Instructions For Use
MagnetOs Easypack Putty Synthetic Bone Void Filler

DESCRIPTION

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

MagnetOs Easypack 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 Easypack 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 Easypack Putty is a ready-to-use product. Pressure applied by manipulation allows users to shape MagnetOs Easypack Putty to conform to the contours of bony defects. MagnetOs Easypack Putty is provided in open-ended syringes in a range of product volumes. MagnetOs Easypack Putty is gamma-sterilized and sterile packaged for single use only.

INDICATIONS FOR USE

MagnetOs Easypack Putty 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 Easypack Putty may be used standalone or with autograft as a bone extender. When used in intervertebral body fusion procedures, MagnetOs Easypack Putty must also be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

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

CONTRAINDICATIONS

Use of MagnetOs Easypack 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 Easypack 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 Easypack 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 Easypack 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.

PRECAUTIONS

MagnetOs Easypack Putty is intended for use by surgeons familiar with bone grafting and rigid fixation techniques.

The radiopacity of the ceramic component in MagnetOs Easypack 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.

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 Easypack 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 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 Easypack 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 remove the (sterile) syringe.
5. Remove the protective cap from the syringe and dispense the graft as required.
6. MagnetOs Easypack 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.
7. The graft is ready to use: mixing with aqueous solutions is not recommended.
8. Mold the graft by hand or tweezer as desired.
9. If used as a bone graft extender, mix MagnetOs Easypack Putty with autograft in a ratio of 1:1 vol%.
10. Fill the defect completely, ensuring good contact with the host bone. Close contact with vital bone is important for the function of MagnetOs Easypack 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.
12. Postoperative patient management should follow the same regimen as similar cases using autologous bone grafting.

STORAGE, SHELF-LIFE, DISPOSAL

MagnetOs Easypack Putty 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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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		