COLLAPAT® II
FOR MAXILLOFACIAL AND ODONTOSTOMATOLOGY SURGERY USE
HAEMOSTATIC BONE SUBSTITUTE
BIOTECH DENTAL GROUP 2.0 DENTAL OFFICE PARTNER.

Since its creation in 1987, Biotech Dental is committed to develop a strong relationship of trust with dentists and dental technicians. Together, we design and develop ever more tailored product lines to the challenges of the future. Our position is located at the crossroads of their expectations, innovation and technology.

Allow practitioners to offer the best products at the best prices for their patients: that is the first objective of Biotech Dental. With more than a million dental implants sold, we have helped to improve the lives of thousands of patients worldwide through all dentists who have trusted us. With our expertise and our know how, we have chosen to be pioneers of this development through innovative technologies.

In recent years, we have integrated new skills, invested over 10 % of our turnover in research and development to be able to develop and propose solutions on the cutting edge innovation.

Today we are a key partner for practitioners of dentistry. We offer our customers a wide range of products and services around dental care, to enable them to meet the different needs of their patients.

Innovation and Technology for practitioners to make affordable excellence to patients: this is Ethical currency of Dental Biotech.

As many products and services serving the dental office 2.0.

Philippe VÉRAN
CEO
**APPEARANCE AND COMPOSITION**

**COLLAPAT® II Sponge haemostatic bone substitute**

COLLAPAT® II consists of a collagen support which contains ceramic hydroxyapatite granules. The hydroxyapatite granules give the material its osteoconductive properties. Hydroxyapatite is the highest mineral component in enamel, dentine and mineralised bone. It resorbs slowly.\(^1\)

The collagen gives COLLAPAT® II its haemostatic power and is completely resorbed in a few weeks.\(^2\) The collagen is extracted from bovine dermis. Recognised stages in the manufacturing process inactivate viruses as well as non-conventional transmissible agents such as Prions. These treatments ensure maximum microbiological safety, particularly regarding the causative agent of BSE.

The presence of collagen allows the bone cells to migrate to the bone substitute, therefore promoting bone regeneration. In a few weeks, the bone growth (immature tissue) will turn into mature bone tissue. The bone substitute is completely colonised by healthy tissue following intense bone regeneration. The collagen matrix is replaced by newly synthesised bone.

**INDICATIONS**

For maxillofacial, oral and stomatology surgery

COLLAPAT® II is used for filling bone lesions during maxillofacial and odontostomatological surgery.

- After removal of wisdom teeth or impacted canine
- After removal of radicular dental cysts
- Periodontal pocket debridement
- Filling for sinus grafts
- Restoration of bone stock following avulsion, trauma or tumours prior to fitting of implants.

**CONTRA-INDICATIONS**

COLLAPAT® II must not be used in patients with allergic predisposition or in the case of known allergy to collagen of bovine origin.

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2. Symatese preclinical data
RECOMMENDATIONS FOR USE AND HANDLING

- COLLAPAT® II must be used in perfectly sterile operating conditions after appropriate preparation of the site to be treated.
- COLLAPAT® II can be cut, using surgical scissors, to the desired dimensions to facilitate its application.
- After being wet with tissue fluids, antibiotics or saline solution, COLLAPAT® II becomes soft and paste-like, making it easy to use to fill the cavity requiring treatment.
- Drainage is strongly recommended however the drains must not come into direct contact with COLLAPAT® II.
- Avoid rinsing the implanted area.

- Removal of COLLAPAT® II must not be performed, except in the case of post-surgical infection.
- In the case of widespread and very deep bone lesions or segment defects of more than 1 to 2 cm, autologous bone shavings or PRP (Platelet Rich Plasma) should be combined with COLLAPAT® II.
- Bone instabilities require supporting osteosynthesis.
**THE PRECAUTIONS BEFORE USE BELOW MUST BE FOLLOWED**

- **COLLAPAT® II** does not offer any form of stability or stress resistance. Therefore, it can only be used to treat loss of unstable bone matter when combined with an osteosynthesis support.

- **COLLAPAT® II** must not be used in dry form and must be impregnated before use.

- In areas of low bone regeneration, **COLLAPAT® II** alone is ineffective; however, it can be used with autologous spongy tissue, a platelet concentrate (PRP: Platelet Rich Plasma) and/or after an autologous bone marrow injection.

- Insufficient regeneration is possible in unfavourable cases, particularly in cases of significant loss of substance or in areas of low bone regeneration. These cases can be avoided by strictly following the instructions and directions for use.

- As there is a poor experience related to the repeated use of **COLLAPAT® II**, it is therefore recommended to be cautious, given the collagen’s external source and potential cause of allergic reactions.

- **COLLAPAT® II** must not be used in the case of acute or chronic infection of the site to be treated or in the case of high dosage corticosteroid treatment.

- **COLLAPAT® II** must not be used on patients demonstrating:
  - Septicaemia
  - Severe bone degeneration or major osteoporosis
  - Osteomalacia
  - Overactive parathyroid gland or severe hypercalcaemia.

- **COLLAPAT® II** must not be used on pregnant women.

- Use **COLLAPAT® II** immediately after opening the packaging.

- Do not use **COLLAPAT® II** beyond the expiry date stated on the packaging.

- Do not use **COLLAPAT® II** if the packaging is in any way damaged.

- If **COLLAPAT® II** is cut to the required size, the remainder must be discarded.

- **COLLAPAT® II** must not be kept for later use once opened as this leads to risks of infection.

- **COLLAPAT® II** is a one-time use product and must not be resterilised.
BENEFITS OF COLLAPAT® II

The SYMATESE Collagen Technology Platform gives to COLLAPAT® II the unique specification:

• The complete process is integrated to ensure SAFETY, QUALITY and RELIABILITY.
• COLLAPAT® II offers cellular affinities for tissue reconstruction, thanks to the preservation of the collagen’s biochemical and biological qualities.
• COLLAPAT® II is perfectly biocompatible thanks to the know-how and expertise of SYMATESE during the extraction and purification process.
• The porous three-dimensional mineral structure of COLLAPAT® II improves osteoblast differentiation and speeds up osteogenesis on the entire grafted area.
• Customized cross-linking process allows maintaining the collagen structure while the patient’s cells colonize the graft and allows for the collagen resorption after bone replacement.
• Osteoconductive: it is generally colonised completely by healthy orthotopic tissues thanks to intensive bone regeneration.

COLLAPAT® II offers:

• Haemostatic effect on the covered bone areas and on the muscles removed and replaced during the procedure, stopping bleeding within a few minutes.
• Ready to use and easy to handle, shape and cut.
• Hydrophilic: the matrix takes a paste consistency upon contact with blood or liquid tissue.
• Fits the anatomical area perfectly.

1 Fernandez de Grado: “Some composite materials containing HA and collagen exist as well, and their combination enhances osteoblast differentiation and accelerates osteogenesis.”
2 Données internes SYMATESE - COLLAPAT® II Clinical Evaluation Report.
3 Symatese preclinical data - Study 7513.
4 Symatese internal data - NOT 138.
SYMATESE has been manufacturing collagen-based medical devices for over 30 years. SYMATESE complies to the ISO 13485 quality standard: 2016. The collagen used for COLLAPAT® II is a type I bovine.

The osteoconductive properties of COLLAPAT® II have been demonstrated during a study carried out on rabbits. COLLAPAT® II was implanted into cortico-cancellous defect measuring 4.2 mm in diameter in the femoral site. Bone regrowth progress was evaluated on histological sections of impacted samples embedded in resin, with a magnifying power of 20 times from months T0 to T3.

The hydroxyapatite granules are dispersed in the collagen matrix.

After 3 months, the bone reconstruction is complete and is characterized by a mature remodeled bone tissue.

**PRECLINICAL DATA**

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

**OBJECTIVES**

- After cyst removal.
- Repair after an avulsion fracture.
- Avulsion, cyst removal, implant and filling.

**USED DEVICE/INSTRUCTIONS AND CONDITIONS FOR USE**

COLLAPAT® II single cube (reference: PAT1x1x1).

**STUDY TYPE**

Series of cases, future, monocentric.

**CENTRE(S)**

Université René Descartes, Dental surgery faculty of Paris V. Jean Claude Gomo.
STUDY PARTICIPANTS (number and characteristics)

- Number of patients: 3 cases.
- 3 cases were analysed.

TREATMENT PROTOCOL

Filling a bone defect with the bone substitute COLLAPAT® II.

DURATION OF USE

COLLAPAT® II is left in place and completely degrades.

EVALUATION CRITERIA

Visually observed bone growth and potential side effects.
Results are presented according to the quality of the bone growth.

RESULTS

For the 3 cases, the clinical test demonstrated good regeneration:

- 1st case: after cyst removal, first bone graft session with COLLAPAT® II on the defect created by the removal of the cyst, second session after 5 months, homogeneous bone structure appears normal, mature to the touch, two implants placement without issue.
- 2nd case: graft after avulsion following a radicular fracture of the back abutment of the cement-retained prosthesis, alveolar curettage and positioning of COLLAPAT® II in the socket.
- 3rd case: cyst avulsion, removal, impact and filled socket with COLLAPAT® II.

In the 3 case studies, no complications or side effects were observed.

PUBLICATION (reference)

“University degree in ongoing odontology training”.

These cases were published in the magazine “Chirurgien-dentiste de France” (“Dental Surgeon in France”), n°1343 dated 3 April 2008, pages 37-39:
“About bone filler material”.

CONCLUSION

COLLAPAT® II is an effective bone substitute in all the cases tested. It is well tolerated with no side effects.

This repair method is limited to bone structures lined by walls or sockets. The material is easy to use. Success depends mainly on the perfect assembly of the edges of the mucous membranes to cover the area.
MAXILLOFACIAL SURGERY CASE STUDY: DENTAL IMPLANT AND SINUS LIFT®

OBJECTIVES
Sinus lift for an implant purpose.

USED DEVICE/INSTRUCTIONS AND CONDITIONS FOR USE
COLLAPAT® II (reference: PAT 35 x 6) with PRF membranes.

STUDY TYPE
Case study.

STUDY PARTICIPANTS (number and characteristics)
42-year-old woman.

TREATMENT PROTOCOL
Filling a bone defect with the bone substitute COLLAPAT® II. COLLAPAT® II was cut and placed between the PRF membranes and the sinus floor. Gingival flap suture at separate points.

DURATION OF USE
COLLAPAT® II is left in place and completely colonised and absorbed.

EVALUATION CRITERIA
Visually observed bone growth and potential side effects.

RESULTS
COLLAPAT® II was easy to use and to handle. The implantation was satisfactory. Two implants were successfully placed 6 months after the graft.

CONCLUSION
COLLAPAT® II is effective and well tolerated in maxillofacial sinus lift surgery. Two implants were placed after bone healing (minimum 6 months).

1SYMATESE internal data - COLLAPAT® II Clinical Evaluation Report.
THE COLLAPAT® II RANGE

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• COLLAPAT® II is sterilised by a radiation dose of 25 kGy.
• COLLAPAT® II sponges are supplied in double packaging impenetrable by light and moisture, in single boxes, apart from the 1 x 1 x 1 cm unit which is supplied in a box of 5.
• COLLAPAT® II must be kept at ambient temperature (+10 °C à +30 °C).
• COLLAPAT® II is the result of COLLAPAT technology that was brought to market in 1980.
Collapati® II is an implantable medical device manufactured by SYMATESE - Z.I Les Troques - 69630 CHAPONOST FRANCE. Images are for representation purpose only. Do not throw in public areas.