



WishBone Wire Ball Kits Instructions for Use

General - Intended Use

The WishBone 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 inward migration of the K-Wire or pin ends.

- **Contents:**
The package contains three K-Wire Balls and a hex wrench for use with protruding ends of K-Wires.
- **Material:**
The devices are made from medical grade stainless steel and plastic.
- **MRI Compatibility:**
These devices have not been evaluated for safety and compatibility in the MR environment and have not been tested for heating or migration in the MR environment.
- **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/device for tasks other than those for which they are intended may result in damaged or broken instruments or patient injury.
- **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).

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:

WishBone Medical's Instruments/devices are packed in protective packaging that is labeled to its contents. All instruments/devices are supplied sterile.

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

Inspection:

Before use, inspect the instrument/device box carefully. Do not use when sterile barrier is visually damaged.

Warning:

Please note that WishBone Medical supplies these instruments/devices as sterile, single use devices.

Once a single use device (SUD) comes into contact with human blood or tissue reprocessing is required. If the end user wishes to re-use the device(s), re-processing can only be performed by an authorized third-party re-processor who has received a 510(k) clearance for such.

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