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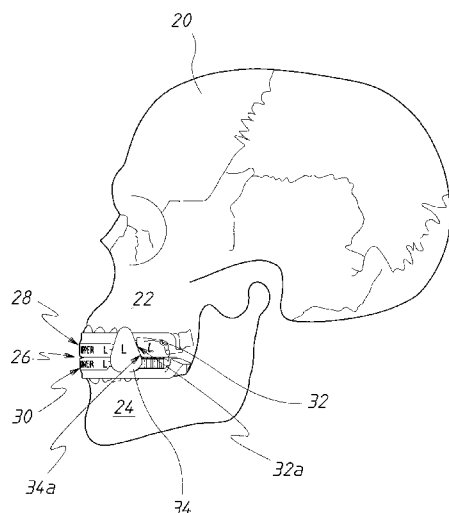


FIG. 1

(57) Abstract: A mandibular advancement device (26) includes a lower part (28), a lower flange (34), an upper part (30) and an upper flange (32). The lower part (28) is releasably attachable to at least a portion of a lower jaw (24). The lower flange (34) has a lower engagement surface extending upwardly from the lower part (28). The upper part (30) is releasably attachable to at least a portion of an upper jaw (22). The upper flange (32) has an upper engagement surface extending downwardly from the upper part (30). The lower flange (34) is connected to the lower part (28) by a lower one way ratchet means configured to only allow uni-directional posterior movement of the lower flange (34) relative to the lower part (28) and/or the upper flange (32). The upper flange (32) is connected to the upper part (30) by an upper one way ratchet means configured to only allow uni-directional anterior movement of the upper flange (32) relative to the upper part (30). When the lower part (28) and the upper part (30) are fitted to the jaws (22,24) of a patient for use in sleep, the lower engagement surface and the upper engagement surface engage in a manner to cause anterior advancement of the lower jaw (24) from the reflex path of opening.

A MANDIBULAR ADVANCEMENT DEVICE

Field of the Invention

[0001] The present invention relates to a mandibular advancement device that has application in the treatment of snoring, obstructive sleep apnea (OSA) and certain temporomandibular joint disorders.

Background of the Invention

[0002] It is generally thought that snoring and OSA occur when there is at least partial occlusion of the airway and that the tongue is involved in this. Snoring and OSA commonly occur during sleep. Mandibular advancement devices advance the lower jaw in an anterior direction, thereby carrying the tongue forward and reducing the likelihood of the tongue impacting on the airway. Numerous forms of mandibular advancement devices are known.

[0003] US patent no. 6604527 discloses a mandibular advancement device having a lower bite block, with a pair of upwardly extending flanges, and an upper bite block, with a pair of downwardly extending flanges. The flanges each carry engagement surfaces. When the bite blocks are fitted to the jaws of a patient for use in sleep, the lower and upper engagement surfaces engage and cause anterior advancement of the lower jaw from the reflex path of opening and maintain that engagement and advancement whilst permitting movement, up to the normal range of jaw opening. This device is custom made for each patient from a desired cast of the patient's jaw. The position of the flanges on the bite blocks are fixed, so as to provide a set amount of jaw advancement for that particular patient. A major advantage of this device is that the jaws are not locked together, which means that the patient is able to speak, yawn and drink whilst wearing the device. The patient can also maintain a lip seal whilst wearing the device. This is essential to prevent the patient's mouth drying out during use, which causes significant discomfort and can lead to non-compliance. However, due to the device being custom manufactured for each patient, it is relatively expensive.

[0004] US patent application publication number US 2012/0255563 discloses a "universal" (i.e. one size fits all) mandibular advancement device. In this device, the upper and lower bite blocks are each a hard flat plastic frame with a tray of mouldable material thereon, the latter facing the

patient's teeth. To fit the device to a patient, the bite blocks are placed in boiling water until the mouldable material softens. The bite blocks are then placed in the patient's mouth and the patient bites down to form an impression of their teeth. The teeth impressions are maintained in the bite blocks once they have cooled. The device includes a central, front mounted, screw type adjuster which is used to set the desired amount of advancement of the lower jaw. The universal fitment nature of the device makes it suited to mass production, which significantly reduces its cost compared to custom devices. However, a significant disadvantage of the device is the adjuster also locks the bite blocks, and thus the patient's jaws, together closed. This makes it difficult to speak, yawn or drink whilst wearing the device. In addition, the adjustment device protrudes outwardly from the user's mouth, breaking the lip seal. This can result in the patient's mouth drying out during sleep.

[0005] US patent application publication numbers US 2013081638 and US 20130160776 also disclose universal fitment type devices. These devices have bite blocks formed from a hard plastic shell, of a U-shaped cross section, with a mouldable insert therein. A disadvantage of these devices include is it is difficult to get a comfortable patient fit as the moulded insert often forms thin sharp edges which can cut the patient's mouth and jaw. It is difficult to manually trim any such sharp edges. Whilst it is possible to reheat and attempt to reshape the insert, it is difficult to push the insert back into the confines of the (U-shaped cross section) tray. The devices have a mechanism for adjusting the advancement of the lower jaw mounted to each side of the bite blocks. A disadvantage of this device is that the adjustment mechanisms are very difficult to use, which can lead to non-compliance. More particularly, adjustment involves manipulating, positioning and locking in place several small components. Further, whilst the adjustment mechanisms do have visible guides for the amount of adjustment, these guides are very hard to see. The adjustment mechanisms also lock the bite blocks/jaws together closed and thus also suffer from the inability to speak, yawn and drink disadvantages discussed above.

Object of the Invention

[0006] It is an object of the present invention to substantially overcome or at least ameliorate one or more of the above disadvantages.

Summary of the Invention

[0007] Accordingly, in a first aspect, the present invention provides a mandibular advancement device including:

- a lower part that is releasably attachable to at least a portion of a lower jaw;
- a lower flange with a lower engagement surface extending upwardly from the lower part;
- an upper part that is releasably attachable to at least a portion of an upper jaw;
- an upper flange with an upper engagement surface extending downwardly from the upper part; and

the lower flange being connected to the lower part by a lower one way ratchet means configured to only allow uni-directional posterior movement of the lower flange relative to the lower part and/or the upper flange being connected to the upper part by an upper one way ratchet means configured to only allow uni-directional anterior movement of the upper flange relative to the upper part,

wherein, when the lower part and the upper part are fitted to the jaws of a patient for use in sleep, the lower engagement surface and the upper engagement surface engage in a manner to cause anterior advancement of the lower jaw from the reflex path of opening.

[0008] In one embodiment, only the lower flange is connected to the lower part by the lower one way ratchet means and the amount of anterior advancement of the lower jaw is adjustable by the positioning of the lower flange relative to the lower part. In this embodiment, the upper flange is fixed to the upper part.

[0009] In another embodiment, only the upper flange is connected to the upper part by the upper one way ratchet means and the amount of anterior advancement of the lower jaw is adjustable by the positioning of the upper flange relative to the upper part. In this embodiment, the lower flange is fixed to the lower part.

[0010] In a further embodiment, the lower flange is connected to the lower part by the lower one way ratchet means and the upper flange is connected to the upper part by the upper one way ratchet means, and the amount of anterior advancement of the lower jaw is adjustable by the positioning of the lower flange relative to the lower part and by the positioning of the upper flange relative to the upper part.

[0011] Preferably, the lower flange includes a left said lower flange and left said lower ratchet means and a right said lower flange and a right said lower ratchet means. Preferably also, the upper flange includes a left said upper flange and left said upper ratchet means and a right said upper flange and a right said upper ratchet means.

[0012] The lower ratchet means preferably includes a lower teeth rack on the lower part and a lower ratchet tooth or teeth on the lower flange. The upper ratchet means preferably includes an upper teeth rack on the upper part and an upper ratchet tooth or teeth on the upper flange.

[0013] The lower part preferably includes a lower opening adapted to releasably receive a handle. The upper part preferably includes an upper opening adapted to releasably receive a handle.

[0014] The lower part is preferably formed from a relatively hard shell (e.g. polyamide) and a heat formable lining (e.g. polycaprolactone [PCL]). In one form, a relatively soft lining (e.g. ethylene vinyl acetate [EVA] or polyurethane) is included in the lower part, with the heat formable lining being positioned between the relatively hard shell and the relatively soft lining.

[0015] The upper part is preferably formed from a relatively hard shell (e.g. polyamide) and a heat formable lining (e.g. polycaprolactone [PCL]). In one form, a relatively soft lining (e.g. ethylene vinyl acetate [EVA] or polyurethane) is included in the upper part, with the heat formable lining being positioned between the relatively hard shell and the relatively soft lining.

[0016] In a second aspect, the present invention provides a mandibular advancement device including:

- a lower part that is releasably attachable to at least a portion of a lower jaw;
- a lower flange with a lower engagement surface extending upwardly from the lower part;
- an upper part that is releasably attachable to at least a portion of an upper jaw;
- an upper flange with an upper engagement surface extending downwardly from the upper part;
- the lower part being formed from a relatively hard lower shell, a relatively soft lower lining and a heat formable lower inner lining therebetween; and
- the upper part being formed from a relatively hard upper shell, a relatively soft upper lining and a heat formable upper inner lining therebetween,

wherein, when the lower part and the upper part are fitted to the jaws of a patient for use in sleep, the lower engagement surface and the upper engagement surface engage in a manner to cause anterior advancement of the lower jaw from the reflex path of opening.

[0017] Preferably, the shells are formed from polyamide, the heat formable inner linings from polycaprolactone [PCL] and the relatively soft linings from ethylene vinyl acetate [EVA].

[0018] In one embodiment, the lower flange is connected to the lower part by a lower one way ratchet means configured to only allow uni-directional posterior movement of the lower flange relative to the lower part. In this embodiment, the upper flange is fixed to the upper part.

[0019] In another embodiment, the upper flange is connected to the upper part by an upper one way ratchet means configured to only allow uni-directional anterior movement of the upper flange relative to the upper part. In this embodiment, the lower flange is fixed to the lower part.

[0020] In a further embodiment, the lower flange is connected to the lower part by a lower one way ratchet means configured to only allow uni-directional posterior movement of the lower flange relative to the lower part and the upper flange is connected to the upper part by an upper one way ratchet means configured to only allow uni-directional anterior movement of the upper flange relative to the upper part.

Detailed Description of the Drawings

[0021] A preferred embodiment of the invention will now be described, by way of an example only, with reference to the accompanying drawings, in which:

[0022] Fig. 1 is a side view of a human skull fitted with an embodiment of a mandibular advancement device, with the jaw in a closed position;

[0023] Fig. 2 shows the skull and the device of Fig. 1, with the jaw in an open position;

[0024] Fig. 3 is a perspective view of a lower bite block of the device shown in Fig. 1;

[0025] Fig. 4 is a side view of the lower bite block shown in Fig. 3;

[0026] Fig. 5 is an top view of the lower bite block shown in Fig. 3;

[0027] Fig. 6 is an enlarged detailed view of a teeth rack and a ratchet used in the bite block shown in Fig. 3;

[0028] Fig. 7 is a cross sectional end view of the bite block shown in Fig. 5 along the line 7-7;

[0029] Fig. 8 is a side view of an upper bite block of the device shown in Fig. 1;

[0030] Fig. 9 is a underside view of the upper bite block shown in Fig. 8;

[0031] Fig. 10 is a side view of the device shown in Fig. 1 adjusted to provide a minimum amount of mandibular advancement;

[0032] Fig. 11 shows the device of Fig. 10 adjusted to provide a maximum amount of mandibular advancement;

[0033] Fig. 12 shows the device of Fig. 10 adjusted to provide an intermediate amount of mandibular advancement;

[0034] Fig. 13 shows the device of Fig. 10 adjusted to provide an intermediate amount of mandibular advancement; and

[0035] Fig. 14 shows the upper bite block shell of Fig. 8 connected to a handle.

Brief Description of the Preferred Embodiments

[0036] Fig. 1 shows a skull 20 with an upper jaw 22 and a lower jaw 24. An embodiment of a mandibular advancement device 26 is fitted to the jaws 22 and 24. The device 26 includes an upper part, in the form of an upper bite block 28, and a lower part, in the form of a lower bite block 30. The upper 28 and lower 30 bite blocks have "UPPER" and "LOWER" markings respectively thereon, together with "L" (left) and "R" (right), to assist in patient fitment. Also shown in Figs. 1 and 2 are a left hand side upper flange 32 and a left hand side lower flange 34. As will be described in more detailed below, the leading edge 32a of the flange 32 acts an engagement surface and the leading edge 34a of the flange 34 acts an engagement surface. A

similar set of flanges, are provided on the right hand side of the bite blocks 28 and 30. The left hand flanges 32 and 34 have an “L” marking thereon to assist in patient fitment. The right hand flanges are similarly marked with an “R”.

[0037] Fig. 3 shows the lower bite block 30 in isolation. The bite block 30 includes a relatively hard shell 36, injected moulded from polyamide, to which is bonded (by epoxy) a heat formable lining 38, injection moulded from PCL. As best shown in Fig. 7, the heat formable lining 38 is covered by a relatively soft lining 40, formed from EVA or polyurethane. The relatively soft lining 40 can also be formed from a heat formable material.

[0038] Returning to Fig. 3, each side of the shell 36 includes a rail 41 on which is formed a teeth rack 42. As best shown in Fig. 6, the flange 34 includes three ratchet teeth 44 formed thereon. As best shown in Fig. 7, the flange 34 includes a dovetail type recess 44a which engages the like-shaped exterior 41a of the rail 41. This engagement allows relative sliding movement whilst keeping the flange 34 engaged with the rail 41. As best shown in Fig. 6, the tooth rack 42 and the ratchet teeth 44 are saw tooth in profile making them uni-directional. The construction and operation of the teeth 42 and 44 is similar to that of a cable-tie or tie-wrap. The ratchet 44 is resiliently biased towards the teeth rack 42 and pivots away from, and then back towards, the teeth rack 42, as indicated by double headed arrow 46, whilst the flange 34 is moved relative to the shell 36 in the direction of arrow 48. Fig. 4 shows that the uni-directional movement of the flange 34 is in the posterior direction, from an initial position to an advanced position (shown in phantom). To assist the user, both the flange 34 and the shell 36 have arrow indicators 50 thereon to indicate the adjustment direction (see Fig. 5).

[0039] As best shown in Fig. 5, a numerical indicator 52 of the amount of adjustment selected by the user is also shown on the top surface of the shell 36. Each incremental movement of adjustment relative to the shell 36 produces a “click” sound and is equal to about 1 mm of movement. If the patient positions the flange 34 past an intended position, the flange 34 can be simply slid off the end of the rail 41 by further movement in the direction of the arrows 50 and then reinstalled at the initial position shown in Fig. 5 for readjustment.

[0040] Fig. 3 also shows the threaded hole 54 in the front of the shell 3, used to fit a handle 55 (see Fig. 14).

[0041] Figs. 8 and 9 show the upper bite block 28, which has a similar shell and liner construction as the lower bite block 30 previously described. The upper bite block 28 also has a similar uni-directional ratchet arrangement for the upper flange 32, as those previously described. The shell of the upper bite block 28 also contains similar numerical and directional indicators on its bottom surface. Fig. 8 also shows that the upper flange 32 can be moved only in the anterior direction, indicated by arrow 56, from an initial position shown to an advanced position (shown in phantom).

[0042] Fig 10. shows the upper and lower bite blocks 28, 30 positioned for use with one another with the engagement surfaces 32a, 34a of the flanges abutting and engaged with one another. In Fig. 10, both of the flanges 32, 34 are at the beginning of their respective ranges of jaw advancement.

[0043] The use of the device 26 will now be described. As shown in Fig. 14, the handle 55 is screwed to the hole in the upper bite block 28. The upper bite block 28 is then placed in boiling water until the heat formable inner lining 38 softens. If the soft lining 40 is also formed from a mouldable material then it will also soften. The bite block 28 is then retrieved from the water by the handle 55. Using the handle the bite block 28 is positioned in the patient's mouth. The patient then bites down to form an impression of their teeth and jaw in the mouldable material 38. The material 38 is then allowed to cool so as to retain the patient's impression therein. If used, the heat mouldable soft lining 40 also retains the patient's impression therein once cooled. The handle 55 is then removed from the upper bite block 28 and a similar process is carried out for the lower bite block 30.

[0044] The upper 32 and lower 34 flanges are [HW1]assembled with the upper 28 and lower 30 bite blocks respectively, by sliding them to the rail 41 until the ratchet teeth 44 make initial engagement with the rack teeth 42. This initial engagement is indicated by an audible click or clicks and a slight resistance to movement in the direction of the arrow 48 (lower) or 56 (upper). This initial assembly is shown in Fig. 10 and provides a minimum amount of mandibular advancement of the patient's lower jaw. The device 26 is then fitted to the patient's jaw and, by trial and error, the flanges 32, 34 can be advanced in their respective single directions in order to adjust the mandibular advancement of the lower jaw to the desired amount. The engagement surfaces 32a, 34a of the upper and lower flanges 32, 34 engage and abut against one another causing the desired amount of mandibular advancement to be maintained.

[0045] Fig. 11 shows the flanges 32, 34 adjusted to provide a maximum amount of mandibular advancement.

[0046] Figs. 12 and 13 each show a similar intermediate amount of mandibular advancement and also demonstrate that a similar amount of mandibular advancement can be achieved whilst positioning the flanges 32, 34 in different locations.

[0047] The device 26 retains the desired amount of mandibular advancement as the lower flange 34 can only move relative to the lower bite block 30 in an anterior direction (i.e. it cannot move in the posterior direction) and the upper flange 32 can only move relative to the upper bite block 28 in the posterior direction (i.e. it cannot move in the anterior direction).

[0048] The device 26 has numerous advantages. Firstly, the device is of the universal fitment type and is thus suited mass production at a relatively low cost compared to custom devices. Secondly, the device allows the patient's jaw to be opened, allowing speaking, yawning and drinking whilst wearing the device. Thirdly, the adjustment devices are contained within the patient's mouth thereby allowing a lip seal to be maintained and avoiding the patient's mouth drying out during asleep. Fourthly, the adjustment of the position of the flanges and thus the mandibular advancement is both relatively simple and also intuitive. More particularly, the various components of the device are clearly marked and the flanges can only be assembled for use in their intended position and direction. There are also clear and easy to read indicators of the positions selected and there are no locks or other smaller or secondary components which need to be manipulated. The device also allows the anterior/posterior position of the flanges in the mouth to be adjusted for maximum patient comfort, independent of the desired amount of the lower jaw advancement (see Figs. 12 and 13). The left hand flanges can also be positioned independently of the right hand flanges, again for maximum patient comfort. The advancement of one side of the jaw can be adjusted differently to the other side of the jaw, if required to best suit the patient's jaw anatomy. Finally, the soft coating over the mouldable lining increases patient comfort due to it providing a soft material in direct contact with the patient's teeth. The soft coating acts as a shock absorber, helps in equal dissipation of occlusal stresses and is compressed during function thereby increasing retention and minimizing trauma by preventing a direct contact of hard material such as the hard shell or the formed heat formable lining.

[0049] Although the invention has been described with reference to a preferred embodiment, it will be appreciated by those persons skilled in the art that the invention may be embodied in many other forms.

CLAIMS:

1. A mandibular advancement device including:
 - a lower part that is releasably attachable to at least a portion of a lower jaw;
 - a lower flange with a lower engagement surface extending upwardly from the lower part;
 - an upper part that is releasably attachable to at least a portion of an upper jaw;
 - an upper flange with an upper engagement surface extending downwardly from the upper part; and

the lower flange being connected to the lower part by a lower one way ratchet means configured to only allow uni-directional posterior movement of the lower flange relative to the lower part and/or the upper flange being connected to the upper part by an upper one way ratchet means configured to only allow uni-directional anterior movement of the upper flange relative to the upper part,

wherein, when the lower part and the upper part are fitted to the jaws of a patient for use in sleep, the lower engagement surface and the upper engagement surface engage in a manner to cause anterior advancement of the lower jaw from the reflex path of opening.
2. The mandibular advancement device as claimed in claim 1, wherein only the lower flange is connected to the lower part by the lower one way ratchet means and the amount of anterior advancement of the lower jaw is adjustable by the positioning of the lower flange relative to the lower part.
3. The mandibular advancement device as claimed in claim 2, wherein the upper flange is fixed to the upper part.
4. The mandibular advancement device as claimed in claim 1, wherein only the upper flange is connected to the upper part by the upper one way ratchet means and the amount of anterior advancement of the lower jaw is adjustable by the positioning of the upper flange relative to the upper part.
5. The mandibular advancement device as claimed in claim 4, wherein the lower flange is fixed to the lower part.

6. The mandibular advancement device as claimed in claim 1, wherein the lower flange is connected to the lower part by the lower one way ratchet means and the upper flange is connected to the upper part by the upper one way ratchet means, and the amount of anterior advancement of the lower jaw is adjustable by the positioning of the lower flange relative to the lower part and by the positioning of the upper flange relative to the upper part.
7. The mandibular advancement device as claimed in any one of the preceding claims, wherein the lower flange includes a left said lower flange and left said lower ratchet means and a right said lower flange and a right said lower ratchet means.
8. The mandibular advancement device as claimed in any one of the preceding claims, wherein the upper flange includes a left said upper flange and left said upper ratchet means and a right said upper flange and a right said upper ratchet means.
9. The mandibular advancement device as claimed in any one of the preceding claims, wherein the lower ratchet means includes a lower teeth rack on the lower part and a lower ratchet tooth or teeth on the lower flange.
10. The mandibular advancement device as claimed in any one of the preceding claims, wherein the upper ratchet means includes an upper teeth rack on the upper part and an upper ratchet tooth or teeth on the upper flange.
11. The mandibular advancement device as claimed in any one of the preceding claims, wherein the lower part includes a lower opening adapted to releasably receive a handle.
12. The mandibular advancement device as claimed in any one of the preceding claims, wherein the upper part includes an upper opening adapted to releasably receive a handle.
13. The mandibular advancement device as claimed in any one of the preceding claims, wherein the lower part is formed from a relatively hard shell and a heat formable lining.
14. The mandibular advancement device as claimed in claim 13, wherein a relatively soft lining is included in the lower part, with the heat formable lining being positioned between the relatively hard shell and the relatively soft lining.

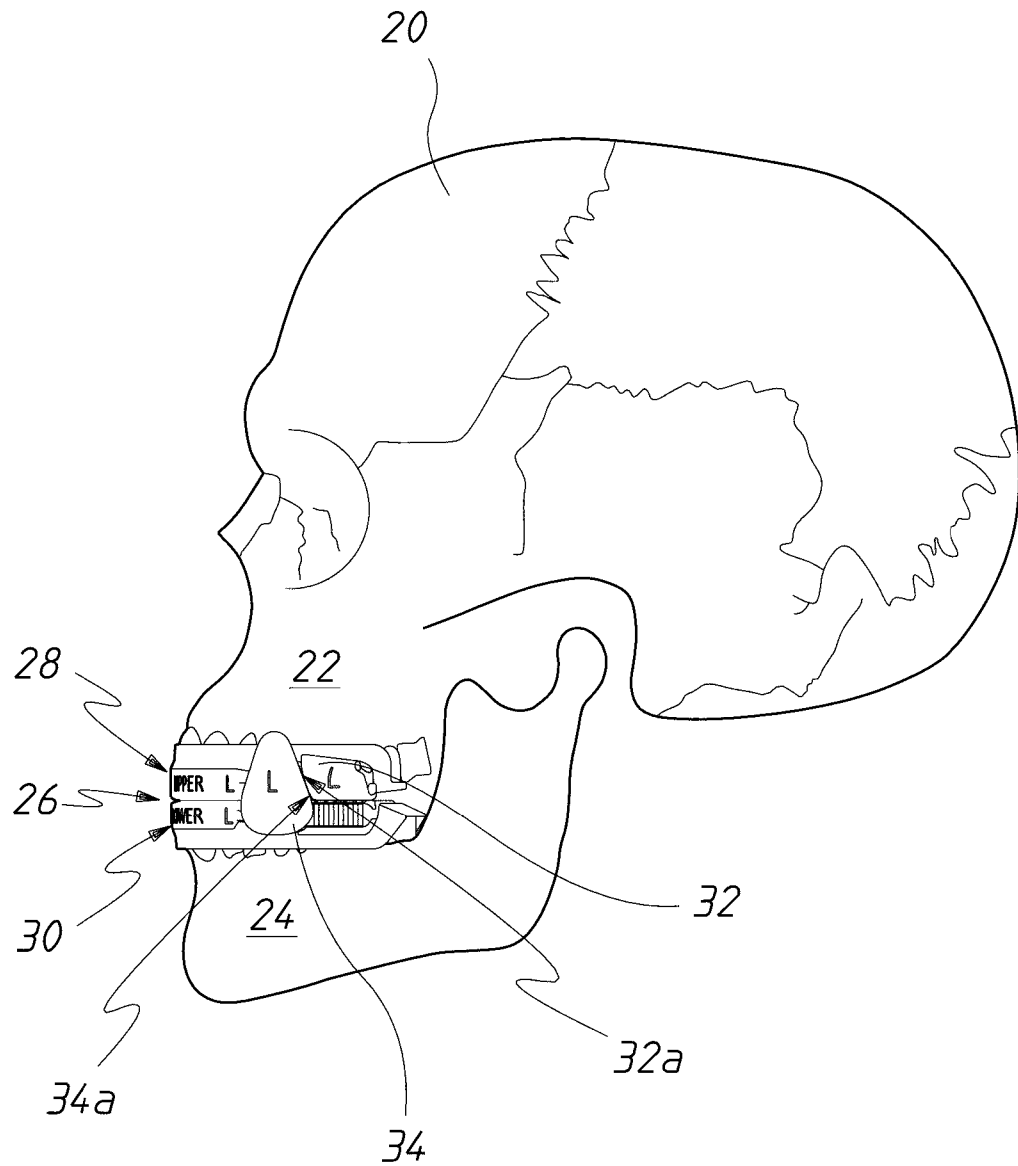
15. The mandibular advancement device as claimed in any one of the preceding claims, wherein the upper part is formed from a relatively hard shell and a heat formable lining.
16. The mandibular advancement device as claimed in claim 15, wherein a relatively soft lining is included in the upper part, with the heat formable lining being positioned between the relatively hard shell and the relatively soft lining.
17. A mandibular advancement device including:
a lower part that is releasably attachable to at least a portion of a lower jaw;
a lower flange with a lower engagement surface extending upwardly from the lower part;
an upper part that is releasably attachable to at least a portion of an upper jaw;
an upper flange with an upper engagement surface extending downwardly from the upper part;
the lower part being formed from a relatively hard lower shell, a relatively soft lower lining and a heat formable lower inner lining therebetween; and
the upper part being formed from a relatively hard upper shell, a relatively soft upper lining and a heat formable upper inner lining therebetween,
wherein, when the lower part and the upper part are fitted to the jaws of a patient for use in sleep, the lower engagement surface and the upper engagement surface engage in a manner to cause anterior advancement of the lower jaw from the reflex path of opening.
18. The mandibular advancement device as claimed in claim 17, wherein the shells are formed from polyamide, the heat formable inner linings from polycaprolactone [PCL] and the relatively soft linings from ethylene vinyl acetate [EVA].
19. The mandibular advancement device as claimed in claim 17 or 18, wherein the lower flange is connected to the lower part by a lower one way ratchet means configured to only allow uni-directional posterior movement of the lower flange relative to the lower part.
20. The mandibular advancement device as claimed in claim 19, wherein the upper flange is fixed to the upper part.

21. The mandibular advancement device as claimed in claim 17 or 18, wherein the upper flange is connected to the upper part by an upper one way ratchet means configured to only allow uni-directional anterior movement of the upper flange relative to the upper part.

22. The mandibular advancement device as claimed in claim 21, wherein the lower flange is fixed to the lower part.

23. The mandibular advancement device as claimed in claim 17 or 18, wherein the lower flange is connected to the lower part by a lower one way ratchet means configured to only allow uni-directional posterior movement of the lower flange relative to the lower part and the upper flange is connected to the upper part by an upper one way ratchet means configured to only allow uni-directional anterior movement of the upper flange relative to the upper part.

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FIG. 1

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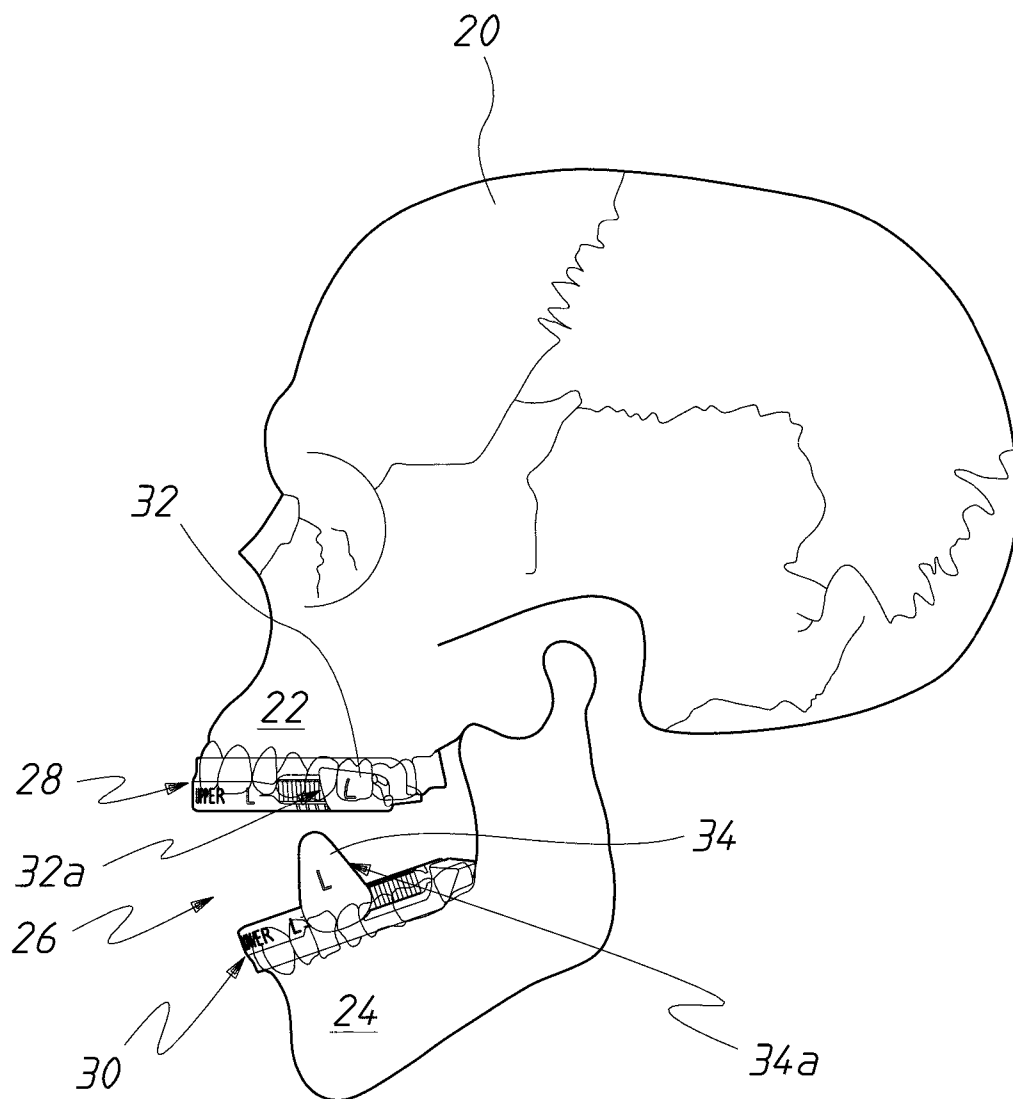


FIG. 2

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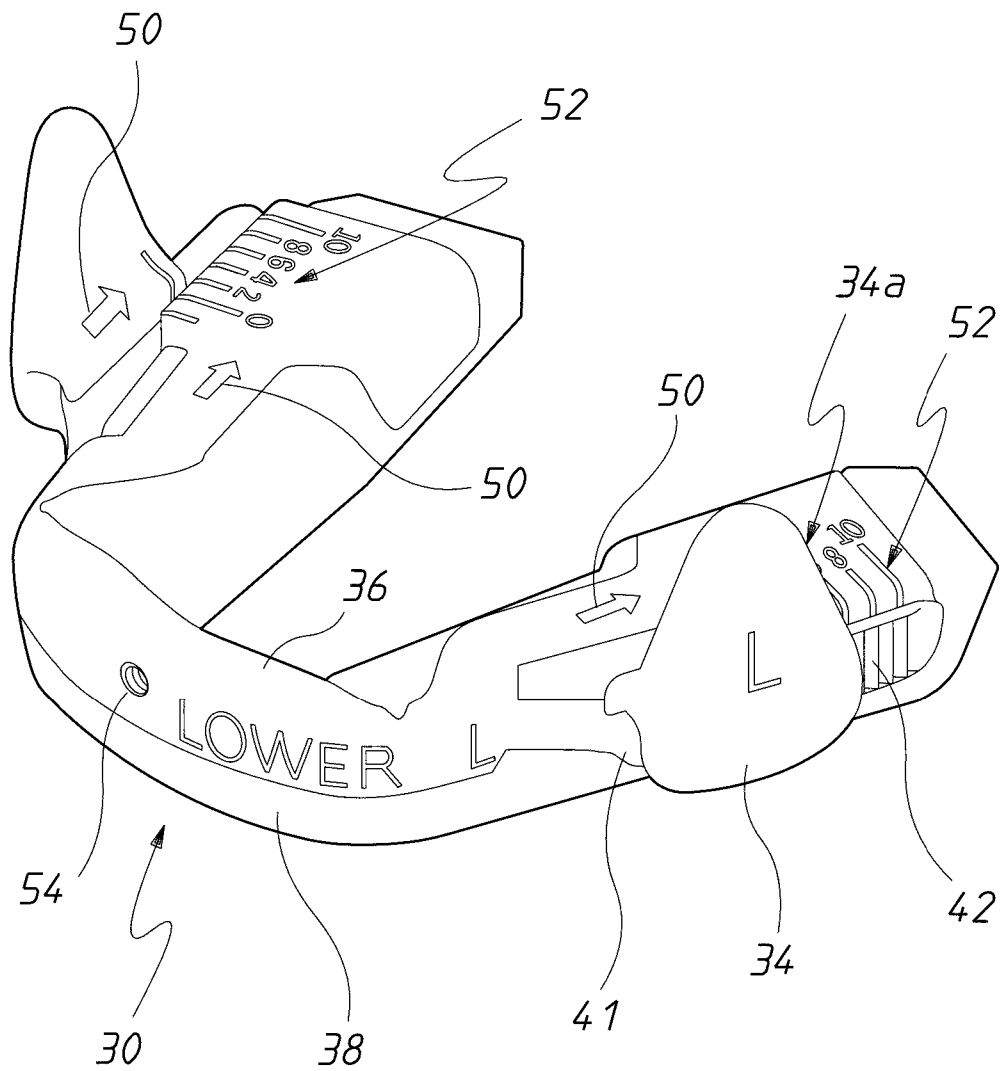


FIG.3

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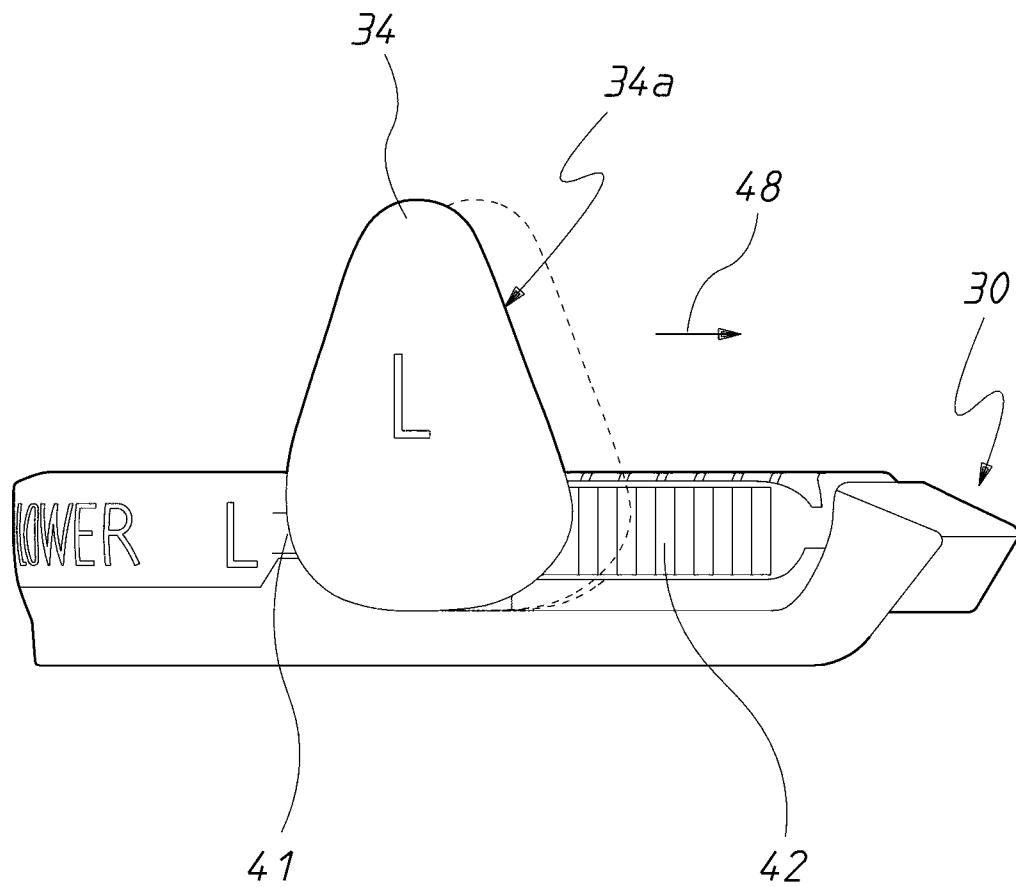


FIG. 4

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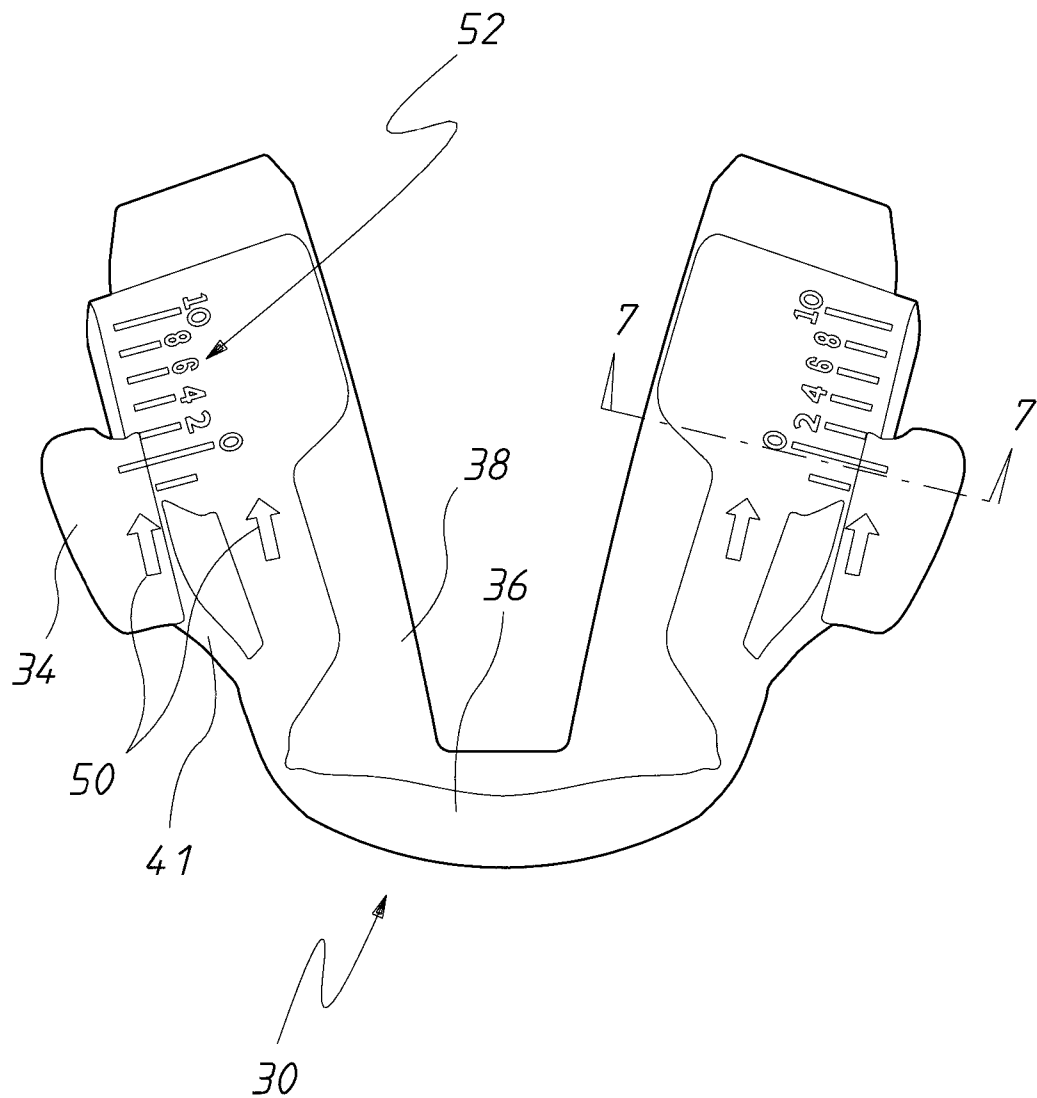


FIG. 5

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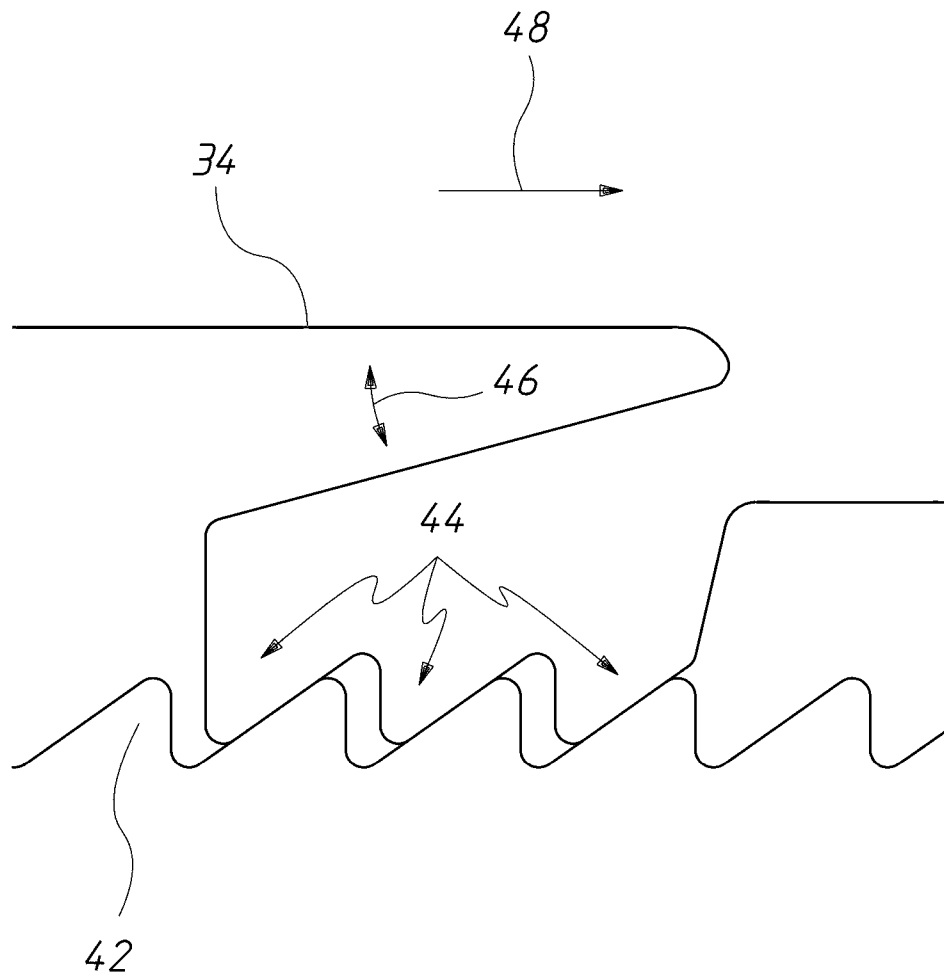


FIG. 6

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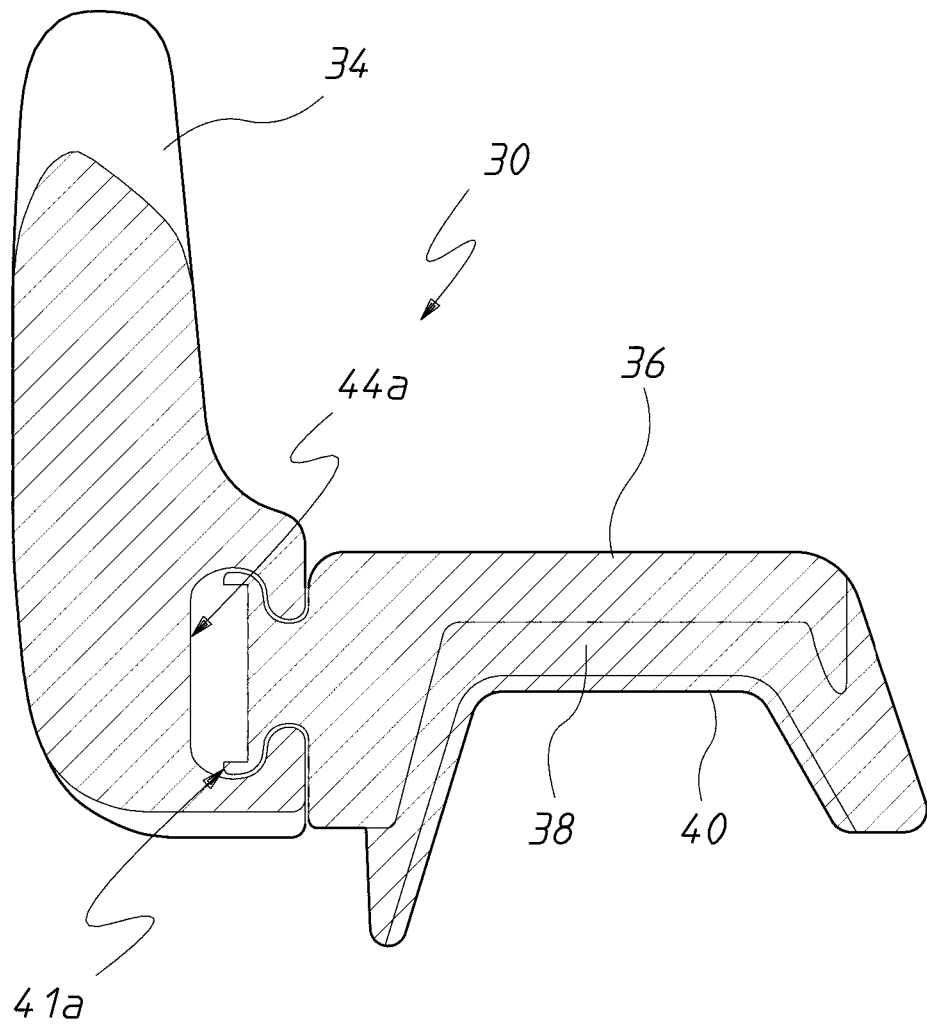


FIG. 7

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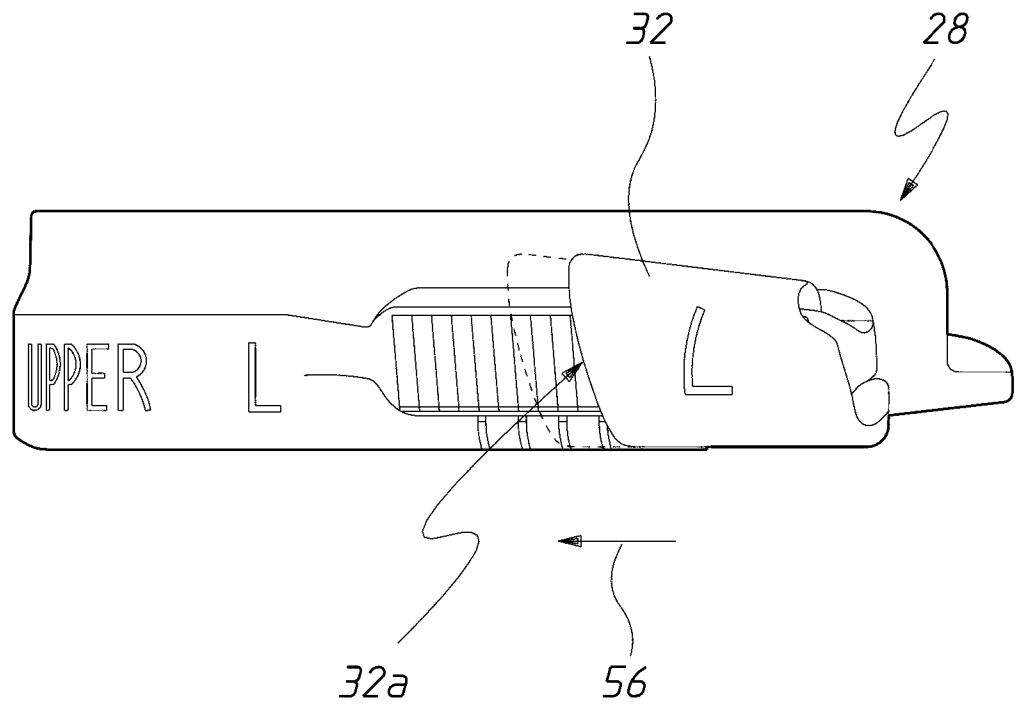


FIG. 8

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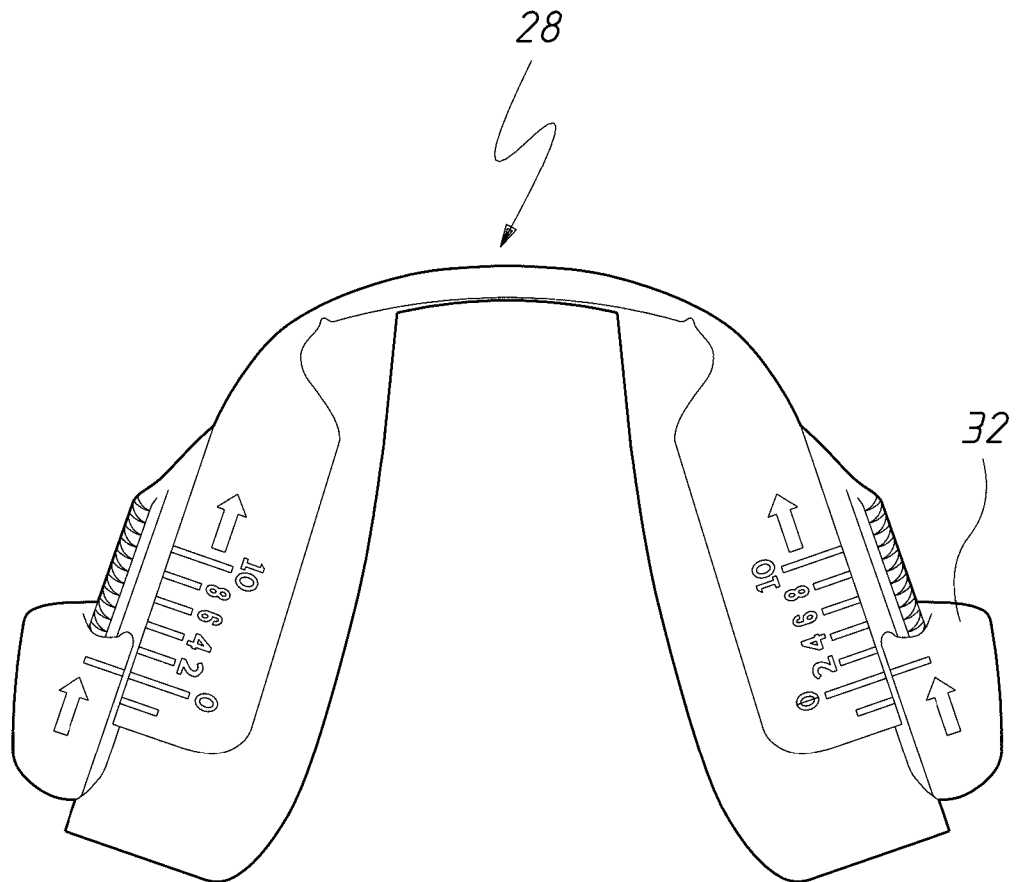


FIG. 9

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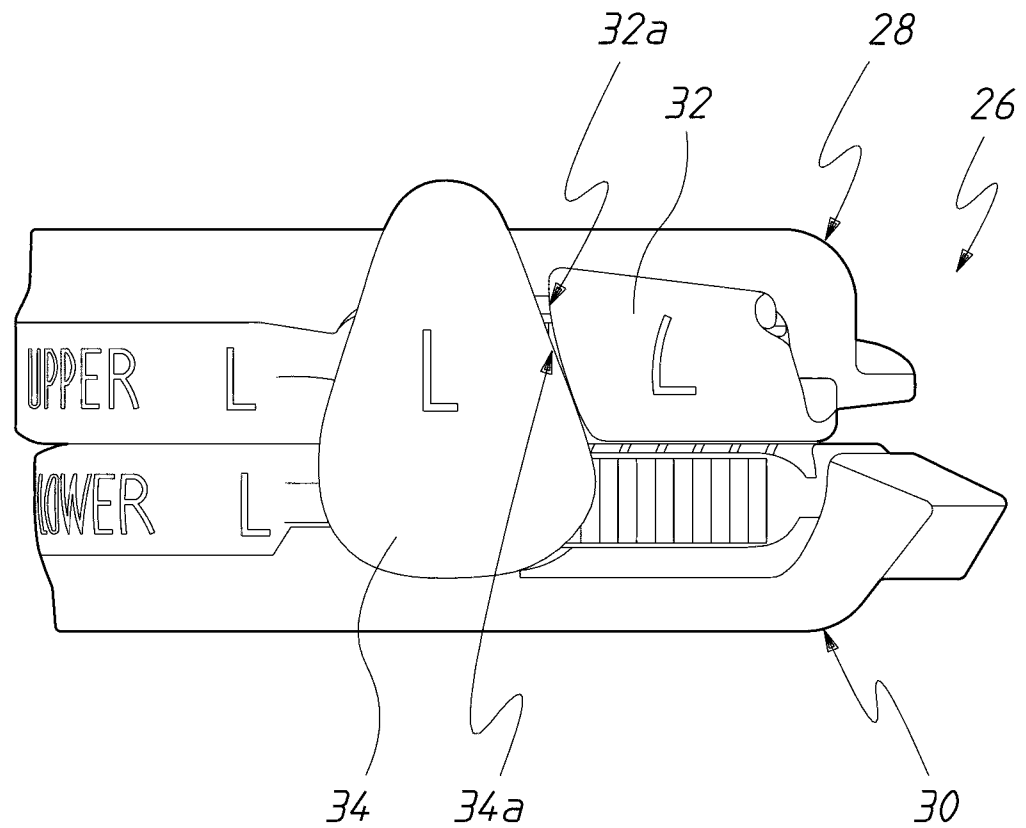


FIG. 10

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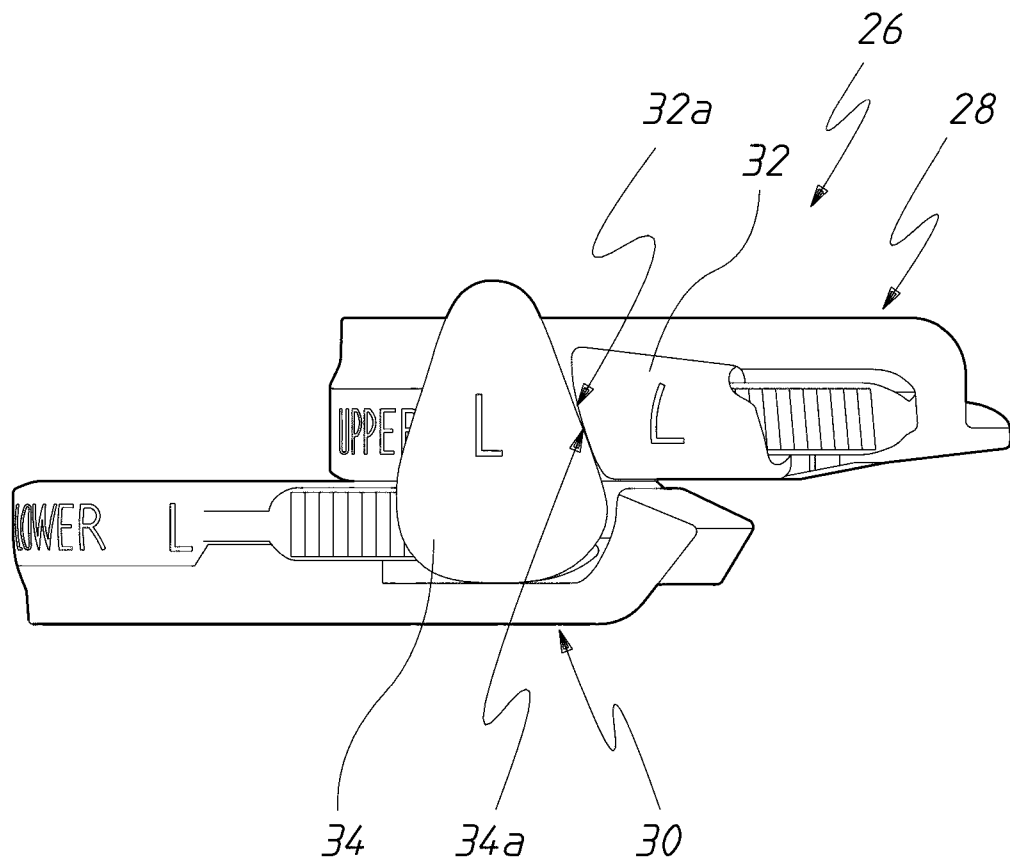


FIG. 11

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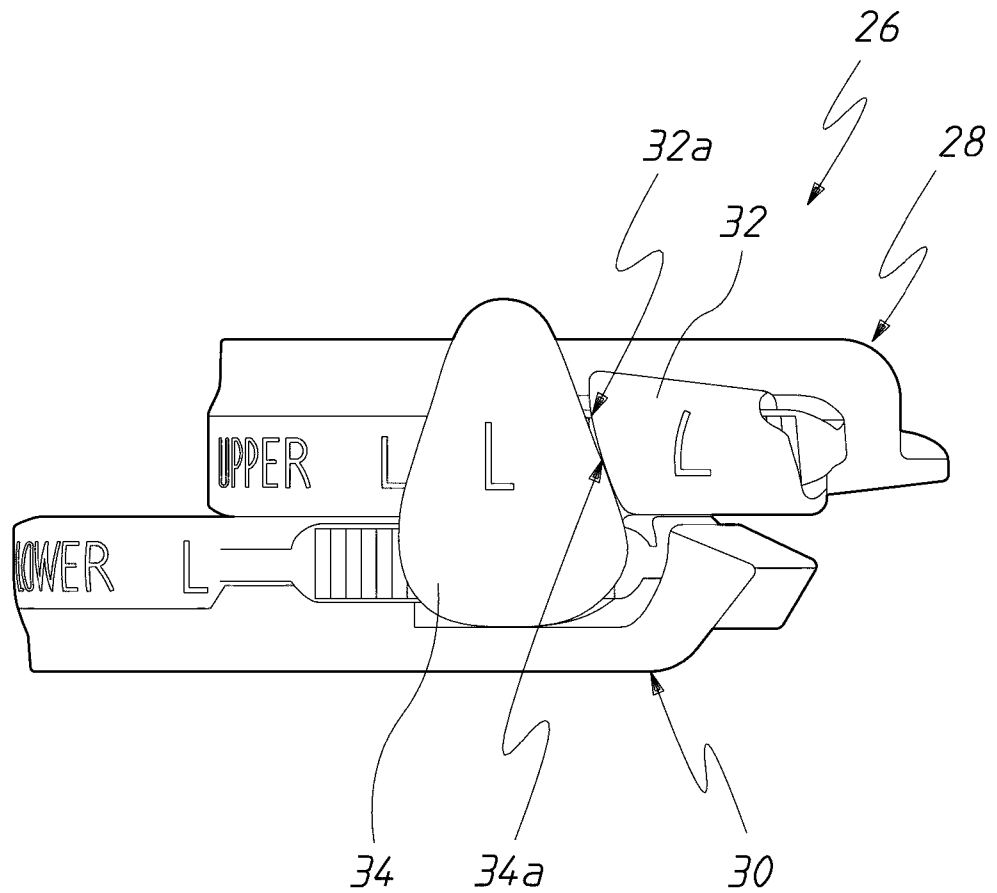


FIG. 12

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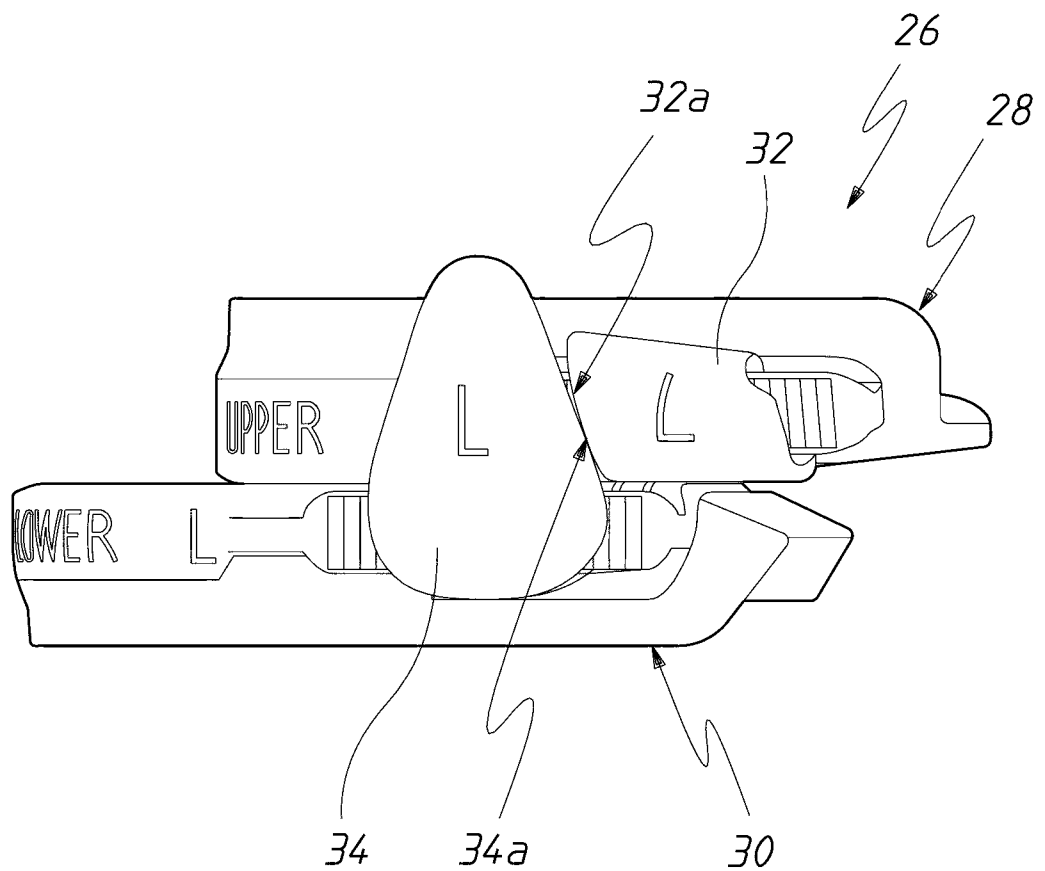


FIG. 13

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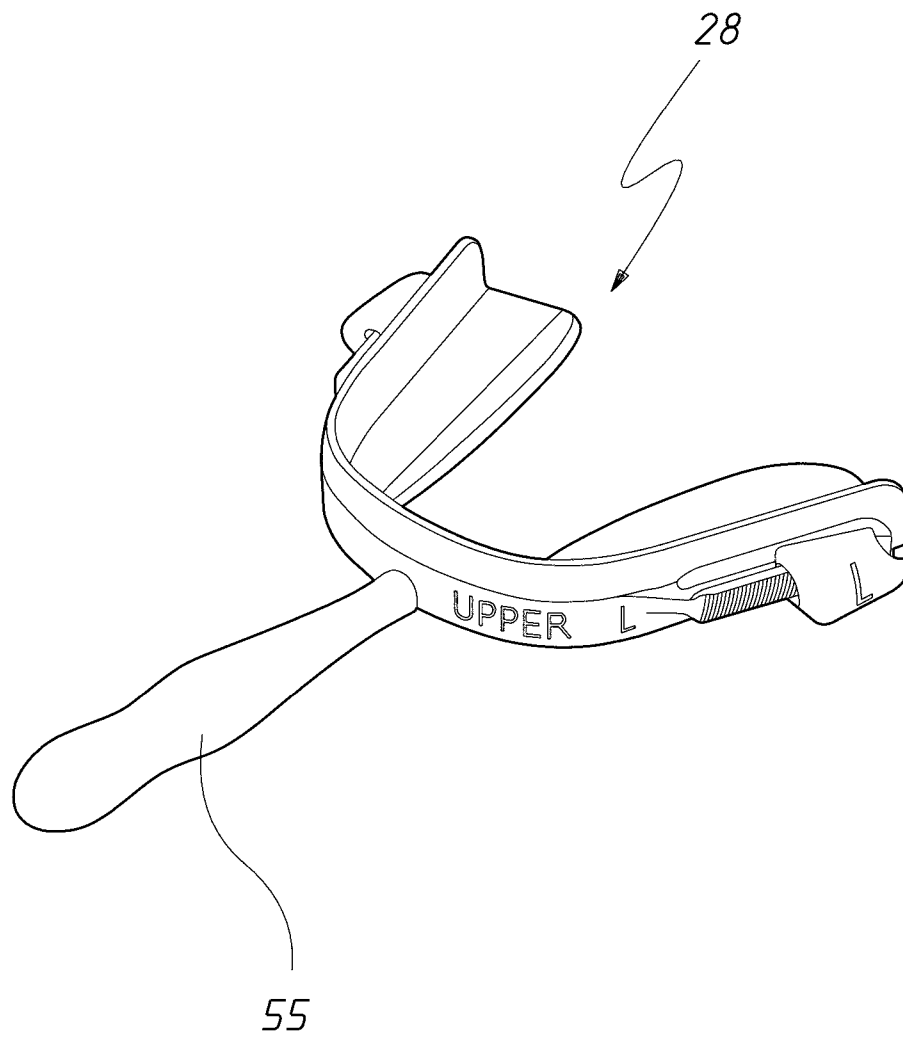


FIG. 14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2016/000347

A. CLASSIFICATION OF SUBJECT MATTER

A61C 7/08 (2006.01) A61F 5/56 (2006.01) A61C 7/36 (2006.01) A61C 7/10 (2006.01)

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)

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)

EPODOC, FULL TEXT: IPC and CPC: **A61C7/08 or A61F5/566 or A61C7/36**

Google patents: Mandibular reposition advance ratchet

applicant and inventor search

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	Documents are listed in the continuation of Box C	

☒ Further documents are listed in the continuation of Box C ☒ See patent family annex

* "A"	Special categories of cited documents: document defining the general state of the art which is not considered to be of particular relevance	"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
"E"	earlier application or patent but published on or after the international filing date	"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
"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)	"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
"O"	document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 22 December 2016	Date of mailing of the international search report 22 December 2016
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA Email address: pct@ipaustalia.gov.au	Authorised officer Ariane Le Guen AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No. 0399359657

Box No. 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.:
because they relate to subject matter not required to be searched by this Authority, namely:
the subject matter listed in Rule 39 on which, under Article 17(2)(a)(i), an international search is not required to be carried out, including
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 No. 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:

See Supplemental Box for Details

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 additional fees, this Authority did not invite payment of additional fees.
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.:
1-12

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT		International application No.
C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		PCT/AU2016/000347
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2012/0145166 A1 (FALLON et al) 14 June 2012 bfbfd	1-12
A	US 2013/0112210 A1 (STEIN) 09 May 2013	
A	US 2010/0261133 A1 (LAX) 14 October 2010	

Form PCT/ISA/210 (fifth sheet) (July 2009)

INTERNATIONAL SEARCH REPORT	International application No. PCT/AU2016/000347
Supplemental Box	
Continuation of: Box III This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. This Authority has found that there are different inventions based on the following features that separate the claims into distinct groups: • Claims 1-16 are directed to a mandibular advancement device. The feature of the one way ratchet means configured to only allow uni-directional posterior movement of the lower flange relative to the lower part and upper flange relative to the upper part is specific to this group of claims. • • • • Claims 17-23 are directed to a mandibular advancement. The feature of parts being formed from a relatively hard shell, soft lining and heat formable lining is specific to this group of claims. • • PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art. When there is no special technical feature common to all the claimed inventions there is no unity of invention. In the above groups of claims, the identified features may have the potential to make a contribution over the prior art but are not common to all the claimed inventions and therefore cannot provide the required technical relationship. The only feature common to all of the claimed inventions and which provides a technical relationship among them is a lower part that is releasably attachable to at least a portion of a lower jaw; a lower flange with a lower engagement surface extending upwardly from the lower part; an upper part that is releasably attachable to at least a portion of an upper jaw; an upper flange with an upper engagement surface extending downwardly from the upper part and wherein, when the lower part and the upper part are fitted to the jaws of a patient for use in sleep, the lower engagement surface and the upper engagement surface engage in a manner to cause anterior advancement of the lower jaw from the reflex path of opening. However this feature does not make a contribution over the prior art because it is disclosed in: D1 WO2014/043008 A1 (DIAZ) 20 March 2014 [see para 24, Fig. 1] D2 US2014/0352701 A1 (INGEMARSSON-MATZEN) [see para 71, 166, 181] Therefore in the light of this document this common feature cannot be a special technical feature. Therefore there is no special technical feature common to all the claimed inventions and the requirements for unity of invention are consequently not satisfied <i>a posteriori</i>. In addition, claims 13 to 16 in the first set of claims are directed to features of the second invention and claims 19 to 23 in the second set of claims are directed to features of the first invention. A consequence is that claims 13 to 16 will only be the subject of a search and opinion upon payment of the additional search fee. Payment of this fee will result in a search and opinion being drawn to the entire claim set. It is considered that search and examination for the second invention will require more than negligible additional search and examination effort over that of the first invention, and therefore an additional search fee is warranted. No additional fees were paid by the applicant. Claims 1-12 were searched for.	
Form PCT/ISA/210 (Supplemental Box) (July 2009)	

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2016/000347**Supplemental Box**

INTERNATIONAL SEARCH REPORT		International application No.	
Information on patent family members		PCT/AU2016/000347	
This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.			
Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	Publication Date	Publication Number	Publication Date
US 2012/0145166 A1	14 June 2012	US 2012145166 A1	14 Jun 2012
		US 8833374 B2	16 Sep 2014
		CA 2844512 A1	07 Mar 2013
		CN 103781442 A	07 May 2014
		CN 103781442 B	19 Oct 2016
		EP 2750641 A1	09 Jul 2014
		HK 1198510 A1	15 May 2015
		JP 2014525321 A	29 Sep 2014
		JP 5993457 B2	14 Sep 2016
		RU 2014105692 A	27 Oct 2015
		WO 2013032884 A1	07 Mar 2013
US 2013/0112210 A1	09 May 2013	US 2013112210 A1	09 May 2013
US 2010/0261133 A1	14 October 2010	US 2010261133 A1	14 Oct 2010
		WO 2010117398 A1	14 Oct 2010
End of Annex			