Russell PneumoFix™

The Russell PneumoFix™ is a sterile chest decompression device designed for the management of tension pneumothorax, simple pneumothorax and pleural effusion.

Designed by practising clinicians who understand the limitations of conventional equipment, the Russell PneumoFix™ has the following features:

- For medical professionals, use of the Russell PneumoFix™ is quick, simple and intuitive.
- Unlike the intravenous cannula, used historically in an improvised way for the management of tension pneumothorax, the Russell PneumoFix™ is designed specifically for this purpose.
- The Russell PneumoFix™ has been designed to be inserted without the need for a scalpel or skin incision.
- The device incorporates a Veress-tipped needle to minimise risk of injury to lung tissue.
- 11cm long catheter – long enough to reach the pleural cavity of the vast majority of patients

- Low pressure one-way valve – to allow air and fluid out but nothing in
- Graduated markings and X-ray detectable catheter – for depth recording and accurate localisation at hospital
- 12-Gauge catheter – allows for rapid venting of air in tension pneumothorax
- Material chosen which minimises the risk of kinking of the catheter
**BACKGROUND**

Needle thoracocentesis (NT) is the insertion of a needle into the pleural space and the drainage of air that has accumulated. This can be life-saving when a patient has a tension pneumothorax as it allows decompression, restoration of the circulatory system and improvement in ventilation.

A needle is inserted into the chest in the 2nd intercostal space in the anterior mid-clavicular line. It is inserted perpendicularly to the chest wall, just above the 3rd rib (to avoid the intercostal neurovascular bundle – a simple schematic is shown Figure 1).

A significant advantage of the Russell PneumoFix™ is that it is long enough to reach into the pleural cavity in the vast majority of subjects. Other marketed products may be too short and some have cannulae that kink easily, which may lead to a further reduction in product effectiveness. There are many published studies documenting the failure of other devices (including improvised use of cannulae) 1-5. The Russell PneumoFix™ has been developed to tackle these known shortcomings in order to provide a new standard of pneumothorax management.

**SOLUTION**

The Russell PneumoFix™ has been designed by clinicians who understand the reality of treating tension pneumothorax and who appreciate the importance of traditional failings of using improvised equipment not designed for purpose. As can be seen, the Russell PneumoFix™ has many features that make it a truly useful tool for the emergency care provider. An overview of the simplicity of use of the Russell PneumoFix™ can be seen in Figure 2.

With no fuss and no over-engineering, the Russell PneumoFix™ provides a cost-effective, simple and intuitive solution to allow this life-threatening condition to be dealt with quickly and effectively for the benefit of the patient.
INSTRUCTIONS FOR USE

DESCRIPTION:
The Russell PneumoFix® is a sterile decompression needle designed for the removal of fluid from the pleural cavity by appropriately trained medical professionals.

FEATURES:
1. Veress tip and indicator device to assist safe insertion with minimal risk of injuring underlying lung.
2. Low pressure release valve to permit release of tension pneumothorax, with minimal potential of subsequent air re-entry
3. 11cm catheter designed to have minimal risk of kinking
4. 12-Gauge for rapid venting
5. Depth markings pronated on surface. Radio-opaque to be seen on X-ray imaging
6. Catheter tip holes to maximise drainage ability and minimise tip occlusion

INSTRUCTIONS FOR USE:
1. Establish the diagnosis 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.
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.
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 (e.g. in effusion) to help identify correct placement.

For reference, some adult studies have shown mean chest wall thicknesses to range between 3.4cm and 4.2cm.1,2
A study of military personnel showed a mean chest wall thickness of 5.36 cm with values ranging from 3.1cm to 9.4cm.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
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

• 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

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 11cm

WARNINGS:

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CAUTION:

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

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

REFERENCES:

