The Russell PneumoFix® 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, or simple pneumothorax
- Patients known to have pleural adhesion (i.e. of visceral and parietal pleurae).
- Patients known to have a chest wall thickness of greater than 11 cm.

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 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 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 before attempting to use this device to treat the 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 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.

REFERENCES
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 pleural space. Extreme care should be exercised as the needle advances past the expected intra-pleural space. Push the whole device approximately 1 cm further into the patient’s chest, or according to local protocol.

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.

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).