Bone Graft Substitute and Fusion Device
Instructions For Use

Manufacturer:
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CAUTION: Federal Law restrict this device to sale by or on the order of a physician

MATERIAL: Bioactive Glass

DESCRIPTION: Bone Graft Substitute

The Bone Graft Substitute (BGS) implants are bone void fillers in the shape of cylinders, blocks or wedges. The devices are osteoconductive, bioactive, bone void fillers. The implants are made from a fiber based bioactive glass. The material can be drilled and tapped, and screws can be placed through it. The device structure allows tissue infiltration between the bioactive glass fibers. The fibers are slowly absorbed and replaced by new bone tissue during the healing process. The material is radiopaque. The devices are completely synthetic and non-collagenous.

The implants are provided sterile and are intended for single use.

INDICATIONS: Bone Graft Substitute

The BGS implant is intended for use as a bone void filler for bony voids or gaps that are not intrinsic to the stability of the bony structure. BGS is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.
The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

CONTRAINDICATIONS: Bone Graft Substitute

BGS is contraindicated:

- Possibility for conservative treatment
- When the device is intended as structural support in load-bearing bone
- Uncooperative patients who will not or cannot follow postoperative instructions, including individuals who abuse drugs and/or alcohol
- Inadequate skin, bone or neurovascular status
- Infection
- Irreparable tendon system
- Growing patients with open epiphyses
- Patients with high levels of activity
- It is not intended for use in the disc space

WARNINGS & PRECAUTIONS: Bone Graft Substitute

- Patients should be made aware of the increased potential for device failure when excessive demands are made upon it. Strenuous loading, excessive mobility and instability may lead to device failure.
- The device should be used with adequate fixation according to standard orthopedic reduction technique and fixation protocol. Bone stock must be adequate to support the device and any fixation hardware used.
- BGS should not be used as a screw anchor. Screws placed through the material should be supported by bone on both sides of the material.
- The device should fill the defect and contact viable bone as much as possible. Some bleeding should be observed originating from the host bone to indicate viability. Do not over-fill the defect site.
- If shaping the device is performed ensure debris has not restricted the pores of the device. Verify that the shaped device surfaces are smooth and free of excessive loose particles.
- This device has not been evaluated for safety and compatibility in the MR environment.
- This device has not been tested for heating or migration in the MR environment

Possible complications are the same as to be expected of autogenous bone grafting procedures. In cases of fracture fixation, standard internal or external stabilization techniques must be followed to obtain rigid stabilization in all planes.

The BGS implant should not be used outside of its intended indication. BGS is intended for use by surgeons familiar with bone grafting and internal/external fixation techniques. Instrumentation used in conjunction with the device must gain purchase in the host bone. Standard postoperative practice for the rehabilitation associated with bone grafting must be strictly followed.

DESCRIPTION: PIP Fusion Device

The PIP Fusion Implant System consists of a cylindrical shape designed to fit into the proximal and distal sides of the proximal interphalangeal joints. The implants are made of bioactive glass material that has been demonstrated to be biocompatible and osteoconductive. The implants are available in multiple diameters and in a straight and angled configuration.

The implants are provided sterile and are intended for single use.

INDICATIONS: PIP Fusion Device

The PIP Fusion Implant System is indicated for fracture fixation, osteotomies, and inter-digital fusion of the fingers, toes and small bones in the presence of appropriate immobilization.

When used in the foot (including hammertoe, claw toe, and mallet toe) patients should be protected weight bearing until fusion or healing has occurred.

CONTRAINDICATIONS: PIP Fusion Device

PIP Fusion Implant is contraindicated:

- Possibility for conservative treatment
- Uncooperative patients who will not or cannot follow postoperative instructions, including individuals who abuse drugs and/or alcohol
- Inadequate skin, bone or neurovascular status
- Infection
- Irreparable tendon system
- Growing patients with open epiphyses
- Patients with high levels of activity

WARNINGS & PRECAUTIONS: PIP Fusion Device

- Patients should be made aware of the increased potential for device failure when excessive demands are made upon it. Strenuous loading, excessive mobility and instability may lead to device failure.
- Proper support at the time of surgery (protective shoe) is critical to the success of the procedure. Bone stock must be adequate to support the device.
- This device has not been evaluated for safety and compatibility in the MR environment.
- This device has not been tested for heating or migration in the MR environment

PRECAUTIONS

It is the responsibility of each surgeon using implants to consider the clinical and medical status of each patient and to be knowledgeable about all aspects of implant procedure and the potential complications that may occur. Each surgeon must evaluate the appropriateness of the procedure used based on personal medical training and experience. Although the company does not recommend a particular surgical technique suitable for all patients, a surgical technique is available for surgeon reference. Proper surgical procedures and techniques are the responsibility of the medial professional.

The benefits derived from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are common. The patient's mental status must also be considered. Willingness and/or ability to follow post-operative instructions may also impact the surgical outcome. Surgeons must balance many considerations to achieve the best result in individual patients.

If excessive loading cannot be prevented an implant should not be used. Abnormal or excessive forces could lead to delayed union, non-union, or failure of the implant. Abnormal loading may be caused by:

- uncorrected instability
- improperly sized implant
- inadequate soft tissue support
- implant malposition
- excessive motion
- uncorrected or recurrent deformity
- patient misuse or overactivity

As with any surgical procedure, care should be used in treating individuals with preexisting conditions that may affect the success of the surgical procedure. This includes individuals with bleeding disorders of any etiology, long-term steroidal therapy, or immunosuppressive therapy.

Use this device as supplied and according to the Handling and Use information provided.

Specialized instruments are designed for use with the implants. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Instruments should be regularly inspected for wear and damage.

ADVERSE EVENTS

Possible adverse effects include but are not limited to:

General Surgery Related Risks

- general complications from anesthesia and/or surgery
- bleeding
- permanent disability
- infection
- loss of use of the extremity
- death

Device Use Related Risks

- hematoma
- site drainage
- bone fracture
- infection or painful, swollen or inflamed implant site
- fracture or extrusion of the implant with or without generation of particulate debris
- deformity of the bone at the site
- incomplete, or lack of osseous ingrowth into the bone void
- delayed union
- failure of fusion
- loss of reduction
- loss of bone graft
- graft protrusion and/or dislodgement
- bone resorption or over-production
- allergic reaction(s) to implant material(s)
- untoward histological responses possibly involving macrophages and/or fibroblasts
- migration of particles possibly resulting in a bodily response
- embolism
- complications requiring revision surgery

STERILIZATION

The product is provided sterile in an unopened or undamaged package. The product has been sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. This product should not be resterilized. This product is for single patient use and should not be reused.

Warning: Do not use this device if the package has been opened or damaged.

Warning: Handle the implant carefully so as not to damage it during placement.

STORAGE CONDITIONS

Products must be stored in a clean, dry environment.

The Surgical Technique Manual is available on the Bio2 Technologies website (www.bio2tech.com) or may be obtained by calling the company +1.781.560.0559

Definitions of symbols and abbreviations.

Symbol	Definition
LOT	Lot Number (Batch Code)
REF	Catalog Number
2	Do not re-use
Rx Only	For prescription use only
⚠	Caution, consult accompanying documents
	Consult operating instructions
	Manufacturer

Symbol	Definition
	Use by
STERILE R	Sterilized using irradiation
SS	Stainless Steel
	Not to be used in case package is damaged
2 STERILIZE	Do not resterilize
	Keep dry

HANDLING AND USE INFORMATION

No special handling or mixing procedures are required prior to use. All device packaging should be inspected prior to use to insure maintenance of sterility.

1. Remove the device from the package either manually or with forceps or similar instrument
2. Irrigate and suction the graft site, then press the graft device into the site
3. Discard packaging. Neither the material nor its packaging can be reused or re-sterilized.

These instructions are intended as guidelines as a part of established techniques. They are not intended to replace or changed standard grafting techniques associated with instrumented stabilization.

PREOPERATIVE PREPARATION

Radiographic evaluation of the defect site is essential to accurately assess the extent of the defect and to aid in the selection and placement of the device and any require fixation device.

POSTOPERATIVE NOTES

Postoperative patient management should follow the same regimen as similar cases utilizing autogenous or allograft. Standard postoperative practices should be followed, particularly as applicable to sites involving the use of fixation devices. The patient should be cautioned against premature ambulation as per physician's orders to ensure reduced loading to prevent collapse and deformity.

STABILITY

The device is provided STERILE unless the package is open or damaged. Resterilization is not possible. Do not use if the sterile package is damaged. The content of each package is design for single use only.