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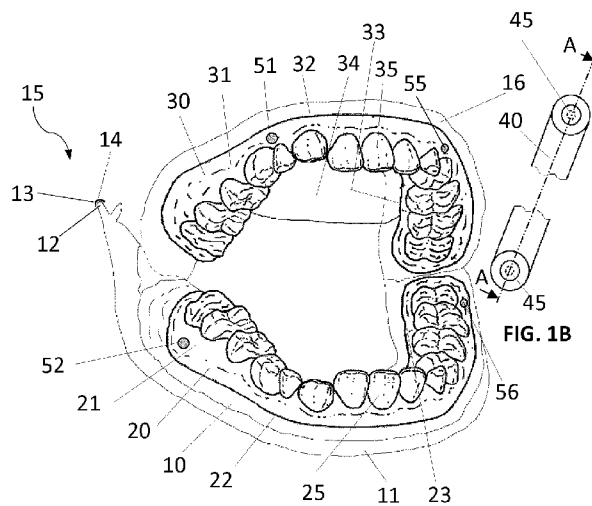


FIG. 1

(57) Abstract: An oral appliance (OA) made as add-on optional feature in a denture of a user with or without implants to facilitate adjustable mandibular advancement assisting in partially or fully reducing snoring and thus ameliorating obstructive sleep apnea (OSA). The mandibular advancement is realized by deployment of pins in the denture set, and a set of straps that may have optional features such as recess, reinforcement, and the OA may be made of bio-compatible materials using several manufacturing approaches including 3D printing, molding, or milling. An optional additional process comprises of economical production of a similar or alternatively simpler, lighter secondary unit that may be offered to a patient ordering a primary denture, at a discounted price that may serve the purpose of cosmetic function as well as anti-snoring function.

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SNORING AND OBSTRUCTIVE SLEEP APNEA PREVENTION DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims benefit of priority from U.S. Serial No. 17/824,897, filed May 26, 2022, the contents of which is incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

Field of the Invention

[0001]. The present invention pertains to oral appliances for the prevention of snoring, sleep apnea, or similar other conditions, more particularly to an oral appliance that can be used by those who wear dentures, methods of their manufacture and use.

Description of the Related Art

[0002]. It is well known and documented that those individuals suffering from sleep-related breathing disorders such as sleep apnea exhibit moderate to excessive snoring which is often ignored or neglected without any preventive or curative measures. It is also well known that this neglect is causing an increased risk resulting in more severe health problems later on such as stroke, atrial fibrillation, hypertension, chronic heart failure, excessive sleepiness in daytime causing driving accidents or equipment operation accidents, and a variety of ailments e.g. diabetes, depression, among others including the fact that an obstructive sleep apnea (OSA) episode can be life threatening; however, 80 percent of the cases of moderate and severe obstructive sleep apnea is likely undiagnosed (Source: American Sleep Apnea Association: Sleep Apnea Information for Clinicians- A very short course on sleep apnea; Hu, Pub. No. US 2020/0129278 dated Apr. 30, 2020). Studies have shown, for instance, that individuals demonstrating snoring are most likely to be suffering from OSA that may lead to one or more of the aforementioned health problems. OSA is characterized by periodic and repetitive collapse of the upper airway during sleep, the frequency of the same is specified as apnea and hypopnea index (AHI) that shows the average number of apneas and hypopnea per hour of sleep. Health care professionals use the terms of respiratory disturbance index (RDI), and AHI interchangeably. While apnea episodes entail total stoppage or pause in breathing typically for 20 to 40 seconds, hypopnea episodes entail typically shallow or partial breathing accompanying 30% or greater reduction in air flow lasting for 10 seconds or longer with an associated greater desaturation in the person's oxygen levels exceeding 4% often resulting in fragmentation of sleep or arousal. The AHI is calculated by dividing the sum of apneas and hypopneas by the number of hours of sleep. AHI values are categorized as follows: severe if more than 30

episodes per hour, moderate if episodes ranging from 15 to 30 per hour, and mild if 5 to 15 episodes per hour. These episodes of reduced airflow are typically caused by the relaxation of the tongue and pharyngeal walls to varying degrees during the several stages of sleep wherein the musculature supporting these tissues relaxes, therefore, as air is inhaled, the tongue and posterior walls of the pharynx collapse, causing snoring that is in fact vibration noise caused by partial or complete obstruction of the airway. The episodes may cause several undesirable conditions such as reduced oxygen level in the blood (hypoxemia), elevated circulating carbon dioxide (hypercapnia), and arousal from sleep to re-establish a stable airway.

[0003]. A rigorous study published in 2019 in Lancet reports (Markets and Markets. Sleep Apnea Devices Market, Report Code: MD 1181, Published Date: Aug 2021) that nearly 1 billion adults aged 30–69 years worldwide could have OSA, and the number of people with moderate to severe OSA, for which treatment is generally recommended, is estimated to be almost 425 million. Major part of the actual market remains untapped or not served as a large number of patients remain undiagnosed (Adam V Benjafield, Najib T Ayas, Peter R Eastwood, Raphael Heinzer, Mary S M Ip, Mary J Morrell, Carlos M Nunez, Sanjay R Patel, Thomas Penzel, Jean-Louis D Pépin, Paul E Peppard, Sanjeev Sinha, Sergio Tufik, Kate Valentine, and Atul Malhotra. Estimation of the global prevalence and burden of obstructive sleep apnoea: a literature-based analysis. *Lancet Respir Med*. 2019 Aug; 7(8): 687–698) as they do not even know the condition and risks because the symptoms arise only while the person is in sleep and often does not believe when very limited close individuals, such as a bed partner may dare to point out, more due to noise creation annoyance such as snoring or in some cases combined with grinding of teeth (known as bruxism) and seldom due to genuine health concerns of the sufferer. The highest number of sufferers are in China, USA, Brazil, and India in decreasing order, with USA estimated to have more than 54.1 million with AHI of 5 or more events per hour; and more than 23.6 million with AHI of 15 or more events per hour. Some estimates are even higher, for example, Ramabadran reported in US Patent No. 11,147,506 dated Oct. 19, 2021 titled “Sleep diagnostic system and method” that close to 65 million American adults suffer from sleep disordered breathing conditions where 1 in 5 adults has obstructive sleep apnea or central sleep apnea conditions and contemplated that out of this large number of estimated sufferers, probably just 1 in 15 adults are properly screened, tested and then treated for this condition, leaving a substantially huge untested and thus unattended population. Canada has a substantial number of affected persons: more than 4.7 million with AHI of 5 or more events per hour; and more than 0.9 million with AHI of 15 or more events per hour. The extent and nature of the problem has attracted ongoing discussions on need for change in the way in which the diagnosis and treatment is currently funded by public health and private insurance coverage (Sachin R. Pendharkar, Marcus Povitz, Nick Bansback, Charles F.P. George, Debra Morrison, Najib T. Ayas for the Canadian Sleep and Circadian Network. Testing and treatment for

obstructive sleep apnea in Canada: funding models must change. CMAJ 2017 December 11;189: E1524-8. doi: 10.1503/cmaj.170393).

[0004]. While severe sleep-related breathing disorders may require Continuous Positive Airway Pressure (CPAP) therapy, less severe sleep-related breathing disorders may be treated with other therapies or devices, such as an Oral Appliance (OA). Generally, an oral appliance includes either a single mono-block device to impart forward advancement of the user's lower jaw (mandible) relative to the user's upper jaw (maxilla); or alternatively a duo-bloc device wherein upper and lower dental trays are coupled together in such a way so as to achieve similar mandibular advancement. Accordingly, an OA is generally referred to as a Mandibular Advancement Device (MAD) or a Mandibular Advancement Splint (MAS). Unblocking of a user's airway during sleep is achieved by the forward advancement of the mandible that helps prevent the soft tissue of the tongue and the throat from collapsing into the airway passage. In an OA, it is important to achieve the correct amount of forward mandibular advancement. For example, the soft tissue of a user's tongue and throat may not be prevented from collapsing into the user's airway and thus they may continue to Suffer from a sleep-related breathing disorder if the forward mandibular advancement imparted by the OA is inadequate. Conversely, a user may experience undesirable discomfort in the mandibular musculature, tooth pain, or even more serious side effects such as temporomandibular joint (TMJ) pain if the forward mandibular advancement imparted by the OA is excessive (as reported, for example, by Marklund, M.; Franklin, K.A. Long-term effects of mandibular repositioning appliances on symptoms of sleep apnoea. J. Sleep Res. 2007, 16, 414–420; and Pliska, B.T.; Nam, H.; Chen, H.; Lowe, A.A.; Almeida, F.R. Obstructive sleep apnea and mandibular advancement splint: Occlusal effects and progression of changes associated with a decade of treatment. J. Clin. Sleep Med. 2014, 10, 1285–1291). In extreme cases, the discomfort may cause the user to stop wearing the OA all together, in many other cases, it is reported that undesirable arousal from sleep may occur.

[0005]. Some oral appliances have been disclosed that include mechanisms for adjusting the amount of mandibular advancement provided by the oral appliance. These are called adjustable or titratable devices.

[0006]. Halstrom describes in U.S. Patent No. 5,365,945 dated Nov. 22, 1994 titled "Adjustable Dental Appliance for Treatment of Snoring and Obstructive Sleep Apnea" an appliance that consists of an upper bite block conforming to the patient's maxillary dentition, a lower bite block conforming to the patient's mandibular dentition, and a connecting assembly secured to an anterior region of the upper and lower bite blocks for adjustably or in a titratable manner coupling the upper and lower bite blocks together.

[0007]. Lowe describes in WO1995019746 dated 27 July 1995 titled "Mandible repositioning appliance for snoring prevention" a device formed by an upper bite block and a lower bite block interconnected by an extendable connector including a posterior section connected to the rear portion of the upper bite block and an anterior section connected to the front portion of the lower bite block and an adjustable threaded element interconnection between the anterior and posterior sections affecting the relative positions.

[0008]. Fenton describes in U.S. Patent No. 5,499,633 dated Mar. 19, 1996 titled "Anti-snoring Device with Adjustable Upper and Lower Relational Members" an anti-snoring device that comprises an upper member for receiving upper teeth of the user, which is joined in a spaced relationship to a lower member for receiving lower teeth of the user. The lower member is selectively positioned with respect to the upper member such that the lower member, by receiving the lower teeth of the user, moves the lower jaw of the user to a position that is forward of its "normal" resting or biting position. This forward movement of the lower jaw is claimed to significantly open the airway of the user, thereby alleviating, reducing, or eliminating snoring.

[0009]. Kidd and Lane describe in U.S. Patent No. 5,829,441 dated Nov. 3, 1998 titled "Customizable Dental Device for Snoring and Sleep Apnea Treatment" a mandible extension dental device which includes adjustable upper and lower arch trays and coupling means designed to pull the lower jaw of a user forwardly during Sleep, so as to minimize snoring and mild apnea conditions. The device is intended to be rapidly fitted in the field without the need for the services of a dentist.

[0010]. Halstrom describes in U.S. Patent No. 5,868,138 dated Feb. 9, 1999 titled "Dental Appliance for Treatment of Snoring and Obstructive Sleep Apnea" yet another configuration of a dentally retained intra-oral appliance worn at night for treatment of snoring and obstructive sleep apnea.

[0011]. Strong describes in U.S. Patent No. 6,526,982 dated Mar. 4, 2003 titled "Anti-snoring Device and Method of Making Same" an anti-snoring device that has maxillary and mandibular bite forms with outwardly extending pivots which are mounted to the bite forms by frameworks which are at least partially embedded in the bite forms supposedly able to retain the pivots securely in place even in the face of extensive bruxing.

[0012]. Palmisano describes in U.S. Patent No. 6,536,439 dated Mar. 25, 2003 titled "Apparatus and methods for treatment of conditions including obstructive sleep apnea and snoring" a maxillary expansion device that is fitted to teeth of the upper jaw, and the maxilla is expanded by operation of a jack screw, such that, after the maxilla stabilizes, the minimum

cross-sectional area of the nasal cavity increases, reducing nasal airway resistance resulting in curing, or ameliorating, obstructive sleep apnea and/or snoring.

[0013]. Palmisano describes in U.S. Patent No. 6,604,527 dated Aug. 12, 2003 titled “Mandibular Advancement Device” a custom made device made for each user from a desired cast of the user’s jaw having a lower bite block, with a pair of upwardly extending flanges, and an upper bite block, with a pair of downwardly extending flanges; the flanges each carry engagement surfaces. When the bite blocks are fitted to the jaws of a user during sleep, the lower and upper engagement surfaces engage and cause anterior advancement of the lower jaw from the reflex path of opening and maintain that engagement and advancement whilst permitting movement, up to the normal range of jaw opening.

[0014]. Palmisano and Mehta describe a version of the above in EP 1094761 published dated 29 Oct. 2008. Bedford discloses some updates and improvements over Palmisano described above, in US 2018/0360646 dated Dec. 20, 2018 and in AU 2021250941 dated Oct. 15, 2021 titled “A Mandibular Advancement Device”. Introduction of a ratchet mechanism to effect the mandibular advancement along with the lower and upper parts being formed from relatively hard lower and upper shells, relatively soft lower and upper linings, and heat formable lower and upper inner linings therebetween appear to be the newly claimed innovative steps.

[0015]. Scarberry et.al. describe in U.S. Patent No. 8,205,617 dated June 26, 2012 titled “Oral Appliance for Treatment of Snoring and Sleep Apnea” an oral appliance system that comprises an upper tray and a plurality of lower trays. The upper tray is adaptable to conform to a user’s maxillary dentition and each of the lower trays is adaptable to conform to the user’s mandibular dentition. The lower trays are structured to engage the upper tray and each of the lower trays is structured to impart a different fixed amount of mandibular advancement and/or different amount of vertical height.

[0016]. Kopp describes in U.S. Patent No. 8,640,705 dated Feb. 4, 2014 titled “Anti-Snoring Device” an arrangement for mandibular advancement wherein elongated holes and so called S-shaped design of a pair of protrusion ties in conjunction with U-shaped upper and lower jaw bars are claimed to provide elasticity and thus spring action.

[0017]. Fallon, Jung, and Fallon describe in U.S. Patent No. 8,833,374 dated Sep. 16, 2014 titled “Intra-oral Mandibular Advancement Appliance” a mandibular advancement device wherein upper and lower tray assemblies having shapes against which the teeth of user’s upper and lower jaws are seated respectively may be adjusted and locked in different positions respective with each other. A tongue rest is also provided to prevent tongue from falling across and blocking the patient’s airway.

[0018]. Petelle and Fleury describe in U.S. Patent No. 9,545,330 dated Jan. 17, 2017 titled "Intraoral orthosis, a method of fabricating such an orthosis, and a method of adjusting it" an intraoral orthosis for treating snoring and sleep-apnea syndrome that includes two shells connected together by an adjustable connection device, the adjustable connection device including two notched tabs that are arranged respectively on either side of one of the shells, each notched tab co-operating in adjustable manner with a respective adjustment housing, arranged correspondingly on either side of the other of the shells, the adjustment housings being molded integrally with the other shell, each adjustment housing being connected to the other shell by a foldable support structure. A version of this was earlier described in U.S. Patent No. 9,095,454 dated Aug. 4, 2015 titled the same.

[0019]. Kim et. al. describe in U.S. Patent No. 9,949,868 dated Apr. 24, 2018 titled "Mandibular Advancement Device" a configuration wherein relative positions of upper and lower fins on upper and lower splints enable desired mandibular advancement, claiming manufacturing a set of at least two devices following a process for digital design based on obtaining electronic data on the shape of user's dentition as the invention.

[0020]. Baratier and Palomino describe in U.S. Patent No. 10,363,160 dated Jul. 30, 2019 titled "Mandibular Repositioning Device" an intra-oral device comprising an upper splint structured to engage with one or more teeth on user's maxilla, a lower splint structured to engage with one or more teeth on user's mandible, a pair of lateral connecting rods (each connecting rod has a first rod end that connects to the lower splint and a second rod end that connects to the upper splint), and the connecting rods are configured to maintain the mandible in an advanced position relative to the maxilla.

[0021]. Veis and Ataii describe in U.S. Patent No. 10,363,161 dated Jul. 30, 2019 titled "Sleep Apnea Oral Appliance for Use During Orthodontic Treatment" a sleep apnea oral appliance in which a pair of appliance trays are worn over orthodontic trays coming in contact with maxillary dentition and mandibular dentition respectively that may comprise a series of different configurations in order to change the position of a user's teeth and/or the shape of the user's jaw.

[0022]. Fallon describes in U.S. Patent No. 10,849,783 dated Dec. 1, 2020 titled "Full Movement Jaw Advancement Oral Appliance to Reduce the Effects of Snoring and/or Sleep Apnea" an oral appliance that includes an upper arch tray assembly against which the user's upper teeth carried are received, a lower arch tray assembly against which the user's lower teeth are received, and an intermediate guide post support tray that is connected at the bottom thereof to the lower arch tray assembly and at the top thereof to the upper arch tray assembly by an upper arch tray retaining post that extends therebetween.

[0023]. Mortadi describes in U.S. Patent 10,888,451 dated Jan. 12, 2021 titled “Oral Device for Preventing Sleep Apnea and a Method of Manufacturing” an oral device that provides an upper plate and lower plate, each adapted to retain the biting surface of the respective set of maxilla and mandible teeth, wherein a pair of S-shaped curved rods pivotally interconnecting both plates are adapted for maintaining an operable spaced apart relationship therebetween.

[0024]. Radmand describes in U.S. Patent 11,191,663 dated Dec. 7, 2021 titled “Oral Appliance and Kit for Treatment of Sleep Apnea” an oral appliance for the treatment of obstructive sleep apnea that includes a mouthpiece embedded with a variety of sensors and a stimulator configured for being received in an oral cavity of a user.

[0025]. Kopelman describes in U.S. Patent No. 11,207,208 dated Dec. 28, 2021 titled “Systems and Methods for Positioning a Patient’s Mandible in Response to Sleep Apnea Status” three different optional embodiments wherein a rotor element, or a linear advancement structure, or a tether element winding and unwinding are deployed along with use of actuator to achieve relative advancement of the bottom part against the upper part.

[0026]. These and similar other oral appliances, however, are all directed for users with natural teeth as the devices are meant to be worn over the mandibular dentition and maxillary dentition. Moreover, they are expensive, complicated to manufacture, and have adjustment mechanisms that are difficult to operate. Furthermore, the OAs currently available that incorporate adjustment mechanisms tend to be bulky, thereby adversely impacting the user's comfort level, additionally, these known OAs are difficult to properly fit, do not allow sufficient vertical or horizontal movement of the jaw when worn, and are not flexible enough to allow to be suitable for those who generally wear standard ordinary, or implant retained dentures also known as overdentures in the art. Accordingly, a need exists for a more specific oral appliance for the avoidance of snoring and thus possible preventive measures or treatment of OSA that can provide a solution for this unaddressed user market segment while overcoming at least partially the aforementioned limitations and other shortcomings associated with known oral appliances.

BRIEF SUMMARY OF THE INVENTION

Statement of the object of the invention

[0027]. Wearable oral device solution OAs for avoiding snoring and thus possibly OSA such as Mandibular Advancement Devices (MADs) are typically very similar to dentures and can be suggested by a dentist or even a denturist for use avoiding the logistical complexity of sleeping overnight in a lab for the Level 1 test required for a physician prescribed intervention. Broad market under sleep disorders includes diagnosis at different levels of complexity (Level 1, Level 2, Level 3 and Level 4 in decreasing order of complexity) interventions followed by CPAP as a

directly physician recommended primary option and subsequently moving on to an OA for mainly those who do not tolerate or do not prefer CPAP. Considerable number of users of CPAP machines have expressed that there are many problems with using them, for example, difficulty getting the right style and size of mask, difficulty in getting used to wearing the device during sleep, difficulty tolerating forced air, dry nose and/or mouth, feeling claustrophobic, mask leak, skin irritation or pressure sores, difficulty falling asleep, and many such inhibitions. The difficulties inherent to CPAP machines lead to a high failure rate perhaps as much as 50% among patients using them (Hu, Pub. No. US 2020/0129278 dated Apr. 30, 2020). This current approach of CPAP as first line of OSA treatment that too only after the situation becomes serious appears to be the main cause for the massive number of undiagnosed sufferers (Benjafield et. al., Lancet, 2019).

[0028]. The niche area we are addressing initially through this invention disclosure is to achieve relatively small but focussed market servicing in the senior citizens (considered as 60+ years in some countries, but may vary from country to country such as lower or higher such as 65+ years in some countries) and near senior citizens (for example 50+ to 55+ years age up to senior citizen age) market who anyways need full or partial dentures irrespective of potential snoring or OSA. According to several estimates quoting the Journal of Prosthetic Dentistry, 37.9 million Americans were estimated to require dentures in 2020 (Douglass et.al. "Will there be a need for complete dentures in the United States in 2020?", J. Prosthet Dent. 2002 Jan;87(1):5-8. doi: 10.1067/mpr.2002.121203). That's nearly 9% of the United States population. As Canadian population is approximately 0.11 of the USA population (Simon Fraser University. Population Comparison of Canada, United States, and Mexico: Profile Report, World Population), assuming similar North American demographics, the estimated denture users in Canada are 4.17 million, adding up the potential users of the disclosed invention to about 42 million. By providing features in these denture devices that either embedded integrally or as add-on optional accessories augment dentures into preventive snoring avoidance and thus a first line of means to avoid early OSA onset or suffering, we would be providing a pioneering solution not available in the market currently.

[0029]. The strategy we have planned through this invention disclosure to address the needs of this niche but substantial market segment is to offer precautionary and preventive anti-snoring option, that addresses the annoyance of snoring noise creation, but also safeguards one from OSA, whether or not diagnosed. It may be noted that all currently available MADs in market described in the earlier section of this disclosure are worn over the natural teeth, and thus the field is wide open without any competitive product that can be worn by this niche market segment.

[0030]. The only option that comes closest to the needs of this niche market that is available currently for full denture wearers is from an Australia headquartered company offered as Somnomed® Edentulous™ costing a considerable amount. However, this product is not part of a denture or cannot be worn over denture; it is an additional product that needs the user to remove their regular denture and to obtain and wear this expensive device separately. Another constraint is that the edentulous option can be offered only from the SomnoDent® Flex or SomnoDent® Classic or SomnoDent® MAS for users with no upper teeth (in the maxilla), which implies that existence of lower teeth (in the mandible) is necessary. In general, it is recommended that as a pre-requisite, a user should have six lower teeth (3-3) in the mandible (as per product brochure SomnoDent-Edentulous-MAS-Brochure.pdf). Therefore, we can conclude from this brief of the statement of the object of the invention that filling a much desirable gap in the field by providing a solution to a substantial number of sufferers from snoring and obstructive sleep apnea would be a first-time introduction of such an option for people without full or partial natural teeth.

Gist of the Invention

[0031]. The preferred embodiment of disclosed invention provides an add-on optional feature in a denture of a user to facilitate adjustable or titratable mandibular advancement assisting in partially or fully reducing snoring and thus ameliorating obstructive sleep apnea. The add-on optional feature in the denture set maybe provided in either a regular denture without implants, such as Removable Partial Dentures (RPDs), Removable Full Dentures (RFDs); or in any of the Implant Supported Dentures (ISDs), viz. single tooth dental implant, multiple-tooth on implant-supported bridge, and multiple-tooth on implant-retained denture. Dentures are also called denture prosthesis.

[0032]. According to one aspect of the invention, the denture set may be provided with an optional set of pins or other means to hold a mandibular part of a denture in an advanced position relative to a maxillary part of the denture using a set of straps of different lengths. Additionally, and optionally, the straps may have a slit or recess to allow relative movement between the mandibular and maxillary parts of the denture.

[0033]. Courting to another aspect of the invention, optionally, but in addition, the straps may be made of light weight flexible bio-compatible material such as Nylon-12 or a stretchable bio-compatible elastomer allowing relative movement between the mandibular and maxillary parts of the denture in multiple directions of 3D space, viz. forward-backward, upward-downward, leftward-rightward. The straps may be manufactured by several alternative means such as molding, 3D printing, blanking or stamping or other methods that may be available in the state-of-the-art.

[0034]. Courting to yet another aspect of the invention, optionally, but in addition, the straps may be made of multi-layer hybrid construction wherein a stronger material such as Kevlar® (DuPont®, Wilmington, Delaware, USA) cord is the core to provide strength over which bio-compatible material such as Nylon-12 is coated allowing a combination of both strength as well as flexibility in the relative movement between the mandibular and maxillary parts of the denture in multiple directions of 3D space, viz. forward-backward, upward-downward, leftward-rightward. The multi-layer construction may be achieved by several alternative manufacturing means such as molding, 3D printing, or other methods that may be available in the state-of-the-art.

[0035]. According to an additional but optional aspect of the invention, the preliminary impression of a patient's mouth obtained by a dentist or denturist by applying pressure to the soft tissues to simulate biting force and extending the borders of the mold to adjacent toothless areas to allow the dentures to better adapt to the gums, usually done in wax to prepare a diagnostic cast or a final cast made of gypsum or other suitable material may be gainfully utilized for the dual purpose of making a denture set as well as a splint set for mandibular advancement.

[0036]. According to another additional but optional method of use of the invention, the configuration of the patient's denture available with a dentist or denturist may be gainfully utilized for the add-on purpose of making an optional light-weight splint set for mandibular advancement providing a preventive measure for avoiding snoring and thus ameliorating obstructive sleep apnea for those willing to wear denture during sleep.

[0037]. According to yet another additional but optional embodiment of the invention, an approximate configuration of a patient's natural teeth or denture partially may be adequate to be utilized for the purpose of making a splint set for mandibular advancement deploying a clamp-on approach instead of a complete-fit approach providing a preventive measure for avoiding snoring and thus ameliorating obstructive sleep apnea.

[0038]. In summary, the disclosed invention of snoring and obstructive sleep apnea prevention device offers considerable improvement and advantages over those described in prior art in general, as an optional accessory for dentures in particular.

BRIEF DESCRIPTION OF THE DRAWINGS

[0039]. FIG. 1A presents a photographic view of a typical conventional full denture set.

[0040]. FIG. 1 shows an overall assembled view of an embodiment of the invention having a maxillary full denture, a mandibular full denture, the two connected by a pair of straps.

[0041]. FIG. 1B presents a view of a typical strap connecting a maxillary denture, and a mandibular denture.

[0042]. FIG. 1C shows a sectional view of the FIG. 1B.

[0043]. FIG. 2A shows a representative set of straps of different lengths to enable different distances of mandibular advancement.

[0044]. FIG. 2B, 2C, 2D show alternative embodiments of configurations of the straps and shapes of pin heads that enable advantages in ensuring securing and ease of change of straps.

[0045]. FIG. 2E shows a sectional view of a typical multi-layer strap configuration with a stronger cord material reinforcing as core to enable improved durability with flexibility.

[0046]. FIG. 3 shows a punch and die set for blanking process as an optional manufacturing process for straps to enable economy of scale.

[0047]. FIG. 4 shows an overall assembled view of an embodiment of the invention having a typical ISD set comprising of a maxillary part, a mandibular part, and a pair of straps connecting the maxillary and mandibular parts to enable desired mandibular advancement.

[0048]. FIG. 5 shows the schematic diagram for an optional additional production and business process offering a secondary discounted priced unit to a patient ordering a primary denture generating add-on revenue.

DETAILED DESCRIPTION OF THE INVENTION

[0049]. An overall illustration of a conventional full denture set is presented in a photographic view of a typical set in Fig. 1A. The set is well known in the art as upper or maxillary denture and lower or mandibular denture. Each denture has a denture base, a denture flange, denture borders and denture teeth.

[0050]. Fig. 1 illustrates a configuration of mandibular and maxillary dentures in relation with the lower and upper jaws of a user respectively, pointing out the locations of different anatomical parts of interest in view of the disclosed inventive aspects for fixation of straps to realize mandibular advancement to mitigate snoring or OSA. The jaws of user are shown in an open state to be able to view the internal parts of oral cavity of the user. The lower jaw has lower gum (also called gingiva) part **10** placed over a bone structure **11** in the mandible. The bone structure extends to the back as a Temporomandibular Joint (TMJ) **15** comprising of parts known in the art as condyle **12**, fossa **13**, and disc **14**. The mandibular denture **20** is placed over the lower gum **10** in a reasonably tight but comfortable fit and remains retained during day-to-day activities of the user such as speaking, chewing, etc. In a standard denture that does not

use any implants to secure the denture to the mandible, the shape and fit between the mandible and the mandibular denture serve the purpose of retention.

[0051]. The user is generally provided with options for increased levels of retention, for example, by inserting or applying between denture **20** and gum **10** bio-compatible human use safe glue materials claiming several characteristics such as being Zinc free, impervious to water, providing soft cushion, quality seal from food particles, ooze-control, use of natural ingredients like gum wax, beneficial herbs, and vitamins. Several glue products are available, for example, Effergrip® denture adhesive cream (manufacturer: Prestige Consumer Healthcare, Irvington, New York; Source: Amazon® USA), Fixodent® Ultra Max Hold Dental Adhesive (Procter & Gamble®, Cincinnati, OH, USA), SECURE® Sensitive Adhesive (Cutting Edge International, LLC, Los Angeles, CA, USA), Instant Smile™ Secure Fit Adhesive (Billy Bob Products Inc., Hardin, IL, USA), Super Poligrip® Denture and Partial Adhesive Cream (Glaxo Smith Kline, Philadelphia, PA, USA), Corega® Denture Adhesive Cream (Glaxo Smith Kline, Bulgaria, Source: Amazon®, USA), Y-Kelin Denture Adhesive Cream (Anhui Greenland Biotech Co. Ltd., Bengbu, Anhui, China), DenSureFit® Lower Denture Reline Kit (OTC Dental Inc., Vancouver, WA, USA), and from many other manufacturers or sources.

[0052]. The use of glue between denture and gum is found to achieve good average retention force in compliance with reported research, for example, in the range of 16.66 ± 7.32 lbs for milled denture bases and in the range of 12.19 ± 6.15 lbs for the conventional heat polymerized denture bases (AlHelal, Abdulaziz Abdullah, "Comparison of Retention between Milled and Conventional Denture Bases: A Clinical Study" (2016), Loma Linda University Electronic Theses, Dissertations & Projects, 323). Our experimental tests have shown that 3D printed dentures provide better or at least comparable retention force relative to milled denture bases. We have found that this retention force is adequate to withstand the mandibular advancement force reported in the art as approximately 1 to 1.2 Newtons per millimeter of mandibular advancement (for example, 1.18 Newtons per millimeters as per J Cohen-Levy, B Pételle, J Pinguet, E Limerat, B Fleury, Sleep Breath, 2013 May;17(2):781-9. doi: 10.1007/s11325-012-0765-4. Epub 2012 Sep 11).

[0053]. The mandibular denture **20** comprises of an exterior wall or flange **21**, an exterior ridge or border **22**, and an interior ridge or border **23**. A cavity known in the art as trough is formed between the exterior and interior walls that fit over the lower gum **10**. A set of teeth **25** that substitute natural teeth known in the art with nomenclature (starting from back or TMJ side, a set of teeth- one on left and one on right sides) Second Molar, First Molar, Second Premolar, First Premolar, Canine or Cuspid, Lateral Incisor, and Central Incisor (front most teeth set) are embedded symmetrically in the mandibular denture in a U-shaped configuration. This is considering the prevailing trend of not having Third Molar or Wisdom teeth at the back

most location, like the natural teeth set where their extraction is recommended by dentist profession, resulting in a total fourteen teeth in the mandibular denture.

[0054]. Analogous to the mandibular denture **20**, the maxillary denture **30** comprises of an exterior wall or flange **31**, an exterior ridge or border **32**, and an interior ridge or border **33**. A cavity known in the art as trough is formed between the exterior and interior walls that fits over the upper gum **16**. Generally, an impression of upper palate of user's oral cavity is obtained to provide a bridge between the left and right sides of interior walls in the maxillary denture. This bridge part known as Palate **34** generally is in close contact with the user's upper palate helping in improved retention of the maxillary denture. The maxillary denture **30** is placed over the upper gum **16** in a reasonably tight but comfortable fit and remains retained during day-to-day activities of the user such as speaking, chewing, etc. In a standard denture that does not use any implants to secure the denture to the maxilla, the shape and fit between the maxilla and the maxillary denture along with palatal contact serve the purpose of retention. The user is generally provided with options for increased levels of retention, for example, by inserting or applying between denture **30** and gum **16** bio-compatible human use safe glue materials claiming several characteristics as mentioned earlier in the context of mandibular denture. A set of teeth **35** that substitute natural teeth known in the art with nomenclature (starting from back or TMJ side, a set of teeth- one on left and one on right sides) Second Molar, First Molar, Second Premolar, First Premolar, Canine or Cuspid, Lateral Incisor, and Central Incisor (front most teeth set) are embedded symmetrically in the maxillary denture in a U-shaped configuration. This is considering the prevailing trend of not having Third Molar or Wisdom teeth at the back most location, like the natural teeth set where their extraction is recommended by dentist profession, resulting in a total fourteen teeth in the maxillary denture.

[0055]. A location **51** on the user's right-side wall **31** of the maxillary denture **30**, and location **52** on the user's right-side wall **21** of the mandibular denture **20** exemplify the locations of connection of pins **45** illustrated in **Fig. 1B** and **Fig. 1C**. Similarly, a location **55** on the user's left-side wall of the maxillary denture **30**, and location **56** on the user's left-side wall of the mandibular denture **20** exemplify the locations of connection of pins **45** illustrated in **Fig. 1B** and **Fig. 1C**. The pins may be integrated structurally with respective denture body while manufacturing the same by molding, milling, 3D printing or additive manufacturing or other fabrication methods. Alternatively, other approaches also may be deployed such as affixing the pins into the denture bodies by adhesion, fitting into receptor holes, or by screwing into receptor threaded holes by having matching threads in the pins, or a combination of such approaches. **Fig. 1B** illustrates a view of a strap **40** assembled with the dentures using the pins **45** as viewed from the front of the walls of the dentures.

[0056]. Fig. 1C illustrates a sectional view of the assembly shown in Fig. 1B wherein the strap 40 is retained or fixed on the maxillary denture 30 and mandibular denture 20 using a pair of pins 45 that have pin heads 46. The pins and pin heads are not sectioned in the section A-A view shown in Fig. 1C. The pin heads 46 may be an integral part of the pins 45 in an embodiment of the invention. The pin heads 46 may be attached to the pins 45 in another optional embodiment of the invention by means such as threads, snap fit, and other methods. The shapes of the pins and the pin heads are shown as circular cylindrical in the embodiment illustrated in the Figs. 1B and 1C, however, those skilled in the art may appreciate that there are several other conceivable shapes possible, and all such shapes are included in the spirit of this invention. The gainful deployment of a few of those shapes are illustrated in Fig. 2D and described in the following paragraphs.

[0057]. Fig. 2A illustrates a set of 4 different lengths of strap 40. The set of different lengths enables customization of the amount of mandibular advancement that may work most effectively for a particular user. Typically, the relative positions of pins 45 fixed on the mandibular denture 20 and maxillary denture 30 is such that use of shortest strap results in maximum mandibular advancement, whereas the use of longest strap results in minimum mandibular advancement. Different strap lengths may be tried between these to optimise the amount of mandibular advancement best suited for a particular user considering factors such as clearance of airway passage, and comfort of use including reduction or management of side effects such as temporomandibular joint (TMJ) pain. Optionally and preferably, the configuration of a strap 40 illustrated in the Figures has a relatively thicker boss area surrounding the pin hole to provide better strength and thus resistance to tear due to the mandibular advancement force reported in the art as approximately 1 to 1.2 Newtons per millimeter of mandibular advancement (for example, 1.18 Newtons per millimeters as per J Cohen-Levy, B Pételle, J Pinguet, E Limerat, B Fleury, Sleep Breath, 2013 May;17(2):781-9. doi: 10.1007/s11325-012-0765-4. Epub 2012 Sep 11, as quoted earlier). Those skilled in the art may appreciate that there may be other number of straps in a set ranging from 2 to 10 or more or even a single strap optimised a priori before handing over to a user, and all such possibilities are within the scope and spirit of this invention disclosure.

[0058]. Fig. 2B illustrates a set of 4 different lengths of another optional configuration of strap 40 wherein there is a slot. The set of different lengths enables customization of the amount of mandibular advancement that may work most effectively for a particular user. Typically, the relative positions of pins 45 fixed on the mandibular denture 20 and maxillary denture 30 is such that use of shortest strap results in maximum mandibular advancement, whereas the use of longest strap results in minimum mandibular advancement. Different strap lengths may be tried between these to optimise the amount of mandibular advancement best suited for a particular user considering factors such as clearance of airway passage, and

comfort of use including reduction or management of side effects such as temporomandibular joint (TMJ) pain. Optionally and preferably, the configuration of a strap **40** illustrated in this Figure has a slot recess connecting the pin holes to provide sliding between the pin and the slot thus better flexibility of movement between maxillary and mandibular jaws in forward-backward, upward-downward, and lateral (leftward-rightward) directions. Those skilled in the art may appreciate that there may be other number of straps in a set ranging from 2 to 10 or more or even a single strap optimised a priori before handing over to a user, and all such possibilities are within the scope and spirit of this invention disclosure.

[0059]. Optionally, and in addition to the configurations described so far, **Fig. 2C** illustrates a circular, elliptical, and a rectangular portion of increased sized recess or slot portion at the middle portion of the strap. This larger recess in the slot of strap is intended to allow a circular, elliptical or rectangular head **46** of pin **45** to come out of the strap facilitating ease of change of strap. This configuration of the invention is incorporated to ameliorate the problem of unwanted disengagement between pin and strap when the pin hole or slot connecting the pin holes is kept too large to facilitate the ease of change of strap. By providing a larger recess only at the middle part, the disengagement during use inside mouth of the user is avoided. As the strap is required to be changed only outside the mouth of user, the maxillary and mandibular dentures can be freely moved to a relative position such that a pin can access the wider recess at the middle of a strap to facilitate removal of strap from pin. The figure shows increase in outer width of the strap to retain strength of the strap at the middle portion.

[0060]. **Fig. 2D** illustrates the different shapes of pin heads **46**, viz. circular, elliptical and rectangular cross-sections, as can be seen in end view-P, whereas, the pin is generally circular cross section in most cases.

[0061]. An optional but additional configuration of the strap has a stronger reinforcement cord embedded inside a relatively weaker strap material to solve a problem that was encountered during trials, namely tearing off or severance of the strap. This is of particular relevance and advantage of this disclosure where the strap is made of flexible material, for example, made of one of the acceptable bio-compatible elastomers (Saliterman, Steven S., "Introductory Medical Device Prototyping: Medical Device Polymers", Presentation, Dept. of Biomedical Engineering, University of Minnesota, USA); whereas the reinforcement cord may be made of a stronger material such as Kevlar® (DuPont®, headquartered at Wilmington, Delaware, USA, manufactured by Advanced Fibre Systems, VA, USA). **Fig. 2E** (not to scale, only indicative representation) shows a sectional view of a typical multi-layer strap configuration with a stronger cord material reinforcing as core to enable improved durability with flexibility. The circular cross section of the reinforcing cord **41** can be seen embedded inside the strap cross-section. The combination of both strength as well as flexibility allows the relative

movement between the mandibular and maxillary parts of the denture in multiple directions of 3D space, viz. forward-backward, upward-downward, leftward-rightward. The multi-layer construction may be achieved by several alternative manufacturing means such as molding, 3D printing, or other methods that may be available in the state-of-the-art, gainfully deployed for this application.

[0062]. Mass production of straps deploying economy of manufacture scale may be an optional yet another additional method deployed as an alternative to a stronger reinforced strap configuration. **Fig. 3** illustrates a perspective view of configuration of a typical punch set showing the contours of the end faces of the punches **310** and **320** that may be deployed for progressive 2-step blanking process, each using a different punch and die set (dies are not shown in the figure) as an optional manufacturing process for straps (for example, the third shape out of the shape options illustrated in **Fig. 2C**) to enable economy of scale, wherein a large number of inexpensive spare straps may be provided instead of stronger and costlier straps. It can be appreciated by those skilled in the art that a punch-die set comprises of closely slidably fitting cavity in a die that receives a correspondingly shaped protrusion known as punch, the relative impact between die and punch piercing the part of a sheet material of interest placed between a punch and a die. In the illustrated case, the pierced part produced by the first set of punch-die interaction will produce an interim part as blank, while the second set of punch and die interaction will produce a useful intended strap part and a scrap or waste part corresponding to the shape of slot or recess in the strap. We have found that bio-compatible versions of materials such as Kapton® (DuPont®, headquartered at Wilmington, Delaware, USA) available readily in sheet form are suitable raw material for such blanking process.

[0063]. While the figures and description in this disclosure has presented in detail full maxillary and mandibular dentures, we have developed several additional and optional embodiments that are covered by the scope and spirit of the overall invention. For example, an embodiment of the invention has a typical RPD set comprising of a maxillary part, a mandibular part, an embrasure clasp, a pair of multiple circlet clasps, and a pair of straps connecting the maxillary and mandibular parts to enable desired mandibular advancement. Clasps are means to secure partial dentures with the help of surviving natural teeth in a person's jaws. The terminology of different types of clasps are well known in the denture related art, but to our knowledge not gainfully deployed or used in oral appliances for obstructive sleep apnea or anti-snoring devices. We have experienced and found the forces that can be withstood by unique designs and arrangements of different types of retainers/ clasp assemblies, without glue, to have enough retention force to withstand mandibular advancement force that is in fact quite small. This is found to be valid for several clasp designs, for example, Circumferential (Circle or Akers) clasp, Ring clasp, Embrasure (Double Akers) Clasp, "C" clasp (Hair-pin or Reverse action), etc.

[0064]. Another optional variant of the embodiment described above is the one wherein an improvised embrasure clasp is deployed to enable facilitation of resting the tongue of wearer constraining it so that it does not slide backwards contributing to airway blockage.

[0065]. In yet another optional and additional variant of the embodiment discussed so far, a combination of multiple improvised clasps is deployed to enable facilitation of adjustable mandibular advancement with or without the need for straps.

[0066]. Furthermore, in another optional variant of the embodiment presented above, a combination of multiple improvised clasps is deployed to enable facilitation of adjustable mandibular advancement without the need for straps, additionally providing for resting the tongue of wearer constraining it so that it does not slide backwards contributing to airway blockage.

[0067]. Furthermore, another optional embodiment of the invention has a typical ISD set comprising of a maxillary part, a mandibular part, and a pair of straps connecting the maxillary and mandibular parts to enable desired mandibular advancement. Fig. 4 illustrates typical locations of implant pins **810** on the mandible's lower gum **10** over bone structure **11**, and implant pins **820** on the upper gum **16** of maxilla that are used to retain the denture on the wearer's jaws, essentially serving the purpose of retention of denture without the use of adhesive. The dentures possess mating holes that slidably and snugly receive corresponding implant pins to form good connection and thus retention of dentures over the gums. These dentures are found to have higher retention force capacity compared to adhesive based retention, thus can very easily overcome the mandibular advancement forces. Those skilled in the art can appreciate that the number of implants and their locations depend on several factors such as jawbone density, jawbone loss, bone grafting, etc.; and thus although 2 to 4 implants per jaw are typical, there may be more implants necessary in some cases, for example, 12 to 16 dental implants have been found necessary in some cases. For the purpose of withstanding the mandibular advancement force of approximately 1 to 1.2 Newtons per millimeter of mandibular advancement, considering that the advancement required is generally within 5 millimeters, these numbers of implants are adequate. Generally, the number of implants needed for the dual purpose of general denture retention for chewing and for mandibular advancement is found to be same or close to the number of implants needed for single conventional purpose of denture retention only for chewing.

[0068]. Furthermore, in another optional but additional variant of the embodiment described above, an improvised embrasure clasp is deployed to enable facilitation of resting the tongue of wearer constraining it so that it does not slide backwards contributing to airway blockage.

[0069]. Furthermore, in yet another optional but additional variant of the embodiment described above, a combination of multiple improvised clasps is deployed to enable facilitation of adjustable mandibular advancement with or without the need for straps.

[0070]. Furthermore, in yet another optional but additional variant of the embodiment described above, a combination of multiple improvised clasps is deployed to enable facilitation of adjustable mandibular advancement without the need for straps, additionally providing for resting the tongue of wearer constraining it so that it does not slide backwards contributing to airway blockage.

[0071]. Additionally, but optionally, a universal version of the invention utilizing a compliant clasp approach is also invented that may be worn over either denture or natural teeth due to its lightweight and ease of attachment-detachment configuration to facilitate anti-snoring provisions.

[0072]. Furthermore, in yet another optional but additional variant of the embodiment described above, another universal version of the invention utilizes a compliant clasp approach enabling stepless mandibular adjustment that may be worn over either denture or natural teeth due to its lightweight and ease of attachment-detachment configuration to facilitate anti-snoring provisions.

[0073]. Furthermore, yet another optional but additional universal version of the invention utilizes a compliant clasp approach that may also be elastic enabling stepless mandibular adjustment with spring characteristic that may be worn over either denture or natural teeth due to its lightweight and ease of attachment-detachment configuration to facilitate anti-snoring provisions with enhanced comfort for the wearer allowing jaw movement.

[0074]. Furthermore, yet another optional but additional universal version of the invention utilizes a reactive latch mechanism that realizes a mandibular advancement only after the user has gone on sleep causing excessive relaxation of the mandible relative to the maxilla, to facilitate anti-snoring provisions with enhanced comfort for the wearer allowing natural or moderate relaxed jaw positions during onset of sleep.

[0075]. **Fig. 5** illustrates the schematic diagram for an optional additional inventive process **1500** comprising of economical production of a secondary unit that may be offered to a patient ordering a primary partial or full, removable or permanent denture; at a discounted price that may serve the purpose of cosmetic function as well as anti-snoring function. This also illustrates gainful deployment of a business process promoting sale of primary denture, and/or add-on revenue generation through sale of secondary denture. This innovative process obtains intra-oral information **1510** that may involve use of either conventional mold material usage such as impression material and allied equipment for capturing the configurations of user's mandibular

gum and maxillary gum or adjacent teeth in addition to the gums in the case of removable partial dentures (RPDs). Alternately, heat, chemically, or catalytically moldable materials may be used to obtain the impression. Optionally, other alternatives such as scanning of user's gum or teeth using imaging devices or scan of mold may be resorted to. This information **1520** is necessary and adequate for manufacture of partial or full, removable or permanent denture, and may be gainfully used or deployed for manufacturing either a primary denture **1540** and/or a secondary denture **1590**. The manufacturing process **1530** may include Computer Aided Design (CAD) and Computer Aided Manufacturing (CAM) comprising of different options such as 3D printing, forming, thermo-forming such as injection molding, or milling.

[0076]. While delivering the primary denture ordered by the user, or before the ordering process, or during the ordering process, or subsequently, an optional sleep study **1550** may be offered to the user. The sleep study may comprise of any of the different levels of sleep studies (Level 1, Level 2, Level 3, Level 4) either at a sleep lab or at home. With or without this optional sleep study, the user of denture may be offered a secondary denture at a discounted price. This offer process step **1560** involves suggestion and counselling **1570** about the advantages of a secondary set of dentures to be worn at night during sleep time that may be either an exact duplicate of the primary denture, or alternatively and preferably; a simpler, lighter, version with provisions such as increased exposure of gums to air as the purpose of this secondary denture is not chewing of food. While serving cosmetic purposes avoiding any embarrassing situations where the user maybe exposed to known or new acquaintances by getting caught off-guard without any denture, the secondary denture also serves the important purpose as an anti-snoring device. Even if the user is not aware or not formally diagnosed for sleep disorders knowingly or un-knowingly, the secondary denture serves an important function of prevention is better than cure motto **1580**. Once the user is convinced of the advantages of acquiring a secondary denture at discounted price, the necessary information **1520** for production that was available earlier for primary denture production may be advantageously re-used for manufacture process **1530** to produce the secondary denture **1590**. While sleep study **1550** is just optional, in case the same is preferred by a user, furthermore optionally, related additional appliances such as a variety of biosensors **1551**, sleep application **1552**, and a kit **1553** comprising of one or more of a sleep mask, ear plugs, cleaning kit, bite re-positioner, jaw position measuring tool, and chewing gum may be offered and deployed for the sleep study. The biosensors **1551** deployed may be one or more biosensors configured to measure one or more sleep parameters, wherein the one or more sleep parameters are selected from heart rate, breathing rate, head movement, body movement, bite force, body temperature, blood glucose levels, actigraphy, oximetry, apnea hypopnea index (AHI), peripheral arterial tone (PAT), cardiac data, chest expansion, respiratory air flow, sleeping position, patient compliance and snoring.

Claims:

We claim:

1. A system for preventing or assisting in reducing condition of snoring or obstructive sleep apnea comprising of
a mandibular part of a denture set;
a maxillary part of the denture set;
a means to hold the parts of dentures inside human oral cavity for enabling mandibular advancement.
2. The system of claim 1, wherein at least one pair of two pins and at least one strap is deployed to enable holding of a mandibular part of a denture set in an advanced position relative to a maxillary part of the denture set.
3. The system of claim 2, wherein a set of straps of different lengths are deployed to vary the amount of mandibular advancement.
4. The system of claim 2, wherein the strap or straps may have a slit or recess to allow relative movement between the mandibular and maxillary parts of the denture.
5. The system of claim 1, wherein denture set may be provided as denture without implants such as Removable Partial Dentures or Removable Full Dentures.
6. The system of claim 5, wherein retention of denture is enhanced by use of glue between denture and gum adequate to withstand mandibular advancement force.
7. The system of claim 1, wherein denture set may be provided as any of the Implant Supported Dentures, such as single tooth dental implant, multiple-tooth on implant-supported bridge, or multiple-tooth on implant-retained denture.
8. The system of claim 1, wherein one or more constituent parts are made of bio-compatible Nylon.
9. The system of claim 1, wherein at least one or more constituent parts are made by 3D printing or additive manufacturing process.
10. The system of claim 1, wherein all constituent parts are made by 3D printing or additive manufacturing process.

11. The system of claim 2, wherein the strap or straps are made from blanking process.
12. The system of claim 2, wherein the strap or straps are made of multi-layer hybrid construction wherein a stronger material such as Kevlar® cord is core to provide strength over which bio-compatible material such as Nylon-12 is coated allowing a combination of both strength as well as flexibility.
13. The system of claim 12, wherein the combination of strength and flexibility facilitates relative movement between the mandibular and maxillary parts of the denture set in multiple directions of 3D space, specifically forward-backward, upward-downward, leftward-rightward, or other possible intermediate directions.
14. A process for increased use of anti-snoring and obstructive sleep apnea reducing means of claim 1 by providing the steps

obtain intra-oral information necessary and adequate for manufacture of denture;
manufacture and provide primary denture set;
suggest and offer a secondary denture set;
follow through consent of user to deploy earlier obtained intra-oral information for
 manufacture of a secondary denture set;
provide secondary denture set.
15. The process of claim 14, wherein a secondary denture set is provided at discounted price for cosmetic or anti-snoring or both purposes.
16. The system of claim 5, wherein retention of denture is enhanced by use of at least one clamp or clasp between a partial denture and one or more natural teeth adequate to withstand mandibular advancement force.
17. The system of claim 1, wherein at least one improvised clasp or optionally a combination of multiple improvised clasps is deployed to enable facilitation of adjustable mandibular advancement.
18. The system of claim 1, wherein at least one improvised clasp is a compliant or elastic clasp or an embrasure clasp additionally and optionally providing for resting tongue of wearer constraining it so that it does not slide backwards.

19. The system of claim 17, wherein the system may be worn over either denture or natural teeth due to its elasticity, lightweight and ease of attachment-detachment configuration.

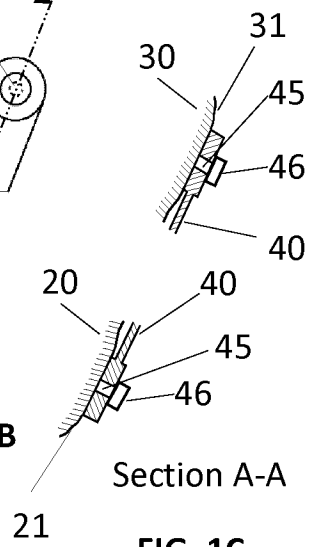
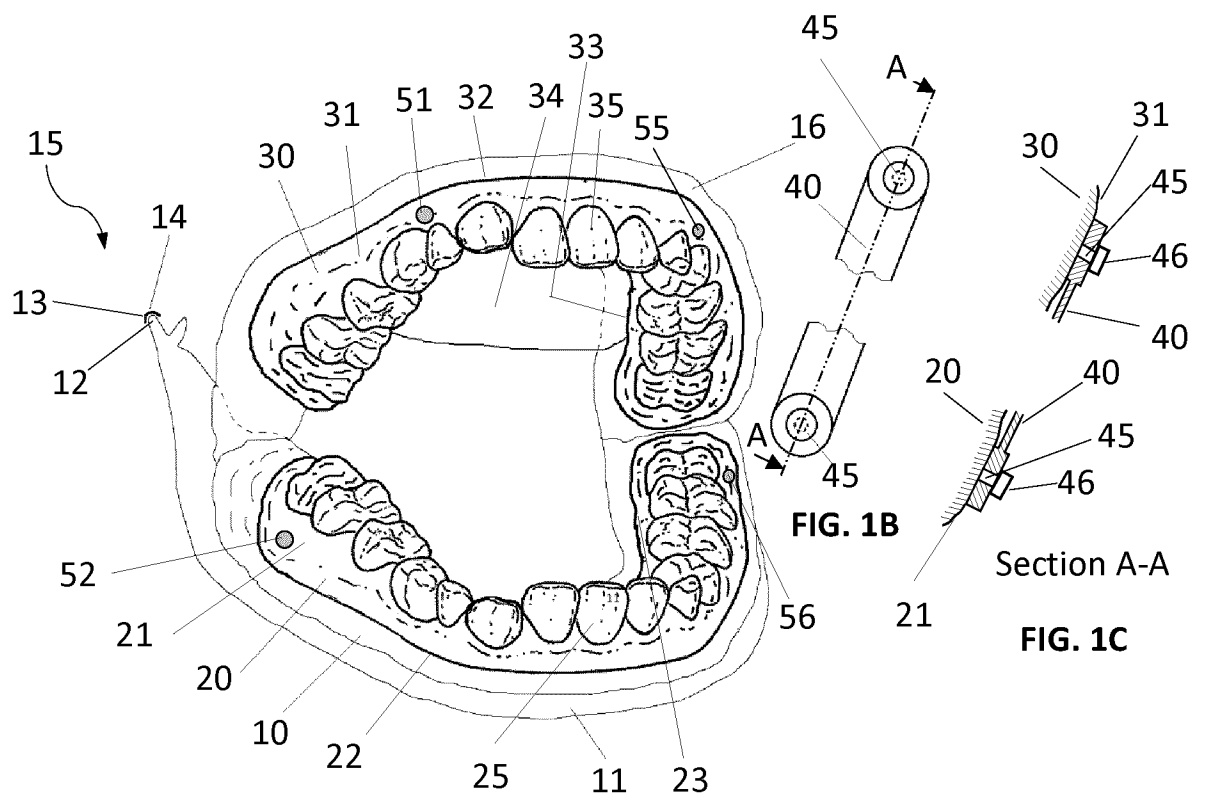
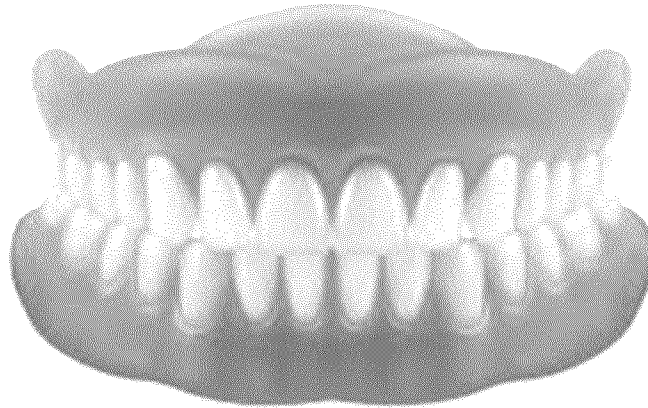


FIG. 1

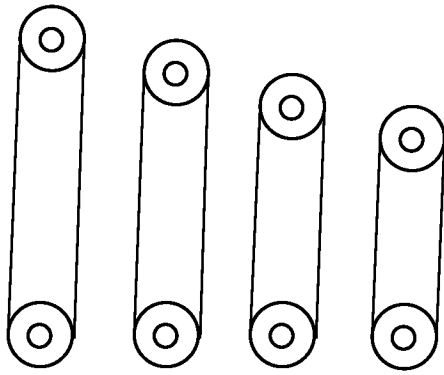


FIG. 2A

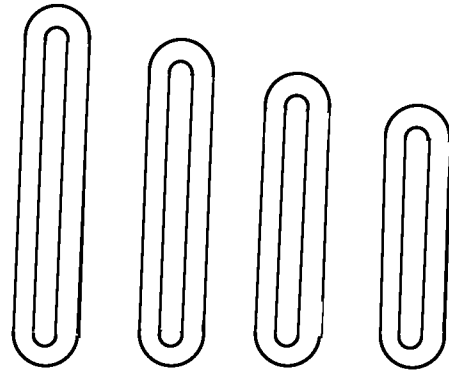


FIG. 2B

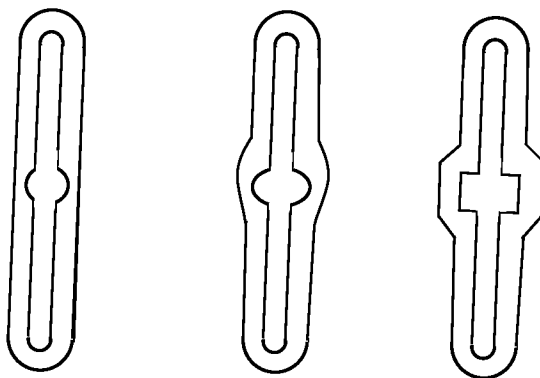


FIG. 2C

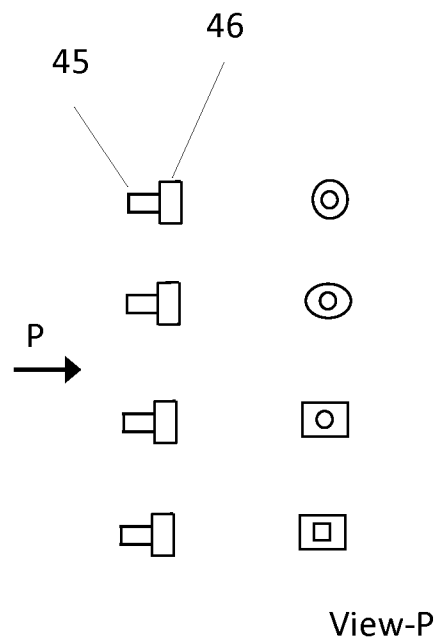


FIG. 2D

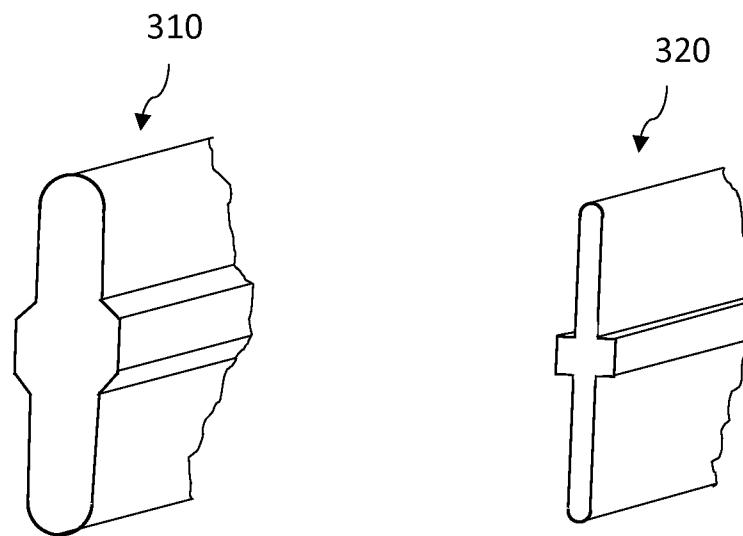
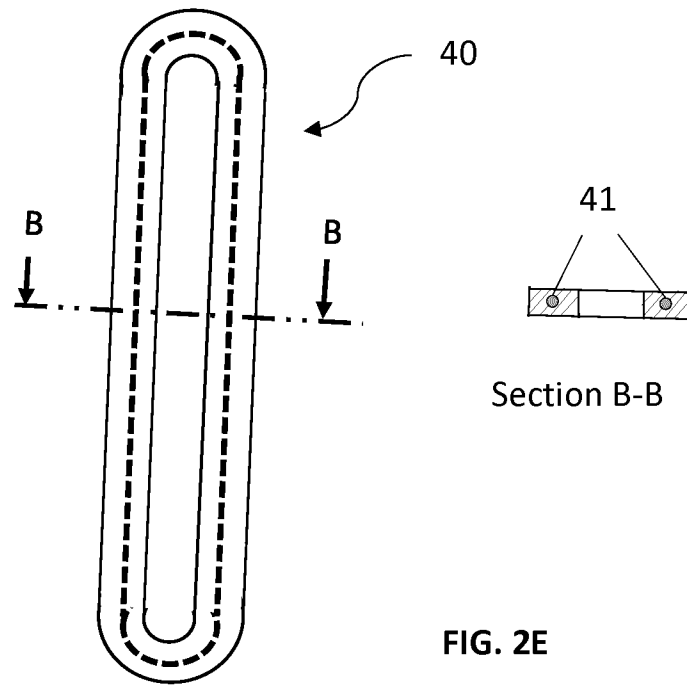


FIG. 3

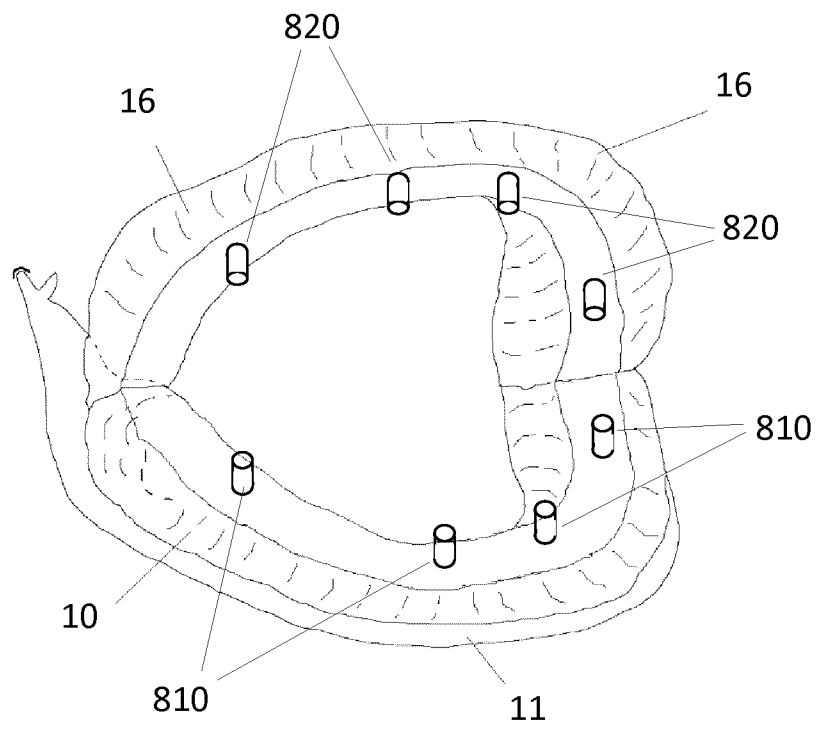


FIG. 4

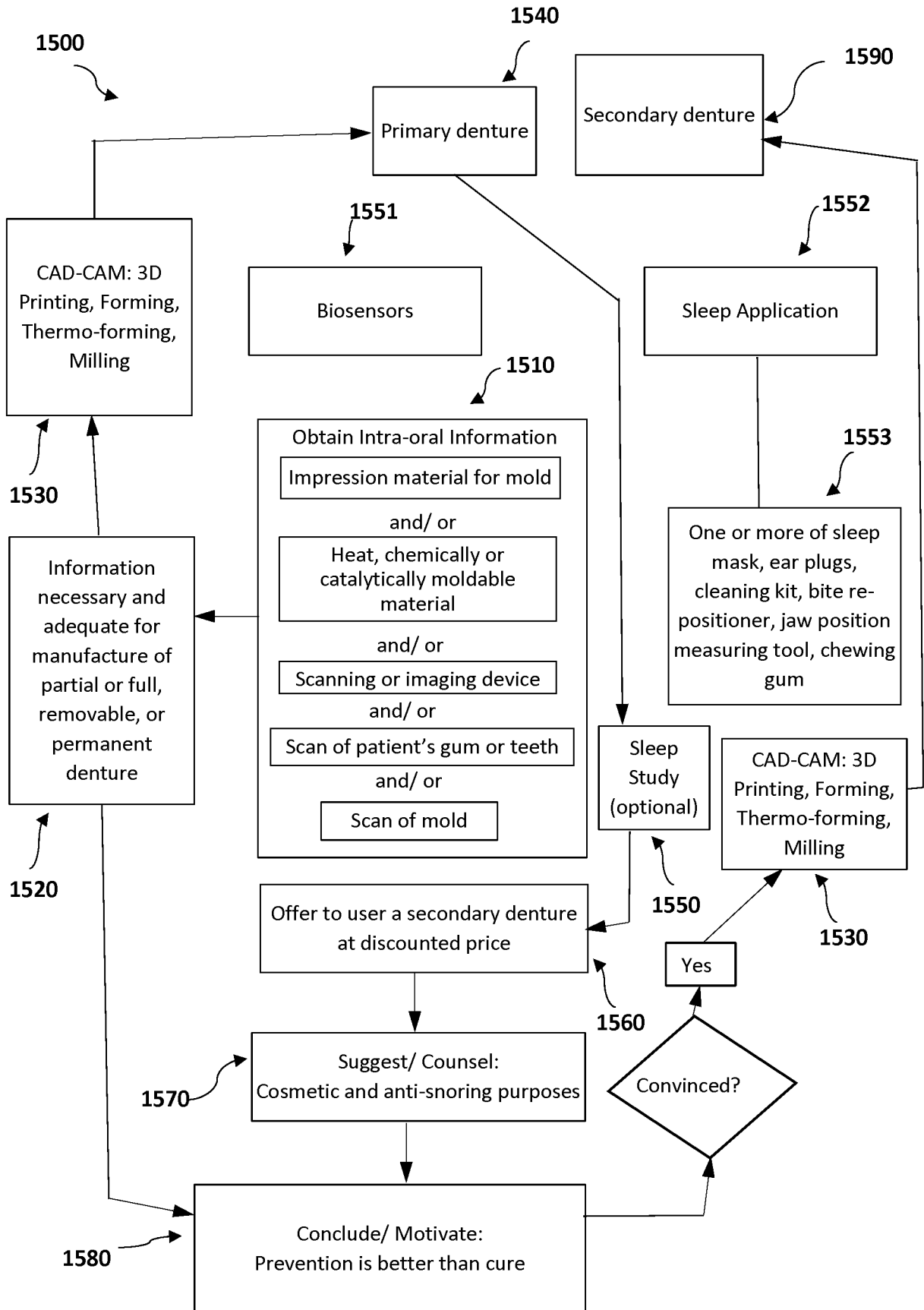


FIG. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2023/050729

A. CLASSIFICATION OF SUBJECT MATTER

IPC: **A61F 5/56** (2006.01), **A61C 7/36** (2006.01)

CPC: **A61F 5/566** (2020.01), **A61C 7/36** (2020.01)

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)

IPC: **A61F 5/56** (2006.01), **A61C 7/36** (2006.01), **A61C 7/08** (2006.01)

CPC: **A61F 5/566** (2020.01), **A61C 7/36** (2020.01)

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

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

Questel Orbit (FAMPAT), Google Patent

Keywords: teeth, denture, strap?, band?, connector?, elastic?, tie?, rod?, bar?, link?, pins, stamp*, blanking, punch*, connector?, 3d print, nylon, Kevlar, snor*, apnea, dental, polyamide, different, length?, set

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US2017189223A1 (SUMMER, J.) 06 July 2017 (06-07-2017) *Fig. 1, abstract; par. 0003, 0076*	1 to 13 and 16 to 19
X	Manalili, T., "Are Dentures at Night Ever the Way to Go?", made public by Glidewell on 8 February, 2021, URL:< https://glidewell dental.com/company/blog/are-dentures-at-night-ever-the-way-to-go >	1 to 19
X	"Digital Dentures", made public by Custom Denture Clinic on 21 January, 2021 (date verified by Google Archive), URL:< https://www.customdentureclinic.com/digital-dentures/ >	14 and 15

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* "A" "D" "E" "L" "O" "P"	Special categories of cited documents: document defining the general state of the art which is not considered to be of particular relevance document cited by the applicant in the international application earlier application or patent but published on or after the international filing date 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) document referring to an oral disclosure, use, exhibition or other means document published prior to the international filing date but later than the priority date claimed	"T" "X" "Y" "&"	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 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 document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art document member of the same patent family
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Date of the actual completion of the international search
01 August 2023 (01-08-2023)

Date of mailing of the international search report
01 August 2023 (01-08-2023)

Name and mailing address of the ISA/CA
Canadian Intellectual Property Office
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50 Victoria Street
Gatineau, Quebec K1A 0C9
Facsimile No.: 819-953-2476

Authorized officer

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/CA2023/050729

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US2012073582A1 (KOPP, H.-P) 29 March 2012 (29-03-2012) *Whole document; Nylon straps of different lengths*	1 to 19
A	US2015216716A1 (ANITUA, A.) 06 August 2015 (06-08-2015) *Whole document; polyamide 12 or Nylon straps*	1 to 19
A	US2020214877A1 (FRANTZ, J et al.) 09 July 2020 (09-07-2020) *Whole document; 3D print, Nylon straps of different lengths*	1 to 19
A	US2004096798A (CLEARY, J.) 20 May 2004 (20-05-2004) *Whole document; straps made by stamping*	1 to 19
A	US5087202A (KRENKEL, C.) 11 February 1992 (11-02-1992) *Whole document; straps made by punching*	1 to 19
A	US5632618A (JENSEN, F.) 27 May 1997 (27-05-1997) *Whole document; system partially covering teeth*	1 to 19
A	AU2016203236A1 (SMITH, J.) 07 December 2017 (07-12-2017) *Whole document; bio-compatible polyamide 12 straps, reinforced straps*	1 to 19
A	US2022054301A1 (WEBSTER, D.) 24 February 2022 (24-02-2022) *Whole document; set of straps*	1 to 19
A	US2021045911A1 (VEIS, R. et al.) 18 February 2021 (18-02-2021) *Whole document*	1 to 19

INTERNATIONAL SEARCH REPORT

International application No.

PCT/CA2023/050729**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of the 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. ☐ Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claim 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. ☐ Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

See supplemental page 7 of 8

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 claim 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 claim 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.

CONTINUATION OF BOX NO. III: Observations where unity of invention is lacking

The claims are directed to a plurality of inventive concepts as follows:

Group A - Claims 1 to 13 and 16 to 19 are directed to a system for preventing/reducing snoring comprising a mandibular part of a denture set, a maxillary part of the denture set and means to hold the parts of the denture set for enabling mandibular advancement.

Group B - Claims 14* and 15 are directed to a process for increased use of anti-snoring means comprising the steps of obtaining intra-oral information, manufacturing a primary denture set, suggesting/selling a secondary denture set and manufacturing the secondary denture set.

*The method of claim 14 being “for use” of the system/means of claim 1 does not bestow unity of invention to the claims, as the method of claim 14 is essentially directed to a sales/procurement method suitable for any denture system/means, where no specific method step relate to the physical features of the system/means of claim 1.

The claims cannot be considered to be one invention in the sense of being so linked as to form a single general inventive concept because each of the groups possess different special technical features and these features do not share any technical relationship.

The claims must be limited to one inventive concept as set out in Rule 13 of the PCT.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/CA2023/050729

IPC: *A61C 7/08* (2006.01)

CPC: N/A

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CA2023/050729

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