MagnetOs Putty Synthetic Bone Void Filler -Patient Information Leaflet

MagnetOs Putty is provided in the following configurations:

Product code	Volume	Size
703-029-AU	1cc	1-2mm
703-041-AU	1.5cc	1-2mm
703-043-AU	2.5cc	1-2mm
703-035-AU	5cc	1-2mm
703-038-AU	10cc (2x 5cc)	1-2mm
703-044-AU	20cc (2 pouches of [2x5cc])	1-2mm

Intended purpose

MagnetOs Putty is intended for use to fill bony voids or gaps in the skeletal system (i.e. extremities, spine and pelvis). These voids/gaps may be surgically created or as the result of traumatic injury to the bone.

Product description and performance

MagnetOs Putty consists of synthetic ceramic granules, premixed with a synthetic polymeric binder that provides cohesion between the granules and allows the device to be moulded into specific shapes, or contoured into a bone defect, as desired by the clinician.

MagnetOs Putty has a porous trabecular structure that resembles the porosity of human bone. While the polymeric binder is rapidly resorbed after implantation, the granules of MagnetOs Putty induce and guide the regeneration of bone in all directions in the defect site into which it is implanted. Over time, the implant resorbs and is replaced with bone during the natural healing process.

MagnetOs Putty is provided sterile and is intended for single patient use only. The exact amount of material used in the procedure is determined by the clinician, based on the size of the defect to be filled.

MagnetOs Putty is a blend of:

- MagnetOs Granules: a synthetic, degradable bone void filler, which consists of 65-75% Tri-Calcium Phosphate (TCP) and 25-35% Hydroxyapatite (HA).
- A biocompatible polymeric binder LEOL. The polymer binder acts as temporary binder for the granules to facilitate handling. It resorbs in less than 48h after implantation.

Undesirable adverse effects

As with any major surgical procedures, there are risks involved in bone grafting surgery such as:

- Pain at the surgery site;
- Swelling at the surgery site;
- Infection;
- Loss of reduction, loss of bone graft, graft protrusion and/or dislodgment;
- General complications associated with anaesthesia use and/or surgery;

In case you experience any of these symptoms, contact a health professional.

Warnings and precautions

- Please verify with your doctor that you are suitable for this type of implant.
- MagnetOs Putty's 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.
- MagnetOs Putty poses no risk in the Magnetic Resonance Imaging (MRI) environment or in computerized tomography (CT) scan.

- Implantation of foreign materials can result in an inflammatory response or allergic reaction. Seek medical advice if you experience any allergic reaction.
- Alcohol consumption and/or smoking habits may delay the bone healing process.

Reporting a problem with the medical device

Serious incidents and/or adverse events potentially associated with MagnetOs Putty should be promptly reported to your doctor. You may also report it to Kuros Biosciences B.V at: cs.international@kurosbio.com

You may also report directly to the Therapeutic Goods Administration (TGA) via the below link: https://www.tga.gov.au/reporting-problems

Legal Manufacturer

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