Mgnum™ BVF

Product Introduction
and Mixing Instructions

Exclusively foot & ankle Paragon 28®

PRODUCT DESCRIPTION

MgNum™ BVF is a fast setting Magnesium-based bone substitute that remodels into bone over time through creeping substitution.

Medium Viscosity | High Viscosity

Applications

Optimized for trauma, extremity, revision, sports medicine, intervertebral body fusions, and posterolateral spine surgery.

- Ready in 30 Seconds
- Moldable/ Injectable
- Cohesive/ Adhesive
- Drillable/ Settable
- Radiopaque

Composition

MgNum™ BVF is made from a fully synthetic, pre-measured blend of magnesium, phosphates, and a proprietary solution.

Magnesium Benefits

Magnesium is critical for bone health and development. Approximately 60% of Magnesium in the body resides in the bones, contributing to the structural development of bone and playing a key role in the absorption and regulation of calcium. Magnesium also controls the active transport of calcium across cell membranes and deficiency can contribute to osteoporosis.

Magnesium increases proliferation of marrow stromal cells, enhances mineralization of the extracellular matrix and stimulates proteins for enhanced bone regeneration.[1] Additionally, it improves attachment and growth of osteoblasts, and initiates apatite layer formation on scaffolds, as well as new bone formation through the scaffold.[2]

PRODUCT DESCRIPTION

Study Data

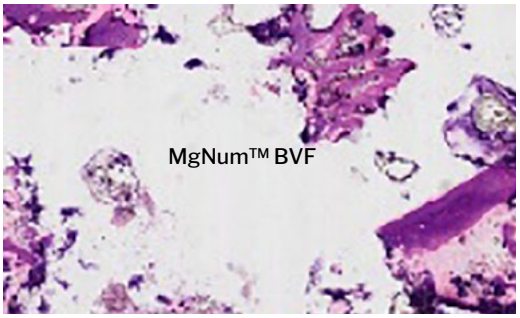
Bone Remodeling:

Study 1 - In a radiographic review of 18 patients, the average grade of resorption was 3.6 ±0.6 at 1 year. This demonstrates clinically relevant resorption, and structural support in challenging bone voids.[3]

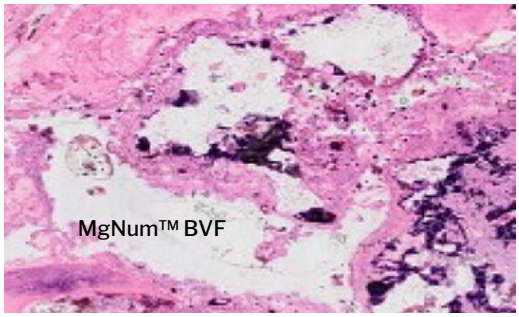
Post-Op

1 year

Histology from a separate study further demonstrates bone remodeling through creeping substitution.[4]



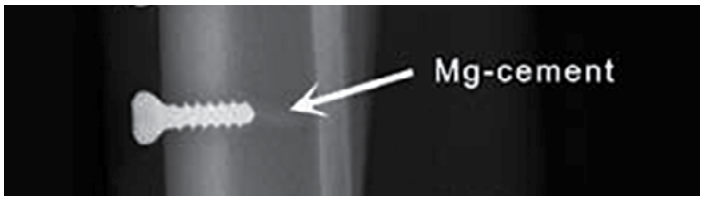
7 days



12 Weeks

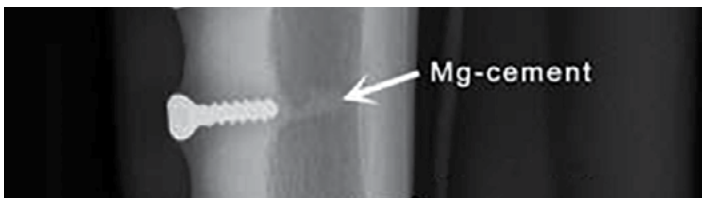
Bone Mineral Density:

Study 2 - When compared to a calcium-based product, MgNum™ BVF showed a 24% increase in bone mineral density adjacent to the screw.[5]

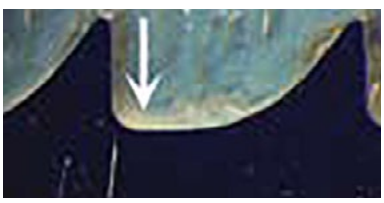


5 days

5 days



26 Weeks



26 Weeks

PRODUCT DESCRIPTION

Regulatory Information

Cleared by FDA 510(k)	K071004, K192674, K161568, K234013
Regulation Number	21CFR 888 3045
Classification Product Code	MQV, OIS

Packaging Specifications

Latex	Not made with natural rubber latex
Storage	Store at room temperature
Shelf Life	36 Months
Sterilization	Gamma irradiation
Sterile	Yes
Single-Use	Yes
MRI Safe	Yes
Dimensions	26cm (l) x 21cm (w) x 8cm (h)

Material Specifications

Setting Temperature	98°F (37° C)
Compressive Strength	36MPa at 48 hours

Biocompatibility

MgNum™ BVF has been evaluated to be biologically safe to use. The materials that comprise this product have been used clinically for many years. The product has been extensively tested in in-vitro and in vivo settings, and follow the requirements of EN ISO 10993-1.

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.

PRODUCT DESCRIPTION

Part #	Description
P02-BVF-0005	Magnesium Bone Void Filler, 5cc
P02-BVF-0010	Magnesium Bone Void Filler, 10cc
P02-BVF-0015	Magnesium Bone Void Filler, 15cc

Each Kit Contains:

Mixing Bowl

Funnel

Spatula

Mechanical Assist Tool

Cannula

Syringe

BVF Powder

- 5cc, 10cc, or 15cc depending on kit

Liquid solutions

- One vial for medium viscosity
- One vial for “putty” viscosity

PRODUCT DESCRIPTION

Additional Instrumentation Kits:

Resorbable Bead Mat Kit - P02-BVF-SBM1

Contains:

- 3 mm Bead Mat (15 cc volume per side)
- Scraper

Mixing and Delivery System Kit - P02-BVF-AUX1

	Kit Components
1	Mixing Syringe
2	Mechanical Advantage
3	11 Gauge Cannula
4	2 Gauge Cannula Pusher
5	2 Gauge Cannula
6	Open Bore Cap
7	Funnel

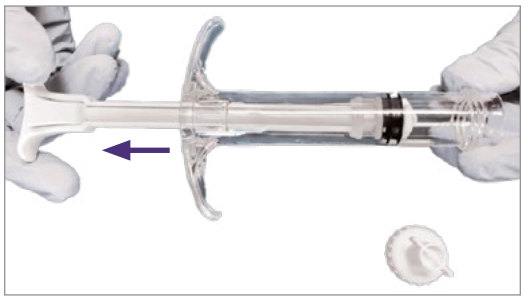
SYRINGE MIXING AND DELIVERY SYSTEM

Controlled, flowable application through a syringe and optional cannula, recommended for hardware removals and other voids.

1 Determine the appropriate bone substitute viscosity for use:

Viscosity	Description	Comparable To	Liquid Amount to Use	Void Types
Medium	Loose, flowable, wet	Toothpaste	2.0 ml / 5 cc powder	Contained
High	Stiffer, fast setting	Grout	1.2 ml / 5 cc powder	Uncontained

2 Remove the preassembled white syringe cap and winged female luer cap at the distal end of syringe by unscrewing counter-clockwise. Pull the plunger all the way back.



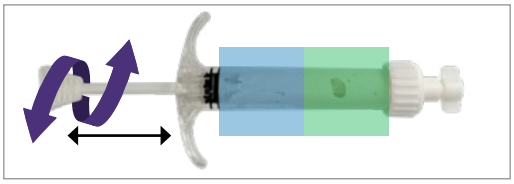
3 Attach funnel on the open bore of the syringe (see note below). Pour the entire powder packet into the syringe.
Add premeasured liquid solution into the syringe and remove the funnel.

NOTE:
For 5 cc kits, the funnel will thread on the outside of the provided 15 cc syringe.
For 10 cc and 15 cc kits, the funnel will sit inside the provided 40 cc syringe.

SYRINGE MIXING AND DELIVERY SYSTEM

4 Replace white syringe cap by screwing clockwise onto the open bore. Make sure the winged female lure cap is connected to the end of the white syringe cap.

5 Remove the support rod from the mixing stick by gently pushing the internal mixing stick out of the support rod. With the syringe oriented horizontally (parallel to the floor), begin mixing the material at the bottom of the syringe (toward the tip) shown in the green area below with a corkscrew plunge-twist-pulll motion. Once the green portion looks to be fully hydrated, begin incorporating the remaining powder mixture from the blue area by pulling the support rod back further a little more each time.



6 Continue mixing until no dry powder remains and the putty does not look gritty. Pull the mixing stick back until plunger is at the base of the syringe and reinstall the support rod on the mixing stick.

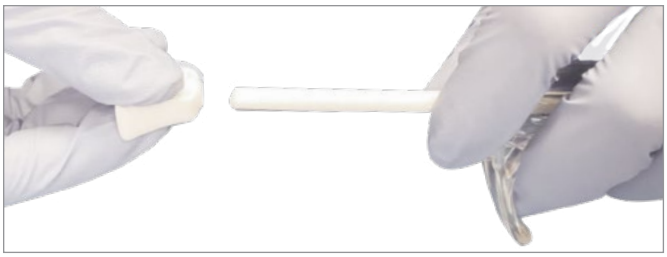
SYRINGE MIXING AND DELIVERY SYSTEM

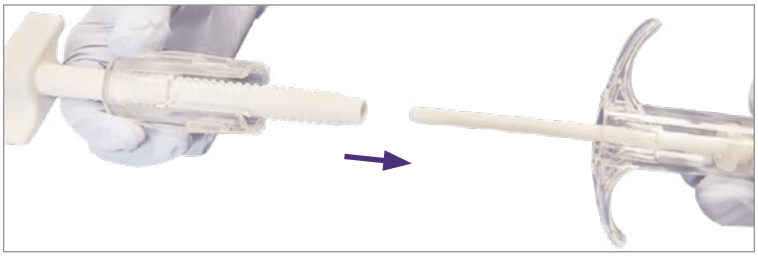
7

Loosen the white syringe cap slightly, then purge the excess air in the syringe by carefully pressing on the plunger. The material is now ready to be injected.

If it is high viscosity, use immediately to prevent premature curing in the syringe; once difficult to inject by hand, use the mechanical assist tool to finish.

- **When using the cannula:** attach it to the syringe tip and cut down to 1 inch in length.
- **If using the mechanical assist tool:** Turn the spindle handle counterclockwise until the ends of the white pole and clear brackets are aligned. Snap off the wedge-shaped end of the mixing stick and then slide the assist tool over it until the clear brackets attach to the syringe (an audible "click" will be heard when attached). The spindle handle can then be turned clockwise for a controlled injection of the material.



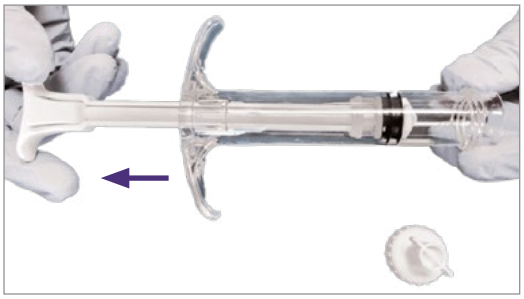


NOTE:
The mechanical assist tool is required when using high viscosity bone substitute with the syringe.

QUICK PUTTY DELIVERY

Fast-setting putty mixed in the syringe and delivered via hand or spatula, recommended for open or uncontained trauma defects and fracture fragments for hardware removals and other voids.

1 Remove the preassembled white syringe cap and winged female luer cap at the distal end of syringe by unscrewing counter-clockwise. Pull the plunger all the way back.



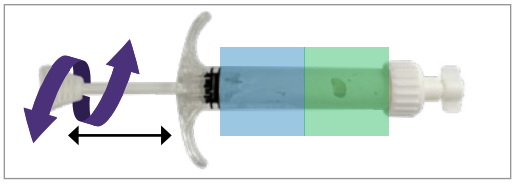
2 Attach funnel on the open bore of the syringe (see note below). Pour powder into the syringe. Add premeasured liquid solution and pour into the syringe and remove the funnel.

	5 cc
Amount of Solution to Use	1.2 cc
	10 cc
Amount of Solution to Use	2.4 cc
	15 cc
Amount of Solution to Use	3.6 cc

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

QUICK PUTTY DELIVERY

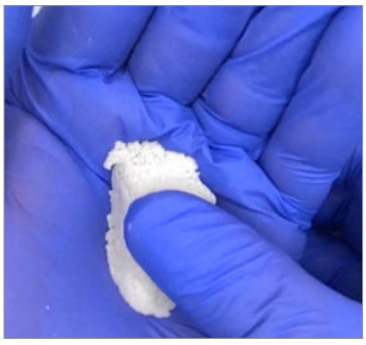
4 Remove the support rod from the mixing stick by gently pushing the internal mixing stick out of the support rod. With the syringe oriented horizontally (parallel to the floor), begin mixing the material at the bottom of the syringe (toward the tip) shown in the green area below with a corkscrew push-and-pull motion. After a few seconds, begin incorporating the remaining mixture in the blue area by pulling the support rod back further a little more each time.



5 Continue mixing until no dry powder remains and the putty does not look gritty. Pull the mixing stick back until plunger is at the base of the syringe and reinstall the support rod on the mixing stick.

6 Remove the syringe cap, push the putty out of the syringe into your hand, and knead by hand to regulate consistenc for up to 2 minutes.

- **More kneading = more tacky**
- **Less kneading = more firm**



7 Place the putty into the osseous defect by hand or with spatula.
Putty can be drilled into immediately.

BEAD MAT DELIVERY

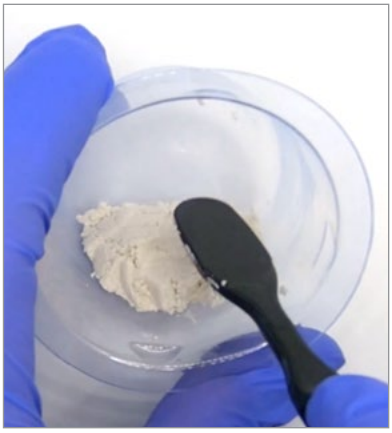
Creates 3 mm pellets useful for osseous defects and dead space management; prepare at start of case to allow optimal curing time for pellets.

1 Ensure that the MgNum BVF powder is equilibrated to room temperature (18-23°C / 65-73°F), then pour the powder into the sterile basin.
Add the appropriate amount of liquid solution (see table).

	5 cc
Amount of Solution to Use	1.3 cc
	10 cc
Amount of Solution to Use	2.6 cc
	15 cc
Amount of Solution to Use	3.9 cc

2 With sterile spatula, mix vigorously until the mixture has the consistency of wet sand and has a tacky consistency.

If needed, add additional liquid dropwise, but only after sufficient mixing has already been conducted.



3 Move the material from the basin onto the bead mat and use the scraper to shape into beads.

4 Bend and twist the bead mat to release the beads. Pellets are now ready to be implanted.

QUICK REFERENCE TABLE

	High Viscosity	Medium Viscosity	Beads
Void Type Use	Uncontained Voids	Contained Voids	Dead space management
Case Examples	Fractures, trauma cases, tibial plateau, pilon, calcaneus,hardware removals, and backfill	Benign bone cysts, bone marrow lesions, percutaneous cases	Osseous defects, dead space management
Mixing Method	Syringe	Syringe	Bowl + Bead Mat
Delivery Method	Syringe w/ Trimmed Cannula or by hand	Syringe w/ Trimmed Cannula	Hand
Mechanical Assist?	Required	Optional	N/A
Solution Amount	1.2cc solution / 5cc powder “Fast Set Putty” packet vial	2.0cc solution / 5 cc powder “Liquid solution” packet vial	1.3cc solution / 5cc powder Measure in syringe
Cure Time Before drilling?	None	2 minutes, then drill	N/A
Technique Pages	Syringe: Pages 8-10 Putty: Pages 11-12	Pages 8-10	Page 13

TIPS AND TRICKS:

- When using the cannula, cut it down to ~1 inch before assembling
- Don’t focus on mixing time, focus on material consistency
  - If gritty, keep mixing until smooth (Plunge-Twist-Pull in syringe)
- With high viscosity material, use immediately when mixed or keep mixing until ready (don’t let it harden in the syringe)

NOTES:

Exclusively foot & ankle

MgNum™ BVF

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED FOR FOOT AND ANKLE BY

Exclusively foot & ankle Paragon 28®

References:

1. Yoshizawa et at. Magnesium ion stimulation of bone marrow stromal cells enhances osteogenic activity, stimulating the effect of magnesium allow degradation. Acta Biometer. 2014; 10(6): 2834-42.4

2. Wong et al. Engineered polycaprolactone-magnesium hybrid biodegradable porous scaffold for bone tissue engineering. Materials International. 2014; 24: 561-567.

3. S. Magister, J. Kolaczko, A. Sattar et al., Clinical parameters and radiographic resorption of a novel magnesium based bone void filler, Injury.

4. Lapine Posterolateral Fusion and Condyle Defect Models. Internal study. Results on file at Bone Solutions, Inc.

5. Am J Vet Res. 2009; 70 (8) 964-972. Hirvinen LJ, Litsky AS, Samii VF, Weisbrode SE, Bertone AL

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DISCLAIMER

The purpose of the MgNum™ BVF Surgical Technique Guide is to demonstrate the optionality and functionality of the MgNum™ BVF. Although various methods can be employed for this procedure, the options demonstrated were chosen for simplicity of explanation and demonstration of the unique feature of this system. CAUTION: Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.