

INSTRUCTIONS FOR USE FOR SURGIFORM'S
SURGISOFT™ ePTFE IMPLANT

INDICATIONS

FOR PLASTIC AND RECONSTRUCTIVE SURGERY

PRODUCT DESCRIPTION

The SurgiSoft™ ePTFE facial implant is an expanded porous polytetrafluoroethylene material that is intended for augmentation or repair of the soft tissues of the facial area. This product is available in both round and oval shapes, both shapes come in a variety of different diameters. SurgiSoft™ ePTFE facial implant strands are packaged with and without an attached stainless steel trocar.

CONTRAINDICATIONS

- Dermal Placement
- Temporomandibular joint (TMJ) reconstruction

STERILITY

SurgiSoft™ facial implants are supplied STERILE. Provided the package has not been open or damaged, it will serve as an effective barrier for a minimum of five years from the date of sterilization.

RECOMMENDED TECHNIQUES

HANDLING

Use clean, sterile gloves and/or instruments when handling SurgiSoft™ facial implants.

OPEN PACKAGE

To open sterile package, peel back lid and carefully remove the SurgiSoft™ facial implant from the tray using aseptic technique.

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

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insertion should be minimized. Postoperative infections should be aggressively treated at the earliest possible time. Antibiotics may be administered at the surgeon's discretion.

SIZING

Trim the material to the desired length using sharp surgical instruments.

IMPLANTATION

It is extremely important that this implant be implanted in the subcutaneous tissue layer below the dermis where there is sufficient tissue to cover the material completely and allow for healing. Do not implant in the dermis. The outer diameter of the implant placement instrument(s) should closely approximate the outer diameter of the implant to assure a good fit and minimize movement of the implant within the implant site. The end of the implant may be tapered with a sharp surgical instrument. It is not necessary to anchor the implant with sutures.

POSTOPERATIVE CARE

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

WARNING

Preattached trocar must be removed from the implant prior to wound closure.

If the implant material becomes exposed during healing, treat to avoid infection. If infection occurs, implant should be removed.

PRECAUTIONS

Federal (U.S.A) law restricts this device to sale by or on the order of a physician.

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

This device is not intended for load bearing applications such as bone, tendon, or ligament replacement. Use non-absorbable sutures for applications requiring attachment strength.

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

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

Patients with 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.

Do not resterilize implant with attached trocar by steam sterilization techniques.

ADVERSE REACTIONS

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

RESTERILIZATION

Should the original sterile package be inadvertently opened or damaged prior to use. With the exception of SurgiSoft™ with trocar these facial implants may be resterilized up to a maximum of one (1) time using either validated steam or EO sterilization methods without compromising its mechanical or structural quality. Do not sterilize this device in the original packaging materials. The device must be repackaged in materials appropriate for sterilization. Sterility of the repackaged device is the responsibility of the health care institution.

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

- Do not expose the device to temperatures greater than 482° F (250° C).
- Do not sterilize the device using radiation sterilization techniques.

STEAM

No part of the original package should be in direct contact with the facial implant during steam sterilization. For gravity displacement and/or prevacuum, (flash) steam sterilizers, autoclave at or above the minimum temperature requirements of 270°F (132°C) for 4 minutes at 30 PSI (2KG/cm²)

Do not steam or flash autoclave implant with attached trocar.

ETYLENE OXIDE (EO) GAS STERILIZATION

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.