SILHOUETTE SOFT®

Summary of Safety and Clinical Performance (SSCP – Switzerland only)

SS.MDD.SSCP.01

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HEALTHCARE PROFESSIONAL SECTION

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of Silhouette Soft.

The SSCP is not intended to replace the Instructions for Use (IFU) as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals. Following this information there is a summary intended for patients.

1 IDENTIFICATION DEVICE AND MANUFACTURER

1.1 Trade Name

Silhouette Soft®

1.2 Legal Manufacturer

Sinclair Pharma US Inc., located at:

18 Technology Drive, Unit 134,
Irvine, California
92618, USA

1.3 Basic UDI-DI

8 cone suture: 506003304180991319192QU
12 cone suture: 50600330418099131919203Q3
12 cone suture (short spacing): 506003304180991319192 33QC
16 cones suture: 50600330418099131919223Q9

1.4 Medical device nomenclature

GMDN 46859, Lift thread, bioabsorbable

1.5 Classification

Medical Device Directive (MDD) 93/42/EEC (as amended) Annex IX, Medical Device Class III, Rule 8. Silhouette Soft is therefore a Medical Device Class III.

1.6 CE Marking

Silhouette Soft (SMS22, SMS23, SMS25) has been CE marked under MDD 93/42/EEC (as amended) since 2012 by Silhouette Lift Inc. now known as Sinclair Pharma US Inc. SMS 100 and SMS 102 were CE marked in 2018, and SMS 26 was CE marked in 2020. Sinclair Pharma US Inc. has been a subsidiary of Sinclair Pharma Ltd since 2014.

1.7 EU Authorised Representative

SINCLAIR FRANCE SAS located at:

8 Chemin du Jubin
69570 Dardilly
France

1.8 Swiss Authorised Representative

Sinclair Pharma GmbH located at:
Zweigniederlassung Gossau SG
Industriestrasse 149, 9200 Gossau SG

1.9 Notified Body

Szutest Uygunluk Degerlendirme A.S.,
Tatlisu Mah. Akif Inan Sk.
No: 1 Ümraniye-34774 Istanbul, Turkey

Notified body number: 2195

2 INTENDED USE OF THE DEVICE

2.1 Intended Purpose

Silhouette Soft is a resorbable sterile implantable single-use device intended to be used in adult patients for facial and neck reconstruction in the treatment of facial morphological asymmetry and ptosis, including but not limited to:

- Effects of facial ptosis or paralysis (e.g. Bell's palsy, benign or malignant tumours, iatrogenic injury, Varicella-zoster virus associated facial palsy, trauma, and congenital palsy).

- Morphological asymmetry (e.g. congenital anomalies, trauma to the face or the temporomandibular joint).

2.2 Indication

As per section 2.1, Intended Purpose.

2.2.1 Target Population

Silhouette Soft is intended to be used in adult patients (over 18) whom are not pregnant or breast feeding.

2.3 Contraindications

Refer to the IFU (available on request).

3 DEVICE DESCRIPTION

3.1 Device Description

Silhouette Soft is a resorbable implantable suspension suture for facial tissue lifting, consisting of a resorbable sterile monofilament of Poly L-Lactic Acid (PLLA) with molded cones made of resorbable material, Poly (L-lactide-co-glycolide) (PLGA).

Devices:
(Short product codes)

- SMS 22: 8 cones
- SMS 23: 12 cones
- SMS 25: 16 cones
- SMS 26: 12 cones (short space)
- SMS 100: Mixed pack 8 & 12 cones
- SMS 102: Small pack of 8 cones

3.2 Product History

Refer to section 1.6.

3.3 Accessories

There are no accessories supplied with Silhouette Soft. The needles required for implantation form part o of the device. The IFU recommends a pre-insertion is made with an 18G needle which is not supplied.

3.4 Combinations

Silhouette Soft is not required to be used in combination with any other device to meet its intended purpose. It is considered a stand-alone device.

4 RISKS and WARNINGS

4.1 Residual Risks and Undesirable Effects

The warning instructions supplied with the product have been applied with consideration of the user and following a comprehensive risk assessment carried out in accordance with the latest and relevant international standard, ISO 14971 and no residual risks remain.

Silhouette Soft devices have been deemed suitable for use in adults based on the safety profile of the products and their equivalents and the small numbers of adverse events (AE) associated with use. Any undesirable side-effect constitutes an acceptable risk when weighed against the performances intended.

4.1.1 Side Effects/ Adverse Events

Refer to the IFU (available on request).

4.2 Warnings and Precautions

4.2.1 Warnings

Refer to the IFU (available on request).

4.2.2 Precautions for Use

Refer to the IFU (available on request).

4.3 Field Safety Corrective Actions

There has been no FSCAs associated with the Silhouette Soft range of products.

5 SUMMARY OF CLINICAL EVALUATION

5.1 Summary of Clinical Data from Equivalent Devices

The data presented within the Clinical Evaluation Report (CER) is based on an analysis of available clinical literature and post market clinical data relevant to the intended use and the clinical experience of Silhouette Soft and/ or products with similar design characteristics.

Equivalent devices are identified from literature and detailed within the report, and are based on their clinical equivalence, critical attributes, technical and biological equivalence. Clinical studies on the identified devices demonstrated clinical efficacy, and safety and performance of the devices are confirmed.

5.2 Summary of Clinical data of the Device

Studies assessing the safety and performance of SS provide pivotal data supporting the device range. Summary information from the clinical study is shown in Table 1.

Table 1 Silhouette Soft Clinical Studies

Study	Procedure
Rezaee Khiabanloo et al. (2019) (n=193)	Eyebrow (n=24), Midface (n=65), Mandibular (n=89) Neck lifting (n=15) (minimum 6 months)
Guida et al. (2018) (n=20)	Mandibular lifting (12 months)
Demosthenous (2015) (n=1)	Morphological asymmetry secondary to Bell's palsy (minimum 3 months)

5.3 Overall summary of clinical performance

MDD requires an evaluation of safety and efficacy of the devices to be certified. The CER is performed based on MDD Annex X MEDDEV-Guideline 2.7/1. "Evaluation of Clinical Data".

Silhouette Soft has an acceptable benefit/risk profile according to current knowledge/ state of the art in the medical fields concerned and according to available medical alternatives. The clinical studies on SS in combination with the clinical studies of the equivalent devices have demonstrated safety and effectiveness.

5.4 Post Market Clinical Follow Up (PMCF)

The adverse event (AE) rate for Silhouette Soft is considered to be low and acceptable. The safety profile of Silhouette Soft is well established from post market surveillance activities. Further post market studies are in discussion.

6 THERAPEUTIC ALTERNATIVES

The patient benefits of suspension sutures are an improvement of impaired body function in the treatment of facial morphological asymmetry or ptosis (Menchetti et al. 2021, Cooper et al. 2017, Nash et al. 2010). Static suspension sutures enable subjects to re-establish facial symmetry and movement (Kim and Byrne, 2016) and have psychological benefits for individuals who have had their image and self-esteem markedly compromised (Perrone, 2012).

Silhouette Soft is intended to be used for facial reconstruction in the treatment of facial morphological asymmetry or ptosis. High levels of satisfaction associated with good levels of performance from both Silhouette Soft, for the treatment of eyebrow, midface, mandibular, and neck lifting were demonstrated after 6 months follow-up (Rezaee Khiabanloo et al. 2019). Also, volumising of the mandible (Guida et al. 2018) were demonstrated in case series assessing Silhouette Soft.

Silhouette Soft repositions sagging tissue by compressing the soft tissue in multiple axes (up and down and from left to right). This claim is based on the action of the bidirectional cones in the midface. The case series by Pizzamiglio (2011) concluded that Silhouette provides significant temporary lifting and volumising of the cheek area.

Silhouette Soft is suitable for tailored made treatment for correcting ptotic tissues around the mandible, neck, malar area and eyebrows. High levels of satisfaction associated with good levels of performance were demonstrated by Silhouette Soft, for the treatment of midface, mandibular, and neck lifting after 6 months follow-up (Rezaee Khiabanloo et al. 2019).

7 SUGGESTED PROFILE AND TRAINING FOR USERS

Silhouette Soft should only be used by medically trained healthcare professionals. The IFU states that 'The physician should be familiar with recommended techniques involving Silhouette Soft as well as proper patient selection and device placement'.

Additional training materials are available on request from Sinclair Pharmaceuticals Ltd.

8 APPLIED STANDARDS

Table 2 details the applied standards referenced for the device.

Table 2 Applied Standards

Standards
EN ISO 13485
EN ISO 15223-1
EN ISO 10993-3
EN ISO 10993-5
EN ISO 10993-7
EN ISO 10993-11
EN ISO 10993-12
EN ISO 10993-13
EN ISO 10993-17
EN 556-1
ISO 639-1
EN 1041
EN 10088-3
ISO 10993-1
EN ISO 10993-4
EN ISO 10993-6
EN ISO 10993-10
EN ISO 11607-1
EN ISO 11607-2
EN ISO 11135
EN ISO 11138-2
EN ISO 11737-1
EN ISO 11737-2
ISO 13781
EN ISO 14155
EN ISO 14630
EN ISO 14644-1
EN ISO 14644-2
EN ISO 14644-3
EN ISO 14698-2
EN ISO 14971
EN 62366-1
PD IEC/TR 62366-2
MEDDEV 2.4/1
MEDDEV 2.7/1
MEDDEV 2.12/1
MEDDEV 2.12/2
ICH Guidelines Q1A
ICH Guidelines Q1E
GHTF SG5/N2R8
Ph.Eur. 0666
ASTM-F88 /F88M
F899
ASTM-F1929
ASTM F2503
USP 43-NF 38 <861>
USP 43-NF 38 <871>
USP 43-NF 38 <881>
USP 43-NF 38 <71>
USP 43-NF 38 Monograph
USP 43-NF 38 <85>, <161>

9 CONCLUSION

Silhouette Soft has an acceptable benefit/risk profile according to current knowledge/the state of the art in the medical fields concerned and according to available medical alternatives. The clinical studies on Silhouette Soft and studies on equivalent devices have demonstrated safety and effectiveness.

The information supplied with the device is reflective of the safe and effective use in its intended applications, the intended purpose and risk reduction measures are adequate.

10 REFERENCES

Cooper L, Lui M, Nduka C. (2017) 'Botulinum toxin treatment for facial palsy: A systematic review'. *Journal of Plastic, Reconstructive and Aesthetic Surgery* 70(6), pp. 833-841.

Demosthenous N (2015) 'Treating a Bell's palsy patient'. *Aesthetics,* 2(90), pp. 33-35.

Guida S, Persechino F, Rubino G, Pellacani G, Farnetani F, Urtis GG. (2018) 'Improving mandibular contour: A pilot study for indication of PPLA traction thread use'. *J Cosmet Laser Ther.,* 20(7-8), pp. 465-469.

Kim L, Byrne PJ. (2016) 'Controversies in Contemporary Facial Reanimation'. *Facial Plast Surg Clin North Am.*, 24(3), pp. 275-97.

Menchetti I, McAllister K, Walker D, Donnan PT. (2021) 'Surgical interventions for the early management of Bell's palsy'. *The Cochrane Database of Systematic Reviews*. 1:Cd007468.

Nash JJ, Friedland DR, Boorsma KJ, Rhee JS. (2010) 'Management and outcomes of facial paralysis from intratemporal blunt trauma: a systematic review'. *The Laryngoscope.* 120 Suppl 4:S214-S214.

Perrone M. (2012) 'Use of triple-convergence polypropylene thread for the aesthetic correction of partial facial paralysis caused by facial nerve injury'. *Rev Col Bras Cir*., 39(5), pp. 368-372.

Pizzamiglio R, Hospital De Marbella, Spain (2011) 'Clinical use of Silhouette Soft Suture in the context of local workshops in Russia and Spain. Summary of results in a letter to the company and clinical reports of the 18 cases performed, started in December 2011.

Rezaee Khiabanloo S, Jebreili R, Aalipour E, et al. (2019) 'Outcomes in thread lift for face and neck: A study performed with Silhouette Soft and Promo Happy Lift double needle, innovative and classic techniques'. *J Cosmet Dermatol*. 00, pp.1–10 (e-pub ahead of print).