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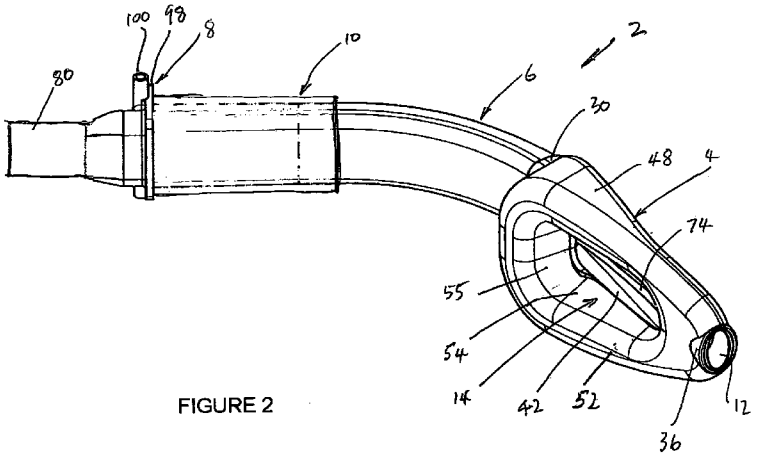

FIGURE 2

(57) Abstract: An artificial airway including: an airway tube including at least one airway conduit; an inflatable cuff mounted on a distal end of the tube; a support member extending into the cuff, the cuff having inner side walls, anterior walls and a posterior wall, the inner side walls being joined to the support member to define a recess which communicates with the airway conduit, the anterior walls and posterior wall, sealingly engaging, in use, about the glottic opening and posterior pharyngeal wall respectively of a patient.

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ARTIFICIAL AIRWAY

FIELD OF THE INVENTION

This invention relates to an artificial airway which can be used in surgical procedures or in emergencies to establish an uninterrupted airway to the lungs of a patient.

BACKGROUND OF THE INVENTION

In recent years the use of supraglottic airways has become widespread. Most of the devices include an airway tube having an inflatable cuff mounted at the distal end. The cuff includes a recess which is in fluid communication with the airway tube to allow anaesthetic gas to be administered to the lungs of a patient, or alternatively in an emergency situation to allow air to pass in an unobstructed way to the lungs of a patient.

It is desirable that the artificial airway should form a good seal around the glottic opening of the patient. This has the advantage that substantially all of the anaesthetic gas supplied through the airway passes to the lungs of the patient. Further, the seal helps to prevent any regurgitated material entering the lungs of the patient.

In some known devices an evacuation tube is provided so as to communicate with the oesophagus of the patient so that any regurgitated material can be vented through the evacuation tube, thereby minimising the possibility that the regurgitated material enters the lungs of the patient. Normally suction is applied to the evacuation tube to facilitate this process as disclosed in AU-B-52036/90 for example.

SUMMARY OF THE INVENTION

The general object of the invention is to provide an improved artificial airway which has improved performance and which is inexpensive to manufacture.

According to a first aspect of the invention there is provided an artificial airway including:

an airway tube including at least one airway conduit;

an inflatable cuff mounted on a distal end of the tube;

a support member extending into the cuff, the cuff having inner side walls, anterior walls and a posterior wall, the inner side walls being joined to the support member to define a recess which communicates with the airway conduit, the anterior walls and posterior wall, sealingly engaging, in use, about the glottic opening and posterior pharyngeal wall respectively of a patient.

Preferably, the support member is integral with the airway tube.

Preferably further, the support member defines a posterior wall of the recess.

The invention also provides an artificial airway including:

an airway tube having at least one airway conduit therein;

an inflatable cuff mounted on a distal end of the airway tube, an end portion of the airway tube extending into the cuff, the cuff including a recess which is defined by the end portion of the airway tube and inner sidewalls of the cuff which are sealingly connected to said end portion and wherein said at least one airway conduit is in fluid communication with said recess;

the cuff including an anterior sealing wall which merges from the inner sidewalls, the anterior sealing wall lying generally in a plane and, in use, sealingly engages the glottic opening of a patient; the cuff further including a posterior wall extending from outer peripheral parts of the anterior sealing wall to extend over said end portion and, in use, being resiliently extended, on inflation of the cuff, to sealingly engage the posterior pharyngeal wall of the patient.

Preferably the anterior sealing wall is only connected to said end portion of the airway adjacent to the distal and proximal ends thereof.

Preferably further, the shape of the cuff is such, that when inflated and in a lateral cross-section section which includes a recess, the posterior wall has an inverted U-shape, the ends of which merge into the outer peripheral parts of the anterior sealing wall and wherein the cuff is spaced from the end portion of the airway tube except where the inner sidewalls thereof are connected to said end portion.

Preferably further, the inflatable cuff is integrally moulded from silicon rubber.

In accordance with another aspect the invention provides an artificial airway including:

an airway tube having at least one airway conduit therein;

a cuff mounted on a distal end of the tube and having a recess which is in fluid communication with the airway conduit;

an evacuation chamber located at a distal end of the cuff, the chamber, in use, being located adjacent to the upper oesophageal sphincter of a patient;

an evacuation conduit in fluid communication with the evacuation chamber; and

a ventilation conduit in fluid communication with the evacuation chamber, the arrangement being such that, in use, suction is applied to the evacuation conduit whereby regurgitated material entering the evacuation chamber is removed through evacuation conduit and wherein the ventilation conduit substantially prevents a negative pressure being applied to the tissue of the patient.

Preferably, the ventilation conduit vents the evacuation chamber to atmosphere.

In this embodiment, there is localised suction at the point where the evacuation conduit opens into the evacuation chamber but because the chamber is vented to atmosphere the pressure at the distal edge of the chamber is atmospheric or only slightly negative thereby avoiding the possibility that the distal edge of the chamber is sucked into contact with the mucosa adjacent to the upper oesophageal sphincter. In this way damage to the mucosa is substantially avoided. Also if negative pressure is applied continuously to

the oesophagus there is a possibility that regurgitation could be encouraged which is undesirable.

The invention also provides an artificial airway comprising:

an airway tube having at least one airway conduit therein;

an inflatable cuff mounted on a distal end of the airway tube, an end portion of the airway tube extending into the cuff, the cuff including a recess which is defined by the end portion of the airway tube and inner sidewalls of the cuff which are sealingly connected to said end portion and wherein said at least one airway conduit is in fluid communication with said recess;

the cuff including an anterior sealing wall which merges from the inner sidewalls, the anterior sealing wall lying generally in a plane and, in use, sealingly engages the glottic opening of a patient; the cuff further including a posterior wall extending from outer peripheral parts of the anterior sealing wall to extend over said end portion and, in use, being resiliently extended, on inflation of the cuff, to sealingly engage the posterior pharyngeal wall of the patient;

a connector body for providing fluid communication with said at least one airway conduit; and

means for sealingly connecting the connector body to the proximal end of the airway tube.

The invention also provides an artificial airway including:

an airway tube having at least one airway conduit therein;

an inflatable cuff mounted on a distal end of the airway tube, an end portion of the airway tube extending into the cuff, the cuff including a recess which is defined by the end portion of the airway tube and inner sidewalls of the cuff which are sealingly connected to said end portion and wherein said at least one airway conduit is in fluid communication with said recess;

the cuff including an anterior sealing wall which merges from the inner sidewalls, the anterior sealing wall lying generally in a plane and, in use, sealingly engages the glottic opening of a patient; the cuff further including a posterior wall extending from outer

peripheral parts of the anterior sealing wall to extend over said end portion and, in use, being resiliently extended, on inflation of the cuff, to sealingly engage the posterior pharyngeal wall of the patient;

an evacuation chamber located at a distal end of the cuff, the chamber, in use, being located adjacent to the upper oesophageal sphincter of a patient;

an evacuation conduit in fluid communication with the evacuation chamber; and

an evacuation chamber vent conduit in fluid communication with the evacuation chamber;

and wherein at least the evacuation conduit and the ventilation conduit are located within said distal end of the airway tube.

The invention also provides an artificial airway including:

an airway tube having at least one airway conduit therein;

an inflatable cuff mounted on a distal end of the airway tube, an end portion of the airway tube extending into the cuff, the cuff including a recess which is defined by the end portion of the airway tube and inner sidewalls of the cuff which are sealingly connected to said end portion and wherein said at least one airway conduit is in fluid communication with said recess;

the cuff including an anterior sealing wall which merges from the inner sidewalls, the anterior sealing wall lying generally in a plane and, in use, sealingly engages the glottic opening of a patient; the cuff further including a posterior wall extending from outer peripheral parts of the anterior sealing wall to extend over said end portion and, in use, being resiliently extended, on inflation of the cuff, to sealingly engage the posterior pharyngeal wall of the patient;

characterised in that the cuff is moulded as single integral moulding.

International Publication No. WO 00/09189 discloses a typical prior art airway which has provision for drainage of the oesophagus. In this device there is a main cuff, back plate and a separate back cuff which are mounted to the distal ends of various tubes. In comparison, the device of the invention essentially eliminates the back plate as a separate component because, from a functional point of view, the end portion of the airway

tube provides the necessary rigidity to this part of the device. Also, in the prior art device the main cuff is formed as an inflatable torus of asymmetrical oval or elliptical shape which is separately moulded from the back cuff. In contrast, in preferred embodiments of the invention, the airway does not have these components separately formed. There are no toroidal or annular inflatable rings in the device. The unitary cuff of the invention is moulded as a single component which has parts which sealingly engage about the glottic opening and the posterior pharyngeal wall of the patient. This effectively eliminates one of the components of the mask (the back plate) and furthermore makes the assembly process much simpler because the back plate and back cuff do not need to be separately moulded and then bonded to the main cuff.

The invention will now be further described with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is an isometric view of an airway device of the invention showing the posterior side thereof;

FIGURE 2 is an isometric view of an airway showing the anterior side of the cuff;

FIGURE 3 is a side view of the airway;

FIGURE 4 is a plan view showing the anterior side of the airway;

FIGURE 5 is a longitudinal cross-sectional view along the line 5-5;

FIGURE 6 is a cross-sectional view along the line 6-6;

FIGURE 7 is a cross-sectional view along the line 7-7;

FIGURE 8 is a cross-sectional view along the line 8-8;

FIGURE 9 is a cross-sectional view along the line 9-9;

FIGURE 10 is a cross-sectional view along the line 10-10;

FIGURE 11 is a side view of the cuff;

FIGURE 12 is a plan view showing the anterior side of the cuff;

FIGURE 13 is an end view of the cuff;

FIGURE 14 is a cross-sectional view along the line 14-14;

FIGURE 15 is an isometric view of the airway tube;

FIGURE 16 is a view of the posterior side of the airway tube;

FIGURE 17 is a side view of the airway tube;

FIGURE 18 is a plan view from the anterior side of the airway tube;

FIGURE 19 is an end view of the airway tube;

FIGURE 20 is a cross-sectional view along the line 20-20;

FIGURE 21 is a cross-sectional view along the line 21-21;

FIGURE 22 is a cross-sectional view along the line 22-22;

FIGURE 23 is a cross-sectional view along the line 23-23;

FIGURE 24 is a cross-sectional view along the line 24-24;

FIGURE 25 is a side view of the connecting body;

FIGURE 26 is a plan view from the anterior side of the connecting body;

FIGURE 27 is a proximal end view of the connecting body;

FIGURE 28 is a distal end view of the connecting body;

FIGURE 29 is a longitudinal cross-sectional view along the line 29-29;

FIGURE 30 is a longitudinal cross-sectional view along the line 30-30;

FIGURE 31 is a transverse cross-sectional view along the line 31-31;

FIGURE 32 is a transverse cross-sectional view along the line 32-32;

FIGURE 33 is an isometric view of a sealing sleeve;

FIGURE 34 is a schematic view of the posterior side of the cuff in a deflated state;

FIGURE 35 is a schematic view of the anterior side of the cuff in a deflated state;

FIGURE 36 to 39 are schematic cross-sectional views of the deflated cuff corresponding to Figures 6 to 9 respectively;

FIGURE 40 is a schematic view of the posterior side of the cuff in an inflated state;

FIGURE 41 is a schematic view of the anterior side of the duff in an inflated state;

FIGURES 42 to 45 are schematic cross-sectional views of the inflated cuff corresponding to the cross-sectional views of Figures 6 to 9 respectively;

FIGURE 46 is a schematic view showing deployment of the artificial airway in a patient;

FIGURE 47 is an isometric view of a distal end component of an airway tube of a second embodiment of the invention;

FIGURE 48 is a view showing the posterior side of the component shown in Figure 47;

FIGURE 49 is a side view of the component of Figure 47;

FIGURE 50 is a plan view showing the anterior side of the component of Figure 47;

FIGURE 51 is a view into the proximal end of the component;

FIGURE 52 is a view into the distal end of the component;

FIGURE 53 is a schematic longitudinal sectional view along the line 53-53;

FIGURE 54 is a cross-sectional view along the line 54-54;

FIGURE 55 is a cross-sectional view along the line 55-55;

FIGURE 56 is a side view of an inflatable cuff of the second embodiment;

FIGURE 57 is a plan view showing the anterior side of the cuff of Figure 56;

FIGURE 58 is a distal end view of the cuff of Figure 56;

FIGURE 59 is a schematic cross-sectional view along the line 59-59;

FIGURE 60 is a schematic cross-sectional view along the line 60-60;

FIGURE 61 is a schematic cross-sectional view along the line 61-61;

FIGURE 62 is an enlarged fragmentary view showing interconnection of the distal end component with the modified form of cuff;

FIGURE 63 is a side view of a second component of the airway tube; and

FIGURE 64 is a plan view showing the anterior side of the second component.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figures 1 to 10 show an artificial airway 2 constructed in accordance with the invention. The artificial airway 2 in the illustrated arrangement is assembled from four components: an inflatable cuff 4, airway tube 6, connector body 8 and joining sleeve 10. In Figures 1 to 10, the inflatable cuff 4 is shown in an uninflated position. As best seen in Figure 3, the cuff 4 has a generally wedge shape as seen in side view. It has however an evacuation chamber 12 at its distal end. As best seen in Figure 4 the cuff also has a generally wedge shape when viewed in plan except that it is somewhat truncated at its distal end where the evacuation chamber 12 is located. As the cuff includes a recess 14

which communicates with conduits in the airway tube 6 to permit an anaesthetic gas or air to be administered to the lungs of a patient, as will be described in more detail below.

The cross-sectional view of Figure 6 shows the cross-sectional configuration of the airway tube 6. It will be seen that it is generally D-shaped in cross-section having a curved posterior side 16 and generally flat anterior side 18. The airway tube 6 includes two airway conduits 20 and 22 which convey anaesthetic gas or air to the recess 14, as will be described in more detail below. The airway tube 6 includes an inflation conduit 24 which is in fluid communication with the interior of the cuff 4 to enable inflation thereof. The airway tube 6 further includes an evacuation conduit 26, the distal end of which is in fluid communication with the interior of the evacuation chamber 12. The airway tube 6 further includes an evacuation chamber vent conduit 28 which also opens to the interior of the evacuation chamber 12.

The cuff includes a proximal connecting spigot 30 which is of complementary shape to the airway tube 6. The spigot 30 is bonded to the outer surface of the airway tube by means of silicon adhesive so as to form a gas-tight seal therewith. The posterior wall 31 of the cuff 4 is a generally semi-cylindrical portion 32 which is contiguous with the adjacent part of the spigot 30, as best seen in Figure 1. The portion 32 accommodates the distal end portion 34 of the tube 6 which enters the cuff 4 as best seen in Figure 5. The distal end of the cuff is formed with a distal spigot 36 which is bonded to the adjacent part of the airway tube 6. The interior of the spigot 36 defines the evacuation chamber 12.

The airway tube 6 is formed with two longitudinally extending airway openings 40 and 42 which communicate with the airway conduits 20 and 22 respectively so as to permit anaesthetic gas to pass into the recess 14. It will be appreciated from Figure 7 that the conduits 24, 26 and 28 are not in fluid communication with the recess 14.

The posterior wall 31 of the cuff includes two laterally extending lobes 44 and 46 which extend laterally from the semi-cylindrical portion 32 and generally extend from the proximal spigot 30 and the distal spigot 36. The cuff includes lateral sidewalls 48 and 50

which extend downwardly from the lobes 44 and 46 and merge into an anterior sealing wall 52. As best seen in Figures 6 and 7, the anterior sealing wall 52 is generally flat, that is to say lies within a single plane. The cuff includes a proximal end wall 51, the edges of which merge into the lateral sidewalls 48 and 50 and the sealing wall 52 In use the anterior sealing wall 52 seals about the epiglottic opening of a patient, as will be described in more detail below. The cuff includes lateral inner sidewalls 53 and 54 which merge upwardly from the anterior sealing wall 52 to define the lateral parts of the recess 14. The cuff also includes proximal and distal inner sidewalls 55 and 57 which also merge upwardly from anterior sidewall 52 to define the end parts of the recess 14. The upper periphery of the inner sidewalls 53, 54, 55 and 57 are formed with a rim 56 which includes a rebate 58 at its inner edge. The rebate 58 is shaped so as to be complementary to the anterior edge of the airway tube 6 adjacent to the openings 40 and 42. Silicon bonding agent is used to bond the rim 56 to the adjacent edges of the airway tube 6 so that the entire upper periphery of the inner sidewalls 54 is bonded so as to form a gas-tight seal therewith.

It will be appreciated that the cuff is joined to the end portion 34 of the airway 6 only at the spigots 30 and 34 and the upper periphery of the sidewalls 54 as described above.

As best seen in Figure 9, the end portion 34 of the airway tube 6 includes a notch 60 which communicates with the inflation conduit 24 so as to permit the cuff 4 to be inflated.

Figures 11 to 13 show the cuff 4 prior to bonding to the end potion 34 of the airway tube 6. The cuff is preferably injection moulded from silicon rubber having a Shore A hardness in the range 25 to 40. The wall thickness is preferably in the range from 1 to 2 mm. In the illustrated embodiment, the wall thickness is uniform and is approximately 1 mm in thickness. Alternatively, the wall thickness could be varied in order to produce differential expansions when inflated and in this case the wall thickness would be about 1 mm in thickness at the thinner parts and about 2 mm at the wider parts. Where wall thickness variation is employed, the wall thickness could be thicker in the walls which

define the anterior sealing wall 52 and the inner sidewalls 53, 54, 55 and 57 and proximal end wall 51 so that these walls tend to maintain their shape during inflation. The lateral sidewalls 48, 50 and the posterior wall 31 are preferably thinner so that these walls expand to a greater extent during inflation.

As mentioned above, the cuff is generally wedge-shaped when viewed from the side, as shown in Figure 11. The apex angle A is preferably 15° to 25° and preferably 20°.

The cuff is also generally wedge-shaped when viewed in plan, as seen in Figure 12, except that the apex is truncated, where the spigot 36 is located. The apex angle B is preferably in the range from 20° to 30° and most preferably about 22.5°. It will also be seen that the sidewalls 48 and 50 when viewed in plan are relatively straight or have only a very slight curve.

It will also be noted that the recess 14 is of a rectangular shape when viewed in plan as seen in Figure 12. Further, the inner sidewalls 53, 54, 55 and 57 are inclined inwardly towards to the rim 56 at an angle of about 15°.

In one embodiment, the length of the cuff 4 as measured in the longitudinal direction is approximately 93 mm and the widest portion, that is to say between the lateral sidewalls 46 and 48, is about 50 mm. The height of the sidewall 48 varies from about 8 mm at the distal end of the cuff to about 20 mm at the proximal end. The distance from the anterior sealing wall 52 to the highest point on the cylindrical portion 32 is about 34 mm adjacent to the spigot 30 and decreases to about 12 mm adjacent to the distal spigot 36. Again, these dimensions can be varied in accordance with the size of the airway tube being made. The aforementioned dimensions refer to the uninflated cuff.

Figures 15 to 24 show the preferred shape of the airway tube 6. The airway tube 6 is preferably injection moulded from silicon rubber having a Shore A hardness of 35 and preferably within the range from 35 to 50. It will be seen from Figure 17 that the end portion 34 forms an angle C with the proximal end portion 70, there being a curved

intermediate portion 72 therebetween. Preferably angle C is in the range 50° to 75° and most preferably about 60°. It is preferred that the airway tube 6 is initially injection moulded in a straight condition and then heated in a former so as to form the curved portion 72. The conduits 20, 22, 24, 26 and 28 can all be formed during the moulding process. Similarly, the openings 40 and 42 can also be formed in the moulding process. As best seen in Figure 18, a central longitudinally-extending ridge 74 is formed between the openings 40 and 42. The ridge 74 imparts additional rigidity to the end portion 34 of the airway tube 6. It further serves to prevent the epiglottis of the patient obstructing the openings 40 and 42. It will also be seen from Figures 16 and 17 that the distal end of the end portion 34 tapers somewhat so as to better conform to the interior shape of the cuff 4. The distal end of the end portion 34 is moulded with an integral hollow projection 76 which is of a generally oval shape in cross-section. The outer shape of the projection 76 is generally complementary to the shape of the distal spigot 36 and is located therein so as to impart additional rigidity to the shape of the evacuation chamber 12. It will be seen from Figure 24 that the distal ends of the conduits 26 and 28 open into the interior of the projection 76 so as to provide fluid communication with the chamber 12. Finally, the notch 60 can also be integrally formed during the moulding process.

It will be appreciated from Figures 17 and 18 that the airway tube 18 could be regarded as being generally uniform in cross-section along its length except that the end part 34 has part of the flat anterior side 18 removed. In an area corresponding to the recess 14, the anterior wall 18 is completely removed in a generally rectangular shape but having rounded corners at the distal and proximal ends, as seen in Figure 18. The edges of the sidewalls 53, 54, 55 and the rim 56 are bonded to the airway tube adjacent to this opening by means of silicone glue. It will be appreciated, however, that from a functional point of view the cuff could be connected to the airway tube in different ways. For instance, parts corresponding to the sidewalls 53, 54, 55 and 57 could be integrally moulded with the airway tube, although this would make moulding of the tube more difficult. If, however, this modification were made the inner edges of the anterior sealing wall 52 could be bonded to the adjacent lower edges of the sidewalls integrally formed with the airway tube. Other intermediate variations would also be possible. It is preferred, however, to mould

the airway tube 6 and the cuff 4 as shown in the drawings.

It will be appreciated that the airway tube 6 could be formed in two separate parts. The end part 34 could be moulded separately from the parts 70 and 72 which could be formed by extrusion bent into the correct shape and then joined to the end portion 34.

In one embodiment, the length of the airway tube 6 is about 170 mm (when straight) and the transverse width is about 25 mm. The height, that is to say as measured from the anterior side 18 to the posterior side 16, is about 15 mm. The dimensions of course can be varied according to the size of the airway device which is to be made.

Figures 26 to 31 illustrate in more detail the connector body 8. In the illustrated arrangement, the connector body is integrally moulded from plastics material such as polycarbonate. It would be possible to mould the body 8 in a number of parts and connect them together by bonding or heat or ultrasonic welding.

The connector body 8 includes a 15mm male Luer connector 80 formed at the proximal end of the body. The body includes an intermediate portion 82 from which project three distal spigots 84, 86 and 88. The spigots 84, 86 and 88 have outer diameters such that they can be snugly inserted in the proximal ends of the conduits 28, 26 and 24 respectively so as to establish fluid communication with these conduits. The spigots may be slightly tapered to facilitate assembly of the connector body 8 onto the airway tube 6. The lengths of the spigots are about 15 mm.

As can be best seen from Figure 26 the intermediate portion 82 includes passages 90, 92 and 94 which communicate with the hollow spigots 84, 86 and 88 respectively. The proximal end of the passage 90 is constituted by a port 96 which is formed in a transverse wall 98 and is open to atmosphere. In use air is admitted through the port 96 so that it can pass into the passage 90 and then through the evacuation chamber vent conduit 28 and be admitted to the evacuation chamber 12. The intermediate portion 82 is formed with a laterally-projecting hollow spigot 100 which communicates with the passage 92. The

passage 92 is in fluid communication with the hollow spigot 86 which in turn establishes fluid communication with the evacuation conduit 26. In use, a source of suction can be applied via the spigot 100 so as to establish suction within the evacuation chamber 12 to which the distal end of the conduit 26 opens. The intermediate portion 82 is also formed with a laterally-projecting hollow spigot 102 which communicates with the passage 94 which is in fluid communication with the hollow spigot 88. The hollow spigot 88 is inserted into the inflation conduit 24. In use positive pressure can be applied to the spigot 102 via a syringe in order to pressurise the inflation conduit and thus inflate the cuff 4 to the required degree.

The anterior side of the intermediate portion 82 is essentially hollow and forms a relatively wide passage 104 which, at the proximal end is in communication with the Luer connector 80 and at the distal end communicates with the ends of the airway conduits 20 and 22. The distal end of the intermediate portion 82 is formed as a shoulder 106 which abuts the adjacent end of the airway tube 6 so that the passage 104 communicates with the conduits 20 and 22. In the illustrated arrangement, the should 106 abutting the end of the tube 6 is preferred because, if connecting spigots were used to establish fluid communications with the airway conduits 20 and 22, there would be undesirable constrictions caused by the spigots. In other words the direct abutment of the shoulder 106 provides the least amount of obstruction to flow of anaesthetic gases. There is little prospect of leakage between the passage 104 and the other passages at the junction because of the insertion of the spigots 84, 86 and 88 into the corresponding conduits essentially isolates them from the passage 104.

In the illustrated arrangement, the overall length of the connecting body 8 is about 101 mm and the maximum width, that is to say as measured between the ends of the spigots 100 and 102, is 40 mm. It will be appreciated that the rigid body 8 mounted on the proximal end of the airway tube 6 provides rigidity at this point of the artificial airway which is sometimes useful for fixing of the position of the artificial airway. This also prevents the airway being damaged or obstructed in the event of the patient biting upon the airway. Furthermore, the connecting sleeve 10 provides a soft resilient surface that will

prevent damage to the patient's teeth should biting occur.

The cross-section shape of the periphery of the intermediate portion as shown in Figure 31 corresponds to the cross-sectional shape at the proximal end of the airway tube 6. This enables the connecting sleeve 10 to be snugly mounted over the intermediate portion 82 and the proximal end of the tube 6.

Figure 33 shows the sleeve 10. It is extruded or moulded from silicon rubber and has a hardness which is similar to that of the airway tube 6. The tube 10 has a bore 120 which is of complementary shape to the outer surface of the intermediate portion 82 and the airway tube 6. The length of the sleeve 10 is preferably about 60 mm. From a functional point of view it needs to be longer than the length of the intermediate portion 82 as measured from the wall 98 to the shoulder 106 so that the sleeve 10 fully covers the exterior of the intermediate portion 82 and about 20 mm of the proximal end of the airway tube 6.

The preferred sequence of fabrication of the device is to separately mould the cuff 4, airway tube 6, connector body 8 and sleeve 10. The initially straight airway tube 6 is then heat formed into a curved shape as described previously. The cuff 4 can then be mounted on the end portion 34 of the airway tube 6 and bonded thereto as described earlier. The sleeve 10 can then be slid along the proximal end of the airway tube 6 so that the spigots 84, 86 and 88 can be inserted into their respective conduits. Silicon bonding agent may also be used to fix them in position. Silicon bonding agent is then applied to the bore 120 of the sleeve and it is moved in a proximal direction so that is proximal end engages the transverse wall 98. In this way a gas tight join is formed between the connector body 8 and the end of the airway tube 6 with the necessary fluid communication paths established.

Figures 34 to 39 schematically illustrate the cuff in its fully deflated position. The cuff can be deflated by connecting a syringe to a lumen (not shown in Figures 34 to 39) connected to the spigot 102. The cuff 4 is deflated so that it can be more easily inserted

through the mouth and throat of the patient. It will be seen that, when the cuff is deflated, the lobes 44 and 46 collapse so as to form laterally-extending wings 130 and 132 which vary in size and shape towards the distal ends of the cuff. The anterior surface 52 and the inner sidewalls 54 collapse so as to form anteriorly-extending wings 134 and 136 which again vary in shape and width along the length of the cuff. The wings 130, 132, 134 and 136 are somewhat randomly oriented but more importantly they can readily be resiliently deflected during the insertion process.

Figures 40 to 45 schematically show the shape of the cuff, in its inflated position. Normally the cuff 4 is inflated to a pressure within the range 40-60 cm H_2O pressure. In the inflated position, the lobes 44 and 46 are somewhat extended laterally. More significantly however the posterior wall 31 is significantly displaced from the posterior wall 16 of the end portion 34 of the airway tube 6, as best seen in Figure 43. In the inflated position, there are still longitudinal depressions 140 and 142 generally located between the lobes 44 and 46 and the adjacent parts of the posterior wall 31, as seen in Figure 43. The depressions 140 and 142 serve to impart some stability to the inflated structure to intend to resist twisting thereof, after or during inflation.

After inflation, the maximum width of the cuff 4 is about 52 mm and the maximum height as measured between the anterior sealing surface 52 and the posterior wall 31 is about 33 mm for a size 4 device and these dimensions will vary with smaller and larger devices as is well known in the art.

Figure 46 diagrammatically illustrates the manner in which the artificial airway 2 is deployed in a patient 150. The cuff 4 is initially deflated by using a syringe 152 which is connected to the spigot 102 by means of a lumen 154 via a valve 156 which normally closes the lumen 154 except when the syringe 152 is connected thereto. The artificial airway 2 can then be inserted through the throat of the patient until the cuff is located adjacent to the glottic opening 158. The distal end of the cuff 4 is located adjacent to the upper oesophageal sphincter 160. The syringe 152 can then be used to inflate the cuff 4 to the required degree. This causes outward expansion of the posterior wall 31 of the cuff so

as to seal against the posterior pharyngeal walls 162 of the patient. Inflation of the cuff also causes some lateral expansion of the sidewalls 48 and 50 so that these seal against the lateral pharyngeal walls of the patient. During this process, the anterior wall 52 will be brought into good sealing contact with the area surrounding the glottic opening 158. Anaesthetic gases or air as required can then be administered to the patient via the Luer connector 80.

The shape of the cuff as described above generally anatomically conforms to the corresponding anatomical features of the patient whereby an excellent seal is maintained between the anterior wall 52 and the area surrounding the glottic opening 158. A prototype of the device has been tested and it has been found that the seal is higher than is available with currently available airway devices. The prototype of the invention has been tested at a pressure of 28 to 36 cm of H_2O whereas most currently available commercial airways typically have a maximum of about 28 cm H_2O.

Also it will be seen that the evacuation chamber 12 is presented to the oesophagus 161 of the patient. A source of suction can be connected via a lumen 164 to the spigot 100 in order to cause suction within the chamber 12. Because however the chamber 12 is vented to atmosphere by the evacuation chamber vent conduit 28, there is only a limited amount of suction towards the proximal part of the chamber 12. This avoids the undesirable effect of having the chamber 12 sucked directly onto the tissue surfaces of the patient which could cause damage. Any material regurgitated from the oesophagus 161 will enter the chamber 12 and will be entrained into the flow of air which passes from the evacuation chamber vent conduit 28 into the evacuation conduit 26. This minimises the possibility that the regurgitated material would enter the glottic opening and into trachea 159. The chamber 120 is vented to atmosphere, there is very little prospect that the chamber could be maintained in a state of suction against the mucosa of the upper oesophageal sphincter or parts adjacent thereto. This avoids the possibility of damage to the tissue of the patient. Also the arrangement has advantages over prior art arrangements in which evacuation tubes can communicate directly with the oesophagus of the patient and apply negative pressure thereto which could have the effect of inducing regurgitation.

It will also be observed that the epiglottis 166 of the patient is normally located adjacent to the recess 14 and the ridge 74 of the airway tube tends to prevent the epiglottis obstructing the airways openings 40 and 42. Also it will be seen from Figure 46 that the teeth 168 of the patient are located adjacent to the sleeve 10 which is resilient as it is formed from silicon rubber. This helps to prevent damage to the patient and to the artificial airway.

Figures 47 to 64 show details of a modified airway constructed in accordance with the invention. In these drawings, the same reference numerals have been used to denote parts which are the same as or correspond to those of the first embodiment.

In this embodiment, the airway tube 6 is made in two components, a distal component 180 which is interconnected with a proximal component 181. These components are joined together by means of bonding or gluing or the like and when connected together correspond in shape to the airway 6. The proximal component 181 can be connected to the joining sleeve 10 as in the previous embodiment. The distal component 180 includes a rebate 182 which, in use, connects to a complementary rebate 183 formed in the distal end of the proximal component 181, as best shown in Figure 64. The rebates 182 and 183 facilitate alignment and gluing or bonding thereto. The component 180 includes a projecting wall 184 which projects somewhat from the anterior side of the component 180. The interior of the wall 184 defines an elongate oval shaped recess 186 which corresponds to the recess 14 of the cuff.

As best seen in Figures 53, 54 and 55, the anterior edge of the wall 184 is formed with a groove 188 and shoulder 190 outwardly adjacent thereto. The component 180 includes a rebate 192 surrounding the vent conduit 28 at its distal end, as best seen in Figures 47 and 53.

By forming the airway tube in proximal and distal components 181 and 180 they are each easier to mould than a single component and this therefore reduces the overall cost of the device.

Figures 57 to 61 illustrate a modified form of cuff 200 which is shaped so as to facilitate mounting onto the component 180. The cuff 200 differs in two significant ways from that shown in the previous embodiment.

The first difference is that the inner sidewalls 53, 54, 55 and 57 are formed with a lip 202 which projects generally inwardly relative to the recess 14. The lip 202 is shaped so as to be received within the groove 188 of the component 180 and adjacent to the shoulder 190. This facilitates bonding and or gluing of the cuff to the component 180. This is best seen in the enlarged schematic view of Figure 62.

The second major change that the cuff 200 has relative to the cuff 4 of the previous embodiment is that the distal spigot 36 is formed with an inwardly directed integral flange 204, as best shown in Figure 59. The flange 204 is, in use, located within the rebate 192 formed at the distal end of the component 180. The provision of the flange 204 therefore defines a smooth entrance to the evacuation chamber 12. Further, any excess glue or bonding agent, if present, will be located inwardly of the proximal end of the airway so that there should not be any rough or sharp edges at the distal end caused by such excess glue or bonding agent. The appearance of the cuff is also enhanced because it has a smooth entrance to the evacuation chamber 12.

In the cuff which is formed with the component 180 and cuff 200, the proximal connecting spigot 30 of the cuff is sufficiently long that it covers the join line between the component 180 and the remainder of the airway tube. This helps to prevent any gas leakages and also gives a neat appearance to the airway. Further, any excess glue or bonding agent used to interconnect the component 180 with the remainder of the airway would be covered by the spigot 30 and therefore avoid any unwanted projections on the exterior of the airway caused by such excess glue or bonding agent.

It will be appreciated by those skilled in the art that the device of the invention is moulded from relatively few components which are inexpensive to make. Further, the assembly process is comparatively simple compared with the assembly needed for known

artificial airways.

It will also be appreciated by those skilled in the art that the shape of the cuff of the invention is wedge shaped, as described above, when viewed in side view and plan. This provides better conformity with the anatomical shape of a patient when the cuff is inflated compared with the elliptical or oval toroidal or annular rings of most prior art devices.

The device of invention is thus inexpensive enough that it can be made as a single use or disposable device but it could be auto-clavable for multiple use.

The described construction has been advanced merely by way of example and many modifications and variations may be made without departing from the spirit and scope of the invention, which includes every novel feature and combination of features herein disclosed.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

The reference in this specification to any prior publication (or information derived from it), or to any matter which is known, is not, and should not be taken as an acknowledgment or admission or any form of suggestion that that prior publication (or information derived from it) or known matter forms part of the common general knowledge.

LIST OF PARTS

artificial airway	2
an inflatable cuff	4
airway tube	6
connector body	8
joining sleeve	10
evacuation chamber	12
recess	14
curved posterior side	16
generally flat anterior side	18
airway conduits	20, 22
inflation conduit	24
evacuation conduit	26
evacuation chamber vent conduit	28
proximal connecting spigot	30
posterior wall	31
semi-cylindrical portion	32
distal end portion	34
distal spigot	36
airway openings	40, 42
extending lobes	44, 46
lateral sidewalls	48, 50
proximal end wall	51
anterior sealing wall	52
inner sidewalls	53, 54
proximal inner sidewall	55
rim	56
distal inner sidewall	57
rebate	58
notch	60

proximal end portion	70
curved intermediate portion	72
central longitudinally-extending ridge	74
integral hollow projection	76
male Luer connector	80
intermediate portion	82
distal spigots	84, 86, 88
passages	90, 92, 94
port	96
transverse wall	98
laterally-projecting hollow spigot	100
laterally-projecting hollow spigot	102
relatively wide passage	104
shoulder	106
bore	120
laterally-extending wings	130, 132
anteriorly-extending wings	134, 136
longitudinal depressions	140, 142
patient	150
syringe	152
lumen	154
valve	156
glottic opening	158
trachea	159
upper oesophageal sphincter	160
oesophagus	161
pharyngeal walls	162
lumen	164
epiglottis	166
teeth	168
distal component	180

proximal component	181
rebate	182, 183
projecting wall	184
recess	186
groove	188
shoulder	190
rebate	192
cuff	200
lip	202
flange	204

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. An artificial airway including:

an airway tube including at least one airway conduit;

an inflatable cuff mounted on a distal end of the tube;

a support member extending into the cuff, the cuff having inner side walls, anterior walls and a posterior wall, the inner side walls being joined to the support member to define a recess which communicates with the airway conduit, the anterior walls and posterior wall, sealingly engaging, in use, about the glottic opening and posterior pharyngeal wall respectively of a patient.

2. An artificial airway as claimed in claim 1, wherein the support member defines a posterior wall of the recess.

3. An artificial airway as defined in claim 1 or 2, wherein the support member is integral with the airway tube.

4. An artificial airway as claimed in claim 1 or 2 wherein the airway tube is formed by a proximal part and a distal part which are separately formed then joined together.

5. An artificial airway as claimed in claim 4 wherein the distal part is integrally formed with said support member.

6. An artificial airway as claimed in claim 5 wherein the support member is moulded with an opening which includes first formations and the inner sidewalls of the cuff are moulded with second formations which are complementary to the first formations, the first and second formations being interconnectable to facilitate joining of the cuff to the support member.

7. An artificial airway as claimed in claim 6 wherein the cuff includes a proximal and distal spigot which overlie adjacent parts of the airway tube and wherein the cuff is only

joined to the airway tube adjacent to said spigots and by said first and second formations.

8. An artificial airway as claimed in claim 7 wherein the airway tube includes an evacuation conduit which communicates with an evacuation chamber located at the distal end of the cuff.

9. An artificial airway as claimed in claim 8 wherein the distal spigot includes an integral posteriorly directed flange which lies within a distal part of the evacuation conduit so that the entrance to the evacuation chamber is defined by the material of the cuff.

10. An artificial airway including:

an airway tube having at least one airway conduit therein;

an inflatable cuff mounted on a distal end of the airway tube, an end portion of the airway tube extending into the cuff, the cuff including a recess which is defined by the end portion of the airway tube and inner sidewalls of the cuff which are sealingly connected to said end portion and wherein said at least one airway conduit is in fluid communication with said recess;

the cuff including an anterior sealing wall which merges from the inner sidewalls, the anterior sealing wall lying generally in a plane and, in use, sealingly engages the glottic opening of a patient; the cuff further including a posterior wall extending from outer peripheral parts of the anterior sealing wall to extend over said end portion and, in use, being resiliently extended, on inflation of the cuff, to sealingly engage the posterior pharyngeal wall of the patient.

11. An artificial airway as defined in claim 10, wherein the anterior sealing wall is only connected to said end portion of the airway tube adjacent the distal and proximal ends thereof.

12. A surgical airway as claimed in claim 10 or 11, wherein the shape of the cuff is such that, when inflated and in a lateral cross-section which includes the recess, the posterior wall has an inverted U-shape, the ends of which merge into the outer peripheral

parts of the anterior sealing wall, and wherein the cuff is spaced from the end portion of the airway tube except where the inner side walls thereof are connected to said end portion.

13. An artificial airway as claimed in any one of claims 1 to 12 wherein the inflatable cuff is integrally moulded from silicon rubber.

14. An artificial airway including:

an airway tube having at least one airway conduit therein;

a cuff mounted on a distal end of the tube and having a recess which is in fluid communication with the airway conduit;

an evacuation chamber located at a distal end of the cuff, the chamber, in use, being in fluid communication with the oesophagus of a patient;

an evacuation conduit in fluid communication with the evacuation chamber; and

a ventilation conduit in fluid communication with the evacuation chamber, the arrangement being such that, in use, suction is applied to the evacuation conduit whereby regurgitated material entering the evacuation chamber is removed through evacuation conduit and wherein the ventilation conduit substantially prevents a negative pressure being applied to the tissue of the patient.

15. An artificial airway as claimed in claim 14 wherein the ventilation conduit vents the evacuation chamber to atmosphere.

16. An artificial airway comprising:

an airway tube having at least one airway conduit therein;

an inflatable cuff mounted on a distal end of the airway tube, an end portion of the airway tube extending into the cuff, the cuff including a recess which is defined by the end portion of the airway tube and inner sidewalls of the cuff which are sealingly connected to said end portion and wherein said at least one airway conduit is in fluid communication with said recess;

the cuff including an anterior sealing wall which merges from the inner sidewalls, the anterior sealing wall lying generally in a plane and, in use, sealingly engages the glottic

opening of a patient; the cuff further including a posterior wall extending from outer peripheral parts of the anterior sealing wall to extend over said end portion and, in use, being resiliently extended, on inflation of the cuff, to sealingly engage the posterior pharyngeal wall of the patient;

a connector body for providing fluid communication with said at least one airway conduit; and

means for sealingly connecting the connector body to the proximal end of the airway tube.

17. An artificial airway including:

an airway tube having at least one airway conduit therein;

an inflatable cuff mounted on a distal end of the airway tube, an end portion of the airway tube extending into the cuff, the cuff including a recess which is defined by the end portion of the airway tube and inner sidewalls of the cuff which are sealingly connected to said end portion and wherein said at least one airway conduit is in fluid communication with said recess;

the cuff including an anterior sealing wall which merges from the inner sidewalls, the anterior sealing wall lying generally in a plane and, in use, sealingly engages the glottic opening of a patient; the cuff further including a posterior wall extending from outer peripheral parts of the anterior sealing wall to extend over said end portion and, in use, being resiliently extended, on inflation of the cuff, to sealingly engage the posterior pharyngeal wall of the patient;

an evacuation chamber located at a distal end of the cuff, the chamber, in use, being located adjacent to the upper oesophageal sphincter of a patient;

an evacuation conduit in fluid communication with the evacuation chamber; and

an evacuation chamber vent conduit in fluid communication with the evacuation chamber;

and wherein at least the evacuation conduit and the ventilation conduit are located within said distal end of the airway tube.

18. An artificial airway as claimed in claim 1, 16 or 17 wherein said distal end of the airway tube provides structural rigidity for the distal end of the artificial airway.

19. An artificial airway as claimed in claim 18 characterised in that the airway does not include a back plate connected to the cuff and/or an inflatable ring.

20. An artificial airway including:

an airway tube having at least one airway conduit therein;

an inflatable cuff mounted on a distal end of the airway tube, an end portion of the airway tube extending into the cuff, the cuff including a recess which is defined by the end portion of the airway tube and inner sidewalls of the cuff which are sealingly connected to said end portion and wherein said at least one airway conduit is in fluid communication with said recess;

the cuff including an anterior sealing wall which merges from the inner sidewalls, the anterior sealing wall lying generally in a plane and, in use, sealingly engages the glottic opening of a patient; the cuff further including a posterior wall extending from outer peripheral parts of the anterior sealing wall to extend over said end portion and, in use, being resiliently extended, on inflation of the cuff, to sealingly engage the posterior pharyngeal wall of the patient;

characterised in that the cuff is moulded as single integral moulding.

21. An artificial airway as claimed in claim 20 characterised in that the airway is moulded with proximal and distal portions which are joined together, the distal portion including said end portion of the airway tube.

22. An artificial airway as claimed in claim 21 wherein the cuff is formed with a proximal spigot which overlies the region where the proximal and distal end portions are joined together.

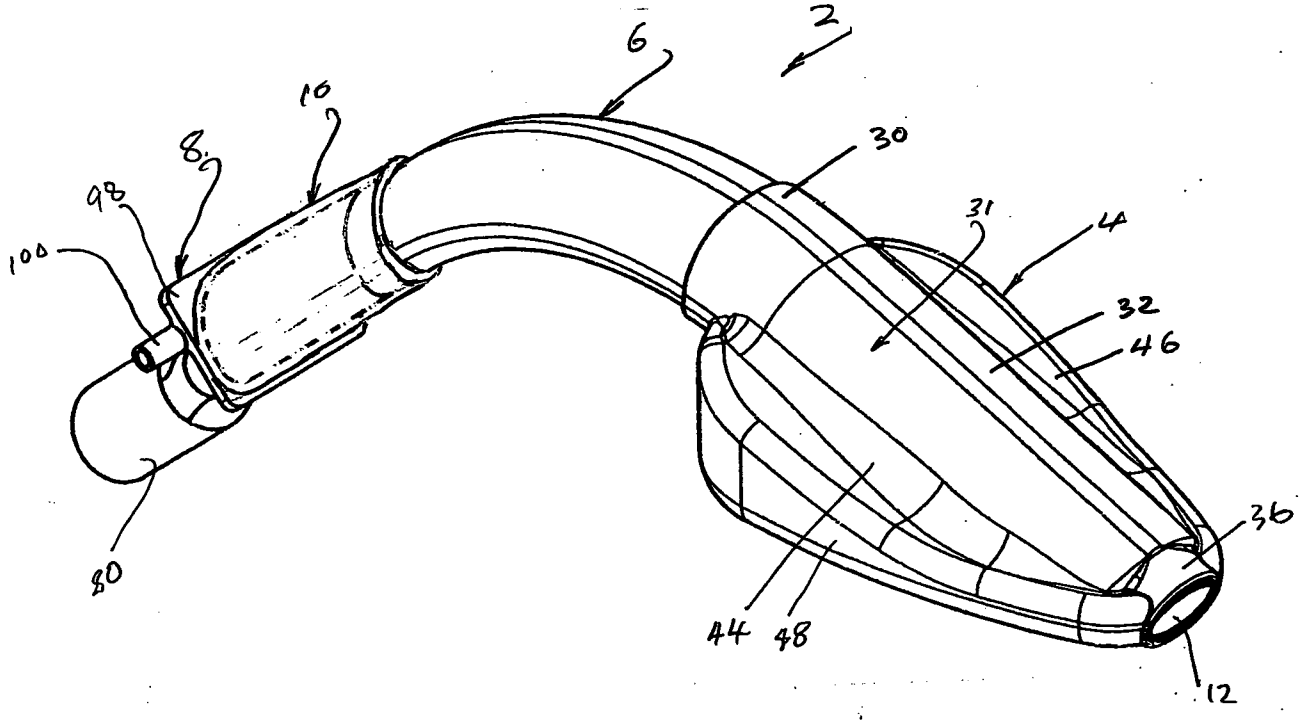

FIGURE 1

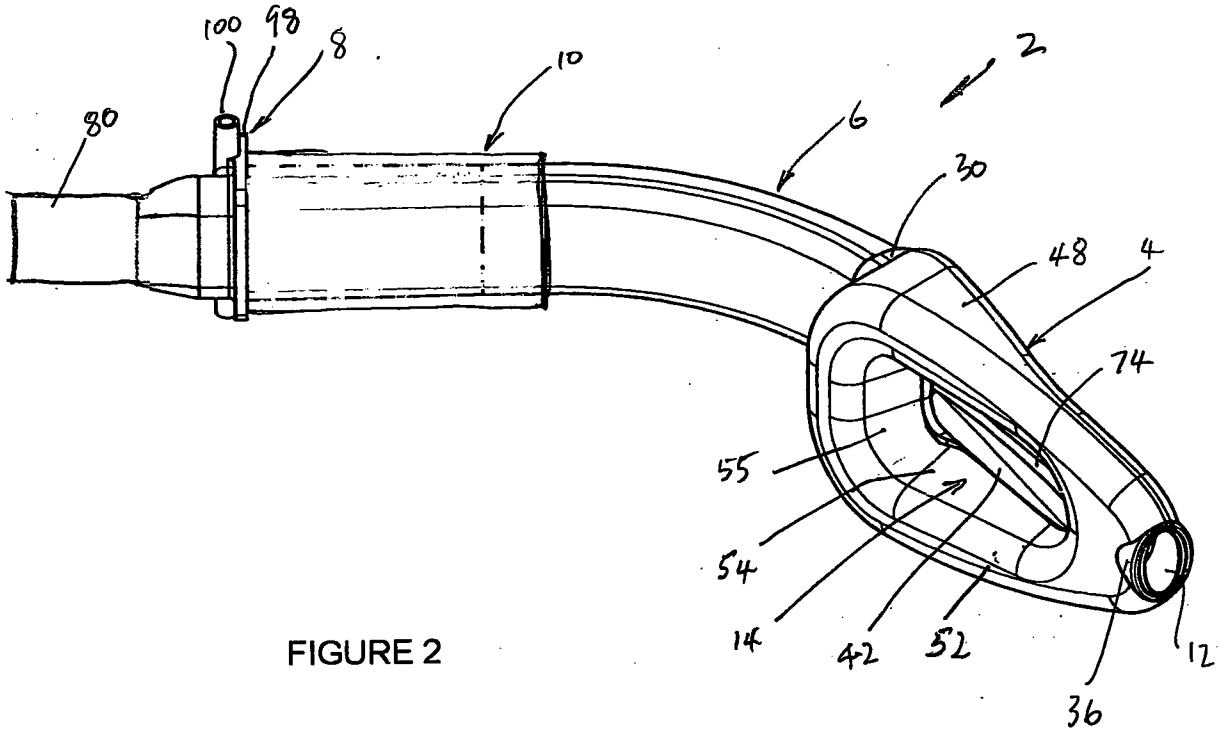

FIGURE 2

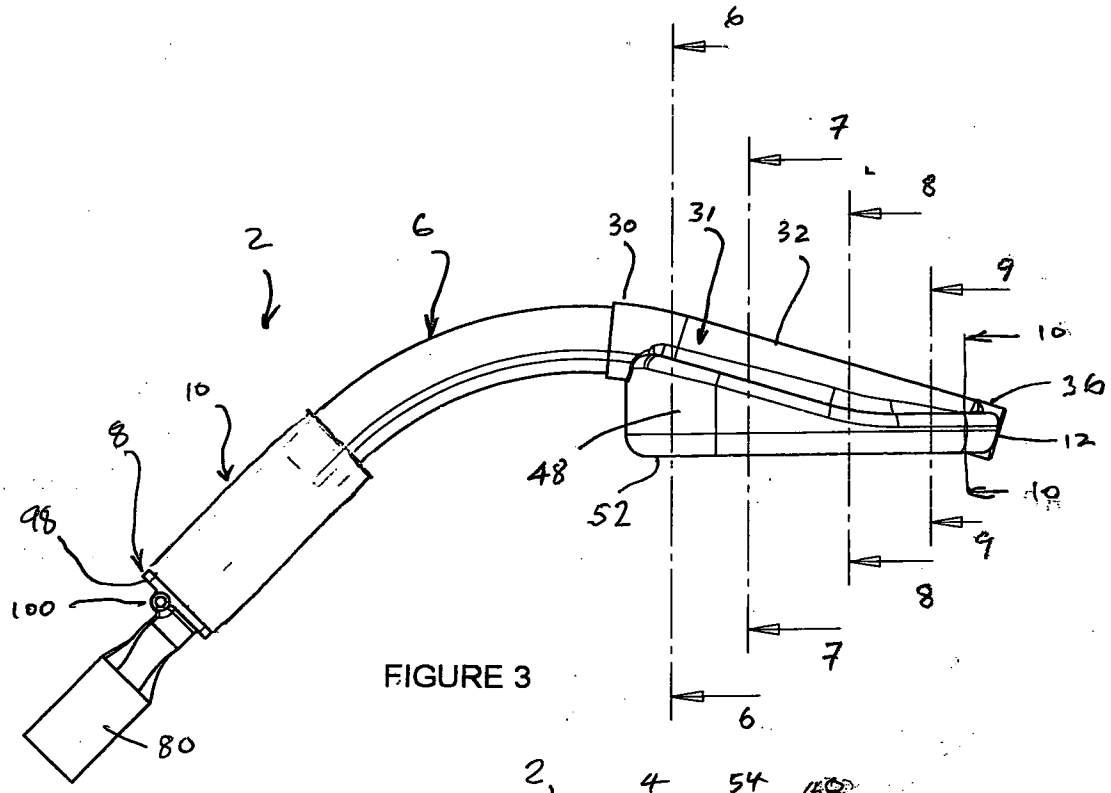

FIGURE 3

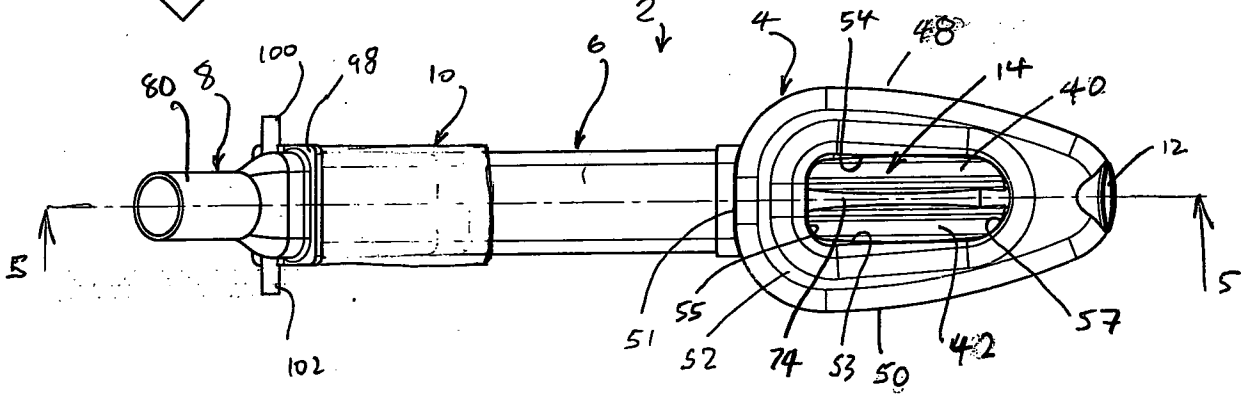

FIGURE 4

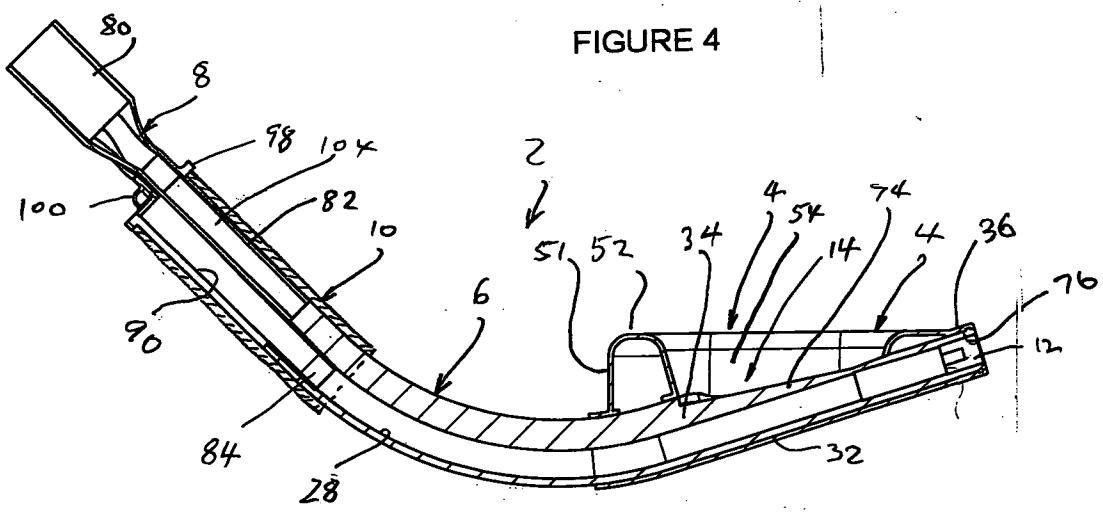

FIGURE 5

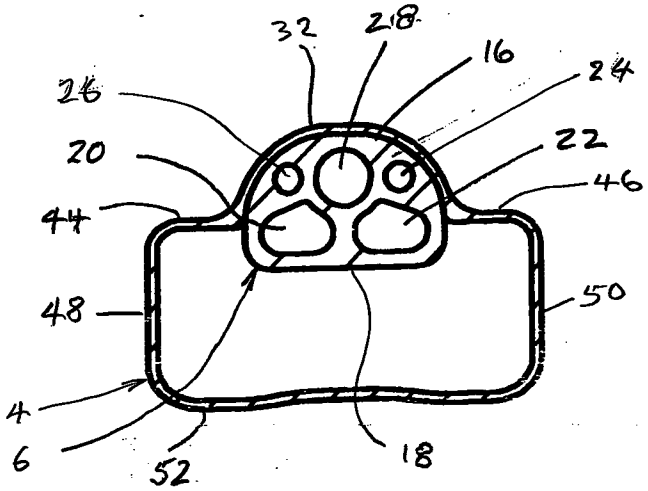

FIGURE 6

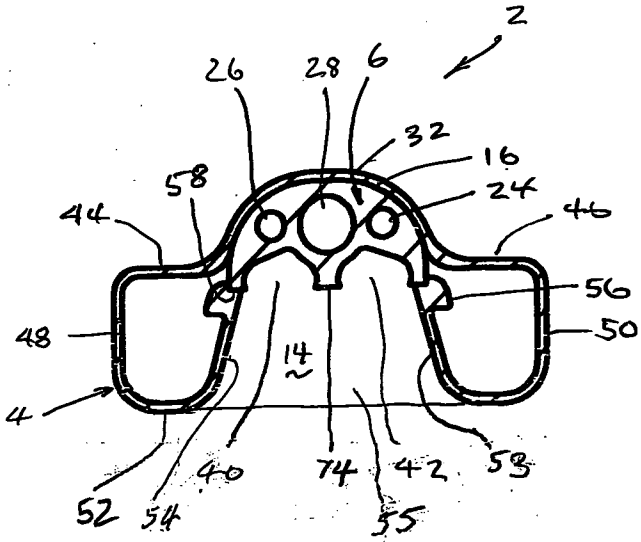

FIGURE 7

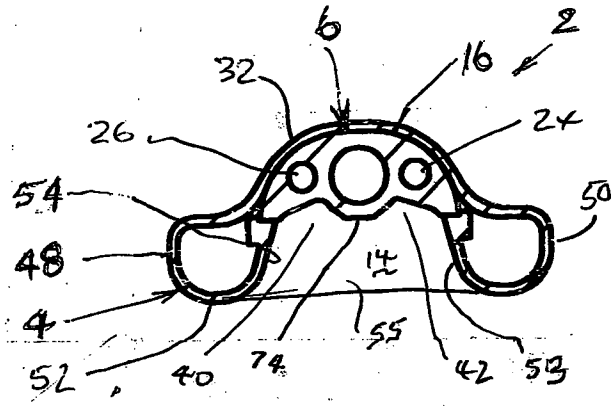

FIGURE 8

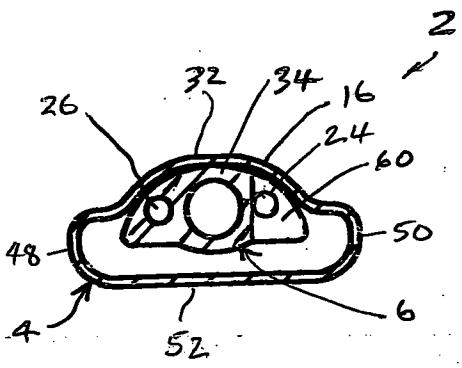

FIGURE 9

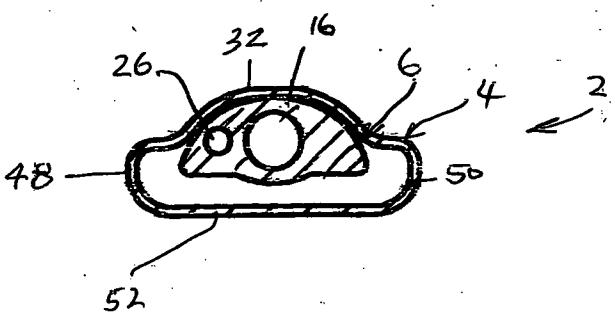

FIGURE 10

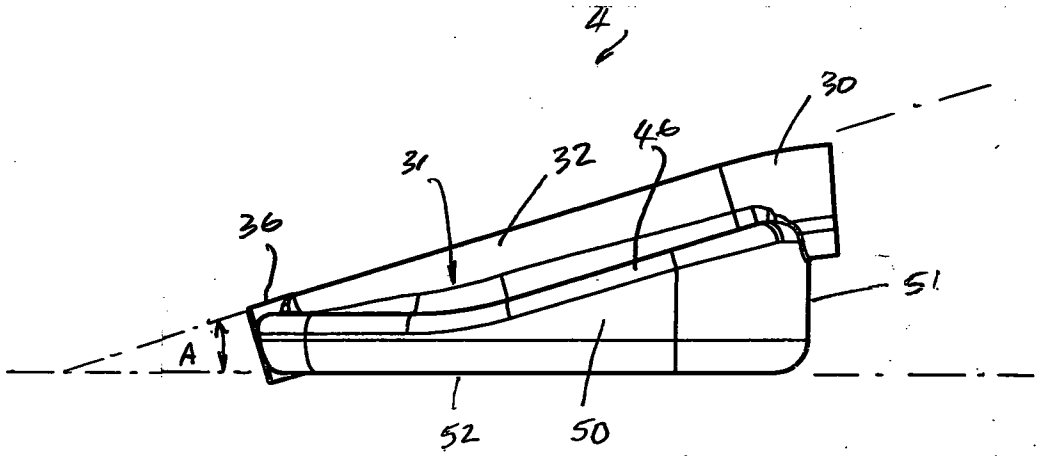

FIGURE 11

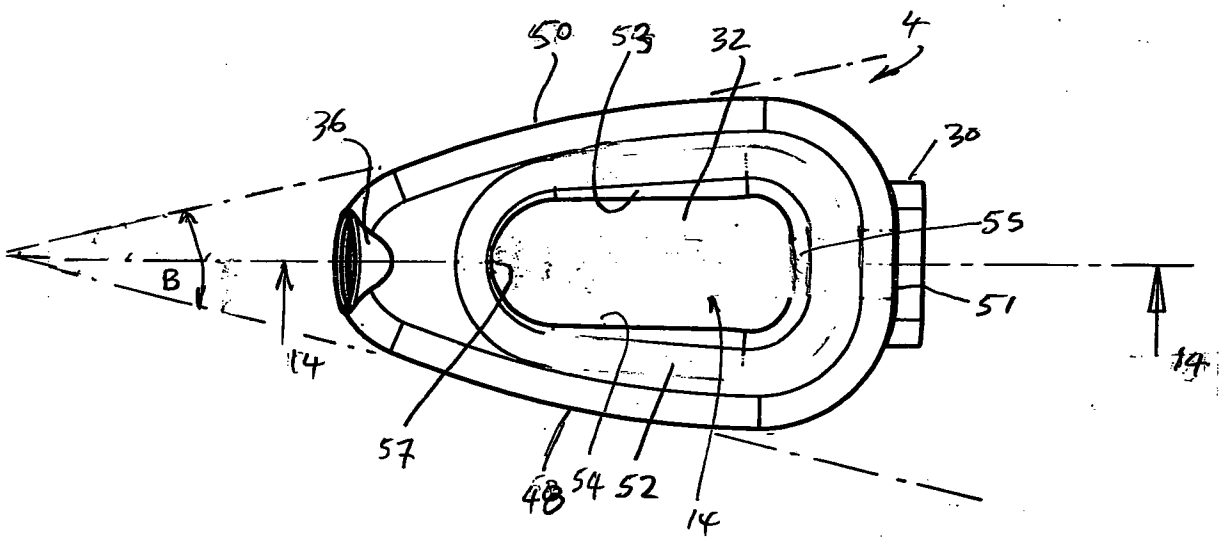

FIGURE 12

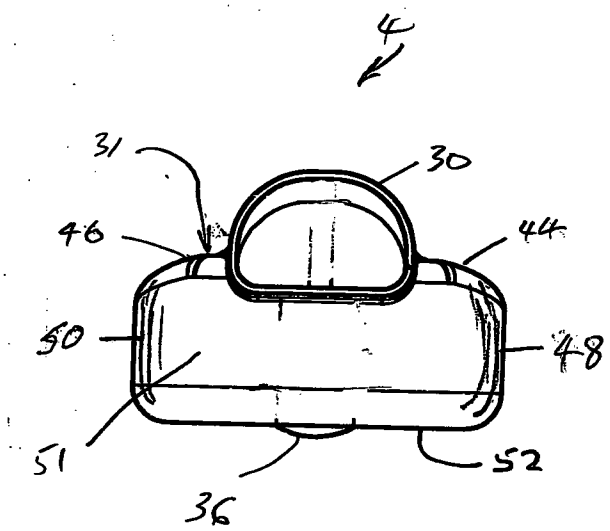

FIGURE 13

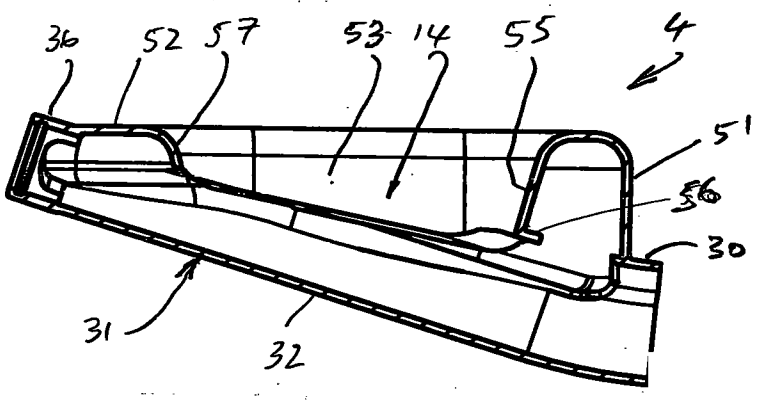

FIGURE 14

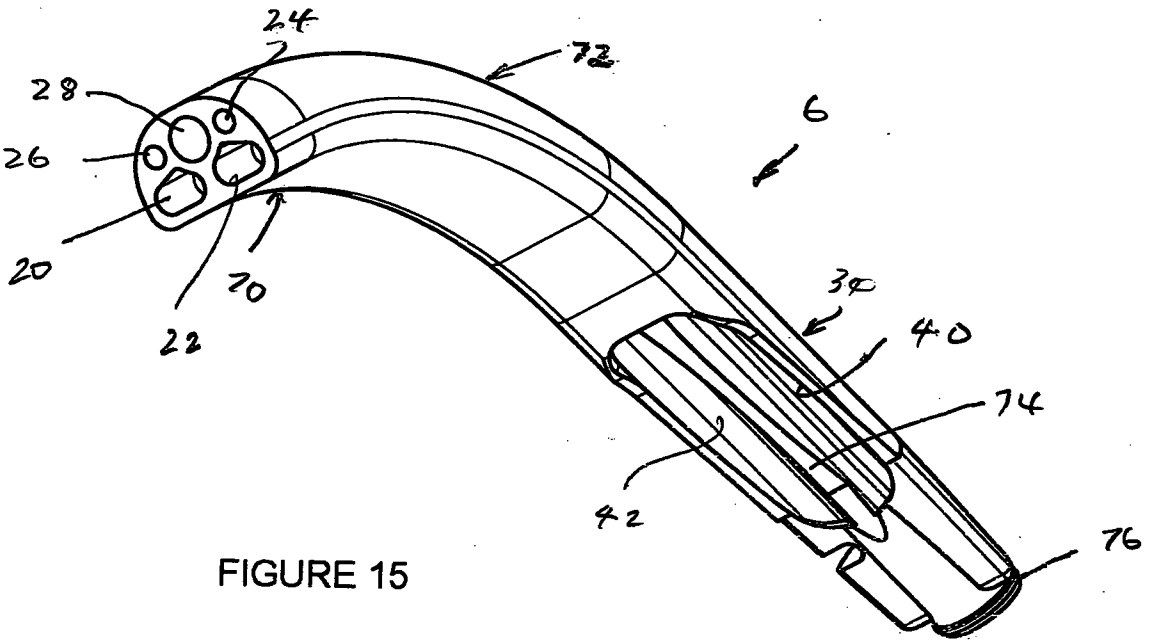

FIGURE 15

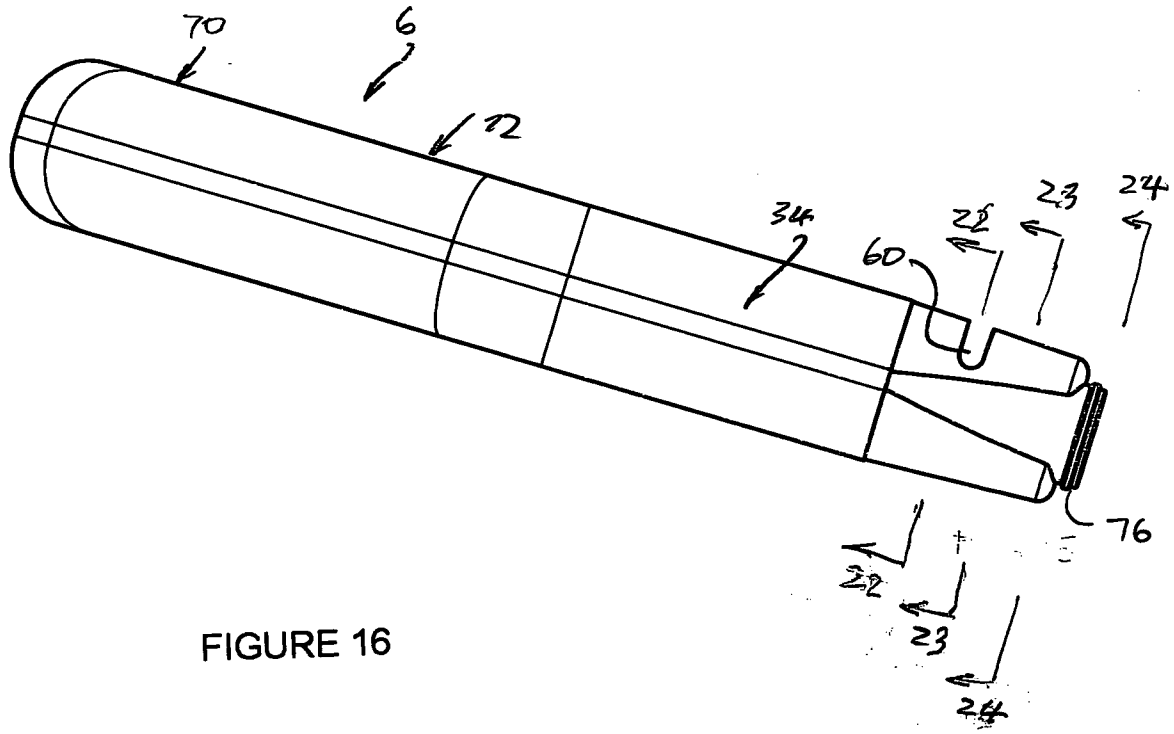

FIGURE 16

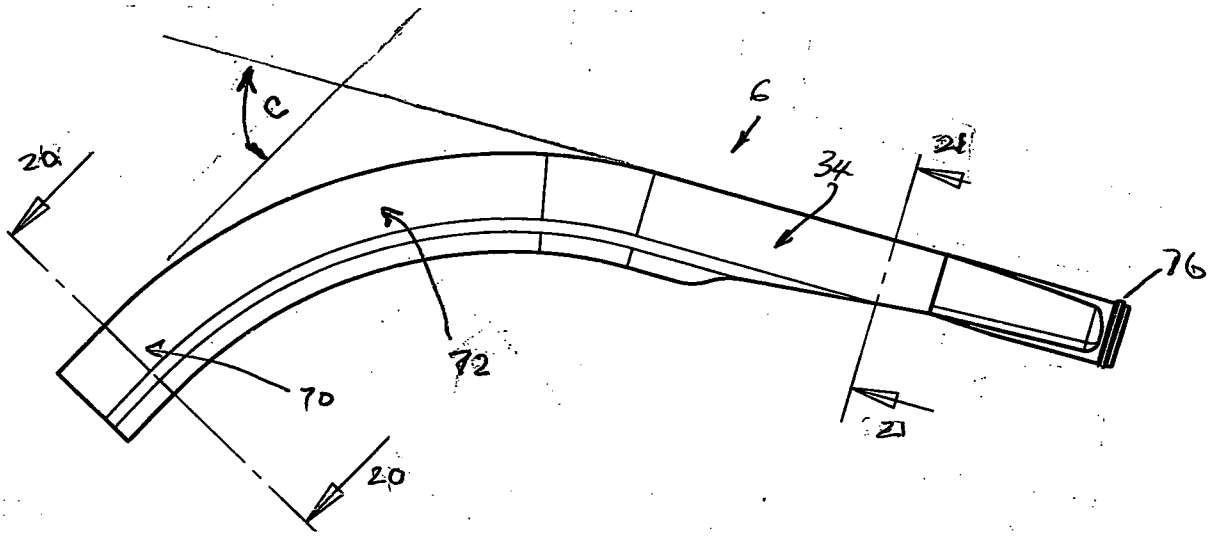

FIGURE 17

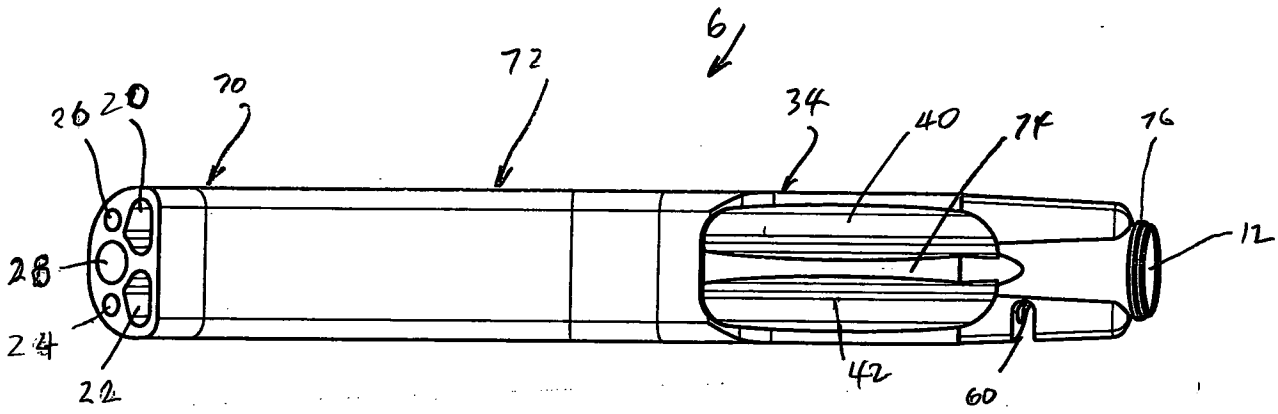

FIGURE 18

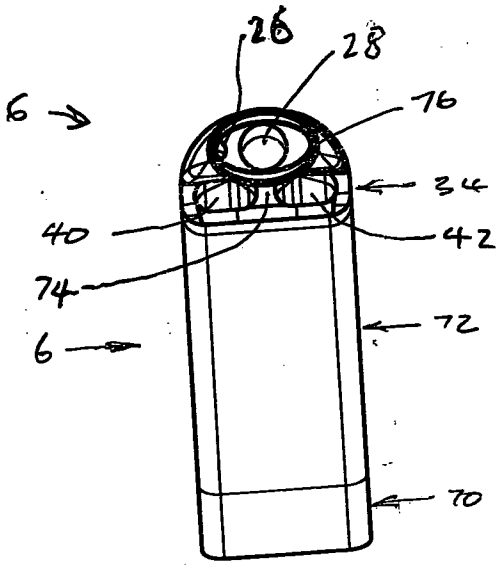

FIGURE 19

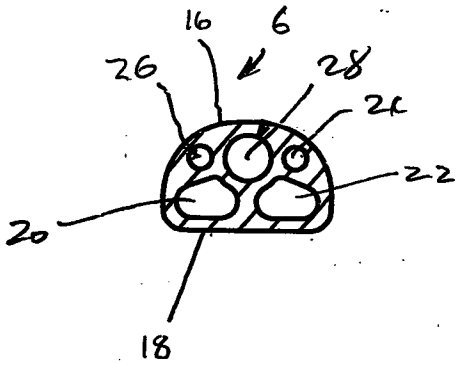

FIGURE 20

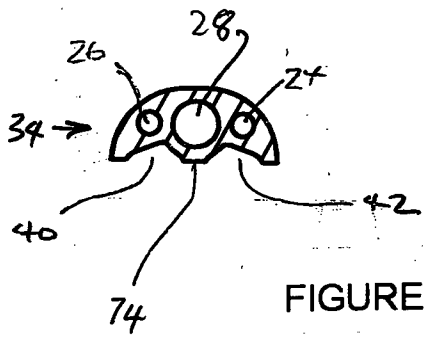

FIGURE 21

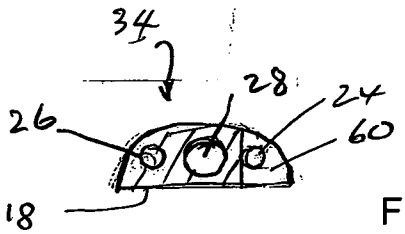

FIGURE 22

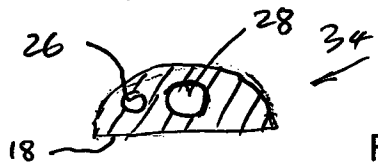

FIGURE 23

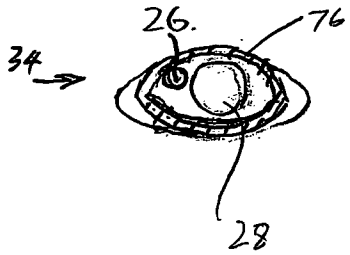

FIGURE 24

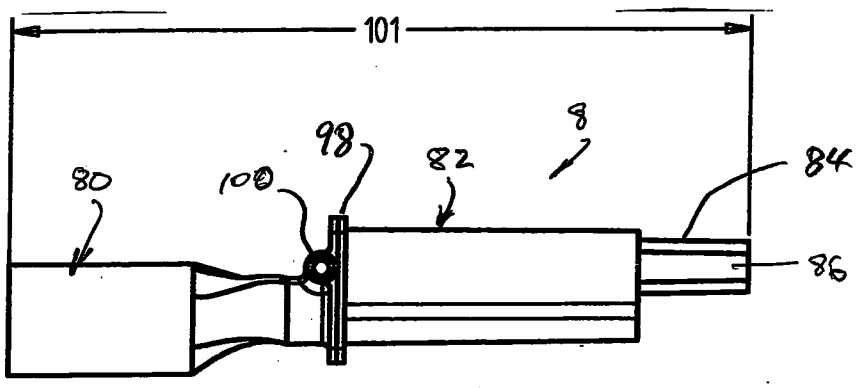

FIGURE 25

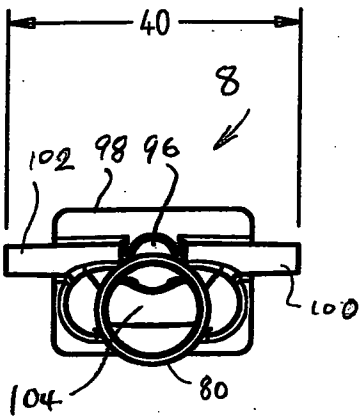

FIGURE 27

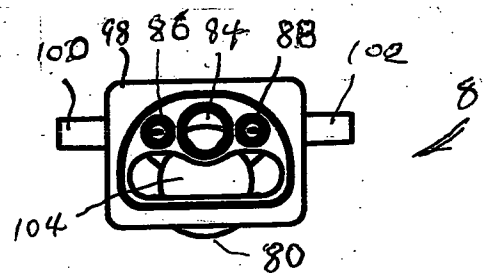

FIGURE 28

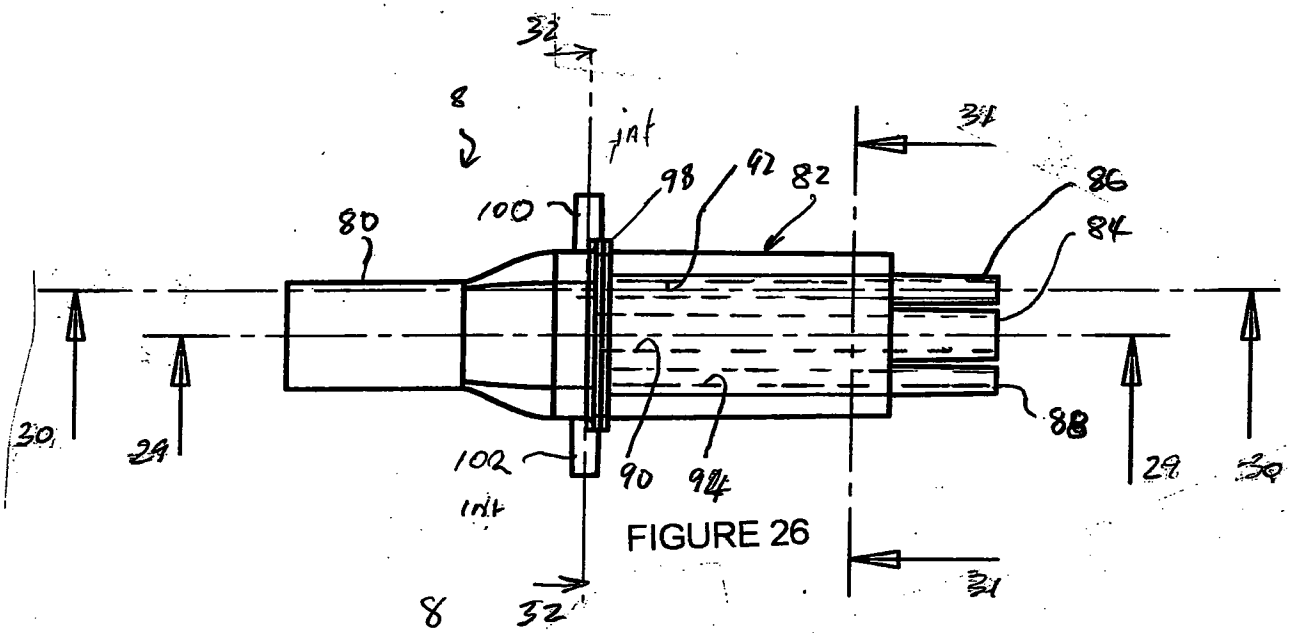

FIGURE 26

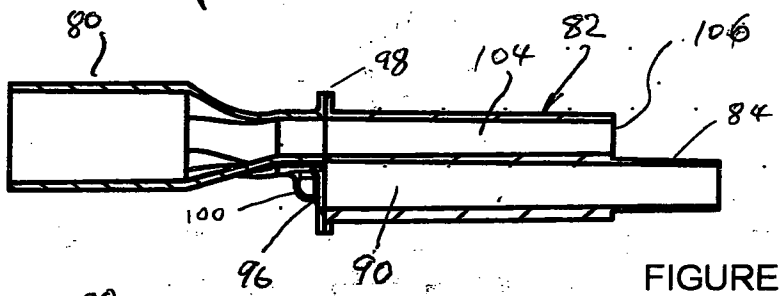

FIGURE 29

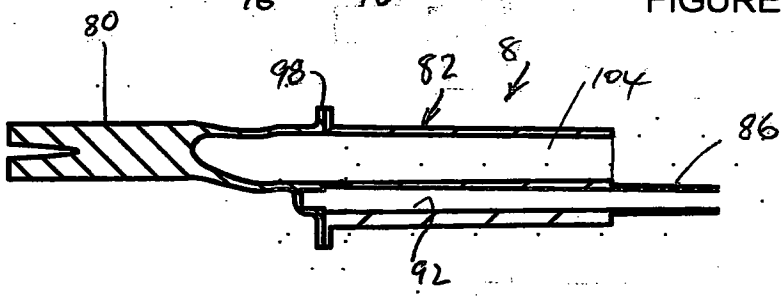

FIGURE 30

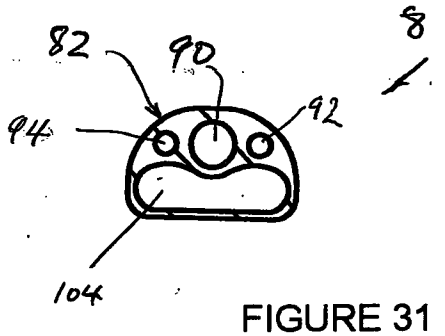

FIGURE 31

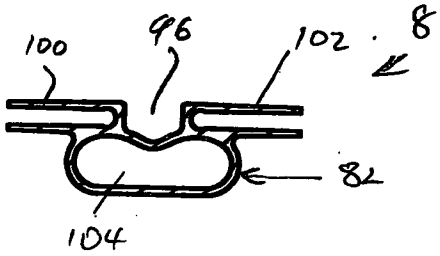

FIGURE 32

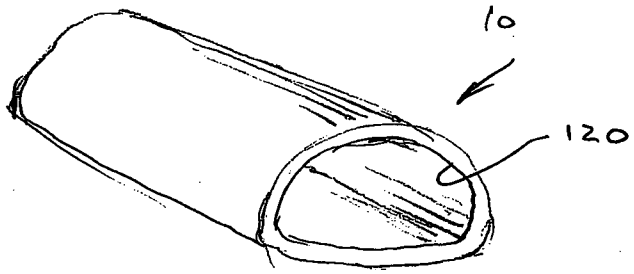

FIGURE 33

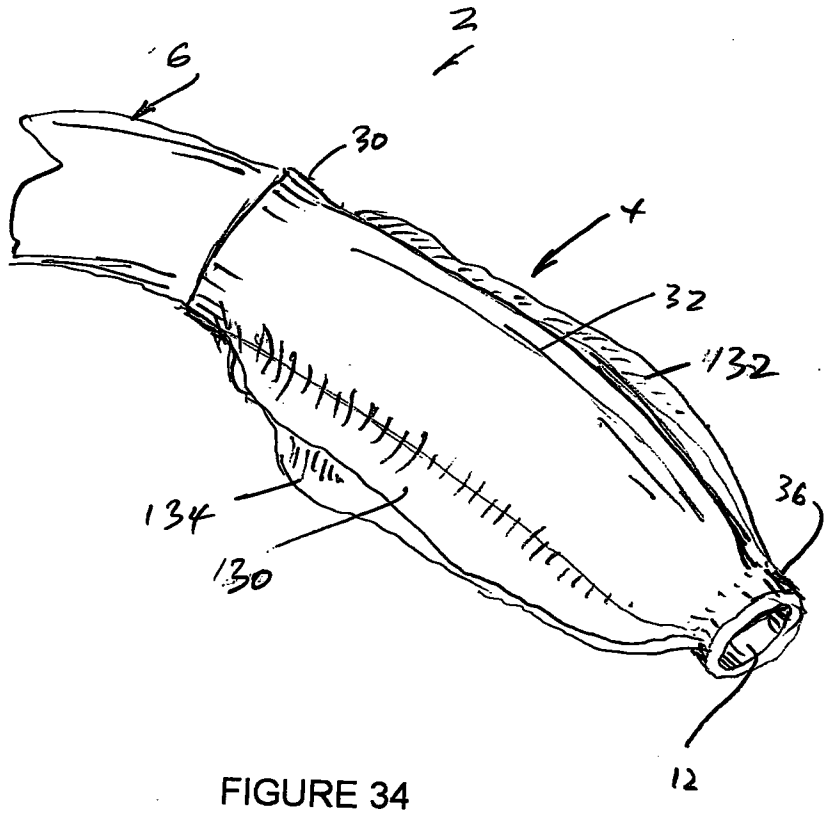

FIGURE 34

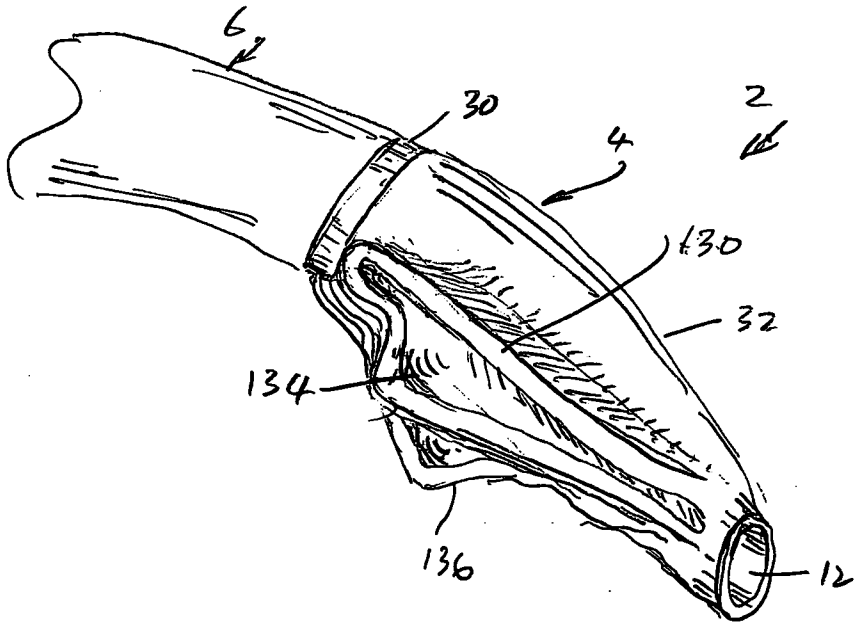

FIGURE 35

13/22

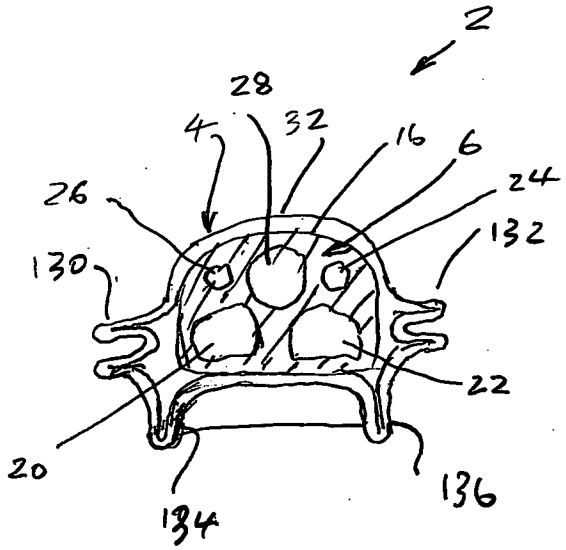

FIGURE 36

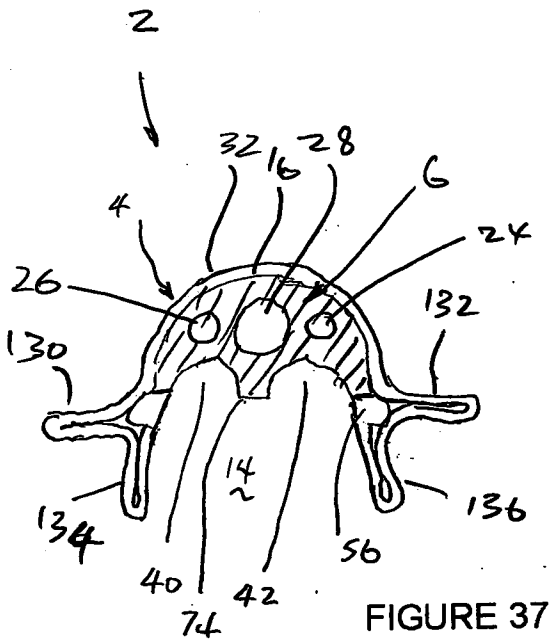

FIGURE 37

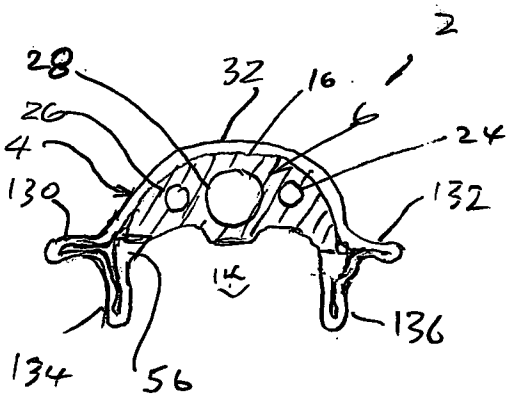

FIGURE 38

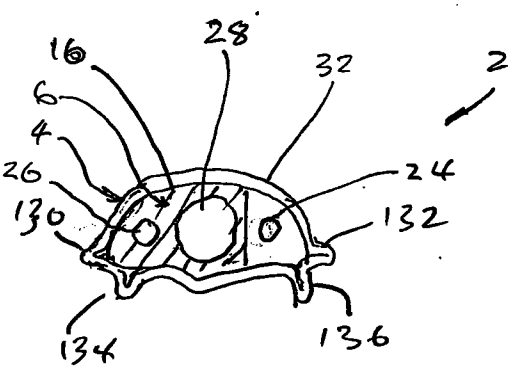

FIGURE 39

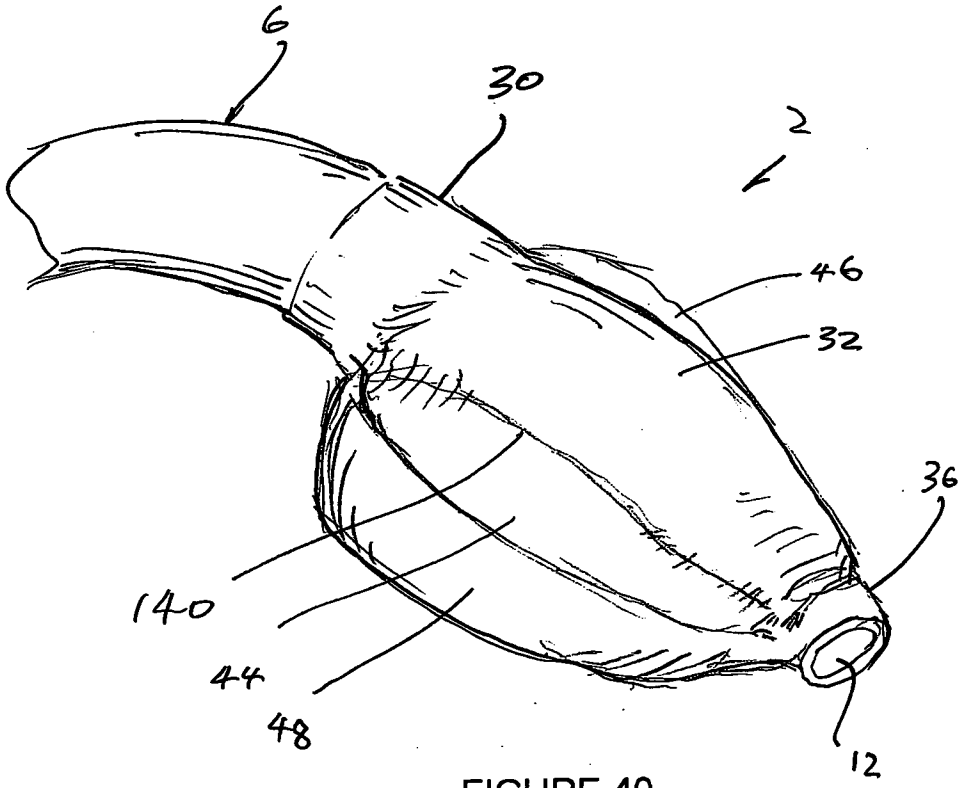

FIGURE 40

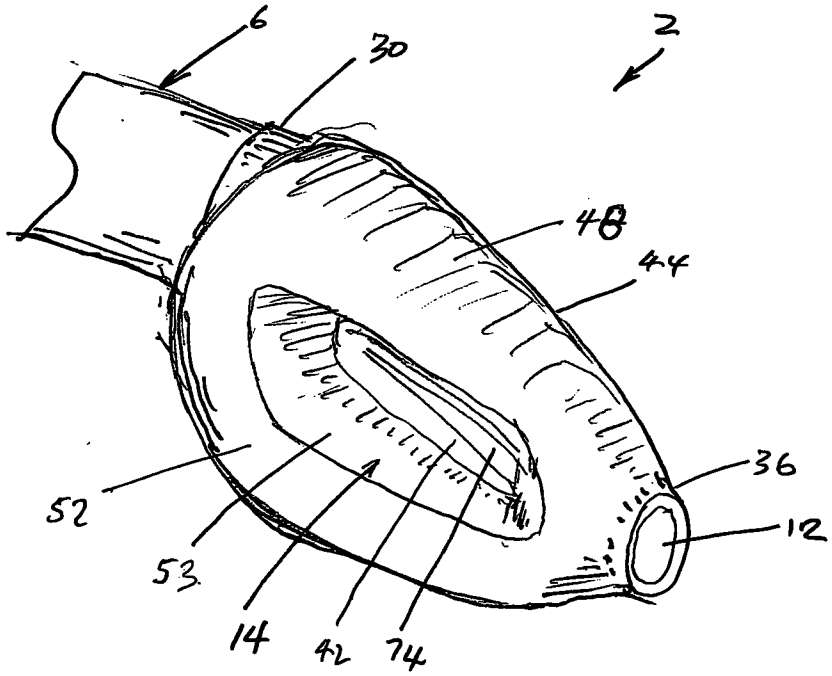

FIGURE 41

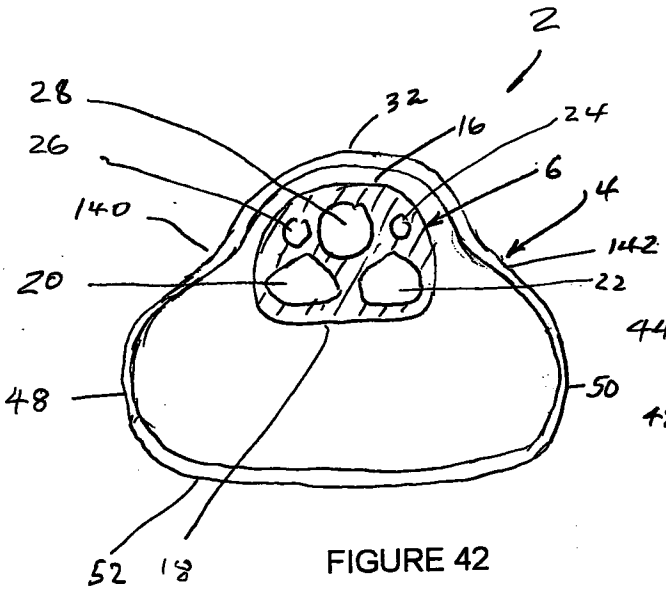

FIGURE 42

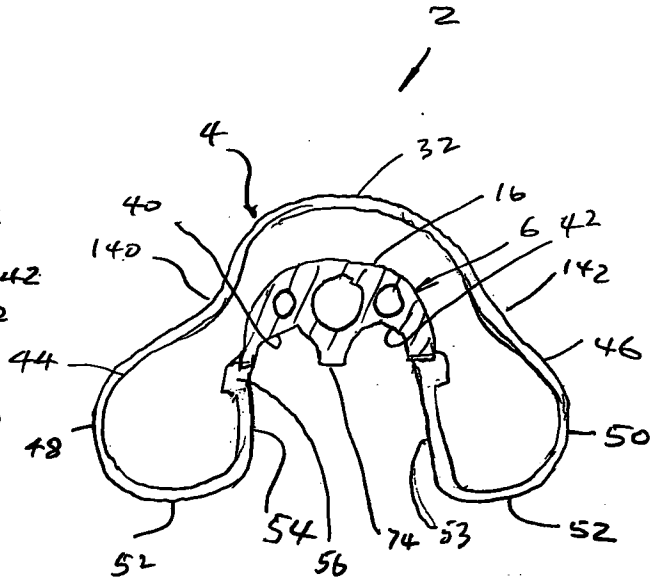

FIGURE 43

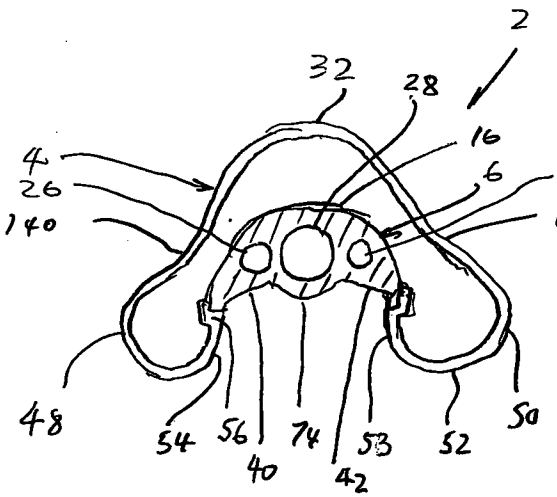

FIGURE 44

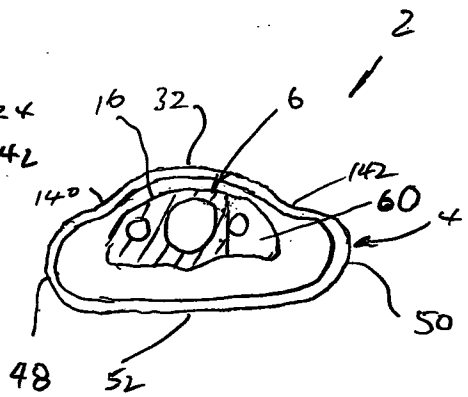

FIGURE 45

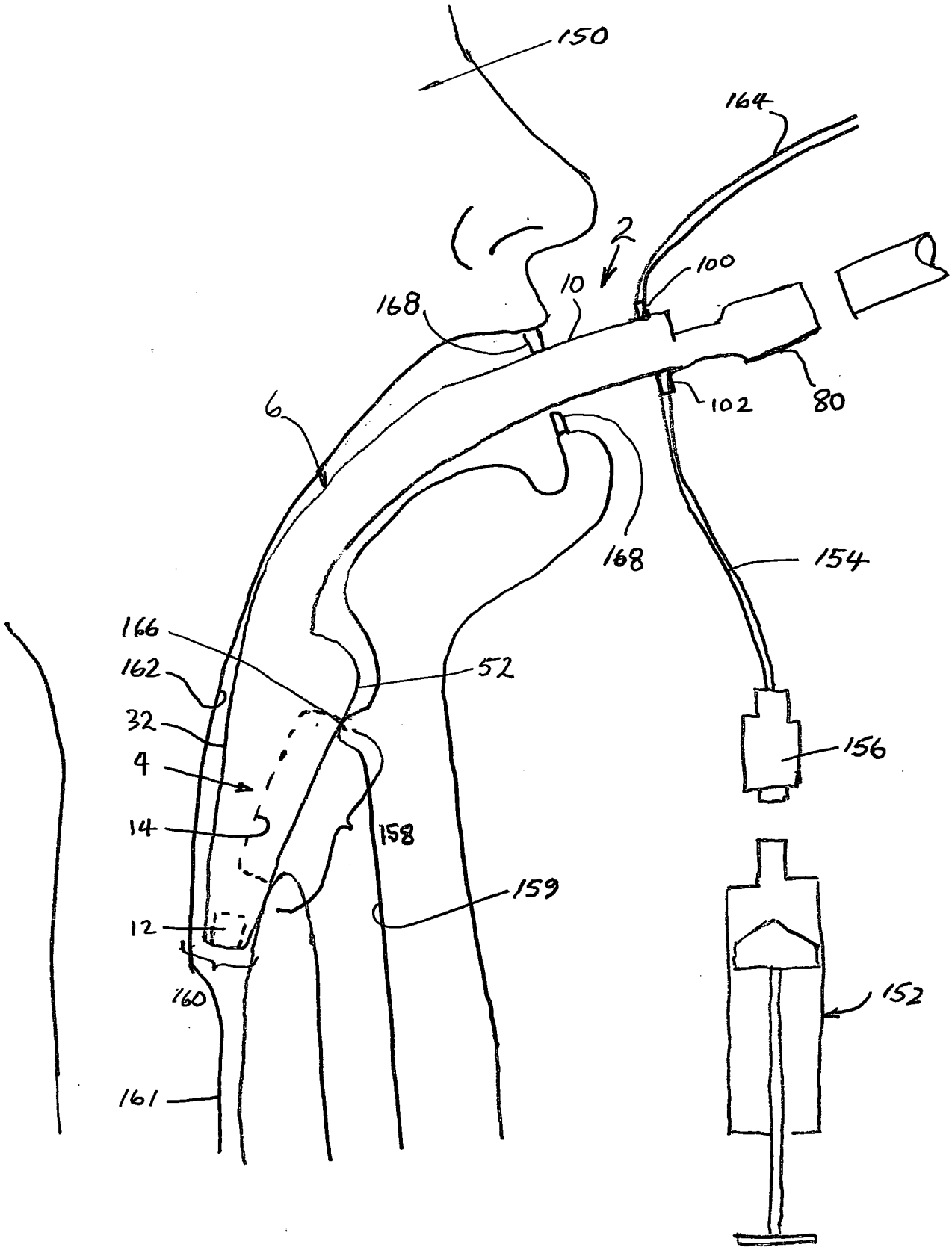
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FIGURE 46

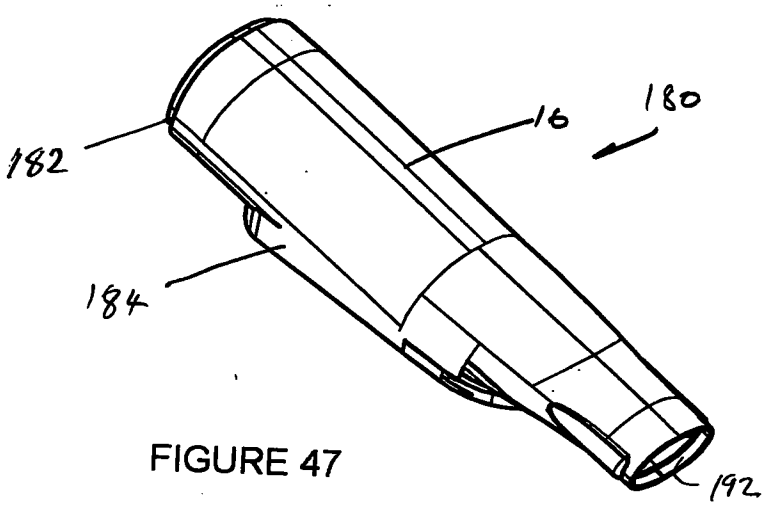

FIGURE 47

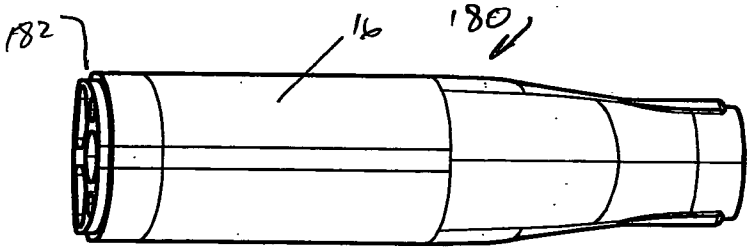

FIGURE 48

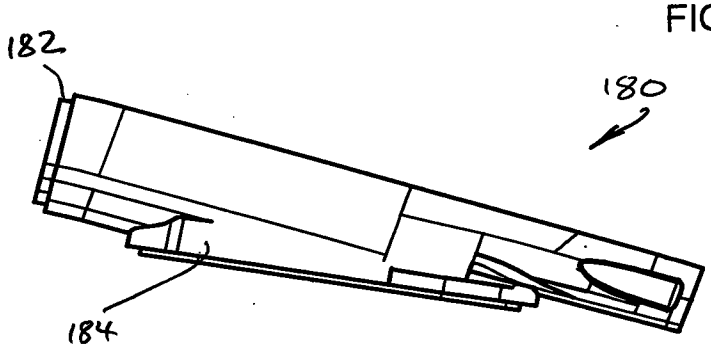

FIGURE 49

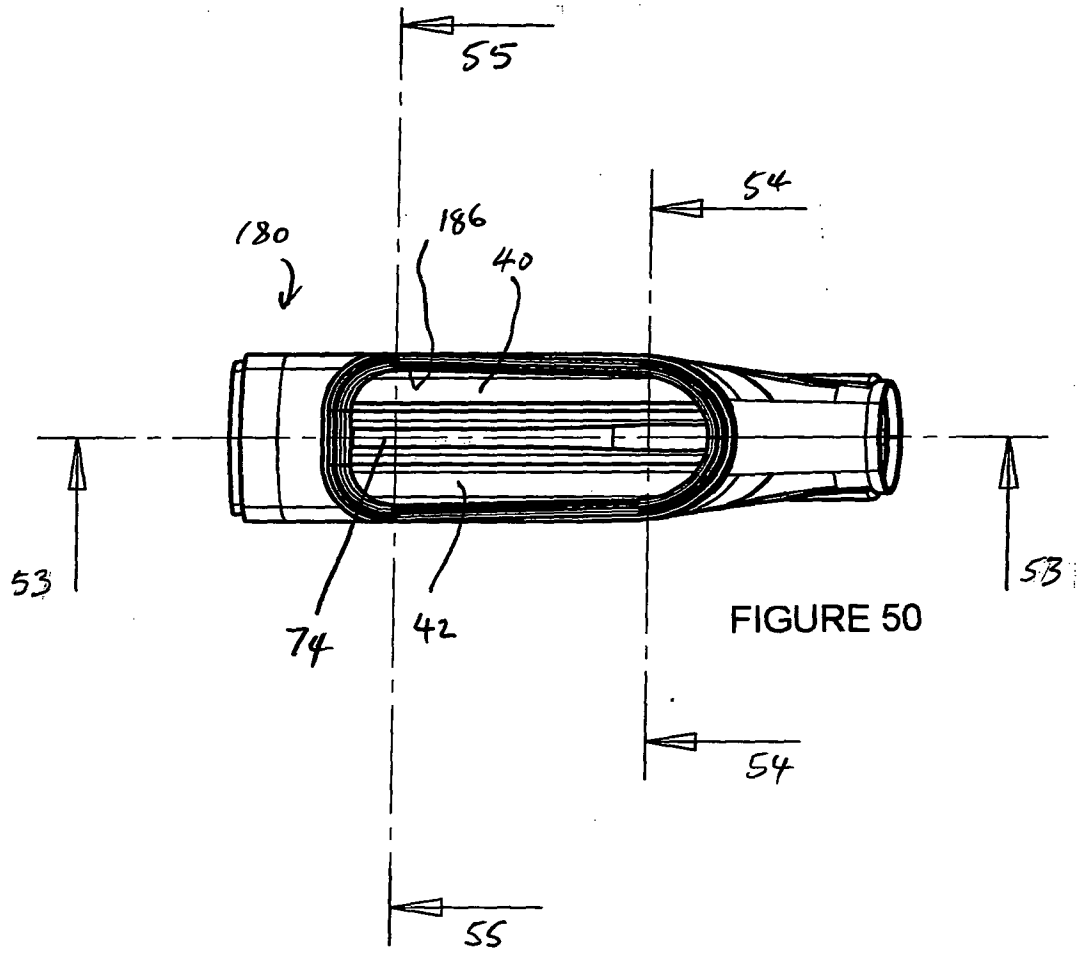

FIGURE 50

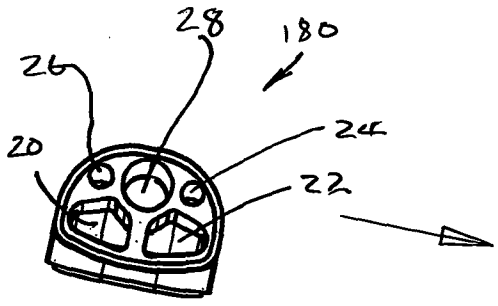

FIGURE 51

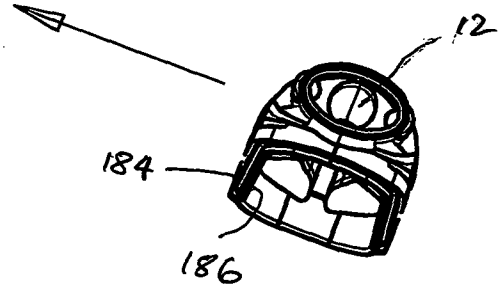

FIGURE 52

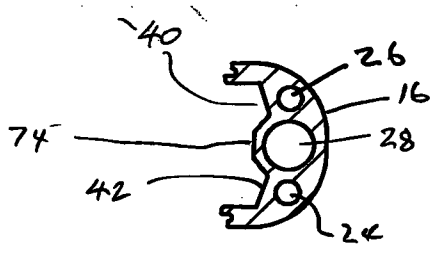

FIGURE 54

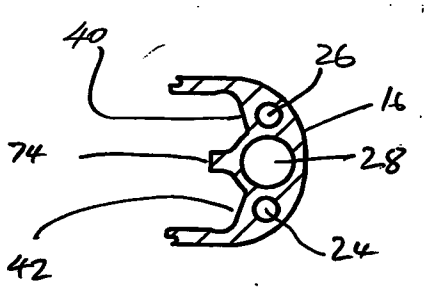

FIGURE 55

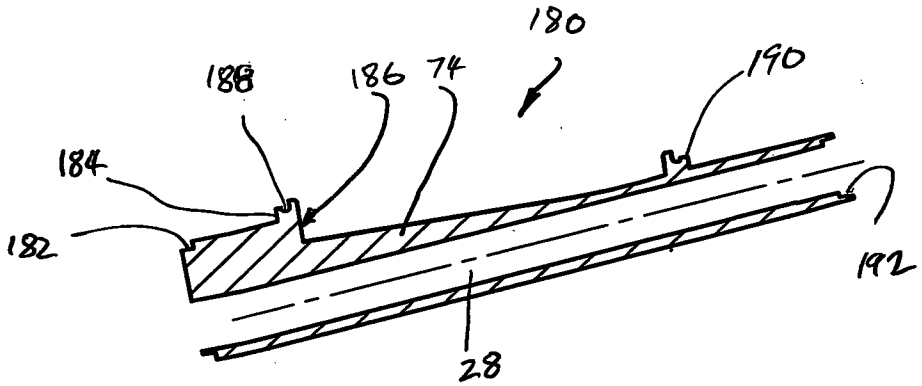

FIGURE 53

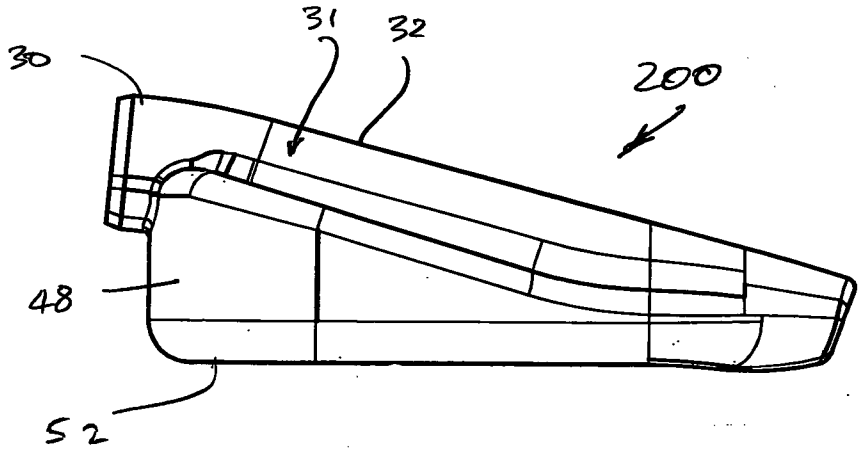

FIGURE 56

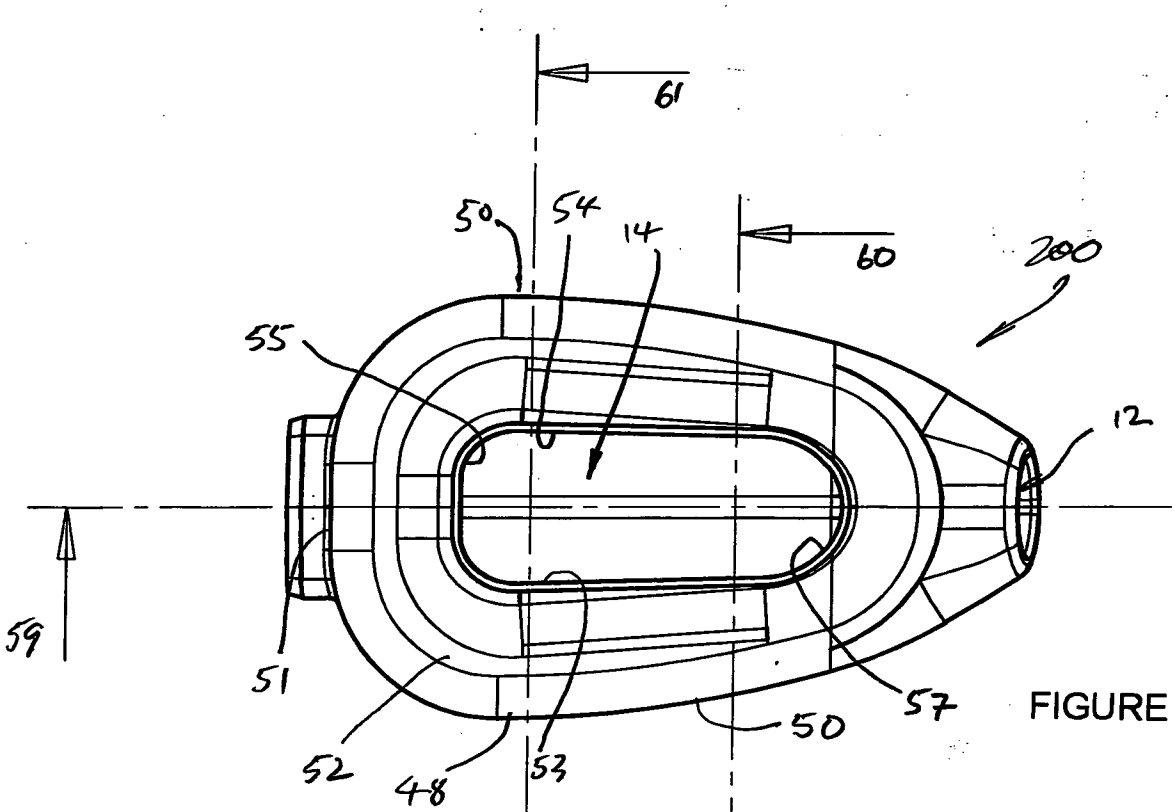

FIGURE 57

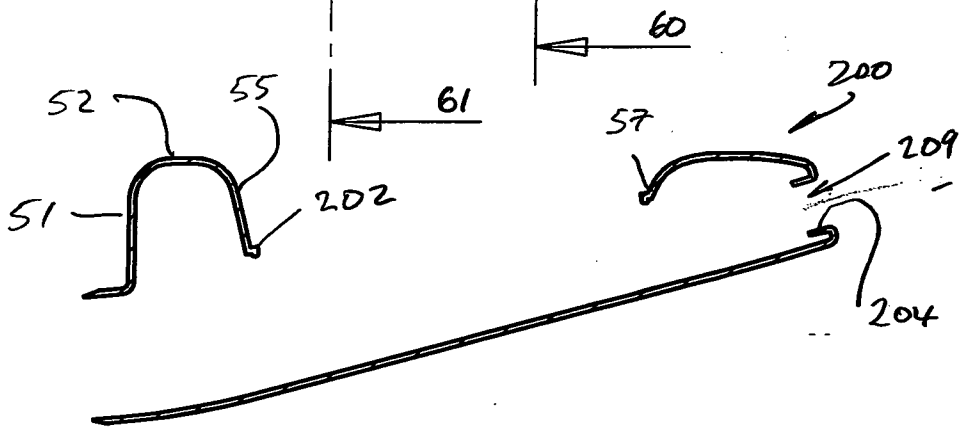

FIGURE 59

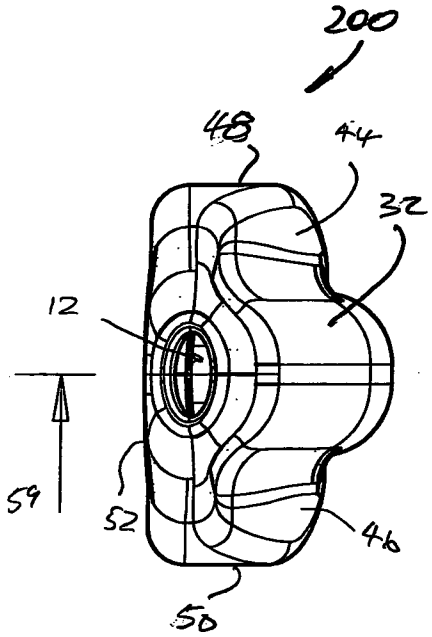

FIGURE 58

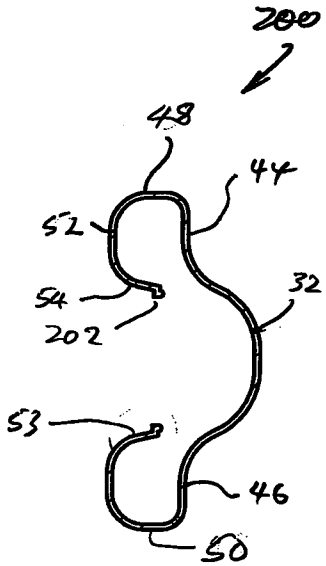

FIGURE 60

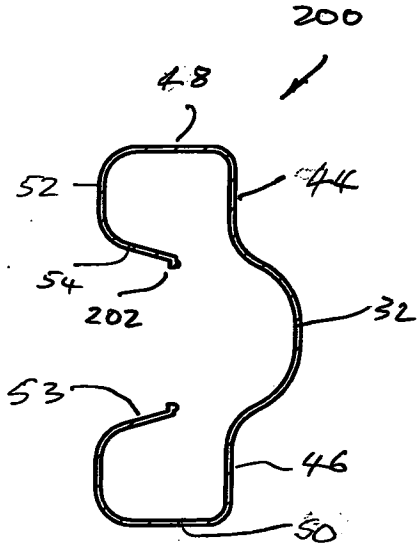

FIGURE 61

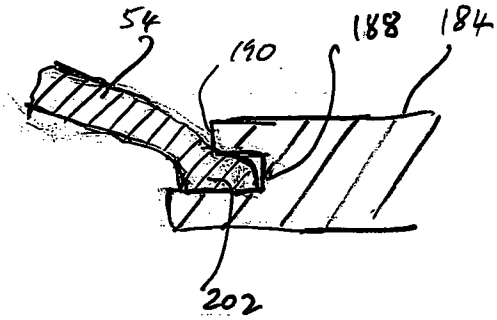

FIGURE 62

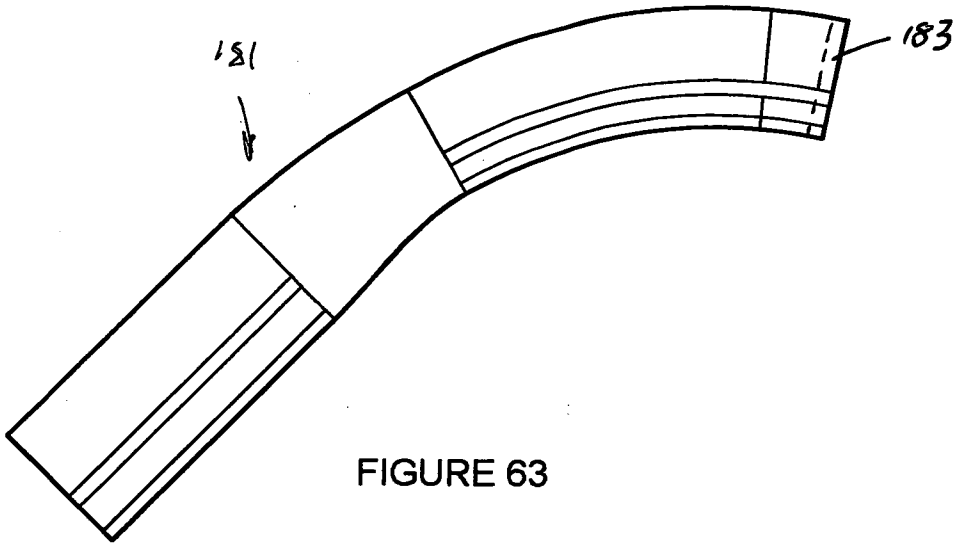

FIGURE 63

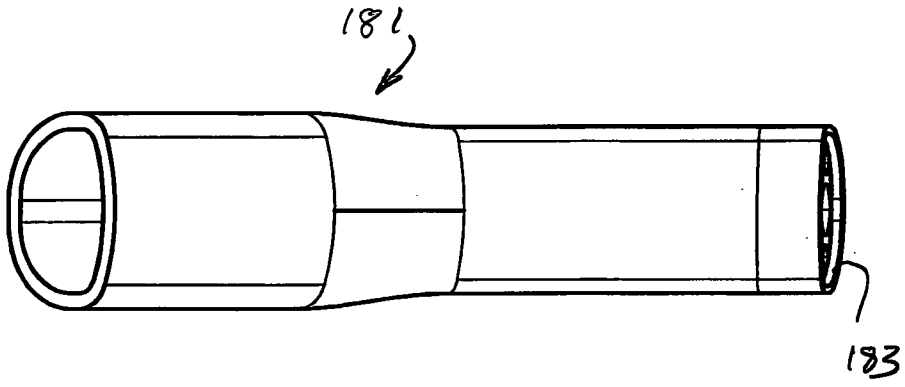

FIGURE 64

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2010/000861

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61M 16/04 (2006.01) ***A62B 9/06*** (2006.01)

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)

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)
EPODOC, WPI: IPC and ECLA A61M 16/-, A62B and keywords: airway, tube, mask, trachea, laryngeal, artificial, anaesthetic, cuff, seal, cushion, pillow, ring, inflation, epiglottic, pharyngeal, laryngeal, suction, vacuum, vent, exhaust, negative pressure; and like terms
PATENT LENS keywords: laryngeal, mask, vent, evacuate, seal
GOOGLE SCHOLAR keywords: laryngeal, mask, vent, evacuate, seal, glottic, negative pressure

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2006/125986 A1 (THE LARYNGEAL MASK COMPANY LIMITED) 30 November 2006 Abstract; page 7, line 1-page 14, line 4; figures 1-24	1-13, 16, 18, 20-22
X	US 5241956 A (BRAIN) 7 September 1993 Abstract; figures 1-9; column 4, line 44-column 10, line 59	1-13, 16, 18-22
X	US 2004/0089307 A1 (BRAIN) 13 May 2004 Abstract; figures 1-12; paragraphs [0034]-[0044], [0078]-[0087]	1-13, 16, 18-22

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 September 2010	29 SEP 2010
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. +61 2 6283 7999	Authorized officer **A. ALI** AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No : +61 2 6283 2607

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2010/000861

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2008/0099026 A1 (CHANG) 1 May 2008 Abstract; figures 1 and 2; paragraphs [0011]-[0049]	14, 15, 17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2010/000861

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See Supplemental Box

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☒ No protest accompanied the payment of additional search fees.

Supplemental Box
(To be used when the space in any of Boxes I to IV is not sufficient)

Continuation of Box No: III

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

This International Searching Authority has found that there are different inventions as follows:

- Claims 1-13, 16, 17 and 18-22 are directed to an artificial airway. These claims are directed to solving the problem of providing a good seal around the glottic opening of the patient which has the advantage that substantially all of the anaesthetic gas supplied through the airway passes to the lungs of the patient and the seal further helps to prevent any regurgitated material entering the lungs of the patient (page 1, lines 10-19). It is considered that "the cuff having inner side walls, anterior walls and a posterior wall, the anterior walls and posterior wall sealingly engaging, in use, about the glottic opening and posterior pharyngeal wall respectively of a patient", comprises a first distinguishing feature.

- Claims 14, 15 and 17-19 are directed to an artificial airway. These claims are directed to solving the problem of removing regurgitated material form the oesophagus of a patient by venting through the evacuation tube so as to minimise the possibility that the regurgitated material from entering the lungs of the patient (page 1, lines 21-25). It is considered that "an evacuation chamber, an evacuation conduit, a ventilation conduit such that, in use, suction is applied to the evacuation conduit whereby regurgitated material entering the evacuation chamber is removed through evacuation conduit and wherein the ventilation conduit substantially prevents a negative pressure being applied to the tissue of the patient", comprises a second distinguishing feature.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

The only feature common to all of the claims is an artificial airway including an airway tube and a cuff mounted on a distal end of the tube. However this concept is not novel in the light of:

D1: WO 2006/125986 A1 (THE LARYNGEAL MASK COMPANY LIMITED) 30 November 2006

This document discloses an airway device 1 including an airway tube 2 and an inflatable cuff 7.

This means that the common feature can not constitute a special technical feature within the meaning of PCT Rule 13.2, second sentence, since it makes no contribution over the prior art.

Because the common feature does not satisfy the requirement for being a special technical feature it follows that it cannot provide the necessary technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention *a posteriori*.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU2010/000861

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
WO	2006/125986	AR	056371	AR	056372	AR	057038
		AR	057039	AU	2006250999	AU	2006251000
		AU	2006251002	AU	2006251003	BR	PI0610053
		BR	PI0610083	BR	PI0610652	BR	PI0610655
		CA	2609468	CA	2609471	CA	2609472
		CA	2609474	CN	101193677	CN	101203261
		CN	101203262	CN	101208125	EP	1885421
		EP	1885422	EP	1885423	EP	1885424
		KR	20080015461	KR	20080031211	KR	20080031212
		KR	20080031213	MX	2007014902	MX	2007014903
		MX	2007014904	MX	2007014905	RU	2007147020
		RU	2007147022	RU	2007147032	RU	2007147034
		US	2008308109	US	2009133701	US	2009145438
		US	2010059061	WO	2006125987	WO	2006125989
		WO	2006125990	ZA	200710522	ZA	200710523
		ZA	200710524	ZA	200710525		
US	5241956	AU	39582/93	AU	45803/93	BR	9306757
		CA	2100998	CA	2107027	CA	2155112
		EP	0651664	MX	9301163	NZ	254213
		US	5305743	US	5355879	US	5391248
		WO	9402191	WO	9417848	ZA	9305289
US	2004/0089307	AU	76743/00	CA	2386208	CN	1378470
		EP	1220701	HK	1047551	IL	148768
		NZ	517995	US	6631720	US	2005066975
		US	7004169	WO	0124860	ZA	200202286
US	2008/0099026	CN	101172180				

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX