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URGENT MEDICAL DEVICE CORRECTION

Level 1® H-2 Pressure Chamber Door and Latch Replacement Kits

14 May 2024

Dear Valued Customers:
Director of Biomedical Engineering
Director of Nursing
Director of Risk Management

Smiths Medical is issuing this letter to notify you of a potential issue with specific Level 1 H-2 Pressure Chamber Door and Latch Replacement Kits. These kits are used to replace the doors and hinges on H-2 Pressure Chambers, which are used with Level 1 Fast Flow Fluid Warmers. This letter details the potential issue, the affected models, and the required steps to perform.

Issue:
During an internal inspection, it was identified that bag hooks in certain Level 1 H-2 Pressure Chamber Door and Latch Replacement Kits may have been assembled in an incorrect position. Refer to Figure 1 for an image of incorrectly installed bag hooks.

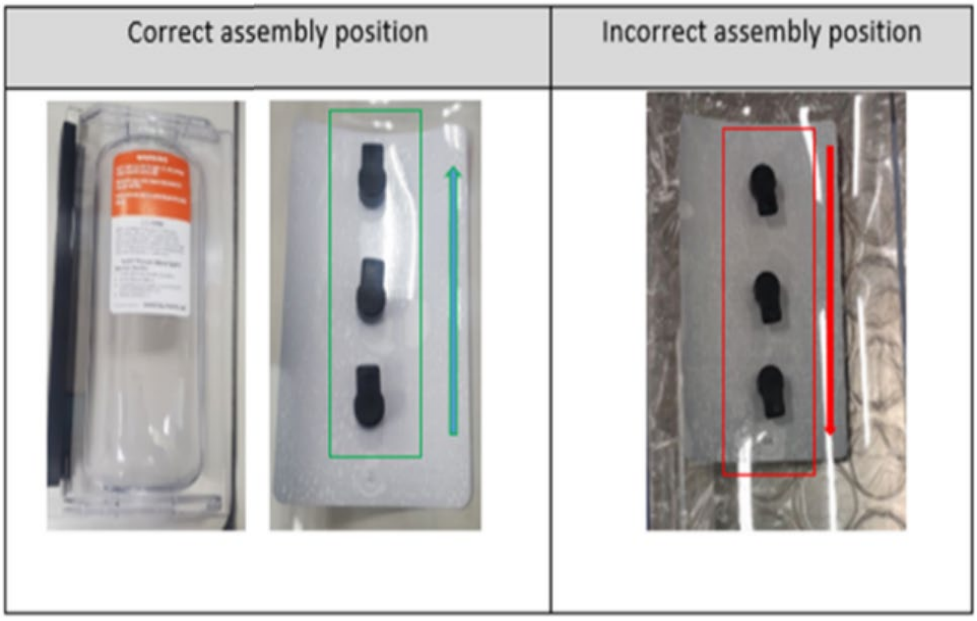


Figure 1: Incorrectly installed bag hooks, misoriented 180°

Potential Risk:
Improperly assembled bag hooks will not allow for proper bag placement within the pressure chamber and may lead to delay of therapy or the inability to complete a full infusion of infusate.

No serious injuries or deaths have been reported to ICU Medical for this issue.

Affected Models:

1,777 kits from potentially affected lots are associated with this notification. Products serviced using these kits may be affected. All customers who received these kits, or devices installed with these kits, are being notified in this communication. Included with your specific response form is a list of the products we shipped to you that may be affected by this notice.

Table 1: Affected Products(s)

Product Name	List Number
H-2 Pressure Chamber Door and Latch Replacement Kit	H2N-KIT-EN
H-2 Pressure Chamber Door and Latch Replacement Kit (EN)	7802722-EN
H-2 Pressure Chamber Door and Latch Replacement Kit (DE)	7802722-DE

Customer Required Actions:

To address the described risk, users must be aware of whether their devices are affected and follow the instructions below.

1. Identify all affected Level 1 H2N or 7802722 kits (including those installed into H-2 Pressure Chambers) in your possession:
    a. Compare the orientation of the bag hooks inside the doors with the correct assembly shown in the above image.
    b. If the bag hooks are assembled correctly, then your product is not affected, and you can continue to use the pressure chamber. Complete the attached Response Form confirming that you have no affected product.
    c. If the bag hooks are assembled incorrectly, then your product is affected, and it will need to be removed from service and replaced. **Do not attempt to use or repair the affected product.** Complete the attached Response Form identifying the number of affected products in your possession.

2. Share this notification with all potential users of the devices to ensure they are aware of the proposed mitigations.

3. Complete and return the attached Customer Response Form to smithsmedical5830@sedgwick.com **within ten days of receipt** to acknowledge your understanding of this notification. Return of this form will initiate the replacement process if you've identified affected product.

4. **DISTRIBUTORS:** If you have distributed potentially affected products to your customers, please immediately forward this notice to them. Request that they complete the Response Form and return it to smithsmedical5830@sedgwick.com.

Follow up actions by Smiths Medical:
Smiths Medical will provide replacement kits for all affected products.

For further inquiries, please contact Smiths Medical using the following information:

Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	globalcomplaints@icumed.com 1-(866)-216-8806	To report adverse events or product complaints
Technical Support	TSC.Support@icumed.com 1-800-241-4002, option 3,4 (M-F, 8:00 am-6:00 pm CT) https://icumed.custhelp.com/	Additional information or technical assistance, including Technical Service Manuals
Field Corrections	icumed.custhelp.com/app/market-action or contact your sales representative	Questions about this Field Correction Notice

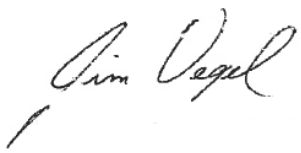
General Information
This notification is being performed with the knowledge of regulatory authorities, including the US Food and Drug Administration (FDA).

Report any adverse health complaints experienced with the use of this product to Smith Medical, events may also be reported to the FDA's MedWatch Adverse Event Reporting Program:

Web: MedWatch website at www.fda.gov/medwatch
Mail: MedWatch, Hf-2, FDA, 5600 Fisher's Lane, Rockville, MD 20852-9787
Phone: 1-(888)-INFO-FDA
Fax: 1-(888)-FDA-0178

Smiths Medical is committed to providing quality products and service to our customers. We apologize for any inconvenience this situation may cause.

Sincerely,



Jim Vegel
Vice President, Quality

Enclosures:
Attachment 1 - Urgent Medical Device Correction
Attachment 2 - Customer Response Form