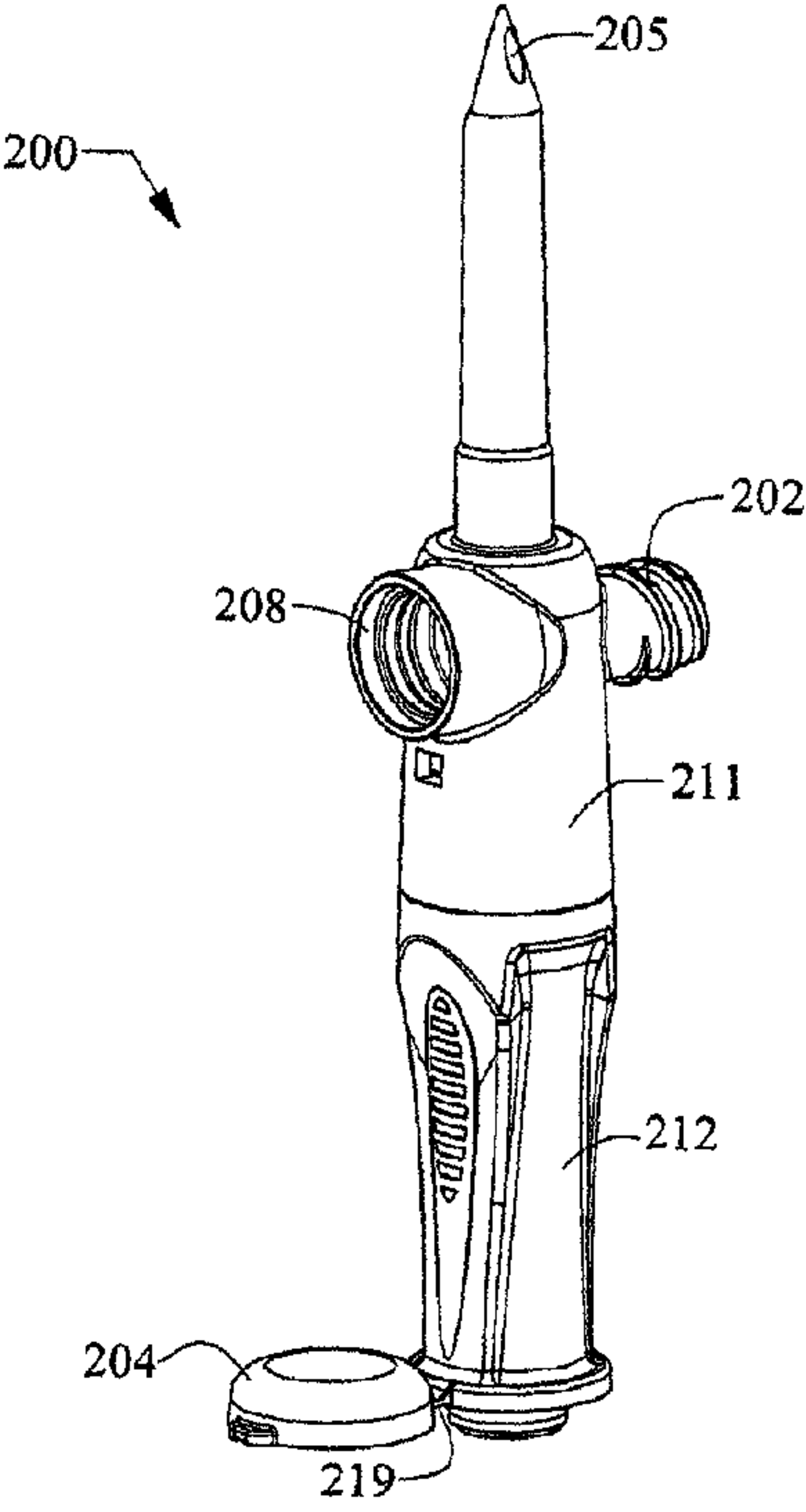


FIG 9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204
219