



WishBone Medical AlloMate Bone Pin Instrument System

Instructions for Use

WishBone Medical AlloMate Bone Pin Instrument System



Manufacturer:

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	• Caution: Federal law restricts this device to sale by or on the order of a physician.
5.1.1	• Manufacturer
5.1.3	• Date of Manufacture
5.4.2	• Single-Use
5.1.6	• Catalog number
5.1.5	• Lot number
	• Quantity
5.4.3	• See instructions for use
	• Sterile – Irradiation
5.1.4	• Use by date
	• Not made with Natural Rubber Latex
5.2.6	• Do not resterilize
5.2.8	• Do not use if package is damaged

CONTENTS

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

DESCRIPTION

The WishBone Medical AlloMate Instrumentation System facilitates in the implantation of allograft bone pins of various diameter ranging from 2.0 - 4.0mm with increments of 0.5mm.

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 WishBone Medical AlloMate Instrumentation System facilitates in the implantation of allograft bone pins of various diameter ranging from 2.0 - 4.0mm with increments of 0.5mm.

INDICATIONS

The AlloMate Bone Pin System sterile instrument procedure pack is used to facilitate implantation of bone pins in pediatric and adult orthopedic and reconstructive procedures used 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).

POTENTIAL 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
- Injury to user
- Injury to patient
- Instrument failure
- Material cause damage to the environment
- Delay of surgery
- Revision
- Pain
- Bone fracture
- Damage of physis / spinal cord
- Glove is cut

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 reesterilization of the device has not been validated.

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

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 reesterilization 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).

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).

SURGICAL TECHNIQUES

Surgical techniques are available describing the uses of this system. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the procedure before use. Surgical techniques can be found on the WishBone Medical website: www.wishbonemedical.com.

DEVICE INTENDED TO BE USED BY A TRAINED PHYSICIAN

This description alone does not provide sufficient background for direct use of WishBone Medical products. Instruction by a surgeon experienced in handling these products is highly recommended.

FOR FURTHER INFORMATION

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

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