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

# URGENT: FIELD SAFETY NOTICE

## Attention: Update to previous communication

**Spinning Spiros™ Male Luer Leaks**

**See Table 1 for Affected Product and Lot Numbers**

13 October 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.

**UPDATED INFORMATION: On 08 September 2020, ICU Medical Inc. issued an Urgent Field Safety Notice letter informing customers of a recall of the potential for leaks to occur with the Spinning Spiros Male Luer in certain lots. As a result of continued evaluation, ICU Medical is expanding the scope of the previously distributed Urgent Field Safety Notice to include additional list and lot numbers that may be affected by this issue. All product lots identified in this communication are impacted by this issue.**

**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:**
**UPDATED INFORMATION: Our records indicate that you may have received some of the affected products, which were distributed in United Kingdom between February 2020 and September 2020. The affected item and lot numbers are provided in Table 1. Please note the list includes the additional affected products as well as affected products previously communicated.**

**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.

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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. 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 | 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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human connections

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## Table 1: Affected Product and Lot Numbers

**Additional affected Spinning Spiros Male Luer devices are in red.**

| List Number | Product Description | Lot Numbers |
|---|---|---|
| 011-CH3261 | 76 cm (30") Admin Set, 2 Spiros® w/Red Cap, 20 Drop In-Line Drip Chamber w/15 Micron Filter, Bag Hanger | 4784390 |
| 011-CH3772 | 206 cm (81") 20 Drop Admin Set w/15 Micron Filter, Check Valve, Clave™, Spiros™ w/Red Cap | 4711264 |
| 011-CH3773 | 246 cm (97") 20 Drop Admin Set w/15 Micron Filter, Check Valve, Clave™, Spiros™ w/Red Cap | 4605516 |
| 011-CH3967 | 155 cm (61") 20 Drop Admin Set w/15 Micron Filter, Check Valve, Clave™, Spiros™ w/Red Cap | 4723103<br>4882016 |
| CH2000S-C | Spinning Spiros® Closed Male Luer, Red Cap | 4749733<br>4749750<br>4749755<br>4750952<br>4763174<br>4763178<br>4774701<br>4774702<br>4895446<br>4896004<br>4902104 |
| CH2000S-PC | Spinning Spiros® Closed Male Luer, Purple Cap | 4727446 |
| CH3034 | 5" (13 cm) Bag Spike Adapter w/Spiros™ w/Red Cap, Vented Cap | 4719927<br>4795452<br>4849233 |
| CH3235 | 30" (76 cm) Appx 4.1 ml, Yellow 20 Drop Admin Set w/15 Micron Filter, Spiros™ | 4763261 |

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# URGENT: FIELD SAFETY NOTICE RESPONSE FORM

## Attention: Update to previous communication

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**See Table 1 for Affected Product and Lot Numbers**

13 October 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, UKSupport@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 UKSupport@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<br>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 MHRA-Medicines and Healthcare Products Regulatory agency or to the ICU Medical at the contact information provided.