Feb. 6, 1968 W. J. PANGMAN 3,366,975

COMPOUND PROSTHESIS

Filed June 4, 1965

Fig. 1

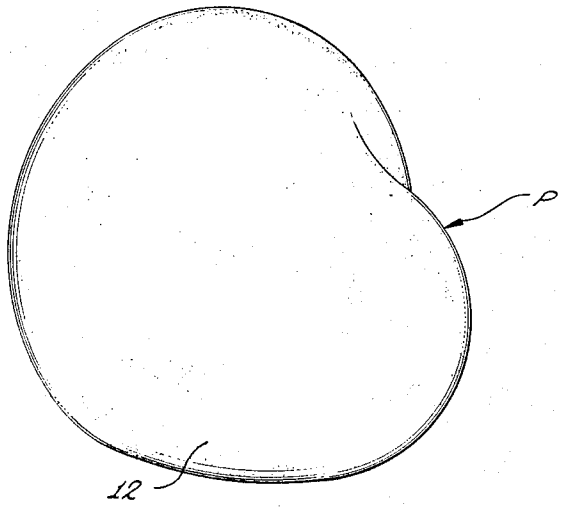



Fig. 3

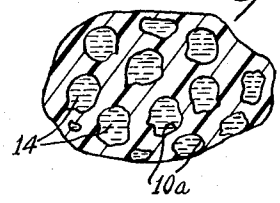



Fig. 2

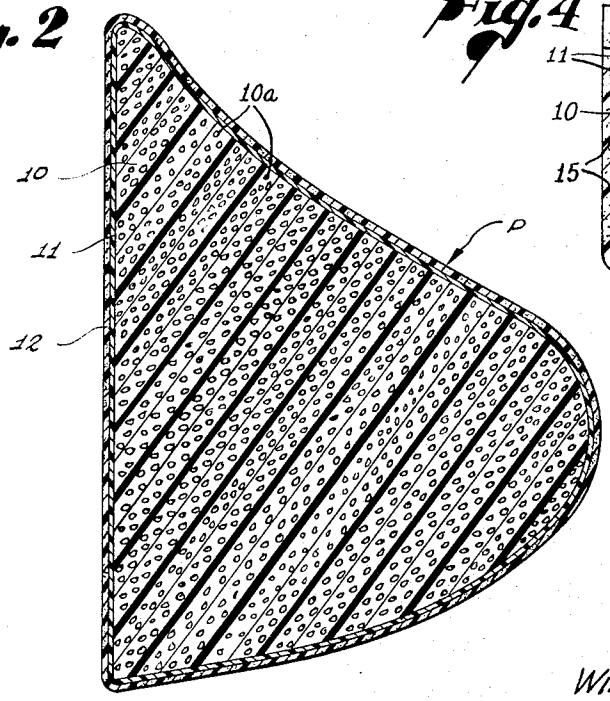
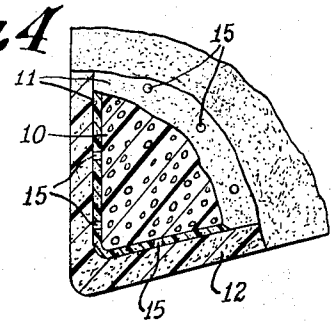



Fig. 4

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# COMPOUND PROSTHESIS

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## ABSTRACT OF THE DISCLOSURE

A compound prosthesis for implanting in the human body has a core of a plastic foam, surrounded by a membrane impervious to fluids and in turn covered by a porous layer to which human tissue can adhere. The core enables the device to retain a given shape, yet can approximate human tissue in density and rigidity to restore the body to its initial shape and appearance.

This invention relates generally to prostheses and, particularly, to an improved compound prosthesis to be implanted within the human body, particularly in the female breast, although the invention is not necessarily limited thereto.

Now it is a well-known practice in the field of plastic surgery to enlarge the female breast by prosthetic implants. In many other instances, it becomes necessary to remove the mammary glands or substantial portions of diseased body tissue in and around the glands, thus leaving voids which may be filled by prosthetic implants. Such implants provide physical support for the surrounding body tissue and organs and, in the case of voids near the skin, preserve the outward appearance of the body. When cancerous, precancerous, or damaged tissue is removed, it is often possible to insert the prosthesis to be implanted through the same surgical incision used for removing the tissue.

Particularly in the cases where a radical removal of tissue has occurred is it desirable to use an implant for the purpose of restoring the human body to its original or natural form. 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 follow extensive operations.

Among the various problems involved in prosthetic implants are those of preserving the natural softness and resiliency of the replaced body tissue and of retaining the implant in position in the body. The prosthesis employed preferably is soft and resilient in order to duplicate as nearly as possible the natural characteristics of the body tissue being replaced or built up. The use of prostheses having soft and resilient characteristics matching those of the replaced body tissues is particularly important in such cases as the female breast. In such cases, the desirability of retaining the implant firmly in place is also obvious, both from the standpoint of appearance and also the comfort of the patient.

The desired degrees of softness and resiliency in a prosthetic implant have been met by the use of inert foam-type plastic sponge materials. Materials of this type are porous so that they absorb blood and other body fluids and become invaded by blood vessels and living body tissue. The result is that the sponge implant and the surrounding body tissue eventually become so interwoven as



to be firmly united. This enables the implant to become anchored firmly to the chest wall and also to the covering skin, thus becoming substantially a part of the body in the same manner as the replaced tissues.

The inherent porosity of such sponge materials, while very beneficial for the reason just mentioned, has also been the source of considerable inconvenience and disappointment after a time when a homogeneous, one-piece sponge implant is employed. The reason for this is that the sponge eventually becomes invaded by fibroblast tissue throughout all or a major portion of the implant. This type of connective tissue, being fibrous, shrinks as it ages, with the result that it compresses the implant and causes the implant to lose both its original size and shape and its original resiliency. Cases are known where shrinkage has been as much as 20–30%.

Other types of implants of a compound or composite construction may include a body of a liquid or fluid substance. Implants of this character are often heavy and subject to an undesirable change in shape because of the ability of the fluid material to flow within the implant and accumulate at a low portion thereof. This change in shape is distressing and embarrassing to the wearer and is obviously undesirable.

Some types of compound prostheses have elements which are more or less discrete, being separable when in use. As a consequence, these prostheses are subject to the accumulation of fluid from the body in an interior void which can form between discrete elements of the prosthesis. In other cases, the possibility arises of extreme irritation of the body tissue after it has penetrated the prosthesis to a position where movement occurs between the discrete elements of the prosthesis that creates an irritation.

These conditions may become aggravated after a period of time to the point where it is necessary to surgically remove the old prosthesis and replace it with a new one. These prior constructions which make certain types of prostheses useful on only a short-term basis are obviously unsatisfactory.

Another shortcoming found to exist with some known prostheses is that they are not completely covered with a cellular layer which can become invaded by living tissue. Instead such a prosthesis has more or less of its external surface provided by an impervious material. Body fluid can, and often does, accumulate between the living tissue and such an impervious surface, causing distortion and, in severe cases, breakdown of tissue at the location of the wound.

Thus it is a general object of the present invention to provide a novel construction for a compound prosthesis so constructed that it is capable of being invaded by body tissue in order to unite it firmly to the body but not to such an extent that the connective tissue upon shrinking will materially change the size or shape of the implant.

It is also an object of the present invention to provide a novel construction for a compound prosthesis which is of unitary construction and provides no relatively movable or separable elements which provide a space in which fluid can accumulate or become a source of irritation to tissue of the patient.

A further object of the invention is to provide a compound prosthesis of the character described which has the qualities of softness and resiliency to the desired degree to resemble the tissue replaced, yet which is stable in

shape and size so that it does not change size or shape with a change in position of the patient and also retains essentially the original size and shape over a long period of time.

These advantages are achieved according to the present invention by providing a unitary compound prosthesis for implanting under the skin which comprises a resilient core of open-cell, foam-type plastic material having numerous pores extending throughout the core so that the core provides a light-weight, resilient structural skeleton; a barrier membrane surrounding and bonded to the core, said membrane being substantially impervious to body cellular tissue in order to exclude said tissue from the core; and a covering external layer which is also a resilient, foam-type plastic having numerous pores throughout the external layer whereby it is pervious to and can become invaded by body cellular tissue to a limited depth, perhaps 1 to 2 millimeters.

In one form of the invention, the cells of the core are filled with a resilient gel which is soft and yielding and thereby does not impair the resilient character of the core material but which is held in place by the structural network of the sponge material of the core. This construction has a very low permeability to body fluids or cellular tissue and has a maximum potential of retaining its original size and shape. With this type of core, the barrier membrane may be entirely impervious to cellular tissue and body fluids.

In another form of the invention, the cells of the core may be left unfilled, becoming eventually filled with fluids from the body. In this embodiment, the cells of the core are preferably smaller than in the form previously mentioned. The barrier membrane is made of a material which is itself an impervious barrier to body fluids but which is preferably provided with a plurality of small openings through which fluids may pass to accumulate in the core, such openings being so few in number and small in size that tissue is substantially excluded from the core.

How the above objects and advantages of the present invention, as well as others not specifically referred to, are attained will be better understood by reference to the following description and to the annexed drawing, in which:

FIG. 1 is a perspective view of a prosthesis shaped to replace a female breast, constructed in accordance with the present invention;

FIG. 2 is a vertical median section through the prosthesis of FIG. 1;

FIG. 3 is a greatly enlarged fragmentary view of the core with the pores infiltrated with gel; and

FIG. 4 is an enlarged fragmentary section and elevation of a variational form of the invention.

Referring now to the drawing, there is shown a surgical prosthesis P for implanting under the skin of a human being constructed according to the present invention. From FIG. 2, it will be seen that the prosthesis comprises three principal parts, core **10**, barrier membrane **11**, and the external layer or covering **12**. The shape of the prosthesis illustrated is solely for purposes of illustration and is not limitative upon the invention, since this prosthesis is one which is suitable for replacing substantially an entire breast, while others will differ in size and shape according to the specific requirements of the particular patient.

In general, a choice of materials is available to the manufacturer, subject to the requirement that the materials be ones which are compatible with each other and can be bonded together and also that the materials, particularly in the outer layer, are materials which are not rejected by the human body. Furthermore, the materials that are most satisfactory are those which are nonabsorbent and are, therefore, not subject to absorption of germs or bacteria but which, on the other hand, can be easily rendered sterile in an autoclave without damage to the prosthesis. Exemplary materials for the prosthesis will be mentioned, but are not necessarily limitative upon the invention.



Core **10** is preferably made of an open-cell polyurethane characterized by a degree of softness and resiliency closely comparable to the human tissue which it replaces. At the same time, the foam-type plastic sponge material is sufficiently strong to retain its original shape after implanting. A silicone sponge can be used but is not as strong as the polyurethane.

Open-cell polyurethane provides a porous structure in which there are numerous pores extending throughout the entire body of the core. These pores are preferably larger than the minimum size and may be characterized as large pores. In one embodiment of the invention, these pores **10***a* are filled with a gel, as shown in FIG. 3 at **14**, which is also soft and resilient so that it does not impair the overall resilient character of the composite core. The foam-type sponge material provides a structural framework or stroma which gives physical strength and shape to the core and supports the small bodies of gel which fill the pores in the core. A core of this type in which the gel fills the pores is characterized by being substantially impervious to body fluids and body tissues.

The open-cell sponge is, usually, more rigid than the gel; and as a consequence, the firmness of the final product can be controlled within the desirable range by proper selection of pore size. A structure having large pores is preferred as it gives the desired firmness while the gel filling the pores is softer or more yielding and so adds bulk without adding too much rigidity. Reduction in pore size increases the firmness of the sponge.

Completely surrounding core **10** and bonded thereto is the barrier membrane **11**. This membrane is preferably made of a material which is impervious to fluids and also impervious to body tissues. Typical of such materials are various silicone polymers of medical grade.

The silicone material may be applied to the core in any suitable manner, as by wrapping the core in a sheet of silicone material which is then bonded to the core over substantially the entire area of the membrane and core in mutual contact, by the application of heat and light pressure. It is preferred to use a silicone of paste-like consistency that can be applied to the core over its entire exterior surface. The silicone is mixed with a room temperature vulcanizing agent, eliminating the need of heating in a mold to cure the silicone. The layer is preferably kept thin, typically about 1.0 millimeter or less and preferably about 0.5 millimeter. This thickness is adequate to be impervious but not thick enough to add undesired rigidity to the final product. Apart from the undesired rigidity, the membrane can be made thicker if desired. Generally speaking, any material that provides a barrier impervious to body cellular tissue is satisfactory for the membrane, provided it is flexible and elastic to substantially the same degree as the core and is medically acceptable.

Surrounding the barrier membrane is a continuous external layer or covering **12** which is also an open-cell, foam-type sponge material. A suitable material for this purpose is a foamed polyether or a polyurethane which can be bonded to the core so that there is substantial adherence between the outer layer and the barrier member over their entire areas in mutual contact.

The covering layer is preferably one which is characterized by small pores. The porosity of the outer layer is designed to permit it to become invaded by body cellular tissue, thereby causing the implant to adhere firmly to the wall of the chest and also to the covering skin and tissues. Thus the implant eventually becomes united with the surrounding tissues over substantially its entire exterior surface.

It has been found advantageous to make the external layer **12** substantially uniform in thickness and relatively thin, it preferably being of the order of 1 or 2 millimeters in thickness, not more than about 2 millimeters being preferred. The advantage of this relatively thin external layer is that while it is thick enough to be-

come thoroughly invaded by human tissue for anchoring the implant to the surrounding body, yet the total mass of the outer layer is also sufficiently small that the shrinkage of the fibroblast as the tissue ages and hardens has little effect in shrinking or changing the shape of the implant. Thus the small volume of the implant which can become invaded by tissue keeps the shrinkage within acceptable limits.

In order to provide the necessary thin layer and keep the layer substantially uniform, the outer covering is preferably applied to the prosthesis in the form of a sheet of material which is shaped over the membrane-covered core and is bonded to the outer surface of the barrier membrane. Joints in the sheet material forming the outer layer are formed with abutting edges of the layer in contact so that they are bonded together and the outer layer is substantially continuous, although minor discontinuities in the outer layer do not interfere with satisfactory functioning of the prosthesis.

A convenient way of making the prosthesis is to apply the outer layer while the barrier membrane **11** is still plastic. The membrane as it cures then bonds to both the core and to the outer layer.

While the prosthesis constituting the present invention is not limited to any particular method of manufacture, it is preferred to cover the porous sponge material of the core with the barrier membrane before filling the pores of the sponge material with the gel. The core can then be impregnated with material in liquid form, using a hollow needle for this purpose. Air in the pores will be displaced by this liquid which forms the gel and can be withdrawn through another hollow needle. A suitable liquid material for this purpose is one of the elastomeric silicone polymers which has been compounded to produce the desired degree of elasticity in the gel produced. One such material is that prepared by Dow Corning as a solution with a 350–360 centistoke viscosity. This silicone compound is mixed just prior to injection with a curing or vulcanizing agent which operates at room temperatures and is currently designated as a room temperature vulcanizing solution. A short time after injection into the core, the pores of the core are completely filled with the gel of a suitable degree of stiffness. The composite nature of the core is such that it remains soft and elastic, but the framework of the sponge-type material holds the gel against flowing or shifting its position with a change in position of the wearer, thus avoiding any change in shape of the completed prosthesis.

As a variation, the invention may be embodied in a prosthesis which is constructed as described except that the gel is omitted and the original pores of the foam-type material are left filled with air at the time of implanting.

With this latter embodiment of the invention, illustrated in FIG. 4, the barrier membrane **11** is perforated in any suitable manner, as with a needle, to provide it with a plurality of small openings **15** which render the membrane pervious to a desired degree to body fluids. The body fluids then flow through these openings into the core, displacing the air therefrom and eventually filling the core with body fluids. Where it is apparent that this end result will be achieved or is desired, the surgeon will select this type of prosthesis with limited access of body fluids to the core.

Otherwise the form of the prosthesis just mentioned is constructed as illustrated and as previously described. The barrier membrane is preferably the same thickness as mentioned, typically about 0.5 millimeter, and the thin external layer **12** is fastened to the membrane in the same manner and has all the same characteristics already mentioned. The outer layer being pervious to body fluids, these body fluids can reach the small perforations in the membrane and pass through these perforations. While such perforations might allow body cellular tissue limited access to the core, yet they are so small and few in number that the amount of tissue which can reach and invade the core is negligible.

Both forms of the invention described provide a structure which is advantageous because all the elements of the prosthesis are firmly bonded together to form an integrated structure. This eliminates all voids within the layers of the prosthesis which could either develop into spaces in which fluid from the body can accumulate or which could become invaded by tissue. When there is the capability of relative movement between portions of the prosthesis into which body tissue has entered, the movement causes irritation of the tissue that results both in the accumulation of fluid and in discomfort to the wearer Both conditions are avoided by the present invention since either one may eventually lead to the necessity for removal of a prosthesis.

In view of the foregoing description, it will be understood that various changes in the detailed construction may occur to persons skilled in the art without departing from the spirit and scope of the present invention. For example, a larger size or sizes of the implant can be designed to fit within a chest cavity or other void within the body. Accordingly, it is to be understood that the foregoing description is considered as being illustrative of, rather than limitative upon, the invention as defined by the appended claims.

I claim:

**1.** A unitary compound surgical prosthesis for implanting under the skin of a human being, comprising:
- a resilient core of open-cell, foam-type plastic material having numerous pores extending throughout the core;
- a barrier membrane surrounding and bonded to the core, said membrane being substantially impervious to body cellular tissue to exclude said tissue from the core;
- and an external layer of a resilient, foam-type plastic having numerous pores throughout the external layer whereby the external layer is relatively pervious to body fluids and body cellular structure;
- said external layer surrounding and being bonded to the barrier membrane.

**2.** A unitary compound surgical prosthesis as in claim **1** in which the thickness of the external layer is not more than about 2 millimeters.

**3.** A unitary compound surgical prosthesis as in claim **1** in which the pores of the core are substantially filled with a resilient gel excluding body fluids from the core but not impairing the resilient character of the core material.

**4.** A unitary compound surgical prosthesis as in claim **3** in which the barrier membrane is impervious to body fluids.

**5.** A unitary compound surgical prosthesis as in claim **1** in which the core and the barrier membrane are both pervious to body fluids.

**6.** A unitary compound surgical prosthesis as in claim **5** in which the barrier membrane is made of a non-porous material and has a plurality of minute perforations which pass body fluids.

**7.** A unitary compound surgical prosthesis as in claim **1** in which the barrier membrane has a plurality of minute perforations providing a controlled permeability to body fluids.

**8.** A unitary compound surgical prosthesis as in claim **1** in which the barrier membrane is not more than about 0.5 millimeter in thickness.

**9.** A unitary compound surgical prosthesis for implanting under the skin of a human being, comprising:
- a resilient core of open-cell, foam-type plastic material having numerous pores extending throughout the core, the pores of the core containing an elastic gel excluding body fluids from the core;
- a barrier membrane not more than about 0.5 millimeter thick surrounding and bonded to the core, said mem-

brane being substantially impervious to body cellular tissue to exclude said tissue from the core;

and an external layer not more than about 2 millimeters thick of a resilient, foam-type plastic having numerous pores throughout the external layer whereby the external layer is relatively pervious to body fluids and body cellular structure,

said external layer surrounding and being bonded to the barrier membrane.



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