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CASE: OB-036
CORPORATE

AUSTRALIA
Patents Act 1990
NOTICE OF ENTITLEMENT

AUSTRALIAN PATENT
APPLICATION NO. 23483/92

I, JILL C. RICHARDSON
of 24 Essex Street. Medford, Massachusetts 02155, U.S.A.

being authorized by the Applicant(s)/Nominated Person(s) in respect of an application entitled:

Dental Tray

state the following:-

1. The Applicant(s)/Nominated Person(s) has/have, for the following reasons, gained entitlement from the actual inventor(s):-

The Applicant/Nominated Person is the assignee of the inventors.

2. The Applicant(s)/Nominated Person(s) is entitled to rely on the basic application listed in the Declaration under Article 8 of the PCT as follows:

The Applicant/Nominated Person is the assignee of the actual inventors.

3. The basic application(s) listed in the Declaration under Article 8 of the PCT is the application first made in a Convention Country in respect of the invention.

- ~~4. The Applicant(s)/Nominated Person(s) is/are~~

DATED this first day of February, 1994

GILLETTE CANADA INC.

BY: Jill C. Richardson

(Signature) Jill C. Richardson, Assistant Secretary

JILL C. RICHARDSON, ASSISTANT SECRETARY
(Name & Title)



AU9223483

(12) PATENT ABRIDGMENT (11) Document No. AU-B-23483/92
(19) AUSTRALIAN PATENT OFFICE (10) Acceptance No. 667193

- (54) Title
DENTAL TRAY
- (51)^s International Patent Classification(s)
A61C 019/06 A61M 035/00
- (21) Application No. : 23483/92 (22) Application Date : 15.07.92
- (87) PCT Publication Number : WO93/01790
- (30) Priority Data
- | | | |
|-------------|-----------|-----------------------------|
| (31) Number | (32) Date | (33) Country |
| 732480 | 18.07.91 | US UNITED STATES OF AMERICA |
| 893185 | 02.06.92 | US UNITED STATES OF AMERICA |
- (43) Publication Date : 23.02.93
- (44) Publication Date of Accepted Application : 14.03.96
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- (57) Claim

1. A tray for holding medicament to be applied to the teeth and gums of a patient, said tray being unitarily formed of a flexible material and including a first generally C-shaped cup portion having a curved middle section and end sections and defining a first concave medicament receiving surface, a second generally C-shaped cup portion having a curved middle section and end sections and defining a second concave medicament receiving surface, straps flexibly uniting said first and second cup portions such that said first and second cup portions normally lie substantially in a plane with said end sections of said first generally C-shaped cup portion facing respective end sections of said second generally C-shaped cup portion, and such that said first and second concave surfaces opening the same direction, a handle extending from said curved middle section of said first cup portion in a direction away from said second cup portion, and a buckle extending from said curved middle section of said second cup portion, said buckle comprising a tongue portion extending from said middle section of said second cup portion and forming a straight edge of a predetermined width generally transverse to said curved middle section, and a retainer strip extending from said second cup portion and surrounding said tongue portion so as to define a narrow space between tongue portion and said retainer strip, said narrow space having a width less than the thickness of said handle, whereby said tray may be folded about said straps such that said first and second cup portions overlie one another with said medicament receiving surfaces facing away from one another and such that said handle of said first

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cup portion may be fitted into said narrow space of said buckle, and whereby the buckle resiliently holds said handle so as to securely maintain said tray in a folded state.

OPI DATE 23/02/93 APPLN. ID 23483/92
AOJP DATE 29/04/93 PCT NUMBER PCT/US92/05910



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/ (PCT)

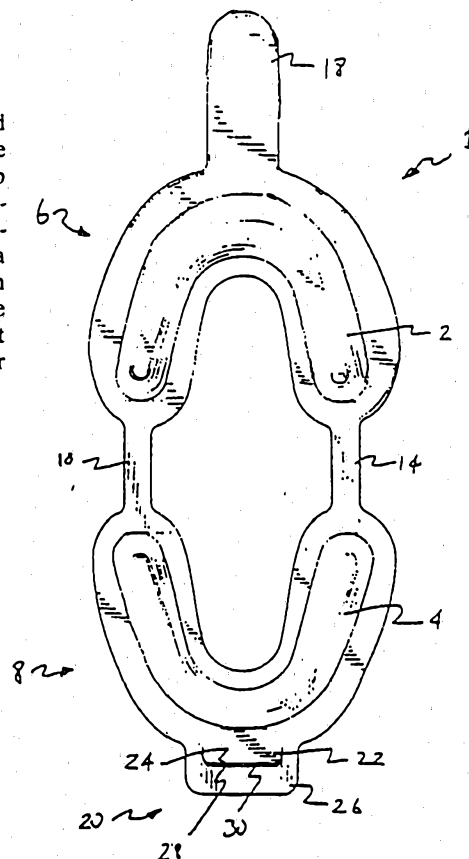
(51) International Patent Classification ⁵ : A61G 17/02, A61C 9/00		A1	(11) International Publication Number: WO 93/01790
			(43) International Publication Date: 4 February 1993 (04.02.93)
(21) International Application Number: PCT/US92/05910		(72) Inventors; and	
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(30) Priority data: 732,480 18 July 1991 (18.07.91) US 893,185 2 June 1992 (02.06.92) US		(74) Agents: GALLOWAY, Peter, D. et al.; Ladas & Parry, 26 West 61 Street, New York, NY 10023 (US).	
(60) Parent Applications or Grants (63) Related by Continuation US 893,185 (CIP) Filed on 2 June 1992 (02.06.92) US 732,460 (CIP) Filed on 18 July 1991 (18.07.91)		(81) Designated States: AT, AU, BB, BG, BR, CA, CH, CS, DE, DK, ES, FI, GB, HU, JP, KP, KR, LK, LU, MG, MN, MW, NL, NO, PL, RO, RU, SD, SE, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LU, MC, NL, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, SN, TD, TG).	
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667193

(54) Title: DENTAL TRAY

(57) Abstract

A gel tray (1) for holding a medicament to be applied to the teeth and gums of a patient includes a handle (18) and an opposing buckle (20). In one embodiment, the buckle (20) includes a tongue portion (22) and a retainer strip (26) surrounding the tongue portion so as to define a narrow space (30) between the tongue portion (22) and the retainer strip (26), the narrow strip having a width less than the thickness of the handle (18). The handle (18) has a tongue reception groove (18b) extending transverse to its length at a position such that the tongue reception groove (18b) is engaged by the tongue when the tray is folded. The tray can be combined with or preloaded with a treatment agent such as from 0.05 to 5 wt.% of a soluble fluoride, either in an acidic gel or a neutral.



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DENTAL TRAY

This invention is directed to a dental treatment tray and a combination of the tray with a medicament gel filling to be applied to the teeth and gums of a patient. More particularly, the present invention is directed to an improved dental treatment tray suitable for holding a gel containing a medicament such as a fluoride compound to be applied to the teeth and gums of a patient.

It is often necessary for a fluoride containing gel or a gel containing another medicament to be applied to the teeth and gums of dental patients. For this purpose, it has been known to form a tray for the application of such a gel. An example of a conventional tray is that sold by Oral-B Laboratories consisting of a unitary tray structure having upper and lower cups. Each of the cups has a shape which roughly conforms to the upper or lower teeth, i.e., a generally C-shape, and has a concave medicament receiving surface. The cups are secured together by straps which normally maintain the cups in a planar relationship with both medicament receiving surfaces facing in the same direction. A gel is then loaded into the medicament receiving surfaces from a container such as a tube, after which the tray is folded about the straps so that the cups overlies one another with the medicament receiving surfaces facing away from one another. The tray,

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in this folded state, is then inserted into the patient's mouth. The patient then bites down firmly into the concave medicament receiving surfaces and holds that position until the
5 treatment is completed, after which the unit is removed from the patient's mouth and discarded.

It is important, in order to correctly position the tray in the patient's mouth, that it securely maintain its folded state as it is being
10 inserted therein. For this purpose, the conventional Oral-B device provides a pair of handles which extend from opposite ends of the cup portions when the tray is in the unfolded state. Upon the folding of the tray, the handles overlap
15 one another, and can be manually gripped. However, this solution has not been found to be fully satisfactory since it relies upon the ability of the technician applying the treatment to securely grip the ends of both handles without slippage.
20 This is not always possible, and so at times the overlap and folded condition cannot be maintained and the medicament treatment is not properly carried out.

U.S. Patent 4,173,219 discloses a
25 disposable dental tray.

Treatment gels containing fluorides and other medicaments, formulated and packaged for filling and application to the teeth and gums of a patient in a dental treatment tray by a dentist are
30 well known.

It is an object of the present invention to provide a tray for holding a medicament to be applied to the teeth and gums of a patient, which tray can be securely held in a folded state.

35 It is a further object of the present invention to provide a tray for holding a medicament to be applied to the teeth and gums of a

patient, which tray can be easily and inexpensively manufactured.

According to a preferred embodiment of the invention, there is provided a tray for holding medicament to be applied to the teeth and gums of a patient, the tray being unitarily formed of a flexible material and including a first generally C-shaped cup portion having a curved middle section and end sections and defining a first concave medicament receiving surface, a second generally C-shaped cup portion having a curved middle section and end sections and defining a second concave medicament receiving surface, straps flexibly uniting the first and second cup portions such that the first and second cup portions normally lie substantially in a plane with the end sections of the first generally C-shaped cup portion facing respective end sections of the second generally C-shaped cup portion, and such that the first and second concave surfaces open in the same direction, a handle extending from the curved middle section of the first cup portion in a direction away from the second cup portion, and a buckle extending from the curved middle section of the second cup portion, the buckle comprising a tongue portion extending from the middle section of the second cup portion and forming a straight edge of a predetermined width generally transverse to the curved middle section, and a retainer strip extending from the second cup portion and surrounding the tongue portion so as to define a narrow space between tongue portion and the retainer strip, the narrow space having a width less than the thickness of the handle, whereby the tray may be folded about the straps such that the first and second cup portions overlie one another with the medicament receiving surfaces facing away from one another and such that the handle of the first cup portion may be fitted into the narrow space of the buckle, and whereby the buckle resiliently holds the handle so as to securely maintain the tray in a folded state.

According to another aspect of the invention, there is provided a gel tray for holding a gel medicament to be applied to the teeth and gums of a patient, said tray being unitarily formed of a laminate of relatively stiff closed cell polyethylene and absorbent open cell polyurethane, said tray including a first generally C-shaped cup portion having a curved middle section and end sections and defining a first concave medicament receiving surface, a second generally C-shaped cup portion having a curved middle section and end sections and defining a second concave medicament receiving surface, straps flexibly uniting said first and second cup portions such that said first and second cup portions normally lie substantially in a plane with said end sections of said first generally C-shaped cup portion facing respective end sections of said second generally C-shaped cup portion, and such that said first and second concave surfaces open in the same direction, an elongate handle extending from said curved middle section of said first cup portion in a direction away from said second cup portion, said elongate handle having a tongue reception groove extending transverse to the length of the handle, a buckle extending from said curved middle section of said



second cup portion, said buckle comprising a rectangular tongue portion extending from said curved middle section of said second cup portion and, a retainer strip extending from said second cup portion so as to surround said tongue portion and to define a narrow space between the tongue portion and said retainer strip, said narrow
5 space having a width less than the thickness of the handle but sufficient to accommodate said tongue reception groove, whereby said tray may be folded about said straps such that said first and second cup portions overlie on another with said medicament receiving surfaces facing away from one another and such that said handle may be fitted into said narrow space with said tongue engaged in said tongue reception groove, and
10 whereby the buckle resiliently holds said handle so as to securely maintain said tray in the folded state.

According to a further aspect of the invention, there is provided a tray for holding medicament to be applied to the teeth and gums of a patient, the tray being unitarily formed of a flexible material and including a first generally C-shaped cup
15 portion having a curved middle section and end sections and defining a first concave medicament receiving surface, a second generally C-shaped cup portion having a curved middle section and end sections and defining a second concave medicament receiving surface, straps flexibly uniting the first and second cup portions such that the first and second cup portions normally lie substantially in a plane with the end sections
20 of the first generally C-shaped cup portion facing respective end sections of the second generally C-shaped cup portion, and such that the first and second concave surfaces open in the same direction, a first slotted tab extending from the curved middle section of the first cup portion in a direction away from the second cup portion, and a second slotted tab extending from the curved middle section of the second cup portion in a
25 direction away from the first cup portion, wherein the first and second slotted tabs each has a slot oriented such that the slots of the first and second slotted tabs may be interfitted to retain the tray in a folded state, the first and second cup portions overlying one another with the medicament receiving surfaces facing away from one another.

According to yet another aspect of the invention, there is provided a tray for
30 holding medicament to be applied to the teeth and gums of a patient, said tray being unitarily formed of a flexible material and including a first generally C-shaped cup portion having a curved middle section and end sections and defining a first concave medicament receiving surface, a second generally C-shaped cup portion having a curved middle section and end sections and defining a second concave medicament
35 receiving surface, straps flexibly uniting said first and second cup portions such that said first and second cup portions normally lie substantially in a plane with said end sections of said first generally C-shaped cup portion facing respective end sections of said second generally C-shaped cup portion, and such that said first and second concave



surfaces open in the same direction, a handle extending from said curved middle section of said first cup portion in a direction away from said second cup portion, and a means for engaging said handle that extends from said curved middle section of said second cup portion and adapted to engage said handle, whereby said tray may be folded about
5 said straps such that said first and second cup portions overlies one another with said medicament receiving surfaces facing away from one another and, such that said means for engaging said handle receives said handle of said first cup portion for engagement therewith, said means for retaining resiliently holding said handle so as to securely maintain said tray in a folded state.

10 A still further aspect of the invention is the combination of the dental treatment tray and treatment agent in a suitable vehicle. The vehicle can be a paste, liquid or gel and is preferably a treatment gel comprising a pharmaceutically effective amount of at least one agent for treating teeth or gums dispersed in a gel medium consisting of essentially and an amount of a water dispersible gelling agent sufficient to form a gel.
15 Preferably, the treatment gel comprises an agent such as from 0.05 to 5 wt. of a soluble fluoride, either in an acidic gel or a neutral. Acidic gels can contain pharmaceutically acceptable, treatment effective amounts of phosphoric acid and hydrofluoric acid, for example. Neutral gels can have a pH modifying



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agents such as sodium hydroxide.

A more complete appreciation of the invention and many of the attendant advantages thereof will be readily obtained as the same
5 becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings, wherein:

Figure 1 is a bottom plan view of an unloaded tray according to an embodiment of the
10 present invention in an unfolded state;

Figure 2 is a top plan view of an unloaded tray according to the embodiment of Figure 1 in an unfolded state;

Figure 3 is a side view of an unloaded
15 tray according to the embodiment of Figure 1 in a folded state;

Figure 4 is a front view of an unloaded tray according to the embodiment of Figure 2 in a folded state;

20 Figure 5 is a sectional view corresponding to a portion of Figure 4; and

Figure 6 is a top plan view of an unloaded tray according to another embodiment in an unfolded state.

25 Embodiments of the present invention will now be described with reference to the attached figures, wherein the same or corresponding reference numerals will be used to identify the same or corresponding parts throughout the several
30 views.

The tray according to the present invention is unitarily formed of foam material. Preferably, it is comprised of a relatively stiff closed cell, foam polyethylene having a layer of
35 open cell polyurethane foam adhesively bonded thereto at the surfaces defining the concave medicament receiving surfaces.

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Referring to Figures 1 and 2, the tray 1 according to the invention has a generally C-shaped cup portion 6 and a generally C-shaped cup portion 8, each of which is concaved to define first and second concave medicament receiving surfaces 2 and 4.

It should be noted that the cup portions 6 and 8 are generally C-shaped only insofar as this shape generally conforms to the arrangement of upper and lower teeth in a patient's jaw. Various other shapes which also generally conform to the arrangement of teeth in a patient's jaw are therefore also included within the reference to the shape of the cup portions being generally C-shaped.

The facing ends of the cup portions are flexibly united by straps 10 and 14 such that the cup portions 6 and 8 normally lie in a plane. As best seen in Figure 2, the straps have hinge creases 10a, 10b and 14a, 14b to increase their flexibility.

The mid-portion of the cup portion 6 is provided with a unitary handle 18 which extends therefrom in a direction opposite to the cup portion 8. The handle has a hinge crease 18a at its base, and also has a tongue reception groove 18b at a position along its length, the groove 18b extending transverse to the length of the handle.

A buckle 20 extends from a mid-portion of the cup portion 8. The buckle comprises a generally rectangular tongue 22 which extends from the cup portion and forms a generally transverse edge 24. A retainer strip 26 also extends from the mid portion of the cup portion 8 so as to surround the tongue portion. The strip defines an internal edge 28 which, together with the edge 24, defines a narrow space 30, the narrow space 30 having a width less than the thickness T of the handle.

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As seen in Figures 3-5, the tray can be folded over at the straps 10 and 14, so that the cup portions 6 and 8 overlies one another with the first and second concave medicament receiving surfaces facing in opposite directions. In this state, the handle 18 is inserted through the narrow space 30 until the tongue portion 22 fits into the tongue reception groove 18b. In this position, the tray is fully folded and the tongue portion 22 resiliently holds the handle, and so securely maintains the tray in the folded state. One can thus, by gripping the distal end of handle 18, insert the tray into the patient's mouth without concern for the tray accidentally shifting from the folded state. In a preferred technique, it is useful to squeeze the sides of folded gel tray together to facilitate inserting the device into a patient's mouth. Since the two sections of the gel tray are held firmly together by the latch, only one hand is needed to insert the tray.

Figure 6 shows another embodiment which is identical to the first embodiment, except as set forth below.

In the second embodiment, a first slotted tab 218 extends from a mid-portion of the cup portion 206. The first slotted tab 218 is elongate and extends in a direction opposite the cup portion 208. A slot 220 extends from one lateral edge of the elongate slot tab 218 in a direction generally transverse to the length of the slotted tab. It terminates at a position near a longitudinal center line of the tab 218, so as to form a hook portion 222 in the region of the tab 218 which is distal of the slot 220.

A short slotted tab 230 extends from a mid portion of the cup portion 208. It includes a slot 232 extending from a lateral edge opposite the

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lateral edge from which the slot 220 extends, with respect to the longitudinal center line of the slot 218. The slot 232 also extends in a direction generally transverse to the length of the tab 218, so as to form a distal hook 234.

In use, when the tray is folded to the folded position shown in Figures 3-5, the slots are inserted into one another, so that the hook portions 222 and 234 interengage one another to securely maintain the tray in the folded position. It has been found that unlatching the tray, which is sometimes required during use, can be done more easily with this second embodiment than with the first embodiment.

The tray is designed to be loaded with a dental treatment agent in a suitable vehicle such as a gel for application to the teeth and gums of a patient. Optionally, the disposable tray can be provided to the dentist already loaded with the treatment gel to be applied. The terms "loaded" and "preloaded", as used herein, are defined to mean that some portion of the treatment agent has been placed in the trough formed by the tray's foam interior. Preferably, the amount of treatment agent loaded in the tray corresponds to the full amount which the dentist wishes to use in the dental tray treatment method.

The medicinal treatment agent contains a medicament or treatment agent for treating teeth or gums in the form of a coating, gel, paste, solution or the like. The gel, paste or solution forms of treatment agent can be applied to the brush by the dentist or it can be provided to the dentist in the preloaded form.

Medicament coatings, solutions, pastes and gels are well known and fully within the skill of the art. The preferred medicament vehicle is a

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gel medium. Treatment gels which are suitable for use with and for preloading the dental treatment tray of this invention are well known and fully within the skill of the art. In general, the gels
5 comprise an aqueous solution of the medicament and pharmaceutically acceptable, non-toxic additives such as aqueous gelling agents, humectants, surfactants, coloring or whitening agents, chlorophyll compounds, flavoring agents,
10 preservatives, optional co-solvents, stabilizers, sweeteners, dyes, and pH modifying agents. Suitable materials and manufacturing processes are described in U.S. Patents 4,418,057, 4,254,101, 4,627,977, 4,806,340, 4,847,070, 4,902,497,
15 4,906,456, and 4,960,586, for example, the entire contents of each of which are incorporated by reference.

Suitable medicaments include antimicrobial treatment agents. Suitable
20 antimicrobial agents include, but are not limited to, quaternary ammonium compounds such as cetylpyridinium chloride, domiphen bromide, benzethonium chloride and the like; antibiotics and related drugs such as nitroimidazoles
25 (metronidazole, etc.), tetracyclines, penicillins, clindamycin, spiramycin, nystatin, amphotericin, erythromycin, and the like; essential oils such as thymol, eucalyptol, menthol, methyl salicylate, and the like; metal salts such as mercurials, zinc
30 salts, aluminum salts, and the like; other treatment compounds such as chlorhexidine, alexidine, hexetidine, IRGASAN DP300, salicylanilides, and the like.

Suitable flavors and fragrances include
35 organic acids, esters, and aldehydes which are both safe and pleasant. Any suitable flavoring or sweetening material may also be employed. Examples

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of suitable flavoring constituents are flavoring oils, e.g. oil of spearmint, peppermint, wintergreen, sassafras, clove, sage, eucalyptus, marjoram, cinnamon, lemon, orange and methyl
5 salicylate. Suitable sweetening agents include sucrose, lactose, maltose, dextrose, levulose, sorbitol, xylitol, d-tryptophan, dihydrochalcones, sodium cyclamate, perillartine, APM (aspartyl phenyl alanine, methyl ester), saccharine and the
10 like.

Biologically active materials which can be included in the gels are growth hormones and other compounds or compositions which enhance or stimulate tissue regrowth and healing.

15 Oxygenating agents which can be included in the gels include sodium perborate, urea peroxide, stabilized hydrogen peroxide, and the like.

Fluorides which can be included in the
20 gels include sodium fluoride, stabilized stannous fluoride, amine fluorides and the like. A suitable stabilized stannous fluoride treatment gel is disclosed in U.S. Patents 4,960,586 and 5,009,883, for example, the entire contents of which are
25 hereby incorporated by reference. The fluoride can be provided in concentrations of from 0.05 to 5.0 weight percent.

Desensitizing agents which can be included in the gels include hydroxyapatite,
30 formaldehyde, soluble oxalates, potassium salts include potassium fluoride, and the like.

Any other soluble, non-toxic pharmaceutically acceptable material which has a beneficial or therapeutic effect on the health,
35 integrity or appearance of oral hard and soft tissues can be incorporated in the gels.

Any conventional humectant can be used.

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Suitable humectants include sorbitol, glycerin, or other edible polyhydric alcohols, the natural or synthetic gums conventionally used as hardening control agents and binders.

5 Suitable gelling agents for use in the composition of this invention include from 0.1 to 10 and preferably from 0.5 to 5 weight percent gelling agent. Gelling agents should be colloidal silica, magnesium aluminum silicate, and silicate
10 free compounds such as Irish moss, gum karaya, gum arabic, gum tragacanth, xanthan gum, other polysaccharide gums, starch, polyvinylpyrrolidone, hydroxyethyl propylcellulose, hydroxybutyl methyl cellulose, hydroxypropyl methyl cellulose,
15 hydroxyethyl cellulose, sodium carboxymethyl cellulose, other hydroxyvinyl polymers, and the like.

The compositions should have a pH within the range of from 2 to 11. One embodiment of
20 treatment gel for treating intact teeth has an acidic pH and contains hydrofluoric and phosphoric acids. A neutral treatment gel is preferred to treat teeth for which acid treatment is not suitable.

25 An optimum acidic gel can have the following approximate composition:

	<u>Component</u>	<u>Amount, %w/w</u>
	Gelling agent	2.5
	Glycerin	5.0
30	Aqueous Hydrofluoric Acid	0.2
	Aqueous Phosphoric Acid	1.5
	Sodium Fluoride	2.6
	Sorbitol solution	45.0
	Water	41.0
35	Xanthan Gum	0.4

An optimum neutral gel can have the following composition:

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	<u>Component</u>	<u>Amount, %w/w</u>
	Gelling agent	1.8
	Sodium Fluoride	1.9
	Sodium Hydroxide Solution	9.0
5	Sorbitol Solution	20.0
	Water	65.2

This invention is further illustrated by the following specific but non-limiting examples of suitable gels which can be applied to the dental treatment tray of this invention.

EXAMPLE 1

Acidic Minute Treatment Gel

The following ingredients are combined to produce an acidic Minute Treatment Gel used for fluoride treatment of teeth.

	<u>Component</u>	<u>Amount, %w/w</u>
	Carbopol ^a	2.500
	FD & C Yellow #10	
	(1.0% aq. solution)	0.085
20	FD & C Blue #1	
	(1.0% aq. solution)	0.025
	Glycerin 96% USP	5.000
	Hydrofluoric Acid, 48% AR	0.174
	Phosphoric Acid 75%, Food Grade	1.490
25	Prosweet Liquid ^b	1.000
	Sodium Fluoride, USP	2.599
	Sodium Saccharin USP Crystals	0.210
	Sorbitol 70.0% Solution USP	45.000
	Spearmint Oil NF, Extra	0.600
30	Titanium Dioxide USP	0.010
	Water, Purified USP	40.927
	Xanthan Gum ^c	0.380

^aCARBOMER 934P NF, carboxyvinyl polymer

^bF&C International

35 ^cKELTROL, Kelco

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EXAMPLE 2Neutral Treatment Gel

The following ingredients are combined to produce an Neutral Treatment Gel used for fluoride treatment of teeth.

	<u>Component</u>	<u>Amount, %w/w</u>
	Carbopol 934P ^a	1.800
	FD&C Blue #1 (1.0% Solution)	0.054
	FD&C Red #33 (1.0% Solution)	0.123
10	Grape flavor #11540 ^b	0.500
	Methylparaben NF	0.150
	Propylparaben NF	0.050
	Prosweet Liquid ^c	1.000
	Sodium Fluoride, USP	1.870
15	Sodium Hydroxide (10% Solution)	9.000
	Sodium Saccharin USP Crystals	0.210
	Sorbitol Solution 70% USP	20.000
	Titanium Dioxide USP	0.010
	Water, Purified USP	65.233
20	^a CARBOMER 934P NF, carboxyvinyl polymer	
	^b Bush, Boake & Allen	
	^c F&C International	

Obviously, numerous modifications and variations of the present invention are possible in light of the above teachings. It is therefore to be understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.

The claims defining the invention are as follows:

1. A tray for holding medicament to be applied to the teeth and gums of a patient, said tray being unitarily formed of a flexible material and including a first generally C-shaped cup portion having a curved middle section and end sections and defining a first concave medicament receiving surface, a second generally C-shaped cup portion having a curved middle section and end sections and defining a second concave medicament receiving surface, straps flexibly uniting said first and second cup portions such that said first and second cup portions normally lie substantially in a plane with said end sections of said first generally C-shaped cup portion facing respective end sections of said second generally C-shaped cup portion, and such that said first and second concave surfaces opening the same direction, a handle extending from said curved middle section of said first cup portion in a direction away from said second cup portion, and a buckle extending from said curved middle section of said second cup portion, said buckle comprising a tongue portion extending from said middle section of said second cup portion and forming a straight edge of a predetermined width generally transverse to said curved middle section, and a retainer strip extending from said second cup portion and surrounding said tongue portion so as to define a narrow space between tongue portion and said retainer strip, said narrow space having a width less than the thickness of said handle, whereby said tray may be folded about said straps such that said first and second cup portions overlie one another with said medicament receiving surfaces facing away from one another and such that said handle of said first cup portion may be fitted into said narrow space of said buckle, and whereby the buckle resiliently holds said handle so as to securely maintain said tray in a folded state.



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~~state.~~

2. A tray of claim 1, wherein said medicament receiving surfaces are formed of an open cell foamed material.
- 5 3. A tray of claim 2, wherein surfaces of said tray, other than said medicament receiving surfaces, is formed of a closed cell, foam polyethylene, and said medicament receiving surfaces are formed of an open cell polyurethane
- 10 foam.
4. A tray of claim 3, wherein said open cell polyurethane foam is adhesively bonded to said closed cell, foam polyethylene.
5. A tray of claim 1, including a reduced
- 15 thickness groove formed in said handle at a position along the length of said handle such that said groove is held in said narrow space when said tray is in said folded state.
6. A tray of claim 5, wherein said tray is
- 20 formed of a sufficiently stiff material to maintain said tray substantially rigid when in said folded state with groove held in said narrow space.
7. A tray of claim 1, wherein said straps connect said facing ends of said first and second
- 25 cup portions.
8. A tray of claim 5, wherein said handle has a length sufficient that a distal end thereof can be manually held when said tray is in said folded state.
- 30 9. A tray of claim 1, in combination with a treatment agent comprising a pharmaceutical effective amount of at least one agent for treating gums or teeth in a non-toxic, pharmaceutically acceptable vehicle.
- 35 10. A tray of claim 9, in combination with a treatment gel comprising a pharmaceutically effective amount of at least one agent for treating



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teeth or gums dispersed in a gel medium consisting essentially of water and an amount of a water dispersible gelling agent sufficient to form a gel.

11. A tray of claim 10, wherein the treatment
5 gel contains from 0.05 to 5 wt.% of a soluble fluoride.

12. A tray of claim 11, wherein the treatment
gel has an acidic pH and contains pharmaceutically
acceptable, treatment effective amounts of
10 phosphoric acid and hydrofluoric acid.

13. A tray of claim 12, wherein the treatment
gel consists essentially of the following
approximate composition:

	<u>Component</u>	<u>Amount, %w/w</u>
15	Gelling agent	2.5
	Glycerin	5.0
	Aqueous Hydrofluoric Acid	0.2
	Aqueous Phosphoric Acid	1.5
	Sodium Fluoride	2.6
20	Sorbitol solution	45.0
	Water	41.0
	Xanthan Gum	0.4

14. A tray of claim 11, wherein the treatment
gel has a substantially neutral pH.

25 15. A tray of claim 14, wherein the treatment
gel consists essentially of the following
approximate composition:

	<u>Component</u>	<u>Amount, %w/w</u>
	Gelling agent	1.8
30	Sodium Fluoride	1.9
	Sodium Hydroxide Solution	9.0
	Sorbitol Solution	20.0
	Water	65.2

16. A gel tray for holding a gel medicament
35 to be applied to the teeth and gums of a patient,
said tray being unitarily formed of a laminate of
relatively stiff closed cell polyethylene and



16. A gel tray for holding a gel medicament to be applied to the teeth and gums of a patient, said tray being unitarily formed of a laminate of relatively stiff closed cell polyethylene and absorbent open cell polyurethane, said tray including a first generally C-shaped cup portion having a curved middle section and end sections and defining a first concave medicament receiving surface, a second generally C-shaped cup portion having a curved middle section and end sections and defining a second concave medicament receiving surface, straps flexibly uniting said first and second cup portions such that said first and second cup portions normally lie substantially in a plane with said end sections of said first generally C-shaped cup portion facing respective end sections of said second generally C-shaped cup portion, and such that said first and second concave surfaces open in the same direction, an elongate handle extending from said curved middle section of said first cup portion in a direction away from said second cup portion, said elongate handle having a tongue reception groove extending transverse to the length of the handle, a buckle extending from said curved middle section of said second cup portion, said buckle comprising a rectangular tongue portion extending from said curved middle section of said second cup portion and, a retainer strip extending from said second cup portion so as to surround said tongue portion and to define a narrow space between the tongue portion and said retainer strip, said narrow space having a width less than the thickness of the handle but sufficient to accommodate said tongue reception groove, whereby said tray may be folded about said straps such that said first and second cup portions overlies on another with said medicament receiving surfaces facing away from one another and such that said handle may be fitted into said narrow space with said tongue engaged in said tongue reception groove, and whereby the buckle resiliently holds said handle so as to securely maintain said tray in the folded state.

17. A tray for holding medicament to be applied to the teeth and gums of a patient, said tray being unitarily formed of a flexible material and including a first generally C-shaped cup portion having a curved middle section and end sections and defining a first concave medicament receiving surface, a second generally C-shaped cup portion having a curved middle section and end sections and defining a second concave medicament receiving surface, straps flexibly uniting said first and second cup portions such that said first and second cup portions normally lie substantially in a plane with said end sections of said first generally C-shaped cup portion facing respective end sections of said second generally C-shaped cup portion, and such that said first and second concave surfaces opening the same direction, a first slotted tab extending from said curved middle section of said first cup portion in a direction away from said second cup portion, and a second slotted tab extending from said curved middle section of said second cup portion in a direction away from said first cup portion, wherein said first and second slotted tabs each has a slot oriented such that said slots of said first and



second slotted tabs may be interfitted to retain said tray in a folded state, said first and second cup portions overlying one another with said medicament receiving surfaces facing away from one another.

18. A tray of claim 17, wherein said first slotted tab is elongate.

18. A tray of claim 17, wherein said first slotted tab is elongate.



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19. A tray of claim 18, wherein said slots define hooks at distal ends of said first and second tabs, said hooks interengaging one another when said slots are interfitted.
- 5 20. A tray of claim 17, wherein said medicament receiving surfaces are formed of an open cell foamed material.
21. A tray of claim 20, wherein surfaces of said tray, other than said medicament receiving
10 surfaces, are formed of a closed cell, foam polyethylene and said medicament receiving surfaces are formed of an open cell polyurethane foam.
22. A tray of claim 16, wherein said open cell polyurethane foam is adhesively bonded to said
15 closed cell, foam polyethylene.
23. A tray of claim 17, wherein said tray is formed of a sufficiently stiff material to maintain said tray substantially rigid when in said folded state.
- 20 24. A tray of claim 17, wherein said straps connect said facing ends of said first and second cup portions.
25. A tray of claim 19, wherein said slots extend from side edges of their respective tabs,
25 which side edges are respectively on opposite sides of a longitudinal center line of said elongate slotted tab.
26. A tray of claim 17, in combination with a treatment gel comprising a pharmaceutically
30 effective amount of at least one agent for treating teeth or gums dispersed in a gel medium consisting essentially of water and an amount of a water dispersible gelling agent sufficient to form a gel.
27. A tray of claim 26, wherein the treatment
35 gel contains from 0.05 to 5 wt.% of a soluble fluoride.
28. A tray of claim 27, wherein the treatment

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gel has an acidic pH and contains pharmaceutically acceptable, treatment effective amounts of phosphoric acid and hydrofluoric acid.

29. A tray of claim 28, wherein the treatment
5 gel consists essentially of the following approximate composition:

	<u>Component</u>	<u>Amount, %w/w</u>
	Gelling agent	2.5
	Glycerin	5.0
10	Aqueous Hydrofluoric Acid	0.2
	Aqueous Phosphoric Acid	1.5
	Sodium Fluoride	2.6
	Sorbitol solution	45.0
	Water	41.0
15	Xanthan Gum	0.4

30. A tray of claim 27, wherein the treatment gel has a substantially neutral pH.

31. A tray of claim 30, wherein the treatment
20 gel consists essentially of the following approximate composition:

	<u>Component</u>	<u>Amount, %w/w</u>
	Gelling agent	1.8
	Sodium Fluoride	1.9
	Sodium Hydroxide Solution	9.0
25	Sorbitol Solution	20.0
	Water	65.2

32. A tray for holding medicament to be applied to the teeth and gums of a patient, said tray being unitarily formed of a flexible material and including a first generally C-shaped cup portion having a curved middle section and end sections and defining a first concave medicament receiving surface, a second generally C-shaped cup portion having a curved middle section and end sections and defining a second concave medicament receiving surface, straps flexibly uniting said first and second cup portions such that said first and second cup portions normally lie substantially in a plane with said end sections of said first generally C-shaped cup portion facing respective end sections of said second generally C-shaped cup portion, and such that said first and second concave surfaces opening the same direction, a handle extending from said curved middle section of said first cup portion in a direction away from said second cup portion, and a means for engaging said handle that extends from said curved middle section of said second cup portion and adapted to engage said handle, whereby said tray may be folded about said straps such that said first and second cup portions overlies one another with said medicament receiving surfaces facing away from one another and, such that said means for engaging said handle receives said handle of said first cup portion for engagement therewith, said means for engaging said handle resiliently holding said handle so as securely to maintain said tray in a folded state.

33. A tray of claim 32, wherein said means for engaging said handle comprises a buckle having a tongue portion extending from said middle section of said second cup portion and forming a straight edge of a predetermined width generally transverse to said curved middle section, and a retainer strip extending from said second cup portion and surrounding said tongue portion so as to define a narrow space between tongue portion and said retainer strip, said narrow space having a width less than the thickness of said handle, whereby said handle of said first cup portion may be fitted into said narrow space of said buckle securely to maintain said tray in a folded state.

DATED this Ninth Day of January 1996

Gillette Canada Inc.

Patent Attorneys for the Applicant

SPRUSON & FERGUSON



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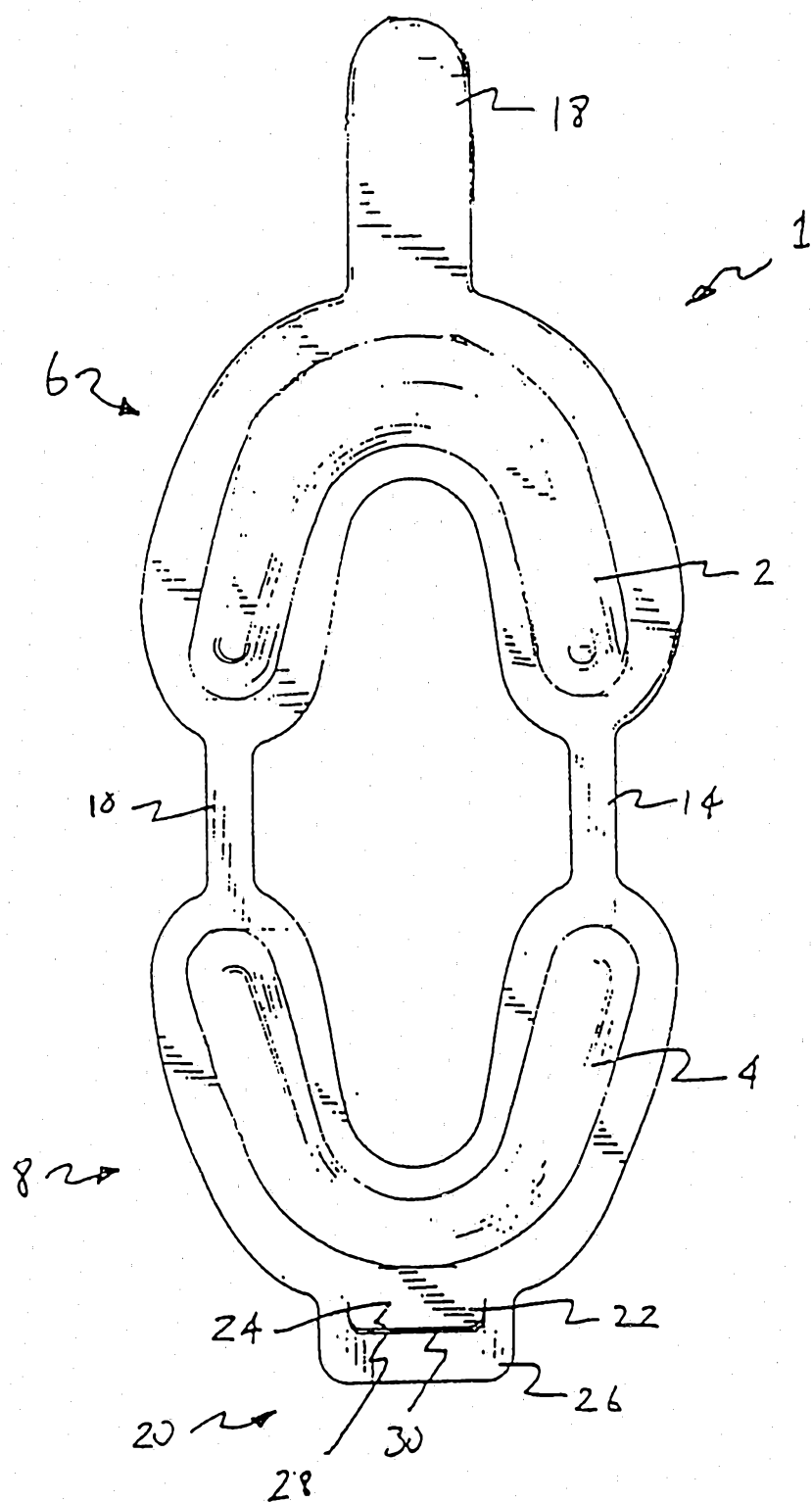


FIGURE 1

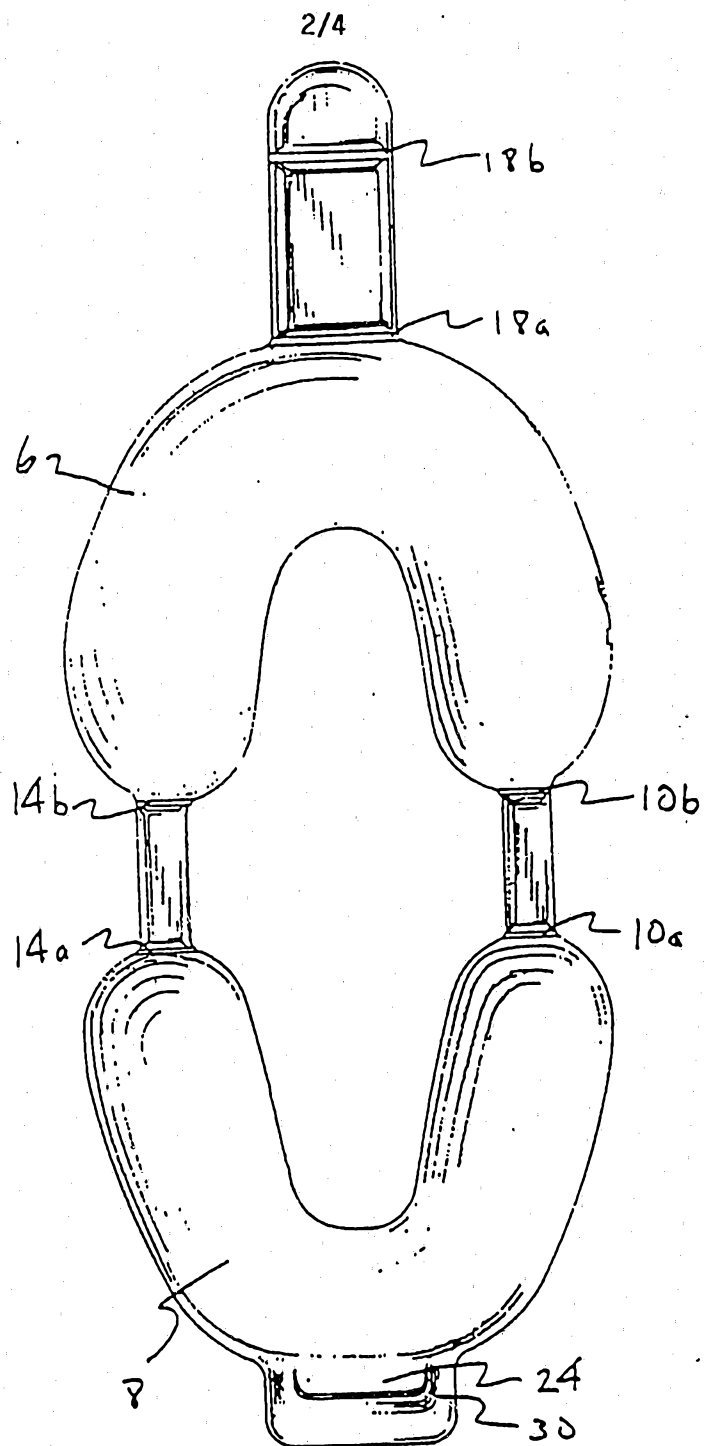


FIGURE 2

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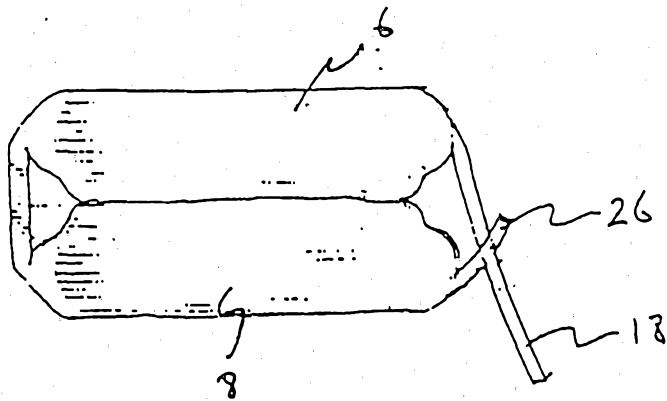


FIGURE 3

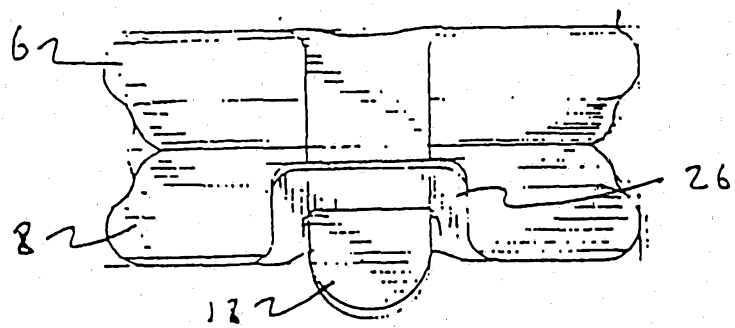


FIGURE 4

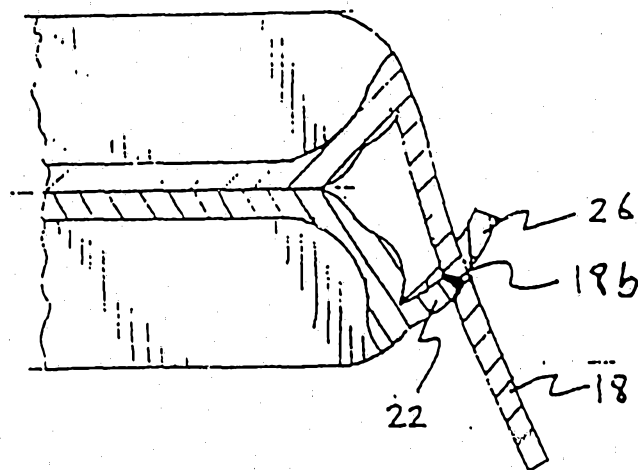


FIGURE 5

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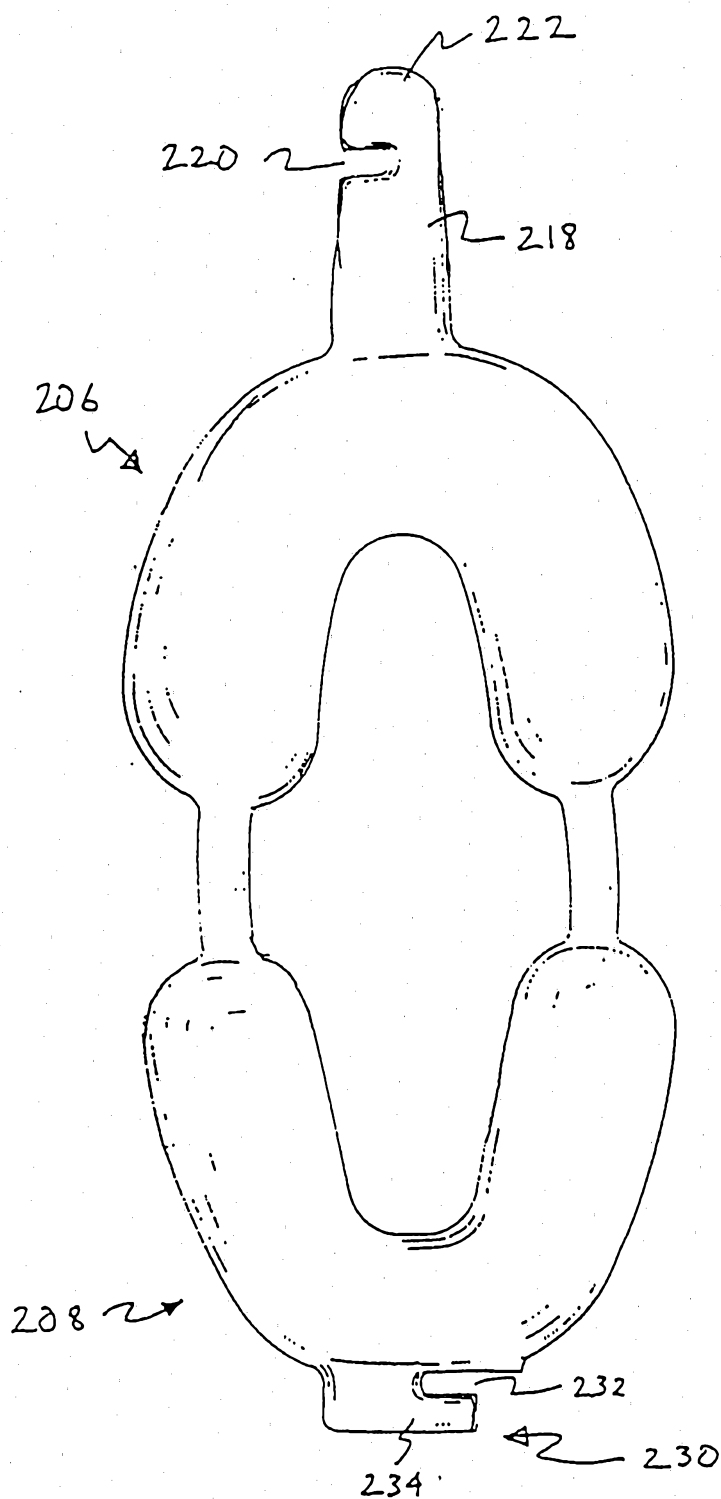


FIGURE 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US92/05910

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) : A61G 17/02; A61C 9/00

US CL : 433/80,37,42,43

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)

U.S. : 433/89;128/861

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)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A, 4,173,219 (LENTINE) 06 NOVEMBER 1979 See the entire document.	1-31
A	US,A, 905,535 (HOLMES) 01 DECEMBER 1908 See the entire document.	1-16
A	US,A, 4,096,986 (FLORIAN) 27 JUNE 1978 See the entire document.	17-21,23-31

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

☐ See patent family annex.

* Special categories of cited documents:

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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

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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

Z

document member of the same patent family

Date of the actual completion of the international search

26 AUGUST 1992

Date of mailing of the international search report

19 NOV 1992

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