URGENT: MEDICAL DEVICE RECALL

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>01C-42640-06</td>
<td>Transpac® IV Monitoring Kit With Safeset™ Reservoir and Blood Sampling Port, 152 cm (60&quot;) Tubing, Disposable Transducer, 03 ml Squeeze Flush Device, Macrodrip (Pole Mount)</td>
</tr>
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<td>Transpac® IV Monitoring Kit With Safeset™ Reservoir and Blood Sampling Port, 60&quot; Tubing, Disposable Transducer, 3 ml Intraflo® Flush, Macrodrip (Pole Mount)</td>
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27 November 2018

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

ICU Medical, Inc. is issuing this Urgent Medical Device Recall letter to notify you of a recall of certain lots of TRANSPAC IV Monitoring Kit with SafeSet Reservoir and Blood Sampling Port. This product notification details the issue and the required steps for you to perform.

Issue:
ICU Medical received reports of pressure tubing separation between the SafeSet sampling port and the high pressure tubing on certain lots of TRANSPAC IV Monitoring Kit with SafeSet Reservoir and Blood Sampling Port. Out of an abundance of caution, ICU Medical is issuing this notification.

Potential Risk:
In the event of a pressure tubing separation during use of the TRANSPAC IV Monitoring Kit with SafeSet Reservoir and Blood Sampling Port, there is a potential for delay in therapy and in rare circumstances, pressure tubing separations could lead to blood loss, air embolism, or contamination of the fluid path. To date, ICU Medical has not received any report involving a serious injury or death related to this issue.

Affected Product:
Our records indicate that you have received some of the affected products, which were distributed in the United States between October 2017 and February 2018. 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 fax number or e-mail address on the form, even if you do not have the affected product.

3) Return affected product using the return label provided with this letter. Contact Stericycle at 1-877-546-7688 (M-F, 8am-5pm ET) if you have not received a return label or require additional labels for returning the affected product. The return labels are for single use only. Please do not reproduce. Please visit http://expertzlabel.com to request additional labels for returning affected product. To ensure proper
and timely credit, follow the instructions on the return label for returning product. 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.

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 contact Stericycle at 1-877-546-7688 (M-F, 8am-5pm ET) to obtain a response form.

Follow-up Actions by ICU Medical:
Product replacement options are available. Please contact Customer Care representatives using the information provided below.

For further inquiries, including product replacement options, please contact ICU Medical using the information provided below.

<table>
<thead>
<tr>
<th>ICU Medical Contact</th>
<th>Contact Information</th>
<th>Areas of Support</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global Complaint Management</td>
<td>1-844-654-7780 (<a href="mailto:ProductComplaintsPP@icumed.com">ProductComplaintsPP@icumed.com</a>)</td>
<td>To report adverse events or product complaints</td>
</tr>
<tr>
<td>Medical Information</td>
<td>1-800-241-4002, option 6 or <a href="mailto:medinfo_us@icumed.onmicrosoft.com">medinfo_us@icumed.onmicrosoft.com</a></td>
<td>Medical inquiries</td>
</tr>
<tr>
<td>Customer Care</td>
<td>1-949-366-4208</td>
<td>Product Replacement Options</td>
</tr>
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</table>

The U.S. Food and Drug Administration (FDA) has been notified of this action.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.
- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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,

Amy Giertych
Vice President, Global Regulatory Affairs

John Beard, MD
Medical Director, Medical Affairs

Enclosures:
- Affected Item and Lot Numbers
- Customer Response Form
Table 1: Affected Product and Lot Numbers Distributed in the United States

<table>
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<tr>
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