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(54) Titre : IMPLANT MAMMAIRE A ENVELOPPE PERMEABLE AUX RAYONS X
(54) Title: BREAST IMPLANT WITH RADIOLOGIC SHELL

(57) **Abrégé/Abstract:**

A breast implant includes a shell fashioned from one of a group of materials which exhibit radiolucency at those x-ray intensities normally encountered for mammographic procedures. The radiolucent shell may be filled with radiolucent fill material as previously taught to thereby comprise a fully radiolucent breast implant. The radiolucent breast implant enhances the use of mammography in detecting tumors in patients having breast implants to more effectively diagnose and treat cancer.



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(21) International Application Number: PCT/US93/07384 (22) International Filing Date: 6 August 1993 (06.08.93) (30) Priority data: 07/952,687 29 September 1992 (29.09.92) US (71) Applicant: LIPOMATRIX INCORPORATED [US/US]; 1850 Embarcadero Road, Palo Alto, CA 94303 (US). (72) Inventors: KNAPP, Terry, Russell ; 915 Sierra Vista Drive, Redding, CA 96001 (US). ANDREWS, Winston, A. ; 575 El Capitan Drive, Danville, CA 94526 (US). (74) Agent: HAFERKAMP, Richard, E.; Rogers, Howell & Haferkamp, 7777 Bonhomme, Suite 1700, St. Louis, MO 63105 (US).		(81) Designated States: AU, BB, BG, BR, BY, CA, CZ, FI, HU, JP, KP, KR, KZ, LK, MG, MN, MW, NO, NZ, PL, RO, RU, SD, SK, UA, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: BREAST IMPLANT WITH RADIOLUCENT SHELL (57) Abstract A breast implant includes a shell fashioned from one of a group of materials which exhibit radiolucency at those x-ray intensities normally encountered for mammographic procedures. The radiolucent shell may be filled with radiolucent fill material as previously taught to thereby comprise a fully radiolucent breast implant. The radiolucent breast implant enhances the use of mammography in detecting tumors in patients having breast implants to more effectively diagnose and treat cancer.		

BREAST IMPLANT WITH RADIOLUCENT SHELL

Background and Summary of the Invention

Breast prostheses are well known in the art and generally include a shell or envelope which is filled with a fluid or gel which desirably is used to enlarge
5 the female breast yet retain its normal appearance, movement, feel, and other cosmetic characteristics. Until recently, the predominant breast implant had been a silicone envelope filled with a silicone gel. However, recent health concerns have prompted the withdrawal of this
10 implant from the market. These concerns generally relate to the health risks caused by migration of the silicone gel from within the shell, breakage of the shell, or other introduction of the silicone gel into the body.

The assignee of the present invention also holds
15 certain rights under U.S. Patent No. 4,995,882, which discloses and claims a breast implant comprised of a silicone shell filled with a radiolucent fill material such as peanut oil, sunflower seed oil, or any other suitable fluid with the same atomic number as breast
20 tissue, $Z=5.9$. As explained in greater detail therein,

mammograms typically are performed by compressing a breast between two plates which flattens the breast and enables a more uniform exposure. A controlled intensity of x-rays are then passed through the breast for a carefully controlled time period to image any artifacts indicative of cancer. As is well known in the art of mammography, great care is taken to minimize the amount of x-ray energy used as studies have shown that certain levels of x-ray exposure will itself increase the risk of developing cancer. Typically, mammographies are conducted at low x-ray energy levels, such as between the range of 25-60 kVp. Hence, this prior patent discloses a useful and valuable invention of utilizing a fill material which is radiolucent using standard mammographic procedures and protocols, and perhaps more importantly, x-ray intensities.

The inventors herein are also aware of U.S. Patent No. 4,863,470 which discloses a standard breast implant comprised of a silicone shell with a silicone gel fill material. As previously mentioned herein, this breast implant construction is well known in the prior art and, up until recently, had been the most popular implant used. In addition, this patent discloses an identification marker or tab which is made from silicone with bismuth trioxide or barium sulfate, both of which are much more "radiopaque" than the silicone used for the standard shell or fill material. Hence, presuming an increased x-ray intensity which would render the standard silicone breast implant radiolucent, a marker or tab would remain opaque and thusly visible. This patent also describes a technique used to read this radiopaque marker which is more similar to a chest x-ray than to a mammogram. As taught therein, the patient lies on her back and the x-rays are directed through her breast and chest cavity. For chest x-rays, energy levels at 125 kVp are common. The intensity of x-rays required for this procedure sub-

stantially exceeds that carefully controlled and timed dosage which is used for mammographic procedures. Therefore, while this patent suggests that a standard silicone gel and silicone fill material may be radiolucent, it is
5 in reality radiopaque for standard mammographic procedures. This deficiency with this prior art implant construction was recognized and dramatically improved upon with the breast implant with radiolucent fill disclosed and claimed in prior U.S. Patent 4,995,882.

10 As an enhancement to the breast implant with silicone shell and radiolucent fill, the inventors herein have succeeded in developing a breast implant with a shell which is also radiolucent. Therefore, with this breast implant, not only is the fill material comprised
15 of a radiolucent material, but the shell also is radiolucent itself, using the standards for judging radiolucency as explained in prior U.S. Patent 4,995,882, i.e. using standard mammographic protocols, procedures, and intensities. The material which the inventors have identified
20 and are contemplating for use for the shell include any one or more of the following: linear aliphatic polyether urethane; linear aliphatic polyester urethane; cyclic aliphatic polyether urethane; cyclic aliphatic polyester urethane; aromatic polyether urethane; aromatic polyester
25 urethane; polybutylene; polypropylene; crosslinked olefinic elastomers; and styrene-ethylene/butylene-styrene block copolymer. All of these materials have an effective atomic number of 6.0 within a range of ± 0.5 , and therefore exhibit the effective atomic number of fat
30 which is the major component of a human breast. Thus, with the present invention, a breast implant is disclosed which includes a radiolucent shell filled with a radiolucent fill material thereby rendering the entire implant optimally radiolucent for mammographic procedures.

It is not believed that a drawing is required or even helpful in understanding the present invention and, hence, none is being submitted.

Detailed Description of the Preferred Embodiment

5 The inventors' preferred embodiment for achieving a breast implant shell which is essentially radiolucent using standard mammographic procedures, protocols, and intensities. The inventors believe that materials having an effective atomic number of 6.0 within a range of ± 0.5
10 satisfy this criteria. As examples thereof, the present invention includes fashioning the shell from any one of a number of materials such as: linear aliphatic polyether urethane; linear aliphatic polyester urethane; cyclic aliphatic polyether urethane; cyclic aliphatic polyester
15 urethane; aromatic polyether urethane; aromatic polyester urethane; polybutylene; polypropylene; crosslinked olefinic elastomers; and styrene-ethylene/butylene-styrene block copolymer. It is anticipated that standard manufacturing techniques well known to those of ordinary
20 skill in the art for producing breast implants will be similarly used with the materials of the present invention. In other words, it is not anticipated that there will be any difficulty encountered by those of ordinary skill in the art in making breast implant shells with the
25 materials suggested herein as radiolucent.

 There are various changes and modifications which may be made to the invention as would be apparent to those skilled in the art. However, these changes or modifications are included in the teaching of the disclosure, and it is intended that the invention be limited
30 only by the scope of the claims appended hereto.

What Is Claimed Is:

1. A breast implant comprised of a shell filled with a filler, both said shell and filler being each made of materials which are themselves substantially radiolucent under accepted mammographic protocols and intensi-
5 ties.

2. The implant of Claim 1 wherein said shell is a material selected from the group consisting of linear aliphatic polyether urethane; linear aliphatic polyester urethane; cyclic aliphatic polyether urethane; cyclic
5 aliphatic polyester urethane; aromatic polyether urethane; aromatic polyester urethane; polybutylene; polypropylene; crosslinked olefinic elastomers; and styrene-ethylene/butylene-styrene block copolymer.

3. In a breast implant comprised of a shell filled with a fill material, the improvement comprising said shell being made of a material which is itself substantially radiolucent under accepted mammographic protocols
5 and intensities.

4. The breast implant of Claim 3 wherein said shell is a material selected from the group consisting of linear aliphatic polyether urethane; linear aliphatic polyester urethane; cyclic aliphatic polyether urethane; cyclic
5 aliphatic polyester urethane; aromatic polyether urethane; aromatic polyester urethane; polybutylene; polypropylene; crosslinked olefinic elastomers; and styrene-ethylene/butylene-styrene block copolymer.

5. A breast implant comprised of a shell filled with a filler, both said shell and filler being made of materials having an effective atomic number of 6.0 within a range of about ± 0.5 .