# 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 an implant that fills bone defects. Bone defects are also called bone voids. These are areas where bone is missing. This can be in areas like arms, legs, spine and pelvis. The treatment is for bone voids caused by surgery or injury. Surgeons pack MagnetOs Putty into these bony voids in your skeleton. Over time, MagnetOs Putty resorbs and is replaced with your own bone.

MagnetOs Putty can be used to fill bone defects in children and adults.

**Product description and performance**

MagnetOs Putty is a synthetic, resorbable material. It consists of granules premixed with a synthetic polymer to hold them together. The granules consist of 65-75% Tri-Calcium Phosphate (TCP, $Ca_3(PO_4)_2$) and 25-35% Hydroxyapatite (HA, $Ca_5(PO_4)_3OH$). The synthetic polymer is composed of repeating units of two types of molecules, Poly(L-lactic Acid) (PLA) and Poly(Ethylene Glycol) (PEG). It consists of 80-90% PEG and 10-20% PLA.

The granules are porous and similar to human bone. The surface has very small needle-shaped features. These characteristics help your bone grow towards and into the implant. As the bone heals, new bone gradually replaces the implant, helping the bone void fill completely.

MagnetOs Putty comes sterile and is for single patient use only. The doctor decides how much material to implant based on the size of the bone defect.

**Expected device lifetime**

After MagnetOs Putty is implanted in your body, the granules begin to resorb. It is fully replaced by new bone. This can take up to 2 years after surgery. The polymer in MagnetOs Putty dissolves within 48 hours after implantation.

**Undesirable adverse effects**

Your doctor will give you information about possible undesirable adverse effects of bone implants. Some of the most common may include:

- Incomplete, or no bone growth into the defect;
- Delayed or absent bone healing;
- Fracture of the implant;
- Inflammatory or allergic reactions;
- Pain or inflammation if the implant contacts a nerve.

If you have any unusual or increased pain, swelling, or redness around your surgery site, please contact your doctor.

**Warnings and precautions**

Warnings:

All surgeries carry risks. There are undesirable reactions that can occur during or after surgery. Bone grafting surgery may also cause undesirable reactions. Some of the most common may include:

- Pain;
- Bruises (haematomas);
- Swelling (oedema);
- Fluid accumulation;
- Inflammation;
- Superficial wound infection;
- Deep wound infection with or without inflammatory disease of the bone (osteomyelitis);
- Loss of alignment of the bone (reduction);
- Movement of the bone implant (implant migration);
- Bulging (protrusion) or displacement (dislodgment) of the implant;
- General complications associated with anaesthesia or surgery.

Precautions:

- MagnetOs Putty is for use by surgeons with bone grafting experience. This includes the use of rigid fixation techniques with plates and screws.
- The granules in MagnetOs Putty may look similar to bone in X-ray imaging. It may hide certain diseases. Your doctor should consider this when evaluating X-rays.
- MagnetOs Putty is safe during medical tests like Magnetic Resonance Imaging (MRI) or Computerised Tomography (CT) scans.
- As with any bone grafting surgery, the result may not be successful in every case. It may be necessary to reoperate to remove or replace the implant. This can be due to medical conditions or failure of MagnetOs Putty.
- Keep the implant card you got after surgery in a safe, dark, and dry place.

**Extra information**

Your doctor may check on you after your surgery as part of routine check-ups.

**Reporting a problem with the medical device**

In the event of a serious incident that is related to the device, contact Kuros Biosciences B.V. (see contact details below). Also contact the Australian Therapeutic Goods Administration (TGA). Serious incidents include any change in your condition requiring unplanned medical or surgical intervention. To report to the TGA, follow the instructions at www.tga.gov.au.

**Legal Manufacturer**

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