

# **Endoscopic Ultrasound Aspiration Needle(FNA) Trident™ Endoscopic Ultrasound Biopsy Needle(FNB)**

## Instructions for Use

A decorative graphic consisting of several parallel, curved lines that start horizontally on the left and curve downwards and then back horizontally on the right, creating a wave-like effect across the middle of the page.



## IMPORTANT INFORMATION

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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

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The Endoscopic Ultrasound Aspiration Needle is designed to sample targeted submucosal and extraluminal gastrointestinal lesions through the accessory channel of suitable ultrasound videoendoscope in adult patients only.

## CONTRAINDICATIONS

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**Contraindications include those specific to the primary endoscopic procedure to be performed in gaining access to the desired position to visualize the targeted site. Relative contraindications include , but are not limited to : coagulopathy.**

## POTENTIAL COMPLICATIONS

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**Potential complications associated with ultrasound endoscopy include, but are not limited to: Perforation, hemorrhage, aspiration, fever, infection, allergic reaction to medication, hypotension, respiratory depression or arrest, cardiac, arrhythmia or arrest and tumor seeding.**

# WARNINGS

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- 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 】** Endoscopic Ultrasound Aspiration Needle

**【 Packaging 】** Tray, Tyvek and Box

**【 Production Date 】** See packaging

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

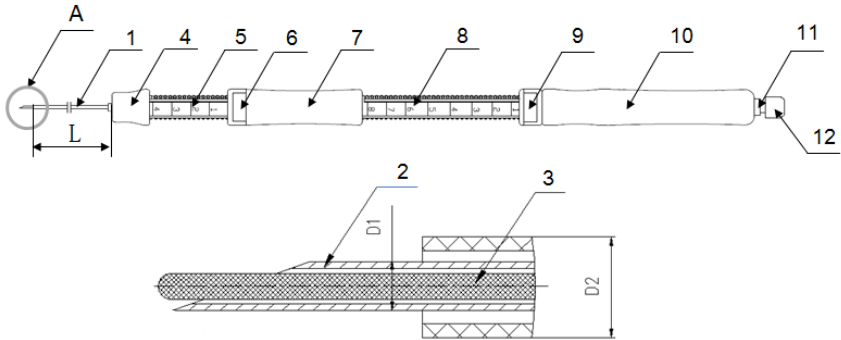
**【 Shelf Life 】** 2 years

**【 Compatible Working Channel 】**  $\geq \varnothing 2.8$  mm

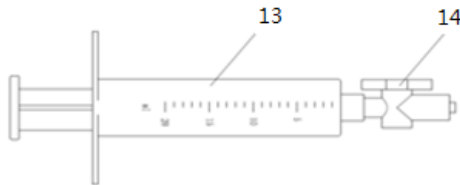
**【 Applicable Endoscopes 】** Any Ultrasound endoscope that is legally marketed in USA that has an accessory channel equal to or greater than 2.8mm diameter.

# STRUCTURE

The Endoscopic Ultrasound Aspiration Needle is composed with Aspiration Needle, Stopcock and Syringe.



No.	Component Name	No.	Component Name
1	Sheath	7	Lower handle
2	Needle	8	Needle indicator
3	Stylet	9	Needle lock
4	Scope connector	10	Upper handle
5	Sheath indicator	11	Proximal connector
6	Sheath lock	12	Stylet lock



No.	Component Name	No.	Component Name
13	Syringe	14	Stopcock

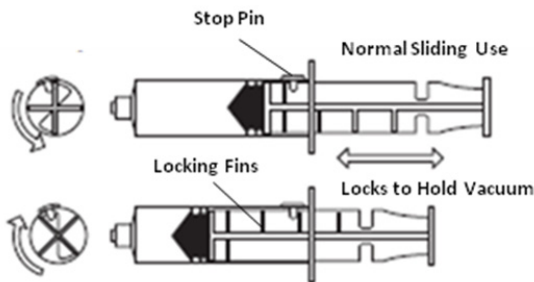
# PREPARATION

1. Read the product label and select the appropriate device for the procedure and endoscope in use.

- The contents are supplied STERILE. Inspect the pouch for damage, if damaged do not use.
  - Open the package carefully after verifying the expiration date.
  - Carefully remove the device and syringe from the package and uncoil it.
- Note:** Do not use excessive force as this may damage the device and affect performance.
- 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 Syringe Preparation and Use



- Examine the stopcock . The stopcock has two luer connections to attach to the needle and syringe. 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.
- 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.
  - 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.

## **b Product Use**

1. Confirm that the needle is fully retracted and that the needle lock (9) is secure in the initial position on the needle indicator (8) (as picture show).  
**Caution:** If the needle lock is pressed, it can be moved. Ensure the lock is engaged before introducing the device into the endoscope.
2. Lower the elevator and straighten the endoscope as much as possible.  
**Caution:** Failure to lower the elevator prior to insertion may cause damage to the device.
3. Introduce the sheath (1) into the working channel and advance in small increments. Continue to advance the device until it exits the endoscope and the sheath is visible in the endoscopic image.  
**Caution:** If resistance is encountered, stop pushing and reposition the sheath or the endoscope. Excessive force could cause damage to the device and or the endoscope.
4. Attach the device to the working channel using the scope connector (4) by turning the device clockwise. If it is necessary to adjust the sheath length, press the sheath lock (6), and move the sheath indicator (5), to reposition it to the appropriate reference point.  
**Caution:** Do not over tighten the scope connection as it may cause damage to the device and or the endoscope.  
**Caution:** Prior to advancing the needle, ensure that the device is securely fastened to the endoscope and both the needle lock (9) and sheath lock (6) 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 endoscope . Use the sheath lock (6) to set the desired length of the sheath and lock it in place. The distal end of the sheath should be visible on the endoscopic image.  
**Caution:** The reference numbers and markings on the sheath indicator (5) 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(9). To control the depth of needle penetration to the target site, press the

needle lock and move the needle lock to the appropriate reference number on the needle indicator (8).

**Caution:** The reference numbers and markings on the needle indicator (8) are intended as reference only. The reference numbers represent the needle(2) extension( in centimeters) when the device is in a straight position.

**Caution:** Ensure the needle lock is secure before advancing the needle.

8. Advance the needle by sliding the upper handle(10) toward the endoscope in a slow and controlled motion to penetrate the target site while observing the ultrasound image.

9. While maintaining the needle position in the target site, carefully remove the stylet (3) from the Proximal connector (11) of the device by gently loosening and pulling it from the device upper handle (10).

**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 syringe and stopcock to the proximal connector (11) on the upper handle (10).

**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. Lower the elevator and straighten the endoscope as much as possible.

**Caution:** Failure to lower the elevator prior to withdrawal may cause damage to the device.

15. Retract the needle fully into the sheath using the device handle by sliding the handle away from the endoscope until it stops moving. Secure the needle using the needle lock(9) .

**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 endoscope or injury to user.

16. Detach the device from the endoscope by turning the scope connection counterclockwise. Slowly and carefully remove the device from the endoscope and set aside for specimen retrieval.

17. After the device has been removed from the endoscope, release the needle lock and carefully advance the device handle to extend the needle out of the

sheath.

18. Remove the locking syringe and stopcock from the proximal connector (11) 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 biopsy needle repeatedly to help release any residual sample.

**Note:** If required the biopsy needle may be flushed with heparinized 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 a 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.

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## 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.

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## 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

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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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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.



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