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.medical.com

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

1-1033738 REV:1
2022.07.28

MICRO-TECH ENDOSCOPY

Areus ™ Endobronchial Ultrasound Aspiration Needle (FNA)
Trident ™ Endobronchial Ultrasound Biopsy Needle (FNB)

Instructions for Use

Micro-Tech (Nanjing) Co., Ltd

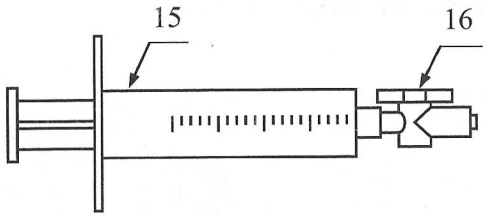


Fig.1B Negative suction device

Fig.1 Product structure

No.	Component Name	No.	Component Name
1	Sheath	9	Needle indicator
2	Stylet	10	Needle lock
3	Needle	11	Upper handle
4	Support sleeve	12	Proximal connector
5	Connector	13	Stylet lock
6	Sheath indicator	14	Adaptor（as required）
No.	Component Name	No.	Component Name
7	Sheath lock	15	Syringe
8	Lower handle	16	Stopcock

PREPARATION

1. Read the product label and select the appropriate device for the procedure and bronchoscope in use.
2. The contents are supplied STERILE. Inspect the pouch for damage, if damaged do not use.
3. Open the package carefully after verifying the expiration date.
4. Carefully remove the device from its packaging and uncoil it.
   Note: Do not use excessive force as this may damage the device and affect performance.
5. Visually inspect the device with particular attention to bends or breaks. If any component appears damaged, or not functioning correctly, do not use the device.

INSTRUCTIONS FOR USE

a Adaptor installation

According to the matching brand of ultrasonic bronchoscope, install the appropriate adaptor (14), as required.Confirm that the adaptor is firmly attached to the instrument channel port of the endoscope.

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. **Patients should be informed of the potential risks and complications, which may lead to injury, illness or death of the patient.**
3. **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.
4. **Do not use this instrument for any purpose other than its intended use.**
5. **The product is only intended for adult populations.**

【 Product Name 】 Areus™ Endobronchial Ultrasound Aspiration Needle (FNA);
Trident™ Endobronchial Ultrasound Biopsy Needle (FNB);
【 Packaging 】 Preformed rigid tray with a die-cut lid
【 Production Date 】 See packaging
【 Sterilization 】 Sterilized by EO (ethylene oxide) gas
【 Shelf Life】 3 years
【 Compatible Working Channel 】 ≥φ2.0 mm
【 Applicable Endoscopes 】 Any Ultrasound Bronchoscope that is legally marketed in USA that has an accessory channel equal to or greater than 2.0mm diameter.

STRUCTURE

The Endobronchial Ultrasound Aspiration Needle is composed of Aspiration Needle, Adaptors and Negative suction device.

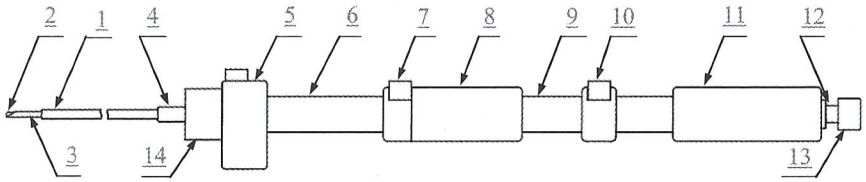
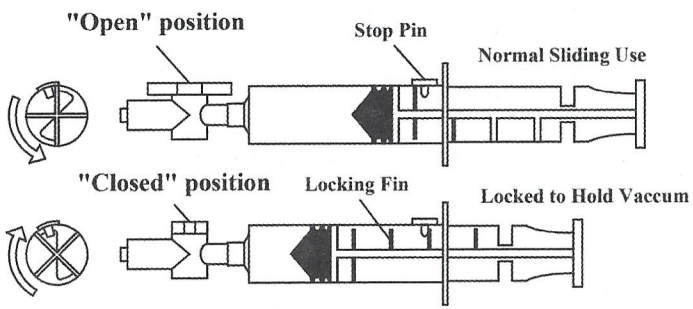


Fig.1A Front view of product

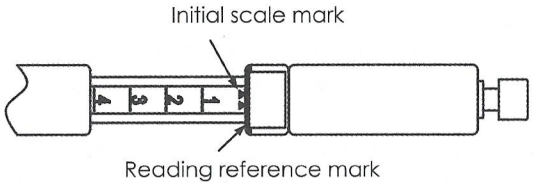
b Negative suction device Preparation and Use



1. Examine the stopcock. The luer connections of the stopcock attach to the needle. Air can be exchanged with the stopcock in the open position. The stopcock is open when it is aligned parallel to the syringe. It is closed when perpendicular to the syringe.
   Caution: The stopcock is required in order to maintain suction during the procedure. If the stopcock is not set properly, adequate suction may not be achieved.
2. Examine the syringe. The syringe barrel has one stop pin and the syringe plunger has four locking fins. The syringe plunger can be maneuvered within the syringe barrel to lock and unlock the syringe. To lock the syringe, pull back on the plunger until it aligns with the desired suction volume. Turn the plunger clockwise so that the locking pin engages with the locking fins on the plunger. Turn the plunger counterclockwise to release.
3. To create and maintain vacuum, withdraw the syringe plunger to the desired position and rotate the plunger clockwise to position one of the locking fins behind the stop pin. Turn the plunger counterclockwise to release.
4. To aspirate fluids without locking the syringe, move the plunger completely forward or completely back, turn the plunger so that the locking fins will not interfere with the stop pin.
5. Attach the stopcock to the syringe and close the stopcock. Withdraw the plunger the desired amount to create a vacuum and lock as directed above. Set syringe aside until needed.

c Product Use

1.Confirm that the needle is fully retracted and that the needle lock (10) is secure in the initial position on the needle indicator (9).
Caution: If the needle lock is pressed, it can be moved. Ensure the lock is engaged before introducing the device into the bronchoscope.



2. Straighten the bronchoscope as much as possible.
3. Introduce the sheath (1) into the working channel. Slowly advance the device through the working channel.
   Caution: If resistance is encountered, stop pushing and reposition the sheath or the bronchoscope. Excessive force could cause damage to the device and or the bronchoscope.
4. Continue to advance the device until it exists the scope and the sheath is visible in the endoscopic image. Attach the device is firmly to the Adaptor.
   Caution: Prior to advancing the needle, ensure that the device is securely fastened to the endoscope and both the needle lock (10) and sheath lock (7) are secure. Failure to do so could result in damage to the device and or endoscope.
5. Determine the appropriate sheath (1) length relative to the length of the bronchoscope. Use the sheath lock (7) to set the desired length of the sheath and lock it in place. The distal end of the sheath should be visible on the endobronchial image.
   Caution: The reference numbers and markings on the sheath indicator (6) are intended as reference only. The reference numbers represent the sheath(1) extension(in centimeters) when the device is in a straight position.
6. Verify the distance from the distal end of the sheath to the target site using the ultrasound image.
7. Adjust the needle penetration depth to the desired position using the needle lock (10). To control the penetration depth of the needle relative to the lesion, press the needle lock to make it in a non-locked state, align the needle lock with the appropriate scale on the needle indicator (9), and release the needle lock to make it in a locked state.
   Caution: The reference numbers and markings on the needle indicator (9) are intended as reference only. The reference numbers represent the needle (3) extension (in centimeters) when the device is in a straight position.
8. Advance the needle by sliding the upper handle (11) toward the broncho-scope in a slow and controlled motion to penetrate the target site while observing the ultrasound image.
   Caution: Prior to advancing the needle pull the stylet back approximately 5mm to expose the needle point.
9. While maintaining the needle position in the target site, carefully remove the stylet (2) from the proximal connector (12) of the device by gently loosening

and pulling it from the device upper handle (11).

Caution: The stylet should be retained for additional needle passes during the same procedure. Failure to properly handle the stylet could result in damage to the device.

Caution: The stylet tip is sharp, take precaution to ensure that the stylet is handled properly. After it has been removed from the needle, the stylet should be treated as infectious material and could create an infection risk.

10. Connect the previously prepared negative suction device to the proximal connector (12) on the upper handle (11).

    Caution: Methods of providing suction other than the supplied syringe are not recommended with this device.

11. Confirm correct placement of the needle tip and turn the stopcock to the open position (parallel to the device handle) to apply suction.
12. Maneuver the needle within the target site to maximize aspiration sample collection while observing needle penetration on the ultrasound image.
13. After an adequate number of passes have been made with the needle, close the stopcock by rotating until it is perpendicular to the syringe.
14. Straighten the bronchoscope as much as possible.
15. Retract the needle fully into the sheath using the device handle by sliding the handle away from the bronchoscope until it stops moving. Secure the needle using the needle lock(10) .

    Caution: Ensure that the needle is fully retracted into the sheath prior to removal. Failure to secure the needle could result in damage to the device and or bronchoscope or injury to user.

16. Detach the device from the adaptor . Slowly and carefully remove the device from the bronchoscope and set aside for specimen retrieval.
17. After the device has been removed from the bronchoscope, release the needle lock and carefully advance the device handle to extend the needle out of the sheath.
18. Remove the negative suction device from the proximal connector (12) and attach an empty clean air-filled syringe. Carefully push the syringe plunger forward to expel and collect the aspiration sample from the needle.

    Caution: Take precautions to ensure that the aspiration sample does not spray when It is expelled from the needle. The aspiration sample should be treated as infectious material and could create an infection risk.

    Note: If necessary, the stylet can be inserted into the needle repeatedly to help release any residual sample.

    Note: If required, the needle may be flushed with air or normal saline to release any remaining sample.

19. Prepare the aspiration sample per institutional protocol.

    Note: Multiple passes may be required to obtain an adequate aspiration sample.

20. If additional passes to the same target site are required, prepare the device by flushing the needle and wiping the stylet with sterile water or saline. Reinsert the stylet into the needle, examine the needle for damage, and repeat step b of Syringe Preparation and Use, and steps 1 through 19 of Product Use.

    Caution: Failure to flush the needle and wipe the stylet prior to reinserting the stylet into the needle could make the stylet difficult to pass or result in damage to the device.

21. Remove the Adaptor from the bronchoscope after completion of the procedure.

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 state and federal 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**

A revision date and number for these instruction is included directly below the contact information. In the event that more than two years have passed between this date and the use of the device, the user should contact Micro-Tech to see if additional product use information is available.

SYMBOL INDICATIONS

	Do not re-use		Do not resterilize
	Date of Manufacture		Manufacturer
	Use-by date		Caution
REF	Catalogue number	STERILE EO	Sterilized using ethylene oxide
	Keep away from sunlight		Do not use if package is damaged and consult instructions for use
	Keep dry		Compatible working channel
	Consult instructions for use		Working length
	Diameter		Contents
LOT	Batch code		Not made with natural rubber latex.
Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician.	SBS	Sterile barrier system/ sterile packaging
	Open here		