



## WishBone Medical Broken Screw Removal System

### Instructions for Use:

# BROKEN Screw Removal
















#### Manufacturer:

**WishBone Medical, Inc.**  
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Warsaw, IN 46582  
United States of America

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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
	5.1.5	Batch code
	5.1.6	Catalogue number
	5.2.3	Sterilized using irradiation
	5.2.6	Do not re-sterilize
	5.2.8	Do not use if package is damaged
	5.4.2	Do not re-use
	5.4.3	Consult instructions for use
	5.4.4	Caution
	5.2.12	Double Sterile Barrier System
		Not made with natural rubber latex
		Quantity
		Prescription Use Only

Symbols: ISO 15223-1:2021

#### CONTENTS

The package contains one or several surgical instrument(s) for use with the removal of broken or damaged screws.

#### DESCRIPTION

The following instruments are included within the contents of the kit: Trephine, EZ Out, Conical Extractor, T-Handle, and Inline Handle.

#### MATERIAL

The instruments are made from medical grade stainless steel & plastic.

#### 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 EFFECTS

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.

#### STORAGE & HANDLING

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).
- Before use, inspect the implant/instrument packaging carefully. Do not use when package is visibly opened or damaged.

#### STERILE:

This device has been sterilized with radiation as indicated on the package label. Caution: For one procedure only. Do not re-sterilize. Do not use if package is open or damaged. This device is provided sterile, and re-sterilization of this device has not been validated.

#### WARNINGS

A single use medical device or accessory is not intended by its manufacturer to be reprocessed and reused. This is a single use device. Reuse 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.

#### 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 Broken Screw System Surgical Techniques describing the uses of the system can be found at [www.WishBoneMedical.com](http://www.WishBoneMedical.com)

#### 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, durability, reliability, safety, effectiveness and/or performance, should notify their WishBone Medical, Inc. Sales representative or email WishBone Medical, Inc. at [WeCare@WishBoneMedical.com](mailto:WeCare@WishBoneMedical.com). When filing out a complaint, please provide all information 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](http://www.WishBoneMedical.com) or contact your authorized representative if further information about this product is needed.