icumedical
human connections

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

URGENT: FIELD SAFETY NOTICE

Spinning Spiros™ Male Luer Leaks
See Table 1 for Affected Product and Lot Numbers

08 September 2020

Dear Valued Customers:

Director of Risk Management
Director of Nursing
Director of Materials Management

ICU Medical, Inc. is issuing this Urgent Field Safety Notice to notify you of a potential for leaks to occur with the Spinning 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 Spinning Spiros to exhibit small amounts of leaks due to manufacturing variability. This information pertains to the spinning version of the Spiros only. The non-spinning version is not affected by this communication.

Potential Risk:
Fluid leakage may potentially cause delay of infusion, contamination of the fluid path, exposure to hazardous medications, or fluid path air-in-line. ICU Medical has received reports of leaks potentially related to this issue and has not received reports of permanent injury or death.

Affected Product:
Our records indicate that you may have received some of the affected products, which were distributed in Denmark between April 2020 and July 2020. 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. In the event specific product is unavailable, consider use of the non-spinning Spiros or the ChemoLock CSTD as alternatives. 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.

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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 them to complete a response form and return to the e-mail address on the form.

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	ProductComplaintsBucharest@icumed.com	To report adverse events or product complaints
ICU Customer Service	EMEAdistributor-support@icumed.com	Additional information or assistance

Danish Medicines Agency (Lægemiddelstyrelsen) 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
CH2000S	Spinning Spiros™, Closed Male Luer	4603678 4726692 4756786
CH2000S-C	Spinning Spiros® Closed Male Luer, Red Cap	4749755 4774701 4774702 4849192 4713516 4749733 4763174

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URGENT: FIELD SAFETY NOTICE RESPONSE FORM

Spinning Spiros™ Male Luer Leaks
See Table 1 for Affected Product and Lot Numbers

08 September 2020

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, EMEAdistributor-support@icumed.com or your ICU Medical sales representative.

Hospital/Facility Name	
ICU Medical Customer # (if applicable)	
Address/City/Postal code	
Contact Name/Title/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, I have followed the instruction provided to me and I am going to contact EMEAdistributor-support@icumed.com to make arrangement to return the affected products.

If affected product is not being returned, please explain below:

- Have you distributed the product further to the retail level? YES___ NO___
  - If yes, have you notified your retail customers? YES___ NO___ (if no, explain below)

If you have distributed the product further, please provide the list of your retail customers, inclusive of customer name, address, city, state, zip code, telephone number and quantity of product distributed along with your completed response form to the contact information listed above so ICU Medical can verify effectiveness of the recall notification to the appropriate level.

Lot Number	Quantity in inventory	Quantity to be returned	Wholesaler/Distributor Name If you purchased from Wholesalers/Distributors include name, address, city, state, zip, quantity from each, and invoice number. If you purchased directly from ICU Medical leave this section blank.	PO, debit memo or invoice
			1.	
			2.	

Adverse events and complaints associated with the use of these products should be reported and emailed to Danish Medicines Agency (Lægemiddelstyrelsen) or to the ICU Medical at the contact information provided.