





# High Strength. Lightweight. Resorbable.

WishBONE Mg 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.<sup>1-8, 13-15</sup>

WishBONE Mg 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.<sup>12</sup>

- 80% resorbable in 26 weeks<sup>9</sup>
- Remodels to normal bone<sup>10, 11</sup>
- Quicker time to union compared to calcium-based BVFs<sup>9, 12</sup>

#### TABLE OF CONTENTS

#### Introduction

Product Overview	2
Kit Components	З
Why Magnesium?	4

#### **Mixing Instructions**

Moldable	. 5
Injectable	7
Working Guidelines - Curing Time	10

eferences
-----------

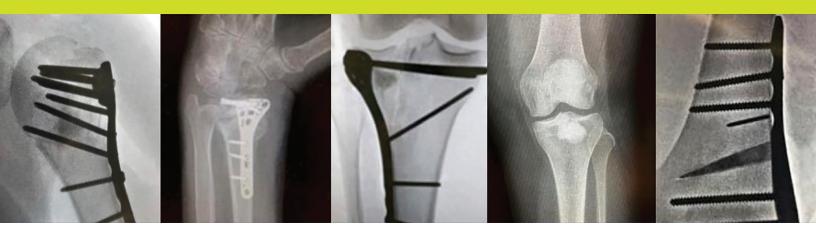
# System Components





#### **MIXING AND DELIVERY SYSTEM**

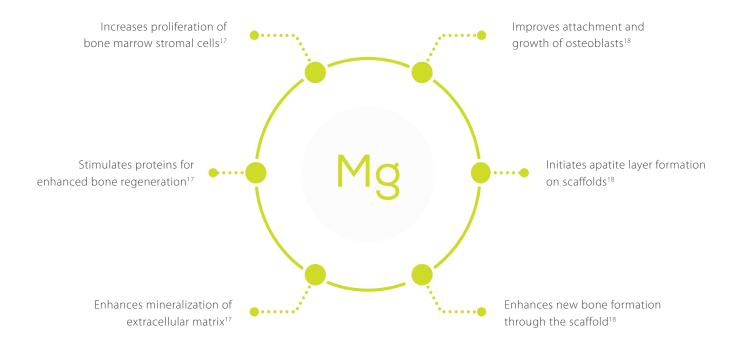
- Mixing Syringe
- 2 Funnel
- Open Bore Cap
- 4 11GA Cannula
- G 2GA Cannula
- 6 Mechanical Advantage
- Open Pusher



#### WHY MAGNESIUM?

A natural nutrient essential for building healthy bones, magnesium is an attractive orthopedic alternative because, unlike stainless steel or titanium, it is biodegradable – eliminating the need for an invasive procedure to remove surgical hardware after initial surgery.

- Plays a role in the active transport of calcium and potassium ions across cell membranes<sup>1</sup>
- Contributes to the structural development of bone<sup>1-8</sup>
- Approximately 60% of Mg in the body resides in bones<sup>16</sup>



For product information, including indications, contraindications, warnings, precautions and potential adverse effects, visit WishBone Medical's Instructions for Use page online: www.WishBoneMedical.com/IFU.

#### STI MIXING USAGE GUIDE: MIXING & DELIVERY SYSTEM

#### MIX

Combine powder (Fig. 1A) and saline in syringe (Fig. 1B). Start timer. Remove support rod and mix with plunger (Fig. 1C).



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

Optional

#### O SPINDLE DRIVE DELIVERY

Remove support rod (Fig. 2A) and snap wedge tip off from mixing stick (Fig. 2B). Attach spindle nut to base of syringe. Insert threaded spindle over mixing stick and advance spindle through nut( Fig. 2C). Remove winged cap from syringe cap and purge excess air by rotating handle clockwise (Fig. 2D).

#### REGULATE CONSISTENCY

Stop mixing.

Avoid further manipulation (Fig 3A, 3B).

00:30>>>>08:00\*

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

#### **4** INJECT

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



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















#### STI MIXING USAGE GUIDE: 5CC MIXING SYRINGE

#### MIX

Combine powder (Fig. 1A) and saline in syringe (Fig. 1B). Start timer. Remove support rod and mix with plunger (Fig. 1C).



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

# REGULATE CONSISTENCY

Stop mixing. Avoid further manipulation.



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

#### **INJECT**

Remove tip from syringe, attach cannula and inject product into defect (Fig. 3).

#### **O** INITIAL CURING

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



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



## STI MIXING USAGE GUIDE: 10CC MIXING SYRINGE

#### MIX

Combine powder and saline in mixing bowl (Fig. 1A). Start Timer. Mix with Spatula (Fig. 1B).



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

# REGULATE CONSISTENCY

Stop mixing. Avoid further manipulation. Transfer to mixing syringe through funnel (Fig 2A). Keep plunger closed until product has been completely transferred. Then, retract plunger and allow product to flow into syringe (Fig. 2B).



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

#### **INJECT**

Remove tip from syringe, attach cannula and inject product into defect (Fig. 3).

#### INITIAL CURING

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



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



Fig. 1B







### STI MIXING USAGE GUIDE: 15CC MIXING SYRINGE

#### MIX

Combine powder and saline in mixing bowl (Fig. 1A). Start Timer. Mix with Spatula (Fig. 1B).



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

# REGULATE CONSISTENCY

Stop mixing. Avoid further manipulation. Transfer to mixing syringe through funnel (Fig 2A). Keep plunger closed until product has been completely transferred. Then, retract plunger and allow product to flow into syringe (Fig. 2B).



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

#### **INJECT**

Remove tip from syringe, attach cannula and inject product into defect (Fig. 3).

#### INITIAL CURING

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



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



Fig. 1B







### STI MIXING USAGE GUIDE: 5CC MIXING BOWL

# 0 MIX

Combine powder and saline in mixing bowl (Fig. 1). Start Timer.



#### **e** wait

Stop mixing. Lay bowl on its side (Fig. 2).



# **© 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 (Fig. 3).

# 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\*



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

#### **9 PLACEMENT**

Stop mixing. Avoid manipulation and place into defect. If product is tacky, spatula can be used to assist with placement (Fig. 3).

#### **6** INITIAL CURING

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





A starting

Fig.1

Fig. 3

## STI MIXING USAGE GUIDE: 10CC MIXING BOWL

## 0 MIX

Combine powder and saline in mixing bowl (Fig. 1). Start Timer.



#### **e** wait

Stop mixing. Set bowl on a flat surface (Fig. 2).



# **© 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 (Fig. 3).

# 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\*



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

#### **9 PLACEMENT**

Stop mixing. Avoid manipulation and place into defect. If product is tacky, spatula can be used to assist with placement (Fig. 3).

#### **6** INITIAL CURING

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





A starting

Fig.1

Fig. 3

## STI MIXING USAGE GUIDE: 15CC MIXING BOWL

#### MIX

Combine powder and saline in mixing bowl (Fig. 1). Start Timer.



#### **e** wait

Stop mixing. Set bowl on a flat surface (Fig. 2).



## **© 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 (Fig. 3).

#### 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

8:00>>>>18:00\*



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

#### **9 PLACEMENT**

Stop mixing. Avoid manipulation and place into defect. If product is tacky, spatula can be used to assist with placement (Fig. 3).

#### **6** INITIAL CURING

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



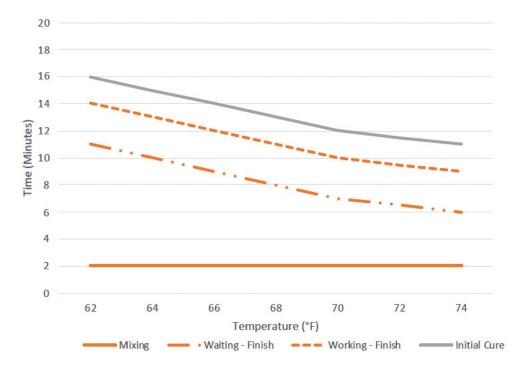


A starting

Fig.1

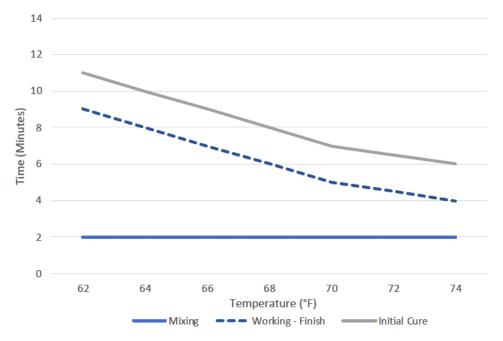
Fig. 3

# WISHBONE MG: WORKING GUIDELINES



**MOLDABLE (5CC)** 

**INJECTABLE (5CC)** 



#### 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.
- 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

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.



®

WishBoneMedical.com 100 Capital Drive Warsaw, IN 46582 +1-574-306-4006

#### Manufactured for: WishBone Medical, Inc.

All trademarks here in are the property of WishBone Medical, Inc. or its subsidiaries unless otherwise indicated. This material is intended for the sole use and benefit of Health Care Professionals and the WishBone Medical Sales Force. It is not to be redistributed, duplicated or disclosed without the express written consent of WishBone Medical. All WishBONE Mg kits are only available as single-use, sterile packed kits. Always confirm product expiration date prior to use.

Caution: Federal law restricts this device to sale by or on the order of a physician.

For product information, including indications, contraindications, warnings, precautions and potential adverse effects, visit **www.WishBoneMedical.com**.