

AmGraft® - Instructions for Use

Product Description

AmGraft® is a dentin matrix, which is made from human teeth. It is produced in chip form between 500-1000 microns and provided freeze dried and sterile.

Properties

AmGraft® is a biocompatible filler to supplement the dentoalveolar bone and provide structural function, by filling and/or augmenting bony voids or gaps in the dentoalveolar region.

Indications for use

AmGraft® is intended to be used to fill and/or augment bony voids or gaps in dentoalveolar surgery.

AmGraft® is recommended for the following clinical uses:

- Augmentation or reconstructive treatment of the alveolar ridge
- Filling of alveolar bone defects after root resection, apicoectomy, and cystectomy
- Filling of alveolar defects following dental extraction
- Filling of periodontal alveolar bone defects
- Filling of peri-implant alveolar bone defects

Contraindications

AmGraft® shall not be used in patients where general oral surgery is contraindicated (e. g. infection at the site of grafting).

Precautions

AmGraft® is restricted to use by a licensed clinician.

AmGraft® is not intended to bear mechanical loads.

A minimum period of 6 months' healing is recommended at the augmented site using AmGraft®. The determination of the appropriate healing time has to be decided by the practitioner based on the diagnosis of the patient's situation and condition.

AmGraft® should be used with special caution in cases of all diseases or therapies which adversely affect the healing of the defect.

The diseases or therapies include but not limited to:

- Acute and chronic infections at or surrounding the operating area (e.g. soft tissue infections; inflamed, bacterial bone diseases; osteomyelitis)
- Metabolic diseases, such as non- or poorly controlled diabetes mellitus, hyperparathyroidism, osteomalacia.
- Disorders of calcium metabolism or treatment by pharmaceuticals interfering with calcium metabolism

- Treatment with steroids, antineoplastic drugs, immunosuppressives, high dose glucocorticoids
- Endocrinological bone diseases
- Severe renal dysfunction, severe liver disease
- Vascular impairment
- Autoimmune disease
- Radiotherapy
- Heavy smoking

Use during pregnancy and lactation

Effect on pregnant or lactating woman is not known.

Use in children

Effect on children is not known.

Duration of use

Permanent implantation.

Adverse events

- Reports on adverse events are not available at the present moment.
- Adverse outcomes potentially attributable to the product must be promptly reported to Ventas Bio Pte Ltd or your distributor, and your country's Competent Authority.

Warnings

- AmGraft® is designed for use in one patient only. DO NOT re-use or re-sterilize.
- DO NOT use if the product label on the box or the outer packaging tray is missing or tampered with.
- DO NOT use if the box or the packaging seals are not intact.
- DO NOT use if the expiration date indicated on the label has passed.
- Care must be taken to prevent contamination and do not use any contaminated product.
- The clinical outcome of mixing AmGraft® with other bone graft materials is not known.

Instruction for Use

- The general principles of sterile handling and patient medication must be followed when using AmGraft®.
- AmGraft® must only be employed by or under the supervision of licensed clinician with experience in the required surgical techniques and the use of biomaterials. The exact operating procedure depends on the location, type and size of the defect.
- To prepare the graft bed, bone fragments, granulation and necrotic tissue must be carefully removed before applying AmGraft®.
- Application
 - Peel open the lid of the outer packaging tray using sterile techniques.

- Transfer the sterile inner packaging tray into a sterile field, using sterile techniques.
- Peel open the lid of the inner packaging tray.
- Empty desired amount of chips into sterile dappen dish.
- The surgeon can place AmGraft® directly at the surgical site. The surgeon may also choose to hydrate or mix the chips with patient's blood obtained from the surgical site or saline to facilitate carrying of the graft to the intended surgical site.
- A sterile spatula, curette or a plastic carrier can be used to carry the chips to site.
- In situ modelling may be performed with a sterile spatula or other suitable instrument.
- The mucoperiosteal flaps can be sutured to achieve primary closure and to minimize particle loss. In some cases the surgeon may want to place a surgical dressing or membrane over the wound.

Storage and Handling

AmGraft® should be kept in its original packaging, stored in a clean, dry place at room temperature 10°C to 30°C.

The expiration date is printed on the box as well as on the outer packaging tray. DO NOT use after expiration date. Residuals are to be disposed as clinical waste.

Method of Sterilization

AmGraft® is provided sterile in a sealed inner packaging tray, as well as in a sealed outer packaging. Both the content of the inner and outer packaging trays are sterile and enclosed in a non-sterile box.

AmGraft® has been sterilized by ethylene oxide.

Manufacturer

Ventas Bio Pte Ltd
2 Tukang Innovation Grove
#07-02
JTC Medtech Hub
Singapore 618305

Upon publication of these instructions for use, all previous versions are superseded.

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