Instructions For Use
MagnetOs MIS Synthetic Bone Void Filler

DESCRIPTION

MagnetOs MIS includes a synthetic, resorbable, osteoconductive bone void filler for the repair of bony defects.

MagnetOs MIS graft material is a mixture of ceramic granules premixed with a synthetic polymeric binder that provides cohesion between the granules. The ceramic portion of MagnetOs MIS consists of 65–75% tri-calcium phosphate (TCP – $Ca_3(PO_4)_2$) and 25–35% hydroxyapatite (HA – $Ca_{10}(PO_4)_6(OH)_2$) granules.

While the polymeric binder is rapidly resorbed after implantation, the granules of MagnetOs MIS guide the three-dimensional regeneration of bone in the defect site into which it is implanted.

New bone will be deposited on the surface of the graft when placed next to viable host bone. The graft resorbs and is replaced by bone during the natural process of bone remodeling.

MagnetOs MIS is a ready-to-use product, which includes a 5cc pre-filled cartridge packed together with a delivery system kit. The MagnetOs MIS delivery system kit allows users to apply the bone graft into the defect. MagnetOs MIS is gamma-sterilized and sterile packaged for single use only.

INDICATIONS FOR USE

MagnetOs MIS is intended to fill bony voids or gaps of the skeletal system, *i.e., the extremities, pelvis, intervertebral disc space, and posterolateral spine*. The osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. In the extremities, pelvis, intervertebral disc space and posterolateral spine, MagnetOs MIS may be used standalone or with autograft as a bone extender. When used in intervertebral body fusion procedures, MagnetOs MIS must also be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

MagnetOs MIS resorbs and is replaced with bone during the healing process.

CONTRAINDICATIONS

Use of MagnetOs MIS 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;
- 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 (e.g., soft tissue infections, osteomyelitis);
- In case of pre-existing calcium metabolism disorder (e.g., hypercalcemia);
- When intraoperative soft tissue coverage is not planned or possible;
- In direct contact with the articular space;
- In case of treatment with pharmaceuticals affecting calcium metabolism.

CAUTION: Rx-only

WARNINGS

- MagnetOs MIS does not possess sufficient mechanical strength to support reduction of the defect site. Rigid fixation techniques are recommended as needed to assure stabilization of the defect in all planes. MagnetOs MIS cannot be used to obtain purchase for screws. Screws must gain purchase in the host bone.
- Do not overfill or attempt to pressurize the bony defect site, because tension-free wound closure is required, and because this may lead to extrusion of the product beyond the site of its intended application and damage to the surrounding tissues, fat embolization, or embolization of the graft into the bloodstream.
- The granules in MagnetOs MIS must not be damaged or altered (e.g., by excessive compaction or crushing of the graft).
- Do not place the graft in direct contact with the nerve root because it may lead to pain and/or inflammation.

POSSIBLE COMPLICATIONS/ADVERSE EVENTS

As with any major surgical procedure, risks are associated with surgeries involving a bone grafting procedure. The following potential adverse events (AEs) have been reported with the use of resorbable bone void filler devices:

- lack of osseointegration, impaired healing, inadequate bone formation;
- delayed or non-union;
- material fracture, altered handling characteristics leading to failure;
- allergic/immune response;
- revisions and/or removals;
- superficial wound or deep wound infection;
- pain/discomfort, swelling, redness, fever, inflammation;
- fluid accumulation, wound dehiscence, drainage;
- debridement/irrigation;
- protrusion, dislodgement, migration, or extravasation (leakage);
- decreased range of motion, loss of motor function, sensory deficit;
- blood pressure change;
- hematoma;
- cyst;
- death;
- general complications associated with anesthesia or surgery.

PRECAUTIONS

- MagnetOs MIS is intended for use by surgeons familiar with bone grafting and rigid fixation techniques.
- The radiopacity of the ceramic component in MagnetOs MIS 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.
- 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 MIS is provided sterile (gamma irradiation). The graft is for SINGLE USE ONLY. The delivery system can be reused during the same surgery for the same patient with additional 5cc refill cartridges, packed separately.
- DO NOT re-sterilize. Re-sterilization may pose additional risks including, but not limited to, transmission of infectious agents.

INSTRUCTIONS FOR USE

1. Radiographic evaluation of the defect site is essential to accurately assess the extent of a 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.
3. Peel open the outer (non-sterile) tray and transfer the inner (sterile) tray to the sterile field using standard sterile technique.
4. Open the inner (sterile) tray and remove the (sterile) pre-filled MagnetOs MIS cartridge and delivery system kit. The delivery system kit comes pre-assembled.
5. Remove the protective end caps from the cartridge and screw the cartridge on to the delivery system kit.
6. Dispense the graft as required. MagnetOs MIS can dispense up to 5cc of bone graft into the defect with each cartridge.
7. The graft is ready to use: mixing with aqueous solutions is not recommended.
8. If used as a bone graft extender, mix MagnetOs MIS with autograft in a ratio of 1:1 vol% and fill the defect completely, ensuring good contact with the host bone.
9. Close contact with vital bone is important for the function of MagnetOs MIS 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).
10. Secure the surgical site after implanting the product to prevent micro-motion and graft migration.
11. Postoperative patient management should follow the same regimen as similar cases using autologous bone grafting.

Re-loading of MagnetOs MIS delivery system kit with a refill cartridge:

1. Retract the plunger by first holding up the black actuator switch located at the rear of the dispenser, followed by pulling back the plunger completely.
2. Detach the empty cartridge by unscrewing it from the delivery system kit.
3. Retrieve a MagnetOs MIS refill cartridge and peel open the outer (non-sterile) pouch and transfer the inner (sterile) pouch to the sterile field using standard sterile technique.
4. Open the inner (sterile) pouch and remove the (sterile) MagnetOs MIS cartridge.
5. Remove the protective end caps from the cartridge and screw the cartridge on to the delivery system kit.
6. Follow instructions 6-11 above to apply the bone graft.

STORAGE, SHELF-LIFE, DISPOSAL

MagnetOs MIS must be stored at ambient temperature (max. 45ºC / 113°F). Higher temperatures may affect the consistency and the ability of the graft to retain its shape.
Confirm the expiration date before use. Do not use if the expiration date has been exceeded.
Unused or remaining material must be discarded. No special disposal is necessary.

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RPT-930 [1]

Last revision of this text: 26 May 2025

GRAPHICAL SYMBOLS			
℞ ONLY	Caution: Federal law restricts this device to sale by or on the order of a physician		
	Consult instructions for use	REF	Catalog number
	Do not re-use	LOT	Lot number/batch code
	Do not use if package is damaged and consult instructions for use	STERILE R	Sterilized using irradiation
	Upper limit of temperature		Use-by date
	Manufacturer		Date of manufacture
	Single sterile barrier system with protective packaging inside		