Mgnum™ BVF

PRODUCT INTRODUCTION
and Mixing Instructions

Paragon®

MgNum™ BVF

Magnesium-Based Bone Void Filler

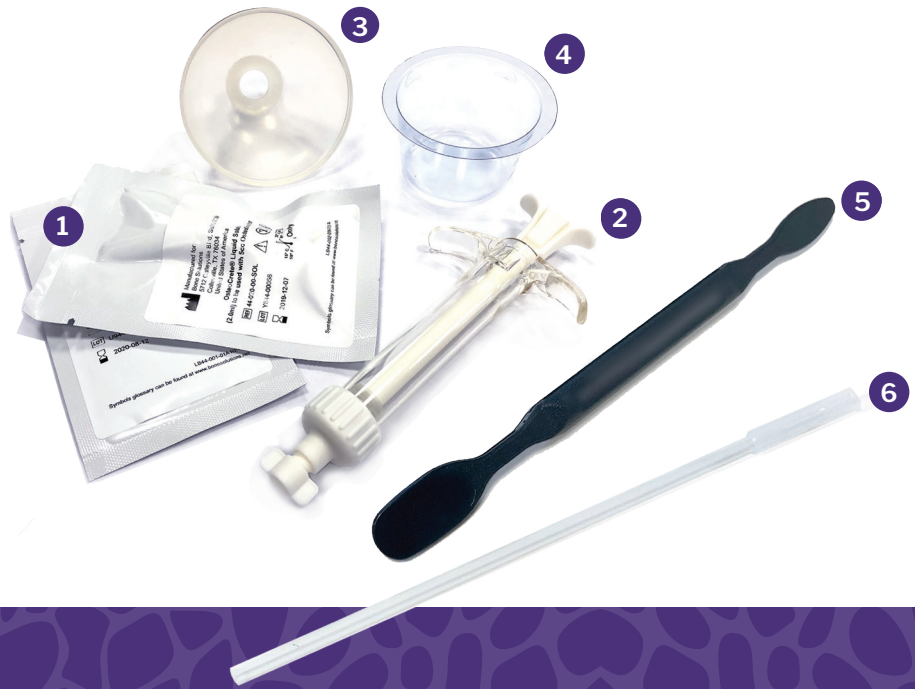
INJECTABLE AND MOLDABLE BVF
FULL KITS FOR MIXING + APPLICATION

HIGH STRENGTH. LIGHTWEIGHT. RESORBABLE.

MgNum™ BVF is a moldable injectable magnesium-based bone void filler that has a unique resorption profile that provides stability while also increasing cell proliferation, advancement of mineralization with a result of enhanced bone regeneration for multiple types of orthopedic applications.[1-8, 13-15]

MgNum™ BVF is made from a pre-measured blend of magnesium, phosphates and a pre-measured proprietary solution. When mixed and molded/injected according to the instructions for use, the product will harden in situ at the defect site.[12]

- 80% resorbable in 26 weeks [9]
- Remodels to normal bone[10, 11]
- Quicker time to union compared to calcium-based BVFs[9, 12]



KIT COMPONENTS	
	LIQUID & POWDER SET
	MIXING SYRINGE
	FUNNEL
	BASIN
	SPATULA
	11 GAUGE CANNULA

Paragon 28®

Mgnum™ BVF

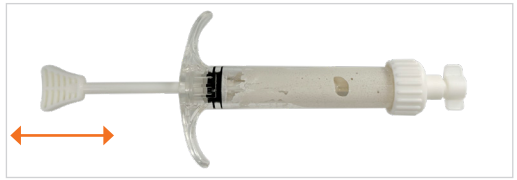
Magnesium-Based Bone Void Filler

MIXING AND DELIVERY GUIDE

*All curing times after mixing are dependent upon ambient temperature. Suggested mixing times are based on 66–68°F.

1 Mix

Combine powder and saline in syringe. Start timer. Remove support rod and mix with plunger.



00:00-00:30

NOTE: Do not remove tip from syringe until ready to inject.

2 Regulate Consistency

Stop mixing.
Avoid further manipulation.

LOW VISCOSITY

HIGH VISCOSITY

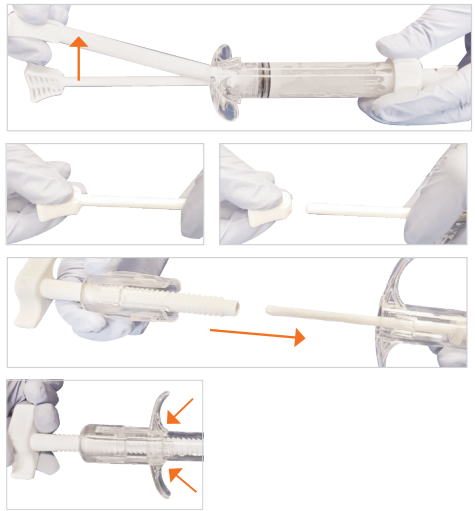
(15cc) (5-10cc)
00:30 >>>>06:00-08:00*
VISCOSITY

NOTE: If product is not ready to be implanted or a higher viscosity is desired, a mechanical advantage will be required.

Optional

3 Spindle Drive Delivery

Remove support rod and snap wedge tip off from mixing stick. Attach spindle nut to base of syringe. Insert threaded spindle over mixing stick and advance spindle through nut. Remove winged cap from syringe cap and purge excess air by rotating handle clockwise.



4 Inject

Remove tip from syringe, attach cannula and inject product into defect.

Inject +02:00

Do not touch for 2 minutes to allow time for initial curing. Hardware placement and/or drilling can occur at this time.

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5CC MIXING SYRINGE

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2 Regulate Consistency

Stop mixing.
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LOW VISCOSITY

HIGH VISCOSITY

00:30 >>>>08:00*

VISCOSITY

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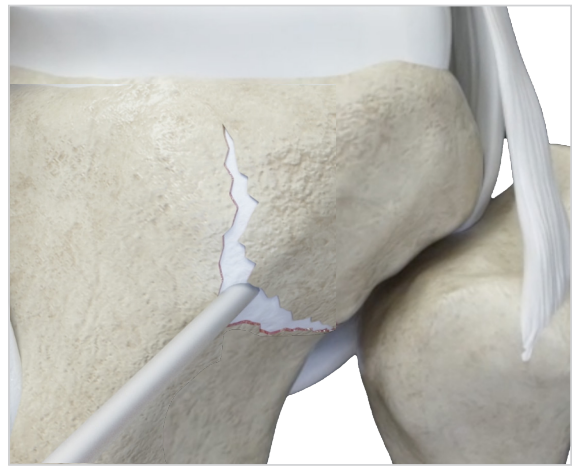
3 Inject

Remove tip from syringe, attach cannula and inject product into defect.

4 Initial Curing



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Magnesium-Based Bone Void Filler

10CC MIXING SYRINGE

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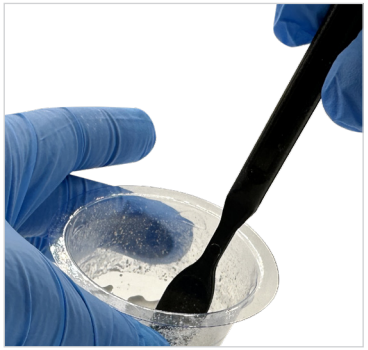
1 Mix

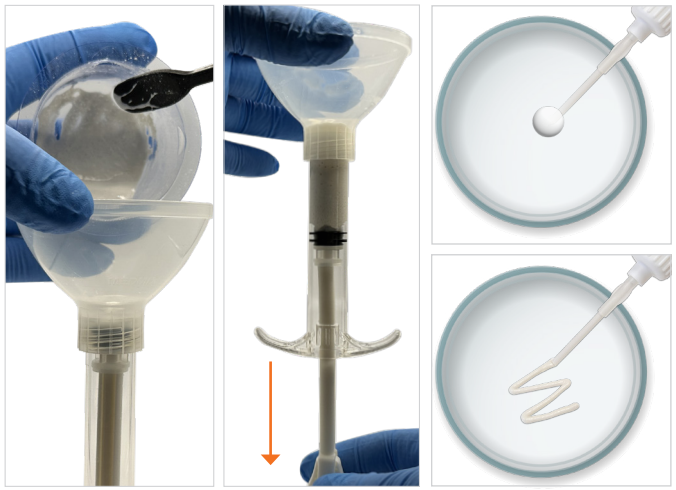
Combine powder and saline in mixing bowl. Start timer. Mix with spatula.



00:00-00:30

2 Regulate Consistency

Stop mixing. Avoid further manipulation. Transfer to mixing syringe through funnel. Keep plunger closed until product has been completely transferred. Then, retract plunger and allow product to flow into syringe.



00:30 >>>>08:00*
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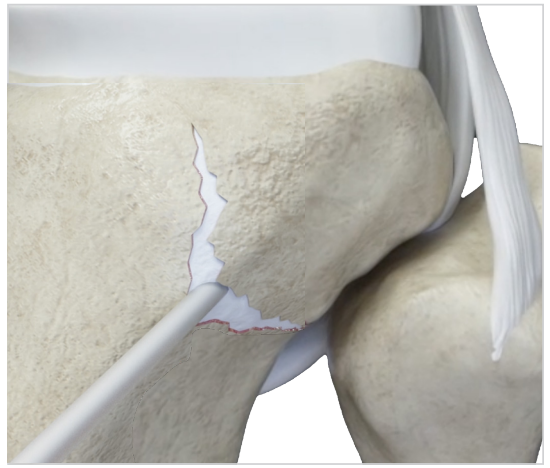

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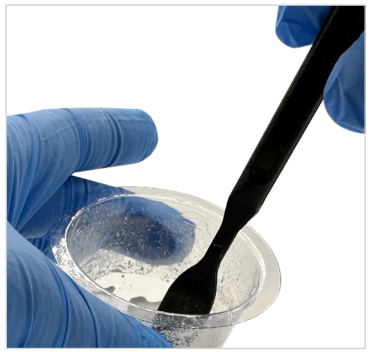

00:00-00:30

2 Regulate Consistency

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00:30 >>>> 06:00*
VISCOSITY

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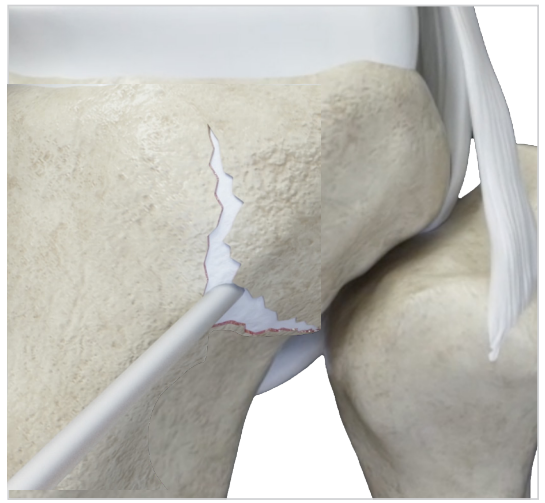

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Magnesium-Based Bone Void Filler

RESCUE KIT: MECHANICAL ASSIST

P02-BVF-AUXI

Optional spindle drive delivery

Remove the support rod from the mixing stick by gently pushing the internal mixing stick out of the support rod (See Step 4).

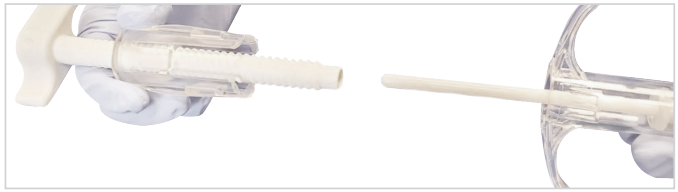
Snap off the wedge-shaped end of the mixing stick. Attach the spindle nut to the base of the syringe.

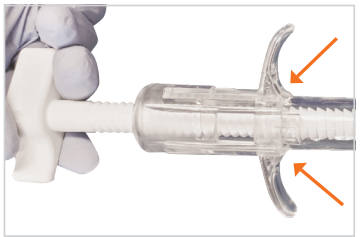
Ensure both sides of the nut are attached.

Insert the threaded spindle over the mixing stick and rotate clockwise to advance the spindle through the spindle nut.

Remove the winged female cap from the white syringe cap. Purge the excess air in the syringe by slowly turning the spindle handle clockwise.

Now, the material is ready to be injected.





Components

(Mixing Syringe, Funnel, Open bore Cap, 4.2 mm Cannula/Pusher, 8 mm Cannula/Pusher & Mechanical Advantage)

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10CC MIXING BOWL

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1 Mix

Combine powder and saline in mixing bowl. Start timer. Mix with spatula.

00:00-00:30

2 Wait

Stop mixing. Lay bowl on its side.

00:30-10:00

3 Evaluate Consistency

Product is ready once it no longer sticks to the spatula. Use the spatula to break up the putty and begin molding into desired consistency.

4 Regulate Consistency

Product can be molded into tackier putty by mixing in the bowl or kneading in the hand. Mix less for firmer putty, mix more for tacky putty. Knead at least once per minute to avoid premature setting.

↑ Manipulation = **Tacky Putty**
↓ Manipulation = **Firmer Putty**

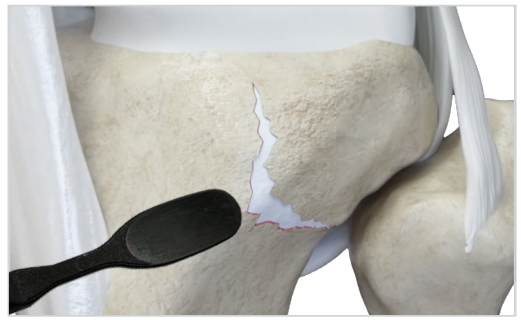
10:00 >>>>20:00*
VISCOSITY

NOTE: If product is not ready to be implanted or a higher viscosity is desired, a mechanical advantage will be required.

5 Placement

Stop mixing. Avoid manipulation and place into defect. If product is tacky, spatula can be used to assist with placement.

6 Initial Curing



Implant +02:00

Do not touch for 2 minutes to allow time for initial curing. Hardware placement and/or drilling can occur at this time.

Mgnum™ BVF

Magnesium-Based Bone Void Filler

15CC MIXING BOWL

*All curing times after mixing are dependent upon ambient temperature. Suggested mixing times are based on 66–68°F.

1 Mix

Combine powder and saline in mixing bowl. Start timer. Mix with spatula.

00:00-00:30

2 Wait

Stop mixing. Lay bowl on its side.

00:30-10:00

3 Evaluate Consistency

Product is ready once it no longer sticks to the spatula. Use the spatula to break up the putty and begin molding into desired consistency.

4 Regulate Consistency

Product can be molded into tackier putty by mixing in the bowl or kneading in the hand. Mix less for firmer putty, mix more for tacky putty. Knead at least once per minute to avoid premature setting.

↑ Manipulation = **Tacky Putty**
↓ Manipulation = **Firmer Putty**

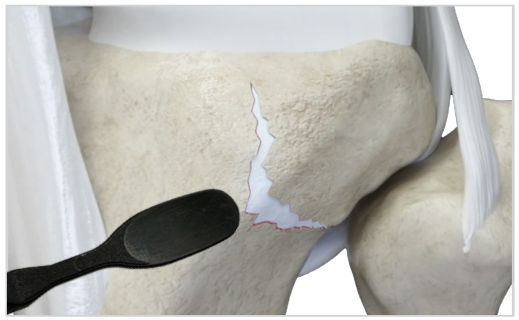
08:00>>>>18:00*
VISCOSITY

NOTE: If product is not ready to be implanted or a higher viscosity is desired, a mechanical advantage will be required.

5 Placement

Stop mixing. Avoid manipulation and place into defect. If product is tacky, spatula can be used to assist with placement.

6 Initial Curing



Implant +02:00

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Mgnum™
Bone Void Filler (BVF)

Exclusively foot & ankle
Paragon 28®

14445 Grasslands Dr,
Englewood, CO 80112
Phone: 888-728-1888
Fax: 888-728-1220

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

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

Mgnum™ 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).

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

INDICATIONS FOR USE

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

CONTRAINDICATIONS

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

Mgnum™ 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 Mgnum™ 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

Mgnum™ 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 Mgnum™ 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.

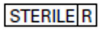
STORAGE CONDITIONS

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

MIXING INSTRUCTIONS:

Refer to STI for Mixing, Delivery and Setting times.

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 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

Exclusively foot & ankle
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Phone: 817-809-8850
Fax: 866-673-0111

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Blood pressure change
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Cyst
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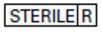
	5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
	5.1.7	Serial Number	Indicates the manufacturer's serial number so that a specific medical 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 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

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References

1. Díaz-Tocados JM, Herencia C, Martínez-Moreno JM, et al. Magnesium Chloride promotes Osteogenesis through Notch signaling activation and expansion of Mesenchymal Stem Cells. Sci Rep. 2017;7(1):7839.
2. Yoshizawa S, Brown A, Barchowsky A, Sfeir C. Magnesium ion stimulation of bone marrow stromal cells enhances osteogenic activity, simulating the effect of magnesium alloy degradation. Acta Biomater. 2014;10(6):2834-2842.
3. He LY, Zhang XM, Liu B, Tian Y, Ma WH. Effect of magnesium ion on human osteoblast activity. Braz J Med Biol Res. 2016;49(7).
4. Wong H, Chu P, Leung K, Cheung M, Luk K, Yeung K. Engineered polycaprolactone-magnesium hybrid biodegradable porous scaffold for bone tissue engineering. Progress in Natural Science: Materials International. 2014;24(5):561-567.
5. Jia J, Zhou H, Wei J, et al. Development of magnesium calcium phosphate biocement for bone regeneration. J R Soc Interface. 2010;7(49):1171-1180.
6. Zeng D, Xia L, Zhang W, et al. Maxillary sinus floor elevation using a tissue-engineered bone with calciummagnesium phosphate cement and bone marrow stromal cells in rabbits. Tissue Eng Part A. 2012;18(7-8):870881.
7. Wu F, Wei J, Guo H, Chen F, Hong H, Liu C. Self-setting bioactive calcium-magnesium phosphate cement with high strength and degradability for bone regeneration. Acta Biomater. 2008;4(6):1873-1884.
8. Zhang Z, Yang Z, Chen Z, et al. A study on bone cement containing magnesium potassium phosphate for bone repair. Cogent Biology. 2018;4(1):1-11.
9. Ref. Bone Solutions Test Report: 10188 Rev. A / Data on file
10. Bertone A, DeMaria M, Johnson A, Weisbrode S, Kowaleski M. Degradable magnesium based cement adheres stainless steel screws into bone. Orthopaedic Research Society; 2006; Chicago, IL.
11. Bertone A, Hackett B, Litsky A, Johnson A, Kaeding C, Lally T. A magnesium injectable formulation adheres bone to bone and tendon to bone. Orthopaedic Research Society; 2005; Washington, D.C.
12. Waselau M, Samii VF, Weisbrode SE, Litsky AS, Bertone AL. Effects of a magnesium adhesive cement on bone stability and healing following a metatarsal osteotomy in horses. Am J Vet Res. 2007;68(4):370-378.
13. Hirvinen LJ, Litsky AS, Samii VF, Weisbrode SE, Bertone AL. Influence of bone cements on bone-screw interfaces in the third metacarpal and third metatarsal bones of horses. Am J Vet Res. 2009;70(8):964-972.
14. Kim MS, Kovacevic D, Milks RA, et al. Bone Graft Substitute Provides Metaphyseal Fixation for a Stemless Humeral Implant. Orthopedics. 2015;38(7):e597-603. 13-15
15. Gulotta LV, Kovacevic D, Ying L, Ehteshami JR, Montgomery S, Rodeo SA. Augmentation of tendon-to-bone healing with a magnesium-based bone adhesive. Am J Sports Med. 2008;36(7):1290-1297.
16. Gröber U, Schmidt J, Kisters K. Magnesium in Prevention and Therapy. Nutrients. 2015;7(9):8199–8226. Published 2015 Sep 23. doi:10.3390/nu7095388
17. Yoshizawa et al. Magnesium ion stimulation of bone marrow stromal cells enhances osteogenic activity, stimulating the effect of magneisum alloy degradation. Acta Biomater. 2014; 10(6): 2834-42.
18. Wong et al. Engineered polycaprolactone-magnesium hybrid biodegradable porous scaffold for bone tissue engineering. Materials International. 2014; 24: 561-567.
19. Ref. Biomet Literature Number: BMET0210.0 REV101512 & 510(k) Summary K090871.
20. Ref. Wright Medical Literature Number: AP-002461B 21-Nov-2018 and 510K Summary K182823.
21. Ref. Stryker Literature Number: 90-07900 LOT B1008 & 510(k) Summary K060061.
22. Ref. DePuy Synthes Literature Number: J11469-A & 510(k) Summary K102722.
23. Ref. http://subchondroplasty.com/healthcare-professionals-indications.html ZimmerBiomet literature number 903.051.13 FDA 510(K) Summary K101557.
24. Ref. Skeletal Kinetics Literature Number: LBL 10208 Rev AD & 510(k) Summary K100986.
25. Ref. Bone Solutions Test Report: TD-328 [A] - OsteoCrete Specification Setting and Sample Size - 5cc
26) Yoshizawa et at. Magnesium ion stimulation of bone marrow stomal cells enhances osteogenic activity, stimulating the effect of magnesium allow degradation. Acta Biometer. 2014; 10(6): 2834-42.4
27) Wong et al. Engineered polycaprolactone-magnesium hybrib biodegradable porous scaffold for bone tissue engineering. Materials International. 2014; 24: 561-567

Claims based on critically sized rabbit lateral condyle defect model, rabbit anterior cruciate ligament reconstruction, equine metacarpal and metatarsal fracture fixation, and equine metatarsal osteotomy. It is unknown how results from the rabbit or equine models compare with clinical results in humans.

For product information, including indications, contraindications, warnings, precautions and potential adverse effects, visit Paragon 28's Instructions for Use page online: Paragon28.com/IFU

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