OSTEOPLUS®
Synthetic Bone Graft Composite

Granules in a Delivery Syringe

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)

IMPORTANT PRODUCT INFORMATION
Please read before use

A. General Information
Device Generic Name: Bone Graft Substitute
Device Trade Name: OsteoPlus® Synthetic Bone Graft Composite

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

B. Materials and Device Description
OsteoPlus® is a bone graft substitute. OsteoPlus® is a microporous and macroporous biphasic calcium phosphate ceramic consisting of 60% Hydroxyapatite (HA) and 40% beta-Tricalcium Phosphate (β-TCP). OsteoPlus® is available in various shapes and sizes.

OsteoPlus® may be used with physiological saline, patient's own serum, whole blood, or bone marrow aspirate (BMA).

OsteoPlus® is provided sterile for single patient use.

C. Indications
OsteoPlus® is intended for use as a bone void filler for bony voids or gaps of the skeletal system (e.g. extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. OsteoPlus® can be used with autograft as a bone graft extender. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

OsteoPlus® is a bone filler without initial mechanical properties. Therefore, rigid fixation techniques may often be recommended.

When packed into a bony site, OsteoPlus® gradually resorbs and is replaced with bone during the healing process.

In addition, when used with appropriate opening osteotomy system devices, plates and screws, OsteoPlus® is intended to be used as a bone void filler in femoral or tibial osteotomies.

OsteoPlus® is to be used in association with adequate post-operative immobilization.

D. Contraindications
OsteoPlus® has limited initial mechanical properties. Therefore, this product is contraindicated where the device is intended as structural support in the skeletal system.

Conditions representing contraindications include also:

- Osteomyelitis
- Implantation in necrotic surgical sites
- Degenerative bone disease
- Intra-articular implantations
- Opening meninx

E. Adverse Effects
Possible adverse effects include but are not limited to:

- Wound complications including hematoma, infection, and other complications that are possible with any surgery
- Incomplete, or lack of, osseous ingrowth into bone void, as is possible with any bone void filler

F. Warning and Precautions
Rigid fixation techniques may be required to assure rigid stabilization of the defect in all planes.

OsteoPlus® must not be used for femoral or tibial osteotomies without appropriate opening osteotomy system devices, plates and screws.

Maximum contact between the product and the recipient bone must be established.

The implantation in a revision surgical site containing non-resorbable fragments of material (e.g. polyethylene ligament waste, carbon fibers) is not recommended.

As with any surgical procedure, care should be exercised in treating individuals with preexisting conditions that may affect the success of the surgical procedure. This includes (but is not limited to) individuals with long-term steroidal therapy or treatment acting on the calcium or phosphorus metabolism.

OsteoPlus® is radiopaque until resorbed. Radiopacity may mask underlying pathological conditions. Radiopacity may also make it difficult to radiographically assess the ingrowth of new bone.

OsteoPlus® is intended for use by surgeons familiar with bone grafting and rigid fixation techniques.

OsteoPlus® has not been tested on pregnant women. The risk of health has not been established.

G. Preparation
1. Use care to avoid destruction of porous structure.
2. OsteoPlus® may be soaked in patient's serum, whole blood, or bone marrow aspirate (BMA) until graft is completely impregnated.
3. Prior to this, OsteoPlus® must be hydrated without excess with physiological saline to prevent osmotic damage.
4. Based on experiments, the ideal proportion of fluid should be 1 volume fluid to 2 volumes of OsteoPlus®.
5. Prepared OsteoPlus® should be used immediately to preserve cell viability.

H. Handling and Use
OsteoPlus® is provided sterile and should be considered sterile unless the inner packaging has been opened or damaged. This product must not be resterilized.

The sterilization process of this product using radiations was validated during its conception. We do not guarantee the sterility of the product if a new sterilization is performed on it.

Precautions must be applied in order to preserve the porous structure.

This device is for single patient use only and should never be reused. The non-respect of the single use can conduct to septic issues. Additionally, the resorption process of this bone substitute started immediately after its implantation on the osseous defect so it cannot be re-used.

OsteoPlus® should be stored at ambient temperature.

DO NOT USE IF PACKAGE IS DAMAGED.

Explanation of Symbols

STERILE R
Sterilized by Radiation


Single Use Only


See Instructions for Use


Use by Date


Do not resterilize


Do not use if package is damaged

OPG10	Contents: 5cc in 20mL Delivery Syringe

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