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### (54) TIME INDICATING CONTAINERS FOR **DENTAL COMPOSITIONS**

(76) Inventors: Dan E. Loveridge, Sandy, UT (US); Dan E. Fischer, Sandy, UT (US); Jeff Wagner, Sandy, UT (US)

> Correspondence Address: Rick D. Nydegger WORKMAN NYDEGGER 1000 Eagle Gate Tower **60 East South Temple** Salt Lake City, UT 84111 (US)

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(57)ABSTRACT

A system for storing a dental composition having a given shelf-life. The storage system includes a container (e.g., a syringe) and activatable time sensitive marking means disposed on or within the container. Upon activation of the time sensitive marking means, the system begins to indicate time lapsed since activation. The time sensitive marking means allows a dental practitioner to determine whether a dental composition within the container has expired, or how much time remains before the composition expires and should either be used up or discarded.

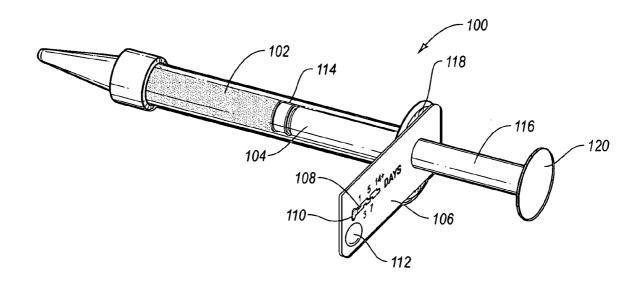


Fig. 1A

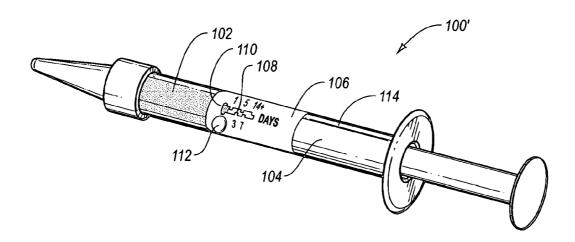
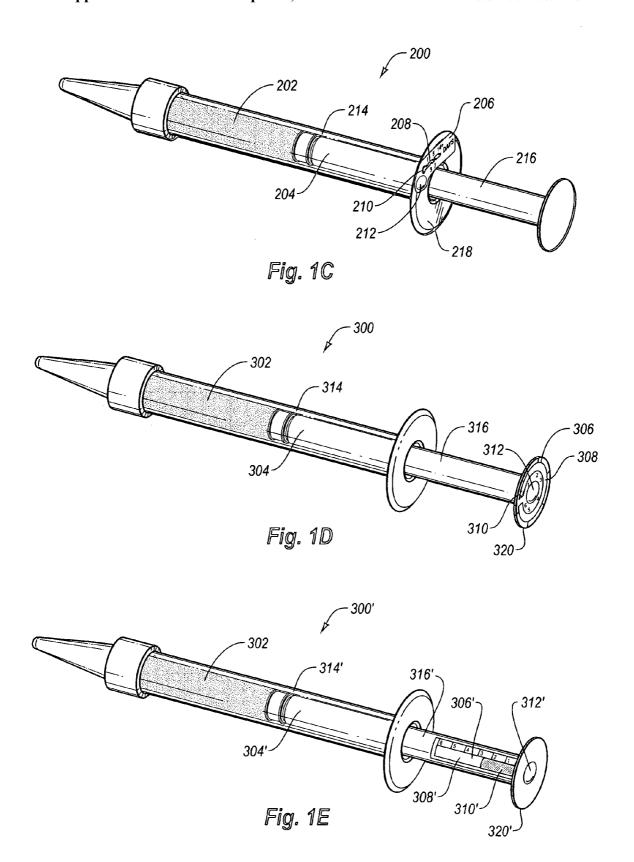


Fig. 18



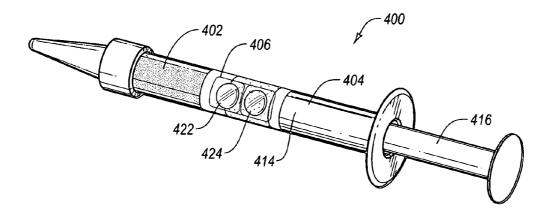


Fig. 2

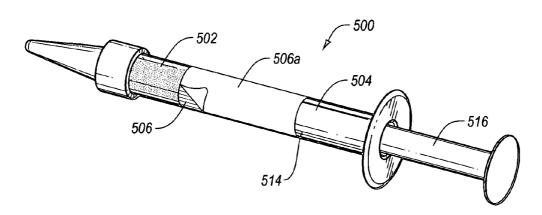


Fig. 3

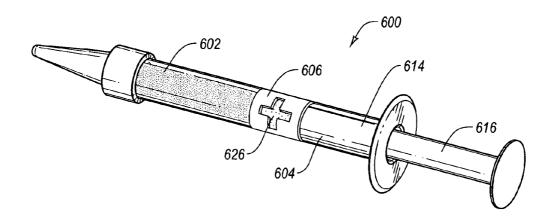


Fig. 4

# TIME INDICATING CONTAINERS FOR DENTAL COMPOSITIONS

#### BACKGROUND OF THE INVENTION

[0001] 1. The Field of the Invention

[0002] The present invention is directed to devices for holding and dispensing dental compositions. More particularly, the invention is directed to containers for holding and dispensing dental compositions having a given shelf-life after which the composition should either be used up or discarded. For example, many multi-part dental compositions require mixing of two separate components, the mixed composition having a particular shelf-life, after which time the mixed composition should be used up or discarded.

[0003] 2. The Relevant Technology

[0004] Many modem formulations are packaged in two initially separate parts, often known as A and B components. Upon mixing, the A and B components form a mixed composition having a particular viable shelf-life, after which the composition should be used up or discarded. In the dental field, for example, several such formulations include two-part dental primers, peroxide and other two-part bleaching compositions, and disinfecting solutions.

[0005] It can be difficult for a dental practitioner to determine whether the shelf-life of a formulation has expired, or how much of the formulation's shelf-life remains. This difficulty can be further complicated in some instances where the shelf-life of a given formulation may depend on the environment in which the formulation is stored. For example, many formulations may have an extended shelf-life if stored in a refrigerated environment as compared to the shelf-life when stored at room temperature.

[0006] It would be an advantage to provide a container system for use with such a formulation that would allow the user to quickly and easily determine how much time remains of the shelf-life of a given formulation. It would be a further advantage if such a system could account for variability in shelf-life due to changes in the formulation storage environment.

#### SUMMARY OF THE INVENTION

[0007] The present invention is directed to a storage system for a dental composition having a given shelf-life. The storage system includes a container (e.g., a syringe), and activatable time sensitive marking means disposed on or within the container, wherein upon activation, the time sensitive marking means identifies time lapsed since activation of the time sensitive marking means. The dental practitioner may activate the time sensitive marking means at an appropriate time to monitor the shelf-life of the dental composition (e.g., immediately after preparing the composition by mixing together initially separate components). The time sensitive marking means allows a dental practitioner to determine whether a dental composition within the container has expired, or how much time remains before the composition expires and should either be used up or discarded.

[0008] In one example, the activatable time sensitive marking means comprises an activatable label disposed on or within the container. One such label includes a length of

a microporous material and a tinted liquid that migrates along the microporous material by capillary action so as to have a migration length that increases as a function of time. The label is activated by causing the tinted liquid to contact the microporous material. In one example, the tinted liquid may initially be contained within a blister or similar packaging adjacent to the microporous material. Upon pressing (i.e., activating) the blister packaging, the tinted liquid contacts the microporous material and begins to wick up along the microporous material due to capillary action. The progress of the tinted liquid is a function of time, such that the migration length of the tinted liquid indicates how much time has lapsed since activation (and thus also the time remaining until the shelf-life of the composition expires).

[0009] In another example, the activatable time sensitive marking means may comprise a label including two adjacent blister packets, each blister packet containing a composition such that the compositions are initially separate from each other. The user presses one or both of the blisters so as to cause a thin membrane between the blister packets to break, which allows the two compositions to mix together, activating the label. The mixed composition begins as characterized by having a first color, and progressively changes to a second color as a function of time. Once the mixed composition has changed to the second color, this indicates to the user that the given shelf-life of a dental composition within the container has expired and should be discarded.

[0010] Another activatable time sensitive marking means may comprise a tape formed of a material that begins to change color from a first color to a second color as a function of time. Once the tape has changed to the second color, this indicates to the user that the given shelf- life of a dental composition within the container has expired.

[0011] Another activatable time sensitive marking means may comprise a label including a microchip configured to measure lapsed time. The microchip is readable by an associated microchip reader so as to indicate to a user how much time remains of a given shelf-life of a composition within the container.

[0012] The activatable time sensitive marking means may be temperature sensitive in addition to being time sensitive. Temperature sensitivity of the marking means allows the system to account for variability in shelf-life due to temperature changes in the storage environment of the dental composition stored within the container.

[0013] A dental composition within the container may have a given shelf-life ranging from less than about a week to 2 years or more. Because of relative instability, many mixed two-part dental compositions have a relatively short shelf-life (e.g., 30 days or less). For example some two-part peroxide bleaching compositions may have a shelf-life of about 10-14 days after mixing, some disinfecting solutions may have a shelf-life of about a week or less, and some two-part dental primers may have a shelf life of about 30 days. Relatively stable single part dental compositions may have a longer shelf-life (e.g., from 6 months up to 2 years or more). Such compositions often include an expiration date stamped or printed on the container, which can be difficult to identify. The time sensitive marking means of the present invention provides a more easily identifiable label, eliminating the need for the user to search for a difficult to find date stamp.

[0014] These and other benefits, advantages and features of the present invention will become more full 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

[0015] In order that the manner in which the above recited and other benefits, advantages and features of the invention are obtained, a more particular description of the invention briefly described above will be rendered by reference to specific embodiments thereof which are illustrated in the appended drawings. Understanding that these drawings depict only typical embodiments of the invention and are not therefore 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:

[0016] FIG. 1A is a perspective view of an exemplary time indicating system for containing a dental composition including a syringe and an activatable time sensitive label disposed on the syringe plunger stem;

[0017] FIG. 1B is a perspective view of another exemplary time indicating container system including a syringe and an activatable time sensitive label disposed on the syringe barrel;

[0018] FIG. 1C is a perspective view of another exemplary time indicating container system including a syringe and an activatable time sensitive label disposed on the syringe barrel flange;

[0019] FIG. 1D is a perspective view of another exemplary time indicating container system including a syringe and an activatable time sensitive label disposed on the head of the plunger stem;

[0020] FIG. 1E is a perspective view of another exemplary time indicating container system including a syringe and an activatable time sensitive label disposed at least partially within the plunger stem of the syringe;

[0021] FIG. 2 illustrates a time indicating container system including a syringe and an activatable time sensitive label having two blister packets for forming a color changing composition;

[0022] FIG. 3 illustrates a time indicating container system including a syringe and a color changing tape disposed on the syringe barrel; and

[0023] FIG. 4 illustrates a time indicating container system including a syringe and an activatable label including a machine readable time monitoring microchip.

# DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

#### I. Introduction

[0024] A detailed description of the invention will now be provided with specific reference to figures illustrating various exemplary embodiments. It will be appreciated that like structures will be provided with like reference designations.

[0025] The present invention is directed to a storage system for dental compositions having a given shelf-life.

The storage system includes a container (e.g., a syringe) and an activatable time sensitive marking means disposed on or within the container. Upon activation, the time sensitive marking means begins to indicate time lapsed since activation of the time sensitive marking means. The dental practitioner may activate the time sensitive marking means at an appropriate time to allow the dental practitioner to monitor the shelf- life of the dental composition (e.g., immediately subsequent to preparing the composition by mixing together initially separate components, exposing the dental composition to air, or exposing the dental composition to light). The time sensitive marking means allows a dental practitioner to determine whether a dental composition within the container has expired, or how much time remains before the composition expires and should be used up or discarded. The container and activatable time sensitive marking means may be relatively inexpensive, allowing the user to discard the entire system once the dental composition has expired.

#### II. Exemplary Dental Composition Container Systems

[0026] FIG. 1A illustrates an exemplary system 100 for both containing and dispensing a dental composition 102. System 100 includes a syringe 104 and an activatable time sensitive label 106. Syringe 104 includes a barrel 114 and a plunger 116. Barrel 114 includes a flange 118 and plunger 116 includes a head 120. Label 106 includes a length of a microporous material 108 and a tinted liquid 110 that is initially contained within a blister 112. In the illustrated system, label 106 includes a hole through which the plunger 116 of syringe 104 passes. Label 106 may be adhered to flange 118 of syringe 104 or may slide with plunger 116.

[0027] Label 106 is activated by causing the tinted liquid to contact the microporous material. In one example, the tinted liquid may initially be contained within a blister or similar packaging adjacent to the microporous material. Upon pressing (i.e., activating) the blister packaging, the tinted liquid contacts the microporous material and begins to wick up along the microporous material due to capillary action. The progress of the tinted liquid is a function of time, such that the migration length of the tinted liquid (i.e., how far along the microporous material the tinted liquid has migrated) indicates how much time has lapsed since activation (and thus also the time remaining until the shelf-life of the composition expires). As illustrated, microporous material 108 may include markings spaced along its length to mark how much time has lapsed since activation (e.g., a number of days, weeks, or months) when the tinted liquid reaches the corresponding mark. One such activatable label including a microporous material and a tinted liquid initially contained within a blister that may be suitable is available from Timestrip Ltd., located in Hitchin, Hertfordshire, United Kingdom.

[0028] FIG. 1B illustrates an alternative system 100' including a syringe 104 containing a dental composition 102 and a label 106 adhered to the barrel 114 of syringe 104. Label 106 includes a length of a microporous material 108 and a tinted liquid 110 that is initially contained within a blister 112. Upon pressing (i.e., activating) blister 112, the tinted liquid 110 is brought into contact with the microporous material 108 and begins to wick up along the microporous material 108 due to capillary action. The progress of the tinted liquid 110 indicates how much time has lapsed since activation.

[0029] FIG. 1C illustrates an alternative system 200 including a syringe 204 containing a dental composition 202 and a label 206 adhered to flange 218 of syringe barrel 214. Label 206 includes a length of a microporous material 208 and a tinted liquid 210 that is initially contained within a blister 212. Upon pressing (i.e., activating) blister 212, the tinted liquid 210 is brought into contact with the microporous material 208 and begins to wick up along the microporous material 208 due to capillary action. The progress of the tinted liquid 210 indicates how much time has lapsed since activation.

[0030] FIG. 1D illustrates an alternative system 300 including a syringe 304 containing a dental composition 302. Syringe 304 includes a barrel 314 and a plunger 316. A label 306 is disposed on head 320 of plunger 316. Label 306 includes a curved length of microporous material 308 and a tinted liquid 310 that is initially contained within blister 312. A substantially straight length of microporous material may alternatively be used. In addition, a curved length of microporous material 308 may also be used with any of the other illustrated embodiments. Such a curved length of microporous material 308 may be particularly suited for the embodiment of FIG. 1C.

[0031] Again referring to FIG. 1D, locating blister 312 on head 320 makes it conveniently placed for activation as plunger 316 is also used to dispense composition 302. Blister 312 can be pressed, forcing tinted liquid 310 into contact with an end of the curve of microporous material 308. Liquid 310 begins to wick up, progressing along microporous material 308 due to capillary action. The progress of the tinted liquid 310 indicates how much time has lapsed since activation under given conditions (e.g., room temperature).

[0032] FIG. 1E illustrates an alternative system 300' including a syringe 304' containing a dental composition 302. Syringe 304' includes a barrel 314 and a plunger stem 316'. A label 306' is disposed at least partially within plunger 316'. Label 306' includes a length of microporous material 308' that is sealed within plunger stem 316'. Microporous material 308' is arranged so as to be along or parallel to the central longitudinal axis of plunger stem 316'. A tinted liquid 310' is initially contained within blister 312' disposed on head 320'. Blister 312' can be pressed, forcing tinted liquid 310' into contact with an end of microporous material 308'. Liquid 310' begins to wick up, progressing along microporous material 308' due to capillary action. The progress of the tinted liquid 310' indicates how much time has lapsed since activation under given conditions (e.g., room temperature). Sealing microporous material 308' within plunger stem 316' provides a controlled humidity environment for microporous material 308', which can provide increased accuracy when used in both dry and humid environments where humidity may not be constant. This is because the rate of progress along the microporous material due to capillary action can be affected by changes in humidity.

[0033] Labels 106, 206, 306, and 306' are examples of activatable time sensitive marking means. Because the labels rely on capillary action of a liquid migrating through a microporous material, the rate of migration of the tinted liquid may be dependent on temperature in addition to time. In other words, the tinted liquid may migrate a given

distance (e.g., about the distance marked "7 days") over a seven day period when stored at room temperature, but may alternatively migrate a shorter distance (e.g., about the distance marked "3 days") if stored in a refrigerated environment (e.g., as a result of increased viscosity of the tinted liquid and/or decreased wetting ability of the microporous material). Surprisingly, it has been found that the temperature dependent variability of the capillary action roughly matches the temperature dependent variability of the shelflife of many dental compositions. For example, the dental composition may be stored in a refrigerated environment, and then later stored at room temperature, and the progress of the tinted liquid along the microporous material may vary according to the environment conditions. This characteristic is advantageous as it allows the label to accurately indicate the remaining shelf-life of a dental composition that varies due to differences in storage environments.

[0034] FIG. 2 illustrates an alternative system 400 including a syringe 404 containing a dental composition 402. Syringe 404 includes a barrel 414 and a plunger 416. A label 406 is disposed on barrel 414. Label 406 includes a first blister 422 and a second blister 424 near first blister 422. First blister 422 contains a first composition and second blister 424 contains a different second composition. Blisters 422 and 424 are initially separated by a thin membrane. In order to activate time sensitive label 406, the user presses one or both of blisters 422 and 424 so as to break the thin membrane and cause the compositions to mix together. The mixed composition begins as a first color and progressively changes to a second different color over time. As long as the mixed composition is not of the second color, the user knows that the dental composition within with container has not yet expired. Once the second color has been reached, the dental composition 402 or system 400 should be discarded. In some embodiments, the mixed composition may include one or more intermediate colors between the initial color and the second color that signifies expiration of the dental composition. One such label including blisters containing initially separate components for forming a color changing mixed composition that may be suitable is available from Vitsab Inc., located in Belmont, N.C.

[0035] Because label 406 relies on a color changing chemical reaction, the rate of reaction may also be dependent on temperature. Surprisingly, it has been found that the temperature dependent variability of the color changing chemical reaction roughly matches the temperature dependent variability of the shelf-life of many dental compositions. This characteristic is advantageous as it allows the label to accurately indicate the remaining shelf-life of a dental composition that varies due to differences in storage environments.

[0036] FIG. 3 illustrates an alternative system 500 including a syringe 504 containing a dental composition 502. Syringe 504 includes a barrel 514 and a plunger 516. A label 506 is disposed on barrel 514. Label 506 is formed of a material that begins to change color from a first color to a second color as a function of time. After activation, as long as label 506 is not of the second color, the user knows that the dental composition 502 within container 504 has not yet expired. Once the second color has been reached, the dental composition 502 or system 500 should be discarded. In some embodiments, the label 506 may change colors so as to include one or more intermediate colors between the initial

color and the second color that signifies expiration of the dental composition. One such label formed of a color changing material that may be suitable is available from Wipak UK Ltd., located in Welshpool, Powys, United Kingdom.

[0037] Label 506 may be activated by exposure of the material to moisture within the air. As such, label 506 may initially include a peelable moisture barrier foil 506a that covers label 506. In order to activate label 506, the user simply removes foil 506a.

[0038] Because label 506 relies on a color changing chemical reaction, the rate of reaction may also be dependent on temperature. Surprisingly, it has been found that the temperature dependent variability of the color changing chemical reaction roughly matches the temperature dependent variability of the shelf-life of many dental compositions. This characteristic is advantageous as it allows the label to accurately indicate the remaining shelf-life of a dental composition that varies due to differences in storage environments.

[0039] FIG. 4 illustrates an alternative system 600 including a syringe 604 containing a dental composition 602. Syringe 604 includes a barrel 614 and a plunger 616. A label 606 is disposed on barrel 614. Label 606 includes a microchip 626 configured to measure lapsed time. Microchip 626 is readable by an associated microchip reader so as to indicate to a user how much time remains in the shelf-life of composition 602 within container 604. One such label including a microchip configured to measure lapsed time and an associated microchip reading device that may be suitable is available from Clinisense Corporation located in Los Gatos, Calif.

[0040] Microchip 626 may also be configured to account for differences in temperature, so as to integrate monitoring of both time and temperature. Such a configuration allows the label accurately indicate the remaining shelf-life of a dental composition that is stored in a variety of environments.

[0041] The dental composition within the syringe or other container may have a given shelf-life ranging from less than about a week to 2 years or more. Because of relative instability many mixed two-part dental compositions have a relatively short shelf-life (e.g., 30 days or less). For example some two-part peroxide bleaching compositions may have a shelf-life of about 10-14 days after mixing, some disinfecting solutions may have a shelf-life of about a week or less, and some two-part dental primers may have a shelf life of about 30 days. Container systems including activatable time sensitive marking means according to the present invention are particularly suitable for use with such mixed dental compositions.

[0042] In addition, relatively stable single part dental compositions may have a shelf-life that is much longer (e.g., from 6 months up to 2 years or more). Such compositions often include an expiration date stamped or printed on the container, which can be difficult to identify. The time sensitive marking means of the present invention provides a more easily used system including a more easily identifiable label, eliminating the need for the user to search for a difficult to find date stamp. The container systems of the present invention may also be used with such compositions.

III. Exemplary Method of Use

[0043] In one exemplary method of use, a dental composition having a given shelf-life is provided. For example, the dental composition may comprise a mixed composition formed by mixing together initially separate components in a syringe-to-syringe mixing device or other suitable mixing apparatus. A container including activatable time sensitive marking means disposed on or within the container is also provided. The container may comprise a syringe of the syringe-to-syringe mixing apparatus such that the dental composition may be container. Alternatively, the dental composition may be introduced into the container (e.g., a syringe) including an activatable time sensitive marking means disposed on or within the container.

[0044] The time sensitive marking means may be activated when needed so as to begin to indicate the remaining shelf-life of the composition. Typically the time of activation will coincide with an event which affects the shelf-life of the composition (e.g., mixing initially separate components to form the dental composition or opening a container to expose the dental composition to air or light). The time sensitive marking means indicates how much time has lapsed since activation, indicating to the user whether the dental composition is usable or not.

[0045] The dental practitioner identifies whether the given shelf-life of the composition is greater than or less than the time lapsed since activation. If the lapsed time is less than the given shelf-life, then the dental practitioner may dispense and use the dental composition. If the given shelf-life is less than the time lapsed since activation, then the dental practitioner may discard the composition or system. The container and activatable time sensitive marking means may be relatively inexpensive, allowing the user to discard the entire system once the dental composition has expired.

[0046] It will be appreciated that the present claimed invention may be embodied in other specific forms without departing from its spirit or essential characteristics. For example, although several specific embodiments of activatable time sensitive marking means have been described, it is to be understood that any structure that can be disposed on or integrated into the container with the ability to indicate time lapsed since activation may be used. The described embodiments are to be considered in all respects only as illustrative, not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

- 1. A time indicating storage system for a dental composition comprising:
  - a container for holding a dental composition; and
  - activatable time sensitive marking means disposed on or within the container, wherein upon activation, the time sensitive marking means identifies time lapsed since activation of the time sensitive marking means.
- 2. A system as recited in claim 1, wherein upon activation, the time sensitive marking means also identifies time remaining until expiration of a dental composition within the container.

- 3. A system as recited in claim 1, the container comprising a syringe including a syringe barrel and a plunger slidably disposed within the syringe barrel.
- **4**. A system as recited in claim 3, wherein the activatable time sensitive marking means is disposed on the syringe barrel of the syringe.
- 5. A system as recited in claim 3, wherein the activatable time sensitive marking means is disposed on the plunger of the syringe.
- 6. A system as recited in claim 1, wherein the time sensitive marking means comprises a label disposed on or within the container, the label including a length of microporous material and a tinted liquid that migrates along the microporous material by capillary action so as to have a migration length that increases as a function of time, the migration length of the tinted liquid indicating time lapsed since activation of the time sensitive marking means.
- 7. A system as recited in claim 6, the label further comprising a blister that initially contains the tinted liquid.
- **8**. A system as recited in claim 6, the length of microporous material being configured as a substantially straight strip.
- **9.** A system as recited in claim 6, the length of microporous material being configured as a curved strip.
- 10. A system as recited in claim 1, wherein the time sensitive marking means comprises a label disposed on or within the container, the label including a blister containing two initially separate components that upon mixing form a mixed composition that begins to change from a first color to a second color as a function of time, the second color indicating that the shelf-life of a composition within the container has expired.
- 11. A system as recited in claim 1, wherein the time sensitive marking means comprises a label disposed on or within the container, the label being formed of a material that upon activation begins to change from a first color to a second color as a function of time, the second color indicating that the shelf-life of a composition within the container has expired.
- 12. A system as recited in claim 1, wherein the time sensitive marking means comprises a label disposed on or within the container, the label including a microchip configured to measure lapsed time, the microchip being readable by an associated microchip reader so as to indicate to a user how much time remains to the shelf-life of a composition within the container.
- 13. A system as recited in claim 1, further comprising a dental composition within the container.
- 14. A system as recited in claim 13, wherein the dental composition comprises a mixed two-part dental primer, a mixed two-part bleaching composition, or a disinfecting solution.
- 15. A system as recited in claim 1, wherein the time sensitive marking means is also temperature sensitive so as to account for variability in shelf-life due to temperature changes in a storage environment.
- **16**. A time indicating storage system for a dental composition comprising:

- a syringe for holding a dental composition, the syringe including a barrel and a plunger stem slidably disposed within the barrel; and
- an activatable label disposed at least partially within the plunger stem comprising:
  - a length of microporous material sealed within the plunger stem; and
  - a blister disposed on a head of the plunger stem, the blister containing a tinted liquid that migrates along the microporous material by capillary action upon activation so as to have a migration length that increases as a function of time, the migration length of the tinted liquid indicating time lapsed since activation.
- 17. A system as recited in claim 16, wherein the migration length of the tinted liquid along the microporous material is also dependent on temperature so as to account for variability in shelf-life due to temperature changes in a storage environment.
- **18**. A method for determining the remaining shelf-life of a dental composition comprising:
  - providing a container including activatable time sensitive marking means disposed on or within the container, wherein upon activation, the time sensitive marking means identifies time lapsed since activation of the time sensitive marking means;
  - providing a dental composition within the container having a given shelf-life;
  - activating the time sensitive marking means disposed on or within the container;
  - identifying whether the given shelf-life of the dental composition is greater than or less than the time lapsed since activation of the time sensitive marking means.
- 19. A method as recited in claim 18, wherein the given shelf-life of the dental composition is less than the time lapsed since activation of the time sensitive marking means, further comprising discarding the container and the dental composition.
- 20. A method as recited in claim 18, wherein the given shelf-life of the dental composition is greater than the time lapsed since activation of the time sensitive marking means, further comprising dispensing at least a portion of the dental composition from the container for use.
- 21. A method as recited in claim 18, wherein the provided dental composition within the container comprises a mixed composition that was previously prepared by mixing together at least two initially separate components to form a mixed dental composition.
- 22. A method as recited in claim 21, wherein the step of activating the time sensitive marking means is performed immediately subsequent to mixing together the at least two initially separate components to form the mixed dental composition.

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