RPT-119 [02] Instructions For Use (IFU) MagnetOs Granules (AU) (ENGLISH MASTER TEXT)
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Instructions For Use MagnetOs Granules Synthetic Bone Void Filler

DESCRIPTION

MagnetOs is a synthetic, 65-75% Tri-Calcium Phosphate (TCP - $Ca_3(PO_4)_2$) and 25-35% Hydroxyapatite (HA-$Ca_{10}(PO_4)_6(OH)_2$) 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 Granules induce and guide the three-dimensional regeneration of bone in the defect into which it is implanted. New bone will be deposited on the surface of the graft when it is placed next to viable host bone. The graft will be resorbed and replaced by bone during the natural process of bone remodelling.

MagnetOs is gamma sterilised, comes in several sizes in granular 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. spine, extremities, and pelvis) and may be combined with autologous bone, blood, PRP and/or bone marrow.

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 Granules synthetic 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;
- 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 stabilisation is not possible);
- If there is 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 (e.g., soft tissue infections, osteomyelitis);
- When intraoperative soft tissue coverage is not planned or possible;
- In direct contact with the articular space;
- If treatment includes a medication affecting calcium metabolism.

WARNINGS

- MagnetOs Granules do not possess sufficient mechanical strength to support reduction of the defect site. Rigid fixation techniques are recommended as needed to assure stabilisation of the defect in all planes. MagnetOs Granules cannot be used to obtain purchase for screws. Screws must gain purchase in the host bone.
- As with any major surgical procedure, risks are associated with surgeries involving a bone grafting procedure, such as pain, hematoma, edema, inflammation, swelling and fluid accumulation, superficial wound infection, deep wound infection, deep wound infection with osteomyelitis, loss of reduction, graft migration, graft protrusion or dislodgment, and general complications associated with anaesthesia use or surgery.
- Do not overfill or attempt to pressurise the bony defect site, because tension-free wound closure is required.
- The granules must not be damaged or altered (e.g. by excessive compaction or crushing of the graft).

PRECAUTIONS

- MagnetOs Granules is intended for use by surgeons familiar with bone grafting and rigid fixation techniques.
- The radiopacity of MagnetOs Granules 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.
- As with any surgery involving a bone grafting procedure, successful results may not be achieved in every surgical case. Reoperation to remove or replace the graft may be required due to specific medical conditions or device failure.
- Inspect all packaging and components for damage before use. Do not use if the package is opened or damaged. Do not use the graft if it is damaged in any way.
- MagnetOs Granules is provided sterile (gamma irradiation). The graft is for SINGLE USE ONLY. DO NOT re-use or re-sterilise. Re-use or re-sterilisation may pose additional risks including, but not limited to, transmission of infectious agents.

POTENTIAL COMPLICATIONS/ADVERSE EVENTS

Possible complications or adverse events may include, but not limited to:

- Incomplete, or lack of, osseous ingrowth into the bone void;
- Delayed union or non-union;
- Fracture of the graft with or without particulate formation;
- Inflammatory response or allergic reaction as a result of tissue reaction to the graft;
- Pain and/or inflammation if the graft is placed in direct contact with the nerve root.

DIRECTIONS FOR USE

1. Radiographic evaluation of the defect site is essential to accurately assess the extent of any traumatic defect and to aid the selection and placement of the graft and fixation devices.
2. The exact operating procedures depend on the location, type and size of the defect. The selection of granule size depends on the size of the defect to be filled. MagnetOs Granules should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously.
3. Peel open the outer (non-sterile) pouch and transfer the inner vial with contents to the sterile field using standard sterile technique.
4. Open the cap of the inner vial and dispense the graft as required.
5. MagnetOs Granules should be dispensed into a separate sterile receptacle from which it can be transferred using surgical instrumentation or by hand.
6. The granules may be mixed with the patient's blood from the defect region or bone marrow or PRP, before application to the defect, to provide handling characteristics of the bone graft. (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.
7. Fill the defect completely with MagnetOs Granules, ensuring good contact with the host bone.
8. Close contact with vital bone is important for MagnetOs Granules to function as a bone regeneration material and, therefore, thorough preparation of the bone surface before applying the graft is recommended (e.g. decortication, removal of bone fragments and necrotic tissue).
9. Secure the surgical site after implanting the product to prevent micro-motion and graft migration.
10. Postoperative patient management should follow the same regimen as similar cases using autologous bone grafting.
11. The implant card and the patient leaflet packed with this Instructions For Use (IFU) should be provided to the patient after the surgery. Fill in 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.

STORAGE, SHELF LIFE and DISPOSAL

Confirm expiration date before use. Do not use if expiration date has passed. Unused or remaining material must be discarded. No special disposal is necessary.

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

Note: It is a legal obligation to provide patients with the implant card and patient information leaflet that is supplied together with the product.

STERILISATION

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

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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.
	Consult instructions for use or consult electronic instructions for use

	Do not re-use
	Catalogue number
	Lot number / batch code
	Sterilized using irradiation
	Use-by date
	Manufacturer
	Date of manufacture
	Medical device
	Single sterile barrier system with protective packaging inside
	Do not use if package is damaged and consult instructions for use
	Patient identification
	Health care centre or doctor
	Date of implantation
	Patient information website
	Unique Device Identifier
	Caution: Federal law restricts this device to sale by or on the order of a physician (US only)