Instructions for Use (IFU) MagnetOs Granules (US) - Graft extender in spine

APPROVAL

	Name	Signature	Date
Author, Senior QA/RA Officer:	U. Appel		
Manager Product Development:	F. de Groot		
Project Manager:	R. Dalmeijer		
CEO:	J. de Bruijn		

AUTHORISATION

	Name	Signature	Date
QA/RA Manager:	Y. Bovell		

1. Instructions

To print the Instruction for Use for packaging purposes, remove page 1, the history section on the last page, header and footer of this document and fit to two pages; print double-sided.

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Instructions For Use
MagnetOs Synthetic Bone Void Filler

GRAPHICAL SYMBOLS	
Rx ONLY	Caution: Federal law restricts this device to sale by or on the order of a physician
⚠	Caution (consult the instructions for use for important cautionary information)
	Do not re-use
REF	Catalogue number
LOT	Lot number / batch code
STERILE R	Sterilized using irradiation
	Use-by date
	Manufacturer

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 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 remodeling.

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

INTENDED USE

MagnetOs is an implant intended to fill bony voids or gaps of the skeletal system, i.e., posterolateral spine. MagnetOs must be used with autograft as a bone graft extender in the posterolateral spine. These 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. MagnetOs resorbs and is replaced with bone during the healing process.

CONTRAINDICATIONS

Use of MagnetOs 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; inflamed, 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 pharmaceuticals interfering with the calcium metabolism.

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WARNINGS 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 assure stabilization 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:	Do not implant the resorbable calcium salt bone filler in a patient with pre-existing calcium metabolism disorder (e.g. hypercalcemia).
Precaution:	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.
Precaution:	Inspect all packaging and components for damage before use. Do not use the device if it is damaged in any way.
Precaution:	Dosage is for SINGLE USE ONLY. DO NOT re-use or re-sterilize.
Precaution:	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. Familiarization 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, mixed with autograft in a ratio of 1:1 vol%. 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 selection of granule size depends on the size of the defect to be filled.

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

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

HOW SUPPLIED

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

Kuros Biosciences B.V.
Prof. Bronkhorstlaan 10, building 48
3723 MB Bilthoven
The Netherlands
www.kurosbiosciences.com
customerservice@kurosbio.com

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History:

Supersedes	Reason
917-023 revision 00	See DCR17-407 and PCR17-005: Company name changed from Xpand to Kuros, document logo in header and manufacturer information at the end of the document updated accordingly; Update in current document template; Section 'Description': correction: replaced 'four sizes' by 'several sizes'; Manufacturer information: updated to new company name and website, added customer service email.