RE-BONE®

RESORBABLE BONE SUBSTITUTE OF BOVINE ORIGIN
(sterile disposable device).

UBGEN SPECIALISTS OF BONE SURGERY IN DENTISTRY

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Intended use

RE-BONE® is a bone substitute intended to be employed in oral-maxillo-facial surgery, implantology, periodontology, oral surgery and endodontics in order to support the guided bone and tissue regeneration, to protect fixtures and to regenerate periodontal tissue. The bone substitute is produced with bovine bone in a controlled and standardized purification process. RE-BONE® is obtained from cattle controlled by the Veterinary Service, then purified, degreased, lyophilized and sterilized through ionizing radiations treatment. Average resorbable time depends on anatomic variables (relation between vital bone surface and volume of graft site) and on individual factors that vary among patients, it may vary from 6 to 8 months.

Cortico cancellous granules vial			
BMREBONE	**00A** 0,25 g - < 0,25 mm	**01A** 0,25 g - 0,25-1,00 mm	
	00B 0,50 g - < 0,25 mm	**01B** 0,50 g - 0,25-1,00 mm	**01E** 0,50 g - 1-2 mm
	00C 1,00 g - < 0,25 mm	**01C** 1,00 g - 0,25-1,00 mm	**01F** 1,00 g - 1-2 mm
	00D 2,00 g - < 0,25 mm	**01D** 2,00 g - 0,25-1,00 mm	**01G** 2,00 g - 1-2 mm
	00DA 5,00 g - < 0,25 mm	**01DA** 5,00 g - 0,25-1,00 mm	**01H** 5,00 g - 1-2 mm
Cancellous granules vial			
BMREBONE	**00E** 0,25 g - < 0,25 mm	**01I** 0,25 g - 0,25-1,00 mm	
	00F 0,50 g - < 0,25 mm	**01J** 0,50 g - 0,25-1,00 mm	**01M** 0,50 g - 1-2 mm
	00G 1,00 g - < 0,25 mm	**01K** 1,00 g - 0,25-1,00 mm	**01N** 1,00 g - 1-2 mm
	00H 2,00 g - < 0,25 mm	**01L** 2,00 g - 0,25-1,00 mm	**01O** 2,00 g - 1-2 mm
	00HA 5,00 g - < 0,25 mm	**01LA** 5,00 g - 0,25-1,00 mm	**01P** 5,00 g - 1-2 mm
Cortical granules vial			
BMREBONE	**00I** 0,25 g - < 0,25 mm	**01Q** 0,25 g - 0,25-1,00 mm	
	00J 0,50 g - < 0,25 mm	**01R** 0,50 g - 0,25-1,00 mm	**01U** 0,50 g - 1-2 mm
	00K 1,00 g - < 0,25 mm	**01S** 1,00 g - 0,25-1,00 mm	**01V** 1,00 g - 1-2 mm
	00L 2,00 g - < 0,25 mm	**01T** 2,00 g - 0,25-1,00 mm	**01W** 2,00 g - 1-2 mm
	00LA 5,00 g - < 0,25 mm	**01TA** 5,00 g - 0,25-1,00 mm	**01X** 5,00 g - 1-2 mm
Block			
BMREBONE	**02A** 10x10x10 mm		
	02B 10x10x20 mm		
Syringe			
BMREBONE	**03A** 0,25 g - 0,25-1 mm	**03BA** 1,00 g - 0,25-1 mm	**03CA** 1,00 g - 1-2 mm
	03B 0,5 g - 0,25-1 mm	**03BB** 1,50 g - 0,25-1 mm	**03CB** 1,50 g - 1-2 mm
	03C 0,5 g - 1-2 mm	**03BC** 2,00 g - 0,25-1 mm	**03CC** 2,00 g - 1-2 mm

All the codes shown in the table are also available in packs of 6 pieces, with the exception of blocks and syringes.

Therapeutic Indications

RE-BONE® is intended to use alone or in combination with suitable regenerative materials (e.g. autologous, allogenic or alloplastic bone, autologous platelet gel) for guided bone and tissue regeneration:

- For surgical bone defects or bone walls defects;
- Within sinus lift surgery, volume augmentation or reconstruction of alveolar crest;
- In treatment of fenestration defects;
- Within parodontal bone defects (defects on one-three walls, defects of forcation class I, II);
- In treatment of dehiscence;
- Following root canal therapy, cystectomy, avulsion of impacted tooth and resection of other bone defects;
- In post-extraction sockets following tooth extraction;
- In immediate or deferred augmentation around fixture in post-extraction sockets.

Instruction for use

RE-BONE® must be used only by professional clinicians who are expert in guided bone and tissue regeneration techniques. RE-BONE® block can be cut dry or wet with dental burs and shaped as the defects to be treated. The use of suitable surgical guide can help in the determination of the needed shape. During RE-BONE® application the general principles of sterility and medication of the patient should be respected. Adequately prepare the graft site, eliminate all the fibrous tissue debris and if it is necessary pierce the receiving tissue in order to facilitate the first phase of regeneration. The product can be hydrated with physiological solution or with APG (Autologous Platelet Gel) that can be obtained with GF-ONE® products. The bone defect must be completely filled with granules. However, to assure a wound closure without tension, it is essential to avoid an excessive filling. Out of site granules must be removed from the soft tissue. It is important to assure that the wound is closed without tension and saliva isn't allowed to enter. In specific circumstances it is advisable to use a layer of autologous cancellous bone in labial and buccal application of RE-BONE® granules, as well as the coating of this layer with periosteum or a membrane. After surgery, the patient shall follow the instruction of their dentist as far as oral hygiene is concerned.

RE-BONE® in granular format is also available with a syringe applicator. The device consists of a syringe with plunger, a reducer for the aspiration of the liquid and a closing cap. During use, the general principles of sterility and patient medication must be observed:

- Completely eliminate the granulated tissue after exposure of the defect;
- Remove the device from the blister;
- While holding RE-BONE® syringe still at the level of the reducer for aspirating liquids, unscrew the cap;
- Hydrate the content by withdrawing physiological solution, the patient's blood or platelet concentrate, pushing the plunger back and forth until the granules are completely rehydrated;
- Push the plunger so as to recompact the RE-BONE® granules and drain the excess liquid;
- Unscrew the tip for the suction of the liquids;
- Apply the bone substitute on the surgical site.

Contraindications, cautions

The clinician shall necessarily ensure the general and local clinical status of the patient, evaluating if treatment contraindications exist. As far as general health is concerned, the following contraindications shall be evaluated: cardiovascular and/or respiratory decompensation, cancers, decompensated diabetes, etc. Also evaluation of local conditions is important.

Do not use RE-BONE® in patients with:

- Acute infections in the oral cavity or acute or chronic inflammations in the graft site;
- Systemic pathologies for whom oral-maxillo-facial, implanter, periodontal, endodontic surgeries or other oral surgeries are not allowed;
- Known hypersensibility towards bovine origin bone.

Studies on the application of RE-BONE® during pregnancy and nursing neither on its influences on human breeding have been carried out. Before grafting RE-BONE® bone substitute, the dentist is obliged to perform an individual assessment of the benefits for the mother and the possible risks for the baby.

No data are available that suggest taking special precautions based on the age of the treated patients.

Side effects

- Rarely have been reported allergic or intolerance reactions towards RE-BONE® bone substitute of bovine origin.
- Seldom inflammatory tissue reactions may occur due to a prolonged duration of absorption.
- Any local pre-existing infections may worsen due to the graft of bone substitute RE-BONE®, as for any non-autologous materials.
- Possible generic complications may also occur during surgery, for example, the recession of the gums, strong bleeding gums, soft-tissue swelling, sensitivity to heat, desquamation of the gingival flap, resorption or ankylosis of the treated root, mild loss of crestal bone height, infection, pain or complications correlated with the use of anesthetic drugs.

Interactions with other products and methods

- The effectiveness of bone substitute RE-BONE® can be reduced by aggregation inhibitors and anticoagulants, since these products can affect the formation of blood clot.
- There are no known interactions in the MRI and, considering the biochemical composition of the bone substitute RE-BONE®, these interactions are not even foreseeable.

Warnings, precautions

- The bone substitute RE-BONE® is to be used only for the uses mentioned above. The device has not been tested clinically in patients with particularly serious surgical implant, periodontal, endodontic defects.
- Clinicians are responsible for informing their patients about any contraindications, side effects and necessary precautionary measures. In the presence of postoperative complaints, such as pain, infection, or other unusual symptoms, the patient should immediately consult the dentist.
- Patients with severe systemic disease (eg. Diabetes mellitus inadequately controlled, severe hypertension, severe peripheral arterial occlusive disease, malignancy or autoimmune diseases) or patients who, for example, have to undergo a long-term steroid treatment or an anticoagulant therapy, are to be managed with particular caution, as in all surgical procedures.
- It is necessary to report any serious accident occurring in relation to this medical device to the manufacturer and the competent authority.

Legend of symbols

UDI	UNIQUE IDENTIFICATION OF THE DEVICE
REF	PRODUCT CODE
LOT	LOT NUMBER
MD	MEDICAL DEVICE
	MANUFACTURING DATE
	EXPIRATION DATE
STERILE R	GAMMA IRRADIATION STERILIZATION PROCESS
5°C 30°C	STORAGE TEMPERATURE 5°C - 30°C
	KEEP DRY
	KEEP AWAY FROM DIRECT SUNLIGHT
	CAREFULLY READ THE INSTRUCTIONS BEFORE USING AVAILABLE AT THE LINK: https://www.ubgen.com/client/area-download.html
	DO NOT USE IF THE PACKAGING IS DAMAGED
	SINGLE USE
STERILIZE	DO NOT RE-STERILIZE

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