



**Mg OSTEONJECT is a fast setting Magnesium-based bone substitute that remodels into bone over time through creeping substitution.**

## APPLICATIONS

Optimized for trauma, extremity, revision, sports medicine.



LOW VISCOSITY

Ready in 30  
Seconds

Moldable/  
Injectable

Cohesive/  
Adhesive

Drillable/  
Settable

Radiopaque

## COMPOSITION

**Mg OSTEONJECT** is made from a fully synthetic, pre-measured blend of magnesium, phosphates, and a proprietary solution.

## MAGNESIUM BENEFITS

Magnesium is critical for bone health and development. Approximately 60% of Magnesium in the body resides in the bones, contributing to the structural development of bone and playing a key role in the absorption and regulation of calcium. Magnesium also controls the active transport of calcium across cell membranes and deficiency can contribute to osteoporosis.

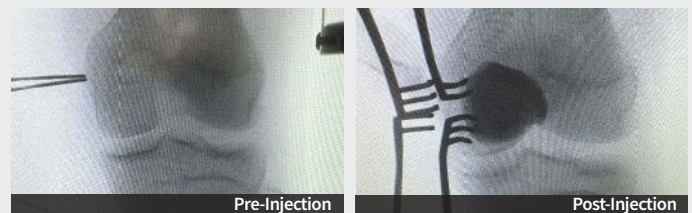
Magnesium increases proliferation of marrow stromal cells, **enhances mineralization** of the extracellular matrix and stimulates proteins for enhanced bone regeneration.<sup>1</sup> Additionally, it improves attachment and **growth of osteoblasts**, and initiates apatite layer formation on scaffolds, as well as **new bone formation** through the scaffold.<sup>2</sup>

### References:

1. Yoshizawa et al. Magnesium ion stimulation of bone marrow stromal cells enhances osteogenic activity, stimulating the effect of magnesium allow degradation. Acta Biomater. 2014; 10(6): 2834-42.4
2. Wong et al. Engineered polycaprolactone-magnesium hybrid biodegradable porous scaffold for bone tissue engineering. Materials International. 2014; 24: 561-567.
3. S. Magister, J. Kolaczko, A. Sattar et al., Clinical parameters and radiographic resorption of a novel magnesium based bone void filler, Injury.
4. Lapine Posterolateral Fusion and Condyle Defect Models. Internal study. Results on file at Bone Solutions, Inc.

## CLINICAL PERFORMANCE

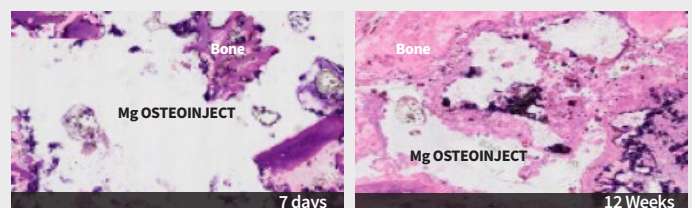
Mg OSTEONJECT is used to fill bone voids or defects of the extremities or pelvis that could result from removal of tumors or cysts, osseous defects from traumatic injury, or subchondral cystic changes related to osteoarthritis. The images below show a Unicameral Bone Cyst removed and completely filled with Mg OSTEONJECT.



## STUDY DATA

### Bone Remodeling:

In a study comparing resorption of magnesium-based material with calcium-based material, it was observed that resorption of Mg OSTEONJECT was 83.3% greater at 12 weeks and 35.6% greater at 26 weeks than the calcium-based bone substitute and that over 80% of the Mg OSTEONJECT was resorbed at 26 weeks. Histology images from this study demonstrate bone remodeling through creeping substitution.<sup>4</sup>



## REGULATORY INFORMATION

<b>Cleared by FDA 510(k)</b>	K221256, K192674, K161568, K234013
<b>Regulation Number</b>	21CFR 888 3045
<b>Classification Product Code</b>	MQV, OIS

## PACKAGING SPECIFICATIONS

<b>Latex</b>	Not made with natural rubber latex
<b>Storage</b>	Store at room temperature
<b>Shelf Life</b>	36 Months
<b>Sterilization</b>	Gamma irradiation
<b>Sterile</b>	Yes
<b>Single-Use</b>	Yes
<b>MRI Safe</b>	Yes
<b>Dimensions</b>	26cm (l) x 21cm (w) x 8cm (h)

## MATERIAL SPECIFICATIONS

<b>Setting Temperature</b>	98°F (37° C)
<b>Compressive Strength</b>	16MPa at 48 hours

### Biocompatibility

Mg OSTEONJECT has been evaluated to be biologically safe to use. The materials that comprise this product have been used clinically for many years. The product has been extensively tested in *in vitro* and *in vivo* settings, and follow the requirements of EN ISO 10993-1.

## INDICATIONS

**Mg OSTEONJECT** is intended for bony voids or defects of the extremities and pelvis that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created by traumatic injury to the bone.

**Mg OSTEONJECT** can be used as an adjunct to conventional rigid hardware fixation by supporting the bone fragments during the surgical procedure only in the extremities and pelvis. Once the material has set, it acts as a temporary support medium and is not intended to provide structural support during the healing process.

**Mg OSTEONJECT** is intended to be placed into bony voids either before or after final fixation. It is resorbed and replaced with bone during the healing process.

**Mg OSTEONJECT** is not intended to treat large defects that in the surgeon's opinion would fail to heal spontaneously.



Part Number	Description
44-050-00-INJ	Mg OSTEONJECT – 5cc
44-100-00-INJ	Mg OSTEONJECT – 10cc

**Kit Contents:** Mg Powder Pouch, Low Viscosity Solution, Mixing Syringe, Funnel, 4.2mm Cannula & Pusher, Mechanical Advantage