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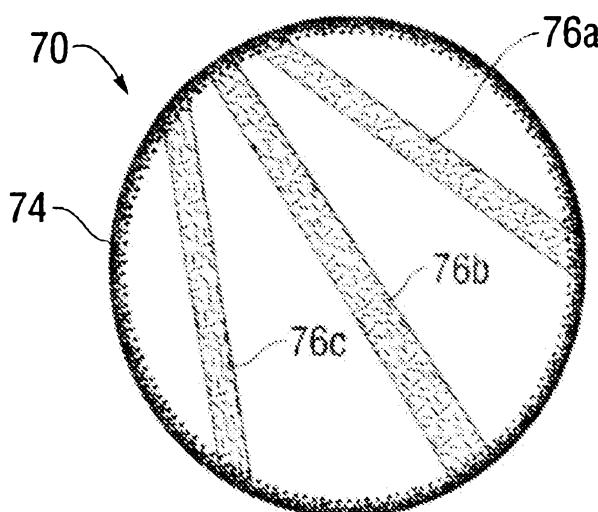
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Fig.6A



(57) Abstract: A soft prosthetic implant shell, such as a silicone breast implant shell, that has discrete fixation surfaces thereon for tissue adhesion. The fixation surfaces (22,24) may be provided on the posterior face of the shell, as well as either on the periphery or at discrete areas on the anterior face. Band-shaped fixation surfaces may be provided on the anterior face of the shell to generally match the angle of pectoralis major or pectoralis minor muscle groups. The fixation surfaces may be roughened areas of the shell, or may be separate elements adhered to the shell.

SOFT FILLED PROSTHESIS SHELL WITH DISCRETE FIXATION SURFACES**By Inventors: Dennis Van Epps and Thomas E. Powell**Cross Reference

This application claims the benefit of U.S. Provisional Patent Application Serial Number 61/088,418, filed on August 13, 2008, the entire disclosure of which is incorporated herein by this specific reference.

Field of the Invention

The present invention relates to soft prosthetic implants and, more particularly, to textured exterior surfaces of such implants, for instance, breast implants.

Background of the Invention

Implantable prostheses are commonly used to replace or augment body tissue. In the case of breast cancer, it is sometimes necessary to remove some or all of the mammary gland and surrounding tissue, which creates a void that can be filled with an implantable prosthesis. The implant serves to support surrounding tissue and to maintain the appearance of the body. The restoration of the normal appearance of the body has an extremely beneficial psychological effect on post-operative patients, eliminating much of the shock and depression that often follows extensive surgical procedures. Implantable prostheses are also used more generally for restoring the normal appearance of soft tissue in various areas of the body, such as the buttocks, chin, calf, etc.

Soft implantable prostheses typically include a relatively thin and flexible envelope or shell made of vulcanized (cured) silicone elastomer. The shell is filled either with a silicone gel or with a normal saline solution. The filling of the shell takes place before or after the shell is inserted through an incision in the patient.

In the United States, women can choose between two different types of breast implant shell surfaces: a smooth surface and a textured surface. The surgeon generally recommends the type of surface based on his or her technique 5 and the shape of the breast implant chosen to best fit the needs of each patient.

Breast implants are not without complications, one of which is termed capsular contracture. This is a complication 10 that occurs upon contraction of a fibrous outer capsule that forms around the implant, which tends to render the implant spherical and stiff and aesthetically undesirable. According to the United States Food and Drug Administration's (FDA) Breast Implant Consumer Handbook (2004), the literature shows 15 that textured surface breast implants may decrease the capsular contracture rate.

Texturing may be provided in a number of ways. Silicone 20 gel breast implants covered with a thin layer of textured polyurethane foam enjoyed considerable popularity in the 1980s because of their remarkable resistance to the early development of fibrous capsular contracture. For example, U.S. Patent No. 3,293,663 describes a soft gel-filled prosthesis with a porous polyester fabric on the back side 25 for tissue ingrowth and anchoring to the chest wall. Although these devices are no longer available in the U.S. because of regulatory constraint, their medical and commercial success stimulated interest in surface texturization of silicone implants.

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Despite many advances in the development of safe and comfortable prosthetic implants, there remains room for improvement.

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Summary of the Invention

The present invention provides a prosthesis suitable for implantation in a human being, for example, a breast implant suitable for use in reconstruction or augmentation of the human breast. The prosthesis generally comprises an implantable member, for example, an elastomeric shell that is filled or is fillable with a liquid or gel. The implantable member has an exterior surface including one or more fixation regions defined thereon and configured, positioned or structured to provide enhanced or controlled tissue ingrowth or adhesion.

A first aspect of the invention provides a breast prosthesis for implantation in a human being, the prosthesis comprising:

an implantable member comprising an elastomeric shell including an exterior surface defined by an anterior face and a posterior face; and

a fixation region defined by a texture molded into the anterior face of the shell, the texture being different from a balance of the exterior surface of the shell, the fixation region comprising a plurality of fixation regions in a radiating configuration;

the prosthesis being structured such that when implanted adjacent a muscle group in a human being, the fixation region can be generally aligned with an alignment of said muscle group.

A second aspect of the invention provides a mammary prosthesis comprising:

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an implantable member comprising a silicone elastomeric shell including an exterior surface defined by an anterior face, a posterior face and a peripheral region between the anterior face and the posterior face, said exterior surface comprising
5 at least one generally elongated fixation region defined by a texture molded into the exterior surface of the shell which is different from a balance of the exterior surface of the shell, the fixation region extending across the peripheral region and across at least one of the posterior face and the anterior
10 face;

the fixation region being configured such that when the prosthesis is implanted in a breast of a human being, the fixation region generally aligns with an alignment of at least one of a pectoralis major muscle group and a pectoralis minor
15 muscle group.

A third aspect of the invention provides a breast prosthesis for implantation in a human being, the prosthesis comprising:

20 an implantable member comprising an elastomeric shell including an exterior surface defined by an anterior face and a posterior face;

a fixation region defined by a first texture integrally molded into the anterior face of the shell; and

25 a second texture integrally molded into the posterior surface of the shell, the second texture being a less textured surface than the first texture.

A fourth aspect of the invention provides a breast prosthesis for implantation in a human being, the prosthesis comprising:

an implantable member comprising an elastomeric shell including an exterior surface defined by an anterior face and a posterior face; and

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a fixation region defined by a texture molded into the anterior face of the shell and having a substantially constant width of between about 2 mm and about 15 mm, the texture being different from a balance of the exterior surface of the shell;

5 the prosthesis being structured such that when implanted adjacent a muscle group in a human being, the fixation region can be generally aligned with an alignment of said muscle group.

A fifth aspect of the invention provides a breast 10 prosthesis for implantation in a human being, the prosthesis comprising:

an implantable member comprising an elastomeric shell including an exterior surface defined by an anterior face and a posterior face; and

15 a fixation region defined by a texture molded into the anterior face of the shell, the texture being different from a balance of the exterior surface of the shell, and the balance of the exterior surface being a matte finish and being relatively less textured than the fixation region texture;

20 the prosthesis being structured such that when implanted adjacent a muscle group in a human being, the fixation region can be generally aligned with an alignment of said muscle group.

In accordance with one aspect of the invention, the 25 fixation surfaces are discrete, generally elongated surface portions extending across an anterior face or a posterior face of the implant. These fixation surfaces, sometimes herein referred to as "fixation regions", are generally defined by a texture, roughness or sheen that is different from a texture, 30 roughness or sheen of adjacent surface portions of the implant.

In some embodiments, the fixation regions have an increased or enhanced texture relative to the balance of the anterior face or posterior face of the implant . In other words,

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the balance of the exterior surface may be relatively less textured than the fixation regions. In some embodiments, the fixation regions are textured and adjacent surfaces, for example, the surface or surfaces that are not defined by the 5 fixation regions, are substantially less textured, or are relatively smooth.

The prosthesis may be structured to encourage enhanced tissue ingrowth or adhesion at the fixation regions, relative 10 to an otherwise identical surface without such texture, roughness or sheen.

In one aspect of the invention, the fixation regions are positioned and/or configured such that the prosthesis, after implantation in the body, moves more naturally with the human body, for example, in relative unity with the muscles of the body. It is contemplated that because the implant moves more naturally with the human body, the implant may be less prone to wear resulting from material stresses relative to conventional implants, for example, implants without such fixation regions. Furthermore, it is contemplated that the present implants will be more comfortable to the patient in that they will move more naturally with the body.

In a more specific aspect of the invention, the fixation regions may be located at specific regions on an anterior face of the shell, that is, a face of the shell which faces the front of the human body when the implant has been appropriately implanted in the human body. Alternatively or additionally, one or more discrete fixation surface may be provided on a periphery of the shell (e.g. circumferentially) and/or on the posterior face of the shell, that is, the face of the shell that faces the back of the human body when the implant has been implanted in the human body.

In an even more specific aspect of the invention, the fixation regions comprise at least one elongated region located on the anterior face of the shell. The at least one elongated region may be, for example, a band-shaped region or alternatively, a plurality of band shaped regions having enhanced texture, roughness or sheen.

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The elongated fixation regions may be positioned to align with one of the pectoralis major muscle groups or pectoralis minor muscle groups of the human body when the implant is implanted in the body. For example, in one embodiment of the invention, the at least one elongated region comprises a diagonally positioned band shaped region intended to align with the pectoralis major muscle group when the implant has been implanted in the body. In another

embodiment, the at least one fixation region comprises a plurality of elongated regions in a radiating configuration generally copying the positioning of the pectoralis minor muscle group wherein the implant has been implanted in the 5 body.

In another broad aspect of the invention, the prosthesis comprises a breast implant having a shell including a fixation region having a first texture and a balance of the 10 shell surface having a second texture that is different from the first texture. In other words, in some embodiments of the invention, the entire, or substantially entire, exterior of the breast implant shell is a textured surface with specific regions thereof having a greater degree of texturing 15 relative to the remaining portions of the textured surface.

It is contemplated that such different texturing will stimulate or encourage different degrees of tissue ingrowth or adhesion at the different fixation regions. For example, 20 in one embodiment, the first fixation region is located on a posterior face of the implant and the second fixation region is located on an anterior face of the implant. The first fixation region may be defined by a texture that is more conducive to tissue interaction and adhesion whereas the 25 second fixation region may be defined by a texture that is relatively less conducive to tissue interaction and adhesion.

In yet another aspect of the invention, the prosthesis comprises a shell having an exterior structured to contact 30 tissue, the shell including a first fixation surface having a first open cell structure, and a second fixation surface having a second open cell structure different than said first open cell structure. In addition, the first fixation surface and the second fixation surface are positioned to encourage 35 respectively different degrees of tissue ingrowth or tissue adhesion by the body at a body-shell interface.

For example, the first open cell structure comprises relatively large open cells and the second open cell structure comprises relatively smaller open cells.

Alternatively or additionally, the first open cell structure 5 may comprise a first distribution of cells and the second open cell structure comprises a second distribution of cells wherein the first distribution of cells is relatively more dense than the second distribution of cells.

10 In yet another specific aspect of the invention, the first open cell structure comprises relatively large rounded open cells and the second open cell structure comprises relatively small rounded open cells. Alternatively, the first open cell structure comprises relatively rounded open 15 cells and the second open cell structure comprises relatively angular open cells.

Advantageously, in accordance with certain embodiments, the first and second fixation surfaces are positioned and 20 structured to be at least somewhat effective to disrupt or disorient capsular tissue formation about the prosthesis after the prosthesis has been implanted in the body.

The present invention further provides a breast 25 prosthesis shell for implantation in a human being, the shell manufactured by the steps of providing a shell precursor; applying a layer of silicone elastomer to the shell precursor, applying solid particles of a first configuration to a portion of the layer of silicone elastomer and applying 30 solid particles of a second configuration to another portion of the layer of silicone elastomer before the layer is fully cured. After the layer including the solid particles embedded therein is cured, the solid particles are then dissolved, for example, by means of a solvent that does not 35 dissolve the silicone elastomer to any appreciable extent. The resulting elastomer shell includes a first open cell texture region formed by said application of the solid particles of the first configuration, and a second open cell

texture region formed by said application of the solid particles of the second configuration.

In yet another aspect of the invention, a method of 5 augmenting or reconstructing a breast of a human being is provided. The method generally comprises providing an implantable member including at least one elongated fixation region as described elsewhere herein and implanting the implantable member into a breast of a human being such that 10 the fixation region generally aligns with one of the pectoralis major muscle group and the pectoralis minor muscle group. The method may further comprise filling the implantable member with a liquid or gel prior to or after the implanting step.

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A further understanding of the nature and advantages of the present invention are set forth in the following description and claims, particularly when considered in conjunction with the accompanying drawings in which like 20 parts bear like reference numerals.

Brief Description of the Drawings

Features and advantages of the present invention will become appreciated as the same become better understood with 25 reference to the specification, claims, and appended drawings wherein:

Figures 1A-1B are a front view and a side elevational view, respectively, of an exemplary round breast implant of the present invention;

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Figures 2A-2B are a front view and side elevational view, respectively, of an exemplary shaped breast implant of the present invention;

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Figures 3A and 3B are schematic views of a woman's upper torso showing, alignment of the pectoralis major muscle group and the pectoralis minor muscle group, respectively;

Figures 4A and 4B are vertical sectional views through a woman's breast and adjacent chest anatomy showing, respectively, subglandular and submuscular placement of a 5 breast implant;

Figures 5A-5B are front and side elevational views of an exemplary round breast implant of the present invention having a generally elongated or band-shaped fixation surface;

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Figures 6A-6B are front and side elevational views of an exemplary shaped breast implant of the present invention having a generally elongated or band-shaped fixation surface;

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Figure 7 is a front elevational view of another breast implant in accordance with the invention including a first fixation region having a first texture and a second fixation region having a second texture different from the first texture.

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Figures 8A and 8B are front and rear elevational views of an exemplary round breast implant of the present invention having a front texture and a rear texture that are different from one another.

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Detailed Description

The present invention provides a saline- or gel-filled soft implant shell, preferably a silicone elastomer shell, with a fixation surface over an exterior portion. The 30 primary application for such soft implants is to reconstruct or augment the female breast. Other potential applications are implants for the buttocks, testes, or calf, among other areas.

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The terms "fixation surface" or "fixation region", as used herein, generally refer to a region or portion of an exterior surface of an implant which is positioned,

structured or adapted to encourage tissue ingrowth or adhesion at a body/implant interface. For example, a fixation region may be a texture, roughness or sheen that is distinct from, for example, more pronounced than, adjacent surfaces of the implant which do not encourage tissue ingrowth or adhesion to the same degree as the fixation region. For example, other regions or surfaces of the implant exterior may be relatively smooth or less textured relative to the fixation regions.

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Such a fixation region may be formed by any suitable means, for example, but not limited to, a salt removal process such as described in U.S. Patent No. 5,007,929, with appropriate changes being made. Alternatively, the fixation surfaces may be formed by separate textured elements such as textured patches or films adhered to the outside of an otherwise "smooth" or less textured implant. Still, another method for forming the discrete fixation regions may be by using a relatively roughened surface portion of a mold used to form the implant. Another method for forming the present fixation regions includes texturing the exterior of the implant after formation. The present invention should not be considered limited to any particular type of texturing or fixation surface, though there might be certain advantages with one or more of these techniques.

Turning now to the Figures, Figures 1A and 1B are front and side elevational views of an exemplary round breast implant 20 of the present invention. Generally, the implant 20 comprises an exterior surface defined by a relatively smooth anterior face 21, a textured posterior face 22 and a textured peripheral region 24 located between the anterior face 21 and the posterior face 22. The relatively smooth anterior face may be a relatively less textured surface (relative to texture of posterior face 22), such as, for example, a fine textured surface or even a matte finish. In some embodiments, the implant 20 has a relatively smooth posterior face, a textured anterior face and a textured or

smooth peripheral region. The fixation surfaces 22, 24 themselves may have differing degrees of texturing. The diameter **D** and front-to-back thickness **T** of the implant are shown and vary depending on the patient's chest size and 5 aesthetic considerations.

In the shown embodiment, the rear fixation surface 22 extends to the apex 26 or generatrix of the convex outer periphery of the implant 20. The peripheral fixation surface 10 24 continues forward a short distance **S** onto the anterior or front surface 21. In some embodiments, the distance **S** is between about 10% and about 30% of the thickness **T**. In some 15 embodiments, the peripheral fixation surface 24 extends substantially entirely around the periphery of the implant 20, such that the implant 20 is axi-symmetric. In other embodiments, the peripheral fixation surface 24 may be abbreviated so as to extend around only a portion of the periphery of the implant, such as the inferior or superior half, or the peripheral fixation surface may be broken up 20 into spaced apart segments. In some embodiments, the peripheral fixation surface 24 comprises substantially evenly spaced segments resulting in alternating smooth and textured areas.

25 Figures 2A-2B illustrate an exemplary shaped breast implant 30 of the present invention having an inferior frontal lobe 32 simulating a natural breast. Like implant 20, implant 30 includes a rear fixation surface 34 and a peripheral fixation surface 36. The width **W**, height **H**, and 30 front-to-back thickness **T** of the implant are shown. If the front projection is round, then **W** = **H**, otherwise **W** may be greater than or less than **H**. When provided with a natural shape, the implant 30 has a proper orientation, namely with the inferior lobe 32 at the lower center. Accordingly, the 35 peripheral fixation surface 36 may extend completely around the periphery of the implant, or may be formed in discrete areas and be oriented relative to the natural shape of the implant. For example, the peripheral fixation surface 36 may

be formed only around the inferior or lower half of the implant, or may be formed only on the sides.

Figure 3A illustrates a woman's upper torso 5 schematically showing on one side placement and alignment of the pectoralis major muscle group, while Figure 3B illustrates the placement and alignment of the pectoralis minor muscle group. These two muscle groups overlap one another and extend generally from the shoulder or collarbone 10 region to the rib cage underneath the breast. One aspect of the present invention is to provide an implant including fixation surfaces such as described elsewhere herein, which are substantially aligned with these muscle groups when the implant is placed in the body.

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While not wishing to be bound by any specific theory of operation, the regions or lines of contact of the implant with the primary chest muscles experience greater movement than other areas of the implant not interfacing the muscles. 20 It is believed by the present inventors that by providing a fixation region of the implant that is substantially coincident with or in substantial alignment with one or more of these muscle groups is more likely to remain secured (i.e., they move with the muscle). In addition, it is 25 contemplated that such discrete fixation regions may provide the benefit of disrupting capsule formation and/or reducing the potential for capsular contraction.

Figure 4A is a vertical sectional view through a woman's 30 breast and adjacent chest anatomy showing a subglandular placement of a breast implant 40. The implant 40 is positioned over the top of the pectoralis major muscle group 42, which in turn overlays the pectoralis minor muscle group 44. The chest wall 48 showing a plurality of ribs 50 is also 35 indicated underneath the pectoralis minor muscle 44. Figure 4B is a vertical sectional view as in Figure 4A but showing a submuscular placement of the implant 40, underneath the pectoralis major muscle group 42. Both these two implant

placements are utilized primarily depending on the surgeon's clinical determination, sometimes influenced by a dialogue between patient and the surgeon and desired outcome.

Depending on the implant placements, the implant 40 may be in 5 contact with one or both muscle groups. In some embodiments of the invention, the implant includes substantially elongated fixation regions as described and shown herein, and said fixation regions being in substantial alignment with the appropriate muscle group which interface the implant when the 10 implant is placed in the body.

For example, Figures 5A-5B are front and side elevational views of an exemplary round breast implant 60 of the present invention having a posterior face 62, a 15 peripheral region 64, and an anterior face including a elongated or band-shaped fixation region 66. The band-shaped fixation region 66 extends generally along a diagonal angle and commences at the front border of the peripheral fixation surface 64. The illustrated embodiment, the fixation region 20 66 has a substantially constant width W as seen from the front in Figure 5A. In one embodiment, the width W is between about 1 mm to about 20 mm, for example, between about 2mm to about 15 mm. Alternatively, although not shown, the fixation region 66 may have a configuration that is other 25 than a constant width.

In one embodiment, the band-shaped fixation surface 66 is generally oriented or aligned with either the pectoralis major muscle group or pectoralis minor muscle group when the 30 implant is implanted in the breast. For instance, if the implant 60 is destined for a submuscular placement such as in Figure 4B, the fixation surface 66 may be oriented to be generally aligned with the pectoralis major muscle group, as seen in Figure 3A. Alternatively, the angle at which the 35 insertion surface 66 is oriented may be an approximation of the average angle of the pectoralis major and pectoralis minor muscle groups. In this way, the implant 60 has a fixation surface 66 to encourage tissue ingrowth or adhesion

along the major stress lines of the implant. Preferably, the fixation surface 66 is angled between about 30-60° with respect to a vertical plane through the implant 60. Of course, if the implant 60 is round as shown, the fixation 5 surface 66 itself defines the orientation thereof. In one embodiment, the band-shaped fixation surface 66 is centered about the center of the implant 60, therefore creating two symmetric orientations about 180° apart. This arrangement facilitates implant by providing two possible orientations 10 for the surgeon.

The band-shaped fixation region 66 may extend substantially across the anterior face of the implant and may be defined by a texture that is different from a balance of 15 the anterior face. The fixation region 66 may also have a different texture, for example, a more pronounced or more aggressive texture, than the rear fixation surface 62 or peripheral surface 64.

20 Figures 6A-6B illustrate another exemplary shaped breast implant 70 of the present invention. The implant 70 again features a rear fixation surface 72, a peripheral fixation surface 74, and a plurality of separate band-shaped fixation surfaces 76a, 76b, 76c. These discrete fixation surfaces 25 76a, 76b, 76c are positioned or configured to align with one or more of the muscle groups described above. For example, the three fixation surfaces 76a, 76b, 76c may be generally oriented relative to the fan-shaped pectoralis minor muscle group. Because the shaped implant 70 is orientation-specific, proper placement of the implant orients the 30 fixation surfaces 76a, 76b, 76c with the particular muscle group. As mentioned above, the various fixation surfaces 72, 74, 76a, 76b, and 76c may be formed with a similar level of roughness, or some may be less textured, such as with a matte 35 finish. For instance, the rear and peripheral fixation surfaces 72, 74 may have a fine, matte finish, while the frontal fixation surfaces 76a, 76b, 76c are more densely

textured. The present invention contemplates all permutations of texturing choices.

In cross-section, the textured implant shells of the 5 present invention may be single- or multi-layered. The overall thickness of the textured implant shell wall may be somewhat greater than a similar smooth-walled shell because of the extra layers of texture.

10 Turning now to Fig. 7, an anterior (front) view of another breast implant of the present invention is shown generally at 110. The implant 110 includes a shell 112 having an exterior surface including a first fixation region 114 having a first texture 116 and a second fixation region 15 118 having a second texture 122 that is different from the first texture 116. In the shown embodiment, the first texture 116 is a more "aggressive" texture than the second texture 122. The first texture 116 is structured to encourage a greater degree of tissue interaction than the 20 second texture 122.

In lieu of the second texture 122, it is contemplated that the second fixation region 118, and perhaps the entire balance of the exterior of the shell 112, may be a low sheen 25 surface, for example, a matte finish.

Turning now to Figs. 8A and 8B, anterior (front) and posterior (rear) views, respectively, of another breast implant in accordance with the invention are shown generally 30 at 210. The implant 210 includes a shell 212 having an anterior face 212a and a posterior face 212b, and including a first fixation region 214 having a first texture 216 and a second fixation region 218 having a second texture 222 that is different from the first texture 216. In the shown 35 embodiment, the first texture 216 may encompass the entire, or substantially entire, anterior face 212a of the implant 210. The first texture 216 is defined by a first distribution of pores, crevices or caverns that is relatively

less dense than that of the second texture 222. The second texture 222, which may encompass the entire, or substantially entire, posterior face 221b of the implant 210, may be structured to encourage a greater degree of tissue
5 interaction and adhesion than that of the first texture 216.

The shells 112 and 212 may be manufactured by a method of the invention comprising the steps of providing a shell precursor; applying a layer of silicone elastomer to the
10 shell precursor, applying solid particles of a first configuration to a portion of the layer of silicone elastomer and applying solid particles of a second configuration to another portion of the layer of silicone elastomer before the layer is fully cured. After the layer including the solid
15 particles embedded therein is cured, the solid particles are then dissolved, for example, by means of a solvent that does not dissolve the silicone elastomer to any appreciable extent. The resulting elastomer shell includes a first open cell texture region formed by said application of the solid
20 particles of the first configuration, and a second open cell texture region formed by said application of the solid particles of the second configuration.

One process for forming flexible implant shells for
25 implantable prostheses involve dipping a suitably shaped mandrel into a silicone elastomer dispersion. Many such dispersions are used in the field. Basically they contain a silicone elastomer and a solvent. The silicone elastomer is typically polydimethylsiloxane, polydiphenyl-siloxane or some
30 combination of these two. Typical solvents include xylene or 1,1,1-trichloroethane. Different manufacturers vary the type and amount of the ingredients in the dispersion, the viscosity of the dispersion and the solid content of the dispersion. Nonetheless, the present invention is expected
35 to be adaptable to have utility with a wide variety of silicone rubber dispersions.

The mandrel is withdrawn from the dispersion and the excess silicone elastomer dispersion is allowed to drain from the mandrel. After the excess dispersion has drained from the mandrel at least a portion of the solvent is allowed to 5 volatilize or evaporate. Normally this is accomplished by flowing air over the coated mandrel at a controlled temperature and humidity. Different manufacturers use various quantities, velocities or directions of air flow and set the temperature and humidity of the air at different 10 values. However, the desired result, driving off the solvent, remains the same.

It is also common for prostheses manufacturers to repeat this dip and volatilize procedure a number of times so that a 15 number of layers are built up on the mandrel to reach a desired shell thickness. A layered structure like most current silicone elastomer shells can be made by sequentially dipping the mandrel in different dispersions. Alternatively, the steps may be repeated in a single dispersion so that the 20 finished product is a single homogenous material or layer. That is, the dipping process may be done in multiple stages or steps, each step adding more material, yet the finished product exhibits no distinct layers and the entire shell wall is homogenous or uniform in composition.

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An exemplary process for forming the fixation surfaces on either a multi-layered shell or a single-layered shell will now be described. After the mandrel is raised out of the dispersion with what is to be the final layer adhering 30 thereto, this layer is allowed to stabilize. That is, it is held until the final coating no longer flows freely. This occurs as some of the solvent evaporates from the final coating, raising its viscosity.

35 Again, it should be understood that alternative methods are contemplated for forming the flexible shell prior to the texturing process. The dip molding process advantageously results in the flexible shell pre-mounted on a dipping

mandrel, which can then be used for the texturing process. However, if the flexible shell is made by another technique, such as by rotational molding, it can subsequently be mounted on a dipping mandrel and the process continued in the same 5 manner.

Once the flexible shell has been stabilized and mounted on the mandrel, any loose fibers or particles are removed from the exterior of the shell, for example, with an anti-10 static air gun. A tack coat layer is then applied. The tack coat layer may be sprayed on, but is desirably applied by dipping the flexible shell on the mandrel into a tack coat dispersion. The operator immerses the flexible shell into the dispersion and returns the mandrel to a rack for 15 stabilization. The time required for stabilization typically varies between 5-20 minutes. A suitable tack coat layer is desirably made using the same material employed in the base layers.

20 At this point, granulated solid particles (i.e., salt crystals) are applied over that portion of the exterior surface that will end up as the fixation surface. The solid particles may be applied manually by sprinkling them over the surface while the mandrel is manipulated, or a machine 25 operating like a bead blaster or sand blaster could be used to deliver a steady stream of solid particles at an adequate velocity to the coating on the mandrel. However, a preferred method of solid particle application is to dip the mandrel/shell into a body of the solid particles or expose it 30 to a suspension of the solid particles. It should be understood that the present invention is not intended to be restricted to any one particular method of applying particles. One possible method to apply solid particles to some but not all of the shell is to mask off areas of the 35 shell for which particles are not to be applied and then apply the particles to the non-masked areas.

The tacky flexible shell may then be immersed in a fluidized (air-mixing) aqueous salt bath having regular cubic salt crystals between about 10 to about 600 microns, or round crystals between about 50-2000 microns or a combination 5 thereof. Varying degrees of texturing may be formed with the salt removal process by using differently sized or shaped salt granules (for example, round salt crystals versus angular salt crystals, large salt crystals versus relatively small salt crystals, high density distribution of salt 10 crystals versus relatively low density distribution of salt crystals), on different areas of the shell. The shell is rotated for even coverage, removed, and then allowed to stabilize. After a suitable period of stabilization, such as between about 5-20 minutes, the flexible shells may be dipped 15 into an overcoat dispersion. A suitable overcoat dispersion may be made using the same material employed in the base layers. The flexible shells on the mandrels are then mounted on a rack and allowed to volatilize, such as, for example, about 15 minutes.

20

The entire silicone elastomer shell structure is vulcanized or cured in an oven at elevated temperatures. The temperature of the oven is preferably kept between about 200°F and about 350°F for a curing time preferably between 25 about 20 minutes and about 1 hour, 40 minutes. Upon removal from the oven, the mandrel/shell assembly is placed in a solvent for the solid particles, and the solid particles allowed to dissolve. The solvent does not affect the structure or integrity of the silicone elastomer. When the 30 solid particles have dissolved, the assembly is removed from the solvent and the solvent evaporated. The shell can then be stripped from the mandrel. At this point, it is preferable to place the shell in a solvent for the solid particles and gently agitate it to ensure complete 35 dissolution of all the solid particles. When the shell is removed from the solvent, the solvent is evaporated.

Dissolving the solid particles leaves behind open, interconnected, cavities in the surface of the shell where the salt had been.

5 After finishing the shell according to the steps described above, the steps required to make a finished breast implant prosthesis may be similar to those known in the art. For example, an opening left by the dip molding process is patched with uncured sheeting, usually made of silicone 10 rubber. Then, if the prosthesis is to be filled with silicone gel, this gel is added and cured, the filled prosthesis packaged, and the packaged prosthesis sterilized. If the prosthesis is to be inflated with a saline solution, a one-way valve is assembled and installed, the prosthesis is 15 post cured if required, and the prosthesis is then cleaned, packaged and sterilized. A combination breast implant prosthesis can also be made wherein a gel-filled sac is positioned inside the shell to be surrounded by saline solution.

20

In addition to the aforementioned dipping process, the flexible shell for the prosthetic implant may be formed using a molding process. For example, a rotational molding process such as described in Schuessler, U.S. Patent No. 6,602,452 25 the entire disclosure of which is incorporated herein, may be used. The process for forming texturing on the exterior surface may be done using a dipping technique after the shell is molded, but another method is to roughen the inside of the mold. For example, a mold having a generally smooth interior 30 surface except for rough areas as described above will produce an implant shell having discrete fixation surfaces. The rotational molding process is advantageous because the entire implant shell may be formed in relatively few manufacturing steps.

35

Although the invention has been described and illustrated with a certain degree of particularity, it is understood that the present disclosure has been made only by

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way of example, and that numerous changes in the combination and arrangement of parts can be resorted to by those skilled in the art without departing from the scope of the invention, as hereinafter claimed.

5

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated integer or step 10 or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

The reference in this specification to any prior publication (or information derived from it), or to any matter 15 which is known, is not, and should not be taken as, an acknowledgement or admission or any form of suggestion that that prior publication (or information derived from it) or known matter forms part of the common general knowledge in the field of endeavour to which this specification relates.

The claims defining the invention are as follows:

1. A breast prosthesis for implantation in a human being, the prosthesis comprising:

5 an implantable member comprising an elastomeric shell including an exterior surface defined by an anterior face and a posterior face; and

10 a fixation region defined by a texture molded into the anterior face of the shell, the texture being different

15 from a balance of the exterior surface of the shell, the fixation region comprising a plurality of fixation regions in a radiating configuration;

15 the prosthesis being structured such that when implanted adjacent a muscle group in a human being, the

fixation region can be generally aligned with an alignment of said muscle group.

2. The prosthesis of claim 1, wherein the fixation region has a first texture and the balance of the exterior surface has a

20 second texture different from the first texture.

3. The prosthesis of claim 1 or claim 2 configured for implantation in a breast of a human being and wherein the fixation region is positioned and configured to generally align

25 with a pectoral muscle group when the prosthesis is so implanted in the breast of the human being.

4. The prosthesis of claim 1 or claim 2 configured for placement in a breast of a human being and wherein the fixation

30 region is positioned to generally align with at least one of a pectoralis major muscle group and a pectoralis minor muscle group when the prosthesis is so implanted in the breast of the human being.

5. The prosthesis of any one of claims 1 to 4, wherein the fixation region extends substantially entirely across said anterior face.

5 6. The prosthesis of any one of claims 1 to 5, wherein the fixation region has as substantially constant width of between about 2 mm and about 15 mm.

7. A mammary prosthesis comprising:

10 an implantable member comprising a silicone elastomeric shell including an exterior surface defined by an anterior face, a posterior face and a peripheral region between the anterior face and the posterior face, said exterior surface comprising at least one generally elongated fixation region defined by a texture molded into the exterior surface of the shell which is different from a balance of the exterior surface of the shell, the fixation region extending across the peripheral region and across at least one of the posterior face and the anterior face;

15 20 the fixation region being configured such that when the prosthesis is implanted in a breast of a human being, the fixation region generally aligns with an alignment of at least one of a pectoralis major muscle group and a pectoralis minor muscle group.

25

8. The prosthesis of claim 7, wherein the at least one generally elongated fixation region includes a plurality of generally elongated regions forming a substantially radiating configuration.

30

9. The prosthesis of any one of claims 1 to 8, wherein the balance of the exterior surface is substantially smooth.

10. The prosthesis of any one of claims 1 to 9, wherein the

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balance of the exterior surface is a relatively less textured surface than the fixation region texture.

11. The prosthesis of claim 10, wherein the balance of the 5 exterior surface is a matte finish surface.

12. A breast prosthesis for implantation in a human being, the prosthesis comprising:

an implantable member comprising an elastomeric shell 10 including an exterior surface defined by an anterior face and a posterior face;

a fixation region defined by a first texture integrally molded into the anterior face of the shell; and

15 a second texture integrally molded into the posterior surface of the shell, the second texture being a less textured surface than the first texture.

13. The prosthesis of claim 12, wherein the second texture is a matte finish surface.

20

14. A breast prosthesis for implantation in a human being, the prosthesis comprising:

an implantable member comprising an elastomeric shell 25 including an exterior surface defined by an anterior face and a posterior face; and

a fixation region defined by a texture molded into the anterior face of the shell and having a substantially constant width of between about 2 mm and about 15 mm, the texture being different from a balance of the exterior surface 30 of the shell;

the prosthesis being structured such that when implanted adjacent a muscle group in a human being, the fixation region can be generally aligned with an alignment of said muscle group.

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15. A breast prosthesis for implantation in a human being, the prosthesis comprising:

an implantable member comprising an elastomeric shell
5 including an exterior surface defined by an anterior face and a posterior face; and

10 a fixation region defined by a texture molded into the anterior face of the shell, the texture being different from a balance of the exterior surface of the shell, and the balance of the exterior surface being a matte finish and being relatively less textured than the fixation region texture;

15 the prosthesis being structured such that when implanted adjacent a muscle group in a human being, the fixation region can be generally aligned with an alignment of said muscle group.

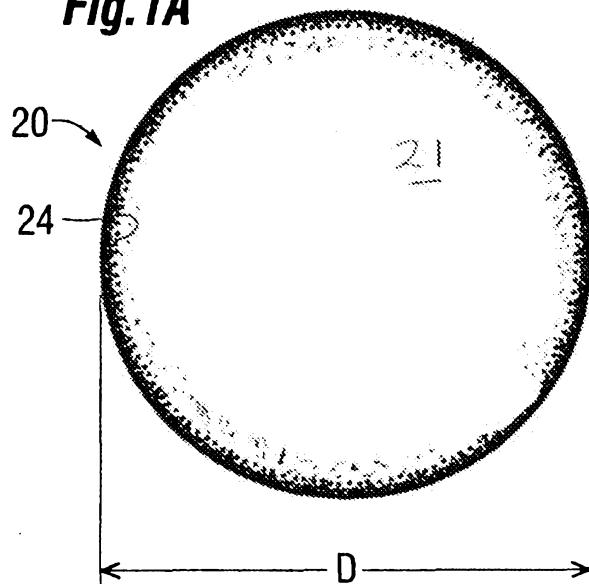
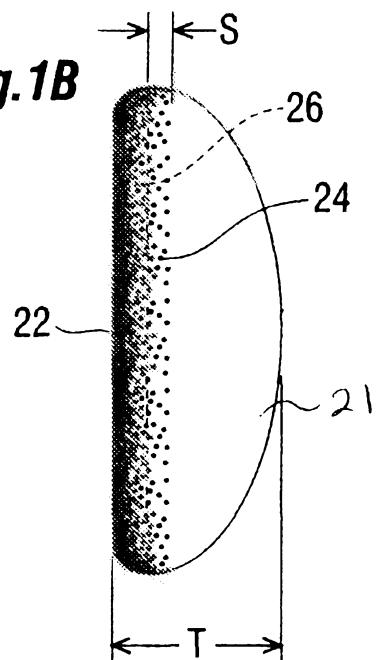
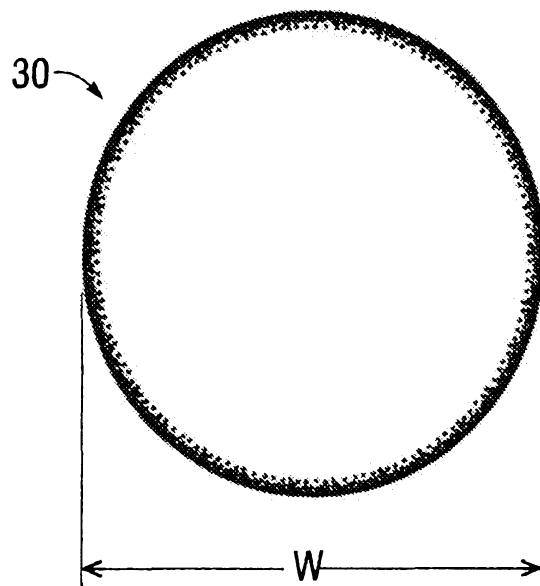
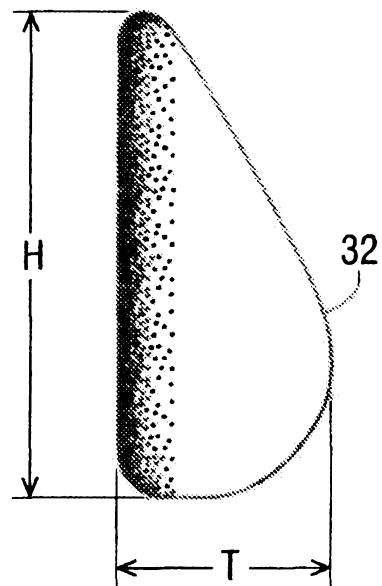
Fig.1A**Fig.1B****Fig.2A****Fig.2B**

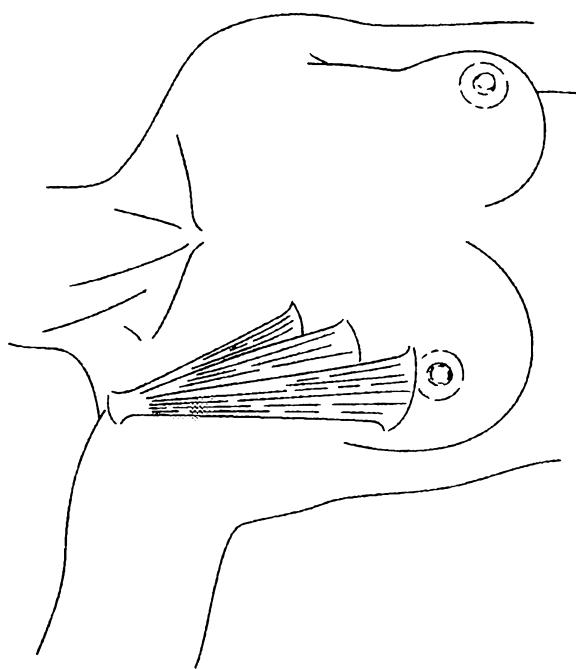
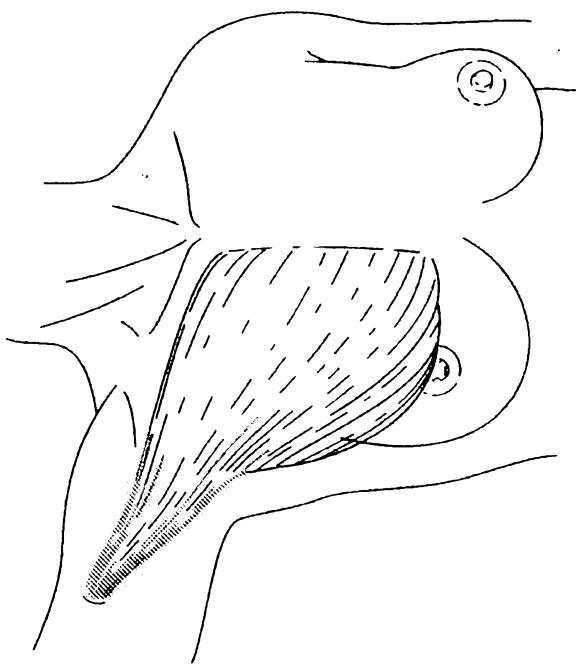
Fig. 3B*Fig. 3A*

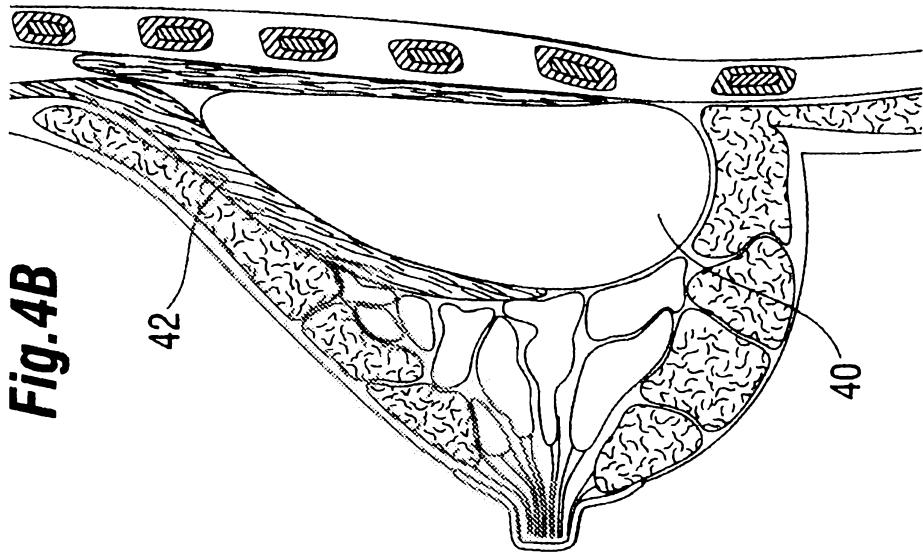
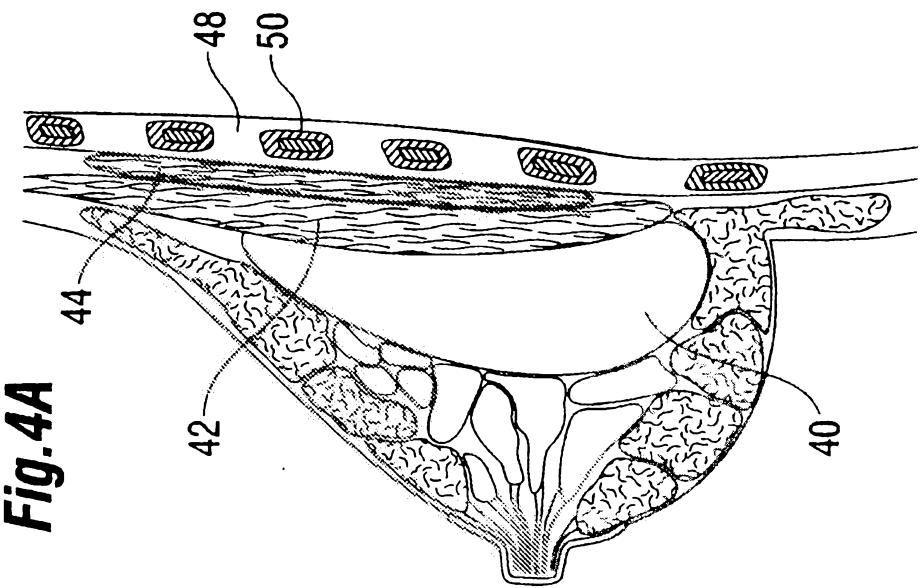
Fig. 4B*Fig. 4A*

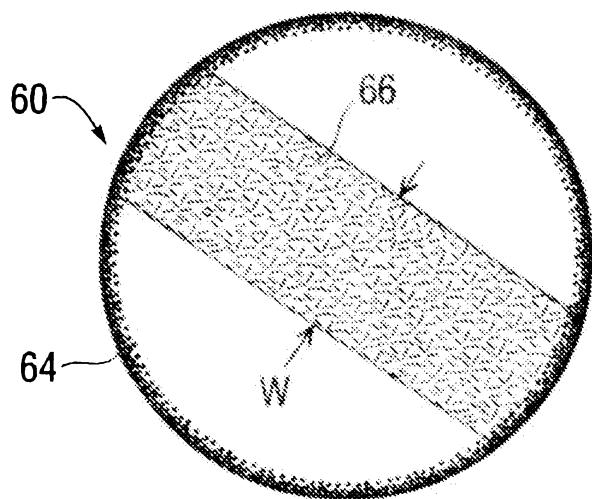
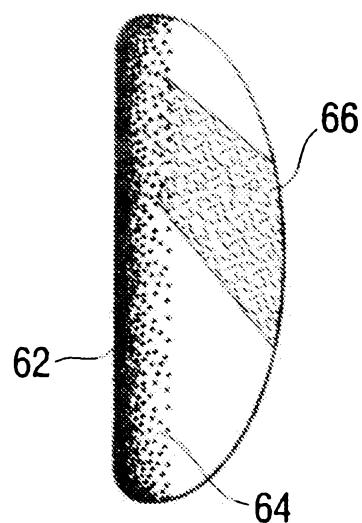
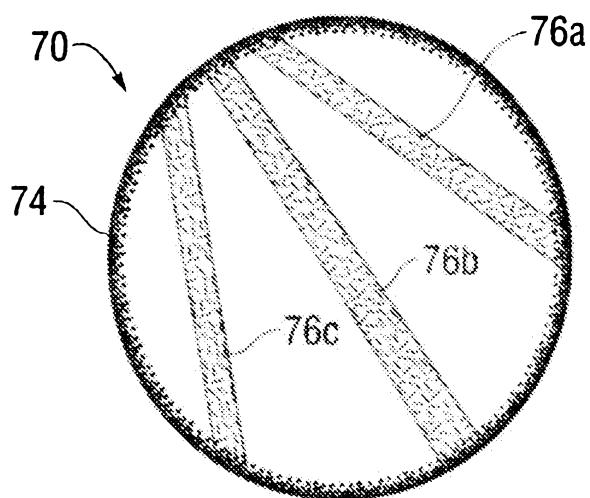
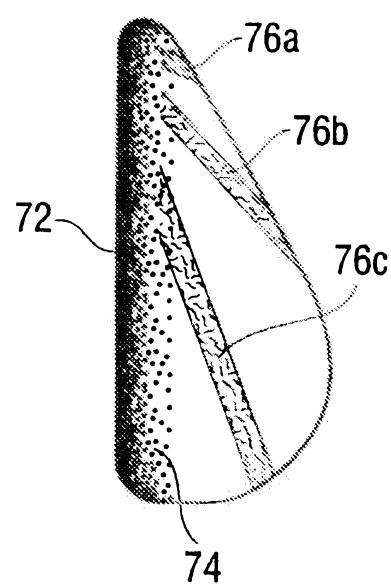
Fig.5A**Fig.5B****Fig.6A****Fig.6B**

Fig. 7

