Instructions For Use
MagnetOs Putty 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
	Catalogue number
	Lot number / batch code
	Sterilized using irradiation
	Upper limit of temperature
	Use-by date
	Manufacturer

DESCRIPTION

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

MagnetOs Putty 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, premixed with a synthetic polymeric binder that provides cohesion between the granules.

While the polymeric binder is rapidly resorbed after implantation, the granules of MagnetOs Putty guide 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 Putty is a ready for use product. Pressure applied by manipulation allows the shaping of MagnetOs Putty to conform to the defect contours.

MagnetOs Putty is gamma-sterilized, comes in four sizes in block form and is sterile packaged for single use only.

INDICATIONS FOR USE

MagnetOs Putty is an implant intended to fill bony voids or gaps of the skeletal system, i.e., posterolateral spine. MagnetOs Putty 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 Putty resorbs and is replaced with bone during the healing process.

CONTRAINDICATIONS

Use of MagnetOs Putty 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 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.

WARNINGS and PRECAUTIONS

Warning: MagnetOs Putty 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 granules contained in MagnetOs Putty 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.

Warning:	As with any major surgical procedures, there are risks involved in bone grafting surgery such pain, swelling, 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 anesthesia use and/or surgery.
Warning:	Implantation of foreign materials can results in an inflammatory response or allergic reaction.
Precaution:	MagnetOs Putty is to be stored at ambient temperature (max 45°C). Higher temperatures may affect the consistency and the ability of the device to retain its shape.
Precaution:	Do not implant the resorbable calcium salt bone filler in a patient with pre-existing calcium metabolism disorder (e.g. hypercalcemia).
Precaution:	MagnetOs Putty's radiopacity of the ceramic component 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.

INSTRUCTIONS FOR USE

1. The device can be shaped by finger manipulation to fit the defect contours.
2. The desired consistency and malleability can be achieved by pressure and warming in surgeon's hands overtime.
3. The product is ready for use: mixing with aqueous solutions is not recommended.
4. Defect site should be filled completely with the device, mixed with autograft in a ratio of 1:1 vol% and secured to prevent migration of the implant.

MagnetOs Putty 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 Putty 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 device is recommended (e.g. removal of bone fragments and necrotic tissue).

The defect must be completely filled with MagnetOs Putty, mixed with autograft in a ratio of 1:1 vol%.

Strong compacting or destruction of the granules 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 MagnetOs Putty 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 Putty is provided sterile (Gamma irradiation). Do not re-sterilize.

HOW SUPPLIED

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

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