WishBone Medical WishFIX™ Growth Control Plating System

Instructions for Use:

WISHFIX™
GROWTH CONTROL PLATING SYSTEM

Manufacturer:
WishBone Medical, Inc.
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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 resterilize
	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
LATEX		Not made with natural rubber latex
QTY		Quantity
T15		T15 Compatible
Rx only		Prescription Use Only

Symbols: ISO 15223-1:2021

CONTENTS
The package contains one or several implants and surgical instrument(s) for the express purpose of deformity correction. WishFIX™ plate templates and other system components are available separately as sterile packed ancillary devices.

DESCRIPTION
The WishBone Medical WishFIX™ Growth Control Plating System consists of two- and four-hole low profile plates and screws that gives the surgeon a way of redirecting the angle of growth of long bone(s). This is useful for gradually correcting angular deformities in growing children.

MATERIALS
Implants are made from 316-stainless steel material in compliance of ASTM F138, and Ti-6Al-4V Titanium alloy compliant to ASTM F136. 316 stainless steel and Ti-Al-4V are biocompatible materials that are readily available and commonly used in implanted medical devices. Instruments are made from medical grade stainless steel and plastic.

MRI SAFETY INFORMATION
The WishBone Medical WishFIX™ Growth Control Plating 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 these devices 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 WishFIX™ Growth Control Plating System is designed for the express and sole purpose of redirecting the angle of growth of long bone(s). This is useful for gradually correcting angular deformities in growing children.

INDICATIONS
Indications for the device include: valgus, varus or flexion, extension deformities of the knee (femur and/or tibia), valgus, varus or plantar flexion deformities of the ankle, valgus or varus deformities of the elbow (humerus), radial or ulnar deviation, flexion or extension deformities of the wrist (radius).

ADVERSE EFFECTS
Possible reactions may include but are not limited to:
- Allergic reactions to metal
- Excess treatment time, leading to over correction
- Delayed healing
- Delay of surgery
- Injury to user
- Adverse biologic reaction
- Revision
- Pain
- Infection
- Implant failure
- Difficulty in removal of hardware
- Nerve/ Tissue damage
- Loss of fixation
- Bone fracture

CONTRAINDICATIONS
- Comminuted bone surface which would mitigate against plate and screw placement.
- Pathologic conditions of bone such as osteopenia which would severely impair the ability to securely fix the plate.
- Foreign body sensitivity to metals including nickel. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.

STORAGE & 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
Procedural kits are sterilized by gamma irradiation, and ancillary components are sterilized by gamma irradiation or ethylene oxide (EO) as indicated on their package label. 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 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 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 for use. Each surgeon must consider the particular needs of each patient and create a surgical plan that uses the appropriate implant(s) for that patient. Take care not to place screws or instruments into the physis of patients with open growth plates.
- Keep these instructions for use accessible to all staff.
- The use of a surgical instrument for tasks other than those for which they are intended may result in damaged or broken instruments or patient injury.
- The surgeon must be familiar with the instrumentation, method of application, and the recommended surgical technique for hemiepiphysiodesis and protection of soft tissue structures during surgery. Use appropriate drill guide when drilling to protect soft tissues from edges of drill flutes.
- Templates are for temporary assessment of plate position only, DO NOT IMPLANT. These templates are not to be used for screw preparation.
- Note: Due to the notch sensitivity of titanium, take care not to notch plate when bending. The plate must never be unbent or reverted to its original shape once it has been contoured.
- Do not bend plates excessively. Do not use instruments to bend plates.
- Progress slowly with drill to prevent plunging through far cortex where vital anatomic structures might be. Fluoroscopy may be needed to confirm desired length.
- Always measure the depth of the guide wire by carefully sliding the Direct Measurement Device over the guide wire. The Direct Measurement Device must be fully seated on the bone prior to measuring.
- Use manual force only with the screwdriver supplied to insert screws. Insert a screw only once. Do not reuse screws as fatigue or damage from a prior insertion may damage the screw.
- Screws and plates are imaged fluoroscopically in order to ensure that screws are fully seated with no gap between plate-bone interfaces.
- Note: Undercorrection and overcorrection are common issues with guided growth. Careful preoperative planning and follow-up as needed can minimize complications and allow for deformity correction with minimal morbidity.
- For one procedure only. Do not resterilize.
- Do not use if package is open or damaged.

SAFETY PRECAUTIONS (CONT.)
- Do not use implants of dissimilar metals in contact with one another (i.e. titamiun screws with stainless steel plate) given the potential for corrosion.
- This is a single-use device. Never reuse an implant or instrument. Reuse can result in the transfer of materials not limited to bone, tissue, blood or infectious disease. Although the device may appear undamaged, previous stresses may have created non-visible 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.
- After closure: Post-operative loading should be restricted to a level determined by the physician.

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 instrumentation, method of application, and recommended surgical techniques before use of these products by reviewing relevant publications and surgical techniques.

The WishFIX Growth Control Plating System Surgical Technique describing the use of this system can be found at 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, druability, 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 informaiton 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.

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