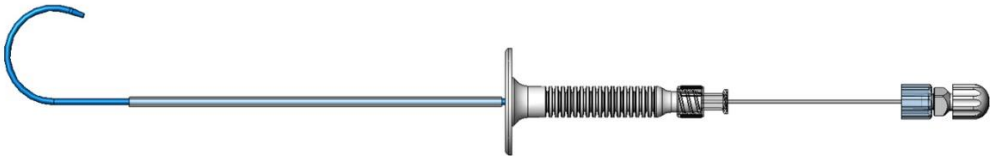
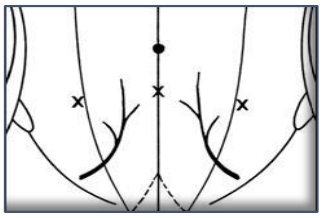
Rocket BLUE™ Needle Drain
INSTRUCTIONS FOR USE



Scope: These instructions cover all **R58800-06-BD and R58800-06-BK Rocket BLUE™ Needle Drains**, kits and derivatives.

Device Description: The device comprises a 6FG x 20cm polyurethane pigtail catheter with flexible support and stitch plate loaded over a cannula/needle assembly.

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



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 aseptic technique to prepare the area for insertion use these possible sites a guide to insertion.
2. Prepare the drain for insertion by sliding the protective sleeve forward to straighten the pigtail.
3. Lock the needle set to the flexible support with a clockwise twisting action.
4. **REMOVE THE STRAIGHTENING SLEEVE and discard before insertion.**
5. If the drain is to be inserted under aspiration, remove the rear cap and attach a 10-20ml syringe to the needle hub.
6. Having chosen the site, it is recommended that a 2-5mm skin incision is made prior to insertion using the scalpel provided in the pack.
7. Grasp the scalpel and carefully extend the blade by moving the slide toward the tip of the scalpel, using the thumb of the hand holding the scalpel. Extend the slider until you reach the positive stop, the slider will locate into a notch when it is completely extended.
8. To retract the blade, grasp the scalpel carefully and move the slide toward the back of the scalpel, using the hand holding the scalpel. 'Clicks' may be felt as the blade is retracted and a positive stop once the blade is completely retracted. To retract the blade permanently, move the slider past the notch at the back of the scalpel.
9. It is recommend that the needle drain is gripped by the stitch plate and flexible stem only.
10. Advance the drain only until a loss of resistance is felt or aspiration of fluid confirms insertion into the space.
11. Unlock the needle set with an anti-clockwise twisting action and withdraw the needle set *whilst advancing the catheter*.
    Do NOT remove the needle set until correct insertion is established. Once correct insertion is established the drain may be fully advanced into the cavity
12. **Do NOT attempt to re-insert the needle set into the catheter during insertion. Remove the whole drain, re-apply the protective sleeve to the catheter and start from #3.**
13. Once correct insertion is established and the needle set removed, the drain may be carefully advanced into the abdominal cavity
14. Connect the drain connector set and attach to an appropriate collection bottle or bag.
15. Confirm the catheter is draining freely prior to completing the procedure.
16. The device can be secured by suturing the stitch plate into position or by applying dressing strips over the flats of the stitch plate and securely fixing to the skin.

WARNING: Do NOT attempt to insert the needle into the drain without first straightening the pigtail with the protective sleeve.
If the needle is allowed to puncture the catheter wall, the drain should be discarded and replaced with a new one.
CAUTION: Where anatomy is potentially distorted or compromised, insertion should only be conducted under continuous imaging such an ultrasound screening. The use of ultrasound guidance on insertion is strongly recommended
This product has been coated with silicone and beads may form on the needle surface during storage.
CONTINUOUS USE SHOULD NOT EXCEED 28 DAYS.

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.

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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.)

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