INTERFACE
Bioactive Bone Graft

BIOACTIVE BONE GRAFT

Instructions for use

Caution: Federal Law (U.S.) restricts this device to sale by or on the order of a physician (or properly licensed practitioner)

A. General Information
Device Generic Name: Interface Bone Void Filler
Device Trade Name: Interface Bioactive Bone Graft

Manufacturer: BioStructures, LLC,
1201 Dove Street, Suite 470
Newport Beach, CA 92660

B. Materials and Device Description
Interface is a synthetic bioactive bone graft for use in the repair of osseous defects. It is supplied as irregular synthetic granules of bioactive glass (45S5 Bioglass), sized from 200 microns to 420 microns. When implanted in living tissue, the material undergoes a time dependent surface modification. The surface reaction results in the formation of a calcium phosphate layer, which is equivalent in composition and structure to the hydroxyapatite found in bone mineral. The biological apatite layer of the granules provides an osteoconductive scaffold for the generation of new osseous tissue. New bone infiltrates around the granules allowing the repair of the defect as the granules are absorbed.

The elemental composition of Interface is Si, Ca, Na, and P.

Interface conforms to ASTM specification F1538 for 45S5 Bioglass.

C. Indications
Interface Bone Void Filler is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structures. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Interface Bone Void Filler is indicated to be gently packed into bony voids or gaps of the skeletal system (extremities and pelvis), and in the posterolateral spine when mixed with autograft. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

D. Contraindications
Interface should NOT be used in patients who:

1. Use medication known to affect the skeleton (e.g. chronic glucocorticoid use >10mg/day for the previous 3 months) Estrogen replacement therapy is allowed.
2. Need chronic anticoagulant therapy (e.g. heparin). Prophylactic use of coumadin or aspirin postoperatively is allowed.
3. Have systemic metabolic disorder know to adversely affect bone healing and mineralization (e.g. insulin-dependent diabetes, renal osteodystrophy, Paget's disease), other than primary osteoporosis.
4. Have a large osseous defect where the total volume of a single defect exceeds 30cm.^{3}

E. Surgical Procedure
Interface should contact as much viable bone as possible. Blood from the host bone at the implantation site is an indicator for the presence of viable bone. Regeneration of bone will occur when adjacent blood vessels can infiltrate into the graft material.
Do not over compress Interface or blot away blood/moisture in the placed graft material. Excess compression may crush granules or force granules into unintended areas.

F. Use in Extremities and Pelvis
Gently peel open the pouch to obtain the vial. Carefully twist off the cap of the vial and pour the contents of the vial into a sterile dish. Add approximately 0.4 ml sterile saline for each 1cc of Interface material, as shown in the adjacent table. Gently mix Interface with the saline.

Remove excess liquid with a moist gauze. Use a spatula to deliver the mixture to the defect site. Remove any excess material and close.

Discard any excess material and packaging. Neither the Interface material nor packaging can be re-sterilized. Discard any opened, unused Interface material.

Part No.	Vial Size	Approximate Volume of Interface Bone Void Filler	Approximate Volume of Sterile Saline to Add
IFBG037	0.37 gram	0.27 cc	0.11 cc
IFBG100	1 gram	0.71 cc	0.28 cc
IFBG175	2 gram	1.43 cc	0.57 cc
IFBG350	4 gram	2.86 cc	1.14 cc
IFBG700	7 gram	5.00 cc	2.00 cc

G. Use in the Posterolateral Spine
Harvest a sufficient quantity of autograft bone and morselize into granules approximately 1 mm to 5 mm in size. Estimate the volume of autograft, which will be mixed 1:1 with Interface.

Gently peel open the pouch to obtain the vial. Carefully twist off the cap of the vial and pour the contents of the vial into a sterile dish.

Add approximately 0.4 ml of the patient's blood for each 1 cc of Interface material, as shown in the table below. Gently mix Interface with the patient's blood. Based on the volume of autograft, wet an equal volume of Interface.

Part No.	Vial Size	Approximate Volume of Interface Bone Void Filler	Approximate Volume of Patient's Blood to Add
IFBG037	0.37 gram	0.27 cc	0.11 cc
IFBG100	1 gram	0.71 cc	0.28 cc
IFBG175	2 gram	1.43 cc	0.57 cc
IFBG350	4 gram	2.86 cc	1.14 cc
IFBG700	7 gram	5.00 cc	2.00 cc

Remove excess liquid with a moist gauze. Mix the morselized autograft with the Interface Bone Void Filler in a volume ratio of 1:1. Use a spatula to deliver the mixture to the defect site. Remove any excess material and close.

Discard any excess material. Neither the Interface material or packaging can be re-sterilized. Discard any opened, unused Interface.

H. Warnings
Possible complications are the same as expected for autogenous bone grafting procedures. Interface does not posses sufficient mechanical strength to support load bearing for the defect prior to soft and hard tissue ingrowth. In cases of fracture fixation, standard internal or external stabilization techniques must be followed to obtain rigid stabilization in all planes.

Complications that may arise as result of surgery may include: superficial wound infection, deep wound infection, deep wound infection with osteomyelitis,

continued

delayed union, loss of reduction, failure of fusion, loss of bone graft, graft protrusion and/or dislodgement, and general complication that may arise from anesthesia and/or surgery.

I. Precautions

1. Underlying infections and pathological conditions should be controlled or eliminated prior to the implantation of Interface.
2. Interface should not be used outside its indications. Interface is intended for use by surgeons skilled in the use of bone grafting and internal/external fixation techniques.
3. Interface must not be used to gain screw purchase or to stabilize screw placement. Instrumentation used in conjunction with Interface must gain purchase in the host bone.
4. Standard postoperative practices for treatment and rehabilitation associated with bone grafting must be strictly followed.

J. How Supplied
Interface is available in the size doses shown in the table below. Each unit is contained in a sealed vial and packaged in a hermetically sealed pouch.

Part No.	Contents
IFBG037	0.37 gram vial
IFBG100	1 gram vial
IFBG175	2 gram vial
IFBG350	4 gram vial
IFBG700	7 gram vial

K. Storage Conditions
Store in a dry place (< 25°C)

L. Shelf Life and Disposal
The contents of each pouch are sterile unless opened or damaged. Discard unused portion immediately after use. Do not re-sterilize the product. For single use only.

DO NOT USE IF PACKAGE IS DAMAGED.

STERILE R — Sterilized by Radiation
Single Use Only
See Instructions For Use
Rx Only — Prescription Only

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