MD **UreSil ® Insertion Cannula for UreSil ® THORA-VENT® Thoracic Vent 11F, 13cm**

Medical device

EN

INTENDED USE: This over-the-wire cannula is intended for Seldinger introduction of UreSil THORA-VENT Thoracic Vent - 11F x 13cm: REF TV11-13. This product is intended for transient use (less than 60 minutes).

INTENDED PATIENT POPULATION: The Insertion Cannula for Thoracic Vent is intended for use with the Thoracic Vent for the following patients 16 years old and above:
- patients with spontaneous, traumatic or iatrogenic simple pneumothoraces
- patients with air in chest after chest tube removal in thoracic surgery

INTENDED USERS: This product is intended only for use by trained clinicians, such as the following users: cardiothoracic surgeon, trauma surgeon, interventional radiologist, pulmonologist, physician's assistant.

CLINICAL BENEFITS: As an accessory for Seldinger introduction of Thoracic Vent device as part of successful outpatient treatment of pneumothorax using Thoracic vent, successful inpatient treatment of pneumothorax using Thoracic Vent (success may be for instance, no clinical symptoms and/or signs relating to pneumothorax, no recurrence, achievement of lung re-expansion), low hospitalization duration when Thoracic Vent is used compared to surgical treatment

PERFORMANCE CHARACTERISTIC: Seldinger introduction of UreSil THORA-VENT Thoracic Vent device.

TO BE USED WITH: This Insertion Cannula for Thoracic Vent is intended to be used with the UreSil Thora-Vent Thoracic Vent device 11F x 13cm REF TV11-13.

INSTRUCTIONS FOR USE:
This package contains instructions for the specific use of the over-the-guidewire cannula. For additional instructions related to the use of the Thoracic Vent, see the instructions for use that are included in the Thoracic Vent Procedure Tray 11F x 13cm REF TV11-13.

1. Select and prepare the site as described in the instructions provided in the Thoracic Vent Procedure Tray.
2. Using the scalpel, make a small incision at the selected site.
3. Using Seldinger technique, dilate the tract to approximately one French size larger than the catheter on the Thoracic Vent.
4. Remove the protective tube from the cannula and insert it through the self-sealing port. Lock the cannula into the Thoracic Vent.

NOTE: The grooved Thoracic Vent trocar is not used when introducing the device using the Seldinger technique.

5. Peel away the center portions of the paper cover from the adhesive patch on the Thoracic Vent.
6. Advance the distal end of the catheter/cannula assembly of the Thoracic Vent over the guidewire and into the pleural space. When the tip of the catheter enters the pleural space: stop advancing, unlock the cannula and introduce the full length of the catheter. Remove the cannula and the guidewire. Do not re-insert the cannula unless the Thoracic Vent has been completely removed from the patient.
7. Read the instructions for use in the Thoracic Vent Procedure Tray for additional information.

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

WARNINGS/COMPLICATIONS:
1. The reuse of this single-use device can lead to patient infection and/or device malfunction.
2. 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.

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REF Catalog number

LOT Batch code

Caution

USA Country of manufacture/Date of manufacture

Use-by date

Quantity

LATEX Not made with natural rubber latex

Consult instructions for use/electronic instructions for use
https://uresil.com

Non-pyrogenic

Do not use if package is damaged and consult instructions for use

UDI Unique Device Identifier

Manufacturer: UreSil, LLC, 5418 W Touhy Ave, Skokie, IL 60077 USA

Telephone Number: 1-800-538-7374 (U.S.A.)

Fax Number: 1-847-982-0106

Do not resterilize

Do not re-use

STERILE EO Sterilized using ethylene oxide/ Single sterile barrier system

℞ Only Caution: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.