



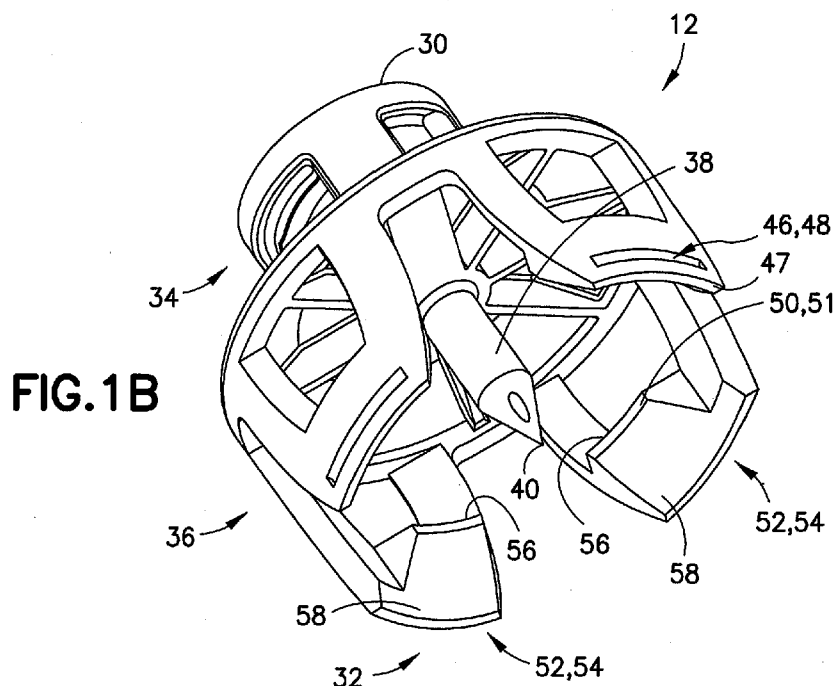
(43) International Publication Date  
14 May 2015 (14.05.2015)

(10) International Publication Number  
**WO 2015/069649 A1**

- (51) International Patent Classification:  
*A61J 1/20* (2006.01)
- (21) International Application Number:  
PCT/US2014/063896
- (22) International Filing Date:  
4 November 2014 (04.11.2014)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:  
61/900,562 6 November 2013 (06.11.2013) US
- (71) Applicant: **BECTON DICKINSON AND COMPANY LIMITED** [IE/IE]; Pottery Road, Kill O'The Grange, Dun Laoghaire (IE).
- (72) Inventor; and
- (71) Applicant (for VC only): **YEV MENENKO, Yan** [US/US]; 303 W 66 Street, Apt. 14CW, New York, New York 10023 (US).
- (72) Inventors: **WEIR, Ross**; 16 Catherine Street, Cambridge CB1 3AW (GB). **MOGENSEN, Lasse, Wesseltoft**; 13 Green Leys, St. Ives PE27 6SB (GB).
- (74) Agents: **QUEEN, Lara, Northrop** et al.; The Webb Law Firm, 420 Ft. Duquesne Blvd., Suite 1200, One Gateway Center, Pittsburgh, Pennsylvania 15222 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE,

[Continued on next page]

(54) Title: ADAPTER FOR VIAL ACCESS DEVICE



(57) Abstract: A system (10) includes a vial access device (12) including a spike (38), with the vial access device attachable to a first vial (80) defining a first vial size (81), and an adapter (14) transitionable between a shield position in which the adapter is attachable to the vial access device such that the adapter shields the spike of the vial access device and a vial position in which the adapter is attachable to a second vial (90) defining a second vial size (91), the second vial size different than the first vial size.



DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, **Published:**

LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE,  
SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA,  
GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

— *with international search report (Art. 21(3))*

## **ADAPTER FOR VIAL ACCESS DEVICE**

### **BACKGROUND OF THE INVENTION**

#### **1. Field of the Disclosure**

[0001] The present disclosure relates generally to an adapter for a vial access device. More particularly, the present disclosure relates to an adapter that is transitionable between a first configuration in which the adapter is attachable to a vial access device, which is attachable to a first vial, such that the adapter shields a spike of the vial access device and a second configuration in which the adapter is attachable to a second vial.

#### **2. Description of the Related Art**

[0002] Health care providers reconstituting, transporting, and administering hazardous drugs, such as cancer treatments, can put health care providers at risk of exposure to these medications and present a major hazard in the health care environment. For example, nurses treating cancer patients risk being exposed to chemotherapy drugs and their toxic effects. Unintentional chemotherapy exposure can affect the nervous system, impair the reproductive system, and bring an increased risk of developing blood cancers in the future. In order to reduce the risk of health care providers being exposed to toxic drugs, the closed transfer of these drugs becomes important.

[0003] Systems for the closed transfer of fluids include vial access devices that include a spike for drug vial access. The spike of a vial access device may result in a patient and/or healthcare worker receiving an inadvertent spike stick injury. Accordingly, there is a need for a component to prevent spike stick injuries.

### **SUMMARY OF THE INVENTION**

[0004] In one aspect, a system includes a vial access device including a spike, with the vial access device attachable to a first vial defining a first vial size, an adapter transitionable between a shield position in which the adapter is attachable to the vial access device such that the adapter shields the spike of the vial access device and a vial position in which the adapter is attachable to a second vial defining a second vial size, the second vial size different than the first vial size.

[0005] The vial access device may further include an adapter connection element and the adapter may further include an access device connection element and a vial connection

element, with the adapter transitionable between the shield position in which the access device connection element is attachable to the adapter connection element of the vial access device to secure the adapter to the vial access device such that the adapter shields the spike of the vial access device and the vial position in which the vial connection element is attachable to the second vial to secure the adapter to the second vial. The access device connection element of the adapter may be an external latch or an internal latch. The vial connection element of the adapter may be a plurality of vial grip members. The plurality of vial grip members may be elastically deformable. The vial access device may further include a first connection element attachable to the first vial to secure the vial access device to the first vial. The second vial size may be less than the first vial size. The system may further include a first vial defining a first vial size, and a second vial defining a second vial size, where the second vial size is different than the first vial size, where the vial access device further comprises a first connection element attachable to the first vial to secure the vial access device to the first vial, and where the adapter is attachable to the second vial. The first connection element of the vial access device may be configured to secure the adapter to the vial access device when the adapter is in the vial position. The adapter may include an alignment guide configured to position the vial access device during installation of the vial access device onto the second vial when the adapter is in the vial position.

[0006] The adapter may include a horizontal shield wall, an outer portion extending from the periphery of the horizontal shield wall, and an inner portion extending from the horizontal shield wall. The horizontal shield wall of the adapter may define a spike cavity that is configured to receive the spike when the adapter is in the vial position. The access device connection element may include a plurality of external latches spaced around a periphery of the outer portion of the adapter, with the vial access device defining a plurality of slots configured to receive the plurality of external latches when the adapter is in the shield position. The access device connection element may include a plurality of locking apertures spaced around a periphery of the outer portion of the adapter, with the vial access device comprising a locking protrusion configured to be received by the plurality of locking apertures when the adapter is in the shield position.

[0007] In a further aspect, a method of accessing a vial includes providing a vial access device and an adapter, where the vial access device comprising a spike and a first connection element attachable to a first vial defining a first vial size to secure the vial access device to the first vial. The method further includes removing the adapter from a shield position in which

the adapter is attached to the vial access device with the adapter shielding the spike of the vial access device, and attaching the adapter to a second vial defining a second vial size.

[0008] The first vial size may be different from the second vial size. For example, the second vial size may be smaller than the first vial size. The method may further include securing the vial access device to the adapter after the adapter is attached to the second vial with the spike of the vial access device entering the second vial. The adapter may include a plurality of vial grip members with the adapter being attached to the second vial via the plurality of vial grip members of the adapter, and the vial access device may include a plurality of vial grip members with the vial access device attached to the adapter via the plurality of vial grip members of the vial access device.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0009] The above-mentioned and other features and advantages of this disclosure, and the manner of attaining them, will become more apparent and the disclosure itself will be better understood by reference to the following descriptions of aspects of the disclosure taken in conjunction with the accompanying drawings, wherein:

[0010] **Fig. 1A** is a side elevation view of a vial access device in accordance with an aspect of the present invention.

[0011] **Fig. 1B** is a bottom, perspective view of a vial access device in accordance with an aspect of the present invention.

[0012] **Fig. 1C** is a perspective view of a vial access device in accordance with an aspect of the present invention.

[0013] **Fig. 1D** is a cross-sectional view of the vial access device of **Fig. 1C** in accordance with an aspect of the present invention.

[0014] **Fig. 2** is a perspective view of an adapter in accordance with an aspect of the present invention.

[0015] **Fig. 3** is a top view of an adapter in accordance with an aspect of the present invention.

[0016] **Fig. 4** is a side elevation view of an adapter in accordance with an aspect of the present invention.

[0017] **Fig. 5** is a bottom view of an adapter in accordance with an aspect of the present invention.

[0018] **Fig. 6** is a perspective view of an adapter in accordance with another aspect of the present invention.

[0019] **Fig. 7** is a side elevation view of an adapter in accordance with another aspect of the present invention.

[0020] **Fig. 8** is a top view of an adapter in accordance with another aspect of the present invention.

[0021] **Fig. 9** is another side elevation view of an adapter in accordance with another aspect of the present invention.

[0022] **Fig. 10** is a bottom view of an adapter in accordance with another aspect of the present invention.

[0023] **Fig. 11** is a perspective view of an adapter attached to a vial access device in a shield position in accordance with an aspect of the present invention.

[0024] **Fig. 12** is a side elevation view of an adapter attached to a vial access device in a shield position in accordance with an aspect of the present invention.

[0025] **Fig. 13** is an enlarged view of the adapter attached to the vial access device in a shield position taken along section **13** of **Fig. 11** in accordance with an aspect of the present invention.

[0026] **Fig. 14A** is a bottom view of an adapter attached to a vial access device in a shield position in accordance with an aspect of the present invention.

[0027] **Fig. 14B** is a cross-sectional view of an adapter attached to a vial access device in a shield position taken along line **14B-14B** of **Fig. 14A** in accordance with an aspect of the present invention.

[0028] **Fig. 15** is a perspective view of an adapter attached to a vial access device in a vial position in accordance with an aspect of the present invention.

[0029] **Fig. 16A** is a bottom view of an adapter attached to a vial access device in a vial position in accordance with an aspect of the present invention.

[0030] **Fig. 16B** is a cross-sectional view of an adapter attached to a vial access device in a vial position taken along line **16B-16B** of **Fig. 16A** in accordance with an aspect of the present invention.

[0031] **Fig. 17** is a perspective view of an adapter attached to a vial access device in a shield position in accordance with another aspect of the present invention.

[0032] **Fig. 18A** is a bottom view of an adapter attached to a vial access device in a shield position in accordance with another aspect of the present invention.

[0033] **Fig. 18B** is a cross-sectional view of an adapter attached to a vial access device in a shield position taken along line **18B-18B** of **Fig. 18A** in accordance with another aspect of the present invention.

[0034] **Fig. 19** is a perspective view of an adapter attached to a vial access device in a vial position in accordance with another aspect of the present invention.

[0035] **Fig. 20A** is a bottom view of an adapter attached to a vial access device in a vial position in accordance with another aspect of the present invention.

[0036] **Fig. 20B** is a cross-sectional view of an adapter attached to a vial access device in a vial position taken along line **20B-20B** of **Fig. 20A** in accordance with another aspect of the present invention.

[0037] **Fig. 21** is a perspective view of a vial access device connected to a first vial in accordance with an aspect of the present invention.

[0038] **Fig. 22A** is a side elevation view of a vial access device connected to a first vial in accordance with an aspect of the present invention.

[0039] **Fig. 22B** is a cross-sectional view of the vial access device connected to the first vial taken along line **22B-22B** of **Fig. 22A** in accordance with an aspect of the present invention.

[0040] **Fig. 23** is a perspective view of a vial access device and an adapter connected to a second vial in accordance with an aspect of the present invention.

[0041] **Fig. 24A** is a side elevation view of a vial access device and an adapter connected to a second vial in accordance with an aspect of the present invention.

[0042] **Fig. 24B** is a cross-sectional view of the vial access device and the adapter connected to the second vial taken along line **24B-24B** of **Fig. 24A** in accordance with an aspect of the present invention.

[0043] **Fig. 25** is a perspective view of a vial access device and an adapter connected to a second vial in accordance with another aspect of the present invention.

[0044] **Fig. 26A** is a side elevation view of a vial access device and an adapter connected to a second vial in accordance with another aspect of the present invention.

[0045] **Fig. 26B** is a cross-sectional view of the vial access device and the adapter connected to the second vial taken along line **26B-26B** of **Fig. 26A** in accordance with another aspect of the present invention.

[0046] **Fig. 27** is an exploded, perspective view of a system in accordance with another aspect of the present invention.

[0047] **Fig. 28** is a perspective view of a vial access device in accordance with another aspect of the present invention.

[0048] **Fig. 29** is a top view of a vial access device in accordance with another aspect of the present invention.

[0049] **Fig. 30** is a bottom, perspective view of a vial access device in accordance with another aspect of the present invention.

[0050] **Fig. 31** is a side elevation view of a vial access device in accordance with another aspect of the present invention.

[0051] **Fig. 32** is another side elevation view of a vial access device in accordance with another aspect of the present invention.

[0052] **Fig. 33A** is another side elevation view of a vial access device in accordance with another aspect of the present invention.

[0053] **Fig. 33B** is a cross-sectional view of a vial access device taken along line **33B-33B** of **Fig. 33A** in accordance with another aspect of the present invention.

[0054] **Fig. 34** is a perspective view of an adapter in accordance with another aspect of the present invention.

[0055] **Fig. 35** is another perspective view of an adapter in accordance with another aspect of the present invention.

[0056] **Fig. 36A** is a top view of an adapter in accordance with another aspect of the present invention.

[0057] **Fig. 36B** is a cross-sectional view of an adapter taken along line **36B-36B** of **Fig. 36A** in accordance with another aspect of the present invention.

[0058] **Fig. 37** is a bottom view of an adapter in accordance with another aspect of the present invention.

[0059] **Fig. 38** is a side elevation view of an adapter in accordance with another aspect of the present invention.

[0060] **Fig. 39** is another side elevation view of an adapter in accordance with another aspect of the present invention.

[0061] **Fig. 40** is another side elevation view of an adapter in accordance with another aspect of the present invention.

[0062] **Fig. 41A** is a perspective view of a vial access device housing component in accordance with another aspect of the present invention.

[0063] **Fig. 41B** is a cross-sectional view of the vial access device housing component of **Fig. 41A** in accordance with another aspect of the present invention.

[0064] **Fig. 42** is an exploded, perspective view of a system in accordance with another aspect of the present invention.

[0065] **Fig. 43** is an assembled, perspective view of the system of **Fig. 42** with an adapter in a shield position in accordance with another aspect of the present invention.



[0066] **Fig. 44** is a perspective view of a system with an adapter in a shield position in accordance with another aspect of the present invention.

[0067] **Fig. 45** is a side elevation view of a system with an adapter in a shield position in accordance with another aspect of the present invention.

[0068] **Fig. 46A** is a top view of a system with an adapter in a shield position in accordance with another aspect of the present invention.

[0069] **Fig. 46B** is a cross-sectional view of a system with an adapter in a shield position taken along line **46B-46B** of **Fig. 46A** in accordance with another aspect of the present invention.

[0070] **Fig. 47** is an exploded, perspective view of a system in accordance with another aspect of the present invention.

[0071] **Fig. 48** is an assembled, perspective view of the system of **Fig. 47** with an adapter in a vial position in accordance with another aspect of the present invention.

[0072] **Fig. 49** is a perspective view of a system with an adapter in a vial position in accordance with another aspect of the present invention.

[0073] **Fig. 50** is a side elevation view of a system with an adapter in a vial position in accordance with another aspect of the present invention.

[0074] **Fig. 51** is a bottom view of a system with an adapter in a vial position in accordance with another aspect of the present invention.

[0075] **Fig. 52** is a side elevation view of a system with an adapter in a vial position in accordance with another aspect of the present invention.

[0076] **Fig. 53** is a perspective view of a vial access device connected to a first vial in accordance with another aspect of the present invention.

[0077] **Fig. 54A** is a side elevation view of a vial access device connected to a first vial in accordance with another aspect of the present invention.

[0078] **Fig. 54B** is a cross-sectional view of the vial access device connected to the first vial taken along line **54B-54B** of **Fig. 54A** in accordance with another aspect of the present invention.

[0079] **Fig. 55** is a perspective view of a vial access device and an adapter connected to a second vial in accordance with another aspect of the present invention.

[0080] **Fig. 56A** is a side elevation view of a vial access device and an adapter connected to a second vial in accordance with another aspect of the present invention.

[0081] **Fig. 56B** is a cross-sectional view of the vial access device and the adapter connected to the second vial taken along line **56B-56B** of **Fig. 56A** in accordance with another aspect of the present invention.

[0082] Corresponding reference characters indicate corresponding parts throughout the several views. The exemplifications set out herein illustrate exemplary aspects of the disclosure, and such exemplifications are not to be construed as limiting the scope of the disclosure in any manner.

#### DETAILED DESCRIPTION

[0083] The following description is provided to enable those skilled in the art to make and use the described aspects contemplated for carrying out the invention. Various modifications, equivalents, variations, and alternatives, however, will remain readily apparent to those skilled in the art. Any and all such modifications, variations, equivalents, and alternatives are intended to fall within the spirit and scope of the present invention.

[0084] For purposes of the description hereinafter, the terms “upper”, “lower”, “right”, “left”, “vertical”, “horizontal”, “top”, “bottom”, “lateral”, “longitudinal”, and derivatives thereof shall relate to the invention as it is oriented in the drawing figures. However, it is to be understood that the invention may assume various alternative variations, except where expressly specified to the contrary. It is also to be understood that the specific devices illustrated in the attached drawings, and described in the following specification, are simply exemplary aspects of the invention. Hence, specific dimensions and other physical characteristics related to the aspects disclosed herein are not to be considered as limiting.

[0085] In the following discussion, “distal” refers to a direction generally toward an end of a component adapted for contact with a container, such as a vial, and “proximal” refers to the opposite direction of distal, i.e., away from the end of a component adapted for engagement with the container. For purposes of this disclosure, the above-mentioned references are used in the description of the components of a system in accordance with the present disclosure.

[0086] **Figs. 1A-5, 11-16B, and 23-24B** illustrate a first exemplary aspect of the present disclosure. Referring to **Figs. 1A-5, 11-16B, and 23-24B**, a first system for the closed transfer of fluids **10** includes a vial access device **12** attachable to a first vial **80** having a first vial size **81** (**Figs. 21-22B**) and a first adapter **14** transitionable between a shield position (**Figs. 11-14B**) in which first adapter **14** is attachable to vial access device **12** such that first adapter **14** shields a spike member **38** of vial access device **12** and a vial position (**Figs. 15-16B and 23-24B**) in

which first adapter 14 is attachable to a second vial 90 defining a second vial size 91, the second vial size 91 different than the first vial size 81. In this manner, first adapter 14 provides reversibility between a shield configuration in which first adapter 14 shields spike member 38 of vial access device 12 to prevent spike stick injuries and an adapter configuration in which first adapter 14 allows first system 10 to accommodate a plurality of vials having different sizes.

[0087] Referring to Figs. 21-22B, with vial access device 12 attached to first vial 80, vial access device 12 provides substantially leak-proof sealing during engagement of a cannula with a vial, during transfer of a substance from a vial chamber to a barrel chamber via the cannula, and during disengagement of the cannula from the vial. Referring to Figs. 23-24B, with vial access device 12 attached to second vial 90 via first adapter 14, first system 10 provides substantially leak-proof sealing during engagement of a cannula with a vial, during transfer of a substance from a vial chamber to a barrel chamber via the cannula, and during disengagement of the cannula from the vial. The leak-proof sealing of the first system 10 substantially prevents leakage of both air and liquid during use of the first system 10. First system 10 is compatible with a needle and syringe assembly for accessing a medication contained within a vial for administering the medication to a patient. First system 10 is also compatible to be used with a drug reconstitution system.

[0088] As described above, first system 10 is capable of accommodating a plurality of vials having different sizes. For example, referring to Figs. 21-22B, first vial 80 defining a first vial size 81 may be a standard drug vial of any type having an open head portion 83 covered by a pierceable septum 84 of an elastomeric material. Walls 85 of first vial 80 define vial chamber 86 for containing a first substance 88. First vial 80 includes flange 87 located adjacent open head portion 83. Vial septum 84 is engaged with head portion 83 of first vial 80 to seal the first substance 88 within vial chamber 86. Referring to Figs. 23-26B, second vial 90 defining a second vial size 91 may be a standard drug vial of any type having an open head portion 93 covered by a pierceable septum 94 of an elastomeric material. Walls 95 of second vial 90 define vial chamber 96 for containing a second substance 98. Second vial 90 includes flange 97 located adjacent open head portion 93. Vial septum 94 is engaged with head portion 93 of second vial 90 to seal the second substance 98 within vial chamber 96. In one aspect, second vial size 91 is less than first vial size 81.

[0089] Vial access device 12 and first adapter 14 provide a first system 10 that is capable of accommodating a plurality of vials having different sizes, e.g., first vial 80 having first vial size 81 and second vial 90 having second vial size 91. In one aspect, it is envisioned that vial

access device **12** and first adapter **14** are compatible with a first vial **80** comprising a 20 mm vial and a second vial **90** comprising a 13 mm vial. In another aspect, it is envisioned that vial access device **12** and first adapter **14** are compatible with a first vial **80** comprising a 28 mm vial and a second vial **90** comprising a 20 mm vial. In another aspect, it is envisioned that vial access device **12** and first adapter **14** are compatible with a first vial **80** comprising a 32 mm vial and a second vial **90** comprising a 28 mm vial. In other aspects, it is envisioned that vial access device **12** and first adapter **14** are compatible with a first vial **80** comprising other vial sizes and a second vial **90** comprising other vial sizes, wherein the second vial size is less than the first vial size.

[0090] Figs. **1A-1D**, **6-10**, **17-20B**, and **25-26B** illustrate a second exemplary aspect of the present disclosure. Referring to Figs. **1A-1D**, **6-10**, **17-20B**, and **25-26B**, a second system for the closed transfer of fluids **20** includes vial access device **12** attachable to first vial **80** having first vial size **81** (Figs. **21-22B**) and a second adapter **24** transitionable between a shield position (Figs. **17-18B**) in which second adapter **24** is attachable to vial access device **12** such that second adapter **24** shields a spike member **38** of vial access device **12** and a vial position (Figs. **19-20B** and **25-26B**) in which second adapter **24** is attachable to second vial **90** defining second vial size **91**, the second vial size **91** different than the first vial size **81**. In this manner, second adapter **24** provides reversibility between a shield configuration in which second adapter **24** shields spike member **38** of vial access device **12** to prevent spike stick injuries and an adapter configuration in which second adapter **24** allows second system **20** to accommodate a plurality of vials having different sizes.

[0091] Referring to Figs. **21-22B**, with vial access device **12** attached to first vial **80**, vial access device **12** provides substantially leak-proof sealing during engagement of a cannula with a vial, during transfer of a substance from a vial chamber to a barrel chamber via the cannula, and during disengagement of the cannula from the vial. Referring to Figs. **25-26B**, with vial access device **12** attached to second vial **90** via second adapter **24**, second system **20** provides substantially leak-proof sealing during engagement of a cannula with a vial, during transfer of a substance from a vial chamber to a barrel chamber via the cannula, and during disengagement of the cannula from the vial. The leak-proof sealing of the second system **20** substantially prevents leakage of both air and liquid during use of the second system **20**. Second system **20** is compatible with a needle and syringe assembly for accessing a medication contained within a vial for administering the medication to a patient. Second system **20** is also compatible to be used with a drug reconstitution system.

[0092] Vial access device 12 and second adapter 24 provide a second system 20 that is capable of accommodating a plurality of vials having different sizes, e.g., first vial 80 having first vial size 81 and second vial 90 having second vial size 91. In one aspect, it is envisioned that vial access device 12 and second adapter 24 are compatible with a first vial 80 comprising a 20 mm vial and a second vial 90 comprising a 13 mm vial. In another aspect, it is envisioned that vial access device 12 and second adapter 24 are compatible with a first vial 80 comprising a 28 mm vial and a second vial 90 comprising a 20 mm vial. In another aspect, it is envisioned that vial access device 12 and second adapter 24 are compatible with a first vial 80 comprising a 32 mm vial and a second vial 90 comprising a 28 mm vial. In other aspects, it is envisioned that vial access device 12 and second adapter 24 are compatible with a first vial 80 comprising other vial sizes and a second vial 90 comprising other vial sizes, wherein the second vial size is less than the first vial size.

[0093] Referring to Figs. 1A-1D, vial access device 12 generally includes first or proximal end 30; opposing second or distal end 32; neck portion 34 disposed adjacent first end 30; body portion 36 disposed adjacent second end 32; spike member 38 including piercing tip 40; fluid transfer channel 42; pressure normalization channel 44; first adapter connection elements 46 comprising end walls 47 and slots 48; second adapter connection elements 50 comprising locking protrusions 51; and vial connection element 52 comprising vial grip members 54, hook protrusions 56, and angled walls 58.

[0094] First end 30 of vial access device 12 is substantially formed by neck portion 34. In one aspect, neck portion 34 may include a guiding groove arranged therein to guide corresponding guiding protrusions on a syringe adapter, for example, to establish a secure attachment between the syringe adapter and vial access device 12 after which fluid communication can be established.

[0095] Referring to Figs. 1A-1D, in one aspect, first end 30 of vial access device 12 may contain a pierceable barrier member. The pierceable barrier member provides for a liquid and gas tight seal between a piercing member and the pierceable barrier member during fluid transfer to minimize leakage and thereby prevent exposure of hazardous medicaments to a user. The pierceable barrier member provides a self-sealing seal that, with vial access device 12 attached to a vial, provides a leak-proof seal preventing any substance contained within the vial chamber from being exposed to a health care provider reconstituting, transporting, or administering a drug using system 10. In one aspect, the pierceable barrier member comprises a resilient material. For example, the pierceable barrier member is preferably a unitary device molded of any flexible, elastomeric material conventionally used for fabricating gas-proof

closures. The pierceable barrier member may be formed of a natural rubber material, polyurethane elastomers, butyl rubbers, or similar materials. It is contemplated that the pierceable barrier member is formed of a material having a Shore A hardness of approximately 10 to 50. It is also envisioned that the pierceable barrier member can have other material hardness values that would provide an appropriate self-sealing material to provide a leak-proof seal with a vial septum of a vial and an syringe adapter, thereby preventing any liquid or medication residue from being exposed to a health care provider reconstituting, transporting, or administering a drug using system 10.

[0096] Second end 32 of vial access device 12 is substantially formed by body portion 36. Referring to Figs. 1A-1D, protruding out from body portion 36 at second end 32 of vial access device 12 is a piercing member or spike member 38 which includes piercing tip 40. The spike member 38 extends in a direction substantially parallel with the plurality of vial grip members 54 and serves the purpose of piercing a fluid container such as first vial 80 during assembly of vial access device 12 to a first vial 80 as is shown in greater detail in Fig. 22B.

[0097] Referring to Fig. 1D, a fluid transfer channel 42 extends through spike member 38 such that piercing tip 40 is in fluid communication with first end 30 of vial access device 12. The purpose of fluid transfer channel 42 is to permit a needle cannula to extend through vial access device 12 and to thereby permit fluid to be transferred through vial access device 12. In one aspect, fluid transfer channel 42 extends inside of spike member 38 as shown in Fig. 1D.

[0098] Referring to Fig. 1D, in one aspect, a pressure normalization channel 44 extends from enter aperture 43 to exit aperture 45. Pressure normalization channel 44 is arranged to provide gas communication between a pressure equalization system and the interior of a vial when the vial access device 12 is connected to a vial. With vial access device 12 connected to a vial, a syringe or cannula assembly may be used to inject fluid into the vial or to withdraw fluid therefrom. Any suitable pressure equalization arrangement may be utilized. For example, in one aspect, an accordion bellows pressure equalization system may be utilized as discussed in more detail below. The use of a pressure equalization system with a system of the present disclosure provides a system for the closed transfer of fluids that provides substantially leak-proof sealing and pressure equalization during engagement of a cannula with a vial, during transfer of a substance from a vial chamber to a barrel chamber via the cannula, and during disengagement of the cannula from the vial. In other aspects, the vial access device 12 may be a vial access device only and not include a pressure equalization arrangement and/or sealing arrangement.

[0099] Referring to **Figs. 1A-1D**, a vial connection element **52** is disposed at second end **32** of vial access device **12**. In one aspect, vial connection element **52** includes a plurality of vial grip members **54** having hook protrusions **56** and angled walls **58**. In one aspect, vial grip members **54** are elastically deformable. Vial grip members **54** are attachable to a first vial **80** to secure vial access device **12** to the first vial **80**. Each vial grip member **54** includes a hook protrusion **56** arranged to engage a corresponding flange **87** on a container such as first vial **80** as shown in **Figs. 21-22B**. Vial connection element **52** of vial access device **12** may be dimensioned to be attached to containers of any size and volume. In other aspects, vial connection element **52** of vial access device **12** may include other connection mechanisms for securing vial access device **12** to first vial **80** such as a threaded portion, a snap fit mechanism, locking tabs, or other similar mechanism. Each vial grip member **54** includes an angled wall **58** arranged to provide a lead-in surface to center and align vial access device **12** on a vial.

[00100] Referring to **Figs. 1A-1D**, vial access device **12** includes a first adapter connection element **46** and a second adapter connection element **50**. In this manner, vial access device **12** is connectable with a plurality of different adapters of the present disclosure as discussed in more detail below. In one aspect, first adapter connection element **46** comprises a plurality of slots **48**. Slots **48** are spaced a distance from one another as shown in **Figs. 1A-1C**. In one aspect, second adapter connection element **50** comprises a plurality of locking protrusions **51**. Locking protrusions **51** are spaced a distance from one another as shown in **Figs. 1A-1C**.

[00101] Referring to **Figs. 2-5**, first adapter **14** generally includes horizontal shield wall **60**; outer portion **61** extending from the periphery of horizontal shield wall **60**, outer portion **61** comprising outer shield wall **62**; inner portion **64** extending from horizontal shield wall **60** and disposed within outer portion **61**, inner portion **64** comprising a plurality of inner shield walls **65** defining spike shield area **66**; spike cavity **67** defined within a central region of horizontal shield wall **60**; access device connection element **68** comprising a plurality of external latches **70** defining a vial access device receiving area **72** and including a locking rib **74**; alignment guides **75**; and vial connection element **76** comprising vial grip members **77**, hook protrusions **78**, and angled walls **79**.

[00102] First adapter **14** is transitionable between a shield position (**Figs. 11-14B**) in which first adapter **14** is attachable to vial access device **12** such that first adapter **14** shields a spike member **38** of vial access device **12** and a vial position (**Figs. 15-16B** and **23-24B**) in which first adapter **14** is attachable to a second vial **90** defining a second vial size **91**, the second vial size **91** different than the first vial size **81**. In this manner, first adapter **14** provides reversibility between a shield configuration in which first adapter **14** shields spike member **38** of vial access

device 12 to prevent spike stick injuries and an adapter or vial configuration in which first adapter 14 allows first system 10 to accommodate a plurality of vials having different sizes.

[00103] Referring to Figs. 2 and 14B, horizontal shield wall 60 and inner shield walls 65 together define a spike shield area 66 which is sized and configured to receive and shield spike member 38 of vial access device 12 with first adapter 14 in a shield position. In this manner, first adapter 14 provides a physical barrier that shields spike member 38 of vial access device 12 and prevents the fingers of a user from contacting piercing tip 40 of spike member 38.

[00104] In one aspect, access device connection element 68 of first adapter 14 includes a plurality of external latches 70 spaced around a periphery of outer shield wall 62 as shown in Fig. 2. External latches 70 are engageable with slots 48 of vial access device 12 to attach first adapter 14 to vial access device 12 with the first adapter 14 in the shield position to shield spike member 38 of vial access device 12 as shown in Fig. 14B and as described in more detail below. In one aspect, external latches 70 are elastically deformable.

[00105] Referring to Figs. 2-5, inner shield walls 65 of first adapter 14 include a vial connection element 76. In one aspect, vial connection element 76 includes a plurality of vial grip members 77 having hook protrusions 78 and angled walls 79. In one aspect, vial grip members 77 are elastically deformable. Vial grip members 77 are attachable to a second vial 90 to secure first system 10 to the second vial 90. Each vial grip member 77 includes a hook protrusion 78 arranged to engage a corresponding flange 97 on a container such as second vial 90 as shown in Figs. 23-24B. Vial connection element 76 of first adapter 14 may be dimensioned to be attached to containers of any size and volume. In other aspects, vial connection element 76 of first adapter 14 may include other connection mechanisms for securing first adapter 14 to second vial 90 such as a threaded portion, a snap fit mechanism, locking tabs, or other similar mechanism. Each vial grip member 77 includes an angled wall 79 arranged to provide a lead-in surface to center and align first system 10 on a vial.

[00106] Referring to Figs. 11-14B, as described above, first adapter 14 is attachable to vial access device 12 such that first adapter 14 shields a spike member 38 of vial access device 12 in a shield position. First adapter 14 is attachable to vial access device 12 by engagement of access device connection elements 68 of first adapter 14 with first adapter connection elements 46 of vial access device 12. For example, end walls 47 of first adapter connection elements 46 can be positioned into respective vial access device receiving areas 72 of external latches 70 of first adapter 14 as shown in Figs. 11 and 14B. In this position, a force can be exerted on vial access device 12 to push vial access device 12 into engagement with external latches 70 of first adapter 14. As force is exerted on vial access device 12 to axially move vial access device 12



into engagement with first adapter 14, external latches 70 of first adapter 14 cooperate with first adapter connection elements 46 of vial access device 12 and deform outward so that end walls 47 of first adapter connection elements 46 move axially downward into vial access device receiving areas 72 of external latches 70 until locking ribs 74 of external latches 70 engage respective slots 48 of first adapter connection elements 46 and lock first adapter 14 to vial access device 12 in the shield position as shown in Figs. 11-14B. In this manner, first adapter 14 is secured to vial access device 12 such that first adapter 14 is prevented from significant relative movement relative to vial access device 12.

[00107] In the shield position, first adapter 14 is particularly advantageous in that it allows a user, such as a patient and/or healthcare worker, to safely handle vial access device 12 without receiving spike stick injuries from piercing tip 40 of spike member 38. With first adapter 14 in the shield position as described above, first adapter 14 provides a physical barrier preventing the fingers of a user from contacting piercing tip 40 of spike member 38. In this manner, the user is prevented from spike stick injuries and the user can conveniently and safely handle vial access device 12 and remove vial access device 12 from packaging. An adapter of the present disclosure is also advantageous in that it protects the package integrity.

[00108] After vial access device 12 is safely removed from packaging and safely handled with first adapter 14 shielding spike member 38 as described above, first adapter 14 may be removed from vial access device 12. Next, if it is desired to use a system that provides substantially leak-proof sealing during engagement of a cannula with a first vial 80 defining a first vial size 81, vial access device 12 can be used and attached to first vial 80 as shown in Figs. 21-22B. Vial grip members 54 of vial access device 12 are attachable to first vial 80 to secure vial access device 12 to first vial 80. Each vial grip member 54 includes a hook protrusion 56 arranged to engage a corresponding flange 87 on a container such as first vial 80 as shown in Fig. 22B. Referring to Figs. 21-22B, with vial access device 12 attached to first vial 80, vial access device 12 provides substantially leak-proof sealing during engagement of a cannula with first vial 80, during transfer of a substance from vial chamber 86 to a barrel chamber via the cannula, and during disengagement of the cannula from first vial 80.

[00109] In another application of first system 10 of the present disclosure, after vial access device 12 is safely removed from packaging and safely handled with first adapter 14 shielding spike member 38 as described above, first adapter 14 may be removed from vial access device 12. Next, if it is desired to use a system that provides substantially leak-proof sealing during engagement of a cannula with a second vial 90 defining a second vial size 91, the second vial size 91 being less than first vial size 81, first adapter 14 can be used and attached to second

vial 90 as shown in **Figs. 23-24B**. After first adapter 14 is removed from vial access device 12, first adapter 14 can be rotated from the shield position as shown in **Figs. 11-14B** to the vial position as shown in **Figs. 15-16B** and **23-24B**. In the vial position, first adapter 14 can be used and attached to second vial 90 as shown in **Figs. 23-24B**. Although **Figs. 23-24B** illustrate vial access device 12 and first adapter 14 attached to second vial 90, first adapter 14 can first be attached to second vial 90 and used to align and guide vial access device 12 during its installation onto second vial 90 as described below. The first adapter 14 is secured to the vial access device 12 by the vial grip members 54 of the vial access device 12 engaging the bottom of the outer portion 61 of the first adapter 14. The vial grip members 54 may be secured to the first adapter 14 in the same manner that the vial grip members 54 are secured to the flange 87 on the first vial 80 as described above.

[00110] Vial grip members 77 of first adapter 14 are attachable to second vial 90 to secure vial access device 12 to second vial 90 via first adapter 14 as shown in **Figs. 23-24B**. Each vial grip member 77 of first adapter 14 includes a hook protrusion 78 arranged to engage a corresponding flange 97 on a container such as second vial 90 as shown in **Fig. 24B**. Referring to **Figs. 23-24B**, with vial access device 12 attached to second vial 90 via first adapter 14, first system 10 provides substantially leak-proof sealing during engagement of a cannula with second vial 90, during transfer of a substance from vial chamber 96 to a barrel chamber via the cannula, and during disengagement of the cannula from second vial 90. In one aspect, after first adapter 14 is attached to second vial 90, alignment guides 75 of first adapter 14 provide a functional benefit by acting as alignment guides for positioning vial access device 12 during its installation onto second vial 90. With first adapter 14 and vial access device 12 secured to second vial 90, spike member 38 of vial access device 12 is able to extend through spike cavity 67 of first adapter 14 as shown in **Fig. 16B**.

[00111] Referring to **Figs. 6-10**, second adapter 24 generally includes horizontal shield wall 100; outer portion 101 extending from the periphery of horizontal shield wall 100, outer portion 101 comprising outer shield wall 102; inner portion 104 extending from horizontal shield wall 100 and disposed within outer portion 101, inner portion 104 comprising a plurality of inner shield walls 105 defining spike shield area 106; spike cavity 107 defined within a central region of horizontal shield wall 100; access device connection element 108 comprising a plurality of internal latches or locking apertures 110; and vial connection element 116 comprising vial grip members 117, hook protrusions 118, and angled walls 119.

[00112] Second adapter 24 is transitionable between a shield position (**Figs. 17-18B**) in which second adapter 24 is attachable to vial access device 12 such that second adapter 24

shields a spike member 38 of vial access device 12 and a vial position (Figs. 19-20B and 25-26B) in which second adapter 24 is attachable to a second vial 90 defining a second vial size 91, the second vial size 91 different than the first vial size 81. In this manner, second adapter 24 provides reversibility between a shield configuration in which second adapter 24 shields spike member 38 of vial access device 12 to prevent spike stick injuries and an adapter or vial configuration in which second adapter 24 allows second system 20 to accommodate a plurality of vials having different sizes.

[00113] Referring to Figs. 6 and 18B, horizontal shield wall 100 and inner shield walls 105 together define a spike shield area 106 which is sized and configured to receive and shield spike member 38 of vial access device 12 with second adapter 24 in a shield position. In this manner, second adapter 24 provides a physical barrier that shields spike member 38 of vial access device 12 and prevents the fingers of a user from contacting piercing tip 40 of spike member 38.

[00114] In one aspect, access device connection element 108 of second adapter 24 includes a plurality of internal latches or locking apertures 100 spaced around a periphery of outer shield wall 102 as shown in Fig. 6. Internal latches 100 are engageable with locking protrusions 51 of vial access device 12 to attach second adapter 24 to vial access device 12 with the second adapter 24 in the shield position to shield spike member 38 of vial access device 12 as shown in Fig. 18B and as described in more detail below.

[00115] Referring to Figs. 6-10, inner shield walls 105 of second adapter 24 include a vial connection element 116. In one aspect, vial connection element 116 includes a plurality of vial grip members 117 having hook protrusions 118 and angled walls 119. In one aspect, vial grip members 117 are elastically deformable. Vial grip members 117 are attachable to a second vial 90 to secure second system 20 to the second vial 90. Each vial grip member 117 includes a hook protrusion 118 arranged to engage a corresponding flange 97 on a container such as second vial 90 as shown in Figs. 25-26B. Vial connection element 116 of second adapter 24 may be dimensioned to be attached to containers of any size and volume. In other aspects, vial connection element 116 of second adapter 24 may include other connection mechanisms for securing second adapter 24 to second vial 90 such as a threaded portion, a snap fit mechanism, locking tabs, or other similar mechanism. Each vial grip member 117 includes an angled wall 119 arranged to provide a lead-in surface to center and align second system 20 on a vial.

[00116] Referring to Figs. 17-18B, as described above, second adapter 24 is attachable to vial access device 12 such that second adapter 24 shields a spike member 38 of vial access device 12 in a shield position. Second adapter 24 is attachable to vial access device 12 by

engagement of access device connection elements 108 of second adapter 24 with second adapter connection elements 50 of vial access device 12. For example, locking protrusions 51 of second adapter connection elements 50 can be positioned into engagement with respective locking apertures 110 of second adapter 24 as shown in Figs. 17 and 18B. For example, a force can be exerted on vial access device 12 to push vial access device 12 into engagement with locking apertures 110 of second adapter 24. As force is exerted on vial access device 12 to axially move vial access device 12 into engagement with second adapter 24, locking protrusions 51 of vial access device 12 cooperate with outer shield wall 102 of second adapter 24 and deform outward so that second adapter connection elements 50 of vial access device 12 move axially downward until locking protrusions 51 of vial access device 12 snap into engagement with respective locking apertures 110 of second adapter 24 and lock second adapter 24 to vial access device 12 in the shield position as shown in Figs. 17-18B. In this manner, second adapter 24 is secured to vial access device 12 such that second adapter 24 is prevented from significant relative movement relative to vial access device 12. In one aspect, vial access device 12 does not need to contain slots 48 when used with second adapter 24 and second system 20.

[00117] In the shield position, second adapter 24 is particularly advantageous in that it allows a user, such as a patient and/or healthcare worker, to safely handle vial access device 12 without receiving spike stick injuries from piercing tip 40 of spike member 38. With second adapter 24 in the shield position as described above, second adapter 24 provides a physical barrier preventing the fingers of a user from contacting piercing tip 40 of spike member 38. In this manner, the user is prevented from spike stick injuries and the user can conveniently and safely handle vial access device 12 and remove vial access device 12 from packaging. An adapter of the present disclosure is also advantageous in that it protects the package integrity.

[00118] After vial access device 12 is safely removed from packaging and safely handled with second adapter 24 shielding spike member 38 as described above, second adapter 24 may be removed from vial access device 12. Next, if it is desired to use a system that provides substantially leak-proof sealing during engagement of a cannula with a first vial 80 defining a first vial size 81, vial access device 12 can be used and attached to first vial 80 as shown in Figs. 21-22B and as described above.

[00119] In another application of second system 20 of the present disclosure, after vial access device 12 is safely removed from packaging and safely handled with second adapter 24 shielding spike member 38 as described above, second adapter 24 may be removed from vial access device 12. Next, if it is desired to use a system that provides substantially leak-proof

sealing during engagement of a cannula with a second vial 90 defining a second vial size 91, the second vial size 91 being less than first vial size 81, second adapter 24 can be used and attached to second vial 90 as shown in Figs. 25-26B. After second adapter 24 is removed from vial access device 12, second adapter 24 can be rotated from the shield position as shown in Figs. 17-18B to the vial position as shown in Figs. 19-20B and 25-26B. In the vial position, second adapter 24 can be used and attached to second vial 90 as shown in Figs. 25-26B. Vial grip members 117 of second adapter 24 are attachable to second vial 90 to secure vial access device 12 to second vial 90 via second adapter 24 as shown in Figs. 25-26B. The second adapter 24 may be secured to the second vial 90 first with the vial access device 12 subsequently placed onto the second adapter 24. The second adapter 24 is secured to the vial access device 12 by the vial grip members 54 of the vial access device 12 engaging the bottom of the outer portion 101 of the second adapter 24. The vial grip members 54 may be secured to the second adapter 24 in the same manner that the vial grip members 54 are secured to the flange 87 on the first vial 80 as described above. Each vial grip member 117 of second adapter 24 includes a hook protrusion 118 arranged to engage a corresponding flange 97 on a container such as second vial 90 as shown in Fig. 26B.

[00120] Referring to Figs. 25-26B, with vial access device 12 attached to second vial 90 via second adapter 24, second system 20 provides substantially leak-proof sealing during engagement of a cannula with second vial 90, during transfer of a substance from vial chamber 96 to a barrel chamber via the cannula, and during disengagement of the cannula from second vial 90. With second adapter 24 and vial access device 12 secured to second vial 90, spike member 38 of vial access device 12 is able to extend through spike cavity 107 of second adapter 24 as shown in Fig. 20B.

[00121] Figs. 27-56B illustrate a third exemplary aspect of the present disclosure. Referring to Figs. 27-56B, a third system for the closed transfer of fluids 300 includes a vial access device or vial access device housing component 202 attachable to a first vial 80 having a first vial size 81 (Figs. 53-54B) and a third adapter 204 transitionable between a shield position (Figs. 42-46B) in which third adapter 204 is attachable to vial access device 202 such that third adapter 204 shields a spike member 228 of vial access device 202 and a vial position (Figs. 47-52 and 55-56B) in which third adapter 204 is attachable to a second vial 90 defining a second vial size 91, the second vial size 91 different than the first vial size 81. In this manner, third adapter 204 provides reversibility between a shield configuration in which third adapter 204 shields spike member 228 of vial access device 202 to prevent spike stick injuries and an adapter

configuration in which third adapter **204** allows third system **200** to accommodate a plurality of vials having different sizes.

[00122] Referring to **Figs. 53-54B**, with vial access device **202** attached to first vial **80**, vial access device **202** provides substantially leak-proof sealing during engagement of a cannula with a vial, during transfer of a substance from a vial chamber to a barrel chamber via the cannula, and during disengagement of the cannula from the vial. Referring to **Figs. 55-56B**, with vial access device **202** attached to second vial **90** via third adapter **204**, third system **200** provides substantially leak-proof sealing during engagement of a cannula with a vial, during transfer of a substance from a vial chamber to a barrel chamber via the cannula, and during disengagement of the cannula from the vial. The leak-proof sealing of the third system **200** substantially prevents leakage of both air and liquid during use of the third system **200**. Third system **200** is compatible with a needle and syringe assembly for accessing a medication contained within a vial for administering the medication to a patient. Third system **200** is also compatible to be used with a drug reconstitution system.

[00123] As described above, third system **200** is capable of accommodating a plurality of vials having different sizes. For example, referring to **Figs. 53-54B**, first vial **80** defining a first vial size **81** may be a standard drug vial of any type having an open head portion **83** covered by a pierceable septum **84** of an elastomeric material. Walls **85** of first vial **80** define vial chamber **86** for containing a first substance **88**. First vial **80** includes flange **87** located adjacent open head portion **83**. Vial septum **84** is engaged with head portion **83** of first vial **80** to seal the first substance **88** within vial chamber **86**. Referring to **Figs. 55-56B**, second vial **90** defining a second vial size **91** may be a standard drug vial of any type having an open head portion **93** covered by a pierceable septum **94** of an elastomeric material. Walls **95** of second vial **90** define vial chamber **96** for containing a second substance **98**. Second vial **90** includes flange **97** located adjacent open head portion **93**. Vial septum **84** is engaged with head portion **93** of second vial **90** to seal the second substance **98** within vial chamber **96**. In one aspect, second vial size **91** is less than first vial size **81**.

[00124] Vial access device **202** and third adapter **204** provide a third system **200** that is capable of accommodating a plurality of vials having different sizes, e.g., first vial **80** having first vial size **81** and second vial **90** having second vial size **91**. In one aspect, it is envisioned that vial access device **202** and third adapter **204** are compatible with a first vial **80** comprising a 20 mm vial and a second vial **90** comprising a 13 mm vial. In another aspect, it is envisioned that vial access device **202** and third adapter **204** are compatible with a first vial **80** comprising a 28 mm vial and a second vial **90** comprising a 20 mm vial. In another aspect, it is envisioned

that vial access device **202** and third adapter **204** are compatible with a first vial **80** comprising a 32 mm vial and a second vial **90** comprising a 28 mm vial. In other aspects, it is envisioned that vial access device **202** and third adapter **204** are compatible with a first vial **80** comprising other vial sizes and a second vial **90** comprising other vial sizes, wherein the second vial size is less than the first vial size.

[00125] Referring to **Fig. 27**, in one aspect, third system **200** includes vial access device **202**, third adapter **204**, pressure equalization system **206**, connector **208**, top housing component **210**, and cap component **212**. **Fig. 27** illustrates pressure equalization system **206** an expanded state, although the pressure equalization system also has a non-expanded state (not shown). Third system **200** includes a pressure equalization system **206** that is designed as an accordion bellows which is compressible and expandable and thus the volume of pressure equalization system **206** can thereby be increased and decreased. **Figs. 41A-56B** illustrate pressure equalization system **206** an expanded state, although the pressure equalization system also has a non-expanded state (not shown). Pressure equalization system **206** is either a non-expanded state or an expanded state, e.g., pressure equalization system **206** is transitionable between a non-expanded state and an expanded state.

[00126] In one aspect, third system **200** includes either top housing component **210** or cap component **212** but not both. In one aspect, vial access device **202**, pressure equalization system **206**, connector **208**, top housing component **210**, and cap component **212** form a single integral component. In another aspect, vial access device **202**, pressure equalization system **206**, connector **208**, top housing component **210**, and cap component **212** are separate components that are attachable theretogether to form a vial access device housing component. The connector **208** is a bayonet-style connection, although the connection **208** may be embodied as any other suitable connection arrangement.

[00127] Third system **200** provides substantially leak-proof sealing and pressure balancing during engagement of a cannula with a vial, during transfer of a substance from a vial chamber to a barrel chamber via the cannula, and during disengagement of the cannula from the vial. The leak-proof sealing of the third system **200** substantially prevents leakage of both air and liquid during use of the third system **200**. Third system **200** is compatible with a needle and syringe assembly for accessing a medication contained within a vial for administering the medication to a patient. Third system **200** is also compatible to be used with a drug reconstitution system as will be described in more detail below.

[00128] Referring to **Figs. 28-33B**, vial access device **202** generally includes first end **220**; opposing second end **222**; neck portion **224** disposed adjacent first end **220**; body portion **226**

disposed adjacent second end 222; spike member 228 including piercing tip 230; fluid transfer channel 232; pressure normalization channel 234; pressure chamber 238; first adapter connection elements 240 comprising locking ribs 242; second adapter connection elements 244; vial connection element 246 comprising vial grip members 248, hook protrusions 250, and angled walls 252; arm portion 254; and pressure equalization connection wall 256.

[00129] First end 220 of vial access device 202 is substantially formed by neck portion 224. In one aspect, neck portion 224 may include a guiding groove arranged therein to guide corresponding guiding protrusions on a syringe adapter, for example, to establish a secure attachment between the syringe adapter and vial access device 202 after which fluid communication can be established.

[00130] Referring to Figs. 28-33B, in one aspect, first end 220 of vial access device 202 may contain a pierceable barrier member. The pierceable barrier member provides for a liquid and gas tight seal between a piercing member and the pierceable barrier member during fluid transfer to minimize leakage and thereby prevent exposure of hazardous medicaments to a user. The pierceable barrier member provides a self-sealing seal that, with vial access device 202 attached to a vial, provides a leak-proof seal preventing any substance contained within the vial chamber from being exposed to a health care provider reconstituting, transporting, or administering a drug using third system 200. In one aspect, the pierceable barrier member comprises a resilient material. For example, the pierceable barrier member is preferably a unitary device molded of any flexible, elastomeric material conventionally used for fabricating gas-proof closures. The pierceable barrier member may be formed of a natural rubber material, polyurethane elastomers, butyl rubbers, or similar materials. It is contemplated that the pierceable barrier member is formed of a material having a Shore A hardness of approximately 10 to 50. It is also envisioned that the pierceable barrier member can have other material hardness values that would provide an appropriate self-sealing material to provide a leak-proof seal with a vial septum of a vial and a syringe adapter, thereby preventing any liquid or medication residue from being exposed to a health care provider reconstituting, transporting, or administering a drug using third system 200.

[00131] Second end 222 of vial access device 202 is substantially formed by body portion 226. Referring to Figs. 28-33B, protruding out from body portion 226 at second end 222 of vial access device 202 is a piercing member or spike member 228 which includes piercing tip 230. The spike member 228 extends in a direction substantially parallel with the plurality of vial grip members 248 and serves the purpose of piercing a fluid container such as first vial 80



during assembly of vial access device **202** to a first vial **80** as is shown in greater detail in **Fig. 54B**.

[00132] Referring to **Fig. 33B**, a fluid transfer channel **232** extends through spike member **228** such that piercing tip **230** is in fluid communication with first end **220** of vial access device **202**. The purpose of fluid transfer channel **232** is to permit a needle cannula to extend through vial access device **202** and to thereby permit fluid to be transferred through vial access device **202**. In one aspect, fluid transfer channel **232** extends inside of spike member **228** as shown in **Fig. 33B**.

[00133] Referring to **Fig. 33B**, in one aspect, a pressure normalization channel **234** extends from enter aperture **235** to exit aperture **236** and then to pressure chamber **238**. Pressure normalization channel **234** is arranged to provide gas communication between a pressure equalization system, such as pressure equalization system **206**, and the interior of a vial when the vial access device **202** is connected to a vial. With vial access device **202** connected to a vial, a syringe or cannula assembly may be used to inject fluid into the vial or to withdraw fluid therefrom. The use of a pressure equalization system, such as pressure equalization system **206**, with a system of the present disclosure provides a system for the closed transfer of fluids that provides substantially leak-proof sealing and pressure equalization during engagement of a cannula with a vial, during transfer of a substance from a vial chamber to a barrel chamber via the cannula, and during disengagement of the cannula from the vial.

[00134] Referring to **Figs. 28-33B**, a vial connection element **246** is disposed at second end **222** of vial access device **202**. In one aspect, vial connection element **246** includes a plurality of vial grip members **248** having hook protrusions **250** and angled walls **252**. In one aspect, vial grip members **248** are elastically deformable. Vial grip members **248** are attachable to a first vial **80** to secure vial access device **202** to the first vial **80**. Each vial grip member **248** includes a hook protrusion **250** arranged to engage a corresponding flange **87** on a container such as first vial **80** as shown in **Figs. 53-54B**. Vial connection element **246** of vial access device **202** may be dimensioned to be attached to containers of any size and volume. In other aspects, vial connection element **246** of vial access device **202** may include other connection mechanisms for securing vial access device **202** to first vial **80** such as a threaded portion, a snap fit mechanism, locking tabs, or other similar mechanism. Each vial grip member **248** includes an angled wall **252** arranged to provide a lead-in surface to center and align vial access device **202** on a vial.

[00135] Referring to **Figs. 28-33B**, vial access device **202** includes a first adapter connection element **240** and a second adapter connection element **244**. In this manner, vial access device

**202** is connectable with third adapter **204** in a shield position and a vial position as discussed in more detail below. In one aspect, first adapter connection element **240** comprises a plurality of locking ribs **242**. Locking ribs **242** are spaced a distance from one another as shown in **Figs. 28-33B**. In one aspect, pressure equalization system **206** includes receiving slots **207** and pressure equalization system **206** is attachable to pressure equalization connection wall **256** of arm portion **254** of vial access device **202** by engagement of connection wall **256** within receiving slots **207** as shown in **Fig. 41B**.

[00136] Referring to **Figs. 34-40**, third adapter **204** generally includes horizontal shield wall **270**; outer portion **272** extending from the periphery of horizontal shield wall **270**, outer portion **272** comprising outer shield wall **274** which defines outer vial access device compartments **276**; inner portion **278** extending from horizontal shield wall **270** and disposed within outer portion **272**, inner portion **278** comprising a plurality of inner shield walls **280** defining spike shield area **282**; spike cavity **284** defined within a central region of horizontal shield wall **270**; access device connection element **286** comprising a plurality of locking apertures **288** and a plurality of locking walls **290**; and vial connection element **292** comprising vial grip members **294**, hook protrusions **296**, and angled walls **298**.

[00137] Third adapter **204** is transitionable between a shield position (**Figs. 42-46B**) in which third adapter **204** is attachable to vial access device **202** such that third adapter **204** shields a spike member **228** of vial access device **202** and a vial position (**Figs. 47-52 and 55-56B**) in which third adapter **204** is attachable to a second vial **90** defining a second vial size **91**, the second vial size **91** different than the first vial size **81**. In this manner, third adapter **204** provides reversibility between a shield configuration in which third adapter **204** shields spike member **228** of vial access device **202** to prevent spike stick injuries and an adapter or vial configuration in which third adapter **204** allows third system **200** to accommodate a plurality of vials having different sizes.

[00138] Referring to **Fig. 34**, horizontal shield wall **270** and inner shield walls **280** together define a spike shield area **282** which is sized and configured to receive and shield spike member **228** of vial access device **202** with third adapter **204** in a shield position. In this manner, third adapter **204** provides a physical barrier that shields spike member **228** of vial access device **202** and prevents the fingers of a user from contacting piercing tip **230** of spike member **228**.

[00139] In one aspect, access device connection element **286** of third adapter **204** includes a plurality of locking apertures **288** spaced around a periphery of outer shield wall **274** as shown in **Fig. 35**. Locking apertures **288** are engageable with locking ribs **242** of vial access device

**202** to attach third adapter **204** to vial access device **202** with the third adapter **204** in the shield position to shield spike member **228** of vial access device **202** as shown in **Figs. 42-46B** and as described in more detail below.

[00140] Referring to **Figs. 34-40**, inner shield walls **280** of third adapter **204** include a vial connection element **292**. In one aspect, vial connection element **292** includes a plurality of vial grip members **294** having hook protrusions **296** and angled walls **298**. In one aspect, vial grip members **294** are elastically deformable. Vial grip members **294** are attachable to a second vial **90** to secure third system **200** to the second vial **90**. Each vial grip member **294** includes a hook protrusion **296** arranged to engage a corresponding flange **97** on a container such as second vial **90** as shown in **Figs. 55-56B**. Vial connection element **292** of third adapter **204** may be dimensioned to be attached to containers of any size and volume. In other aspects, vial connection element **292** of third adapter **204** may include other connection mechanisms for securing third adapter **204** to second vial **90** such as a threaded portion, a snap fit mechanism, locking tabs, or other similar mechanism. Each vial grip member **294** includes an angled wall **298** arranged to provide a lead-in surface to center and align third system **200** on a vial.

[00141] Referring to **Figs. 42-46B**, as described above, third adapter **204** is attachable to vial access device **202** such that third adapter **204** shields a spike member **228** of vial access device **202** in a shield position. Third adapter **204** is attachable to vial access device **202** by engagement of locking apertures **288** of third adapter **204** with locking ribs **242** of vial access device **202** to attach third adapter **204** to vial access device **202** with the third adapter **204** in the shield position to shield spike member **228** of vial access device **202** as shown in **Figs. 42-46B**. In this manner, third adapter **204** is secured to vial access device **202** such that third adapter **204** is prevented from significant relative movement relative to vial access device **202**.

[00142] In the shield position, third adapter **204** is particularly advantageous in that it allows a user, such as a patient and/or healthcare worker, to safely handle vial access device **202** without receiving spike stick injuries from piercing tip **230** of spike member **228**. With third adapter **204** in the shield position as described above, third adapter **204** provides a physical barrier preventing the fingers of a user from contacting piercing tip **230** of spike member **228**. In this manner, the user is prevented from spike stick injuries and the user can conveniently and safely handle vial access device **202** and remove vial access device **202** from packaging.

[00143] After vial access device **202** is safely removed from packaging and safely handled with third adapter **204** shielding spike member **228** as described above, third adapter **204** may be removed from vial access device **202**. Next, if it is desired to use a system that provides substantially leak-proof sealing during engagement of a cannula with a first vial **80** defining a

first vial size 81, vial access device 202 can be used and attached to first vial 80 as shown in Figs. 53-54B. Vial grip members 248 of vial access device 202 are attachable to first vial 80 to secure vial access device 202 to first vial 80. Each vial grip member 248 includes a hook protrusion 250 arranged to engage a corresponding flange 87 on a container such as first vial 80 as shown in Fig. 54B. Referring to Figs. 53-54B, with vial access device 202 attached to first vial 80, vial access device 202 provides substantially leak-proof sealing during engagement of a cannula with first vial 80, during transfer of a substance from vial chamber 86 to a barrel chamber via the cannula, and during disengagement of the cannula from first vial 80.

[00144] In another application of third system 200 of the present disclosure, after vial access device 202 is safely removed from packaging and safely handled with third adapter 204 shielding spike member 228 as described above, third adapter 204 may be removed from vial access device 202. Next, if it is desired to use a system that provides substantially leak-proof sealing during engagement of a cannula with a second vial 90 defining a second vial size 91, the second vial size 91 being less than first vial size 81, third adapter 204 can be used and attached to second vial 90 as shown in Figs. 55-56B. After third adapter 204 is removed from vial access device 202, third adapter 204 can be rotated from the shield position as shown in Figs. 42-46B to the vial position as shown in Figs. 47-52 and 55-56B. In the vial position, third adapter 204 can be used and attached to second vial 90 as shown in Figs. 55-56B. The third adapter 204 is secured to the vial access device 202 by the vial grip members 248 of the vial access device 202 engaging the bottom of the outer portion 272 of the third adapter 204. The vial grip members 248 may be secured to the third adapter 204 in the same manner that the vial grip members 248 are secured to the flange 87 on the first vial 80 as described above. In this manner, third adapter 204 is secured to vial access device 202 such that third adapter 204 is prevented from significant relative movement relative to vial access device 202.

[00145] Vial grip members 294 of third adapter 204 are attachable to second vial 90 to secure vial access device 202 to second vial 90 via third adapter 204 as shown in Figs. 55-56B. Each vial grip member 294 of third adapter 204 includes a hook protrusion 296 arranged to engage a corresponding flange 97 on a container such as second vial 90 as shown in Fig. 56B. The third adapter 204 may be secured to the second vial 90 first with the vial access device 202 subsequently secured to the third adapter 204. Referring to Figs. 55-56B, with vial access device 202 attached to second vial 90 via third adapter 204, third system 200 provides substantially leak-proof sealing during engagement of a cannula with second vial 90, during transfer of a substance from vial chamber 96 to a barrel chamber via the cannula, and during

disengagement of the cannula from second vial 90. With third adapter 204 and vial access device 202 secured to second vial 90, spike member 228 of vial access device 202 is able to extend through spike cavity 284 of third adapter 204 as shown in **Fig. 56B**.

**[00146]** While this disclosure has been described as having exemplary designs, the present disclosure can be further modified within the spirit and scope of this disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the disclosure using its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this disclosure pertains and which fall within the limits of the appended claims.

**WHAT IS CLAIMED IS:**

1. A system comprising:  
a vial access device including a spike, the vial access device attachable to a first vial defining a first vial size; and  
an adapter transitionable between a shield position in which the adapter is attachable to the vial access device such that the adapter shields the spike of the vial access device and a vial position in which the adapter is attachable to a second vial defining a second vial size, the second vial size different than the first vial size.
2. The system of claim 1, wherein the vial access device further comprises an adapter connection element and the adapter further comprises an access device connection element and a vial connection element, the adapter transitionable between the shield position in which the access device connection element is attachable to the adapter connection element of the vial access device to secure the adapter to the vial access device such that the adapter shields the spike of the vial access device and the vial position in which the vial connection element is attachable to the second vial to secure the adapter to the second vial.
3. The system of claim 2, wherein the access device connection element of the adapter comprises an external latch.
4. The system of claim 2, wherein the access device connection element of the adapter comprises an internal latch.
5. The system of any of claims 2-4, wherein the vial connection element of the adapter comprises a plurality of vial grip members.
6. The system of claim 5, wherein the plurality of vial grip members are elastically deformable.
7. The system of any of claims 1-6, wherein the vial access device further comprises a first connection element attachable to the first vial to secure the vial access device to the first vial.

8. The system of any of claims 1-7, wherein the second vial size is less than the first vial size.

9. The system of any of claims 1-8, further comprising a first vial defining a first vial size, and a second vial defining a second vial size, the second vial size different than the first vial size, wherein the vial access device further comprises a first connection element attachable to the first vial to secure the vial access device to the first vial, and wherein the adapter is attachable to the second vial.

10. The system of any of claims 7-9, wherein the first connection element of the vial access device is configured to secure the adapter to the vial access device when the adapter is in the vial position.

11. The system of any of claims 1-10, wherein the adapter comprises an alignment guide configured to position the vial access device during installation of the vial access device onto the second vial when the adapter is in the vial position.

12. The system of any of claims 2-11, wherein the adapter comprises a horizontal shield wall, an outer portion extending from the periphery of the horizontal shield wall, and an inner portion extending from the horizontal shield wall.

13. The system of claim 12, wherein the horizontal shield wall of the adapter defines a spike cavity that is configured to receive the spike when the adapter is in the vial position.

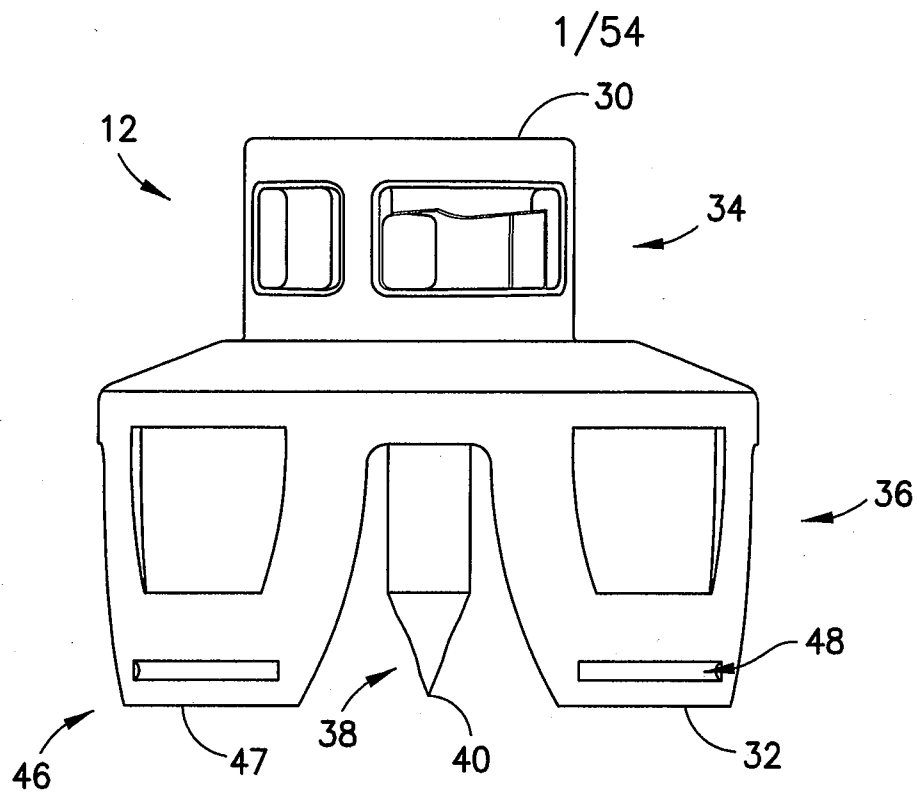
14. The system of any of claims 12-13, wherein the access device connection element comprises a plurality of external latches spaced around a periphery of the outer portion of the adapter, the vial access device defining a plurality of slots configured to receive the plurality of external latches when the adapter is in the shield position.

15. The system of any of claims 12-14, wherein the access device connection element comprises a plurality of locking apertures spaced around a periphery of the outer portion of the adapter, the vial access device comprising a locking protrusion configured to be received by the plurality of locking apertures when the adapter is in the shield position.

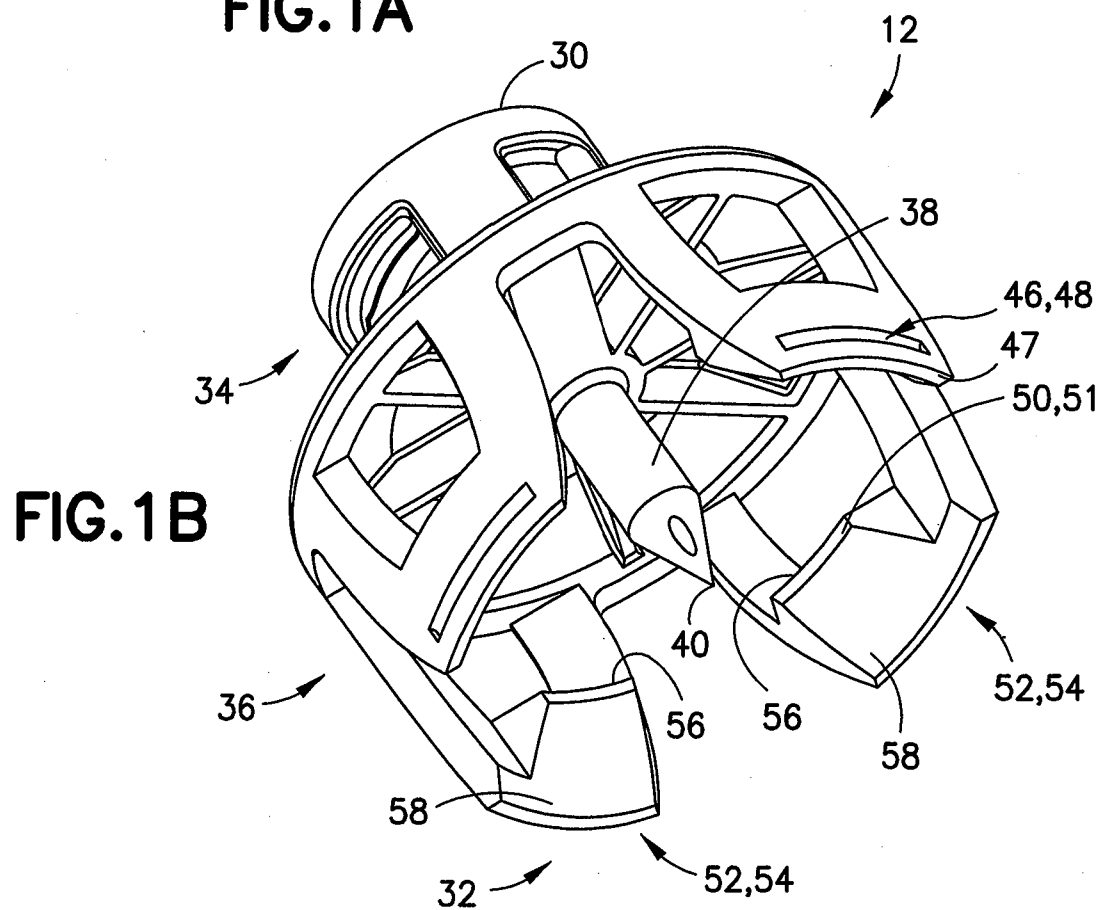
16. Use of the system of claim 1 to access a vial having one of the first vial size or the second vial size.

17. A method of accessing a vial comprising:  
providing a vial access device and an adapter, the vial access device comprising a spike and a first connection element attachable to a first vial defining a first vial size to secure the vial access device to the first vial;  
removing the adapter from a shield position in which the adapter is attached to the vial access device with the adapter shielding the spike of the vial access device; and  
attaching the adapter to a second vial defining a second vial size, wherein the first vial size is different from the second vial size.

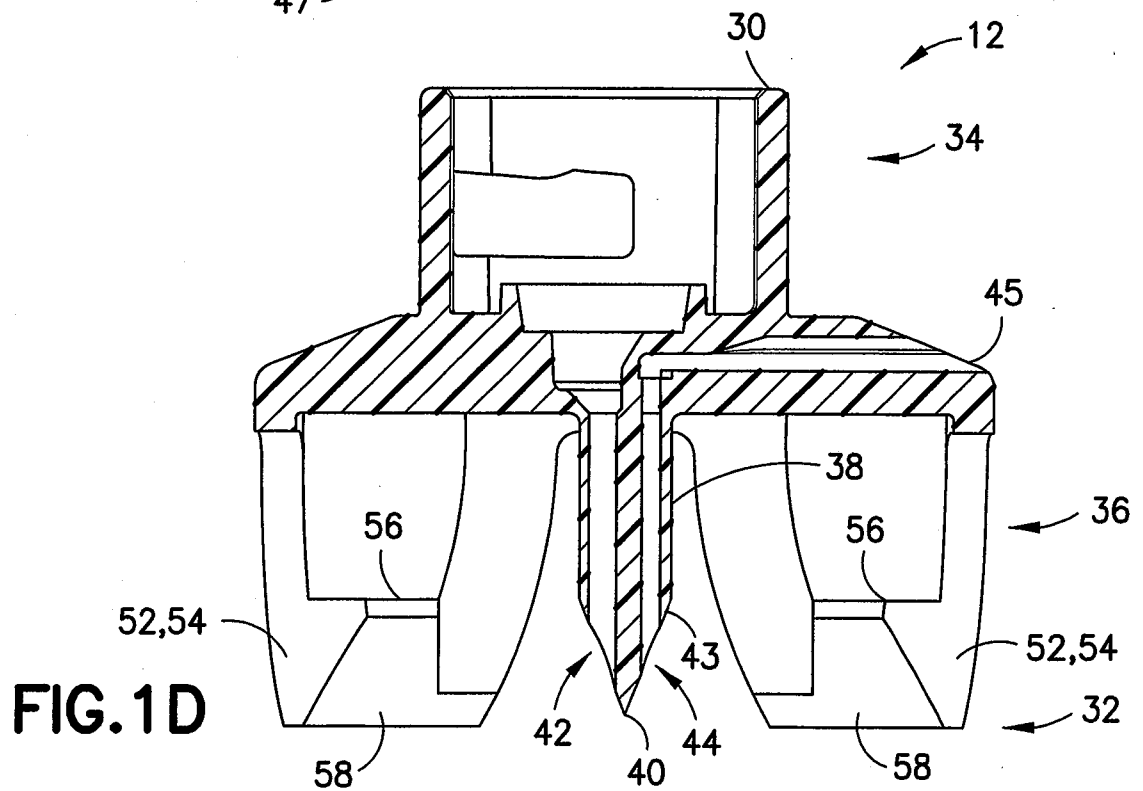
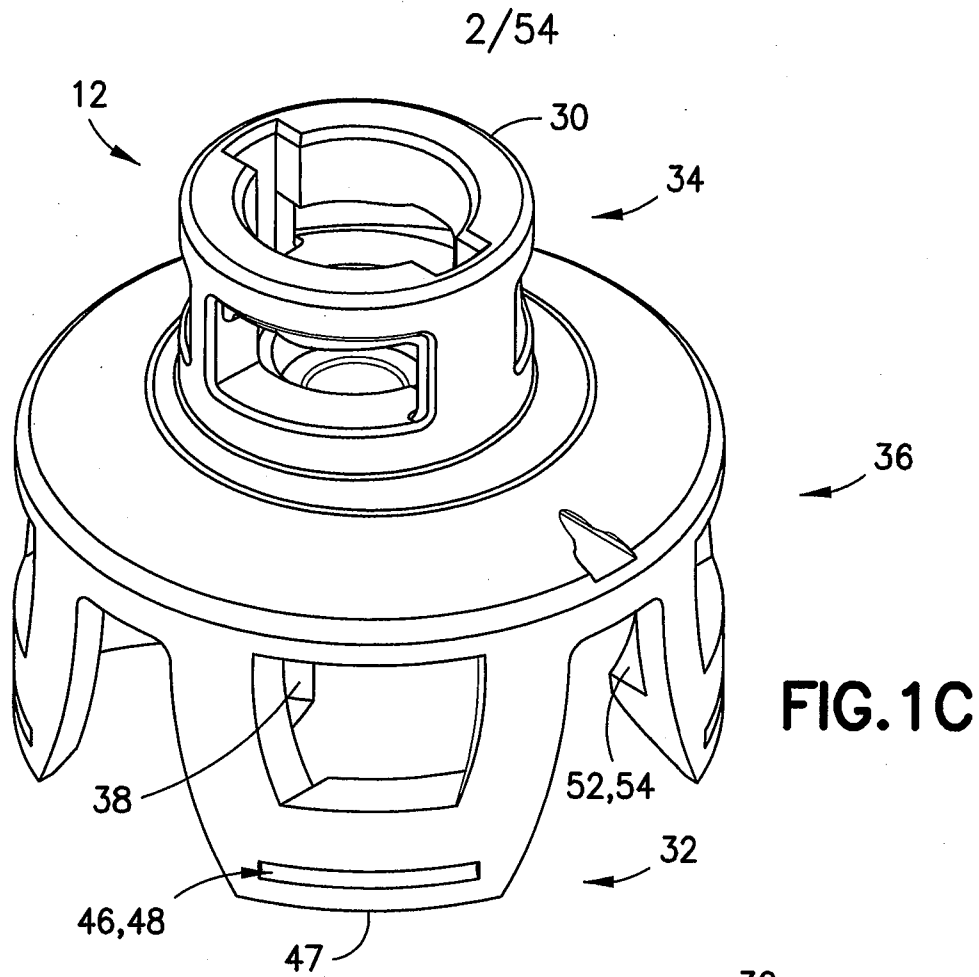


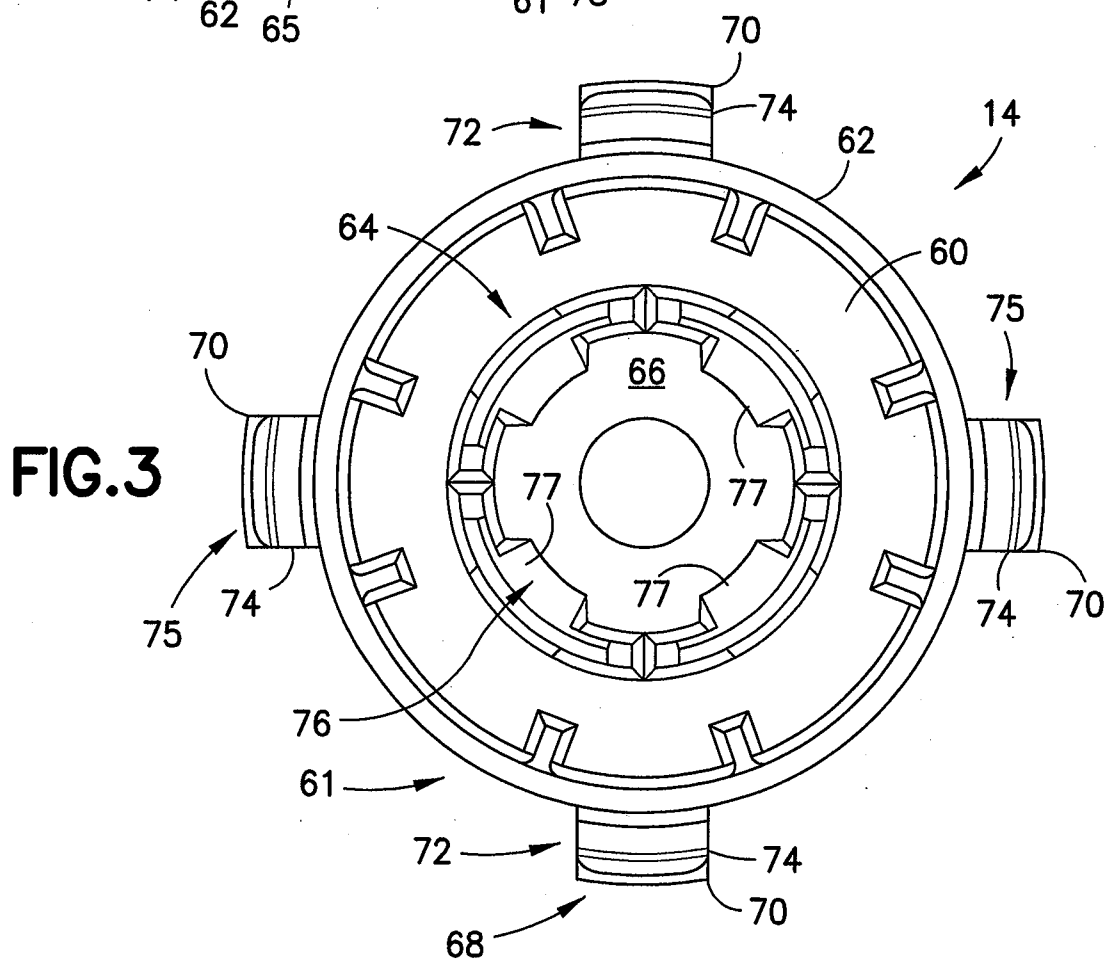
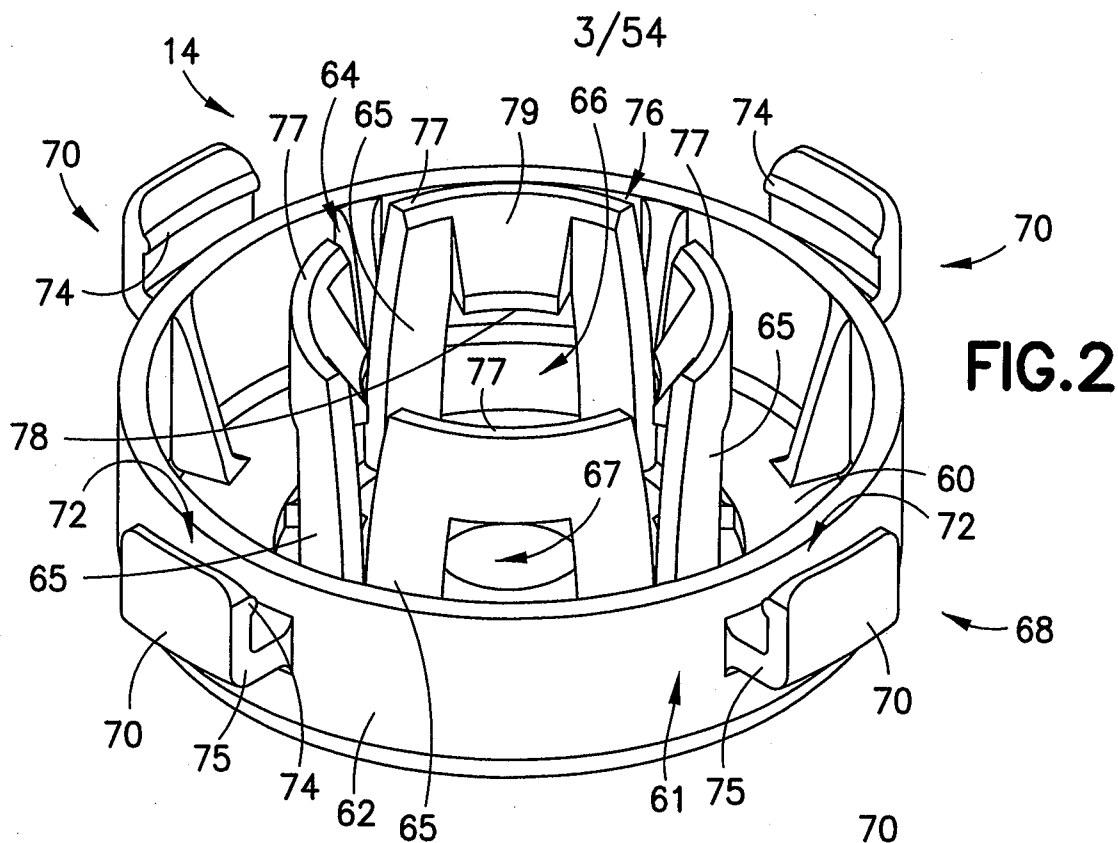


**FIG. 1A**

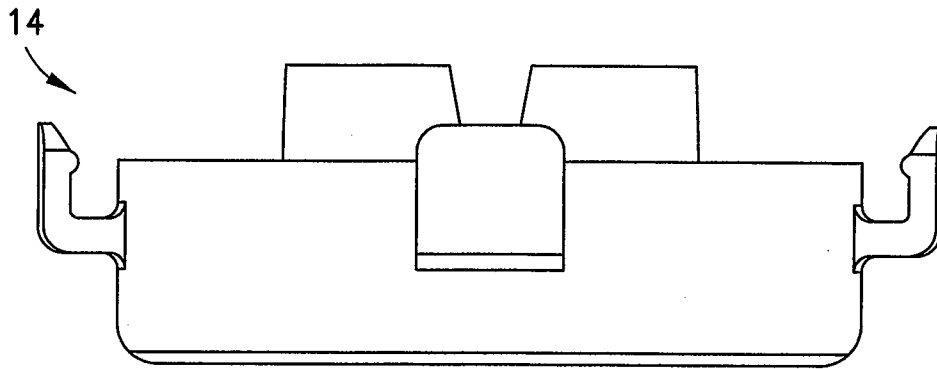


**FIG. 1B**

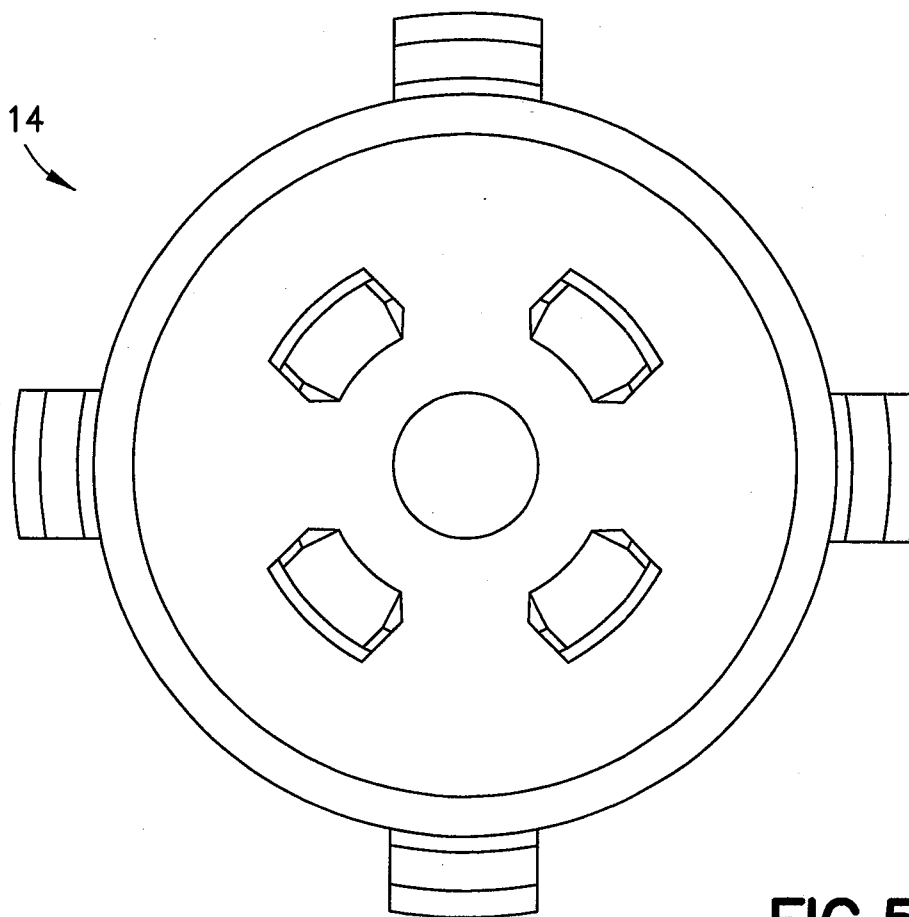




4/54



**FIG. 4**



**FIG. 5**

5/54

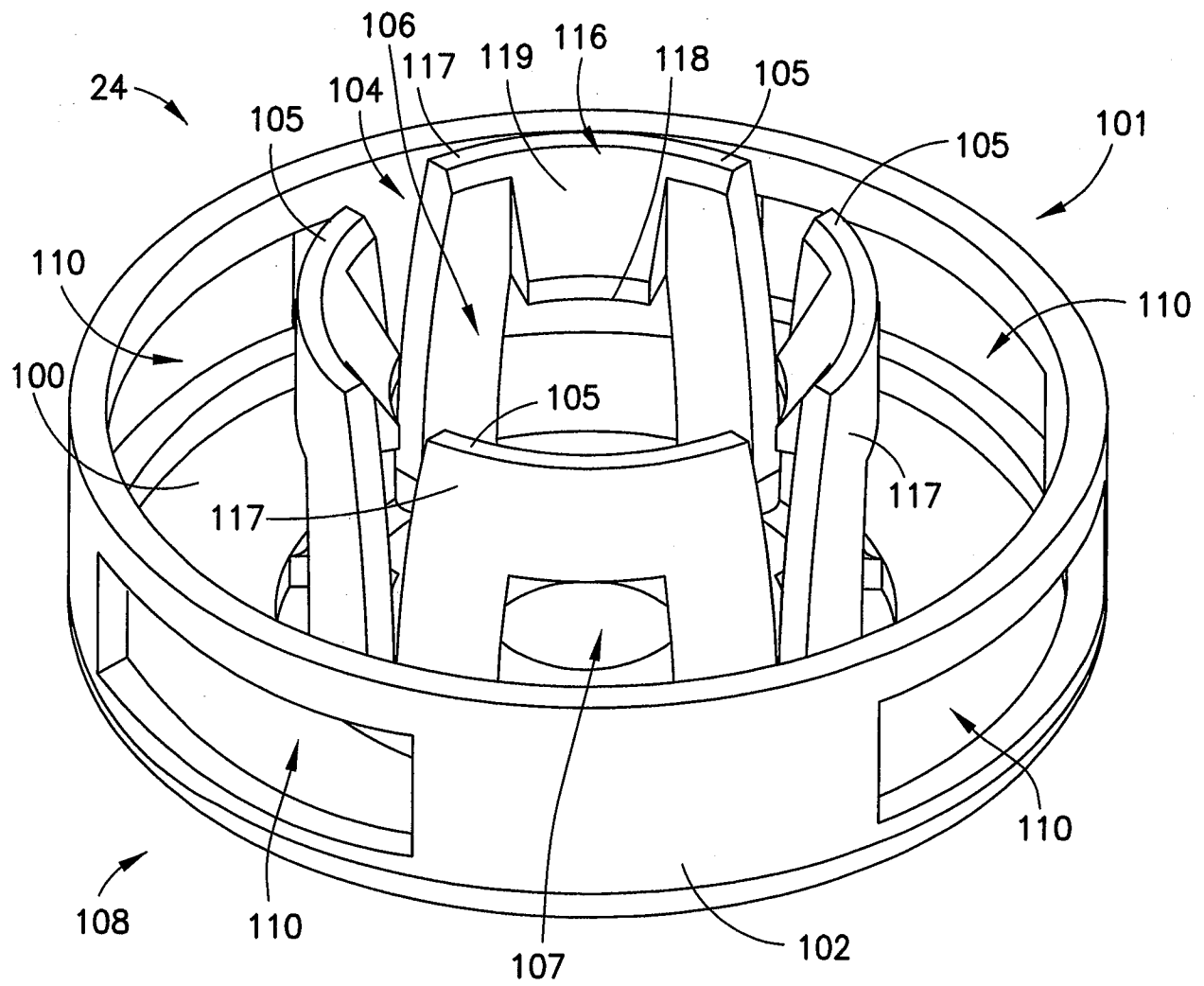
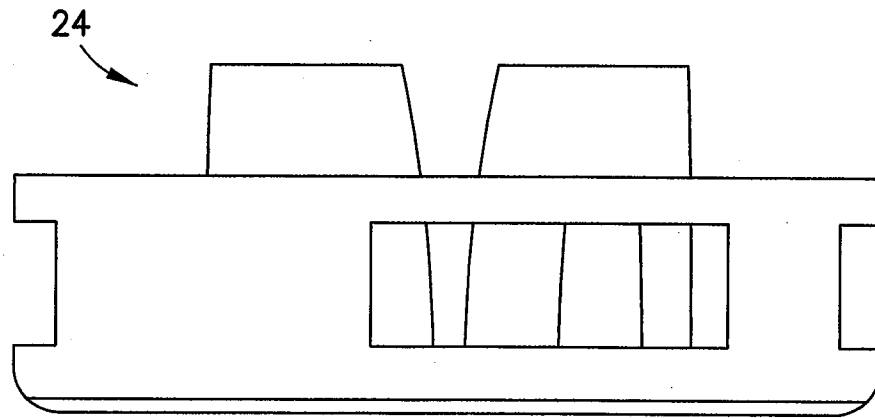
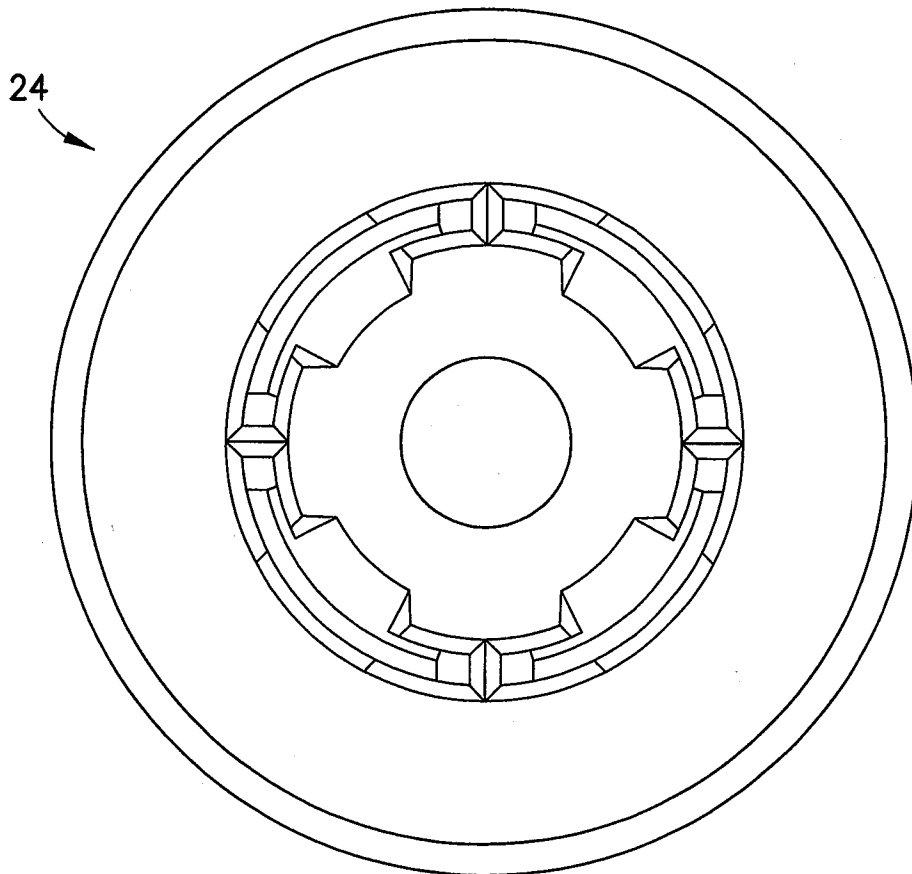


FIG. 6

6/54

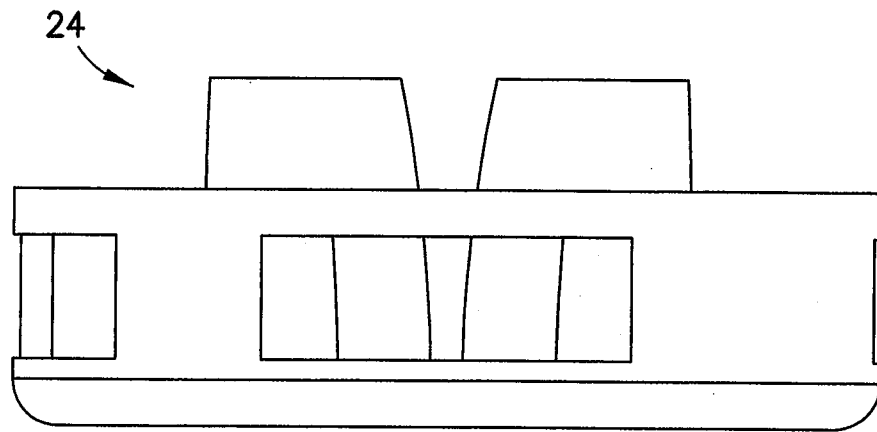


**FIG. 7**

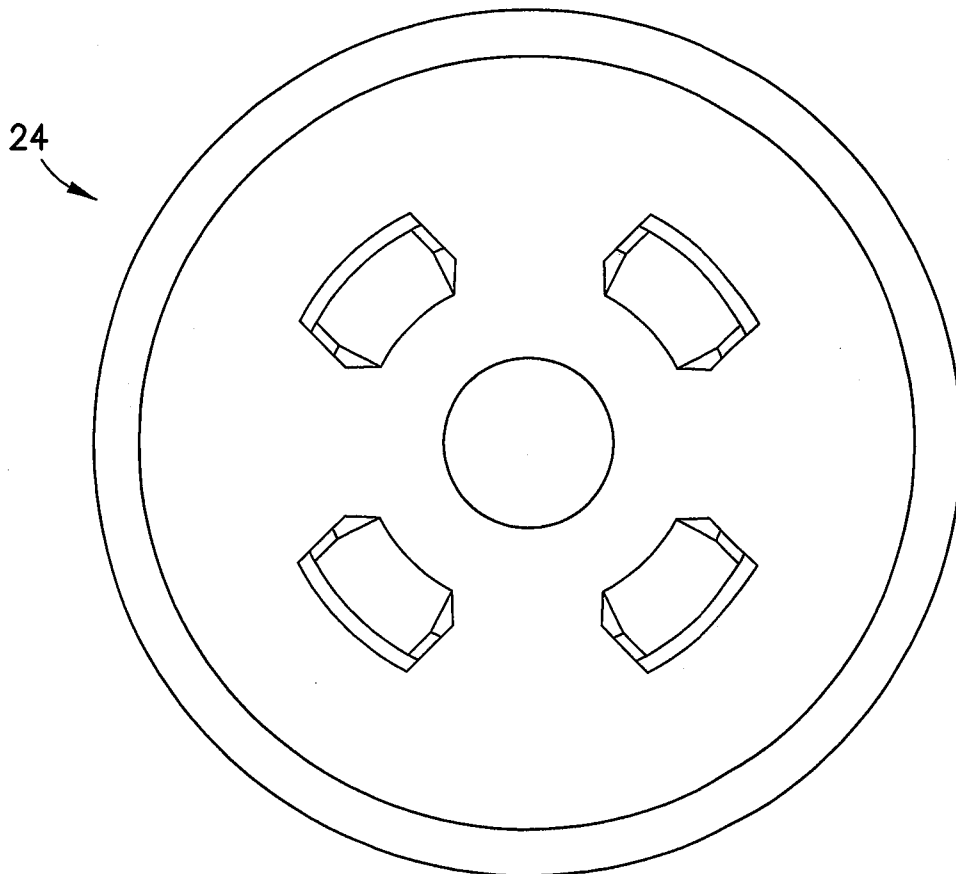


**FIG. 8**

7/54



**FIG. 9**



**FIG. 10**

8/54

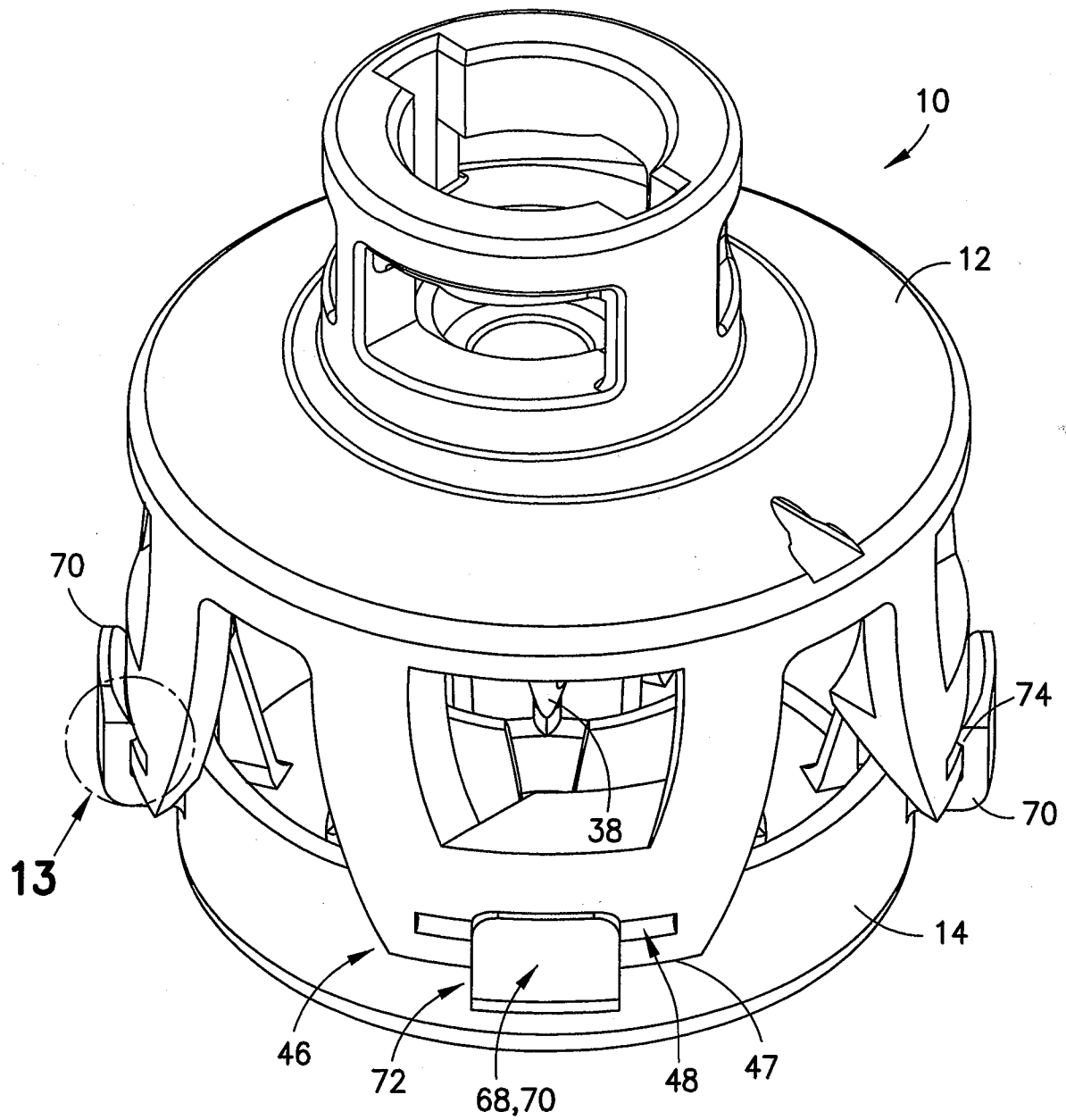
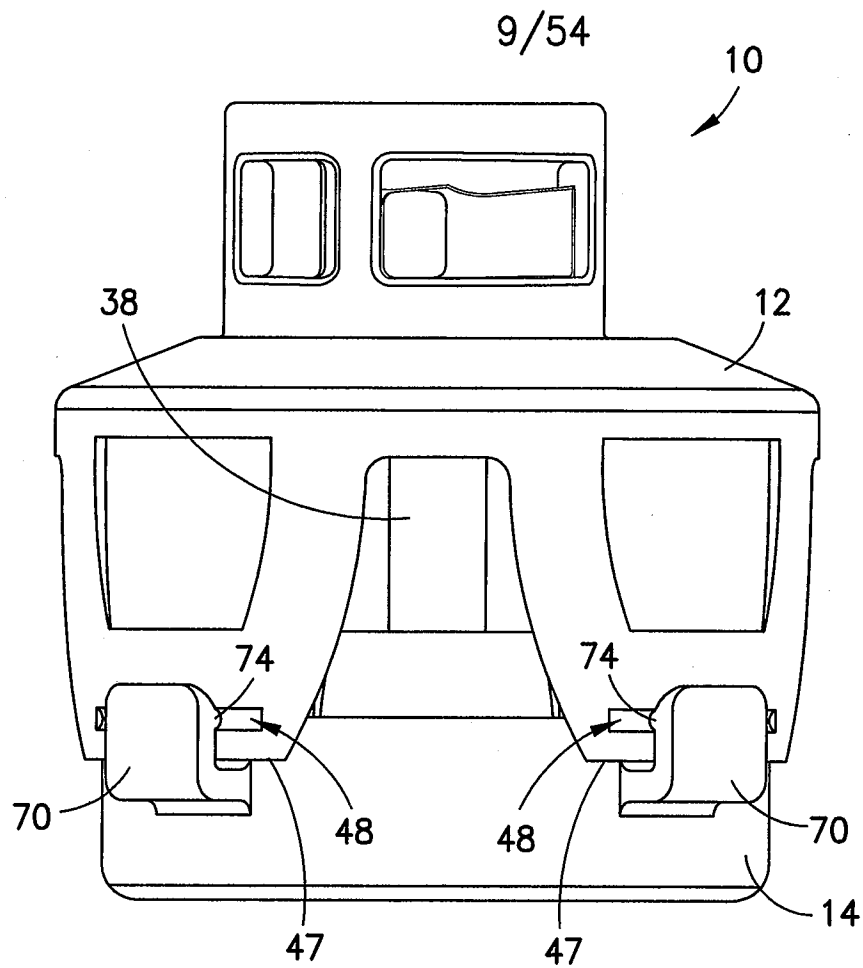
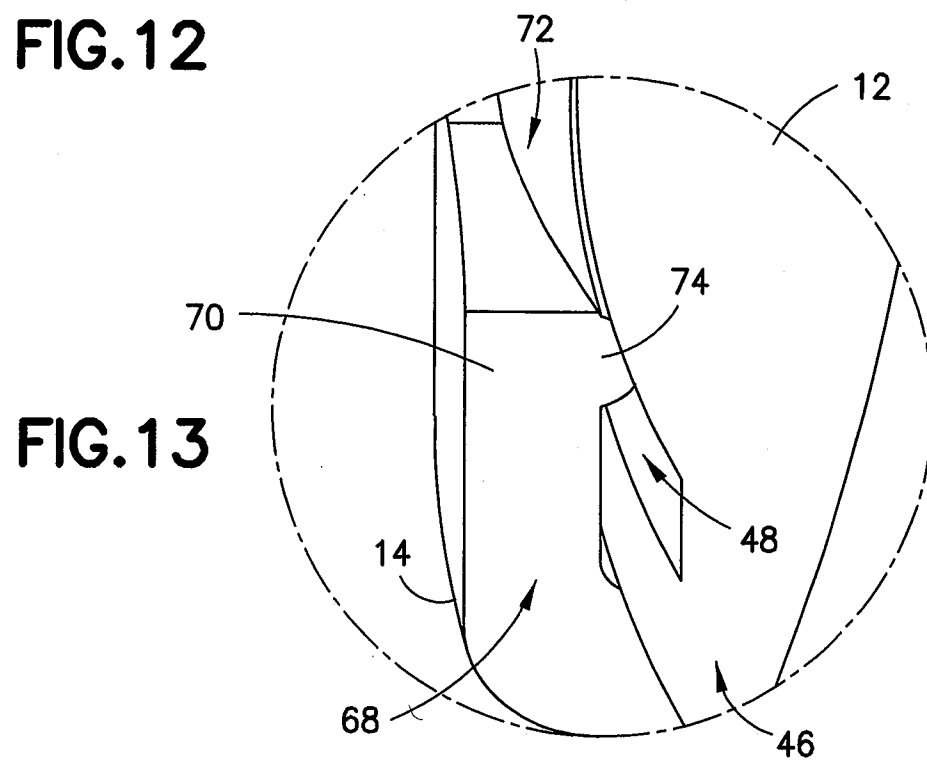


FIG. 11





**FIG. 12**



**FIG. 13**

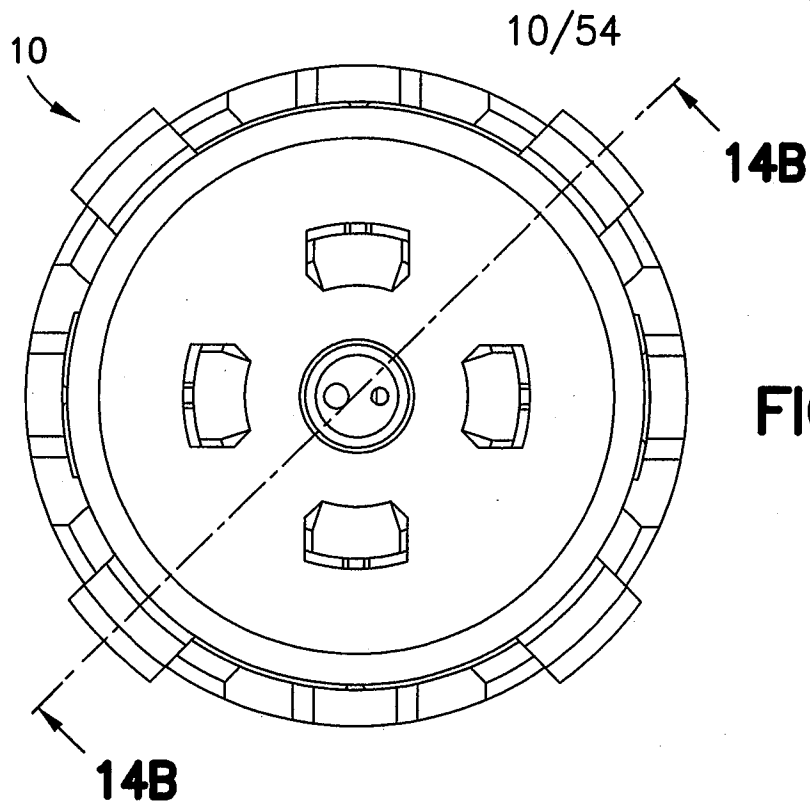
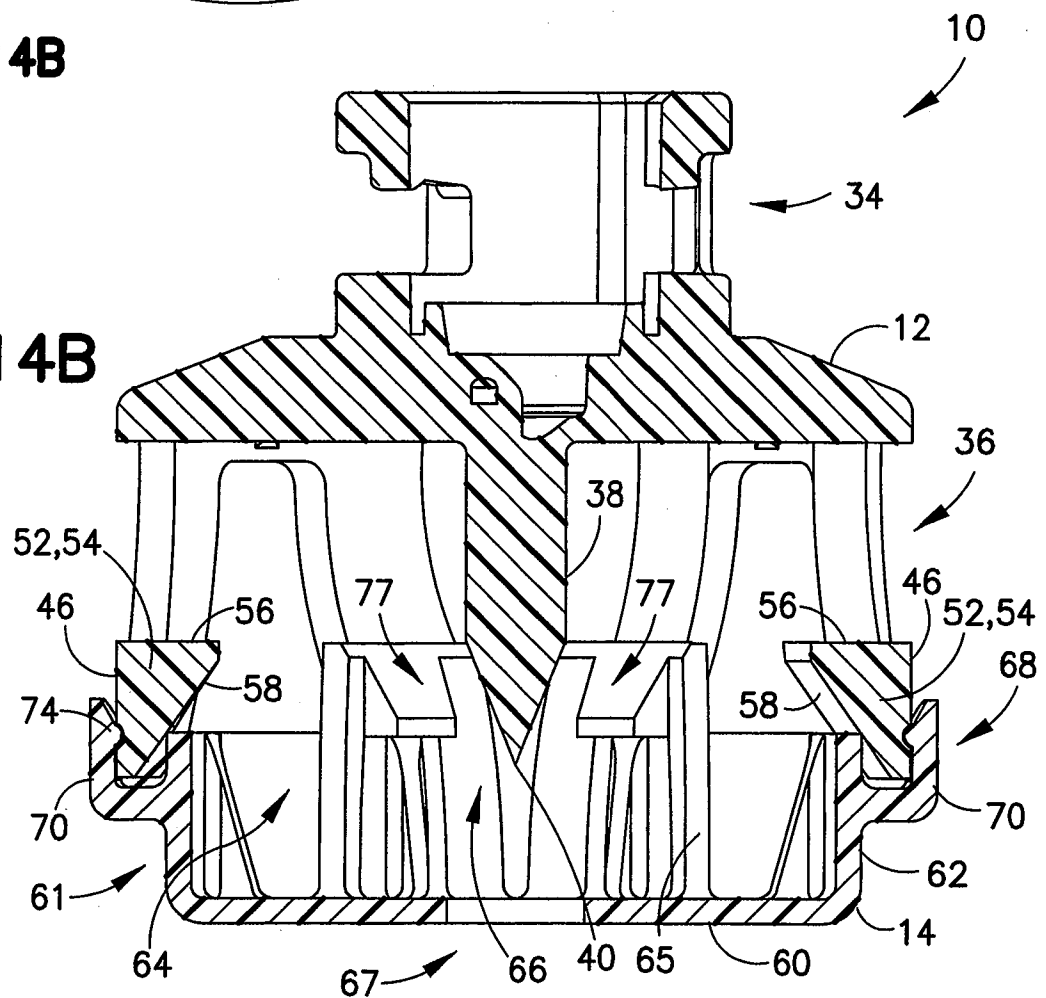
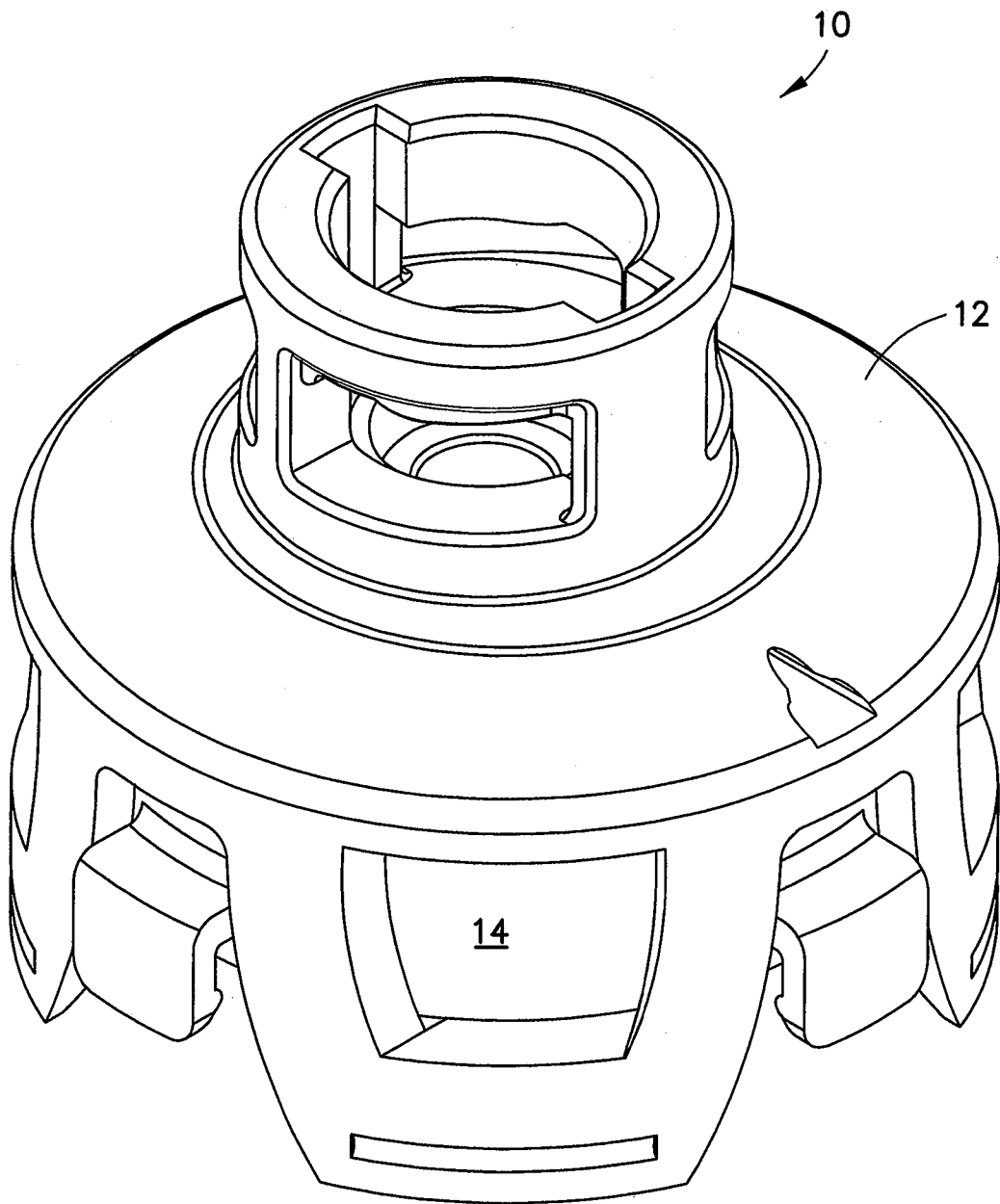


FIG. 14A

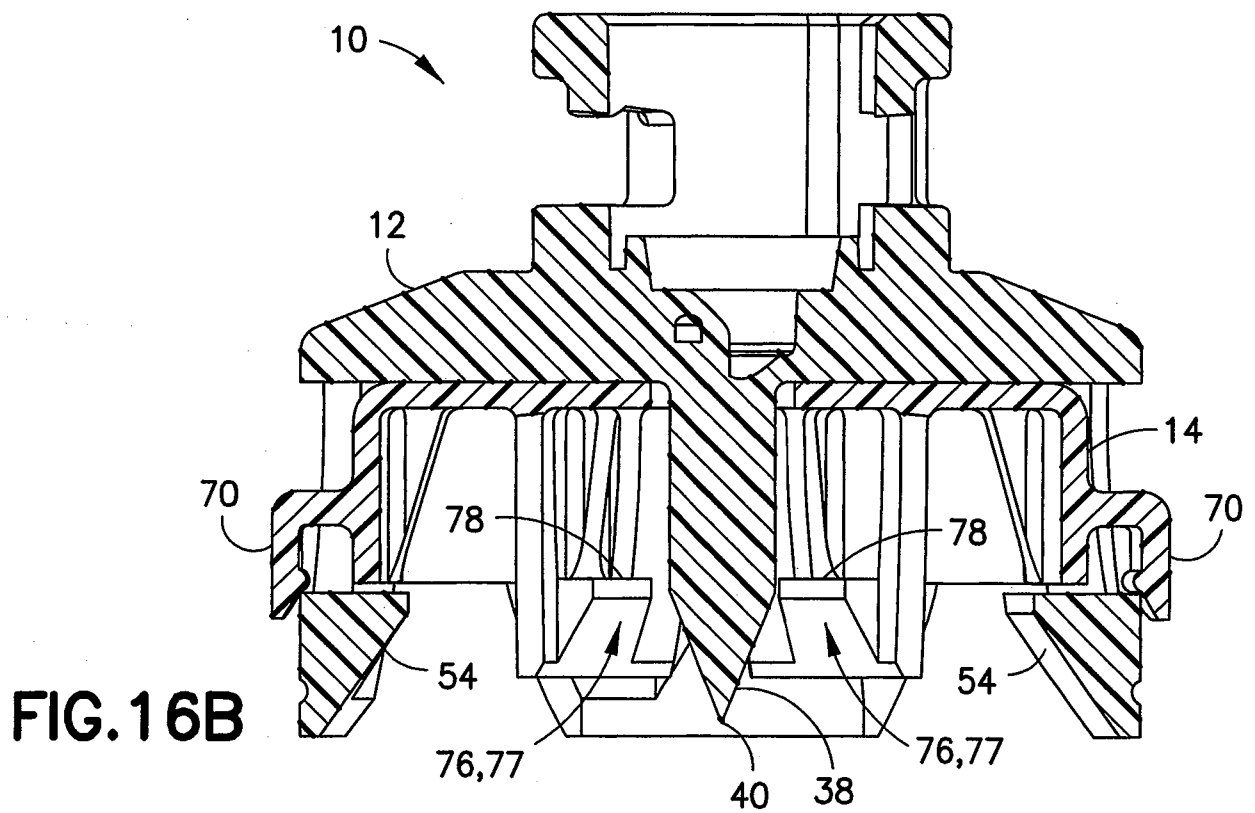
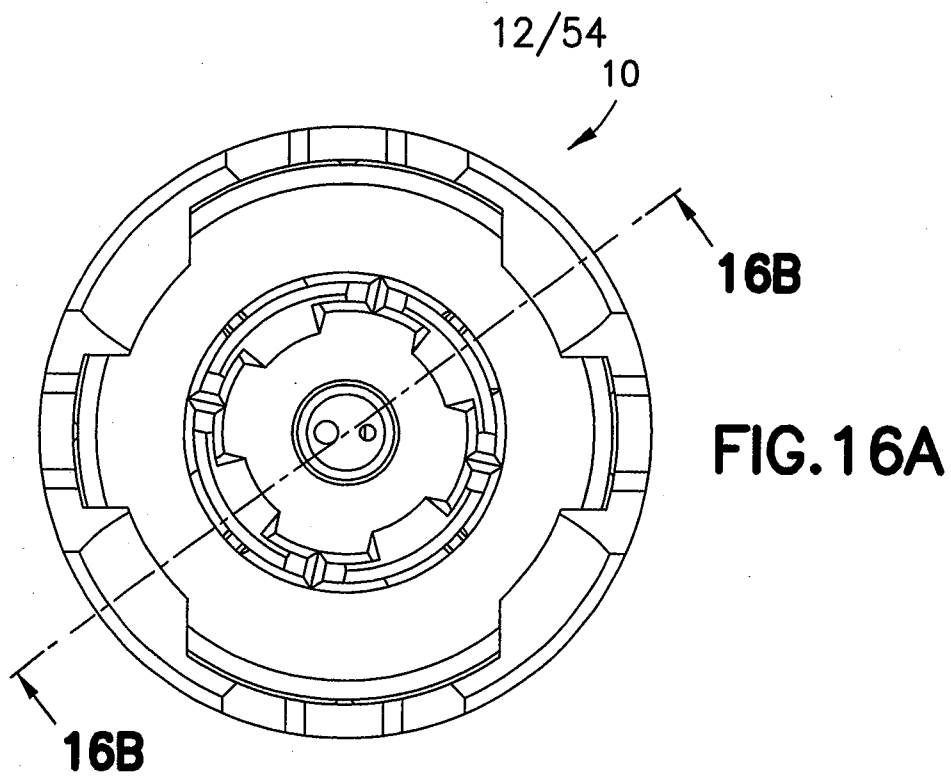
FIG. 14B



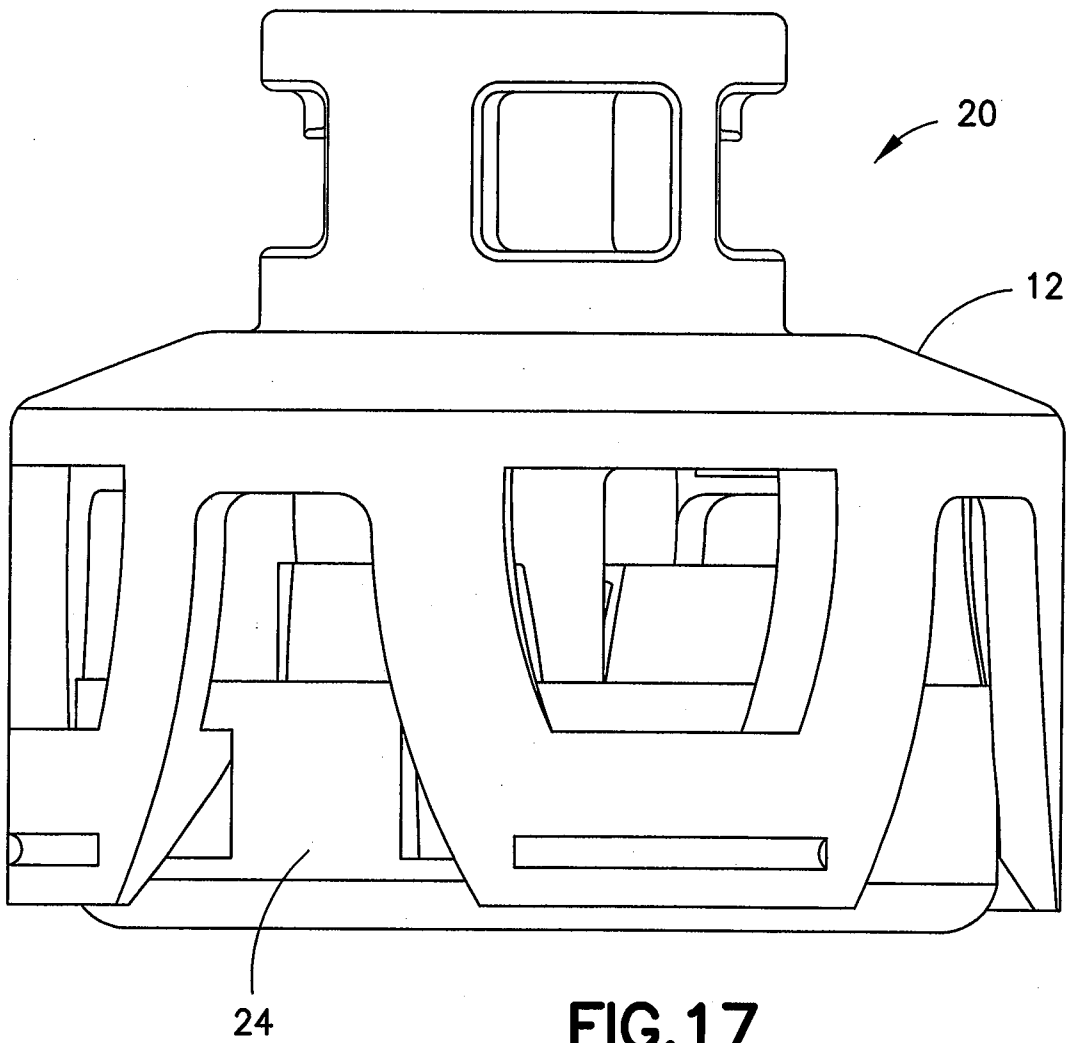
11/54

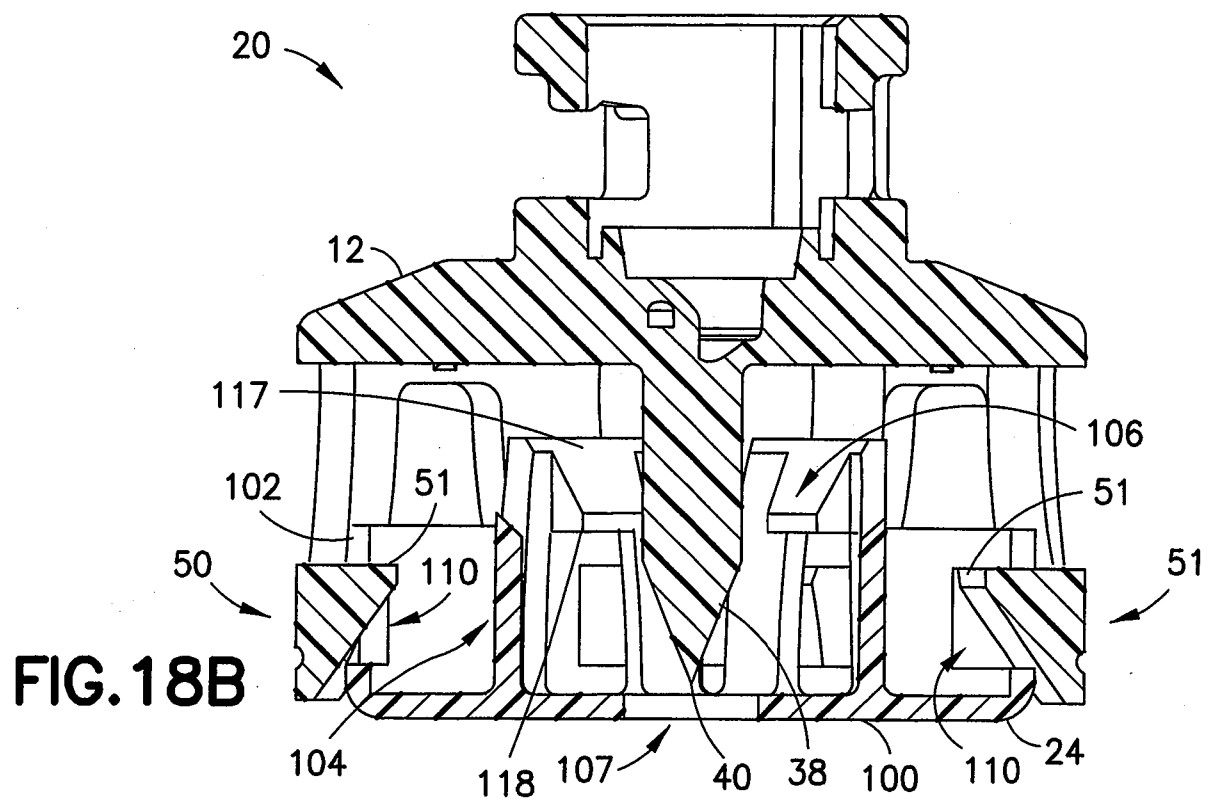
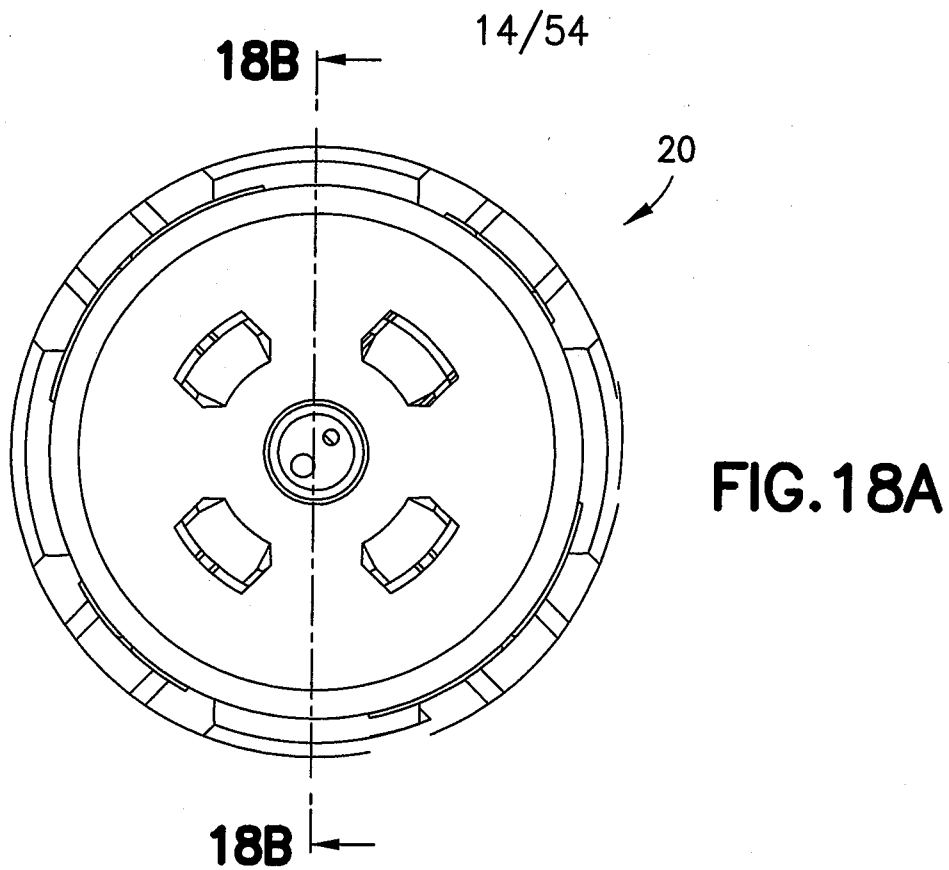


**FIG.15**



13/54





15/54

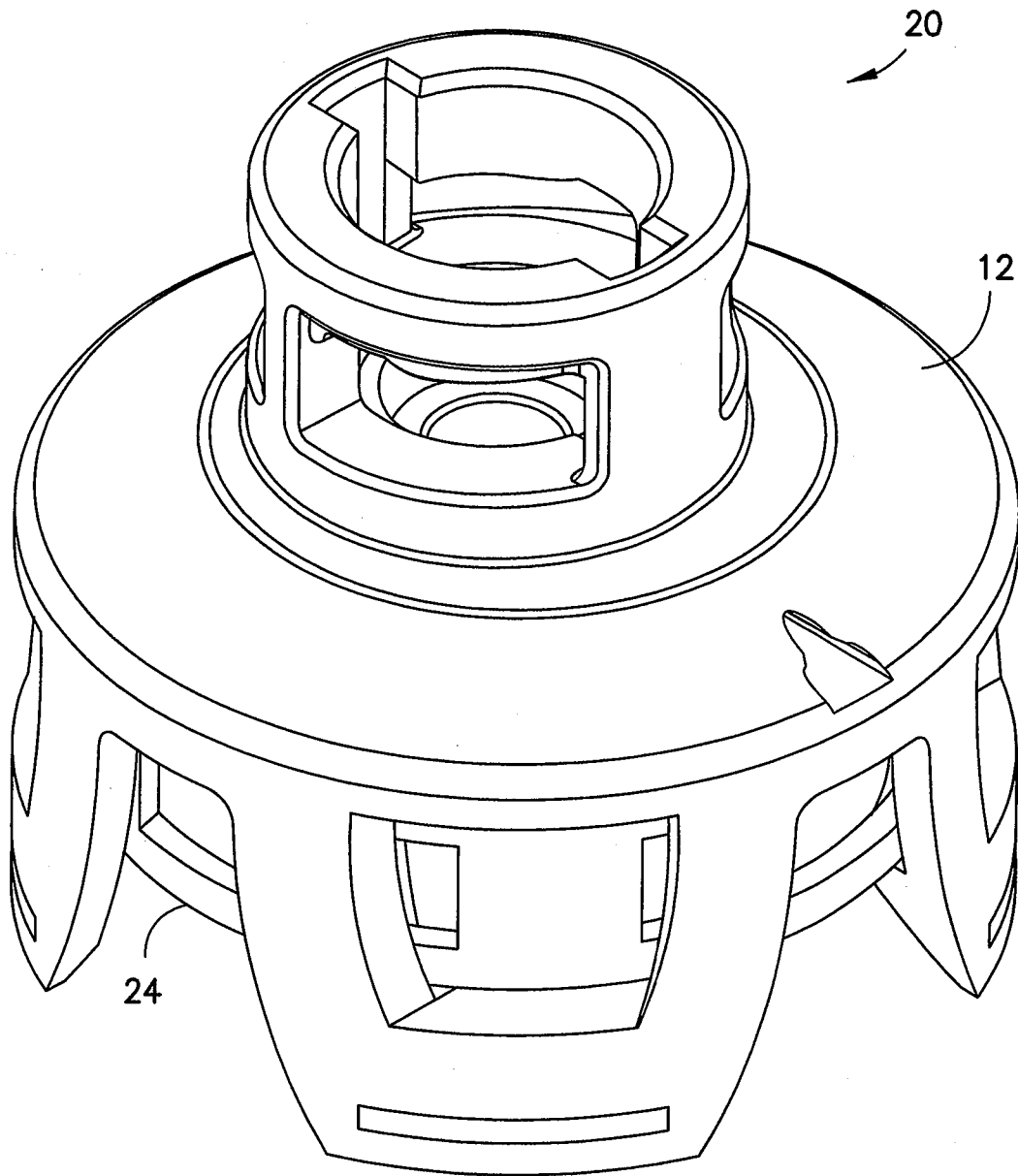


FIG. 19

16/54

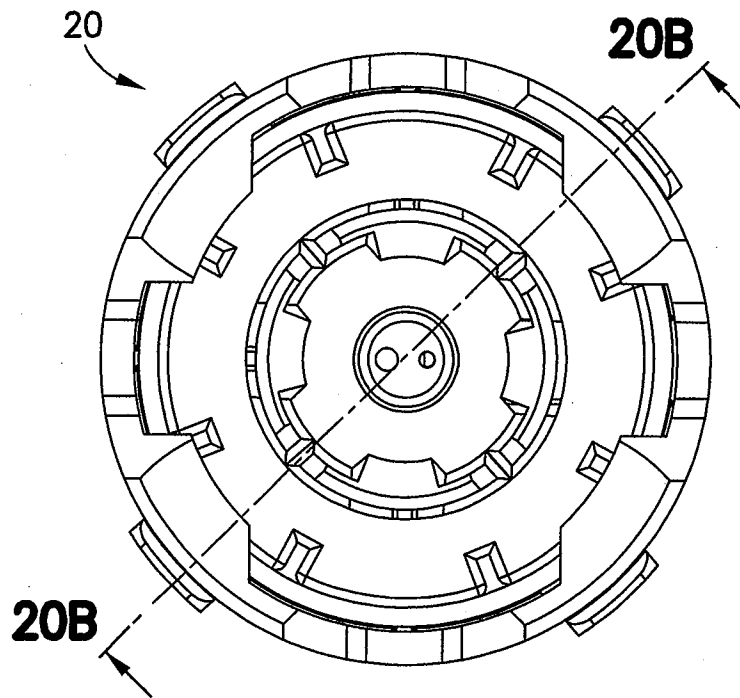


FIG. 20A

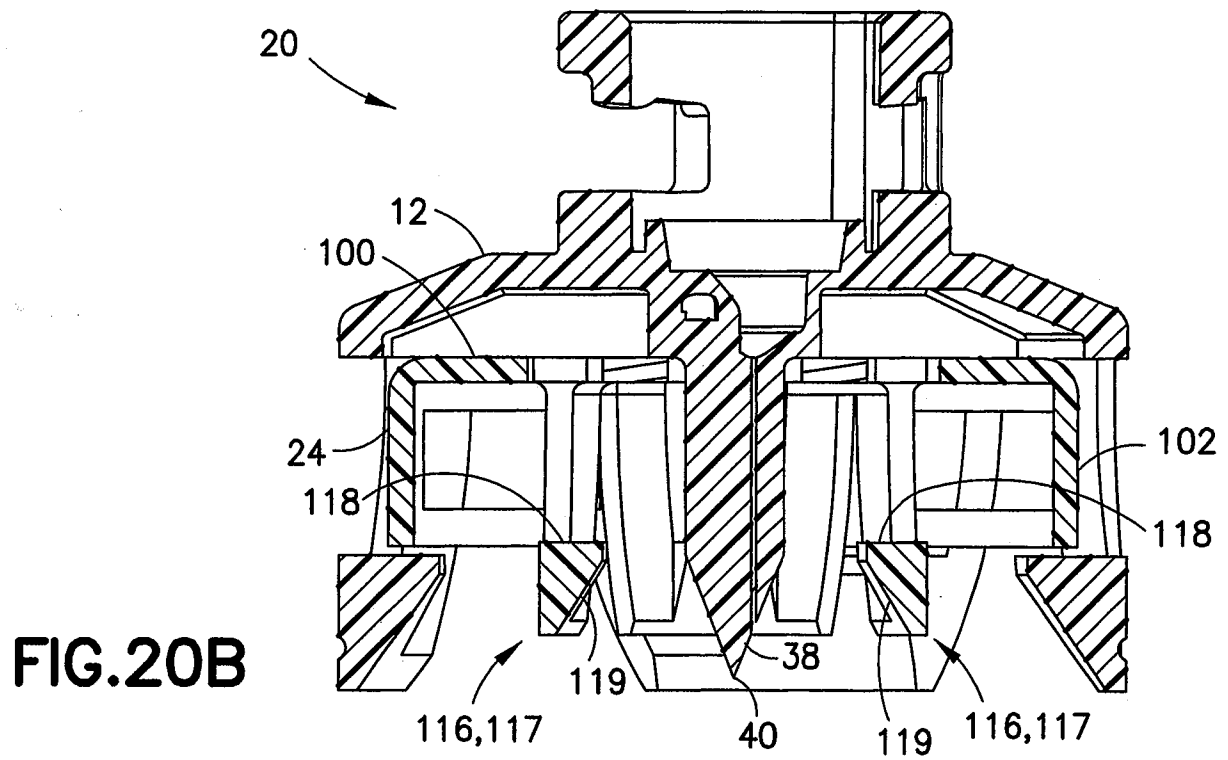


FIG. 20B



17/54

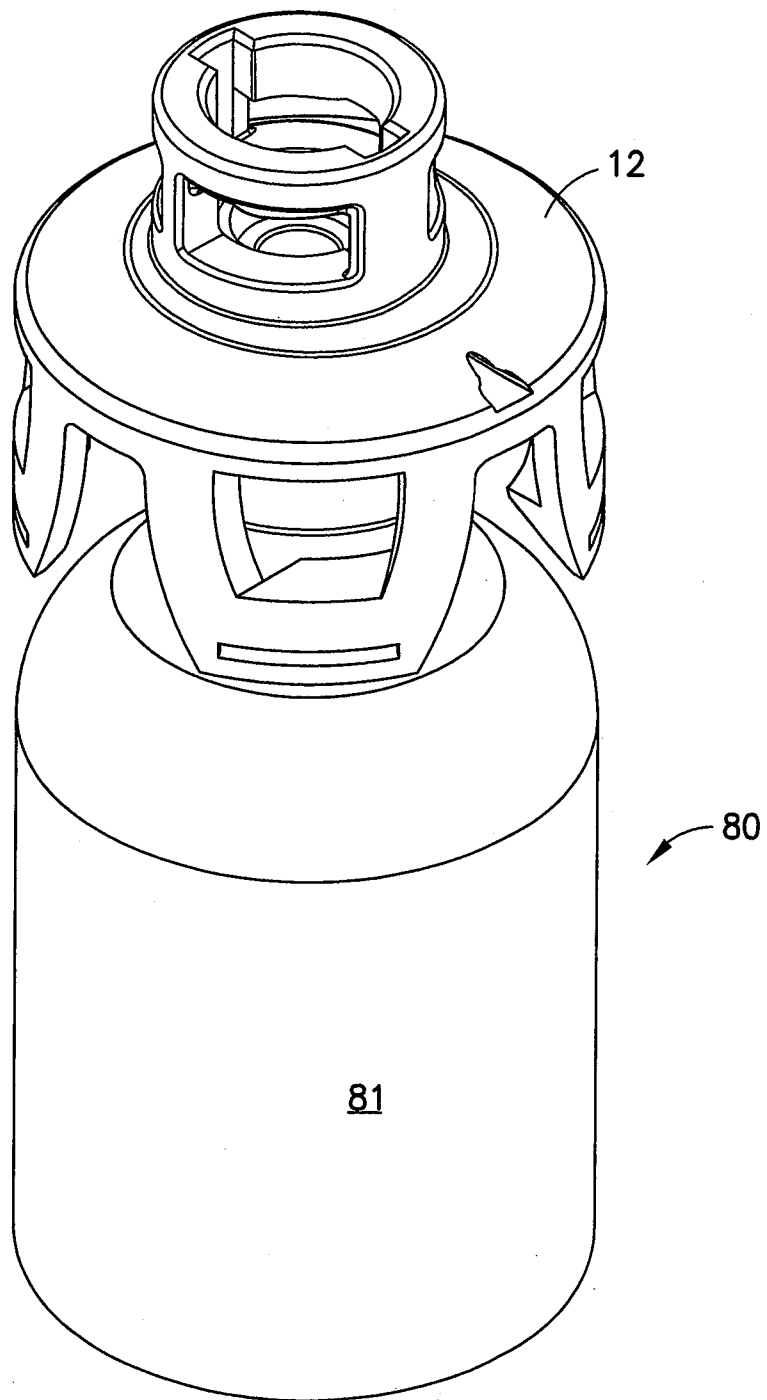
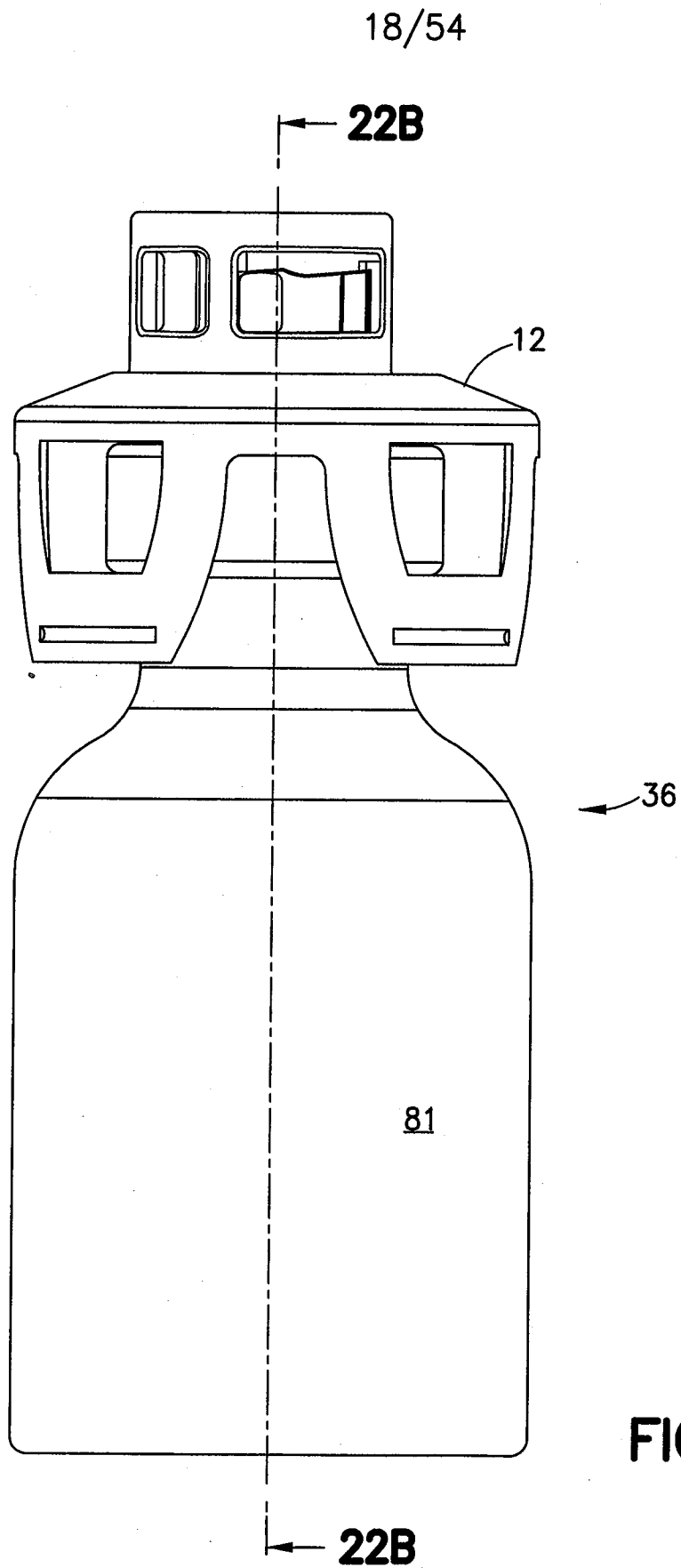


FIG.21



19/54

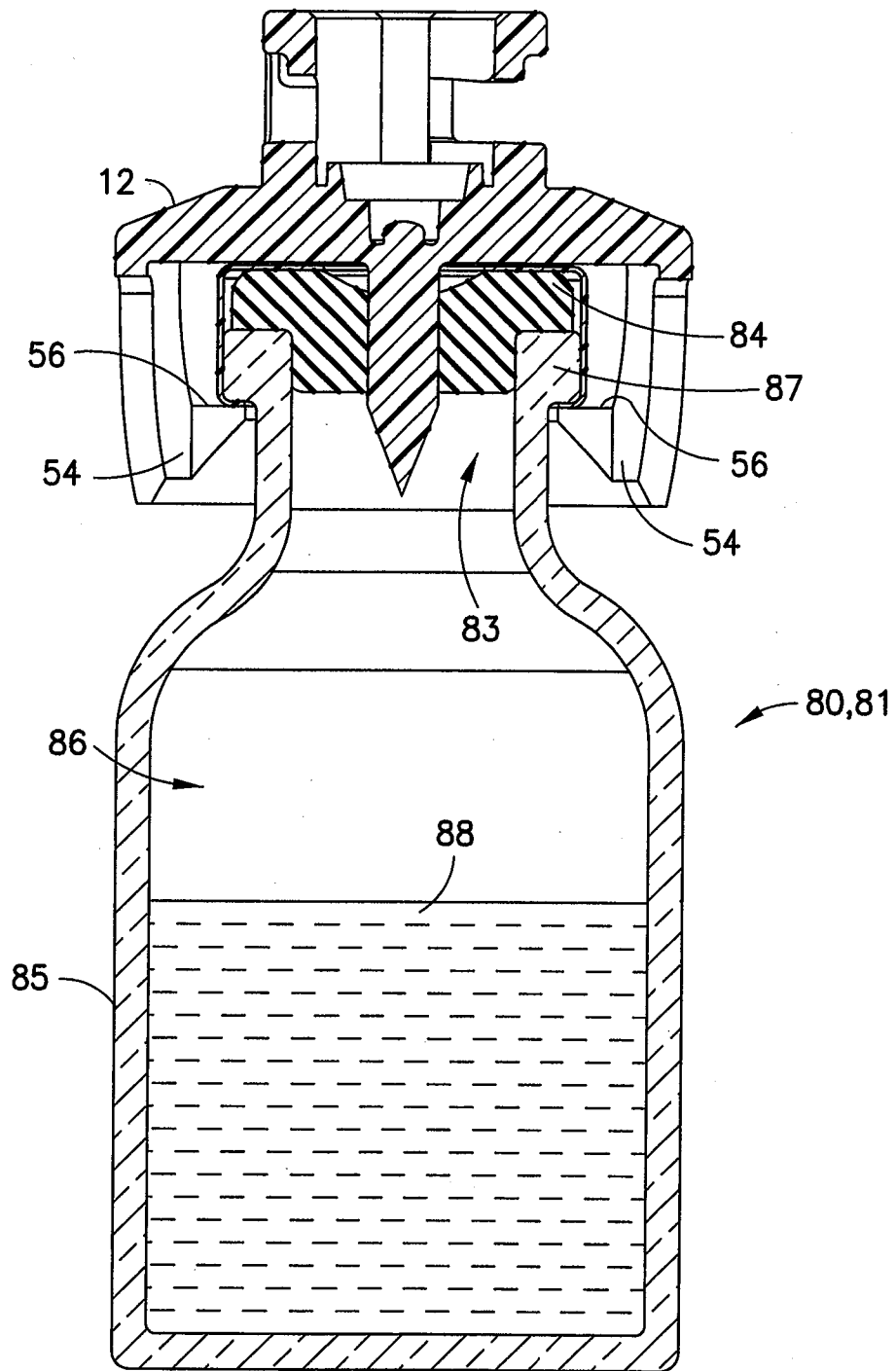


FIG.22B

20/54

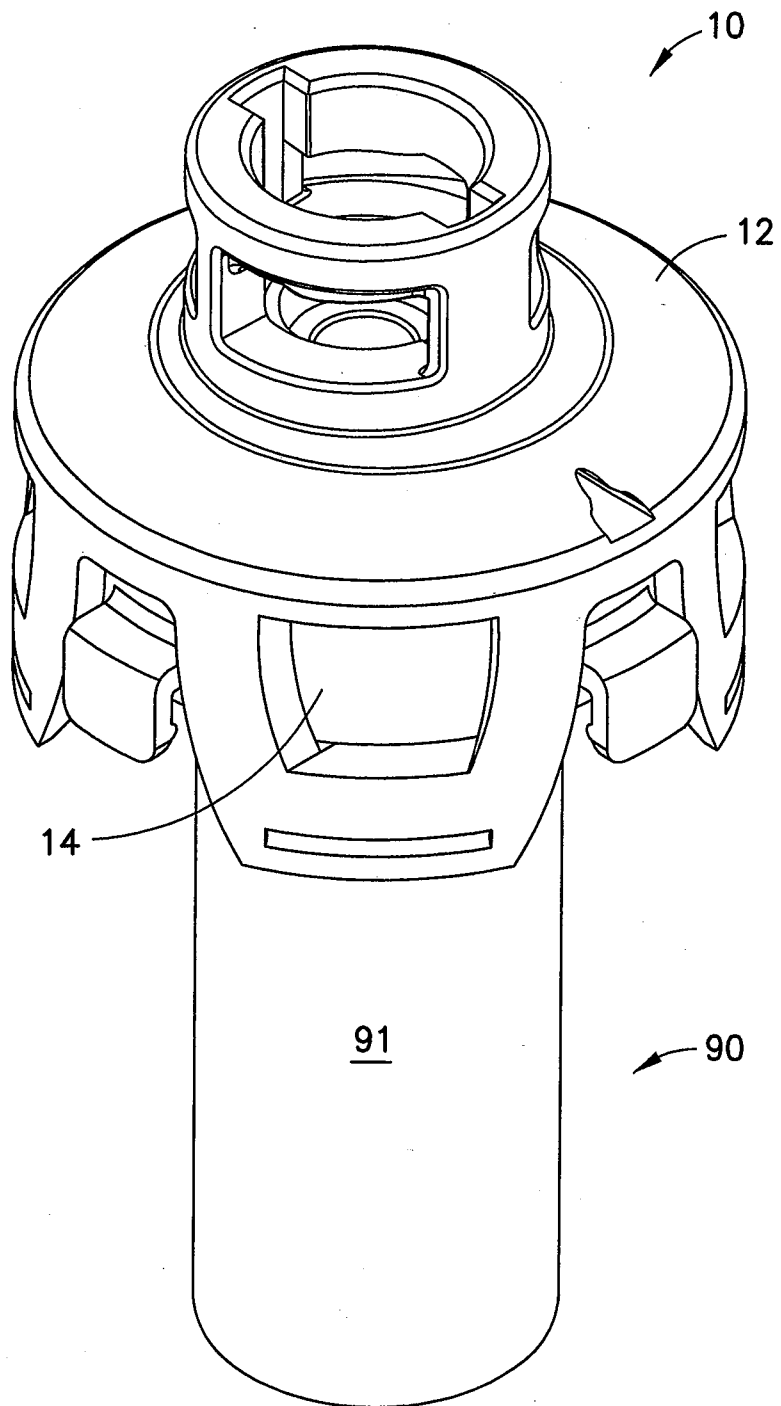
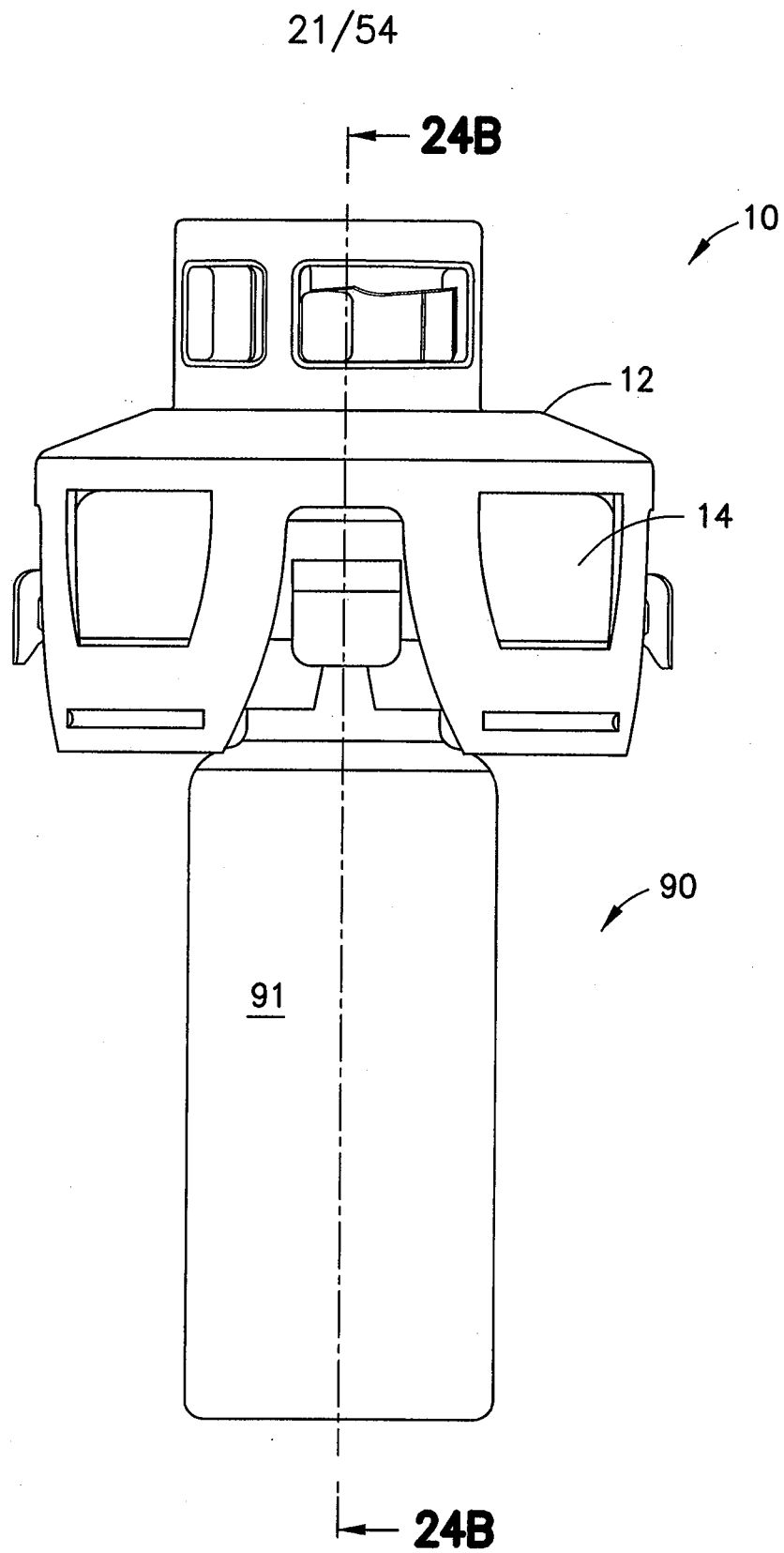


FIG.23



22/54

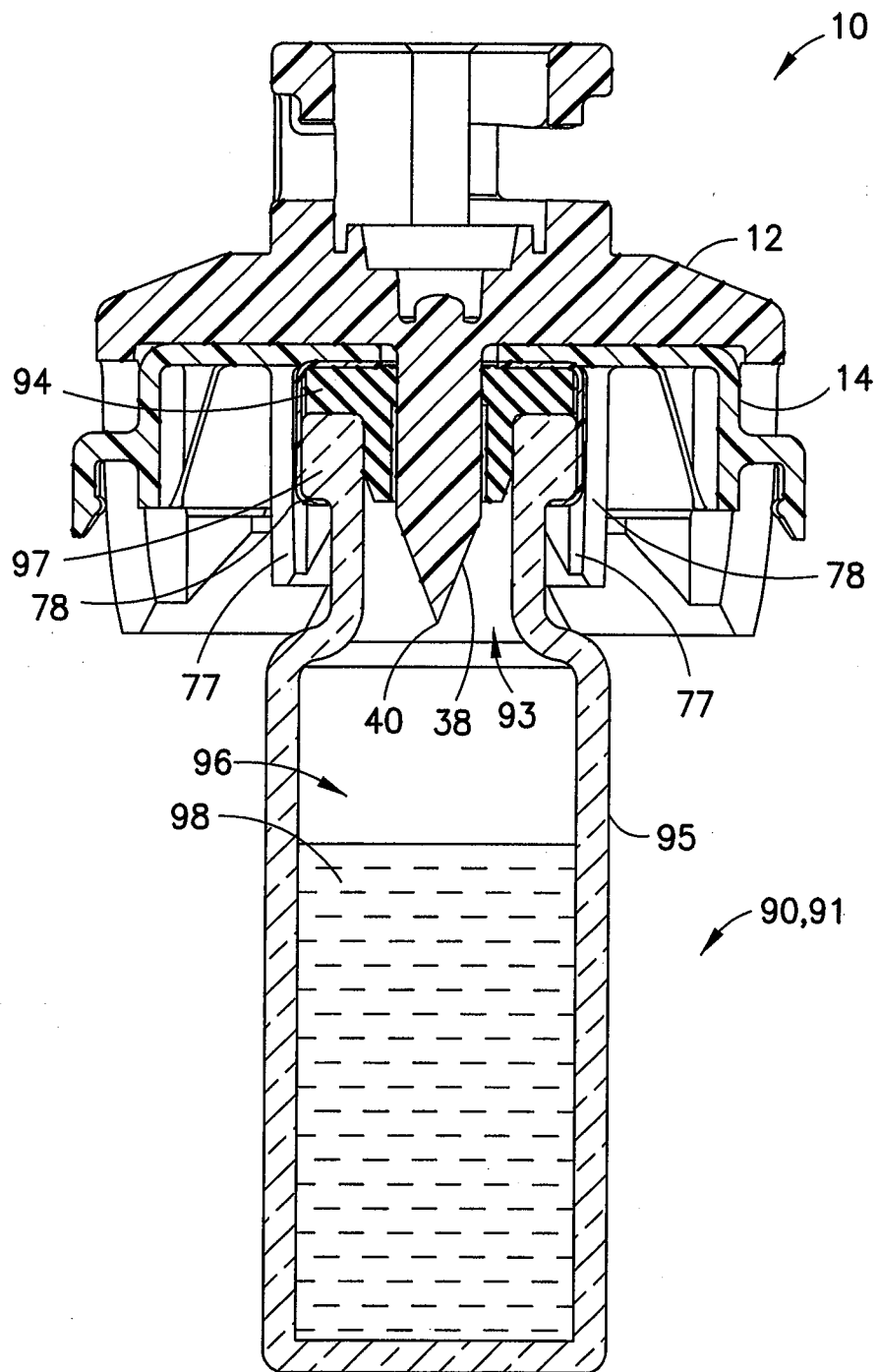


FIG.24B

23/54

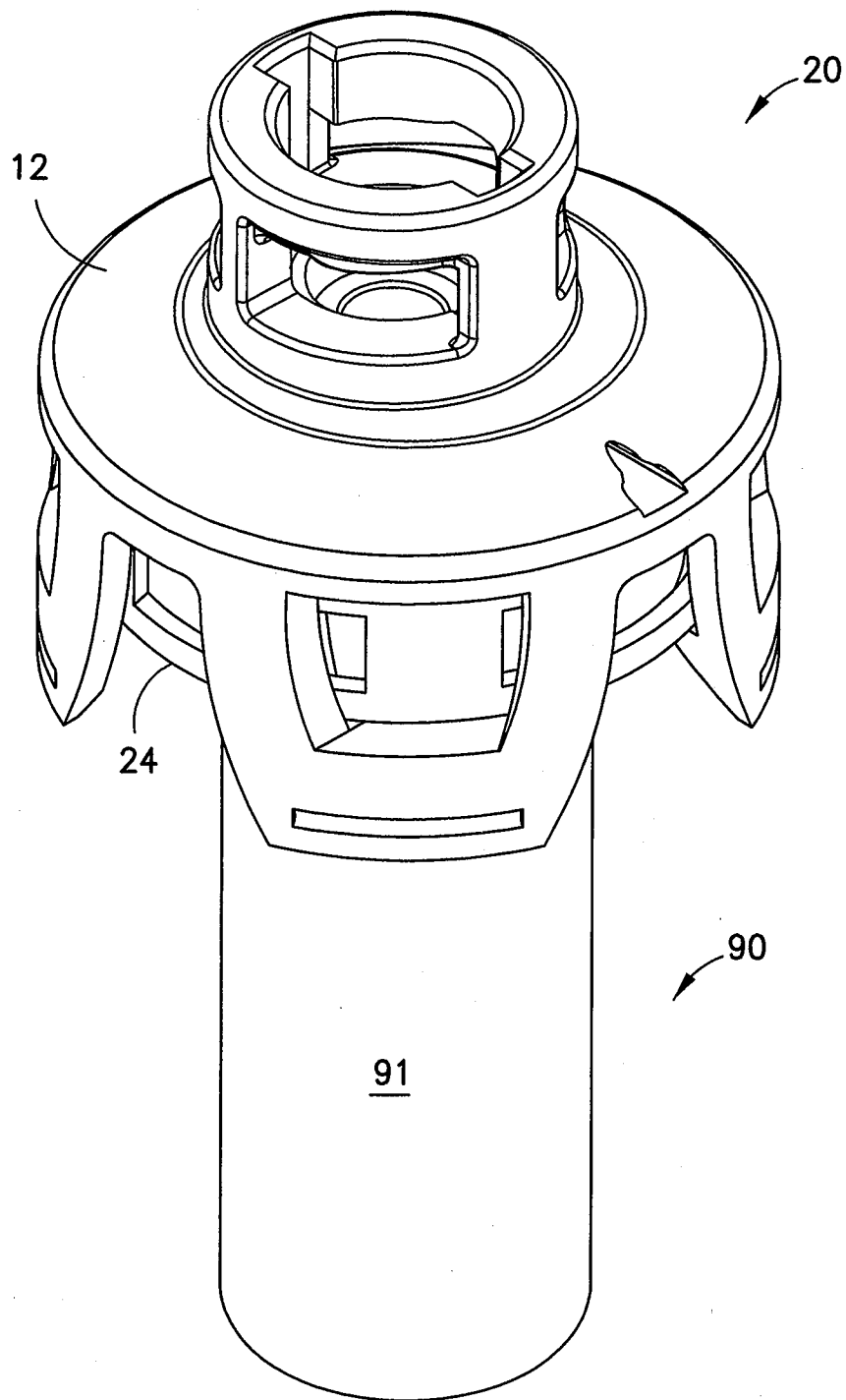


FIG. 25

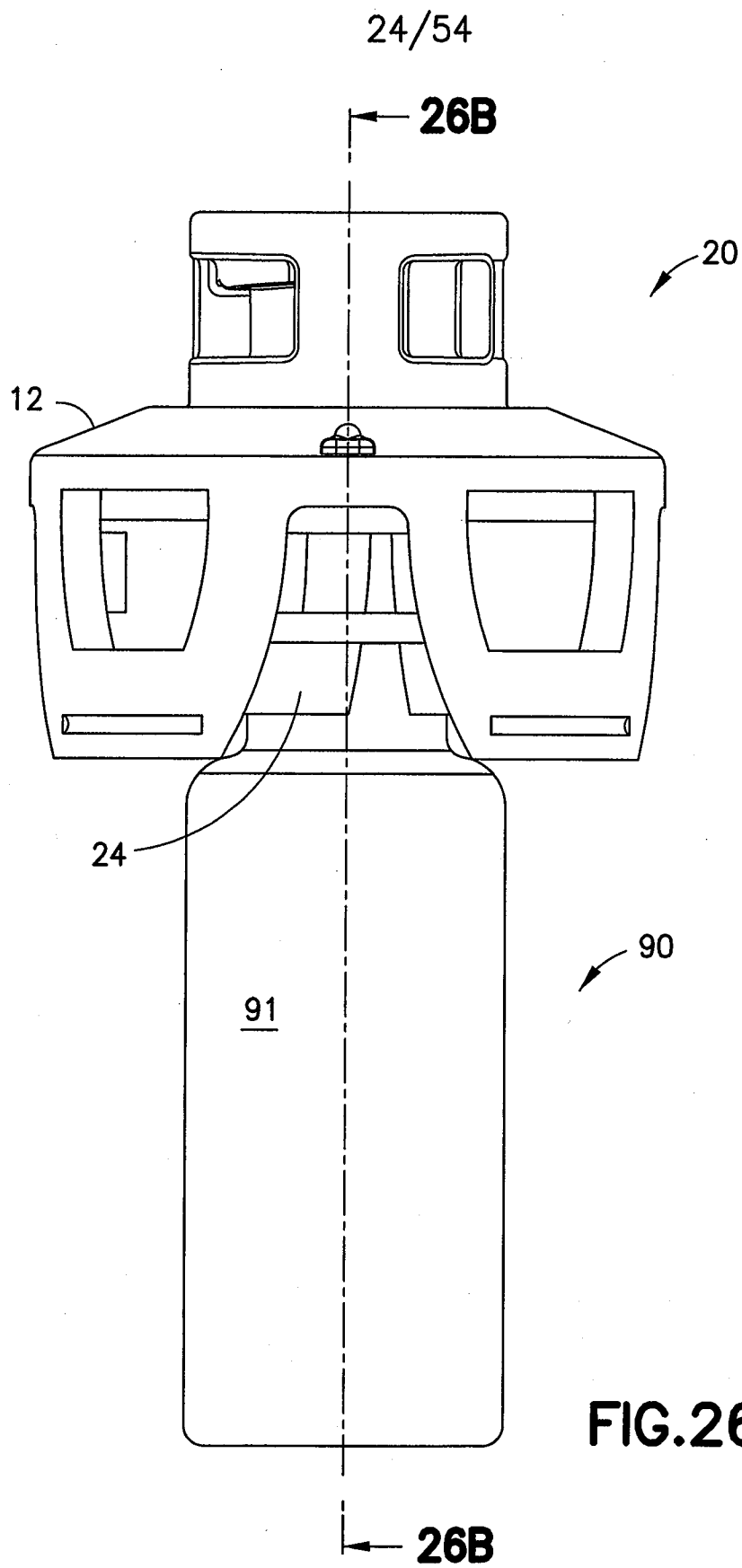


FIG. 26A



25/54

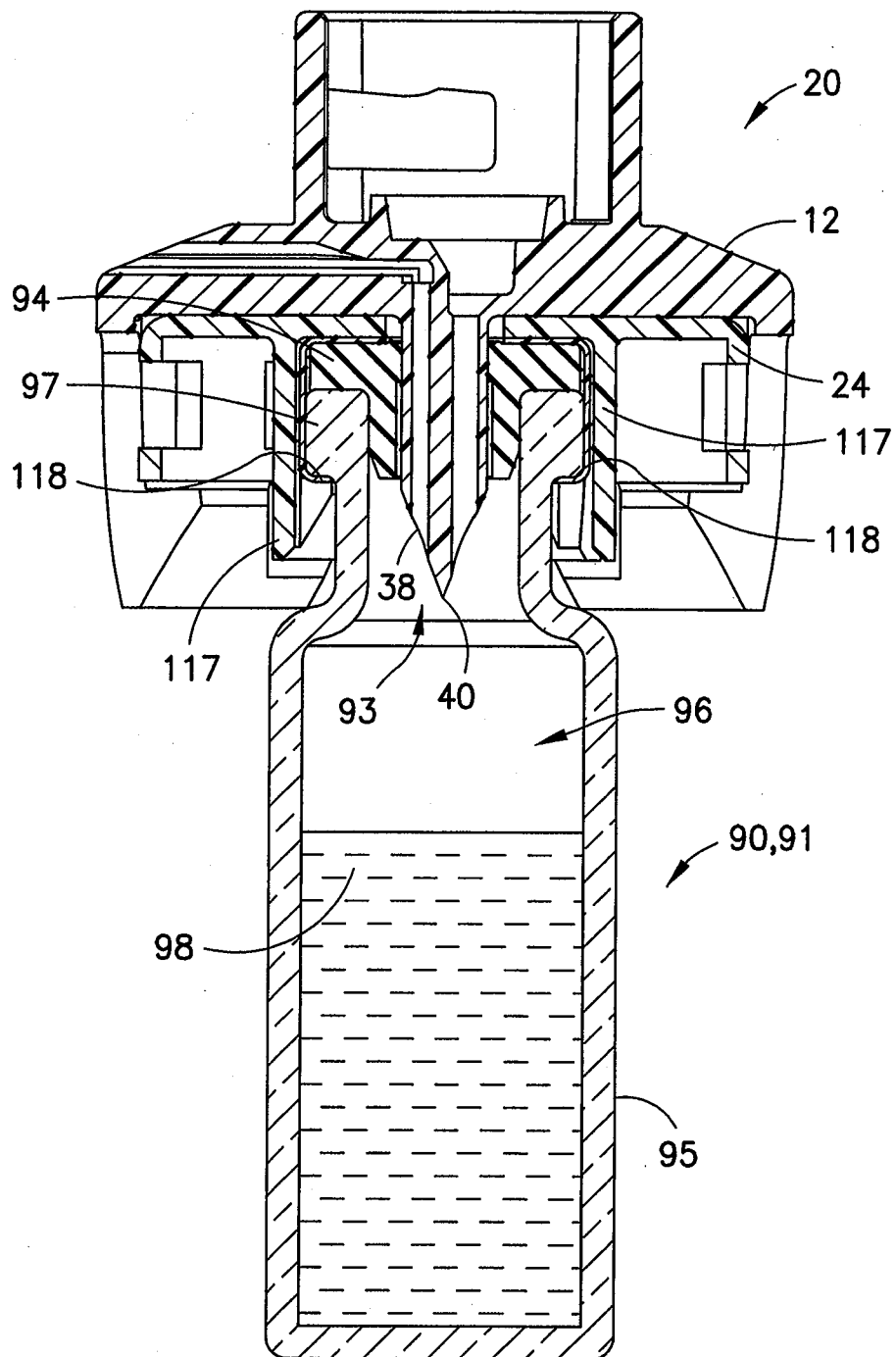
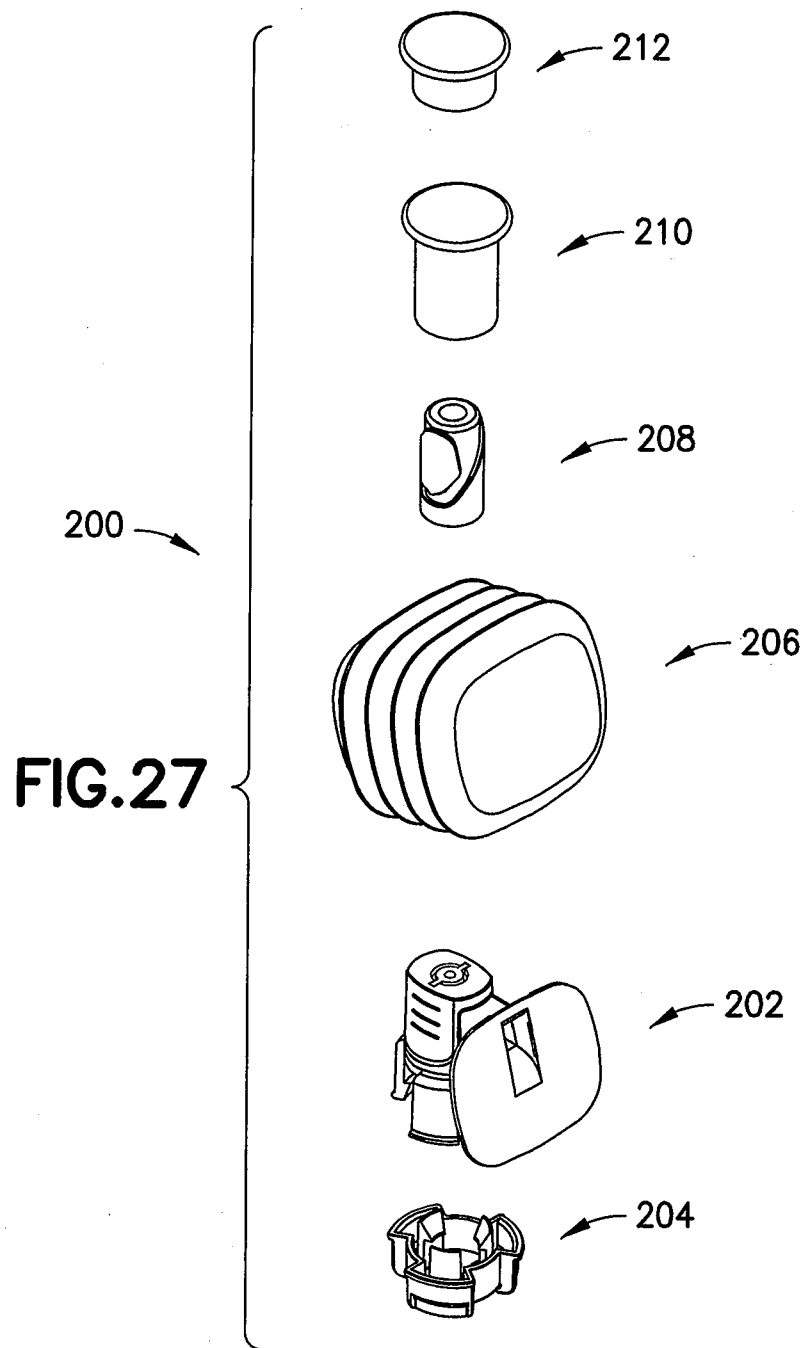
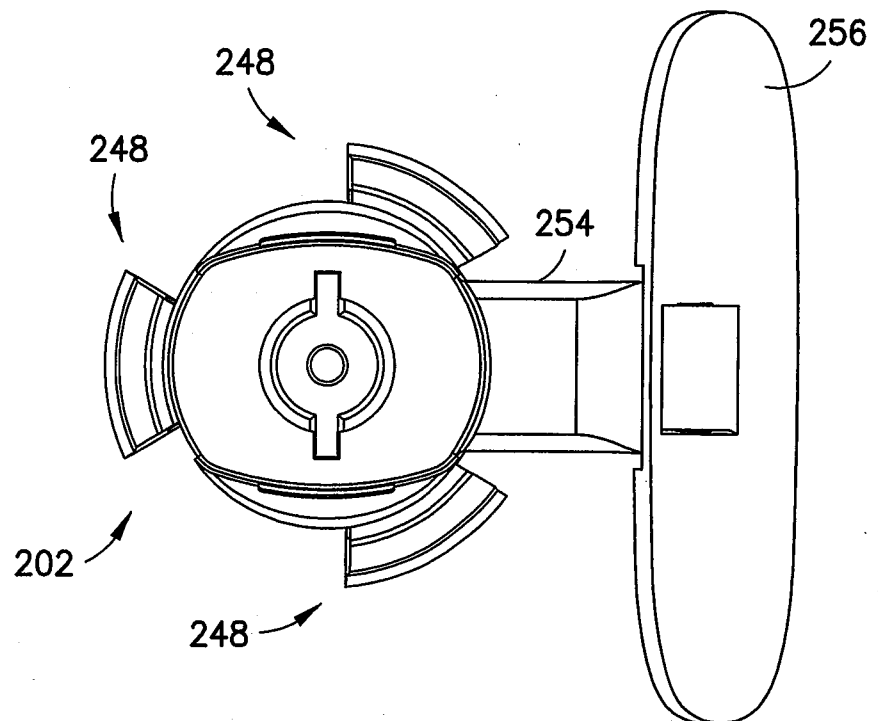
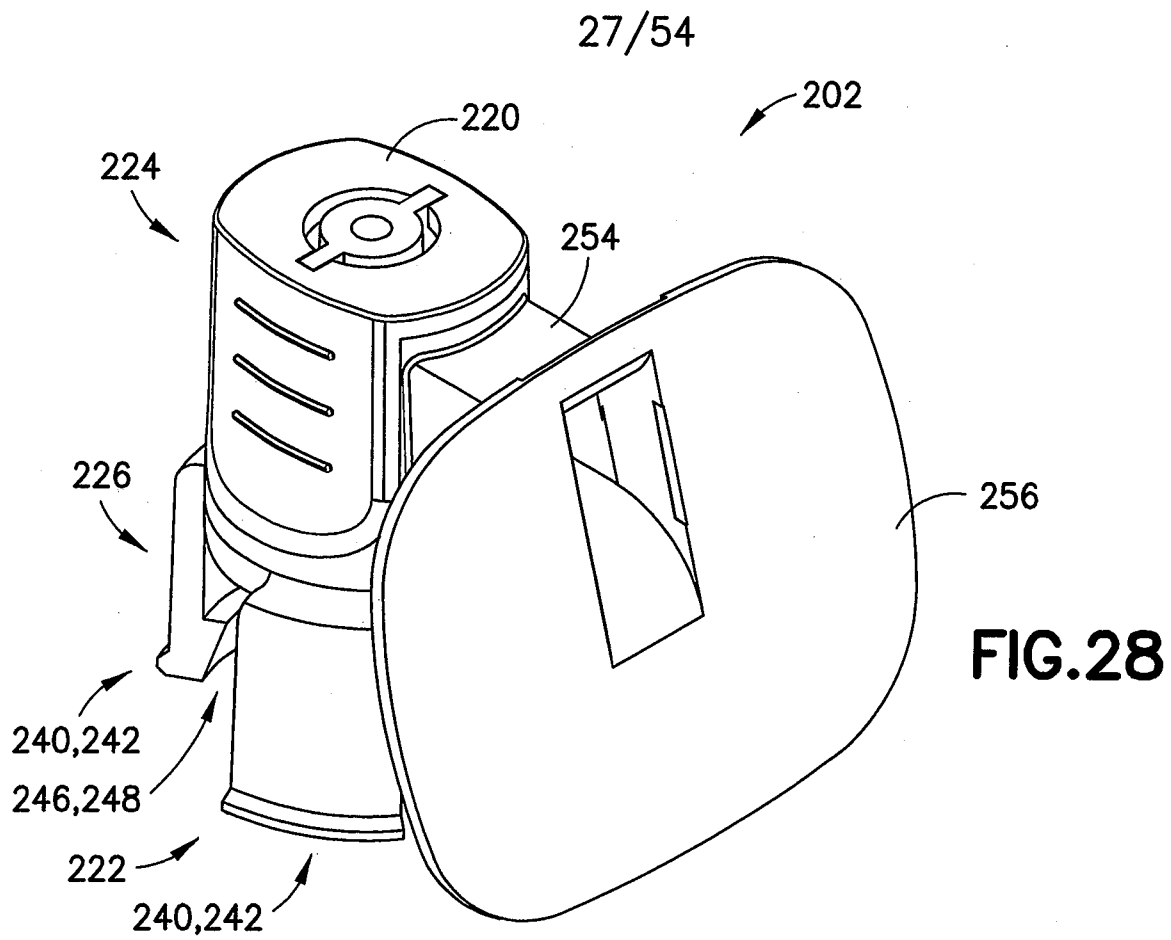
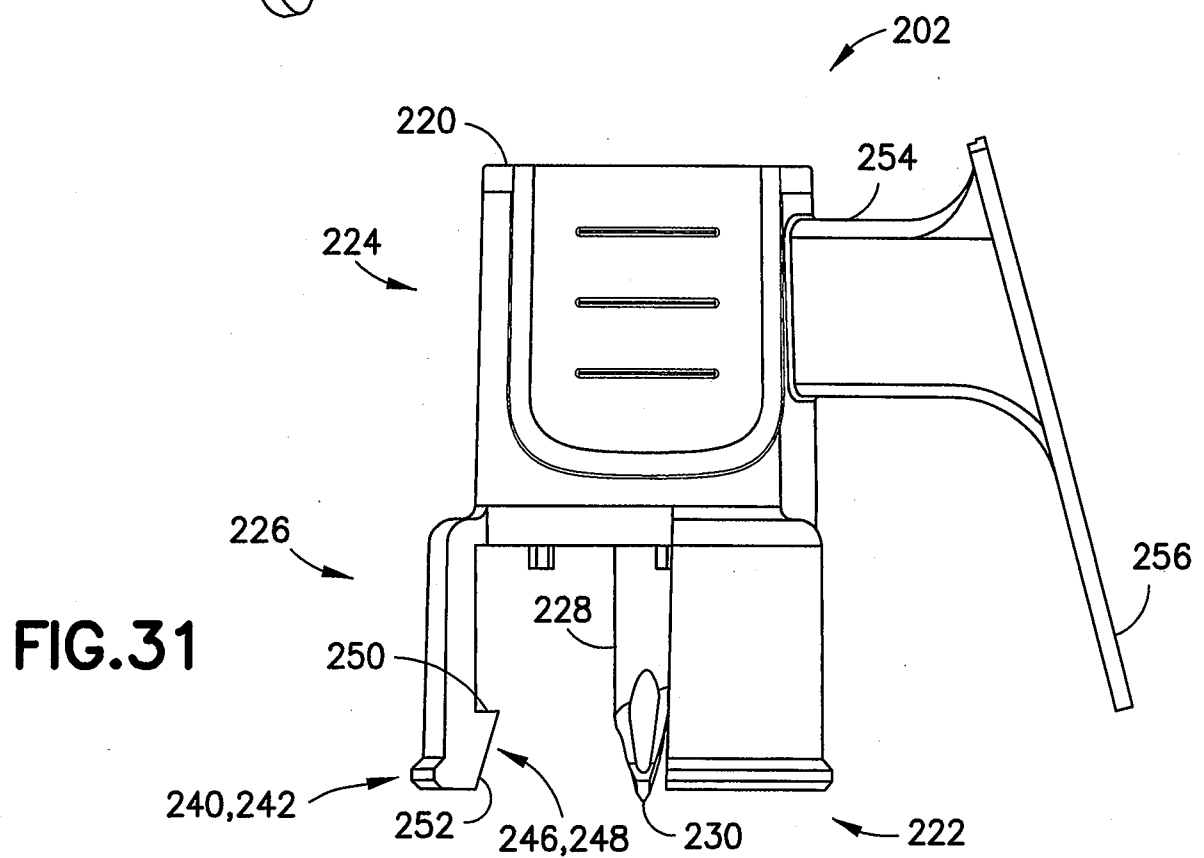
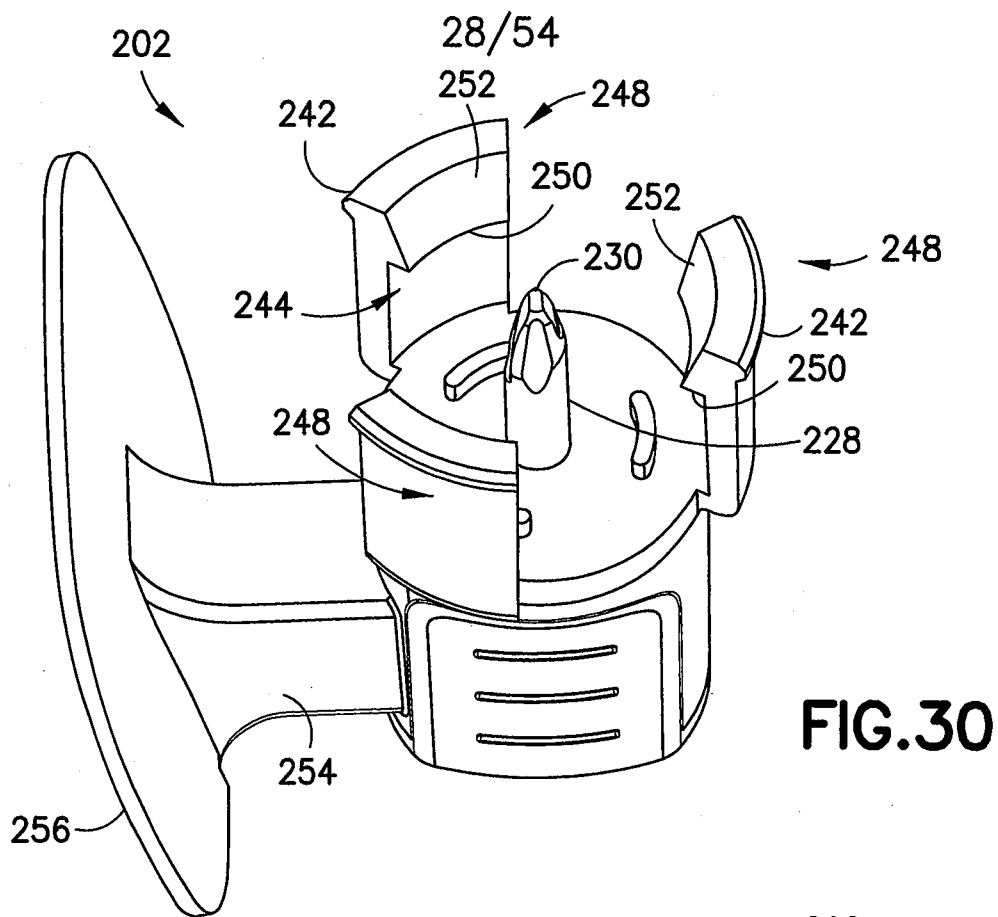


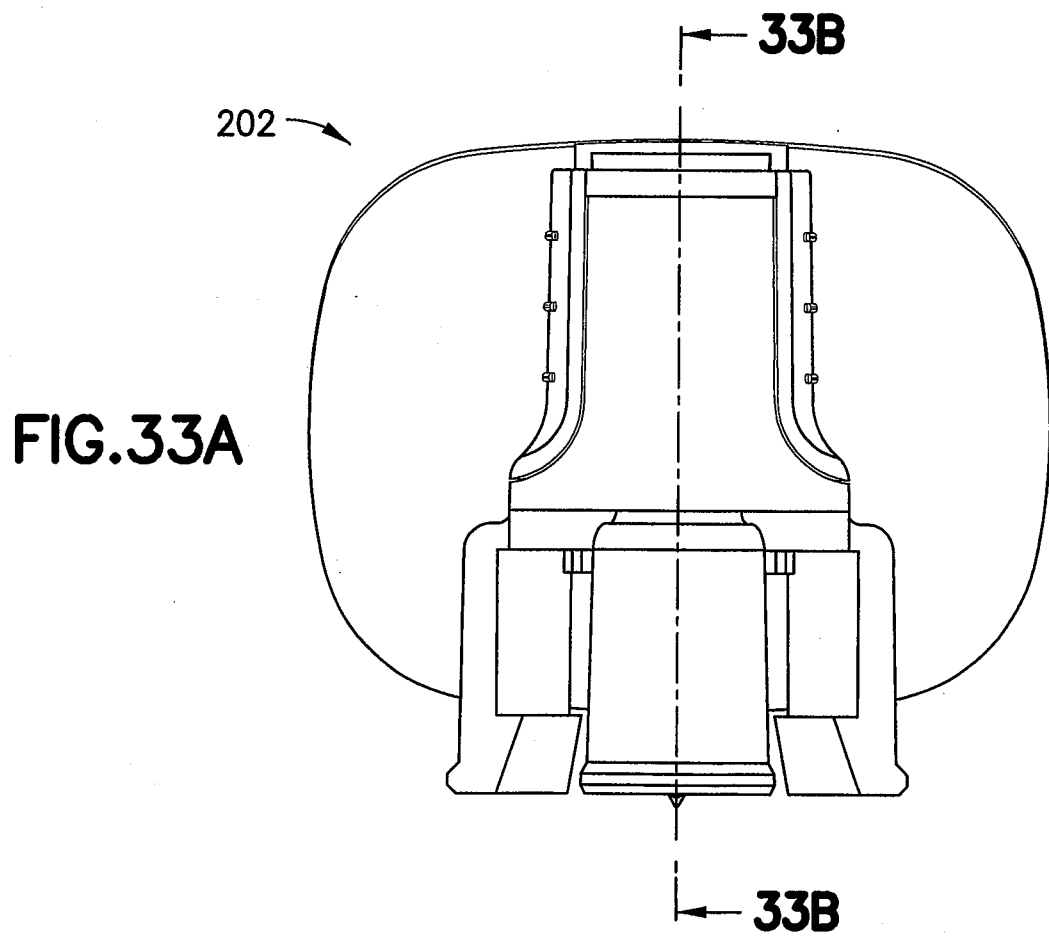
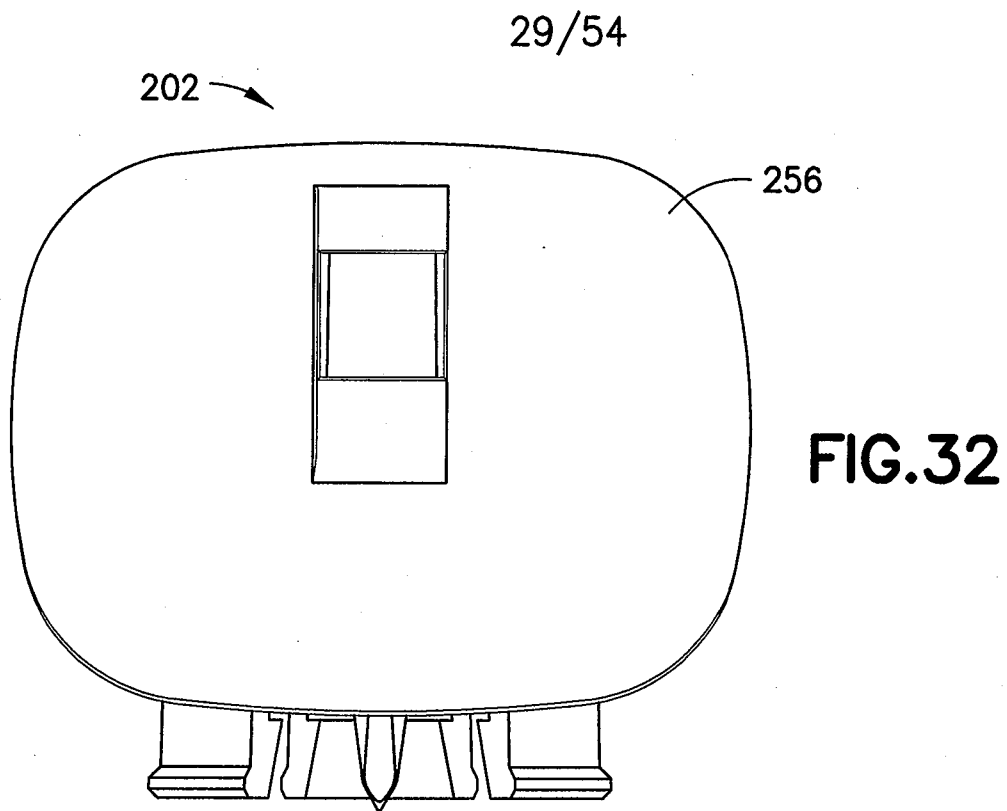
FIG.26B

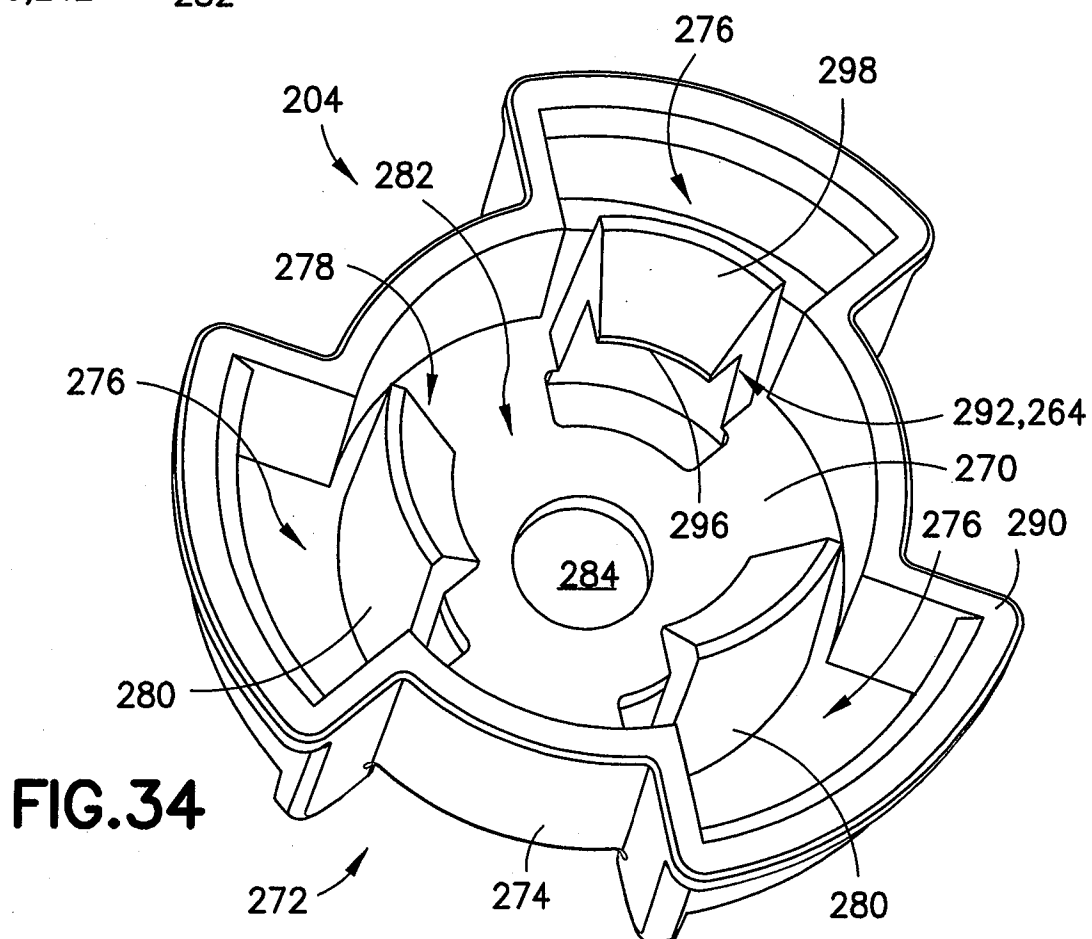
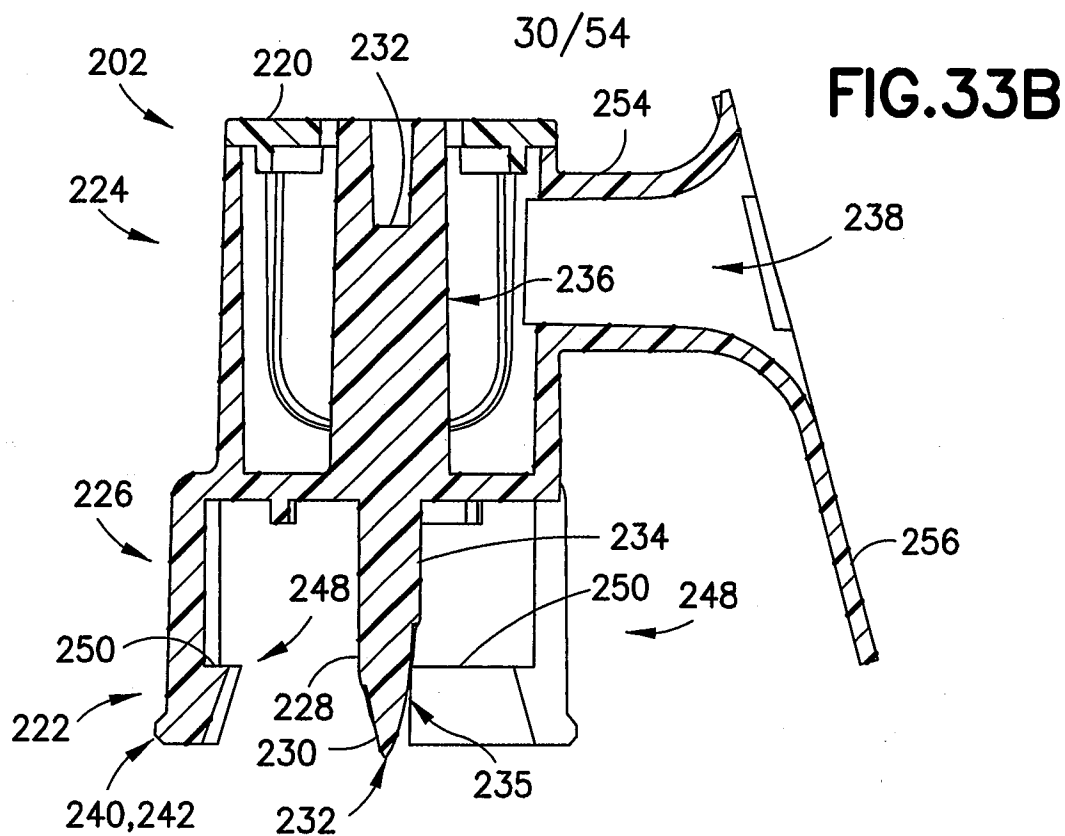
26/54



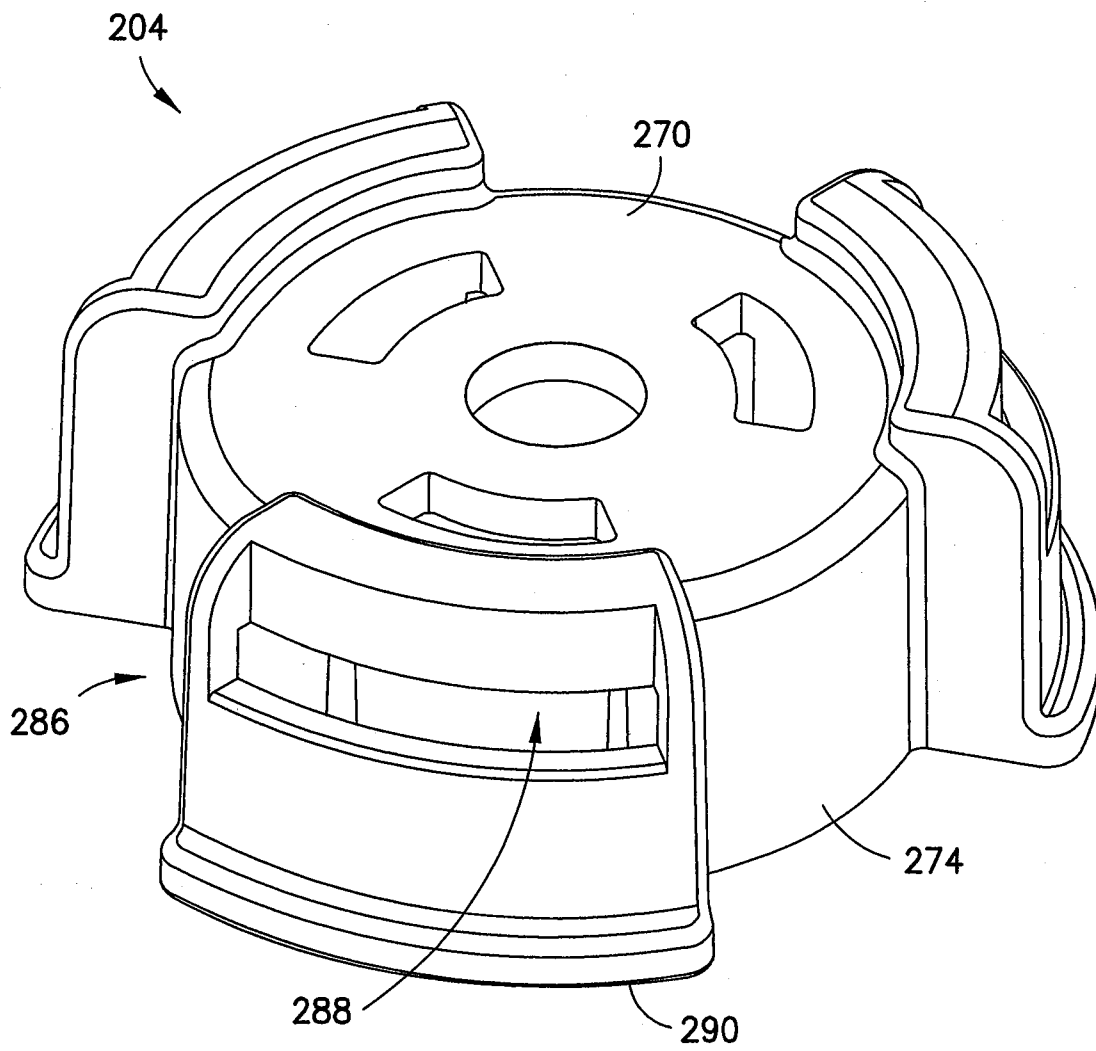




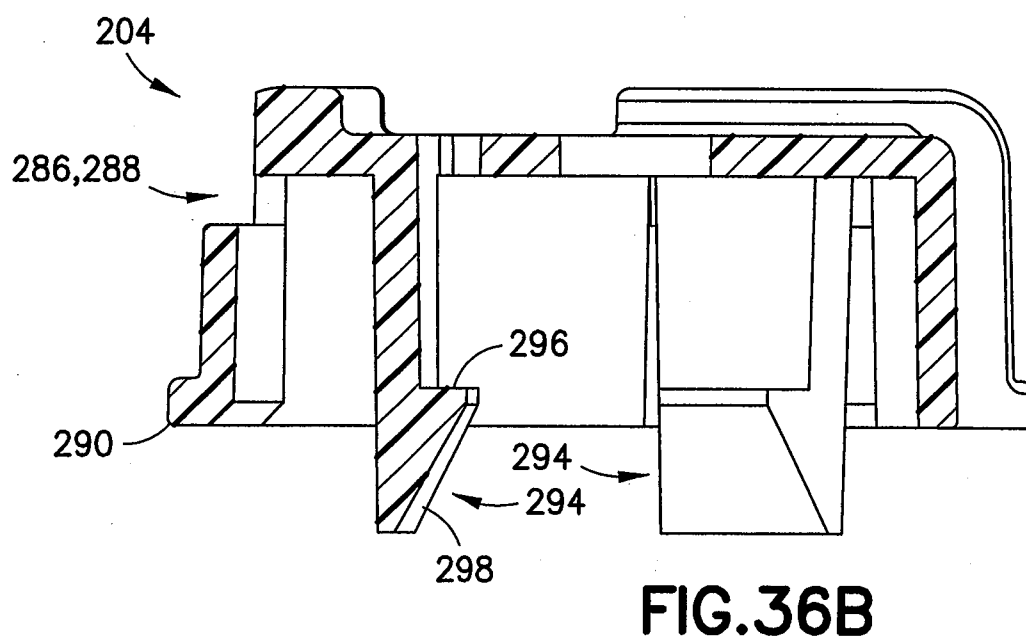
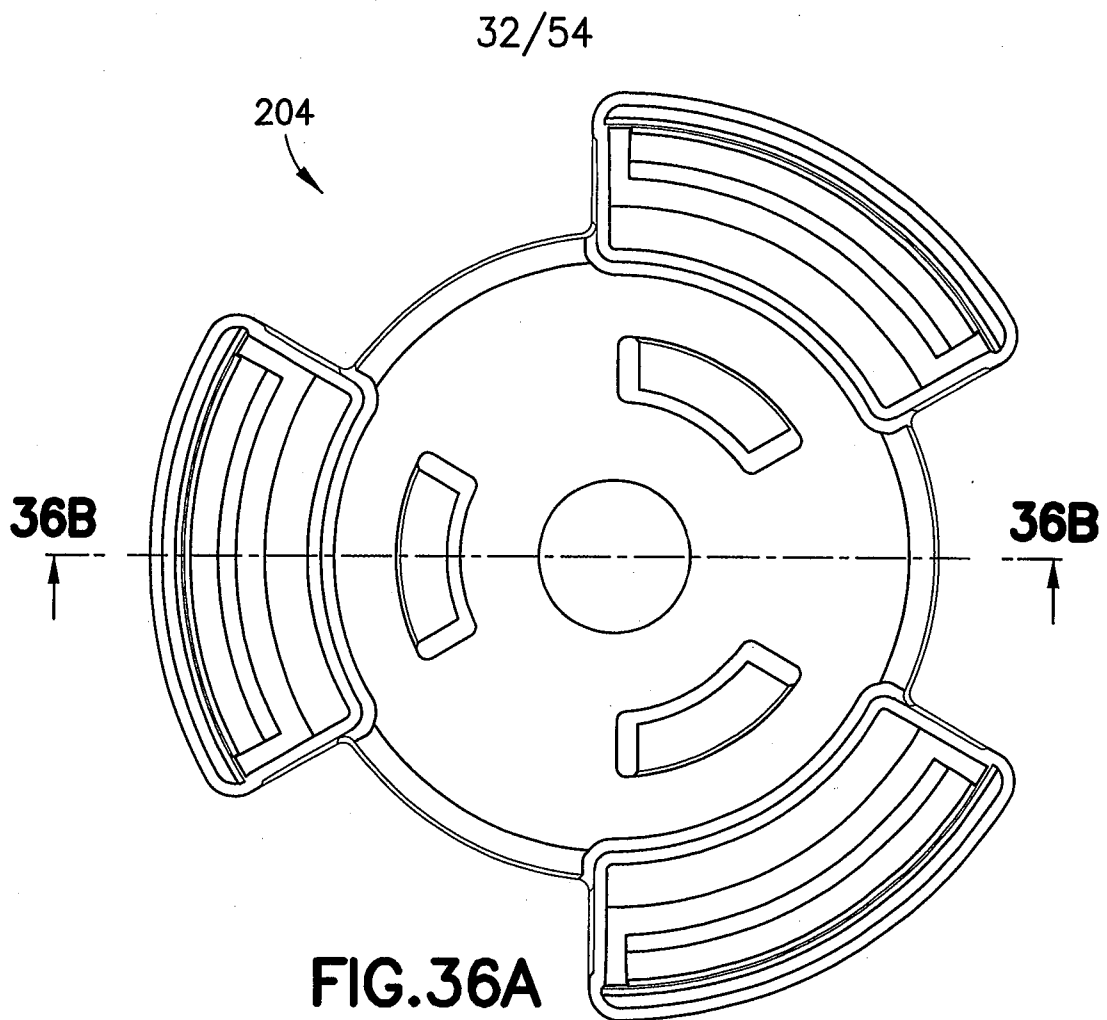




31/54

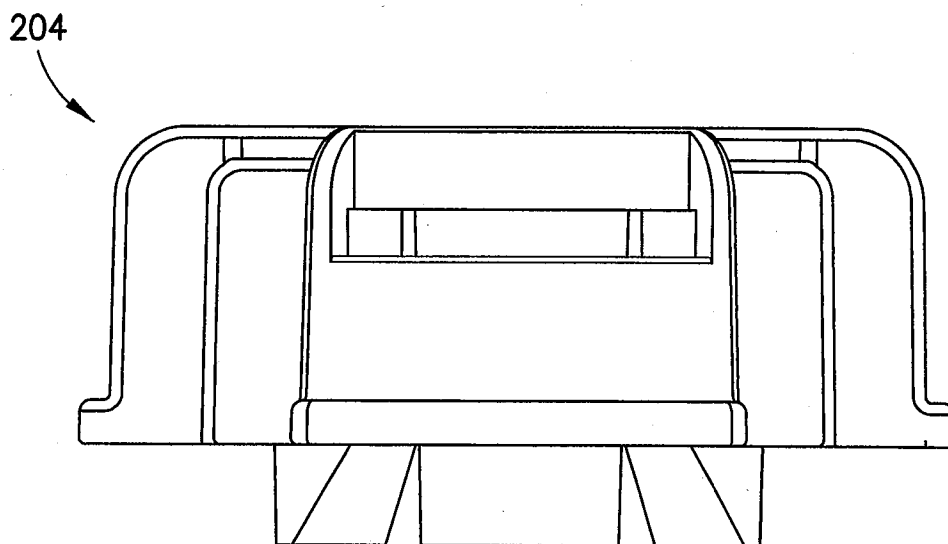
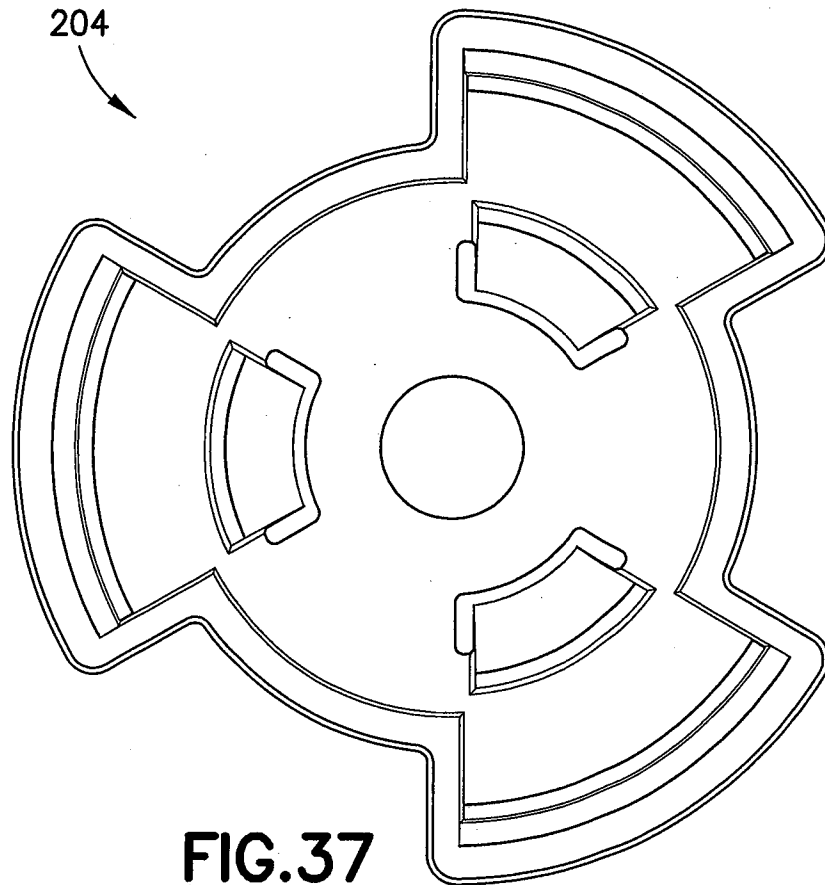


**FIG.35**





33/54



34/54

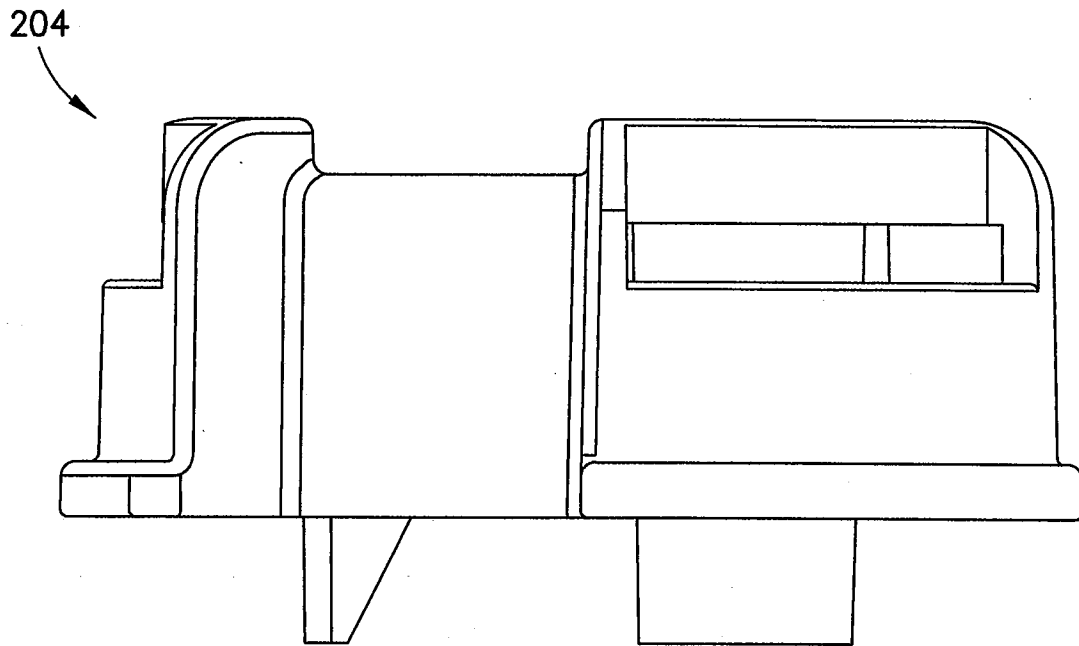


FIG. 39

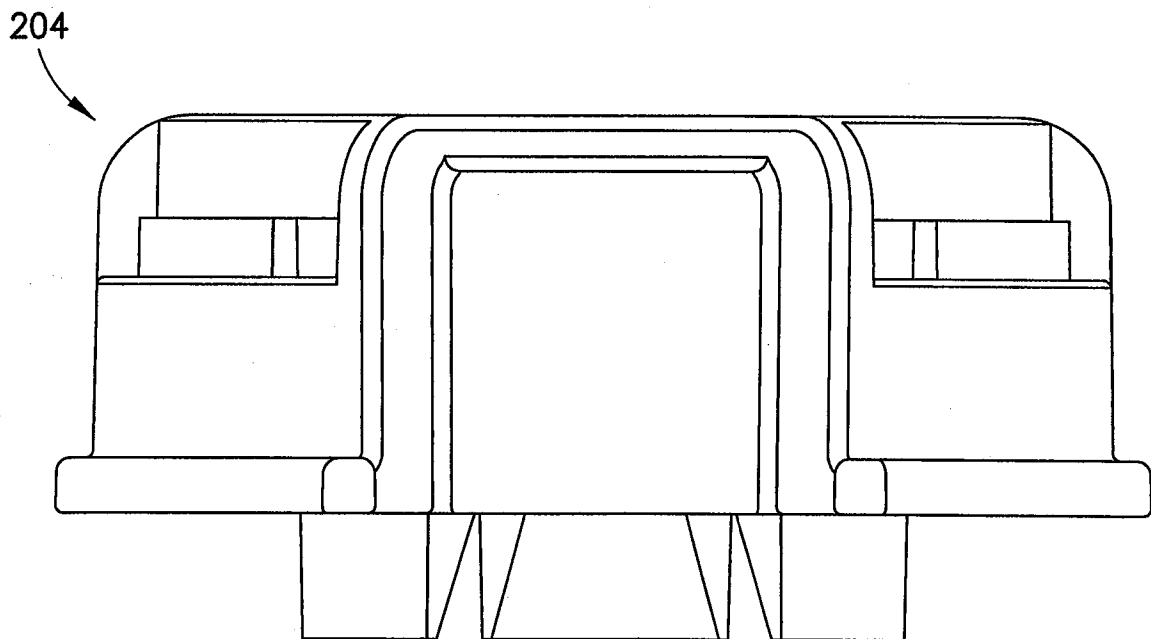
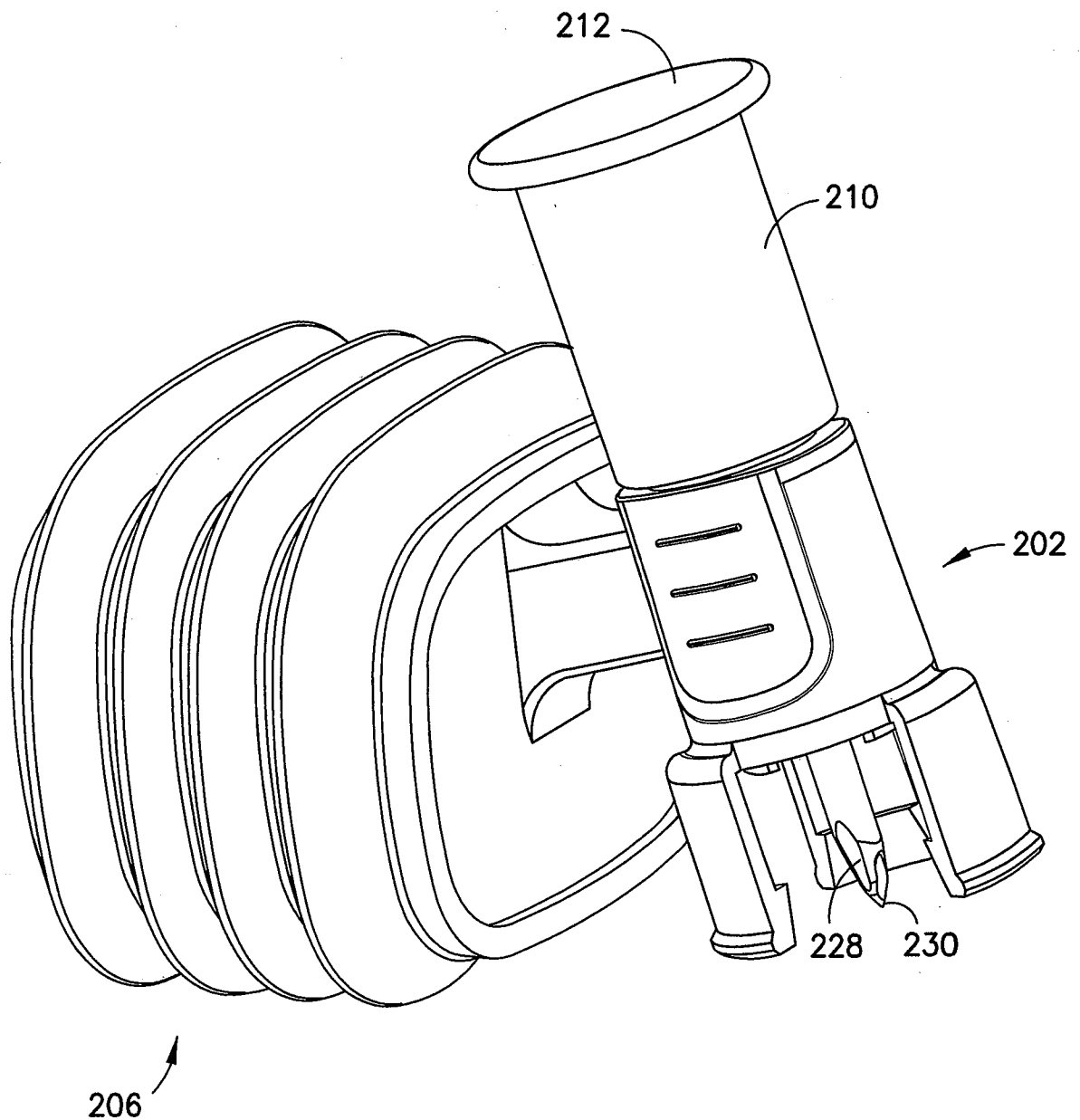


FIG. 40

35/54

**FIG. 41A**

36/54

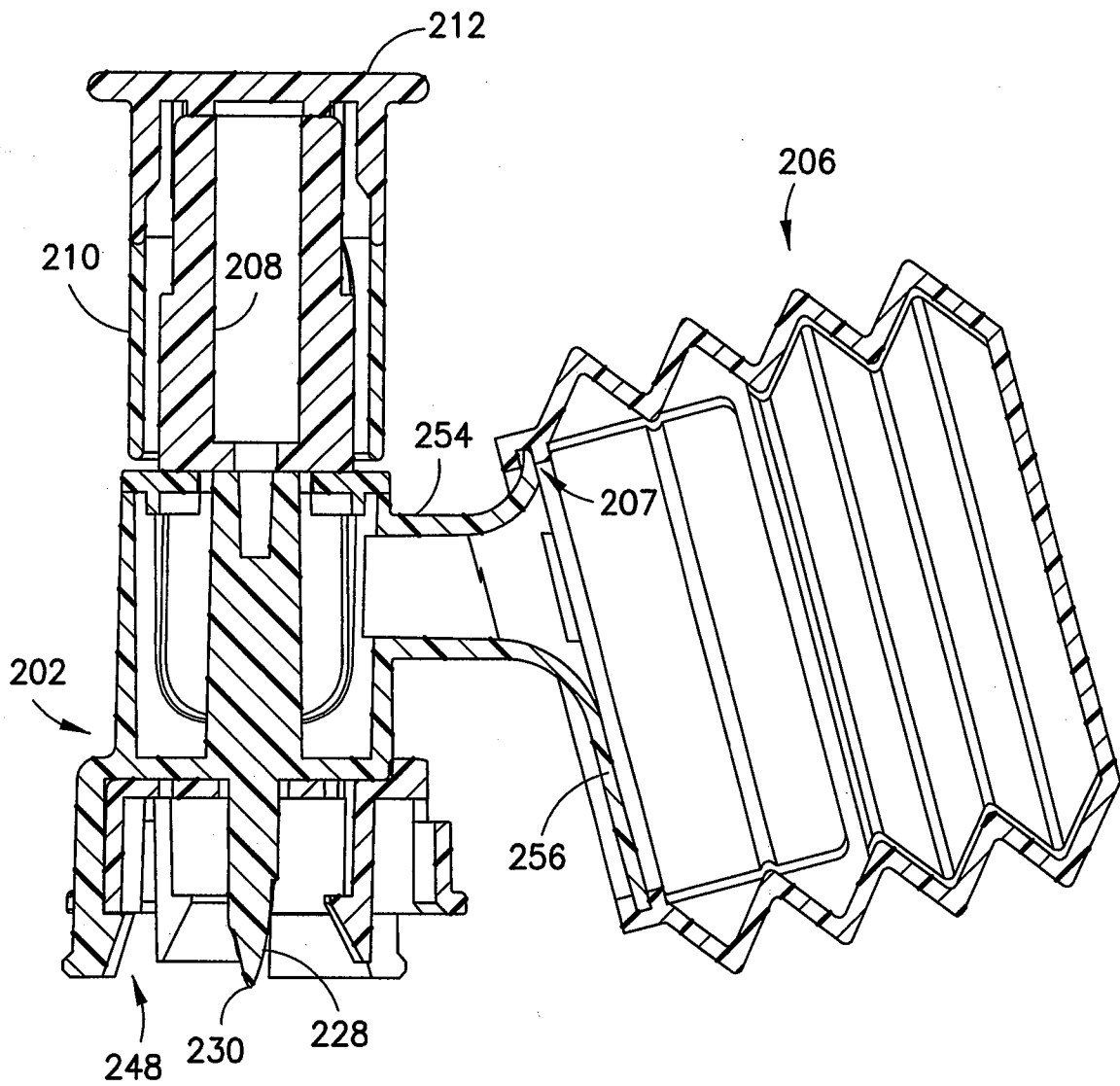


FIG. 41B

37/54

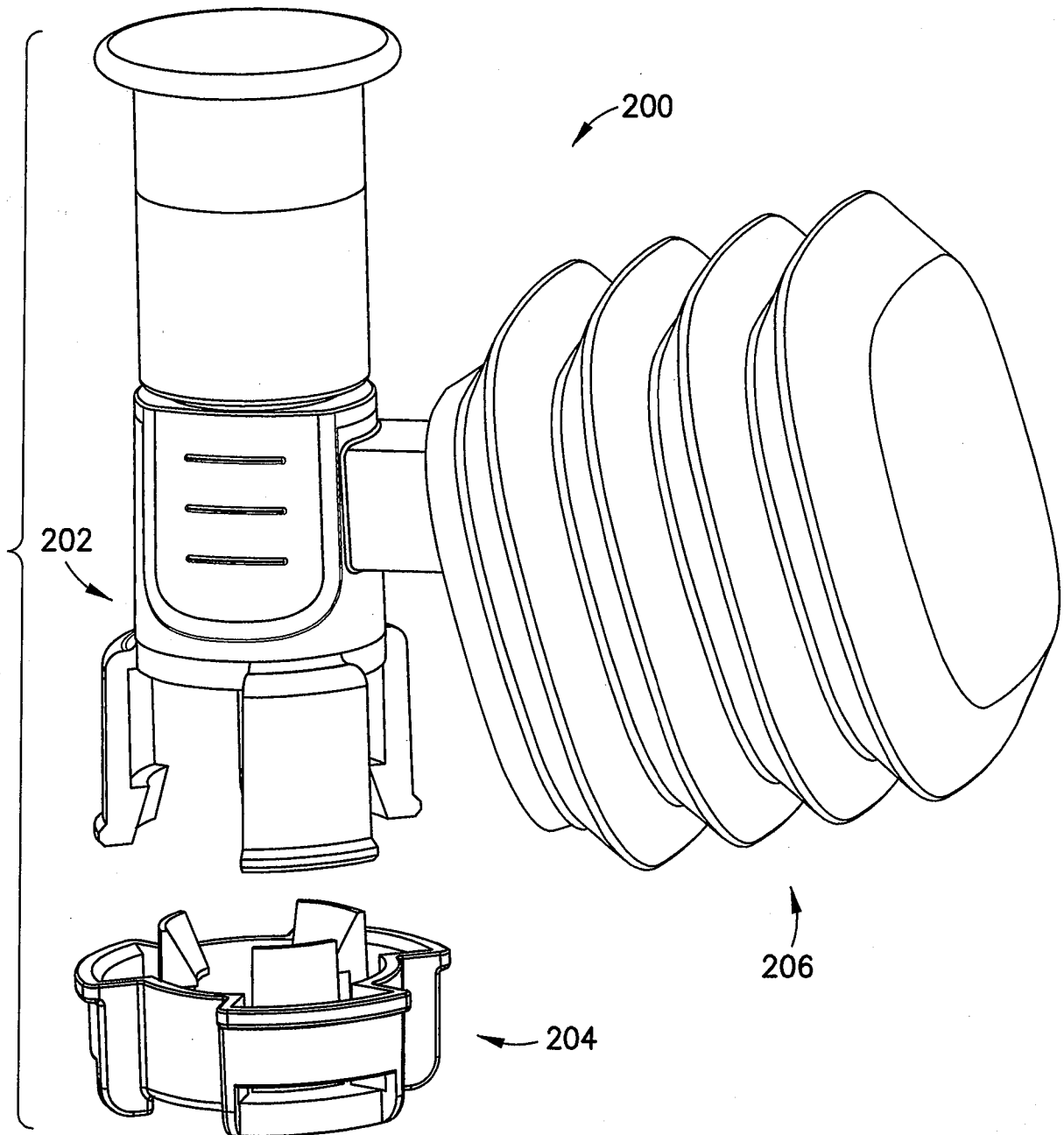


FIG. 42

38/54

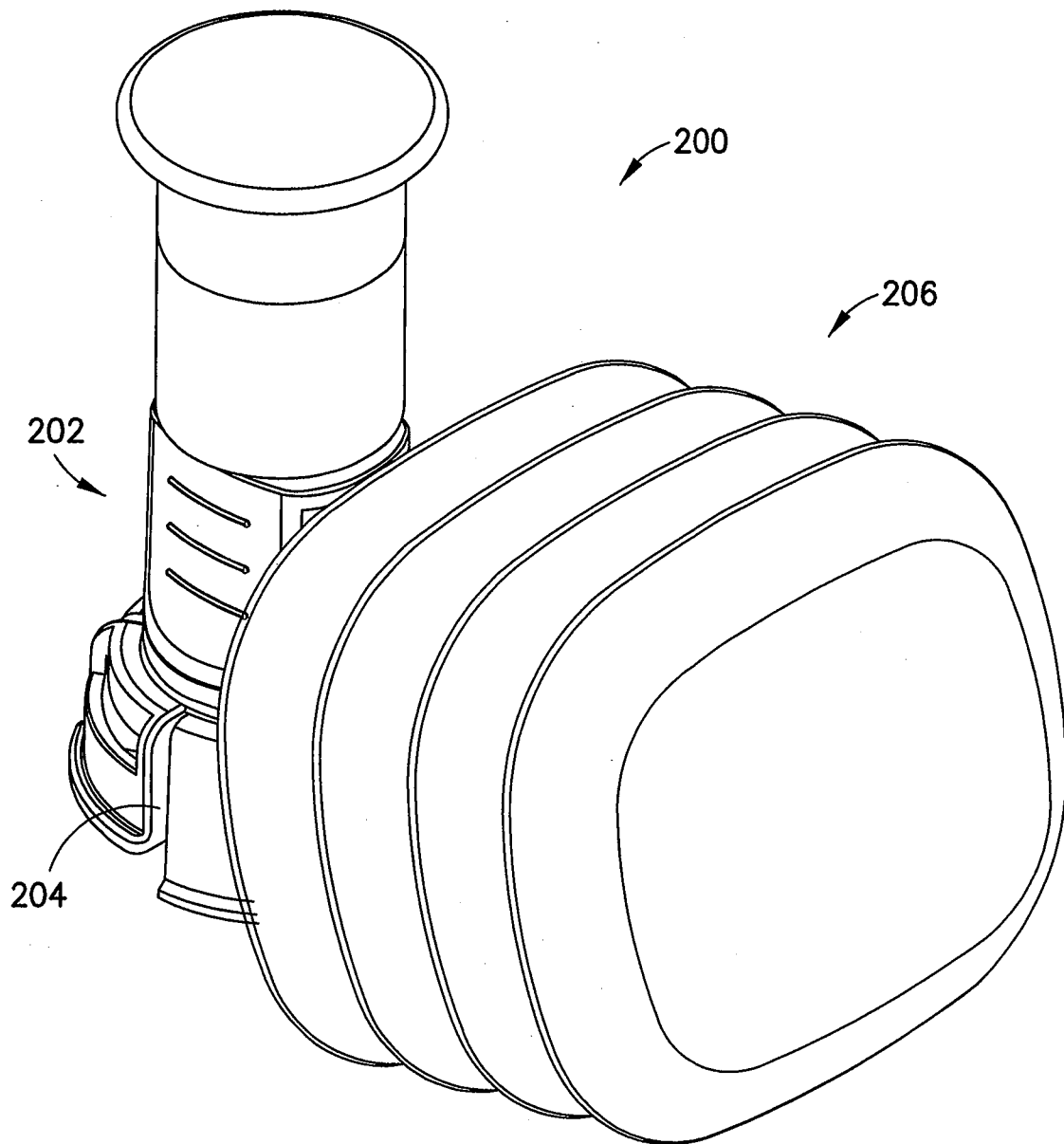
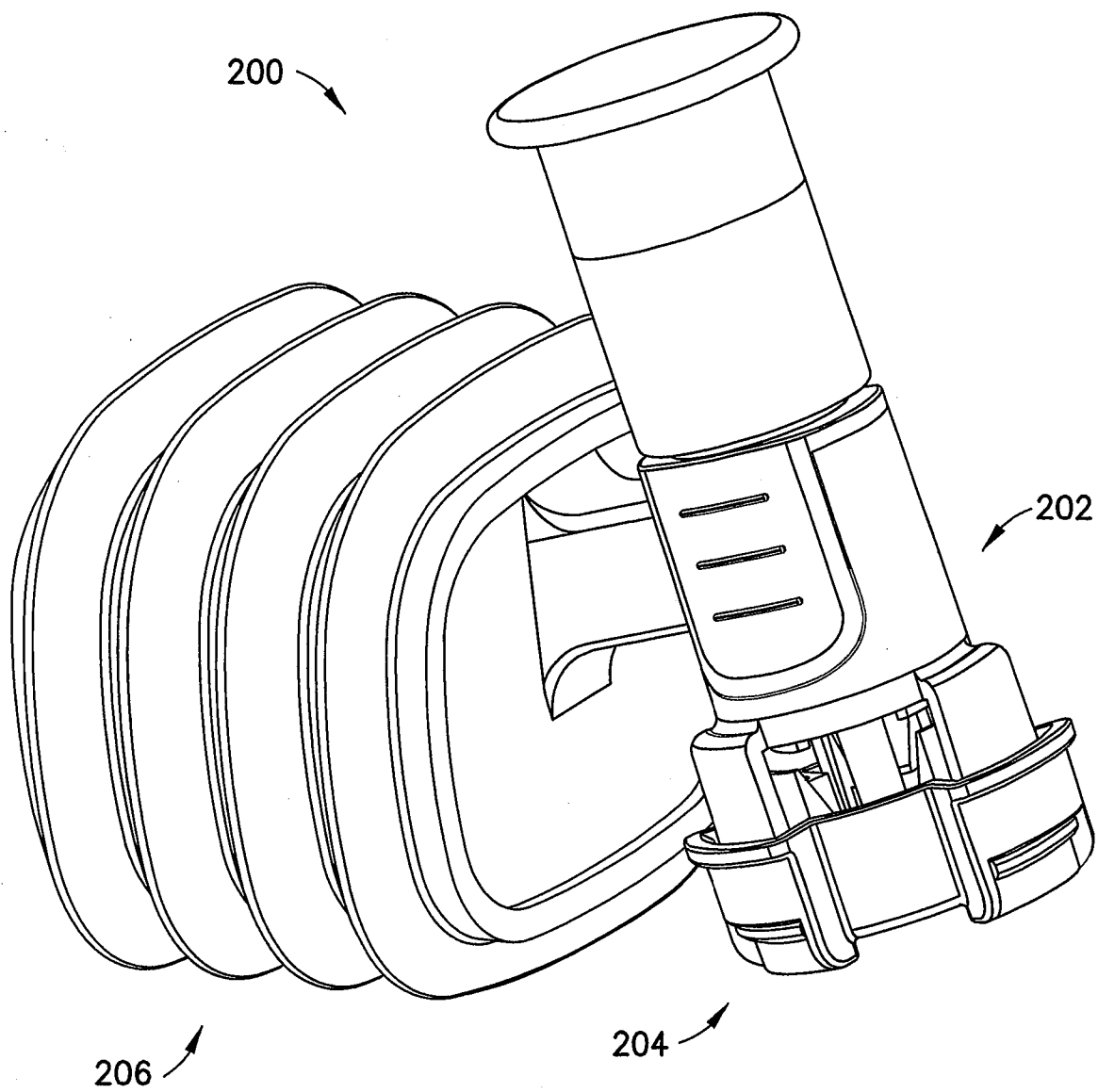


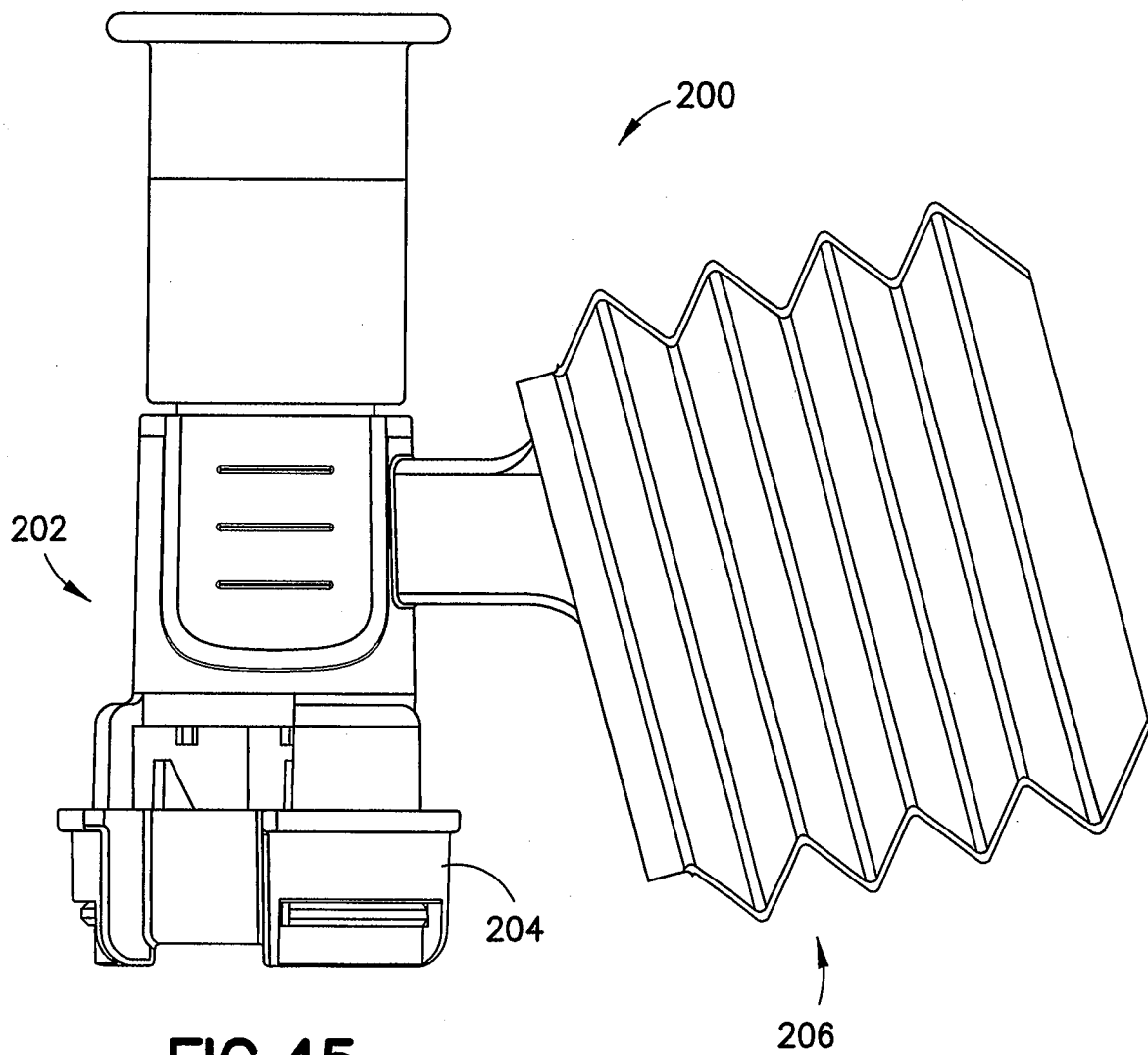
FIG. 43

39/54



**FIG. 44**

40/54



**FIG.45**



41/54

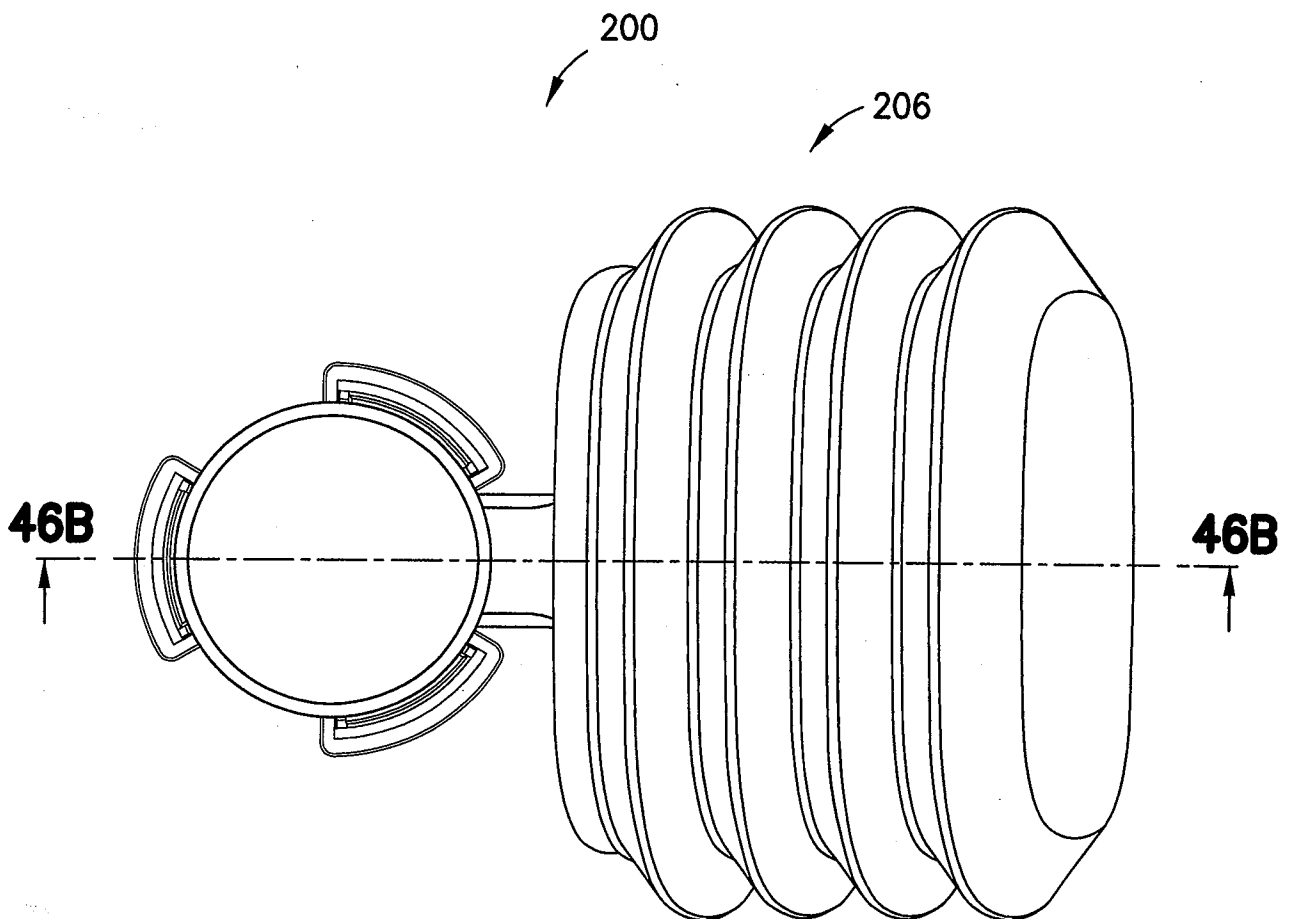
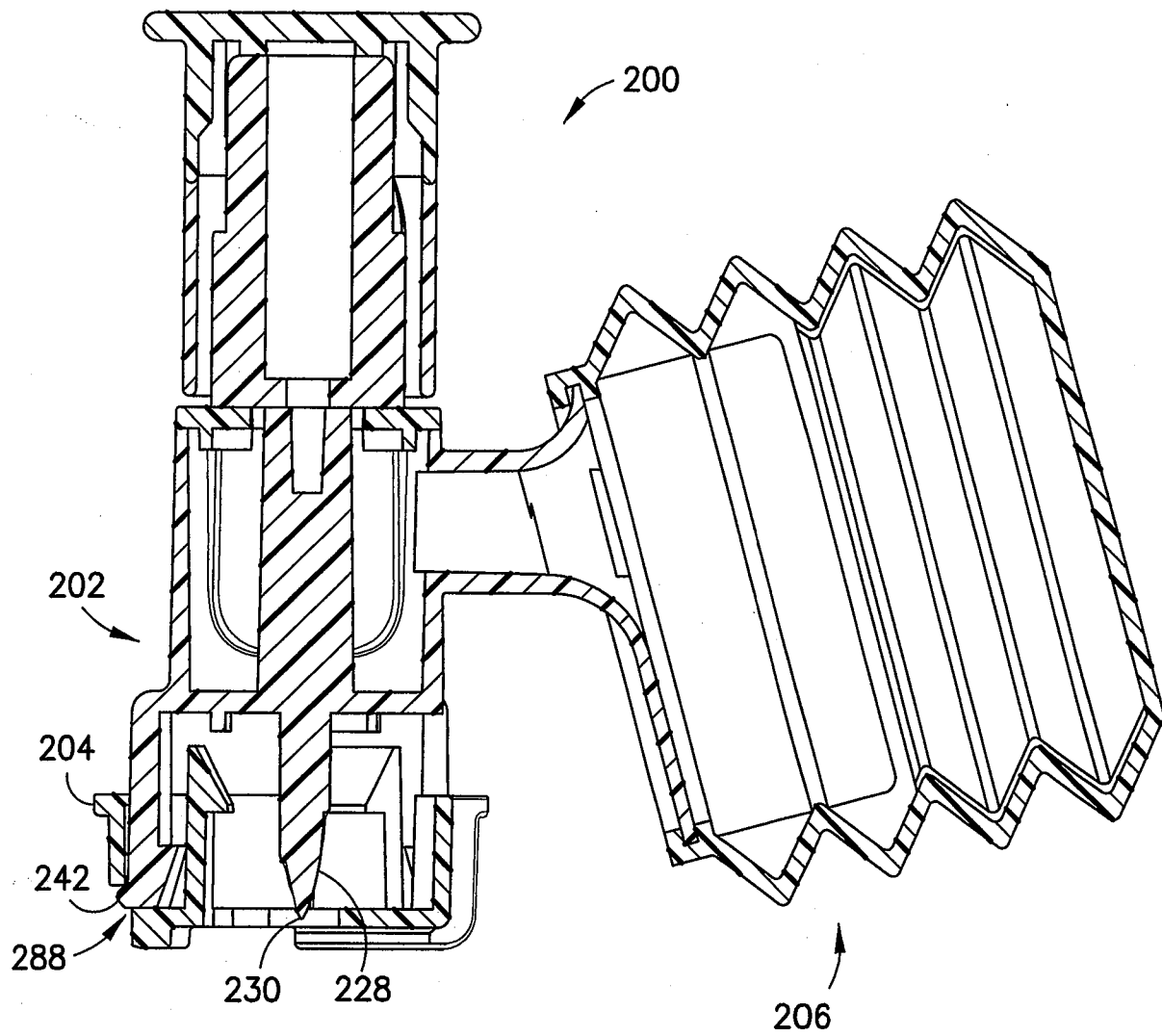


FIG. 46A

42/54



**FIG. 46B**

43/54

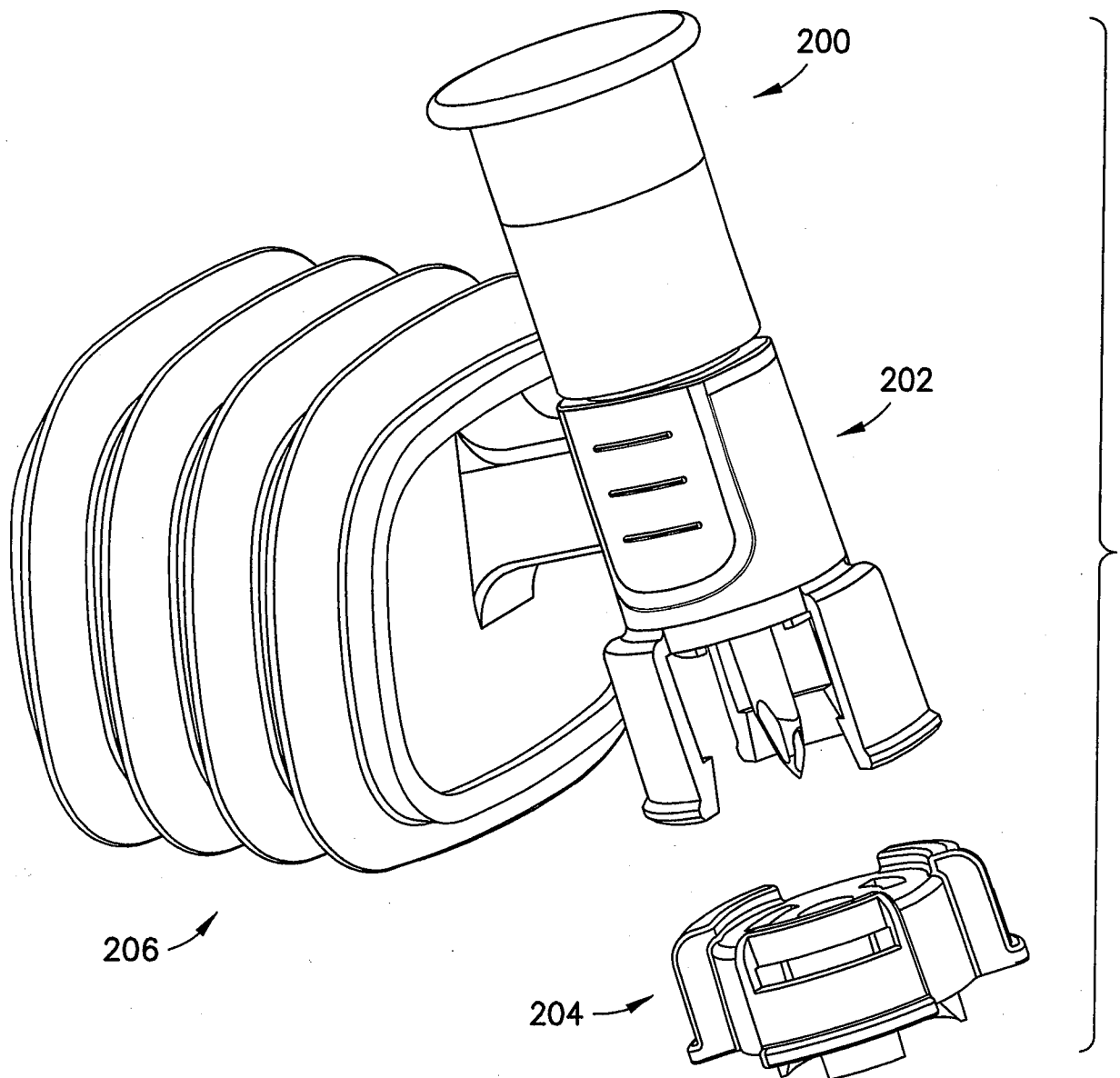


FIG. 47

44/54

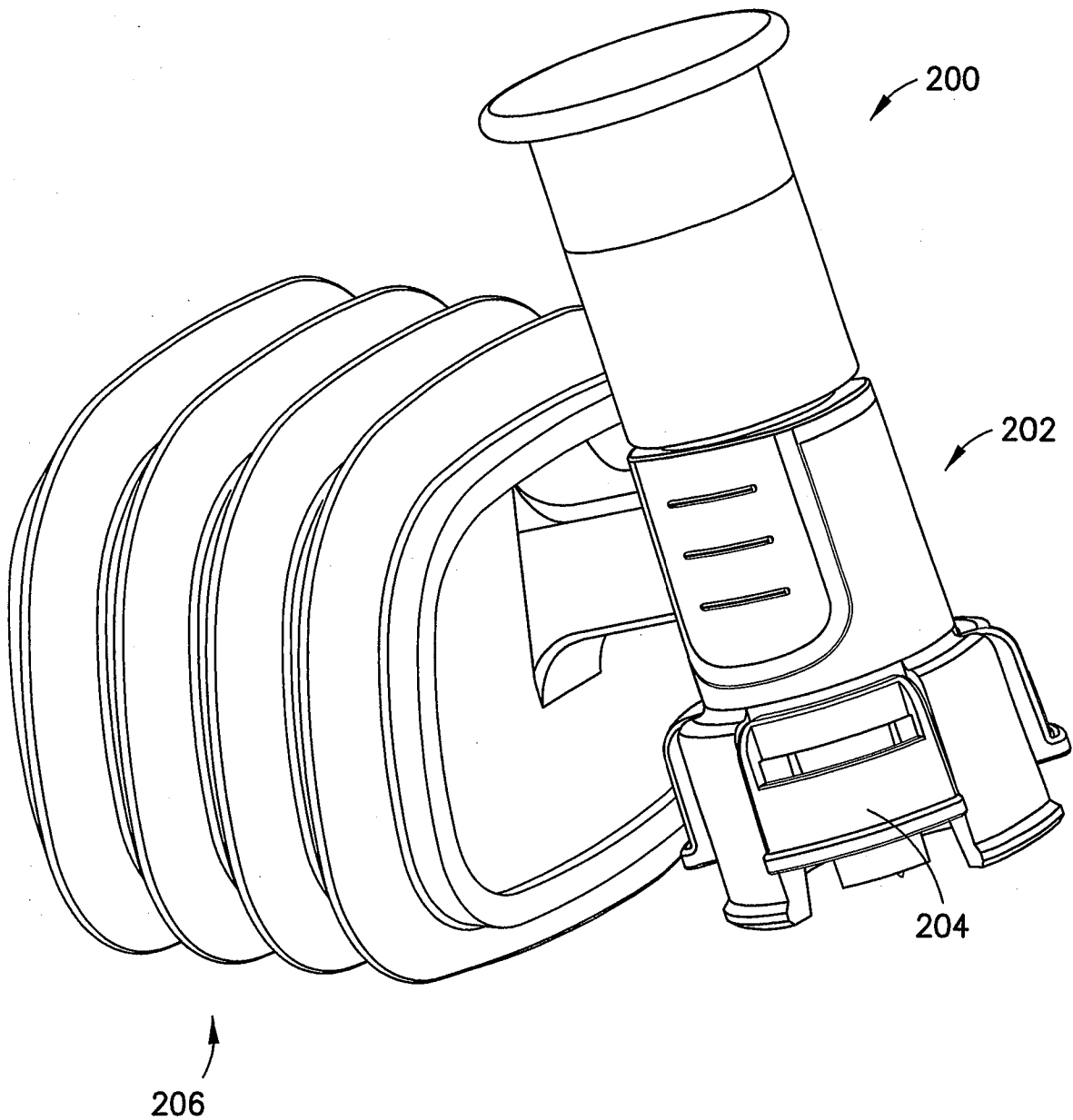


FIG.48

45/54

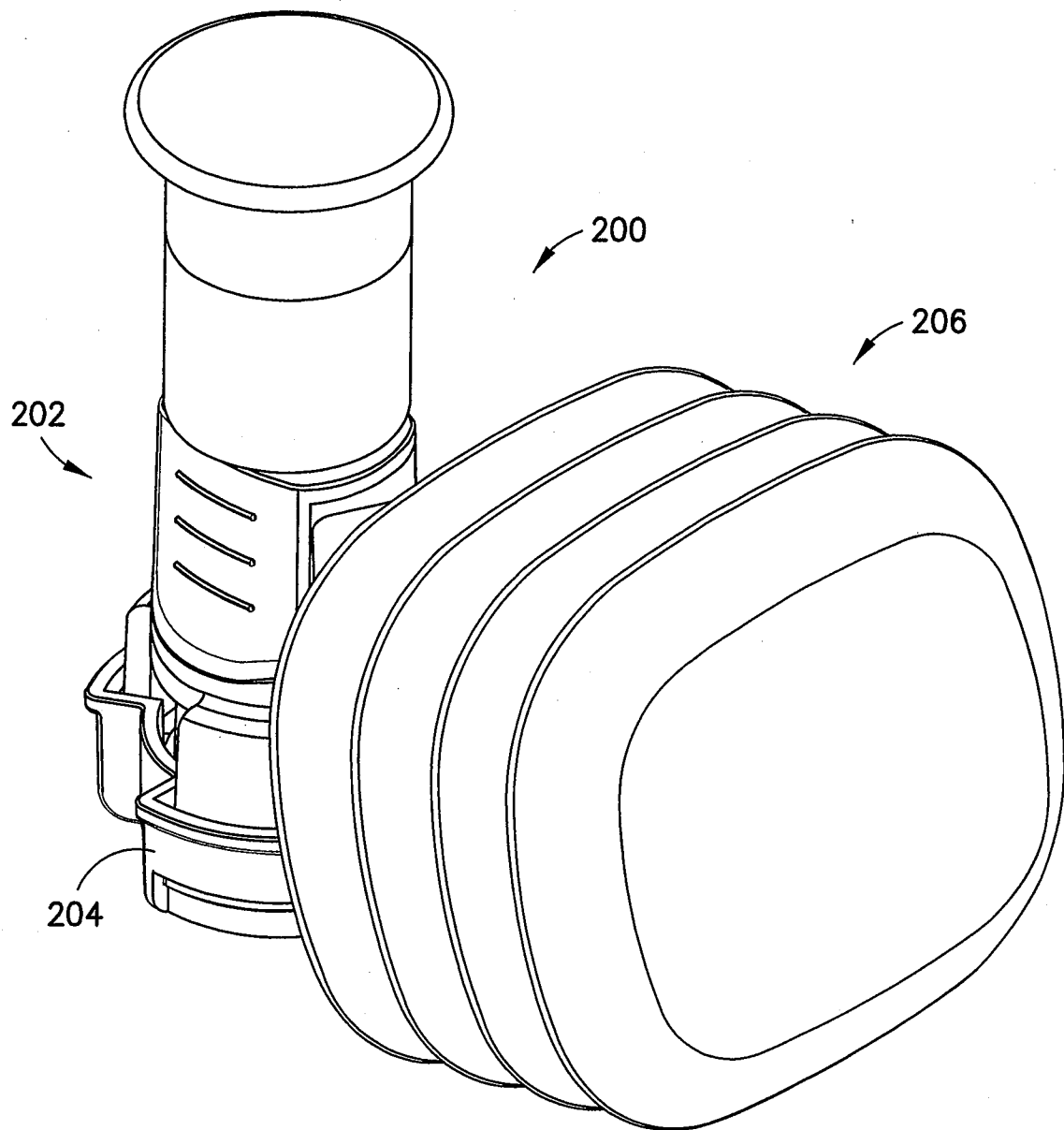
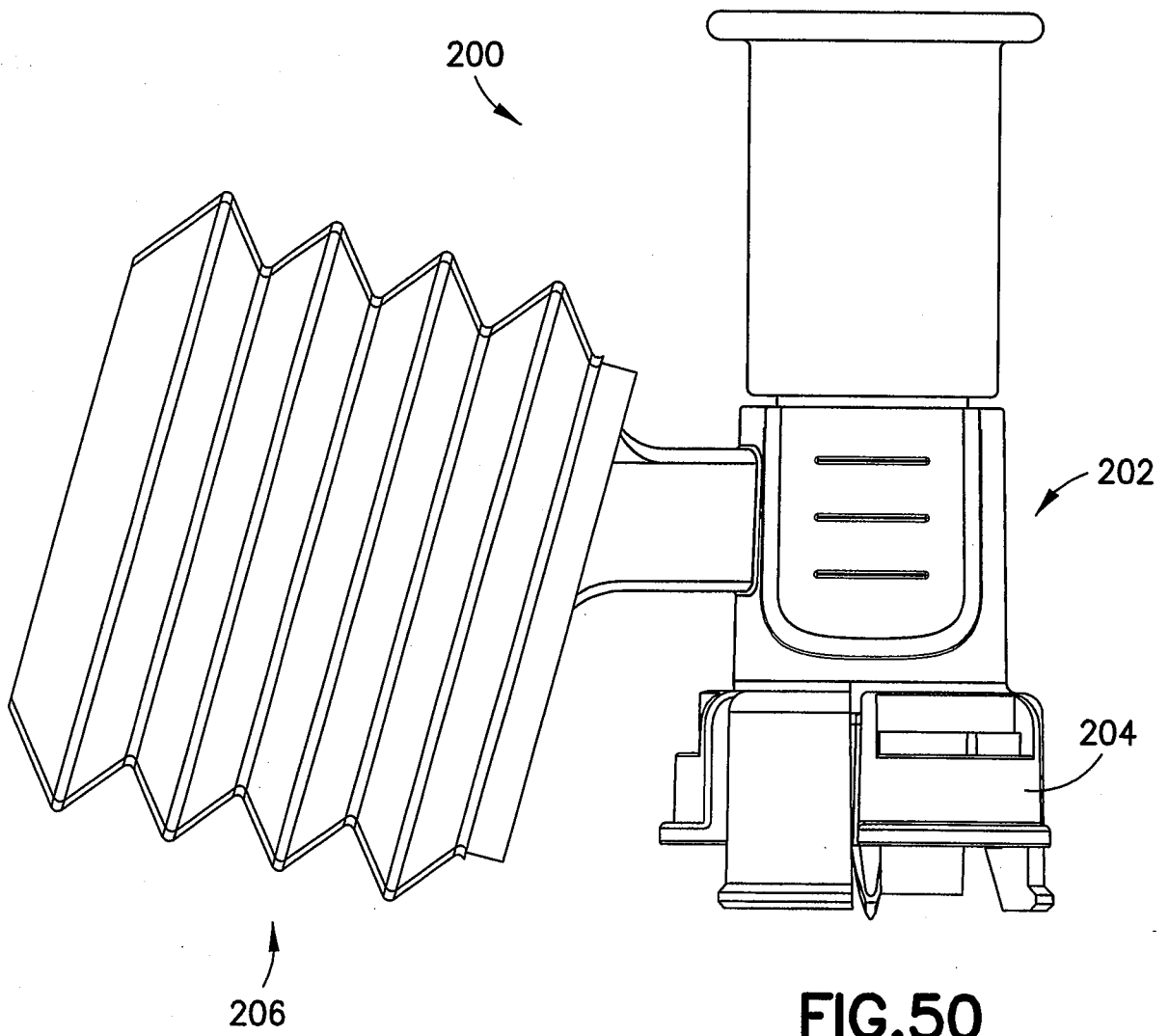
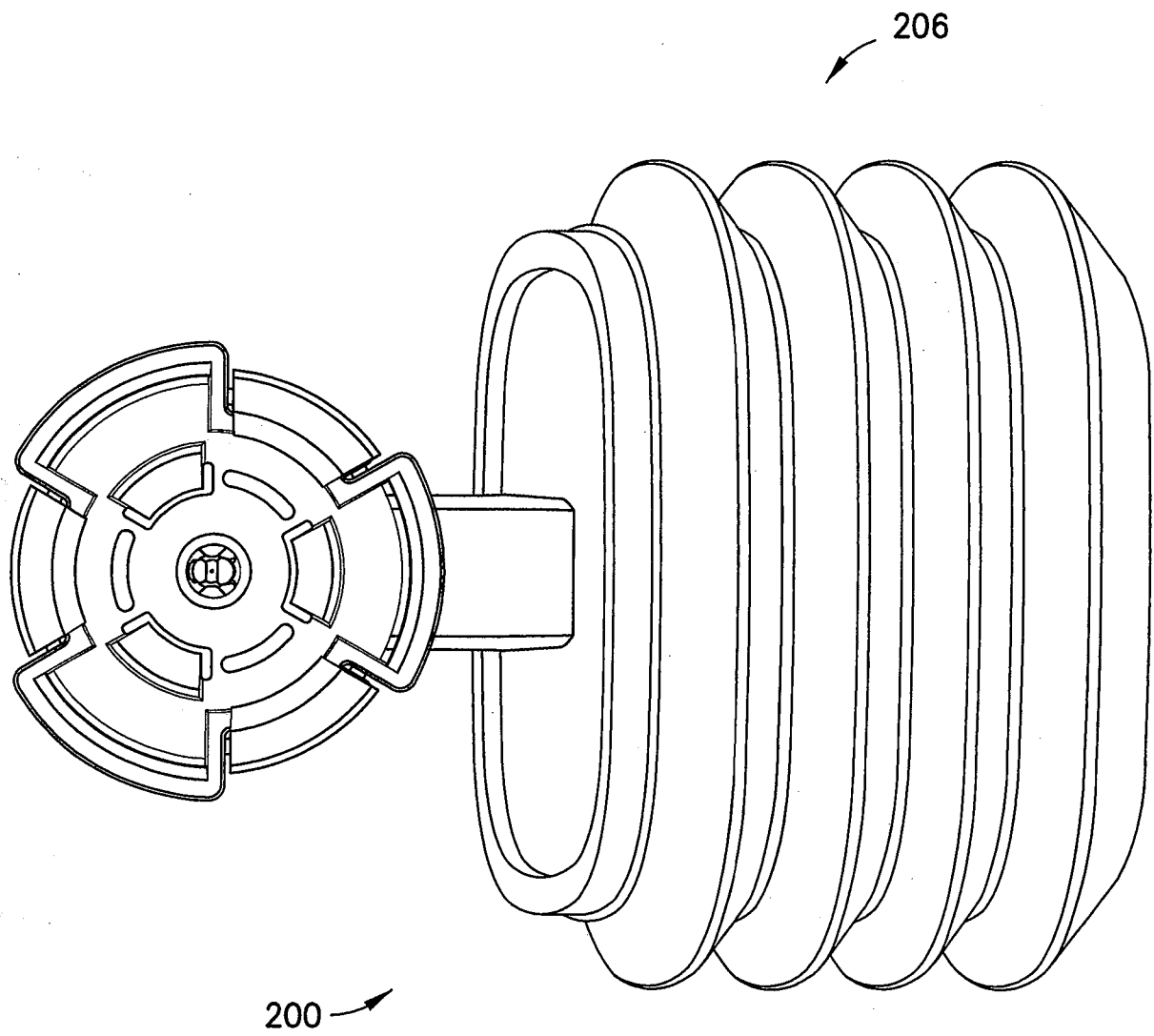


FIG.49

46/54



47/54



**FIG.51**

48/54

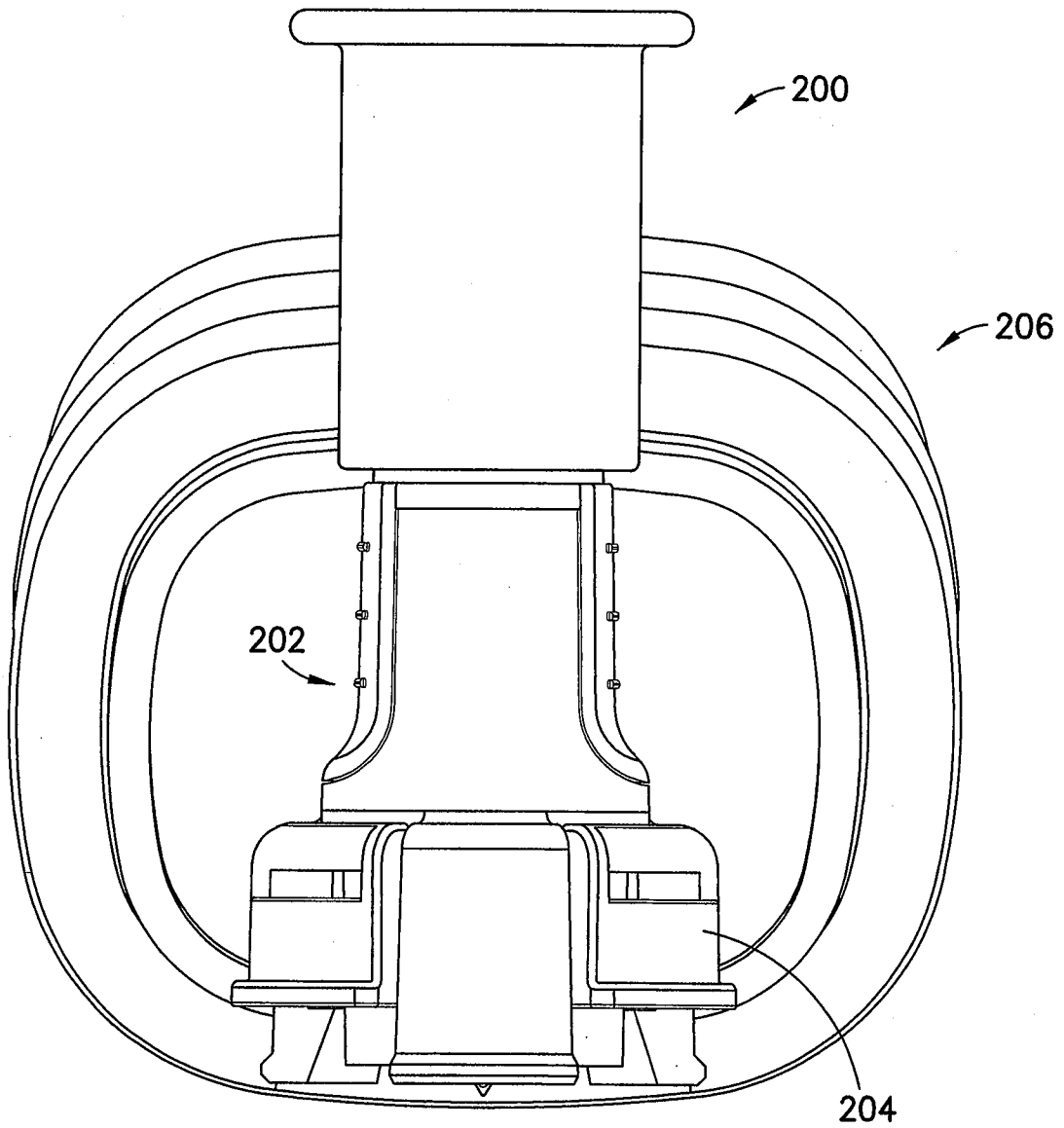


FIG. 52



49/54

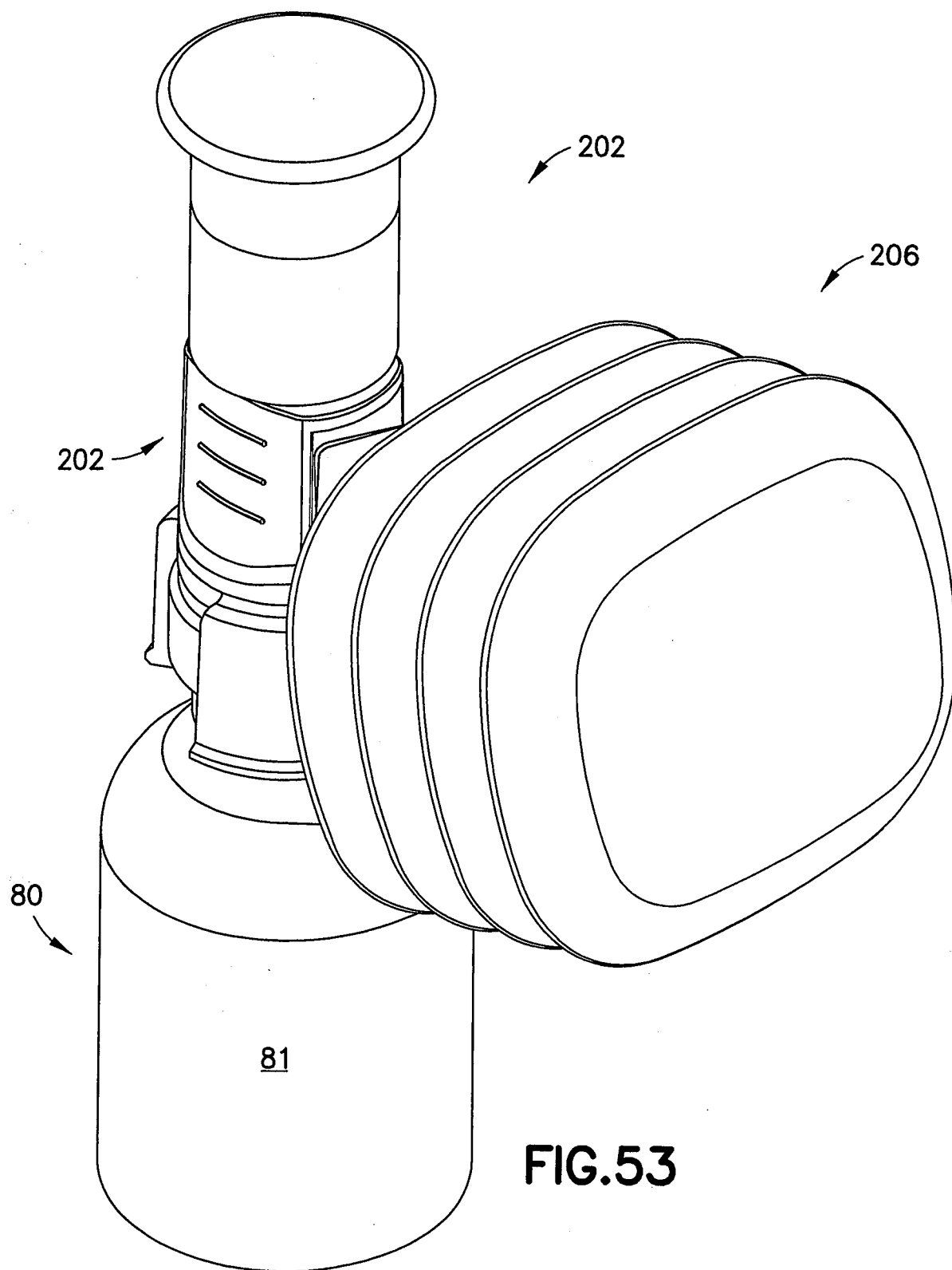
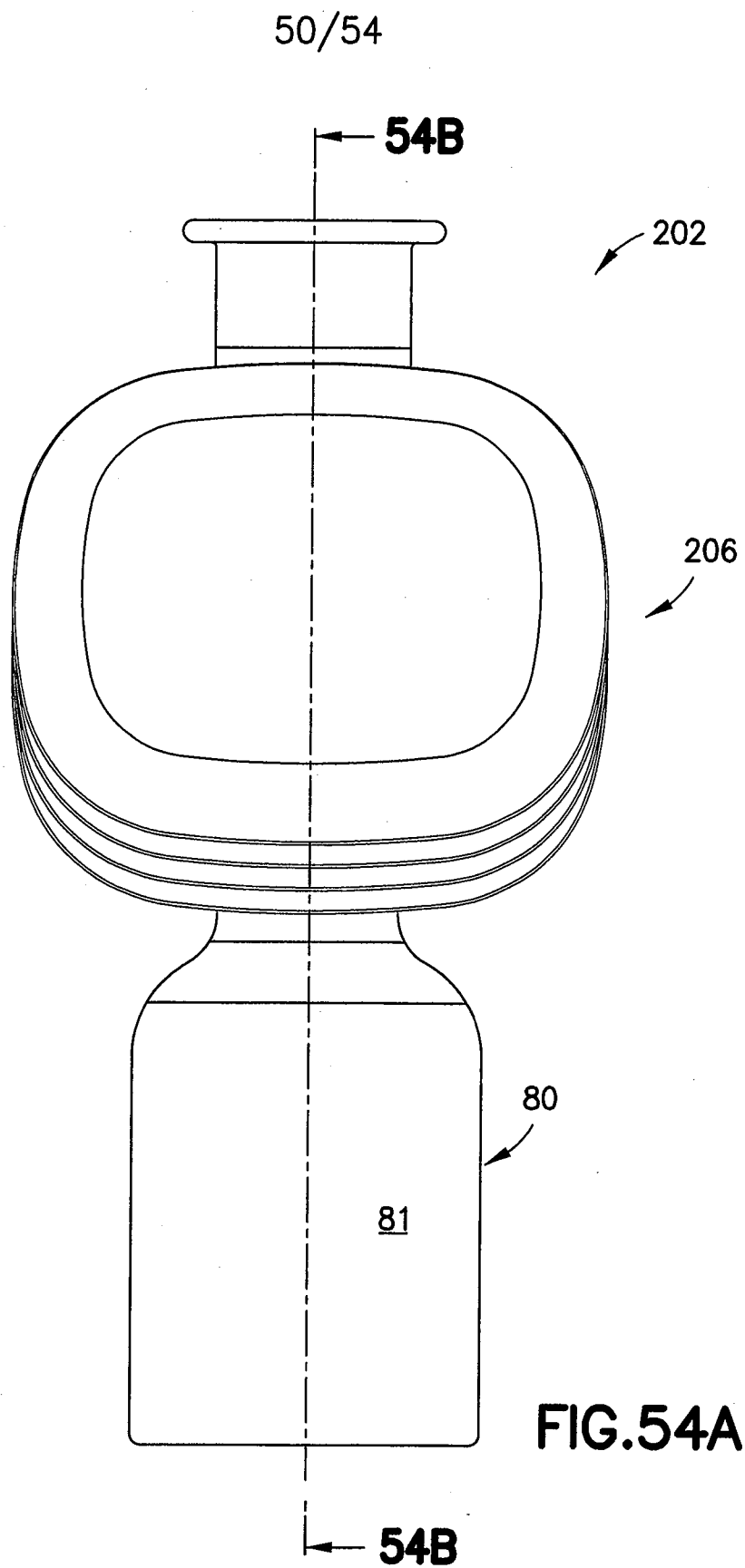


FIG.53



51/54

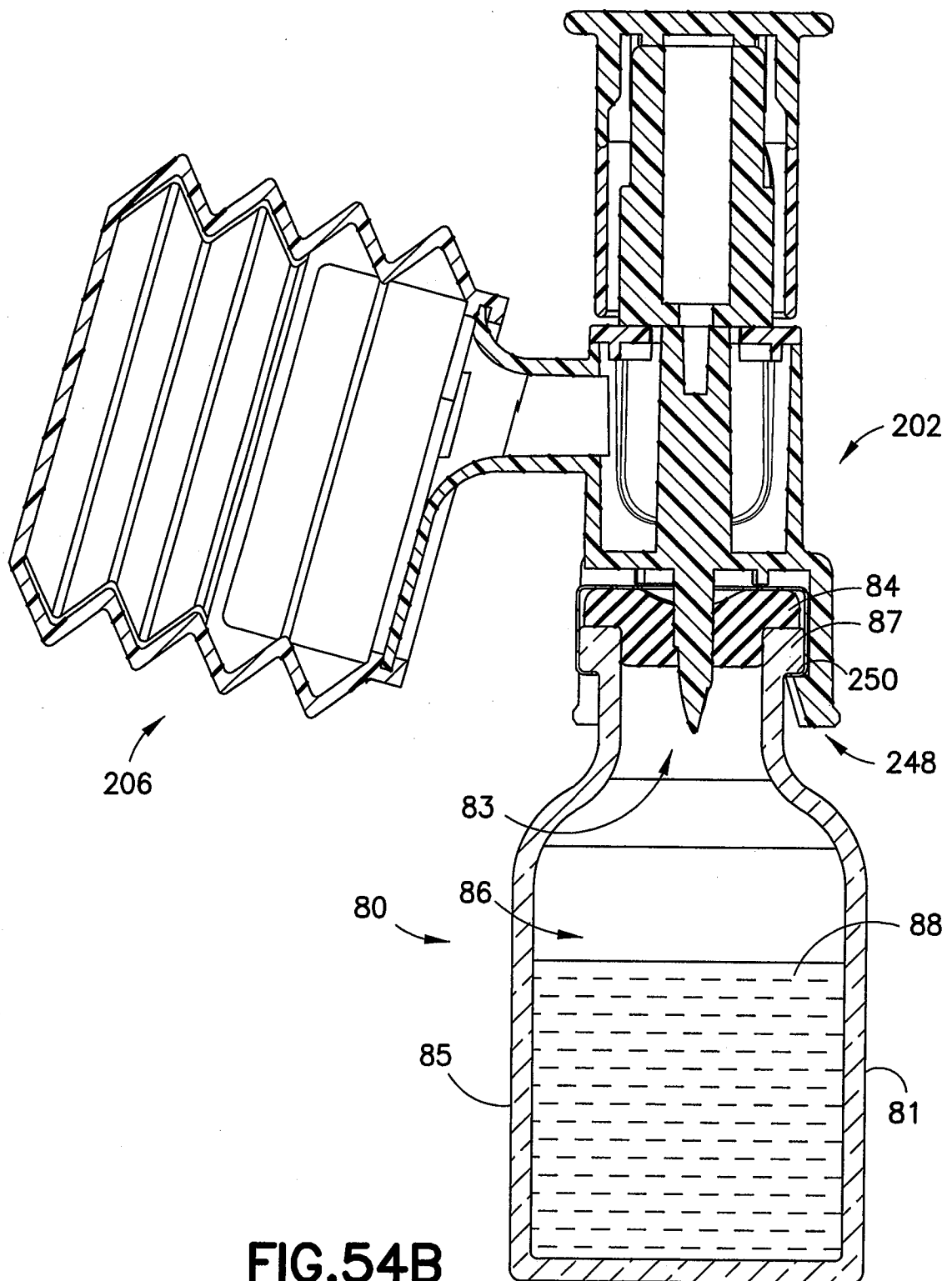
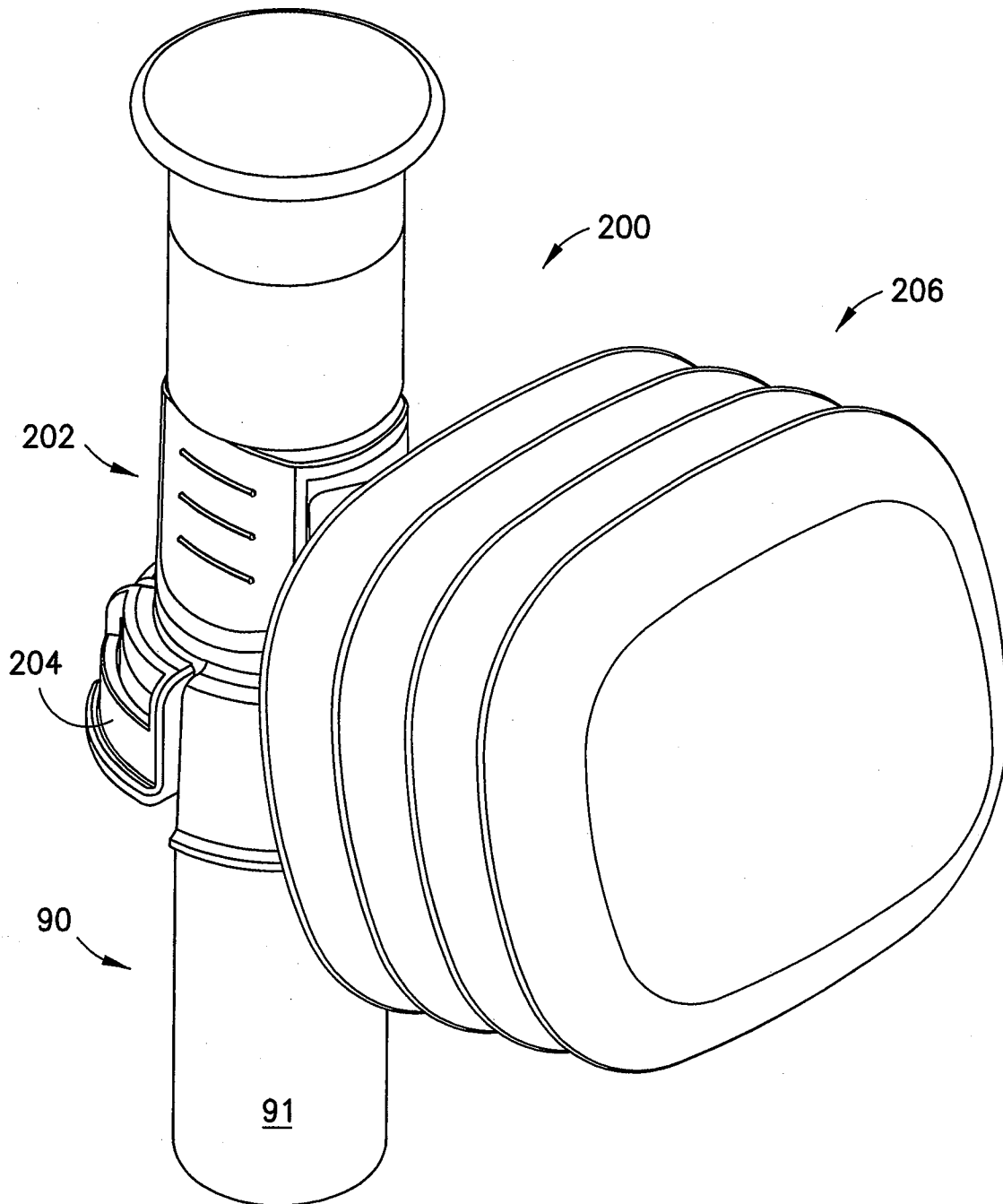
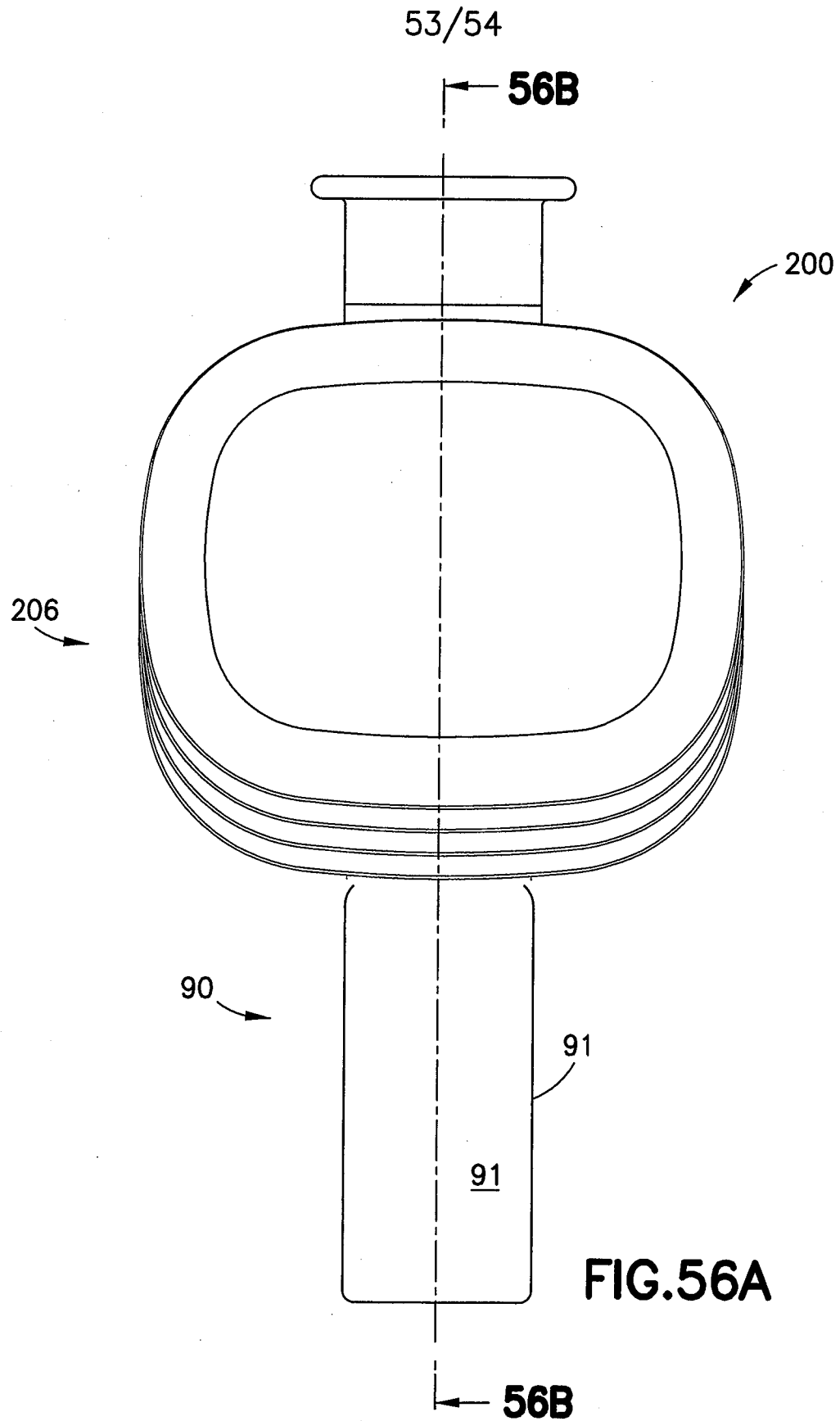


FIG. 54B

52/54



**FIG.55**



54/54

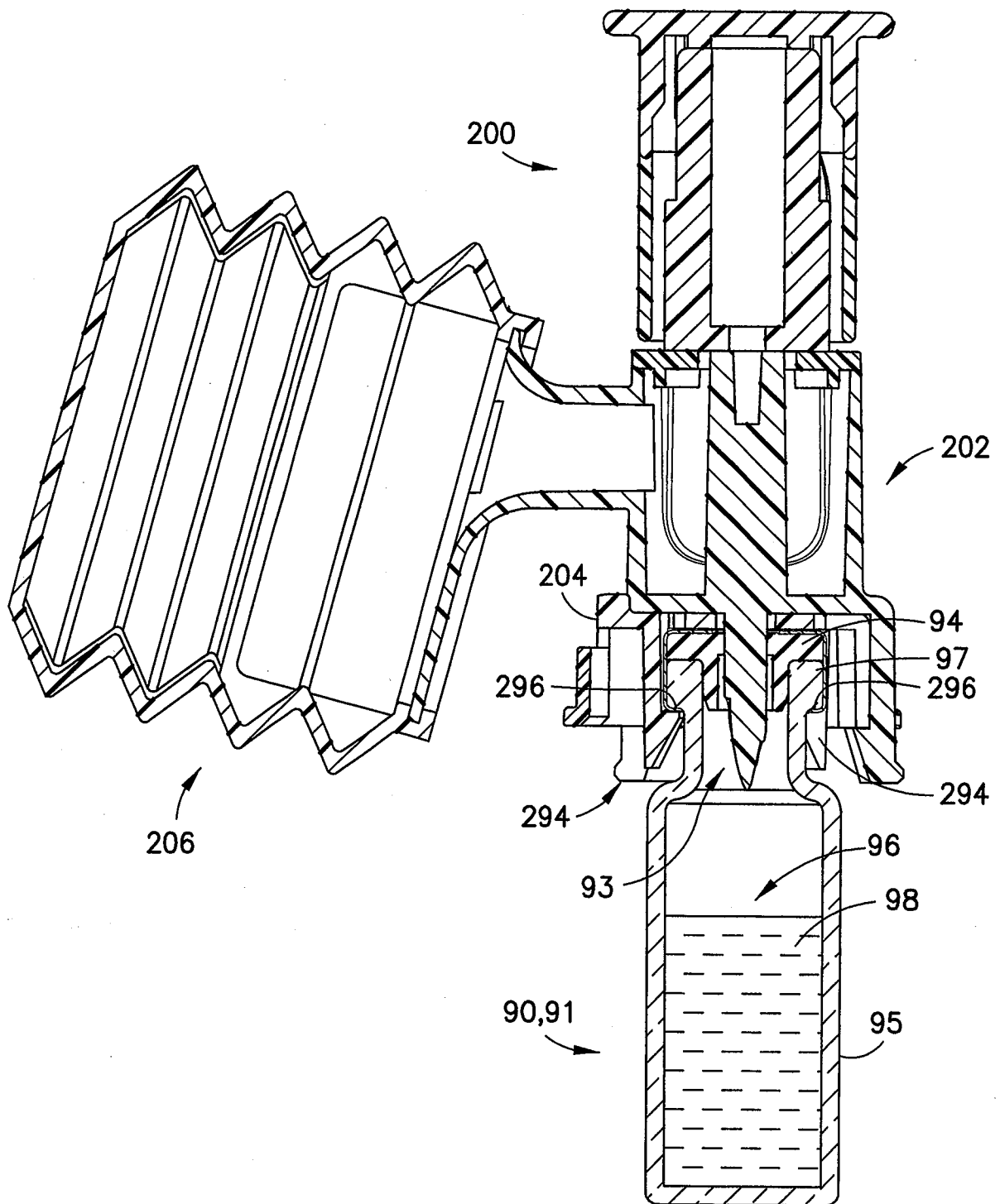


FIG. 56B

## INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2014/063896

A. CLASSIFICATION OF SUBJECT MATTER  
INV. A61J1/20  
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
A61J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 783 879 A2 (BIOJECT INC [US]) 16 July 1997 (1997-07-16)  column 4, lines 29-30; figures 1-3, 6-8, 10-13 column 5, lines 8-14 column 6, lines 18-26 column 7, lines 41-43 column 8, lines 5-26 -----	1,2, 4-13, 15-17
X	US 5 647 845 A (HABER TERRY M [US] ET AL) 15 July 1997 (1997-07-15) column 4, lines 33-42, 55-65; figures 1-2, 4-7 column 5, lines 33-52 column 6, lines 1-11, 31-42 column 7, lines 34-45 ----- -/-	1-3,5-17



Further documents are listed in the continuation of Box C.



See patent family annex.

\* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

17 February 2015

Date of mailing of the international search report

25/02/2015

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040,  
Fax: (+31-70) 340-3016

Authorized officer

Koszewski, Adam

## INTERNATIONAL SEARCH REPORT

International application No

PCT/US2014/063896

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/199139 A1 (FOWLES THOMAS A [US] ET AL) 7 October 2004 (2004-10-07)  paragraph [0025]; figures 1,48-49 -----	1,2,5,6, 8-13, 15-17
X	US 2002/104584 A1 (SPERO RICHARD [US] ET AL) 8 August 2002 (2002-08-08) paragraph [0034]; figures 9-10 -----	1,2,4, 7-13,16



# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2014/063896

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0783879	A2	16-07-1997	AT 240709 T 15-06-2003
		CA 2192623 A1	13-07-1997
		DE 69628275 D1	26-06-2003
		DE 69628275 T2	01-04-2004
		DK 0783879 T3	15-09-2003
		EP 0783879 A2	16-07-1997
		ES 2200041 T3	01-03-2004
		JP 3916713 B2	23-05-2007
		JP H09290012 A	11-11-1997
		PT 783879 E	30-09-2003
		US 5893397 A	13-04-1999
-----			
US 5647845	A	15-07-1997	NONE
-----			
US 2004199139	A1	07-10-2004	AU 2004311934 A1 21-07-2005
		CA 2546842 A1	21-07-2005
		CN 1897908 A	17-01-2007
		EP 1701684 A1	20-09-2006
		JP 2007516037 A	21-06-2007
		KR 20060123372 A	01-12-2006
		MX PA06006476 A	23-08-2006
		US 2004199139 A1	07-10-2004
		US 2005137566 A1	23-06-2005
		US 2008300570 A1	04-12-2008
		WO 2005065625 A1	21-07-2005
		WO 2005065626 A1	21-07-2005
-----			
US 2002104584	A1	08-08-2002	CA 2435339 A1 15-08-2002
		EP 1355612 A1	29-10-2003
		JP 2004524082 A	12-08-2004
		MX PA03006948 A	24-05-2004
		US 2002104584 A1	08-08-2002
		WO 02062288 A1	15-08-2002
-----			