Bond Apatite®

Bone Graft Cement
Instructions for use

(EN) English

CE 0344

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INSTRUCTIONS FOR USE
Bond Apatite® is a bone graft cement composed of biphasic calcium sulfate and hydroxyapatite.
Please read this entire circular before performing the procedure.
This device is for sale by, or on the order of a physician, or licensed practitioner.

COMPOSITION
Each syringe contains highly pure medical grade biphasic calcium sulfate, hydroxyapatite granules and physiological saline.

PRODUCT DESCRIPTION
Bond Apatite® is a synthetic, osteoconductive, composite graft cement composed of biphasic calcium sulfate and hydroxyapatite granules. Bond Apatite® functions as a scaffold for bone regeneration in dental procedures, and is intended to fill, augment, or reconstruct bony defects in the oral and maxillofacial region.

STERILIZATION
Bond Apatite® sterilization is carried out using γ - irradiation.

INDICATIONS FOR USE
Bond Apatite® is a synthetic osteoconductive, bone grafting cement composed of hydroxyapatite and biphasic calcium sulfate in granulated powder form, intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region.

EXAMPLES OF CLINICAL APPLICATIONS
• Sinus floor augmentation • Periodontal bone defects • Dehiscence; fenestrations • Alveolar ridge augmentation • Horizontal defect (and crest widening) • Filling bony defects pre implant placement • Filling of cyst cavities

CONTRAINDICATIONS
• The customary contraindications in oral and maxillofacial surgery with other implant materials should be observed.
• Lack of adequate training of the practitioner is a major risk for the success of the implant procedure.

ABSOLUTE CONTRAINDICATION
Acute and chronic active infection at the site of the implant.

RELATIVE CONTRAINDICATION
• Serious disturbance of bone metabolism • Serious bone diseases of endocrine etiology • Severe or difficult to control diabetes mellitus • Severe renal dysfunction, severe liver disease • Vascular impairment at the implant site • Immunosuppressive and radiation therapy • Ongoing treatment with glucocorticoids, mineralocorticoids and with agents affecting calcium metabolism • Malignancies • Lactating and pregnancy • Effect on pediatric patients is not known

PRECAUTIONS AND WARNINGS
• The material is supplied for single use only. DO NOT RESTERILIZE. Bond Apatite® must no longer be used in case of partially opened or defective primary packaging (syringe) or secondary packaging (peel-off-blister) since the sterility of the material is no longer ensured • Do not use when the temperature of the product is below 10°C (50°F). If used in low temperatures, wait until the product restores room temperature (low temperatures will slow the setting reaction of the material) • It is not recommended to mix Bond Apatite® with other bone graft materials • It is not recommended to mix Bond Apatite® with blood • The expiration date is printed on the peel-off blister and on the external package. Do not use after indicated expiry date • Bond Apatite® does not possess sufficient mechanical strength to support load bearing defects prior to tissue in-growth. In case load support is required, standard internal or external stabilization techniques must be followed to obtain rigid stabilization in all planes • Bond Apatite® must not be used to stabilize screw placement • Bond Apatite® is intended for use by clinicians familiar with bone grafting procedures • Possible complications are the same as to be expected of autogenous bone grafting procedures. These may include: superficial wound infection, deep wound infection, deep wound infection with osteomyelitis, delayed union, loss of reduction, failure of fusion, loss of bone graft, graft protrusion and/or dislodgement, and general complications that may arise from anesthesia and/or surgery • Complications specific to oral/dental use are those as

may be typically observed for similar bone grafting procedures and may include: tooth sensitivity, gingival recession, flap sloughing, resorption or ankylosis of the treated root, abscess formation, nerve injury.

STORAGE
Store at temperatures between 5°C (41°F) to 30°C (86°F). Avoid contact with a source of heat.
Do not store the product in direct sunlight.

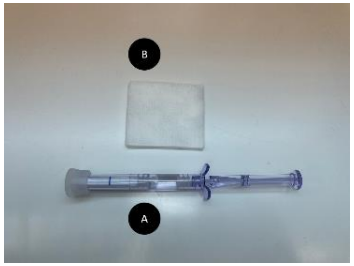
HANDLING
Bond Apatite® is available as granulated powder packed within a syringe. The syringe is separated into 2 compartments, one contains sterile standard saline solution (0.9% Sodium Chloride for injection) and the second contains the powder.

IMPORTANT
• Read all steps of the instructions (1-3) before using Bond Apatite® • We highly recommend practicing the use of Bond Apatite® before first usage.

Instructions for site preparation:
• Reflect the mucoperiosteal flap • Remove the undesired soft tissue from the exposed bone surface.
• Prepare the defected area for augmentation procedure
Note that a membrane is not required in most surgical procedures. In addition, primary flap closure is recommended but not essential for proper healing (since soft tissue may grow on top of Bond Apatite®).

STEP BY STEP
Read all instruction steps (1-3) before using Bond Apatite®.
It is recommended that the augmented site will be completely debrided and prepared before activating the material, the material should be injected to the site **immediately** after its activation.

PREPARATION STEP
Before applying Bond Apatite®, make sure you have the items described:
A - A sterile Bond Apatite® syringe
B - Dry sterile gauze pads



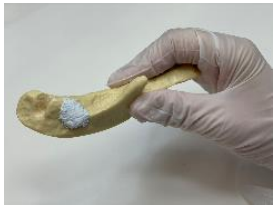
STEP 1.

Place your index finger firmly on syringe cap and slowly push the shaft towards the line marked on the syringe tube until the first plunger reaches the line. This will activate the material and prepare it for ejection.

Note: While pushing the shaft, mild pressure is required.

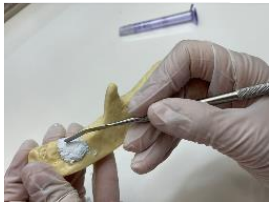
STEP 2.
Remove the cap by twisting and pulling it out.

STEP 3.
Continue to push the shaft and eject the material into the required site.
Note: The paste should be in direct contact with the bone and slightly overfilled.



After injecting the material into the required site:

Place a dry, sterile gauze pad on the material and firmly condense the cement by exerting pressure with a finger above the gauze for 3 seconds. Next, replace the finger pressure by applying additional compaction using periosteal elevator or spatula on the gauze for 3-5 second. **The material must be well compacted from all directions.**



Remove the gauze and slightly shape, if required.

Press on the material once again with dry gauze.

Remove the gauze and proceed with soft tissue coverage and wound closure.

POST TREATMENT CARE

- A surgical dressing may be placed over the wound for one to two weeks.
- Do not place any removeable, provisional appliance above the grafted site during the entirety of the healing stage.
- Instructions that include an appropriate analgesic, antibiotic and home care regimen should be delivered to the patient after surgical intervention.
- When Bond Apatite® is used for filling bony defects pre implant placement, let the site heal for 3 months to 6 months before dental implant placement.
- Prior to implant placement the grafted site must be evaluated to ensure that adequate bone healing has occurred.
- Place the dental implant and abutment according to the cleared indications and instructions for the dental implant/abutment system used.

RESORPTION PROFILE

The resorption of Bond Apatite® follows the resorption rate of the two components. The biphasic calcium sulfate component is completely resorbed in approximately 12 weeks.
The hydroxyapatite component is wholly or mostly absorbed by the body within six months

WASTE DISPOSAL AFTER USAGE

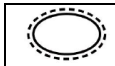
The disposal of the syringe after use should be in accordance with contaminated medical waste disposal instructions.

INCIDENT REPORTING

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

KEY TO USED CODES

* ISO 15223-1: Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied. – Part 1: General requirements

	Manufacturer (5.1.1)*
	**Authorized representative in the European Union** MedNet EC-REP III GmbH, Borkstrasse 10, 48163 Münster, Germany (5.1.2)*
	**CE Mark** with Notified Body identification number. (MDR 2017/745)
	Date and Country of manufacturer (5.1.3, 5.1.11)*
	Use-by date (5.1.4)*
	Batch code (5.1.5)*
	Catalogue/Part number (5.1.6)*
	Importer Indicates the entity importing the medical device into the locale. This symbol shall be accompanied by the name and address of the importing entity adjacent to the symbol. (5.1.8)*
	Distributor Indicates the entity distributing the medical device into the locale. This symbol shall be accompanied by the name and address of the distributing entity adjacent to the symbol. (5.1.9)*
	Sterilized using irradiation (5.2.4)*
	Do not resterilize (5.2.6)*
	Do Not Use if package is damaged (5.2.8)*
	Single sterile barrier system with protective packaging inside (5.2.13)*
	Single sterile barrier system with protective packaging outside (5.2.14)*
	Keep away from sunlight (5.3.2)*
	Temperature limit Indicates the temperature limits to which the medical device can be safely exposed. (5.3.7)*
	Do not re-use/ single use/ use only once (5.4.2)*
	Consult electronic instructions for use (5.4.3)*
	Caution Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that, for a variety of reasons, cannot be presented on the medical device itself. (5.4.4)*
	Medical Device (5.7.7)*
	Unique Device Identifier (5.7.10)*
℞ only	Prescription only Caution: US federal law restricts this product for sale by or on the order of a dentist or physician. (21 CFR 801.15 (c) (1)(i) (F), 801.109)
Qty	Quantity
cc	Dosage