

Ultrasonic Bronchoscopy Simulator Compatible with EBUS-TBNA

LM-099

Instruction Manual

Thank you for purchasing the LM-099 Ultrasonic Bronchoscopy Simulator.
Please read this instruction manual carefully to ensure correct use of the product,
and store it in a safe place for easy access.

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Handling and Safety Precautions

These precautions should be strictly observed in order to ensure safe, long-term use of the product.

The following precautions should be observed particularly strictly:

1. The simulator is made with special silicone rubber to simulate the texture of human skin, so we recommend that it be handled carefully in the same manner as an actual person.
2. Do not place objects directly on the main body of the bronchi, as doing so may alter its shape.
3. Do not use organic solvents such as thinners or benzene on the simulator, as they may cause discoloration or alter its shape.
4. Do not use oil-based inks or dyes on the simulator, as they may cause permanent staining.
5. When transporting the simulator in the provided black case, please ensure that all components are placed in their designated position in the sponge case. Be careful not to tilt the case or subject it to strong impacts to prevent damage to the simulator and the case.
6. Lubricant (silicone spray) is not included in the kit. Follow the precautions below for use.
 - Use only silicone oil-type aerosol lubricant (silicone spray). Using grease or a spray that contains oil other than silicone oil may damage the model.
 - Before proceeding with use, spray a small amount of the pre-prepared lubricant (silicone spray) on the neck skin and other parts that do not impede functioning of the model and confirm that there are no problems.



Handling and Safety Precautions

These precautions should be strictly observed in order to ensure safe, long-term use of the product.

Caring for the simulator after use

1. To clean the simulator and the inside of the case (except the sponge case), wipe with a piece of gauze or soft cloth soaked in water or a mild detergent diluted with water.
2. Prolonged exposure to sunlight or UV may alter the simulator's shape or cause discoloration. When not in use, place the simulator in the designated position inside the case, close the lid, and store on a flat surface away from sunlight and UV.
3. When the puncture site is not in use, wrap it in paper towel or other soft paper material and store it inside the resealable polypropylene bag provided.

1. The contents of this instruction manual are subject to change without notice.
2. This instruction manual may not be reproduced in part or in its entirety without permission.
3. Please contact the manufacturer in the event that any errors or omissions are found in the contents of this instruction manual.
4. This product should be used only as described in this instruction manual. In particular, the product should not be used in any way that contravenes the precautions noted in the instruction manual.

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1. Description and Features

Description

This simulator can be used not only for conventional ultrathin bronchoscope insertion training, but also for endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) training.

Features

1. This simulator enables practical training for endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA), in which the target lymph node is punctured while visualizing ultrasonic bronchoscopy images of lymph nodes embedded in the puncture site. In addition, because the sensation of touching the puncture site and cartilage with an endoscope has been closely reproduced, it is also possible to conduct practical training using the external cylinder method.
2. The ultrathin structures of the bronchi in the bronchi main body were reproduced using a special manufacturing method, including the 5th order bronchi (e.g., B₁ai α). Ultrathin bronchoscopes can be inserted up to the 5th order bronchi.
3. A head model is attached, enabling insertion of the ultrasonic bronchoscope from the oral cavity and confirmation of the bifurcation of the bronchi and esophagus.
4. The bronchi main body and the bronchi-support stand can be easily removed from the case.
5. The peripheral parts of the three-dimensional bronchi can be fully opened, and easily washed with water following endoscope insertion training.
6. The material used is a special silicone rubber. Its elasticity confers a human body-like texture when inserting the bronchoscope. The inside of the bronchi is also similar in color to the human body.

*The external cylinder method:

This is a method in which a puncture is made by first pushing the external cylinder of the puncture needle against the bronchial wall immediately before puncture, and then advancing the entire bronchoscope back and forth and fitting the tip of the external cylinder of the puncture needle into the depressed region between the cartilages. This method is expected to further improve the diagnostic yield by enabling reliable tissue collection while avoiding cartilage puncture.

Takeo Inoue, Noriaki Kurimoto, et al.

New Technique for Endobronchial Ultrasound-guided Transbronchial Needle Aspiration to Improve Diagnostic Yield

J Bronchol Intervent Pulmonol 2013; 20: 28-32

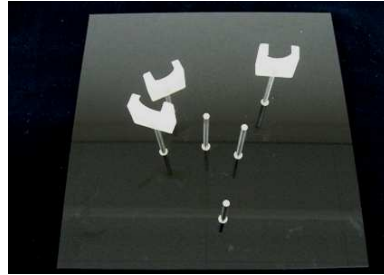
*Caution

- During the production process, small bubbles and chips may form at the bronchial bifurcation; these cannot be repaired.
- The material used for molding in the manufacturing process may remain in the bronchial unit. In this case, use your fingers to massage the bronchus and then rinse off the remaining material.

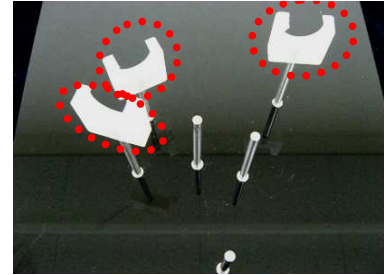
2. Components and Configuration



Black case (with sponge case)



Stand



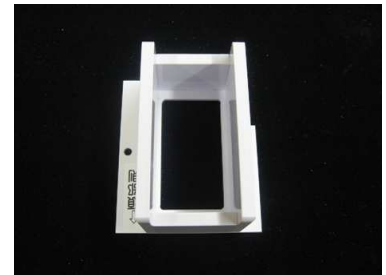
Bronchi supporter (3 ×)



Head model
(with mounting hook and positioning lever)



Bronchi unit



Puncture site box



Bronchi/puncture site box holder



M3 × 8 truss head screw (2 ×)

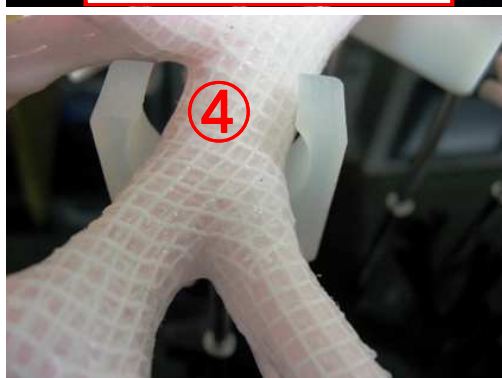
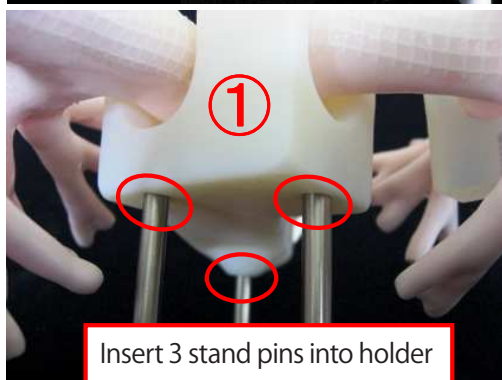
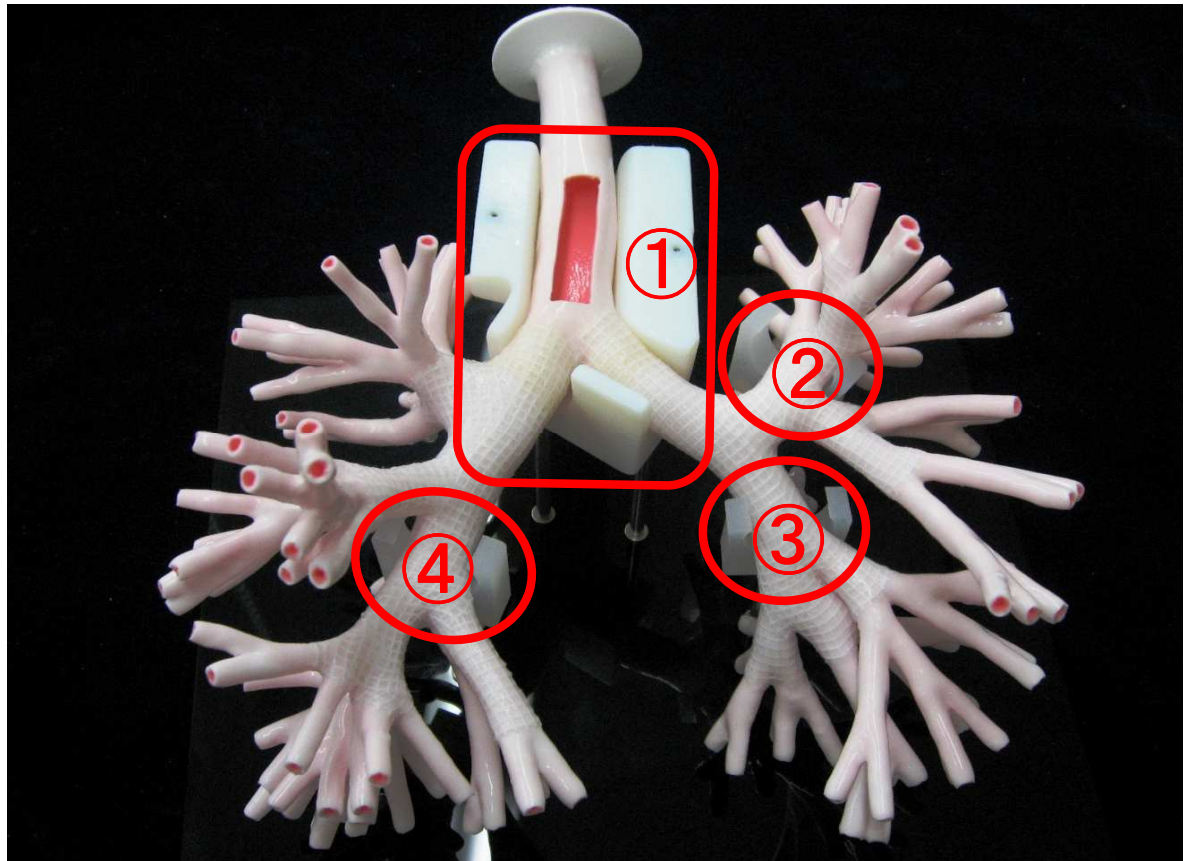
Consumable items



Puncture site

1) Bronchi supporter & bronchi/ puncture site box holder attachment positions

* See step 12 of '2) Caring for the simulator after use' on page 15 for details on how to attach the bronchi/puncture site box holder.



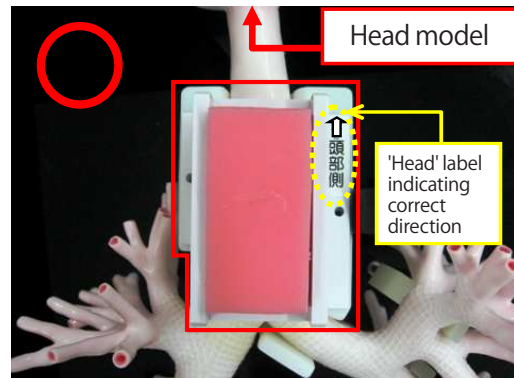
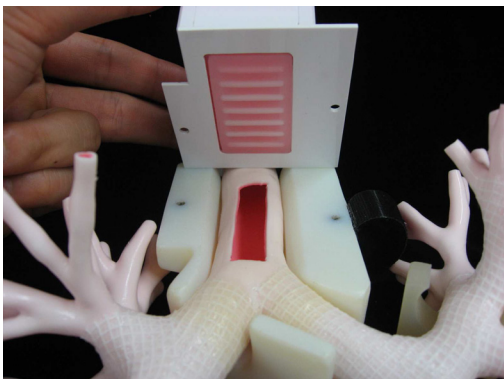
2) Puncture site and puncture site box attachment positions

* See step 13 of '2) Caring for the simulator after use' on page 16 for details on how to attach the bronchi/puncture site box holder.



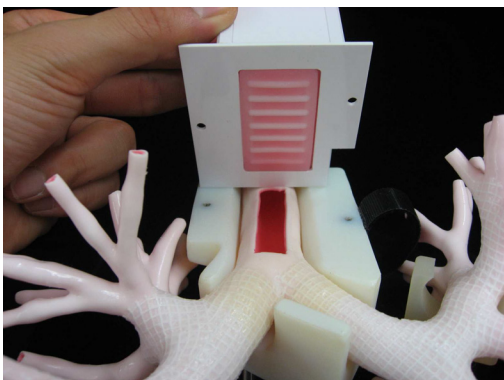
Correct attachment position

* The puncture site box is mounted on the bronchi/puncture site box holder so that the respective shapes align and the 'Head' label points in the direction of the head model.



Incorrect attachment position

* If the puncture site box is mounted on the bronchi/puncture site box holder with the 'Head' label pointing away from the head model and their respective shapes not in alignment, the puncture site will not appear at its correct position during bronchoscope insertion.



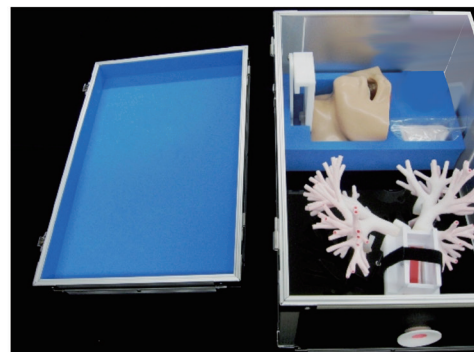
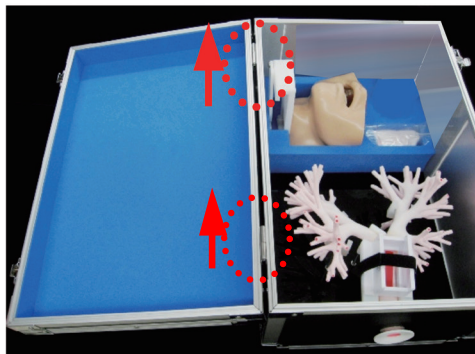
3. Handling the simulator

1) Setting up the simulator

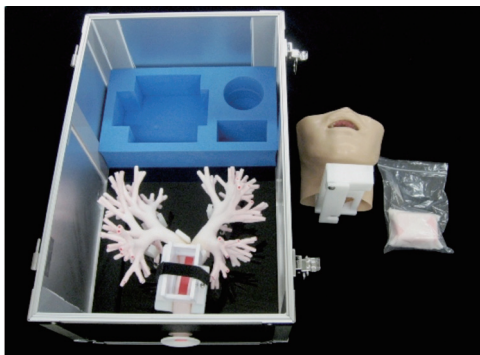
* Before inserting a bronchoscope into the simulator, spray the inside of the bronchi and the oral cavity of the head model with the lubricating silicone spray.

* Lubricant (silicone spray) is not included in the kit. Prepare lubricant in advance, referring to the precautions.

(1) Open the case and remove the lid by sliding it in the direction indicated by the arrows.



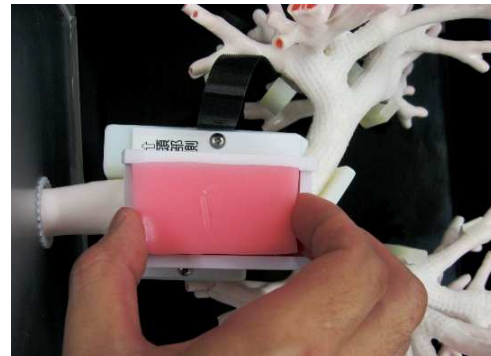
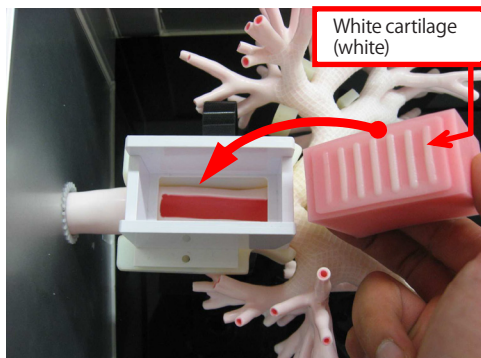
(2) Remove the head model and puncture site from the sponge case.



(3) Remove the puncture site from the resealable polypropylene bag.

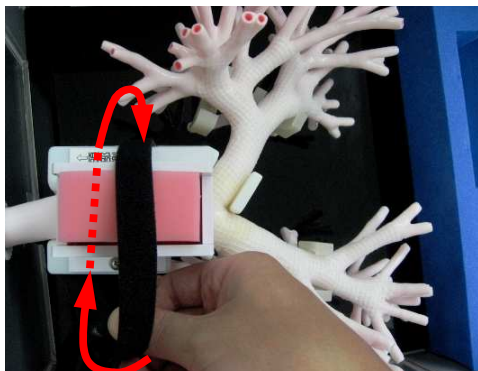


(4) Remove the Velcro tape securing the bronchi/puncture site box holder and place the puncture site in the puncture site box so that the white cartilage side is facing downwards.

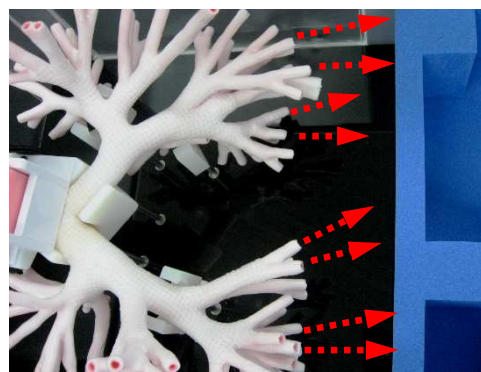


(5) Lightly secure the puncture site by wrapping the Velcro tape around the bronchi/puncture site box holder and fastening it underneath.

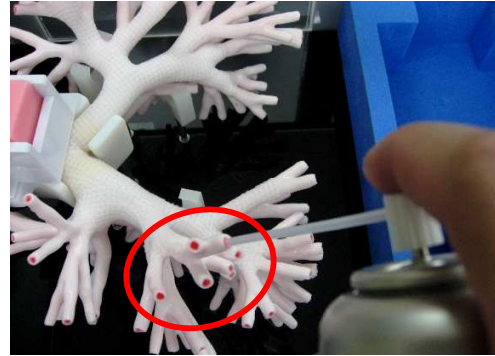
* Securing the Velcro tape too firmly may alter the shape of the puncture site and cause the model lymph nodes to appear oval-shaped instead of circular in ultrasonic images.



(6) Insert the nozzle of the silicone spray into the bronchi main body via the bronchoscope insertion slot and spray until the silicone aerosol can be seen emitting from openings of the peripheral parts of the bronchi.



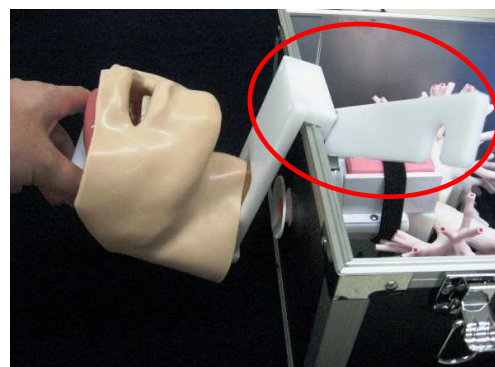
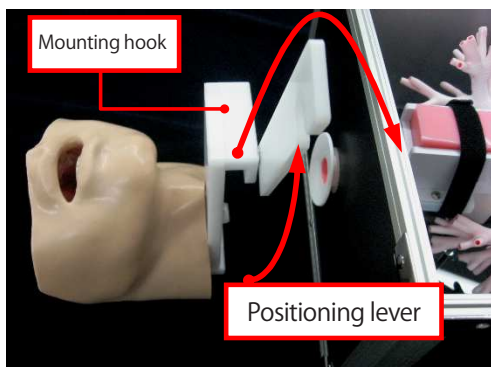
(7) The silicone spray may not reach the upward-facing peripheral parts of the bronchi when applied via the bronchoscope insertion slot, in which case you can also insert the spray nozzle directly into the individual openings of the peripheral parts of the bronchi.



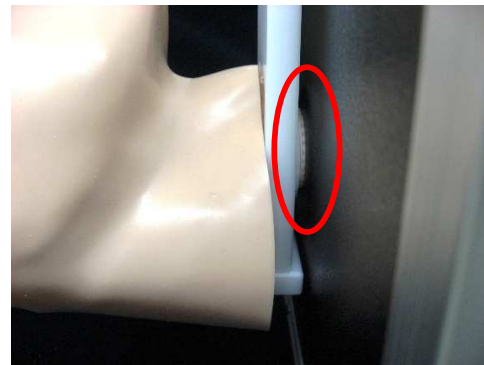
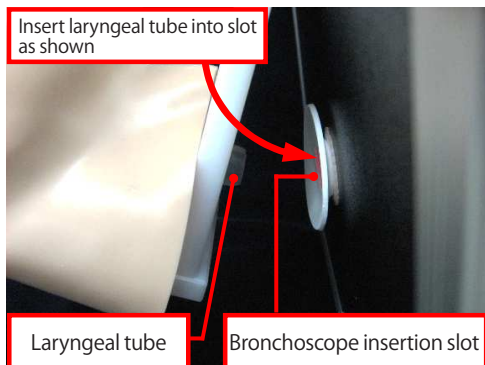
(8) Apply the silicone spray to the oral cavity and larynx of the head model.



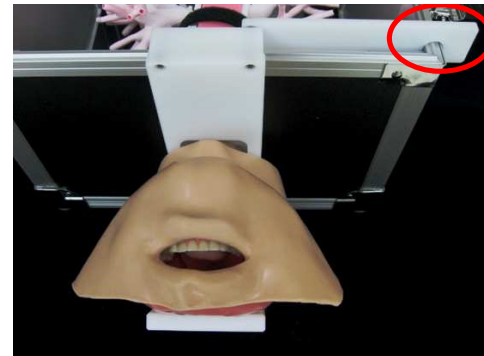
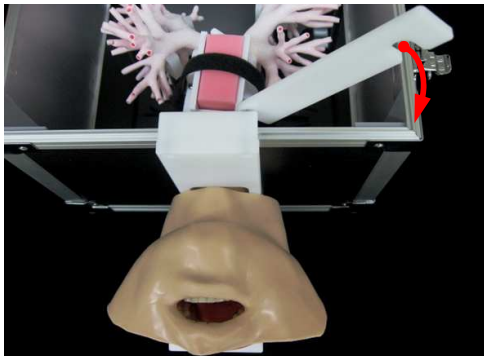
(9) With the positioning lever facing upwards, place the mounting hook of the head model over the bronchoscope insertion slot-side of the case so that it hangs slightly diagonally.



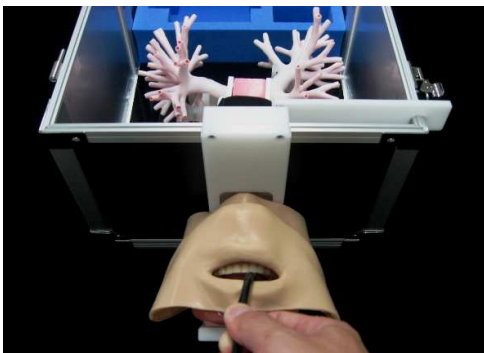
(10) Align the laryngeal tube of the head model with the bronchoscope insertion slot on the bronchi side and then insert the tube into the slot.



(11) Slide the positioning lever downwards over the side of the case to secure the head model.



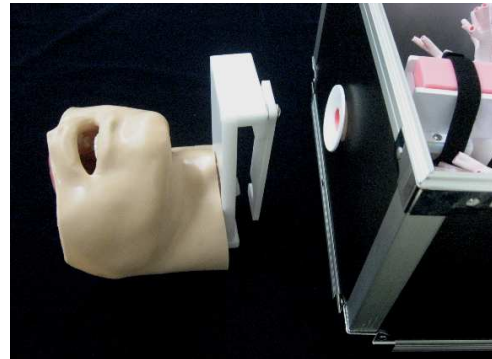
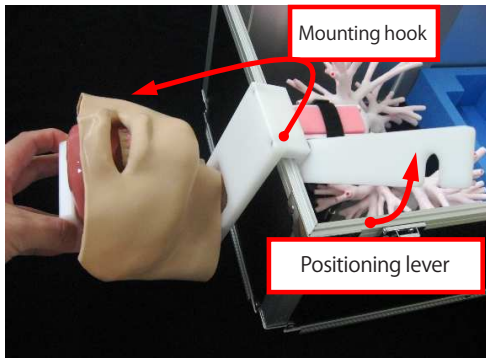
(12) The simulator is now ready for use.



2) Caring for the simulator after use

To clean the bronchi main body, follow the instructions provided below.

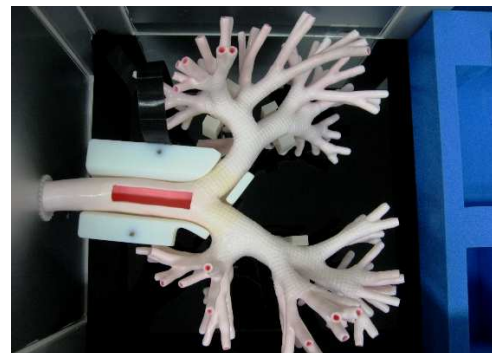
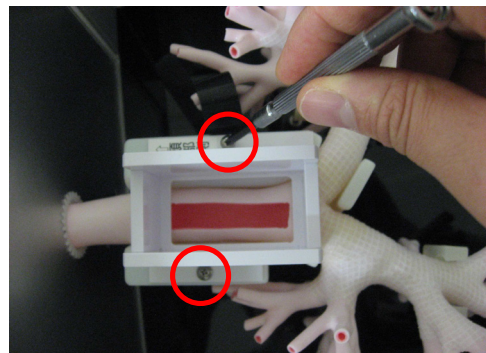
(1) Detach the head model from the case by raising the positioning lever and lifting the mounting hook diagonally upwards.



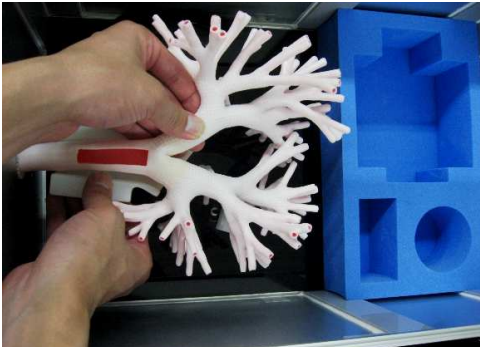
(2) Remove the Velcro tape from the bronchi/puncture site box holder.



(3) Remove the puncture site and undo the two screws (circled in red) securing the puncture site box to the bronchi/puncture site box holder using a screwdriver.

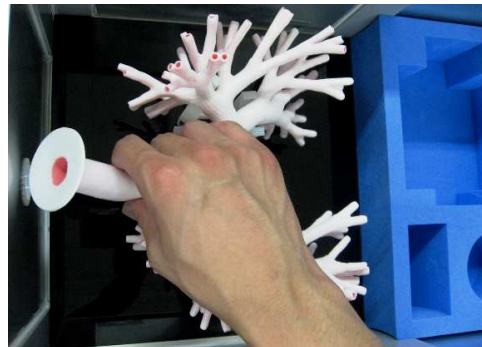
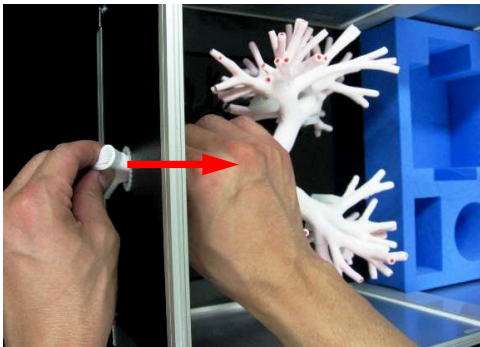


(4) Remove the bronchi main body from the supporters and, with the unit slightly raised, lift out the bronchi/puncture site box holder.



(5) Pinch the outer rim of the bronchoscope insertion slot for the main body of the bronchi between your fingers and push it inwards through the hole on the case.

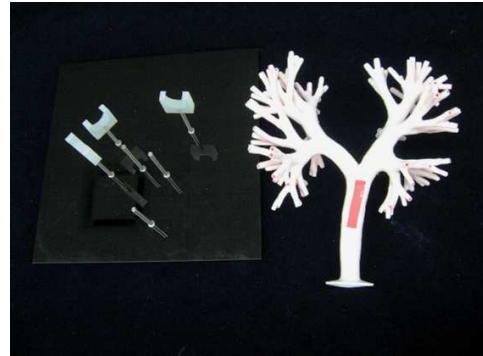
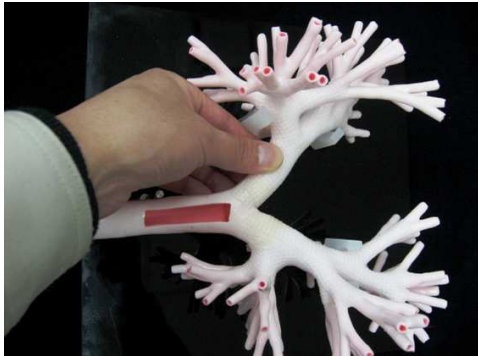
* Do not use excessive force when removing the bronchi main body from the case to avoid damaging it.



(6) Remove the bronchi main body from the case together with the stand.

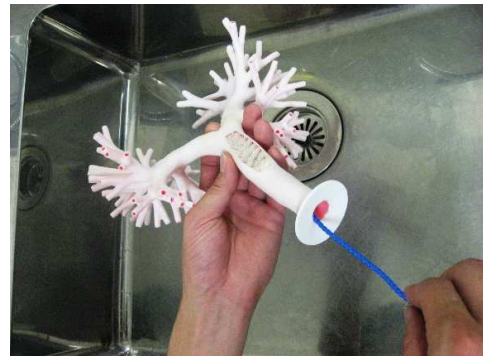


(7) Detach the main body of the bronchi from the bronchi supporters of the stand.



(8) Clean the inside of the bronchi main body with a mild detergent using a test tube brush, etc.

* Do not attempt to force the cleaning brush too far inside the bronchi main body to avoid damaging the unit.



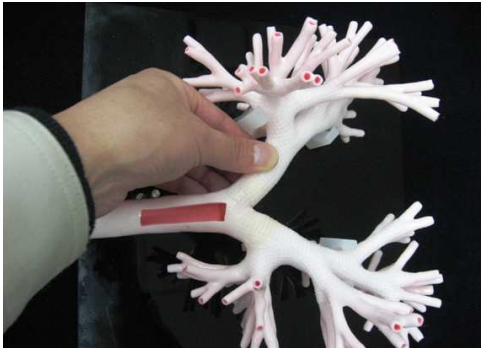
(9) While softly massaging the main body of the bronchi, hold the bronchoscope insertion slot under running water to rinse the parts of the main body of the bronchi that could not be reached with the cleaning brush, then wipe the main body of the bronchi dry. Gently shake the unit to remove water from inside the bronchi, then allow it to dry in a location away from direct sunlight.

* Please refrain from using your finger nails when massaging the bronchi during cleaning, as splits or cracks in the silicone rubber may cause the simulator to malfunction.

* Make sure that the main body of the bronchi has dried properly, as residual moisture may cause mold to form inside the bronchi.

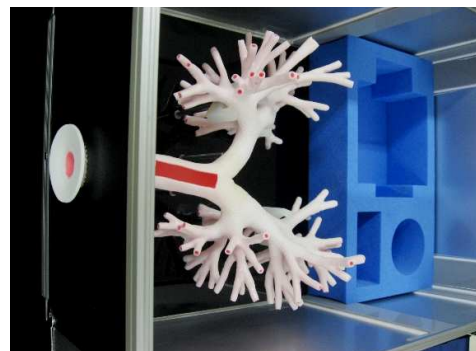
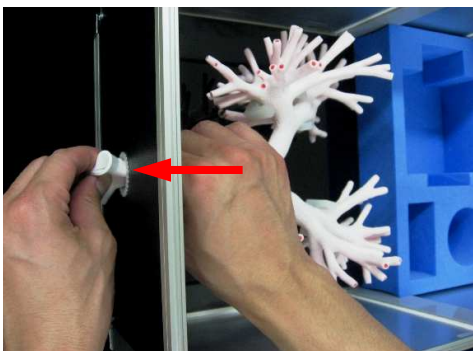


(10) Reattach the main body of the bronchi to the bronchi supporters of the stand.



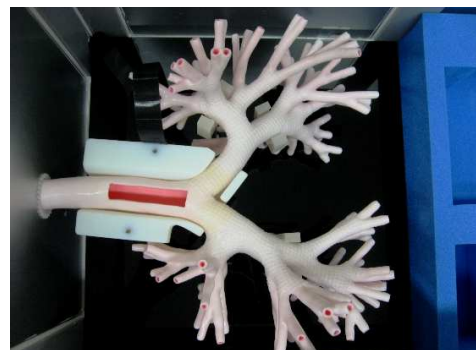
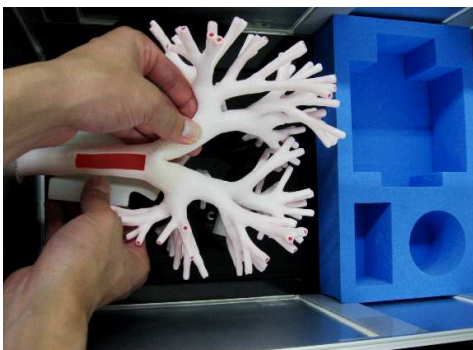
(11) Place the stand and main body of the bronchi inside the case and push the outer rim of the bronchoscope insertion slot for the main body of the bronchi through the hole on the inside of the case.

* Do not use excessive force to avoid damaging the main body of the bronchi.



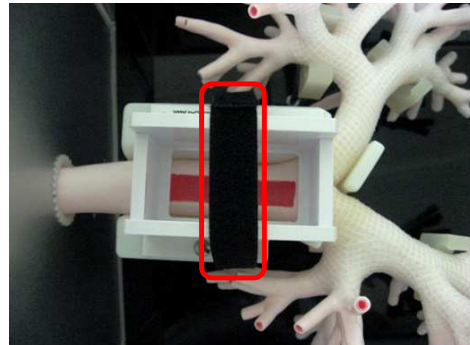
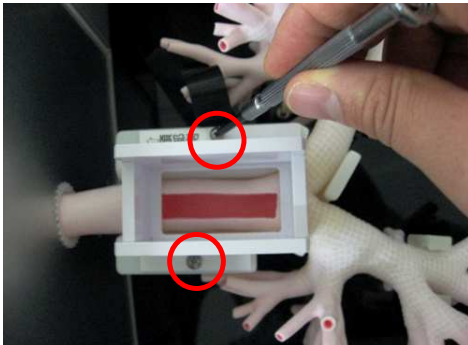
(12) Detach the main body of the bronchi from the supporters and, with the main body slightly raised, secure the bronchi/puncture site box holder underneath the main body of the bronchi, then reattach the main body to the supporters.

* See '1) Bronchi supporter & bronchi/puncture site box holder attachment positions' on page 6 for instructions on positions to attach the main body of the bronchi and holder.



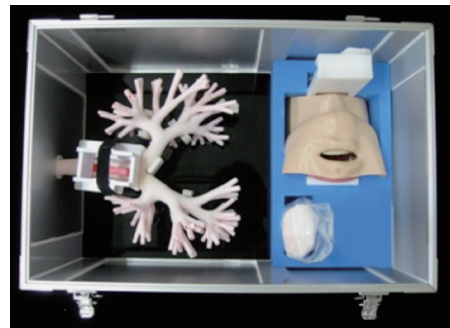
(13) Place the puncture site box on the bronchi/puncture site box holder, insert the two screws (circled in red) using a screwdriver, and secure with the Velcro tape.

* See '2) Puncture site and puncture site box attachment positions' on page 7 for instructions on positions to mount the puncture site box.

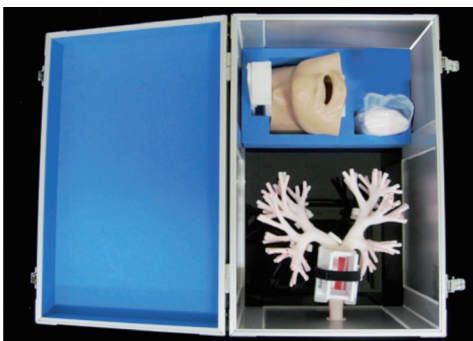


(14) Wrap the puncture site in paper towel or other soft paper material and place it inside the resealable polypropylene bag. Place the puncture site in the case's sponge case, along with the head model.

* Place the head model in the sponge case in the same direction as the photo below. Incorrect placement may cause damage to the head model or sponge case.



(15) Reattach the lid to the case and store on a flat surface away from sunlight and UV.



4. Model Configuration Chart

Product name	Quantity
Bronchi main body	1
Black case (with sponge case)	1
Stand	1
Bronchi supporters	3
Head model	1
Puncture site	1
Puncture site box	1
Bronchi/puncture site box holder	1
M3 × 8 mm truss head screws	2
Instruction manual	1

Consumable items

Product name	Product No.
Puncture site for ultrasonic bronchoscopy (2 ×)	LM-099A

5. Specifications

Product name	Length	Width	Height	Weight
Bronchi main body	Approx. 25 cm	Approx. 24 cm	Approx. 16 cm	Approx. 200 g
Black case (includes stand, bronchi supporters & sponge case)	Approx. 32 cm	Approx. 46 cm	Approx. 27 cm	Approx. 3.6 kg
Head model	Approx. 17 cm	Approx. 16 cm	Approx. 15 cm	Approx. 700 g
Puncture site	Approx. 3 cm	Approx. 6 cm	Approx. 4 cm	Approx. 100 g