

(12) UK Patent Application (19) GB (11) 2 164 424 A

(43) Application published 19 Mar 1986

(21) Application No **8522546**

(22) Date of filing **11 Sep 1985**

(30) Priority data

(31) **8422866**

(32) **11 Sep 1984**

(33) **GB**

(51) INT CL⁴

F16K 15/03

(52) Domestic classification

F2V W23

(56) Documents cited

None

(58) Field of search

F2V

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(54) A voice prosthesis device

(57) A self-retaining voice prosthesis device (1) comprises duct means defining an air passageway for communication with a wearer's trachea and having a rigid flap valve (28) pivotally mounted therein between open and closed positions. The flap valve (28) is designed to be gravity biased into the open motionless position during normal inhalation and exhalation but to be moved into its closed position when a wearer exhales with a greater than normal force, e.g. as when making "speech". An adjustment means (12) is provided for adjusting the gravity biased open position of the flap valve (28).

The device (1) suitably includes attachment means (3) separable from the duct means, the attachment means being self-retaining in a wearer's trachea stoma requiring no ties or adhesive to retain it in position. In certain conditions of use, e.g. when the wearer sleeps or rests, the attachment means (3) may be used by itself as a stoma button.

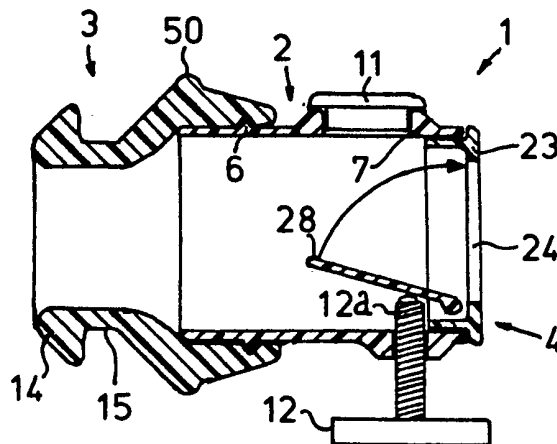


FIG. 7

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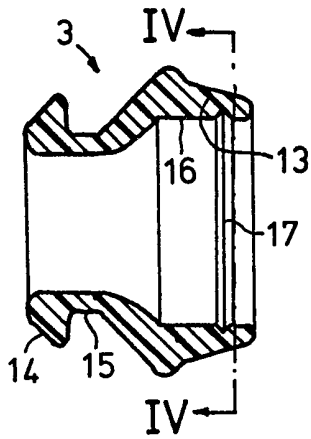


FIG. 1

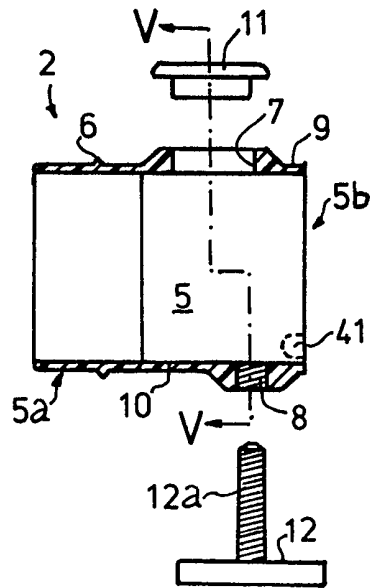


FIG. 2

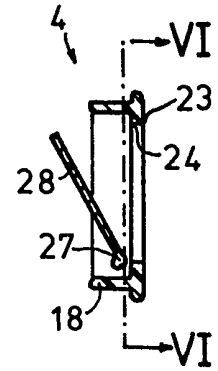


FIG. 3

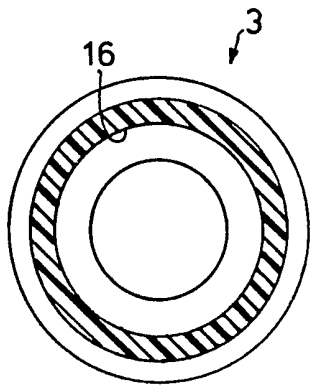


FIG. 4

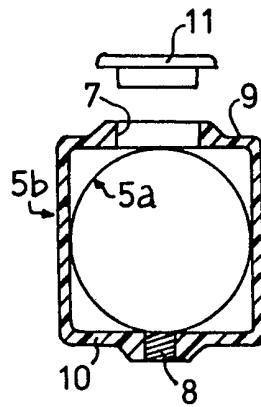


FIG. 5

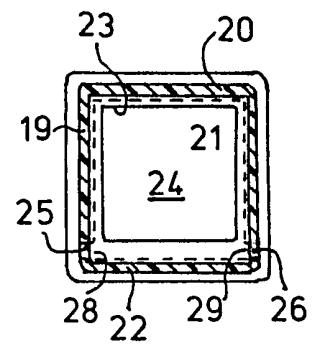


FIG. 6

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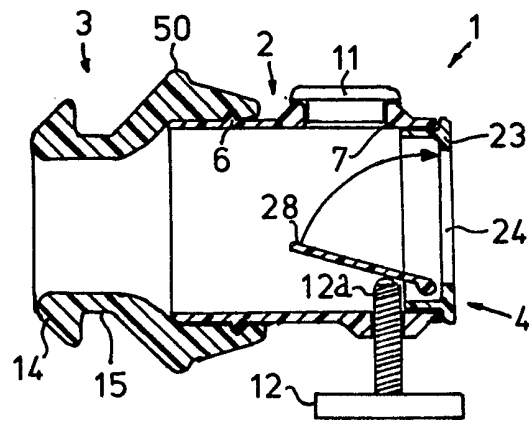


FIG. 7

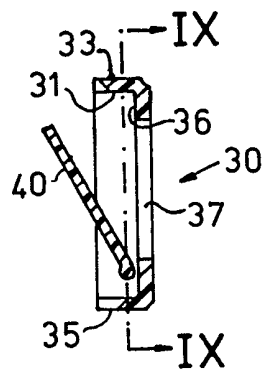


FIG. 8

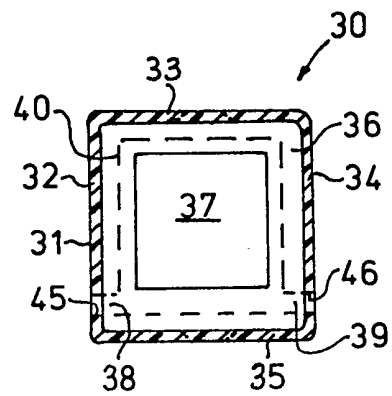


FIG. 9

SPECIFICATION

A voice prosthesis device

5 This invention relates to a self-retaining voice prosthesis device for fitting in a trachea of a wearer who, for example, has undergone a laryngectomy with neoglottis operation.

According to the invention a self-retaining
10 voice prosthesis device comprises duct means defining an air passageway for communication with a wearer's trachea, a rigid flap valve pivotally mounted within the duct means for movement between an open position to allow
15 passage of air through said air passageway and a closed position to block passage of air through said air passageway, the rigid flap valve, in use of the device, being gravity biased into its open position and being moved
20 into its closed position when a wearer exhales with sufficient force into the air passageway, and adjustment means enabling the gravity biased open position of said flap valve to be adjusted.

25 In use a voice prosthesis device according to the invention is intended to be detachably fitted into, for example, a tracheostoma. During normal inspiration and expiration of a wearer, the rigid flap valve is designed to be
30 motionless in its open position to enable air to flow through the air passageway into and out of the trachea. If the wearer wishes to make a vocal sound, the design of the flap valve is such that the increased flow of air
35 from the lungs through the trachea is sufficient to pivot the flap valve into its closed position so that the air from the trachea cannot pass through the air passageway but instead passes through tracheo-pharyngeal fistula or
40 tracheo-oesophageal fistula to enable the creation of vocal sounds. The adjustment means is intended to be positioned exteriorly of the wearer's body, e.g. at the front of the neck, to facilitate manual adjustment by the wearer
45 of the open position of the rigid flap valve, so that the force of exhaled air required to close the flap valve against the gravity biasing can be adjusted. In this way it is possible to provide a gravity hinged or pivoted rigid flap
50 valve mounted for positive closing action on occurrence of a slight increase in expiring air flow.

Preferably the voice prosthesis device includes a safety means designed to enable
55 outflow of air from the duct means when the flap valve is in its closed position on occurrence of a larger than expected air pressure in the duct means. Such an overpressure may occur when a wearer coughs, and, in this
60 case, the safety means is brought into operation to prevent probable damage to the flap valve or to prevent the prosthesis device being dislodged from its fitted position communicating with the trachea. Conveniently the safety
65 means comprises either a safety plug

mounted in an opening in a wall of the duct means or a valved opening communicating with the duct means.

70 Suitably the adjustment means may comprise an adjustable screw providing an adjustable stop against which the rigid flap valve is positioned when in its open position.

Conveniently the flap valve is mounted in a removable part of the voice prosthesis device.
75 Preferably the removable part is designed to be positioned exteriorly of a wearer, when the device is positioned with said air passageway in communication with a wearer's trachea, so that the removable part can be easily removed
80 for cleaning purposes.

A voice prosthesis device according to the invention suitably includes attachment means for enabling detachable attachment of the device to an opening, e.g. a tracheostoma, in a
85 wall of a wearer's trachea.

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

90 Figures 1 to 3 are longitudinal sectional views of three component parts of a voice prosthesis device according to the invention,

Figures 4 to 6 are sectional views taken, respectively, on line IV-IV of Figure 1, line V-V of Figure 2 and line VI-VI of Figure 3,

95 Figure 7 is a longitudinal sectional view through said voice prosthesis device with the three component parts shown in Figures 1 to 6 assembled together,

100 Figure 8 is a longitudinal sectional view of an alternative third component part for the voice prosthesis device shown in Figure 7, and

Figure 9 is a sectional view taken on the line IX-IX of Figure 8.

105 Figures 1 to 7 show one embodiment of a voice prosthesis device according to the invention and generally designated by the reference number 1 (see Figure 7). The voice prosthesis device 1 comprises a body part, generally designated 2 (see Figures 2 and 5), an attachment part, generally designated 3 (see
110 Figures 1 and 4) and a valve part, generally designated 4 (see Figures 3 and 6), which parts are assembled together in the manner shown in Figure 7.

115 The body part 2 comprises a duct member 5, typically injection moulded from a plastics material, e.g. a medical grade silicone material. The duct member 5 is defined by a first tubular portion 5a of substantially circular cross-section (typically having an external diameter of 14 mm) and a second tubular portion 5b of substantially square cross-section, the first and second portions 5a and 5b being integrally joined together. An annular rib 6 is
120 formed on the outer cylindrical surface of the first tubular portion 5a and a smooth walled cylindrical bore 7 and a screw-threaded bore 8 are formed, respectively, in opposed, parallel side walls 9 and 10 of the second tubular
130

portion 5*b*. The cylindrical bore 7 is designed to re-receive a plug member 11 in a push fit, interference connection and the screw-threaded bore 8 receives a screw-threaded shank 12*a* of an adjustment member 12. The tip of the screw-threaded shank 12*a* is suitably modified, e.g. by soldering, to prevent inadvertent withdrawal by unscrewing of the member 12 from the bore 8.

The attachment part 3 is tubular, of generally circular cross-section and typically also injection moulded from a plastics material, e.g. a medical grade silicone material. The attachment part 3 consists of a connecting portion 13 (typically having an internal diameter of 15 mm) defining one end of the part 3 and designed to fit over the tubular portion 5*a* of the duct member 5, a grooved flange 14 defining the other end of the part 3 and a neck portion 15 integrally joining the connecting portion 13 to the flange 14. The connecting portion 13 has an inner cylindrical surface 16 provided with an annular recess 17.

The valve part 4 comprises a square-section tubular portion 18 having side walls 19-22 (see Figure 6) and an end wall 23 at one end of the tubular portion and provided with an aperture 24 of square cross-section (typically having a side of 10 mm). Conveniently the part 4 is also injection moulded from a plastics material, e.g. a medical grade silicone material. Recesses 25 and 26 are formed, respectively, in the side walls 19 and 21 adjacent the common connecting wall 22. These recesses 25 and 26 are designed to receive lugs 28 and 29, respectively at opposite ends of a pivot portion 27 of a substantially square flat and rigid closure member constituting a flap valve 28 (shown only in dashed lines in Figure 6). To provide a rust proof valve, the valve closure member is suitably made of a light-weight plastics material, e.g. plastics such as methacrylates, polyethylenes, polypropylenes, various vinyl polymers or copolymers, and other similar plastics.

The parts 2-4 are assembled together (as shown in Figure 7) by inserting the tubular portion 5*a* into the open end of the connecting portion 13 so that the annular rib 6 is snap-fitted into correspondingly shaped annular recess 17 and by push fitting the tubular portion 18 into the open end of the second tubular portion 5*b* so as to make an interference connection therewith. The plug member 11 is positioned in the cylindrical bore 7 and is retained in position by means of an interference fit. The adjustment member 12 is screwed into the screw-threaded bore 8 so that the free end of the shank 12*a* projects inside the duct defined by the duct member 5.

In use, the voice prosthesis device 1 is designed to communicate with the trachea (not shown) of a wearer. In particular the grooved flange 14 and neck portion 15 are designed to make a removable snap-fit connection with

an opening, e.g. a tracheostoma, in the wearer's trachea. When part 13 is so connected, the device projects forwardly from the wearer's neck, with the second tubular portion 5 and the valve part 4 positioned externally of the wearer's neck and with the adjustment member 12 projecting downwardly as shown in Figure 7.

In operation of the voice prosthesis device 1 when fitted to a wearer, the rigid flap valve 28 is gravity biased into an open motionless position (as shown in Figure 7), resting against a stop provided by the end of the shank 12*a*, during normal inspiration and expiration of the wearer. Thus, when the flap valve 28 is in its open position, air is able to flow in either direction through the aperture 24 so that air can be inspired through the duct member 5, into the wearer's trachea for passage to the wearer's lungs and can be expired from the lungs, through the wearer's trachea and passed out through the duct member 5. Since the flap valve 28 is rigid and since it is motionless in its open position (i.e. the flap valve does not flex or move into and out of its open position during normal inspiration and expiration), the size of the valved opening does not change during normal inspiration and expiration.

If the wearer wishes to produce vocal sounds, the increase of air flow from the lungs and through the trachea causes the flap valve 28 to pivot about the pivot portion 27, in the direction indicated by the arrow in Figure 7, from its open position into a closed position (not shown) blocking the aperture 24. In this closed position the flap valve 28 seats against the end wall 24 which provides a valve seat for the valve. When the flap valve 28 is in its closed position, air passing along the trachea from the lungs cannot pass through the aperture 24 and is thus diverted through surgical tracheo-pharyngeal fistula or tracheo-oesophageal fistula to enable the production of vocal sounds. On a reduction in air flow through the trachea, when the wearer ceases making vocal sounds, gravity causes the flap valve 28 automatically to pivot back into its open position (shown in Figure 7).

In the event of the occurrence of a sudden exhalation or surge of air passing through the trachea from the lungs, e.g. as a result of the wearer coughing, the flap valve 28 is caused to pivot into its closed position. The pressure of air in the duct member 5 could be sufficient either to cause probable damage to the flap valve 28 or to cause the device 1 to become disconnected from the trachea of the wearer. However the provision of the plug member 11 is designed to prevent either of these events occurring. In particular, the plug member 11 acts as a safety valve which is designed either to be blown out of the cylindrical bore 7 on the occurrence of excessive pressures inside the duct member 5 or be

temporarily removed from the bore 7 by the wearer before occurrence of the excess pressure. After removal of the plug member 11 from the bore 7, the flap valve 28 pivots back under gravity into its open position and the plug member 11 is re-positioned in the bore 7. Alternatively, the plug member 11 can be removed to enable means (not shown) to be connected to the bore 7 for measuring the pressure within the device 1 during speech production.

The sensitivity of the voice prosthesis device 1 depends on the position of the flap valve 28 when it is in open position. The adjustment member 12 enables the open position of the flap valve 28 to be easily manually adjusted by a wearer when in use. Thus a wearer is able to alter the sensitivity of the device 1 to his particular need at any particular time. Typically in the least sensitive condition of the device 1, the flap valve 28 will be required to pivot approximately 90° between its open and closed position whereas in the most sensitive condition of the device, the flap valve 28 will only be required to pivot approximately 45° between its open and closed position.

Figures 8 and 9 show a modified valve part, generally designated 30, for the voice prosthesis device 1. The valve part 30 comprises a square-section tubular portion 31 having side walls 32-35 and an end wall 36 provided with an aperture 37 of square cross-section and defining a valve seat. The tubular portion 31 is of slightly larger cross-section than the tubular portion 18 of the valve part 4 and is designed to fit outside, instead of inside, the open end of the second tubular portion 5b and to make an interference fit therewith. The side walls 32 and 34 are provided with recesses 45 and 46 for receiving pivot lugs 38 and 39, respectively, of a pivotably mounted flat, rigid closure member, e.g. of plastics material constituting a flap valve 40. In order to enable the valve part 30 to be fitted to the body part 2 it is necessary to modify the body part 5 by providing recesses 41 (one of which is shown in dashed lines in Figure 2) in opposed side walls of the second portion 5b for receiving the lugs 38 and 39.

The valve part 4 and the valve part 30 can be easily removed from the device 1 to enable cleaning of the flap valve if desired.

The parts 2 and 4 (or 2 and 30) are ideally of a standard size. Although preferably detachable, the parts 2 and 4 (or 2 and 30) can be designed as a single integral unit. The attachment part 3 may be designed in different sizes having differently sized flanges 14 and/or neck portions 15 to enable connection of the device 1 to differently sized tracheostoma. Suitably the device 1 is provided with an enlarged portion, e.g. a flange 50 (see Figure 7), forwardly of the neck portion 15 to prevent the device 1 being accidentally inhaled by a

wearer.

It will be appreciated that the attachment part 3 may be used by itself as a stoma button, e.g. whilst the wearer sleeps, without the valve parts 2 and 4 (or 2 and 30) connected thereto. The valve parts are easily detachable from the attachment part 3 although the engagement of the annular rib 6 in the annular recess 17 ensures that, when connected, the valve parts will not accidentally become detached from part 3. The rib 6 and recess 17 thus ensure that the valve parts are "self-retained" in the attachment part 3. The provision of the grooved flange 14 ensures that part 3 is releasably self-retained in an opening in the wearer's trachea, e.g. a trachea stoma, and does not require additional means, e.g. adhesive means or ties, to retain it in position.

In other embodiments of the invention alternative safety valves, e.g. flap valves, may be provided to replace the plug member 11.

In the embodiments herein illustrated and described, the various parts and components are preferably formed of any suitable plastics material, e.g. silicone or acrylic material, but may also include metal parts or components, e.g. pivot pins, typically formed of stainless steel or the like.

Although specific embodiments of the invention have been described, by way of example, herein, it will be appreciated by persons skilled in the art that various changes and modifications may be made without departing from the principal invention defined in the following claims.

CLAIMS

1. A voice prosthesis device comprising duct means defining an air passageway for communication with a wearer's trachea, a rigid flap valve pivotally mounted within the duct means for movement between an open position to allow passage of air through said air passageway means and a closed position to block passage of air through said air passageway, the rigid flap valve, in use of the device, being gravity biased into its open position and being moved into its closed position when a wearer exhales with sufficient force into the air passageway, and adjustment means enabling the gravity biased open position of said flap valve to be adjusted.

2. A device according to claim 1, including safety means designed to enable outflow of air from the duct means when the flap valve is in its closed position on occurrence of a larger than expected air pressure in the duct means.

3. A device according to claim 2, in which the safety means comprises a safety plug mounted in an opening in a wall of the duct means.

4. A device according to claim 2, in which the safety means comprises a valved opening

communicating with the duct means.

5. A device according to any of the preceding claims, in which the adjustment means comprises an adjustable screw providing an adjustable stop against which the rigid flap valve is positioned when in its open position.

6. A device according to any of the preceding claims, in which the flap valve is mounted in a removable part of the voice prosthesis device.

7. A device according to claim 6, in which the removable part is designed to be positioned exteriorly of a wearer, when the device is positioned with said air passageway in communication with a wearer's trachea, so that the removable part can be easily removed for cleaning purposes.

8. A device according to any of the preceding claims, including attachment means for enabling detachable attachment of the device to an opening, e.g. a tracheostoma, in a wall of a wearer's trachea.

9. A device according to claim 8, in which the duct means is detachably attached to the attachment means, the latter being usable by itself when attached to said tracheal opening, e.g. during period of rest or sleep of the wearer.

10. A device according to any of the preceding claims, including external means to prevent inadvertent inhalation of the device.

11. A device according to claim 10, in which the external means comprises a flange.

12. A voice prosthesis device constructed and arranged substantially as herein described, with reference to, and as illustrated in, Figures 1 to 7 or Figures 1, 2, 4, 5, 8 and 9 of the accompanying drawings.

13. A voice prosthesis device, preferably self-retaining, comprising body means defining an air passageway for communication with a wearer's trachea, a rigid flap valve movable between an open position for allowing passage of air through said air passageway and a closed position for blocking passage of air through said air passageway and adjustment means enabling adjustment of the open position of said rigid flap valve.

14. A device according to claim 13, in which the flap valve is pivotally mounted within the body means, the flap valve, in use of the device, being gravity biased into its open position during normal inhalation and exhalation through the air passageway and being moved into its closed position on occurrence of flow of air through the air passageway from the trachea at a flow rate greater than for normal exhalation.