Opus™ Mg Set

ORTHOFIX®

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

Opus™ Mg Set is a magnesium-based synthetic bone void filler that is drillable, resorbable, radiopaque, and osteoconductive. The Opus™ Mg Set Packet contains powder (Magnesium based compound) and a mixing solution (Buffered saline). The device is sterile, single use only.

Opus™ Mg Set 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).

Opus™ Mg Set is indicated as a bone graft extender used with autograft bone in the posterolateral spine.

INDICATIONS FOR USE

Opus™ Mg Set is intended for bony voids or defects of the extremities, 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. Opus™ Mg Set 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. Opus™ Mg Set is intended to be placed into bony voids either before or after final fixation. Opus™ Mg Set is resorbed and replaced with bone during the healing process. Opus™ Mg Set must be used with morselized autograft bone at a ratio of 1:1 by volume in the posterolateral spine. Opus™ Mg Set is not intended to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

CONTRAINDICATIONS

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

Opus™ Mg Set 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 Opus™ Mg Set 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

Opus™ Mg Set has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Opus™ Mg Set in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

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:

Moldable:

Preparation:
The surgical field should be irrigated to remove any loose debris and dried prior to placement of OSTEOREVIVE™.
Before starting mixing make sure that OSTEOREVIVE™ is equilibrated to room temperature:(18-23°C/65-73°F)
Step 1:
Open the Opus™ Mg Set sterile powder pouch and sterile liquid solution and pour both into sterile basin. (18-23°C/65-73°F).
Step 2:
With sterile spatula, mix vigorously for 2 minutes. Stir until a consistent "slurry" is produced. (18-23°C/65-73°F)
Step 3:
Wait 3 minutes after mixing to allow the implant to cure. Do not disturb the Opus™ Mg Set while curing during the waiting time. (18-23°C/65-73°F)
***Technique Tip: Increased ambient temperature of the operating room will accelerate the waiting time.

Step 4:
After the waiting time, the product will be in a moldable putty form and ready implantation. It can be manipulated for an additional 3 minutes It can be contoured manually or with an instrument as desired. (18-23°C/65-73°F)
Step 5:
Once implanted, the Opus™ Mg Set begins to initially set approximately 2 minutes following implantation and may be considered final set 10 minutes after the initial implantation time is completed. (37°C/98.6°F)

Injectable:

Refer to the Instructions for Use for the **Mixing and Delivery System**.

SYMBOLS GLOSSARY:

Symbol	Reference Number	Title of Symbol	Description of Symbol per Standard[1]
	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 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	Indicates 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	Indicates 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 resterilized.
	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 sale by or on the order of a physician
	21 CFR 801.109(b)(1)	Prescription only	Requires prescription in the United States

[1]With the exception of the Rx Only symbol, all information is from ISO 15223-1:2016, Medical Devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements, FR recognition number 5-117.

PRODUCT COMPLAINTS:

Any healthcare professional who has any complaints or is dissatisfied with this product should notify Orthofix US LLC,
3451 Plano Pkwy, Lewisville, TX 75056
Phone: (214) 937-2000
Fax: (800) 445-1923
Email: OSI-CustomerService@Orthofix.com

FURTHER INFORMATION:

For product information, sales inquiries, customer service, or to obtain a surgical technique, please contact your sales representative or Orthofix US LLC Customer Service at Email: OSI-CustomerService@Orthofix.com

ORTHOFIX®

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