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(54) **Title:** THREE LAYER BREAST PROSTHESIS

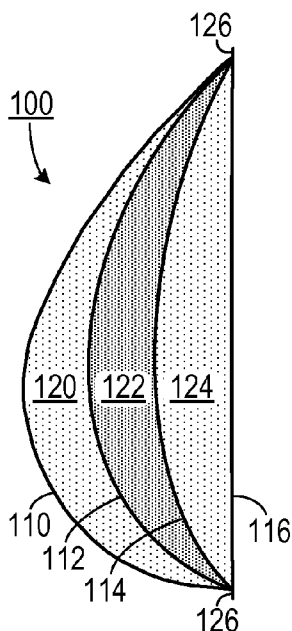


FIG. 2

(57) **Abstract:** A breast prosthesis (100) includes an outer first layer (120), a middle second layer (122) and an inner third layer (124). The outer first layer (120) includes a first material (212) that has a first firmness. The first firmness allows for a 20 mm to a 25 mm penetration by a cone penetrometer. The first layer (120) has a shape corresponding to a shape of a breast form. The middle second layer (122) is disposed adjacent to the first layer (120) and includes a second material (214) that has a second firmness that is greater than the first firmness. The inner third layer (124) is disposed adjacent to the second layer (122) opposite from the first layer (120) and includes a third material (216) that has a third firmness that is less than the second firmness.

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THREE LAYER BREAST PROSTHESIS

CROSS-REFERENCE TO RELATED APPLICATION(S)

[0001] This application claims the benefit of US Provisional Patent Application Serial No. 61/383,558, filed 09/16/2010, the entirety of which is hereby incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates to breast prostheses and, more specifically, to a multi-chamber breast prosthesis.

[0004] 2. Description of the Related Art

[0005] Many women who have had a mastectomy wear a breast prosthesis at the affected site. Typically, a breast prosthesis is made to look like a natural breast. It is placed against the patient's chest and is typically supported by a brassiere.

[0006] A common type of breast prosthesis is made from a soft silicone gel. Such a prosthesis includes an envelope made from a thin plastic film into which uncured silicone gel is injected. The pouch and the uncured silicone gel are then placed in a metallic mold having an interior that is complementary in shape to the desired shape of the prosthesis. The mould is then placed in an oven, where the silicone gel is heated until it is cured.

[0007] The silicone gel must be cured until it has a firmness so that it will maintain the shape of a natural breast during regular use. However, prostheses having such firmness have two disadvantages: (1) they can be uncomfortable when placed against the chest of the user; and (2) their outer surface does not drape naturally, thereby giving user an unnatural, asymmetric appearance.

[0008] Therefore, there is a need for a breast prosthesis that is firm enough to maintain a natural breast form shape during regular use, but that is comfortable to wear and that gives a natural drape.

SUMMARY OF THE INVENTION

[0009] The disadvantages of the prior art are overcome by the present invention which, in one aspect, is a breast prosthesis that includes an outer first layer, a middle second layer and an inner third layer. The outer first layer includes a first material that has a first firmness. The first firmness allows for a 20 mm to a 25 mm penetration by a cone penetrometer. The first layer has a shape corresponding to a shape of a breast form. The middle second layer is disposed adjacent to the first layer and includes a second material that has a second firmness that is greater than the first firmness. The inner third layer is disposed adjacent to the second layer opposite from the first layer and includes a third material that has a third firmness that is less than the second firmness.

[0010] In another aspect, the invention is a breast form prosthesis that includes four films that are welded together at a single weld to form three chambers having a shape of a breast form footprint. The three chambers include: a first chamber, a second chamber and a third chamber. An outer first layer is disposed in the first chamber and includes a first material that has a first firmness. The first layer has a shape corresponding to a shape of a breast form. The first material includes a silicone gel with a first concentration of a methyl hydrosiloxane polymer cross-linker. The middle second layer is disposed adjacent to the first layer in the second chamber and includes a second material that has a second firmness that is greater than the first firmness. The second material includes a silicone gel with a second concentration, greater than the first concentration, of a methyl hydrosiloxane polymer cross-linker. The inner third layer is disposed in the third chamber and adjacent to the second layer opposite from the first layer. The inner third layer includes a third material that has a third firmness that is less than the second firmness. The third material includes a silicone gel with a third concentration, less than the second concentration, of a methyl hydrosiloxane polymer cross-linker.

[0011] In yet another aspect, the invention is a method of making a breast prosthesis, in which four flexible films are welded together with a single weld so as to form a breast form envelope. The breast form envelope includes a first chamber, a second chamber and a third chamber. Each chamber has a shape of a breast form footprint. The breast form envelope is placed into a mold having a shape that is complementary in shape to a breast form. A first material is injected into the first chamber. The first material has a first firmness that allows for a 20 mm to a 25 mm penetration by a cone penetrometer when cured. A second material is injected into the second chamber. The second material has a second firmness when cured. The second firmness is greater than the first firmness. A third material is injected into the third chamber. The third material has a third firmness when cured. The third firmness is less than the second firmness. The mold, the breast form envelope, the first material, the second material and the third material are heated to a temperature sufficient to cure the first material to the first firmness, the second material to the second firmness and the third material to the third firmness.

[0012] These and other aspects of the invention will become apparent from the following description of the preferred embodiments taken in conjunction with the following drawings. As would be obvious to one skilled in the art, many variations and modifications of the invention may be effected without departing from the spirit and scope of the novel concepts of the disclosure.

BRIEF DESCRIPTION OF THE FIGURES OF THE DRAWINGS

[0013] **FIG. 1** is a front elevational view of one embodiment of a three layer breast prosthesis.

[0014] **FIG. 2** is a cross-sectional view of the breast prosthesis shown in FIG. 1 taken along line 2-2.

[0015] **FIGS. 3A-3F** are a series of schematic drawings showing one method of making a breast prosthesis.

DETAILED DESCRIPTION OF THE INVENTION

[0016] A preferred embodiment of the invention is now described in detail. Referring to the drawings, like numbers indicate like parts throughout the views. Unless otherwise specifically indicated in the disclosure that follows, the drawings are not necessarily drawn to scale. As used in the description herein and throughout the claims, the following terms take the meanings explicitly associated herein, unless the context clearly dictates otherwise: the meaning of “a,” “an,” and “the” includes plural reference, the meaning of “in” includes “in” and “on.”

[0017] U. S. Patent Nos. 4,247,351 and 4,249,975 disclose prostheses of silicone gel encased in polyurethane film and, therefore, are incorporated herein by reference. U.S. Patent Nos. 4,950,291, 5,895,423, 5,922,023 and 7,759,354 disclose multi-chambered breast prosthesis and methods of making the same and are also, therefore, incorporated herein by reference.

[0018] One embodiment of a breast prosthesis includes three layers of silicone gel enclosed in polyurethane film. The shape of the prosthesis conforms to the shape of a female breast. The layers of silicone are arranged such that a layer of soft conformable silicone is closest to the chest of the wearer and can conform to any irregularities in the chest. The middle layer of silicone is firm and provides support for the prosthesis, and the third layer of silicone positioned in the front of prosthesis (furthest away from the body) is soft and provides a natural drape to the prosthesis, which gives the wearer's chest a natural look and a symmetric appearance.

[0019] As shown in FIGS. 1 and 2, one embodiment of a three layer breast prosthesis **100** includes an exterior layer **120** that is relatively soft, a middle layer **122** that is relatively firm and an interior layer **124** that is also relatively soft. Each of the layers, **120**, **122** and **124**, typically include a silicone gel with the middle layer **122** including a higher concentration of cross-linker to give it additional firmness. The layers are held in flexible chambers that would typically include polyurethane film (typically of about 60 micron to 90 micron thickness) that are sealed together along their periphery along a single weld **126**.

[0020] In one embodiment, a first polyurethane film **110**, a second polyurethane film **112**, a third polyurethane film **114** and a fourth polyurethane film **116** are welded together along a single weld **126** to form three chambers. The single weld **126** has the footprint of a breast form. The first material of the first layer **120** is placed in a first of the three chambers. The second material of the second layer **122** is placed in a second of the three chambers. The third material of the third layer **124** is placed in a third of the three chambers.

[0021] The first material, the second material and the third material can each include silicone gels. In one embodiment, the silicone gels include a two-component addition-cure silicone gel composition that includes a first combination, including a vinyl polymer, a silicone oil and a cross-linker, and a second combination, including a vinyl polymer, a silicone oil and a catalyst (such as a platinum and silicone complex). (One example of suitable silicon gels include prosthesis gels manufactured by Wacker Chemie GmbH.) A typical cross-linker includes a methyl hydrosiloxane polymer.

[0022] In one embodiment the exterior layer **120** and the interior layer **124** have a firmness that allows for a 20 mm to a 26 mm penetration by a cone penetrometer when cured and the middle layer **122** has a firmness that allows for a 10 mm to a 13 mm penetration by a cone penetrometer when cured. In one embodiment, micro-spheres can be added to one or all of the silicone gels to reduce the weight of the resulting prosthesis **100**. Similarly, pigments can be added to give the prosthesis a natural look.

[0023] In one experimental embodiment, all silicone gel penetrations were determined on a Humboldt H1200 penetrometer. The probe employed a 65 mm diameter cone (the dimensions corresponded to part number 18-0122 from Petrolab Company) and the total probe weight was 24.9 g.

[0024] This breast prosthesis **100** provides a soft back layer **124** that conforms to the chest of the wearer and also a soft front layer **120** that provides a natural drape and fit. The middle layer **122** has sufficient firmness to maintain the shape of the breast form during regular use.

[0025] In one embodiment of a method of making a breast form, as shown in FIGS. 3A-3F, four sheets of polyurethane film (**110**, **112**, **114** and **116**) are welded together along a single weld **126** thereby forming an envelope **118** that includes three different chambers and that has a shape corresponding to a desired breast form. The breast form can be asymmetric (as in the example shown in FIG. 1) or it can be symmetric. The weld includes a corresponding three sprue inlets (**111**, **113** and **117**) that open the chambers to the outside. The envelope **118** is placed in a mold **230** including a front portion **232** and a back portion **236**. The mold **230** defines a cavity **234** having a shape that is complementary to the desired shape of a breast form.

[0026] Once in the mold **230**, the first material **212** is injected into the first chamber through the first sprue **111**, the second material **214** is injected into the second chamber through the second sprue **113** and the third material **216** is injected into the third chamber through the third sprue **117**. This forms an uncured breast form **210**, from which any air is removed. The sprues (**111**, **113** and **117**) are sealed and the mold **230** with the uncured breast form **210** therein is placed in an oven **240** and heated to a sufficient temperature for a sufficient amount of time to cure the first material **212**, the second material **214** and the third material **216**, thereby forming a cured breast form **220**. The exact temperature and time depend on the specific mixture of silicone gel used; however, it can readily be determined from the manufacturer's data sheet. The cured breast form **220** is removed from the oven **240**, is allowed to cool, removed from the mold **230** and any excess film is trimmed away from the weld, resulting in a breast prosthesis **100**.

[0027] The final prosthesis **100** includes a layer **124** closest to the patient that is soft and conforms to the chest of the wearer for comfort. The middle layer **122** is firm and provides a stable structure to the prosthesis. The front layer **120** is soft enough to provide a natural drape to the prosthesis **100** so as to give it an appearance of natural breast tissue.

[0028] The above described embodiments, while including the preferred embodiment and the best mode of the invention known to the inventor at the time of filing, are given as illustrative examples only. It will be readily appreciated that many deviations may be made from the specific embodiments disclosed in this specification without departing from the spirit and scope of the invention. Accordingly, the scope of the invention is to be

determined by the claims below rather than being limited to the specifically described embodiments above.

CLAIMS

What is claimed is:

1. A breast prosthesis, comprising:
 - (a) an outer first layer including a first material that has a first firmness that allows for a 20 mm to a 25 mm penetration by a cone penetrometer, the first layer having a shape corresponding to a shape of a breast form;
 - (b) a middle second layer disposed adjacent to the first layer and including a second material that has a second firmness that is greater than the first firmness; and
 - (c) an inner third layer disposed adjacent to the second layer opposite from the first layer and including a third material that has a third firmness that is less than the second firmness.
2. The breast prosthesis of Claim 1, wherein the firmness of the second material is such that the second material allows for a 10 mm to a 13 mm penetration by a cone penetrometer.
3. The breast prosthesis of Claim 1, wherein the firmness of the third material is such that the third material allows for a 22 mm to a 26 mm penetration by a cone penetrometer.
4. The breast prosthesis of Claim 1, wherein the first material comprises silicone gel with a first concentration of a cross-linker, the second material comprises silicone gel with a second concentration of cross-linker, and the third material comprises silicone gel with a third concentration of cross-linker, wherein the second concentration is greater than both the first concentration and the third concentration.
5. The breast prosthesis of Claim 4, wherein the cross-linker comprises a methyl hydrosiloxane polymer.

6. The breast prosthesis of Claim 1, wherein at least one of the first material, the second material and the third material comprises micro-spheres added thereto so as to reduce the weight of the breast prosthesis.
7. The breast prosthesis of Claim 1, further comprising four films that are welded together to form three chambers having a shape of a breast form footprint, the three chambers including: a first chamber into which the first material is disposed, a second chamber into which the second material is disposed and a third chamber into which the third material is disposed.
8. The breast prosthesis of Claim 7, wherein the four films each comprise a polyurethane film.
9. The breast prosthesis of Claim 7, wherein the four films are welded together at a single weld.
10. A breast form prosthesis, comprising:
 - (a) four films that are welded together at a single weld to form three chambers having a shape of a breast form footprint, the three chambers including: a first chamber, a second chamber and a third chamber;
 - (b) an outer first layer disposed in the first chamber and including a first material that has a first firmness, the first layer having a shape corresponding to a shape of a breast form, the first material including a silicone gel with a first concentration of a methyl hydrosiloxane polymer cross-linker;
 - (c) a middle second layer disposed adjacent to the first layer in the second chamber and including a second material that has a second firmness that is greater than the first firmness, the second material including a silicone gel with a second concentration, greater than the first concentration, of a methyl hydrosiloxane polymer cross-linker; and
 - (d) an inner third layer disposed in the third chamber and adjacent to the second layer opposite from the first layer and including a third material that has a third firmness that is less than the second firmness the third material

including a silicone gel with a third concentration, less than the second concentration, of a methyl hydrosiloxane polymer cross-linker.

11. The breast form prosthesis of Claim 10, wherein the firmness of the first material is such that the first material allows for a 20 mm to a 25 mm penetration by a cone penetrometer.
12. The breast form prosthesis of Claim 10, wherein the firmness of the second material is such that the second material allows for a 10 mm to a 13 mm penetration by a cone penetrometer.
13. The breast form prosthesis of Claim 10, wherein the firmness of the third material is such that the third material allows for a 22 mm to a 26 mm penetration by a cone penetrometer.
14. A method of making a breast prosthesis, comprising the steps of:
 - (a) welding together four flexible films with a single weld so as to form a breast form envelope, the breast form envelope including a first chamber, a second chamber and a third chamber, each chamber having a shape of a breast form footprint;
 - (b) placing the breast form envelope into a mold having a shape that is complementary in shape to a breast form;
 - (c) injecting a first material into the first chamber, the first material having a first firmness that allows for a 20 mm to a 25 mm penetration by a cone penetrometer when cured;
 - (d) injecting a second material into the second chamber, the second material having a second firmness when cured, the second firmness being greater than the first firmness;
 - (e) injecting a third material into the third chamber, the third material having a third firmness when cured, the third firmness being less than the second firmness; and
 - (f) heating the mold, the breast form envelope, the first material, the second material and the third material to a temperature sufficient to cure the first

material to the first firmness, the second material to the second firmness and the third material to the third firmness.

15. The method of Claim 14, wherein the firmness of the second material is such that the second material allows for a 10 mm to a 13 mm penetration by a cone penetrometer.
16. The method of Claim 14, wherein the firmness of the third material is such that the third material allows for a 22 mm to a 26 mm penetration by a cone penetrometer.
17. The method of Claim 14, wherein the first material comprises silicone gel with a first concentration of a cross-linker, the second material comprises silicone gel with a second concentration of cross-linker, and the third material comprises silicone gel with a third concentration of cross-linker, wherein the second concentration is greater than both the first concentration and the third concentration.
18. The method of Claim 17, wherein the cross-linker comprises a methyl hydrosiloxane polymer.
19. The method of Claim 14, further comprising the step of adding micro-spheres to at least one of the first material, the second material and the third material so as to reduce the weight of the breast prosthesis.

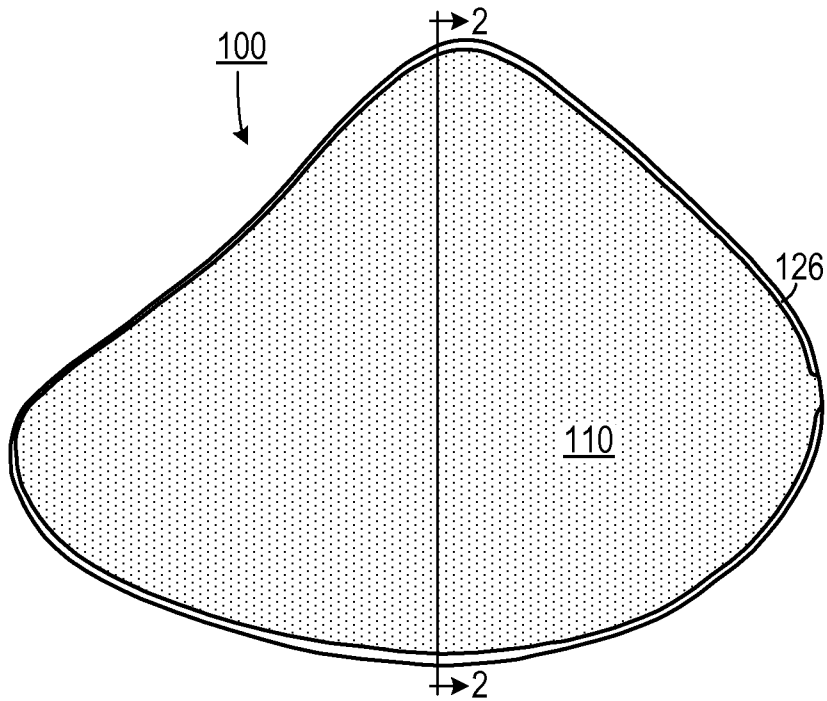


FIG. 1

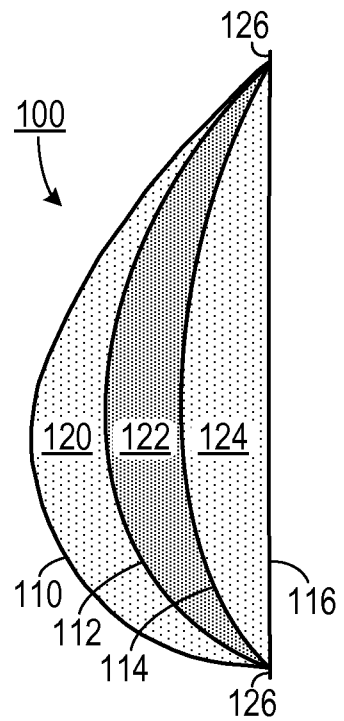


FIG. 2

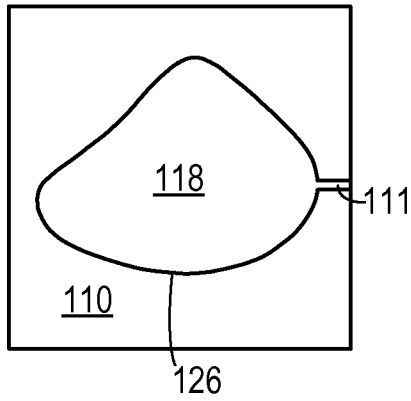


FIG. 3A

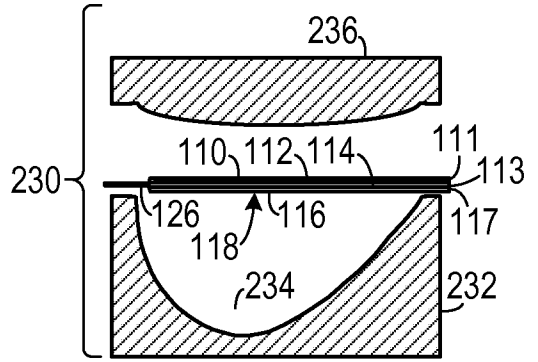


FIG. 3B

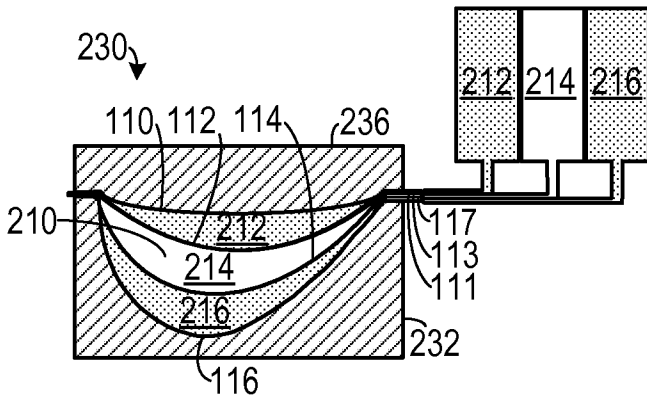


FIG. 3C

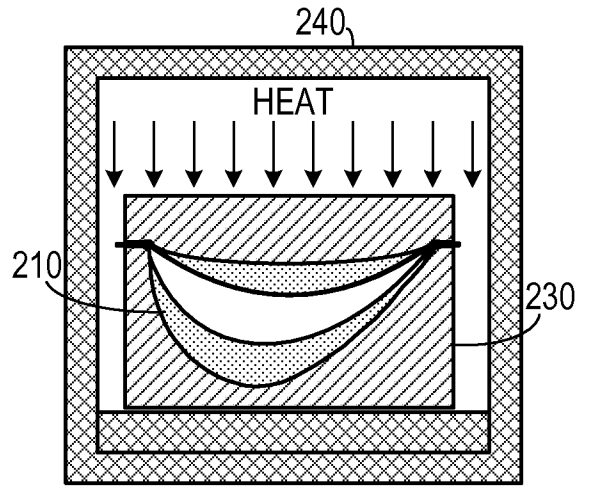


FIG. 3D

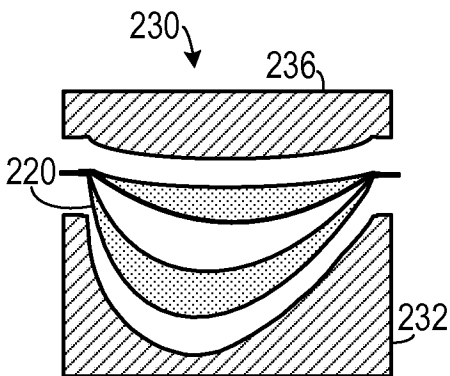


FIG. 3E

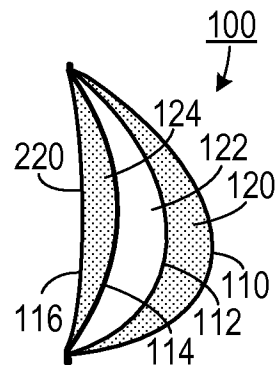


FIG. 3F