SILIMED

EN

INSTRUCTIONS FOR USE / INFORMATION ON THE PRODUCT

DESCRIPTION

MAMMARY IMPLANT - SILICONE GEL - POLYURETHANE FOAM COATED SURFACE

It is made of a chemically and mechanically resistant silicone elastomer envelope that is thin, soft and polyurethane foam coated. It contains a defined volume of high performance, transparent and highly resilient Biodesign silicone gel, whose shape, density and overall consistency have been developed to resemble the human tissue.

[1]There is scientific evidence pointing out the efficiency of the polyurethane foam coating in the sharp decrease of capsular contracture occurrence. This coating permits a close interaction between the implant and the surrounding tissue, inducing physiological conditions that prevent fibroblasts migration to the pocket, consequently reducing the synthesis of collagen, which is the precursor of fibrotic capsule. The irregular surface of the polyurethane foam is unfavorable to the formation of linear fibrotic capsule, favoring multiplane formation of collagen fibrils. The formation of microcapsules around the irregularities of the polyurethane structure makes the contracture force multi-oriented instead of having a single direction. Presenting multiple vectors, these forces tend to annul each other, thus reducing capsular contracture.

It is presented in a set of types, the result of the clinical experience obtained among medical professionals.

Note 1: For further information regarding the implants, consult the table available on the cover of these Instructions for Use.

Note 2: The Natural, Nuance and Enhance models can present a position indicator on the anterior and/or posterior faces in order to facilitate the positioning of the product during the surgical procedure.

Note 3: The difference among the models is on the dimensions and/or volumes of the product

Accessories: The Mammary Implant - Silicone Gel - Polyurethane Foam Coated Surface is supplied with an auxiliary sleeve for implantation. This accessory is not sold separately.

The physician is responsible for the appropriate selection of the type to meet the clinical and esthetical requirements of each case.

[1] Pitanguy I, Salgado F, Radwanski HN & Stersa RM – Estágio Atual dos Implantes mamários. Ver bras Cir, 1991; 81(6): 291-299

Rebello C - Augmentation Mammaplasties With Polyurethane Foam-Coated Silicone Prosthesis. Rev da Soc Bras Cir Plast Est Reconst, 1993; 8 (1,2,3): 47 - 57.

CONSTITUENT MATERIALS - The raw-materials are medical-grade and biocompatible. The environmental conditions and productive techniques are controlled by the Good Manufacturing Practices for Medical Devices from FDA (GMP) and from ANVISA, as well as ISO 9001 and ISO 13485 standards.

Envelope: Elastomer, composition of Polydimethylsiloxane and Dimethyl Fluoro-Silicone Copolymer catalyzed by platinum compound.

- Envelope coating: Polyurethane Foam adhered to the envelope by a vulcanization process.
- Filling product: Silicone gel catalyzed by a platinum complex.

The polyurethane foam may present a variation in color, ranging from cream to light brown.

PRESENTATION - Supplied sterile and apyrogenic, in double package, within a sealed outer box containing the documents related to the product.

The label on the external package contains, among other, the following information: description of the product, reference number, amount of products per package, serial number, sterilization expiry date, size and/or volume. The surface of the product is identified by the color used on its label, as follows:

- Polyurethane Foam Coated Surface: Orange

The symbols used on this label indicate the characteristics of the product and are described in a printed sheet attached to these instructions for use.

STERILIZATION - One of the following sterilization processes is used:

- Ethylene Oxide

The sterilization process and its expiry date are shown on the packaging labels, meeting the requirements of the country to which the product is destined and which granted the register for commercialization. Each sterilization lot receives individual confirmation.

It is forbidden to re-process.

INDICATION FOR USE - Aesthetic or reconstructive surgeries for unilateral or bilateral mammary augmentation, reconstitution or correction to create a natural appearance.

CONTRAINDICATIONS - SILIMED considers the existence of infection anywhere in the body as an absolute contraindication for placement of the implant.

PRECAUTIONS - During the pre-operative evaluation of the patients, the physicians shall take the following into account: any recent occurrence of an abscess or tumors in the region of the implant, namely recurring cancer or metastasis; psychological instability of the patient; history of sensitivity to foreign bodies; history of severe allergy; sequelae from high exposure to ionizing radiation; unsuitable cover tissue in the region of the implant; history of earlier dissatisfaction with the use of implants; advanced fibrocystic disease; diabetes and cardiovascular problems.

INSTRUCTIONS FOR HANDLING AND USE -

- Opening the Package:

1 - Make sure that the outer plastic covering has not been opened;

2 - Remove the double packaging from the interior of the sealed box. This shall be examined thoroughly before the device