



نقدم بثقة
Moving Forward
with Confidence



To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)

Director General of Engineering Affairs, MOH

Director General of Royal Hospital

Director General of Khoula Hospital

Director General of Medical Supplies (MOH)

Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)

Hospital Director (Al Nahda Hospital)

Hospital Director (Al Massara Hospital)

The Head of Medical Services in SQU Hospital

The Head of Medical Services in Royal Oman Police

The Head of Medical Services in Ministry of Defence

The Head of Medical Services in The Diwan

The Head of Medical Services in The Sultan's Special Force

The Head of Medical Services in Internal Security Services

The Head of Medical Services in Petroleum Development of Oman

The Head of Medical Services in LNG Oman

ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 69 dated 23/3/2025 Regarding SFDA Recall of Rocket Thoracentesis Catheter 6Fg & 8Fg from (mfr: Rocket Medical PLC).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DSC
- Director of Pharmacovigilance & Drug Information Dept, DSC
- Director of Drug Control Department, DSC
- Director of Pharmaceutical Licensing Department, DSC
- Director of Central Quality Control Lab., DSC
- Supdt. of Central Drug Information



DSC
مركز سلامة الدواء
Drug Safety Center



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489

☒ @DSCPHO Email: dscpho@moh.gov.om



Circular No. 69/2025

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23 -09-1446 H

23 -03-2025

Recall of Rocket Thoracentesis Catheter 6Fg & 8Fg from Rocket Medical PLC.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/324
Product	Rocket Thoracentesis Catheter 6Fg & 8Fg.
Manufacturer	Rocket Medical PLC.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Product Code (Product Name, Basic UDI): 1- R51551-08-00 (Rocket Thoracentesis Catheter 8Fg, 050552709TF06DXY) 2- R51551 (Rocket Thoracentesis Catheter - 6Fg, 050552709TF06DXY) Please refer to the attachment for the affected lot numbers
Reason	During the production of the affected 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.
Action	1. Please do not use any of the affected devices. Rocket Medical recommends returning any devices with the affected lot numbers, replacement units will be provided. Refer to the attachment for more details. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: vigilance-md@moh.gov.om

Ph. Ibrahim Nasser Al Rashdi
Director General



ROCKET MEDICAL PLC
SEDLING ROAD
WASHINGTON
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ENGLAND

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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):

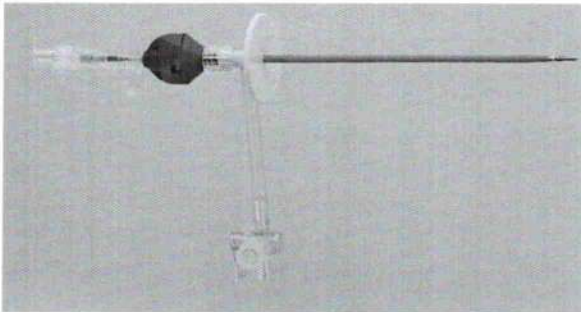


Figure 1: R51551-08-00 Rocket Thoracentesis Catheter 8Fg

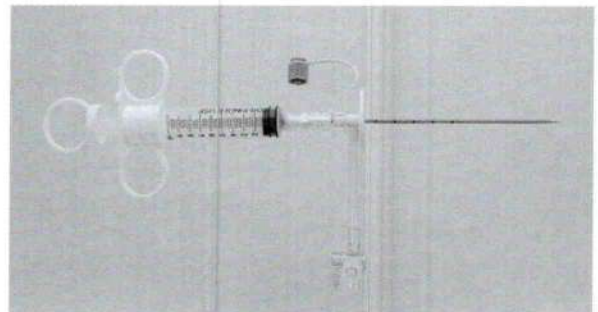


Figure 2: R51551 Rocket Thoracentesis Catheter - 6Fg



Figure 3: Location of Rocket Medical LOT numbers on labels

REGISTERED OFFICE
IMPERIAL WAY
WATFORD WD24 4XX

REGISTERED IN ENGLAND
NO. 03276608

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 fieldsafetyntotices@rocketmedical.com. Once completed forms are received, a replacement unit(s) will be processed.

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ENGLAND

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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.