WISHBONE MEDICAL

WishBone Medical K-Wire System

Instructions for Use
WishBone Medical K-Wire System

K-WIRE SYSTEM

Manufacturer:

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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**
5.4.2	• **Single-use**
REF 5.1.6	• **Catalog number**
LOT 5.1.5	• **Lot number**
QTY	• **Quantity**
5.4.4	• **Caution: See instructions for use**
STERILE R 5.2.3	• **Sterile – Irradiation**
Rx Only	• **Prescription Use Only**
5.1.4	• **Use by date**
LATEX	• **Not made with Natural Rubber Latex**
5.2.6	• **Do not resterilize**
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 use with bone fixation, fracture management, and/or reconstructive surgery. Certain products are available separately as sterile packed ancillary devices, please contact your sales representative to determine what is available in your region.

DESCRIPTION
The WishBone Medical K-Wire System provides the surgeon a means of bone fixation and assists in the management of fracture and reconstructive surgery. It is not intended to replace normal body structures. WishBone Medical 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/INDICATIONS FOR 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.

CONTRAINDICATIONS
- Active infection.
- Patient conditions including blood supply limitations, and insufficient quantity or quality of bone.
- Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
- Foreign body sensitivity.

POSSIBLE 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 backed out of the surgical site
- Delay of surgery
- Infection
- Injury to user
- Soft tiisue / bone damage
- Revision
- Pain

SAFETY PRECAUTIONS
- Prior to use, thoroughly read these instructions for use.
- 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.
- Immobilization in addition to this internal fixation until bone healing should be achieved by routine methods (casting,
- splints, etc.)
- Reduction of the site should be achieved and maintained prior to implanting the K-Wire.
- The use of implants for tasks other than those for which they are intended may result in damaged/ broken implants or patient injury.
- 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.
- WishBone Medical implants should only be used in conjunction with WishBone Medical instruments applicable for the respective sizes.

STERILE Rx Only STERILE R

Sterilized via 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. 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.

SURGICALTECHNIQUE:
1. Depending on patient anatomy, select the appropriately sized K-wire to be inserted.
2. The K-wire soft tissue protector may be used during insertion.
3. Fluoroscopic guidance may be used to place the K-wire.
4. Multiple K-wires may be used to stabilize the fracture/reconstruction.
5. After all K-wires have been inserted and final positioning has been verified, a K-wire ball may be placed on the portion of the K-wire external to the patient (before or after cutting). Using the hex driver provided, unscrew the set screw by turning counterclockwise to remove it from the packaging skewer. Then slide onto K-wire in desired position and tighten with hex driver.

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.

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