

Disposable Hot Biopsy Forceps

Instructions for Use



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

This device is used for endoscopic histological sampling or electrocoagulation of various tissues, within the gastrointestinal and bronchial tracts, via the operating channel of endoscopic instruments.

CONTRAINDICATIONS

Contraindications include those specific to the primary endoscopic procedure to be performed in gaining access to the desired biopsy or polypectomy site. Contraindications to gastrointestinal mucosal biopsy and polypectomy include, but are not limited to: coagulopathy and insufficiently prepped bowel.

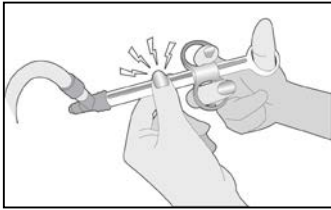
POTENTIAL COMPLICATIONS

Potential complications with endoscopic mucosal biopsy or polypectomy include, but are not limited to: transmural burns, thermal injury to the patient, explosion.

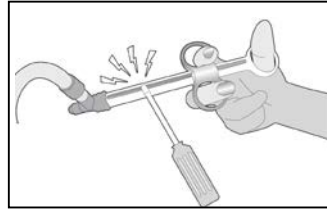
WARNINGS

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. When using the instrument in the vicinity of the heart, be sure to use it with the minimum necessary output. Spark discharge during operation may affect the heart.
9. When using an electrocardiograph or other physiological monitoring equipment simultaneously with the instrument, any monitoring electrodes should be placed as far away as possible from the electrodes used with the electrodes unit. Needle monitoring electrodes should not be used. Physiological monitoring equipment incorporating high-frequency current limiting devices is recommended.
10. When the endoscopes are used with the device, the patient leakage currents may be additive.
11. Prepare monitoring equipment and rescue equipment to control unpredictable risks.
12. Before use, please check the insertion patients body parts, ensure that no sharp edge.
13. No modification of this equipment is allowed.
14. In the use of high frequency endoscopic accessories area, should avoid high explosive gas exist, in case of an explosion hazard.
15. This product in the process of the electricity, hands CAN NOT touch the chute of handle, like picture a.

16. This product in the process of the electricity, SHALL NOT make external conductive objects in contact with the handle, like picture b.
17. The instrument, when applied to a patient with a pacemaker implanted, may cause malfunction or failure of the pacemaker, seriously affecting the patient. Always confirm that it is safe to proceed with a cardiologist or the manufacturer of the pacemaker before proceeding.



picture a



picture b

18. Use of this equipment adjacent to or stacked with other equipment (other than manufacturer defined equipment) should be avoided because it could result in improper operation.
19. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
20. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
21. The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating to re-orienting the equipment.
22. Since supporting the use of Olympus endoscopic system, Olympus endoscopic system's light source may affect Disposable Hot Biopsy Forceps' temperature to exceed 41°C, to minimize the risk of injury, please ensure the correct use of it according to Olympus endoscopic system and the manufacturer's instructions.

【 Product Name 】 Disposable Hot Biopsy Forceps

【 Packaging 】 Packed in Pouch

【 Production Date 】 See packaging

【 Sterilization 】 Sterilized by EO (ethylene oxide) gas

【 Shelf Life】 Four years

【 Applicable Endoscopes 】

Endoscope which is legal listing in USA is recommended such as Olympus.

【 Compatible Working Channel 】 $\geq \phi 2.8 \text{ mm}$

【Applicable Electrosurgical Unit】

High-frequency electrosurgical unit which is legal listing in USA is recommended such as CONMED Electrosurgery 60-8200-230 and its matched SN-UAC active cord.

【Rated High-Frequency Voltage】

CUT: 1200 Vp (2400 Vp-p)

DO NOT use higher repeated peak voltage than the Cut -1200 Vp (2400 Vp-p)

COAG: 2560 Vp (5120 Vp-p)

DO NOT use higher repeated peak voltage than the Coag -2560 Vp (5120 Vp-p)

STRUCTURE

The hot biopsy forceps consists of jaws, a tube, a plug and a handle. (See Figure 1.)

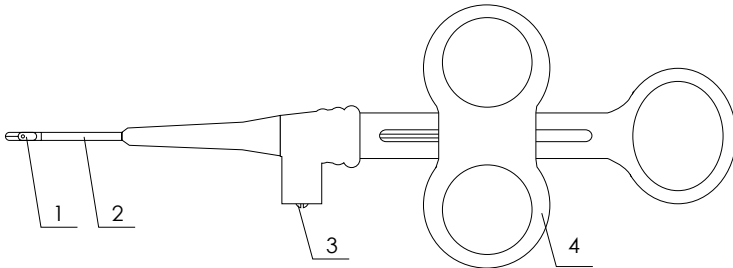


Figure 1. Structural Sketch of Hot Biopsy Forceps
Jaws 2. Tube 3.Plug 4. Handle

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. Endoscopically visualize area to be biopsied or polyp to be removed.
2. With cups closed, insert forceps into accessory channel of endoscope.
3. Advance forceps in 1-2 cm increments until it is visualized exiting endoscope.
Note: Keep end of forceps that is extending from accessory channel straight at all times. Allowing forceps to hang from accessory channel may cause damage to device.
4. Advance forceps to desired biopsy site or polyp, then open cups and advance into tissue to be biopsied or polyp to be removed.
5. Following electrosurgical unit manufacturer's instructions for settings, verify desired settings and activate electrosurgical unit.
6. Using slight pressure on handle, close forceps around tissue or polyp. Isolate tissue by gently pulling away from mucosal wall.
Caution: When applying current, ensure metal tip of forceps does not come in contact with endoscope. Contact of forceps tip with endoscope may result in grounding, injury to patient and/or operator, as well as damage to endoscope and/or forceps.
7. Maintain gentle handle pressure to keep cups closed and gently withdraw forceps from site.
8. Continue to apply slight pressure on handle and withdraw forceps from channel. While withdrawing forceps from endoscope, wipe excess secretions from cable.
9. Prepare specimen for examination per institutional guidelines.
10. Upon completion of procedure, turn electrosurgical unit off, disconnect active cord from handle, then dispose of device per institutional guidelines for biohazardous medical waste.
11. Don't touch the wire in the handle.

EMC CONDITIONAL

Guidance and manufacturer's declaration - electromagnetic emissions - for all ME EQUIPMENT and ME SYSTEM.

Table 1 - Emission		
Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class A	Professional healthcare facility environment
Harmonic distortion	IEC 61000-3-2 Class A	
Voltage fluctuations and flicker	IEC 61000-3-3 Complies	

Guidance and manufacturer's declaration - electromagnetic immunity - for all ME EQUIPMENT and ME SYSTEM.

Table 2 - Enclosure Port		
Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Electrical fast transients/bursts	IEC 61000-4-4	±2kV, 100kHz (AC power port) ±1kV, 100kHz (signal input/output parts port)
Surges	IEC 61000-4-5	±0.5kV, ±1kV (line to line); ±0.5kV, ±1kV, ±2kV (line to ground)
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15MHz-80MHz; 6V in ISM band between 0.15MHz and 80MHz
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz
Voltage dips	IEC 61000-4-11	0% U _i ; 0.5cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°; 0% U _i ; 1 cycle at 0° 70% U _i ; 25/30 cycles at 0°
Voltage interruptions	IEC 61000-4-11	0% U _i ; 250/300 cycles

Guidance and manufacturer's declaration – electromagnetic immunity for ME EQUIPMENT and ME SYSTEM that are not LIFE-SUPPORTING.

Table 3 – Proximity fields from RF wireless communications equipment		
Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		

1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

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 4 years.

OPERATION ENVIRONMENT

Operation environment	Environment temperature	10-40 °C (50-104 °F)
	Relative humidity	30-85%
	Barometric pressure	700-1060hPa (0.7-1.1Kgf/cm ³) (10.2-15.4psia)

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.

Limited Warranty and Disclaimers

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

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