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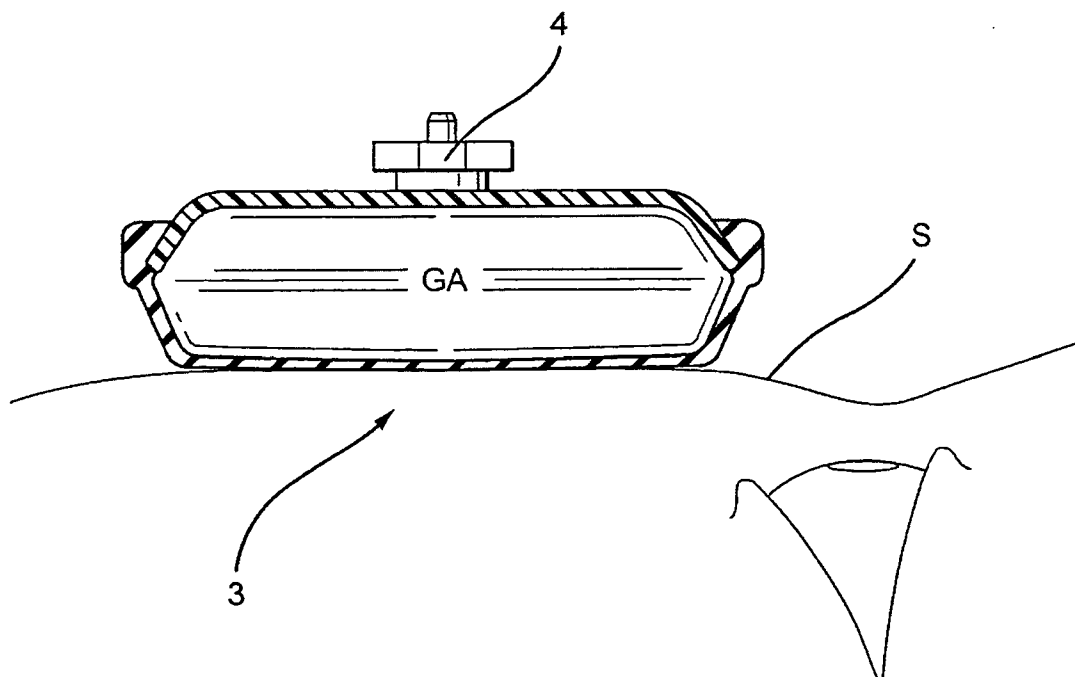
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(54) Title: FOREHEAD PAD FOR A BREATHING MASK AND METHOD FOR MAKING THE SAME



(57) Abstract: A forehead pad for a breathing mask includes a substantially dimensionally stable first wall element (1) and an elastomer second wall element (2) coupled to the first wall element (1). The second wall element (2) has a contact zone (3) adapted to contact a surface (S) of a user in use. The first and second wall elements (1, 2) define a filling-material-receiving chamber (GA) adapted to receive a filling material.

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FOREHEAD PAD FOR A BREATHING MASK AND METHOD FOR MAKING THE SAME

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of German Patent Application No. 10 2005 034 143.8, filed July 19, 2005, which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to a structure for placement on a patient's face, and in particular to a forehead pad for a breathing mask.

BACKGROUND OF THE INVENTION

[0003] Breathing masks are used particularly for administering a breathable gas mixture, such as ambient air, at a pressure level that is above the ambient pressure. Delivering the breathing gas at a pressure level that is above the ambient pressure can serve for instance to perform CPAP therapy for treating stroke-related breathing problems or Obstructive Sleep Apnea (OSA).

[0004] A breathing mask for administering a breathable gas to a user is known from the International Patent Application PCT/EP02/11798 of the present Applicant, which is incorporated herein by reference in its entirety. By means of this breathing mask, it becomes possible, in collaboration with the surface of the face of a mask user, to seal off an interior of the breathing mask from the environment. Such breathing masks are used particularly in conjunction with medical or therapeutic administration of breathable gases as well as in the industrial field, such as in the field of respiratory protection. Typically, in these breathing masks, the sealing off of the surface of the face of the breathing mask user is achieved by means of a sealing lip structure extending all the way around the mask opening and pointing inward and seated on the surface of the face and made from an elastically deformable material. To keep the breathing mask in the application position, a headband device or headgear is typically used, which is wrapped around the region of the back of the user's head and forces the breathing mask against the surface of the user's face. The breathing mask may

include a forehead pad, which makes bracing of the breathing mask possible in a region located above the bridge of the user's nose. The sealing action attained with such breathing masks having such sealing lips generally increases with the contact pressure against the surface of the face. When the contact pressures are high, long-term use of such breathing masks can be unpleasant and can cause pressure points in the region of the contact zones.

SUMMARY OF THE INVENTION

[0005] One aspect of the invention is to provide solutions to the above-described problem that make it possible to create a forehead pad which is distinguished by especially great wearing comfort and which in terms of manufacturing can be produced efficiently and inexpensively.

[0006] According to an aspect of the invention, a forehead pad for a breathing mask includes a substantially dimensionally stable first wall element and an elastomer second wall element coupled to the first wall element. The second wall element has a contact zone adapted to contact a surface of a user in use. The first and second wall elements define a filling-material-receiving chamber adapted to receive a filling material.

[0007] This arrangement creates a forehead pad for a breathing mask that may transmit the forces, possibly acting on the forehead support, with an advantageous distribution of pressure per unit of surface area.

[0008] In an embodiment of the invention, the filling-material-receiving chamber is formed by detachment of the second wall element from the first wall element. The filling-material-receiving chamber may be filled with a viscous medium, e.g., a gel material such as silicone gel. In an embodiment of the invention, the first wall element and the second wall element are coupled to one another in portions via one or more adhesion-bonding zones. The one or more adhesion-bonding zones may be generated by selective treatment of defined regions of the first wall element, e.g., by means of a corona or plasma treatment. It is also possible to generate the adhesion-bonding zone by other kinds of treatment of the first wall element, e.g., by applying adhesion promoters.

[0009] The forehead pad may be designed such that when viewed in a direction essentially perpendicular to the main surface it rests on, it has a substantially circular cross section or outline.

[0010] The forehead pad may have a polygonal or kidney-shaped outline and may be integrated with a suitable forehead support such that in the application position, the forehead pad is supported in a region of the forehead located over the eyebrows of the user.

[0011] The first wall element may be made from a thermoplastic material. The material properties of this plastic material may be selected such that the detachment of the elastomer material of the second wall element may be achieved without the addition of parting agents. Moreover, the plastic material intended for forming the first wall element may be selected such that the adhesion zone may be achieved reliably by suitable treatment, e.g., corona or plasma treatment.

[0012] The first wall element may also form an integral component of a structural part of a forehead support of the breathing mask. In particular, the first wall may form part of a forehead-support plate of a forehead support. The first wall element may also be embodied such that it may be coupled, including the same forehead support, to the forehead support in an easily replaced way. To that end, the first wall element may be provided with a fastener, such as a threaded or bayonet mounting structure.

[0013] Using the elastomer material, it is also possible to make other functional portions of the forehead pad, e.g., a pivot peg by way of which the forehead pad may be secured to the breathing mask.

[0014] Another aspect of the invention relates to a breathing mask for administering a breathable gas, at a pressure level that at least in one phase is above ambient pressure. The breathing mask includes a structure including a contact face adapted to contact a face surface portion on a user's face. The structure is formed by an elastomer wall and a counterpart surface structure. The elastomer wall and the counterpart surface structure define a filling-material-receiving chamber that extends therebetween. The elastomer wall is initially constructed as a wall that is formed integrally onto the counterpart surface structure and subsequently lifted from the counterpart surface structure.

[0015] Another aspect of the invention relates to a method for forming a forehead pad. The method includes providing a substantially dimensionally stable first wall element, molding an elastomer second wall element onto the substantially dimensionally stable first wall element, and introducing a filling material into a chamber defined between the first and second wall elements such that the second wall element detaches from the first wall element in regions that require detachment but remains attached to the first wall element in a defined adhesion bonding zone.

[0016] Another aspect of the invention relates to a method for forming a forehead pad. The method includes forming a first mold chamber with first and second tool segments to mold a substantially dimensionally stable first wall element; after the first wall element has hardened, removing the second tool segment from the first tool segment to expose a portion of the first wall element; treating the exposed portion of the first wall element to create an adhesion-bonding zone; forming a second mold chamber with the first tool segment and a third tool segment to mold an elastomer second wall element onto the substantially dimensionally stable first wall element; after the second wall element has hardened, removing the third tool segment from the first tool segment to expose the second wall element; and introducing a filling material into a chamber defined between the first and second wall elements such that the second wall element detaches from the first wall element in regions that require detachment but remains attached to the first wall element in the adhesion bonding zone.

[0017] Another aspect of the invention relates to a multi-part molding tool for forming a forehead pad including a first wall element and a second wall element. The multi-part molding tool includes a first tool segment, a second tool segment adapted to be positioned with respect to the first tool segment to form a first mold chamber to mold the first wall element, and a third tool segment adapted to be positioned with respect to the first tool segment after the second wall element is removed following molding of the first wall element. The third tool segment and the first tool segment adapted to form a second mold chamber to mold the second wall element onto the first wall element.

[0018] Other aspects, features, and advantages of this invention will become apparent from the following detailed description when taken in conjunction with the accompanying drawings, which are a part of this disclosure and which illustrate, by way of example, principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

- [0019] The accompanying drawings facilitate an understanding of the various embodiments of this invention. In such drawings:
- [0020] Fig. 1a is a simplified sectional view illustrating the structure of a forehead pad according to an embodiment of the invention, in an unfilled state;
- [0021] Fig. 1b is a simplified sectional view illustrating the structure of a partially filled forehead pad, formed from the structure of Fig. 1a;
- [0022] Fig. 1c is a simplified sectional view illustrating the structure of a filled forehead pad, formed from the structure of Fig. 1a;
- [0023] Fig. 2 is a sectional view illustrating the structure of a forehead pad according to another embodiment of the invention whose contact zone is made up of a plurality of beads;
- [0024] Fig. 3 is a perspective view illustrating the structure of a forehead pad according to another embodiment of the invention, having a substantially circular outline;
- [0025] Fig. 4 is a perspective view illustrating the structure of a forehead pad according to another embodiment of the invention, having a substantially kidney-shaped outline;
- [0026] Figs. 5A-5D illustrate a production method for forming a forehead pad according to an embodiment of the invention; and
- [0027] Fig. 6 is a perspective view of a breathing mask including a forehead pad according to an embodiment of the invention.

DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

[0028] In Fig. 1a, a preliminary stage of a forehead pad according to an embodiment of the invention for a breathing mask is shown. The forehead pad includes a substantially dimensionally stable first wall element 1, e.g., made from a thermoplastic material or a metal material, and an elastomer second wall element 2, coupled to the first wall element 1. The second wall element 2, in the state shown in Fig. 1c, forms a contact zone 3 intended for contacting the surface S of a user's forehead. The forehead pad shown in Figs. 1a to 1c also includes securing structures 4, by way of which the forehead pad can be attached to a forehead support of a breathing mask. It is also possible to embody the first wall element 1 as a component of the forehead support, e.g., integrally form the first wall element 1 with the

forehead support.

[0029] The second wall element 2 shown in Fig. 1a is formed by injection molding an elastomer material, e.g., liquid silicone rubber (LSR), onto the first wall element 1. The filling-material-receiving chamber GA that can be seen in Figs. 1b and 1c, which is intended for receiving a filling material, is formed by detachment of the second wall element 2 from the first wall element 1. Detachment is made possible by selecting the surface properties of the first wall element 1 such that in the surface region that requires detachment, no adhesive bond is created between the elastomer material of the second wall element 2 and the first wall element 1. In the illustrated embodiment, an outer circumferential region of the first wall element 1 is treated such that a defined adhesion-bonding zone Z is created here. The adhesion-bonding zone can be generated by corona or plasma treatment. It is also possible to generate this adhesion-bonding zone by applying an adhesion promoter.

[0030] The filling-material-receiving chamber GA may be filled with a viscous medium, e.g., a jelly-like or gel-like medium, such as partly cross-linked silicone rubber. It is also possible to fill the filling-material-receiving chamber GA with a gaseous medium or a relatively low-viscosity medium, such as water.

[0031] Fig. 1a illustrates the forehead pad in its unfilled state wherein the elastomer second wall element 2 is molded onto the first wall element 1. As the filling material is introduced into the chamber GA, the second wall element 2 detaches from the first wall element 1 in the regions that require detachment but remains attached to the first wall element 1 in the defined adhesion bonding zone Z, i.e., the outer circumferential or perimeter region of the first wall element 1. Fig. 1b illustrates the forehead pad in a partially filled state wherein the second wall element 2 begins to detach from the first wall element 1. Fig. 1c illustrates the forehead pad in a filled state wherein the chamber GA is completely filled with the filling material.

[0032] In Fig. 2, a further variant of a forehead pad according to another embodiment of the invention is shown. In this variant, the first wall element 1 is provided with ribs 4, 5, by which the gel-receiving chamber GA is partitioned off. Moreover, the ribs 4, 5 generate additional adhesion-bonding points 8, which prevent disproportionate lifting off of the second wall element 2 from the first wall element 1. The ribs 4, 5 may be dimensioned such that in the region of the face-contact zone 3 they create small channels 6, which enables ventilation of the surface of the contact zone 3 that rests on the surface of the user's forehead.

[0033] In an embodiment, the chamber GA may include two or more partitions that are communicated with one another such that the partitions can be filled with a filling material via one inlet port. In another embodiment, the chamber GA may include two or more partitions that are isolated from one another such that the partitions are filled with a filling material via two or more inlet ports, e.g., inlet port for each partition. In such an arrangement, the isolated partitions may be filled with different filling materials to provide different rigidities in different regions of the forehead pad.

[0034] In Fig. 3, a variant of a forehead pad according to another embodiment of the invention with a substantially circular outline is shown. The forehead pad may be filled with a filling material, e.g., a gel, in such a way that an outer circumferential or perimeter region of the second wall element 2 includes a bead portion 10 that extends in beadlike fashion around the circumferential edge of the first wall element 1. On a side of the forehead pad facing away from the face-contact zone 3, a securing peg 7 is provided, by way of which the forehead pad can be fixed to a suitable structure of a breathing mask. It is possible to form peg 7 with a filling conduit through which gel is provided to the filling-material-receiving chamber GA (e.g., see Fig. 1c).

[0035] In Fig. 4, a variant of the forehead pad according to another embodiment of the invention is shown which has a substantially kidney-shaped outline. To achieve this kidney-shaped outline, the first wall element 1 and the second wall element 2, initially injection molded onto it, are shaped accordingly. By filling the filling-material-receiving chamber formed between the two wall elements 1, 2, it becomes possible to inflate the second wall element 2 in such a way that it forms a relatively soft bead portion 10 that projects radially past the first wall element 1 (e.g., in a manner similar to that of Fig. 3).

[0036] By special adaptation of the local wall thicknesses of the second wall element, it is possible to vary the force transmission behavior, e.g., the reduction in pressure per unit of surface area, toward the edge of the face-contact zone.

[0037] The invention is not limited to the exemplary embodiments described above. In particular, the invention is not limited to forehead pads for breathing masks. For example, aspects of the invention may be suitable for making structure for placement on the faces of the kind employed with eyeglasses.

[0038] The production of the forehead pad according to embodiments of the invention, or a corresponding structure for placement on the face, may be done largely in

fully automated fashion by multi-part tools. For example, as shown in Fig. 5A, it is possible to use a multi-part molding tool including tool segments M_1 and M_2 for producing the first wall element 1, which first forms only the mold chamber required for forming the first wall element 1. The plastic material may enter the mold chamber defined by tool segments M_1 and M_2 via channel 15. After the plastic material placed in this mold chamber has hardened, the molding tool may be opened by removing tool segment M_2 , as shown in Fig. 5B. As illustrated, the first wall element 1 may be treated to create an adhesion-bonding zone Z as described above. The treating may occur at any one of the steps shown in Figs. 5A to 5C, and may be incorporated into one of the tool segments M_2 or M_3 . Next, as shown in Fig. 5C, the molding tool is closed by means of a new tool segment M_3 , which itself, in cooperation with the remaining tool segment M_1 and with the first wall element 1, defines a mold chamber of the kind needed for forming the second wall element 2. This mold chamber may now be filled with an elastomer plastic material, e.g., LSR, via channel 17. After the second plastic material has hardened, the tool segment M_3 may be removed and a viscous medium, e.g., silicone gel, may be introduced via channel 15 in M_1 into a conduit embodied in the first wall element 1, and into a boundary region defined between the second wall element 2 and the first wall element 1 as shown in Fig. 5D. By successive introduction of the appropriate filling material, the second wall element 2 is lifted from the first wall element 1, thus forming a gel cushion. The filling conduit for introducing the gel material may also be closed in automated fashion.

[0039] Fig. 6 illustrates a breathing mask 20 including a forehead pad with first and second wall elements 1, 2 such as those described above. Further details of the breathing mask are described in PCT/EP02/11798, which is incorporated herein by reference in its entirety.

[0040] While the invention has been described in connection with what are presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments, but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the invention. Also, the various embodiments described above may be implemented in conjunction with other embodiments, e.g., aspects of one embodiment may be combined with aspects of another embodiment to realize yet other embodiments. In addition, while the invention has particular application to patients who suffer from OSA, it is to be appreciated

that patients who suffer from other illnesses (e.g., congestive heart failure, diabetes, morbid obesity, stroke, barriatric surgery, etc.) can derive benefit from the above teachings.

Moreover, the above teachings have applicability with patients and non-patients alike in non-medical applications.

WHAT IS CLAIMED IS:

1. A forehead pad for a breathing mask, comprising:
a substantially dimensionally stable first wall element; and
an elastomer second wall element coupled to the first wall element, the second wall element having a contact zone adapted to contact a surface of a user in use,
wherein the first and second wall elements define a filling-material-receiving chamber adapted to receive a filling material.
2. The forehead pad in accordance with claim 1, wherein the second wall element is formed by injection molding an elastomer material onto the first wall element.
3. The forehead pad in accordance with claim 1 or 2, wherein the filling-material-receiving chamber is formed by detachment of the second wall element from the first wall element.
4. The forehead pad in accordance with at least one of claims 1 through 3, wherein the filling-material-receiving chamber is filled with a gel material.
5. The forehead pad in accordance with at least one of claims 1 through 4, wherein the first wall element and the second wall element are coupled to one another in portions via an adhesion-bonding zone.
6. The forehead pad in accordance with claim 5, wherein the adhesion-bonding zone is formed by corona or plasma treatment of defined and selected regions of the first wall element.
7. The forehead pad in accordance with at least one of claims 1 through 6, wherein the forehead pad has a substantially circular outline.
8. The forehead pad in accordance with at least one of claims 1 through 7,

wherein the forehead pad has a polygonal or kidney-shaped outline.

9. The forehead pad in accordance with at least one of claims 1 through 8, wherein the first wall element is made from a thermoplastic material.

10. The forehead pad in accordance with at least one of claims 1 through 9, wherein the first wall element is part of a forehead support.

11. The forehead pad in accordance with at least one of claims 1 through 10, wherein the first wall element is provided with a fastener to couple the first wall element to a forehead support.

12. A breathing mask including a forehead pad in accordance with at least one of claims 1 through 11.

13. A breathing mask for administering a breathable gas, at a pressure level that at least in one phase is above ambient pressure, comprising:

a structure including a contact face adapted to contact a face surface portion on a user's face,

the structure being formed by an elastomer wall and a counterpart surface structure, the elastomer wall and the counterpart surface structure defining a filling-material-receiving chamber that extends therebetween, and the elastomer wall is initially constructed as a wall that is formed integrally onto the counterpart surface structure and subsequently lifted from the counterpart surface structure.

14. The breathing mask in accordance with claim 13, wherein the structure forms a forehead pad.

15. The breathing mask in accordance with claim 13, wherein the structure forms a component of a sealing lip device.

16. A method for forming a forehead pad, comprising:

providing a substantially dimensionally stable first wall element;
molding an elastomer second wall element onto the substantially dimensionally stable first wall element; and

introducing a filling material into a chamber defined between the first and second wall elements such that the second wall element detaches from the first wall element in regions that require detachment but remains attached to the first wall element in a defined adhesion bonding zone.

17. The method in accordance with claim 16, wherein introducing a filling material into a chamber includes filling the chamber with a gel material.

18. The method in accordance with claim 16 or 17, wherein the defined adhesion bonding zone is provided along an outer circumferential region of the first wall element.

19. The method in accordance with at least one of claims 16 through 18, further comprising forming the adhesion bonding zone by corona or plasma treatment of defined and selected regions of the first wall element.

20. A method for forming a forehead pad, comprising:
forming a first mold chamber with first and second tool segments to mold a substantially dimensionally stable first wall element;

after the first wall element has hardened, removing the second tool segment from the first tool segment to expose a portion of the first wall element;

treating the exposed portion of the first wall element to create an adhesion-bonding zone;

forming a second mold chamber with the first tool segment and a third tool segment to mold an elastomer second wall element onto the substantially dimensionally stable first wall element;

after the second wall element has hardened, removing the third tool segment from the first tool segment to expose the second wall element; and

introducing a filling material into a chamber defined between the first and second wall elements such that the second wall element detaches from the first wall element

in regions that require detachment but remains attached to the first wall element in the adhesion bonding zone.

21. The method in accordance with claim 20, wherein the forming, removing, treating, and introducing steps are automated.

22. A multi-part molding tool for forming a forehead pad including a first wall element and a second wall element, comprising:

a first tool segment;

a second tool segment adapted to be positioned with respect to the first tool segment to form a first mold chamber to mold the first wall element; and

a third tool segment adapted to be positioned with respect to the first tool segment after the second wall element is removed following molding of the first wall element, the third tool segment and the first tool segment adapted to form a second mold chamber to mold the second wall element onto the first wall element.

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Fig. 1a

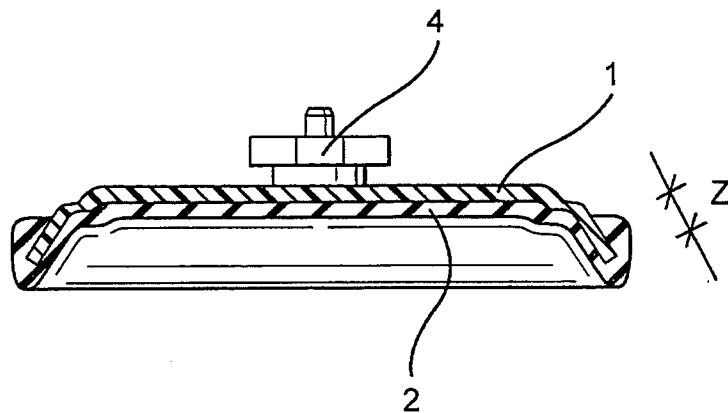


Fig. 1b

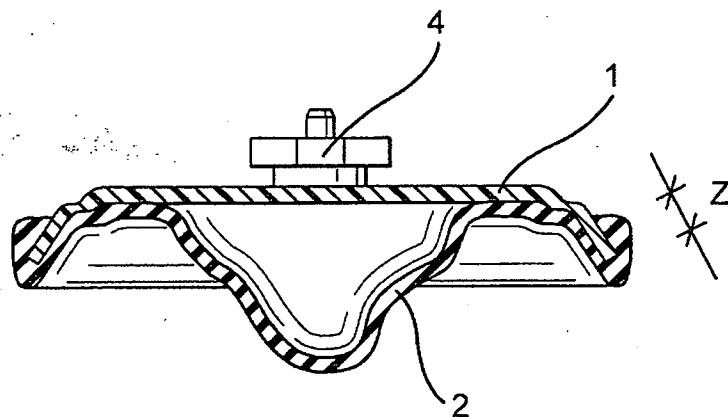
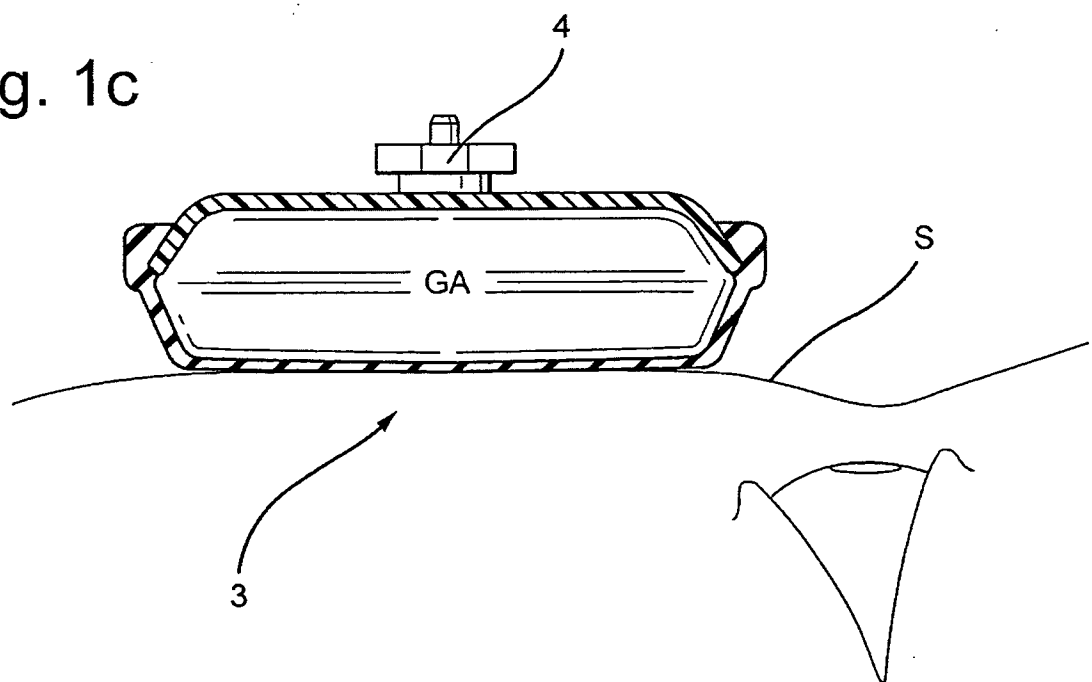


Fig. 1c



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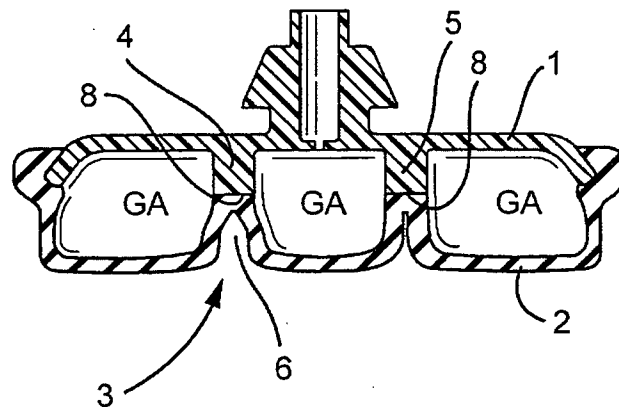


Fig. 2

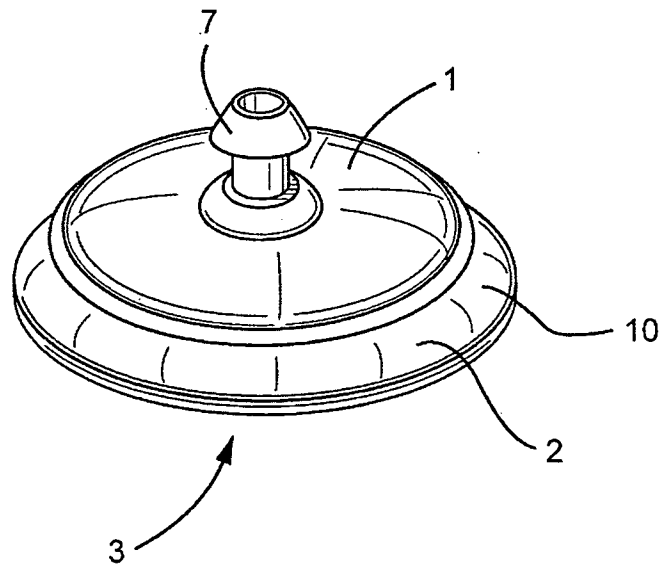


Fig. 3

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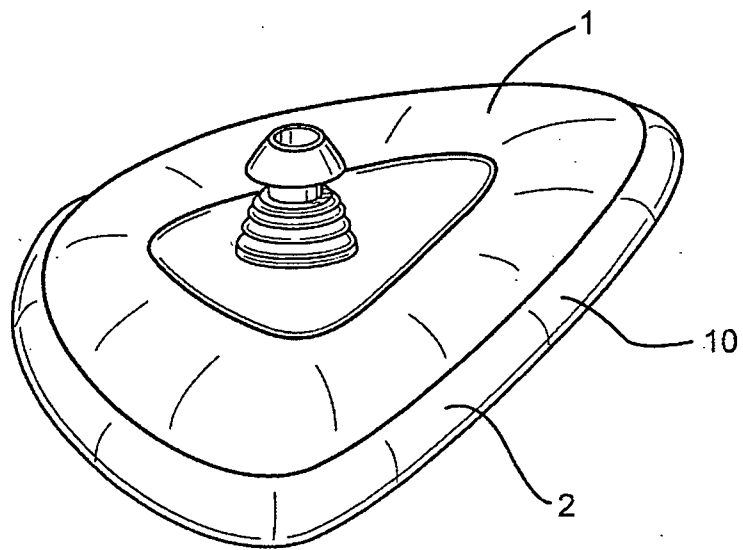


Fig. 4

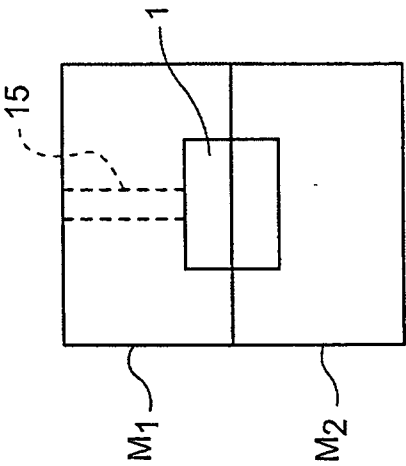


Fig. 5A

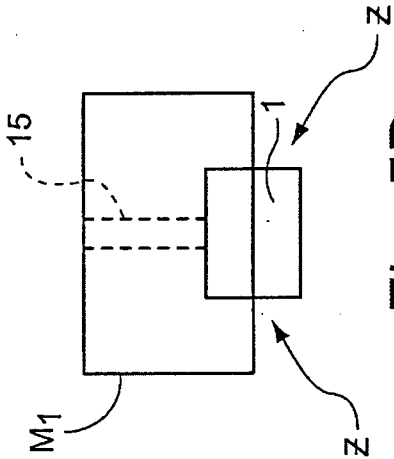


Fig. 5B

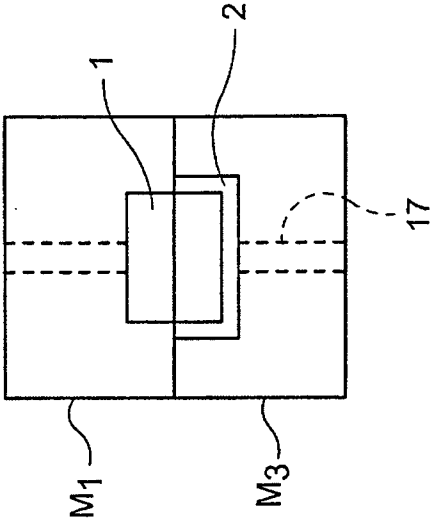


Fig. 5C

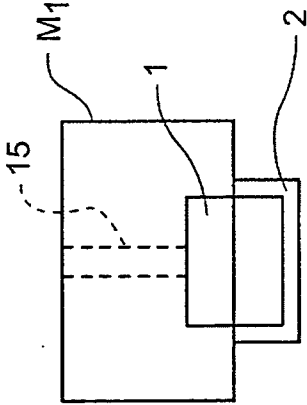


Fig. 5D

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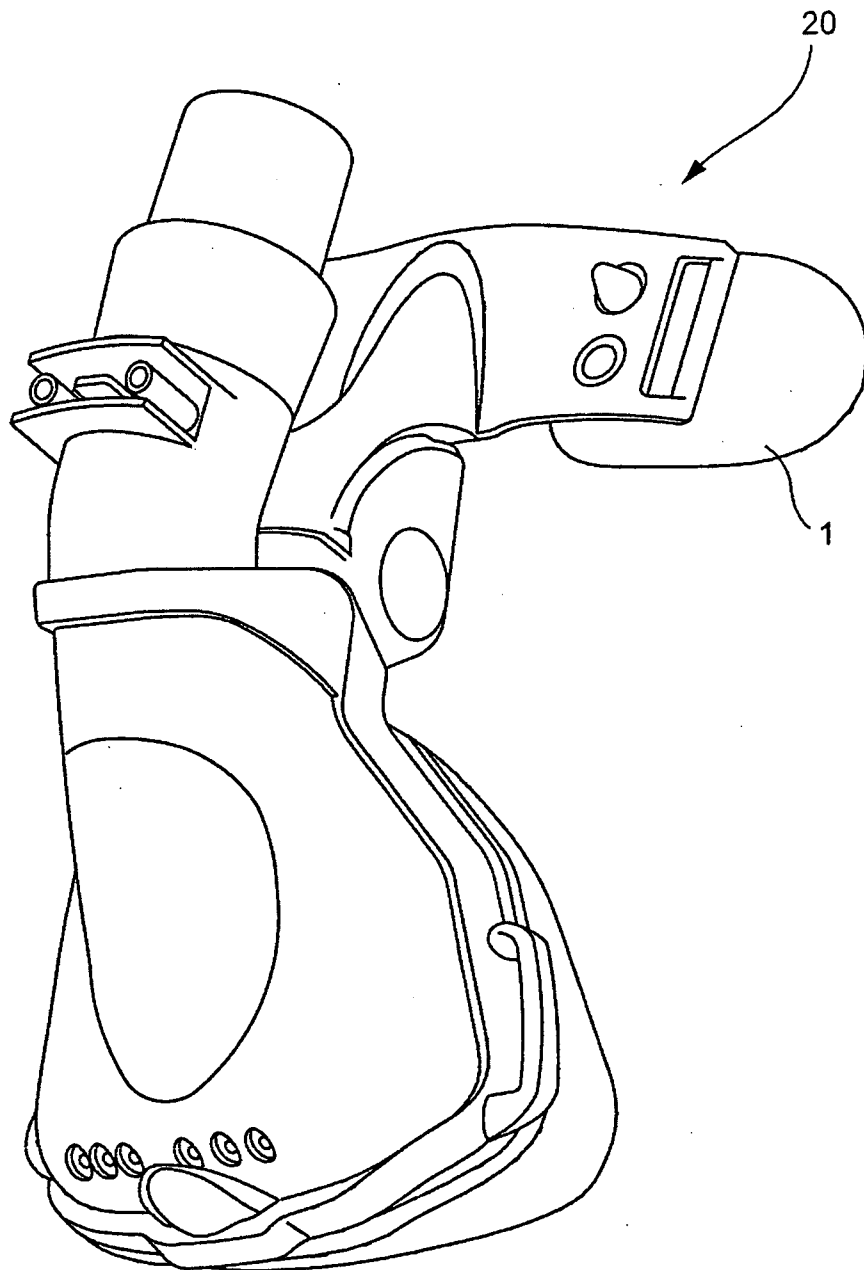


Fig. 6

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2006/007118

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M16/06

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 practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/105921 A2 (MAP MEDIZIN TECHNOLOGIE GMBH [DE]; LANG BERND [DE]; BIENER ACHIM [DE];) 24 December 2003 (2003-12-24) page 15, line 12 - page 29, line 10; figures 18a-e	1-22
X A	US 6 467 483 B1 (KOPACKO RALPH E [US] ET AL) 22 October 2002 (2002-10-22) column 7, line 23 - column 10, line 25	1-19
X A	EP 1 099 452 A2 (MAP GMBH [DE]) 16 May 2001 (2001-05-16) paragraph [0037] - paragraph [0051]	13,15,22 1-6, 9-12, 16-21
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☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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Date of the actual completion of the international search

27 October 2006

Date of mailing of the international search report

07/11/2006

Name and mailing address of the ISA/

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International application No
PCT/EP2006/007118

G(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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