

Date: 15th November 2024

Distributor Instructions (UK) Urgent Field Safety Notice NVFSN-08

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

Dear Distributor,

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. Due to this, we are conducting a product recall on the device(s) and lot(s) listed in table 1.



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



Figure 2: R51551 Rocket Thoracentesis Catheter - 6Fg

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

Table 1

We are aware that the above LOTs have been supplied to your region. Due to the previously mentioned issue, we have deemed it necessary to supply all affected customers with an FSN (Field Safety Notice).

The distributor should complete the following actions to ensure this process is carried out:

Actions Required:

- Do not use any of the affected devices and dispose of any stock with LOTs listed in **Table 1**.
- This notice needs to be passed on to all those who need to be aware, within your organisation or to any organisation where the potentially affected devices have been transferred or on which this action has an impact. Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the recall action.
- **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 applicable regulatory authorities of the issues with this device.

Rocket Medical would like to apologise for the inconvenience caused by this issue and thank you for your continued custom.

Yours Sincerely,

David Ashby
Regulatory Affairs Manager
Rocket Medical Plc.