



WishBone Medical Scalpel Handle Dissector

Instructions for Use

WishBone Medical Scalpel Handle Dissector

Manufactured by:

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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
5.2.3	• Sterile – Irradiation
5.1.4	• Use by date
	• Not made with Natural Rubber Latex
5.2.8	• Do Not Use If Package is Damaged

Symbols: ISO-15223

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.

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/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)

INSTRUCTIONS

Scalpel blades are to be assembled to the Scalpel Handle Dissector via gripping the blade holder and twisting the scalpel handle on 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.

SURGICAL TECHNIQUES

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

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.
- For one procedure only. Do not resterilize.
- Do not use if package is open or damaged.
- This is a single-use device. Never reuse an implant or instrument. Reuse can result in the transfer of materials not limited to bone, tissue, blood or infectious disease. 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.
- This device is provided sterile and resterilization of the device has not been validated.

STERILE:

Sterilized by ethylene oxide or gamma irradiation (please see package label). 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.

DEVICE INTENDED TO BE USED 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.

FOR FURTHER INFORMATION

Please contact WishBone Medical Inc. or your authorized representative if further information about this product is needed.

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