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 24-006**

Summary of safety and clinical performance Document revision: **Rev0**

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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 **Precise - HA Filler EYE**. 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 name is **Precise - HA Filler EYE**

TRADE NAME	CATALOGUE NUMBER	BOX COMPOSITION
PRECISE-HA Filler EYE	401012	2 blisters / box including 1 injection device and 2 needles per blister.

Trade name 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]
PRECISE-HA Filler EYE	**376017216PPFASYPML**

BASIC UDI-Di

1.4 YEAR WHEN THE DEVICE WAS FIRST CE-MARKED

Precise - HA Filler EYE: (under evaluation, this will be updated before upload to EUDAMED).

2 INTENDED USE OF THE DEVICE

2.1 INTENDED PURPOSE

Precise - HA Filler EYE is intended for non-medical use only.
Precise - HA Filler EYE is intended to modify the skin anatomy and facial appearance.

2.2 INDICATIONS AND INTENDED PATIENT GROUPS

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

[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.

*Injection area of **Precise - HA Filler EYE***

Precise - HA Filler EYE is used in adult subjects, excluding pregnant and breastfeeding women**.**
Precise - HA Filler EYE is not to be used in persons who are less than 18 years old.
Note that due to limited clinical data, caution should be exercised when envisaging to use Precise - HA Filler EYE on:

- Male
- Population aged from 18 to 29 years old and older than 69

2.3 CONTRAINDICATIONS

Precise - HA Filler EYE is contraindicated in:

- Minors.
- Subjects with a known allergy to hyaluronic acid, lidocaine or amide local anesthetics.
- Subjects with porphyria[2].
- Subjects with an autoimmune disorder[3], or using an immunosuppressant medication[4].
- Pregnant or breastfeeding women.
- Subjects with inflammation, infection or cutaneous disorders at the treatment site or nearby.
- Subjects with bleeding disorders or in patients receiving thrombolytic[5] or anticoagulant[6] 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

Precise - HA Filler EYE contains 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[7] and not crosslinked)
- Lidocaine

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

- Sodium chloride
- Sodium dihydrogeno phosphate dihydrate
- Disodium phosphate dihydrate
- Water for Injection

The gel in the syringe is sterilized by moist heat (air/steam mixture) and the registered needles supplied are sterilized by radiation.
Precise - HA Filler EYE is 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

Precise - HA Filler EYE contain lidocaine hydrochloride (3 mg/mL). It is added in order to reduce pain during and post injection procedure.

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

Precise - HA Filler EYE acts 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.

On average, with 0,5 mL injected of Precise - HA Filler EYE per ring in one session, between 68.4 and 71.9% of subjects are noticeably improved at 9 months (clinical study results obtained with the Global Aesthetic Improvement Scale).

According to the clinical investigation, the expected lifetime (duration of effect or time to loss stability) of **Precise - HA Filler EYE** is 12 months. The absorption time is comprised between 12 to 18 months according to clinical and preclinical outcomes.

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

Precise - HA Filler EYE does 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

Potential risks have been controlled or managed by mitigation methods, the main ones being 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.
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.

4.2 REMAINING RISKS AND UNDESIRABLE EFFECTS

According to SYMATESE policy the residual risks have been identified, reduced as far as possible. 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 with the labelling, instruction for use and training. 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.

Hyaluronic acid based dermal fillers cause some adverse effects related to the device or the procedure. Most of them are injection site reactions (ISR). These reactions are common, expected and generally resolved spontaneously without sequala after a few hours or days without any treatment. Based on clinical investigations on **Precise - HA Filler EYE**, the most common ISRs with their occurrence probability are: redness (68.3%), pain/ tenderness (58.3%), bruising (51.7%), swelling (40.7%), Lumps/ bumps (22.0%), Induration/ firmness 18.3%), Itching (8.5%) and Discoloration (5.0%).

The adverse events are composed of ISRs which last longer than expected or require a corrective treatment, and non-local injection site complication related to the device or the procedure. The duration of these events varies from a few days to several months. Based on the clinical investigation on **Precise - HA Filler EYE**, the following adverse events related to the device or the procedure were reported with their rate of occurrence in the study population: injection site edema (3.3%), hematoma (1.7%), Tyndall effect[8] (1.7%) and headache (1.7%). These adverse events were minor, expected and common to other hyaluronic filler available on the market. No serious adverse event related to the device or the procedure was reported. In case of doubt or complication, patient should contact the healthcare professional to make a monitoring. Appropriate treatment is at the discretion of the healthcare professional and is in accordance with the laws of the territories.

The following adverse events have been reported with regard to hyaluronic acid fillers by the state of science and medical knowledge: abnormal hepatic function, acne, bleeding, bruising /[9] hematoma / ecchymosis / contusion, capillary disorders / telangiectasia[10], discoloration, discomfort or pain / tenderness, dryness / xerosis, erosion / exfoliation, erythema / redness, eyes disorders / vision disorder /blindness, facial asymmetry, granuloma[11], headache, hyperbilirubinaemia[12], induration[13] / firmness, infection / folliculitis, inflammation, ischemia[14] / necrosis, mass / lumps /bumps / nodules / irregularities, migration of the device, muscle tightness / twitching, needle track marks, nerve injury, numbness /paraesthesia[15] / anaesthesia / hypoesthesia[16], pruritus / itching, rosacea[17], scarring / scar hyperpigmentation and hypertrophy[18], sensation of foreign body / burning sensation / hyperaesthesia[19], seroma[20], severe allergic reaction / hypersensitivity / angioedema[21] / rash[22], superficial wound, swelling / oedema / lymphadenopathy[23], syncope /dizziness, Tyndall effect, vascular damage / vascular compromise, vesicles[24], warmth.

[8] The product is visible under the skin, which takes on a bluish tone.
[9] The "/" between two adverse events shows that these adverse events have globally the same meaning.
[10] Small dilated blood vessel that can occur near the surface of the skin or mucous membranes.
[11] Small inflammatory vascular injury or tumor or various forms of cell clusters that appear on the skin.
[12] Clinical condition describing an elevation of blood bilirubin level due to the inability to properly metabolize or excrete bilirubin, a product of erythrocytes breakdown
[13] Hardening of biological tissue.
[14] Restriction in blood supply to any biological tissue, causing a shortage of oxygen that is needed to keep tissue alive.
[15] Abnormal sensation of the skin.
[16] Reduced sense of touch or sensation.
[17] Long-term skin condition that typically affects the face, resulting in redness, pimples, swelling, and small dilated blood vessels.
[18] Increase in the volume of a tissue.
[19] Abnormal increase in sensitivity to stimuli of the sense.
[20] Pocket of clear serous fluid.
[21] Area of swelling of the lower layer of skin and tissue just under the skin.
[22] Change of the human skin which affects its color, appearance, or texture.
[23] Disease of the lymph nodes, in which they are abnormal in size or consistency.
[24] Small blister.

Adverse Events related to Lidocaine: Overdosage toxic reactions / Drug interactions (antiarrhythmics[25], amide type anaesthetics), Hypersensitivity / Allergy, Porphyria[2].
Precautions related to Lidocaine: Systemic or local adverse events may occur for patients with epilepsy, impaired cardiac conduction, severely impaired hepatic function or severe renal dysfunction.

4.3 WARNINGS AND PRECAUTIONS

- **Precise - HA Filler EYE** is not recommended for use in subject with an active or history of streptococcal diseases[26].
- 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[27] occlusion or compression, ischemia[28] or necrosis[29]. 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.
- Never try to straighten a bent needle. throw it away and replace it.

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.

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.
- 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[30] or hypertrophic scars[31], or with pigmentation disorders or any other scarring disorders.
- Having received chemotherapy agents or systemic corticosteroids in the three months prior to injection.

Due to presence of Lidocaine, special precautions must be taken with subjects with:
- epilepsy, impaired cardiac conduction, severely impaired hepatic function or severe renal dysfunction.

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.

[25] Antiarrhythmic agents, are a group of pharmaceuticals that are used to suppress abnormally fast cardiac rhythms.
[26] A streptococcal disease is caused by streptococci, Gram-positive bacteria which cause diverse human diseases.
[27] Relating to, affecting, or consisting of a vessel or vessels, especially those which carry blood.
[28] Condition in which the blood flow (and thus oxygen) is restricted or reduced in a part of the body.
[29] Necrosis is the death of body tissue.
[30] Keloid, also known as keloid disorder and keloidal scar, is the formation of a type of scar.
[31] A hypertrophic scar is a thick raised scar.

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.
It is recommended not to inject **Precise - HA Filler EYE** into an area that has already been corrected with implants other than those in the ESTYME® / Precise - HA fillers range until complete resorption (no clinical data available).

It is recommended not to inject into an area that has already been treated with a permanent implant.
Based on the clinical data, per session, it is recommended to not inject more than 1.0 mL of PRECISE-HA Filler EYE per side.
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 **Precise - HA Filler EYE** contains lidocaine, the practitioner must consider the total dose of lidocaine and other anesthetics of the amide type 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.
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 **Precise - HA Filler EYE** there is a theoretical risk of eliciting an inflammatory reaction at the implant site. This also applies if **Precise - HA Filler EYE** is 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. As per clinical investigation, it is recommended that the healthcare practitioner monitors the subject for at least 10 minutes after the injection and follow up for up to 12 months.

Concerning the needles supplied with **Precise - HA Filler EYE**:
-Only the needles provided with the products should be used for the injection, as the combination of these two devices has been validated.
-If the needle is obstructed, do not increase the pressure with the tip of the plunger. Stop the injection and use a new needle
-In case of increased pain during injection, stop the procedure and withdraw the needle.

Considering the composition of **Precise - HA Filler EYE** 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.

Precise - HA Filler EYE has not any novel feature. **Precise - HA Filler EYE** is not an innovative device. It belongs to Hyaluronic acid (HA) based dermal fillers. This kind of device is well-known and commonly used in facial rejuvenation. **Precise - HA Filler EYE** has similar characteristics to other HA based dermal fillers available in the market.

5.2 THE CLINICAL EVIDENCE FOR THE CE-MARKING

Precise - HA Filler EYE was assessed during a clinical investigation (identification number in Eudamed: not available) on the device itself, in 60 subjects to correct infraorbital hollows. The study included women and men (with a predominance of women) aged from 30 to 69 years. Safety and performance were measured at different time points with methods commonly used. The study lasted 12 months.

5.3 SAFETY

Precise - HA Filler EYE is 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.

Precise - HA Filler EYE was used in 60 patients to correct infraorbital hollows. The device was well tolerated. Indeed, reported injection site reactions are common and comparable to similar devices for the same use. Considering adverse device events, a few minors were observed and are similar to other HA fillers available on the market. No serious or unexpected adverse device event was reported. Meanwhile, a significant improvement of the infraorbital hollows was reported after injection by the evaluator with a dedicated scale. A global aesthetic improvement was also observed by the subject and the evaluator after injection. The results persisted to 12 months, the end of the study. The clinical benefit, which are the aesthetic appearance and self-esteem improvement of the subject, was clearly observed throughout the clinical study by the subjects themselves, as shown by the subject's GAIS outcomes. Regarding the safety profile and the performance, **the benefit-risk ratio of Precise - HA Filler EYE for correcting infraorbital hollows is acceptable.**

These data support the use of Precise - HA Filler EYE for modifying the skin anatomy and appearance of the infraorbital hollow**. When used as intended Precise - HA Filler EYE showed a noticeable aesthetic improvement after injection and a favourable safety profile.** Identified risks have been mitigated as far as possible without

adversely affecting the benefit-risk ratio by reduction measures. The residual risks mainly related to undesirable side-effects are consistent with a high level of protection for the safety and health of persons. **The potential benefit is acceptable considering the identified residual risks associated with the intended use of Precise - HA Filler EYE.**

Therefore, the clinical data indicate that **Precise - HA Filler EYE, when used under the conditions and for the purposes intended, is performant and presents a risk which is consistent with a high level of protection for the safety and health of persons**.

The clinical data of **Precise - HA Filler EYE** indicate that it performs as intended and that the device has a good safety profile.
In order to confirm these data, SYMATESE decided to proactively generate clinical data and thus reinforce performance and safety information. Proactive actions are planned according to the post market clinical follow-up plan of **Precise - HA Filler EYE**.
The post -market clinical study CLIN2108 is expected to confirm the lifetime and to evaluate in real life the safety (long-term adverse event evaluation) and the performance of **Precise - HA Filler EYE**. In addition, specific questionnaires will be completed by users in order to complete data in real life.

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. **Precise - HA Filler EYE** is not intended to be handled directly by the subject.