SECTION B: SSCP FOR PATIENTS

A Summary of the Safety and Clinical Performance (SSCP) of the device, intended for patients, is given below:

Manufacturer's reference number for the SSCP: **FASY MDR 22-073**

Summary of safety and clinical performance Document revision: **Version 1**

Date issued: **2023/03/20**

This summary of safety and clinical performance is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of ESTYME® / Precise - HA Filler devices. The information presented below is intended for patients or lay persons. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document. The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions For Use to provide information on the safe use of the device.

1 DEVICE IDENTIFICATION AND GENERAL INFORMATION

1.1 DEVICE TRADE NAMES

The device trade names are **ESTYME®** and **Precise - HA Filler**

TRADE NAME	CATALOGUE NUMBER	BOX COMPOSITION
ESTYME® SMOOTH	SMOO1-300	1 blister / box including 1 injection device and 2 needles per blister.
	SMOO1-301	1 blister / box including 1 injection device and 2 needles per blister.
	SMOO2-300	2 blisters / box including 1 injection device and 2 needles per blister.
	SMOO2-301	2 blisters / box including 1 injection device and 2 needles per blister.
ESTYME® LIPS	LIPS1-300	1 blister / box including 1 injection device and 2 needles per blister.
	LIPS1-301	1 blister / box including 1 injection device and 2 needles per blister.
	LIPS2-300	2 blisters / box including 1 injection device and 2 needles per blister.
	LIPS2-301	2 blisters / box including 1 injection device and 2 needles per blister.
ESTYME® SCULPT	SCUL1-300	1 blister / box including 1 injection device and 2 needles per blister.
	SCUL1-301	1 blister / box including 1 injection device and 2 needles per blister.
	SCUL2-300	2 blisters / box including 1 injection device and 2 needles per blister.
	SCUL2-301	2 blisters / box including 1 injection device and 2 needles per blister.
ESTYME® LIFT	LIFT1-300	1 blister / box including 1 injection device and 2 needles per blister.
	LIFT1-301	1 blister / box including 1 injection device and 2 needles per blister.
	LIFT2-300	2 blisters / box including 1 injection device and 2 needles per blister.
	LIFT2-301	2 blisters / box including 1 injection device and 2 needles per blister.
PRECISE-HA Filler EYE	401012	2 blisters / box including 1 injection device and 2 needles per blister.
PRECISE-HA Filler SOFTEN	401005	2 blisters / box including 1 injection device and 2 needles per blister.
PRECISE-HA Filler LIPS	401010	2 blisters / box including 1 injection device and 2 needles per blister.
PRECISE-HA Filler SCULPT	401008	2 blisters / box including 1 injection device and 2 needles per blister.
PRECISE-HA Filler SMOOTH	401001	2 blisters / box including 1 injection device and 2 needles per blister.
Related to ESTYME® devices, the catalogue numbers **XXXXX-300** are available in English, Spanish, Portuguese, Turkish and Arabic, while the catalogue numbers **XXXXX-301** are available in English, French, German, Italian, Dutch and Greek.		

Trade names and catalogue numbers

1.2 MANUFACTURER; NAME AND ADDRESS

SYMATESE SAS
ZI LES TROQUES
69630 CHAPONOST – France

1.3 BASIC UDI-DI

Trade name	BASIC UDI -DI [1]
ESTYME® SMOOTH PRECISE-HA Filler SOFTEN	**376017216PPFASYSMS**
ESTYME® LIPS PRECISE-HA Filler LIPS	**376017216PPFASYLMC**
ESTYME® SCULPT PRECISE-HA Filler SCULPT	**376017216PPFASYXF3N**

[1] The Basic UDI-DI is the primary identifier of a device model. It is the device identifier assigned at the level of the device unit of use. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity.

ESTYME® LIFT PRECISE-HA Filler SMOOTH	**376017216PPFASYFLY**
PRECISE-HA Filler EYE	**376017216PPFASYPML**

BASIC UDI-Dis

ESTYME® LIFT and **Precise - HA Filler SMOOTH** are identical devices.
ESTYME® LIPS and **Precise - HA Filler LIPS** are identical devices different.
ESTYME® SMOOTH and **Precise - HA Filler SOFTEN** are identical devices.
ESTYME® SCULPT and **Precise - HA Filler SCULPT** are identical devices.

1.4 YEAR WHEN THE DEVICE WAS FIRST CE-MARKED

ESTYME® LIFT: not applicable under Medical Device Regulation (EU) 2017/745. *
ESTYME® LIPS: not applicable.
ESTYME® SMOOTH: not applicable.
ESTYME® SCULPT: not applicable.
Precise - HA Filler SMOOTH: not applicable under Medical Device Regulation (EU) 2017/745. *
Precise - HA Filler LIPS: not applicable.
Precise - HA Filler SOFTEN: not applicable.
Precise - HA Filler SCULPT: not applicable.
Precise - HA Filler EYE: not applicable.

CE marked[2] in January 2021 under Medical Device Directive (93/42/EEC) for the brand name **ESTYME® LIFT and **PRECISE-HA Filler LIFT** (renamed as **Precise - HA Filler SMOOTH**).*

2 INTENDED USE OF THE DEVICE

2.1 INTENDED PURPOSE

ESTYME® and **Precise - HA Filler** devices are intended for non-medical use only.
ESTYME® and **Precise** - HA Filler devices are intended to modify the skin anatomy and facial appearance.

2.2 INDICATIONS AND INTENDED PATIENT GROUPS

ESTYME® LIFT and **Precise - HA Filler SMOOTH** are indicated to correct nasolabial folds.
ESTYME® LIFT and **Precise - HA Filler SMOOTH** are injected into dermis to hypodermis.

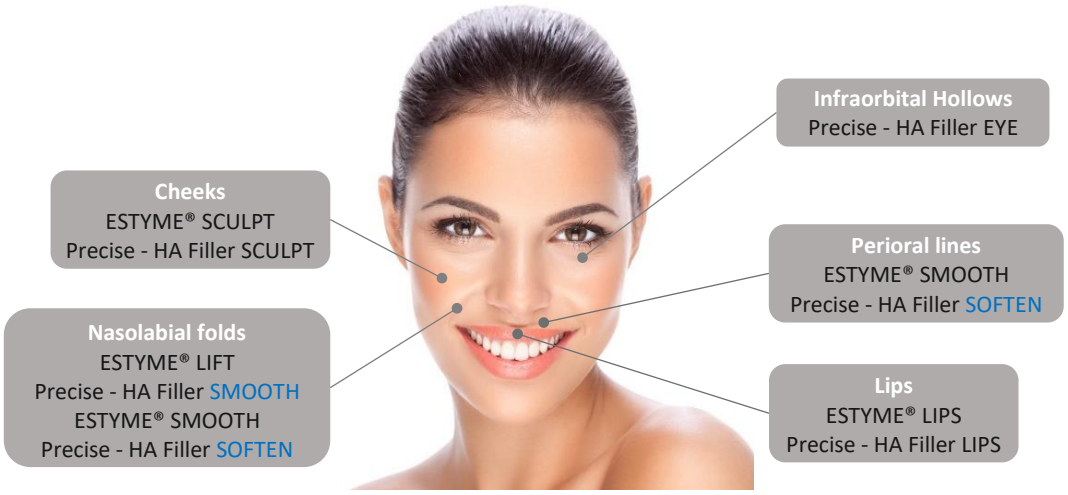
ESTYME® LIPS and **Precise - HA Filler LIPS** are indicated to correct the volume and the shape of the lips.
ESTYME® LIPS and **Precise - HA Filler LIPS** are injected into dermis, hypodermis and labial mucosa.

ESTYME® SMOOTH and **Precise - HA Filler SOFTEN** are indicated to correct nasolabial folds and perioral lines.
ESTYME® SMOOTH and **Precise - HA Filler SOFTEN** are injected into dermis to hypodermis.

ESTYME® SCULPT and **Precise - HA Filler SCULPT** are indicated to restore cheek volume loss.
ESTYME® SCULPT and **Precise - HA Filler SCULPT** are injected into hypodermis and supraperiosteal.

Precise - HA Filler EYE is indicated to correct infraorbital hollows.
Precise - HA Filler EYE is injected into dermis to hypodermis and supraperiosteal.

[2] The CE mark on a product indicates that the manufacturer or importer of that product affirms its compliance with the relevant EU legislation and the product may be sold anywhere in the European Economic Area.



*Injection areas of **ESTYME® /Precise - HA Filler** range*

2.3 CONTRAINDICATIONS

ESTYME® /Precise - HA Filler range is contraindicated in:

- Minors.
- Subjects with a known allergy to hyaluronic acid, lidocaine or amide local anesthetics.
- Subjects with porphyria[3].
- Subjects with an autoimmune disorder[4], or using an immunosuppressant medication[5].
- Pregnant or breastfeeding women.
- Subjects with inflammation, infection or cutaneous disorders at the treatment site or nearby (herpes, acne, etc.).
- Subjects with bleeding disorders or in patients receiving thrombolytic[6] or anticoagulant[7] treatment.
- Areas other than those recommended in the intended use.

3 DEVICE DESCRIPTION

3.1 DEVICE DESCRIPTION AND MATERIAL/SUBSTANCES IN CONTACT WITH PATIENT TISSUES

ESTYME® / Precise - HA Filler devices contain a sterile gel in an injection device. The injectable gel is based on hyaluronic acid, crosslinked with 1,4-butanediol diglycidyl ether (BDDE), containing viscous non-crosslinked hyaluronic acid and lidocaine, packed in a 1 mL plastic syringe and supplied with two ultra-thin needles.
The components of the gel are:

- Sodium hyaluronate (crosslinked[8] and not crosslinked)
- Lidocaine
- Sodium chloride
- Sodium dihydrogeno phosphate dihydrate
- Disodium phosphate dihydrate
- Water for Injection

[3] Porphyria is a group of liver disorders in which substances called porphyrins build up in the body, negatively affecting the skin or nervous system.
[4] Condition in which the body's immune system mistakes its own healthy tissues as foreign and attacks them.
[5] Agent that decreases the body's immune responses.
[6] Thrombolytic therapy is the use of drugs to break up or dissolve blood clots, which are the main cause of both heart attacks and stroke.
[7] Anticoagulants are medicines that help prevent blood clots.
[8] Chemical bond formed between adjacent chains of a complex molecule such as a polymer.

The gel in the syringe is sterilized by moist heat (air/steam mixture) and the registered needles supplied are sterilized by radiation.
ESTYME® / **Precise - HA Filler** are single-use devices that are intended to be used on one individual during a single procedure.

3.2 INFORMATION ABOUT MEDICINAL SUBSTANCES IN THE DEVICE, IF ANY

The **ESTYME®** / **Precise - HA Filler** devices contain lidocaine hydrochloride (3 mg/mL) It is added in order to reduce pain and improve comfort during and post injection.

3.3 DESCRIPTION OF HOW THE DEVICE IS ACHIEVING ITS INTENDED MODE OF ACTION

ESTYME® and **Precise - HA Filler** devices act by adding volume to the tissue, thereby restoring the skin contours, the volume and shape of face to the desired level. The volume and structuring capacity originate from the ability of the cross-linked hyaluronic acid gel to hold its shape in the tissue, thus maintaining over time the volume and projection obtained at injection. The duration of effect depends on the area treated, the depth of injection, individual factors and injected volume. Overall, the maximum expected lifetime is 18 months for **ESTYME®** / **Precise - HA Filler devices.** The syringe ensures that the gel remains sterile during storage, and serves for injection when used with the needles supplied or compatible cannulas.

3.4 DESCRIPTION OF ACCESSORIES

ESTYME® / **Precise - HA Filler** do not include any accessories**.**

4 RISKS AND WARNINGS

Contact your healthcare professional if you believe that you are experiencing side effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

4.1 HOW POTENTIAL RISKS HAVE BEEN CONTROLLED OR MANAGED

According to the manufacturer's risk assessment process, the actions taken by the manufacturer to mitigate any identified risks do not impact the patient safety.

The main method of mitigation is the design control of the device, validation of usability of the device to the foreseeable use errors, manufacturing controls and then the information provided to the user (labelling, instruction for use, …).

4.2 REMAINING RISKS AND UNDESIRABLE EFFECTS

According to SYMATESE policy the residual risks have been identified, reduced as far as possible. These residual risks are all considered as acceptable under normal conditions of use, which is consistent with a high level of protection for the safety and health of persons. This is in accordance with the state of science and medical knowledge.

Based on clinical investigations, the adverse events related to **ESTYME®** / **Precise - HA Filler** range are minor, reversible and similar to other hyaluronic filler available on the market.

The following adverse events have been reported with regard to hyaluronic acid fillers by the state of science and medical knowledge: acne, bleeding, bruising /[9] hematoma /ecchymosis /contusion, capillary disorders

[9] The "/" between two adverse events shows that these adverse events have globally the same meaning.

/telangiectasia[10], capsule formation[11] /contracture, compartment pressure problems /compartment syndrome[12], discoloration, discomfort or pain /tenderness, dryness /xerosis, erosion /exfoliation, erythema /redness, eyes disorders /vision disorder /blindness, facial asymmetry, granuloma[13], headache, induration[14] /firmness, infection /folliculitis, inflammation, interruption of wound healing, ischemia[15] /necrosis, mass /lumps /bumps /nodules /irregularities, migration of the device, muscle tightness /twitching, needle track marks, nerve injury, numbness /paraesthesia[16] /anaesthesia /hypoesthesia[17], pruritus /itching, rosacea[18], scarring /scar hyperpigmentation and hypertrophy[19], sensation of foreign body /burning sensation /hyperaesthesia[20], seroma[21], severe allergic reaction /hypersensitivity /angioedema[22] /rash[23], superficial wound, swelling /oedema /lymphadenopathy[24], syncope /dizziness, Tyndall effect[25], vascular damage /vascular compromise, vesicles[26], warmth.

4.3 WARNINGS AND PRECAUTIONS

- **ESTYME® / Precise - HA Filler** devices are not recommended for use in subject with an active or history of streptococcal diseases[27].
- No device other than hyaluronic acid must be implanted in the area to be treated.
- The gel must not be mixed with other products.
- The gel must not be injected into or next to blood vessels. This could lead to vascular[28] occlusion or compression, ischemia[29] or necrosis[30]. An unintended intravascular administration can cause high blood concentrations and acute central nervous system and cardiovascular toxic symptoms. Ensure that an appropriate recovery procedure is in place in case of vascular issues.
- The product must never be used:
  - After the expiry date indicated on the packaging.
  - If the packaging is damaged.
  - If the gel looks blurry or cloudy. The gel must be colorless.
- Sterility is not guaranteed in the event of reuse or re-sterilization. This may result in the contamination and/or deterioration of the gel, thus reducing its performance.

Subjects must be evaluated based on their medical history and informed as to the foreseeable outcome of the treatment and potential adverse effects. After evaluating the compatibility of the subject's specific medical treatments with the injection procedure, the practitioner must inform the subject as to potential adverse events relating to their treatment. Injection procedures can lead to the reactivation of latent or subclinical herpes virus infections.

[10] Small dilated blood vessel that can occur near the surface of the skin or mucous membranes.
[11] Formation of a scar tissue around the implant.
[12]Increase in pressure inside a muscle, which restricts blood flow and causes pain.
[13] Small inflammatory vascular injury or tumor or various forms of cell clusters that appear on the skin.
[14] Hardening of biological tissue.
[15] Restriction in blood supply to any biological tissue, causing a shortage of oxygen that is needed to keep tissue alive.
[16] Abnormal sensation of the skin.
[17] Reduced sense of touch or sensation.
[18] Long-term skin condition that typically affects the face, resulting in redness, pimples, swelling, and small dilated blood vessels.
[19] Increase in the volume of a tissue.
[20] Abnormal increase in sensitivity to stimuli of the sense.
[21] Pocket of clear serous fluid.
[22] Area of swelling of the lower layer of skin and tissue just under the skin.
[23] Change of the human skin which affects its color, appearance, or texture.
[24] Disease of the lymph nodes, in which they are abnormal in size or consistency.
[25] Skin takes on a bluish tone.
[26] Small blister.
[27] A streptococcal disease is caused by streptococci, Gram-positive bacteria which cause diverse human diseases.
[28] Relating to, affecting, or consisting of a vessel or vessels, especially those which carry blood.
[29] Condition in which the blood flow (and thus oxygen) is restricted or reduced in a part of the body.
[30] Necrosis is the death of body tissue.

Special precautions and knowledge of the anatomy of the treatment site is necessary in order to prevent the perforation or compression of blood vessels, nerves and vulnerable structures.

Special precautions must be taken with subjects:

- With unattainable expectations.
- With diabetes, epilepsy, impaired cardiac conduction, severely impaired hepatic function or severe renal dysfunction.
- On whom another treatment based on an active dermal response has been already applied in the area to be treated.
- With a tendency to form keloid[31] or hypertrophic scars[32], or with pigmentation disorders or any other scarring disorders.
- Having received chemotherapy agents or systemic corticosteroids in the three months prior to injection.

The safety for use in sites in the presence of other implants (including permanent implants) has not been studied.
The gel should not be injected too superficially as this may result in visible lumps and/or bluish discoloration.
It is recommended that the practitioner considers any previous procedures, accidents, conditions, medications or other simultaneous treatments of the consumer that may affect the procedure.
The practitioner shall enquire how and when new injections can be placed at previously injected locations.
The practitioner must follow aseptic techniques to prevent the risks of infection inherent in all intradermal injections.
Due to incompatibility with hyaluronic acid, it is recommended to not use quaternary ammonium salts to disinfect the skin.
There is an increased risk of ischemia in areas with limited collateral circulation; these areas should be treated with caution.
The practitioner must use the device with caution in facial areas with limited soft tissue support or soft tissue cover, in order to avoid the formation of palpable lumps/bumps.

As **ESTYME® / Precise - HA Filler** gels contain lidocaine, the practitioner must consider the total dose of lidocaine administered if the subject is using a device or medicinal treatment that delivers lidocaine, as the systemic toxic effects can be additive. High doses of lidocaine (more than 200 mg/day) can cause acute toxic reactions manifesting as symptoms affecting the central nervous system and cardiac conduction.

No more than 10 mL **ESTYME®/ Precise - HA Filler** devices per session shall be injected to a patient, with a maximum of 2 treatment sessions annually. The injection volume per session is dependent upon the correction required and the area to be treated. For **ESTYME® LIPS / Precise - HA Filler LIPS**, it is advised that no more than 2 mL should be injected in lips during a session. For **PRECISE-HA Filler EYE**, it is advised that no more than 1 mL should be injected in the treatment area during one session It is important to not overcorrect (overfill).

If laser treatment, chemical peeling or any other procedure based on active dermal response is considered after treatment with **ESTYME® / Precise - HA Filler** devices there is a theoretical risk of eliciting an inflammatory reaction at the implant site. This also applies if **ESTYME® / Precise - HA Filler** devices are administered before the skin has healed completely after such a procedure.

The subject must be informed of post-injection care. In the event of local inflammation, the subject must avoid extreme temperature conditions (intense cold, sauna, etc.) until any signs have disappeared.

It is recommended to the practitioner to proceed with a post-administration monitoring time in order to identify any potential undesirable side-effects.

[31] Keloid, also known as keloid disorder and keloidal scar, is the formation of a type of scar.
[32] A hypertrophic scar is a thick raised scar.

Considering the composition of ESTYME® / Precise - HA Filler there is no warning, precaution and/or measure to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures.

4.4 SUMMARY OF ANY FIELD SAFETY CORRECTIVE ACTION, (FSCA INCLUDING FSN) IF APPLICABLE

Not applicable.

5 SUMMARY OF CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP

5.1 CLINICAL BACKGROUND OF THE DEVICE

Almost all products having moisturizing, skin protective, and anti-aging properties consists of hyaluronic acid. It has been acknowledged for its ability to replenish moisture in the skin. The water holding ability of hyaluronic acid results in softer, smoother, and radiant skin. The hydration of the skin also leads to slow down the wrinkles formation and improves deep fine lines and already developed wrinkles which generally appears with age. The skin hydration and antioxidant effects of HA also promote cell regeneration and stimulate production of collagen due to its nutricosmetic effects. There are various products of hyaluronic acid being used as dermal filler for cosmetic procedure. Hyaluronic acid is non-toxic and non-sensitizing; therefore, it is safely used for all types of skin with no risk of allergic reactions. This naturally-occurring biomolecule has commonly been used to inject into the skin (as dermal filler) to restore skin volume and minimize the appearance of wrinkles. They are specifically injected into skin folds, deep wrinkles to lift and reshape the face due to its unique characteristics that mimic the natural materials found in our cells. Hyaluronic acid based dermal fillers require very minimal downtime and show immediate results, subtle enough to be the most comfortable rejuvenation technique among available anti-ageing treatment. One clear advantage of hyaluronic acid is their temporary nature, as over time, they will get degraded. They also may be rapidly degraded by hyaluronidase in the event of complications.

5.2 THE CLINICAL EVIDENCE FOR THE CE-MARKING

During clinical studies, **ESTYME® / Precise - HA Filler** devices were used in 272 subjects for modifying the skin anatomy and appearance in different specific areas of the face. Significant positive outcomes were observed by the evaluator and the subject from injection to 9 or 12 months. 3D imaging was applied in three clinical investigations which confirming the effect and the stability of the devices over time. Some adverse device events[33] were observed. All are minor, reversible and similar to other hyaluronic fillers available on the market. These data **support the use of ESTYME® / Precise - HA Filler range for modifying the skin anatomy and facial appearance**.

5.3 SAFETY

ESTYME® / **Precise - HA Filler** devices are intended to produce, in a safety way a perceptible modification of the anatomy of facial skin, resulting an improvement in the visual appearance. This leads to subject's satisfaction, increase of self-esteem and self-confidence, ultimately improving subject's quality of life.

Undesirable side effects identified by the clinical studies on **ESTYME®** / **Precise - HA Filler** devices, correspond to those found in the literature as well as those listed in the risk assessment. They are acceptable under normal conditions of use, which is consistent with a high level of protection for the safety and health of persons.

[33] Adverse device event is an adverse event related to the use of a device.

Considering that adverse events reported by the **ESTYME® / Precise - HA Filler** range are minor, reversible and comparable to similar devices used in the same indications, it may be concluded that **ESTYME® / Precise - HA Filler range has an excellent safety profile to modify the skin anatomy and facial appearance**.

In order to confirm these data, SYMATESE decided to proactively generate clinical data and thus reinforce performance and safety information. Post-market clinical investigations are planned.

6 POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

General description of therapeutic alternatives

Hyaluronic acid is the most commonly used dermal fillers for modifying the skin anatomy and facial appearance. For subjects requiring extensive facial changes, surgical procedure seems more adapted.

7 SUGGESTED TRAINING FOR USERS

Not applicable. ESTYME® / Precise - HA Filler devices are not intended to be handled directly by the subject.