(12) STANDARD PATENT (11) Application No. **AU 2015233157 B2**
(19) AUSTRALIAN PATENT OFFICE

(54) Title
Fixation apparatus

(51) International Patent Classification(s)
A61M 11/00 (2006.01) ***A61M 16/08*** (2006.01)
A61M 16/04 (2006.01) ***F16L 27/00*** (2006.01)

(21) Application No: **2015233157** (22) Date of Filing: **2015.03.20**

(87) WIPO No: **WO15/140576**

(30) Priority Data

(31) Number	(32) Date	(33) Country
1405132.0	**2014.03.21**	**GB**

(43) Publication Date: **2015.09.24**
(44) Accepted Journal Date: **2019.08.15**

(71) Applicant(s)
Indian Ocean Medical Inc.

(72) Inventor(s)
Young, Peter

(74) Agent / Attorney
Shelston IP Pty Ltd., L 9 60 Margaret St, Sydney, NSW, 2000, AU

(56) Related Art
US 4270778 A
EP 1355101 A2
US 5251616 A
US 2008/0210232 A1

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
24 September 2015 (24.09.2015)

WIPO | PCT

(10) International Publication Number
WO 2015/140576 A1

(51) International Patent Classification:
A61M 11/00 (2006.01) *A61M 16/08* (2006.01)
A61M 16/04 (2006.01) *F16L 27/00* (2006.01)

(21) International Application Number:
PCT/GB2015/050841

(22) International Filing Date:
20 March 2015 (20.03.2015)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
1405132.0 21 March 2014 (21.03.2014) GB

(71) Applicant: **INDIAN OCEAN MEDICAL INC.** [SC/SC]; Revolution Avenue, PO Box 18, Mahe (SC).

(72) Inventor; and
(71) Applicant *(for ZW only)*: **YOUNG, Peter** [GB/GB]; The Old Parsonage, Church Lane, Roydon, King's Lynn Norfolk PE32 1AR (GB).

(74) Agent: **JACOB REUBEN E**; RGC Jenkins & Co., 26 Caxton Street, London Greater London SW1H 0RJ (GB).

(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, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, 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).

[Continued on next page]

(54) Title: FIXATION APPARATUS

(57) Abstract: Fixation apparatus for releasably securing a fixation structure to an airway tube of an artificial airway device is provided, the apparatus (1) being adapted to allow captive axial movement thereof relative to the airway tube (3) in a release position, and to substantially prevent axial movement thereof relative to the airway tube (3) in a secured position.

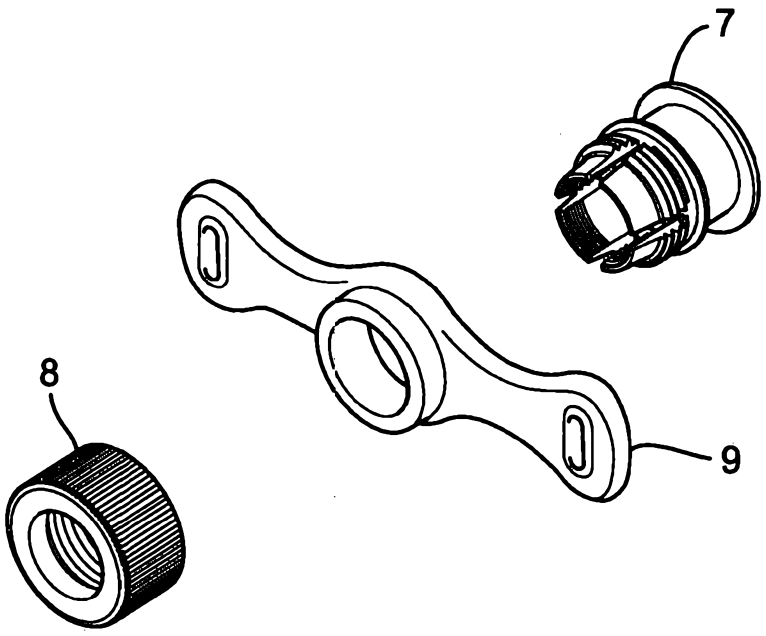


Fig. 2

WO 2015/140576 A1

Published:

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

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

Fixation Apparatus

The invention relates to fixation apparatus for an artifical airway device, an artificial airway device including such apparatus, an endotracheal or tracheostomy tube including said apparatus, and a method for using a said device.

Patients kept alive by mechanical ventilators or respirators often require an artificial airway such as an endotracheal, or tracheostomy tube. Such devices are very well known and have been used for many years. Over that period the art has advanced and developed to offer clinicians a wide range of devices with enhanced features and properties, sometimes at the expense of the basic requirements of ease of insertion and reliability in use. Thus when correctly placed the tube passes from outside of the mouth, through the oral cavity, through the pharyngeal space, past the vocal cords, through the laryngeal space and into the trachea. This pathway follows a variable distance and number and pattern of curves depending on the nature of the patient's anatomy and as a result correct insertion can be difficult and is a job for a skilled practitioner. Once correctly inserted, it is clearly of high importance that the tube remains so, but with patient movement such as intra-oral movements of the tongue and manipulation by medical staff the tube can move and the distal tip can pull back from the trachea and even be completely removed thereby losing control of ventilation of the lungs, which is a clinical emergency. To avoid this a number of techniques have evolved, such as at its simplest, securing the protruding portion of the tube to the patient with tape, but this does not provide for a very secure attachment. More usefully, fixation devices have been devised that can be secured to the tube and which include ancillary structures such as for example straps which allow for a more secure and convenient attachment to the patient. An example of such a device can be found in Applicant's own "Young LoTrach ETT" and "PneuX" devices.

Endotracheal and tracheostomy tubes include inflation lumens within their walls, and sometimes also include add on features, such as additional lumens for suction or irrigation . Examples of some known devices can be found in GB 2 324 735A, WO 03/061747 and WO 2005/118039, which describes devices including

2015233157 21 Jun 2019

various configurations of lumens located within the tube wall. It has been found that problems can arise when these types of more secure fixation device are employed on tubes including lumens located within the tube wall. It will be understood that in order to function correctly, a fixation device for securing a tube to a patient must itself be secured to the tube, and, depending on its configuration, will almost certainly need to be movably fixable thereon, so that differing patient anatomies can be accommodated. A fixation device must substantially avoid placing the tube wall under compression such that wall located lumens are occluded.

Any discussion of the prior art throughout the specification should in no way be considered as an admission that such prior art is widely known or forms part of common general knowledge in the field.

It is an object of the present invention to overcome or ameliorate at least one of the disadvantages of the prior art, or to provide a useful alternative.

According to a first aspect of the invention there is provided fixation apparatus for releasably securing a fixation structure to an airway tube of an artificial airway device, the apparatus being adapted to allow captive axial movement thereof relative to the airway tube in a release position, and to substantially prevent axial movement thereof relative to the airway tube in a secured position, wherein the assembly includes compression means for application of compressive load to an area of the airway tube outer surface when the apparatus is in the secured position, there being radial load focussing means disposed to focus the compressive load onto the airway tube outer surface, wherein the fixation apparatus comprises a through bore defining a longitudinal axis and sized to receive the airway tube of an artificial airway device such that, when the fixation device is not in the secured position, the fixation device is freely slidable axially along the airway tube to any desired position, wherein the radial load focussing means comprises one or more set of a plurality of closely spaced ridges.

The invention preferably provides a releasable fixation assembly that provides for secure fixation against axial movement.

2015233157 21 Jun 2019

It is preferred that the apparatus comprises a collet defining a bore, and that the compression means comprises resilient arms of the collet arranged to cooperate with a nut such that fitment of the arms into a bore of the nut causes progressive radial compression thereof thereby reducing the diameter of the collet bore to the secured position. It is further preferred that the internal surface of the nut and the external surfaces of the arms are provided with cooperating screw threads.

It is preferred that the radial load focussing means comprises one or more set of a plurality of closely spaced ridges. It is further preferred that the radial load focussing means comprises at least two sets of a plurality of closely spaced ridges, the sets being spaced apart from one another in the axial direction by a distance greater than the spaces between ridges in a set.

It is preferred that the fixation apparatus includes one or more fixation strap.

According to a second aspect of the invention there is provided an artificial airway device for use in establishing an airway in a patient, comprising an airway tube, and fixation apparatus for releasably securing a fixation structure to the airway tube, the fixation apparatus being adapted to allow captive axial movement thereof relative to an outer surface of the airway tube in a release position, and to substantially prevent axial movement thereof relative to the airway tube in a secured position, wherein the assembly includes compression means for application of compressive load to an area of the airway tube outer surface when the apparatus is in the secured position, there being radial load focussing means disposed to focus the compressive load onto the airway tube outer surface, wherein the fixation apparatus comprises a through bore defining a longitudinal axis and sized to receive the airway tube of an artificial airway device such that when the fixation device is not in the secured position the fixation device is freely slidable axially along the airway tube to any desired position, wherein the radial load focussing means comprises one or more set of a plurality of closely spaced ridges.

2015233157 21 Jun 2019

It is preferred that the artificial airway device comprises an endotracheal tube. Alternatively, it is preferred that the artificial airway device comprises a tracheostomy tube.

Preferably, the airway tube includes an intra-wall lumen.

According to a third aspect of the invention there is provided a method of intubating a patient comprising the steps of inserting an endotracheal tube or tracheostomy tube of an artificial airway device according to the above to a desired position and securing it in place.

Unless the context clearly requires otherwise, throughout the description and the claims, the words “comprise”, “comprising”, and the like are to be construed in an inclusive sense as opposed to an exclusive or exhaustive sense; that is to say, in the sense of “including, but not limited to”.

The invention will further be described by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a perspective view of apparatus according to the invention;

Figure 2 is an exploded view of the apparatus of Figure 1;

Figure 3 is a front view of an airway device according to the invention;

Figure 4 is an enlarged perspective view of a component of the apparatus of Figure 1;

Figure 5 is an end view of the component of Figure 4;

Figure 6 is a longitudinal sectional view along line A-A in Figure 5;

2015233157 21 Jun 2019

Figure 7 is a plan view of a component of the device of Figure 1;

Figure 8 is a longitudinal sectional view along line A-A in Figure 7;

Figure 9 is a perspective view of the component of Figure 7;

Figure 10 is a plan view of a component of the apparatus of Figure 1;

Figure 11 is a sectional view along line A-A in Figure 10;

Figure 12 is a sectional view along line B-B in Figure 10;

Figure 13 is a longitudinal sectional view of an alternative device according to the invention; and

Figure 14 is an enlarged view of a section of the device of Figure 14 showing apparatus according to the invention.

Referring generally to the drawings, there is illustrated fixation apparatus 1 for releasably securing a fixation structure 2 to an airway tube 3 of an artificial airway device 4, the assembly 1 being adapted to allow captive axial movement thereof relative to the airway tube 3 in a release position, and to substantially prevent axial movement thereof relative to the airway tube 3 in a secured position, wherein the apparatus includes compression means 5 for application of compressive load to an area of the airway tube outer surface when the apparatus is in the secured position, there being radial load focussing means 6 disposed to focus the compressive load onto the airway tube outer surface.

Referring firstly to Figures 1 and 2, and 4 to 12, in this embodiment of the invention, apparatus 1 takes the form of a fixation assembly comprising three main components; a collet 7; a collet nut 8; and a fixation strap 9.

The collet 7 has a cylindrical body 10 including a through bore 11 defining a longitudinal axis and sized to receive an airway tube 3 of an artificial airway device 4 such as an endotracheal tube (Figure 3) or a tracheostomy tube (Figure 13). At one end the body 10 includes a circumferential end flange 12 which extends a short distance normal to the longitudinal axis of the bore. At its other end the collet 7 includes compression means 5, which here take the form of four circumferentially extending equally spaced compression arms.

Each compression arm 5 consists of an arcuate generally rectangular main body having an inner surface 14 and an outer surface 15 relative to the bore 11. On the inner surface of each arm 5 there is provided radial load focussing means 6, which here takes the form of two sets of ridges 16, each set including three individual parallel ridges, the sets being spaced apart along the longitudinal axis on the inner surface 14. On the outer surface of each arm 5 there is provided a part-screw thread 17 positioned proximal to the collet body and a cam surface 20 positioned distal thereto. At the point of attachment 18 of each arm 5 to the collet body, the thickness of the arm body is reduced, relative to the thickness of the arm body elsewhere along its length. The collet 7 is formed, for example by moulding, from a resiliently deformable plastics material and by virtue of this, and also the reduced thickness areas 18, the compression arms 5 can be moved radially inwardly as by bending, relative to the bore 11, the movement being accommodated and facilitated by gaps 19 between the arms 5.

Referring now in particular to Figures 7 to 9, there is illustrated collet nut 8. Collet nut 8 comprises a cylindrical body 20 including a through bore 21 dimensioned to fit onto airway tube 3 and over compression arms 5. The inner surface of bore 21 is provided with screw thread 22 and internal circumferential flange 23. Flange 23 includes bevelled edge 24 immediately adjacent to and downstream from screw thread 22. Collet nut 8 preferably is formed from a plastics material by moulding.

Referring now in particular to Figures 10 to 12, there is illustrated fixation strap 9. Fixation strap 9 is of generally known type, and includes a cylindrical body 25 dimensioned to fit onto an airway tube 3 via through-bore 26, and radially outwardly

projecting wings 27. It is preferred that collet strap 9 comprises a resilient material such as silicone.

Figures 3 and 13 illustrate how apparatus 1 is used in conjunction with, respectively, an endotracheal tube and a tracheostomy tube. In use, the components of apparatus 1 are placed onto the airway tube 3 of a device 4 by sliding, such that the collet 7 is disposed with collet arms 5 directed towards the proximal end, and in loose engagement with nut 8. It is important that nut 8 is oriented with screw thread 22 towards arms 5. Fixation strap 9 is conveniently mated to collet 7 prior to placement onto the tube. The collet 7 and strap 9 are thus captive on and freely slidable axially along the tube 3 to any desired position. Once a desired position has been selected, an operator can manipulate nut 8 axially so that collet arms 5 are received within bore 21 and screw threads 17 and 22 engage. Rotation of nut 8 relative to collet 7 about the threads 17 brings the two parts axially together and causes cam surfaces 20 of arms 5 to contact bevelled edge 24. As the collet 7 and nut 8 move closer together, edge 24 slides over cam surfaces 20, causing arms 5 to move radially inwardly, reducing the diameter of the gaps 19 therebetween and accordingly the bore defined by the collet 7 and arms 5 are thus brought into contact with the surface of the airway tube 3 via ridges 16.

Ridges 16 achieve an important dual function, which is to both form a secure but releasable connection between collet 7 and airway tube 3, whilst also spreading the radial compression sufficiently around the outer surface of the airway tube 3 to avoid crushing its surface and occluding sub-surface structures such as lumens that are often formed within the wall. It has been found that this dual function is most effectively achieved by the provision of a group or groups of ridges 16 as described above, rather than a single ridge. A single ridge can focus compression onto too small an area of the surface if the nut 8 is over-tightened. In clinical situations, particularly emergency situations, staff cannot and should not be expected to make precise adjustments to apparatus of this kind because they are required to focus their attention on the welfare of the patient. The invention thus provides a type of safety check that helps ensure that

a secure fixation is achieved without damage to delicate tube structures and without the need for precise operation in the clinical setting.

2015233157 21 Jun 2019

Claims

1. A fixation apparatus for releasably securing a fixation structure to an airway tube of an artificial airway device, the apparatus being adapted to allow captive axial movement thereof relative to an outer surface of the airway tube in a release position, and to substantially prevent axial movement thereof relative to the airway tube in a secured position, wherein the assembly includes compression means for application of compressive load to an area of the airway tube outer surface when the apparatus is in the secured position, there being radial load focussing means disposed to focus the compressive load onto the airway tube outer surface, wherein the fixation apparatus comprises a through bore defining a longitudinal axis and sized to receive the airway tube of an artificial airway device such that, when the fixation device is not in the secured position, the fixation device is freely slidable axially along the airway tube to any desired position, wherein the radial load focussing means comprises one or more set of a plurality of closely spaced ridges.

2. The apparatus according to claim 1, comprising a collet defining a bore, and a collet nut.

3. The apparatus according to claim 2, wherein the compression means comprises resilient arms of the collet arranged to cooperate with the nut such that fitment of the arms into a bore of the nut by rotation causes progressive radial compression thereof thereby reducing the diameter of the collet bore to the secured position.

4. The apparatus according to claim 3, wherein an internal surface of the nut and external surfaces of the resilient arms comprise cooperating screw threads.

2015233157 21 Jun 2019

5. The apparatus according to any one of the preceding claims, wherein the radial load focussing means comprises at least two sets of a plurality of closely spaced ridges.

6. The apparatus according to claim 5, wherein the sets are spaced apart from one another in the axial direction by a distance greater than the spaces between individual ridges in a set.

7. The apparatus according to any one of the preceding claims, including one or more fixation strap.

8. An artificial airway device for use in establishing an airway in a patient, comprising an airway tube, and fixation apparatus for releasably securing a fixation structure to the airway tube, the fixation apparatus being adapted to allow captive axial movement thereof relative to an outer surface of the airway tube in a release position, and to substantially prevent axial movement thereof relative to the airway tube in a secured position, wherein the assembly includes compression means for application of compressive load to an area of the airway tube outer surface when the apparatus is in the secured position, there being radial load focussing means disposed to focus the compressive load onto the airway tube outer surface, wherein the fixation apparatus comprises a through bore defining a longitudinal axis and sized to receive the airway tube of an artificial airway device such that when the fixation device is not in the secured position the fixation device is freely slidable axially along the airway tube to any desired position, wherein the radial load focussing means comprises one or more set of a plurality of closely spaced ridges.

9. The device according to claim 8, comprising an endotracheal tube.

10. The device according to claim 8, comprising a tracheostomy tube.

2015233157 21 Jun 2019

11. The device according to any one of claims 8 to 10, wherein the airway tube includes an intra-wall lumen.

12. A method of intubating a patient comprising the steps of inserting an endotracheal tube or tracheostomy tube according to claim 9 or claim 10 to a desired position and securing it in place.

13. Use of a fixation apparatus according to any one of claims 1 to 7 to releasably secure a fixation structure to an airway tube of an artificial airway device.

14. Use of an artificial airway device according to any one of claims 8 to 11 to establish an airway in a patient.

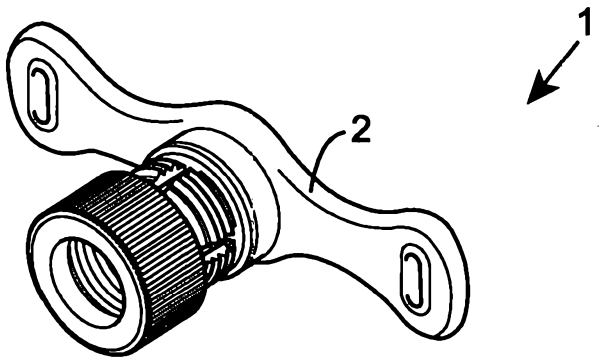


Fig. 1

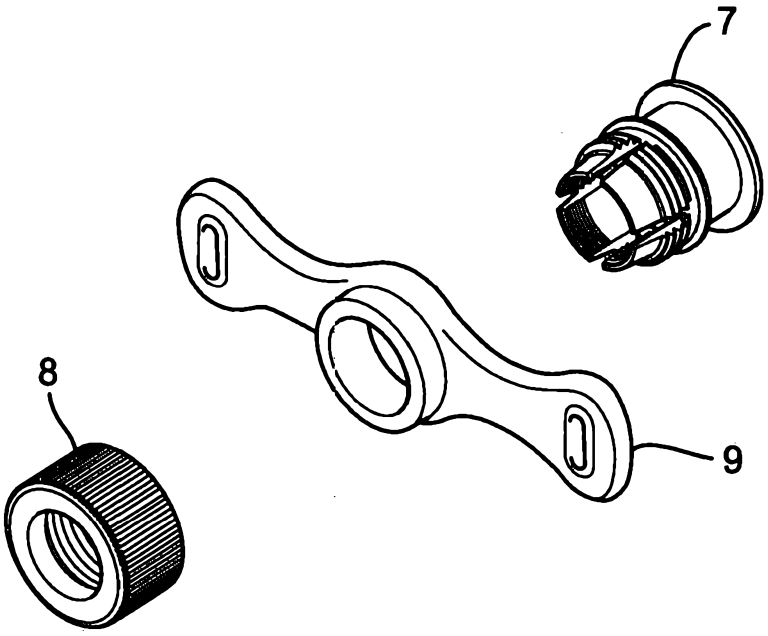


Fig. 2

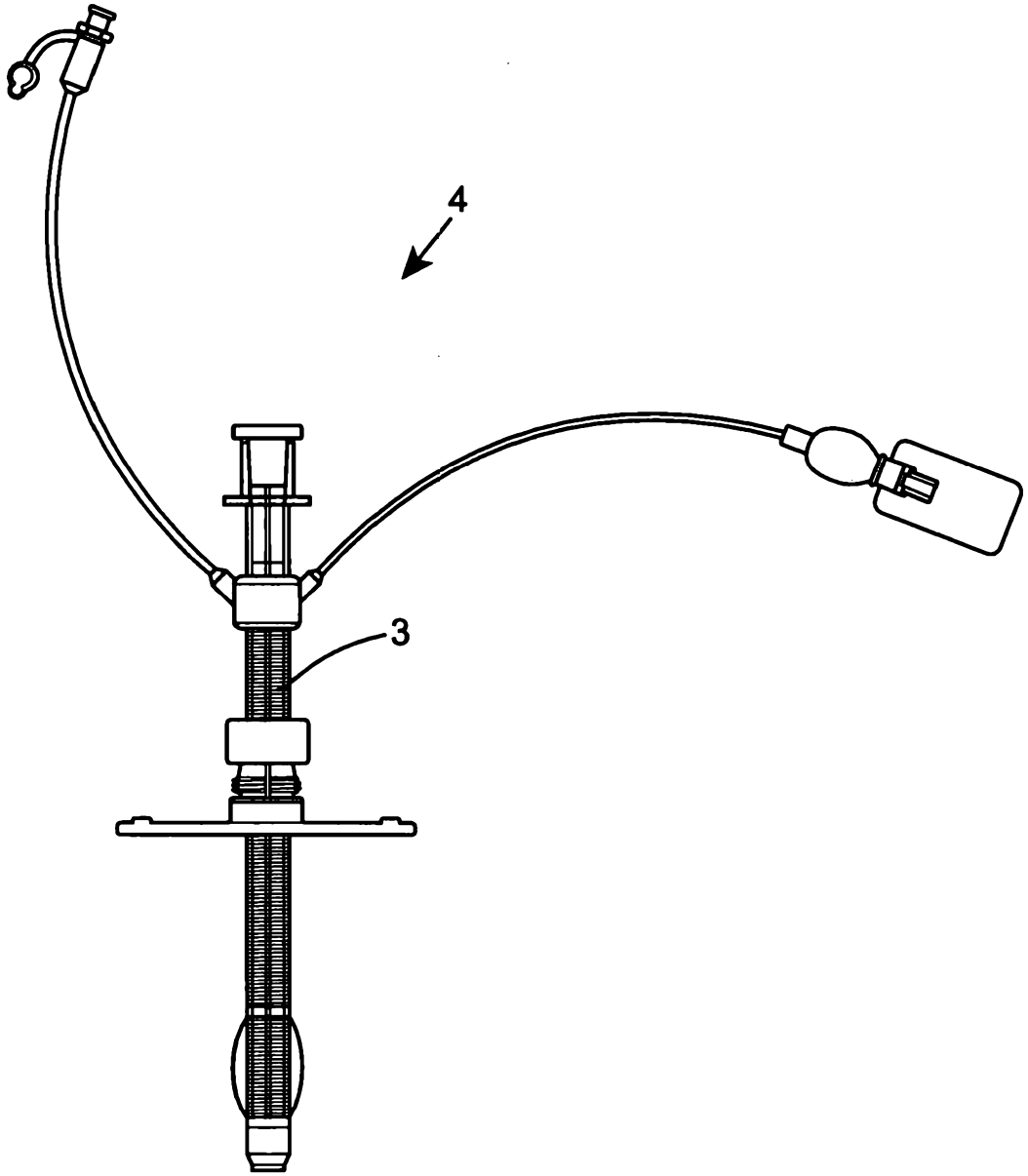


Fig. 3

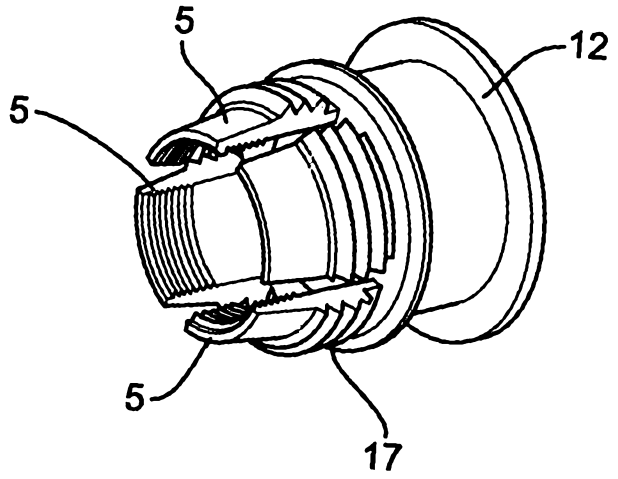


Fig. 4

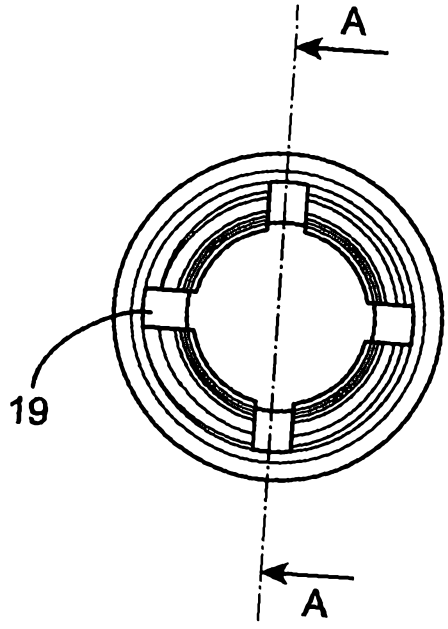


Fig. 5

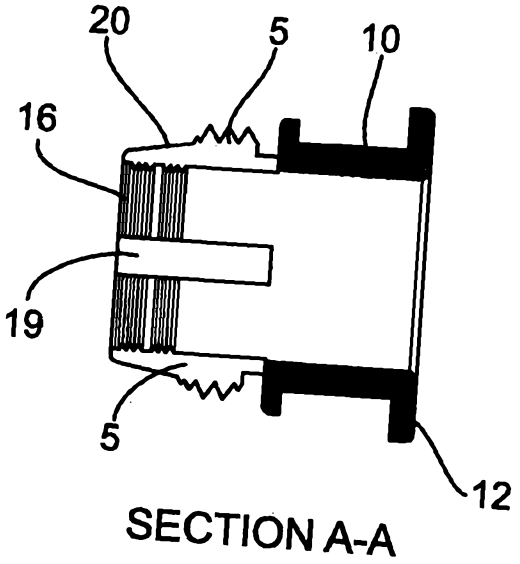


Fig. 6

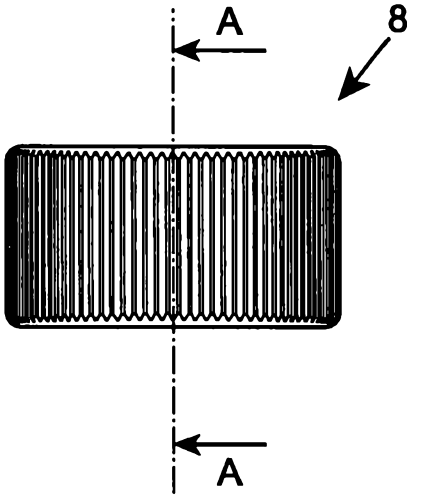
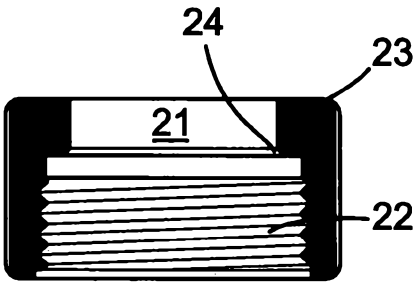


Fig. 7



SECTION A-A

Fig. 8

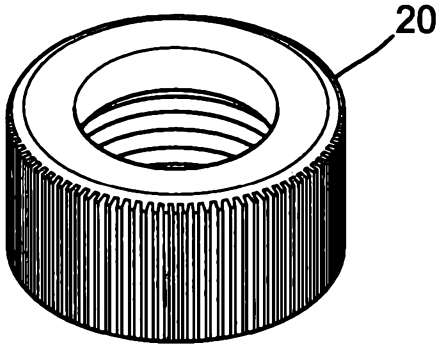
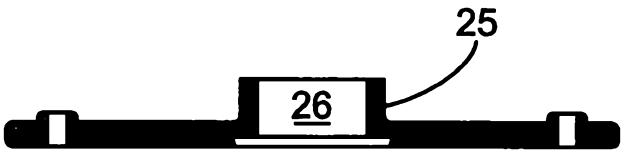


Fig. 9



SECTION A-A

Fig. 11

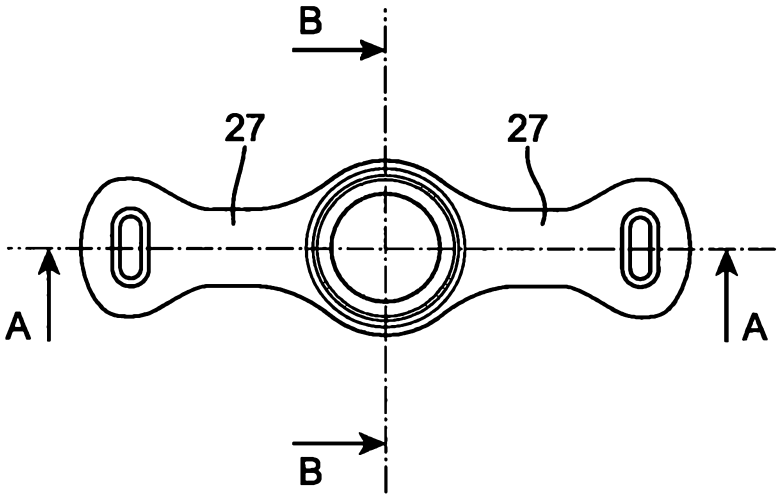


Fig. 10

SECTION B-B

Fig. 12

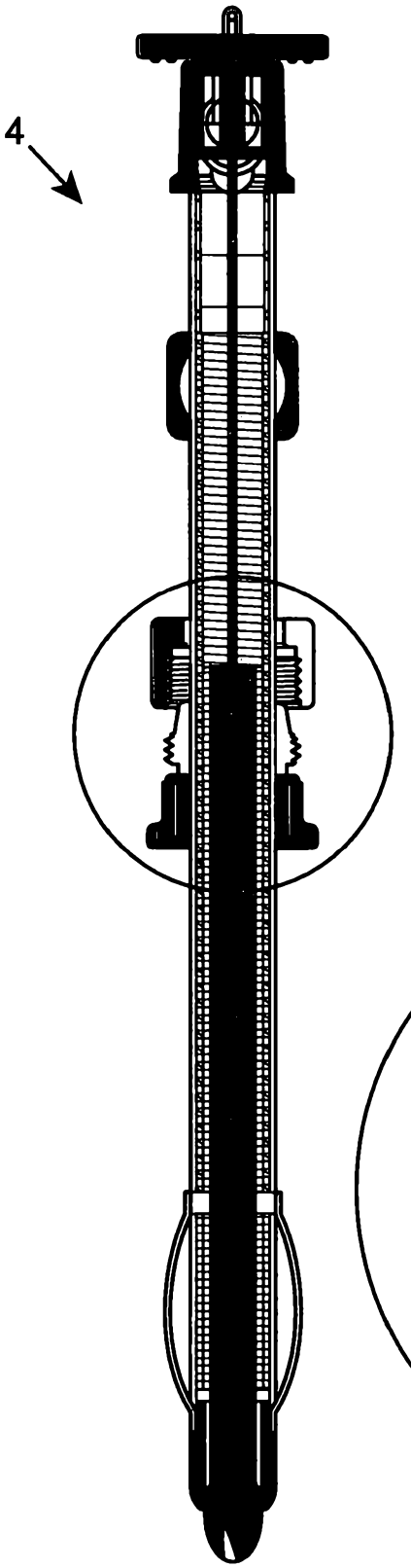


Fig. 13

SECTION A-A
SCALE 1:1

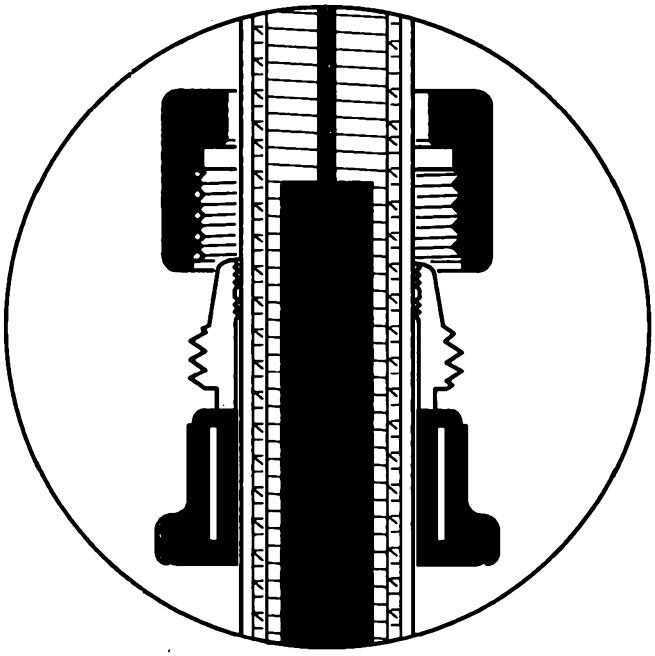


Fig. 14