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(54) Title: HEALTHY PLEASURABLE INHALATION DEVICE

(57) Abstract: A human inhalation device about the size of a typical cigarette and having an internal reservoir containing a supply of flavoi ful or medicinal particulate The device is internally configured to mix particulate with air as the air is drawn through the device by the user The internal configuration provides a two-phase flow of air and particulate at a rate that provides a pleasurable experience from the first inhalation on The internal configuration automatically meters the flow of particulate into the air and, through an aperture, deposits the particulate in the mouth and on the tongue of the user as the two-phase flow exits the aperture.



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION
HEALTHY PLEASURABLE INHALATION DEVICE

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Background of the Invention.

The field of the invention pertains to oral devices that provide a pleasurable experience. Foods and similar items, such as chewing gum, provide such experiences. Non-food items, such as cigarettes, cigars, smoking pipes and chewing tobacco, also provide such experiences. Disclosed below is a device intended to healthfully substitute for cigarettes, cigars and smoking pipes, in particular.

The human respiratory tract can be divided into upper and lower airways. The upper airway tract includes the nose, mouth, pharynx and larynx. The lower airway tract consists of the trachea, bronchi and bronchioles. The division between the upper and lower airways is usually taken as the junction of the larynx and the trachea. The new device, and its technology, is based on oral inhalation.

Considering the oral airway tract, the passage for oral flow can also be divided into three regions: (1) the entrance consisting of lips, front teeth and the leading edge of the tongue, (2) the middle region and arching channel bounded by the tongue and the hard palate, and (3) the oral pharynx where the passage joins the nasopharynx and the flow becomes vertical. While the flow rate of air obviously varies, the flow rate is assumed to be 0.5 L/sec.

In general, inhalation devices have been developed for specific medical treatments. One category of devices is for the treatment and relief of asthma, such as disclosed in U.S. Pat. No. 6,408,846. This device contains passageways of a very complicated configuration to finely break and atomize granular medicines into a very fine powder. The powder particles must be as small as possible to reach the smallest passages in the lungs to treat asthma. As a result, the device is many times larger than a cigar or cigarette and therefore far less convenient for a patient to carry at all times.

A second category of device is more directed to other treatments wherein the desire is to accomplish passage of the medicine through the lung tissue and into the bloodstream of a patient. The technology for this category is largely the same because the fundamental object is to deposit an aerosolized liquid or fine powder into the tiniest portions of the lungs (bronchioles) where the medicine in the aerosol can be

absorbed into and through the mucus to provide the intended relief. A purely tubular inhalation device for the treatment of asthma is disclosed in U.S. Pat. No. 6,234,169, which utilizes the Coanda Effect to aerosolize the particulate medicament. As with the other devices, the object is to assure that as much medicine as possible reaches the lungs.

Summary of the Invention.

An objective of the invention is to enable people to “enjoy” the sensation of inhalation. The invention in its fundamental form consists of a generally tubular device with or without a mouthpiece configuration. The tubular portion contains a flavored particulate and a configuration that meters the flow of particles into the air stream leading to the mouth. The size and shape of the tubular portion can vary, depending on the amount of particulate capacity desired for the device and also depending on appearance and comfort factors pertinent to the users.

Use of the new device is somewhat similar to the use of smoking tobacco. When the user inhales through the device, fresh air flows into the distal end, through the internal configuration of the tubular portion and mouth portion, and then into the user’s mouth. With each inhalation, flavored particulate or medicinal particulate is mixed with the flowing air to be deposited in the user’s mouth and on the tongue.

Upon inhalation, the particles purposely deposit on the tongue, in particular. Since the human tongue is particularly sensitive to taste and certain nasal passages sense smell during exhalation, the brain develops a pleasurable experience with the device. By design, the device causes deposit of the particulate in the front portion of the respiratory tract, namely from the teeth to the middle portion of the palate. Deposition of the particulate in this portion of the respiratory tract is important because some forms of the particulate can cause bitterness if the particles reach the pharynx.

The device is designed to control the two-phase flow (of air and particulate) for deposit of the particles on the tongue and in the mouth (oral cavity) and to avoid deposit of particles in the esophagus and lungs. To achieve this particular result with the two-phase flow, the new device allows variation of the following physical aspects: the airflow speed, volumetric airflow rate, airflow direction, the particulate density, particle size and quickness of particulate solubility in saliva.

With the capability of controlling deposit of the particulate on the tongue and inside the mouth, the device has application where the delivery of a medicament is intended for the tongue and mouth and the particulate is intended to dissolve in saliva. Thus, the new inhalation device is not only intended as a pleasurable substitute for smoking but can also serve as a delivery device for medicaments, or both, depending upon the formulation of the particulates. This application discloses further development of an inhalation device first disclosed in Int. Pub. Doc. WO 2005/049449 incorporated herein by reference.

10 Description of the Drawings.

- FIG. 1 is a perspective view of the exterior of the device;
FIG. 2 is a perspective section of the exterior tube of the device;
FIG. 3A is a perspective view of the inner tube or particulate reservoir of the device;
FIG. 3B is a cross-section view of the inner tube of FIG. 3A;
FIG. 3C is a bottom view of the inner tube of FIG. 3A;
FIG. 4 illustrates the assembly of the inner tube in the exterior tube;
FIG. 5A is an end view of the distal end cap;
FIG. 5B is a perspective view of the distal end cap;
FIG. 5C is a cross-section of the distal end cap taken along line C-C of FIG. 5A;
FIG. 5D is a front view of the distal end cap;
FIG. 6 is a perspective section of the entire assembled device;
FIG. 7A is a cut-away section of the distal end illustrating movement of the particulate material from the inner tube;
FIG. 7B is a cut-away section of the distal end;
FIG. 8 is a cut-away section of the distal end illustrating the option of a seal and tab for the inner tube;
FIG. 9 is a perspective section of the entire assembled device with the seal and tab for the inner tube;
FIG. 10 illustrates an unsealed moisture-proof pouch for the device;
FIG. 11 illustrates the unsealed pouch of FIG. 10 with the device of FIG. 9 therein;

FIG. 12 illustrates a sealed pouch with the tab permanently affixed by the pouch seal;

FIG. 13 illustrates opening the pouch from the notch end;

FIG. 14 illustrates withdrawing the device from the pouch leaving behind the
5 tab;

FIG. 15 is a perspective section of the entire assembled device with a modification to the proximal end of the device;

FIG. 16 illustrates the device inserted in a small bottle;

FIG. 17 illustrates use of the small bottle and device;

10 FIG. 18 illustrates a small cup version of the device;

FIG. 19 is a cross-sectional view of the device inserted in a small bottle;

FIG. 20 illustrates one form of construction of the device;

FIG. 21 illustrates the sealing tab version of the small bottle and device; and

FIG. 22 illustrates removal of the small bottle and device from a pouch.
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Description of the Preferred Embodiments.

Illustrated in FIG. 1 is the general appearance of the device having a proximal end 102 and a distal end 103. The device 101 is about the size of an ordinary cigarette but not restricted to such size. The proximal end 102 serves as the
20 mouthpiece area, and air or two-phase air and particulate flow is drawn into the user's mouth through aperture 100.

The exterior tube 101 of the device is internally configured 104 at the proximal end 102 to hold in alignment the closed end 105 of the inner tube 109, as shown in FIGs. 2 and 3A. The inside 108 of inner tube 109 serves as a reservoir for
25 the flavored or medicament particulate. The internal baffle configuration 104 also serves to guide the air and particulate two-phase flow over the closed end 105 of the inner tube 109 and on into the hole leading to the aperture 100.

At the distal end 110 of the inner tube 109 is a ring or flange divided by two slots 106 and 107, as also shown in FIGs. 3B and 3C. As more fully disclosed below,
30 the slots 106 and 107 direct the two-phase flow about the outside of the inner tube 109.

The inner tube 109 is shown fully assembled into the exterior tube 101 of the device, as shown in FIG. 4, wherein the closed end 105 of the inner tube 109 fits into

the internal baffle configuration 104 providing plural passages for two-phase flow leading to the hole and aperture 100. At the distal end 103, the inner tube 109 and slotted ring end 110 terminate well inside the exterior tube 101 of the device. The slots 106 and 107 provide an entranceway to the annular cavity formed by the inner tube 109 and exterior tube 101.

FIG. 5 discloses the configuration of the distal end cap 111 in detail. The cap 111 includes a plurality of slots 113 for the admittance of air through the cap from the cap bottom 112. The top of the cap is formed with a cylindrical stud 114 divided by three slots 118 opening out adjacent the slots 113. The cylindrical slotted stud 114 forms a central space 115 within the stud.

As shown in FIG. 6, the distal end cap 111 is inserted into the distal end 103 with cap skirt 116 tightly fitting in the end. An annular space 117 is formed by the exterior tube, the cap 111 and stud 114, and the ring 110. The space 117 communicates with the central space 115 through slots 118 and, in turn, the open interior 108 of inner tube 109. The space 117 also communicates through slots 106 and 107 with the annular cavity 132.

In FIG. 7A, the distal end 103 is shown with particulate 120 in the inner tube 109, a small portion of which has entered space 117 through slots 118. In normal operation, air passing through slot 113 mixes with particulates in space 117 and passes on through slots 106 and 107 and is two-phase flow indicated by arrow 119 (FIG. 6) in annular cavity 132. The two-phase flow exits (arrow 120) from the aperture 100. To retain the distal end cap 111 in proper position, the tip 149 of the exterior tube is thermally bent over, as shown in FIG. 7B.

Research has shown that the flow patterns of air and particulate in the annular space 117 are actually much more complicated than immediately apparent. At least a portion of the air drawn in through slots 113 is deflected within space 117 through slots 118 and up into the inside 108 of inner tube 109. The result is a vigorous churning of the particulates 120 in the lower end of inner tube 109, the central space 115, the annular space 117 and through the slots 106 and 107. Thus, the result is a smooth, even flow of particulates as the user inhales, regardless of whether the inside 108 is full or almost exhausted of particulates.

During the extended period of time between manufacture and use, it may be advantageous to physically prevent the exit of particulates from inner tube 109 or the

entrance of air or moisture. FIGs. 8 through 14 disclose an option for sealing the inner tube 109, regardless of orientation of the device during shipment or storage. A paper tab 121 is positioned between the bottom of inner tube 109 and the top of distal cap 111. The paper tab 121 extends between the skirt 116 and exterior tube 101 so that the tab can be extracted manually by the user just before use, thereby allowing particulate 120 to flow into space 115 and 117.

Illustrated in FIG. 10 is a plastic pouch 122 for a single device to prevent moisture or contaminants from reaching the device. The pouch 122 is heat sealed 124 about three sides, leaving the fourth side 126 open 123 for insertion of a device therein. A notch 125 is formed in the sealed side opposite the open side. In FIG. 11, the device has been inserted with the paper tab 121 extending out of the pouch 122, and in FIG. 12, the fourth side 126 has been sealed with the tab sticking out.

To remove the device from the sealed pouch 122, the pouch is torn open from the notch 125, as shown in FIG. 13, and the device is removed from the pouch, as shown in FIG. 14. Removal of the device from the pouch 122 automatically extracts the tab 121 from the device because the tab is affixed to the pouch when the fourth side 126 is sealed.

In FIG. 15, a further optional feature of the device comprises an annular groove 130 formed in the proximal end 102 of the device. When the user is not inhaling through the device, the user may hold the device in many different positions and, due to motion and gravity, particulate may fall out of the aperture 100. To minimize the loss of particulate and deposition on clothes, the annular groove 130 serves as a temporary trap for particulate in the annular cavity 132. With further motion, the particulate will return to the annular cavity 132 and be drawn through aperture 100 with the next inhalation by the user.

The characteristics of the particulate, regardless of flavor or medicament, are very important to the proper operation of the device. At the distal end, the particles must not clog but rather be evenly mixed in the air, regardless of whether the reservoir is full or almost empty and regardless of the air flow rate within the limits of normal human inhalation through the device. At the proximal end, the particles must be well mixed in the air as the two-phase flow passes through the aperture 100 and, further, immediately upon passing through the aperture, the particle density must

cause the particles to deposit on the tongue and the immediate oral cavity with few, if any, particles continuing on in the air flow into the lungs.

Additional constraints on the particles comprise solubility in water for immediate dissolution in saliva and safety in the event some particles reach the lungs or esophagus. Meeting all of the above constraints is a non-trivial exercise; however, through extensive testing, applicant has determined that the particles should be granulated and substantially dust-free.

Since the force of gravity is an important factor in causing the particles to deposit on the tongue, the material of the particles determines the "equivalent diameter" (the combination of diameter and density of a particle). For example, sugar granules are relatively dense, and maltodextrin particles are relatively less dense. Through testing, applicant has determined that 40 mesh is about the higher limit of particle size and that the range of particle size should be upward from about 100 mesh. Furthermore, the slots 113 at the distal end are sized to generally prevent most particles from falling out of the device, regardless of the position or movement of the device by the user.

The particles may be consistent in composition, thereby achieving the same density, or individual particles may be of different composition and therefore of differing density and size. For example, there may be flavor particles and granulated sugar particles that are thoroughly mixed together just prior to filling the reservoir 109. An anti-caking agent may also be added to the particulate before filling the reservoir.

FIG. 16 illustrates the device 101 affixed in a small bottle 140. The essence of the idea is "drinking flavored air," as best shown in FIG. 17 wherein a person 142 is shown drawing on a nozzle 146 extending from the bottle 140. FIG. 18 illustrates that the small bottle may be a cup 144 or other container.

In FIG. 19, the small bottle 140 is shown with the device 101 within the bottle and the nozzle 146 extending the device aperture 100 above the top 148 of the bottle. At the bottom 150 of the bottle 140 is a second aperture 152 permitting air to be drawn into the device 101 enclosed within the bottle. The bottle bottom 150 is formed with a circular ring 154 to retain the device 101 centered on the aperture 152. The bottom 150 may be a separate piece as shown in FIG. 20 that is adhesively attached or molded to the rest of the bottle 140. Or, in the alternative, the small

bottle 140 may be blow molded and trimmed to the shape shown before inserting the device 101.

As above, the device 101 within the bottle 140 may have the sealing tab 156 extending from the bottom through the aperture 152, as best shown in FIG. 21, and
5 the entire bottle 140 may be packaged in a pouch 158 that can be torn open, as best shown in FIG. 22. Here again, the sealing tab 156 is attached to the pouch bottom 160 when the pouch bottom is sealed upon insertion of the bottle 140 into the pouch.

CLAIMS

1. A pleasurable human inhalation device comprising a generally tubular portion having a distal end and a proximal end, the proximal end to be placed in a user's mouth and having at least one proximal aperture for the admittance of a two-phase flow into the mouth,
- means on the device to admit air therein in response to inhalation through the at least one proximal aperture,
- a supply of particulate in a reservoir within the tubular portion,
- means to meter mixing of air with particulate to form a two-phase flow, and
- means to direct the two-phase flow to the at least one proximal aperture,
- wherein the means to meter include mixing of air with particulate in at least a portion of the reservoir.
2. The pleasurable human inhalation device of claim 1, including a tubular reservoir and a passageway adjacent the reservoir, the passageway being in communication with the proximal aperture.
3. The pleasurable human inhalation device of claim 1 wherein the density and size of individual particles of the particulate cause deposition of the particles in the oral cavity.
4. The pleasurable human inhalation device of claim 1 wherein the particle size is on average smaller than 40 mesh, greater than 100 mesh, and substantially devoid of dust.
5. The pleasurable human inhalation device of claim 1 wherein the particulate is immediately soluble upon contact with human saliva.
6. A method to deposit particles on the human tongue and in the human mouth from a two-phase moving flow of air and particles comprising the steps of,
- preparing particles of a predetermined average density and physical size that will drop and spread from the two-phase flow in response to gravitational effects on the particles as the two-phase flow exits at least one orifice in a device having the proximate end formed with the orifice substantially positioned at the lips of the mouth,

storing the particles in a reservoir within the device, and
combining the particles with moving air to create the two-phase flow
in the device in response to inhalation through the device and orifice.

7. The method of claim 6, including the step in the preparation of
5 particles comprising mixing sugar particles with flavored particles.

8. The method of claim 6, including the step in the preparation of
particles of mixing sugar particles with medicinal particles.

9. The method of claim 6, including the step in the preparation of
particles of adding particles containing nicotine.

10 10. The method of claim 6, including the step in the preparation of
particles of mixing unlike particles just prior to feeding the particles into the
reservoir.

11. The method of claim 6, including the step in the preparation of
particles of adding particles containing fruit flavors.

15 12. The method of claim 6, including the step in the preparation of
particles of adding particles containing spice flavors.

13. The method of claim 6 wherein at least a portion of the moving air
enters the reservoir at a flow rate sufficient to agitate some of the particles in the
reservoir and thereby to create two-phase flow exiting the reservoir.

20 14. The method of claim 6 wherein at least some particles move from the
reservoir in response to the effects of gravity and mechanical movement of the device
by a user.

25 15. The pleasurable human inhalation device of claim 1, including means
to seal the reservoir from contamination within the device, said means to seal being
removable by the user.

16. The pleasurable human inhalation device of claim 1, including an
external air and moisture tight package enclosing the device, the package including a
notch for initiating tearable opening.

30 17. The pleasurable human inhalation device of claim 16, including means
to seal the reservoir within the device, said means to seal the reservoir connected to
the external package.

18. The pleasurable human inhalation device of claim 17 wherein the means to seal the reservoir is automatically removed upon removal of the device from the package.

19. The pleasurable human inhalation device of claim 1, including means
5 in the proximal end to temporarily entrap particles during periods of non-inhalation.

20. In the treatment of addiction to nicotine, the use of a device externally simulating a common smoking means, the device having a reservoir therein containing particulate, means in the device for air to flow through the device from a distal end to a proximate end, means in the device to mix particulate from the
10 reservoir with the flowing air in response to human inhalation of air through the device, the particulate passing through the proximate end and being deposited on the human tongue and within the oral cavity in response to the effect of gravity on the particulate.

21. The use of a device as claimed in claim 20 wherein the device is
15 substantially the size and shape of a common cigarette.

22. The human use of the device as claimed in claim 1 to provide a pleasurable experience.

23. The human use of the device as claimed in claim 1 to provide delivery of a medicament to the tongue and oral cavity.

20 24. The human use of the method as claimed in claim 6 to provide a pleasurable experience.

25. The human use of the method as claimed in claim 6 to provide delivery of a medicament to the tongue and oral cavity.

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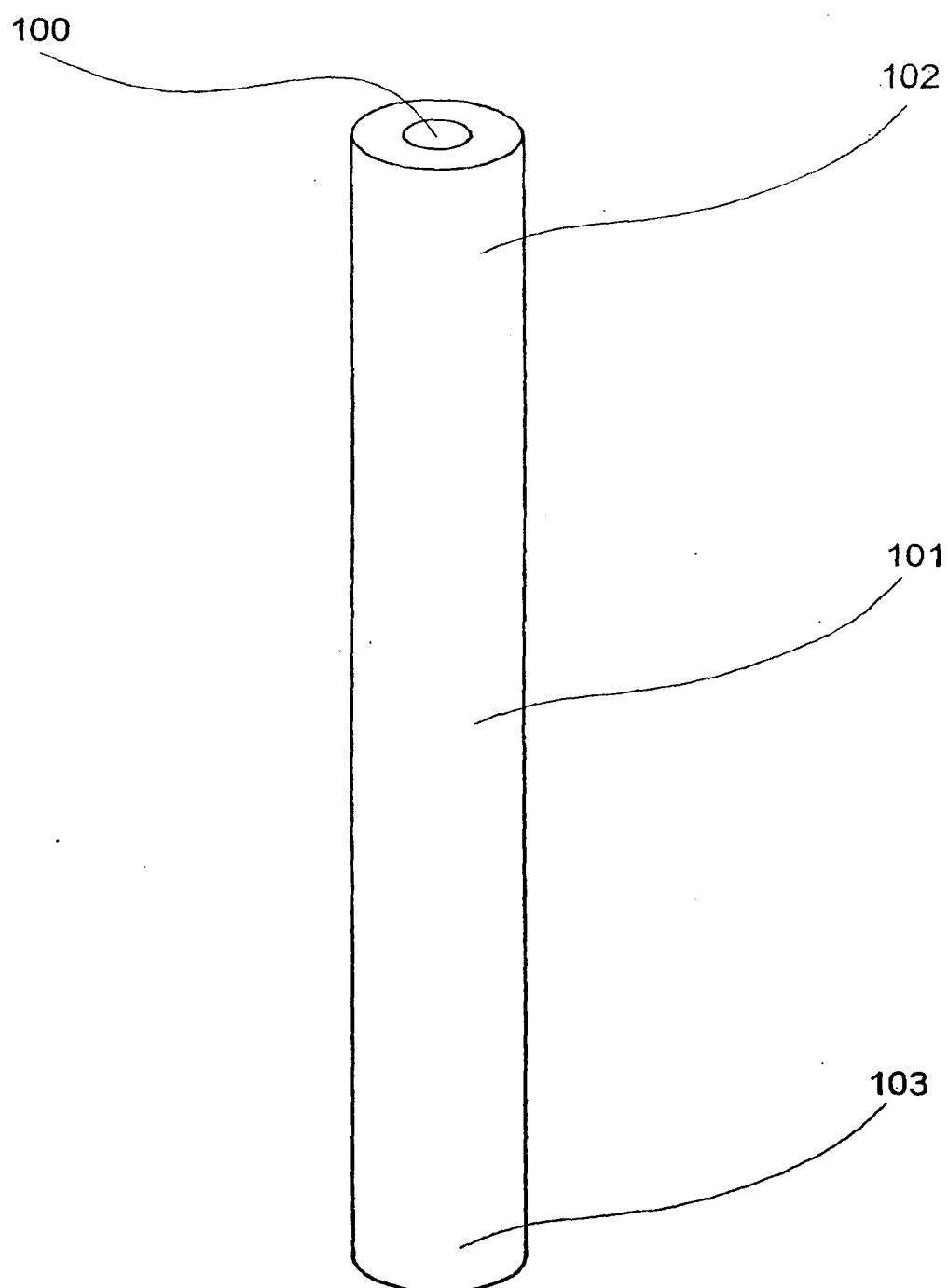


Fig. 1

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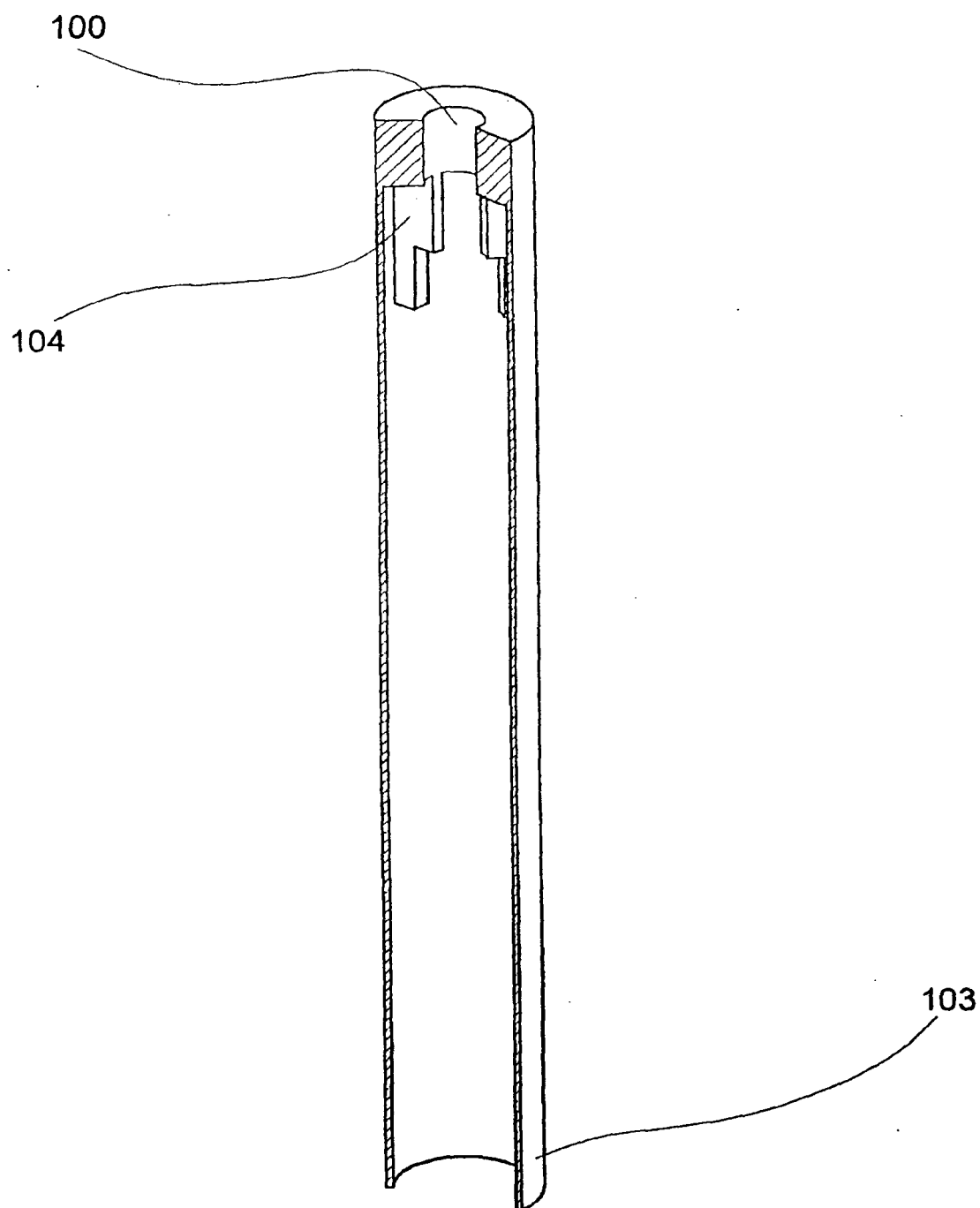


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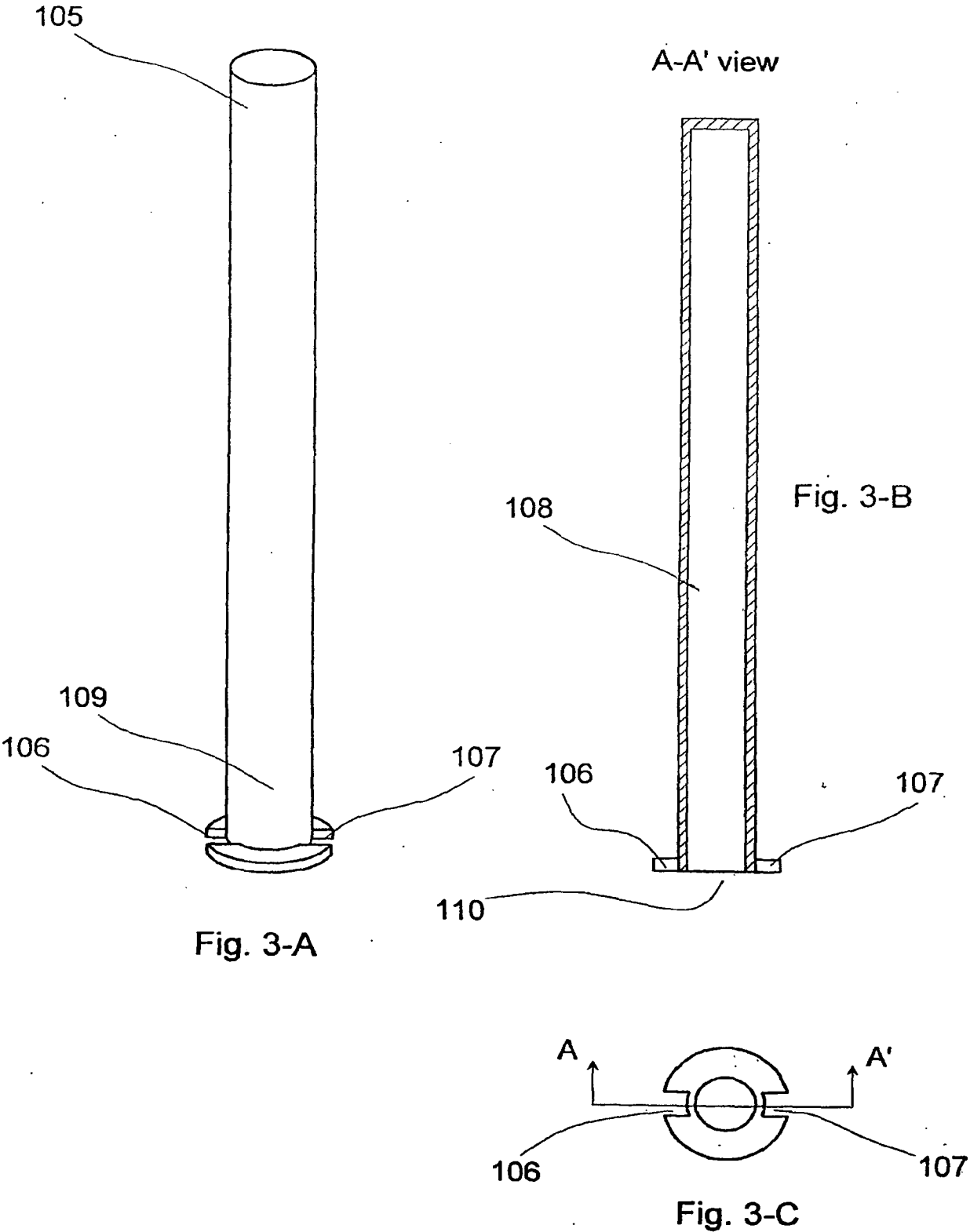


Fig. 3

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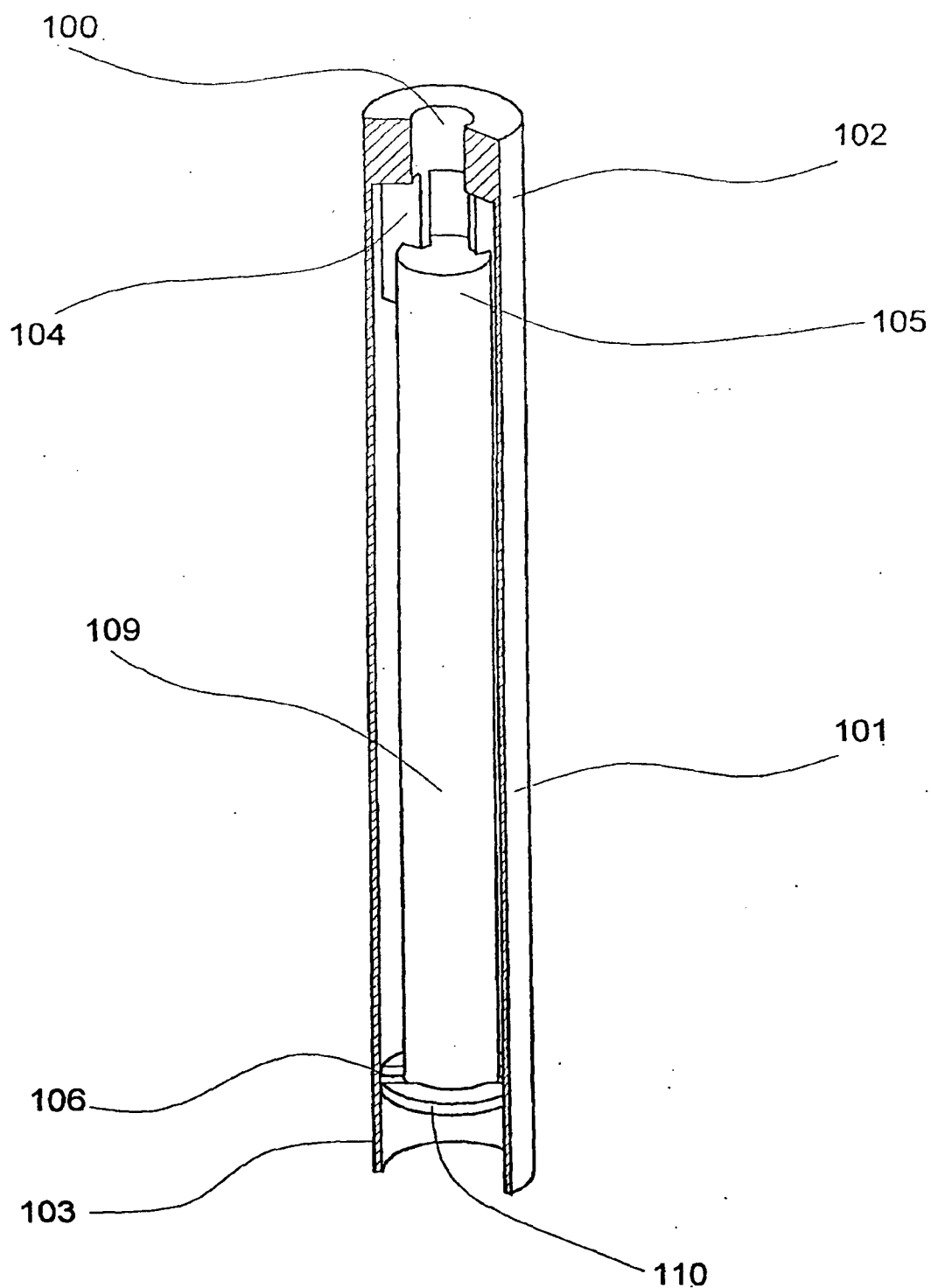


Fig. 4

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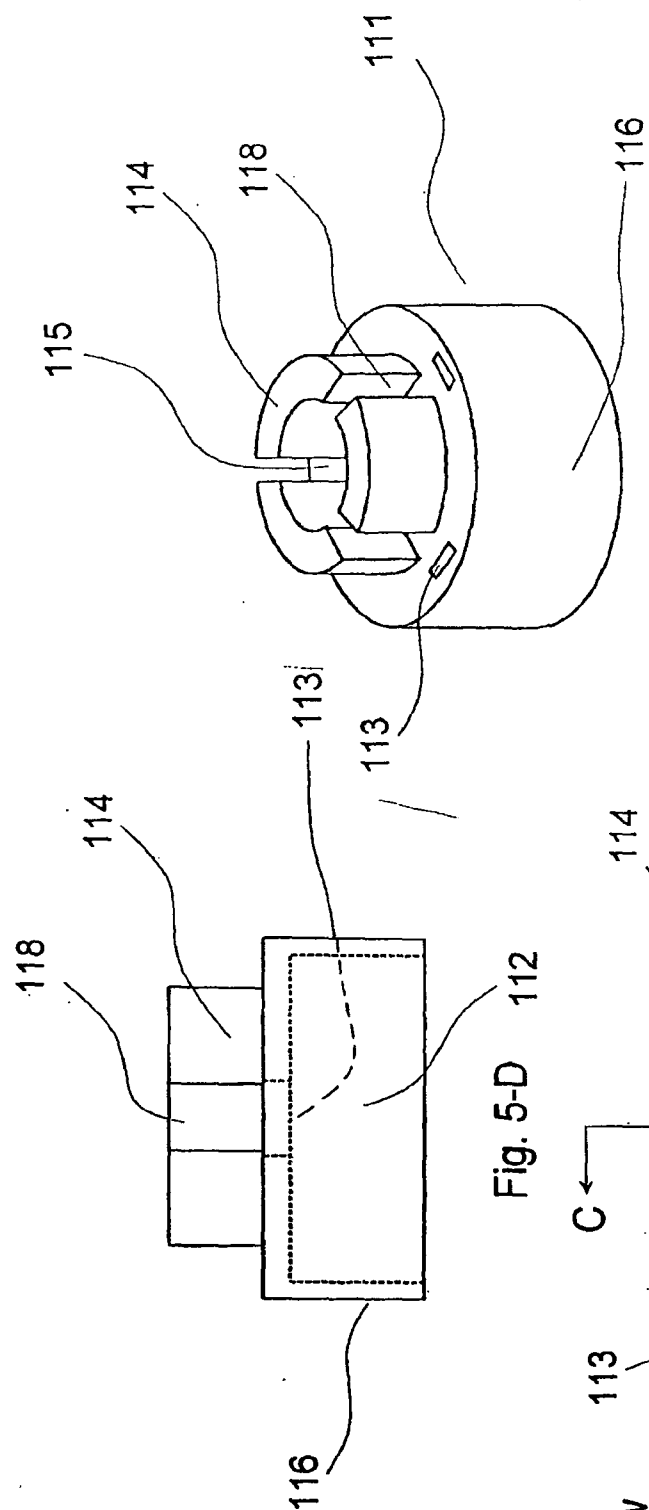


Fig. 5-B

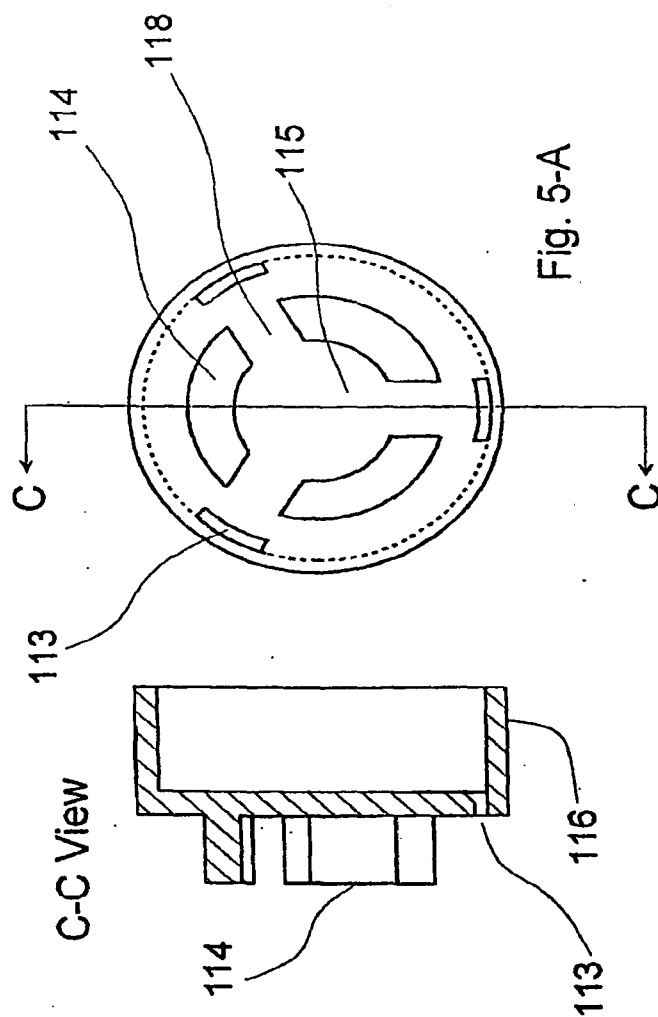


Fig. 5-A

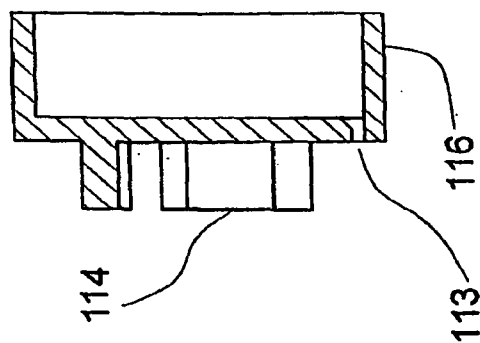


Fig. 5-C

Fig. 5

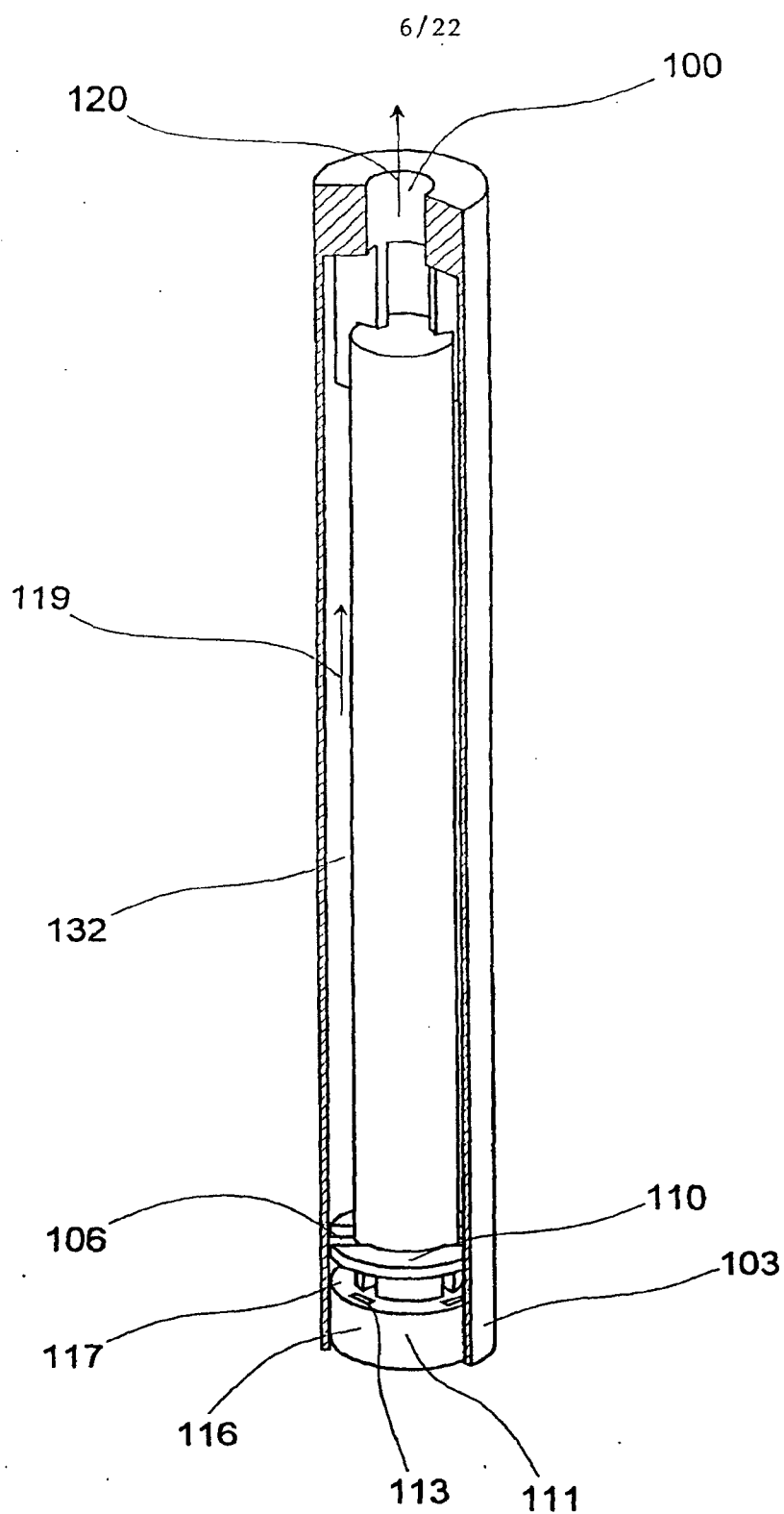


Fig. 6

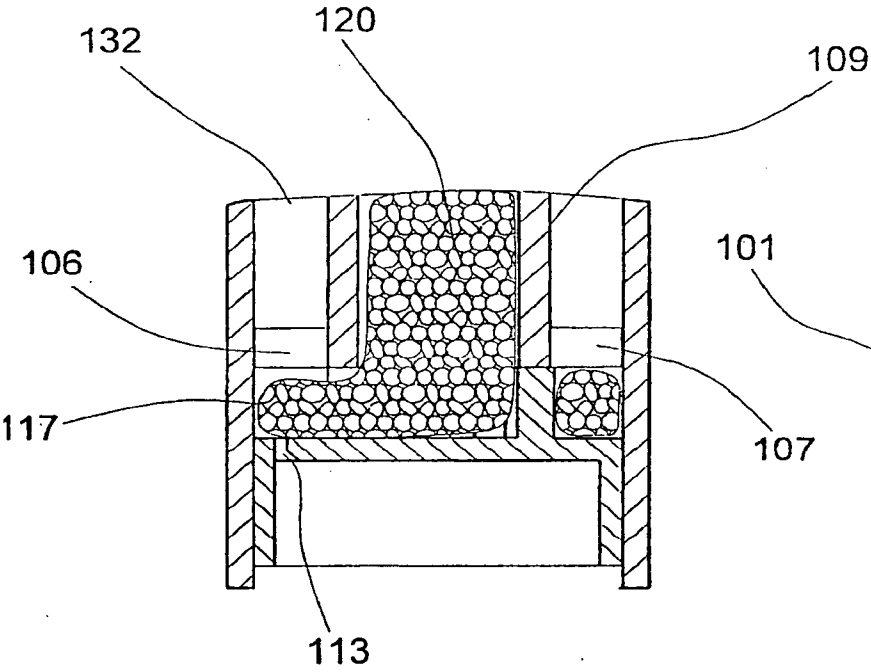


Fig. 7-A

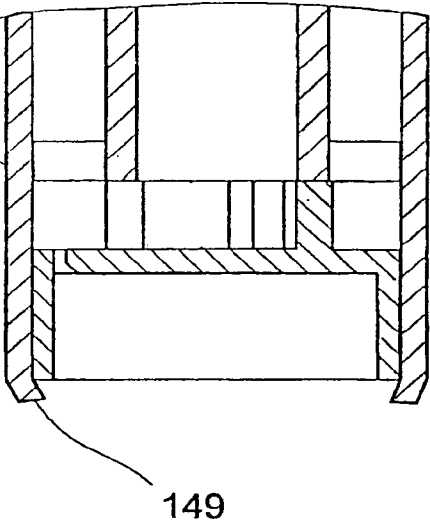


Fig. 7-B

Fig. 7

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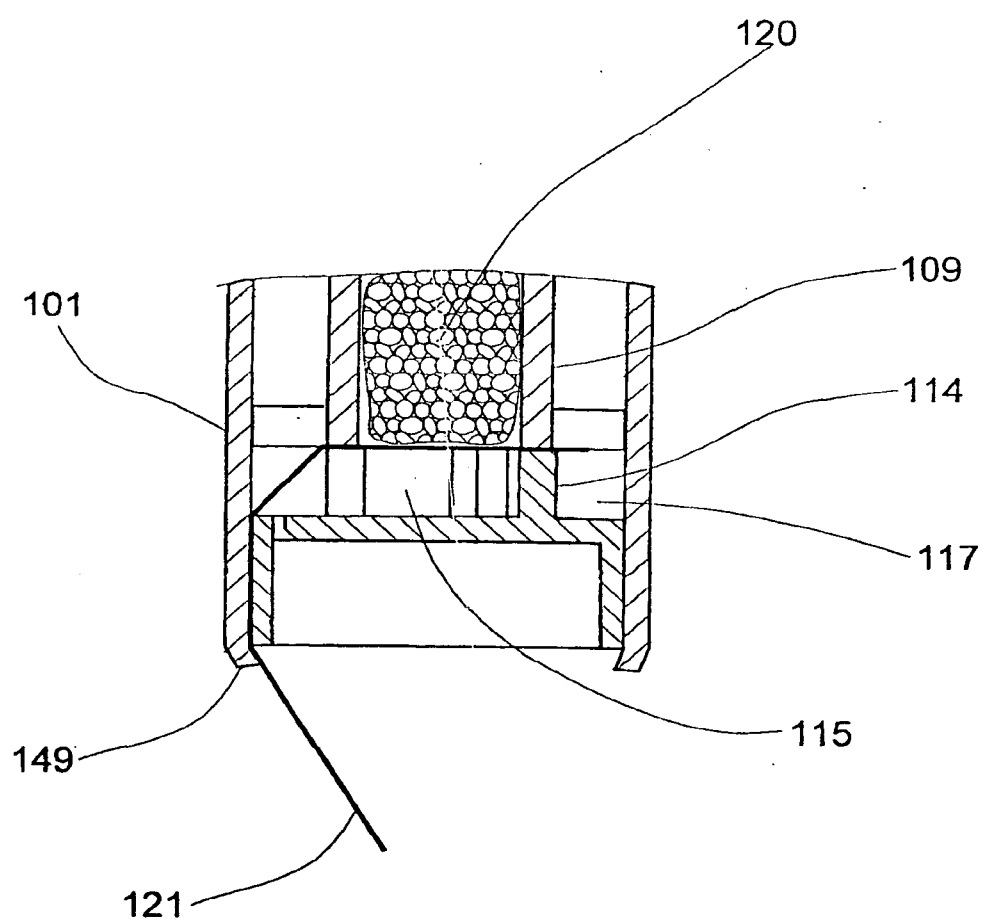


Fig. 8

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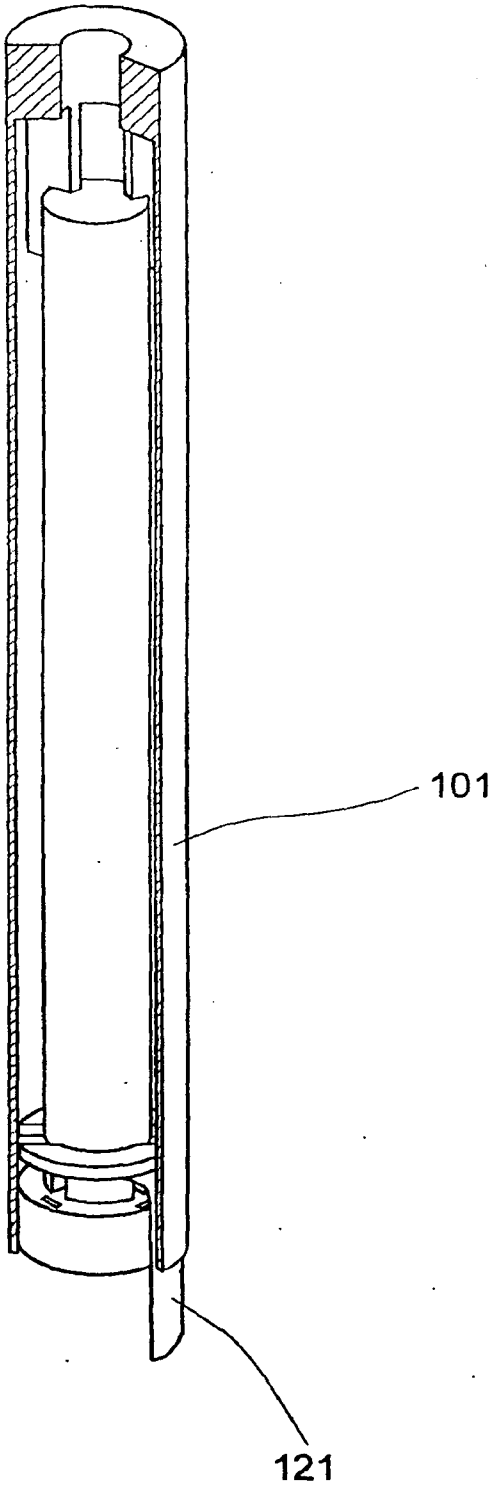


Fig. 9

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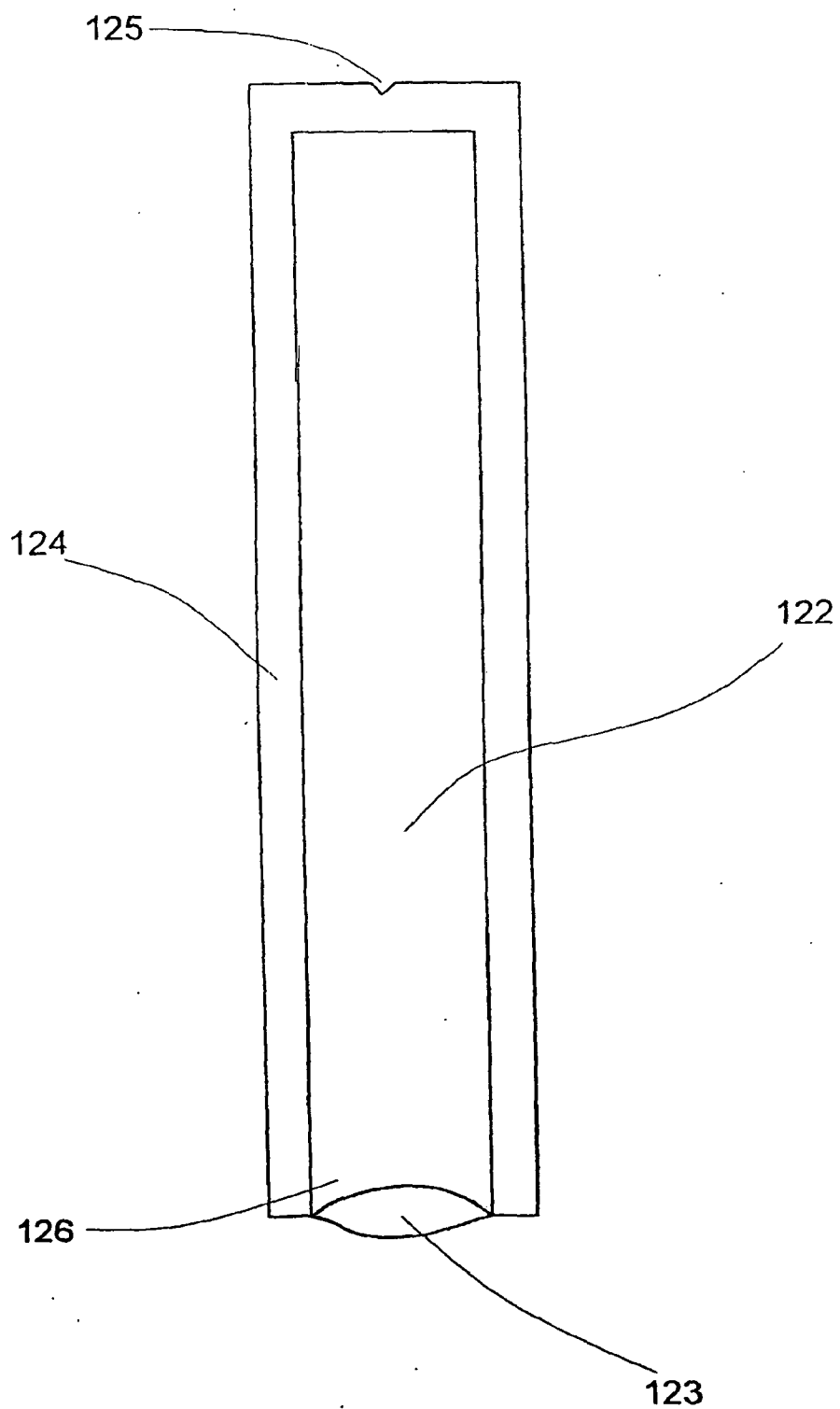


Fig. 10

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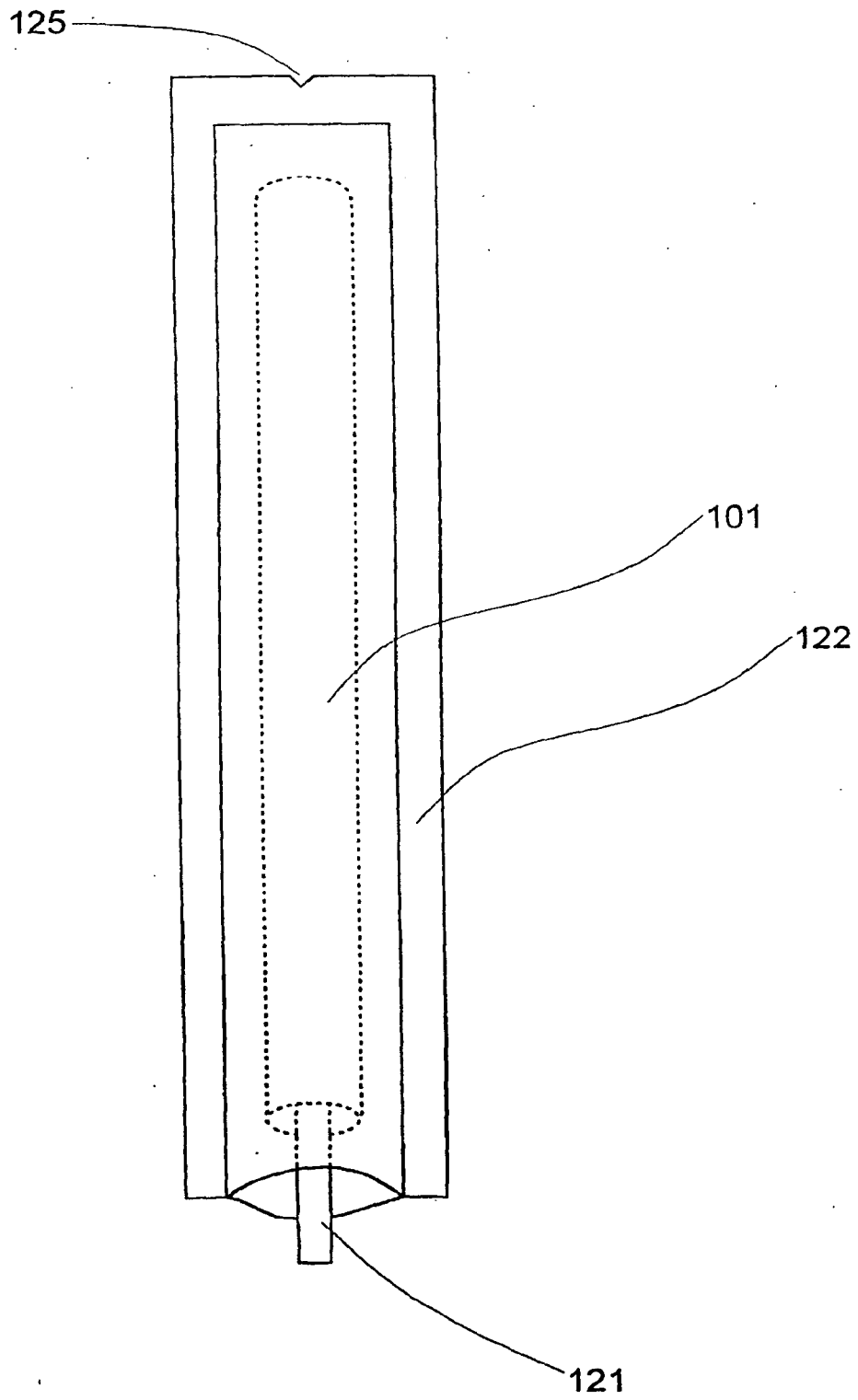


Fig. 11

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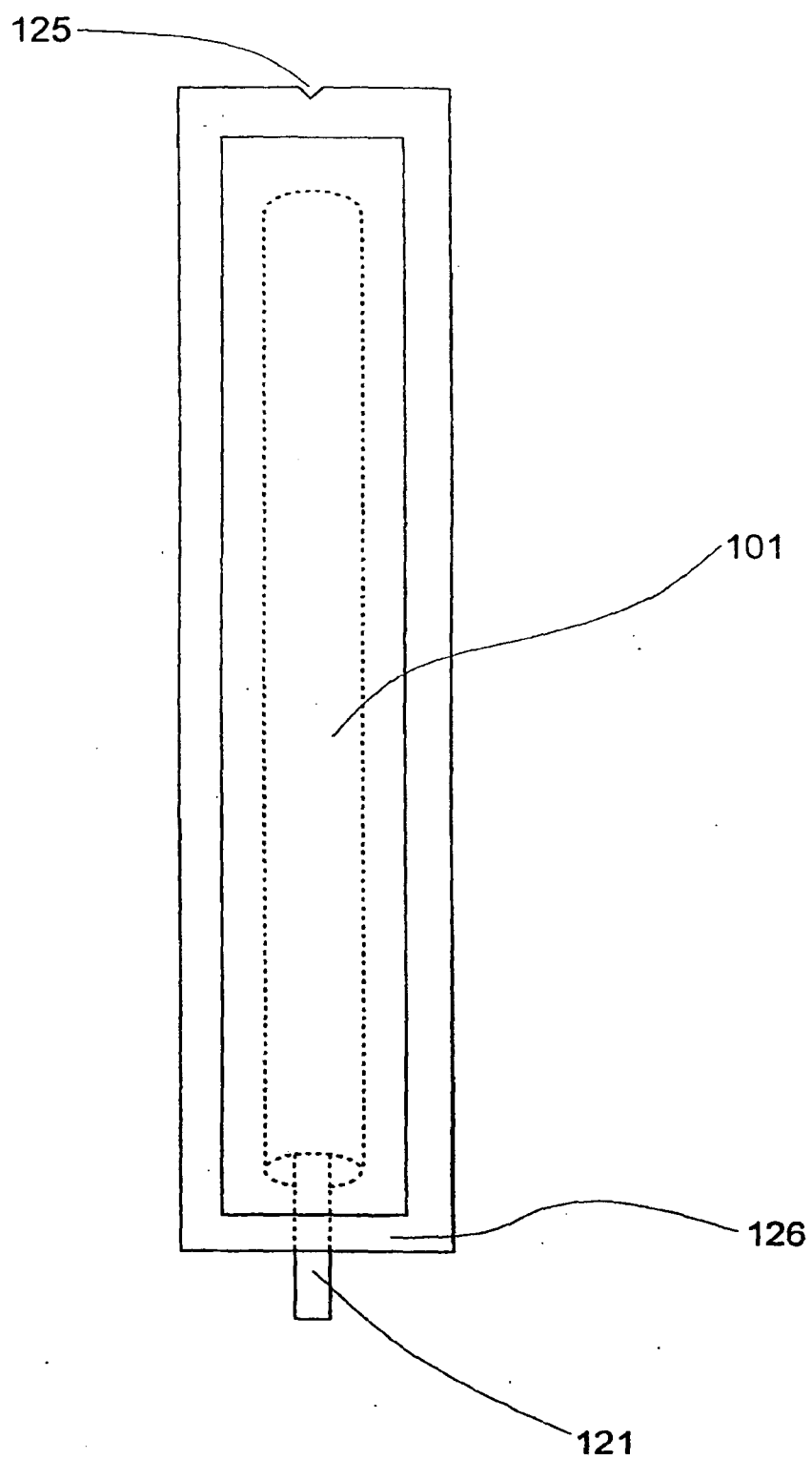


Fig. 12

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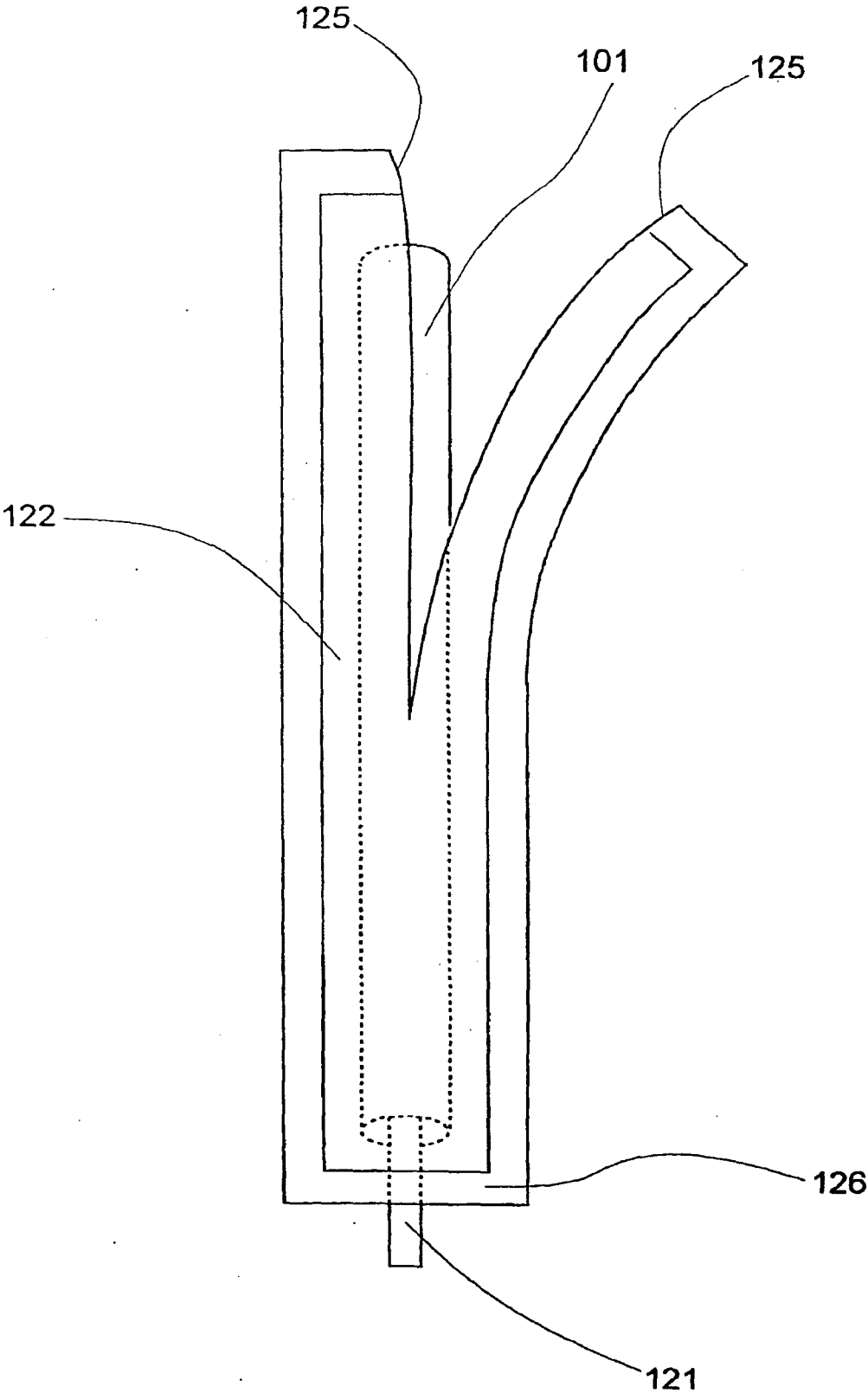


Fig. 13

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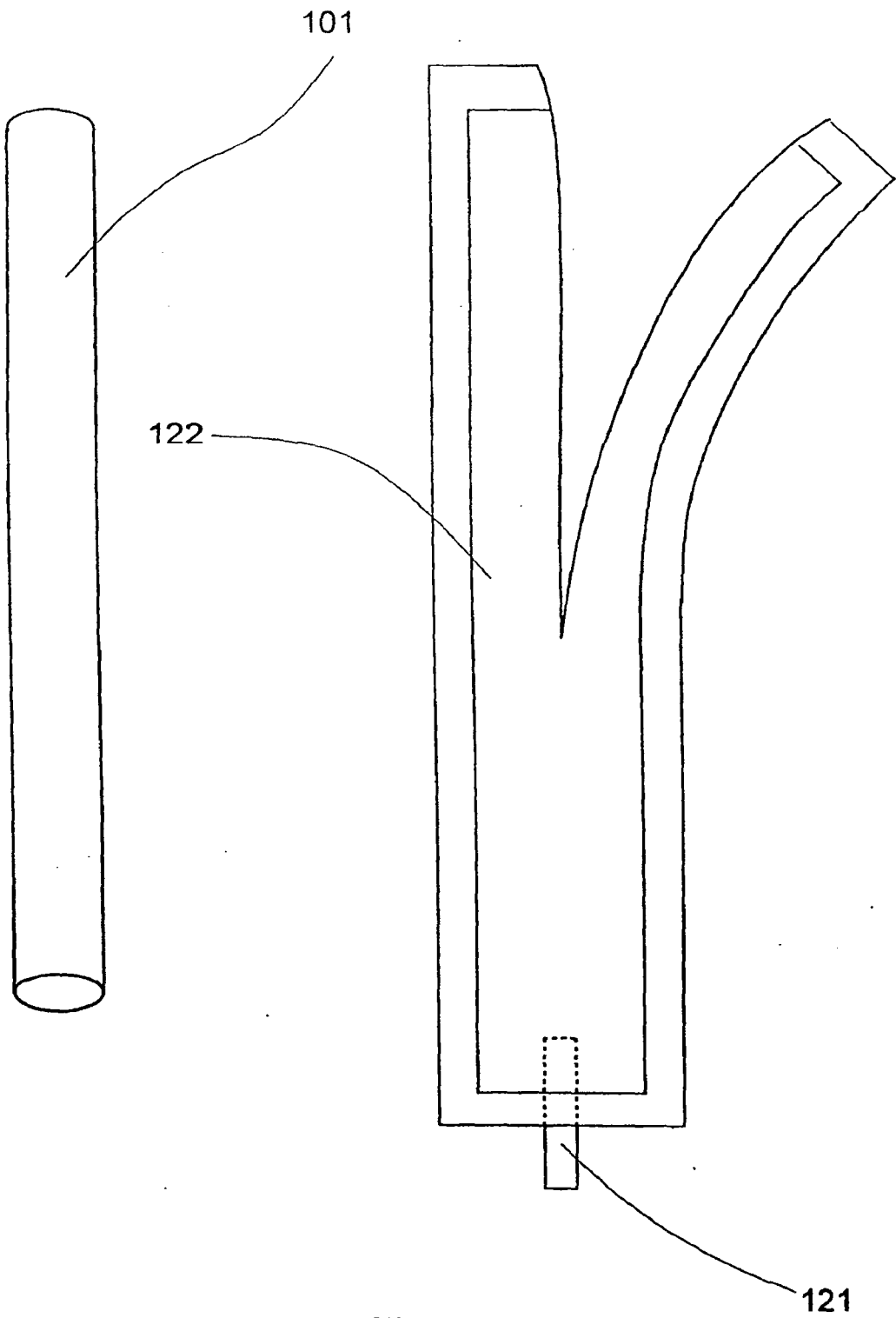


Fig. 14

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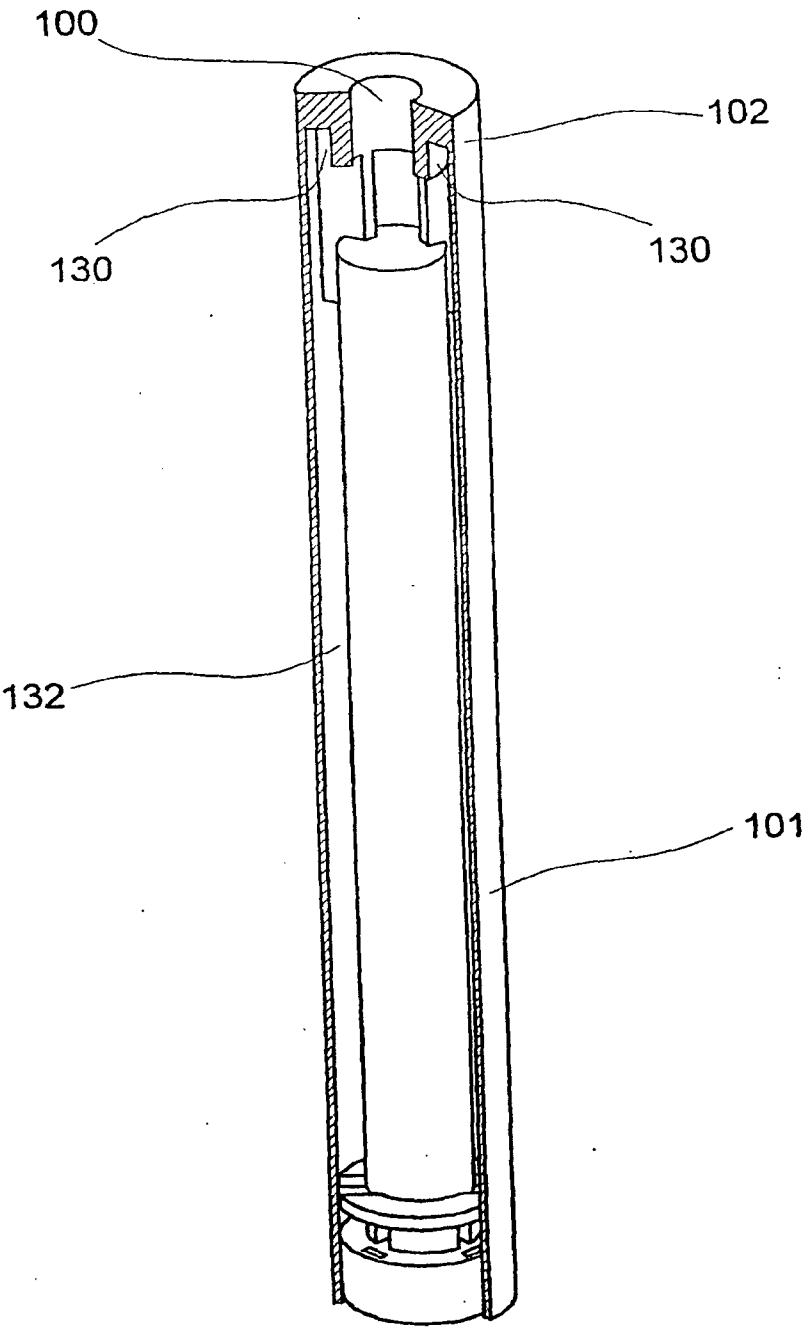


Fig. 15

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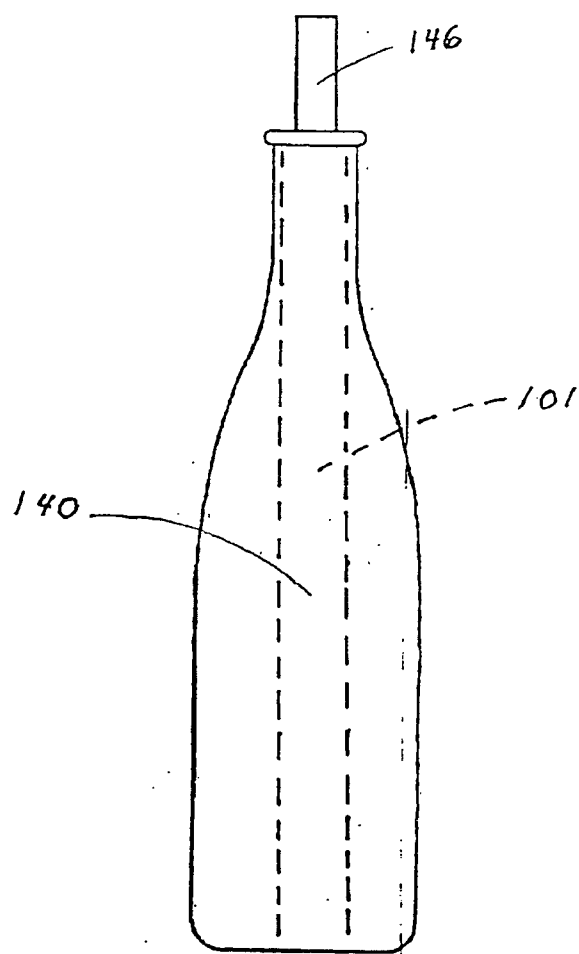


FIG. 16

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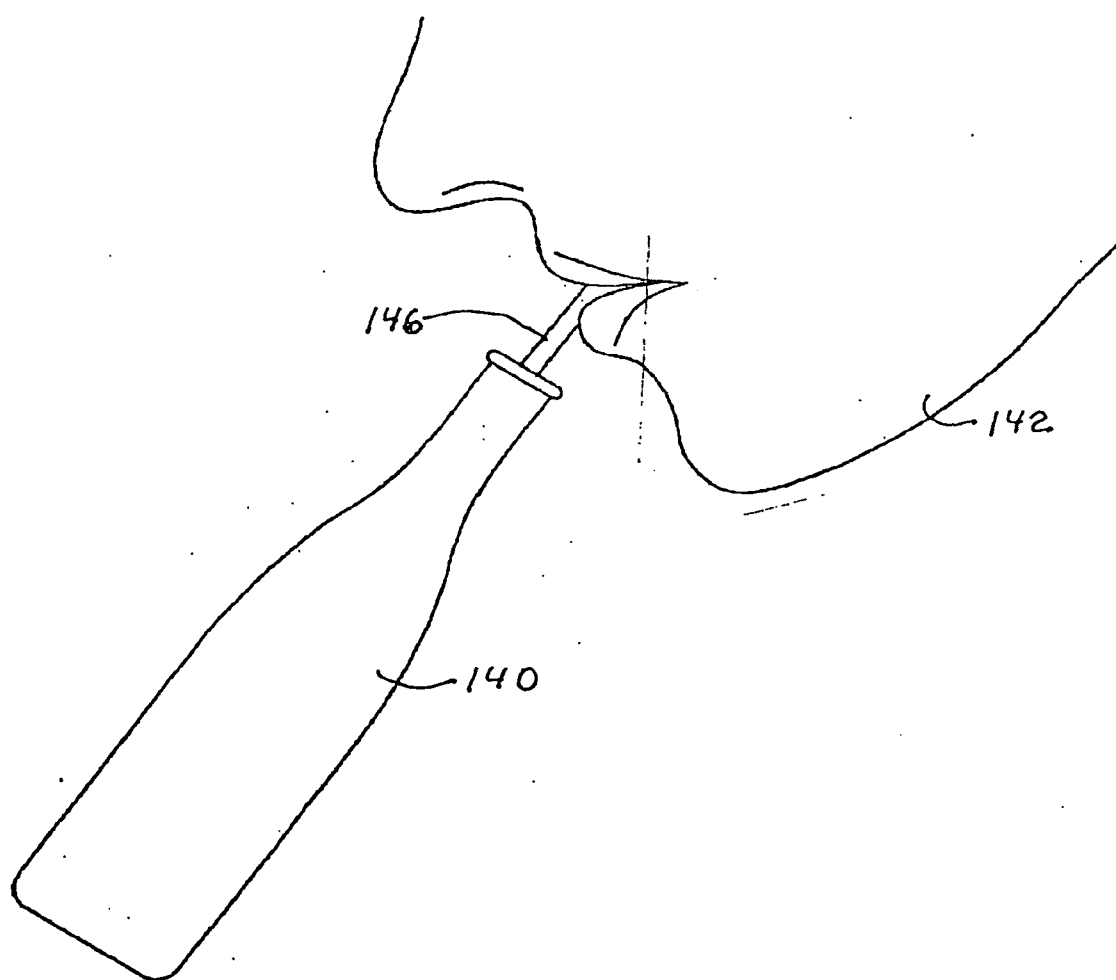


FIG. 17

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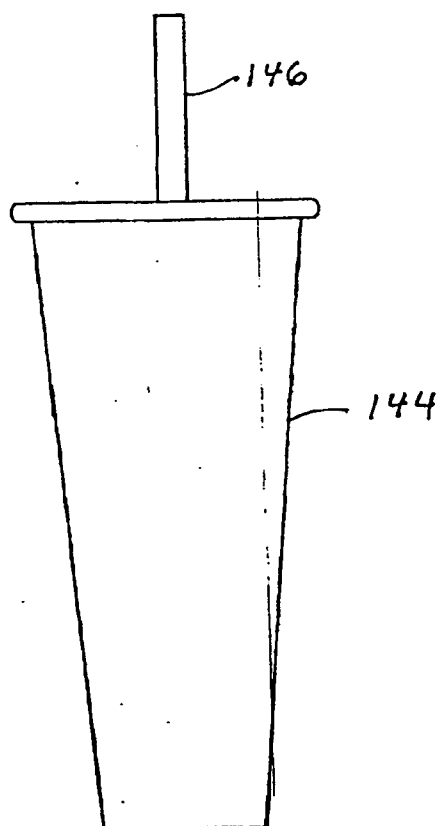


FIG. 18

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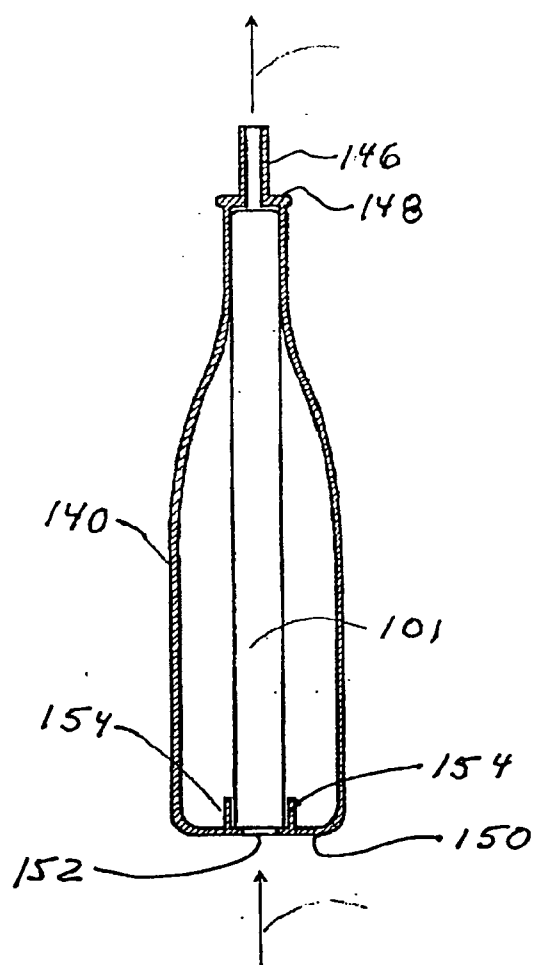


FIG. 19

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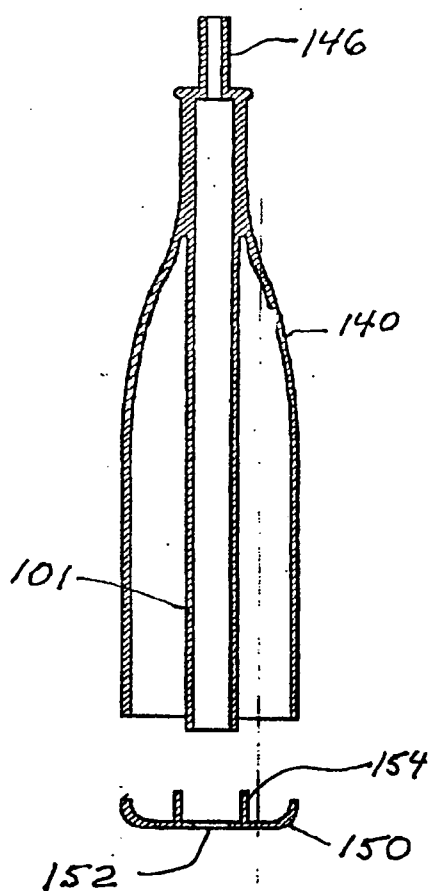


FIG. 20

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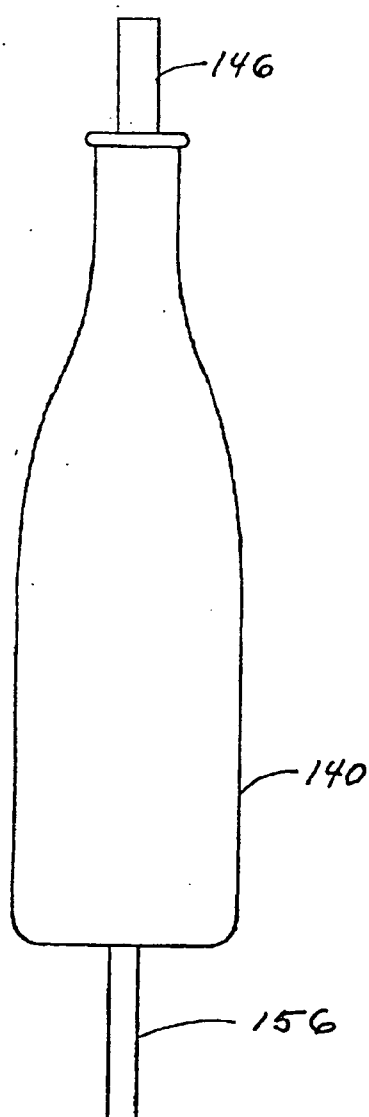


FIG. 21

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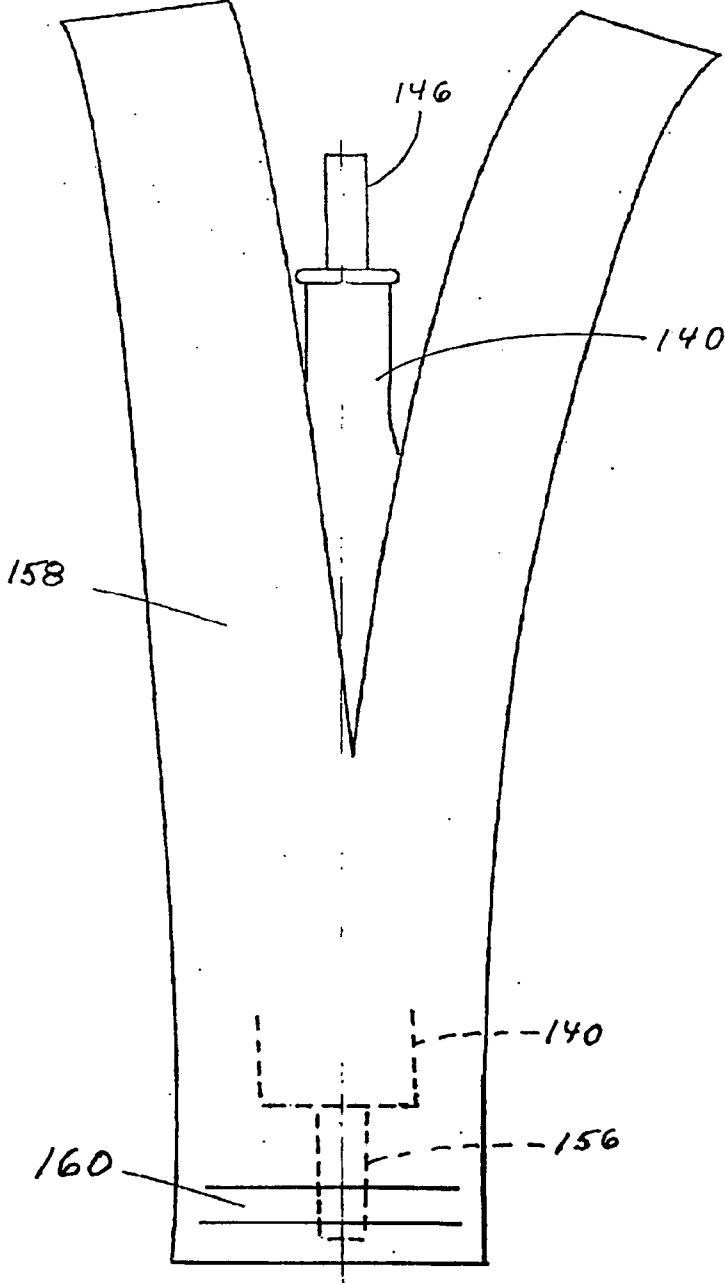


FIG. 22