Instructions For Use
MagnetOs Flex Matrix Bone Void Filler

DESCRIPTION

MagnetOs™ Flex Matrix is a resorbable and osteoconductive bone graft for the repair of bony defects.

MagnetOs Flex Matrix is comprised medical grade purified type I collagen matrix and synthetic resorbable MagnetOs Granules composed of 65–75% tri-calcium phosphate (TCP – $Ca_3(PO_4)_2$) and 25–35% hydroxyapatite (HA – $Ca_{10}(PO_4)_6(OH)_2$).

MagnetOs Granules is osteoconductive and has a porous trabecular structure that resembles the interconnected porosity of human cancellous bone. The surface of MagnetOs Granules is covered with needle-shaped features that are submicron in size. The collagen incorporated in MagnetOs Flex Matrix has a native structure which provides a fibrous matrix that helps contain the MagnetOs Granules at the surgical site while providing an open network of porosity to maximize access between the host biology and the needle-shaped surface of MagnetOs Granules.

The combination of the collagen matrix and porous calcium phosphate granules provides an optimal structure to 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 Flex Matrix comes in several sizes, is packed using a single sterile barrier system with protective packaging inside, is gamma-sterilized and for single-use only.

INDICATIONS FOR USE

MagnetOs Flex Matrix is intended to fill bony voids or gaps of the skeletal system, i.e., posterolateral spine. In the posterolateral spine, MagnetOs Flex Matrix must be hydrated with bone marrow aspirate (BMA) and used as an extender to autograft bone. 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. MagnetOs Flex Matrix resorbs and is replaced with bone during the healing process.

CONTRAINDICATIONS

Use of MagnetOs Flex Matrix synthetic bone void filler is CONTRAINDICATED in the presence of one or more of the following clinical situations:

- MagnetOs Flex Matrix must not be used in patients with a history of anaphylaxis, history of multiple allergies, known allergies to bovine collagen, or who are being treated for desensitization to meat products because this product contains bovine collagen
- 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 Flex Matrix 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 Flex Matrix 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 Flex Matrix 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 Flex Matrix is intended for use by surgeons familiar with bone grafting and rigid fixation techniques.

The radiopacity of the ceramic component in MagnetOs Flex Matrix 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 Flex Matrix 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 Flex Matrix size depends on the size of the defect to be filled.
3. Peel open the outer (sterile barrier) blister and transfer the blister with contents to the sterile field using standard sterile technique.
4. Open the inner (protective) blister. Hydrate the graft with bone marrow aspirate at a ratio of 0.8cc per 1cc of graft material.
5. Mold the graft by hand or tweezer as desired.
6. Mix the hydrated MagnetOs Flex Matrix with autograft in a ratio of 1:1 vol%

Size	BMA	Autograft
S	1.8 cc	2.3 cc
M	4.0 cc	5.0 cc
L	8.0 cc	10.0 cc
XL	12.1 cc	15.1 cc

7. Fill the defect completely with MagnetOs Flex Matrix, ensuring good contact with the host bone.
8. Close contact with vital bone is important for the function of MagnetOs Flex Matrix 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).
9. Secure the surgical site after implanting the product to prevent micro-motion and graft migration.
10. Postoperative patient management should follow the same regimen as similar cases using autologous bone grafting.

STORAGE, SHELF-LIFE, DISPOSAL

MagnetOs Flex Matrix must be stored at ambient temperature (max.40ºC / 104 °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		
BIO	Medical device contains biological tissue derivative of animal origin		Do not use if package is damaged and consult instructions for use
	Consult instructions for use	REF	Catalog number
	Do not re-use	LOT	Lot number/batch code
	Upper limit of temperature	STERILE R	Sterilized using irradiation

	Use-by date		Single sterile barrier system with protective packaging inside
	Manufacturer		Date of manufacture