

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
26 April 2012 (26.04.2012)

(10) International Publication Number
WO 2012/054800 A1

(51) International Patent Classification:
A61C 5/14 (2006.01)

(21) International Application Number:
PCT/US2011/057210

(22) International Filing Date:
21 October 2011 (21.10.2011)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
13/278,336 21 October 2010 (21.10.2010) US
61/455,912 29 October 2010 (29.10.2010) US

(72) Inventor; and

(71) Applicant : **DIEDWARDO, William, A.** [US/US]; 1971
NE 31st Street, Lighthouse Point, FL 33064 (US).

(74) Agent: **TADROS, Jacqueline**; 500 West Dypress Creek
Road, Suite 350, Fort Lauderdale, FL 33309 (US).

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ,

CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO,
DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP,
KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD,
ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI,
NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU,
RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ,
TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA,
ZM, ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ,
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD,
RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ,
DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT,
LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS,
SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM,
GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: DENTAL PROTECTIVE DEVICE AND METHOD OF USE

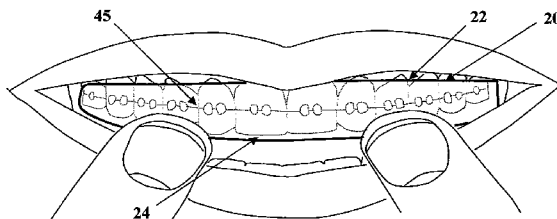


FIGURE 2B

(57) Abstract: The present invention relates generally to the protection of a wearer of an installed dental appliance, such as braces, against pain, discomfort and injury due to the lips, cheek and tongue of the wearer rubbing against a rough or sharp edge of the braces. A dental protective device is used for protection against this discomfort and injury from the braces. The dental protective device is a moisture-activated self-adhering protective strip loosely adhered to a backing strip and packaged in a sealed foil pouch. In use, the protective strip is peeled away from the backing and applied to an area in need of protection.



WO 2012/054800 A1

DENTAL PROTECTIVE DEVICE AND METHOD OF USE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. provisional application number
5 61/455,912 filed October 29, 2010, the disclosure of which is incorporated herein by
reference.

FIELD OF THE INVENTION

[0002] The present invention relates generally to a dental protective device. One
10 embodiment of the invention relates to the dental protective device configured to
protect a user's lips, tongue and cheek from injury due to rubbing against an
installed dental appliance, such as orthodontic braces. The dental protective device
of the present invention may also be configured to protect a user's lips, tongue and
cheek from injury due to rubbing against other dental appliances, such as
15 orthodontic retainers, or other dental appliances, such as bridges, or partials.

BACKGROUND

[0003] Dental braces are used to straighten and align teeth. Dental braces, or
"braces" mainly consist of metal brackets installed around each tooth and an arch
20 wire connecting the teeth of each jaw. The teeth move when the arch wire applies
force to the brackets and teeth. Sometimes, springs or rubber bands are used to put
additional force in a specific direction and location. When braces are installed, the

braces often create pain, discomfort and injury due to the lips, tongue and the inside of the cheek moving relative to rough and sharp edges of the braces.

[0004] Traditionally, dental wax has been utilized to protect the lips, inside cheek and gums from the rough and sharp edges of the braces. Dental wax may offer effective protection, but it has its' drawbacks. One drawback is that the dental wax must be rolled-up into a ball to apply to the target area. Once the rolled-up ball of wax is applied to the target area of the braces, it must be shaped to the right final configuration inside the mouth. This can be a time-consuming and frustrating process. If this process not done accurately, the dental wax will not afford proper protection from pain, discomfort and injury. Another drawback of using dental wax is that for dental wax to be effective, the wax must be applied with the correct pressure. Too much pressure and the wax is susceptible to becoming lodged in areas between the teeth and braces, making removal difficult. Too little pressure, and the wax quickly falls-off. Even with the correct amount of pressure, the wax generally remains in place for only a few hours and may fall-off if food or drink is consumed.

[0005] Due to the above mentioned problems with the use of dental wax, other solutions to the use of wax have been utilized in the past, with mixed success. One solution was the use of plastic shields, which resemble sport mouth guards. While these plastic shields may offer effective protection from the pain and discomfort of the braces, they are bulky and may be uncomfortable and unsightly to wear. The plastic shields may also interfere with the ability to speak clearly. Another solution was the use of a different type of plastic shield, one in which the shield clips-on

directly to the arch wire of the braces. While in some ways an improvement over the above plastic shield, this clip-on plastic shield has disadvantages in that it is still relatively bulky and is designed to be used over several teeth, when only one localized area is in need of shielding. Additionally, clip-on shields are not efficient
5 when orthodontic braces are not in a straight line, or are offset. In this instance, separate shields may be required on each side of the offset. Both plastic shields have the disadvantages of having to be cleaned before reuse, potentially compromising oral hygiene and being relatively expensive, as the shields may require a custom fit to the user.

10 [0006] An additional solution was the use of wax impregnated cloth. While the wax impregnated cloth overcomes some of the disadvantages of the plastic shields, the wax impregnated cloth retains some of the disadvantages of the use of wax alone. These disadvantages include having to mold the wax impregnated cloth around the braces such that there is adequate protection, without being too bulky. As with wax
15 alone, molding the wax impregnated cloth into shape may likely be a tedious and frustrating process. Additionally, the wax impregnated cloth may require heating to become fully pliable.

[0007] A further solution was proposed in which thermoplastic material is preformed in the shape of a strip and allowed to cool. For a custom fit, the wearer heats-up the
20 thermoplastic strip and then applies the strip to the area being protected. The heated strip is applied to the area being protected and allowed to cool, thereby creating the custom-fit protective strip. This further solution has the disadvantage of being time-consuming to form and also presents oral hygiene problems by having to

reapply a non-hygienic strip, thoroughly cleaning the strip after each use, or repeatedly shaping a new heated strip to the area being protected.

[0008] For the above reasons, there is a need for a dental protective device which overcomes the above drawbacks. This dental protective device overcomes the above drawbacks by being inexpensive, by facilitating oral hygiene by being
5 disposable and preventing most foods from lodging under braces, by not being bulky, by one size being usable in all applications, by not facilitating unwanted moisture, or saliva formulation, by being quick and easy to apply and by not interfering with speaking, drinking or eating.

10

SUMMARY OF THE INVENTION

[0009] The present invention is directed toward an improved dental protective device capable of overcoming the above drawbacks. The dental protective device of the present invention is configured as a moisture-activated self-adhering protective strip
15 loosely adhered to a backing strip and packaged in a sealed foil pouch. The dental protective device is disposable. The dental protective device may be marketed in packaging containing multiple protective strips. The dental protective device is latex-free.

[0010] In use, the protective strip is peeled away from the backing and installed to
20 the localized area in need of protection. The thickness of the protective strip is such that the strip provides protection without being bulky. If desired, the protective strip may be trimmed before application to facilitate installation. The protective strip may be worn as long as needed. When installed properly, the protective strip is safe to

use while sleeping and while consuming most food and beverage. When installed properly, the protective strip protects the lips, inside cheek and gums from rough and sharp edges of the braces. The protective strip only need be removed when brushing, as micro-particles of food may be present under the edges of the
5 protective strip.

[0011] An embodiment of the present invention may include the protective strip being clear, or tooth enamel colored. An embodiment of the present invention may include the protective strip being flavored, such as mint flavored. An embodiment of the present invention may include the protective strip being infused with medication, or
10 antibiotics.

[0012] An embodiment of the present invention may include the protective strip being manufactured of some, or all of Carbomer 980, Hydroxyethyl Cellulose (HEC), Sorbitol, Polyvinylpyrrolidone (PVP), Polyethylene and Polypropylene, Acrylates Copolymer, flavoring, such as mint and water.

15 [0013] An embodiment of the present invention may include these and other features, aspects, and advantages of the present invention will become better understood with regard to the following description, appended claims, and accompanying drawings.

20

DRAWINGS

[0014] FIG. 1A illustrates the dental protective device supplied in a sealed foil pouch. FIG. 1B shows a plan view of the dental protective device.

[0015] FIG. 2A illustrates the protective strip of the dental protective device ready to be installed on a desired area of a wearer's teeth and braces. FIG. 2B illustrates the protective strip of the dental protective device beginning to be installed on the desired area of a wearer's teeth and braces. FIG. 2C illustrates the protective strip of the dental protective device undergoing final installation on a wearer's teeth and braces.

[0016] FIG. 3 illustrates a method of using the dental protective device.

DETAILED DESCRIPTION

[0017] As illustrated on FIGs 1A and 1B, an embodiment of the present invention is directed toward the dental protective device 10. The dental protective device 10 is utilized to protect against unwanted pain, discomfort and injury in the oral cavity from an installed dental appliance, such as orthodontic braces 45 (FIGs 2B and 2C). The dental protective device 10 consists of a protective strip 20 and a backing strip 30 loosely adhered to the protective strip 20 on a dental appliance contacting side 28 (FIG 2A). The backing strip 30 is of a larger area than the protective strip 20 when viewed from above, to facilitate easy removal of the protective strip 20 from the backing strip 30. The protective strip 20 is configured as a base material 23 coated with water soluble adhesive 27 on the dental appliance contacting side 28 of the protective strip 20. To ensure proper oral hygiene, the dental protective device 10 is supplied in a sealed foil pouch 35.

[0018] In one embodiment of the invention, the protective strip 20 base material 23 may be polyethylene. In one embodiment of the invention, the backing strip 30

material may be polypropylene. In one embodiment of the invention, the water soluble adhesive 27 composition may include Carbomer 980, Hydroxyethyl Cellulose (HEC), Sorbitol, Polyvinylpyrrolidone (PVP), Acrylates Copolymer, water and a flavoring, such as mint.

5 [0019] As illustrated on FIGs 2A – 2C, in use, the protective strip 20 is installed on the desired area 40 in need of protection. The protective strip 20 and loosely adhered backing strip 30 may be trimmed to size with scissors if the desired area 40 in need of protection is small. Just before applying the protective strip 20, the teeth and mouth areas of a wearer of the protective strip 20 are moistened. After any
10 desired trimming, the backing strip 30 is peeled away from the protective strip 20 and discarded. The protective strip 20 is then grasped between fingers of the wearer of the protective strip 20. As illustrated on FIG 2A, the protective strip 20 is then inserted into the mouth of the wearer and directed to the desired area 40 needing protection. As illustrated on FIG 2B, a first edge 22 of the protective strip 20
15 is then applied to the gum line of the desired area 40 needing protection. The protective strip 20 is then applied over the desired area 40 of the braces 45 needing protection. Finally, as illustrated on FIG 2C, the protective strip 20 is wrapped over a second edge 24 and a back portion 26 of the desired area 40 needing protection. After application, to insure proper adhesion, and to reduce size, the protective strip
20 20 is then rubbed with the wearers' fingers, particularly proximal the braces 45 and at the edges of the protective strip 20 such that the protective strip 20 is firmly adhered the braces 45 and proximal areas of the teeth. At this time, the protective strip has been installed to the installed position 49.

[0020] FIG 3 illustrates a method 100 of use of the dental protective device 10. In step 110, the dental protective device 10 is removed from the sealed foil pouch 35. In step 120, the dental protective device 10 is trimmed, if desired, to a desired shape based upon the desired area 40 of the braces 45 needing protection. The trimming should be limited so as to still include adequate surface area for adhesion of the protective strip 20 to the desired area 40 of the braces 45 needing protection. In step 130, just before applying the protective strip 20, the teeth and mouth areas of a wearer of the protective strip 20 are moistened to facilitate adhesion of the water soluble adhesive 27 on the contacting side 28 of the protective strip 20. In step 140, the backing strip 30 is peeled away from the protective strip 20. In step 150, the protective strip 20 is grasped between fingers of the wearer of the protective strip 20 and the protective strip 20 is inserted into the mouth of the wearer of the protective strip 20. In step 160, a first edge 22 of the protective strip 20 is then applied to the gum line proximal the desired area 40 needing protection. In step 170, the protective strip 20 is then applied over the desired area 40 of the braces 45. In step 180, the protective strip 20 is then wrapped over the second edge 24 and the back portion 26 of the desired area 40 needing protection. In step 190, to ensure proper adhesion of the water soluble adhesive 27, and to reduce the size of the installed protective strip 20, the protective strip 20 is then rubbed with the wearer's fingers, particularly proximal the braces 45 and at edges of the protective strip 20 to achieve the installed position 49. In step 200, the protective strip is worn during eating, drinking and sleeping and will prevent most food from being lodged under braces 45. In step 210, when a wax dental impression is being made of the wearer's teeth, the

protective strip 20 is worn to prevent dental prevention wax from being lodged under a wearer's teeth, which saves time for an orthodontist, or dentist. In step 220, the protective strip 20 is removed when the wearer's teeth are cleaned and a new protective strip 20 is installed after cleaning.

- 5 [0021] Although the present invention has been described in considerable detail with references to certain preferred versions thereof, other versions are possible. Therefore, the spirit and scope of the appended claims should not be limited to the description of the preferred version contained herein.

What is Claimed is:

1. A dental protective device comprising:
 - a protective strip, the protective strip configured as a base material coated with a water soluble adhesive coating on a dental appliance contacting side of the protective strip,
5 protective strip,
 - a backing strip loosely adhered to the dental appliance contacting side of the protective strip,
 - wherein the protective strip is capable of adhering to an installed dental appliance by the water soluble adhesive being exposed to moisture.
- 10 2. The dental protective device of claim 1, wherein the installed dental appliance is orthodontic braces.
3. The dental protective device of claim 1, wherein the protective strip base material is polyethylene.
4. The dental protective device of claim 1, wherein the backing strip material is
15 polypropylene.
5. The dental protective device of claim 1, wherein the water soluble adhesive coating is composed of materials including Carbomer 980, Hydroxyethyl Cellulose (HEC), Sorbitol, Polyvinylpyrrolidone (PVP), Acrylates Copolymer, water and flavoring.
- 20 6. The dental protective device of claim 1, wherein the protective strip base material is polyethylene the backing strip material is polypropylene.
7. The dental protective device of claim 1, wherein the protective strip base material is polyethylene the backing strip material is polypropylene and the water

soluble adhesive composition includes Carbomer 980, Hydroxyethyl Cellulose (HEC), Sorbitol, Polyvinylpyrrolidone (PVP), Acrylates Copolymer, water and mint flavoring.

8. The dental protective device of claim 1, wherein the backing strip is of a larger
5 area than the protective strip when viewed from above.

9. The dental protective device of claim 1, wherein the dental protective device is supplied in a sealed foil pouch.

10. The dental protective device of claim 1, wherein the protective strip is capable of remaining adhered to the installed dental appliance while eating, drinking and
10 sleeping and preventing most foods from being lodged under the installed dental appliance.

11. A dental protective device comprising:

a protective strip, the protective strip configured as a polyethylene base material coated with a water soluble adhesive coating on a dental appliance
15 contacting side of the protective strip,

a backing strip loosely adhered to the dental appliance contacting side of the protective strip,

wherein the protective strip is capable of adhering to an installed dental appliance by the water soluble adhesive being exposed to moisture,

20 wherein the installed dental appliance is orthodontic braces.

12. The dental protective device of claim 11, wherein the dental protective device is supplied in a sealed foil pouch.

13. The dental protective device of claim 11, wherein the protective strip is capable of remaining adhered to the installed dental appliance during eating, drinking and sleeping.

14. A method of using a dental protective device, the dental protective device
5 capable of protecting a wearer's lips, inside cheek and gums of an installed dental appliance from rough and sharp edges of the installed dental appliance, the method comprising:

a) trimming the dental protective device to a desired shape for use in covering a desired area of the installed dental appliance,

10 b) separating a backing strip from a protective strip of the dental protective device,

c) moistening the desired area surrounding an installed dental appliance to facilitate adhesion of the protective strip,

d) installing the protective strip in the desired area to an installed position,

15 e) the installed protective strip is then capable of being worn during eating, drinking and sleeping,

f) the installed protective strip is capable of being easily removed when a wearer's teeth require cleaning, and

g) installing a new protective strip after cleaning to the installed position.

20 15. The method of using the dental protective device of claim 14, wherein the protective device is capable of being installed in the desired area to the installed position by the following steps:

a) grasping the protective strip between fingers of the wearer of the protective strip and inserting the protective strip into a mouth of the wearer of the protective strip,

b) applying a first edge of the protective strip to a gum line of the desired area
5 needing protection,

c) applying the protective strip over the desired area of the installed dental appliance,

d) wrapping the protective strip over a bottom edge and a back portion of the desired area,

10 e) rubbing with the wearer's fingers the installed protective strip, particularly proximal the installed dental appliance and at edges of the protective strip to ensure proper adhesion of a water soluble adhesive on the protective strip, and to reduce the size of the protective strip.

16. The method of using the dental protective device of claim 14, wherein
15 installed dental appliance is orthodontic braces.

17. The method of using the dental protective device of claim 14, wherein the protective strip is capable of remaining adhered to the installed dental appliance while eating, drinking and sleeping and preventing most foods from being lodged under the installed dental appliance.

20 18. The method of using the dental protective device of claim 14, wherein the protective strip is configured as a base material coated with a water soluble adhesive coating on a dental appliance contacting side of the protective strip.

19. The method of using the dental protective device of claim 18, wherein the protective strip base material is polyethylene and the backing strip material is polypropylene.

20. The method of using the dental protective device of claim 14, wherein the
5 protective strip is capable of being worn when a wax dental impression is being made of a wearer's teeth, and the worn protective strip is capable of preventing dental prevention wax from being lodged under the wearer's teeth.

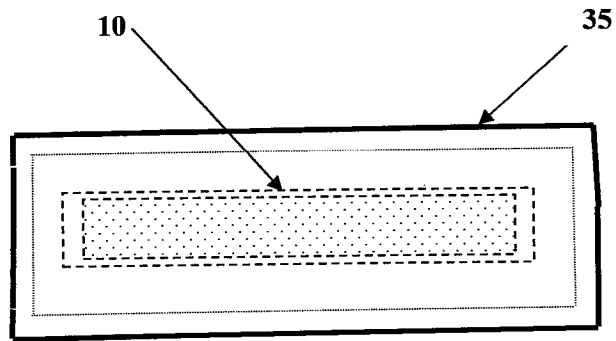


FIGURE 1A

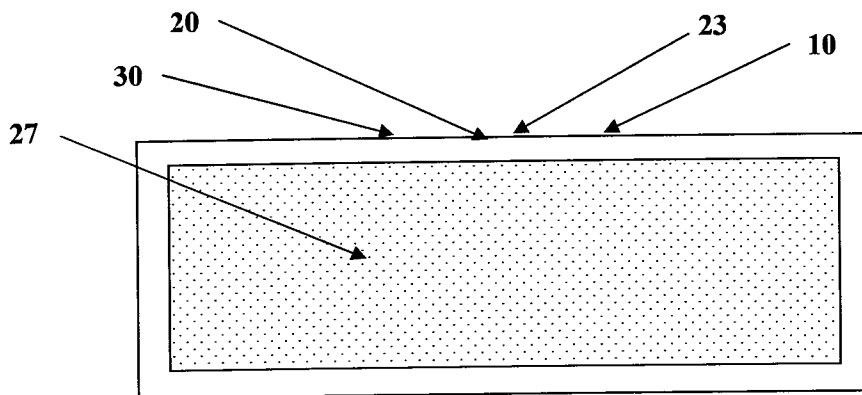


FIGURE 1B

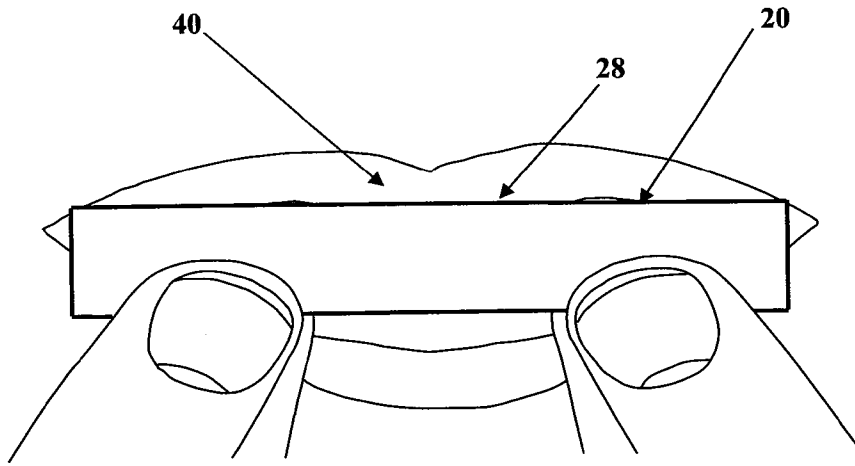


FIGURE 2A

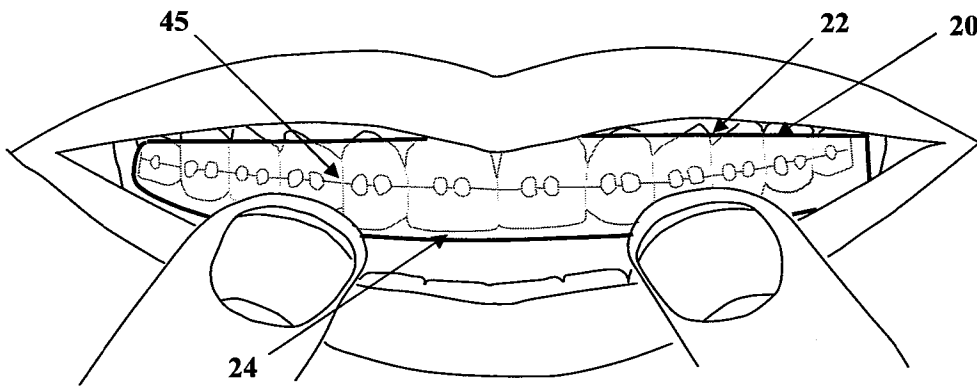


FIGURE 2B

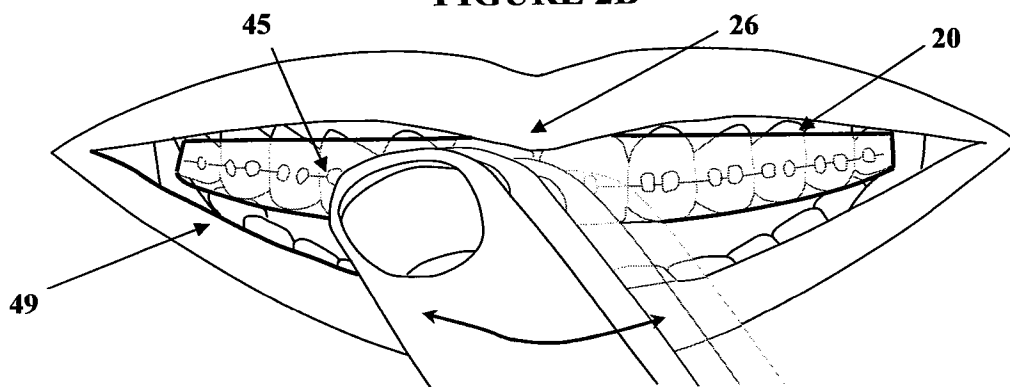


FIGURE 2C

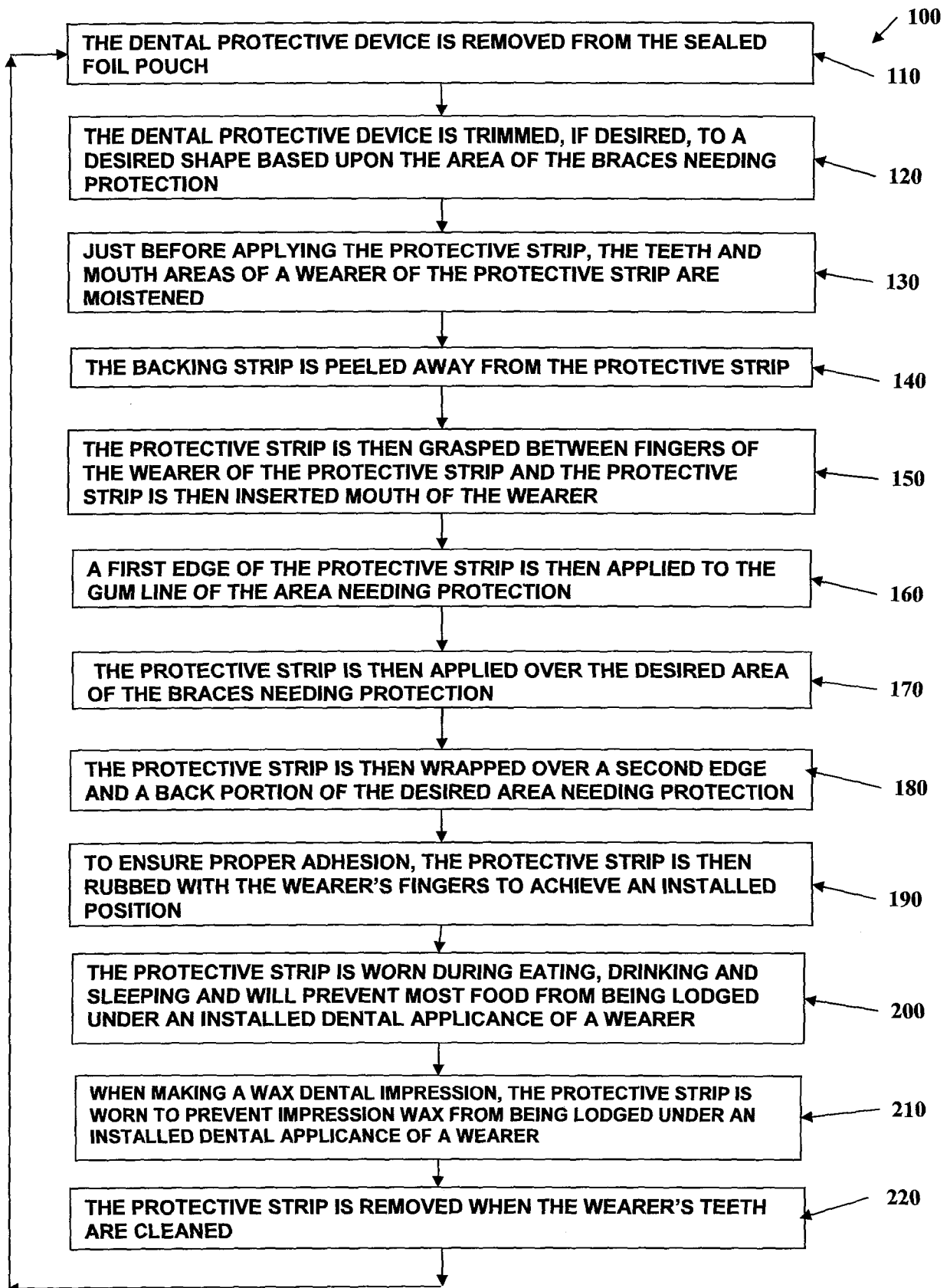


FIGURE 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/057210

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61C 5/14 (2012.01)
USPC - 433/6
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(8) - A61C 5/14, 15/00, 15/04, 17/00; A61K 7/16, 7/18, 49/00; B21D 51/44 (2012.01)
USPC - 132/321; 413/13, 18; 424/9.6, 49; 433/6, 140, 142, 216; D29/108

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase; Google Scholar

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2008/0230087 A1 (BLANCHARD et al) 25 September 2008 (25.09.2008) entire document	1-20
A	US 2008/0233541 A1 (DE VREESE et al) 25 September 2008 (25.09.2008) entire document	1-20
A	US 3,491,776 A (FLEMING) 27 January 1970 (27.01.1970) entire document	1-20
A	US 5,037,296 A (KARWOSKI) 06 August 1991 (06.08.1991) entire document	1-20
A	US 2005/0058602 A1 (RAMJI et al) 17 March 2005 (17.03.2005) entire document	1-20

Further documents are listed in the continuation of Box C.

* Special categories of cited documents:
 "A" document defining the general state of the art which is not considered to be of particular relevance
 "E" earlier application or patent but published on or after the international filing date
 "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
 "O" document referring to an oral disclosure, use, exhibition or other means
 "P" document published prior to the international filing date but later than the priority date claimed
 "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
 "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
 "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
 "&" document member of the same patent family

Date of the actual completion of the international search 09 January 2012	Date of mailing of the international search report 20 JAN 2012
--	--

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774
---	---