

#### WARRANTY AND LIABILITY STATEMENT

Prometheus DeltaTech and its Affiliates warrant to the first purchaser of this device that reasonable care has been exercised in the design and fabrication of this device. If any suspected damage is found please call the Prometheus DeltaTech representative. This limited product warranty is in place of all other warranties, whether express or implies, including but not limited to any impaired warranty of merchantability or fitness for a particular purpose. Prometheus DeltaTech and its Affiliates under this limited device warranty will be limited to replacement of defective device. Under no circumstances will Prometheus DeltaTech and its Affiliates be liable for any indirect, incidental or consequential damages resulting from your handling or use of this device.

#### References

1. Zengerink, I et al. Needle Thoracostomy in the Treatment of a Tension Pneumothorax in Trauma Patients: What Size Needle?  
*J Trauma*. 2008;64:111–114.
2. Givens ML, Ayotte K, Manifold C. Needle thoracostomy: implications of computed tomography chest wall thickness. *Acad Emerg Med*. 2004 Feb;11(2):211-3.
3. Harcke, HT et al. Chest Wall Thickness in Military Personnel: Implications for Needle Thoracostomy in Tension Pneumothorax. *Military Medicine* 2007;172(12):1260-1263.
4. Laan, D.V. et al. Chest Wall Thickness and Decompression Failure: A Systematic Review and Meta-analysis Comparing Anatomic Locations in Needle Thoracostomy. *Injury*. 2016 April ; 47(4): 797–804.

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#### DESCRIPTION

The Russell PnuemoFix®-8 is a sterile decompression needle designed for the removal of fluid from the pleural cavity by appropriately trained medical professionals.

#### CONTRAINDICATIONS

- Patients without evidence of tension pneumothorax, simple pneumothorax or pleural effusion.
- Patients known to have pleural adhesion (i.e. of visceral and parietal pleurae).
- Patients known to have a chest wall thickness of greater than 8cm.

#### CONDITIONS OF USE AND STORAGE

The Russell PnuemoFix®-8 should be stored and transported in a normal environment, i.e. away from extreme temperatures and humidity. Do not use if the sterile barrier is damaged and/or deteriorated. This product is for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the integrity of the set and/or lead to failure, which may result in patient injury, illness or death. Also reuse, reprocessing and resterilization may introduce a risk of contamination of the set and/or cause patient infection or cross-infection to another patient, which may lead to injury, illness or death.

#### PRECAUTIONS

These precautions for use should be fully understood before using the device:

- Do not use the Russell PnuemoFix®-8 if it has reached or passed its use by date.
- Do not use the Russell PnuemoFix®-8 if it is found to be damaged on removal from its packaging.
- Use of the Russell PnuemoFix®-8 should be restricted to medical personnel who have appropriate training and an understanding of the technical principles, clinical applications and risks associated with treating pneumothorax before attempting to use this device to treat the condition.
- The different components of the Russell PnuemoFix®-8 and their uses should be properly understood before using the device.
- Care is advised when using on patients under 50kg and those with thin chest walls to take care that the needle is not advanced so as to cause harm to underlying tissues.
- The Russell PnuemoFix®-8 is a single-use device.
- Careless technique or insertion to excessive depth may lead to serious harm or death to the patient.
- If insertion through the skin proves difficult please do not apply excessive force and instead make a small nick in the skin with a suitable punch or scalpel blade.
- The Russell PnuemoFix-8 should not be used on a patient with a flail chest injury.

#### CAUTION:

Professional Use Only. Sale and use of this medical device possible only under direction of a healthcare provider.



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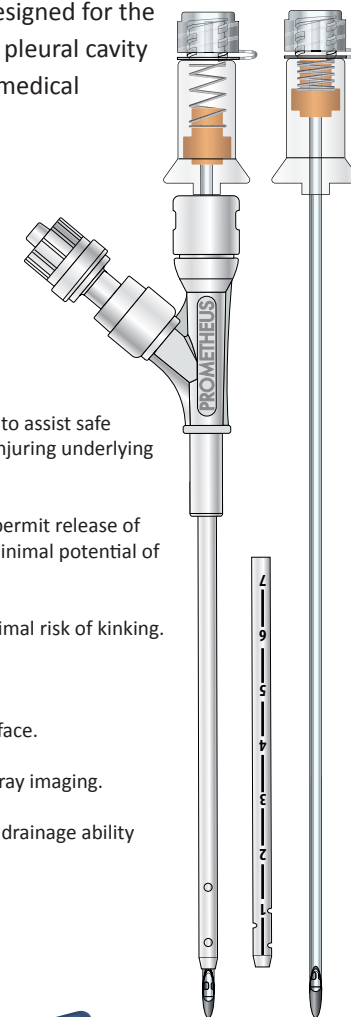
Rx Only



**STERILE EO**

# RUSSELL PNEUMOFIX®-8

The Russell PnuemoFix®-8 is a sterile decompression needle designed for the removal of fluid from the pleural cavity by appropriately trained medical professionals.



#### FEATURES

Veress tip and indicator device to assist safe insertion with minimal risk of injuring underlying lung.

Low pressure release valve to permit release of tension pneumothorax, with minimal potential of subsequent air re-entry.

Catheter designed to have minimal risk of kinking.

14-Gauge for rapid venting.

Depth markings printed on surface.

Radio-opaque to be seen on X-ray imaging.

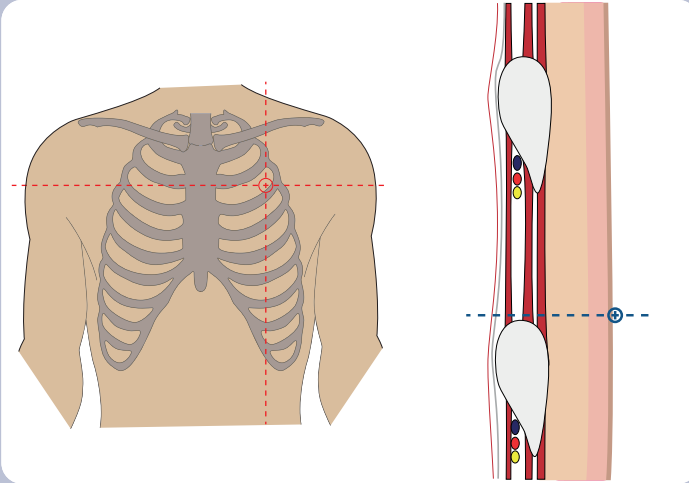
Catheter tip holes to maximize drainage ability and minimize tip occlusion.



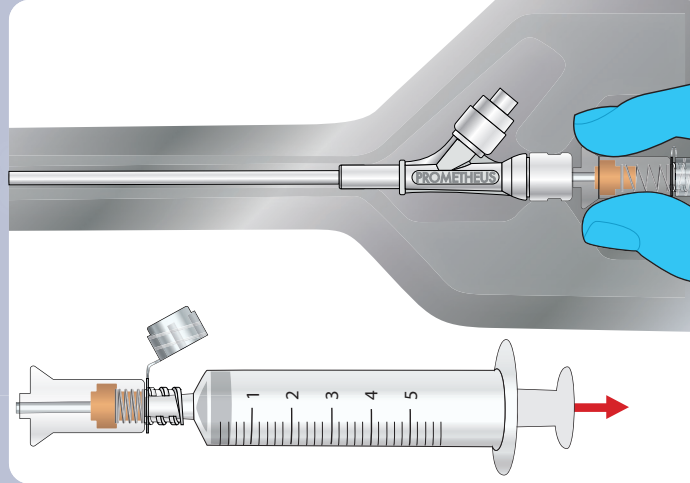
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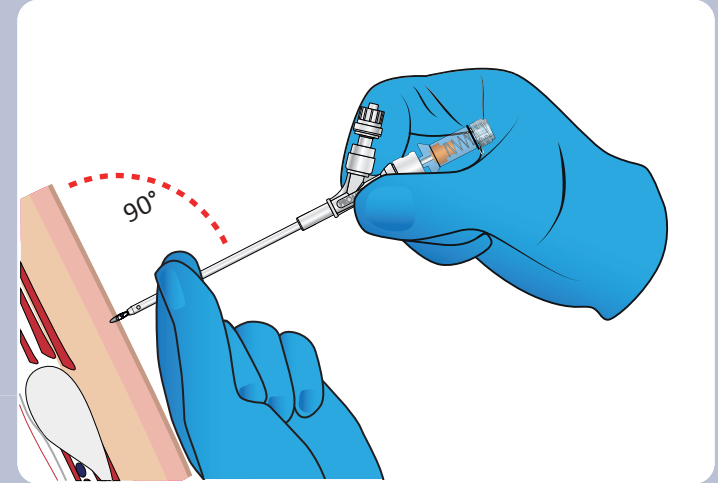
## INSTRUCTIONS FOR USE FOR THE TREATMENT OF TENSION PNEUMOTHORAX



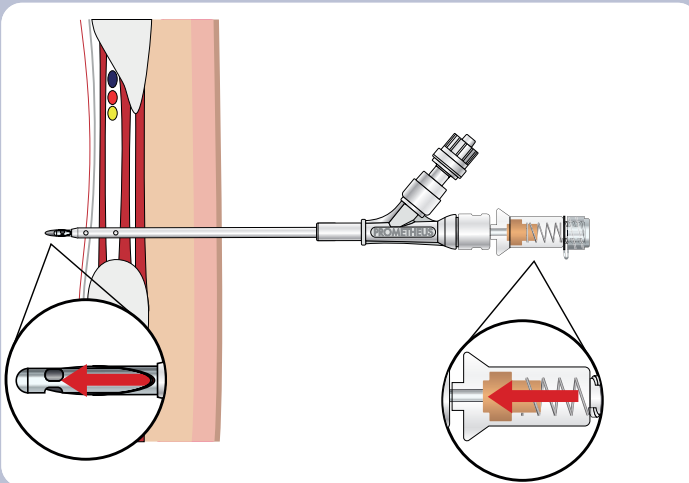
1. Establish the diagnosis of tension pneumothorax, and identify which side of the chest the tension pneumothorax exists: this is the side where the procedure should be carried out.
2. The insertion site should be just above the upper border of the third rib (i.e. into the second intercostal space) in the anterior mid-clavicular line, to avoid the intercostal neurovascular bundle.



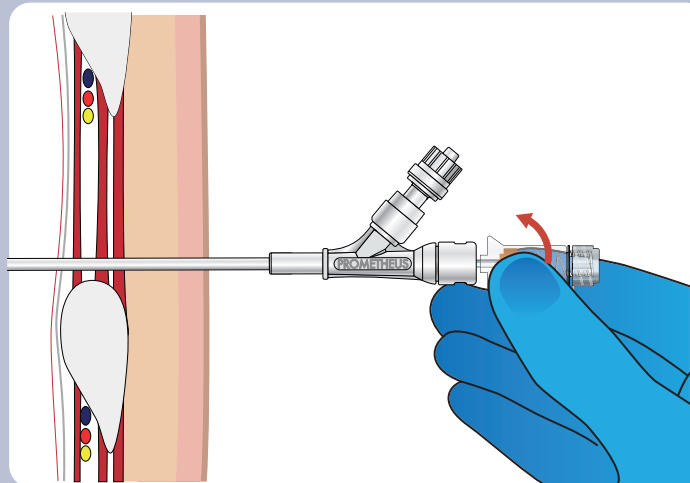
3. Clean the site with an appropriate antimicrobial solution according to local guidelines.
4. Open the Russell PneumoFix®-8 and remove from its packaging by holding the hub of the Veress Needle.
5. A syringe can be attached to the female luer connector of the Veress needle if required (withdrawing plunger to detect air or fluid during insertion thus helping identify when the pleural space has been reached) depending on local guidelines. Please remove cap to attach the syringe.



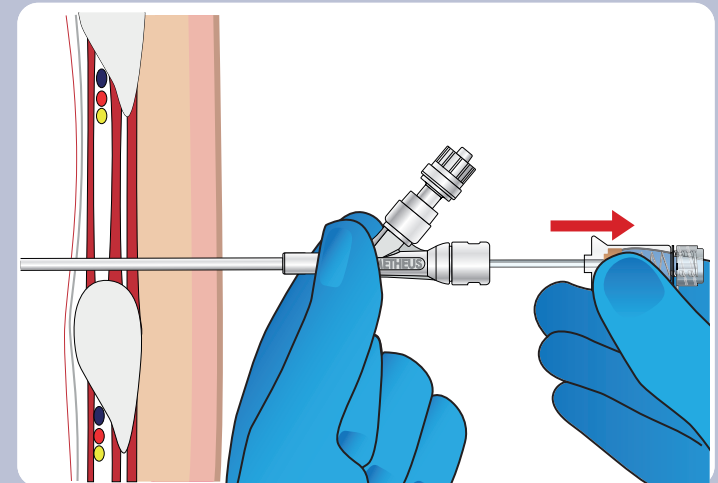
6. Grip the Russell PneumoFix®-8 at the catheter hub marked 'Prometheus' for greatest stability. Insert the needle end into the intercostal space at a 90-degree angle to the chest wall. NOTE: do not insert the needle medial to the mid-clavicular line and avoid directing towards the heart. Preferably the user should aseptically grasp the needle assembly during insertion with their other hand in order to stabilise it and control depth of insertion. Skin strength varies from person to person. If insertion through the skin proves difficult please do not apply excessive force and instead make a small nick in the skin with a suitable punch or scalpel blade.



7. Insert into the pleural space and note the sudden movement of the orange indicator towards the patient: this suggests that the needle tip is in the intra-pleural space. Push the whole device approximately 1cm further into the patient. The movement of the orange indicator may not always occur. Extreme care should be exercised as the needle advances past the expected chest wall thickness. If the movement of the orange indicator cannot be seen or heard the user may consider adding a syringe to aspirate for air or fluid to help identify correct placement.



For reference, some adult studies have shown mean chest wall thicknesses to range between 3.4 cm and 4.2 cm<sup>(1,2)</sup>. A study of military personnel showed a mean chest wall thickness of 5.36 cm with values ranging from 3.1 cm to 9.4 cm<sup>(3)</sup>. A recent meta-analysis showed the mean mid-clavicular line chest wall thickness to be 4.3 cm and the anterior axillary line chest wall thickness to be 3.4 cm<sup>(4)</sup>.



8. Fix the depth of the catheter and fully withdraw the Veress needle by twisting to unlock and then lifting out of the hub, leaving the catheter in place.
9. Dispose of the needle by inserting it carefully into a sharps safety device.
10. If considered necessary, secure the catheter with medical tape to the patient's chest, or according to local protocol.