

[72] Inventor **Samuel Greenberg**  
 Philadelphia, Pennsylvania  
 (Stump Road & Commerce Drive  
 Montgomeryville, Pa. 18936)

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[56]

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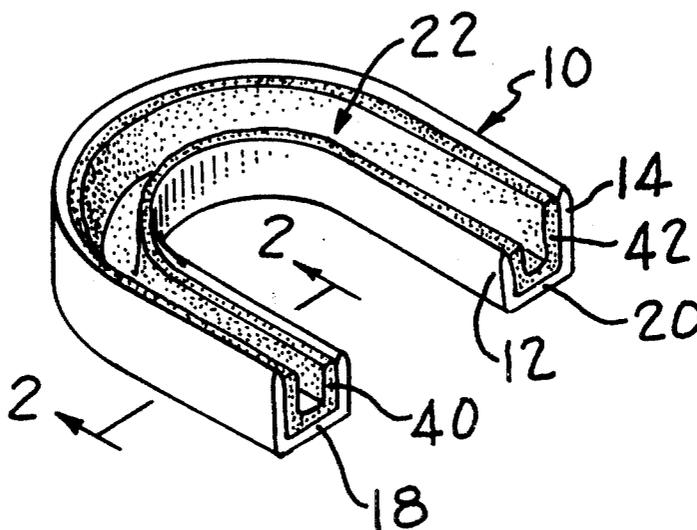
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Primary Examiner—Adele M. Eager  
 Attorney—McClure, Weiser and Millman

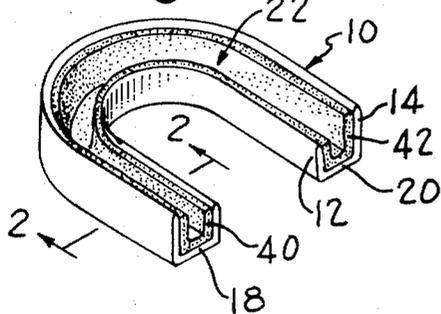
[54] **MEDICAMENT APPLICATOR FOR TREATMENT OF TEETH AND/OR GUMS**  
 10 Claims, 9 Drawing Figs.

[52] U.S. Cl. .... 128/260,  
 128/136, 32/1  
 [51] Int. Cl. .... A61m 7/00  
 [50] Field of Search ..... 128/155,  
 156, 157, 260, 261, 268, 517; 32/1

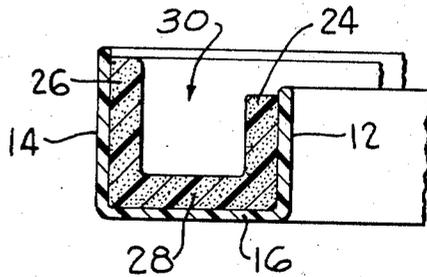
**ABSTRACT:** An applicator for the treatment of teeth and/or gums with fluorides or other medicaments and method of making the same wherein the applicator comprises a flexibly resilient substantially horseshoe-shaped tray of channel cross-section and a medicament carrier substantially coextensive therewith and also of channel cross-section secured in the tray so that when the applicator is applied to the teeth it can be readily accommodated thereto and when moderate pressure is applied to the applicator the medicament will invest the teeth and/or gums.



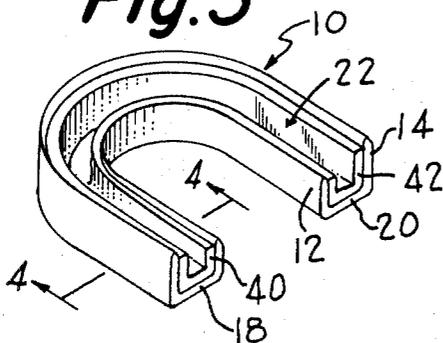
**Fig. 1**



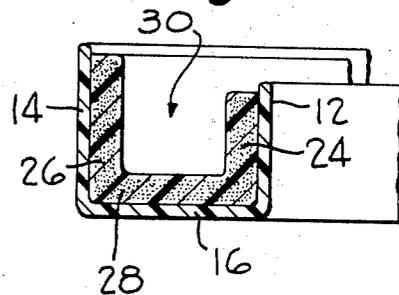
**Fig. 2**



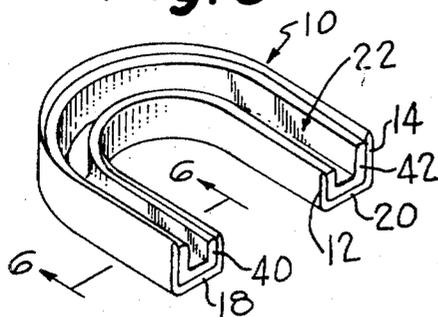
**Fig. 3**



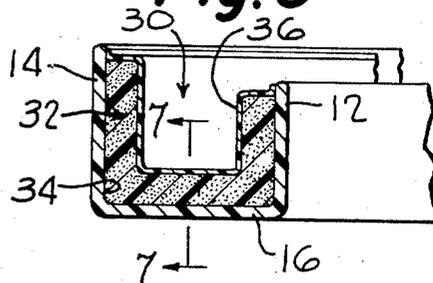
**Fig. 4**



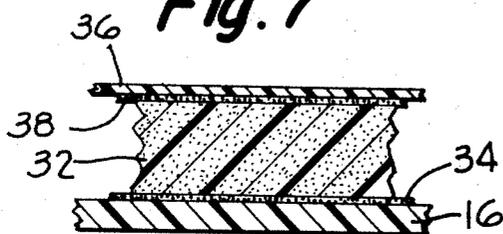
**Fig. 5**



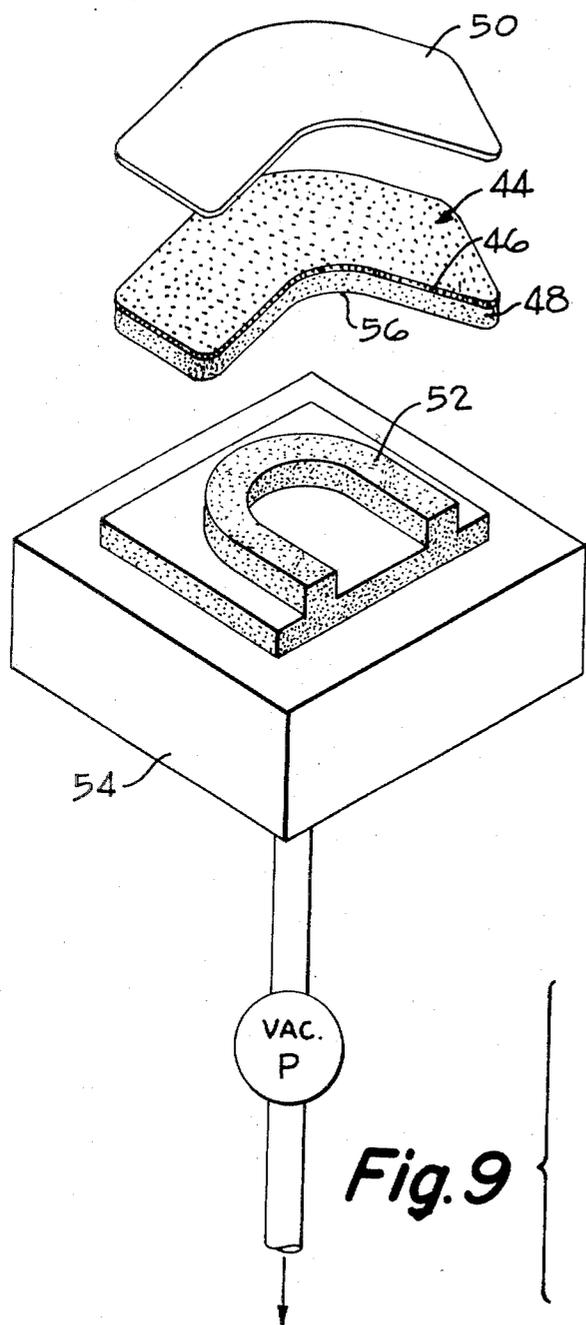
**Fig. 6**



**Fig. 7**

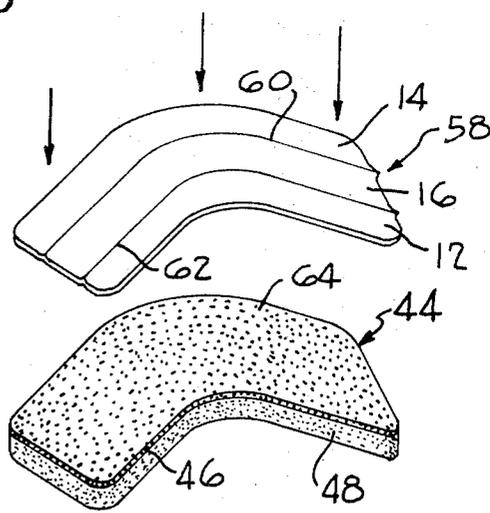


INVENTOR  
SAMUEL GREENBERG  
BY *Max R. Hillman*  
ATTORNEY



**Fig. 8**

**Fig. 9**



INVENTOR  
SAMUEL GREENBERG

BY *Max R. Hillman*  
ATTORNEY

## MEDICAMENT APPLICATOR FOR TREATMENT OF TEETH AND/OR GUMS

This invention relates to a medicament applicator for the treatment of teeth and/or gums, the primary object of which is to insure proper investment of the teeth and/or gums with the medicament with efficiency, accuracy and relative ease.

Another object of the invention is to provide a medicament applicator as a standard unit for the treatment of teeth and/or gums which can be readily applied and accommodated to teeth of various sizes and which employs a cushioning material as the medicament carrier that spreads the medicament and causes it to properly invest the teeth and/or gums when moderate pressure is applied to the applicator.

Another object of the invention is to provide a medicament applicator of the character described wherein the cushioning material serving as the medicament carrier is of closed or open cell or pore formation. With the closed cell material more pressure will be required to press the applicator against the teeth but it has the advantage of being easily cleaned for reuse. With the open cell material less applied pressure is required and it may be cleaned for reuse with somewhat greater difficulty but it has the advantage of greater adaptability to the teeth since it is less resistant to deformation.

Another object of the invention is to provide a medicament applicator of the character described wherein the cushioning material serving as the medicament carrier is of open cell formation, the exposed surface of which has secured thereto a thin resiliently flexible film of liquid-impermeable material so that the cushioning material is easily cleaned but is substantially as adaptable to the teeth as is the open cell material itself.

Another object of the invention is to provide a method of efficiently and accurately making a medicament applicator of the character described which lends itself to the use of mass production techniques.

These and other objects of the invention will become more apparent as the following description proceeds in conjunction with the accompanying drawings, wherein:

FIG. 1 is a perspective view of one form of the applicator;  
FIG. 2 is a sectional view taken on the line 2—2 of FIG. 1;  
FIG. 3 is a view similar to FIG. 1 of a second form of applicator;

FIG. 4 is a sectional view taken on the line 4—4 of FIG. 3;  
FIG. 5 is a view similar to FIG. 1 of a third form of applicator;

FIG. 6 is a sectional view taken on the line 6—6 of FIG. 5;  
FIG. 7 is an enlarged sectional view taken on the line 7—7 of FIG. 6;

FIG. 8 is a group perspective view illustrating the method of making the applicator; and

FIG. 9 is a view similar to FIG. 8 of a variant of the method.

Specific reference is now made to the drawings wherein similar reference characters are used for corresponding elements throughout.

This invention relates to means for readily and efficiently applying medicaments such as sodium fluoride, stannous fluoride, hydrogen peroxide, antibiotics, etc. to the teeth and/or gums for the treatment or prevention of dental caries, pyorrhea, gingivitis and other diseases. The means generally comprises a horseshoe-shaped flexibly resilient liquid-impermeable tray of channel cross-section with an inner cushioning material to serve as a medicament carrier whereby moderate pressure on the applicator will cause the medicament to spread and invest the teeth and/or gums.

With reference to FIGS. 1 and 2, the applicator comprises a tray or shell 10 formed in substantially U or horseshoe-shape and of channel cross-section thereby providing inner and outer flanges 12 and 14 connected by a web 16 and having open distal ends 18 and 20. The tray can be made by conventional injection molding techniques of liquid-impermeable materials such as polyethylene, polystyrene, ethylene-vinyl acetate copolymers of the type disclosed in U.S. Pat. No. 3,250,272 or of the type sold by Du Pont under the trademark

Alathon, vinyl coated paper, polyvinyl chloride, polyurethane, etc., the preferred thickness of the tray being in the order of magnitude of .010—.100 mm. Because of the nature of the materials from which the tray is made and the fact that it is relatively thin and of channel horseshoe construction it is flexibly resilient.

Coextensive with and secured in the interior of the tray is a medicament carrier 22 which is also substantially U or horseshoe-shaped and of channel cross-section to provide inner and outer portions 24 and 26 connected by a web 28 thereby forming a continuous tooth receiving channel 30 which extends from one distal end to the other of the tray. As will appear hereinafter the contacting surfaces of the carrier 22 and tray 10 are affixed to each other by suitable adhesion, the use of films with pressure sensitive adhesive surfaces or lamination.

The carrier 22 may be made of open cell or foam cushioning material shown in FIGS. 1 and 2 or closed cell cushioning material shown in FIGS. 3 and 4. Such materials for example as latex, polystyrene, polyurethane, or polyester may be employed. A good cushioning material of closed cell formation is Rubatex R-314-V, Grade VE (ASTM D-1667), a cellular vinyl-hycar product of the Rubatex Corp. of Bedford, Va. Polyurethane foam was found to be a good open cell material for use in making the carrier 22.

In use, measured amounts of the medicament are placed on the carrier at various spaced points along its length and the applicator is applied over the teeth with the teeth entering the channel 30. By applying moderate pressure on the tray against the teeth either by the fingers or biting against it, the cushioning material of the carrier will compress to spread the medicament and cause it to invest the teeth and/or gums. The applicator will be held in place for the length of time required in the treatment. With the closed cell cushioning material shown in FIGS. 3 and 4 more pressure is required to keep the applicator against the teeth but the applicator can be easily rinsed and cleaned for reuse. With the open cell or foam material shown in FIGS. 1 and 2, less pressure is required to keep the applicator against the teeth and because it offers less resistance to deformation it adapts more completely to the teeth upon compression. Rinsing and cleaning of this unit offers somewhat more difficulty.

The form of invention shown in FIGS. 5—7 combines the advantages of both the closed cell and open cell cushioning material used for the medicament carrier. Thus the carrier which is coextensive with the tray and of channel cross-section is made of a core of open cell or foam material 32. Its inner surface is secured by adhesion or lamination to the inner surface of the tray 10 as shown at 34. Its exposed or outer surface, *i.e.* the wall of the tooth receiving channel 30, is covered by a flexibly resilient liquid-impermeable film 36 which is secured to the foam by means preferably of a pressure sensitive adhesive 38 that coats the inner surface of the film. Any number of films can be used, such for example as Mylar, a polyethylene terephthalate film made by Du Pont, coated on one or both of its surfaces with a pressure sensitive adhesive formulated generally of a synthetic rubber base, such as butadiene, styrene, etc., a plasticizer such as dibutylphthalate and a tackifier such as the melamine or acrylic resins. The adhesive layer 34 may be in the form of a flexibly resilient film with pressure sensitive adhesive on both faces to effect adhesion of the foam 32 and tray 10 to each other along their inner surfaces. Similarly, the adhesive layer 38 may be a flexibly resilient film with pressure sensitive adhesive on both faces, in which case one face will serve to secure the film to the outer face of the foam whereas the other adhesive face will secure the liquid-impermeable resiliently flexible thin film 36, such as Mylar, polyethylene, etc.

When the applicator of FIGS. 5—7 is applied to the teeth, the carrier will compress and adapt to the teeth and/or gums substantially as does the foam carrier shown in FIGS. 1 and 2, but the medicament will be held on the liquid-impermeable resiliently flexible film 36.

In all the modifications of the applicator it will be seen that the distal ends 18 and 20 of the tray and 40 and 42 of the carrier are open. Thus the applicator can be used as a standard unit for application to teeth and jaws of varying sizes. The resilient flexibility of the entire unit will permit it to be readily accommodated to the teeth and the open distal ends of the unit can be snapped off to shorten the unit as required to comfortably and accurately receive the teeth.

Coming now to FIG. 8 showing the method of making the applicator, a flexibly resilient liquid-impermeable film 44 with pressure sensitive adhesive on both faces, as described hereinbefore, is secured upon one face 46 of a substantially flat piece of cushioning material, closed or open cell, of the type set forth hereinbefore. A substantially flat piece 50 of tray material of desired thickness is then secured upon the cushioning material via the exposed pressure sensitive adhesive layer of the film 44. If desired the tray piece 50 can be laminated to the cushioning carrier piece 48.

Thereafter, either in sheet form or die cut to a predetermined size and shape as shown in the figure to eliminate unnecessary gathering and trimming, the composite unit, *i.e.* 50, 48, is heated to soften the tray material 50 and is then placed on a male mold form or block 52 shaped to conform to the desired size and contour of the final applicator. The mold form is porous and operatively connected to a vacuum manifold 54 and when vacuum is applied the composite unit sets to the desired final product as shown in FIGS. 1—4. When a male mold form is used, the cushioning material 42 contacts the form. It is understood that a female mold form can also be used, in which case the tray material 50 will contact the mold form. To make the applicator shown in FIGS. 5—7, the same method can be carried out except that the film 36 is first applied to the undersurface 56 of the cushioning material. Thus a laminate can be formed having the tray material 50 and film 36 on the outside and a core of cushioning material 48 between them and this composite unit is then heated and vacuum formed to produce the final product.

A variant of the process is shown in FIG. 9. Here the composite unit of the cushioning material 48 and film 44 is made as described hereinbefore. The tray member 58 is preformed into the horseshoe-shaped channel member. By applying pressure manually or mechanically, on the preformed tray in the direction of the arrows, the tray will substantially flatten out except possibly for slightly raised ridges 60 and 62 corresponding to the corners of the tray where the web 16 joins the flange members 12 and 14. In this substantially flattened condition the tray 58 is pressed against the pressure sensitive adhesive surface 64 on the film 44. When the tray is released, its spring action causes it to assume its preformed condition in which the cushioning member 48 is drawn into the tray resulting in the final product as shown in FIGS. 1—4. Here again the final product shown in FIGS. 5—7 can be made by laminating the core of cushioning material 48 between the film or adhe-

sive layer 44 and the outer pliable liquid-impermeable film 36 before the tray 58 is flattened and held with pressure against the pressure sensitive adhesive 64.

While preferred embodiments of the invention have here been shown and described skilled artisans may make minor variation without departing from the spirit of the invention and the scope of the appended claims.

I claim:

1. An applicator for the treatment of teeth and/or gums with fluorides or other medicaments comprising a substantially U-shaped trough-like resiliently flexible tray of channel cross-section made of a liquid-impermeable material, a medicament carrier substantially coextensive therewith and also of channel cross-section, and means securing said carrier in said tray, said carrier being made of cushioning material so that when the applicator is applied with moderate pressure to the teeth, the carrier will resiliently deform and thereby cause the medicament to invest the teeth and/or gums, said means securing said carrier in said tray being a liquid-impermeable film having pressure sensitive adhesive on the opposite surfaces thereof, one surface contacting the inner surface of said tray, the other surface contacting the adjacent surface of said carrier.

2. The applicator of claim 1 wherein the distal ends of said tray and carrier are open.

3. The applicator of claim 1 wherein said cushioning material is of open cell foam formation.

4. The applicator of claim 1 and a resiliently flexible liquid-impermeable film secured upon the exposed surface of said foam.

5. The applicator of claim 1 and a liquid-impermeable flexible film adhered upon the exposed surface of said carrier, said carrier being made of an open cell foam texture.

6. The applicator of claim 1 wherein said cushioning material is of closed cell formation.

7. A method of making an applicator for the treatment of teeth and/or gums with fluorides or other medicaments comprised of securing a sheet of cellular plastic to a sheet of deformable liquid-impermeable plastic, to provide a composite unit, heating the composite unit to soften it, placing it against the male portion of a horseshoe-shaped member with the cellular plastic contacting the male portion, and draping and forming the composite unit around the male portion with a pressure differential across the male portion.

8. The method of claim 7 wherein the sheet of cellular plastic is secured to the sheet of liquid-impermeable plastic by lamination.

9. The method of claim 7 wherein the sheet of cellular plastic is secured to the sheet of liquid-impermeable plastic by pressure sensitive adhesive.

10. The method of claim 7 wherein the deformed unit is trimmed after removal from the male mold to form the final product.

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