

- [54] **PROSTHESIS WITH FIXATION MEANS**
 [75] Inventors: **Donald K. McGhan**, Santa Barbara;
John E. Williams, Los Angeles, both
 of Calif.
 [73] Assignee: **Heyer-Schulte Corporation**, Santa
 Barbara, Calif.; by said McGhan
 [22] Filed: **Oct. 24, 1972**
 [21] Appl. No.: **300,170**

- [52] U.S. Cl. 3/36, 3/1, 128/334 R
 [51] Int. Cl. A61f 1/24, A41c 3/10
 [58] Field of Search 3/1, 36, 13; 128/334 R,
 128/334 C, 348, 351, 1 R, DiG. 21; 32/10 A

[56] **References Cited**
UNITED STATES PATENTS

3,293,663	12/1966	Cronin	3/36
3,462,765	8/1969	Swanson	3/1
3,514,791	6/1970	Sparks	3/1
3,596,292	8/1971	Erb dt [l.	3/1
3,663,965	5/1972	Lee, Jr. et al.	3/1

OTHER PUBLICATIONS

"Prosthesis for the Temporary Closure of a Tracheostomy Stoma" by K. D. Rudd et al., The Journal of Prosthetic Dentistry, Vol. 16, No. 6, Nov. -Dec. 1966,

pp. 1,159-1,161.

The Blade Vent, Advertisement by Implant Research Corp., Pennsauken, N.J., Copyright 1968.

Lin Kow Blade Vents, Advertisement by Park Dental Research Corp., 19 West 34th St., New York, N.Y.

Primary Examiner—Richard A. Gaudet

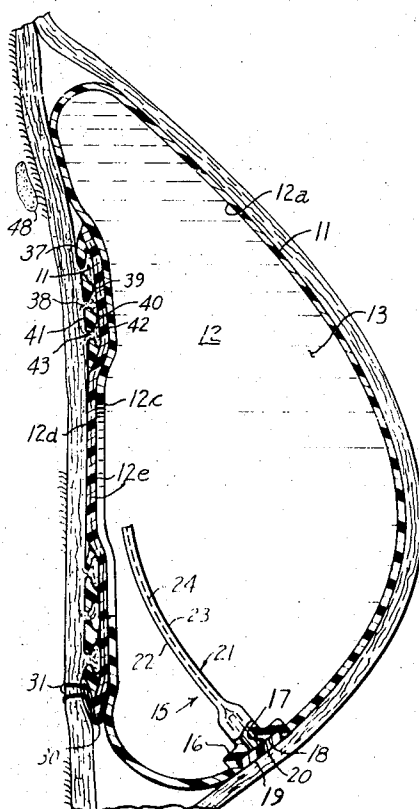
Assistant Examiner—Ronald L. Frinks

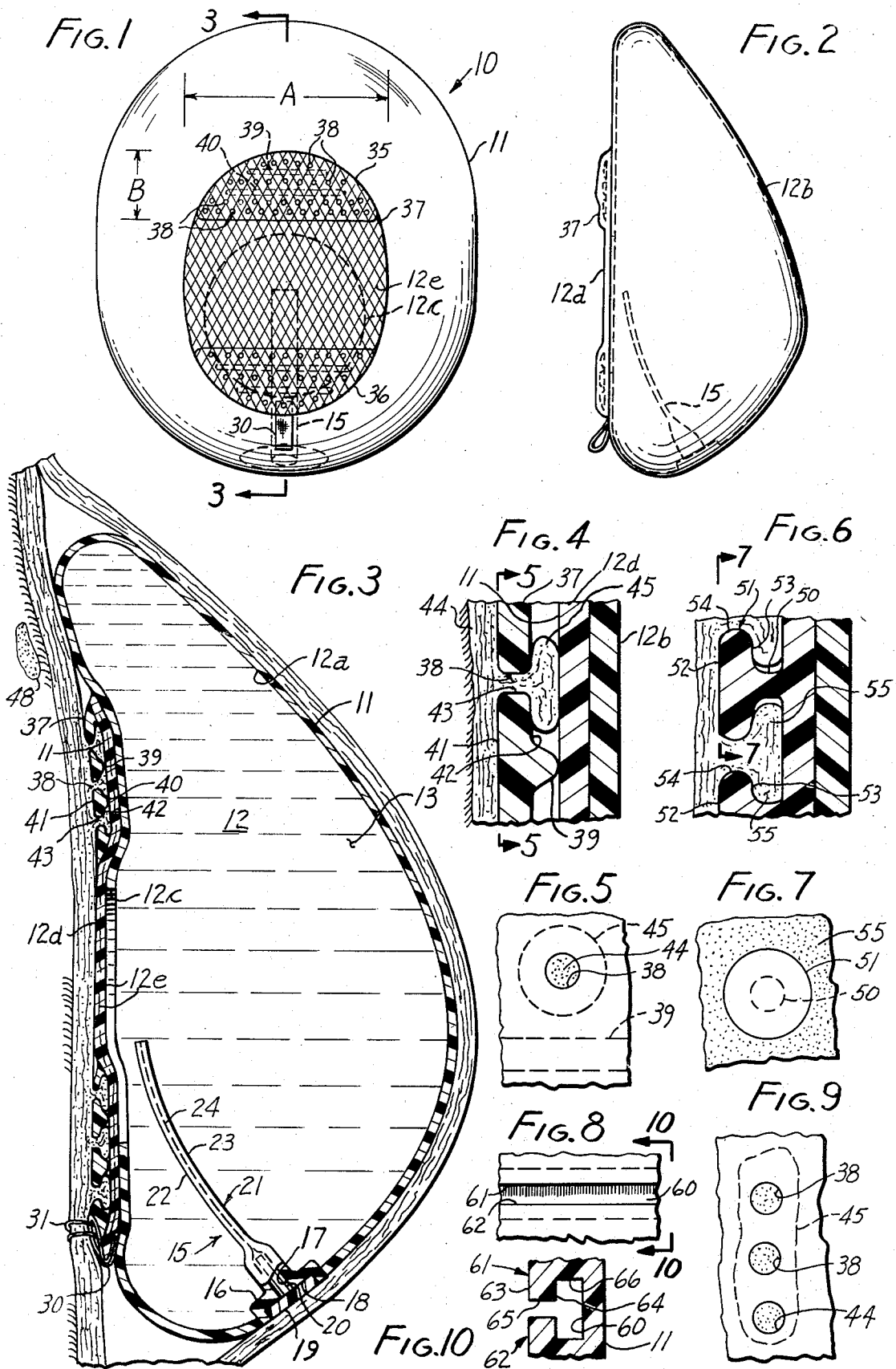
Attorney, Agent, or Firm—Donald D. Mon

[57] **ABSTRACT**

A prosthesis for implantation in the human body to fill a cavity left by the removal of a portion of the anatomy or to change an existing body contour. The prosthesis has fixation means around which tissue will grow so as to hold the prosthesis in place. An optional flexible, inelastic loop provides temporary fixation until the tissue has grown around the fixation means. The fixation means can be made of a silicon elastomer, which is compatible with tissue. The fixation means may, for example, take the form of a perforated sheet-like body spaced from the exterior wall of the prosthesis, or of a button-like body held by a stem to the exterior wall, or of a pair of overhanging flanges which form a key slot relative to the exterior wall.

8 Claims, 10 Drawing Figures





PROSTHESIS WITH FIXATION MEANS

This invention relates to a prostheses which are used to fill a cavity left by the removal of a portion of the anatomy or to reshape an existing contour, such as by enlargement of a female breast, and to fixation means for holding the prosthesis in place after implantation.

Prostheses for the stated purposes are widely known. Known examples are shown in United States patents to Pangman U.S. Pat. Nos. 2,842,775 and 3,189,921. These prostheses have an impervious envelope which is sometimes filled with a fluid, and which sometimes have fixation means surrounding them. A well known example of the latter is shown in the aforesaid Pangman U.S. Pat. No. 3,189,921 where the fixation means comprises an outer layer of open cell foam which encapsulates the envelope, and into which tissue can grow after implantation to hold the envelope in place. The use of polyurethane foam for this purpose is known. Other implantation techniques involve the use of polyurethane cloth in the form of a velour or other looped material, into which loops the tissue can grow.

The aforesaid known fixation means do function for their intended purpose, and they are widely used. They do have the inherent problem that the tissue ingrowth may in time become relatively hard and therefore palpable from the outside of the body, which is undesirable, especially in prostheses such as are used for mammary gland replacements. Furthermore, there is some question whether polyurethane in any form is as suitable for use in the human body as is a silicone elastomer. However, prior to this invention there has been no known structure which could utilize silicone elastomer as a fixation means. This invention enables a silicone elastomer to be used for fixation means, and to provide, with the involvement of only a relatively small area, sufficient fixation forces to hold in place a relatively heavy implant. By this means, the major portion of the prosthesis is free and uninvolved with tissue ingrowth, and therefore will not be palpable.

A prosthesis according to this invention has an exterior wall, and fixation means attached to the exterior wall. The fixation means is in the form of a body which has a first surface that faces away from the exterior wall, a second surface which faces toward the exterior wall, and a third surface which joins the first and second surfaces. Spacer means spaces the surfaces from the exterior wall, whereby the said surfaces are contactable by tissue which will embrace the body, at least in part and hold the prosthesis in place.

According to a preferred but optional feature of the invention, the body comprises a sheet-like body, the first and second surfaces being the opposite sides thereof, there being a perforation passing through the sheet and having a sidewall, the sidewall forming the third surface. In the preferred form of this embodiment, a plurality of spaced-apart perforations are formed in rows, and the spacer means comprises a rib on the body.

According to another preferred but optional feature of the invention, the three surfaces may bound a button-shaped body, the body being attached to the exterior wall by a stem whose lateral dimensions are smaller than the respective lateral dimensions of the third surface.

According to still another preferred but optional feature of the invention, the fixation means is made of silicone elastomer.

The above and other features of this invention will be fully understood from the following detailed description and the accompanying drawings in which:

FIG. 1 is a back view of a mammary prosthesis showing the presently preferred embodiment of fixation means;

FIG. 2 is a side view of FIG. 1;

FIG. 3 is a cross-section taken at line 3—3 of FIG. 1;

FIG. 4 is an enlarged fragmentary cross-section of part of FIG. 3;

FIG. 5 is a cross-section taken at line 5—5 of FIG. 4;

FIG. 6 is a fragmentary cross-section of another embodiment of the invention;

FIG. 7 is a cross-section taken at line 7—7 of FIG. 6;

FIG. 8 is a fragmentary cross-section of still another embodiment of the invention;

FIG. 9 is an enlarged fragmentary view of a portion of FIG. 3; and

FIG. 10 is a section taken at line 10—10 of FIG. 8.

In FIG. 1 there is shown a flexible and pliable prosthesis 10 which has an exterior wall 11 which is flexible and impermeable. The wall is comprised on a fluid-impermeable envelope 12a formed of a crown section 12b which has an aperture 12c and a closure 12d cemented across the aperture to close it. The envelope defines a cavity 12 which is filled with a fluid material which may be saline solution or a silicone gel, this fluid being shown schematically by numeral 13.

The fluid is injected into the prosthesis in the amount needed to give it the desired firmness, through a filler valve 15. Filler valve 15 comprises a plug 16 with a passage 17 therethrough. The plug has a recess 18 into which a stopper 19 can be fitted to close passage 17. The plug is sealed to the envelope and has a neck 20 extending into the cavity upon which is stretched a valve element 21.

Valve element 21 comprises a first and a second blade element 22, 23 which are joined at their edges so as to form a flat boundary 24 between them. This forms a miter valve of the type known as "bronx cheer" which can be opened by fluid pressure exerted in passage 17, and which will close to prevent reverse flow by the pressure of the fluid's forcing the two blade elements together.

The crown section is conveniently formed by applying silicone elastomer in liquid form to a mold of the desired contour, curing the coating and then stripping it from the mold. This will leave the aperture open, and it is later closed by the closure 12d. The closure has an embedded reinforcement web 12e of some kind of reinforcing cloth, such as Dacron mesh. The crown section and the closure are made of silicone elastomer, and the closure may be cemented to the crown section by means of a silicone elastomer cement.

In the preferred embodiment of the invention, the outer wall is smooth, and without protuberances or discontinuities, except at the filler valve at the joint of the crown section and the closure.

A loop 30, which is flexible and inelastic, and which may be formed of any desired material such as fabric-

reinforced silicone elastomer, is also cemented to the prosthesis (for example, to its exterior wall) to form a temporary fixation means, such as by means of a suture 31 (FIG. 3), to hold the prosthesis during the time before the tissue ingrowth has occurred. The loop is "connected to the prosthesis" in the illustrated embodiment by being cemented to and between the fixation means and the exterior wall. The loop is therefore directly connected (attached) to both. It is evident that the terminology "connected to the prosthesis" encompasses the attachment of the loop to something such as the fixation means which is in turn attached to the prosthesis, and is not limited to the direct attachment of the loop to the exterior wall.

Fixation means 35 is attached to the exterior wall such as by being cemented to the closure. The presently preferred embodiment is shown in FIG. 1. In this case, two fixation means 35 and 36 in the form of patches are used, and which are identical. Only means 35 will be described in detail. It comprises a flexible sheet 37 (sometimes called a "sheet-like body") preferably made of silicone elastomer, which has several rows of perforations 38 passing therethrough, and a pair of ribs 39, 40 projecting from the sheet which act as "spacer means" to hold the surfaces where the perforations are located away from the exterior wall. The thickness of the sheet may be approximately 0.020 inch, the holes approximately 0.040 inch in diameter (there being approximately 25 to 30 of them), and the ribs extend about 0.040 inch from the sheet. The sheet is attached at its edges to the exterior wall of the prosthesis.

The sheet has a first surface 41 which faces away from the exterior wall, a second surface 42 which faces toward that wall, and a third surface 43 which joins the first and second surfaces. In the embodiment shown, the third surfaces 43 are the sidewalls of perforations 38. With such an arrangement, tissue 44 (see FIG. 4) can grow through the perforations and contact the first, second and third surfaces, forming a sort of bulb 45 on the rear side and embracing the body (sheet), at least in part. As can best be seen in FIG. 9, it is possible for these bulbs to grow into one another so as to form a reinforcing plate 45 of tissue which is substantially unitary adjacent to the second surface of the sheet and encapsulating a substantial part of it. This, in many ways, resembles results secured in wall plastering construction.

When the prosthesis is first implanted, there will, of course, be no initial tissue encapsulation. In order to provide initial support for the prosthesis until tissue encapsulation occurs, loop 30 is sutured to adjoining structure such as the rib cage, and will carry some of the weight of the prosthesis. Within a few weeks, tissue adjacent to rib cage 48 will grow through the perforations and behind the sheet to form the structure as best shown in FIGS. 4, 5 and 9. After this structure is formed, then the loop is no longer required, because the encapsulation of tissue will support the prosthesis. The loop is left in place, and does no harm, even though it is no longer relied on.

It will also be noted that, in this and all the other embodiments, the major portion of the area of the prosthesis is not covered with fixation means. Instead, the fixation means is entirely located on the backside, where it is not palpable. No palpability is caused by the fixation means because it is a solid silicone elastomer,

and tissue does not ingrow into this material —only around it. This will be true wherever the device is implanted, the mammary prosthesis simply being one example of the utility of this invention.

FIG. 6 shows another embodiment of fixation means wherein the exterior wall has attached to it a stem 50 which acts as "spacer means" and connects to a button-shaped body 51 that is defined by first second and third surfaces 52, 53 and 54, the first surface facing away from the exterior wall, the second surface facing toward it, and the third surface interconnecting them. The tissue 55 grows around the button and attaches itself thereto in substantially the same way as shown in FIG. 4.

FIG. 8 shows another embodiment of fixation means attachable to the exterior wall. A key slot 60 is formed by means of a pair of overhanging flanges 61, 62, these flanges having first, second and third surfaces, 63, 64 and 65. The third surfaces interconnect the first and second surfaces. The flanges are held in place by spacer means 66. In this case, the tissue can grow into the key slot to fix the prosthesis in place. The overhanging flanges are sometimes called a "body".

The constructions shown enable elastomer to be used for fixation means, thereby securing all of its advantages of compatibility with human tissue. They give a strong enough attachment that they can be used in relatively small patches, for example, patches with a longer dimension A between 4.8 and 6.0 centimeters and a shorter dimension B between about 1.6 and 2.5 centimeters, with about 25 to 30 holes each (FIG. 1). Two of these patches will permit tissue ingrowth which will support a prosthesis of practical size for implantation into the human breast. The prosthesis can, therefore, be supported from an internal surface of the body and need not include structures which can be palpated from the outside of the body.

The bodies comprising the fixation means are inherently flexible. Their surfaces are impervious to ingrowth of tissue, and differ in this regard from known prosthesis fixation means of foam or cloth wherein the surfaces of the fixation means are purposely pervious to tissue ingrowth, with the objective of having a full-area ingrowth for attachment, in contrast to the embracing or interlocking type of attachment provided by this invention.

While the invention is shown in use with a mammary prosthesis filled with gel, it is to be understood that prostheses for other uses, and with other fillings, may also be used.

This invention is not to be limited by the embodiments shown in the drawings and described in the description, which are given by way of example and not of limitation, but only in accordance with the scope of the appended claims. We claim:

1. in combination: a flexible and pliable prosthesis having an exterior wall, and fixation means comprising a flexible sheet-like body attached to the exterior wall at the edge of the body, the area of the body and the area of that portion of the exterior wall it covers being substantially equal, the body having a first surface facing away from the exterior wall, a second surface facing toward the exterior wall, the first and second surfaces being generally parallel and comprising the opposite sides of the body, and a plurality of third surfaces joining the first and second surfaces, there being a plurality of perforations passing through the body and extending

5

between and interconnecting the first and second surfaces, each perforation having a sidewall, each sidewall forming a respective third surface, and spacer means spacing the second surface from the exterior wall, whereby the said three surfaces are contactible by tissue which will thereby embrace portions of the body and hold the prosthesis in place, said surfaces being impervious to ingrowth of tissue.

2. A combination according to claim 1 in which a plurality of rows of said perforations is formed in the body, and in which a plurality of said bodies is attached to the exterior wall.

3. A combination according to claim 1 in which the fixation means is made of silicone elastomer.

4. A combination according to claim 2 in which the

6

fixation means is made of silicone elastomer.

5. A combination according to claim 1 in which a flexible, relatively inelastic loop is connected to the prosthesis for the purpose of being sutured in place for initial support of the prosthesis.

6. A combination according to claim 5 in which a plurality of rows of said perforations is formed in the body, and in which a plurality of said bodies is attached to the exterior wall.

7. A combination according to claim 5 in which the fixation means is made of silicone elastomer.

8. A combination according to claim 6 in which the fixation means is made of silicone elastomer.

* * * * *

20

25

30

35

40

45

50

55

60

65

UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 3,852,832
DATED : December 10, 1974
INVENTOR(S) : DONALD K. McGHAN

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

[57] Abstract, line 8	"silicon" should read --silicone--
Col. 1, line 52,	after "part" insert a comma
Col. 2, line 29,	"on" should read --of--
Col. 2, line 33,	"caavity" should read --cavity--
Col. 2, line 56,	"a" should read --an--
Col. 3, line 21,	before "pref-" insert a comma
Col. 4, line 9	after "first" insert a comma
Col. 4, line 24,	after "enable" insert --silicone--
Col. 4, line 48,	before "gel" insert --a--

Signed and Sealed this

eleventh Day of November 1975

[SEAL]

Attest:

RUTH C. MASON
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents and Trademarks