



## WishBone Broken Screw Removal System Instructions for Use

### General - Intended Use

The WishBone Screw Removal System includes screwdriver shafts for all WishBone Medical screw sizes and drives, as well as extraction instruments for extracting broken and damaged screws. The instruments are divided into kits, depending on the screw size.

- **Contents:**  
The package contains one or several surgical instrument(s) for use with the removal of broken or damaged screws.
- **Material:**  
The instruments are made from medical grade stainless steel, plastic; or carbide.
- **MRI Compatibility:**  
The instruments 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 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:

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 WishBone Medical supplies these instruments 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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