# Just Bone Orthopedic Solutions, LLC / AlloMate Bone Pin Instrument System

**Instructions for Use:**

AlloMate BONE PIN SYSTEM


Manufacturer for JBOS, LLC:

**Red Star Contract Manufacturing**

1560 IN-5, Lawrwill, Indiana 46764
(260) 327-3145
www.redstarcontractmfg.com


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

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|---|---|---|
| | 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 resterilize |
| | 5.2.8 | Do not use if package is damaged |
| | 5.4.2 | Do not re-use |
| | 5.4.3 | Consult instrucitons for use |
| | 5.4.4 | Caution |
| | 5.2.12 | Double Sterile Barrier System |
| LATEX | | Not made with natural rubber latex |
| QTY | | Quanity |
| Rx 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 Just Bone Orthopedic Solutions, LLC 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 resterilize. Do not use if package is open or damaged. This is a single use device. This device is provided sterile, and resterilization 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 resterilization) 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 Just Bone Orthopedic Solutions, LLC 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 Just Bone Orthopedic Solutions, LLC website: www.justboneimplants.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 pance, should notify their Just Bone Orthopedic Solutions, LLC sales representative or email Just Bone Orthopedic Solutions, LLC at support@justboneimplants.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 Just Bone Orthopedic Solutions, LLC at (844) FIX-BONE (349-2663) or www.justboneimplants.com or contact your au-thorized representative for further information about this product.


Just Bone Orthopedic Solutions, LLC.
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