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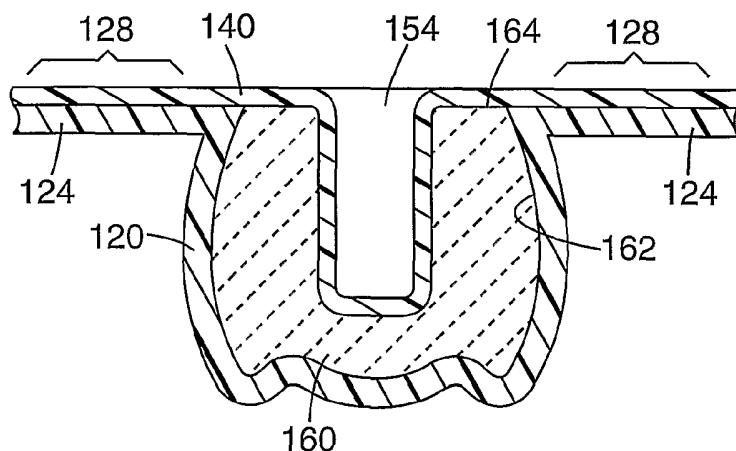
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(54) Title: HARDENABLE DENTAL ARTICLE AND METHOD OF MANUFACTURING THE SAME



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(57) Abstract: Methods of manufacturing hardenable dental articles, packaged hardenable dental articles, and methods of packaging hardenable dental articles are disclosed. In various embodiments, the manufacturing may involve molding a hardenable dental material in a mold cavity that may be lined with a mold liner. The mold body may also form the package of the hardenable dental article formed within the mold cavity. In other embodiments, the hardenable dental articles may be provided in mold cavities located in sacrificial mold bodies that may be torn, stretched, softened, dissolved, etc. to release the hardenable dental articles in the mold cavities.



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## HARDENABLE DENTAL ARTICLE AND METHOD OF MANUFACTURING THE SAME

### BACKGROUND

5 Restorative dentistry is an important market in today's dental industry. In particular, tooth repair with temporary and permanent crowns is a common procedure, typically requiring multiple dental appointments. Conventional technologies use liners, adhesives, pastes, two-part powder/liquid systems, preformed metal temporary crowns, and ceramic or porcelain/metal permanent crowns.

10 Among the problems associated with the conventional technologies are the need for multiple visits to a dentist if a customized dental article is desired. Conversely, if customization is not desired, the dental article used may have a less than desirable fit and/or appearance, e.g., a metallic finish, larger gaps between proximal teeth, significant color variations from natural teeth, etc.

15 Hardenable dental materials have been developed to address some of these issues. Examples of some of these materials are described in, e.g., International Publication No. WO 03/015720 (Karim et al.) and U.S. Publication No. 03-0114553-A1, published June 19, 2003. For the purposes of the present invention, "hardenable dental materials" are materials that are capable of being hardened to form dental articles such as crowns, etc.

20 Although these materials may address the issues identified with respect to conventional technologies, they raise issues of their own with respect to the manufacturing, handling, and packaging of dental articles constructed of such materials. Many of these hardenable dental materials may exhibit significant levels of adhesion during manufacturing. As a result, shaping and handling of the hardenable dental materials into dental articles as a part of the manufacturing process may present challenges.

25 Another potential issue raised with some hardenable dental materials is that the techniques used to form the hardenable dental materials into usable dental articles may contribute to or detract from the finished appearance of the dental articles. In other words, the hardenable dental material may exhibit an undesirable rough appearance due to less than desirable forming techniques and/or packaging.

In addition, although the exact shape of dental articles manufactured of the hardenable materials before final hardening may be adjusted, significant shaping of the materials may not be possible or desirable depending on the properties of the hardenable dental material being used. For example, the dentist may prefer that the materials be 5 provided in a shape that is close to the final desired shape of the dental article - subject to some minor shaping to provide a more customized fit and/or appearance. By providing the hardenable dental materials in a form that is close to the final form needed by the dentist, the time required for the dentist to complete any given dental procedure in which the dental article is used can be reduced. Such forming, however, may exacerbate the 10 problems identified in the preceding paragraphs.

#### SUMMARY OF THE INVENTION

The present invention provides methods of manufacturing hardenable dental articles, packaged hardenable dental articles, and methods of packaging hardenable dental 15 articles. In various embodiments, the manufacturing may involve molding a hardenable dental material in a mold cavity that may be lined with a mold liner. The mold body may also form the package of the hardenable dental article formed within the mold cavity. In other embodiments, the hardenable dental articles may be provided in mold cavities located in sacrificial mold bodies that may be torn, stretched, softened, dissolved, etc. to 20 release the hardenable dental articles in the mold cavities.

The use of a mold liner during manufacturing of hardenable dental articles from hardenable dental materials may provide a number of potential advantages such as assisting with release of the hardenable dental article from the mold cavity; protecting the hardenable dental article from contamination, enhancing the finish of the hardenable 25 dental article by providing a smooth finish on the article during the forming process (if the liner itself is smooth), and enhancing the finish of the dental article after hardening (if the smooth inside surface of the mold liner is retained in intimate contact with the outer surfaces of the hardenable dental article during hardening).

If a mold liner is used in connection with the manufacturing of a hardenable dental 30 article, it may be preferred that the mold liner be in intimate contact with the outer surfaces of the hardenable dental article after release of the hardenable dental article from

the mold cavity. Alternatively, the hardenable dental article may release from the mold liner after or during its removal from the mold cavity.

If the mold liner is retained on the outer surfaces of the hardenable dental article, various advantages may potentially be obtained. If, for example, the dental article is a 5 crown and the hardenable dental material is a photocurable material, the mold liner may function as an actinic light barrier to retard the passage of actinic radiation that could otherwise prematurely harden the photocurable hardenable dental material. If the liner is malleable, the dentist may be able to customize or adjust the shape of the dental crown with the liner in place. Alternatively, the dentist may remove the liner before customizing.

10 The liner may also function as a protective barrier for the outer surfaces of the hardenable dental article. If the liner is maintained in place on the outer surfaces of the hardenable dental article during hardening, it may protect the outer surfaces from, e.g., exposure to oxygen before and during the hardening process. If the liner is to be retained in place during hardening, the liner may be flexible to allow the dentist to customize or 15 shape the hardenable dental article before hardening (if desired).

By retaining the liner in place on the outer surfaces of the hardenable dental articles, the liner may also function as a portion of the packaging of the hardenable dental articles manufactured of hardenable dental materials in accordance with the present invention. For example, the liner (in intimate contact with the outer surfaces of the 20 hardenable dental article) may function as a package cover while a package base is attached to contain the hardenable dental article therein (in a manner similar to a "blister pack").

Although mold cavities formed in reusable mold bodies made of conventional materials such as metals, etc. may be used in connection with manufacturing of hardenable 25 dental articles of the present invention, the present invention may also include the use of mold cavities located in sacrificial mold bodies that include, e.g., lines of weakness formed therein, such that after molding or forming of the hardenable dental material into the shape of the selected hardenable dental article, the sacrificial mold body can be separated along the lines of weakness to remove the hardenable dental article from the 30 mold cavity. Other sacrificial mold bodies may be manufactured of materials that can either be stretched or torn to remove the hardenable dental article in the absence of defined lines of weakness. Still other sacrificial mold bodies may be manufactured of materials

that can be softened or dissolved by contact with a solvent (such as, e.g., water) that does not significantly adversely affect the hardenable dental article. For example, sacrificial mold bodies could be manufactured of water-soluble materials such that exposure to water (by, e.g., sprays, baths, etc.) softens or dissolves the sacrificial mold body such that the 5 hardenable dental article can be removed - preferably without distorting the shape of the hardenable dental article. All of such mold bodies are described as "sacrificial" because they cannot be reused due to their destruction during the removal process.

Removal of a hardenable dental article from a sacrificial mold body may be performed as part of the manufacturing process, with the shaped hardenable dental article 10 being packaged for delivery to a customer after the hardenable dental article has been removed from the sacrificial mold cavity. Alternatively, the sacrificial mold body itself may form a part of the packaging of the hardenable dental article located therein, with removal of the hardenable dental article from the sacrificial mold cavity being performed by, e.g., the dentist or an assistant, at the point of use of the hardenable dental articles. 15 Such sacrificial mold bodies may be used in connection with mold liners as well.

As used herein, the term "dental article" includes, but is not limited to, dental restoratives and dental prostheses, including, e.g., temporary, intermediate, and permanent crowns and bridges, inlays, onlays, implants, dentures, and artificial teeth, etc., as well as orthodontic appliances (e.g., retainers, night guards, etc.), tooth facsimiles or splints, 20 maxillofacial prostheses, and other customized structures.

As used herein, a "hardenable dental article" may optionally be defined as a self-supporting structure of a hardenable dental material that is dimensionally stable and will maintain its shape (e.g., the preformed shape of a dental crown) without significant deformation at room temperature (i.e., about 20°C to about 25°C) for at least two weeks 25 when free-standing (i.e., without any external support). Preferably, the hardenable dental articles of the present invention are dimensionally stable at room temperature for at least about one month, and, more preferably, for at least about six months. Also, it may be preferred that the hardenable dental articles of the present invention are dimensionally stable at temperatures above room temperature, more preferably up to about 40°C, even 30 more preferably up to about 50°C, and even more preferably up to about 60°C. This definition applies in the absence of conditions or materials that would otherwise act to

harden the hardenable dental article and in the absence of an external force other than gravity.

In one aspect, the present invention provides a method of manufacturing a hardenable dental article by providing a mold cavity in a shape of a hardenable dental article, wherein the mold cavity has an opening; forcing a hardenable dental material into the mold cavity through the opening; providing a liner between the hardenable dental material and the mold cavity; and removing the hardenable dental material and the liner from the mold cavity, wherein the hardenable dental material has the shape of the hardenable dental article.

10 In another aspect, the present invention provides a packaged hardenable dental article including a mass of hardenable dental material in the shape of a hardenable dental article, wherein the hardenable dental article has a base and outer surfaces extending from the base; a package cover conforming to and in intimate contact with the outer surfaces of the hardenable dental article, wherein the package cover includes a polymeric film 15 plastically deformed by the mass of hardenable dental material; and a package base facing the base of the hardenable dental article; wherein the package cover and the package base are attached together about a periphery of the base of the hardenable dental article such that the hardenable dental article is contained within the package base and the package cover.

20 In another aspect, the present invention provides a dental article that includes a sacrificial mold body with a sacrificial mold cavity in the shape of a hardenable dental article, wherein the sacrificial mold body includes at least one line of weakness formed therein, the at least one line of weakness defining at least two mold sections in the sacrificial mold body; and a mass of hardenable dental material located within the volume 25 of the sacrificial mold cavity such that the hardenable dental material is in the shape of the hardenable dental article.

30 In another aspect, the present invention provides a packaged hardenable dental article that includes a mass of hardenable dental material in the shape of a hardenable dental article, wherein the hardenable dental article has a base and outer surfaces extending from the base; a package cover conforming to and in intimate contact with the outer surfaces of the hardenable dental article, wherein the package cover includes a sacrificial mold body with a sacrificial mold cavity in the shape of the hardenable dental

article, and wherein the sacrificial mold body includes at least one line of weakness formed therein, the at least one line of weakness defining at least two mold sections in the sacrificial mold body; and a package base facing the base of the hardenable dental article; wherein the package cover and the package base are attached together about a periphery of 5 the base of the hardenable dental article such that the hardenable dental article is contained within the package base and the package cover.

In another aspect, the present invention provides a dental article that includes a sacrificial mold body with a sacrificial mold cavity in a shape of a hardenable dental article, wherein the sacrificial mold cavity conforms to and is in intimate contact with 10 outer surfaces of the hardenable dental article; and a mass of hardenable dental material located within the volume of the sacrificial mold cavity such that the hardenable dental material is in the shape of the hardenable dental article.

In another aspect, the present invention provides a method of manufacturing a hardenable dental article by providing a sacrificial mold body with a sacrificial mold 15 cavity in a shape of a hardenable dental article, wherein the sacrificial mold body includes a water soluble polymer; and forcing a hardenable dental material into the sacrificial mold cavity through the opening, wherein the hardenable dental material takes the shape of the hardenable dental article.

In another aspect, the present invention provides a method of manufacturing a hardenable dental article by providing a sacrificial mold body with a sacrificial mold cavity in a shape of the hardenable dental article, wherein the sacrificial mold cavity has an opening, and wherein the sacrificial mold body includes at least one line of weakness 20 formed therein, the at least one line of weakness defining at least two mold cavity sections in the sacrificial mold body; and forcing a hardenable dental material into the sacrificial mold cavity through the opening, wherein the hardenable dental material takes the shape 25 of the hardenable dental article.

These and other features and advantages of the present invention may be described in more detail in connection with various illustrative embodiments of the invention below.

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#### BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is an exploded schematic diagram of one illustrative manufacturing process according to the present invention.

FIG. 2 is a cross-sectional view of one illustrative hardenable dental article in a package according to the present invention.

FIG. 3 is a schematic diagram of one illustrative variation in a manufacturing process according to the present invention.

5 FIG. 4 is a schematic diagram of another illustrative variation in a manufacturing process according to the present invention.

FIG. 5 is a schematic diagram of an alternative illustrative manufacturing process according to the present invention.

10 FIG. 6 is a schematic diagram of the manufacturing process of FIG. 5, with the hardenable dental material located within the mold cavity.

FIG. 7 is a schematic diagram of still another alternative illustrative manufacturing process according to the present invention.

FIG. 8 is a plan view of the base of one illustrative hardenable dental article in a package in accordance with the present invention.

15 FIG. 9 is a cross-sectional view of the hardenable dental article of FIG. 8 taken along line 9-9 in FIG. 8.

FIG. 10 is a perspective view of the outer surface of one illustrative sacrificial mold cavity/body used in connection with the present invention.

20 FIG. 11 is a perspective view of the opposite side of the sacrificial mold of FIG. 10 depicting the mold cavity formed therein.

FIG. 12 is a side elevational view of an illustrative hardenable dental article on a base of the sacrificial mold body of FIG. 10 after removal of the mold sections.

FIG. 13 is a cross-sectional view of another illustrative sacrificial mold cavity according to the present invention.

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## DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

### OF THE INVENTION

In the following detailed description of illustrative embodiments, reference is made to the accompanying figures of the drawing, which form a part hereof, and in which are 30 shown, by way of illustration, specific embodiments in which the invention may be practiced. It is to be understood that other embodiments may be utilized and structural changes may be made without departing from the scope of the present invention.

FIG. 1 is an exploded diagram illustrating one process of forming a hardenable dental article according to the present invention. The illustrated process includes a mold cavity 10 formed in a body 12. The mold cavity 10 includes an opening 14 leading to the volume of the mold cavity itself, which is depicted in cross-section in FIG. 1. In the 5 depicted embodiment, the mold cavity 10 is in the shape of a dental crown. It should, however, be understood that the hardenable dental articles of the present invention may include a wide variety of articles as discussed above.

The mold body 12 may be formed in any suitable material or combination of materials, e.g., metals, polymeric materials, etc. that provide sufficient structural integrity 10 to withstand the forming process as described herein. In some instances, the mold body 12 may be formed in separable sections to facilitate removal of a hardenable dental article formed therein. Also, the mold body 12 may be made of or coated with a material adapted to aid release of a hardenable dental article from the interior surfaces of the mold cavity 10. For example, the interior surfaces of the mold cavity 10 may be coated with, e.g., 15 fluorinated polymers (e.g., PTFE, etc.), boron carbide, chrome, thin dense chrome, chromium nitride, electroless nickel infused with fluorinated polymers, modified tungsten disulfide (e.g., DICRONITE), etc.

In other variations, the mold cavity 10 may be temperature controlled to assist in the molding process by, e.g., heating and/or cooling the temperature of the interior 20 surfaces of the mold cavity 10. In yet other variations, the mold cavity 10 may be vented or evacuated during the molding process to enhance molding. Ultrasonic or other vibrational energy may also be used to enhance filling of the mold cavity 10 and/or assist with release the article from the mold cavity 10.

A mold liner 20 is depicted in FIG. 1 as positioned in between a mass of 25 hardenable dental material 30 and the opening 14 into the mold cavity 10. A pin liner 40 is positioned between the mass of hardenable dental material 30 and a core pin 50. The core pin 50 is preferably used to force the mass of hardenable dental material 30 into the mold cavity 10 through the opening 14 therein. As a result, the core pin 50, a portion of the pin liner 40, the hardenable dental material 30, and a portion of the mold liner 20 are 30 all advanced in the direction of arrow 52 as depicted in FIG. 1.

The mass of hardenable dental material 30 may be pre-formed into a shape suitable for molding into the desired finished dental article. The hardenable dental material 30

may be provided in the shape of, e.g., a circular cylinder, circular cone, rectangular prism, spherical pellet, etc.

Further, the shape of the core pin 50 may be selected such that it enhances molding of the hardenable dental material 30 within the mold cavity 10. In addition, it may be 5 desirable if the core pin 50 is shaped such that it seals or closes the mold cavity to, e.g., define the edge of the molded hardenable dental article and/or to prevent or reduce the chances of unwanted voids in the hardenable dental material 30 within the mold cavity 10. The shape of the core pin 50 may also be selected to impart a desired shape to the interior profile of the finished hardenable dental article.

10 The process illustrated in FIG. 1 may be described as a compression molding process. It should, however, be understood that the hardenable dental material 30 may be formed into the shape of the hardenable dental article by any suitable process. Some suitable processes may include, but are not limited to, e.g., injection molding, forging, casting, vacuum forming, extrusion molding, thermoforming, transfer molding, blow 15 molding, etc.

In the process, the mold liner 20 may be stretched to conform to the shape of the mold cavity 10. At the same time, the mass of hardenable dental material 30 is also molded to conform to the shape of the mold cavity 10. The hardenable dental material 30, will, however, be slightly smaller than the mold cavity 10 because the mold liner 20 is 20 interposed between the hardenable dental material 30 and the interior surfaces of the mold cavity 10.

Stretching of the mold liner 20 may reduce the chances of unwanted voids in the molded hardenable dental article (due to, e.g., wrinkling of the mold liner 20). Furthermore, stretching of the mold liner 20 during the molding process may also enhance 25 intimate contact between the mold liner 20 and the outer surfaces of the molded hardenable dental article.

It should be understood that the mold liner 20 is an optional component in the molding process. In other words, it may be possible to force the hardenable dental material 30 into the mold cavity 10 and remove it therefrom after molding. The mold liner 30 20 may, however, provide some potential advantages as discussed herein with respect to removal of the hardenable dental material from the mold cavity 10, packaging of the hardenable dental article, etc.

The mold liner 20 may be constructed of a variety of different materials. For example, the mold liner 20 may be manufactured of a deformable material that may be provided in sheet form over the opening 14 of the mold cavity 10 and deformed under the molding conditions (e.g., temperature, pressure, etc.) used to form the hardenable dental material 30 into the desired shape. Examples of some suitable materials for the mold liner 20 may include, but are not limited to, e.g., polypropylenes, polyethylenes, polyurethanes, vinyls, thermoplastic elastomers, elastomeric films (e.g., rubber, latex, etc.), fluorinated polymers (e.g., FEP, PFA, THV, ECTFE, etc.), plasticized PVC, elastic-plastic films (e.g., blends of KRATON and polypropylene), copolymers, water soluble polymers (e.g., 5 selected from the group consisting of polyvinylpyrrolidones, polyvinylpyrrolidone/vinyl acetate copolymers, polyvinyl alcohols, polyethylene oxides, polyacrylamides, polyacrylic acids, polysaccharides and synthetically modified polysaccharides (e.g., cellulose ether polymers), alginates (e.g., sodium alginate), polyethyl oxazolines, esters of polyethylene oxide, esters of polyethylene oxide and polypropylene oxide copolymers, urethanes of 10 polyethylene oxide, urethanes of polyethylene oxide and polypropylene oxide copolymers, etc.). Further, the mold liner 20 may include one or more coatings (e.g., silicone, etc.) to enhance formability, release from the hardenable dental article, etc.

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Although the mold liner 20 is depicted as a unitary layer, it should be understood that it could be provided as a multilayer or other non-homogeneous structure to, e.g., 20 provide different properties for the surface facing the hardenable dental material 30 as compared to the surface facing the interior surfaces of the mold cavity 10. Examples of some different properties that may be achieved by a multilayer structure, coating, etc. may include, but are not limited to the tensile strength of the mold liner 20, formability, durability, etc.

25 Also, it should be understood that the mold liner 20 itself may be treated or processed to improve its molding properties during forming of the hardenable dental material 30 in the mold cavity 10. For example, it may be desirable to preheat or heat the mold liner 20 during or just before the molding process begins to enhance its formability.

In the depicted process, the pin liner 40 is also optional, i.e., it may or may not be 30 provided. One potential advantage of providing a pin liner 40 between the core pin 50 and the hardenable dental material 30 is that adhesion between the core pin 50 and the hardenable dental material 30 may be prevented. Another potential advantage is that the

pin liner 40 may be incorporated into a package for the hardenable dental material 30 after it has been molded into the shape of the mold cavity 10.

If the pin liner 40 is not present, it may be desirable that the core pin 50 have an outer surface (i.e., the surface that contacts the hardenable dental material 30) that exhibits 5 limited or no adhesion to the hardenable dental material 30 during the molding process. For example, the core pin 50 may be coated with, e.g., fluorinated polymers (e.g., PTFE, etc.), boron carbide, chrome, thin dense chrome, chromium nitride, electroless nickel infused with fluorinated polymers, modified tungsten disulfide (e.g., DICRONITE), etc.

The core pin 50 may be temperature controlled to assist in the molding process by, 10 e.g., heating and/or cooling the temperature of the core pin 50. In other variations, the core pin 50 may be vented or include vacuum orifices to assist in forming the hardenable dental material 30. In some instances, ultrasonic or other vibrational energy may be supplied to the core pin 50 during the forming process.

In other instances, the core pin 50 may be provided as a separate piece part 15 attached to a driver such that the core pin 50 can remain attached to the molded hardenable dental material 30 after it is removed from the mold cavity 10 to assist in handling and/or packaging of the hardenable dental article.

The pin liner 40 may be constructed of a variety of different materials. For example, the pin liner 40 may be manufactured of a stretchable material that may be 20 provided in sheet form between the core pin 50 and the hardenable dental material 30 and deformed under the molding conditions (e.g., temperature, pressure, etc.) used to form the hardenable dental material 30 into the shape of the mold cavity 10. Examples of some suitable materials for the pin liner 40 may include, but are not limited to the same materials described herein for the mold liner 20.

25 Stretching of the pin liner 40 may reduce the chances of unwanted voids in the molded hardenable dental article (due to, e.g., wrinkling of the pin liner 40). Furthermore, stretching of the pin liner 40 during the molding process may also enhance intimate contact between the pin liner 40 and the molded hardenable dental article.

Although the pin liner 40 is depicted as a unitary layer, it should be understood that 30 it could be provided as a multilayer or other non-homogeneous structure to, e.g., provide different properties for the surface facing the hardenable dental material 30 as compared to the surface facing the outer surfaces of the core pin 50. Examples of some different

properties that may be achieved by a multilayer structure, coating, etc. may include, but are not limited to the tensile strength of the pin liner 40, formability, durability, control over surface energy, control over release properties, etc.

Also, it should be understood that the pin liner 40 itself may be treated or 5 processed to improve its molding properties during forming of the hardenable dental material 30. For example, it may be desirable to preheat or heat the pin liner 40 during or just before the molding process begins to, e.g., enhance its formability.

After removing the hardenable dental material 30 and mold liner 20 from the mold cavity 10, at least a portion of the liner 20 may be retained in intimate contact with the 10 outer surfaces of the hardenable dental article formed of the hardenable dental material 30. One example of such a construction is depicted in FIG. 2.

In FIG. 2, one embodiment of a packaged, shaped hardenable dental article 160 manufactured in accordance with the present invention is depicted in a cross-sectional view. The hardenable dental article 160 includes outer surfaces 162 that are in intimate 15 contact with package cover 120. The hardenable dental article 160 also includes a base 164 and a package base 140 located over the base 164.

The package cover 120 may include a flange 124 extending away from the hardenable dental article 160 proximate the base 164. The flange 124 may provide a 20 convenient location at which the package base 140 may be attached to the flange 124 such that the hardenable dental article 160 is sealed within the package cover 120 and the package base 140. The seal 128 between the package cover 120 and the package base 140 may be accomplished by any suitable technique or combination of techniques, e.g., heat sealing, adhesives, cold sealing, chemical welding, ultrasonically, etc. The seal 128 may 25 be a peelable seal, i.e., separation of the package cover 120 and the package base 140 be accomplished without significant deformation of the hardenable dental article 160 located therein.

The area of the flange 124 (or any other location on package cover 120 or package base 140) may also provide a convenient location for indicia that may be useful to identify 30 the hardenable dental article, the hardenable dental material, a date by which the hardenable dental article should be used, etc.

With reference to the process illustrated in FIG. 1, the package cover 120 may be formed from the mold liner 20 and the package base 140 may be formed from the pin liner

40. If the hardenable dental article 160 is to be a hollowed out dental crown, then a void 154 may be formed in the base 164 of the hardenable dental article 160 as seen in FIG. 2.

Although the package cover 120 and the package base 140 are each depicted as unitary layers, it should be understood that one or both could be provided as a multilayer 5 or other non-homogeneous structure to, e.g., provide different properties for the surface facing the hardenable dental article 160 as compared to the surface facing away from the hardenable dental article, to provide vapor barrier properties, to provide moisture barrier properties, to provide sealing layers (e.g., heat sealable thermoplastic layers, adhesive layers, etc.).

10 In a variation from the process as shown in FIG. 1, the package base 140 may not be deformed as part of the process of forming the hardenable dental material. Rather, the package base 140 may be provided as a pre-formed piece having the shape seen in FIG. 2 that is inserted into the mass of hardenable dental material (30 in FIG. 1). In such an embodiment, the package base 140 may include a void 154 as depicted in FIG. 2 that may 15 receive a core pin shaped driver (see, e.g., core pin driver 50 in FIG. 1) during the manufacturing process. Alternatively, the package base 140 may be formed with a solid mass of material in the volume of the void 154, with that solid mass of material having sufficient strength to deform the hardenable dental material during manufacturing of the hardenable dental article 160.

20 If the hardenable dental article 160 is manufactured of, e.g., a photocurable material, the package cover 120 and/or package base 140 may function as an actinic light barrier to provide protection from actinic radiation that may otherwise prematurely harden the hardenable dental material forming the hardenable dental article 160. For example, the package cover 120 and/or the package base 140 may transmit less than 1% of actinic 25 radiation incident thereon. Methods and materials of providing such light barrier properties (e.g., by pigments, etc.) are known to those skilled in the art. Examples may be described in U.S. Patents 5,538,129 (Chester et al.); 5,552,177 (Jacobs et al.); 5,636,736 (Jacobs et al.); and 5,785,178 (Kvitrud et al.), etc.

30 The package cover 120 and/or package base 140 materials and/or construction may be selected to provide a desired level of oxygen permeability to control exposure of the hardenable dental article 160 located therein to oxygen during, e.g., storage.

FIG. 3 illustrates another variation in the manufacturing process in which a mold liner 220 is located over the opening 214 of a mold cavity 210. The depicted mold liner 220 is partially deformed before the hardenable dental material 230 is introduced into the mold cavity 210. The preforming may be accomplished by forcing the liner 220 into the 5 mold cavity 210. Alternatively, preforming of the mold liner 220 may occur outside of the mold cavity 210. Preforming of the mold liner 220 in this manner may be accomplished with a tool (not shown) or by any other suitable technique such as fluid pressure, vacuum within the mold cavity 210, etc. It may be helpful if the mold liner 220 is heated or otherwise processed to improve its formability.

10 FIG. 4 also illustrates another variation in the manufacturing process in which the mold liner 320 is deformed such that it replicates the shape of the mold cavity 310 before hardenable dental material 330 is introduced into the mold cavity 310. As above, preforming of the mold liner 320 in this manner may be accomplished with a tool (not shown) or by any other suitable technique such as, e.g., fluid pressure, vacuum within the 15 mold cavity 310, etc. It may be helpful if the mold liner 320 is heated or otherwise processed to improve its formability.

FIGS. 5 & 6 depict another manufacturing process in which the hardenable dental material 430 is located within a pocket 421 formed in mold liner 420 before the mold liner 420 and hardenable dental material 430 are introduced into the mold cavity 410. As seen 20 in FIG. 5, the process includes an optional pin liner 440 located between the hardenable dental material 430 and the core pin 450. FIG. 6 depicts the hardenable dental material formed into the shape of a hardenable dental article 460 within cavity 410, including a void 454 formed by the core pin 450.

The pocket 421 in mold liner 420 may be formed under conditions of pressure, 25 temperature, etc. using the hardenable dental material 430 itself. For example, upstream of the portion of the manufacturing process depicted in FIG. 5, the hardenable dental material 430 may be forced against the mold liner 420 under conditions of temperature, pressure, etc. such that the portion of the mold liner 420 forming the pocket 421 is permanently or plastically deformed. Alternatively, the mold liner 420 itself may be 30 deformed by, e.g., vacuum forming, blow molding, cold forming/embossing, thermoforming, injection molding, compression molding, etc., such that the pocket 421 is formed before the hardenable dental material 430 is placed therein.

The mold liner 420 and pin liner 440 may be retained in intimate contact with the hardenable dental article 460 and attached together to form a package containing the hardenable dental article 460 after removal from the mold cavity 410 if so desired (and as described with respect to other embodiments elsewhere herein).

5 FIG. 7 depicts still another alternative manufacturing process according to the present invention in which the hardenable dental material 530 is located within a volume defined by a mold liner 520 and a pin liner 540 before the hardenable dental material 530 and the mold liner 520 are introduced into the mold cavity 510. In this embodiment, the mass of hardenable dental material 530 may also be sealed within the mold liner 520 and 10 pin liner 540 before forming. For example, the mold liner 520 and pin liner 540 may be adhered together, heat sealed, cold sealed, chemically welded, ultrasonically welded, etc. to enclose the hardenable dental material.

15 As discussed with respect to FIGS 5 & 6, the hardenable dental material 530 may be located within a pocket 521 formed in the mold liner 520. Alternatively, however, the pin liner 540 may be used to form a pocket in addition to or in place of the pocket 521 formed in the mold liner.

20 FIG. 8 is a plan view of the base 664 of a hardenable dental article 660 located within a liner 620 and FIG. 9 is a cross-sectional view of the hardenable dental article 660 and liner 620 taken along line 9-9 in FIG. 8. The liner 620 is preferably in intimate contact with the outer surfaces 662 of the hardenable dental article 660. The hardenable dental article 660 and liner 620 depicted in FIGS. 8 & 9 may be manufactured using the methods described above.

25 The liner 620 includes a flange portion 628 extending away from the hardenable dental article 660. The liner 620 may be a stretchable film or other structure such that deforming (e.g., stretching, tearing, etc.) the liner 620 causes it to release from the outer surfaces 662 of the hardenable dental article 660 with little or no deformation of the shape of the hardenable dental article 660. To improve the release characteristics, it may be desirable to provide one or more slits 626 in the flange portion 628 of the liner 620 and grasp the flange portions 628 to stretch the liner 620 in the directions of arrows 627 and/or 30 tear it along the slits 626. If the liner 620 is made of a water soluble polymer, removal of the hardenable dental article 660 may be facilitated by contacting the liner 620 with water (by, e.g., spraying, immersion in a water bath, etc.).

FIGS. 10 & 11 are perspective views, respectively, of the outer and base surfaces of one exemplary embodiment of a sacrificial mold cavity that may be used to manufacture and, potentially, package a hardenable dental article according to the present invention. The sacrificial mold cavity 710 is formed in a sacrificial mold body 712 that 5 may include one or more lines of weakness 716 formed therein, wherein the lines of weakness define sections 717 in the sacrificial mold body 712.

The interior surfaces 711 of the sacrificial mold cavity 710 (see FIG. 11) are in the shape of the desired hardenable dental article such that when hardenable dental material is forced into the sacrificial mold cavity 710, it takes the shape of the desired hardenable 10 dental article in the sacrificial mold cavity 710 itself.

The lines of weakness 716 may define lines along which the sacrificial mold body 712 may separate when tension is applied across the line of weakness 716 or when a shearing force is generated on opposite sides of the line of weakness 716. The lines of weakness 716 may take a variety of forms, e.g., thinned lines in which the wall thickness 15 of the mold body 712 is reduced relative to the surrounding wall thickness, score lines formed after the mold body 712 is manufactured, etc. In yet another variation, each line of weakness 716 may be defined by a filament molded in the body 712 such that the body preferentially separates along the filament. Other variations of providing a means of separation for a sacrificial mold cavity may be envisioned by those skilled in the art.

20 Lines of weakness may be provided in any desired orientation on the sacrificial mold body 712 (i.e., the depicted lines of weakness 716 are not to be construed as limiting the orientation of lines of weakness used in connection with the invention). For example, for a sacrificial mold cavity 710 forming a dental crown, lines of weakness that extend around the sacrificial mold body 712 in helical spirals from the portion of the mold cavity 25 712 forming the margin to the incisal/occlusal surfaces of the dental crown may alternatively be provided. Other variations in the orientation or paths of lines of weakness used in connection with sacrificial mold cavities of the present invention may also be provided.

The mold body 712 may also include a flange or tab 718 associated with one or 30 more of the mold sections 717. The tabs 718 may be used to facilitate handling of the mold body 712, to provide a location on which a package base may be attached to seal the sacrificial mold cavity 710 after locating the hardenable dental material therein, and/or to

provide a location at which the mold body 712 may be grasped to apply the force required to separate the one or more lines of weakness 716 in the mold body 712.

The flanges 718 (or any other location on the mold body 712) may also provide a convenient location for indicia that may be useful to identify the hardenable dental article, 5 the hardenable dental material, a date by which the hardenable dental article should be used, etc.

Separation of the sacrificial mold body 712 along the one or more lines of weakness 716 may be facilitated by a variety of optional features. For example, notches 715 may be provided at the ends of the lines of weakness 716. The notches 715 may act 10 as stress concentrators to initiate separation along the lines of weakness 716. In the depicted embodiment, the notches 715 are formed in between adjacent tabs 718, with the notches 715 transitioning into thinned lines of weakness 716.

Another optional feature depicted in connection with the sacrificial mold body 712 is a base line of weakness that extends about the periphery of the mold body 712 15 proximate, e.g., the incisal/occlusal surfaces formed by the mold cavity 710. As each section 717 is separated from its adjacent section or sections 717 (in a process similar to, e.g., peeling petals from flower), the sections may be separated completely from the mold body 712 along base line of weakness. After all of the sections 717 are removed, the base line of weakness may preferably define a base 772 that may remain attached to the 20 hardenable dental article 760 as seen in FIG. 12. A post or stud 774 attached to the base 772 as depicted may facilitate handling of the hardenable dental article 760.

The mold body 712 may be manufactured of any suitable material or materials that may be provided in the desired shape and that will function to form or shape the hardenable dental material used to form the hardenable dental article 760. Examples of 25 suitable materials for the mold body 712 may include, but are not limited to, thermoplastic polymers, thermoplastic elastomers, polyethylenes, polypropylenes, polystyrenes, polyesters (e.g., poly(ethylene terephthalate)), etc.

A number of approaches may be employed to facilitate release of the interior 30 surface 711 of the sacrificial mold cavity 710 from the hardenable dental material used to form the hardenable dental article 760. For example, additives may be provided in the material used to form the mold body. Examples of some suitable additives may include, but are not limited to, fluoropolymers, graphite, fatty acids, low molecular weight

polyethylene, silicone, hydrocarbon waxes, metallic stearates, etc. In another example, the interior surfaces 711 of the sacrificial mold cavity 710 may include a coating formed thereon to enhance release from the hardenable dental material, e.g., silicone, fluorinated polymers, etc.

5 In still another approach, a mold liner (as described above with respect to FIGS. 1 and 3-7) may be used in connection with the sacrificial mold cavity 710. If a mold liner is used, it may be retained in intimate contact with the outer surfaces of the hardenable dental article after removal of the mold body 712.

Furthermore, if no mold liner is used in connection with sacrificial mold cavity 10 710, it is preferred that the lines of weakness 716 do not include any voids, perforations, or other structures that could fill with the hardenable dental material during the molding process because such features would change the shape of the hardenable dental article 760 thus formed. For example, it may be preferred that, on the interior surfaces 711 of the sacrificial mold cavity 710, the lines of weakness 716 be indistinguishable from the 15 remainder of the interior surfaces 711 of the sacrificial mold cavity 710. If, however, a mold liner is used, then the lines of weakness 716 may include voids (e.g., lines of perforations formed in the mold body 712) because such perforations could be sealed by the mold liner. Furthermore, such perforations may act to vent the sacrificial mold cavity 710.

20 Although the exemplary embodiment of a sacrificial mold cavity of FIGS. 10-12 includes lines of weakness formed therein, other sacrificial mold cavities used in connection with hardenable dental articles of the present invention may not include lines of weakness to assist in removal of the hardenable dental articles. For example, another sacrificial mold cavity may be made of, e.g., an elastomeric material (e.g., rubber, 25 thermoplastic elastomers, etc.) or a material exhibiting a low tear strength.

The internal surfaces of a sacrificial mold cavity may have the shape of the hardenable dental article while the external surfaces of the sacrificial mold body in which the mold cavity is located may conform to the shape of the hardenable dental article located within the cavity. One example of such a sacrificial mold body and cavity is 30 depicted in, e.g., FIG. 2 in the form of the package cover 120.

Alternatively, the exterior shape of a sacrificial mold cavity may not conform to the shape of the hardenable dental article located within the mold cavity. For example, the

exterior shape of the sacrificial mold cavity may be a generic shape such as, for example, a block, cylinder, etc.

If any sacrificial mold body used in connection with the present invention does not, itself, possess sufficient strength to mold or form the hardenable dental material, then the 5 sacrificial mold body (and the mold cavity it contains) may be supported by a support structure during the molding process. One example of a suitable support structure may be, e.g., the mold cavity 10 depicted in connection with FIG. 1 and described as one example of a structure used to form the package cover 120 of FIG. 2.

Typically, the support structure will preferably conform to the exterior shape of the 10 sacrificial mold body in which the sacrificial mold cavity is located. As a result, if the exterior shape of the sacrificial mold body (such as package cover/mold body 120 of FIG. 2) conforms to the shape of the hardenable dental article, then the support structure used to support the mold body will include interior surfaces that also conform to the exterior shape of the sacrificial mold body. If the exterior shape of the sacrificial mold body is generic, 15 i.e., in the shape of a cylinder, block, etc., then the support structure used to support the mold body will typically include interior surfaces that conform to the generic shape of the sacrificial mold body.

One illustrative example of a sacrificial mold cavity having a generic outer shape and an inner cavity in the shape of a desired hardenable dental article is depicted in FIG. 20 13, where mold body 812 defines a mold cavity with inner surfaces 810. A hardenable dental article 860 is formed within the mold cavity defined by inner surfaces 810. The hardenable dental article 860 may include an inner cavity 854.

The mold body 812 may be formed of, e.g., elastomeric materials and/or materials exhibiting low tear strength to facilitate removal of the hardenable dental article 860 as 25 discussed above. Alternatively, the mold body may be formed of soluble polymers (e.g., water soluble polymers selected from the group consisting of polyvinylpyrrolidones, polyvinylpyrrolidone/vinyl acetate copolymers, polyvinyl alcohols, polyethylene oxides, polyacrylamides, polyacrylic acids, polysaccharides and synthetically modified polysaccharides (e.g., cellulose ether polymers), alginates (e.g., sodium alginate), 30 polyethyl oxazolines, esters of polyethylene oxide, esters of polyethylene oxide and polypropylene oxide copolymers, urethanes of polyethylene oxide, urethanes of polyethylene oxide and polypropylene oxide copolymers, etc.). The hardenable dental

article 860 could be removed from the sacrificial mold body 812 at some point after the forming operation either by softening and/or dissolving the soluble mold body 812 through contact with an appropriate solvent (e.g., a water bath or spray for water soluble polymers).

5       Illustrative embodiments of this invention are discussed and reference has been made to possible variations within the scope of this invention. These and other variations and modifications in the invention will be apparent to those skilled in the art without departing from the scope of the invention, and it should be understood that this invention is not limited to the illustrative embodiments set forth herein. Accordingly, the invention  
10      is to be limited only by the claims provided below and equivalents thereof.

## CLAIMS:

1. A method of manufacturing a hardenable dental article, the method comprising:
  - 5 providing a mold cavity in a shape of a hardenable dental article, wherein the mold cavity comprises an opening;
  - forcing a hardenable dental material into the mold cavity through the opening;
  - providing a liner between the hardenable dental material and the mold cavity; and
  - removing the hardenable dental material and the liner from the mold cavity, wherein the hardenable dental material has the shape of the hardenable dental article.
- 10 2. A method according to claim 1, further comprising locating the liner over the opening of the mold cavity, wherein forcing the hardenable dental material into the mold cavity comprises simultaneously forcing the liner into the mold cavity, wherein both the liner and the hardenable dental material take the shape of the hardenable dental article.
- 15 3. A method according to claim 1, further comprising:
  - locating the liner over the opening of the mold cavity; and
  - forcing the liner into the mold cavity before forcing the hardenable dental material into the mold cavity.
- 20 4. A method according to claim 3, wherein forcing the liner into the mold cavity comprises only partially replicating the mold cavity with the liner.
- 25 5. A method according to claim 4, wherein forcing the hardenable dental material into the mold cavity further forces the liner into the mold cavity, wherein both the liner and the hardenable dental material take the shape of the hardenable dental article.
- 30 6. A method according to claim 3, wherein forcing the liner into the mold cavity comprises replicating the mold cavity with the liner, wherein the liner takes the shape of the hardenable dental article before forcing the hardenable dental material into the mold cavity.

7. A method according to claim 1, wherein providing the liner between the hardenable dental material and the mold cavity comprises:
  - deforming the liner to form a pocket therein; and
  - locating the hardenable dental material within the pocket in the liner before forcing the hardenable dental material into the mold cavity.
8. A method according to claim 1, wherein providing the liner between the hardenable dental material and the mold cavity comprises deforming the liner to form a pocket therein by forcing the hardenable dental material into contact with the liner, wherein the hardenable dental material is located within the pocket before forcing the hardenable dental material into the mold cavity.
9. A method according to claim 1, wherein at least a portion of the liner is retained on the surface of the hardenable dental article after removing the hardenable dental article from the mold cavity.
10. A method according to claim 9, wherein the liner comprises a film and wherein the method comprises removing the hardenable dental article from the film by deforming the film.
11. A method according to claim 1, wherein the liner comprises a water soluble polymer.
12. A method according to claim 11, wherein at least a portion of the liner is retained on the surface of the hardenable dental article after removing the hardenable dental article from the mold cavity, and further wherein the method comprises removing the hardenable dental article from the liner by contacting the liner with water.
13. A method according to claim 1, wherein the hardenable dental article comprises a hardenable dental crown.
14. A packaged hardenable dental article comprising:
  - a mass of hardenable dental material in the shape of a hardenable dental article,

wherein the hardenable dental article comprises a base and outer surfaces extending from the base;

a package cover conforming to and in intimate contact with the outer surfaces of the hardenable dental article, wherein the package cover comprises a polymeric film

5 plastically deformed by the mass of hardenable dental material; and

a package base facing the base of the hardenable dental article;

wherein the package cover and the package base are attached together about a periphery of the base of the hardenable dental article such that the hardenable dental article is contained within the package base and the package cover.

10

15. A packaged dental article according to claim 14, wherein the package cover comprises a sacrificial mold body.

16. A packaged dental article according to claim 14, wherein the polymeric film

15 comprises a water soluble polymer.

17. A packaged dental article according to claim 14, wherein the package base

comprises a film.

20 18. A packaged dental article according to claim 14, wherein the package base and the package cover are attached together by a heat seal bond.

19. A packaged dental article according to claim 14, wherein the package base and the package cover are adhesively attached together.

25

20. A packaged dental article according to claim 14, wherein the hardenable dental article comprises a hardenable dental crown.

21. A dental article comprising:

30 a sacrificial mold body comprising a sacrificial mold cavity in the shape of a hardenable dental article, wherein the sacrificial mold body comprises at least one line of

weakness formed therein, the at least one line of weakness defining at least two mold sections in the sacrificial mold body; and

5 a mass of hardenable dental material located within the volume of the sacrificial mold cavity such that the hardenable dental material is in the shape of the hardenable dental article.

22. A dental article according to claim 21, wherein the at least one line of weakness comprises a line of weakness that bisects the sacrificial mold body such that the separation of that line of weakness separates the sacrificial mold body into halves.

10

23. A dental article according to claim 21, wherein the at least one line of weakness comprises a plurality of lines of weakness.

15

24. A dental article according to claim 21, wherein the at least one line of weakness defines two or more mold sections separated by the lines of weakness.

25. A dental article according to claim 24, wherein each mold section comprises a flange.

20

26. A dental article according to claim 21, wherein the sacrificial mold body comprises a water soluble polymer.

27. A dental article according to claim 21, wherein the hardenable dental article comprises a hardenable dental crown.

25

28. A packaged hardenable dental article comprising:  
a mass of hardenable dental material in the shape of a hardenable dental article, wherein the hardenable dental article comprises a base and outer surfaces extending from the base;

30

a package cover conforming to and in intimate contact with the outer surfaces of the hardenable dental article, wherein the package cover comprises a sacrificial mold body comprising a sacrificial mold cavity in the shape of the hardenable dental article, and

wherein the sacrificial mold body comprises at least one line of weakness formed therein, the at least one line of weakness defining at least two mold sections in the sacrificial mold body; and

5            a package base facing the base of the hardenable dental article; wherein the package cover and the package base are attached together about a periphery of the base of the hardenable dental article such that the hardenable dental article is contained within the package base and the package cover.

29.        A packaged hardenable dental article according to claim 28, wherein the package  
10      base is attached to a flange of each of the mold sections.

30.        A packaged hardenable dental article according to claim 28, wherein the package cover comprises a water soluble polymer.

15      31.        A packaged hardenable dental article according to claim 28, wherein the package base and the package cover are attached together by a heat seal bond.

32.        A packaged hardenable dental article according to claim 28, wherein the package base and the package cover are adhesively attached together.

20      33.        A packaged hardenable dental article according to claim 28, wherein the at least one line of weakness comprises a plurality of lines of weakness.

25      34.        A packaged hardenable dental article according to claim 28, wherein each mold section comprises a flange.

35.        A packaged hardenable dental article according to claim 28, wherein the hardenable dental article comprises a hardenable dental crown.

30      36.        A dental article comprising:  
                  a sacrificial mold body comprising a sacrificial mold cavity in a shape of a

hardenable dental article, wherein the sacrificial mold cavity conforms to and is in intimate contact with outer surfaces of the hardenable dental article; and

5 a mass of hardenable dental material located within the volume of the sacrificial mold cavity such that the hardenable dental material is in the shape of the hardenable dental article.

37. A dental article according to claim 36, wherein the sacrificial mold body comprises a water soluble polymer.

10 38. A dental article according to claim 36, wherein the hardenable dental article comprises a hardenable dental crown.

15 39. A dental article according to claim 36, wherein the sacrificial mold body comprises an exterior shape that conforms to the shape of the hardenable dental article located within the sacrificial mold cavity.

40. A method of manufacturing a hardenable dental article, the method comprising: providing a sacrificial mold body comprising a sacrificial mold cavity in a shape of a hardenable dental article, wherein the sacrificial mold body comprises a water soluble polymer; and

20 forcing a hardenable dental material into the sacrificial mold cavity through the opening, wherein the hardenable dental material takes the shape of the hardenable dental article.

25 41. A method according to claim 40, wherein the sacrificial mold body is supported within a support structure when forcing the hardenable dental material into the sacrificial mold cavity.

42. A method according to claim 40, further comprising removing the hardenable dental article from the sacrificial mold cavity by contacting the sacrificial mold body with water.

43. A method of manufacturing a hardenable dental article, the method comprising:  
providing a sacrificial mold body comprising a sacrificial mold cavity in a shape of  
the hardenable dental article, wherein the sacrificial mold cavity comprises an opening,  
and wherein the sacrificial mold body comprises at least one line of weakness formed  
5 therein, the at least one line of weakness defining at least two mold cavity sections in the  
sacrificial mold body; and  
forcing a hardenable dental material into the sacrificial mold cavity through the  
opening, wherein the hardenable dental material takes the shape of the hardenable dental  
article.

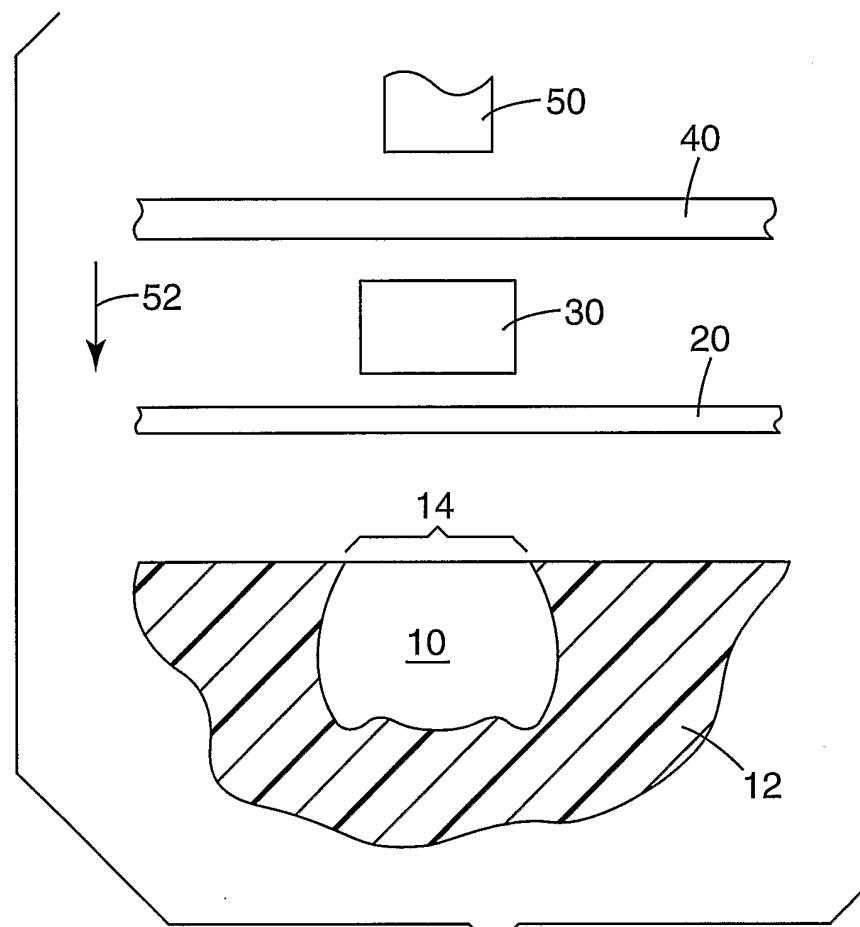
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44. A method according to claim 43, further comprising removing the hardenable  
dental article from the sacrificial mold cavity by separating the sacrificial mold body along  
the at least one line of weakness.

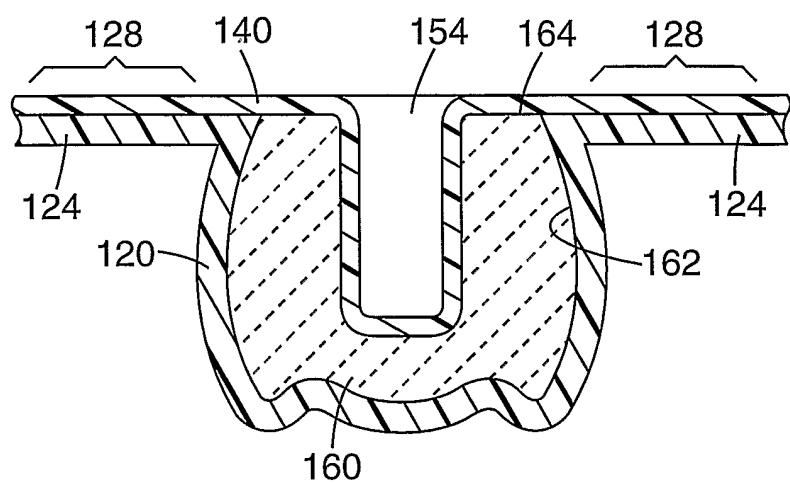
15 45. A method according to claim 44, further comprising a flange on one or more of the  
mold cavity sections, the flange located proximate the opening into the sacrificial mold  
cavity, and wherein separating the at least one line of weakness comprises grasping the  
flange of at least one of the mold cavity sections.

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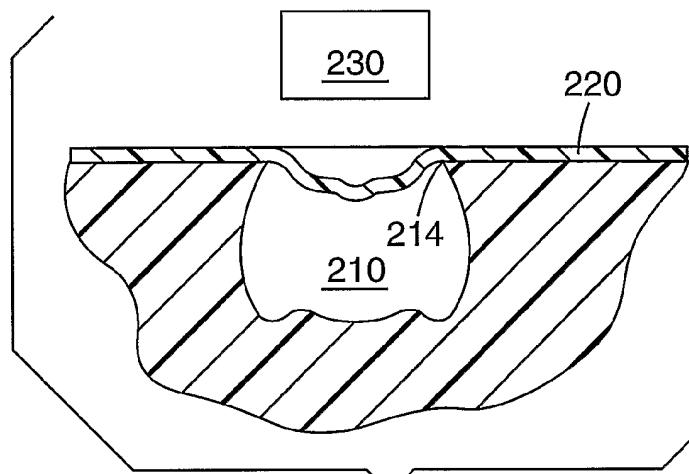


*Fig. 1*

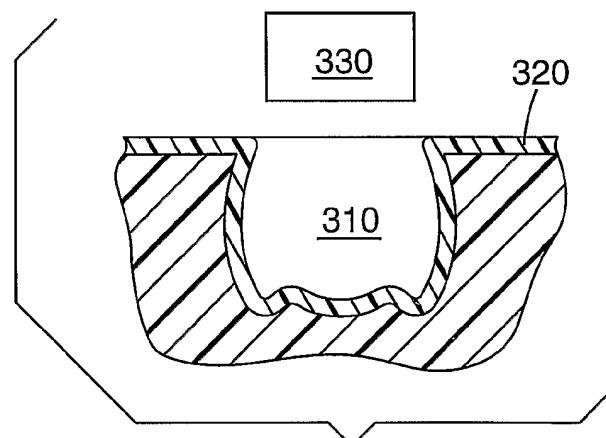


*Fig. 2*

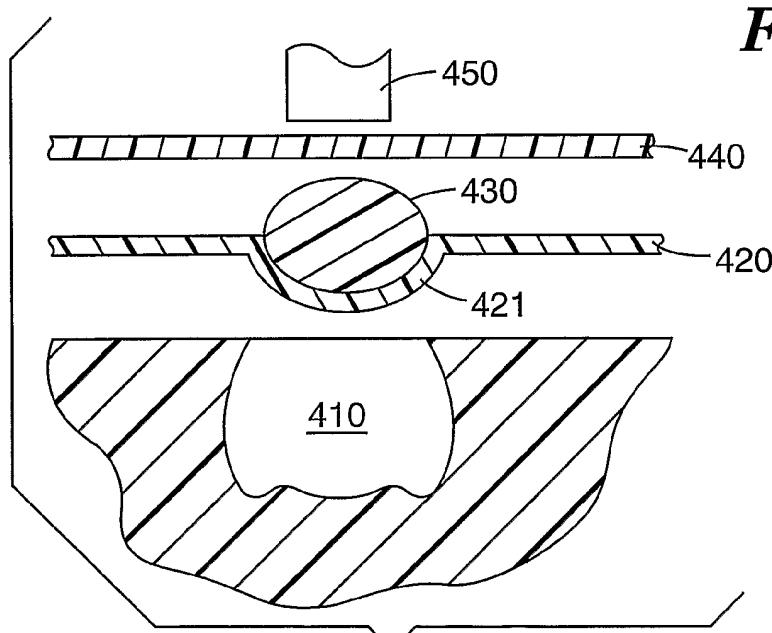
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*Fig. 3*

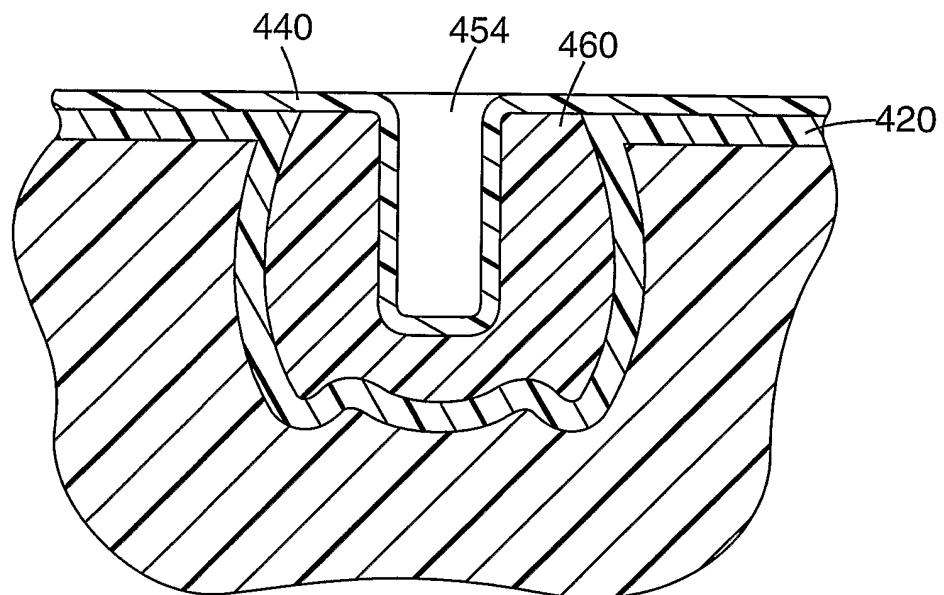


*Fig. 4*

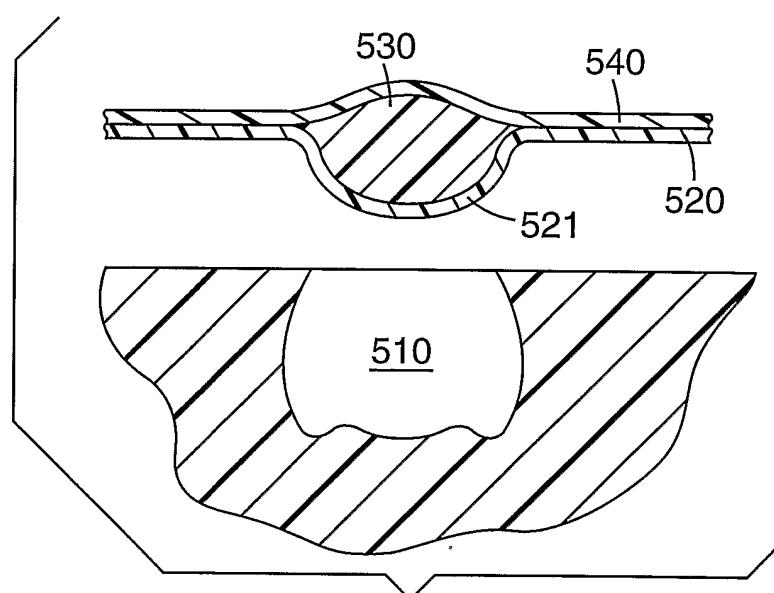


*Fig. 5*

3/6

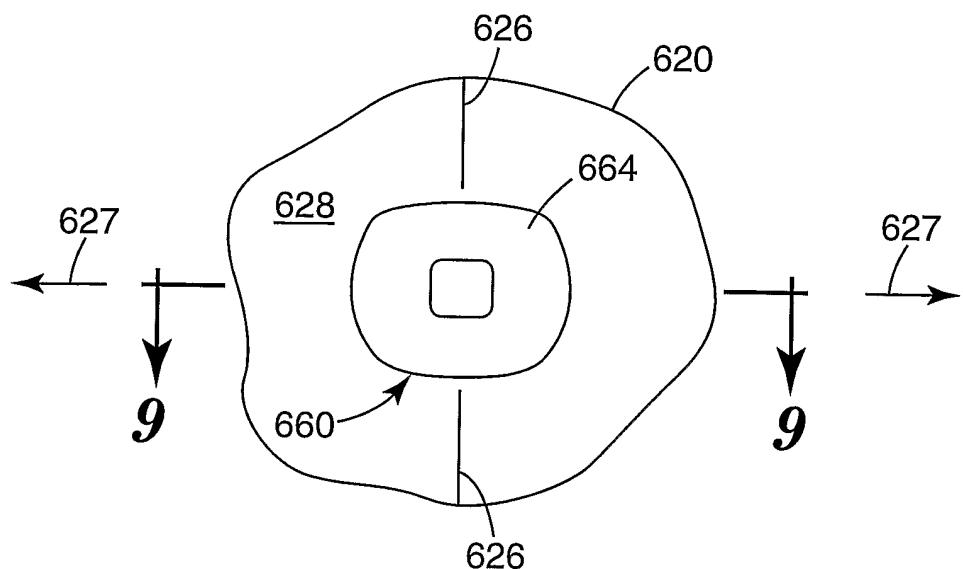


*Fig. 6*

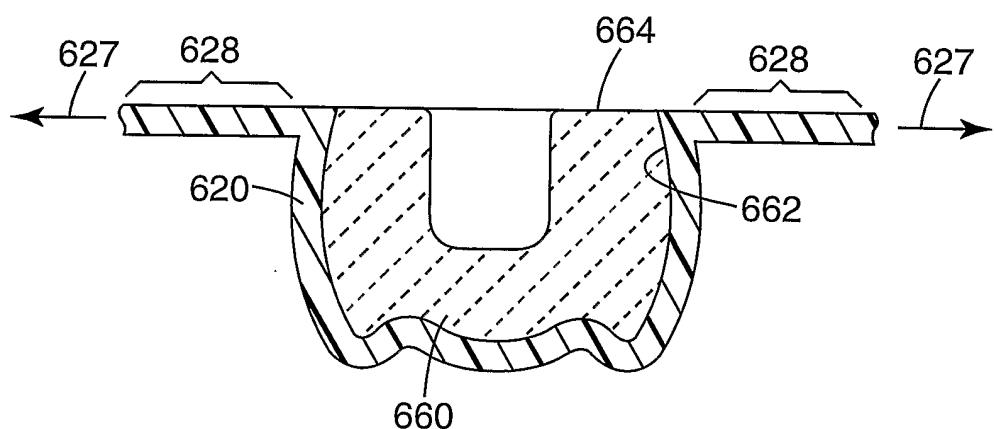


*Fig. 7*

4/6

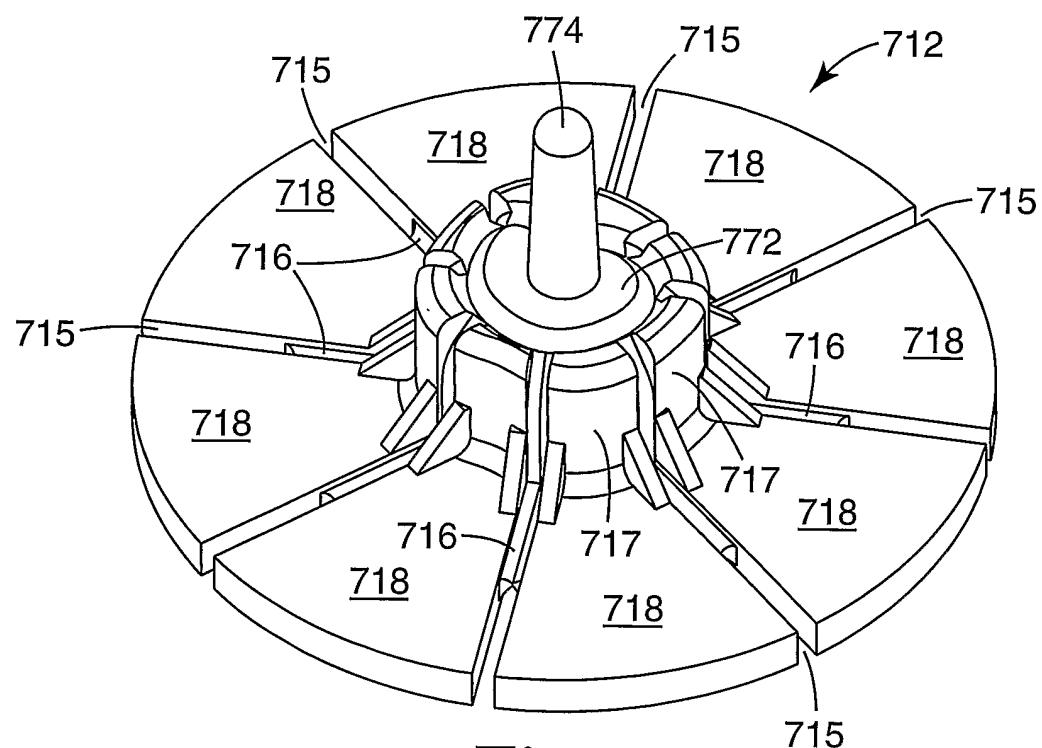


*Fig. 8*

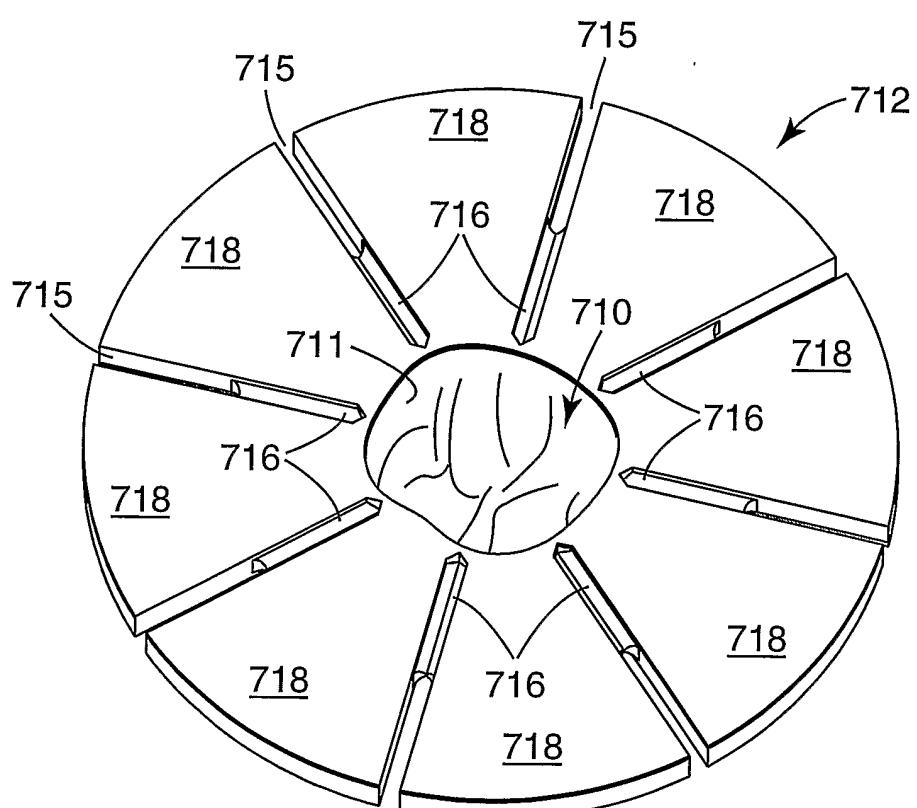


*Fig. 9*

5/6

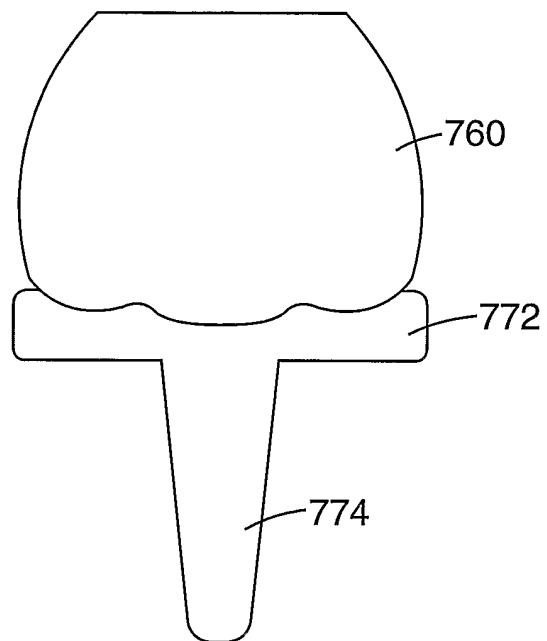


*Fig. 10*

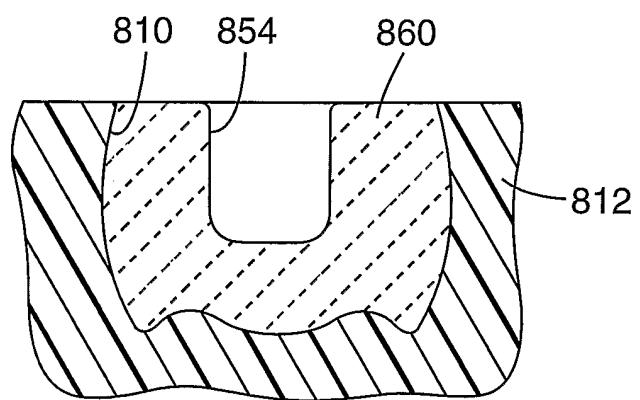


*Fig. 11*

6/6



*Fig. 12*



*Fig. 13*