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

# URGENT: FIELD SAFETY NOTICE

| Item No. | Description |
|---|---|
| 011-41424-03 | THERMOSET® ROOM TEMPERATURE CLOSED-LOOP INJECTABLE DELIVERY SYSTEM WITH IN-LINE TEMPERATURE PROBE. |
| 011-41423-03 | ICED THERMOSET®CLOSED-LOOP INJECTATE DELIVERY SYSTEM FOR COLD INJECTATE |

16 October 2018

Dear Valued Customers:
Director of Risk Management
Director of Nursing
Director of Materials Management
Director of Anesthesia

ICU Medical is issuing this letter to notify you of potential leaks with certain lots of THERMOSET® Closed Loop Delivery Systems. This product notification details the issue and the required steps for you to perform.

**Issue:** ICU Medical received reports of leakage with some lots of THERMOSET® products distributed in EMEA between January 2018 and August 2018. Our investigation identified a defect in the thermoset check valve component used in the affected lots that may lead to leakages.

**Potential Risk:** A set with this defect can result in leakage of sterile solution, clinically significant blood loss, air embolism or systemic infection. To date, ICU Medical has not received any reports involving adverse events related to this issue.

**Affected Product:** Our records indicate that you have received some of the affected products, which were distributed in EMEA between January 2018 and August 2018. The affected item numbers and lots are provided in Table 1.

**Required Actions for Users:**

1) Please stop 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) Please contact ICU Medical Customer Service or your Sales representative for assistance on how to return the products affected.

4) 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.

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**Follow-up Actions by ICU Medical:** ICU Medical implemented corrective actions to correct the manufacturing process that led to the minor defects in the thermoset check valve. For product replacement options please contact Customer Care representatives using the information provided below.

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

| ICU Medical Contact | Contact Information | Areas of Support |
|---|---|---|
| Global Complaint Management | EMEA-Quality@icumed.com | To report adverse events or product complaints |
| Customer Service | DistributorsEurope@icumed.com | Product Replacement Options |

SwissMedic 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
- Customer Response Form

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

| Item No. | Description | Lot Numbers |
|---|---|---|
| 011-41424-03 | THERMOSET® ROOM TEMPERATURE CLOSED-LOOP INJECTABLE DELIVERY SYSTEM WITH IN-LINE TEMPERATURE PROBE. | 3585777 |
| | | 3598038 |
| | | 3627756 |
| | | 3643150 |
| 011-41423-03 | ICED THERMOSET®CLOSED-LOOP INJECTATE DELIVERY SYSTEM FOR COLD INJECTATE | 3585765 |

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# URGENT FIELD SAFETY NOTICE RESPONSE FORM

| Item No. | Description |
|---|---|
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16 October 2018

**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 this completed form to EMEA-Quality@icumed.com, DistributorsEurope@icumed.com or your responsible sales representative.

| | |
|---|---|
| Name of Hospital / Facility | |
| Hospital / Facility Address | |
| Telephone Number | |
| Name of Person Completing this Form | |
| Signature of Person Completing this Form | |
| Date | |

☐ I have **NO** affected product (complete and return this form to the e-mail above).
☐ **YES**, I have affected product (complete and return this form to the e-mail above. Your support team will contact you for returning the product).

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)

| Lot Number | 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. | |
| | | 3. | |

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