United States Patent

Perras

[15] **3,681,787**

[45] **Aug. 8, 1972**

[54] **IMPLANTABLE BREAST PROSTHESIS FILLED WITH GELS OF DIFFERENT DENSITIES**

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[22] Filed: **March 26, 1971**

[21] Appl. No.: **128,500**

Related U.S. Application Data

[63] Continuation of Ser. No. 782,345, Dec. 9, 1968, abandoned.

[52] **U.S. Cl.** **3/36**

[51] **Int. Cl.** **A61f 1/24**

[58] **Field of Search** .....3/1, 36; 128/462, 463, 464, 128/478–481, DIG. 21

[56] **References Cited**

UNITED STATES PATENTS

2,636,182	4/1953	Freedman	3/36
3,293,663	12/1966	Cronin	3/36

FOREIGN PATENTS OR APPLICATIONS

1,085,676	7/1954	France	3/36
1,506,272	11/1967	France	3/36

OTHER PUBLICATIONS

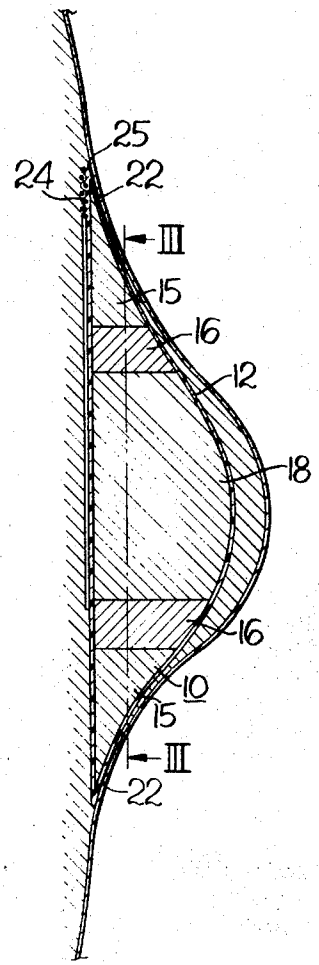
" Mammaplasty Utilizing a Silastic Implant," The Bulletin of the Dow Corning Center for Aid to Medical Research, Vol. 10, No. 2, April 1968, Midland, Mich., page 7.

Primary Examiner—Richard A. Gaudet
Assistant Examiner—Ronald L. Frinks

[57] **ABSTRACT**

A breast prosthesis having a porous polyester fabric for connecting the prosthesis to the chest wall and filled with layers of silicon gel material of varying viscosity to provide a more natural appearance of the breast.

8 Claims, 3 Drawing Figures



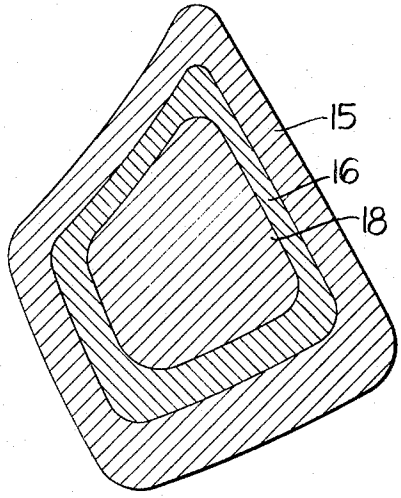


Fig. 3

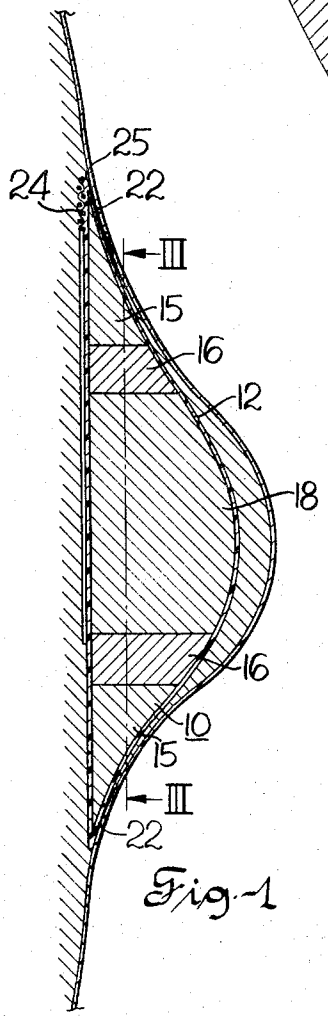


Fig. 1

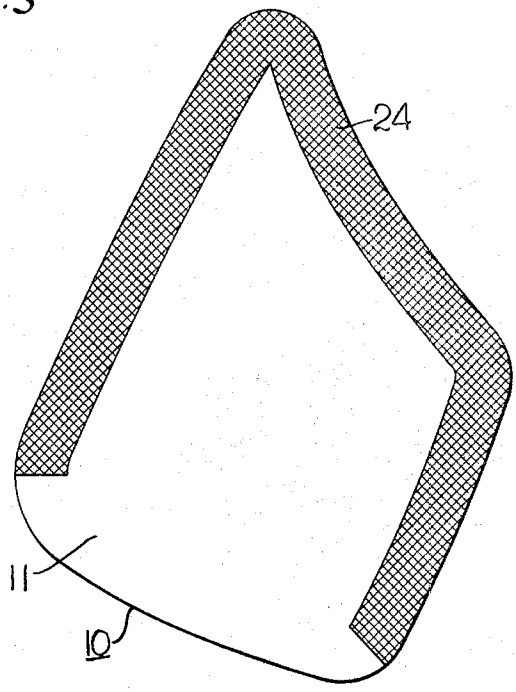


Fig. 2

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IMPLANTABLE BREAST PROSTHESIS FILLED WITH GELS OF DIFFERENT DENSITIES

This application is a continuation of application Ser. No. 782,345 filed Dec. 9, 1968, now abandoned.

This invention relates generally to a breast prosthesis suitable for implanting within the human breast. More specifically this invention relates to improved means for holding breast prosthesis in place and retaining its configuration over longer periods of time.

In recent years great strides have been made in the field of breast prosthesis. U.S. Pat. No. 3,293,663 issued to T. D. Cronin, Dec. 27, 1966 teaches a gel filled silicone rubber breast prosthesis that utilizes a polyester fabric to connect the prosthesis to the chest wall. The polyester fabric is positioned against the chest and retained there so that the body tissue actually grows through and fabric to anchor the prosthesis to the body. In practice there has been a tendency for this type of prosthesis to lose its configuration after a few months use. Also, the edges of the prosthesis tend to pull away from the chest wall and form a ridge or bulge around the upper portion of the breast.

This invention overcomes the problems mentioned above by providing an improved means of anchoring the prosthesis to the body. The invention also incorporates a novel means of filling the prosthesis with materials of varying viscosity to maintain the configuration of the prosthesis over a longer period of time while also retaining the desired consistency of the breast.

Therefore it is the object of this invention to provide a new and improved breast prosthesis that more nearly resembles that of a natural human breast.

Another object of this invention is to provide a new and improved breast prosthesis that will retain its natural shape over longer periods of time.

Another object of this invention is to provide a breast prosthesis that more firmly adheres to the chest wall.

Other objects and advantages will be apparent from the following description when read in connection with the accompanying drawings, in which:

FIG. 1 is a sectional view of the breast prosthesis of this invention attached to the chest wall and positioned beneath the mammary gland;

FIG. 2 is a rear view of the prosthesis of FIG. 1;

FIG. 3 is a cross section view of the prosthesis of FIG. 1 taken along the line III—III.

The prosthesis of this invention is made up of an envelope or container **10** having a back section **11** which is generally flat and adapted to fit against the chest wall and a front section **12** that generally resembles the shape of a human breast. The prosthesis can be positioned beneath the mammary gland as shown in FIG. **1** as well as being used as a substitute for breasts that have been removed. This changes the configuration of the breasts but allows the wearer to nurse in a normal way and does not interfere in any way with the normal functioning of the mammary gland. The container **10** is made of a material that has characteristics that resemble that of the normal human breast such as softness and resiliency. The material also must be of a type that does not cause tissue reaction with the wearer. A suitable material for the prosthesis container is silicone rubber made in accordance with the teachings of U.S. Pat. No. 3,189,662.

The container is filled with a suitable material to give the prosthesis the proper shape and resiliency. Silicone gel made in accordance with U.S. Pat. No. 3,020,260 is a good example of the type of material suitable for use in the prosthesis of this invention. In the preferred embodiment the container is filled with silicone rubber gels of varying density with the stiffest most viscous gel filling the outer portion of the container and the less viscous gels forming the next layers and center portion being filled with the softest material.

A preferred gel for use in this invention is a liquid methyl silicone resin capable of being vulcanized to an elastomer blended with a dimethyl silicone fluid. A suitable fluid is General Electric's "Viscasil" and an appropriate resin recommended for this use is General Electric's elastomeric resin TRV615. The proportion of resin to fluid may vary from 1:1 to 1:10 in order to obtain the proper gel consistency. The resin contains RzSiOz groups, RzSiO groups and Si0z groups where R represents methyl groups. The ratio of the groups one to the other determines the consistency of the gel. Cross linking of the resin may be done by means of an addition type reaction or by exposure to radiation. After mixing the resin and fluid the combination may be injected into the prosthetic container **10** and heated to initiate cross- linking (vulcanization) of the resin. Heating time and temperature may be varied over a wide range from several days at room temperature to 10 minutes at over 300° F. The gel consistency may be adjusted by any or all of the following steps:

1 by altering the proportion of the various chemical groups in the resin;
2. by altering the resin/fluid ratio;
3. by varying the viscosity of the fluid used;
4. by varying the radiation dosage.

It is desirable to fill the container before placing the prosthesis in the body. However this is not always convenient. In the illustrated prosthesis, the outer two layers **15, 16** are formed in the container prior to placing the prosthesis in the human body. There are many suitable techniques for filling the container well known in the synthetic material art. For example, the outer section of the container **10** is lined with an outer or more viscous layer **15** of gel which is allowed to set before the inner or second less viscous layer **16** is placed in the container. As the gels "cure" they are vulcanized to the inside of the container and adjacent layers of gel to form an integral unit. Any desired number of layers of gel may be used to form the prosthesis. The final portion of the container may be filled with a quantity of gel **18** after the prosthesis has been planted in the body. This may be done in any number of suitable ways such as through the use of a hypodermic needle inserted through the layers of gel into the center section of the container. The gel is then forced into the container in a sufficient quantity to give the breast the desired size and configuration. After the container has been filled the ends of the stem are folded over and sealed by suitable means. The stem is then positioned underneath the prosthesis and the flesh sewed over the prosthesis.

To provide a smooth contour of the skin over the prosthesis, the edge of the container where the front and back portions are joined is provided with a narrow rim **22** around its entire periphery. This rim is solid rubber but is tapered to a very fine edge at the outer periphery so as to blend in with the body. When skin is drawn over the prosthesis it forms a smooth continuous

surface and the juncture of the prosthesis and the body cannot be noticed except upon close scrutiny.

A suitable porous material **24** is connected to the back **11** of the container **10** and attached to the body to anchor the prosthesis in place. The material is porous to allow human tissue to grow in and around the material to securely anchor the prosthesis to the chest wall. A suitable material for this purpose is a fabric of polyester fibers commonly sold under the trademark Dacron. The fabric is preferably corrugated and is affixed to the back section of the prosthesis by suitable glue that will not be absorbed or destroyed by the body cells.

As shown in the drawings, the fabric material **24** extends across the top and more than half way around the periphery leaving only the bottom edge unattached to the chest wall. In this way the fabric provides a more uniform support for the prosthesis so that it does not tend to become disfigured or pull away from the chest wall due to constant weight of the gel in the unsupported prosthesis. The porous material or fabric extends to the outer edge **25** of the rim **22** of the container **10** so as to anchor the tip of the container rim to the chest wall without forming a fold or ridge at the junction between the prosthesis and the body.

I claim:

1. A surgically implantable breast prosthesis comprising,

a flexible container formed from a surgically implantable material and having an outer shape approximating that of the human breast,

a solid rim tapered outwardly to a fine edge provided around the outer periphery of said container,

a silicone gel filling the inside of the container,

said gel being more viscous around the outer periphery than in the center of said container,

and a tissue permeable strip attached to the back of the container to provide for tissue ingrowth.

2. The prosthesis according to claim **1** wherein said container is formed from an organopolysiloxane polycarbonate.

3. The prosthesis according to claim **1** wherein said strip is formed from a polyester fabric.

4. The prosthesis according to claim **1** wherein said silicone gel includes a liner of viscous gel around the outer section of said container and a less viscous gel provided inwardly of said liner of viscous gel.

5. The prosthesis according to claim **4** wherein said liner of said viscous gel is vulcanized to said container and to said less viscous gel.

6. A surgically implantable breast prosthesis comprising,

a container formed from an organopolysiloxane polycarbonate and having an outer shape approximating that of the human breast,

a solid rim tapered outwardly to a fine edge provided around the outer periphery of said container,

a silicone gel filling the inside of the container,

said gel being more viscous around the outer periphery than in the center of said container,

and a fabric strip attached to the back of said rim to provide for tissue ingrowth.

7. The breast prosthesis according to claim **6** wherein said silicone gel includes a liner of viscous gel around the outer section of said container and a less viscous gel provided inwardly of said liner of viscous gel.

8. The breast prosthesis according to claim **7** wherein said liner of said viscous gel is vulcanized to said container and to said less viscous gel.

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