REGULATORY PURPOSE OF THE DOCUMENT

The following document describes the regulatory content of the **COLLAPAT® Patient Pages** in order to answer to the article 18 of the Regulation EU 2017/745 concerning the Implant Card.

The links to the **COLLAPAT® Patient pages** is the following:

https://www.symatese.com/fr/collapat/

All the necessary information is available in the following languages according to the targeted countries and references:

Brand name	Variants	References
COLLAPAT® II	24 languages	PAT1X1X1
		PAT35X6
		PAT7X11
COLLAPAT® Dental	24 languages	DPAT1X1X1
		DPAT35X6
COLLAPAT® II	2 languages	ZPAT1X1X1
		ZPAT35X60
		ZPAT7X11
COLLAPAT® Dental	2 languages	ZDPAT35X6
		ZDPAT1X1X1

24 languages: EN – FR – DE – NL – EL – ES – IT – PT-PT – SV – DA – FI – HU – NO – PL – CS – RO – RU – SK – SL – BG – VI – HR – TR – AR

2 languages: EN - FR

COLLAPAT® II / COLLAPAT® DENTAL PATIENT PAGE

IMPLANT CARD

IMPLANT CARD: WHAT IS IT FOR?

Your healthcare practitioner has given you your personalized implant card because you have been treated with a COLLAPAT® II or COLLAPAT® Dental range medical device.

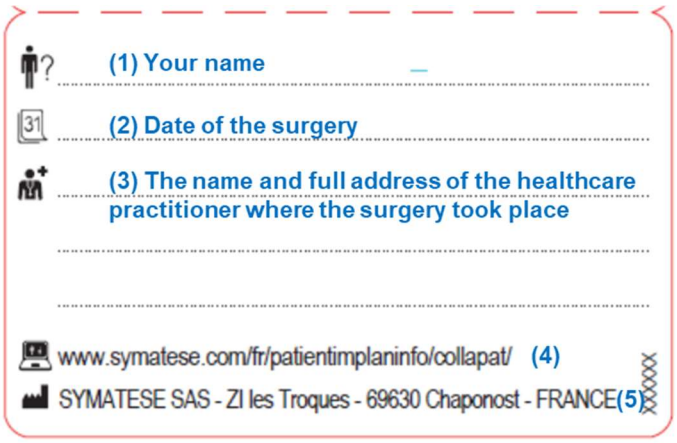
You must keep it and it is recommended to scan it to ensure preservation of information.

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:

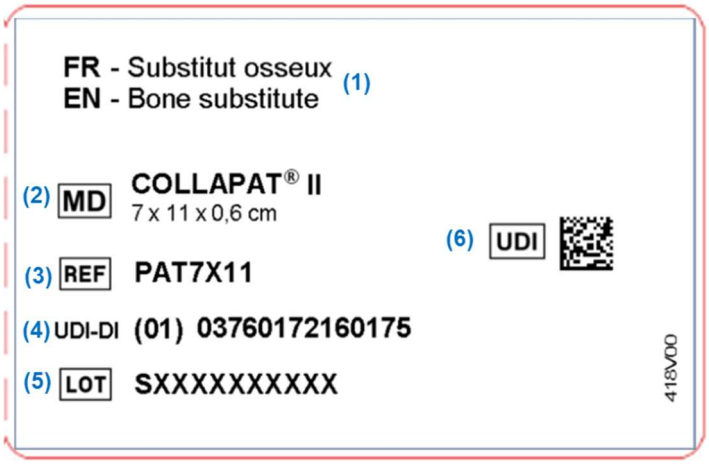
Make sure your healthcare practitioner has filled in the following fields (1), (2), (3) on the front side:



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

(5) Name and postal address of the manufacturer of your medical 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 COLLAPAT® DEVICES

WARNING AND PRECAUTION WITH THE USE OF COLLAPAT® DEVICES

❖ Remaining risks and undesirable effects

Neither complications nor adverse events were reported in relation with the use of COLLAPAT® II / COLLAPAT® DENTAL.
Although no allergic reaction to this product has been observed to date, this phenomenon cannot, a priori, be excluded with certitude and may occur in exceptional cases.
Lack of osseous ingrowth into the treated bone void may occur and is a known possibility associated with any bone filler.
Complications related to surgery include infection, hematoma, local inflammation, wound dehiscence, pain, treatment failure and reoperation.

❖ Warning and precautions

No patient warning or precaution after implantation for COLLAPAT® II / COLLAPAT® DENTAL except the recommendations after implantation as described in the following paragraph “Necessary follow-up after implantation of COLLAPAT® devices”. All warnings and precautions are detailed in the Summary of Safety and Clinical Performance – Section B (SSCP for patients).

NECESSARY FOLLOW-UP AFTER IMPLANTATION OF COLLAPAT® DEVICES

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 COLLAPAT® DEVICES

COLLAPAT® II / COLLAPAT® Dental is completely colonized by bony cells and replaced by newly synthesized bone approximatively between 3 months to 12 months. This time frame varies depending on the type of surgical procedure, the severity of the injury, the patient's health conditions and inter-patient variability.

QUALITATIVE AND QUANTITATIVE INFORMATION ON THE MATERIAL USED FOR THE MANUFACTURING OF COLLAPAT® DEVICES

Here are the details on the composition of your COLLAPAT® II / COLLAPAT® Dental devices:

- Native type I bovine collagen: 14,6 - 17.8% (on dry weight)
- Synthetic Hydroxyapatite: 74.5 - 89.0% (on dry weight)

COLLAPAT® II / COLLAPAT® Dental devices do not contain:

- Medicinal substances, tissues or blood products.
- CMR, endocrine-disrupting substances, phthalate in the device.

LINKED DOCUMENTATION

- SSCP-PAT: Section B