



## WishBone Medical K-Wire Ball Kits







### Instructions for Use

WishBone Medical K-Wire Ball Kits

### Manufactured by:

**WishBone Medical, Inc.**  
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Warsaw, IN 46582

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<b>Caution: Federal law restricts this device to sale by or on the order of a physician.</b>		
	5.4.2	• Single-use
	5.1.6	• Catalog number
	5.1.5	• Lot number
	5.4.3	• See instructions for use
	5.2.3	• Sterile - ethylene oxide
	5.1.4	• Use by date

Symbols: ISO 15223-1

### CONTENTS

The package contains WishBone Medical K-Wire Balls and a hex wrench to protectively cap the protruding ends of K-wires.

### DESCRIPTION

Protective K-wire balls.

### MATERIAL

The 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

WishBone Medical K-Wire Ball Kits offer safe, dependable protection against the protruding ends of K-wires and external fixator pins. Patients are protected against painful snagging, gouging, or re-injury as well as potential inward migration of the K-wire or pin ends.

### ADVERSE REACTIONS

Possible reactions may include but are not limited to:

- Clinical failure due to inappropriate usage.
- Necrosis due to thermal load (power driven tools).

### SAFETY PRECAUTIONS

- Prior to use, thoroughly read this instruction 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.

### 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 instruments are packed in protective packaging that is labeled to its contents. All instruments are supplied sterile.

- Always store the instruments in the original protective packaging.
- Store the instruments in a dry and dust-free place (standard hospital environment).

### INSPECTION:

Before use, inspect the 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.