URGENT: Medical Device Recall Notification

SmartSite® Extension Set
Model Number 20029E
Lot Number 13085791

March 19, 2014

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

CareFusion is recalling the SmartSite® Extension Set, model 20029E, lot number 13085791. We have received reports of disconnections and leakages at the connection of the smallbore tubing and the SmartSite Y-port on lot number 13085791.

**Issue:** CareFusion has identified potential risks with model code 20029E, lot number 13085791 due to disconnection and leakage issues. This lot number of the SmartSite Extension Set may not have solvent between the connection of the smallbore tubing and the SmartSite Y-port. Disconnection and leakage may be observed during infusion.

**Potential Risk:** A disconnection and leakage from an extension 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 this lot number and contact CareFusion for a replacement lot of the SmartSite Extension Set.

CareFusion is requesting that if you have inventory of this model code and lot number, 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 number and replacement of the affected lot.**

- **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>
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</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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<tr>
<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