


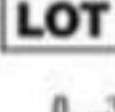
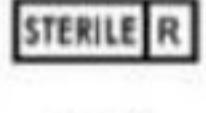









Read this package insert completely before use and comply with the instructions for use.

# BestAid<sup>®</sup> Collagen Bone Graft

DOH-MD-No. 003864

## GRAPHICAL SYMBOLS

	Single use only		Catalog number
	Read instructions before use		Lot number
	Sterilization by irradiation		Store at 15-30°C
	Do not re-sterilize		Keep away from sunlight
	Use by expiry date		Do not use if package is damaged
	Manufacturer		Recycling

## Description

BestAid<sup>®</sup> Collagen Bone Graft is a synthetic graft substitute comprised of highly purified type I collagen and hydroxyapatite (HA)/beta-tricalcium phosphate ( $\beta$ -TCP) granules. It functions as an osteogenic stimulus to which the patient's bone marrow may be added prior to implantation. The bone graft mimics the composition of natural bone and is biocompatible. BestAid<sup>®</sup> Collagen Bone Graft provides an osteoconductive environment for new bone formation. When coated with autogenous bone marrow, the osteoinductive and osteogenic properties of BestAid<sup>®</sup> Collagen Bone Graft enable it to be used as a substitute for autogenous bone graft. The purified fibrillar collagen component has a high constitute of purified bovine tendon Type I collagen. The mineral component is a biphasic mixture of beta-tricalcium phosphate and hydroxyapatite. The HA /  $\beta$ -TCP particles are formed by a sintering process into irregularly shaped granules. The purified fibrillar collagen and HA /  $\beta$ -TCP composite serves as the matrix for osteogenesis process to occur. In situ, the collagen and beta-tricalcium phosphate components of the ceramic are resorbed and replaced by new bone, similar to the resorption and remodeling observed with autogenous bone.

## Intended use

BestAid<sup>®</sup> Collagen Bone Graft is mainly intended use to induce osteoconduction to repair the bone defects in the bony voids or gaps that are not intrinsic to the stability of the bony structure. BestAid<sup>®</sup> Collagen Bone Graft can be mixed with autogenous bone marrow prior to use at the physician's discretion to induce osteoinduction which has the same efficiency as the autograft. BestAid<sup>®</sup> Collagen Bone Graft also can be the vector of cells or growth factors to promote proliferation and differentiation of bone cells. The product provides bone void filler that resorbs and is replaced by the growth of new bone during the healing process.

## Indications for use

BestAid<sup>®</sup> Collagen Bone Graft is indicated for use in bone defects which may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product should be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). In weight bearing situations, BestAid<sup>®</sup> Collagen Bone Graft does not have the function to maintain the bone structural stability and has to be used in conjunction with internal or external fixation devices. The fracture defect treated with BestAid<sup>®</sup> Collagen Bone Graft should not exceed 30 mL.

## Contraindications

BestAid<sup>®</sup> Collagen Bone Graft is not designed or sold for any use except as indicated. Do not use BestAid<sup>®</sup> 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 operative sites with inflammatory bone disease such as osteomyelitis. (5) For fractures of the epiphyseal plate. (6) In sites with severe vascular or neurological impairment proximal to the graft site. (7) In the presence of metabolic or systemic bone disorder. (8) In contaminated wounds with existing acute or chronic infections.

## Potential adverse events and complications

Possible adverse reactions may include but are not limited to the followings: Total resorption of the graft, malunion, pseudoarthrosis, hypersensitivity, bleeding at the bone marrow aspiration site, thrombophlebitis, embolus, loss of fixation, neurological complication, and deformity at site. As with any other orthopedic and grafting procedures, wound complications may occur, which include hematoma, edema, swelling and fluid accumulation, tissue thinning, infection, or other complications that are possible with any surgery.

## Precaution

The safety and efficacy of BestAid<sup>®</sup> 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. The safety of using BestAid<sup>®</sup>

- Collagen Bone Graft in pregnant women or in children has not been established.
- BestAid<sup>®</sup> Collagen Bone Graft is intended for use by surgeons familiar with bone grafting and internal fixation techniques. Care should be exercised to avoid a load directly on the implant.
- 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.

## Instructions for using BestAid<sup>®</sup> Collagen Bone Graft

Strip type and granule type of BestAid<sup>®</sup> Collagen Bone Graft may be prepared prior to use. Initial debridement and wound management should be performed in an open fracture. Exercise care to minimize periosteal stripping. Contamination wounds should be treated with appropriate prophylactic antibiotic coverage, prior to the graft procedure. All procedures should be performed in the operating room under aseptic conditions. Follow accepted procedures for grafting with fixation. Bone marrow maybe collected from the iliac crest, using standard bone marrow collection techniques. If marrow from the fracture site is used, it is important that the marrow has not been contaminated. Exercise care not to collect blood. Transfer the BestAid<sup>®</sup> Collagen Bone Graft to a sterile tray containing bone marrow and coat all surfaces with marrow. Add 1 mL of bone marrow per cc of BestAid<sup>®</sup> Collagen Bone Graft. The BestAid<sup>®</sup> Collagen Bone Graft may be used as is or molded to fit the defect shape. Extra care should be taken in molding the BestAid<sup>®</sup> Collagen Bone Graft in order to avoid crushing the strips/granules or damaging the marrow cell. The defect site should be filled as completely as possible.

## Specifications

BestAid<sup>®</sup> Collagen Bone Graft, a sterile ( $\gamma$ -irradiation) bone graft substitute, is supplied in prefabricated block, strips or granules of various volumes.

Product type	Specifications
GA-B01	12.0 mm × 10.5 mm × 45.0 mm
GA-S01	15.0 mm × 3.5 mm × 50.0 mm
GA-GL0025	0.25 cc Granules (1.0 - 3.0 mm)
GA-GL005	0.5 cc Granules (1.0 - 3.0 mm)
GA-GL02	2 cc Granules (1.0 - 3.0 mm)
GA-GL05	5 cc Granules (1.0 - 3.0 mm)
GA-GL10	10 cc Granules (1.0 - 3.0 mm)
GA-GS0025	0.25 cc Granules (0.5 - 1.0 mm)
GA-GS005	0.5 cc Granules (0.5 - 1.0 mm)
GA-GS02	2 cc Granules (0.5 - 1.0 mm)
GA-GS05	5 cc Granules (0.5 - 1.0 mm)
GA-GS10	10 cc Granules (0.5 - 1.0 mm)

## Storage

BestAid<sup>®</sup> Collagen Bone Graft should be stored at room temperature (15-30°C) in a dry place. Do not expose BestAid<sup>®</sup> Collagen Bone Graft to extreme environmental conditions. Do not use after expiration date.

## Packaging

Packages for each of the components should be intact upon receipt. Products should be carefully examined for completeness, and for lack of damage, prior to use. Damaged packages or products should not be used, and should be returned to the agent.

## Warning

- BestAid<sup>®</sup> Collagen Bone Graft is intended for use only as indicated.
- BestAid<sup>®</sup> Collagen Bone Graft contains bovine collagen and must not be used in patients with a history of allergies to any bovine collagen product, including but not limited to injectable collagen, collagen implants, hemostatic sponges and collagen based sutures, because these patients are likely to have hypersensitivity to bovine collagen in BestAid<sup>®</sup> Collagen Bone Graft. Hypersensitivity reactions reported with the use of other products containing bovine collagen include erythema, swelling, induration, and/or urticarial at implantation sites.
  - BestAid<sup>®</sup> Collagen Bone Graft does not possess sufficient mechanical strength for load-bearing uses. It is important to ensure that the implantation site has been properly secured mechanically with standard internal fixation. External stabilization alone is not sufficient.

## MDA Reg. No: 0000

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