Instruction for Use

THE Graft is intended for use as a bone grafting material to fill, augment or reconstruct periodontal or oral/maxillofacial defects.

DESCRIPTION
THE Graft is a natural, porous bone mineral matrix. It is produced by removal of all organic components from porcine bone. Due to its natural structure the anorganic bone mineral of THE Graft likens physical and chemical aspects of mineralized matrix of human bone. When packed into a bone defect, THE Graft gradually resorbs and is replaced with bone during the healing process. It is available in cancellous granules packaged in vial. THE Graft is sterilized using gamma irradiation.

PROPERTIES/ACTIONS
The anorganic bone matrix of THE Graft has macro and microscopic structures similar to human bone. The formation and ingrowth of new bone at the implantation site of THE Graft is favored, due to its trabecular architecture, interconnecting macro and micro pores and its natural consistency. The use of THE Graft may be considered when autogenousbone is not indicated, or insufficient in quantity to fulfill the needs of the proposed surgical procedure.

INDICATIONS AND USAGE
THE Graft is recommended for:
- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony 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.
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

INSTRUCTIONS FOR USE
- After exposure of the bony defect with a mucoperiosteal flap, all granulation tissue must be carefully removed.
- Mix THE Graft with autogenous bone, osseous coagulum, patient's blood or sterile normal saline using surgical curettes or graft material spoons with bone mixing bowl. If large maxillofacial defects are present, THE Graft should be mixed with autogenous bone in an approximate ratio of 1:1. The amount of blood or sterile normal saline used may be about 1/3 of the mixed bone, and it can vary depending on the surgeon's preference.
- In order to assure the formation of new bone, THE Graft should only be placed in direct contact with well vascularized bone.
- Loosely pack THE Graft granules into osseous defect using a sterile instrument, e.g., surgical curettes or graft material spoons. Use of excessive force will result in compression of the particles and loss of trabecular architecture.
- Overfilling of the defects should be avoided.
- The mucoperiosteal flaps should be sutured to achieve primary closure, if possible. A surgical dressing may be placed over the wound for one to two weeks.
- If primary wound closure cannot be achieved completely, further immobilization of the flap (e.g., by incision through the periosteum) should be performed and/or a bioabsorbable membrane should be placed over the bone graft site.

CONTRA-INDICATIONS

THE Graft has limited initial mechanical properties. Therefore, this product is contra-indicated where the device is intended as structural support. Conditions representing contraindications include also:

- osteomyelitis
- implantation in necrotic surgical sites
- degenerative bone disease
- intra-articular implantations
- as with any surgical procedure, care should be exercised in treating individuals with preexisting conditions that may affect the success of the surgical procedure. This includes (but is not limited to) individuals with long-term steroidal therapy or treatment acting on the calcium or phosphorus metabolism.

ADVERSE-EFFECTS

Possible adverse effects include but are not limited to:

- Wound complications including haematoma, infection, and other complications that are possible with any surgery

PRECAUTIONS

1. Do not use if package has been opened or damaged prior to use.
2. Do not reuse or re-sterilize THE Graft.
3. THE Graft is not designed for use under load bearing conditions.
4. THE Graft should not be used in the presence of active infection
5. THE Graft has been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination.
6. THE Graft should be kept in aseptic condition until using the product.
7. THE Graft is to be handled and implanted by trained and qualified persons having read this instruction for use
8. Do not mix or combine THE Graft with the other materials except that were mentioned at 'Instructions For Use'.

STORAGE

THE Graft should be stored at temperatures between 15~20℃ in a dry place.

THE Graft should be kept away from sunlight.

DISPOSAL

THE Graft is a degradable material. The manufacturing process and sterilization minimize the risk of contamination with pathogens. THE Graft can be disposed as ordinary waste.

SYMBOLS


Do not reuse

Sterilization using Irradiation


Attention, see instruction for use


Manufacturer

EU representative

	Temperature limitation
	Keep away from sunlight
	Do not resterilize
	Product code
	Expiration date
	Lot number
	Do not use if package is damaged
	Keep dry
Rx Only	Prescription only

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