

Pre-Vacuum (also known as high-vacuum) Steam Sterilizer:

8 minutes at 270°F (132°C).

When steam autoclaving, the user should verify that the sterility procedure will produce a sterility assurance level of  $10^{-6}$  by using an appropriate biological indicator and validation programs as specified in Chapters 1035 and 1211 of the United States Pharmacopeia.

**WARNING: IMPLANTS SHOULD BE ALLOWED TO COOL THOROUGHLY AFTER AUTOCLAVING.**

## PRODUCT EXAMINATION AND HANDLING

1. Prior to implantation, products should be visually examined for any evidence of particulate contamination or damage. **DAMAGED PRODUCTS SHOULD NOT BE IMPLANTED.** Do not attempt to repair damaged products.
2. Care must be taken to prevent possible surface contamination by talc, duct, and skin oils which might adversely affect the suitability of the implant.

***Surgiform***<sup>®</sup>  
*Aesthetic Surgery Products*

1566 Whiting Way  
Lugoff, SC 29078  
803-462-1714  
803-462-1743 Fax  
866-225-5785 Toll-Free  
[www.surgiform.com](http://www.surgiform.com)

Surgiform Silicone Implants are manufactured for Surgiform™ Technologies Ltd. by Surgical Technology Laboratories, Inc.

# **Surgiform™ Silicone Facial Implants**

INSTRUCTIONS FOR USE FOR SURGIFORM'S SILICONE FACIAL IMPLANT

## INDICATIONS

FOR FACIAL PLASTIC AND RECONSTRUCTIVE SURGERY

## PRODUCT DESCRIPTION

Surgiform Silicone Facial Implants are three-dimensional anatomical designs fabricated of silicone elastomer. The Surgiform Silicone Facial Implant is available in a variety of shapes and sizes. The devices are intended for augmentation or repair of the soft tissues of the facial areas. **These are single use devices only.**

## CONTRAINDICATIONS

- Dermal placement
- Temporomandibular joint (TMJ) reconstruction
- When there is a lack of sufficient tissue covering

NOTE: EVERY PATIENT SHOULD BE MADE AWARE OF THE FOLLOWING FACTS:

Facial augmentation surgery can provide satisfaction to patients. Nevertheless, it is not without potential complications and risks. Facial implantation surgery is an ELECTIVE PROCEDURE and the patients should be well counseled on the risk-benefit relationship. The possibility of explants surgery taking place at any time after implantation should also be discussed with the patient.

SURGIFORM TECHNOLOGIES, INC. RELIES ON THE SURGEON TO ADVISE THE PATIENT OF THE COMPLICATIONS AND RISK ASSOCIATED WITH BOTH THE IMPLANT AND THE SURGERY ITSELF.

## COMPLICATIONS / ADVERSE EVENTS

Resorption of bone underlying the implant can occur.

Inadequate tissue covering, inadequate size surgical pocket or too large an implant can result in tissue necrosis and extrusion of the implant

Displacement or shifting of the implant can occur from too large a pocket. Formation of a fibrous tissue capsule surrounding the implant is a normal physiologic response to any foreign body. Contracture of the fibrous tissue capsule can result in firmness, implant displacement or buckling, discomfort, or pain.

Possible complications or adverse reactions with any facial implant device may include, but are not limited to: inflammation, infection; fistula formation, migration, extrusion, hematoma; serous fluid accumulation or seroma formation; induration, nerve damage or irritation; neuralgia; loss of sensation; poor reaction to medication/surgical procedures; poor wound healing, patient intolerance to any foreign implant, and inadequate or excessive augmentation.

Due to the wide variety of patients' physical responses to implant surgery and the differences in surgical techniques and medical treatments, as well as the possibility of complications or trauma, **PATIENTS SHOULD BE ADVISED THAT THESE SHOULD NOT BE CONSIDERED LIFETIME IMPLANTS AND EXPLANT SURGERY MAY BE INDICATED AT ANYTIME. SURGIFORM TECHNOLOGIES, LTD. MAKES NO REPRESENTATIONS FOR THE TERM OF IMPLANTATION OF THE DEVICE.**

Implants are intended for single patient use only.

**WARNING: UNDER NO CONDITIONS SHOULD AN EXPLANTED PRODUCT BE REIMPLANTED!** This is because recommended recleaning and resterilization may not adequately remove biological residues such as blood, tissue, and other matter, which could retain resistant pathogens.

## SURGICAL PROCEDURE

Proper surgical procedures and techniques are the responsibility of the medical profession. Each surgeon must evaluate the suitability of the procedure based upon current accepted techniques, individual judgment, and experience.

Proper size and shape of implants must be determined for the individual patient by the surgeon. Sizer kits are available for **Surgiform Silicone Facial Implants** for the convenience of the surgeon.

## SIZING

If necessary, trim the device to the desired size using sharp surgical instruments. Avoid using dull instruments as they can result in excessive shear forces on the device.

## IMPLANTATION

This device is intended to be implanted at an adequate depth below the dermis where there is sufficient tissue to cover the device completely and allow for normal healing.

**Do not implant in the dermis.**

## PRECAUTIONS

The device should not be implanted in the dermis. This could lead to complications such as fistula formations, infection, extrusion and induration.

This device is not intended for load bearing applications such as bone, tendon or ligament replacement. Patients with healing disorders, such as autoimmune disease or diabetes, may not experience normal wound healing.

Utmost care should be taken to avoid damage to the implant during handling or in surgery. Avoid contact with sharp objects, such as surgical instruments or suture needles. Avoid undue handling with blunt instruments or manipulation.

## SUPPLIED STERILE OR NON-STERILE

Implants supplied in sterile form are processed by a validated, strictly controlled cycle. Sterility is verified in accordance with AAMI / ANSI / ISO Standards. Sterility of the implant is maintained only if the package is intact and undamaged.

If the sterile implant becomes contaminated prior to implantation, it may be recleaned and resterilized by autoclaving according to procedures described below. The implant should not be resterilized by ethylene oxide gas, since excessive accumulation of ethylene oxide residuals may cause adverse tissue reaction.

Implants supplied in non-sterile form, must be sterilized by autoclaving before use. (SEE STERILIZATION INSTRUCTIONS)

## PACKAGING

Sterile product is supplied in a sealed double package. Sterility is not guaranteed if the package has been damaged or opened.

Non-sterile product is supplied in a sealed, single package.

A tear-off patient chart record is provided on both sterile and non-sterile packages.

## TO OPEN STERILE PRODUCT

1. Peel open outer pouch under clean aseptic conditions.
2. Invert outer pouch over sterile field, allowing sealed inner package to fall on field.
3. Using aseptic precautions peel open inner package and retrieve implant.

NOTE: Attach patient record portion of the label to patient's chart.

## NON-STERILE PRODUCT AND SIZER KITS

1. If sterilization or resterilization is required, the following cleaning and sterilization techniques have been found effective.
2. Remove implant from its package in a clean environment using gloved hands. Do not sterilize in the packaging system supplied. Utmost caution should be taken to avoid contamination as lint, fingerprints, talc, and other surface contaminants can cause foreign reactions.
3. Sterilize per STERILIZATION INSTRUCTIONS below.

NOTE: Attach patient record portion of label to patient's cart.

## STERILIZATION INSTRUCTIONS

The Sterilization Instructions provided are to be used only as a guide. We recommend that the efficacy of the specific autoclaving cycle employed be established by appropriate methods such as the use of commercially available chemical or biological monitors.

**DO NOT USE ETHYLENE OXIDE STERILIZATION.**

**DO NOT USE RADIATION STERILIZATION.**

**DO NOT EXPOSE THE DEVICE TO TEMPERATURES GREATER THAN 482°F (250°C).**

Wrap implant in a clean, lint-free material and place in a clean, open autoclaving tray. (Do not sterilize the device in the original packaging materials. The device should be repackaged in materials appropriate for sterilization.) Sterilize by one of the following gravity displacement or pre-vacuum autoclaving cycles: