

Your Vision, Our Future

For Healthcare Professionals

Radial EBUS / Guide Sheath Bronchoscopy for Peripheral Pulmonary Lesions Handbook

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Supervising Doctors

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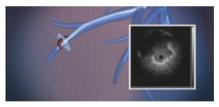
*This handbook is for your general knowledge and background only. Radial Endobronchial Ultrasound (EBUS) is to be performed according to standard technique and is left to the operator's experience and skills. Olympus makes no representations warranties or other expressed or implied warranties or guarantees regarding the accuracy, reliability or completeness of the information.

Introduction

Bronchoscopy using Radial EBUS probe with Guide Sheath (EBUS-GS) is a procedure for the bronchoscopist interested in finding an less invasive, more reliable method of reaching and sampling peripheral pulmonary lesions. The Guide Sheath (GS) functions as an extended working channel beyond the reach of a bronchoscope, through which devices can be exchanged in order to facilitate the convenient transfer of devices for repeated sampling of peripheral pulmonary lesions.

Features and Benefits

- EBUS-GS for sampling is a cost effective and minimally invasive procedure that provides adequate samples.
- 2 When used with the Radial EBUS probe, physicians can confirm the location of the lesion, and therefore ensure that the sample is being obtained directly from the target site.



- 3 Procedure time is reduced because securing the GS in place eliminates the need for the physician to relocate the lesion several times.
- 4 The GS minimizes tissue damage because devices are passed through the catheter, protecting the bronchial wall from damage caused by the devices rubbing against the epithelium.

Indications

EBUS-GS is used as a less invasive method for reaching and sampling peripheral pulmonary lesions in order to diagnose and stage various respiratory diseases including lung cancer.





- 1) Radial EBUS probe
- (2) Endoscopic ultrasound processor
- ③ Probe driving unit
- ④ Guide Sheath Kit
- (5) Bronchoscope

	Thin Guide Sheath Kit		Thick Guide Sheath Kit	
Model Number	K-201	K-202	K-203	K-204
Kit Content	Guide Sheath, Biopsy forceps, Cytology brush	Guide Sheath, Biopsy forceps	Guide Sheath, Biopsy forceps, Cytology brush	Guide Sheath, Biopsy forceps
Applicable Channel Diameter	φ2.0mm		φ2.6mm	
Guide Sheath Maximum Outer Diameter	φ1.95mm		φ2.55mm	
Applicable Probe	UM-S20-17S		UM-S20-20R	
Compatible Bronchoscope [#]	BF-P190 BF-MP160F BF-H190 BF-Q190 BF-P290 BF-P260F		BF-1TH190 BF-1TQ180 BF-1T180 BF-1TQ290	
	BF-H290 BF-Q290		BF-1T260	
Compatible Guiding Device	CC-6DR-1			
Compatible Ultrasound Imaging Equipment [#]	EU-ME2 EU-ME1 EU-M60 EU-M2000 * A probe driving unit (MAJ-1720/MAJ-935) is required.			

#: Some of these devices are only available in certain countries

★Thin Guide Sheath versus Thick Guide Sheath

There are two types of a Guide Sheath, a thin type and a thick type. Although, no evidence has yet been presented to clearly show which type is better; the thick Guide Sheath is capable of collecting larger tissue samples because this kit contains larger biopsy forceps. The forceps are equipped with a swing mechanism and have a larger cup size than the thin Guide Sheath.

3 Preparation

1) Preparing the Guide Sheath (GS)

- Insert the cytology brush, the biopsy forceps and the guiding device into the GS and position them as illustrated in <Fig. 1>. Next attach the ET stopper.
- ② Insert the Radial EBUS probe into the distal end of the GS so that the transducer at the tip of the probe extends from the distal end of the GS. Next, attach the US stopper.

<Fig. 1>

[Cytology Brush] Align the distal end of the GS with the distal end of the sheath of Brush.



[Biopsy forceps] With the cups of the biopsy forceps open, withdraw the forceps as close as possible to the edge of the sheath.

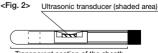


[Guiding Device] Extend the Guiding Device until the bending section of the second joint comes out of the sheath.



[Radial EBUS probe] Position the transducer at the distal end of the probe so that it extends from the distal end of the GS. * The position of the ultrasonic transducer is





Transparent section of the sheath

NOTE

- Use the US stopper for the Radial EBUS probe and insert the probe in the direction of the arrow in <Fig. 3>.
- It may be difficult to insert the Radial EBUS probe into the US stopper, due to resistance. If this occurs, place a piece of absorbent cotton, moistened with a disinfectant (ethanol), along the length of the Radial EBUS probe. This will ease the insertion of the probe.



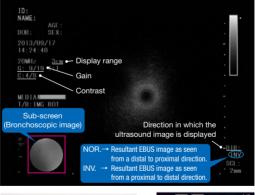
2) Setting up the ultrasound imaging equipment

Scan direction
Gain value
Contrast value
Picture quality (in EU-ME1)

INVERSE (INV) 9/19 4/8 Picture quality 1

NOTE

- Scan direction NORMAL refers to the image seen from the distal end of the probe towards the proximal section to allow a comparison between the EBUS images and the CT images. Under bronchoscopy, NORMAL should be switched to INVERSE. (Example: When the EBUS image is seen on the right side of the screen, the lesion is located on the right side.)
- It is also important to add a sub-screen on which to check the image of the lumen during bronchoscopy.

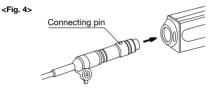




3) Connecting Radial EBUS probe

To connect the Radial EBUS probe to the Probe Driving Unit, hold the probe with the connecting pin facing up and insert the probe straight into the Probe Driving Unit **<Fig. 4>**.

(If the connecting pin is not facing up; there may be difficulty disconnecting the Radial EBUS probe from the Probe Driving Unit) Be sure to turn off the ultrasound imaging equipment when connecting and disconnecting the Radial EBUS probe.



4) Anesthesia

The EBUS-GS procedure can take longer than a regular bronchoscopy. Therefore, sufficient local anesthesia and sedation are needed.

* Reference: Examples of pre-procedure anesthesia, performed at National Cancer Center Hospital are shown below.

	Dr. Takehiro Izumo (National Cancer Center Hospital)		
	Trachea intubation not required. Procedure performed under local anesthesia with concomitant use of sedatives		
Preliminary medication	Pethidine hydrochloride (injection of 35 mg/1 mL of Opystan [®]) is injected intravenously. Injection quantities are shown below: Weight > 50 kg → 0.5 mL		
	Weight \leq 50 kg \rightarrow 0.25 mL Age > 80 years old \rightarrow 0.25 mL Age \leq 80 years old \rightarrow 0.5 mL		
Local anesthesia	Five milliliters of 4% lidocaine is sprayed using a pharyngeal spray to anesthetize the pharyngeal and laryngeal areas.		
Sedation	 Midazolam (Dormicum[®]) is diluted as follows: 1A (10 mg/2 mL) + 8 mL of saline = A total of 10 mL of dilute midazolam solution. 2-3 mL of the diluted solution will be injected intravenously. Injection quantities are shown below: 		
	Weight > 50 kg \rightarrow 3 mL Weight < 50 kg \rightarrow 2 mL Age > 80 years old \rightarrow 2 mL Age \leq 80 years old \rightarrow 3 mL		
During bronchoscopy	 If severe coughing occurs, 1-2 mL of 2% lidocaine is injected through the biopsy port of the bronchoscope, or an additional 1-2 mL of the midazolam solution diluted as shown above is injected intravenously. 		

4 Actual EBUS-GS Procedures

NOTE

Prior to inserting the GS, advance the bronchoscope as far as possible into the periphery. Slowly inject 5-8 mL of saline through the working channel. This will extend the bronchial lumen, facilitating insertion of the GS.

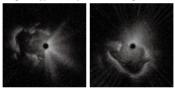
Note: If the lesion has a significant ground glass component, do not inject saline. Injecting saline can obscure the EBUS image of the lesion.

1) Leading the Guide Sheath to the targeted lesion

To access the lesion, insert the Radial EBUS probe into the GS and advance it into the bronchial tract. Lesion location should be determined by plain chest radiograph, fluoroscopy, CT and virtual bronchoscopy.

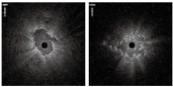
2) Actual EBUS images

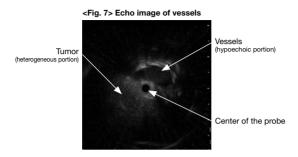
FREEZE the ultrasonic transducer during the insertion process. Once the position of the probe within the lesion is confirmed by fluoroscopy, release the FREEZE button. Maneuver the probe and GS as an entity during the scanning process. (Record the EBUS image that best depicts the internal structure of the lesion.) Thereafter, while observing the EBUS image, retract the probe and GS slightly until the size of the cross-sectional view of the lesion becomes smaller.





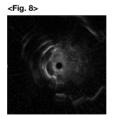






3) Distortion in the probe image

If the probe transducer touches or gets caught in the pleural membranes and bronchial walls, the EBUS images can appear distorted **<Fig. 8>**. If this occurs, avoid applying too much force when advancing the probe, as this may damage it.



NOTE

Problems may arise if Radial EBUS probe cannot be inserted into the targeted lesion. Below are possible solutions:

- Select a different bronchial branch to insert the probe into under direct bronchoscopic view.
- ② Select a different bronchial branch to insert the probe into under x-ray fluoroscopy.

If the probe is not within the lesion, adjust the bronchoscope tip towards the target using the UP/DOWN lever and withdraw the probe. Thereafter, advance the probe while maintaining the same angle on the UP/DOWN lever. This will allow the probe tip to move towards the lesion.

③ Select a different bronchial branch to insert the probe into under ultrasound image.

If the probe is adjacent to the lesion as seen on EBUS image, use the UP/DOWN lever to check which angle will bring the probe closer to the lesion. Withdraw the probe and advance it while maintaining the same angle on the UP/DOWN lever. This will allow the probe tip to move towards the lesion.

④ Use a Guiding Device

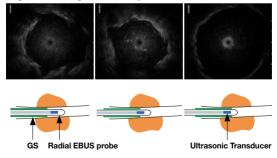
When solutions ① through ③ fail to lead the probe into the lesion, use the Guiding Device (CC-6DR-1). Remove the probe without moving the GS and insert the Guiding Device until it extends from the distal end of the GS. Rotate and angulate the tip of the Guiding Device toward the direction of the lesion. (The trick is to bend the tip lightly. Bending the tip severely can damage the bronchial wall.) Then withdraw the Guiding Device slowly. If there is a bifurcation along the way, the tip of the Guiding Device will enter the desired bronchial branch. The Guiding Device can then be successfully inserted into the lesion. Advance the GS along the Guiding Device towards the lesion. Remove the Guiding Device and re-insert Radial EBUS probe into the GS to check if the probe has been successfully inserted into the lesion on the EBUS image.

4) Positioning the GS

While observing the lesion in the EBUS images, withdraw the GS slightly up to the proximal side of the lesion, where the size of the cross-sectional view of the lesion becomes smaller.

Then, the assistant slowly advances and retracts the probe while the operator keeps the GS in position. As the assistant advances and retracts the probe, the EBUS images will change as follows: When the entire transducer is retracted into the GS, ultrasound is attenuated by being reflected from the GS, so that the brightness of the EBUS images is reduced. When the transducer is advanced back into the lesion, the EBUS image will return. This phenomenon will confirm that the GS is successfully placed within the lesion <**Fig. 9**.

During the procedure, memorize where the marker of the GS tip is located under x-ray fluoroscopy.



<Fig. 9> EBUS image attenuated by GS reflection

5) Collecting cells / tissues

Insert the cytology brush and biopsy forceps into the GS, until they reach the position of the ET stopper. Usually, the biopsy procedure is repeated, until approximately 5 specimens are collected.

Cytology brush

The assistant pushes the brush along the GS until it extends into the lesion, and scrapes the area distal to the tip of the GS. The assistant may face slight resistance during insertion of the brush. If the lesion is located directly below the pleural membranes, extra care should be taken not to push the brush too far out.

Biopsy forceps

Ideally, the cups of the forceps should be open without moving the GS. If the cups are not open, the operator must make slight jabbing movements with the forceps until the cups open under fluoroscopy. Once the cups are open the forceps are pushed against the lesion. The cups are then closed while feeling the solid presence of tissue.

NOTE

When removing the cytology brush and biopsy forceps from the GS, hold the GS joint and sheath section together as shown in the picture **<Fig. 10>**. Otherwise the GS may become kinked making it difficult to insert devices.

<Fig. 10>



6) Processing Samples

*This is the example of processing samples, peformed at National Cancer Center Hospital.

- Before starting the procedure, prepare the materials for specimen collection:
 - a) For cytology examination
 - glass slides 1)
 - glass slide container with 95-97% ethanol for wet fixation for Papanicolaou stain (2)
 - vial with saline for rinsing of brush and forceps (3)
 - empty vial for flush out of the GS material ④
 - syringe with 3 mL saline and empty vial for GS flushing (5)
 - b) For histology examination
 - small pieces of white filter paper (6)
 - pick up forceps 7
 - vials with formalin (8)



(2) Push the brush out of its sheath and smear on two glass slides <Fig. 11>. While still wet, immediately soak one slide preparation in the container with ethanol (wet fixation for Papanicolaou stain) <Fig. 12>. The other slide preparation is allowed to dry for Romanowsky stain (Diff-Quik) for rapid on-site cytology evaluation (ROSE) <Fig. 13>. Rinse off the remaining cells in the brush in the vial with 3 mL saline <Fig. 14>. This can then be sent as liquid cytology sample.



③ Open the biopsy forceps cup and transfer the collected specimen onto a white filter paper <Fig. 15, 16> before placing it in the vial with formalin <Fig. 17>. For cases that need imprint cytology examination, stamp the specimen on two glass slides for wet and dry fixation <Fig. 18> before placing the specimen in formalin. Again, rinse off the remaining cells in the biopsy forceps cup in the same vial with 3 mL saline that was used for brush rinsing <Fig. 19>.



④ Flush out the GS material into an empty vial using the syringe with 3mL saline <Fig. 20>. It may be necessary to push some air through the syringe to collect all the remaining fluid in the GS <Fig. 21>.





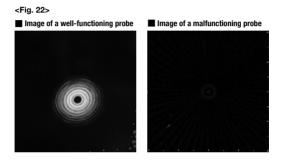


7) Removing the GS

If bleeding occurs, leave the sheath at the biopsy site for a few minutes (approximately 2 minutes). This will act as a pressure hemostasis. After leaving it for a few minutes, remove the GS and confirm that the bleeding has stopped. After removing the sheath, use saline to flush the cells left inside the GS and submit the solution for cytology and bacteriological examination.

5 Handling Radial EBUS probe

There may be instances when an EBUS image cannot be obtained despite the probe being connected to the imaging system and the ultrasonic transducer turned on **<Fig. 22>**. This may be caused by a breakage in the probe or by air bubbles left in the probe. The method for removing air bubbles is shown below:



1) Removing air bubbles from the Radial EBUS probe

Check that there are no air bubbles in the transparent section of the probe. If air bubbles are present around the transducer **<Fig. 23>**, removing the air bubbles can improve the EBUS image quality.

<Fig. 23> Checking for the presence of air bubbles



Transparent section of the sheath

Removing air bubbles

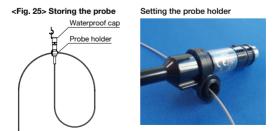
Hold the probe 5 cm away from the tip. With the probe tip facing down, and protected by the index finger, shake the probe vigorously until all of the air bubbles disappear from the transparent section of the probe **<Fig. 24>**. Connect the Radial EBUS probe again and check to see that the EBUS image has been restored to its original round shape.

<Fig. 24> Removing air bubbles



2) Storing the Radial EBUS probe

Store the Radial EBUS probe with the probe tip facing down as shown in **<Fig. 25>**. This will help prevent air bubbles from entering the periphery of the transducer.



List of Product Names/ Models

Single Use Guide Sheath Kit K-201, K-202, K-203, K-204 Guiding Device CC-6DR-1 ULTRASONIC PROBE UM-S20-17S, UM-S20-20R EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-P190, BF-Q190, BF-H190, BF-1TH190 EVIS LUCERA ELITE BRONCHOVIDEOSCOPE 0F-P290, BF-Q290, BF-H290, BF-1TQ290 EVIS EXERAII BRONCHOVIDEOSCOPE BF-P17180, BF-1TQ180 EVIS EXERAI BRONCHOVIDEOSCOPE OLYMPUS BF TYPE MP160F EVIS LUCERA BRONCHOFIBERVIDEOSCOPE OLYMPUS BF TYPE MP160F EVIS LUCERA BRONCHOFIBERVIDEOSCOPE OLYMPUS BF TYPE P260F EVIS LUCERA BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 17260 EVIS LUCERA BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 17260 EVIS EUS ENDOSCOPIC ULTRASOUND CENTER OLYMPUS EU-ME2 UNIVERSAL ENDOSCOPIC ULTRASOUND CENTER OLYMPUS EU-ME1 EUS EXERA ENDOSCOPIC ULTRASOUND CENTER OLYMPUS EU-M60 ENDOECHO ENDOSCOPIC ULTRASOUND CENTER EU-M2000 PROBE DRIVING UNIT MAJ-1720, MAJ-935

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