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Vitoss®
Bone Graft Substitute

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DESCRIPTION: Vitoss® Bone Graft Substitute is a resorbable porous calcium phosphate bone void filler for the repair of bony defects. It is an osteoconductive porous implant with a trabecular structure that resembles the multidirectional interconnected porosity of human cancellous bone. Pore diameters in the scaffold range from 1µm to 1000µm (1mm). The implant is provided sterile in block and morsel forms.

Vitoss Bone Graft Substitute guides the three-dimensional regeneration of bone in the defect site into which it is implanted. When Vitoss Bone Graft Substitute is placed in direct contact with viable host bone, new bone grows in apposition to the calcium phosphate surfaces of the implant. As the implant resorbs, bone and other connective tissues grow into the space previously occupied by the scaffold. Results from animal studies demonstrate that 80% of Vitoss Bone Graft Substitute is resorbed within twelve weeks.

INTENDED USE AND INDICATIONS: Vitoss Bone Graft Substitute is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Vitoss Bone Graft Substitute is indicated for use in the treatment of surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. Vitoss should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

Vitoss Bone Graft Substitute is intended to be packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine, and pelvis) and may be combined with autogenous blood and/or bone marrow. Following placement in the bony void or gap, the calcium phosphate scaffold resorbs and is replaced with bone during the healing process.

CONTRAINDICATIONS: Use of Vitoss Bone Graft Substitute is CONTRAINDICATED in the presence of one or more of the following clinical situations:

- ❑ Growth plate fractures;
- ❑ Segmental defects;
- ❑ Conditions where the surgical site may be subjected to excessive impact or stresses, including those beyond the load strength of fixation hardware;
- ❑ Significant vascular impairment proximal to the graft site;
- ❑ Metabolic or systemic bone disorders that affect bone or wound healing;
- ❑ Infected sites;
- ❑ Defect site stabilization is not possible;
- ❑ Intraoperative soft tissue coverage is not planned or possible;
- ❑ In direct contact with the articular space;
- ❑ Conditions in which general bone grafting is not advisable.

WARNINGS: Vitoss Bone Graft Substitute does not possess sufficient mechanical strength to support reduction of a defect site. Rigid fixation techniques are recommended as needed to assure stabilization of the defect in all planes. Vitoss Bone Graft Substitute cannot be used to obtain purchase for screws. Screws must gain purchase in the host bone.

Complete postoperative wound closure is essential. Vitoss Bone Graft Substitute must not be used to repair bone defects where soft tissue coverage cannot be achieved.

PRECAUTIONS: Vitoss Bone Graft Substitute is intended for use by surgeons familiar with bone grafting and rigid fixation techniques.

Vitoss Bone Graft Substitute's radiopacity is comparable to that of bone and diminishes as it is resorbed. This moderate radiopacity may mask underlying pathological conditions and must be considered when evaluating X-rays.

ADVERSE EVENTS: The following complications have been reported to result from bone grafting procedures and are considered to be potential complications for Vitoss Bone Graft Substitute: Superficial wound infection, deep wound infection, deep wound infection with osteomyelitis, nonunion, wound dehiscence, delayed union, malunion, loss of reduction, refracture, cyst recurrence, hematoma, and cellulitis. Occurrence of one or more of these conditions may require an additional surgical procedure and may also require removal of the bone void filler.

DIRECTIONS FOR USE: Familiarization with the device and proper bone grafting and rigid fixation techniques are extremely important. Radiographic evaluation of the defect site is essential to accurately assess the extent of a traumatic defect and to aid in the selection and placement of the bone void filler and fixation devices.

The block form of Vitoss may be used in its given form or shaped to a desirable size using a scalpel. High speed burring can generate particulate matter and therefore should not be used to shape the material.

After shaping, insert the material into the surgical site and pack it into place. Smaller pieces that have been cut from the block may be used to fill in irregularly shaped voids in the defect site. Vitoss morsels are similarly supplied to fill irregular defects. Exercise care to not crush the implant.

The material may be placed into the surgical site in either a wet or dry state. For best results, Vitoss Bone Graft Substitute must fill the defect and contact as much viable host bone as possible.

Fixation of the implant site must be sufficient to prevent collapse and deformity secondary to functional loading. Anatomical reduction and rigid fixation in all planes must be obtained to ensure that the graft is not supporting load.

Postoperative patient management should follow the same regimen as similar cases utilizing autogenous bone grafting. Standard postoperative practices should be followed, particularly as applicable to defect repairs involving the use of fixation devices.

STERILIZATION: Vitoss Bone Graft Substitute is provided sterile by prior exposure to gamma radiation. Vitoss Bone Graft Substitute cannot be resterilized by any method. Excess material and opened but unused product must be discarded.

Inspect the package of any sterile product for structural integrity prior to use. If the seal of any inner or outer container is broken or otherwise damaged, the product must be assumed to be nonsterile.

HOW SUPPLIED: Vitoss Bone Graft Substitute is provided sterile in block and morsel forms.

- ❑ Blocks: 1.2cc typ. and 10cc trays
- ❑ Morsels: 5cc, 10cc, 15cc, and 30cc vials
- ❑ Micro-Morsels: 5cc, 10cc, 15cc, and 30cc vials
- ❑ Macro-Morsels: 15cc and 30cc vials

CAUTION: Rx-only.

US PATENT NUMBER: Vitoss Bone Graft Substitute may be covered by one or more of the following: U.S. Patent No. 5,939,039; 6,325,987; 6,383,519; 6,521,246; 6,969,501; 6,991,803.

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EC REP	European Authorized Representative Vertretung in Europa Représentant europeo autorizzato Rappresentante europeo Representante autorizado na Europa Europese gemachigde vertegenwoordiger	Representante autorizado europeo Europeisk auktoriserad representant Εξουσιοδοτημένος αντιπρόσωπος στην Ευρώπη Europæisk autoriseret repræsentant Avrupa Yetkili Temsilcisi

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