Instructions For Use
MagnetOs Putty Synthetic Bone Void Filler

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 with a porous trabecular structure that resembles the interconnected porosity of human cancellous bone. The granules in MagnetOs Putty are 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.
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 Putty is a ready-to-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 several sizes in block form and is sterile packaged for single use only.
MagnetOs Putty is MRI (Magnetic Resonance Imaging) Safe.

INDICATIONS FOR USE

MagnetOs Putty is an implant intended to fill bony voids or gaps of the skeletal system, *i.e., the extremities, pelvis, intervertebral disc space, and 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 may be used standalone or mixed with autograft. When used in intervertebral body fusion procedures, MagnetOs Putty must also be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.
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 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 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 Putty 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 anesthesia or surgery.
- 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 Putty must not be damaged or altered (e.g., by excessive compaction or crushing of the graft).

POSSIBLE COMPLICATIONS/ADVERSE EVENTS

Possible complications or adverse events may include but are 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 of tissue to the graft.
- Pain and/or inflammation if the graft is placed in direct contact with the nerve root.

RPT-140 [04] Instructions For Use (IFU) MagnetOs Putty (US) (ENGLISH MASTER TEXT) ***Note: Remove header from document when preparing print-version, print double-sided***

PRECAUTIONS

- MagnetOs Putty is intended for use by surgeons familiar with bone grafting and rigid fixation techniques.
- The radiopacity of the ceramic component in MagnetOs Putty 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 Putty is provided sterile (gamma irradiation). The graft is for SINGLE USE ONLY. DO NOT re-use or re-sterilize. Re-use or 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 in 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 MagnetOs Putty size depends on the size of the defect to be filled.
3. Peel open the outer (non-sterile) pouch and transfer the inner pouch with contents to the sterile field using standard sterile technique.
4. Open the inner (sterile) pouch and dispense the graft as required.
5. MagnetOs Putty should be dispensed into a sterile gloved hand or a separate sterile receptacle from which it can be transferred using surgical instrumentation or by hand.
6. The graft is ready to use: mixing with aqueous solutions is not recommended. If not used as a standalone graft, MagnetOs Putty may be mixed with autologous bone in a ratio of 1:1 vol%.
7. The desired consistency and malleability can be achieved by pressure and warming in the surgeon's hands over time.
8. Mold the graft by hand or with a surgical instrument as desired. The product can be shaped by finger manipulation to fit the contours of the defect.
9. Fill the defect completely with MagnetOs Putty, ensuring good contact with the host bone.
10. Close contact with vital bone is important for the function of MagnetOs Putty 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).
11. Secure the surgical site after implanting the product to prevent micro-motion and graft migration. Rigid fixation techniques shall be used as needed to stabilize the defect in all planes and to ensure that the graft is not supporting load.
12. Postoperative patient management should follow the same regimen as similar cases using autologous bone grafting.

STORAGE, SHELF-LIFE, DISPOSAL

MagnetOs Putty must be stored at ambient temperature (max. 45ºC / 113°F).
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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GRAPHICAL SYMBOLS			
℞ ONLY	Caution: Federal law restricts this device to sale by or on the order of a physician		
	Consult instructions for use or consult electronic 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	MD	Medical device