



## WishBone Medical AlloMate Bone Pin System

### Instructions for Use







WishBone Medical AlloMate Bone Pin System

#### Manufactured by:

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<b>Caution: Federal law restricts this device to sale by or on the order of a physician.</b>	
 5.4.2	• Single-use
 5.1.6	• Catalog number
 5.1.5	• Lot number
 5.4.3	• See instructions for use
 5.2.3	• Sterile - irradiation
 5.1.4	• Use-by date

Symbols: ISO-15223

#### CONTENTS

The package contains single-use, sterile surgical instrument(s) for allograft cortical bone pin insertion in surgery.

#### DESCRIPTION

The WishBone Medical AlloMate Bone Pin System gives the surgeon a means of bone fixation and helps in the management of fracture and reconstructive surgery.

#### MATERIAL

Instruments are made from medical grade stainless steel & plastic.

#### MRI SAFETY INFORMATION

The instruments have not been evaluated for safety and compatibility in the MRI environment. The system has not been tested for heating, migration, or image artifact in the MRI environment. The safety of the instruments in the MRI environment is unknown. Scanning a patient who has this device may result in patient injury.

#### INTENDED USE

The AlloMate Bone Pin System is intended to be used in a number of pediatric orthopedic and reconstructive procedures. Intended for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodesis or bone grafts in the presence of appropriate additional immobilization (e.g., cast, brace). May also fill a void left after screw removal.

#### ADVERSE EFFECTS

Possible reactions may include but are not limited to:

- Allergic reactions to metal
- Delayed, mal-union and/or non-union of bone
- Delayed healing

#### SAFETY PRECAUTIONS

- Prior to use, thoroughly read these instructions.
- Keep these instructions accessible to all staff.
- The use of surgical instruments for tasks other than those for which they are intended may result in damaged or broken instruments or patient injury.
- For one procedure only. Do not resterilize.
- Do not use if package is visibly open or damaged.
- Handle instruments with care; instruments have sharp points.
- This is a single-use device. Never reuse an implant or instrument. Reuse can result in the transfer of materials including but not limited to bone, tissue, blood or infectious disease. Although the device may appear undamaged, previous stresses may have created nonvisible damage that could result in device failure. The manufacturer accepts no responsibility for a reused implant or instrument.
- This device is provided sterile and resterilization of the device has not been validated.
- WishBone Medical implants should only be used in conjunction with WishBone Medical instruments applicable for the respective sizes.
- Always store the devices in the original protective packaging.
- Store the devices in a dry and dust-free place (standard hospital environment).

#### STERILE:





**Sterilized with gamma irradiation. Caution: For one procedure only. Do not resterilize. Do not use if package is visibly open or damaged. This is a single-use device. Reuse of this device can result in the transfer of materials not limited to bone, tissue, blood or infectious disease. This device is provided sterile and resterilization of the device has not been validated.**

#### HOW SUPPLIED/STORAGE:

The devices are packed in protective packaging that is labeled to its contents. All implants and instruments are supplied sterile.

- Always store the devices in the original protective packaging.
- Store the devices in a dry and dust-free place (standard hospital environment).

#### INSPECTION:

Before use, inspect the package carefully. Do not use when sterile barrier is visibly damaged.

#### WARNING

Please note that using a single-use device which comes into contact with human blood or tissue constitutes reprocessing & that reprocessing can only be performed by an authorized third-party reprocessor who has received 510(k) clearance for such.

#### FOR FURTHER INFORMATION

Please contact WishBone Medical, Inc. or your authorized representative for further information about this product.