

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
5 March 2009 (05.03.2009)

PCT

(10) International Publication Number
WO 2009/026659 A1

(51) International Patent Classification:
A61C 7/00 (2006.01) A61C 7/36 (2006.01)

(21) International Application Number:
PCT/AU2008/001293

(22) International Filing Date: 29 August 2008 (29.08.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
2007904670 29 August 2007 (29.08.2007) AU

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, 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, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, 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
— with amended claims

(54) Title: AN ORTHODONTIC APPLIANCE

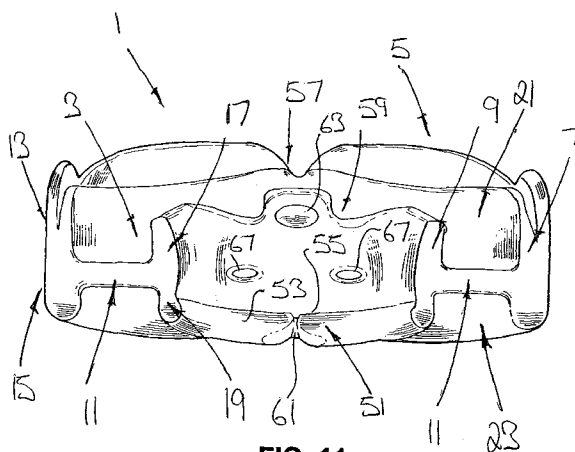


FIG. 11

(57) Abstract: An orthodontic appliance (1) that is particularly useful for correcting a class occlusion is disclosed. The appliance (1) includes a mounting arrangement (3) for mounting over an upper arch of a user having a front region and two arm regions extending rearward from the front region. The mounting arrangement (3) includes an outer wall (7) and an inner wall (9) and a web (11) extending there between. The outer wall (7), the web (11), and the inner wall (9) collectively define an upper channel (21) within which the upper arch and teeth of a user are received to mount the appliance (1). They also define a lower channel (23) for receiving the lower arch and teeth. The outer wall (7) has an upper portion (17) spaced forward of the upper arch teeth and gums forming an outer spacing formation (4) for holding the buccal mucosa away therefrom. The appliance (1) also includes a tongue elevator (51) on a lower portion of the inner wall (19) for raising the position of a user's tongue. The appliance is made of a resiliently flexible material that when deformed out of a resting position corresponding to an arch form will tend to return to the desired arch form. Further the resilient flexibility assists fitting of the appliance.



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AN ORTHODONTIC APPLIANCE

FIELD OF THE INVENTION

This invention relates to an orthodontic appliance.

5 This invention relates particularly but not exclusively to an active orthodontic appliance for use in the treatment of a Class 3 malocclusion. It will therefore be convenient to hereinafter describe the invention with reference to this example application. However at the same time it is to be clearly understood that the invention is capable of broader application. For example the appliance may also have application in the
10 treatment of other conditions and other types of malocclusions. Further the orthodontic appliance can also be used as a functional orthodontic appliance and as a passive orthodontic appliance.

BACKGROUND TO THE INVENTION

15 Humans have an upper jaw called a maxilla forming an upper arch and a hinged lower jaw called a mandible forming a lower arch. A patient has correct dental occlusion when the upper arch matches the size and shape of the lower arch such that the teeth of the upper and lower jaw come together when the jaws are closed. Further individual teeth of the upper and lower arch are correctly positioned along the length of the arch relative to each other such that they match each other correctly.

20 However while the upper and lower arches are broadly of the same size they are subtly offset relative to each other. Specifically the teeth of the upper arch are off set relative to the teeth of the lower arch so that at least part of each tooth of the upper arch is positioned outward of the corresponding tooth on the lower arch. The incisors of the lower arch are positioned behind the incisors of the upper arch.

25 Figs. 1 and 2 are respectively a side view and a rear view of a user's upper and lower arches showing correct dental occlusion. Fig 1 clearly shows the incisors of the upper jaw positioned forward of the incisors of the lower jaw. Further the rear view shows how this offset of the teeth of the lower jaw relative to the upper jaw extends along the full length of the jaw and is clearly visible on the rear molars.

30 However malocclusions which involve a mismatch in the sizes of the upper and lower jaw are a relatively common condition in human populations around the world.

 A Class 2 occlusion occurs when the upper jaw of a patient is larger than the lower jaw. A Class 2 occlusion is caused by a lack of development in the lower jaw of a user resulting in a lower jaw with a smaller arch than the upper jaw. A consequence of this is
35 that the teeth of the upper jaw project out anteriorly proud of the teeth of the lower jaw

producing a deep bite curve between the teeth of the upper and lower jaws. Caucasian populations are particularly prone to a Class 2

Another type of occlusion is a Class 3 occlusion in which the lower arch is more developed than the upper arch and does not correctly match the size of the upper arch. Typically this includes having a mid facial region that is underdeveloped, e.g. the anterior region of the maxilla on the upper arch is underdeveloped and is positioned behind the anterior region of the lower arch. This can cause the anterior incisor teeth of the lower arch to project out anteriorly proud of the incisor teeth of the upper arch as shown in Fig 3 of the drawings. As discussed in the description of correct dental occlusion above, the incisors of the lower arch should be received behind those of the upper arch with an offset of about 2mm.

The class 3 occlusion typically extends the full arcuate length of the arch and affects the canine regions and the molar regions as well as the incisor region. For example the molar region of the upper arch may be underdeveloped and of narrower width than that of the lower arch. The mismatch of the upper and lower arches in the molar region of a patient is shown in Fig 4 of the drawings. Class 3 occlusions are particularly common in Asian populations around the world.

Essentially the class 3 occlusion is caused by a mismatch in the growth of the long bones of the maxilla and mandible in the developmental stages of a child's growth. This can be caused by myofunctional habits that encourage inhibiting forces to be applied to structures of the upper arch and encourage promoting forces to be applied to structures of the lower arch. For example the tongue can apply a considerable pressure to an arch of a patient such as the lower arch to promote its development. Further the lips and cheeks of a user can apply a considerable inward pressure to the arch, e.g. the upper arch of a user, to retard or inhibit development of the upper arch.

One way of treating a Class 3 occlusion is by surgical intervention. The lower arch or mandible is physically broken and then reset in the ideal bite position with correct dental occlusion. However this treatment is very aggressive and invasive. Further the results achieved with this treatment can be mixed.

Another way of treating a class 3 malocclusion has been to custom build an appliance known as a Frankel cage to fit the jaw and mouth of a user. A custom made Frankel appliance is shown in Fig 5. Essentially the Frankel cage is made by taking bite impressions of a user's mouth and then building a model of a patient's bite. A cage that is sized and shaped to clip onto the arch of that particular user is built up from this bite model in a dental laboratory. The cage is clipped into position in the upper and lower

arches. However the results obtained by orthodontists from treating a Class 3 occlusion with a Frankel cage have been mixed. While some success has been obtained with widening the upper arch width in the molar region, the mid facial region, or anterior incisor region of the upper arch can tend to remain underdeveloped. Further the time taken to
5 achieve reasonable correction of a class occlusion can often be very lengthy.

Clearly therefore it would be advantageous if a less aggressive and less invasive form of treating a Class 3 occlusion than maxilla surgery could be devised. It would also be advantageous if a treatment could be devised that encouraged the mismatch in sizes of the upper and lower arches to be corrected along the full length of the arch
10 simultaneously. Yet further it would be advantageous if the treatment times for treating class 3 occlusions in a developing child could be reduced.

SUMMARY OF THE INVENTION

According to one aspect of this invention there is provided an orthodontic appliance for being received in the mouth of a user, comprising:

15 a mounting arrangement for mounting over an upper arch of a user, and an outer spacing formation on the mounting arrangement for holding a portion of the buccal mucosa away from at least one of the incisor and canine regions of a user's upper arch so that the spaced portion of the buccal mucosa does not apply an inward force to this region/s of the upper arch.

20 The outer spacing formation may hold a portion of the buccal mucosa away from the incisor region of the user's upper arch. The outer spacing formation may also hold a portion of the buccal mucosa away from the molar region of the user's upper arch. Yet further the spacing formation also holds a portion of the buccal mucosa away from the canine region of the user's upper arch. Conveniently the outer spacing formation may
25 extend continuously across all of the incisors, the canines and the molars of a user.

The mounting arrangement may comprise an outer wall and an inner wall, and a web extending between the inner and the outer walls. The outer wall the web and the inner wall may collectively define an upper channel within which the upper arch teeth and can be received to mount the appliance to an upper arch of a user.

30 The outer spacing formation may be formed by the outer wall of the mounting arrangement.

The outer and inner walls of the mounting arrangement may include an incisor region extending across the incisor region of a user's arch and two canine regions on each side of the incisor region for extending across the canine regions of a user, and two

molar regions on each side(of the canine regions) for extending across the molar regions of a user.

The mounting arrangement including the inner and outer walls may have a generally curved form with a curved incisor region. The canine and molar regions may be in the form of two arms or arm regions extending rearward from each end of the incisor region whereby to correspond generally to arch shape. Thus the mounting arrangement may have a U shaped or parabolic form.

The mounting arrangement may be resiliently flexible. In particular the outer and inner walls and the web may be able to flex resiliently when the arms are moved or displaced out of a resting position, e.g. corresponding to a desired arch form, to accommodate a different arch width in a user, e.g. a narrow upper arch. The deformed walls and the web may apply a return force to the arch tending to return it to the resting position. The resilience of the inner and outer walls may also assist in fitting the appliance to the arch and teeth.

In addition to defining the upper channel described above, the outer wall, the web, and the inner wall may also define a lower channel within which the lower arch teeth can be received. The web may be positioned intermediate the upper and lower terminal edges of the inner and outer walls whereby to define the upper and lower channels. The mounting arrangement may have a generally H shaped cross section along its length.

The outer wall defined above, may comprise an outer wall upper portion that is above the web, and a outer wall lower portion that is below the web. Similarly the inner wall may have an inner wall upper portion that is above the web and an inner wall lower portion that is below the web.

Looking now at the different surfaces on the outer and inner walls, the outer wall may have a buccal outer surface, an outer wall upper channel surface and an outer wall lower channel surface. The inner wall may have a lingual inner surface, an inner wall upper channel surface and an inner wall lower channel surface. The web may include an upper channel web surface and a lower channel web surface.

The upper channel may be defined by the outer wall upper channel surface, the upper channel web surface and an inner wall upper channel surface described above. In use the teeth and gums of the upper arch of a user make contact with one or more of these tissues to mount the mounting arrangement thereto. Correspondingly the lower channel may be defined by the outer wall lower channel surface, the lower channel web surface and the inner wall lower channel surface described above, that similarly make contact with teeth and gum tissues of the lower arch, e.g. to fit the mounting formation on

the arch/es. Further the mounting arrangement assists in the correct positioning of a user's lower arch relative to their upper arch by having upper and lower channels for receiving respectively the teeth of the upper and lower arches.

5 The outer wall upper channel surface may be vertically off-set relative to the outer wall lower channel surface. Specifically the lower channel surface may be set back relative to the upper channel surface by a distance of 0.5mm -2.0mm, e.g. 1.0mm to 1.5mm. In addition, the inner wall upper channel surface may be vertically off-set relative to the inner wall lower channel surface.

10 The upper channel web surface may be substantially planar, e.g. flat and planar with some curvature as the web surface leads into the outer wall and inner wall upper channel surfaces. The outer wall upper channel surface may also be substantially linear as it extends upward away from the web surface, although overall it may curve along its length together with the curved form of the outer wall.

15 The outer wall upper channel surface may have a substantially upright orientation (as distinct from a sloping orientation) and may extend upwardly away from the upper channel web surface at an angle of 80 degrees to 100 degrees to the upper channel web surface, e.g. at 85 degrees to 90 degrees.

20 The buccal surface of the upper portion of the outer wall may also extend upwardly away from the upper channel web surface at an angle of 80 degrees to 100 degrees to the upper channel web surface, e.g. at 85 degrees to 90 degrees.

In one form the upper portion of the outer wall, including the outer wall channel surface and the upper portion of the buccal surface of the outer wall, may be substantially vertically extending.

25 The outer wall channel surface may extend up to a height of at least 8 mm, e.g. at least 10mm, above the upper channel web surface along the incisor region thereof. In some forms the outer wall channel surface may extend up to a height of 11 to 15 mm above the upper channel web surface. The outer wall channel surface may have a minimum height (or lowest height) along its full length of at least 8 mm above the upper channel web surface.

30 The upper channel web surface the outer wall upper channel surface may be suitably dimensioned to permit development of the upper arch of a user and consequent displacement of the teeth of the upper arch relative to the lower arch over time. The upper channel web surface may have a greater width between the outer and inner walls than the lower channel web surface.

The outer wall upper channel surface may have a step formation defined therein intermediate the web upper channel surface and the terminal edge of the outer wall. The wall is thicker below the step formation and this may confer additional strength to the below step region thereof. The step formation may step outward and may extend
5 substantially the full length of the outer wall parallel to the upper channel web surface.

Apart from the step formation, the upper portion of the outer wall may have a substantially even cross sectional thickness in the direction of its height and also along its length.

The inner wall upper channel surface is arranged and positioned so that it bears
10 up against the teeth and associated gum of the upper arch of a user, e.g. with a snug fit that makes contact with the teeth and associated gums of a user. In particular the inner wall upper channel surface may be sized to fit snugly against the teeth and associated gums along the full arch length. This may assist with fitting the mounting formation to the arch and teeth.

15 The inner wall upper channel surface of the inner wall may curve upward and away from the upper channel web surface in a direction away from the upper channel web surface, e.g. towards the interior of the U shaped form of the inner wall. The curvature of the inner wall upper channel surface may be quite pronounced. Further the width or extent of the inner wall upper channel surface may deplete in a direction towards the rear
20 of the U shaped wall. The inner wall upper channel surface may be short and substantially upright towards its rear ends.

The lower web surface, like the upper web surface, may be substantially planar for having end surfaces of a user's teeth bearing against it. Overall the web may be of broadly similar cross sectional thickness across its width and along its length.

25 The outer wall lower channel surface may extend downwardly at an angle of 80 degrees to 90 degrees to the lower web surface and also to the upper web surface, e.g. at 85 to 89 degrees to the lower web surface.

The vertical extent of the lower portion of the outer wall may be significantly less than that of the upper portion of the upper wall. For example the vertical extent of vertical
30 height of the lower portion may be 2 to 8 mm, from the lower channel web surface to a terminal end thereof.

The lower portion of the outer wall is designed to fit closely to the teeth and lower arch of a user and is not dimensioned to be spaced from the buccal surface of the teeth, like the upper portion of the outer wall.

The lower portion of the buccal surface of the outer wall may be substantially linear, but may be inclined relative to the upper portion of the buccal surface of the outer wall, e.g. at an angle of 2 to 10 degrees.

5 The orthodontic appliance may further include a tongue elevating formation on the mounting arrangement for elevating the tongue of a user to a position where it does not apply pressure to the lower arch of a user. The tongue elevating formation may be formed on the inner wall, e.g. the lower portion of the inner wall.

10 The inner wall lower channel surface may curve outwardly away from the lower channel surface of the web in a direction away from the lower channel web surface, e.g. towards the interior of the U shaped form. The lower portion of the lingual surface of the inner wall may also curve downwardly in a similar fashion.

The lower portion of the inner wall may include a terminal lower end on the lower portion of the inner wall, and a terminal edge region extending along the lower end. The tongue elevating formation may be positioned on the terminal edge region.

15 The tongue elevating formation may be formed by forming the terminal edge region of increased thickness along at least part of its length. In particular the terminal edge region may be a bulbous terminal edge region extending along at least the intermediate region of the inner wall. The bulbous terminal edge region may have a diameter of 3-6mm.

20 The bulbous terminal edge region may extend along the incisor region and may also extend along at least part of the canine and/or molar regions of the inner wall. In one form the bulbous terminal edge region may extend at least half of the length of the inner wall.

25 The bulbous terminal edge region may encourage a user's tongue to adopt a position sitting on an upper surface of the bulbous terminal edge region and thereby lift up the position of the tongue in a user's mouth so that it does not exert a significant pressure to the lower arch whereby to promote over development of the lower arch. The tongue elevating formation may have an uppermost point, and the uppermost point of the elevating formation may be positioned 2 mm to 6 mm beneath the lower channel web surface, e.g. 3 to 5mm below the lower channel web surface.

30 The outer wall may have a cut away in the incisor region thereof for permitting the molar regions of the inner and outer walls to be moved towards and away from each other to accommodate different arch sizes in different users. The cutaway may be located in the upper portion of the outer wall, and conveniently the cutaway may be broadly centrally positioned.

35

Similarly the inner wall may have at least one cutaway defined broadly in the incisor region for facilitating the arms of the inner wall being moved towards and away from each other to accommodate varying arch widths. Conveniently the inner wall may have cutaways defined in both the upper and lower portions thereof to achieve this
5 functionality.

The upper portion of the outer wall may include two further recess cutaways on respectively the left and right arms of the mounting arrangement, e.g. in the molar region thereof. These further recess cutaways contour around a bony protrusion at this point along the upper arch and thereby permit the protrusion to project there through. This
10 feature therefore increases user comfort when the appliance is worn.

The inner wall may further have a tongue tab formed in the upper portion thereof. The tongue tab indicates a correct tongue position to a user when the tip of their tongue bears against the tongue tab. The tongue tab typically is located in a front central position on the inner wall and may be formed integrally with the inner wall as a part thereof. The
15 tongue tab is quite different to the tongue elevating formation in that it does not actively direct a user's tongue to adopt a correct position. It simply provides a locator for the tongue tip that helps a user to voluntarily position their tongue correctly.

Conveniently the inner wall may have two said cutaways on the lower portion thereof, one on either side of the tongue tab. The tongue tab is quite different to the
20 tongue elevating formation in that it does not actively direct a user's tongue to adopt a correct position. It simply provides a locator for the tongue tip that helps a user to voluntarily position their tongue correctly.

The mounting arrangement may have breathing apertures defined therein. In particular the mounting arrangement may have two laterally spaced breathing apertures
25 passing through the outer wall, the web, and the inner wall, in the incisor regions thereof. The breathing apertures enable a user to breathe through their mouth when wearing the appliance and thereby assist wearer comfort.

The mounting arrangement comprising the outer wall, the inner wall and the web may be integrally formed. For example these components may be integrally formed in a
30 moulding operation, e.g. an injection moulding operation. Similarly the tongue elevating formation, the tongue tab and the breathing apertures may be integrally formed with the inner and outer walls and web when they are moulded.

The external structural features of the orthodontic appliance that interact with a user's mouth have been described above. The appliance may include some internal
35 structure that assist it to carry out its function will be described below.

The appliance may further include a base member that is received internally, e.g. encased, within the teeth contacting member. The base member may be made of a stiffer material than the teeth contacting member for conferring some stiffness and structural rigidity on the mounting arrangement while still providing it with an ability to resiliently flex
5 to enable it to be deformed out of a resting position to accommodate different users.

The base member may comprise a framed structure, e.g. an open framed structure, to assist in conferring the requisite stiffness and structural rigidity while still providing said resilience. The open frame structure may comprise a framed web portion broadly coextensive with the web of the mounting arrangement and a framed wall portion
10 that is broadly coextensive with the outer wall. The framed wall portion may comprise an upper framed wall portion on one side of the web portion extending across the upper portion of the outer wall, and a lower framed wall portion extending across the lower portion of the outer wall.

Each said frame portion may comprise two longitudinal frame members and a
15 plurality of cross members extending between the two longitudinal members at spaced intervals along their length. One of the longitudinal members of the frame upper wall portion may be joined to one of the longitudinal members of the frame lower wall portion, and one of the longitudinal members of the frame web portion may be joined to a longitudinal member of the frame upper wall portion.

20 The frame lower wall portion may be vertically offset with respect to the frame upper wall portion. In particular the frame lower wall portion may be set back relative to the frame upper wall portion by a distance on 0.5 to 2.0mm, e.g. 1.0mm to 1.5mm. This corresponds broadly to the similar offset between the outer wall upper channel surface and the outer wall lower channel surface.

25 As described above the frame structure of the base member may be made of a material that is selected to provide sufficient stiffness and rigidity while still permitting some resilient deformation and flexing of the member to accommodate different arch widths in different users. The material of the framed structure of the base member may be selected from the group consisting of polyamides, polyethylene, polypropylene,
30 polyurethanes, polycarbonate or santoprene. Conveniently the framed structure may be made from a polyamide material, e.g. formed by condensation polymerization of amide monomers or a ring opening polymerization of caprolactam. In particular the polyamide polymer may be a material sold under the trade mark of NYLON TM. The combination of stiffness and rigidity on the one hand and resilience on the other hand has been found
35 unexpectedly to be particularly useful. While capable of flexing when subjected to a

bending force this polyamide material has a good memory and tends to return its original resting position or its original form. The framed structure may be formed as an integral article made of a homogeneous material in a moulding operation, e.g. an injection moulding operation.

5 The mounting arrangement may include a teeth contacting member made of a cushioning material for enabling the mounting arrangement to be comfortably fitted against the gums of a user. The teeth contacting member may be made of a polymeric material containing silicon as a repeating monomer unit within the polymer, e.g. a siloxane polymer or a silane polymer, e.g. a synthetic elastomer which is a cross linked polymer
10 reinforced with silica, yielding a soft silicon rubber material. Conveniently medical grade silicon rubber may be used because it is already widely used in medical applications and has been approved for use in relation to humans. Silicon rubber has some ability to deform like a cushion and is therefore soft and comfortable against the gums and teeth of a user. Instead the teeth contacting member may be made of an addition polymer such as
15 PVC (polyvinylchloride). This material is available in different grades and a soft grade can be chosen for this application. The teeth contacting member may be moulded as an integral article, around said base member, in a second injection moulding operation.

According to another aspect of this invention there is provided an orthodontic appliance for being received in the mouth of a user, comprising:

20 a mounting arrangement for mounting over an upper arch of a user, and a tongue elevator mounted on the mounting arrangement for elevating the tongue of a user to a position where it does not apply significant developmental pressure to the lower arch of a user.

25 The mounting arrangement may comprise an outer wall and an inner wall, and a web extending between the inner and the outer walls. The outer wall the web and the inner wall may collectively define an upper channel within which the upper arch teeth can be received and a lower channel within which the lower arch teeth can be received. The tongue elevating formation may be mounted on the inner wall and may open into the lower channel.

30 The appliance may further include an outer spacing formation on the mounting arrangement, and the outer spacing formation may be formed by the outer wall of the mounting arrangement, e.g. an upper portion thereof defining the upper channel.

According to another aspect of this invention there is provided an orthodontic appliance for being received in the mouth of a user, comprising:

a mounting arrangement for mounting over an upper arch of a user having an arch shape, the mounting arrangement being formed from a resiliently flexible material so that the mounting arrangement is operatively able to adapt to the arch shape and associated teeth of the user; and

5 an outer spacing formation on the mounting arrangement for holding a portion of the buccal mucosa spaced away from at least part of a user's upper arch so that the spaced portion of the buccal mucosa does not apply an inward force to this region of the upper arch.

10 The mounting arrangement may be formed with an arch form corresponding to correct dental occlusion so that when the appliance is applied to a user having an underdeveloped upper arch, the mounting arrangement is resiliently flexed out of its original position and as a result will apply a return force to the teeth and arch tissues of the upper arch of a user that will tend to expand the upper arch of a user.

15 The mounting arrangement may comprise an outer wall and an inner wall, and a web extending between the inner and the outer walls defining an upper channel for the arch having a form corresponding to correct dental occlusion in its original position. The outer spacing formation may be formed by the outer wall of the mounting arrangement and may extend continuously over the incisor, canine and molar regions of a user's mouth.

20 The mounting arrangement may have a curved incisor region with trailing arm regions extending rearward from each side of the incisor region.

The trailing arm regions may be resiliently flexed out of their resting position, and the mounting arrangement will apply a return force tending to return the arm regions to the resting position when this occurs.

25 The arm regions of the channel may be moved towards each other to accommodate a narrowed upper arch width, and in response thereto the mounting arrangement will apply a return force in an outward direction tending to expand the upper arch to a position corresponding to the original position of the mounting arrangement.

30 The distortion of the web part of the mounting arrangement may generate a significant proportion of the return force when the mounting arrangement is deformed out of its original position by virtue of the fact that its major surfaces are deformed by the movement of the arm regions towards and away from each other. The reduced profile of the web in the forwardmost incisor region assists in enabling the arm regions to be moved towards and away each other. In a fortuitous coincidence the incisor teeth have a thinner

end profile than the molar teeth thereby facilitating this reduced profile of the web in the incisor region.

The upper and lower channels may have sufficient dimensional tolerance to be fitted to a range of users with different teeth sizes.

5 The mounting arrangement may be made of a resiliently flexible material that is also soft for forming a cushion for bearing against the teeth and gums of a user, e.g. that has some ability to conform to the contours of the surface of arch and teeth tissues against which it bears.

10 The appliance may include a base member encased within the mounting arrangement made of a material having a resilient flexibility that is more stiff than the mounting arrangement.

The appliance may include a tongue elevating formation mounted on the inner wall. The tongue elevating formation may be integrally formed with the inner wall and thereby the rest of the mounting arrangement by moulding, e.g. injection moulding.

15 According to yet another aspect of this invention there is provided an orthodontic appliance comprising:

a mounting arrangement for mounting over an upper arch of a user including an outer wall and an inner wall, and a web extending between the outer wall and the inner wall, wherein the outer wall, the web, and the inner wall collectively define an upper
20 channel within which the upper arch and associated teeth of a user can be received whereby to mount the mounting arrangement to the upper arch, and a lower channel for receiving the lower arch and associated teeth of a user, wherein the outer wall has an upper portion that is configured to form an outer spacing formation for holding the buccal mucosa spaced away from the gums and teeth of the upper arch.

25 The mounting arrangement may have an incisor region and two arms extending back from the incisor region that extend across the canine and molar regions of the upper arch of a user, and wherein the mounting arrangement is resiliently flexible to enable the arms to be moved towards and away from each other to some extent to accommodate different arch sizes. The resiliently flexible mounting arrangement also helps the mounting
30 arrangement to be fitted onto the arch and teeth of a user.

The appliance may include a tongue elevating formation below the web for interfering with the tongue of a user and forcing the tongue to be elevated. The tongue member may open into the lower channel.

35 According to another aspect of this invention there is provided a method of manufacturing an appliance including:

moulding a base member from a material that when moulded has stiffness and rigidity while still permitting some resilient flexing thereof in a first moulding step;

moulding a mounting arrangement onto the base member in a second moulding step having an integrally formed outer spacing formation for spacing part of the buccal
5 mucosa away from the upper arch.

The method may include forming a tongue elevating formation on the mounting arrangement that is integrally moulded therewith.

The mounting arrangement may be moulded from a material that has resilient flexibility.

10 The base member and the mounting arrangement may each be moulded by injection moulding from a polymeric material. The technique whereby an internal base member is made of a first polymeric material in a first injection moulding operation, and then the teeth contacting member is moulded from a second polymeric material onto the base member to effectively encase the base member within the teeth contacting member
15 is referred to as dual moulding.

The appliance may be manufactured on a commercial scale with a moulding apparatus in several standard appliance sizes that can then be fitted to the bulk of prospective user's in the population. Applicant envisages that three to five different sizes of appliance may be required to cover the overwhelming majority of prospective user's
20 within human populations. Thus the appliance is in the nature of a manufactured appliance that is moulded in a standard size without any reference to the individual arch characteristics of the ultimate end user. It is not a custom built appliance that is manufactured in a laboratory.

According to another aspect of this invention there is provided a method of treating
25 a malocclusion of upper and the lower jaws, including:

fitting an orthodontic appliance as defined in any one of the first to fourth aspects of the invention above to a patient.

The method may include instructing the patient to wear the appliance on repeated occasions at spaced apart time intervals over a treatment period. The instructing may
30 include instructing a user to wear the appliance for several hours a day, e.g. overnight while a user is sleeping. The method may include instructing a patient to wear the appliance at spaced intervals. The treatment period may be at least 12 months, e.g. at least 18 months.

The method may include selecting one size of appliance from a range of sizes in which the appliance is manufactured, the chosen size of appliance being the one that best fits the arch and teeth of the user.

5 The method may be used for treating a class 3 malocclusion, and the treatment period may continue until the malocclusion has been substantially corrected, e.g. the incisors on the lower arch are received behind the incisors on the upper arch.

The method may include monitoring a correction of the malocclusion at spaced intervals over the treatment period.

10 The method may further include maintaining correct dental occlusion in a patient after the malocclusion has been corrected. This may involve directing the patient to wear the appliance less frequently in a given time period such as a week than when active correction of the malocclusion was being carried out.

According to another aspect of the invention there is provided an orthodontic appliance for being received in the mouth of a user, comprising:

15 a mounting arrangement for mounting over an upper arch of a user, the mounting arrangement comprising an outer wall and an inner wall, and a web extending between the inner and the outer walls, so as to define collectively an upper channel and a lower channel within which the upper arch teeth and the lower arch teeth is received respectively, the outer wall defining an outer wall upper channel surface and a outer wall
20 lower channel surface that are vertically offset relative to each other.

The outer wall lower channel surface may be set back relative to the outer wall upper channel surface by a distance of between about 0.5mm and 2.0mm.

25 The inner wall may define an inner wall upper channel surface and a lower wall channel surface and the inner wall lower channel surface may be set back relative to the inner wall upper channel surface. The off set distance may be between about 0.5mm and 2.0mm.

The offset may occur along the full length of the inner wall and the off set may also occur along the full length of the outer wall.

30 The offset brings the teeth of the upper and lower arches into correct dental occlusion in the final stages of displacement of the teeth. If the channel surfaces were vertically aligned with each other the upper and lower teeth would be brought into edge to edge abutment. However this does not represent correct dental occlusion and thus has shortcomings.

The outer wall may form an outer spacing formation as described above and the appliance may include a tongue elevating formation formed on the inner wall as described above.

DETAILED DESCRIPTION OF THE INVENTION

5 An orthodontic appliance for treating inter alia a Class 3 occlusion in accordance with this invention may manifest itself in a variety of forms. It will be convenient to hereinafter describe at least one embodiment of the invention in detail with reference to the accompanying drawings. The purpose of providing this detailed description is to instruct persons having an interest in the subject matter of the invention how to carry the
10 invention into practical effect. However it is to be clearly understood that the specific nature of this detailed description does not supersede the generality of the preceding broad description. In the drawings:

Fig. 1 is a schematic side view of a patient's teeth showing correct dental occlusion;

15 Fig 2 is a rear view of the model of showing correct dental occlusion;

Fig 3 is a schematic side view of a patient's teeth showing a Class 3 occlusion with the incisor teeth of the lower arch positioned proud of the incisors of the upper arch;

Fig 4 is a schematic rear view of a patient's teeth showing a Class 3 occlusion with the upper arch being of narrower width than the lower arch;

20 Fig 5 is a schematic three dimensional view of a Frankel cage mounted on a patient;

Fig. 6 is a lower three dimensional view from the rear of an orthodontic appliance in accordance with the invention;

25 Fig. 7 is an upper three dimensional view from the front of the orthodontic appliance of Fig. 6;

Fig. 8 is a top plan view of the appliance of Fig. 6;

Fig. 9 is a bottom plan view of the appliance of Fig. 6;

Fig. 10 is a front view of the appliance of Fig. 6;

Fig. 11 is a rear view of the appliance of Fig. 6;

30 Fig. 12 is an upper three dimensional view from the front of an internal frame structure forming part of the orthodontic appliance shown in Fig 6;

Fig. 13 is a lower three dimensional view from the rear of the frame structure shown in Fig 12;

Fig 14 is a front view of the frame structure shown in Fig 12;

35 Fig 15 is a side view of the frame structure shown in Fig 12;

Fig 16 in an upper three dimensional view from the front of the appliance of Fig 6 showing the internal frame structure encased within the appliance;

Fig 17 shows a three dimensional part sectional view of the appliance of Fig 16 with the section taken along a midline of the appliance;

5 Fig 18 shows a three dimensional part sectional view of the appliance of Fig 16 with the section taken at an intermediate position along the appliance;

Fig 19 is a schematic side view showing the appliance fitted onto the upper and lower arches of a user;

10 Fig 20 is a plan view of the appliance fitted within the mouth of a user showing the teeth of the upper arch received within an upper channel thereof;

Fig. 21 is a schematic sectional side view of the appliance of Fig. 6 fitted in the mouth of a user, with the mouth tissues and teeth of a user also being shown in section;

15 Fig. 22 is a part sectional rear view showing the appliance fitted in the mouth of a user with the upper arch and teeth being received within an upper channel and the lower arch and teeth being received within a lower channel; and

Figs. 23 to 25 show the progressive development of the upper arch and movement of the associated upper arch teeth over the course of a correction of a class 3 occlusion using the appliance.

20 Figs. 1 and 2 are schematic illustrations of a dental model showing correct occlusion of the upper and lower jaws and associated teeth. Figs. 3 and 4 are schematic drawings illustrating a class 3 occlusion. Correct dental occlusion and the characteristics of a class 3 occlusion are described in some detail in the background to the invention section and will not be described further in this detailed description.

25 Fig 5 is a schematic drawing of a Frankel cage mounted on a dental model of a patient. It shows a custom made appliance that is made in a dental laboratory from bite impressions that is designed to fit only that specific user. Significantly it has no members or formations extending across the incisor or canine regions of the upper arch.

Figs. 6 to 11 show the external shape and configuration of an appliance in accordance with the invention that is indicated generally by the reference numeral 1.

30 The appliance 1 comprises broadly a mounting arrangement shown generally by numeral 3 for mounting over an arch of a user and an outer spacing formation shown by numeral 5 for holding a portion of the buccal mucosa away a user's upper arch so that it does not apply an inward pressure to this region and thereby inhibit development of the upper arch.

The mounting arrangement 3 comprises an outer wall 7 and an inner wall 9 and a web 11 extending between the outer and inner walls 7, 9. The web 11 is positioned intermediate upper and lower edges of the outer and inner walls 7, 9. The outer wall 7 in turn comprises an outer wall upper portion 13 above the web 11 and an outer wall lower portion 15 below the web 11. Similarly the inner wall comprises an inner wall upper portion 17 above the web 11 and an inner wall lower portion 19 beneath the web 11.

The upper portion of the outer wall 13, the web 11 and the upper portion of the inner wall 17 collectively define an upper channel 21 facing upwardly for receiving the upper arch. The lower portion of the outer wall 15, the web 11 and the lower portion of the inner wall 19 define a lower channel 23 facing downwardly for receiving the lower arch of a user. The mounting arrangement 3 have a generally curved incisor region shown by numeral 25 corresponding to the incisor region of a user's arch, and canine regions 27 on each side thereof for extending across the canine regions of a user's mouth, The arrangement also includes molar regions 29 after the incisor regions 27 for extending across at least part of the molar regions in a user's mouth. Each canine and molar region 27, 29 on a side of the incisor region 25 may be in the form of an arm shown generally by numeral 30 extending back from the incisor region 25. Overall the mounting arrangement 2 has a U shaped or parabolic arch form. The mounting arrangement has an H shaped cross section along its length.

The outer wall 7 may have a buccal outer surface 31 facing outwardly, an outer wall upper channel surface 33 facing into the upper channel 21 and an outer wall lower channel surface 35 facing into the lower channel 23. Correspondingly the inner wall 9 has a lingual surface 37 facing away from the channels 21, 23 into the middle of the U shape. It also has an inner wall upper channel surface 39 facing into the upper channel 21 and an inner wall lower channel surface 41 facing into the lower channel 23. Further the web 11 may comprise an upper channel web surface 43 and a lower channel web surface 45.

The upper channel 21 may be defined by the outer wall upper channel surface 33, the upper channel web surface 43 and the inner wall upper channel surface 39. Correspondingly the lower channel 23 may be formed by the outer wall lower channel surface 35, the lower channel web surface 45 and the inner wall lower channel surface 41. It is these surfaces defining the upper and lower channels 21, 23 that in use make contact with the teeth and surrounding mouth tissues of a user.

As is shown particularly clearly in Figs. 11, 17 and 22 the outer wall upper channel surface 33 is vertically offset relative to the outer wall lower channel surface 35. The outer wall lower channel surface 35 is retracted relative to the outer wall upper channel surface

33 by an amount of about 1.0mm to 1.5mm to correspond to the offset with correct dental occlusion as shown in Fig 1.

There is also some offset of the inner wall upper channel surface 39 relative to the inner wall lower channel surface 41 shown clearly in Figs. 11, 17 and 22 once again to reflect the position in correct dental occlusion.

The mounting arrangement 3 with the upper and lower channels 21, 23 is made of a resilient material that can be deformed out of its resting or original unstressed condition (corresponding to a desired arch form) and then when the deforming force is removed it returns to its original or resting unstressed position. This feature enables the appliance 1 to be fitted to different users having different arch sizes and teeth arrangements. The inner and outer walls 9, 7 around the upper and lower channels 21, 23 as well as the web 11 can be deformed to receive the teeth and arches of a user. In particular the arms 30 (encompassing the regions 27 & 29) of the arrangement 3 can be moved towards each other to accommodate a narrow underdeveloped upper arch. When the appliance 1 is fitted to a user with an underdeveloped upper arch the appliance 1 will typically be deformed inwardly out of its resting position (by movement of the arms towards each other) and as a result the return force applied by the resilience of the material will urge it outwardly applying an outward force to the arch and teeth of a user. This tends to encourage growth and development of the upper arch of a user. It also assists with mounting the appliance onto the teeth and gums of a user.

Thus the ability of the material to resiliently flex enables the channels 21, 23 to receive an underdeveloped arch. It also enables the channels to receive an arch in which the teeth that are not perfectly aligned and also arches having different sizes of teeth.

The outer spacing formation 5 is formed by the upper portion of the outer wall 13 which holds the buccal mucosa of a user away from the upper arch and associated tissues of a user so that it does not apply an inward pressure to these tissues. As shown in the drawings the outer spacing formation 5 formed by the upper portion of the outer wall 13 extends continuously along the full length of the incisor, canine and molar regions. This resists the application of inward pressure along all these regions to allow the upper arch to develop.

The web 11 may be of a broadly even cross section or thickness across its width with between the inner and outer walls 9, 7. Further the upper channel web surface 43 and the lower channel web surface 45 may both be substantially planar.

The outer wall 7 as a whole, and specifically the outer wall upper channel surface 33, has a substantially upright orientation and extends upwardly away from the upper

channel web surface 43 at an angle of about 85 to 90 degrees, i.e. it is near perpendicular to the upper channel web surface 43. The buccal surface 31 of the outer wall upper portion 13 may be at a similar angle to the outer wall upper channel surface 33, e.g. at about 85 degrees to 90 degrees to the upper channel web surface 43.

5 The outer wall upper channel surface 33 extends up to a height of at least 8mm above the upper channel web surface 43 along a major portion of its length, and in some regions may have a height of about 12 to 14 mm. This prominent height extends over the bone structure of the upper arch and resists the buccal mucosa from applying pressure thereto. Further the upper channel may be dimensioned to accommodate some expansion
10 of the upper arch during the course of treatment and progressive correction over time of a class 3 occlusion.

 The outer wall upper channel surface 33 has an outward step formation defined therein, intermediate the web upper channel surface 43 and its terminal upper edge, that extends substantially the full length of the wall. A portion of the outer wall is thicker than
15 the remainder thereof to receive an internal frame structure encased therein as will be described in more detail below.

 The inner wall upper channel surface 39 is quite different in shape and character to the outer wall channel surface 33. It is positioned so that it bears up against the lingual surface of the gums and associated teeth of a user with a snug fit. The snug fitting upper
20 portion of the inner wall 17 can apply pressure to the lingual surface of the gums and associated teeth, e.g. to encourage expansion of the upper arch. The snug fit can also assist in mounting the appliance 1 on the arch.

 The inner wall upper channel surface 39 curves upward and away from the upper channel web surface 43 towards the interior of the U shape of the mounting arrangement
25 3. The lingual surface 37 of the upper portion of the inner wall 17 complements broadly the inner wall upper channel surface 39. The vertical extent of the upper portion of the inner wall 17, which extends to a height of 3 to 5 mm above the web surface 43, is considerably less than that of the upper portion of the outer wall 13.

 The degree of curvature of the upper portion of the inner wall 17 is pronounced
30 and the width of the inner wall upper channel surface 39 depletes in a direction away from the incisor region. Each rear end of the upper portion 17 comprises a short upright wall section.

 The lower inner and outer wall portions 15, 19 will now be discussed. The lower portion of the outer wall 19 may extend downwardly below the web 11 at a small angle to
35 the upper portion of the outer wall 13. The vertical extent of the lower portion of the outer

wall 19 is much less than that for the upper portion 17, e.g. depending down a distance of about 4 to 6 mm below the lower channel web surface 45.

The lower portion of the outer wall 15 is designed to fit closely to the teeth and lower arch of a user. In contrast to the upper portion 13 it is not required to form an outer spacing formation for resisting the application of pressure by the buccal mucosa to the
5 upper arch tissues. Further it is not required to provide space for expansion of the lower arch.

Similarly the lower portion of the inner wall 19 is designed to fit closely to the teeth and lower arch of a user. The lower portion of the inner wall 19 curves away from the
10 lower web surface into the space between the arms 30. Both the inner wall lower channel surface 41 and the lingual surface 37 of the lower portion of the inner wall 19 curve away from the web 11 in this fashion. The lower portion of the inner wall 19 depends downwardly below the web 11 a similar distance to the lower portion of the outer wall 15.

As with the upper portion of the inner wall 17 the degree of curvature is
15 pronounced and the width of the inner wall lower channel surface 41 depletes in a direction away from the incisor region 25 towards the rear of the molar regions 29. At the rear of the inner wall 9, the inner wall 9 is short and is substantially upright.

The appliance 1 also includes a tongue elevating formation (tongue elevator) 51
20 on the lower portion of the inner wall 19 for elevating the position adopted by a user's tongue in their mouth so that it does not apply a developmental pressure against the lower arch of a user.

The lower portion of the inner wall 19 defines a lower terminal edge and a terminal edge region 53 extending along the edge. The tongue elevator 51 is formed by having a thickened terminal edge region 53 along the incisor region 25 of the inner wall 9. In the
25 illustrated embodiment the thickened terminal edge region 53 is in the form of a bulbous edge region having a diameter of 3-6mm that is formed integrally with the inner wall 9. The elevator 51 has an uppermost point shown at 55 and the uppermost point is about 2-4mm below the lower channel web surface. The elevator 51 forces a tip region of a user's tongue to adopt a position that is on top of the elevator as shown in the drawings where its
30 influence on the bone and tissue structures of the lower arch is reduced.

The rear ends of each arm of the mounting arrangement 3 are rounded as shown in the drawings. Specifically both the outer and inner walls 7, 9 are rounded and the walls curve respectively upwardly and downwardly away from the rear end of the web 11 which forms the rearmost point of each arm. This feature is shown most clearly in Figs. 6 and 7.

The outer wall 7 has a cutaway 57 defined in the upper portion 17 thereof. The cutaway 57 is shown positioned centrally in the incisor region 25 and permits the arms of the appliance 1 to be moved towards and away from each other. The inner wall 9 has two cutaways 59 on its upper portion 17 and a further cutaway 61 on its lower portion 19.

5 These cutaways 59, 61 are broadly centrally positioned and facilitate movement of the arms of the appliance 1 towards and away from each other to accommodate different arch widths.

Further a tongue tab 63 is located on the upper portion of the inner wall between the two cut away formations 59. The tongue tab 63 provides a tab against which a user

10 can locate the tip of their tongue to correctly position their tongue. It should be understood that this is in the nature of a voluntary indicator to a user of a correct tongue position. It does not force the tongue to adopt a desired position to achieve a certain orthodontic effect like the elevator 51.

The upper portion of the outer wall 13 may include two further recess cutaways 65

15 on the molar regions 29 thereof, e.g. on left and right arms of the mounting arrangement. These further recess cutaways 65 are configured to contour around a bony protrusion on the gum tissues of the upper arch and thereby permit the protrusion to project through the cutaway 65. This feature therefore enhances user comfort when the appliance 1 is worn by a user but does not perform any orthodontic purpose.

20 Further the mounting arrangement 3 has a pair of breathing apertures 67 defined through the outer wall 7, the web 11 and the inner wall 9. The breathing apertures 67 enable a user to breathe through their mouth when wearing the appliance 1.

The external form and shape of the appliance 1 is determined by the mounting arrangement 3 described above. However the appliance 1 includes another component

25 that is a base member 71 encased within the mounting arrangement 3 to help provide the appliance 1 with sufficient stiffness and rigidity to return to its arch form after being resiliently flexed and also to hold the outer spacing formation 5 which is the upper portion of the outer wall 13 away from the teeth and associate tissues of the upper arch.

The base member 71 which is shown in Figs. 12 to 18 is in the form of an open

30 frame structure comprising a framed web portion 73 that is broadly coextensive with the web 11 and a framed wall portion 75 that is broadly coextensive with the outer wall 7. In turn the framed wall portion 75 may comprise an upper framed wall portion 77 coextensive with the upper portion of the outer wall 13 and a lower framed wall portion 79 coextensive with the lower portion of the outer wall 15.

Each of the upper and lower framed wall portions 77, 79 and also the web portion 73 comprises two longitudinal frame members 81 and a number of cross members 83 extending between the longitudinal frame members 81 along their length. Further as shown in the drawings one longitudinal frame member 81 of the upper framed wall portion 5 77 is joined to one longitudinal frame member 81 of the lower framed wall portion 79. Yet further one longitudinal frame member 81 of the framed web portion 73 is joined to the joined frame members 81 of the upper and lower framed wall portions 77, 79. Further the lower framed wall portion 79 is offset, in an inward direction, from the upper framed wall portion 77, by an offset distance of about 1.0mm to 1.5mm. This offset mimics the offset of 10 the upper portion of the outer wall 13 to the lower portion of the outer wall 15 and particularly to the outer wall channel surfaces 33, 35 thereof.

The framed structure 71 also includes breathing passages 81 there through from the lingual to buccal surfaces thereof corresponding to those on the mounting arrangement 3. The passages 81, 67 in respectively the framed structure 71 and the 15 mounting arrangement 3 coincide so that both sets of passages are in flow communication with each other.

The framed structure 71 is made from a material that provides a suitable amount of stiffness and thereby structural strength while still being able to flex resiliently. The framed web portion 73 is thereby able to adjust to different arch forms and arch widths 20 while applying a return force as it tries to return to its original position. The framed wall portion 75 is also required to have sufficient inherent strength to hold the soft tissues of the cheek and buccal mucosa away from the upper arch tissues of a user so that it does not apply a force to the maxilla bone of the upper arch.

The framed structure 71 is made of a resilient polymeric material that is capable of 25 being moulded that is selected from the group consisting of polyamide, polyethylene, polypropylene, polyurethane, polycarbonate, or santoprene. In the illustrated embodiment the framed structure 71 is formed from a polyamide material sold under the trade mark NYLON™. This material has been found to have a suitable level of stiffness and rigidity while permitting resilient flexing out of its resting position. Further this material has a good 30 memory and retains its ability to return to its original form when the flexing force is removed.

The mounting arrangement 3 includes a teeth contacting member which also has the ability to resiliently flex and can be conveniently formed of a silicon rubber material. Silicon rubber has an ability to flex and deform and has some resilience such that it will 35 tend to return to its original form once the flexing force is removed. Further silicon rubber

is soft and has some ability to conform to a surface against which it bears much like a cushion. It is therefore soft and comfortable when bearing against the gum tissues and teeth of a user. In the illustrated embodiment medical grade silicon rubber is used for the teeth contacting member that is approved for use on medical devices and can be
5 purchased readily as a staple polymer.

The appliance 1 can be manufactured by the following method. The framed structure 71 is moulded from a polymeric material such as a polyamide in a first mould in an injection moulding operation. Thereafter the first mould is removed and replaced with a second mould and the teeth contacting member of silicon rubber is moulded onto the
10 framed structure 71 in a second injection moulding operation. The mounting arrangement 3 is moulded directly onto the frames structure 71 in a process that is known as dual moulding. The final appliance 1 can be formed in two moulding operations and this minimal labour and manual effort is required to manufacture the appliance.

The entire mounting arrangement 3 including the outer wall 7 forming the outer spacing formation 5 and the tongue elevator 51 is formed integrally in the second injection
15 moulding operation. Further other features such as the cutaways 57, 59, 61 on the inner and outer walls 9, 7 and the tongue tab 63 and the breathing apertures 67 are also formed integrally in the second injection moulding operation. The appliance 1 can be manufactured in three different to five different sizes with a corresponding number of
20 different sized moulds and the applicant envisages that these sizes will be able to be used on the overwhelming majority of patients within the general population.

In use the appliance 1 can be used by a treatment provider that is a dental practitioner to treat dental malocclusions, particularly class 3 occlusions.

Generally the appliance 1 will be used on patients showing the initial signs of Class 3
25 occlusion while they are still in the developmental stages of arch growth and arch formation. Generally this is the age group of 8 -14 years. The treatment is commenced by an inspection of the dental occlusion of the patient by the dentist. The dentist will record the bite of the patient at the commencement of treatment by taking bite impressions and building a bite model of the upper and lower arches of a patient.

30 The dentist then selects a certain size of appliance from the range of sizes and fits it in position in a user's mouth.

As illustrated in Figs. 19 to 25, the teeth of an upper arch 85 of a user are received in the upper channel 21 and the teeth of the lower arch 87 are received in the lower channel 21. Fig. 19 shows a side view and Fig. 20 shows a top plan view of the upper
35 arch 85 and teeth received within the upper channel 21. The section is taken through a

midline of the appliance 1 and thus it shows a front region of the member 3. As shown the outer wall upper portion 13 holds the buccal mucosa of the user away from the upper arch 85 and gums of the user. There is a space between the upper arch 85 and the outer wall upper channel surface 33.

5 Fig. 21 shows a section through a user's mouth and through an appliance 1 mounted in position in the user's mouth. The section is taken through a midline of the appliance 1 and thus it shows a front region of the member 3. As shown the outer wall upper portion 13 holds the buccal mucosa of the user spaced away from the upper arch 85 and gums of the user.

10 Fig. 21 also shows the position of the tongue 89 of the user being raised by the tongue elevator 51 on the lower portion of the inner wall 19. The drawing clearly shows how the elevator 51 raises the position of the tongue 89 above the height where it will have an influence on the bone growth of the lower arch 87.

15 Fig. 22 shows a rear view of the appliance 1 with the user's mouth tissues in the molar region being shown in section. Again the drawing shows a space between the gums over the teeth of the upper arch 85 and the outer wall upper channel surface 33.

Further these drawings show how the upper and lower channels 21, 23 are held in fixed position relative to each other to fix the upper and lower arches 85, 87 that are received in these channels in the correct relative position to each other to encourage
20 correct dental occlusion.

If necessary the dentist then tries appliances of different sizes until they identify the appliance size that best fits the patient. The appliance 1 does not require any moulding, e.g. in boiling water or the like to fit it to the specific contours of a patient's mouth. The silicon outer layer is reasonable soft and conformable to some extent and the
25 appliance 1 can generally be worn without discomfort.

By positioning the tongue 89 above the lower arch 87 so that it does not apply pressure thereto the lower arch 87 is not encouraged to develop further. Further by holding the buccal mucosa 91 away from the upper arch tissues so that it does not apply an inward pressure thereto the upper arch 86 is permitted to develop and expand.

30 During treatment the patient will be directed to wear the appliance 1 for several hours a day and particularly at night time. At periodic intervals the dentist checks on the progress of the treatment. Over the time the upper arch 85 is encouraged to develop and expand to match the lower arch 87. In particular the width of the arch 85 in the molar regions should expand. Further the anterior incisor region of the upper arch 85 should

develop in an anterior direction to develop the mid facial region at the same time that the width of the arch 85 is expanding.

After some time the incisors 93 of the lower arch 87 should be received behind the incisors 95 of the upper arch 85 instead of the other way around. This is an important stage in the treatment because then the upper arch incisors 95 tend to hold the incisors of the lower arch 93 in their position and counter balance any outward force on the lower arch 87.

The treatment is complete when the incisors of the upper arch are about 1.5mm to 2mm in front of the incisors of the lower arch as shown in Fig 1. Further a portion of each molar on the upper arch 87 should be positioned outside of the corresponding molar of the lower arch 85 as shown in Fig 2. The progression of treatment of this malocclusion is shown in Figs. 23 to 25.

Once the class 2 occlusion has been corrected the application may be worn for shorter periods but still worn regularly to maintain the correct dental occlusion. Thus it acts as both an active and a passive orthodontic appliance

An advantage of the appliance described above with reference to the drawings is that it works at several different levels simultaneously to help correct a class 3 malocclusion. It relieves the pressure of the buccal mucosa against the upper arch along the full extent of the arch. It also elevates the tongue position so that it does not apply an outward pressure against the lower arch. Further the resilience in the appliance which has a resting position corresponding to desired arch form applies an outward pressure to the arch when it is fitted to an under developed upper arch.

In particular the outer wall of the appliance and particularly the upper portion of the outer wall forms an outer spacing formation that holds the buccal mucosa and associated soft tissues in the cheek of the user spaced away from the outer surface of the upper arch. By removing the force of the soft tissues bearing against the arch a force inhibiting development of the upper arch is removed and this encourages upper arch development. A further advantage is that by having a continuous outer wall that extends along the full incisor, canine and molar regions the application of an inward pressure along the full length of the upper arch is alleviated. This encourages the full length of the upper arch including the mid facial region to develop and grow simultaneously.

A further advantage of the appliance described above with reference to the drawings is that it has a tongue positioning formation that lifts the position of the tongue up so that it bears against the anterior incisor teeth of the upper arch and not the incisor teeth of the lower arch. The pressure of a tongue bearing against the incisor teeth of the lower

arch promotes development of the lower arch and may cause overdevelopment of the lower arch relative to the upper arch. By repositioning the tongue so that it does not bear against the teeth of the lower arch the force imparting lower arch growth and development is removed.

5 A further advantage of the mounting arrangement and outer wall is that it has an ability to resiliently flex out of a desired arch form while still retaining a good memory. Thus when the mounting arrangement is moved or flexed out of its resting arch form it will exert a return force tending to return the arch to its original resting form. This can apply an outward force to the upper arch encourage it to expand outwardly. Further the stiffness of
10 the outer wall provides the necessary strength to enable the outer spacing formation formed thereby to hold the buccal mucosa away from the teeth and gum tissues of the upper arch so as not to inhibit development thereof.

 A further advantage of the appliance described above is that notwithstanding its stiffness and resilient strength the surface of the appliance that contacts the teeth and
15 gum tissues is soft and conformable and is comfortable against the gums of a user. This is important if the appliance is to be worn by a user when they sleep at night.

 A yet further advantage of the resilient flexibility of the mounting arrangement with the inner and outer walls and the web is that it can be fitted to different user's with different arch sizes and different teeth.

20 A yet further advantage of the appliance described above is that it has upper and lower channels for forcing the upper and lower arches of a user to take up the correct positions relative to each other when the appliance is worn by a user. This promotes and encourages the arches to adopt the correct relative position to each other which is an important part of correct dental occlusion. When a user places their teeth of their upper
25 and lower arches in the respective channels then the arches are forced to take up a certain position relative to each other.

 A yet further advantage of the appliance described above is that the upper and lower channels and particularly the outer channel surfaces thereof are off-set relative to each other by 1.0mm to 1.5mm to replicate correct dental occlusion. That is the teeth of
30 the upper arch are positioned outwardly of the corresponding teeth of the lower arch. Consequently in the final stages of treatment the appliance will tend to move the teeth to the point where the teeth of the lower arch are correctly set back from those of the upper arch instead of bringing them into edge to edge alignment which does not represent correct dental occlusion.

A further advantage of the appliance described above with reference to the drawings is that it can be formed by injection moulding. The features of the teeth mounting arrangement described above can be moulded integrally with the rest of the arrangement. By forming the structural features integrally with the rest of the member the appliance can
5 be manufactured more easily. The internal framed structure can be injection moulded in a first step and then the teeth contacting member may be moulded onto the base member in a second injection moulding step. These features also enable the appliance to be manufactured on a commercial scale so that it can be supplied as an off the shelf item. Applicant envisages that it will be made with three different arch sizes and these arch
10 sizes will be able to be fitted to most users. The appliance will not be custom moulded to fit the mouth of each patient in a dental laboratory and as a result the technology can be provided at a lower cost and be made more accessible to the patient population at large.

It will of course be realised that the above has been given only by way of illustrative example of the invention and that all such modifications and variations thereto,
15 as would be apparent to persons skilled in the art, are deemed to fall within the broad scope and ambit of the invention as is herein set forth.

CLAIMS:

1. An orthodontic appliance for being received in the mouth of a user, comprising:
a mounting arrangement for mounting over an upper arch of a user, and an outer spacing formation on the mounting arrangement for holding a portion of the buccal mucosa away from at least one of the incisor and canine regions of a user's upper arch so
5 that the spaced portion of the buccal mucosa does not apply an inward force to this region of the upper arch.
2. An orthodontic appliance according to claim 1, wherein the outer spacing formation holds a portion of the buccal mucosa away from the incisor region of the user's upper
10 arch.
3. An orthodontic appliance according to claim 1 or claim 2, wherein the outer spacing formation also holds a portion of the buccal mucosa away from the molar region of the user's upper arch.
4. An orthodontic appliance according to claim 4, wherein the outer spacing formation
15 extends continuously across of the incisor region, the canine region and the molar region of the user's upper arch.
5. An orthodontic appliance according to claim 4 or claim 5, wherein the mounting arrangement comprises an outer wall and an inner wall, and a web extending between the inner and the outer walls, and wherein the outer wall, the web, and the inner wall
20 collectively define an upper channel within which the upper arch teeth can be received to mount the appliance to an upper arch of a user.
6. An orthodontic appliance according to claim 6, wherein the outer spacing formation is formed by the outer wall of the mounting arrangement.
7. An orthodontic appliance according to claim 7, wherein each of the outer and inner
25 walls includes an incisor region extending across the incisor region of a user's arch and two canine regions on each side of the incisor region for extending across the canine regions of a user, and two molar regions on each side for extending across the molar regions of a user, and wherein the mounting arrangement, including each of the inner and outer walls, has a generally curved form with a curved incisor region and the canine and
30 molar regions being in the form of two arms extending rearwardly from each end of the incisor region whereby to correspond generally to the form of the arch of a user.
8. An orthodontic appliance according to any one of claims 5 to 7, wherein the mounting arrangement is resiliently flexible.

9. An orthodontic appliance according to claim 9, wherein the outer and inner walls and the web are able to flex resiliently to be deformed out of a resting position corresponding to a desired arch form to accommodate a different arch width in a user, and the walls and the web apply a force to the arch of a user tending to return it to the resting
5 position.

10. An orthodontic appliance according to any one of claims 6 to 9, wherein the outer wall, the web, and the inner wall, in addition to said upper channel, also define a lower channel within which the lower arch teeth can be received.

11. An orthodontic appliance according to claim 10, wherein the outer wall has an
10 upper outer wall portion above the web and a lower outer wall portion below the web, and the inner wall has an upper inner wall portion above the web and a lower inner wall portion below the web.

12. An orthodontic appliance according to claim 10 or claim 11, wherein the outer wall has a buccal outer surface, an upper channel surface and a lower channel surface, and
15 the inner wall has a lingual inner surface, an upper channel surface and a lower channel surface, and the web includes an upper channel web surface and a lower channel web surface.

13. An orthodontic appliance according to claim 12, wherein the upper channel is defined by the outer wall upper channel surface, the upper channel web surface and the
20 inner wall upper channel surface, and wherein the lower channel is defined by the outer wall lower channel surface, the lower channel web surface and the inner wall lower channel surface.

14. An orthodontic appliance according to claim 12 or claim 13, wherein the outer wall upper channel surface is vertically off-set relative to the outer wall lower channel surface.

25 15. An orthodontic appliance according to claim 14, wherein the outer wall lower channel surface is set back relative to the outer wall upper channel surface by a distance of 0.5mm -2.0mm.

16. An orthodontic appliance according to any one of claims 12 to 15, wherein the upper channel web surface is substantially planar and the outer wall upper channel
30 surface extends upwardly away from an outer end of the upper channel web surface at an angle of 80 degrees to 100 degrees to the upper channel web surface.

17. An orthodontic appliance according to any one of claims 12 to 16, wherein the outer wall channel surface extends up to a height of at least 10 mm above the upper channel web surface along the incisor region thereof.

18. An orthodontic appliance according to any one of claims 12 to 17, wherein the outer wall upper channel surface has a height of at least 8 mm above the upper channel web surface along substantially its full length.

19. An orthodontic appliance according to claim any one of claims 12 to 18, wherein
5 the upper channel surface of the inner wall is arranged and positioned so that it bears up against the teeth and associated gums of the upper arch of a user.

20. An orthodontic appliance according to claim 19, wherein the upper channel surface of the inner wall is arranged to bear up against the teeth and associated gums with a snug fit and the snug fit extends along the full length of the arch of a user.

10 21. An orthodontic appliance according to claim 19 or claim 20, wherein the upper channel surface of the inner wall curves away from the upper channel web surface in a direction up from the upper channel web surface.

22. An orthodontic appliance according to claim 11, wherein the appliance further includes a tongue elevating formation on the mounting arrangement for elevating the
15 tongue of a user to a position where it does not apply pressure to the lower arch of a user.

23. An orthodontic appliance according to claim 22, wherein the tongue elevating formation is formed on the lower portion of the inner wall.

24. An orthodontic appliance according to claim 23, wherein the lower portion of the lingual surface of the inner wall and the lower channel surface of the inner wall, both curve
20 outwardly away from the lower channel surface of the web in a direction away from the upper channel web surface.

25. An orthodontic appliance according to claim 24, wherein the lower portion of the inner wall includes a terminal edge defining a lower terminal edge region of the lower portion of the inner wall, and the tongue elevating formation is positioned on the lower
25 terminal edge region of the inner wall.

26. An orthodontic appliance according to claim 25, wherein the tongue elevating formation is formed by having a terminal edge region of increased thickness along at least part of its length.

27. An orthodontic appliance according to claim 26, wherein the enlarged lower
30 terminal edge region of the inner wall comprises a thickened and bulbous terminal edge region extending along at least the incisor region of the inner wall, and wherein a user's tongue is encouraged to adopt a position sitting on an upper surface of the bulbous terminal edge region.

28. An orthodontic appliance according to claim 27, wherein the tongue elevating
35 formation is vertically positioned relative to the web such that an uppermost point of the

tongue elevating formation is positioned 2 mm to 6 mm beneath the lower channel web surface so as to position a user's tongue such that it does not exert pressure against the lower arch of a user.

29. An orthodontic appliance according to any one of claims 6 to 18, wherein the outer wall has a cut away in the incisor region thereof for permitting the molar regions of the inner and outer walls to be moved towards and away from each other to accommodate different arch widths in users.

30. An orthodontic appliance according to claim 29, wherein the inner wall has at least one cutaway broadly in the incisor region for facilitating the molar regions of the outer and inner walls being moved towards and away from each other to accommodate varying arch widths in users.

31. An orthodontic appliance according to any one of claims 11 to 16, wherein the mounting arrangement is formed from a teeth contacting member made of a cushioning material for comfortable fitting against the gums of a user, and a base member made of a stiffer material than the teeth contacting member for providing sufficient structural rigidity to the mounting arrangement while still permitting some resilience to the mounting arrangement.

32. An orthodontic appliance according to claim 31, wherein the base member is encased within the teeth contacting member.

33. An orthodontic appliance according to claim 32, wherein the base member comprises an open frame structure to assist in providing some resilience, and wherein the open frame structure comprises a frame web portion broadly coextensive with the web of the mounting arrangement and a frame wall portion that is broadly coextensive with the outer wall of the mounting arrangement.

34. An orthodontic appliance according to claim 33, wherein the frame wall portion comprises an upper frame wall portion on one side of the web portion extending across the front of the upper channel and a lower frame wall portion extending across the front of the lower channel.

35. An orthodontic appliance according to claim 35, wherein each of the frame web portion and the frame upper wall portion and the frame lower wall portion comprise a separate open frame structure.

36. An orthodontic appliance according to claim 35, wherein each said frame portion comprises two longitudinal frame members and a plurality of cross members extending between the two longitudinal members at spaced intervals along their length.

37. An orthodontic appliance according to claim 36, wherein one of the longitudinal members of the frame upper wall portion is joined to one of the longitudinal members of the frame lower wall portion, and wherein one of the longitudinal members of the frame web portion is joined to a longitudinal member of the frame upper wall portion.

5 38. An orthodontic appliance according to any one of claims 34 to 37, wherein the frame lower wall portion is vertically offset with respect to the frame upper wall portion.

39. An orthodontic appliance according to any one of claims 34 to 38, wherein the frame lower wall portion is set back relative to the frame upper wall portion by a distance on 0.5 to 2.0mm.

10 40. An orthodontic appliance according to any of claims 34 to 37, wherein the base member is made of a material that confers sufficient stiffness and rigidity on the base member and overall mounting arrangement while still permitting some resilient deformation of the mounting arrangement to accommodate different arch sizes in different users.

15 41. An orthodontic appliance according to claim 40, wherein the material of the frame wall portion and the frame web portion is selected from the group consisting of a polyamide, a polyethylene, a polypropylene, a polyurethane, a polycarbonate and/or a santoprene.

20 42. An orthodontic appliance according to any one of claims 31 to 41, wherein the teeth contacting member is made of a soft cushioning silicon rubber material.

43. An orthodontic appliance for being received in the mouth of a user, comprising:

25 a mounting arrangement for mounting over an upper arch of a user, and a tongue elevator mounted on the mounting arrangement for elevating the tongue of a user to a position where it does not apply significant developmental pressure to the lower arch of a user.

44. An orthodontic appliance for being received in the mouth of a user, comprising:

30 a mounting arrangement for mounting over an upper arch of a user having an arch shape, the mounting arrangement being formed from a resiliently flexible material so that the mounting arrangement is operatively able to adapt to the arch shape and associated teeth of the user; and

an outer spacing formation on the mounting arrangement for holding a portion of the buccal mucosa spaced away from at least part of a user's upper arch so that the spaced portion of the buccal mucosa does not apply an inward force to this region of the upper arch.

45. An orthodontic appliance according to claim 44, wherein the mounting arrangement is formed with an arch form corresponding to correct dental occlusion so that when the appliance is applied to a user having an underdeveloped upper arch the mounting arrangement is resiliently flexed out of its original position and as a result will apply a return force to the teeth and arch tissues of the upper arch of a user that will tend to expand the upper arch of a user.

46. An orthodontic appliance according to claim 45, wherein the mounting arrangement comprises an outer wall and an inner wall, and a web extending between the inner and the outer walls defining an upper channel for the arch having a form corresponding to correct dental occlusion in its original position, wherein the outer spacing formation is formed by the outer wall of the mounting arrangement.

47. An orthodontic appliance according to claim 44 or claim 45, wherein the mounting arrangement extends in a curved fashion along substantially the full length of a user's arch and the mounting arrangement has a curved incisor region with trailing arm regions extending rearward from each side of the incisor region.

48. An orthodontic appliance according to claim 47, wherein the trailing arm regions arms can be resiliently flexed out of their resting position, and the mounting arrangement will apply a return force tending to return the arm regions to the resting position when this occurs.

49. An orthodontic appliance according to claim any one of claims 46 to 48, wherein the upper and lower channels may have sufficient dimensional tolerance to be fitted to a range of users with different teeth sizes.

50. An orthodontic appliance according to any one of claims 44 to 49, wherein the outer spacing formation hold a portion of the buccal mucosa away from the molar regions and the incisor region of the user's upper arch.

51. An orthodontic appliance according to claim 46, wherein the appliance include a tongue elevating formation mounted on the inner wall, the tongue elevating formation being integrally formed with the inner wall and thereby the rest of the mounting arrangement by moulding.

52. An orthodontic appliance comprising:

a mounting arrangement for mounting over an upper arch of a user having a front region and two arm regions extending rearward from the front region, the mounting arrangement including

an outer wall and an inner wall and a web extending between the outer wall and the inner wall, and wherein the outer wall, the web, and the inner wall collectively define

an upper channel within which the upper arch and associated teeth of a user can be received whereby to mount the mounting arrangement to the upper arch, and a lower channel for receiving the lower arch and associated teeth of a user,

5 wherein the outer wall has an upper portion for holding the buccal mucosa away from the gums and teeth of the upper arch.

53. An orthodontic appliance according to claim 52, wherein the inner wall defines a tongue elevating formation below the web for interfering with the tongue of a user and forcing the tongue to be elevated up to a position where it does not apply a developmental pressure to the lower arch of a user.

10 54. A method of manufacturing an appliance including:

moulding a base member from a material that when moulded has stiffness and rigidity while still permitting some resilient flexing thereof in a first moulding step;

15 moulding a mounting arrangement onto the base member in a second moulding step from a further resiliently flexible material that is softer than the material from which the base member is formed, and forming an outer spacing formation integrally with the mounting arrangement for spacing part of the buccal mucosa away from the upper arch.

55. A method of treating a malocclusion of upper and the lower jaws in a patient, including:

20 fitting an orthodontic appliance as defined in any one of claims 1 to 40 to the patient.

AMENDED CLAIMS
received by the International Bureau on 15 January 2009

CLAIMS:

1. An orthodontic appliance for being received in the mouth of a user, comprising:
a mounting arrangement for mounting over an upper arch of a user, and an outer
5 spacing formation on the mounting arrangement for holding a portion of the buccal
mucosa away from at least one of the incisor and canine regions of a user's upper arch so
that the spaced portion of the buccal mucosa does not apply an inward force to this region
of the upper arch.
2. An orthodontic appliance according to claim 1, wherein the outer spacing formation
10 holds a portion of the buccal mucosa away from the incisor region of the user's upper
arch.
3. An orthodontic appliance according to claim 1 or claim 2, wherein the outer
spacing formation also holds a portion of the buccal mucosa away from the molar region
of the user's upper arch.
- 15 4. An orthodontic appliance according to claim 3, wherein the outer spacing formation
extends continuously across of the incisor region, the canine region and the molar region
of the user's upper arch.
5. An orthodontic appliance according to claim 3 or claim 4, wherein the mounting
arrangement comprises an outer wall and an inner wall, and a web extending between the
20 inner and the outer walls, and wherein the outer wall, the web, and the inner wall
collectively define an upper channel within which the upper arch teeth can be received to
mount the appliance to an upper arch of a user.
6. An orthodontic appliance according to claim 5, wherein the outer spacing formation
is formed by the outer wall of the mounting arrangement.
- 25 7. An orthodontic appliance according to claim 6, wherein each of the outer and inner
walls includes an incisor region extending across the incisor region of a user's arch and
two canine regions on each side of the incisor region for extending across the canine
regions of a user, and two molar regions on each side for extending across the molar
regions of a user, and wherein the mounting arrangement, including each of the inner and
30 outer walls, has a generally curved form with a curved incisor region and the canine and
molar regions being in the form of two arms extending rearwardly from each end of the
incisor region whereby to correspond generally to the form of the arch of a user.
8. An orthodontic appliance according to any one of claims 5 to 7, wherein the
mounting arrangement is resiliently flexible.

tongue elevating formation is positioned 2 mm to 6 mm beneath the lower channel web surface so as to position a user's tongue such that it does not exert pressure against the lower arch of a user.

29. An orthodontic appliance according to any one of claims 6 to 18, wherein the outer wall has a cut away in the incisor region thereof for permitting the molar regions of the inner and outer walls to be moved towards and away from each other to accommodate different arch widths in users.

30. An orthodontic appliance according to claim 29, wherein the inner wall has at least one cutaway broadly in the incisor region for facilitating the molar regions of the outer and inner walls being moved towards and away from each other to accommodate varying arch widths in users.

31. An orthodontic appliance according to any one of claims 11 to 16, wherein the mounting arrangement is formed from a teeth contacting member made of a cushioning material for comfortable fitting against the gums of a user, and a base member made of a stiffer material than the teeth contacting member for providing sufficient structural rigidity to the mounting arrangement while still permitting some resilience to the mounting arrangement.

32. An orthodontic appliance according to claim 31, wherein the base member is encased within the teeth contacting member.

33. An orthodontic appliance according to claim 32, wherein the base member comprises an open frame structure to assist in providing some resilience, and wherein the open frame structure comprises a frame web portion broadly coextensive with the web of the mounting arrangement and a frame wall portion that is broadly coextensive with the outer wall of the mounting arrangement.

34. An orthodontic appliance according to claim 33, wherein the frame wall portion comprises an upper frame wall portion on one side of the web portion extending across the front of the upper channel and a lower frame wall portion extending across the front of the lower channel.

35. An orthodontic appliance according to claim 34, wherein each of the frame web portion and the frame upper wall portion and the frame lower wall portion comprise a separate open frame structure.

36. An orthodontic appliance according to claim 35, wherein each said frame portion comprises two longitudinal frame members and a plurality of cross members extending between the two longitudinal members at spaced intervals along their length.

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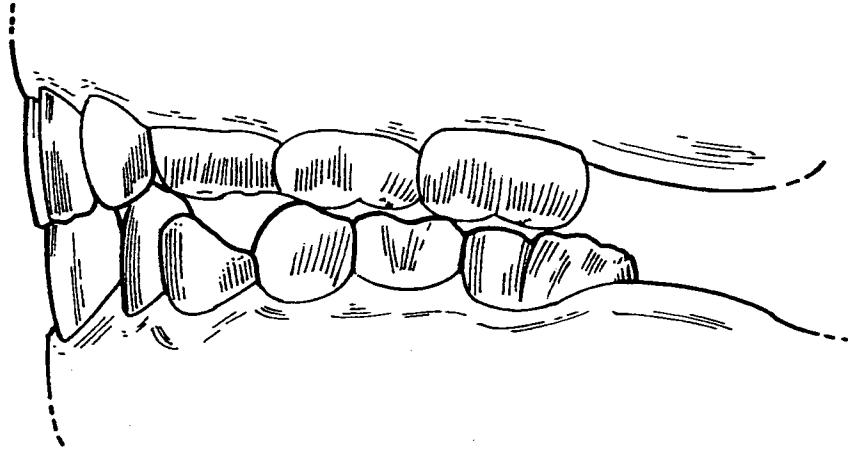


FIG. 1

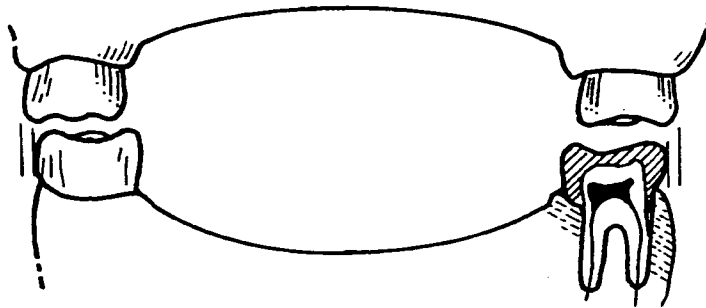


FIG. 2

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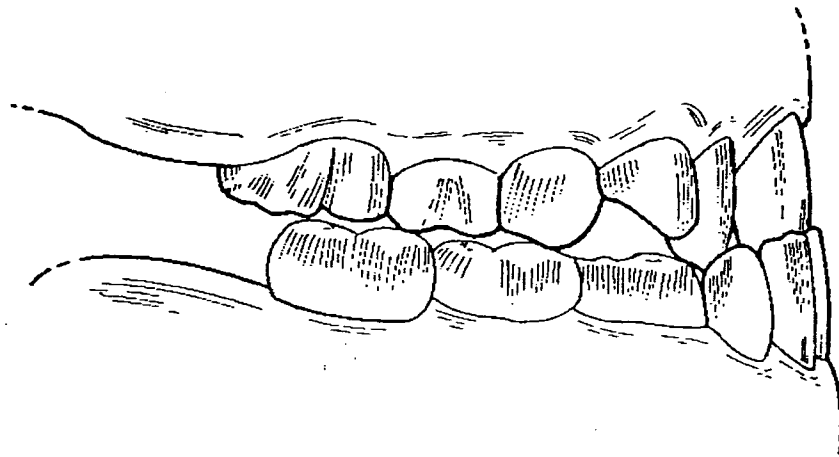


FIG. 3

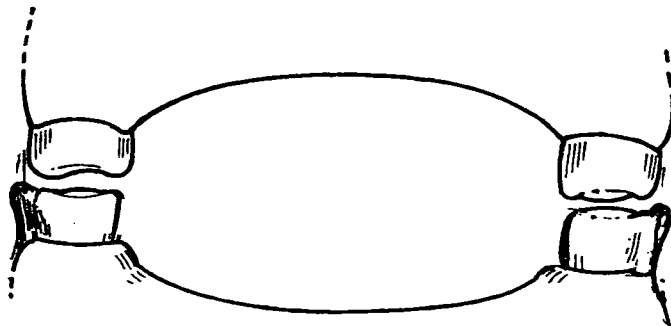


FIG. 4

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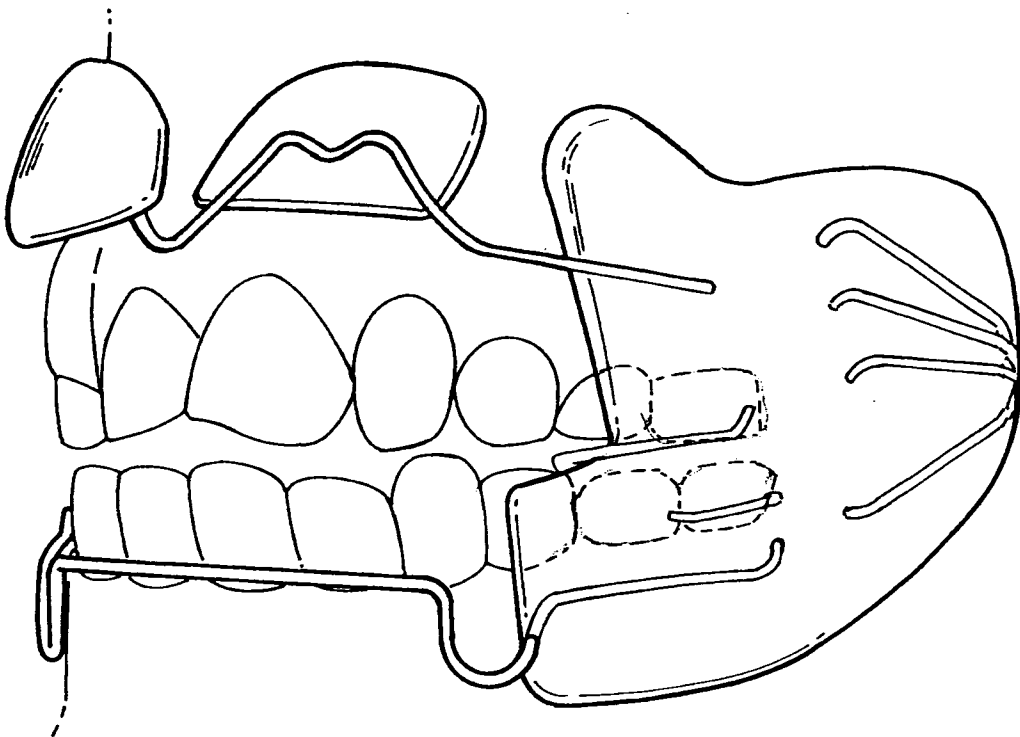


FIG. 5

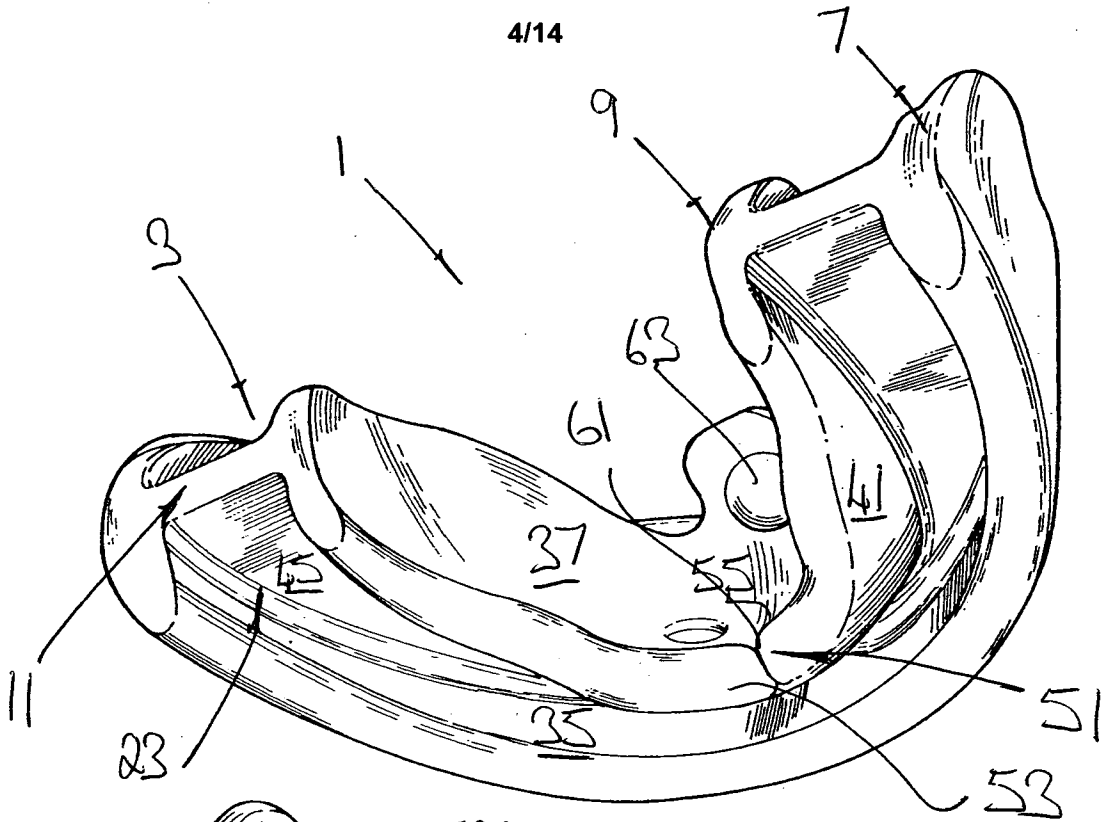


FIG. 6

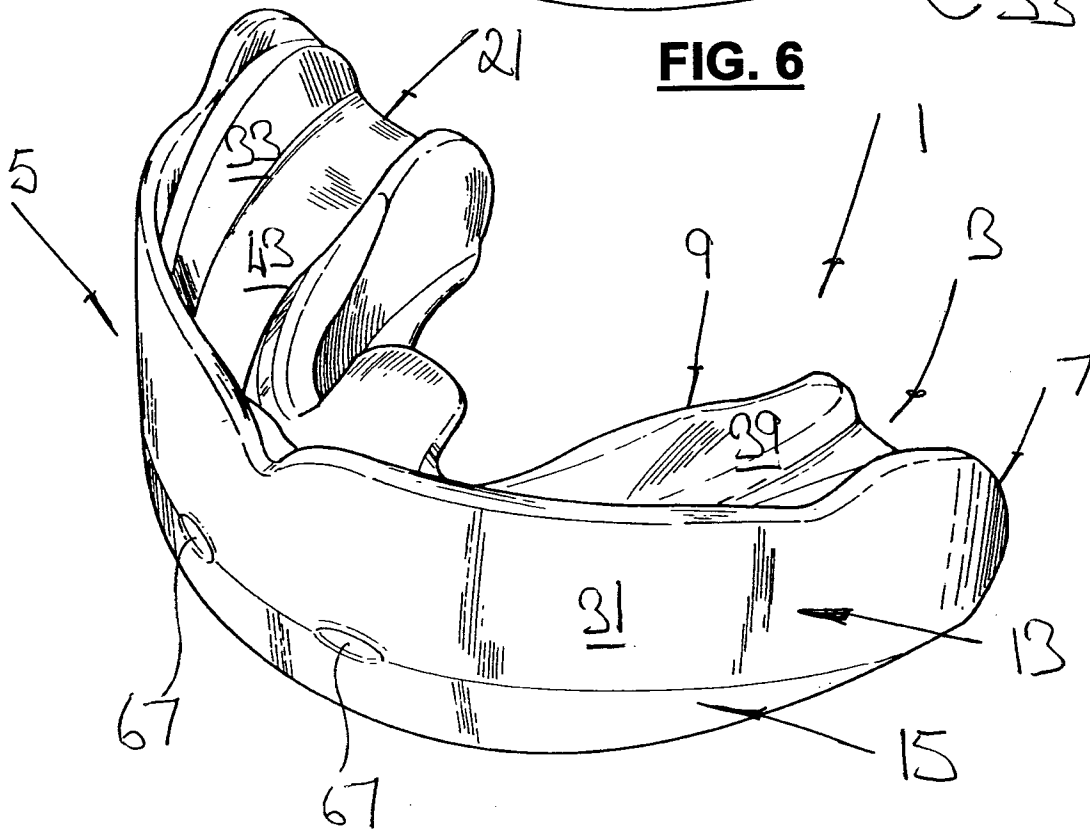
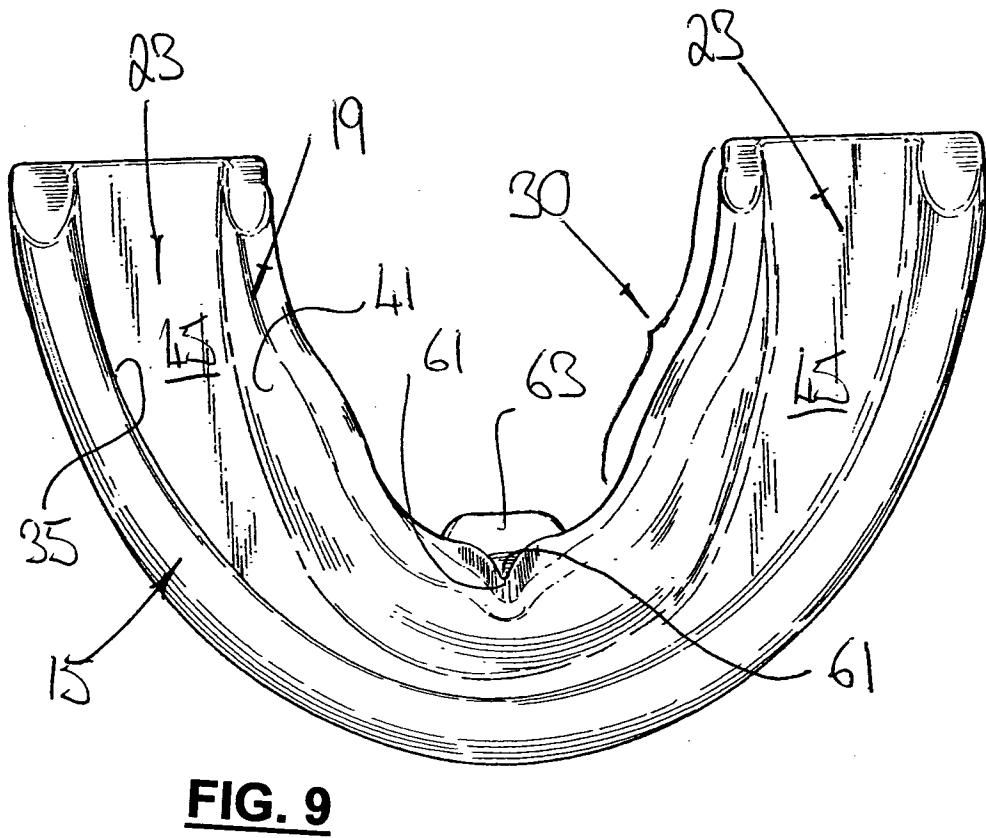
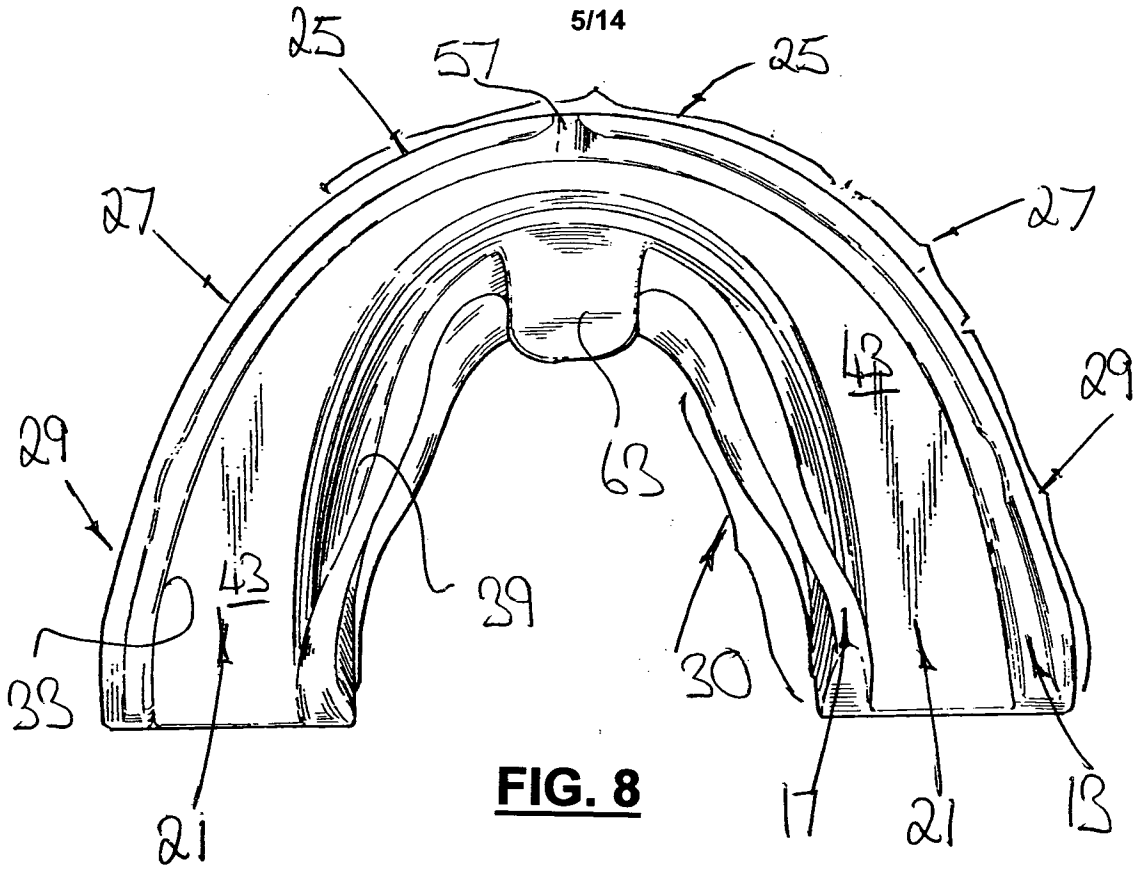


FIG. 7



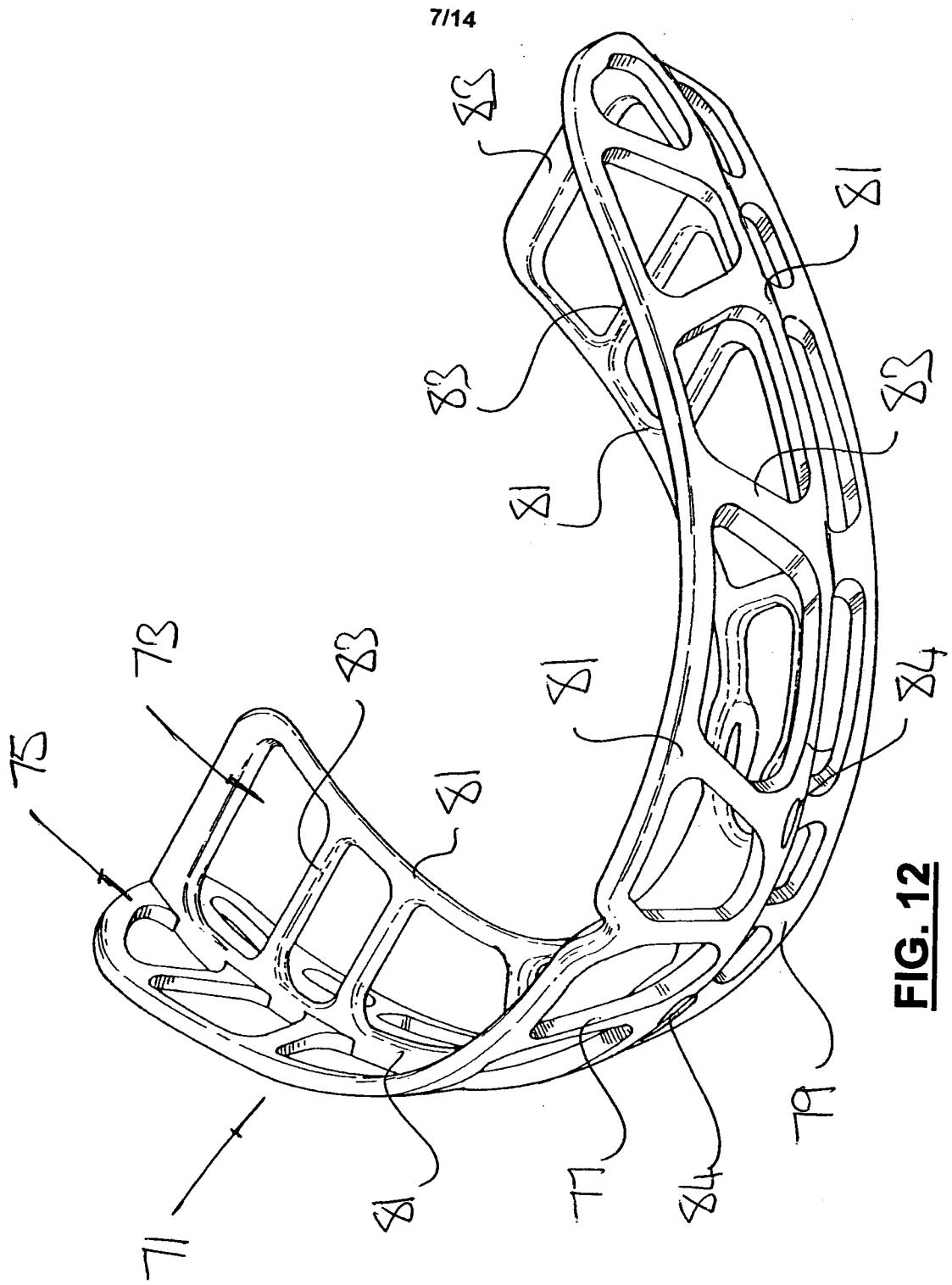


FIG. 12

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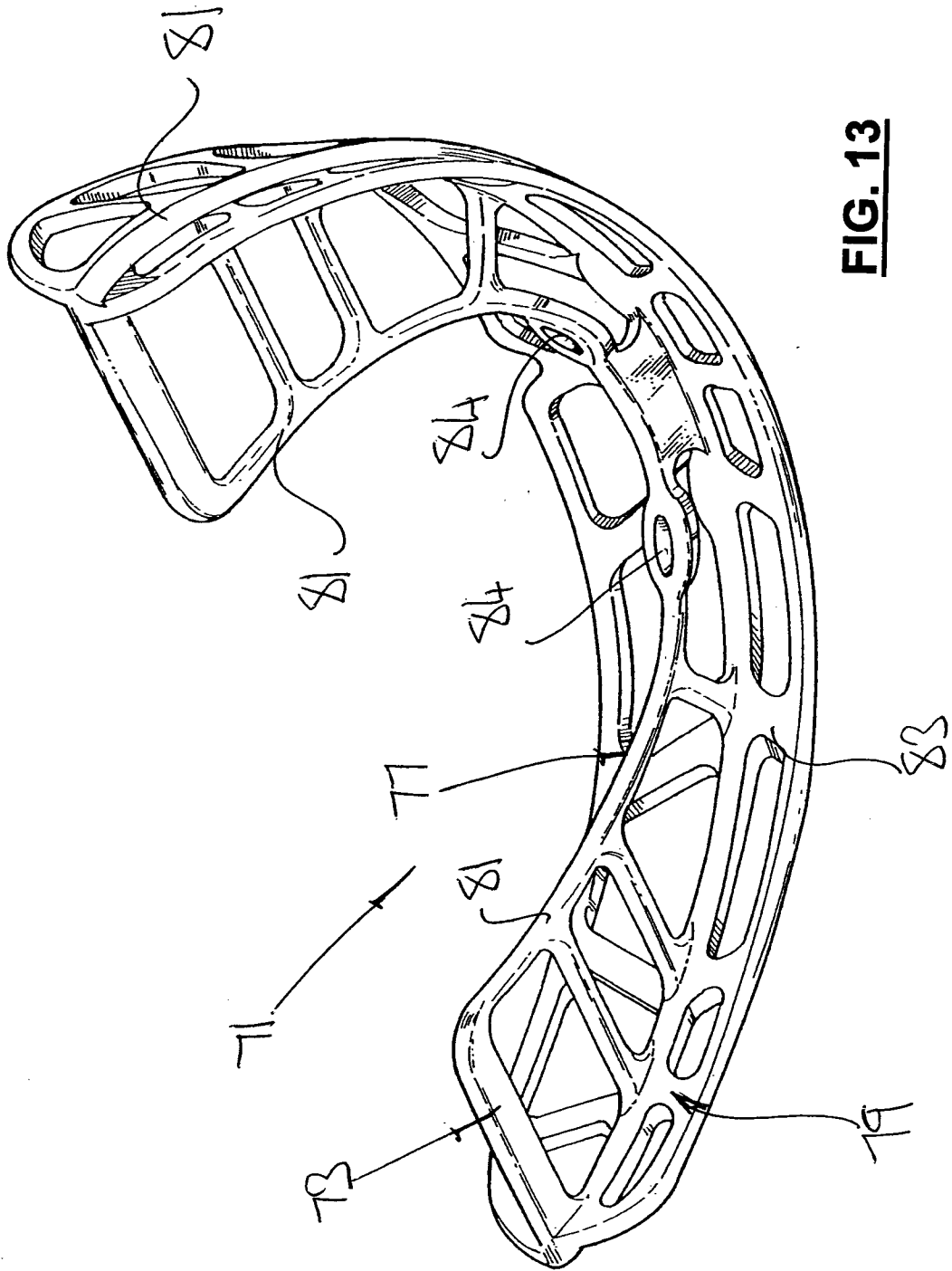


FIG. 13

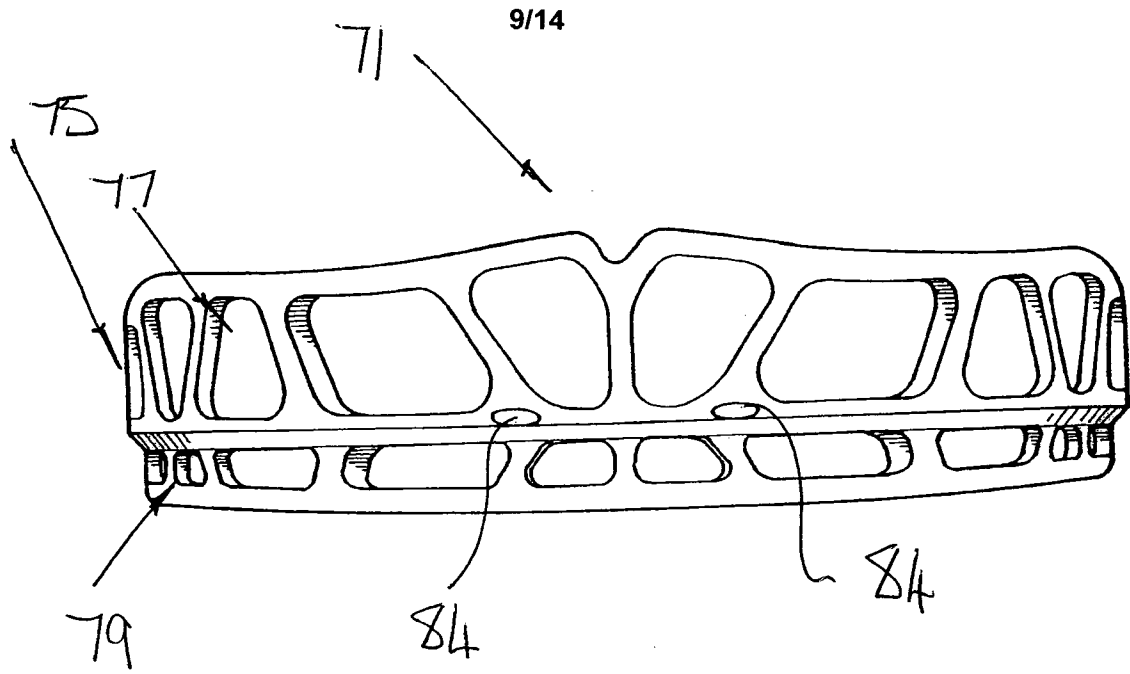


FIG. 14

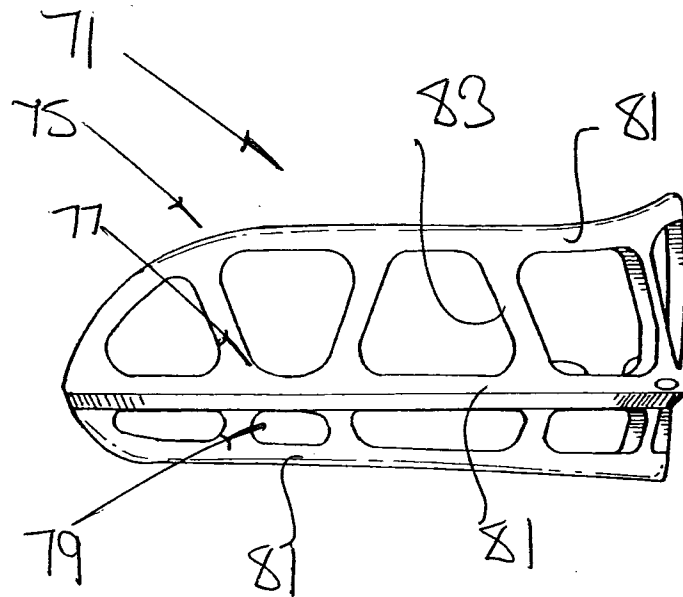


FIG. 15

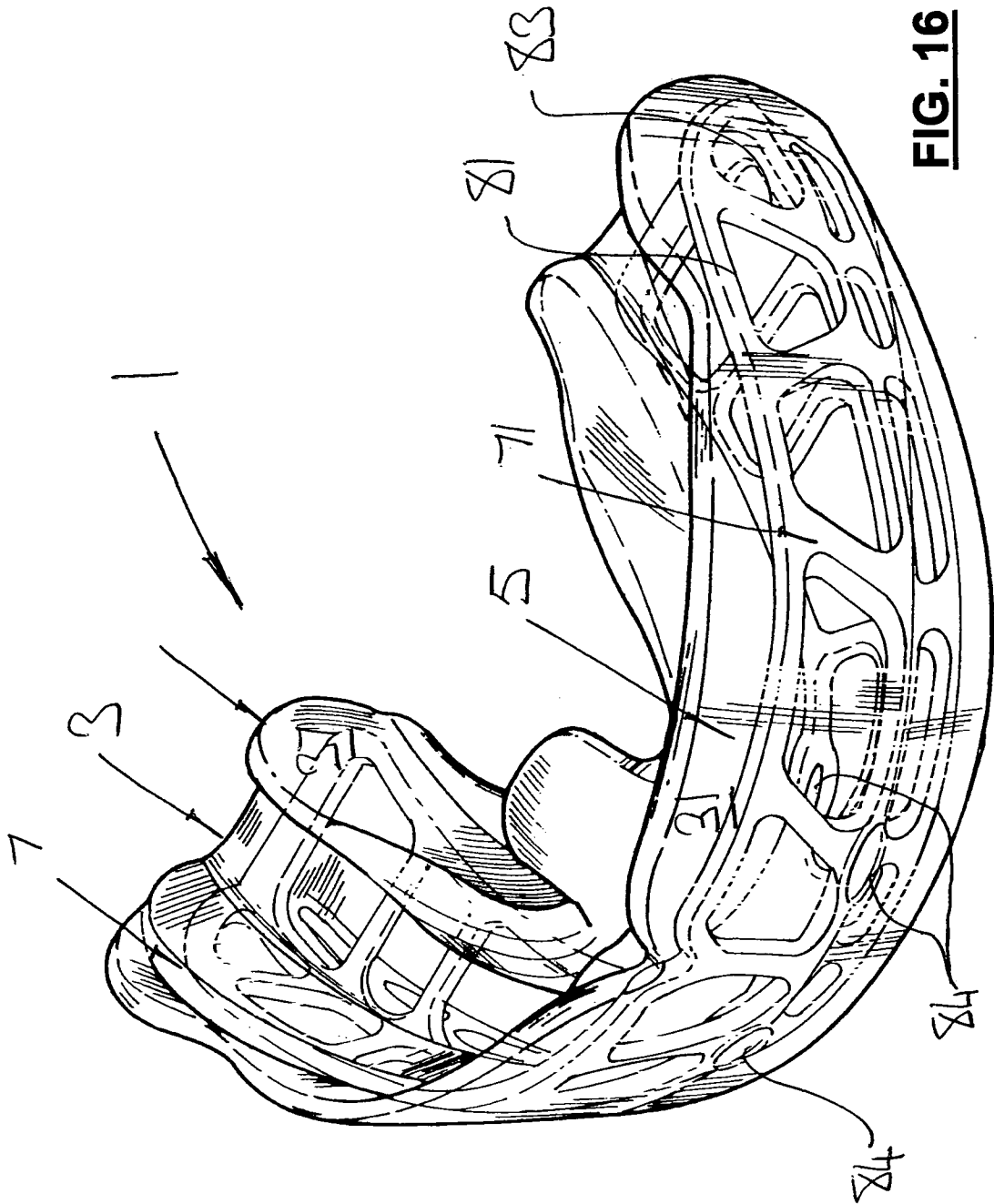


FIG. 16

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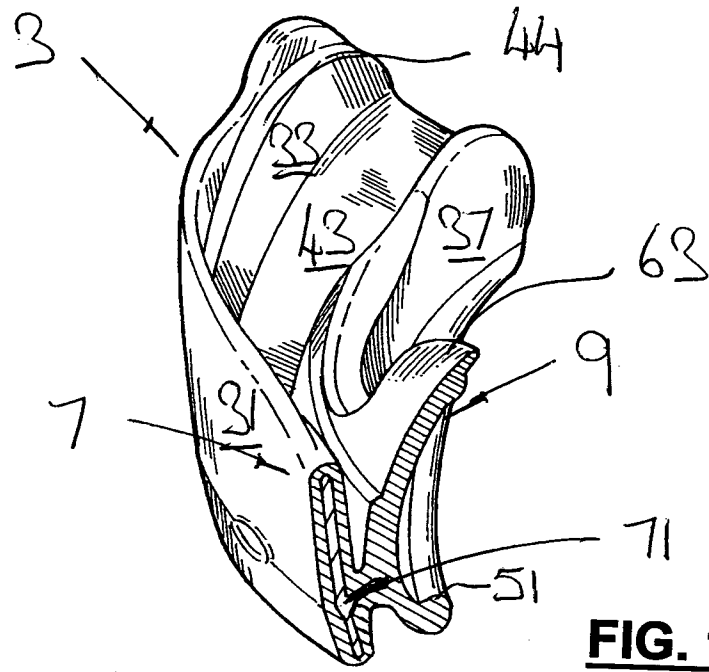


FIG. 17

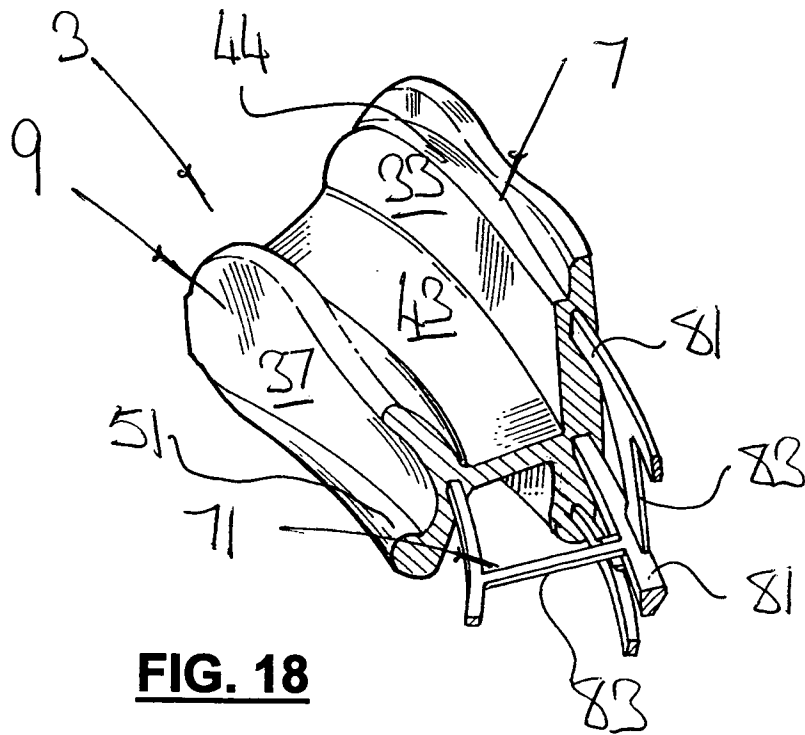


FIG. 18

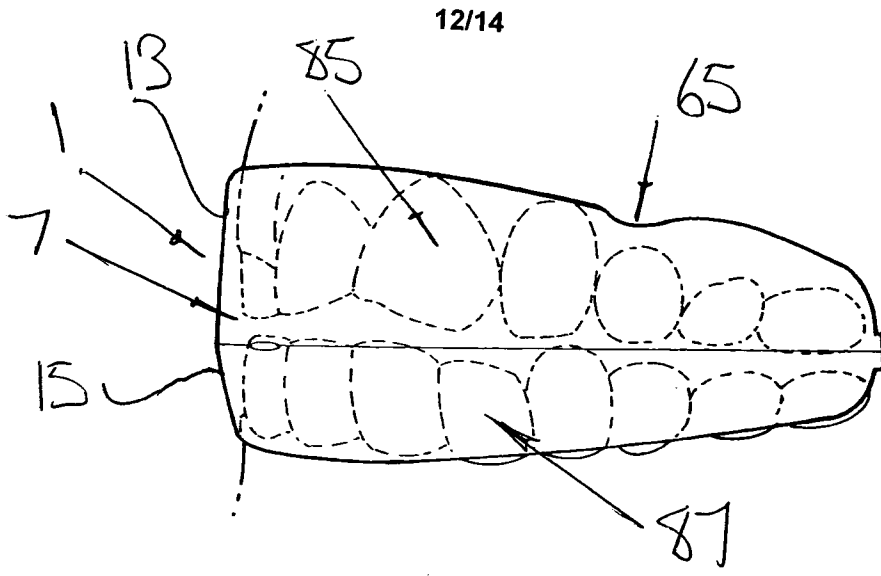


FIG. 19

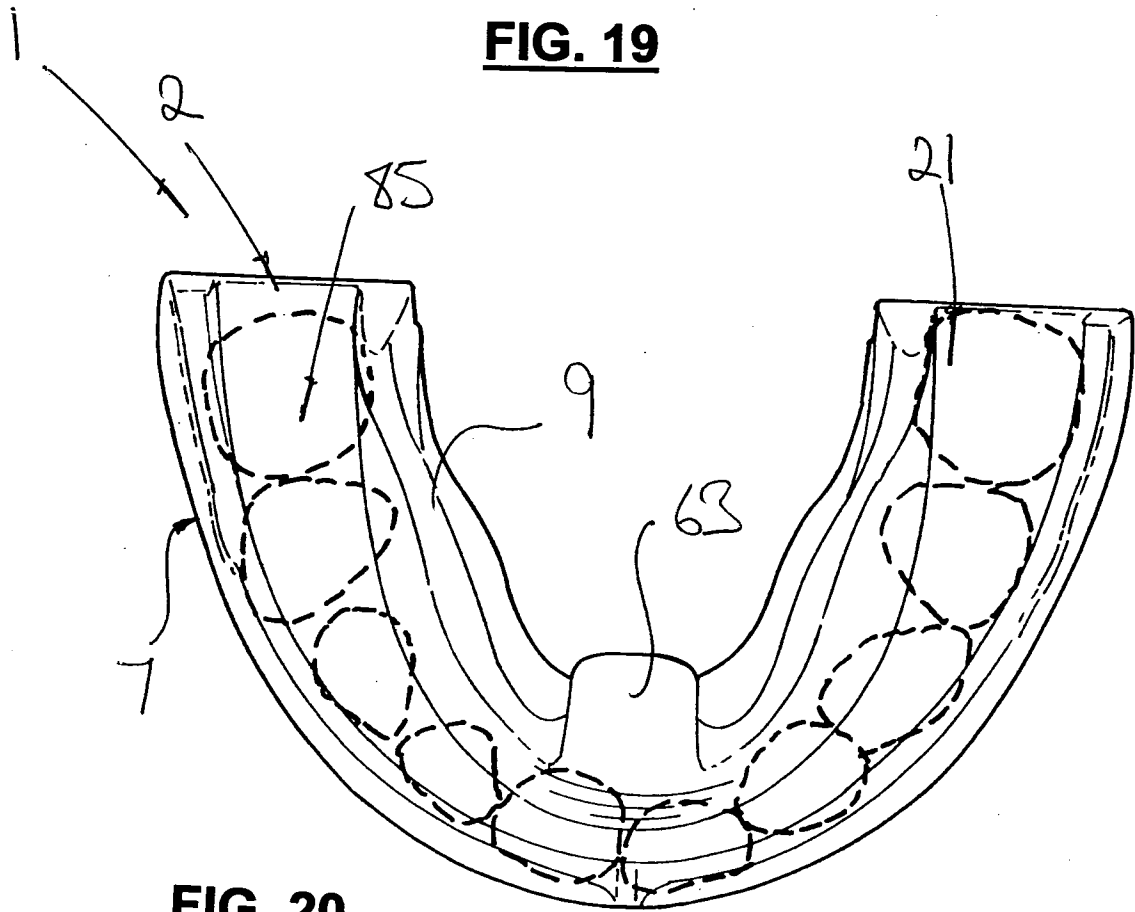


FIG. 20

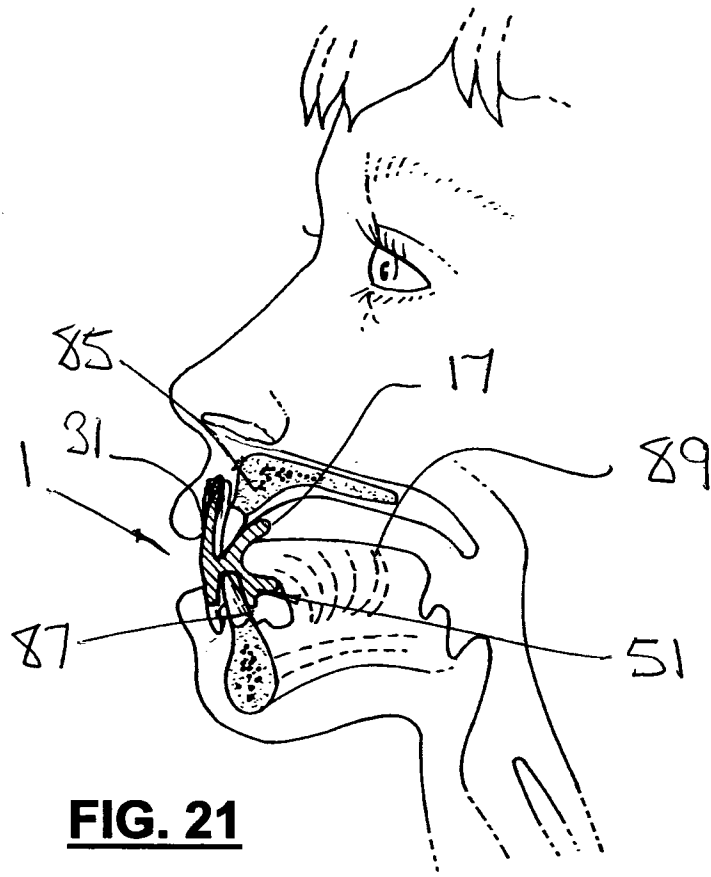


FIG. 21

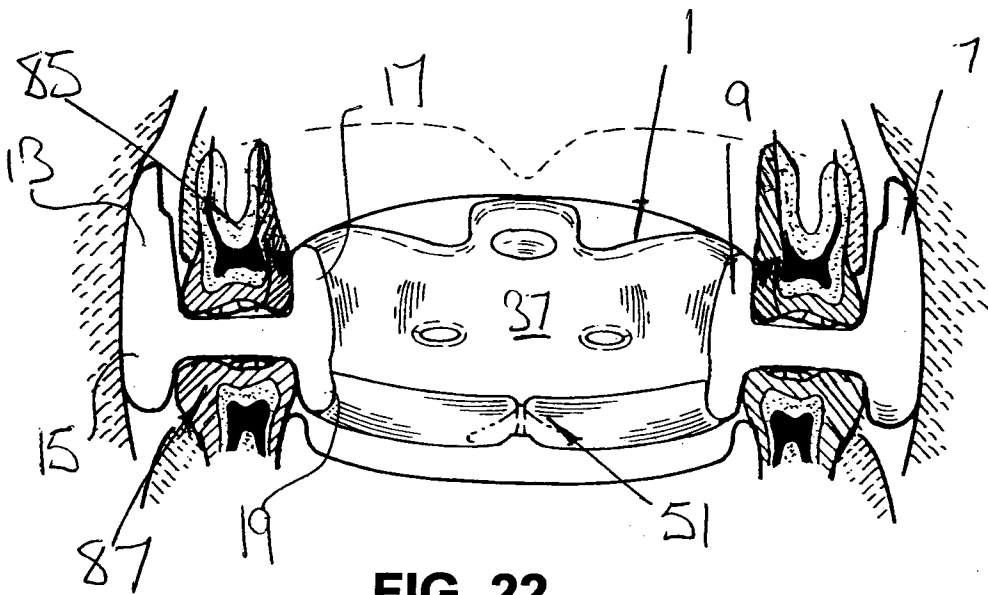


FIG. 22

FIG. 23

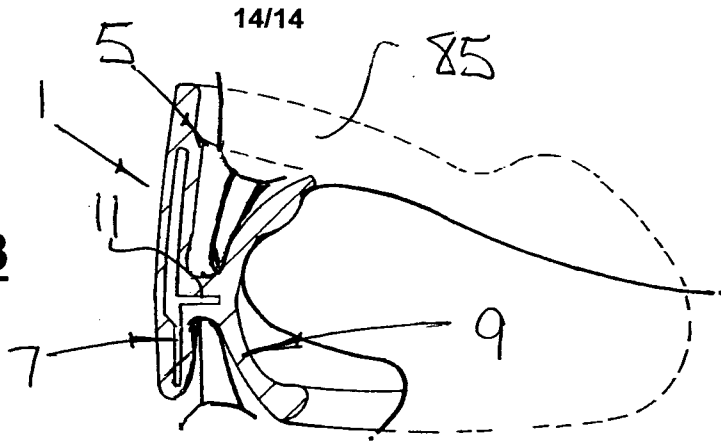


FIG. 24

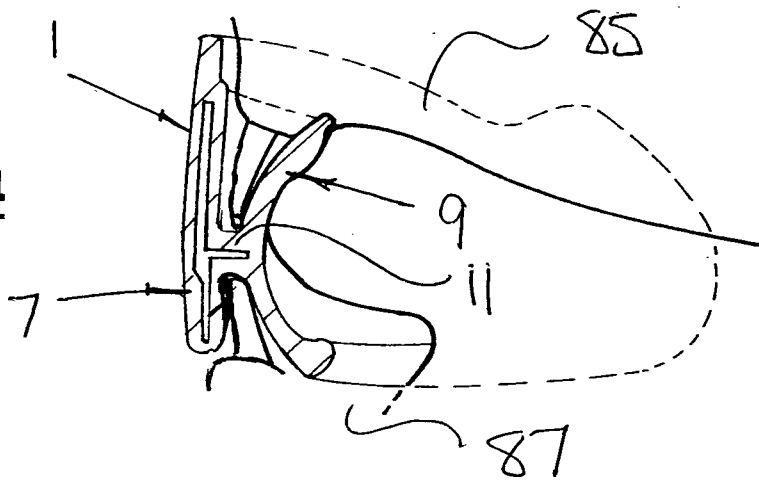
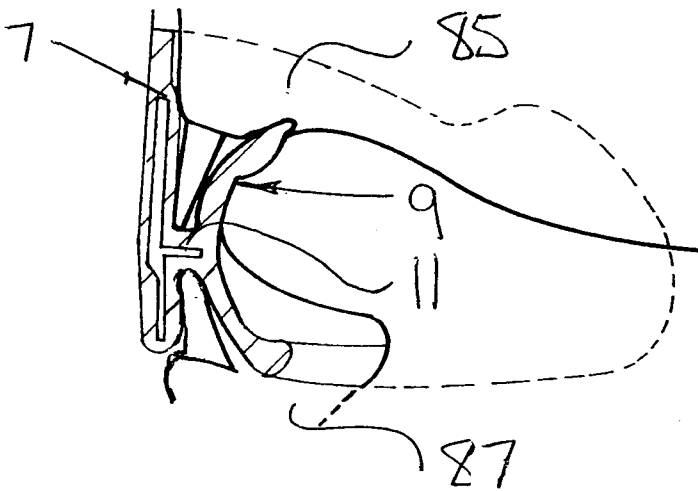


FIG. 25



INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2008/001293

A. CLASSIFICATION OF SUBJECT MATTER Int. Cl. <i>A61C 7/00</i> (2006.01) <i>A61C 7/36</i> (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) EPOQUE: IPC A61C & KEYWORDS :- orthodontic, dentist, ,mouthguard, mouthpiece, malocclusion, underbite, maxilla, upper, buccal mucosa, inner, cheek & others		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO2003101331A2 (BERGERSEN) 11 December 2003 see figures 1a-1b & page 20 lines 20-30	
A	AU 2002335795B2 (WILLIAMS) 3 July 2003 see figures 1, 1a, 1b & page 6 lines 19- page 9 line 3	
A	US 6368106B1 (CLARK) 9 April 2002 see column 2 line 40- column 3 line 11 & figures	
A	US 6837246B1 (DELUKE) 4 January 2005 see figures 1-2 & column 2 line 34 – column 3 line 3	
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> 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 11 December 2008	Date of mailing of the international search report 22 DEC 2008	
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. +61 2 6283 7999	Authorized officer M.S. HAYNES AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No : +61 2 6283 2170	

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2008/001293

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:

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 separate sheet

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.:

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.
PCT/AU2008/001293

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, A	US2007/0240724A1 (BERGERSEN) 18 October 2007 see entire specification	

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2008/001293

Supplemental Box

(To be used when the space in any of Boxes I to IV is not sufficient)

Continuation of Box No: 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.

In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

This International Searching Authority has found that there are different inventions as follows:

- Claims 1-42 and 44-55 are directed to an orthodontic appliance comprising a mounting arrangement over an upper arch of a user and an outer spacing for holding a portion of the buccal mucosa of away from at least one of the incisor or canine regions of a user's upper arch so that the spaced portion of the buccal mucosa does not apply an inward force to this region. It is considered that combination of features comprises a first distinguishing feature.
- Claim 43 is directed to an orthodontic appliance comprising a mounting arrangement over an upper arch of a user and a tongue elevator for elevating the tongue of a user to a position where it does not apply significant development pressure to the lower arch of a user. It is considered that this combination of features comprises a second distinguishing feature.

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.

Each of the abovementioned groups of claims has a different distinguishing feature and they do not share any feature which could satisfy the requirement for being a special technical feature. Because there is no common special technical feature it follows that there is no technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention *a priori*.

As the second invention could be searched and examined with only negligible additional effort this International Searching Authority chose not to invite additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2008/001293

This Annex lists the known "A" publication level 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 Cited in Search Report	Patent Family Member					
WO 2003101331	AU 2003237309	BR PI0311372	CA 2484059	CN 1655731	EP 1509154	MX PA04011378
	PL 373642	RU 2004138305	US 2003224313	YU 103104		
AU 2002335795	AU 36534/99	AU 2003252469	AU 2004240608	BR 0116610	BR 9909793	BR PI0213251
	CA 2329212	CA 2433329	CA 2461762	CA 2525882	CN 1487809	CN 1589124
	DE 19828157	EP 1073378	EP 1345547	EP 1450719	EP 1626668	MX PA03005897
	MX PA04003362	MX PA05012276	US 5919042	US 6036488	US 6241517	US 6402510
	US 6520772	US 6719557	US 6877982	US 7094051	US 2002025502	US 2002031741
	US 2002172909	US 2003194675	WO 9953856	WO 02074179	WO 03032859	WO 2004103200
US 6368106	AU 42573/01	CA 2404209	EP 1265548	US 7018203	US 2003031976	WO 0170126
US 6837246	NONE					
US 2007240724	AR 060517	WO 2007123866				
<p>Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.</p> <p style="text-align: right;">END OF ANNEX</p>						