

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
12 October 2006 (12.10.2006)

PCT

(10) International Publication Number
WO 2006/106327 A1

- (51) International Patent Classification:
A61F 5/56 (2006.01)
- (21) International Application Number:
PCT/GB2006/001243
- (22) International Filing Date: 4 April 2006 (04.04.2006)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
0506832.5 4 April 2005 (04.04.2005) GB
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- (81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,

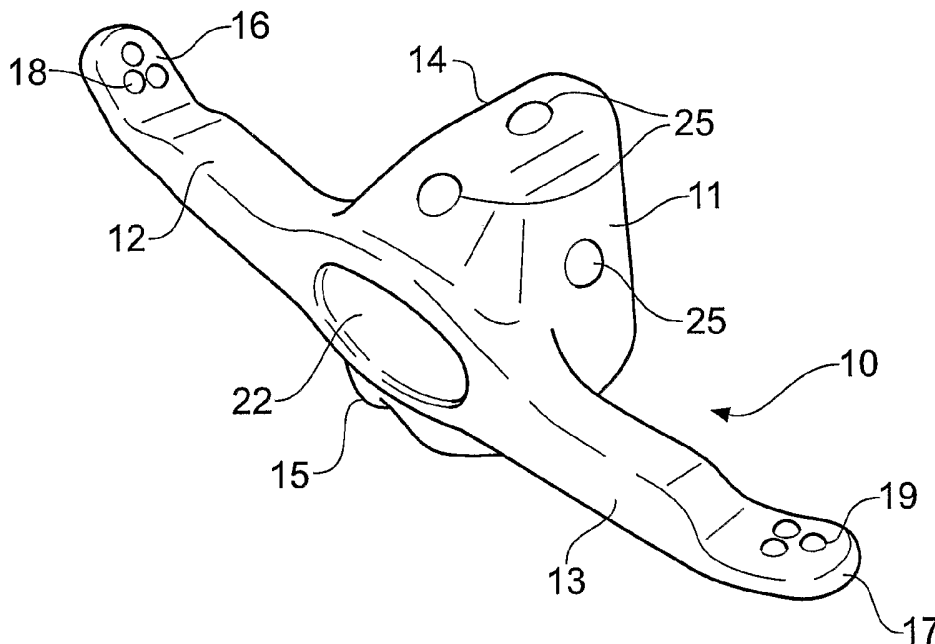
AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,
CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,
GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE,
KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV,
LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI,
NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG,
SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US,
UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,
FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT,
RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA,
GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— with international search report
— before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: ORAL INSERT



(57) Abstract: An oral insert device (10) comprises a resilient body member (11) shaped so as to be accommodated, in use, in the mouth, the body member having a substantially flat rear wall surface (20) and incorporating a cavity (22) with an aperture opening to the rear wall to accommodate the tongue, in use. The device may also include laterally-extending arms (12, 13) which, in use, are gripped between the teeth of the upper and lower jaws and include one or more pressure sensors (25) and associated pressure recordal means.

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Oral Insert

This invention relates to oral inserts and is intended to provide an oral insert device which can be used to exercise the muscles of the lower jaw and tongue and the accompanying lymph nodes, to enhance the removal of waste products from the facial area, and to reduce facial puffiness associated with lymphatic fluid retention.

Movement of the tongue within the oral cavity is controlled by, or has an effect on, various groups of muscles and on lymph nodes, saliva glands and associated vessels located in the vicinity of the mouth and neck. Movement of the lower jaw and tongue therefore influences, among other things, the digestive process and the removal by drainage of waste products which, otherwise, accumulate in and around the facial area, resulting in an appearance of swelling or puffiness especially in the region of the lower jaw.

It is an object of the invention to provide an oral insert device which, by enabling particular muscles to be exercised, facilitates muscle toning and drainage of waste products. In particular, the object of the invention is to enable lifting and toning of the lower jaw muscles for cosmetic purposes; stimulation of the lymph nodes and vessels in and around the tongue, jaw and neck areas to improve the complexion by removal of accumulated toxins; strengthening of the soft palette to reduce or eliminate problems associated with snoring; and to benefit stroke victims by correction of muscle asymmetry caused by strokes, dysphagia or cerebral palsy.

In one aspect, the present invention provides an oral insert device comprising a resilient body member shaped so as to be accommodated, in use, in the mouth, the body member having a substantially flat rear wall surface and incorporating an aperture opening to the rear wall to accommodate the tongue, in use.

Preferably, the body member comprises a generally nose-shaped upper surface profile, a substantially flat lower surface and is arranged to fit in the mouth behind the teeth, the upper profile being accommodated by the forward or front part of the roof of the mouth.

In devices according to the invention, the tongue-receiving aperture isolates the tongue generally in the centre of the mouth cavity, the upper and lower portions of the device, respectively defining the upper and lower walls of the tongue aperture, providing resistance to upward and downward movement of the tongue. When the tongue is urged against the lower wall of the aperture, towards the floor of the mouth, the muscles which are thereby targeted include the genioglossus, the hyoglossus and the styloglossus muscles whereas, when the tongue is urged against the upper wall of the aperture, towards the roof of the mouth, the muscles which are targeted include the mylohyoid, digastric, geniohyoid, platoglossus and stylohyoid muscles.

The nose-shaped upper surface profile of devices according to the invention is intended to enable the device to conform to the roof of the mouth, thereby to provide resistance to upward movement of the tongue substantially without initial distortion or displacement to occupy any free space between the device and the roof of the mouth. The lower surface of the device, intended in use to be located behind the lower teeth and in front of the tongue, preferably has a slot formation to accommodate the frenulum connecting the lower surface of the tongue with the floor of the mouth, behind the front teeth.

Although devices according to the invention are formed from a resilient material, the body member is preferably provided, preferably both below and above the tongue aperture, with apertures or cavities which have the function of increasing the resilience or the ability of the body member to be compressed by the tongue, either against the roof or the floor of the mouth, such apertures preferably opening to the substantially flat rear wall of the device. The apertures or cavities formed for this purpose are preferably blind-ended whereas, by contrast, the tongue aperture preferably communicates with the front or nose tip of the device, to allow expulsion of air as the tongue is inserted from the rear wall. The apertures or cavities may comprise an array of cavities of different diameters or other dimension which, optionally, are capable of being filled either with the same or another material so as to influence the resilience properties either generally or, especially for treatment of particular "one-sided" conditions, on one side or the other of a vertical centre line.

Preferably, devices according to the invention also include laterally-extending arms which, in use, are gripped between the teeth of the upper and lower jaws and, more preferably, extend outside the mouth to facilitate insertion and removal of the device in or from the mouth and also act as a safety measure, to prevent the device from moving towards the throat, for example in an involuntary swallowing action.

In use, the device, which is preferably formed from a biologically-acceptable and tasteless resilient thermoplastic polymeric material such as a urethane elastomeric plastics material, is washed under running water or, at the preference of the user, sterilised in a suitable sterilisation fluid, and inserted in the oral cavity with the tongue engaged in the aperture by insertion from behind the rear wall. Optionally, some or all of the apertures or cavities above and below the tongue aperture are initially filled with either a liquid polymeric material, subsequently allowed to cure, or a palette or cylinder of a pre-formed material which is subsequently removable, to influence the resilience properties, optionally asymmetrically on either side of the centre line. With the device thus in place, the tongue can be exercised to exert pressure in an upwardly and/or downwardly direction, whereby the muscles associated with such movement are exercised and the benefits thereby obtained.

Devices according to the invention may include one or more pressure sensors and associated pressure recordal means. Preferably, the pressure sensors are attached at selected locations to the outer surface of the body member for the purpose of recording pressures applied in a particular direction, for example upwardly, towards the roof of the mouth, by the tongue, or for providing a target pressure and a visual or audible indication that the target pressure has been attained. However, pressure sensors may also be embedded in the body member. Suitable pressure sensors are of the type comprising a diaphragm incorporating a foil strain gauge and Wheatstone bridge circuit and may be attached to the body member of the oral insert device by means of a suitable non-toxic adhesive. Alternatively, electrically conductive particles may be combined with the material of the body member to provide a quantum tunnelling compound for pressure sensing purposes.

Surface breaking electrodes may also be applied to or embedded in devices according to the invention, for the purpose of stimulating muscle movement.

Exercise of the musculature of the tongue and lower jaw results in lifting and toning of the lower jaw without associated muscle growth and, indeed, with reduction in the size of the muscles. Lymphatic drainage of the face, through stimulation of the lymph nodes and vessels of the jaw and tongue, enhances the removal of waste products from the facial area and reduces facial puffiness associated with lymph fluid retention.

Devices according to the invention may also be used during surgery, to restrain the tongue or to prevent its being "swallowed".

Embodiments of the invention will now be described with reference to the accompanying drawings, of which

Figure 1 is a perspective view from above, one side and the front of a device according to the invention, and

Figure 2 is a perspective view from the rear, one side and above of the device of Figure 1.

Referring firstly to Figure 1, the device, shown generally at 10, consists essentially of a body portion 11 with arm or wing members 12, 13 extending laterally from the front part thereof. The body member 11 is generally triangular or nose-shaped in its upper profile 14 and has an under portion 15, as shown more clearly in Figure 2. The arms 12, 13 terminate at their distal ends in flattened portions 16, 17 formed with protrusions 18, 19 for gripping purposes. The device is made from a thermoplastic polymer of the type available from Kraiburg TPE and known as Thermolast K.

With particular reference to Figure 2, the body portion 11 is formed with a flat rear face 20. The lower portion 15 has a longitudinally-disposed central aperture 21 to accommodate, in use, the frenulum. The body portion 11 has a generally oval through-aperture 22 which, in use, accommodates the tongue. The rear wall 20 of the device also contains the openings

of an array of different-sized blind-ended apertures or cavities disposed respectively above, 23, and below, 24, the tongue aperture 22.

In use, the apertures 23, 24 can selectively accommodate solid, optionally resilient, material to alter the compressive or resilient properties of the body portion, formed as it is from a resilient polymeric material.

Referring back to Figure 1, optional pressures sensors 25 are attached to the outer surface of the body portion 11 at selected locations with connections (not shown but which may be wire-less) to reader, display or control means.

Claims

1. An oral insert device comprising a resilient body member shaped so as to be accommodated, in use, in the mouth, the body member having a rear wall surface and incorporating a cavity with an aperture opening to the rear wall to accommodate the tongue, in use.
2. A device according to claim 1, in which the rear wall is substantially planar.
3. A device according to claim 1 or claim 2, in which the body member comprises a generally nose-shaped upper surface profile, a substantially flat lower surface and is arranged to fit in the mouth behind the teeth.
4. A device according to any preceding claim, in which the lower surface of the device includes a slot formation to accommodate the frenulum connecting the lower surface of the tongue with the floor of the mouth, behind the front teeth.
5. A device according to any preceding claim, in which the body member is provided with further apertures or cavities which vary the resilience of the body member.
6. A device according to claim 5, in which the further apertures or cavities open to the rear wall of the device.
7. A device according to any preceding claim, including laterally-extending arms which, in use, are gripped between the teeth of the upper and lower jaws.
8. A device according to any preceding claim, the device including one or more pressure sensors and associated pressure recordal means.
9. A device according to claim 8, in which pressure sensors are embedded in the body member.
10. A device according to claim 8 or claim 9, in which surface breaking electrodes are applied to or embedded in the body member.
11. A method of exercising the lower jaw and/or tongue musculature, the method comprising inserting a device according to any preceding claim in the mouth; inserting the tip end region of the tongue in the tongue-receiving cavity and urging the tongue against the walls of the cavity.
12. A method according to claim 11, in which the device includes further apertures or cavities which are selectively filled with material whereby the resilience properties of the body member are varied.

13. A method according to claim 11 or claim 12, in which the device includes pressure sensors and associated pressure recordal means, the method including recording or regulating pressure applied by the tongue.

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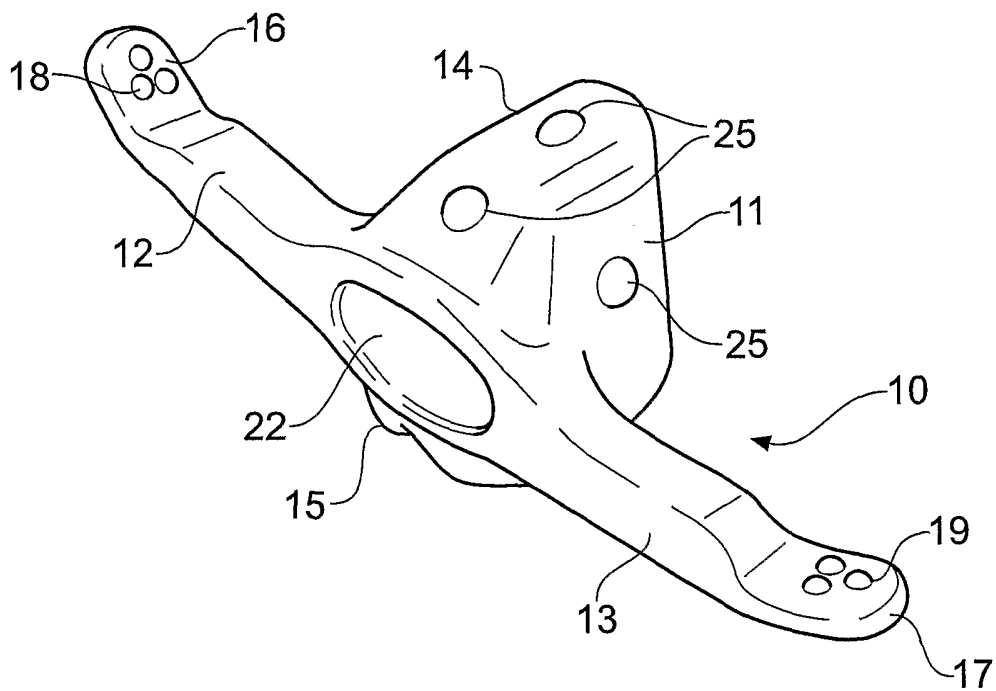


Fig. 1

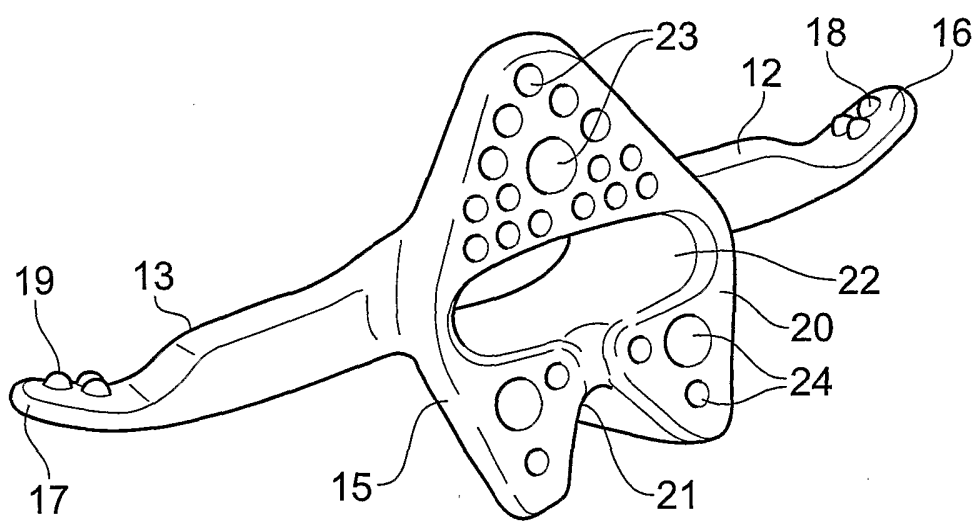


Fig. 2

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2006/001243

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F5/56

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)
A61F

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, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/134490 A1 (ROBERTSON CHRISTOPHER JOHN [NZ] ET AL) 15 July 2004 (2004-07-15)	1, 2, 4
Y		3, 5, 6
Y	page 1, paragraph 19 - page 2, paragraph 21	8-10
Y	----- DE 656 806 C (CARL GOEHLICH) 15 February 1938 (1938-02-15) the whole document	3
X	US 5 465 734 A (ALVAREZ ET AL) 14 November 1995 (1995-11-14) column 4, line 13 - line 64	1
Y	column 5, line 34 - line 41	5, 6
X	US 4 169 473 A (SAMELSON, CHARLES F) 2 October 1979 (1979-10-02) column 3, line 18 - column 4, line 11	1-3, 7
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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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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

10 July 2006

Date of mailing of the international search report

01/08/2006

Name and mailing address of the ISA/
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Mingrino, A

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2006/001243

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6 089 864 A (BUCKNER ET AL) 18 July 2000 (2000-07-18) column 4, line 56 - column 5, line 16 -----	8-10
A	US 6 055 986 A (MEADE ET AL) 2 May 2000 (2000-05-02) the whole document -----	1-10
A	US 2004/211430 A1 (PIVOVAROV ALEXANDER R) 28 October 2004 (2004-10-28) the whole document -----	1-10
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A	DE 407 949 C (AMALIE DRAGUHN GEB. GOTHKNECHT) 5 January 1925 (1925-01-05) the whole document -----	3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2006/001243

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 11-13
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No PCT/GB2006/001243

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