URGENT: Medical Device Recall Notification

SmartSite® Low Sorbing Infusion Set
Model Number 10015862,
Lot numbers 12056016, 12057027, and 12107105

January 13, 2015

Dear Director of Nursing, Director of Risk Management, and Director of Materials Management:

CareFusion is recalling the SmartSite® Low Sorbing Infusion Set, model 10015862, Lot numbers 12056016, 12057027, and 12107105. We have received reports of disconnections and leakages between the upper fitment and the tubing for these lot numbers.

**Issue:** CareFusion has identified potential risks with model code 10015862, Lot numbers 12056016, 12057027, and 12107105 due to disconnection and leakage issues. Disconnection and leakage may be observed during priming or during infusion.

**Potential Risk:** A disconnection and leakage from an infusion set can cause a delay of infusion, an interruption of infusion, exposure to medication or hazardous infusates, an underinfusion or potentially air entering the fluid path. We have not received any reports of serious injuries or death related to this issue.

**Immediate Actions:** Discontinue use of these lot numbers and contact CareFusion for a replacement lot of the SmartSite Low Sorbing Infusion Set.

CareFusion is requesting that if you have inventory of this model code and lot numbers, return the product for replacement using the following instructions.

- **Immediately complete and return to CareFusion the enclosed, pre-addressed and postage paid, Recall Response Card.** Note on the card your distributor’s name and quantities that will be returned.

- **Once CareFusion receives the Recall Response Card, the CareFusion Support Center will provide instructions for return of the affected lot numbers and replacement of the affected lots.**

- **All recalled product should be returned directly to the distributor from whom it was purchased.** Customers will receive their return goods processed through their distributor if the products were purchased through a distributor.

- **Your distributor has already been notified of this recall. If you have any questions, please contact your distributor directly, or call the CareFusion Support Center at the number listed below.”**
The US Food and Drug Administration (FDA) has been notified of this action. Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by:

- Web: MedWatch website at [www.fda.gov/medwatch](http://www.fda.gov/medwatch)
- Phone: 1-800-FDA-1088/1-800-332-1088
- Fax: 1-800-FDA-0178/1-800-332-0178
- Mail: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville MD 20852-9787

Please use the chart provided below for questions and support:

<table>
<thead>
<tr>
<th>CareFusion Contact</th>
<th>Contact Information</th>
<th>Areas of Support</th>
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</thead>
<tbody>
<tr>
<td>CareFusion Support Center</td>
<td>Phone: 1-888-562-6018</td>
<td>Recall Related Questions</td>
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<tr>
<td></td>
<td>Hours: 7am to 4pm PST</td>
<td></td>
</tr>
<tr>
<td>Customer Advocacy</td>
<td>Phone: 1-888-812-3266</td>
<td>Adverse Event Reports</td>
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<tr>
<td></td>
<td>Email: <a href="mailto:customerfeedback@carefusion.com">customerfeedback@carefusion.com</a></td>
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<td></td>
<td>Hours: 24 hours a day, 7 days a week</td>
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</tr>
<tr>
<td>Technical Support</td>
<td>Phone: 1-888-812-3229</td>
<td>Technical Questions</td>
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<tr>
<td></td>
<td>Hours: 7am to 5pm PST</td>
<td>Regarding the Alaris System</td>
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Please promptly complete and return the enclosed mandatory Customer Response Card to acknowledge the receipt of this communication and to expedite the corrective action process.

CareFusion is committed to serving your infusion product needs and our primary objectives are patient safety, 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,

Chuck Donlon
Vice President, Quality and Regulatory, Infusion
CareFusion

Enclosures:
Recall Response Card