

OSTEOGENE TECH CORP
InRoad® Dental Synthetic Bone Graft
Instructions for Use

Before using this product, the surgeon/practitioner should carefully study the indications, contraindications, precautions, warnings, and directions for use and fully comply with them. The manufacturer, the importer and the distributor of these products are not liable for complications, other negative effects or damages that might occur for reasons such as incorrect indications or surgical technique, unsuitable choice of material or handling thereof, unsuitable use or handling of the instruments, asepsis and so on. The surgeon/practitioner is responsible for any such complications or other consequences.

Description

InRoad® Dental Synthetic Bone Graft is a synthetic, semi-dense multi-porous bioceramic for bone regeneration. It is comprised of 90 ± 5% hydroxyapatite (HA) and 10 ± 5% β -tricalcium phosphate (β -TCP). The granules are provided sterile (gamma irradiated) in a capped vial packaged in a sealed tray with lid.

InRoad® Dental Synthetic Bone Graft granules are designed to resemble trabecular bone structure. InRoad® Dental Synthetic Bone Graft consists of interconnected primary open pores, secondary channel-like structure, and tertiary small holes on the surface in a biocompatible and osteoconductive biomaterial. The multi-porous structure of the material makes it possible for the bone cells to migrate into the matrices and for new bone to grow.

InRoad® Dental Synthetic Bone Graft are packaged in the following configurations.

Please note that not all configurations are available in every country or region:

REF	Description	Volume
HA90D05S	InRoad® Small (0.3 – 1.0 mm) Dental Synthetic Bone Graft granules	0.5 cc
HA90D10S	InRoad® Small (0.3 – 1.0 mm) Dental Synthetic Bone Graft granules	1.0 cc
HA90D20S	InRoad® Small (0.3 – 1.0 mm) Dental Synthetic Bone Graft granules	2.0 cc
HA90D30S	InRoad® Small (0.3 – 1.0 mm) Dental Synthetic Bone Graft granules	3.0 cc
HA90D05L	InRoad® Large (0.8 – 1.8 mm) Dental Synthetic Bone Graft granules	0.5 cc
HA90D10L	InRoad® Large (0.8 – 1.8 mm) Dental Synthetic Bone Graft granules	1.0 cc
HA90D20L	InRoad® Large (0.8 – 1.8 mm) Dental Synthetic Bone Graft granules	2.0 cc
HA90D30L	InRoad® Large (0.8 – 1.8 mm) Dental Synthetic Bone Graft granules	3.0 cc

InRoad® Dental Synthetic Bone Graft should only be used by, or under the supervision of, specialized personnel experienced in the required techniques and in the use of biomaterials.

Indications for Use

InRoad® Dental Synthetic Bone Graft is indicated for the filling and reconstruction of multi-walled bone defects such as:

- Defects after removal of bone cysts
- Augmentation of the atrophied alveolar ridge
- Sinus lift and sinus floor elevation (subantral augmentation)
- Filling of alveolar defects following tooth extraction for alveolar ridge preservation
- Filling of extraction defects to create an implant bed
- Filling of two- or multi-walled infra-bony pockets and bi- and trifurcation defects
- Support function for a membrane in controlled tissue regeneration (CTR)
- Defects after surgical removal of retained teeth or corrective osteotomies
- Other multi-walled bony defects of the alveolar processes

Contraindications

InRoad® Dental Synthetic Bone Graft should not be used in patients with:

- Acute and chronic infections at the operation site
- Severe metabolic diseases (diabetes, hyperparathyroidism, osteomalacia)
- Chronic high dose therapy with corticosteroids
- Osteomyelitis at the surgical site
- Vascular impairment at the implant site
- Severe renal dysfunction, liver disease
- Radiotherapy in the surgical region
- Nicotine abuse
- Disorders of calcium metabolism
- Drugs that interfere with calcium metabolism such as steroid hormones immunosuppressive therapy
- Endocrinological bone diseases

InRoad® Dental Synthetic Bone Graft may still be used to fill bony defects despite the presence of some of the circumstances listed above based on the experience of the trained dental professional. The patient should be informed appropriately about the possible effects of the complicating circumstances on the expected success of the use of InRoad® Dental Synthetic Bone Graft.

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Warnings

The following warnings should be heeded when using InRoad® Dental Synthetic Bone Graft:

- InRoad® Dental Synthetic Bone Graft cannot assume a load bearing function. Depending on the nature and localization of the bone defect to be treated, additional osteosynthetic measures may be necessary.
- For endosseous dental implants a period of 4-6 months and for sinus lift a period of 6-12 months should elapse between defect filling with InRoad® Dental Synthetic Bone Graft and insertion of the implant.
- Tension-free and saliva-proof wound closure is always required when using InRoad® Dental Synthetic Bone Graft in oral and maxillofacial surgery and dentistry.
- The use of a membrane is advised especially for larger defect surfaces.
- Do not overfill defect or apply excessive force when implanting InRoad® Dental Synthetic Bone Graft at the surgical site
- InRoad® Dental Synthetic Bone Graft is for single use only, do not re-sterilize or reuse. Reuse may cause lack of effectivity, infection, and/or loss of bone or soft tissue.

Adverse Effects

No adverse reactions have been reported.

Principle of Use

InRoad® Dental Synthetic Bone Graft granule size is selected by the user based on the size of the bony defect to be filled. InRoad® Dental Synthetic Bone Graft is then applied to the prepared graft bed. The multi-porous structure of InRoad® Dental Synthetic Bone Graft makes it possible for the bone cells to migrate and regenerated bone to grow into the matrices.

InRoad® Dental Synthetic Bone Graft may only be used by, or under the supervision of, specialized personnel experienced in the required techniques and in the use of biomaterials. The choice of application form and the exact surgical procedure depend on the localization, nature, and scope of the defect.

Instructions for Use

- After exposure of the bony defect with mucoperiosteal flap, all bone fragments, inflammatory or necrotic tissue, and debris must be carefully and completely removed. Thoroughly rinse out the bony defect site with saline before introduction of InRoad® Dental Synthetic Bone Graft. Direct contact between InRoad® Dental Synthetic Bone Graft and bleeding vital bone is essential.
- Mixing InRoad® Dental Synthetic Bone Graft with the patient's blood from the wound site may be helpful. Additional venous autologous blood may be required to keep the granules saturated. InRoad® Dental Synthetic Bone Graft can be mixed with autologous blood in a sterile dish.
- Fill in the defect site gently with InRoad® Dental Synthetic Bone Graft to avoid crushing of the granules and loss of porous architecture.
- Bone defect should be filled completely. Overfilling the defect should be avoided to achieve tension-free closure.
- Implanted InRoad® Dental Synthetic Bone Graft and wound should be protected with a sutured mucosal periodontal flap or membrane (for large defects).
- The patient should be informed appropriately about the possible effects of the complicating circumstances on the expected success of the use of InRoad® Dental Synthetic Bone Graft.

Storage

InRoad® Dental Synthetic Bone Graft should be stored in a dry place at ambient temperature.

Glossary of Symbols

	Consult instructions for use		Do not re-sterilize
	Do not reuse		Do not use if packaging is damaged
	Use by date (YYYY-MM-DD)	LOT	Batch code
	Sterilized using irradiation	REF	Catalog number
Rx Only	Prescription only		Manufacturer address
	Single sterile barrier system with protective packaging inside		Date of manufacture (YYYY-MM-DD)
UDI	Unique device identifier		Keep Dry

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