ROCKET MEDICAL PLC
SEDLING ROAD
WASHINGTON
TYNE & WEAR NE38 9BZ
ENGLAND

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

Date: 15th November 2024

Urgent Field Safety Notice NVFSN-08

Rocket Thoracentesis Catheter 8Fg (R51551-08-00) & Rocket Thoracentesis Catheter - 6Fg (R51551)

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 Code(s):

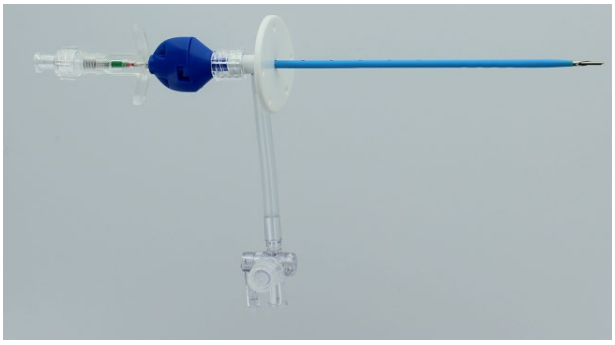

Figure 1: R51551-08-00 Rocket Thoracentesis Catheter 8Fg

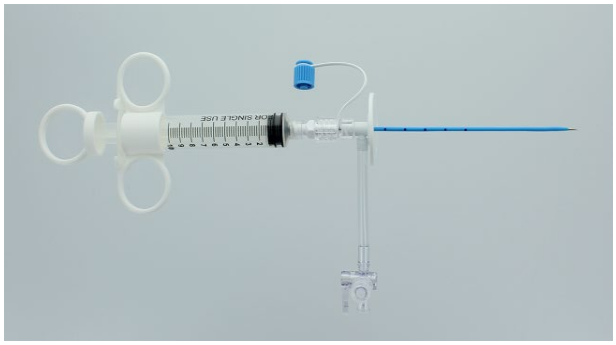

Figure 2: R51551 Rocket Thoracentesis Catheter - 6Fg

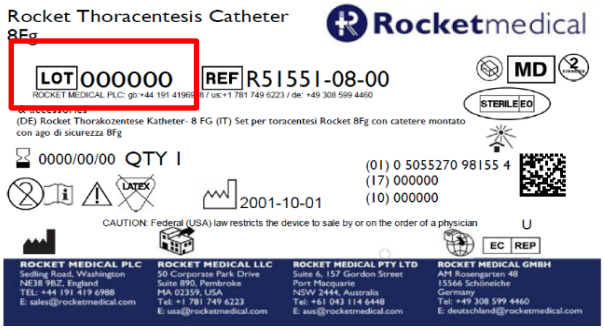

Figure 3: Location of Rocket Medical LOT numbers on labels

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Product Code	Product Name	LOT Number	Basic UDI
R51551-08-00	Rocket Thoracentesis Catheter 8Fg	499776 500749 501012 501287 501685 501703 501909 501998 502144 502339	050552709TF06DXY
R51551	Rocket Thoracentesis Catheter - 6Fg	500616 500984 501149 501397 501543 501702 501840 501970 501996 502143 502530	050552709TF06DXY

Table 1

ROCKET MEDICAL PLC – SRN: **GB-MF-000025375**

Description of the problem:

Rocket Medical PLC has identified a manufacturing issue affecting devices from the lot(s) listed in **Table 1**. During the production of these specific lots, 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 of the device(s). If the device has already been used on a patient please note there is no ongoing 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 recommends returning any devices with the lot numbers listed in **Table 1**.
- 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 it to fieldsafetynotices@rocketmedical.com. Once completed forms are received, a replacement unit(s) will be processed.

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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.

Please complete both forms at the end of this document these being the **Customer acknowledgement form** and **Rocket Medical replacement form** then return to fieldsafetynotices@rocketmedical.com.

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

We have notified the applicable regulatory authorities of the issues with this device.

We greatly appreciate your cooperation in this matter. We sincerely apologise for the inconvenience caused by this issue and thank you for your continued business.

If you have any questions on this issue, please contact your Rocket Medical sales representative.

Yours Sincerely,

Laura Hutchinson
Head of Quality & Regulatory Affairs
Rocket Medical Plc.

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Customer Acknowledgement Form

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

Device affected:

- Rocket Thoracentesis Catheter 8Fg: **R51551-08-00** Lot listed in **Table 1**
- Rocket Thoracentesis Catheter - 6Fg: **R51551** Lot listed in **Table 1**

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	

Return completed forms by email to:

Name	Joshua Huldie
Position	Regulatory Affairs, *Officer*
Organisation	Rocket Medical PLC
Email	fieldsafetynotices@rocketmedical.com
Subject of email	Rocket Thoracentesis Catheter 8Fg (R51551-08-00) & Rocket Thoracentesis Catheter - 6Fg (R51551)

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Rocket Medical Replacement Form

Dear Customer,

We regret to inform you of the issue encountered with device(s) **R51551** & **R51551-08-00**, outlined in the Field Safety Notice attached to this form. We would like to ensure customers receive alternative lots for the faulty lot(s) received.

To ensure you are reimbursed correctly, please fill out the form below and return it, along with the FSN acknowledgement form, to fieldsafetynotices@rocketmedical.com.

FROM:

Customer Name				
Company Name				
Customer Location (Country)				
Address				
Affected device(s) – Tick all that apply	R51551-08-00 ☐		R51551 ☐	
Please indicate the number of devices to be returned from each LOT	LOT	Number of devices disposed	LOT	Number of devices disposed
	499776		500616	
	500749		500984	
	501012		501149	
	501287		501397	
	501685		501543	
	501703		501702	
	501909		501840	
	501998		501970	
	502144		501996	
	502339		502143	
			502530	

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Name	Joshua Huldie
Position	Regulatory Affairs, *Officer*
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