English

COLLAPAT® II

Bone substitute biomaterial
Composed of collagen and hydroxyapatite
Osteoconductive and haemostatic
For repairing bone substance losses

CE 0459

(2002)

1. Description:

COLLAPAT® II is a haemostatic bone substitute biomaterial presented in a sponge form.
It is composed of a collagen structure in which ceramised hydroxyapatite granules are dispersed.
The granules of hydroxyapatite give the material its osteoconductive properties.
The hydroxyapatite is slowly resorbed.
The collagen gives COLLAPAT® II its strong haemostatic power and is completely resorbable in a few weeks.
The collagen is extracted from bovine dermis.
The manufacturing procedure comprises stages recognised to inactivate viruses and non-conventional transmissible agents such as Prions. These treatments make it possible to ensure maximum microbiological safety for COLLAPAT® II, in particular in respect to the agent responsible for BSE.

2. Indications:

In orthopaedics:
COLLAPAT® II is used to promote the repair of various types of bone lesions:
- After extracting cortico-spongoid bone fragments.
- After tumour resection.
- In revision cases.
- In surgical spondylodeses.
- In cases of pseudarthrosis.
- In certain fractures treated by osteosynthesis.

COLLAPAT® II is also used to induce bone substance replacement in maxillo facial surgery and odonto-stomatology.
- After removal of wisdom teeth or impacted cupsids,
- After removal of radicular or dental cysts,
- Periodontal pocket debridement,
- Filling for a sinus graft
- Restoration of bone stock following avulsion, trauma or tumours prior to fitting of implants.

3. Properties:

COLLAPAT® II is osteoconductive.
It is generally completely colonised by the healthy orthotopic tissue thanks to intensive bone regeneration.
COLLAPAT® II exerts a haemostatic effect on the bone surfaces that it covers and on the muscles that are partially freed and replaced during surgery, stopping bleeding in a few minutes.

4. Contraindications:

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

5. Adverse effects:

Although no allergic reaction to this product has been observed to date, this phenomenon cannot, a priori, be excluded with certitude in exceptional cases.

6. Interactions with other agents:

Since collagen reduces the adhesive power of cement (methyl methacrylate), COLLAPAT® II must not be applied on bone surfaces on which implant material must be fixed using this cement.

7. Precautions for use:

- COLLAPAT® II presents no shape stability or resistance to constraints. It therefore can only be used for the treatment of instable losses of bone substance in association with supporting osteosynthesis
- COLLAPAT® II must not be used dry, but must be wet before use.
- In regions with low bone regeneration, COLLAPAT® II alone is ineffective, but can be used in association with an autologous spongious tissue transplant, PRP (Platelet Rich Plasma) and/or after injection of autologous bone marrow.
- Insufficient regeneration is possible in unfavourable cases, in particular in the case of very great substance loss or in regions of weak bone regeneration. These cases can be avoided by strictly observing the indications and instructions for use.
- We only have very limited experience in the repeated use of COLLAPAT® II. It is therefore recommended to be prudent, taking into account the exogenous origin of the collagen, a source of possible allergic reactions.
- COLLAPAT® II should not be used in patients presenting with acute or chronic infection of the surgical site or in those receiving high doses of corticosteroids.
- COLLAPAT® II should not be used in patients presenting with:
  - Septicaemia,
  - Severe bone degeneration or major osteoporosis,
  - Osteomalacia,
  - Hyper-parathyroidism or severe hypercalcaemia.
- COLLAPAT® II should not be used in pregnant women.
- Do not use COLLAPAT® II after the expiry date indicated on the package.
- Do not use COLLAPAT® II if the package has been damaged.
- COLLAPAT® II must be used immediately after opening the package.
- If COLLAPAT® II is cut to size, the rest of the pad must be discarded.
- COLLAPAT® II must not be stored for later use once the package has been opened as this might create a risk of infection for the patient.
- COLLAPAT® II is a single-use product, it must not be re-sterilised.

8. Method of administration:

- COLLAPAT® II must be used in perfectly sterile operating conditions after adequate 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.
- Draining is strongly recommended but the drains must not be in direct contact with COLLAPAT® II.
- Rinsing of the implanted area is to be avoided.
- COLLAPAT® II is not designed to be removed 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.

9. Storage:

COLLAPAT® II should be stored at room temperature (10°C - 30°C).

10. Sterilisation:

COLLAPAT® II is sterilised by irradiation at 25 kGy.

11. Pad sizes:

COLLAPAT® II pads are available in three sizes:
1 x 1 x 1 cm
3.5 x 6 x 0.6 cm
7 x 11 x 0.6 cm

COLLAPAT® II pads are presented in light- and water-proof double wrapping, one unit per box, except for the 1 x 1 x 1 cm pads which are presented in boxes containing five units.

12. Information last updated:

January 2013

13. Meaning of the pictograms on the box

	Product for single-use only. Do not use again.
	Caution, please refer to the instructions for use
LOT	Batch number
	Expiry date
STERILE R	Sterile: the product has been sterilised by irradiation.
CE	CE marking in compliance with Directive 93 /42CEE relative to medical devices
10°C 30°C	Store between 10°C and 30°C
	Do not re-sterilise
	Ensure the package has not been damaged before use
	Product manufacturer

14. Additional information:

Additional information can be obtained from:

Responsible Manufacturer:

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