



WishBone Medical Scalpel Handle Dissector

Instructions for Use

WishBone Medical Scalpel Handle Dissector

Manufacturer:

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	Prescription use only
5.4.2	Do not re-use
5.1.6	Catalog number
5.1.5	Batch code
5.4.3	Consult instructions for use
5.2.3	Sterilized using Ethylene Oxide
5.1.4	Use-by-date
5.2.8	Not made with natural rubber latex
5.2.8	Do not use if package is damaged
5.1.1	Manufacturer
5.1.3	Date of Manufacture
5.4.4	Caution

Symbols: ISO 15223-1:2021

CONTENTS

The package contains one or several surgical instrument(s) for use of performing a dissection.

DESCRIPTION

Scalpel handle used to hold miniature blades (#6400, #6700) and also contains a tapered flat end.

MATERIAL

The instrument is made from medical grade Stainless Steel.

INTENDED USE & INDICATIONS FOR USE

The Scalpel Handle Dissector is intended for manipulation of bone and/or soft tissue. This handle is for use with scalpel blades for the dissection of soft tissue.

ADVERSE REACTIONS

- Possible reactions may include but are not limited to:
- Delay of surgery
 - User injury
 - Patient injury
 - Clinical failure due to inappropriate usage (revision)

STORAGE AND 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 instrument packaging carefully. Do not use when the package is visibly opened or damaged.

STERILE

Sterilized by ethylene oxide. Caution: For one procedure only. Do not re-sterilize. Do not use if package is open or damaged. Re-use of this device can result in the transfer of materials not limited to bone, tissue, blood or infectious disease.

SAFETY PRECAUTIONS

- Prior to use, thoroughly read these instructions for use. Each surgeon must consider the particular needs of each patient and create a surgical plan that uses the appropriate implant(s) for that patient.
- 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.
- This is a single-use device. Never reuse an implant or instrument. Although the device may appear undamaged, previous stresses may have created non-visible damage that could result in device failure. The manufacturer accepts no responsibility for a reused implant or instrument.

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.

Surgical techniques are available describing the uses of this system. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the procedure before use. Surgical Techniques can be found on the WishBone Medical website. www.WishBoneMedical.com

INSTRUCTIONS

Scalpel blades are to be assembled to the Scalpel Handle Dissector via gripping the blade holder and twisting the scalpel handle on the the blade without touching the blade itself. The blade may be used to make an incision, and the tapered flat end may be used to dissect soft tissue.

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. 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 or contact your authorized representative for further information about this product.