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(71) Applicant: **ULTRADENT PRODUCTS, INC.** [US/US]; 505 West 10200 South, South Jordan, UT 84095 (US).

(72) Inventors: **ALLRED, Peter, M.**; 3136 West 13680 South, Riverton, UT 84065 (US). **JESSOP, Neil, T.**; 11538 Colchester Drive, Sandy, UT 84092 (US).

(74) Agents: **NYDEGGER, Rick, D.** et al.; Workman, Nydegger, 1000 Eagle Gate Tower, 60 East South Temple, Salt Lake City, UT 84111 (US).

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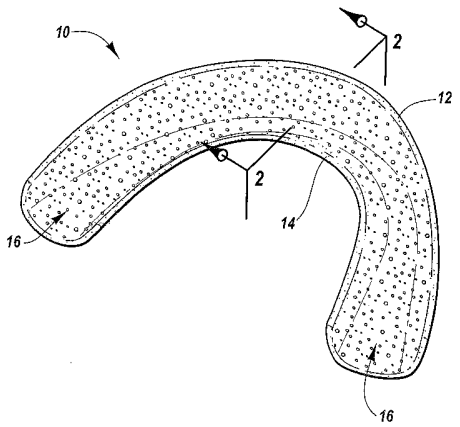
(54) Title: SUBTANTIALLY SOLID DENTAL BLEACHING COMPOSITIONS IN A TRAY-LIKE CONFIGURATION AND KITS AND METHODS THAT UTILIZE SUCH COMPOSITIONS



(57) Abstract: Dental bleaching compositions (10) are in the shape of a dental tray or traylike configuration (12, 14, 16). Shaped bleaching compositions (10) comprise a substantially solid dental bleaching composition that has increased adhesiveness to teeth when moistened with saliva or water. The shape of the dental bleaching composition (10) facilitates placement of the composition (10) over a person's teeth with substantially less manipulation compared to the use of initially flat bleaching strips. The substantially solid dental bleaching composition (10) becomes more adhesive when moistened with saliva or water, yet remains intact and coherent after the dental bleaching composition (10) is placed over a person's teeth during bleaching, particularly when used in combination with a moisture-resistant barrier. The result is that the moistened dental bleaching composition (10) is able to reliably adhere against a user's teeth during a bleaching procedure. The dental bleaching compositions (10) may be packaged together as a kit, optionally in combination with one or more dental desensitizing composition in the shape of a dental tray or having a tray-like configuration.

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SUBSTANTIALLY SOLID DENTAL BLEACHING COMPOSITIONS IN A TRAY-LIKE CONFIGURATION AND KITS AND METHODS THAT UTILIZE SUCH COMPOSITIONS

BACKGROUND OF THE INVENTION

1. The Field of the Invention

The present invention is in the field of dental bleaching compositions used to bleach a person's teeth. More particularly, the invention relates to a substantially solid dental bleaching composition in the shape of a dental tray or tray-like configuration that becomes more adhesive when moistened (*e.g.*, with saliva on a user's teeth), as well as methods and kits that utilize such bleaching compositions.

2. The Relevant Technology

Virtually all people desire white or whiter teeth. To achieve this goal, people either have veneers placed over their teeth or have their teeth chemically bleached. In the past, patients who desired to have their teeth bleached had to submit to conventional in-office bleaching techniques. The process generally involves: (1) making an alginate impression of the patient's teeth; (2) making a stone cast or model of the impression; (3) vacuum forming a dental tray from the model, usually from a heated sheet of thin ethyl vinyl acetate (EVA) material, and (4) trimming to exclude gingival coverage. This method results in a tray that is soft and flexible, that is customized to very accurately fit over the patient's teeth, and that is therefore very comfortable to wear. However, the process for making a customized tray is time consuming, often taking days or weeks before the customized tray is available to the patient, and the resulting tray can be expensive.

Because of the time and cost associated with customized trays, less time consuming and costly alternatives have been developed. Contrary to marketing campaigns, however, many alternatives have substantial disadvantages, primarily in terms of their effectiveness (or ineffectiveness) in actually bleaching teeth. They also have their own unique issues relating to ease of use, comfort and poor taste (bleaching compositions are, after all, placed directly into a person's mouth).

One alternative to customized dental trays are non-customized trays that approximate the shapes and sizes of a variety of users' dental arches. While non-customized dental trays can be used without the need for a professional customization

procedure by a dentist, such trays tend to be more bulky and less comfortable than custom-fitted trays. Dental Trays that can be self-customized (*e.g.*, so-called "boil and bite" trays) are somewhat more comfortable and better-fitting compared to non-custom trays but less comfortable than trays that are customized by a dentist.

Another alternative tooth bleaching method involves painting a bleaching composition directly onto the surfaces of a person's teeth to be bleached. An advantage of this procedure is that it eliminates the need to obtain a customized tray, or even a non-custom tray. The main disadvantage, however, is that the bleaching composition remains directly exposed to the person's saliva and disruptive forces and movements normally found within a person's mouth. The result is that a significant portion of the bleaching composition does not remain on the tooth where bleaching is desired. Instead, some or all of the composition can dissolve away into the person's saliva and/or be transferred to adjacent oral tissues. Because paint-on dental bleaching compositions, like all dental bleaching compositions, contain peroxide-based bleaching agents, irritation to soft oral tissues within the user's mouth and throat is a potential problem when using such compositions.

Yet another alternative tooth bleaching method involves placing a flexible bleaching strip over a user's tooth surfaces. Bleaching strips typically comprise a flexible plastic strip coated with a moist dental bleaching gel on the side of the strip facing the user's teeth. To install the bleaching strip, a portion of the bleaching strip is first placed over the front surfaces of the user's teeth, followed by folding the remainder of the strip around the occlusal edges of the teeth and back against a portion of the lingual surfaces. Like paint-on bleaching compositions, this procedure does not require the user to obtain a customized tray, or even a non-custom tray, into which a bleaching composition must be placed by the user prior to use. An advantage of bleaching strips over paint-on bleaching compositions is that bleaching strips include a barrier that, at least in theory, protects the dental bleaching gel from diffusing into the user's mouth.

In reality, however, because of the generally poor adhesion of bleaching strips to the user's teeth, coupled with their generally flimsy nature, it is often difficult for the user to maintain the bleaching strips in their proper position. Bleaching strips are prone to slip off the teeth through even minimal movement of the user's mouth, jaw

or tongue. Indeed, it is recommended that the user not eat, drink, smoke or sleep while wearing the bleaching strip. In practice, it is difficult to talk while maintaining the bleaching strips properly oriented over the teeth to be bleached.

Even if a user successfully maintains the bleaching strip in its proper position during the entire bleaching event, the flowable bleaching gel can diffuse into the person's saliva, potentially causing a poor taste in the user's mouth and possibly discomfort to soft oral and throat tissues. The tendency of the bleaching gel to diffuse into the user's mouth can be accelerated through even minimal shifts of the bleaching strip over the user's teeth, with each shift potentially exposing a new portion of the bleaching gel that remains adhered to the newly exposed surface of the user's teeth. In some cases, the bleaching strip can become so dislodged or mangled that it must be removed by the user and replaced with a fresh bleaching strip to complete the recommended bleaching time. This multiplies the cost and hassle of the bleaching strip method.

In practical terms, the use of bleaching strips can greatly inhibit even the simplest of activities that involve movement of the user's mouth or tongue, such as talking, smiling, making other facial expressions, or even swallowing (which normally occurs subconsciously throughout the day). Indeed, the time when a person's mouth and tongue are prone to move the least is at night while the person is sleeping. Unfortunately, it is recommended that bleaching strips not be used while sleeping, presumably to prevent accidental choking on an inadvertently dislodged bleaching strip. This only confirms the tendency of such bleaching strips to easily dislodge from a user's teeth.

Ultimately, the main impediment to successful bleaching is the failure of users to complete the prescribed bleaching regimen. If the bleaching apparatus is difficult to use, requires numerous repetitions to achieve observable results, or is simply uncomfortable or a hassle to wear, the user may simply give up and abort the bleaching process altogether. Thus, even if significant dental bleaching is possible using a particular bleaching product, it is less likely to occur where the inadequacies of the bleaching apparatus or method causes users to become discouraged before desired results are attained.

Tooth sensitivity is a common problem for many dental patients and can impede dental bleaching regimens due to patient discomfort and pain. Sensitivity may result from or be associated with the existence of a cavity, tooth or root fractures, gingival recession, exposed dentin, toothbrush abrasion, bleaching, attrition, erosion, grinding, or trauma from periodontal disease. Tooth sensitivity can become so uncomfortable that it may prevent a patient from eating or drinking certain foods, being outdoors in cold weather, or maintaining good oral hygiene practices. Tooth sensitivity is also a common complaint during dental bleaching regimens. Dental bleaching compositions, which typically comprise a peroxide bleaching agent, can cause tooth sensitivity and pain that, if left untreated, may cause the user to prematurely abort the bleaching process.

To relieve tooth sensitivity, there are currently many non-permanent treatment options available. The most common options include using desensitizing toothpastes, varnishes, gels, and rinses. These products may include, but are not limited to, desensitizing agents such as potassium nitrate, other potassium salts, citric acid, citrates, strontium chloride, stannous fluoride, and sodium fluoride.

Desensitizing dentifrices are a popular treatment option in treating sensitivity. To use desensitizing dentifrices, it is usually recommended that the patient use the dentifrice twice daily. However, results are not immediate. It usually takes an extended period of time (about 1-4 weeks) to be effective and to relieve sensitivity. The main reason for this is that people typically only brush their teeth for about 60 seconds or less, which translates into extremely limited contact time between the desensitizing agent and the person's teeth.

An alternative treatment involves the use of desensitizing gels that are applied using custom-fitted or non-customized trays, such as those mentioned above for bleaching teeth.

In view of the foregoing, there is an ongoing need for improved bleaching and desensitizing compositions that are simple and easy to use, that more reliably remain in position over the user's teeth, and that result in less diffusion of bleaching and/or desensitizing composition into a user's oral cavity. Such improvements would be expected to improve or encourage compliance by the user.

BRIEF SUMMARY OF THE PREFFERED EMBODIMENTS

The present invention generally relates to shaped dental bleaching compositions used to bleach a person's teeth, as well as methods and kits that utilize such bleaching compositions. Briefly summarized, the inventive dental bleaching compositions are in a substantially solid form and shaped like a dental tray or in tray-like configuration. The substantially solid dental bleaching composition becomes more adhesive to teeth when moistened (*e.g.*, by saliva or water). When placed over a person's teeth, the dental bleaching composition reliably adheres to the teeth, maintaining contact between the teeth to be bleached and a bleaching agent within the bleaching composition. The shaped bleaching composition is preferably used in combination with a barrier layer that protects the dental bleaching composition from ambient saliva or moisture found within the person's mouth. To the extent that a barrier layer is subsequently applied or attached to a shaped bleaching composition, the shaped bleaching composition may be considered to be an intermediate to a finished bleaching device comprising the bleaching composition and a barrier layer. Kits according to the invention may include multiple dental bleaching devices, optionally in combination with one or more dental desensitizing devices, described more fully below.

The optional barrier layer comprises a thin, flexible membrane formed from a moisture-resistant polymer material. Nevertheless, it is within the scope of the invention to provide barrier layers having any desired thickness or rigidity. In a preferred embodiment, the barrier layer comprises a thin layer of a polyolefin, polyester, polyurethane, or similar moisture-resistant material. The barrier layer may comprise a conventional dental tray, examples of which include both customized and non-custom dental trays. The barrier layer may be as simple as a layer of a moisture resistant material that is sprayed or painted on, applied by dipping, or otherwise applied to a substantially solid dental bleaching or desensitizing composition (hereinafter "treatment composition") in the form of a dental tray or that has a tray-like configuration.

The shaped bleaching composition comprises a substantially solid, coherent dental bleaching composition, as opposed to a liquid, gel, or dry particulate or powdery bleaching composition. As such, the substantially solid bleaching

composition does not run or flow. Compared to bleaching gels, the substantially solid and coherent bleaching composition better adheres to a person's teeth and does not readily diffuse into the surrounding oral cavity on its own, absent becoming diluted by saliva or moisture in a person's mouth. This, in turn, promotes better tooth whitening and patient compliance.

The substantially solid dental bleaching compositions according to the invention include at least one dental bleaching agent and at least one tooth adhesion agent. Preferred dental bleaching agents include solid complexes of hydrogen peroxide. Non-limiting examples of dental bleaching agents that are a solid complex of hydrogen peroxide are carbamide peroxide and sodium perborate, although it is within the scope of the invention to use other dental bleaching agents known in the art.

In one embodiment, the tooth adhesion agent advantageously remains substantially non-adhesive when the dental bleaching composition is in a dry or substantially solid condition but becomes adhesive to teeth when the dental bleaching composition is moistened with, *e.g.*, water or saliva. A non-limiting example of a suitable tooth adhesion agent is polyvinyl pyrrolidone (PVP), although it is within the scope of the invention to use other tooth adhesion agents known in the art.

The dental bleaching composition may include other components as desired to yield a final composition having desired properties. Examples of other components include, but are not limited to, plasticizers and humectants (*e.g.*, glycerin, sorbitol, and polyethylene glycol), volatile solvents (*e.g.*, water and alcohols), stabilizing agents (*e.g.*, EDTA), neutralizing agents, thickening agents (*e.g.*, fumed silica), desensitizing agents (*e.g.*, potassium nitrate), remineralizing agents (*e.g.*, sodium fluoride or other fluoride salts), antimicrobial agents (*e.g.*, chlorhexidine), antiplaque agents, anti-tartar agents, other medicaments, flavorants, sweeteners, and the like.

According to one embodiment, the dental bleaching composition is made by first forming a flowable liquid or gel composition that is later subsequently dried to form a substantially solid bleaching layer. This may be performed by heating or otherwise causing one or more volatile solvents to be driven off by evaporation, thus leaving behind a substantially solid bleaching composition. The drying process may

be performed before or after the bleaching composition is placed into contact with a barrier layer.

According to one embodiment, shaped dental bleaching compositions according to the invention can be made by spreading a flowable dental bleaching composition onto the surface of a large or continuous polymeric sheet. The polymeric sheet and bleaching composition are then heated, such as in a forced air oven, to drive off a substantial portion of the water or other solvent that was used to form the flowable dental bleaching composition in order to yield a substantially solid layer of bleaching composition. Thereafter, individual tray-like dental bleaching devices can be molded or stamped from the polymeric sheet coated with the substantially solid layer of bleaching composition and then separated as individual bleaching devices suitable for placement over a person's teeth. Such bleaching devices include a bleaching layer comprising a shaped dental bleaching composition according to the invention. Alternatively, the solid sheet of bleaching composition can be separated from the polymer sheet and molded, stamped or otherwise formed into a desired shape of a bleaching composition.

Alternatively, a flowable or substantially solid dental bleaching composition can be directly molded or shaped into a desired tray-like configuration comprising the bleaching layer. Alternatively, the flowable composition can be cast onto a forming surface and dried to form a substantially solid sheet of bleaching composition that is thereafter molded, stamped or otherwise formed into a desired shape. Thereafter, a barrier layer can be attached or applied to an outer surface of the bleaching layer. In one embodiment, a dental tray can be coated with a flowable dental bleaching composition, such as by painting or spreading, and then heated or allowed to dry at room temperature to form a shaped bleaching composition that is substantially solid.

The size and shape of dental bleaching devices according to the invention can be tailored to more readily fit a person's upper or lower dental arch. They may also be tailored to fit person's having differently sized or shaped dental arches. The dental bleaching devices are advantageously designed so as to substantially cover the front and lingual surfaces of the teeth to bleached. Bleaching both surfaces yields more esthetically appealing teeth. Moreover, bleaching both the front and lingual surfaces helps in bleaching the interproximal spaces between adjacent teeth. The dental

bleaching devices are advantageously flexible and adhesive so as to readily conform to a wide variety of differently-sized teeth and dental arches.

The dental bleaching compositions according to the invention are preferably in the shape of a dental tray having a front side wall, a rear side wall, and a trough between the front and rear side walls. Having the shape of a dental tray facilitates placement of the shaped dental bleaching composition over a person's teeth by minimizing the amount of manipulation that is necessary to obtain a good fit between the composition and the person's teeth. Dental bleaching compositions in the shape of a dental tray that become more adhesive when moistened with water or saliva are easier to install over a person's teeth than flat bleaching strips, as are bleaching devices that incorporate such compositions. In addition, dental bleaching devices that include the shaped dental bleaching composition are designed to more reliably remain in place over the person's teeth compared to conventional bleaching strips. The result is more effective tooth bleaching and better patient compliance.

According to one embodiment, the dental bleaching composition has a horseshoe shape and a U-shaped trough like a conventional bleaching tray. In another embodiment, the bleaching composition has an L-shaped profile or "trough". It will be appreciated, however, that dental bleaching compositions according to the invention can have any longitudinal profile or shape (*e.g.*, they can be straight or have any desired degree of longitudinal curvature from one end of the device to the other). The trough may have any desired cross-sectional shape (*e.g.*, the trough can be V-shaped, trapezoidal, rectangular, or other geometric shape).

To facilitate the ability of a dental treatment composition to conform to the various shapes and sizes among dental arches, the dental treatment composition may include mechanical features such as a notch within the front side wall, preferably within an edge near the center of the front side wall, and/or a notch within the rear side wall, preferably within an edge near the center of the rear side wall. Notches allow the tray-like bleaching composition to more easily conform to differently-sized dental arches. In this way, the dental bleaching composition can be designed so as to be "one-size fits all".

The dental bleaching compositions of the invention, as well as bleaching devices incorporating such compositions, can be designed to be worn for any desired

time period. Increasing the concentration of dental bleaching agent generally reduces the required bleaching time. Nevertheless, due to the extremely comfortable fit and reliable adhesion between the shaped dental bleaching composition and the person's teeth, it is possible to maintain such compositions against a person's teeth for extended periods of time in order to ensure even and thorough bleaching. Dental bleaching compositions according to the invention can be designed to be worn while, *e.g.*, talking, sleeping, eating, drinking, smiling, frowning, grimacing, yawning, coughing, smoking, or making virtually any facial expression or mouth contortion. This greatly decreases their intrusiveness into everyday activities compared to conventional bleaching strips, which do not reliably adhere to teeth, or intrusive bleaching devices such as large, bulky bleaching dental appliances.

The dental bleaching compositions, as well as devices incorporating such compositions, can be designed to be worn for as little as a few minutes or as long as several hours. By way of example, not limitation, a typical bleaching session of fast duration may last from about 10 to about 30 minutes. A bleaching session of intermediate duration may last from about 30 minutes to about 2 hours. A bleaching session of long duration, including professional bleaching or overnight bleaching while a person is sleeping, may last from about 2 hours to about 12 hours. Bleaching sessions may be repeated as many times as are needed to obtain a desired degree of whitening. In some cases, a clinical whitening effect has been observed after only 1-3 whitening sessions. A typical bleaching regimen will preferably include 1-20 bleaching sessions, more preferably 2-15 bleaching sessions, and most preferably 3-10 bleaching sessions.

For convenience of use, multiple dental bleaching compositions, as well as bleaching devices incorporating such compositions, may be packaged together and sold as a kit. In one embodiment, the number of dental bleaching compositions or devices provided with each kit can equal the number of sessions that represent a prescribed bleaching regimen. To efficiently utilize the space within a kit package, multiple dental bleaching compositions or devices can be stacked and interested together. The dental bleaching compositions or devices can be sealed collectively or individually as desired. The bleaching composition may contain a removable protective layer on its interior surface to protect it from contamination or moisture,

both of which can possibly cause premature decomposition of the peroxide bleaching agent. It is within the scope of the invention to provide barrier layers and the inventive shaped bleaching compositions that are initially separate and that are brought together by the end user. For example, the shaped bleaching composition may be a dry or substantially solid insert that is placed into a customized or non-custom bleaching tray, that is coated with an initially flowable barrier material, or that is covered with a flexible barrier sheet.

The present invention also relates to kits and methods for bleaching and desensitizing teeth. The dental bleaching compositions according to the invention may be used together with a dental desensitizing composition in order to effectively bleach a person's teeth while eliminating, or at least reducing, pain and discomfort that may be caused by tooth bleaching. The dental desensitizing compositions within such kits are substantially solid and, like the substantially solid dental bleaching compositions, becomes more adhesive to teeth when moistened (*e.g.*, by saliva or water). The desensitizing compositions may be manufactured in the same way as the dental bleaching compositions, as described above, except that an initially flowable precursor desensitizing composition is used to form the substantially solid desensitizing composition.

For convenience of use, one or more dental bleaching compositions and one or more desensitizing compositions can be packaged together and sold as a kit. In one embodiment, the number of dental bleaching compositions provided with each kit can equal the number of sessions that represent a prescribed bleaching regimen. An appropriate number of desensitizing compositions may also be provided with the kit in order to treat tooth sensitivity. The number of desensitizing compositions may be tailored depending on need (*i.e.*, whether or not the user is prone to having sensitive teeth). Multiple bleaching and desensitizing compositions can be stacked and interested together. They can be sealed collectively or individually as desired. They may contain a removable protective layer on their interior surfaces to protect the active treatment layer from contamination or moisture. They may optionally include barrier layers. It is within the scope of the invention to provide barrier layers, bleaching compositions and desensitizing compositions that are initially separate and that are brought together by the end user. The bleaching and/or or desensitizing

compositions may be a dry or substantially solid insert or it may be a liquid or gel that is applied to the barrier and allowed to dry prior to placement of the finished dental treatment device over the person's teeth.

The dental bleaching and desensitizing compositions can be used at any time and in any order in order to bleach and desensitize teeth in a desired manner. By way of example and not limitation, a person with very sensitive teeth can utilize one or more desensitizing compositions according to the invention as needed to relieve or prevent sensitivity before starting the bleaching regimen and in between bleaching sessions as needed to prevent or relieve tooth sensitivity. A person with moderately sensitive teeth might, for example, alternate between bleaching and desensitizing as desired to bleach teeth while minimizing or preventing sensitivity. A person who is not prone to having sensitive teeth may, for example, use the desensitizing compositions periodically as needed to relieve sensitivity or discomfort that may arise, if at all.

These and other advantages and features of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

To further clarify the above and other advantages and features of the present invention, a more particular description of the invention will be rendered by references to specific embodiments thereof, which are illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. The invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

Figure 1 is a perspective view of an exemplary dental bleaching (or desensitizing) composition according to the invention that is substantially solid and that is in the shape of a dental tray comprising a front side wall, a rear side wall, and a trough between the front and rear side walls;

Figure 2 is a cross-sectional view of the shaped dental bleaching (or desensitizing) composition depicted in Figure 1;

Figure 3 illustrates the shaped dental bleaching (or desensitizing) composition of Figure 1 contained within a sealed protective package having a peelable cover;

Figure 4 is a perspective view of an exemplary shaped dental bleaching (or desensitizing) composition that is similar to the bleaching composition depicted in Figure 1, but that further includes a terminal side wall on each longitudinal end;

Figure 5 is a perspective view of an exemplary shaped dental bleaching (or desensitizing) composition having an L-shaped trough and a curved longitudinal profile;

Figure 6 is a perspective view of an exemplary shaped dental bleaching (or desensitizing) composition having a U-shaped trough and a substantially straight longitudinal profile;

Figure 7 is a perspective view of an exemplary shaped dental bleaching (or desensitizing) composition having a V-shaped trough and a curved longitudinal profile;

Figure 8 illustrates a person placing a dental bleaching or desensitizing composition according to the invention over the upper dental arch; and

Figure 9 illustrates a person placing a dental bleaching or desensitizing composition according to the invention over the lower dental arch, with a dental bleaching or desensitizing composition already placed over the upper dental arch.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

I. INTRODUCTION AND DEFINITIONS

The present invention generally relates to shaped dental bleaching compositions used to bleach a person's teeth, as well as kits and methods that utilize such bleaching compositions. The shaped dental bleaching compositions are in a substantially solid form and become more adhesive to teeth when moistened with water or saliva. When placed over a person's teeth, the dental bleaching composition reliably adheres to the teeth, maintaining contact between the teeth to be bleached and a bleaching agent within the bleaching composition. A barrier layer may be provided that protects the dental bleaching composition from diffusing away from the person's teeth as a result of ambient saliva or moisture found within the person's mouth.

The dental bleaching compositions may optionally be used in combination with dental desensitizing compositions to prevent or treat tooth sensitivity. Such

desensitizing compositions may also include a moisture-resistant barrier layer and become become more adhesive to teeth when moistened with water or saliva.

The shaped bleaching and desensitizing compositions are more adhesive to teeth than conventional bleaching strips. The shaped dental bleaching and desensitizing compositions are also less intrusive than bulky, over-the-counter, non-custom or boil and bite dental trays. In some ways they are as reliable, or even more reliable, than custom-fitted dental trays in maintaining a dental bleaching agent or desensitizing agent against a person's teeth. In some cases, they are also as comfortable, or even more comfortable, than custom-fitted trays.

The term "barrier layer", as used herein, refers to one or more layers of a moisture-resistant material that can be used to protect a shaped bleaching or desensitizing composition from ambient moisture and saliva found within a person's mouth when the dental bleaching or desensitizing composition is placed over the person's teeth. The barrier layer may also serve to protect the bleaching or desensitizing composition from moisture or other contaminants during storage and prior to use. The barrier layer may be in any desired form including, but not limited to, a sheet laminated to a surface of the bleaching or desensitizing composition, a coating applied to a pre-shaped bleaching or desensitizing layer, or a dental treatment tray.

The term "shaped bleaching composition", as used herein, refers to a dental bleaching composition that has been formulated or processed so as to be substantially solid, coherent, and non-flowable. The term "shaped desensitizing composition", as used herein, refers to a dental desensitizing composition that has been formulated or processed so as to be substantially solid, coherent, and non-flowable.

The term "substantially solid", as used herein, refers to a dental bleaching or desensitizing composition that is in a solid or semi-solid condition so that it can be handled and placed against a person's teeth much like a dental tray. In one aspect, a "substantially solid" bleaching or desensitizing composition can be characterized as a continuous or cohesive mass that does not readily flow or separate when subjected to gravitational forces and which cannot be readily expressed through a syringe outlet or other similarly-sized opening or orifice. Thus, the term "substantially solid" excludes runny bleaching liquids, viscous bleaching liquids, and even thick bleaching or

desensitizing gels that are able to flow when subjected to gravity and/or which can be readily expressed through a syringe outlet or other similarly-sized opening or orifice. The term "substantially solid", when used in the context of a bleaching or desensitizing composition or layer, also excludes dry particulate bleaching or desensitizing compositions or powders because dry particulates and powders readily flow when subjected to gravity and/or are readily separated (*i.e.*, the particles as a whole have little or no internal cohesion). Moreover, powders or particulates, when viewed as a whole, as not "shaped", coherent, or solid.

One characteristic of "substantially solid" bleaching or desensitizing compositions according to the invention is that they become more adhesive when an exposed surface thereof is moistened with, *e.g.*, saliva or water. When moistened, the surface of the bleaching or desensitizing composition turns into a sticky material that is able to more strongly adhere to teeth compared to a substantially solid bleaching or desensitizing composition that has not been moistened. The composition at the surface may become a viscous liquid, paste or gel, at least temporarily, depending on the amount of moisture that is applied to the surface of the "substantially solid" bleaching or desensitizing composition. Nevertheless, the consistency of the moistened surface can remain "substantially solid" depending on the degree of initial moistening, or it can stiffen and even revert back to being "substantially solid" as the initial quantity of surface moisture diffuses into a remaining portion of the "substantially solid" bleaching or desensitizing composition over time (*e.g.*, during a bleaching or desensitizing procedure in which the bleaching or desensitizing composition is protected from saliva and ambient moisture in a person's mouth by a water-proof barrier layer).

The term "dental tray", as used herein, refers to any article of manufacture or device having a tray-like shape so as to facilitate placement of the device or shaped structure over at least a portion of a person's dental arch. A "dental tray" or "tray-like" device includes a front side wall configured to engage front surfaces of a person's teeth when in use, a rear side wall extending laterally from the front side wall, either abruptly by one or more distinct angles or non-abruptly by a curved transition, configured to engage lingual surfaces of the person's teeth, and a trough between said front and rear side walls. A "dental tray" may be configured so that a

portion of the front side wall, rear side wall, or a transition portion thereof engages the incisal or occlusal edges of the person's teeth when in use. The dental tray may be curved or straight in a longitudinal dimension.

The term "trough", as used herein, refers to the region that is at least partially bounded by the front side wall, the rear side wall, and a plane or imaginary curved dome extending from an upper edge of the front side wall and an upper edge of the rear side wall. Thus, a "trough" can theoretically exist whenever the front and rear side walls have a space therebetween and are laterally offset by an angle of less than 180°. In practice, the front and rear side walls will be offset by an angle that is preferably less than about 150°, more preferably less than about 120°, and most preferably less than about 90°.

In the case of a trough having a U-shaped or rectangular cross section, at least a portion of the front and rear side walls may be substantially parallel (*i.e.*, be offset by an angle of approximately 0°). In the case of a trough having a V-shaped or trapezoidal cross section, at least a portion of the front and rear side walls may be offset by an acute angle (*i.e.*, by an angle between 0-90°). In the case of a trough having an L-shaped cross section, at least a portion of the front and rear side walls will be offset by an angle centered around approximately 90° (*e.g.*, by an angle in a range of about 70° to about 110°). Thus, a trough having an L-shaped cross section can be a subset or slight variation of a trough having a V-shaped cross section.

The terms "longitudinal", "longitudinal dimension" and "longitudinal profile", as used herein when used to refer to a dental tray, dental treatment device, or shaped bleaching composition, shall refer to the lengthwise dimension of the tray, device, or shaped composition. The tray, device or shaped bleaching composition may be straight in the "longitudinal dimension" or it may be horseshoe-shaped or otherwise "longitudinally curved" in the longitudinal dimension so as to approximate the curvature of a person's dental arch, or at least facilitate placement of the tray, device, or shaped composition over the dental arch.

The term "molecular weight", as used herein, refers to number average molecular expressed in Daltons unless otherwise specified.

II. DENTAL BLEACHING DEVICES

The shaped dental bleaching compositions can exist alone or in combination with a barrier layer as part of a dental bleaching device. Dental bleaching devices typically include a shaped bleaching layer that becomes more adhesive to teeth when moistened by, *e.g.*, saliva or water, and a moisture-resistant barrier layer that protects the bleaching layer from ambient moisture within a person's mouth during use. Following are preferred examples of materials and characteristics of barrier layers and bleaching compositions or layers according to the invention.

A. Barrier Layers

According to one embodiment, the barrier layer comprises a thin, flexible membrane formed from a moisture-resistant polymer material. In a preferred embodiment, the barrier layer comprises a thin, flexible layer of a polyolefin or similarly moisture-resistant material, such as wax, metal foil, paraffin, ethylene-vinyl acetate copolymer (EVA), ethylene-vinyl alcohol copolymer (EVAL), polycaprolactone (PCL), polyvinyl chloride (PVC), polyesters, polycarbonates, polyamides, polyurethanes or polyesteramides. Such materials may be provided in the form of large, flat, flexible sheets to which the bleaching layer is applied. Alternatively, such sheets may be applied or attached to an existing bleaching layer comprising a substantially solid dental bleaching composition.

Notwithstanding the foregoing, it is within the scope of the invention to provide barrier layers having any desired material, thickness or rigidity so long as the barrier layer provides at least some moisture protection relative to the shaped bleaching composition. The barrier layer may comprise a conventional dental tray, examples of which include both customized and non-custom dental trays. The barrier layer may be as simple as a layer of a moisture resistant material that is sprayed or painted on, applied by dipping, or otherwise applied to an existing shaped bleaching composition in the form of a dental tray or that has a tray-like configuration.

Examples of suitable polyolefins for use in making the barrier layer include, but are not limited to, polyethylene (PE), high density polyethylene (HDPE), low density polyethylene (LDPE), ultra low density polyethylene (ULDPE), polypropylene, and polytetrafluoroethylene (PTFE) (*e.g.*, TEFLON). An example of a suitable polyester for use in making the barrier layer includes, but is not limited to,

polyethylene terephthalate (PET), an example of which is MYLAR, sold by DuPont. An example of a suitable polyurethane barrier material is a polyurethane film manufactured by ArgoTech, which is located in Greenfield, Massachusetts. Plasticizers, flow additives, and fillers known in the art can be used as desired to modify the properties of any of the foregoing polymers used to form the barrier layer.

As will be discussed below, some dental bleaching compositions will be more adhesive to polymer materials comprising the barrier layer than others, often depending on the tooth adhesion agent that is used. It has been found that, as between polyethylene, paraffin and polyethylene terephthalate, substantially solid dental bleaching compositions tend to adhere more strongly to polyethylene terephthalate, particularly MYLAR.

It is also within the scope of the invention to utilize barrier layers that are formed onto a surface of a previously formed bleaching layer, such by adhering a sheet or tray-like barrier layer to the shaped bleaching composition. Alternatively, the barrier layer may itself be initially flowable and later hardened, such as a lacquer that contains a barrier material (*e.g.*, a cellulosic ether, cellulose acetate, wax, plastic, polyvinyl acetate, polyvinyl alcohol, or shellac) dissolved in one or more solvents that are later removed; a chemical or light-cure material (*e.g.*, a methacrylate or acrylate resin); or a thermoplastic melt (*e.g.*, any thermoplastic resin). Examples of useful cellulosic ethers that can be used to form a barrier layer include, but are not limited to, ethyl cellulose, propyl cellulose, isopropyl cellulose, butyl cellulose, *t*-butyl cellulose, and the like.

B. Shaped Bleaching Compositions and Layers

Prior to being moistened in preparation for or during use, the bleaching layer within a dental bleaching device comprises a substantially solid and coherent dental bleaching composition shaped as a dental tray or having a tray-like configuration, as opposed to an amorphous liquid, an amorphous flowable gel, or an amorphous dry powder or particulate bleaching composition. Providing a substantially solid and coherent bleaching layer better maintains the bleaching composition between the barrier layer and the teeth being bleached instead of diffusing into the surrounding oral cavity, as compared to conventional bleaching gels that are loaded into customized or non-customized dental trays or that are applied using bleaching strips.

This, in turn, promotes better tooth whitening and reduces irritation to surrounding oral tissues and/or at least some of the bad taste normally associated with dental bleaching.

Substantially solid, shaped dental bleaching compositions according to the invention include at least one bleaching agent and at least one tooth adhesion agent. In a preferred embodiment, the bleaching agent is dispersed within a substantially solid matrix comprising the tooth adhesion agent. Following are preferred bleaching agents and tooth adhesion agents, as well as other components that may be included as desired.

1. Bleaching Agents

A common dental bleaching agent that is known to bleach teeth and that has been found to be safe for oral use is hydrogen peroxide. However, hydrogen peroxide does not itself exist free in nature, but only as an aqueous solution or as a complex. Preferred dental bleaching agents comprise complexes of hydrogen peroxide because they are more stable than aqueous hydrogen peroxide, which tends to be unstable when heated, especially when water is removed by evaporation.

Non-limiting examples of complexed hydrogen peroxide include carbamide peroxide and metal perborates. Other bleaching agents that can be used to bleach teeth include, but are not limited to, metal percarbonates, peroxides, chlorites, and hypochlorites, peroxy acids, and peroxy acid salts.

Bleaching agents within the shaped dental bleaching compositions according to the invention can have any desired concentration, *e.g.*, between 1-90% by weight of the substantially solid dental bleaching composition. The concentration of the dental bleaching agent can be adjusted depending on the intended treatment time for each bleaching session. In general, the shorter the treatment time, the more bleaching agent will be added to accelerate dental bleaching so as to effect bleaching in a shorter time period.

The one or more bleaching agents are preferably included in an amount in a range of about 5% to about 80% by weight of the substantially solid dental bleaching composition, more preferably in a range of about 10% to about 60% by weight of the substantially solid dental bleaching composition, and most preferably in a range of

about 20% to about 50% by weight of the substantially solid dental bleaching composition.

2. Tooth Adhesion Agents

The tooth adhesion agent may comprise any known tackifying agent that is substantially non-adhesive, or less adhesive, when the dental bleaching composition is substantially dry but which becomes more adhesive to teeth when the dental bleaching composition is moistened with, *e.g.*, water or saliva. A presently preferred tooth adhesion agent is polyvinyl pyrrolidone (PVP). PVP polymers have been found to provide excellent adhesion to polymer barrier layers made from PE, PET and paraffin, to be substantially non-adhesive when the dental bleaching composition is dry to the touch, and to have superior adhesion to teeth when a surface of a substantially solid dental bleaching composition is moistened with saliva or water.

Non-limiting examples of polyvinyl pyrrolidone polymers that have been used in formulating bleaching compositions according to the invention include Kollidon 30, a polyvinyl pyrrolidone polymer sold by BASF having a molecular weight of 50,000, Kollidon VA 60, a polyvinyl pyrrolidone polymer having a molecular weight of 60,000, and Kollidon 90 F, a polyvinyl pyrrolidone polymer having a molecular weight of 1.3 million. Because PVP polymers having widely varying molecular weights have been found to provide similar adhesion and wetting properties, it is believed that PVP polymers of any molecular weight, at least those having a molecular weight between 50,000 and 1.3 million, will be useful in formulating substantially solid bleaching compositions according to the invention.

Other tooth adhesion agents that may be used in addition to, or instead of, PVP within the scope of the invention include, but are not limited to, carboxypolymethylene (*e.g.*, CARBOPOL, sold by Novean, Inc.), polyethylene oxide (*e.g.*, POLYOX, made by Union Carbide), polyacrylic acid polymers or copolymers (*e.g.*, PEMULEN, sold by Novean, Inc.), polyacrylates, polyacrylamides, copolymers of polyacrylic acid and polyacrylamide, PVP-vinyl acetate copolymers, carboxymethylcellulose, carboxypropylcellulose, polysaccharide gums, proteins, and the like.

Although polyethylene oxide polymers comprises a less preferred tooth adhesion agent, it has been found that a polyethylene oxide polymer having a

molecular weight of 1 million provides better adhesion to barrier layers such as MYLAR than a polyethylene oxide polymer having a molecular weight of 100,000.

The one or more tooth adhesion agents are preferably included in an amount in a range of about 10% to about 90% by weight of the substantially solid dental bleaching composition (exclusive of any bound water or other solvent), more preferably in a range of about 20% to about 80% by weight of the substantially solid dental bleaching composition, and most preferably in a range of about 40% to about 75% by weight of the substantially solid dental bleaching composition.

3. Other Components

The shaped dental bleaching composition may include other components as desired to yield a composition having desired properties. Examples of other components include, but are not limited to, plasticizers and humectants (*e.g.*, glycerin, sorbitol, and polyethylene glycol), volatile solvents (*e.g.*, water and alcohols, such as ethanol), stabilizing agents (*e.g.*, EDTA), neutralizing agents (*e.g.*, sodium hydroxide), thickening agents (*e.g.*, fumed silica), desensitizing agents (*e.g.*, potassium nitrate, other potassium salts, citric acid, citrates, and sodium fluoride), remineralizing agents (*e.g.*, sodium fluoride, stannous fluoride, sodium monofluorophosphate, and other fluoride salts), antimicrobial agents (*e.g.*, chlorhexidine, troclosan, and tetracycline), antiplaque agents, anti-tartar agents (*e.g.*, pyrophosphates salts), other medicaments, flavorants, sweeteners, and the like.

When water is used as a solvent when manufacturing shaped bleaching composition according to the invention and then driven off by evaporation to yield a substantially solid composition, it is postulated that a significant amount of water remains bound or associated with the hydrophilic components within the bleaching composition, including the dental bleaching agent, the tooth adhesion agent, and any polyols added as humectants. Although the amount of residual water has not yet been determined, it is believed that approximately 10% of the water added initially remains after the initially flowable dental bleaching composition is dried sufficiently to yield a substantially solid bleaching composition.

C. Characteristics of Dental Bleaching Compositions and Bleaching Devices Incorporating such Compositions

Dental bleaching compositions according to the invention, as well as bleaching devices incorporating such compositions, are preferably in the shape of a dental tray having a front side wall, a rear side wall, and a trough between the front and rear side walls. Having the shape of a dental tray facilitates placement of the dental bleaching composition or device over a person's teeth by reducing the amount of manipulation that is necessary to obtain a good fit between the composition or device and the person's teeth.

Dental bleaching compositions and devices that are in the shape of a dental tray and that comprise a shaped bleaching composition that becomes more adhesive when moistened with water or saliva are easier to install over a person's teeth compared bleaching strips or patches, which are initially flat and which must be manipulated so as to wrap the initially flat strip or patch around the occlusal or incisal edges of the teeth in order to cover the front and lingual tooth surfaces. In addition, the inventive dental bleaching compositions and devices are designed to more reliably adhere and remain in place over the person's teeth compared to conventional bleaching strips, which employ a dental bleaching gel that is already flowable prior to placing the bleaching strip over a person's teeth to be bleached. The result is more effective tooth bleaching and better patient compliance. In contrast to conventional bleaching strips, which are not recommended for use while a person eats, drinks, smokes or sleeps, dental bleaching compositions and devices according to the invention can be designed so as to be worn while talking, sleeping, eating, drinking, smiling, frowning, grimacing, yawning, coughing, smoking, or making virtually any facial expression or mouth contortion.

According to one currently preferred embodiment, the dental bleaching composition, as well as bleaching devices incorporating such compositions, have a horseshoe shaped longitudinal profile and has a trough with a U-shaped cross section, much like a conventional bleaching tray. A shaped bleaching composition in the form of a dental tray device is depicted in Figures 1 and 2. It should be understood that the shaped compositions shown in the drawings may also be understood to represent

dental desensitizing compositions. In such cases, the dental bleaching agent is augmented or replaced with a desensitizing agent.

Figure 1 is a perspective view of a dental bleaching composition 10 having a front side wall 12 and a rear side wall 14 that together have a generally horseshoe shape in a longitudinal dimension and that define a trough 16 having a generally U-shaped cross section. The U-shaped cross section of the trough is seen even more clearly in Figure 2.

The shaped bleaching composition 10 may further include a barrier layer (not shown), preferably comprising a moisture-resistant material, adjacent to an outer surface 18 of the dental bleaching composition 10. As best seen in Figure 2, the bleaching composition 10 includes an exterior surface 18 and an interior bleaching surface 20 designed to directly contact a person's teeth when the dental bleaching device 10 is in use. An upper edge 22 of the front side wall can be designed so as to terminate at or shy of the gingival margin of a person's dental arch when in use.

In order to protect a dental bleaching composition according to the invention from contaminants during storage and prior to use, the dental bleaching composition can be packaged within a sealed container or package. As illustrated in Figure 3, the dental bleaching composition 10 can be sealed within a protective package 30 that includes a rigid support layer 32 and a peelable cover 34. When it is desired to use the dental bleaching composition 10, including optionally forming a dental bleaching device therefrom, the peelable cover 34 is removed and the bleaching composition 10 is removed or separated from the support layer 32. In addition to, or instead of, the protective package 30, the dental bleaching composition 10 may alternatively include a removable protective layer (not shown) that is temporarily placed adjacent to the interior bleaching surface 26 of the bleaching layer 20. When it is desired to use the dental bleaching device 10, the removable protective layer is removed so as to expose the interior bleaching surface 20.

Figure 4 illustrates a shaped dental bleaching composition 40 that is a variation of the U-shaped dental bleaching composition 10 of Figure 1. The main difference is that each longitudinal end 42 of the dental bleaching composition 40 is raised so as to at least partially enclose the last tooth on each side of a person's dental arch when the bleaching composition 40 is in use.

Figure 5 illustrates an alternative embodiment of a shaped dental bleaching composition 50 according to the invention that is L-shaped. More particularly, the dental bleaching composition 50 includes a front side wall 52 and a rear side wall 54 extending laterally from the front side wall 52 so as to form a trough 56 having an approximate L-shaped cross section. The L-shaped bleaching composition 50 of Figure 5 is somewhat easier to initially place over a person's dental arch compared to the U-shaped bleaching compositions of Figures 1-4. This is due to the approximately planar orientation of the rear side wall 54 relative to the occlusal or incisal edges of a person's teeth when the front side wall 52 of the dental bleaching composition 50 is initially placed and adhered against the front surfaces of a person's teeth. On the other hand, more manipulation of an L-shaped composition is generally required to form and adhere the rear side wall 54 against the lingual surfaces of the person's teeth as a result of the greater initial offset angle between the front side wall 52 and rear side wall 54. However, the ability of dental bleaching compositions according to the invention to adhere to tooth surfaces almost immediately, or within a few seconds, after being wetted facilitates the process of conforming the front side wall 52 and rear side wall 54 to the person's tooth surfaces.

In the case of the dental bleaching composition 50 having an L-shaped cross section, it may be more correct to say that the rear side wall 54 extending laterally from the front side wall 52 is really a bottom wall rather than a rear side wall. Nevertheless, because this erstwhile "bottom wall" of an L-shaped bleaching composition or device is folded back against the lingual tooth surfaces during use, it can be readily seen that a bleaching composition or device having an L-shaped trough is merely a variation of a composition or device having a V-shaped trough. Thus, for purposes of this disclosure and the appended claims, the side wall 54 shall constitute, and fall within the definition of, a "rear side wall".

To facilitate the ability of a dental treatment composition to conform to the varying shapes and sizes among dental arches, the dental treatment composition may include mechanical features such as one or more notches within the front or rear side walls. As shown in Figure 5, the dental bleaching composition 50 includes a notch 58 in an outer edge near the center of the front side wall 52 and a notch 59 in an outer edge near the center of the rear side wall 54. Notches 58 and 59 allow the tray-like

bleaching composition to more easily spread open or compress when being conformed to differently-sized dental arches. In this way, the dental bleaching composition 50 can more easily be a "one-size fits all" device.

Figure 6 depicts an alternative embodiment of a shaped dental bleaching composition 60 according to the invention, which includes a front side wall 62 and a rear side wall 64 that define a U-shaped trough 66. Instead of being horseshoe shaped like the dental bleaching compositions of Figures 1-5, or otherwise having a curved longitudinal profile, the dental bleaching composition 60 of Figure 6 has a substantially straight or linear longitudinal profile.

Figure 7 depicts yet another alternative embodiment of a shaped dental bleaching composition 70 according to the invention. The dental bleaching composition 70 includes a front side wall 72 and a rear side wall 74 that define a V-shaped trough 76 and a curved longitudinal profile. The main difference between the V-shaped bleaching composition 70 of Figure 7 and the L-shaped bleaching composition 50 of Figure 5 is the angle at which the front and rear side walls are laterally offset from each other.

Notwithstanding the foregoing examples, it will be appreciated that dental bleaching compositions according to the invention can have any longitudinal shape (*e.g.*, they can have a straight or curved longitudinal profile from one end to the other). The front and rear side walls may define a trough of any desired cross-sectional shape (*e.g.*, the trough can be trapezoidal, rectangular, or any other desired geometric shape).

The size and shape of dental bleaching compositions according to the invention, as well as bleaching devices incorporating such compositions, can be tailored to more readily fit either a person's upper dental arch or lower dental arch. They can be sized so as to bleach all or merely a subset of a person's teeth. The dental bleaching compositions or devices may be sufficiently adhesive and flexible so as to readily conform to a wide variety of differently-sized teeth and dental arches. The dental bleaching compositions or devices are advantageously designed so as to substantially cover the front and lingual surfaces of the teeth to bleached. Bleaching both surfaces yields more esthetically appealing teeth, although it is certainly within the scope of the invention to bleach more of one surface than another. Bleaching the

front and lingual surfaces helps to bleach the interproximal spaces between adjacent teeth.

In general, the thickness of the barrier layer and/or the shaped bleaching composition within a bleaching device can be adjusted to yield a dental bleaching device having a desired strength and flexibility. In order for the barrier layer to remain flexible so as to conform to a person's teeth, the barrier layer will generally have a thickness ranging from about 0.025 mm to about 1.5 mm.

The shaped bleaching composition will generally have a thickness ranging from about 0.1 mm to about 3 mm. The thickness of the shaped bleaching composition can also be selected depending on the intended duration of each bleaching session. In general, increasing the thickness of the bleaching composition will provide a longer or more sustained release of active dental bleaching agent. By way of example, for short wear times, the shaped bleaching composition will preferably have a thickness ranging from about 0.1 mm to about 0.5 mm. For intermediate wear times, the shaped bleaching composition will preferably have a thickness ranging from about 0.5 mm to about 2 mm. For professional use and for overnight bleaching, the shaped bleaching composition will preferably have a thickness ranging from about 2 mm to about 3 mm.

III. DENTAL DESENSITIZING DEVICES

It is within the scope of the invention to utilize dental desensitizing compositions or devices in combination with dental bleaching compositions or devices in order to relieve tooth sensitivity that may occur, or that may be exacerbated, as a result of dental bleaching. Such dental desensitizing compositions or devices are substantially similar to the dental bleaching compositions or devices according to the invention except that they include a desensitizing agent instead of, or in addition to, the dental bleaching agent (*e.g.*, at least a portion of the bleaching agent is replaced by a dental desensitizing agent). In most other respects they may be virtually identical to dental bleaching compositions or devices according to the invention. The drawings exemplifying dental bleaching compositions described above apply equally well to dental desensitizing compositions in many cases.

Exemplary and preferred barrier layers, tooth adhesion agents, and other components include those set forth above with respect to dental bleaching compositions and devices. Preferred thicknesses for the barrier and desensitizing compositions within desensitizing devices are the same as those given above with respect to the barrier layer and bleaching composition, respectively, within the inventive bleaching compositions or devices.

A common dental desensitizing agent that is known to desensitize teeth and that has been found to be safe for oral use is potassium nitrate. Other desensitizing agents that can be used to desensitize teeth include, but are not limited to, other potassium salts, citric acid, citrates, strontium chloride, stannous fluoride, and sodium fluoride.

Desensitizing agents within substantially solid dental desensitizing compositions according to the invention can have any desired concentration, *e.g.*, between 0.01-50% by weight of the substantially solid dental desensitizing composition. The concentration of the dental desensitizing agent can be adjusted depending on the intended treatment time for each desensitizing session. In general, the shorter the treatment time, the more desensitizing agent will be added to accelerate dental desensitizing so as to effect desensitizing in a shorter time period.

In a preferred embodiment, potassium nitrate is the preferred desensitizing agent and is preferably included in an amount in a range of about 0.01 to about 50% by weight of the substantially solid dental desensitizing composition, more preferably in a range of about 0.1% to about 25% by weight of the substantially solid dental desensitizing composition, and most preferably in a range of about 0.5% to about 10% by weight of the substantially solid dental desensitizing composition.

Embodiments including other desensitizing agents instead of potassium nitrate, such as but not limited to, other potassium salts, citric acid, citrates, strontium chloride, sodium fluoride, and stannous fluoride, preferably include such agents in an amount in a range of about 0.1 to about 10% by weight of the substantially solid dental composition, and most preferably in a range of about 1-7% by weight of the substantially sold dental desensitizing composition.

In embodiments combining a desensitizing agent, such as potassium nitrate, with a bleaching agent, such as but not limited to hydrogen peroxide, the desensitizing

agent is preferably included in an amount in a range of about 0.01 to about 2% by weight of the substantially solid dental desensitizing composition, more preferably in a range of about 0.05% to about 1% by weight of the substantially solid dental desensitizing composition, and most preferably in a range of about 0.5% by weight of the substantially solid dental desensitizing composition. It has been found that including potassium nitrate within these ranges creates a synergistic effect with the dental bleaching agent that appears to enhance tooth whitening. It also provides the highest level of tooth desensitization when used with a bleaching agent.

III. METHOD OF MAKING SHAPED DENTAL TREATMENT COMPOSITIONS AND DEVICES INCORPORATING SUCH COMPOSITIONS

According to one embodiment, the shaped dental bleaching or desensitizing compositions are made by first forming a flowable bleaching or desensitizing composition that is later dried to form a substantially solid bleaching or desensitizing composition. This may be performed by heating or otherwise causing one or more volatile solvents to be driven off by evaporation, thus leaving behind a substantially solid bleaching or desensitizing composition. The drying process may be performed before or after the bleaching or desensitizing composition is placed into contact with a barrier layer.

According to one embodiment, substantially solidified dental bleaching or desensitizing compositions can be made by spreading a flowable dental bleaching or desensitizing composition onto the surface of a large or continuous polymeric sheet. The polymeric sheet and bleaching or desensitizing composition are then placed into a forced air oven or other appropriate desiccation device in order to heat and drive off a substantial portion of the water or other solvent used to form the flowable dental bleaching or desensitizing composition. Removal of the volatile solvent yields a substantially solid bleaching or desensitizing composition. Thereafter, individual tray-like dental bleaching or desensitizing devices can be molded, such as by vacuum forming, pressing or stamping from the coated polymeric sheet and then separated into individual bleaching or desensitizing devices suitable for placement over a person's teeth. Alternatively, the substantially solid bleaching or desensitizing

composition can be separated from the polymeric sheet and then molded, stamped or otherwise formed into a desired shape.

Alternatively, a flowable or substantially solid dental bleaching or desensitizing composition can be directly molded or shaped into a desired tray-like configuration comprising the bleaching or desensitizing layer. Alternatively, the flowable composition can cast onto a forming surface and dried to form a substantially solid sheet of bleaching or desensitizing composition that is thereafter molded, stamped or otherwise formed into a desired shape. Thereafter, a barrier layer can be attached or applied to an outer surface of the shaped bleaching or desensitizing composition. In this embodiment, the barrier layer may initially comprise a flowable barrier material or precursor that is later cured or hardened, such as by removing a solvent by evaporation, by chemical or light curing, or by cooling a thermoplastic melt.

In yet another embodiment of the invention, a barrier layer in the form of a dental tray or tray-like device (*e.g.*, a customized or non-custom tray) can be coated with a flowable dental bleaching or desensitizing composition. The bleaching or desensitizing composition is then heated together with the dental tray or otherwise allowed to dry in order to form a shaped bleaching or desensitizing layer comprising a substantially solid bleaching or desensitizing composition. This process can be performed during commercial manufacture of the bleaching or desensitizing device by an end user.

IV. METHODS OF USING DENTAL TREATMENT COMPOSITIONS AND DEVICES INCORPORATING SUCH COMPOSITIONS

Shaped dental bleaching or desensitizing compositions according to the invention, as well as treatment devices incorporating such compositions, can be designed to be worn for any desired time period. Increasing the concentration of dental bleaching or desensitizing agent generally reduces the time required to effect bleaching or desensitization. Nevertheless, due to the extremely comfortable fit and reliable adhesion between the inventive dental bleaching or desensitizing compositions or devices and the person's teeth, it is possible to wear such compositions or devices for extended periods of time in order to ensure more uniform bleaching or desensitization. They may be designed to be worn while performing

normal daily activities, such as talking, eating, drinking, smoking, coughing, smiling, frowning, grimacing, or while sleeping. This greatly decreases their intrusiveness into everyday activities compared to conventional bleaching strips, which do not reliably adhere to teeth, or intrusive bleaching or desensitizing devices such as large, bulky bleaching dental appliances.

Dental bleaching or desensitizing compositions or devices according to the invention may be worn over a person's upper dental arch, lower dental arch, or both simultaneously. The ability to reliably and comfortably wear dental bleaching or desensitizing compositions or devices over the upper and lower dental arches simultaneously is another departure from bleaching strips, which are not recommended for use in bleaching the upper and lower dental arches at the same time.

To remove the bleaching or desensitizing compositions or device, a user can pry open a corner of the barrier layer or bleaching or desensitizing composition using a fingernail or rigid tool and then pull the remainder off. Any residual bleaching or desensitizing composition that remains adhered to the person's teeth can be removed by washing or flushing water over the person's teeth, and/or by brushing. Although dental bleaching or desensitizing compositions are very adhesive to teeth when protected from excessive moisture, they can be formulated to quickly break down and dissolve when flushed with excess water and/or by gentle mechanical action (*e.g.*, brushing).

The dental bleaching or desensitizing compositions or devices can be worn for as little as a few minutes and as long as several hours. By way of example, not limitation, a typical bleaching or desensitization session of fast duration may last from about 10 to about 30 minutes. A bleaching or desensitization session of intermediate duration may last from about 30 minutes to about 2 hours. A bleaching or desensitization session of long duration, including professional bleaching or overnight bleaching while a person is sleeping, may last from about 2 hours to about 12 hours.

Bleaching or desensitization sessions may be repeated as many times as are needed to obtain a desired degree of bleaching and/or desensitization. In some cases, a clinical whitening effect has been observed after only 1-3 whitening sessions. A typical bleaching regimen will preferably include 1-20 bleaching sessions, more preferably 2-15 bleaching sessions, and most preferably 3-10 bleaching sessions.

The number of desensitization sessions that are carried out in conjunction with the bleaching sessions may vary greatly depending on the amount of sensitivity, if any, experienced by the user. A typical desensitization regimen will preferably include 1-20 desensitization sessions, more preferably 2-15 desensitization sessions, and most preferably 3-10 desensitization sessions.

A dental desensitizing composition or device may be used preliminarily to a dental bleaching composition or device, subsequent to applying a dental bleaching composition or device, or simultaneous with applying a dental bleaching composition. In the latter case, a dental bleaching agent and desensitizing agent can be combined within a single treatment composition or layer.

VI. DENTAL TREATMENT KITS

For convenience of use, multiple dental bleaching compositions or devices may be packaged together and sold as a kit. In one embodiment, the number of dental bleaching compositions or devices provided with each kit will equal the number of sessions that represent a prescribed bleaching regimen. Because of the ease of placing the inventive dental bleaching compositions or devices over a person's teeth, coupled with the reliability with which they adhere to teeth, the likelihood that a particular bleaching compositions or device will not work as intended or fail is greatly decreased compared to conventional bleaching strips.

To efficiently utilize the space within a kit package, multiple dental bleaching compositions or devices can be stacked or interested together. The dental bleaching compositions or devices can be sealed collectively or individually as desired. A protective package 30 is depicted in Figure 3. The shaped bleaching compositions may optionally contain a removable protective layer on an interior surface to protect the bleaching composition from contamination or moisture.

It is within the scope of the invention to provide barrier layers and shaped bleaching compositions that are initially separate and that are brought together by the end user. For example, the shaped bleaching composition may be a dry or substantially solid insert that is placed into a customized or non-custom bleaching tray, that is coated with an initially flowable barrier material, or that is covered with a flexible barrier sheet. Alternatively, a flowable dental bleaching composition can be

placed within the trough of a tray-like barrier layer and allowed to solidify so as to yield a shaped dental bleaching composition.

According to one embodiment, one or more dental bleaching compositions or devices may be packaged together and sold as a kit together with one or more dental desensitizing compositions or devices. The number of dental bleaching compositions or devices provided with each kit may equal the number of sessions that represent a prescribed bleaching regimen. The number of desensitizing compositions or devices may be selected depending on the how sensitive a person's teeth are.

For example, people with very sensitive teeth may wish to purchase a kit that includes a relatively large number of desensitizing compositions or devices (*e.g.*, a number that equals or exceeds the number of bleaching compositions or devices in the kit). People with moderately sensitive teeth may wish to purchase a kit that includes a moderate number of desensitizing compositions or devices (*e.g.*, from half up to the number of bleaching compositions or devices in the kit). People with teeth that are not prone to sensitivity may wish to purchase a kit that includes a smaller number of desensitizing compositions or devices (*e.g.*, from none up to half the number of bleaching compositions or devices in the kit). One purpose for modifying the number of desensitizing compositions or devices in a particular kit to reflect the amount of desensitization that is required is to reduce the cost and bulkiness of the kit where less desensitization is necessary.

It is within the scope of the invention to provide barrier layers, bleaching compositions and desensitizing compositions that are initially separate and that are brought together by the end user. For example, shaped bleaching and desensitizing compositions may be a substantially solid insert that is placed into a customized or non-custom tray, that is coated with an initial flowable barrier material, or that is covered with a flexible barrier sheet. Alternatively, flowable dental bleaching and desensitizing compositions can be placed within the trough of a tray-like barrier layer and allowed to solidify so as to yield a shaped dental bleaching or desensitizing composition or layer.

VI. EXAMPLES OF THE PREFERRED EMBODIMENTS

The following are several examples of dental bleaching and desensitizing compositions that have been formulated and manufactured according to the invention.

Such exemplary formulations and manufacturing conditions are given by way of example, and not by limitation, in order to illustrate dental bleaching and desensitizing compositions that have been found to be useful for bleaching and desensitizing a person's teeth. Unless otherwise indicated, all percentages are by weight.

EXAMPLE 1

An initially flowable dental bleaching composition suitable for use in manufacturing a substantially solid, cohesive, and non-flowable shaped dental bleaching composition was formed by mixing together the following components:

Carbamide Peroxide	16%
Polyvinyl pyrrolidone (M.W. = 1.3 million)	38%
Water	46%

The resulting bleaching composition was spread over the surfaces of three types of flexible polymer sheets: polyethylene sheets having a thickness of approximately 0.15 to 0.18 mm; sheets made of paraffin having a thickness of approximately 0.05 to 0.08 mm; and MYLAR sheets having a thickness of approximately 0.38 mm. The bleaching composition was spread using a spatula. The coated sheets were heated in a forced air oven heated to a temperature of 50-70° C. for approximately 1 hour. The coated sheets were removed from the oven and inspected. The bleaching composition had dried sufficiently so as to form a solid, coherent layer of bleaching composition on the surface of the polymer sheets. The dried bleaching composition adhered well to each of the polymer sheets. The coated sheets were placed back into the oven overnight to remove additional water and to determine whether prolonged heating of the dried composition would cause the carbamide peroxide bleaching agent to decompose.

The coated sheets were removed from the oven a second time, cut apart into smaller-sized pieces, and shaped into tray-like dental bleaching devices suitable for placement over a person's teeth. The tray-like bleaching devices included front and rear side walls that defined a trough having an approximate U- or V-shaped cross section and were curved in the longitudinal dimension to roughly approximate the curvature of a dental arch. They also included a shaped bleaching composition according to the invention in combination with a barrier layer.

The tray-like dental bleaching devices were tested by placing them over a person's teeth. The residual saliva present on the tooth surfaces moistened the exposed surface of the dry dental bleaching composition and caused it to become sticky and very adhesive to teeth almost immediately. The bleaching devices were pressed against the teeth, which caused them to conform to the natural irregularities of the dental arch and adhere firmly against the teeth.

The tray-like dental bleaching devices were worn for varying time periods ranging from several minutes to several hours without becoming dislodged. The formation of oxygen bubbles within the moistened bleaching composition against the person's teeth indicated that the peroxide bleaching agent remained active and was suitable for bleaching teeth even after the bleaching composition was heated overnight in an oven. In some cases a noticeable bleaching effect was detected after just one bleaching session (*e.g.*, a 2-hour bleaching session). In all cases, noticeable bleaching was detected after 1-3 bleaching sessions.

In another experiment, the dried bleaching composition, when still in the form of a flat sheet, was separated from the barrier and then vacuum formed into the shape of a dental tray. This demonstrated that substantially solid bleaching compositions according to the invention can be shaped independent of a barrier layer.

EXAMPLE 2

An initially flowable dental bleaching composition suitable for use in manufacturing a substantially solid, cohesive, and non-flowable shaped dental bleaching composition was formed by mixing together the following components:

Carbamide Peroxide	16%
PolyOx WSR 101(M.W. = 1 million)	7%
Water	77%

The resulting bleaching gel was spread over the surface of MYLAR sheets using a spatula. The coated sheets were heated in a forced air oven heated to a temperature of 50-70° C. for approximately 1 hour. The coated sheets were removed from the oven and inspected. The bleaching composition had dried sufficiently so as to form a solid, coherent layer of bleaching layer on the surface of the polymer sheets. Unlike the bleaching composition of Example 1, the dried bleaching composition did

not adhere strongly to the polymer sheets but was easily separated from the sheets. The coated sheets were placed back into the oven overnight.

The coated sheets were removed from the oven a second time, cut apart into smaller-sized pieces, and shaped into tray-like dental bleaching devices suitable for placement over a person's teeth. The tray-like bleaching devices included front and rear side walls that defined a trough having an approximate U- or V-shaped cross section and were curved in the longitudinal dimension to roughly approximate the curvature of a dental arch.

The tray-like dental bleaching devices were tested by placing them over a person's teeth. The residual saliva present on the tooth surfaces moistened the exposed surface of the dry dental bleaching composition and caused it to become sticky and adhesive to teeth within a few seconds. The results of Example 2 indicate that, while polyethylene oxide was a satisfactory teeth adhesion agent, it was less satisfactory in promoting adhesion between a dried dental bleaching composition and a polymer sheet.

A substantially solid dental bleaching composition formed from the initially flowable bleaching composition of Example 2 is shaped into the form of a dental tray or tray-like configuration independent of a barrier layer.

EXAMPLE 3

An initially flowable dental bleaching composition suitable for use in manufacturing a substantially solid, cohesive, and non-flowable shaped dental bleaching composition was formed by mixing together the following components:

Carbamide Peroxide	16%
Carbopol 974P	5%
Aqueous NaOH (50%)	6%
Water	73%

The resulting bleaching gel was spread over the surface of MYLAR sheets using a spatula. The coated sheets were heated in a forced air oven heated to a temperature of 50-70° C. for approximately 1 hour. The coated sheets were removed from the oven and inspected. Although the bleaching composition dried sufficiently to form a solid, it shrunk considerably, probably because of the large amount of water that was needed to cause Carbopol to form a gel. Shrinkage of the bleaching

composition caused the polymer sheet to become partially shriveled up. Whereas shriveling of the polymer sheet was not desired, using carboxypolymethylene as a tooth adhesion agent resulted in a dried bleaching composition that adhered to a polymer sheet.

Thereafter, the coated sheets were removed from the oven after heating overnight, cut apart into smaller-sized pieces, and shaped into tray-like dental bleaching devices suitable for placement over a person's teeth. When placed over a person's teeth it took about 5 seconds for the dental bleaching composition to become moistened enough to start becoming sticky and adhesive to teeth. The dental treatment device was able to conform to the person's teeth and remain in place after being pressed against the teeth for about 30-60 seconds.

The results of Example 3 indicate that, while Carbopol 974 P is able to adhere to a MYLAR sheet and appears to be a satisfactory tooth adhesion agent once the bleaching composition is sufficiently moistened, it presents a shrinkage problem that can cause undesirable deformation of thin, flexible polymer sheets. One would expect Carbopol 974 P to work better when used with less flexible sheets and/or preformed dental trays of sufficient rigidity to avoid shriveling or unwanted deformation.

A substantially solid dental bleaching composition formed from the initially flowable bleaching composition of Example 3 is shaped into the form of a dental tray or tray-like configuration independent of a barrier layer.

EXAMPLE 4

An initially flowable dental bleaching composition suitable for use in manufacturing a substantially solid, cohesive, and non-flowable shaped dental bleaching composition was formed by mixing together the following components:

Polyethylene Oxide (M.W. = 100,000)	20%
Glycerin	2.5%
Sodium Percarbonate	2.4%
Water	75.1%

The resulting bleaching gel was spread over the surface of MYLAR sheets as in Example 2. The coated sheets were heated in a forced air oven heated to a temperature of 50-70° C. for approximately 1 hour. The coated sheets were removed from the oven and inspected. The bleaching composition had dried sufficiently so as

to form a solid, coherent layer of bleaching layer on the surface of the polymer sheets. The bleaching composition of Example 4 did not adhere at all to the MYLAR sheets. This indicates that the lower molecular weight polyethylene oxide of Example 4 was even less adhesive to MYLAR sheets than the higher molecular weight polyethylene oxide of Example 2. Sheets comprising a solid layer of the bleaching composition of Example 2 could also be formed by spreading the composition on a solid surface such as glass, drying the composition, and then peeling off the dried composition.

By comparison, when the bleaching composition of Example 1 was applied to a glass surface and then dried, it adhered so strongly that it could not readily be peeled off the glass surface. Instead, it had to be forcefully chipped or pried off using a razor blade.

The dried bleaching composition of Example 4 did, however, adhere to a person's teeth when moistened, although not as well as the bleaching compositions of Examples 1-3. This indicates that the composition of Example 4 might have commercial application in a tray-like dental bleaching device to the extent that problems adhering to the barrier layer are overcome or are not an issue.

A substantially solid dental bleaching composition formed from the initially flowable bleaching composition of Example 4 is shaped into the form of a dental tray or tray-like configuration independent of a barrier layer.

EXAMPLE 5

An initially flowable dental bleaching composition suitable for use in manufacturing a substantially solid, cohesive, and non-flowable shaped dental bleaching composition was formed by mixing together the following components:

Carbamide Peroxide	10%
Water	25%
Ethanol	25%
Polyvinyl pyrrolidone (M.W. = 1.3 million)	38%
Glycerin	73%

The resulting bleaching composition was spread over the surfaces of polyethylene, paraffin, and MYLAR sheets as described in Example 1. The coated sheets were heated in a forced air oven heated to a temperature of 50-70° C. for approximately 45 minutes. The coated sheets were removed from the oven and

inspected. The bleaching composition had dried sufficiently so as to form a solid, coherent layer of bleaching layer on the surface of the polymer sheets. Using a mixture of water and ethanol as the solvent allowed the bleaching composition to dry in less than time than the compositions of Examples 1-4. The inclusion of glycerin helped the bleaching composition remain more flexible and less brittle after drying. The dried bleaching composition adhered well to each of the polymer sheets. After initial drying, the coated sheets were placed back into the oven overnight.

The coated sheets were removed from the oven a second time, cut apart into smaller-sized pieces, and shaped into tray-like dental bleaching devices suitable for placement over a person's teeth. The tray-like bleaching devices included front and rear side walls that defined a trough having an approximate U- or V-shaped cross section and were curved in the longitudinal dimension to roughly approximate the curvature of a dental arch. The tray-like dental bleaching devices adhered almost immediately when placed over a person's teeth and caused a noticeable bleaching effect within 1-3 sessions.

A substantially solid dental bleaching composition formed from the initially flowable bleaching composition of Example 5 is shaped into the form of a dental tray or tray-like configuration independent of a barrier layer.

EXAMPLE 6

An initially flowable dental bleaching composition suitable for use in manufacturing a substantially solid, cohesive, and non-flowable shaped dental bleaching composition was formed by mixing together the following components:

Carbamide Peroxide	10%
Water	21%
Ethanol	21%
Kollidon VA 64 (M.W. = 60,000)	40%
Carboxy methyl cellulose	3%
PEG 600	5%

Kollidon VA 64 is a polyvinyl pyrrolidone polymer sold by BASF. The resulting bleaching composition was spread over the surfaces of polyethylene, paraffin, and MYLAR sheets as described in Example 1. The coated sheets were heated in a forced air oven heated to a temperature of 50-70° C. for approximately 45

minutes. The coated sheets were removed from the oven and inspected. The bleaching composition had dried sufficiently so as to form a solid, coherent layer of bleaching layer on the surface of the polymer sheets. The inclusion of polyethylene glycol helped the bleaching composition remain more flexible and less brittle after drying. The dried bleaching composition adhered well to each of the polymer sheets. The coated sheets were placed back into the oven overnight.

The coated sheets were removed from the oven a second time, cut apart into smaller-sized pieces, and shaped into tray-like dental bleaching devices suitable for placement over a person's teeth. The tray-like bleaching devices included front and rear side walls that defined a trough having an approximate U- or V-shaped cross section and were curved in the longitudinal dimension to roughly approximate the curvature of a dental arch. The tray-like dental bleaching devices adhered almost immediately when placed over a person's teeth and caused a noticeable bleaching effect within 1-3 sessions.

A substantially solid dental bleaching composition formed from the initially flowable bleaching composition of Example 6 is shaped into the form of a dental tray or tray-like configuration independent of a barrier layer.

EXAMPLE 7

An initially flowable dental bleaching composition suitable for use in manufacturing a substantially solid, cohesive, and non-flowable shaped dental bleaching composition was formed by mixing together the following components:

Carbamide Peroxide	11.6%
Ethanol	55.8%
Kollidon VA 90 F (M.W. = 1.3 million)	24.4%
Carboxy methyl cellulose	2.3%
PEG 600	5.8%

The resulting bleaching composition was spread over the surfaces of polyethylene, paraffin, and MYLAR sheets as described in Example 1. The coated sheets were heated in a forced air oven heated to a temperature of 50-70° C. for approximately 30 minutes. The coated sheets were removed from the oven and inspected. The bleaching composition had dried sufficiently so as to form a solid, coherent layer of bleaching layer on the surface of the polymer sheets. Using ethanol

as the only solvent allowed the bleaching composition to dry in even less time than the compositions of Examples 5 and 6. The dried bleaching composition adhered well to each of the polymer sheets. The coated sheets were placed back into the oven overnight.

The coated sheets were removed from the oven a second time, cut apart into smaller-sized pieces, and shaped into tray-like dental bleaching devices suitable for placement over a person's teeth. The tray-like bleaching devices included front and rear side walls that defined a trough having an approximate U- or V-shaped cross section and were curved in the longitudinal dimension to roughly approximate the curvature of a dental arch. The tray-like dental bleaching devices adhered almost immediately when placed over a person's teeth and caused a noticeable bleaching effect within 1-3 sessions.

A substantially solid dental bleaching composition formed from the initially flowable bleaching composition of Example 7 is shaped into the form of a dental tray or tray-like configuration independent of a barrier layer.

EXAMPLE 8

An initially flowable dental bleaching composition suitable for use in manufacturing a substantially solid, cohesive, and non-flowable shaped dental bleaching composition was formed by mixing together the following components:

Carbamide Peroxide	10%
Ethanol	65%
Kollidon VA 90 F (M.W. = 1.3 million)	20%
PEG 600	5%

The resulting bleaching composition was spread over the surfaces of polyethylene, paraffin, and MYLAR sheets as described in Example 1. The coated sheets were heated in a forced air oven heated to a temperature of 50-70° C. for approximately 30 minutes. The coated sheets were removed from the oven and inspected. The bleaching composition had dried sufficiently so as to form a solid, coherent layer of bleaching layer on the surface of the polymer sheets. The dried bleaching composition adhered well to each of the polymer sheets. The coated sheets were placed back into the oven overnight.

The coated sheets were removed from the oven a second time, cut apart into smaller-sized pieces, and shaped into tray-like dental bleaching devices suitable for placement over a person's teeth. The tray-like bleaching devices included front and rear side walls that defined a trough having an approximate U- or V-shaped cross section and were curved in the longitudinal dimension to roughly approximate the curvature of a dental arch. The tray-like dental bleaching devices adhered almost immediately when placed over a person's teeth and caused a noticeable bleaching effect within 1-3 sessions.

A substantially solid dental bleaching composition formed from the initially flowable bleaching composition of Example 8 is shaped into the form of a dental tray or tray-like configuration independent of a barrier layer.

EXAMPLE 9

An initially flowable dental bleaching composition suitable for use in manufacturing a substantially solid, cohesive, and non-flowable shaped dental bleaching composition was formed by mixing together the following components:

Carbamide Peroxide	10%
Ethanol	64%
Kollidon VA 90 F (M.W. = 1.3 million)	25%
PEG 600	1%

The resulting bleaching composition was spread over the surfaces of polyethylene, paraffin, and MYLAR sheets as described in Example 1. The coated sheets were heated in a forced air oven heated to a temperature of 50-70° C. for approximately 30 minutes. The coated sheets were removed from the oven and inspected. The bleaching composition had dried sufficiently so as to form a solid, coherent layer of bleaching layer on the surface of the polymer sheets. The dried bleaching composition adhered well to each of the polymer sheets. The coated sheets were placed back into the oven overnight.

The coated sheets were removed from the oven a second time, cut apart into smaller-sized pieces, and shaped into tray-like dental bleaching devices suitable for placement over a person's teeth. The tray-like bleaching devices included front and rear side walls that defined a trough having an approximate U- or V-shaped cross section and were curved in the longitudinal dimension to roughly approximate the

curvature of a dental arch. The tray-like dental bleaching devices adhered almost immediately when placed over a person's teeth and caused a noticeable bleaching effect within 1-3 sessions.

A substantially solid dental bleaching composition formed from the initially flowable bleaching composition of Example 9 is shaped into the form of a dental tray or tray-like configuration independent of a barrier layer.

EXAMPLE 10

An initially flowable dental bleaching composition suitable for use in manufacturing a substantially solid, cohesive, and non-flowable shaped dental bleaching composition was formed by mixing together the following components:

Carbamide Peroxide	10%
Ethanol	64%
Kollidon VA 90 F (M.W. = 1.3 million)	23%
PEG 600	1%
Aerosil 200	2%

The resulting bleaching composition was spread over the surfaces of polyethylene, paraffin, and MYLAR sheets as described in Example 1. Aerosil 200 was added as a tackifying agent to promote adhesion of the wet bleaching composition to the polymer sheets. The coated sheets were heated in a forced air oven heated to a temperature of 50-70° C. for approximately 30 minutes. The coated sheets were removed from the oven and inspected. The bleaching composition had dried sufficiently so as to form a solid, coherent layer of bleaching layer on the surface of the polymer sheets. The dried bleaching composition adhered well to each of the polymer sheets. The coated sheets were placed back into the oven overnight.

The coated sheets were removed from the oven a second time, cut apart into smaller-sized pieces, and shaped into tray-like dental bleaching devices suitable for placement over a person's teeth. The tray-like bleaching devices included front and rear side walls that defined a trough having an approximate U- or V-shaped cross section and were curved in the longitudinal dimension to roughly approximate the curvature of a dental arch. The tray-like dental bleaching devices adhered almost immediately when placed over a person's teeth and caused a noticeable bleaching effect within 1-3 sessions.

A substantially solid dental bleaching composition formed from the initially flowable bleaching composition of Example 10 is shaped into the form of a dental tray or tray-like configuration independent of a barrier layer.

EXAMPLE 11

An initially flowable dental bleaching composition suitable for use in manufacturing a substantially solid, cohesive, and non-flowable shaped dental bleaching composition was formed by mixing together the following components:

Carbamide Peroxide	10%
Ethanol	66.9%
Kollidon VA 90 F (M.W. = 1.3 million)	20%
PEG 600	0.1%
Aerosil 200	3%

The resulting bleaching composition was spread over the surfaces of polyethylene, paraffin, and MYLAR sheets as described in Example 1. The coated sheets were heated in a forced air oven heated to a temperature of 50-70° C. for approximately 30 minutes. The coated sheets were removed from the oven and inspected. The bleaching composition had dried sufficiently so as to form a solid, coherent layer of bleaching layer on the surface of the polymer sheets. The dried bleaching composition adhered well to each of the polymer sheets. The coated sheets were placed back into the oven overnight.

The coated sheets were removed from the oven a second time, cut apart into smaller-sized pieces, and shaped into tray-like dental bleaching devices suitable for placement over a person's teeth. The tray-like bleaching devices included front and rear side walls that defined a trough having an approximate U- or V-shaped cross section and were curved in the longitudinal dimension to roughly approximate the curvature of a dental arch. The tray-like dental bleaching devices adhered almost immediately when placed over a person's teeth and caused a noticeable bleaching effect within 1-3 sessions.

A substantially solid dental bleaching composition formed from the initially flowable bleaching composition of Example 11 is shaped into the form of a dental tray or tray-like configuration independent of a barrier layer.

EXAMPLE 12

An initially flowable dental bleaching composition suitable for use in manufacturing a substantially solid, cohesive, and non-flowable shaped dental bleaching composition was formed by mixing together the following components:

Carbamide Peroxide	10%
PolyOx (M.W. = 1 million)	7.5%
Water	75.5%
Glycerin	5%
Aerosil 200	2%

The resulting bleaching gel was spread over the surface of MYLAR sheets as in Example 2. The coated sheets were heated in a forced air oven heated to a temperature of 50-70° C. for approximately 1 hour. The coated sheets were removed from the oven and inspected. The bleaching composition had dried sufficiently so as to form a solid, coherent layer of bleaching layer on the surface of the polymer sheets. The bleaching composition of Example 12 did not adhere well to the MYLAR sheets. It also shrunk somewhat after extended drying. The dried bleaching composition of Example 12 was able to adhere to a person's teeth when moistened.

A substantially solid dental bleaching composition formed from the initially flowable bleaching composition of Example 12 is shaped into the form of a dental tray or tray-like configuration independent of a barrier layer.

EXAMPLE 13

An initially flowable dental bleaching composition suitable for use in manufacturing a substantially solid, cohesive, and non-flowable shaped dental bleaching composition was formed by mixing together the following components:

Carbamide Peroxide	10%
Kollidon 90 F (M.W. = 1.3 million)	10%
Kollidon 30 (M.W. = 50,000)	20%
Water	53%
Glycerin	5%
Aerosil 200	2%

The resulting bleaching composition was spread over the surfaces of polyethylene, paraffin, and MYLAR sheets as described in Example 1. The coated

sheets were heated in a forced air oven heated to a temperature of 50-70° C. for approximately 1 hour. The coated sheets were removed from the oven and inspected. The bleaching composition had dried sufficiently so as to form a solid, coherent layer of bleaching layer on the surface of the polymer sheets. The dried bleaching composition adhered well to each of the polymer sheets. The coated sheets were placed back into the oven overnight.

The coated sheets were removed from the oven a second time, cut apart into smaller-sized pieces, and shaped into tray-like dental bleaching devices suitable for placement over a person's teeth. The tray-like bleaching devices included front and rear side walls that defined a trough having an approximate U- or V-shaped cross section and were curved in the longitudinal dimension to roughly approximate the curvature of a dental arch. The tray-like dental bleaching devices adhered almost immediately when placed over a person's teeth and caused a noticeable bleaching effect within 1-3 sessions.

A substantially solid dental bleaching composition formed from the initially flowable bleaching composition of Example 13 is shaped into the form of a dental tray or tray-like configuration independent of a barrier layer.

EXAMPLE 14

An initially flowable dental bleaching composition suitable for use in manufacturing a substantially solid, cohesive, and non-flowable shaped dental bleaching composition was formed by mixing together the following components:

Carbamide Peroxide	10%
Kollidon 90 F (M.W. = 1.3 million)	27%
Water	50%
Glycerin	7%
Aerosil 200	6%

The resulting bleaching composition was spread over the surfaces of polyethylene, paraffin, and MYLAR sheets as described in Example 1. The coated sheets were heated in a forced air oven heated to a temperature of 50-70° C. for approximately 1 hour. The coated sheets were removed from the oven and inspected. The bleaching composition had dried sufficiently so as to form a solid, coherent layer of bleaching layer on the surface of the polymer sheets. The dried bleaching

composition adhered well to each of the polymer sheets. The coated sheets were placed back into the oven overnight.

The coated sheets were removed from the oven a second time, cut apart into smaller-sized pieces, and shaped into tray-like dental bleaching devices suitable for placement over a person's teeth. The tray-like bleaching devices included front and rear side walls that defined a trough having an approximate U- or V-shaped cross section and were curved in the longitudinal dimension to roughly approximate the curvature of a dental arch. The tray-like dental bleaching devices adhered almost immediately when placed over a person's teeth and caused a noticeable bleaching effect within 1-3 sessions.

A substantially solid dental bleaching composition formed from the initially flowable bleaching composition of Example 14 is shaped into the form of a dental tray or tray-like configuration independent of a barrier layer.

EXAMPLE 15

An initially flowable dental bleaching composition suitable for use in manufacturing a substantially solid, cohesive, and non-flowable shaped dental bleaching composition was formed by mixing together the following components:

Carbamide Peroxide	10%
Kollidon 90 F (M.W. = 1.3 million)	28%
Water	50%
Glycerin	7%
Aerosil 200	5%

The resulting bleaching composition was spread over the surfaces of polyethylene, paraffin, and MYLAR sheets as described in Example 1. The coated sheets were heated in a forced air oven heated to a temperature of 50-70° C. for approximately 1 hour. The coated sheets were removed from the oven and inspected. The bleaching composition had dried sufficiently so as to form a solid, coherent layer of bleaching layer on the surface of the polymer sheets. The dried bleaching composition adhered well to each of the polymer sheets. The coated sheets were placed back into the oven overnight.

The coated sheets were removed from the oven a second time, cut apart into smaller-sized pieces, and shaped into tray-like dental bleaching devices suitable for

placement over a person's teeth. The tray-like bleaching devices included front and rear side walls that defined a trough having an approximate U- or V-shaped cross section and were curved in the longitudinal dimension to roughly approximate the curvature of a dental arch. The tray-like dental bleaching devices adhered almost immediately when placed over a person's teeth and caused a noticeable bleaching effect within 1-3 sessions.

A substantially solid dental bleaching composition formed from the initially flowable bleaching composition of Example 15 is shaped into the form of a dental tray or tray-like configuration independent of a barrier layer.

EXAMPLE 16

An initially flowable dental desensitizing composition suitable for use in manufacturing a substantially solid, cohesive, and non-flowable dental desensitizing composition was formed by mixing together the following components:

Sodium Fluoride	0.25%
Polyvinyl pyrrolidone (M.W. = 1.3 million)	30%
Water	69.75%

The resulting desensitizing composition was spread over the surfaces of three types of flexible polymer sheets: polyethylene sheets having a thickness of approximately 0.15 to 0.18 mm; sheets made of paraffin having a thickness of approximately 0.05 to 0.08 mm; and MYLAR sheets having a thickness of approximately 0.38 mm. The desensitizing composition was spread using a screeding device. The coated sheets were heated in a forced air oven heated to a temperature of 50-70° C. for approximately 1 hour. The coated sheets were removed from the oven and inspected. The desensitizing composition had dried sufficiently so as to form a solid, coherent layer of desensitizing layer on the surface of the polymer sheets. The dried desensitizing composition adhered well to each of the polymer sheets.

The coated sheets were removed from the oven a second time, cut apart into smaller-sized pieces, and shaped into tray-like dental desensitizing devices suitable for placement over a person's teeth. The tray-like desensitizing devices included front and rear side walls that defined a trough having an approximate U- or V-shaped

cross section and were curved in the longitudinal dimension to roughly approximate the curvature of a dental arch.

The tray-like dental desensitizing devices were tested by placing them over a person's teeth. The residual saliva present on the tooth surfaces moistened the exposed surface of the dry dental desensitizing composition and caused it to become sticky and very adhesive to teeth almost immediately. The desensitizing devices were pressed against the teeth, which caused them to conform to the natural irregularities of the dental arch and adhere firmly against the teeth.

The tray-like dental desensitizing devices were worn for varying time periods ranging from several minutes to several hours without becoming dislodged. In some cases a noticeable desensitizing effect was detected after just one desensitizing session (e.g., a 2-hour desensitizing session). In all cases, noticeable desensitizing was detected after 1-3 desensitizing sessions.

A substantially solid dental desensitizing composition formed from the initially flowable desensitizing composition of Example 16 is shaped into the form of a dental tray or tray-like configuration independent of a barrier layer.

EXAMPLE 17

An initially flowable dental desensitizing composition suitable for use in manufacturing a substantially solid, cohesive, and non-flowable dental desensitizing composition was formed by mixing together the following components:

Sodium Citrate	5%
Polyvinyl pyrrolidone (M.W. = 1.3 million)	20%
Water	75%

The resulting desensitizing composition was manufactured into desensitizing devices according to the method described in Example 16. The dried desensitizing composition adhered well to the barrier layers comprising polymer sheets.

The tray-like dental desensitizing devices were tested by placing them over a person's teeth. The residual saliva present on the tooth surfaces moistened the exposed surface of the dry dental desensitizing composition and caused it to become sticky and very adhesive to teeth almost immediately. The desensitizing devices were

pressed against the teeth, which caused them to conform to the natural irregularities of the dental arch and adhere firmly against the teeth.

The tray-like dental desensitizing devices were worn for varying time periods ranging from several minutes to several hours without becoming dislodged. In some cases a noticeable desensitizing effect was detected after just one desensitizing session (e.g., a 2-hour desensitizing session). In all cases, noticeable desensitizing was detected after 1-3 desensitizing sessions.

A substantially solid dental desensitizing composition formed from the initially flowable desensitizing composition of Example 17 is shaped into the form of a dental tray or tray-like configuration independent of a barrier layer.

EXAMPLE 18

An initially flowable dental desensitizing composition suitable for use in manufacturing a substantially solid, cohesive, and non-flowable dental desensitizing composition was formed by mixing together the following components:

Potassium Nitrate	3%
Polyvinyl pyrrolidone (M.W. = 1.3 million)	15%
Ethanol	30%
Water	52%

The resulting desensitizing composition was manufactured into desensitizing devices according to the method described in Example 16. The dried desensitizing composition adhered well to the barrier layers comprising polymer sheets.

The tray-like dental desensitizing devices were tested by placing them over a person's teeth. The residual saliva present on the tooth surfaces moistened the exposed surface of the dry dental desensitizing composition and caused it to become sticky and very adhesive to teeth almost immediately. The desensitizing devices were pressed against the teeth, which caused them to conform to the natural irregularities of the dental arch and adhere firmly against the teeth.

The tray-like dental desensitizing devices were worn for varying time periods ranging from several minutes to several hours without becoming dislodged. In some cases a noticeable desensitizing effect was detected after just one desensitizing

session (e.g., a 2-hour desensitizing session). In all cases, noticeable desensitizing was detected after 1-3 desensitizing sessions.

A substantially solid dental desensitizing composition formed from the initially flowable desensitizing composition of Example 18 is shaped into the form of a dental tray or tray-like configuration independent of a barrier layer.

EXAMPLE 19

An initially flowable dental desensitizing composition suitable for use in manufacturing a substantially solid, cohesive, and non-flowable dental desensitizing composition was formed by mixing together the following components:

Potassium Nitrate	0.5%
Sodium Fluoride	0.25%
Polyvinyl pyrrolidone (M.W. = 1.3 million)	32%
Ethanol	30%
Water	37.25%

The resulting desensitizing composition was manufactured into desensitizing devices according to the method described in Example 16. The dried desensitizing composition adhered well to the barrier layers comprising polymer sheets.

The tray-like dental desensitizing devices were tested by placing them over a person's teeth. The residual saliva present on the tooth surfaces moistened the exposed surface of the dry dental desensitizing composition and caused it to become sticky and very adhesive to teeth almost immediately. The desensitizing devices were pressed against the teeth, which caused them to conform to the natural irregularities of the dental arch and adhere firmly against the teeth.

The tray-like dental desensitizing devices were worn for varying time periods ranging from several minutes to several hours without becoming dislodged. In some cases a noticeable desensitizing effect was detected after just one desensitizing session (*e.g.*, a 2-hour desensitizing session). In all cases, noticeable desensitizing was detected after 1-3 desensitizing sessions.

A substantially solid dental desensitizing composition formed from the initially flowable desensitizing composition of Example 19 is shaped into the form of a dental tray or tray-like configuration independent of a barrier layer.

EXAMPLE 20

An initially flowable desensitizing bleaching composition suitable for use in manufacturing a substantially solid, cohesive, and non-flowable desensitizing bleaching composition was formed by mixing together the following components:

Potassium Nitrate	0.5%
Sodium Fluoride	0.25%
Carbamide Peroxide	15%
Polyvinyl pyrrolidone (M.W. = 1.3 million)	33%
Water	51.25%

The resulting desensitizing composition was manufactured into desensitizing devices according to the method described in Example 16. The dried desensitizing composition adhered well to the barrier layers comprising polymer sheets.

The tray-like desensitizing bleaching devices were tested by placing them over a person's teeth. The residual saliva present on the tooth surfaces moistened the exposed surface of the dry dental desensitizing composition and caused it to become sticky and very adhesive to teeth almost immediately. The desensitizing bleaching devices were pressed against the teeth, which caused them to conform to the natural irregularities of the dental arch and adhere firmly against the teeth.

The tray-like dental desensitizing devices were worn for varying time periods ranging from several minutes to several hours without becoming dislodged. In some cases a noticeable desensitizing effect was detected after just one desensitizing session (*e.g.*, a 2-hour desensitizing session). In all cases, noticeable bleaching was detected after 1-3 desensitizing sessions.

A substantially solid dental desensitizing composition formed from the initially flowable desensitizing composition of Example 20 is shaped into the form of a dental tray or tray-like configuration independent of a barrier layer.

EXAMPLE 21

Any of the dental bleaching compositions or devices of Examples 1-15 is combined with any of the dental desensitizing compositions or devices of Examples 16-20 to form a kit according to the invention suitable for bleaching and desensitizing a person's teeth.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A dental bleaching device having a tray-like configuration suitable for placement over a person's teeth in order to carry out dental bleaching, comprising:

a substantially solid and coherent dental bleaching composition having a tray-like configuration comprising a front side wall, a rear side wall, and a trough between said front and rear side walls,

said dental bleaching composition having increased adhesiveness to teeth when moistened by saliva or water,

said dental bleaching composition comprising:

at least one dental bleaching agent; and

at least one tooth adhesion agent that forms a substantially solid matrix within which said dental bleaching agent is dispersed and that at least partially contributes to said increased adhesiveness to teeth when said dental bleaching composition is moistened by saliva or water.

2. A dental bleaching device as defined in claim 1, said dental bleaching composition being initially horseshoe shaped prior to use so that said dental bleaching device at least approximately conforms to a person's dental arch with minimal longitudinal shaping.

3. A dental bleaching device as defined in claim 1, said dental bleaching composition initially having a substantially straight longitudinal profile prior to use so that longitudinal curving of said dental bleaching composition is required when said dental bleaching device is placed over a person's teeth.

4. A dental bleaching device as defined in claim 1, at least a portion of said trough having a cross section that is approximately U-shaped, V-shaped, L-shaped, rectangular, or trapezoidal.

5. A dental bleaching device as defined in claim 1, said dental bleaching agent comprising at least one of carbamide peroxide, metal peroxide, percarbonate, perborate, peroxy acid, peroxy acid salt, chlorite, or hypochlorite.

6. A dental bleaching device as defined in claim 1, said dental bleaching agent having a concentration in a range of about 5% to about 80% by weight of said dental bleaching composition.

7. A dental bleaching device as defined in claim 1, said dental bleaching agent having a concentration in a range of about 10% to about 60% by weight of said dental bleaching composition.

8. A dental bleaching device as defined in claim 1, said dental bleaching agent having a concentration in a range of about 20% to about 50% by weight of said dental bleaching composition.

9. A dental bleaching device as defined in claim 1, said tooth adhesion agent comprising polyvinyl pyrrolidone.

10. A dental bleaching device as defined in claim 1, said tooth adhesion agent comprising at least one of carboxypolymethylene, polyethylene oxide, polyacrylic acid, copolymer of polyacrylic acid, polyacrylate, polyacrylamide, copolymer of polyacrylic acid and polyacrylamide, PVP-vinyl acetate copolymer, carboxymethylcellulose, carboxypropylcellulose, polysaccharide gum, protein.

11. A dental bleaching device as defined in claim 1, said tooth adhesion agent having a concentration in a range of about 10% to about 90% by weight of said dental bleaching composition.

12. A dental bleaching device as defined in claim 1, said tooth adhesion agent having a concentration in a range of about 20% to about 80% by weight of said dental bleaching composition.

13. A dental bleaching device as defined in claim 1, said tooth adhesion agent having a concentration in a range of about 40% to about 75% by weight of said dental bleaching composition.

14. A dental bleaching device as defined in claim 1, said dental bleaching composition further comprising at least one humectant.

15. A dental bleaching device as defined in claim 1, wherein said dental bleaching composition is sized and configured so as to fit over at least a portion of a person's upper dental arch or lower dental arch.

16. A dental bleaching device as defined in claim 1, wherein said dental bleaching composition has a cross-sectional thickness in a range of about 0.1 mm to about 3 mm.

17. A dental bleaching device as defined in claim 16, wherein said dental bleaching composition has a cross-sectional thickness in a range of about 0.1 mm to about 0.5 mm.

18. A dental bleaching device as defined in claim 16, wherein said dental bleaching composition has a cross-sectional thickness in a range of about 0.5 mm to about 2 mm.

19. A dental bleaching device as defined in claim 16, wherein said bleaching composition has a cross-sectional thickness in a range of about 2 mm to about 3 mm.

20. A dental bleaching device as defined in claim 1, wherein said dental bleaching composition is sized and configured so as to approximately terminate at or near a person's gingival margin when said dental bleaching device is in use.

21. A dental bleaching device as defined in claim 1, wherein said dental bleaching device is contained within a sealed package prior to use.

22. A kit for use in bleaching a person's teeth comprising a plurality of dental bleaching devices according to any of claims 1-21.

23. A kit as defined in claim 22, further comprising at least one desensitizing device comprising a substantially solid desensitizing composition having a tray-like configuration.

24. A kit as defined in claim 23, wherein at least some of said dental bleaching devices and/or desensitizing devices are stacked and interested together.

25. A kit for use in bleaching and desensitizing a person's teeth, comprising:

at least one substantially solid dental bleaching composition having a tray-like configuration and comprising at least one dental bleaching agent and at least one tooth adhesion agent having increased adhesiveness to teeth when said dental bleaching composition is moistened by saliva or water; and

at least one substantially solid dental desensitizing composition having a tray-like configuration and comprising at least one dental desensitizing agent and at least one tooth adhesion agent having increased adhesiveness to teeth when said desensitizing composition is moistened by saliva or water.

26. A kit as defined in claim 25, at least one of said dental bleaching composition or said desensitizing composition being initially horseshoe shaped prior to use so as to at least approximately conform to a person's dental arch with minimal longitudinal shaping.

27. A kit as defined in claim 25, at least one of said dental bleaching composition or said desensitizing composition having a substantially straight longitudinal profile prior to use so that longitudinal curving is required when said bleaching or desensitizing composition is placed over a person's teeth.

28. A kit as defined in claim 25, at least a portion of said trough of at least one of said dental bleaching composition or said desensitizing composition having a cross section that is approximately U-shaped, V-shaped, L-shaped, rectangular, or trapezoidal.

29. A kit as defined in claim 25, said dental desensitizing agent comprising at least one of potassium nitrate, other potassium salts, citric acid, citrates, strontium chloride, sodium fluoride, or stannous fluoride.

30. A kit as defined in claim 25, said dental desensitizing agent having a concentration in a range of about 0.01% to about 50% by weight of said desensitizing composition.

31. A kit as defined in claim 25, said dental desensitizing agent having a concentration in a range of about 0.5% to about 25% by weight of said desensitizing composition.

32. A kit as defined in claim 25, said dental desensitizing agent having a concentration in a range of about 0.1% to about 10% by weight of said desensitizing composition.

33. A kit as defined in claim 25, said tooth adhesion agent comprising polyvinyl pyrrolidone.

34. A kit as defined in claim 25, said tooth adhesion agent comprising at least one of carboxypolymethylene, polyethylene oxide, polyacrylic acid, copolymer of polyacrylic acid, polyacrylate, polyacrylamide, copolymer of polyacrylic acid and polyacrylamide, PVP-vinyl acetate copolymer, carboxymethylcellulose, carboxypropylcellulose, polysaccharide gum, or protein.

35. A kit as defined in claim 1, said tooth adhesion agent having a concentration in a range of about 20% to about 80% by weight of said bleaching composition or said desensitizing composition.

36. A kit as defined in claim 1, wherein at least one of said dental bleaching composition or said desensitizing composition is sized and configured so as to approximately terminate at or near a person's gingival margin when said dental bleaching composition or said dental desensitizing composition is in use.

37. A kit as defined in claim 1, wherein at least one of said bleaching composition or said desensitizing composition is contained within a sealed package prior to use.

38. A method for bleaching a person's teeth comprising obtaining a dental bleaching composition according to any of claims 1-21 and then placing said dental bleaching composition over at least a portion of the person's teeth for a desired time period.

39. A method for bleaching a person's teeth, comprising:

(a) obtaining a substantially solid and coherent dental bleaching composition in the shape of a dental tray comprising a front side wall, a rear side wall, and a trough between said front and rear side walls, said dental bleaching composition having increased adhesiveness to teeth when moistened by saliva or water, said dental bleaching composition comprising:

at least one dental bleaching agent; and

at least one tooth adhesion agent that forms a substantially solid matrix within which said dental bleaching agent is dispersed and that at least partially contributes to said increased adhesiveness to teeth when said dental bleaching composition is moistened by saliva or water;

(b) moistening an interior bleaching surface of said bleaching composition so as to increase adhesiveness of said bleaching composition to teeth; and

(c) placing said dental bleaching composition over at least a portion of the person's teeth for a desired time period, the moistened bleaching surface adhering and retaining said dental bleaching composition against the person's teeth during the desired time period.

40. A method for bleaching a person's teeth as defined in claim 39, wherein (b) is performed by contacting said bleaching surface with water or saliva.

41. A method for bleaching a person's teeth as defined in claim 39, said dental bleaching composition being allowed to remain in place over the person's teeth for about 10 to about 30 minutes.

42. A method for bleaching a person's teeth as defined in claim 39, said dental bleaching composition being allowed to remain in place over the person's teeth for about 30 minutes to about 2 hours.

43. A method for bleaching a person's teeth as defined in claim 39, said dental bleaching composition being allowed to remain in place over the person's teeth for about 2 hours to about 12 hours.

44. A method for bleaching and desensitizing a person's teeth, comprising:

(1) placing a substantially solid dental bleaching composition having a tray-like configuration over the person's teeth for a desired period of time, said bleaching composition comprising:

at least one dental bleaching agent; and

at least one tooth adhesion agent having increased adhesiveness to teeth when said bleaching composition is moistened by saliva or water;

(2) removing said dental bleaching composition;

(3) placing a substantially solid dental desensitizing composition having a tray-like configuration over the person's teeth for a desired period of time, said desensitizing composition comprising:

at least one dental desensitizing agent; and

at least one tooth adhesion agent having increased adhesiveness to teeth when said dental desensitizing composition is moistened by saliva or water; and

(4) removing said dental desensitizing composition.

45. A method as defined in claim 44, wherein acts (1) and (2) are performed prior to acts (3) and (4).

46. A method as defined in claim 44, wherein acts (3) and (4) are performed prior to acts (1) and (2).

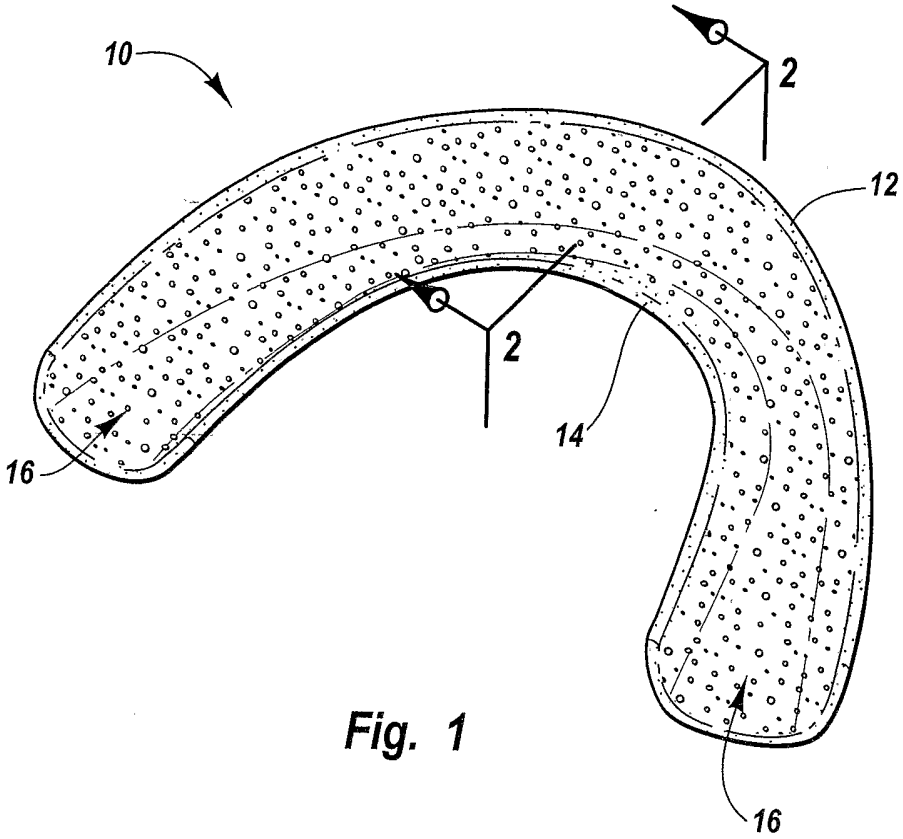

Fig. 1

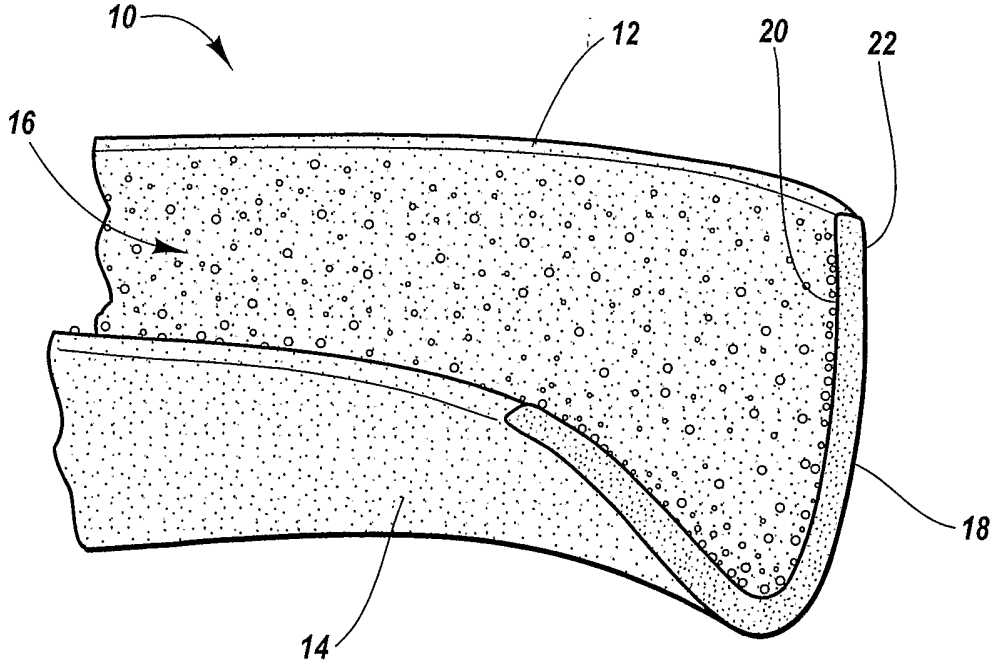

Fig. 2

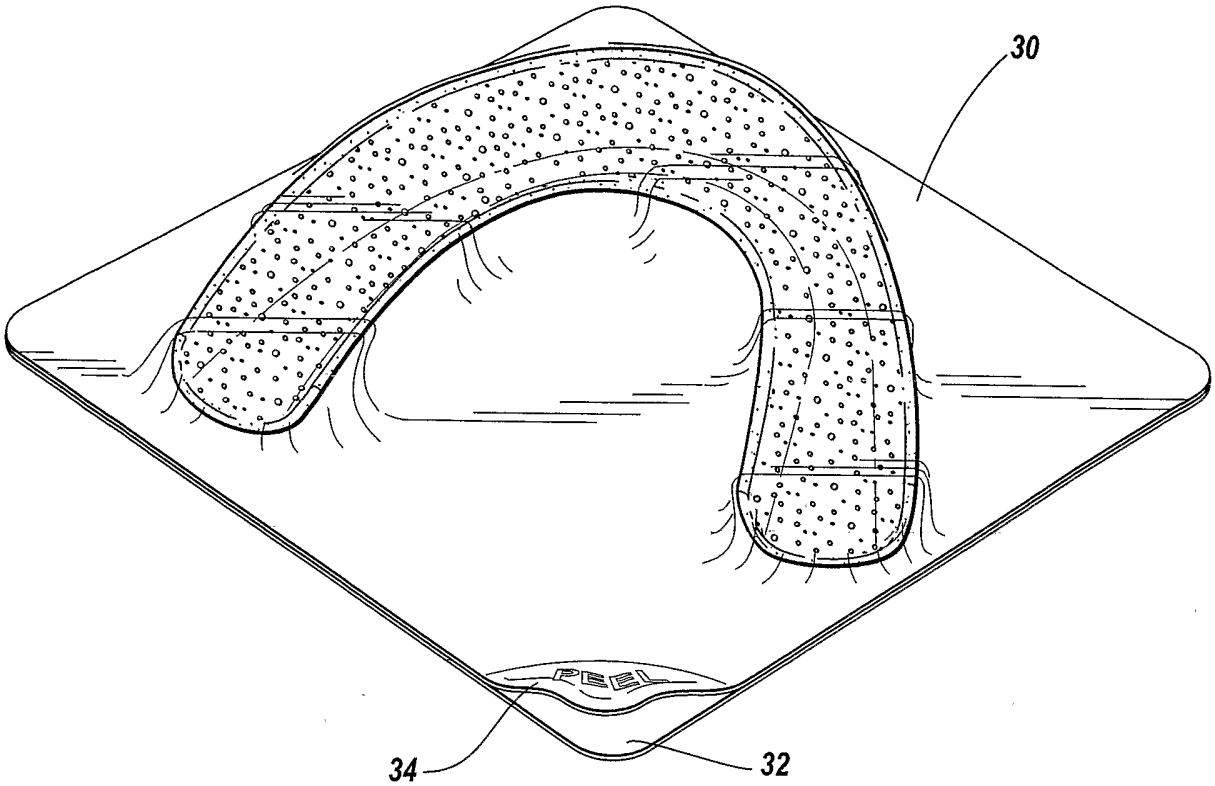

Fig. 3

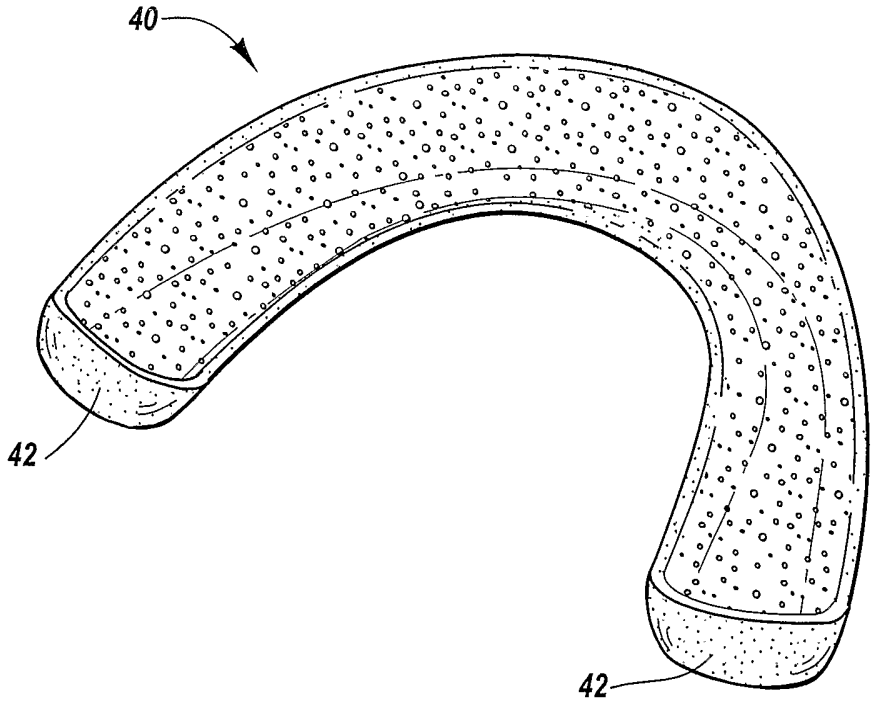

Fig. 4

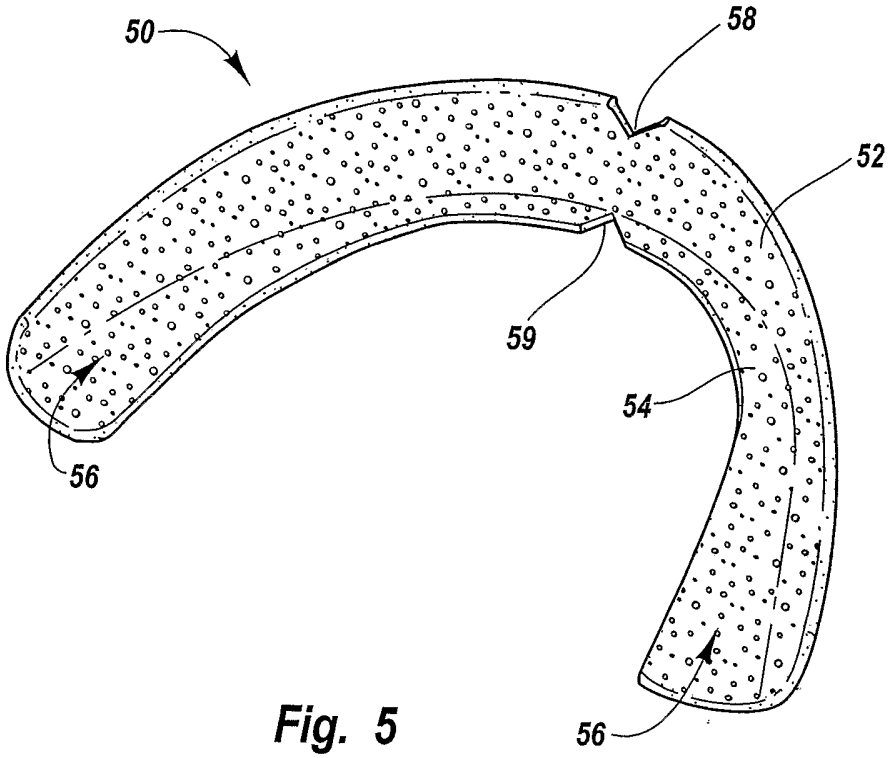

Fig. 5

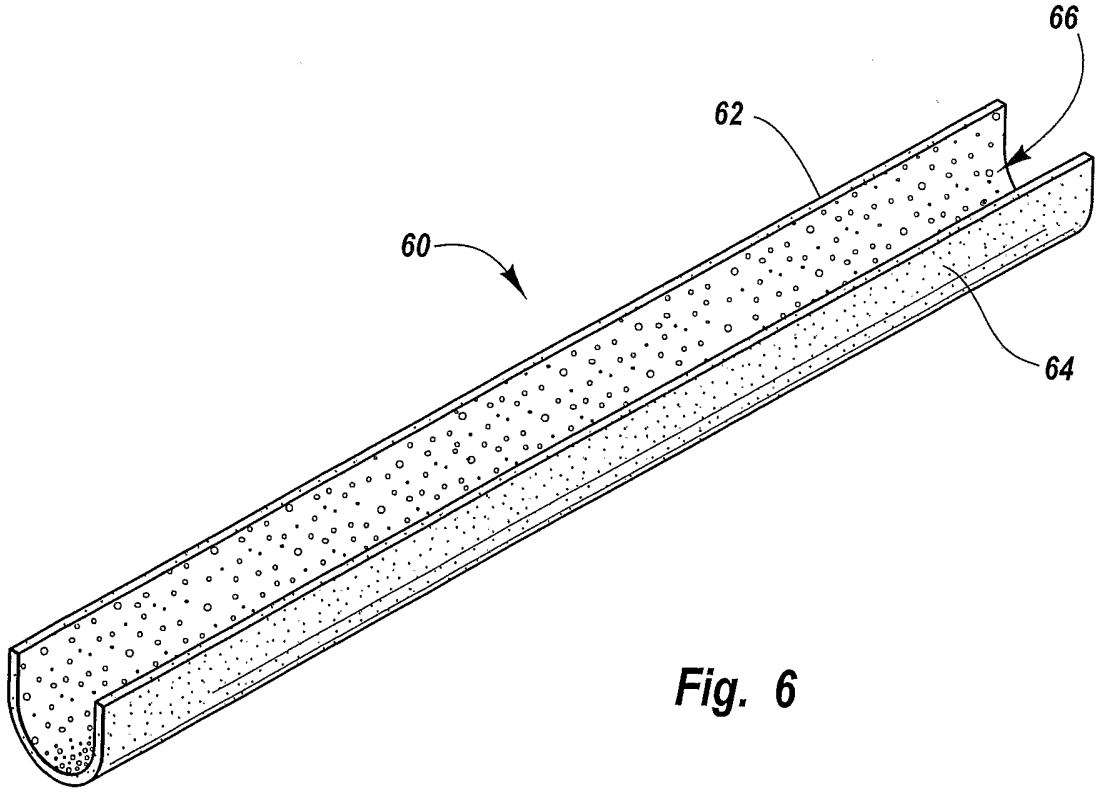

Fig. 6

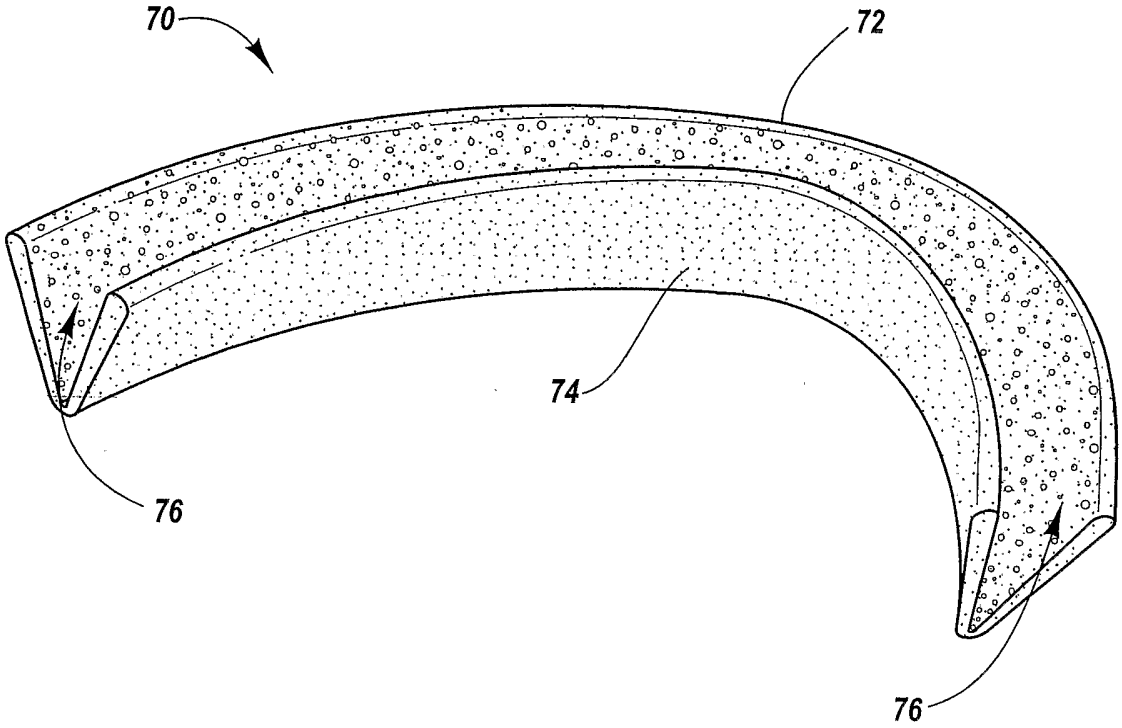

Fig. 7

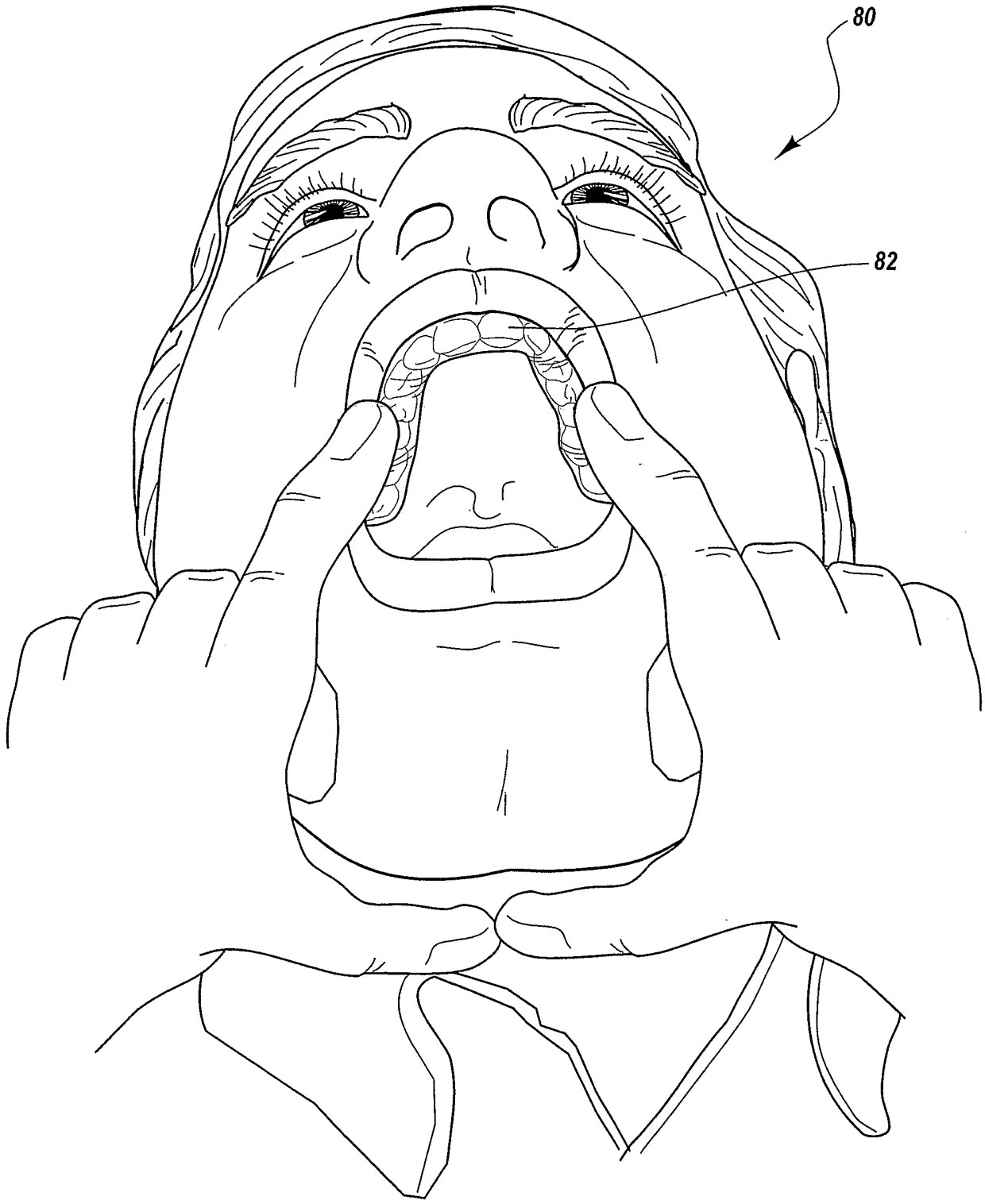

Fig. 8

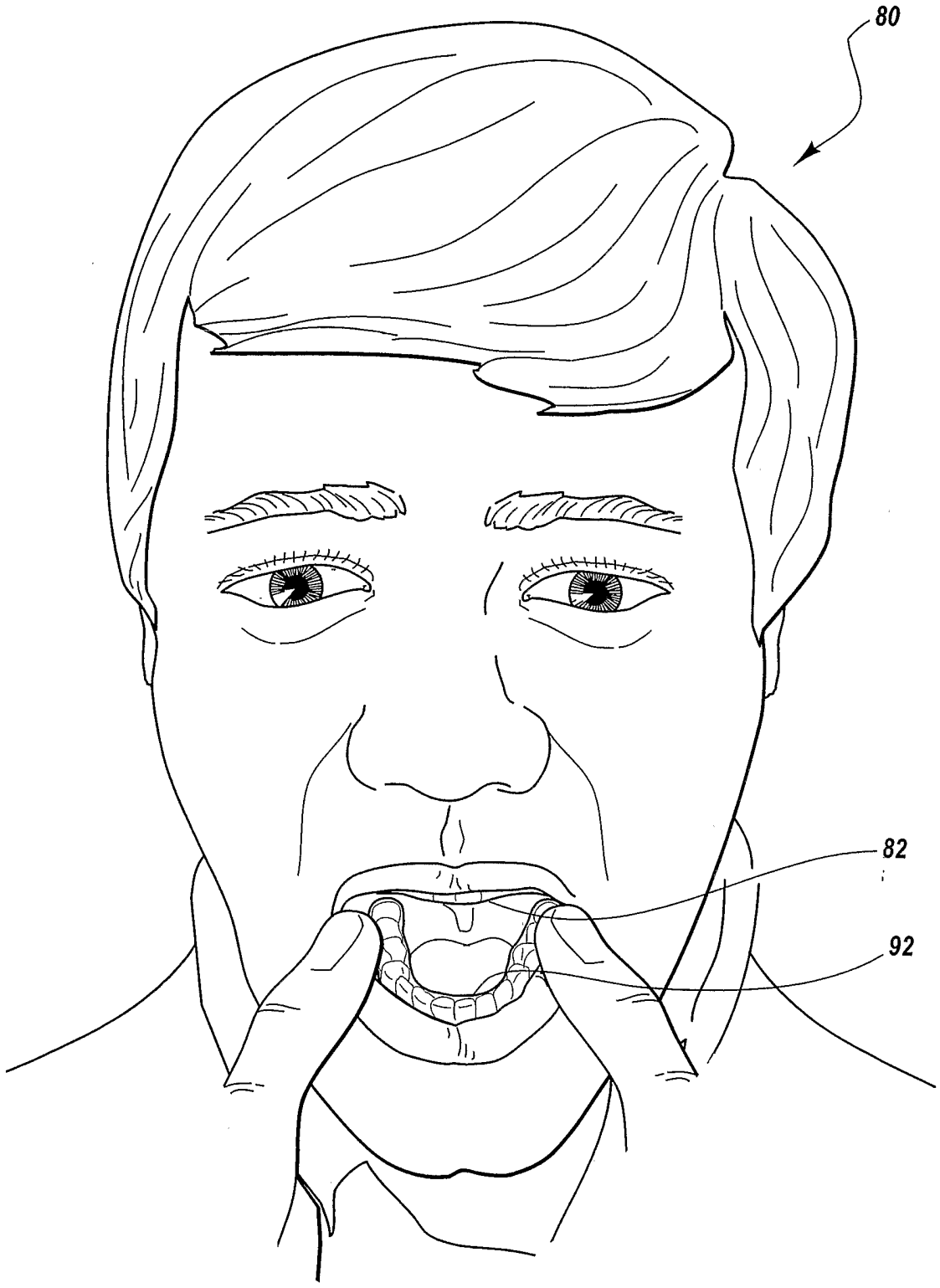

Fig. 9