Mg OSTEOCRETE™

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STERILE IMPLANT KIT - Single Use Only

CAUTION:
FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

IMPORTANT INFORMATION FOR PHYSICIANS, SURGEONS, AND/OR STAFF

DESCRIPTION

Mg OSTEOCRETE™ is a magnesium-based synthetic bone graft substitute that is moldable/injectable, drillable/settable, adhesive/cohesive, radiopaque, osteoconductive, remodels into bone over time through creeping substitution.

The Mg OSTEOCRETE™ Packet contains powder (Magnesium based compound) and a mixing solution (modified saline). The device is sterile, single use only.

Mg OSTEOCRETE™ is indicated as a bone graft substitute (used alone) to fill bone voids or defects of the extremities or pelvis; these defects may be traumatic or surgically created (including but not limited to: surgical excision of bony lesions, cysts, fibromas, or tumors; core decompression for avascular necrosis/osteonecrosis; excision and grafting of osteochondritis dissecans lesions).

Mg OSTEOCRETE™ is indicated as a bone graft extender used with autograft bone in the posterolateral spine and with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

INDICATIONS FOR USE

Mg OSTEOCRETE™ is intended for bony voids or defects of the extremities, posterolateral spine, intervertebral disc space, and pelvis that are not intrinsic to the stability of the bony structure. These osseous defects may be the result of benign bone cysts and tumors (in adults), 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.
Mg OSTEOCRETE™ is resorbed and replaced with bone during the healing process.
Mg OSTEOCRETE™ must be used with morselized autograft bone at a ratio of 1:1 by volume in the posterolateral spine.
When used in intervertebral body fusion procedures Mg OSTEOCRETE™ must be used with morselized autograft bone at a ratio of 1:1 by volume with an intervertebral body fusion device cleared by FDA for use with a bone void filler.
Mg OSTEOCRETE™ is not intended to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

CONTRAINDICATIONS

Mg OSTEOCRETE™ is not intended to provide structural support during the healing process. Mg OSTEOCRETE™ is contraindicated where the device is intended as structural support in the skeletal system.

Mg OSTEOCRETE™ is contraindicated for vertebroplasty or kyphoplasty, or pedicle screw augmentation.

Conditions representing relative contraindications include:

Severe neurological or vascular disease
Uncontrolled diabetes
Hypercalcemia
Pregnancy
Where stabilization of fracture is not possible
Segmental defects without supplemental fixation
Where there is significant vascular impairment proximal to the graft site
When there are systemic and/or metabolic disorders that affect the bone or wound healing
Any patient unwilling or unable to follow postoperative instructions.

WARNINGS

1. Remove any excess Mg OSTEOCRETE™ prior to closure.
2. When used for filling defects of the extremities and pelvis, do not mix the product with any other substance.
3. When used in the posterolateral spine, the product must be used with morselized autograft bone at a ratio of 1:1 by volume.
4. Highly pressurized application of the product into confined space with ready venous or arterial access is not recommended.
5. Do not use the product in infected sites.
6. Do not disturb placement site once the product begins to harden.
7. Do not overfill the defect area.
8. Do not reuse. The product is single use only.

MRI Safety Information

Mg OSTEOCRETE™ is **MR Safe.**

MR

PRECAUTIONS

The long-term effects of extraosseous or intra-articular use of the product (material injected into the joint space) are unknown.
Arthritis may be a possible complication of intra-articular use of the product.
The safety and effectiveness of the product has not been established in:

- Traumatic open injuries which are predisposed to infection.
- Patients with compromised health (e.g. metabolic, vascular, or severe neurological disease, infection, immunologic deficiencies).
- Patients who are skeletally immature.
- Pregnant or nursing women.
- Patients undergoing concurrent radiotherapy or chemotherapy treatment.
- Patients with renal impairment.

All users should become familiar with the product mixing instructions prior to use.

- The product powder and liquid should be stored at room temperature.
- The product powder and liquid should be equilibrated to 18-23°C/65-73°F prior to mixing for optional results.
- The safety and effectiveness of the product in contact with adjacent allograft, acrylic, silicone, or polymer materials has not been established.
- Do not over-pressurize the device because this may lead to extrusion of the device beyond the site of its intended application and damage to the surrounding tissue.
- Do not over-pressurize the defect site since this may lead to fat embolization or embolization of the device material into the bloodstream.
- Skin Exposure: Wash area with soap and water
- Eye Exposure: Flush thoroughly with running water

ADVERSE EVENTS

The following adverse events can occur with the use of bone void fillers:

- Revisions and/or removals
- Superficial wound or deep wound infection
- Pain/discomfort, swelling, redness, fever, inflammation
- Fluid accumulation, wound dehiscence, drainage
- Debridement/irrigation
- Delayed or nonunion, lack of osseointegration, impaired healing, inadequate bone formation
- Material fracture, altered handling characteristics leading to failure
- Protrusion, dislodgement, migration, or extravasation (leakage)
- Decreased range of motion, loss of motor function, sensory deficit
- Allergic/immune response
- Blood pressure change
- Hematoma
- Cyst
- Death

STERILIZATION

This device is provided sterile (gamma radiation).
Contents are **STERILE** unless the barrier packaging is open or damaged; **DO NOT USE** if the package is open or damaged.

STORAGE CONDITIONS

Sterile devices must be stored in the original unopened packaging and should not be used after the expiration date.

MIXING INSTRUCTIONS

Refer to the Mixing Usage Guide for Mixing, Delivery and Setting times.

SYMBOLS GLOSSARY

Symbol	Reference Number	Title of Symbol	Description of Symbol per Standard
	5.1.1	Manufactuer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EC, 93/42/EEC and 98/79/EC.
	5.1.4	Use-by-date	Indicates the date after which the medical device is not to be used
	5.1.5	Batch Code	Indicate the manufacturer's batch code so that the batch or lot can be identified
	5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
	5.1.7	Serial Number	Indicate the manufacturer's serial number so that a specific medical device can be identified
	5.2.4	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation
	5.2.6	Do not resterilize	Indicates a medical device that is not to be sterilized.
	5.2.8	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened
	5.4.2	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
	5.4.3	Consult instructions for use	Indicates the need for the user to consult the instructions for use
	5.4.4	Caution	Caution: Federal Law restricts this device to the sale by or on the order of a physician
	21 CFR 801.109(b)(1)	Prescription only	Requires prescription in the United States
	Fig. 1 ASTM F2503-23	MR Safe	An an item that poses no known hazards resulting from exposure to any MR environment.

With the exception of the RX symbol & MR, all information is from ISO 15223-1:2016, Medical Devices - Symbols to be used with medical device label, labeling and information to be supplied - Part1: General requirements, FR recognition number 5-117.

PRODUCT COMPLAINTS

Any healthcare professional who has any complaints or is dissatisfied with this product should notify Bone Solutions Inc, 5712 Colleyville Blvd., Colleyville, TX 76034, USA.
Telephone: 817 809-8850
Email: customerservice@bonesolutions.net

FURTHER INFORMATION

For product information, sales inquiries, customer service, or to obtain a surgical technique, please contact your sales representative or Bone Solutions Inc. Customer Service at Email: customerservice@bonesolutions.net