BIOTECH DENTAL
REGENERATION

Collapat® II

MAXILLOFACIAL SURGERY & ODONTO-STOMATOLOGY

HAEMOSTATIC BONE SUBSTITUTE

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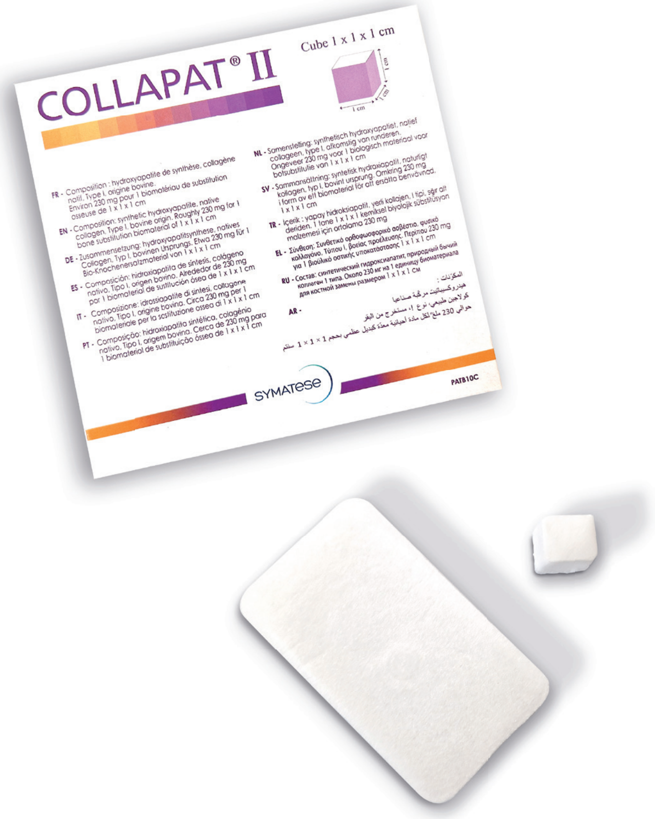


TABLE OF CONTENTS

ASPECT & COMPOSITION

COLLAPAT® II haemostatic bone substitute in spoge form

COLLAPAT® II is composed of a collagen structure in which ceramised hydroxyapatite granules are dispersed.
The granules of hydroxyapatite give the material its **osteoconductive**[1] properties.
Hydroxyapatite is the most important mineral component of enamel, dentin and mineralised bone. It is slowly resorbed[2].

As a collagen medical device, COLLAPAT® II has a strong haemostatic power and is **completely resorbable in a few weeks**[3]. Collagen is extracted from bovine dermis.

The manufacturing process includes proven steps for inactivating viruses and non-conventional transmissible agents such as Prions. These treatments ensure maximum microbiological safety for COLLAPAT® II, especially for the agent responsible for BSE[4].

The presence of collagen helps bone cells to migrate into the bone substitute, promoting bone regeneration[2]. **Neoformed bone (immature tissue) will transform into mature bone tissue within a few weeks**. Bone substitute is completely filled with healthy tissue following intense bone regeneration. The collagen matrix is replaced by newly synthesised bone.

[1] Arcos, D., & Vallet-Regı, M. (2020). Substituted hydroxyapatite coatings of bone implants. Journal Of Materials Chemistry B, 8(9), 1781-1800. https://doi.org/10.1039/c9tb02710f
[2] Fernandez de Grado et Al. J Tissue of Engineering. 2018; 9:1-18.
[3] Symatese preclinical data
[4] 16 hours in a lime-sulphide treatment : Diringer, H. and H.R. Braig, Infectivity of unconventional viruses in dura mater. The lancet, 1989. 1: p. 2.
1 hour in soda ≥ 1N. : Grobben, A.H., et al., Inactivation of the bovine-spongiform-encephalopathy (BSE) agent by the acid and alkaline processes used in the manufacture of bone gelatine. Biotechnol Appl Biochem, 2004. 39(Pt 3): p. 329-38.

INDICATIONS

In maxillofacial, oral and stomatology surgery

COLLAPAT® II is used to fill bone lesions in maxillofacial surgery and dentistry.

- After removal of wisdom teeth or impacted canines
- After removal of radiculodental cysts
- Debridement of periodontal pockets
- Filling for sinus grafting
- Reconstitution of bone stock following avulsion, trauma or oncological pathology, prior to implant placement

CONTRAINDICATION

COLLAPAT® II should not be used in patients with a known allergy to bovine collagen.

DIRECTIONS FOR USE

- COLLAPAT® II must be used under **perfectly sterile** operating conditions after appropriate site preparation.
- COLLAPAT® II can be cut to size with **surgical scissors** to facilitate application.
- Once soaked in tissue fluid, antibiotic or physiological serum, COLLAPAT® II softens and becomes a **paste that fills the cavity**.
- Following aspiration, COLLAPAT® II can be placed.
- COLLAPAT® II is not intended to be removed, except in the event of **postoperative infection**.
- In the case of very deep extensive bone lesions or segmental defects of more than 1 to 2 cm, it is recommended to **combine COLLAPAT® II with autologous bone chips or allograft granules**.
- Bone instabilities require **supportive osteosynthesis**.

ADVERSE EFFECTS & MONITORING

No allergic reactions to this product have been observed to date. Allergy cannot be excluded with certainty in some exceptional cases. Contact SYMATESE if you think you have observed any side effects linked to the device or if you are concerned.

Material safety alerts and corrective actions applied to COLLAPAT® II are available on the ANSM* website and EUDAMED once it is fully operational.

EXPERT ADVICE

The use of COLLAPAT® II has shown that it is recommended to aspirate blood prior to implant placement.

- it must be pressed between the thumb and forefinger (not cut except in avulsion)
- it must be inserted dry

*French Ministry Of Health (Agence Nationale de Sécurité du Médicament)

INSTRUCTIONS

- COLLAPAT® II has no stability in shape or resistance to strain. It can therefore only be used to treat unstable bone loss if combined with supportive osteosynthesis.
- COLLAPAT® II must not be used in the event of acute or chronic infection of the surgical site or in the event of high-dose corticosteroid treatment.
- COLLAPAT® II must not be used in patients with:
  - Septicaemia
  - Severe bone degeneration or major osteoporosis
  - Osteomalacia
  - Hyperparathyroidism or severe hypercalcaemia
- As a precaution, COLLAPAT® II should not be used on pregnant women.
- COLLAPAT® II should be used immediately after opening.
- Do not use COLLAPAT® II after the expiry date indicated on the packaging.
- Do not use COLLAPAT® II if packaging is damaged.
- If COLLAPAT® II (35x60 mm) needs to be cut to improve insertion, any remaining product must be removed.
- COLLAPAT® II must not be stored after opening for later use, which would lead to a risk of infection.
- COLLAPAT® II is a single-use product and must not be sterilised again.
- For further information on safety precautions, please refer to the COLLAPAT® II instructions for use (reference: PATN04H).

COLLAPAT® II BENEFITS

SYMATESE's collagen technology gives COLLAPAT® II its unique characteristics.

- The industrial process ensures SAFETY, QUALITY and RELIABILITY.
- Thanks to SYMATESE's expertise and knowledge of the collagen extraction and purification process, COLLAPAT® II is biocompatible*.
- Thanks to its unique manufacturing process, COLLAPAT® II can be exposed to salivary enzymes: it is therefore not necessary to protect it with a membrane after application.
- COLLAPAT® II's three-dimensional porous structure improves osteoblast differentiation and accelerates osteogenesis throughout the receiving site[1].
- The unique reticulation process allows COLLAPAT® II to be exposed to saliva while maintaining the collagen structure during the bone regeneration of the graft by osteoblasts. Collagen resorption contributes to bone replacement[2].
- COLLAPAT® II is osteoconductive, and filled by healthy bone tissues thanks to intensive regeneration[3].

[1] Fernandez de Grado : «Some composite materials containing HA and collagen exist as well, and their combination enhances osteoblasts differentiation and accelerates osteogenesis.»
[2] SYMATESE internal data - COLLAPAT® II Clinical Evaluation Report.
[3] SYMATESE preclinical data – Study 280632

*Complies with ISO 10993-1

- COLLAPAT® II has a haemostatic effect on the bone surfaces it covers and on the surrounding soft tissues[4].
- COLLAPAT® II is ready to use and easy to handle, shape and cut[5].
- Perfect adaptation to the anatomical area. The matrix turns into a paste when exposed to blood or tissue fluids[6].

COLLAPAT® II provides

- an alternative to autologous or allogeneic grafts[4].
- immediate availability and an unlimited quantity of product, unlike autologous bone, to avoid comorbidities.

[4] Julien-Marsollier, F., et al., Can hydroxyapatite charged collagen sponge help reduce perioperative blood loss in adolescent idiopathic scoliosis surgery? Preliminary results in 68 patients. Eur Spine J, 2023. 32(3): p. 883-888 .
[5] Post-market surveillance, unpublished - SYMATESE internal reports
[6] Symatese preclinical data - Study 6473

THERAPEUTIC STRATEGY

Autograft is the reference bone filling material. However, because of the disadvantages associated with its collection (limited quantity of bone, morbidity due to grafting), bone substitutes can be used, such as allografts, xenografts and synthetic substitutes.

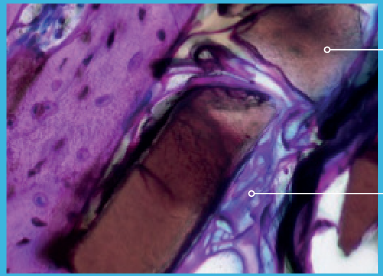
As part of the therapeutic strategy, COLLAPAT® II is used as a bone substitute (filling, reconstruction, fusion) when autologous solutions are not applicable or sufficient.

PRECLINICAL DATA[7]

SYMATESE has been manufacturing collagen-based medical devices for over 30 years.
SYMATESE complies with the ISO 13485: 2016.

Collagen used for COLLAPAT® II is bovine type I collagen.
The osteoconductive properties of COLLAPAT® II have been established in a preclinical evaluation performed on rabbits. COLLAPAT® II was implanted in a cortico-spongiosa defect of 4.2 mm diameter in a femoral site. The progression of bone regeneration was assessed by histological sections using resin samples . The magnification was set at 20 times on month T0 up to T3.

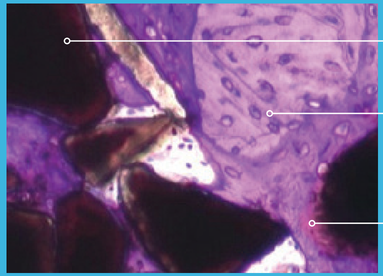
Hydroxyapatite granules are spread in the collagen matrix



Hydroxyapatite granules

Collagen

After 3 months, bone reconstruction is complete, with mature remodelled bone tissue



Hydroxyapatite granules

Bone lamella and increased osteocyte density

Development of normal bone marrow tissue

[7]Symatese preclinical data - Study 6473

CLINICAL DATA

Dr. Gomo - Three cases of bone reconstruction in oral and dental surgery

GOALS

3 applications

- Following removal of a cyst.
- Repair after avulsion.
- Avulsion, cyst removal, implant placement and filling.

PRODUCT

COLLAPAT® II cube alone (reference: PAT1x1x1)

TYPE OF STUDY

Prospective and monocentric clinical cases

CENTRE

René Descartes University, University of Dental Surgery, Paris V. Jean Claude Gomo

CANDIDATES

Patients number: 3 cases have been analysed

TREATMENT PROTOCOL

COLLAPAT® II is placed in the receiving site to promote bone regeneration

DESCRIPTION

- **1st indication:** after cyst removal, the bone defect is filled with COLLAPAT® II. A 5-month period of regeneration resulted in a homogenous bone structure, enabling two implants to be placed without difficulty.
- **2nd indication:** following a root fracture of the posterior abutment of a cemented prosthesis, an avulsion with precise alveolar curettage is performed. COLLAPAT® II is then inserted into the residual bone defect for definitive implant treatment.
- **3rd indication:** to treat a dental cyst, the tooth is removed followed by cyst avulsion and prosthetic placement. COLLAPAT® II is then used to fill the residual cavity.

No complications or adverse effects were reported in any of the 3 cases studied.

STUDY

These three cases were published by Doctor Jean-Claude GOMO, in charge of continuing education in odontology at the Faculty of Dental Surgery, Paris V: 'à propos d'un matériau de comblement osseux', in the French Dental Surgeon Journal, No. 1343, 3 April 2008, pages 37-39.

CONCLUSION

In all 3 cases, the collection of clinical data showed good bone regeneration and an effective bone substitute in these indications. The product is well accepted and has no adverse effects.

Maxillofacial surgery case study: Dental implant and sinus lift[3]

GOALS

Sinus lift for implant purposes

PRODUCT

COLLAPAT® II (reference: PAT 35 x 6)

TYPE OF STUDY

Case report to gather clinical data

CANDIDATES

42-year-old woman with stable biology

TREATMENT PROTOCOL

COLLAPAT® II is cut and fixed with FRP membranes on the sinus floor. The gingival flap was sutured with separate stitches.

COLLAPAT® II was left in situ and completely filled and assimilated, allowing the sinus floor to be thickened by bone regeneration.

[3]SYMATESE internal data - COLLAPAT® II Clinical Evaluation Report

LENGTH

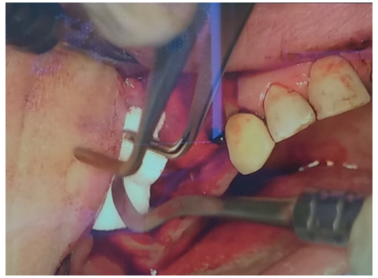
This report describes the pre-implant use of COLLAPAT® II in a sinus lift (two-stage surgery).

During the first surgery, COLLAPAT® II is placed on the sinus floor. Its placement is acceptable because it is easy to use and handle.
Six months after placing COLLAPAT® II in the sinus, the good qualiity of the bone neoformation allowed to place successfully 2 implants.

No complications or adverse effects related to COLLAPAT® II were reported during the implant placement, bone neoformation and dental implants insertion.

CONCLUSION

COLLAPAT® II is effective and well tolerated in implant surgery for sinus lift.



COLLAPAT® II RANGE

REFERENCES	DIMENSIONS	UNITS
PAT1X1X1	COLLAPAT® II Cube 1 x 1 x 1 cm	5
PAT35X6	COLLAPAT® II 3.5 x 6 x 0.6 cm	1

- COLLAPAT® II is sterilised by 25 kilogray irradiation.
- COLLAPAT® II sponges come in double packaging. COLLAPAT® II Cube 1 x 1 x 1 cm packages contain 5 products. A patient label is available for each product.
- COLLAPAT® II should be stored at room temperature (+10°C to +30°C).
- COLLAPAT® II is the result of a technology transfer from COLLAPAT® to SYMATESE and has been CE marked since 2002.

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Dedicated to health professionals. Before use, consult the product's instructions for use. Medical device registered in title III of the list of refundable products provided for in article L165-1 of the French social security code. COLLAPAT® II is a haemostatic bone replacement biomaterial and COLLAPAT® II is only refundable for orthopaedic surgery and not for oral or dental surgery. COLLAPAT® II has been granted CE marking by the certified body G-MED n°0459 and is a Class III implantable medical device designed to replace and regenerate bone structure, manufactured by SYMATESE - Chaponost - FRANCE. CNEDiMTS opinion of 30 January 2024 concerning the renewal of the COLLAPAT® II registration, a bone substitute from bovine origin. Non contractual visuals. Do not throw in public areas. Printed by VALLIERE - 163, Avenue du Luxembourg - ZAC des Molières - Miramas - France.

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