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(54) Title: A LARYNGEAL MASK ASSEMBLY

(57) Abstract: The present invention concerns improvements relating to a laryngeal mask comprising an inflatable cuff (1), a mask element (2) and a tubular element (3), wherein the mask element (2) is provided with a reinforcement tongue (7) for receiving and supporting the tubular element (3) and providing an extensive contact for assembly, e.g. by adhesion, between the mask element (2) and the tubular element (3).

A Laryngeal Mask Assembly

The present invention relates to improvements of a laryngeal mask assembly comprising an inflatable cuff, a mask element, a tubular element having a mouth end and a patient end, and where said tubular element is attached to the mask element at said patient end.

An artificial airway device of this kind is described in US 4,509,514. Laryngeal masks are used to facilitate lung ventilation in an unconscious patient, e.g. during anaesthesia, and more specifically the masks are designed in such a way that they may be placed in the oropharynx of the patient in order to prevent airway obstruction.

The masks comprise an airway tube, a mount and an inflatable mask or cuff at one end. The tube is inserted into the patient's mouth so that this cuff is located in the hypopharynx and so that the mask forms a seal in this region with the surrounding tissue. An air inflation tube is provided for inflating or deflating the cuff. This air flow tube is provided along the airway tube, as shown e.g. in US 6,705,318.

Other examples of laryngeal mask assemblies are known from EP 1 219 316, US 5,318,017, EP 1 207 928, EP 1 119 386, US 2003/0192548, EP 0 712 638, WO 00/61213, WO 00/20062, EP 1 207 928 and WO 2004/064908.

Another example of a laryngeal mask is known from WO 2004/089453 where the components of the laryngeal mask are manufactured integrally in a combined injection moulding process.

Various drawbacks have been identified by the known airway devices either in the manufacture or in relation to the use. Consequently, it is an object of the invention to provide improvements in relation to a laryngeal mask assembly and its manufacture.

The invention concerns a laryngeal mask of the initially mentioned kind, wherein the mask element is provided with a reinforcement tongue for receiving and supporting

the tubular element and thereby providing an asymmetric contact surface for assembly between the mask element and the tubular element at the patient end thereof.

Hereby, a good adhesive contact between the mask element and the tubular element is provided. According to the invention, the laryngeal mask assembly and particularly the assembly of the mask and tube can be made firm and endurable also if different kinds of materials are used for the mask and tube elements. Preferably, said asymmetric surface providing support and surface contact for adhesion or the like at the patient end of the tubular element at the side of the tubular element facing towards the inflatable cuff, so that the two parts are permanently joined together by adhesion. To improve the strength of the assembly, the tubular element may be provided with a notch which is adapted to cooperate with a corresponding groove provided in the tongue of the mask element.

In an embodiment, there is provided a reinforcement portion in the tubular element by fitting a tube piece inside the tubular element. Hereby, the risk of blocking the airway passage through the tubular element is prevented.

Moreover, the tubular element may be provided with a connector piece at the mouth end, said connector piece having a machine connector portion a stop flange and an insert portion, which is in engagement with the tubular element.

In a preferred embodiment, there is provided a reinforcement portion in the tubular element by prolonging the protruding part of the connector piece further inside the end of the tubular element. Hereby, the connector piece performs a dual function as the connector piece besides being an adapter for machine connection also prevents the tubular airway passage from collapsing, e.g. if the patient bites around it went inserted. The extension of the insert portion into the tube from the mouth end thereof may be chosen according to the diameter of the tube and the size of the patient. Accordingly, it is found advantageous that said prolonged protruding part, which constitutes the insert portion of the connector piece, may be provided with ratio

between its length and outer diameter between 3 and 5, preferably between 4 and 5 and most preferably approx. 4.5.

The insert portion of the connector piece may advantageously be designed with reinforced side portions. More preferably, the insert portion may be provided with an external substantially oval cross-section or similar external shape, such as side portions protruding out of the generally circular shape and preferably the insert portion is provided with an internal substantially cylindrical cross-section. Hereby, a reinforcement of the mouth end of the laryngeal mask so that the connector piece may be regarded as also being a biting block.

In an embodiment of the invention, the inflatable cuff is connected to air supply means comprising an air inflation line and a pilot balloon which is connectable to an air supply source. In particular, there is preferably provided a recess either in the tongue of the mask element or elsewhere in the mask element for accommodating the inflation line of the air supply means for inflating the cuff. In an embodiment thereof, the recess is provided internally. More specifically, it may be found advantageous that the recess is provided in the groove for receiving the assembly notch of the tubular element such that the inflation line may be fitted therein as the groove is provided with a depth at least equal to the height of the corresponding notch and the diameter of the inflation line. This embodiment of providing the inflation line in the mask element may be advantageous since the risk of damaging the inflation line and its connection to the cuff is reduced when the inflation line is accommodated in mask element.

In an embodiment of the invention, there is provided a reinforced cuff tip by providing a strip of material on the cuff material prior to the blow moulding manufacture process of the cuff. According to another embodiment of the invention, the cuff is provided with a first thickness on a first side and a second thickness on a second side, where said first thickness is larger than the second thickness and that said first side is the side of the cuff facing against the mask element. By a laryngeal mask assembly according to any of these embodiments of the invention, if insertion should be considered in need of being facilitated, e.g. if there is a concern that the

frontal portion of the laryngeal mask, i.e. the frontal portion of the mask portion and the cuff, would flip backwards with the risk of blocking the air passage way in which the mask is being inserted. This is due to design with the thicker, harder or otherwise more stiff upper side of the cuff and/or the "inner mounting" of the mask portion in the intermediate cuff balloon.

In an embodiment of the invention, the laryngeal mask assembly of any of the above-mentioned kinds is produced by providing a tubular member in a moulding apparatus; blow moulding a balloon from the tubular member in the moulding apparatus; slitting the blow moulded balloon and inverting the balloon by turning said balloon inside out and then punching the central aperture of the cuff and substantially simultaneously welding the inner perimeter of the cuff, whereby the resulting inflatable cuff is an essentially seamless cuff having a smooth exterior surface is provided.

Preferably, in relation to the laryngeal mask assembly comprising an airway tube, a mask portion, an inflatable cuff, and a connector piece, at least said airway tube, mask portion and inflatable cuff are permanently assembled. However, it is furthermore found advantageous to have the connector piece permanently mounted in the tubular element.

In the following, the invention is described in detail with reference to the drawings, in which:

Fig. 1 is a principle side view of a laryngeal mask according to a first embodiment of the invention;

figures 2 to 5 show different side views according to embodiments of a connector piece of a laryngeal mask according to the invention;

figures 6 to 8 show front views according to embodiments of a connector piece of a laryngeal mask according to the invention;

fig. 9 is a side view of a laryngeal mask according to another embodiment of the invention;

figures 10 to 12 show cross-section views of fig. 9;

fig. 13 is a principle side view of the cuff manufacturing tool prior to the start of the process;

fig. 14 is a principle top view of the intermediate balloon product in the cuff manufacturing;

fig. 15 shows the same in a side view;

fig. 16 is a principle side view of a further cuff manufacturing step;

fig. 17 is a principle side view of a cuff according to an embodiment of the invention;

fig. 18 is a top view of the cuff shown in fig. 17;

fig. 19 is a principle side view of an assembly with the intermediate cuff balloon with a mask portion mounted therein according to a second embodiment of the invention;

fig. 20 is the finished cuff according to this second embodiment;

fig. 21 is an explanatory illustration of the cuff manufacturing step succeeding the assembly of fig. 19;

fig. 22 is a schematic side view of a laryngeal mask according to a further embodiment of the invention;

fig. 23 is a bottom view of the laryngeal mask of fig. 22;

fig. 24 is a perspective view of a mask portion of the laryngeal mask of figures 22 and 23;

fig. 25 is a side view of a laryngeal mask according to a preferred embodiment of the invention; and

figures 26 and 27 are perspective views of a mask element according to a preferred embodiment.

With reference to the figure 1, the laryngeal mask includes a tubular element 3, a mask element 2, where said two elements are joined together by glue or the like. A cuff 1 is fixed to the mask element 2. The cuff 1 is inflatable so that it blocks the relevant areas in the throat. An air inflation tube 5 connects the cuff 1 to a pilot balloon 6 which may be supplied with air from an external air supply source (not shown) via a non-return valve 9 in the pilot balloon 6, whereby the cuff 1 is inflated and the air pressure in the cuff 1 can be constantly monitored by watching the pilot balloon 6.

The pilot balloon 6 has a volume which is at least three times smaller than the volume of the cuff 1. Hereby, it is possible to control the inflation of the cuff 1 accurately by monitoring the pilot balloon 6.

In the distal end of the tubular element 3, a connector piece 4 is inserted into the end of the tubular element 3.

The tubular element 3 is preferably provided with a bend 8 on approx. 90° which facilitates the use of the laryngeal mask. The mask element 2 is adapted to receiving the tubular element 3. On the inside of the bend 8 of the tubular element 3, the mask element 2 is provided with a supporting reinforcement tongue 7. This tongue 7 supports the tubular element 3 in the bend region and reinforces the laryngeal mask in the area of the bend 8 and prevents the tubular element 3 of the laryngeal mask from kinking, i.e. collapsing during insertion. The tongue 7 is provided with a shape corresponding to the outer contour of the tubular element 3. The inside of this reinforcement tongue 7 of the mask element 2 ensures a large area of contact between the tubular element 3 and the mask element 2, which provide a large adhesive contact ensuring a firm adhesive assembly between the tubular element 3 and the mask element 2.

On the inside of the bend 8, a recess may be provided in which an air inflation tube 5 may be provided connecting the inflatable cuff 1 with an air supply source. Alternatively, this air inflation tube 5 could be provided in a recess inside the tube 3. In yet another embodiment, the air inflation tube is connected directly to a flow channel provided in the mask element 2 where this flow channel is in flow communication with the cuff 1.

As shown in figure 9, tubular reinforcement 31 may be provided on the tubular element 3. This reinforcement may constitute a so-called biting bloc, which is preferably provided by extruding a tubular piece which is fitted inside the tube 3.

As an alternative or in supplement to the tubular piece 31, the biting bloc may be provided by the connector piece 4, which is provided with a protruding portion 43, which protrudes into the mouth end of the tubular element 3 and is circumscribed by the tube 3. This protrusion 43 is preferably between one to five times the diameter of the tube, more preferably between three and five times the diameter of tube.

The tubular element is provided a bend of 70° - 110°, preferably approx. 90°, above the mask element.

The total wall thickness of the tubular element is preferably 2.2-3.0 mm with the reinforcement tube and 1.2-2.0 mm without reinforcement.

The tubular element is provided with a wall thickness of 2.3-2.8 mm and in particular with a wall thickness in a central portion of 2.7-3.2 mm.

With reference to figures 2 to 8, the connector piece 4 is provided at the distal end – i.e. mouth end - of the laryngeal mask. The connector piece 4 is made of a material having a Shore A hardness of 90 plus or minus 20. The tube element 3 and the mask portion 2 are preferably made with a Shore A hardness of 65. This means that the distal end of the tubular element 3 is resilient compared to the insert protrusion of the connector piece 4 and that the distal end may be deformed as the connector piece 4 is inserted.

The Shore hardness is measured with an apparatus known as a Durometer and consequently is also known as 'Durometer hardness'. The hardness value is determined by the penetration of the Durometer indenter foot into the sample. Because of the resilience of rubbers and plastics, the indentation reading change over time so the indentation time is sometimes reported along with the hardness number. The ASTM test method designation is ASTM D2240 00 and is generally used in North America. Related methods include ISO 7619 and ISO 868; DIN 53505; and JIS K 6301, which was discontinued and superseded by JIS K 6253.

Laryngeal mask are provided in different sizes according to the size of the patients. Accordingly, the diameter of the tube element 3 is different and consequently the connector piece 4 must also be adapted to the sizes. In the figures 2 to 4, three examples of connector pieces 4 adapted for different tube element diameters are shown.

The connector piece 4 includes an external connector portion 41, a stop flange 42 and an insertion portion 43. A bore 44 is provided through the entire connector piece 4. In a first embodiment of the invention, the bore 44 is provided with a circular cross-section with or without different diameters in the connector portion 41, the flange portion 42 and the insertion portion 43 depending on the size of laryngeal mask. However, it is realised that other cross-section shapes could be provided, e.g. an elliptical shape and/or internal recesses in the bore 44 for accommodating the air inflation tube or the like.

The connector portion 41 is cylindrical having a circular cross-section. The dimensions of the connector portion 41 are the same for all sizes of the laryngeal masks so that it is connectable to standard ventilation equipment, such as a respiratory apparatus or an anaesthetic system, when the laryngeal mask is placed in a patient irrespective of the size of the laryngeal mask and the patient. The insertion portion 43 is dimensioned according to the size of the tube element 3. The insertion portion 43 is preferably provided with a length *L*, which is one to five times the internal diameter of the tube element 3, in some embodiments preferably one to three times and in other embodiments between three and four times.

The insertion portion 43 may be provided with a circular cross-section as shown in fig. 6. However, in another embodiment shown in fig. 7 the cross-section is oval or elliptical thereby utilising that the distal end of the tubular element 3 is more resilient than the insert protrusion of the connector piece 4 whereby the distal end may be deformed as the connector piece 4 is inserted. This is advantageous as the side portions 43a of the insertion portion 43 are reinforced and thereby the tube is prevented from being collapsed by a patient's bite on the mouth end of the laryngeal mask. In fig. 8, yet another embodiment of the insertion portion cross-section is

shown with side portions 43a reinforcing the tube and thereby prevents kinking or otherwise collapse of the tube at the mouth end of the laryngeal mask.

The parts of the laryngeal mask, i.e. the tubular element 3, the mask element 2, the inflatable cuff 1 and the connector piece 4 may be produced by extrusion, injection moulding, blow moulding or any combination thereof. The materials used for the four parts are selected in accordance with the desired characteristics of the individual parts.

As an alternative to the mask portion design of figure 1, it is realised that the tubular element 3 and the mask element 2 may be integrally formed as a tubular airway mask element by injection moulding.

The cuff 1 is fixed to the mask element 2. The cuff 1 is inflatable so that it blocks the relevant areas in the throat. The cuff 1 is manufactured by blow moulding, as an extruded tubular piece is heated and blown into a balloon inside a cavity in a blow moulding form. The balloon is cut off from the tubular piece and removed for further processing. This further processing includes providing a slit in the middle portion of the balloon and thereby deflating the balloon and subsequently turning the balloon inside out so that inner side becomes the outer side. The advantage by this process is that the assembly between the upper and lower mould parts now faced inside and the burrs or flashes along this assembly line also face inside and cannot irritate the tissue in the patient's throat. After this, the "reversed" balloon is formed into an annular cuff by stamping out and welding together a central aperture generally corresponding to the footprint of the mask element to which the cuff is to be fixed.

The cuff 1 is preferably with different dimensions. As shown in the top and side views of the cuff 1 the cuff is provided with a wall thickness of 0.2 to 0.6 mm. In a preferred embodiment, the cuff 1 may be provided with a larger thickness of the upper side than the underside of the cuff.

Moreover, the cuff 1 could be provided with a reinforcement strip 7 in the front end of the cuff 1 where the thickness of the inflatable cuff wall is approx. 0.8 to 0.9 mm.

This reinforcement can be provided during the manufacture of the cuff 1 by extruding or otherwise providing a strip parallel to the extruded tubular piece and which may be bonded together with tube tubular piece in the heated extrusion form. The temperature is approx. 170° C and by the subsequent blow moulding process, the strip and the cuff balloon will melt together for providing the reinforced portion of the cuff 1. By providing the reinforcement on the resulting blow-moulded balloon, no sharp edges will occur, as the balloon is reversed.

As explained above and with reference to the figures 13 to 21, the cuff 1 is manufactured by blow moulding, where an extruded tubular web 100, for instance made by two strips of material of different thickness, is heated and blown into a balloon 105 inside a cavity 103 in a blow moulding form 101, 102. A strip of material 104 may be provided for reinforcement of the cuff tip. The balloon 105 is subsequently cut off from the tubular piece 100 and removed for further processing.

This further processing includes providing a slit 110 in the middle portion of the balloon 105 and thereby deflating the balloon 105 and subsequently turning the balloon 105 inside out so that inner side becomes the outer side, i.e. into an inverted balloon 105' where any welding fins 107 are located on the inside resulting in a smooth outer surface of the resulting cuff. The advantage by this is that as the burrs or flashes along this assembly line face inside this cannot irritate the tissue in the patient's throat.

After this step of slitting and inverting the balloon 105, the inverted balloon 105' is formed into an annular cuff. In a first embodiment, this is done by stamping out and welding together a central aperture generally corresponding to the footprint of the mask element to which the cuff is to be fixed.

In a second embodiment (see fig. 21), a receiving aperture 113 is provided in the upper side of the balloon 105' for receiving the mask portion 2. The mask portion 2 is provided with mounting surfaces 21 and 22 forming an annular mounting surface around the opening 113 and which makes contact with the annular region 111 and 112 of the inverted balloon 105'. The mask portion 2 is glued to the balloon 105' and

is thereby fixed to the inside of the inflatable cuff 1. After this assembly, the cuff is formed by pressing the lower portion of the inverted balloon 105' towards the mask portion as indicated by the arrow P and stamping or otherwise cutting the material and welding the rim edge flange to the mask portion rim flange whereby the inflatable cuff 1 is formed. By this way of assembling the mask portion, a large adhesive contact surface is provided, which in turn results in a firm fixation of the cuff to the mask portion ensuring that the cuff does not disengage during use which would have fatal consequences for the patient. Moreover, by this cuff assembly design the cuff cannot disengage from the mask portion of the laryngeal mask, since even if the adhesive contact fall to function, the cuff will hang from the mask portion since the mask portion is mounted from within.

With reference to figures 22, 23 and 24, a further embodiment of a laryngeal mask according to an aspect of the invention is shown. The laryngeal mask includes a tubular element 3, a mask element 2, where said two elements are joined together by glue or the like. The cuff (not shown in fig. 22) is to be fixed to the mask element 2. A connector piece 4 is provided in the distal end of the tubular element 3 opposite the end 73 of the tubular element 3 where the tubular element 3 is assembled to the mask element 2.

The mask element 2 is adapted to receiving the tubular element 3. On the inside of the bend 8 of the tubular element 3, the mask element 2 is provided with a supporting reinforcement tongue 7 as shown in fig. 1. This tongue 7 supports the tubular element 3 in the bend region and reinforces the laryngeal mask in the area of the bend 8 and prevents the tubular element 3 of the laryngeal mask from kinking, i.e. collapsing during insertion. The tongue 7 is provided with a shape corresponding to the outer contour of the tubular element 3. The inside of this reinforcement tongue 7 is provided with an axially oriented groove 72 (see fig. 24) which corresponds to an axially oriented notch 71 (see figures 22 and 23) provided on the tubular element 3 to facilitate a correct fit between the mask element 2 and the tubular element 3 when said elements are assembled. This ensures a correct assembly of the two elements.

In figure 25, there is shown another embodiment of a laryngeal mask according to the invention. A mask element 2 is joined with an inflatable cuff 1 and a tubular member 3. The cuff 1 is connected to an inflation line 5, which is accommodated in a recess or the like in the mask element 2 – either internally or externally. The inflation line 5 is terminated in a pilot balloon 6, which can be inflated together with the cuff when the break off connector 61 is removed. The mask element 2 is shown in more detail in figures 26 and 27. The mask element 2 is essentially a tubular member with an opening 74 where the inflatable cuff 1 is mounted to the rim flange 77 surrounding the opening 74. At the opposite end of the mask element 2, a tubular element receiving portion 75 is provided. This tube receiving portion 75 includes a tongue 7 with a groove 72 provided therein which may be designed to cooperate with the notch 71 on the patient end 73 of the tubular element 3. The groove 72 may - alternatively or as a supplement - be design to accommodate the inflation line 5 in the mask element 2. The mask element 2 is provided with a back plate portion 76 forming the rim flange 77 at the distal end and extending into the tube receiving portion 75 at the other end. The back plate portion 76 forms a bowl-like shape behind the inflatable cuff 1 with an angle α between the plane of the cuff and the plane of the back plate portion 76 of preferably 21.75° ± 5°.

In the embodiment shown in fig. 25, the tubular element 3 is provided with a bend 8 of substantially 90° ± 20° and the mask element 2 may preferably be produced in a relatively soft material where the tongue 7 may be produced pointing in an axial direction, whereby the tongue 7 is being formed by the curvature of the bending portion 8 of the tubular element 3 thereby ensuring a good surface contact between the tongue 7 and the inner curvature 8 of the tube 3 due to the resiliency of the material the mask element 2 an in particular the tongue 7 is made from.

The tubular element 3 may be produced by extruding the tube and providing the tube 3 with the desired shape, such as a bend in the patient end of the tube or a curvature extending over a longer section or even the entire tube 3. In an embodiment of the invention, the tube 3 or at least its distal mouth end 73 may after its extrusion be placed in an injection moulding form, wherein the mask element 2 is

moulded around the tubular element 3 so that a permanent assembly between the tube 3 and the mask 2 is provided.

At the opposite end, the mouth end, of the tube 3, the adapter for machine connection is provided as a biting block connector 4. The connector 4 comprises an insert portion 43, an external connector portion 41 extending out of the end of the tubular element 3, and a stop flange 42 delimiting the length of entry of the insertion portion 43 into the tubular element 3 as well as a stop for the machine connection on the connector portion 41. The biting block connector 4 is made of a relative hard material, so that the tubular element 3 is reinforced at the mouth section. The inserted portion 43 extends a relative long way into the tube 3 so that any flattening, e.g. "kinking" or other deformations that could cause a restriction or even blockage of the tube are prevented. Accordingly, it is realised that the machine connector piece 4 could advantageously be provided as a biting block connector, i.e. with a dual function so that the connector also constitutes a reinforcement or biting block whereby the patient by biting around the tubular element when the laryngeal mask according to the invention is inserted cannot restrict or block the airway passage through the laryngeal mask.

Above and in the claims, the term attachment is sometimes used in describing features of the invention and their interrelation. By the term attached is meant any joining or fixing of the relevant elements.

The invention is described with reference to some preferred embodiments of the invention as described above. However, it is realised that other variations may be provided without departing from the scope of the invention.

Patent Claims:

1. A laryngeal mask assembly comprising
an inflatable cuff,
a mask element,
a tubular element having a mouth end and a patient end, and where said tubular element is attached to the mask element at said patient end,
characterised in that
the inflatable cuff is produced with a seamless cuff exterior surface whereby an essentially smooth exterior surface is provided.

2. A laryngeal mask assembly according to claim 1, wherein the mask element is provided with a reinforcement tongue for receiving and supporting the tubular element and thereby providing an asymmetric contact surface for assembly between the mask element and the tubular element at the patient end thereof.

3. A laryngeal mask assembly according to claim 1 or 2, wherein said asymmetric surface providing support and surface contact for adhesion or the like at the patient end of the tubular element at the side of the tubular element facing towards the inflatable cuff.

4. A laryngeal mask assembly according to any of claims 1 to 3, wherein the tubular element is provided with a notch which is adapted to cooperate with a corresponding groove provided in the tongue of the mask element.

5. A laryngeal mask assembly according to any of claims 1 to 4, wherein there is provided a reinforcement portion in the tubular element by fitting a tube piece inside the tubular element.

6. A laryngeal mask assembly according to any of claims 1 to 5, wherein the tubular element is provided with a connector piece at the mouth end, said connector piece having a machine connector portion a stop flange and an insert portion, which is in engagement with the tubular element.

7. A laryngeal mask assembly according to claim 6, wherein there is provided a reinforcement portion in the tubular element by prolonging the protruding part of the connector piece further inside the end of the tubular element.

8. A laryngeal mask assembly according to claim 6 or 7, wherein said prolonged protruding part being the insert portion of the connector piece and is provided with ratio between its length and outer diameter between 3-5, preferably between 4-5 and most preferably approx. 4.5.

9. A laryngeal mask assembly according to any of claims 6 to 8, wherein the insert portion is provided with reinforced side portions.

10. A laryngeal mask assembly according to claim 9, wherein the insert portion is provided with an external substantially oval cross-section.

11. A laryngeal mask assembly according to claim 9 or 10, wherein the insert portion is an internal substantially cylindrical cross-section.

12. A laryngeal mask assembly according to any of the preceding claims, wherein the inflatable cuff is connected to air supply means comprising an air inflation line and a pilot balloon which is connectable to an air supply source.

13. A laryngeal mask assembly according to claim 12, wherein there is provided a recess in the tube wall of tubular element for accommodating the inflation line of the air supply means for inflating the cuff, said recess being provided either internally or externally.

14. A laryngeal mask assembly according to claim 12, wherein there is provided a recess in the tongue of the mask element for accommodating the inflation line of the air supply means for inflating the cuff.

15. A laryngeal mask assembly according to claim 14, wherein the recess is provided internally.

16. A laryngeal mask assembly according to claim 14 or 15, wherein the recess is provided in the groove for receiving the assembly notch of the tubular element such that the inflation line may be fitted therein as the groove is provided with a depth at least equal to the height of the corresponding notch and the diameter of the inflation line.

17. A laryngeal mask assembly according to any of the preceding claims, wherein there is provided a reinforced cuff tip by providing a strip of material on the cuff material prior to the blow moulding manufacture process of the cuff.

18. A laryngeal mask assembly according to any of the preceding claims, wherein the cuff is provided with a first thickness on a first side and a second thickness on a second side, where said first thickness is larger than the second thickness and that said first side is the side of the cuff facing against the mask element.

19. A laryngeal mask assembly according to any of the preceding claims, wherein the inflatable cuff is blow moulded from a tubular member, whereby a seamless cuff having a smooth exterior surface is provided.

20. A laryngeal mask assembly according to any of the preceding claims, wherein the tubular element is provided a bend of 70° - 110°, preferably approx. 90°, above the mask element.

21. A laryngeal mask assembly according to any of the preceding claims, wherein the total wall thickness of the tubular element is preferably 2.2-3.0 mm with the reinforcement tube and 1.2-2.0 mm without reinforcement.

22. A laryngeal mask assembly according to claim 21, wherein the tubular element is provided with a wall thickness of 2.3-2.8 mm and in particular with a wall thickness in a central portion of 2.7-3.2 mm.

23. A laryngeal mask assembly comprising an inflatable cuff, a mask element, a tubular element, wherein the inflatable cuff is produced by providing a tubular member in a moulding apparatus; blow moulding a balloon from the tubular member in the moulding apparatus; slitting the blow moulded balloon and inverting the balloon by turning said balloon inside out and then punching the central aperture of the cuff and substantially simultaneously welding the inner perimeter of the cuff, whereby the resulting inflatable cuff is an essentially seamless cuff having a smooth exterior surface is provided.

24. A laryngeal mask assembly comprising
an airway tube,
a mask portion,
an inflatable cuff, and
a connector piece, wherein at least said airway tube, mask portion and inflatable cuff are permanently assembled.

25. A laryngeal mask assembly comprising
an airway tube,
a mask portion,
an inflatable cuff,
a connector piece,
wherein the mask element is provided with a reinforcement tongue for receiving and supporting the tubular element and providing a good adhesive contact between the mask element and the tubular element.

26. A laryngeal mask assembly comprising
an airway tube,
a mask portion,
an inflatable cuff, and
a connector piece, wherein the connector piece is a biting block connector piece.

27. A method of manufacture of the cuff for a laryngeal mask assembly according to any of the preceding claims, said method including one or more of the following steps:

providing a tubular member in a moulding apparatus;

blow moulding a balloon from the tubular member in the moulding apparatus;

slitting the blow moulded balloon and inverting the balloon by turning said balloon inside out;

punching the central aperture of the cuff and substantially simultaneously welding the inner perimeter of the cuff.

28. A method according to claim 27, whereby the tubular member is an extruded tubular member of a flexible thin sheet-like material, such as low density polyethylene (LDPE), PVC or any other biologically inert material.

29. A method according to claim 27 or 28, including the step of providing e.g. by extruding, a reinforcement strip of material in parallel with the tubular member and joining said strip to the outside of the tubular member.

30. A method according to any of claims 27 to 29, where the tubular member is provided with a first thickness on a first side and a second thickness on a second side, where said first thickness is larger than the second thickness and that said first side becomes the upper side of the manufactured cuff.

31. A method according to any of claims 27 to 30, wherein a hole is provided in the slit inverted balloon and that the mask portion is adhesively attached to the cuff by positioning the mask portion in said hole.

32. A method of manufacturing a laryngeal mask assembly comprising an inflatable cuff, a mask element, a tubular element, said method comprising the steps of:

extruding a tubular element in a first extrudable material, whereby a tubular element having a first end and a second end,

placing at least the first end of the extruded tubular element in an injection moulding device, and then

moulding the mask element in a second extrudable material around at least said first end of the tubular element thereby providing a joined a mask and tubular element,

producing an inflatable cuff according to any of the claims 27 to 31, and

assembling the mask and tubular element and the inflatable cuff.

33. A method according to claim 32, whereby the extruded tubular element is provided with a bend during the extrusion process.

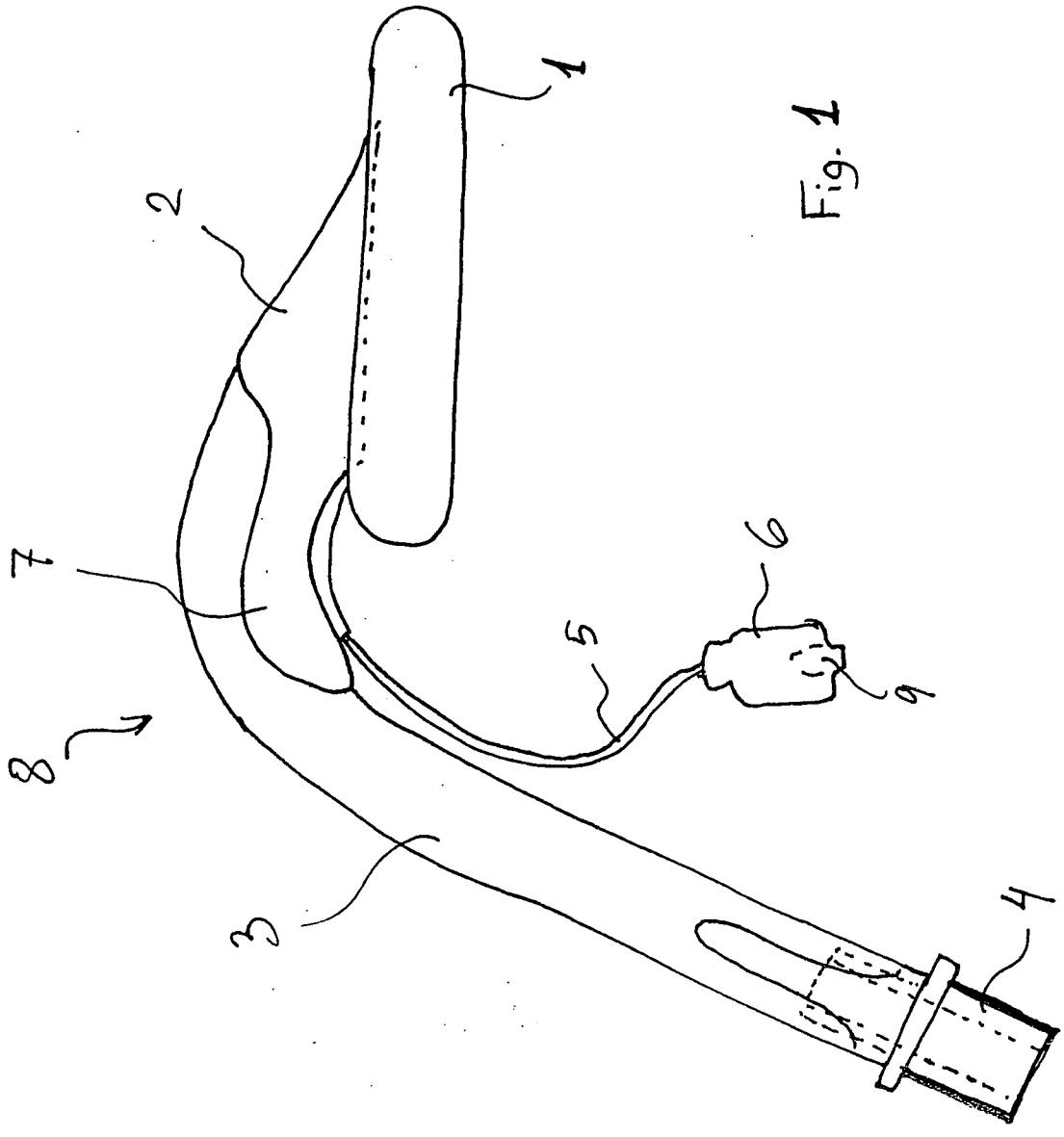


Fig. 1

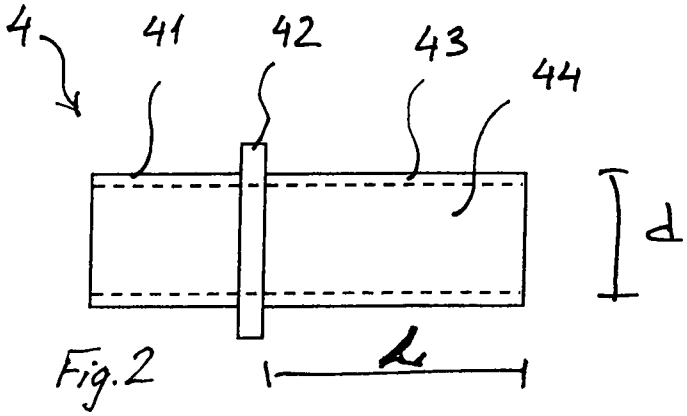


Fig. 2

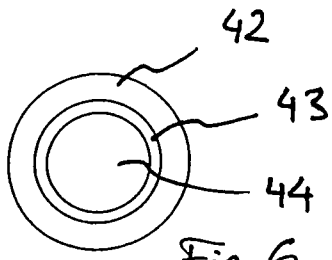


Fig. 6

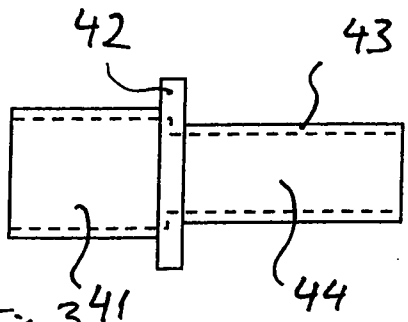


Fig. 3

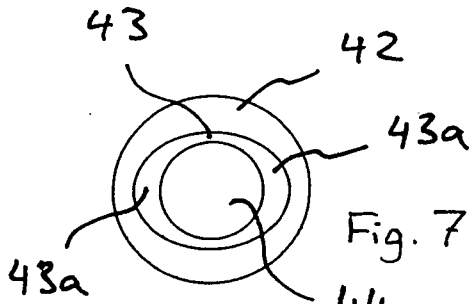


Fig. 7

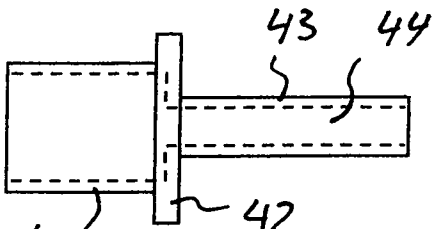


Fig. 4

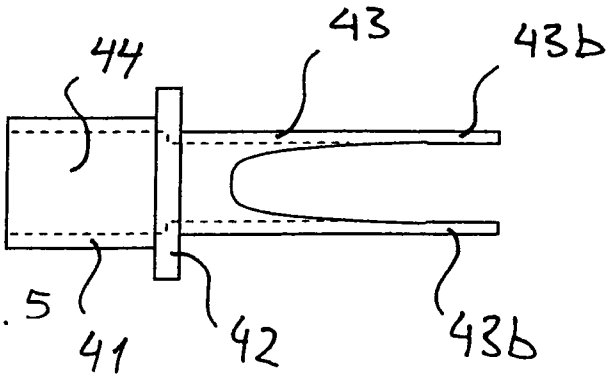


Fig. 5

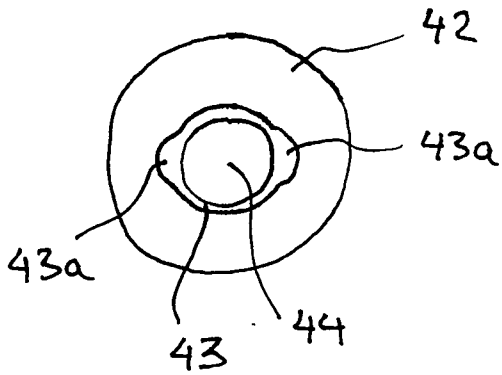


Fig. 8

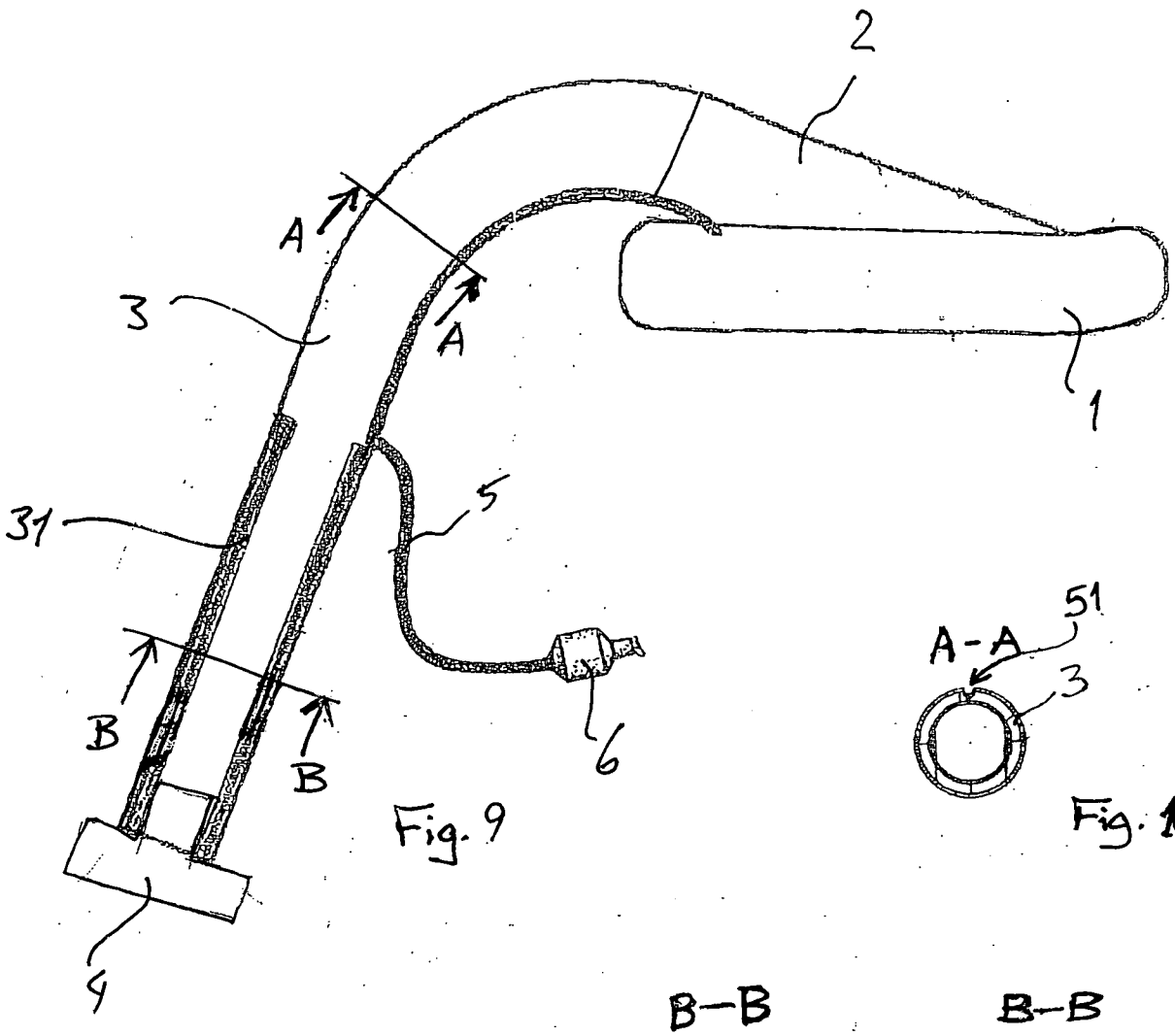
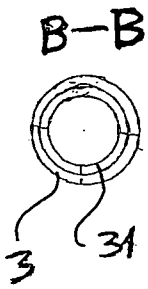


Fig. 9

Fig. 10



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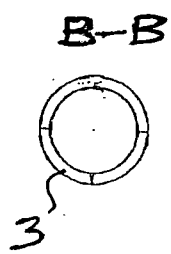

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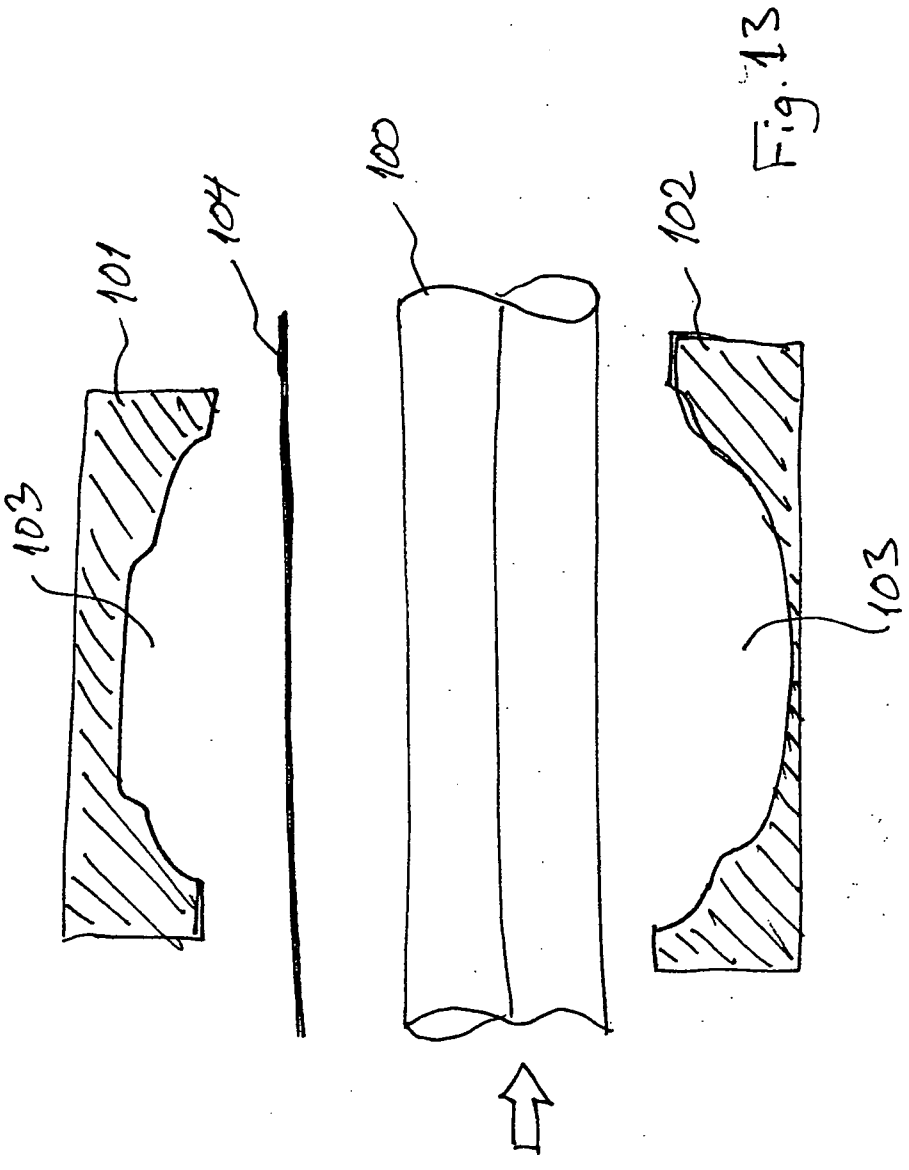


Fig. 13

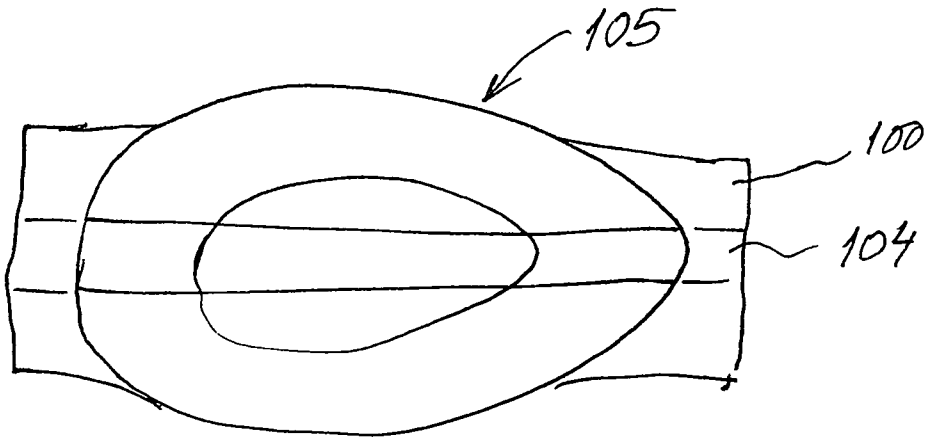


Fig. 14

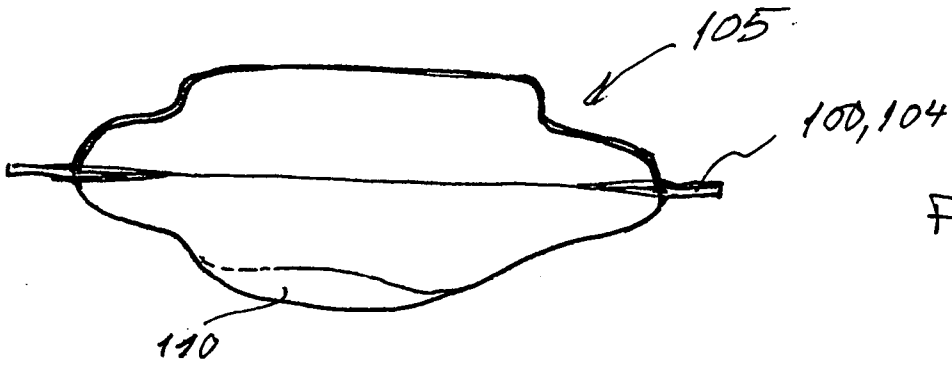


Fig. 15

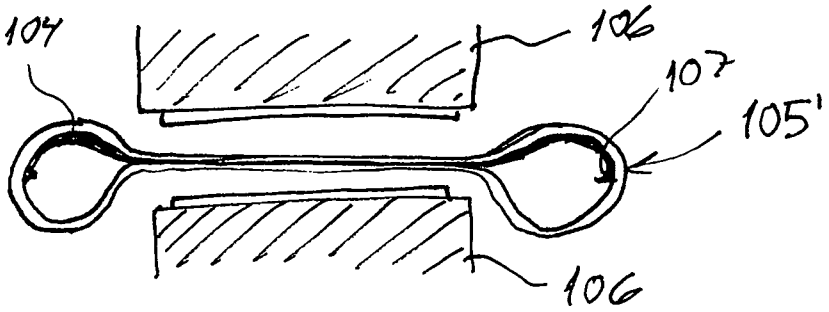


Fig. 16

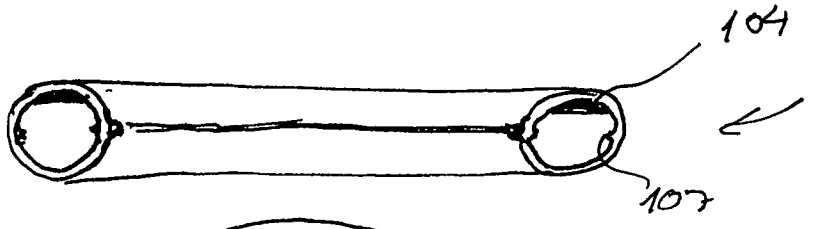


Fig. 17

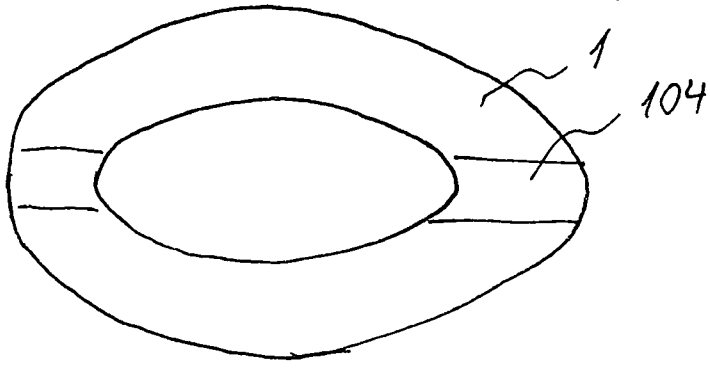


Fig. 18

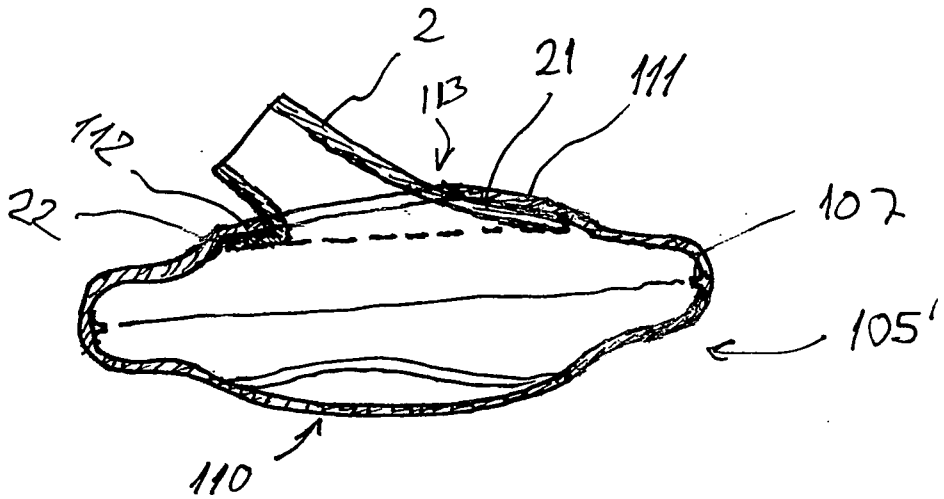


Fig. 19

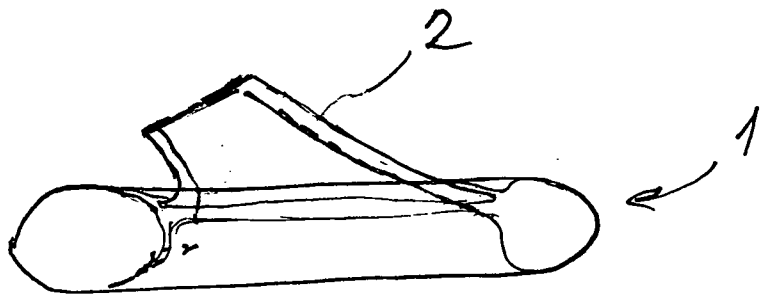


Fig. 20

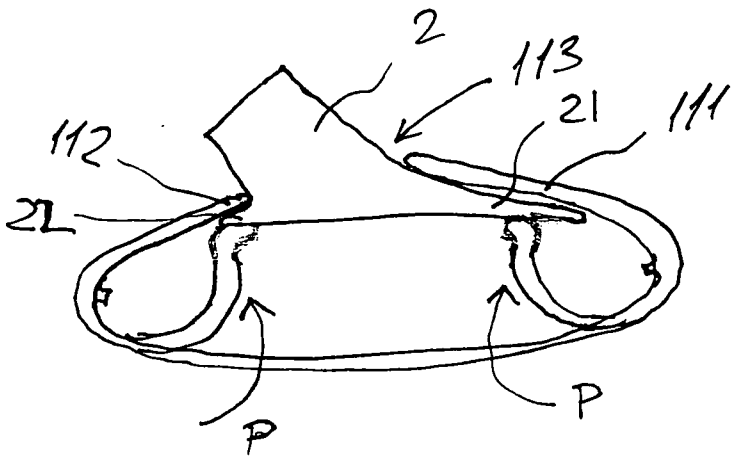


Fig. 21

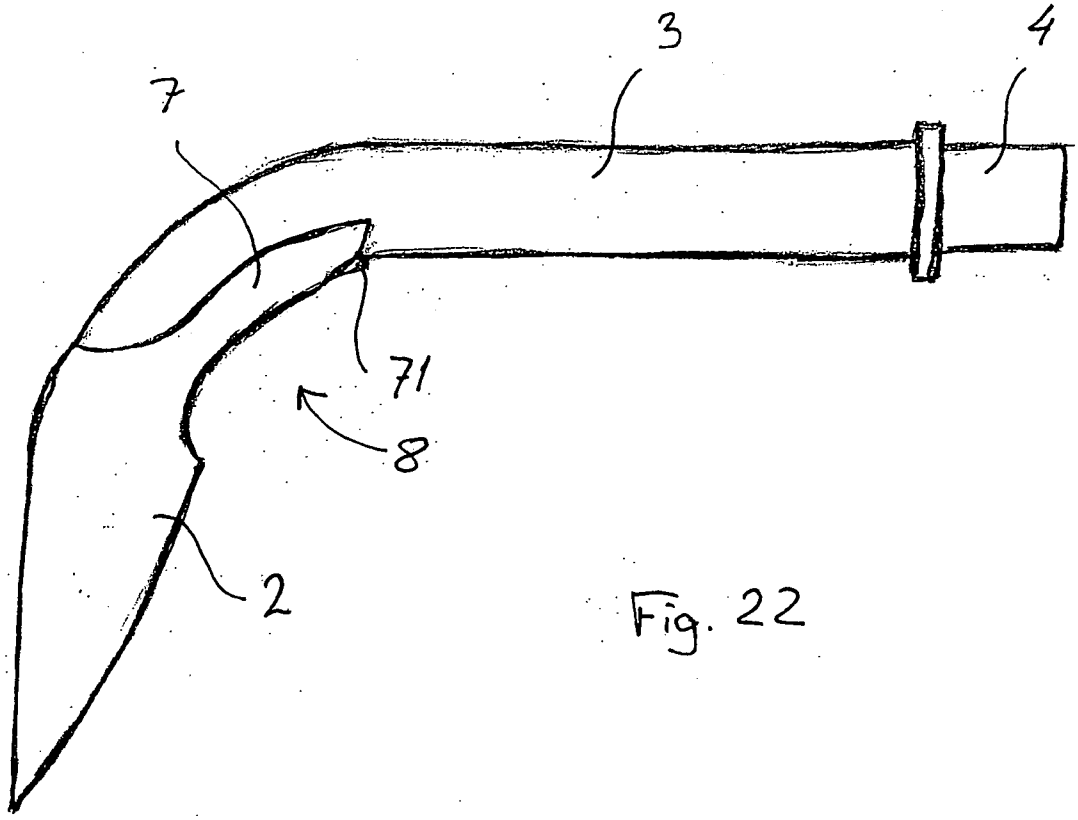
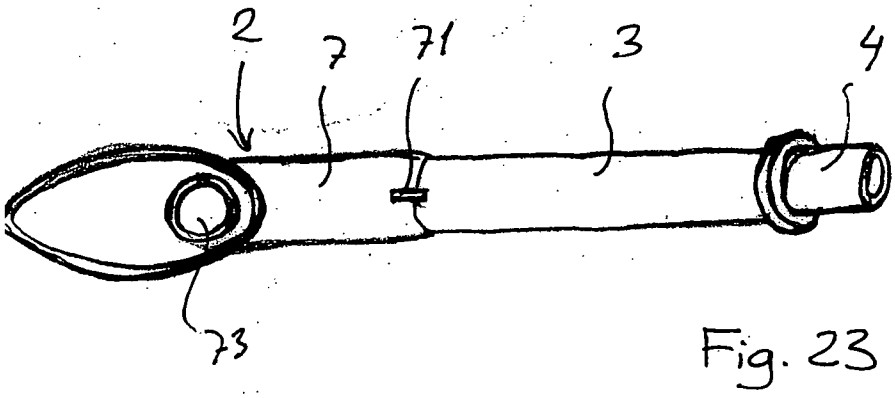


Fig. 22



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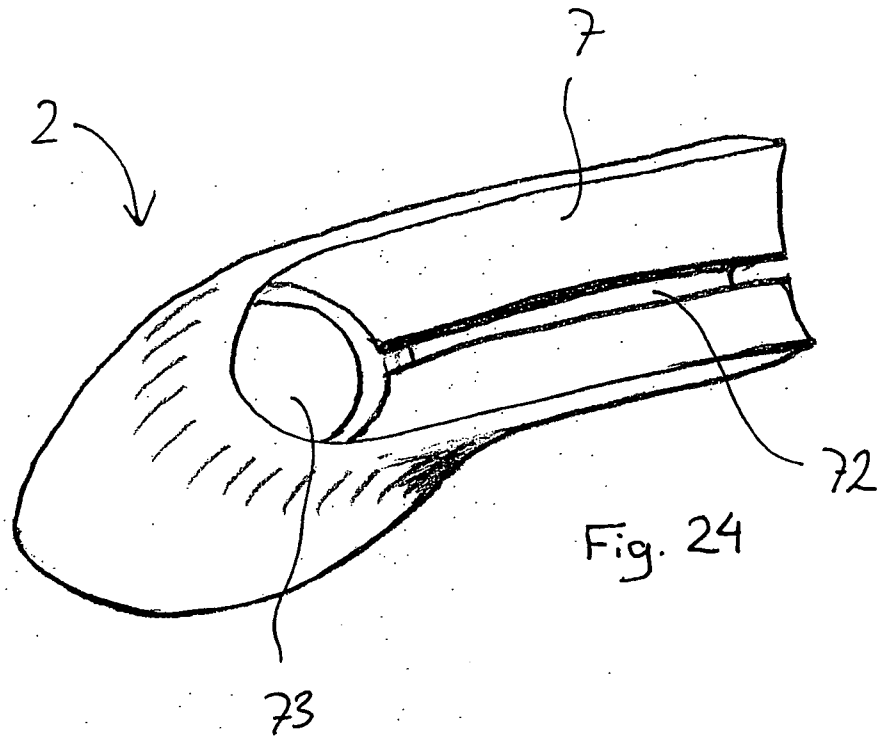

Fig. 24

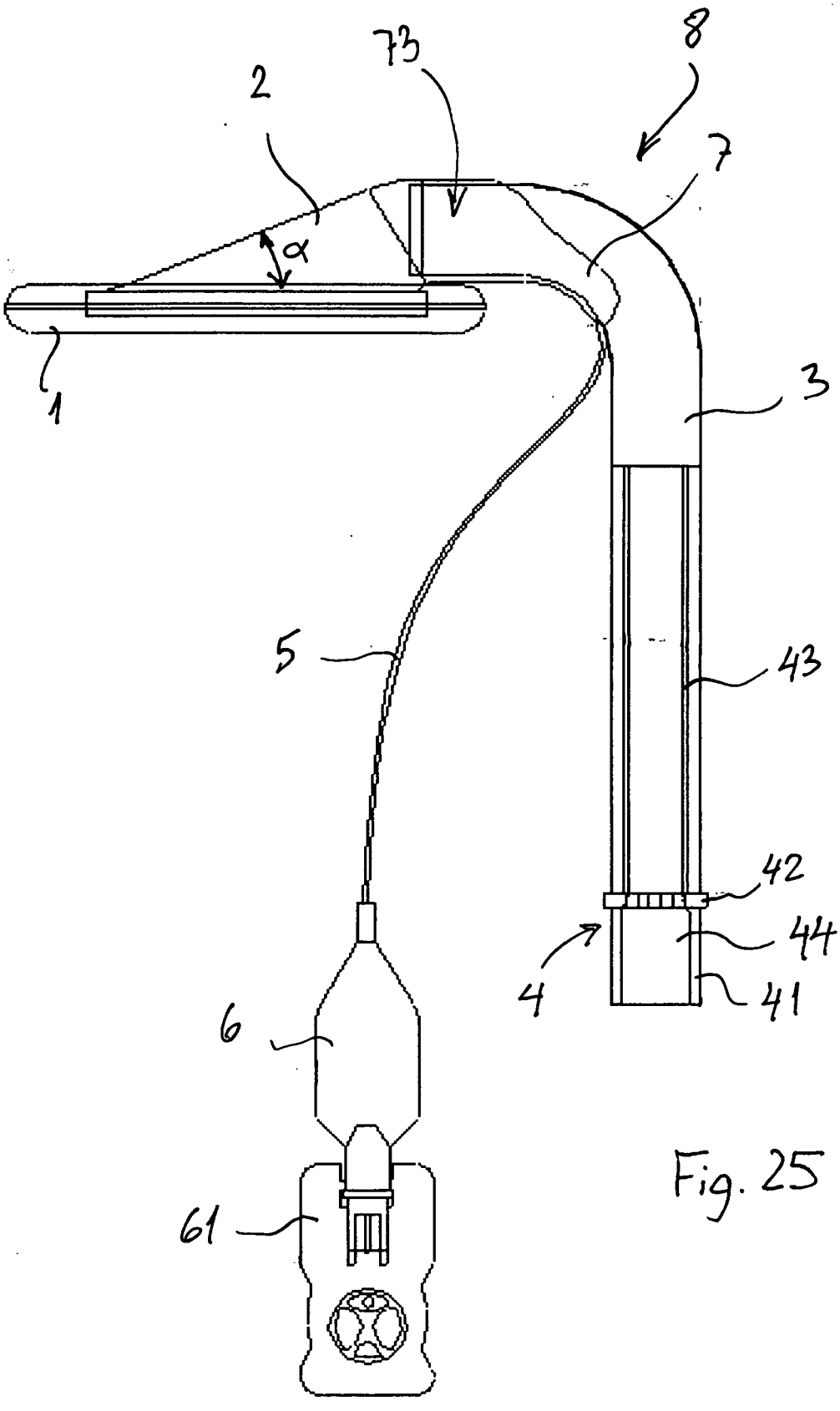

Fig. 25

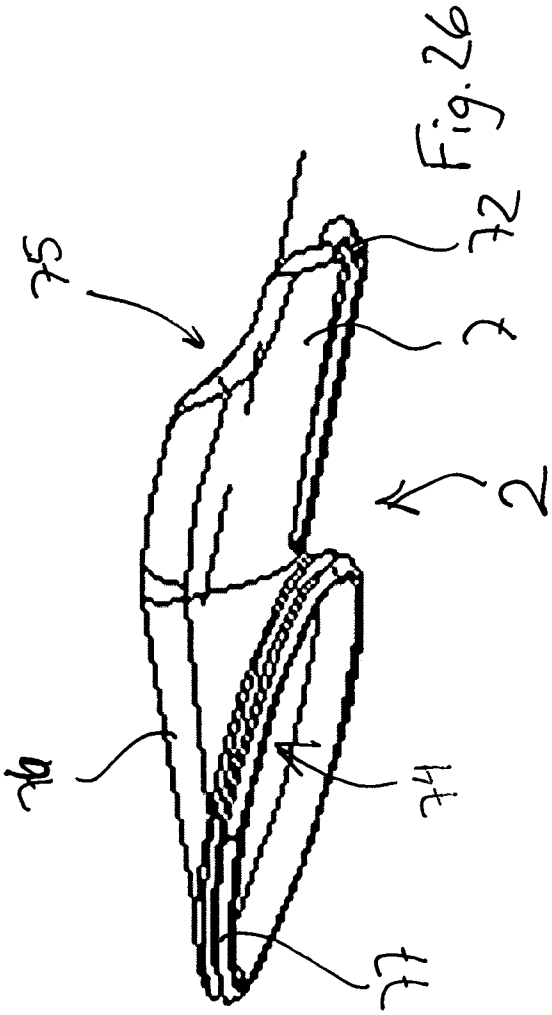

Fig. 26

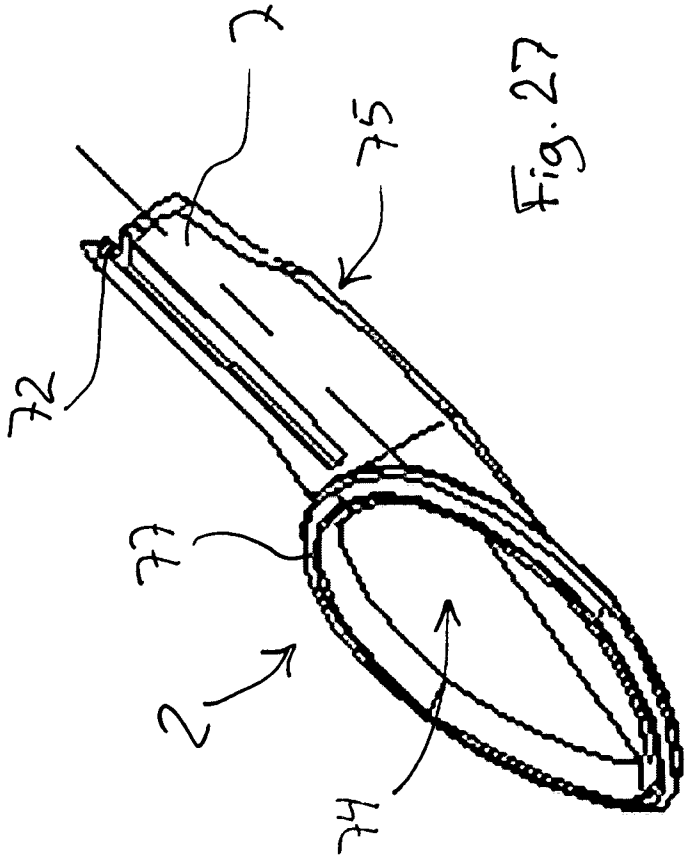

Fig. 27