Instructions For Use MagnetOs Synthetic Bone Void Filler

DESCRIPTION

MagnetOs is a synthetic, 65-75% TCP (Tri-Calcium Phosphate - $Ca_3(PO_4)_2$) and 25-35% Hydroxyapatite ($Ca_{10}(PO_4)_6(OH)_2$) resorbable micro-structured bone void filler for the repair of bony defects.

MagnetOs is both osteoconductive and osteoinductive and has a porous trabecular structure that resembles the interconnected porosity of human cancellous bone.

MagnetOs induces and guides the three-dimensional regeneration of bone in the defect site into which it is implanted. When placed next to viable host bone, new bone will be deposited on the surface of the implant. The implant resorbs and is replaced by bone during the natural process of bone remodelling.

MagnetOs is gamma sterilised, comes in several sizes in granular or chip form and is sterile packaged for single use only.

INTENDED USE

MagnetOs is intended for use as bone void filler for voids and gaps that are not intrinsic to the stability of the bony structure. MagnetOs is indicated for use in the treatment of surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. MagnetOs is intended to be packed into bony voids or gaps of the skeletal system (i.e. extremities, spine, cranial, mandible, maxilla and pelvis) and may be combined with autogenous bone, blood, PRP and/or bone marrow.

MagnetOs should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously. In load bearing situations, MagnetOs must be used in conjunction with internal or external fixation devices.

Application in general bone surgery (entire skeletal system)

Replacing or supplementing autogenous / allogenous spongiosa, e.g. for:

- Filling and bridging of skeletal bone defects including spine;
- Plastic reconstruction of damaged or resectioned bone areas;
- Filling of intervertebral implants.

Application in oral and maxillofacial surgery and dentistry

Filling or reconstruction of multiple walled (artificial or degenerative) bone defects, e.g.:

- Defects after the extirpation of bone cyst;
- Augmentation of an atrophied alveolar ridge;
- Sinus lift or sinus floor elevation;
- Filling of alveolar defects after tooth extraction for preservation of the alveolar ridge;
- Filling of extraction defects for creating an implant bed;
- Filling of two- or multiple-walled bone pockets as well as the bi- and trifurcations of teeth;
- Defects after operative removal of retained teeth or corrective osteotomies;
- Other multiple-walled bone defects of the alveolar processes and the facial skull.

CONTRAINDICATIONS

Use of MagnetOs synthetic cancellous bone void filler is CONTRAINDICATED in the presence of one or more of the following clinical situations:

- To treat conditions in which general bone grafting is not advisable;
- In conditions where the surgical site may be subjected to excessive impact or stresses, including those beyond the load strength of fixation hardware (e.g. defect site stabilization is not possible);
- In case of significant vascular impairment proximal to the graft site;
- In case of severe metabolic or systemic bone disorders that affect bone or wound healing;
- In case of acute and chronic infections in the operated area (soft tissue infections; inflammation, bacterial bone diseases; osteomyelitis);
- When intraoperative soft tissue coverage is not planned or possible;
- In direct contact with the articular space;
- In case of treatment with medication interfering with the calcium metabolism.

Despite the presence of some of the listed circumstances, the use of MagnetOs may be the best solution for rectifying bone defects. The patient must be duly informed of the possible effects of complicating circumstances on the anticipated success of using MagnetOs.

WARNINGS, CAUTIONS and PRECAUTIONS

Warning: MagnetOs does not possess sufficient mechanical strength to support reduction of the defect site. Rigid fixation techniques are recommended as needed to ensure stabilisation of the defect in all planes. MagnetOs cannot be used to obtain purchase for screws. Screws must gain purchase in the host bone.

Warning: The granule structure of MagnetOs must not be damaged or altered (e.g. by excessive compaction or crushing of the implant). Avoid overfilling of the defect as tension free wound closure is required.

Caution: MagnetOs' 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.

Caution: Inspect all packaging and components for damage before use. Do not use the device if it is damaged in any way.

Caution: Dosage is for SINGLE USE ONLY. Remaining material must be discarded. DO NOT re-use or re-sterilise. Re-use or re-sterilisation of the device may pose additional risks including, but not limited to, transmission of infectious agents.

Caution: Confirm expiration date before use. Do not use if expiration date has been exceeded.

DIRECTIONS FOR USE

MagnetOs is intended for use by surgeons familiar with bone grafting and rigid fixation techniques. Familiarisation with the device and proper knowledge of 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. MagnetOs must only be employed by or under the supervision of medical professionals with experience in the required surgical techniques and the use of biomaterials.

The exact operating procedures depend on the location, type and size of the defect. Close contact with vital bone is important for its function as a bone regeneration material and, therefore, a thorough freshening of the bone surface before applying the granules is recommended (e.g. removal of bone fragments and necrotic tissue).

The defect must be completely filled with granules. Strong compacting or destruction of granule structure (e.g. by crushing) must be avoided. Overfilling must be avoided to achieve a tension free closure.

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.

The granules may be mixed with the patient's blood from the defect region or bone marrow, before application to the defect. (During operation in a bloodless area, the patient's venous blood may be used for admixture). For large defects MagnetOs can be admixed with spongiosa of comparable size. The selection of granule size depends on the size of the defect to be filled.

Post-operative patient management should follow the same regimen as similar cases utilising autogenous bone grafting. Standard post-operative practices should be followed, particularly as applicable to defect repairs involving the use of fixation devices.

Particulars on application in oral and maxillofacial surgery and dentistry

For endosseous dental implants a time interval of 4 – 6 months should pass between filling defects with MagnetOs and placing of the implant, in case of a sinus lift 6 months if judged appropriate by the surgeon. In cases of larger defects surfaces in oral and maxillofacial surgery and dentistry, the user must decide on the use of membrane technique (GBR = Guided Bone Regeneration).

STERILISATION

MagnetOs is provided sterile (gamma irradiation). Do not re-sterilise.

HOW SUPPLIED

MagnetOs is provided as a sterile, single use device. Do not use if package is opened or damaged.

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