

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: 11<sup>th</sup> 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):**

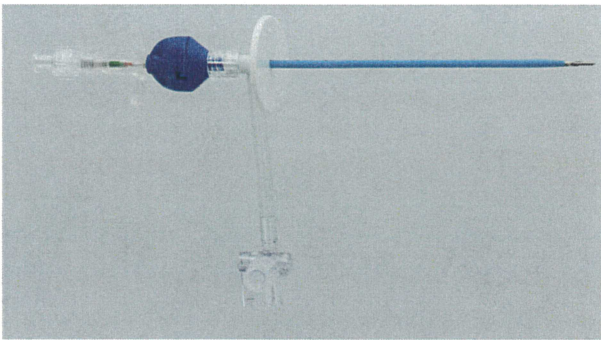


Figure 1: R51551-08-00 Rocket Thoracentesis Catheter 8Fg

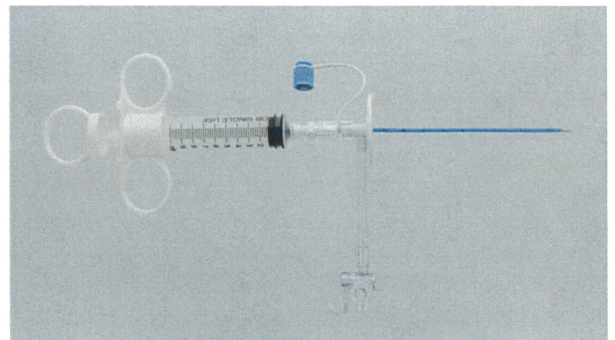


Figure 2: R51551 Rocket Thoracentesis Catheter - 6Fg

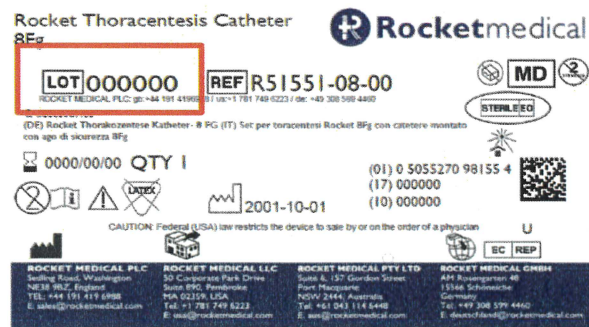


Figure 3: Location of Rocket Medical LOT numbers on labels

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

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 Rocket Medical will collect. 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 Rocket Medical replacement form and then return it to [fieldsafety@rocketmedical.com](mailto:fieldsafety@rocketmedical.com). Once completed forms are received, a replacement unit(s) will be processed.

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](mailto:CustomerServices@rocketmedical.com)  
[www.rocketmedical.com](http://www.rocketmedical.com)



**Return Instructions:** Rocket Medical will replace any of the above-listed lot numbers from **Table 1**, to ensure this process is smooth and we replace each affected unit 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](mailto: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,

A handwritten signature in cursive script, appearing to read 'Laura Hutchinson'.

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

## Distributor 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:**

<b>Organisation</b>	
<b>Position</b>	
<b>Name</b>	
<b>Email</b>	
<b>Telephone no.</b>	
<b>Date</b>	
<b>Signature</b>	

**Return completed forms by email to:**

<b>Name</b>	Joshua Huldie
<b>Position</b>	Regulatory Affairs, <i>Officer</i>
<b>Organisation</b>	Rocket Medical PLC
<b>Email</b>	<a href="mailto:fieldsafetynotices@rocketmedical.com">fieldsafetynotices@rocketmedical.com</a>
<b>Subject of email</b>	Rocket Thoracentesis Catheter 8Fg (R51551-08-00) & Rocket Thoracentesis Catheter - 6Fg (R51551)

### 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](mailto:fieldsafetynotices@rocketmedical.com).

**FROM:**

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

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



**Device Collection Information:**

Contact name (For replacement units)	
Device Collection Address	
Contact telephone number	
Email address	

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