

[54] **BRASSIERE WORN BREAST PROSTHESIS**[75] Inventors: **John Ashley Kirby; Louis J. Colonnese**, both of Fairfield, Conn.[73] Assignee: **George C. Batcheller Co., Inc.**, Bridgeport, Conn.[22] Filed: **Dec. 14, 1972**[21] Appl. No.: **315,003**[52] U.S. Cl. **3/36, 128/462**[51] Int. Cl. **A41c 3/10**[58] Field of Search **3/36; 128/462**[56] **References Cited****UNITED STATES PATENTS**

2,544,300	3/1951	Davenport et al.	128/462
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3,663,968	5/1972	Mohl	3/36

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Assistant Examiner—J. Yasko

Attorney, Agent, or Firm—Mattern, Ware and Davis

[57] **ABSTRACT**

An outer bag comprises two formed surfaces joined at

their peripheries. The formed surfaces are substantially the same size and shape as the brassiere bust cup within which the prosthesis is to be worn, and each includes a vertical extension having an air valve therein and an underarm extension. An inner liquid-filled bag is suspended by two hangers from the top periphery of the outer bag at either side of the valve. The inner bag is also formed of two substantially identical formed surfaces joined at their peripheries of the same shape as the bust cup, but of smaller size, and comprise an underarm extension and a somewhat shorter vertical extension. When worn the inner bag of the prosthesis is supplied with a volume of jell-like liquid equal to 40 to 75 percent of the total volume of the outer bag. The space between the bags is filled with air. Preferably the percentage of the volume of total prosthesis when worn is 50 to 60 percent liquid in the inner bag and 40 to 50 percent air in the outer bag. The prosthesis can be worn in either the right or the left breast cup. The then back formed surfaces of the bags are randomly flattened and cooperate with the air and gel to provide the deformation and tactile qualities of the human breast. The prosthesis is provided with an outer fabric cover and a thin, soft, flat pad against the back surface of the fabric cover, a hook for hanging the fabric cover from a brassiere shoulder strap, and a smooth-to-the-touch backing behind the hook.

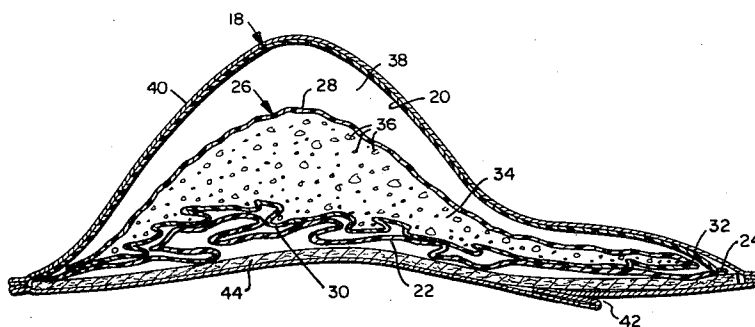
30 Claims, 9 Drawing Figures

FIG. 1

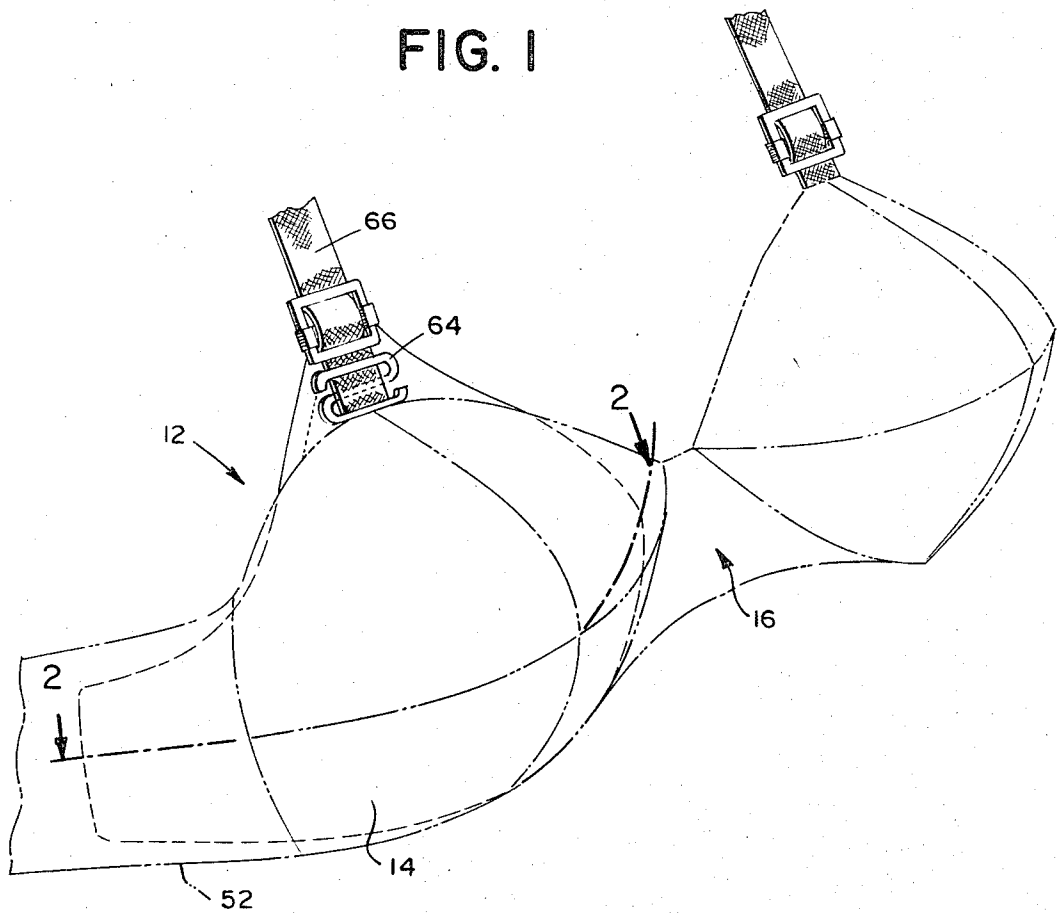


FIG. 2

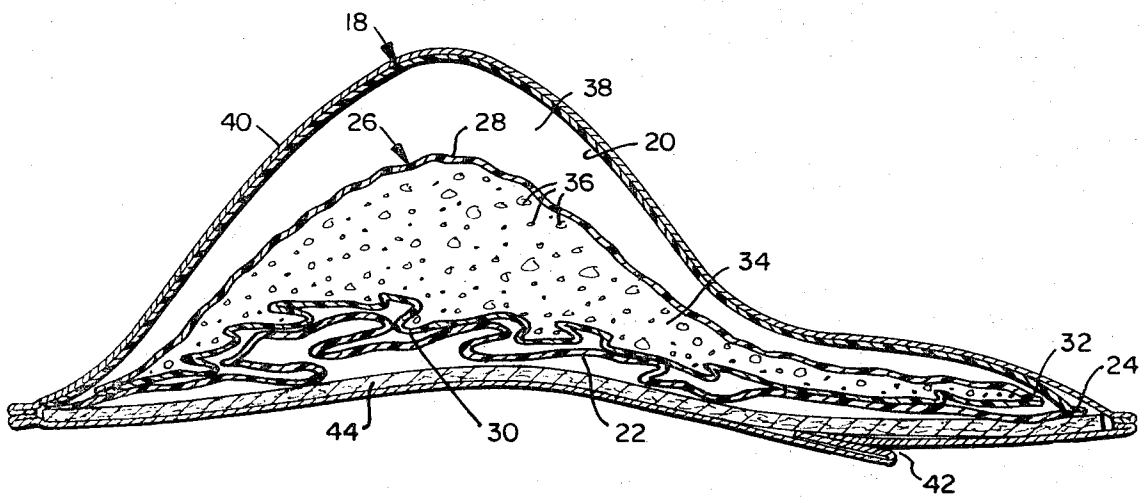


FIG. 3

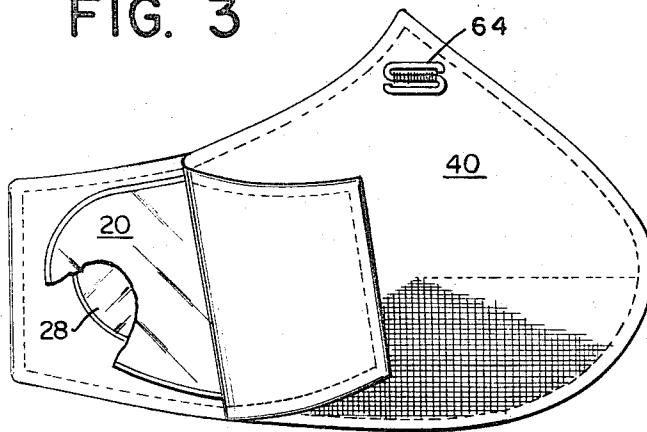


FIG. 7

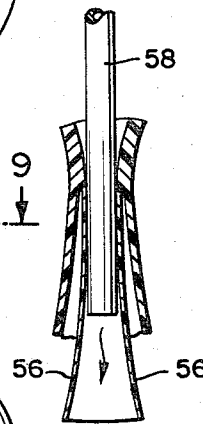


FIG. 8

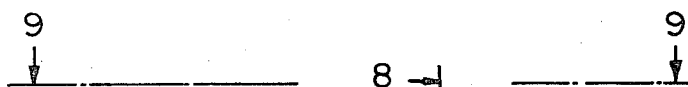
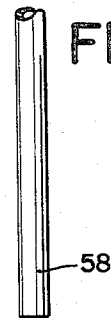


FIG. 4

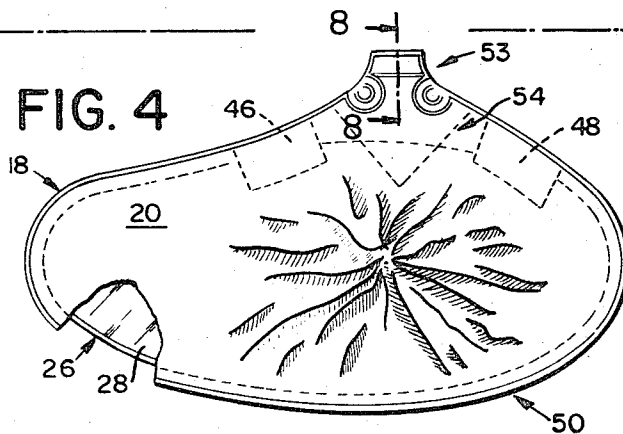


FIG. 9

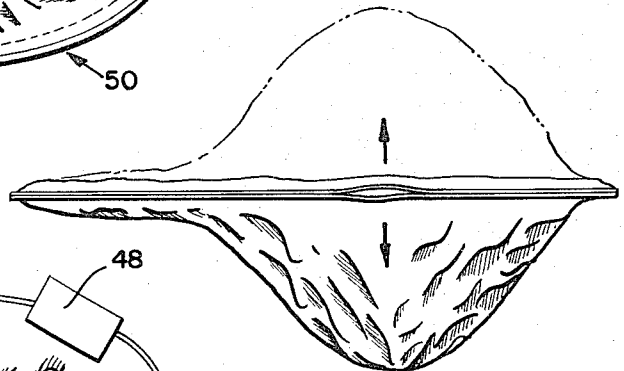


FIG. 5

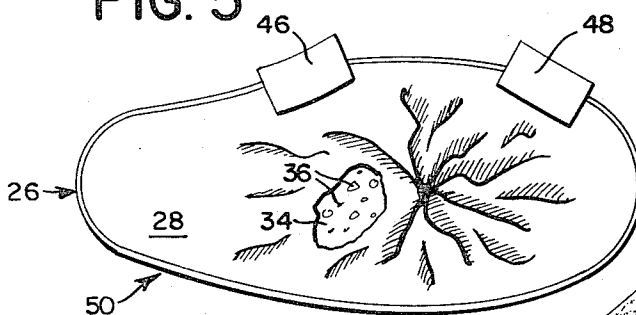
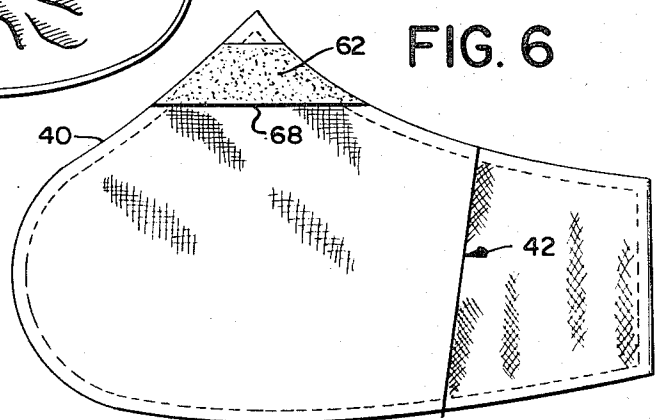


FIG. 6



BRASSIERE WORN BREAST PROSTHESIS**SUMMARY OF THE INVENTION**

Many prosthesis have been devised for mastectomy patients. Those that have been successful in the past are based on different philosophies. One comprises an envelope the same size and shape as the bust cup within which it is to be worn, completely filled with a jell-like liquid. The philosophy is that the liquid, being weighty, will supply the mass of the removed breast tissue and thus provide the wearer with the weight of the removed breast. Another device is merely filled with air to take the same size and shape of the removed breast within the normal brassiere and is preferably provided with a valve for adjusting the amount of air in the device. This device presupposes that it is not necessary to provide any weight to the brassiere. It has been found that the philosophies of both of these devices are incorrect in that the normal breast does not provide weight to the brassiere equal to its own weight, some of its own weight being carried by the breast tissue itself, and it has therefore been proposed that a breast prosthesis comprise an outer bag filled with air containing an entirely freely disposed inner liquid-filled bag. In U.S. Pat. No. 3,663,968 issued to Wilhelm Mohl et al. on May 23, 1972 and entitled "Artificial Breast," it is proposed that the inner and outer bags be flat backed and that an air valve be provided to the air space between the bags. The inner bag is filled with liquid to give "to the artificial breast a weight about equal the weight of a natural breast" and the air space provides some adjustability.

However, all of these prior art devices leave much to be desired in providing the mastectomy patients with a prosthesis which as closely as possible duplicates for the patient all of the qualities of the normal breast.

OBJECTS OF THE INVENTION

It is therefore a primary object of the invention to provide a breast prosthesis adapted to be worn within a brassiere that provides as many of those qualities of the normal human breast as possible. Some of these qualities are that it transfer to the chest wall and to the brassiere and to the brassiere back and shoulder straps the same forces created by its weight as the normal breast does when the patient assumes any position, e.g., lying down, standing up, leaning over, bending to the side, etc.

Another quality that it is desired to simulate is to fill the brassiere bust cup in the same way as the removed body tissue and be able to compensate for various degrees of radical surgery.

Further qualities that it is desired to simulate are the deformation and tactile qualities of the normal breast.

Other objects of the invention are to provide a breast prosthesis of the above character which is adjustable in size, which can be manufactured from a few basic sizes for all mastectomy patients, which is comfortable to wear, which is attractive to the mastectomy patient, and which provides one appliance that can be worn in either the right or left breast cup.

Other objects of the invention will in part be obvious and will in part appear hereinafter.

The invention accordingly comprises an article of manufacture possessing the features, properties, the relation of elements, the features of construction, combi-

nations of elements, and arrangements of parts which will be exemplified in the construction hereinafter set forth. The scope of the invention is indicated in the claims.

In general, the above objects are achieved by providing an outer air-filled bag formed of two shaped pieces of plastic sheet the same size and shape as the bust cup within which the prosthesis is to be worn. These formed sheets of plastic are joined at their peripheries. An inner bag within the outer bag is filled with a jell-like liquid. The inner bag is also formed of two substantially identical formed sheets of plastic which are smaller in size than the outer bag but of substantially the same shape as the bust cup. These sheets are also joined at their peripheries to form the inner bag. The inner bag is suspended from the outer bag by two hangers connected between the upper peripheries of the inner and outer bags. Between the two hangers there is located a valve for admitting air into and out of the space between the inner and outer bag. The valve is formed in a vertical extension of the outer bag which helps to fill in the vertical extension or tail of the breast normally removed during a mastectomy. The outer and inner bags are preferably provided with an elongated horizontal extension for filling in after radical surgery. However, if radical surgery has not been performed this extension will collapse under the force of the brassiere and thus will adjust to the degree of radical surgery.

When the volume of liquid is between 40 and 75 percent of the total volume of air within the prosthesis when worn in the brassiere, the wearer is given substantially all of those qualities previously mentioned of the normal breast within the brassiere. For the vast majority of mastectomy patients, it has been found that the preferred range of liquid volume to air volume is 50 to 60 percent liquid and 40 to 50 percent air.

The entire prosthesis is contained within a fabric cover which makes it attractive and comfortable to wear. Between the back of the plastic cover and the bags of the prosthesis there is preferably incorporated a thin, flat, very soft pad. When worn, the flattened rear portions of the bags forming the prosthesis bunch up in a random manner and play a part in providing the wearer with the deformation qualities of the normal breast within the brassiere. The fabric cover is provided with a hook for hinging the appliance from the brassiere shoulder strap.

The completed appliance with cover ranges in weight from 30 to 70 percent of the tissue removed in the mastectomy. Smaller sizes prefer as little as 30 to 35 percent weight replacement, and the preferred replacement ranges up to 60 to 70 percent in the larger sizes.

For a fuller understanding of the nature and objects of the invention, reference should be had to the following detailed description taken in connection with the accompanying drawings in which:

FIG. 1 is a perspective view of the breast prosthesis of the invention incorporated in a brassiere;

FIG. 2 is a cross-sectional view of the breast prosthesis of the invention taken along the plane 2-2 of FIG. 1;

FIG. 3 is a front view of the breast prosthesis of FIG. 1 with the fabric cover turned back and the outer bag partially cut away;

FIG. 4 is a rear view of the portion of the breast prosthesis of FIG. 1 with the fabric cover removed and the outer bag partly cut away;

FIG. 5 is a rear view of the inner bag of the breast prosthesis of FIG. 1 cut away to show the jell-like liquid therein;

FIG. 6 is a rear view of the breast prosthesis of FIG. 1;

FIGS. 7 and 8 are fragmentary diagrammatic cross-sectional views taken along the lines 7—7 of FIG. 4; and

FIG. 9 is a diagrammatic view taken along the line 9—9 of FIG. 4.

The same reference characters refer to the same elements through out the several views of the drawings.

DETAILED DESCRIPTION

In FIG. 1, the breast prosthesis of the invention is generally indicated at 12 in phantom lines. It is worn within the bust cup 14 of a conventional brassiere 16. Referring to FIG. 21 the prosthesis comprises an outer envelope 18 of plastic sheet material such as polyvinylchloride or polyethylene, which is air-impervious. The outer bag 18 is formed of two substantially identical formed sheets 20 and 22 joined at their peripheries 24 by means of heat sealing or the like. The surfaces 20 and 22 thus formed are of substantially the same size and shape as the inner contours of the bust cup 14.

An inner bag, generally indicated at 26, is also formed of two formed sheets 28 and 30 of the same or similar plastic material, which is air and liquid impervious. The formed sheets 28 and 30 are of the same shape as the bust cup 14 but of smaller size. They are joined at their peripheries 32 as by heat sealing or the like, and the inner bag thus formed is filled with a jell-like liquid 34 such as the carboxymethylcellulose known in the prior art.

Although the liquid 34 contains some air bubbles 36, these are merely left by the manufacturing process and the inner bag 26 is substantially filled with a jell-like liquid 34. The space 38 between the inner and outer bags 18 and 26 is filled with air. It will be noted that the back surfaces 22 and 30 of the outer bag 18 and inner bag 26 form themselves into random folds and are disposed generally flat along the chest wall of the wearer. The prosthesis is preferably provided with a fabric cover 40 of nylon tricot or the like and can be inserted or withdrawn therefrom through the opening 42 in the back thereof. The prosthesis is further preferably provided with a soft, thin, flat pad 44 which may be a foam plastic material covered with fabric on both sides thereof to provide strength, so that the random folds of the back surfaces 22 and 30 of the inner and outer bags 26 and 18 will not irritate the wearer.

It has been found through extensive testing that the vast majority of mastectomy patients prefer a breast prosthesis constructed as disclosed herein when the ratio of air to liquid volume is such that the prosthesis within the brassiere when worn on the mastectomy patient comprises between 50 and 60 percent liquid and 40 to 50 percent air. It has been further found that all patients feel comfortable if the range of air to liquid volume is such that the prosthesis as disclosed herein is filled with 40 to 75 percent liquid and 25 to 60 percent air.

The complete appliance 12 is found to preferably weigh 30 to 35 percent of the removed tissue for small

sizes such as 34A or 32B. The percentage of weight replacement preferred by the patient increases for increasing size reaching 60 to 70 percent of the weight of the removed tissue for large sizes such as 44D or 42C. These results are consistent with the observation that the larger sizes of normal breasts require greater brassiere support, i.e., a larger percentage of the weight of the breast is transferred to the brassiere in the larger sizes.

It has been found that six or seven sizes of appliances constructed according to the invention are sufficient to meet the needs of all mastectomy patients.

Now referring to FIGS. 4 and 5, the inner bag 26 is suspended from the outer bag 18 by means of two tab-like supports or hangers 46 and 48 sealed to the top peripheries thereof by heat sealing. During manufacturing, the tabs 46 and 48 are applied to the inner bag 26 by heat sealing after the inner bag has been formed and filled with the liquid 34 and then the outer bag 18 is heat-sealed around its entire periphery 24, thus sealing the hangers 46 and 48 to the outer bag 18.

Still referring to FIG. 4, both the inner and outer bags are preferably provided with the extended underarm extension generally indicated at 50 (see also FIG. 2), which in cooperation with the horizontal brassiere strap 52 of FIG. 1 will fill in for the underarm extension of the breast if it has been removed during radical surgery. The pressure of the horizontal brassiere strap 52 will cause the underarm extension 50 to substantially collapse if such radical surgery was not extensive, thus compensating for variations between patients.

The prosthesis 12 is provided with a vertical extension generally indicated at 53 in FIG. 4 to: 1) fill in the so-called tail of the breast if it has been removed by radical surgery in the same manner as the underarm extension 50, and 2) to provide for a valve generally indicated at 54 comprising valve triangle plastic pieces 56 (best seen in FIGS. 7 and 8) which cooperate with a tube 58 in FIGS. 7 and 8 for adding or subtracting air from the device in a known manner. Thus, the patient can add or subtract air to fill the breast cup 14 until she is comfortable with the prosthesis.

In FIG. 6 the back of the fabric cover 40 is shown, better illustrating the opening 42 by which the plastic bags can be inserted or removed from the fabric cover 40.

Also shown is a soft, smooth-to-the-touch plush pad 62 sewn on the back of the fabric cover 40 to prevent any discomfort from the hook 64 on the opposite side, shown in FIG. 3.

The hook 64 may be used to attach the prosthesis to the brassiere strap 66 as shown in FIG. 1, to help keep it in proper registration within the bust cup 14.

An opening 68 is also shown in FIG. 6, through which the tube 58 may be introduced into the valve 54.

By reference to FIG. 9, it may be seen how the prosthesis may be everted to be used in either the left or the right bust cup of a brassiere. In both cases, whatever becomes the back portions 22 and 30 of the plastic bags 18 and 26 (see FIG. 2) dispose themselves in the random flattened manner as shown in FIG. 2 and, in addition to providing a device that can be worn either in the right or the left bust cup, this symmetry between the front and the back of the inner and outer bags 18 and 26 is important in providing the prosthesis with the deformation and tactile qualities of a normal breast. However, even though the inner and outer plastic bags

18 and 26 may be everted to be used in either the right or the left breast cup, the fabric covers 14 are preferably separately provided for the left and the right bust cup so that (1) the back portion 70 of the fabric cover 40 (FIG. 2) may be flat, and (2) so that the hook 64 and plush pad 62 (FIGS. 3 and 6) may be provided.

It will thus be seen that the objects set forth above among those made apparent from the preceding description are efficiently attained and, since certain changes may be made in the above article and construction without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention herein described, and all statements of the invention which, as a matter of language, might be said to fall therebetween.

Having described our invention, what we claim as new and desire to secure by Letters Patent, is:

1. A breast prosthesis adapted to be worn in the bust cup of a brassiere comprising, in combination:

A. an outer air impervious bag, the front surface of which is substantially the same size and shape as the bust cup within which it is to be worn;

B. an inner air and liquid impervious bag within said outer bag containing a liquid;

C. a valve for admitting or releasing air to or from said outer bag; and

D. means joining said inner and outer bags to each other along the top peripheries thereof.

2. The breast prosthesis defined in claim 1, further defined in that when the prosthesis is worn in a brassiere by a mastectomy patient and inflated to match the volume of the removed breast the prosthesis is filled with less than substantially 75 percent liquid and more than substantially 25 percent air by volume.

3. The breast prosthesis defined in claim 2, more specifically defined in that the breast prosthesis is filled with substantially 40 to 75 percent liquid and 25 to 60 percent air by volume when worn by the mastectomy patient.

4. The breast prosthesis defined in claim 3, further defined in that, when the prosthesis is worn by the mastectomy patient, the weight of the prosthesis ranges between 30 and 70 percent of the weight of the removed tissue.

5. The breast prosthesis defined in claim 1, more specifically defined in that the breast prosthesis is filled with substantially 50 to 60 percent liquid and 40 to 50 percent air by volume when worn by the mastectomy patient.

6. The breast prosthesis defined in claim 5, further defined in that, when the prosthesis is worn by the mastectomy patient, the weight of the prosthesis ranges between 30 to 70 percent of the weight of the removed tissue.

7. A breast prosthesis adapted to be worn in the bust cup of a brassiere comprising, in combination:

A. an outer air impervious bag, the front surface of which is substantially the same size and shape as the bust cup within which it is to be worn;

B. an inner air and liquid impervious bag within said outer bag containing a liquid, the space between said inner and outer bags being such that the pro-

thesis is filled with substantially 50 to 60 percent liquid and 40 to 50 percent air by volume when worn by the mastectomy patient; and,

C) means joining said inner and outer bags to each other such that a substantial portion of the liquid in said inner bag does not flow to fill the bottom of said outer bag.

8. The breast prosthesis defined in claim 7, further defined in that, when the prosthesis is worn by the mastectomy patient, the weight of the prosthesis ranges between 30 and 70 percent of the weight of the removed tissue.

9. The breast prosthesis defined in claim 8, and:

C. an air valve located at the top of said inner air bag.

10. The breast prosthesis defined in claim 8, wherein said outer bag comprises a vertical extension at the top thereof.

11. The breast prosthesis defined in claim 10, and:

C. an air valve located in said vertical extension.

12. The breast prosthesis defined in claim 10, wherein said outer bag comprises an underarm extension.

13. The breast prosthesis defined in claim 12, wherein said inner bag also comprises an underarm extension.

14. The breast prosthesis defined in claim 8, wherein the front surface of said inner bag when worn by the mastectomy patient is substantially the shape of the bust cup within which it is worn but of a smaller size.

15. The breast prosthesis defined in claim 8, wherein said outer bag is formed of two substantially identical surfaces which are the same size and shape as the bust cup within which it is worn whereby the breast prosthesis may be worn in both the left or the right cup of a brassiere.

16. The breast prosthesis defined in claim 15, wherein said inner bag is comprised of two surfaces, each of which is substantially the same shape as the bust cup within which it is worn but of smaller size.

17. The breast prosthesis defined in claim 8, and:

C. a fabric cover surrounding said breast prosthesis having a front surface which is substantially the same size and shape as the bust cup within which it is worn and a substantially flat back surface joined at their peripheries.

18. The breast prosthesis defined in claim 17, and:

D. a thin, soft, deformable pad within said fabric cover against and substantially the same size and shape as said flat back surface of said fabric cover.

19. The breast prosthesis defined in claim 17, wherein said outer bag and said fabric cover comprise vertical extensions, and:

D. a hanger attached to the vertical extension of said fabric cover adapted for hanging said fabric cover from a brassiere shoulder strap.

20. The breast prosthesis defined in claim 19, wherein said hanger is attached to the front of said vertical extension of said fabric cover, and:

E. a soft piece of material smooth to the touch attached to the back of said vertical extension of said fabric cover behind said hanger.

21. A breast prosthesis adapted to be worn in the bust cup of a brassiere comprising, in combination:

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- A. an outer air impervious bag formed of two surfaces which are substantially the same size and shape as the bust cup within which it is to be worn by a mastectomy patient, said two surfaces joined at their peripheries whereby the prosthesis may be everted and worn in a right or a left bust cup; 5
- B. an inner air and liquid impervious bag within said outer bag containing a liquid; and,
- C. means joining said inner and outer bag to each other along the top peripheries thereof. 10
22. A breast prosthesis as defined in claim 21, wherein said inner bag is formed of two surfaces, each of which is substantially the same shape as the bust cup within which it is to be worn by the mastectomy patient but of smaller size. 15
23. The breast prosthesis defined in claim 22, wherein said outer bag is provided with an underarm extension. 15
24. The breast prosthesis defined in claim 23, wherein said outer bag is provided with a vertical extension, and: 20
- D. a valve for the introduction or release of air into or out of said outer bag within said vertical extension.
25. The breast prosthesis defined in claim 21, and: 25
- D. a fabric cover surrounding said breast prosthesis having a front surface which is substantially the same size and shape as the bust cup within which it is to be worn and a substantially flat back surface. 30
26. The breast prosthesis defined in claim 25, and:
- E. a thin, soft, deformable pad within said fabric cover against and substantially the same size and shape as said flat back surface of said fabric cover. 35
27. A breast prosthesis adapted to be worn in the bust cup of a brassiere comprising, in combination:
- A. an outer air impervious bag formed of two sur-

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- faces joined at their peripheries, each of which is substantially the same size and shape as the bust cup within which it is to be worn, and comprising a vertical extension within which is located a valve for admitting or releasing air to or from said outer bag, and further comprising an underarm extension; and
- B. an inner, air and liquid impervious, liquid-filled bag within said outer bag also formed of two surfaces joined at their peripheries, each of which is substantially the same shape as the bust cup within which it is to be worn by the mastectomy patient but of smaller size; said inner bag having an underarm extension and being suspended along the upper periphery thereof from the upper periphery of said outer bag, said prosthesis when worn by the mastectomy patient being filled with substantially 50 to 60 percent liquid in said inner bag and 40 to 60 percent in said outer bag air and weighing 30 to 70 percent of the weight of the removed tissue.
28. The breast prosthesis defined in claim 27, and:
- C. a thin, soft, deformable pad within said fabric cover against and substantially the same size and shape as said flat back surface of said fabric cover.
29. The breast prosthesis defined in claim 28; wherein said outer bag and said fabric cover comprise vertical extensions, and:
- D. a hanger attached to the vertical extension of said fabric cover adapted for hanging said fabric cover from a brassiere shoulder strap.
30. The breast prosthesis defined in claim 29, wherein said hanger is attached to the front of said vertical extension of said fabric cover, and:
- E. a soft piece of material smooth to the touch attached to the back of said vertical extension of said fabric cover behind said hanger.

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