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 (the product) is an injectable, moldable, and biocompatible Bone Void Filler. The Opus™ Mg Set Bone Void Filler Packet contains powder (Magnesium based compound) and a mixing solution (Buffered saline). The device is sterile, single use only.

INDICATIONS:
Opus™ Mg Set Bone Void Filler is intended only for bony voids or defects that are not intrinsic to the stability of the bony structure.
Opus™ Mg Set Bone Void Filler is intended to be placed or injected into bony voids or gaps of the skeletal system (the long bones and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. Opus™ Mg Set Bone Void Filler is not intended to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

PRECAUTIONS:
Long Term Effects

The long-term effects of extraosseous of the product 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.
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.
- •The product is for single use only and may not be resterilized.

Skin Exposure: Wash area with soap and water
Eye Exposure: Flush thoroughly with running water

WARNINGS:
1. Remove any excess of the Bone Void Filler prior to closure.
2. Do not mix the product with any substance.
3. Highly pressurized application of the product into confined space with ready venous or arterial access is not recommended.
4. Do not use the product in infected sites.
5. Do not disturb placement site once the product begins to harden.
6. Do not overfill the defect area.
7. Do not reuse. The product is single use only.

USE SPECIFIC POPULATIONS
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.

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 Opus™ Mg Set
Before stating mixing make sure that Opus™ Mg Set **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

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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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