



WishBone Medical Broken Screw Removal System







Instructions for Use

WishBone Medical Broken Screw Removal System

Manufactured by:

WishBone Medical, Inc.
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Caution: Federal law restricts this device to sale by or on the order of a physician.	
 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 one or several surgical instrument(s) for use with the removal of broken or damaged screws.

DESCRIPTION

General instruments such as Drills, Drill Guides, Depth Gauges, Implant Holders, Screwdriver Bits, AO Handles, Trephines, Reamers, K-Wire Applicators and Plate Benders.

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

The WishBone Broken Screw Removal System includes screwdriver shafts for all WishBone Medical screw sizes and drives, and extraction instruments for extracting broken and/or damaged screws. The instruments are provided in kits grouped by screw size.

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 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.

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 visibly 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.