Hofspoor 3
3994 VZ Houten
The Netherlands
www.icumed.com

URGENT: FIELD SAFETY NOTICE

Spinning and Non-Spinning Spiros™ Male Luer Leaks

16 March 2021

Dear Valued Customers:
Director of Risk Management
Director of Nursing
Director of Pharmacy

ICU Medical, Inc. is issuing this Urgent Field Safety Notice to notify you of a potential for leaks to occur with the Spiros Male Luer in certain lots. This Urgent Field Safety Notice letter details the issue and the required steps for you to perform.

Issue:
ICU Medical has identified the potential for certain lots of the Spiros to exhibit small amounts of leaks due to a molding defect. The leak occurs when the Spiros is not activated and prior to connecting to a patient's intravenous administration set. This issue pertains to both Spinning and Non-Spinning Spiros and was discovered through internal testing.

Potential Risk:
Fluid leakage prior to connection to an intravenous administration set may potentially cause delay of infusion or exposure to hazardous/allergenic medications. ICU Medical has not received reports of leaks or patient harm related to this issue.

Affected Product:
Our records indicate that you may have received some of the affected products, which were distributed directly from ICU Medical in United Kingdom between February 02, 2021 and February 05, 2021. The affected item and lot numbers are provided in Table 1.

Required Actions for Users:

1) Please discontinue the use and distribution of the affected product immediately. Check your inventory and quarantine all affected product at your facility.

2) Inform potential users of the product in your organization of this notification and complete the attached response form. Return the completed response form to the e-mail address on the form, even if you do not have the affected product.

3) ICU Medical has some lots of unaffected product available today and is actively increasing the amount of available inventory. Please contact ICU Medical customer service for product availability.

4) Upon receipt of the completed response form and return of the affected product, ICU Medical will credit you for any product returned. You will only receive credit for product that you return.
NOTE: Credits for product purchased through distributor will be credited by the distributor.

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5) If you have distributed the product further, immediately notify your accounts that received the product identified in the Affected Product / Table 1 sections of this notification and ask your customers to complete a response form and return to you for overall completion.

Follow up Actions by ICU Medical:

Please contact Customer Service using the information provided below for assistance reordering replacement product.
For further inquiries, please contact ICU Medical using the information provided below.

ICU Medical Contact	Contact Information	Areas of Support
Global Complaint Management	ProductComplaintsPP@icumed.com	To report adverse events or product complaints
ICU Customer Service	UKSupport@icumed.com	Additional information or assistance

MHRA-Medicines and Healthcare Products Regulatory agency has been notified of this action.

ICU Medical is committed to patient safety and is focused on providing exceptional product reliability and the highest level of customer satisfaction. Thank you for your prompt support on this important matter. We appreciate your cooperation.

Sincerely,

Corine Broekhuizen
Director, Quality and Regulatory Affairs
ICU Medical BV

Enclosures:

- Affected Product and Lot Numbers
- Response Form

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Table 1: Affected Product and Lot Numbers

List Number	Product Description	Lot Numbers
011-CH3967	155 cm (61'') 20 Drop Admin Set w/15 Micron Filter, Check Valve, Clave™, Spiros™ w/Red Cap	5125174
CH3235	30" (76 cm) Appx 4.1 ml, Yellow 20 Drop Admin Set w/15 Micron Filter, Spiros™	5125276

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human connections

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URGENT: FIELD SAFETY NOTICE RESPONSE FORM

Spinning and Non-Spinning Spiros™ Male Luer Leaks

16 March 2021

Please check your inventory and complete the information below, even if you do not have the affected product. *Failure to complete all sections of this page may result in improper, delayed or denied credit.*

Please return the completed form to EMEA-Quality@icumed.com, UKSupport@icumed.com and your ICU Medical sales representative.

Hospital/Facility Name	
ICU Medical Customer # (if applicable)	
Address/City/Postal code	
Contact Name/Phone/E-mail Address	
Completed by: Printed Name/Signature/Date	

☐ I have **NO** affected product (complete and return this form to the e-mail addresses above).
☐ **YES**, I have affected product

If you have affected product on hand, please complete table below:

TABLE 1

List Number	Lot Number	Quantity in inventory	PO, debit memo or invoice

If you have distributed the product further, please complete table below with collated information received from your customers and respond to ICU Medical with the overall information.

TABLE 2

List Number	Lot Number	Quantity destroyed locally by customer	Quantity returned to distributor

☐ I have followed the instructions provided to me and I will **destroy** affected products on site (complete and return provided Certificate of Destruction to the email addresses on the certificate).

☐ I have followed the instructions provided to me and I will contact my ICU Medical CS Representative to make arrangement to **return** the affected products.

Adverse events and complaints associated with the use of these products should be reported and emailed to MHRA or to the ICU Medical at the contact information provided.