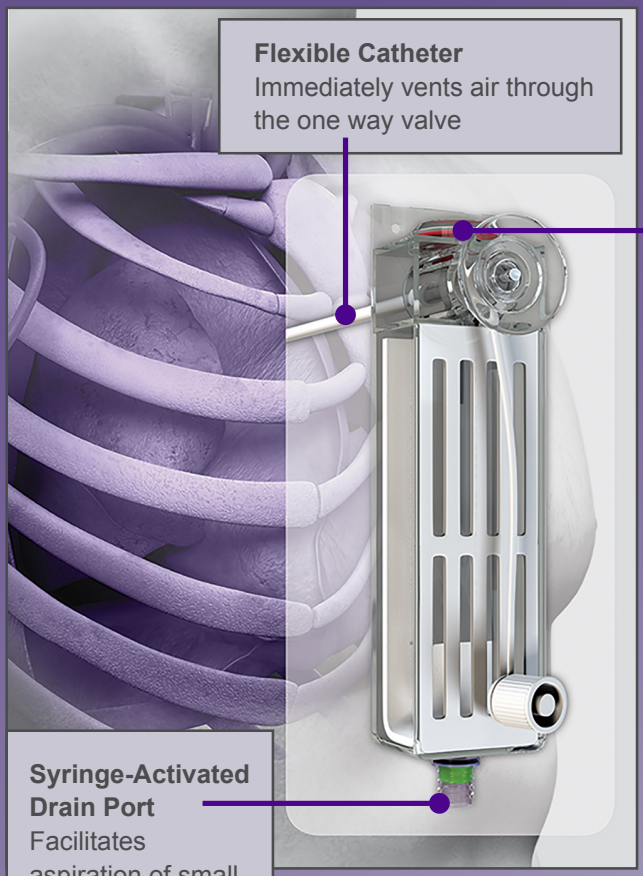
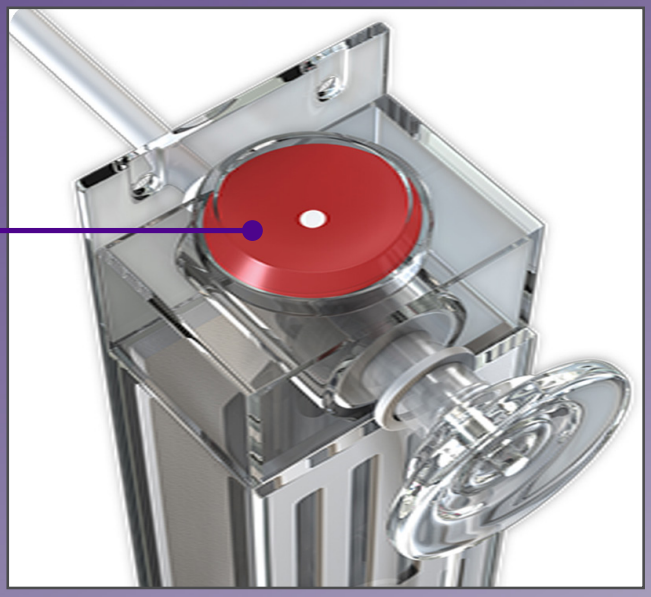
THORA VENT®



Flexible Catheter
Immediately vents air through the one way valve

Syringe-Activated Drain Port
Facilitates aspiration of small amounts of fluid



Red Signal Diaphragm

- Fluctuation demonstrate entry of the catheter into the pleural cavity with pressures greater than 2mm Hg and less than - 2mm Hg
- Continues to fluctuate with respiration until the pneumothorax is resolved as confirmed by x-ray

- UreSil's flagship product, the Thora-Vent has become one of the most commonly accepted choices for physicians treating simple pneumothorax throughout the world.
- Thora-Vent is unique in that it allows for active monitoring of the patient's pneumothorax during treatment and provides for maximum ambulation as well.
- Available in multiple sizes, Thora-Vent is an excellent option for the resolution of simple pneumothorax.
- Available with an over the wire insertion option.
- Every kit includes the following: Thora-Vent with Trocar, Aspiration Cannula, Suction Tubing Set, 60cc Syringe, Halstead Forceps, Vent Occlusion Plug, Gauze Sponges, Protected Disposable Scalpel, CSR Wrap and Fenestrated Drape.

THORA-VENT Procedure Tray

Product Code	Size/Length	Units/Box
TV11-10	11 F / 10 cm	1
TV11-13	11 F / 13 cm	1
TV13-10	13 F / 10 cm	1
TV13-13	13 F / 13 cm	1

THORA-VENT Accessories

Product Code	Description	Units/Box
TVST	Thora-Vent Suction Tubing	5
TVOCP	Vent Occlusion Plug	5
OTW11-13	Over-the wire insertion Cannula for TV11-13	5

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UreSil®

UreSil® THORA-VENT® Thoracic Vent Procedure Tray

INTENDED USE: The Thoracic Vent device is designed for the treatment of spontaneous, traumatic or iatrogenic simple pneumothorax. It can also be used for evacuating air from the chest following thoracic surgery and for treatment of pneumothoraces that may result after chest tube removal. This product is intended for short-term use (less than 30 days).
INTENDED USERS: This product is intended only for use by trained clinicians.

INSTRUCTIONS FOR USE:

1. Select a site, preferably at the second interspace in the midclavicular line or at another appropriate location.
2. Prepare the site using standard procedure. Using the scalpel, make a small skin incision at the selected site. If desired, the included forceps may be used to bluntly dissect the incision.
3. Remove the protective tube from the trocar and introduce the trocar into the device through the self-sealing port. The point of the trocar should extend slightly beyond the tip of the catheter.
4. Remove the protective sheath from the catheter. Peel away the center portions of the paper cover from the adhesive patch.
5. With thumb over the trocar handle, position the device and introduce the trocar/ catheter assembly into the pleural space through the prepared incision staying immediately above the superior border of the rib. Do not encroach the rib or its periosteum.
6. Entry of the catheter into the pleural cavity will be demonstrated by fluctuation of the red signal diaphragm, the red signal diaphragm will deflect upwards when a pressure of greater than (>) 6 mm Hg (+8.16 cm water) is transmitted through the catheter and will retract when a pressure of less than (<) negative 6 mm Hg (-8.16 cm water) is transmitted through the catheter. When the tip of the catheter enters the pleural space, stop advancing the trocar and introduce the full length of the catheter. Remove the trocar. Do not reinsert the trocar unless the catheter has been completely removed from the patient. While the tip of the catheter is in the pleural space, the red signal diaphragm will deflect upwards when a pressure of greater than (>) 6 mm Hg (+8.16 cm water) is transmitted through the catheter and will retract when a pressure of less than (<) negative 6 mm Hg (-8.16 cm water) is transmitted through the catheter. The indicator will not properly function if the patient is being ventilated or is on constant suction.
7. Peel away the paper on the side flaps of the adhesive patch and adhere the patch to the chest wall. The skin surface must be completely dry in order to promote adhesion of the patch.
8. When the self-sealing port is not in use (not engaged), seal it with the tethered cap.
9. If the patient is expected to be active, sutures should be sewn through the adhesive patch and the suture holes on the top of the device to further anchor it to the patient's skin.
10. If additional tape is used to further anchor the device, do not tape over the air vents (see diagram).

CHECK FOR CONTINUOUS AIR LEAK:

1. The Thoracic Vent occlusion plug can be used to check for a continuous air leak from the patient's lung. To occlude the Thoracic Vent, insert and secure the occlusion plug to the luer lock on the self-sealing port. With the occlusion plug in place, the system will vent no more than .02 cc/min of air at a pressure of 15mm Hg. Warning: Remove the occlusion plug when the check is complete. The Thoracic Vent will not vent air when the occlusion plug is in place. Seal the self-sealing port with the tethered cap after the occlusion plug is removed.

ASPIRATION

1. Air can be manually pumped out of the pleural space using the aspiration cannula. Insert the aspiration cannula into the vent through the self-sealing port. Attach the 60 cc syringe to the aspiration cannula using the luer fitting, and utilize the syringe to evacuate air from the pleural space. Do not attach the syringe directly to the self-sealing port. Remove the aspiration cannula by gently twisting and pulling on the flange (see diagram) of the aspiration cannula. Immediately seal the self-sealing port with the tethered cap after removing the aspiration cannula.
2. If small amounts of naturally occurring fluid accumulate in the device, the fluid can be removed via the drainage port using a syringe.

EXTERNAL SUCTION ATTACHMENT

1. If attachment to a suction system is desired, remove the suction tubing set from its pouch. Close the clamp on the tubing set while the set is being connected. Insert the cannula through the self-sealing port on the Thoracic Vent and lock it in place by twisting the luer lock. Attach the funnel to the suction system and then open the clamp. Appropriate evacuating pressures should be used. Do not exceed a 14.7 mm Hg (20 cm water) vacuum. Always clamp the suction tubing set when suction is not being applied to the Thoracic Vent. If the suction tubing set is no longer required, remove it and immediately seal the self-sealing port with the tethered cap.

WARNINGS/COMPLICATIONS:

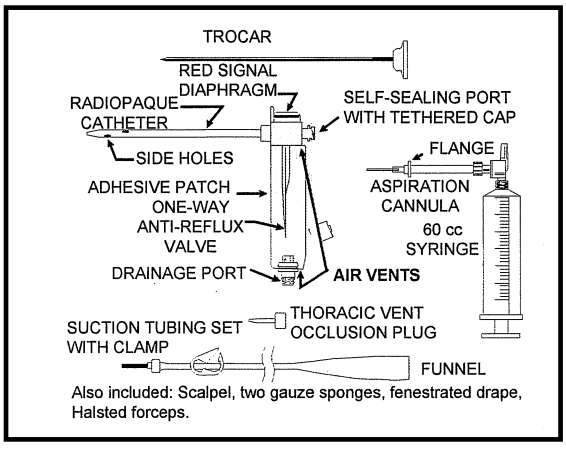
1. Do not rotate the trocar during its introduction through or removal from the self-sealing port on the Thoracic Vent.
2. Do not attempt to reinsert the trocar unless the catheter has been completely removed from the patient.
3. DIFFICULT CATHETER REMOVAL. If the catheter is inadvertently introduced through the rib periosteum or the trocar is reintroduced after placement of the catheter in the chest wall, the catheter may be damaged and locked within the patient. Removal of the catheter should be unresisted. If resistance is encountered, the catheter may be restrained. It is recommended that a restrained catheter be released by direct surgical intervention or by cutting the catheter from its proximal attachment to the device, securing it and percutaneously passing dilators over the catheter until it is released from its attachment.
4. MAINTAIN PROPER SEAL. An air-tight seal must be maintained to prevent subcutaneous emphysema.
5. In case of a threatening tension pneumothorax, multiple vents or a large catheter (chest tube) may be required to achieve adequate venting.
6. Continuous drainage of air over extended periods should alert a consideration for additional interventional treatment.
7. The physician should be aware of complications associated with the treatment of pneumothorax including re-expansion and laceration of intercostal vessels.
8. Always clamp the suction tubing set when suction is not being applied to the Thoracic Vent.
9. Do not disinfect the Thoracic Vent with alcohol (propanol). Alcohol (propanol) will degrade the Thoracic Vent.
10. If the occlusion plug was used to perform the air leak check, remove the occlusion plug when the check is complete. The Thoracic Vent will not vent air when the occlusion plug is in place.
11. Dispose of sharps using approved sharps container in accordance with applicable regulations and institutional policy.

CONTRAINDICATIONS:

NOT FOR HEMOTHORAX OR OTHER LIQUID DRAINAGE.
The THORA-VENT Thoracic Vent is not indicated for Hemothorax or fluid evacuation other than air. Even though the device can accommodate small amounts of liquid (5cc) without affecting function, larger amounts of fluid can affect device function. If upon insertion a hemothorax or other liquid collection is present, an alternative procedure should be utilised.

Do not use on patients with known tape or adhesive allergies.

WARNING: The reuse of this single-use device can lead to patient infection and/or device malfunction. Sterile if package is unopened and undamaged. Do not use if the sterile package is damaged or is unintentionally opened before use.
SAFE DISPOSAL: Dispose of used device in container marked for biohazard (i.e. contaminated with potentially infectious substances of human origin).
REPORTING SERIOUS INCIDENTS: Any serious incident that has occurred in relation to the device should be reported to UreSil as the manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.



Also included: Scalpel, two gauze sponges, fenestrated drape, Halsted forceps.

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