WishBone Medical EpiFIX Growth Control Plating System

Instructions for Use

WishBone Medical EpiFIX Growth Control Plating System

Manufactured by:

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Rx only	• **Caution: Federal law restricts this device to sale by or on the order of a physician.**
5.4.2	• **Single-use**
REF 5.1.6	• **Catalog number**
LOT 5.1.5	• **Lot number**
5.4.3	• **See instructions for use**
STERILE R 5.2.3	• **Sterile – Irradiation**
STERILE EO 5.2.3	• **Sterile – Ethylene Oxide**
5.1.4	• **Use by date**
LATEX	• **Not made with Natural Rubber Latex**
5.2.8	• **Do Not Use If Package is Damaged**

Symbols: ISO-15223

CONTENTS
The package contains one or several implants and surgical instrument(s) for the express purpose of deformity correction. EpiFIX plate templates are available separately as a sterile packed accessory item.

DESCRIPTION
The WishBone Medical EpiFIX 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.

IMPLANT AND INSTRUMENT MATERIAL SPECIFICATIONS
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 & plastic.

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

INTENDED USE
The WishBone Medical EpiFIX Growth Conrol 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).

POTENTIAL 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

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.

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

STERILE:
Procedural kits are sterilized by gamma irradiation, and the EpiFIX plate templates are sterilized by ethylene oxide (EO). Caution: For one procedure only. Do not re-sterilize. Do not use if package is open or damaged. This is a single-use device. Re-use 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 re-sterilization 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 implant/instrument box carefully. Do not use when sterile barrier is visibly damaged.

WARNINGS
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 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 adequate fracture repair and protection of soft tissue structures during surgery. Use appropriate drill guide when drilling to protect soft tissues from edges of drill flutes.
- Plate 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 Variable Angle Drill Guides 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 Measuring Device over the guide wire. The Direct Measuring 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 plate 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 re-sterilize.
- Do not use if package is open or damaged.

SAFETY PRECAUTIONS (CONT.)

- This is a single-use device. Never re-use an implant or instrument. Re-use 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 re-used implant or instrument.
- This device is provided sterile and re-sterilization 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.

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 if further information about this product is needed.