




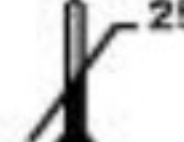







Read this package insert completely before use and comply with the instructions for use.

GingivAid Collagen Bone Graft

DOH-MD-No.003196

GRAPHICAL SYMBOLS

	Single use only		Catalog number
	Read instructions before use		Lot number
	Sterilization by irradiation		Store at room temperature
	Do not re-sterilize		Keep away from sunlight
	Use by expiry date		Do not use if package is damaged
	Manufacturer		

Description

GingivAid Collagen Bone Graft is a synthetic dental graft substitute comprised of highly purified type I collagen and hydroxyapatite (HA)/ β -tricalcium phosphate (TCP). The purified fibrillar collagen component has a high constituent of purified bovine tendon Type I collagen. The mineral component of GingivAid Collagen Bone Graft is a biphasic mixture of hydroxyapatite and β -tricalcium phosphate. The HA/ β -TCP particles are formed by a sintering process into irregularly shaped granules of 0.5-1.0 mm in diameter. The bone graft mimics the composition of natural bone and is biocompatible. GingivAid Collagen Bone Graft provides an osteoconductive environment for new bone formation. In situ, the collagen and β -tricalcium phosphate component of the ceramic are resorbed and replaced by new bone, similar to the resorption and remodeling observed with autogenous bone. GingivAid Collagen Bone Graft can eliminate the trauma and complication for second site surgery in order to harvest the patient's own autograft.

Indications

GingivAid Collagen Bone Graft is indicated for filling and/or augmenting intraoral/maxillofacial osseous defects. GingivAid Collagen Bone Graft can be used in the following treatments

- Augmentation/reconstruction of bone defect of the alveolar ridges.
- Filling of tooth extraction sites.
- Filling of bone dehiscence and sinus floor augmentations.
- Filling of intrabony periodontal osseous and furcation defects.
- Filling of periodontal defect, support products intended for guided tissue regeneration (GTR) and guided bone regeneration (GBR)

Instructions for using GingivAid Collagen Bone Graft

The general principles of sterile handling and patient medication must be followed when using GingivAid Collagen Bone Graft.

- Complete elimination of granulation tissue following exposure of the defect.
- Application:
 - a)Block and strip type of GingivAid Collagen Bone Graft may be cut to the required size with sterile tweezers and scissors, in dry form or after moistening (with blood or physiological saline solution). The material is applied using sterile instruments, e.g. tweezers.
 - b)Granule type of GingivAid Collagen Bone Graft can be may mixed with patient's blood or physiological saline solution to form putty before implantation. GingivAid granule is placed into the defect site, using sterilized instrument (spatula or spoon). Patient's blood can either be taken from the surgical site or venous blood. Recommendation: 0.3 - 0.5ml of patient blood or physiological saline solution per 1g granule type of GingivAid Collagen Bone Graft.

- In situ modeling may be performed with a sterile spatula or other suitable instrument.
- It is advisable to cover GingivAid Collagen Bone Graft with a membrane barrier
- When closing the wound the soft tissue flap should completely cover the implanted GingivAid Collagen Bone Graft and should be fixed by sutures
- If primary wound closure cannot be achieved completely, further mobilization of the flap (incision through the periosteum) should be performed or wound covering should be achieved with a membrane.

Precaution

- The safety and efficacy of GingivAid Collagen Bone Graft have not been established in patients with pathological fractures caused by severe degenerative bone disease, pre-existing severe vascular or neurological disease in the affected limb as a result of uncontrolled diabetes, alcoholism, or other pathology, or in patients with clinically significant immune-mediated systemic disease, or disease of bone.
- GingivAid Collagen Bone Graft is intended for use by dentists familiar with dental grafting and internal fixation techniques.
- Confirm expiration date before use. Do not use if expiration date has been exceeded.
- Do not use if packaging is damaged, as sterility of the contents cannot be assured.
- Dosage is for single use only. Do not re-sterilize or re-use. When GingivAid Collagen Bone Graft is mistakenly re-used, it may cause cross-infection.

Contraindications

GingivAid Collagen Bone Graft is not designed or sold for any use except as indicated. Do not use GingivAid Collagen Bone Graft in the presence of any contraindication.

- (1) in patients with a history of severe allergies manifested by a history of anaphylaxis and known allergies to bovine collagen.
- (2) in patients known to be undergoing desensitization injections to meat products, as these injections can contain bovine collagen.
- (3) in children and pregnant women.
- (4) in the presence of metabolic or systemic bone disorder.
- (5) in contaminated wounds with existing acute or chronic infections.
- (6) patients with autoimmune disease

Specifications

GingivAid Collagen Bone Graft, a sterile (γ -irradiation) bone graft substitute, is supplied in prefabricated block, strips or granules of various volumes.

Product type	Specifications
GA-S01	10 mm× 10 mm× 10.5 mm
GA-S02	15 mm× 22.5 mm× 3.5 mm
GA-S03	15 mm× 45.0 mm× 3.5 mm
GA-S04	12 mm× 45.0 mm× 10.5 mm
GA-G01	1 cc Granules (1.0~3.0 mm)
GA-G02	2 cc Granules (1.0~3.0 mm)
GA-G03	0.25 cc Granules (0.5 - 1 mm)
GA-G04	0.5 cc Granules (0.5 - 1 mm)
GA-G05	1 cc Granules (0.5 - 1 mm)
GA-G06	2 cc Granules (0.5 - 1 mm)

Suggestions for use:
 Block: Elevation of the maxillary sinus floors.
 Strip: Augmentation/reconstruction of alveolar ridge.
 Granule: Filling of the intrabony periodontal osseous and furcation defect.

Storage:

GingivAid Collagen Bone Graft should be stored at room temperature in a dry place. Do not expose GingivAid Collagen Bone Graft to extreme environmental conditions. Do not use after expiration date.

Caution:

Federal law restricts this device to sale by or on the order of a dentist.

Warnings

GingivAid Collagen Bone Graft cannot be autoclaved because the collagen fibrous structure as well as the packaging will be damaged. GingivAid Collagen Bone Graft should not be re-sterilized. Residual portions of GingivAid Collagen Bone Graft should be discarded after use.

GingivAid Collagen Bone Graft contains bovine collagen and must not be used to patients with a history of allergy to collagen products. Hypersensitivity reactions reported when using collagen products including erythema, swelling, induration, and/or urticaria.

MBI Maxigen Biotech Inc.

No. 17, Wuchiuan 8th Rd., Wugu District, New Taipei City 24891, Taiwan(R.O.C)

Tel: +886-2-2298-2345 Fax: +886-2-5591-9522