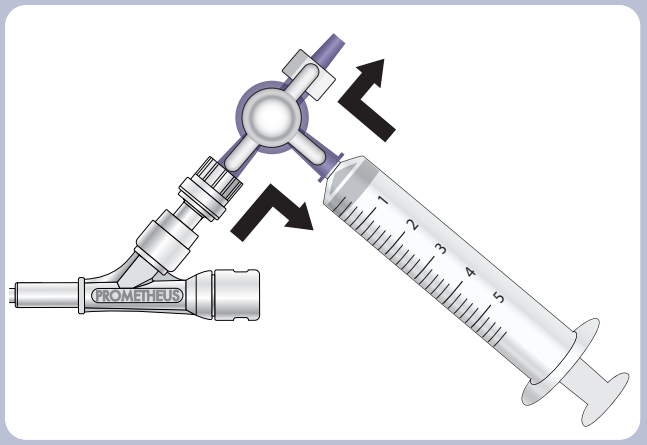
INSTRUCTIONS FOR USE FOR THE ASPIRATION OF SIMPLE PNEUMOTHORAX OR PLEURAL EFFUSION

1. Establish the diagnosis, indication for aspiration, and site for drainage according to local policy.
2. The insertion site should be just above the upper border of the appropriate rib (i.e. into the intercostal space), to avoid the intercostal neurovascular bundle.

3. Follow steps 3-10 overleaf.



4. Connect a 'three-way tap' to the female luer connector of the side port and use a syringe to evacuate air and fluid. Empty syringe and repeat as necessary.
5.Remove the Russell PneumoFix® once the aspiration procedure is complete.

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 Thoracentesis in Tension Pneumothorax. Military Medicine 2007;172(12):1260-1263.

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PROMETHEUS MEDICAL LTD

INDICATIONS

The intended use of the Russell PneumoFix® is the treatment of tension pneumothorax, simple pneumothorax and pleural effusion.

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 11cm.

CONDITIONS OF USE AND STORAGE

The Russell PneumoFix® 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 of 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 PneumoFix® if it has reached or passed its use by date.
- Do not use the Russell PneumoFix® if it is found to be damaged on removal from its packaging.
- Use of the Russell PneumoFix® 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 and/or pleural effusion before attempting to use this device to treat the respective condition.
- The different components of the Russell PneumoFix® 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 PneumoFix® 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 PneumoFix should not be used on a patient with a flail chest injury.

WARRANTY AND LIABILITY STATEMENT

Promepla 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 Promepla 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. Promepla and its Affiliates under this limited device warranty will be limited to replacement of defective device. Under no circumstances will Prompela and its Affiliates be liable for any indirect, incidental or consequential damages resulting from your handling or use of this device.

Manufactured for Prometheus DeltaTech Ltd by;
Promepla SAM
Le Copori
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MC 98000
Monaco

STERILE EO

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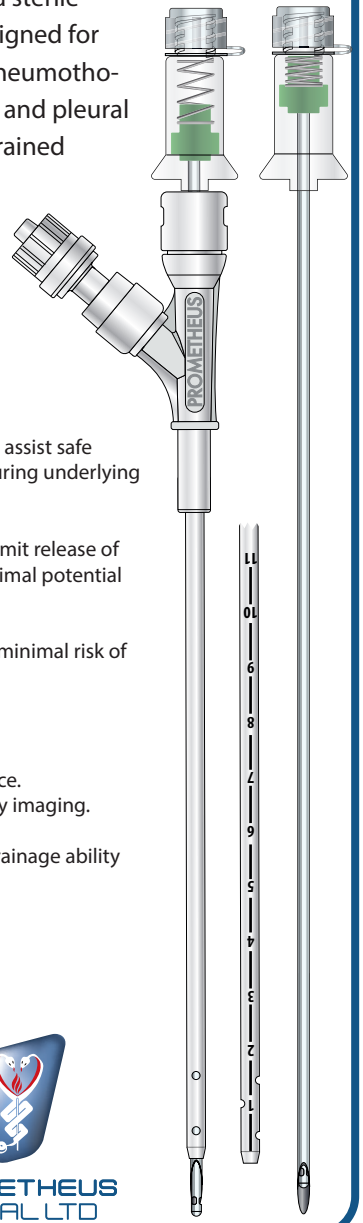
RUSSELL PNEUMOFIX®

The Russell PneumoFix® is a sterile decompression needle designed for the treatment of tension pneumothorax, simple pneumothorax, and pleural effusion 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.

11cm catheter designed to have minimal risk of kinking.

12-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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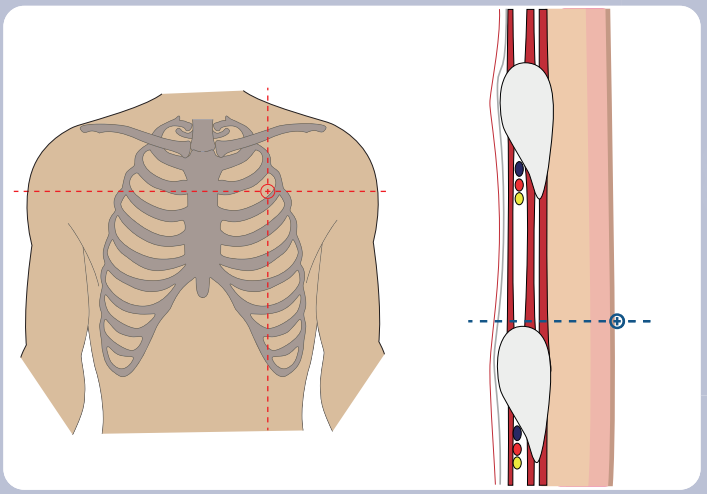
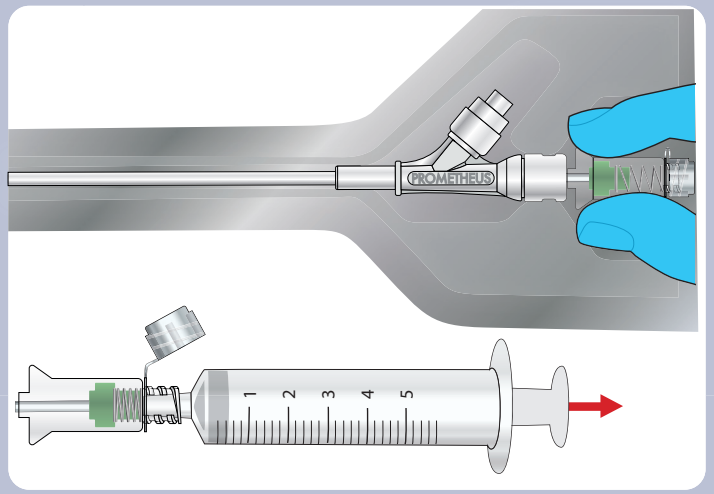
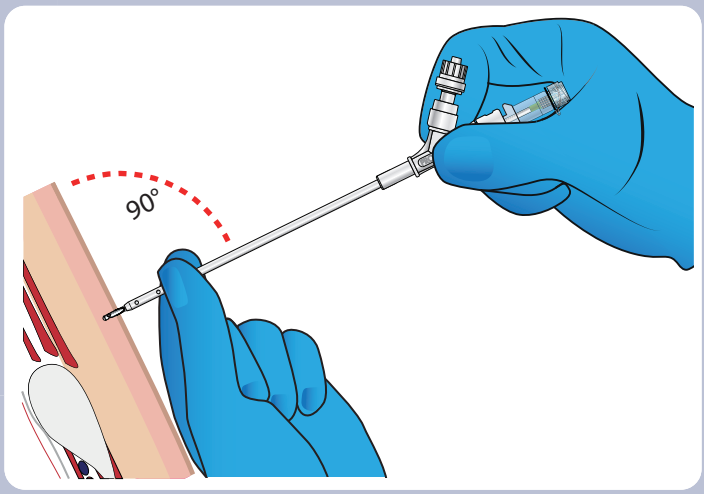
INSTRUCTIONS FOR USE FOR THE TREATMENT OF TENSION PNEUMOTHORAX



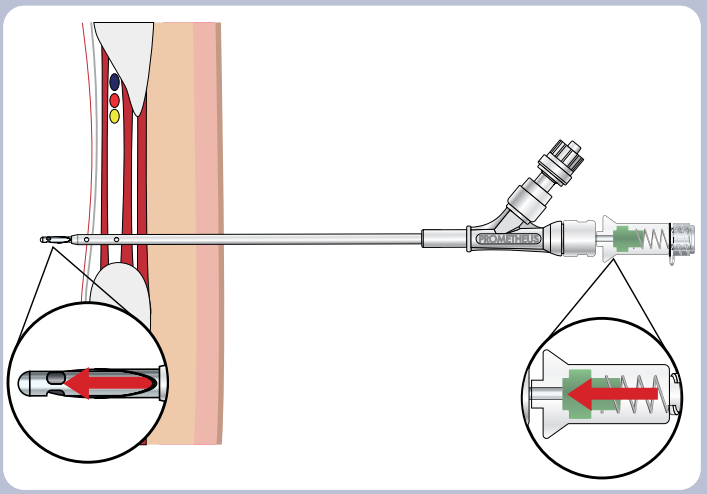
1. Establish the diagnosis of tension pneumothorax, and identify which side of the chest the tension pneumothorax exists: this is the side where the procedure should be carried out.
2. The insertion site should be just above the upper border of the third rib (i.e. into the second intercostal space) in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



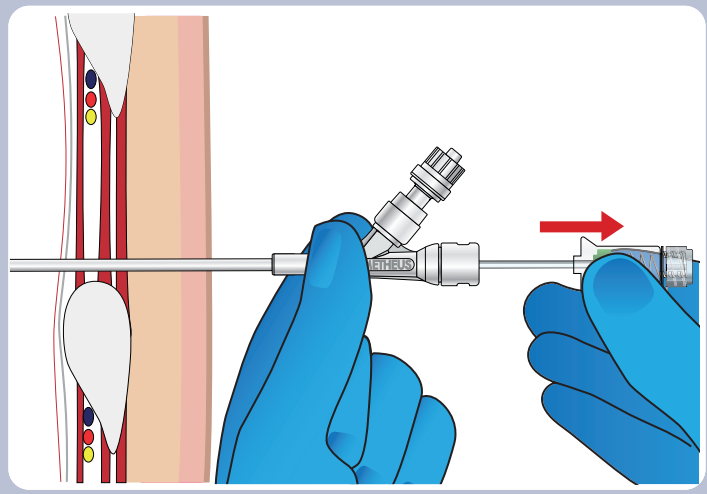
3. Clean the site with an appropriate antimicrobial solution according to local guidelines.
4. Open the Russell PneumoFix® and remove from its packaging by holding the hub of the Veress Needle.
5. A syringe can be attached to the female luer connector of the Veress needle if required (withdrawing plunger 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® 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.

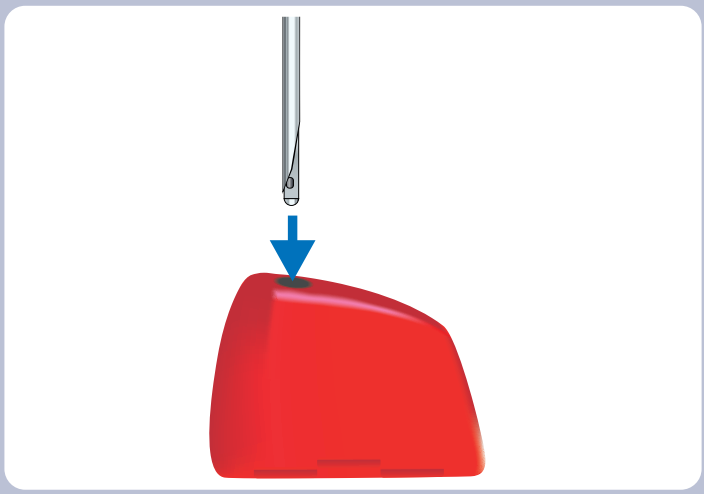


7. Insert into the pleural space and note the sudden movement of the green indicator towards the patient: this suggests that the needle tip is in the intra-pleural space. Push the whole device approximately 1cm further into the patient. The movement of the green indicator may not always occur. Extreme care should be exercised as the needle advances past the expected chest wall thickness. If the movement of the green 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 [1,2].
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 [3].

8. Fix the depth of the catheter and fully withdraw the Veress needle, leaving the catheter in place.



9. Dispose of the needle by inserting it carefully into the provided NeedleVise® sharps safety device. To minimize risk of needle-stick injury, do not hold the NeedleVise® by hand when pushing the Veress needle into it. After use, dispose in accordance with local policy.

10. If considered necessary, secure the catheter with medical tape to the patient's chest, or according to local protocol.