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Field Safety Notice

Name of the affected product: 3M™ Ranger™ Blood/Fluid Warming High Flow Sets, catalog number 24355
FSCA-identifier: 2022-11 FSCA Ranger
Type of action: Disposal of affected products

Date: November 7th, 2022

Attention: 3M Health Care Business Customers

Dear Customer,

3M is notifying all customers in impacted countries of the above-mentioned 3M™ Ranger™ Blood/Fluid Warming High Flow Sets, catalog number 24355 of a field safety corrective action.

Description of the problem and potential hazard and risk for the patient/user:
This corrective action has been initiated due to the identification of a manufacturing issue with the auto-venting bubble trap. There is the risk of a blood or fluid leak while priming the sets and/or during fluid administration. The products could be unable to deliver the therapy as per intended use and could expose the user to blood, blood products, and IV fluids during a leak.

Details on affected devices:
The following lots of 3M™ Ranger™ Blood/Fluid Warming High Flow Sets are subject to this field safety corrective action and were supplied after March 22nd, 2022:

Catalogue number	Lot number
24355	HX9137, HX9158, HX9162, HX9167, HX9169, HX9179, HX9181, HX9183, HX9184, HX9189, HX9190, HX9192, HX9198, HX9200, HX9202, HX9204, HX9214

Action to be taken by all customer:

1. Ensure all your internal and external customers are informed about this corrective action.
2. Please inform us if you supplied the affected items to customers outside your home country.
3. Please identify the affected product listed above and immediately cease use of affected models and lots of 3M™ Ranger™ Blood/Fluid Warming High Flow Sets.
4. Please discard all remaining affected product listed above per facility procedures.
5. Complete and return by e-mail to meddev.de@mmm.com the enclosed Acknowledgement Form, indicating that the corrective action was understood and executed. Please also indicate the number of devices you have disposed of.

Transmission of this Field Safety Notice:
Please pass on this notice immediately to all departments who might use the concerned products. In addition, ensure that the information is provided to any organisation where the concerned products potentially have been distributed.

Thank you for your immediate attention and cooperation. We apologise for any inconvenience this matter may cause.

Contact reference person:
If you have questions, please contact your local 3M representative.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Dr. Marie Isabel Cobbers
Safety Officer
3M Deutschland GmbH, Health Care Business
Carl-Schurz-Strasse 1, 41453 Neuss, Germany
Mail: meddev.de@mmm.com

Acknowledgement Form – FSN 2022-11 FSCA Ranger

Email completed form to: meddev.de@mmm.com

Please examine your inventory to determine if you have any of the 3M™ Ranger™ Blood/Fluid Warming High Flow Sets listed. Note, this corrective action only applies to the affected catalogue numbers and lots listed and does NOT apply to any other 3M™ Ranger™ products.

☐ Acknowledge that you have read and understood this letter and will complete the actions requested.

☐ We have examined our inventory and identified and disposed of the following number of 3M™ Ranger™ Blood/Fluid Warming High Flow Sets:

Catalogue number	**Lot number**	**Quantity of sets in inventory that have been disposed**
24355	HX9137, HX9158, HX9162, HX9167, HX9169, HX9179, HX9181, HX9183, HX9184, HX9189, HX9190, HX9192, HX9198, HX9200, HX9202, HX9204, HX9214	

☐ We have examined our inventory and do not have the affected 3M™ Ranger™ Blood/Fluid Warming High Flow Sets in stock.

Email completed form to: meddev.de@mmm.com

Person completing this form:

Name		Company /Hospital Name	
Signature		City, Country	
Date		Phone	
		E-mail	