WishBone Medical

wish BONE 12 Mg

MAGNESIUM-BASED BONE VOID FILLER

MIXING INSTRUCTIONS

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wishBONE 12 Mg

MAGNESIUM-BASED BONE VOID FILLER

Injectable and **Moldable BVF** | **Full Kits** for Mixing + Application

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.[1-8, 13-15]

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.[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. 11GA Cannula

FEATURES AND BENEFITS

INJECTABLE & MOLDABLE
Designed with optimized consistency for use in multiple orthopaedic applications[13, 15]

ENHANCED BONE REGENERATION
Greater than 80% bone remodeling in 26 weeks[9]

FULLY SYNTHETIC MATERIAL
Enhanced quality control and increased product availability with reduced product morbidity compared to human tissue

RADIOPAQUE
Product easily identifiable in situ

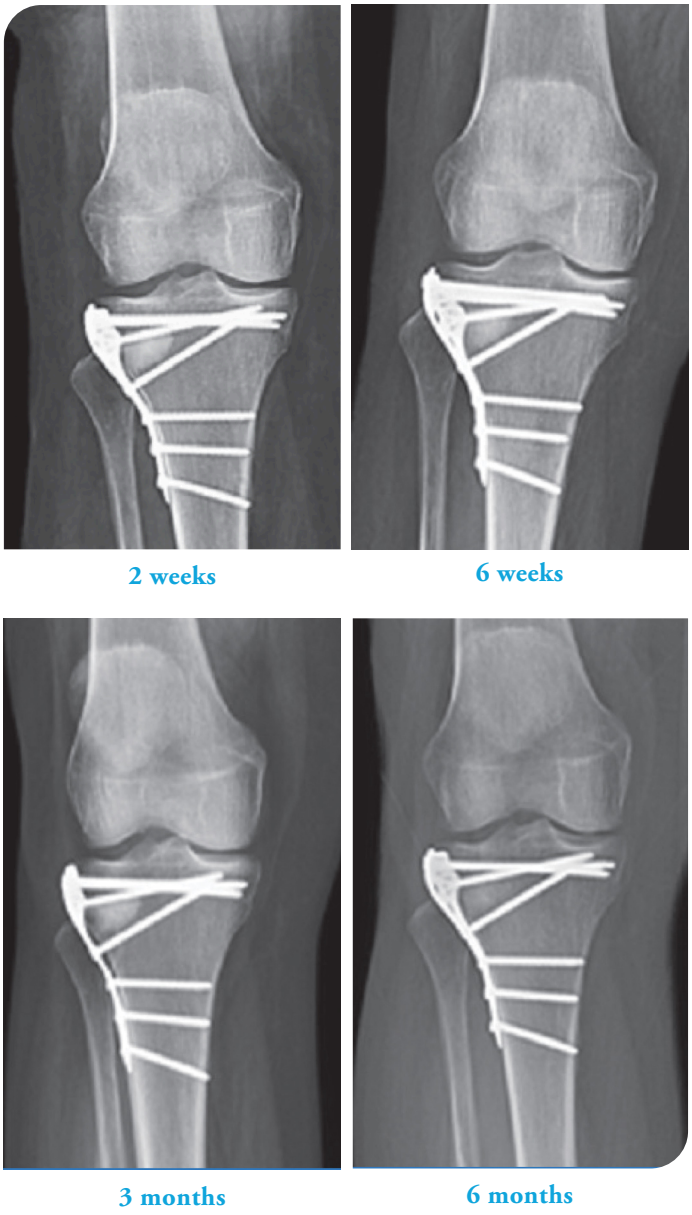
OSTEO-CONDUCTIVE/HIGH COMPRESSIVE STRENGTH
Surface topography to support bone formation enhancing structural stability and biocompatibility[12, 14]

TEMPERATURE SETTING CONTROL
Designed for optimal workability and curing time[13, 14]

THIXOTROPIC PROPERTIES
Easily manageable curing time designed to allow for intra-operative flexibility and reduction of waste[13]

EXCELLENT BINDING CHARACTERISTICS
Optimal product stability and fixation at operative site[9, 12]

CASE STUDY – 2 weeks, 6 weeks, 3 months and 6 months
Tibia Plateau Fracture, treated with 10cc OsteoCrete



2 weeks | 6 weeks

3 months | 6 months

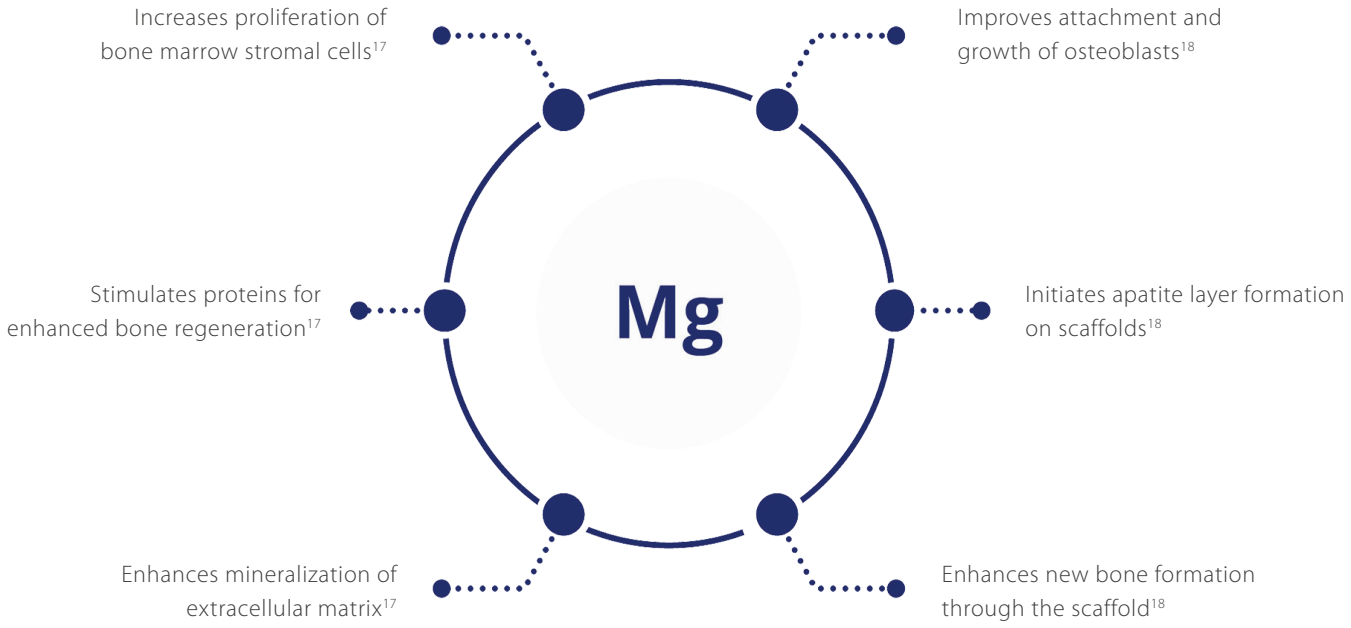
Images courtesy of Dr. Wetzel – University Hospital – Cleveland, OH

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.

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[1]
- Contributes to the structural development of bone[1-8]
- Approximately 60% of Mg in the body resides in bones[16]



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**.

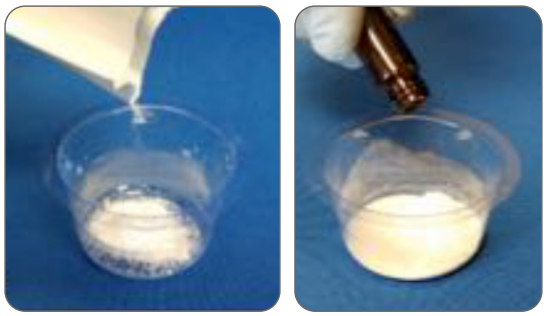
PRODUCT COMPARISON: WISHBONE MG VS. COMPETITOR OFFERINGS

Product	Synthetic	Injectable	Moldable	Radiopaque	Osteo-Conductive	High Compressive Strength	Mixing Delivery System Provided	Temperature Setting Control	Binding Characteristics	Thixotropic Waste Reduction Properties	Enhanced Bone Regeneration
WishBONE Mg (WishBone Medical)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
CERAMENT™ (BoneSupport)[19]	✓	✓	✓		✓		✓				
Pro-Dense™ (Wright Medical)[20]	✓	✓	✓	✓	✓	✓	✓				
HydroSet™ (Stryker)[21]	✓	✓	✓	✓	✓	✓	✓				
Norian® (DePuy Synthes)[22]	✓	✓	✓	✓	✓	✓		✓			
AccuFiLL® BSM (Zimmer Biomet)[23]	✓	✓		✓	✓		✓	✓			
Pro-Dense™ (Wright Medical)[20]	✓	✓	✓	✓	✓	✓	✓	✓			
Callos® Inject (Acumed/Skeletal Kinetics)[24]	✓	✓	✓	✓	✓	✓	✓	✓			

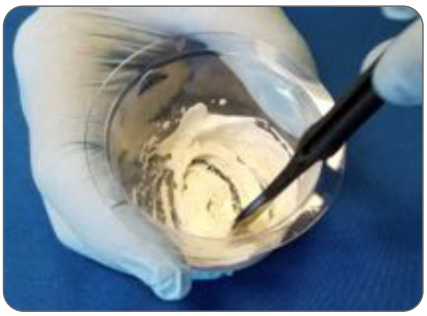
MIXING INSTRUCTIONS: **MOLDABLE**

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

1. Open the wishBONE Mg powder pouch and premeasured liquid solution and pour both into the sterile basin **(18-23°C / 65-73°F)**.

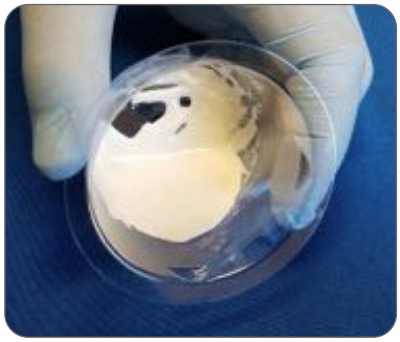


2. With the spatula, mix until powder and liquid solution for 2 minutes until product is thoroughly mixed into a smooth material **(18-23°C / 65-73°F)**.



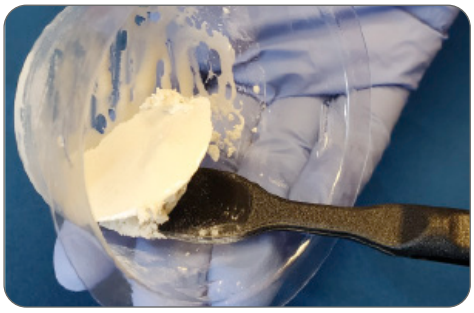
3. Wait until a skin is formed on the product during the curing process **(18-23°C / 65-73°F)**.

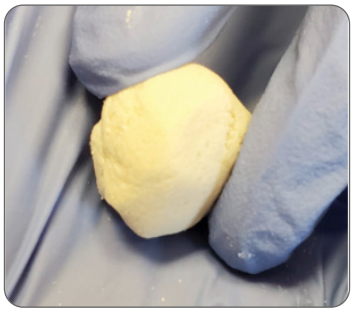
   Technique Tip: Increased ambient temperature of the operating room will accelerate curing time.



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

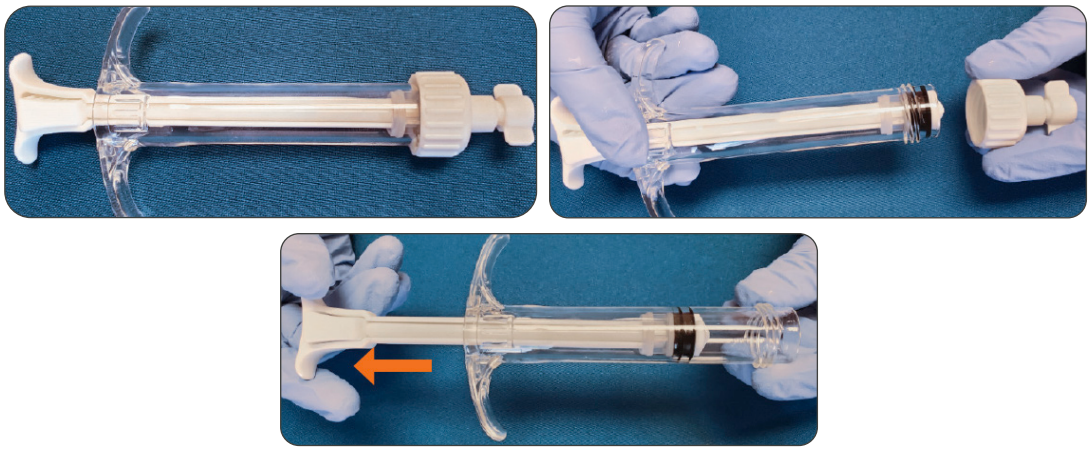
   For mixing and curing times, reference chart on pg. 10.





MIXING INSTRUCTIONS: **INJECTABLE**

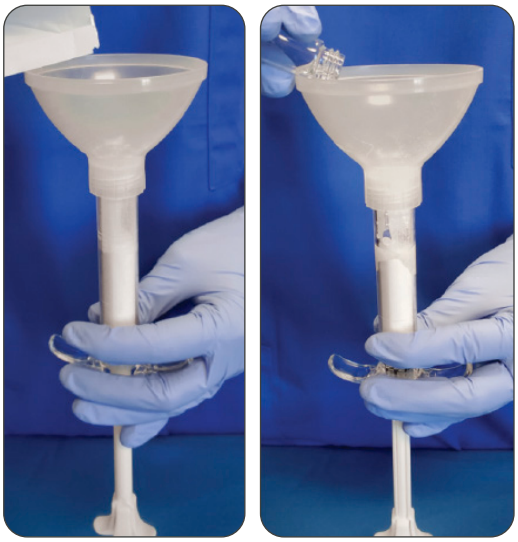
1. Remove the white cap assembly at the distal end of the syringe by turning counter clockwise. Pull the plunger all the way back.



2. Attach the funnel to the distal end by turning clockwise. Transfer the powder into the syringe. Make sure all powder is transferred.

   This might require light tapping of the funnel to completely transfer the material into the syringe.

   Add the premeasured liquid solution into the syringe.



3. Remove the funnel and reattach the white cap assembly. Be sure the cap and wing nut are both secured tightly.

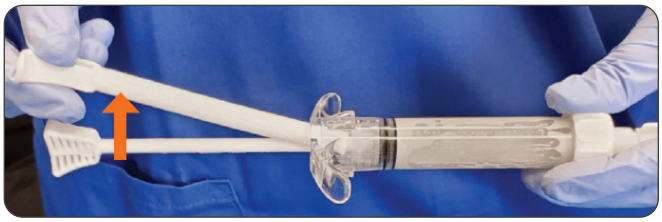
MIXING INSTRUCTIONS: **INJECTABLE** (CONT.)

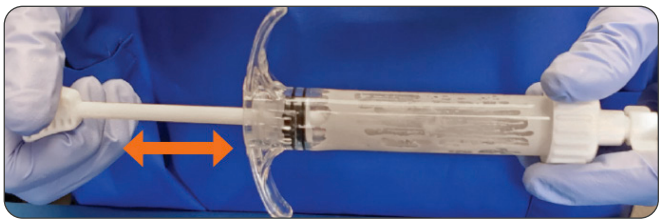
4. Remove the white cap assembly at the distal end of the syringe by turning counter clockwise. Pull the plunger all the way back. Remove the stopper to enable the mixing element.

   Reminder: Do not discard the stopper at this point. Mix back and forth for 2 minutes with a twisting motion until powder and liquid solution are thoroughly mixed to a smooth material.

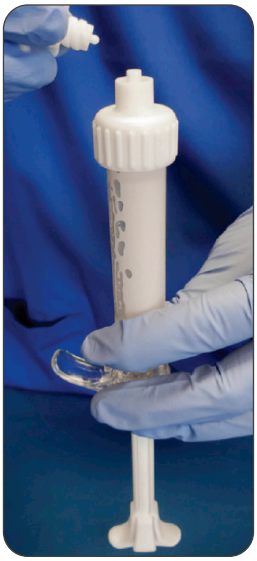
   Technique Tip: Increased ambient temperature of the operating room will accelerate the curing time.

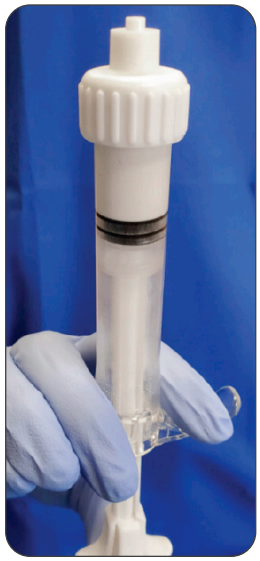
   Technique Tip: Continue mixing product to prolong set time.

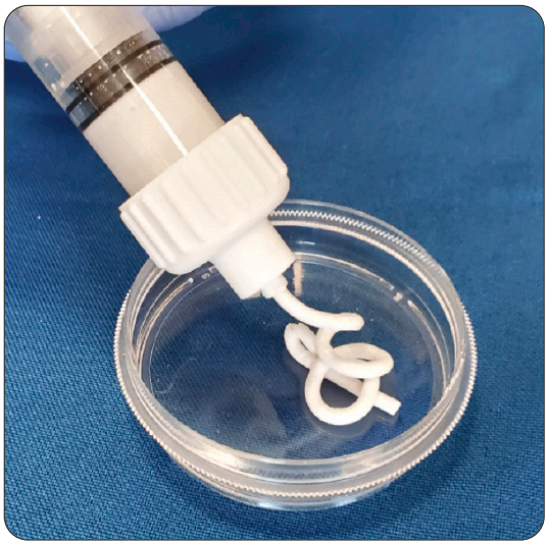




5. Pull the mixing element all the way back and reattach the stopper (see step 4). Remove the wing nut from the distal cap and plunge the material to remove the air from syringe. Attach a luer compatible device a begin injecting material as needed.

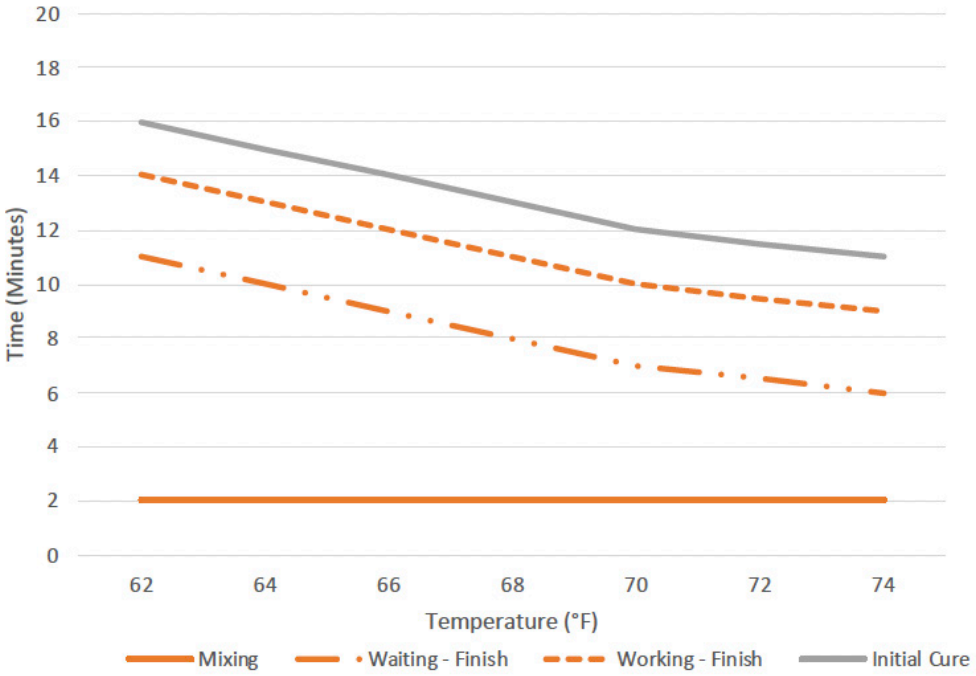




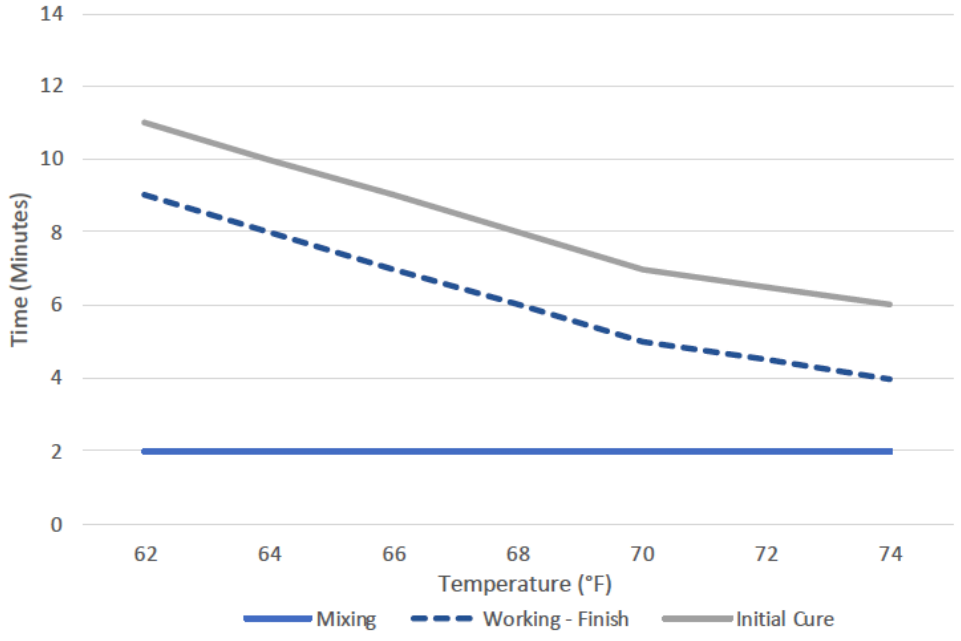


WISHBONE MG WORKING GUIDELINES[25]

Moldable (5cc)



Injectable (5cc)



ORDER INFORMATION

KIT NUMBER	DESCRIPTION
PK-BVF05	WishBONE Mg Bone Void Filler Kit, 5cc
PK-BVF10	WishBONE Mg Bone Void Filler Kit, 10cc
PK-BVF15	WishBONE Mg Bone Void Filler Kit, 15cc

Kit Contents:. Liquid & Powder Set, Mixing Syringe, Funnel, Basin, Spatula & 11GA Cannula

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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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.

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Manufactured for:
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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.