



**SUMMARY OF SAFETY AND CLINICAL PERFORMANCE
(SSCP)**

COLLAPAT®II / COLLAPAT® DENTAL - BONE SUBSTITUTE

SSCP date	2022/06/06
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SSCP EUDAMED version	Rev0

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: **SSCP-PAT**

Summary of safety and clinical performance Document revision: **Rev 0**

Date issued: **2022/06/06**

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 the device. 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 NAME

COLLAPAT®II and COLLAPAT® DENTAL

COLLAPAT® Dental is identical to COLLAPAT®II. COLLAPAT® Dental is a brandname dedicated only to dental indications while COLLAPAT® II is dedicated to dental and orthopaedic indications.

1.2 MANUFACTURER: NAME AND ADDRESS

SYMATESE SAS
ZI LES TROQUES
69630 CHAPONOST – France

1.3 BASIC UDI-DI

The basic UDI-DI is 376017216PATHC

1.4 YEAR WHEN THE DEVICE WAS FIRST CE-MARKED

COLLAPAT®II was first CE-marked in 2002.

2 INTENDED USE OF THE DEVICE

2.1 INTENDED PURPOSE

COLLAPAT® II/ COLLAPAT® DENTAL is used in the filling and reconstruction of bone defects resulting from surgery, trauma or pathology.

2.2 INDICATIONS AND INTENDED PATIENT GROUPS

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 defects management procedures.

In dental and maxillofacial surgery, COLLAPAT®II / 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.

COLLAPAT® II/COLLAPAT® Dental is placed on the bone surfaces and is in contact with surrounding soft tissues that are partially removed and put back in place during surgery. COLLAPAT®II/COLLAPAT® Dental is implanted in contact with bone.

In orthopaedic surgery, COLLAPAT®II is used at level of limbs (upper and lower) and spine.

In dental and maxillofacial surgery, COLLAPAT®II / COLLAPAT® DENTAL is used at level of maxilla and mandible.

COLLAPAT® II is used for women and men undergoing orthopaedic surgical operation.

COLLAPAT®II /COLLAPAT® DENTAL is used for women and men undergoing oral maxillofacial or odontostomatology surgery.

2.3 CONTRAINDICATIONS

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 with pregnant women since the effect on pregnant or lactating women is not known.

COLLAPAT® II/COLLAPAT® DENTAL must not be used with children since the effect on children is not known.

COLLAPAT® II/COLLAPAT® DENTAL must not be used where there is significant vascular impairment proximal to the graft site.

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.

3 DEVICE DESCRIPTION

3.1 DEVICE DESCRIPTION AND MATERIAL/SUBSTANCES IN CONTACT WITH PATIENT TISSUES

COLLAPAT® II/COLLAPAT® DENTAL is a composite product made of a resorbable Type-I bovine collagen three-dimensional open porous matrix in which are dispersed ceramised hydroxyapatite granules. The collagen is extracted from bovine dermis.

The components of COLLAPAT® II/COLLAPAT® DENTAL are:

- Native Type I bovine collagen
- Synthetic Hydroxyapatite

COLLAPAT® II/COLLAPAT® DENTAL is sterilized by irradiation.

COLLAPAT® II/COLLAPAT® DENTAL is a single-use device that is intended to be used on one individual during a single procedure.

3.2 INFORMATION ABOUT MEDICINAL SUBSTANCES IN THE DEVICE, IF ANY

The device does not contain any medicinal substances.

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

Regarding the bone substitution properties, once positioned in contact with the surgical site, COLLAPAT® II/COLLAPAT® DENTAL is colonized by bony cells and replaced by newly synthesized bone. It is completely resorbed during the natural process of healing (bone formation and remodelling).

The hydroxyapatite supports effective and reliable bone formation.

The presence of collagen allows good handling of COLLAPAT® II/COLLAPAT® DENTAL and its maintenance on the surgical site.

COLLAPAT® II/COLLAPAT® DENTAL can be hydrated easily with tissue fluids or saline solution. It can also be directly hydrated in the surgical site, in contact with blood of adjacent healthy bone. COLLAPAT® II/COLLAPAT® DENTAL is malleable and adapts perfectly to the contour of the bone defect that needs to be filled.

3.4 DESCRIPTION OF ACCESSORIES, IF ANY

COLLAPAT® II/COLLAPAT® DENTAL device is not supplied with 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

According to the manufacturer's risk assessment process, the actions taken by the manufacturer to mitigate any identified risks do not impact the benefit/risk ratio for the patient and reinforce patient safety.

The main method of mitigation is the design control of the device (design verification and validation program), 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, ...).

4.2 REMAINING RISKS AND UNDESIRABLE EFFECTS

Risk management report indicates that the residual risks associated with COLLAPAT II/COLLAPAT® DENTAL are acceptable after implementation of mitigation procedures.

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.

4.3 WARNINGS AND PRECAUTIONS

a) Warning

The haemostatic properties of COLLAPAT® II/ COLLAPAT® DENTAL can be altered in patient with coagulation troubles.

In orthopaedic surgery, COLLAPAT® II should not be used in segmental defects without supplemental fixation.

b) Precautions for use

COLLAPAT® II/COLLAPAT® DENTAL must not be used after the expiry date indicated on the package.

COLLAPAT® II/COLLAPAT® DENTAL must not be used if the package is damaged.

COLLAPAT® II/COLLAPAT® DENTAL should be used immediately after opening the package.

When COLLAPAT® II/COLLAPAT® DENTAL is cut to size, the remaining product must be discarded.

COLLAPAT® II/COLLAPAT® DENTAL must be hydrated in place or before being placed and not implanted in dry form.

It is recommended to avoid the contact of COLLAPAT® II/COLLAPAT® DENTAL with iodine solutions.

COLLAPAT®II/COLLAPAT® DENTAL must not be re-implanted when removed from an implantation site.

Rigid fixation of the defect site is recommended for proper stabilization of the bone defect.

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

In case of bone defects, the natural bone healing process cannot fill the bone void without the surgical addition of a support material. The standard surgical method is the use of an autologous bone graft, which involves removing pieces of bone from a secondary surgical site (donor site). This method is not always feasible and does not always allow the harvest of the necessary amount of bony shavings.

Bone substitutes such as COLLAPAT® II/COLLAPAT® DENTAL can be used to help bone reconstruction. COLLAPAT® II/COLLAPAT® DENTAL acts as a guide for bony cells that will colonize the bone substitute and will replace missing bone gradually. At the end of the bone regeneration process, bone substitute will have been completely replaced by newly synthesized bone.

COLLAPAT®II bone substitute does not claim to be a new device, with new design characteristics or using a new technology. COLLAPAT®II/COLLAPAT® DENTAL is similar to others devices already on the market. The technology of the product is well established.

SYMATESE has documents clinical data of COLLAPAT®II/COLLAPAT® DENTAL for supporting the safety and performance of the device.

5.2 THE CLINICAL EVIDENCE FOR THE CE-MARKING

COLLAPAT®II/COLLAPAT® DENTAL conformity is based on clinical data gathered in the device itself.

During clinical studies, COLLAPAT®II/COLLAPAT® DENTAL was used in 332 patients including 251 in orthopaedic and traumatic surgery and 81 in oral, maxillofacial and dental surgery. No complications or adverse events related to the use of COLLAPAT®II were reported. Positive outcomes were observed in all indications and types of surgery. Depending on the type and severity of the lesion as well as interindividual variability, COLLAPAT®II/COLLAPAT® DENTAL allows bone consolidation between 1 and 12 months. One medical device vigilance has been reported after use of COLLAPAT®II in a dental application (Guided Bone Regeneration procedure), but no links between the device and the events have been established. COLLAPAT®II has never been subject to batch recalls since its initial placement on the market in 2002. Considering these outcomes and the absence of related adverse events on the 332 patients followed-up in filling and reconstruction of bone defect, clinical results are satisfactory.

5.3 SAFETY

On the grounds of clinical data sourced from foot, spine, hip and knee surgeries as well as from maxillofacial and dental surgeries (sinus lift, alveolar ridge augmentation, socket preservation after tooth extraction, guide bone regeneration, cyst removal or implant stabilization), the benefit/risk ratio is acceptable and favourable for the use of the COLLAPAT®II/COLLAPAT® DENTAL as a bone substitute for the following indications:

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 defects management procedures.

In dental and maxillofacial surgery, COLLAPAT®II / 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.

On the whole studied population, no adverse events related to COLLAPAT®II/COLLAPAT® DENTAL were reported. The only observed adverse events are usual complications related to the surgical procedure.

Undesirable side effects identified in the literature correspond to those listed in the risk assessment. They are acceptable under normal conditions of use when weighed against benefits to the patient. Besides, no adverse events related to the use of COLLAPAT®II were observed by the clinical investigations and by the post-market surveillance.

Considering the absence of adverse events reported on COLLAPAT®II/COLLAPAT® DENTAL and lack of new complications on similar device used in the same indications, it may be concluded that COLLAPAT®II/COLLAPAT® DENTAL has good safety profile in all tested indications.

In order to renew and complete data, SYMATESE decided to proactively generate clinical data and thus reinforce performance and safety information. 2 prospective clinical investigations are currently ongoing, one on orthopaedic indications and the other on dental indications. These clinical studies were approved by an ethical committee the 17th of November 2020 and the 8th of January 2021.

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

The autograft is the benchmark bone filling material. However, due to drawbacks related to its removal (limited amount of bone, morbidity related to engraftment), other bone substitutes can be used such as:

- allografts
- xenografts
- synthetic substitutes

7 SUGGESTED TRAINING FOR USERS

COLLAPAT® II/ COLLAPAT® DENTAL product is a bone substitute intended to be used by an orthopaedic surgeon qualified in spines or limbs surgery for orthopaedic indications, or by dental, maxillofacial surgeons and stomatologists concerning dental indications.