

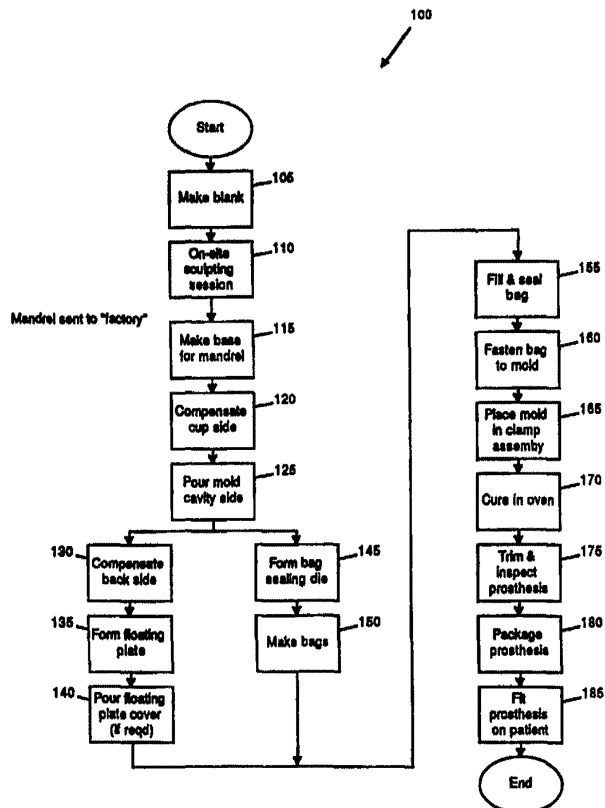
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(54) Title: DESIGNING AND MANUFACTURING A CUSTOM BREAST PROSTHESIS

(57) Abstract

The present invention is directed to custom-fitted breast prostheses, and more particularly relates to systems and methods for designing and manufacturing custom-fitted breast prostheses. One method (100) involves the creation of a visual mandrel using three-dimensional scanning equipment and computer aided design software. The visual mandrel may be stored in a computer and later reused and/or modified as needed by a custom breast prosthesis wearer. A further method involves the creation of a physical mandrel by an interactive sculpting process (110), wherein a patient and a designer develop the shape of the physical mandrel through the exchange of information including comfort, feel, and fit of the mandrel, as well as prior prostheses.



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## DESIGNING AND MANUFACTURING A CUSTOM BREAST PROSTHESIS

## FIELD OF THE INVENTION

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This invention relates in general to external breast prostheses, and more particularly relates to systems and methods for designing and manufacturing custom-fitted breast prostheses.

## BACKGROUND OF THE INVENTION

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It is an unfortunate fact that many women are diagnosed with breast cancer and must have the affected breast removed. After removal of one or both of her breasts, most mastectomy patients in today's society seek a prosthetic replacement to feel whole, and present a normal appearance beneath clothing. Another goal of breast prostheses is to maintain the balance of the body and to assist in reducing stress on the spine. Early fabric prostheses were never satisfactory, and surgically implanted prostheses are expensive and

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involve health risks. Therefore, external silicone breast prostheses have become extremely popular with mastectomy patients.

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Mastectomy patients may choose from a variety of "off the shelf" external silicone prostheses. Each of the different types of prostheses employ various features in an attempt to provide an acceptable level of comfort and to duplicate the form, feel, weight distribution, fullness, and softness of the natural breast.

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The first external silicone breast prostheses included a single volume of a two-component cross-linked silicone material contained within a cavity formed by two pieces of polyurethane film. The silicone material is cured in a mold that determines the shape of the prosthesis. Such prostheses were designed to be worn inside a brassiere. An example of such a prosthesis and a mold are described in U.S. Patent Nos. 4,172,298 and 4,247,351 to Rechenberg.

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Later, prosthesis designers determined that certain advantages could be obtained by forming a prosthesis of two volumes of silicone rubber materials having different softness. Such prostheses include three pieces of polyurethane film, which are welded together along a common peripheral edge to form front and rear chambers. In some products, the firmer silicone is in the front chamber. In others, the firmer silicone is in the rear chamber.

U.S. Patent No. 4,950,291 to Mulligan describes a two-chamber prosthesis in which the front chamber is relatively thin. The silicone rubber in the larger rear chamber, which is placed next to the chest wall, is softer than that in the front chamber. The softer silicone conforms to the shape of the chest wall and moves with the body, thereby providing a natural appearance. The softer silicone helps redistribute the weight of the prosthesis across and against the chest wall and away from the brassiere shoulder strap, which reduces stress on the shoulder. The firmer silicone in the front chamber supports the soft rear chamber, prevents the prosthesis from collapsing, and gives shape to the product.

As mentioned above, other two-chamber prostheses place the firmer silicone in the rear chamber. An example of a two-chamber prosthesis of this type is sold by the assignee of the present invention under the trademark "DELTA PERSONALLY." In this prosthesis, the rear chamber, which contains the firmer silicone, is relatively thin. The larger front chamber contains the softer silicone material. This configuration is advantageous because the firmer rear chamber simulates the pectoralis chest muscles while the softer front chamber moves like a natural breast. This prosthesis provides a significant natural drape with softness to fill and mold to a brassiere cup completely and naturally. The overall softness of the prosthesis helps the prosthesis mold to the chest wall contributes to redistributing the weight of the prosthesis across and against the chest wall and away from the brassiere shoulder strap.

Subsequent developments led to the introduction of attachable prostheses, which could be attached to the skin of the wearer. Like the earlier silicone prostheses, the attachable products included a single volume of a two-component cross-linked silicone material contained within a cavity formed by two pieces of polyurethane film. The prosthesis is held in place on the wearer's chest by a skin support or fastening slab, which has a skin-friendly adhesive on one side and attachment members on the other side. The prosthesis is attached to the skin support by complementary attachment members. U.S. Patent Nos. 5,071,433 to Naestoft et al. and 5,352,307 to Wild describe attachable prostheses that employ hook-and-loop fasteners, where the hook material is on the prosthesis and the loop materials forms one side of the skin support.

Although many women are able to be fitted with the types of products described above, there are many mastectomy patients who, due to variations in their surgery, their size, or other factors, are more difficult to properly fit with off the shelf external prostheses. This has resulted in the introduction of custom fitted external breast prostheses.

The custom breast prostheses that have been previously available suffer from several drawbacks. First, the fitting requires that a plaster cast be made of the patient's entire chest. Second, the finished product is fairly rigid, and does not look or feel like a natural breast under clothing. In addition, custom breast prostheses are relatively expensive. Despite these drawbacks, custom breast prostheses provide the best alternative for some mastectomy patients.

Therefore, there is a need in the art for an improved system and method for fitting, designing, and manufacturing custom external breast prostheses. The improvement should provide a custom breast prosthesis that duplicates the form, feel, weight distribution, fullness, and softness of the patient's natural breast as closely as possible, while remaining affordable to the majority of mastectomy patients.

#### SUMMARY OF THE INVENTION

The present invention provides a system and method for designing and manufacturing a custom breast prosthesis. The invention employs novel methods, materials, and apparatus to improve the design and manufacturing processes associated with the production of custom breast prostheses. The invention results in a custom breast prosthesis that provides mastectomy patients with a viable alternative to surgery while duplicating as much as possible the look and feel of the natural breast under clothing. The present invention provides a method of design and manufacture that allows significant involvement of the patient in order to ensure optimum customer satisfaction while also keeping costs down. The resulting custom breast prosthesis is highly durable and will retain satisfactory fit and appearance even when the patient experiences typical seasonal body changes. Finally, a custom breast prosthesis in accordance with the present invention duplicates the form, feel, weight distribution, fullness, and softness of the natural breast more closely than any other products currently on the market.

The various aspects of the present invention may be more clearly understood and appreciated from a review of the following detailed description of the disclosed embodiments and by reference to the appended drawings.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a flow chart of an exemplary method of designing and manufacturing a custom breast prosthesis.

Fig. 2 illustrates an exemplary blank, which is used to form a mandrel.

Fig. 3 illustrates a mandrel formed from the blank of Fig. 2.

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