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.

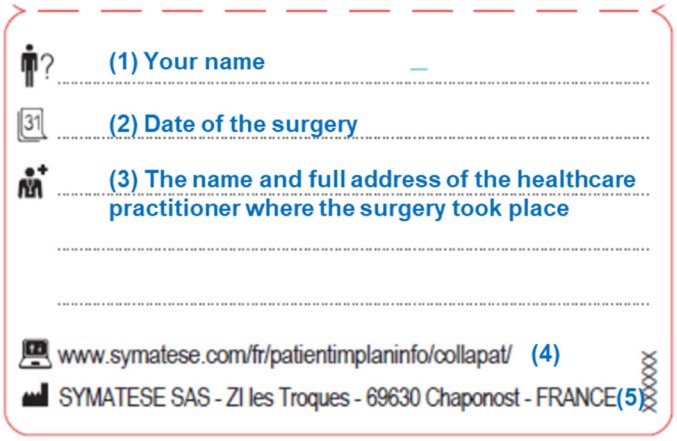
You must keep it and it is recommended to scan it to ensure preservation of information.

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:

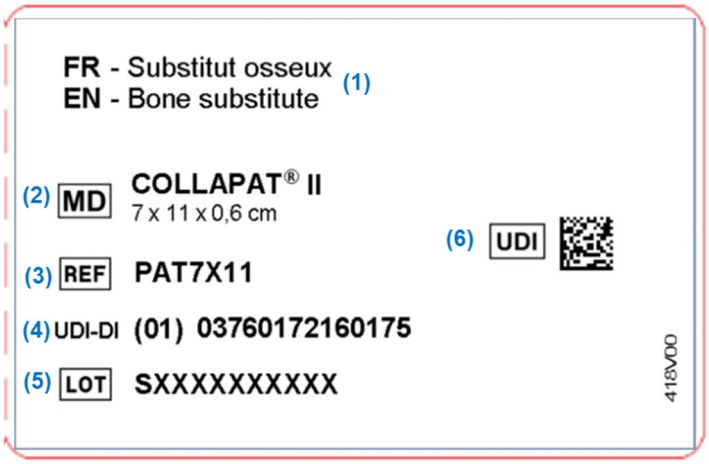
Make sure your healthcare practitioner has filled in the following fields (1), (2), (3) on the front side:



(4) Link to the website where all necesary information on your medical device are available

(5) Name and postal adress of the manufacturer of your medical device

IMPLANT CARD BACK SIDE:



(1) Device type

(2) Medical device designation / identification

(3) Medical device reference

(4) Unique Device Identifier – readable format

(5) Batch number

(6) Unique Device Identifier – QR code format

IMPORTANT INFORMATION CONCERNING YOUR COLLAPAT® DEVICES

- ❑ COLLAPAT® II and/or COLLAPAT® Dental are/is used in the filling and reconstruction of bone defects resulting from surgery, trauma or pathology.
- ❑ COLLAPAT® II and/or COLLAPAT® Dental are/is used for women and men of all ages undergoing surgical operations (maxillofacial surgery/odonto-stomatology/orthopaedics).
- ❑ COLLAPAT® II and/or COLLAPAT® Dental are/is intended to be used by a physicians qualified in surgery.

BRIEF DESCRITPION OF YOUR COLLAPAT® DEVICES

- ❑ The hydroxyapatite gives COLLAPAT® II / COLLAPAT® Dental its osteoconductive properties.

- ❑ The collagen matrix gives COLLAPAT® II / COLLAPAT® Dental its haemostatic properties, its handling characteristics and allows to tailor the product to the morphology of the defect.
- ❑ COLLAPAT® II / COLLAPAT® Dental is gradually resorbed during the natural process of bone healing and replaced by healthy bone.
- ❑ COLLAPAT® II / COLLAPAT® Dental is provided as a sterile, biocompatible, dry material. It can be cut and molded to fit the bone defect.
- ❑ COLLAPAT® II / COLLAPAT® Dental complies with the requirements of Regulation Nº EU 722/2012 with respect to implantable medical devices and medical devices manufactured utilising tissues of animal origin.

INDICATIONS FOR USE OF COLLAPAT® DEVICES

Device Name	Indications	Reference
COLLAPAT® Dental	In dental and maxillofacial surgery, COLLAPAT® Dental is indicated for: • Bone reconstruction and filling in alveolar ridge treatment. • Bone defect filling or sinus lift for prosthetic implantation. • Bone filling after dental avulsion.	DPAT1X1X1 DPAT35X6 ZDPAT1X1X1 ZDPAT35X6
COLLAPAT® II	In orthopaedic surgery, COLLAPAT® II is indicated for: • Bone fusion during spinal fusion, arthrodesis and osteosynthesis procedures. • Bone reconstruction during arthroplasty and revision procedures. • Bone filling during bone defect management procedures. In dentistry and maxillofacial surgery, COLLAPAT® II is indicated for: • Bone reconstruction and filling in alveolar ridge treatment. • Bone defect filling or sinus lift for prosthetic implantation. • Bone filling after dental avulsion.	PAT1X1X1 PAT35X6 PAT7X11 ZPAT1X1X1 ZPAT35X6 ZPAT7X11

CONTRA INDICATIONS FOR USE OF COLLAPAT® DEVICE

COLLAPAT® devices are contraindicated in the following situations:

- ❑ COLLAPAT® II / COLLAPAT® Dental contains bovine collagen and it must not be used in patients with a known allergy to collagen.
- ❑ COLLAPAT® II / COLLAPAT® Dental must not be used in patients presenting with septicemia, acute or chronic infection of the surgical site.
- ❑ COLLAPAT® II / COLLAPAT® Dental must not be used in patients receiving high doses of corticosteroids.
- ❑ COLLAPAT® II / COLLAPAT® Dental must not be used in patients presenting systemic and/or metabolic disorders that affect the bone or wound healing such as osteomalacia, hyper-parathyroidism or severe hypercalcaemia.
- ❑ COLLAPAT® II / COLLAPAT® Dental must not be used in regions of weak bone regeneration.
- ❑ COLLAPAT® II / COLLAPAT® Dental should not be used with pregnant women since the effect on pregnant or lactating women is not known.
- ❑ COLLAPAT® II / COLLAPAT® Dental should not be used where there is significant vascular impairment proximal to the graft site.
- ❑ COLLAPAT® II / COLLAPAT® Dental must not be used with children since the effect on children is not known.

RISKS AND WARNING WITH THE USE OF COLLAPAT® DEVICES

See the summary of safety and clinical performaces – Part B specifically intended for patients:

- ❖ SSCP-PAT: Section B - § 4 - RISKS AND WARNINGS

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.

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 does not contain:

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

REFERENCES TO ANY HARMONISED STANDARD APPLIED USED FOR REGULATORY CONFORMITY

Harmonised standards applied for COLLAPAT® II / COLLAPAT® Dental range:
EN ISO 13485/AC; EN ISO 13485/A11; EN ISO 14971/A11; EN ISO 10993-9; EN ISO 10993-12; EN ISO 10993-23; EN ISO 11737-1/A1; EN ISO 11737-2; EN ISO 15223-1.

UNDESIRABLE SIDE-EFFECTS REPORT AFTER THE USE OF **COLLAPAT®** DEVICE

Any serious incident that might have been caused by COLLAPAT® II / COLLAPAT® Dental devices should be reported to the manufacturer or the Competent Health Authority of the country where the event occurred.

LINKED DOCUMENTATION

- ❖ SSCP-PAT: Section B - § 4 - RISKS AND WARNINGS