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(71) Applicant: **Universita' Degli Studi "G. d'Annunzio"
Chieti-Pescara
66013 Chieti (IT)**

(72) Inventor: **TRIPODI, Domenico
66013 CHIETI SCALO (IT)**

(74) Representative: **Currado, Luisa et al
Cantaluppi & Partners
Viale della Tecnica, 205
00144 Roma (IT)**

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(54) **MOUTHPIECE OF DIVING REGULATOR OF AQUALUNG AND/OR SNORKEL SUPPORTING THE COMPLETE DENTAL ARCH**

(57) Mouthpiece of diving regulator of aqualung and/or snorkel comprising a tubular connection portion (2) wherein said tubular connection portion has a through hole (3) internally engaged at a distal portion (4) with a complementary tubular portion of said aqualung and/or snorkel to allow the air passage; and a bite (5) connected to said tubular connection portion at the lower edge (6) of the proximal end (7) extending complete arch acting as a support for a dental arch.

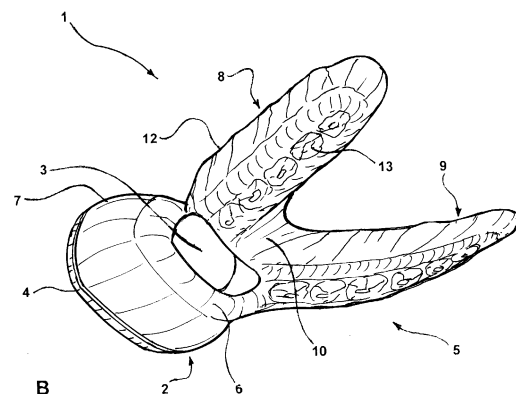
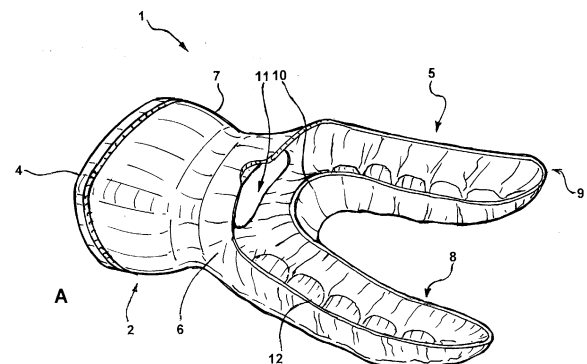


FIG.1

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Description**Field of the Invention**

5 **[0001]** The present invention refers to the field of diving equipment and in particular to a mouthpiece of diving regulator of aqualung and/or snorkel having a particular shape, so as to fit to a complete dental arch, namely the upper dental arch, and allowing the user to hold it into the mouth without any stress, i.e. without applying a force to bite a bite portion inside the mouth.

10 **State of the art**

[0002] Many mouthpieces of diving regulator of aqualung and/or snorkel are known in the art, and many of them can be customized on the user's mouth and teeth.

15 **[0003]** International patent application No. WO 2008/013529 A1 discloses a customizable and reusable breathing apparatus comprising a non-deformable U-shaped core member and bitewings of elastomeric material, located in the distal portion of the legs of said U-shaped member and along the horizontal bite plane, having a cavity with channels for gas or liquid flow wherein said bitewings of elastomeric material fill the cavity partially or completely. Said bitewings are deformed by one user's dental impression but return to the original shape after use, so that they are customized when used but can be reused by another individual with a different dental impression.

20 **[0004]** European patent No. EP 1,005,386, US patent No. 5,865,170, US patent No. 5,305,741 and International Patent application No. WO 99/04859 disclose several U-shaped customizable mouthpieces presenting, in the distal portion of the leg portions arms of the U-shaped member and along the horizontal bite plane, flanges of thermo-formable material which can mold on the user's teeth.

25 **[0005]** US patent No. 5,031,611 in turn discloses some U-shaped customizable mouthpieces wherein the leg portions are completely made of thermo-formable material so that they can assume the mold of upper and lower lateral portion of user's teeth.

[0006] French patent No. 2,700,473 discloses a mouthpiece for patients with respiratory failure such as myopathy or tuberculosis, not for diving regulator. Said mouthpiece comprises a bite leaning on both the upper and lower dental arch, which need to be bitten with a certain strength.

30 **[0007]** Also US Patent No. 3,107,667 discloses a U-shaped diving mouthpiece wherein the bite portion leans on the dental arch and should be retained into the mouth of the user by biting it.

[0008] Mouthpieces, known in the art, have lateral portion helping the retention of the mouthpiece in the mouth.

35 **[0009]** In the devices known in the art, the action of retaining the mouthpiece in the mouth is performed in two ways: by tightening the teeth, usually involving molars and bicuspid, i.e. only the lateral portions of each dental semi-arch, or because the device leans on the teeth, on the upper dental arch, on the lower dental arch or both.

[0010] Customizable mouthpieces, known in the art, present lateral portion to be bite by the user which are made of suitable deformable material wherein the dental mold, corresponding to molar and bicuspid, can be impressed.

[0011] The above mentioned deformable material warps, upon heating, so that is the same user who stamps the teeth mold on the mouthpiece, biting it.

40 **[0012]** On some materials the mold is permanent while on other material the mold can be deleted by heating so it can be impressed again by further uses.

[0013] The mouthpieces known in the art present some drawbacks: for example they should be kept in the mouth by biting, involves only the lateral portion of dental semi-arch, corresponding to molar and bicuspid.

45 **[0014]** The step of keeping the mouthpiece in the mouth by biting it affects breathing through aqualung/snorkel because Masticatory Muscles tighten the mouthpiece in the buccal cavity.

[0015] Furthermore, in the customizable mouthpieces, known in the art, the molding of the dental impression on the mouthpiece is done by the same user by biting the portions made of deformable material in a much or more precise way.

50 **[0016]** The mouthpiece of the present invention overcomes the drawbacks of the devices known in the art because it wedges in the upper dental arch and gets stuck to the entire dental arch. In this way no muscle effort is needed to maintain the mouthpiece in the mouth.

[0017] Moreover, the shape of the mouthpiece of the present application, supporting the entire dental arch of the user, facilitates the use and improves breathing efficiency.

Object of the invention

55 **[0018]** The technical problem of the present invention is solved by providing a mouthpiece of diving regulator of aqualung and/or snorkel:

a tubular connection portion and a bite;

wherein the a tubular connection portion present a through hole internally engaged at a distal portion thereof with a complementary tubular portion of said aqualung and/ or snorkel to allow the air passage;

and said bite is connected to said tubular connection portion at the lower edge of the proximal end thereof, so as to symmetrically extend on both sides thereof;

aid mouth pieces is characterised in that the bite extends on a complete arch acting as a support for a dental arch,

and said bite and said tubular connection portion a hole is formed in connection with said through hole,

wherein at said arch arms the bite portion has a U-shaped cross section, so as to wrap the user's teeth at his upper dental arch at both sides thereof.

[0019] Further characteristic of the present invention will be clear from the following detailed description with reference to the attached drawings.

Brief description of the drawings

[0020]

In figure 1: view 1A shows an upper prospective view of the mouthpiece, and view 1B shows a lower prospective view of the mouthpiece.

Figure 2 shows the mouthpiece connected to a diving regulator of aqualung.

Figure 3 shows the mouthpiece connected to a snorkel.

Figure 4 shows how the mouthpiece wedged in the upper dental arch of an individual.

Detailed description of the Invention

[0021] With reference to figure 1, the mouthpiece 1 according to the present invention, is disclosed.

[0022] Said mouthpiece 1 can be connected both to a diving regulator of aqualung and to a snorkel, as disclosed in figures 2 and 3.

[0023] The mouthpiece 1 is made of two main parts: a tubular connection portion 2 and a bite portion 5.

[0024] The tubular connection portion 2 connect the mouthpiece to the aqualung or to the snorkel; in fact, presenting a through hole 3, internally engaged at a distal portion 4 therefor with a complementary tubular portion of said aqualung or snorkel to allow the air passage from the diving regulator through the tubular connection portion in the user's mouth, allowing breathing.

[0025] The bite portion 5 is connected to said tubular connection portion 2 at the lower edge 6 of the proximal end 7 thereof. Between said bite portion 5 and said tubular connection portion 2 a hole 11 is formed, in connection with the through hole 3 allowing the air flow in the user's mouth.

[0026] The bite portion 5 supports the whole user's dental arch thanks to it shape of a complete arch.

[0027] More in detail, said bite portion 5 has the a shape of a complete dental arch, namely the upper dental arch, and it comprises two arch arms 8, 9 respectively and a central portion 10 and further comprises a hollowed cross-section wherein the complete dental arch of the user is mold.

[0028] At said arch arms 8, 9, the bite portion 5 has a U-shaped cross section, so as to wrap the user's teeth at his upper dental arch at both sides thereof.

[0029] In particular, the proximal edge of bite 5 has a protruding border 12 extending through the whole length of the central portion 10 and the whole length of the arch arms 8, 9, allowing the bite to engage to the user's upper dental arch teeth. In this way, the mouthpiece is kept into the mouth not because the user is biting it but because, thanks to its shape, the bite lean on the complete dental arch.

[0030] A better grip is due to the mold of the user's teeth and the protruding border which get stuck with the upper dental arch of the user.

[0031] Perfect dental occlusion of user's teeth is due to the mold of the lower dental arch which is impressed in the lower surface of the bite 5.

[0032] In a preferred embodiment, as showed in figure 2, the mouthpiece 1 of the present invention is connected to a diving regulator aqualung by means the through hole 3 of tubular connection portion 2 internally engaged at the distal portion 4 thereof with the complementary tubular portion of said aqualung.

[0033] The mouthpiece of the present invention can be made of any plastic polymeric material or non-allergenic rubber such as ethylene-vinyl acetate or silicon.

[0034] As an example the mouthpiece of the present invention is manufactured by a process providing the steps of: obtaining a dental mold of a user; optionally preparing a cast of said mold, and printing and/or modeling the bite of the mouthpiece based on said mold.

[0035] Within the meaning of the present invention, obtaining a dental mold means all the steps allowing to imprint on a suitable moldable material, such as alginates or silicon, the shape of the dental arch of the user, wherein the dental arch is the upper dental arch or the lower dental arch or both, according the ordinary dental techniques or alternatively the steps allowing processing digital data revealed with a video camera or intra-oral scanner in a three dimensional pattern of user's teeth.

[0036] Within the meaning of the present invention, mold means a model of the object to be realized on the basis of the dental mold.

[0037] Within the meaning of the present invention, printing and/or modeling means preparation of the product by means of any printing technique or manufacturing technique by means digital processing and three dimensional printing.

[0038] For example, the dental mold of a user is taken by means of a impression try filled with alginate or another silicon material and rimmed with wax, and the occlusal registration is controlled. After, a chalk model is prepared and transferred on a articulator, finally an individual impression try and a mold of the tubular connection portion of the mouthpiece is made and said elements are connect together using resin or chalk.

[0039] The so obtained model is inserted in a thermo-printing machine loaded with one or two sheets of ethylene-vinyl acetate of suitable thickness, optionally stained as desired, and two steps of thermo-printing are performed, one occlusal and the other on the opposite side. The so obtained product is rough-cut and finished in an articulator.

[0040] Alternatively, the model is prepared by means of the negative-model technique in a lab muffle, by injecting the resin in the muffle followed by hardening in a pressure cooker.

[0041] As a further example, the mouthpiece of the present invention can be manufactured by a process providing the prior digital acquisition of the dental record of upper and lower dental arches of the user and of the tubular connection portion of the mouthpiece by means of an intra-oral scanner; followed by tridimensional designing, with a suitable digital software, of the dental arches and the mouthpiece, linking each digital scans for digital printing of the mouthpiece followed by optional mechanical finishing of the product.

[0042] All the manufacturing processes provide storage and duplication of the product for optional changes to be done after use.

[0043] The innovative manufacturing shows many advantages.

[0044] Mainly, the mouthpiece of the present invention should not be retain by the user by biting it, giving complete freedom of mandibular movement avoiding prolonged stress for Masticatory Muscles, resulting useful and comfortable especially during professional or sport diving.

[0045] Furthermore, the spirometry essays, herein reported, demonstrated that the particular shape of the mouthpiece of the present invention avoid that the whole oral cavity is engaged with the mouthpiece, thus ameliorating breathing efficiency in comparison to mouthpieces known in the art.

[0046] Additionally, the mouthpiece of the present invention is much safer in dangerous situations in comparison to mouthpieces known in the art. In case of fainting, sudden illness or tetany, a common mouthpiece is released because of weakness of masticatory muscles while the mouthpiece of the present invention is retained in the mouth without muscular effort so it cannot be expelled or lost, allowing the diver to breath.

[0047] Since the mouthpiece of the present invention is passively retained in the mouth it can be used by individual with disease or disability causing weakness of masticatory muscles or difficulty in retaining a common mouthpiece in the mouth.

[0048] The mouthpiece of the present invention can be used by totally or partially edentulous patients without wearing dental prosthesis.

[0049] A further advantage of the mouthpiece of the present invention is that teeth mold is precisely and customized impressed in the bite during manufacturing thanks to dental technology to obtain a final product perfectly fitting with the teeth of the user, thus rendering, the mouthpiece of the present invention more comfortable and suitable for curing temporal-mandibular diseases.

[0050] The so-obtained precise teeth mold allow to manufacture a durable and long lasting mouthpiece because the material of which it is composed is less subject to thinning and breakage in comparison to the already known mouthpieces wherein the mold is empirically made by the individual before use.

Examples

[0051] Three devices were compared: common or traditional mouthpiece, customizable "boil and bite" mouthpiece and the mouthpiece of the present invention. Spirometry, electromyography and stabilometry were performed together with in water tests with each single patient.

[0052] Sixteen (16) patients with average age 30 years were divided in two groups. Group A composed by professional divers and group B composed by patients non-professional divers including two patients with dysfunctions. Dental and sport-medicine examinations were performed on each single patient before using the devices, followed by dental mold for manufacturing personal devices and optionally modify dental occlusion after clinical and instrumental gnathological examination (stabilometric footboard and electromyography) and laboratory steps ending with the of consignment personal devices.

[0053] Three devices were compared for every single diver; common or traditional mouthpiece, customizable "boil and bite" mouthpiece and the mouthpiece of the present invention.

Spirometry

[0054] Spirometry was performed in C.U.M.S. nel Reparto di Medicina dello Sport dell'Università di Chieti. Assay performed on each patient with all the different mouthpieces evaluating the following parameters: Tidal Volume VC, Forced expiratory volume in 1 second FEV1, FEV1/FVC Tiffeneau index i.e. ratio between FEV1 and Forced vital capacity FVC, FEV1/VC i.e. ration between FEV1 (Forced expiratory volume in 1 second) and VC (Tidal Volume), peak expiratory flow PEF, maximal expiratory flow at 75% of FVC MEF75, , maximal expiratory flow at 50% of FVC MEF50, maximal expiratory flow at 25% of FVC MEF25.

[0055] Spirometry assays show the improvement of Tidal Volume VC, Forced expiratory volume FEV, peak expiratory flow PEF using the mouthpiece of the present invention and known common mouthpiece and "boil and bite" as shown in the results in table 1, wherein for each parameter the predefined percentage used as control is reported (%Pred.).

Table 1

| common mouthpiece | | boil and bite | | invention | | invention | | PARAMETER |
|-------------------|--------|---------------|--------|-----------|--------|-----------|--------|-----------|
| | %PRED. | | %PRED. | | %PRED. | | %PRED. | |
| 4,56 | 96 | 5,10 | 107 | 5,28 | 111 | 5,29 | 111 | VC |
| 3,99 | 107 | 4,38 | 118 | 4,53 | 122 | 4,63 | 125 | FEV1 |
| 88 | 111 | 86 | 109 | 86 | 109 | 87 | 111 | FEV1/FVC |
| 76 | 96 | 83 | 105 | 86 | 109 | 88 | 111 | FEV1/VC |
| 8,14 | 91 | 8,23 | 92 | 8,65 | 97 | 8,62 | 97 | PEF |
| 8,13 | 105 | 8,00 | 103 | 8,52 | 110 | 8,14 | 105 | MEF75 |
| 6,07 | 125 | 7,1 | 146 | 5,48 | 113 | 7,36 | 151 | MEF50 |
| 2,15 | 106 | 2,24 | 110 | 3,07 | 151 | 2,66 | 131 | MEF25 |

Electromyography

[0056] Electromyography was performed on temporal and masseter muscles, evaluating the muscular effort with every type of mouthpiece with BTS Tmjjoint system (BTS Bioengineering Corp./USA). The data from electromyography, as shown in figure 4, underlines ameliorate performance with the mouthpiece of the present invention in comparison with those of the prior art (data not shown).

Use evaluation

[0057] All the patient submit a questionnaire regarding the use of the three different types of mouthpiece, considering: facility of positioning, of inhalation and exhalation, comfort, adaptability, encumbrance, seal, safety, durability, wear and damage, anchorage, possibility of speaking or moving the jaw or chew.

[0058] From the submitted questionnaires, all the patients reported, with the mouthpiece of the present invention in comparison with those known in the art, easy positioning, easy of inhalation and exhalation, enhanced comfort, adaptability, reduced encumbrance, enhanced seal, safety, enhanced retaining in the mouth (time), reduced wear and damage,

enhanced anchorage, ability of speaking or moving the jaw or chew.

Claims

1. Mouthpiece of diving regulator of aqualung and/ or snorkel (1) comprising:

a tubular connection portion (2) with a through hole (3) internally engaged at a distal portion (4) thereof with a complementary tubular portion of said aqualung and/ or snorkel to allow the air passage;
a bite portion (5) connected to said tubular connection portion (2) at the lower edge (6) of the proximal end (7) thereof:

characterised in that the bite portion (5) symmetrically extends at both the sides of said tubular connection portion (2), on a complete arch having two arch arms (8, 9) and a central portion (10) acting as a support for a dental arch, wherein between said bite portion (5) and said tubular connection portion (2) a hole (11) is formed in connection with said through hole (3), and wherein, at said arch arms (8, 9), the bite portion (5) has a U-shaped cross section, so as to wrap the user's teeth at his upper dental arch at both sides thereof.

2. Mouthpiece according to claim 1, wherein the bite portion (5) has a cross-section hollowed at least at the central portion (10), so as to produce a protruding border on the proximal edge (12) of said bite portion (5).

3. Mouthpiece according to claim 2, wherein on the bite (5) a mold is made of a complete upper dental arch.

4. Mouthpiece according to any of the preceding claims, made of polymeric plastic material or non-allergenic rubber.

5. Mouthpiece according to claim 4, wherein the non-allergenic plastic material is ethylene-vinyl acetate or silicone.

6. Process for the manufacture of the mouthpiece according to any of the preceding claims, comprising the following steps: obtain a dental impression from a subject, optionally generating a mold form said dental impression and printing and/or moulding the bite according to said impression.

7. Diving regulator of aqualung comprising the mouthpiece of any of claims from 1 to 5.

8. Diving snorkel comprising the mouthpiece of any of claims from 1 to 5.

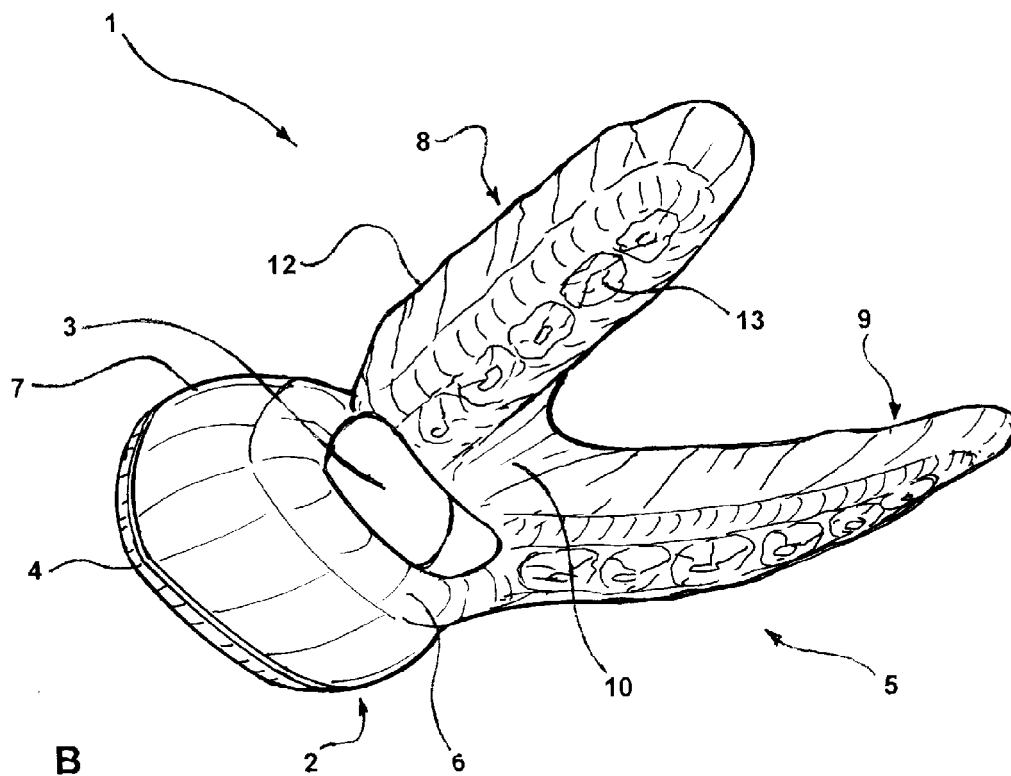
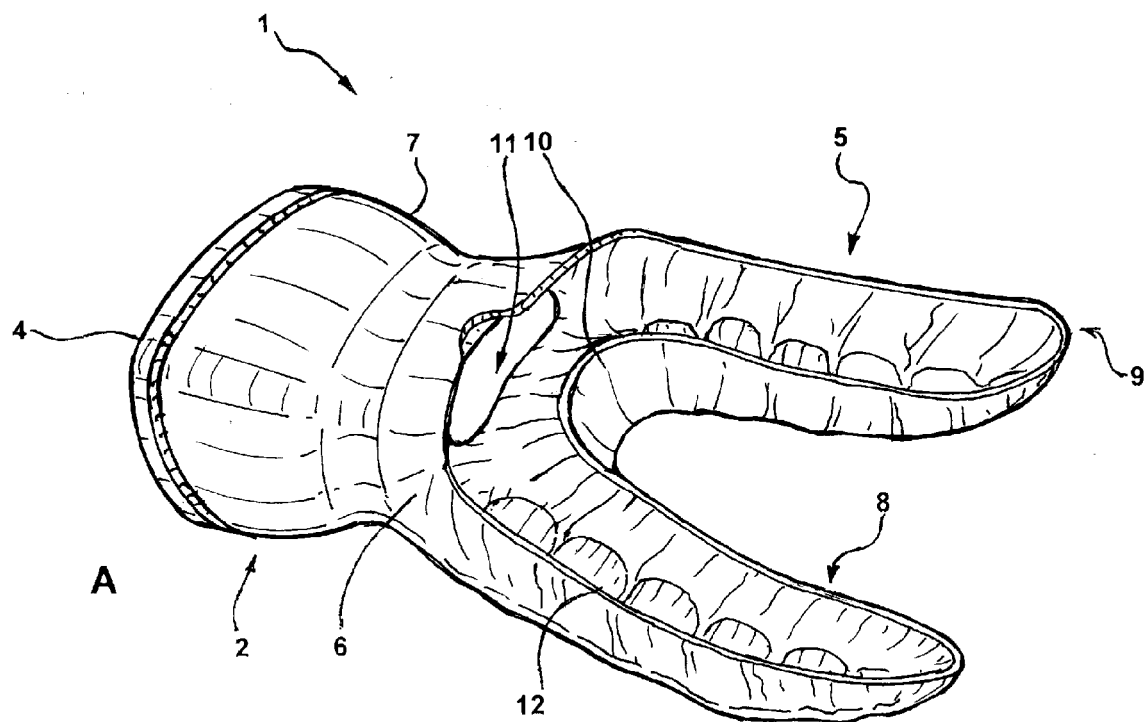


FIG. 1

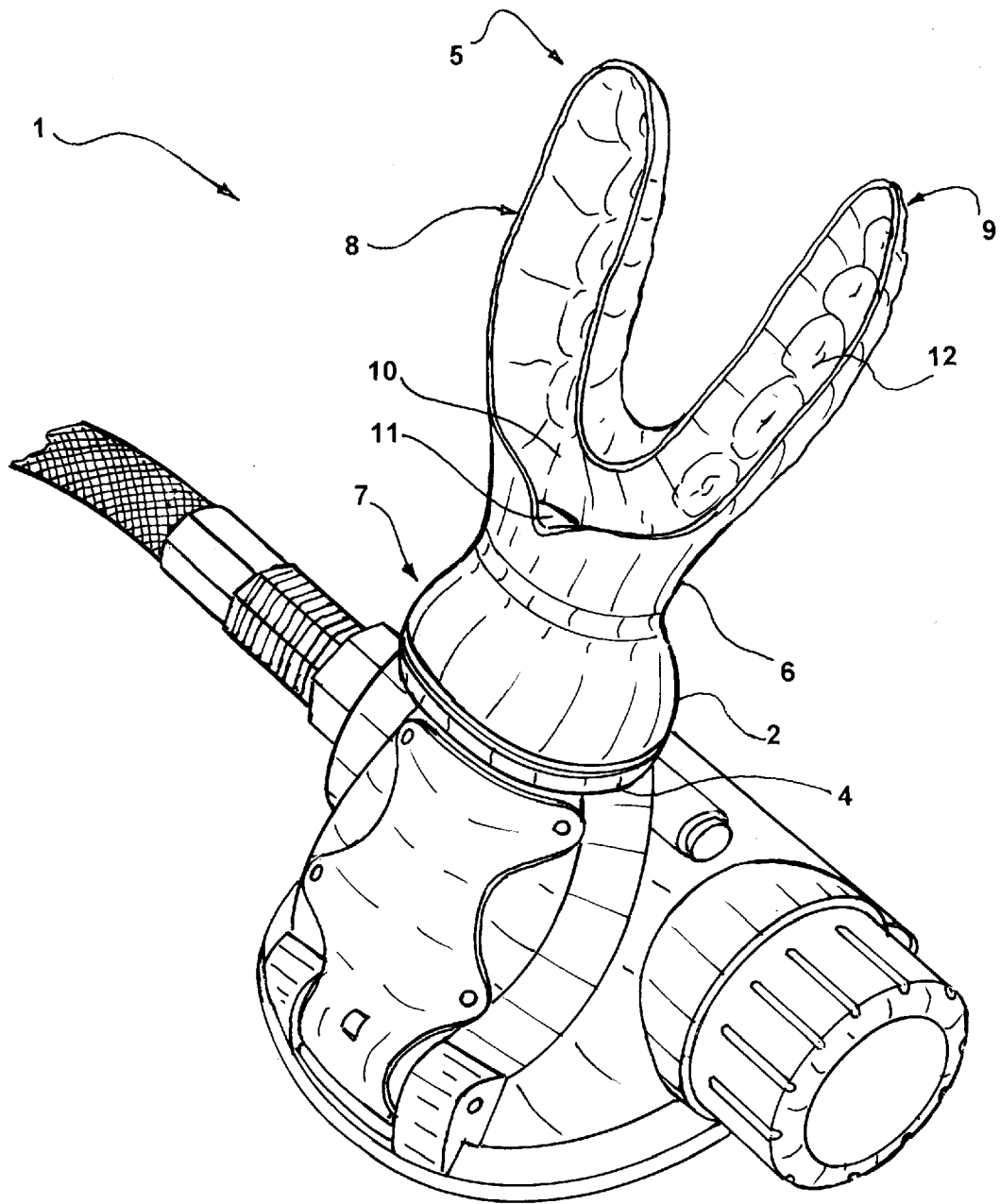


FIG.2

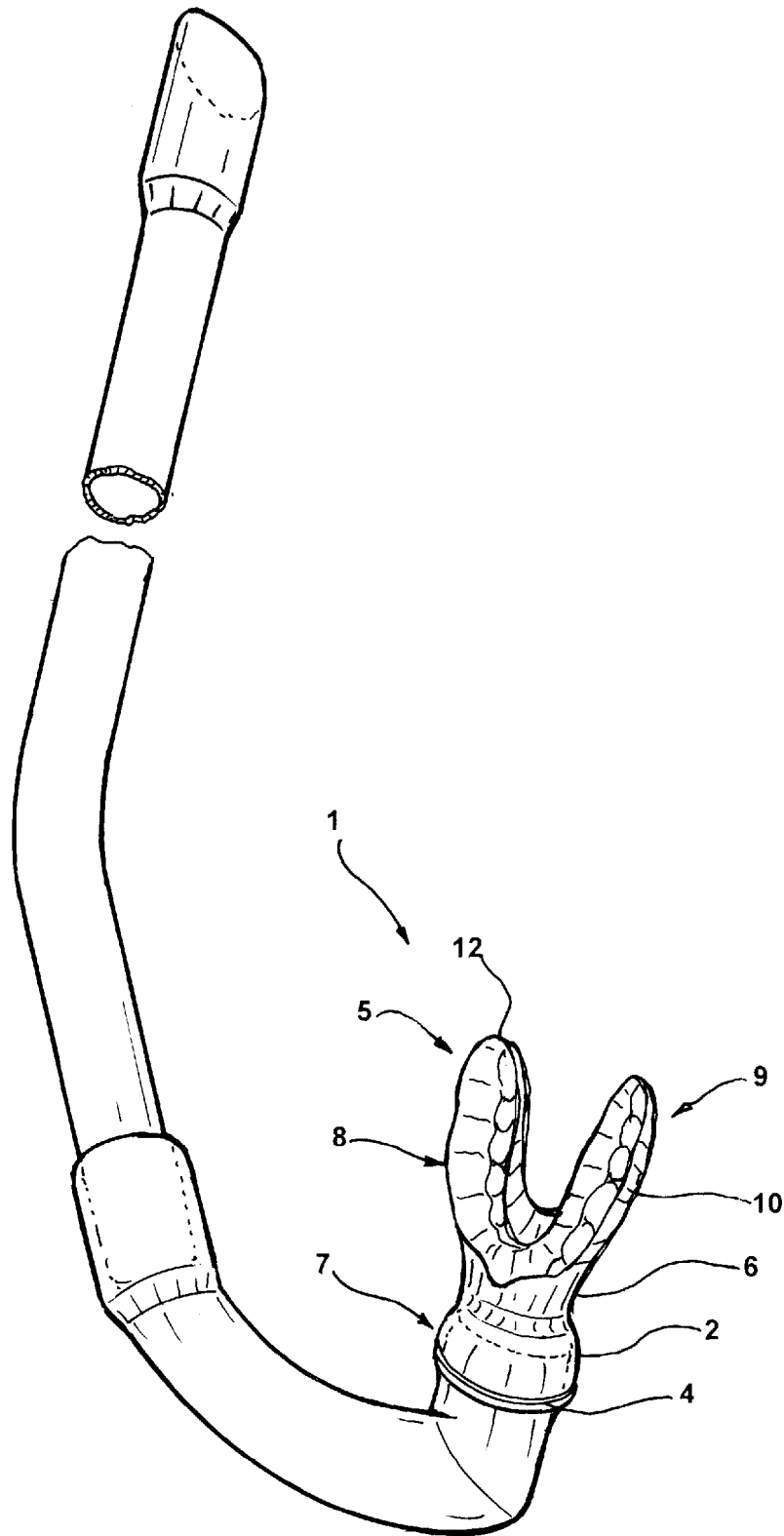


FIG.3



EUROPEAN SEARCH REPORT

 Application Number
EP 16 15 1871

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| | | | TECHNICAL FIELDS SEARCHED (IPC) |
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| The present search report has been drawn up for all claims | | | |
| Place of search The Hague | | Date of completion of the search 20 May 2016 | Examiner Székely, Zsolt |
| CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document | | | |

EPO FORM 1503 03/82 (P04C01)

**ANNEX TO THE EUROPEAN SEARCH REPORT
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5 This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
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20-05-2016

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