6000 Nathan Lane N.
Minneapolis, MN 55442
https://www.icumed.com

# URGENT: FIELD SAFETY NOTICE

# Jelco® IV Catheter 4013

6th Sept 2023

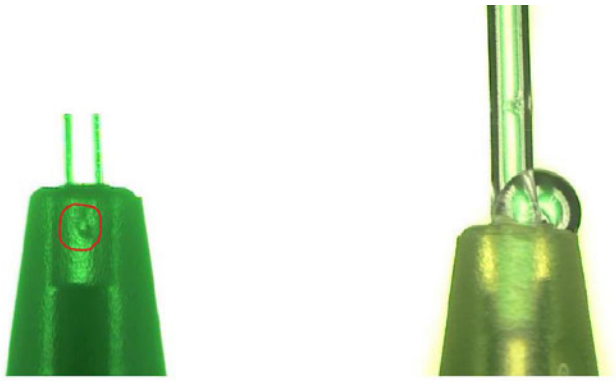
Dear Valued Customers:

Smiths Medical, Inc. is issuing this Urgent Field Safety Notice to notify you of a potential defect with the Jelco® IV Catheters. This letter details the issue and the required steps for you to perform.

**Issue:**
Smiths Medical has identified the potential for a manufacturing defect within specific lots of the 24-gauge Jelco® IV catheters which may result in leakage at the insertion site.

**Potential Risk:**
This manufacturing defect can potentially create a leak path in the catheter tubing underneath the catheter hub. Figure 1 depicts the defect within the catheter hub and the resulting leak at the junction between the hub and the tubing. A potential concern would be any fluid loss that would disrupt routine fluid delivery, drug delivery or administration of blood. To date, Smiths Medical has not received any reports of serious injury or death associated with this issue.

**Figure 1.** 24GA Jelco showing catheter hole circled in red causing leakage



**Affected Product:**
Our records indicate that you may have received some of the affected products which were distributed in Germany in October and November 2022. The affected item and lot numbers are provided in Table 1, below:

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

| Item Number | Product description | Lot Number |
|---|---|---|
| 4013 | 24G Jelco IV Catheter | 4306603<br>4306605<br>4298910 |

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**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, even if you do not have affected product. Please indicate on the form whether you intend to return this product to Smiths Medical or destroy it locally and return the completed response form to EMEA-Quality@icumed.com .

3) 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.

4) Please contact Customer Service using the information provided below for assistance reordering replacement product.

**Follow up Actions by Smiths Medical:**
Upon receipt of the affected product, or upon receipt of a Certificate of Destruction, Smiths Medical will credit you for any product returned/destroyed. You will only receive credit for product that you return or that you certify has been destroyed locally. NOTE: Credits for product purchased through a distributor will be credited by the distributor.

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

| Smiths Medical Contact | Contact Information | Areas of Support |
|---|---|---|
| Global Complaint Management | globalcomplaints@icumed.com | To report adverse events or product complaints |
| Customer Support | https://www.icumed.com/about-us/contact-us | Additional information or assistance |

Your country regulatory agency has been notified of this action.

Smiths 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,

Enclosures:

- Customer Response Form (page 3 of this notice)
- Certificate of Destruction (separate file)

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# URGENT: FIELD SAFETY NOTICE – RESPONSE FORM

## Jelco® IV Catheter 4013

6th Sept 2023

**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, Smiths Medical Customer Service and your local sales representative.

| | |
|---|---|
| Name of Hospital / Facility | |
| Hospital / Facility Address | |
| Telephone Number | |
| Name and Title of Person Completing this Form | |
| Signature of Person Completing this Form | |
| Date | |
| If Purchased through a distributor, please list distributor name/location here for traceability purposes | |

**Please select one:**

☐ I have **NO** affected products (complete and return this form to the e-mail address above)

☐ **YES,** I have affected products

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 Smiths Medical CS Representative to make arrangements to **return** the affected products.

☐ I have followed the instructions provided to me. If affected product is not being returned, please explain below:

**Adverse events and complaints associated with the use of this product should be reported and emailed to Smiths Medical's Global Complaint Management Department at globalcomplaints@icumed.com.**