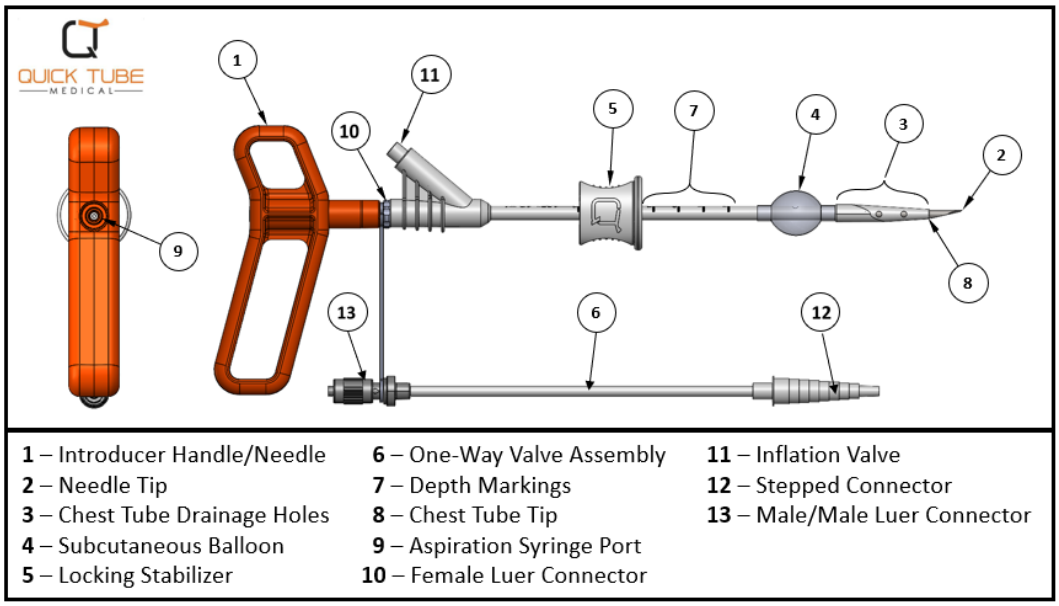
# Chest Tube Kit – 16Fr




| | | |
|---|---|---|
| **1** – Introducer Handle/Needle | **6** – One-Way Valve Assembly | **11** – Inflation Valve |
| **2** – Needle Tip | **7** – Depth Markings | **12** – Stepped Connector |
| **3** – Chest Tube Drainage Holes | **8** – Chest Tube Tip | **13** – Male/Male Luer Connector |
| **4** – Subcutaneous Balloon | **9** – Aspiration Syringe Port | |
| **5** – Locking Stabilizer | **10** – Female Luer Connector | |

**Figure 1: QT Chest Tube Kit**

Note: Two (2) 10ml syringes are included, but not shown.

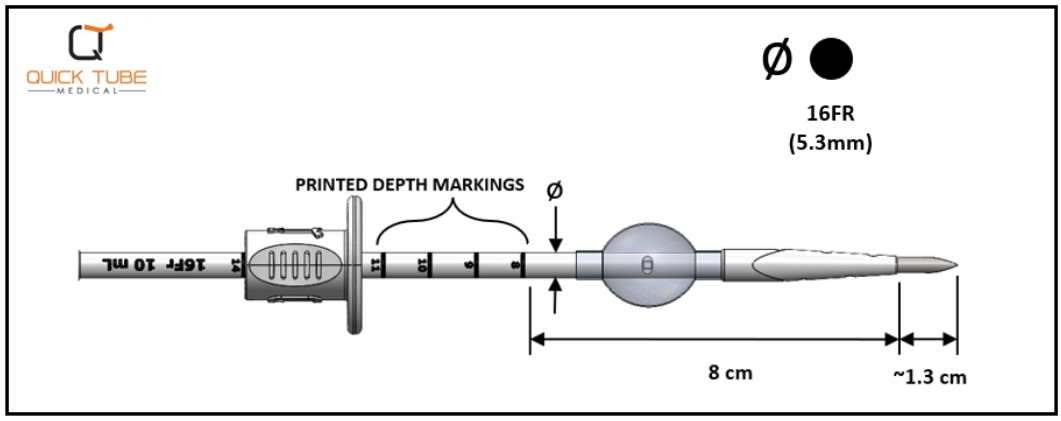



**Figure 2: QT Chest Tube Dimensions (Not to Scale)**

Note: The numbers on the chest tube shaft indicate the distance from the distal tip of the chest tube, measured in centimeters. The tip of the needle extends approximately 1.3 cm beyond the distal tip of the chest tube.

**CONTENTS OF PACKAGE:**

- (1) QT Chest Tube and delivery system
- (2) 10mL syringe

**CAUTION**

Federal (USA) Law restricts this device to sale by or on the order of a physician.

Do not use on pregnant or lactating patients.

**DEVICE DESCRIPTION**

The QT Chest Tube Kit (Figure 1) is a sterile, single use chest tube and delivery system. The Introducer Handle ① contains a sharp, beveled needle tip ② that allows percutaneous introduction of the chest tube to the pleural cavity without the need of a scalpel incision. After placement of the chest tube, the Introducer Handle/Needle is withdrawn and a subcutaneous balloon ④ is inflated. A Locking stabilizer ⑤ slides forward to secure the chest tube in place without the need for sutures. A one-way valve assembly ⑥ is then placed in line with, and is secured to, the chest tube. A commercially available suction device may be attached, if desired.

The QT Chest Tube is available in 16FR. Physicians should ensure the size of the device is appropriate for the specific procedure and patient. Printed graduation marks ⑦, measured in centimeters, indicate distance as measured from the distal tip of the chest tube ⑧ (see Figure 2.)

The patient contacting portions of the QT Chest Tube are constructed of radiopaque Pebax and Pellethane. The QT Chest Tube Kit does not contain Di-ethylhexyl phlalate (DEHP) or latex.

**INTENDED USE / INDICATIONS FOR USE**

The QT Chest Tube Kit is intended for percutaneous introduction and placement of the QT Chest Tube for the evacuation of air and/or fluids from the chest cavity such as may occur with pneumothorax, hemothorax, chylothorax, pleural effusion, or empyema.

**CONTRAINDICATIONS**

Relative contraindications to chest tube use may include pulmonary adhesions, lack of a pleural space, and hematologic abnormalities such as bleeding diatheses or coagulopathy.

**WARNING**

- Do not use after expiration date.
- Upon removal from package, inspect the product to ensure no damage has occurred. Do not use if the package is open or damaged.
- For single patient 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.

**PRECAUTIONS**

- This product is intended for use by physicians trained and experienced in the treatment of conditions requiring chest tube placement. Standard universal precautions for placement of chest tubes should be employed.
- Care should be taken during insertion, fixation and removal of the chest tube. Lung puncture may result in an air embolus, which could lead to ischemia or infarction of major organs, including the brain or cardiac system.
- The drainage holes on the distal portion of the chest tube must remain inside the thoracic cavity at all times during patient use.

**HOW SUPPLIED**

Supplied sterilized by ethylene oxide gas in peel-open packages. Intended for one-time use. Sterile if package is unopened or undamaged.

**HANDLING AND STORAGE**

Store in a dark, dry, cool place. Avoid extended exposure to light.

**DEVICE PREPARATION AND USE**

1. Prep, drape and sterilize the access site. The standard insertion site is the fourth intercostal space at the mid-axillary line.
2. Introduce a local anesthetic through the skin and subcutaneous tissue down to the pleura. ***Anesthesia may be omitted in an emergency decompression.***
3. Attach one (1) of the included (10 mL, not shown) syringes to the Aspiration Syringe Port ⑨ located in the Introducer Handle/Needle ①.
4. Remove the plastic needle tip protector (not shown) to expose the sharp, beveled needle tip ②.
5. Use the Introducer Handle to guide the needle tip through the skin, over the rib and into the pleural space.
6. The Depth Markings on the chest tube (per Figure 2) can be utilized to assist in controlling and confirming insertion depth.
7. Once inserted into the pleural space, begin pulling back on the plunger of the syringe attached to the Introducer Handle to aspirate air or fluid from the pleural space.
8. Once aspiration has occurred, and the tip of the chest tube is confirmed to be within the pleural space, remove syringe from Introducer handle.
9. While gripping the hub of the chest tube with one hand, rotate the Introducer Handle ① counter-clockwise with the opposite hand to disengage the Introducer Handle ① from the Luer fitting ⑩.
10. Withdraw the Introducer Handle/Needle ① until the needle fully exits the chest tube. NOTE: A small amount of resistance upon rotation or withdrawal is expected. If significant resistance is felt during rotation or withdrawal, release the introducer handle to relax any tension or torque on the needle, rotate the needle in the opposite direction (being sure not to re-engage with the luer on the proximal end of the catheter), confirm the needle rotates freely inside the catheter, then withdraw.
11. Fill the second (10 mL) syringe with 10 mL of air. Firmly attach this air-filled syringe to the Inflation Valve ⑪ and inflate the Subcutaneous Balloon ④ with 10 mL of air. While maintaining pressure on the plunger of the syringe, quickly remove the syringe from the inflation valve. Gently pull back on the chest tube to confirm that the balloon is holding the chest tube in place within the pleural cavity.
12. Place petrolatum gauze around the insertion site, between the Locking Stabilizer and the patient's skin.
13. Pinch the contoured, ribbed sides of the Locking Stabilizer ⑤ to unlock it. Position the Locking Stabilizer firmly against the petrolatum gauze and release the Locking Stabilizer to secure the chest tube in place.
14. Position the One-Way Valve Assembly ⑥ in-line with the chest tube and secure the parts together by connecting the Male/Male Luer Connector ⑬ to the Luer Fitting ⑩.
15. The Stepped Connector ⑫ may then be connected to a commercially available water seal suction apparatus or similar suction device, if desired.
16. While chest tube is in place, maintain a sterile occlusive dressing per standard fashion.
17. Replace the tip protector to cover the exposed sharp beveled needle tip ②.

**VERIFICATION OF TUBE PLACEMENT**

Confirm device placement using a standard chest radiograph or with fluoroscopy. The chest tube is radiopaque to allow visualization of the distal tip and main shaft.

**DEVICE MAINTENANCE**

Chest Tube may remain in place for up to 30 days.
Confirm the device securement every 72 hours, at a minimum, by lightly tugging on the device to ensure the balloon remains fully inflated. Add a couple of ml of air to the balloon, as needed.
Avoid excessive tension on chest tube or connections.
If needed, the one-way valve assembly ⑥ may be detached to allow the attachment of a syringe to the Luer fitting ⑩ for flushing of the chest tube.

**DEVICE REMOVAL**

To remove the chest tube:

1. Firmly attach an empty 10mL (or larger) syringe to the inflation valve ⑪.
2. Pull back the syringe plunger to deflate the Subcutaneous Balloon ④.
3. Have the patient inhale and hold a deep breath as the Chest Tube is quickly withdrawn.

4. Apply a sterile occlusive dressing.

**DEVICE DISPOSAL**

Dispose of Device in accordance with local and Federal regulations.

**MR SAFETY INFORMATION**


MRI Safety Information

A person with Quick Tube's Chest Tube Device may be safely scanned at 1.5T or 3.0T under the following conditions. Failure to follow these conditions may result in injury.

| **Parameter** | **Condition** |
|---|---|
| Device Name | Quick Tube's Chest Tube Device |
| Static Magnetic Field Strength (B0) | 1.5T and 3.0T |
| MR Scanner Type | Cylindrical |
| B0 Field Orientation | Horizontal |
| Maximum Spatial Field Gradient | 20 T/m (2,000 Gauss/cm) |
| RF Excitation | Circularly Polarized (CP) |
| RF Transmit Coil Type | Integrated Whole Body Transmit Coil |
| Operating Mode | Normal Operating Mode |
| Scan Duration | 2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks) |
| Image Artifact | The presence of Quick Tube's Chest Tube Device may produce an image artifact external to the patient body. Some manipulation of scan parameters may be needed to compensate for the artifact. |

**SYMBOLS GLOSSARY**

| | | |
|---|---|---|
|  DO NOT USE IF PACKAGE IS DAMAGED |  CAUTION |  USE BY |
|  DATE OF MANUFACTURE |   CATALOGUE NUMBER |  KEEP DRY |
|   BATCH CODE |   STERILIZED USING ETHYLENE OXIDE |  CONSULT INSTRUCTIONS FOR USE |
|  KEEP AWAY FROM SUNLIGHT |   DO NOT RESTERILIZE |  DO NOT REUSE |
|   RX ONLY (USA) |   MR CONDITIONAL | |

| | | |
|---|---|---|
|  Manufacturer | **QuickTube Medical, LLC**<br>3049 Kingston Pike,<br>Knoxville, TN 37919 | Phone Number:<br>763-442-1848 |