



Jacket™ Disposable Biopsy Valve

Instructions for Use



Consult Instructions For Use



Do Not Reuse



Do Not Resterilize



Do Not Use If Package Is Damaged



Non-Sterile



Sterilized Using Ethylene Oxide



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 USA.

INTENDED USE

The Jacket™ Disposable Biopsy Valve is used to cover the opening to the biopsy/suction channel of Olympus® and Fujinon® or Pentax Medical gastrointestinal endoscopes. It provides access for endoscopic device passage and exchange, helps maintain insufflation, minimized leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.

CONTRAINDICATIONS

Contraindications include, but are not limited to, those specific to any endoscopic procedure.

WARNINGS AND PRECAUTIONS

- **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 USA assumes no liability with respect to instruments reused, re-sterilized or reprocessed.
- Do not use this instrument for any purpose other than its intended use.
- **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.
- The appropriate products are to be used with the compatible endoscope, based on scope type/manufacture. Refer to the label to check the compatibility.
- Do not use a sharp or pointed object to prime the valve prior to use.
- Do not leave a device hanging from the valve. Doing so can cause the creation of a larger valve slit/hole that may cause leakage.
- If the lid of the valve is opened while attached to the endoscope during a procedure, scope suction will be compromised, and leakage may occur. If leakage occurs, a sterile gauze should be used to cover the valve.

【 **Product Name** 】 Jacket™ Disposable Biopsy Valve

【 **Material** 】 Silicon Dioxide

This device is not made with natural rubber latex.

【 **Production Date** 】 See packaging

【 **Sterilization** 】 Sterilized by EO (ethylene oxide) gas where applicable

【 **Shelf Life** 】 3 years

【 **Model & Specifications** 】 See below chart:

Model	Specification	Application: Endoscope Compatibility	How Supplied
A	MD-A-BV01	Compatible with Olympus and Fujinon GI Endoscopes	Sterile
	MD-A-BV02	Compatible with Olympus and Fujinon GI Endoscopes	Non-Sterile
	MD-A-BV03	Compatible with Olympus and Fujinon GI Endoscopes	Bulk Non-Sterile
B	MD-B-BV01	Compatible with Pentax Medical GI Endoscopes	Sterile
	MD-B-BV02	Compatible with Pentax Medical GI Endoscopes	Non-Sterile
	MD-B-BV03	Compatible with Pentax Medical GI Endoscopes	Bulk Non-Sterile

PREPARATION

1. Read the product label and choose the appropriate device for the chosen endoscope.
2. Contents for MD-A-BV01 and MD-B-BV01 are supplied STERILE.
3. Inspect the package before use for any damage. Do not use if package is damaged.
4. If this device shows any signs of damage, do not use. Do not attempt to repair a nonfunctional or damaged device.
5. Verify the expiration date. Do not use if expired.

INSTRUCTIONS FOR USE

1. Open the package and remove the Jacket Disposable Biopsy Valve.
2. Securely place the Jacket Disposable Biopsy Valve onto the biopsy/suction channel port of the endoscope.
3. Close the lid of the biopsy valve prior to use. The lid may be opened to facilitate the passage of larger diameter devices such as dilation balloons.
4. Insert devices as needed through the slit on the Jacket Disposable Biopsy Valve by aligning the device with the endoscope port and advancing slowly in a straight manner.

NOTE: The valve features a double seal that is designed to minimize leakage. If preferred, apply a small amount of water-based lubricant to the valve, to reduce friction when introducing devices.

5. At the end of the procedure, remove and discard the Jacket Disposable Biopsy Valve.

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. The product shelf life is 3 years.

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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1. Limited Warranty to Buyer. Micro-Tech USA warrants to Buyer that, for the earlier of one (1) year from the date of purchase, or until the product is used by Buyer, the products will be free from defects in materials and workmanship when stored and used in accordance with the instructions for storage and use provided by Micro-Tech USA and in accordance with applicable regulatory requirements. Descriptions or specifications appearing in Micro-Tech USA's literature are meant to generally describe the products and do not constitute any express warranties. In the event that Micro-Tech USA gives technical advice with respect to the product, it is agreed that such advice is given without any liability on Micro-Tech USA's part. Any guarantee of specific properties of or in the products shall only be effective if and to the extent specifically confirmed by Micro-Tech USA in writing. These warranties shall not apply for product failure or deficiency due to improper storage, alteration, or the consequences of uses for which the products were not designed or that adversely affect the products' integrity, reliability, or performance.
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