Rocket 8Fg Thoracentesis Catheter
INSTRUCTIONS FOR USE

Rocketmedical

Scope: These instructions cover all Rocket 8Fg Thoracentesis Catheters and derivatives.
This device should only be used by, or under the supervision of, appropriately trained personnel and in conjunction with current local clinical practice guidelines

Device Description: The Rocket Thoracentesis Catheter contains an 8Fg catheter with 6 fenestrations, 1 cm markings that start 1cm from last fenestration, one-way valve, stitch plate, tubing extension, 3-way tap. Verres needle, easy aspiration syringe, 60ml syringe, protection sheath, scalpel and 2L drainage bag (accuracy +/-10%).

Indications: For the percutaneous introduction of a catheter into the chest for the drainage of air & fluid. This device should only be used by, or under the supervision of, appropriately trained personnel and in conjunction with current local clinical practice guidelines.

Contraindications: Not intended for the drainage of blood or empyema.

WARNING Risk of tension pneumothorax. This device is NOT to be used with closed drainage bags when draining air.

For the draining of air you **MUST** use a properly vented, chest drainage bag with a non-return flutter or Heimlich type valve such as the Rocket Ambulatory Bag R54564.

Procedure:

1. Ensure that adequate imaging has been performed to confirm the presence of pleural effusion prior to the use of this aspiration equipment. Pleural ultrasound is recommended prior to drainage of a pleural effusion to ensure the presence of fluid and to identify the optimal site for drainage.
2. Following local hospital policy, prepare the catheter insertion site with an approved solution and drape as required to maintain asceptic technique.
3. Administer appropriate and adequate local anaesthetic to the catheter insertion site and the underlying tissue.
4. Using the small scalpel make a small skin incision 4-5mm.
5. Remove the protection sheath from the catheter and begin to slowly insert the needle through the skin incision over the superior border of the rib and into the pleural space.
6. During insertion through the intercostal muscle, the hub window will show RED to indicate the needle tip is exposed.
7. As the needle passes through the parietal pleura a distinct 'click' can be heard as the spring-loaded obturator snaps forward to aid in protecting the internal organs from the needle point.
8. Check the hub window is showing GREEN to indicate the obturator is fully forward.
9. A RED indicator showing or partially showing indicates that the obturator is retracted and the needle tip may be exposed. In this condition, remove the needle, ensure that there is no tissue obstructing the free movement of the obturator and repeat the insertion procedure
10. The aspiration of fluid should be used to verify correct position.

WARNING: Do not over insert the needle into the chest. Only insert the needle sufficiently to be able to aspirate fluid.

11. When the placement of the needle and catheter has been correctly identified as being in the pleural cavity undo the connection between the needle and syringe to the one-way valve by gently rotating the connection cap anti clockwise and pulling gently.
12. Slowly advance the catheter into the pleura whilst removing the needle from the catheter.
13. When the verres needle is removed, and the catheter is in the pleura, ensure the stitch plate is against the patient's chest wall. At this point secure the stitch plate to the chest wall using a suture or tape.

DO NOT ATTEMPT TO REINSERT THE PUNCTURE NEEDLE THROUGH THE DEVICE

14. Attach the valve cap.
15. If draining air go to step 18.
16. If draining fluid connect to the 2L drainage bag to the 3-way tap.
17. If required use the 60ml syringe connected to the 3 way tap to aspirate fluid from the chest, if the viscocity of the effusion permits, you can allow the fluid to drain into the collection bag.

WARNING: Ensure that the fluid being drained is observed and recorded.
Observe the patient for any signs of distress whilst draining fluid.

18. If draining air prime the Rocket Medical Ambulatory Bag R54564 as per the IFU.
19. Attach the luer lock fir tree connector to the 3-way tap. Attach the primed Ambulatory bag to the fir tree connector.

Disposal: This device should be handled and disposed of in accordance with local hospital policy and with regard to all applicable regulations, including but without limitation to, those pertaining to human health & safety and care of the environment.

ROCKET MEDICAL PLC Sedling Road, Washington,
England, NE38 9BZ www.rocketmedical.com

For Single Use Only. Do not reuse on another person, reprocess or re-sterilise as doing so may compromise the structural integrity of the device, leading to device failure; potentially the cause of serious harm to patients and users. Reuse, reprocessing or re-sterilisation may also result in serious harm to patients and users from cross-contamination and infection with transmissible diseases**. Unless opened or damaged, contents of package are sterile.**

CONTINUOUS USE SHOULD NOT EXCEED 28 DAYS

