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S F A M

Surgiform™ Augmentation Material

INSTRUCTIONS FOR USE FOR STL's EXPANDED POLYTETRAFLUOROETHYLENE SUGIFORM S.F.A.M. MATERIAL

INDICATIONS

FOR PLASTIC AND RECONSTRUCTIVE SURGERY

PRODUCT DESCRIPTION

The Surgiform S.F.A.M. is intended for augmentation or repair of the soft tissues of the facial area. The product is available in flat and contoured sheets in the following sizes.

Flat Sheets

Length	Width	Thickness
7.0 cm	3.0 cm	0.02 – 4.0 cm
7.0 cm	7.0 cm	0.02 – 4.0 cm
14.0 cm	7.0 cm	0.02 – 4.0 cm
24.0 cm	19.0 cm	0.02 – 1.0 cm

Contoured Sheets

Length	Width	Thickness
24.0 cm	19.0 cm	0.02 – 1.0 cm

CONTRAINDICATIONS

- Cardiovascular defects
- Tempormandibular joint (TMJ reconstructions)
- Cosmetic lip filler
- Dermal placement

STERILITY

S.F.A.M. sheeting is 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 three years from the date of sterilization printed on the box. There is no expiration date for the product function or characteristics.

RECOMMENDED TECHNIQUES

HANDLING

Use clean sterile gloves and/or atraumatic (blunt) instruments when handling the S.F.A.M. implant material.

MAINTAINING ASEPSIS

To help maintain asepsis during surgery, special precautions and extremely careful preoperative site preparations are necessary. Contact with the implant during handling and insertion should be minimized. 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-SINGLE SHEET ONLY

Trim the material to the desired length 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 material 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

WARNING

If the material becomes exposed during healing, treat to avoid infection. If infection occurs, remove the material.

PRECAUTIONS

- Use non-absorbable sutures for applications requiring attachment strength.
- The material should not be implanted in the dermis. This could lead to complications such as fistula formation, infections, extrusion and induration.
- The material should not be implanted in infected or potentially infected tissue beds or over open cavities, because infection or extrusions may result.
- This material is not intended for load bearing applications such as bone, tendon, or ligament replacement.

ADVERSE REACTIONS

Possible adverse reactions with any implantable ePTFE material may include, but are not limited to: inflammation, infection, fistula formation, extrusion, hematoma, induration, seroma formation, and inadequate and excessive augmentation.

RESTERILIZATION

This product may be re-sterilized up to three times using validated steam or Ethylene Oxide (EO) methods without compromising its mechanical or structural quality. Do not sterilize in the original packaging materials. The product must be re-packaged in materials appropriate for the sterilization method. The sterility of re-packaged product is the responsibility of the healthcare institution.

Clean, unused, and undamaged portions of the product may be re-sterilized 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 484° 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 high-vacuum) steam sterilizer, autoclave at or above these minimum requirements: **270°F (132° C) for 4 minutes.**

ETHYLENE OXIDE

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