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(54) Title: AN ARTIFICIAL AIRWAY DEVICE WITH DOUBLE WALLED CONNECTOR

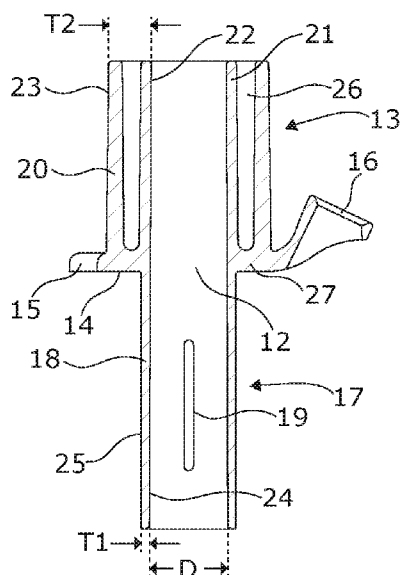


Fig. 6

(57) Abstract: An artificial airway device (1) with an airway tube (5) adapted to be inserted into a patient, the airway tube having a bore extending from a proximal end (6) to a distal end (7) of the airway tube, the airway tube further comprising a connector (2) with a longitudinal bore (12) and a first wall section (18) extending from a flange part (14) and adapted for insertion into the bore at the proximal end of the airway tube, a machine connector part (13) with a second wall section (20) extending from the flange part in a direction opposite to the first wall section and adapted for connecting to a breathing apparatus, the machine connector part further comprising a third wall section (21) extending from the flange part in the direction opposite to the first wall section, wherein the third wall section preferably extends inside the second wall section.



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An artificial airway device with double walled connector

The present invention relates to an artificial airway device with a connector.
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It is well known in the art of artificial airway devices such as laryngeal masks and endotracheal tubes to provide a connector at the proximal end of the airway tube for allowing connection of the artificial airway device to a breathing apparatus such as a ventilator. Such connector is known from e.g. the publication
10 WO 2007/071429 discloses a connector for a laryngeal mask, which connector comprises a connector body, a flange part extending radially from the connector body, an insertion section adapted for insertion into the bore at the proximal end of an airway tube of the laryngeal mask to support the airway tube in use and a machine connector part.

15 Typically, an artificial airway device is connected to a breathing apparatus such as a ventilator with a breathing circuit so that a circuit is formed from the patient to the breathing apparatus. In that situation a dead space at the patient end distal from the breathing apparatus that determines the amount of re-breathing of exhaled gases. The dead space is the volume of air which is inhaled
20 that does not take part in the gas exchange, i.e. the exchange of oxygen and carbon dioxide. This is typically not an issue for adults with larger tidal lung volumes, but it can be a problem for paediatric patients where the tidal volume approaches dead space at the patient end. Generally, rebreathing of exhaled gases in the dead space of an artificial airway device can be an issue for any patient,
25 paediatric or adult, whether breathing spontaneously or mechanically ventilated. Build-up of CO₂ due to rebreathing of exhaled gases can ultimately lower tissue pH which can have significant consequences. Moreover, a build-up of CO₂ can be associated with diminished oxygen which can have more urgent and dire consequences. This is especially problematic for paediatric patients, but also for other
30 patients with a small oxygen reserve such as obese, asthma, restrictive lung disease patients.

These issues are addressed in US2014/0338669 in which a double walled connector for an airway tube is disclosed. Although this connector solves the problem of the dead space as such, the connector has some drawbacks, in
35 particular in relation to hospital procedures, but also in relation to manufacture.

More specifically the double walled connector of US/2014/0338669 comprises a central annular rib with a central aperture. At the proximal end, i.e. the end adapted to be connected to the breathing circuit there are two concentric wall sections extending from the central rib, the external surface of the outer concentric wall is configured as a standard interface to be connected to the standardized tube from the breathing apparatus. The inner concentric wall is in communication with the central aperture to allow air to pass. The heights of the two concentric walls are basically the same, so that an annular cavity is formed between them. The air in this is quasi-stationary and will not take part in the air exchange through the connector, thus *de facto* reducing the dead space.

In a somewhat similar manner, two concentric walls sections are also provided on the opposite side of the central rib, i.e. extending towards distal end of the connector, and with the inner concentric wall in communication with the central aperture to allow air to pass. The respective inner surfaces of both the inner concentric wall and the outer concentric wall parts are both tapered in order to receive the proximal end of an airway tube leading to a patient. The details of the airway tube are not disclosed. In this way, depending on the desired size of the airway tube, the airway tube may be inserted into the slightly conical cavity formed by the interior surface of either the outer or inner wall part.

Adapting the connector for the insertion of an airway tube this way provides at least two problems.

One problem is that the connector cannot be used with some airway tubes, such as laryngeal masks, which at their proximal attachment end may have external grooves or other surface features, and typically have an opposite taper i.e. narrowing from the proximal attachment end towards the mask portion at the distal end.

Another problem is that the correct insertion of the airway tube is not easily verifiable. That is to say, hospital personnel have to have a simple way of ensuring that the airway tube is fully inserted, because if not the dead space will undesirably be increased and this increase likely will go undetected. Visual inspection is not possible because the outer and inner concentric wall parts, will distort or obscure vision, in particular when the tube is inserted into the inner cylindrical wall part. The same evidently applies to quality control by the manufacturer if the airway device is shipped preassembled, although the manufacturer of course will have other possibilities for quality control during manufacturing.

In view of the above it is an object of the invention to provide an artifi-

cial airway device with a verifiable reduced dead space.

In a first aspect of the invention this object is achieved with an artificial airway device with an airway tube adapted to be inserted into a patient, the airway tube having a bore extending from a proximal end to a distal end of the airway tube and a connector connected to the proximal end of the airway tube, the connector has a longitudinal bore and comprising: a first wall section extending from a flange part and adapted for insertion into the bore at the proximal end of the airway tube, a second wall section extending from the flange part in a direction opposite to the first wall section and adapted for connecting to a breathing apparatus, wherein the connector further comprises a third wall section extending from the flange part in the direction opposite to the first wall section. By having the first wall section extending from the flange part and adapted for insertion into the bore at the proximal end of the airway tube adapting, the connector may simply be inserted into the airway tube until the proximal end of the airway tube abuts the flange. This abutment gives definite tactile feedback that the connector is fully and correctly inserted and, in case of doubt, this is easily verifiable by simple visual inspection that there is no gap between the flange and the proximal end of the airway tube. At the same time, the provision of the third wall significantly reduces the dead space especially for connectors used in paediatric size artificial airway devices. The provision of a third wall section extending in the same direction as the second wall section allows for a reduction or adjustment of the interior dead space of the connector. The connector is typically injection moulded and therefore the third wall section may be provided without need of additional cooling to avoid warping of the second wall section, which must be moulded within precise tolerances in order to always fit perfectly with a standard connector of for instance a breathing circuit or resuscitator.

In an embodiment the longitudinal bore of the connector is formed by the first wall section and the third wall section. In a further embodiment the third wall section extends inside the second wall section. Further it is practically preferred that the wall sections are cylindrically shaped. In a further practical embodiment the second wall section and the third wall section are coaxial.

In a second aspect of the invention is object is achieved with a connector adapted to be connected to the proximal end of the airway tube, the connector has a longitudinal bore and comprising: a first wall section extending from a flange part and adapted for insertion into the bore at the proximal end of the airway tube,

a second wall section extending from the flange part in a direction opposite to the first wall section and adapted for connecting to a breathing apparatus, wherein the connector further comprises a third wall section extending from the flange part in the direction opposite to the first wall section.

5 In a practical embodiment of the second aspect of the invention the connector further comprises a third wall section extending from the flange part in the direction opposite to the first wall section.

In an embodiment the longitudinal bore of the connector is formed by the first wall section and the third wall section. In a further embodiment the third
10 wall section extends inside the second wall section. Further it is practically preferred that the wall sections are cylindrically shaped. In a further practical embodiment the second wall section and the third wall section are coaxial.

The invention will now be described in greater detail based on non-limiting exemplary embodiments and with reference to the drawings, on which:

15 Fig. 1 shows a laryngeal mask with a connector according to the invention,

Figs. 2 and 4 are different perspective views of the connector according to the invention,

Fig. 3 is a side view of a connector according to the invention,

20 Fig. 5 is another side view of a connector according to the invention,

Fig. 6 is a cross sectional view of Fig. 5 taken along the line A-A.

In Fig. 1 is shown a laryngeal mask 1 with a connector 2 according to an embodiment of the invention. The laryngeal mask 1 shown is of the kind which comprises a gastric tube 3 allowing for removal of gastric matter in case of re-
25 gurgitation while the laryngeal mask 1 is placed in the patient, where the laryngeal inlet of the patient is sealed by a mask portion 4 so that the patient can be ventilated via an airway tube 5. The airway tube is adapted to be inserted into a patient. The schematically depicted laryngeal mask with the provision of a gastric tube 3 is known from now expired US-A-4995388 and especially from US-A-
30 5241956. However, as will become apparent from the following description, the connector according to the invention is not limited to this specific type of laryngeal masks. In the following description the invention is described in connection with a laryngeal mask. However, it will become apparent to the skilled person the connector 2 according to the invention may be used in combination with other
35 artificial airway devices such as as laryngeal tubes and endotracheal tubes.

As the laryngeal mask 1 is to be inserted into a patient it is preferably

made of a phthalate free PVC. The airway tube 5 of the laryngeal mask 1 has a bore extending from a proximal end 6 to a distal end 7 of the airway tube 5, which terminates in an aperture surrounded by the mask portion 4. Generally, artificial airway devices according to the invention are provided with an inflatable
5 cuff such as the mask portion 4 in the illustrated embodiment. The inflatable cuff serves to keep the artificial airway device in position and/or seal once correctly placed in the patient. The airway tube 5 is configured such that in use, the teeth of the patient contact the proximal end at a point of tooth contact. The connector 2, preferably made of a copolyester, is fitted into the proximal end 6 of the air-
10 way tube 5. For the sake of completeness, the laryngeal mask device also comprises an inflation tube 8, a distal end of which is in communication with the mask portion 4 for inflation thereof and a proximal end of the inflation tube terminates in a pilot balloon 9, which allows for a tactile detection of the inflation pressure of the mask portion 4. The pilot balloon 9 comprises a valve 10 adapted
15 for insertion of the tip of a syringe for inflation and deflation of the mask portion via the pilot balloon 9 and the inflation tube 8.

The connector is shown alone in Figs. 2 to 6. The connector 2 is substantially cylindrical with a through-going longitudinal bore 12. A proximal end of the connector 2 comprises a standardized machine connector part 13 adapted to
20 connect the laryngeal mask to a breathing apparatus. A flange part 14 extends radially from the connector body and serves as a stop when the connector 2 is inserted into the airway tube 5. The flange part 14 may have a cut-away portion 15 adapted to releasably hold the inflation tube 8. Further, the flange part 14 may have a cut-away or a bore 16 adapted for holding and guiding the gastric
25 tube 3. A distal end of the connector 2 is provided with an insertion section 17 adapted for insertion into the bore at the proximal end of the airway tube 5. Thereby the insertion section 17 serves to support the airway tube 5 in use. The connector 2 may be releasably connected to the proximal end of the airway tube 5. This is for instance appreciated when the connector 2 is used with an artificial
30 airway device such as an endotracheal tube, where the airway tube 5 traditionally is cut to length after insertion into the patient. As explained above, this is one of the situations where the present invention is advantageous over the prior art, because the present invention allows for the verification of the correct assembly or re-assembly of the connector and the endotracheal tube, by feeling and seeing
35 that the endotracheal tube abuts the flange part 14. Likewise if the intubation with the endotracheal tube is made through a laryngeal mask. In that case the

connector of the endotracheal tube needs to be removed in order to extract the laryngeal mask, and subsequently refitted.

The insertion section 17 is formed by a single first cylindrical wall 18 extending longitudinally away from the flange part 14. An elongate slot 19 may be provided in the first cylindrical wall 18 in order to facilitate removal of the connector from the mould after injection moulding. The machine connector part 13 comprises a second cylindrical wall 20 which extends in a longitudinal direction opposite to the first cylindrical wall 18. The outer shape and configuration of the second wall section 20 of the machine connector part 13 is determined by the common standards for such machine connector parts. As seen in Fig. 4 the machine connector part 13 further comprises a third cylindrical wall 21, which extends in the same direction as the first cylindrical wall 20. Generally, the wall sections 18, 20, 21 are cylindrical or substantially cylindrical. By substantially cylindrical is meant that the wall sections may be slightly frustro-conical to facilitate removal from a moulding tool. In the embodiment shown an outer surface 23 of the second wall section 20 is slightly frustro-conical in order to ensure a stable connection to a standard connector of a breathing circuit or a breathing device such as a resuscitator. The third wall section 21 is coaxial with the second wall section 20 and extends inside the second wall section 20 so that a lumen 26 is formed between the third wall section 21 and the second wall section 20.

As best seen from Fig. 6 the flange part 14 forms a connection between the second wall section 20 and the third wall section 21 intermediate the proximal end and the distal end of the connector 2, where the insertion part 17 is positioned at the distal end and the machine connector part 13 is positioned at the proximal end of the connector 2. The first wall section 18 of the insertion part 17 has a thickness T1 taken radially from an inner surface 24 of the first wall section 18 to an outer surface 25 of the first wall section 18. The machine connector part 13 has a thickness T2 taken radially from an inner surface 22 of the third wall section 21 to the outer surface 23 of the second wall section 20. The thickness T2 is at least two times the thickness T1. Preferably, T2 is about 3-4 times T1. The flange part 14 preferably extends radially from the first wall section 18 and may extend beyond the second wall section 20 of the machine connector part 13. This allows provision of cut-aways and bores 15, 16. Evidently, the flange part may take many forms and may in a simple embodiment only extend to the outer surface 23 of the second wall section 20. Likewise, the transition from the first wall section 18 to the second wall section 20 may be more curved and smooth than

the illustrated embodiment depending on the configuration of the proximal end of the airway tube 5 and the bore at the proximal end of the airway tube.

Basically, the flange part 14 is formed by an annular ring 27 from which the wall sections 18, 20, 21 extend. The first wall section 18 and the third wall section 21 extend in opposite directions from an inner edge of the annular ring 27, whereas the second wall section 20 extends from an outer edge of the annular ring 27. Hence the annular ring 27 forms a bottom wall delimiting the lumen 26 formed between the third wall section 21 and the second wall section 20. The through-going longitudinal bore 12 with an inner diameter D of the connector 2 is formed by the first wall section 18 and the third wall section 21. Hence the first wall section 18 and the third wall section 21 substantially have the same inner diameter D throughout the length of the bore 12. The bore 12 thus presents a bore surface which is both circumferentially and longitudinally smooth and continuous. In particular in the vicinity of the flange part 14 this is advantageous over the prior art of US2014/0338669 where a extraction passage with a protruding rim is provided, because these features complicates injection moulding as compared the smooth through bore 12 of the present invention.

The reduction in dead space provided by the embodiments according to the invention may for paediatric airway devices reduce the dead space with about 50 % or more compared to legacy connectors with only the first and second wall segments where the thickness of the machine connector part 13 is not substantially thicker than the thickness of the first wall section 18. For paediatric airway devices such reduction in the dead space may have a significant clinical difference. Especially when the connector is used with endotracheal tubes for children or infants where the dead space of the connector 2 constitutes a significant part of the total dead space of the airway device, because the endotracheal tubes may have lumens as small as 1-2 mm diameter.

If desirable the lumen 26 between the second wall section 20 and the third wall section 21 may be filled with a moulding material such as an UV curing adhesive. Alternatively, a connector 2 with reduced dead space may be provided by integrally moulding the machine connector part 13 without the lumen 26, where the machine connector part 13 only comprises one wall section. The thickness of the wall section then forming the machine connector part should then have a thickness T2 which is at least two times the thickness T1 or more. However, such approach would also require cooling during the manufacturing process to avoid warping of the machine connector part after moulding in order to comply

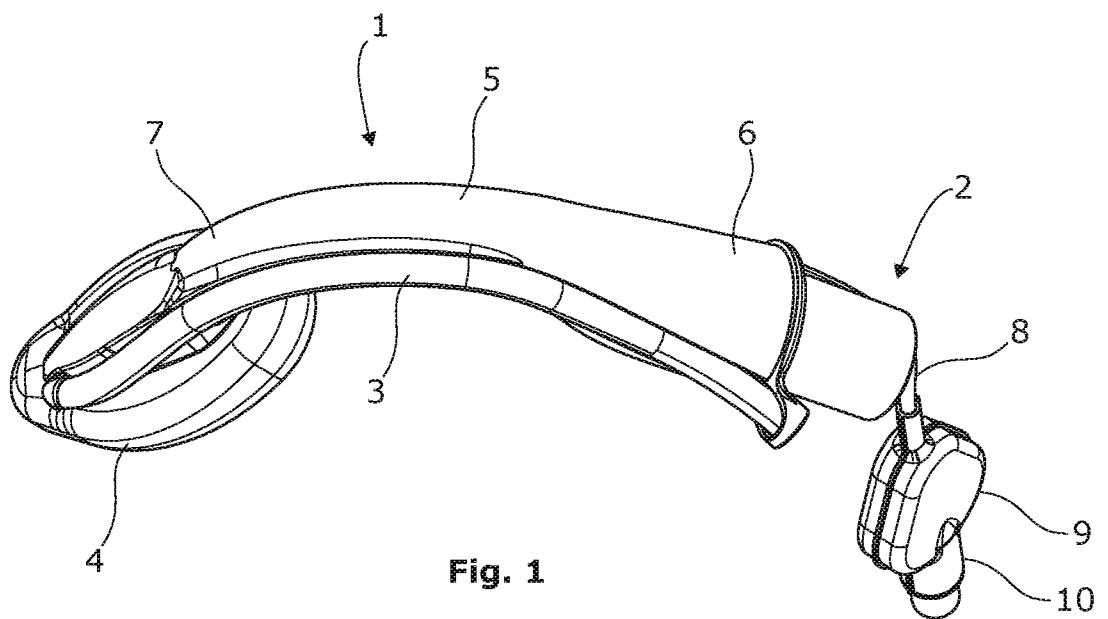
with the required tolerances for standards machine connector parts. Hence a connector 2 with such configuration would be more costly and cumbersome to manufacture as compared to a connector 2 as depicted in Fig. 2 to 6, where the reduction in dead space is provided by provision of a third wall section 21 so as

5 to reduce the dead space of the connector 2.

P A T E N T C L A I M S

1. An artificial airway device with an airway tube adapted to be inserted into a patient, the airway tube having a bore extending from a proximal end to a distal end of the airway tube and a connector connected to the proximal end of
5 the airway tube, the connector has a longitudinal bore and comprising:
 - a first wall section extending from a flange part and adapted for insertion into the bore at the proximal end of the airway tube,
 - a second wall section extending from the flange part in a direction opposite to the first wall section and adapted for connecting to a breathing apparatus,
- 10 wherein the connector further comprises a third wall section extending from the flange part in the direction opposite to the first wall section.
2. An artificial airway device according to claim 1, wherein the longitudinal bore of the connector is formed by the first wall section and the third wall section.
- 15 3. An artificial airway device according to claim 1 or 2, wherein the third wall section extends inside the second wall section.
4. An artificial airway device according to claim 1 to 3, wherein the wall sections are cylindrically shaped.
5. An artificial airway device according to 4, wherein the second wall
20 section and the third wall section are coaxial.
6. An artificial airway device according to any one of the preceding claims, wherein the longitudinal bore has a bore surface, which at least in the vicinity of the flange part is circumferentially and longitudinally smooth and continuous,
- 25 7. An artificial airway device according to any previous claim, wherein the airway device is a supraglottic airway device, preferably a laryngeal mask.
8. An artificial airway device according to any previous claim, wherein the airway device is an endotracheal tube.
9. A connector adapted to be connected to the proximal end of the air-
30 way tube, the connector has a longitudinal bore and comprising:
 - a first wall section extending from a flange part and adapted for insertion into the bore at the proximal end of the airway tube,
 - a second wall section extending from the flange part in a direction opposite to the first wall section and adapted for connecting to a breathing apparatus,
- 35 wherein the connector further comprises a third wall section extending from the flange part in the direction opposite to the first wall section.

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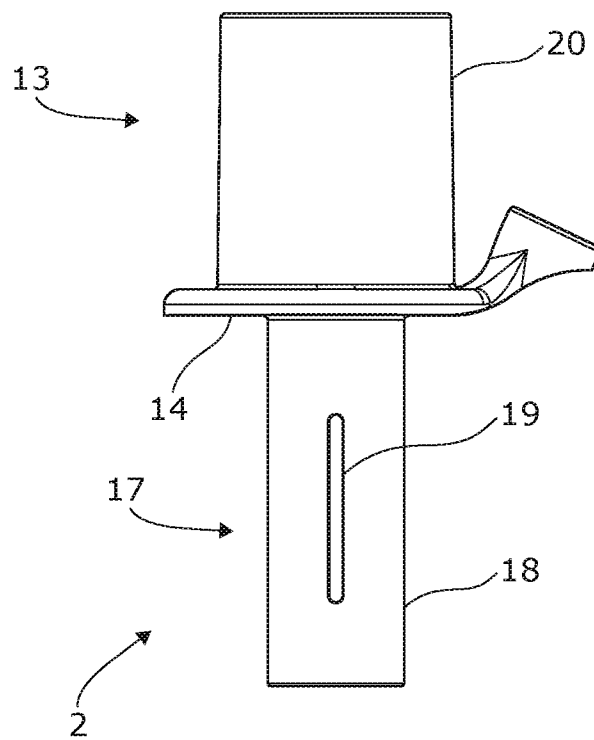
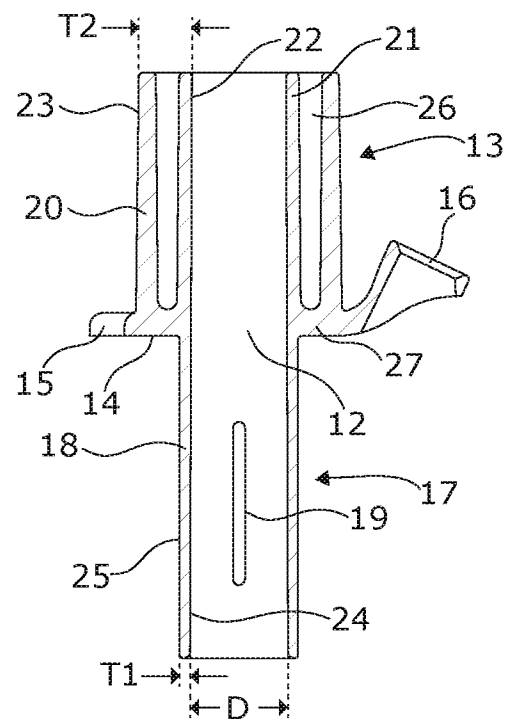
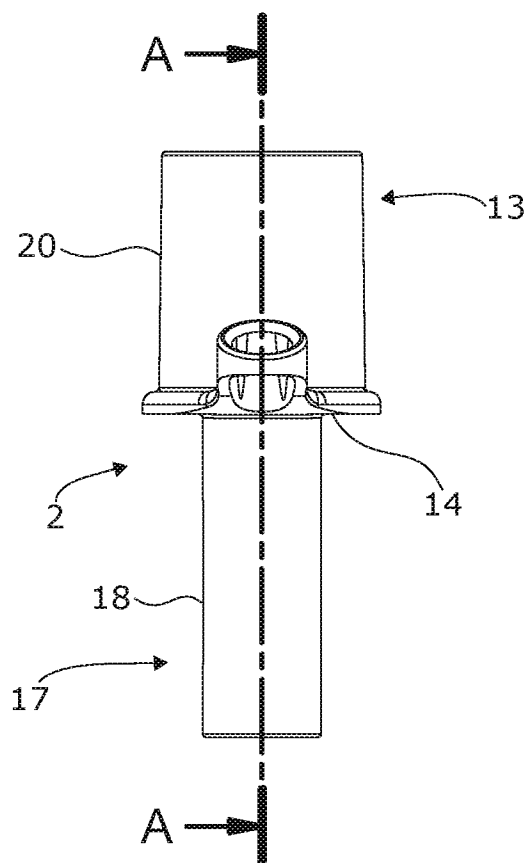
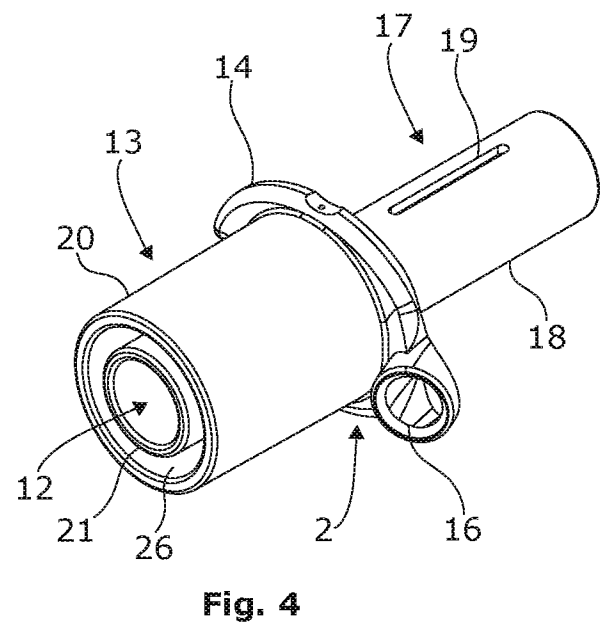
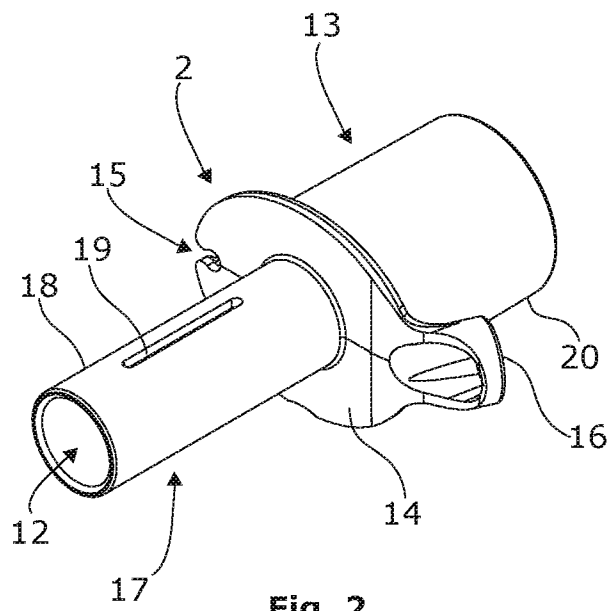


Fig. 3

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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
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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)
A61M

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)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 295 08 911 U1 (SCHEU ROLF RAINER [DE]) 17 August 1995 (1995-08-17) The whole document, especially figures 2 and 3 -----	1-9
X	US 2014/338669 A1 (ZHAO HUALIN [CN] ET AL) 20 November 2014 (2014-11-20) cited in the application	1-9
Y	the whole document -----	1-8
X	GB 2 218 909 A (HARNEDY JOHN) 29 November 1989 (1989-11-29)	9
Y	The whole document, especially Fig. 1 -----	1-8



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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