Mgnum™ BVF

Product Introduction
and Mixing Instructions

Exclusively foot & ankle
Paragon 28®

MgNum™ BVF

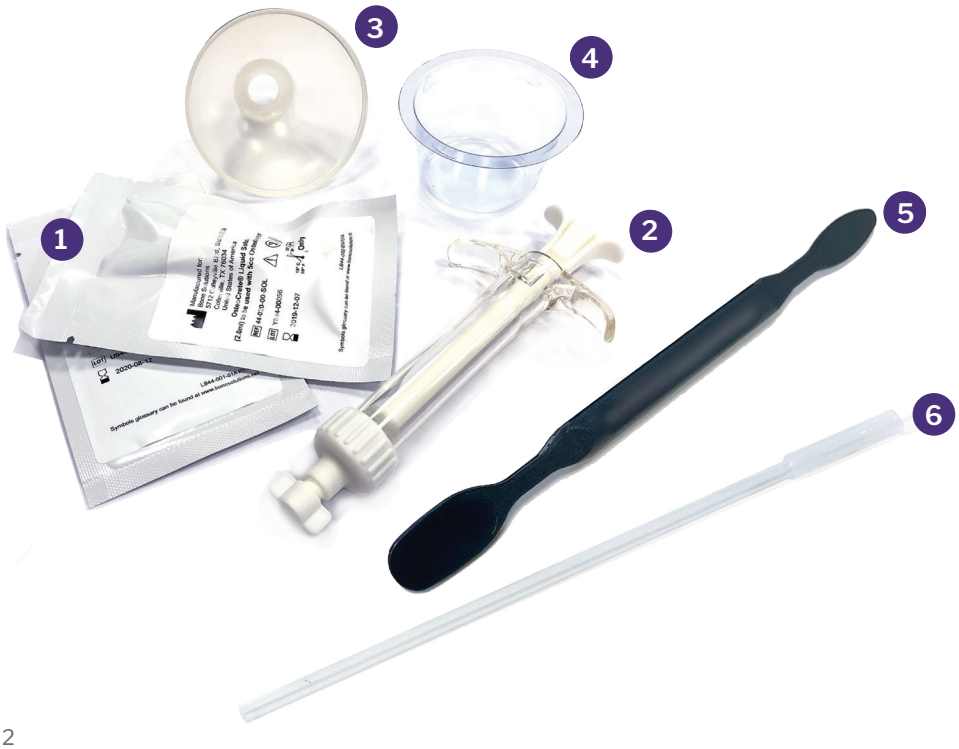
INJECTABLE AND MOLDABLE BVF | FULL KITS FOR MIXING + APPLICATION

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]

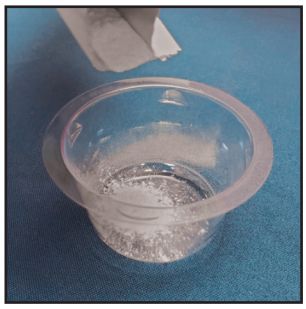


KIT COMPONENTS	
1	LIQUID & POWDER SET
2	MIXING SYRINGE
3	FUNNEL
4	BASIN
5	SPATULA
6	11 GAUGE CANNULA

MIXING INSTRUCTIONS: Moldable

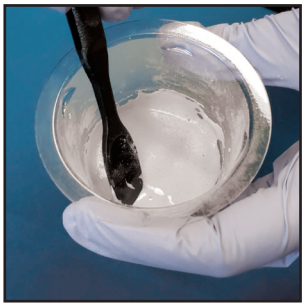
Preparation: The surgical field should be irrigated to remove any loose debris and dried prior to placement of MgNum™ BVF. Before mixing, ensure that MgNum™ BVF is equilibrated to room temperature: **(18-23°C / 65-73°F)**

1. Open the MgNum™ BVF sterile powder pouch and sterile liquid solution and pour both into sterile basin. (Images 1A and 1B) **(18-23°C / 65-73°F)**.

1A 

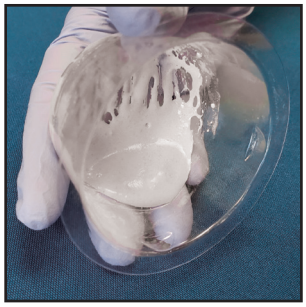
1B 

2. With sterile spatula, mix vigorously for 2 minutes. (Image 2) Stir until a consistent "slurry" is produced. **(18-23°C / 65-73°F)**.

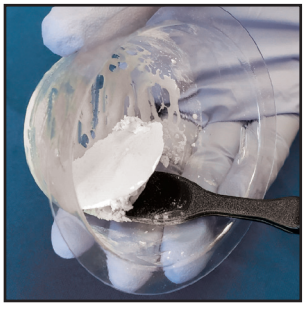
2 

3. Wait 3 minutes after mixing to allow the implant to cure. (Image 3) Do not disturb the MgNum™ BVF while curing during the waiting time. **(18-23°C / 65-73°F).**

TECHNIQUE TIP:
Increased ambient temperature of the operating room will accelerate curing time.

3 

4. After the waiting time, the product will be in a moldable putty form and ready for implantation. It can be manipulated for an additional 3 minutes. It can be contoured manually or with an instrument as desired. (Images 4A and 4B) **(18-23°C / 65-73°F).**

4A 

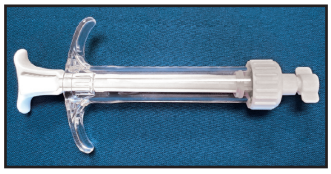
5. Once implanted, the MgNum™ BVF begins to initially set approximately 2 minutes following implantation and may be considered final set 10 minutes after the initial implantation time is completed. **(37°C/98.6°F)**

NOTE:
For mixing and curing times, reference chart on pg. 7.

4B 

MIXING INSTRUCTIONS: Injectable

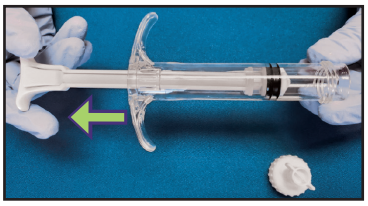
MgNum™ BVF Syringe



1. Remove the preassembled white syringe cap (Image 5A) and winged female luer cap at the distal end of syringe by unscrewing counter clockwise. (Image 5A) Pull the plunger all the way back. (Image 5B)

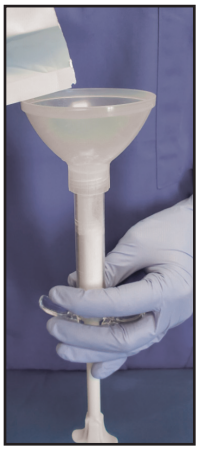
5A

5B



2. Attach funnel on the open bore of the syringe. Pour powder into the syringe. (Image 6A) Open vial of premeasured liquid solution and pour into the syringe and remove the funnel. (Image 6B)

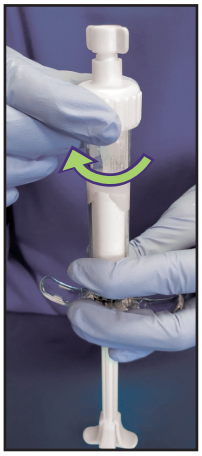
6A



6B

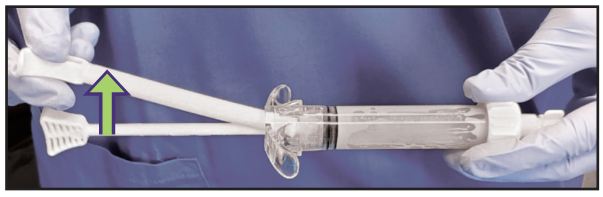
3. Replace white syringe cap by screwing clockwise onto the open bore. (Image 7) Make sure the winged female lure cap is connected to the end of the white syringe cap.

7

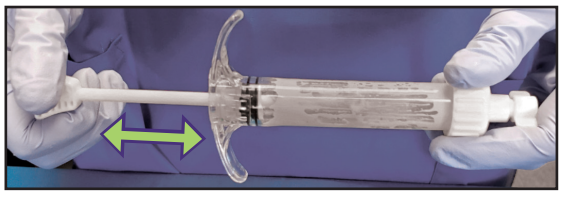


4. Remove the support rod from the mixing stick by gently pushing the internal mixing stick out of the support rod. (Image 8A) Vigorously push and pull the mixing stick for a minimum of 2 minutes with a twisting motion until the powder and liquid solution are thoroughly mixed and have a slurry consistency. (Image 8B)

8A

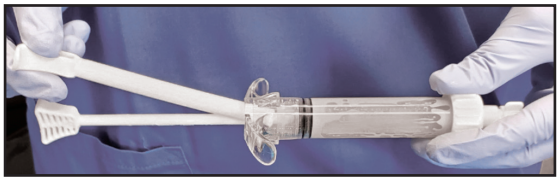


8B



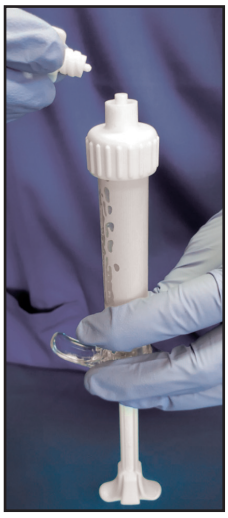
5. Pull the mixing stick back until plunger is at the base of the syringe and reinstall the support rod on the mixing stick (See step 4). (Image 9)

9



MIXING INSTRUCTIONS: Injectable

6 Remove winged female cap from the white syringe cap. (Image 10A) Then, purge the excess air in the syringe by carefully pressing on the plunger. (Image 10B) The material is now ready to be injected. (Image 10C)

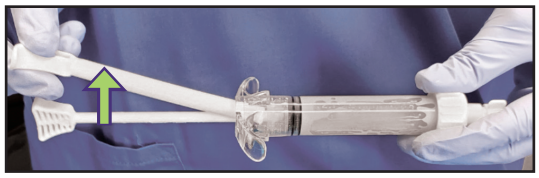
10A 

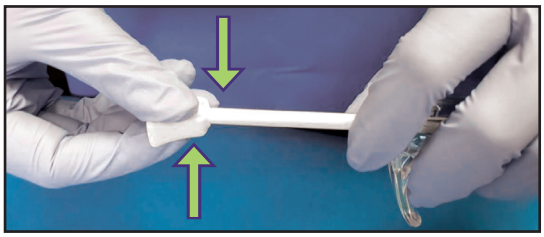
10B 

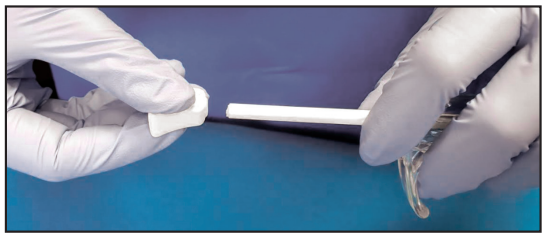
10C 

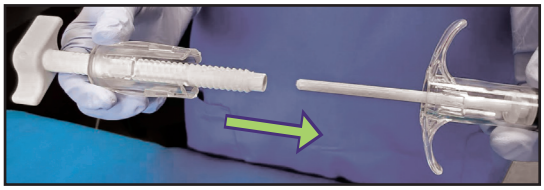
7 **Optional spindle drive delivery**

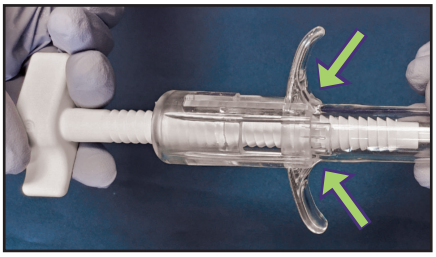
Remove the support rod from the mixing stick by gently pushing the internal mixing stick out of the support rod. (Image 11A) Snap off the wedge-shaped end of the mixing stick. (Images 11B-C) Attach the spindle nut to the base of the syringe. Ensure both sides of the nut are attached. Insert the threaded spindle over the mixing stick and rotate clockwise to advance the spindle through the spindle nut. (Images 11D-E) Remove the winged female cap from the white syringe cap. Purge the excess air in the syringe by slowly turning the spindle handle clockwise. The material is ready to be injected. (Image 11F)

11A 

11B 

11C 

11D 

11E 

11F 

MIXING INSTRUCTIONS: Injectable

DELIVERY INSTRUCTIONS:

Option 1, Luer cannula:

Attach the open luer cannula to the preassembled white syringe cap by threading its end into the luer of the white syringe cap.

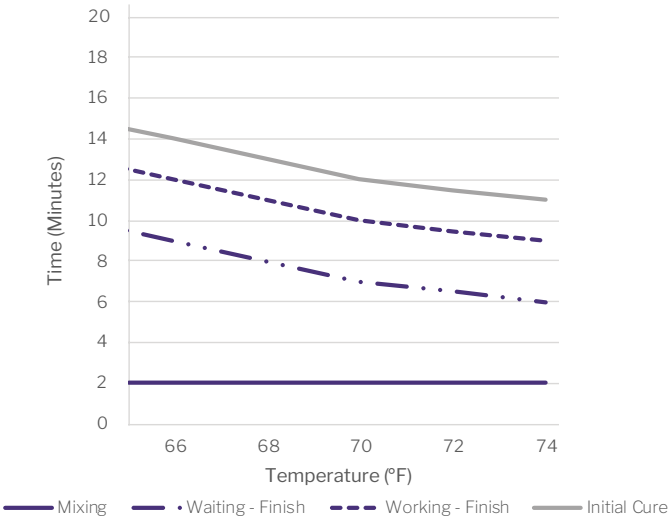
Option 2, Open bore cannula:

Step 1. Remove the preassembled white syringe cap on the distal end of the syringe. Attach the open bore syringe cap by threading it clockwise onto the syringe barrel. Attach the open threaded cannula to the syringe cap by threading it clockwise onto the open bore syringe cap.

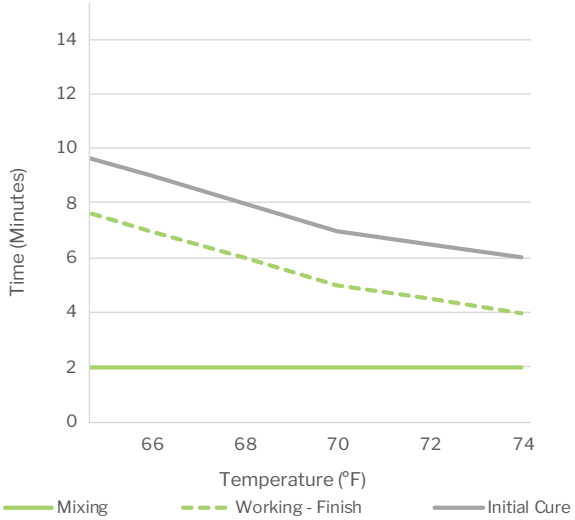
Step 2. Material that is trapped within the open threaded cannula can be fully extruded. Detach the open bore syringe cap and open threaded the cannula assembly from the syringe barrel by threading it counterclockwise. Insert the pusher tip into the underside of the open bore syringe cap until all material is removed.

WORKING GUIDELINES: Moldable and Injectable

MgNum™ BVF Working Guidelines - Moldable



MgNum™ BVF Working Guidelines - Injectable



IFUS: MgNum™ BVF Mixing and Delivery System

INDICATIONS
The MgNum™ BVF Mixing and Delivery System is intended to be used for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site

'PRECAUTIONS
Surgeons are advised to review the product specific surgical technique prior to performing any surgery.
General use instructions are below.
Contact your Paragon 28 representative for an onsite demonstration.

WARNINGS
1. Prior to use, thoroughly read these instructions for use. Follow the instructions outlined in this document for successful mixing of the graft material.
2. Before use, inspect the instrument carefully for damage, wear and / or non-functioning parts.
3. Keep the instructions for use accessible to all staff.
4. Never use or process damaged or defective devices. Contact your local sales representative or Paragon 28 for replacement.
5. DO NOT RESTERILIZE: The MgNum™ BVF Mixing and Delivery System is intended for single use only.
6. DO NOT REUSE: The MgNum™ BVF Mixing and Delivery System is intended to be used for mixing one time only - to only mix one mixture of materials. Repeated use could result in device failure and/or contamination of graft materials from previous use debris.
7. Only mix with the specified volumes of materials as directed by the IFU of the graft materials.
8. DO NOT OVERFILL: Do not overfill mixing syringe with materials. Overfilling syringe could result in device failure and/or ineffective mixing of the graft material.
9. If the MgNum™ BVF Mixing and Delivery System does not function correctly as outlined in the instructions of this document, DO NOT USE. Discard the MgNum™ Mixing and Delivery System and graft materials contained in it.
10. The use of a surgical instrument for tasks other than those for which they are intended may result in damaged or broken instruments or patient injury.
11. Make sure the product is only used by qualified or trained staff.
12. Follow the general guidelines and aseptic principles when handling sterile items.

CONTRAINDICATIONS
Contraindications include, but are not limited to:
1. Blood supply limitations and previous infections, which may retard healing.
2. Any active infection or blood supply limitations.
3. Do not use for kyphoplasty or vertebroplasty procedures.

IFUS: MgNum™ Bone Void Filler

INDICATIONS
MgNum™ Bone Void Filler is intended only for bony voids or defects that are not intrinsic to the stability of the bony structure. MgNum™ 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. MgNum™ 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 use 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 sterile use only and may not be resterilized

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

WARNINGS
1. Remove any excess of the MgNum™ 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.

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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.
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24. Ref. Skeletal Kinetics Literature Number: LBL 10208 Rev AD & 510(k) Summary K100986.
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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
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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

P02-STG-0001 Rev B

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