



## WishBone Medical K-Wire System

### Instructions for Use








WishBone Medical K-Wire System

### Manufactured for:

**WishBone Inc. (WBM)**  
2150 North Pointe Drive  
Warsaw, IN 46582

P: (574) 306-4006  
F: (574) 376-4746

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

	5.4.2	• <b>Single use</b>
	5.1.6	• <b>Catalog number</b>
	5.1.5	• <b>Lot number</b>
	5.4.3	• <b>See instructions for use</b>
	5.2.3	• <b>Sterile - ethylene oxide</b>
		• <b>Prescription Use Only</b>
	5.1.4	• <b>Use by date</b>

Symbols: ISO-15223

### CONTENTS

The package contains one or several implants and surgical instrument(s) for use with bone fixation, fracture management, and/or reconstructive surgery.

### DESCRIPTION

The WishBone K-Wires gives the surgeon a means of bone fixation and helps in the management of fracture and reconstructive surgery; It is not intended to replace normal body structures. The WishBone K-Wires are made of Stainless Steel.

### MATERIAL

Implants are made from medical grade stainless steel, instruments are made from medical grade stainless steel & plastic.

### MR SAFETY INFORMATION

The instruments 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 the instruments in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

### INTENDED USE

The WishBone K-Wire System, is intended to be used for fixation of pediatric bone fractures, bone reconstruction; and guide pins for insertion of other implants

### ADVERSE EFFECTS

Possible reactions may include but are not limited to:

- Allergic reactions to metal
- Delayed or non-union of bone
- Delayed healing
- K-Wires may break
- K-Wires may be extruded or back out of the surgical site

### SAFETY PRECAUTIONS

- Prior to use, thoroughly read these instructions for use.
- Keep the 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.
- For one procedure only. Do not re-sterilize.
- Do not use if package is open or damaged.
- Handle K-Wires with care, K-Wires have sharp points.
- 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.
- Always store the devices in the original protective packaging.
- Store the devices in a dry and dust free place (standard hospital environment).

### STERILE:



**Sterilized with ethylene oxide gas. 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 visually 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.

### FOR FURTHER INFORMATION

Please contact WishBone Medical Inc. or your authorized representative if further information about this product is needed.