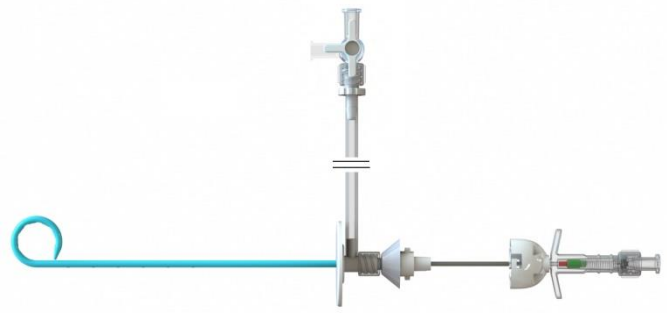
Rocket® Safety Drain
INSTRUCTIONS FOR USE

Scope: These instructions cover all **R58800-08-SD Rocket® Safety Drains** and derivatives. The device comprises an 8FG x 15cm polyurethane pigtail catheter with fixation plate and drainage port loaded over 14G needle with a sprung obturator.

Indications: For external drainage of abdominal ascites by a one-step puncture. This device should only be used by, or under the supervision of, appropriately trained personnel in conjunction with local and/or national clinical practice guidelines such as those published by the Royal College of Radiologists and Royal College of Surgeons.

Contraindications: Not to be used where the risks of insertion outweigh the benefits of drainage or where the anatomy cannot be adequately determined by ultrasound.



Procedure:

1. Following local hospital guidelines, use an aseptic technique to prepare the site for insertion. Administer appropriate and adequate local anaesthetic to the catheter insertion site and the deep underlying tissue. It is recommended that this device is inserted with imaging support.
2. Remove the protective cover from the catheter and discard. Retain the safety scalpel
3. If the drain is to be inserted under aspiration and attach a 10ml syringe to the needle hub.
4. Excercising caution and consideration for patient morphology, use the safety scalpel provided; insert the blade vertically through the skin at the insertion point to create a 5mm wide ‘skin nick’ with associated 15mm penetration of the subcutaneous tissues.
5. Gently insert the needle through the skin incision into the abdominal space. During insertion through the abdominal wall, the needle hub window will show RED to indicate the sprung obturator is retracted and the needle tip is exposed.
6. As the needle passes through the peritoneum, a distinct 'click' can typically be heard as the spring loaded obturator snaps forward to aid protection of the internal organs from the needle point.
7. Check the needle hub window is showing GREEN to indicate the obturator is fully forward. 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 drain assembly, ensure that there is no tissue obstructing the free movement of the obturator and repeat the insertion procedure.
8. The aspiration of fluid or imaging should be used to verify correct position.

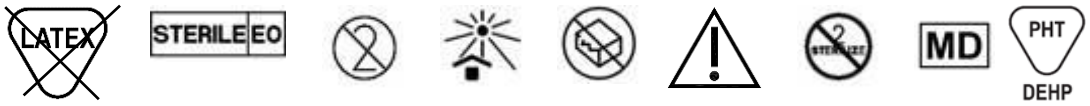
   WARNING: Do not over insert the needle into the cavity. Only insert the needle sufficient to ensure the tip of the drainage catheter is located beyond the peritoneum and in the abdominal space.
9. When correct placement of the needle and catheter has been confirmed, grip the drain body and gently rotate the connection cap anti clockwise to release the insertion needle.
10. Using the needle to support the catheter, slowly advance the drain into the abdominal cavity. Withdraw the needle from the catheter when insertion is complete.
11. Attach the valve cap supplied in the pack.
12. Connect the drainage connection tubing to the side arm, attach to an appropriate collection bag and open the stopcock to permit drainage.
13. Confirm the catheter is draining freely prior to completing the procedure. Confirm the drain postion via imaging.
14. The device can be secured by applying four dressing strips over each of the flats of the fixtion plate to securely fix to the skin. Suturing of the fixation plate may be required where patient compliance is a concern.

WARNING: Do NOT attempt to re-insert the needle into the device

CAUTION: Where anatomy is potentially distorted or compromised, insertion should only be conducted under continuous imaging such as ultrasound.

The use of ultrasound guidance on insertion is strongly recommended

CONTINUOUS USE SHOULD NOT EXCEED 28 DAYS



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Potential for DEHP Exposure from use of this device. DEHP may leach from this device, which may cause reproductive harm in male neonates, pregnant women carrying male fetuses, and peripubertal males. The extent of exposure largely depends upon the medical treatments administered and the duration of the treatment. Lack of research in humans means it is difficult to predict the adverse effects of DEHP because certain animal models may not apply to humans. Most studies utilise mice and rats, however breakdown of DEHP in the human body differs to the mechanism observed in these animals. These effects are also seen only at levels far in excess of normal human exposure. (For further details please see ‘POL58’ at www.rocketmedical.com.)

