

[54] **IMPLANTABLE PROSTHESIS HAVING A
REMOVABLE FIXATION MEANS**

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128/334 C, 92 C, 92 CA, Dig. 21;
32/10 A

[51] Int. Cl. A61f 1/24; A41c 3/10

[58] **Field of Search**3/1, 36; 128/92, 334; 32/10

[56]

References Cited

UNITED STATES PATENTS

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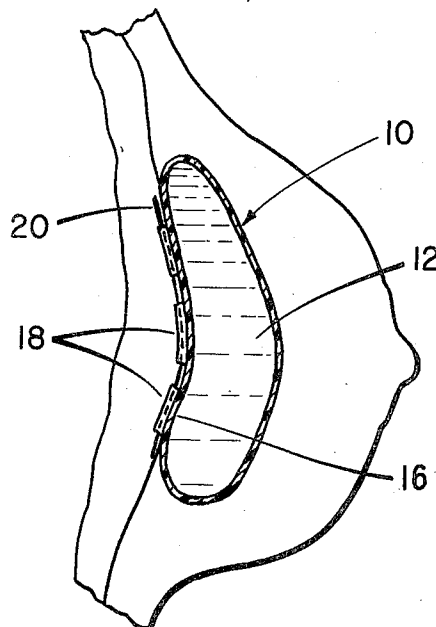
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[57]

ABSTRACT

This is an implanted prosthesis having easily removable fixation means. The prosthesis includes a container, an attachment means and the fixation means, the attachment means is engageable with the fixation means by one or more loops.

4 Claims, 5 Drawing Figures



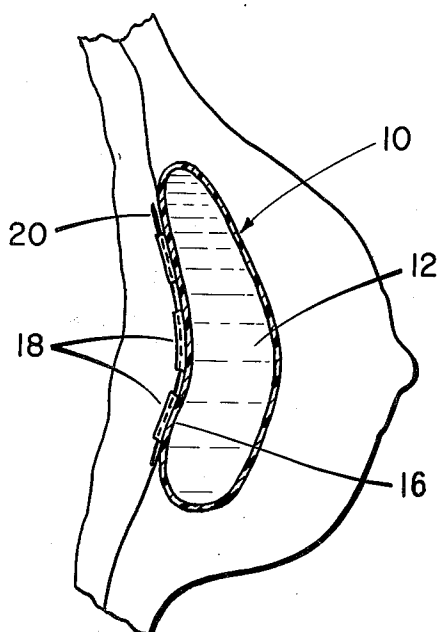


Fig. 1

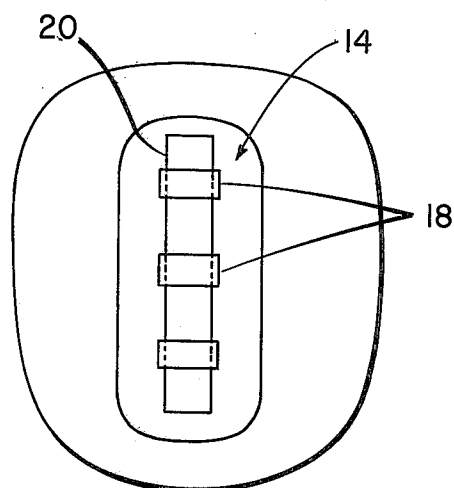


Fig. 2

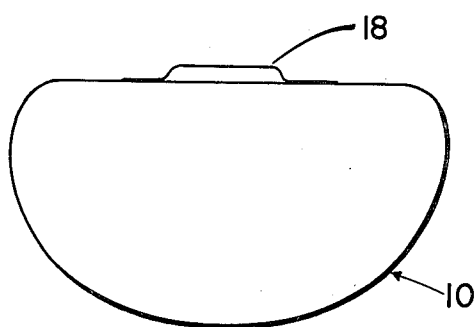


Fig. 3

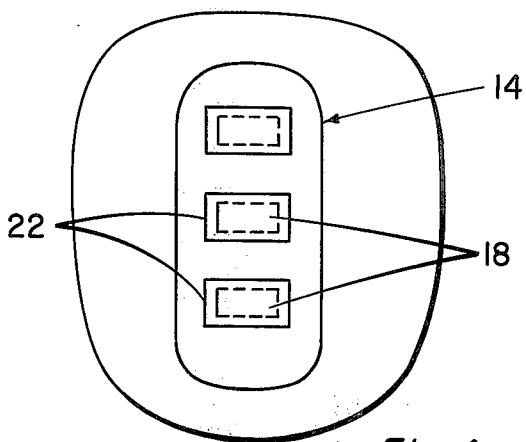


Fig. 4

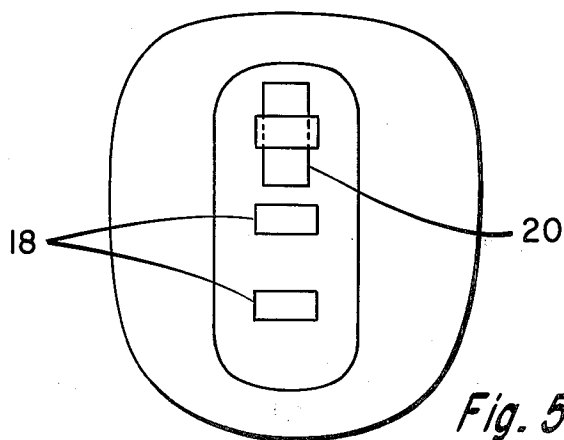


Fig. 5

IMPLANTABLE PROSTHESIS HAVING A REMOVABLE FIXATION MEANS

BACKGROUND OF THE INVENTION

There are several specific methods for restoring or improving normal body contour to the female breast either for cosmetic or support reasons. Two of these methods of achieving the required result are the use of an external removable prosthesis attached to the body by a harness arrangement or an implanted prosthesis.

Originally implanted prostheses were made from foam type materials, which tended to absorb body fluids and were susceptible to invasion by blood vessels and fibrous tissue that advantageously fixed the prosthesis in position but unfortunately caused the prosthesis to lose resiliency and to change in size. In the case of a breast prosthesis resilience is very important to most wearers.

The Pangman U.S. Patent 2,842,775 issued July 15, 1958 utilizes a breast implant having an external wall of foam material, a wall of impermeable material and an inner core of foam material, surrounded by the wall of impermeable material. The theory being that although the external wall will be invaded by blood vessels the wall of impermeable material will prevent the invasion from continuing into the inner core.

The patent to T. D. Cronin, U.S. Patent 3,293,663 issued December 27, 1966 discloses a breast prosthesis having a layer of porous material adhered by daubs of cement to the container. The porous material positions the container allowing tissue ingrowth and anchoring the prosthesis to the chest wall. The porous material may be cut in patches and adhered to different positions on the container. Loops of material are used in some cases as fixation means.

There are presently two schools of thought concerning tissue fixation of implantable prosthesis; either you use an implant fixation means or none at all. Surgeons that favor the latter approach maintain that omitting the fixation means provides a more resilient result without any considerable incidence of the implant moving away from the chest wall. All of the prostheses known to the applicant either have fixation means attached to the envelope or container of the prosthesis in such a manner that it would be very difficult to remove or do not have fixation means. This state of affairs requires manufacturers, distributors, and hospitals to maintain inventory of both types of prostheses.

SUMMARY OF THE INVENTION

This invention is directed to an augmentation prosthesis comprising (1) a flexible container approximating the shape of the cavity to be filled, (2) an attachment pad adhered or otherwise attached to the rear wall of the container having attachment means associated with the pad and (3) a fixation means which may be removably engaged to the attachment pad. The attachment pad can also be engaged to any nonfixation implantable material where the choice of adding fixation is desirable.

An object of the present invention is to provide an implantable prosthesis which may be quickly con-

verted from one with tissue fixation means to one without tissue fixation means.

Another object of the present invention is to provide an implantable prosthesis having an attachment pad engaged therewith the attachment pad having loops for engaging a fixation means.

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects and attendant advantages of the present invention will become obvious to those skilled in the art from a reading of the following detailed description when read in conjunction with the accompanying drawings wherein:

FIG. 1 is a sectional view showing a type of prosthesis in place in a human breast.

FIG. 2 is a top plan view of the prosthesis shown in FIG. 1 including the fixation strip showing the attachment strip dotted in to show engagement with the attachment pad.

FIG. 3 is a side elevation of the prosthesis shown in FIG. 2.

FIG. 4 is a top plan view of the prosthesis shown in FIG. 2 showing the loops covered with tape.

FIG. 5 is a top plan view of the prosthesis shown in FIG. 2 with the fixation strip only engaged to one loop.

DESCRIPTION OF PREFERRED EMBODIMENTS

In the drawings there is shown a mammary prosthesis comprising an envelope or container 10 filled with a gel 12. The envelope 10 is formed of a flexible silicone rubber membrane and the gel 12 is a semi-fluid silicone of liquid methyl silicone resin capable of having a consistency which will provide resiliency and maintains the proper contour of the container 10. The container 10 could be of the type which can be inflated at the time of implantation such as disclosed in U.S. Patent 3,683,424. The container 10 can be formed in several ways such as by a dip process on a mandrel, by vacuum forming or by assembly of a cup portion to a back wall utilizing vulcanization or adhesion to join the two parts.

The container may be formed of a physiological inert elastomeric material which includes several plastics although the inventor prefers to use one of the family of silicone rubbers. Under certain circumstances organic rubbers made from butyl polymer or the natural polymer from the hevea tree could be utilized. The silicone rubbers which may be used in this invention can be either of the heat vulcanizing or room temperature vulcanizing type. Since these rubbers are intended for medical purposes, fillers, vulcanizing agents and other constituents should be chosen for their non-toxic, physiological inert characteristics.

A patch or attachment means 14 made of a flexible, physiological inert material such as the material used to form the container is adhered or otherwise attached to the rear wall 16 of the container 10. If desired, material from which the patch 14 is made may be reinforced. The patch 14 may have a rectangular, oval or other convenient shape and is fairly thin. The patch 14 includes a series of spaced loops 18 in

transverse relation to the longitudinal axis of the patch 14. Each loop is formed by a pair of spaced, parallel slits, and is contiguous to the plane of the patch 14. The loop 18 can be bowed away from the plane and the remaining portion of the patch 14 allowing a fixation strip 20 to be inserted thereunder. The fixation strip 20 may be made of Dacron mesh or of any toxicologically acceptable, open lattice work such as sponge or Dacron felt.

Using the inventor's prosthesis the surgeon may implant it with the fixation strip 20 if he desires ingrowth or remove the fixation strip and place the loops 18 in their contiguous position if he does not desire ingrowth. If desired, tape 22 formed of physiologically inert material may be placed over the loops 18 in their contiguous position to assure that accidental fixation with the loops does not take place.

As shown in FIG. 1 of the drawings if fixation is desired by the surgeon the loops 18 are engaged to the fixation strip 20 and over a period of time tissue from the chest wall, in the case of a mammary prosthesis, will grow into the interstices of the open lattice work, preventing inadvertent or undesired migration of the prosthesis. If the doctor should not desire a total fixation or should desire to suspend the prosthesis he can cut the anchoring means so that only the upper loop engages it and the lower two loops are pushed against the body of the container. On the other hand, he may desire to do this with the bottom loop or the bottom two loops only.

Another possibility is that after removal of the anchoring means a dab of implantable medical adhesive can be placed under the loop and the loop pushed against the container, thereby preventing fixation.

When fixation is desired, the doctor may secure the implant to adjacent tissue using absorbable sutures, thereby holding the implant in a desired position and location until ingrowth takes place.

Obviously the container may be shaped to support other animal body contouring such as the buttocks,

hips, testicles, or in cases of pectus excavatum, the chest.

That which is claimed is:

1. An implantable, prosthetic device for use in an animal body including a container having an external surface, attachment means associated with the external surface and the attachment means having tissue permeable anchoring means connected thereto, the attachment means including at least one loop engageable with the anchoring means and the anchoring means easily separable from the attachment means and having a width less than the width of the external surface.

2. A prosthetic device as set forth in claim 1 wherein the anchoring means is formed of a thin sheet of material and is rectangular in configuration.

3. An implantable prosthetic device for use in an animal body including a container having an external surface, attachment means associated with the external surface and the attachment means having tissue permeable anchoring means connected thereto, the attachment means including at least one loop engageable with the anchoring means, the anchoring means formed of a thin sheet of physiological inert material, and rectangular in configuration, the anchoring means easily separable from the attachment means.

4. An implantable prosthetic device for use in an animal body including a container having an external surface, attachment means associated with the external surface and the attachment means having tissue permeable anchoring means connected thereto, the attachment means including at least one loop engageable with the anchoring means, the anchoring means formed of a thin sheet of physiological inert material, and easily separable from the attachment means, and the attachment means adhered to the external surface of the container.

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