ESTYME® PATIENT PAGE

IMPLANT CARD

IMPLANT CARD: WHAT IS IT FOR?

Your healthcare professional has given you your personalized implant card because you have been treated with an **ESTYME®** dermal filler.

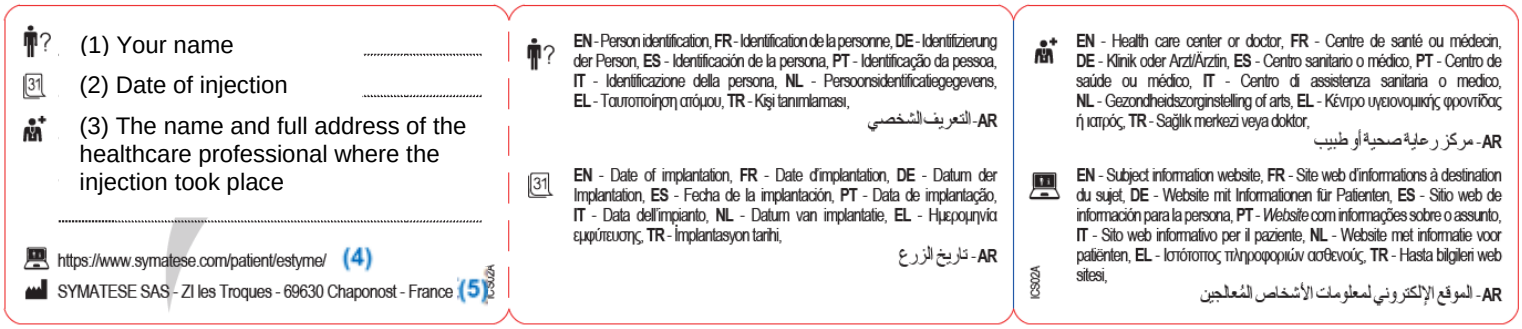
You must keep it and it is recommended to scan it to ensure preservation of information.

Your implant card is both-sided. The front side is intended to be completed with your personal information while the back side includes information about your device and its traceability.

IMPLANT CARD: CONTENT

IMPLANT CARD FRONT SIDE:

Make sure your healthcare professional has filled in the following fields (1), (2), (3) on the front side:



(4) Link to the website where all necessary information on your device is available

(5) Name and postal address of the manufacturer of your device

IMPLANT CARD BACK SIDE:

(1) Device type
(2) Device name
(3) Catalogue number
(4) Unique Device Identifier – Device identifier
(5) Batch code
(6) Unique Device Identifier

IMPORTANT INFORMATION CONCERNING YOUR ESTYME® DERMAL FILLERS

ESTYME® dermal fillers are intended for non-medical use only.
ESTYME® dermal fillers are intended to modify the skin anatomy and facial appearance.

ESTYME® SMOOTH is indicated to correct nasolabial folds and perioral lines. ESTYME® SMOOTH is injected into dermis to hypodermis.
ESTYME® LIPS is indicated to correct the volume and the shape of the lips. ESTYME® LIPS is injected into dermis, hypodermis and labial mucosa.
ESTYME® LIFT is indicated to correct nasolabial folds. ESTYME® LIFT is injected into dermis to hypodermis.
ESTYME® SCULPT is indicated to restore cheek volume loss. ESTYME® SCULPT is injected into hypodermis and supraperiosteal.

ESTYME® dermal fillers shall only be administered by appropriately trained healthcare professionals who are qualified or accredited in accordance with national law in injection techniques for the modification of facial anatomy.

ESTYME® dermal fillers are used in adult subjects excluding pregnant and breastfeeding women.
ESTYME® dermal fillers are not to be used in persons who are less than 18 years old.

Due to limited clinical data, caution should be exercised when envisaging to used ESTYME® SMOOTH on: - Male - Population aged from 18 to 34 years old and older than 75.
Due to limited clinical data, caution should be exercised when envisaging to used ESTYME® LIPS on: - Male - Population aged from 18 to 34 years old and older than 75.
due to limited clinical data, caution should be exercised when envisaging to use ESTYME® LIFT on: - Male - Population aged from 18 to 37 years old and older than 70.
due to limited clinical data, caution should be exercised when envisaging to use ESTYME® SCULPT on: - Male - Population aged from 18 to 35 years old and older than 65.

EXPECTED PERFORMANCE AND LIFETIME

ESTYME® dermal fillers act by adding volume to the tissue, thereby restoring the skin contours and the volume and shape of the face to the desired level. The volume and lifting capacity originate from the ability of the crosslinked 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 and the depth of injection, and may vary from one subject to another.

ESTYME® SMOOTH	On average, with 1,2 mL injected into the nasolabial folds and 0.5 ml injected into lip fine lines, in one session, 93% of subjects are noticeably improved at 9 months (clinical study results obtained with the Global Aesthetic Improvement Scale). Note: During the clinical study, the treatment of perioral fine lines with ESTYME® SMOOTH was performed in conjunction with the treatment of the lips. The proximity of these two areas may potentially have had a slight influence on the doses used and the performance results obtained. It is recommended to take into account the proximity of neighboring treated areas to avoid overcorrections. **The expected lifetime for ESTYME® SMOOTH is 12 months.**
ESTYME® LIPS	On average, with 1 mL injected into the lips in one session, 93% of subjects are noticeably improved at 9 months (clinical study results obtained with the Global Aesthetic Improvement Scale). **The expected lifetime for ESTYME® LIPS is 12 months.**
ESTYME® LIFT	On average, with 0.9 mL injected per nasolabial fold in one session, 82% of subjects are noticeably improved at 9 months (clinical study results obtained with the Global Aesthetic Improvement Scale). **The expected lifetime for ESTYME® LIFT is 9 months.**
ESTYME® SCULPT	On average, with 1,1 mL injected per cheek in one session, between 58.2 and 60% of subjects are noticeably improved at 9 months (clinical study results obtained with the Global Aesthetic Improvement Scale).

	The expected lifetime for ESTYME® SCULPT is 15 months.

ESTYME® dermal fillers contain local anesthetic lidocaine in order to reduce pain and post-injection procedure.

CONTRAINDICATIONS

ESTYME® Fillers are contraindicated in:

- Minors.
- Subjects with a known allergy to hyaluronic acid, lidocaine or amide local anesthetics.
- Subjects with porphyria.
- Subjects with an autoimmune disorder, or using an immunosuppressant medication.
- Pregnant or breastfeeding women.
- Subjects with inflammation, infection or cutaneous disorders at the treatment site or nearby.
- Subjects with bleeding disorders or in subjects receiving thrombolytic or anticoagulant treatment.
- Areas other than those recommended.

RESIDUAL RISKS AND POTENTIAL UNDESIRABLE SIDE-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 (labelling, instruction for use,…). 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.

The adverse events related to ESTYME® dermal fillers are minor, reversible and similar to other hyaluronic filler available on the market.

The most common side-effects are injection site reactions (swelling, tenderness/pain, firmness, bruising, lumps/bumps, redness, itching, discoloration). Most of these reactions disappear spontaneously after a few hours or days without any treatment. When these symptoms persist, they can be treated with analgesics, topical steroids or non-steroidal anti-inflammatory drugs (NSAIDs). Lumps and bumps can also be treated with hyaluronidase. 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:

abnormal hepatic function, acne, bleeding, bruising /hematoma /ecchymosis /contusion, capillary disorders /telangiectasia, discoloration, discomfort or pain /tenderness, dryness /xerosis, erosion /exfoliation, erythema /redness, eyes disorders /vision disorder /blindness, facial asymmetry, granuloma, headache, hyperbilirubinaemia, induration /firmness, infection /folliculitis, inflammation, ischemia /necrosis, mass /lumps /bumps /nodules /irregularities, migration of the device, muscle tightness /twitching, needle track marks, nerve injury, numbness /paraesthesia /anaesthesia /hypoesthesia, pruritus /itching, rosacea, scarring /scar hyperpigmentation and hypertrophy, sensation of foreign body /burning sensation /hyperaesthesia, seroma, severe allergic reaction /hypersensitivity /angioedema /rash, superficial wound, swelling /oedema /lymphadenopathy, syncope /dizziness, Tyndall effect, vascular damage /vascular compromise, vesicles, warmth.

Vascular compromise may occur due to an inadvertent intravascular injection or as a result of vascular compression associated with implantation of any injectable product. This may manifest as ischemia or necrosis at the implant site or in the area supplied by the blood vessels affected, or very rarely as ischemic events in other organs due to embolization. Following facial esthetic treatments, isolated rare cases have been reported regarding ischemic events affecting the eyes (leading to loss of vision) and the brain (resulting in cerebral infarction). After injection closed to the nose, ischemia or necrosis may occur, especially in subjects who have previously undergone rhinoplasty.

Symptoms of inflammation at the implant site commencing either shortly after injection or after a delay of up to several weeks have been reported on hyaluronic acid fillers. In case of unexplained inflammatory reactions, infections should be considered and treated if necessary, since inadequately treated infections may progress into complications.
For subjects who have experienced clinically significant reactions, any decision to repeat treatment must take into consideration the cause and severity of previous reactions.
Rare cases of granuloma have been reported in the literature and may occur after a few months or even several years.

Adverse Events related to Lidocaine: Overdosage toxic reactions / Drug interactions (antiarrhythmics, amide type anaesthetics), Hypersensitivity / Allergy, Porphyria.

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.

DECLARATION

The sterile gel of ESTYME® dermal fillers does not contain CMR (carcinogenic, mutagenic or toxic for reproduction) and/or endocrine-disrupting substances.

WARNING AND PRECAUTIONS

No device other than hyaluronic acid must be implanted in the area to be treated.

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

In the event of local inflammation, you must avoid extreme temperature conditions (intense cold, sauna, etc.) until any signs have disappeared.

Considering the composition of ESTYME® dermal fillers, 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

QUALITATIVE AND QUANTITATIVE INFORMATION ON THE MATERIAL USED FOR THE MANUFACTURING OF ESTYME® DERMAL FILLERS

Here are the details on the composition of your ESTYME® dermal fillers.

ESTYME® dermal fillers 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.

The components of the ESTYME® DERMAL FILLERS gel are:

	Reference	ESTYME® SMOOTH	ESTYME® LIPS	ESTYME® LIFT	ESTYME® SCULPT
Main ingredients	Total Sodium Hyaluronate	20 mg/g	20 mg/g	22 mg/g	23 mg/g
	Lidocaine	3 mg/g	3 mg/g	3 mg/g	3 mg/g
Other ingredients	Sodium chloride	9 mg/g	9 mg/g	9 mg/g	9 mg/g

	NaCl				
	Sodium dihydrogeno phosphate dihydrate NaH_2PO_4 , $2H_2O$	0.02 mg/g	0.02 mg/g	0.02 mg/g	0.02 mg/g
	Disodium phosphate dihydrate Na_2HPO_4 , $2H_2O$	0.22 mg/g	0.22 mg/g	0.22 mg/g	0.22 mg/g
	Water for Injection (WFI)	QSP 1g	QSP 1g	QSP 1g	QSP 1g
Volume per syringe		1 mL	1 mL	1 mL	1 mL

MAXIMUM DOSAGE

ESTYME® SMOOTH	Based on the clinical data, per session, it is recommended to not inject more than 1.2 mL of ESTYME® SMOOTH per nasolabial fold and to not inject more than 1.4 mL of ESTYME® SMOOTH for perioral lines during one session. As ESTYME® SMOOTH 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.
ESTYME® LIPS	Based on the clinical data, per session, it is recommended to not inject more than 1.0 mL of ESTYME® LIPS into the upper lip and to not inject more than 1.3 mL of ESTYME® LIPS into the lower lip. As ESTYME® LIPS gel 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.

ESTYME® LIFT	Based on the clinical data, per session, it is recommended to not inject more than 2.0 mL of ESTYME® LIFT per nasolabial fold. As ESTYME® LIFT gel 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.
ESTYME® SCULPT	Based on the clinical data, per session, it is recommended to not inject more than 3.0 mL of ESTYME® SCULPT per side. As ESTYME® SCULPT gel 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.

- ✓ **Information about medicinal substance in the device**: ESTYME® dermal fillers contain lidocaine hydrochloride (3 mg/mL). It is added in order to reduce pain during injection and improve comfort during and after the injection procedure.

- ✓ The sterile gel of ESTYME® dermal fillers **do not contain CMR (carcinogenic, mutagenic or toxic for reproduction), endocrine-disrupting substances, phthalate in the device.**

- ✓ ESTYME® dermal fillers **do not contain and are not manufactured with tissue of neither animal origin nor any animal tissue derivative.**

- ✓ ESTYME® dermal fillers **do not include any derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable.**

INFORMATION ON WHEN AND HOW TO REPORT UNDESIRABLE SIDE-EFFECTS

Please be aware that any serious incident that might have been caused by ESTYME® dermal fillers should be reported directly or through the distributor to the manufacturer or the Competent Health Authority of the country where the event occurred.

INFORMATION ON WHEN TO CONTACT HEALTHCARE PROFESSIONAL

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or if you are concerned about risks.

LINKED DOCUMENTATION

SSCP- Section B (Patient)

SSCP ESTYME® SMOOTH	FASY MDR 24-003
SSCP ESTYME® LIPS	FASY MDR 24-004
SSCP ESTYME® LIFT	FASY MDR 24-005
SSCP ESTYME® SCULPT	FASY MDR 24-007