



URGENT: Medical Device Recall Notification

Elcam Medical Plastic Cannula - 11 Gauge Model Number 9391-0200 Multiple Lot Numbers

June 2017

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

Elcam Medical, a supplier for BD, is recalling the Plastic Cannula – 11 gauge model number 9391-0200. This recall has been initiated due to punctures in the blister packaging that was detected during the packaging process in the Elcam Medical manufacturing site. Please see the list of the overall affected lot numbers (Attachment A).

Potential Risk: Use of punctured blister packaging may lead to a potential risk of contamination. There have been no reports of serious injuries or death related to this issue.

Immediate Actions: Discontinue use of these lot numbers and contact BD for a replacement lot of the Elcam Medical Plastic Cannula – 11 gauge.

Unaffected lots can be used.

BD 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 BD 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 BD receives the Recall Response Card, the BD 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 BD 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:

BD Contact	Contact Information	Areas of Support
BD Support Center	Phone: 1-888-562-6018 Hours: 7am to 4pm PST	Recall Related Questions
Customer Advocacy	Phone: 1-888-812-3266 Email: customerfeedback@BD.com Hours: 24 hours a day, 7 days a week	Adverse Event Reports
Technical Support	Phone: 1-888-812-3229 Hours: 7am to 5pm PST	Technical Questions Regarding the Alaris System

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.

BD 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
Senior Director, Quality Manufacturing
MMS WWID, EMEA

Attachments:

Attachment A – overall affected lot numbers

Enclosures:

Recall Response Card

Attachment A

VersaSafe Plastic Cannula Affected Lot Numbers

VersaSafe Plastic Cannula – 11 Gauge Model Code 9391-0200
Lot Numbers:
1470303001
1470303002
1470304601
1470306301
1470306602
1470311301
1470311302
1470314801
1570314802
1570317701
1570317702
1570317703
1570317704
1570322001
1660771501
TOTAL: 15 lot numbers



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Customer Response Card

**AFFECTED DEVICES: Elcam Medical Plastic Cannula - 11 Gauge
Model Number 9391-0200
Multiple Lot Numbers**

June 2017

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 BD via mail, email, or fax; which serves as a confirmation that you have received this notification. A cover sheet is not required.

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

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

(PLEASE PRINT)

Facility Name: _____

Facility Address: _____

Completed By: _____

Title: _____ Phone: _____

Signature: _____ Date: _____

Quantity for return: _____ Cases _____ Each

If purchased through a Distributor, Name: _____

Contact: _____ Phone: _____

Return Address

**BD Support Center
10020 Pacific Mesa Blvd
San Diego CA 92121**

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(Staple here)