WISHBONE MEDICAL

WishBone Medical K-Wire System

Instructions for Use

K-Wire SYSTEM

Manufacturer:
WishBone Medical, Inc.
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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 EO	5.2.3	Sterilized using Ethylene Oxide
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		Quantity
T15		T15 Compatible
T20		T20 Compatible
Rx only		Prescription Use Only

Symbols: ISO 15223-1:2021

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 WishBone Medical K-Wire 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 system in the MR environment is unknown. Performing an MR exam on a person who has this device may result in injury or device malfunction.

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.

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

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.

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 box carefully. Do not use when packaging is visibly opened or damaged.

STERILE
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. This device is provided sterile and re-sterilization of the device has not been validated.

WARNINGS
A single use medical device or accessory is not intended by its manufacturer to be reprocessed and reused. Re-use 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 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.
- 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.

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 full K-Wire System Surgical Techniques describing the uses of the system can be found at www.WishBoneMedical.com.

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 counter-clockwise to remove it from the packaging skewer. Then slide onto K-wire in desired position and tighten with hex driver.

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 CustomerService@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.

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