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AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ,  
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(54) Title: CUSHION MEMBER AND METHOD OF MANUFACTURING SAME

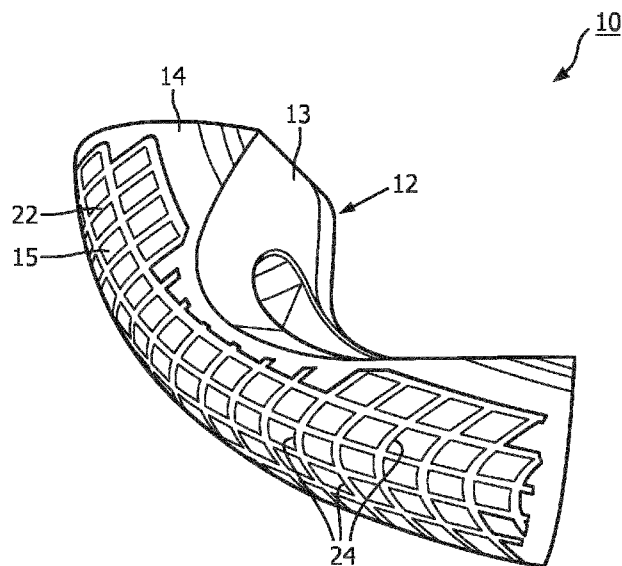


FIG. 4

(57) Abstract: A cushion member (10) for a mask structured to be worn on a face of a user. The cushion member includes a cushion portion (12) having a sealing portion (13) and a body portion (14) extending from the sealing portion, the sealing portion being structured to engage the face of the user; and at least one mesh member (22) embedded in at least one of the sealing portion and the body portion.

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,  
KM, ML, MR, NE, SN, TD, TG).

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- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

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## CUSHION MEMBER AND METHOD OF MANUFACTURING SAME

### CROSS-REFERENCE TO RELATED APPLICATIONS

[01] This patent application claims the priority benefit under 35 U.S.C. § 119(e) of U.S. Provisional Application No. 62/345,030 filed on June 3, 2016, the contents of which are herein incorporated by reference.

### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

[02] The present invention relates to non-invasive ventilation and pressure support systems wherein a mask is used to deliver a flow of breathing gas to a user, and in particular to cushion members for such masks. The present invention is also related to methods of manufacturing cushion members.

#### 2. Description of the Related Art

[03] There are numerous situations where it is necessary or desirable to deliver a flow of breathing gas non-invasively to the airway of a user, i.e., without intubating the user or surgically inserting a tracheal tube in their esophagus. For example, it is known to ventilate a patient using a technique known as non-invasive ventilation. It is also known to deliver positive airway pressure (PAP) therapy to treat certain medical disorders, the most notable of which is obstructive sleep apnea (OSA). Known PAP therapies include continuous positive airway pressure (CPAP), wherein a constant positive pressure is provided to the airway of the patient in order to splint open the patient's airway, and variable airway pressure, wherein the pressure provided to the airway of the patient is varied with the patient's respiratory cycle. Such therapies are typically provided to the patient at night while the patient is sleeping. Non-invasive ventilation and pressure support therapies as just described involve a gas flow generator to produce a flow of breathing gas, and the placement of a patient interface device including a mask component on the face of a patient. The gas flow generator produces positive air pressure by taking air in from the surroundings and spinning a fan to push the air out of the machine, through a delivery conduit, and into the patient interface device to be delivered to the patient.

[04] Traditional cushion members for patient interface devices include a sealing portion that is structured to engage the face of the patient in order to provide a seal therewith, as well as a body portion that is structured to provide support to the sealing portion. Known drawbacks of traditional cushion members include discomfort, undesirable red marks formed on the face of the patient, and leaks due to overstretching of the cushion member. More specifically, when pressure support therapy is being delivered, moisture in the breathing gas causes traditional cushion members to undesirably stretch, such that the integrity of the seal between the patient and the cushion member is compromised.

#### SUMMARY OF THE INVENTION

[05] Accordingly, it is an object of the present invention to provide a cushion member for a mask structured to be worn on a face of a user. The cushion member includes a cushion portion having a sealing portion and a body portion extending from the sealing portion, the sealing portion being structured to engage the face of the user; and at least one mesh member embedded in at least one of the sealing portion and the body portion.

[06] It is yet another object of the present invention to provide a method of manufacturing a cushion member comprising the steps of providing at least one mesh member; and overmolding a cushion portion on the at least one mesh member, the cushion portion having a sealing portion and a body portion extending from the sealing portion, the sealing portion being structured to engage a face of a user, the at least one mesh member being embedded in at least one of the sealing portion and the body portion.

[07] These and other objects, features, and characteristics of the present invention, as well as the methods of operation and functions of the related elements of structure and the combination of parts and economies of manufacture, will become more apparent upon consideration of the following description and the appended claims with reference to the accompanying drawings, all of which form a part of this specification, wherein like reference numerals designate corresponding parts in the various figures. It is to be expressly understood, however, that the drawings are for the purpose of

illustration and description only and are not intended as a definition of the limits of the invention.

### BRIEF DESCRIPTION OF THE DRAWINGS

- [08] FIG. 1 is a simplified isometric view of a pressure support system, in accordance with a non-limiting embodiment of the disclosed concept;
- [09] FIG. 2 and FIG. 3 are different exploded isometric views of a cushion member for the pressure support system of FIG. 1;
- [10] FIG. 4 is an isometric view of the cushion member of FIG. 2 and FIG. 3, modified such that the mesh member is on an exterior portion of the cushion portion for purposes of illustration only;
- [11] FIGS. 5-8 are simplified elevation views of alternative mesh members, in accordance with non-limiting alternative embodiments of the disclosed concept; and
- [12] FIGS. 9-11 are simplified isometric views of alternative cushion members, in accordance with non-limiting alternative embodiments of the disclosed concept.

### DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

- [13] As used herein, the singular form of “a”, “an”, and “the” include plural references unless the context clearly dictates otherwise. As used herein, the statement that two or more parts or components are “coupled” shall mean that the parts are joined or operate together either directly or indirectly, i.e., through one or more intermediate parts or components, so long as a link occurs. As used herein, “directly coupled” means that two elements are directly in contact with each other. As used herein, “fixedly coupled” or “fixed” means that two components are coupled so as to move as one while maintaining a constant orientation relative to each other.
- [14] As employed herein, the statement that two or more parts or components “engage” one another shall mean that the parts exert a force against one another either directly or through one or more intermediate parts or components. As employed herein, the term “number” shall mean one or an integer greater than one (i.e., a plurality).
- [15] Directional phrases used herein, such as, for example and without limitation, left, right, upper, lower, front, back, on top of, and derivatives thereof, relate

to the orientation of the elements shown in the drawings and are not limiting upon the claims unless expressly recited therein.

[16] As used herein, the term “mesh member” shall mean a component having a plurality of thru holes through which a viscous elastomeric material can permeate and/or flow in order that a mechanical bond is formed between the mesh member and the elastomeric material. A mesh member may be, for example and without limitation, a material consisting of a network of interlaced or otherwise entangled natural or artificial fibers, threads, or wires. A mesh member may also be, for example and without limitation, a perforated sheet of a material such as metal or plastic.

[17] As used herein, the phrase “mechanical bond” shall mean a bond formed as a result of the curing (i.e., solidifying) of a material, such as a monomer, a polymer, and a mixture of a monomer and a polymer (e.g., without limitation, an elastomeric material such as silicone), to a mesh member. For example and without limitation, a bond formed when a viscous elastomeric material flows through a mesh member and is thereafter cured is a mechanical bond. As used herein, the term “embedded” shall mean enclosed and/or encapsulated on all sides.

[18] FIG. 1 is a schematic diagram of a pressure support system 2 in accordance with one non-limiting embodiment of the disclosed concept. Pressure support system 2 includes a gas flow generator 4 (shown in simplified form), a gas delivery conduit (e.g., without limitation, hose 6, shown in simplified form), and a cushion member 10 for a mask structured to be worn on a face of user, such as a patient interface device. Gas flow generator 4 is structured to generate a flow of breathing gas to be delivered to an airway of the user, and may be a blower used in a conventional CPAP or bi-level pressure support device. Hose 6 fluidly couples gas flow generator 4 to cushion member 10, which is structured to engage the face of the user. In this manner, hose 6 allows gas flow generator 4 to deliver the flow of breathing gas to the airway of the user.

[19] FIG. 2 and FIG. 3 show rear and front exploded isometric views, respectively, of cushion member 10. As shown, cushion member 10 includes a cushion portion 12 and a mesh member 22 that, as described herein, is embedded within cushion portion 12. Cushion portion 12 has a sealing portion 13 and a body portion 14 extending

from sealing portion 13. Sealing portion 13 is structured to engage the face of the user in order to provide a seal therewith and allow gas flow generator 4 to effectively deliver the breathing gas to the user.

[20] In accordance with the disclosed concept, mesh member 22 is embedded in at least one of sealing portion 13 and body portion 14. In the example depicted in FIG. 2 and FIG. 3, mesh member 22 is structured to be embedded within body portion 14. More specifically, mesh member 22 has a plurality of edge portions 24 that each define a respective thru hole 25. In the exemplary embodiment, during manufacturing of cushion member 10, cushion portion 12 is overmolded on mesh member 22 such that the viscous elastomeric material (e.g., without limitation, silicone) comprising cushion portion 12 flows, or permeates, through the thru holes 25 defined by edge portions 24 in order that mechanical bonds are formed between the viscous elastomeric material and edge portions 24 when the elastomeric material has cured. That is, cushion portion 12 extends through each of the plurality of thru holes 25 of mesh member 22 in order to be mechanically bonded to mesh member 22.

[21] Additionally, when the elastomeric material of cushion portion 12 has cured, resulting body portion 14 has an embedding portion (generally indicated with reference numeral 15) and mesh member 22 is embedded within embedding portion 15. Embedding mesh member 22 within embedding portion 15 provides significant mechanical advantages for cushion member 10. For instance, in one example embodiment, mesh member 22 is made of a first material and cushion portion 12 is made of a second material different than the first material. The first material of mesh member 22 may be, for example and without limitation, a fabric material and/or a metallic material, while the second material of cushion portion 12 may be, for example and without limitation, an elastomeric material. The first material of mesh member 22 may have a modulus of elasticity less than the second material of cushion portion 12. The difference in materials and moduli of elasticity, combined with the mechanical bond between cushion portion 12 and edge portions 24, advantageously causes cushion member 10 to experience reduced elongation when subjected to tensile loads. In other words, mesh member 22 limits the stretch of cushion member 10 when cushion member

10 is subjected to tensile loads. As a result, cushion member 10 is structured to maintain a relatively strong seal and cause less red marks with users over time, as compared to prior art cushion members (not shown). Furthermore, moisture that accumulates during pressure support therapy will not significantly compromise the integrity of cushion member 10, which is an advantage over prior art cushion members.

[22] Additionally, embedding mesh member 22 within cushion portion 12 significantly improves the ability of cushion member 10 to withstand tearing after repeated use. More specifically, mesh member 22 limits the stretch of cushion portion 12 to below its tear threshold. Also, if a tear does begin to form in cushion portion 12, mesh member 22 provides a physical barrier to prevent propagation of the tear.

[23] As shown in FIG. 4, which depicts mesh member 22 slightly offset from cushion portion 12 for purposes of illustration only, mesh member 22 has substantially the same shape as embedding portion 15. Accordingly, mesh member 22 is relatively flexible such that during manufacturing, when the viscous elastomeric material that comprises cushion portion 12 cures, mesh member 22 becomes shaped substantially the same as embedding portion 15. In this manner, mesh member 22 advantageously assists cushion portion 12 in retaining its shape.

[24] Mesh member 22 has been described herein as being embedded within embedding portion 15 of body portion 14, and not being embedded in sealing portion 13. However, it will be appreciated that a similar suitable alternative mesh member (not shown) may be embedded within a different embedding portion of body portion 14, and/or may be embedded within sealing portion 13. That is, a similar suitable alternative cushion member (not shown) may include any number of mesh members embedded anywhere within a respective cushion portion in order to perform the desired function of providing improved mechanical advantages as described above.

[25] FIGS. 5-8 show alternative mesh members 42,52,62,72, respectively, that may be embedded in cushion portion 12 in place of mesh member 22, and/or in addition to mesh member 22, in accordance with non-limiting alternative embodiments of the disclosed concept. Referring to FIG. 5, mesh member 42 has a body 43 having a number of circular-shaped thru holes 45. FIG. 6 shows mesh member 52 having a body 53



having a number of elongated slots 55. FIG. 7 shows mesh member 62 having a body 63 having a number of square-shaped thru holes 65, and FIG. 8 shows mesh member 72 having a body 73 having a number of hexagonal-shaped thru holes 75.

[26] Thru holes 45 each have a respective diameter 44, slots 55 each have a respective height 54, thru holes 65 each have a respective side length 64, and thru holes 75 each have a respective height 74. Diameters 44, heights 54, 74, and side lengths 64 are each greater than about 0.003 millimeters. The inventors have found that diameters, heights, and side lengths less than 0.003 millimeters are impermeable to the flow of viscous elastomeric material, such as during a molding operation. In this manner, because of the size of holes 45, 65, 75 and slots 55, viscous elastomeric material is advantageously able to permeate therethrough and allow for a relatively strong mechanical bond. Additionally, bodies 43, 53, 63, 73 of mesh members 42, 52, 62, 72 may be made of any material suitable to perform the desired function of forming mechanical bonds with elastomeric materials and becoming shaped according to corresponding embedding portions. For example and without limitation, bodies 43, 53, 63, 73 of mesh members 42, 52, 62, 72 may be made of metallic materials, such as perforated metal sheets.

[27] Accordingly, it will be appreciated that a method of manufacturing cushion member 10 includes the steps of providing at least one mesh member 22, 42, 52, 62, 72, and overmolding cushion portion 12 on mesh member 22, 42, 52, 62, 72. The overmolding step further includes the steps of extending body portion 14 and/or sealing portion 13 through mesh member 22, 42, 52, 62, 72 in order to mechanically bond body portion 14 and/or sealing portion 13 to mesh member 22, 42, 52, 62, 72, and extending body portion 14 and/or sealing portion 13 through the plurality of thru holes of mesh member 22, 42, 52, 62, 72.

[28] Although the disclosed concept has been described in association with cushion member 10 being a nasal cushion member, it is within the scope of the disclosed concept to employ any number of mesh members (not shown) substantially the same as mesh members 22, 42, 52, 62, 72 in suitable alternative cushion members (not shown) for patient interface devices, including, but not limited to, pillows style cushion members,

nasal/oral cushion members, and full face cushion members. The disclosed concept may also be used with alternative mask devices, including, without limitation, scuba masks and firefighter masks. It is also within the scope of the disclosed concept to embed any number of mesh members (not shown) substantially the same as mesh members 22, 42, 52, 62, 72 in other suitable members, including, but not limited to, heart rate monitors and/or other devices worn on the wrist or elsewhere, elastomeric frames for patient interface devices, and/or straps for swimming goggles.

[29] For example, FIGS. 9-11 show simplified views of alternative non-limiting embodiments of the disclosed concept. FIG. 9 shows an example heart rate monitor 110 structured to be worn on a wrist of a user. Heart rate monitor 110 includes a body portion 112 and a mesh member 122 (depicted with a curvilinear indicia) embedded in body portion 112. FIG. 10 shows a mask frame 210 for a patient interface device. Mask frame 210 includes a frame member portion 212 and a mesh member 222 (depicted with a curvilinear indicia) embedded in frame member portion 212. FIG. 11 shows a strap member 310 for use with a pair of swimming goggles (not shown). Strap member 310 includes a body portion 312 and a mesh member 322 embedded in body portion 312. Mesh members 122, 222, 322 may be substantially the same as mesh members 22, 42, 52, 62, 72, discussed hereinabove. Accordingly, by incorporating mesh members 122, 222, 322 in the respective portions 112, 212, 312 in substantially the same manner as mesh members 22, 42, 52, 62, 72 and cushion portion 12, the aforementioned mechanical advantages discussed above in association with cushion member 10 likewise apply to heart rate monitor 110, mask frame 210, and strap member 310.

[30] In the claims, any reference signs placed between parentheses shall not be construed as limiting the claim. The word “comprising” or “including” does not exclude the presence of elements or steps other than those listed in a claim. In a device claim enumerating several means, several of these means may be embodied by one and the same item of hardware. The word “a” or “an” preceding an element does not exclude the presence of a plurality of such elements. In any device claim enumerating several means, several of these means may be embodied by one and the same item of hardware. The

mere fact that certain elements are recited in mutually different dependent claims does not indicate that these elements cannot be used in combination.

[31] Although the invention has been described in detail for the purpose of illustration based on what is currently considered to be the most practical and preferred embodiments, it is to be understood that such detail is solely for that purpose and that the invention is not limited to the disclosed embodiments, but, on the contrary, is intended to cover modifications and equivalent arrangements that are within the spirit and scope of the appended claims. For example, it is to be understood that the present invention contemplates that, to the extent possible, one or more features of any embodiment can be combined with one or more features of any other embodiment.

What is Claimed is:

1. A cushion member (10) for a mask structured to be worn on a face of a user, the cushion member comprising:

a cushion portion (12) having a sealing portion (13) and a body portion (14) extending from the sealing portion, the sealing portion being structured to engage the face of the user; and

at least one mesh member (22, 42, 52, 62, 72) embedded in at least one of the sealing portion and the body portion.

2. The cushion member according to claim 1, wherein the at least one of the sealing portion and the body portion extends through the at least one mesh member; and wherein the at least one of the sealing portion and the body portion mechanically bonds to the at least one mesh member.

3. The cushion member according to claim 2, wherein the at least one mesh member has a plurality of thru holes (25, 45, 55, 65, 75); and wherein the at least one of the sealing portion and the body portion extends through each of the plurality of thru holes.

4. The cushion member according to claim 3, wherein the plurality of thru holes are selected from the group consisting of circular-shaped thru holes having a diameter (44) greater than about 0.003 millimeters, elongated slots having a height (54) greater than about 0.003 millimeters, square-shaped thru holes having a side length (64) greater than about 0.003 millimeters, and hexagonal-shaped thru holes having a height (74) greater than about 0.003 millimeters.

5. The cushion member according to claim 1, wherein the cushion portion has a first modulus of elasticity; and wherein the at least one mesh member has a second modulus of elasticity less than the first modulus of elasticity.

6. The cushion member according to claim 1, wherein the at least one of the sealing portion and the body portion comprises a first embedding portion (15); wherein the at least one mesh member comprises a first mesh member (22) embedded in the first embedding portion; and wherein the first mesh member is shaped substantially the same as the first embedding portion.

7. The cushion member according to claim 1, wherein the at least one mesh member is made of a fabric material; and wherein the cushion portion is made of an elastomeric material.

8. The cushion member according to claim 1, wherein the mask is a patient interface device.

9. A method of manufacturing a cushion member (10) comprising the steps of:

providing at least one mesh member (22, 42, 52, 62, 72); and

overmolding a cushion portion (12) on the at least one mesh member, the cushion portion having a sealing portion (13) and a body portion (14) extending from the sealing portion, the sealing portion being structured to engage a face of a user, the at least one mesh member being embedded in at least one of the sealing portion and the body portion.

10. The method according to claim 9, wherein the overmolding step further comprises:

extending the at least one of the sealing portion and the body portion through the at least one mesh member in order to mechanically bond the at least one of the sealing portion and the body portion to the at least one mesh member.

11. The method according to claim 10, wherein the at least one mesh member has a plurality of thru holes (25, 45, 55, 65, 75); and wherein the overmolding step further comprises:

extending the at least one of the sealing portion and the body portion through each of the plurality of thru holes.

12. The method according to claim 11, wherein the plurality of thru holes are selected from the group consisting of circular-shaped thru holes having a diameter (44) greater than about 0.003 millimeters, elongated slots having a height (54) greater than about 0.003 millimeters, square-shaped thru holes having a side length (64) greater than about 0.003 millimeters, and hexagonal-shaped thru holes having a height (74) greater than about 0.003 millimeters.

13. The method according to claim 9, wherein the cushion portion has a first modulus of elasticity; and wherein the at least one mesh member has a second modulus of elasticity less than the first modulus of elasticity.

14. The method according to claim 9, wherein the at least one mesh member is made of a first material; and wherein the cushion portion is made of a second material different than the first material.

15. The method according to claim 14, wherein the first material is a fabric material; and wherein the second material is an elastomeric material.

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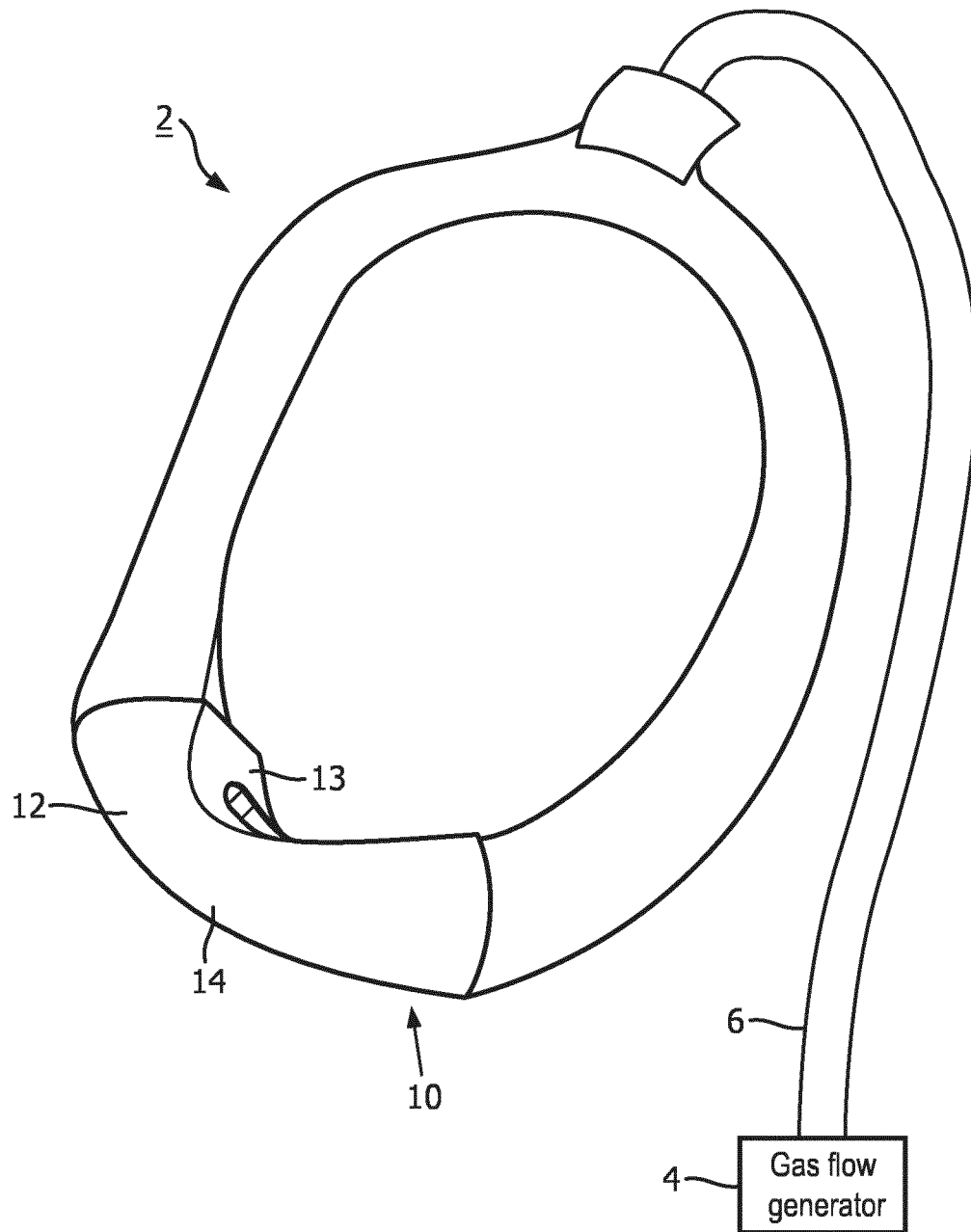


FIG. 1

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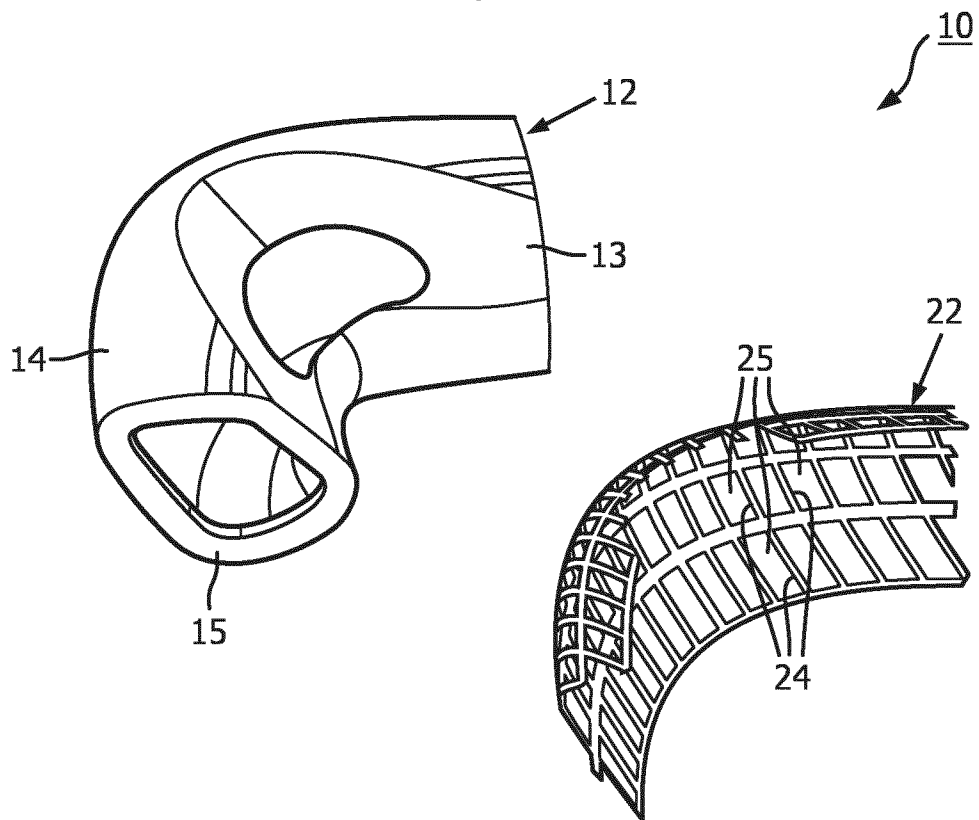


FIG. 2

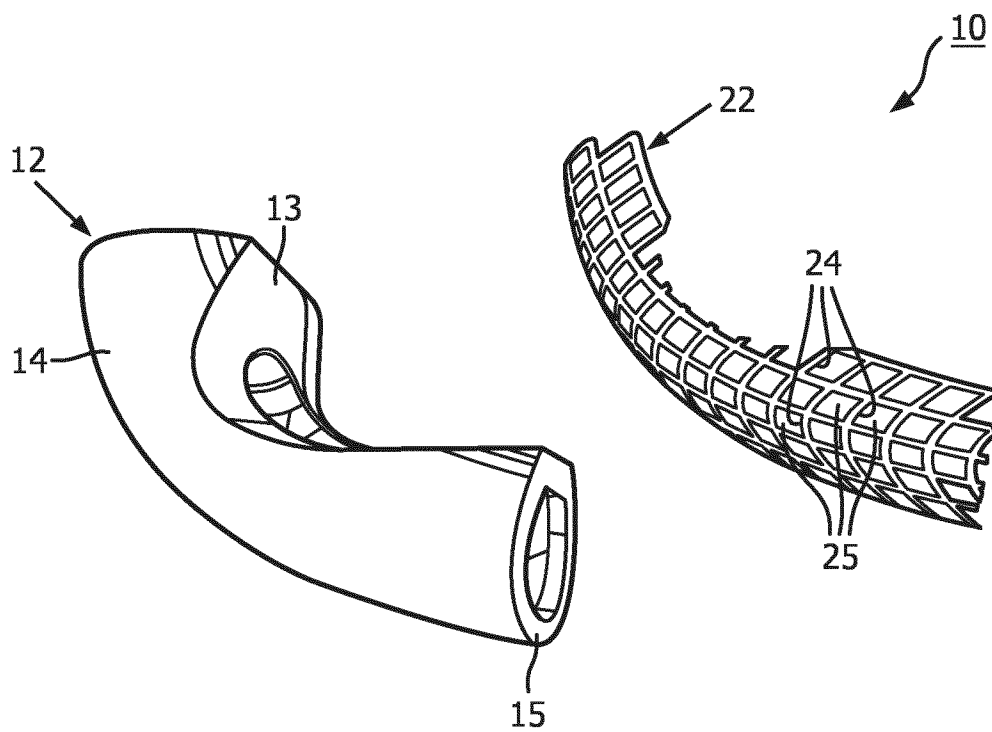


FIG. 3



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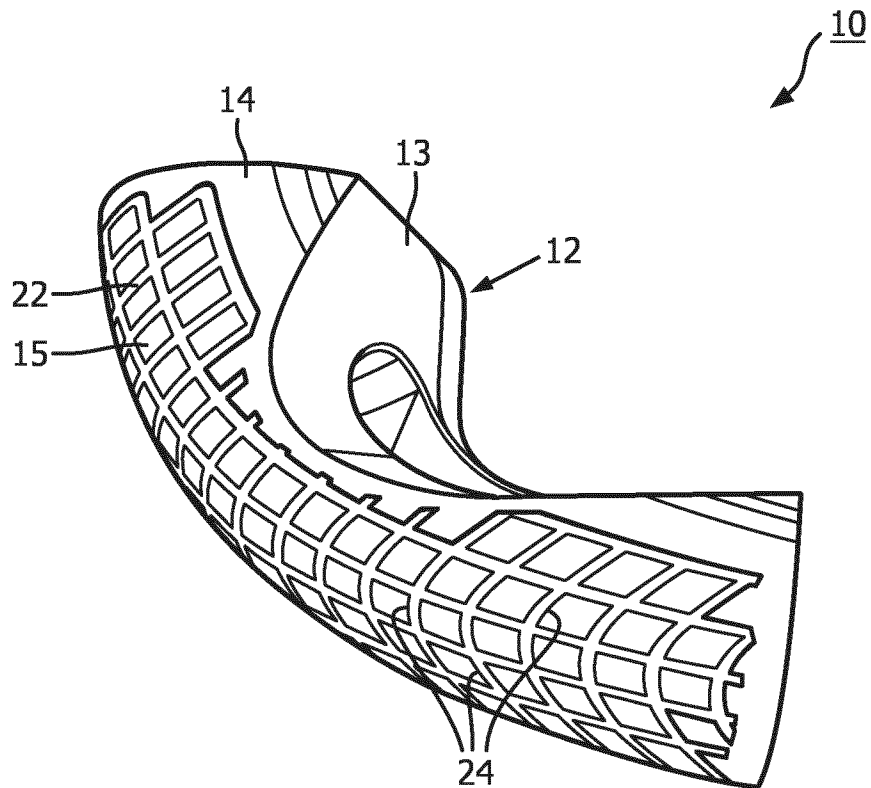


FIG. 4

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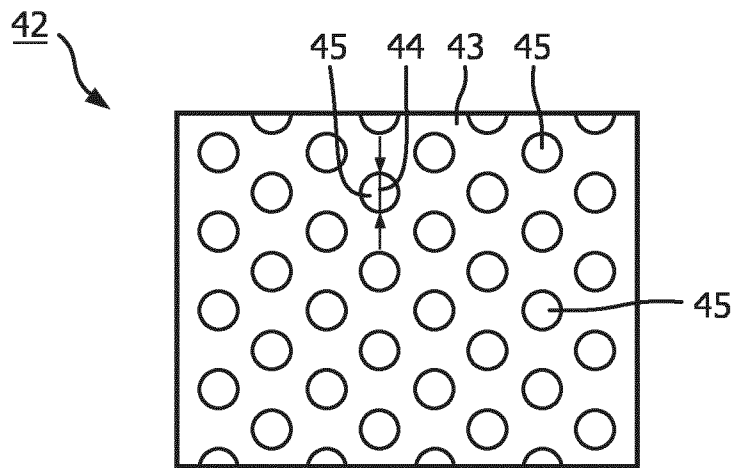


FIG. 5

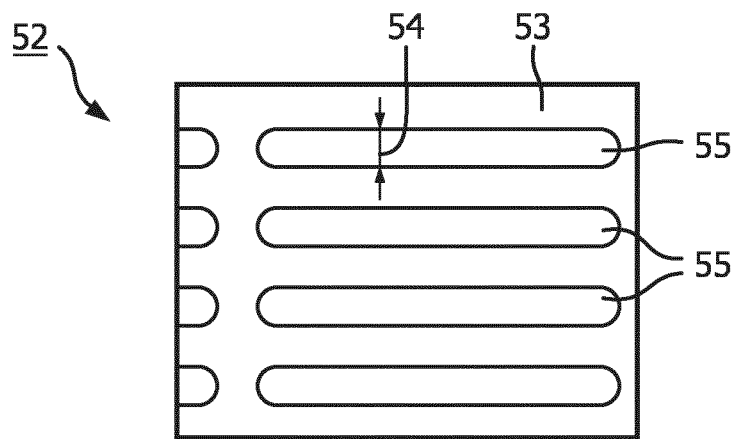


FIG. 6

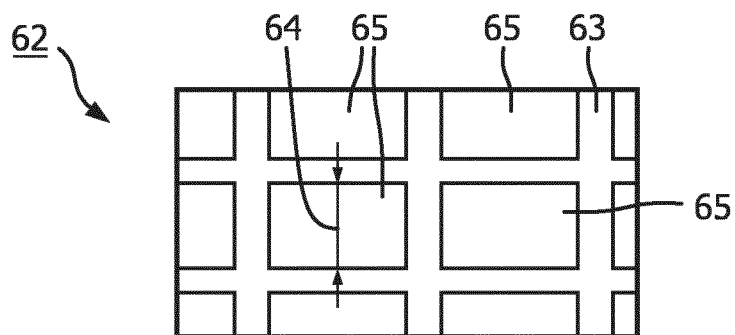


FIG. 7

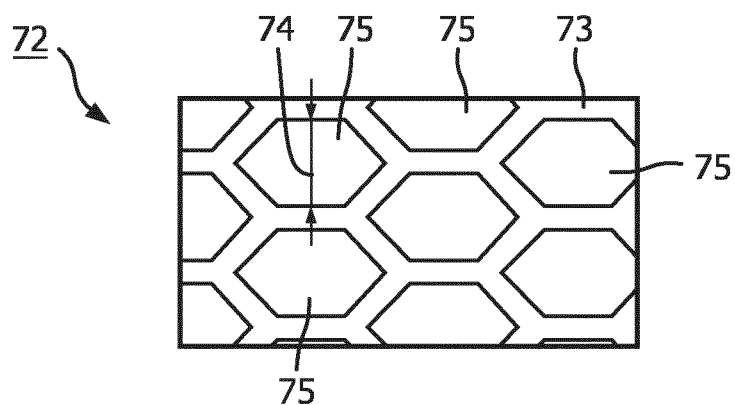


FIG. 8

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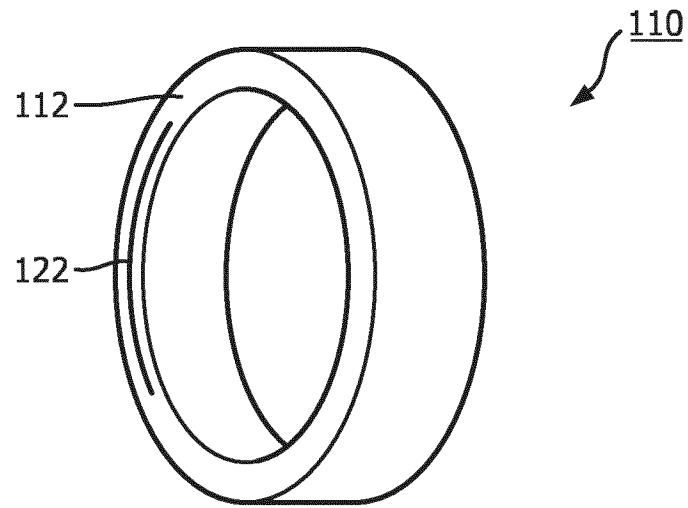


FIG. 9

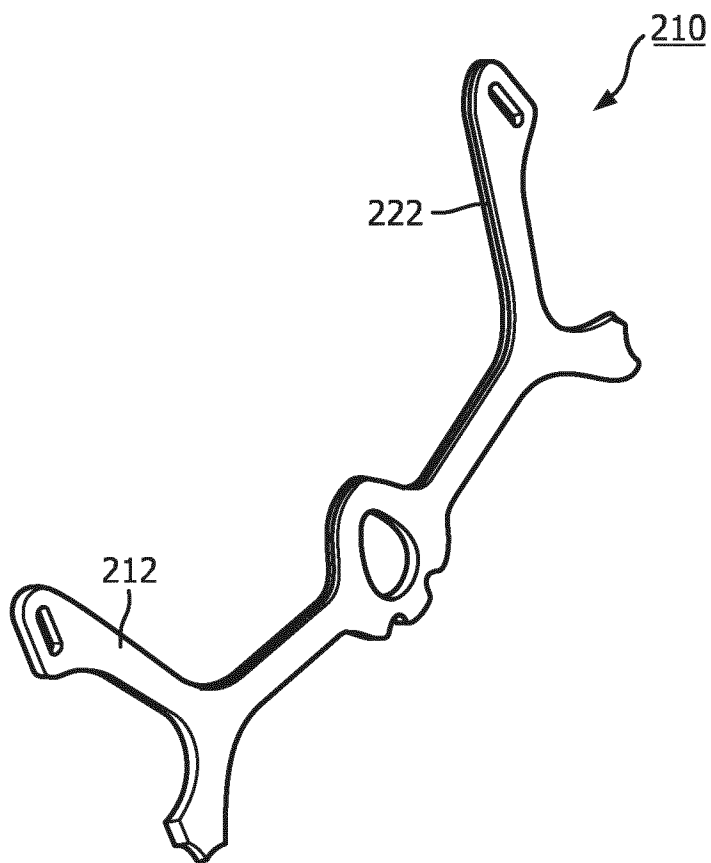


FIG. 10

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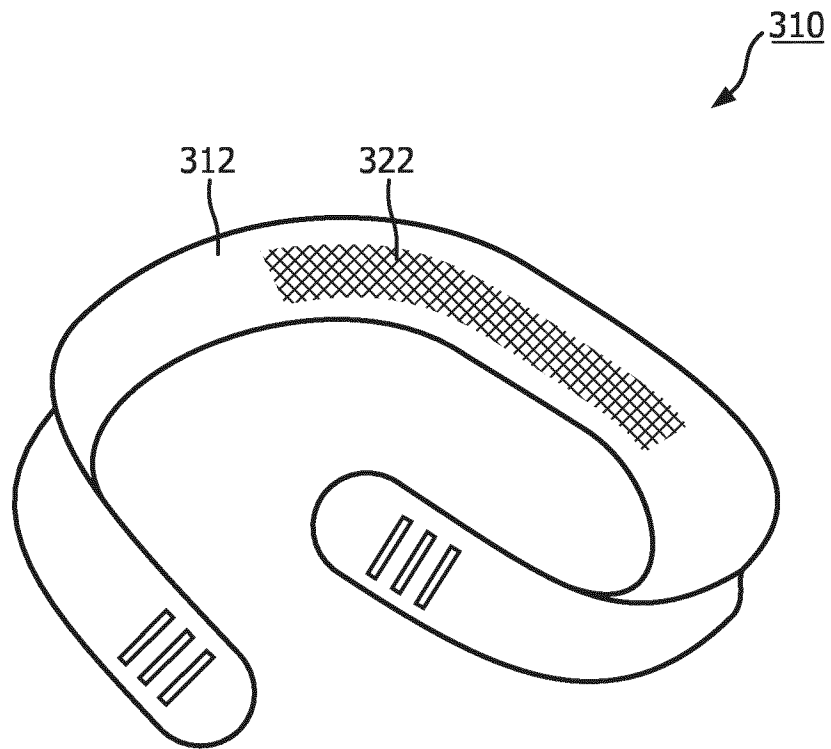


FIG. 11

## INTERNATIONAL SEARCH REPORT

International application No  
PCT/EP2017/063236

A. CLASSIFICATION OF SUBJECT MATTER		
INV.	A61M16/06 B29D99/00	A61B5/024 A62B18/02 A63B33/00 B29C45/00
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 A61B A62B A63B B29C B29D		
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		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/229868 A1 (RUMMERY GERARD MICHAEL [AU] ET AL) 16 September 2010 (2010-09-16) paragraphs [0176], [0180], [0185]; figure 8f -----	1-15
X	US 6 152 137 A (SCHWARTZ ALAN N [US] ET AL) 28 November 2000 (2000-11-28) column 7, line 58 - column 8, line 13 column 14, line 52 - column 15, line 37 figures 14,22,23,25 -----	1-5,9-12
A	WO 2013/084109 A1 (KONINKL PHILIPS ELECTRONICS NV [NL]) 13 June 2013 (2013-06-13) paragraph [0045]; figure 4 ----- -/-	1-15
<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  31 July 2017		Date of mailing of the international search report  09/08/2017
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  Borowski, Aleksander

## INTERNATIONAL SEARCH REPORT

International application No  
PCT/EP2017/063236

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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