MEDORAH MEDITEK

PIVOT® Endoscopic Ultrasound Aspiration Needle

Instructions for Use

Medorah Meditek Pvt. Ltd.

www.medorah.com

PIVOT® Endoscopic Ultrasound Aspiration Needle

Intended Use / Indications for use

Intended use- PIVOT® Endoscopic Ultrasound Aspiration Needle is intended to be used for sample targeted submucosal gastrointestinal lesions through the accessory channel of an ultrasound endoscopy.

PIVOT® Endoscopic Ultrasound Aspiration Needle is supplied sterile and is intended for single use only.

Device Description

PIVOT® Endoscopic Ultrasound Aspiration Needle can be coupled to the aspiration channel of a Curvilinear Array (CLA) Echoendoscope with a standard luer connection and delivered into the digestive tract.

The device sheath length can be adjusted to accommodate different model echoendoscopes. The needle is used to acquire samples from lesions within and adjacent to the digestive system's major lumens that can be identified and targeted using the echoendoscope. Both the sheath and needle length can be adjusted based on distance to the target lesion. The sheath and needle length adjustments are set and locked by the physician by using the locking knob mechanisms on the handle of the device. A sample is obtained by penetrating the lesion with the needle while applying suction and manipulating the needle in a back-and-forth motion to acquire a sample. The sample can be prepared per normal institutional protocol. The PIVOT® Endoscopic Ultrasound fine aspiration has echogenic (visible under ultrasound) features at the distal end to facilitate real time visualization of the device under ultrasound.

This needle system consists of four-layer configuration; a handle assembly for controlled advancement of the needle with a dedicated port for the needle stylet and an attachment for a vacuum syringe; a semi-rigid protective sheath; a hollow needle and a stylet to avoid perforation and damage to the endoscope's working channel.

PIVOT® Endoscopic Ultrasound Aspiration Needle Specifications

Working Length: 137.5 cm to 141.5 cm adjustable

Needle Length: 0 cm to 8 cm adjustable

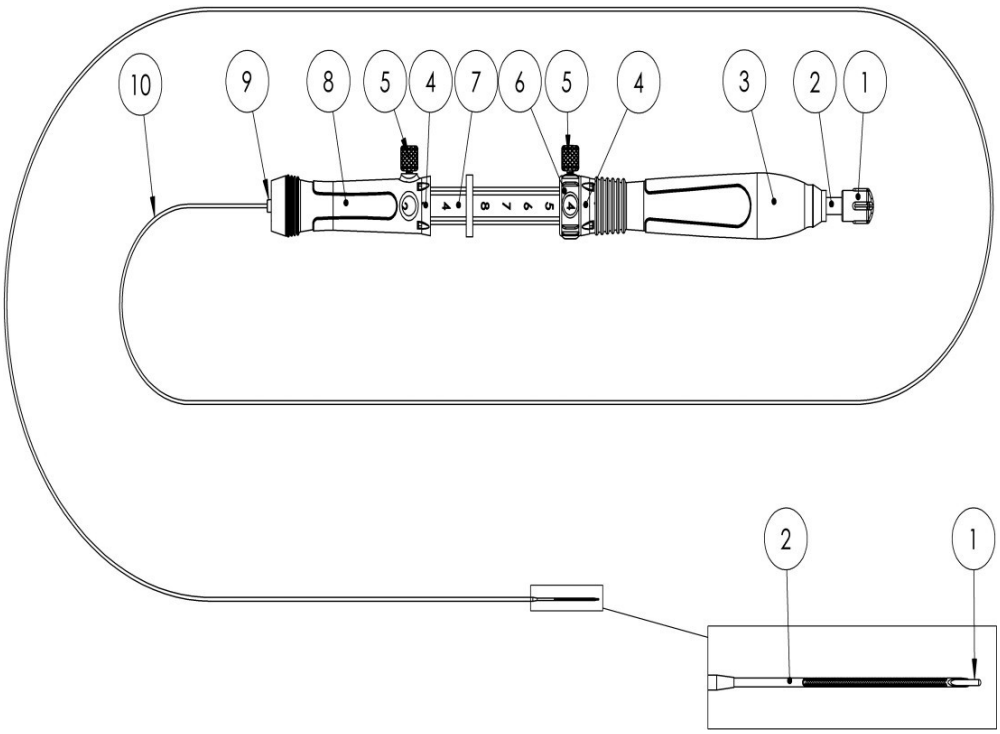
Diameter: 22

gauge 22-gauge

OD: 0.72mm

Minimum Working Channel: 2.8mm

Sheath Diameter: 1.8mm



①	Stylet
②	FNA Needle Shaft
③	Upper Cylinder
④	C-ring Housing
⑤	Locking Screw
⑥	Lock Ring
⑦	Middle Cylinder
⑧	Lower Cylinder
⑨	Luer Lock Fitting
⑩	Outer sheath

Contraindications

- Contraindications for this device are those specific to the primary endoscopic procedure to be performed in gaining access to the desired site.
- Relative contraindications include, but are not limited to: coagulopathy.

Potential Complications

Complications associated with Ultrasound Endoscopy may include:

- Bleeding
- Perforation
- Pancreatitis
- Peritonitis
- Inflammation
- Fever
- Allergic Reaction to medication
- Hypotension
- Respiratory Depression or Arrest
- Cardiac Arrhythmia or Arrest
- Tumor Seeding
- Hemorrhage

Warnings

The entire User's Manual must be read thoroughly before using the device. A detailed knowledge of the techniques, procedures, clinical applications and risks associated with the procedure is necessary before using the device.

- Contents supplied STERILE using an ethylene oxide (EO) process. Do not use it if the sterile barrier is damaged.
- For single use only. Do not **reuse, reprocess or re-sterilize**. Reuse, reprocessing or re- sterilization 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. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.
- Do not use this device for any purpose other than stated intended use. If a package is opened or damaged when received, do not use it. Visually inspect with particular attention

to kinks, bends and breaks. If an abnormality is detected that would prohibit proper working conditions, do not use.

- The device is not for use in the heart or vascular system. The tip of the needle and stylet are sharp and could cause injury to the patient or user if not used with caution.
- Patients should be informed of the potential risks and complications, which may lead to injury, illness or death of the patient.
- The instrument is intended for use under the direct supervision of a suitably trained physician only.

Precautions

- Read the entire directions for use before using the PIVOT® Endoscopic Ultrasound Aspiration Needle.
- The PIVOT® Endoscopic Ultrasound Aspiration Needle should only be used by or under the supervision of physicians trained in Endoscopic Ultrasound and Fine Needle aspiration.
- Refer to the package label for minimum channel size required for this device.
- Needle must be retracted into the sheath and the locking-screw on the lock ring must be securely locked to hold the needle in place prior to introduction, advancement, or withdrawal of the device. Failure to retract the needle may result in damage to the endoscope.
- When removing the needle from the package, ensure that the needle sheath is locked in place on the needle and the sheath covers the end of the needle tip. If the needle sheath is not locked into place on the needle, user injury may result.
- Ensure that the stylet is fully inserted when advancing the needle into the aspiration site.

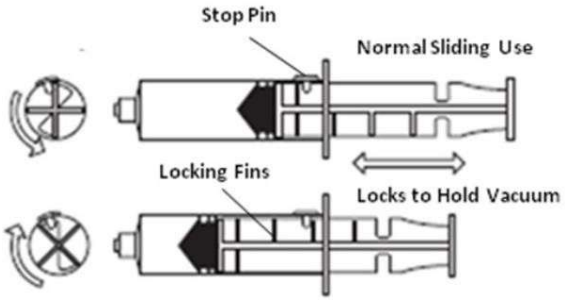
Procedure

Product Preparation:

1. Open device package and remove plastic insert containing PIVOT® Endoscopic Ultrasound Aspiration Needle device and syringe.
2. Carefully remove the device and syringe from the package and uncoil it.

Caution: Visually inspect the stopcock when removed from the package to confirm it is in the open position; otherwise, DO NOT USE IT.

Syringe Preparation and Usage



1. 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.

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.

Product Usage

1. Remove the needle from the package and examine it for any sort of damage or kinks before use.
2. Confirm that the needle is fully retracted and that the needle adjustment lock is secure in the zero position.

Caution: If the needle lock is pressed, it can be moved. Ensure the lock is engaged before introducing the device into the endoscope.

3. Determine the desired sheath length relative to the length of the echoendoscope. Use the sheath adjustment lock to set the required sheath length and lock it in place. Turn the sheath adjustment lock clockwise to lock the sheath 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 are intended as reference only. The reference numbers represent the sheath extension (in centimetres) when the device is in a straight position.

4. Turn the endoscope elevator control knob to lower the elevator.

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

5. Introduce the catheter into the echoendoscope working channel and slowly advance the device in small increments until luer-lock fitting at the base of the sliding sheath meets fitting on the accessory channel.

Caution: If resistance is encountered, stop pushing and reposition the catheter or the echoendoscope. Pushing too hard could cause damage to the echoendoscope.

6. Tighten the luer attachment by turning clockwise to attach the device to the working channel port of the echoendoscope.

Caution: Do not tighten the luer connection too tightly to the echoendoscope as it may cause damage to the echoendoscope.

Prior to advancing the needle, ensure that the device is securely fastened to the echoendoscope and both the needle adjustment and sheath adjustment locks are secure. Failure to do so could result in damage to the echoendoscope.

Insufflation performance may be diminished when the device is attached to the echoendoscope.

7. Verify the distance from the distal end of the sheath to the target site using the ultrasound image.
8. Adjust the needle penetration depth to the desired position using the needle adjustment lock. To control the depth of needle penetration to the target site, loosen the needle adjustment lock by turning the knob counterclockwise. Align the needle adjustment lock with the appropriate reference number on the device handle. **Note**: Number in needle adjustment lock ring window indicates extension of needle in centimetres. Lock in place by turning the needle adjustment lock clockwise.
9. Advance the needle by sliding the handle toward the echoendoscope in a slow and controlled motion to penetrate the target site while observing the ultrasound image.
10. Remove the stylet from the needle port of the device by gently loosening and pulling back on the plastic hub seated in metallic fitting of needle handle.

Caution: Failure to properly handle the stylet could result in damage to the device.

Caution: The stylet tip is sharp. Take precautions 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.

11. Prepare the supplied syringe and stopcock as previously noted. Rotate the stopcock to the closed position, perpendicular to the syringe. Pull the syringe plunger to the desired volume and use the locking fins and stop pin on the syringe to secure the plunger in place.

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

12. Connect the supplied syringe to the aspiration port on the device handle.
13. Turn the stopcock to the open position (parallel to the device handle) to apply suction.
14. Manoeuvre the needle within the target site to maximize sample collection while observing needle penetration on the ultrasound image.
15. After an adequate number of passes have been made with the needle, close the stopcock by rotating until it is perpendicular to the syringe. This will stop suction.
16. Retract the needle fully into the sheath using the device handle by sliding the handle away from the echoendoscope until it stops moving. Secure the needle using the needle adjustment lock prior to withdrawing the device from the echoendoscope. Lock the needle adjustment lock ring to 0 cm mark.

Caution: Ensure that the needle is fully retracted into the sheath. Failure to secure the needle could result in damage to the echoendoscope or injury to the user.

17. Lower the elevator on the echoendoscope.

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

18. Disconnect Luer-lock fitting from the accessory channel and slowly withdraw the entire device from the echoendoscope.
19. After the device has been removed from the echoendoscope, release the needle adjustment lock and advance the device handle to extend the needle out of the sheath.
20. Remove the syringe and stopcock from the aspiration port.
21. Open the stopcock on the syringe by rotating it to the position that is parallel to the syringe. Pull the syringe plunger back to pull air into the syringe.
22. Reconnect the syringe to the aspiration port.
23. Push the syringe plunger forward to expel the sample from the needle.

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

24. Prepare the sample per institutional protocol.
25. 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 steps 2 through 24.

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.

Change of performance

If the device's performance is changed or the intended purpose is lost, further actions shall be taken according to the medical specialist's decision considering the clinical condition of patients.

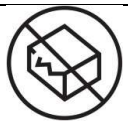
Disposal of a used device

After use, this product may be a potential biohazard. It must be disposed of according to hospital, local and country regulations. Disposal is the responsibility of user.

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.

Explanation of Symbols

	Date of Manufacture		Use-By Date
	Catalogue Number		Do not re-use
	Consult instructions for use		Caution
	Keep away from sunlight		Batch Code
	Do not use if package is damaged		Manufacturer
	Non-Pyrogenic		Keep dry
	Do Not resterilize		Sterilized using Ethylene Oxide

Warranty

Medorah Meditek Pvt. Ltd. warrants that this product has been manufactured by following appropriate procedures and reasonable care has been applied in designing and manufacturing of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this device as well as other factors relating to patient, diagnosis, treatment, surgical procedures, and other matters beyond Medorah Meditek Pvt. Ltd.'s control directly affect the device and the results obtained from its use. Medorah Meditek Pvt. Ltd.'s obligation under this warranty is limited to the repair or replacement of this device and Medorah Meditek Pvt. Ltd. shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. Medorah Meditek Pvt. Ltd. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. Medorah Meditek Pvt. Ltd. assumes no liability with respect to devices reused, reprocessed or re-sterilized and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such devices.

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