

Surgisis® Biodesign™

FACIAL IMPLANT STRAND

FP0038-1H



Manufactured by:

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INTENDED USE:

The Surgisis® Biodesign™ Facial Implant Strand is intended for use to provide soft tissue repair or reinforcement in plastic and reconstructive surgery of the face and head. This device is supplied sterile and is intended for one-time use.

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

CONTRAINDICATIONS:

- This device is derived from a porcine source and should not be used in patients with known sensitivity to porcine material.

WARNING:

- **Do not use if needle is buckled or kinked.**
- Preattached needle must be removed from the implant prior to wound closure.

PRECAUTIONS:

- **Do not resterilize.** Discard all open and unused portions.
- Device is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken.
- Discard the device if mishandling has caused possible damage or contamination, or if the device is past its expiration date.
- Ensure that the device is rehydrated prior to implanting.
- This device is not intended for use in load bearing applications such as bone, tendon or ligament repair.
- This device should not be implanted in infected or potentially infected tissue beds or over open cavities, because infection or extrusion may result.
- Use of this device in patients with severe acne may result in device contamination, leading to infection.
- Device placement, removal, and repeat placement, or use of a single device for multiple procedures, may result in device contamination, leading to infection.
- The device should not be implanted into the dermis. **Implant below the dermis into the subcutaneous tissue to ensure sufficient depth for healing and to minimize occurrence of extrusion, fistula formation, infection, and induration.**
- Compromised patients (such as those with autoimmune disease or diabetes) may not experience normal wound healing.
- Care should be taken to avoid unintentional puncturing of adjacent organs

POTENTIAL COMPLICATIONS:

Complications that can occur with soft tissue reconstruction or facial implant include, but are not limited to: hematoma, inflammation, induration, prolonged palpability, fistula formation, migration, extrusion, seroma formation, numbness, paresthesia, infection, and insufficient or excessive augmentation. If any of the following conditions occur and cannot be resolved, device removal should be considered:

- Infection
- Acute or chronic inflammation (Initial application of surgical graft materials may be associated with transient, mild, localized inflammation)
- Allergic reaction

STORAGE: This device should be stored in a clean, dry location at room temperature.

STERILIZATION: This device has been sterilized with ethylene oxide.

SUGGESTED INSTRUCTIONS FOR USING THE FACIAL IMPLANT

STRAND: These recommendations are designed to serve only as a general guideline. They are not intended to supersede the institutional protocols or professional clinical judgment concerning patient care.

NOTE: Always handle device using aseptic technique. For best results, use caution to minimize Facial Implant Strand contact with latex gloves. Follow a "no-touch" technique for device preparation and implant.

Required Materials

- A sterile dish (kidney dish or other bowl)
- Sterile forceps
- Rehydration fluid: at least 100 mL of room temperature sterile saline or sterile lactated Ringer's solution for each Facial Implant Strand.

1. Using aseptic technique, remove the inner pouch containing the Facial Implant Strand from its outer bag, and place the inner pouch in the sterile field.
2. Using sterile, gloved hands, open the inner pouch and remove the tray holding the device. Aseptically remove the Facial Implant Strand from the tray by gripping the shaft of the needle.
3. Place the Facial Implant Strand into the sterile dish in the sterile field.
4. Add at least 100 mL of rehydration fluid to the dish.
5. Allow the Facial Implant Strand to rehydrate, fully submerged, for three to five minutes.
6. Prepare the graft site, incising as necessary.
7. **Important:** Make small entry and exit incisions, at least the size of the needle diameter, through the dermal layer. This action reduces the force required to pull the implant in place.
8. Using aseptic technique, introduce the pre-attached needle of the Facial Implant Strand through the entry incision, into the targeted subcutaneous layer, and out of the exit incision.
9. Draw the Facial Implant Strand into the implant site until the entire needle has been pulled through the exit incision. If the desired placement is not achieved with the first pass through the tract, remove the device and replace it with a new device. If unintentional release of the Facial Implant Strand from the needle occurs before placement is complete, remove both the strand and needle, and replace them with a new device.
10. Once appropriate placement is confirmed, cut the implant from the needle and trim the implant to the appropriate length. The device should not protrude through the skin after trimming.
11. Complete the procedure and close the incision sites.
12. Discard the needle into an appropriate medical sharps container, and discard any unused portions of the Facial Implant Strand.

POSTOPERATIVE CARE:

Instruct the patient on appropriate postoperative care to minimize the potential for complications and to promote normal healing. Patient should not massage area for at least one week.