English

ReSolve®

Thoracostomy Tray

INSTRUCTIONS FOR USE

DESCRIPTION
The ReSolve® Thoracostomy Tray contains products used to access the pleural space and remove air and fluid.

INDICATIONS FOR USE
The ReSolve Thoracostomy Tray is indicated for the percutaneous removal of air and fluid from the pleural space.

CLINICAL BENEFITS
The ReSolve Thoracostomy Tray allows air and fluid to be drained from the pleural space through a minimally invasive percutaneous approach rather than through an open surgical approach.

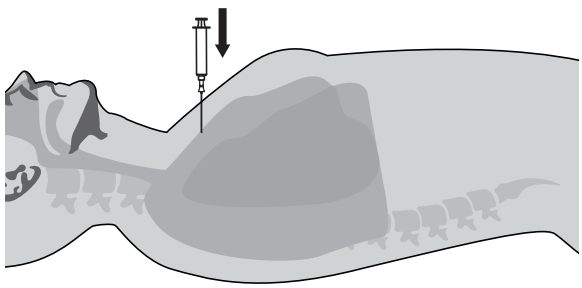
CONTRAINDICATIONS
None known.

WARNINGS
- For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization 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 resterilization 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 device in a manner consistent with standard protocols for biohazard waste disposal.
- Improper connection of the Heimlich valve can result in pneumothorax which may lead to injury, illness, or death of the patient.
- If the stopcock is open between the patient and atmosphere a pneumothorax can occur.

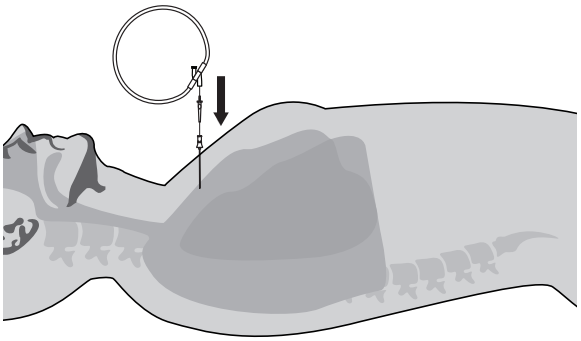
PRECAUTIONS
- Leave in a patient less than 30 days.
- Use this device only if you are a qualified health professional experienced in the treatment of pneumothorax or pleural effusions.

POTENTIAL COMPLICATIONS
Potential complications (in alphabetical order) include, but are not limited to any of the following complications:
- Accidental catheter displacement, breakage, or removal
- Bleeding
- Exposure to bodily fluids
- Hydrothorax
- Infection
- Nerve injury
- Ongoing or worsening of symptoms
- Organ damage or puncture
- Pain
- Pneumothorax
- Re-expansion pulmonary edema
- Skin irritation
- Vascular injury

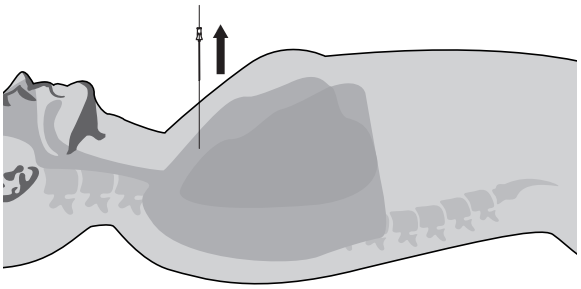
INSTRUCTIONS FOR USE
1. Identify site for insertion.
2. Prep the skin at the insertion site by using a skin cleansing agent.
3. Remove the adhesive backing from the fenestrated drape and place it over the intended puncture site.
4. Attach a needle to the syringe and aspirate Lidocaine into the syringe.
5. Anesthetize the area.
6. A small incision may be made at the puncture site.
7. Using appropriate technique, insert introducer needle into pleural space.



8. Insert guide wire into pleural space through the introducer needle.
   WARNING: Do not advance the guide wire if resistance is met.
   WARNING: Withdrawal, pulling back, or manipulation of the guide wire distal tip through the needle tip may result in breakage and/or particulate generation.



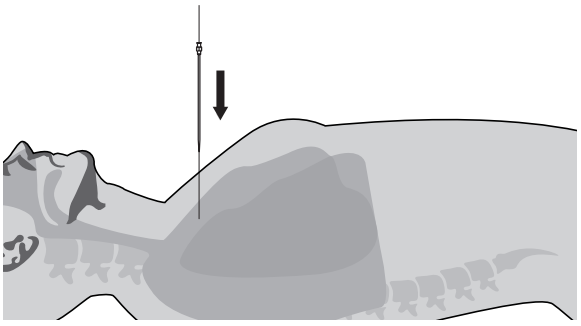
9. Remove the introducer needle leaving the guide wire in place.



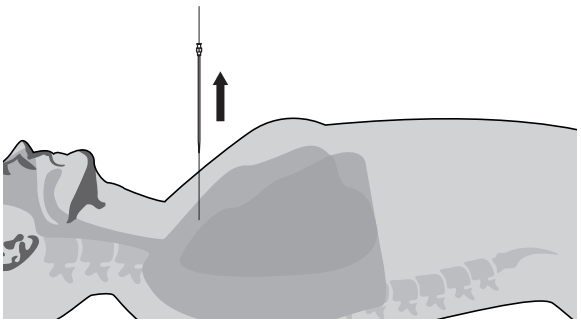
10. Place the stiffening cannula into catheter and tighten the luer lock fittings.

11. Ensure the skin incision is wide enough to accommodate dilator passage and there are no skin bridges between guide wire and incision.

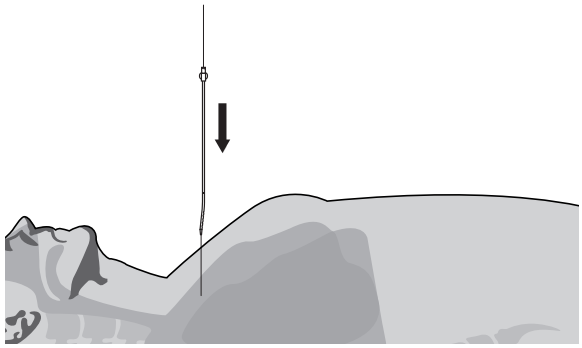
12. Place the dilator over guide wire through the tissue into pleural space to dilate the tissue track.



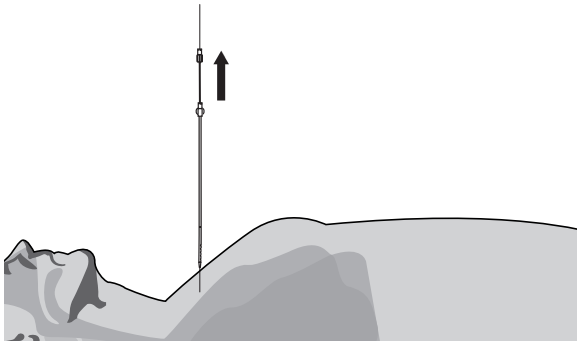
13. Remove the dilator leaving the guide wire in place.



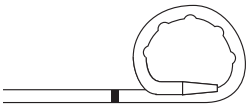
14. Feed the stiffening cannula/drainage catheter over the guide wire into the desired location in the pleural space.



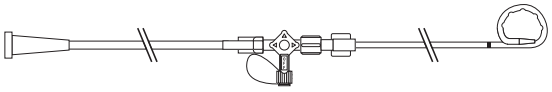
15. Remove the guide wire and stiffening cannula and check proper catheter position.



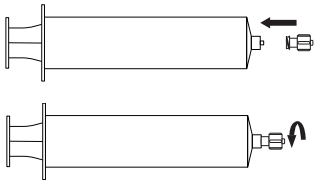
NOTE: The radiopaque marker band is intended to show the location of the drainage holes under x-ray and is not intended to be used as a depth marker during insertion. The radiopaque marker band is placed just proximal to the most proximal drainage hole. The radiopaque marker band and drainage holes should be placed within the pleural space.



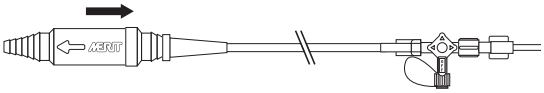
16. Attach the stopcock and connecting tubing assembly to the catheter.



NOTE: If at any time, a fluid sample is taken using a syringe, attach a non-vented cap to the syringe to prevent fluid from leaking.



17. Attach the cone adapter of the connecting tubing to appropriate device. Confirm all connections are tight to prevent air leak.



WARNING: Improper connection to the valve system can result in pneumothorax which may lead to injury, illness, or death of the patient.

NOTE: If using a Heimlich valve, attach Heimlich valve to tubing by pushing the blue cone connector of the Heimlich valve into the blue cone adapter of the tubing. The arrow on the Heimlich valve indicates the direction of flow.

18. Secure the catheter and tubing in place so that it can be easily maintained in place without changing position of the catheter.

CAUTION: Avoid kinking the catheter or tubing.

CATHETER REMOVAL

NOTE: There is no locking loop on this catheter.

19. Remove securement method.
20. Instruct the patient to stop breathing.
21. Quickly pull catheter out of patient.

NOTE: Resistance may be felt as the catheter straightens.

22. Dress site with desired method.

	Manufacturer
EC REP	Authorized Representative in European Community
REF	Catalog number
LOT	Batch code
	Use by date: YYYY-MM-DD
	Single use
	Do not resterilize
STERILE EO	Sterilized using ethylene oxide
	Consult Instructions for Use For electronic copy scan QR code, or go to www.merit.com/ifu and enter IFU ID. For printed copy, call U.S.A. or EU Customer Service
	Do Not Use If Package is Damaged and Consult Instruction for Use
	Caution
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Date of Manufacture: YYYY-MM-DD
MD	Medical Device
	Single Sterile Barrier System
UDI	Unique Device Identifier

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