FOR IMMEDIATE RELEASE—December 9, 2022—Minneapolis, Minnesota—Smiths Medical issued an Urgent Medical Device Correction Letter to notify affected customers of two potential issues with CADD™ Infusion System Infusion Sets related to potential lack of delivery or underdelivery and false no disposable attached (NDA) alarms. The letter details the issues, the affected items, the required steps to perform, and specific instructions for treatment of patients requiring life sustaining therapy.

The first issue, lack of delivery or underdelivery, may occur due to manufacturing variations that can potentially cause the green CADD Flow Stop arm to compress partially occlude the tubing before clinical use. If this happens, there is a potential that the occlusion does not resolve when the CADD reservoir or administration set is connected to the pump, and the pump may not detect the occlusion. This may result in underdelivery or non-delivery of medication, despite the pump displaying that the infusion is running properly. A copy of the customer notification, which outlines the potential risks associated with underdelivery, lists the affected products, and provides specific actions users should take in the event of such an occurrence, can be found here (hyperlink to be added).

The second issue, false “no disposable attached” (NDA) alarms, is specific to CADD-Legacy pumps, which Smiths Medical announced the discontinuation of sale effective December 31, 2022. There is a potential that CADD-Legacy pumps may not detect that 50 mL and 100 mL CADD Medication Cassette Reservoirs with Flow Stop are attached to the pump when they are properly attached. When this happens, the pump will initiate an NDA alarm if the NDA double-beep warning is not resolved within 2 minutes. The user must clear the alarm and resolve the cause of the NDA event before using the pump. This issue does not impact 250 mL Flow-Stop and non-Flow Stop CADD Medication Cassette Reservoirs. A copy of the customer notification, which outlines the potential risks associated with NDA alarms, lists the affected products, and provides specific actions users should take in the event of such an occurrence, can be found here (hyperlink to be added).

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

<table>
<thead>
<tr>
<th>Smiths Medical Contact</th>
<th>Contact Information</th>
<th>Areas of Support</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global Complaint Management</td>
<td><a href="mailto:globalcomplaints@smiths-medical.com">globalcomplaints@smiths-medical.com</a></td>
<td>To report adverse events or product complaints</td>
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<tr>
<td>1-(866)-216-8806</td>
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<tr>
<td>Technical Assistance</td>
<td>1-(800)-258-5361</td>
<td>Additional information or technical assistance</td>
</tr>
</tbody>
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The U.S. Food and Drug Administration (FDA) has been notified of this action.

If you wish to contact the FDA regarding any adverse events or quality problems associated with this notice, use the following contact information.

- www.fda.gov/medwatch
- 1-(888)-INFO-FDA

Media Contact:
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