

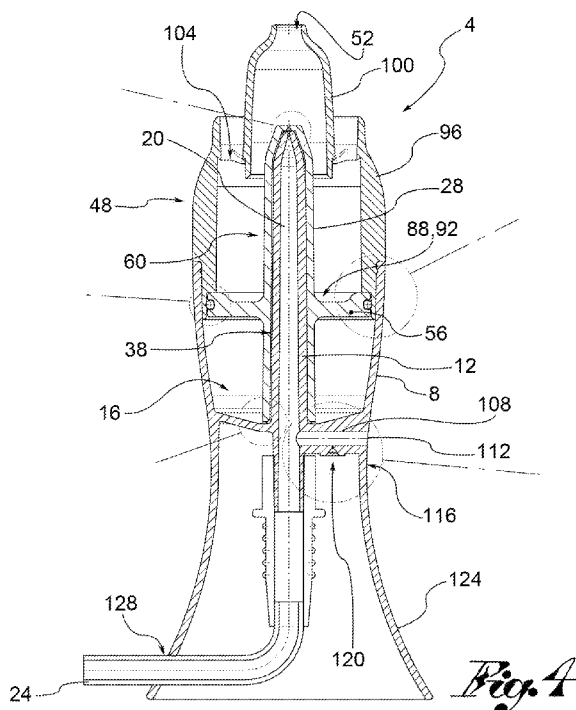


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[Continued on next page]

(54) **Title:** NASAL IRRIGATION DEVICE



(57) **Abstract:** Nasal irrigation device (4) comprising a base body (8) fitted with a nozzle (12) suitable for being fluidically connected to a compressed air source, the nozzle (12) having a dispenser hole (14) of said compressed air, the base body (8) defining a first chamber (16) for receiving a medical substance to be dispensed through said nozzle (12). The device further comprises a nozzle-cap (28) suitable for being fitted at least partially around the nozzle (12) to act in conjunction with it for the dispensing of the medical substance, and a cover (48), fitted on the base body (8), around the nozzle-cap (28), and provided with an exit hole (52) of the medical substance. Advantageously, the nozzle-cap (28) comprises a separation septum (56) which, acting in conjunction with the cover (48), identifies a second chamber (60), fluidically separate from said first chamber (16) so as to permit the collection of the medical substance used earlier for washing.

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DESCRIPTION**"NASAL IRRIGATION DEVICE"**

[0001] The present invention relates to a nasal irrigation device.

5 [0002] In particular, nasal irrigation devices are suitable for being sprayed in the nostrils so as to spray a medical substance therein. In the continuation of the description, medical substance shall be understood to also comprise mere physiological water or other liquid
10 which, when sprayed, helps to dissolve the mucus present in the upper airways.

[0003] The devices of the prior art comprise a nozzle, operatively connected to a source of compressed air, and a nozzle-cap, commonly known as a "pisper", making it
15 possible to subject the medical substance to be used to the action of the compressed air so as to be able to spray and dispense it in the nostrils.

[0004] The solutions of the prior art present several drawbacks.

20 [0005] For example, said devices comprise a plurality of components for identifying separate chambers so as to be able to easily and separately collect the medical substance to be sprayed and the washing fluid used earlier and sent inside the nostrils.

25 [0006] Such washing fluid must in fact be expelled from the

nose and collected separately from the medical substance so as to permit a correct and effective nasal rinse.

[0007] The devices of the prior art therefore comprise a plurality of components which make them expensive to make
5 and complicated to use, especially in the dismantling and rinsing operations after use.

[0008] The purpose of the present invention is to make a nasal irrigation device which overcomes the drawbacks mentioned in relation to the prior art.

10 [0009] Such drawbacks and limitations are resolved by a device according to claim 1.

[0010] Other embodiments of the device according to the invention are described in the subsequent claims.

[0011] Further features and advantages of the present
15 invention will be more clearly comprehensible from the description given below of its preferred and non-limiting embodiments, wherein:

[0012] figure 1 shows a perspective view of a nasal irrigation device according to one embodiment of the
20 present invention, in an assembled configuration;

[0013] figure 2 shows a view in separate parts, of the device in figure 1;

[0014] figure 3 shows a cross-section view in separate parts, of the device in figure 1;

25 [0015] figure 4 shows a further cross-section view, in an

assembled configuration, of the device in figure 1;

[0016] figures 5,6,7,8,9 show views of enlarged details V,VI,VII,VIII,IX in figure 4, respectively;

[0017] figure 10 shows a perspective view of a nasal
5 irrigation device according to an embodiment variation of the present invention, in an assembled configuration;

[0018] figure 11 is an exploded perspective view of the device in figure 10;

[0019] figure 12 shows a cross-section view of the device
10 in figure 10 in an assembled configuration; and

[0020] figure 13 is a transversal cross-section of the device in figure 10, along the line A-A in figure 12.

[0021].The elements or parts of elements common to the embodiments described below will be indicated using the
15 same reference numerals.

[0022] With reference to the aforementioned figures, reference numeral 4 globally denotes a nasal irrigation device suitable for being fluidically connected to a compressed air source (not shown), such as for instance
20 the compressor of a medical device for aerosol therapy.

[0023] The nasal irrigation device 4 comprises a base body 8 fitted with a nozzle 12 suitable for being fluidically connected to a compressed air source, the nozzle having a dispenser hole 14 of said compressed air.

25 [0024] The base body 8 defines a first chamber 16 for

receiving a medical substance to be dispensed through said nozzle 12; said medical substance is received in a liquid phase.

[0025] The base body 8 comprises, for example, a lower wall
5 18 which defines the bottom 19 of said first chamber for the collection of the medical substance.

[0026] The nozzle 12 encloses a supply channel 20 of compressed air directed along a main extension X-X and fluidically connected to a compressed air source, for
10 example by means of a connection to a supply tube 24 of compressed air.

[0027] Preferably, the nozzle 12 crosses said lower wall 18 and the connection between the nozzle 12 and the supply tube is made under the lower wall 18.

15 [0028] The base body 8 preferably has an hourglass shape suitable for improving the ergonomics of the device 4, facilitating manual gripping thereof by a user.

[0029] The device 4 further comprises a nozzle-cap 28 suitable for being fitted at least partially around the
20 nozzle 12 to act in conjunction with it for the dispensing of the medical substance.

[0030] In particular, the nozzle-cap 28 in an assembled configuration rests at one of its lower ends 32 on said bottom 19; the lower end 32 comprises at least one slit
25 36 to permit the uptake of the medical substance

collected on the bottom 19.

[0031] In a configuration of the nozzle-cap 28 assembled on the nozzle 12, channels 38 are identified between the nozzle-cap 28 and the nozzle 12 to permit the passage of
5 the medical substance from the lower end 32 of the nozzle-cap 28, at which they take up the medical substance from the first chamber 16, to an upper end 40 directly facing the dispensing hole 14 of the nozzle 12.

[0032] The upper end 40 of the nozzle-cap 28 is open to
10 permit the passage of the fluid.

[0033] For example, said channels 38 may be obtained by making grooves and/or ribs on the side wall of the nozzle 12 or on the inner side wall of the nozzle-cap 28.

[0034] The device 4 further comprises a cover 48, fitted on
15 the base body 8, around the nozzle-cap 28, and provided with an exit hole 52 of the medical substance.

[0035] Advantageously, the nozzle-cap 28 comprises a separation septum 56 which, acting in conjunction with the cover 48, identifies a second chamber 60, fluidically
20 separate from said first chamber 16, so as to permit the collection of the medical substance used earlier for washing and any mucus dissolved therein. In other words, the separation between the chambers 16, 60 makes it possible to collect the washing fluid, after its use,
25 without it mixing with the medical substance to be

sprayed.

[0036] According to one embodiment, the separation septum 56 is a disc, positioned coaxially to the nozzle 12, the disc being fitted with sealing means 64 between a lateral rim 68 of the disc and an inner lateral wall 72 of the cover 48. Preferably, said lateral rim 68 of the disc comprises a recess 76 which acts as a seat for sealing means 64, such as, for instance, an O-ring.

[0037] The lateral rim 68 of the disc and the inner lateral wall 72 of the cover 48 are shaped so as to form a shaped coupling, to detachably join the separation septum 56 and the cover 48.

[0038] For example, the inner lateral wall 72 of the cover 48 comprises a bracket 80 which acts in conjunction with the sealing means 64 of the disc so as to join the cover 48 and the nozzle-cap 28 to each other.

[0039] In particular, in an assembled configuration of the cover 48 and the nozzle-cap 28, the bracket 80 interfaces with the sealing means 64 so as to form an undercut with them suitable for countering the mechanical separation of the cover 48 and the nozzle-cap 28. The undercut made by the bracket 80 interferes with the sealing means 64, which are flexible, but not with the separation septum 56 which rather presents a radial clearance 84 with the inner side wall 72.

[0040] This way it is possible to couple together and uncouple the cover 48 and the nozzle-cap 28 thanks to the elastic deformation of the sealing means 64 at the interface with the bracket 80

5 [0041] The separation septum 56 comprises a hollow seat 92 on the upper side 88 facing the associable cover 48 suitable for favouring the collection of the medical substance used earlier for washing.

[0042] The cover 48 comprises a cover body 96 and a cap 100
10 having said exit hole 52.

[0043] The cap 100 is positioned coaxially to the nozzle-cap 28 so as to channel the outgoing fluid from the dispensing hole 14 of the nozzle 12 towards said exit hole 52. Preferably, between the cap 100 and the cover
15 body 96 apertures are present 104 which open onto the second chamber 60, so as to enable drainage of the used medical substance into the second chamber 60.

[0044] Preferably, said apertures are positioned coaxially to the cap 100.

20 [0045] According to one embodiment, the base body 8 comprises an activation channel 108 which fluidically intercepts the supply channel 20 and which ends externally in an activation hole 112 made on an outer side wall 116 of the base body 8 so as to be easily
25 occluded by the user by pressure of the fingers.

[0046] Preferably, the activation channel 108 is made inside the lower wall 18 which defines the bottom 19 of the first chamber 16 for the collection of the medical substance.

5 [0047] The opening, that is to say the through cross-section, of the activation channel 108 and especially of the activation hole 112 is greater than the opening of the dispenser hole 14 of the nozzle 12. This way, while the activation hole 112 remains open, the compressed air
10 coming from the lower end 32 of the nozzle 12 tends to flow out through the activation channel 108 and relative activation hole 112 without coming out of the dispensing hole 14.

[0048] Preferably, the activation channel 108 comprises a
15 vent hole 120, positioned between the supply channel 20 and the activation hole 108, wherein the vent hole 120 is calibrated so as to prevent overpressures inside the nozzle 12.

[0049] Preferably, the vent hole 120 faces towards a
20 support base 124 of the base body 8 and is enclosed inside the base body 8 so as to prevent the possible projection of fluid against the user, in the event of fluid coming out from the vent hole 120.

[0050] According to one embodiment, the support base 124 of
25 the base body 8 comprises a slot 128 for the passage of a

supply tube 24 of compressed air, said slot 128 coming out on the lower rim 132 of the support base 124 so as to permit a stable support of the device 4 even in the configuration of the supply tube being fitted.

5 [0051] In one embodiment variation shown in figures 10-13, an activation button 200 is associated with the activation hole 11 suitable for occluding said hole 112.

[0052] In particular, said activation button 200 comprises a central actuation portion 202, facing the activation
10 hole 112, a pair of lateral arms 204, and a thin membrane 206 which connects said central actuation portion 202 to the lateral arms 204. The latter are inserted with interference in respective conical seats 208 made in the base body 8.

15 [0053] The activation button 200 is thus permanently attached to the base body 8 thanks to the lateral arms 204 inserted without the possibility of extraction in the respective conical seats 208. The thin membrane 206 allows the user to press the central actuation portion
20 202 against the activation hole 112 and to return to a rearward open position of said hole upon ceasing of pressure exerted by the user.

[0054] Advantageously, the activation button 200 is made in a single piece, does not require separate attachment
25 means to the base body 8 and does not need separate

elastic means for its return to an inactive position.

[0055] In the embodiment variation shown in figures 10-13, moreover, the cap 100 with the exit hole 52 is separate from the cover body 96, so as to permit the use of
5 different, interchangeable, caps 100, differing for example in the dimensions of the end part suitable for being inserted in the user's nostril.

[0056] In particular, the cover body 96 is fitted with a truncated-cone or cylindrical collar 96', for example
10 made in one piece with said cover body 96, which extends coaxially round the upper end 40 of the nozzle-cap 28 and which acts as a means of coupling to a cap 100.

[0057] Each cap 100 is suitable for being fitted on said collar 96' and is provided at the bottom with coupling
15 sectors 101 fitted with coupling teeth 102 which snap engage into the undercut defined by the lower rim of the collar 96'.

[0058] The functioning and assembly of a nasal irrigation device according to the invention will now be described.

20 [0059] In particular, after connecting the device 4 to a compressed air dispenser, such as for example a device for aerosol therapy, the user may activate the dispensing of compressed air.

[0060] Said air flows from the supply tube of compressed
25 air into the nozzle 12: if the activation hole 112 is

covered by the user's finger or by the activation button 200, the compressed air is dispensed through the dispensing hole 14 of the nozzle.

[0061] Coming out from said activation hole 14, the air
5 creates a depression which aspirates the medical substance contained in the first chamber: said medical substance can in fact move up from the first chamber 16 through the slits and channels as far as the dispensing hole 14 where it mixes with the compressed air.

10 [0062] The mixture thus obtained can then pass through the open upper end 40 of the nozzle-cap 28, the cover 48 and then be dispensed in the nostrils through the exit hole 52.

[0063] If the user removes his finger from the activation
15 hole 112 or releases the activation button 200, the air comes out through said activation hole 112 which has a larger opening than the dispensing hole 14 of the nozzle 12 and, consequently, offers less resistance to the passage of air than the dispensing hole 14 of the nozzle
20 12.

[0064] This way, whenever the user wishes to suspend even solely for an instant the nasal irrigation treatment, he can simply remove his finger from the activation hole 112 so as to expel the compressed air laterally in relation
25 to the base body 8 without dispensing medical substance

which would otherwise be wasted. This operation can be performed instantly and in an extremely easy and intuitive manner without having to turn off the dispensing device of compressed air every time.

5 [0065] In fact, with the devices of the prior art the user would have to turn off the dispenser device of compressed air each time he needs to distance the device from his nostrils to interrupt the treatment, to prevent wastage of medical substance.

10 [0066] In addition, the configuration of the lower rim 132 of the base body 8, provided with a hole or slot 128 for the passage of the supply tube 24, makes use of the nasal irrigation device 4 even easier.

[0067] In fact, despite the supply tube 24, the device 4
15 may still be stably rested for example on a shelf: this way it is even easier to suspend and resume the nasal irrigation treatment. In fact, every time the user wishes to suspend treatment, he can merely take his finger off the activation hole 112, to prevent the
20 dispersion of medical substance in the air, and rest the device 4 on a shelf in a stable manner given that the supply tube 24 does not interfere with the lower rim 132 of the base body 8.

[0068] This operation may be easily repeated providing at
25 all times a valid support for the device and preventing

any wastage of medical substance without having to turn off the dispenser device of compressed air each time.

[0069] During the treatment, the washing fluid continually flows back towards the cap 100 by gravity and, passing
5 through the apertures 104, falls into the second chamber 60 so as to remain separate at all times from the first chamber 16 containing the medical substance yet to be dispensed.

[0070] At the end of treatment, the cover 48 can be
10 extracted taking with it the attached nozzle-cap 28: the cover 48 and nozzle-cap 28 assembly encloses the second chamber 60 inside which the used washing fluid is collected. By dismantling the cover 48 the second chamber can be easily cleaned. In addition, following removal of
15 the cover 48 and nozzle-cap 28 assembly, the first chamber can be easily accessed to clean it or if needed, fill it with new medical substance.

[0071] As may be appreciated from the description, the nasal irrigation device according to the invention makes
20 it possible to overcome the drawbacks of the prior art presented.

[0072] In particular, the device according to the present invention is particularly convenient and easy to use.

[0073] In fact the device comprises a limited number of
25 components which are easy to assemble and separate so as

to permit easy filling of the device with the medical substance but also easy emptying thereof after use.

[0074] In particular the step of cleaning the device after use is particularly facilitated. In fact, after the
5 washing, the medical substance has already flowed back into the second chamber: the cap can then be detached taking with it the nozzle-cap with which it delimits the second chamber.

[0075] The nozzle-cap can then be separated from the cap so
10 as to permit easy cleaning of the second chamber. At the same time the nozzle and first chamber can also be cleaned, easily accessible following the joint removal of the cap and nozzle-cap.

[0076] Moreover the device proves very easy to use during
15 nasal irrigation.

[0077] In fact, as seen, the presence of the activation hole makes it possible to activate or prevent the dispensing of compressed air, and therefore of medical substance, from the dispensing hole, without having to
20 turn off the dispensing device of compressed air.

[0078] In addition, the configuration of the lower wall of the base body, provided with a hole or slot 128 for the passage of the supply tube 24, makes use of the nasal irrigation device 4 even easier.

25 [0079] A person skilled in the art may make numerous

modifications and variations to the nasal irrigation devices described above so as to satisfy contingent and specific requirements, all contained within the scope of the invention as defined by the appended claims.

Claims

1. Nasal irrigation device (4) comprising
- a base body (8) fitted with a nozzle (12) suitable for being fluidically connected to a compressed air source,
 - 5 the nozzle (12) having a dispenser hole (14) of said compressed air,
 - the base body (8) defining a first chamber (16) for receiving a medical substance to be dispensed through said nozzle (12),
 - 10 -a nozzle-cap (28) suitable for being fitted at least partially around the nozzle (12) to act in conjunction with it for the dispensing of the medical substance,
 - a cover (48) fitted on the base body (8), around the nozzle-cap (28), and provided with an exit hole (52) of
 - 15 the medical substance,
- characterised in that
- the nozzle-cap (28) comprises a separation septum (56) which, acting in conjunction with the cover (48), identifies a second chamber (60), fluidically separate
 - 20 from said first chamber (16) so as to permit the collection of the medical substance used earlier for washing.
2. Nasal irrigation device (4) according to claim 1, wherein the separation septum (56) is a disc, positioned
- 25 coaxially to the nozzle (12), the disc being fitted with

sealing means (64) between the lateral rim (68) of the disc and an inner lateral wall (72) of the cover (48).

3. Nasal irrigation device (4) according to claim 2, wherein the lateral rim (68) of the disc and the inner
5 lateral wall (72) of the cover (48) are shaped according to a shaped coupling, so as to detachably join the separation septum (56) and the cover (48).

4. Nasal irrigation device (4) according to claim 2 or 3, wherein the inner lateral wall (72) of the cover (48)
10 comprises a bracket (80) which acts in conjunction with the sealing means (64) of the disc so as to join the cover (48) and the nozzle-cap (28) to each other.

5. Nasal irrigation device (4) according to any of the previous claims, wherein the separation septum (56),
15 comprises a hollow seat (92) on the upper side (88) facing the associable cover (48) suitable for favouring the collection of the medical substance used earlier for washing.

6. Nasal irrigation device (4) according to any of the previous claims, wherein the base body (8) comprises a
20 lower part (18) which defines a bottom (19) of said first chamber (16) for the collection of the medical substance, and in which the nozzle-cap (28) in an assembled configuration rests on one of its lower ends (32) on said
25 bottom (19), said lower end (32) comprising at least one

slit (36) to permit the uptake of the medical substance collected on the bottom (19).

7. Nasal irrigation device (4) according to any of the previous claims, wherein, in a configuration of the
5 nozzle-cap being assembled to the nozzle (12), channels are identified between the nozzle-cap (28) and the nozzle (12) to permit the passage of the medical substance from a lower end (32) of the nozzle-cap (28) at which they take up the medical substance from the first chamber (16)
10 to an upper end (40) directly facing the dispensing hole (14) of the nozzle (12).

8. Nasal irrigation device (4) according to any of the previous claims, wherein the cover (48) comprises a cover body (96) and a cap (100) having an exit hole (52), the
15 cap (100) channelling the outgoing fluid from the dispensing hole (14) of the nozzle (12) towards said exit hole (52), and wherein between the cap (100) and the cover body (96) apertures are present (104) which open onto the second chamber (60), so as to enable drainage of
20 the used medical substance into the second chamber (86).

9. Nasal irrigation device (4) according to any of the previous claims, wherein the nozzle (12) encloses a supply channel (20) of compressed air directed along a main extension (X-X) and fluidically connected to a
25 compressed air source, and wherein the base body (8)

comprises an activation channel (108) which fluidically intercepts the supply channel (20) and which ends externally in an activation hole (112) made on an outer lateral wall (116) of the base body (8) so as to be easily occluded by the user by pressure of the fingers.

10. Nasal irrigation device (4) according to claim 9, wherein said activation channel (108) is made inside a lower wall (18) of the base body (8) which defines the bottom (19) of said first chamber (16) for the collection of the medical substance.

11. Nasal irrigation device (4) according to claim 9 or 10, wherein said activation channel (108) comprises a vent hole (120), positioned between the supply channel (20) and the activation hole (112), the vent hole (120) being calibrated so as to prevent over pressure inside the nozzle (12).

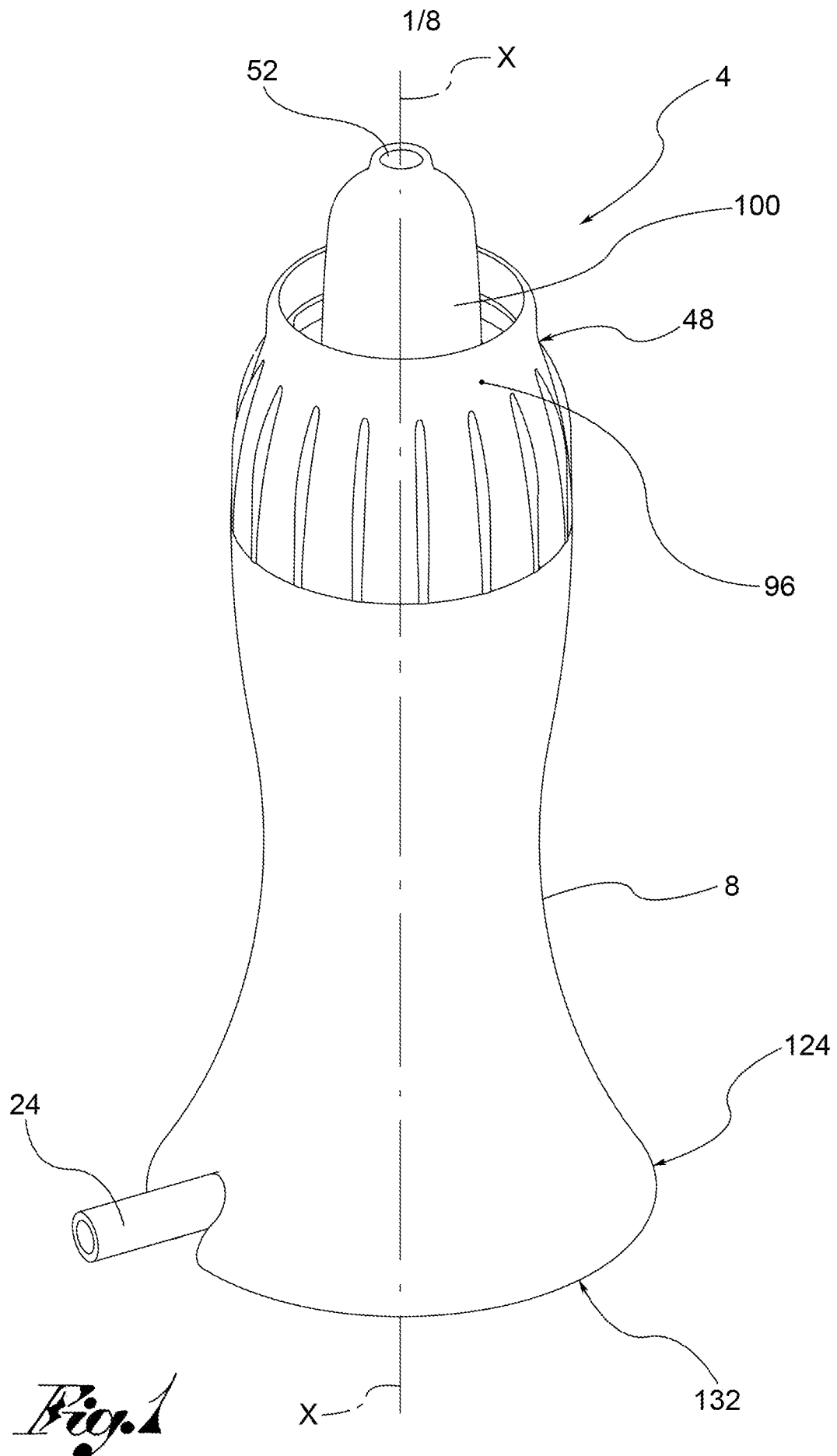
12. Nasal irrigation device (4) according to claim 11, wherein said vent hole (120) faces towards a support base (124) of the base body (8) and is enclosed inside the base body (8) so as to prevent the possible projection of the fluid against the user.

13. Nasal irrigation device (4) according to any of the previous claims, wherein a support base (124) of the base body (8) comprises a slot (128) for the passage of a supply tube (24) of compressed air, said slot (128)

coming out on a lower rim (132) of the support base (124) so as to permit stable support of the device (4) even in the configuration of the supply tube being fitted.

14. Nasal irrigation device (4) according to any of the
5 claims 9-13, wherein an activation button (200) is associated to the activation hole (112) suitable for occluding said activation hole (112), said activation button (200) comprising a central actuation portion (202), facing the activation hole (112), a pair of
10 lateral arms (204) inserted with interference in respective conical seats (208) made in the base body (8), and a thin membrane (206) which connects said central actuation portion (202) to the lateral arms (204) so as to permit the excursion of the central actuation portion
15 (202) between a rearward inactive position and an advanced occlusion position of the activation hole (112).

15. Nasal irrigation device (4) according to any of the claims 8-14, wherein the cap (100) is connected in a detachable manner to the body cover (96), said cap (100)
20 and said body cover (96) being provided with reciprocal snap coupling means (96', 101, 102)



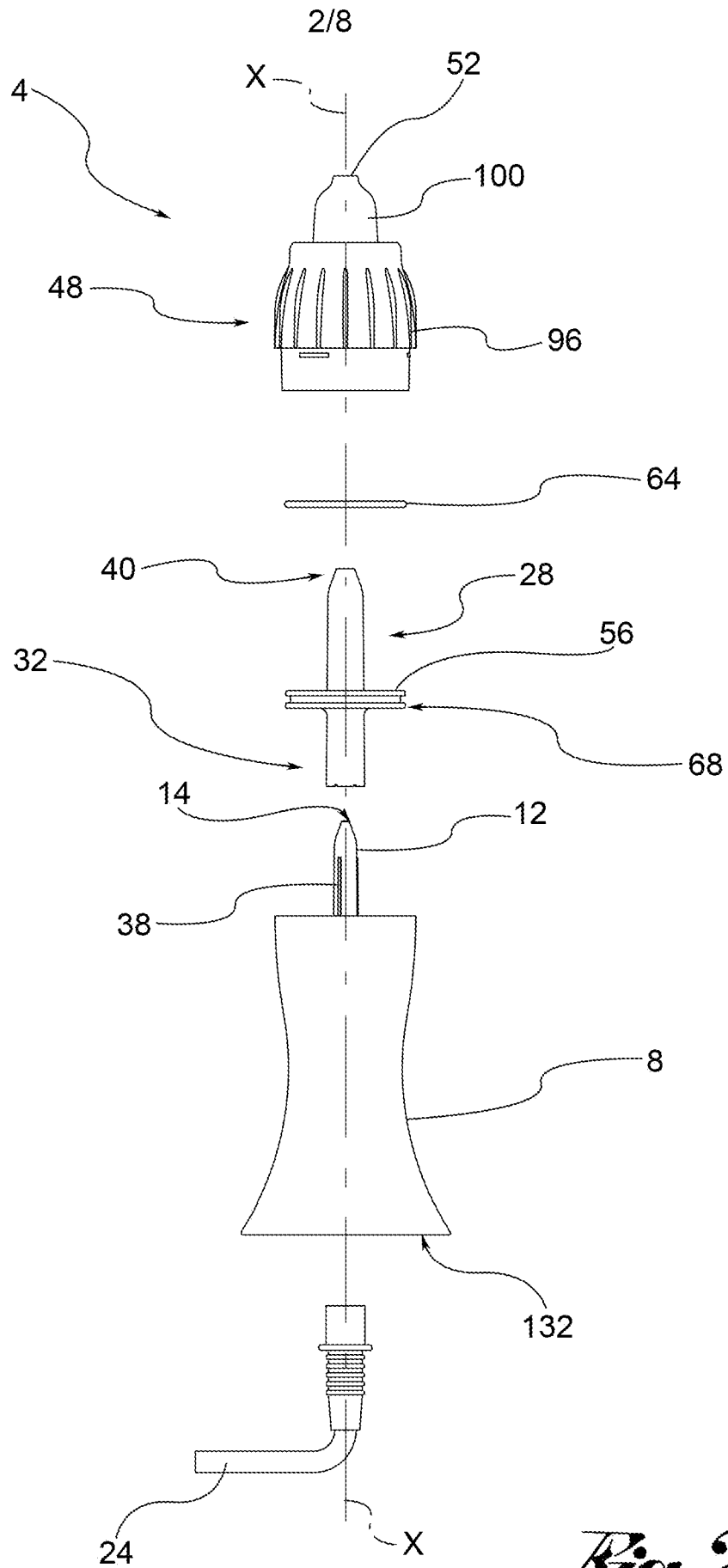


Fig. 2

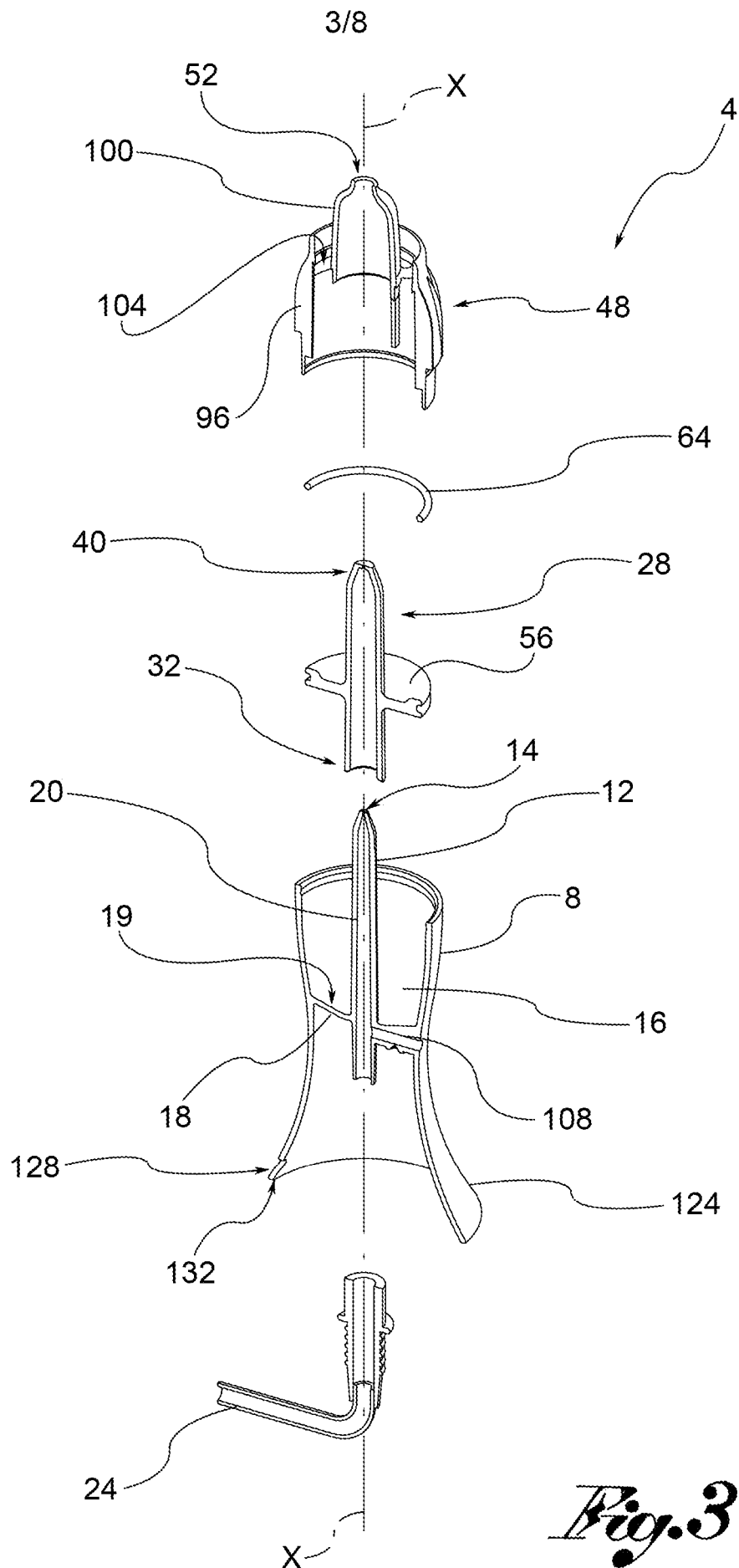
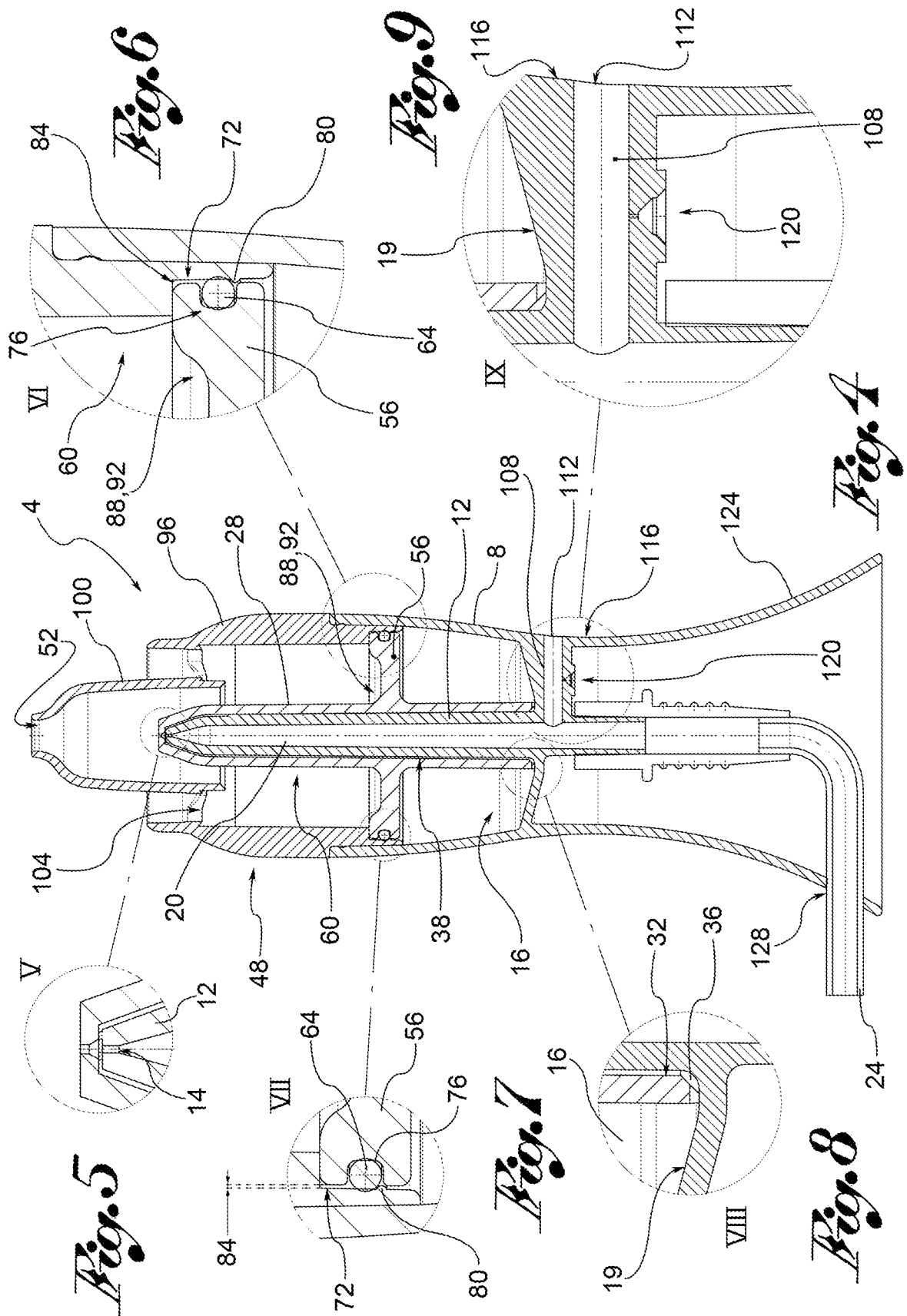
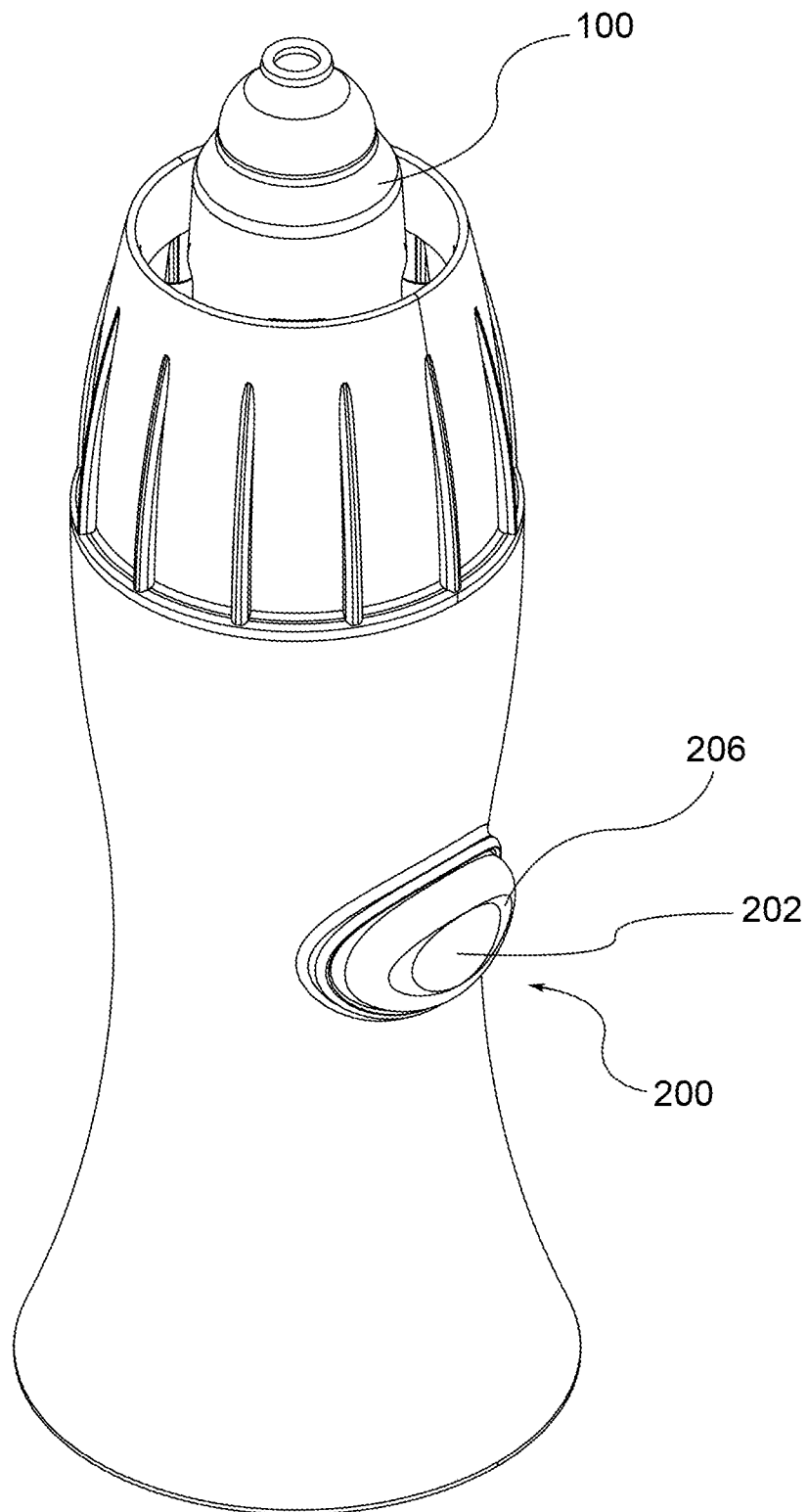


Fig. 3



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*Fig. 10*

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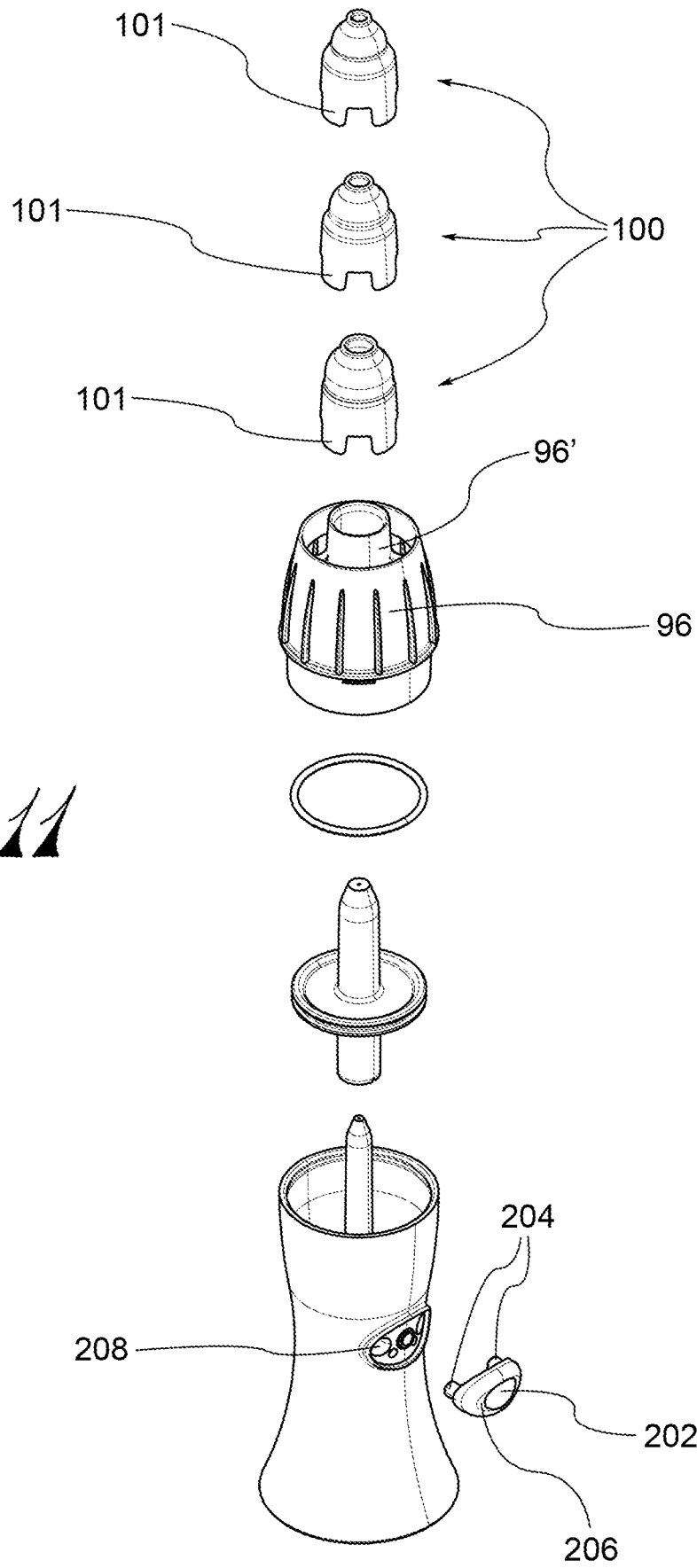
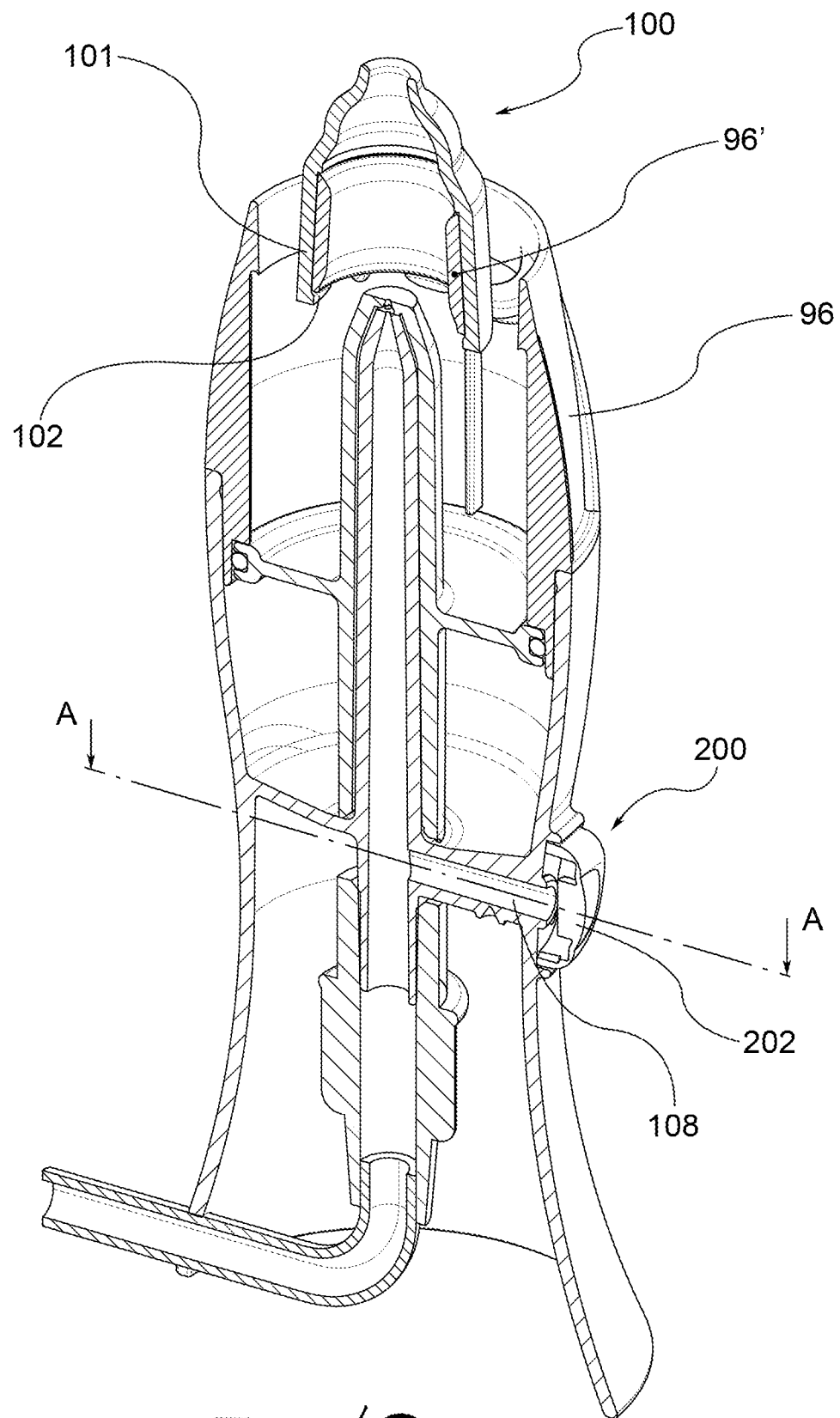


Fig. 11

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*Fig. 12*

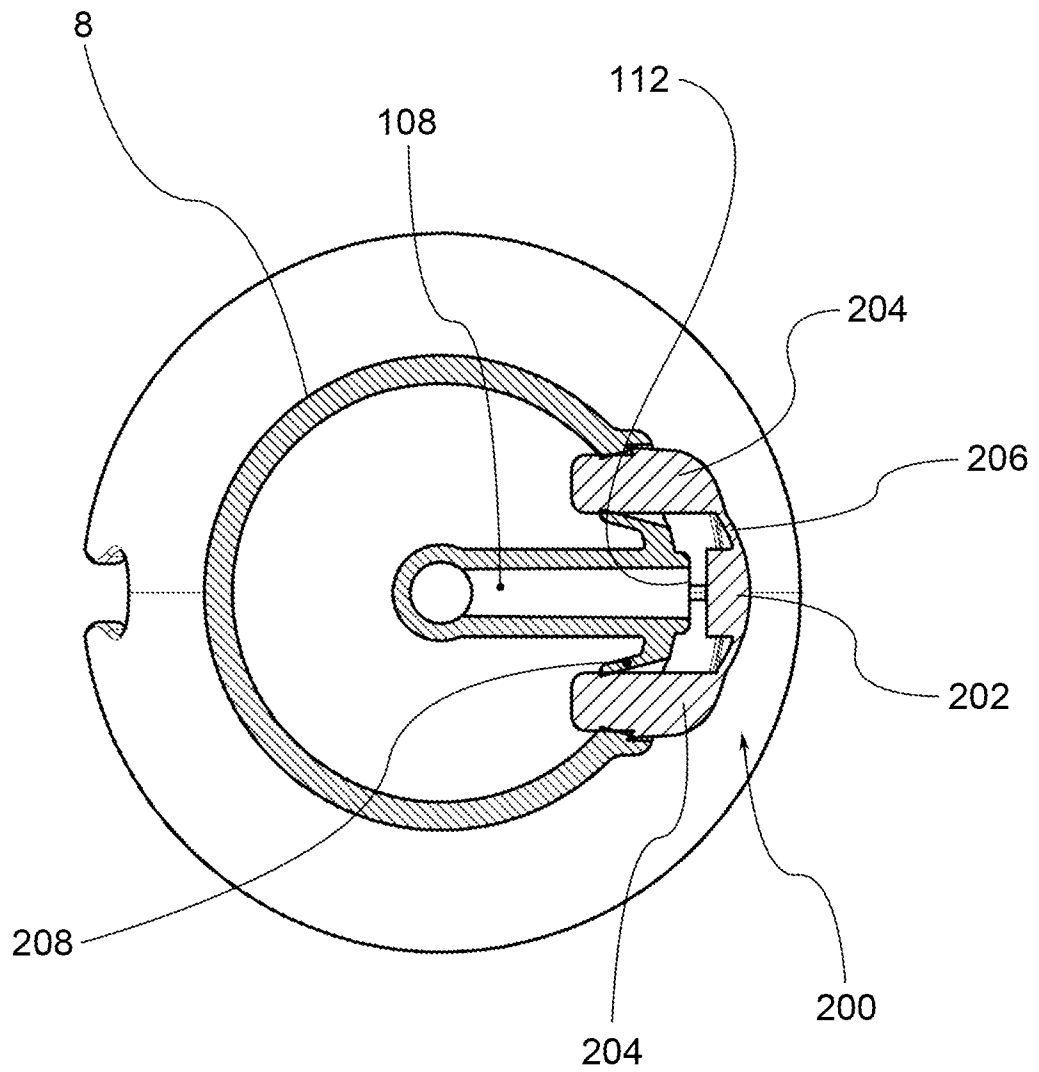


Fig. 13