A device to assist breathing includes a central body with outwardly splayed wing members. At least a portion of a lower surface of the central body has at least a roughened portion thereon. In use the device, is held in place in the mouth by engagement of the upper side of the wing members with the upper teeth, which in turn holds the tongue in position via the engagement of at least a portion of the roughened portion of the lower surface of the central body with at least a portion of an upper surface of the tongue, while at the same time the device holds the lower jaw in place via the engagement of the lower side of the wing members with the lower teeth. A method of preparing the device for use is also included.

**Fig. 1**

**Title:** DEVICE TO ASSIST BREATHING
DEVICE TO ASSIST BREATHING

FIELD OF THE INVENTION

The invention relates to a device to assist breathing and to a method of preparing the device for use. The invention is directed particularly but not solely towards a device that can be inserted into a mouth to alleviate snoring or sleep apnoea.

BACKGROUND OF INVENTION

Breathing can involve snoring and sleep apnoea which are problems that have been around for as long as there have been people on earth. Both snoring and sleep apnoea problems can result from relaxation, during sleep of two muscles associated with the airway i.e. the tongue and the lower jaw muscle. As these muscles relax the back of the tongue falls back and partially or completely blocks the airway. Because the tongue is attached to the lower jaw, a reduction in snoring can be achieved by forcefully preventing one or the other from falling back, but this is very difficult to do simultaneously and independently.

Snoring is not just a problem for the sufferer who may experience disrupted sleep but for any sleeping companion(s) either in the same bed or in the same room. In contrast sleep apnoea which can also be disruptive for the patient and companion(s), can lead to disrupted breathing possibly leading to death in some cases.

There are some devices on the market are too difficult to use while some require too forceful use with respect to the tongue and jaw (e.g. suction on the tongue) for long periods at night, causing discomfort and in some cases injury to the user.

In this specification unless the contrary is expressly stated, where a document, act or item of knowledge is referred to or discussed, this reference or discussion is not an admission that the document, act or item of knowledge or any combination thereof was at the priority date, publicly available, known to the public, part of common general knowledge; or known to be relevant to an attempt to solve any problem with which this specification is concerned.

All references, including any patents or patent applications cited in this specification are hereby incorporated by reference. No admission is made that any reference constitutes prior
art. The discussion of the references states what their authors assert, and the applicants reserve the right to challenge the accuracy and pertinence of the cited documents. It will be clearly understood that, although a number of prior art publications may be referred to herein; this reference does not constitute an admission that any of these documents form part of the common general knowledge in the art, in New Zealand or in any other country.

**OBJECT OF THE INVENTION**

It is an object of the invention to provide an improved device to assist breathing and method of preparing the device for use that ameliorates some of the disadvantages and limitations of the known art or at least provide the public with a useful choice.

**SUMMARY OF INVENTION**

In a first aspect the invention resides in a device to assist breathing for a mouth including upper and lower teeth and upper and lower jaws forming an airway there between, the device includes a central body with outwardly splayed wing members, whereby in use the central body and wing members have an upper surface and lower surface, a front end rear end with edges wherein at least a portion of the lower surface of the central body has at least a roughened portion thereon, wherein in use the device, itself being held in place in the mouth by engagement of the upper side of the wing members with the upper teeth, which in turn holds the tongue in position via the engagement of at least a portion of the roughened portion of the lower surface of the central body with at least a portion of an upper surface of the tongue, while at the same time the device holds the lower jaw in place via the engagement of the lower side of the wing members with the lower teeth.

Preferably gripping the tongue prevents the tongue from falling back and blocking the airway when the user is asleep while the tongue is relaxed, while at the same time the wing members are gripped by the upper and lower teeth. Preferably engagement of the wing members of the lower teeth into a lower section of the device prevents the lower jaw from falling back.

Preferably engagement by the upper teeth and lower teeth to the wing members includes gripping the wing members.

Preferably the gripping includes gripping the wing members whereby the teeth intermesh with complementary depressions formed in each wing member.
Preferably the central body is a channel shaped body including a square shaped cross sectional shape and includes a base and side walls.

Preferably, at least one wing cap member encases or covers at least a portion of each wing member and are planar in shape being oriented parallel to the wing member.

Preferably, the device is formed of a thermoplastics material wherein the channel shaped body is formed from a high melting point thermoplastics material and the wing members or cap members are formed from a low melting point thermoplastics material.

Preferably, the side walls of the channel shaped body are substantially vertical having a sloping top end edge.

Preferably, the front end edge includes a front end edge of the wing members and/or wing cap member are rounded in a horizontal plane.

Preferably, front end edge includes a front edge of the side wall being rounded in a vertical plane.

Preferably, the rear end edge of the wing cap members are rounded in the horizontal plane whereas the rear end edge of the channel shaped body and wing member are straight.

Preferably, the device has a greater length dimension from side to side than front to rear.

Preferably the wing cap members are positioned on the wing members to extend rearwardly beyond an end edge of the wing members, be recessed from a front end edge of the front end edge of the channel shaped body and extend beyond a side end edge of the wing members whereby there is a gap between the side of wing cap member and side wall of the channel shaped body.

In a second aspect, the invention resides in a method of preparing a device for use, the device to assist breathing for a mouth including upper and lower teeth and upper and lower jaws forming an airway there between, the device includes a central body with outwardly splayed wing members, whereby in use the central body and wing members have an upper surface and lower surface, a front end rear end with edges wherein at least a portion of the lower surface of the central body has at least a roughened portion thereon, wherein in use the device, itself
being held in place in the mouth by engagement of the upper side of the wing members with
the upper teeth, which in turn holds the tongue in position via the engagement of at least a
portion of the roughened portion of the lower surface of the central body with at least a
portion of an upper surface of the tongue, while at the same time the device holds the lower
jaw in place via the engagement of the lower side of the wing members with the lower teeth,
wherein the wing members are formed from a low melting point thermoplastics material
wherein the method includes the following steps of.

1. Boil water in a container such as a pot or saucepan;
2. Familiarize yourself with the parts of the therapeutic device;
3. Use a mirror to practice positioning the device in your mouth ready for biting whereby
   the curved end 10 is positioned at a front end of the mouth and roughened portion
   faces downward to abut an upper surface of the tongue;
4. The device should be centralized on the lower teeth side to side and slid forward as far
   as it will go into the mouth;
5. When the water is boiling, place the device in the water for a couple of minutes;
6. Then place the device in the mouth with the roughened portion 20 facing downwardly
   on to an upper surface of the tongue;
7. Using the lower jaw advanced as far as possible, without any strain or discomfort, bite
down on the wing members 22, 23 but avoid biting so hard that the upper and lower
   teeth touch together, this biting down will cause the formation of engagement means
   in the form of depressions of at least part of the outside surface shape of the teeth;
8. Hold this position until the device has cooled and
9. To then use, place the device 1 in position in the mouth, pushing the tongue far
   enough forward so that the roughened portion 20 grips downwardly on top of the
tongue when the upper and lower jaws are closed to grip or engage with the upper and
   lower teeth being located in the formed depressions.
BRIEF DESCRIPTION

The invention will now be described, by way of example only, by reference to the accompanying drawings:

**Figure 1** is a perspective view in accordance with a first preferred embodiment of the invention.

**Figure 2** is a top plan view with regard to figure 1

**Figure 3** is a side view with regard to figure 1

**Figure 4** is a front end view with regard to figure 1

**Figure 5** is perspective view of another embodiment of the invention

**Figure 6** is top plan view with regard to figure 5

**Figure 7** is a side view with regard to figure 5

**Figure 8** is a front end view with regard to figure 5

DESCRIPTION OF THE PREFERRED EMBODIMENT(S)

The following description will describe the invention in relation to preferred embodiments of the invention, namely a device 1 to assist breathing and method of use or installation. The invention is in no way limited to these preferred embodiments as they are purely to exemplify the invention only and that possible variations and modifications would be readily apparent without departing from the scope of the invention.

As shown in figures 1-8 device 1 is an intra oral device which is useful in assisting with breathing or alleviating or reducing snoring and/or sleep apnoea. The device 1 is adapted for use in a mouth having upper and lower teeth or teeth and upper and lower jaws or jaws forming an airway therebetween. In use facing the device 1 is shaped from a planar material having a central body 3 of any shape that allows contact with the tongue, like for example a semi circle or shaped as a channel shaped body comprising a base 4 and side walls 5, with wing members 7, 8 extending substantially horizontally outwardly on each side at a top edge 9 of side walls 5, away from central body 3.
The channel shaped body 3 assists in stiffening the body so that gentle pressure that is needed for the roughened portion 20 to grip the tongue does not bend channel shaped body 3 out of shape. Additionally the channel shaped body lowers the roughened portion 20 with respect to the teeth so as to not require the tongue to be pushed forward too much, to allow gripping to take place without discomfort though this depends on each particular mouth shape and structure. What is unique is the way in which the invention is able to control the tongue. Additionally the invention is able to simultaneously and independently control the lower jaw.

Facing the device 1 with the channel shaped body 3 extending away from you defines a front end edge 10 and rear end edge 11 of the device 1 while the distance from the left and right define a width and sides 12 of the device. Additionally an underneath surface of the base 4 of the channel shaped body and under the wing members defines a lower surface 15 and a surface within the channel shaped body 3 and on top of the wing members 7, 8 defines an upper surface 16.

Lower surface 15 of the channel shaped body 3 has at least a portion of that surface 15, with protrusions or roughness or roughened portion 20 which can be for example in the form of small spikes. Side walls 5 can be the same height from front to rear/back or can be a different height at the front to the rear causing there to be a sloping top edge 9 from front (or rear) to rear (or front).

Wing members 7, 8 can be horizontal or angled to any desire orientation with respect to side walls 5 and can be shaped in any suitable shape in plan such as rectangular or trapezoidal with rounded or angled corners. Wing members 7, 8 can have suitable roughness on any of its surfaces and can be covered with a suitable covering if required.

Attached to or formed as part of wing members 7 and 8, there are wing cap members 22 and 23. Winged cap members 22 and 23 are formed as bulbous type formations or covers on at least a portion of wing members 7 & 8 and in use are designed to be gripped by the teeth in the mouth. In another option the wing members 7 & 8 themselves can be gripped the teeth.

Front end edge 10 of the device 1, includes a front edge in a horizontal plane for channel shaped member 3 being straight, front edge of wing members 7, 8 being rounded from a point at the top end edge 9 of side walls 5 and front edge of wing caps 22, 23 being rounded. Rear edge 11 of the device has the rear edge of the channel shaped member 3 and wing members 7, 8 being level or straight and wing caps 22, 23 being rounded in a horizontal plane.
Vertically the front edge of side walls 5 is upwardly curved in a vertical plane. The rear end edge vertically for the channel shaped member 3, wing members 7, 8 and wing cap members 22, 23 are level with each other being substantially vertical in a vertical plane. As seen in plane view (see figures 2 and 6) the area of the wing cap members 22, 23 can be larger than the area of the wing members 7, 8 or be such that they extend rearwardly beyond an end edge of wing members 7, 8 but be recessed back from the front end edge 10 of the wing members 7, 8 and extend laterally beyond a side edge of wing members 7, 8. Also as shown the side edge of the wing cap members are spaced by a gap 24 from an outer surface of the side walls 5 of the channel shaped member 3.

As seen in figures 1, 2, 5 and 6 in use, front end 10 (as in use) is curved and the roughened portion 20 faces outwardly of the channel shaped body 3 and downwardly (when in use) to abut and intermesh and grip with an upper surface of the tongue. In plan view the wing cap members 22, 23 are rounded being recessed back in the front from the front end edge 10 of the channel shaped member and extend rearwardly beyond the rear end edge 11. Front end edge 10 can be rounded or curved 25 in a vertical plane. Wing members 7, 8 and wing cap members 22, 23 need to be shaped or comprise at least a part of, of a material that allows them at least, to be able to be deformed by biting or pressing down when being prepared for use (see method), to form depressions that match exactly or be similar or close to the shape of at least an end portion of the teeth and to remain deformed during normal use of the device 1.

As shown in the figures device 1 is an intra oral device which can be for example injection moulded from one melting point like for example a low melting point thermoplastics material to allow moulding by user with hot water and bending or alternatively the device can include parts of the device 1 formed of different melting points. For the different melting points, the channel shaped central body 3 with or without the wing members 7 & 8 can be formed of a high melting point thermoplastics material and the wing cap members 22 & 23 can be formed of a low melting point thermoplastics material.

Wing cap members 22 and 23 can be as large or as small and shaped as required or can simply be formed integrally as part of the wing members 7 and 8 whereby the wing members themselves perform this function but the wing cap members 22, 23 and/or wing members 7 and 8, must be malleable or soft enough to allow biting thereon by teeth, to hold the device 1 in place in the mouth. As shown in the figures each wing cap member can be planar in overall shape similar to each wing member but of the same shape or not and are planar in shape being
oriented parallel to each wing member which also can be planar in shape. The planar shape of
the wing cap members or wing members can include a substantial horizontal plane parallel
with the overall planar shape having a width or length being less than a thickness or vertical
depth.

When in use the device 1 itself, is held in place in the mouth by engagement of the upper side
of the wing members or wing cap members with the upper teeth, which in turn holds the
tongue in position via the engagement of the roughened portion of the lower surface of the
central body with an upper surface of the tongue, while at the same time the device holds the
lower jaw in place via the engagement of the lower side of the wing members with the lower
teeth. The engagement by the upper teeth and lower teeth includes gripping whereby the teeth
intermesh with complementary depressions in the wing member which are formed when the
device is prepared for use as given by the method disclosed in this specification.

Gripping the tongue is to prevent the tongue from falling back and blocking the airway when
the user is asleep while the tongue is relaxed while at the same time the wing members are
gripped by the upper and lower teeth.

**Method for preparing the device for use - one melting point of low temperature**

In one option, initially device 1 can be moulded in a flat form and the user then warms the
device in hot water to a point where it can be folded over, bending naturally at the narrowed
hinge section, then insert into the mouth and bitten down on to, to from the semi-circular
wings into the shape of the users back teeth with the lower jaw in the position in which the
jaws naturally close together. That is, there is no need to pull the lower jaw forward into a
position which would become uncomfortable after a while.

Once the device 1 is formed to the shape of the teeth and before it has cooled, a plate with
hundreds of tiny, forward leaning spikes on the surface is attached to the device via small
studs which are part of the plate moulding. The studs are an interference fit in the
corresponding holes in the device, so as the device cools it grips the plate studs firmly. The
plate is injection moulded in a fairly hard (Shore D) high melt temperature thermoplastics
material.

When the tongue is inserted into the device and the jaws brought together, the spikes on the
plate engage with the naturally rough surface of the top of the tongue to grip the tongue and
prevent it from falling back and blocking the airway when the user is asleep and the tongue is relaxed. At the same time the engagement of the lower teeth into the lower section of the device prevents the lower jaw from falling back.

An adjustable elastic chin strap can be included in the pack for those users whose upper and lower jaws tend to fall open while sleeping.

**Method of preparing the device for use - different melting points**

Central channel shaped body with high melting point and the wing cap members or wing member with a low melting point whereby the method of preparing the device for use includes the follow steps of:

1. Boil water in a container like for example a pot or saucepan;

2. Familiarize yourself with the parts or components of the therapeutic device;

3. Use a mirror to practice positioning the device in your mouth ready for biting whereby the curved end 10 is the front end (facing outwardly from the mouth) and the roughened portion 20 faces downward onto an upper surface of the tongue;

4. The device should be centralized on the lower teeth side to side and slid forward as far as it will go into the mouth;

5. When the water is boiling, place the device in the water for a certain time (eg couple of minutes);

6. Then place the device in the mouth with the roughened portion 20 downwardly abutting the top of the tongue;

7. Using the lower jaw advanced as far as possible, without any strain or discomfort, bite down on the wing members 7, 8 or cap members 22, 23 but avoid biting so hard that the upper and lower teeth touch together. This biting down will cause the formation of engagement means in the form of depressions shaped similar to at least a part of the teeth eg at least a portion of an end part of the outer surface shape of the teeth,

8. Hold this position until the device has cooled and
9. To use the device, place the device in position in the mouth pushing the tongue far enough forward so that the roughened portion 20 grips the tongue when the upper and lower jaws are closed to grip or engage with the upper and lower teeth being located in the formed depressions.

In general, boiling device 1 again will reform the wing cap members 22, 23 back to their original shape. One needs to try the device 1 before sleeping as a user may find that their individual jaw structure would better suit an adjusted starting position (for the device or your lower jaw) or a different level of bite-down. One can re-boil or re-bite as many times as required to achieve a better fit for the mouth, remembering that the desired outcome is for the tongue to be held as far forward as possible without discomfort. Some users of the device 1 may notice an increase in saliva production which is normal and will settle down very quickly as the mouth gets used to having the device 1 there. During use of the device 1 with the upper and lower jaws closed the upper and lower teeth might also grip the wing members 7, 8 or wing cap members 22, 23.

For the engagement by gripping which forms the depressions in the wing members or wing cap members, these depressions can be formed during boiling as in the above method but can also be formed when the wing members or wing cap member are softened by heat or even just by biting. Alternatively the engagement can just be by gripping without the depressions.

Though the device 1 is carefully designed and manufactured to give the maximum benefit to the maximum number mouth types, there are so many human anatomical differences meaning that the device may not be suitable for some mouths. An adjustable elastic chin strap can be included in the pack for those users whose jaws tend to fall open while sleeping.

**ADVANTAGES**

a) Able to simultaneously and independently control both the tongue and the lower jaw

b) Minimal discomfort through use of the device

c) Able to be used to not cause discomfort or injury

d) Direct control of the tongue

d) Simultaneously and independently control the lower jaw
c) Improves sleeping and/or breathing
f) Simple manufacture
g) Modest cost
h) Easy to use
i) Able to be reused
j) Simple method for preparing for use

VARIATIONS

To those skilled in the art to which the invention relates, many changes in construction and widely differing embodiments and application of the invention will suggest themselves without departing from the scope of the invention as defined in the appended claims. The disclosures and the descriptions herein are purely illustrative and are not intended to be limiting. The terms 'front', rearwardly and 'rear' or similar type words, can be referenced with respect to the mouth where the 'rear' is at or near the back of the mouth and front is at the lips-end end of the mouth or that end that faces outwardly.

The examples and the particular proportions set forth are intended to be illustrative only and are thus non-limiting. Device 1 can be formed from any suitable material able moulded to fit a mouth or be a material able to be repeatably heated and deformed such as regular polypropylene for the body 3 and a propylene-based elastomer (PBE) like for example Vistammaxx™ for the wing members 7, 8 and or wing cap member 22, 23. The device 1 of the present invention can be formed from any suitable material and can be formed as a one piece item or from components assembled together during manufacture or during use.

Central body 3 can be any shape and cross section that allows the roughened portion 20 to contact and grip the top or upper surface of the tongue while optionally the wing members 7, 8 and/or wing cap members 22, 23 can be gripped by closing the jaws causing the lower and upper teeth to grip each wing member or wing cap member. For example central body 3 can be angular or curved or a combination of both. Roughened portion 20 is designed in terms of shape, spacing and sharpness to cause a self gripping with the tongue sort of like, hook and
loop type fasteners (eg velcro tm) even when the mouth is opened without any upward or downward pressure from the teeth and/or jaw.

The wing cap members 22, 23 or roughened portion 20 can be formed as separate portions or be formed as part of the whole device 1. Roughened portion 20 can be formed in any form or shape that allows for holding with the upper surface of a tongue. For example, roughened portion 20 can be raised flattened areas or conversely recessed areas leaving raised areas there between, spurs, knobs etc. or can be an add on piece to at least a portion of base 15 of the channel shaped body 3. Side walls, channel shaped body 3, wing cap members and wing members can be of any suitable dimension or shape and can be solid and/or hollow members or member with holes or apertures and/or be meshed or grid like in pattern or be formed of different colours or include antibacterial formulations therein.

Wing member 7, 8 and/or wing cap members 22, 23 can be any desired area and volume or can be made up of or added in extra layers if required. Gap 24 can also be any dimension from nothing and greater. The wing cap members 22, 23 can be joined to each wing member 7, 8 by any suitable means such as for example hot melting, spot welding, glued, adhered or fastened thereto. The word "member(s)"s is used implying being formed integrally though equally the word "members" can be replaced by the word "portions". Various slots, apertures or recesses can also be formed in any portion of the device 1. Additionally curves or bevels can be included.

The invention has been described with particular reference to certain embodiments thereof. It will be understood that various modifications can be made to the above-mentioned embodiment without departing from the ambit of the invention. The skilled reader will also understand the concept of what is meant by purposive construction.

It will also be understood that where a product, method or process as herein described or claimed and that is sold incomplete, as individual components or steps, or as a "Kit of Parts", that such exploitation will fall within the ambit of this invention even though there may not be any claim to a kit of parts included in the following claims. The device 1 can be formed as a flat packed item which can be folded to a desired shape or can be assembled or include replaceable components or parts for the wing members or wing cap members.

It is acknowledged that the term 'comprise' may, under varying jurisdictions, be attributed with either an exclusive or an inclusive meaning. For the purpose of this specification, and
unless otherwise noted, the term 'comprise' shall have an inclusive meaning - i.e. that it will be taken to mean an inclusion of not only the listed components it directly references, but also other non-specified components or elements. This rationale will also be used when the term 'comprised' or 'comprising' is used in relation to one or more steps in a method or process.
What we claim is:

1. A device to assist breathing for a mouth including upper and lower teeth and upper
and lower jaws forming an airway there between, the device includes a central body with
outwardly splayed wing members, whereby in use the central body and wing members have
an upper surface and lower surface, a front end rear end with edges wherein at least a portion
of the lower surface of the central body has at least a roughened portion thereon, wherein in
use the device, itself being held in place in the mouth by engagement of the upper side of the
wing members with the upper teeth, which in turn holds the tongue in position via the
engagement of at least a portion of the roughened portion of the lower surface of the central
body with at least a portion of an upper surface of the tongue, while at the same time the
device holds the lower jaw in place via the engagement of the lower side of the wing members
with the lower teeth.

2. The device to assist breathing as claimed in claim 1 wherein gripping the tongue
prevents the tongue from falling back and blocking the airway when the user is asleep while
the tongue is relaxed, while at the same time the wing members are gripped by the upper and
lower teeth wherein engagement of the wing members of the lower teeth into a lower section
of the device prevents the lower jaw from falling back.

3. The device to assist breathing as claimed in claim 2 wherein engagement by the upper
teeth and lower teeth to the wing members includes gripping the wing members.

4. The device to assist breathing as claimed in claim 3 wherein whereby the gripping
includes the teeth intermeshing with complementary depressions formed in each wing
member.

5. The device to assist breathing as claimed in claim 4 wherein the central body is a
channel shaped body including a square shaped cross sectional shape which includes a base
and side walls.

6. The device to assist breathing as claimed in claim 5 wherein, at least one wing cap
member encases or covers at least a portion of each wing member and are planar in shape
being oriented parallel to the wing member.

7. The device to assist breathing as claimed in claim 6 wherein, the device is formed of a
thermoplastics material wherein the channel shaped body is formed from a high melting point
thermoplastics material and the wing members and/or cap members are formed from a low melting point thermoplastics material.

8. The device to assist breathing as claimed in claim 7 wherein, the side walls of the channel shaped body are substantially vertical having a sloping top end edge.

9. The device to assist breathing as claimed in claim 8 wherein, the front end edge includes a front end edge of the wing members and wing cap member are rounded in a horizontal plane.

10. The device to assist breathing as claimed in claim 9 wherein, front end edge includes a front edge of the side wall being rounded in a vertical plane.

11. The device to assist breathing as claimed in claim 10 wherein, the rear end edge of the wing cap members are rounded in the horizontal plane whereas the rear end edge of the channel shaped body and wing member are straight.

12. The device to assist breathing as claimed in claim 11 wherein, the device has a greater length from side to side than front to rear.

13. The device to assist breathing as claimed in claim 12 wherein the wing cap members are positioned on the wing members to extend rearwardly beyond an end edge of the wing members, be recessed from a front end edge of the front end edge of the channel shaped body and extend beyond a side end edge of the wing members whereby there is a gap between the side of wing cap member and side wall of the channel shaped body.

14. A method of preparing a device for use, the device to assist breathing for a mouth including upper and lower teeth and upper and lower jaws forming an airway there between, the device includes a central body with outwardly splayed wing members, whereby in use the central body and wing members have an upper surface and lower surface, a front end rear end with edges wherein at least a portion of the lower surface of the central body has at least a roughened portion thereon, wherein in use the device, itself being held in place in the mouth by engagement of the upper side of the wing members with the upper teeth, which in turn holds the tongue in position via the engagement of at least a portion of the roughened portion of the lower surface of the central body with at least a portion of an upper surface of the tongue, while at the same time the device holds the lower jaw in place via the engagement of the lower side of the wing members with the lower teeth, wherein the wing members are
formed from a low melting point thermoplastics material wherein the method includes the steps of:

1. Boil water in a container such as a pot or saucepan;

2. Familiarize yourself with the parts of the therapeutic device;

3. Use a mirror to practice positioning the device in your mouth ready for biting whereby the curved end 10 is positioned at a front end of the mouth and roughened portion faces downward to abut an upper surface of the tongue;

4. The device should be centralized on the lower teeth side to side and slid forward as far as it will go into the mouth;

5. When the water is boiling, place the device in the water for a couple of minutes;

6. Then place the device in the mouth with the roughened portion 20 facing downwardly on to an upper surface of the tongue;

7. Using the lower jaw advanced as far as possible, without any strain or discomfort, bite down on the wing members 22, 23 but avoid biting so hard that the upper and lower teeth touch together, this biting down will cause the formation of engagement means in the form of depressions shaped similar to at least a part of the outer surface of the teeth;

8. Hold this position until the device has cooled and

9. To then use, place the device 1 in position in the mouth, pushing the tongue far enough forward so that the roughened portion 20 grips downwardly on top of the tongue when the upper and lower jaws are closed to grip or engage with the upper and lower teeth being located in the formed depressions.
A. CLASSIFICATION OF SUBJECT MATTER

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

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 database consulted during the international search (name of database and, where practicable, search terms used)

WPI and EPDOC; IPC, CPC: A61F5/--; A61C7/--; Keywords: snoring, breathing, sleep apnea, airway, oral, mouth, teeth, mouth guard, retainers, thermoplastic, Rough, uneven and like terms.

Espace and Google patents: Keywords: snoring, breathing, sleep apnea, airway, oral, mouth, teeth, mouth guard, retainers, thermoplastic and like terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
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</table>

Documents are listed in the continuation of Box C

Further documents are listed in the continuation of Box C

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
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Date of the actual completion of the international search
24 February 2014

Date of mailing of the international search report
24 February 2014

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Ian Carroll
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<th>Category</th>
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<th>Relevant to claim No.</th>
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<td>US 5915385 A (HAKIMI) 29 June 1999&lt;br&gt;Abstract: Column 3, lines 23-24; Column 4, lines 57-59; Column 3, line 63 - Column 4, line 3; Column 5, lines 2-4 and 47; Figures 1-3 and 5.</td>
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<td>WO 1996/01 1653 A1 (KENNARD) 25 April 1996&lt;br&gt;Abstract: page 1, lines 5, 17-18; page 2, lines 1-2; page 4, lines 35-36 - page 5, line 1; Figures 1-3.</td>
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<td>EP 0312368 B1 (HAYS &amp; MEADE, INC.) 29 December 1993&lt;br&gt;Column 1, lines 17-21; Column 2, lines 16-18; Column 3, lines 13-15; Column 4, lines 40-45; Figures 1-4.</td>
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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.

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