

# Cytology Brush

## 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**

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** 】

REF	Endoscopy types	Working channel ø (mm)
CYB-20S-12C	Bronchoscopes	≥2.0
CYB-20S-18C	Gastrosopes	≥2.8
CYB-30S-12C	Bronchoscopes	≥2.0
CYB-30S-18C	Gastrosopes	≥2.8
CYB-30S-24C	Gastrosopes, Colonoscopes	≥2.8
CYB-50S-12C	Bronchoscopes	≥2.0
CYB-50S-24C	Gastrosopes, Colonoscopes	≥2.8

## **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.

## **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 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.
2. Disclaimer and Release. **THE WARRANTIES, OBLIGATIONS, AND LIABILITIES OF Micro-Tech USA AS SET FORTH HEREIN ARE EXCLUSIVE. BUYER HEREBY WAIVES ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, ARISING BY LAW OR OTHERWISE, WITH RESPECT TO THE PRODUCTS AND ANY OTHER GOODS OR SERVICES DELIVERED BY BUYER, INCLUDING, BUT NOT LIMITED TO: (1) ALL OTHER EXPRESS AND IMPLIED WARRANTIES, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND (2) ANY IMPLIED WARRANTY ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING, OR USAGE OF TRADE.**
3. Implied Warranties. The purchase of products may be subject to laws in the territories applicable to the sale of the products by Micro-Tech USA to Buyer that impose implied warranties, conditions, or obligations that cannot be excluded, restricted, or modified, or can only be excluded, restricted, or modified to a limited extent. The provisions of Paragraphs 2 and 4 shall apply to the greatest extent allowed by such laws.
4. Limitation of Liability. **EXCEPT TO THE EXTENT PROHIBITED BY APPLICABLE LAW, Micro-Tech USA'S LIABILITY UNDER THIS WARRANTY IS LIMITED TO: (a) THE REPLACEMENT OF THE PRODUCTS OR THE RE-SUPPLY OF EQUIVALENT PRODUCTS; (b) THE REPAIR OF THE PRODUCTS OR PAYMENT OF THE COST OF REPAIRING THE PRODUCTS; or (c) PAYMENT OF THE COST OF REPLACING THE PRODUCTS OR ACQUIRING EQUIVALENT PRODUCTS. MICRO-TECH USA SHALL HAVE NO OBLIGATION OR LIABILITY, WHETHER ARISING IN CONTRACT (INCLUDING WARRANTY), TORT (INCLUDING ACTIVE, PASSIVE, OR IMPUTED NEGLIGENCE, STRICT LIABILITY, OR PRODUCT LIABILITY) OR OTHERWISE, FOR ANY SPECIAL, CONSEQUENTIAL, PUNITIVE, INCIDENTAL, OR INDIRECT DAMAGES, OR FOR LOSS OF USE, LOSS OF REVENUE, LOSS OF BUSINESS, LOST PROFIT, OR OTHER FINANCIAL LOSS ARISING OUT OF OR IN CONNECTION WITH ANY PRODUCT OR OTHER GOODS OR SERVICES FURNISHED BY MICRO-TECH USA, EVEN IF MICRO-TECH USA WAS AWARE OF THE POSSIBILITY OF SUCH DAMAGES OR LOSS.**



## **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](mailto:info@micro-tech.com.cn)

[www.micro-tech.com.cn](http://www.micro-tech.com.cn);

## **Distributed By**

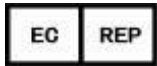
### **Micro-Tech USA Inc.**

2855 Boardwalk Drive,Ann Arbor,MI 48104 USA

Tel: 734-259-3768

Toll free: 877-552-4027

[info@micro-tech-usa.com](mailto:info@micro-tech-usa.com)



Shanghai International Holding Corp. GmbH(Europe)

Eiffestrasse 80, 20537 Hamburg Germany

1-0005064 REV: 2

2018-03-12