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
SMS 31-PLG-3.0.1-NA

Instructions for Use

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SYMBOLS USED ON LABELING:

	Catalogue number
	Expiry Date
	Date of Manufacture
	Batch Number
	Legal Manufacturer
	Warning
	Consult Instructions for Use
	Sterilized using Ethylene Oxide
	Keep away from sunlight
	Minimum and Maximum storage temperature
	Do not re-sterilize
	Single use only
	Do not use if package is damaged
	Keep Dry
	Magnetic Resonance safe
	Serial number
	Medical Device
Rx ONLY	Caution: United States Federal law restricts this device to sale by or on the order of a physician

WARNING: Only inner surface of Tyvek pouch is sterile.
Do not introduce pouch into sterile field.

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:
This device is intended to be used by trained healthcare practitioners in adult patients (over 18) whom are not pregnant or breast-feeding and are deemed appropriate for treatment by the healthcare practitioner.
Silhouette Instalift is an implantable suspension suture for facial tissue lifting with resorbable cones. It is a 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 PLGA resin (100% Poly (L-lactide-co-glycolide) (co-monomer ratio: L-Lactide =82mol%: glycolide=18mol%). The 30 centimeter suture (-± 10 %) (SMS 28-PLG-3.0.1- NA), 27.5 centimeter suture (-± 10 %) (SMS 29-PLG-3.0.1-NA and SMS 31-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 stainless steel 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)

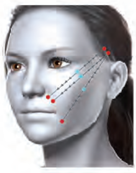

Figure 2. Anesthetic points

Figure 3. Entry point of needle

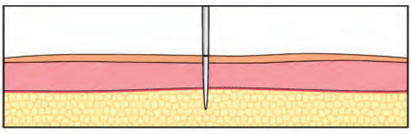

Figure 4. The first 23G/12 centimeter long needle is inside the tissue

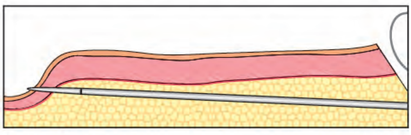

Figure 5. The first set of cones is inside the tissue

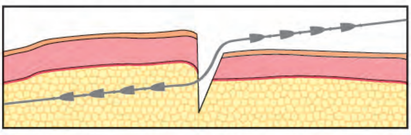

Figure 6. The second needle enters the tissue
from the same entry puncture

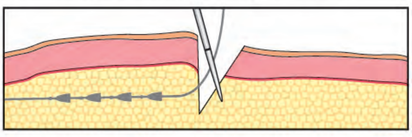

Figure 7. The second needle is inside the tissue

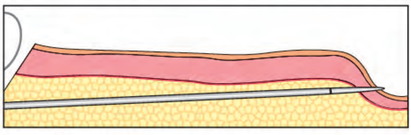

Figure 8. The second set of cones is implanted

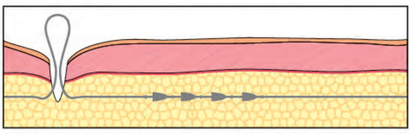

Figure 9. The whole Silhouette Instalift device is inside the tissue

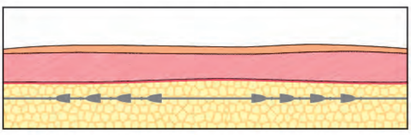

Figure 10. Compression of the soft tissue by the healthcare practitioner

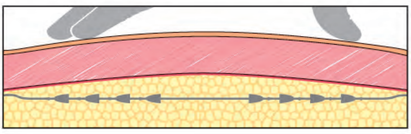

Figure 11. OPTIONAL: Anchor permanent monofilament suture to Instalift and fascia

CONTRAINDICATIONS:
Patients with foreign body sensitivity or known or suspected allergies to implant or instrument materials in particular plastic/biomaterial should not undergo the procedure. Patients appearing to have very thin soft tissue of the face in which the implant may be visible or palpable. Do NOT use in patients with active sepsis or infection, active (or history of) autoimmune disease, patients under 18 years of age, pregnant or breastfeeding women, or patients with limited ability or un- willingness to follow post- treatment recommendations.

WARNINGS:
In the handling of the suture and any other suture- like material, care should be taken to avoid damage from handling, if the device appears damaged prior to use, do not use. Avoid crushing or crimping damage. Too superficial placement of this device may lead to any of the adverse reactions detailed below. Too deep placement of the suture (e.g. in the muscle) can cause pain. Do not use if the packaging is damaged or open. Although the combination use of Silhouette with other aesthetic procedures has been reported in literature, the safety of such combination treatments has not been formally established. Some devices may require removal prior to their absorption due to discomfort, infection, reaction or other concerns

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.
Single use only. Re- use of this suspension suture may result in hazardous biocontamination resulting in severe injury to the patient. Do not re- sterilize. 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.

PRECAUTIONS:
The healthcare practitioner should be familiar with recommended techniques involving Silhouette Instalift as well as proper patient selection and device placement. Ensure procedure is carried out in a sterile environment. Knowledge of anatomy of the site to be treated and specific precautions are essential in order to avoid damage to fragile structures such as nerves and blood vessels. Patients with extensive skin laxity, thin skin and/or severe malar fat sagging are not good candidates for this procedure. Take extra precautions for patients with neurological conditions. Take extra care with patients who have bleeding disorders and with patients who are taking medications that inhibit blood clotting (e.g. vitamin E, acetylsalicylic acid and salicylic acid derivatives and nonsteroidal anti- inflammatory drugs).
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.

POST- TREATMENT RECOMMENDATIONS:
Apply cold packs immediately after procedure if required (cold packs should be wrapped to avoid direct contact with skin and insertion point). Take analgesia, e.g. paracetamol, in case of pain. Refrain from applying make- up for as long as possible (minimum 24 hours). Sleep face up, in an elevated position for 3- 5nights. Wash, shave and dry face gently without rubbing or massaging (5 days). Avoid excessive face and neck movements (2 weeks). Avoid over- exposure to direct sunlight and do not use tanning beds (2 weeks). Avoid high impact sports e.g. running (2 weeks). Do not use saunas and hammams (3 weeks). Avoid dental surgery (3 weeks). Avoid face and neck massages and facial aesthetic treatments (4 weeks).

ADVERSE REACTIONS:
Like all procedures of this type there is a possibility of adverse events, although not everybody experiences them. These adverse events may include but are not limited to: infection, inflammatory tissue reaction, pain (which may be temporary or persistent in nature), swelling and oedema, transient haematoma or bruising and transient rippling or dimple formation. Other potential adverse events include ecchymosis, sensory/motor nerve injury, asymmetry, banding, thread migrations, palpable cones and palpable thread ends/knots. Material sensitivity/allergic reactions in patients following surgery may occur. The onset of any adverse event must be reported immediately. Please contact the local Sinclair representative or authorised Silhouette distributor. Alternatively send the details to quality@sinclairpharma.com

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, of 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 ºC and 8 ºC 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.

CONTENTS OF THE CARTON:
SMS 28: 5 packs of SMS 28-PLG-3.0.1-NA (2 units), 5 x patient chart labels, 1 x Ruler, 1 x Instructions for Use.
SMS 29: 5 packs of SMS 29-PLG-3.0.1-NA (2 units), 5 x patient chart labels, 1 x Ruler, 1 x Instructions for Use.
SMS 30: 5 packs of SMS 30-PLG-3.0.1-NA (2 units), 5 x patient chart labels, 1 x Ruler, 1 x Instructions for Use.
SMS 31: 5 packs of SMS 31-PLG-3.0.1-NA (2 units), 5 x patient chart labels, 1 x Ruler, 1 x Instructions for Use.

If you have any complaints then please contact quality@sinclairpharma.com

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Made in USA