

Date: 23 September 2024

**Urgent Field Safety Notice NVFSN-06**

**Rocket Safety Needle Drain 8FG x 16cm paracentesis catheter with blunt obturator needle (R58800-08-SD)**

Dear Customer,

Rocket Medical is issuing this Field Safety Notification to inform you of a recall of the devices listed in Table 1. Our records indicate that you have one or more of these devices.

**Affected Product Codes:**

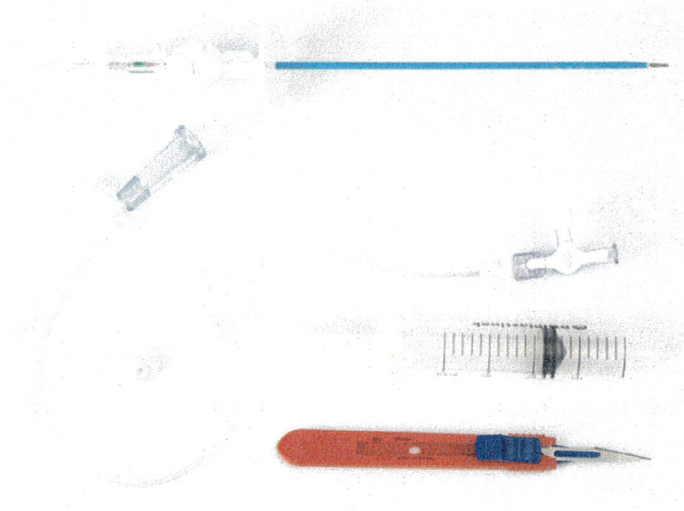


Figure 1: This is an image showing R58800-08-SD

Product Code	Product Name	LOT Number
R58800-08-SD	Rocket Safety Needle Drain 8FG x 16cm paracentesis catheter with blunt obturator needle	501875

Table 1

**Description of the problem:**

Rocket Medical PLC has identified a manufacturing issue affecting devices from only **Lot 501875**. During the production of this specific lot, the adhesive/glue used to secure the drainage line to the stitch plate was not correctly applied. As a result, the drainage line may separate from the tap. Some users may have resorted to using adhesive tape to secure the connection. Using tape to secure the drainage line is not an acceptable fix and should not be performed.

If you have not used the device please do not use it and dispose in line with local hospital policy. If the device has already been used on a patient please note there is no on-going risk to the patient following the procedure.

**Actions Required:**

We understand that you received the above referenced product(s) and therefore request that you follow the steps listed below:

- Do not use any of the affected devices. Rocket Medical recommend the disposal of any devices with the LOT number: 501875. Dispose of the device as per the disposal statement listed below however if you would prefer to return the device please do so.
- Ensure a copy of this FSN is available to all users or potential users of this device
- Complete the FSN acknowledgment form at the end of this document and return to: [fieldsafetynotices@rocketmedical.com](mailto:fieldsafetynotices@rocketmedical.com) by the **4<sup>th</sup> October 2024**.

**Disposal Instructions:** This device, its accessories and the consumables used with it, should be handled and disposed of in accordance with policy of the healthcare setting and with regard to all applicable regulations, including but without limitation to, those pertaining to human health and safety and care of the environment. Failure to do so may increase the risks of infection or other microbial hazards. Take care when handling sharps, to avoid needlestick injuries. Ensure sharps are disposed of in sharps containers.

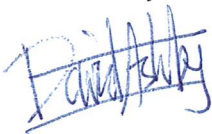
Rocket Medical PLC. does not expect any disruption in the supply of this device as a result of this issue.

We have notified the Medicines and Healthcare products Regulatory Agency (MHRA) of the issues with this device as per MEDDEV 2 12-1 5.4.4.2.

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.

For questions regarding replacement/reimbursement of the device please contact your local distributor.

Yours Sincerely,



David Ashby  
Regulatory Affairs Manager  
Rocket Medical Plc.

## Customer acknowledgement form

Please complete this form *even if you have not seen this issue*.

Device affected: Rocket Safety Needle Drain 8FG x 16cm paracentesis catheter with blunt obturator needle: **R58800-08-SD LOT 501875**

On behalf of this organisation, I acknowledge that I have read and understood this FSN 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.

### FROM:

Organisation	
Position	
Name	
Email	
Telephone no.	
Date	
Signature	

Number of units in lot number 501875	
Result of affected devices (Please tick one of the below):	
Destroyed: <input type="checkbox"/>	Returned to Distributor: <input type="checkbox"/>

### Return completed forms by email to:

Name	Joshua Huldie
Position	Regulatory Affairs, <i>Officer</i>
Organisation	Rocket Medical PLC
Email	<a href="mailto:fieldsafetynotices@rocketmedical.com">fieldsafetynotices@rocketmedical.com</a>
Subject of email	URGENT FIELD SAFETY NOTICE R58800-08-SD Rocket Safety Needle Drain 8FG x 16cm paracentesis catheter with blunt obturator needle