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W. J. PANGMAN
COMPOUND PROSTHESIS DEVICE

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Fig. 1

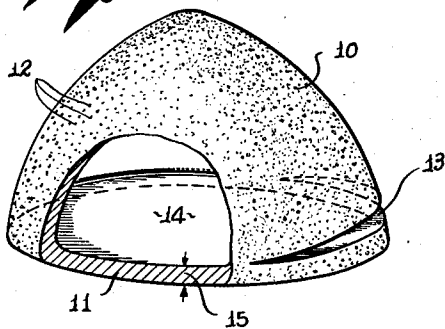


Fig. 2

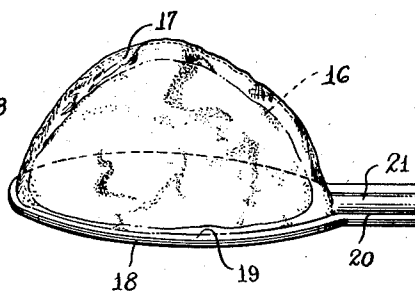


Fig. 4

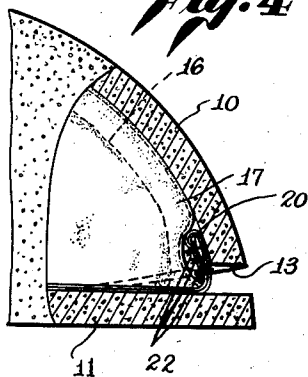


Fig. 3

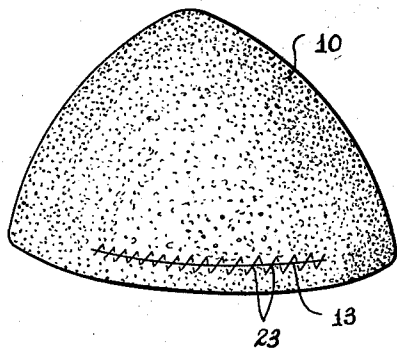
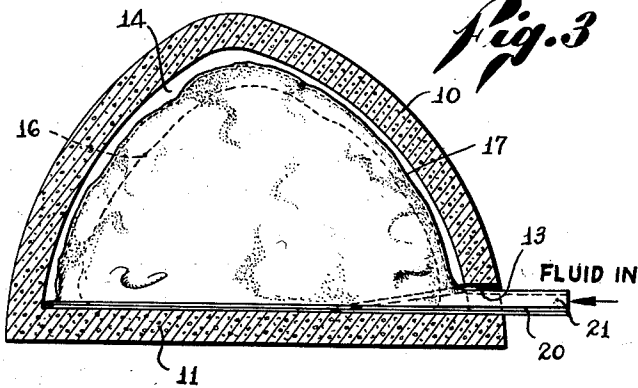


Fig. 5

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COMPOUND PROSTHESIS DEVICE

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3 Claims. (Cl. 3—36)

This invention relates generally to prosthesis and more particularly to a compound prosthesis device adapted to fill voids under a person's skin resulting from certain types of surgical operations.

In plastic surgery, large portions of damaged or infected tissue are frequently removed, after which the resulting void is filled with an artificial body or appliance. Such body provides not only adequate structural support for the surrounding organs and tissue area, but, just as important, preserves the appearance of the patient. In many instances where cancerous, precancerous or otherwise abnormal or damaged tissue is removed from internal portions of the patient, it is possible to insert the prosthesis device under the original skin, making use of the same surgical incision used for removing such tissue for inserting the artificial body. The incision is then stitched and properly treated whereby it is extremely difficult to detect any abnormality whatever. In other instances, new skin may be grafted over the prosthesis device.

Where the removed tissue is normally resilient and soft in nature, the prosthesis body substituted therefor is usually formed from an inert foam type plastic sponge material. One such material manufactured under the trade name "Ivalon" is ideally suited for this purpose, particularly in female breast operations wherein the entire mammary gland may be removed. The plastic sponge is of such a nature that it will absorb the blood and body fluids and be invaded by blood vessels and living fibrous tissue whereby the sponge becomes actually interwoven with living portions of the area involved. This action is highly desirable in that it permanently retains the prosthesis device in position, and when the skin is properly fixed over the body, it is extremely difficult to detect the presence of any type of prosthesis whatever.

On the other hand, it has been found that the very nature of the inert type sponge which yields the above-noted advantages, renders the use of such prosthesis bodies substantially worthless over long periods of time. More specifically, it is found that after a prolonged period of time the prosthesis device tends to atrophy and become extremely hard. The principal cause for this undesirable result is the fact that the blood and body fluids eventually permeate the entire prosthesis body, resulting in its losing its resiliency, shrinking, and becoming heavy and hard.

The present invention has as its primary object, the provision of a novel prosthesis device which overcomes the above-noted disadvantage of complete absorption and eventual atrophy and hardening.

More specifically, it is an object of the invention to provide a prosthesis device particularly useful in breast operations which will be partially invaded by blood vessels and fibrous tissue for adequate support, and yet will not atrophy or become hard after a prolonged time.

Other objects of the invention are to provide a prosthesis device of the above type which is light in weight, retains its initial resiliency or flexibility, and can be shaped in

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any desired pattern whereby it is virtually impossible to discern its presence.

These and additional objects and advantages of the invention are attained by providing a foam type plastic sponge of the conventional type employed in plastic surgery operations, but including a hollowed out interior portion defining a chamber. Within this chamber an insert material of substantially the same characteristics as the sponge is positioned. A fluid tight sac of flexible material surrounds this insert and thus separates the insert from the interior walls of the chamber. If desired, the flexible sac itself may be employed alone, suitable fluid being pumped into the sac to give it body.

The resulting compound prosthesis device has all of the advantages of a conventional type sponge but is not subject to ultimate hardening or atrophy. The outer layer of sponge material is of sufficient thickness to be invaded by blood vessels and fibrous tissue and thus insure that the device will be adequately secured and maintained in position. Yet such invasion by the surrounding tissue area is checked by the flexible sac and thus such absorption is limited. The insert within the sac will therefore remain soft and pliable and will not shrink or become weighted with fluid.

A better understanding of the invention will be had by referring to the following detailed description and accompanying drawings illustrating a preferred embodiment of one type of compound prosthesis device useful in breast surgery. In the drawings,

Fig. 1 is a perspective view of one component of the compound prosthesis device of the invention;

Fig. 2 is a perspective view of an insert component and surrounding fluid sac;

Fig. 3 illustrates in cross section the assembled device just prior to final insertion of filler fluid;

Fig. 4 is a view, partly in section, of a portion of the device in Fig. 3 illustrating the device after filling with fluid and sealing off of the fluid sac; and

Fig. 5 is another perspective view of the completed compound prosthesis device.

While the invention has numerous applications, for the sake of concreteness it will be described in connection with a breast prosthesis. Referring to Fig. 1, there is shown a foam type inert plastic sponge 10, for example, of polyvinyl sponge material, such as Ivalon, of generally hemispherical or cone shape having a relatively flattened bottom portion 11. In the case of breast prosthesis, the flat portion 11 is adapted to lie against the patient's chest wall.

The material of sponge 10 is characterized by numerous small sponge like openings 12 which are normally invaded by the surrounding blood vessels and fibrous tissue of the patient. Such invasion as previously pointed out is normally desirable in that it securely retains the device in proper position. Too much invasion or absorption of bodily fluids, however, results in hardening and eventual atrophy of the sponge 10.

In accordance with the present invention, the prosthesis sponge 10 is modified as follows. A circumferential slit 13 is made adjacent the base of the sponge 10 and the inside hollowed out to define a chamber 14. The size of the chamber 14 is such that the thickness dimension of the chamber walls as indicated at 15, is sufficient to absorb the surrounding fibrous tissue.

Referring to Fig. 2, there is shown an insert 16 of foam type plastic inert sponge material which may constitute a portion of the sponge 10 formerly filling the chamber 14 and removed through the slit 13. This insert 16 is enclosed within a flexible sac preferably of an animal tested polyethylene material. The sac is shaped similarly to the insert and may constitute a cone shaped upper sheet 17 and a generally circularly shaped bottom

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sheet 18 suitably sealed to the peripheral base edges of the cone sheet as at 19. As a preferred feature, there is provided at a circumferential point on the sac, extensions 20 of the sheet material sealed along their peripheral edges only to define a tubular opening 21 communicating with the interior of the sac.

Referring now to Fig. 3, the insert 16 and enclosing sac 17 are shown positioned within the chamber 14 of the sponge 10. This insertion may be easily accomplished by simply squeezing the insert 16 and surrounding sac 17 into a flattened shape and pushing the same through the circumferential slit 13 in the sponge. The tubular opening 21 permits air within the sac 17 to escape during this inserting operation. After the insert and sac are within the chamber 14, the insert sponge will spring out to its original size to expand the sac 17, air being drawn in through the opening 21.

The assembly as shown in Fig. 3, with the tube 21 still open, is then sterilized, preferably by vacuum and sterilizing gas, using known techniques. Assurance is thus provided that the interior of the sac and contents are surgically sterile, as well as the entirety of the sponge 10.

The incision made in the patient's skin in the case of a breast operation wherein a substantial portion of the gland is removed, is usually located about the base portion of the breast. To insert the prosthesis, the compound structure shown in Fig. 3 is collapsed and urged through this incision, the bottom relatively flat portion of the sponge 11 lying on the chest wall. The sponge then springs back to its normal shape pushing the patient's outer dermal layer into its original shape. At this point, fluid such as air may be pumped into the sac 14 through the inlet passage 21, as indicated in Fig. 3, to further expand the sac 14 against the interior walls of the chamber. Alternatively, in some cases it may be preferable to insert only the sac 17 without the insert, and pump in fluid such as normal saline solution to expand the sac and thus fill the chamber 14.

After the compound prosthesis device has been properly positioned under the patient's skin, and after a suitable fluid has been introduced, the extending ends 20 of the inlet tube are folded over and tied off by means of threads 22 to seal the sac 17 as indicated in Fig. 4. Alternatively, the extending tubular end may simply be folded and tucked within the chamber 14, the various folds serving to seal the tube closed. The sponge cut 13 is then stitched closed as by threads 23 as illustrated in Fig. 5, and the patient's skin incision stitched in the usual manner to complete the operation.

Because of the use of the plastic flexible sac or container 17, and the fact that it is fluid tight, the prosthesis device cannot atrophy more than a negligible amount. Further, the sac 17 prevents the invasion of body fluids and blood vessels beyond the interior of the walls of the sponge 10. Thus the insert 16 within the sac retains its resilient and flexible state and the device remains firm, yet soft and resilient so that it is substantially identical

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to a normal healthy breast. The fact that an inert plastic sponge encloses the insert 16 and sac 17, results in sufficient invasion by surrounding tissue to retain the prosthesis device in position and prevent any possibility of dislocation.

The operation described above has proved highly successful. The compound prosthesis device of the present invention provides all of the advantages of former prosthesis devices of this sort without any of the attendant disadvantages resulting after prolonged use.

Various modifications within the scope and spirit of the present invention will occur to those skilled in the art. While the invention has been described in connection with a breast operation, it is to be understood that compound prosthesis devices of this type may be employed as substitutes for a lung or other organs of the body with great success. The invention is therefore not to be thought of as limited to the specific embodiment chosen for illustrative purposes.

I claim:

1. A compound surgical prosthesis for insertion under the skin of a patient to spatially replace a removed body organ, comprising: a hollow body of the shape of the removed organ, whose exterior defining walls consist entirely of a foam type resilient plastic surgical sponge material having openings entering into its exterior surfaces and extending throughout the interior thereof into which living body tissues and fluids may penetrate, there being an access slit in a wall of said body, a flexible fluid-impermeable sac inserted inside said hollow body through said access slit and adapted to substantially fill said hollow body, a filler tube joined to said sac and being accessible through said access slit, said tube being adapted to be closed in a fluid-tight manner, and a yieldable filler material inside said sac.

2. The subject matter of claim 1, wherein said filler material comprises a resilient sponge.

3. The subject matter of claim 1, wherein said filler material comprises a fluid.

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