Mg OSTEOCRETE™

MAGNESIUM-BASED BONE SUBSTITUTE

Manufactured by Bone Solutions, Inc., distributed by Alliant Biotech, LLC.

PRODUCT FACT SHEET

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

MEDIUM VISCOSITY

HIGH VISCOSITY

APPLICATIONS

Optimized for trauma, extremity, revision, sports medicine, intervertebral body fusions, and posterolateral spine surgery.

Ready in 30 Seconds

Moldable/ Injectable

Cohesive/ Adhesive

Drillable/ Settable

Radiopaque

COMPOSITION

Mg OSTEOCRETE 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.[1] Additionally, it improves attachment and **growth of osteoblasts**, and initiates apatite layer formation on scaffolds, as well as **new bone formation** through the scaffold.[2]

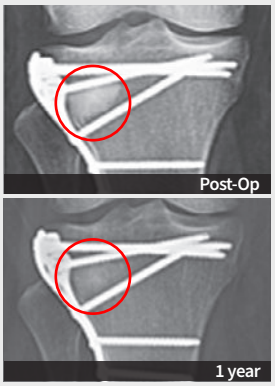
References:

1. Yoshizawa et at. Magnesium ion stimulation of bone marrow stromal cells enhances osteogenic activity, stimulating the effect of magnesium allow degradation. Acta Biometer. 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.
5. Am J Vet Res. 2009; 70 (8) 964-972. Hirvinen LJ, Litsky AS, Samii VF, Weisbrode SE, Bertone AL
6. Orthopaedic Research Society 2006; Chicago, IL. Bertone A, DeMaria M, Johnson A, Weisbrode S, Kowaleski M

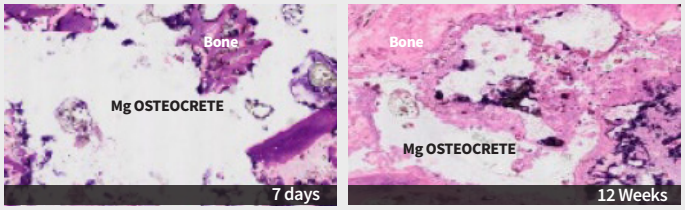
STUDY DATA

Bone Remodeling:

Study 1 - In a radiographic review of 18 patients, the average grade of resorption was 3.6 ±0.6 at 1 year. This demonstrates clinically relevant resorption, and structural support in challenging bone voids.[3]

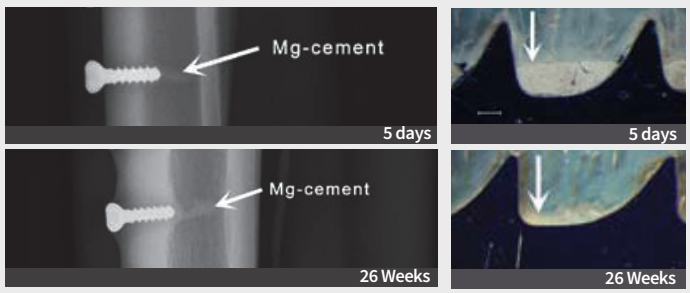


Histology from a separate study further demonstrates bone remodeling through creeping substitution.[4]



Bone Mineral Density:

Study 2 - When compared to a calcium-based product, Mg OSTEOCRETE showed a 24% increase in bone mineral density adjacent to the screw.[5]



REGULATORY INFORMATION

Cleared by FDA 510(k)	K071004, K192674, K161568, K234013
Regulation Number	21CFR 888 3045
Classification Product Code	MQV, OIS

PACKAGING SPECIFICATIONS

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

MATERIAL SPECIFICATIONS

Setting Temperature	98°F (37° C)
Compressive Strength	36MPa at 48 hours

Biocompatibility
Mg OSTEOCRETE 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 OSTEOCRETE is intended for bony voids or defects of the extremities, intervertebral disc space, posterolateral spine, 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 OSTEOCRETE 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 OSTEOCRETE 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 and must be used with morselized autograft bone at a ratio of 1:1 by volume with an intervertebral body fusion device and in the posterolateral spine. **Mg OSTEOCRETE** is not intended to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

Part Number	Description
44-050-00-BSI	Mg OSTEOCRETE – Full Kit – 5cc
44-100-00-BSI	Mg OSTEOCRETE – Full Kit – 10cc
44-150-00-BSI	Mg OSTEOCRETE – Full Kit – 15cc

Kit Contents: 5cc Mg Powder, High Viscosity Solution (30-Second Putty), Medium Viscosity Solution, Mixing Syringe, Funnel, Basin, Spatula & 4.2mm Cannula/Pusher, Mechanical Advantage

Part Number	Description
44-050-00-STR	Mg OSTEOCRETE – Basic Kit – 5cc
44-100-00-STR	Mg OSTEOCRETE – Basic Kit – 10cc
44-150-00-STR	Mg OSTEOCRETE – Basic Kit – 15cc

Kit Contents: 5cc Mg Powder, High Viscosity Solution (30-Second Putty), Medium Viscosity Solution, Basin, Spatula