

(19) World Intellectual Property Organization
International Bureau



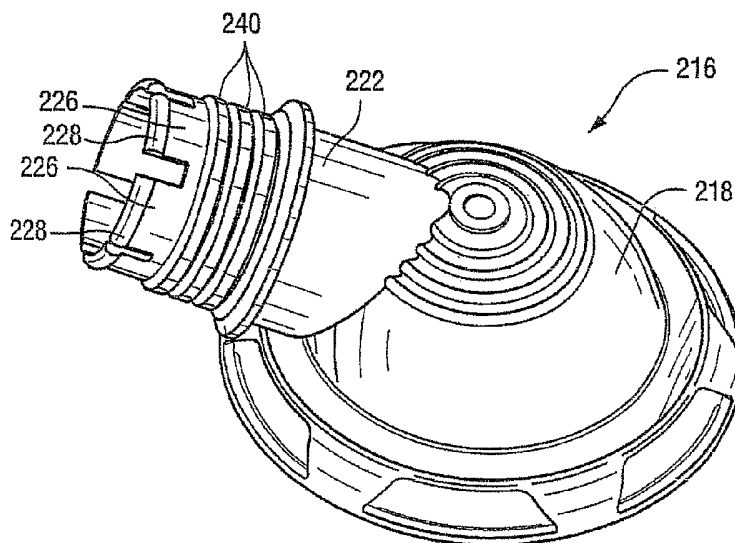
(43) International Publication Date
21 December 2006 (21.12.2006)

PCT

(10) International Publication Number
WO 2006/133480 A1

- (51) International Patent Classification:
A61M 16/06 (2006.01)
- (21) International Application Number:
PCT/AU2006/000768
- (22) International Filing Date: 5 June 2006 (05.06.2006)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/690,870 16 June 2005 (16.06.2005) US
- (71) Applicant (for all designated States except US): **RESMED LIMITED** [AU/AU]; 1 Elizabeth Macarthur Drive, Bella Vista, New South Wales 2153 (AU).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **CRUMBLIN, Geoffrey** [AU/AU]; C/- ResMed Ltd, 1 Elizabeth Macarthur Drive, Bella Vista, New South Wales 2153 (AU). **EDWARDS, Craig, David** [AU/AU]; C/- ResMed Ltd, 1 Elizabeth Macarthur Drive, Bella Vista, New South Wales 2153 (AU). **GUNEY, Memduh** [AU/AU]; C/- ResMed Ltd, 1 Elizabeth Macarthur Drive, Bella Vista, New South Wales 2153 (AU). **JUDSON, Daniel, Robert** [AU/AU]; C/- ResMed Ltd, 1 Elizabeth Macarthur Drive, Bella Vista, New South Wales 2153 (AU). **MARSHALL, Bryony, Louise** [AU/AU]; C/- ResMed Ltd, 1 Elizabeth Macarthur Drive, Bella Vista, New South Wales 2153 (AU).
- (74) Agents: **DAVIDSON, Geoffrey, Robert** et al.; Halford & Co., 1 Market Street, Sydney, New South Wales 2000 (AU).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Declaration under Rule 4.17:**
— of inventorship (Rule 4.17(iv))
- Published:**
— with international search report
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SWIVEL ELBOW FOR MASK ASSEMBLY



(57) Abstract: A swivel elbow (216) for a mask assembly includes an elbow (218) adapted to be provided to the mask assembly and a swivel (20) detachably connected to the elbow (218). The elbow (218) includes a plurality of spaced apart rings (240) that provide a controlled clearance between the elbow (218) and an interior surface of the swivel (20).

WO 2006/133480 A1

SWIVEL ELBOW FOR MASK ASSEMBLY

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 60/690,870, filed June 16, 2005, which is incorporated herein by reference in its entirety.

[0002] Also, U.S. Patent Application No. 11/027,689, filed January 3, 2005, is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0003] The present invention relates to a swivel elbow for use with a mask assembly for Non-invasive Positive Pressure Ventilation (NIPPV) and for continuous positive airway pressure (CPAP) therapy of sleep disordered breathing (SDB) conditions such as obstructive sleep apnea (OSA).

BACKGROUND OF THE INVENTION

[0004] Treatment of sleep disordered breathing (SDB), such as obstructive sleep apnea (OSA), by continuous positive airway pressure (CPAP) flow generator systems involves the continuous delivery of air (or other breathable gas) pressurized above atmospheric pressure to the airways of a human or other mammalian patient via a conduit and a mask. Typically, the mask fits over the mouth and/or nose of the patient. Pressurized air flows to the mask and to the airways of the patient via the nose and/or mouth. As the patient exhales, carbon dioxide gas may collect in the mask. A washout vent in the mask or conduit discharges the exhaled gas from the mask atmosphere.

[0005] Known masks include a swivel elbow provided to the frame. The swivel elbow receives pressurized breathable gas from a suitable source of pressurized air. The leak rate through the swivel elbow forms part of the overall leak rate from the mask, incorporating the vent flow rate and the mask leak at the cushion of the mask. One key purpose of the vent flow rate is to provide sufficient CO₂ washout from the mask. It is advisable to control the flow rate from the mask in order to provide constant known characteristics to the flow generator for prediction of pressure, flow and leakage from the cushion of the mask.

Excessive leakage from the swivel elbow may also lead to noise and disturbance to the patient.

SUMMARY OF THE INVENTION

[0006] One aspect of the invention relates to a swivel elbow that reduces the leak rate at the elbow/swivel interface and reduces the variation in the leak rate at this interface.

[0007] Another aspect of the invention relates to a swivel elbow that allows ease of swivel.

[0008] Another aspect of the invention relates to a swivel elbow for a mask assembly including an elbow adapted to be provided to the mask assembly and a swivel detachably connected to the elbow. The elbow includes a plurality of spaced apart rings that provide a controlled clearance between the elbow and an interior surface of the swivel.

[0009] Another aspect of the invention relates to a swivel elbow for a mask assembly including an elbow adapted to be provided to the mask assembly and a swivel detachably connected to the elbow. The elbow includes a lip seal that provides a controlled interference between the elbow and the swivel.

[0010] Another aspect of the invention relates to a swivel elbow for a mask assembly including an elbow adapted to be provided to the mask assembly and a swivel detachably connected to the elbow. The elbow forms a seal with the swivel at two sealing locations.

[0011] Another aspect of the invention relates to a swivel elbow for a mask assembly including an elbow adapted to be provided to the mask assembly and a swivel detachably connected to the elbow. The swivel includes a lip seal that provides a controlled interference between the elbow and the swivel.

[0012] Yet another aspect of the invention relates to a swivel elbow for a mask assembly including an elbow adapted to be provided to the mask assembly and a swivel detachably connected to the elbow. The elbow includes a saw-toothed or waved shaped exterior surface that is structured to engage in complementary relation a saw-toothed or waved shaped interior surface of the swivel.

[0013] Still another aspect of the invention relates to a swivel elbow for a mask assembly including an elbow adapted to be provided to the mask assembly and a swivel detachably connected to the elbow. The swivel includes a flexible spring arm that provides a controlled interference between the elbow and the swivel.

[0014] Other aspects, features, and advantages of this invention will become apparent from the following detailed description when taken in conjunction with the accompanying drawings, which are a part of this disclosure and which illustrate, by way of example, principles of this invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] The accompanying drawings facilitate an understanding of the various embodiments of this invention. In such drawings:

[0016] Fig. 1 is a front view of a respiratory mask assembly including a swivel elbow;

[0017] Fig. 2 is a side view of the respiratory mask assembly shown in Fig. 1;

[0018] Fig. 3 is a cross-sectional view of the swivel elbow shown in Fig. 1 removed from the respiratory mask assembly;

[0019] Fig. 4 is an enlarged cross-sectional view of the swivel elbow shown in Fig. 3;

[0020] Fig. 5 is an exploded cross-sectional view of the swivel elbow shown in Fig. 1 removed from the respiratory mask assembly;

[0021] Fig. 6 is a cross-sectional view of a swivel elbow constructed according to an embodiment of the present invention;

[0022] Fig. 7a is a perspective view of a swivel elbow constructed according to another embodiment of the present invention;

[0023] Fig. 7b is a cross-sectional view of the swivel elbow shown in Fig. 7a;

[0024] Fig. 8 is a cross-sectional view of the swivel elbow shown in Fig. 7a including a swivel;

[0025] Figs. 9-10 are cross-sectional views of a portion of a swivel elbow constructed according to another embodiment of the present invention in partial and fully connected states;

[0026] Figs. 11-12 are perspective views of a portion of a swivel elbow constructed according to another embodiment of the present invention;

[0027] Figs. 13-15 are cross-sectional views of portion of the swivel elbow shown in Figs. 11-12 in partial and fully connected states;

[0028] Figs. 16-17 are cross-sectional views of a portion of a swivel elbow constructed according to another embodiment of the present invention in partial and fully connected states;

[0029] Figs. 18-19 are cross-sectional views of a portion of a swivel elbow constructed according to another embodiment of the present invention in partial and fully connected states;

[0030] Figs. 20-21 are cross-sectional views of a portion of a swivel elbow constructed according to another embodiment of the present invention in partial and fully connected states;

[0031] Figs. 22-23 are cross-sectional views of a portion of a swivel elbow constructed according to another embodiment of the present invention in partial and fully connected states;

[0032] Figs. 24-25 are cross-sectional views of a portion of a swivel elbow constructed according to another embodiment of the present invention in partial and fully connected states;

[0033] Figs. 26-27 are cross-sectional views of a portion of a swivel elbow constructed according to another embodiment of the present invention in partial and fully connected states;

[0034] Figs. 28-29 are cross-sectional views of a portion of a swivel elbow constructed according to another embodiment of the present invention in partial and fully connected states;

[0035] Figs. 30-31 are cross-sectional views of a portion of a swivel elbow constructed according to another embodiment of the present invention in partial and fully connected states;

[0036] Figs. 32-33 are cross-sectional views of a portion of a swivel elbow constructed according to another embodiment of the present invention in partial and fully connected states;

[0037] Figs. 34-35 are cross-sectional views of a portion of a swivel elbow constructed according to another embodiment of the present invention in partial and fully connected states;

[0038] Figs. 36-37 are cross-sectional views of a portion of a swivel elbow constructed according to still another embodiment of the present invention in partial and fully connected states; and

[0039] Figs. 38-39 are cross-sectional views of a portion of a swivel elbow constructed according to yet another embodiment of the present invention in partial and fully connected states.

DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

1. Related Art Mask Assembly

[0040] Figs. 1-2 illustrate a mask assembly 10 disclosed in U.S. Patent Application No. 11/027,689, filed January 3, 2005, the entirety incorporated herein by reference. As illustrated, the mask assembly 10 includes a frame 12 in the form of a shell, and a cushion 14 that is provided, e.g., attached, to the frame 12. A headgear assembly (not shown) may be removably attached to the frame 14, e.g., via headgear clips 15, to maintain the frame 14 and cushion 14 in a desired adjusted position on the patient's face. A swivel elbow 16 is rotatably coupled or provided to the frame 12. The swivel elbow 16 is structured to be connected to an air delivery tube that delivers breathable gas to the patient.

2. Related Art Swivel Elbow

[0041] Figs. 3-5 show the swivel elbow 16 of the mask assembly 10 in greater detail. The swivel elbow 16 includes an elbow 18 and a swivel 20 rotatably coupled to the elbow 18. As best shown in Figs. 5, the elbow 18 includes an inlet conduit 22 having a hose end 24 with a plurality of resiliently deformable tabs 26 that are structured to allow selective attachment to and detachment from the swivel 20 with a snap-fit. Each tab 26 includes a radially extending protrusion 28 that locks in place within an interior groove 30 of the swivel 20. Figs. 3 and 4 show the assembled position. The elbow 18 is preferably made from a polyester, e.g., natural POCAN®, a Bayer product, although other materials are possible. The swivel 20 may be made of clear polycarbonate, although other materials are possible. Further details of the swivel elbow 16 are provided in the above-noted U.S. Patent Application No. 11/027,689.

3. Swivel Elbows with Leak Restricting Features

[0042] Figs. 1-5 illustrate one embodiment of a swivel elbow 16 having a snap-fit elbow/swivel connection. Figs. 6-39 illustrate additional embodiments of swivel elbows that provide leak restricting features to improve the seal between the elbow and the swivel and to obtain a desired or controlled leak rate. While aspects of the invention are described with reference to a swivel elbow of the type described above, it is also applicable to other swivel elbows or other swivel conduits. That is, the swivel elbow is merely exemplary, and the sealing relationship between the swivel and the elbow may be incorporated into other swivel elbows or other swivel conduits of any suitable mask assembly, e.g., full-face mask, mouth mask, or a nasal mask.

[0043] As described in greater detail below, the leak restricting feature (e.g., leak restrictor) is provided at the swivel/elbow interface and may be in the form of a controlled clearance, a controlled interference, and/or a longer sealing path. It is noted that Figs. 9-39 show portions of a swivel elbow, e.g., a swivel and an end portion of an elbow. It should be understood that the remaining portion of the swivel may be similar to the swivel elbow of the type describe above or any other suitable swivel elbow or swivel conduit.

3.1 Controlled Clearance Between Swivel/Elbow

[0044] To control the leak rate between the swivel and the elbow, the swivel interface of the elbow may be provided with a controlled clearance that does not significantly effect the ease of rotation.

3.1.1 Separate Rings in the Sealing Diameter

[0045] In order to provide an enhanced sealing capacity between the elbow and the existing swivel, the elbow may incorporate at least one sealing ring of approximately the same wall thickness as the rest of the elbow. This arrangement improves the moldability of the part, and therefore improves the roundness and enhances the sealing capacity with the existing swivel 20.

[0046] One embodiment of this aspect of the invention is shown in Fig. 6. As illustrated, the inlet conduit 222 of the elbow 218 includes a sealing ring 240 that provides a controlled small clearance of about 0.05-0.3mm between the elbow 218 and the swivel 20.

Undercut U allows the sealing ring 240 to maintain a thickness similar to the rest of the elbow 218 and this in turn allows the length L of the sealing ring 240 to be greater than the thickness of the elbow 218. The increased length of the sealing ring 240 increases the length of small clearance and hence reduces leakage flow.

[0047] Figs. 7a, 7b, and 8 illustrate a swivel elbow 216 constructed according to another exemplary embodiment of the present invention. As illustrated, the inlet conduit 222 of the elbow 218 includes three separate rings 240 in the sealing interface or sealing diameter region. This arrangement provides a controlled clearance of about 0.05-0.3mm between the elbow 218 diameter and the swivel 20 diameter. The controlled clearance helps to reduce the leak rate and control the variation in the leak rate between these two parts.

[0048] Specifically, the sealing diameter region of the elbow 218 is split into three separate rings 240 each having a width of about 1mm and spaced apart from one another by about 1.2mm. This arrangement maintains uniform wall sections throughout the elbow 218 to improve the moldability and therefore control clearance. The remaining portions of the inlet conduit 222 remain substantially similar to the inlet conduit 22, e.g., resiliently deformable tabs 226 with protrusions 228 to allow selective attachment to and detachment from the swivel 20 with a snap-fit. Fig. 8 shows the assembled position. It is noted that any suitable number of rings 240 may be provided, e.g., less than or greater than three rings.

[0049] In the illustrated embodiment, the swivel elbow 216 controls leak without significantly increasing the rotational resistance. Additionally, the width of the collar 244 at the outer rim may be reduced, or the draft angle on the back face of the collar 244 may be reduced in order to reduce the wall section in this area of the elbow 218 to improve the moldability of the part. Indeed, a further embodiment may have no collar 244.

3.2. Controlled Interference or Interface Between Swivel/Elbow With Lip Seal

[0050] Instead of controlling the clearance between the elbow and the swivel as described above in Figs. 6-8, a controlled interference or interface in the form of an insert molded (co-molded) lip seal may be provided to maintain the rotational resistance between the elbow and the swivel at required limits. This controlled interface provides a constricted flow path to improve seal. In the illustrated embodiments, the lip seal is formed of a TPE material (thermoplastic elastomer) or a similar suitable material.

3.2.1 Insert Molded TPE (Internal Lip)

[0051] Figs. 9-10 illustrates a swivel elbow 316 constructed according to another exemplary embodiment of the present invention. As illustrated, a lip seal 350 is provided on the elbow 318. In an embodiment, the lip seal 350 is formed of a TPE material and is insert molded to the elbow 318. The lip seal 350 is an internal lip seal in that the lip seal 350 forms a seal with the interior surface 32 of the existing swivel 20. The lip seal 350 improves sealing between the elbow 318 and the swivel 20 without significantly increasing the rotational resistance. Also, the design or material of the swivel 20 does not need to be modified. Further, the internal lip seal 350 is relatively small and positioned between the elbow the swivel so it will not be susceptible to user abuse.

[0052] When the swivel 20 is coupled to the elbow 318, the swivel 20 is moved towards the elbow 318 until the protrusion 328 engages with the groove 30 of the swivel 20 with a snap-fit. Moreover, the lip seal 350 engages the interior surface 32 of the swivel 20 and resiliently deforms to form a seal. Fig. 10 shows the assembled position. As illustrated, the leak path between the elbow 318 and the swivel 20 is restricted by the internal lip seal 350. The lip seal 350 contacts the interior surface 32 of the swivel 20 under pressure, but does not substantially increase the rotational resistance.

3.2.1.1 Mechanical Locked Insert Molded TPE (Internal Lip)

[0053] The lip seal described above may be provided on the elbow by an insert molding process that includes mechanical locking as well. This allows a large range of material to choose from including existing materials (e.g., POCAN® for the elbow) that do not require chemical bonding. For example, Figs. 11-15 illustrate an embodiment of swivel elbow 416 having an elbow 418 with a mechanical locked insert molded lip seal 450.

[0054] As illustrated, the lip seal 450, e.g., formed of a TPE material or other suitable material, includes a seal portion 452, a tube portion 454, and locking portions 456. When the lip seal 450 is insert molded to the elbow 418, the locking portions 456 interlock with openings 458 provided in the elbow 418. As shown in Figs. 14-15, the seal portion 452 of the lip seal 450 engages the interior surface 32 of the swivel 20 and resiliently deforms to form a seal.

3.2.2 Insert Molded TPE (External Lip)

[0055] Figs. 16-17 illustrate a swivel elbow 516 constructed according to another exemplary embodiment of the present invention. As illustrated, a lip seal 550 is provided on the elbow 518. In an embodiment, the lip seal 550 is formed of a TPE material or other suitable material and is insert molded to the elbow 518. The lip seal 550 is an external lip seal in that the lip seal 550 is structured to form a seal with the exterior surface 34 of the existing swivel 20. The lip seal 550 improves sealing between the elbow 518 and the swivel 20 without significantly increasing the rotational resistance. Also, the design or material of the swivel 20 does not need to be modified.

[0056] When the swivel 20 is coupled to the elbow 518, the swivel 20 is moved towards the elbow 518 until the protrusion 528 engages with the groove 30 of the swivel 20 with a snap-fit. Moreover, the lip seal 550 engages the exterior surface 34 of the swivel 20 and resiliently deforms to form a seal. Fig. 17 shows the assembled position. As illustrated, the leak path between the elbow 518 and the swivel 20 is restricted by the external lip seal 550. The lip seal 550 contacts the exterior surface 34 of the swivel 20 under pressure, but does not substantially increase the rotational resistance.

[0057] The lip seal 550 may be provided on the elbow by an insert molding process that includes mechanical locking as well, similar to the lip seal 450. This allows a large range of material to choose from including existing materials (e.g., POCAN® for the elbow) that do not require chemical bonding. The structure of the elbow 518 may change to include lip locking features, e.g., openings.

3.2.3 Insert Molded TPE (Axial Lip)

[0058] Figs. 18-19 illustrate a swivel elbow 616 constructed according to another exemplary embodiment of the present invention. As illustrated, a lip seal 650 is provided on the elbow 618. In an embodiment, the lip seal 650 is formed of a TPE material and is insert molded to the elbow 618. The lip seal 650 is an axial lip seal in that the lip seal 650 is structured to form a seal with the front face surface 36 (in the axial direction) of the existing swivel 20. The lip seal 650 improves sealing between the elbow 618 and the swivel 20 without significantly increasing the rotational resistance. Also, the design or material of the swivel 20 does not need to be modified.

[0059] When the swivel 20 is coupled to the elbow 618, the swivel 20 is moved towards the elbow 618 until the protrusion 628 engages with the groove 30 of the swivel 20 with a snap-fit. Moreover, the lip seal 650 engages the front face surface 36 of the swivel 20 and resiliently deforms to form a seal. Fig. 19 shows the assembled position. As illustrated, the leak path between the elbow 618 and the swivel 20 is restricted by the external lip seal 650. The lip seal 650 contacts the front face surface 36 of the swivel 20 under pressure, but does not substantially increase the rotational resistance.

[0060] The lip seal 650 may be provided on the elbow by an insert molding process that includes mechanical locking as well, similar to the lip seal 450. This allows a large range of material to choose from including existing materials (e.g., POCAN® for the elbow) that do not require chemical bonding. The structure of the elbow 618 may change to include lip locking features, e.g., openings.

3.3 Controlled Interference or Interface Between Swivel/Elbow With Flexible Spring Arm

[0061] A controlled interference or interface between the swivel and the elbow may also be provided by a flexible spring arm. This flexible spring arm introduces interference to provide a constricted flow path to improve seal. In embodiments, the flexible spring arm may be made with a more flexible material, e.g., polypropylene, instead of existing polycarbonate or POCAN® materials or any other suitable material to reduce the stiffness of the spring arm and introduce interference to improve the sealing feature.

3.3.1 Encapsulated Swivel End

[0062] Figs. 20-21 illustrate a swivel elbow 716 constructed according to another exemplary embodiment of the present invention. As illustrated, a flexible spring arm 760 is provided on the elbow 718. In the illustrated embodiment, the flexible spring arm 760 is formed in one-piece along with the elbow 718. The flexible spring arm 760 allows the elbow 718 to encapsulate the end of the existing swivel 20 so as to form a seal with interior and exterior surfaces 32, 34 of the existing swivel 20. The flexible spring arm 760 improves sealing between the elbow 718 and the swivel 20 without significantly increasing the rotational resistance. Also, the design or material of the swivel 20 does not need to be modified.

[0063] As illustrated, the flexible spring arm 760 forms a tapered slot or groove 762 in the elbow 718 to encapsulate the end of the swivel 20. The tapered slot 762 is defined by inner and outer tapered surfaces 764, 766. In an embodiment, the outer tapered surface 766 is steeper than the inner tapered surface 764 and contacts the swivel 20 first during assembly.

[0064] When the swivel 20 is coupled to the elbow 718, the swivel 20 is moved towards the elbow 718 until the protrusion 728 engages with the groove 30 of the swivel 20 with a snap-fit. Moreover, the inner and outer tapered surfaces 764, 766 engage interior and exterior surfaces 32, 34 of the swivel 20 to form a seal. The flexible spring arm 760 may flex as the swivel 20 is snap-fit to the elbow 718, which provides an interference fit between the tapered surfaces 764, 766 and the swivel 20. Thus, the elbow 718 encapsulates the end of the swivel 20 and uses interference at two edge contacts to provide two point contact seals. Fig. 21 shows the assembled position. The two seals in series not only improve seal, but also create greater leak resistance to any leaking air.

[0065] While there is interference between the elbow 718 and the swivel 20 to create a seal, the contact areas are relatively small. Therefore, the friction torque between the elbow 718 and the swivel 20 is not substantial so as to substantially increase the rotational resistance.

[0066] Because the flexible spring arm 760 is formed in one-piece along with the elbow 718, existing materials (e.g., POCAN® for the elbow) may be used. Also, geometric inaccuracies in the elbow 718 (e.g., parallelism and roundness) are accommodated by the tapered surfaces 764, 766 and interference fit.

3.3.2 Encapsulated Swivel End with Spring-Arm Seal

[0067] Figs. 22-23 illustrate a swivel elbow 816 constructed according to another exemplary embodiment of the present invention. As illustrated, a flexible spring arm 860 is provided on the elbow 818. In the illustrated embodiment, the flexible spring arm 860 is formed in one-piece along with the elbow 818. The flexible spring arm 860 allows the elbow 818 to encapsulate the end of the existing swivel 20 and form a seal with the existing swivel 20 at two sealing locations. The flexible spring arm 860 improves sealing between the elbow 818 and the swivel 20 without significantly increasing the rotational resistance. Also, the design or material of the swivel 20 does not need to be modified.

[0068] As illustrated, the flexible spring arm 860 is in the form of a thin-walled cylindrical section that forms a slot 862 in the elbow 818 to encapsulate the end of the swivel 20. When the swivel 20 is coupled to the elbow 818, the swivel 20 is moved towards the elbow 818 until the protrusion 828 engages with the groove 30 of the swivel 20 with a snap-fit. Moreover, the inner surface 864 of the slot 862 engages the interior surface 32 of the swivel 20 to form a seal, and the flexible spring arm 860 includes a protrusion 866 that engages the exterior surface 34 of the swivel 20 to form a seal. The flexible spring arm 860 may flex as the swivel 20 is snap-fit to the elbow 818, which provides an interference fit between the protrusion 866 and the swivel 20. Thus, the elbow 818 encapsulates the end of the swivel 20 and provides two contact seals.

[0069] The first seal is a controlled clearance annular flow seal between inner surface 864 and interior surface 32. The second seal is a relatively light interference seal between protrusion 866 and exterior surface 34. The designed-in flexibility of the flexible spring arm 860 is intended to allow a relatively stiff material, e.g., such as POCAN®, to provide a relatively small interference force at the outer seal location, which is fairly insensitive to tolerance control. Fig. 23 shows the assembled position. The two seals in series not only improve seal, but also create greater leak resistance to any leaking air.

[0070] While there is interference between the elbow 818 and the swivel 20 to create a seal, the contact areas and interference force are relatively small. Therefore, the friction torque between the elbow 818 and the swivel 20 is not substantial so as to substantially increase the rotational resistance.

[0071] Because the flexible spring arm 860 is formed in one-piece along with the elbow 818, existing materials (e.g., POCAN® for the elbow) may be used. Also, geometric inaccuracies in the elbow 818 (e.g., parallelism and roundness) are catered for by the flexibility of the spring arm 860.

3.3.3 Lip on Swivel at Sealing Land

[0072] Figs. 24-27 illustrate swivel elbows 916 constructed according to another exemplary embodiment of the present invention. As illustrated, a lip seal 950 is provided on the swivel 920. In the illustrated embodiment, the lip seal 950 is formed in one-piece along with the swivel 920. The lip seal 950 allows the swivel 920 to form a seal with the existing

elbow 18 at the sealing land 38 of the elbow 18. The lip seal 950 improves sealing between the elbow 18 and the swivel 920 without significantly increasing the rotational resistance. Also, the design or material of the elbow 18 does not need to be modified.

[0073] As shown in Figs. 24 and 25, the lip seal 950 may have a rounded configuration. Alternatively, as shown in Figs. 26 and 27, the lip seal 950 may have a sharper or more pointed configuration. Other configurations are also possible.

[0074] When the swivel 920 is coupled to the elbow 18, the swivel 920 is moved towards the elbow 18 until the protrusion 28 engages with the groove 930 of the swivel 920 with a snap-fit. Moreover, the lip seal 950 engages the sealing land 38 of the elbow 18 and resiliently deforms to form a seal. Figs. 25 and 27 show the assembled positions of both lip seal configurations. As illustrated, the leak path between the elbow 18 and the swivel 920 is restricted by the lip seal 950. The lip seal 950 contacts the sealing land 38 of the elbow 18 under pressure, but does not substantially increase the rotational resistance.

[0075] Both sealing lip configurations use a lip seal 950 to create interference between the swivel 920 and the sealing land 38 of the elbow 18. The main difference between the two configurations is in the amount of contact pressure generated between the lip seal 950 and the sealing land 38. For example, because the sharper lip seal 950 has a smaller contact area with the elbow 18, it creates greater contact pressure and hence more interference and presumably better seal. In an embodiment, the sharper lip seal 950 of the swivel 920 may create a very small groove in the sealing land 38 of the elbow 18 which may help to even out the effects of poor roundness and further improve the seal.

[0076] While there is interference between the elbow 18 and the swivel 920 to create a seal, the contact areas and interference force are relatively small. Therefore, the friction torque between the elbow 18 and the swivel 920 is not substantial so as to substantially increase the rotational resistance.

[0077] Because the lip seal 950 is formed in one-piece along with the swivel 920, existing materials (e.g., polycarbonate for the swivel) may be used. Also, geometric inaccuracies in the elbow 18 (e.g., parallelism and roundness) are catered for by the interference fit.

3.4 Long Sealing Path Between Swivel/Elbow To Provide a Constricted Flow Path

[0078] A long sealing path or more tortuous sealing path may be provided between the elbow and the swivel to control the inadvertent leak between these parts.

3.4.1 Long Sealing Path – External Seal Only

[0079] Figs. 28-31 illustrate swivel elbows 1016 constructed according to another exemplary embodiment of the present invention. As illustrated, a saw-tooth shaped sealing land 1070 is provided on the swivel 1020 and a saw-tooth shaped sealing land 1072 is provided on the elbow 1018. In the illustrated embodiment, the sealing land 1070 is formed in one-piece along with the swivel 1020 and the sealing land 1072 is formed in one-piece along with the elbow 1018. The saw-tooth shaped sealing lands 1070, 1072 compensate for poor geometric accuracy in the elbow 1018 by introducing a tortuous flow path for the leaking air. The saw-tooth shaped sealing lands 1070, 1072 improve sealing between the swivel 1020 and the elbow 1018 without significantly increasing the rotational resistance.

[0080] In the illustrated embodiment, the sealing lands 1070, 1072 have complementary saw-tooth configurations. As illustrated, each sealing land 1070, 1072 has about 3 saw teeth. However, any suitable number of saw teeth may be provided, e.g., 1, 2, or 3 saw teeth. Alternatively, the sealing lands 1070, 1072 may have complementary wave-like configurations as shown in Figs. 30-31. Other configurations are also possible.

[0081] When the swivel 1020 is coupled to the elbow 1018, the swivel 1020 is moved towards the elbow 1018 until the protrusion 1028 engages with the groove 1030 of the swivel 1020 with a snap-fit. Moreover, the sealing lands 1070, 1072 engage with one another in a complimentary relation to form a seal. The design of the saw-tooth or wave profile generates a relatively light detent feel as the parts pass over each other during assembly & disassembly. Figs. 29 and 31 show the assembled positions of both configurations. As illustrated, the leak path between the elbow 1018 and the swivel 1020 is saw-like, wave-like, or tortuous.

[0082] As pressure is introduced to the mask, the elbow 1018 and swivel 1020 may tend to separate axially from each other until restrained by contact between the saw-tooth shaped sealing lands 1070, 1072. This contact will further aid the seal that is generated by the tortuous flow path.

[0083] Because the saw-tooth or wave shaped sealing lands 1070, 1072 are formed in one-piece along with the swivel 1020 and the elbow 1018, existing materials (e.g., POCAN® for the elbow and polycarbonate for the swivel) may be used or some other suitable material. Also, the interference between the elbow 1018 and the swivel 1020 is not substantial so as to substantially increase the rotational resistance.

3.4.2 Inner and Outer Seal with Existing Elbow

[0084] Figs. 32-35 illustrate swivel elbows 1116 constructed according to another exemplary embodiment of the present invention. As illustrated, a flexible spring arm 1160 is provided on the swivel 1120. In the illustrated embodiment, the flexible spring arm 1160 is formed in one-piece along with the swivel 1160. The flexible spring arm 1160 allows the swivel 1120 to encapsulate the end of the existing elbow 18 and form a seal with the existing elbow 18 at two sealing locations. The flexible spring arm 1160 improves sealing between the elbow 18 and the swivel 1120 without significantly increasing the rotational resistance. Also, the design or material of the elbow 18 does not need to be modified.

[0085] As shown in Figs. 32 and 33, the flexible spring arm 1160 may have a planar or flat sealing surface. Alternatively, as shown in Figs. 34 and 35, the flexible spring arm 1160 may have a protrusion or lip 1166 that provides a sealing surface. Other configurations are also possible.

[0086] The flexible spring arm 1160 forms a slot 1162 in the swivel 1120 to encapsulate the end of the elbow 18. When the swivel 1120 is coupled to the elbow 18, the swivel 1120 is moved towards the elbow 18 until the protrusion 28 engages with the groove 1130 of the swivel 1120 with a snap-fit. Moreover, the inner surface 1164 of the swivel 1120 engages the exterior sealing land 72 of the elbow 18 to form a seal, and the flexible spring arm 1160 engages the interior surface 74 of the elbow 18 to form a seal. Thus, the swivel 1120 encapsulates the end of the elbow 18 and provides two contact seals. Figs. 33 and 35 show the assembled positions of both spring arm configurations. The two seals in series not only improve seal, but also create greater leak resistance to any leaking air.

[0087] While there is interference between the elbow 18 and the swivel 1120 to create a seal, the contact areas and interference force are relatively small. Therefore, the friction

torque between the elbow 18 and the swivel 1120 is not substantial so as to substantially increase the rotational resistance.

[0088] Because the flexible spring arm 1160 is formed in one-piece along with the swivel 1120, existing materials (e.g., polycarbonate for the swivel) may be used. Also, the swivel design shown in Figs. 34-35 may provide easier removal of the swivel from a mold core.

3.4.3 Inner and Outer Seal – Relocated Snap

[0089] Figs. 36-39 illustrate swivel elbows 1216 constructed according to yet another exemplary embodiment of the present invention. As illustrated, the location of the snap-fit and sealing have been swapped with respect to swivel elbows described above, e.g., Figs. 32-35. Specifically, a flexible spring arm 1260 is provided on a non-patient end of the swivel 1220, and a protrusion 1228 is provided on a patient end of the swivel 1220. Also, a groove 1230 is provided on an inner portion of the inlet conduit 1222 of the elbow 1218, and inner and outer sealing protrusions 1280, 1282 are provided on inner and outer surfaces of the outer portion of the inlet conduit 1222. Alternatively, the inner and outer surfaces of the outer portion of the inlet conduit 1222 may have substantially flat sealing lands 1280, 1282 for a controlled clearance seal as shown in Figs. 38-39. Other configurations are also possible.

[0090] In the illustrated embodiment, the flexible spring arm 1260 is formed in one-piece along with the swivel 1220, and the sealing lands 1280, 1282 are formed in one-piece along with the elbow 1218. The flexible spring arm 1260 allows the swivel 1220 to encapsulate the end of the elbow 1218 and form a seal with the elbow 1218 at two sealing locations. The flexible spring arm 1260 improves sealing between the elbow 1218 and the swivel 1220 without significantly increasing the rotational resistance.

[0091] The flexible spring arm 1260 forms a slot 1262 in the swivel 1220 to encapsulate the end of the elbow 1218. When the swivel 1220 is coupled to the elbow 1218, the swivel 1220 is moved towards the elbow 1218 until the protrusion 1228 engages with the groove 1230 of the elbow 1218 with a snap-fit. Moreover, the inner surface 1264 of the swivel 1220 engages the outer sealing lands 1282 of the elbow 1218 to form a seal, and the flexible spring arm 1260 engages the inner sealing lands 1280 of the elbow 1218 to form a seal. Thus, the swivel 1220 encapsulates the end of the elbow 1218 and provides two contact

seals. Figs. 37 and 39 show the assembled positions of both configurations. The two seals in series not only improve seal, but also create greater leak resistance to any leaking air. As illustrated in Figs. 36-37, the leak path between the elbow 1218 and the swivel 1220 is wave-like or tortuous.

[0092] While there is interference between the elbow 1218 and the swivel 1220 to create a seal, the contact areas and interference force are relatively small. Therefore, the friction torque between the elbow 1218 and the swivel 1220 is not substantial so as to substantially increase the rotational resistance.

[0093] Because the flexible spring arm 1260 is formed in one-piece along with the swivel 1220 and the sealing lands 1280, 1282 are formed in one-piece along with the elbow 1218, existing materials (e.g., POCAN® for the elbow and polycarbonate for the swivel) may be used. Also, the swivel design may provide easier removal of the swivel from a mold core.

[0094] While the invention has been described in connection with what are presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments, but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the invention. Also, the various embodiments described above may be implemented in conjunction with other embodiments, e.g., aspects of one embodiment may be combined with aspects of another embodiment to realize yet other embodiments. In addition, while the invention has particular application to patients who suffer from OSA, it is to be appreciated that patients who suffer from other illnesses (e.g., congestive heart failure, diabetes, morbid obesity, stroke, bariatric surgery, etc.) can derive benefit from the above teachings. Moreover, the above teachings have applicability with patients and non-patients alike in non-medical applications.

WHAT IS CLAIMED IS:

1. A swivel elbow for a mask assembly, comprising:
an elbow adapted to be provided to the mask assembly; and
a swivel detachably connected to the elbow,
wherein the elbow includes a plurality of spaced apart rings that provide a controlled clearance between the elbow and an interior surface of the swivel.
2. The swivel elbow according to claim 1, wherein one of the elbow and the swivel includes a radially extending protrusion that locks in place within a groove provided in the other of the elbow and the swivel with a snap-fit.
3. The swivel elbow according to any one of claims 1-2, wherein the elbow includes three spaced apart rings.
4. A swivel elbow for a mask assembly, comprising:
an elbow adapted to be provided to the mask assembly; and
a swivel detachably connected to the elbow,
wherein the elbow includes a lip seal that provides a controlled interference between the elbow and the swivel.
5. The swivel elbow according to claim 4, wherein the lip seal is an internal lip seal structured to form a seal with an interior surface of the swivel.
6. The swivel elbow according to claim 4, wherein the lip seal is an external lip seal structured to form a seal with an exterior surface of the swivel.
7. The swivel elbow according to claim 4, wherein the lip seal is an axial lip seal structured to form a seal with a front face surface of the swivel.
8. The swivel elbow according to any one of claims 4-7, wherein the lip seal is inset molded onto the elbow.

9. The swivel elbow according to any one of claims 4-8, wherein the lip seal is mechanically locked to the elbow.
10. The swivel elbow according to any one of claims 4-9, wherein the lip seal is formed of a thermoplastic elastomer material.
11. A swivel elbow for a mask assembly, comprising:
an elbow adapted to be provided to the mask assembly; and
a swivel detachably connected to the elbow,
wherein the elbow forms a seal with the swivel at two sealing locations.
12. The swivel elbow according to claim 11, wherein the elbow includes a flexible spring arm that provides a controlled interference between the elbow and the swivel.
13. The swivel elbow according to claim 12, wherein the flexible spring arm forms a slot to encapsulate an end of the swivel.
14. The swivel elbow according to any one of claims 12-13, wherein the flexible spring arm includes a protrusion that forms a seal with the swivel.
15. A swivel elbow for a mask assembly, comprising:
an elbow adapted to be provided to the mask assembly; and
a swivel detachably connected to the elbow,
wherein the swivel includes a lip seal that provides a controlled interference between the elbow and the swivel.
16. The swivel elbow according to claim 15, wherein the lip seal is structured to form a seal with an exterior surface of the elbow.
17. A swivel elbow for a mask assembly, comprising:
an elbow adapted to be provided to the mask assembly; and

a swivel detachably connected to the elbow,
wherein the elbow includes a saw-toothed or waved shaped exterior surface that is structured to engage in complementary relation a saw-toothed or waved shaped interior surface of the swivel.

18. A swivel elbow for a mask assembly, comprising:
an elbow adapted to be provided to the mask assembly; and
a swivel detachably connected to the elbow,
wherein the swivel includes a flexible spring arm that provides a controlled interference between the elbow and the swivel.
19. The swivel elbow according to claim 18, wherein the flexible spring arm forms a slot to encapsulate an end of the elbow.
20. The swivel elbow according to any one of claims 18-19, wherein the elbow forms a seal with the swivel at two sealing locations.
21. The swivel elbow according to any one of claims 18-20, wherein the flexible spring arm includes a protrusion that forms a seal with the elbow.
22. The swivel elbow according to any one of claims 18-20, wherein the elbow includes protrusions on interior and exterior surfaces thereof that form a seal with the swivel.
23. A mask assembly for a patient, comprising:
a frame;
a cushion provided to the frame; and
a swivel elbow according to any one of claims 1-22 provided to the frame.

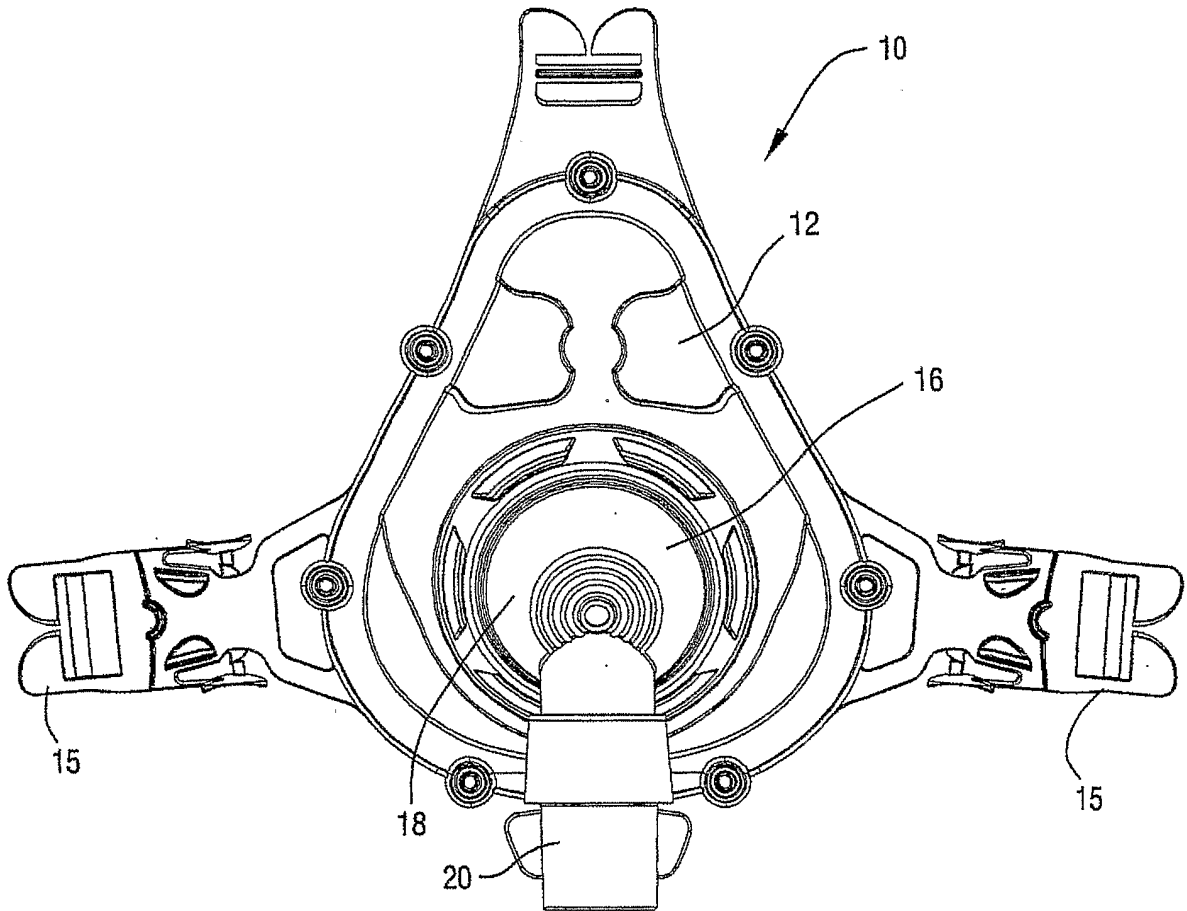


Fig. 1

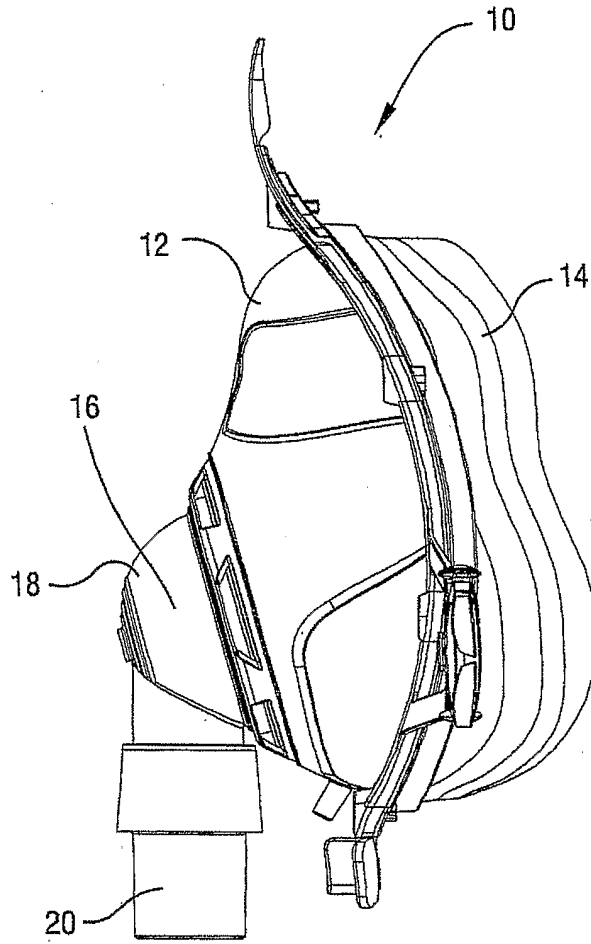


Fig. 2

3/21

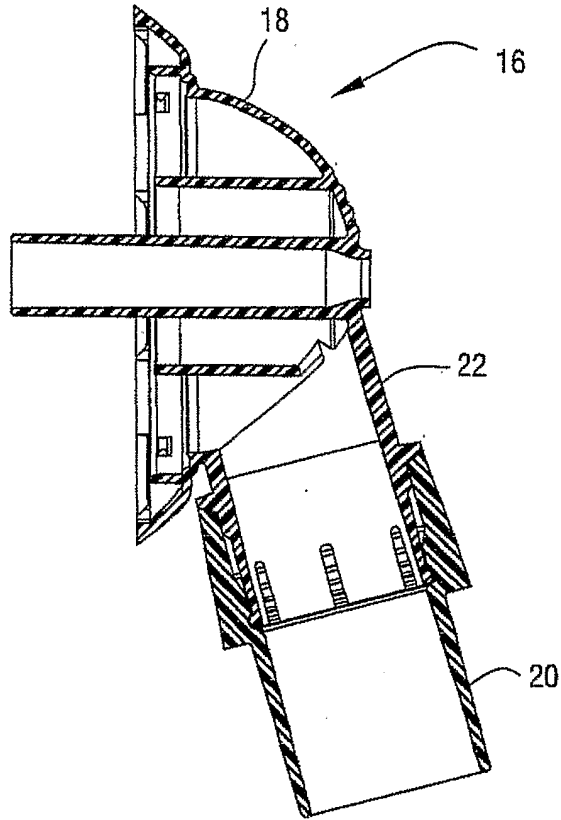


Fig. 3

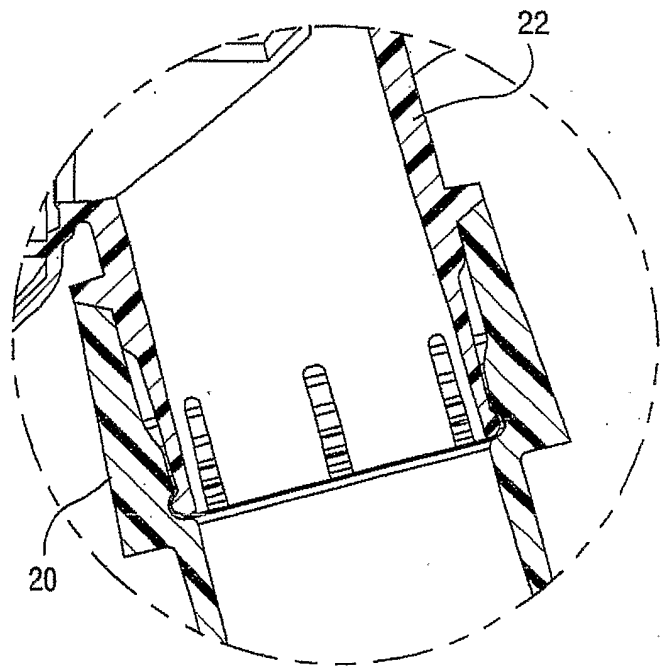
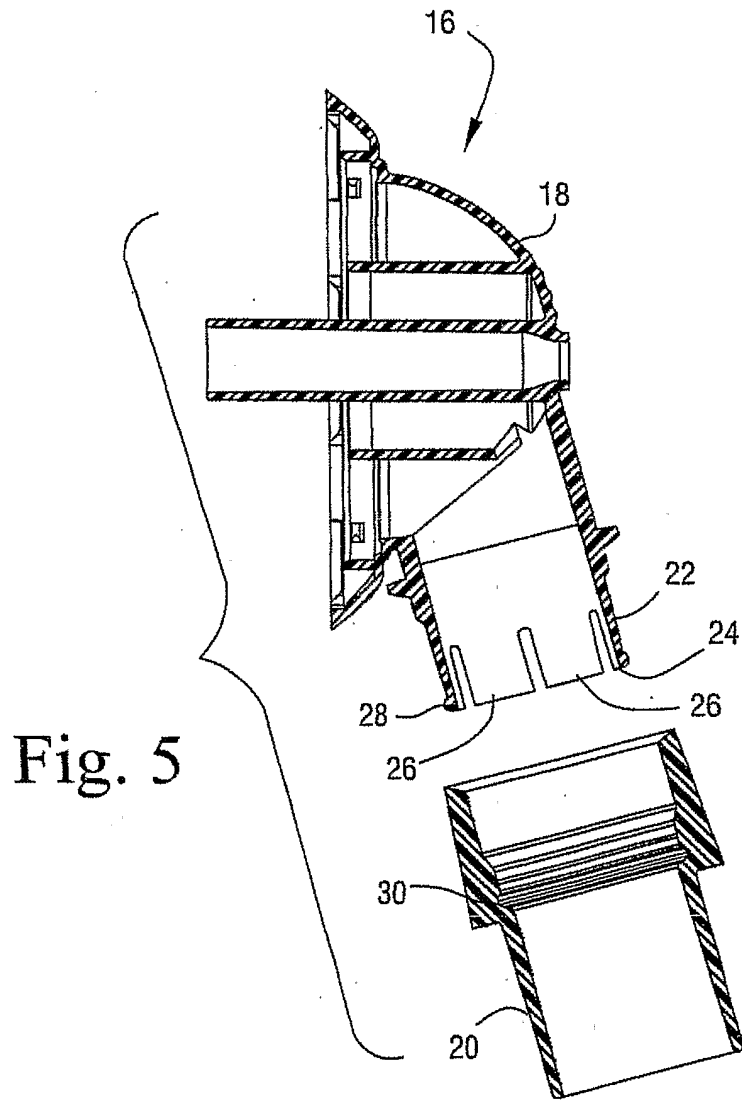
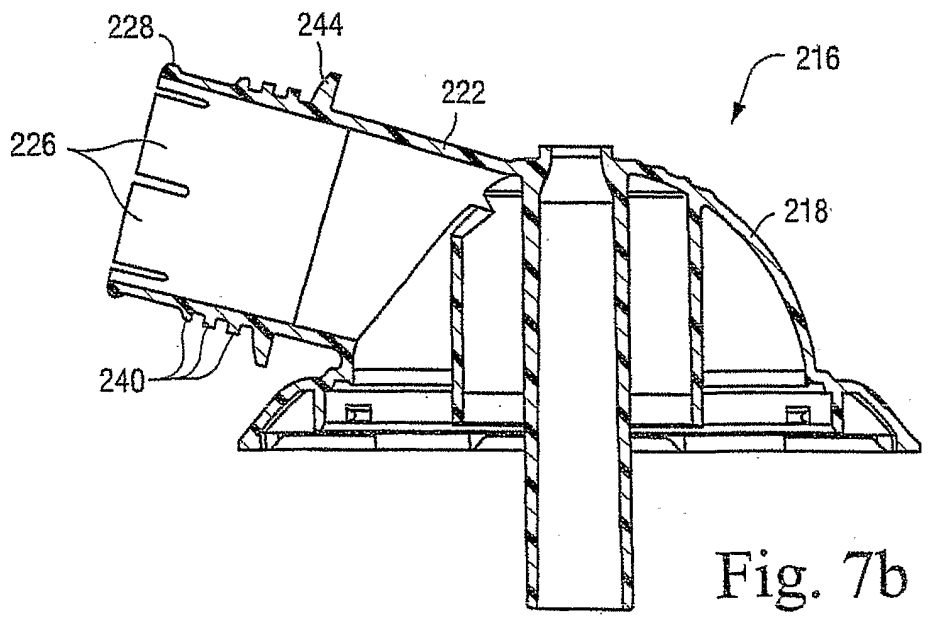
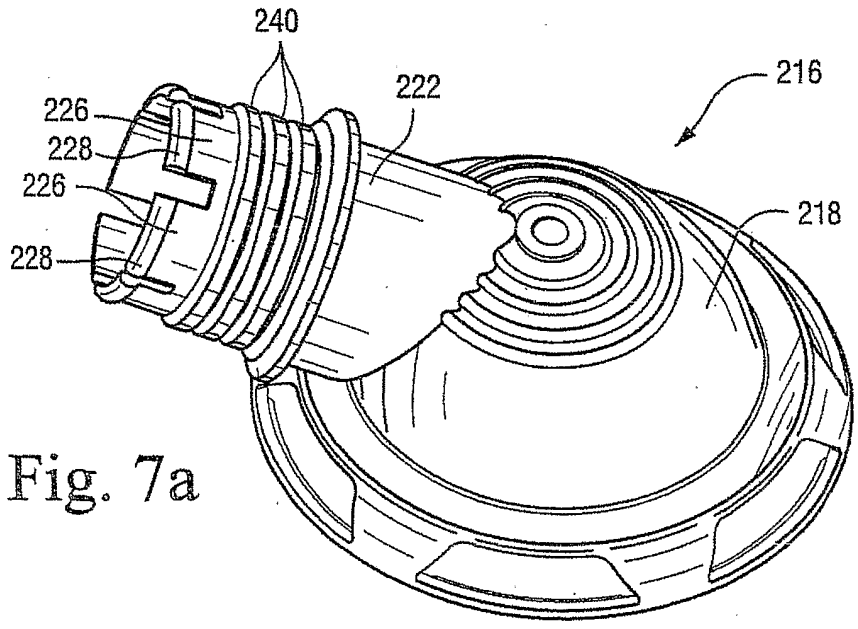
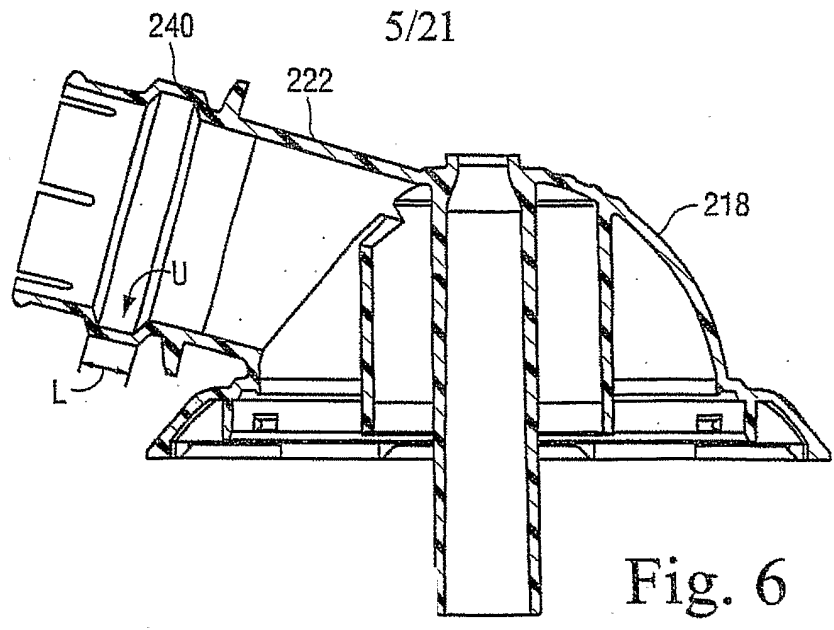


Fig. 4

4/21





6/21

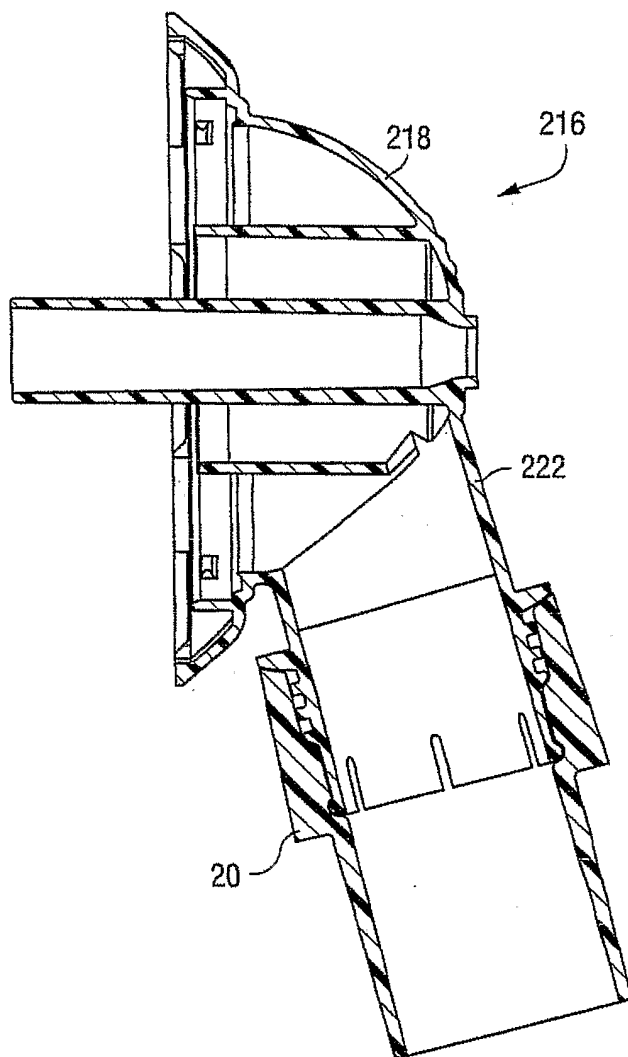


Fig. 8

7/21

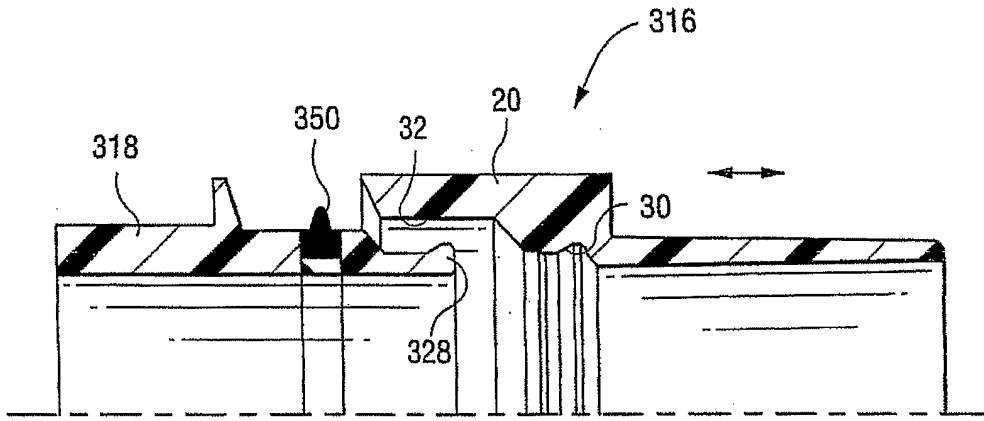


Fig. 9

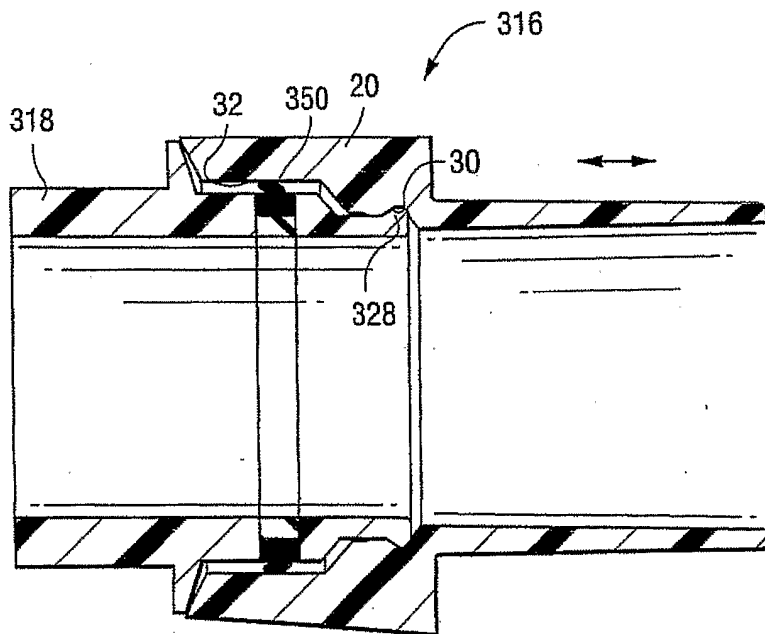


Fig. 10

8/21

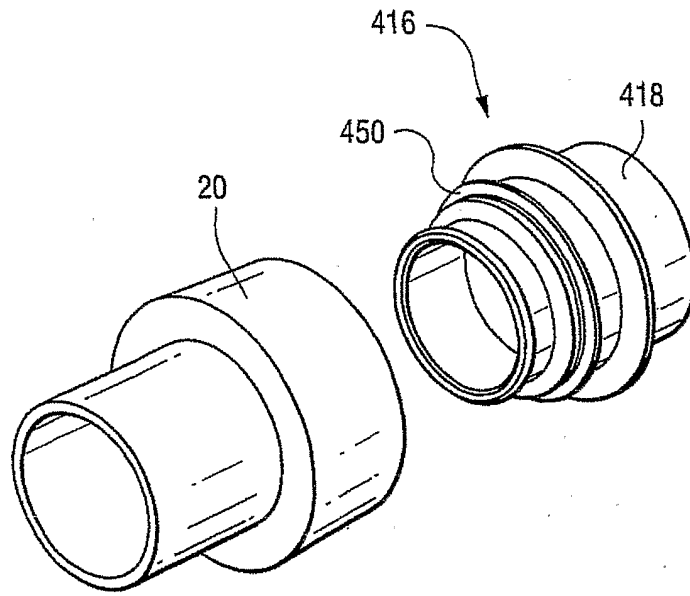


Fig. 11

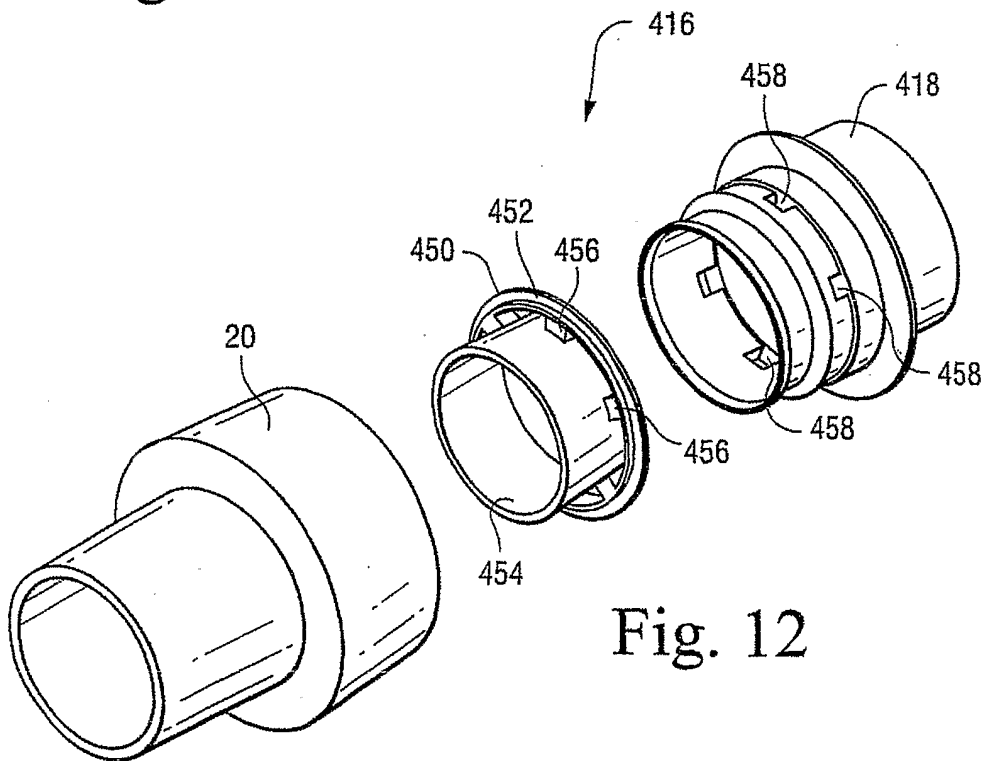


Fig. 12

9/21

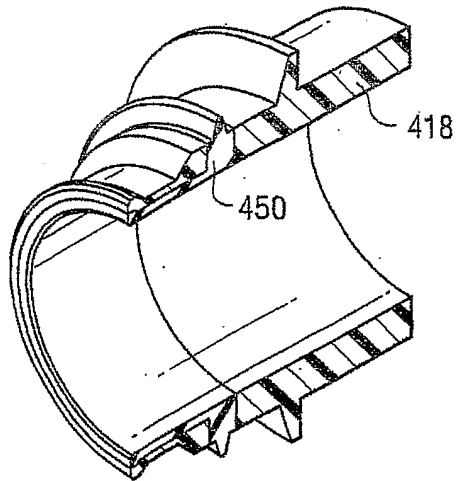


Fig. 13

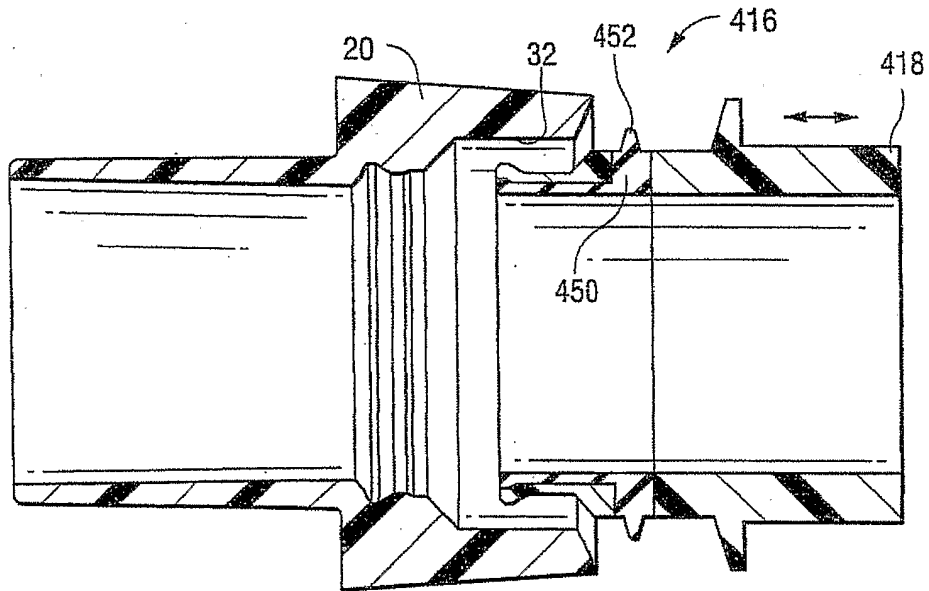


Fig. 14

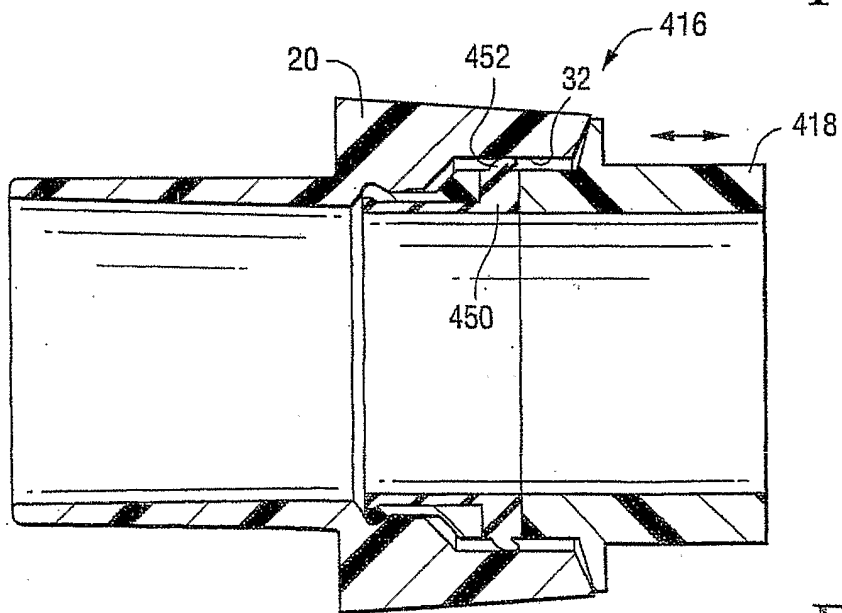


Fig. 15

10/21

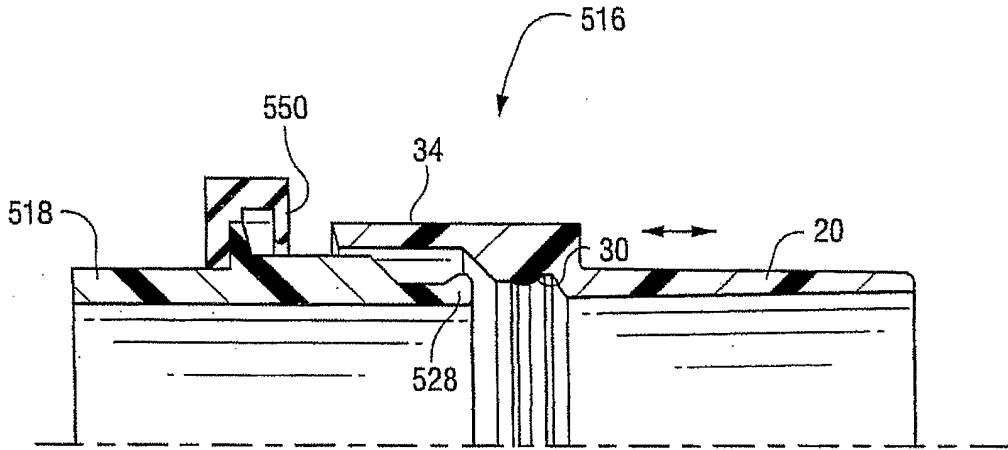


Fig. 16

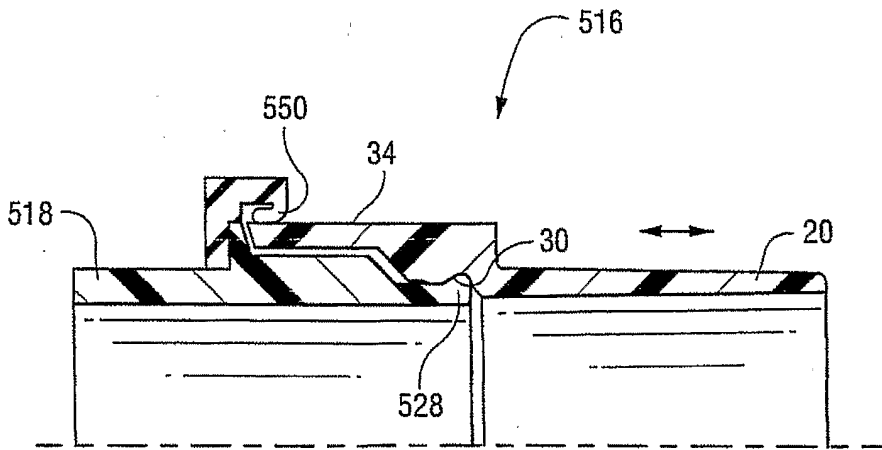


Fig. 17

11/21

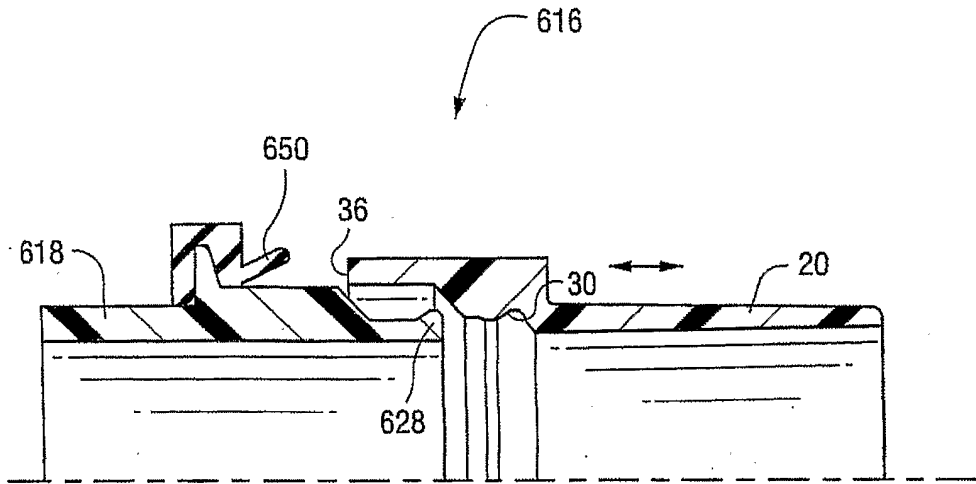


Fig. 18

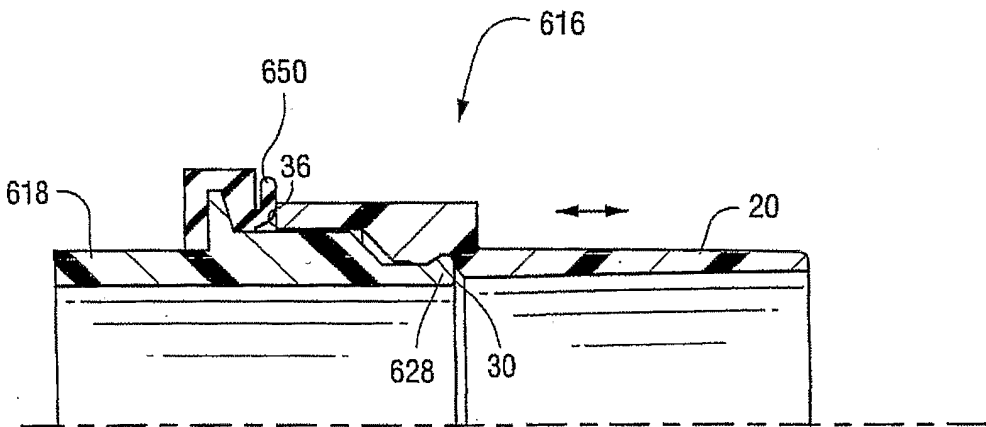


Fig. 19

12/21

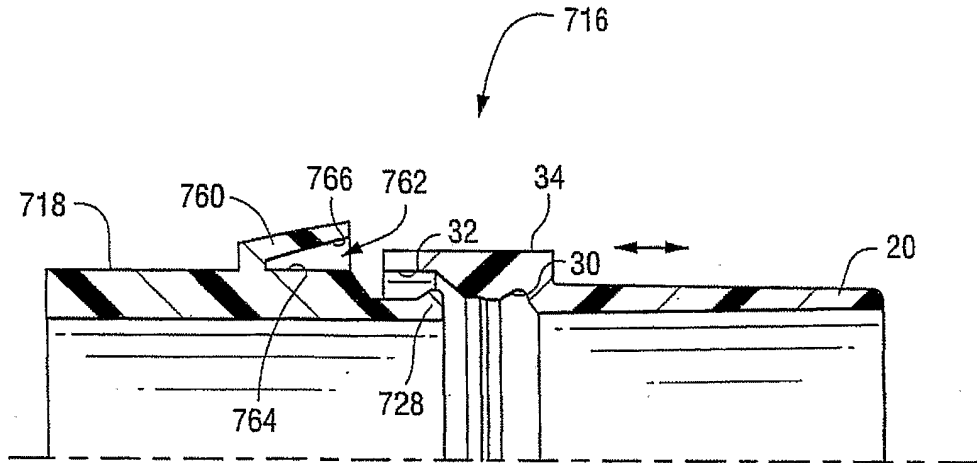


Fig. 20

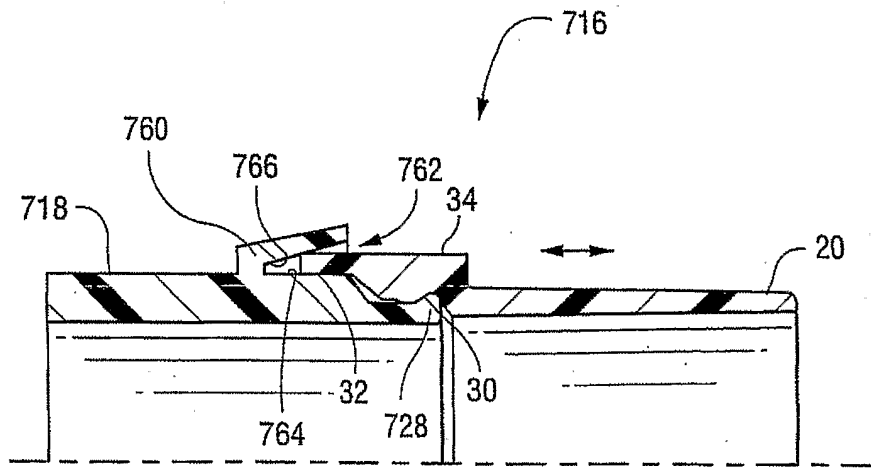


Fig. 21

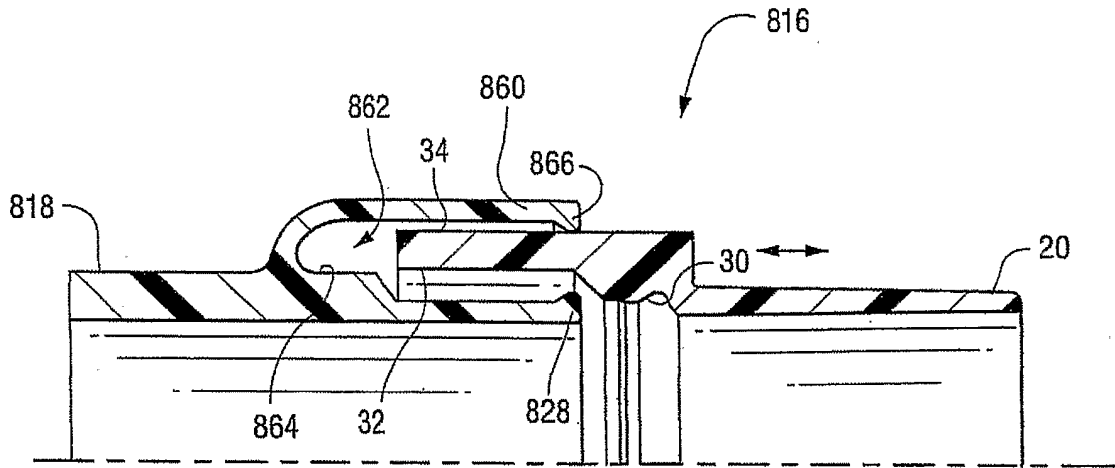


Fig. 22

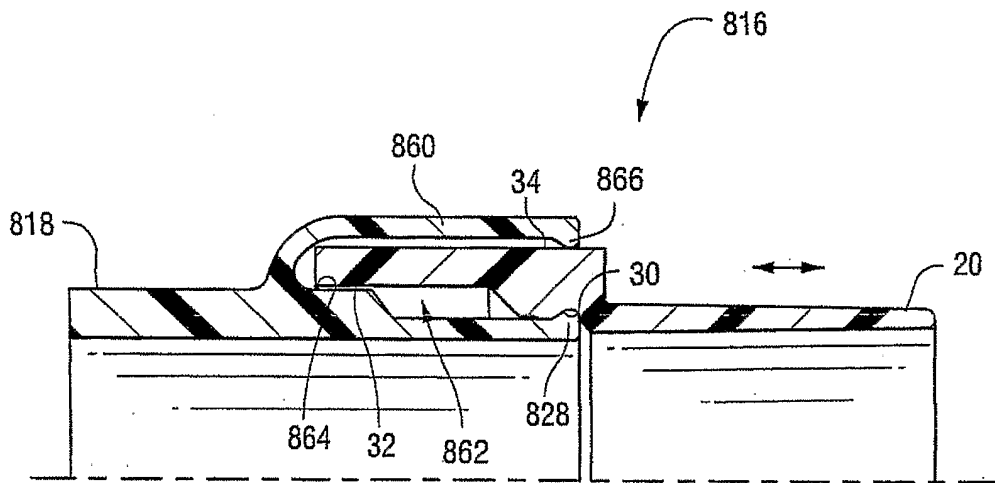


Fig. 23

14/21

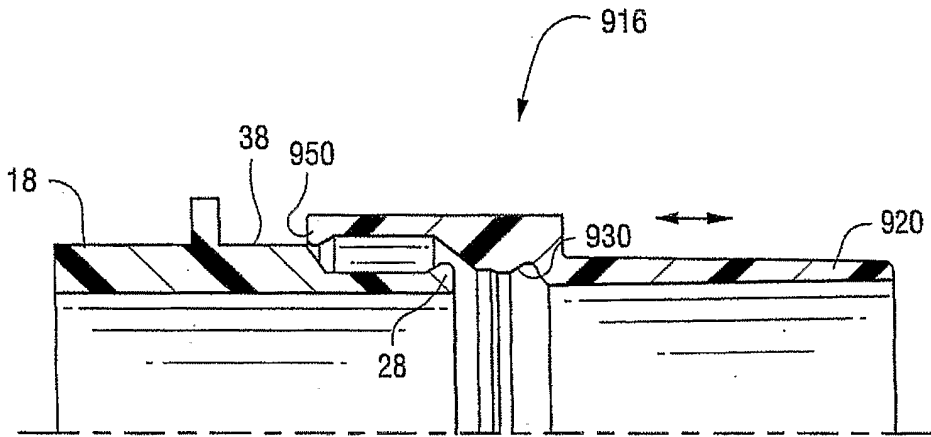


Fig. 24

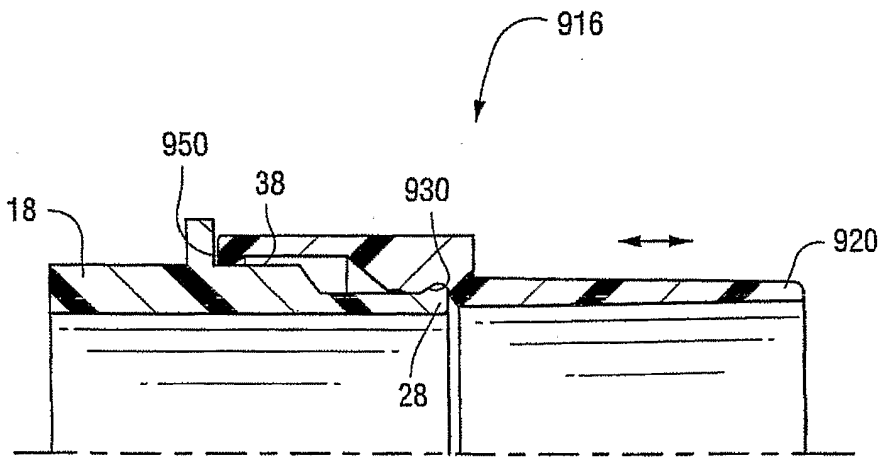


Fig. 25

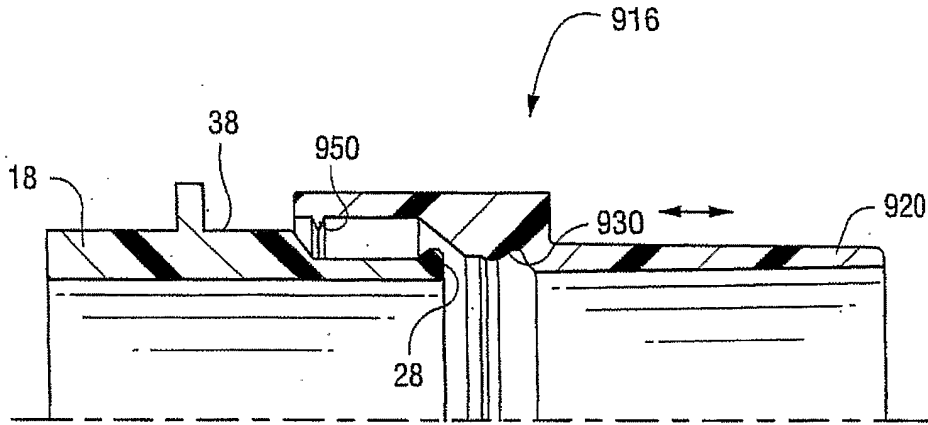


Fig. 26

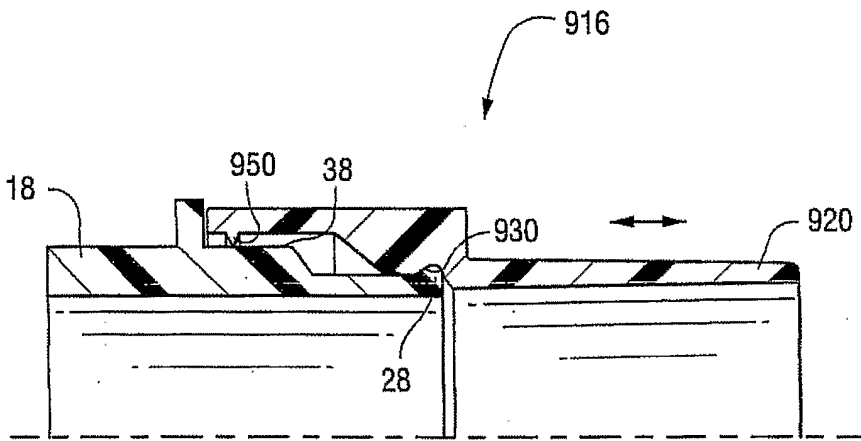


Fig. 27

16/21

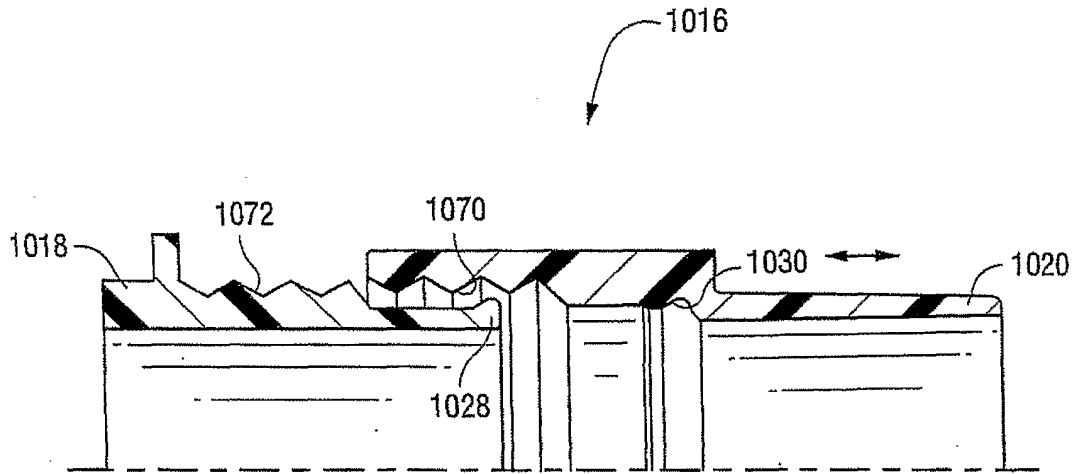


Fig. 28

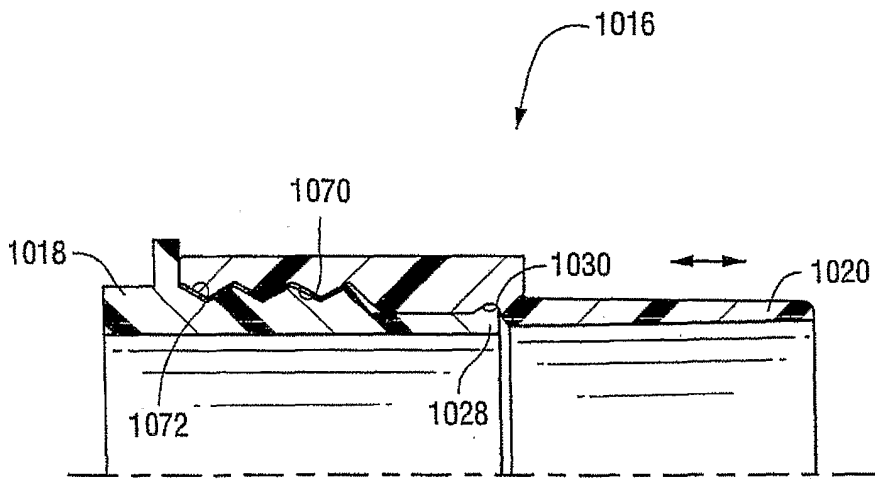


Fig. 29

17/21

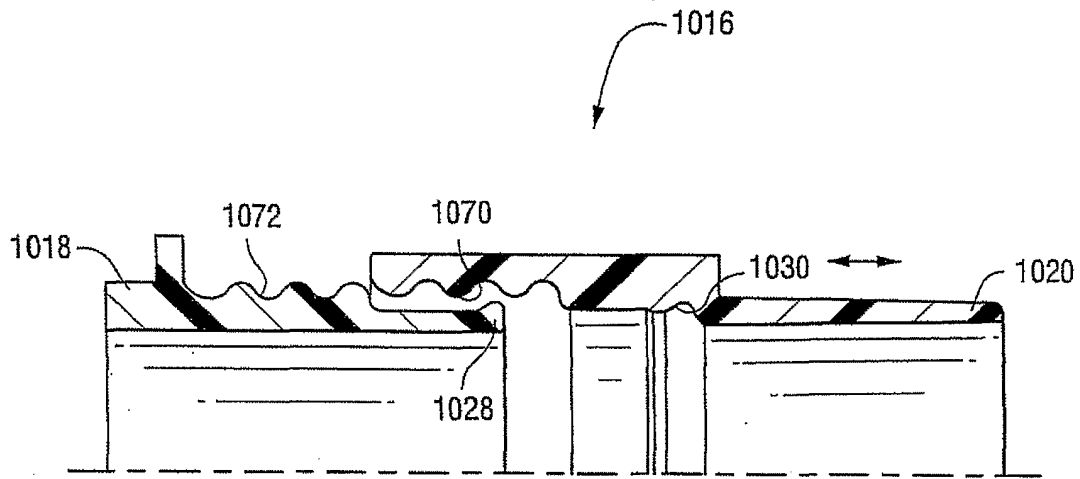


Fig. 30

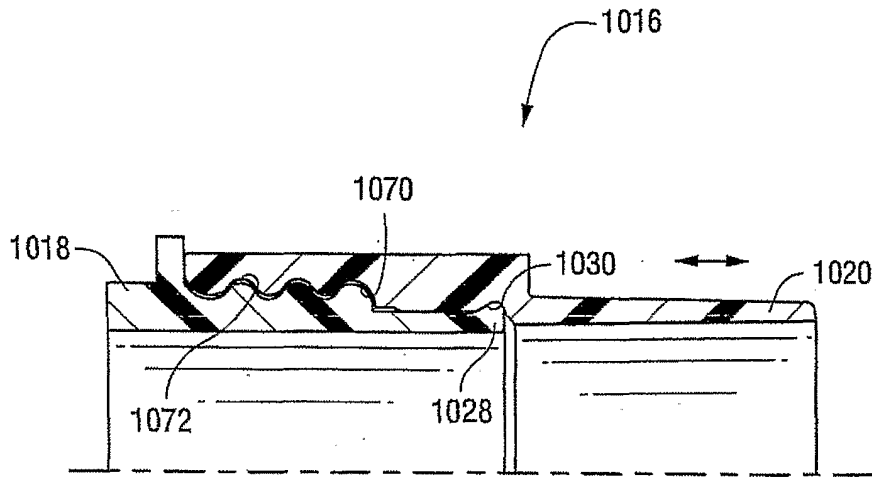


Fig. 31

18/21

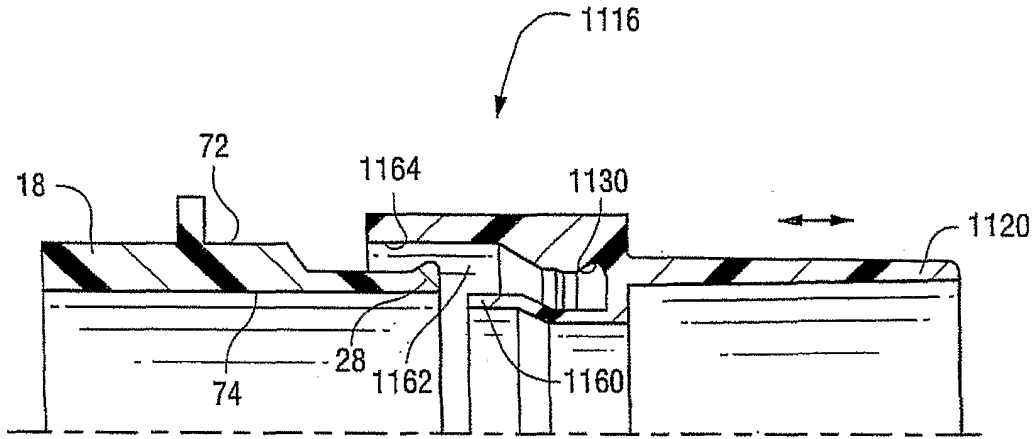


Fig. 32

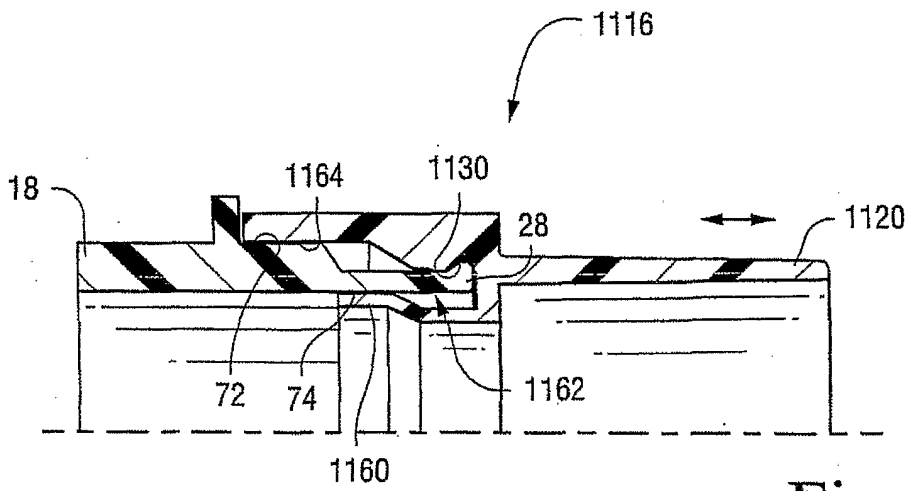


Fig. 33

19/21

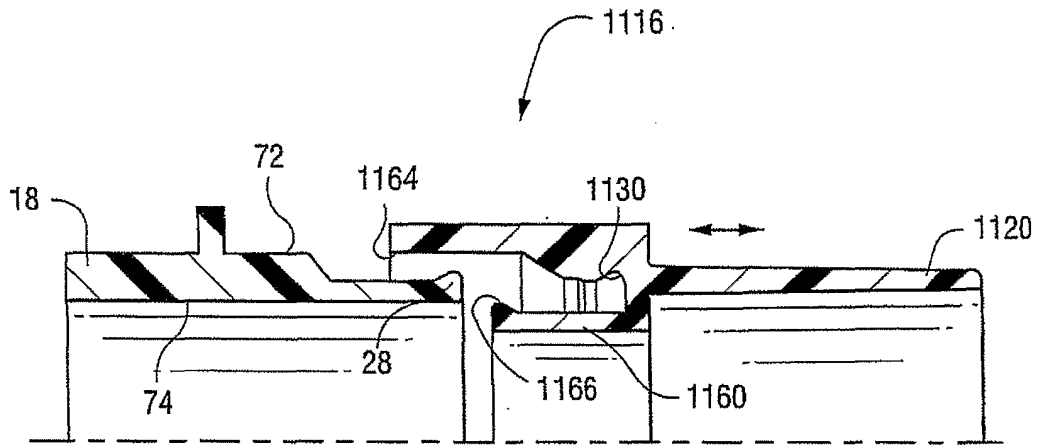


Fig. 34

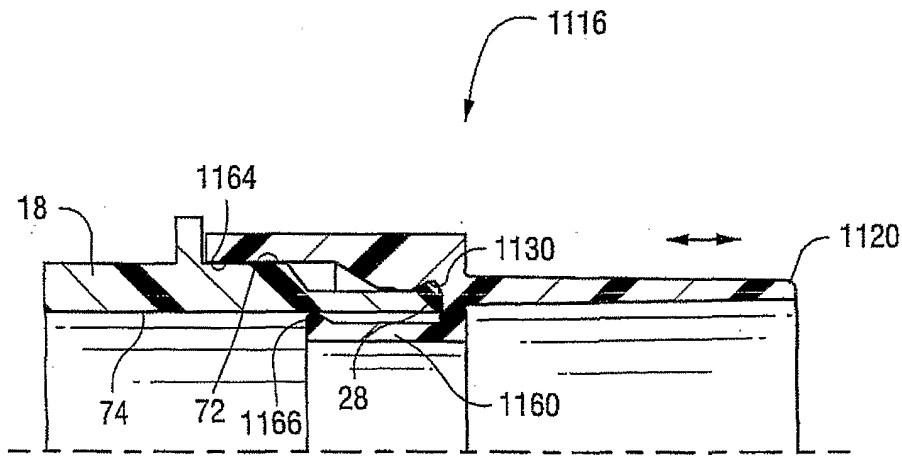


Fig. 35

20/21

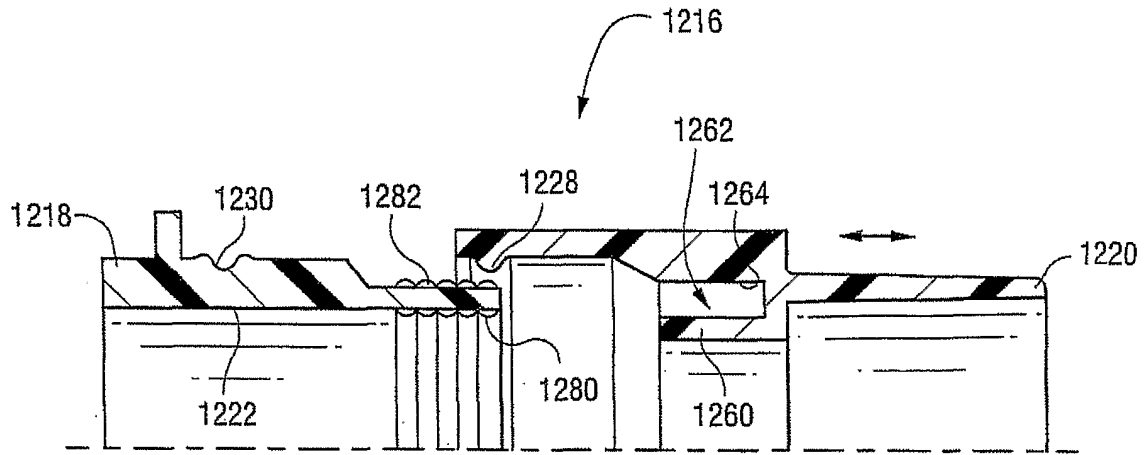


Fig. 36

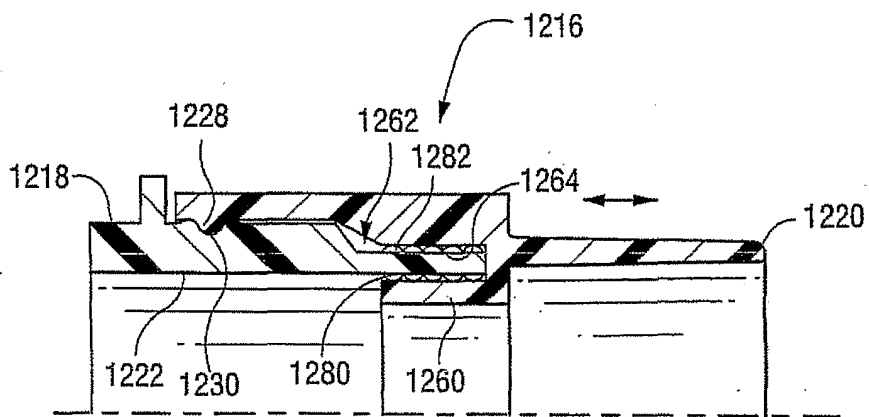


Fig. 37

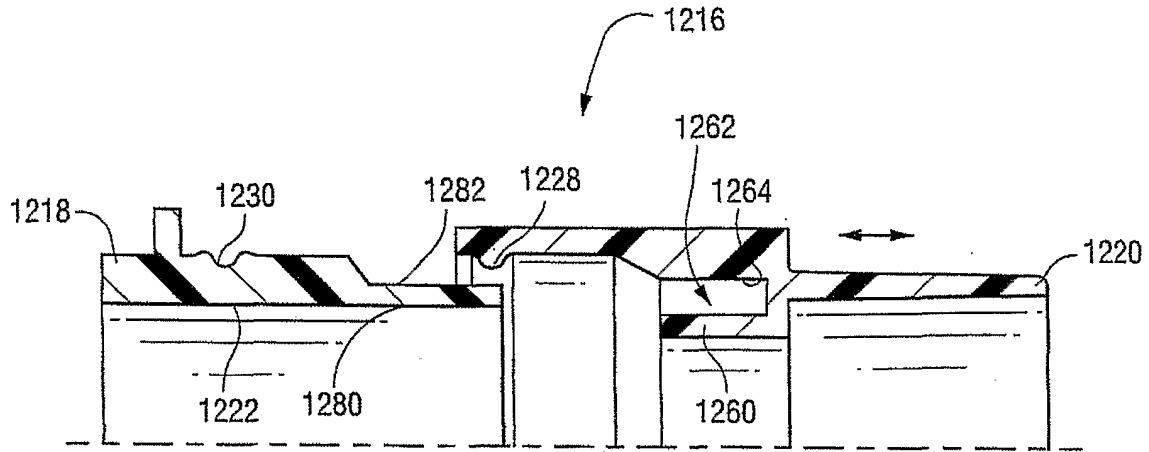


Fig. 38

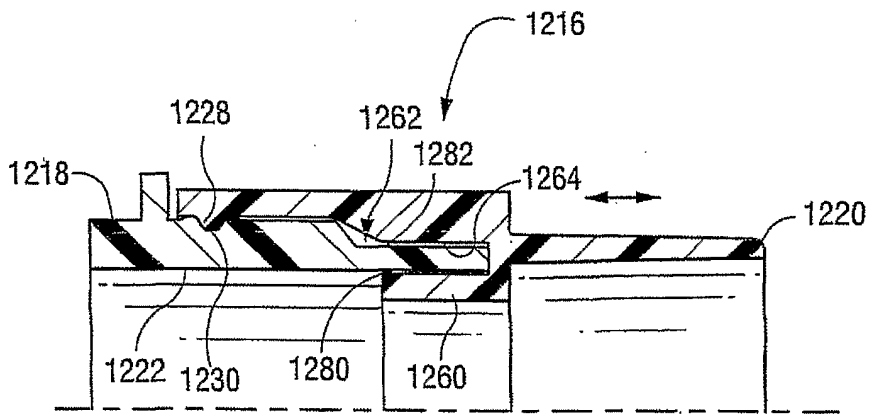


Fig. 39

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2006/000768

A. CLASSIFICATION OF SUBJECT MATTER		
Int. Cl. <i>A61M 16/06</i> (2006.01)		
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)		
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)		
DWPI and keywords:		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5062420 A (LEVINE) 5 November 1991 Whole document	4-23
X	DE 19757703 C1 (MAP MEDIZINTECHNIK ARZT & PATIENT GMBH) 14 October 1994 Abstract, figure 2	1-6,9-11, 15,16,23
X	US 6192886 B1 (RUDOLPH) 27 February 2001 Column 5 line 56 to column 6 line 10	4-16,18-23
X	GB 2069849 A (G.D. SEARLE & CO.) 3 September 1981 Page 1 lines 64 to 82	4-16,18-23
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> 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 22 August 2006		Date of mailing of the international search report 30 AUG 2006
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929		Authorized officer DAVID MELHUIH Telephone No : (02) 6283 2426

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2006/000768

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 6615830 B1 (SEROWSKI et al.) 9 September 2003 Column 4 lines 19 to 26	18,23
A	DE 20201347 U1 (KUO) 28 March 2002 Abstract, figure 1	17

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2006/000768

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member	
US	5062420	NIL	
DE	19757703	NIL	
US	6192886	NIL	
GB	2069849	NIL	
US	6615830	US 5937851	US 2004035419
DE	20201347	NIL	
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.			
END OF ANNEX			