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(54) Title: TRACHEOSTOMY TUBE ASSEMBLIES AND INNER CANNULAE

(57) Abstract: A tracheostomy tube assembly includes an outer tube (1) and an inner cannula (2) removably inserted in the outer tube. The connector (15) on the machine end of the outer tube is rotatable through about a quarter turn and has a screw thread (30) on its inner surface. The hub (33) on the machine end of the inner cannula (2) is also formed with a screw thread (35) arranged to engage with the screw thread (30) in the connector. The inner cannula (2) is pulled into the outer tube (1), or is pushed outwardly of the tube, by rotating the connector.

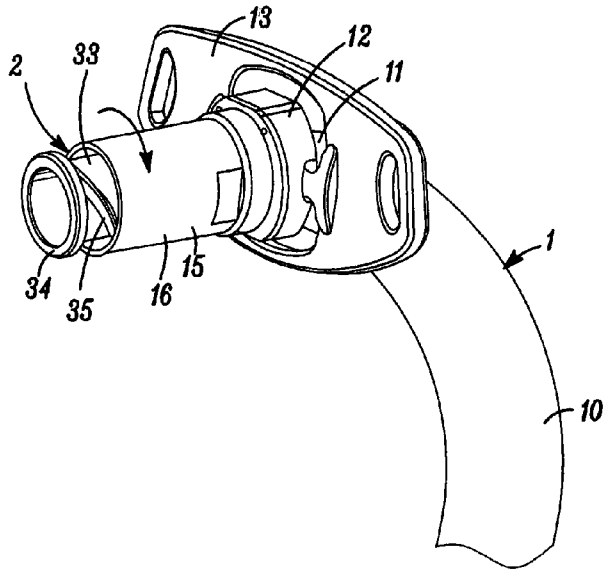


FIG. 1

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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).

Declarations under Rule 4.17:

— *as to the identity of the inventor (Rule 4.17(i))*

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *of inventorship (Rule 4.17(iv))*

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TRACHEOSTOMY TUBE ASSEMBLIES AND INNER CANNULAE

This invention relates to tracheostomy tube assemblies of the kind including an outer tracheostomy tube and an inner cannula removably inserted to extend along the bore of the tracheostomy tube.

Tracheostomy tube assemblies commonly include an outer tube and an inner tube or cannula that is a removable fit within the outer tube. The inner cannula can be removed and replaced periodically to ensure that the passage through the assembly does not become blocked by secretions. This avoids the need to remove the outer tube frequently.

The inner cannula presents various problems because it must be thin walled and a close fit within the outer tube so as to provide a large bore and thereby limit the resistance to flow of gas along the assembly. It must, however, also be sufficiently stiff to be inserted in the outer tube without buckling or kinking and must be readily removable, preferably with only minimal force being exerted on the tube. WO94/01156 and WO2004/101048 describe inner cannulae made of PTFE. EP1938857 describes an arrangement of tracheostomy tubes and inner cannulae where the hubs of the inner cannulae of different sizes are shaped differently so that they will only fit in the appropriate tracheostomy tube. EP2224985 describes an arrangement for attaching a hub to the shaft of an inner cannula. GB2056285 describes an inner cannula having a wall corrugated both externally and internally and a longitudinal groove or other reinforcement member traversing at least some of the corrugations. US4817598 describes a smooth-walled inner cannula having a ring-pull formation at its rear, machine end. US5119811 describes an inner cannula with a flared patient end and formed of two layers of different materials. US5386826 describes an inner cannula with an outer helical filament or layer of low friction material. US5983895 describes an inner cannula with straight sections at opposite ends joined by an intermediate curved section. US6019753 describes an inner cannula with two elongate regions of different flexibility so that the cannula has a plane of preferential bending. US6019753 describes an inner cannula having a shaft formed with slots to make it more flexible, the slots being covered by an outer thin sheath. US6135110 describes a curved inner cannula that is retained with the outer tube by means of a rotatable spring fitting. Tracheostomy assemblies are also available where the inner cannula is attached with a 15mm male tapered connector that is screw threaded onto the hub of the tracheostomy tube. These arrangements have the advantage that they

reduce the pulling and pushing force otherwise needed to remove and insert an inner cannula. The problem with such arrangements, however, is that, when the inner cannula is removed the tracheostomy tube lacks a connector. There is also a risk that the connector may become unscrewed from the tube inadvertently when connected in a breathing circuit and cause leakage of ventilation gas, thereby preventing effective ventilation. Other inner cannula arrangements are described in, for example, US6024730, WO2014/132015, WO2014/132016, WO2015/110773, WO2015/118288, WO2015/136232, WO2015/145099, WO2015/166200, GB2531902 and PCT/GB2016/000069.

It is an object of the present invention to provide an alternative tracheostomy tube assembly and inner cannula.

According to one aspect of the present invention there is provided a tracheostomy tube assembly of the above-specified kind, characterised in that the tracheostomy tube includes a rotatable member towards its machine end attached with a hub of the tube in a manner that allows the member to rotate relative to the hub about the axis of the hub through at least a limited angle, that the rotatable member has a surface formation on an inner surface, and that the inner cannula has a surface formation on its outer surface adapted to engage with the surface formation on the rotatable member in such a manner that rotating the rotatable member in one direction relative to the tracheostomy tube pulls the inner cannula into the tracheostomy tube and rotating in the opposite direction pushes the inner cannula out of the tracheostomy tube.

The rotatable member may be a connector of the tracheostomy tube. The connector preferably has a tapered outer surface. Alternatively, the rotatable member may a rotatable ring separate from a connector on the outer tube. The surface formations on the rotatable member and the inner cannula preferably include cooperating screw threads. The rotatable member is preferably rotatable by less than a full rotation, such as through an angle of about a quarter turn. The rotatable member and a hub of the outer tube are preferably both provided with markings that align when the rotatable member is at its locked or unlocked states. The rotatable member and a part of the outer tube may be provided with cooperating engagement members arranged to resist rotation from the locked position.

According to another aspect of the present invention there is provided an inner cannula for use in a tracheostomy assembly according to the above one aspect of the present invention.

Two embodiments of tracheostomy assemblies including an inner cannula, both in accordance with the present invention, will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a perspective view of a first embodiment of the assembly with the inner cannula protruding from the outer tube and not fully inserted or locked in position;

Figure 2 is a perspective view of the assembly with the inner cannula fully inserted and locked in position;

Figure 3 is a cross-sectional side elevation of the machine end of the outer tube;

Figure 4 is a side elevation view of the machine end of the inner cannula;

Figure 5 is a cross-sectional side elevation view of the assembly with the inner cannula in a locked position;

Figure 6 is a cross-sectional view of the assembly along a plane at an angle inclined to the cross-sectional plane of Figure 5;

Figure 7 is a perspective view of a second embodiment of the invention in a locked position;

Figure 8 is an enlarged cross-sectional side elevation view of the machine end of the second embodiment with the inner cannula locked in position;

Figure 9 is an enlarged cross-sectional side elevation view of the machine end of the second embodiment with the inner cannula partially ejected; and

Figure 10 is an enlarged transverse sectional view from the patient end showing the locking ring in an intermediate position.

With reference first to Figures 1 and 6, the first embodiment of the tracheostomy tube assembly comprises an outer tracheostomy tube 1 and a removable inner cannula 2 inserted within the outer tube. The outer tube 1 has a shaft 10, which is shown as being uncuffed but which could have a sealing cuff towards its patient end in the usual way. At its rear or machine end 11 the outer tube 1 has a hub 12 and flange 13 to which a retaining tape (not shown) can be fastened for securing the tube with the patient's neck. The outer tube 1 could have an internal diameter between about 2mm and 10mm, and its length could be between 60mm and 200mm. The hub 12 has a 15mm male connector 15 secured with it, the connector having a tapered outer surface 16, which is adapted to mate with the inside surface of a cooperating female connector. The connector 15 has an inwardly-facing annular lip 17 at its forward, patient end to the rear of which extends an annular recess 18 (Figure 5). A short collar 19 projects rearwardly from the hub 12 within the forward end of the connector 15, the collar having an outwardly-projecting lip 20 with an inclined face 21. The lip 20 on the hub 12 is aligned with the recess 18 around the connector 15 and is snapped into the recess to form a permanent attachment of the connector to the hub. The attachment provided in this way enables the connector 15 to be rotated relative to the hub 12 about the axis of the hub and through only a limited angle of about one quarter of a turn, that is, 90°.

The forward end face 22 of the connector 15 and the hub 12 have cooperating engagement members in the form of a shallow recess 23 (Figure 6) on the connector that is adapted to receive within it a shallow projection or dimple 24 projecting rearwardly from the face 25 of the hub 12. The

position of the dimple 24 and recess 23 are such that they align and engage when the connector 15 is rotated to its full extent relative to the hub 12 in the clockwise, locking direction. The size and shape of the dimple 24 and recess 23 are such that their engagement is sufficient to retain the connector 15 in the locked position against normal forces experienced during use and requires an increased initial unlocking twisting force applied by the user to release the connector so that it can be twisted anticlockwise in the unlocking direction.

Towards its forward, patient end the connector 15 has a visible marking 26 (Figure 2) on its outside surface that is movable to align with one of two visible markings 27 and 28 on the rear facing face 25 of the hub 12 to indicate a locked or unlocked state respectively. It will be appreciated that the hub could just have one marking to indicate either the locked or the unlocked state.

The inside of the connector 15 has an enlarged, tapered opening 29 at its open, rear or machine end (Figure 3). Forwardly of the opening 29 the interior of the connector 15 is moulded with a surface formation 30 in the form of a screw thread with a relatively wide pitch that extends forwardly by about one third the length of the connector 15.

With particular reference to Figure 4, the inner cannula 2 includes a shaft 32 of circular section and of a thin, stiff plastics material, such as PVC, polyurethane, polyethylene, polypropylene, PTFE or other flexible or semi-rigid plastics material. The external diameter of the shaft 32 is selected to be just smaller than the inner diameter of the shaft 10 of the outer tube 1 so that the inner cannula 2 can be readily inserted and removed from the outer tube. The shaft 32 is curved to the same curvature as the shaft 10 of the outer tube 1 in which it is to be used. The rear or machine end of the cannula 2 has an integral hub or machine end fitting 33 with a thicker wall than the shaft 32. The hub or machine end fitting 33 is shaped to locate and secure within the connector 15. More particularly, the hub 33 has a radially enlarged annular rim 34 at its rear, machine end that is shaped to be a snug fit within the enlarged opening 29 of the connector 15. Forwardly of the rim 34 the outer surface of the machine end fitting 33 is moulded with a surface formation in the form of a projecting screw thread 35 arranged to engage cooperatingly with the thread 30 on the inside of the connector 15. The threads 30 and 35 on the connector 15 and inner cannula 2 cooperate so that, by rotating the connector, the inner cannula can be pulled into or pushed out of the connector. The curved shape of its shaft 32 prevents the inner cannula 2 being rotated significantly when the connector 15 is rotated so that the

major part of the rotational movement of the connector is translated into linear movement of the inner cannula.

Figure 1 shows the assembly with the inner cannula 2 only partially inserted in the outer tube 1 and with a part of its rear or machine end hub 33 protruding from the connector 15. The thread 35 on the inner cannula 2 is only partially engaged with the thread 30 on the inside of the connector 15. In this state the connector 15 is in an unlocked position where it is rotated to its full extent anticlockwise. The marking 26 on the connector 15 is not visible in Figure 1 but is aligned with the "unlocked" mark 28 on the hub 12. To load the inner cannula 2 fully in the outer tube 1 and lock it in position the user simply grips the outside of the connector 15 and twists this through a quarter turn clockwise (as indicated by the arrow in Figure 1). In this way the threads 30 and 35 on the connector 15 and inner cannula 2 engage and act to pull the inner cannula forwardly into the outer tube until it reaches the position shown in Figure 2 where the rear end of the inner cannula is drawn level with the rear end of the connector. In this position the marking 26 on the connector 15 has been rotated to align with the "locked" marking 27 on the hub 12.

To remove the inner cannula 2, such as when it needs to be cleaned or replaced by another cannula, the connector 15 is simply twisted back anticlockwise, which has the effect of jacking the inner cannula rearwardly to the position shown in Figure 1 where its rim 34 can be gripped to enable it to be pulled manually fully out of the outer tube 1.

The embodiment described above has a screw thread surface on the inside of a rotatable connector that engages a screw formation on the outside of the inner cannula. However, in other embodiments the connector could be fixed and the assembly instead include some other rotatable member with an inner surface formation that engages a formation on the outside of the inner cannula.

With reference now to Figures 7 to 10 there is shown a second embodiment of the present invention with an inner cannula 2' that differs from the cannula described in the first embodiment in that, instead of having a screw thread formed along its hub, it has a surface formation in the form of a narrow lug 40 projecting outwardly from the shaft 41 upwardly, that is, on the outside of the curvature of the shaft. The outer, tracheostomy tube 1' also differs in having a fixed connector 15' and a rotatable locking ring 44 mounted coaxially of the connector, between the connector and the hub 12'.

The outer edge 45 of the ring 44 is knurled to improve grip. The mounting of the locking ring 44 on the hub 12' allows for only limited angular rotation of 90°. The inner surface of the locking ring 44 has a short, divided screw thread 46 shaped to engage opposite faces of the lug 40 on the inner cannula 2'. Figure 8 shows a condition where the locking ring 44 is rotated fully clockwise and it can be seen that one part of the thread 46 on the ring lies on the outer, left-hand surface of the lug 40, thereby forcing the inner cannula 2' inwardly into the outer tube 1' until the rim 48 at the end of the inner cannula hub 47 engages the outer end of the connector 15'. Rotating the locking ring 44 in the opposite, anticlockwise sense brings the rearwardly-facing surface of the other part of the screw thread 46 on the ring into engagement with the forwardly-facing surface of the lug 40 on the inner cannula 2', thereby pushing the inner cannula out of the outer tube 1' by a short distance, as shown in Figure 9. The distance by which the locking ring 44 ejects the inner cannula 2' is only small but is sufficient to enable the rim 48 at the end of the inner cannula to be gripped so that it can be pulled fully out of the outer tube by hand.

The arrangement of the present invention can be used to overcome the problems of previous arrangements where the action of removing and replacing an inner cannula results in uncomfortable and possibly damaging forces applied to the delicate tissues around the patient's stoma. The twist mechanism of the present invention ensures that the inner cannula is drawn smoothly into or pushed smoothly out of the outer tube. The invention also allows for the connector to remain securely attached with the outer tube so that it can be used with or without an inner cannula.

CLAIMS

1. A tracheostomy tube assembly including an outer tracheostomy tube (1, 1') and an inner cannula (2, 2') removably inserted to extend along the bore of the tracheostomy tube, characterised in that the tracheostomy tube includes a rotatable member (15, 44) towards its machine end attached with a hub (12, 12') of the tube (1, 1') in a manner that allows the member to rotate relative to the hub about the axis of the hub through at least a limited angle, that the rotatable member (15, 44) has a surface formation (30, 46) on an inner surface, and that the inner cannula (2, 2') has a surface formation (35, 40) on its outer surface adapted to engage with the surface formation (30, 46) on the rotatable member (15, 44) in such a manner that rotating the rotatable member in one direction relative to the tracheostomy tube (1, 1') pulls the inner cannula (2, 2') into the tracheostomy tube and rotating in the opposite direction pushes the inner cannula out of the tracheostomy tube.

2. A tracheostomy tube assembly according to Claim 1, characterised in that the rotatable member is a connector (15) of the tracheostomy tube (1).

3. A tracheostomy tube assembly according to Claim 2, characterised in that the connector (15) has a tapered outer surface (16).

4. A tracheostomy tube assembly according to Claim 1, characterised in that the rotatable member is a rotatable ring (44) separate from a connector (15') on the outer tube (1').

5. A tracheostomy tube assembly according to any one of the preceding claims, characterised in that the surface formations on the rotatable member (15, 44) and the inner cannula (2, 2') include cooperating screw threads (30, 46 and 35, 40).

6. A tracheostomy tube assembly according to any one of the preceding claims, characterised in that the rotatable member (15, 44) is rotatable by less than a full rotation.

7. A tracheostomy tube assembly according to Claim 6, characterised in that the rotatable member (15, 44) is rotatable through an angle of about a quarter turn.

8. A tracheostomy tube assembly according to any one of the preceding claims, characterised in that the rotatable member (15) and a hub (12) of the outer tube (1) are both provided with markings (26, 27) that align when the rotatable member is at its locked or unlocked states.

9. A tracheostomy tube assembly, characterised in that rotatable member (15) and a part of the outer tube (1) are provided with cooperating engagement members (23 and 24) arranged to resist rotation from the locked position.

10. An inner cannula (2, 2') for use in a tracheostomy tube assembly according to any one of the preceding claims.

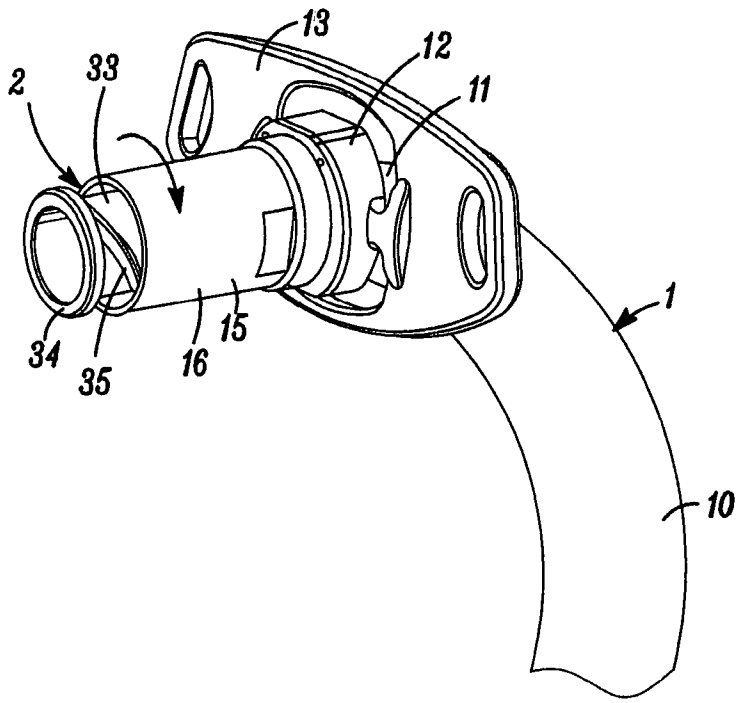


FIG. 1

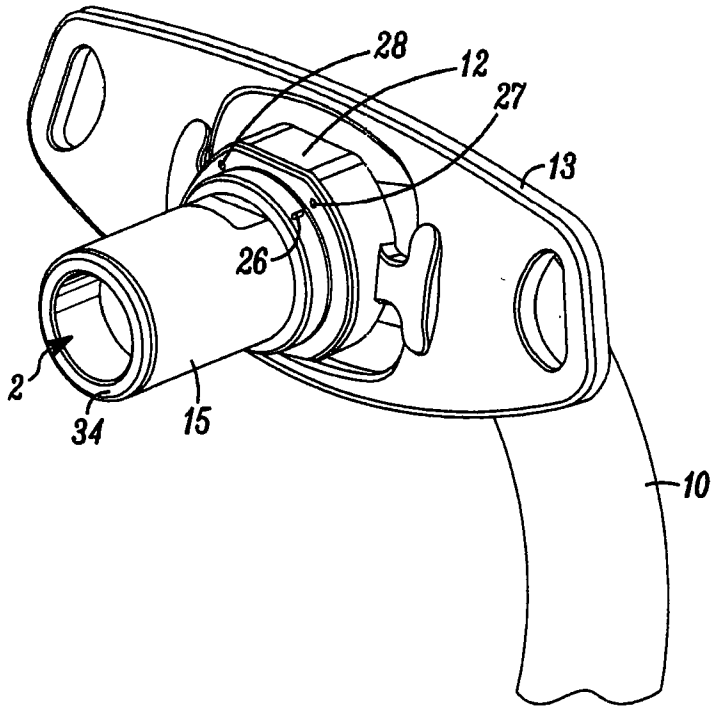


FIG. 2

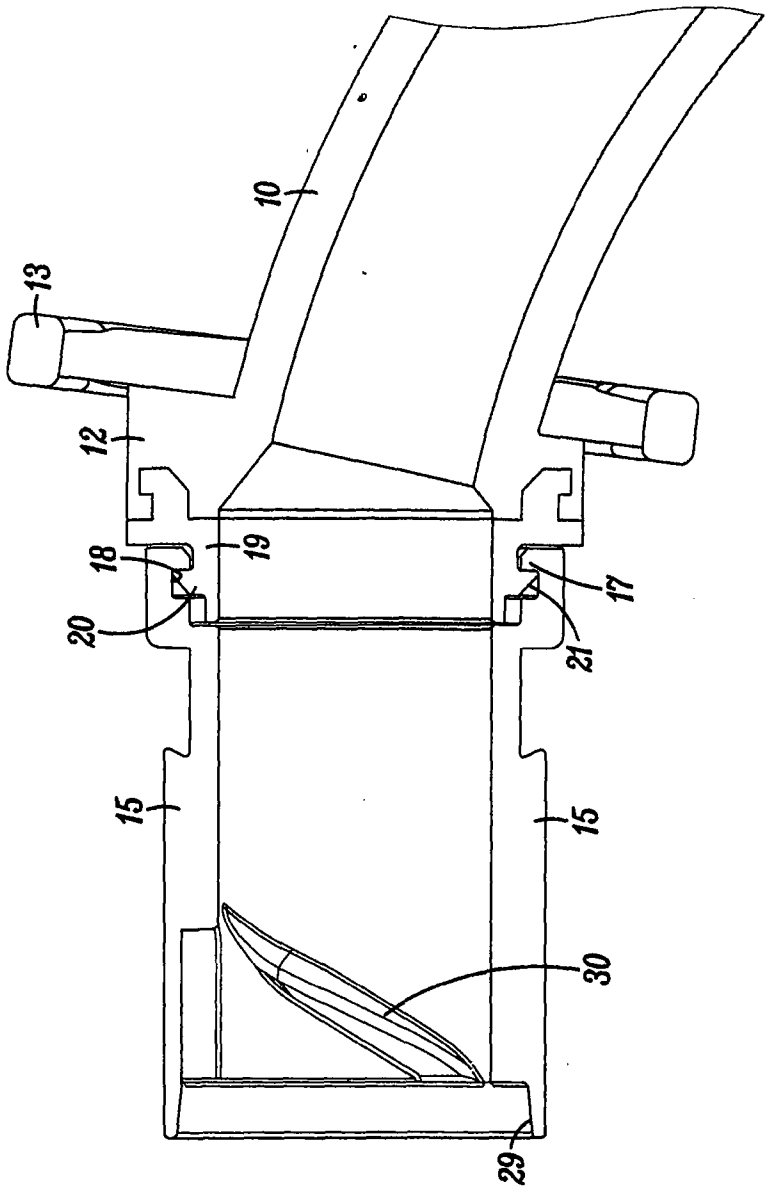


FIG. 3

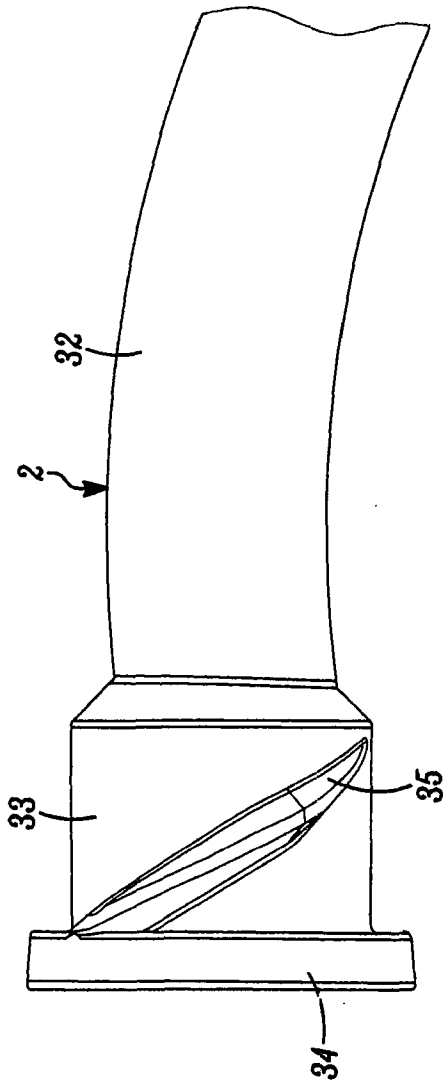


FIG. 4

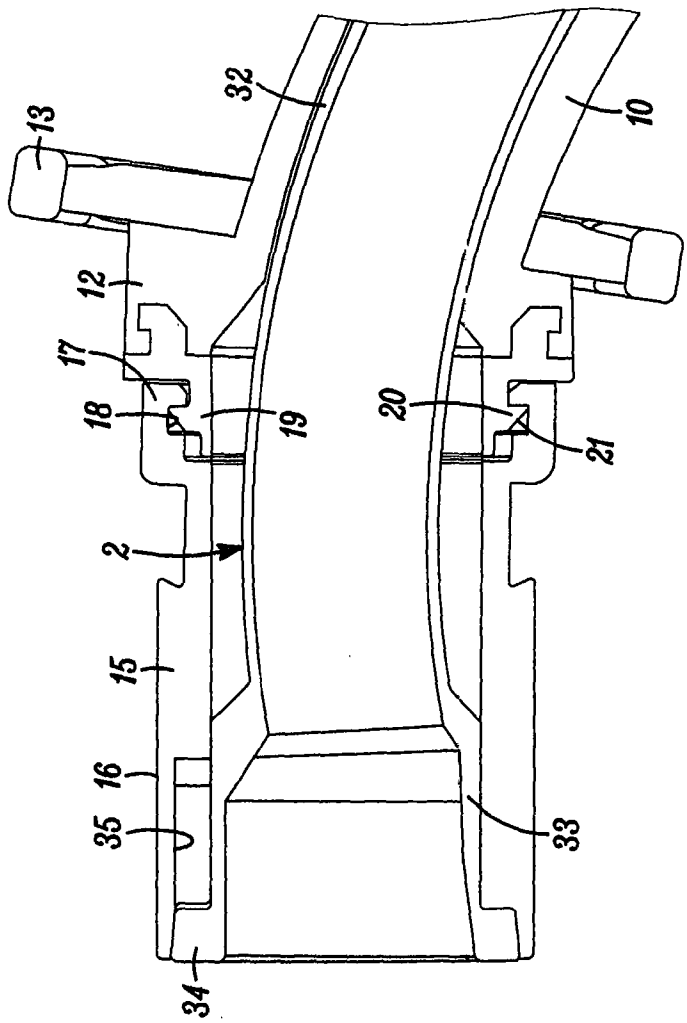


FIG. 5

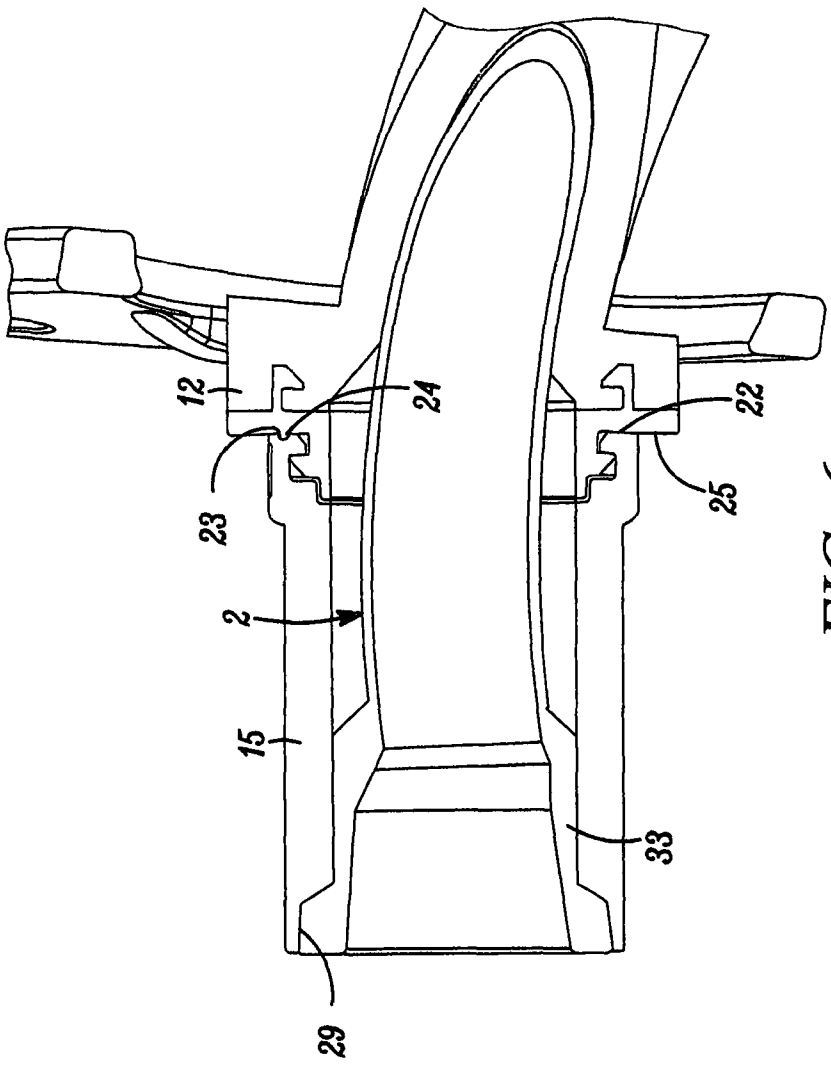


FIG. 6

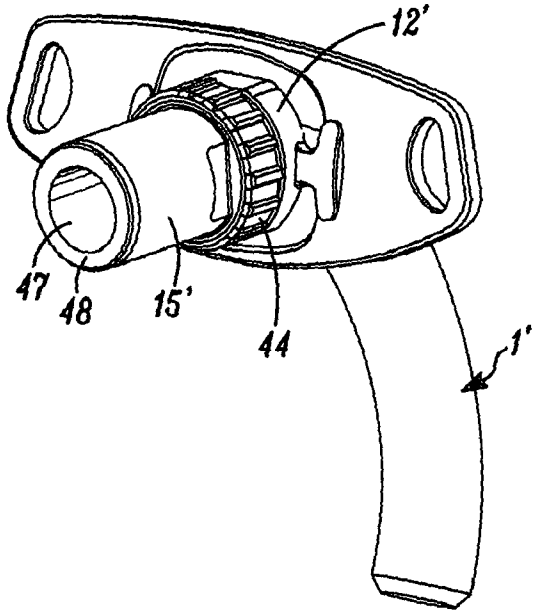


FIG.7

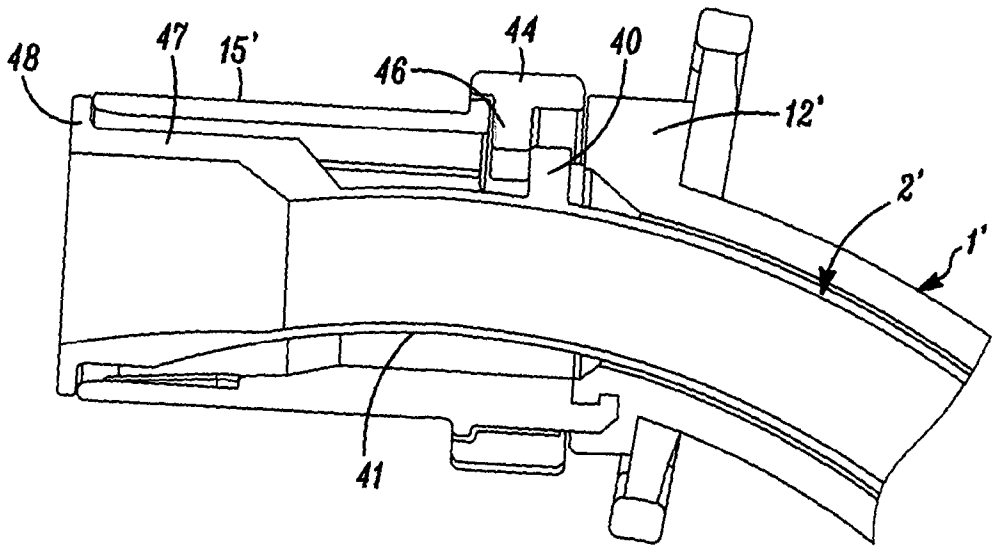


FIG.8

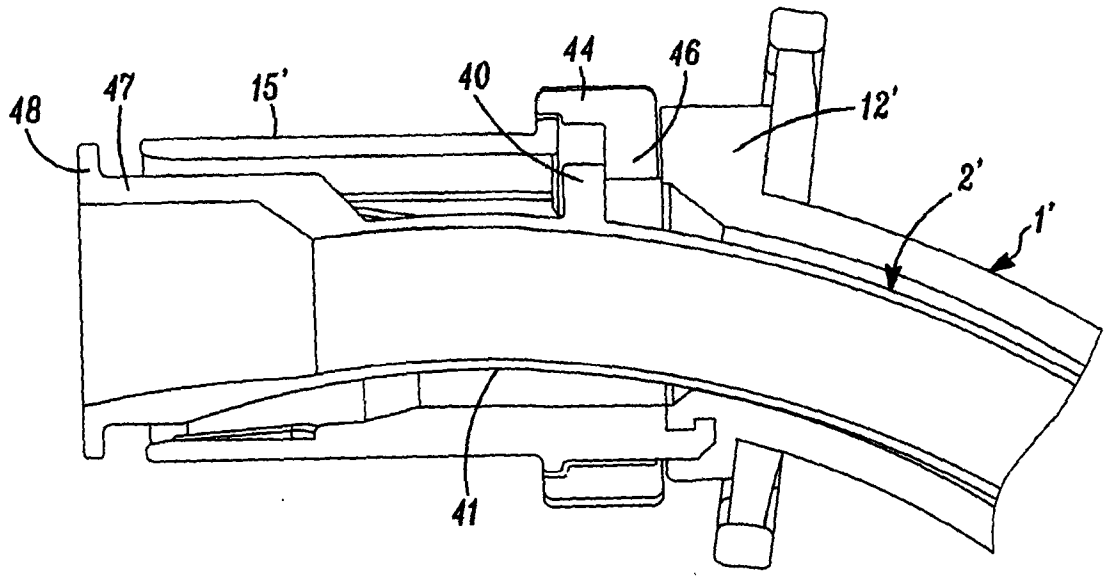


FIG.9

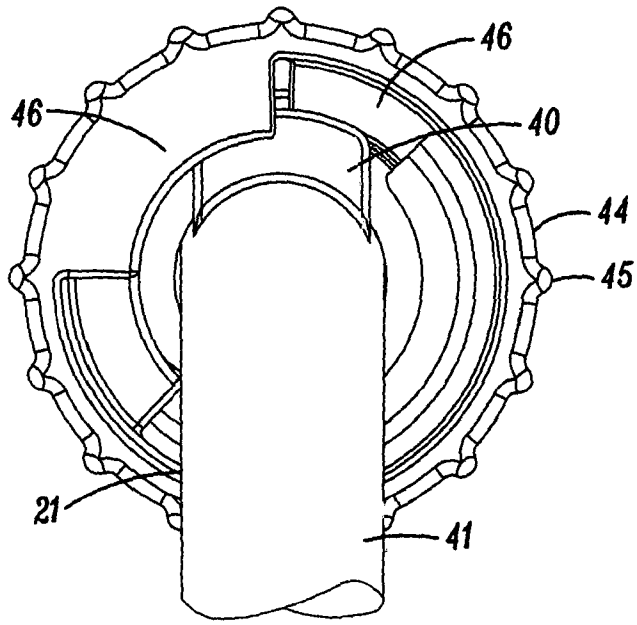


FIG.10

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2016/000108

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M16/04
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
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)
EPO-Internal, BIOSIS, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/083672 A1 (WEBSTER ROBERT J [US] ET AL) 14 April 2011 (2011-04-14) abstract paragraph [0037] - paragraph [0039]	1-10
A	GB 2 028 139 A (SMITHS INDUSTRIES LTD) 5 March 1980 (1980-03-05) abstract; figures 1-5	1-10
A	US 4 304 228 A (DEPEL WILLIAM) 8 December 1981 (1981-12-08) abstract; figures 1-6	1-10
A	US 3 659 612 A (SHILEY DONALD P ET AL) 2 May 1972 (1972-05-02) abstract; figures 1-7	1-10

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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Date of the actual completion of the international search	Date of mailing of the international search report
20 July 2016	03/08/2016

Name and mailing address of the ISA/	Authorized officer
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1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
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