SILHOUETTE INSTALIFT™

Silhouette Instalift™ Products:

SMS 28-PLG-3.0.1-NA
SMS 29-PLG-3.0.1-NA
SMS 30-PLG-3.0.1-NA

Instructions for Use

SYMBOLS USED ON LABELING:


Use by Date


Date of Manufacture


Single use only


Do not resterilize


Consult Instructions for Use

STERILE EO
Sterilized using Ethylene Oxide


Do not use if package is damaged

LOT
Batch

MR
MR Safe


Warning


Minimum and maximum storage temperature


Manufacturer

Manufactured For:
Silhouette Lift Inc.
1 Technology Drive
Suite F 211
Irvine, California 92618 USA

Silhouette Instalift™ Device Instructions for Use
PN: SMS 28-PLG-3.0.1-NA
PN: SMS 29-PLG-3.0.1-NA
PN: SMS 30-PLG-3.0.1-NA

INDICATIONS:
The Silhouette Instalift device is indicated for use in mid-face suspension surgery to temporarily fixate the cheek sub dermis in an elevated position.

DESCRIPTION:
The Silhouette Instalift device is an absorbable, sterile, surgical product that consists of a monofilament and injection molded cones. It is manufactured from a USP size 3-0 Poly/Glycolide/l-lactide suture material and an implantable grade of bioabsorbable resin. The 30 centimeter suture (± 10 %) (SMS 28-PLG-3.0.1-NA), 27.5 centimeter suture (± 10 %) (SMS 29-PLG-3.0.1-NA) or 26.8 centimeter suture (± 10 %) (SMS 30-PLG-3.0.1-NA) are attached to two 12 centimeter straight needles.

All products are supplied sterile (EO) for single use only.

MODE OF ACTION:
The Poly/Glycolide/l-lactide cones utilize an opposing cone orientation to achieve tissue lift and compression by grabbing and holding facial tissue in the elevated position. The Poly/Glycolide/l-lactide suture elicits a minimal acute inflammatory reaction in tissue that is followed by gradual encapsulation.

INSTRUCTIONS:
1. Remove sutures from protective pouch and place in sterile field using aseptic procedures.
2. Mark the location where the Silhouette Instalift devices are to be placed (Figure 1).
3. Infiltration of local anesthetic at the entry and exit points in the desired area (Figure 2).
4. If an optional permanent suture will be attached (see step 9) a dissection is made in the proximal exit point using the surgeon's typical approach.
5. Punctures are made in the midface area; the distal straight needle is inserted through the puncture to the required depth (Figure 3) and advanced along the pre-marked location for each suture placement exiting the skin (Figure 4).
6. The distal straight needle exits through the pre marked location, the needle is pulled through so that the first set of cones is in place in the tissue (Figure 5). The needle is cut from the suture leaving a small portion of the suture exposed.
7. Repeat for the second needle to insert the other half of the suture (Figure 6-9).
8. Apply tension to the sutures in place, followed by compression of the soft tissue to achieve the desired lift (Figure 10).
9. As an option, the suture can be secured to the fascia in the following manner: after elevating the device to the desired position, as an optional step, a permanent monofilament suture may be attached to the proximal end of the Instalift suture device and into the fascia where the soft tissue is of adequate thickness. Secure the suture longitudinally in two locations, and vertically in two locations (Figure 11). Use caution if securing the Instalift with permanent, braided suture. The braided suture may damage the device if it is tied too tightly.
10. Trim the excess ends of the sutures. It is desirable to bury the end of the sutures either under adjacent, mobilized soft tissue or fascia to avoid possible erosion of the device through the skin. Close the incision using the surgeon's typical technique.
11. Repeat for each Silhouette Instalift device implanted.
12. If adjustment or removal of the implant is desired, one may remove the suture and extract the device under direct or endoscopic guidance.
13. If removal of the device is required in the post-operative period, a small incision to release the anchoring to the fascia and remove the device may offer the most straightforward method.

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner

Figure 1. Preoperative Marking (Lateral view)

Figure 2. Anesthetic points

Figure 3. Entry point of needle

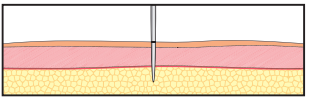


Figure 4. The first 23G/12 centimeter long needle is inside the tissue

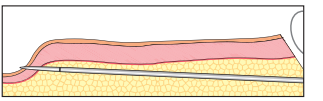


Figure 5. The first set of cones is inside the tissue

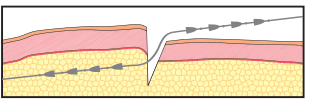


Figure 6. The second needle enters the tissue
from the same entry puncture

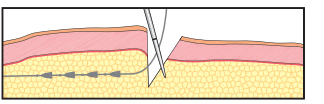


Figure 7. The second needle is inside the tissue

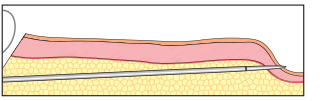


Figure 8. The second set of cones is implanted

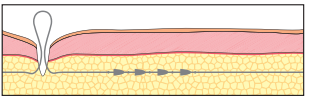


Figure 9. The whole Silhouette Instalift device is inside the tissue

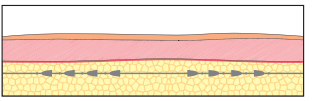


Figure 10. Compression of the soft tissue by the physician

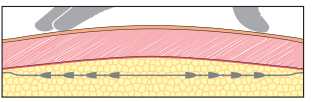
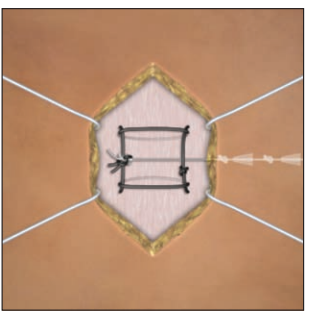


Figure 11. OPTIONAL: Anchor permanent monofilament suture to Instalift and fascia



CONTRAINDICATIONS:
Any known allergy or foreign-body sensitivities to plastic biomaterial. Situations where internal fixation is otherwise contraindicated (e.g. infection). Patients appearing to have very thin soft tissue of the face in which the implant may be visible or palpable.

WARNINGS:
User should be familiar with recommended techniques involving Silhouette Instalift devices, as well as proper patient selection and suture placement.
Sterility is guaranteed unless package is opened or damaged. **Do not re-sterilize. Single use only. Discard open, unused product. Product should be disposed of in a manner that complies with the regulatory requirements of the country where it is sold.**
This is a single-use device. Re-use of this device may result in hazardous bio contamination resulting in severe injury to the patient.

PRECAUTIONS:
In the handling of the suture and any other suture-like material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage.
The superficial placement of this device may lead to visual or palpable identification or extrusion. Some devices may require removal prior to their absorption due to discomfort, infection, reaction or other concerns.

Inform the patient that this is not a permanent implant and the effects in correcting facial sagging are temporary.

ADVERSE REACTIONS:
Include minimal acute inflammatory tissue reaction, pain and edema. Minimal swelling and bruising. Material sensitivity/ allergic reactions in patients following surgery should be reported. Implantation of foreign materials in tissue can result in histological reactions. Potential side effects include sensory nerve injury, asymmetry and banding.

RESORPTION PROFILE:
Preclinical studies demonstrate that tissue in growth is evidenced as early as 30 days post-implantation with encapsulation of the device in collagen at 30 days. The suture shows no absorption at 91 days, at a time when the device is encapsulated in collagen. Localized partial absorption of the suture starts at 181 days post-implantation. At 364 days the cones show evidence of very early degradation.

CLINICAL STUDY:
A prospective, clinical study was performed to assess treatment with Silhouette Instalift without use of a permanent, monofilament, anchor suture. In this study, 20 subjects were assessed pretreatment, and compared to 1, 8, and 12 weeks following treatment.
Subjects responded positively to subject-reported outcomes questions regarding their satisfaction with treatment. the FACE-Q Patient Reported Outcome Measures tool was used to assess patient feedback. Cheek satisfaction scores at 8 weeks and 12 weeks, as well as age appraisal scores through 12 weeks post-treatment showed improvement.
Canfield 3D Vectra M3 Face and Neck System was used in the post-treatment period to measure clinical results. The adverse events reported during the study were generally mild, or short duration, and resolved without sequelae. There were no serious adverse events, unanticipated problems, unanticipated adverse device effects, or deaths.

STORAGE INSTRUCTIONS:
Store between 0˚C and 8˚C in a dry place out of direct sunlight. Do not use beyond listed expiration date on package.

MRI SAFETY INFORMATION:
The Silhouette Instalift is MR Safe.

HOW SUPPLIED:
Silhouette sutures are supplied in packs of 2 sutures.

SILHOUETTE INSTALIFT™

Made in USA