



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

MAILI.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 MaiLi.

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.

1 IDENTIFICATION DEVICE AND MANUFACTURER

1.1 Trade Name

MAILI

1.2 Legal Manufacturer

The Legal Manufacturer, is:

KYLANE LABORATOIRES SA located at:

Chemin Pré-Fleuri 1-3
CH-1228 Plan-Les-Ouates
Switzerland

The distributor for MaiLi is Sinclair Pharmaceuticals Ltd.

1.3 Medical device nomenclature

GMDN 47887, Dermal tissue reconstructive material, microbe-derived, anaesthetic

1.4 Classification

Medical Device Directive (MDD) 93/42/EEC (as amended) Annex IX, Medical Device Class III, Rule 8 & Rule 13. MaiLi is therefore a Medical Device Class III.

1.5 CE Marking

Under Annex IX of MDD this sterile crosslinked hyaluronic acid (HA) with lidocaine based medical device has been CE marked since 2020.

1.6 EU Authorised Representative

SINCLAIR FRANCE SAS located at:

8 Chemin du Jubin
69570 Dardilly
France

1.7 Notified Body

BSI Group The Netherlands B.V.

Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
NETHERLANDS

Notified body number: 2797

2 INTENDED USE OF THE DEVICE

2.1 Intended Purpose

MaiLi devices are intended for correction of facial wrinkles or folds, for the definition or enhancement of the lips, and for the restoration of enhancement of the facial volume.

2.2 Indication

As per section 2.1, Intended Purpose.

2.2.1 Target Population

MaiLi is intended to be used in adult patients whom are not pregnant or breast feeding.

2.3 Contraindications

Refer to the IFU (available on request).

3 DEVICE DESCRIPTION

3.1 Device Description

MaiLi is a sterile, transparent, and resorbing gel of cross-linked hyaluronic acid (injectable implant). The product is intended for single use only. Each device in the MaiLi family is designed for different application areas and/ or depths, consequently the devices are provided with the needle best suited for use in its intended application area.

The application areas are detailed in Table 1.

Table 1 Product Range Description

Product	Application areas
MALI PRECISE	For dermis or lips mucosa injection. Facial reconstruction of structural defects (congenital or medical origin) (scar tissue). Aesthetic treatment of fine lines, medium-sized skin depressions, lip definition or enhancement at the level of the face.
MAILI DEFINE	For deep dermis or lips mucosa injection. Facial reconstruction of structural defects (congenital or medical origin) (scar tissue). Aesthetic treatment of deep skin depressions, lip enhancement at the level of the face.
MAILI VOLUME MAILI EXTREME	For subcutaneous fat tissue injection or into the supraperiostic zone. Facial reconstruction of structural defects (congenital or medical origin) (volume lost by HIV-associated lipoatrophy). Aesthetic treatment of deep skin depressions at the level of the face, augmentation of the volume of facial tissue. *MAILI EXTREME is intended for aesthetic treatment of facial volume restoration.

**Maili Touch is not distributed by Sinclair*

Lidocaine is added to Maili to reduce pain resulting from injection during treatment. The hyaluronic acid has been cross-linked with butanediol diglycidyl ether (BDDE).

3.2 Product History

Refer to section 1.5.

3.3 Accessories

MaiLi Precise and Maili Define are supplied with 4 x 30G ½” needles and Maili Volume and Maili Extreme are supplied with 4 x 27G ½” needles. The needles supplied with MaiLi are CE-marked devices.

3.4 Combinations

MaiLi 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 international standard ISO 14971. After having implemented the risk control measures which enable to reduce the risks as low as possible and to an acceptable level, it does not remain any unacceptable and major risk, and the residual risk is acceptable for the use of MaiLi in its intended use, when the device is used according to the IFU.

MaiLi 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.

4.2 Warnings and Precautions

4.2.1 Warnings

Refer to the IFU.

4.2.2 Precautions for Use

Refer to the IFU

4.3 Field Safety Corrective Action (FSCA) / Field Safety Notice (FSN)

MaiLi has not been the subject of any FSCA's or FSN's to date.

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 MaiLi and/ or products with similar design characteristics.

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

Study assessing the safety and performance of MaiLi provide pivotal data supporting the device range. Summary information from the clinical study is shown in Table 2.

Table 2 MaiLi Clinical Study

Study (n)	Products	Duration of Effect
Conducted by Kylane Laboratoires SA (n=50)	MaiLi in a comparative study	Clinical study on the safety and effectiveness of MaiLi (12 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".

The benefit of MaiLi is to correct facial wrinkles or folds, for definition or enhancement of the lips, and for restoration or enhancement of facial volume. Lidocaine is added to reduce pain resulting from injection during treatment.

MaiLi 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 study on MaiLi in combination with the clinical studies of the equivalent devices have demonstrated safety and effectiveness.

5.4 Post Market Clinical Follow Up

The adverse event (AE) rate for MaiLi is considered to be low and acceptable. The safety profile and performance of Lidocaine used within MaiLi is well established. Further post market studies are planned.

6 THERAPEUTIC ALTERNATIVES

6.1 Age related volume loss

Dermal filler is a minimally invasive technique that offers a non-permanent alternative to more permanent fillers, laser treatments, or more involved surgical procedures. Dermal fillers, and injectable medical devices are commonly used for facial rejuvenation. Most dermal fillers are passive space filling agents and can be used in facial augmentation, whether used solely or combined (Sherman, 2009).

Since the introduction of the first dermal fillers to the USA in 1981, the practice of minimally invasive facial rejuvenation has grown exponentially. In 2010, US physicians performed more than 1 million injectable HA treatments alone (Breithaupt et al. 2012).

Fillers can also be classified according to their mechanism of action: volumisers i.e., Volume fillers and stimulators i.e., tissue stimulating agents. Volumisers increase volume and fill out skin directly. Stimulators can also directly create volume but also stimulate a long-term or permanent collagen deposition. Some fillers exhibit both actions and fall into both categories.

6.2 HIV Facial lipoatrophy

HIV-associated lipoatrophy affects 40-80% of patients treated with first-generation antiretroviral drugs and still affects a considerable number of HIV-infected patients. The condition is characterized by redistribution of fat with lipoatrophy of the face, arms, and legs and/or central truncal lipohypertrophy of the abdomen, thorax and dorsocervical areas, respectively. The most stigmatizing aspects of HIV-associated lipoatrophy are the cosmetically disfiguring changes affecting facial appearance and leading decreased quality of life, diminished self-esteem, and progressive social withdrawal; occasionally, these changes contribute to a reduction in patients' adherence to antiretroviral therapy, therefore seriously endangering their health. Treatment strategies for HIV-associated facial lipoatrophy include soft tissue augmentation procedures performed using autologous fat grafting or injectable dermal fillers (Becker, 2015).

HA soft-tissue fillers have a lower incidence of adverse events compared with permanent fillers given that the recovery process of adipose tissue continues after antiretroviral treatment has been modified, which could result in an overcorrection of the lipoatrophic area if permanent fillers were used. A study was conducted to evaluate the long-term efficacy and safety of HA filler that can be injected in patients into deeper skin layers during 3 years of follow-up. The treatment effects were evaluated using ultrasound, the Global Aesthetic Improvement Scale, visual analogue scale (VAS) and the Rosenberg self-esteem scale. The results indicated that the hyaluronic acid product is a durable and well-tolerated dermal filler for treating HIV-positive patients with facial lipoatrophy (Skeie et al. 2010).

The relevance of an appearance improvement in patients suffering from serious diseases complicated by facial fat wasting is viewed as significant supported by the results of quality-of-life questionnaires in clinical studies. Social isolation and low self-acceptance may cause depression. Decreased quality of life associated with lipodystrophy may lead to rejection of therapy by patients. HIV-associated lipodystrophy constitutes a threat to human health and life. Applying an optimal method of treatment reduces the stigma associated with facial lipodystrophy and significantly improves patients' quality of life (Szczerkowska-Dobosz et al. 2015).

6.3 Atrophic Scars

The treatment of atrophic scars is difficult and dermal filler materials provide a simple alternative with immediate results (Hasson, 2010). Scar formation is an inevitable result of surgery and trauma that results in full thickness epidermal loss (Shilpa et al. 2016).

Acne scars are present in 95% of patients with acne and can cause profound psychosocial morbidity. Fillers are commonly used for facial soft tissue augmentation, and there is increasing interest in their use for the treatment of acne scars, particularly for the atrophic subtype. The evidence for the use of temporary, semi-permanent and permanent fillers for acne scars have been investigated following four studies associated with the use of HA fillers in acne scarring. All studies demonstrated improvement in acne scar appearance with minimal or transient side effects (Forbat, 2017).

The management of acne scarring includes various types of resurfacing (chemical peels, lasers, dermabrasion); use of injectable fillers; and surgical methods. Different factors, e.g., colour, texture, and morphology, can affect the treatment choice for each individual scar. Injectable filler injections used for atrophic scars are indicated to improve the appearance of acne scars. Collagen, autologous fat transfer, and artificial injectable fillers are the most commonly used fillers. Their effect lasts from three to 18 months, depending on the type of filler used (Abdel Hay et al. 2016).

7 SUGGESTED PROFILE AND TRAINING FOR USERS

MaiLi should only be used by an authorized health care professional in accordance with the local legislation. The IFU states 'The health care professional shall have a deep knowledge of the anatomy of the area to be treated and shall be used to perform similar intervention (i.e., cross-linked HA injection in the face area).

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

8 APPLIED STANDARDS

Table 3 details the applied standards referenced for the device.

Table 3 Applied Standards

Standard Identification
EN 556-1
EN 1041
EN ISO 10993-1
EN ISO 10993-3
EN ISO 10993-5
EN ISO 10993-6
EN ISO 10993-9
EN ISO 10993-10
EN ISO 10993-11
EN ISO 10993-12
EN ISO 10993-16
EN ISO 10993-17
EN ISO 10993-18
EN ISO 11607-1
EN ISO 11737-1
EN ISO 13485
EN ISO 14155
EN ISO 14630
EN ISO 14644-1
EN ISO 14971
EN ISO 15223-1
EN ISO 17665-1
EN ISO 80369-7
ISO 639-1
ASTM F1980
ASTM D4169
ASTM D4332

9 CONCLUSION

MaiLi 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 study on MaiLi 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

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