3750 Torrey View Court
San Diego, CA 92130
1-888-562-6018 (toll-free)

www.carefusion.com

CareFusion
has joined BD

URGENT: Medical Device Recall Notification

SmartSite Add-On Bag Access Device
Model Number 10013365
Multiple Lot Numbers

November 2016

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

CareFusion is recalling the SmartSite Add-On Bag Access Device Model Number 10013365, multiple lot numbers. We have received reports of leakages between the spike port and the drip chamber spike.

Issue: CareFusion has identified potential risks with the SmartSite Add-On Bag Access Device Model Number 10013365 for 29 lot numbers (noted below). Separation or leakage between the spike port and the drip chamber spike. The separation and leakage may occur during infusion.

Affected Lot Numbers: Total:

15055146	15077085	15127413
15055702	15085031	16015324
15056299	15085156	16015325
15056618	15086107	16015607
15065645	15095014	16025824
15075740	15095411	16025948
15076166	15106928	16027008
15076167	15116928	16035527
15076664	15125952	16036131
15076729	15126069	**29 lot numbers**

Potential Risk: Leakages can cause delay of infusion, interruption of infusion, exposure to medication or hazardous infusates, or underinfusion. We have not received any reports of serious injuries or death related to this issue.

Immediate Actions: Discontinue use of the SmartSite Add-On Bag Access Device Model Number 10013365. The affected lot numbers are listed below. Contact CareFusion for a replacement lot of the SmartSite Add-On Bag Access Device Model Number 10013365.

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
- 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:

CareFusion Contact	Contact Information	Areas of Support
CareFusion Support Center	Phone: 1-888-562-6018 Hours: 7am to 4pm PST	Recall Related Questions
Customer Advocacy	Phone: 1-888-812-3266 Email: customerfeedback@carefusion.com Hours: 24 hours a day, 7 days a week	Adverse Event Reports

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,

[redacted]

Niel Smith
Senior Director, Quality Manufacturing
MMS WWID, EMEA

3750 Torrey View Court
San Diego, CA 92130
1-888-562-6018 (toll-free)

www.carefusion.com

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URGENT: Medical Device Recall Notification

SmartSite® Add-On Bag Access Device
Model Number 10013365-0006
Multiple Lot Numbers

November, 2016

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

CareFusion is recalling the SmartSite Add-On Bag Access Device Model Number 10013365-0006, 19 lot numbers noted below. We have received reports of leakages between the spike port and the drip chamber spike.

Issue: CareFusion has identified potential risks with the SmartSite Add-On Bag Access Device Model Number 10013365-0006, 19 lot numbers. Separation or leakage between the spike port and the drip chamber spike. The separation and leakage may occur during infusion.

Affected Lot Numbers:

15055147	15086162
15065148	16015892
15065656	16026530
15075252	16026626
15075795	16026705
15076168	16027007
15085110	16035155
15085157	16035526
15085608	16036182
15086108	**19 Lot Numbers**

Potential Risk: Leakages can cause delay of infusion, interruption of infusion, exposure to medication or hazardous infusates, or underinfusion. We have not received any reports of serious injuries or death related to this issue.

Immediate Actions: Discontinue use of the SmartSite Add-On Bag Access Device Model Number 10013365-0006. The affected lot numbers are listed below. Contact CareFusion for a replacement lot of the SmartSite Add-On Bag Access Device Model Number 10013365-0006.

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 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
- Phone: 1-800-FDA-1088/1-800-332-1088
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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,

_____
Niel Smith

Enclosures:

- Recall Response Card

10020 Pacific Mesa Blvd.
San Diego, CA 92121
1-888-562-6018 (toll-free)

www.carefusion.com

CareFusion

URGENT: Medical Device Recall Notification

Customer Response Card

AFFECTED DEVICES: SmartSite Add-On Bag Access Device
Model Number 10013365 and 10013365-0006
Multiple Lot Numbers

November 2016

Please assist us in making this Medical Device Recall Notification follow-up process efficient and convenient for you by completing and returning this card to CareFusion via mail, email, or fax; which serves as a confirmation that you have received this notification. A cover sheet is not required.

ADDRESS: CareFusion Support Center
10020 Pacific Mesa Blvd
San Diego CA 92121

PHONE: 1-888-562-6018
FAX: 1-858-617-4851
EMAIL: SupportCenter@CareFusion.com

(PLEASE PRINT)

Facility Name: _____

Facility Address: _____

_____

_____

Completed By: _____

Title: _____ Phone: _____

Signature: _____ Date: _____

Quantity for return: _____ Cases _____ Each

If purchased through a Distributor, Name: _____
Distributor Contact: _____
Distributor Phone: _____

Return Address

_____

_____

_____

CareFusion Support Center
10020 Pacific Mesa Blvd
San Diego CA 92121

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(Staple here)