Instructions For Use MagnetOs Granules Synthetic Bone Void Filler

DESCRIPTION

MagnetOs is a synthetic, 75-65% 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 osteoconductive 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 and pelvis) and may be combined with autologous 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 autologous / allogenic spongiosa, e.g. for:

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

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 or 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 calcium metabolism.

POTENTIAL ADVERSE EVENTS

Potential adverse events may include but not limited to:

- As with any major surgical procedures, there are risks involved in bone grafting surgery such as pain, hematoma, edema, swelling and fluid accumulation, superficial wound infection, deep wound infection, deep wound infection with osteomyelitis, loss of reduction, loss of bone graft, graft protrusion and/or dislodgment, and general complications associated with anaesthesia use and/or surgery;
- Incomplete, or lack of, osseous ingrowth into the bone void;
- Delayed union or non-union;
- Fracture of the implant with or without particulate formation;
- Inflammatory response or allergic reaction as the results of the tissue reaction to the implant.

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.

Precaution: Successful results may not be achieved in every surgical case. Reoperation to remove or replace an implant may be required due to specific medical conditions or device failure.

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.

Note: Remove header from document when preparing print-version, print double-sided

Caution: Dosage is for SINGLE USE ONLY. Remaining material must be discarded. No special disposal is necessary. 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 and secured to prevent migration of the implant. 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 autologous/ allogenic 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 autologous bone grafting. Standard post-operative practices should be followed, particularly as applicable to defect repairs involving the use of fixation devices.

The implant card and the patient leaflet packed with this IFU should be provided to the patient after the surgery.

Note 1: Responsibility for proper selection of patients, for adequate training, for experience in the choice and placement of MagnetOs, and for the choice of post-operative follow-up procedures rests entirely with the physician.

Note 2: It is a legal obligation to provide patients with the implant card and patient information leaflet that is supplied together with the product. Please fill out the relevant blank entry fields on the card (i.e. patient name/ID, name and address of the healthcare institution or doctor, date of implantation) before handing the implant card over to the patient.

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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GRAPHICAL SYMBOLS			
CE 0344	Products with the CE mark fulfil the requirements of the European legislation related to medical devices. The numbers identify the Notified Body of manufacturers.		Patient identification
	Caution (consult the instructions for use for important cautionary information)		Health care centre or doctor
	Do not re-use	31	Date of implantation
REF	Catalogue number		Patient information website
LOT	Lot number / batch code	UDI	Unique Device Identifier
STERILE R	Sterilized using irradiation	℞ ONLY	Caution: Federal law restricts this device to sale by or on the order of a physician (US only)

	Use-by date		