Manufactured By:
Surgical Technology Laboratories, Inc.
1566 Whiting Way
Lugoff, SC 29078

Telephone: 866-225-5785
Fax: 803-462-1743

For:
Surgiform Technologies, Ltd
1566 Whiting Way
Lugoff, SC 29078

Telephone: 866-225-5785
Fax: 803-462-1743
www.surgiform.com

PureForm
3-D ePTFE Facial Implants

Instructions for Use for Surgiform's PureForm Polytetrafluoroethylene (ePTFE) Facial Implant

INDICATIONS

For Plastic and Reconstructive Surgery

DEVICE DESCRIPTION

The Surgiform PUREFORM Facial Implant is an expanded polymer implant device intended for augmentation or repair of the soft tissues of the facial area. The device is offered in pre-formed nasal, chin and malar (cheek) shapes.

CONTRAINDICATIONS AND WARNINGS

- Dermal Placement
- Tempormandibular Joint (TMJ) Reconstructions

STERILITY

PureForm ePTFE Facial Implants are supplied **STERILE**. Provided that the integrity of the package is not compromised in any way, the package will serve as an effective barrier for a minimum of two years from the date of sterilization. This date is indicated by the expiration date. There is no expiration date for product function or characteristics.

RECOMMENDED TECHNIQUES

HANDLING

Use clean, sterile gloves and/or atraumatic instruments when handling the device.

MAINTAINING ASEPSIS

To help maintain asepsis during surgery, special precautions and extremely careful preoperative site preparations are necessary. Any postoperative infections should be aggressively treated at the earliest possible time. Preoperative and postoperative antibiotics may be used at the surgeon's discretion.

SIZING

Trim the material to the desired size using sharp surgical instruments. Avoid using dull instruments because they can result in excessive shear forces on the material, which may cause material thickness separation.

IMPLANTATION

This prosthesis is intended to be implanted at an adequate depth below the dermis where there is sufficient tissue to cover the material completely and allow for normal healing. **DO NOT IMPLANT IN THE DERMIS.**

POSTOPERATIVE CARE

Instruct the patient on appropriate postoperative care to promote normal healing and avoid complications.

WARNINGS

Exposure of this material to the external environment during healing should be avoided. If the material becomes exposed during healing, treat to avoid infection.

An unresolved infection may require removal of the material.

PRECAUTIONS

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

The device **is not intended** for load bearing applications such as, bone, tendon, or ligament replacement.

Use nonabsorbable sutures for applications requiring attachment strength.

The material **should not be implanted** in infected or potentially infected tissue beds or over open cavities, because infection or extrusion may result.

Introduction of the material either through the nose or mouth **should be avoided** due to increased potential for infection.

Patient s with healing disorders, such as autoimmune disease or diabetes, may not experience normal wound healing.

Use of this device in patients with severe acne may result in device contamination and lead to infection.

ADVERSE REACTIONS

Possible Adverse reactions with any facial implant material may include, but are not limited to: inflammation, infection, fistula formation, extrusion, hematoma, induration, seroma formation, inadequate healing, and inadequate or excessive augmentation.

RESTERILIZATION

The product may be resterilized up to three times using steam or gas techniques without compromising its mechanical or structural quality. **Do not sterilize this product in the original packaging materials.** The product must be repackaged in materials appropriate for sterilization. Sterility of repackaged product is the responsibility of the health care institution.

Clean, unused, and undamaged portions of the product maybe resterilized if handled with clean gloves and/or atraumatic instruments such as dry transfer forceps. Protect the product from heavy or sharp objects during sterilization.

- Do not expose the product to temperatures greater than 482°F (250°C)
- Do not sterilize the product using radiation

STEAM

Using a validated gravity-displacement steam sterilizer, autoclave at or above these minimum requirements: 250°F (121°C) for 30 minutes or 270°F (132°C) for 15 minutes.

Using a validated pre-vacuum (also known as a high-vacuum) steam sterilizer, autoclave at or above these minimum requirements: 207°F (132°C) for 4 minutes.

ETHYLENE OXIDE

Due to the tremendous variation in gas sterilization equipment, the choice and validation of specific cycles and aeration parameters are the responsibility of the health care institution.