



WishBone Medical AlloMate Bone Pin Instrument System

Instructions for Use:



Manufacturer:
WishBone Medical, Inc.
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 Warsaw, IN 46582
 United States of America

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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
	5.1.4	Use-by-date
LOT	5.1.5	Batch code
REF	5.1.6	Catalogue number
STERILE R	5.2.4	Sterilized using Irradiation
	5.2.6	Do not re-sterilize
	5.2.8	Do not use if package is damaged
	5.4.2	Do not re-use
	5.4.3	Consult instructions for use
	5.4.4	Caution
	5.2.12	Double Sterile Barrier System
		Not made with natural rubber latex
QTY		Quantity
R_x only		Prescription Use Only

Symbols: ISO 15223-1:2021

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 and Arthroscopic Osteochondritis Dissecans (OCD) Instrumentation supports allograft bone pin insertion.

MATERIALS

Instruments are made from medical grade stainless steel & plastic.

MRI SAFETY INFORMATION

The Instrument System has not been evaluated for safety in the MR environment. The system has not been tested for heating or unwanted movement in the MR environment. The safety of the Instrument System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

INTENDED USE

The WishBone Medical AlloMate Instrumentation System and Arthroscopic OCD Instrumentation facilitates the implantation of allograft bone pins of various diameters.

INDICATIONS

The AlloMate Bone Pin System sterile instrument procedure pack & AlloMate Arthroscopic OCD Instrument Systems are 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).

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

STORAGE AND HANDLING

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).
- Before use, inspect the implant/instrument packaging carefully. Do not use when package is visibly opened or damaged.

STERILE

Sterilized with gamma irradiation. Caution: For one procedure only. Do not re-sterilize. Do not use if package is open or damaged. This is a single use device. This device is provided sterile, and re-sterilization of the device has not been validated.

WARNINGS

A single use medical device or accessory is not intended by its manufacturer to be reprocessed or reused. Reuse of this device can result in the transfer of materials not limited to bone, tissue, blood or infectious disease.

Products intended for single-use must not be reused in a subsequent procedure. Reuse or reprocessing (e.g., cleaning and re-sterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death. Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

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.
- 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.
- WishBone Medical implants should only be used in conjunction with WishBone Medical instruments applicable for the respective sizes.

FOR USE 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. 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 are available describing the uses of this system. Surgical techniques can be found on the WishBone Medical website: www.WishBoneMedical.com.

PRODUCT COMPLAINTS

Any health care professional (e.g. customer or user of this system of products) who has any complaints or who has experienced dissatisfaction in the product quality identity, durability, reliability, safety, effectiveness and/or performance, should notify their WishBone Medical, Inc. Sales representative or email WishBone Medical, Inc. at WeCare@WishBoneMedical.com. When filing out a complaint, please provide all information listed below:

- Nature of the complaint
- Address or facility where the complaint took place
- Name and address of the complaint representative
- Implant, instrument, or component(s) name
- Implant, instrument, or component(s) part number(s)
- Implant, instrument, or component(s) lot number(s)
- Patient's name or patient's identifier
- Patient's age & gender

FOR FURTHER INFORMATION

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