

**Instruction for Use**

**CoreBone  
Bioactive Bone Graft  
Natural Coral Mineral and Silicium**

**CoreBone 500S /CoreBone 1000S /CoreBone 2000S  
Dental**

CoreBone’s bioactive bone graft is composed from the pure mineral part of the coral; calcium carbonate crystals (>95%), in the form of Aragonite enriched by silicium and other non-organic substances. CoreBone is a resorbable, graft with structure and strength similar to human bone. It offers a natural and viable alternative to bovine and human derived grafts. CoreBone graft is intended for bone void filling in dental, maxillofacial and orthopedic conditions.

**DENTAL INDICATIONS:**

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of intrabody periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy.
- Filling of extraction sockets to enhance preservation of the alveolar ridge.
- Elevation of the maxillary sinus floor (closed and open sinus lift).
- Augmentation of facial bone defects in cosmetic surgery
- Maxillofacial reconstructive surgery,

**DIRECTIONS FOR USE**

**GENERAL – DENTAL**

As for any bone graft substitute, some specific rules must be followed when using CoreBone: CoreBone graft must be in intimate contact on all sides with bone tissue or minimally have a high surface area in contact with bone tissue. It can be applied at sites where autologous osteogenic cells are present to increase osteogenic capacity. It can be used in combination with autologous bone marrow. Cortical bone should be mechanically perforated to facilitate ingrowth of new blood vessels and bone forming cells. Stability of the graft in the implant site must be evident. Overfilling of the defects should be avoided. CoreBone can be used in contact with implant

**CoreBone granules :** Mix CoreBone granules with the patient’s blood or with physiological saline in a sterile vessel. Place the mixture into the defect, using sterile instruments (spatula or spoon). It is advisable to cover CoreBone with resorbable dental membrane. Soft tissue flap should completely cover the graft and should be fixed by sutures.’

**PRECAUTIONS**

In order to facilitate the formation of new bone, CoreBone should only be implanted in direct contact with a well vascularized bony tissue ,and if necessary microfracturation of the adjacent bone might be performed. Dental Implant placement depends on the local bone volume at the time of implant insertion, typically 4-6 months

In larger defects a mixture of autogenous bone or bone marrow may improve the formation of new bone.

CoreBone should be secured to prevent motion and migration, use in areas where the graft can be adequately contained (cannot move or escape).

Do not to use Corebone in the following cases:







- In acute and chronic infected sites (osteomyelitis).
- Vascular impairment at the implantation site
- Metabolic diseases (diabetes, hyperparathyroidism, osteomalacia)
- Autoimmune disease
- In a patient under steroid treatment.
- In conjunction with tumor cells or tissue.
- In ischemic tissue or if wound healing is disturbed.
- When patient under immunodepressant therapy.
- Heavy smoking
- In Diabetes mellitus.
- Effect on pregnant or lactating women is not known.

**ADVERSE REACTIONS:**

As with any other bone graft, Incompatibility reactions with CoreBone cannot be excluded. Possible complications which may occur with any surgery include swelling at the surgical site, flap sloughing, bleeding, local inflammation, bone loss, infection or pain.

**PRODUCT OFFERING**

Product Name	Granule Size $\mu\text{m}$	Volume ml
CoreBone 500-S	250-600 $\mu\text{m}$	0.25 0.5 1.0
CoreBone 1000-S	600-1000 $\mu\text{m}$	0.25 0.5 1.0
CoreBone 2000-S	1000-2000 $\mu\text{m}$	1.0 2.0

	ISO 13485:2016
<b>Disposal</b>	No special disposal instructions for unused CoreBone. opened or used vials must be disposed in clinical waste
	Sterilized by Gamma irradiation.
	Single Use Only Do not re-sterilize or re-use.
	Shelf Life – Three years from sterilization
	Storage- Keep in room temperature. 15°-30°C and in a dry place.
	CoreBone Ltd 17 Tchelet St., Misgav, 20174, Israel <a href="mailto:Info@core-bone.com">Info@core-bone.com</a>

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