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(54) Title: SPEAKING VALVES, TRACHEOSTOMY TUBES AND ASSEMBLIES

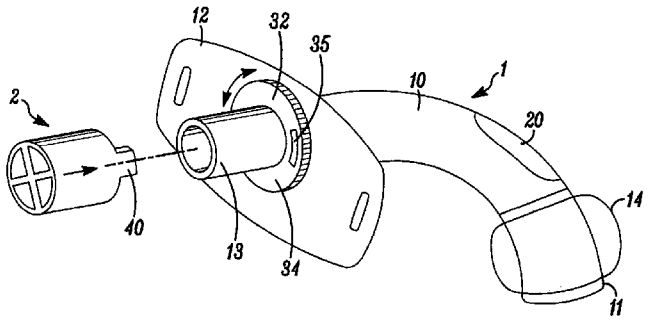

FIG. 1

(57) Abstract: A fenestrated tracheostomy tube (1) includes a slider (21) that is movable to open or close the fenestration (20) in the tube. The rear end of the slider (21) is divided into two narrow toothed fingers (27) and (28) bent at right angle to engage teeth (33) around a rotatable bezel (32) extending around the machine end connector (13). The bezel (32) is rotatably mounted on a fixed boss (36) so that rotating the bezel displaces the slider (21) to open or close the fenestration (20). Both the bezel (32) and boss (36) have slots (35) and (38) that align with one another when the slider (21) is in a position where the fenestration (20) is open. A speaking valve (2) for use with the tube (1) has two projecting legs (40). The valve (2) can only be operatively fitted on the connector (13) when its legs (40) extend through the aligned slots (35) and (38) in the bezel (32) and boss (36). The projecting legs (40) prevent the bezel (32) being rotated and the fenestration (20) closed when the speaking valve (2) is fitted.

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SPEAKING VALVES, TRACHEOSTOMY TUBES AND ASSEMBLIES

This invention relates to an assembly of the kind including a fenestrated tracheostomy tube and a speaking valve that can be fitted on a machine end coupling of the tube, the tube including a closure member extending at one end from one or more fenestrations in the wall of the tube to the region of the machine end coupling at an opposite end, the closure member being movable from a first position where it substantially closes the fenestration to a second position where it substantially opens the fenestration to allow air to flow through it.

Tracheostomy tubes are used to ventilate patients during and after surgery. As the patient begins to recover, it is preferable for him to be gradually weaned off breathing through the tube before it is completely removed. In order to enable the patient to speak it is necessary to allow at least a part of the air exhaled by the patient to flow up to the vocal folds instead of out through the machine end of the tube. This can be done by partially deflating the cuff of the tube. Alternatively, a fenestrated tracheostomy tube can be used having one or more small openings in its side wall, so that a part of the patient's breathing passes through these openings and via his nose or mouth, instead of through the machine end of the tracheostomy tube. When the patient needs to speak it is common practice to fit a speaking valve to the machine end of the tube. The speaking valve includes a one-way valve that enables air to be inhaled by the patient through the valve but prevents or limits flow out through the valve so that air instead flows to the larynx via the fenestrations or around the outside of a tube with a deflated cuff. Examples of speaking valves are described in, for example, US4325366, GB2164424, GB2214089, GB2313317, EP78685, EP214243, EP18461, DE2505123 and DE3503874. GB2340401 describes a fenestrated tube where the fenestration can be opened or closed by pulling or pushing a handle at the machine end of the tube that is connected with a closure member movable relative to the fenestration.

A problem arises when a speaking valve is used with an unfenestrated tracheostomy tube while the sealing cuff is inflated since there is no path for exhaled air from the patient. This can lead to the patient suffocating.

It is an object of the present invention to provide an improved speaking valve, tracheostomy tube and assembly.

According to one aspect of the present invention there is provided an assembly of the above-specified kind, characterised in that the opposite end of the closure member is arranged in the first position to prevent the speaking valve being coupled with the machine end coupling and is arranged in the second position to allow the speaking valve to be coupled with the machine end coupling such that the speaking valve can only be operatively coupled with the tube when the fenestration is open.

The tube and valve are preferably arranged such that the fenestration cannot be closed while the speaking valve is fitted on the tube. The closure member is preferably movable at its one end along the length of the tube. The closure member at its opposite end may be arranged to engage a rotatable assembly. The rotatable assembly preferably includes a member rotatable about the axis of the machine end coupling of the tube. The rotatable assembly and the speaking valve may have cooperating surface formations arranged such that the speaking valve can be operatively fitted with the tube only when the rotatable assembly is rotated to a position at which the fenestration is open. The surface formation on the rotatable assembly is preferably provided by a recess and the surface formation on the speaking valve is preferably provided by a projection. The rotatable assembly may include a rotatable bezel mounted rotatably on a fixed boss, both the bezel and boss each having a recess that is aligned with one another when the fenestration is open. The projection on the speaking valve preferably extends through the recess in the bezel and into the recess in the boss to lock the bezel against rotation and prevent the fenestration being closed. The speaking valve preferably can only be fitted with the tube when the recess in the bezel is aligned with the recess in the boss to enable full insertion of the projection on the speaking valve through the recess in the bezel and into the recess in the boss.

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

According to a further aspect of the present invention there is provided a speaking valve for an assembly according to the above one aspect of the present invention.

A tracheostomy tube and speaking valve according to 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 the assembly with the speaking valve separated from the tube;

Figure 2 is cross-sectional side elevation of the tube;

Figure 3 is a perspective view of a closure member of the tube:

Figure 3A shows the closure member of Figure 3 engaged with a rotatable assembly around the machine end coupling; and

Figure 4 is an exploded view of the rotatable assembly.

With reference first to Figures 1 and 2, the assembly comprises a tracheostomy tube 1 and a speaking valve 2, shown separated in Figure 1 but, in use, fitted on to the machine end of the tube.

The tracheostomy tube 1 includes a curved shaft 10 of a plastics material and having a circular cross-section. The tube 1 extends from a patient end 11 to a neck flange 12 and a machine end coupling 13 of the conventional 15mm male tapered kind. A sealing member in the form of an inflatable cuff 14 encircles the shaft 10 towards the patient end 11, the interior of the cuff communicating with an inflation line (not shown) extending along the shaft to a conventional pilot balloon and sealing valve. Tubes of other shapes, such as with a straight patient and machine end and a curved intermediate section, could be used. Alternative couplings could also be used.

With reference now also to Figures 3 to 4 the shaft 10 is formed with a fenestration or opening 20 just above the sealing cuff 14 at a position where it will be located in the trachea to enable air to flow to and from the vocal folds via the fenestration. When the fenestration is open this enables the patient to speak. The fenestration 20 can be opened or closed by means of a movable member in the form of a slider 21 located in a lumen 22 aligned with the fenestration. The slider 21 is shown in more detail in Figures 3 and 3A. The slider 21 has a shutter plate 23 at one end. This shutter plate 23 is rectangular with an elongate opening 24 through it that is slightly less than half the length of the plate and is located at the machine end half of the plate. The opening 24 is substantially the same size and shape as the fenestration 20 in the shaft 10. The patient end half 124 of the shutter plate 23 is imperforate. Instead of having an opening, the shutter plate could be entirely imperforate and arranged to be displaced between a position where it covers the fenestration 20 and another position where the fenestration is not covered. The slider 21 has a reduced width extension 25 projecting from the machine end of the plate 23. At its machine end, the extension 25 is further reduced in width to form a flexible strap 26. The machine end of the strap 26 is bent at right angles to the plane of the plate 23 and is bifurcated to form two curved fingers 27 and 28 the concave surfaces of which are formed with a series of teeth 29 and 30. The fingers 27 and 28 of the slider 21 project from the machine end of the lumen 22 along the shaft 10, through the neck flange 12 and extend parallel to the plane of the neck flange beneath a rotatable bezel 32 extending around the machine end coupling 13 and shown in more detail in Figure 4. The bezel 32 is rotatable through a limited angle about the axis of the machine end coupling 13 and is formed on an internal surface with two curved, toothed racks 33 facing outwardly to engage the teeth 29 and 30 on the fingers 27 and 28 of the slider 21. The two fingers 27 and 28 engage the toothed bezel 32 asymmetrically so that rotating it in one direction pulls and bends the strap 26 and pulls the slider 21 towards the machine end. Rotating the bezel 32 in the opposite direction pushes the strap 26 and slider 21 towards the patient end 11 of the tube 1.

The dimensions of the slider 21 are arranged such that, in a first position at one extent of rotation of the bezel 32, the patient end, imperforate half 124 of the shutter plate 23 is aligned with the fenestration 20 in the tube shaft 10, thereby blocking it and preventing any substantial air flow out through the fenestration. This first position setting of the bezel 32 is

for normal use where the patient is to breathe entirely through the machine end coupling 13, or when he is ventilated via an external circuit. If the bezel 32 is rotated by its full extent in the opposite direction to a second position it pushes the slider 21 towards the patient end 11 of the tube 1 and locates the opening 24 in the shutter plate 23 in alignment with the fenestration 20 so that a significant proportion of air flow to and from the lungs is via the fenestration. This second position setting is used when the patient is to be weaned off a ventilator or when the patient wishes to speak. To enable speech, however, the machine end coupling 13 must be blocked so that the majority of exhaled air flows through the fenestration 20 to the vocal folds. This is achieved by fitting the speaking valve 2 to the machine end coupling 13. The speaking valve 2 may be similar to the conventional kind of generally cylindrical shape and including a membrane flap valve or the like towards its machine end that opens to allow inhalation through the valve and closes when gas pressure is elevated to prevent any substantial exhalation flow through the valve. The patient end of the speaking valve 2 has a tapered bore adapted to fit on the machine end coupling 13. The speaking valve 2 differs from conventional valves by having one or more surface formations arranged to prevent the speaking valve being fully, operatively fitted on the machine end coupling 13 unless the bezel 32 has been rotated to its second position at which the fenestration 20 is fully open. In particular, the surface formations on the speaking valve 2 are provided by two projections or legs 40 (only one of which is visible in Figure 1) diametrically arranged on opposite sides of the valve and projecting from the patient end of the valve parallel to its axis. Other numbers and configurations of surface formations on the speaking valve could be used.

The front face 34 of the bezel 32, that is, the exposed face facing away from the patient, is formed with two diametrically arranged recesses or slots 35 on either side, the size, shape and position of the slots being chosen to receive the legs 40 on the speaking valve 2. The bezel 32 forms a part of a rotatable assembly, which also includes a fixed circular mounting boss 36 (shown in Figure 4), which is fixed and projects from the front face of the neck flange 12. The bezel 32 embraces the boss 36 with the rear 34' of its front face 34 in close sliding contact with the face 36' of the boss and having a knurled outer ring 37 extending around the outside edge of the boss. The boss 36 is also formed with two recesses or slots 38 arranged to align with the slots 35 in the bezel 32 when the bezel is rotated to the open position in which the slider 21 opens the fenestration 20 in the tube 1. In order to fit the

speaking valve 2 fully on the machine end coupling 13, that is, where it makes a sealing engagement on the tapered surface of the machine end coupling sufficient to retain the valve on the coupling in a gas-tight manner, the bezel 32 must be rotated to the position in which its slots 35 align with the slots 38 in the underlying mounting boss 36. This enables the legs 40 on the speaking valve 2 to extend through the slots 35 in the bezel 32 and into the slots 38 in the boss 36 so that the main body of the speaking valve can be fully pushed onto the coupling 13. It will be appreciated that, when the speaking valve 2 is fitted on the coupling 13, its legs 40 will lock the bezel 32 in position and prevent it rotating out of the open fenestration position. This provides a useful safety feature. If the bezel 32 were in any other position, the legs 40 of the speaking valve 2 could be inserted in the slots 35 of the bezel 32 but the depth of these slots alone would be insufficient to allow the speaking valve to be fully fitted. If the speaking valve 2 were not fully fitted on the coupling 13 it would provide a gas path between the outside of the coupling and the speaking valve.

The tube 1 and speaking valve 2 ensure that the speaking valve can only be fitted when the fenestration 20 is open and when the patient, therefore, has an open path for exhalation via the fenestration. This prevents the valve 2 being fitted when the fenestration 20 is not open and thereby avoids the risk of the patient suffocating. The arrangement also ensures that the fenestration 20 is held open while the speaking valve 2 is fitted, thereby avoiding the risk of the fenestration being inadvertently closed.

The fenestration in the tube could be of various sizes and shapes and there could be two or more fenestrations spaced along the tube. The movable member by which the or each fenestration is closed and opened need not be displaceable along the length of the tube but could, for example, be displaceable rotationally around the tube to one side of the fenestration. In such an arrangement the lumen within which the movable member is contained would need to be wider to allow for it to be displaced rotationally.

CLAIMS

1. An assembly of a fenestrated tracheostomy tube (1) and a speaking valve (2) that can be fitted on a machine end coupling (13) of the tube, the tube including a closure member (21) extending at one end from one or more fenestrations (20) in the wall of the tube to the region of the machine end coupling (13) at an opposite end, the closure member (21) being movable from a first position where it substantially closes the fenestration (20) to a second position where it substantially opens the fenestration to allow air to flow through it, characterised in that the opposite end (25 to 28) of the closure member (21) is arranged in the first position to prevent the speaking valve (2) being coupled with the machine end coupling (13) and is arranged in the second position to allow the speaking valve (2) to be coupled with the machine end coupling (13) such that the speaking valve can only be operatively coupled with the tube (1) when the fenestration (20) is open.

2. An assembly according to Claim 1, characterised in that the tube (1) and valve (2) are arranged such that the fenestration (20) cannot be closed while the speaking valve (2) is fitted on the tube (1).

3. An assembly according to Claim 1 or 2, characterised in that the closure member (21) is movable at its one end (23) along the length of the tube (1).

4. An assembly according to any one of the preceding claims, characterised in that the closure member (21) at its opposite end is arranged to engage a rotatable assembly (32, 36).

5. An assembly according to Claim 4, characterised in that the rotatable assembly includes a member (32) rotatable about the axis of a machine end coupling (13) of the tube.

6. An assembly according to Claim 4 or 5, characterised in that the rotatable assembly (32, 36) and the speaking valve (2) have cooperating surface formations (35, 38, 40)

arranged such that the speaking valve (2) can be operatively fitted with the tube (1) only when the rotatable assembly (32, 36) is rotated to a position at which the fenestration (20) is open.

7. An assembly according to Claim 6, characterised in that the surface formation on the rotatable assembly (32, 36) is provided by a recess (35, 38) and the surface formation on the speaking valve (2) is provided by a projection (40).

8. An assembly according to Claim 7, characterised in that rotatable assembly includes a rotatable bezel (32) mounted rotatably on a fixed boss (36), that the bezel (32) and boss (36) each have a recess (35, 38) that is aligned with one another when the fenestration (20) is open.

9. An assembly according to Claim 8, characterised in that the projection (40) on the speaking valve (2) extends through the recess (35) in the bezel (32) and into the recess (38) in the boss (36) to lock the bezel (32) against rotation and prevent the fenestration (20) being closed.

10. An assembly according to Claim 8 or 9, characterised in that the speaking valve (2) can only be operatively fitted with the tube (1) when the recess (35) in the bezel (32) is aligned with the recess (38) in the boss (36) to enable full insertion of the projection (40) on the speaking valve (2) through the recess (35) in the bezel (32) and into the recess (38) in the boss (36).

11. A tracheostomy tube (1) for an assembly according to any one of the preceding claims.

12. A speaking valve (2) for an assembly according to any one of Claims 1 to 10.

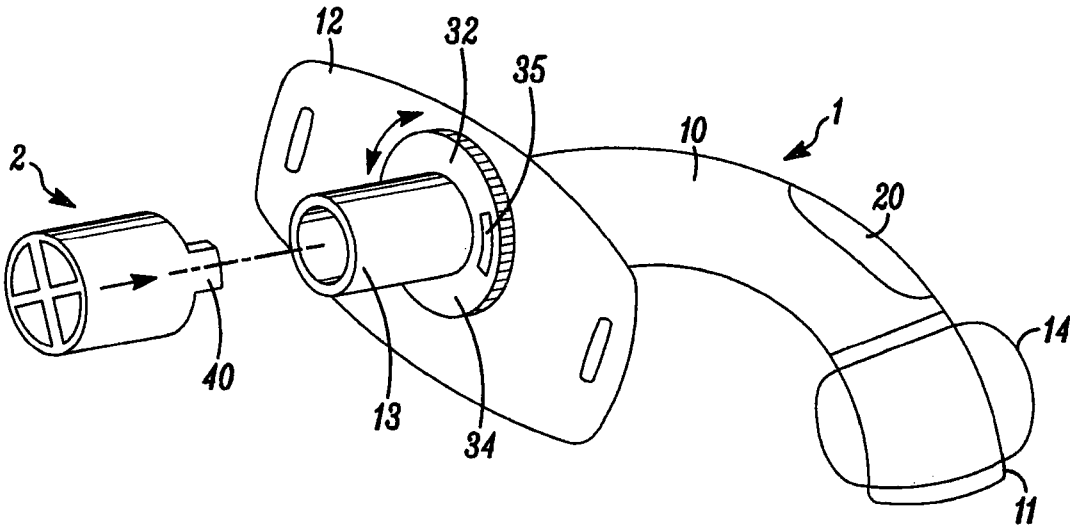

FIG. 1

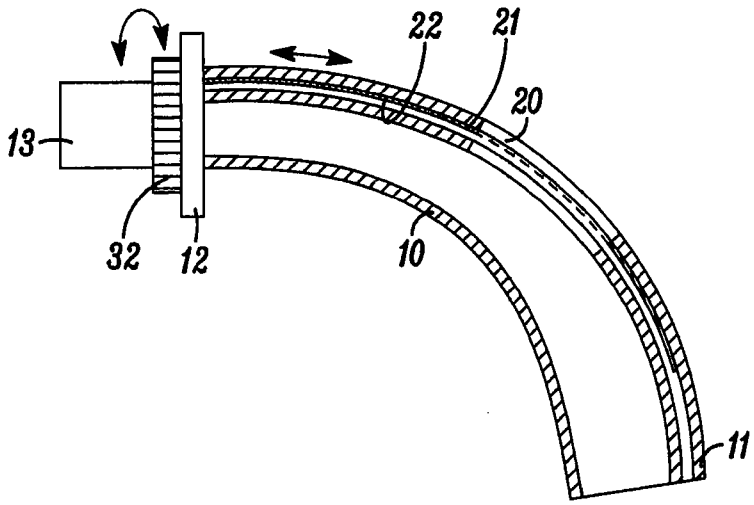

FIG. 2

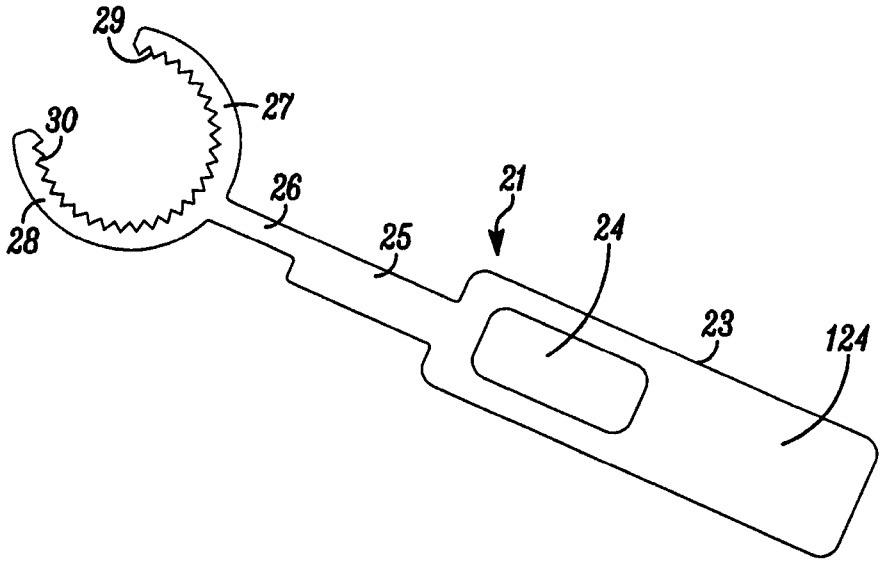
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FIG. 3

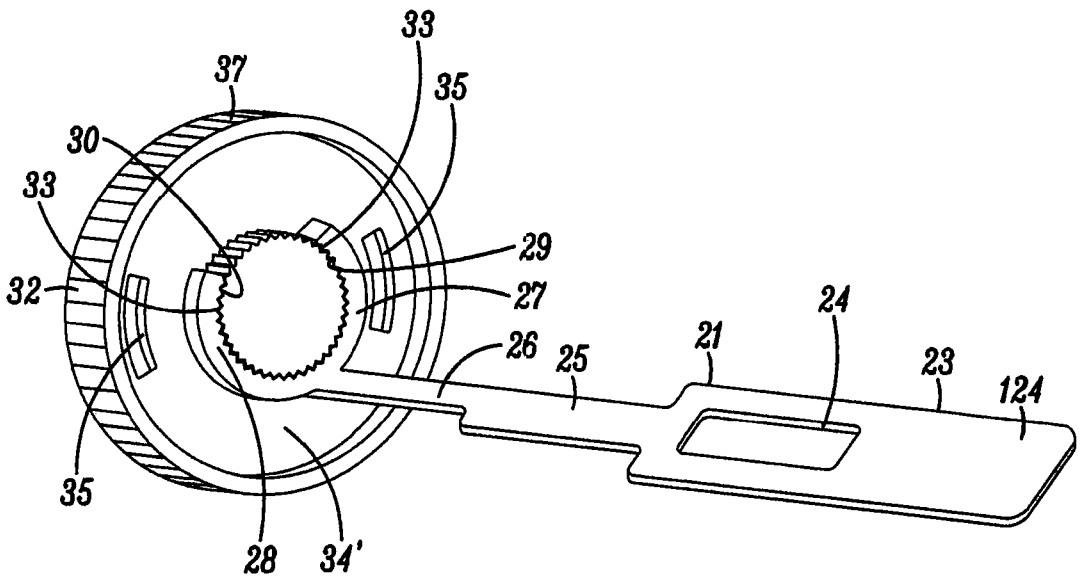
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FIG. 3A

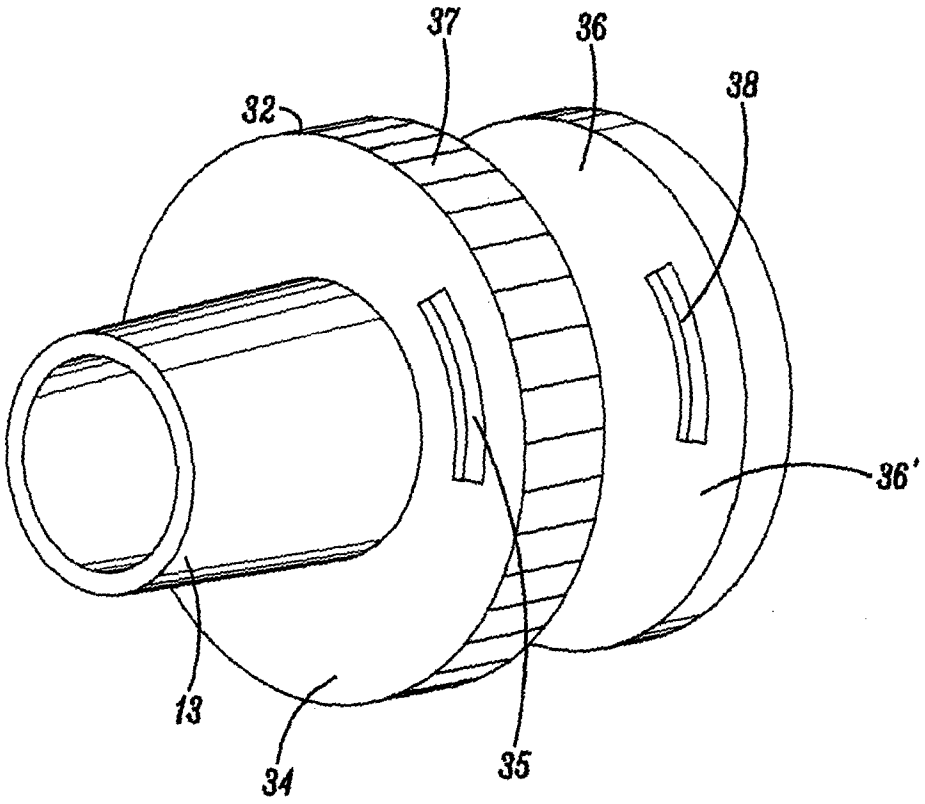

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2015/000224

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, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	GB 2 340 401 A (SMITHS INDUSTRIES PLC [GB]) 23 February 2000 (2000-02-23) cited in the application figures 1 ref 1,9,20,24 abstract page 1, line 22 - page 2, line 11 page 3, line 11 - page 4, line 10 claims 1-4	1-12
A	US 2004/123868 A1 (RUTTER MICHAEL JOHN [US]) 1 July 2004 (2004-07-01) figure 1 paragraph [0003]	1-12
A	DE 10 2006 035887 A1 (TRACOE MEDICAL GMBH [DE]) 7 February 2008 (2008-02-07) figures 1-3 paragraph [0041] - paragraph [0042] paragraph [0046] - paragraph [0049]	1-12

☐ 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
21 September 2015	07/10/2015

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Cecchini, Stefano

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
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