

ROCKET MEDICAL PLC
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UNITED KINGDOM
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Email: regulatoryaffairs@rocketmedical.com
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ROCKET MEDICAL PLC – SRN: GB-MF-000025375

Urgent Field Safety Notice NVFSN-10

Rocket Seldinger Chest Drain Kit

16 OCT 2025

Dear Customer,

Rocket Medical is issuing this Field Safety Notice regarding the devices listed in Table 1. Our records indicate that you have one or more of these devices.

Affected Product Codes: R54544-12-SG, R54544-18-SG, R54544-12-PK, R54544-18-PK, R54549-16-PK and R54549-20-PK



SG Seldinger Chest Drainage Kit



PK Seldinger Chest Drain Kit

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Product Code(s)	Product Description(s)	Affected LOT(s)	Basic-UDI(s)
R54544-12-PK	Rocket 12Fg Seldinger Catheter Procedure Tray	496708 501186 496903 501548 497147 502122 497292 502317 497344 502534 497664 502949 499226 503201 499276 503429 499415 503732 499462 503899 499806 503935 499902 504283 500404 504581 500474 504637 500757 504821 500955 505025	
R54544-12-SG	Rocket 12Fg Seldinger Catheter with Safety Guard	497012 502660 497561 502780 497763 502978 498069 503202 499335 503384 499541 503406 499903 503536 500405 503733 500630 503900 500706 504179 500812 504397 501030 504628 501615 504822	050552709TF06DXY
R54544-18-PK	Rocket 18Fg Seldinger Catheter Procedure Tray	496899 500956 497076 501169 497584 501188 499227 502430 499417 502951 499461 503306 499897 503430 499898 503529	

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		499899	504180	
		499908	504543	
		500407	504823	
		500477		
		496809	501616	
		497346	501710	
		497665	502431	
		498972	503735	
		499909	503937	
		500782	504573	
		501256	504824	
R54544-18-SG	Rocket 18Fg Seldinger Catheter with Safety Guard	496659	497629	
R54549-16-PK	Rocket 16Fg Seldinger Catheter Procedure Tray	496918	499814	
		497077	500408	
R54549-20-PK	Rocket 20Fg Seldinger Catheter Procedure Tray	496455	499910	
		496811	500480	
		496919	501734	
		497516	503706	
		499083	504152	

Table 1

Description of the problem:

The Instructions for Use (IFU) (ZDOCK180) for the devices listed above contains the instruction "*The chest tube can now be secured to the skin by using the fixation device R54960-PG-FX or suture or both and is ready for connection to a suitable sealed drainage system such as the Rocket Blue Bottle or Rocket Ambulatory Bag*".

The IFU has been updated to include revised guidance regarding the need for a suture, in steps 14 and 15. The updated text now states: "*The chest tube must now be secured to the skin by suture and is ready for connection to a suitable sealed drainage system such as the Rocket Blue Bottle or Rocket Ambulatory Bag. Further support to the catheter can be provided by the fixation device.*"

The revised IFU is attached to this communication, and we kindly ask that you read it carefully to ensure continued safe and effective use of the device.

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Actions Required by Customers:

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

- Ensure a copy of this FSN and the updated IFU 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:
CustomerServices@rocketmedical.com

Stock Instruction:

- Stock is not affected; no action is required.

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

We have notified the relevant regulatory authorities of this issue and resulting Field Safety Corrective Action.

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

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Laura Hutchinson'.

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

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Customer Acknowledgement Form

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

Product Code(s)	Product Description(s)	Affected LOT(s)		Basic-UDI(s)
R54544-12-PK	Rocket 12Fg Seldinger Catheter Procedure Tray	496708	501186	050552709TF06DXY
		496903	501548	
		497147	502122	
		497292	502317	
		497344	502534	
		497664	502949	
		499226	503201	
		499276	503429	
		499415	503732	
		499462	503899	
		499806	503935	
		499902	504283	
		500404	504581	
		500474	504637	
R54544-12-SG	Rocket 12Fg Seldinger Catheter with Safety Guard	500757	504821	
		500955	505025	
		497012	502660	
		497561	502780	
		497763	502978	
		498069	503202	
		499335	503384	
		499541	503406	
		499903	503536	
		500405	503733	
		500630	503900	
		500706	504179	
		500812	504397	
		501030	504628	
R54544-18-PK	Rocket 18Fg Seldinger Catheter Procedure Tray	501615	504822	
		496899	500956	
		497076	501169	
		497584	501188	
		499227	502430	
		499417	502951	

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		499461 503306 499897 503430 499898 503529 499899 504180 499908 504543 500407 504823 500477	
R54544-18-SG	Rocket 18Fg Seldinger Catheter with Safety Guard	496809 501616 497346 501710 497665 502431 498972 503735 499909 503937 500782 504573 501256 504824	
R54549-16-PK	Rocket 16Fg Seldinger Catheter Procedure Tray	496659 497629 496918 499814 497077 500408	
R54549-20-PK	Rocket 20Fg Seldinger Catheter Procedure Tray	496455 499910 496811 500480 496919 501734 497516 503706 499083 504152	

On behalf of this organisation, I acknowledge that I have read and understood this FSN, completed the indicated actions 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.

Number of Units in Affected LOTs:	
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Organisation		Location (Country)	
Address			
Email		Telephone no.	
Name		Position no.	
Signature		Date	

Return completed forms by email to:

REGISTERED OFFICE: SEDLING ROAD, WASHINGTON, UNITED KINGDOM, NE389BZ
COMPANY NUMBER: 03276608

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Name	David Ashby
Position	Regulatory Affairs Manager
Organisation	Rocket Medical PLC
Email	CustomerServices@rocketmedical.com
Subject of email	URGENT FIELD SAFETY NOTICE Seldinger Chest Drainage Kit

