Cytology Brush
Instructions for Use

Micro-Tech (Nanjing) Co., Ltd
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 Cytology Brush is used to collect cells from the bronchi and upper and lower gastrointestinal tracts.

CONTRAINDICATIONS
Contraindications include those specific to the primary endoscopic procedure to be performed in gaining access to the desired cytology site.
This device is not indicated for use with ultrasound or fluoroscopy guidance.

POTENTIAL COMPLICATIONS
Potential complications associated with pulmonary or gastrointestinal endoscopy include, but are not limited to: perforation, hemorrhage, aspiration, fever, infection, hypotension, respiratory depression or arrest, 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. Should there occur any irregularities, dispose the instrument and replace it with a new one.

【Product Name】Cytology Brush
【Packaging】Packed in Pouch
【Production Date】See packaging
【Sterilization】Sterilized by EO (ethylene oxide) gas
【Shelf Life】2 years
【Compatible Working Channel】

<table>
<thead>
<tr>
<th>REF</th>
<th>Endoscopy types</th>
<th>Working channel ø (mm)</th>
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<tbody>
<tr>
<td>CYB-20S-12C</td>
<td>Bronchoscopes</td>
<td>≥2.0</td>
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<tr>
<td>CYB-20S-18C</td>
<td>Gastroscopes</td>
<td>≥2.8</td>
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<tr>
<td>CYB-30S-24C</td>
<td>Gastroscopes, Colonoscopes</td>
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<td>CYB-50S-24C</td>
<td>Gastroscopes, Colonoscopes</td>
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**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 Brush Tip 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. Upon removal of the device from the package, visually inspect with particular attention.
2. Endoscopically inspect the area to be sampled.
3. Advance in 1-2 cm increments until the tip of the device is visualized exiting the endoscope.
4. Advance the device to the desired sampling site, then advance the brush out of the sheath by pushing forward on the handle.
5. Brush the area to be sampled several times to obtain adequate cellular material.
6. Pull the brush back into the sheath and withdraw the device from the endoscope.
7. Prepare the specimen for examination per institutional guidelines.
8. Upon completion of the procedure, dispose of the device per institutional guidelines for biohazardous medical waste.

STORAGE

Store the instrument in the sterile package at room temperature in a clean and dry environment. Do not store the instrument in direct sunlight. Ensure that the package is not crushed by surrounding objects during storage.

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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Manufacturer
Micro-Tech (Nanjing) Co., Ltd.
No.10 Gaoke Third Road, Nanjing National Hi-Tech Industrial Development Zone, Nanjing 210032, Jiangsu Province, PRC
TEL:+ 86 25 58609879, 58646393
FAX:+ 86 25 58744269
Email: info@micro-tech.com.cn
www.micro-tech.com.cn;

Distributed By
Micro-Tech USA Inc.
2855 Boardwalk Drive, Ann Arbor, MI 48104 USA
Tel: 734-259-3768
Toll free: 877-552-4027
info@micro-tech-usa.com

Shanghai International Holding Corp. GmbH(Europe)
Eiffelstrasse 80, 20537 Hamburg Germany