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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 5/56

A1

(11) International Publication Number: **WO 98/26736**

(43) International Publication Date: 25 June 1998 (25.06.98)

(21) International Application Number: PCT/US97/22708

(22) International Filing Date: 15 December 1997 (15.12.97)

(30) Priority Data:
08/766,651 16 December 1996 (16.12.96) US

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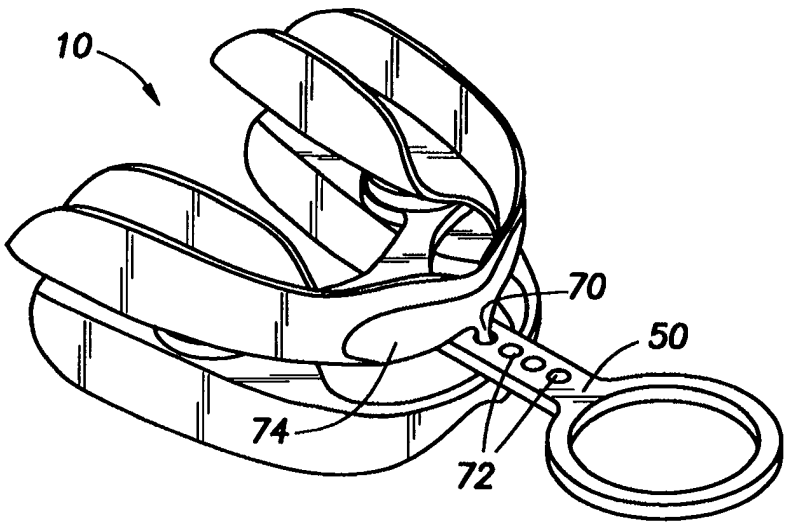
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: DISPOSABLE MANDIBULAR ADVANCEMENT APPLIANCE

(57) Abstract

A mandibular advancement, or positioning, device for short–term or one–time use is described. The appliance has an upper tray and a lower tray holding impression material, into which the patient bites. The impression material, and optional adhesive, serve as a way to secure the trays to the patient's upper and lower teeth, and, therefore, to the patient's maxilla and mandible. Preferably, the front portions of the trays are bendable or flexible, for allowing the use of just a few sizes of trays for all patients. A connector is attached to a rear area of the lower tray and adjustably connects to the upper tray at or near the center of the upper tray front area, so that the connector easily may be manually pulled forward and temporarily locked in place to advance the mandible. The device is particularly useful for short–term use in applications which do not require long–term comfort and durability, such as sleep–lab testing of the usefulness of mandibular advancement in treating a particular patient, or as a step in surgical anesthesia to enlarge a patient's pharyngeal airway space.



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DISPOSABLE MANDIBULAR ADVANCEMENT APPLIANCE

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates generally to oral appliances for controlling the position of the human mandible to effect the size of the pharyngeal airway. More specifically, this invention relates to a removable mandibular advancement appliance which pulls the jaw forward and opens the bite vertically. The invention may be used for preventing snoring and obstructive sleep apnea (OSA), for testing the efficacy of such an appliance on snoring or OSA patients, or for keeping the airway open during anesthesia or other situations in which there is a risk of obstruction of the airway due to the position or state of the user. A preferred embodiment of the invention is a disposable appliance that can be conveniently, quickly, and safely used in sleep labs and surgical settings without custom-building the appliance for the individual patient.

Related Art

It is well documented in the literature that an oral appliance that opens the bite and moves the mandible forward will greatly reduce sleep apnea and snoring. It is believed that such appliances work by opening the airway for greater airflow, by moving the mandible an/or tongue forward to increase the pharyngeal airway space.

What is still needed, however, is a disposable appliance which is effective for short-term use without custom construction or adjustment. A disposable appliance is needed for testing of snoring or sleep apnea patients and for use by anesthesiologists and other medical practitioners needing short-term mandibular advancement. These needs are satisfied by the present invention.

SUMMARY OF THE INVENTION

An object of the present invention is to provide effective, convenient, quick, safe, and reliable mandibular advancement for situations in which the advancement, and the resulting opening of the airway, is needed for shorter periods of time, for example, during several hours of surgery or over-night in a sleep lab. The appliance of the present invention is effective without requiring custom-fitting or expensive lab work, so that the invention may be economically used and disposed of after one use. The present invention is particularly effective as a disposable, economical testing or "titration" device to help medical professionals determine whether a mandibular advancement appliance alleviates the patient's snoring or OSA problems, and whether that added investment in a custom-built appliance would be beneficial. The present invention is also particularly effective as a disposable device for one-time use by anesthesiologists, to prevent a patient's airway from becoming obstructed by the patient's own tongue while under anaesthesia.

Both installation and removal of the invented appliance are quick and straight-forward, allowing quick action in preparation for surgery or testing or during an emergency in surgery. The appliance of the present invention comprises two trays, an upper tray for temporary securement to the user's maxillary dentition, and a lower tray for temporary securement to the patient's mandibular dentition. The appliance also comprises a connection means for connecting the upper and lower trays in a position

which pulls the tray, and therefore, the mandible, forward relative to the upper tray and the maxilla. Minimal adjustment is needed to obtain an effective advancement of the mandible, and the advancement may be done by a quick movement of preferably a single connector.

The trays are preferably of the general type that may be referred to as bite trays, for holding an impression material, such as silicone putty like Kerr's Citricon TM into which the patient bites. The putty hardens enough against the teeth and gums, and particularly into the undercut areas of the generally bell-shaped teeth, so that the putty acts as the securement means to hold the upper and lower trays in place on the maxillary and the mandibular dentition, respectively, during the testing or surgery. Preferably, bite planes or other spacers extend from either the upper tray or the lower tray, to occlude against the opposite tray to open the bite.

The connection means is preferably engaged, as soon as the securement of the trays to the dentition is accomplished, to pull the mandible forward. The connection means is preferably incrementally adjustable, so that the medical professional may choose one of several "settings" for the connection means, and therefore, one of several amounts of mandibular advancement. The connection may be elastic, however, the preferred connector is generally non-elastic, to prevent significant stretching of the connector by the patient and the consequent backward movement of the mandible that might obscure the testing results or allow the mandible and tongue to fall backward during surgery. Thus, the preferred connection means provides the testing professional or anesthesiologist an adjustable but exact, repeatable and known amount of advancement for the short-term use of the appliance. Precision and repeatability are normally a high priority for these short-term uses, rather than comfort and patient acceptance, which are priorities for long-term applications.

The connection means of the present invention is also preferably a quickly connectable, and quickly removable or releasable connector. Preferably, the connector comprises a single connector or fastener with a single handle for extending out the front of the patient's mouth for easy access. In this way, the technician or anesthesiologist can quickly install and incrementally adjust the connector for use, and can quickly disconnect the connector in an emergency.

Typically, during sleep-lab testing or surgery, the connector will be adjusted several times. In the sleep-lab, the technician will typically start the testing with the connector in a relatively posterior (rearward) position, that is, pulling the lower tray forward little or none to get a reference point for the patient's response. The technician will then incrementally adjust the connector and lower tray forward to monitor the patient's response. In a surgical application, an anesthesiologist will typically first adjust the connector and lower tray to relatively anterior (forward) position to ensure the mandible and tongue is advanced during the crucial early stages of anesthesia. During the surgery, the anesthesiologist may release the connector or lock it in a relatively rearward (non-advanced) position. After surgery, the anesthesiologist again may advance the connector and lower tray in preparation for the patient's coming out of anesthesia.

Most adult patients can be quickly fitted into one of three standard sizes of upper and lower trays. The trays are preferably adapted to flex slightly during the insertion and/or biting steps, to enhance the fit of the standard sizes to the particular size and shape of the patient's mouth. Alternatively, the trays may be rigid and therefore offered in a wide variety of sizes to fit many different mouth sizes and shapes.

Once the short-term use of the present invention is over, the connection means may be disconnected and the

trays pulled off of the dentition for removal of the appliance from the patient's mouth. The appliance may then be discarded without great loss of investment in time and equipment.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of the one embodiment of the invention, showing upper and lower trays and connector, but with the lower tray not yet pulled forward.

Figure 2 is a perspective view of the embodiment of Figure 1, showing the lower tray pulled forward and the connector engaged to the upper tray.

Figure 3 is a detail perspective view of an embodiment of a securement means for holding the tray on the patient's teeth and soft tissues, that is, impression putty for being received in an upper tray for being bitten into by the upper teeth of a patient.

Figure 4 is a perspective view of the lower tray and connector of the embodiment of Figure 1 and 2, showing button spacers onto which the connector is attached.

Figure 5A is a top view of the lower tray and connector of the embodiment of Figure 1 and 2.

Figure 5B is a bottom view of the upper tray of the embodiment of Figures 1 and 2, shown without the connector of Figure 5A attached to the upper tray.

Figure 6 is a cross-sectional view of the lower tray of Figure 5A, along the line 6-6 in Figure 5A, showing the button without the pull-strap attached.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to Figures 1-6, there is shown one, but not the only, embodiment of the invented mandibular advancement appliance 10. Depicted in Figure 1 are upper tray 12 and lower tray 14, without impression putty, but arranged generally as they would be in patient's mouth before advancement of the lower tray 14 and the mandible. In this description and in the claims, portions of the appliance 10

described as "anterior", "front", or "forward" refer to areas or directions generally near or toward the anterior teeth (front six teeth). The terms "posterior", "rear", or "rearward" refer to areas or directions generally near or toward the posterior teeth (back from the front six teeth).

The trays 12, 14 are generally U-shaped, and each has an anterior portion (hereafter, also called "front portion 26, 28") and left and right side posterior portions (hereafter, also called side portions 36, 36', 38, 38'). The left and right side posterior portions have side troughs 16, 16', 18, 18', and the anterior portions have smaller front troughs 40, 42. Into the troughs are placed ropes of putty 20 (as shown in Figure 3), such as silicone putty, a vinyl polysiloxane impression material, or other impression material, such as may be known now in the dental arts or others developed in the future. The putty 20 preferably extends all the way from the tray left ends 22, 24, around the front portions, 26, 28, and to the tray right ends 22', 24'. Upon placement of the putty-filled trays 12, 14 into the patient's mouth, the patient's teeth (not shown) extend into the troughs 16, 16', 18, 18', 40, 42, and the patient is instructed or caused to bite into the putty 20 in the troughs. The putty 20 moves around the slightly bell-shaped teeth to extend into the teeth undercuts, and hardens around the teeth and against the soft tissues, in order to secure the trays 12, 14 onto the upper and lower teeth and tissues.

The tray front portions 26, 28 are preferably designed to be flexible to an extent that allows each tray to flex near the front portions 26, 28 to conform more accurately to the particular patient's mouth. While it is anticipated that about three standard adult sizes and about three standard pediatric sizes will fit most patients, the additional feature of tray flexing at the tray front 26, 28 helps fit in-between-size or unusually-shaped mouths. To achieve this flexibility, the preferred tray front portions 26, 28 are narrower or flatter than their side portions 36,

36', 38, 38'. That is, the front trough 40, 42 widths are small relative to the side troughs, for holding the putty 20 for the front teeth while not interfering with flexibility of the front walls 44, 46. Thus, the side troughs 16, 16', 18, 18' are wide enough from side wall to side wall to receive the patient's molars, while the front troughs 40, 42 may be just wide enough from side wall to side wall to hold the putty into which bite the front teeth.

An alternative embodiment comprises upper and lower trays with non-flexible, rigid anterior (front) portions. With such an embodiment, the medical professional would be supplied with a large assortment of trays, giving him/her the choice of a wide variety of tray sizes.

An alternative, less preferred embodiment, eliminates the front troughs 40, 42. In such an embodiment, the side troughs and putty comprise the securement means.

Figures 1, 2, 4 and 5A show a connection means that is a single "pull-strap" connector, for pulling and locking the lower tray in a forward position. The pull-strap 50 is generally a Y-shape, with two wigs 62, 62' for connection to the lower tray 14 and a handle 64 for connection to the upper tray 12 and for extending forward out of the patient's mouth. The wings 62, 62' each have a ring 66 with a hole for snapping around the buttons 68 located on the left and right upper surfaces of the lower tray 14 about midway along the tray side portions 38, 38'. A pin 70 or other protrusion extends from the front portion 26 of the upper tray 12 to engage in the plurality of holes 72 in the handle 64. As shown in Figure 5A, the line of holes 72 generally corresponds to incremental adjustments in advancement of the lower tray 14 and the mandible forward relative to the upper tray 12 and the maxilla. By snapping the pull-strap handle 64 up to receive the pin 70, typically in one of the more rearward of the holes 72, the lower tray 14 is locked in place anterior relative to the upper tray 12, until the pull-strap 50 is snapped down off

of the pin 70. As shown in Figure 2, when the pull-strap 50 is pulled forward to the more rearward of the holes 72, the front portion 28 of the lower tray can be seen to be significantly forward of the front portion 26 of the upper tray.

In addition to serving as attachment points for the pull-strap 50, the buttons 68 serve as spacers or bite planes to separate the trays 12, 14 during use, and therefore, to open the bite of the patient. As discussed above, this further contributes to the opening of the airway of the patient.

In use, the technician or anesthesiologist selects a small, medium, or large tray size for the patient. He/she places a rope of putty 20 in both the upper and lower trays. Optionally, he may first spray an adhesive into the tray to further attach the putty to the trays beyond the degree that the putty will naturally stick to the tray due to its inherent adhesiveness. The lower tray 14 has been previously fitted with a pull-strap 50, by snapping or pushing the rings 66 down around the buttons 68. Both trays are than inserted into the patient's mouth, and the patient bites down into the putty. After sufficient time for the putty to adequately set up, typically about a minute, the pull-strap 50 is pulled forward and locked on the upper tray pin 70 at a position desired by the technician or anesthesiologist. This position may be adjusted as desired to increase or decrease the amount of advancement.

Optionally, the appliance may be pre-fitted to the patient by a nurse or technician several minutes or hours before the testing or surgery, removed from the patient after the putty has hardened, and then reinserted just prior to testing or surgery. For this reinsertion, the medical professional may also apply a spray-on adhesive on the surface of the hardened putty before reinsertion in to the patient's mouth, to further enhance the securement of the putty to the teeth.

Various putty materials and methods of handling the putty may be used, but the preferred embodiment comprises improved putty packaging and methods of handling. Silicone putty is provided in a single-use amount and packaged in a single flexible pouch along with a vial or capsule of accelerator. In this embodiment, the user obtains the single pouch, releases the accelerator by breaking open the vial by a quick snap of the vial through the material of the pouch, kneads the accelerator into the putty to the thorough mixing. The user then cuts or zips open the pouch and squeezes out the putty to form two ropes for the trays.

The invented appliance 10 may be made by various methods, preferably by injection molding of plastic such as acrylic or PETG. The Pin 70 may be a protrusion extending integrally from the molded material, or, alternatively, may be part of a separate piece 74 bonded onto the front wall 44 of the upper tray, for example. The pull-strap 50 may be made of thick urethane, for example, to make the pull-strap 50 resilient enough to snap onto and off of the buttons 68 and the pin 70, but not elastic enough to allow significant stretching of the pull-strap by the patient during use.

Optionally, all interior surfaces of the trays may be texturized. All trough interior surfaces and surfaces that may be contacted by the impression material may be texturized to better bond with the impression material.

Alternatively, other connection means may be used to lock the lower tray to the upper tray in an advanced position, For example, a cord may connect to the lower tray on both buccal sides of the lower tray and may extend up to attach to a forward protrusion of the upper tray by hooking into one of several notches in a surface of the forward protrusion. Other connection means may include a plurality of fasteners and may include fasteners that range from elastic to rigid, but the described preferred connection means is very effective because of its simplicity and ease of use, and because it does not stretch

to create an unknown amount of advancement. The described preferred connection means is also easy to use because it consists of only a single part that attaches easily to both sides of the lower tray to pull the lower tray forward uniformly. The preferred connection means is controlled by a single handle from outside the patient's mouth and with a single action of the hand. Preferably, but not necessarily, the single connector handle extends at least on inch forward from the front portion of the upper tray, even when the connector is adjusted to its rearmost position, for easy access by the medical professional.

The buttons 68 are preferably an integral part of the lower tray, rather than being removable and changeable. Optionally, the pull-strap 50 may be integral with the lower tray, and need not be removed from the lower tray for the short-term use of the invention. Alternatively, the buttons may be attached to the tray by some method that would not pose the risk of the buttons tearing off during use.

Although this invention has been described above with reference to particular means, materials and embodiments, it is to be understood that the invention is not limited to these disclosed particulars, but extends instead to all equivalents within the scope of the following claims.

IN THE CLAIMS:

1. An oral appliance for use in advancing a patient's lower jaw, comprising:

upper and lower, generally "u" shaped bite trays each including troughs along both sides and the front portions and adapted to fit over the upper and lower teeth of the patient,

the upper tray having fastening means near its front portion,

a supply of material which, when applied to the troughs of each tray, is adapted to adhere thereto, and, when the trays are fitted over the teeth, form an impression which adheres to the teeth to the extent necessary to be temporarily retained in the patient's mouth, and

connecting means having

an inner end connected to the lower tray rearwardly of the fastening means when the trays are in place and

of such length that its outer end extends forwardly of the patient's lips, and

means intermediate its inner and outer ends which is releasably fastenable to the fastening means of the upper tray,

said connecting means being sufficiently elastic that its outer end may be manipulated to permit it to be fastened to the upper tray in different forward and rearward positions, or, with the connecting means releasably fastened to the lower tray prior to installation of the trays, the lower tray will, when installed, force the lower tray and thus the lower jaw to a desired forward position with respect to the upper tray, but

nevertheless being sufficiently non-elastic as to prevent substantial movement of the lower tray from the position in which it is releasably fastened,

said trays and said impressions, upon hardening, being sufficiently elastic that they may be removed from the teeth.

2. As in claim 1, wherein
the inner end of the connecting means is releasably connected to the lower tray.

3. As in claim 1 or 2, wherein
each side of one tray has a bite plane engageable with the bite surfaces on the other tray.

4. As in claim 3, wherein
the bite planes are on the lower tray.

5. As in claim 4, wherein
each bite plane is formed on the means releasably attaching the inner end of the connecting means to the lower tray.

6. As in claim 1, wherein
the inner end of the connecting means has wings each connected to an opposite side of the tray.

7. As in claim 6, wherein
each wing is releasably connected to a side of the tray by a hole in one tightly fittable over a button on the other.

8. As in claim 1 or 2, wherein
the means for releasably fastening the inner end of the connecting means to the front position of each tray comprises a pin on one and a series of

spaced holes on the other fittable closely over the pin.

9. As in claim 8, wherein
the pin is on the front portion of the upper tray, and the holes are formed in the outer end of the connecting means.

10. As in claim 1, wherein
each tray is of such construction that its sides may flex inwardly and outwardly to accommodate different sized jaws.

11. As in claim 10, wherein
the supply of impression material is prepackaged for storage and supply along with the trays and connecting means, and includes components which, when combined, are adapted to be formed into a moldable shape for application to the troughs.

12. As in claim 1, including
means on the trays for enhancing the adherence of the impressions material to the troughs.

13. As in claim 1, wherein
the impression material is of such consistency as to flow and harden in the undercut areas of the teeth.

14. A method of advancing a patient's lower jaw, with the use of an oral appliance which includes upper and lower, generally "u" shaped bite trays each including troughs along both sides and the front portion thereof and adapted to fit over the upper and lower teeth of the patient, the upper tray having fastening means near its forward portion,

a supply of impression material, and connecting means having an inner end connected to the lower tray rearwardly of the fastening means when the trays are in place, and means intermediate its inner and outer ends which is releasably fastenable to the fastening means of the upper tray, so that its outer end extends beyond the front portion of the lower tray, the steps of

applying the impression material to the troughs of each tray so as to cause it to adhere thereto,

fitting the troughs of the upper and lower trays to the upper and lower teeth including their undercut portions to form an impression of the teeth,

manipulating the outer end of the connecting means so as to locate the fastening means thereon in a position to releasably engage the fastening means on the upper tray,

fastening the connecting means to the upper tray when so located, and

pulling the outer end of the connecting means to unfasten it from the upper tray and thereafter manipulating the upper end of the connecting means to refasten it, and

refastening the connecting means to the upper tray in another position, or, if desired, enabling the appliance to be removed by lifting the trays from the teeth.

15. A method of advancing a patient's lower jaw, with the use of an oral appliance which includes upper and lower, generally "u" shaped bite trays each

including troughs along both sides and the front portion thereof and adapted to fit over the upper and lower teeth of the patient, the upper tray having fastening means near its forward portion, supply of impression material, and connecting means having an inner end connected to the lower tray rearwardly of the fastening means when the trays are in place, and means intermediate its inner and outer ends which is releasably fastenable to the fastening means on the upper tray, so that its outer end will extend beyond the front portion of the lower tray, the steps of

applying the impression material to the troughs of each tray so as to cause it to adhere thereto,

fitting the troughs of the upper and lower trays to the upper and lower teeth to form an impression of the teeth,

removing the trays from the patient's teeth,

manipulating the outer end of the connecting means so as to locate the fastening means thereon in a position to releasably engage the fastening means on the upper tray,

fastening the connecting means to the upper tray when so located, and

by fitting the upper and lower trays and impressions over the upper and lower teeth so as to advance the lower teeth with the lower tray a distance corresponding to the advance of the lower tray, and

thereafter manipulating the outer end of the connecting means to release its fastening means from that of the upper tray so that the

connecting means may be refastened to the upper tray in another position, or, if desired, permit the appliance to be removed by lifting the trays from the teeth.

FIG. 1

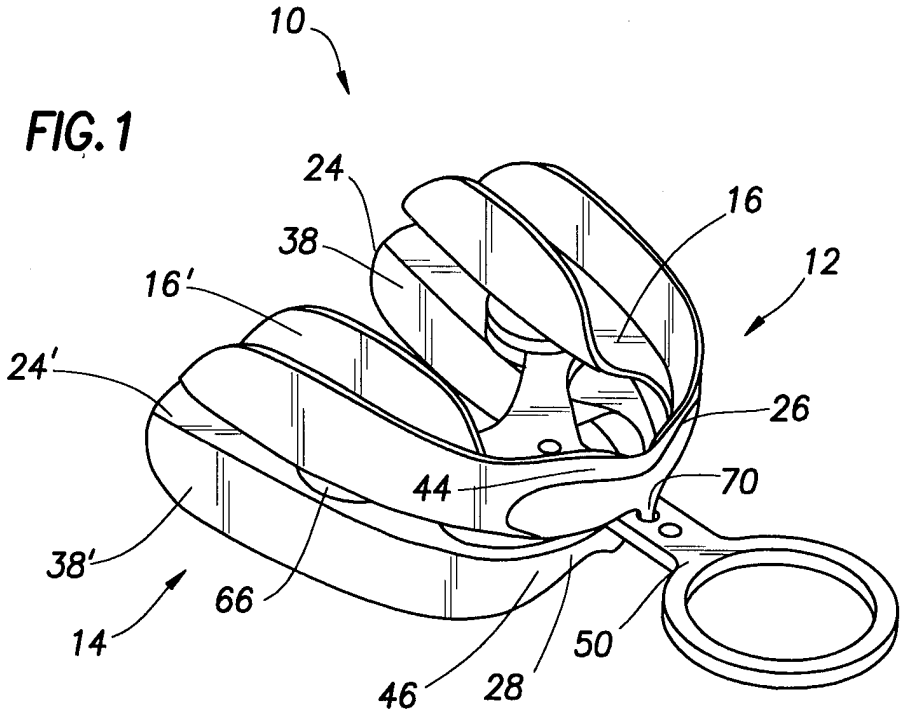


FIG. 2

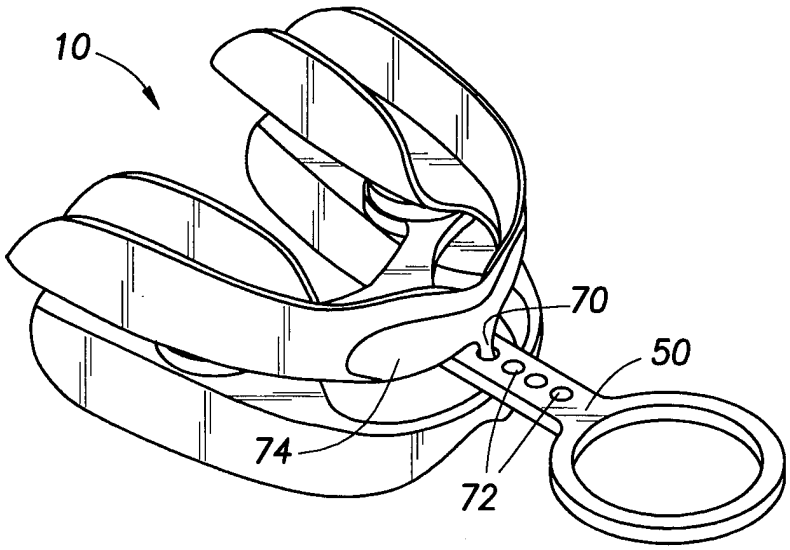


FIG.3

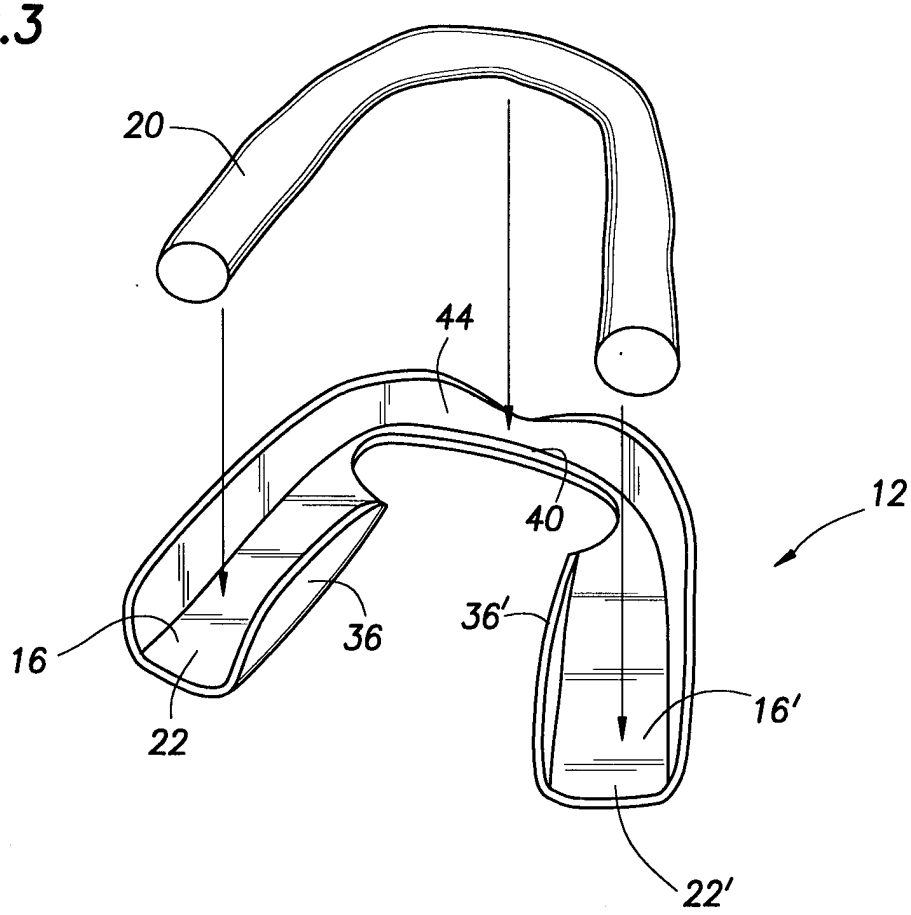


FIG.4

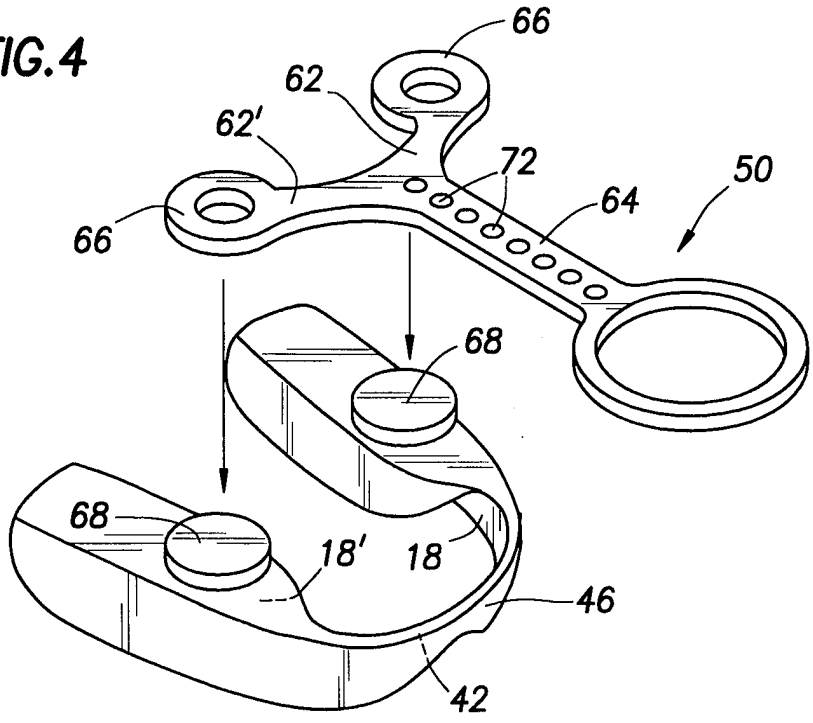


FIG.5B

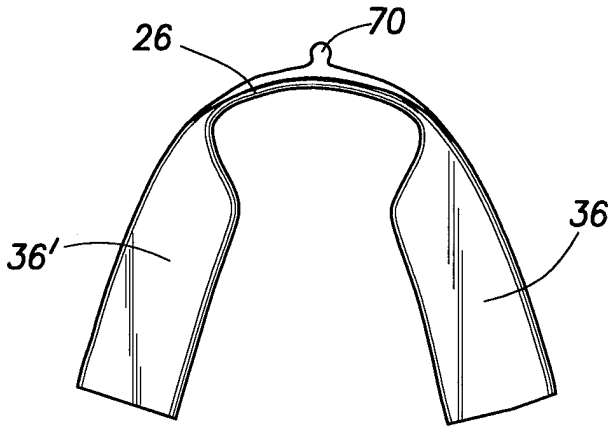


FIG.5A

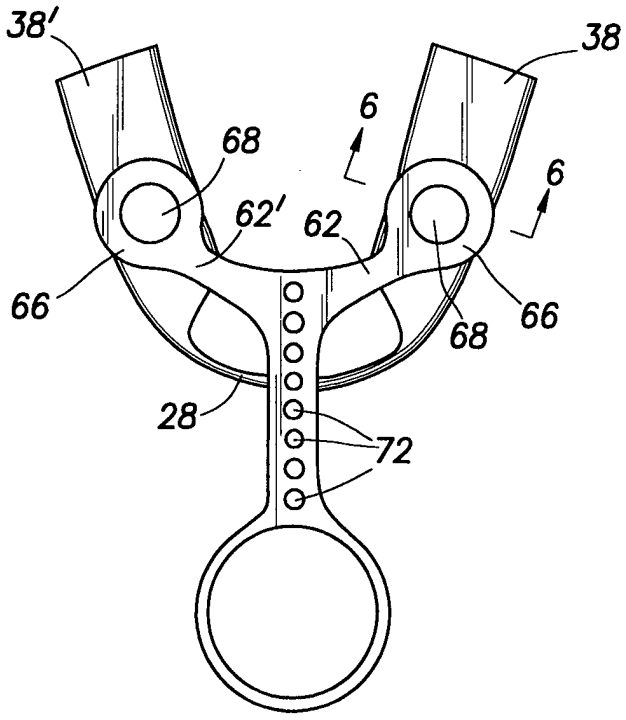
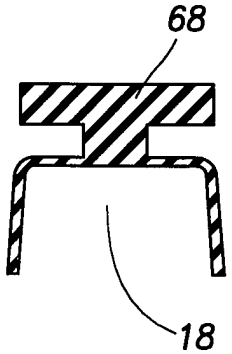


FIG.6



INTERNATIONAL SEARCH REPORT

Int· ational Application No
PCT/US 97/22708

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F5/56

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 313 960 A (TOMASI BARBARA R) 24 May 1994 see abstract; figures	1,14,15
A	US 5 562 106 A (HEEKE DAVID W ET AL) 8 October 1996 see abstract; figures 1-5	1,14,15
A	WO 94 28832 A (HILSEN KENNETH L) 22 December 1994 see claims 1,9; figures	1
A	US 5 570 704 A (BUZZARD RONALD D ET AL) 5 November 1996	
A	US 5 499 633 A (FENTON DOUGLAS F) 19 March 1996	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
20 April 1998	28/04/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Sánchez y Sánchez, J

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int ational Application No
PCT/US 97/22708

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5313960 A	24-05-94	NONE	
US 5562106 A	08-10-96	NONE	
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US 5570704 A	05-11-96	NONE	
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