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.

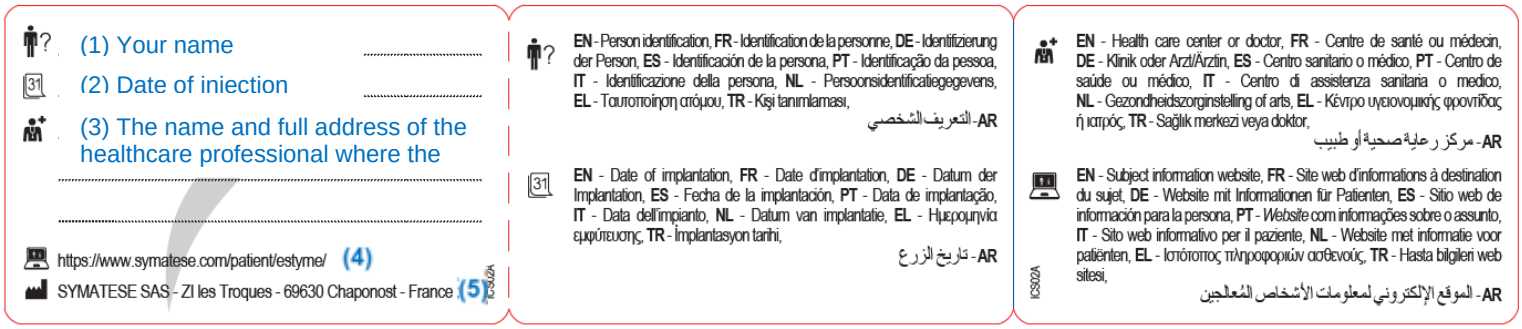
You must keep it and it is recommended to scan it to ensure preservation of information.

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

WARNING AND PRECAUTION AFTER INJECTION OF ESTYME® DERMAL FILLERS

- 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.

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

In case of common side-effects such as overdosing, swelling, hardening, nodules and immune responses, you should consult a medical professional if needed.
The following adverse events have been reported with regard to hyaluronic acid fillers: acne, bleeding, bruising /hematoma /ecchymosis /contusion, capillary disorders /telangiectasia, capsule formation /contracture, compartment pressure problems /compartment syndrome, discoloration, discomfort or pain /tenderness, dryness /xerosis, erosion /exfoliation, erythema /redness, eyes disorders /vision disorder /blindness, facial asymmetry, granuloma, headache, induration /firmness, infection /folliculitis, inflammation, interruption of wound healing, 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.
If you 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.

- Warning and precautions

No device other than hyaluronic acid must be implanted in the area to be treated.
Injection procedures can lead to the reactivation of latent or subclinical herpes virus infections.

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

NECESSARY FOLLOW-UP AFTER INJECTION OF ESTYME® DERMAL FILLERS

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

LIFETIME OF ESTYME® DERMAL FILLERS

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.

The maximum expected in-situ lifetime for ESTYME® dermal fillers is 18 months.

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 NaCl	9 mg/g	9 mg/g	9 mg/g	9 mg/g
	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

- ✓ **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.** The needles used or injection contain Cobalt in a concentration above 0.1wt%

- ✓ 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.**

LINKED DOCUMENTATION

- ❖ SSCP-FASY MDR 22-073: Section B