

**URGENT: FIELD SAFETY NOTICE**  
**Spinning and Non-Spinning Spiros™ Male Luer Leaks**

12 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 Belgium, France, Italy, South Africa, Spain and United Kingdom between January 25, 2021 and February 10, 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.

- 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.

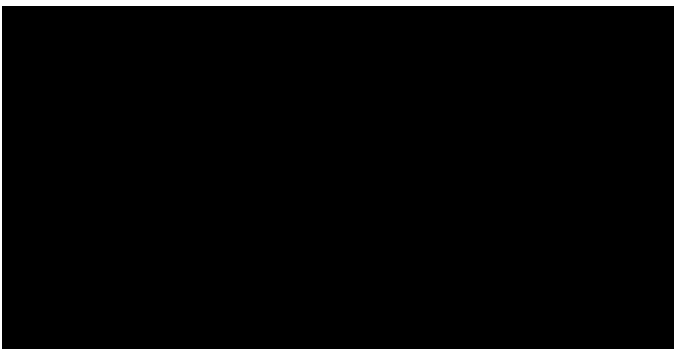
For further inquiries, please contact ICU Medical using the information provided below.

ICU Medical Contact	Contact Information	Areas of Support
Global Complaint Management	<a href="mailto:ProductComplaintsPP@icumed.com">ProductComplaintsPP@icumed.com</a>	To report adverse events or product complaints
ICU QA Department	<a href="mailto:EMEA-Quality@icumed.com">EMEA-Quality@icumed.com</a>	Additional information or assistance
ICU Customer Service Department	Belgium: <a href="mailto:BelgiumSupport@icumed.com">BelgiumSupport@icumed.com</a> France: <a href="mailto:FrenchSupport@icumed.com">FrenchSupport@icumed.com</a> Italy: <a href="mailto:servizioclienti@icumed.com">servizioclienti@icumed.com</a> Spain: <a href="mailto:serviciocliente.es@icumed.com">serviciocliente.es@icumed.com</a> UK: <a href="mailto:UKSupport@icumed.com">UKSupport@icumed.com</a> Distributors: <a href="mailto:EMEA distributor-support@icumed.com">EMEA distributor-support@icumed.com</a>	Additional information or assistance

National Competent Authorities have 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,



- Affected Product and Lot Numbers
- Response Form

**Table 1: Affected Product and Lot Numbers**

<b>List Number</b>	<b>Product Description</b>	<b>Lot Numbers</b>
011-CH3967	155 cm (61") 20 Drop Admin Set w/15 Micron Filter, Check Valve, Clave™, Spiros™ w/Red Cap	5125174
011-H2864- HSR	180 cm (71") PUR Ambr. Deflussore con Spiros®, Camera, Reg. Flusso, BCV, Y-CLAVE® e LL Gir.	5142887
011-H3597	42 cm (16.5") PUR Yellow Transfer Set, Bag Spike w/Clave® Additive Port, Check Valve, Spiros®, Purple Cap	5125225
034-H2629	Appx 1.0 ml, Adaptador universal para sistemas IV con Spiros™	5125301
CH2000S-PC	Spinning Spiros® Closed Male Luer, Purple Cap	5125296
CH3034	5" (13 cm) Bag Spike Adapter w/Spiros™ w/Red Cap, Vented Cap	5125305
CH3235	30" (76 cm) Appx 4.1 ml, Yellow 20 Drop Admin Set w/15 Micron Filter, Spiros™	5125276

**URGENT: FIELD SAFETY NOTICE RESPONSE FORM**

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12 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](mailto:EMEA-Quality@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 National Competent Authorities or to the ICU Medical at the contact information provided.**