

Rocket Medical PLC – SRN: **GB-MF-000025375**

Urgent Field Safety Notice: CUST-OCC665 Revision 2

Rocket 6FG BLUE Needle Drain (REF: R58800-06-BD)

06-Mar-2026

NOTE: This FSN was originally released to affected customers in November 2023. Following a subsequent review of distribution records, Rocket Medical has identified the need to reissue this FSN to ensure all potentially affected customers have received the information. This reissue is therefore being sent to customers who may potentially hold in-date stock.

Dear Customer,

This Field Safety Notice regarding the Rocket Medical 6FG BLUE Needle Drain (REF: R58800-06-BD) has been issued. We are contacting you as our records indicate that you have received this product.

Affected Product Codes: **R58800-06-BD**

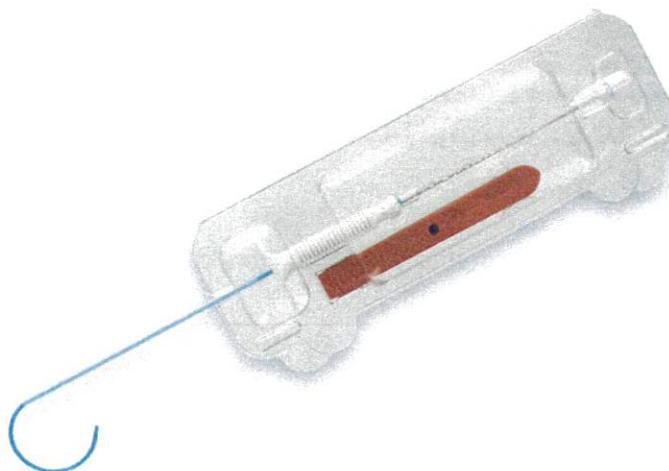


Figure 1

Product Code(s)	Product Description(s)	Affected LOT(s)	Basic-UDI(s)
R58800-06-BD	Rocket Multipurpose Blue Needle Drain Catheter	499948	050552709TF06DXY

Table 1

Description of the problem:

Rocket Medical has been made aware of the following potential issue with the Rocket 6FG BLUE Needle Drain (REF: R58800-06-BD).

In rare cases, there have been instances where, as part of manufacturing, the needle of the blue drain device has punctured the catheter wall, rendering the device unusable and presenting a possible needle stick injury opportunity to users. Figure 2 shows an example of the aforementioned issue.

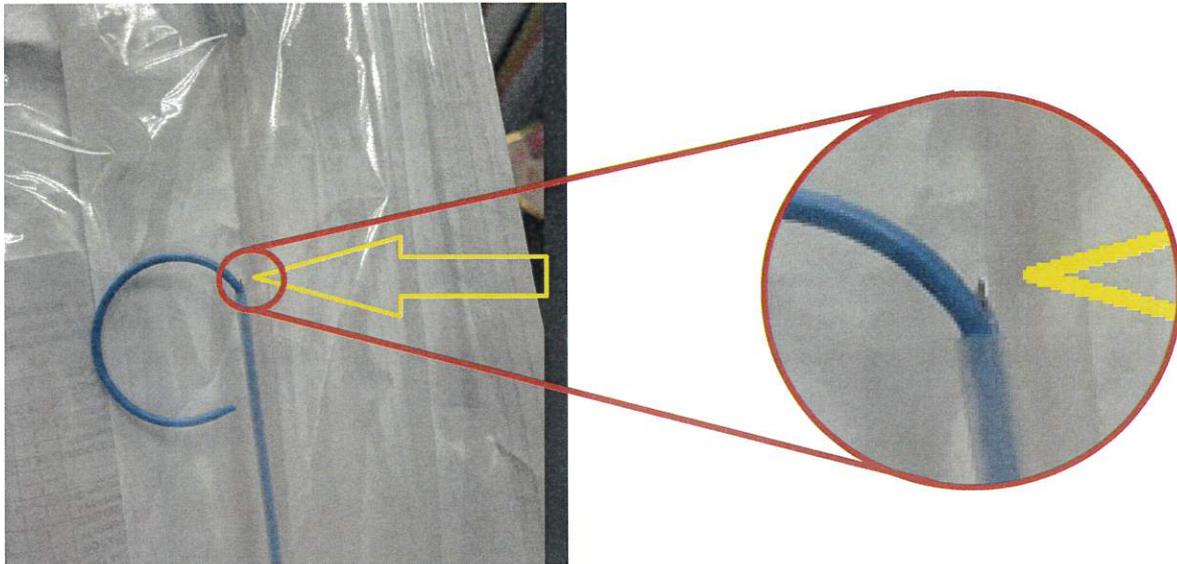


Figure 2

Actions Required by Customers:

We understand that you received an affected lot of R58800-06-BD and therefore request that you follow the steps listed below:

- Only if the needle can be seen protruding through the wall of the catheter (as shown in Figure 1), the device should be discarded immediately without being used.
- There is no need to discard stock that is visibly unaffected.
- Ensure a copy of this FSN is available to all users or potential users of this device
- Complete the FSN acknowledgement form at the end of this document and return to: CustomerServices@rocketmedical.com

ROCKET MEDICAL PLC
SEDLING ROAD
WASHINGTON
NE38 9BZ
UK

TEL: +44 191 419 4488
FAX: +44 191 419 5693
Email: CustomerServices@rocketmedical.com
www.rocketmedical.com



Stock Instruction:

- Stock is not affected; no action is required.

Rocket Medical PLC. does not expect any disruption in the supply of this device because of this issue.

We have notified the relevant regulatory authorities of this issue and the resulting Field Safety Corrective Action.

Your cooperation in this matter is greatly appreciated. We would like to sincerely apologise for the inconvenience caused by this issue and thank you for your continued custom. If you have any questions on this issue, please contact your Rocket Medical sales representative.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'Laura Hutchinson'.

Laura Hutchinson

Head of Quality and Regulatory Affairs

Rocket Medical Plc.

06-Mar-2026

Customer Acknowledgement Form

Product Code(s)	Product Description(s)	Affected LOT(s)	Basic-UDI(s)
R58800-06-BD	Rocket Multipurpose Blue Needle Drain Catheter	499948	050552709TF06DXY

Table 2

On behalf of this organisation, I acknowledge that I have read and understood this FSN, completed the indicated actions and that the information will be displayed in a prominent position within the appropriate clinical environment for a minimum of one month from the date of receipt.

Number of Units Affected (Lot 499948)		
Have Affected Units been Destroyed	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Replacement(s) Required	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Organisation		Location (Country)	
Address			
Email		Telephone no.	
Name		Position no.	
Signature		Date	

Name	David Ashby
Position	Regulatory Affairs Manager
Organisation	Rocket Medical PLC
Email	CustomerServices@rocketmedical.com
Subject of email	URGENT FIELD SAFETY NOTICE Seldinger Chest Drainage Kit