



- (51) International Patent Classification:
A61M 16/04 (2006.01)
- (21) International Application Number:
PCT/IB2012/051365
- (22) International Filing Date:
22 March 2012 (22.03.2012)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
1104865.9 23 March 2011 (23.03.2011) GB
- (72) Inventor; and
- (71) Applicant : MILLER, Donald Munro [ZA/ZA]; 12 Monawee 316 Main Road Kenilworth, 7708 Cape Town (ZA).
- (74) Agent: TRUTER, Kenneth Colin; Brian Bacon & Associates Inc., 2nd Floor Mariendahl House, Newlands-on-Main Main Road Newlands, 7700 Cape Town (ZA).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ,

CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

- Published:**
- with international search report (Art. 21(3))
 - before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

(54) Title: ORAL SURGERY LARYNGEAL MASK DEVICE

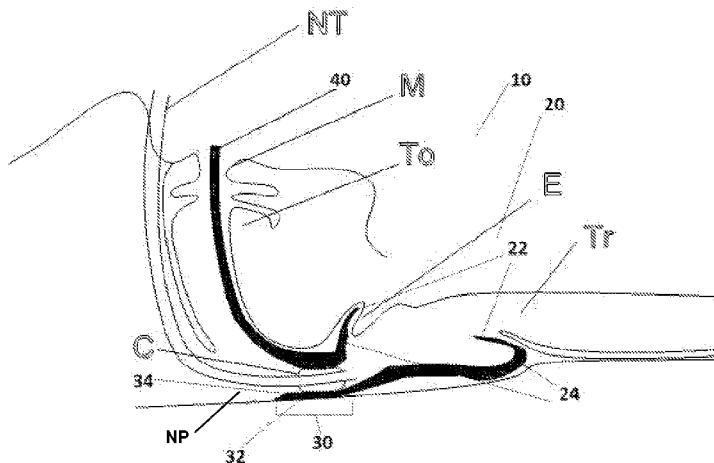


Figure 8

(57) Abstract: An airway device (10) includes a proximal peri-laryngeal sealing mask (20) with a sealing mechanism (22) and a proximal opening (26) for communicating with the lungs, a distal vestibule (30) with a vacant distal opening (36) and being long enough for housing a cuffed inflatable tube and short enough for the distal opening (36) to the vestibule to be aligned with the nasopharynx, and distal extraction means (40) that is long enough to extend out of the mouth. The vestibule (30) can receive a tracheal tube that can be blind placed via the nose. The airway device (10) is placed in position by means of a cuffed tracheal tube (NT) inserted into the vestibule (30) and/or with a laryngoscope.



ORAL SURGERY LARYNGEAL MASK DEVICE

FIELD OF THE INVENTION

5 The present invention relates to respiratory apparatus in the form of an artificial airway device for placement into the oro-pharynx of an unconscious patient.

10 BACKGROUND TO THE INVENTION

In order to support respiration and therefore life, an unconscious patient may require some or all of the following objectives, namely: the maintenance of airway patency, attachment to respiratory apparatus, either spontaneous or controlled positive pressure ventilation, and prevention of inhalation into the
15 lungs of extraneous matter such as vomitus, mucus or blood.

The words “proximal” (near the patient) and “distal” (further from the patient) as used herein, provide references with respect to the patient body cavities.

20 During anaesthesia or resuscitation, airway management may be achieved by means of an endotracheal tube with an inflatable cuff around the proximal end of the tube, which is placed with the help of other instruments within the trachea. The disadvantage is the need for accurate placement that requires specially trained skills and it is more invasive requiring the placement of a
25 tube into a relatively sterile area and may also require a laryngoscope for placement. Its placement often requires the administration of muscle paralyzing drugs. Placement of tracheal tubes may cause damage to the vocal cords and permanent voice changes is a risk that can be avoided if a supraglottic airway can be used instead. Inflatable cuffs in tracheal tubes
30 themselves can cause pressure damage where the recurrent laryngeal nerve lies in close proximity to the trachea.

Many of these problems could be overcome by using a type of laryngeal mask airway (LMA™). This may involve the use of an inflatable cuff surrounding a

bowl shaped end of a tube for sealing the entrance to the larynx. It is less invasive than endotracheal tubes described above and it does not require muscle relaxation.

5 When oral surgery is to be performed, medical devices in the oral cavity should be kept to a minimum and the use of conventional supraglottic airways and/or reinforced LMA laryngeal masks is not ideal. By contrast, the use of tracheal tubes placed via the nose is a particularly desirable technique from the surgeon's point of view because it provides good free surgical access via
10 the mouth. However, the problems related to the use of tracheal tubes makes the compromise of using a flexible armoured tube laryngeal mask a worthwhile alternative even though it does partially interfere with the surgery. There are no supraglottic airway devices that allow for administration of anaesthesia and the control of the airway via a nasal tube.

15

There are many designs of laryngeal mask and their descriptions involve describing key components such as the actual sealing masks and how they may be manufactured. In doing so, these descriptions of the sealing components mention the part where the tube is to be attached. This part is
20 designed for accommodating a tube to be firmly attached to the device. It is not designed to be detachable, which would constitute a potential weakness or fault. These laryngeal masks with fixed tubes are clearly not suitable for nasal intubation.

25 The primary objective of the present invention is to allow for the administration of anaesthesia and the control of the airway via a nasal tube, that preferably obviates the need for tracheal intubation.

30 BRIEF DESCRIPTION OF THE INVENTION

According to the present invention there is provided an airway device comprising a proximal part and a distal part with a distal extraction means; said proximal part comprising a perilaryngeal sealing mask with a sealing mechanism comprising a balloon inflated cuffed sealing mechanism, a soft

solid cushion sealing mechanism or a hollow self-energizing sealing chamber, for sealing within and against the mucosal walls of the pharynx of a patient, and the proximal part defining a proximal opening on the ventral aspect of the proximal part, for communicating with the patient's lungs; and said distal part
5 defining a distal chamber or vestibule with a vacant distal opening approximately perpendicular to the proximal ventral opening, and the vestibule having longitudinal dimension sufficient for housing a cuffed inflatable tube such as a cuffed tracheal tube and short enough in projection from the dorsal aspect of the sealing mechanism for the distal opening to the
10 vestibule to be located opposite to, i.e. be generally aligned with the patient's nasopharynx when the device is correctly placed in the patient's hypopharynx and with a distal extraction means that is long enough to extend out of the mouth.

15 In order that the vestibule may receive a tracheal tube passed via the patient's nose, it is preferable that the cross-sectional shape of the vestibule is approximately oval shaped with long axis in the lateral dimension. It may be preferable if said oval shape is modified to be flattened in the dorsal aspect so that it lies flat against or flush with the patient's posterior pharyngeal wall to
20 receive with ease the blind placement of a tracheal tube that is passed through the patient's nose.

It may also be preferable if the edge of the vestibule is shaped with an outward taper so that the flat edge lies flush against the patient's posterior
25 pharyngeal mucosa.

The extracting means may comprise a strip of material extending preferably from the ventral aspect of the edge of the distal entrance to the vestibule.

30 The device may be placed in position by means of a cuffed tracheal tube inserted into the vestibule, with the cuff inflated. The device may then be firmly attached to the tracheal tube which is used to direct the mask into the correct position in the patient's pharynx. Alternatively a laryngoscope may be inserted into the vestibule and used to insert the device into the patient's

hypo-pharynx. Both the tracheal tube and a laryngoscope may be used for placement, with the cuffed tracheal tube located behind the laryngoscope blade.

5

BRIEF DESCRIPTION OF THE DRAWINGS:

For a better understanding of the present invention and to show how it may be carried into effect, the invention will now be described by way of non-limiting example with reference to the accompanying drawings, in which:

10

Figure 1 shows a diagonal dorsal view of a first embodiment of an airway device according to the present invention;

Figure 2 shows a longitudinal section through the device of Figure 1;

Figure 3 shows a three dimensional view of the device of Figure 1;

15 Figure 4 shows a three dimensional view of the device of Figure 1, approximately from the vestibule entrance;

Figure 5 shows the possible use of the device of Figure 1 with a laryngoscope;

20 Figure 6 shows a longitudinal section through the device of Figure 1 that is essentially the same as Fig.2, but with the device in a shape when in position;

Figure 7 shows a longitudinal section through a second embodiment of an airway device according to the present invention, which is generally similar to that shown in Figure 1, with the addition on an inflatable cuff;
25 and

Figure 8 shows a longitudinal section of the device of Figure 1, in situ, with a nasotracheal tube, which has a cuff that is inflated in a vestibule of the airway device.

30

KEY TO ANATOMICAL REFERENCES IN FIGURE 8

| | |
|----|---------------------|
| E | Epiglottis |
| M | Mouth |
| NT | Naso-tracheal tube. |

NP Naso-pharynx
To Tongue
Tr Trachea
C Cuff of tracheal tube inflated in vestibule

5

DETAILED DESCRIPTION OF THE DRAWINGS

Referring to the drawings, a supraglottic embodiment of an airway device in accordance with the present invention is generally indicated by reference numeral 10.

10

As can be seen in Figure 1, the airway device 10 comprises a proximal part 20 and a distal part 30 with a distal extraction means 40.

15 The proximal part 20 comprises a perilaryngeal sealing mask with a sealing mechanism for sealing within and against the mucosal walls of the pharynx of a patient. The sealing mechanism can be a balloon inflated cuffed sealing mechanism 22 (as shown in the second embodiment of the invention in Figure 7), a soft solid cushion sealing mechanism in place of the balloon 22 or a
20 hollow self-energizing sealing chamber 24 (as shown in the first embodiment of the invention in Figures 1 to 6, and 8). The proximal part defines a proximal opening 26 on its anterior or ventral aspect, for communicating with the patient's lungs.

25 The distal part defines a distal, approximately cylindrically shaped chamber or vestibule 30 with side walls 32 and a vacant distal opening 36. The inner cavity of the vestibule 30 is open to the inside of the proximal part 20 and the distal entrance or opening 36 is approximately perpendicular to the proximal ventral opening 26. The vestibule 30 has longitudinal dimension sufficient for
30 housing a cuffed inflatable tube (as shown in Figure 8), such as a cuffed tracheal tube NT (when placed through the nose) and is short enough in projection from the dorsal aspect of the sealing mask for the distal entrance 36 to the vestibule to be located opposite to the naso-pharynx NP (as shown in Figure 8). When the distal entrance 36 is in this position, the naso-tracheal

tube emerges to enter the vestibule 30 via the entrance 36 when the device 10 is correctly placed in the hypo-pharynx.

5 The distal extraction means 40 is a deformable, elongate formation that is attached to the vestibule 30, adjacent the entrance 36 on the anterior or ventral side and that is long enough to extend out of the mouth M of a patient, when the device 10 is correctly placed in the hypo-pharynx as described above.

10 In order that the vestibule 30 with sidewalls 32 may receive a tracheal tube passed via the nose, it is preferable that the cross-sectional shape of the vestibule is approximately oval shaped with long axis in the lateral dimension and with a distal wall edge 34 that is tapered so that it lies flush against the posterior pharyngeal wall.

15 It may be preferable if the oval shape of the vestibule 30 were modified to be flattened in the dorsal aspect 38 of the vestibule as shown in Figure 4, so that it lies flat against the posterior pharyngeal wall to receive with ease the blind placement of a tracheal tube NT that is passed through the nose.

20 The device 10 can be placed in position through the mouth M by means of a cuffed tracheal tube NT inserted into the vestibule. Before placing the device 10, the cuff C is inflated inside the vestibule 30, so that the device is firmly attached to the tracheal tube NT. The tracheal tube NT is used to direct the device 10 through the mouth M into the correct position in the pharynx.

25 Alternatively a laryngoscope (including a handle LH and a blade LB) may be inserted into the vestibule 30 and used to insert the device 10 into the hypo-pharynx as shown in Figure 5). Both the tracheal tube NT and a laryngoscope LH.LB may be used for placement of the device 10, with the cuffed tracheal tube located behind the laryngoscope blade LB.

30

After the device 10 has been correctly positioned in the hypo-pharynx, with the extraction means 40 protruding from the mouth M, the tracheal tube NT may be removed from the mouth M and then passed via the nose, through the

naso-pharynx NP and inserted into the vestibule 30, where the cuff C is re-inflated, thereby securing the attachment within the vestibule, as shown in Figure 8. The use of a cuffed tracheal tube NT is preferred, because inflating the cuff C ensures a firm attachment within the vestibule 30.

5

Unlike existing laryngeal masks that are configured to receive tubes firmly (not removably), the device 10 is a supraglottic airway that is specifically designed to have a part (vestibule 30) of the sealing laryngeal mask airway opening that is designed to accommodate a tube NT that is passed blindly via the nose and

10 to allow for the tube to be automatically directed into a passage or vestibule/chamber where the proximal end of that tube can be sealed.

CLAIMS:

1. An airway device (10) comprising a proximal part (20) and a distal part (30) with a distal extraction means (40);
5 said proximal part (20) comprising a peri-laryngeal sealing mask with a sealing mechanism (22) for sealing within and against the mucosal walls of the pharynx of a patient, and said proximal part (30) defining a proximal opening (26) on a ventral aspect of the proximal part, for communicating with said patient's lungs; and
10 said distal part (30) defining a distal vestibule with a vacant distal opening (36) approximately perpendicular to the proximal opening (26), and said vestibule having longitudinal dimension sufficient for housing a cuffed inflatable tube and short enough in projection from a dorsal aspect of the sealing mechanism (22) for the distal opening (36) to the vestibule to be generally aligned with said patient's nasopharynx, when the device (10) is correctly placed in the patient's hypo-pharynx.
15
2. An airway device (10) as claimed in claim 1, **characterised in that** said sealing mechanism is a balloon (22) inflated cuffed sealing mechanism.
20
3. An airway device (10) as claimed in claim 1, **characterised in that** said sealing mechanism is a soft solid cushion sealing mechanism.
- 25 4. An airway device (10) as claimed in claim 1, **characterised in that** said sealing mechanism is a hollow self-energizing sealing chamber (24).
5. An airway device (10) as claimed in any one of the preceding claims, **characterised in that** said distal extraction means (40) is long enough
30 to extend out of the mouth.
6. An airway device (10) as in any one of the preceding claims, **characterised in that** said vestibule (30) is configured to receive a tracheal tube passed via the patient's nose.

7. An airway device (10) as claimed in claim 6, **characterised in that** the cross-sectional shape of the vestibule (30) is approximately oval shaped with long axis in the lateral dimension.

5

8. An airway device (10) as claimed in claim 7, **characterised in that** the cross-sectional shape of the vestibule (30) is flattened in the dorsal aspect and is configured to lay flat against the patient's posterior pharyngeal wall.

10

9. An airway device (10) as claimed in claim 8, **characterised in that** an edge (34) of the vestibule (30) is shaped with an outward taper to form a flat edge that is configured to lay flush against the patient's posterior pharyngeal mucosa.

15

10. An airway device (10) as claimed in claim 9, **characterised in that** the extracting means (40) comprises a strip of material extending from a ventral aspect of the edge (34) of the distal opening (36) of the vestibule (30).

20

11. An airway device (10) as claimed in any one of the preceding claims, **characterised in that** the device (10) can be placed in position by means of a cuffed tracheal tube (NT) inserted into the vestibule (30).

25

12. An airway device (10) as claimed in any one of the preceding claims, **characterised in that** the device can be placed with a laryngoscope, inserted into the vestibule (30) and used to insert the device (10) into the patient's hypo-pharynx.

30

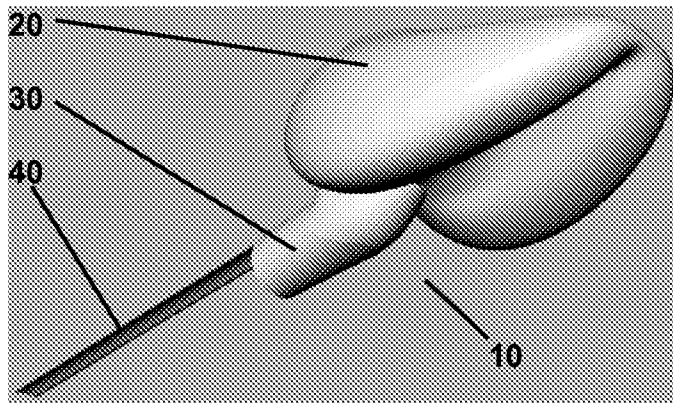


Figure 1

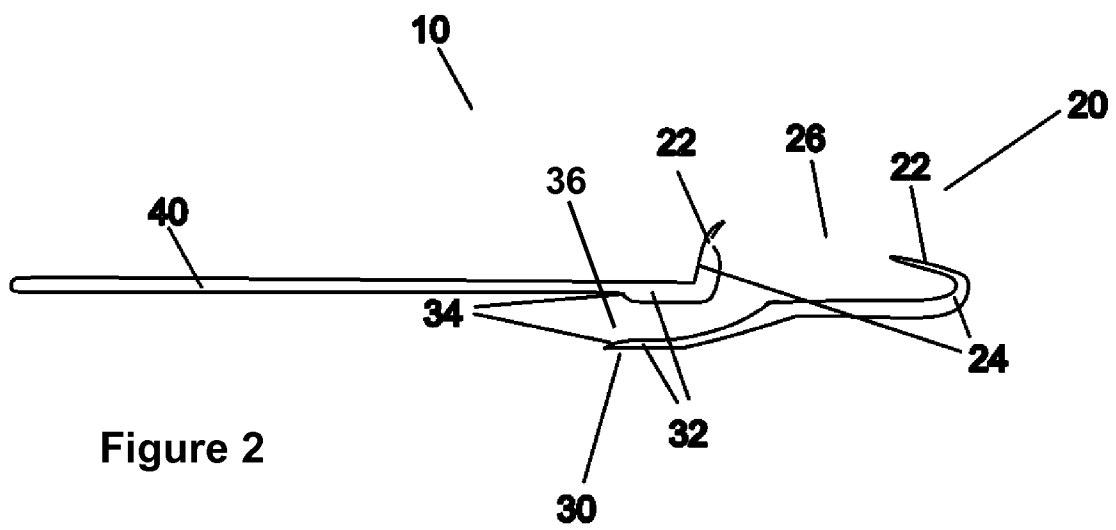


Figure 2

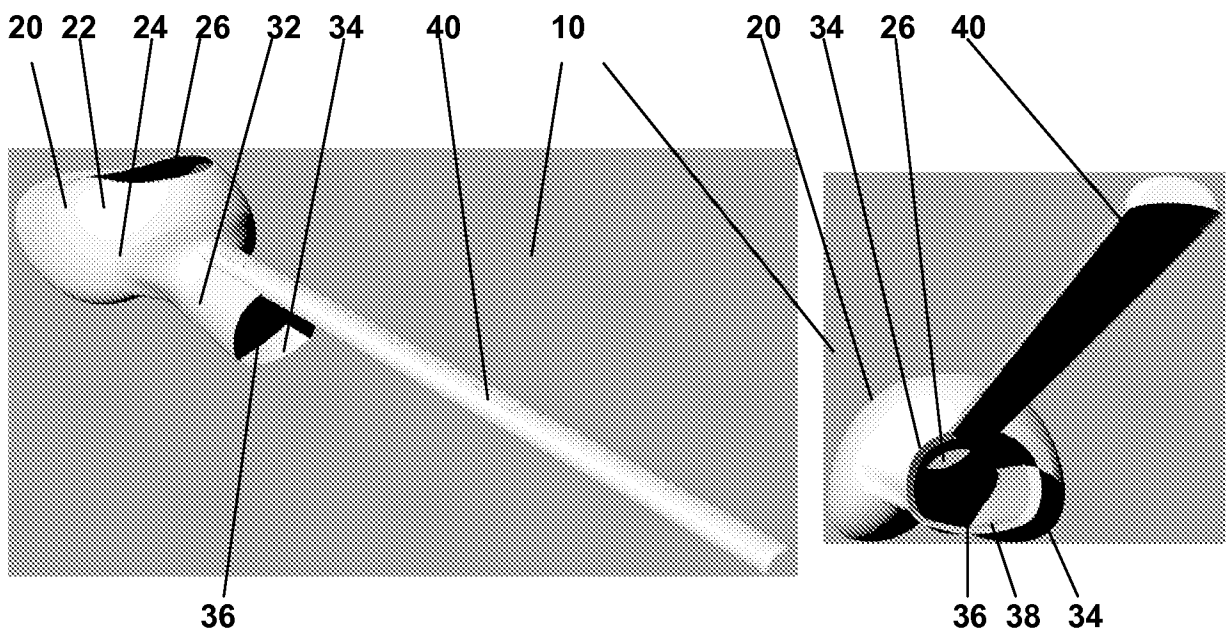


Figure 3

Figure 4

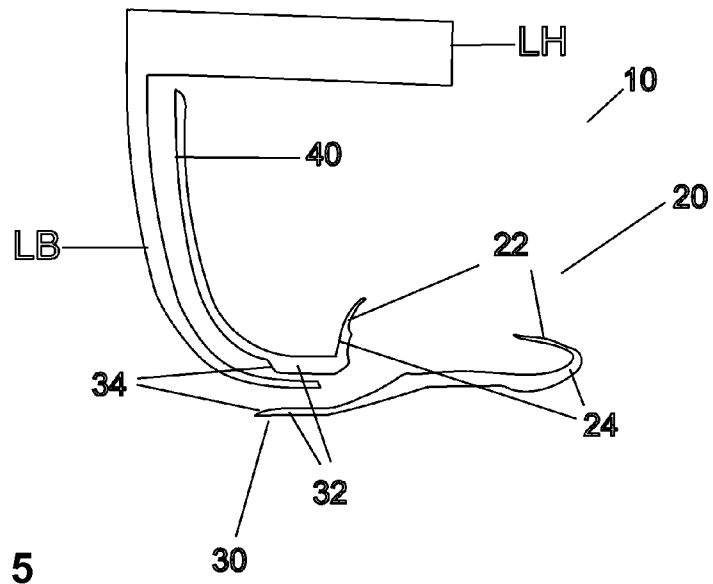


Figure 5

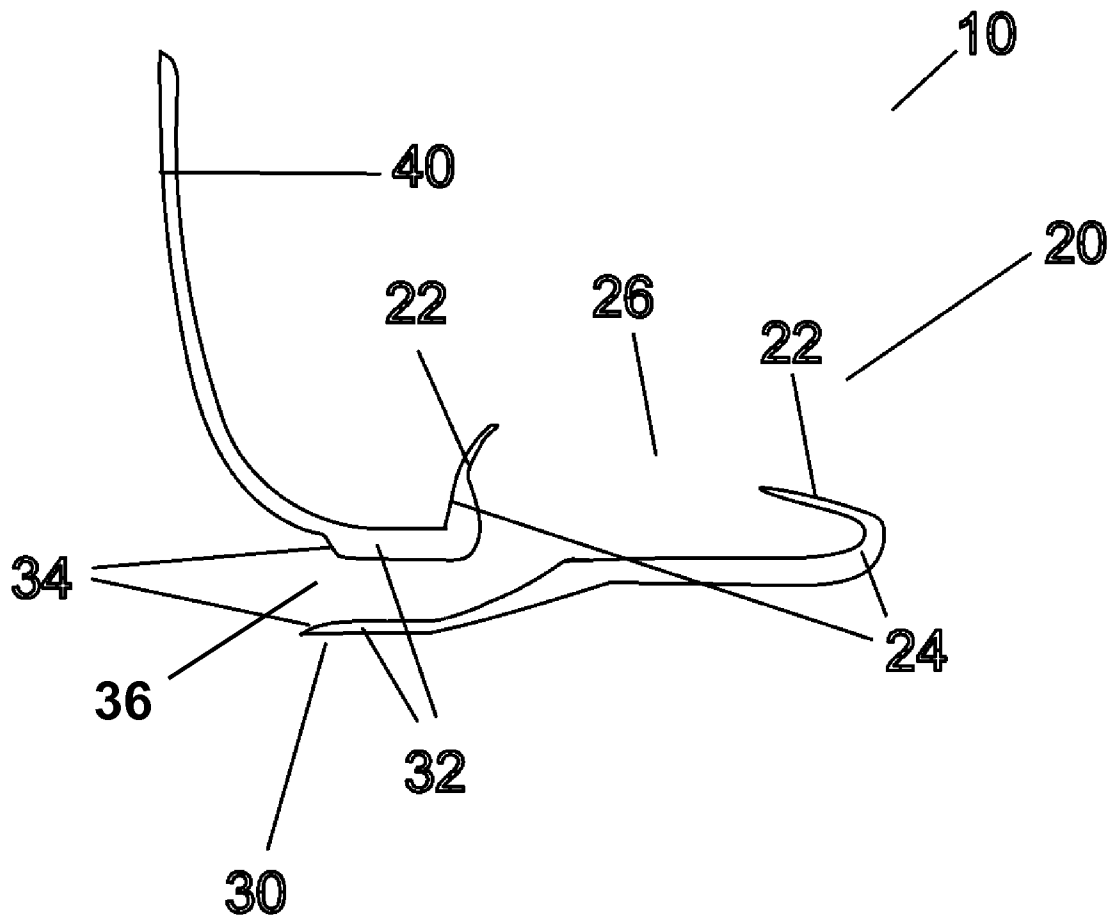


Figure 6

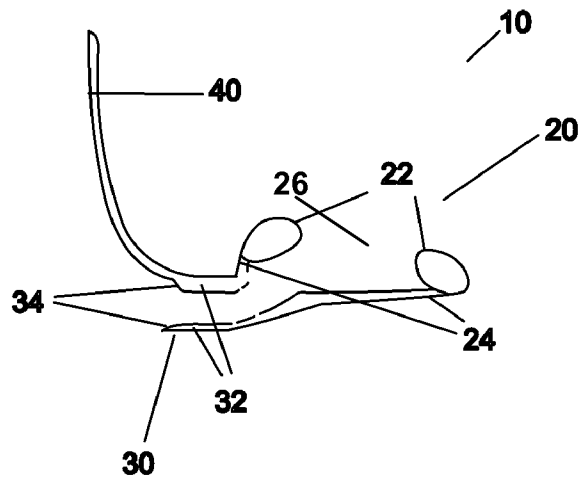


Figure 7

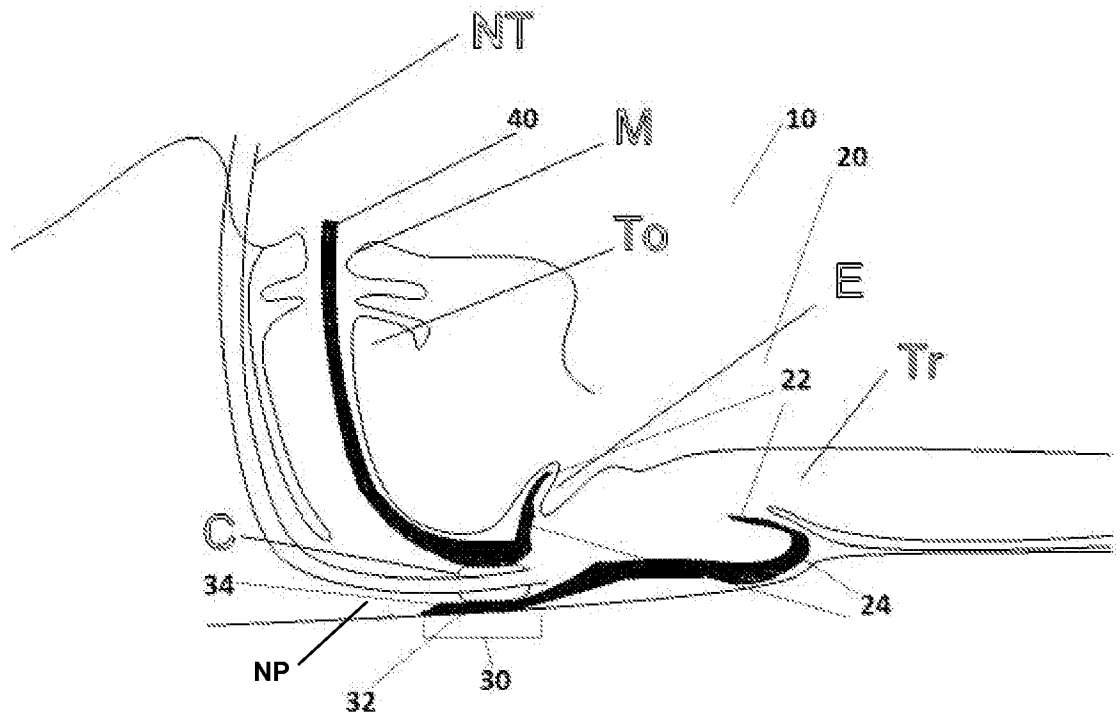


Figure 8

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2012/051365

| A. CLASSIFICATION OF SUBJECT MATTER INV. A61M16/04 ADD. | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| According to International Patent Classification (IPC) or to both national classification and IPC | | |
| B. FIELDS SEARCHED | | |
| Minimum documentation searched (classification system followed by classification symbols) A61M | | |
| Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched | | |
| Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO-Internal, WPI Data, BIOSIS | | |
| C. DOCUMENTS CONSIDERED TO BE RELEVANT | | |
| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| X | EP 0 448 878 A2 (BRAIN ARCHIBALD IAN JEREMY [GB]) 2 October 1991 (1991-10-02) | 1-6,11 |
| Y | abstract; figures 1-4 column 4, line 12 - line 21 column 4, line 47 - line 53 column 5, line 50 - line 58 column 6, line 1 - line 13 column 6, line 56 - line 58 column 7, line 1 - line 10 column 5, line 33 - line 40 column 5, line 2 - line 16 column 3, line 44 - line 52 ----- -/-- | 7-10,12 |
| <input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> 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 28 June 2012 | | Date of mailing of the international search report 27/07/2012 |
| Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016 | | Authorized officer Moraru, Liviu |

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2012/051365

| C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT | | |
|------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| Y | <p>RODENSTEIN D O ET AL: "PHARYNGEAL SHAPE AND DIMENSIONS IN HEALTHY SUBJECTS SNORERS AND PATIENTS WITH OBSTRUCTIVE SLEEP APNEA", THORAX, vol. 45, no. 10, 1990, pages 722-727, XP002678705, ISSN: 0040-6376 abstract; figures 2,3 last paragraph of the Results section.; page 724</p> <p style="text-align: center;">-----</p> | 7-9 |
| Y | <p>US 5 937 859 A (AUGUSTINE SCOTT D [US] ET AL) 17 August 1999 (1999-08-17) figures 1a, 3 column 9, line 5 - line 28</p> <p style="text-align: center;">-----</p> | 10 |
| Y | <p>US 2006/162730 A1 (GLASSENBERG RAYMOND [US] ET AL) 27 July 2006 (2006-07-27) paragraph [0010]</p> <p style="text-align: center;">-----</p> | 12 |

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2012/051365

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|----------------------------------------|------------------|-------------------------|------------------|
| EP 0448878 | A2 | AU 7004491 A | 29-08-1991 |
| | | EP 0448878 A2 | 02-10-1991 |
| ----- | | | |
| US 5937859 | A | NONE | |
| ----- | | | |
| US 2006162730 | A1 | AU 2006208080 A1 | 03-08-2006 |
| | | CA 2595604 A1 | 03-08-2006 |
| | | CN 101374565 A | 25-02-2009 |
| | | EP 1841480 A1 | 10-10-2007 |
| | | JP 2008528131 A | 31-07-2008 |
| | | US 2006162730 A1 | 27-07-2006 |
| | | US 2006180155 A1 | 17-08-2006 |
| | | WO 2006081326 A1 | 03-08-2006 |
| ----- | | | |