

Single-use Biopsy Forceps

Instructions for Use

Rx only



IMPORTANT INFORMATION

Caution: Federal law restricts this device to sale by or on the order of a physician. Read all instructions carefully before use. They contain essential information on using this device safely and effectively. Keep these instructions in a safe, accessible location, as you may need to refer to them again. If you have any questions or comments about any information in these instructions, please contact Micro-Tech.

INTENDED USE

The Single-use Biopsy Forceps are used for endoscopic histological sampling of various tissue sites within the gastrointestinal tracts via the operating channel of endoscopic instruments. A thorough understanding of the technical principles, clinical applications, and risks associated with gastrointestinal endoscopy, mucosal biopsy and foreign body retrieval is necessary before using this device. Biopsy forceps should only be used by, or under the supervision of, physicians thoroughly trained in therapeutic endoscopy, mucosal biopsy and foreign body retrieval.

CONTRAINDICATIONS

1. Coagulopathy
2. Tissue samples from vessel injury in ulceration
3. Insufficient prepped bowel
4. Primary endoscopy, colonoscopy, rectoscopy

POTENTIAL COMPLICATIONS

1. Perforation
2. Hemorrhage
3. Infection
4. Sepsis
5. Allergic reaction to contrast or medication
6. Hypotension
7. Respiratory depression or arrest
8. Cardiac arrhythmia or arrest

WARNINGS

- 1. **The product is intended for single use only! DO NOT re-use, re-sterilize, and/or reprocess.** Re-use, re-sterilization or reprocessing may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Re-use, re-sterilization or reprocessing may also create a risk of contamination of the device and/or cause patient infectious disease(s). Contamination of the device may lead to injury, illness or death of the patient. Micro-Tech assumes no liability with respect to instruments reused, re-sterilized or reprocessed .
- 2. **Do not use this instrument for any purpose other than its intended use.**
- 3. **The product is only intended for adult populations.**
- 4. This device is not made with natural rubber latex.
- 5. Patients should be informed of the potential risks and complications, which may lead to injury, illness or death of the patient.
- 6. **The instrument is intended for use under the direct supervision of a suitably trained physician only.** A thorough understanding of the technical principles, clinical applications, and associated risks is expected before usage.
- 7. Confirm that the endoscopy view is clear before use. Do not insert the instrument into the endoscope unless you have a clear endoscopic field of view. Insertion without clear endoscopic field of view could cause patient injury, such as perforation, hemorrhage or mucous membrane damage. Damage to the endoscope and/or the instrument may also occur.
- 8. If the sample is too large to close the forceps cups sufficiently, withdraw the forceps to the tip of the endoscope and then withdraw the endoscope and biopsy forceps simultaneously.
- 9. Should there occur any irregularities, dispose the instrument and replace it with a new one.

- 【 Product Name 】 Single-use Biopsy Forceps
- 【 Packaging 】 Packed in Pouch
- 【 Production Date 】 See packaging
- 【 Sterilization 】 Sterilized by EO (ethylene oxide) gas
- 【 Shelf Life 】 See packaging
- 【 Compatible Working Channel 】

External diameter of Jaws \varnothing (mm)	working channel \varnothing (mm)
1.8	≥ 2.0
2.3	≥ 2.8
2.4	
3.0	≥ 3.2

PREPARATION

1. Reference the product label and choose the appropriate device.
2. Contents supplied STERILE.
3. Inspect the package before use for any damage. Do not use if package is damaged. Open the package carefully after verifying the shelf life.
4. Carefully remove the device from its packaging and uncoil it. Do NOT use excessive force as this may damage the device and affect performance.
5. Before use, check the clip and the spring tube to ensure that there are no sharp edges.
6. If this device shows any signs of damage, do not use. Do not attempt to repair a nonfunctional or damaged device.

INSTRUCTIONS FOR USE

1. Visually inspect the biopsy forceps with particular attention to bends or breaks. If it appears damaged, do not use the device.
2. Perform the diagnostic endoscopy and visualize the area to be biopsied. Insert the biopsy forceps with the cups closed into the accessory channel in small increments.
3. Open the cups and advance the device into the tissue to be biopsied.
4. Close the biopsy forceps cups using slight pressure on the handle. Maintain gentle handle pressure to keep the cups closed while gently withdrawing the forceps from the tissue.
5. Withdraw the biopsy forceps from the channel. Continue to apply slight pressure on the handle to hold the cups closed.
6. Prepare the specimen for examination per institutional guidelines.
7. Dispose of for single use only products according to the guidelines for biohazardous medical waste.

STORAGE

The product should be stored in a cool, dry, clean, well-ventilated, non-corrosive gas environment.

Do not expose the package to organic solvent, ionizing radiation or ultraviolet radiation.

PRODUCT DISPOSAL

After use, this product may be a potential biohazard. Handle and dispose of in accordance with hospital, local and administrative laws and regulations.

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