

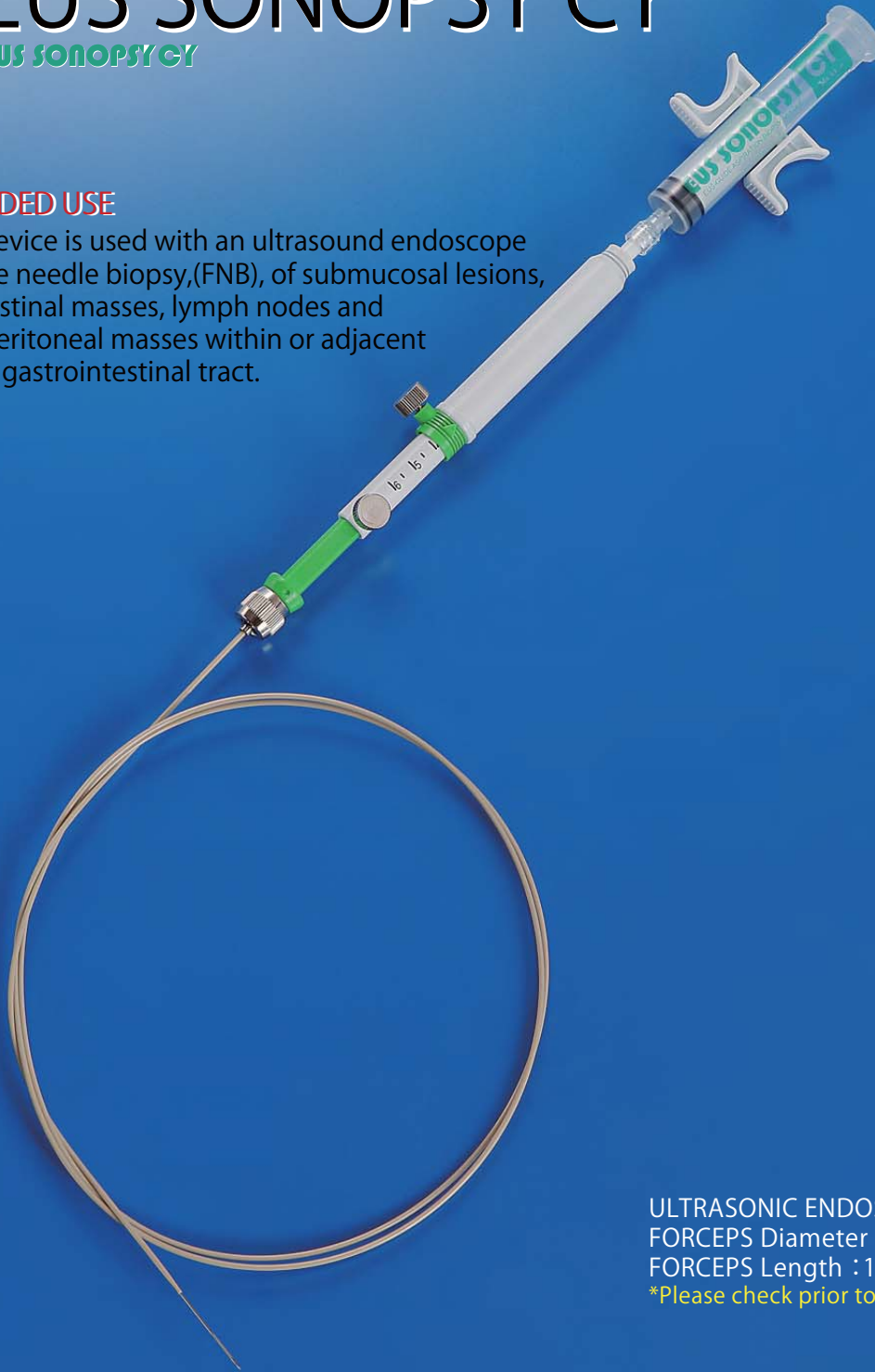
Endoscopic ultrasound fine needle aspiration (EUS-FNA) biopsy

EUS SONOPSY CY

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INTENDED USE

This device is used with an ultrasound endoscope for fine needle biopsy (FNB), of submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the gastrointestinal tract.



ULTRASONIC ENDOSCOPE: CONVEX TYPE
FORCEPS Diameter : more than ϕ 2.0mm
FORCEPS Length : 1400mm(+15,-10mm)
*Please check prior to use.

Description

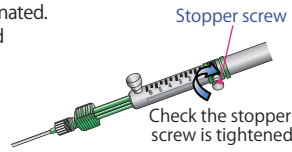
- Puncture Length is variable 0~60mm and 55mm adjustable of Protective tube.
- Menghini Type Needle Tip for easy puncture to lesion.
- Do not need to remove the stylet before Biopsy by a fewer procedure more simply and more intuitively.
- One hand action Biopsy.

This device is designed for single use only.

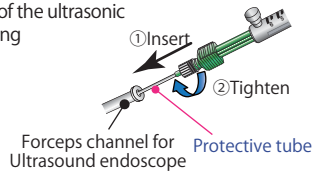
Attempts to reprocess, resterilize, and/or reuse may lead to device failure and/or transmission of disease.

Instructions for Use

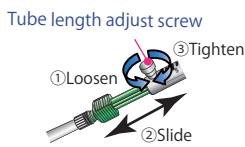
1) Remove the product from the package while taking care not to get the product contaminated. Check that the puncture needle is properly placed in the protective tube and that the stopper screw is tightened. Also check that the aspiration barrel locking ring is firmly tightened.



2) Insert the product into the forceps channel of the ultrasonic endoscope and then lock the inner barrel locking ring by tightening it at the forceps connector of the ultrasonic endoscope.



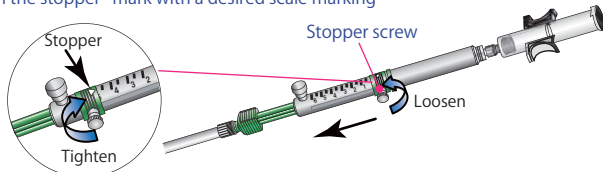
3) Loosen the tube length adjusting screw, slide the inner barrel, adjust the protective tube so that its leading end projects by about 5 mm from the distal end of the forceps channel of the ultrasonic endoscope, and then firmly tighten the adjusting screw.



4) Set a puncture target under endoscopic ultrasound guidance and determine puncture depth.

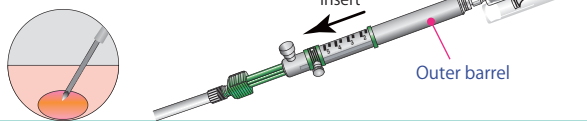
5) Loosen the stopper screw, adjust the stopper to the target puncture depth (outer needle), and then firmly lock the stopper by tightening the stopper screw.

○ Adjusting puncture depth (outer needle):
Align the stopper mark with a desired scale marking

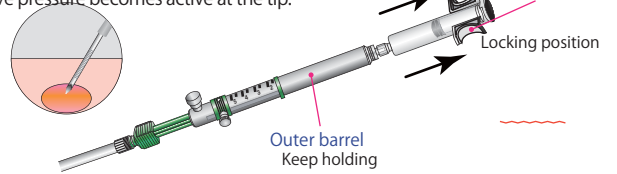


For 5cm as an example

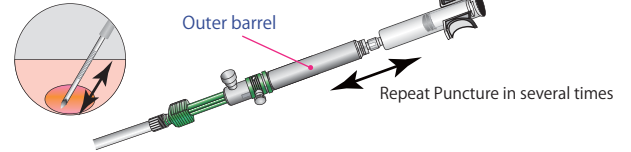
6) In the position where the intended site is most clearly imaged under endoscopic ultrasound guidance, move forward the outer barrel while ultrasonographically observing the needlepoint, until the puncture needle is slightly inserted into the intended site.



7) Draw the aspiration piston until it is locked, while holding the outer barrel. Wait for more than three seconds until negative pressure becomes active at the tip.

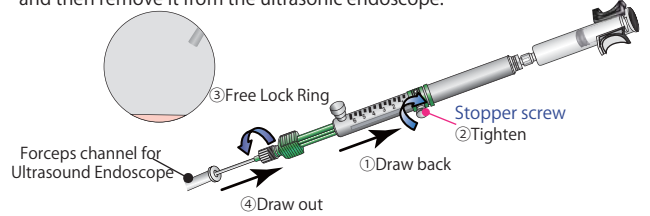


8) Quickly push forward the puncture needle to pass it through the intended site. Additionally puncture the intended site with the puncture needle several times.

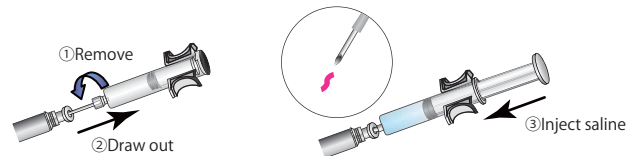


9) Draw back the puncture needle.

With the puncture needle housed completely, tighten the stopper screw to lock it, unlock the inner barrel locking ring, and then remove it from the ultrasonic endoscope.

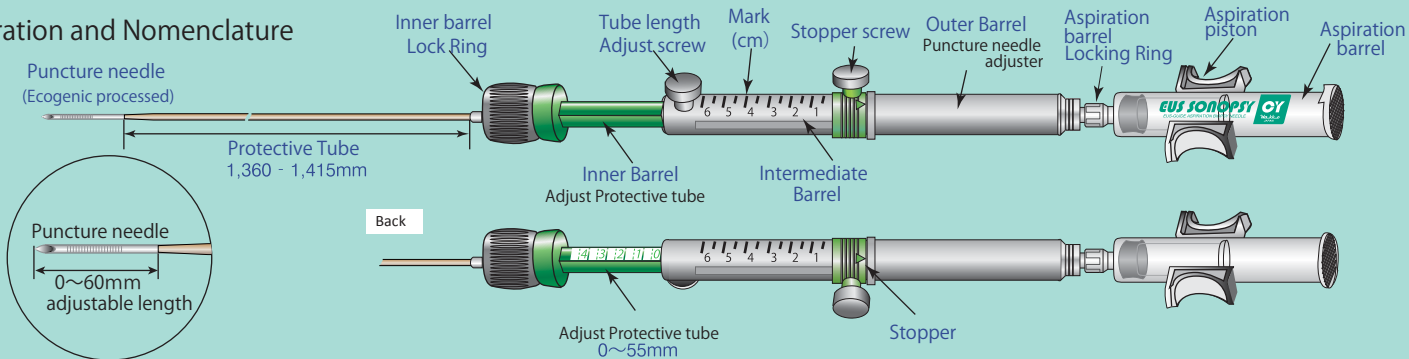


10) Remove the aspiration (tissue collection) barrel locking ring and remove the inner needle together with the aspiration barrel. Remove the outer puncture needle from the protective tube, attach a luer taper syringe to the outer barrel, and then push tissue pieces from the outer puncture needle with saline.



If the above procedure does not work, the following steps may improve the collection efficiency:
After 7), perform step 8) Move forward the puncture needle to pass it through the intended site while drawing back the aspiration piston. Wait for several seconds until the negative pressure is felt at the leading end. Additionally puncture the intended site several times. Perform step 10).

Illustration and Nomenclature



SPECIFICATIONS

Product Code	Puncture Needle	Protective Tube length	Package
22033110	0.8(21G)x0-60mm	φ 1.9x1,360-1,415mm	1 unit per Box, Peel package, Eto Sterilized